How to Close the Loop on Catheters

Exploring limitations and opportunities at the end-of-life of single-use catheters

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Exploring opportunities and limitations at the end-of-life of single-use catheters

by

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Sterre de Jong
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Executive summary

While lives are saved through the use of medical devices; they have a significant negative impact on the environment. In particular single-use medical devices make up a large part of the healthcare sector's negative environmental impact as they contribute significantly to generating more medical waste and greenhouse gas emissions. Approximately 90% of medical waste consists of single-use products or components. The incineration of medical waste is still common practice, leading to harmful environmental and human health effects. Additionally, devices that could potentially be recycled, reused or repurposed in another way to help close the loop of a product's life cycle are incinerated instead, which sustains and fuels the unsustainable linear economic model. This research aims to identify opportunities at the end-of-life of single-use catheters that could sustain value and limit the amounts of medical waste produced.

A method is presented that supports approaching this aim, called the *recovery assessment tool* for single-use catheters. The presented method allows for identifying components of a catheter that limit or provide opportunities for recovery purposes at the end-of-life. Two protocols have been developed to guide this process. The first protocol covers the dismantling process to explore the build-up of a catheter and separate components to establish a Bill of Materials. The second protocol describes the procedure that was followed to analyse a catheter. The Bill of Materials is used as an input to assess a catheter at the sub-assembly and component level. The assessment evaluates a catheter on three types of indices: disassembly indices, hygienic recovery indices and material recovery indices. The outcome of the assessment is a graphical visualisation that highlights areas of attention for recovery. By interpreting these results using the explanations given with each index, components can be identified that limit or provide opportunities for recovery purposes at the end-of-life of single-use catheters.

Two single-use catheters of Philips were assessed as a case study with the proposed methodology. A Bill of Materials for each catheter was established with the results of a material investigation in the lab. The results of the case studies led to several limitations and opportunities for catheter recovery. The first limitation is that cleaning catheters can be challenging, given their long tubular shape and the fact that almost all components and sub-assemblies cannot be disassembled and reassembled again. This limitation may impede recovery options since catheters must be cleaned and sterilised after use if considered for recovery purposes because they come into contact with blood. Additionally, catheters are lightweight devices, meaning they make up only a small amount of the piles of medical waste produced daily. Still, catheters are high-value devices; therefore, any form of recovery is valuable. Opportunities for recovery at the end-of-life of catheters have also been identified. It was determined that catheters contain valuable metals that could be recovered to reduce medical waste, sustain value and potentially decrease the demand to collect raw materials. Also, most of the materials used in the case studied catheters seem compatible with ethylene oxide sterilisation which provides an opportunity for recovery; however, this must be thoroughly validated. Finally, it is suggested to reconsider the design or build-up of a catheter. Investigating opportunities for a hybrid design and exploring the possibility of recovery of functional modules for new catheters at the end-of-life are suggested.

The outcomes of this research indicate that closing the loop on single-use catheters is a complex problem in terms of circularity due to their hygienic criticality and light weight compared to the waste produced daily per hospital bed. The amount of medical waste produced due to the use of catheters is only the tip of the iceberg. However, as Philips aims to have products with minimal material usage and maximum circulation to realise the transition to a circular economy, all small steps to achieving this goal are welcome.

List of Abbreviations and Glossary

Abbreviations

BOM	Bill of Materials
CAD	Coronary Artery Disease
CE	Circular Economy
CS	Common Specifications
EoL	End-of-Life
EtO	Ethylene Oxide
IGT-D	Image-Guided Therapy Devices
IVUS	Intravascular Ultrasound
LCA	Life-Cycle Assessment
MDR	Medical Device Regulation
OEM	Original Equipment Manufacturer
RoHS	Restrictions on Hazardous Substances
SUD	Single-Use Device

Glossary

Circular Economy	"A circular economy (CE) is an industrial system that is restorative or regenerative by intention and design. It replaces the 'end-of-life' concept with restoration, shifts towards the use of renewable energy, eliminates the use of toxic chemicals, which impair reuse and return to the biosphere, and aims for the elimination of waste through the superior design of materials, products, systems, and business models" [1].
Disassembly	Disassembly is considered the reversible process of removing the connectivity of parts in a product so the product is separated into its constituent parts, components, sub-assemblies or other groupings. Reassembling is the process of putting the disassembled parts of a product back together [2], [3].
Dismantling	Dismantling is considered the irreversible process of removing the connectivity of parts in a product. A destructive operation is required to dismantle a device, often resulting in damage to parts of the product [2], [3].
End-of-life	The life cycle stage when a product reaches the state of obsolescence and therefore, reaches the end of a functional life. The product then becomes waste in a linear economy but this process can be reverted in a circular economy [4].
Obsolescence	"A loss of perceived value of the product that leads to it being discarded from the economic system when the user considers it as no longer useful" [5].
Recovery	Any operation with the primary aim of reversing obsolescence [5].

Recycling	Recycling is the process of recovering a device by breaking it down into its constituent parts or materials and reassembling it into a new usable form or product. In recycling, the initial identity and functionality of the products and components are lost [6], [7].
Refurbishing	Refurbishing, also often referred to as remanufacturing, is a process in which manufacturers recollect devices - usually high-complexity, long-life devices - when they reach end of their lifetime and put them back into service through upgrading and replacing parts [7], [8].
Reprocessing	"Reprocessing means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device" [9].
Single-use device	A 'single-use device' (SUD) is defined in the MDR as a device intended to be used on one individual during a single procedure and to be discarded after the procedure [9]. Also referred to as consumable or medical disposable.
Sub-assembly	A sub-assembly is a group of components integrated into a unit that forms a part of a larger assembly, being the product as a whole [2].

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1 Introduction

This chapter gives an introduction to the background and relevance of the subject of this thesis, followed by the problem statement and research questions that are addressed in this thesis. The context and scope of the project, and a description of the outline of this thesis are given subsequently.

1.1. Background

While lives are saved through the use of medical devices, they have a significant negative impact on the environment. The healthcare industry is responsible for 4.4-4.6% of global greenhouse gas emissions caused by healthcare facilities directly or indirectly from the supply chain of healthcare goods and supplies [10], [11]. Although the healthcare industry has always been resource-intensive, one of the concerns is the growing reliance on single-use disposable medical devices, particularly in high-income countries [12]. In addition, COVID-19 caused a surge in tens of thousands of tonnes of extra medical waste, which made The World Health Organization call for reforms surrounding medical waste disposal [13].

Single-use medical devices are a large part of the healthcare sector's negative environmental impact as they contribute to generating more medical waste and greenhouse gas emissions. Approximately 90% of medical waste consists of single-use or disposable products or components [14]. Single-use devices are typical for a linear economy in which products are manufactured from the earth's finite natural resources, used only once and discarded after use. This linear pattern ('take-make-waste') leads to high levels of waste and pollution, thereby threatening human health and the biosphere [10], [15], [16]. In Europe, incineration of medical waste after disposal is still common practice, which can harm human health and the environment. On top of that, devices - and their constituent components and materials - that could potentially be recycled, reused or repurposed in another way are incinerated instead, which sustains and fuels this unsustainable linear economic model [17].

Initially, the introduction of single-use medical devices was perceived by hospitals as a medical safety measure and an enhancement in convenience [18]. For manufacturers, opportunities arose to guarantee sales revenues by selling single-use medical devices instead of their reusable counterparts [8], [19]. However, at this moment, the growing concern and awareness regarding the climate crisis make single-use medical devices a glaring issue [20]. Single-use devices (SUDs) - also often referred to as disposables or medical consumables - present a challenge to pursuing sustainable practices, given their linear life cycle. The growing numbers of waste are primarily due to the growing disposable culture in healthcare [14], [21]. Significant changes at all levels, from global to the hospital floor, are required to manage this healthcare waste stream and support solving the climate problem [13].

In recent years, the concept of a *circular economy* (CE) has gained widespread attention for improving product sustainability. The number of studies from academia on circular economy strategies and principles has also been rapidly growing [8], [10]. In contrast to a linear economy that assumes disposal at the end-of-life (EoL) of a product, the concept of circular economy aims to radically limit the extraction of raw materials and production of waste via recovering and reusing products and materials as much as possible at the end-of-life

to sustain value [1], [22]. End-of-life is the stage where a product is discarded and becomes waste in the linear economy, whereas, in the CE, the value can be restored at the end-of-life via recovery methods [4].

Despite the awareness of the environmental impact and large amounts of waste due to single-use medical devices, resources that guide towards more circular solutions are limited in this field [8]. This can be explained by the fact that patient safety and device performance requirements are top priorities in the medical device industry. They make it challenging to implement circular initiatives for single-use devices. Even though the delivery of high-quality care is the top priority of hospitals, it is evident that comprehensive waste minimisation and circular recovery methods can both save environmental and financial resources [15], [18].

Single-use medical devices often result in several times higher fossil fuel consumption and global greenhouse gas emissions on a life cycle basis than their reusable counterparts. Several studies proved this through conducting a life-cycle assessment (LCA) that compares single-use versus reusable medical devices [23]–[26]. A LCA study on electrophysiology catheters indicates that the global warming impact is reduced by 50.4% and the abiotic resource use by 28.8% when using a recovered catheter as an alternative to an electrophysiology catheter that is discarded after a single-use [4].

The European Commission intends to promote the European Union's transition to a more circular and sustainable economy via the European Green Deal. The Green Deal impacts the healthcare sector in many ways: policy, regulations, and strategies are and will be laid out in the coming months and years to achieve the set sustainability goals [27]. In the Netherlands, healthcare institutions, government authorities and companies have already set out agreements in the Green Deal to jointly accelerate the sustainability of the healthcare sector to ensure that healthcare not only benefits people but also fosters the reduction of the impact on the environment [28], [29]. More than 200 parties in the healthcare sector, including Philips, signed this agreement to achieve this goal and create more circular initiatives. One of the four pillars of the Green Deal is to produce less waste and reuse more materials and products [30].

Unless medical devices are designed for multiple resource cycles or if more solutions exist for end-of-life objectives of single-use medical devices, the burden on medical waste management and inventory management will grow with no end in sight [8], [10]. The time is ticking, and more initiatives should be taken toward minimising the amounts of medical waste and optimising recovery methods to recover as much of the value of products at the end-of-life and achieve the sustainability goals.

1.2. Problem description

1.2.1. Research context

This research has been conducted in collaboration with Philips, which transformed over the years into a focused leader in health technology. Philips aims to improve people's health and well-being through meaningful innovation. This purpose drives them to improve 2.5 billion lives annually by 2030, including 400 million in under-served communities. The circular economy is one of the key pillars of Philips' sustainability programme and transformation strategy. They operate sustainably, according to high Environmental, Social and Governance (ESG) standards. This thesis focuses on the environmental aspect and the two corresponding UN Sustainable Development Goals: 12. Ensure sustainable consumption and production patterns and 13. Take urgent action to combat climate change and its impacts [31], [32].

1.2.2. Scope

The research in this thesis is limited to Philips' Intravascular Ultrasound (IVUS) catheters. This is one of the categories of single-use devices that Philips has in its portfolio of Image-Guided Therapy (IGT) Devices. These devices must be discarded after use, meaning that they will be incinerated or buried in a landfill and that nothing is recovered after use.

IVUS catheters are high-value disposable devices (~1000 dollars) used for diagnostic procedures to visualise the inside of coronary arteries [33], [34]. These catheters provide cross-sectional images that can assess the presence and extent of plaque pre-and post-treatment. The imaging transducer at the tip of an IVUS catheter sends out high-frequency sound waves that bounce off vessel walls and are reflected to the system in different intensities, depending on the tissue [34], [35]. The function and application of IVUS catheters in general and

the catheters that will be studied in this research will be explained in more detail in Chapter 2.6.

1.2.3. Problem statement

Currently, circular principles have not been implemented for Philips' IVUS catheters, given that the design focus for catheters has always been on performance and safety requirements instead of circularity. However, Philips' ambition for 2025 is to design all of its products optimised for circularity and to have an optimised material footprint over the entire life cycle. All products should have minimal material usage and maximum circulation to realise the transition from linear to circular strategies. Currently, all of these catheters are discarded after use, contributing to the growing amounts of medical waste. Therefore more initiatives should be taken to recover value at the end-of-life.

1.2.4. Research aim and questions

Given the push toward implementing circular initiatives in the healthcare sector and the reliance on single-use medical devices, the aim of this study is to identify opportunities at the end-of-life of single-use catheters that sustain value and limit the environmental impact.

This research will be guided by the following research questions:

1. What product and material recovery methods exist in the medical device industry?
2. What type of recovery methods are suitable for catheters?
3. How to assess the readiness for recovery purposes of catheters?
4. How does a catheter currently score in terms of recovery?
5. What limitations and opportunities can be identified based on the assessment of a catheter on recovery purposes?

The first two research questions will be answered through the use of literature. The third research question will be answered through the development of a new method, and the last two research questions will be answered based on the results and interpretations of the results of this method.

1.3. Structural outline

This thesis consists of 6 chapters that are described briefly below in Table 1.1.

Chapter	Description
1. Introduction	This chapter gives an introduction to the background and relevance of the subject of this research, followed by the problem statement and research questions. The context of the project, scope and the outline of this thesis are given subsequently.
2. Theoretical Background	This chapter provides a general basis of knowledge about the circular economy and frameworks with regard to circular strategies. The objective is to provide an overview of the background information and literature that is relevant. All the key concepts and terms that are used throughout this thesis are highlighted.
3. Methodology	This chapter presents the development of a method that evaluates the readiness of a single-use catheter for recovery purposes at end-of-life. This method will be validated through two-case studies of which the results are discussed in the next chapter.
4. Results	This chapter presents the results of two case studies that use the proposed methodology.
5. Discussions and limitations	This chapter discusses the meaning and relevance of the results of the case studies, in line with the research questions. After discussing the applied method and results, the study's limitations are presented. The chapter will conclude with recommendations for future research and the study's significance for Philips.
6. Conclusion	This chapter concludes this thesis by summarising the key research findings in relation to the research aim and questions and discussing its value.

Table 1.1: **Thesis outline**

2

Theoretical Background

The objective of this chapter is to provide an overview of the background information and literature that is relevant. All the key concepts and terms that are used throughout this thesis are highlighted.

2.1. Introduction

This chapter presents information that helps to answer the first two research questions of this thesis:

- What product and material recovery methods exist in the medical device industry?
- What type of recovery methods are suitable for catheters?

The chapter is, however, not limited to this. Before exploring the recovery methods in the medical device industry, a general introduction to the linear and circular economy will be provided. Also, the concepts 'end-of-life' and 'recovery' that are used frequently across this thesis, are explained in more detail. The most commonly used circular frameworks are presented, followed by a more detailed look on circular product design and circular strategies that encourage product recovery of medical devices in specific. Finally, background information is presented on the devices that are considered for research in the following chapters.

2.2. Circular frameworks

2.2.1. The linear economy

The linear economy is represented by a take-make-waste pattern. We harvest and extract materials from the earth, use them to manufacture products, and discard them as waste when they can no longer serve their purpose - a linear process. This model is based on depletion and extraction while disturbing the natural equilibrium existing in the environment [16], [22]. The term used for the mechanism by which products in the linear economy become 'waste' is called '*obsolescence*': 'a loss of perceived value of the product that leads to it being discarded from the economic system'. A product can become obsolete when the user considers it no longer useful or significant [5]. For single-use medical devices, this means that a device already becomes obsolete after one use. In a linear economy, reaching the state of obsolescence is permanent when a product is discarded. In a circular economy, conversely, the state of obsolescence is not considered permanent as it can also be reversed.

2.2.2. The circular economy

In a circular economy, on the other hand, the value of materials is preserved for as long as possible by keeping them in the system by lengthening the life of the products formed from these materials or by *looping* them back into the system to be reused [5]. Ideally, waste and pollution are eliminated; all products and materials are reused, and nature is regenerated, constituting a closed-loop. According to the foundations of a circular economy, obsolescence of a product or material should not result in waste because products and materials are, in principle, reused and cycled indefinitely. Actions of '*recovery*' should be taken to remove the product or material from its state of obsolescence, thereby returning them into the economic system while restoring perceived value. Recovery can be seen as the term for any operation aiming to reverse or postpone obsolescence [5], [8]. As indicated before, the state of reaching obsolescence is permanent in a linear economy. In

contrast, in a circular economy, the state of obsolescence can be reversed via an action of recovery at the end of a life cycle.

2.2.3. End-of-Life (EoL)

In a linear economy, reaching the state of obsolescence means reaching the end of a functional life of a product. This is considered the '*end-of-life*' stage of a product, where it becomes waste and the product cannot be recovered in a linear economy. A circular economy, however, is built on principles that eliminate waste and that keep products and materials in use by restoring value at the end of a product's life. Therefore, the end-of-life stage should never be reached in an ideal circular economy; products and materials should keep flowing and circulating through the circular economy system. This system and the processes that keep products and materials in circulation are illustrated in the Butterfly Diagram.

2.2.4. The Butterfly diagram

The butterfly diagram in Figure 2.1, also called the circular economy system diagram, illustrates the desired flow of materials in the circular economy. Two cycles can be distinguished: the green, biological cycle and the blue, technical cycle [22]. The biological cycle illustrates the nutrients from biodegradable materials that are returned to the earth. The technical cycle refers to products, components and materials that are kept in circulation in our economy for as long as possible by reusing, repairing, remanufacturing and recycling. Accordingly, materials will be kept in use and never become waste [22], [36].

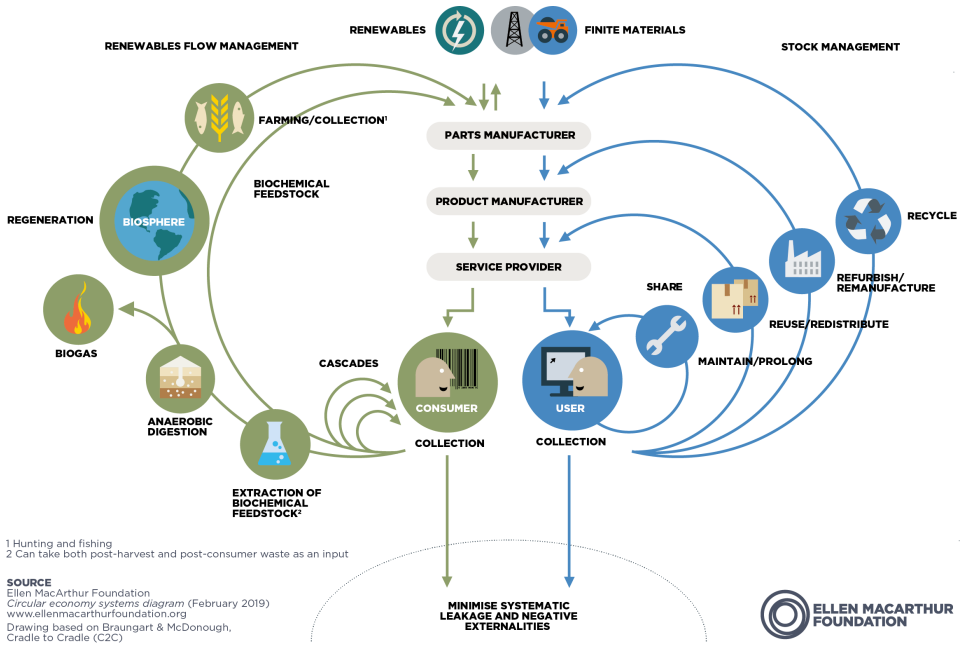

Figure 2.1: **Butterfly diagram.** From Ellen MacArthur Foundation [22]

The circular strategies that can be distinguished from the blue, technical cycle are the loops that are depicted on the right-hand side of the diagram. These circular strategies are methods of recovery at the end of a product's life cycle to remove a product from its state of obsolescence. These loops represent the processes of sharing, maintaining, prolonging, reusing, redistributing, refurbishing, remanufacturing and recycling.

The closer the loop is to the middle of the diagram, the most value can be captured in the system; these loops have a lower environmental impact and lower waste production because they retain most of the embedded value of a product by keeping it whole. The closer the loop is to the middle of the diagram, the less a product needs to be changed to be suitable for reuse, and the faster it turns back to use, the greater the savings on material, labour, energy and capital embedded in the product, as well as the reduction of green house gases, emissions, waste and water [1]. Retaining the value of a product is most effective when it is maintained and used again with the same function and therefore, the inner loops should be prioritised [16], [36].

The strategy of breaking down the product into components and into their constituent materials for recycling is least desired and is considered as a last resort. However, while the embedded value is lost by reducing a product back to basic materials with recycling, it is still an important recovery strategy given that the product or its materials are not ending up as waste [16], [22], [36]. Given the highly regulated landscape of healthcare, it is more difficult to apply these recovery strategies, this will be discussed in more detail in section 2.4.2.

2.2.5. The 9R framework

Another conceptual framework that is often used to describe different circular strategies that can be adopted within the production chain, can be seen in Figure 2.2. This list is referred to as the 9R framework, it presents R-strategies that have been developed to achieve less resource and material consumption in product chains and make the economy more circular. Over the years, many adjustments and additions have been made to this list, specified for different industries to support the adoption of circular strategies [37].

Similar to the prioritisation of recovery methods in the butterfly diagram, the 9R framework sorts the circular strategies in order of priority: the range of strategies are ordered from high circularity (low R-number) to low circularity (high R-number). A distinction is made between three types of strategies:

- R0-R2 are strategies that focus on smarter product use and manufacturing that reduce the consumption of natural resources and materials applied in a product chain: refuse, rethink and reduce.
- R3-R7 are strategies that focus on extending the lifespan of products and its parts: reuse, repair, refurbish, remanufacture and re-purpose.
- R8 and R9 are strategies that focus on useful application of materials: recycle and recover.

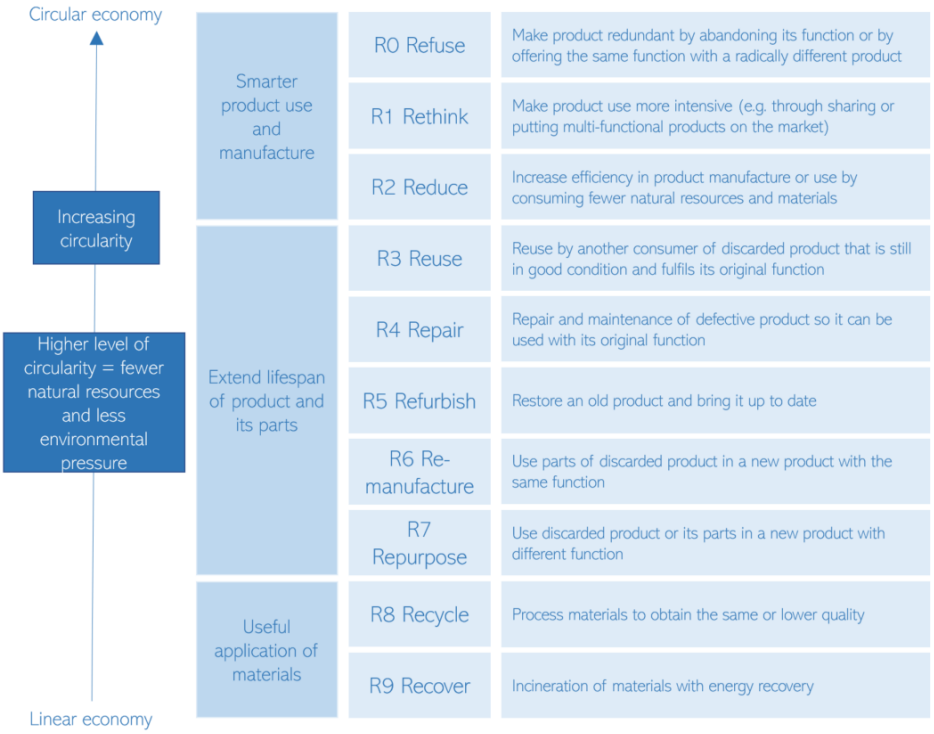

Figure 2.2: **The 9R framework of circularity strategies in order of priority.** Adapted from Potting, Hekkert, Worrell, *et al.* [37]

In comparison with the Butterfly diagram, the 9R framework is also making an effort to pay attention to circular strategies on a higher level with taking refuse, rethink and reduce into account. Unlike the recovery methods from the Butterfly diagram, these strategies do not involve only actions that can be taken to restore value at the end of a life cycle of a product. These strategies demand the reconsideration of the way a product is currently used. In this framework, recovery is seen as energy recovery from incineration of materials, this definition of recovery is not adopted in the rest of this research.

2.3. Circular economy at Philips

As mentioned in Chapter 1, Philips has an end-to-end approach to circularity, reducing, reusing and recycling wherever possible. It aims to minimise the use of new materials and resources while simultaneously maximising the lifetime value of its products and solutions through innovative service models, smart digital solutions, and product take-back, refurbishment and parts recovery. Figure 2.3 illustrates the business models that Philips is currently adopting to drive the transition from a linear to a circular economy. Vertically, the life cycle of a product in the linear economy can be seen, the take-make-waste pattern. The loops on the right describe the circular business models and visualise the circular product life cycle. These business models help to optimise the value and utilisation of resources in different ways. These loops have enabled Philips to start closing the loop on their medical equipment. Philips wants to minimise or avoid extracting virgin materials and avoid making waste. Just as in the Butterfly diagram from Figure 2.1, the loops closer to the middle of the diagram in Figure 2.3 are most valuable for Philips.

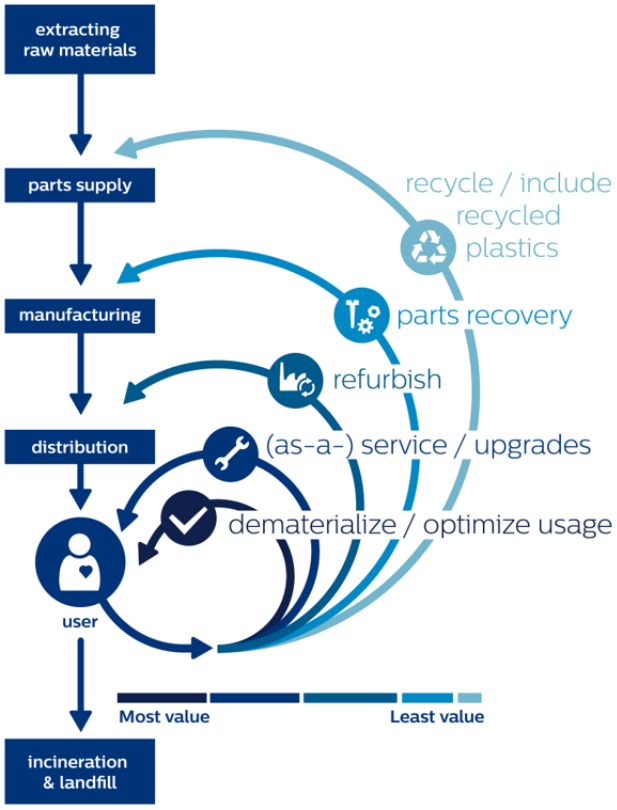

Figure 2.3: **Circular Business Models by Philips.** Adapted from Philips [32]

Philips offers a portfolio of pre-owned systems with thoroughly refurbished, upgraded and quality-tested equipment at a lower cost. The portfolio includes Mobile C-arm, CT, MRI and Ultrasound systems that are ensured to have the same-as-new quality and performance. Refurbished parts are also used for Philips' maintenance services. When refurbishing a larger system is not feasible, valuable parts are always recovered to service other systems and maximise lifetime [32]. These are examples of recovery methods that Philips is already applying throughout their businesses to drive the transition to a circular economy. At the time of this study, no research had been done into the possibilities for recovery methods at the end-of-life of catheters.

2.3.1. Circular product design and EcoDesign

In an ideal circular economy, the value of materials is always preserved by either extending the life of products or by looping them back in the system to be reused [5]. It has been briefly outlined what types of circular strategies exist to facilitate the enactment of the circular economy in the production chain via recovery methods. However, it is unrealistic to believe that from now on all products can be circular and that no more waste will be produced in a short time [38]. Therefore, the principle of EcoDesign will be briefly explained as it is essential to not only focus on circular design but also on how to sustain most value at the end-of-life of products.

Circular product design principles should not be confused with EcoDesign principles given that these principles have an overlap but also fundamental differences. EcoDesign principles, strategies and methods are rooted in the linear economy. EcoDesign is a strategic design process defined as the systematic integration of environmental considerations into product design with the purpose of enhancing the product's environmental performance across its full life cycle considering packaging, products, processes, services, organisations and systems [39]. One of the guiding principles of EcoDesign is the waste hierarchy that details a priority order for managing waste: from prevention of waste, to reuse, recycling, recovery and finally disposal. The fact that EcoDesign principles hinge on the assumption that a product will become waste at a moment in time, does not align with the principles of a circular economy where waste does not exist [5].

By contrast, the inertia principle was introduced by Walter Stahel as a guiding principle for circular product design: "do not repair what is not broken, do not remanufacture something that can be repaired, do not recycle a product that can be remanufactured". This inertia principle can be used for products and components: replace or treat only the smallest possible part in order to maintain the existing economic value of the technical system and keep the highest level of product integrity as possible [40]. This is also illustrated by the fact that the closer the loop is to the center of the diagram, and thus the smaller, the more profitable it is and that the effectiveness of the loops is enhanced by keeping them as small as possible, as also stated by Wahel. In terms of circular product design, this means that the intention of a product must be to stay as close to the original product's function for as long as possible and hence minimising environmental and economic costs. From a circular product design perspective, recycling is thus the least desired option as the integrity of the product is destroyed. Recovery is defined for this purpose as the term for any operation with the aim of reversing obsolescence [5].

According to the inertia principle, products should first be designed to prevent the occurrence of obsolescence and second, if obsolescence cannot be avoided, to ensure that products can be recovered with the highest level of integrity. These two circular objectives can be aimed for at the level of products and components, and at the level of materials. At the level of materials, this is referred to as design for recycling: when the product's integrity is lost, it should be designed to be dismantled and make sure that the materials can be recycled and thus looped back into the system. At product and component level, the products need to be designed to prevent or reverse the state of obsolescence, which is referred to as design for product integrity [5]. As this research focuses on disposables in the medical sector only, the next chapter will consider what ways of product recovery exist for medical devices.

2.4. Circular economy in the healthcare sector

2.4.1. Introduction

The aforementioned circular economy strategies and recovery methods promote improving product sustainability and taking steps to extend the lifetime of products and work towards a closed-loop system [41]. However, the medical sector or healthcare industry is particularly interesting, given its enormous waste production and the highly regulated landscape. It is challenging to implement circular design concepts due to the clinical challenges of safety and sterility that limit the possibility of the reuse of medical devices [8], [15]. Circular strategies that can be implemented to design household appliances for refurbishment cannot be directly implemented for medical devices. Handling used, infectious, or non-infectiously contaminated medical devices are subject to regulations that prioritise health and safety. This makes the implementation of circular principles for medical devices a challenging and high-risk field, where any loss of functionality or other risks could threaten patient lives [8].

In the following section, first, the categories of recovery strategies already encouraged in the medical device

industry will be discussed, followed by a framework in section 2.4.3 that broadly categorises medical devices according to their most suitable recovery strategy. Subsequently, it will be discussed in section 2.4.4 which strategy, based on literature, is most suitable for the recovery of catheters at end-of-life.

2.4.2. Medical device recovery methods

A study by Kane, Bakker & Balkenende is used as a frame of reference to identify the different recovery strategies for medical devices. By conducting a literature review and examining existing industry examples, they analysed examples of applications of circular economy in the medical sector. As a result of this, a set of recovery strategies for medical devices was established that help designers and engineers approach the design of a circular medical product [8].

First, a *circular product* is defined as a product that can withstand repeated cycles of obsolescence and recovery while maintaining integrity and value. The research identifies the types of product and material recovery in the healthcare industry, followed by an analysis of these types of recovery. Eventually, they proposed a framework that categorises medical devices according to their most suitable recovery strategy. The following categories of medical device recovery were identified based on literature research and examining existing industry examples [8]. These categories of recovery methods are adhered to for this study:

- Refurbishment
- Repair and maintenance
- Recycling
- Reprocessing

Refurbishment

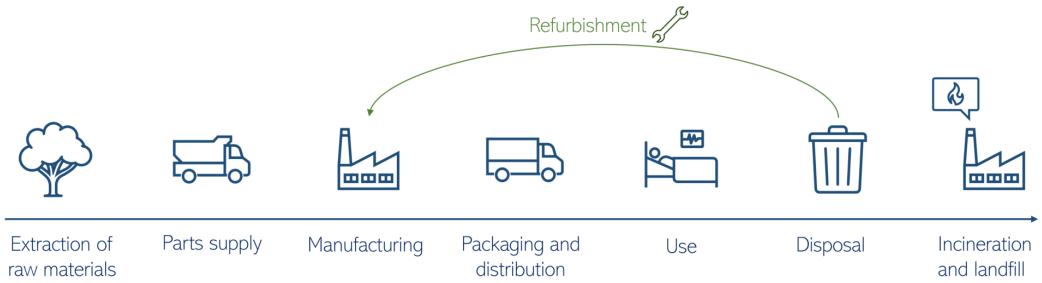

Figure 2.4: **Simplification of a refurbishment life cycle.**

Refurbishing, also referred to as remanufacturing, is a process in which manufacturers recollect devices - usually high-complexity, long-life devices - when they reach the end of their lifetime and put them back into service. This procedure is already widespread across the medical industry. A simplified version of the life cycle of a refurbished device can be found in Figure 2.4. Siemens Healthineers, GE and Philips, three top medical equipment manufacturers, have instituted take-back programs with dedicated refurbishment facilities. They sell their refurbished equipment following an independently certified process leading to a quality level comparable to new ones and covered by a full warranty [42]–[44]. Most of the refurbished medical equipment market consists of high-cost, high-complexity, large imaging devices such as X-Ray equipment, CT scanners and MRI machines. Refurbishment programs are well-established and regulated in most parts of the world, and international guidelines on quality standards for refurbished medical equipment exist [8], [45]. A typical refurbishment process conducted by experts entails the following steps: cleaning and disinfection if needed; de-installation; extensive component and sub-component checks; replacement of worn parts with original parts; software and, if needed, hardware updates and individual configuration. Refurbishing offers the same functionality and quality of new equipment after original manufacturing, with a similar warranty and support contracts [42], [43].

Different reasons can represent the end-of-life phase and reason to send the equipment back for refurbishing: e.g. hospitals that retire their equipment because they want an upgrade to the latest equipment; hospitals that have other expectations of the equipment; malfunctioning of the equipment. Companies will buy back their own equipment after this type of end-of-life and sell it to new consumers for a lower price after refurbishment. This circular strategy for medical equipment is a successful product recovery method to retain value after end-of-life for large equipment without the need for aggressive sterilisation. Waste is reduced with refurbishing, and resources are conserved. Also, the lower price of refurbished systems (20-60% of the price compared to new equipment) makes high-cost equipment accessible for lower-resource settings [8], [43]. For this research, refurbishing is not considered given that it is not cost-effective to refurbish catheters. As stated, devices that are typically considered for refurbishment are large capital imaging devices like X-ray, CT and MRI systems [45].

Repair and Maintenance

The repair and maintenance process at the end-of-life concerns the steps that need to be taken to recover a product from temporary functional obsolescence, e.g. breakdowns or performance errors, or to ensure that planned servicing procedures prevent obsolescence. This service is often offered by original equipment manufacturers or third parties with trained biomedical engineers that are accredited to provide this service, whereas this was formerly performed by in-house biomedical technicians primarily [8], [46]. The objective of using repair services is to minimise costs while maximising the operational period of the medical equipment. These services, however, are high in costs, which explains why only large equipment with a long lifespan is considered most of the time for repair & maintenance. For smaller equipment, like catheters, repair & maintenance processes are not cost-effective [47].

Reprocessing

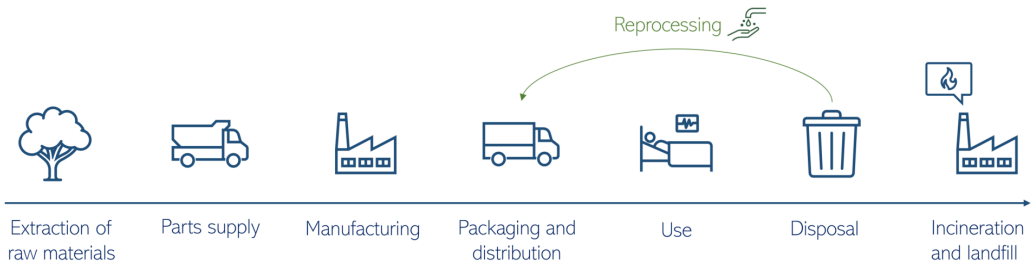

Figure 2.5: **Simplification of a reprocessing life cycle.**

A simplified version of the life cycle of a reprocessed device can be found in Figure 2.5. *Reprocessing* is defined in the European Medical Device Regulation as "a process carried out on a used device in order to allow its safe reuse. It includes its cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device" [9]. The US Food and Drug Administration (FDA) has a similar definition: "reprocessing includes all the steps performed to make a contaminated reusable or single-use device ready for patient use. The steps may include cleaning, functional testing, repackaging, relabeling, disinfection or sterilisation" [48].

This means, amongst others, that the device considered for reprocessing must withstand several cycles of cleaning and sterilisation. When it concerns devices that enter sterile tissues or the vascular system, this process involves devices that become hygienically obsolete after use and need cleaning and sterilisation processes to reverse their state of hygienic obsolescence [49]. In terms of obsolescence, it can be defined as 'hygienic obsolescence' when a medical device becomes obsolete after use as it is no longer considered sterile and thus does not meet the hygienic criteria for any recovery method. It is called hygienic recovery when a device is recovered from hygienic obsolescence via cleaning, disinfection and sterilisation methods [8]. This type of recovery was reported most frequently for single-use devices (SUDs), also called disposables, that are designated to be used during a single medical procedure on one individual and discarded after the procedure. These devices are, by definition, not intended to be reprocessed or used on another patient. However,

reprocessing of SUDs has grown in acceptance across the world, which requires close monitoring of these processes and establishing strict regulations. The US FDA and the European Union (EU) established a set of regulatory requirements governing reprocessing and further use of these devices [9], [50]. A summary of the European and US regulations on reprocessing SUDs and the steps that must be taken in a reprocessing cycle are presented in Appendix A.2

Most SUDs being reprocessed are medium-complexity, high- or medium-criticality devices such as catheters, endoscopes and surgical staplers. These devices were formerly reusable and sterilised in hospitals. However, the widespread use of 'plastics' in the 1950s caused single-use versions of these devices to emerge and take over, given their convenience and economic advantage [49]. Many studies have been conducted investigating the reprocessing of SUDs, sometimes resulting in degradation and reduced functionality that can be hazardous. According to cleaning guidelines, the ability to disassemble the device and remove biological soil from crevices and joints is critical for cleaning effectiveness [51]. Based on the EU MDR guidelines and US FDA, the most critical requirements for reprocessing a device are that the device should enable disassembly & reassembly to allow cleaning, sterilisation and repair or replacement of parts if required during reprocessing. Also, the materials a device consists of should withstand cleaning and sterilisation processes and a device should be constructed to allow these cleaning and sterilisation processes. A summary of the regulations on which these requirements are based can be found in Appendix A.2

Recycling

Figure 2.6: **Simplification of a recycling life cycle.**

Recycling is the process of recovering a device by breaking it down into its constituent parts or materials and reassembling it into a new usable form or product. A simplified version of a recycling life cycle can be found in Figure 2.6. Recycling is mainly a way to reduce waste that would otherwise be sent to incineration or landfill when no other recovery method is suitable. From an environmental perspective, recycling is the least desired product recovery method as the embedded value of a product's function is lost, and substantial energy and transport are needed [8], [52]. Still, recycling is very critical in decreasing the enormous volume of medical waste that is being produced across the world. The design of a device determines the suitability of a product for recycling: e.g., materials and components should be easy to separate; the use of fewer different materials can facilitate a more straightforward recycling process, and the selection of used materials also determines how suitable a device is for recycling [19].

Recycling medical equipment on a large scale is restrained by the presence of infectious medical waste and strict regulations. However, technologies have emerged in the past years that sterilise infectious waste, grind the material into granules, and treat it with high temperatures, microwaves or chemicals to make it suitable for processing. Unfortunately, this is an expensive process that generally cannot be performed on-site [8], [52]. This makes incineration and landfilling the safest and cheapest options to handle medical waste with significant disadvantages; valuable materials are lost, and the processes can emit pollutants.

2.4.3. Categorisation of recovery methods for medical devices

Based on the analysis of the identified types of recovery of medical devices, a framework is proposed by Kane, Bakker & Balkenende that broadly categorises a medical device according to its most preferable recovery strategy. The factors that contributed most to determining the required recovery strategy for a particular medical device are the *hygienic criticality* and the *product value* of the medical device in question.

Product value

The first identified factor found across literature is the product value, considering whether recovering the device is more cost-effective than disposing of and replacing it. Some devices will always be disposable, given that recovering them will always be more expensive than the cost of the device itself. Recycling at the material level may be the only viable option for the recovery of these devices. Thus, designers and engineers should develop a design optimised to enable recycling at end-of-life to contribute to a circular economy for low-value devices.

Hygienic criticality

The second factor affecting medical device's recovery is their hygienic criticality, as delineated by the Spaulding classification. This classification represents a ranking that ranges from simple disinfection to sterilisation, based on the risks associated with their use, ranging from 'critical' (high-risk) through 'semi-critical' to 'non-critical' (low risk). Critical devices are the highest risk devices that enter a 'sterile' area of the body such as the bloodstream, sterilisation of these devices is required and paramount. As semi-critical devices only contact mucous membranes or non-intact skin, they are considered to pose a lower risk. Thus, cleaning with sterilisation is advised, and high-level disinfection if sterilisation is not feasible. By contrast, non-critical devices present the lowest risk to patients: these devices only contact intact skin and only low- or intermediate-level disinfection is recommended [53]. The category in which the device is classified according to the Spaulding Scale describes how aggressive the hygienic recovery of a device should be. Devices with high criticality require more aggressive cleaning than semi- and non-critical devices. Hence, the device should also be able to withstand the aggressive forms of sterilisation required in order to be reused. Additionally, the criticality of a device also affects the cost/benefit ratio of recovery as more aggressive cleaning methods are, in turn, more expensive [8].

Framework based on product value and hygienic criticality

The analysis of different recovery strategies was based on these two factors. The product value is considered a logical determining factor in choosing which of the aforementioned recovery strategies for medical devices to implement. In contrast, the criticality determines what design requirements a particular medical device must meet to be hygienically recovered after its use. Kane et al. pointed out that when mapping different types of medical devices along axes with these two factors, you can make a judgement about the types of recovery most suitable for a particular device. Hence, what designers should take account of to advance the recoverability of their medical device [8]. This research will consider different recovery methods for single-use catheters using this framework.

Figure 2.7 on the next page shows the matrix or diagram that plots different types of medical devices along axes with these two factors. Four categories of medical devices can be deducted from this diagram based on criticality and product value, depicted as the four quadrants. Each category has its design challenges and opportunities for circularity, which will be discussed later and can be found in Figure 2.8. Figure 2.7 is based on the framework by Kane et al., however it is adapted and supplemented according to estimated product values and the classification of the devices according to their criticality. Also, IVUS catheters have been added to the framework. Exact details on the values and criticality of the devices can be found in Appendix A.1.

The vertical 'product value' axis in Figure 2.7 indicates the product value of a medical device, ranging from low to high value, from the bottom to the top of the matrix. Devices with a high value are, for example, imaging equipment that consists of highly technological components and that involves a variety of second- and third-tier suppliers. Devices with a low value, like syringes, bandages or compression sleeves, consist of fewer (technological) components and involve fewer suppliers. The horizontal 'criticality' axis classifies the devices according to their hygienic criticality, based on the Spaulding scale, as explained before. Non-critical devices are on the left-hand side of the matrix, whereas critical, invasive devices can be found on the right-hand side of the matrix.

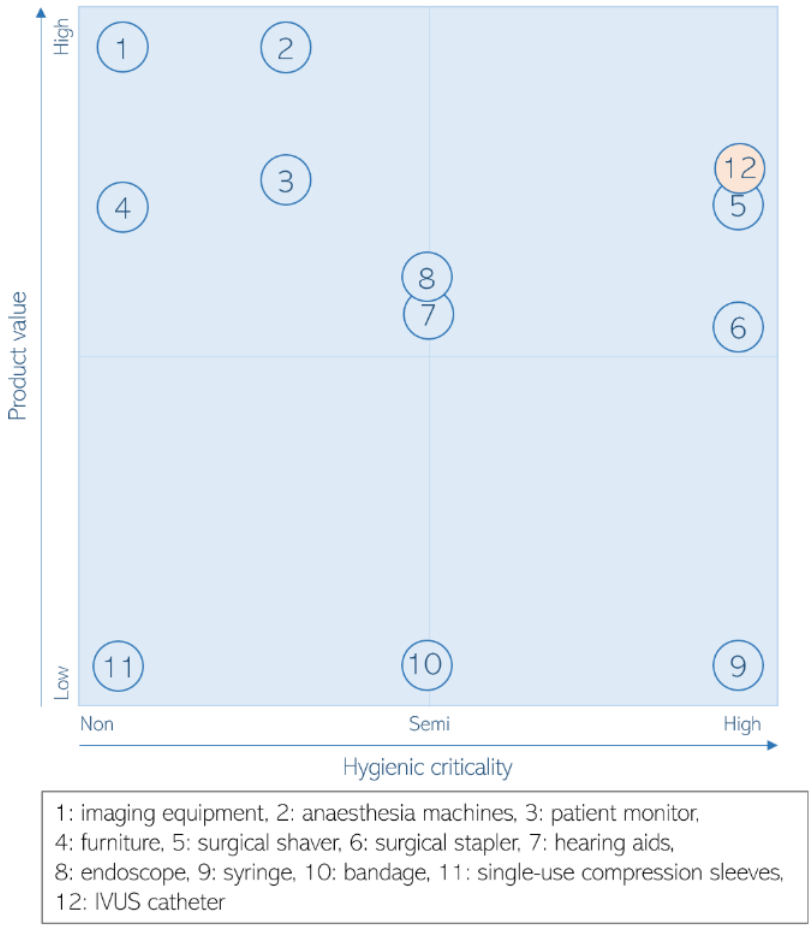

Figure 2.7: **Framework for circular medical devices: product value versus hygienic criticality** Adapted from Kane, Bakker, and Balkenende [8], complemented with information from Appendix A.1.

Recovery strategy per category

As mentioned before, four categories of medical devices emerged from Figure 2.7. Each of these four categories has design challenges and opportunities for circularity, as indicated in Figure 2.8. This matrix aids visualising trade-offs that need to be considered when selecting a suitable circular strategy in the design of a medical device.

Quadrant 1 refers to high-value devices that can be recovered without the need for aggressive hygienic recovery, like imaging equipment or large surgical equipment designed to last for a long time. Quadrant 2 is the quadrant that catheters comprise, consisting of critical devices with a medium-to-high value that require hygienic recovery after use. As IVUS catheters belong to this quadrant, this will be examined in more detail below. Quadrant 3 encompasses devices that are low in value and are not critical. Recycling is the most viable recovery option for these devices, and guidelines exist to support designers in optimising recycling for non-critical medical devices. Quadrant 4 is the most difficult to develop a circular strategy for; it involves low-to-medium value high criticality devices for which recycling is not cost-effective given the cleaning and sterilisation process that must precede given their hygienic obsolescence after use.

Catheters fall within the group of surgically invasive devices intended to control, diagnose, monitor or correct a defect of the heart or the central circulatory system. Accordingly, catheters are considered a Class III device under the EU Medical Device Regulation and a Class II device under the US FDA Code of Federal Regulations and considered a critical device [9], [54]. Therefore, the focus will be on the right-hand side of the matrix, focusing on critical devices only. Regarding the value of an IVUS catheter, an IVUS catheter is considered a medium-to-high value device as imaging equipment, anaesthesia machines and patient monitors are way above the price of an IVUS catheter. In contrast, syringes, bandages, single-use compression sleeves and

packaging materials are below the price of an IVUS catheter; refer to Appendix A.1 for an elaboration of this diagram, with estimated prices of devices and how it was determined that IVUS catheters belong to quadrant 2 in Figure 2.7.

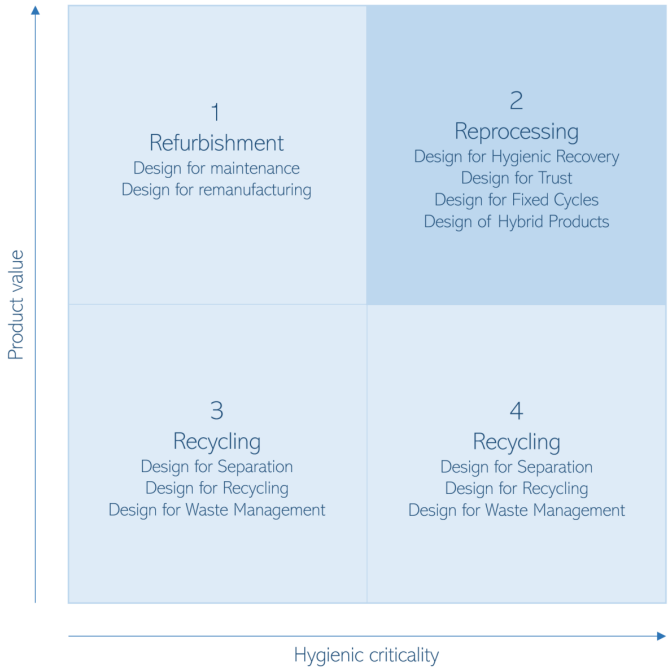

Figure 2.8: **Design strategies for recovery of circular medical devices.** Adapted from Kane, Bakker, and Balkenende [8].

2.4.4. Recovery strategies for catheters

As discussed before, catheters belong to the top-right quadrant of Figure 2.7. Figure 2.7 corresponds with Figure 2.8, which shows the design strategies per quadrant which correlate with the quadrants from the presented design framework for circular strategies in Figure 2.7. The top-right quadrant of Figure 2.7 correlates with quadrant 2 of Figure 2.8. This quadrant considers the medium-to-high value, high-criticality devices, referring to products whose cost-benefit analysis suggests more product-integral forms of recovery given the higher value of the device. Recovery, however, can be challenging because of the high criticality of the device. As proposed by Kane et al., this framework is intended to guide and inspire designers and engineers to make healthcare more sustainable.

The framework by Kane et al. suggests focusing on reprocessing as a recovery strategy for IVUS catheters optimising these devices for hygienic recovery. Other design strategies suggested for devices in this category are Design for trust, Fixed cycles and Hybrid products. An example of Design for trust is, for example, to embed markers in devices that explicitly convey to the physician which number of cycles the device has left in its lifetime to make physicians trust reprocessed equipment. Design for fixed cycles is a supplementary strategy that allows a device to be used for a fixed number of cycles by using materials that can last a known number of cycles before losing a certain quality standard. Moreover, a hybrid design can be considered when a product is considered that consists of both components that enter the normally sterile tissues of the patient but also components that do not. These devices could be designed to have detachable components that can be hygienically recovered or disposed of [8].

In conclusion of this section, it can be argued that reprocessing is the most suitable type of recovery for IVUS catheters based on the literature. The remaining question is whether this can also be concluded by an assessment of an actual IVUS catheter. Therefore, in the following section, requirements will be addressed that help to evaluate the readiness for the recovery of catheters. These requirements are considered in developing a new assessment tool and method in Chapter 3.

2.5. Assessing catheters for recovery methods

The following section will present the aspects that are considered most critical in identifying if a single-use catheter is ready for recovery purposes. These aspects will be included in developing an assessment tool and method for catheters.

2.5.1. Ease of disassembly

In order to carry out any product recovery method for medical devices, considering repair, refurbishment, reprocessing and recycling, a pre-requisite is readiness for disassembly. Disassembly is the process of removing the connectivity of parts in a product, so the product is separated into its constituent parts, components, sub-assemblies or other groupings, which facilitates the recovery of valuable components [2], [3]. The process of irreversibly removing connectivity between parts that could cause damage is called dismantling. A sub-assembly is a group of components that is integrated into a unit that forms a part of a larger assembly, being the product as a whole [2]. Disassembly enables the ease of carrying out maintenance-related activities, whether for simple products or for larger complex machines that need to be disassembled partially for the purpose of repair or periodic maintenance [55], [56]. Also, it facilitates the recovery of valuable components for re-utilisation and separation of decontaminated materials for reprocessing. Hence, disassembly not only allows maintenance and repair, but also supports maintaining the purity of materials for reprocessing and facilitates the safe isolation of hazardous substances [2]. Other studies have also reported that the ease of disassembly of a product contributes significantly to the recycling and reuse yield and increases the potential of retrieving high-value parts of a product at the end-of-life [41], [57], [58]. The processes of disassembly are closely related to a product's design specifications. Therefore, designers or engineers should pay attention to incorporating disassembly consideration into a product during the early design stages to make disassembly easier when reaching the end-of-life phase [56]. Accordingly, design for disassembly is a technique that involves a product to be disassembled for more accessible repair & maintenance, refurbishment & remanufacturing, recycling and reuse of components or materials [59].

On top of that, disassembling a product not designed for disassembly may not be cost-effective given the ineffective design that could result in a higher disassembly time and, therefore, higher labour costs. Designing for disassembly and remanufacturing can deliver more significant savings than products not designed with this intention [57]. The requirements for the ease of disassembly are crucial to allow all of these recovery strategies; e.g. design for disassembly improves access to internal components for repair or easier recovery of components that can be recycled or reused without destroying the whole device [41]. Additionally, in various design considerations for cleaning and sterilisation is also suggested that devices that need reprocessing should be designed for disassembly as it makes it easier to get at and adequately clean all surfaces. The ease of disassembly also avoids human error that could affect the safety and functionality of the device by the sterile reprocessing technician [60], [61]. If a device can be disassembled, this also allows more easy cleaning as this facilitates access to components.

2.5.2. Hygienic recovery

A prerequisite for catheters to be recovered is that they must withstand cleaning and disinfection or sterilisation processes, given that they are considered critical devices according to Spaulding's classification. This requirement is not only to possibly be reused in its entirety (i.e., reprocessing) but also if recovery of components or if only material recycling is considered. To be eligible for these processes, the design of a catheter should be optimised as much as possible for hygienic recovery.

To render a medical device safe for further reuse, typically, two steps are involved in this process: cleaning and either disinfection or sterilisation. The cleaning, disinfection and sterilisation processes differ depending on the indicative use of a medical device. Cleaning, the removal of soil residues, is the first step and should always be done, regardless of the device's classification. Disinfection or sterilisation, however, should be executed dependent on the criticality or classification of the device depending on its intended use. Non-critical devices involving intact skin require cleaning and low or intermediate-level disinfection. On the other hand, semi-critical devices contact mucous membranes or non-intact skin and require cleaning and high-level disinfection or sterilisation. Finally, critical devices like catheters contact the bloodstream or normally sterile tissue, therefore requiring cleaning and aggressive sterilisation to render the device free from viable microorganisms [50], [62], [63].

Different design aspects must be considered when a device is considered for hygienic recovery purposes: compatibility of materials for these processes, the type of tissue contact of the components and the device's physical design [62]. If a medical device or component is considered for recovery, the material's ability to resist multiple use cycles and the associated cleaning and sterilisation processes should always be validated. Porous materials, for example, are notorious for retaining high levels of soil and are difficult to clean. Coatings of materials can also be harmed via cleaning methods, and several polymer materials can degrade when exposed to chemicals in cleaning, disinfection or sterilisation processes. Therefore, the compatibility of materials for these processes is an essential requirement for recovery methods. In Section 3.2.2 on the Methodology, is elaborated on this [62], [63].

The exact type of cleaning and sterilisation process depends on the intended use of the entire medical device. This means that the entire device is subject to the same cleaning and disinfection method, independent of the components' different types of tissue contact. To illustrate, it might be that the device's handle does not contact the ordinarily sterile tissue of a patient. However, it should still be sterilised because it concerns a critical device that requires sterilisation after use. The part of the device that enters the body and is in contact with the bloodstream requires a thorough cleaning and sterilisation protocol, but the fact that the other part does not enter the bloodstream can give opportunities, such as as a hybrid design as explained before [50], [63].

In addition to the resistance of a material to the appropriate cleaning method and the type of tissue contact, the physical design of the device must also allow cleaning processes. The size and shape of components has a large effect on the ease of cleaning. Cleaning can be challenging for devices with complex or small structures that trap soil and are difficult to clean through conventional cleaning processes. Rough or bubbly surfaces can also be difficult to clean, as are sharp angles. These design features may result in soil retention or need to be disassembled to be completely cleaned unless it can be validated for effective cleaning [50]. Whichever cleaning, disinfection, or sterilisation process is suggested by a device manufacturer, the device's compatibility with these methods and the ability to successfully clean, disinfect or sterilise the devices should always be validated and then stated in the instructions for use. This validation should report that soil and contaminants can be effectively removed and that the device can be rendered free of viable microorganisms [9], [50].

2.5.3. Material characteristics

The materials that a catheter consists of must also be appropriate for the intended recovery methods. That means using single materials for components can increase the possibilities for recycling [64]. Also, coatings can influence the opportunities at the end-of-life. They are applied to improve a device's aesthetics or have functional properties. The use of an aesthetic coating can have a negative impact on the possibility of recycling as it can result in undesirable mixing of the recovered material. As the EU highly depends on importing raw materials, waste collection and recycling are extremely important [65]. Functional coatings, in contrast, might need to be reapplied after a cleaning and sterilisation procedure to maintain the intended function of the component [50]. Finally, the value and type of material are also crucial as this helps indicate if recovery methods could be cost-effective.

2.6. Background case study on catheters

This section will briefly outline the technology, procedure and function of the single-use catheters that will be case-studied to get a better understanding of the scope of the research. First, the intravascular ultrasound catheter is highlighted, followed by the laser atherectomy catheter. Also, the Philips devices that were selected for the case studies are presented here.

2.6.1. IVUS catheters

A wide variety of catheters is available that vary in shape, design and specific function. A *catheter* is a flexible tube that can be introduced into a blood vessel or hollow organ to introduce or remove fluids, implant medical devices, or perform diagnostic tests or therapeutic interventions. The intravascular ultrasound (IVUS) technology uses an ultrasound transducer at the tip that generates sound waves and produces pictures of the inside of blood vessels. An IVUS catheter is only used for imaging and diagnosis, not to treat the lesion.

IVUS catheters are conventionally used in combination with a guidewire and a console connected to a computer workstation that converts the sound waves from the transducer tip into real-time images on a monitor. The available literature indicates that the price of an IVUS catheter in the United States is 600-1000 dollars, and an IVUS console 100,000-200,000 dollars [33].

IVUS procedure

An IVUS procedure is an invasive diagnostic procedure executed by an interventional cardiologist that is used to view the inside of coronary arteries. IVUS can support in assessing the presence and extent of the disease by clarifying the degree and type of stenosis of an artery. The lumen area, thickness, distribution, and composition of plaques and remodelling of the vessel wall can be depicted by IVUS images. This can be used as preparation for, during, or to review the results of a cardiac catheterisation procedure in patients suspected of coronary artery disease (CAD). During the procedure, the interventional cardiologist can make different therapeutic decisions based on the IVUS images. The need for further treatment of the lesion by placing a stent or a balloon, also referred to as an angioplasty procedure, can, for instance, be considered based on the images, accompanied by the size and exact location where the stent or balloon needs to be placed. After placement of the balloon or stent, the outcome can be evaluated by new IVUS images to assess the need for further treatment [35], [66], [67].

IVUS technology

Intravascular ultrasound (IVUS) is an imaging modality that supports determining the severity and composition of lesions in patients with coronary artery disease (CAD). IVUS catheters evaluate the plaque build-up in coronary arteries using the IVUS technology that provides real-time cross-sectional grey-scale images of the arterial wall. The IVUS catheter is placed over a guidewire that has been placed in the relevant coronary artery. The ultrasonic tip of the catheter is situated beyond the lesion of interest. While the guidewire is kept still, the IVUS catheter is retracted to produce detailed images of the interior walls of the artery, including morphological and pathological structures. The transducer tip of the catheter emits high-frequency sound waves that echo off vessel walls and are sent back to the system in varying intensities depending on the tissue. Blood and healthy muscular tissue are echolucent, meaning they are translucent to ultrasonic waves, returning no images and appearing as black spaces on the monitor. In contrast, the blood vessel wall inner lining, plaque build-up and connective tissues are echogenic and reflect the ultrasound waves; hence they are visible on the monitor [67].

IVUS can overcome some limitations of coronary (CT) angiography, which is considered the golden standard for the diagnosis of coronary artery disease, by providing more information about the dimensions of the vessel lumen, plaque characteristics and stent deployment. Figure 2.9 shows the differences between coronary angiography and IVUS imaging. Coronary angiography can only diagnose coronary artery disease based on an x-ray diagram in 2D [35]. IVUS can be used as an adjunct to angiography but IVUS can also be used as the sole diagnostic tool when angiography is contraindicated or when the computed tomographic (CT) scan is inconclusive [68]. Please note that a comparison of coronary angiography and intravascular ultrasound for estimating coronary stenosis and plaque build-up is beyond the scope of this research.

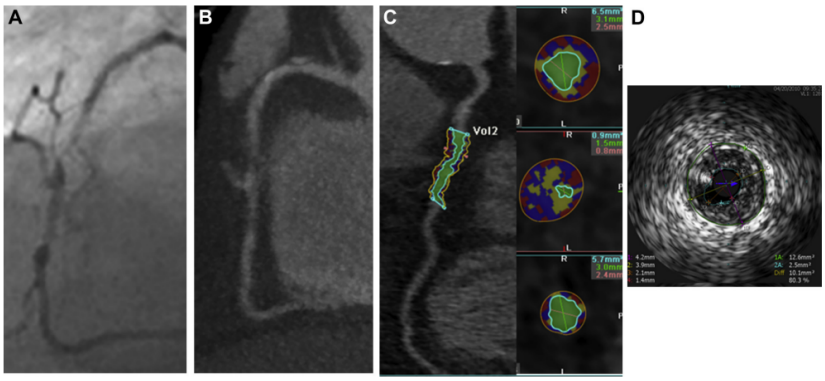

Figure 2.9: **Automated vessel and coronary lesion measurements by CT angiography and IVUS.** (A) Invasive coronary angiogram shows a severe complex stenosis in the mid portion of a right coronary artery. (B) Corresponding coronary CT angiogram shows severe stenosis. (C) Automated assessment of vessel area, lumen area (shaded light green), as well as lumen diameters (straight lines) at 3 reference sites: before, at and after the stenosis. (D) Corresponding IVUS image at the area of worst area stenosis shows measurements of the vessel area, lumen area, and lumen and vessel diameters. Adapted from Fischer, Hulten, Belur, *et al.* [69]

2.6.2. Laser atherectomy catheters

Instead of allowing imaging of the inside of a vessel like IVUS catheters do, laser atherectomy catheters are used in procedures to treat patients with peripheral arterial disease, mostly in lower extremities. These catheters are indicated for use in the treatment, of limb ischemia and occlusions, including atherectomy.

First, a guidewire is inserted and placed across the lesion that needs treatment, after which the catheter can be passed over the guidewire. The distal tip of the catheter is introduced over the guidewire, and the catheter is guided towards the lesion to deliver ultraviolet light. The lesions must be traversable by a guidewire and composed of atherosclerotic plaque and/or calcified material. Pulses of high-energy ultraviolet light are emitted that can remove plaque and unblock the artery. The advantage of using this method instead of placing a conventional stent or balloon angioplasty is that the plaque deposits are debulked and vaporised. Also, this procedure can cross blocked lesions in such a way that a balloon alone would not be able to cross [70], [71].

2.6.3. Philips catheters

Philips has several IVUS catheters in its portfolio, of which one is selected for the case study of this research: the *Eagle Eye Platinum Digital IVUS catheter*, illustrated in Figure 2.10. This IVUS catheter makes use of the technology of an ultrasound transducer, also known as cMUT (capacitive Microfabricated Ultrasonic Transducer). It allows for real-time, cross-sectional in-vivo imaging of arteries that can aid in the diagnosis of arterial diseases and provide information on vascular pathologies such as plaque structure and lesion type [72]. It is the market-leading IVUS catheter in the US.

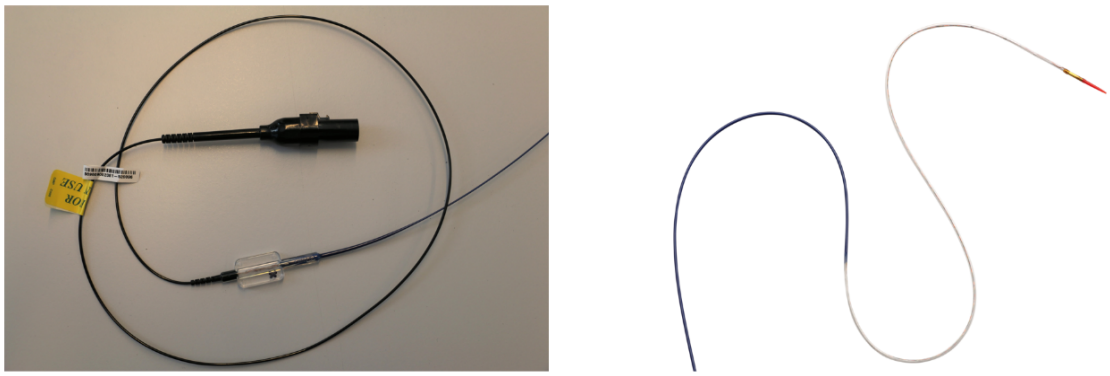

Figure 2.10: **Product images Eagle Eye Platinum Digital IVUS catheter.** Left image taken by Sterre de Jong. Right image is a Philips internal document.

The second catheter that would initially be used for the case study in this research is the *Visions PV.018 Digital IVUS catheter* of Philips. However, due to unforeseen circumstances, a sample of this IVUS catheter or another IVUS catheter was not available for research. Therefore, it was decided to use another type of catheter available for a second case study. This catheter is the *Turbo-Elite Laser atherectomy catheter*, illustrated in Figure 2.11. Instead of allowing imaging of the inside of a vessel like IVUS catheters do, laser atherectomy catheters are used in procedures to treat patients with peripheral arterial disease, mostly in lower extremities. The Turbo-Elite catheter is indicated for use in the treatment of infrainguinal stenoses and occlusions, including atherectomy,.

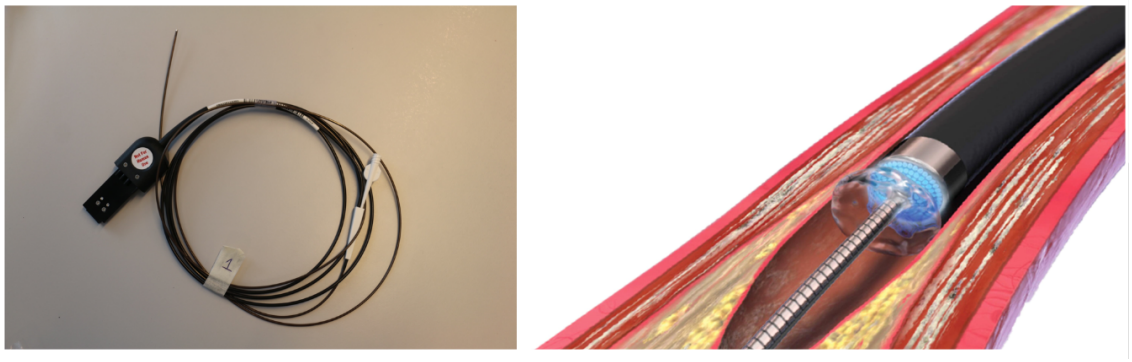

Figure 2.11: **Product images Turbo-Elite Laser Atherectomy catheter.** Left image taken by Sterre de Jong. Right image is a Philips internal document.

2.6.4. Life cycle of single-use catheters

Both of the catheters that are used for the case studies are single-use medical devices. Meaning that, these devices are intended for use one single patient and one procedure only. By definition, these devices are not intended to be reprocessed or reused on another patient [9], [73]. The life cycle of single-use devices, and thus single-use catheters, is illustrated in Figure 2.12. When single-use devices are disposed in Europe, they end up being incinerated or put into landfill. The advantages of incineration over landfilling are the reduction in the volume of medical waste and the killing of pathogens. The residual products of the incineration process are sent to landfill as well. However, waste incineration is seen as one of the main causes of the release of environmental pollutants dioxins and furans into the environment, and although it is theoretically feasible to manage this pollution, in practice, this is not feasible with the growing numbers of waste [74]. Applying recovery strategies should be preferred to this polluting linear life cycle.

Figure 2.12: **Life cycle of a single-use catheter.**

3

Methodology

This chapter presents a method that supports in diagnosing the readiness of a single-use catheter for recovery purposes at end-of-life, called the recovery assessment method. In the first part of this chapter, it will be explained how this method is developed through using an existing method as a basis. In the next part of this chapter, it will be explained how the method should be used and what is needed to use the method. The method will be validated in the next chapter through two case studies.

3.1. Introduction

Currently, a single-use catheter becomes immediately obsolete when reaching the end-of-life stage after its use, whereas several recovery strategies exist for medical devices discussed in the previous chapters (e.g., reprocessing, refurbishing and recycling). The objective of the method that is developed in this chapter is to evaluate the readiness of a single-use catheter for recovery purposes at end-of-life to remove the product, component, or material from its state of obsolescence and return them to the economic system by restoring its value. In doing so, this chapter addresses the third research question:

- How to assess the readiness for recovery purposes of single-use catheters?

3.2. Development of the method

A method developed by de Aguiar et al. serves as a basis for developing a new tool that evaluates the readiness of single-use catheters for recovery purposes. First, the concept of the tool by de Aguiar et al. is shortly introduced, after which the new method is discussed in more detail [58].

3.2.1. Recyclability tool

A diagnostic tool was proposed to evaluate product recyclability to support in decision-making during the design stage by de Aguiar et al. This tool can be deployed to design products for recyclability when recovery is not possible at product or component level. It aims to help designers compare different recyclability scenarios and choose the less impacting one for the environment. The method was validated by using it for a portable cassette and CD player to diagnose the most critical parts of this product while it is still in the design phase, thereby improving the performance on recyclability at the end-of-life [58].

The Bill of Materials (BOM) of the product is used as the basis for filling in the Excel-based tool. A BOM of a product lists all the sub-assemblies, components and materials a product consists of. A graphical diagnosis of the product's recyclability grade can then be made via an evaluation of indices on each sub-assembly and component level of the BOM. The study includes two types of indices: product disassembly indices and material recycling indices.

A colour scale from green to red is used to visualise the performance of each component for the different indices. This colour scale is illustrated in Figure 3.1. A lower index score is displayed in green. It indicates proximity to the ideal status of the component for recycling in the study by de Aguiar et al. A higher index score is displayed in red and indicates the undesired state of a component, therefore suggesting room for

improvement. The type of indices included in the tool of de Aguiar et al. are listed in Table 3.1 on the next page [58].

Components can be identified that limit or provide opportunities for recycling based on the graphical output of the tool. Components indicated during the evaluation with red scores on multiple indices indicate worse conditions for recycling and should therefore be resolved first. Accordingly, a potential product redesign can be made to improve its end-of-life performance in recycling based on the results of the tool.

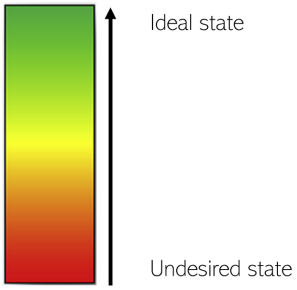

Figure 3.1: **Colour scale that is used for recyclability indices.** Adapted from Aguiar, Oliveira, Silva, *et al.* [58]

3.2.2. Recovery assessment method for single-use catheters

This section covers the structure of the proposed new method to evaluate single-use catheters using a tool. The following section explains the procedure and associated resources required to use the tool. The method by de Aguiar et al. only aims to diagnose if a product is ready for recycling. In contrast, the objective of the proposed new method is to support evaluating if single-use catheters are ready for recovery purposes at the end-of-life. This expands the focus of the tool to all recovery methods for medical devices, as addressed in Chapter 2. The new method is called the *recovery assessment method for single-use catheters*. The method aims to identify components of catheters that limit or provide opportunities for recovery purposes at the end-of-life.

The new method uses the same Excel-based structure as proposed in the recyclability tool before; the components and sub-assemblies of a catheter must be assessed individually using indices. Some indices have been added and omitted to make the tool suitable for critical medical devices and other recovery strategies than recycling only. An empty version of the new tool can be found in Figure 3.2; an explanation of how the tool should be used follows in section 3.3. First, the indices covered in the tool are presented. An overview of the indices proposed in the recyclability method and an overview of the indices included for the proposed new tool are shown in Table 3.1. The indices are explained in more detail in the following section.

BOM data				Disassembly indices					Hygienic recovery indices			Material recovery indices				Notes
BOM level	Item	Material	Weight (in g)	TFI	Reversibility	QFI	%FI	AI	TCI	ECI	SCI	MSI	MGI	MCI	MVI	
1															❐	
2															❐	
3															❐	
4															❐	
5															❐	
6															❐	
7															❐	
8															❐	
9															❐	
10															❐	
11															❐	
12															❐	
13															❐	
14															❐	
15															❐	
16															❐	
17															❐	
...															❐	
		Total	0		Total	0										

Figure 3.2: **Recovery assessment tool.** Empty version of the recovery assessment tool.

Indices recyclability tool [58]	**Indices recovery assessment tool**
Product disassembly indices	***Device disassembly indices***
Quantity of Fasteners Index (QFI)	Quantity of Fasteners Index (QFI)
Percentage of Fasteners Index (%FI)	Percentage of Fasteners Index (%FI)
Type of Fasteners Index (TFI)	Type of Fasteners Index (TFI)
Quantity of Types of Fasteners (QFTI)	Reversibility of Fasteners
Accessibility Index (AI)	Accessibility Index (AI)
	Hygienic recovery indices
	Tissue Contact Index (TCI)
	Ease of Cleaning Index (ECI)
	Sterilisation Compatibility Index (SCI)
Material recycling indices	***Material recovery indices***
Infrastructure Index (II)	
Material Separation Index (MCI)	Material Separation Index (MSI)
Material Group Index (MGI)	Material Group Index (MGI)
	Material Coating Index (MCI)
	Material Value Index (MVI)

Table 3.1: **List of indices included in the proposed methodology**

3.2.3. Bill of Materials (BOM)

A BOM is a source of information that contains all the components, sub-assemblies and materials a product consists of. The BOM consists of different levels that show the hierarchical structure of a device, e.g. to indicate from which sub-assembly a component is part of. When there is no access to a BOM, it can be compiled by analysing the product yourself. In section 3.3.1 a dismantling protocol is discussed that guides the constitution of a BOM. The BOM information collected through this process is used as input for the new method. This can be seen on the four columns at the left-hand side of Figure 3.2. An assessment can then be made via analysing the product on the proposed indices.

3.2.4. Colour coding

The recovery assessment method uses colour coding to distinguish between the different scores on indices. These colours should be interpreted with the help of the explanations that are given with each index. In contrast with the colour coding in the recyclability method, red should not be interpreted as an 'undesired state', and green should not be interpreted as the 'ideal state'. The new method's colour coding helps to highlight areas of attention in red if recovery methods are considered. Each user of the method can then make their interpretations and draw conclusions using the attached explanations. Next to the colour scale from green to red, an index score is coloured grey if there is insufficient rationale or information available to evaluate a particular component of the device.

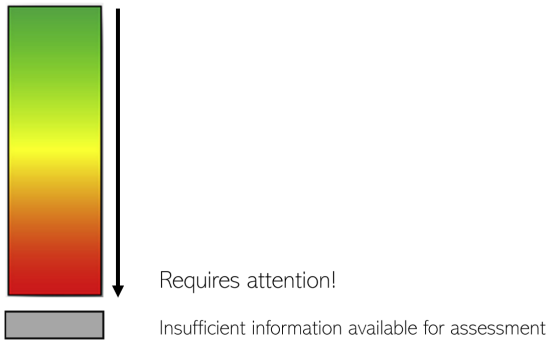

Figure 3.3: **The colour scale that is used for the recovery assessment indices.** A red score on indices highlights areas of attention and grey indicates a lack of information for a proper assessment.

3.2.5. Assessment indices

The following section elaborates on the indices used in the recovery assessment tool for catheters. The proposed indices are to be deployed with the BOM of a catheter. The three categories of indices are the disassembly indices, hygienic recovery indices and material recovery indices.

Disassembly indices

The disassembly indices help identify if a catheter can be disassembled to facilitate recovery processes like cleaning or provide access to components for repair or recycling as explained in section 2.5.1.

Quantity of Fasteners Index (QFI) and Percentage of Fasteners Index (%FI) - Considering that the ease of disassembling a product is inversely proportional to the number of fasteners required to connect the product components to each other [58]. As the number of fasteners is highly dependent on the exact function of a product, it is not realistic to set a limit for this index. Accordingly, the percentage of fasteners is adopted to indicate which components have the most fasteners relative to the total number of fasteners. If a set of fasteners (e.g. screws) holds several components together, the number of fasteners is reported for the most internal component.

Type of Fasteners Index (TFI) and Reversibility of Fasteners - Next to the number of fasteners or connectors, the type of fasteners is also essential in evaluating a product for disassembly. The type of fastener determines whether a component needs to be disassembled using a destructive or a non-destructive approach. Non-destructive disassembly facilitates the ability to retrieve parts or reassemble the product. As the recyclability method was not developed for medical devices, some indices (e.g. Velcro, scotch tape, nylon tag fastener, blind rivet) were left out for this research, given that it is not likely to find these types of connections in small medical devices like catheters. For this study, the fasteners that require the most attention are both adhesive bonding with different types of glues and energy bonding like soldering, blazing, welding and moulding. This is given the fact that these connections are most challenging for disassembly purposes and require a destructive operation during dismantling of a component that cannot be reverted [55]. The scores for this index are based on the study by de Aguiar et al. that considered, amongst others, time of disassembly and force measurement for disassembly to calculate the index numbers. In addition, the reversibility of the fasteners in question is indicated separately.

Fasteners Index values	Type of fastener
1.07	Snap-fit
1.60	Screw
1.60	Nut and bolt
1.60	Magnetic attachment
1.60	Pin
2.67	Nail
2.93	Adhesive and energy bonding
0	Unclear

Accessibility Index (AI) - The accessibility index refers to the ease of reaching a component by hand or with a tool for dismantling. Four levels of accessibility are considered, from level 1 being a free surface and thus representing the ideal circumstance, and level 4 representing an inaccessible surface that would require attention if it is considered for recovery purposes.

Accessibility Index values	Description
1	Free access
2	50% or more accessible
3	50% or more inaccessible
4	Inaccessible
0	Unclear

Hygienic Recovery indices

This research aims to evaluate single-use catheters on readiness for end-of-life recovery purposes; new indices have been added that support the evaluation of a catheter on hygienic obsolescence. Given that catheters are high-criticality medical devices, the devices should withstand cleaning, disinfection and sterilisation methods to reverse hygienic obsolescence and be suitable for recovery methods like reprocessing or recycling. Based on the framework used in the theoretical background highlighting the trade-off between product value and criticality of the device, these indices are called the hygienic recovery indices. Three hygienic recovery indices are identified and presented here.

Devices should be evaluated on the ease of cleaning, e.g., whether the device has features that could easily trap and retain soil and impede cleaning [75]. Next to the ease of cleaning, the devices should also be able to withstand aggressive sterilisation procedures, e.g., can the material withstand the aggressive sterilisation process. The mechanical, thermal and/or chemical impact of a sterilisation process can influence the properties of a material and thus deteriorate the component and its function [76]. Finally, it should also be addressed if the components of the device are in contact with the human body and if a component enters the normally sterile body sites. Examples of sterile body sites are blood, bone, joint fluids and internal body organs like the brain, heart or liver [77].

Tissue Contact Index (TCI) - The tissue contact index indicates whether a component or sub-assembly is in (in)direct contact with the patient and in what kind of contact. This is based on the ISO standard for biological evaluation of medical devices within a risk management process. Medical devices are classified according to the nature and the duration of the anticipated contact with human tissues in use, as explained in Chapter 2. For catheters, it is mainly circulating blood and surrounding tissues with which there is contact. Blood is considered both a fluid and a connective tissue with specialised cells that serve particular functions, which explains the name of this index.

Tissue Contact Index values	Description
1	Component has neither direct nor indirect contact with patient's body tissues
2	Component has only surface contact with patient
3	Component has indirect tissue contact with patient's body tissues
4	Component enters sterile tissues of the patient's body
0	Unclear

A catheter is considered a critical Class II device under the US FDA and a Class III device under the EU MDR because it is a surgically invasive device that controls, diagnoses, monitors or corrects a defect of the central circulatory system through direct contact with those parts of the body [9], [54]. This means that the entire device is considered a critical device and all components should be sterilised accordingly if it is considered for reuse. However, since not the entire device comes into contact with these sterile tissues, some parts of the device may not be contaminated and therefore easier to clean than the parts that enter the vasculature. This can be illustrated by the handle of a catheter that only comes into contact with a user's gloved hand. As stated, these components must currently also be cleaned and sterilised but could potentially provide opportunities for redesign for recovery purposes. This index only indicates which parts of the catheter are in contact with the patient, not the physician or assistant's gloved hands.

Requirements are usually less stringent for materials with indirect or no contact with body tissues, which offers opportunities for the use of more sustainable materials. It is considered in the ISO standard indirect contact when a medical device component or the medical device itself does not physically contact body tissue. For this category of devices and components no further biological evaluation of the component is necessary if the component can be shown to be made from materials in common use for other consumer products with similar nature of contact. To illustrate, for devices with indirect contact with circulating blood, less hemo-

compatibility tests are required [78]. Surface contacting components are considered components that are in contact with intact skin, intact mucous membranes and breached or otherwise comprised body surfaces [79]. Also, the use of recycled material in medical equipment that contacts normally sterile body sites is forbidden by regulations [80].

Ease of Cleaning Index (ECI) - This index indicates the estimated ease of cleaning of a single component. A list of design features that may pose challenges to cleaning of a device is given in Appendix A.4. This lists illustrates what type of components are seen as a challenge in cleaning processes or cannot be adequately cleaned using standard equipment. Explanations are also provided in Appendix A.4 on the reason why these features make cleaning difficult. By using this list an estimation can be made how hard it is to clean a component. For instance, smooth surfaces of components facilitate the cleaning procedure whereas components with ridges or irregularities are prone to retain debris or soil and affect the ease of cleaning [9], [60], [75].

Ease of Cleaning Index values	Description
1	Easy to clean component
2	50% or more of the component is easy to clean
3	50% or less of the component is easy to clean
4	The component consists mainly of features that make cleaning challenging
0	Unclear

Sterilisation Compatibility Index (SCI) - This index evaluates the compatibility of a component with a sterilisation process. After the cleaning process, the device should be sterilised to be completely hygienically recovered. As catheters are most likely to be sterilised with ethylene oxide (EtO), the compatibility of the catheter components with ethylene oxide are assessed here [81]. It is an effective sterilant given its ability to diffuse through solid materials and its compatibility with many materials, of which many are sensitive to heat, high humidity and radiation [81], [82]. In Appendix A.5, a material compatibility list is given that supports in evaluating the compatibility of a component to EtO sterilisation. This list is based on a paper that discusses the effects of sterilisation on medical materials and welded devices [83] [84]. Suppose a component consists of a material not included in the provided list. In that case, a free search can be conducted into other studies that can provide information about the EtO sterilisation effects on a specific material, and the component can still be assessed.

Sterilisation Compatibility Index values	Description
1	Component is highly compatible with EtO sterilisation
2	Component is likely to be compatible with EtO sterilisation
3	Component is not likely to be compatible with EtO sterilisation
4	Component is not compatible with EtO sterilisation
0	Unclear

Material Recovery indices

This category of indices intends to evaluate both in which components the most value in terms of materials can be found and the suitability of the individual components for recovery.

Material Separation Index (MSI) - This index relates to the possibility of separating materials from a component or sub-assembly for recycling given that a lower variety of materials entails better recycling possibilities. In the recyclability method this is defined as compatible, low-compatibility or non-compatible materials, which was considered too vague for this research. Therefore, the index was slightly changed into levels

that indicate the difficulty or possibility to separate two or more materials of a component or sub-assembly. Sometimes when two or more materials are used together, the materials can hardly be separated and thus the recycling yield is very low or non-existing. It will have to be estimated whether it is challenging to separate the materials of a component or to separate the component from the sub-assembly.

Material Separation Index values	Description
1	Component consists of only one material or materials can easily be separated
2	Materials can be separated through an automated process
3	Materials can be separated but it is a challenging process
4	Not possible to separate the materials
0	Unclear

Material Group Index (MGI) - This index refers to the presence of hazardous substances in materials and the risk they could potentially pose to human life and the environment when being used or recycled. Several updates have been done the past years on the Restrictions on Hazardous Substances (RoHS) list. This list was originally created to regulated products in the electronics industry but medical devices are now also subject to it. The RoHS list is a database that contains 4753 unique hazardous substances [85]. The database has a search function that can be consulted. Every component of a device should be considered for RoHS compliance, from plastics, metals, paints, coatings, adhesives, lubricants, screws, printed circuit boards (PCBs), connectors, cables, packaging to textiles [86]. It is necessary to examine if a material is on this list. If it is unclear whether the material of a component contains a hazardous substance, this is marked grey to pay attention since it needs more research. When a component is suspected to contain hazardous substances, but this needs more research to be confirmed, this is marked orange.

Material Group Index values	Description
1	Component does not contain a hazardous substance
2	Component is not likely to contain a hazardous substance
3	Component contains most likely a hazardous substance
4	Component contains a hazardous substance
0	Unclear

Material Coating Index (MCI) - This index indicates whether a component has a coating or not. Coatings can be implemented for functional (e.g. hydrophilic, hydrophobic, lubricious, anti-clotting) or aesthetic reasons (e.g. colours or gloss). When a device or component is considered for reuse and components contain functional coatings, these should be reapplied, and attention should be paid to this. Also, a recycling stream can be contaminated by components or devices that contain coating that pollutes a stream of mono-materials. The tool provides an option to select Yes, No or Unclear from a drop-down menu.

Coating Index values	Description
1	Component does not contain a coating
4	Component contains a coating
0	Unclear

Material Value Index (MVI) - This index indicates where the most value lies in terms of material type. An estimate must be made of which materials of the device are most valuable, and a checkbox can be ticked accordingly. Examples of these are (precious) metals and their alloys. Next to identifying if a component is

potentially eligible for recycling, given the ease of separation and the absence of coating, it is also useful to have an estimation of the most valuable materials incorporated in the design when recovery methods are considered.

3.3. Research protocols

This section explains the steps to be taken to apply the proposed methodology and the resources that are required to conduct the study. First, the dismantling process is described, after which the procedure in which the tool is filled out is described. An illustration of the process to be followed can be found in Figure 3.4.

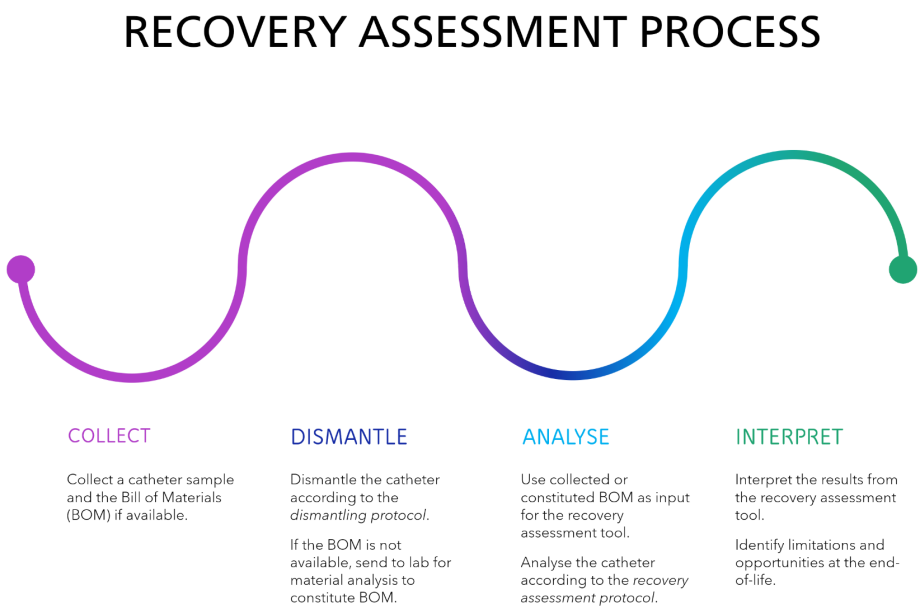

Figure 3.4: **Blueprint of the recovery assessment process.**

3.3.1. Dismantling protocol

In order to identify the type of fasteners or connections used, the product architecture and to identify the materials used, a dismantling process must be executed. To ensure that the dismantling process is repeatable and comparable with other assessments, a research protocol is adopted that is reported here.

The dismantling process must be fully recorded with a video camera for reference purposes. After the dismantling process, pictures must be taken from all of the components separately, then all components should be weighed separately, and a picture of all the components together should also be taken. Since a Bill of Materials (BOM) was lacking for the research executed here, the materials need to be send to a Philips lab in Drachten for analysis. However, if a BOM is available for future research, this step can be skipped or if there are no lab facilities for material analysis, an estimate of the type of materials used in the device can be made.

The following resources are required for the dismantling process:

- Video + photo camera with tripod:
  To record everything for reference purposes later.
- Tools (scissors, screwdriver, diagonal pliers, knife):
  These tools were sufficient to dismantle the devices in this study.
- Gram + milligram scales:
  To weigh the components, the milligram scales were consulted if the component weighed too little for the regular scales.
- Magnifying glass:
  To provide a close-up view of the connections between components and components themselves.

- Laptop with the Recovery Assessment tool:
  To report data immediately in a during the dismantling process, as well as during analysis after the process.

The following research protocol is suggested for the dismantling process:

1. Prepare the set-up
   The set-up is prepared with a frontal camera on a tripod so the process can be videotaped appropriately. All the essential tools must be prepared and placed within reach. The process must be entirely captured on camera from this moment on. Every action must be clearly videotaped, and speech can be used to explain how the action was executed to avoid confusion during reviewing afterwards.
2. Dismantle the product
   Remove the catheter from its packaging and dismantle the whole product into its components. The components must be gently dismantled with the appropriate tool for each component. If it concerns a sub-assembly, the sub-assembly must be detached first and then dismantled into its components. The process is finished when no components could not be taken apart any further with the named tools. To illustrate, a component where injection moulding was performed to merge connectors and wires into a single piece cannot be taken apart further with the tools available during the dismantling process of this study.
3. Weigh and take pictures of all components
   All components must be weighed, and photos must be taken. A photo must also be taken of all the components together. The larger components can be weighed on a gram scales, whereas the smaller components (<0.2 grams) must be weighed on the milligram scales. Weights must be listed per component in the tool presented in Figure 3.2. If no BOM is available for research, all components can be stored in separate bags to give to the lab for material analysis.
4. Evaluation after the recording
   A first overview of all the components and sub-assemblies is made in the tool during the dismantling process. All components must be listed following the order of dismantling, and the weight must be noted. This way, a BOM can be constituted in combination with the lab-analysis of the materials needed to use the proposed new method. When the material analysis was completed, the full analysis of the catheters using the video recordings and exact material compositions could be completed. The steps to be followed are explained in the following protocol.

3.3.2. Recovery assessment protocol

The following procedure must be followed for analysis of the catheters using the proposed recovery assessment tool:

1. Each component of the device must be evaluated for each of the different indices individually, using the given explanations from section 3.2.2. All indices except for the quantity and percentage of fasteners can be selected from a drop-down menu that automatically colours the corresponding cell green, yellow, orange or red in accordance with the chosen index. Each sub-assembly must also be reported in the tool, and all of the disassembly indices and the tissue contact index must be filled in for each sub-assembly.
   - BOM data:
     The first four columns can be filled in based on the gathered information during the dismantling process and the material analysis. The BOM level represents the level of a component or sub-assembly. If a component is part of a sub-assembly, the sub-assembly is given a number, and the components can be indicated by numbers after the decimal point (e.g. sub-assembly 1 consists of three components: 1.1, 1.2 and 1.3)
   - Fastener info:
     The type of fastener can be selected from a drop-down menu in the tool and it must also be indicated if it involved a reversible fastener or not.
   - Disassembly indices:
     The disassembly indices can be filled in using the video recordings as a reference. If the quantity of fasteners is filled in, the tool automatically generates the percentage of fasteners index. The accessibility index can be selected from a drop-down list in the tool.
   - Hygienic recovery indices:
     The three hygienic indices can also be selected from a drop-down list in the tool. The tissue contact

index must be filled in for both sub-assemblies and components whereas the ease of cleaning index and sterilisation compatibility index must only be filled in for the components.

- Material recovery indices:
  The material recovery indices can also both be selected from a drop-down list in the tool. All of the material recovery indices must only be filled in for the components and not for the sub-assemblies.

2. If information is lacking to fill in one of the indices, the corresponding cell must be coloured in grey to give a fair view of the situation.
3. The outcome of the table can be evaluated after filling everything in. Red indices indicate points of attention when the device is considered for recovery purposes. In section 3.3.3 is discussed how the results can be interpreted.
4. Based on the outcome of the tool, modifications can be made to the design of the device if desired. If modifications have been done to the design, the tool can be filled in again or changed accordingly.

3.3.3. Interpretation of the tool's results

After filling out the recovery assessment tool, the outcome can be interpreted to identify which components limit or provide opportunities for recovery purposes at the end-of-life. The tool does not suggest which recovery method to focus on. Components can be identified that currently limit recovery methods and need a redesign or, by contrast, that provide opportunities that can be discovered further.

The colour coding provides a graphical visualisation of the output by highlighting areas of attention in red and a lack of information in grey. Exploring this graphical diagnosis with an intended recovery method in mind makes the most sense. To illustrate, the separation of a component into pure materials is not relevant if a device is considered for reprocessing, whereas this is interesting for recycling. For reprocessing, hygienic recovery indices are the most critical consideration.

Additionally, it is also suggested to analyse the type of materials the identified components consist of and the weight. The material value index already helps to indicate the components with the most economical value. This way, an estimation can be made on which components of the device contain the most value in terms of materials and are, therefore, also interesting for recovery. However, not only should attention be paid to the value of individual components but also the combination of several components in sub-assemblies.

4

Results

This chapter presents the results of two case studies that use the previously proposed method and accompanying protocols for evaluating the readiness of single-use catheters for recovery purposes at end-of-life.

4.1. Introduction

The two case studies involve single-use catheters from a Philips product family. These catheters have already been introduced in section 2.6. Both case studies were conducted in Drachten with Mark-Olof Dirksen, Recycling Expert and Senior Project lead Advanced Developments of Philips, according to the presented methodology. The Chemical Analysis Group of Philips extensively analysed the materials of the catheters because the Bill of Materials (BOM) was not available. The detailed results of this material analysis are presented in Appendix B and are used throughout this chapter.

4.2. Case study 1

The first case study considered is the Eagle Eye Platinum Digital Intravascular Ultrasound (IVUS) catheter. Table 4.1 on the next page presents the Bill of Materials (BOM) of the Eagle Eye catheter. A drawing of the Eagle Eye catheter and illustration of the treatment procedure are depicted in Figure 4.1. A picture of all the dismantled sub-assemblies and components can be found in Figure 4.2. Section 4.2.1 provides a description of the device that describes the connections between the sub-assemblies and components. Finally, the results of the recovery assessment tool of the Eagle Eye catheter are presented in Section 4.2.3, the details of which can be found in Figure 4.3 and enlarged in Appendix C.

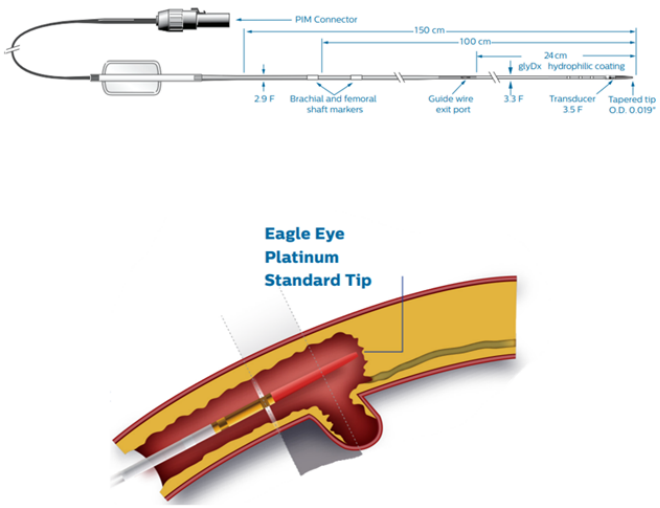

Figure 4.1: **Eagle Eye IVUS catheter, visualisation of procedure.** Philips internal documents

4.2.1. Description of the Eagle Eye catheter

The Eagle Eye IVUS catheter can be inserted into a vasculature allowing imaging of the inside of the vessel. In order to do this, the PIM connector must be connected to an IVUS console or patient interface module (PIM) that allows the signal transfer. Electrical wires are contained in the catheter from the proximal end to the distal end to allow this signal transfer. The PIM connector is the proximal end of the catheter that consists of a housing with incorporated electrical connections. These electrical connections are connected to electrical wires within the PIM connector. The PIM connector is connected to a black connection cable that terminates with a strain relief part that transitions into the black cable. This black cable ends in the wire connector. The wire connector is the area for transition between the portion of the catheter inserted in the patient and the portion that remains outside the patient's body during a procedure. The wire connector connects the electronics from the black cable to the electronics in the blue cable. Whereas the black cable contained electrical wires with an outer shaft only, the blue cable incorporates both electrical wires to guide the signals and a stainless-steel cable to provide more strength and stability during catheter placement. The blue cable transitions into a 25 centimetres-long transparent tube that incorporates both electrical wires and three radiopaque markers that improve the catheter's visibility and more precise positioning. A series of ultrasonic transducers are mounted near the distal end of the catheter. The small red tip is the distal end of the catheter and is connected to the ultrasound transducer and allows the smooth entering and navigating through a vessel.

4.2.2. Results material analysis Eagle Eye catheter

As already pointed out, the detailed results of the material analysis can be found in Appendix B. An overview of the dismantled device is shown in Figure 4.2. For some of the components of the Eagle Eye, no material investigation has been done. These materials are shown in italics in Table 4.1. The ultrasonic transducer part consisted of multiple layers and therefore needed further analysis. An assumption was made together with Mark-Olof Dirksen that the electrical wires and pins are made from copper alloys. The total weight of the Eagle Eye was 15.5 grams, excluding the packaging and the total length is 150 cm.

BOM level	**Item name**	**Weight (in g)**	**Material + coating**
1	Distal tip	0.00547	Polyamide-12 + PVP coating
2	Ultrasonic transducer part	0.01582	*Multi-layer component* + PVP coating
3	Transparent tube with markers	0.1035	-
3.1	Transparent tube	0.1	PEBA (Polyamide-12 elastomer)
3.2	Radiopaque markers	0.0035	Platinum-iridium
3.3	Electrical wires	0.1	*Copper alloy*
4	Blue cable	1.8	-
4.1	Outer shaft blue cable	0.4	Polyamide-12
4.2	Electrical wires	0.2	*Copper alloy*
4.3	Stainless steel cable	1.2	Grade 301 stainless steel
5	Wire connector	4.2	Polycarbonate
6	Black cable	1.0	-
6.1	Outer shaft black cable	0.1	PEBA (Polyamide-12 elastomer)
6.2	Electrical wires	0.1	*Copper alloy*
7	Black connection cable	0.9	PEBA (Polyamide-12 elastomer)
8	Black strain relief	0.6	PEBA (Polyamide-12 elastomer)
9	Electrical PIM connector	6.7	-
9.1	Housing PIM connector	6.7	Polyetherimide
9.2	Electrical pins PIM	-	*Copper alloy*

Table 4.1: **BOM of the Eagle Eye IVUS catheter.** Materials are the result of the analysis of Appendix B.

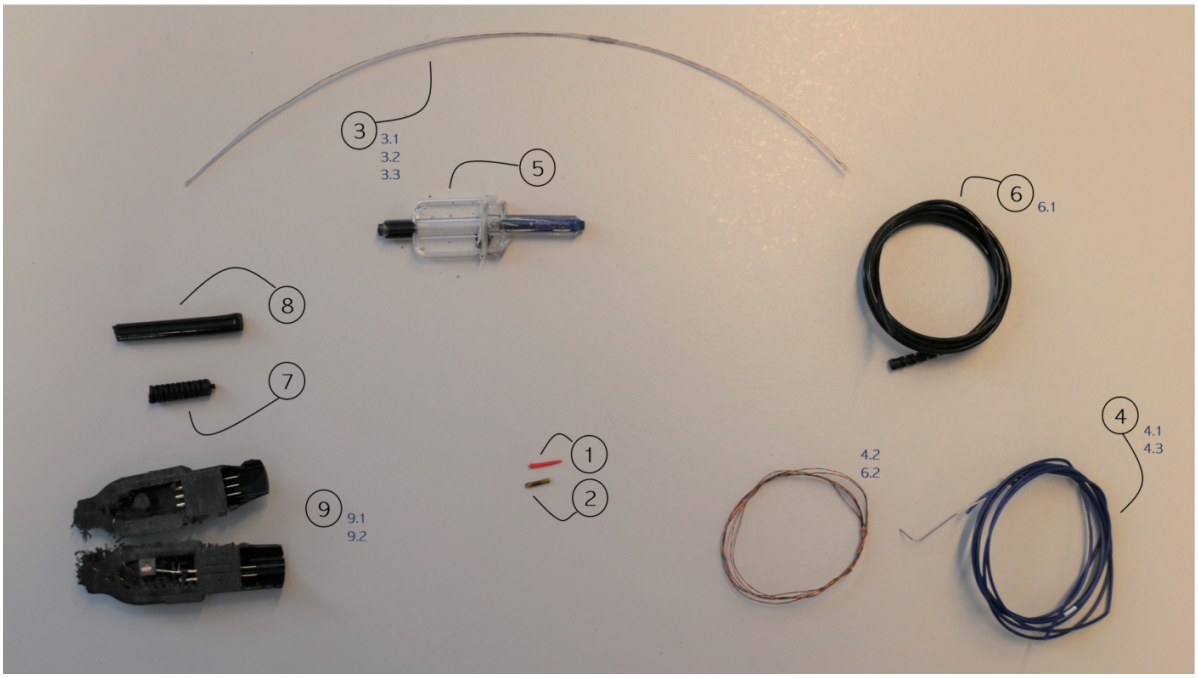

Figure 4.2: **Full dismantling overview of the Eagle Eye IVUS catheter.** Numbered according to Table 4.1.

4.2.3. Results recovery assessment Eagle Eye catheter

This section presents the results of the recovery assessment tool of the Eagle Eye IVUS catheter. The complete overview of the recovery assessment tool for the Eagle Eye catheter can be found in Figure 4.3 and enlarged in Appendix C. Here the results obtained through the analysis with the recovery assessment tool are described.

Eagle Eye Platinum IVUS Catheter

BOM data				Disassembly indices					Hygienic recovery indices			Material recovery indices				
BOM level	Item	Material	Weight (in g)	TFI	Reversible?	QFI	%FI	AI	TCI	ECI	SCI	MSI	MGI	MCI	MVI	Notes
1	Distal tip	Polyamide-12 + PVP coating	0,00547	Adhesive c	No	1	5%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	*PVP is hydrophilic coating preventing clotting*
2	Ultrasonic transducer part	*Multi-layer component + PVP coating*	0,01582	Adhesive c	No	1	5%	Free acces	Componer	Smooth su	Componer	Unclear	Unclear	Componer	☐	*materials under further investigation*
3	*Transparent tube with markers*			Adhesive c	No	1	5%	Free acces	Componer						☐	
3.1	Transparent tube	PEBA (Polyamide-12 elastomer)	0,1	Adhesive c	No	1	5%	50% or mo	Componer	Smooth su	Componer	Materials (	Componer	Componer	☐	
3.2	Radiopaque markers	Platinum-iridium	0,0035	Adhesive c	No	1	5%	50% or mo	Componer	The compo	Componer	Materials (	Componer	Componer	☑	*markers can be disassembled from transp tube*
3.3	Electrical wires	*Copper alloy*	0,1	Adhesive c	No	1	5%	50% or mo	Componer	The compo	Componer	Materials (	Unclear	Componer	☐	*type of copper has not been analysed*
4	*Blue cable*			Adhesive c	No	1	5%	Free acces	Componer						☑	*wires insulated in shaft*
4.1	Outer shaft blue cable	Polyamide-12	0,4	Adhesive c	No	1	5%	50% or mo	Componer	Smooth su	Componer	Materials (	Componer	Componer	☑	
4.2	Electrical wires	*Copper alloy*	0,2	Adhesive c	No	1	5%	50% or mo	Componer	The compo	Componer	Materials (	Unclear	Componer	☑	
4.3	Stainless steel cable	Stainless Steel grade 301	1,2	Adhesive c	No	1	5%	50% or mo	Componer	The compo	Componer	Materials (	Componer	Componer	☐	
5	Wire connector	Polycarbonate	4,2	Adhesive c	No	1	5%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☑	
6	*Black cable*			Adhesive c	No	1	5%	Free acces	Componer						☐	*wires insulated in shaft*
6.1	Outer shaft black cable	PEBA (Polyamide-12 elastomer)	1	Adhesive c	No	1	5%	50% or mo	Componer	Smooth su	Componer	Materials (	Componer	Componer	☑	
6.2	Electrical wires	*Copper alloy*	0,1	Adhesive c	No	1	5%	50% or mo	Componer	The compo	Componer	Materials (	Unclear	Componer	☐	
7	Black strain relief part	PEBA (Polyamide-12 elastomer)	0,6	Adhesive c	No	1	5%	Free acces	Componer	The compo	Componer	Materials (	Componer	Componer	☐	
8	Black connection cable	PEBA (Polyamide-12 elastomer)	0,9	Adhesive c	No	1	5%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
9	*Electrical PIM connector*			Adhesive c	No	1	5%	Free acces	Componer						☑	
9.1	Housing PIM connector	Polyetherimide (PEI)	6,7	Adhesive c	No	1	5%	Free acces	Componer	50% or mo	Componer	Not possib	Componer	Componer	☐	
9.2	Electrical pins	*Copper alloy*	-	Adhesive c	No	1	5%	Inaccessib	Componer	The compo	Componer	Not possib	Unclear	Componer	☑	*you have to bisect the handle to get to the pins*
		Total	15,5		Total	19										

Figure 4.3: **Results recovery assessment tool Eagle Eye catheter.**

Disassembly indices

The connections between components and sub-assemblies in the Eagle Eye catheter are all irreversible and needed a destructive operation for dismantling. The only component not accessible with standard tools is part of the electrical PIM connector sub-assembly; the electrical pins inside the connector are only visible on the images because the connector was sawed in half to see the connection.

Three parts of cable could be distinguished from the proximal to the distal end of the catheter, each of which had different components encapsulated in an outer shaft. These are the transparent tube, blue cable and black cable. All of these cables are separate sub-assemblies consisting of different components. E.g. the blue cable sub-assembly consists of an outer shaft, electrical wires and a stainless steel cable. The sub-assembly of each of the three cables is considered directly accessible. The outer shafts of the cables were scored with 50% or more accessible because they are situated at the surface but still need to be detached of the inner

components for dismantling. In contrast, the inner components (e.g. electrical wires, stainless steel cable, radiopaque markers) were scored with 50% or less accessibility since the outer shaft was first removed before there was access to these components.

Hygienic recovery indices

The components from level 1, the distal tip, to 4, the blue cable of the catheter, enter the normally sterile areas of the patient's body. However, some components have only indirect patient contact as they are contained within the outer shaft of the cable that contacts the inside of a vessel, whereas the component itself does not have direct contact with the vessel. The total weight of the components that enter the patient's body is 2.0 grams, representing 13% of the total weight. The components from level 5, the wire connector, to the proximal end of the catheter, the PIM connector, are not in contact or indirect contact with areas of the patient's body. The total weight of these components is 13.5 grams, representing 87% of the total weight. These components are only in contact with the physician's or assistant's gloved hands.

The inner components of the catheter make cleaning challenging because the outer shafts of the cables envelop them. The list from Appendix A.4 that presents design features that are challenging to clean indicates that long tubular cavities, in general, are hard to clean. Although the most extensive surfaces of the PIM connector are smooth, the PIM connector has several aspects like ridges and sharp angels that make cleaning challenging. The black strain relief part of the cable is also hard to clean as the spring part that is wrapped around the cable has edges where soil could accumulate.

Most of the components are made of materials compatible with ethylene oxide (EtO) sterilisation, based on the list provided in Appendix A.5 that lists the compatibility of several materials with EtO sterilisation. The wire connector is made of polycarbonate (PC), which is considered mostly compatible with EtO sterilisation. Some formulations of PC may be subject to stress cracking and loss of tensile properties. The PIM connector made out of polyetherimide (PEI) is also considered mostly compatible based on Appendix A.5 because PEI is compatible with EtO sterilisation depending on the formulation and application of the material.

Material recovery indices

The three cable sub-assemblies consist of components that are challenging to separate, given that the inner components are encapsulated in the shafts of the cables. The electrical pins of the PIM connector cannot be separated as they are fused into the polyetherimide housing of the connector. For the ultrasonic transducer, the possibility for separation is unclear, given the unclarity of its material build-up that is still under investigation in Drachten.

All materials have been checked against the RoHS list of hazardous substances. Given that it is unclear which copper alloys are used in the catheter, no judgement can be made for these components. The only component suspected of possibly containing a hazardous substance based on the RoHS list is the wire connector, made of polycarbonate (PC). In the manufacturing process of polycarbonate, bisphenol A might be used, which is considered a hazardous substance.

The material investigation only detected the presence of a coating on the distal tip and ultrasonic transducer part. These components had a coating of polyvinylpyrrolidone (PVP), which is a hydrophilic coating that prevents the formation of blood clotting on the surface. Finally, the identified valuable materials in the Eagle Eye catheter were platinum-iridium, copper alloys and stainless steel grade 301.

4.3. Case study 2

For the second case study, the Turbo-Elite Laser Atherectomy device was considered. This research intended to focus only on intravascular ultrasound (IVUS) catheters, but in the absence of a second IVUS catheter for this research, an atherectomy catheter was selected. A short explanation is presented in Section 2.6.2 to give some basic understanding of the functioning of a laser atherectomy catheter and the procedures in which this type of catheter is used. Table 4.2 presents the BOM of the Turbo-Elite catheter. An illustration of an atherectomy procedure is given in Figure 4.4. A picture of all the dismantled sub-assemblies and components can be found in Figure 4.5. Finally, the results of the recovery assessment tool of the Turbo Elite catheter are presented in Section 4.3.4, the details of which can be found in Figure 4.6 and enlarged in Appendix C.

4.3.1. Laser atherectomy catheter

Instead of allowing imaging of the inside of a vessel like IVUS catheters do, laser atherectomy catheters are used in procedures to treat patients with peripheral arterial disease, mostly in lower extremities. The Turbo-Elite catheter is indicated for use in the treatment, of limb ischemia and occlusions, including atherectomy.

4.3.2. Description of the Turbo-Elite catheter

The Philips Turbo-Elite atherectomy catheter uses ultraviolet to ablate plaque in a vessel via the distal tip. The proximal connector of the Turbo Elite catheter is connected to a laser system that delivers laser energy. The catheter is passed over a guidewire proximal to the lesion; this is done by introducing the tip of the catheter over a guidewire. The proximal connector comprises a housing consisting of a front and back cover and an inner component. This connector is connected to the black cable that encapsulates a glass fibre bundle with a black shaft via the proximal cable connector. This black cable containing a bundle of glass fibre transitions into the brown cable via the Y connector part. The Y connector part encompasses a guidewire port through which the guidewire can be pulled out. The Y connector also contains a connector part that connects the black cable and guidewire port to the brown cable. A set of glass fibres in the brown cable is arranged around the guidewire lumen within the outer shaft. This guidewire lumen guides the guidewire from the port to the distal tip of the catheter. The distal tip of the catheter excites the laser energy and ablates while being in contact with the lesion of a patient.

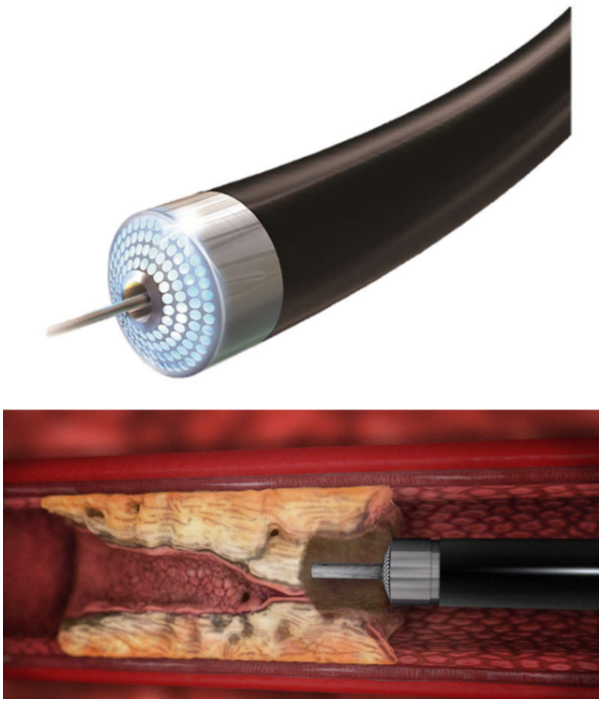

Figure 4.4: **Turbo-Elite Laser atherectomy catheter, visualisation of procedure.** Philips internal documents

4.3.3. Results material analysis Turbo-Elite catheter

The detailed results of the material analysis can be found in Appendix B. For some of the components of the Turbo-Elite, no material investigation has been done. These materials are in italics in Table 4.2. The distal tip has not been analysed in the lab. The glass fibres inside the black and brown cable neither; however, it is clear that it concerns glass optical fibre. The exact composition and presence of glass fibre coating are still under investigation. The total weight of the Turbo-Elite catheter was 49.4 grams, excluding the packaging and the length is 150 cm.

BOM level	Item name	Weight (in g)	Material
1	Distal tip	0.1	-
2	Brown cable	7.4	-
2.1	Outer shaft brown cable	1.0	Polyamide-12
2.2	Guidewire lumen	0.8	Polytetrafluorethylene (PTFE)
2.3	Glass fibre bundle brown	5.6	*Glass fibre*
3	Y connector	2.2	-
3.1	Connector part	1.3	Polyamide-12
3.2	Guidewire port	0.9	Polyamide-12
4	Black cable	13.4	-
4.1	Outer shaft black cable	4.2	Polyamide-12
4.2	Glass fibre bundle black	9.2	*Glass fibre*
5	Proximal cable connector	1.1	Styrene-ethylene-butylene-styrene (SEBS)
6	Proximal connector	25.2	-
6.1	Connector housing front	8.4	Acrylonitril-butadiene styrene (ABS)
6.2	Connector housing back	3.9	Acrylonitril-butadiene styrene (ABS)
6.3	Inside connector	12.9	Aluminium 6061

Table 4.2: **BOM of the Turbo-Elite atherectomy catheter.** Materials are the result of the analysis of Appendix B.

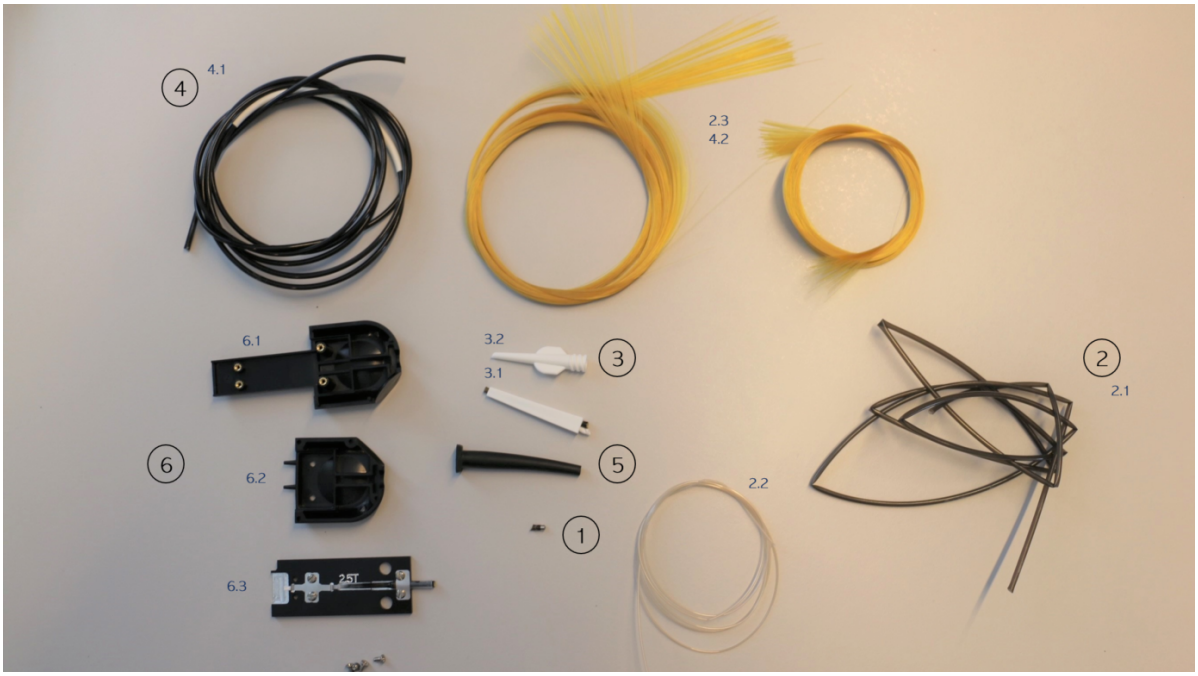

Figure 4.5: **Full dismantling overview of the Turbo-Elite atherectomy catheter.** Numbered according to Table 4.2.

4.3.4. Results recovery assessment Turbo-Elite catheter

This section presents the results of the recovery assessment of the Turbo-Elite Laser atherectomy catheter. The complete overview of the recovery assessment tool for the Turbo-Elite catheter can be found in Figure 4.6 and enlarged in Appendix C. Here the results obtained through the analysis with the recovery assessment tool are described.

Turbo Elite Laser Atherectomy Catheter

BOM data				Disassembly indices					Hygienic recovery indices			Material recovery indices				Notes
BOM level	Item	Material	Weight (in g)	TFI	Reversible?	QFI	%FI	AI	TCI	ECI	SCI	MSI	MGI	MCI	MVI	
1	Distal laser tip	-	0,1	Adhesive	No	1	6%	Free acces	Componer	Smooth su	Componer	Componer	Unclear	Componer	☐	*material not analysed*
2	*Brown cable*			Adhesive	No	1	6%	Free acces	Componen	t enters st					☐	*lumen and fibres insulated in shaft*
2.1	Outer shaft brown cable	Polyamide-12	1	Adhesive	No	1	6%	50% or mc	Componer	Smooth su	Componer	Materials	Componer	Unclear	☐	
2.2	Guidewire lumen	Polytetrafluorethylene (PTFE)	0,8	Adhesive	No	1	6%	50% or mc	Componer	The compo	Componer	Materials	Componer	Componer	☐	
2.3	Glass fibre bundle	*Glass fibre*	5,6	Adhesive	No	1	6%	50% or mc	Componer	The compo	Componer	Materials	Unclear	Unclear	☐	*type of glass fibre has not been analysed*
3	*Y-connector*			Adhesive	No	1	6%	Free acces	Componen	t has neith					☐	
3.1	Connector part	Polyamide-12	1,3	Adhesive	No	1	6%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
3.2	Guidewire port	Polyamide-12	0,9	Adhesive	No	1	6%	Free acces	Componer	50% or mc	Componer	Componer	Componer	Componer	☐	
4	*Black cable*			Adhesive	No	1	6%	Free acces	Componen	t has neith					☐	*only fibres insulated in shaft*
4.1	Outer shaft black cable	Polyamide-12	4,2	Adhesive	No	1	6%	50% or mc	Componer	Smooth su	Componer	Materials	Componer	Componer	☐	
4.2	Glass fibre bundle	*Glass fibre*	9,2	Adhesive	No	1	6%	50% or mc	Componer	The compo	Componer	Materials	Unclear	Unclear	☐	*type of glass fibre has not been analysed*
5	Proximal cable part	Styrene-ethylene-butylene-styrene (SEBS)	1,1	Adhesive	No	1	6%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
6	*Proximal connector*			Adhesive	No	1	6%	Free acces	Componen	t has neith					☐	
6.1	Connector housing front cover	Acrylonitrile butadiene styrene (ABS)	8,4	Screws	Yes	0	0%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
6.2	Connector housing back cover	Acrylonitrile butadiene styrene (ABS)	3,9	Screws	Yes	0	0%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
6.3	Inside connector	Aluminium 6061	12,9	Screws	Yes	4	24%	50% or mc	Componer	50% or mc	Componer	Componer	Componer	Componer	☐	
		Total	49,4		Total	17										

Figure 4.6: **Results recovery assessment tool Turbo-Elite catheter.**

Disassembly indices

Unlike the Eagle Eye catheter, that consists of only irreversible connections, the Turbo-Elite has one sub-assembly that holds its components together with screws. The proximal connector's front-and-back housing is connected with four screws; in this way, the aluminium inside of the connector is firmly anchored in the housing components. Taking these components apart was done with a conventional screwdriver and is therefore reversible. Aside from this connection, all other connections were irreversible and needed a destructive operation during dismantling.

For the Turbo-Elite catheter, two parts of cable could be distinguished from the proximal to the distal end of the catheter: a black and a brown part. Both of these cables are separate sub-assemblies that consist of different components. The sub-assemblies of both the cables are considered freely accessible. The outer shafts of these cables were scored with 50% or more accessibility. In contrast, the inner components of this catheter (guidewire lumen and glass fibre bundles) were scored with 50% or less accessibility since it was also possible to get the lumen and fibre bundles out of the shaft but first, the outer shaft needed to be detached.

Hygienic recovery indices

As for the Turbo-Elite catheter, the components from level 1, the tip and level 2, the brown cable, enter the normally sterile areas of the body. The guidewire lumen and glass fibre bundle have only indirect contact with the vasculature as they are contained within the outer shaft of the brown cable. The total weight of the components that enter the patient's body is 7.5 grams, representing 15% of the total weight of the catheter. From level 3, the Y connector, until level 6, the proximal connector, all components are not in contact and also not in indirect contact with areas of the patient's body. The total weight of these components is 41.9 grams, representing 85% of the total weight. These components are only in contact with the physician's or assistant's gloved hands.

The inner components of the catheter cables make cleaning challenging, given that the outer shafts sheathe them. The outer shafts of the cable are considered easy to clean as they are on the surface of the device and have a smooth shaft that eases cleaning. However, just like in the Eagle Eye, the fact that the catheter has a lumen makes cleaning especially challenging as this requires the full lumen to be cleaned, based on Appendix A.4. The inside of the connector is also less easy to clean as it requires the housing to be removed first before there is access.

All materials of the Turbo-Elite catheter are, in theory, compatible with EtO sterilisation. Except for glass fibre, every material was on the list of Appendix A.5 and considered compatible. A free search into the compatibility of glass fibre indicated that exposure to EtO sterilisation does not produce any effects on fibre strength and does not cause any degradation, however this should be validated [87].

Material recovery indices

The brown and black cable parts consist of components that are challenging to separate, given that the glass fibre bundles and lumen are encapsulated by an outer shaft. The exact composition of the glass fibre bundles has not been analysed. Other than that, all other components of the catheter consist of one single material and do not pose challenges for separation of materials.

Finally, all materials have been checked against the RoHS list of hazardous substances for medical devices. None of the identified materials contains a hazardous substance. However, given that the material of the distal tip and glass fibre bundles is unclear, no judgement can be made here.

The material investigation did not detect any presence of coatings on the components that have been analysed. The presence of glass fibre coating is being researched in the lab but is not yet available. Finally, aluminium was identified as the most valuable material of the Turbo-Elite catheter.

5

Discussion & Limitations

This chapter discusses the meaning and relevance of the results of this research. These results will be placed in a broader perspective, in line with the research questions. After discussing the applied method and results, the current study's limitations are presented. The the chapter will conclude with recommendations for future research and the study's significance for Philips.

5.1. Research contribution

Given the push toward implementing circular and sustainable initiatives in the healthcare sector and the reliance on single-use medical devices, this research aimed to identify opportunities at the end-of-life of single-use catheters that sustain value and limit the environmental impact. Not only because the production of medical devices and treatment of medical waste significantly impact greenhouse gas emissions but also because valuable and possibly scarce materials that could possibly be repurposed are lost in the process of medical waste disposal. Accordingly, five research questions were introduced, of which the answers will be discussed in this chapter.

1. What product and material recovery methods exist in the medical device industry?

This research question has been addressed through a literature study presented in Chapter 2, Theoretical Background. Implementing circular recovery methods for medical devices is challenging given the clinical challenges of safety and sterility that present challenges to reuse. Infectiously or non-infectiously contaminated medical devices should be handled with extreme care, according to the intended use of the medical device in question. These safety and sterility challenges make it harder to innovate with sustainable recovery methods in the medical device industry than in other manufacturing industries (e.g. electrical equipment, computers, furniture, automobiles or clothing and textiles).

The identified medical device industry's product and material recovery methods are repair & maintenance, reprocessing, refurbishment and recycling. Refurbishment is the collection of devices - usually large and highly complex - at end-of-life and putting them back into service, after which they can be sold again for a lower price. This way, resources are conserved, value is retained, and waste is reduced. Repair & maintenance is recovering a device from temporary functional obsolescence like breakdown or performance errors. This method requires the support of experienced engineers that are accredited to provide this service and is high in cost, explaining why this service is only cost-effective for large equipment with a long lifespan. Reprocessing is making a used device, reusable or single-use, ready for another use. It may include cleaning, disinfection and sterilisation procedures but also restoring the technical and functional safety of the device. Finally, recycling is the process of breaking down a device into its components to be able to recover materials that can be used to make new components or products. From an environmental perspective, this is the least desired recovery method as the embedded value of a product's function is lost, and substantial energy and transport are needed for the process.

2. What type of recovery methods are suitable for catheters?

Catheters are high-cost single-use devices that enter the sterile areas of the body, making them critical devices. If they are considered for recovery methods, they must be rendered free from all forms of microorganisms through appropriate cleaning and sterilisation procedures. The recovery methods of refurbishment and repair & maintenance are not suitable for catheters since these processes are complex and costly. These recovery methods are only cost-effective for large-capital equipment with a long lifespan such as X-ray, MRI, and CT systems.

That leaves reprocessing and recycling as suitable product recovery methods for catheters. A framework was presented in Chapter 2 that considered reprocessing the most suitable recovery method for catheters, given their relatively high value as a single-use device and their criticality. Additionally, reprocessing is generally preferred over recycling because the most value is preserved through retaining most of the embedded value of a product by keeping it whole and with the same function. Whereas single-use medical devices are by definition designated to be used during a single medical procedure on one individual and discarded after the procedure, reprocessing has grown in acceptance globally. Hence, the US FDA and EU established regulatory requirements that govern reprocessing and further use of these devices. The processes to render a single-use device fit for a subsequent use should be thoroughly validated with cleaning, sterilisation, functional performance data that demonstrate that each single-use device will remain substantially equivalent after reprocessing.

Recycling is often seen as a last resort recovery method because the embedded value of the device's function is lost. Still, while the embedded value is lost by reducing a product back to its materials with recycling, the process of recycling may turn waste into a valuable resource and it reduces the need to collect new raw materials. The design of a device determines the suitability for recycling; e.g. using fewer different materials can facilitate a more straightforward recycling process and how components are connected determines how easy it is to separate materials for recycling. However, as catheters enter sterile areas of the body, devices should be cleaned and sterilised adequately before or during the recycling process.

3. How to assess the readiness for recovery purposes of catheters?

This research question is addressed through the development of a tool presented in Chapter 3, Methodology. The *recovery assessment tool* helps to assess the readiness of catheters for recovery purposes and is the first tool to analyse whether a single-use medical device is ready for recovery purposes. These medical devices are not designed and manufactured to be used more than once and should be disposed of immediately after use. However, the problem of the growing amounts of valuable medical waste needs to be tackled. The tool supports identifying catheter components that limit or provide opportunities for recovery purposes at the end-of-life.

The tool uses the Bill of Materials of a catheter as input; this list contains all the components, sub-assemblies and materials a device comprises in hierarchical order. A catheter can then be assessed via analysing the components and sub-assemblies on three categories of proposed indices: device disassembly indices, hygienic recovery indices and material recovery indices. The method uses colour coding to distinguish between the different scores on indices and these colours can be interpreted by using the explanations given with each index. The colour-coding system helps highlight areas of attention if recovery methods are considered and when insufficient rationale or information is available to evaluate a particular component.

Three categories of indices are considered essential to analyse a catheter for recovery purposes. The first category of *device disassembly indices* pinpoints the type of fasteners used to make connections between components or sub-assemblies and the degree of accessibility of components or sub-assemblies. The ease of disassembly involves separating a device into its components or sub-assemblies, which facilitates recovery methods. *Hygienic recovery indices* are the second category of indices integrated into the tool. Since catheters are critical devices, they must be optimised as much as possible for cleaning and sterilisation procedures to be rendered safe for recovery methods after use. This category of indices evaluates which parts of the device

enter the sterile areas of the body, the estimated ease of cleaning and whether the component's material is compatible with a sterilisation procedure. The third category of *material recovery indices* evaluates where the most value in terms of materials can be found and if the individual components are suitable for recovery taking their material build-up into account. The components are evaluated on the possibility of material separation for recycling, the presence of hazardous substances that could pose risks when considered for recovery purposes, the presence of coatings on components and an estimation of their individual value.

The tool's output is acquired if an entire device is analysed on its sub-assembly and component levels through an evaluation of each of the indices. This output is a graphical visualisation that identifies attention points when a device is considered for recovery purposes. Through an interpretation of the results, components can be identified that currently limit recovery methods and need a redesign or, by contrast, that provide opportunities that can be discovered further.

4. How does a catheter currently score in terms of recovery?

Two catheters were assessed as a case study with the proposed methodology. The results of these two case studies are presented in Chapter 4, which will be interpreted and discussed here. A Bill of Materials was established according to the protocol presented in Chapter 3, Methodology, to be used with the recovery assessment tool. The first evaluated catheter was the Eagle Eye Platinum Digital IVUS catheter and the second was the Turbo-Elite Laser Atherectomy catheter due to the absence of a second IVUS catheter for a case study.

Device disassembly indices
All the connections of the assessed catheters, except for one, were permanent and could not be reversibly disconnected, needing a destructive operation for dismantling. The presence of only irreversible connections in the studied catheters impedes the ease of disassembly to clean the device properly and separate them for recycling purposes. These permanent connections are adopted for functional, safety and aesthetic reasons. However, adopting reversible connections can provide opportunities which will be addressed in the last research question.

The components of the catheters that were most hard to access were the inner components within the shaft and within both proximal connectors. The longest part of the studied catheters consists of a cable containing at minimum one component, either a glass fibre bundle or electrical wires enveloped by an outer shaft. These inner components are hard to reach for cleaning purposes.

Hygienic recovery indices
Half of the number of catheter components enter the patient's normally sterile body sites during a procedure; however, these in-body components represent only 13 and 15% of the weight of the case-studied catheters. Both catheters house a component that establishes the connection between the cables from the in-patient part of the catheter to the part outside the patient and only contacts the physician's gloved hand during the procedure. Rethinking the catheter design could provide opportunities that will be discussed later.

Furthermore, the recovery assessment method results suggest that the devices could be suitable for cleaning and sterilisation processes. However, the long tubular shape of catheters that partly houses a hollow cavity to guide guidewires make cleaning challenging. Although the materials of these catheters seem to be mostly compatible with ethylene oxide sterilisation, extensive validation is needed if the device would be considered for reprocessing.

Material recovery indices
For one of the case-studied catheters, it was found that a hydrophilic coating was present on the part that enters the body. This functional coating prevents the formation of blood clotting on the surface of the catheter. If a potential reprocessing protocol is considered, the coating must be reapplied after cleaning and sterilisation. These shafts with hydrophilic coatings must first be cleaned or sterilised after use before recovery can take place. Additionally, it is unclear if a cleaning and sterilisation process removes all the coating and if the coating affects the recycling possibilities.

As stated above, cables make up the longest part of the catheters. These cables consist of different types of components enveloped by an outer shaft. It was also identified that some of these components contain valuable non-ferrous metals, i.e. copper alloys, stainless steel, aluminium and platinum-iridium. These valuable materials can be recovered if it is possible to clean and sterilise them accordingly, either before or during a recycling process. This could potentially reduce the need to collect new valuable raw materials.

This discussion supports answering the question of how a catheter currently scores in terms of recovery. These outcomes are translated into limitations and opportunities for recovery purposes in the section that follows.

5. What limitations and opportunities can be identified based on the assessment of a catheter on recovery purposes?

This research question can be addressed by interpreting the results discussed above of the recovery assessment method. However, it can not be stressed enough that catheters are critical devices used inside the human body; therefore, safety must always be prioritised. In order to be ready for any recovery purpose, a catheter should always be cleaned and sterilised adequately. The following limitations and opportunities are identified based on the results of the two case studies:

Limitations
The presence of almost exclusively permanent connections can challenge the ease of cleaning and other recovery methods. Since components cannot be disassembled and reassembled again it can be more difficult to render the device ready for recovery purposes. Furthermore, the components of the device are hard to reach for cleaning due to the long tubular shape of catheters, that partly houses a narrow hollow cavity for guidewires.

It can be seen as a limitation of this study that the products considered for the case study are relatively lightweight products, respectively 15.5 and 49.4 grams for the Eagle Eye and Turbo-Elite catheter. Comparatively, 3-4 kilograms of waste are approximately produced per hospital bed per day in European countries [88], [89]. It can be argued that these catheters are just a drop in the bucket compared to the significant amounts of medical waste produced in total. Still, every step in the right direction of diminishing these incredible amounts of medical waste is one. Furthermore, catheters are single-use, high-value devices, so any form of recovery or re-purposing that can save money and is better for the impact on the environment will be beneficial.

One of the catheters contains a hydrophilic coating on the components that enter the body. It is unclear what kind of effect this coating has on recovery possibilities, this needs to be examined in follow-up studies.

Finally, a limitation based on the assessments of this study is that two different types of catheters have been studied due to the unavailability of two catheters of the same type. The two case-studied catheters have distinct functions and applications, making it more difficult to draw more specific conclusions.

Opportunities
Whereas catheters are considered difficult to clean, most materials seem compatible with ethylene oxide sterilisation; however, extensive validation is always required to ensure safety and performance. Especially for suitability for reprocessing, extensive analyses should be considered to establish and validate a reprocessing protocol, as explained elaborately in the summary of regulations in Appendix A.2. Even if reprocessing might be possible, this needs to be researched extensively since this can have major consequences if it goes wrong.

The catheters examined contain valuable metals. The EU is significantly dependent on the imports of raw materials for the industry with a dependency rate from 48% for copper to 100% to cobalt and platinum [65]. If these materials can be recovered, these valuable non-ferrous metals are saved from incineration and can be repurposed. Automatic cable strippers can remove insulation or outer sheaths from electrical wires and cables. Machines exist that strip cables starting from a diameter of 1 millimetre to recover materials for recycling purposes [90]. More methods exist that can recover metals on a larger scale via mechanical and physi-

cal methods, e.g. electronic magnetic separation, electronic-conductivity-based separation or density-based separation. Cables are then shredded first, and the selected technique effectively liberates the metallic parts from plastics [91]. This way, valuable metallic materials can be recovered on an industrial scale. However, the question is whether it is cost-effective to clean and sterilise the devices first and recycle them afterwards via these methods. Alternatively, recycling methods should be explored that can coop with contaminated waste. Moreover, as discussed throughout the thesis, recycling is the least desired recovery method from an environmental perspective as the embedded value of a device's function is lost, and substantial energy is required for the process. Still, this recovery method can already be investigated further and would immediately help reduce the production of medical waste and recover valuable materials.

Instead of only focusing on recovery methods at the end-of-life of catheters, it can also be valuable to reconsider the current design or build-up of a catheter. The existence of almost exclusively permanent connections can pose limitations now, but they can also provide opportunities for a redesign. Reversible connections like snap-fit connections have opportunities for implementing a hybrid design in catheters to separate the in- and out-body parts and to allow disassembly for disconnection. Suppose the out-patient part could be a reusable part of the console the catheter is connected to, and the in-patient part would be detached and disposed of after use. In that case, safety can be guaranteed for the sterile, in-body part, and 85% of the weight of the catheter can be recovered through reprocessing the out-body part.

In contrast to only focusing on value in terms of individual materials, several components assembled together in a sub-assembly or possible module can also be valuable to harvest as a technical unit at the end-of-life. The value of the materials separately may not be worth much, but the combination of their functionalities can be, especially if reprocessing is considered.

5.2. Limitations of the recovery assessment method

This section discusses the developed method's limitations, which will be presented using bullet points.

- Unfortunately, the impact of a particular component on the environment can not be assessed with the proposed method. It would have been useful to also have an indicator for *environmental impact* per component or for the whole product. An example of this could be an LCA - life-cycle assessment - score that indicates the environmental impact of a product or component from cradle-to-grave. The appropriate data and time resources were lacking to do an analysis of the environmental impact of the different components and how this impact would change if a particular recovery method would be considered.

- For this study, no attention has been paid to *circular business models*. The conventional business model depends on recurring revenue from selling single-use devices. It would also be interesting to consider the financial resources that can be saved for hospitals and how a sufficiently profitable business model can remain for companies.

- The list of *compatible materials* for ethylene oxide sterilisation used for the assessment method is strictly meant to be used as a guideline. No direct conclusions may be drawn from this list; expert input is always required. Several validation tests must always be performed with cleaning and sterilisation processes to test if materials are actually compatible with these processes.

- Catheters that are already considered for multiple uses are most of the time sterilised with *ethylene oxide*. Therefore, it was chosen to keep the focus of this research only on this sterilisation method, whereas different other methods also exist. Ethylene oxide sterilisation can have environmental effects that were not considered in this study either.

- The *packaging* of catheters is not considered for assessment in the current method, whereas this also makes up a big part of the amount of medical waste. A Dutch hospital analysed bags of non-hazardous plastic waste and found that over 50% of plastic waste was composed of disposables packaging [92]. It can be considered a limitation of this study that no attention was given to this set of low-hanging fruit.

- Whereas the method has been discussed several times with different stakeholders, the tool's *usability* has not been validated explicitly. It would be interesting for follow-up research to let different types of stakeholders use the tool. In this way, it can be found where they see value in the method and which

essential aspects are missing. Next, it would also be interesting to find out the time and effort they must put in to use the tool.

- Although comprehensive protocols and explanations are provided with the developed method, elaborating on the results is *subjective*. The results of filling out the assessment tool will always be more or less the same if all required information regarding materials and components of the device is available. However, the interpretation of these results to identify limitations and opportunities will depend on the knowledge of materials and recovery methods for medical devices of the user. Organising workshops with suggestions on interpreting the results can help solve this problem.

- The only value currently indicated within the tool is an estimation of the individual material values for potential recycling. Components assembled in a sub-assembly might be of more value together than individually because they fulfil a complex technical function together. It would be worth investigating if it is possible to reuse these sub-assemblies in the future.

5.3. Recommendations for further research

- A limitation that was identified is the absence of the environmental impact of a component or recovery method. For further research, it is recommended to investigate if it is feasible to incorporate an index that evaluates the environmental impact of the different components or the impact of implementing a recovery method. The promising results of a reduction of 50.4% of the global warming impact when using a recovered electrophysiology catheter as an alternative to a new one support this recommendation [4].

- It is recommended for further research to validate the tool with different groups of potential users. Due to a lack of time, this has not yet been done and only individual meetings took place to validate the first version of the developed method. Organising workshops on adapting the method to their wishes and requirements are suggested. Based on these workshops, capabilities can be added or deleted from the method.

- While the current output of the proposed method can be interpreted with the support of the accompanying explanations, it is recommended to develop a more extensive dashboard as output. This dashboard could then, for instance, assist the intended user in directing to the most notable opportunities and limitations for recovery methods.

- Medical device reprocessing has evolved over the years and is widespread in other countries by third parties. Third parties even received clearance from the US FDA to reprocess and sell Philips catheters, even the Eagle Eye catheter assessed in this research. [93]. The reprocessor is then considered to be the new manufacturer and is subject to all associated obligations. These obligations are in the EU and US said to be more stringent than regulations for original manufacturers. Reprocessing companies must include whole categories of validation data that original manufacturers are not required to submit [9], [50]. The remaining question is whether it is interesting for Philips to design catheters that are built for reprocessing or to investigate other opportunities to support reprocessing while maintaining high levels of safety. This is a very critical process that should be thoroughly and carefully scrutinised in compliance with medical regulations. Also, new business models should then be considered.

- As the assessed catheters contained valuable non-ferrous metals, it would be interesting to explore which recycling methods are suitable for recovery on an industrial scale. Especially it would be interesting to investigate if methods already exist that can grind the contaminated materials and clean and sterilise them in the same process. Next to identifying these methods, it would be interesting to calculate how much weight of waste can be kept out of incineration through recycling. Lastly, exploring how to set up this logistic process and scrutinising if this can be cost-effective is advised.

- The currently developed method is intended for the assessment of single-use catheters. For future research, it is suggested to investigate how the current tool can be generalised to be used for other single-use devices. Alternatively, another recommendation and opportunity is to develop versions of the tool that can be used for different categories of other single-use devices that have potential value after end-of-life.

- This study has only estimated if cleaning and sterilisation processes would be feasible for the case-studied catheters. It would be interesting for future studies to set up a more significant assessment of current catheter cleaning and sterilisation possibilities. Hence, it can be confirmed or not if the estimations that cleaning might be challenging are true. Furthermore, to find out which components are most critical for cleaning and sterilisation. Based on this real assessment, suggestions can be made to redesign them optimised for cleaning processes and therefore recovery methods.

- Methods already exist that support decision-making at the end-of-life of products. These models compare different recovery methods (i.e. reuse, remanufacturing, recycling) according to various variables and parameters to determine which recovery method is recommended [94]. It would be interesting to explore if it is possible to develop such a decision-making model for single-use medical devices that consider the different environmental impacts, financial savings, reductions in raw material depletion and possible risks, amongst others. This way, an argument can be built on which end-of-life recovery method is most valuable.

- For further research it is recommended to explore the effect of coatings on recovery processes. At present, it is unclear if a catheter's coating is entirely eliminated after one cleaning and sterilisation process and if these coatings contaminate a recycling process.

5.4. Significance of the study

This study aimed to identify opportunities at the end-of-life of single-use catheters to sustain value and limit the environmental impact. In the first stages of this research, methods were explored that could help with this aim. No method was found that was considered deployable to assess a single-use catheter for various reasons; hence the *recovery assessment tool* was developed. However, some studies had similar purposes and valuable features that will be discussed here.

- Researchers of the Delft University of Technology developed the HotSpot Mapping tool to help designers redesign their products for ease of disassembly, as this facilitates recovery strategies like repair and recycling. The tool supports assessing which parts of a product are most critical in terms of economic and environmental impact for disassembly so a redesign can be considered. The tool is primarily intended for mass consumer goods like household appliances that contain different sizes of components and different types of connections. While investigating this tool, it was found that a catheter is too small and contains too many small permanent connections, making many functionalities of this method redundant or impossible to use correctly. The light weight of a catheter also makes it impossible to estimate the environmental and economic value with the used database. Additionally, this tool is not fit for medical devices as it does not cover the criticality and focuses merely on redesign rather than on current end-of-life strategies. Finally, the structure of the HotSpot Mapping to evaluate a product on different component and sub-assembly levels was considered helpful and a similar structure was therefore used for the development of the new tool [95].

- Another tool by the University of Cambridge was identified that aimed to be useful for all types of medical devices, the maturity grid assessment tool. The tool's purpose was to provide useful information and direction for medical device designers in creating more sustainable medical devices. However, this tool is a very high-level tool that tracks the progressions of a company towards sustainable goals instead of analysing a medical device itself. It supports in tracking how sustainable the transport and packaging of devices are and what kind of energy is needed during production and use. Only one section of the tool focused on end-of-life strategies of medical devices, i.e. estimating the ability to disassemble and the potential to recycle or reprocess the device. However, this only entailed making an estimation of whether this was possible for the studied device [14].

- The tool that was used as inspiration for developing a new tool was a tool by Brazilian researchers to diagnose product recyclability. This method has been highlighted in more detail in Chapter 3. It makes use of a product's Bill of Materials to diagnose if a product is ready for recycling at the end-of-life. However, this tool was only suitable to assess if a product is recyclable and not specified for medical devices yet. Still, the way a product can be assessed on different component and sub-assembly levels with this tool, just as with the HotSpot Mapping tool, was considered useful. Hence, the method was enhanced to make it suitable for single-use catheters and allow it to focus beyond recycling [58].

- Finally, Philips also has several tools available to improve the product's end-of-life performance. Different tools exist that guide designers to design for disassembly and dismantling. These tools have been translated into requirements and guidelines for the design of new products and devices. The disassembly tools support especially in assessing current devices to identify redesign focus areas for repair, upgrade, refurbishment and parts recovery. This tool was considered too complex to analyse a small single-use device like a catheter with almost exclusively irreversible connections and identify opportunities at their end-of-life. With the dismantling tools, the focus is more on analysing if the type of materials used are suitable for recycling purposes, if they can be liberated and whether they do not contain hazardous or polluting components. These tools are both very precise and time-consuming. Therefore, the decision was made to develop a new tool specified for single-use catheters that is less time-consuming and has a simpler structure.

5.5. Significance for Philips

The identified problem for this research was that single-use medical devices contribute significantly to the growing amounts of medical waste. Philips has several single-use image-guided therapy devices in its portfolio. As Philips has the ambition to design all of their products optimised for circularity and to have optimised the material footprint over the full life cycle, this research focused on exploring opportunities for single-use catheters. The material investigation executed as a part of this thesis is used as input for a pilot Philips participates in to explore opportunities for recovery of single-use medical devices. Although this research might be only a small step in research that explores the recovery of single-use medical devices and no hard conclusions can be drawn yet, it can serve as a stepping stone for the conversation about rethinking single-use devices. Specifically, as third parties are already working on reprocessing Philips' catheters, it is important for Philips to investigate how they envision optimising catheters for circularity in the long run.

6

Conclusion

The growing concern and awareness regarding the climate crisis make single-use medical devices a glaring issue. Discarding devices that could potentially be repurposed or recycled are incinerated instead, sustaining and fueling an unsustainable linear economic model. Therefore, this research aimed to identify opportunities at the end-of-life of single-use catheters that could sustain value and limit the amounts of medical waste produced. A method was developed that supports approaching this aim, called the *recovery assessment tool*. The presented method allows for identifying components of a catheter that limit or provide opportunities for recovery purposes at the end-of-life. The method's output is a graphical visualisation that identifies attention points for when a device is considered for a recovery method. Based on this visualisation, components can be identified that currently limit recovery methods or, conversely, that provide opportunities that can be discovered further.

Two single-use catheters were used as a case study with the proposed methodology. Based on the presented protocols, the catheters were dismantled to their components and analysed accordingly. The results of these case studies led to several limitations and opportunities for catheter recovery. The main limitation is that the results suggest that cleaning catheters can be challenging given their long tubular shape and the fact that almost none of the components can be disassembled reversibly to allow adequate cleaning. This limitation may impede recovery options since catheters must be cleaned and sterilised after use as they have been in contact with the circulatory system. Also, the fact that components cannot be disassembled and reassembled again can impede other recovery methods like reprocessing and recycling. However, it still needs to be validated if the cleaning process of catheters is challenging. Another identified limitation is that catheters are lightweight devices that are only a drop in the bucket compared to the significant amounts of medical waste produced in total. Still, catheters are high-value devices, so any form of recovery can be valuable. Finally, due to the unavailability of two catheters of the same type, two different types of catheters have been assessed, making it more difficult to draw more specific conclusions.

The results of the case studies also led to opportunities. It was found that both catheters contain valuable metals currently ending up in incineration, whereas they could potentially be recovered. Although recycling is the least desired recovery method from an environmental perspective, as the embedded value of a device's function is lost, this method would immediately help reduce medical waste, recover value and potentially decrease the demand to collect raw materials. Most of the materials the catheters contained seem compatible with ethylene oxide sterilisation; however, as cleaning the devices is seen as challenging and needs to be validated, this must also be thoroughly validated. Furthermore, next to opportunities for recovery that could already be explored further with current catheters, it can also be valuable to reconsider the design or build-up of a catheter. A hybrid design is suggested to consider if the out-body part of the catheter could be designed to be reusable and connected with a reversible connection to a single-use in-body part to recover a significant portion of the weight and still guarantee the patient's safety. Lastly, in contrast to only focusing on value in terms of materials individually, an opportunity was identified to look into the recovery of functional modules at the end-of-life of new catheters. Currently, that is not possible given the permanent connections; however, this could be considered for future designs.

It can be concluded that some opportunities can be identified to sustain the value of single-use catheters at end-of-life; however, extensive investigations are needed to explore these further. Also, some limitations of the current method have been addressed. One of the most significant limitations of this study is that the environmental impact of the individual components could not be assessed with the current method and that the results do not suggest which recovery method is most valuable to focus on. This environmental impact needs to be estimated by the user of the method. A recommendation for future research is to add a factor that assesses which components have the most negative impact on the environment. Another limitation is that although the method has been discussed with relevant stakeholders, the usability has not been validated explicitly. Doing this validation by organising workshops to gather insights for an enhanced version of the method is recommended.

In conclusion, it turned out that single-use catheters are a complex problem in terms of circularity due to their hygienic criticality and light weight compared to the waste produced daily per hospital bed. However, as Philips aims to have products with minimal material usage and maximum circulation to realise the transition to a circular economy, all small steps to achieving this goal and closing the loop on catheters are welcome.

As a wise young lady once said: ***"a journey of a thousand miles starts with with a single(-use) step".***

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A

Appendix A

A.1. Product value versus criticality matrix

A.1.1. Estimated product value

In the following table an estimation of the prices of the medical devices that are used in the framework to compare criticality and product value are made. These estimations are based on different kind of sources, either websites that sell the device or articles that included the price for their research or by assumption.

Estimated product value of the functional products	
1. Imaging equipment	$ 100,000 -$ 500,000+ [96]
2. Anesthesia machines	$ 30,000 -$ 150,000+ [97]
3. Patient monitors	$ 2,000 -$ 10,000+ [98]
4. Furniture (e.g. hospital bed)	$ 500 - $ 10,000+ [99]
5. Surgical (arthroscopy) shaver	$ 1,000 - $ 3,000+ [100]
6. Surgical stapler	$ 750 - $ 2000 [101]
7. Hearing aids	$ 2000 - $ 3000 [102]
8. Endoscope	$ 2000 - $ 4000 [103]
9. Syringe	<$ 10
10. Bandages	<$ 10
11. Single-use compression sleeves	<$ 10
12. Intravascular ultrasound catheter	$ 1,500 - $ 3,000 [33]

Table A.1: **Estimated values of medical devices.** According to accompanied sources.

A.1.2. Criticality

In the first table below, Table A.3 the classification of the medical devices used in the framework of Chapter 2 is given according to the European Medical Device Regulation. The classification of medical devices is a risk-based system that takes into account the vulnerability of the human body and the potential risks that are associated with the medical device in question. In the second table, Table A.2, the classification of the devices is presented according to the Spaulding classification. The Spaulding classification ranges from simple disinfection to aggressive sterilisation, based on the intended use of the device and infection risk associated with a device. Critical devices present the highest risk as they enter normally 'sterile' ares of the body (e.g. the bloodstream, brain or heart) where typically no microorganisms can be found and thus require aggressive sterilisation. Semi-critical devices only contact mucous membranes (e.g. nose, mouth, lungs, stomach) or non-intact skin and require high-level disinfection. Non-critical devices present the lowest potential infection risks as they may only contact intact skin and only require low-level disinfection [53].

Medical device	Classification	Notes
1. Imaging equipment	Non-critical	No infection risk
2. Anesthesia machines	Non/semi-critical	The machine itself only requires low-level disinfection, face masks need high-level disinfection.
3. Patient monitors	Non/semi-critical	Monitor itself only requires low-level disinfection, features need high-level disinfection.
4. Furniture (e.g. hospital bed)	Non-critical	No infection risk
5. Surgical (arthroscopy) shaver	Critical	Contact usually sterile tissues
6. Surgical stapler	Critical	Contact usually sterile tissues
7. Hearing aids	Semi-critical	Contact mucous membranes.
8. Endoscope	Semi-critical	Contact mucous membranes
9. Syringe	Critical	Contact usually sterile tissues
10. Bandages	Semi-critical	Wound management devices that contact non-intact skin are considered semi-critical
11. Single-use compression sleeves	Non-critical	Only contact intact skin with compression
12. Intravascular ultrasound catheter	Critical	Contact usually sterile tissues (vascular system)

Table A.2: **Classification of the medical devices.** According to Spaulding Medical Device Coordination Group [104]

Medical device	Classification	Notes
1. Imaging equipment	Class IIa or IIb	Active devices intended for diagnosis and monitoring if they are intended to supply energy which will be absorbed by the body or that emits radiation and is intended for diagnostic or therapeutic radiology
2. Anesthesia machines	Class IIb or III	Active therapeutic device intended to administer and/or remove medicinal products to or from the body and with integrated diagnostic function
3. Patient monitors	Class IIb	Active device intended to allow direct diagnosis or monitoring of vital physiological processes
4. Furniture (e.g. hospital bed)	Class I	All active devices not covered by other rules, e.g. electric hospital beds
5. Surgical (arthroscopy) shaver	Class IIa	Surgical invasive device intended for short-term use
6. Surgical stapler	Class IIa	Surgical invasive device intended for short-term use
7. Hearing aids	Class IIa	All active therapeutic devices intended to administer or exchange energy, in this case sound.
8. Endoscope	Class IIa	Invasive device with respect to body orifices
9. Syringe	Class IIa	Surgical invasive device intended for transient use
10. Bandages	Class I	Mechanical barrier for compression or absorption of exudates
11. Single-use compression sleeves	Class I	Mechanical barrier for compression or absorption of exudates
12. Intravascular ultrasound catheter	Class III	Surgically invasive device intended to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system

Table A.3: **Classification of the medical devices.** According to European Medical Device Regulation Medical Device Coordination Group [104]

A.2. Reprocessing

Single-use devices (SUDs), or disposables, are designated to be used during a single medical procedure on one individual and to be discarded after the procedure. These devices are not intended to be reprocessed or used on another patient by definition. However, reprocessing of single-use devices has grown in acceptance across the whole world. This required closely monitoring these processes and establishing strict regulations. Nevertheless, reprocessing of these single-use devices provides an opportunity and can offer a favourable impact on environmental waste and costs saving [9], [73].

A.3. Regulations on reprocessing of medical devices in Europe and the US

Whereas it is considered to be out of scope for this research to delve very deep into all medical regulations on reprocessing, it is still considered to be important to provide a basic understanding of the current regulations that apply to reprocessing of single-use devices, in this case catheters. For this research the focus will only be on the regulation in Europe and the United States. Both the FDA and the European Union offer a guidance document on reprocessing of (single-use) medical devices that will be outlined hereafter. For this research, the interest lies mainly with the technical and clinical requirements on the devices, rather than the processes that need to be organised to manage this.

A.3.1. EU regulations on reprocessing

The following definition of reprocessing applies for the purpose of the European Medical Device Regulation (MDR) that governs the production and distribution of medical devices in Europe:

> *"Reprocessing means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device."*

Article 17 of the EU MDR is dedicated to the regulation of reprocessing and further use of single-use devices. Article 17 allows each individual Member State of the EU to regulate reprocessing and further use of single-use devices at a national level, but in accordance with the requirements laid down in this Article. It is stated also in this Article that reprocessing should be performed in accordance with the Common Specifications established for the reprocessing of single-use devices, that have been published separately by the European Commission [9], [105].

Any reprocessor of a single-use device within the European Union is considered to be the manufacturer of the reprocessed device and shall assume all associated obligations. Member States may decide to make an exemption for single-use devices reprocessed and used within health institutions. They may choose to not apply all the rules relating to manufacturers' obligations if the health institution can ensure that the safety and performance of the reprocessed device is equivalent to that of the original device and if they comply with Common Specifications for the reprocessing of single-use devices. Member States may also allow to let single-use devices be reprocessed by an external reprocessor at the request of a health institution. In such case, the external reprocessor needs to comply as well with the previously mentioned requirements and thus has full product liability. The MDR requires reprocessors to engage a notified body to certify compliance with Common Specifications [105].

Common Specifications

Common Specifications (CS) are defined in the EU MDR as a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system. In this case, the Common Specifications were published by the European Commission in 2020 and became recently applicable on May 26, 2021. They lay down general requirements on safety and performance for reprocessing. Most of the common specifications are, logically, focused on the legal obligations incumbent on reprocessors, however, as mentioned before, for this research the area of interest lies with the technical and clinical requirements. This is because if these requirements are known, it is possible to see if the current design of catheters is suitable for reprocessing.

Health institutions, together, with the external reprocessors, when applicable, are responsible for the safety and performance of the reprocessed device. This means that by these common specifications, the original manufacturer will not held responsible for the safety and performance of a reprocessed catheter. However,

the original manufacturer can make sure that the design of their device is inherently safe to withstand cycles of reprocessing.

Prior to starting the process of reprocessing a single-use device, it should be assessed by the health institution if a device is suitable for reprocessing. It needs to be evaluated whether the safety and reprocessing of a single-use device is equivalent to the original single-use device. An analysis should be conducted that considers the properties of the single-use device, including all available documentation and information on the device to ensure sufficient understanding on know-how on design, constructional properties, material characteristics, functional properties and other risks factors related to the reprocessing of the single-use devices, including its previous use. After this analysis, a decision will be provided if the device is suitable for reprocessing. Based on this information and the results of a technical assessment including, when appropriate, physical, electrical, chemical, and biological and microbiological tests, and reverse engineering. It is stated that the reprocessing cycle shall not change the intended purpose of the single-use device, shall take into account the scientific and technical knowledge, and, if applicable, the original method of sterilisation and the relevant standards. Taking into account these assessments, a reprocessing cycle will be established and validated that is suitable for the device in question. This reprocessing cycle must always be monitored through periodic routine tests and contamination controls, physical, electrical, chemical and biological monitoring and testing of process parameters and calibration.

Reprocessing procedure in the European Union

A summary of the steps in a reprocessing cycle are presented in Figure A.1 on the next page. This cycle is based on the EU and FDA regulations together. The most important aspects in terms of design requirements that can be derived from the common specifications will be discussed together with the requirements based on FDA guidelines in section A.3.3.

A.3.2. US regulation on reprocessing

The reprocessing of single-use devices in the United States is regulated and supervised by the Food and Drug Administration (FDA). The following definition applies to reprocessing in the United States:

> *"Reprocessing: the validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilisation."*

Single-use device reprocessors are placed in the same regulatory framework as original equipment manufacturers (OEMs) by the FDA. A reused single-use device will thus have to comply with the same regulatory requirements as the original single-use device. This regulation only applies to third party reprocessors and hospitals that engage in reprocessing devices for single use.
Several documents are published by the FDA for guidance for Industry and FDA Staff in reprocessing SUDs. In 2000, a document was published listing requirements for third party and hospital reprocessors with the purpose of describing FDA's enforcement priorities for third parties and hospitals that reprocess single-use devices. The following requirements are covered and explained in detail: registration and listing of medical devices; medical device adverse event reporting; medical device tracking systems; medical device corrections and removals; quality system regulation of medical devices; labelling; and premarket requirements [73].

With the enactment of the Medical Device User Fee and Modernization Act (MDUFMA) of 2002, the reprocessing of single-use devices became codified and legally supported. FDA published another guidance document that describes the types of validation data that the FDA recommends being submitted for reprocessed single-use devices. It requires reprocessors to include validation data for pre-market notification submissions for certain reprocessed single-use devices. These validation data include cleaning, sterilisation data, and functional performance data demonstrating that each single-use device will remain substantially equivalent after reprocessing [50].

Further, a reprocessed SUD is subject to pre-market review by FDA, unless the agency has, by regulation, declared the device to be exempt from pre-market requirements. With regard to pre-market review, SUD reprocessors are subject to more stringent regulation by FDA compared with original manufacturers because, pursuant to provisions added to the FDA by the MDUFMA, FDA withdrew the exemptions from the premarket notification requirement for a considerable number of previously exempt reprocessed devices, though

the 'original' devices remain exempt from premarket review [106]. Also, reprocessors, must include whole categories of data that original manufacturers are not required to submit.

Reprocessing procedure in the US

Based on the guidance documents by the FDA and the EU, a standard reprocessing procedure is illustrated in Figure A.1. By the FDA, the process that should be followed for reprocessing is adapted from ISO 14937: "sterilisation of medical devices – general requirements for characterisation of a sterilising agent and the development, validation and routine control of a sterilisation process for medical devices.". This standard scheme serves as a template for the process of reprocessing single-use devices. A reiteration of the provisions of these standards is considered unnecessary by the FDA for the guidance on reprocessing single-use devices. Devices with features that may result in soil retention or have features that make them difficult to clean, may need to be disassembled in order to be completely cleaned unless effective cleaning is validated without disassembly. Instructions for adequate disassembly should be included in the cleaning instructions.

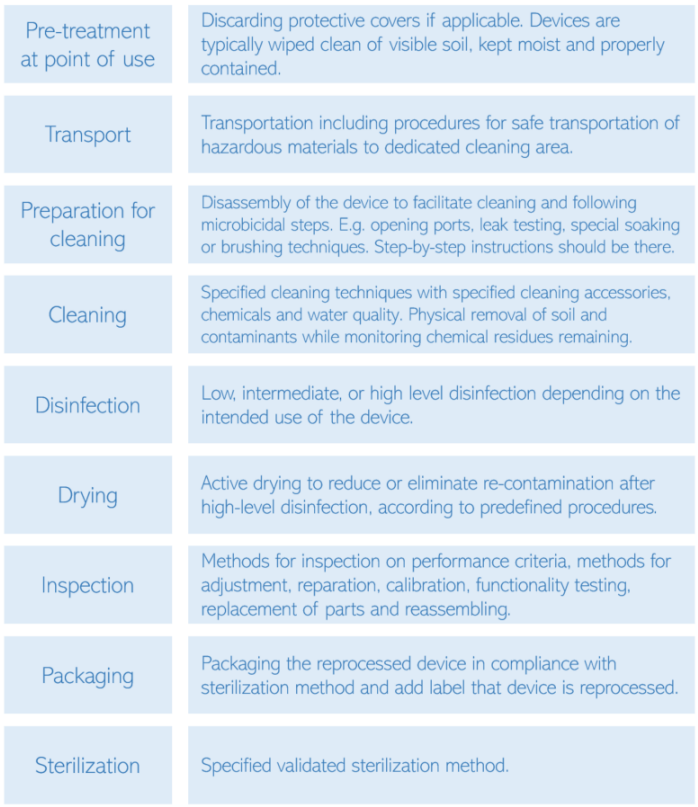


Figure A.1: **Overview of steps in a reprocessing cycle.** The steps that a reprocessing cycle should cover according to the European Commission and US FDA. Adapted from U.S. Department of Health and Human Services [48] and The European Commission [105].

A.3.3. Requirements for reprocessing based on EU MDR and FDA guidelines

Based on the EU MDR guidelines and US FDA, the most critical requirements for reprocessing a device are that the device should enable disassembly & reassembly to allow cleaning, sterilisation and repair or replacement of parts if required during reprocessing. Also, the materials a device consists of should withstand cleaning and sterilisation processes and a device should be constructed to allow these cleaning and sterilisation processes.

A.4. Design features that pose challenges to cleaning processes

Design feature	Explanation
Articulation	Joint that connects two components and has a gap in between that can entrap soil and that is challenging to clean.
Clamps	Clamps with serrated jaws that cannot be fully opened for cleaning and where soil can get entrapped and is challenging to clean.
Dead-ended chambers	In dead-ended chambers soil and detergents can accumulate and cannot be flushed through.
Fittings with close tolerances	A tight fitting can have edges where soil can accumulate and that are hard to reach with cleaning tools.
Grooves	Grooves are an ideal place for soil to accumulate and that are challenging to clean.
Hinges	Movable joint that connects components where soil can entrap and that is challenging to clean.
(Inaccessible) crevices and cracks	Crevices and cracks are an ideal spot for soil to accumulate and retain.
Interior device channels	Similar as a lumen, cavities that can entrap soil and are challenging to clean.
Internal movable components	Internal movable components can have joints that can entrap soil and that make cleaning challenging.
Internal ridges	Internal ridges can entrap soil and are challenging to clean.
Joints with gaps	Joints with gaps can entrap soil and are challenging to clean.
Junctions between insulating sheaths	Close-fitting sheaths around cables provide areas that can easily entrap soil and make cleaning challenging.
Luer locks	Luer locks are used in syringes to allow a leak-free connection for example where a female fitting fits tightly into a male fitting but that can make cleaning challenging.
Lumens	A lumen is a long tubular cavity, e.g. a hollow tube. Especially long narrow and dead end lumens are challenging to clean because it is hard to permit a brush to pass through.
Porous materials	Porous materials can have channels and cavities that can entrap soil and make cleaning challenging. Smooth materials are desirable as they allow easier cleaning.
Ridges	Ridges can entrap soil and are challenging to clean. E.g. jaws, ribs, whorls.
Rough surfaces	Similar to porous materials, irregularities can entrap soil and make cleaning challenging.
Shafts within lumens	Similar to junctions between insulating sheaths, these tubular cavities make cleaning challenging and can entrap soil.
Sharp angles	Sharp angles allow the accumulation of soil.
Springs	A coil spring has features that can easily get soild and make cleaning challenging.
Stopcock	A stopcock is a type of valve that controls the flow of liquids, which has features that can entrap soil and make cleaning challenging.

Table A.4: **Features of medical devices that may pose challenges during cleaning and sterilisation processes.** Adapted from Patel, Pope, and Neilson [60] and U.S. Food & Drug Administration [75]

A.5. Material compatibility to ethylene oxide sterilisation

Material	Compatibility with EO sterilisation
Thermoplastics	
Acrylic	Generally compatile, some loss in tensile properties and some crazing.
Acrylonitrile butadiene styrene copolymer (ABS)	Compatible
Nonplasticised polyvinyl chloride (PVC)	Compatible
Plasticised polyvinyl chloride (PVC)	Compatible
Polyacetal	Compatible
Polyamide (nylon, all classes)	Compatible
Polyarylsulfone	Compatible
Polycarbonate	Generally compatible, some formulations may be subject to stress cracking and loss of tensile properties.
Polyether sulfone	Compatible
Polyetheretherketone (PEEK)	Compatible
Polyethylene (PE, UHMWPE, LDPE, LLDPE, HDPE)	Generally compatible. HDPE may lose some tensile properties.
Polyethylene terephtalate glycol copolymer (PETG)	Compatible
Polymethylmethacrylate (PMMA)	Compatible
Polyphenylene oxide	Compatible
Polypropylene (PP)	Generally compatible, may be some long-term effect on tensile modulus.
Polystyrene	Poor compatibility, embrittlement and loss of tensile strength for some formulations has been reported.
Polysulfone	Compatible
Polytetrafluoroethylene (PTFE)	Compatible
Polyvinyl chloride	Generally compatible, rigid PVC may decrease impact resistance after exposure to EO sterilisation.
Styrene acrylonitrile copolymer (SAN)	Fairly compatible, for one cycle, but may embrittle and lose tensile properties on multiple cycles.
Styrenic block copolymers (SBS, SIS, SEBS)	Compatible
Polyester	Compatible
Polyetherimide (PEI)	Generally compatible, depending on formulation and application.
Polyurethane	Generally compatible, depending on formulation, cure conditions, material thickness and end use stresses.
Silicone (RTV)	Compatible
Ethylene propylene diene (EPDM)	Generally compatible, but changing curing method may result in formation of polyethylene oxide inside matrix of material.
Latex	Generally compatible, limited to the number of repeat cycles.
Neoprene	Compatible
Polyvinylidene fluoride elastomer	Compatible
Silicone elastomer	Compatible
Teflons	Compatible
Thermosets	
Epoxy	Compatible
Phenolics	Compatible
Polyimide	Compatible
Polyurethanes	Fairly compatible
Acetal	Compatible
Elastomers	
Butyl	Compatible
Ethylene propylene diene monomer (EPDM)	Compatible
Nitrile	Compatible
Polyacrylic	Fairly compatible, only one cycle.
Polychlorophrene	Compatible
Silicone	Compatible
Metals	Most metals are compatible with EO sterilisation
Ceramics	Most ceramics can be sterilised with EO sterilisation, e.g. aluminum oxides, silica, zirconium oxide
Glasses	Most glasses can be sterilised with EO sterilisation
Bioresorbable polymers	
PLA, PGLA	Poor compatibility

Table A.5: **Compatibility of materials with EtO sterilisation.** Adapted from Rogers [83]

B

Appendix B

B.1. Dismantling study and material investigation Drachten

As no Bill of Materials (BOM) was available for both catheters of this study, all materials were investigated by material experts of the Chemical Analysis Group at The Philips Technical Expert Group (TEG) in Drachten. The chemical analysis group received all of the components of the two case-studied catheters for material characterization and investigation. In this section of the Appendix the details of the material investigation are presented.

B.1.1. Bill of Materials (BOM)

Tables B.1 and B.2 list the results of all the material analyses. Some of the materials have not been analysed by the lab in Drachten; these are shown in italics. From the Eagle Eye catheter, components 3.3, 4.2, 6.2 and 9.2 have not been analysed because it was clear for 3.3, 4.2 and 9.2 that these were electrical wires or pins made of copper alloys. Component 6.2 was impossible to dismantle from the PIM connector, but it was estimated that this also concerned a copper alloy. Moreover, component 2 is still under investigation as this concerns a multi-layer component. It was clear, however, that the component was coated with PVP, just as component 1, the distal tip. From the Turbo-Elite catheter, components 1, 2.3 and 4.2 have not been analysed. The material of component 1 is unknown, and it was estimated and evident that components 2.3 and 4.2 were bundles of glass fibre. The exact composition and presence of glass fibre coating are still under investigation and were not yet clear for this research.

BOM level	**Item name**	**Weight (in g)**	**Material + coating**
1	Distal tip	0.00547	Polyamide-12 + PVP coating
2	Ultrasonic transducer part	0.01582	*Multi-layer component* + PVP coating
3	Transparent tube with markers	0.1035	-
3.1	Transparent tube	0.1	PEBA (Polyamide-12 elastomer)
3.2	Radiopaque markers	0.0035	Platinum-iridium
3.3	Electrical wires	0.1	*Copper alloy*
4	Blue cable	1.8	-
4.1	Outer shaft blue cable	0.4	Polyamide-12
4.2	Electrical wires	0.2	*Copper alloy*
4.3	Stainless steel cable	1.2	Grade 301 stainless steel
5	Wire connector	4.2	Polycarbonate
6	Black cable	1.0	-
6.1	Outer shaft black cable	0.1	PEBA (Polyamide-12 elastomer)
6.2	Electrical wires	0.1	*Copper alloy*
7	Black connection cable	0.9	PEBA (Polyamide-12 elastomer)
8	Black strain relief	0.6	PEBA (Polyamide-12 elastomer)
9	Electrical PIM connector	6.7	-
9.1	Housing PIM connector	6.7	Polyetherimide
9.2	Electrical pins PIM	-	*Copper alloy*

Table B.1: **Bill of Materials of the Eagle Eye IVUS catheter.** Based on the accompanied material analysis results from TEG Drachten.

BOM level	Item name	Weight (in g)	Material
1	Distal tip	0.1	-
2	Brown cable	7.4	-
2.1	Outer shaft brown cable	1.0	Polyamide-12
2.2	Guidewire lumen	0.8	Polytetrafluorethylene (PTFE)
2.3	Glass fibre bundle brown	5.6	*Glass fibre*
3	Y connector	2.2	-
3.1	Connector part	1.3	Polyamide-12
3.2	Guidewire port	0.9	Polyamide-12
4	Black cable	13.4	-
4.1	Outer shaft black cable	4.2	Polyamide-12
4.2	Glass fibre bundle black	9.2	*Glass fibre*
5	Proximal cable connector	1.1	Styrene-ethylene-butylene-styrene (SEBS)
6	Proximal connector	25.2	-
6.1	Connector housing front	8.4	Acrylonitril-butadiene styrene (ABS)
6.2	Connector housing back	3.9	Acrylonitril-butadiene styrene (ABS)
6.3	Inside connector	12.9	Aluminium 6061

Table B.2: **Bill of Materials of the Turbo-Elite atherectomy catheter.** Based on the accompanied material analysis results from TEG Drachten.

B.1.2. FT-IR spectra

Some of the materials were investigated by means of Fourier Transform Infrared spectroscopy (FT-IR), which allows measuring infrared fingerprint spectra of materials and comparing them with known spectra from the internal library of the lab. The results of the FT-IR analysis can be found on the following two pages. The names of components are indicated, and the names of the materials whose spectra from the internal library matched.

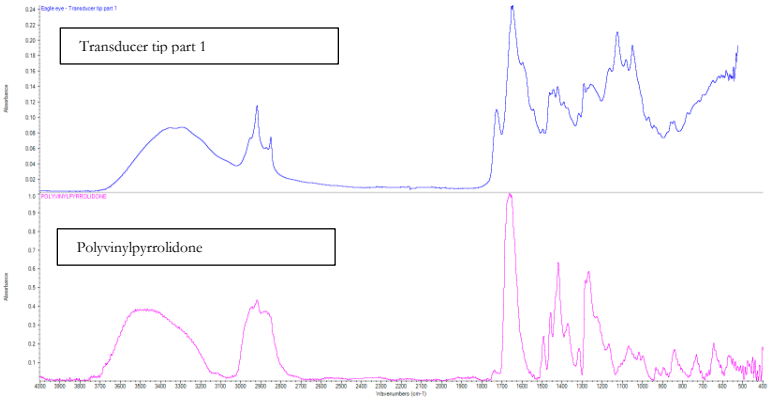
The materials of components 1, 2, 3.1, 4.1, 5, 6.1, 7, 8, and 9.1 of the *Eagle Eye* catheter are analysed through FT-IR spectroscopy. These spectra are presented on the next page. The materials of components 2.1, 2.2, 3.1, 3.2, 4.1, 6.1 and 6.2 of the *Turbo-Elite* catheter are analysed utilising FT-IR spectroscopy. These spectra are presented on the page after.

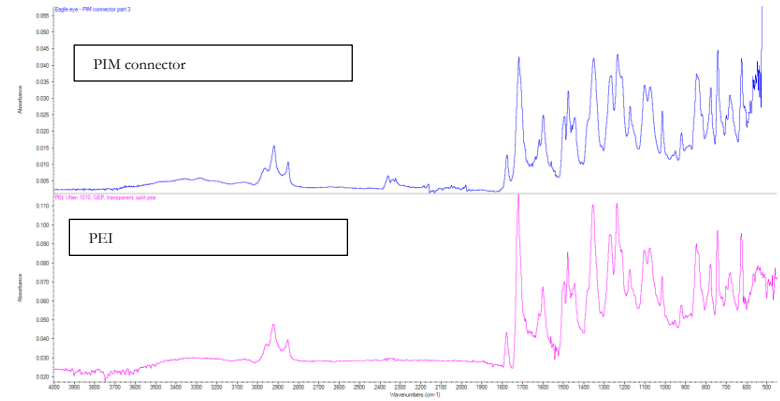
For component 3.1, 6.1, 7 and 8 of the Eagle Eye catheter the material hypothesis of the lab was PEBA, an elastomer in the Polyamide-12 family, based on the FT-IR spectra and the melting temperature information provided by the DSC curve. These curves are presented with the other analyses.

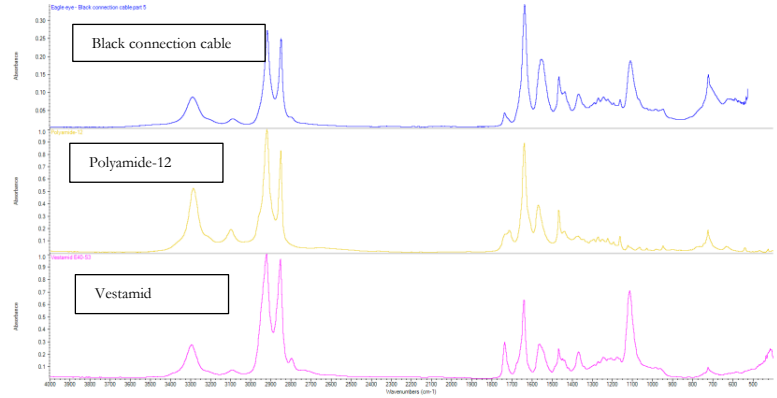
B.1.3. Other analyses

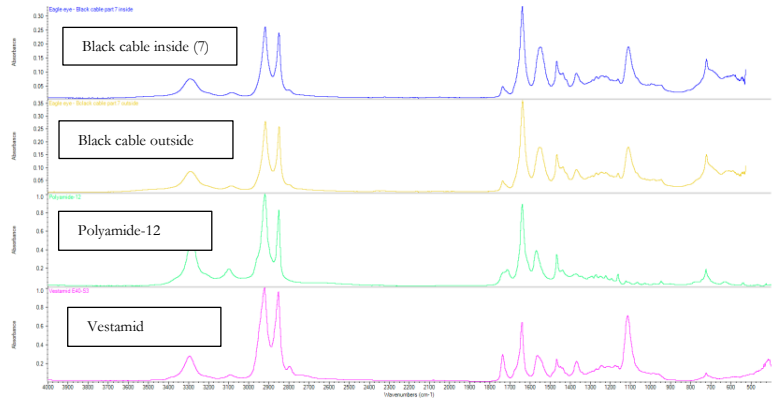
Two metals were investigated by means of the X-Ray fluorescence (XRF) technique, the stainless steel cable of the Eagle Eye catheter (4.3) and the inside of the proximal connector of the Turbo Elite (6.3). These results can also be found on the next page. The effect of X-ray fluorescence is based on the excitation of atoms in the sample. An X-ray is emitted and hits an inner shell electron of the material and ejects it. This open position is then filled by an electron from an outer shell and fluorescence radiation is emitted, of which the energy is equal to the energy difference between the two shells. Hence, the energy of this radiation is specific for the atom and can indicate which atom is present in the sample [107].

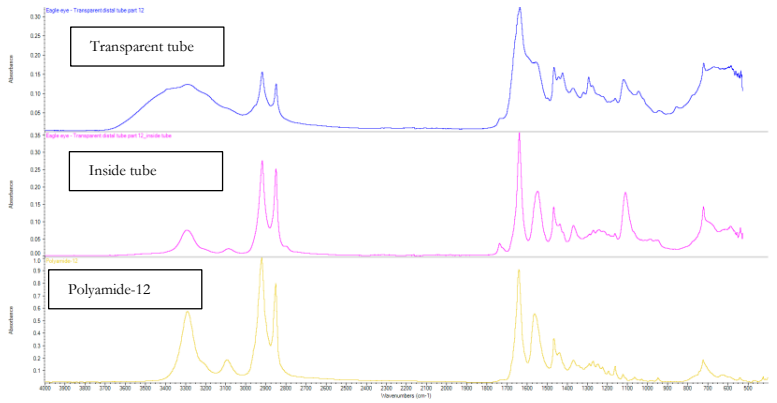
Due to the small size of the radiopaque markers of the Eagle Eye catheter, X-ray fluorescence was not possible to identify the metal composition. Therefore, Scanning electron microscopy (SEM) and energy dispersive X-ray spectroscopy (EDS) were used to analyse these markers. The SEM element spectra can also be found on the next page. SEM translates electrons interactions into optical signs and the EDS detector measures the energy of the emitted photons in the X-ray spectrum. It was identified that the radiopaque markers were made of Platinum-Iridium.

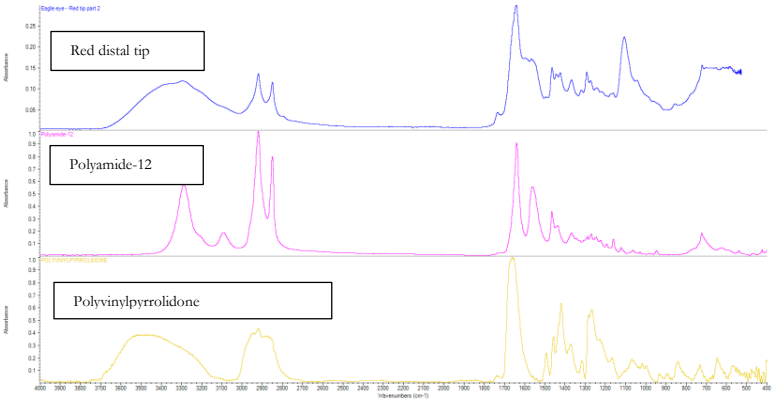


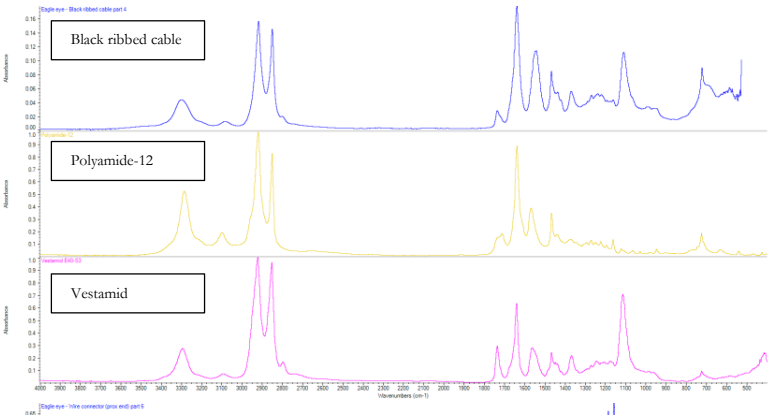


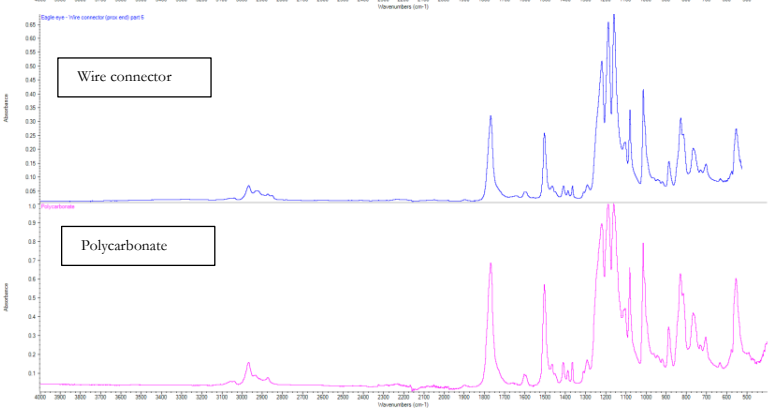


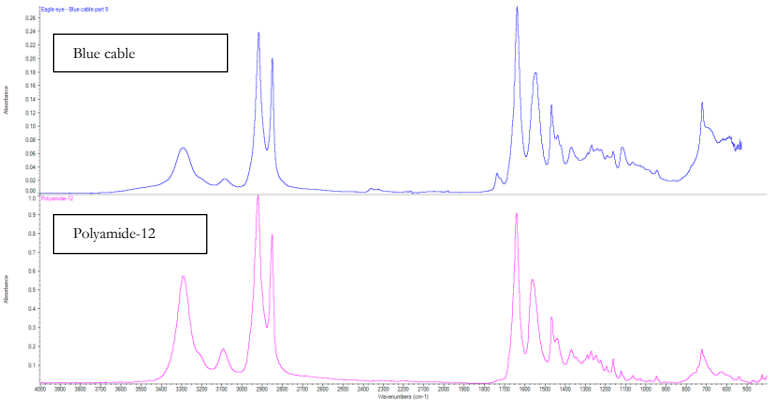








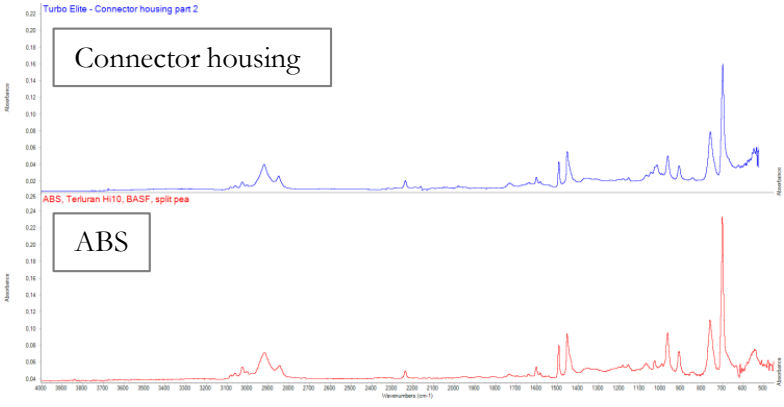




FT-IR Spectra
Eagle Eye IVUS catheter

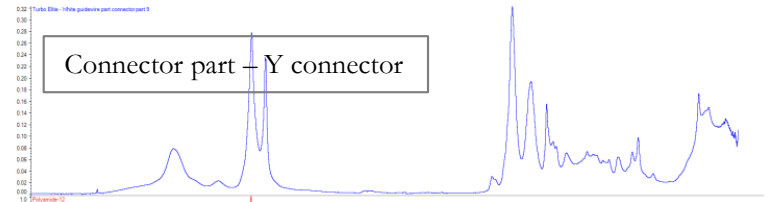
FT-IR Spectra
Turbo – Elite Atherectomy Catheter

Connector housing

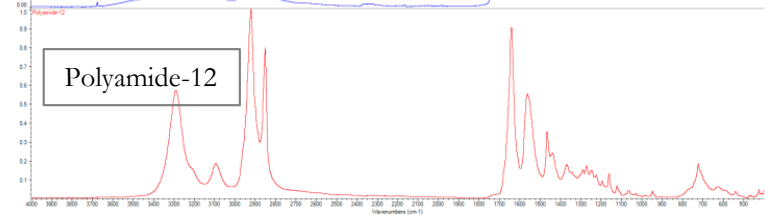


ABS

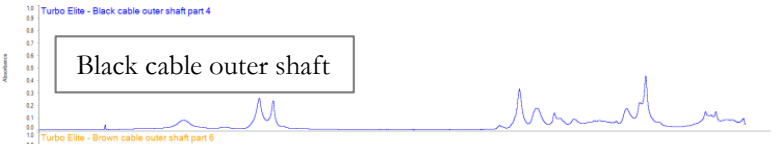
Connector part – Y connector



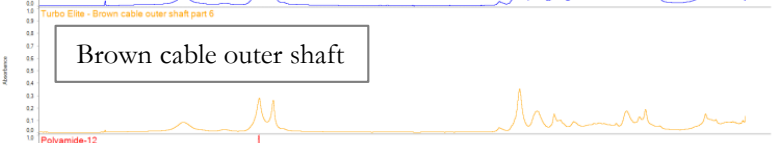
Polyamide-12



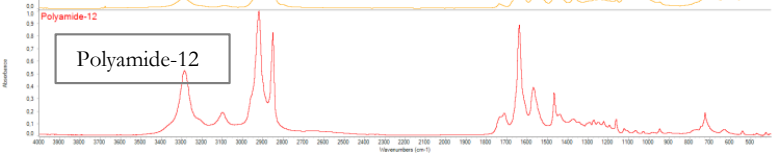
Black cable outer shaft



Brown cable outer shaft

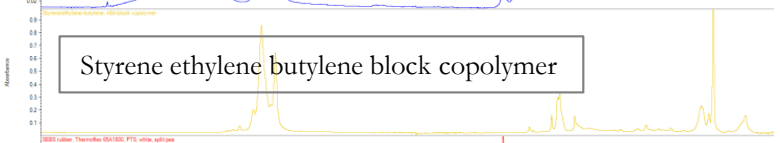


Polyamide-12

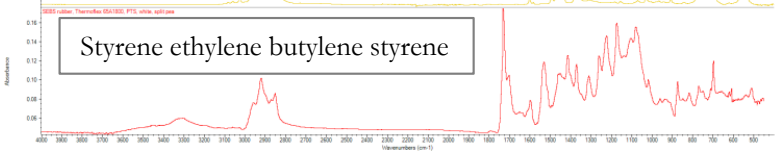


Guidewire port – Y connector

Styrene ethylene butylene block copolymer

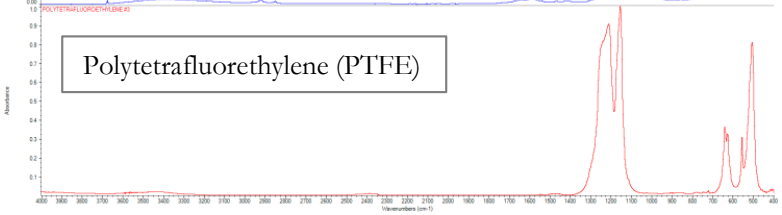


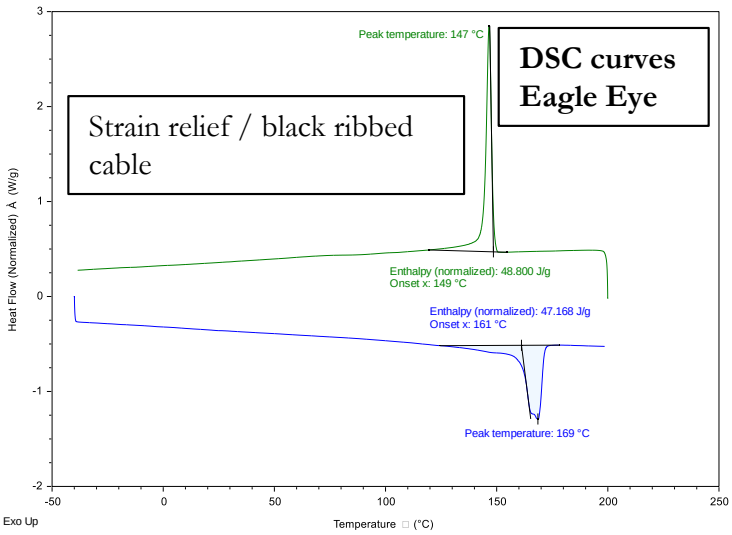
Styrene ethylene butylene styrene

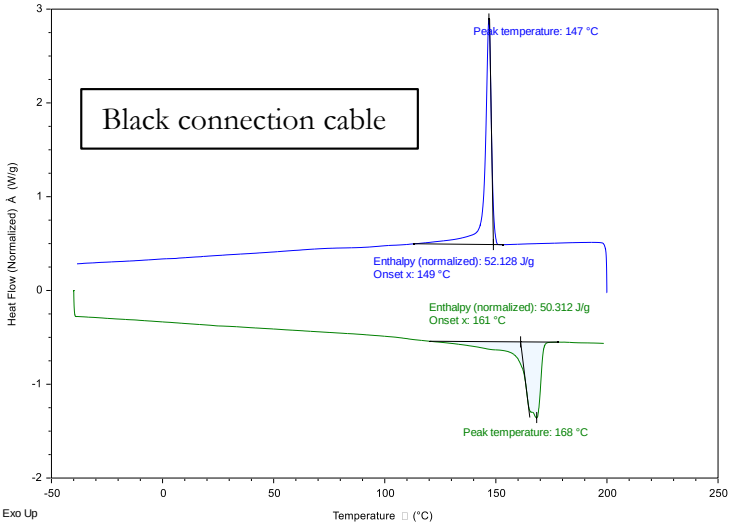


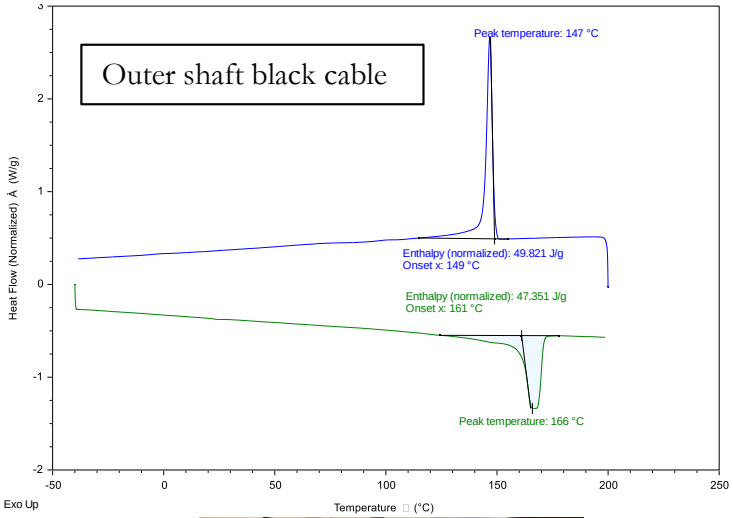
Guidewire lumen

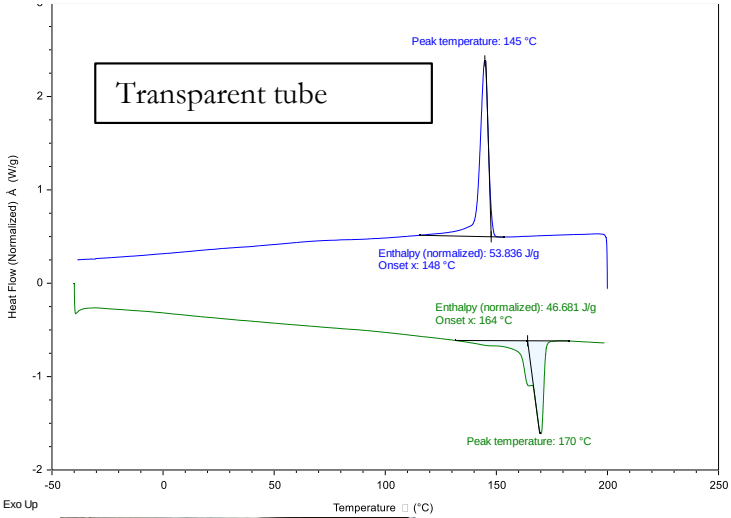
Polytetrafluorethylene (PTFE)

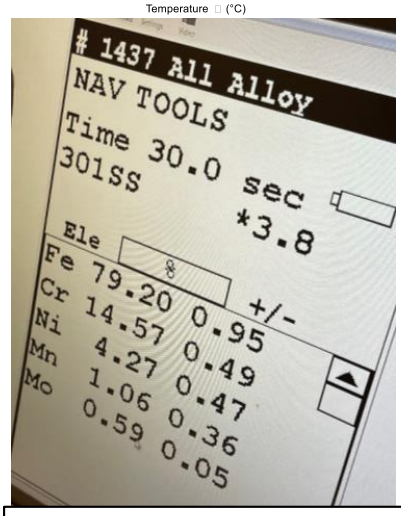




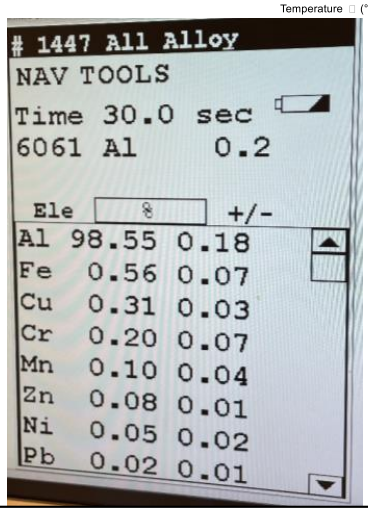




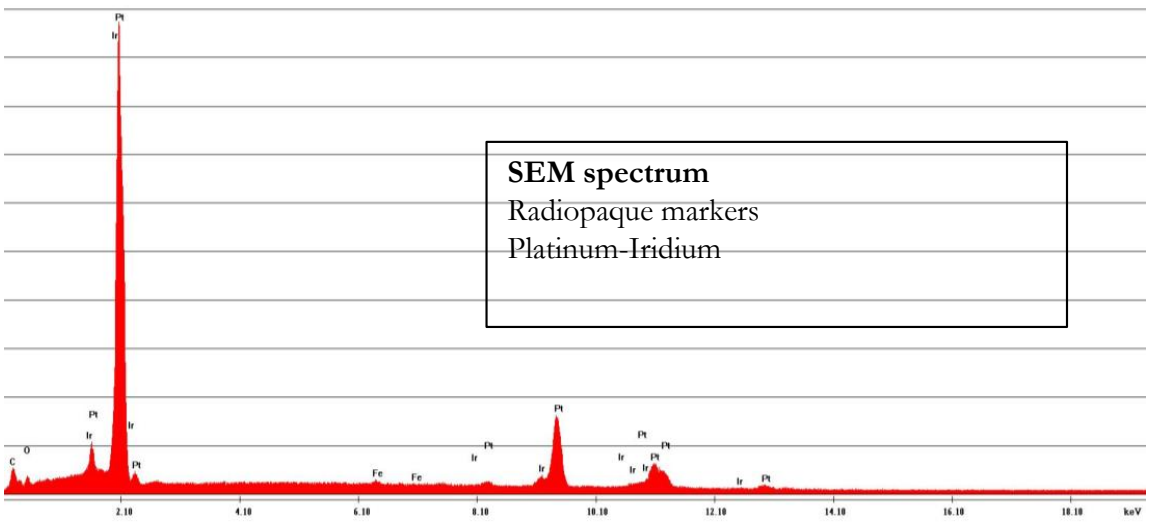




XRF Analysis – Eagle Eye
Stainless steel cable
301 Stainless steel



XRF Analysis – Turbo Elite
Inside connector
Aluminium 6061



SEM spectrum
Radiopaque markers
Platinum-Iridium

C

Appendix C

C.1. Results recovery assessment tool

An enlarged picture of the results of both case studies can be found on the next page. The left table presents the results of the first case study with the Eagle Eye catheter and the right table presents the results of the second case study with the Turbo-Elite catheter. Both catheters have been analysed according to the research protocols presented in the Methodology chapter. The protocols explain how to constitute the BOM and use the developed recovery assessment tool and all results are described in more detail in Chapter 4.

Results Case study 2

Turbo Elite Laser Atherectomy Catheter

BOM data				Disassembly indices					Hygienic recovery indices			Material recovery indices				Notes
BOM level	Item	Material	Weight (in g)	TFI	Reversible?	QFI	%FI	AI	TCI	ECI	SCI	MSI	MGI	MCI	MVI	
1	Distal laser tip	-	0,1	Adhesive d	No	1	6%	Free acces	Componer	Smooth su	Componer	Componer	Unclear	Componer	☐	*material not analysed*
2	*Brown cable*			Adhesive d	No	1	6%	Free acces	Componen	t enters st					☐	*lumen and fibres insulated in shaft*
2.1	Outer shaft brown cable	Polyamide-12	1	Adhesive d	No	1	6%	50% or mo	Componer	Smooth su	Componer	Materials	Componer	Unclear	☐	
2.2	Guidewire lumen	Polytetrafluorethylene (PTFE)	0,8	Adhesive d	No	1	6%	50% or mo	Componer	The compo	Componer	Materials	Componer	Componer	☐	
2.3	Glass fibre bundle	*Glass fiber*	5,6	Adhesive d	No	1	6%	50% or mo	Componer	The compo	Componer	Materials	Unclear	Unclear	☐	*type of glass fiber has not been analysed*
3	*Y-connector*			Adhesive d	No	1	6%	Free acces	Componen	t has neith					☐	
3.1	Connector part	Polyamide-12	1,3	Adhesive d	No	1	6%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
3.2	Guidewire port	Polyamide-12	0,9	Adhesive d	No	1	6%	Free acces	Componer	50% or mo	Componer	Componer	Componer	Componer	☐	
4	*Black cable*			Adhesive d	No	1	6%	Free acces	Componen	t has neith					☐	*only fibers insulated in shaft*
4.1	Outer shaft black cable	Polyamide-12	4,2	Adhesive d	No	1	6%	50% or mo	Componer	Smooth su	Componer	Materials	Componer	Componer	☐	
4.2	Glass fibre bundle	*Glass fiber*	9,2	Adhesive d	No	1	6%	50% or mo	Componer	The compo	Componer	Materials	Unclear	Unclear	☐	*type of glass fiber has not been analysed*
5	Proximal cable part	Styrene-ethylene-butylene-styrene (SEBS)	1,1	Adhesive d	No	1	6%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
6	*Proximal connector*			Adhesive d	No	1	6%	Free acces	Componen	t has neith					☐	
6.1	Connector housing front cover	Acrylonitrile butadiene styrene (ABS)	8,4	Screws	Yes	0	0%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
6.2	Connector housing back cover	Acrylonitrile butadiene styrene (ABS)	3,9	Screws	Yes	0	0%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
6.3	Inside connector	Aluminium 6061	12,9	Screws	Yes	4	24%	50% or mo	Componer	50% or mo	Componer	Componer	Componer	Componer	☑	
		Total	49,4		Total	17										

Results Case study 1

Eagle Eye Platinum IVUS Catheter

BOM data				Disassembly indices					Hygienic recovery indices			Material recovery indices				Notes
BOM level	Item	Material	Weight (in g)	TFI	Reversible?	QFI	%FI	AI	TCI	ECI	SCI	MSI	MGI	MCI	MVI	
1	Distal tip	Polyamide-12 + PVP coating	0,00547	Adhesive d	No	1	5%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	*PVP is hydrophilic coating preventing clotting*
2	Ultrasonic transducer part	*Multi-layer component + PVP coating*	0,01582	Adhesive d	No	1	5%	Free acces	Componer	Smooth su	Componer	Unclear	Unclear	Componer	☐	*materials under further investigation*
3	*Transparent tube with markers*			Adhesive d	No	1	5%	Free acces	Componer						☐	
3.1	Transparent tube	PEBA (Polyamide-12 elastomer)	0,1	Adhesive d	No	1	5%	50% or mo	Componer	Smooth su	Componer	Materials	Componer	Componer	☐	
3.2	Radiopaque markers	Platinum-iridium	0,0035	Adhesive d	No	1	5%	50% or mo	Componer	The compo	Componer	Materials	Componer	Componer	☑	*markers can be disassembled from transp tube*
3.3	Electrical wires	*Copper alloy*	0,1	Adhesive d	No	1	5%	50% or mo	Componer	The compo	Componer	Materials	Unclear	Componer	☐	*type of copper has not been analysed*
4	*Blue cable*			Adhesive d	No	1	5%	Free acces	Componer						☑	*wires insulated in shaft*
4.1	Outer shaft blue cable	Polyamide-12	0,4	Adhesive d	No	1	5%	50% or mo	Componer	Smooth su	Componer	Materials	Componer	Componer	☑	
4.2	Electrical wires	*Copper alloy*	0,2	Adhesive d	No	1	5%	50% or mo	Componer	The compo	Componer	Materials	Unclear	Componer	☑	
4.3	Stainless steel cable	Stainless Steel grade 301	1,2	Adhesive d	No	1	5%	50% or mo	Componer	The compo	Componer	Materials	Componer	Componer	☐	
5	Wire connector	Polycarbonate	4,2	Adhesive d	No	1	5%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☑	
6	*Black cable*			Adhesive d	No	1	5%	Free acces	Componer						☐	*wires insulated in shaft*
6.1	Outer shaft black cable	PEBA (Polyamide-12 elastomer)	1	Adhesive d	No	1	5%	50% or mo	Componer	Smooth su	Componer	Materials	Componer	Componer	☑	
6.2	Electrical wires	*Copper alloy*	0,1	Adhesive d	No	1	5%	50% or mo	Componer	The compo	Componer	Materials	Unclear	Componer	☐	
7	Black strain relief part	PEBA (Polyamide-12 elastomer)	0,6	Adhesive d	No	1	5%	Free acces	Componer	The compo	Componer	Materials	Componer	Componer	☐	
8	Black connection cable	PEBA (Polyamide-12 elastomer)	0,9	Adhesive d	No	1	5%	Free acces	Componer	Smooth su	Componer	Componer	Componer	Componer	☐	
9	*Electrical PIM connector*			Adhesive d	No	1	5%	Free acces	Componer						☑	
9.1	Housing PIM connector	Polyetherimide (PEI)	6,7	Adhesive d	No	1	5%	Free acces	Componer	50% or mo	Componer	Not possib	Componer	Componer	☐	
9.2	Electrical pins	*Copper alloy*	-	Adhesive d	No	1	5%	Inaccessib	Componer	The compo	Componer	Not possib	Unclear	Componer	☑	*you have to bisect the handle to get to the pins*
		Total	15,5		Total	19										