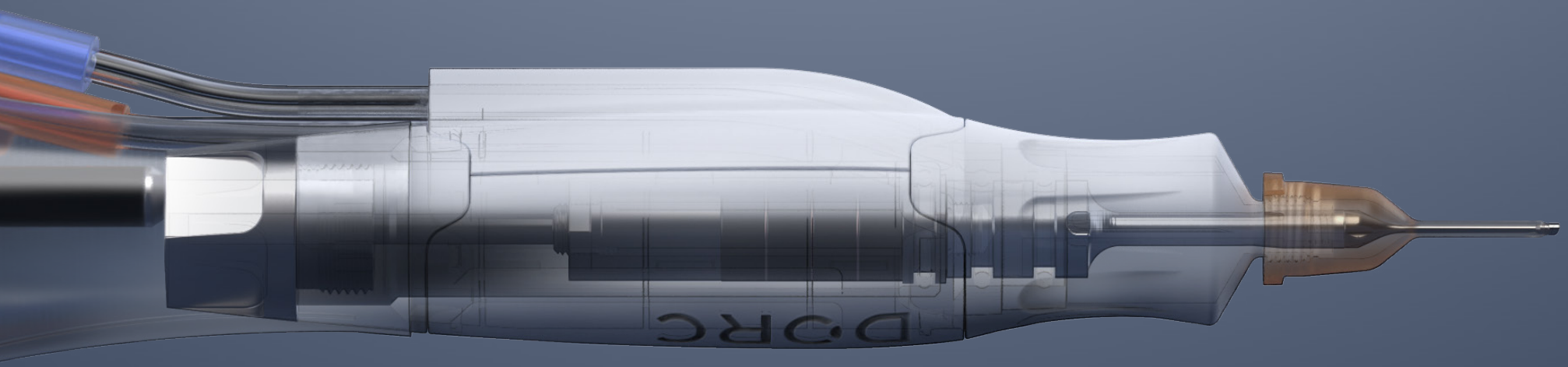


Driving circularity in eye surgery with a semi-disposable phacoemulsification redesign

Hybrid Phaco

TU Delft
DORC

Lars Timmerman
Integrated Product Design
MSc. Graduation Thesis

Preface

This research began with a strong desire to make a positive impact socially and environmentally. Focused on sustainability, engineering, and social responsibility in ophthalmic medical devices, this thesis aims to reflect the commitment I had during the project.

In this thesis, I present a novel design for a phaco handpiece. Besides a functional and sterile solution, it also offers a more sustainable solution in the medical device field. I hope this work adds to the conversation about how circular design and sustainability are achievable in the medical world through inventive solutions and careful consideration, including sustainability data in Life Cycle Assessments (LCAs).

As circular design gains traction in medicine, through this thesis I aim to show aims to show that sustainable options are not just theoretical but practical. I want this research to contribute to the shift towards sustainable choices in medical device innovation, setting an example for a future where functionality aligns with environmental responsibility.

Please enjoy the read,

Lars Timmerman

Aknowledgements

First and foremost, I want to acknowledge and thank my company mentor, Joost, whose guidance in the early phases and assistance with everyday questions truly aided my process and allowed it to run smoothly. This support extended to the extent of accompanying me on a company visit to Germany, an experience not nearly as enjoyable without Joost. Not only this, Joost also infused my project with more enthusiasm than I could muster on my own, enabling me to give my full 100%. Throughout this project, Joost has come across as a friend to me, and for that, I am truly grateful.

I would also like to express my appreciation to Mart, who also showed continued support and provided valuable insights into the project. His insights and collaboration significantly enriched the development of this thesis, and I truly believe that with Mart at the helm, the continuation of this project has a bright future.

I also want to express gratitude to my team at TU Delft, with J.C. not only providing concrete insights into the project but also enabling some wonderful collaborations with healthcare professionals. With his time being valuable, I appreciate all the energy he gave me for this project.

My thanks to Stefan, who, with his approach to design teaching, has been the perfect mentor for me. He has been as valuable in terms of collaboration on the design itself, and I want to especially thank him for guiding me through some of my lower points during this project.

Both J.C. and Stefan, thank you for helping me save myself sometimes. The project would not have looked the same without you.

Thanks to all the people at the R&D department—Nadieh, Frank S., Frank L., Quentin, Pedro, Juan, Ronald, and frankly everyone else at R&D—for making going to the remote and obscure Zuidland so much fun and rewarding. I also want to thank you for helping me, be it through meetings, developing prototypes, or even mundane questions. It would not have been as rewarding without all of you.

Special thanks to Michal and Pieter for setting up the project and providing the perfect graduation opportunity.

The entire experience with the TU and DORC teams has been unforgettable, and I look forward to future collaborations.

To the Wefis GmbH team—Stefan, Till, and Joachim—thank you for your expertise, time, enthusiasm, and patience in translating between English and German. Your collaboration has been instrumental in the success of this project.

I acknowledge the AED team Foresight for their work on the project, which provided valuable insights and direction, contributing to a flying start during my graduation.

I want to thank my family and friends for not only supporting me through this journey of a graduation project but also for making it all a lot more fun with trips, visits, and just nice conversations to put my mind at ease.

Lastly, I want to thank Emma, simply for being there even though I may not have been as emotionally available during the more tense phases of the project. Your daily support and affirmation have been indispensable for me to reach what I wanted to achieve in this project, and you have made it all the more fun and enjoyable.

Table of contents

Reading guide

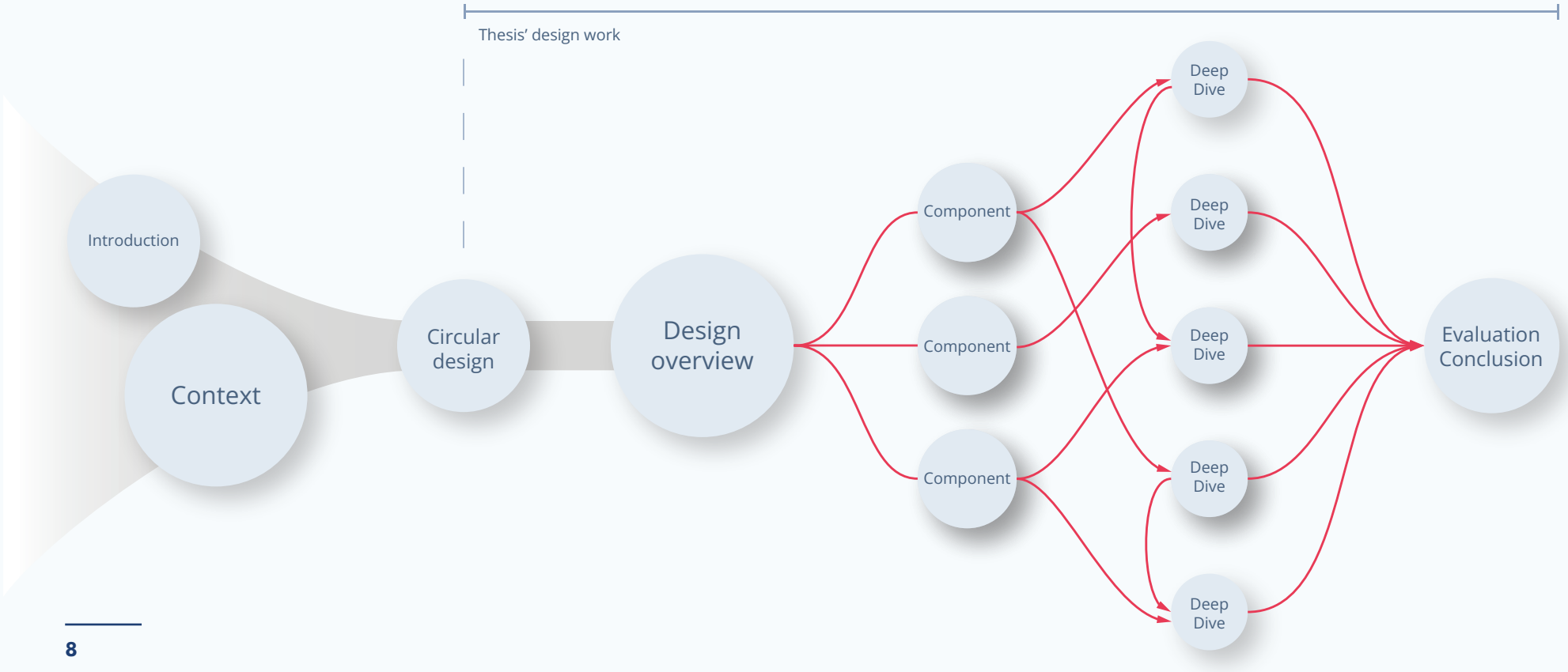
The foundation of the project is set by an introduction, and the foundation of the product is established by discussing the complete context.

From these foundations, the circular design is defined and discussed, marking the beginning of this thesis's design work.

The design overview summarizes the design, and the chapters on each component delve deeper into the design features and considerations.

The Deep Dives each address a different studied topic and further explain design considerations made for each of the components.

From the Deep Dives, the research questions are answered, and conclusions (and recommendations) for the project are formulated.



Executive summary

Cataract surgeries using phacoemulsification (phaco) are standard practice, accounting for the large majority of all cataract surgeries. Reliance on sterilization processes has significant environmental implications, giving its energy and resource intensive nature.

Vision of Hybrid Phaco

This thesis introduces a novel hybrid phaco handpiece design (visualised in Figure 1), eliminating the need for sterilization by adding a disposable to facilitate sterile use, combined with a reusable as driver of ultrasound. This product is the first step towards a proposed fully circular system. This project has a focus on reducing impact, while maintaining phaco functionality; it does so by testing for phaco ultrasound characteristics and functioning fluidics while addressing the challenges associated with sterilization. The design emphasizes quick, secure, and sterile assembly in the operating room (OR) while maintaining cost-effectiveness and minimizing environmental impact.

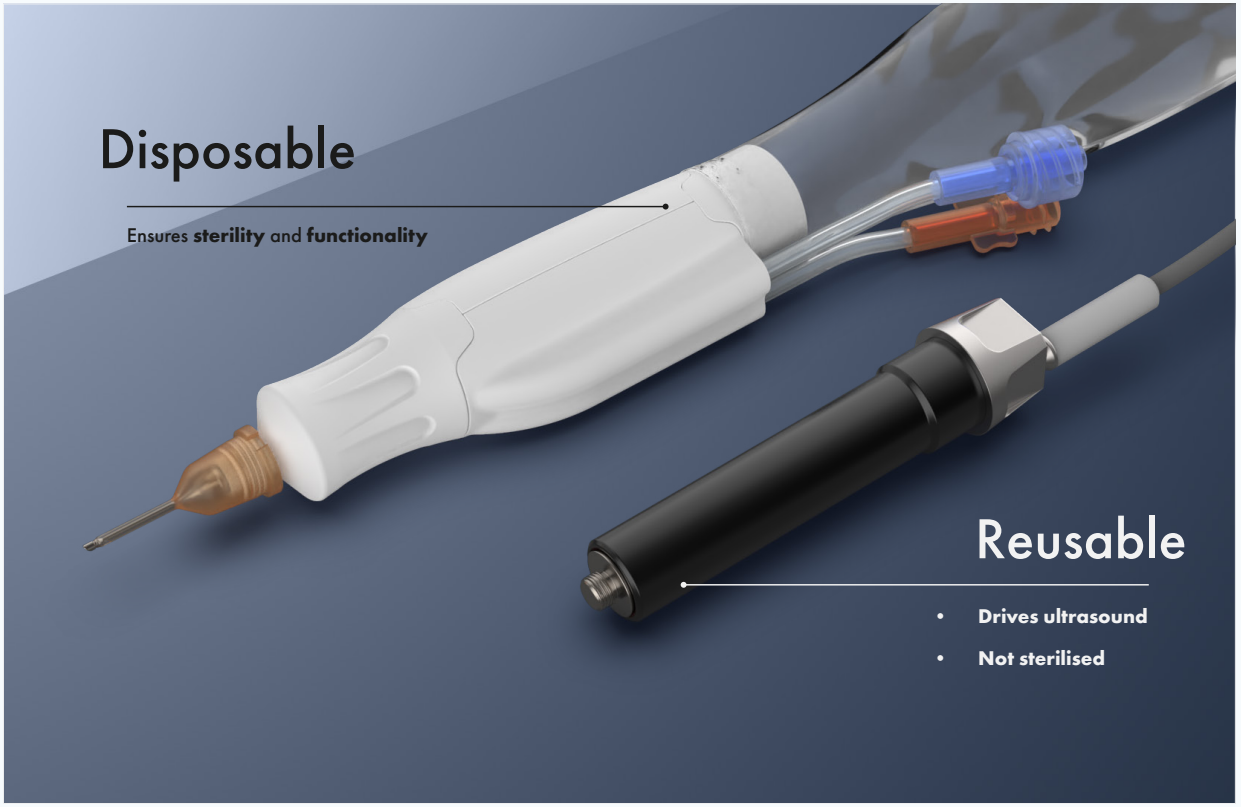


Figure 1 *Design overview of both the reusable driver, and disposable product, with their highlighted general functions*

Ultrasound and fluidics

The hybrid phaco handpiece achieves its functional design by carefully managing the components responsible for ultrasound and fluidics. The internal sonotrode, driving ultrasound, is split between the disposable and reusable components, connected securely through a threaded interface (Figure 2). Fluidics are managed by splitting off before reaching the reusable part, employing a simple yet effective O-ring design in the disposable product (Figure 3).

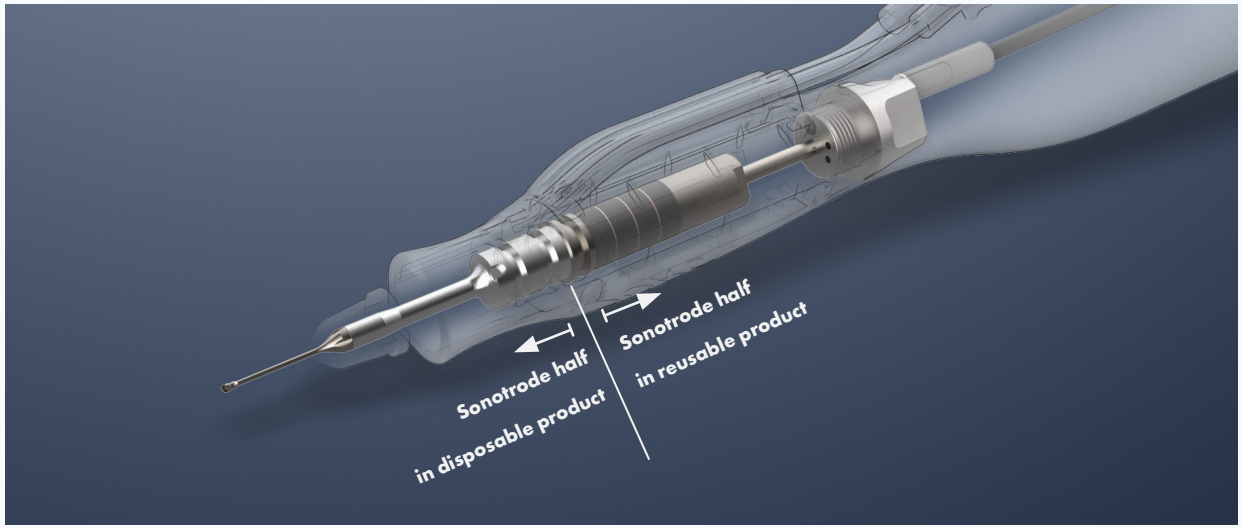


Figure 2 *X-ray view of assembled hybrid phaco handpiece, visualised with the ultrasonic sonotrode being split at the threaded connection over the disposable and reusbale product,*

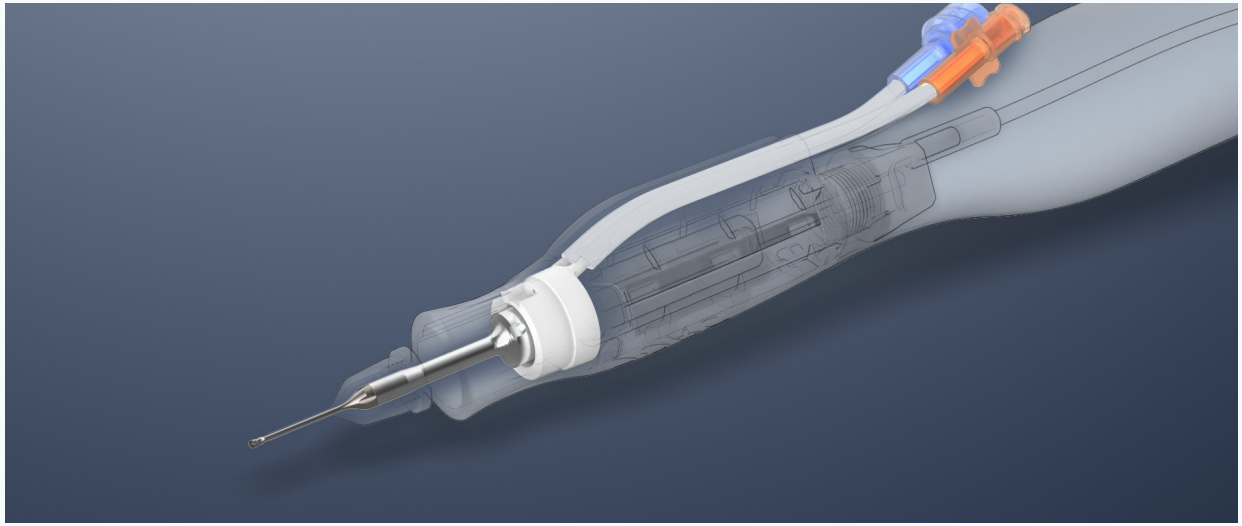


Figure 3 *X-ray view of assembled hybrid phaco handpiece, visualised with the fluidics system of the disposable handpiece splitting off before the reusable*

Sterile design fit for safe OR usage

Maintaining sterility in the OR is a critical aspect of the hybrid phaco handpiece design. Mechanical seals in O-rings provide internal sterile barriers, and a blister pack facilitates sterile interaction between non-sterile and sterile components (Figure 4, panel 1). The contact-free assembly of the disposable into the reusable ensures a tight connection, validated by a torque ridge that breaks at a specified torque, offering a visual cue for successful connection (Figure 5). This usability design, validated with healthcare professionals, adds safety and fits the quick nature of cataract procedures.

Seamless while sterile

The innovative sterile handover method is implemented through the packaging itself, acting as a sterile barrier between different nurses handling the disposable and reusable components. During handover, a pre-attached sterile tube sleeve is unrolled over the non-sterile component. This ensures a seamless and sterile transition during assembly, minimizing the risk of contamination (Figure 4, panel 2-3).

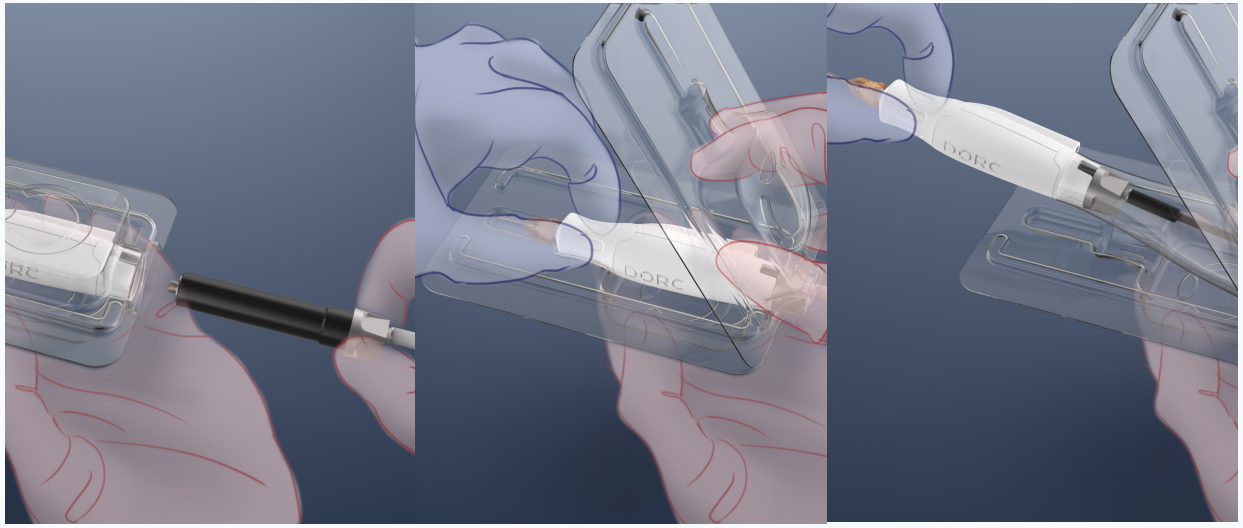


Figure 4 *Assembly steps using making for a contact free assembly of reusable into disposable (panel 1), and facilitating a contact free handover with the blister pack as physical barier (panel 2), with a preassembled sterile tube sleeve unrolling to cover the non-sterile cable (panel 3)*

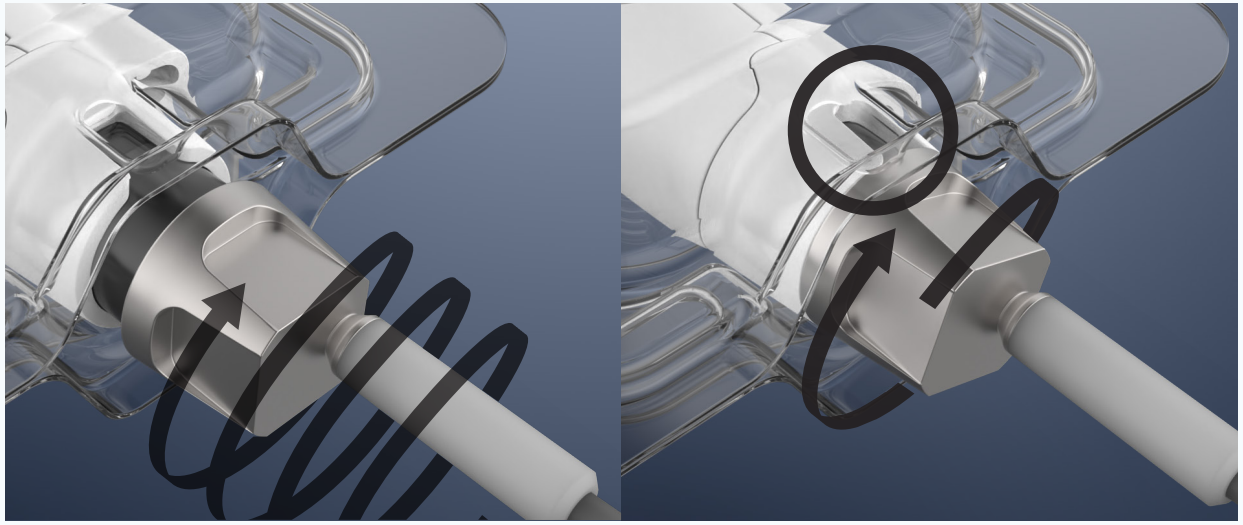


Figure 5 *Torque ridge design in use, ensuring a secure connection when assembling the handpiece in the OR, showing threading in of reusable driver (panel 1), and showing the torque ridge breaking and handpiece turning at specified torque limit (panel 2)*

Impact reduction while maintaining functionality

A comprehensive functional analysis validates the hybrid design, ensuring it meets specifications. Insights gained from this analysis guide further mechanical tuning, particularly in aspects influencing ultrasound characteristics. Beyond functionality, the hybrid phaco handpiece design has profound environmental implications. By eliminating the need for energy-intensive sterilization procedures and reducing waste from disposable wraps (Figure 7), the design reduces its climate impact by 67% over the entire life cycle (Figure 6).

Hybrid design in healthcare

In conclusion, this hybrid phaco handpiece design represents a step towards a circular system in the field of cataract surgeries. Balancing functionality, sterility, and environmental impact, this novel approach not only provides new insight into sustainable phacoemulsification procedures, but also shows the potential of hybrid reusable and disposable products in healthcare.

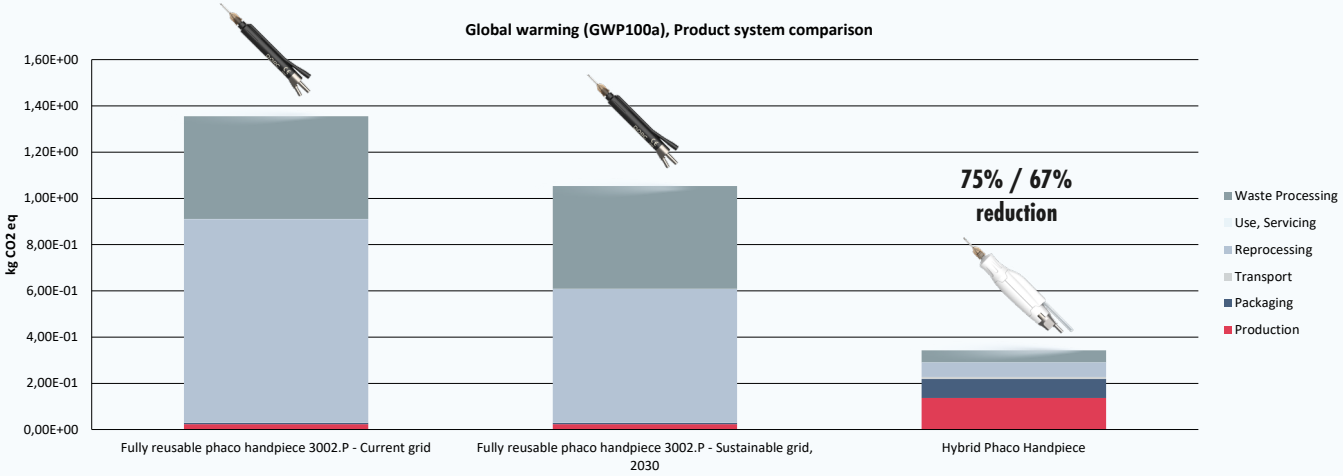


Figure 6 *Sensitivity analysis of LCAs concerning the energy grid used for the sterilization process, on Climate change (kg CO2 eq) per functional unit of a single cataract surgery*

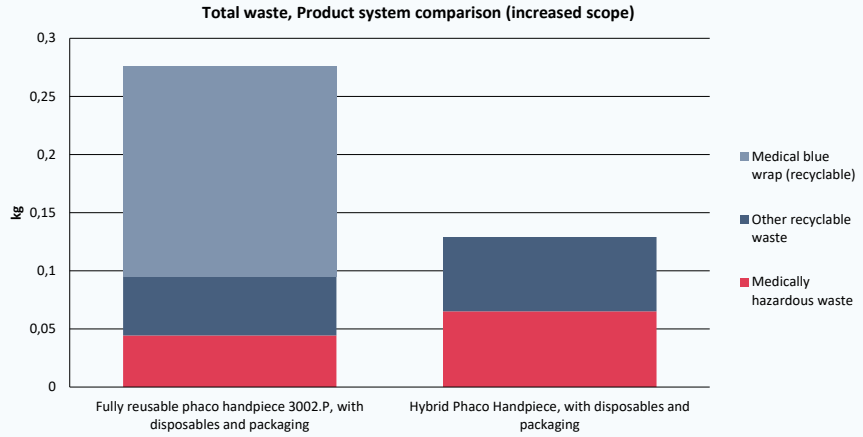


Figure 7 *Amount of waste in kg for lifecycle of 3002.P and Hybrid design, separated by medically hazardous and recyclable, and medical blue wrap. Increased scope to include disposables and packaging*

1. Project introduction

The current design of phacoemulsification handpieces relies on autoclave sterilization, a highly energy- and resource-intensive process. In light of the increasing awareness regarding carbon footprint reduction and the adoption of circular economy principles, this section introduces a project aimed at providing a more sustainable solution for DORC Global and its subsidiaries.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1.1 Problem statement

The healthcare industry stands as a significant driver of climate change and global resource depletion. In the Netherlands, the healthcare sector alone accounts for approximately 7% of the nation's greenhouse gas emissions (Barlow, 2022), while globally, it represents nearly 5% of total emissions (Hanson & Hitchcock, 2009). This substantial environmental impact can be attributed, in part, to the prevailing linear consumption patterns within the industry.

This project focusses on the design and environmental footprint of the phacoemulsification handpiece, a critical surgical instrument used in anterior eye procedures, particularly cataract surgery. The handpiece features a welded titanium body and houses valuable electronics. It requires sterilization after each use, a procedure known for its excessive resource and energy demands. Presently, the handpiece's reusability is limited to a mere 200 cycles, with repair options being both financially and practically unfeasible (expert consultation). Thus, the handpiece does not align with any sustainable circular business model.

As phaco handpieces are crucial surgical tools used in the invasive procedure of lens removal from the eye, the need for an entirely sterile solution with consistent phacoemulsification performance becomes apparent. These unconditional requirements for sterility and performance stand as the main limitation when to developing a (semi) disposable phaco handpiece that aligns with circular economy principles and minimizes its environmental footprint.

1.2 Involved companies

Figure 1.2 - 1 *Logo Dutch Ophthalmic Research Center (DORC, n.d.)*

Figure 1.2 - 2 *Logo Delft University of Technology (TU Delft, n.d.)*

1.2.1 DORC

As a global supplier of ophthalmic surgical equipment, Dutch Ophthalmic Research Center (International) B.V. (DORC), based in Zuidland, the Netherlands, is dedicated to driving innovation and advancements in eye surgical technology. With a primary focus on serving surgeons, DORC is committed to delivering innovative and cost-effective solutions for a wide range of eye surgeries. Globally, the company boasts nearly 800 employees.

Under Eurazeo (soon Carl Zeiss Meditec), D.O.R.C. has set a target to achieve net neutrality by 2040. This objective involves a assessment of their use of natural resources and defining projects aimed at reducing the environmental impact of their products throughout their lifecycle.

This project represents one of the stepping stones for D.O.R.C. in its journey towards adopting a complete circular phaco business model and expanding its product portfolio with circular solutions. As a contributor to this portfolio, this project has the potential to elevate D.O.R.C.'s position as a leading sustainable provider of ophthalmic surgical equipment.

With this graduation project I further developed a solution to fit circular business models established within D.O.R.C. by Michal Adar. My work at D.O.R.C. was done under supervision of Mart Gahler and Joost Vervaet, whose guidance has been essential for the development process.

1.2.2 TU Delft

This product development procedure was initiated as an Advanced Embodiment Design project undertaken by student team Foresight (hereafter referred to as 'student team') under supervision of Gerard Nijenhuis from the TU Delft and Pieter van het Hof from D.O.R.C..

Additionally, this graduation project was jointly initiated with the support of Professor Jan-Carel Diehl from the faculty of Industrial Design Engineering. Throughout the course of this project, further guidance and coaching were provided by Stefan Persaud. Both guided me in the design process and have provided invaluable council for the project.

Figure 1.2 - 3 *logo Wefis GmbH (Wefis GmbH, n.d.)*

1.2.3 Wefis GmbH

The German based WEFIS GmbH is the primary manufacturer of ophthalmic surgery equipment, including the phacoemulsification handpiece currently distributed by D.O.R.C.. Stefan Wörsdörfer and Joachim Karnbach as the key contacts at WEFIS, have played a pivotal role in contributing their expertise and understanding of phaco handpiece development and performance to this project.

My visit to WEFIS in which the performance of the prototype was further finetuned, has also been crucial in development of the final product.

1.3 Scope and key drivers

This project is centred on advancing the product development of the phaco handpiece. Building on the insights gained from the development of circular business models and the initial project undertaken by the student team, we have established a high-level product architecture. This architecture features a phaco handpiece equipped with reusable electronics, while the remaining components are designed for disposability. These reusable electronics are designed to remain unsterilized, as they are safeguarded by the disposable elements, ensuring sterility.

The circular business models established by Michal Adar will be the basis for this design project. We should note that the main focus is on improving the handpiece's design itself, not the entire system it works within. Therefore, while the student team's previous work is valuable, it was not used as a strict starting point. Instead, these results will be used as input, seeing that the student team's primary focus was also on the handpiece's development.

The phaco handpiece used by DORC is an integral part of their EVA Nexus platform. Although the handpiece is closely connected to the EVA Nexus system and relies on it for operation, our redesign project will specifically focus on improving the handpiece itself. It's important to note that components like the needle and sleeve, which make up the handpiece's tip, will not be part of this redesign.

Figure 1.3 - 1 *Items out of design scope: EVA Nexus surgical system, needles, and sleeves, (DORC, n.d.)*

1.3.1 Scope

The main goal of this project is to develop a phaco handpiece that fits a predefined circular business model. Sustainability is a primary driver, given its crucial role in this objective. Sterility and performance, especially in the context of cataract surgeries, are also key considerations.

In addition, affordability and manufacturability become apparent when examining the market context (detailed in Chapter 2.4.2 "Current phaco market"). The handpiece's potential for use in low-resource settings, stemming from its hybrid design, is noteworthy. Compliance with regulations and policies is acknowledged as a long-term requirement.

Ensuring sterility in a hybrid phaco handpiece ultimately hinges on achieving a secure interface between disposable and reusable components, eliminating contamination risks.

All scope items have been assessed and categorized based on their importance: some are deemed essential, others conditional, and a few optional, dependent on available project resources. Additionally, these scope items have been categorized as either inherent to the concept of a hybrid handpiece or within the scope of my personal focus, further indicating the contents of this graduation project.

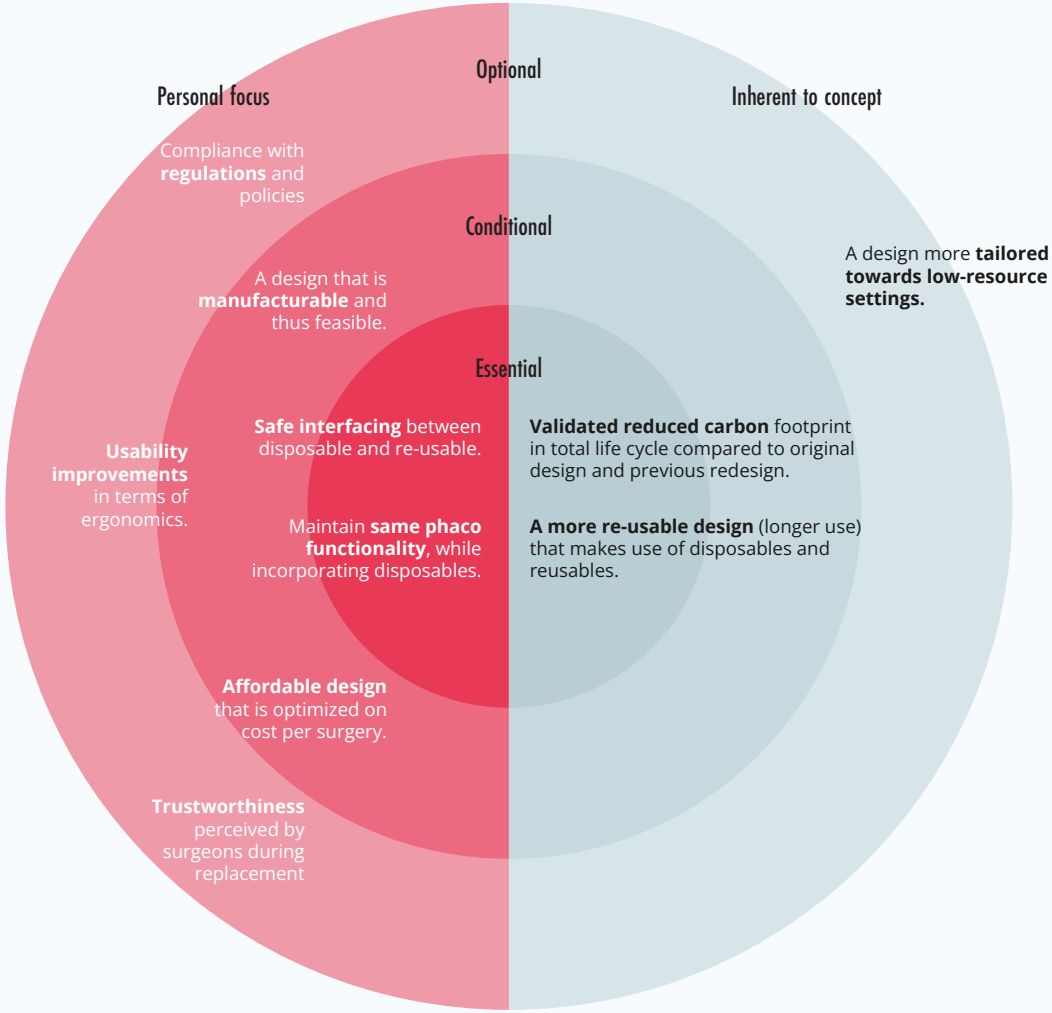


Figure 1.3 - 2 *Project scope, split into personal focus, and elements inherent to concept, along with corresponding urgency regions*

1.3.2 Project goals

The project goals are defined as follows.

“Develop an embodied concept design for a hybrid (semi-disposable, semi-reusable) phaco handpiece”

“Prove the feasibility of a hybrid phaco handpiece functionality through testing of prototypes”

“Validate a use case that ensures sterility and usability, with input from OR personnel”

“Design a product that demonstrates a reduced carbon footprint across its entire lifecycle compared to the 3002.P (or “original design”), and validate this reduction”

1.4 Research questions

RQ1: What ensures the phacoemulsification functionality of a phaco handpiece?

1.1. What are limitations to fluid line changes in a phaco handpiece?

1.2. What variables influence ultrasonic vibration characteristics of the phaco handpiece?

1.3. What ensures proper transmission of ultrasonic vibration between disposable and reusable?

RQ2: How can safety in terms of sterility be ensured for a hybrid reusable and disposable handpiece?

2.1. How can sterility within the phaco handpiece be ensured when implementing the reusable electronics during surgical procedures?

2.2. How can a hybrid design be assembled in a way that ensures sterility?

RQ3: How can a phaco handpiece be redesigned to make use of disposables?

3.1. Where are opportunities in terms of environmental impact for developing a hybrid phaco handpiece?

3.2. Can a feasible design be defined for a hybrid phaco handpiece, also considering all prerequisites?

RQ4: How does the hybrid disposable handpiece compare in terms of environmental impact?

4.1. What is the current environmental impact of the phaco handpiece over its entire lifetime?

4.2. What is the environmental impact of a functional hybrid phaco handpiece?

1.5 Research and design

1.5.1 Process

I initiated the project by closely examining the current design of the phaco handpiece, aiming to distil all its functions and understand how it ensures phaco functionality. This analysis served as a basis for preserving the original design's phaco functionality as closely as possible.

Simultaneously, I delved into the circular business model and previous life cycle assessments related to the phaco handpiece. I closely analysed this prior work and extracted design principles from it.

In the early phases, I also conducted a thorough examination of regulations and rules, particularly focusing on sterilization requirements, to distil potential design guidelines.

Addressing subproblems such as fluid separation and shell design involved a creative approach, where I developed solutions through various methods, including creativity techniques and a comprehensive analysis of existing solutions, especially detailed operating principles. I followed quick iterative loops, encompassing conceptualization, embodiment, prototyping, and validation, to select the most suitable concepts.

My exploration of factors influencing proper phaco functionality and limitations on changes to fluid lines extended beyond literature research to include practical testing methods like heat analyses, resonance frequency measurements, and stroke flow analyses. In essence, my investigation of phaco functionality relied heavily on practical and experimental validation using prototypes, with theoretical groundwork as a preliminary step.

Furthermore, I considered design aspects that impact the handpiece's usability in an operating environment, collaborating closely with healthcare professionals, OR personnel and surgeons.

1.5.2 Methodology

In my process, I followed the general diverging-converging structure of the double diamond approach, with initial concept development and selection for the first diamond, followed by more detailed embodiment design technical testing and refinement in the second diamond. Additionally, I incorporated smaller iterative loops, where I focused on specific themes such as "sonotrode connection method" and "outer shell design," aligning more with design sprint methods.

In my design process, I utilized design sensitivity analysis to map the impact of variations in specific design variables on the objective functions related to phaco functionality. This qualitative approach guided my decision-making process. The results of this sensitivity analysis, referred to as a sensitivity map, informed my final design. I then validated this sensitivity map through my final design iteration.

The main focus of my Life Cycle Analysis (LCA) was on the Life Cycle Inventory. This analysis aimed to validate the effectiveness of measures taken to reduce the product's carbon footprint over its entire life cycle. Given the availability of LCAs for the current phaco handpiece and the results from the student project, the LCA played a central role in my final validation.

2. Context

Before delving into my design work within this project, it is essential to establish context. This section will address the current product use and functionality within surgical procedures. Additionally, it will zoom in on the current design, highlighting its features. To provide a complete context, this section will also consider the features and design considerations of the initial student redesign, ensuring complete clarity on all previous phaco designs.

To conclude the context overview, this section will address rules and regulations relevant to the project, as well as the current market and stakeholders associated with D.O.R.C. phaco handpieces.

Figure 2.1 - 1 *Cataract patient, showing crystallised lens, retrieved from (Abejo, 2021)*

2.1 Current product use and functionality

2.1.1 Cataract surgeries

Cataract surgeries are the most commonly performed eye surgeries worldwide, with approximately 175,000 surgeries carried out annually in the Netherlands alone (Zorginstituut Nederland, n.d.) and around 27 million worldwide (Q-bital Healthcare Solutions, 2021). Regarded as a routine procedure in eye surgery, cataract surgery is highly successful (UCI Health, 2018).

These surgeries become necessary when the natural lens becomes cloudy, leading to blurred vision. The surgical process involves removing the clouded lens and replacing it with an artificial intraocular lens (IOL) to restore clear vision. This core process is visualised in Figure 2.1 - 2 .

A key technique employed in this procedure is phacoemulsification, or phaco, which is a modern and widely used method to break up and emulsify the cloudy lens before extraction. This is achieved using an ultrasonic device known as a phacoemulsification handpiece, which applies ultrasonic vibrations through a needle to break down the clouded lens.

The phaco handpiece plays a pivotal role in the success of cataract surgery. Phacoemulsification enables the lens to be broken into small pieces, requiring only a small incision in the eye. This minimally invasive approach reduces recovery time and discomfort, contrasting with the traditional cataract surgery method extracapsular (or ECCE) (MyVision.org, 2022), where the lens is removed in one piece through a larger incision.

Another type of cataract surgery is Femtosecond Laser-Assisted Cataract Surgery (FLACS), where a laser is used to make an incision, open the lens capsule, and fragment the lens instead of manual operation. While this method demands more expensive equipment and greater expertise, it offers higher precision (MyVision.org, 2022). However, due to the wider availability of phaco and the fact that FLACS does not result in fewer complications (Doran, 2017), phaco remains the most frequently performed option.

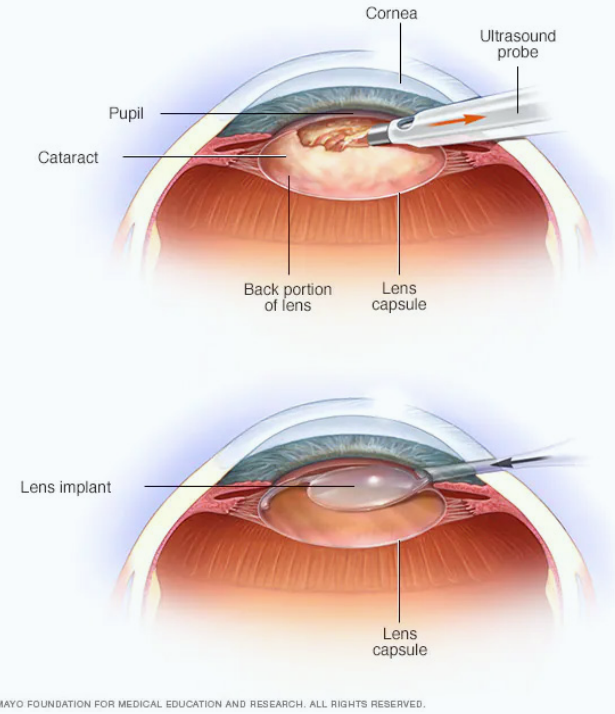


Figure 2.1 - 2 *Phacoemulsification and IOL placement steps of cataract surgery visualised, (Mayo Clinic, 2023)*

Outlined here are a key few steps of cataract surgery, especially relevant to this project.

1. Anesthesia:

The eye is usually locally numbed with anaesthesia, typically administered in the form of eye droplets.

2. Incision:

A small incision is made in the cornea of the patient, providing access to the lens.

3. Capsulorhexis:

A round opening is created in the thin, transparent membrane encapsulating the lens, allowing access to the natural lens.

4. Phacoemulsification:

The phacoemulsification handpiece is introduced through the incision, and ultrasonic vibrations are applied to the lens through the needle. These vibrations break up the crystallized lens (or cataract) into tiny pieces, which are emulsified with applied fluids. While various techniques can be employed to break up the lens, the most common is the Divide and Conquer technique (Central Queensland Cataract Centre, 2022), where the lens is chopped into four quadrants, and these quadrants are further broken up into smaller pieces and emulsified. (Figure 2.1 - 3)

5. Aspiration and irrigation:

The emulsified lens pieces are aspirated or suctioned from the eye through the needle hole in the phaco handpiece. Simultaneously, the eye is irrigated through the tip of the phaco handpiece with a basic saline solution (BSS) to apply fluids for aspiration and to maintain the shape and internal pressure of the eye.

6. Refinement:

Separate irrigation and aspiration tools (I/A tools) are used to remove residual debris of the cataract, typically found around the edges of the natural lens capsule.

7. IOL Implantation:

After the lens is completely removed, an artificial intraocular lens (IOL) is inserted through the same small incision. The lens is either folded right before insertion or comes pre-folded in an application tool. After insertion, it unfolds to assume its proper position within the eye.

8. Closure:

Usually, this minimally invasive surgery does not require stitching to close the incision and is typically self-healing.

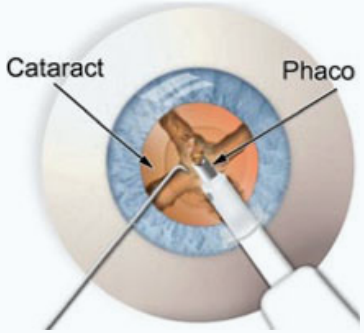


Figure 2.1 - 3 *Divide-and-conquer technique most commonly used in cataract surgery (Central Queensland Cataract Centre, 2022)*

2.1.2 Product use and environment

2.1.2.1 Sterile environment

Within the sterile zone, products outside the sterile barrier include integral components like the surgical system, microscope pedal, surgical system footswitch/pedal, patient monitoring system, and surgical video monitoring.

These are complemented by products within the sterile barrier, arranged on the mayo tray or sterile cart. This encompasses specific tooling and products essential for the surgery, notably those crucial to phacoemulsification.

For phacoemulsification, a needle (available in both reusable and disposable forms), disposable irrigation sleeve/tip, and the tubing set connecting the handpiece to the cartridge are used.

This use environment with all its elements is visualized in Figure 2.1 - 4

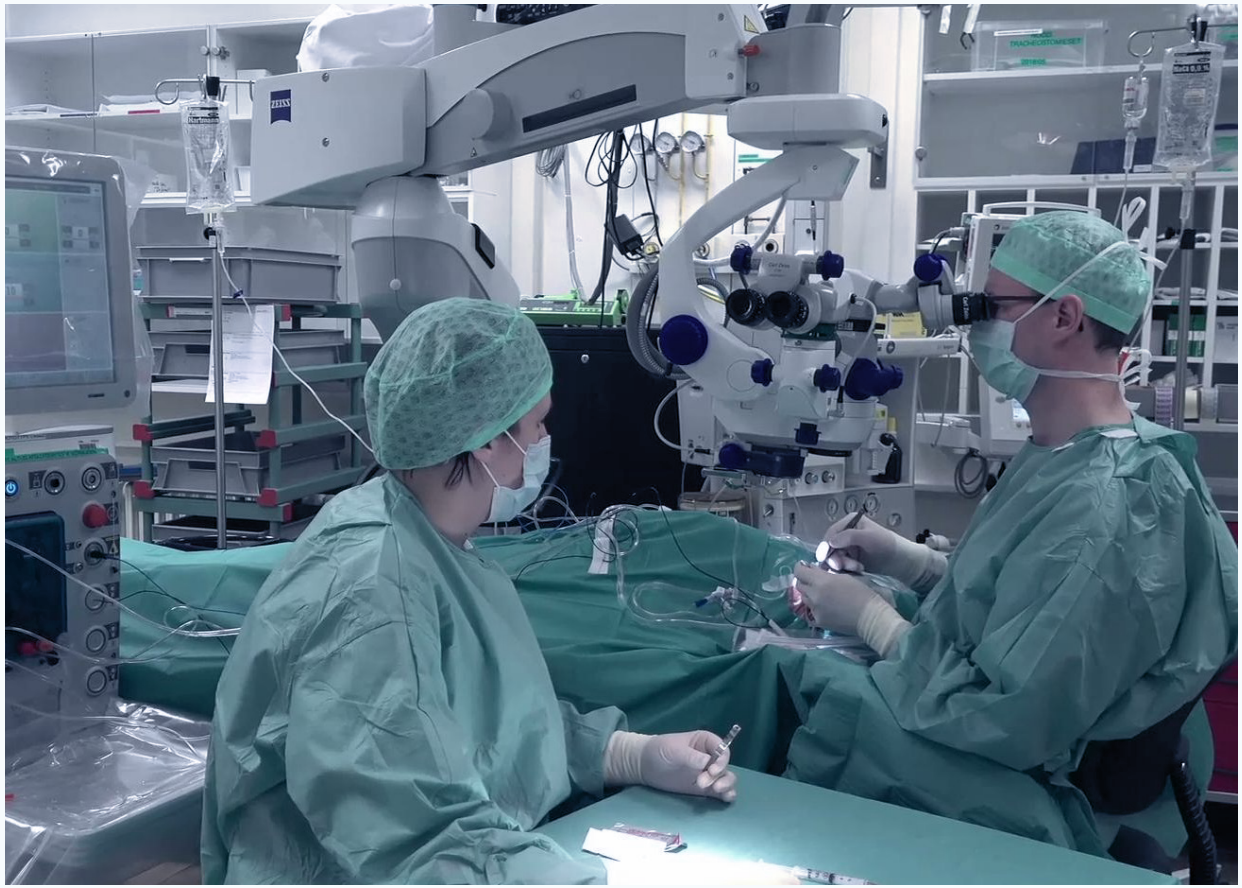


Figure 2.1 - 4 *Use environment of a cataract surgery, visualising the operating room with a surgical system, instruments, patient, surgeon, and personnel (Mayo Clinic, 2023)*

2.1.2.2 Roles personnel in the sterile environment

The surgeon is a central figure, undertaking critical responsibilities such as surgical planning, executing the surgery, and conducting pre- and postoperative assessments.

Working in tandem, the OR assistant plays a pivotal role in maintaining sterility by handling equipment, assisting in anaesthesia, preparing and managing the operating room and its equipment, and providing instruments to the surgeon.

The circulating nurse performs crucial tasks outside the sterile field, including non-sterile handling, managing supplies, facilitating patient transfer and aftercare, as well as meticulously documenting and verifying various aspects of the surgical process.

In the broader context of the surgical setting, responsibilities may vary, but the key roles and duties of each individual remain consistent. This coordination and adherence to sterile practices establish a seamless and secure surgical environment, ensuring the success of cataract surgeries.

2.1.2.3 Use case

In cataract surgeries, where each procedure typically spans a mere 10-15 minutes, a seamless and sterile flow of patients and equipment is paramount. The use case for the phaco handpiece has stages of preparation, active use during surgery, and subsequent steps.

As the phaco handpiece makes its entrance into the sterile environment in a sterile blue wrap, it arrives alongside an arranged sterile phaco kit of disposables, with needle and sleeve chosen by preference of the surgeon. The following process involves the precise application of the needle and sleeve, taking into consideration the alignment of the irrigation sleeve.

This prepared assembly is then transferred to the operating site, where it is connected to the surgical system. This step necessitates the transition of the sterile OR assistant's plug to a non-sterile nurse for the connection of the cable to the surgical system. Sterile irrigation and aspiration tubing is also connected to the disposable/reusable cartridge of the surgical system. With the application of the priming sleeve, the system can begin its priming program, a step often marked as a crucial time bottleneck.

During the cataract surgery, the phaco handpiece is instrumental in executing the key steps outlined in the surgical process from chapter "2.1.1 Cataract surgeries". At some point, the tubing is detached from the luer connectors and attached to the irrigation and aspiration (I and A) tooling.

Following the surgery, disposable elements such as the needle and sleeve are carefully removed. The used handpiece, along with other used surgical tools, is then transferred to sterilization within the hospital or at an external facility.

2.1.3 Phaco Functionality

This chapter aims to provide insight into the functionality of phacoemulsification from the surgeon's perspective, contributing to the contextual understanding of cataract surgery. For a more technical exploration of phaco functionality, readers are referred to Chapter 5.1 "Deep dive: Ultrasound performance".

During the phacoemulsification step of cataract surgery, surgeons uses a foot pedal or footswitch to modulate the power output of the phaco handpiece. In practical terms, increasing pressure on the pedal results in a higher stroke, while reducing pressure achieves a lower stroke. The intensity of power needed correlates with the hardness, crystallization, or development stage of the cataract.

Through consultation with OR surgeons, I determined that minimizing the amount of phaco energy is crucial for reducing the risks of complications. It is imperative to minimize the transfer of energy via the phaco handpiece into the eye. An essential precondition for this is the efficiency of the system, ensuring that the energy input into the handpiece is predominantly converted into movement at the needle's tip, avoiding excessive movement or heat generation in the rest of the handpiece.

Collaborating with this efficiency is the cooling system, a critical component in dissipating inevitable heat without introducing complications. In addition, precise tuning of the fluid system, specifically adjusting irrigation and aspiration pressure, is crucial. This fine-tuning is essential to uphold the natural eye pressure, or intraocular pressure (IOP), consistently, even during the aspiration of fragmented lens material. This ensures the preservation of a stable anterior chamber of the eye.

Key insights

General insights

- Phacoemulsification using a phaco handpiece is one of the steps in cataract surgery, a procedure in total taking around 10-15 minutes
- Phaco is the most common type of cataract surgery performed

RQ2: How can safety in terms of sterility be ensured for a hybrid reusable and disposable handpiece?

- Sterile use on the OR means an intact sterile field, where nothing unsterilized can enter
- Surgeons and OR assistants operate within sterile field, circulating nurses outside it

2.2 Product function analysis

For a comprehensive understanding of how the original phaco handpiece retains its functionality, an extensive functional analysis has been conducted on the original 3002.P phaco handpiece produced by Wefis GmbH. This chapter delves into the primary functions of a phaco handpiece, considering technical operation, usability, and sterility, based on the standard archetype phaco handpiece design. The function analysis performed on the 3002.P can be found in the confidential Appendix VIII and Figure 2.2 - 2. All information supporting this analysis has been obtained through design descriptions, consultations with the manufacturing party in later project stages, detailed technical testing, and hands-on analysis of disassembled handpieces.

It is noteworthy that, for the purpose of this functional analysis, the scope is limited to the phaco handpiece, aligning with the project's scope. Many functions related to phacoemulsification (such as driving, fluid collection, efficiency, monitoring, feedback, etc.) are ensured through the NEXUS EVA device. A visualization of this complete system is depicted in Figure 2.2 - 1

The primary use of a standard archetype phaco handpiece can be defined as follows:

"Enable safe phacoemulsification for multiple cataract surgeries."

Derived from this definition, several main functions are identified:

- Technical Operation: Cut and emulsify the lens.
- Technical Operation: Remove emulsified lens.
- Technical Operation: Maintain the eye at the right pressure and fluid level.
- Usability: Facilitate various types of surgical procedures.
- Usability: Enable multiple cataract surgeries.
- Usability: Enable handling by the surgeon.
- Sterility: Maintain sterility within the handpiece.

From these main functions, additional sub-functions are further delineated. The complete schematic is illustrated in Figure 2.2 - 1.

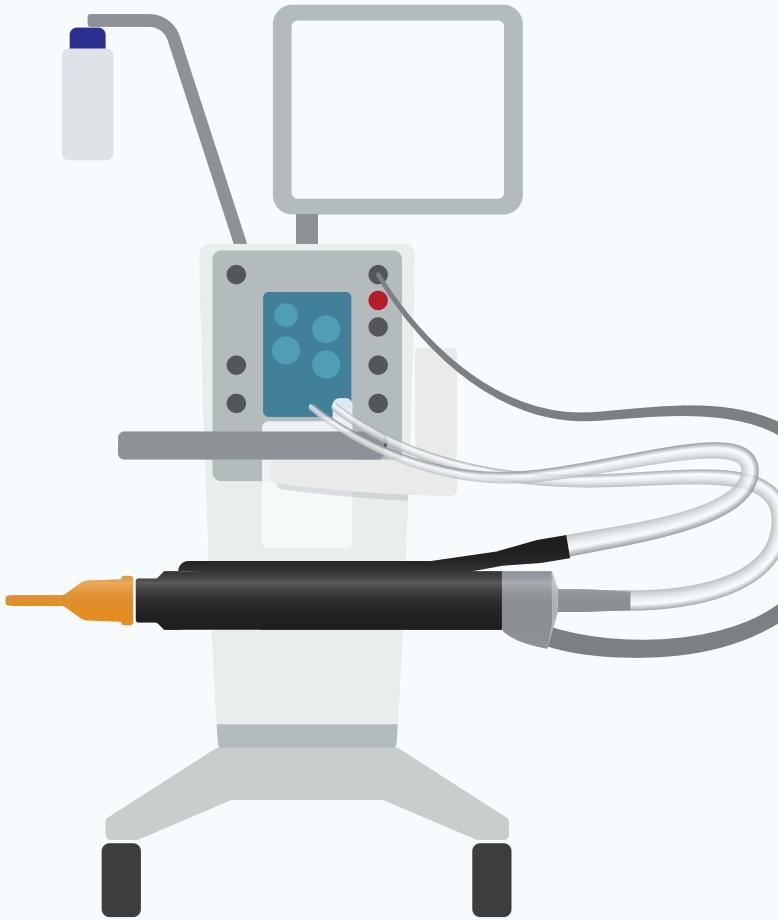


Figure 2.2 - 1 *Original phaco handpiece as used and connected to the EVA Nexus surgical unit, showing fluid lines and electrical connection; indicating the many functions able to be attributed to the EVA Nexus*

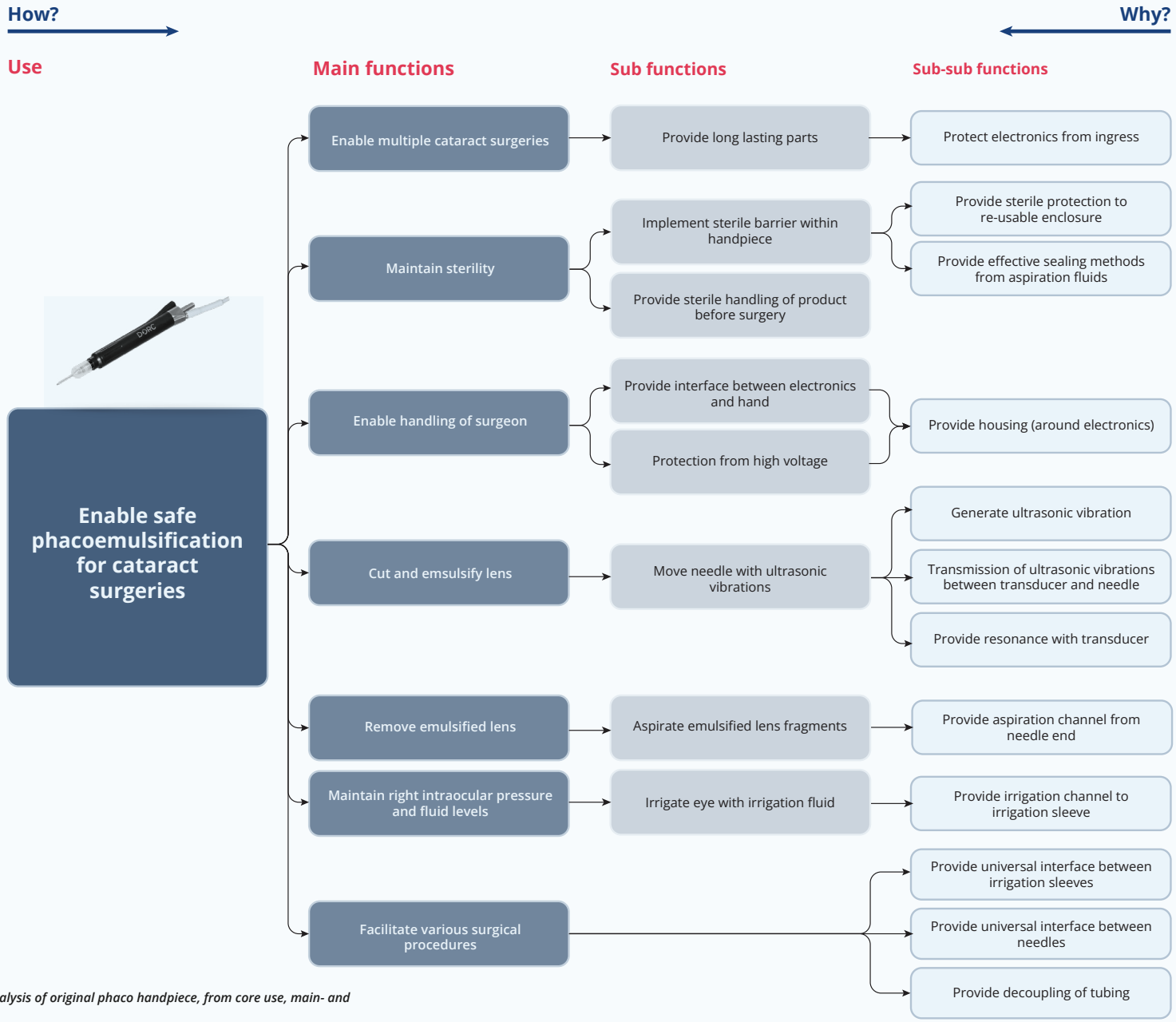


Figure 2.2 - 2 *Function analysis of original phaco handpiece, from core use, main- and subfunctions. Implementations of which can be found in Appendix VIII*

Key insights

General insights

- Primary use of a phaco handpiece is to enable safe phacoemulsification for multiple cataract surgeries

2.3 Previous work on embodiment design

2.3.1 Project evolution

To comprehensively document the project's evolution, a thorough examination of the work conducted on the hybrid phaco's development is essential. Initially focused on creating a fully disposable phaco project, sustainability and cost concerns led to the exploration of a hybrid phaco handpiece concept. The key modification involved eliminating the need for sterilization, allowing extended reuse of electronics and reducing environmental impact.

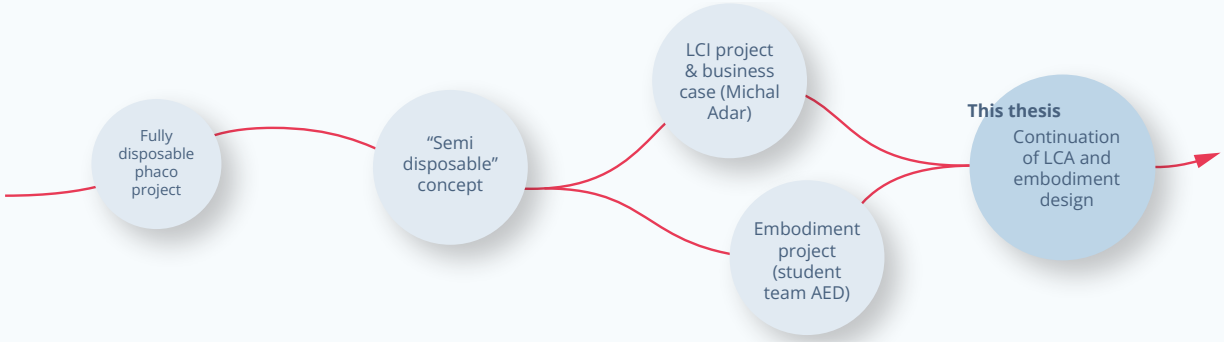


Figure 2.3 - 1 *Visualisation of project development over multiple consecutive projects*

The hybrid phaco concept spawned two parallel projects, as visualized in Figure 2.3 - 1. One project aimed to validate the sustainability claims, assessing the hybrid phaco's environmental impact throughout its life cycle (detailed results in Chapter "6.3 Environmental evaluation" on page 180). The second project focused on conceptualizing an embodiment design and was executed by a student team at TU Delft as part of the Advanced Embodiment Design course. I served as a Teaching Assistant and a member of the student design council for the AED team. It's crucial to note that all presented work, insights, and design considerations in this chapter are the students' contributions.

The student project, a precursor to the embodiment design phase, played a vital role in providing design input. The research from the student project serves as source material for this project. Although the design has been reevaluated and reconceptualized, drawing from the initial concept definition, the following section outlines the main features and design considerations from the student project.

2.3.2 Student design features and design considerations

2.3.2.1 Product architecture

In the initial stages of the student project, significant conceptualization focused on redesigning the general product architecture. The main emphasis was on rerouting fluids to avoid interfacing with electronics housed in the reusable part. The chosen design featured a fluid interface close to the needle, utilizing a flexible aspiration sleeve to capture fluids from the disposable transmission shaft (function visualized in Figure Figure 2.3 - 2). Other design directions were deemed unfeasible due to required changes to piezoelectric elements (piezos) or overall feasibility.

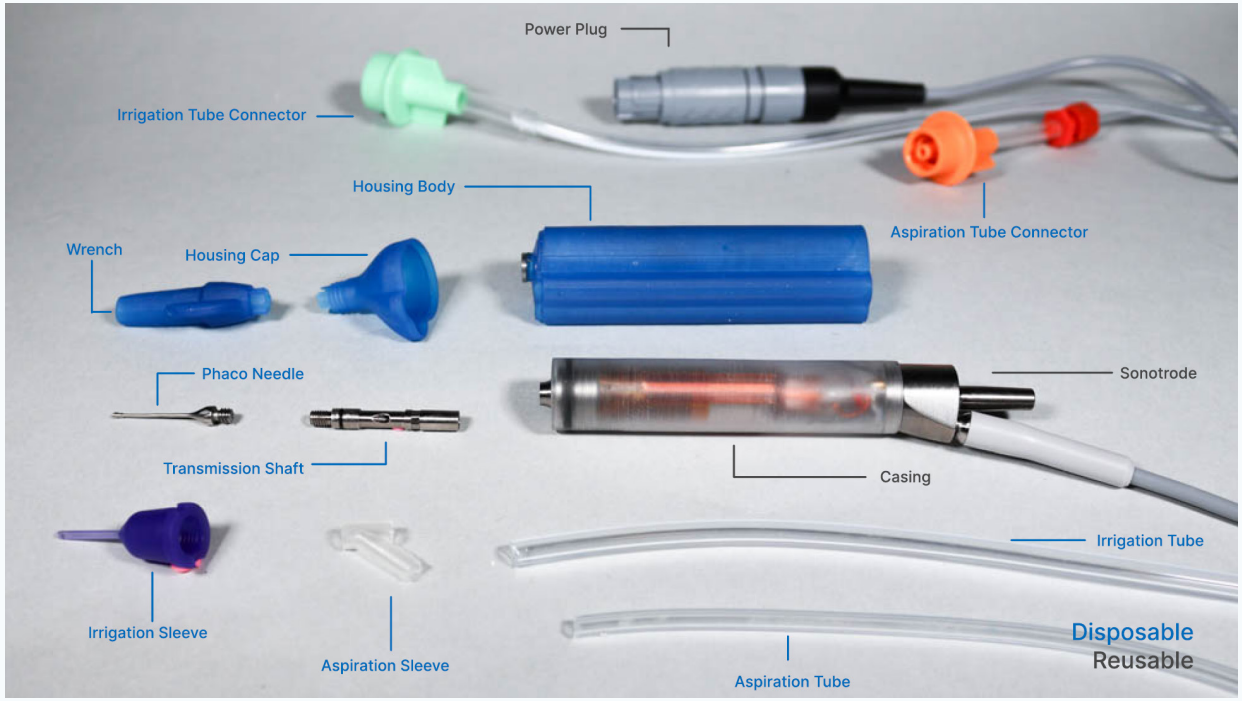


Figure 2.3 - 2 *Final embodiment design done by student team, highlighting different components and functions*

2.3.2.2 Ergonomics

An ergonomics study was conducted by the students, involving employees within DORC (n=6). Three different designs with varying holding diameters (16.8mm, 15.8mm, and the original 3002.P handpiece with 10mm diameter) were explored. The study revealed diverse preferences during sustained usage, providing valuable insights into ergonomic considerations.

2.3.2.3 Sterile assembly

The student design also addressed the sterile assembly method within the operating room for the disposable and reusable parts of the handpiece. The correct identification of sterile and non-sterile fields and handling approaches served as the starting point for the redesign in this project.

2.3.2.4 Sonotrode design

Regarding the sonotrode design, the student approach aimed to stay close to the original geometry to maintain correct phaco performance. While more redesigning was carried out in the subsequent project, the overarching approach of adhering closely to the original design remained.

Despite the redesigned fluid interface being unsuccessful in testing, leading to failure under ultrasonic load (shown in Figure 5.1 - 6), this served as a starting point for the redesign within the same product architecture.

2.3.3 Student design project limitations

2.3.3.1 Ultrasound functionality

The student project had set ultrasound functionality out of scope, creating a clear limitation for the student project. The limited groundwork in ultrasound understanding during the student project constrains the exploration in this area for the final prototype iteration.

2.3.3.2 Material exploration

Material selection underwent some exploration, considering embodied energy and biocompatibility, leading to the choice of polypropylene. However, this exploration has limitations, with unanswered questions about the impact on product qualities and heat resistance. The selection of a polycarbonate housing and a titanium transmission shaft, both with high environmental impact, is acknowledged with this limitation in mind.

2.3.3.3 Fluidics interface testing

Limited exploration of different concepts to a prototypeable level restricts the substantiation for the chosen solution of a flexible aspiration sleeve. Testing resulting in the irrigation sleeve failing under ultrasonic load is identified as a limitation to the project.

2.3.3.4 I/A tooling

With the unfortunate late realization of a requirement for a luer interface being accessible during the surgery for the I/A tooling, this design solution falls short. This has promptly been identified as recommendation for my project.

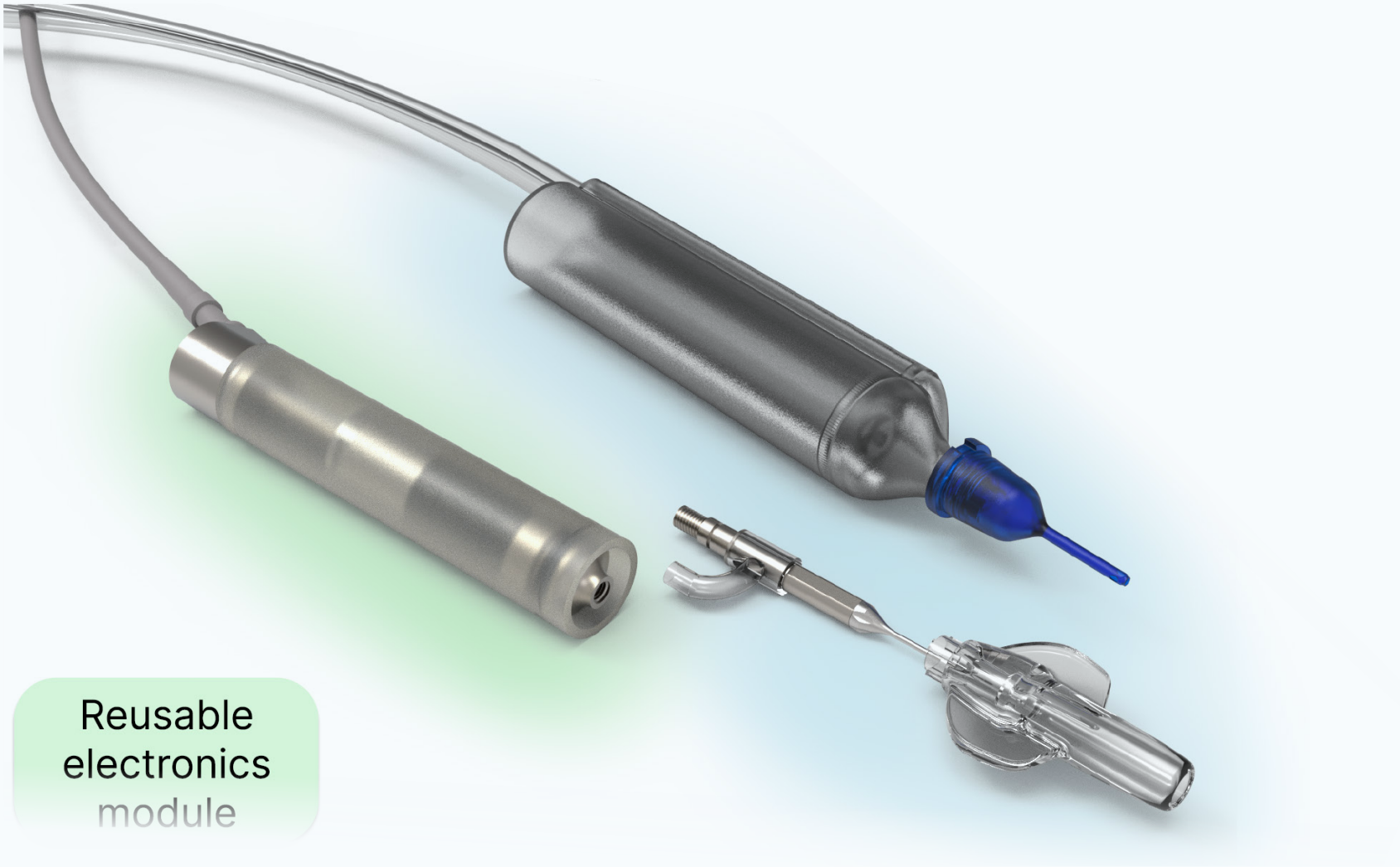


Figure 2.3 - 3 *Final embodiment design done by student team,*

Key insights

General insights

- Previous efforts in hybrid phaco research have included conducting a Life Cycle Assessment (LCA), business case development, and student-led embodiment design.

RQ3: How can a phaco handpiece be redesigned to make use of disposables?

- Embodiment design limitations were exploring ultrasound functionality, testing fluidics interfaces, and assessing the impact of material choices on functionality.

2.4 Regulation, market, and stakeholders

To contextualize this project, a broad overview of the current market, regulatory considerations, and a summary of project stakeholders is provided. While these areas are not the primary focus of the project, they serve as important boundary conditions to enhance the understanding of the project. Due to their supportive role, these topics are not explored in detail.

2.4.1 Rules and regulations

Medical device regulations are designed to safeguard patient health. They go beyond regulating product specifications, since they mandate a methodical approach to ensure the delivery of safe healthcare solutions. Manufacturers must adhere to strict quality management systems, pre-market approval processes, and rigorous testing and documentation procedures. This contributes to the medical device market being a highly regulated market.

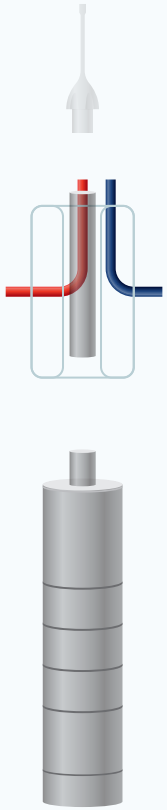
With phaco specifically having little literal requirements on the product level, in this chapter I will outlie some general relevant regulation standards for phaco and to the circular vision of this project.

2.4.1.1 General applicable regulation

Within the European Union, the Medical Device Regulation (MDR) serves as a comprehensive framework, delineating general performance and safety regulations for all medical device manufacturers in EU markets. It sets standards for product conformity assessments, post-market surveillance, and the requisite quality documentation for introducing medical devices to the market. The MDR employs specific classifications to determine corresponding requirements. Although not directly pertinent to the thesis's product development, the redesigned products (both reusable and disposable) adhere to MDR classifications outlined in Annex VIII (European Union, 2017) for future development, as depicted in Figure 2.4 - 1 along with the corresponding clause.

Considering the packaging's crucial role in sterile handling and the integral functioning of ultrasound transmission, it is accorded the same MDR classification, with more details on the design available in Chapter 4.5.5 "Blister packaging".

On a global scale, ISO standards, particularly ISO IEC 60601-1-12:2014 - Medical electrical equipment, play a vital role. Part 1, emphasizing general requirements for basic safety and essential performance, establishes fundamental safety principles for medical electrical equipment. Essential performance, defining critical functions for patient safety and intended clinical results, is introduced. General guidelines for



Class IIA,
Rule 2 of MDR Annex VIII

Non-invasive device intended for channeling liquids into the body

Class IIA/IIB,
Rule 9 of MDR Annex VIII

Active device intended to administer energy (with the human body in a potentially hazardous way)

Figure 2.4 - 1 *MDR classification phaco concept and corresponding clause*

products requiring sterilization, referencing the Spaulding classification (Nanosonics, n.d.), are outlined. Further details on sterilization requirements are expounded in Chapter 5.4 "Deep dive: Sterility".

2.4.1.2 Circular design initiatives in the medical sector

Circular design principles in the medical sector are not specifically regulated by a dedicated set of rules or regulations. However, there are broader sustainability initiatives, and guidelines that can indirectly influence or encourage circular design practices in the medical field. v

The European Union is driving sustainability with flagship initiatives such as the EU Green Deal (European Commission, 2021) and Circular Economy Action Plan (or CEAP) (European Commission, 2020), both presenting circular principles for a more resilient economy. At the national level, the Netherlands addresses circularity through its Nationaal Programma Circulaire Economie (Ministerie van Algemene Zaken, 2023), a strategic vision spanning 2023-2030. In tandem, the Waste Framework Directive (European Commision, n.d.) establishes the legal framework for efficient waste management practices. While this does not apply explicitly to medically hazardous waste , it does outline general some objectives.

The most recent addition to these agreements is the EU-approved Ecodesign for Sustainable Products Regulation (European Commission, 2023), a component of the CEAP. This regulation aims to establish sustainable products as the standard in the EU by enhancing durability, improving energy and resource efficiency, facilitating easier repair and recycling, minimizing substances of concern, and increasing recycled content. It enables the establishment of performance and information requirements for key products in the EU market. Specific consideration is given to medical devices, emphasizing the importance of patient safety in the context of circular design approaches (European Commission, 2022).

Within the medical device sector, these initiatives advocate for eco-design and waste reduction, urging manufacturers to integrate circular solutions for prolonged product life cycles.

2.4.2 Current phaco market

A general description of the global phaco market will be outlined in this chapter, without specifically incorporating statistics specific to DORC products.

The global phacoemulsification (phaco) market has witnessed significant growth, fuelled by the increasing prevalence of cataracts and the surge in demand for advanced surgical interventions (Technavio, 2023). With cataracts affecting a substantial portion of the aging population, phaco surgeries have become a cornerstone in addressing this vision impairment.

Annually an estimated 27 million phaco surgeries are performed worldwide (Q-bital Healthcare Solutions, 2021), reflecting the widespread adoption of this minimally invasive technique. The escalating numbers can be attributed to the rising global aging demographic, as cataracts are predominantly age-related. With a growing elderly population, the demand for cataract surgeries, particularly phacoemulsification, has surged. Among all the regions, North America is expected to account for the largest share in the cataract surgery devices market. Owing to significant growth factors such as rising prevalence cataracts due to the increasing prevalence of diabetes, hypertension, obesity, and the aging population (DelveInsight, 2023).

With other methods like FLACS (plus phaco) still only accounting for around 3% of the global market, and phaco accounting for nearly 70% (and projected growth to 72% in 2026) (Market Scope, 2021) phaco will be the predominant player in the cataract surgery market.

2.4.3 Competitors

In the global phaco market, DORC Global contends with major industry players such as Alcon, Bausch & Lomb, Johnson & Johnson (J&J), and Hoya Surgical Optics, among others. Recognizing the significance of competition is crucial for discerning market trends and technological advancements.

While the foundational product architecture of phaco handpieces remains consistent across competitors, variations arise in sealing methods, impacting autoclave sterilization resistance and overall durability. Additionally, distinctions in the layout of piezo elements, responsible for ultrasound production, influence surgeon preferences and brand adoption.

Companies further differentiate themselves through proprietary longitudinal and torsional phaco techniques, each varying in efficiency and surgical feel (elaborated in Chapter 5.1.1 “Mechanical principles of ultrasound in phaco”). Johnson & Johnson’s Veritas Swivel design (Figure 2.4 - 2) stands out for prioritizing usability and ergonomics, addressing user experience and procedural efficiency.

Distinguishing DORC from other phaco manufacturers is their emphasis on combined surgery of both anterior and posterior segments, facilitated by their surgical system. This system, the EVA Nexus, accommodates both phacoemulsification and vitrectomy procedures.

Notably, dedicated sustainable solutions are a seemingly unexplored field in the phaco market, presenting an opportunity for hybrid phaco to introduce sustainable practices. Given the industry’s focus on technological advancements and product efficacy, integrating sustainable solutions holds promise for future developments.

Figure 2.4 - 2 *Competitors handpieces showing general similar product architecture. From left to right: Alcon Active Sentry, Bausch and Lomb Stellaris, Johnson & Johnson Ellips FX and J&J Veritas Swivel (Ophthalmon, 2020)*

Key insights

General Insights

- Regulation pose strict guidelines on project quality management, and product safety, performance, sterilization, and more.
- Circularity design practices are influenced, but not yet regulated, by growing sets of initiatives by the EU. These initiatives advocate for circular solutions.
- With an annual 27 million worldwide surgeries, phaco accounts for 70% (and growing) of global cataract market.
- All competitors have similar product architecture handpieces, with sustainable solutions remaining unexplored.

2.5 Stakeholder analysis

Internally DORC has conducted a thorough stakeholder analysis. This chapter will spotlight key considerations and noteworthy stakeholders crucial for the development of a hybrid phaco handpiece from this stakeholder analysis. Stakeholders addressed in this chapter with substantial interest and influence in the project, highlighted in Figure 2.5 - 1, hold pivotal roles in shaping its direction and outcomes.

The inclusion of “environmental health” as a stakeholder is noteworthy. Defined without human attributes, this stakeholder lacks direct power by definition. Moreover, the concept of “interest” is extended to encompass this stakeholder. For the sake of creating a more holistic overview of relevant factors in this project, this stakeholder was included.

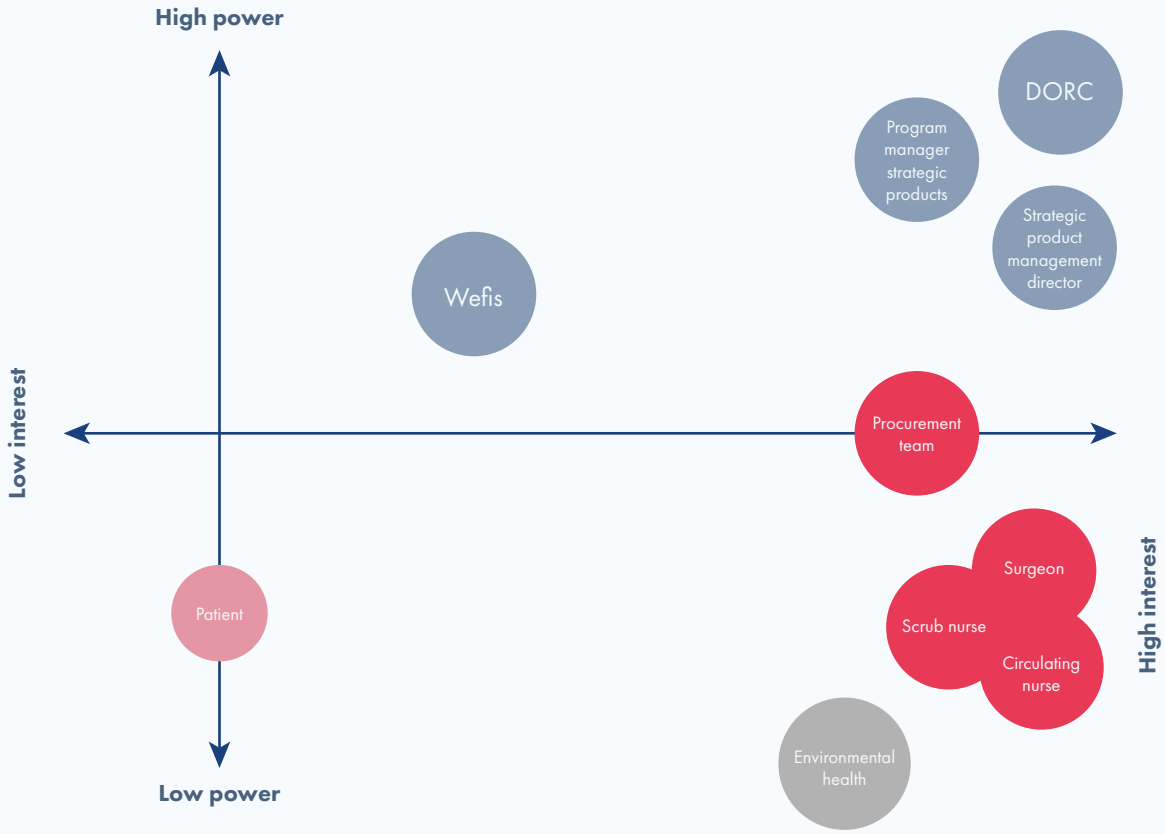


Figure 2.5 - 1 *Condensed stakeholder analysis, showing most substantial interest and influence in the project, furthe examined in chapter 2.5*

2.5.1 Hospital

2.5.1.1 Surgeons

The medical professional with the most significant interaction during the use phase of surgery is the surgeon. Their primary objectives include ensuring patient safety, achieving optimal surgical outcomes, and minimizing waste generated during procedures. Overcoming barriers, such as the acceptance of a new handpiece, is a challenge. Surgeons often prefer familiar tools for their confidence in ensuring positive patient outcomes, as highlighted in DORC internal expert consultations. Convincing surgeons of the sustainability benefits, especially with the introduction of a seemingly new disposable, and addressing concerns about the sterility and stability of the redesigned handpiece, is indispensable. Therefore, engaging surgeons in the later stages of this project through consultations is crucial for success.

2.5.1.2 Scrub nurses/OR assistants

While the surgeon is most involved with the handpiece during the use phase, the scrub nurse plays a crucial role during the preparation phase. The scrub nurse "scrubs in" to support the surgeon in sterile procedures and is responsible for preparing instruments within the sterile barrier.

Usability considerations must be closely aligned with scrub nurses, given their expertise in both formal and informal procedures in the operating room. Their role is pivotal in maintaining a sterile field and ensuring the security of the instrumentation. Collaboration with scrub nurses is essential to address usability concerns effectively in the design and implementation of the handpiece.

2.5.1.3 Circulating nurses

The circulating nurse holds responsibility for all non-sterile tasks in the operating room, ranging from preparing the operating room and managing product stock to pre- and post-patient care. In the current handpiece setup, the circulating nurse has minimal interaction, mainly plugging the handpiece into the EVA Nexus. However, with a redesign that includes a non-sterile reusable component in the hybrid, the circulating nurse assumes additional responsibilities in preparing part of the instrument. This shift highlights the importance of considering the impact on the circulating nurse's role in the implementation of the redesigned handpiece.

2.5.1.4 Procurement teams

The procurement team plays a vital role in selecting companies and products for hospital use, extending beyond the influence of surgeons in the decision-making process for phaco handpieces. In addition to considering surgeons' requirements and sustainability considerations, procurement teams weigh factors such as costs per surgery and initial investment expenses

2.5.2 Internal

2.5.2.1 DORC

DORC, as an entity, aspires to develop its own handpiece that preserves the quality of the original while enhancing sustainability and relieving surgeons of their concerns about cross-contamination in eye surgery. Backed by substantiated environmental impact analyses, positive user feedback, and a viable business case aligned with circular product design principles, DORC expresses a keen interest in advancing the vision proposed by this project.

2.5.2.2 Wefis GmbH

Wefis, the original equipment manufacturer (OEM) of the phaco handpiece, possesses extensive knowledge in the development of this critical component. Since its acquisition by DORC, Wefis has become an integral player in the redesign process. Their unparalleled expertise in phaco functionality and mechanical tuning of sonotrode designs to achieve specific phaco characteristics has proven indispensable in shaping the development of the redesigned handpiece.

2.5.2.3 Design Usability & Risk Control Manager

This individual within DORC serves as the primary liaison between the OEM and the rest of the company. Holding the most comprehensive knowledge within DORC regarding the handpiece and instruments in general, and having been instrumental in implementing usability changes to the product assembly, this product owner is poised to play a pivotal role in the ongoing progression of this project.

2.5.2.4 Strategic Product Management Director

This individual within DORC serves as a crucial link between users and the R&D department. Part of their role in product development involves engaging with surgeons to understand their needs, and they are frequently present in the operating room alongside surgeons. In the acceptance of the redesign by surgeons, this person might play a significant role, leveraging their close connection with end-users to ensure that the redesigned product aligns seamlessly with surgeons' requirements and preferences.

3. Circular design

This chapter emphasizes sustainability as the primary driver of the project, particularly focusing on the proposal for a circular design. It delves into the approach to circularity and sustainability within the disposable phaco project, exploring key definitions of the circular economy. Additionally, it examines prior internal work on the circular design proposal within DORC. Alongside the proposal, the chapter considers the business aspect of the circular design, addressing it as a value proposition and incorporating cost considerations. This exploration contributes to shaping the circular business case for the project.

Figure 3.1 - 1 *Sterile storage sterilizated reusable instruments of hospital central sterile services department, retrieved from (Elite Medical Equipment, 2023)*

3.1 Definition of the circular economy

The circular economy offers an alternative to the linear, cradle-to-grave approach of traditional economic principles. In the conventional model, materials are produced, and the value created is ultimately destroyed through incineration or in landfills at the End of Life (EoL). In contrast, the circular economy retains value and transforms resource pathways into ongoing circular flows (Ellen MacArthur Foundation, 2013) (Bakker, 2019).

"The circular economy is a system where materials never become waste and nature is regenerated. In a circular economy, products and materials are kept in circulation through processes like maintenance, reuse, refurbishment, remanufacture, recycling, and composting"

An exact definition of the circular economy is presented by Kirchherr et al. (2017), synthesizing 114 definitions of the circular economy:

"A circular economy describes an economic system that is based on business models which replace the 'end-of-life' concept with reducing, alternatively reusing, recycling and recovering materials in production/distribution and consumption processes, thus operating at the micro level (products, companies, consumers), meso level (eco-industrial parks) and macro level (city, region, nation and beyond), with the aim to accomplish sustainable development, which implies creating environmental quality, economic prosperity and social equity, to the benefit of current and future generations".

The ultimate goal of circular design practices is not to create the perfect circular economy, given that leakage is inevitable and some value will always be lost. Pursuing this circular economy, the environmental impact of created products can be vastly reduced.

The Circular Economy is a practice through which impact is reduced, value is retained, and value pathways become circular loops. This practice ultimately requires a systematic shift in considering value, fitting business models, and applicable products.

3.1.1 Value hill and resource cycles

At the basis of the circular economy lies the value hill, a basic model that visualizes a product's increased value from production to its highest point in the use phase and the subsequent destruction of value after use in a completely linear approach. This value appreciation remains the same in circular approaches, with higher-level recovery pathways such as reuse/redistribute retaining the most value from the post-use phase to the use phase. In contrast, lower-level recovery pathways like recycling retain less value from the post-use phase into the pre-use phase. Implementing higher-level recovery pathways results in the highest value retention. The value hill model also incorporates basic R frameworks, further adapted in the 9R framework (chapter 3.1.2 "9R framework").

The resource cycles, as implemented in the value hill model, are further refined by Bocken et al. (2016), where resource cycles are specified into three dimensions for improving circular design: slowing loops, closing loops, and narrowing loops. The dimension of narrowing loops, using fewer resources per product, is not necessarily aimed at cyclic use but is more of an efficient approach to cradle-to-grave. Another dimension, slowing loops, involves extending or intensifying the utilization period of products, achievable through design for long-life products (such as durability) or through product-life extension (such as repair/remanufacturing). The final dimension, closing loops, involves forming a loop between post-use and pre-use/use through recycling in the most general sense.

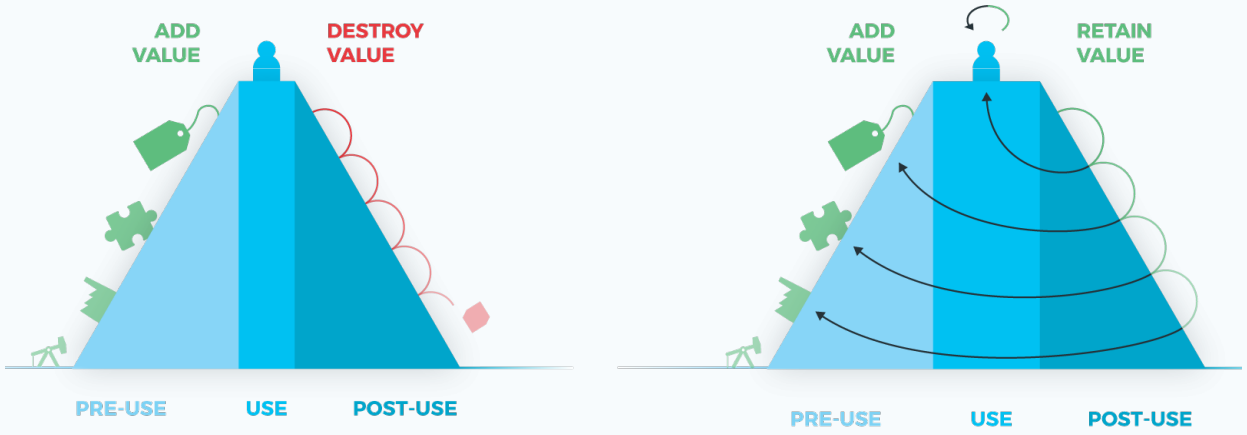


Figure 3.1 - 2 *Value hill model, showing the increasing value up until use-phase, with consequent destruction of value post-use. A circular model shown next, where value is retained in varying levels. Retrieved from (Circle Economy, n.d.)*

3.1.2 9R framework

In the circular economy, R frameworks describe distinct recovery paths, ranking them on circularity. This adapted 9R framework (Potting et al., 2017) outlines nine strategies, introducing "recover" as an R (Kirchherr et al., 2017), signifying energy recovery through incineration, a linear approach. This provides a complete scale from linear to fully circular approaches (Figure 3.1 - 3).

Generally, higher-level circular pathways like "Reuse," "Refurbish," and "Remanufacture" closely align with circular economy principles, prioritizing resource preservation and extended product lifespans, carrying lower environmental pressures. In contrast, lower-level pathways such as "Recycle," "Recover," and "Redistribute" contribute to circularity but may involve additional energy or resource inputs and varying environmental impact.

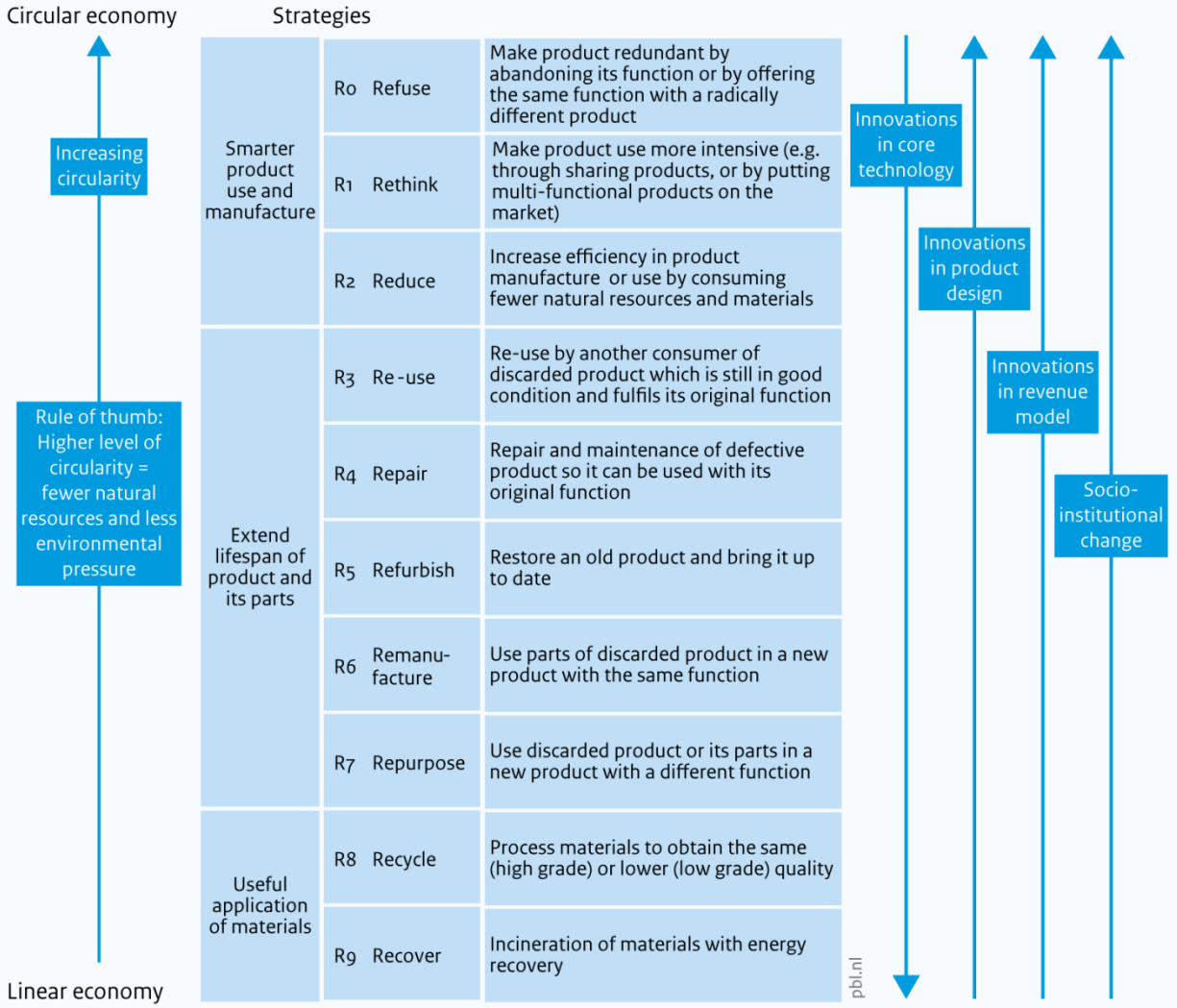


Figure 3.1 - 3 *9R framework, showing an different levels of circular pathways, retrieved (Potting et al., 2017)*

Key insights

General insights

- The Circular Economy is a practice through which impact is reduced, value is retained, and value pathways become circular loops.
- Value retention and resource cycles in Circular Economy is best characterized by the value hill model, showing increasing and decreasing value over a products life cycle.
- 9R framework adopts these principles and formulates them into distinct ranked circular design strategies

3.2 The circular approach

This thesis primarily focuses on the feasibility study of an embodied design aligning with specific circular models. In essence, the question addressed is whether a split design, comprising a non-sterile reusable and a sterile disposable component, can function effectively, taking the clinical context into account:

The concept design presented in this thesis, along with the embodied design, marks the initial phase toward establishing a fully circular system (Figure 3.2 - 1)

This chapter not only presents a proposed product system map for this initial step but also identifies potential future steps to move closer to a perfect circular system. While these steps are somewhat speculative, they are grounded in the analysis of the Life Cycle Assessment (LCA) conducted on the current redesign. The suggested future steps in this chapter address aspects of the lifecycle with high impact on a product level.

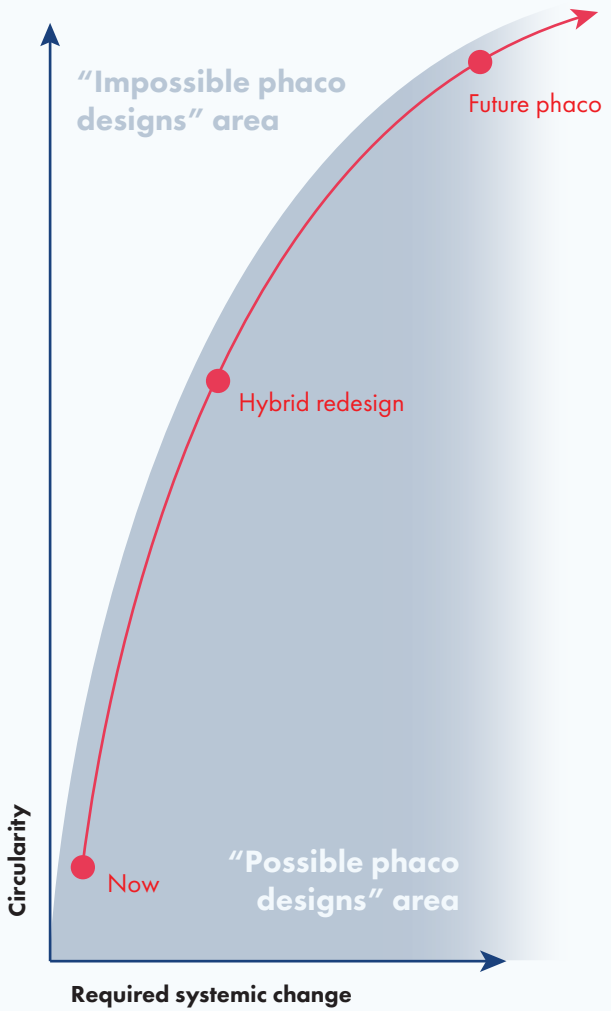


Figure 3.2 - 1 *Road towards circularity, showing hybrid phaco as first leap towards circularity, while not requiring as much systemic change.*

3.2.1 First step: current redesign

The current redesign emphasizes strategies for enhancing the circularity and efficiency of resource cycles. This initial step is deemed feasible within the existing facilities of DORC and the hospital, requiring minimal systemic changes.

3.2.1.1 Closing and slowing the loop

Water damage from autoclave sterilization is a significant cause of handpiece breakage, resulting in a guaranteed lifetime of approximately 200 cycles. Although field reports suggest lifetimes sometimes nearing 500 cycles, this falls below average competitor's guarantee.

By reimagining the product, the need for sterilization is eradicated, leading to increased product durability. This aligns with the circular approach of long-life products, contributing to slowing the loop (Bocken et al., 2016).

A significant cause of handpiece breakage is plug issues and the piezos physically cracking. While the plug can be replaced in reparation, a facility already in use at Wefis GmbH, the piezos breaking means the original handpiece cannot be repaired. This is due to the welded and pressed titanium body. The proposed redesign allows for repair, addressing piezos concerns and following the product-life extension circular approach (Bocken et al., 2016), thereby closing the loop further.

The simplified product system map visualised using the value hill model (chapter "3.1.1 Value hill and resource cycles") is illustrated in Figure 3.2 - 2. A comprehensive visualization of both the original handpiece and the proposed product system maps can be found in Appendix VI.

3.2.1.2 Narrowing the loop on disposable

By eliminating sterilization, a significant aspect of the Life Cycle Assessment (LCA) is removed (refer to chapter "6.3 Environmental evaluation" on page 180), aligning with the "Rethink" principle in the 9R framework (Potting et al., 2017). The introduction of the disposable, whose value will be ultimately destroyed through incineration, increases the system's footprint. Incineration is necessary as the disposable is considered biohazardous material (Environmental Health & Safety [EH&S], n.d.). Thus, narrowing the loop in this aspect is crucial for achieving circularity.

An efficient embodiment design in terms of CO2eq of the disposable is developed (chapter 4.4 "Disposable components"). Key focus points for the redesign of the hybrid phaco handpiece are identified through the analysis of the Life Cycle Assessment conducted during the student project (chapter "6.3 Environmental evaluation" on page 180).

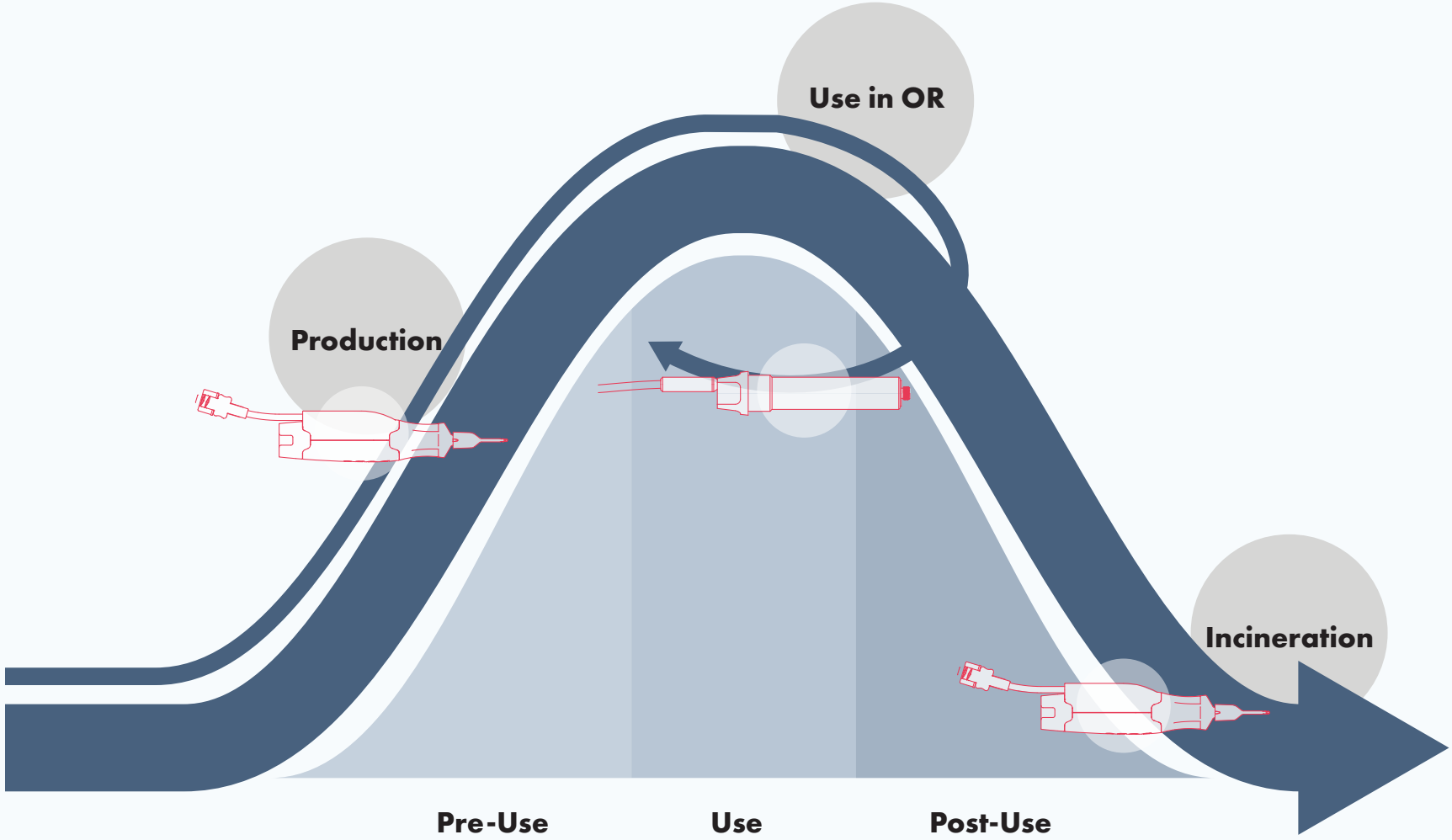


Figure 3.2 - 2 *First step towards circular economy as designed for in this thesis, visualised using a value hill like - modelProposal future steps*

3.2.2 Proposal future steps

While the suggested redesign presents a highly feasible path to a circular system, this chapter will delve into potential future steps to move closer to an ideal circular system. It's important to note that these steps are primarily driven by further impact reduction within the system and are less framed within the context of a comprehensive circular business model. Additionally, the specific impacts of these proposed future changes are not quantified but are derived from the Life Cycle Assessment (LCA) results of this embodiment design and the general principles of the circular economy outlined in chapter "6.3 Environmental evaluation" on page 180. This section will detail potential systemic challenges and advantages associated with these future steps.

3.2.2.1 Further reduction in impact of disposable component

Having conducted the Life Cycle Assessment (LCA) on the disposable component (chapter "6.3 Environmental evaluation" on page 180), additional efforts can be directed towards further reducing the environmental impact of the disposed components.

Potential avenues for reduction may involve minimizing the weight of each component, with a focus on optimizing the packaging design, shown in chapter 4.5.5 "Blister packaging".

Exploring alternative materials with lower inherent environmental impact, such as recycled materials or biopolymers, could be a promising direction. The use of these materials is associated with lower embodied energy compared to virgin fossil-based polymers (Haffmans et al., 2018) (The Association of Plastic Recyclers, 2020) (Singh et al., 2022). However, it's crucial to note that even with these materials, the disposable items remain classified as hazardous materials, necessitating incineration in current waste processing systems and preventing a complete closure of the loop. This strategy is visualised under pathway 1 in Figure 3.2 - 3.

The adoption of recycled materials and biobased polymers raises challenges related to the biocompatibility of these materials for use in disposable housing bodies. Existing solutions like Bio-PP by Borealis, known as "Bornewables" (Borealis, n.d.), guarantee no a change in biocompatibility compared to fossil-based alternatives. Nevertheless, extensive research will need to be done on the biocompatibility of these alternative materials considering their use case.

3.2.2.2 Higher level recovery pathways for disposal

Exploring higher-level recovery pathways for both fossil-based and biobased polymer hazardous waste, beyond the common practice of incineration, could contribute to further reducing the environmental impact at the End of Life (EoL) stage. Ritzen et al., (2023) provides a comprehensive overview of potential higher-level recovery pathways for biobased and fossil-based polymers. Consideration of these alternatives aligns with the circular economy principles of maximizing value retention and minimizing environmental pressures throughout a product's lifecycle.

Implementing higher recovery pathways for hazardous medical waste, particularly for mono-material products (requiring an additional redesigned of hybrid phaco), would necessitate changes in the operating room (OR) for effective waste separation. Additionally, significant shifts in the handling of medically hazardous materials at end-of-waste processing facilities and regulatory frameworks would be essential. The advantages and feasibility of such initiatives for DORC, as well as potential collaboration with waste processors, need to be thoroughly explored to drive meaningful change in waste management practices. This strategy is visualised under pathway 2 in Figure 3.2 - 3.

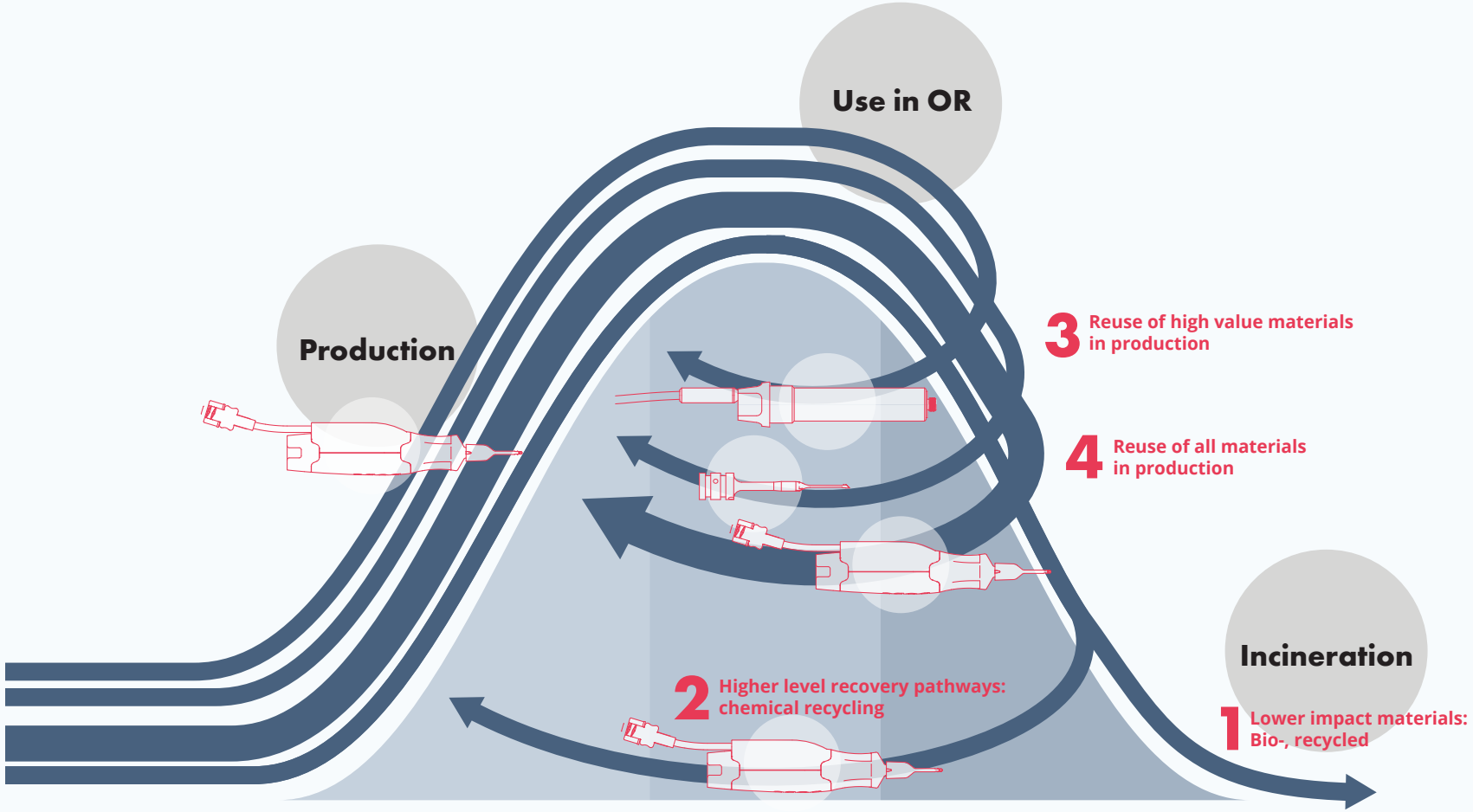


Figure 3.2 - 3 *Possible strategies towards circular economy proposed in this thesis, visualised using a value hill like - model*

3.2.2.3 Closing the loop on valuable materials

Utilizing the insights from the Life Cycle Assessment (LCA) conducted on the current redesign (chapter “6.3 Environmental evaluation” on page 180), emphasis can be placed on pinpointing areas where impact reduction is most impactful during the production phase. The consideration of highly valuable materials, such as the aluminium horn and titanium needle, for reuse in the production of new disposables for handpieces presents a promising avenue to close the loop in a high-value recovery pathway.

For the reuse of the needle and horn, treating them as hazardous medical waste, a systematic process involves separating the components from the handpieces, washing them, and conducting quality assessments (QA), potentially in local hubs. Subsequently, the components need to be collected and subjected to sterilization, either through Ethylene Oxide (EtO) or other sustainable alternatives suitable for the material (Massey, 2005). The viability of this process might necessitate a large-scale implementation worldwide, possibly in conjunction with automated separation and QA processes. Comparing the environmental impacts of autoclave sterilization (Snijder & Broeren, 2022) versus EtO sterilization (Schulte et al., 2021) per piece, EtO sterilization in bulk could present a more sustainable solution, even when considering transportation. An in-depth Life Cycle Assessment (LCA) comparing the LCAs of the components should be conducted to quantify any potential differences.

A significant advantage for DORC could be a notable reduction in costs for components used in disposable production, especially given that the disposable horn and needle are relatively the most expensive components (chapter 5.10 “Deep dive: Cost price”). However, this would necessitate substantial systemic changes for DORC, involving the installation of facilities like local QA hubs for efficient reuse and a broader scale of reused components across DORC’s product portfolio to justify viability. This option remains speculative and could be more suitable for future steps towards achieving circularity. This strategy is visualised under pathway 3 in Figure 3.2 - 3

3.2.2.4 Closing the loop on all materials

As recovery pathways are established for valuable materials, a logical progression is to develop a design that is suitable for 100% component reuse and remanufacturing. This would necessitate not only a redesign on the component level with higher-quality materialization for durability but also a design that can be disassembled, potentially through automation. This step would utilize the same facilities proposed in chapter 3.2.2.3, involving washing, (local) quality assessment, transportation, and EtO sterilization. This strategy is visualised under pathway 4 in Figure 3.2 - 3

Key insights

RQ4.2: What is the environmental impact of a functional hybrid phaco handpiece?

- Hybrid Phaco is the first step towards a circular system, requiring little systemic change.
- First step is characterized by closing the loop on the reusable increasing its lifetime, and by decreasing impact of the disposable as much as possible.
- Future steps could lie in further impact reduction of materials used, and by reusing used high value and lower value parts in production after surgery through washing, QA, and EtO sterilization

3.3 Circular system design for hybrid phaco

This chapter systematically reviews key elements in the circular design of the hybrid phaco redesign. Beginning with a comprehensive examination of the product system map and the life cycle inventory and assessment by Michal Adar, done internally in DORC. The proposed circular system is further visualized, emphasizing environmental impact visualization for a holistic perspective on sustainability.

We revisit circular business cases proposed by Michal Adar, offering strategic insights. The chapter concludes by scrutinizing the value proposition and cost considerations. Detailed LCA results as performed by Michal Adar on the original product, and performed on the hybrid phaco redesign for final environmental evaluation can be found in chapter 6.3 “Environmental evaluation”.

3.3.1 Product life cycle and circular system

This chapter delves into the product life cycle and the corresponding circular system, drawing insights from the work conducted by Michal Adar. The comprehensive product system map (appendix Appendix VI) serves as a foundational guide, showing material flows and their corresponding stages. Furthermore, the life cycle assessment, offers a detailed examination of the environmental impact of both the original reusable handpiece as well as the student redesign.

I visualized these LCAs as a "circular system" in Figure 3.2 - 2 and Figure 3.3 - 3 to illustrate the impact of this project on the value chain and the environmental footprint. The visualization depicts the impact of distinct material flows through arrows of varying sizes, with each roughly representing their respective impact.

Notably, the scope of these visualizations includes the complete phaco kit as distributed by DORC, not just the handpiece. This is done to present the new disposables in the context of all disposables provided by DORC.

3.3.1.1 Original reusable handpiece system

In the context of the original system, the visualizations (Figure 3.3 - 2) spotlight the substantial environmental footprint associated with the production of a complete disposable phaco kit . Additionally, they show on the environmental impact of transportation and packaging for disposable components, as well as material circulation between the operating room (OR) and sterilization facilities, and the substantial impact of autoclave sterilization including their required blue medical wrap waste, and the existing repair and servicing infrastructure for Wefis handpieces.

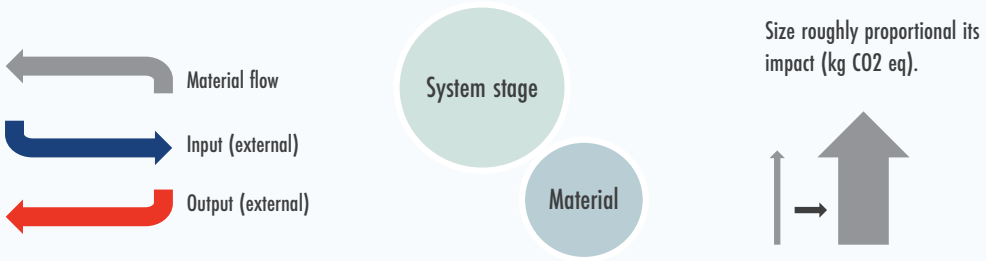


Figure 3.3 - 1 *Legend to product system map of Figure 3.3 - 2 and Figure 3.3 - 3*

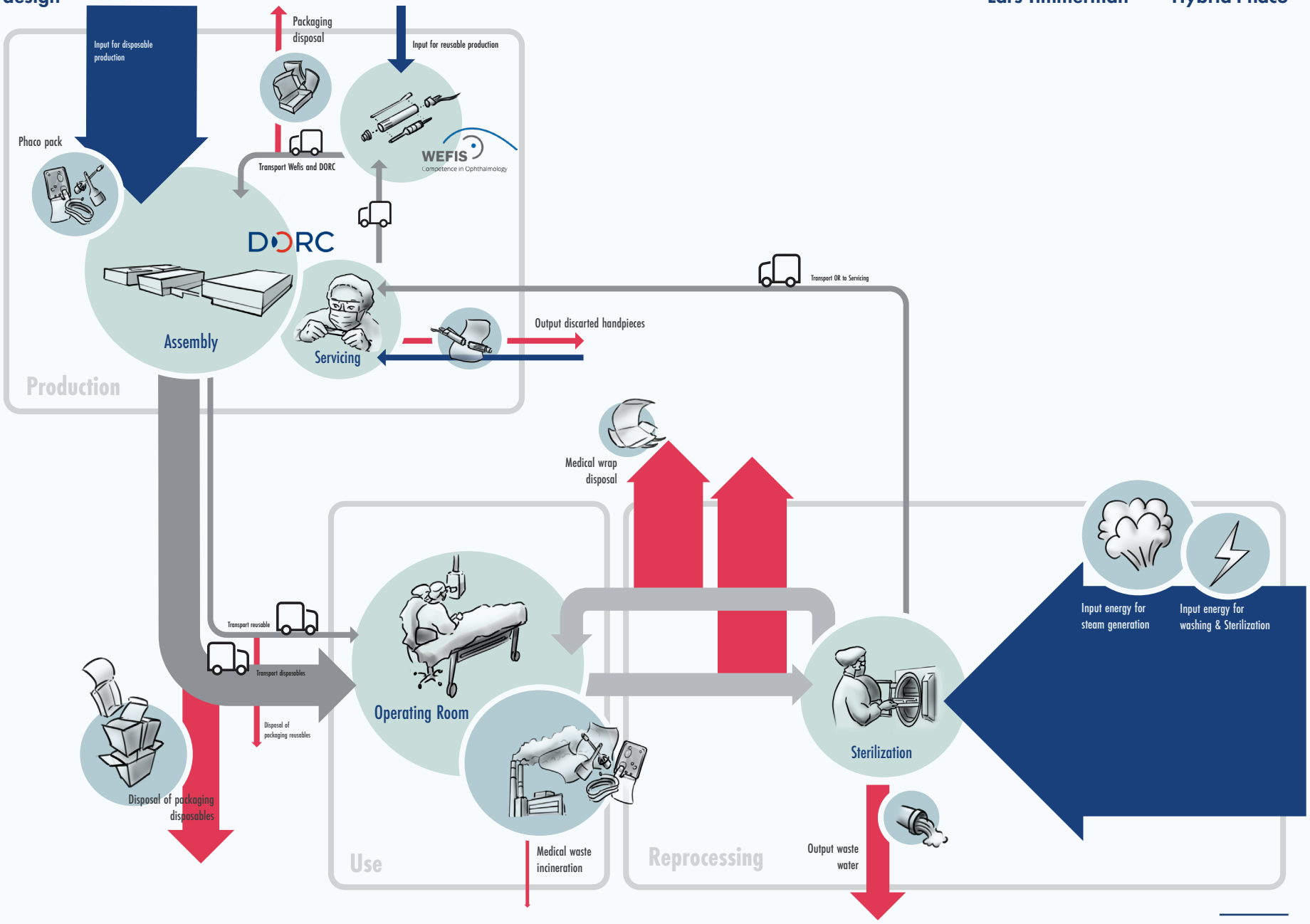


Figure 3.3 - 2 *LCA results of 3002.P handpiece from Michal Adar visualised through arrow weight in this product system map, including material flows, energy flows, inputs and outputs*

3.3.1.2 Redesigned circular system

Expanding on the initial circular system depiction in Figure 3.3 - 2, Figure 3.3 - 3 illustrates the amplified impact associated with the manufacturing of new disposables in contrast to original. It showcases the direct reuse of reusable components without the need for sterilization, thereby eliminating the substantial impact of sterilization processes. The comparison between the two figures signifies the envisioned impact reductions and streamlining introduced to the product system map.

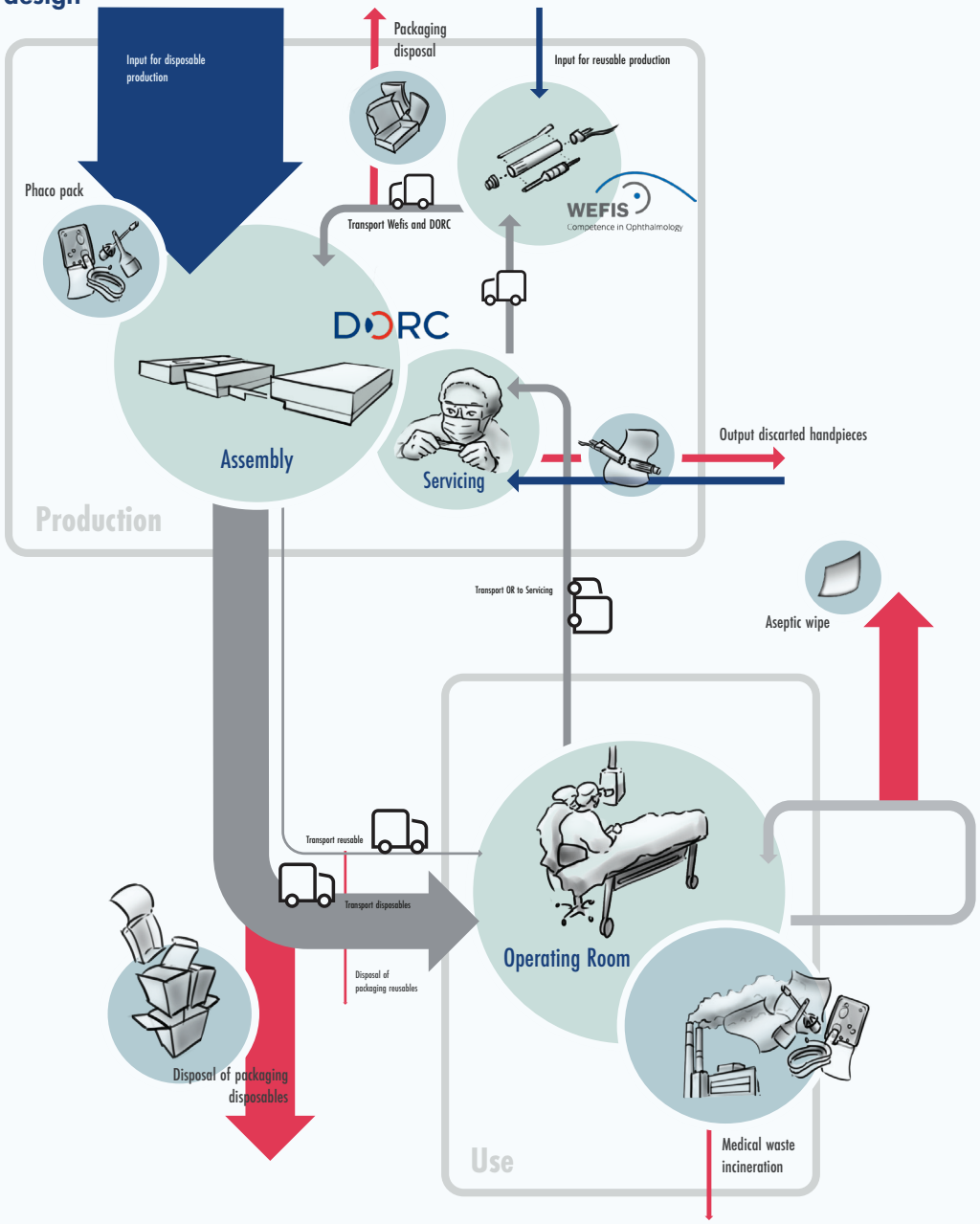


Figure 3.3 - 3 *LCA results of (student data) hybrid handpiece redesign from Michal Adar visualised through arrow weight in this product system map, including material flows, energy flows, inputs and outputs*

3.3.2 Circular business case

For the hybrid phaco concept, Michal Adar has formulated several business cases to align with the circular system. These cases intend to provide additional value to hospitals, including take-back programs for the reusable, warranty options, repair services, or subscription services to alleviate investment costs. This chapter will not delve into these business cases but will instead explore the value proposition derived from the final embodied design. Additionally, it will discuss cost considerations for the phaco handpiece.

3.3.2.1 Value proposition

The key elements of the value proposition are outlined on page 67:

1. *Lower access point facilitated by reduced investment costs.*

2. *Smaller carbon footprint (67% reduction on climate change)*

3. *Extended lifetime of the reusable component (250 cycles to estimated 750+ cycles)*

4. *Elimination of sterilization requirement for the phaco handpiece.*

Lower access point

In the case of the original handpiece, a significant number of units are required to support its usage in the operating room. Based on consultations with surgeons and OR assistants, I estimated that approximately 9 handpieces undergo sterilization for every handpiece in active use. This is due to the time-consuming nature of sterilization processes in facilities, whether within the hospital or externally, as surgeries proceed rapidly.

Considering the redesigned handpieces' elimination of the need for sterilization, it can be inferred that the adoption of this redesigned system necessitates significantly fewer investments. Additionally, the reusable component of the handpiece is notably simpler and, consequently, more cost-effective (further details in chapter 4.3 "Sonotrode design, and reusable components") compared to the original handpiece.

These reduced investments may lead to lower revenue for DORC, which is further discussed in chapter 5.10 "Deep dive: Cost price".

Smaller carbon footprint

The hybrid design, as outlined in chapter "6.3 Environmental evaluation", boasts a significantly smaller carbon footprint compared to the original handpiece, presenting a sustainable solution in a medical market witnessing an increasing demand for sustainable options (as discussed in chapter "2.4.3 Competitors"). Despite the overall reduction in environmental impact throughout its life cycle, including a substantial decrease in total waste generation (Figure 6.3 - 8 on page 183), a nuanced distinction needs to be made.

While the hybrid design diminishes recyclable waste, particularly in the form of (mechanically) recyclable blue medical wrap, it introduces more hazardous waste in the shape of the new disposable component. Processing medical hazardous waste incurs some costs for hospitals (consultation with expert), a factor excluded when evaluating the cost of this system. Nonetheless, considering the significant reductions in environmental impact, this aspect contributes clear added value.

Longer lifetime handpiece

The elimination of sterilization in the hybrid design enables a significantly extended lifespan for the reusable component compared to the original handpiece. This not only contributes to the smaller carbon footprint (chapter "6.3 Environmental evaluation" on page 180) but also results in reduced breakage during use in the operating room, necessitating fewer replacements. Additionally, the option for repair provides hospitals with the flexibility to further extend the lifetime of the reusable driver for minimal additional costs, depending on the chosen business case.

No sterilization facility required

The elimination of sterilization for the hybrid phaco handpiece opens up the possibility for adoption in hospitals with limited or no sterilization facilities, particularly in lower resource settings. However, further examination is required, given the numerous instruments used during cataract surgery that still require sterilization (Figure 3.3 - 4). Nonetheless, the hybrid phaco design reduces the burden on sterilization facilities, benefitting both high-resource and low-resource settings. Notably, the original design's requirement for tubing attachment to the handpiece for each sterilization cycle adds to the eliminated load on these facilities.

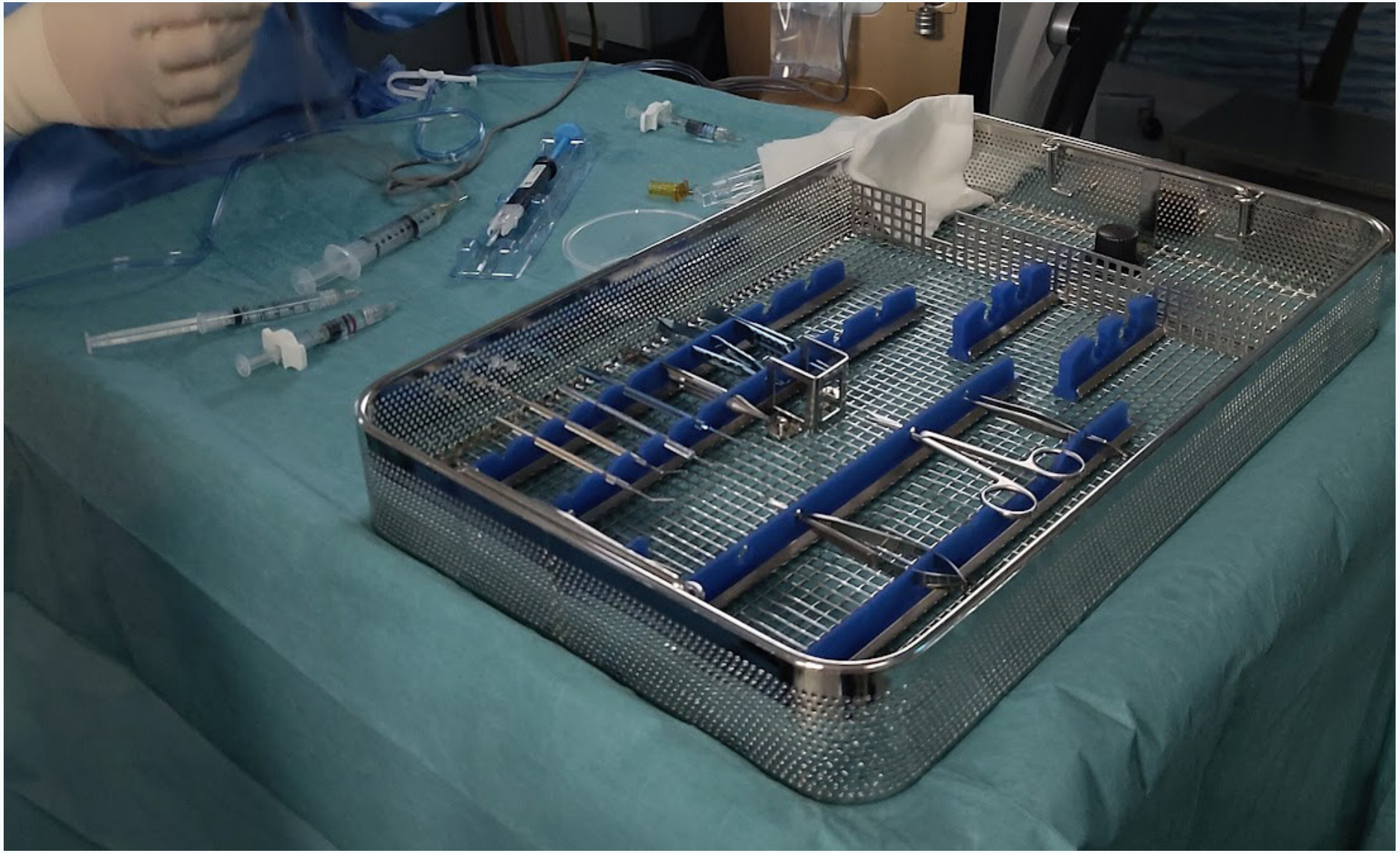


Figure 3.3 - 4 *Cataract surgery tray, showing the amount of instrument still requiring sterilization for a single cataract surgery*

3.3.2.2 Cost price considerations

In assessing the cost price of the hybrid phaco design, we won't delve into specific business cases but rather outline the current business case situation for both the hybrid redesign and the original design.

With cost calculations done for both the original handpiece and the redesign excluding additional components like the phaco kit, we see that the price per surgery in some instances is higher for hybrid phaco (Appendix VII). While the price per surgery for the hybrid design is allowed to be slightly higher (estimated 10%) due to its positioning as a more sustainable (premium) option, it must still compete with the original design in terms of cost per operation. This is only advantageous to the hospitals, but is not interesting for DORC as a business. This is why simply just considering price per surgery falls short, and value needs to be added through more compelling business models.

Moving on to investment considerations, the lower cost per reusable and the reduced number of units required for adoption contribute to lower investment costs for the hybrid design. Despite the increased lifetime per handpiece and more intensive usage, I assume the reinvestment time to be approximately the same.

Whether willingness to adapt a phaco system is most dependant on height of investment, on height of price per surgery, or on other additional points of value offered through the offers plans, is something that needs to be considered for this hybrid concept. This cost estimation exercise is done on the original business plan of investing in the reusable and purchasing disposable kits for surgeries. The business cases proposed by Michal Adar need to be considered in conjunction with the investment considerations outlined in this chapter.

Key insights

RQ4.1: What is the current environmental impact of the phaco handpiece over its entire lifetime?

- Visualised product circular systems show the impact of eliminating sterilization from product system on environmental impact

General Insights

- Main points of value proposition lie in a system who's initial investment costs are lowered, who's carbon footprint is reduced by 67%, with a handpiece that does not require sterilization, and can be reused for longer.

- Price per surgery has to be evaluated in parallel with business cases; willingness to pay (for sustainability premium) is not guaranteed

4. Hybrid phaco embodiment

This chapter will go into the embodiment design of the hybrid phaco design. It will go into the product architecture as a whole, as well as dive into every component, and touch on the results of all research and analysis done to reach the embodied features or choices. From these descriptions the reader will be referred to the corresponding deep dives outlined in chapter 5, for further substantiation.

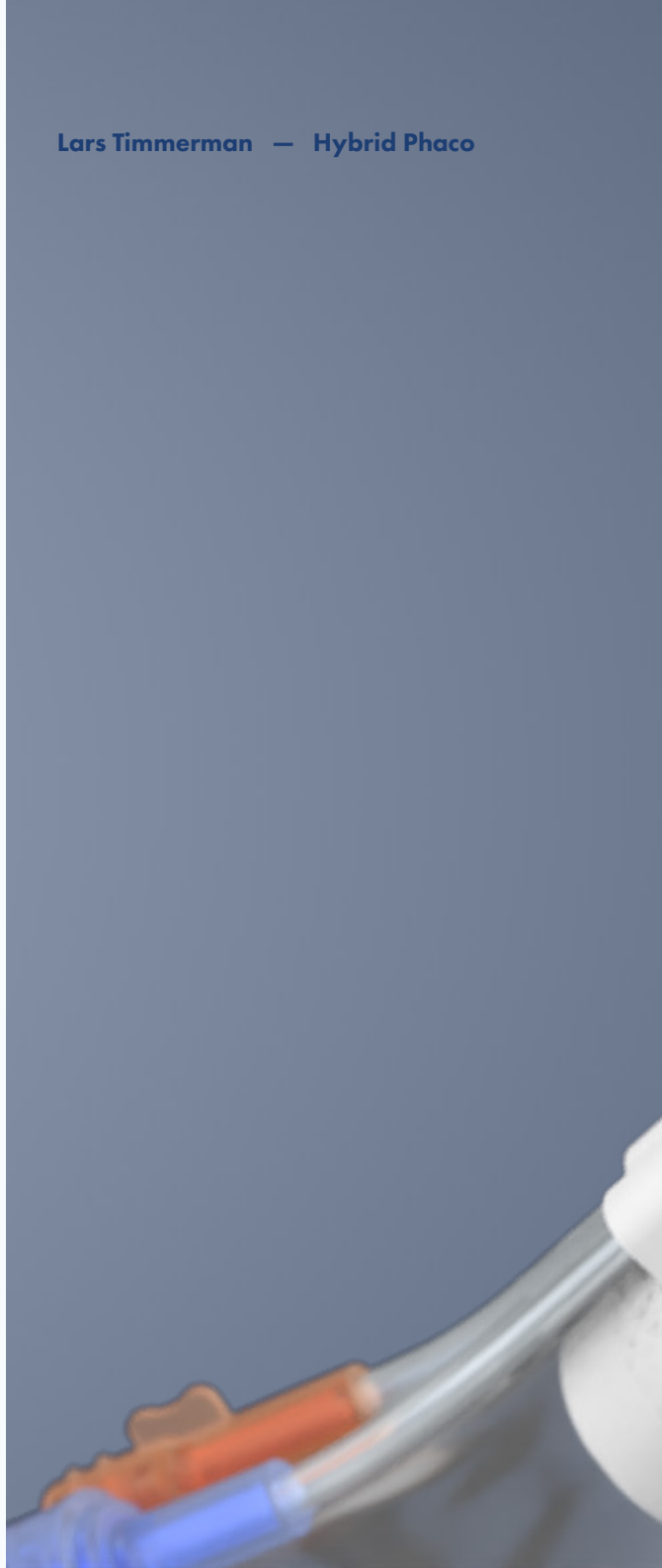
This chapter will delve into detailed explanations for each component, providing insights into final design choices. This comprehensive approach aims to serve as a reference for further considerations and design choices in the ongoing phases of this project.

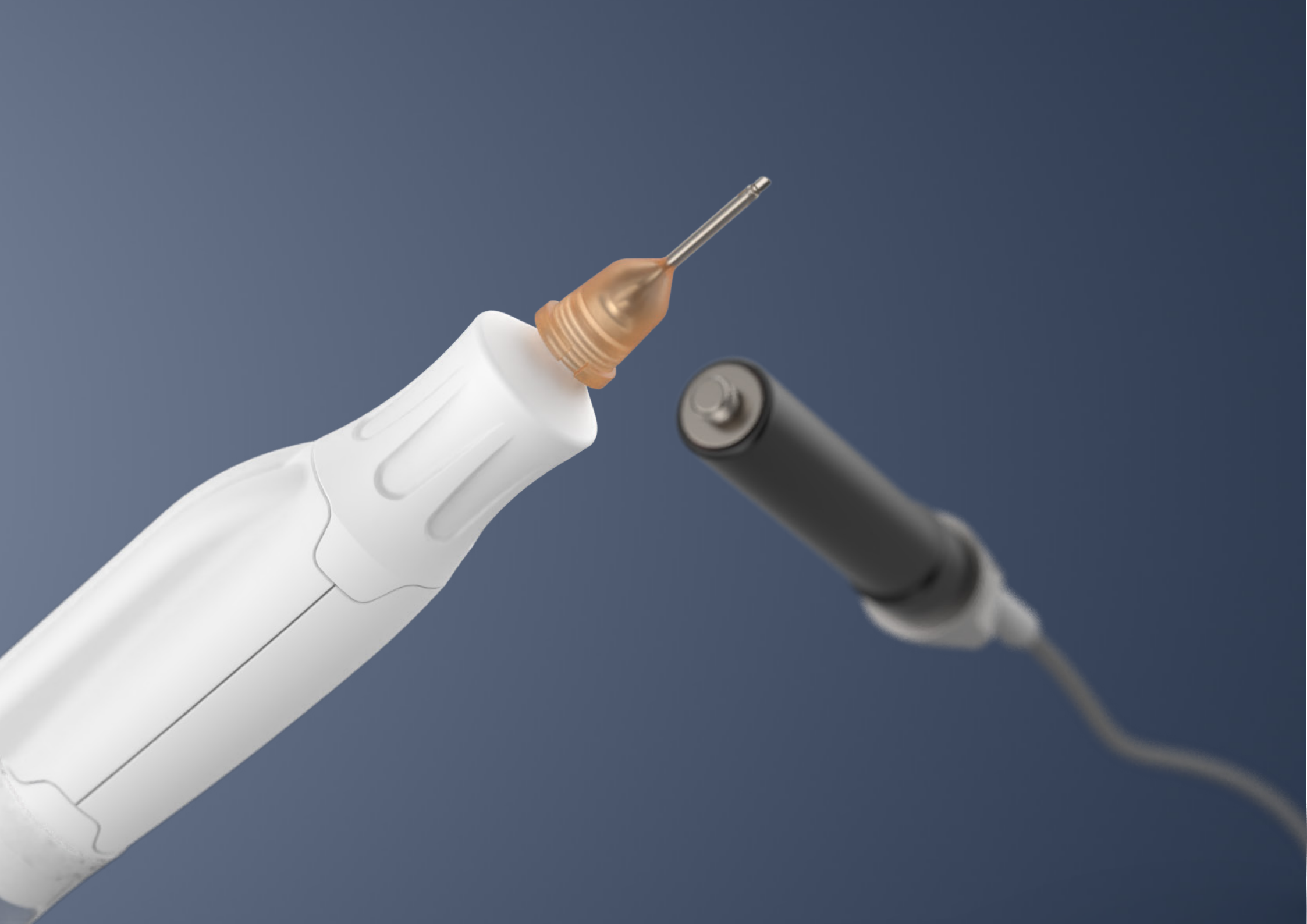
4.1 Design scope

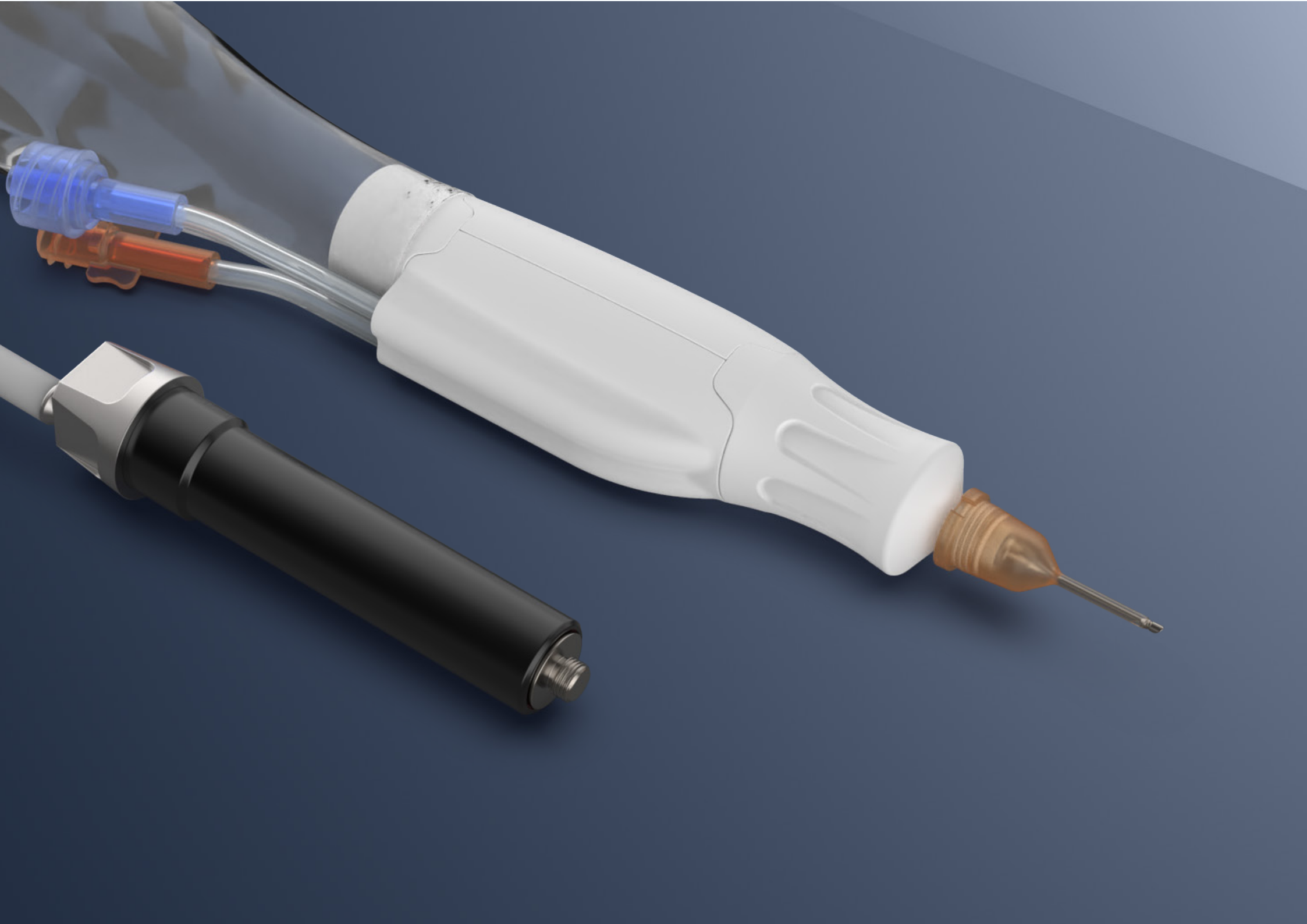
Given the semi-disposable nature of the hybrid design, integrating the needle and sleeve into the disposable component might seem reasonable. However, to maintain a focused scope for this project, these components were excluded due to their intricate nature and critical role in phaco functionality.

Furthermore, aspects beyond the cable, such as the EVA Nexus, plug, and cable itself, were excluded to maintain a focused scope within this project. However, it is important to note considerations, such as the extended lifetime of the reusable, leading to potential increased wear on the plug, and the contrasting aspect that the reusable theoretically does not need to be unplugged for sterilization at all.

By limiting the scope to the handpiece itself, the project maintains a clear focus on conducting a feasibility, usability, and sustainability study centred on the handpiece.







4.2 Product architecture and design overview

This chapter will provide a comprehensive overview of the complete phaco design, including its two components, namely the disposable product and the reusable product. It will highlight the main concepts and features that ensure the fulfilment of the primary functions and requirements for the hybrid phaco design. These main functions can be summarized as follows:

- A hybrid phaco design comprising a disposable product and a reusable product, ensuring the appropriate phaco ultrasound characteristics and functioning fluidics.

- Capable of being prepared in an operating room (OR), signifying quick, secure, and, most importantly, sterile assembly.

- Cost-effective design with minimal environmental impact through circular design practices

4.2.1 Assembled handpiece overview

Figure 4.2 - 1 provides an X-ray overview of the entire product, emphasizing the sterile outer disposable component that fully encapsulates the non-sterile reusable component. This encapsulation is crucial to prevent the reusable part from entering the sterile field in the operating room, as it lacks sterility.

A notable feature is the complete ultrasonic transducer highlighted in Figure 4.2 - 2, encompassing all central components from the back connector through the disposable horn to the disposable needle. This implies that the components responsible for ultrasound generation are distributed between the disposable and reusable sections. The connection between the disposable sonotrode half and reusable sonotrode half is established through a threaded connection, ensuring a secure linkage that facilitates the transmission of ultrasound. When a tight connection is achieved between the disposable and reusable components, the complete sonotrode ensures the desired phaco characteristics.

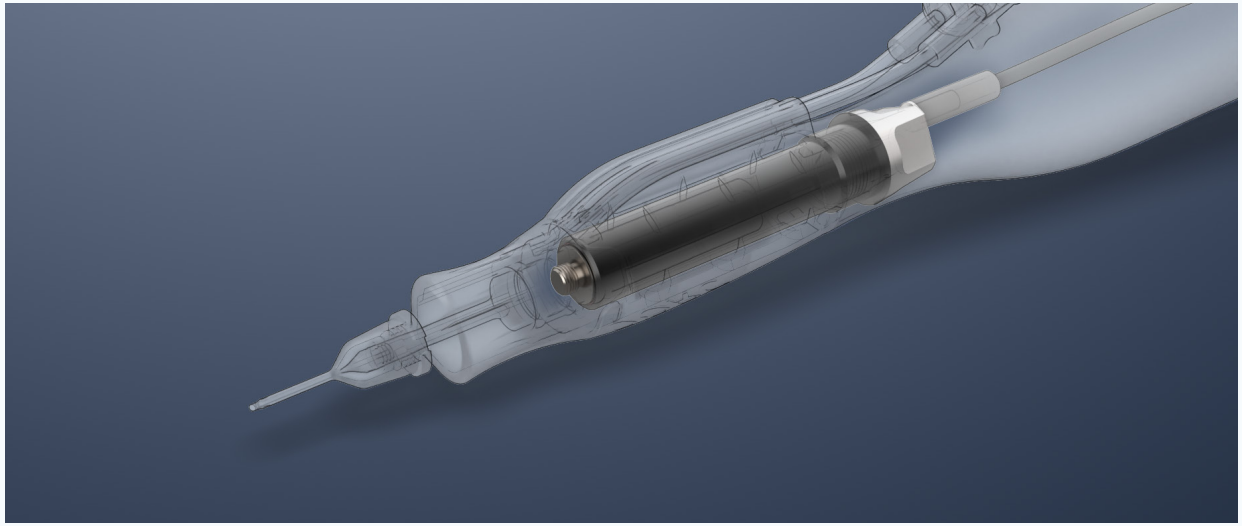


Figure 4.2 - 1 *X-ray view of assembled hybrid phaco handpiece, showing the reusable driver encapsulated by the disposable housing, providing sterile handling*

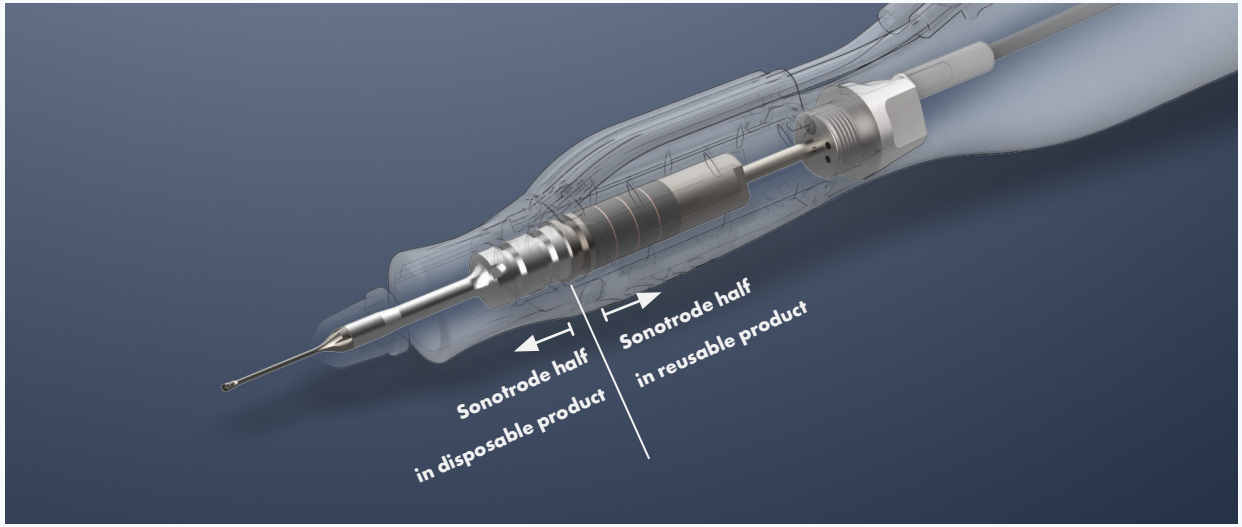


Figure 4.2 - 2 *X-ray view of assembled hybrid phaco handpiece, visualised with the ultrasonic sonotrode being split at the threaded connection over the disposable and reusbale product,*

4.2.2 Disposable and reusable product

The disposable component comprises plastic shells forming the housing, an aluminium horn, and internal tubing. This disposable element not only contributes to the phaco ultrasound characteristics but also manages the fluidics essential for phacoemulsification. It redirects aspiration fluids from the needle's centre to the outside of the disposable without coming into contact with the non-sterile components (5.4 "Deep dive: Sterility"). The fluidic pathways are detailed in chapter 5.6 "Deep dive: Fluid separation" and visualized in Figure 4.2 - 3.

Regarding phaco ultrasound characteristics, the disposable transmits the ultrasound generated by the reusable driver through the disposable and into the needle. The disposable doesn't just transmit ultrasound; it also plays a crucial role in shaping the ultrasound characteristics.

Cost-effectiveness is a critical attribute of the disposable, considering its significant impact on the price per surgery. Further considerations on cost pricing are detailed in chapter 5.10 "Deep dive: Cost price".

Circular design principles are also integrated into the disposable, aiming to minimize environmental impact during its production lifecycle. Considerations such as reduced material usage and opting for environmentally friendly materials are reflected in the disposable design (more in chapter 6.3 "Environmental evaluation").

The reusable product, responsible for driving ultrasound, closely follows the design of the original 3002.P to maintain consistent phaco characteristics. The piezos and other driving components housed in the reusable remain the same. However, this redesign introduces repairability, extending the reusable's lifetime to approximately 750+ cycles by eliminating sterilization as a main cause of breakage and using durable materials. The reusable design is geared towards durability and long life.

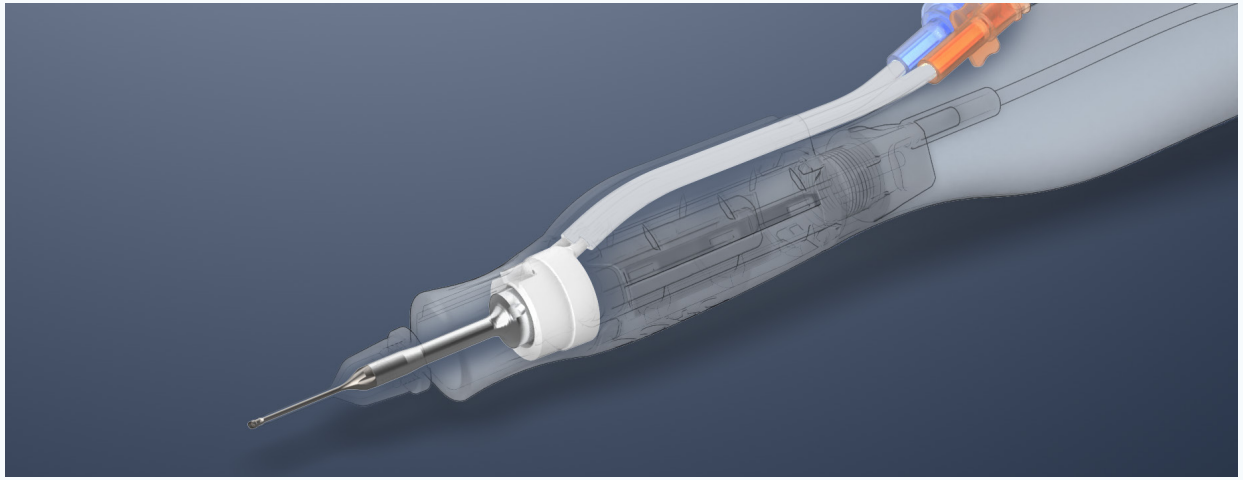


Figure 4.2 - 3 *X-ray view of assembled hybrid phaco handpiece, visualised with the fluidics system of the disposable handpiece splitting off before the reusable*

4.2.3 Assembly

In the assembly of both the disposable and reusable products, several factors are critical. Achieving a secure yet easily connectable sonotrode connection via the threaded connection is of utmost importance. This connection needs to be made in a sterile manner to ensure the overall integrity of the handpiece.

To aid in achieving the correct torque during assembly, the blister pack incorporates a breakable “torque application ridge.” This visual cue ensures that the threaded connection is tightened to the appropriate torque, guaranteeing a secure assembly each time (Figure 4.2 - 5).

The blister pack itself serves as a physical sterile barrier, preventing direct contact between non-sterile personnel and the sterile internal components (Figure 4.2 - 4). Additionally, an assembly and handover method design has been implemented. This method allows for the sterile assembly of the two components and facilitates a handover method without direct physical contact. During this handover process, an integrated sterile tube sleeve is rolled over the non-sterile cable, maintaining the physical sterile barrier throughout the procedure.

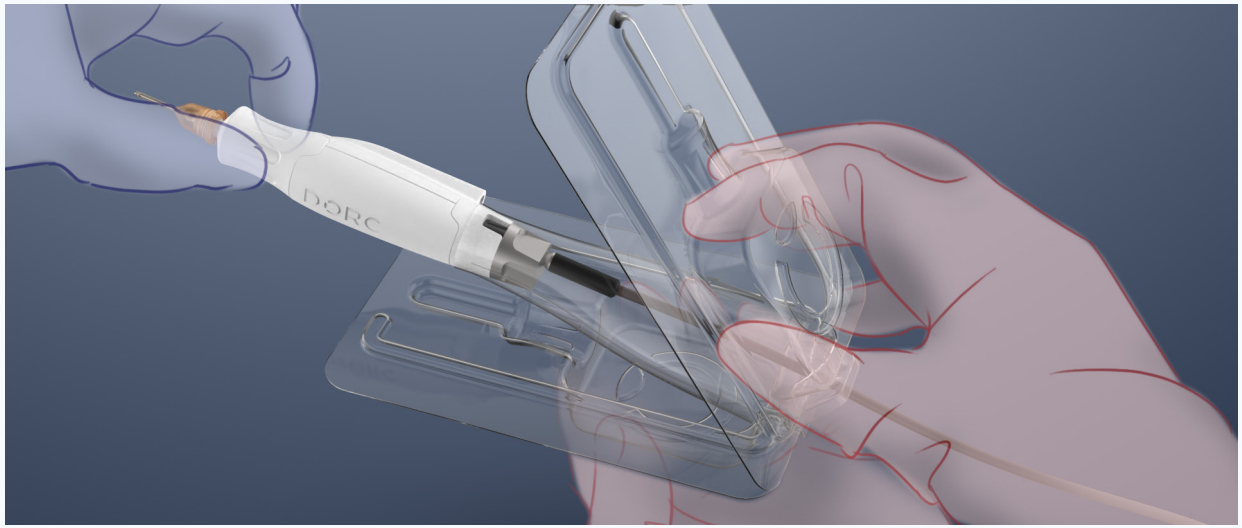


Figure 4.2 - 4 *Handover method, showing sterile user (blue) and non sterile user (red) being separated by blister pack, and sterile tube sleeve unfolding*

Figure 4.2 - 5 *Visualisation of torque ridge reaching limit, collapsing due to rotation, and entire handpiece turning, indicating that the handpiece is assembled securely*

Key insights

RQ1.3: What ensures proper transmission of ultrasonic vibration between disposable and reusable?

- Connection with thread in split sonotrode between reusable and disposable is crucial for proper ultrasound transmission
- Torque application ridge is required to ensure a secure connection of the sonotrode in assembly of the OR

RQ3: How can a phaco handpiece be redesigned to make use of disposables?

- Functions attributed to the reusable are housing of piezos and driving of ultrasound.
- Functions attributed to disposable are ultrasound transmission and characterisation, managing and redirecting fluidics, as well as maintaining the sterile barrier.

RQ2.2: How can a hybrid design be assembled in a way that ensures sterility?

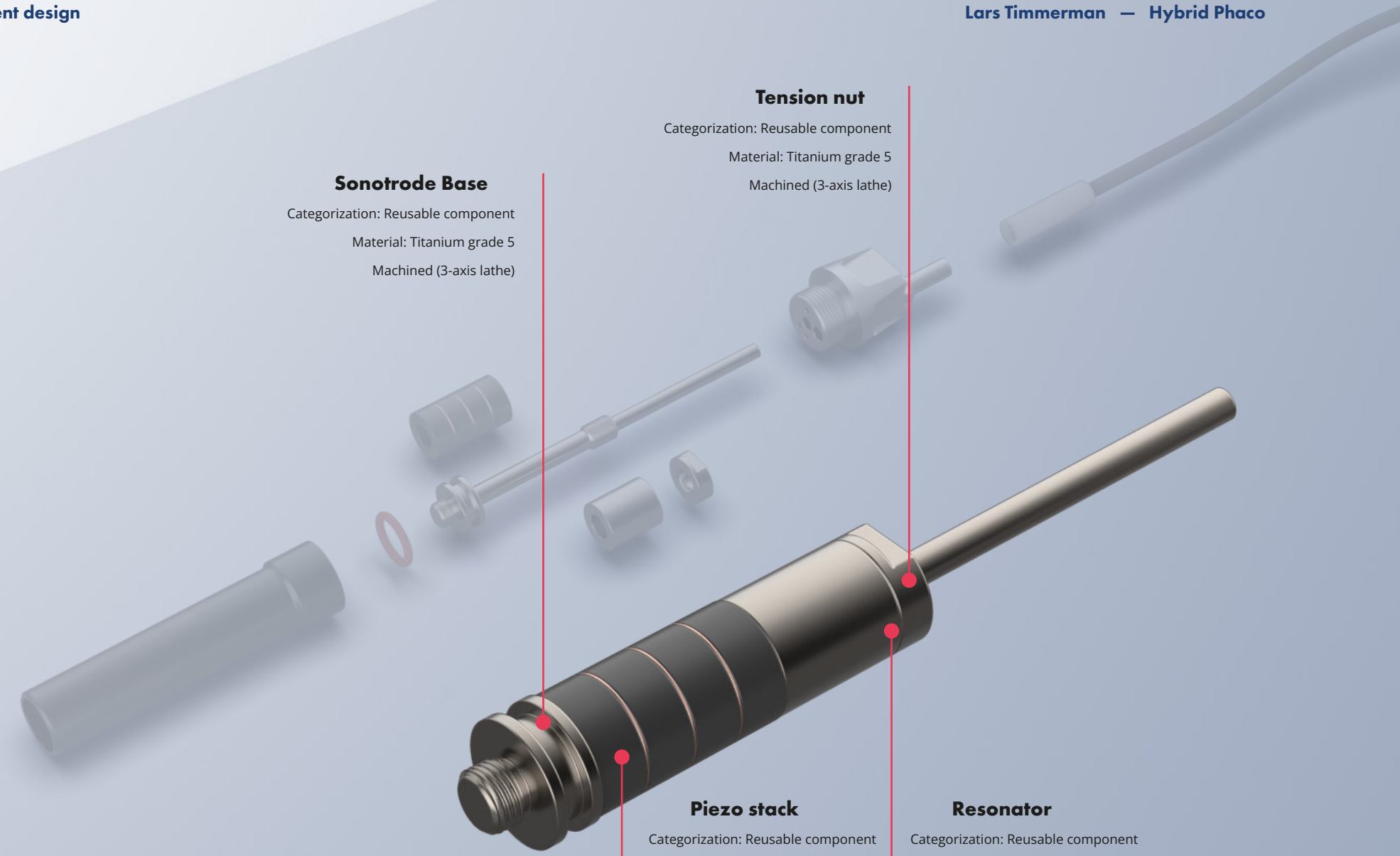
- Assembly and handover method of handpiece with blister pack is required for sterile assembly of non-sterile driver and sterile disposable

4.3 Sonotrode design, and reusable components

The sonotrode in the phaco handpiece is effectively divided into three crucial components: the sonotrode base housing all piezoelectric elements outside of the sterile field, a disposable horn containing the fluidics interface, and the needle. This chapter will delve into these key components along with other elements contributing to the sonotrode design, such as the piezos, resonator, and O-rings.

It's important to note that all sonotrode components collectively influence the system's phaco performance, including the transducer frequency (see Chapter 5.1.1 "Mechanical principles of ultrasound in phaco"). As this applies to all sonotrode components, it will not be reiterated for each one individually.

In pursuit of achieving the correct phaco performance, a design strategy was adopted, closely aligning with the original sonotrode design of the 3002.P. Many aspects of dimensioning and functional design were developed with the 3002.P as the foundational reference point.



Tension nut

Categorization: Reusable component

Material: Titanium grade 5

Machined (3-axis lathe)

Sonotrode Base

Categorization: Reusable component

Material: Titanium grade 5

Machined (3-axis lathe)

Piezo stack

Categorization: Reusable component

Material: PZT-5

Purchase part

Resonator

Categorization: Reusable component

Material: Titanium grade 5

Machined (3-axis lathe)

4.3.1 Sonotrode base

The sonotrode base serves as the foundation for transmitting vibrations from the piezos. Along with the tension nut, it imparts pretension on the piezos, ensuring their proper alignment and contributing to the sonotrode performance and durability (refer to Chapter 5.1.1 “Mechanical principles of ultrasound in phaco”). Material properties, such as elastic modulus and density, play a critical role in achieving the desired phaco performance. Consequently, the sonotrode base is constructed from grade 5 titanium, following a more durable design.

The sonotrode base design closely mirrors that of the 3002.P design, maintaining identical total length, diameters, and materialization for both sonotrode designs. This adherence to the original design yielded phaco performance closely resembling the original (refer to Chapter 5.1.2 “Dimensional sensitivity”). Notably, the original sonotrode design featured a hollow tube for aspiration fluidics, while the redesign, with its modified fluidics interface, doesn’t require this.

Deviating from the original design with the hybrid approach, a threaded connection (Mf5 x 0.5) is employed to connect the disposable part to the reusable part. This choice is made to ensure effective ultrasound transmission while accommodating spatial constraints for the connection method (refer to Chapter 5.3.1 “Connection method requirements”). The fine thread variant was chosen specifically for its higher clamping force with applied torque, and for its even smaller form factor.

Additionally, the sonotrode base incorporates a groove for an O-ring (refer to Chapter 4.3.4 “O-rings”). This O-ring is crucial for maintaining a ingress seal between the sonotrode and the reusable housing (Chapter 4.3.6 “Reusable housing”), contributing to durability and facilitating disassembly of the design.

4.3.2 Piezo stack, resonator, and tension nut

The piezo stack, resonator, and tension nut collectively contribute to the desired phaco performance, each serving individual and shared functions.

The piezo stack is responsible for converting the AC electrical signal from the surgical system into mechanical motion (refer to Chapter 5.1.1 “Mechanical principles of ultrasound in phaco”), generating vibrations in the handpiece. Copper solder washers are integrated to ensure the piezo stack has terminals with the correct polarity.

The resonator plays a unique role by not only adding mass to the overall system, influencing resonant frequency (refer to Chapter 5.1.2 “Dimensional sensitivity”), but also reflecting some ultrasonic vibrations back into the handpiece, redirecting them toward the tip.

The tension nut is threaded onto the sonotrode to provide pretension to the piezo stack, impacting their resonant frequency and safeguarding against piezo cracking. A loose piezo, allowed to “bounce around” more freely (even when slightly tightened), can lead to piezo breakage (consultation with OEM expert).

Disposable horn

Categorization: Disposable component

Material: 7075-T6 aluminium

Machined (3-axis lathe)

4.3.3 Disposable horn

The disposable horn plays a pivotal role in ensuring phaco functionality by encompassing ultrasound transmission, amplification, and a fluidics interface. Through the O-rings it serves as one of the two points of contact for the sonotrode with the outer housing, it contributes to the overall stability of the needle.

The horn is constructed from 7075-T6 aluminium, a material with properties relatively close to grade 5 titanium, crucial for proper ultrasound transmission (reader is referred to chapter 5.1.3 “Material considerations”). The decision to opt for aluminium over titanium for this disposable component is influenced by cost considerations outlined in chapter 5.10 “Deep dive: Cost price”, as well as concerns about its high environmental impact detailed in chapter “6.3 Environmental evaluation” on page 180.

The horn’s fundamental dimensions (largest diameter, horn length, base length) significantly impact the ultrasound performance of the handpiece. Detailed testing of the primary horn dimensions is extensively discussed in chapter 5.1.2 “Dimensional sensitivity”. The results indicate ultrasound performance very close to the original handpiece..

To ensure proper ultrasound transmission, threaded connections are incorporated at the horn’s tip for the needle and at the base for the reusable driver. Establishing precise ultrasound transmission further requires specifying flatness for both surfaces in contact with the needle and reusable driver. However, the quantification of this flatness specification is not provided in this project.

Ultrasound vibration stroke is minimal at the piezos and the base of the horn, with stroke amplification occurring through the horn’s tapered shape, tapering down into the smaller diameter of the tip (reader is referred to chapter 5.1.1.5 “Stroke amplification”).

The aspiration fluid lines traverse the disposable horn, initially centric through the tip (necessary for the central aspiration style of the needle) and later splitting off at 90-degree angles (selected for manufacturability) to exit the sides of the disposable (fluid path shown in Figure 5.6 - 6 on page 153). The fluid is then contained between the horn, the O-rings (for which the horn provides grooves), and the fluid conduit (further explained in chapter 4.4.1 “Fluid conduit”). Diameters of the internal fluid paths are set to be multiples larger than the minimal diameter of the needle, as detailed in chapter 5.6.4 “Testing current implementation”.

Finally, the horn features two recesses on its tapered face. These are incorporated to establish an interface for mating with the outer housing, allowing torque application to the threaded connection at the base of the disposable without causing the horn to spin freely. This feature seemingly does not impact the ultrasound performance of the handpiece (reader is referred to chapter 5.1.2 “Dimensional sensitivity”). However, this feature might be considered unnecessary, as the pressure from the O-rings already provides some torsional holding power. For watertightness a minimum and maximum O-ring compression is defined. For holding power however, more O-ring compression is better, potentially interfering with the watertightness requirement. Thus the decision was made against adding this functionality to the O-rings.

Connector

Categorization: Reusable component

Material: titanium grade 5

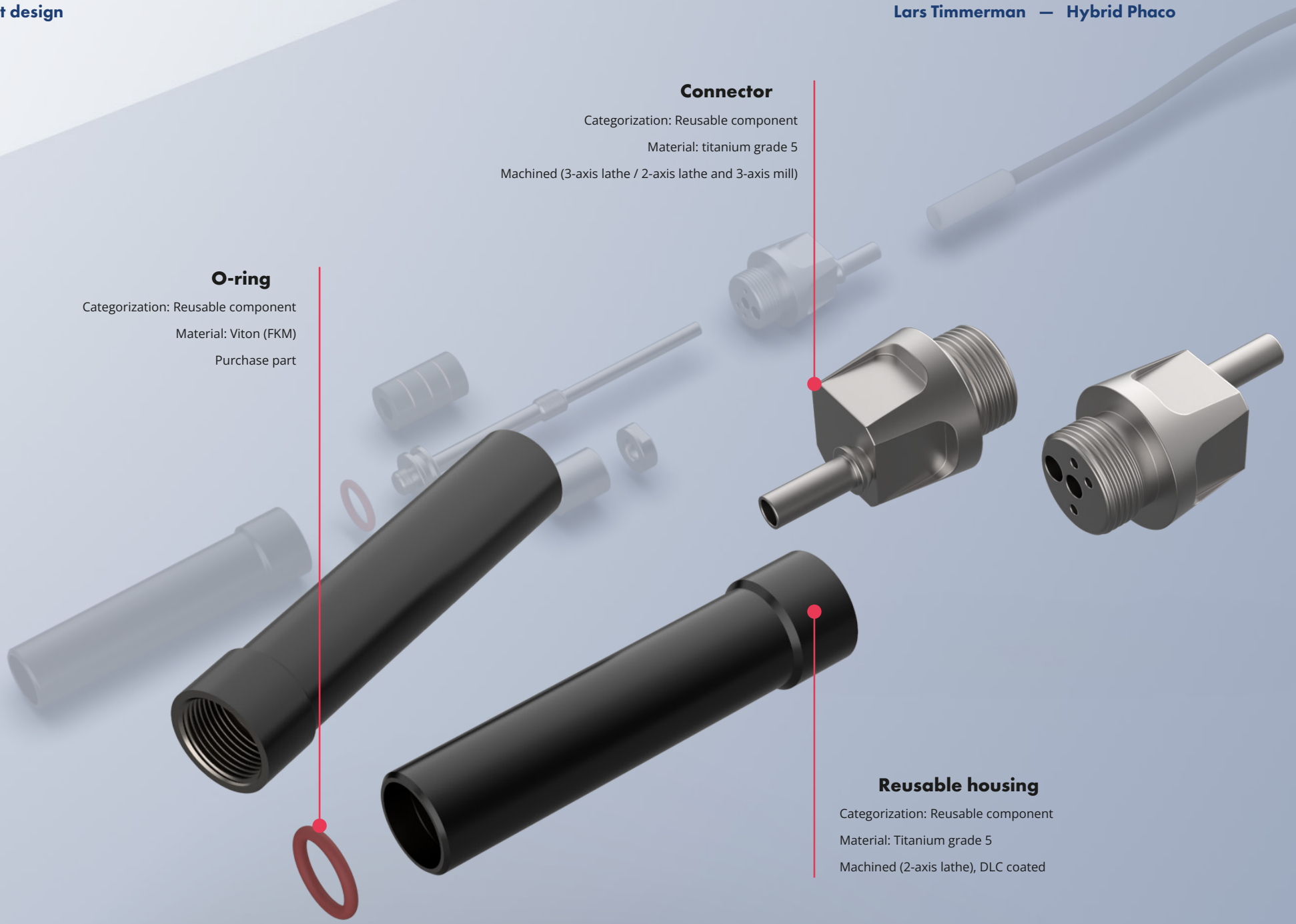
Machined (3-axis lathe / 2-axis lathe and 3-axis mill)

O-ring

Categorization: Reusable component

Material: Viton (FKM)

Purchase part



Reusable housing

Categorization: Reusable component

Material: Titanium grade 5

Machined (2-axis lathe), DLC coated

4.3.4 O-rings

The handpiece incorporates two types of O-rings, each serving distinct purposes.

In the disposable product, O-rings play a crucial role in sealing the fluidics lines to maintain sterility within the handpiece. To ensure cost-effectiveness, nitrile is selected as the material, and standard available sizes are chosen. The dimensions of these disposable O-rings are determined to balance the need for proper sealing pressure with ease of assembly. Through multiple rounds of prototyping, the final compression of these O-rings falls between 8% and 21%, considering typical tolerances of relevant dimensions.

In the reusable product, an O-ring is employed to ensure the durability of the driver. After each day of use, antiseptic wipes are applied to the driver (reader is referred to chapter 5.4.1 "Defining sterility for a hybrid (phaco) design"), and to prevent moisture from reaching the piezos, an O-ring is utilized. This O-ring also facilitates the disassembly of the driver, distinguishing it from a permanent solution like potting. For this application, Viton (or FKM) O-rings are chosen due to their superior chemical resistance and temperature resistance, contributing to enhanced durability and the extended lifetime of the reusable.

4.3.5 Connector

The connector serves multiple functions, primarily connecting the cable to the internal wiring leading to the piezo stack. It's through-hole allows the cable to pass through and split into separate leads, connecting to the solder terminals of the piezos, maintaining the same function as the original phaco handpiece.

Additionally, the flat sides of the connector serve as an ergonomic handling interface for rotating during threaded connections. In the OR assembly use case, circulating nurses apply approximately 30 cNm torque to the reusable driver, facilitated by the flat sides on the connector.

Constructed from SAE 316 stainless steel, machinable by a 2-axis lathe and a 3-axis (CNC) mill, the choice of material allows production at the original OEM, something not possible with the previous connector. Stainless steel is chosen to maintain the quality of the original titanium connector and increase the weight to match that of the original handpiece. This weight adjustment preserves the dampening functionality for residual vibrations in the handpiece. SAE 316 is specifically chosen for its common application in medical devices and good availability, although this choice requires further specification.

4.3.6 Reusable housing

The reusable housing serves the purpose of protecting the piezo stack from moisture ingress, utilizing an O-ring application. The inner bore diameter is adjusted to achieve the same O-ring compression as the disposable O-ring application (chapter 4.3.4 "O-rings"). The increased outer diameter allows for a threaded connection to the connector and facilitates assembly without the O-ring catching on the threads. Threads also aid in the repair of the driver.

The inner cavity of the housing accommodates the copper solder washers and Kapton tape used for the ultrasonic transducer, slightly increasing its total diameter. A slight chamfer on the front of the driver eases assembly in the OR.

The material choice for the housing is titanium grade 5, selected for its high durability. However, the option of stainless steel should be considered for its lower embodied energy. While titanium's relatively poor thermal conductivity may be a concern for its secondary function as a thermal conductor for the piezos, its thin-walled nature is predicted to mitigate this issue. Further details on thermal management can be found in chapter 5.7 "Deep dive: Heat transfer".

A DLC (diamond-like carbon) coating is employed on the reusable housing, for a highly durable (Malisz et al., 2023) black colouring, adding to the aesthetics of the reusable. This specific method is also chosen because of its existing application in the original phaco handpiece. Additionally, it offers the capability for laser engraving and labelling.

Key insights

RQ1: What ensures the phacoemulsification functionality of a phaco handpiece?

- The disposable horn is important redesigned component, having functionality in rerouting fluids, connecting driver to needle and transmitting ultrasound, characterising ultrasound by its material and dimensioning, and more.

RQ1.2: What variables influence ultrasonic vibration characteristics of the phaco handpiece?

- Design of reusable is as close to original product as possible to maintain phaco performance of the original product.

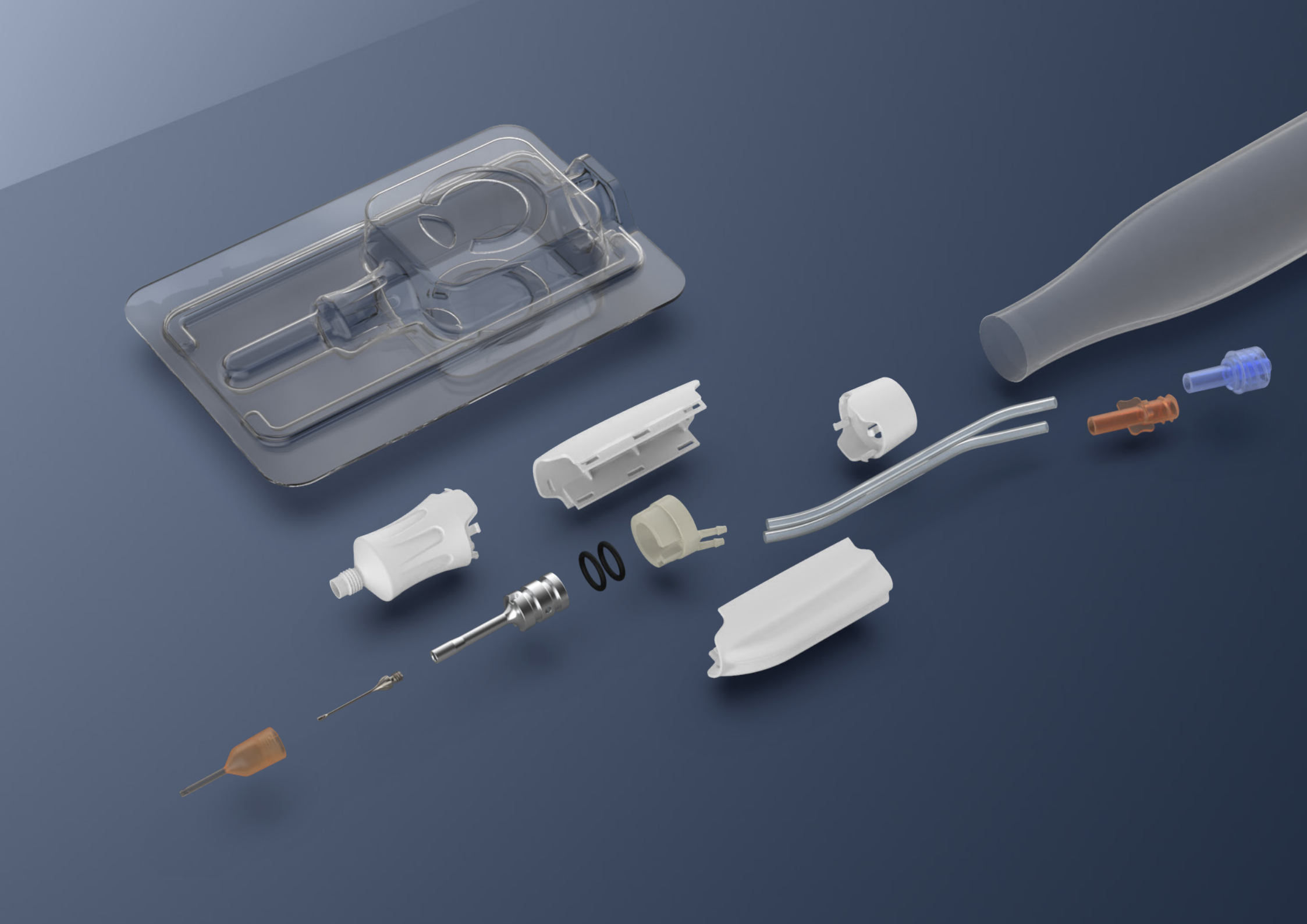
- Sonotrode base, piezo stack, resonator and tension nut form basis of driver and are most critical in forming ultrasound functionality in generating and characterizing the ultrasound.

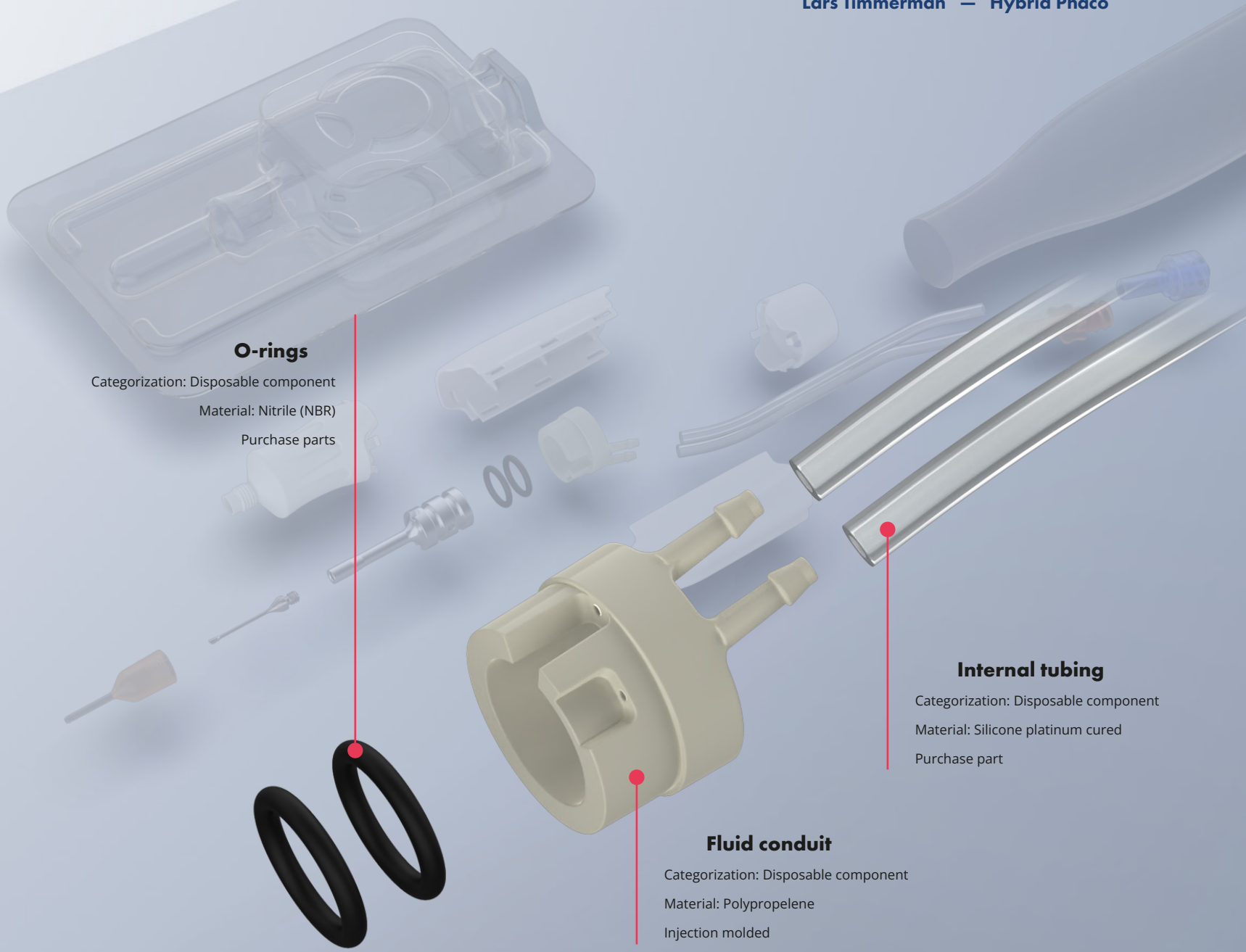
- Connector, and reusable housing not only houses the electronics and cable assembly, but also function as damper of residual ultrasonic vibrations.

4.4 Disposable components

This chapter addresses the remaining disposable components of the handpiece, excluding the disposable horn, which was discussed in the sonotrode design chapter 4.3.3 “Disposable horn”.

Design considerations for these disposable components adhere to a distinct set of requirements, emphasizing environmental impact reductions, aesthetics, and ergonomics. Additionally, cost reductions, including assembly considerations and basic part costs, play a more prominent role in the design choices for these disposable components.





O-rings

Categorization: Disposable component

Material: Nitrile (NBR)

Purchase parts

Internal tubing

Categorization: Disposable component

Material: Silicone platinum cured

Purchase part

Fluid conduit

Categorization: Disposable component

Material: Polypropelene

Injection molded

4.4.1 Fluid conduit

The fluid conduit serves to transmit fluidics channels to and from the internal tubing, ensuring water-tightness in the system and, consequently, maintaining sterility (reader is referred to chapter 5.4.1 "Defining sterility for a hybrid (phaco) design").

The irrigation channel runs through a tubing connector within the fluid conduit to the internal chamber of the housing, flowing over the horn, and ultimately out the handpiece. The front O-ring seals off this internal chamber, separating the irrigation channel from the aspiration channel. The aspiration channel, originating from the angled channels in the disposable horn, is captured by the fluid conduit. Together with a matching rib, also with tapered sides, from the housing, it forms a space through which the fluid can flow to the tubing connector.

The fluid conduit is secured using a tapered "luer" style connection around the entire component. Luer connections are common in the medical industry, providing a reliable leak-free connection and being economical to produce (Anesthesia Patient Safety Foundation & Hansel, 2021). The luer connection utilizes a specific angle of 1.72°, also found on corresponding faces of the housing. Through this shape, the fluid conduit can be pressed into the housing during the disposable assembly. Due to this pressing, a gap is designed between the front-facing faces of the conduit and the housing when assembled. This design prevents the conduit from encountering a housing feature before being tightened securely, ensuring a safe luer connection when applied with a set pressure (not determined in this thesis).

Lengths of these luer connections are roughly based on existing luer connectors and space restrictions in the housing. The tapered design of the luer connection accommodates feasible wall thickness and a right diameter fluid channel, addressing the space constraints in the housing.

The luer connector features an inner chamfered edge for ease of assembly with pre-applied O-rings on the disposable horn. These O-rings have a relatively low designed compression (chapter 4.3.4 "O-rings"), further facilitating assembly.

The tube connectors within the conduit are angled, presenting a challenge in terms of mouldability (consultation with the producer). This was done to accommodate space restrictions with the assembled reusable housing. Further consideration is required in this area to enhance the mouldability of the part.

4.4.2 Internal tubing and luer connectors

The internal tubing in the handpiece runs from the fluid conduit, along the outer side of the disposable housing, and into the luer connectors. The tubing is positioned outside the sterile sleeve (chapter 5.4.1 "Defining sterility for a hybrid (phaco) design") and within the sterile field, underscoring the importance of a secure connection. This design ensures that the tubing connectors are always accessible for the use of I/A tooling during a cataract procedure, as highlighted in chapter 2.1.1 "Cataract surgeries".

The luer connectors themselves are not thoroughly detailed, given their nature as purchase parts. The connection method between the tubing and luer connectors is not specified, leaving options such as mechanical or adhesive connections. Security against disconnection needs to be considered in selecting the type of connection, alongside assembly considerations.

Platinum-cured silicone is chosen for the tubing due to its tighter maximum bend radius of 4xOD. This is necessary for the space considerations of the designed blister packaging (chapter 4.5.5 "Blister packaging"). The material is also well-suited in terms of biocompatibility (Hongju Technology, 2023).

The length of the tubing is chosen so that the connectors extend beyond the assembled handpiece, allowing the tubing to snugly rest against the handpiece. Further examination of the ergonomic implications of connector placement is recommended.

4.5 Disposable housing assembly

The disposable housing of the hybrid redesign adheres to several key requirements, including cost-effectiveness (covering both part cost and assembly), low environmental impact, ergonomic, and aesthetics considerations.

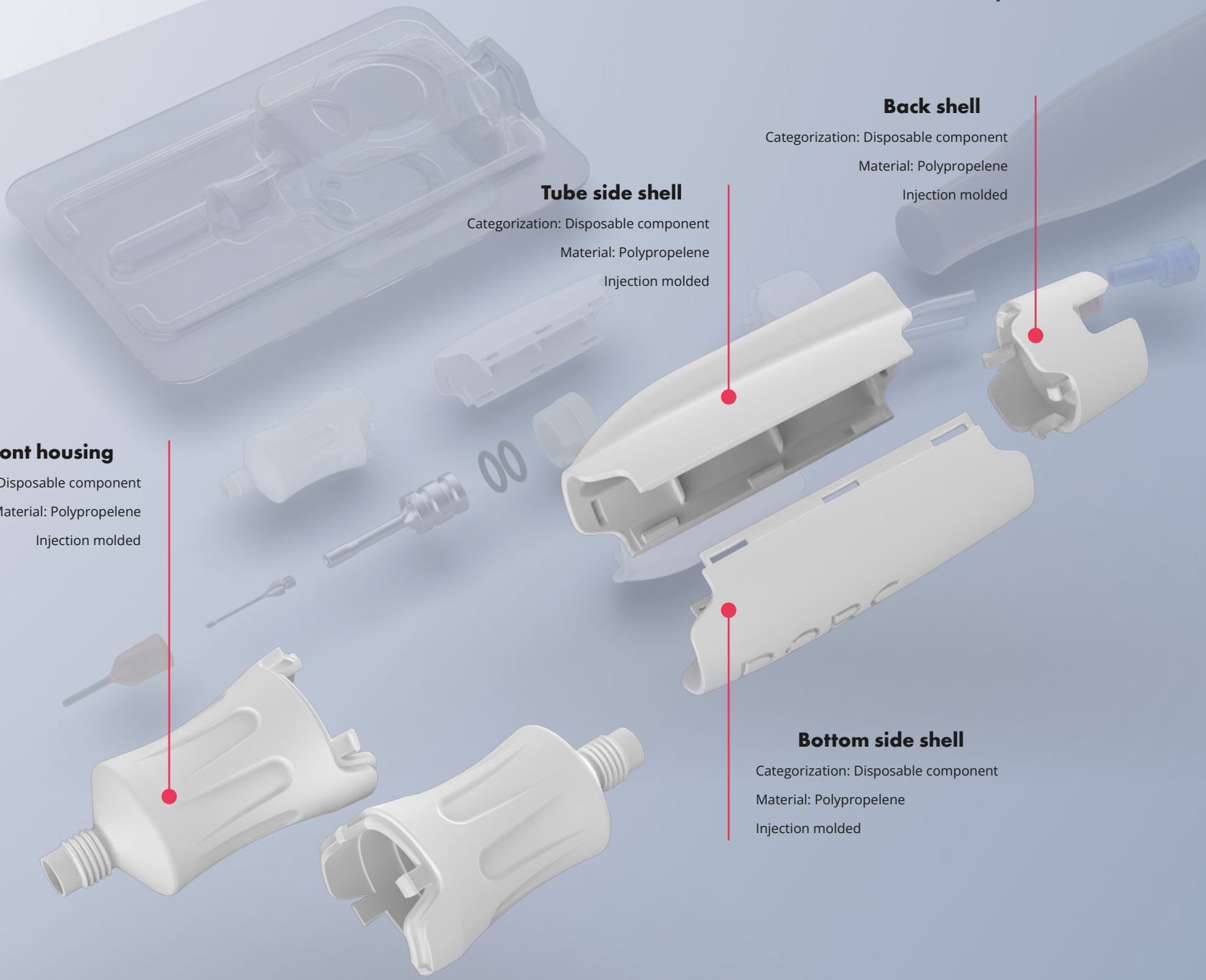
Given its significant physical weight and thus its impact on the production phase of the life cycle assessment (LCA) (refer to chapter “6.3 Environmental evaluation” on page 180), polypropylene (PP) was selected as the material for all housing shells. Further details on this material choice can be found in chapter 5.1.3 “Material considerations”.

The disposable housing serves as the primary interface for the entire handpiece. In addition to addressing ergonomics (chapter 5.8 “Deep dive: Ergonomics”), ensuring the structural integrity of the complete housing and the connection between the housing shells is critical. The layout of these shells is a result of the product architecture design process, as detailed in chapter 5.2 “Deep dive: Product Architecture”. All shells are interconnected using sets of snap fits, and structural reinforcement is achieved through the incorporation of ribs.

Wall thicknesses, rib structures, as well as snap fits dimensioning were determined through prototyping of SLA printed components, using resins with comparable elastic moduli to the final material PP. The gaps designed in between all shell parts is set to accommodate the tolerances of the SLA printing, and needs to be reassessed for an injection moulded design.

This housing design proposes an injection-mouldable structure, but certain liberties have been taken in designing undercuts and ensuring proper release angles. A reassessment is necessary to achieve a fully compatible design for injection moulding.

Subsequent chapters will provide a more detailed examination of each housing shell.



Back shell

Categorization: Disposable component

Material: Polypropelene

Injection molded

Tube side shell

Categorization: Disposable component

Material: Polypropelene

Injection molded

Front housing

Categorization: Disposable component

Material: Polypropelene

Injection molded

Bottom side shell

Categorization: Disposable component

Material: Polypropelene

Injection molded

4.5.1 Front housing

The front housing serves as the primary user interface and plays a crucial role in the fluidics system. Its threaded connection on the tip mates with the phaco sleeve, ensuring watertightness of the fluidics channels. The internal design includes features that secure the integrity of the fluidics system.

The luer fit type tapers on the inside facilitate a secure connection with the fluid conduit (chapter 4.4.1 “Fluid conduit”), and a rib, serving as an insert for the fluid conduit, features tapered sides and closes off the aspiration channel. Two additional ribs on the shell mate with notches on the disposable horn (chapter 4.3.3 “Disposable horn”), ensuring torque transmission during assembly in the operating room, preventing free spinning.

The shape of the back face of the shell is designed for both aesthetics and practicality, guiding the snap-fit connection during assembly (Appendix VII). This back face includes a lip, acting as a moisture barrier during surgery, and a chamfer for ease of assembly. The grip pattern enhances ergonomics (chapter 5.8 “Deep dive: Ergonomics”) and contributes to the overall aesthetics, as detailed in chapter 5.9 “Deep dive: Aesthetics”. Similar aesthetic and ergonomic considerations are applied to the concave shape of the shell.

4.5.2 Tube side shell and bottom side shell

The two side shells constitute the majority of the disposable housing. They are interconnected using overlapping snap-fit connections, with ribs providing additional structural integrity, a feature identified through rounds of prototyping. Together, the front and back sides of these shells create a shape that aligns with the front housing, facilitating ease of assembly.

The tube side shell accommodates the internal tubing, which runs through the two external channels and exits at the back of the shell assembly. To secure the tubing in place and provide a clear path for the reusable driver during OR assembly 5.5.3 “Implementation sterile usability steps”, two sets of ridges are added to the exits of these channels.

The bottom side shell features only a debossed DORC logo, contributing to the aesthetics and branding of the design.

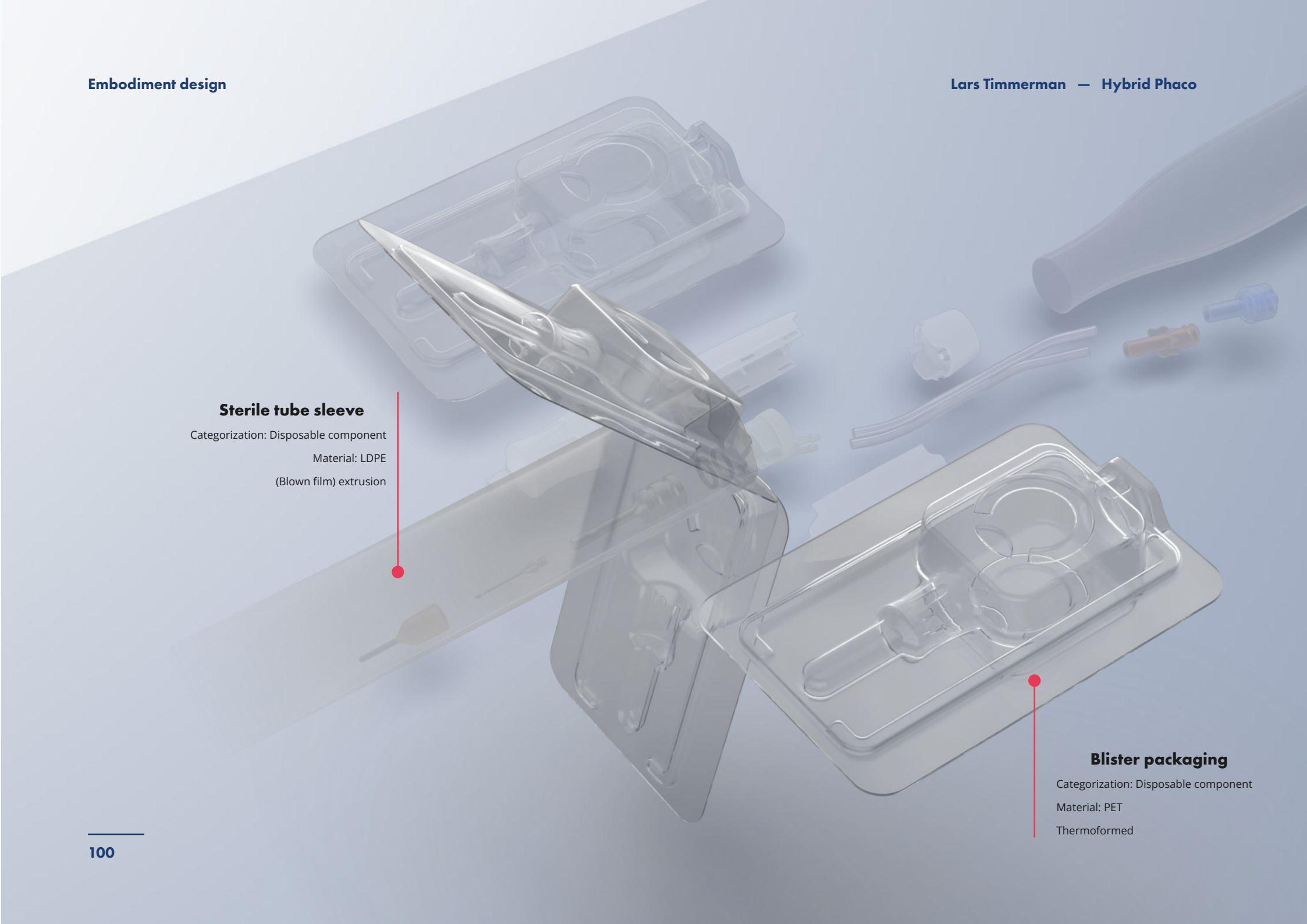
4.5.3 Back shell

The back of the housing serves as the connection point from the handpiece to the sterile sleeve, playing a crucial role in usability:

The back housing features a cutout designed to mate with the torque nib of the packaging (chapter 4.5.5 “Blister packaging”). This arrangement ensures the correct torque application to the sonotrode during OR assembly (refer to chapter 5.5.3 “Implementation sterile usability steps”).

The sterile sleeve is attached to this shell part to maintain the sterility of the handpiece. This bond is essential for the sterile handling of the handpiece (chapter 5.4.1 “Defining sterility for a hybrid (phaco) design”). A proposed method for this design is heat-pressed permanent bonding. However, alternative options, such as adhesives, could be explored further for potential cost-effectiveness and faster assembly.

The back shell also serves as the second point of contact for the reusable, with the disposable horn O-rings being the first. This configuration ensures the stability of the handpiece.



Sterile tube sleeve

Categorization: Disposable component

Material: LDPE

(Blown film) extrusion

Blister packaging

Categorization: Disposable component

Material: PET

Thermoformed

4.5.4 Sterile tube sleeve

The sterile tube sleeve serves the purpose of covering the non-sterile cable and reusable driver, thereby maintaining the sterile barrier (refer to chapter 5.5.3 “Implementation sterile usability steps”). It envelops the entire cable, extending from the back shell of the disposable housing to the cable plug when unfolded.

The sleeve is fixated through a heat-press connection on the back shell and is similarly attached to the blister pack. With connections on both ends, the tube sleeve can be unfolded over the cable by pulling the packaging back toward the plug, ensuring a sterile interaction (as detailed in chapter 5.5.3 “Implementation sterile usability steps”).

The sleeve’s design prioritizes minimal weight, contributing to a reduced environmental impact. Additionally, the choice of using LDPE film aligns with industry standards for sterile plastic films, making it a practical and feasible option.

4.5.5 Blister packaging

The blister packaging serves the dual purpose of ensuring the safe shipment of the handpiece and maintaining its sterility. It accommodates the disposable handpiece, including the needle and sleeve, as well as the sterile tube sleeve.

The packaging features a form-fitted cavity for the disposable housing, aligning it within the pack, and ample space for the needle and sleeve. The two halves of the pack are sealed at the back using a film hinge, effectively closing one end securely. A ridge and groove, incorporating an undercut around the pack’s perimeter, ensure that the two halves stay closed until intentionally folded open.

When folded, the blister pack includes an opening for inserting the reusable driver. This opening incorporates a ridge to ensure the correct torque for the threaded connection, optimizing ultrasound transmission (refer to chapter 5.3.3 “Torque testing”). Consideration has been given to methods ensuring the packaging cannot be opened unless the correct torque is applied, enhancing the safety of the system, although this has not been implemented in the embodiment design yet.

The spacious cavity in the folded pack is designated for storing the folded tube sleeve, connected close to the opening for the reusable driver (shown in figure Figure 5.4 - 4 on page 138). This facilitates a deliberate unfolding process, which has been prototyped once, indicating its feasibility. Further testing is required to validate this design, along with the optimal thickness tube sleeve.

When unfolded, the packaging reveals the assembled handpiece. The broad body of the pack acts as a physical barrier between the non-sterile and sterile hands of the nurses.

Key insights

RQ2.1: How can sterility within the phaco handpiece be ensured when implementing the reusable electronics during surgical procedures?

- Fluid conduit in combination with O-rings is most instrumental in rerouting fluids, and maintaining internal sterility in the handpiece; it forms barrier between reusable product and fluids.

RQ4.2: What is the environmental impact of a functional hybrid phaco handpiece?

- Disposable housing shells (PP injection moulded) are not only the main components that define the aesthetics and ergonomics of the product, but with significant weight they have a impact on production phase in LCA.

- Sterile tube sleeve and blister packaging account for substantial amount of impact on production phase in LCA.

RQ2.2: How can a hybrid design be assembled in a way that ensures sterility?

- Sterile tube sleeve and blister packaging together form the sterile barrier implemented in the OR for covering the non-sterile reusable driver

5. Deep Dives

This chapter will give a comprehensive overview of most researched topics I have done for this thesis. With the product design being completely described, this chapter stand to support the final choices as shown in chapter 4 "Hybrid phaco embodiment". It will do this by providing the reason for researching a certain topic, the results of said research topic, and more generalized design considerations.

Figure 5.1 - 1 *Test setup used for testing of sonotrode performance at Wefis GmbH and other sensitivity analyses*

5.1 Deep dive: Ultrasound performance

As main driver to this project, the phaco performance plays a pivotal role. Ultrasonic energy, besides fluidics, is the main ingredient to making phacoemulsification work. Choices made for ensuring the right ultrasound performance have shaped virtually all subsequent design choices, which makes a fundamental understanding of the phenomenon indispensable.

Understanding ultrasound as a complete picture is too much for this project, so this chapter will go into the fundamental characteristics of ultrasound important to phaco. Ultrasonic vibrations with a specific performance in the needle is used to break up the lens into fragments, which are then emulsified with fluids. Ultrasound “performance” in phaco is typically characterized by a number of metrics, namely resonant frequency, stroke length (or displacement of the needle tip), and efficiency (namely the amount of energy)

This chapter will also showcase the extensive testing done for finetuning the ultrasound performance, and mapping its variables, as will it go into the extensive expert consultation done to get to this point.

Figure 5.1 - 2 *Sonotrode prototypes as used in a number of ultrasound performance tests*

5.1.1 Mechanical principles of ultrasound in phaco

5.1.1.1 Piezoelectric effect

At the basis of all ultrasound applications in phaco is the application of piezoelectric elements. The PZT (lead zirconate titanate) piezos in a phaco handpiece make use of the inverse piezoelectric effect: converting the electrical energy applied to them into kinetic, or mechanical energy (Holterman & Groen, 2013).

Simplified: when applying an AC signal with a certain frequency over the piezo element, it will provide a vibration at that frequency, by expanding and contracting along the polarization direction (Figure 5.1 - 3). One of the critical factors to this principle, besides for example the phase angle, is the resonant frequency of the piezo and the complete sonotrode it is part of. Matching the resonant frequency of the complete sonotrode (so piezos, sonotrode base, disposable horn, and needle) is crucial is achieving any significant stroke and efficiency of the sonotrode.

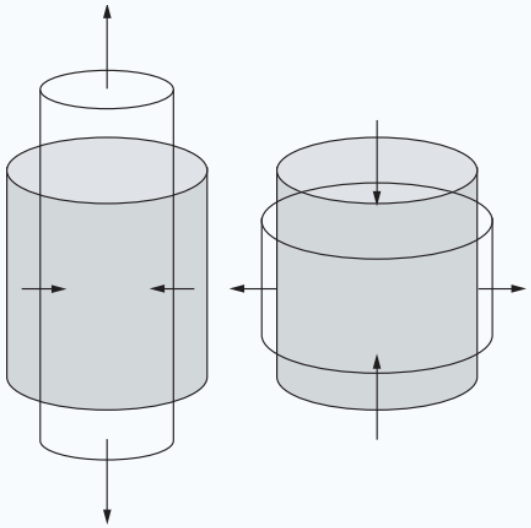


Figure 5.1 - 3 *Visualisation of inverse piezoelectric effect when applying voltage over piezoelectric elements with vertical polarization direction (Graff, 2015)*

5.1.1.2 Mass damper spring system approach

When considering the resonant frequency of the sonotrode, the sonotrode roughly abides to the same principles of a forced spring mass damper system:

$$m\frac{d^2x}{dt^2} + c\frac{dx}{dt} + kx = F(t)$$

Most relevant to such a phaco system are a the following variables: the spring value (k), mostly analogous to the sonotrode materials' ability to undergo elastic deformation (and its dimensioning such as length and thickness). The dampening value (c), analogous to the internal material friction in the sonotrode, and damping factor of the eye. The mass value (m), analogous to the relevant masses in the sonotrode, and their distance from the piezoelectric elements, including the piezos themselves. The external force (F(t)), analogous to the forced vibrations of the piezo elements.

Concluding in terms of the sonotrode design: added masses to the system will influence resonant frequency, as will mass distribution, material choices, dimensioning, and the list goes on (and this is excluding other metrics of phaco performance).

5.1.1.3 Harmonics and resonant frequency

A resonant frequency is a frequency at which a system responds most intensely to vibrations induced by piezos, resulting in non-cancelling superimposed vibrations and increased amplitude.

A system in resonance displaying standing waves, nodes with zero amplitude and anti-nodes with maximal amplitude are crucial considerations for a phaco handpiece. Placement of said node should be at the needle tip, where amplitude is vital.

Each harmonic, or point of resonance (of which a ultrasonic transducer has many), in the system corresponds to specific eigen modes or displacement modes, influencing longitudinal, transverse, and torsional vibrations (Figure 5.1 - 4), or any combination of the six degrees of freedom. Multiple harmonics in the system form the basis for two types of phaco in cataract surgeries: longitudinal phacoemulsification (LPKE) and torsional phacoemulsification (TPKE). Designing for a fully longitudinal mode requires accounting for displacement modes to achieve the desired displacement at the needle tip.

Designing for resonant frequency, node placement, and eigen mode shape involves complex considerations, including mass distribution, piezo design, dimensioning, material choices, and more.

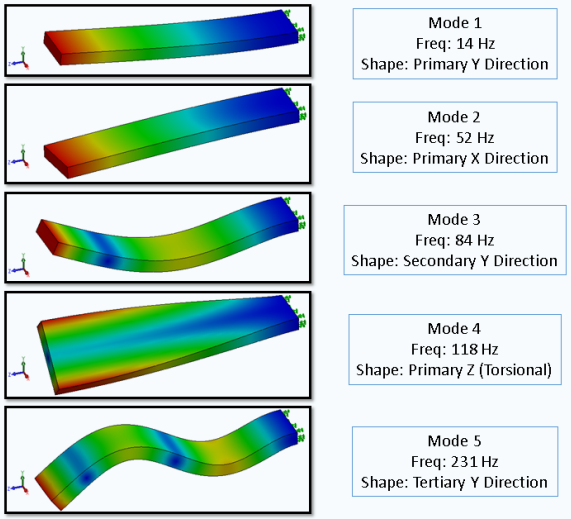


Figure 5.1 - 4 *Visualisation eigenmode shapes of first 5 natural frequencies of a three dimensional cantilever beam, (Karabulut, 2021)*

5.1.1.4 Efficiency and heat generation

A desired needle tip displacement in a theoretical unbreakable ultrasonic transducer can nearly always be achieved by increasing power input, thus increasing the inverse piezoelectric effect. However, factors like resonance at the desired frequency with the right displacement mode drastically enhance this energy efficiency. Higher energy input at high frequencies can lead to increased heat generation due to the dielectric dissipation factor, a material property influenced by imperfections in the piezo ceramic material (Collins, 2022). Other imperfection factors such as impedance mismatches (more in chapter 5.1.3 “Material considerations”) and mating surface imperfections further reduce efficiency and increase heat generation.

In this thesis, “efficiency” for phaco is defined in terms of the energy efficiency needed to attain a specific needle tip displacement, while keeping piezo-generated heat at a minimum.

5.1.1.5 Stroke amplification

The displacement from the inverse piezoelectric effect is inherently small, resulting in a minimal longitudinal stroke directly at the piezos. To enhance stroke, a transducer's diameter can be reduced, introducing an amplification factor (M) roughly expressed as:

$$M = \frac{A_{large}}{A_{small}}$$

This amplification relies on energy conservation, redistributing the same energy over a smaller material area. However, this amplification leads to increased internal stresses, as depicted in Figure 5.1 - 5 (source 58), posing a challenge illustrated by the breaking of the transmission shaft in a student design (Figure 5.1 - 6). To address this, the fluid interface was moved behind the amplifier, accommodating the desired material choice of aluminium: With alumnium having a lower fatigue limit than titanium, and titanium already failing at the stress concentrations (Figure 5.1 - 6), moving this interface is required for an aluminium part.

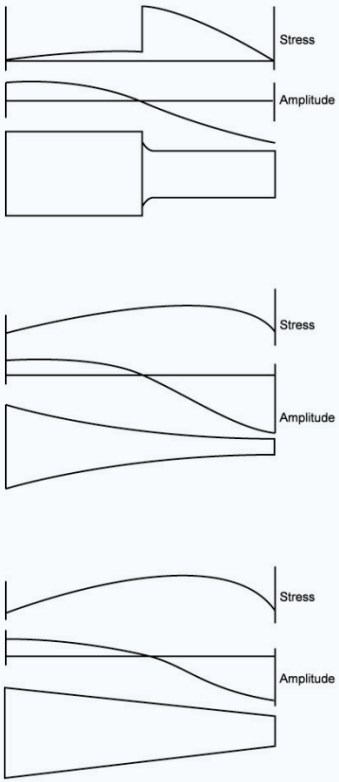


Figure 5.1 - 5 *Stepped horn, exponential horn, and tapered horn showing increase in stroke (amplitude) and increase in stress*

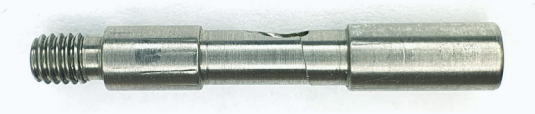


Figure 5.1 - 6 *Tested transmission shaft student design showing a crack due to added load from stroke amplification (at a stress concentration)*

Key insights

RQ1.2: What variables influence ultrasonic vibration characteristics of the phaco handpiece?

- Ultrasonic transducer with piezoelectric elements can be characterised as a mass damper spring system, influences by elasticity, internal friction, and mass distribution of the transducer material.
- Resonant frequencies with their harmonics (mode shapes) and position of anti-nodes influence the needle tip displacement.
- Lower efficiency transducers require more energy for the same stroke, increasing heat generation
- Needle tip stroke is amplified through a mechanical amplifier, implementing a tapered horn design.

5.1.2 Dimensional sensitivity

To maintain performance close to the original phaco handpiece, the strategy prioritized adherence to the original design. However, alterations in the fluid interface, the introduction of a new disposable-to-reusable connection method, and the incorporation of O-ring grooves led to changes in the sonotrode dimensions, consequently affecting the handpiece's ultrasound performance (Figure 5.1 - 7).

Given the intricate nature of the transducer and the interconnected influence of geometric changes on various performance metrics, a purely theoretical approach becomes impractical. Finite Element Analysis (FEA) methods, including modal and harmonic response analyses, might offer valuable insights in understanding dimensional sensitivity. However, setting up such a theoretical model is complex, sensitive to errors (which became evident after setting up such a model), and incomplete without empirical physical testing using prototypes.

Hence, this thesis adopts an empirical approach to ascertain the dimensional sensitivity of the sonotrode redesign, complementing the theoretical foundation outlined in chapter 5.1.1 "Mechanical principles of ultrasound in phaco".

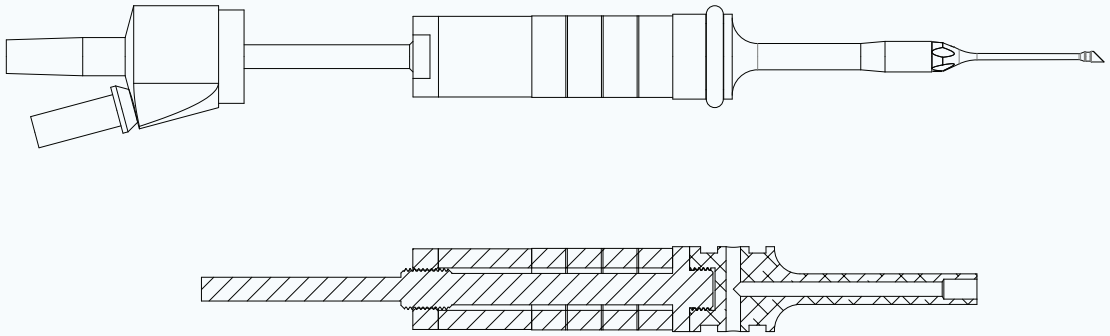


Figure 5.1 - 7 *Sonotrode 3002.P and hybrid redesign, indicating main differences in general geometry*

5.1.2.1 Method

In conducting the dimensional sensitivity analysis, various design variations are compared to a baseline design, assessing their phaco performance in terms of resonant frequency, stroke, and efficiency.

The baseline design (Appendix IX), featuring the redesigned phaco handpiece sonotrode with additional elements like the fluid interface, O-ring grooves, and threaded connection interface, most closely aligns with the original phaco sonotrode design. Notably, the baseline design has adjusted dimensions compared to the original sonotrode, such as a longer horn base length and front length due to the added features.

Design variations involve isolating and altering a single dimension while keeping other factors consistent. The analysed dimensions include the horn front length, horn base length, horn diameter, and thread type, (Figure 5.1 - 8) each varied by ±1mm. Careful assembly of reusable drivers itself, and connecting the disposable, by utilizing a torque measuring screwdriver (CEDAR DID-4A) for consistent threading, minimizes variations between designs, ensuring the isolation of only one variable per design.

All redesign disposable horn prototypes and reusable driver prototypes used for this test are machined out of 7075-T6 aluminium, the type of aluminium which is aimed for in the redesign (chapter 5.1.3 “Material considerations”). This is done to negate the effect of material differences between titanium and aluminium.

Resonant frequency measurement uses an impedance analyser (Hioki IM3570). Stroke assessment involves driving the transducer at 30% power using a custom phaco board from DORC, and stroke calculation is performed through visual analysis aided by a stroboscope and microscope with custom software also provided by DORC (as shown in Figure 5.1 - 1 on page 105).

Efficiency, defined by the power needed for a given stroke, is directly related to stroke. Lower or higher strokes are directly proportional to lower or higher efficiencies. This is why efficiency is integrated into the stroke evaluation for these tests.

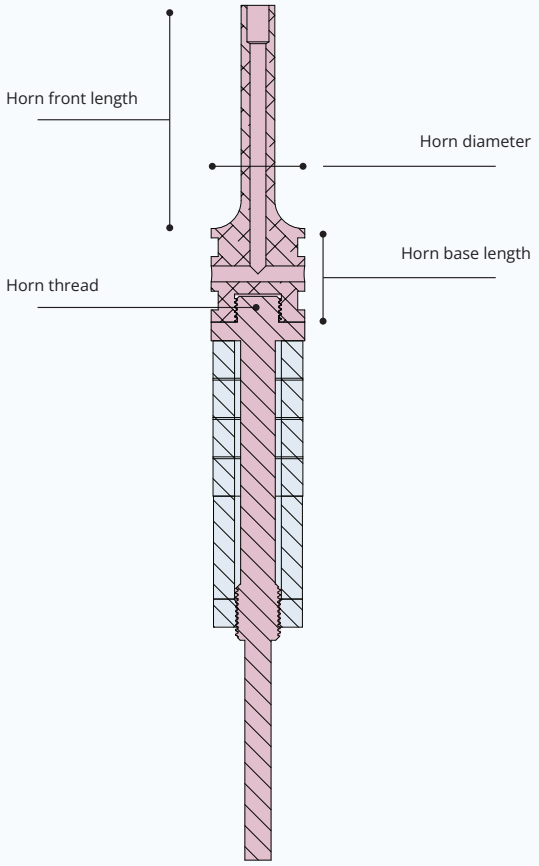


Figure 5.1 - 8 *Redesign’s main changed dimensions compared to 3002.P tested for in chapter 5.1.2 “Dimensional sensitivity”*

5.1.2.2 Results

Measurements from the dimensional sensitivity tests are shown in Table 5.1 - 1

For stroke length test results, a variance of less than +/-10% can be expected, similar to testing multiple 3002.P handpieces. Results within this variance range can be considered non-significant. These tests serve the dual purpose of evaluating the redesigned handpiece and comparing its performance to the original design. The original handpiece undergoes a similar analysis using the same experimental setup for a comprehensive performance assessment. Noteworthy are the results for the horn diameter (+1mm) prototype, showing resonance around 39kHz but in a different eigenmode shape, namely with a mainly transverse vibrational eigenmode shape.

Table 5.1 - 1 *Results from dimensional sensitivity analysis for hybrid phaco redesign, showing resonant frequency and stroke, with their respective relative change to the redesign baseline. Also included are test results for 3002.P*

	Eigenfrequency [kHz]	Relative difference to baseline	Stroke length @ 30% power (µm)	sd	Relative difference to baseline
3002,P	38,775	-1.34%	71,60	1,72	5.85%
Alu 7075 - Baseline	39,300	-	67,64	1,04	-
Alu 7075 - Horn base length +1mm	39,700	1,02%	56,40	1,16	-16,62%
Alu 7075 - Horn base length -1mm	40,225	2,35%	50,86	2,28	-24,81%
Alu 7075 - Horn front length +1mm	39,050	-0,64%	76,80	2,3	13,54%
Alu 7075 - Horn front length -1mm	40,950	4,20%	60,25	1,54	-10,93%
Alu 7075 - Horn diameter +1mm	39,375	0,19%	41,36	9,99	-38,85%
Alu 7075 - Horn diameter -1mm	38,750	-1,40%	58,44	2,98	-13,60%
Alu 7075 - Horn thread Mf4	40,225	2,35%	73,40	1,43	8,52%
Alu 7075 - Horn thread Mf6	39,175	-0,32%	63,72	2,2	-5,80%

5.1.2.3 Conclusions

The conclusions regarding dimensional sensitivity are visually summarized in Figure 5.1 - 9, offering a preliminary estimation of the influence of various components on performance metrics. This serves as an initial tool for understanding the system and reflects the breadth of understanding of ultrasound performance gained in this project.

It is important to note the significance of testing; some results cannot be explained as they cannot be attributed to a single factor, highlighting the complexity of the system. Only strongly significant findings should be considered for further design considerations. This should especially be considered for implications on stroke length / efficiency, where a high variability in results show the uncertainty of these characteristics.

Connector

The connector, rigidly attached to the sonotrode, acts as a fixed mass in the resonant system. Its mass dampens residual vibrations from the sonotrode, with minimal impact on phaco performance (consultation with expert).

Handpiece reusable

The 3002.P's titanium body, press-fit onto the connector, collaborates with the connector's weight to dampen residual vibrations, preventing energy transfer to the surgeon's hand. The redesigned stainless steel connector replicates this dampening effect, maintaining similar weight and performance, despite the absence of the titanium body in the disposable version. It hardly influences phaco performance metrics.

Sonotrode back length

As the primary variable for determining the total length of the handpiece, this feature influences the resonant frequency and efficiency of the handpiece. It is directly connected to the connector, serving as a fixed point, and thus determines the node placement at the tip of the needle for a certain wavelength.

Clamping nut

The clamping nut, tightening down the piezos, is crucial in the efficiency and resonance of the system (consultation with expert). Only with proper pretension can the sonotrode be considered a single resonant system. If piezos are too loose, no resonance will be found, and will cause the piezos to bounce around freely leading to potential breakage. Conversely, excessive pretension can result in high internal stresses, impacting durability. Achieving the right pretension is crucial for proper resonance and efficiency. Therefore, the clamping nut's pretension remains unchanged in the redesign to maintain this delicate balance.

O-ring interface

With the O-rings having a much lower elastic modulus, resulting in a significant impedance mismatch (further discussed in chapter 5.1.3), the transmission of ultrasonic energy can be considered negligible. Additionally, the O-rings are hardly placed in the longitudinal vibrational direction. The O-ring interface connection might slightly influence efficiency, as a small amount of energy is absorbed by the softer material.

Through testing redesigns (chapter 5.1.4 "Influence bordering components in the handpiece"), I observed that the O-rings have a dampening effect on extra harmonics present in the sonotrode and other residual vibrations, resulting in a cleaner sinusoidal signal. This suggests that significantly softer materials could also have a beneficial effect on phaco performance.

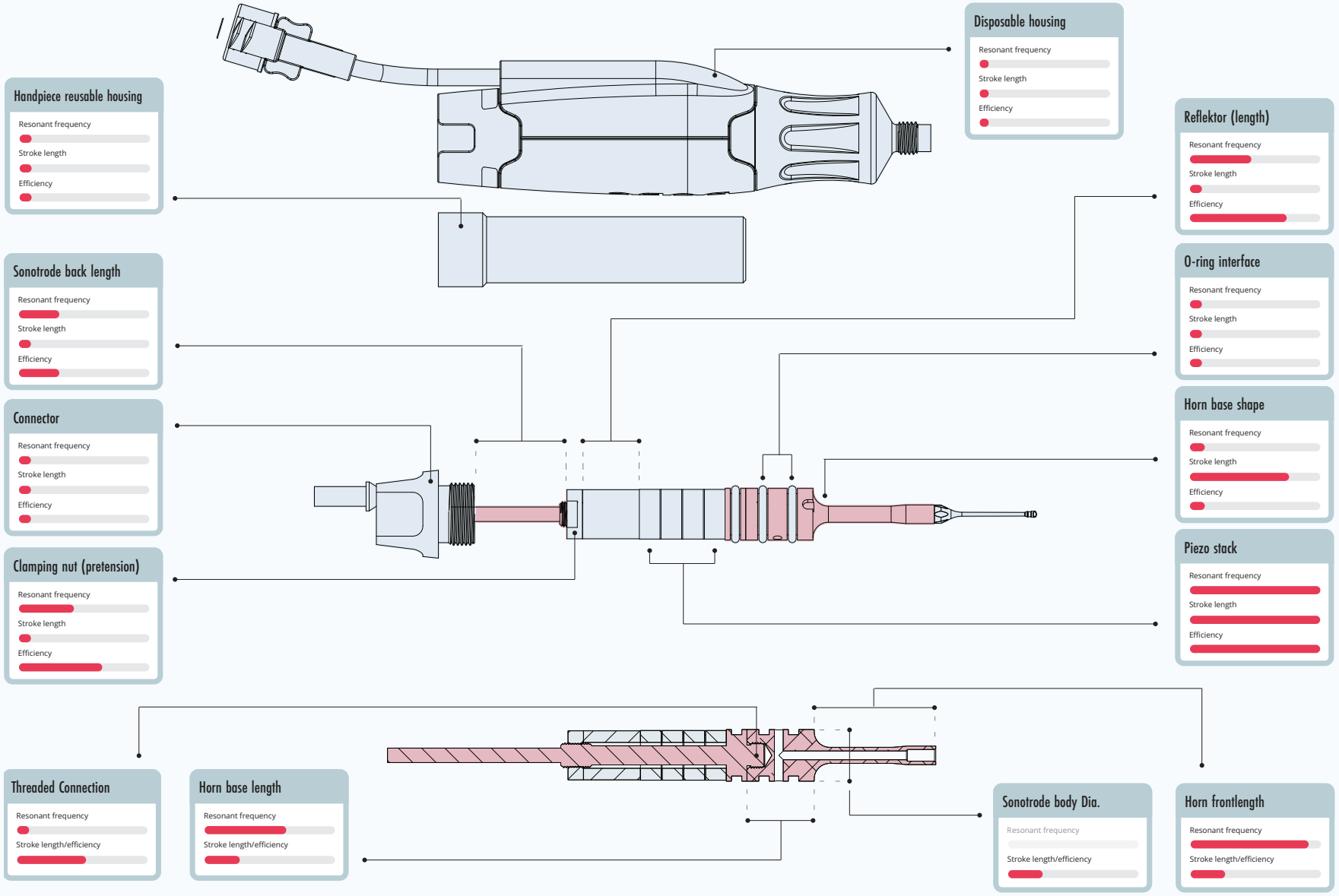


Figure 5.1 - 9 *Sensitivity analysis of elements in 3002.P and in phaco redesign, offering general approximate overview of relative influence on phaco performance per variable / component.*

Piezo stack

The piezo stack is a critical component of the driver, and its material quality significantly impacts efficiency. The dielectric and piezoelectric properties of the piezos are crucial for achieving the right resonant frequency and stroke. Given the complexity of reconsidering piezos and the basic sonotrode layout, the approach was to adhere to a basic split sonotrode design resembling the original, rather than exploring alternative product architectures. The project's goal was to demonstrate the feasibility of a sonotrode design fitting the hybrid concept, and starting from scratch would have been beyond the project's scope.

Horn base shape

The horn base and its final diameter play a crucial role in amplifying the sonotrode stroke, as discussed in Chapter 5.1.2 "Dimensional sensitivity". However, these dimensions have minimal impact on overall geometry and mass distribution, resulting in little influence on resonant frequency and efficiency.

Resonator

The resonator in the sonotrode design serves a unique function as the back mass of the system, significantly influencing the resonant frequency by shifting the direct mass distribution of the handpiece. As the piezos expand and contract, they transmit vibrations to the back of the handpiece. The resonator's mass acts as a reflector, sending these vibrations back to the front. Proper mechanical tuning of its weight and length is crucial to ensure in-phase vibrations, impacting efficiency. The inverse, improper tuning, can result in destructive interference of the ultrasound. This resonator design is also retained from the original design.

Threaded connection

A proper mating surface area (flat on flat) is crucial for ultrasound performance. The thread sizes in the redesign influence the surface area of these mating surfaces, with the male thread not reaching the bottom. For a predetermined thread torque, a smaller thread size (like the Mf4 x 0.5) yields a greater clamping force but results in a smaller maximum torque. Testing results indicate a similar eigenfrequency across thread sizes but an inverse relationship with stroke length: smaller thread sizes yield higher stroke length. This might be explained by decreased transmission efficiency for a smaller mating surface, though results may not be significant considering their relatively small variance.

Sonotrode body diameter

The sonotrode body diameter influences the weight of the disposable sonotrode, which could impact ultrasound performance. A lower weight might result in a higher resonant frequency, but results show nearly identical outcomes. Stroke length results are inconclusive, given the different eigenmode shape of the larger diameter prototype. The decrease in stroke length of the small diameter prototype might be due to energy loss; the diameter mismatch of the sonotrode (10mm) and the horn prototype (9mm) could result in some energy loss.

Horn front length

The decreased horn front length, resulting in a higher resonant frequency, is expected and is also observed in the results. The difference in stroke length for the two horn prototypes might be more difficult to explain and is most likely due to the anti-node placement not being directly on the needle tip.

Horn base length

The horn base length also influences the resonant frequency of the system, but the results for this variable are less significant due to its low variance in results. The stroke lengths are also significantly lower for both prototypes compared to the baseline prototype, something most likely attributed to the anti-node placement.

Key insights

RQ1: What ensures the phacoemulsification functionality of a phaco handpiece?

- Dimensional sensitivity of variables on phaco characteristics can roughly be visualised in a sensitivity map.
- Resonant frequency is most strongly characterized by the piezo stack and resonator, but most easily tuned by changing the horn base and front length.
- Stroke length is strongly influenced by the horn base shape, the mechanical amplifier, and is dimensional sensitivity of this phaco characteristic is largely inconclusive. Horn thread tightness seems to have most influence.

5.1.3 Material considerations

To transmit ultrasound vibrations within the sonotrode the acoustic properties of materials used is critical. Acoustic impedance (Z) being the most relevant characteristic, dependant on the density and elastic modulus of the material:

$$Z = \rho \cdot \sqrt{\frac{E}{\rho}}$$

A significant mismatch in acoustic impedance may result in negligible ultrasonic energy transfer, while a closer match indicates more efficient energy transfer. The reflection coefficient (Γ) (Figure 5.1 - 10) plays a role in this transition between materials, with the equation (AAPT, n.d.):

$$\left|\frac{E_{1r}}{E_{1i}}\right| = \Gamma = \frac{Z_2 - Z_1}{Z_2 + Z_1}$$

Table 5.1 - 2 includes impedance values and their reflection coefficients for various materials, such as titanium grade 5 (used in both the current and redesign), Aluminium 7075-T6, Aluminium 2024-T4 (commonly used in sonotrode designs), and common aluminum types like 6061 and 3003.

Figure 5.1 - 10 *Visualisation of reflected energy (E_{1r}) due to acoustic impedance mismatching, retrieved from (AAPT, n.d.)*

Table 5.1 - 2 *Acoustic impedances and reflection coefficients with TiAl6V4 of different relevant materials*

	ρ[kg/m³]	E[GPa]	$Z_{acoustic}$[Ry]	Reflection Coefficient Γ
TiAl6V4	4430	114,0	2,25E7	**0,00**
7075-T6	2810	71,7	1,42E7	**0,23**
2024-T4	2780	73,1	1,43E7	**0,22**
6061-T6	2700	68,9	1,36E7	**0,24**
3003-H18	2730	68,9	1,37E7	**0,24**

Considering the intended use of aluminium for the disposable horn component and its expected acoustic mismatch with titanium, testing was essential to understand the impact of this mismatch. For the sono-trode redesign, the choice of 7075-T6 aluminium was taken, aligning with its widespread application in ultrasonic transducers. This selection is further validated by Wefis GmbH's use of the same aluminium type in a fully disposable design. Notably, 7075-T6 shows a relatively low reflection coefficient compared to certain other aluminium types.

Performance testing was done to determine the influence of material differences in a split sonotrode design

5.1.3.1 Method

Performance metrics were evaluated using the methods outlined in Chapter 5.1.2.1 "Method", utilizing an impedance analyser for resonance measurement and a stroboscope microscope setup for stroke measurement at a consistent 30% power setting. Horn thread tension was maintained at 50nCm using a torque measuring screwdriver (CEDAR DID-4A) to isolate variables.

Testing involved baseline prototypes with reusable components made from TiAl6V4 and 7075-T6, accompanied by baseline disposable horns from TiAl6V and 7075-T6. Various combinations of these components were examined in the tests.

5.1.3.2 Results

Results from material difference test can be seen in Table 5.1 - 3.

Table 5.1 - 3 *Phaco performance results from performance test for material differences, showing all four combinations of titanium and aluminium horn and sonotrode*

	Eigenfrequency [kHz]	Stroke length @ 30% (µm)	sd
Sonotrode Alu 7075 + Horn Tit	37,375	52,29	2,22
Sontrode Alu 7075 + Horn Alu 7075	39,700	56,40	1,16
Sonotrode Tit + Horn Tit	37,725	48,97	1,74
Sontrode Tit + Horn Alu 7075	40,100	67,59	1,29

5.1.3.3 Conclusions

Evident is the fact that combining materials in the sonotrode does not have a detrimental effect on eigenfrequency: ultrasound transmission between materials is possible. Another finding is the higher resonant frequency and higher stroke length for the aluminium horns, which is to be expected for a mass damper spring system with a weaker spring (effectively the case for aluminium compared to titanium). No significant differences can be observed for the aluminium or titanium sonotrode, indicating their limited role in the phaco characteristics of the system.

With the titanium sonotrode and the aluminium horn showing phaco characteristics closest to the original 3002.P, I conclude that this design is most suited and should be considered in further design.

Key insights

RQ1.3: What ensures proper transmission of ultrasonic vibration between disposable and reusable?

- Transitions between materials can influence the efficiency of ultrasound transmission, which is why specific aluminium choice of 7075-T6 is recommended.

RQ1.2: What variables influence ultrasonic vibration characteristics of the phaco handpiece?

- Titanium sonotrode and aluminium horn combination is most beneficial for ultrasound characteristics.

5.1.4 Influence bordering components in the handpiece

In determining the relevant masses in the handpiece that influence the aforementioned impedance matching becomes relevant. Considering the O-rings as interfaces with the fluid conduit and housing bodies, tests were conducted to evaluate the impact of different shore hardnesses of the O-rings on phaco performance metrics.

5.1.4.1 Method

Performance metrics testing followed the methodology outlined in chapter 5.1.2.1 “Method”, utilizing an impedance analyzer for resonance measurement and a stroboscope microscope setup for stroke measurement, maintaining a consistent 30% power setting. The 7075-T6 sonotrode, with a 7075-T6 horn prototype, was used to minimize material differences. Various shore hardness values (70A, 80A, and 90A) and materials (NBR, EPDM, FKM, and Silicone) were tested to assess their impact on phaco characteristics. Comparisons of prototypes with different O-rings connecting the sonotrode with bordering components were made against a baseline test with a sonotrode lacking an O-ring and bordering components to quantify the effects of O-rings and the other disposable components.

5.1.4.2 Results

The results of the performance tests for different O-ring hardnesses are presented in Table 5.1.4.

Table 5.1.4 Performance testing results of baseline test, and different O-ring materials and hardnesses

	Eigenfrequency [kHz]	Relative difference to baseline	Stroke length @ 30% power (µm)	sd
Baseline - no O-ring	37,725	-	48,97	1,74
Shore 70A - Nitril	37,775	0,13%	52,92	1,05
Shore 70A - EPDM	37,600	-0,33%	46,95	1,15
Shore 90A - Silicone	37,775	0,13%	53,72	0,83
Shore 80A - Viton	37,700	-0,07%	50,59	0,99
Shore 90A - Nitril	37,625	-0,27%	52,20	1,23

5.1.4.3 Conclusions

What can clearly be concluded is that O-rings have no effect on the phaco characteristic metrics. With both the eigenfrequency and the stroke length results staying well within the expected variance range, I conclude all results to be similar. This is also to be expected, considering how soft the O-rings are compared to the metal horn, even for the 90A shore hardness variants. Because of this, the is a strong impedance mismatch, further explained in chapter 5.1.3 “Material considerations”, resulting in no ultrasound transmission.

5.1.4.4 Bordering components axial direction

The tests primarily focused on quantifying the impact of components connected perpendicular to the sonotrode’s axis. However, the front housing, with torque-transmitting ribs engaging the disposable horn, is connected axially, directly affecting the ultrasound’s longitudinal direction.

To counteract this, a decoupling system was developed (Figure 5.1 - 11): the disposable horn is preassembled in the housing with full contact with the torque transmission ribs. Tightening the reusable driver causes its connector to contact the back of the disposable housing. By tightening the threaded connection in the horn’s last turns, the horn is pulled back into the reusable, effectively decoupling it from the housing. The designed 0.3mm gap accommodates the 90µm stroke, with the effective gap dependent on the tolerance chain in the reusable driver and disposable housing shells. Further development is recommended and considered in this thesis without detailed examination.

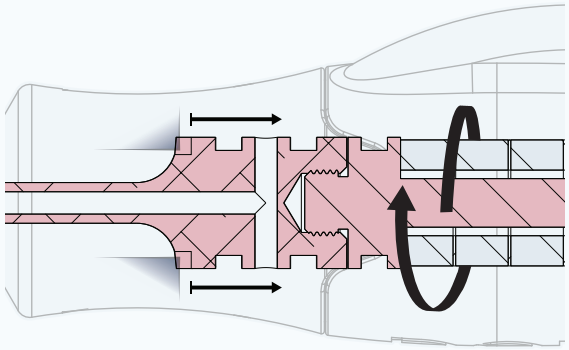


Figure 5.1 - 11 *Visualisation of decoupling system used to eliminate effect of component in axial direction on phaco characteristics*

Key insights

RQ1.2: What variables influence ultrasonic vibration characteristics of the phaco handpiece?

- Independent of O-ring hardness, bordering components have no influence on phaco performance.
- Decoupling system is used in the design so influence of components in axial direction is prevented.

5.2 Deep dive: Product Architecture

The product architecture significantly influences the embodiment design, aligning closely with decisions impacting the ultrasound performance of the phaco handpiece. The term “product architecture” refers to the division between disposable and reusable components: defining where this division occurs, its embodiment, and the rationale behind it. It outlines the allocation of functions to each half and the underlying reasons guiding these choices.

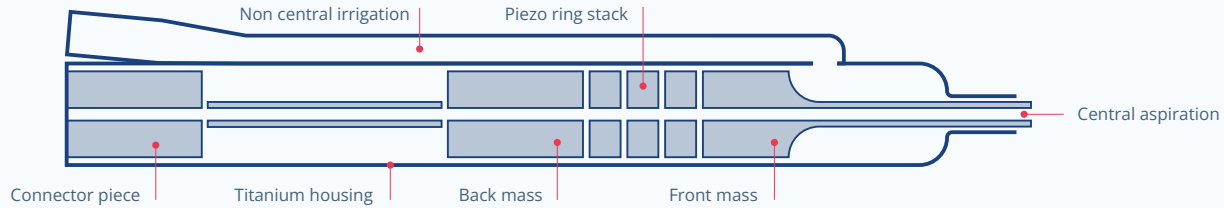


Figure 5.2 - 1 *Visualisation of generalised product architecture of phaco handpieces*

5.2.1 Existing phaco architecture

To assess the hybrid redesign, understanding the prevalent product architecture of current phaco handpieces in the market is essential. While there are variations in dimensions, ergonomics, phaco types (more in chapter 5.1.1.3 “Harmonics and resonant frequency”), and aesthetics, virtually all phaco handpieces share the same fundamental product architecture (see Figure 2.4 - 2 on page 43), including those offered by DORC. This architecture is depicted schematically in Figure 5.2 - 1.

The figure illustrates the sonotrode design, featuring a variable number of piezoelectric elements, a tapered horn leading to the needle thread, and a connection to the end component housing internal wiring. The aspiration channel traverses the sonotrode, exits through the end component, and connects to the luer connection. The irrigation channel typically runs alongside the handpiece, integrated into the main housing, often crafted entirely from titanium to provide both ergonomic grip and aesthetic appeal.

5.2.2 Exploration and foundation

The foundational basis for the redesign in this thesis is the student-designed hybrid phaco handpiece, detailed in chapter 2.3.2 "Student design features and design considerations". I undertook a comprehensive review and assessment of this foundational concept, leading to the exploration of various design ideas as depicted in Figure 5.2 - 2. However, these explorations did not yield significant advantages in phaco functionality, resource efficiency, or sterility. They either presented more complex versions of the student redesign (Bowden cable & Tattoo gun) or were unfeasible within the project's timeframe (Side loader & Cantilever transducer).

Additionally, a reconsideration of the student team's explorations led to similar conclusions—either more intricate versions of the final design or impractical for realization within the project's constraints.

Ultimately, the chosen design for this project is a straightforward split sonotrode configuration, where the disposable encompasses the outer body, fluidic lines diverging before the electronics, and a portion of the sonotrode. This choice is a continuation of the student design with variations necessitated by specific solutions developed for aspiration capture and the disposable sonotrode component's failure under ultrasonic load. The split line between disposable and reusable sonotrode was adjusted accordingly.

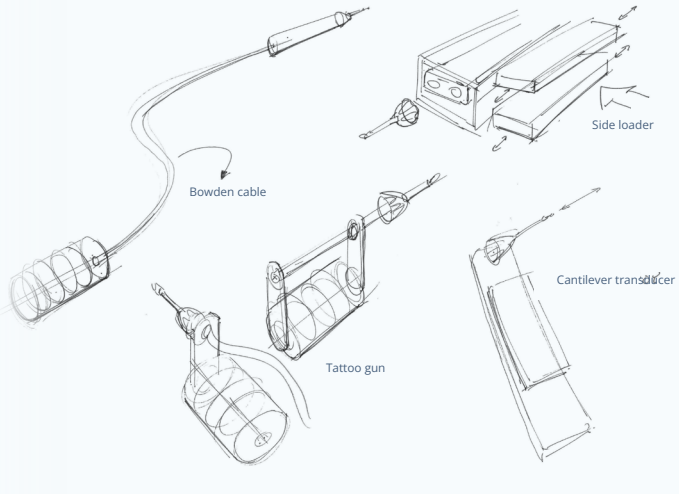


Figure 5.2 - 2 *Sketches of novel phaco product architectures*

Key insights

RQ3.2: Can a feasible design be defined for a hybrid phaco handpiece, also considering all prerequisites?

- Split sonotrode configuration chosen as architecture, stemming from student project exploration and test results.

5.3 Deep dive: Sonotrode connection methods

A division between the disposable and reusable sonotrode components is essential to uphold sterility, as detailed in chapter 5.4.1 “Defining sterility for a hybrid (phaco) design”, within the selected product architecture (chapter 5.2 “Deep dive: Product Architecture”). For efficient ultrasound transmission, a connection method between these sonotrode components is devised.

This connection method not only ensures optimal ultrasound transmission but also dictates the assembly process between the disposable and reusable components in the operating room (OR). This assembly process is critical for seamless sterile assembly between the non-sterile reusable part and the sterile disposable part in the fast-paced environment of cataract surgeries. The primary goal of the connection method is to:

Design an assembly method that makes sterile assembly easiest / quickest while meeting requirements

5.3.1 Connection method requirements

5.3.1.1 Requirement 1: Feasibility

"The design must demonstrate practical feasibility at the small scale through testing, expert evaluation, and successful prototyping"

The connection method, as a component of the sonotrode, operates on a small physical scale, introducing a unique set of requirements, particularly concerning feasibility for mass production. While reusable components might accommodate a more intricate design, the disposable counterpart necessitates a simpler, cost-effective, and highly feasible design to justify its large-scale production.

Given the challenges of physically prototyping and testing every design direction, expert evaluation played a crucial role. Conversations with the OEM Wefis GmbH provided valuable insights and assessments of various design concepts.

5.3.1.2 Requirement 2: Durability

"The design's durability at a small scale under ultrasonic load must be indicated through testing, expert evaluation, or successful prototyping"

Parts subjected to ultrasonic vibrations undergo a distinct form of repeated high loads. For instance, small cracks and stress concentrations in ultrasonic transducer parts can quickly lead to failure as they experience high stresses 40,000 times per second (for 40kHz transducers).

This aspect of ultrasonics introduces a unique requirement for durability. Understanding the implications of durability under ultrasonic load on embodiment design considerations may be challenging for those unfamiliar with ultrasonic transducer testing. Hence, testing, validation, and consultation with experts, such as Wefis GmbH, have been indispensable for the development of novel connection methods.

5.3.1.3 Requirement 3: Ultrasound transmission

"The design must facilitate correct surface mating and pressure in axial direction for efficient ultrasound transmission."

Ultrasonic horns, as seen in applications like ultrasonic welding, come with specified torque tension requirements, indicating the need for specific clamping pressure between mating surfaces to ensure proper ultrasound transmission (Ye et al., 2022). This clamping pressure requirement is evident in tests for the threaded connection used in the disposable needle, where inadequate torque tension results in no resonance.

The strength and direction of clamping are crucial factors. The force should be applied axially, not perpendicular to the axis (for example as in a collet connection). This consideration aligns with the longitudinal direction of ultrasound vibrations and prevents high stresses in material sections due to a decrease in surface area in collet connections. This phenomenon is visualised in Figure 5.1 - 5 on page 109.

5.3.2 Idea generation and selection

The developed ideas fall into two main categories: novel connection methods and thread application methods. Selections within these clusters were made based on the specified requirements and the core goal of the connection method: compatibility with the sterile and quick nature of cataract surgeries.

5.3.2.1 Novel connection methods

During the initial exploration of connection types, several novel connection methods were developed (Figure 5.3 - 1), each aimed at simplifying OR assembly compared to a hand-threaded connection.

The “clamp quick connect” and “collet connection” methods did not meet requirement 3: ultrasound transmission, and none satisfied requirement 2: durability. This became evident after consulting with Wefis GmbH, who highlighted the high stresses present in ultrasonic applications.

Further exploration through prototyping of the “toggle clamp” and “collet connector” (Figure 5.3 - 1) revealed the durability shortcomings, with small components unable to withstand even simple assembly, let alone ultrasonic loads.

The proven direction of a threaded connection was ultimately chosen as the connection method that fulfilled all requirements, leaving only concerns about ease of assembly.

5.3.2.2 Thread application methods

In the application of threaded connections, ease of assembly is crucial. Threaded connections are typically associated with torque tension requirements, so ensuring the right tension is important for proper handpiece functionality.

Hand-threading, as utilized in the phaco needle application, proves challenging in the OR, where inconsistencies may result in insufficient tension, leading to a lack of resonance. Therefore, a “torque-finding” design was pursued to ensure the correct torque regardless of user variations.

Early exploration of torque wrench-like designs (depicted in Figure 5.3 - 2), inspired by dental scaler torque wrenches, introduced an additional product into the system, which is suboptimal. Designs with torque limiters on the sterile side of the disposable or on the reusable side added complexity to the OR assembly. Added concerns were about sterility, were torque wrench design on the disposable side would need to be sterilized or disposable.

Exploring options to integrate the torque limiter into the reusable driver itself revealed challenges in creating a feasible design at the small scale of the driver. Designs using friction pads show the most promise, although wear on this subassembly may impact durability and the overall driver’s lifetime.

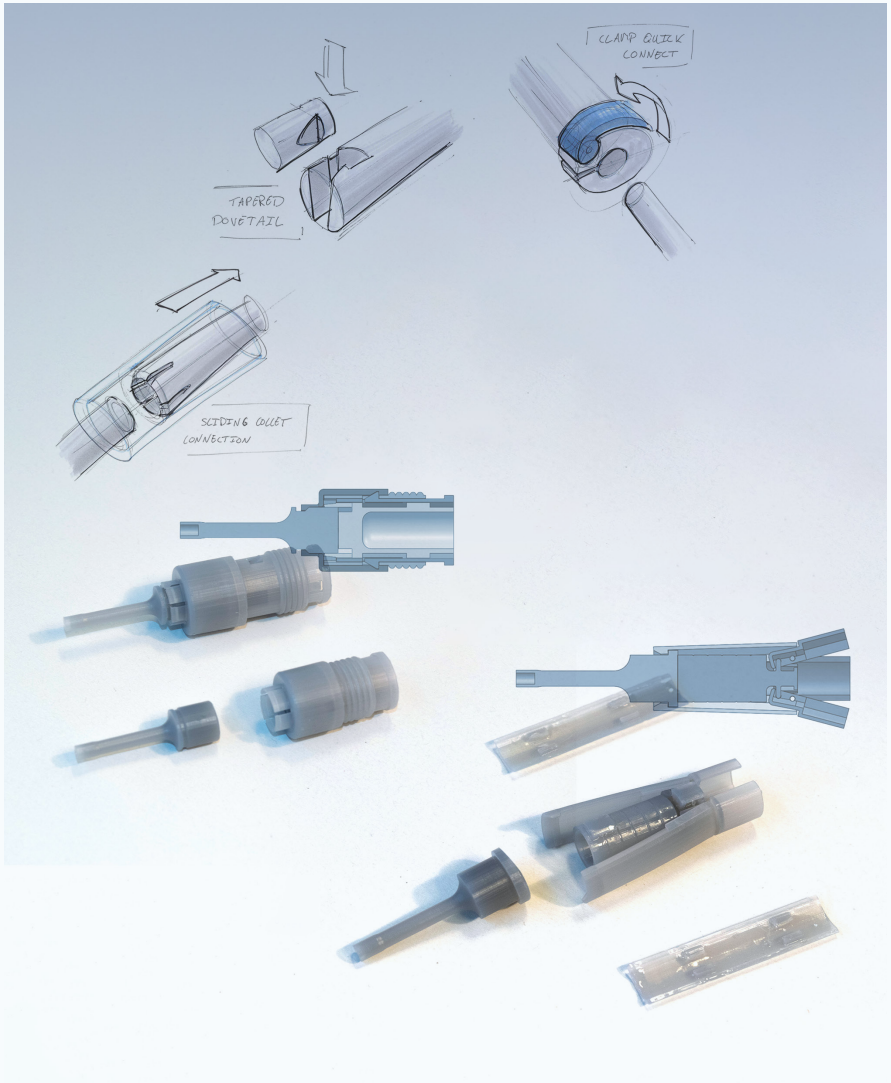


Figure 5.3 - 1 *Relevant ideas and embodied concepts in the exploration of novel connection methods*

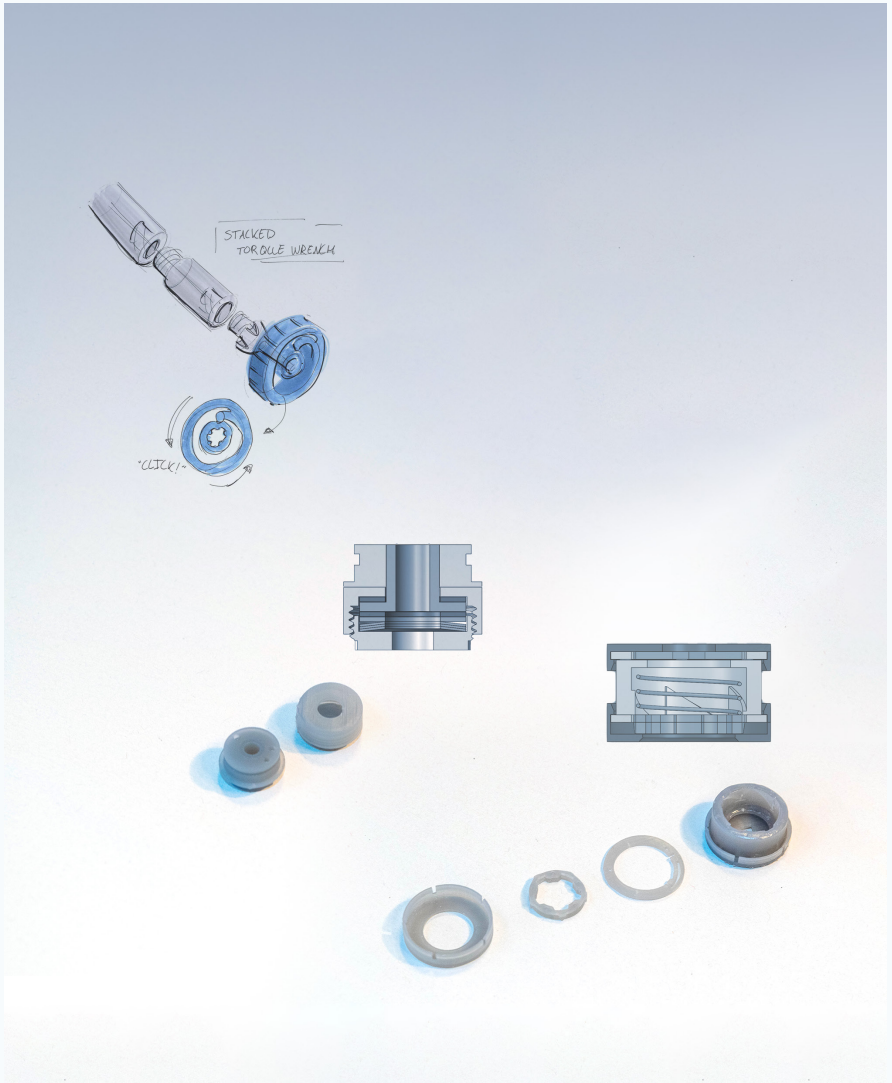


Figure 5.3 - 2 *Relevant ideas and embodied concepts in the exploration of thread application methods*

Figure 5.3 - 3 *Prototyping done on the packaging design concept direction, thermoformed PET*

5.3.2.3 Packaging designs

Integrating a torque-limiting design into the blister pack of the disposable (Figure 5.3 - 3), an already required component in the design, enhances ease of assembly and provides a sterile interface for assembly by non-sterile personnel (further detailed in chapter 5.5.3 “Implementation sterile usability steps”).

Through testing on thermoformed PET blister pack designs, two concepts were explored: integrating a band to tighten the CAM-like shape of the disposable and later, after unsuccessful testing of the band design, incorporating a crushable ridge design. The latter design demonstrated potential in testing of prototypes.

The final design involves a crushable ridge that gets compressed through the corresponding hole in the disposable at a specified torque. A proof of concept was developed, featuring a packaging design hinging at the side of the opening for the reusable, firmly connecting the two halves of the packaging and preventing it from opening when torque is applied to the disposable.

This design relies on the visual indication of the ridge getting crushed and the disposable turning freely. Further development could explore additional features, such as allowing the package to open only when the ridge is crushed, ensuring that the right torque is applied.

Detailed exploration of the packaging and ridge dimensions for the appropriate torque limit is recommended for future development of the project.

Figure 5.3 - 4 *Prototyping done on packaging design, showing CAM shape concept (left) and crushable ridge design (right)*

5.3.3 Torque testing

While the packaging design is not developed to a stage where the ridge crushes at a specified applied torque, I conducted tests to determine the required torque tension on the disposable. This aims to validate the feasibility of such a packaging design and assess whether applying the specified torque is achievable in terms of ergonomics. Results of this ergonomics test are detailed in chapter 5.8.3 “Ergonomics in assembly”.

The objective of this test was to investigate the torque required at the threaded connection to achieve proper ultrasound transmission.

5.3.3.1 Method

For this test, a 7075-T6 sonotrode design with Mf5 thread is utilized, along with a corresponding baseline aluminum horn prototype. Proper ultrasound transmission in this study will be tested by analyzing resonance and resonant frequency. Resonant frequency measurement uses an impedance analyzer (Hioki IM3570). The torque is applied to the thread through a torque measuring screwdriver (CEDAR DID-4A).

In this study, no clear point of resonance or a clear drop in resonant frequency means there is no proper ultrasound transmission. The expected result for a design is a flat resonant frequency response at high torques, a drop at lower torques, with a cessation of resonance at even lower torques. This expected result aligns with findings in literature on ultrasonic horn assembly variables by Ye et al. (2022).

The drop-off point and point of no-resonance are key factors that I examined in these tests.

5.3.3.2 Results

The results of the torque tension tests are visualized in figure Figure 5.3 - 5. The frequency response clearly flattens out after 50 cNm and starts to drop steeply lower than 25 cNm. Torque tensions lower than 25 cNm also show less clear points of resonance.

5.3.3.3 Conclusions

It can be concluded that proper ultrasound transmission can be ensured at torque tensions of 30 cNm and higher. This is approximately the same torque required for properly applying the phaco needle, suggesting that reaching this design in terms of ergonomics is feasible.

Moreover, based on the experience of applying 30 cNm using a torque wrench and testing thermoformed PET packaging prototypes, I infer that the torque ridge packaging design is feasible and suitable for further engineering.

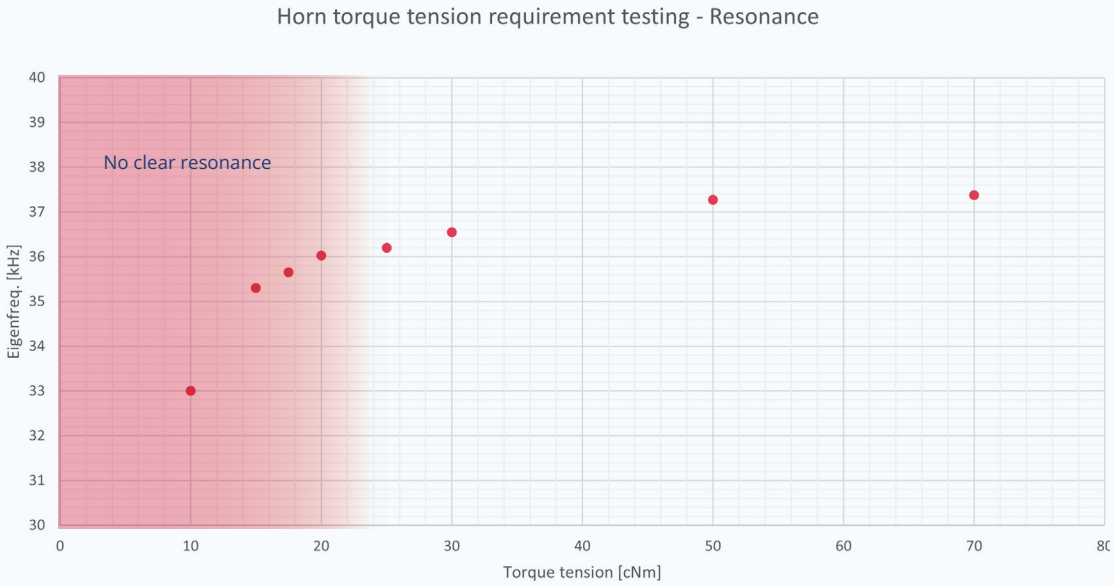


Figure 5.3 - 5 *Applied torque on disposable horn to reusable driver thread, against yielded resonant frequency*

Key insights

RQ3.2: Can a feasible design be defined for a hybrid phaco handpiece, also considering all prerequisites?

- Novel connection methods and methods for making thread application easier are explored but ultimately rejected based on feasibility, durability, or functional considerations

- Packaging design used for securing threaded connection is ultimately chosen as it facilitates sterility in assembly, as well as integrates a torque application feature, without adding an extra product in the system.

RQ1.3: What ensures proper transmission of ultrasonic vibration between disposable and reusable?

- Torque tightness testing resulted in 30cNm as required torque for proper ultrasound transmission with and Mf5x0,5mm thread design.

5.4 Deep dive: Sterility

Sterility is a crucial consideration in the feasibility study of this thesis, specifically in determining whether it is possible to establish a hybrid product with both sterile and non-sterile components while maintaining sterile barriers. The concept of sterile barriers involves implementing physical barriers to prevent the ingress of microorganisms, thereby preserving aseptic conditions. This is essential for the proper functioning of an operating room (OR).

This chapter will delve into the implementation of sterile barriers, providing a rationale for sterility in a hybrid phaco handpiece. It will further discuss the integration of this rationale at the product level and within the broader context of an OR.

5.4.1 Defining sterility for a hybrid (phaco) design

Adhering to the Spaulding classification (Figure 5.4 - 1), which categorizes devices based on the level of disinfection or sterilization required according to the associated infection risk, a phaco handpiece falls into the critical category. This classification mandates sterilization for such devices. Additionally, the Medical Device Regulation (MDR) (European Union, 2017) emphasizes the necessity for a comprehensive risk assessment.

While for this thesis no exhaustive risk analysis is conducted, an examination of risks related to sterile use allows for the identification of additional requirements for sterilization. This consideration aligns with the regulatory framework and underscores the importance of stringent sterilization measures for critical medical devices like the phaco handpiece.

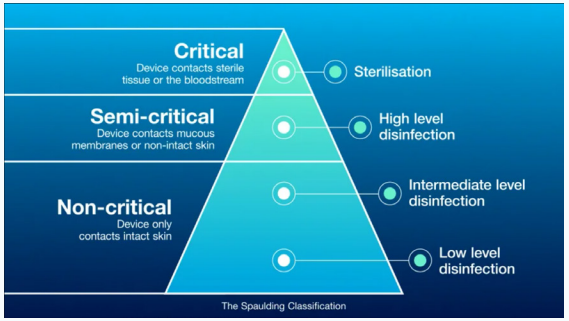


Figure 5.4 - 1 *Spaulding classification showing different sterilization/ disinfection requirement., retrieved from (Nanosonics, n.d.)*

5.4.1.1 Sterility and product architecture

In an effort to reduce the functions of the sterilized disposable component and simplify it, a consideration can be made to designate the aspiration line as a non-contact part, suggesting it could be part of the non-sterile reusable (Figure 5.4 - 2). This can be considered since only new fluids are suctioned through this line and do not come in contact with the next patient. However, this approach poses risks, particularly concerning backflush and the potential for minuscule amounts of fluids to run back from the aspiration lines, making it unsuitable. Consequently, the decision was made to integrate all fluid lines as part of the disposable component.

Assuming that the disposable maintains sterile barriers, it follows that the reusable component will not be directly contaminated during surgery. However, defining the handpiece as sterile upon arrival in the OR would be inaccurate. In the OR, a device cannot be labelled as sterile if it has not been sterilized. During use, it is inevitable that some microorganisms will become present on the reusable component, rendering it non-sterile. This definition underscores that the critical aspect is not the disassembly of the handpiece but rather the assembly in the OR, where the non-sterile reusable is assembled with the sterile disposable in a sterile manner, as further highlighted in chapter 5.5.1 “Development sterile interaction method”.

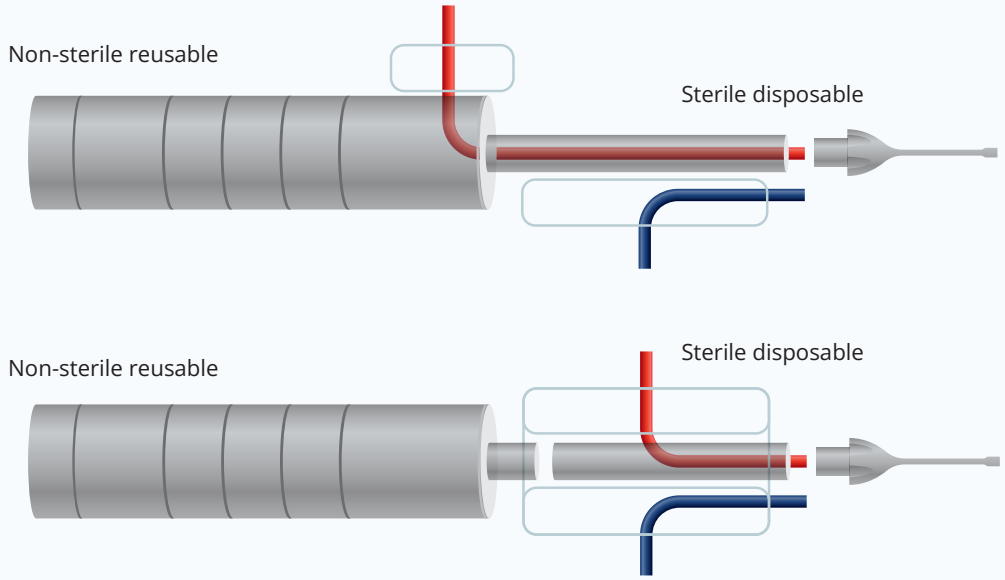


Figure 5.4 - 2 *Sterility considerations for a hybrid phaco handpiece, depicting a non-sterile aspiration line (top), and a sterile aspiration line (bottom)*

5.4.1.2 Sterilization disposable

The disposable component is designated for sterilization using Ethylene Oxide (EtO), a method that involves flooding a chamber with EtO gas to effectively eliminate all microorganisms (Centers for Disease Control and Prevention, 2016). EtO sterilization, conducted at low heat, is particularly suitable for large-scale sterilization of medical devices.

Autoclave sterilization, which utilizes hot steam, is not chosen due to its unsuitability for the plastics used in the disposable and its high environmental impact (Snijder & Broeren, 2022). Another common sterilization method involving hydrogen peroxide is not preferred, given its lesser prevalence at DORC, where EtO is the primary method for sterilizing nearly all products. Therefore, EtO sterilization is selected for this project.

An important design consideration for EtO sterilization is ensuring that the EtO gas can penetrate all areas requiring sterilization. Additionally, post-sterilization, thorough aeration is necessary to prevent EtO residue, which can occur due to the absorption of gases by certain materials. Clear limits for EtO residue are established in medical devices (NEN-ISO, 2022), although this aspect is not explored in-depth in this thesis and is recommended for further investigation.

5.4.1.3 Sterility reusable

While some components do not necessitate sterilization, such as the surgical system (EVA Nexus) and the reusable driver, a risk assessment prompts the establishment of disinfection requirements for these components. These requirements are essential as these components are located in a surgical environment. Although disinfection standards may vary across hospitals, there are general guidelines available for disinfecting such equipment (Centers for Disease Control and Prevention, 2016). **Specifically for the reusable driver, the defined practice involves using an aseptic wipe after each use.** This measure is implemented to further mitigate the risk of contamination.

5.4.2 Defining sterile use

This chapter aims to explain sterility during use of the hybrid phaco handpiece, with the non-sterile reusable and sterile disposable components.

5.4.2.1 Sterility in the OR

Sterility in the operating room (OR) is precisely defined by a sterile field, where non-sterile components or personnel are restricted. As discussed in Chapter 2.5.1 “Hospital”, the typical surgical environment for cataract surgery involves a sterile scrub nurse or OR assistant, alongside a non-sterile circulating nurse. Although these individuals cannot directly touch or interact with components within the sterile field, established methods address situations that necessitate interaction. For instance, if a package containing sterile components needs to be opened, the circulating nurse will open the package and leave it on a table for the sterile nurse to handle, ensuring the integrity of the sterile field.

However, the combination of non-sterile and sterile components in the hybrid design introduces challenges. Non-sterile personnel cannot directly handle sterile components without compromising the sterile field, and vice versa. Both the reusable driver and disposable components require interaction from the circulating nurse for assembly, and they must be transferred to the sterile nurse. This usability problem and its solution are explored in more detail in Chapter 5.5.3 “Implementation sterile usability steps”.

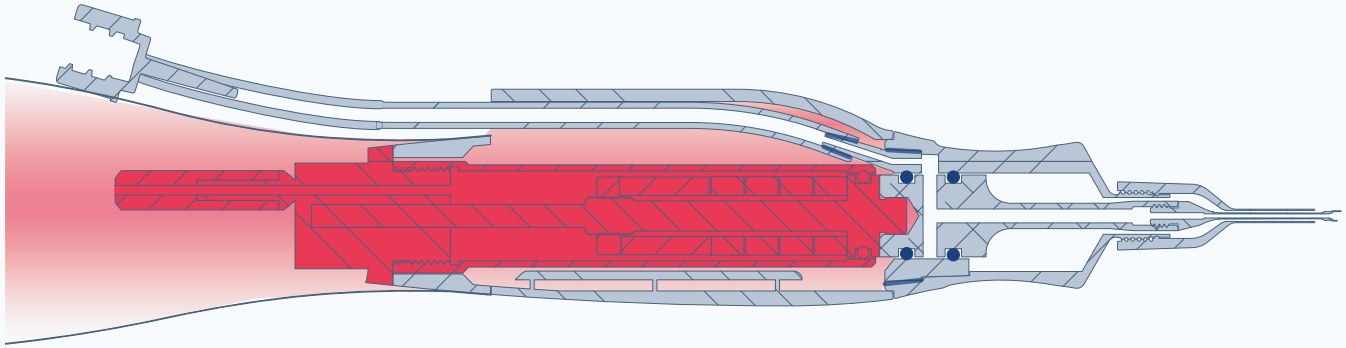


Figure 5.4 - 3 *Visualisation of highlighted sterile barriers (dark blue) in a section view of the hybrid phaco redesign, depicting non-sterile areas (red) and sterile areas*

5.4.2.2 Implementation of sterile barriers

On a product level, several sterile barriers are implemented, as depicted in Figure 5.4 - 3. These barriers effectively separate the non-sterile interior of the handpiece from the sterile environment outside the handpiece.

These sterile barriers mirror the features that ensure the watertightness of the fluidics lines, including the O-ring application and the luer-style connection perimeter of the fluid conduits (see chapter 4.4.1 “Fluid conduit”). Additionally, the borders between the housing shells are sealed using internal lips on the disposable shell parts. While the effectiveness of the watertight seals is well defined and tested, the gaps between the shell components lack validation through testing to determine their efficacy in preventing cross-contamination.

Furthermore, the sterile barriers remain intact when considering the disposable still within its packaging. The folded sterile tube sleeve, connected to both the blister packaging and the disposable, serves as a sterile barrier against the reusable during assembly (Figure 5.4 - 4).

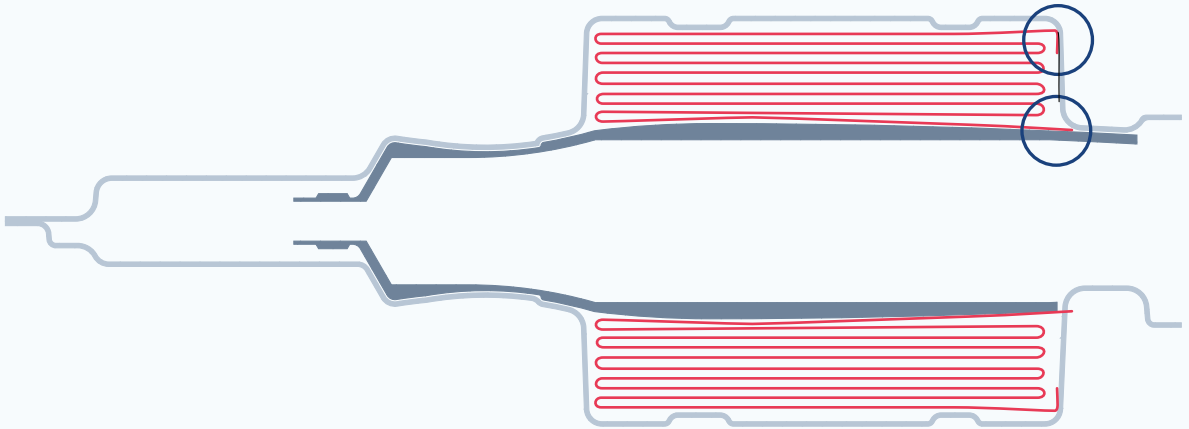


Figure 5.4 - 4 *Visualisation folded up sterile sleeve in packaging design, section view, depicting the sterile barier already being in tact when entering the hospital*

Key insights

RQ2: How can safety in terms of sterility be ensured for a hybrid reusable and disposable handpiece?

- Risks associated with sterile use make it so that aspiration fluid line has to be integrated into the sterile half of the product, something not directly required when considering Spaulding classification.
- Disposable will be sterilized using EtO, the most used sterilization method for mass product manufacturing. Requirements for EtO sterilization (penetration and residue) are not examined.
- Reusable driver will be cleaned after use using an aseptic wipe
- Sterility in the OR means sterile products cannot be handled by non-sterile personnel and non-sterile products cannot be handled by sterile personnel.

RQ2.1: How can sterility within the phaco handpiece be ensured when implementing the reusable electronics during surgical procedures?

- Sterile barriers are implemented within the product using seals from tapered form fits, O-rings, and through the pre-folded and pre-attached sterile tube sleeve in the packaging.

5.5 Deep dive: Usability

As discussed in Chapter 5.4 “Deep dive: Sterility”, the need for both sterile and non-sterile personnel to handle the hybrid design poses a challenge in terms of usability. Usability, alongside other factors, plays a crucial role in selecting a surgical system for use in a hospital. Therefore, this aspect of the design is pivotal for the success of the project.

This chapter will not primarily focus on the usability of the handpiece during surgery, as this aspect has remained largely unchanged, except for considerations related to ergonomics (discussed in Chapter 5.8 “Deep dive: Ergonomics”). Instead, the focus will be on the usability aspect of preparing the handpiece for use and disposing of the handpiece, providing a comprehensive examination of these crucial steps in the device’s lifecycle.

5.5.1 Development sterile interaction method

An assembly challenge arises in the handpiece, necessitating the involvement of both sterile and non-sterile personnel and a point of interaction between the two.

A sterile interaction method has been devised to address the assembly problem and the interaction points, illustrated in Figure 5.5 - 1 until Figure 5.5 - 4. Further exploration of sterile assembly and disassembly methods on a product level is presented in Appendix II.

Initial validation of the concepts for the sterile interaction method has been carried out in close collaboration with healthcare professionals. An initial user evaluation involved healthcare professionals with varying OR experience (n=3), followed by collaboration with OR personnel (n=3), surgeons (n=2), and on-site observations in later stages. The interactions were simulated with hypothetical prototypes in relevant environments, informally discussed, and refined through multiple rounds of testing.

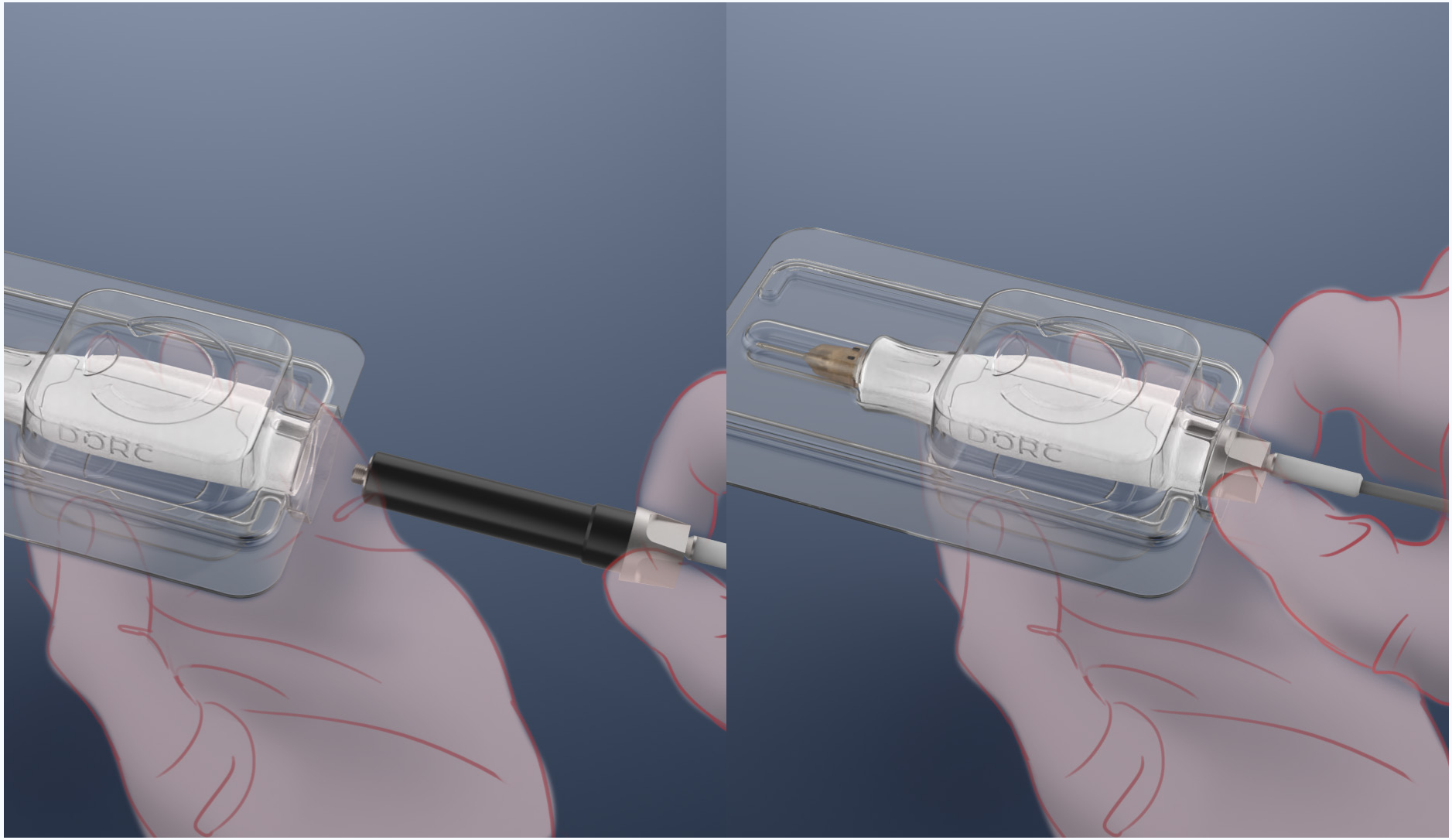


Figure 5.5 - 1 *First step of sterile assembly method: inserting the reusable drive in opening of blister pack*

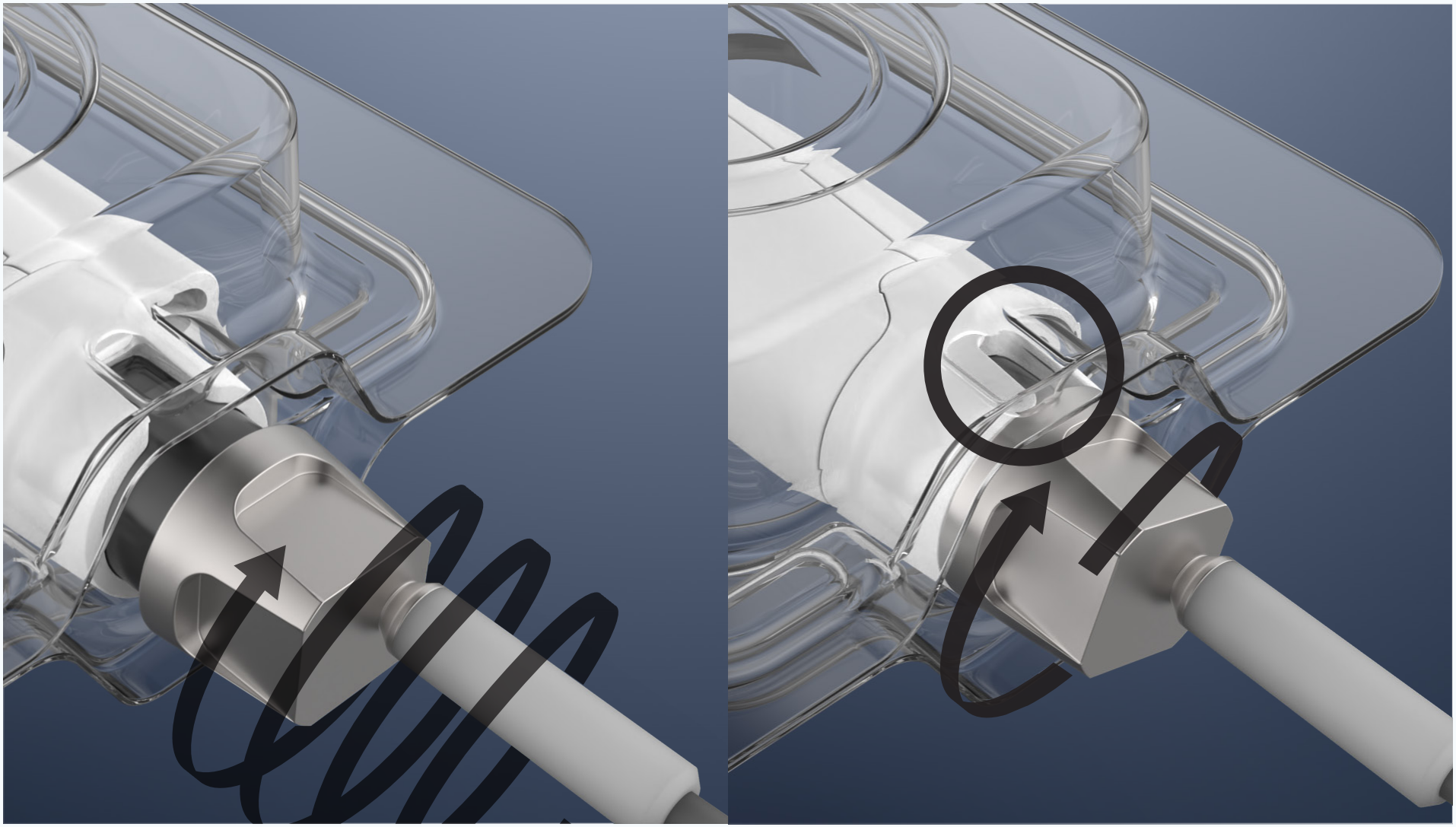


Figure 5.5 - 2 *Second step of sterile assembly method: Applying torque to ridge until it compresses, indicating the handpiece is assembled correctly*

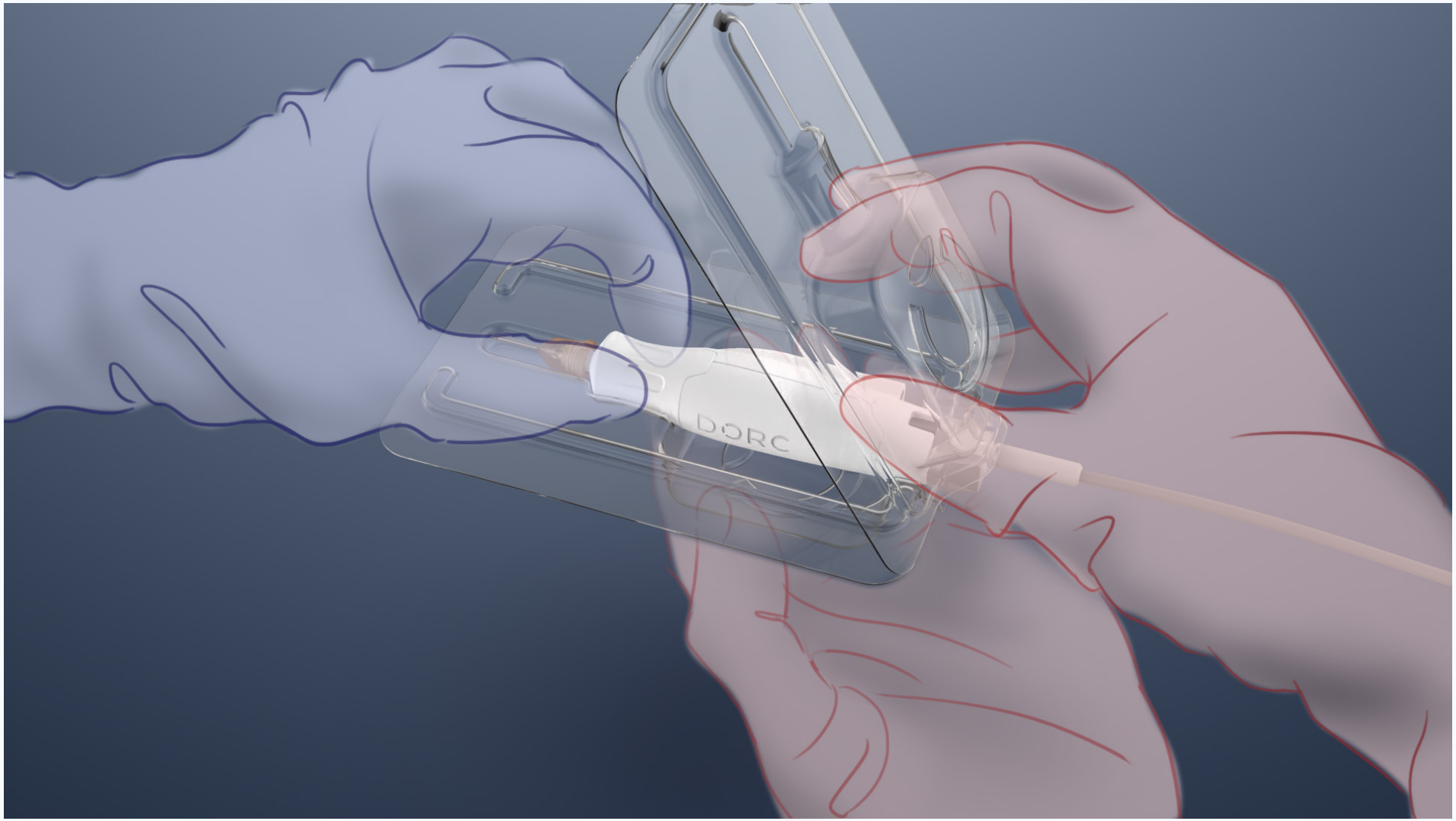


Figure 5.5 - 3 *Third step of sterile assembly method: Opening blister pack and presenting still sterile insides to OR assistant*

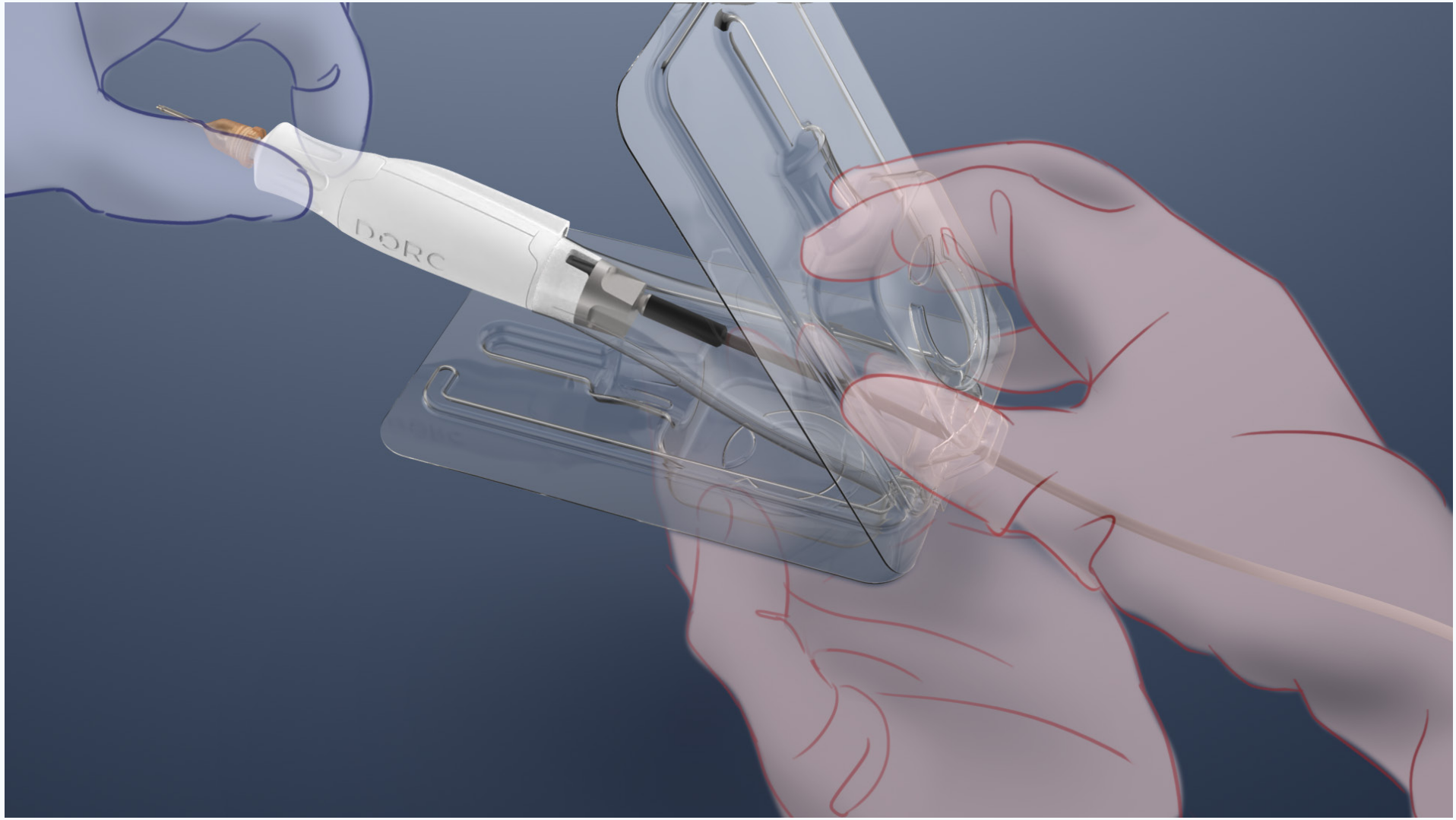


Figure 5.5 - 4 *Fourth step of sterile assembly method: Pulling out handpiece, simultaneously unfolding the sterile tube sleeve over the non-sterile cable*

5.5.2 Requirements sterile interaction

Requirements that became evident through the aforementioned user testing are outlined here.

5.5.2.1 Requirement 1: Assembly cover

A cover that serves as an intermediary for personnel interaction with sterile components is necessary. This cover physically shields either the sterile component for handling by non-sterile personnel or covers the non-sterile component for handling by sterile personnel. Interaction methods involving sterile personnel interacting with a component held by non-sterile personnel were considered too risky for maintaining sterility.

5.5.2.2 Requirement 2: Physical interaction barrier

When transferring the sterile component from one personnel to another, it is essential to have either a physical barrier in place or the ability to create a physical distance between the two users during the usability steps.

Although certain OR interaction methods involve direct hand-to-hand transfer (such as handing over a cable plug for the surgical system), prioritizing risk management necessitates the implementation of this requirement.

5.5.2.3 Requirement 3: Assembly speed

The assembly process of the phaco handpiece, encompassing the fluid priming procedure and the assembly of the needle and sleeve, is already often a bottleneck of OR preparation. Introducing additional time requirements for the hybrid device's preparation could undermine the appeal of this concept. Despite gaining time with the pre-assembly of the needle and sleeve on the disposable, this time-saving advantage could be offset by the assembly of the reusable component. Therefore, it is crucial to optimize this process to ensure that the overall time spent on the phaco handpiece remains manageable. While this requirement hasn't been quantified, concepts for assembly have been informally assessed based on estimations and prototype analyses.

5.5.3 Implementation sterile usability steps

During the interaction for handover, the packaging design (Figure 5.5 - 5) serves as a sterile handling apparatus. The external side is non-sterile, while the internal side, housing the disposable, remains sterile. This division between the non-sterile exterior and sterile interior is maintained by the sterile barriers discussed in chapter 5.5.2.2 “Requirement 2: Physical interaction barrier”.

To enhance the sterile interaction during the handover of the handpiece, the packaging dimensions play a crucial role. Taking into account feedback and concerns from user testing and evaluations with OR personnel, adjustments were made to the packaging design. The goal was to create a better physical barrier between the non-sterile hands of the circulating nurse holding the packaging and the sterile nurse receiving the handpiece. The design was modified by widening the blister packaging, thereby further reducing the risk of contamination.

The integration of the sterile tube sleeve ensures that the sterile barrier is established when shipping the disposable. This eliminates the need to apply the sterile barrier in the OR during the assembly, as is done for the sterile sleeves of endoscopes (Shockwave Medical, 2023) or imaging ultrasound probes (Stepwards, 2019).

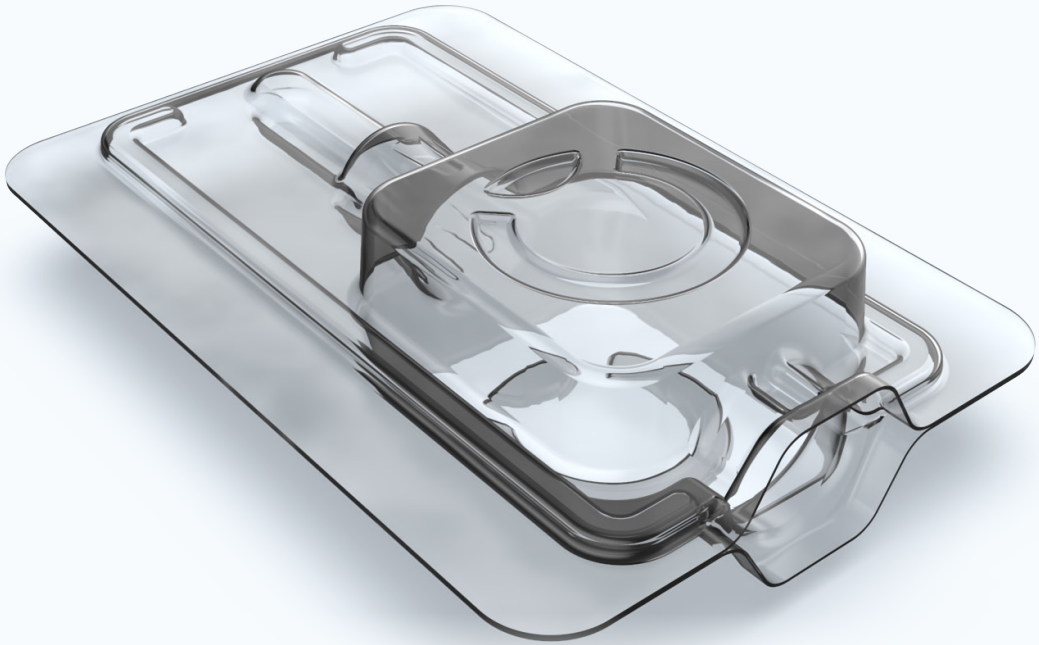


Figure 5.5 - 5 *Packaging design as used in sterile interaction*

Key insights

RQ2.2: How can a hybrid design be assembled in a way that ensures sterility?

- Sterile interaction method has been developed in close consideration with healthcare professionals, through addressing identified risks

RQ3.2: Can a feasible design be defined for a hybrid phaco handpiece, also considering all prerequisites?

- Required for a feasible design is not only a sterile design, by means of a physical interaction barrier, but also by facilitating a quick assembly of the handpiece.

5.6 Deep dive: Fluid separation

In accordance with the production architecture detailed in chapter 5.2 “Deep dive: Product Architecture”, where the disposable houses the fluidics lines and part of the sonotrode, the method of separating fluids from the disposable to the reusable becomes crucial. It is noteworthy that the aspiration line begins at the centre of the needle, a concept retained for this project. Although other existing (patented) solutions employ different needle designs (Surgical Design Corporation, n.d.), these are not further considered for this thesis.

This chapter will delineate the exploration undertaken on fluid separation methods, their requirements, and the current implementation and testing conducted on this design.

5.6.1 Foundation and exploration

With preliminary exploration conducted on the fluid lines shaping the general product architecture (see Appendix III), a broad direction was chosen to entirely circumvent the reusable components and physically branch off the fluid lines. The exploration of fluid lines aimed to:

Design a fluid separation method that could allow for easy and cheap assembly, reduced complexity, while meeting requirements

The fluid separation method significantly influences the design choices for other components in the embodiment. Several fluid separation methods were prototyped and tested in the early stages of the design process due to this reason. These concepts are illustrated in Figure 5.6 - 2 until Figure 5.6 - 5.

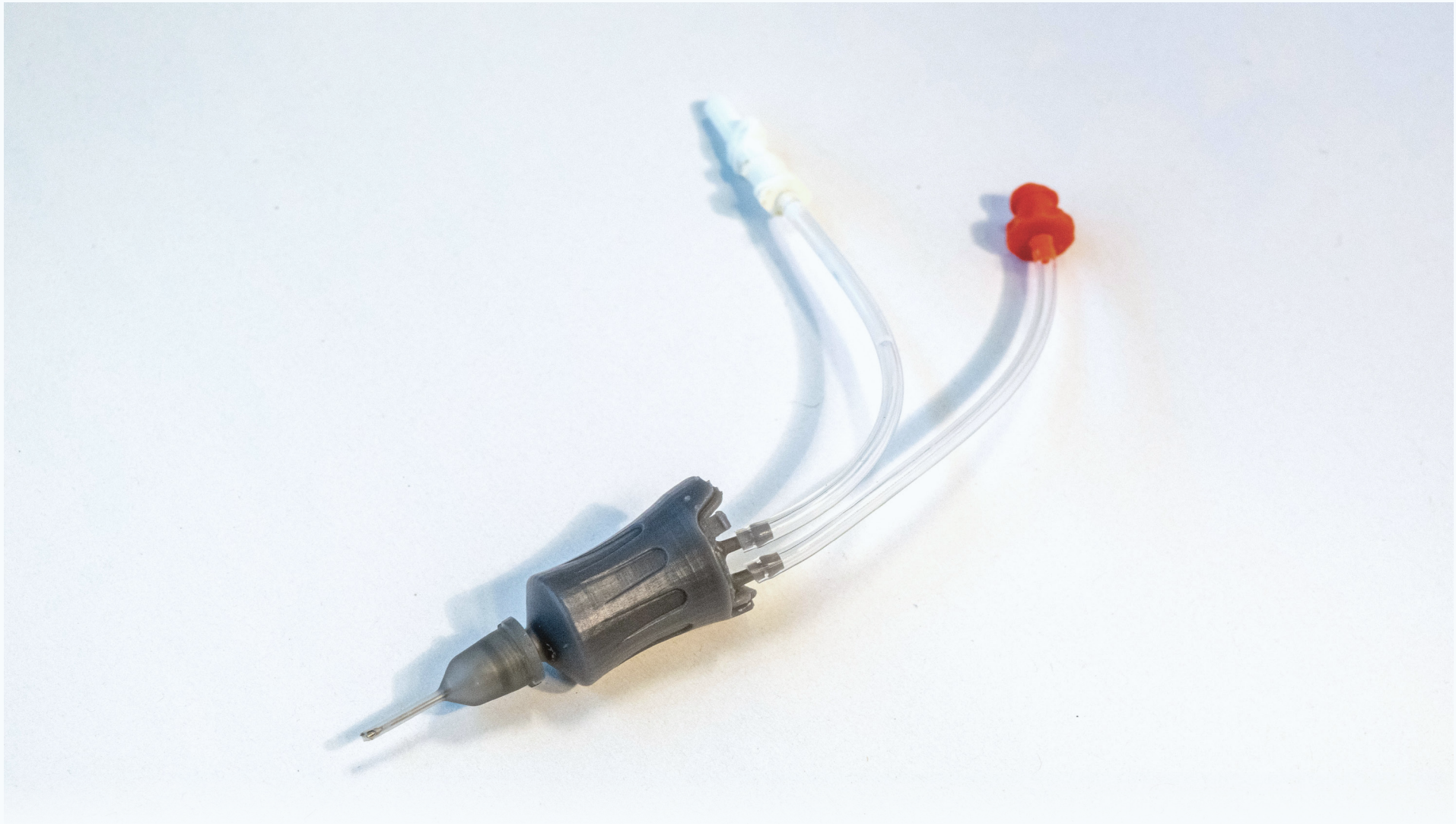


Figure 5.6 - 1 *Final fluid separation prototype as tested for in chapter 5.6.4 "Testing current implementation"*

5.6.2 Fluid separation method requirements

The requirements on which the final concepts were selected are outlined in this chapter.

5.6.2.1 Requirement 1: I/A tooling

"The design must facilitate for tubing also used in the coupling of I/A tooling during use in the OR"

The design should accommodate tubing for connecting I/A (irrigation/aspiration) tooling during cataract surgery in the operating room (OR), as detailed in Chapter 2.1.2 "Product use and environment". This involves the connection of I/A tooling essential for cataract surgery. To meet this requirement, a distinct luer interface is necessary, and the option of "direct injection" is dismissed due to its inadequacy in fulfilling this specific need.

5.6.2.2 Requirement 2: Horn diameter

"The design must not require a big change in horn diameter compared to the original 3002.P horn diameter"

As outlined in Chapter 5.1.2 "Dimensional sensitivity", any increase in horn diameter significantly affects the sonotrode stroke and other ultrasound characteristics. Consequently, the "Tube inserter" concept is not considered suitable as it fails to comply with this specific requirement.

5.6.2.3 Requirement 3: Symmetry in sonotrode

"The design must not require an asymmetric horn design"

Symmetry in the sonotrode is crucial to avoid transverse vibrations. The student redesign of the sonotrode demonstrated the undesired effects of asymmetric designs. Consequently, the "Direct injection" concept is not aligned with this requirement.

5.6.2.4 Requirement 4: Watertightness

"The design must demonstrate a likeliness of reaching watertightness in the final design, through testing of prototypes"

Although some prototype failures may be acceptable in the early stages, the importance of fluid line watertightness, especially under ultrasonic load, necessitates this requirement. The "Silicone gasket" concept, failing to provide proper sealing at all, clearly did not meet this requirement in the prototype testing.

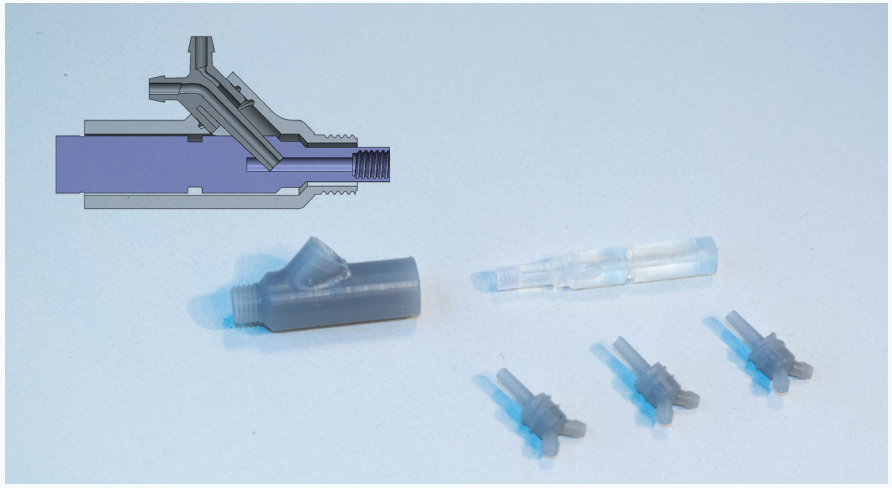


Figure 5.6 - 2 *Discontinued fluid separation method concept "direct injection"*

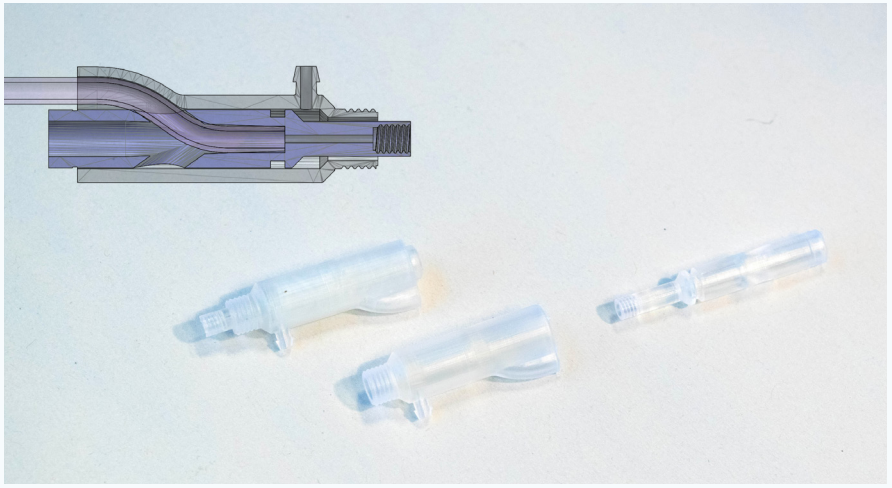


Figure 5.6 - 3 *Discontinued fluid separation method concept "tube inserter"*

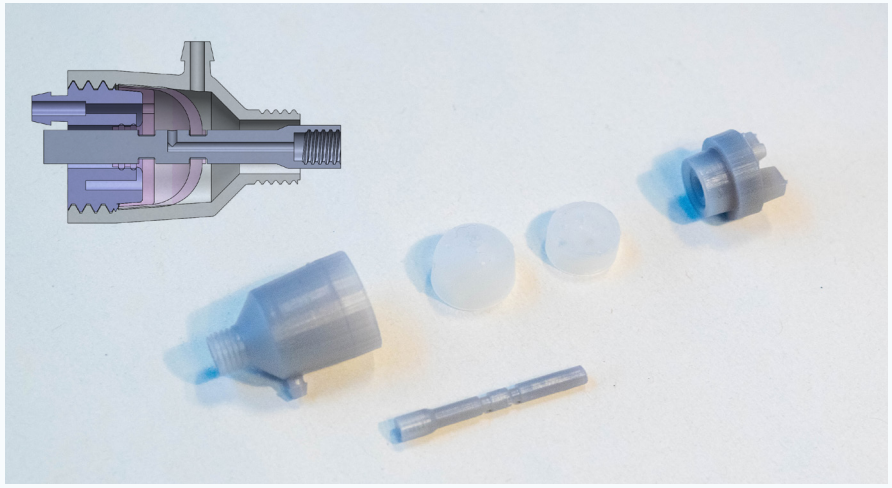


Figure 5.6 - 4 *Discontinued fluid separation method concept "silicone gasket"*

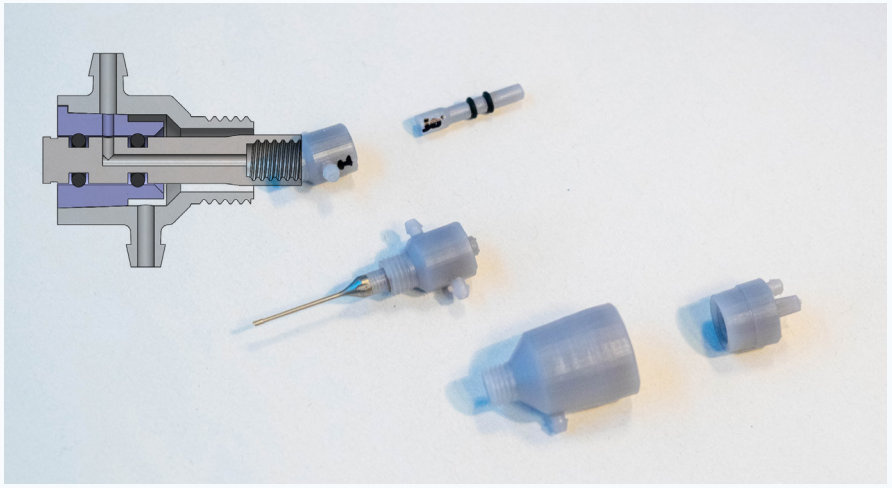


Figure 5.6 - 5 *Continued fluid separation method concept "O-ring chamber"*

5.6.3 Current implementation of fluid separation

The O-ring chamber concept, incorporating a set of O-rings to encase the aspiration line transition from the sonotrode to tubing, demonstrated effective watertightness even with initial prototypes. Its utilization of O-rings suggests a promising approach in terms of durability under ultrasonic load, aligning with the use of O-rings in current phaco handpieces.

5.6.3.1 Aspiration

The aspiration line originates from the tip of the needle, passing centrally through the front of the sonotrode horn, adhering to the product architecture outlined in 5.2 “Deep dive: Product Architecture”. At the end of the disposable horn, the aspiration fluid undergoes a right-angled turn before exiting the horn. O-rings play a crucial role in sealing the aspiration line, positioned between the disposable horn, the fluid conduit, and the angled ridge in the front housing, effectively closing off the aspiration line. The aspiration fluid is then transported through the silicone tubing, which runs alongside the reusable driver, exiting from the back of the handpiece.

A visual representation of the aspiration fluid line is given in Figure 5.6 - 6.

5.6.3.2 Irrigation

The irrigation fluid follows a comparable path, entering the fluid conduit through a similar tube. It is then directly injected into a chamber within the front housing, also housing the disposable horn. The irrigation line experiences minimal alterations in its fluid path. The primary change involves the removal of integration of the irrigation side channel into the original housing body. Heat dissipation from this fluid line is consequently also removed, a concept further examined in chapter 5.7 “Deep dive: Heat transfer”.

A visual representation of the irrigation fluid line is given in Figure 5.6 - 7.

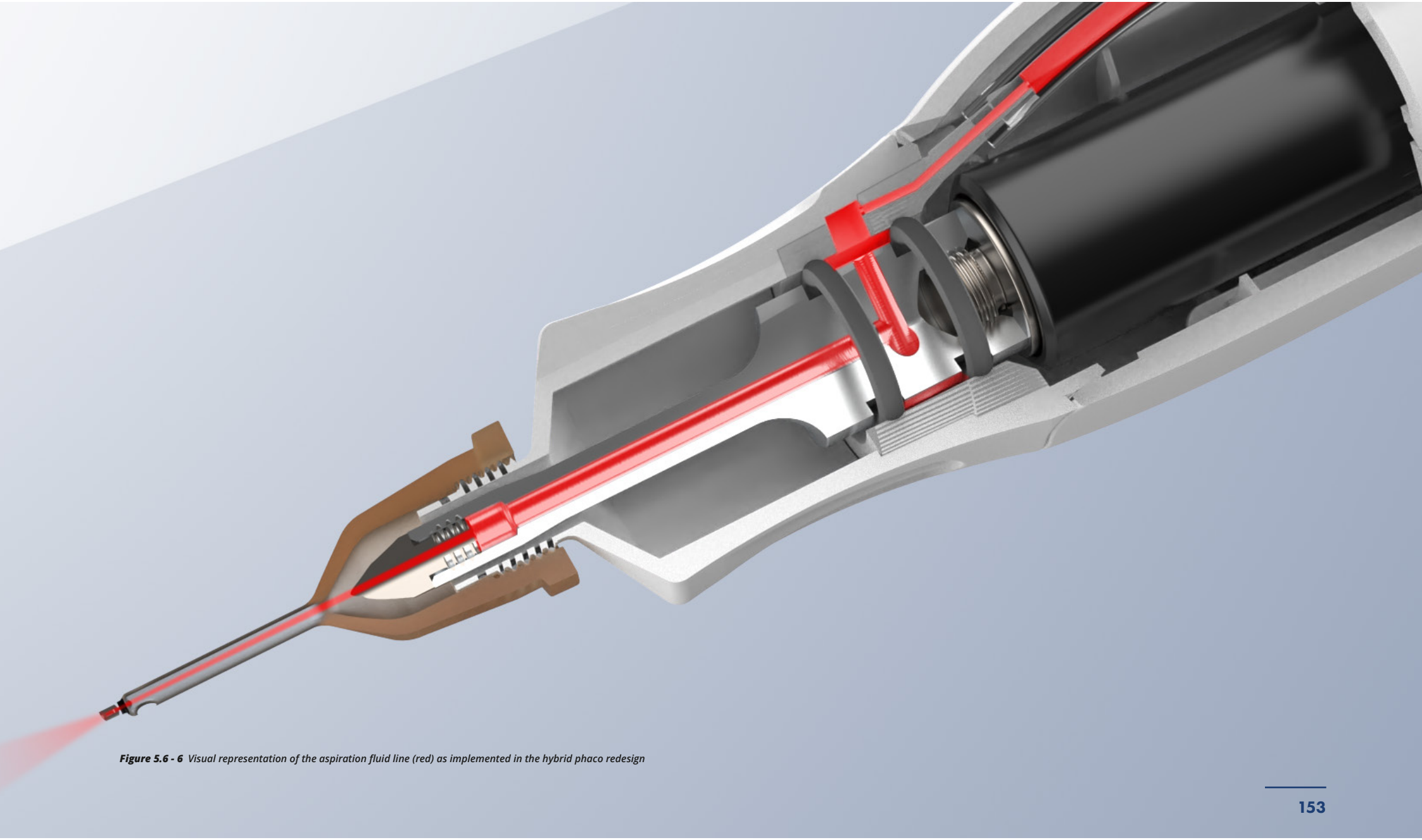


Figure 5.6 - 6 *Visual representation of the aspiration fluid line (red) as implemented in the hybrid phaco redesign*

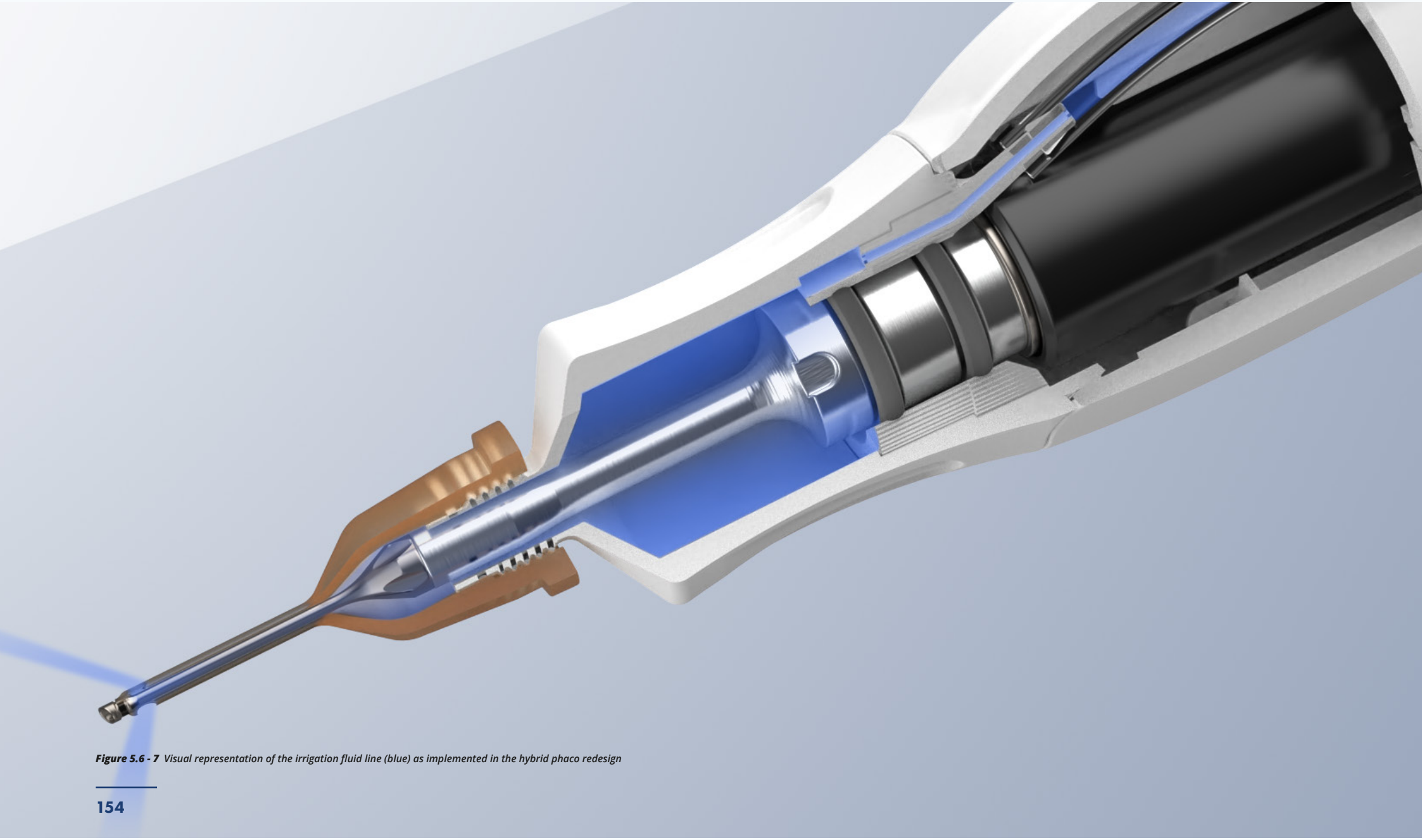


Figure 5.6 - 7 *Visual representation of the irrigation fluid line (blue) as implemented in the hybrid phaco redesign*

5.6.4 Testing current implementation

The Smart IOP (Intraocular Pressure) system in the EVA Nexus surgical system by DORC employs a tuned control mechanisms for accurate eye pressure management. Concerns about potential fluid resistances or turbulences in the redesigned right angled aspiration line prompted a test to assess their impact on the Smart IOP system's requirements within the EVA Nexus Fluidics module, focusing on intraocular pressure management accuracy. This test does not address occlusion concerns, as the aspiration line's minimal inner diameter matches the inner needle diameter, with other diameters at least 3 times this value, measuring 1.7mm.

5.6.4.1 Method

This test utilized a prototype hybrid phaco handpiece featuring fluidic lines, including an accurate model of the front housing, fluid conduit, disposable horn with angled fluid lines, and tubing (Figure 5.6 - 1). The prototype underwent testing employing a Keller-style pressure sensor, a pressure sensor within the fluidics module, and a flow sensor in the fluidics module.

The test aimed to achieve a specific aspiration vacuum of 250mmHg, deemed a realistic scenario for cataract surgery, with flow not being a tuned parameter. The handpiece was positioned in an open container to avoid influencing pressure differentials.

Key fluidics characteristics, such as accuracy and precision (possibly affected by turbulences), setting time, and maximum deviation (PID controller not tuned for this design), were measured over a 10-second period, allowing for a maximum flow of 160ml/min and an aspiration vacuum of 250 mmHg. Results were plotted and manually assessed.

5.6.4.2 Results

The tests were conducted at an average flow of approximately 40ml/min, reaching the setpoint for vacuum of 250mmHg. A comparative analysis with a 3002.P is necessary to evaluate whether excessive resistances exist in the handpiece.

The final fluid characteristics' (shown completely in Appendix I) results are shown in Figure 5.6 - 8 and Table 5.6 - 1.

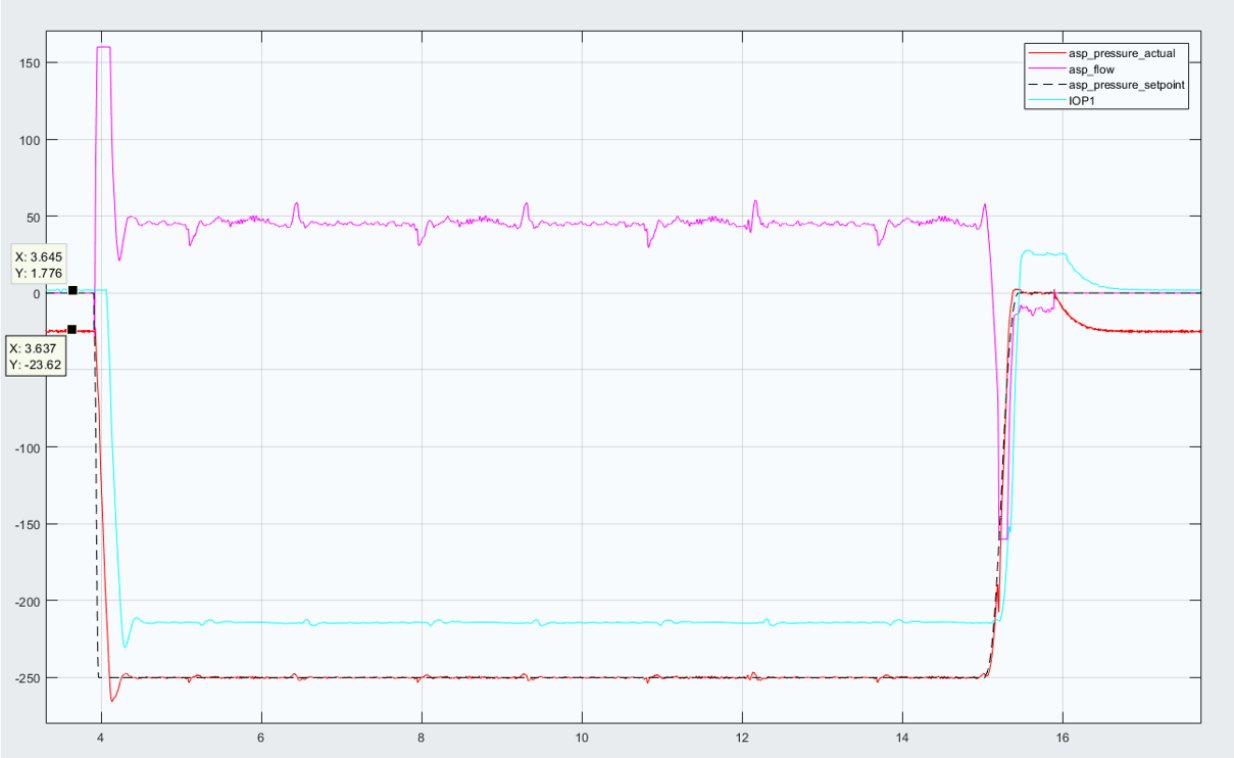


Figure 5.6 - 8 *Plotted test results of aspiration vacuum characteristics Smart IOP with average flow of ~40ml/min (pink), setpoint of 250mmH (black), and the measured aspiration pressure at Keller sensor (blue)*

Table 5.6 - 1 *Test results of aspiration vacuum characteristics Smart IOP with average flow of ~40ml/min, setpoint of 250mmHg*

	Accuracy (-25.4 offset) [mmHg]	Precision [mmHg]	Max. Deviation [mmHg]	Setting time [s]
Hybrid phaco fluidics prototype	10.6	4.4	16.3	0.7

5.6.4.3 Conclusion

The conducted tests indicate that the proposed embodiment design for the aspiration line not only achieves watertightness but also performs in accordance with the fluidics requirements. Given the changes made to the aspiration line, it can be reasonably inferred that similar conclusions apply to the irrigation line.

Key insights

RQ1.1: What are limitations to fluid line changes in a phaco handpiece?

- Fluid separation method requires a watertight design, with a symmetrical sonotrode design, and consistent horn diameter, and features removable tubing for I/A tooling.
- Chosen method of O-ring chamber was chosen because of its simplicity, functionality, and successful test results.
- Implementation of fluid separation method of irrigation and aspiration is tested, and both meet requirements set for fluidics in the phaco procedure by the EVA Nexus platform.

5.7 Deep dive: Heat transfer

The original product featured the aspiration line passing through the electronics, and the irrigation line running on the side of the metal body. This arrangement not only facilitated fluidics for phaco but also potentially provided cooling for the handpiece, contributing to improved product lifetime.

With the fluid lines now changed to accommodate a new fluid separation method, as discussed in Chapter 5.6.3 "Current implementation of fluid separation", the heat management function is also altered. This chapter will outline the exploration conducted on heat management in the original handpiece to analyse whether thermal management might pose a problem for the redesign. Additionally, potential mitigations for any identified issues and other considerations concerning thermal management in the redesign will be discussed.

5.7.1 Thermal management analysis

To analyse whether the changed fluid lines, particularly the redesigned aspiration line, would pose challenges in thermal management, the first step was to examine which components in the current handpiece play the most significant role in thermal management. The rationale behind this approach is to identify whether thermal regulation in the current design heavily relies on heat transfer in the aspiration line. If this is the case, the redesign may require alternative methods for heat dissipation. It is also plausible that thermal management is primarily achieved through direct heat transfer to the surrounding air or that the overall thermal mass of the handpiece and static fluids is sufficient to maintain adequate cooling.

To investigate this, the original handpiece underwent thorough testing based on various hypotheses, each focusing on isolating a specific component within the handpiece that could contribute to thermal management:

HP1: *"Irrigation fluid line (in combination with heat transfer through air) plays a dominant role in thermal management"*

HP2: *"Aspiration fluid line (in combination with heat transfer through air) plays a dominant role in thermal management"*

HP3: *"Heat transfer through air plays a dominant role in thermal management"*

HP4: *"Extra thermal mass plays dominant role in thermal management"*

5.7.1.1 Method

The original phaco handpiece, integrated with the surgical system (EVA Nexus), underwent testing with varied fluidic conditions. Thermal assessments were conducted using a thermal camera, capturing temperature dynamics on the titanium body. This not only reveals the final temperature but also elucidates the temperature rise progression within the handpiece.

Tests involved subjecting the device to multiple stress tests and scenarios simulating real-world usage:

***Run A:** Irrigation & Aspiration (30sec 100%, irrigation and aspiration running)*

***Run B:** Irrigation (30sec 100%, just irrigation running)*

***Run C:** Aspiration (30sec 100%, just aspiration running)*

***Run E:** Dry run (30sec 100%, no priming)*

***Run F:** Primed run “use case” (7sec 100%, primed)*

***Run G:** Dry run “use case” (7sec 100%, no priming)*

The hypothesis were testing for through comparing two test runs for each hypothesis.

HP1: Run B: Irrigation has similar results to A: Irrigation & Aspiration

HP2: Run C: Aspiration has similar results to A: Irrigation & Aspiration.

HP3: Run E: Dry run has similar results to A: Irrigation & Aspiration.

HP4: Run F: Primed run “use case” has significantly better results to G: Dry run “use case”.

Test setup is shown in Figure 5.7 - 1

Figure 5.7 - 1 *Test setup as used for 3002.P thermal management analysis*

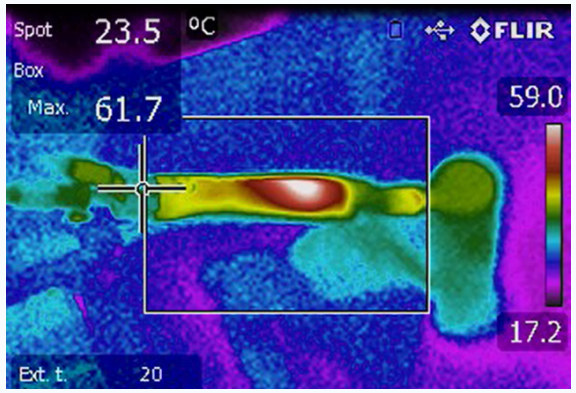


Figure 5.7 - 2 *Thermal test results of Run A - Baseline. Snapshot at t=30s*

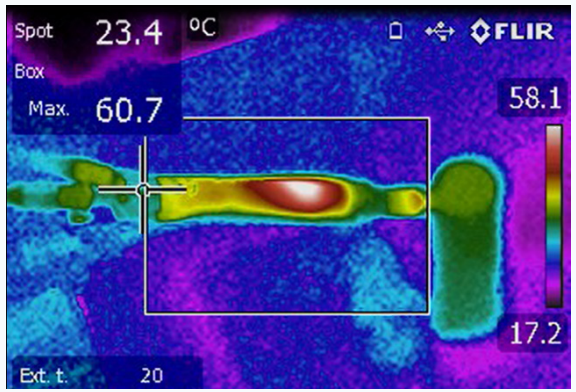


Figure 5.7 - 3 *Thermal test results of Run B - Irrigation. Snapshot at t=30s*

5.7.1.2 Results

Test results of run A and Run B are shown in Figure 5.7 - 2 and Figure 5.7 - 3, showing snapshots of the thermal videos at t=30. Rest of the test results are shown in Appendix IV.

Hypothesis HP1 accepted, given the similar maximum temperatures in both Run A and Run B (61.7°C and 60.7°C). Contrarily, all other hypotheses are rejected due to high temperatures relative to the baseline and inconsistent outcomes in Runs F and G. Notably, the anticipated higher temperature in a dry run with reduced thermal mass is contradictory with initial assumptions, as the primed run, with greater thermal mass, exhibits a higher temperature

5.7.1.3 Discussion and conclusions

The observed inconsistencies in Runs F and G may be attributed to differential heat transfer mechanisms. Run F (Figure 5.7 - 4), with a filled irrigation chamber, facilitates heat transfer through the titanium horn, whereas in Run G (Figure 5.7 - 5), a dry run, heat must traverse the air layer within the titanium housing. This insulating layer may create a misleading perception that heat is more effectively managed in the dry run.

Nevertheless, it is evident that the primary contributor to thermal management is the irrigation line. Asserting the success of the proposed fluid separation method from Chapter 5.6.3 “Current implementation of fluid separation” is still not ensured:

In the original product, the irrigation line, positioned alongside the handpiece, not only cools the device by passing over the sonotrode horn but also directly cools the side walls of the housing body. Figure 5.7 - 3 illustrates this effect, with the bottom side appearing cooler than the non-irrigated side.

However, with the redesigned disposable horn made of 7075-T6 aluminium, possessing higher thermal conductivity than grade 5 titanium (130W/m-K vs 6.7W/m-K), heat transfer to the irrigation fluids could potentially improve. This enhancement may result in a slightly closer approach to the patient's body temperature.

It can be definitively stated that the removal of the central aspiration line will not adversely impact the thermal management of the handpiece.

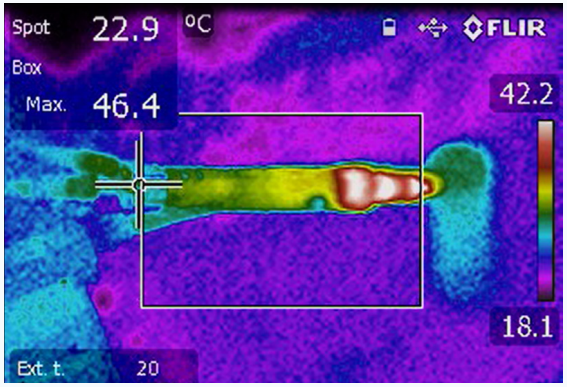


Figure 5.7 - 4 *Thermal test results of Run F - Primed run. Snapshot at t=7s*

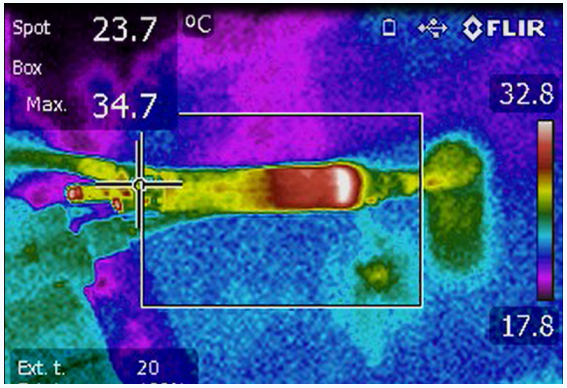


Figure 5.7 - 5 *Thermal test results of Run G - Dry run. Snapshot at t=7s*

Key insights

RQ1.1: What are limitations to fluid line changes in a phaco handpiece?

- Testing shows irrigation channel to be predominant factor in heat management of original product, addressing concerns about heat management due to changed aspiration line in redesign

5.8 Deep dive: Ergonomics

Ergonomics was not a primary focus of this project; rather, the approach was taken to ensure that the redesign presented in this thesis does not adversely affect the ergonomics of phaco usage. The physical ergonomics of the phaco redesign can be divided into two topics: handling the assembled handpiece and ergonomics during the assembly of disposable and reusable sections before use.

This chapter will explain why the ergonomics in handling have either remained the same or improved. It will also elaborate on how the threaded connection requirement (further detailed in Chapter 5.3.1 "Connection method requirements") used in assembly is deemed feasible considering ergonomics.

5.8.1 Dimensioning and handling

5.8.1.1 Length

The original phaco handpiece design incorporates specific ergonomic features, most notably its overall length and weight. The original 3002.P stands out for its shorter length compared to other standard archetype phaco handpieces; the 3002.P measures 128mm long (including the needle), while the 3002.M, an older and more standard phaco handpiece, is 157mm long. The phaco redesign is longer due to the sonotrode split and features to accommodate this split, measuring 139mm in length. In terms of length, it is closer to the 3002.P than the 3002.M variant.

5.8.1.2 Overall geometry

Arguably more crucial than just length is the overall geometry of the handpiece. The slim form factor of the 3002.P easily fits in the hand, akin to a regular pen. However, the redesign features a thicker design to accommodate fluid lines and disposable housing. Even with this increased thickness, Figure 5.8 - 1 illustrates how these features fit into a "gap" in the user's hand, addressing ergonomic concerns. It also demonstrates how the added length may not adversely affect the handpiece's ergonomics. The figure displays the P10 and P90 hands (for hand length) based on data from the age group 20-60, both male and female (DINED, 2004).

5.8.1.3 Weight distribution

Weight distribution has changed compared to the 3002.P. While in the 3002.P, the centre of mass is roughly in the middle of the handpiece, the centre of mass of the redesign has shifted further to the back (Figure 5.8 - 2) due to the large stainless steel connector at the back of the reusable. This new centre of mass still falls between the points of support in the hand, as shown in Figure 5.8 - 1, so overall ergonomics are not expected to be impacted.

Informal handling tests were conducted with a surgeon and other internal test subjects, and no concerns were raised regarding ergonomics. However, formal testing in a simulated clinical setting needs to be undertaken to confirm this.

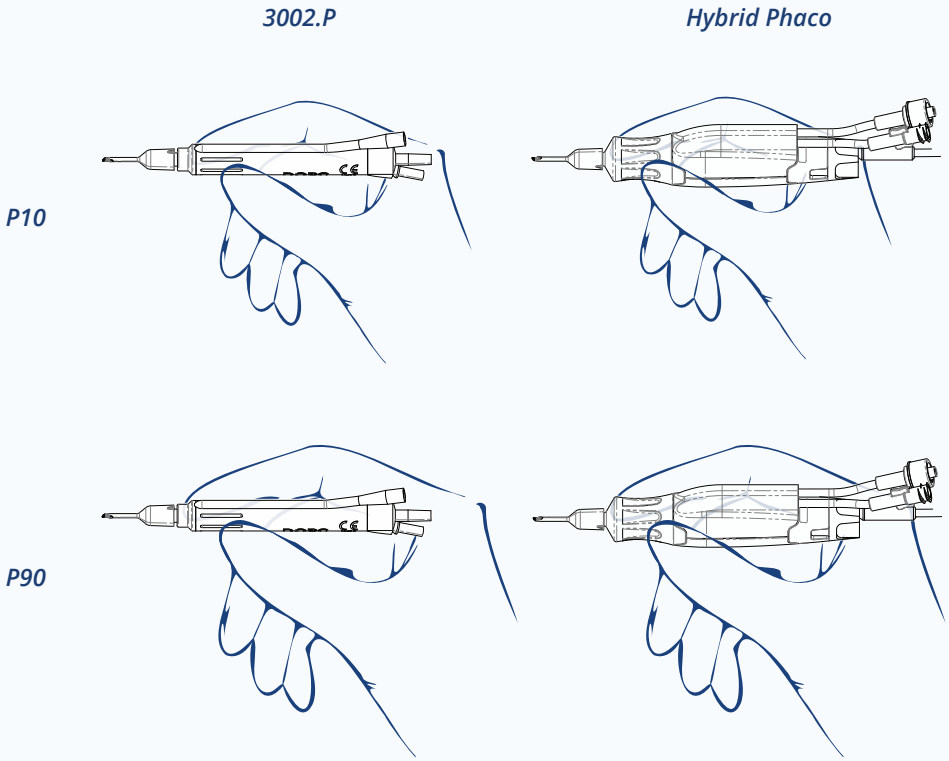


Figure 5.8 - 1 *To scale visualisation of 3002.P and Hybrid phaco concepts in the hands of both a P10 and P90 user (20-60 M+F)*

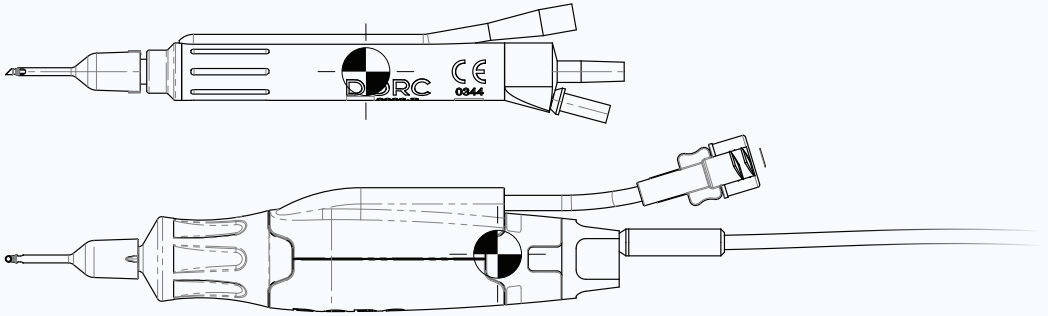


Figure 5.8 - 2 *Visualisation of center of mass for both the 3002.P and Hybrid Phaco concept, showing the center of mass being further back on the handpiece.*

5.8.2 Grip

5.8.2.1 Outer diameter

In the original handpiece, grip on the handpiece is ensured through several design features. Firstly, the grip diameter, 12mm in the 3002.P, is increased for the phaco redesign to 15.7mm (measuring at the narrowest point in the grip curve) to accommodate the fluid separation method. Both grip diameters only slightly deviate from the 3002.P internal design requirement of an outer holding diameter of 13 mm - 15 mm. The effect of this diameter increase has not been tested, and this remains a recommendation.

5.8.2.2 Groove pattern

Another factor for ensuring grip in the 3002.P is the grip grooves along the outer diameter. The redesign features more prominent grip grooves, contributing to the aesthetics of the handpiece (discussed further in Chapter 5.9 “Deep dive: Aesthetics”). These new grip grooves are crucial for indexing when turning the handpiece axially, providing tactile feedback during rotation, a common action in cataract procedures. The grip grooves appear to be more than adequate for this function, based on feedback from a surgeon during informal testing. However, further testing is required to confirm this.

5.8.2.3 Surface

Lastly, additional grip in the 3002.P is achieved through a sandblasted surface finish of the external DLC coating. As the DLC coating is inherently shiny and slippery when wet, the outer surface is treated. A surface finish for the injection-moulded disposable housing shells has not been specified for this redesign and also remains a recommendation.

5.8.3 Ergonomics in assembly

With the redesigned product architecture featuring a split sonotrode, a threaded connection method is introduced. This threaded connection requires secure tightening, for which the blister packaging with its torque ridge is designed. While this design ensures limited torque, it does not assist in applying the required torque of 30 cNm (chapter 5.3.1 "Connection method requirements"). This chapter explores whether applying the required torque is feasible considering ergonomics—can a nurse in the OR effectively apply 30 cNm on the reusable section of the handpiece?

Do the flat sides on the connector design assist in applying torque? Is the diameter of the connector large enough to apply the right amount of torque? How much effort does the user need to use to assemble the handpiece?

These questions are relevant, given that, during a day, a nurse needs to apply this torque approximately 16 to 20 times (in the context of 8 to 10 cataract procedures, including assembly and disassembly).

5.8.3.1 Method

For this, participants are asked to apply torque to three different SLA printed prototypes: a 17mm, a 19mm, and a 21mm maximum diameter connector model. The 17mm diameter represents the connector in the hybrid phaco redesign, and two larger diameters were chosen to assess if the required effort decreases and/or the maximal torque output increases.

The prototypes are connected to a torque measuring screwdriver (CEDAR DID-4A). Participants are instructed to hold the screwdriver in their non-dominant hand and the prototype in the other. Subsequently, they are asked to apply "a comfortable strength, around 25%," "a medium strength, around 75%," and their "full strength, 100%" in torque to the prototypes. Half of the participants are instructed to do this in ascending strength (25% > 75% > 100%), and half in descending strength (100% > 75% > 25%), to mitigate the effects of fatigue and discomfort in the results. The output of the torque measuring screwdriver can only be seen by the researcher, not by the participants.

5.8.3.2 Results

Participants are selected based on their age, aiming for an age distribution similar to circulating nurses in an OR. Additionally, participants are chosen based on their gender, with a majority being female participants, as this is estimated to be more closely representative of circulating nurses. Participant demographics are detailed in Table 5.8 - 1.

Results are shown in figure Figure 5.8 - 3

Table 5.8 - 1 *Participant demographics of ergonomics testing on torque application*

Variables	Gender		Age				
Categories	**Male**	**Female**	**0-20**	**20-30**	**30-40**	**40-50**	**50+**
N	2	6	0	3	3	1	1

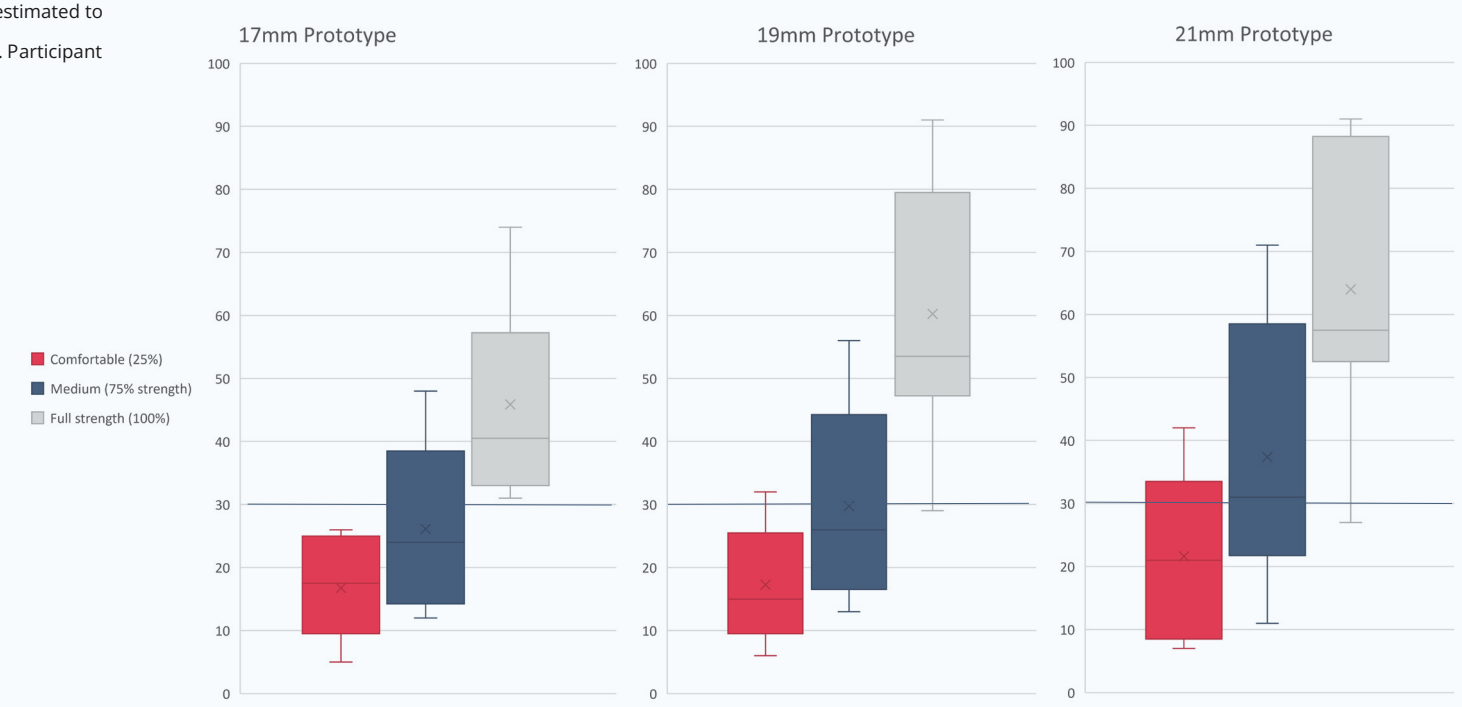


Figure 5.8 - 3 *Test results of achieved torque by participants on different diameter connector prototype, at different strength levels*

5.8.3.3 Discussion and conclusions

From the boxplots in Figure 5.8 - 3, it is evident that, for the current design, only at full strength, requiring maximum effort, is the likely threshold for reaching the required 30nCm. However, requiring maximum effort is not desirable for the design. Therefore, it is concluded that a larger diameter is needed.

The 19mm and 21mm prototypes exhibit fairly similar results, with the majority of users able to apply 30nCm at medium effort for the 21mm prototype.

Another notable finding is that the sharp edges of the connector prototypes caused discomfort when applying medium to full strength, particularly in participants with smaller hands. These sharp edges are visible at the sides of the four flat surfaces in the connector. This discomfort may exacerbate considering the fact that this part will be machined from 316 stainless steel.

Given the sharp edges and the need for a larger diameter, I recommend a comprehensive reconsideration of the entire connector to better suit torque application. Flat sides should be incorporated without sharp edges and with a larger total diameter, or the flat sides should be replaced with a completely different grip feature. Despite the current limitations, the test results show potential with these improvements, which is why I continue to discourage the addition of an extra component (such as a wrench) for applying torque. Such an addition significantly impacts the usability of the entire concept.

Key insights

- Length and weight distribution of redesign compared to original design suggest likeliness of a design that is still ergonomic.
- Grip pattern is introduced to improve handling of the handpiece compared to the original product.

RQ3.2: Can a feasible design be defined for a hybrid phaco handpiece, also considering all prerequisites?

- Testing shows that improvements have to be made to the connector design to ensure users are able to assemble the handpiece securely in the OR without maximum effort.

5.9 Deep dive: Aesthetics

While aesthetics weren't identified as a primary design factor in this project, the handpiece's visual appeal can influence perceived trustworthiness and reliability—crucial considerations for surgeons in a surgical system.

The aesthetic design of the hybrid phaco handpiece adheres to the DORC brand aesthetic, and also employs basic aesthetic principles such as repeating shapes, patterns, and geometry. This chapter will delve into the aesthetic analysis of the DORC brand and its implementation in the hybrid phaco design.

5.9.1 DORC brand aesthetics

Based on internal expert consultation, several micro-level aesthetic product design aspects (geometry, material composition, parts, and other visible and tangible features) were derived from the vitrectome design, considered key for portraying the DORC product design brand (shown in Figure 5.9 - 1).

5.9.1.1 Curve in, curve out

The outer shape of the complete vitrectome exhibits an inward curve at the grip area and an outward curve at the extension handle. These shapes are repeated in the overall geometry of the hybrid phaco design.

5.9.1.2 Tapered front

The front of the vitrectome features a tapered shape directed towards the needle. This tapered shape is echoed in the hybrid phaco design, where the phaco sleeve, in combination with the tapered front shell, forms a tapered tip.

5.9.1.3 Grip pattern

The grip pattern, serving both ergonomic function and aesthetic appeal in the vitrectome design, is repeated in the hybrid phaco design within the front shell.

5.9.1.4 Materialisation and colouring

The white colour and lack of texture in the handpiece align with the "medical professional" look typical of DORC products, consistent with the vitrectome design. The reusable housing component, with a black DLC (diamond-like-carbon) coated outer surface, closely adheres to the aesthetic considerations of the original phaco handpiece. This coating ensures a durable, unchanging appearance over a high number of cycles.

Figure 5.9 - 1 *Aesthetic comparison of the DORC vitrectome design and the hybrid phaco concept, with aesthetic design aspects highlighted*

5.9.1.5 General aesthetic aspects

5.9.1.6 Repeating form language

The parting lines of the disposable housing shells in the hybrid phaco design exhibit a distinct indented shape, serving a functional purpose in assembly fitting. This shape also shows some of the form language of the handpiece and is evident in the cutout for the torque ridge in the back shell and the ergonomic grip surfaces on the reusable driver-connector. This creates a three-step repeating pattern. This indent can also seen in the ergonomic grip pattern on the front shell.

5.9.1.7 Form-follows-function

The integration of irrigation and aspiration fluid lines into the tube-side shell follows a form-follows-function approach, prioritizing the general curve-in, curve-out shape of the complete handpiece.

5.9.1.8 Branding features

In addition to labelling, the reusable housing component features the DORC logo and branding. This branding is also present on the disposable underside, where the DORC logo and name are embossed in the bottom side shell.

Key insights

- Aesthetics of the handpiece come from DORC brand aesthetics based on vitrectome design, as well as general aspects such as repeating form language and form-follows-function

5.10 Deep dive: Cost price

In the acquisition of a surgical system, the price per surgery remains one of the most important metrics. This chapter discusses the cost price calculations performed for the hybrid phaco redesign in this thesis, as well as the considerations that went into these calculations.

The price per surgery for the original product primarily relied on the handpiece's price over the maximum number of surgeries and the price per reprocessing/sterilization cycle. In contrast, the price per surgery for the new concept centres around the cost of disposable components, with the machined disposable horn being the most expensive, along with the cost of assembly at DORC—both of which are incurred for every surgery.

The analysis of the price per surgery is conducted within the context of a complete phaco handpiece, considering disposables such as the phaco needle, phaco sleeve, tubing set, etc.

All considerations concerning cost price calculations are stated in Appendix VII. Conclusions of these calculations will be discussed here and in Appendix VII.

5.10.1 Conclusions

Based on the calculations for the price per surgery, the hybrid phaco design is approximately 15% more expensive when comparing to cheap sterilization, but around 8% cheaper compared to expensive sterilization. This leads to the conclusion that the hybrid phaco is a favourable choice for clinics with more expensive sterilization costs. Additionally, an argument can be made for hospitals with cheap sterilization, considering that the 15% price increase can be viewed as a sustainability premium. Willingness to buy with this premium is not considered in this thesis and is left as a recommendation.

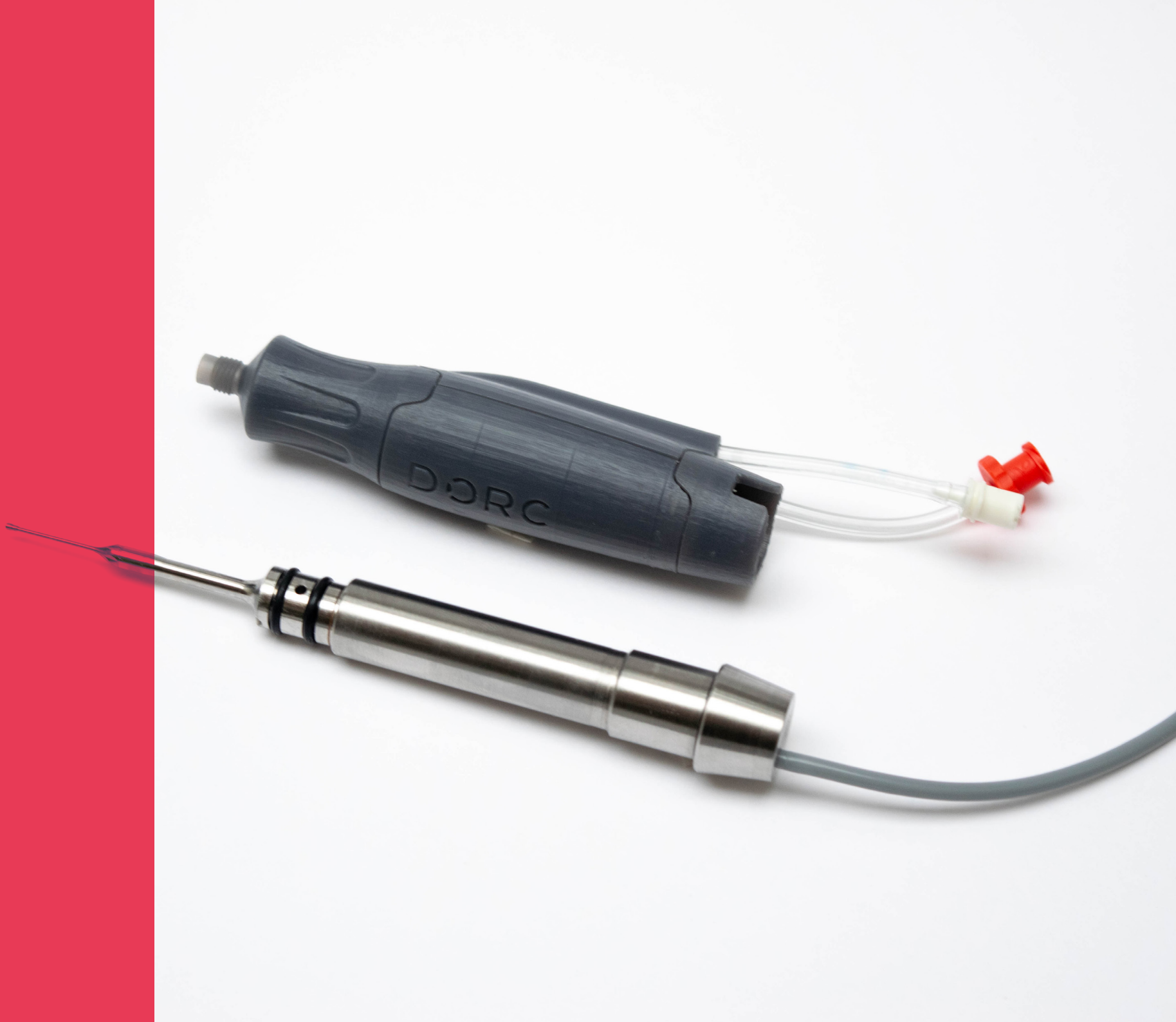
Key insights

- Price per surgery of Hybrid Phaco is mostly based on part cost of disposable horn, and on assembly costs.
- Price per surgery could be 15% higher compared to cheap sterilization options, and 8% cheapter compared to expensive sterilization options.

6. Evaluation and conclusions

To conclude this design project, we will evaluate critical aspects outlined in the primary research questions: functionality, sterility, environmental impact, and design implications. This section aims to formulate a thorough summary of these elements, addressing the research questions and functioning as the conclusive segment of the design project.

Furthermore, it will delve into broader implications that may hold significance for both industry and academia. Additionally, we will explore the project's limitations and present recommendations for the ongoing development of hybrid phaco.


DORC

6.1 Functional evaluation

In this chapter, we assess the functional aspects of the final design, focussing on ultrasound characteristics and fluidics. The assessment is grounded in various testing methodologies, including dimensional analysis, material studies, threaded connection testing, and measurements of flow and pressure.

Additionally, we delve into the testing conducted on the fully functional prototypes in the latter stages of this design project.

6.1.1 Functional Assessment and Testing Insights

The dimensional analysis revealed that the proposed design in this thesis not only closely matches phaco characteristics but is also mechanically tuneable in key aspects, with resonant frequency being the most adjustable by altering the front or base length of the disposable horn.

It identified features with minimal impact on ultrasound characteristics, providing design flexibility, particularly evident in plastic components of the disposable and the O-rings connecting them to the sonotrode.

Efficiency and stroke length, however, proved challenging to assess due to their high variability during testing.

Material studies demonstrated the feasibility of using lower-impact 7075-T6 aluminium for this application, considering the differences in material behaviour in ultrasound analyses.

Testing on the threaded connection confirmed the feasibility of the design and provided clear insights into the required torque for a proper connection.

Furthermore, fluid line testing indicated that the modified fluid lines are not only watertight under ultrasonic load but also maintain fluidics characteristics within specifications.

6.1.2 Analysis of final prototype

6.1.2.1 Other performance attributes

The final prototype (shown in Figure 6.1 - 1), although limited by having some non-final dimensioning, and materialisation (SAE 316 SS connector and reusable housing, and titanium sonotrode and horn), was assessed on factors like stability during usage, residual vibrations in the handpiece, and the integrity of fluid lines, among others.

Despite its limited dimensioning and material variations, the final prototype demonstrated stability during internal testing. Phaco remained consistent, and fluidics stayed watertight and stable over prolonged periods. However, the prototype exhibited some residual ultrasound vibrations in the connector, potentially caused by the weight of the stainless steel. Direct contact with bare hands resulted in a sharp tingling sensation, a departure from the original design. While this issue may not be critical, it requires further analysis, especially considering that the sterile tube sleeve and surgeons' gloves effectively dampen these vibrations.

Unfortunately, the evaluation could not be conducted with healthcare professionals due to the prototype's operational limitations on the day of testing (Other internal capacitance or resistance values than permissible by the latest DORC surgical unit).

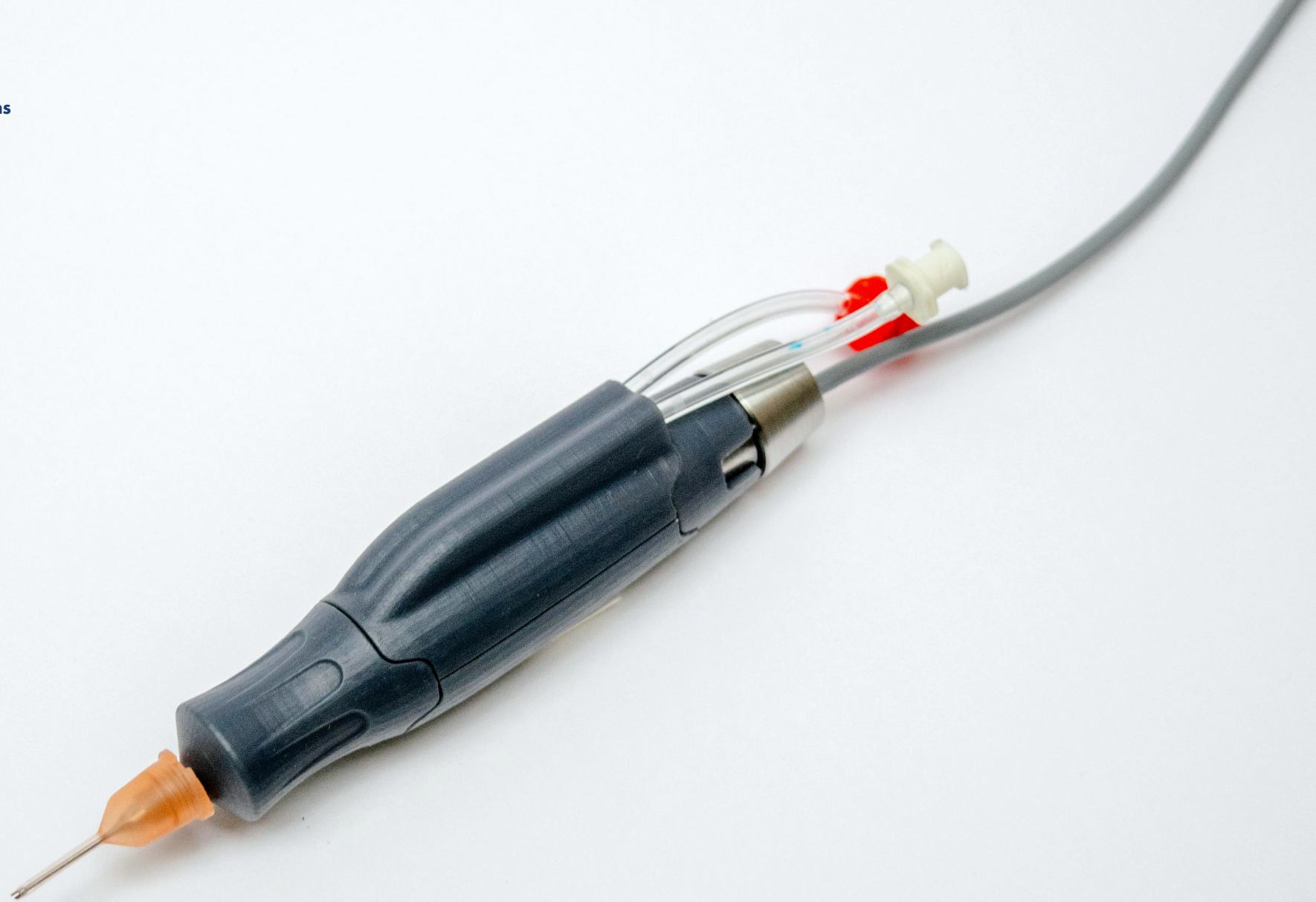


Figure 6.1 - 1 *Final prototype, as used in final evaluative study, showing a fully functional sonotrode and disposable housing, including functional fluid lines.*

6.1.2.2 Usability and ergonomics

The final prototype underwent a usability and ergonomics assessment by a healthcare professional (Figure 6.1 - 2). While the findings on ergonomics remain inconclusive due to the single-test subject scenario, the evaluation yielded valuable qualitative insights for potential design enhancements.

Recommendations for improvements include ensuring that the needle alignment guarantees the tubing faces upwards at a 180-degree turn. To counteract the pulling of fluid lines on the handpiece, consider shifting luer connectors for I/A tubing backward. Generally, the handling of the device is well-received, considering size and weight distribution, with seemingly improved indexing during turning compared to the original design.

Regarding product assembly, although testing with the final complete prototype was not conducted, isolated testing suggests that, with some improvements to the connector design, users should be able to apply the required torque on the handpiece for proper connection with moderate effort.

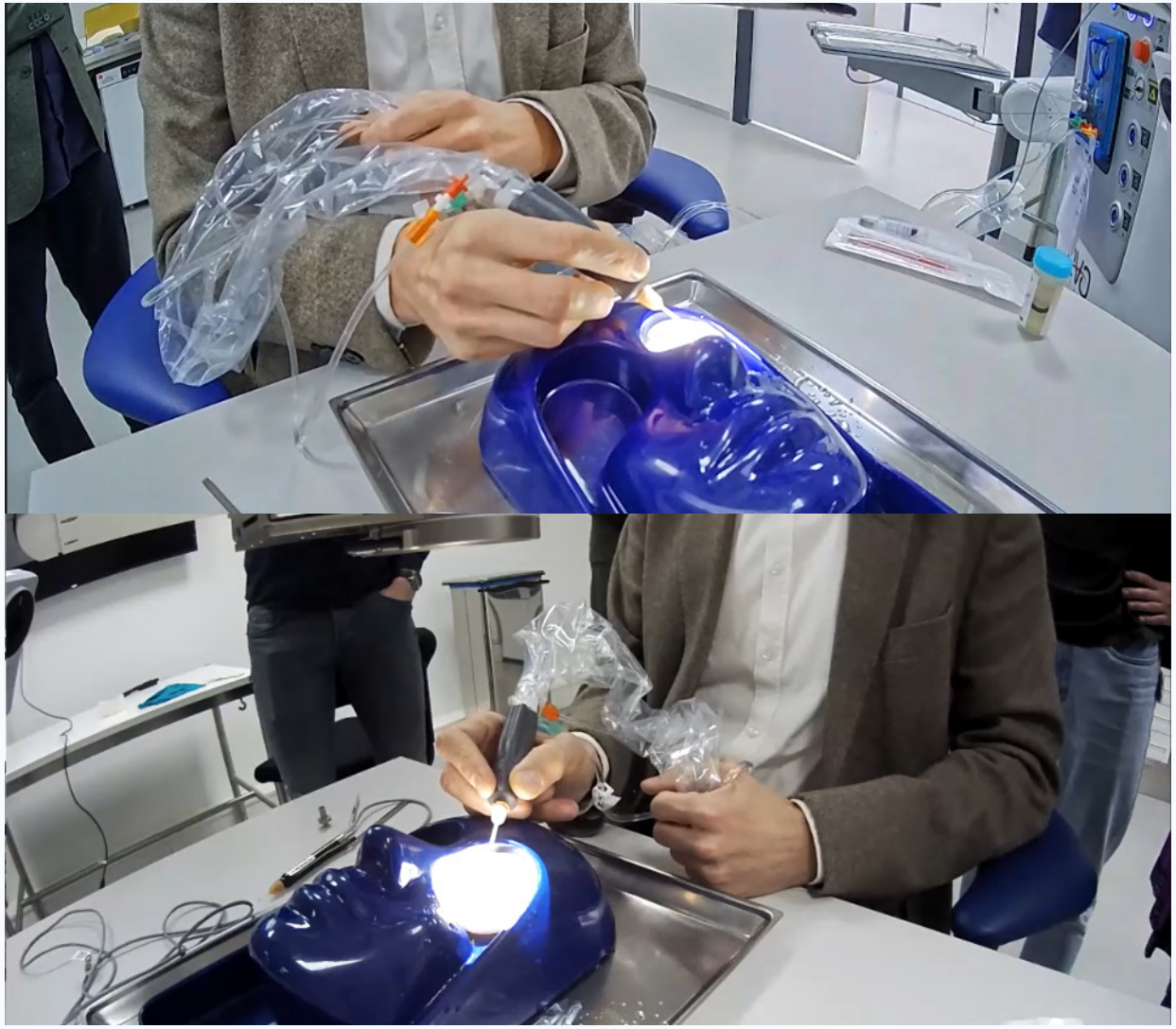


Figure 6.1 - 2 *Usability prototype in use during usability evaluation with healthcare professional*

Key insights

RQ3.2: Can a feasible design be defined for a hybrid phaco handpiece, also considering all prerequisites?

- Testing with healthcare professionals on functionality is not performed, but in laboratory environment the design was fully functional, showing the feasibility of the design

- With some recommended improvements, the general ergonomics and handling are well perceived

6.2 Sterility evaluation

This chapter provides an overview of the sterility evaluation conducted on the handpiece, encompassing the sterile assembly method, the sterile handover method facilitated by the blister packaging design, and the internal sterility of the handpiece.

1.1.1 Sterile assembly and handover method

The sterile assembly method and handover method, designed with direct input from healthcare professionals and further evaluated for potential risks by a surgeon and OR assistant, are deemed feasible for sterile usage in the operating room (OR). While no explicit tests, such as marking or tracking non-sterile particles, were conducted, these conclusions are based on the assessments of experienced OR professionals. According to their expertise, no significant potential risks were identified in terms of sterility for this assembly and handover method. The design aligns with their current practices of handling products in the OR.

1.1.2 Internal sterility

The conclusion regarding internal sterility relies on the effectiveness of the O-rings. As the primary barrier between the sterile and non-sterile sides within the handpiece, the watertightness of the system contributes to ensuring this aspect of sterility.

However, the evaluation did not consider the potential spread of particulates from the inside of the handpiece through the split lines in the shell design to the outside, potentially reaching the surgeon's hands. Examining this aspect is recommended for future evaluations.

Key insights

RQ2: How can safety in terms of sterility be ensured for a hybrid reusable and disposable handpiece?

- Multiple rounds of risk assessment with healthcare professionals resulted in a design with finally no significant potential risks identified
- Particulate spread on product level is not tested for

6.3 Environmental evaluation

In this chapter, we explore the LCA results conducted by Michal Adar and the LCAs on the redesign proposed in this thesis. We discuss key findings from the complete life cycle analyses of the original handpiece and the student redesign, emphasizing the impact of the redesigned circular system. Additionally, we delve into the LCA results focused on the production of the disposable handpiece outlined in the student design. Finally, we analyse the outcomes of the final evaluation of the hybrid redesign presented in this thesis.

6.3.1 Scope and methodology

Noteworthy boundaries set for all LCAs are the exclusion of impact related to the phaco needle set, tubing, and energy consumption during use, as these factors remained consistent between the original and redesigned systems. The focus of the LCA was specifically tailored to the Netherlands, considering various factors such as energy usage, sterilization facilities, and waste management. Additionally, the LCA employed an End-of-Life (EoL) allocation “cut-off” approach, meaning full responsibility of process requisites associated with incineration, with no credit from heat generated and electricity recovered being allotted to DORC (Allacker et al., 2017) (Lee et al., 2004).

LCAs are heavily dependent on the quality of data collected. In this thesis, an examination has been conducted on previously performed LCAs, with no re-evaluation undertaken for data rated at low certainty. The LCA presented in this thesis for the proposed redesign is derived from the LCA performed on the student redesign by Michal Adar. Data collection for this LCA involved accessing EcoInvent LCI databases through the EcoChain Mobius platform (Ecoinvent Centre, 2023) and direct measurements from developed 3D models, along with scaled measurements from prototypes.

The sensitivity analysis in this thesis’ LCA (Figure 6.3 - 7) addresses uncertainties arising from energy use for the reprocessing phase of the 3002.P, which makes up the bulk of the impact of the original handpiece. It is assumed that this uncertainty is consistent for the derived LCA in this thesis and, therefore, not re-evaluated.

The impact categories chosen for this thesis’ LCA (Figure 6.3 - 1

until Figure 6.3 - 6) align with those selected in previous LCAs. These categories were specifically chosen for use in the interpretation stage, as they align with the study’s objective of identifying opportunities for carbon footprint reduction and interventions related to circularity.

6.3.2 Results LCA

Results from the LCA done by Michal Adar on the original handpiece and results from the LCA done by me on the hybrid redesign are shown in Figure 6.3 - 1 until Figure 6.3 - 9.

Figure 6.3 - 1 until Figure 6.3 - 6 show the system comparisons of all six chosen impact catergories. Legend for these system comparisons in shown below

Figure 6.3 - 7 shows a sensitivity analysis, including the scenario of a sustainable energy grid (switch from natural gas boiler to electric boilers with the more sustainable energy grid in 2030).

Noteworthy is the change in scope of Figure 6.3 - 8. This graph shows the waste of the total system including the disposables and packaging (per functional unit of one cataract surgery).

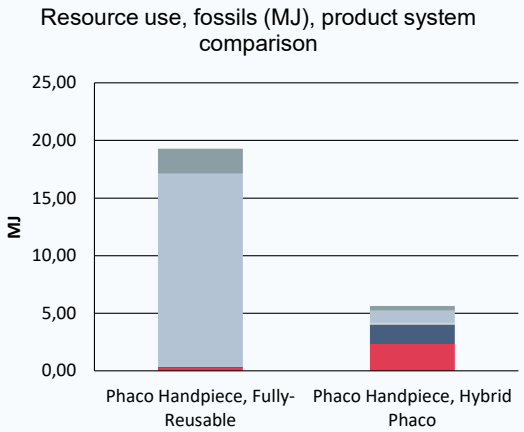


Figure 6.3 - 1 *LCA results 3002.P and hybrid redesign on Resource use, fossils (MJ)*

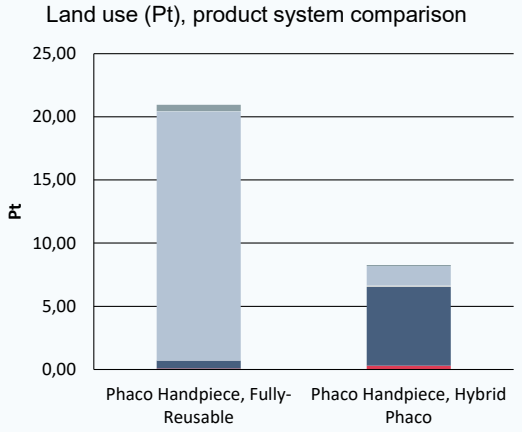


Figure 6.3 - 2 *LCA results 3002.P and hybrid redesign on Land use (Pt)*

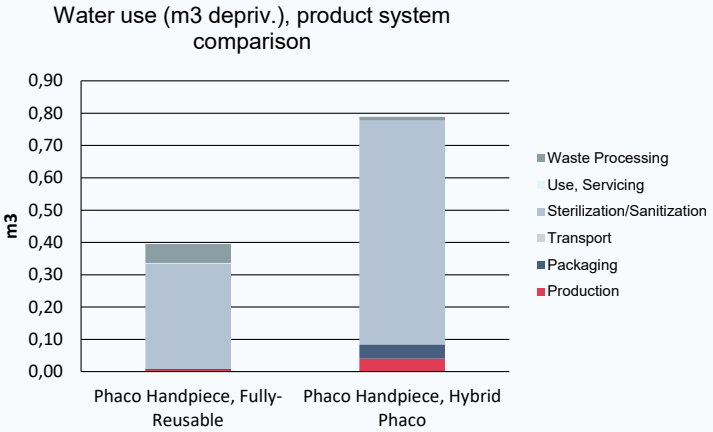


Figure 6.3 - 3 *LCA results 3002.P and hybrid redesign on Water use (m3 depriv.)*

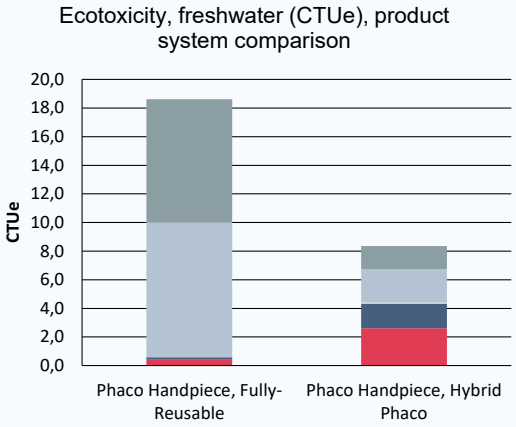


Figure 6.3 - 4 *LCA results 3002.P and hybrid redesign on Ecotoxicity, freshwater (CTUe)*

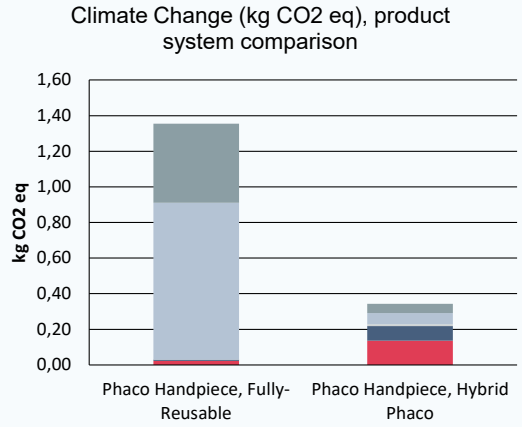


Figure 6.3 - 5 *LCA results 3002.P and hybrid redesign on Climate change (kg CO2 eq)*

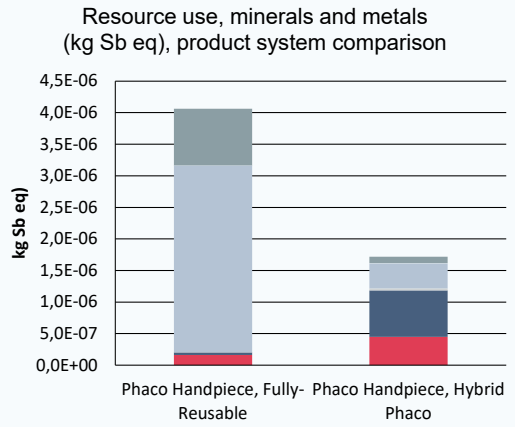


Figure 6.3 - 6 *LCA results 3002.P and hybrid redesign on Resource use, minerals and metals (kg Sb eq)*

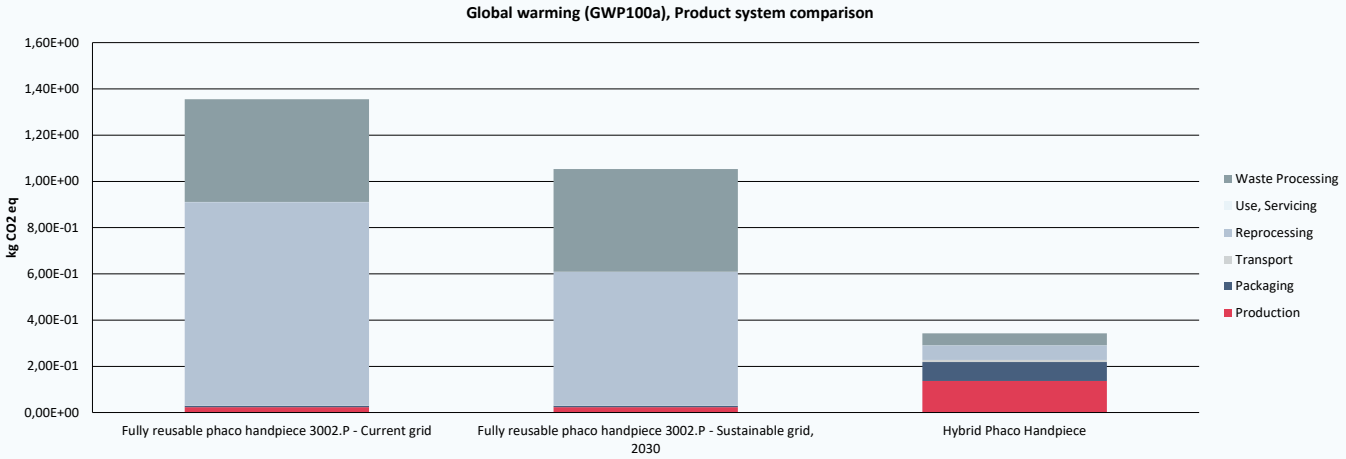


Figure 6.3 - 7 *Sensitivity analysis of LCAs concerning the energy grid used for the sterilization process, on Climate change (kg CO2 eq)*

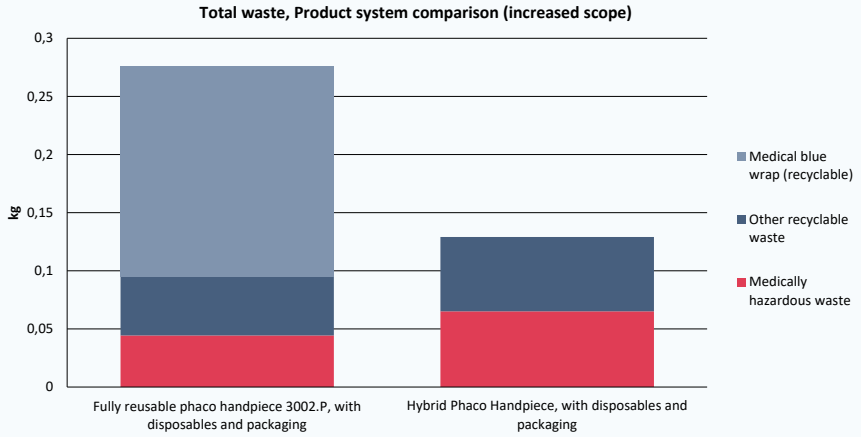


Figure 6.3 - 8 *Amount of waste in kg for lifecycle of 3002.P and Hybrid design, separated by medically hazardous and recyclable, and medical blue wrap. Increased scope to include disposables and packaging*

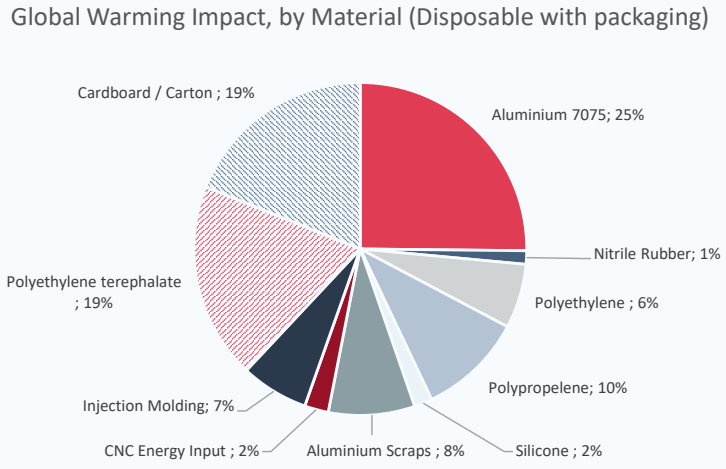


Figure 6.3 - 9 *Global warming impact of production phase (solid fill) and packaging (hashed fill), of the hybrid redesign*

6.3.3 Conclusions LCA

Shown in Figure 6.3 - 8, the total waste amount is reduced from 276 grams to 129 grams, including in the analysis packaging and a set of disposables used for the phaco handpiece. This reduction is primarily attributed to eliminating the use of medical blue wrap in reprocessing. Although some medically hazardous waste is introduced, the overall waste amount is decreased by 50%, resulting in a substantial reduction. This analysis covers only part of the packaging (specifically that of the disposable) and not all other phases of the product life cycle.

When considering the impact of the total life cycle, there is a logical decrease in climate change impact (Figure 6.3 - 7) due to the elimination of energy-intensive sterilization. There is also a significant reduction in both resource use impact categories (Figure 6.3 - 1 and Figure 6.3 - 6). This may seem counterintuitive given the introduction of a new disposable component. However, the medical blue wrap, accounting for about 95% of the impact in terms of resource use in the sterilization phase of the original product, is a major factor.

Sensitivity in this life cycle assessment (LCA) is evident in the dominance of the medical blue wrap's impact in the original concept. Additionally, the type of energy used in the sterilization process is critical. Figure 6.3 - 7 demonstrates the impact of using electric boilers on a more sustainable grid for sterilization. Even with a drastic decrease in the impact of energy usage, reprocessing remains a significant contributor, largely due to the sterile blue wrap. Waste processing also maintains a substantial impact, indicating that even with sustainable energy production, waste water and medical waste processing play crucial roles.

These factors are absent in the hybrid phaco concept, where the production and packaging phases of the disposable play major roles. As shown in Figure 6.3 - 9, the metal component in the disposable still contributes about 33% of the impact, and packaging, with its three layers of cardboard and larger blister pack, constitutes 38% of the impact in these phases.

Sensitivity related to medical blue wrap and energy sources needs further investigation for a more sustainable option. While this LCA assumes the use of blue medical wrap, and the possibility of switching to a green grid is considered, future analysis should explore sustainable alternatives to medical blue wrap.

In conclusion, there is a significant reduction in environmental impact in the scenarios analysed in this LCA. Areas of improvement, particularly in the production and packaging phase, involve reducing the amount of cardboard and minimizing the weight and size of the aluminium horn. Additionally, the potential for reusing high-value materials, as proposed in chapter 3.2.2.3 "Closing the loop on valuable materials", should be assessed through a dedicated LCA, which is specifically recommended for future consideration.

Key insights

RQ4: How does the hybrid disposable handpiece compare in terms of environmental impact?

- With the phaco handpieces and their entire lifecycle in scope, Hybrid Phaco performs favourably on nearly all environmental impact categories.
- When considering handpiece plus disposables for handpieces, the total waste reduces by around 53%, only slightly increasing amount of medically hazardous waste.
- Also when comparing to autoclave sterilization using sustainable energy sources, in stead of natural gas, Hybrid Phaco reduces impact by 67%.
- Medical blue wrap plays major role in impact of original product, indicating sensitivity of this LCA.

6.4 Overall conclusions

This thesis has presented a novel phaco design, marking a step towards a circular system for cataract surgeries, with minimized environmental impact. The elimination of sterilization needs by introducing a disposable element for sterile use, complemented by a reusable component driving ultrasound, is at its core. The primary focus of this project is on minimizing environmental impact while upholding phaco functionality:

RQ1: What ensures the phacoemulsification functionality of a phaco handpiece?

RQ2: How can safety in terms of sterility be ensured for a hybrid reusable and disposable handpiece?

RQ3: How can a phaco handpiece be redesigned to make use of disposables?

RQ4: How does the hybrid disposable handpiece compare in terms of environmental impact?

A functional design of the hybrid phaco handpiece is presented. Through thorough testing this thesis provides proof of this design on ultrasound characteristics, and fluidics. The internal sonotrode, driving ultrasound, is securely split between the two, connected through a threaded interface. Fluidics are managed by splitting off before reaching the reusable part, incorporating a simple yet effective, and sterile O-ring design in the disposable product.

Ensuring sterility within the operating room is crucial. The hybrid handpiece incorporates a validated design of mechanical seals in O-rings to establish internal sterile barriers. A blister pack facilitates sterile interaction, and a contact-free assembly method ensures a tight, visually validated connection through a torque ridge. The sterile handover method is a standout feature, utilizing the packaging itself as a sterile barrier during component handover between nurses. A pre-attached sterile tube sleeve minimizes contamination risks, ensuring a seamless and sterile transition during assembly. Said assembly methods are evaluated with healthcare professionals and assessed on their potential risks.

Beyond functionality, the hybrid phaco handpiece has environmental implications. Through the elimination of energy-intensive sterilization procedures and a significant reduction in waste from disposable wraps, the design reduces its climate impact by an impressive 70% over the entire life cycle.

In conclusion, this hybrid phaco handpiece design not only provides cataract surgeries a step towards a circular system but also exemplifies the potential of hybrid reusable and disposable products in healthcare. Balancing functionality, sterility, and environmental impact, this novel approach provides valuable insights into sustainable phacoemulsification procedures, providing an example for future healthcare.

6.5 Implications

6.5.1 Environment

The adoption of the hybrid phaco handpiece design carries environmental implications. The reduction in waste generated during cataract surgeries, coupled with a significantly lower overall impact, highlights the potential for a more sustainable healthcare landscape. This innovation prompts a reconsideration of environmentally conscious design, suggesting that disposables, as a replacement for traditional sterilization methods, could yield substantial environmental gains.

6.5.2 DORC

For DORC, the introduction of hybrid designs not only marks a step in medical device innovation but also sets the stage for more comprehensive circular design projects. The project offers DORC valuable insights into circular business strategies, potentially influencing a broader integration of circular principles across its diverse product portfolio.

6.5.3 Hospitals/clinics

The hybrid phaco handpiece project provides hospitals and clinics with a unique perspective on environmental impact, shedding light not only on the waste generated in operating rooms but also on the broader consequences of relying on pure reusables requiring sterilization. Beyond environmental considerations, products like the hybrid phaco handpiece present a cost-effective and safe alternative for performing phaco procedures, adding value through sustainable solutions for healthcare professionals.

6.5.4 Academia

In academia, the project contributes to the advancement of circular design practices within a circular system. Serving as an embodiment design project, it serves as a case study demonstrating the integration of Life Cycle Assessment (LCA) results not only as input for conceptual design but also in the detailed embodiment design phase, where the impact of production is most important. This approach aligns with the broader trend towards sustainable and environmentally conscious design practices, adding to future research and educational endeavours in this realms.

6.6 Limitations & recommendations

While this project provides a comprehensive detailed design, essential for conducting in-depth feasibility, environmental, and usability studies in this thesis, it is not without limitations. Both at a conceptual level and in specific details, this project faces constraints. Certain strategic inquiries, circular design considerations, and sterility-related questions remain unanswered, posing challenges before delving into the remaining detailed design aspects. This chapter presents an overview of these limitations and offers recommendations to enhance the project's overall success.

6.6.1 Strategic Studies

This project, primarily focused on the detailed design of the hybrid phaco handpiece, lacks an in-depth exploration of strategic aspects. Business cases, detailed value propositions, and market research, like for low-income countries, were not extensively analysed. It is recommended to delve into the strategic implications, market viability, and potential willingness to pay for a sustainable solution. This involves considering a sustainability premium and gauging market responses to eco-friendly solutions.

6.6.2 Conceptual Circular Studies

While the project thoroughly examines the impact of the embodied product design, certain crucial aspects, such as alternatives to sterile blue wrap in sterilization processes, were not within its scope. This could significantly influence the Life Cycle Assessment (LCA) result. It is recommended to explore alternatives for sterile product packaging, considering its potential impact on the hybrid phaco handpiece's sustainability comparison, especially considering the still long timeline for adoption of this product.

Additionally, studying the recovery of high-value materials from operating rooms warrants evaluation of its business, environmental, and legislative implications.

6.6.3 Sterility and Usability Testing

Rigorous testing for sterility, including internal particulate spread within the handpiece, residual Ethylene Oxide (EtO) analysis, and the development and testing of a disassembly method for the sterile tube sleeve, should be considered. High-fidelity prototypes need to undergo testing to validate these aspects. Usability testing, especially in the operating room and simulated use cases, is crucial.

6.6.4 Embodiment Design studies

Continuation of the project should address various embodiment design questions. This includes:

- Conducting a quantitative ergonomics study for the entire handpiece,
- Redesigning the blister pack for proper torque application in collaboration with manufacturers.
- It should also include analysing the applicability of lower-impact materials, like recycled or bioplastics. The analyses of these materials should encompass biocompatibility and cost implications
- Durability studies on the reusable driver should also be performed, including an analysis of the effectiveness of sealing methods against ingress, to determine the increased life expectancy of such a driver.

6.6.5 Cost Analysis and Assembly Trials

A comprehensive cost analysis is essential, involving detailed examinations of parts in the reusable driver, assembly trials at cleanrooms for cost assessment, and inquiries on sterilization costs. This ensures a holistic understanding of the financial aspects associated with the hybrid phaco handpiece.

6.6.6 Detailed Design and optimization

If strategic studies, circular design studies, and sterility studies are performed, and the project were to continue with the specific detailed design of the hybrid phaco handpiece presented in this thesis, this paragraph offers detailed design changes still at hand for hybrid phaco.

- A tolerance chain analysis for horn decoupling dimensioning should be performed.
- Lengthening internal tubing, to move back the luer connectors for a more ergonomic hold.
- General design for manufacturing considerations, like reconsideration of undercuts and drafts on injection moulded components.
- An analysis for assembly method of blister pack and folded up sterile tube sleeve, possibly forming the most difficult and time consuming task of assembly.

Optimizations for the disposable horn:

- changing the diameter to 8 or 9 mm- making more space for fluid lines as well as optimizing the design on material use and costs.
- Thread size should be changed from Mf5x0.5 to Mf4x0.5, making for higher clamping force with the same applied torque.
- Also, the recessed in the horn, used for to counteract the applied torque on the horn, should be changed to two larger flat sides, able to withstand higher forces (this should include FEM analyses)

6.7 Personal reflection

Embracing Complexity in Design

In the early phases of this project, I dove into ready-to-go questions, using methods like sketching, prototyping, and testing. The journey led into a theoretical exploration of ultrasonic transducer design, eventually moving into the practice with the development and validation of prototypes. This multi-faceted approach showed in much of my work, tackling numerous topics in parallel—feasibility studies, sterility considerations, usability, ergonomics, environmental impact, and more.

The ambitious scope initially proposed for the project was even broader than what I eventually addressed, underscoring the breath of the questions I sought to answer. The interconnectedness of these topics, such as the influence of sonotrode connection methods on usability, feasibility, ergonomics, and sterility, highlighted the complexity of the design process.

Prioritization in Design

Reflecting on this, I recognize an opportunity for improvement in forming a clearer focus and prioritizing key questions: I still tend to believe that a project's success hinges on addressing every question completely.

This realization marks a lesson for me as a designer, emphasizing the importance of strategic prioritization and focused efforts. Success in design is not solely about addressing every question to the fullest extent but about hitting the right notes on crucial aspects, with the rest logically following after.

Bridging Theory and Practice

Navigating the theoretical story of ultrasonic transducer design brought me the depths of modelling of the system and modal analyses, which was too deep. However, the realization came that this theoretical foundation should have been complemented by a simultaneous empirical design approach—bridging the gap between theory and a hands-on understanding of complexity through prototyping and testing.

Design Communication

Moreover, effectively communicating the intricacies of this complexity posed a challenge. The breadth of topics addressed in this project runs deep, and condensing them into a coherent thesis was extremely demanding.

This aligns with my nature as a designer, where my strength lies in addressing specific questions within a project and forming a design around them. In this context, the design itself becomes a form of conclusion—a physical manifestation of problem-solving and exploration.

Achieving the goal

The primary objective of this project was to take a clear step further with the hybrid phaco design by developing a functional prototype and a detailed design that improved on previous iterations. While focused on this immediate goal, the need to zoom out and consider broader questions related to circular design and sterility remained evident. For example, it was only in the later stages of the design process that I fully grasped the sensitivity of the life cycle assessment (LCA), particularly

regarding the impact of the medical blue wrap.

Acknowledging the time constraints inherent in a graduation project, I came to understand that having some questions still open is a natural aspect of the design process. Despite the challenges of navigating the complexity of circular design and sterility concerns, the project has laid a foundation for further exploration and development.

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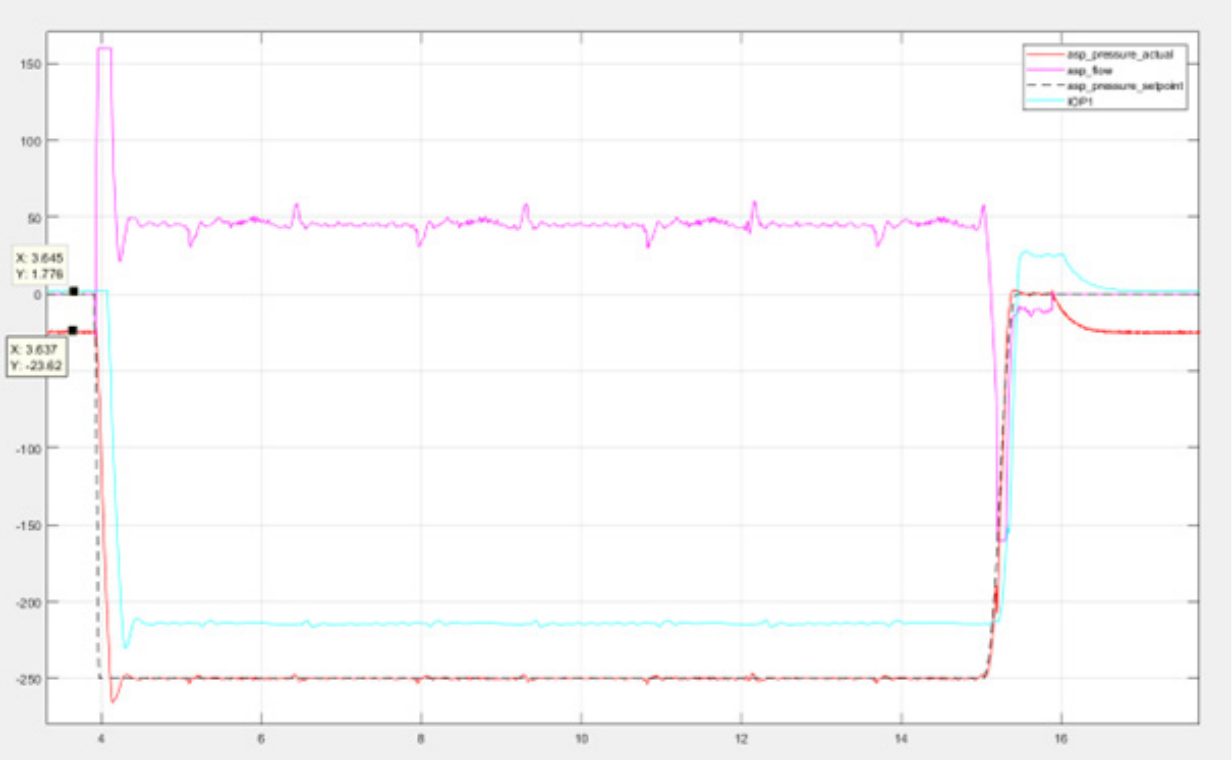
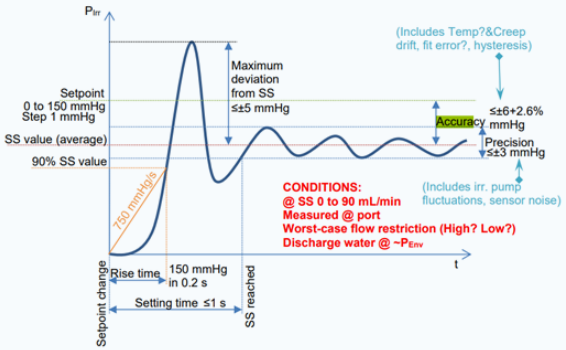
Appendices

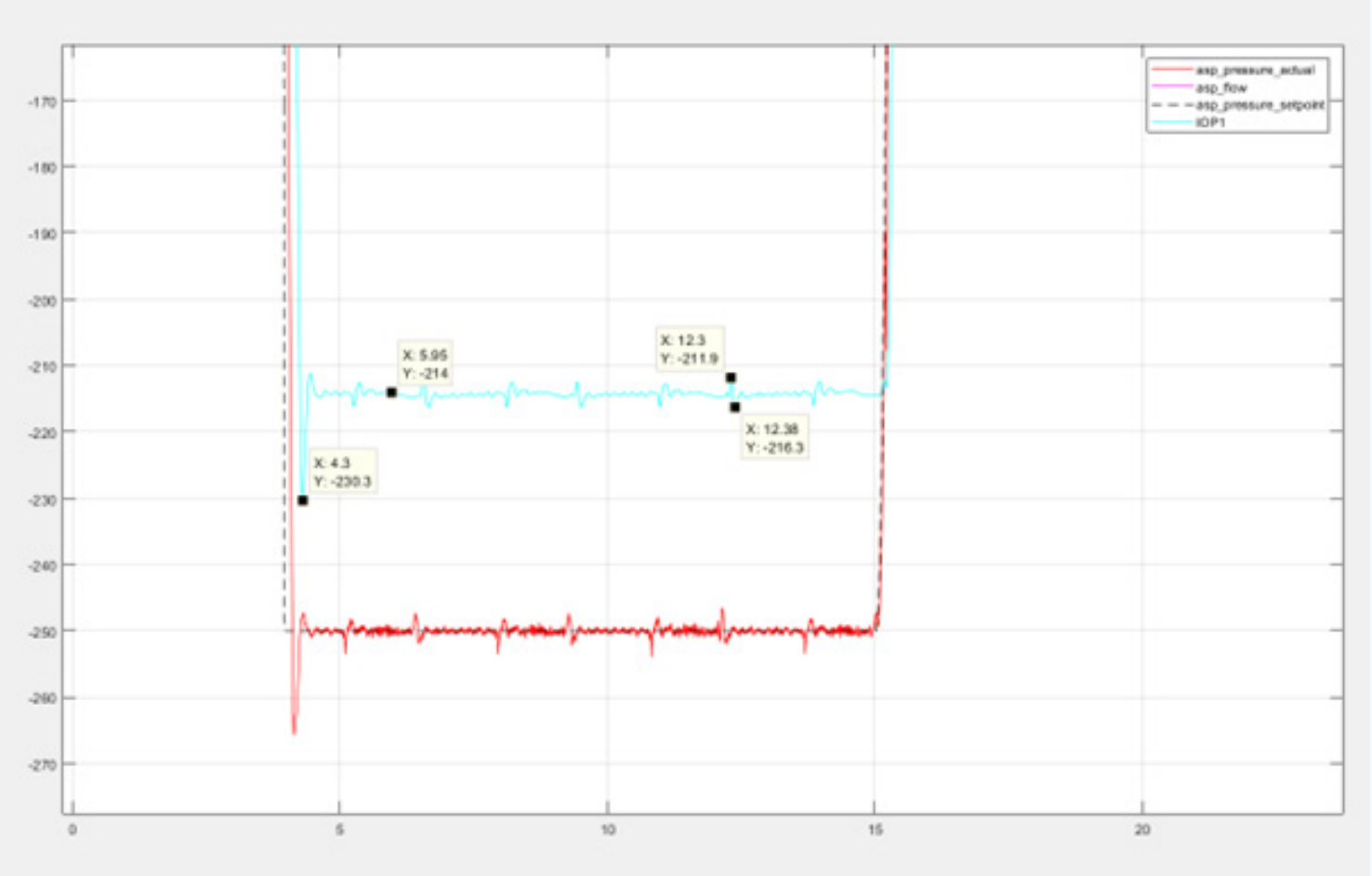
Public appendices

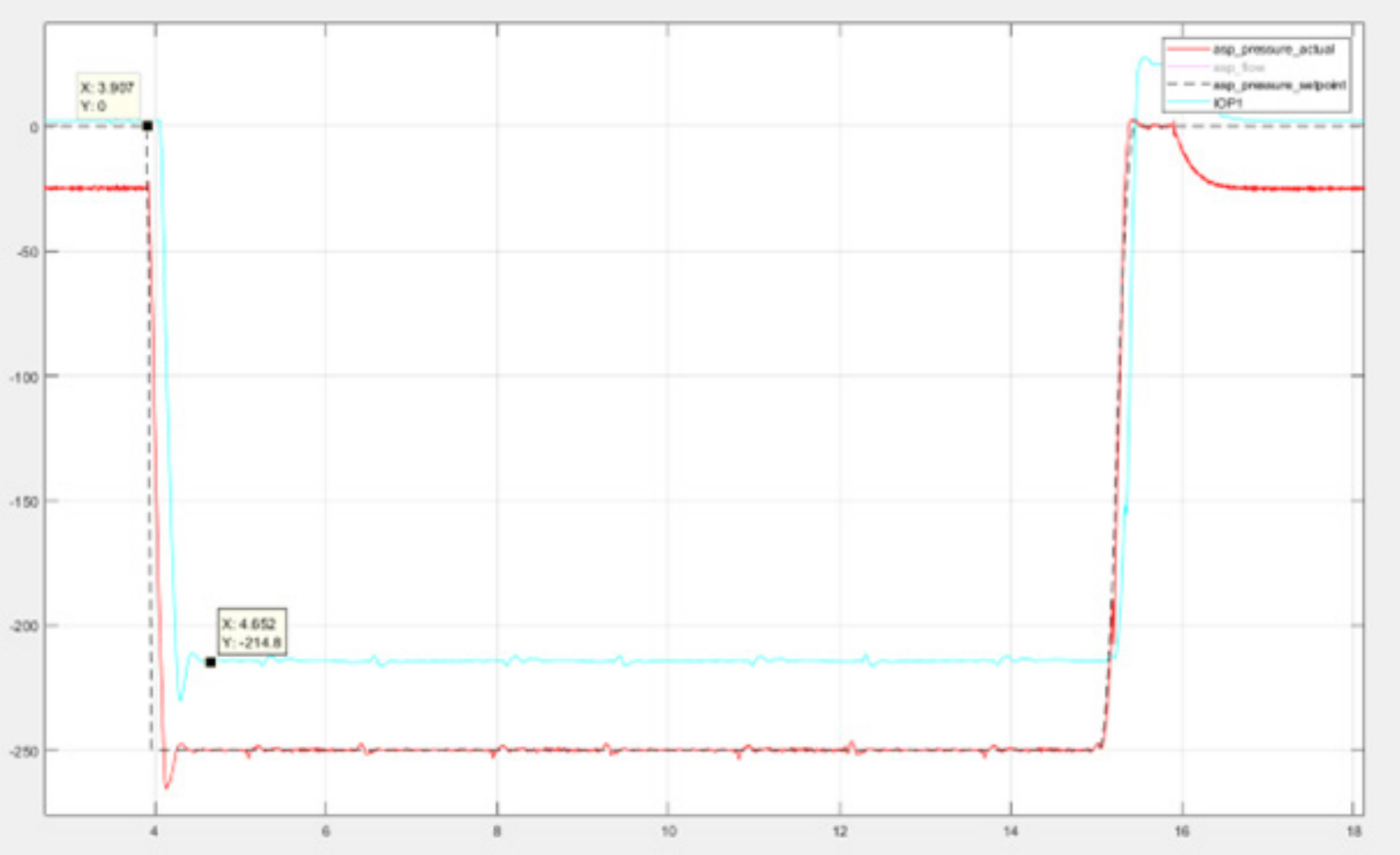
Confidential appendices

Appendix I : Results fluid line characteristics testing

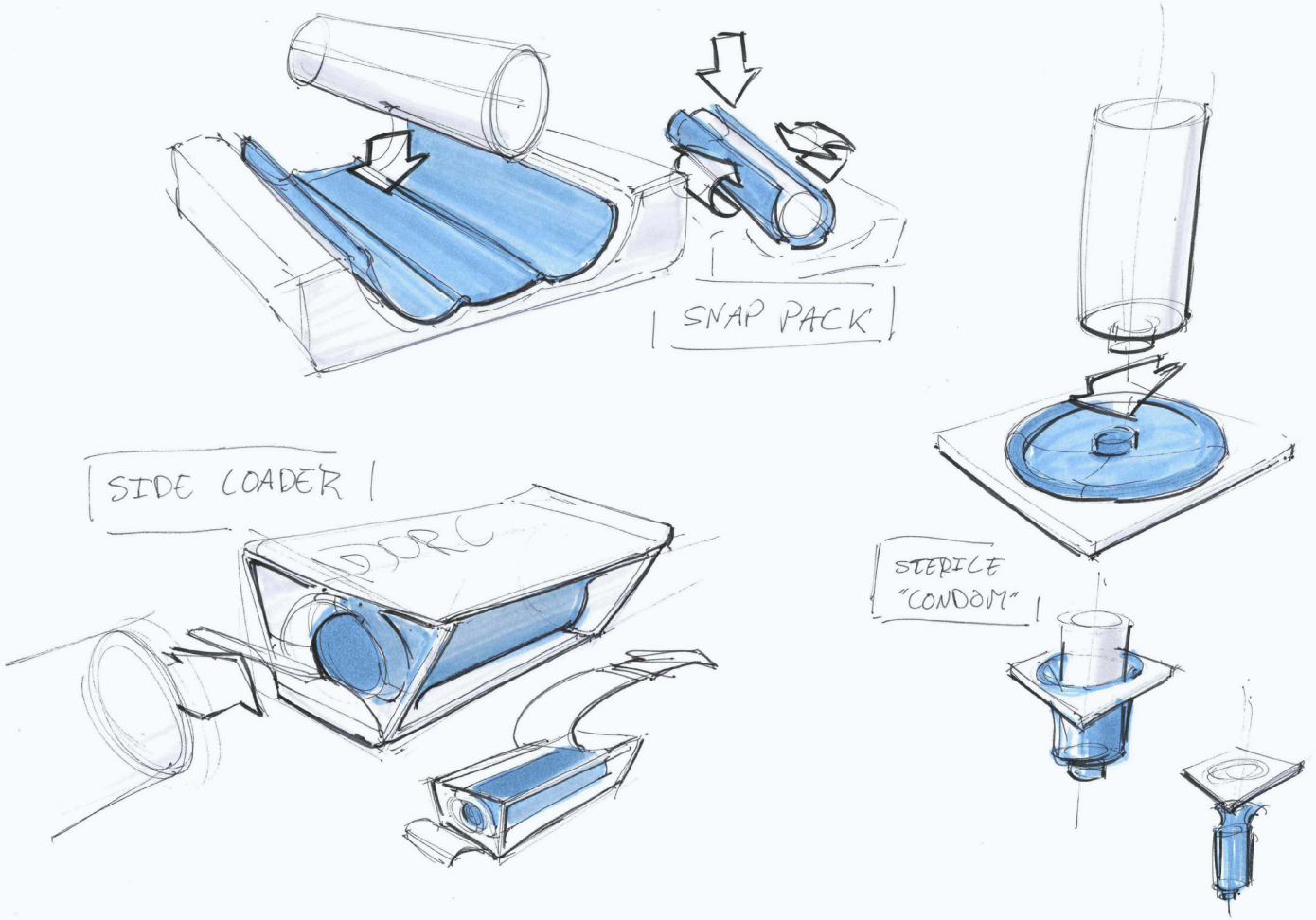


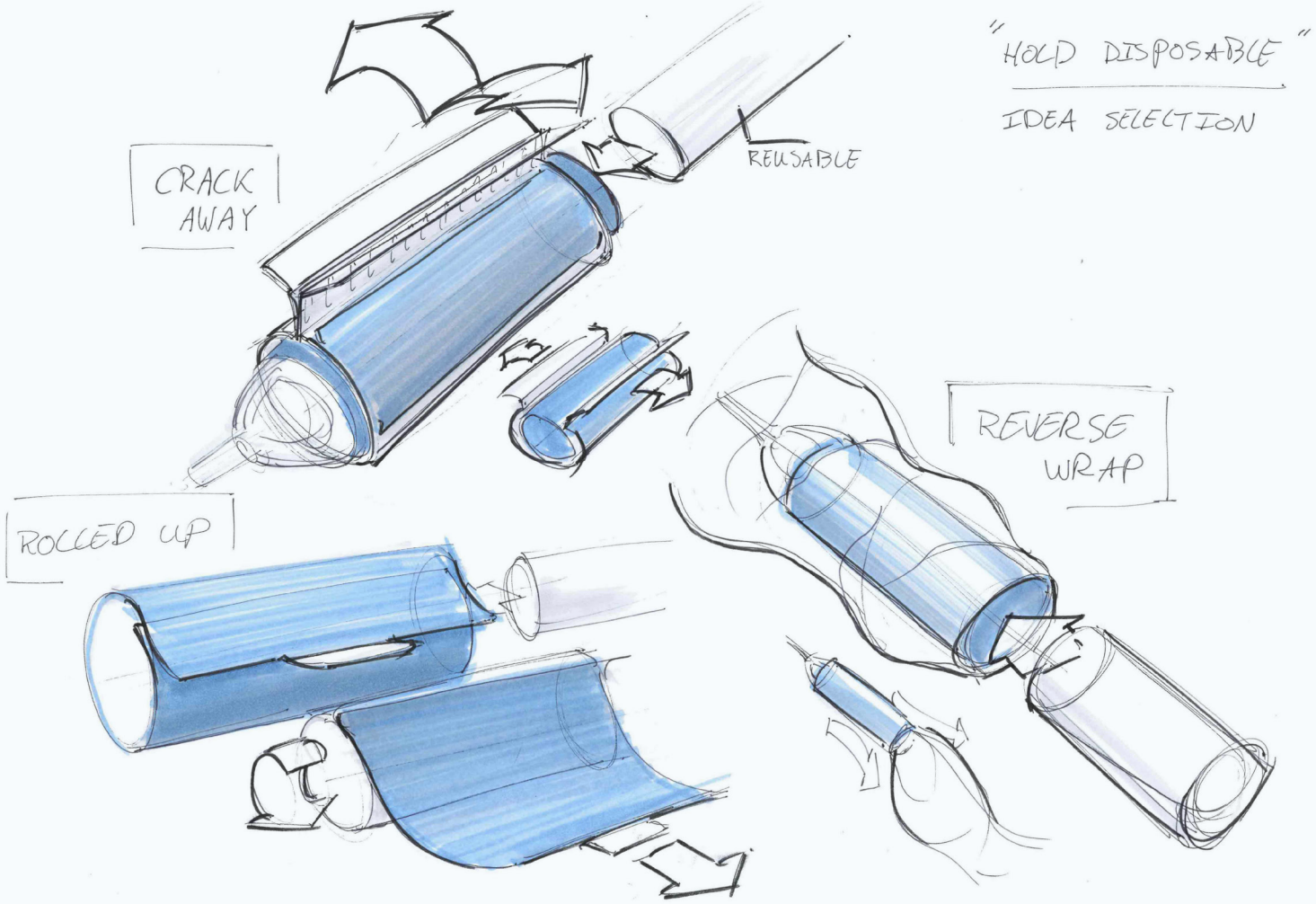



asp_pressure_actual
asp_flow
asp_pressure_setpoint
IOP1
X: 5.95
Y: -214
X: 12.3
Y: -211.9
X: 12.38
Y: -216.3
X: 4.3
Y: -230.3
-170
-180
-190
-200
-210
-220
-230
-240
-250
-260
-270
0
5
10
15
20

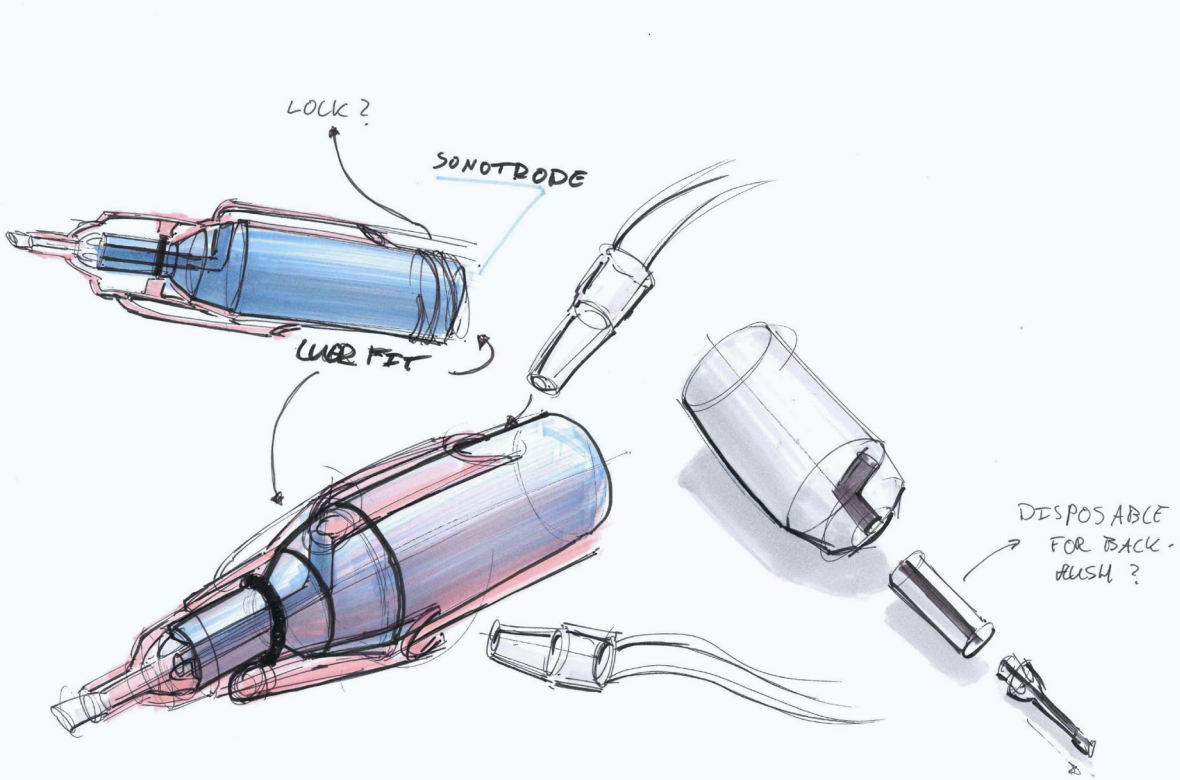

X: 3.907
Y: 0
X: 4.652
Y: -214.8
asp_pressure_actual
asp_flow
asp_pressure_setpoint
IOP1
0
-50
-100
-150
-200
-250
4
6
8
10
12
14
16
18

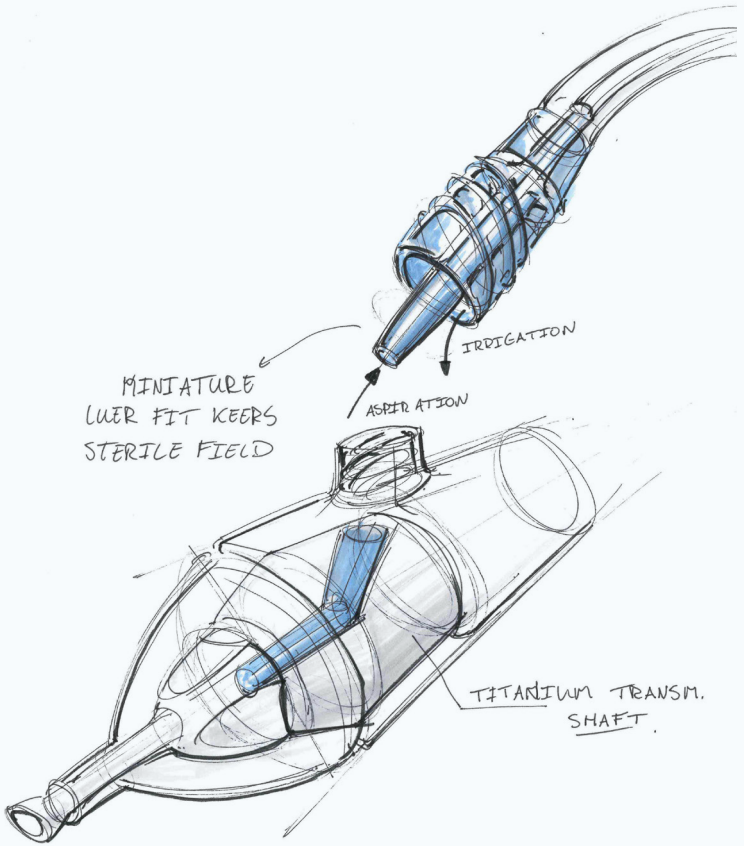
Appendix II : Sterile (dis)assembly method exploration

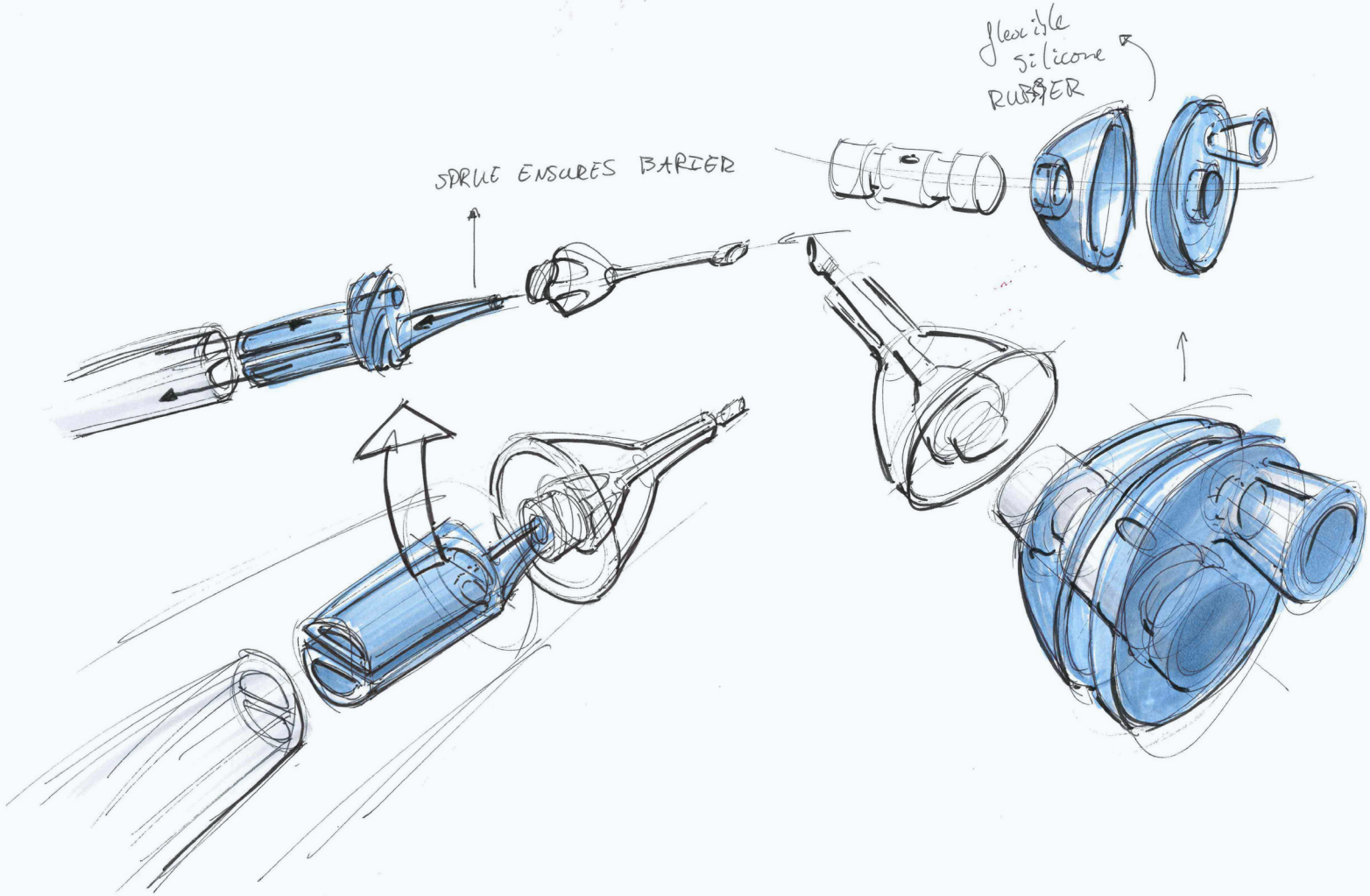


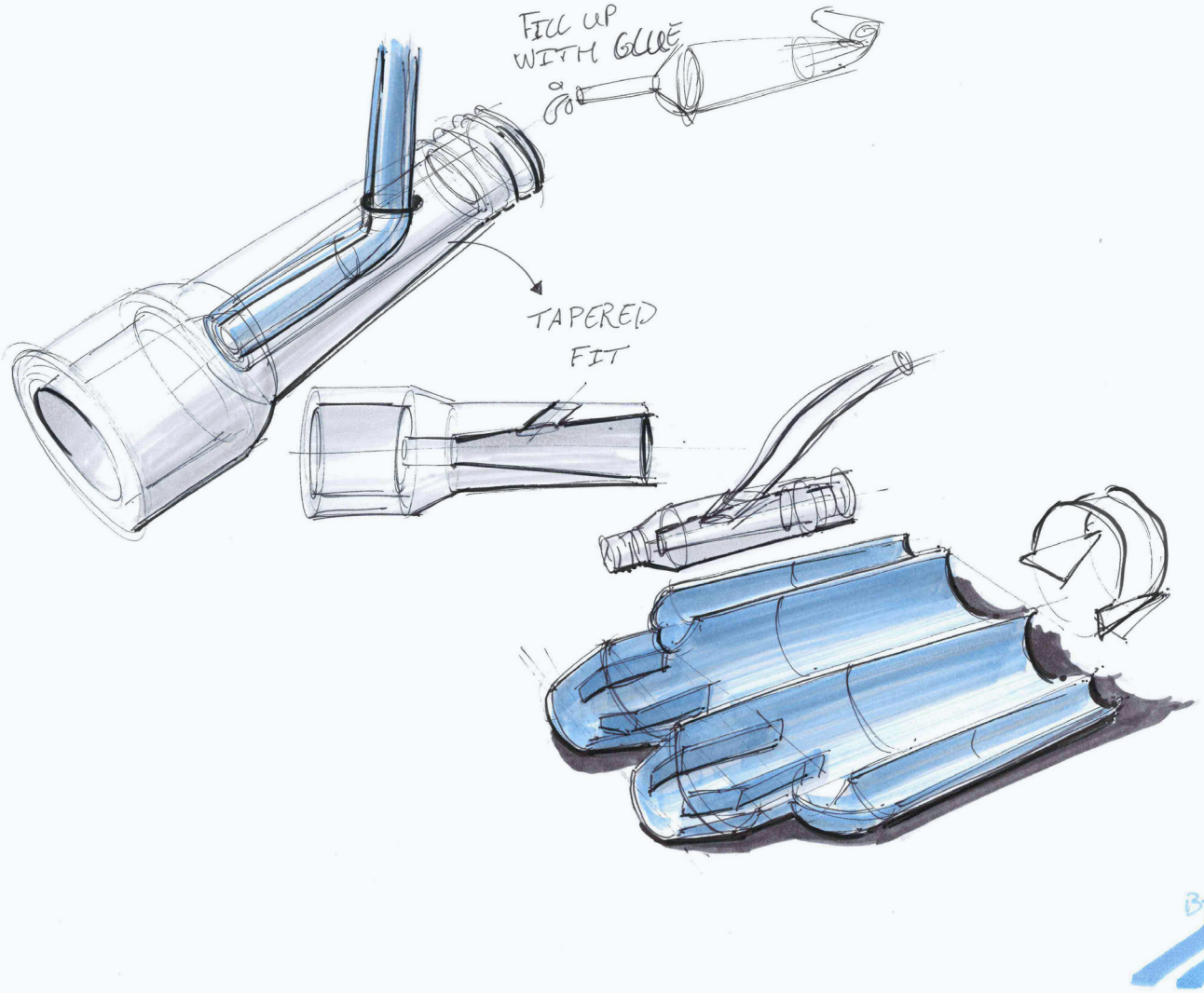

"HOLD DISPOSABLE"
IDEA SELECTION
CRACK AWAY
REUSABLE
REVERSE WRAP
ROLLED UP

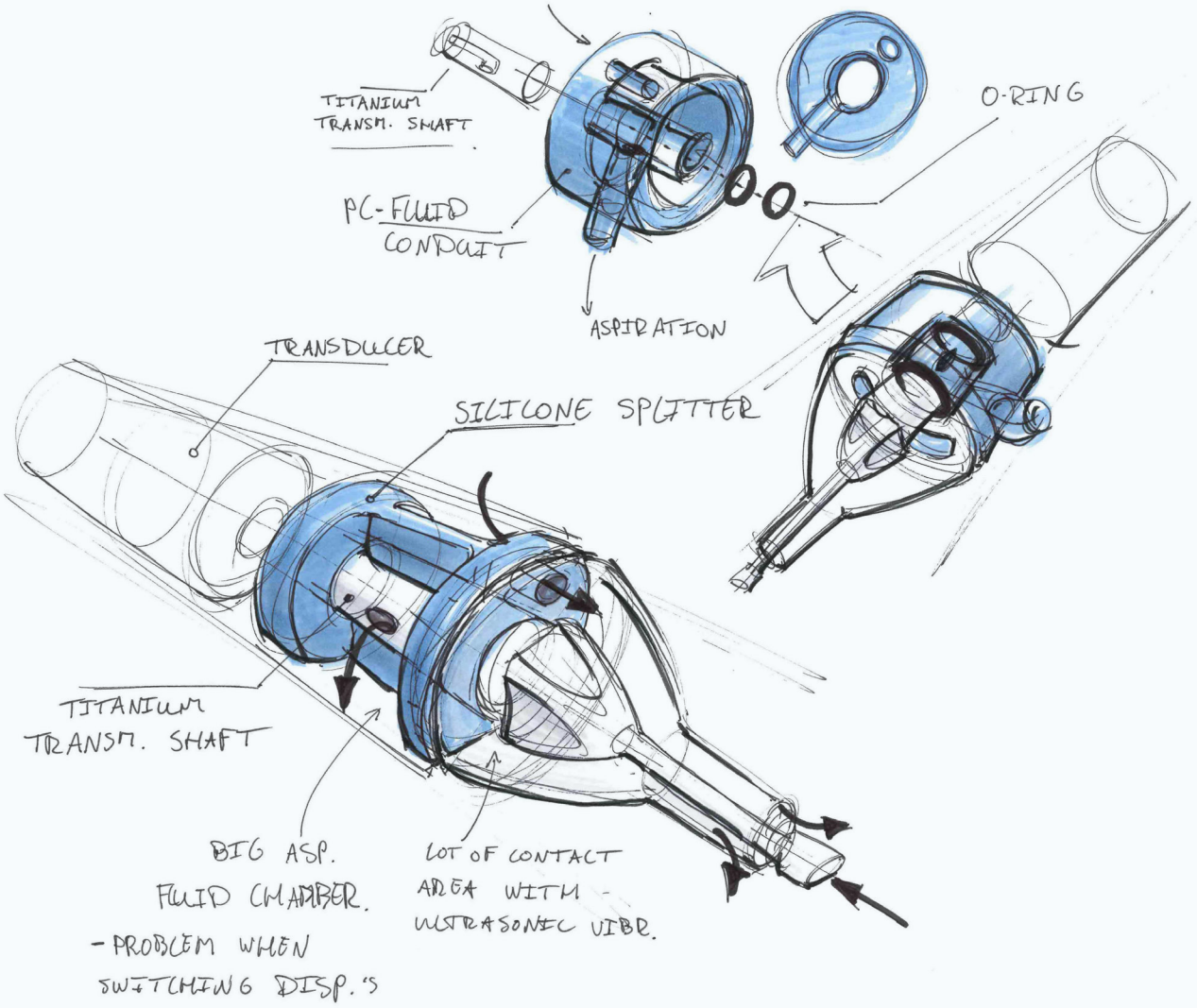
Appendix III : Fluid line redesign exploration



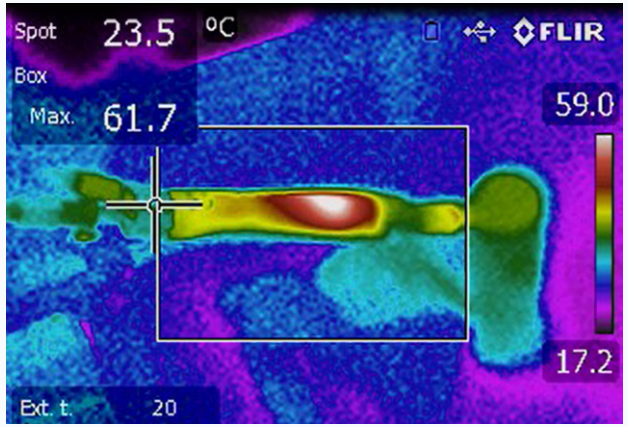



flexible
silicone
RUBBER
SPRUE ENSURES BARIER

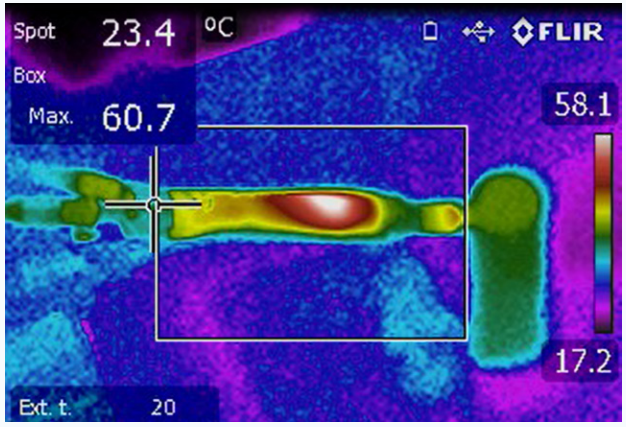

FILL UP
WITH GLUE
TAPERED
FIT


TITANIUM TRANSM. SHAFT
O-RING
PC-FLUID CONDUIT
ASPIRATION
TRANSDUCER
SILICONE SPLITTER
TITANIUM TRANSM. SHAFT
BIG ASP. FLUID CHAMBER.
- PROBLEM WHEN SWITCHING DISP.'S
LOT OF CONTACT AREA WITH ULTRASONIC VIBR.

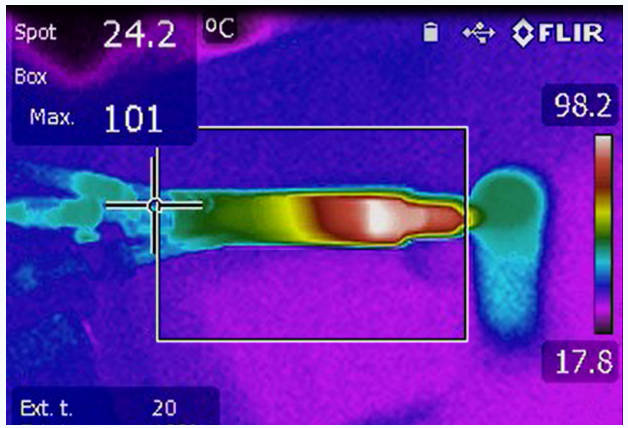
Appendix IV : Heat transfer analysis test results



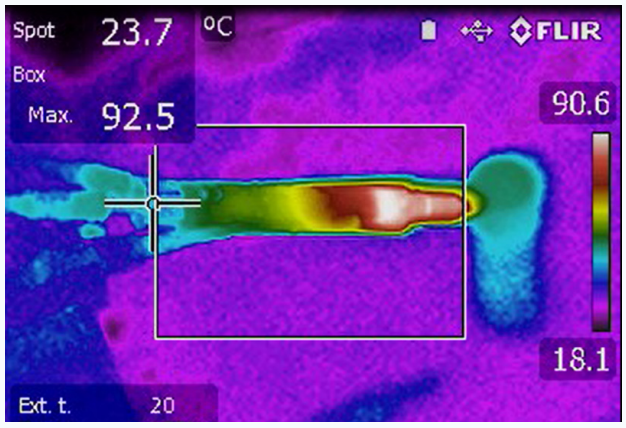
Run A - Aspiration and irrigation, 100% power, after 30 sec



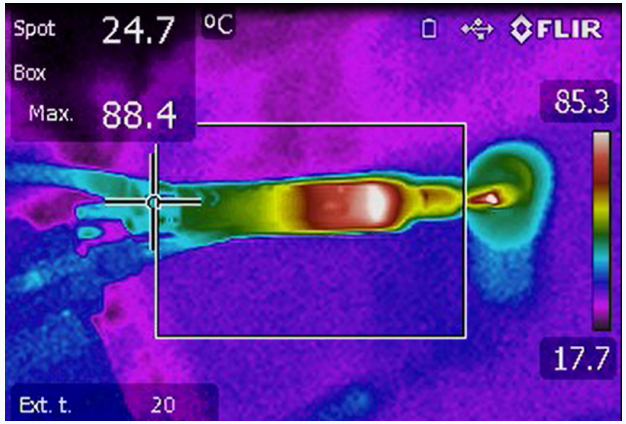
Run B - Irrigation, 100% power, after 30 sec



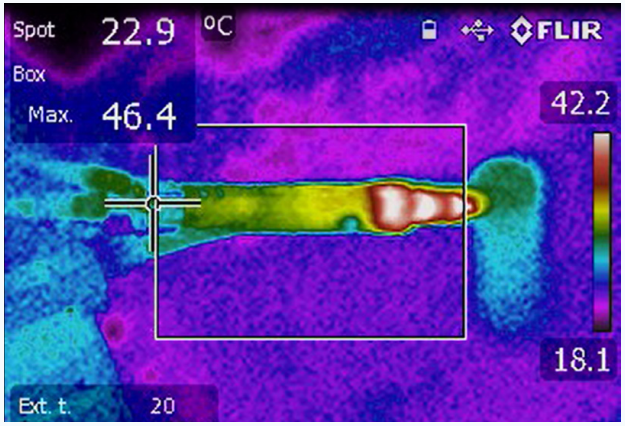
Run C - Aspiration, 100% power, after 30 sec



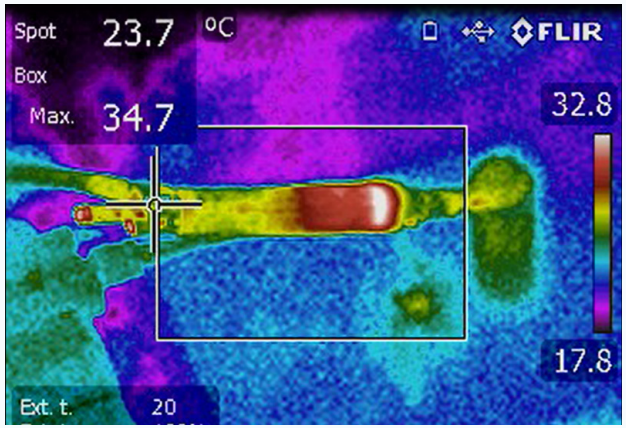
Run D - Just priming, 100% power after 30 sec



Run E - No priming, 100% power, after 30 sec



Run F - Primed , 50% power, after 10 sec



Run G - No priming, 50% power, after 10 sec

Appendix V : Project brief

Personal Project Brief - IDE Master Graduation

Circular Redesign of Cataract Surgery Tool — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 11 - 07 - 2023 22 - 01 - 2023 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

The project operates within the context of cataract surgeries, serving both low-resource and high-resource settings. It aims to develop a handpiece that is both reusable and disposable to address the different needs and concerns in these settings.

The main stakeholders involved include DORC, the manufacturer of the current phaco handpiece, procurement teams in both low-resource and high-resource settings, and surgeons who perform cataract surgeries using the handpiece.

DORC seeks to enhance the reusability of the handpiece while maintaining or improving its functionality. They value cost-effectiveness and recognize the sterilization concerns associated with the current design, particularly in high-resource settings where diseases like Creutzfeldt–Jakob disease pose risks. Their goal is to provide a solution that incorporates disposables, allowing for easier sterilization and addressing concerns in both low-resource and high-resource settings.

Procurement teams in low-resource settings prioritize patient well-being and require an affordable handpiece with improved usability and disposability. They seek a reliable solution enabling them to perform more cataract surgeries efficiently, without the use for sterilization since these facilities are not a given in these contexts.

In high-resource settings, procurement teams share similar concerns regarding sterilization. They prioritize patient safety and seek a handpiece design that reduces the risk of transmitting diseases such as Creutzfeldt–Jakob disease. The new design presents an entirely different value proposition for these settings. With a longer reusable tool and fewer handpieces in the sterilization rotation for a hospital, the more disposable design offers a lower access point. This appeals to high-income countries and low income countries as it provides increased convenience and cost-effectiveness.

Surgeons utilizing the handpiece in both low-resource and high-resource settings prioritize patient safety and value reliability. They seek a design that is perceived as safe, trustworthy, and incorporates disposables to mitigate the risks associated with sterilization challenges.

An important opportunity arises from developing a handpiece that utilizes disposables. By employing disposables, the project can potentially reduce the overall carbon footprint and the total amount of waste generated. Resource-intensive sterilization processes, as well as (for example) packaging to and from sterilization facilities, may outweigh the amount of disposables used in a disposable handpiece design. This presents an opportunity for a lower carbon footprint and a reduction in the overall amount of disposables required. The entire system for performing a phaco surgery will need to be taken into account here.

In summary, the project aims to develop a handpiece that caters to the needs of both low-resource and high-resource settings. By understanding the interests and priorities of the stakeholders involved and considering the opportunities presented by disposable designs, the project seeks to create a handpiece that effectively addresses sterilization concerns, reduces the carbon footprint, and offers an entirely different value proposition for high-income countries.

space available for images / figures on next page

Personal Project Brief - IDE Master Graduation

TU Delft

introduction (continued): space for images

image / figure 1: Original Reusable phaco handpiece design by D.O.R.C.

image / figure 2: Partially disposable phaco handpiece result by AED team "Foresight"

TU Delft

Personal Project Brief - IDE Master Graduation

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The project's scope includes several key challenges that need to be addressed. The first challenge is to design a phaco handpiece that is more reusable but affordable, specifically tailored for low-resource settings. This entails exploring design options that can withstand multiple use cycles without compromising functionality and safety. The goal is to provide a cost-effective solution that can be utilized in settings with limited resources.

Another crucial challenge is assessing the environmental impact of the current handpiece design and validating design choices to improve sustainability. By reducing resource intensive sterilization and making environmentally conscious decisions throughout the design process, the project aims to minimize its ecological footprint.

Manufacturability is a significant consideration in the project. The objective is to develop a mature design that can be mass-produced efficiently and at a lower cost. This involves considering various cost-effective manufacturing processes to ensure the handpiece's feasibility and scalability.

Safety is a top priority in the project. Firstly, the focus is on enabling a sterile design that meets the specific requirements of both low-income and high-income countries. Different approaches may be needed to ensure the handpiece can be used in a sterile way in various resource settings.

Usability concerns, including ergonomics, is not a primary challenge and depend on time constraints.

Aspects outside the project's scope include the nexus system, sterilization system design, and needle tip/sleeve redesign. The project's primary focus is on developing a more reusable, affordable, and sustainable handpiece that addresses the specific challenges within its defined scope.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

This project aims to develop concepts for a phaco handpiece that integrates reusability, affordability, manufacturability, safety, and sustainability. An analysis will be conducted to compare the environmental impact of the current design with the proposed new design. Embodied prototypes and detailed designs will be created to test the handpiece's reusability and safety, and assess the manufacturability and affordability.

The objective is to deliver an embodied and detailed functional prototype that significantly improves sustainability and reusability compared to the original DORC design, while also enhancing affordability and feasibility compared to the AED redesign. The new handpiece will incorporate a combination of disposables and well-protected reusables, clearly defining the boundary between the two for sterile use in both high-income and low-income countries.

The final design will be validated on engineering to ensure its performance and reliability. Initial testing will involve modeling the product, including Finite Element Method (FEM) analysis and modeling of the ultrasonic transducer. Subsequently, usability testing will be conducted in a simulated environment to evaluate the design's usability.

The new design will clearly define the process of changing out disposables, ensuring user safety by providing a sterile device for each use. This enhances usability, reliability, and instills confidence among surgeons.

Through a comprehensive life cycle assessment, the redesign will aim to reduce the total carbon footprint associated with the handpiece, taking into account its complete system context within phaco procedures. By considering the environmental impact throughout its life cycle, including production, usage, and disposal, the project will prioritize a more environmentally friendly and sustainable solution.

Initials & Name L. Timmerman 6680 Student number 4680022

Title of Project Circular Redesign of Cataract Surgery Tool

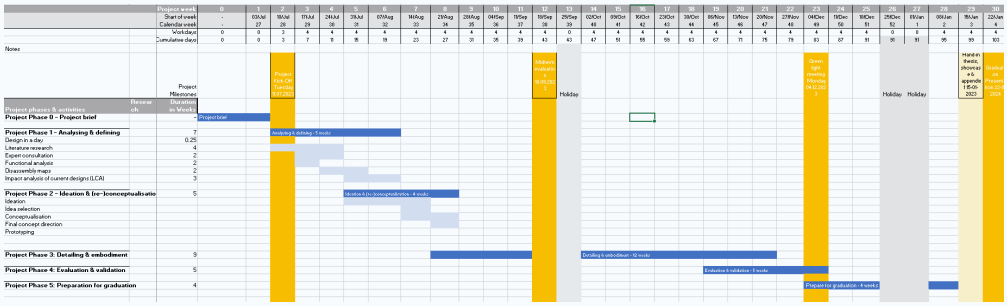
TU Delft

Personal Project Brief - IDE Master Graduation

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 11 - 7 - 2023 22 - 1 - 2023 end date



Initials & Name L. Timmerman 6680 Student number 4680022

Title of Project Circular Redesign of Cataract Surgery Tool

TU Delft

Personal Project Brief - IDE Master Graduation

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

For my graduation project, I am driven by my passion for embodiment design, which was cultivated during my time as a student and teaching assistant at the AED course. Working at Spark Design further refined my skills as a product design engineer, focusing on technical testing, prototyping, 3D modeling, and concept design. Now, during my tenure at TU Delft, I aim to expand my portfolio by incorporating circular product design and acquiring competences in modeling, FEM analysis, integration of design insights, life cycle analyses, and designing for circularity within the medical design space. Additionally, I seek to enhance my competences in detailed embodiment design, including prototyping, manufacturing, and testing.

I specifically set out this project to add circular product design to my portfolio and add the methodology for circular product assessment and design to my toolbox. This is something that I have not yet done in my tenure at IDE and is highly valuable and needed in this time. These methods include disassembly maps and detailed life cycle assessments (LCAs).

Moreover, I wish to further develop my skills in detailed design, a skill that I have cultivated throughout time at the TU Delft and practical experiences. This project's emphasis on embodiment design provides more than enough opportunities for me to enhance these skills.

Additionally, I wish to gain some level of expertise in designing medical products, as I have limited experience in this field. Graduation serves as a secure environment to gain first exposure to this challenging field and broaden my understanding of medical design practices.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Initials & Name L. Timmerman 6680 Student number 4680022

Title of Project Circular Redesign of Cataract Surgery Tool