TU Delft

Johnson & Johnson

TOWARDS CIRCULAR SELF-INJECTORS

Designing an Auto-injector for Non-destructive Automated Disassembly

Master Thesis

Integrated Product Design

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Towards Circular Self-Injectors:

Designing an auto-injector for non-destructive automated disassembly

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Abstract

Each year, billions of medical injections are administered through the use of self-injectors. These devices allow patients to self-administer their injectable medication. Globally, aging populations coupled with a rise in chronic diseases and pressures on healthcare systems are leading to increased prescriptions of biologics and therapeutics to manage these conditions. This trend is resulting in steady growth in the popularity of self-injection devices. However, the vast majority of these injectors are single-use disposable devices, contributing significantly to the waste generated within the healthcare sector. The circular economy, rooted in principles of designing out waste and using waste as a resource, might offer a solution. Possible circular strategies include reuse, remanufacturing, and recycling. However, given the complexity of the healthcare supply chain and the stringent focus on safety and hygiene within the industry, these strategies still face challenges that need to be overcome.

This thesis explored the redesign of auto-injectors to integrate circular economy (CE) principles, focusing on the Ypsomate auto-injector. Assigned by pharmaceutical company Johnson & Johnson (J&J), who have shown interest in developing circular systems for self-injectors, this study aimed to make CE design principles tangible for J&J. Key research questions addressed included identifying barriers and opportunities for CE in disposable self-injectors and applying potential circular strategies to redesign the Ypsomate.

The project followed a creative problem-solving approach involving literature research, expert interviews, co-creation and a field visit to J&J's innovation site. Findings highlighted industry trends focus on patient safety and usability as well as several sustainability developments. However, end-of-life design considerations remain underexplored. The study identified major barriers to CE integration, such as the challenge of combining safety with reuse strategies due to the low value and high hygiene criticality of auto-injectors.

The most promising opportunity was found in the safe, cost-effective separation of hygiene-critical from non-critical components, reducing reprocessing requirements. An in-depth product analysis of the Ypsomate identified relevant circular strategies: Design for Recycling, Disassembly, Component Reuse, and Extended Life. A redesign concept, the MediLoop was developed and prototyped to demonstrate the feasibility of significantly improving CE strategies for end-of-life recovery.

Acknowledgements

It's been a long time in the making but here it finally is!

I would, first and foremost, sincerely like to thank my two lovely mentors, Conny and Karl for their never-ending support during this project. People say life is about falling and getting back up and at several moments during this project I felt I had fallen hard. Losing myself in the complexity of this problem and at times losing trust in myself and my abilities. It was at these times that Conny and Karl gave me the space to learn and the advice to get me back on my feet. Next to that, Conny and Karl never failed to motivate and to push me to do my very best for this project. During our meetings it was always so inspiring to see how passionately dedicated you both are to your respective fields. Conny with your seemly endless knowledge on the world of CE, continuously popping up in all the reference lists of the ground-breaking research I came across. And Karl with your endless energy and your ever-present big smile whenever we discussed our projects. Thank you, from the bottom of my heart, for helping me on this journey.

Furthermore, I would like to thank my company mentor, Cédric. Not every student get's the chance to say that they have been able to work on sustainable development together with industry-leading companies like Johnson & Johnson. Thank you sincerely for that opportunity. I sincerely appreciate the effort and time you put in to make things happen during this project, including the opportunity to visit you in Neuhausen. It's positively thrilling to see how you are pushing boundaries in this challenging industry.

I would like to thank my peers, my amazing housemates, my friends, my family and Laura for all the laughs, joyful conversations, continuous support, encouragement, listening ears, proofreading, brainstorming, diners, shoulders-to-cry-on and the all so important gezellige koffie-pauzes. There are too many things to list but you know who you are and what you've meant for me. Thank you.

To anyone who may be reading this, I wish you much reading pleasure and hope this thesis inspires you.

Now, let's get into the report.

Lars van Wolfswinkel

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1. Introduction

Every year billions of self-injectors are used worldwide to facilitate patients' self-management of chronic diseases such as, diabetes, rheumatoid arthritis, and multiple sclerosis (Thompson et al., 2013). These conditions occur with increasing frequency and, as of today, cannot be cured. However, symptoms can be treated through injectable drugs via the use of a self-injector (Niedermann, 2019). A self-injector is a small handheld device that can be used by patients at home to self-administer their drugs with minimal medical training (see Figure 1). These injections are administered subcutaneously (*under the skin*) through the use of an injection-needle. Once used, special care is required to handle this potentially hazardous injector to prevent accidental cross-contamination. The vast majority of these devices are single-use and disposable and therefore end up contributing to the growing problem of medical waste (Gerner et al., 2020). To alleviate the risk of infection, the industry norm is to incinerate medical waste leading to the destruction of the contained materials and the creation of toxic pollutants and greenhouse gasses (GHGs) (World Health Organization, 2016).

Figure 1 - An auto-injector in use.

Around the world, the healthcare sector is notorious for the significant amount of waste that it produces and accounts for around 5% of GHG emissions; more than the aviation, shipping and railway industries combined (Figure 2) (Lenzen et al., 2020;Ritchie et al., 2023). The amount of waste and environmental impact the sector produces is increasing rapidly for instance due to global demographic changes (aging populations and population growth) as well as continuous improvements in healthcare access (Deloitte, 2023).

When considering the emission of greenhouse gases, a distinction is made between Scope 1, 2 and 3 emissions (Read et al., 2022):

- Scope 1 emissions are 'direct' emissions caused by a company while operating its processes, facilities and vehicles.
- Scope 2 emissions are 'indirect' emissions caused by other companies that produce the electricity, heating or cooling a company buys.
- Scope 3 emissions are also 'indirect'. These emissions are those that come from the entire value chain required to deliver a company's product or service: raw material supply, manufacturing, transportation and waste disposal.

Within the healthcare industry, 71% of the GHG emissions are attributed to indirect emissions (scope 3) (Karliner et al., 2019).

Figure 2 - Healthcare sector emissions by scope (Karliner er al., 2019)

In response to the alarming environmental impact of the healthcare sector, several healthcare institutions and pharmaceutical companies have already committed to reducing their GHG emissions (Booth, 2023). The UK's NHS is proving to be a front runner and planning to implement procurement requirements by 2028 obligating suppliers to carbon footprint individual products to better compare the environmental impact of their products (Deloitte, 2023). These trends demonstrate an increased awareness within the industry of their role in protecting the environment and natural resources to support the health of the planet. Commitments in the industry include optimizing manufacturing and distribution, and responsible sourcing of energy, water, and raw materials. Opportunities exist around the implementations of these strategies to make a significant impact.

One of the significant contributors to the healthcare sector's Scope 3 emissions is the increasing amount of waste produced due to the normalization of single-use disposable medical products (NHS, 2022;Heinemann et al., 2022). As previously mentioned, this medical waste is most often incinerated or deposited in landfill at end-of-life. The circular economy is being recognised as a potential solution to this problem (Hoveling et al., 2023). The circular economy is a model designed around allowing products and their materials to be continuously reintegrated into the economy through reuse, remanufacturing, or recycling. Effective implementation of the circular economy processes will require the redesign of both medical products, the systems in which they exist and their business models.

In the healthcare industry, there are extra complications that need to be considered during the implementation of circular economy principles. Medical products are typically high-risk with the potential of severe consequence on patient life. Therefore, reduction in functionality and any increase in infection risk need to be mitigated. This "safety-first" attitude has contributed significantly to widespread use of disposable devices that consequently contribute to the great amount of healthcare waste. Hazardous healthcare waste, if inadequately treated, poses a significant risk to human health. However, studies by the World Health Organization have found that only 15% of the hazardous medical waste stream actually contains hazardous substances

(Janik-Karpinska et al., 2023). The majority of the hazardous waste stream (85%) is therefore incorrectly categorised and non-hazardous (Figure 3).

Figure 3 - Percentage of hazardous waste (WHO, 2018)

As a supplier of medical products, pharmaceutical company Johnson&Johnson (J&J) shares responsibility for Scope 3 emissions in the healthcare sector and is therefore in an excellent position to make a significant positive impact. One of the key areas identified as a major opportunity was to explore how the self-injectable devices J&J supply worldwide can be redesigned to fit within a more sustainable circular economy as current devices are not designed to be recycled or reused. J&J recognises a need for change here and even see potential for value to be captured (Gysel, 2023). J&J have already started development of a system to collect and disassemble self-injectors for improved waste management. However, further development is required.

1.1. Problem Statement

Approximately one-third of all medical procedures involve the utilization of an injection device (Blais et al., 2019). Furthermore, estimates by the WHO suggest that more than 16 billion injections are administered around the world annually (World Health Organization, 2016). The WHO consequently estimate that 90% of these injections are provided for therapeutics. For patients living with chronic diseases, therapeutic injection devices are vital to the treatment of their conditions. The development and introduction of self-injectables in the 1970s has served as a significant advancement in the treatment of chronic diseases by enabling patients to self-administer their medicine from the comfort of their own homes, eliminating the need for frequent visits to healthcare facilities (Thompson et al., 2013). These devices are typically in the form of auto-injectors or similar handheld devices and enable individuals to deliver precise doses of medication on their own in a timely fashion, safely and with ease.

However, as with many of today's medical devices, the current status-quo for self-injectors is that they are part of a linear economy and most fall under the category of Singe Use Devices (SUDs) (Thompson et al., 2013). They are made, used and disposed of after which the majority is incinerated but, in some cases, still end up in landfill (Gold, 2011). The widespread use of

disposable self-injectables raises significant environmental concerns as this depletes resources while generating a tremendous amount of waste and environmental impact in the form of pollutants and greenhouse gases (World Health Organisation, 2018). Thus, the valuable materials, time and energy in these devices are unnecessarily wasted. From both an economic and an environmental perspective, there is an immediate opportunity for improvement in this inherently unsustainable system.

With the core mission to improve people's quality of life, the healthcare industry is realising that a duality exists in the positive effect on patients they treat and the negative impact on people and planet at large (Frist, 2023).

As self-injectors are designed primarily as disposable SUDs with a single use cycle, there is little to no consideration being put into what happens with the device at its end-of-life. The result is that self-injectors are made up of a plethora of different materials that are excessively difficult to separate. This makes it impractical to retrofit circular design strategies like recycling, reprocessing or reuse as this becomes time, labour and cost intensive. Therefore, the problem to be addressed is how injectors can be redesigned such that the materials contained within them can be reutilised instead of wasted. This problem has led to the formulation of the following research questions:

RQ1 How might we redesign the Ypsomate for integration into a circular system?

- **RQ1.1 What are the current barriers and opportunities for circular economy for disposable self-injectors?**
- **RQ1.2 What circular design strategies are most opportunistic for the Ypsomate auto-injector?**
- **RQ1.3 How might we apply the potential circular strategies in a redesign of the Ypsomate and its circular system?**

Answering these research questions will allow work on the design goal which is:

To redesign the Ypsomate for integration into a circular system in which the product as well as components and materials are recirculated, and the value of the device is maintained.

It will be of utmost importance that a redesign preserves the primary value driver of the product which is patient centricity with a focus on safety and user-friendliness of the device. A circular redesign is intended to extend material and product life which aims to reduce the overall footprint on the environment. Combined with new circular business models this could provide J&J with an improved value proposition. Currently long supply chains exist in the healthcare industry which adds to the complexity of this problem. The future circular model will, therefore, require careful synthesis between many interconnected systems and stakeholders in order to function effectively. The use of devices designed with circular material streams in mind is one of them.

1.2. Scope

This graduation project is a collaboration with the pharmaceutical company: Johnson & Johnson (J&J). The project's aim is to demonstrate opportunities for more sustainable self-injection devices by redesign the Ypsomed Ypsomate™ (see Figure 4), a specific auto-injector within J&J's catalogue. Although J&J doesn't manufacture injection devices themselves, they closely partner with equipment manufacturers like Ypsomed to establish design requirements for their drug delivery devices. As a consumable product, disposable auto-injectors fall into the

category of low-cost, hygiene-critical medical devices. This makes them a particularly difficult category of product to deploy circularity strategies on.

Figure 4 - Patient holding an YpsoMate auto-injector (Noble, 2024)

The main objective is to identify and address the circular challenges this device faces by redesigning the Ypsomate for integration into a circular system. While the Ypsomate serves as a specific product example, this project carries broader significance as a valuable case study, providing practical insights and recommendations applicable to other single-use medical products.

This master thesis aims to make circular design principles for disposable self-injection devices more tangible for J&J and provide recommendations for the transition towards a more sustainable healthcare industry.

2. Approach and Method

To better understand the steps taken to conduct this thesis project, this chapter describes the approach and methods used to answer the previously proposed research questions. On their own, sustainability and healthcare are both immensely complex and multifaceted issues that influence and are impacted by many different stakeholders. Combining these two fields poses an even greater challenge and therefore require a methodical approach to break them down into smaller, more manageable problems while understanding and respecting the interconnected elements within the system.

In pursuing this challenge it is accepted that fundamental systemic change is required and this project is intended as a (very) small step in this sustainable healthcare transition. For this reason, the creative problem-solving method (van Boeijen, 2020), focused on product level, combined with elements of the systemic design process, focused on the system level, was applied (Design Council, 2021). This process was applied to spark critical thinking, educated decision making and methodical problem-solving.

Inherent to these methods are the following principles:

- Iteration: Repeatedly refine and improve a design by going back and forth through various stages of the design process.
- Divergent vs. Convergent thinking: Looking wide and narrow allows design assumptions to be challenged and the right problem definitions to be formulated. Asking the right questions will lead to more valuable answers.
- System-level vs. Product-level: Zooming in and out considers the broader context and interactions within a system as well as focusing on the specifics of individual components or products.
- Testing and Demonstrating: Continuously evaluate new ideas and prototypes to gather feedback and make informed improvements.
- Collaborating and Connecting: Sharing ideas, knowledge, and expertise among stakeholders can elevate the value of design.

These principles are fundamental to the design cycles found in the systemic design process and the creative problem-solving method. The Design Council (2021) has developed their own terminology for design cycles and refers to them as *diamonds*. For an overview of the design process used in this thesis to get from the initial problem frame to the eventual design outcome see Figure 5. Also included are the design methods for each process step.

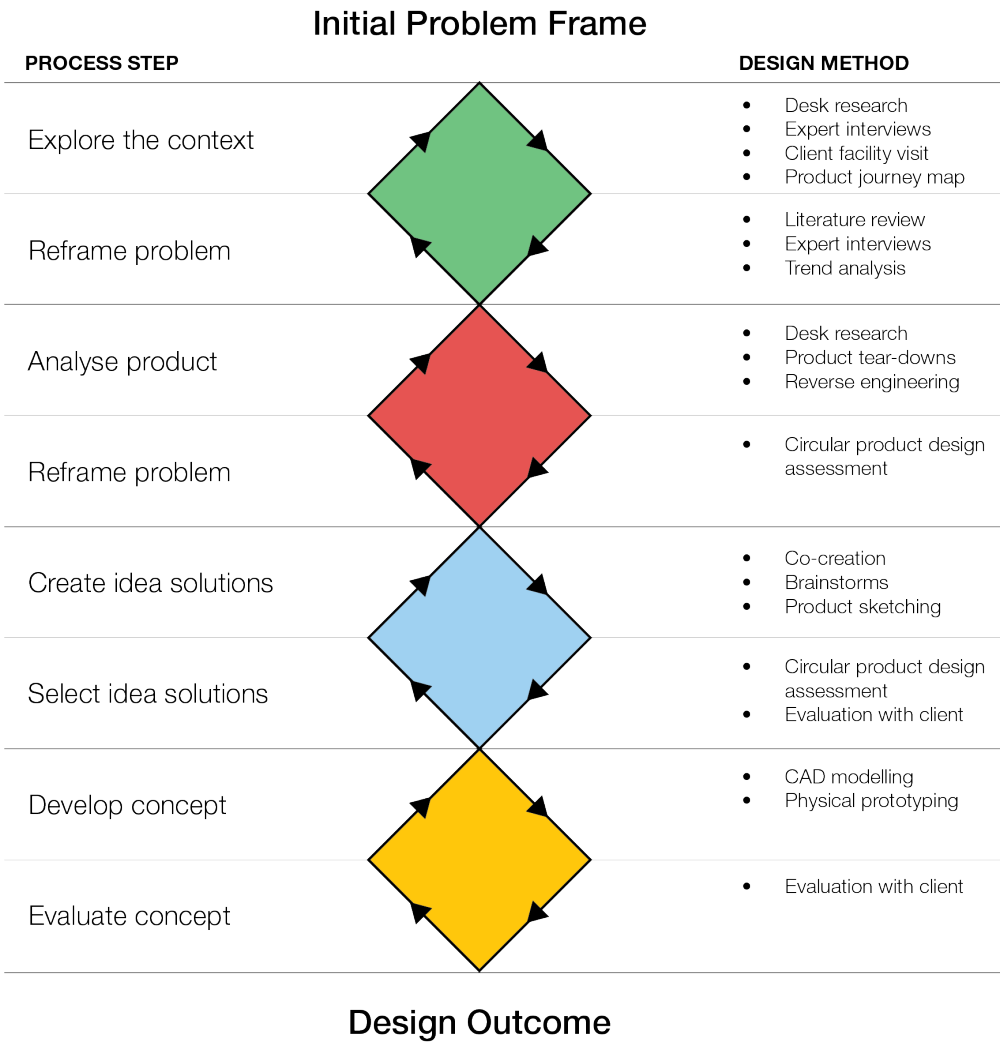


Figure 5 - Overview of the design process (Design Council, 2021) from initial problem frame to design outcome and the used methods for this project.

Through this process, the context was explored, and a case-study product (the Ypsomate auto-injector) was analysed. The findings from both were used to create idea solutions and develop a demonstrator concept. An evaluation of the demonstrator was conducted to conclude with learnings and recommendations for future research. Figure 6 depicts a more detailed layout of these process steps, each of which is further elaborated on in this report.

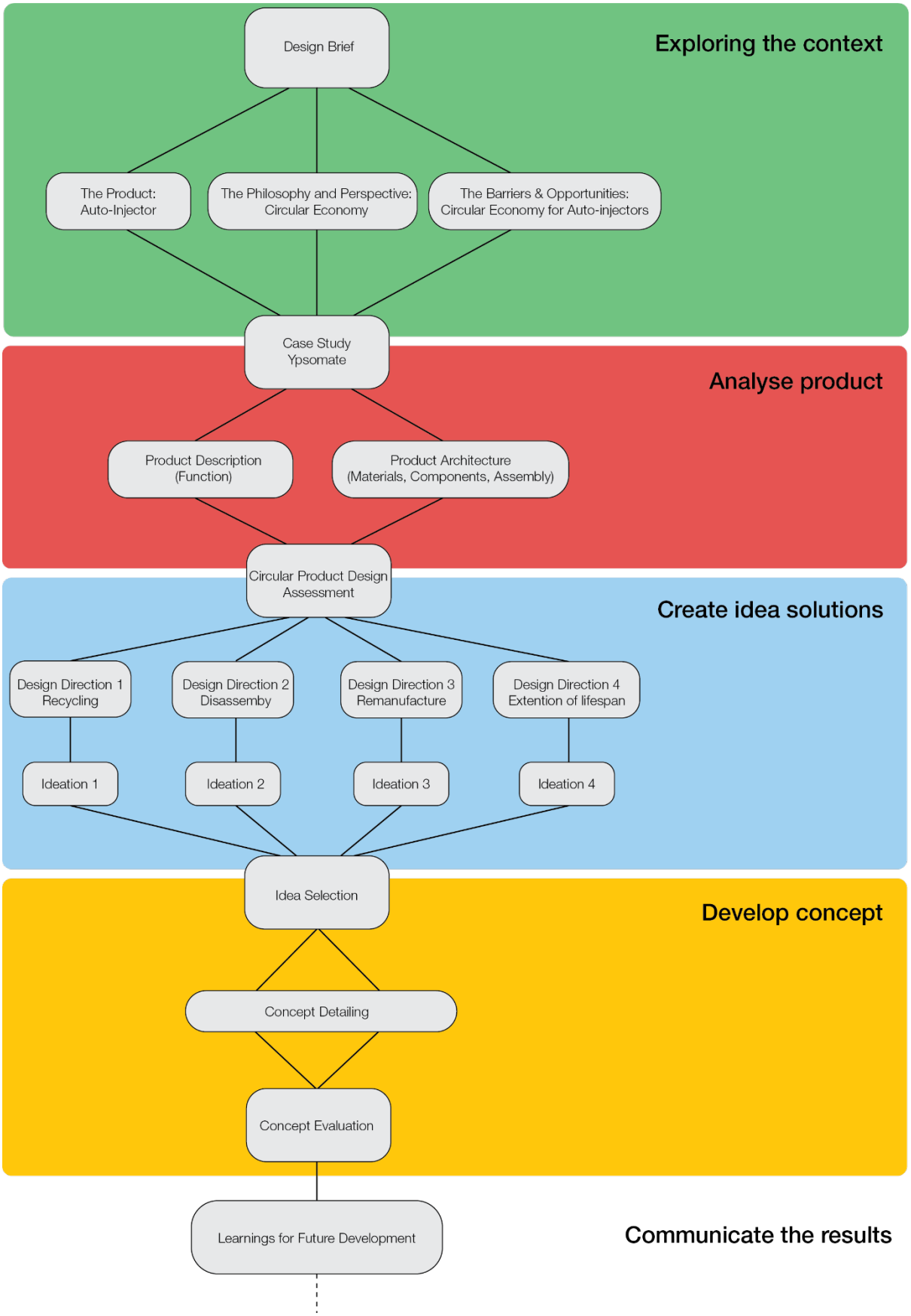


Figure 6 - Detailed overview of design process steps in this project

3. Context

This chapter explores the context of the project to better understand the auto-injector within its ecosystem, the circular economy, and the circular economy's barriers and opportunities for auto-injectors. It first distinguishes between the different types of self-injectors to highlight the typical features, properties, and use cases for auto-injectors in comparison to other self-injectors. The chapter continues by exploring the market trends and developments for auto-injectors to gain insight into where the future market is headed. Following this, the philosophy of the circular economy is briefly outlined, and the barriers and opportunities for auto-injectors within a circular economy are investigated. Understanding the auto-injector context allows for a better formulation of the problem frame and should enable the generation of more fitting solutions.

3.1. Self-Injectors

This thesis examines circular product strategies within the challenging scope of disposable medical devices, focusing specifically on auto-injectors. Auto-injectors belong to the broader category of self-injectors, and it's important make some distinctions within this product category. The term “self-injector” encompasses a wide range of medical devices designed to enable patients to self-administer their injectable medication, safely and effectively with minimal training (Roy et al., 2021). This device category includes prefilled syringes, needle-safe syringes, auto-injectors, and pen injectors, each offering unique features and benefits to meet the varying needs of patients (Shire, 2015) (See Figure 7 for an overview). These devices find broad application across various medical contexts, with two primary uses being the management of chronic diseases such as diabetes, multiple sclerosis, and rheumatoid arthritis, and emergency interventions for conditions like anaphylaxis and migraine (Thompson et al., 2013).

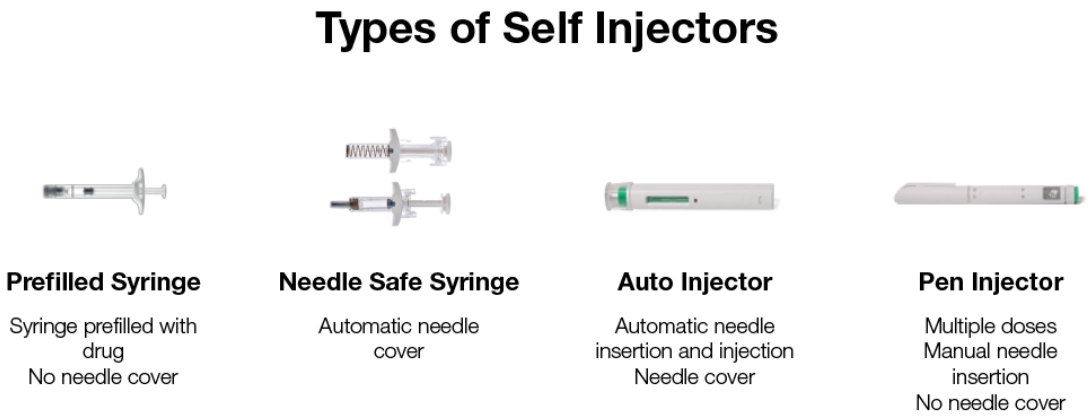


Figure 7 - Overview of the types of self-injector and their features. Adapted from Shire (2015).

The global market for self-injector devices continues to grow rapidly due to several factors including global increasing instances of chronic diseases (e.g. diabetes), increasing development of injectable biologic therapeutic drugs and increased demand for self-treatment due to pressures on healthcare systems (Thompson et al., 2013;Roy et al., 2021). The benefits of self-injectors are clear, as they reduce strain on the healthcare system while at the same time enabling patients to actively manage their health conditions safely and conveniently. Additionally, research indicates that self-injectors contribute to improved therapy adherence,

enhancing treatment effectiveness and thereby potentially help reduce healthcare costs in the long run (Berteau, 2010).

Self-injectors play an indispensable role in modern healthcare; however, the significant amount of waste generated by these mostly disposable devices is a source of serious concern (Heinemann et al., 2022).

The most commonly used forms of self-injectors are auto-injectors and pen injectors, designed primarily for patient safety and easy usability (Roy et al., 2021). Prefilled syringes and needle-safe syringes, on the other hand, are less frequently prescribed and are typically reserved for patients with injection experience or those desiring more control over the injection process. Pens and autoinjectors have developed over time to offer high levels of patient-friendly functionality. Studies have shown clear preference for disposable devices over reusable ones due to their increased convenience, despite their higher overall costs and increased amount of waste (Roy et al., 2021). Figure 8 illustrates the convenient use case of an automatic injection provided by auto-injectors. As of today, the majority of self-injectors include a needle for either subcutaneous or intramuscular injection (Roy et al., 2021). Figure 9 provides a visual representation of the skin layers and the typical injection depth for an auto-injector.

Figure 8 - Typical product use case of an auto-injector ([Two-step instructions for the use of an EpiPen.], (n.d.))

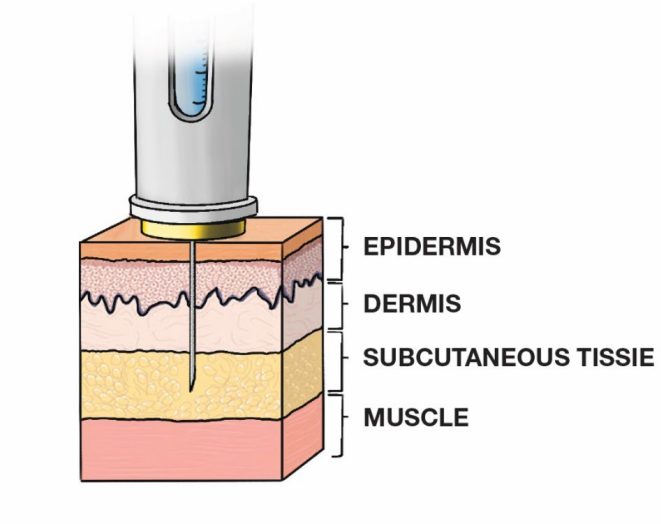


Figure 9 - Skin layer diagram with visual representation of typical auto-injector injection depth (not to scale). Own image based on Ogston-Tuck (2014)

3.1.1. Auto-injectors compared to Pen injectors

While auto-injectors and pen injectors may appear similar, their applications vary. A well-known example of an auto-injector is the *EpiPen*, used for time-critical emergency allergic reactions, whereas pen injectors are commonly used for insulin therapy for example, where doses are much smaller and the patient self-injects on a much more frequent basis. The primary distinction between these devices lies in the their specific use cases. Factors influencing their respective designs include frequency of injection, dose volume, needle safety and patient experience (Thompson et al., 2013). Table 1 provides a comprehensive comparison between auto-injectors and pen injectors.

Table 1 - Comparison between auto-injector and pen injector features (Thompson et al., 2013;Roy et al., 2021)

Feature/Property	Auto-injector	Pen Injector
Mode of Injection	Automatic needle insertion and full dose injection, often spring-driven	Manual dosing system and injection, often spring assisted
Needle	Concealed needle deploys upon activation, combating needle phobia. Typical larger needle (guage: 29G-25G) Subcutaneous – Intramuscular injection depth Needle-safety mechanism against needle stick injury.	Exposed replaceable needle attachment. Typical smaller needle (guage: 32-29G) Subcutaneous injection depth No needle-safety mechanism
Drug Reservoir and Dose	Typically use prefilled syringes with full premeasured dose up to 5.5ml	Typically use cartridge-based systems with variable dose between 0.02-0.6ml (e.g., for insulin)
Frequency of Use	Often used for less frequently injected drugs, particularly biologics. Ranging from 1x per week to 1x per several months. Or for one-off emergency situations.	Frequently used for daily or regular weekly injections.
Form Factor	Typically bulkier in size due to larger more complex mechanism required for all the convenience features	Pen-sized and discreet in size due to less complex mechanisms.
Lifecycle	Typically entire device is disposable and classified as sharps waste. Some reusable cartridge based platforms exist.	Needle is removable and therefore only the needle or cartridge containing needle is classified as sharps waste. The pen dosing mechanism is reusable.

In summary, the key difference between an auto-injector and injection pen lies in the ease of use offered by the auto-injector's injection process. Features such as automated activation (e.g. by pressing the injector against the skin), audible clicks signalling the start of injection, a concealed needle, and needle safety mechanisms, are all design elements to enhance the safety and usability of auto-injectors. These enhancements aim to simplify the injection process and boost patient confidence (van den Bemt, 2019). See Figure 10 for the typical components found in an auto-injector.

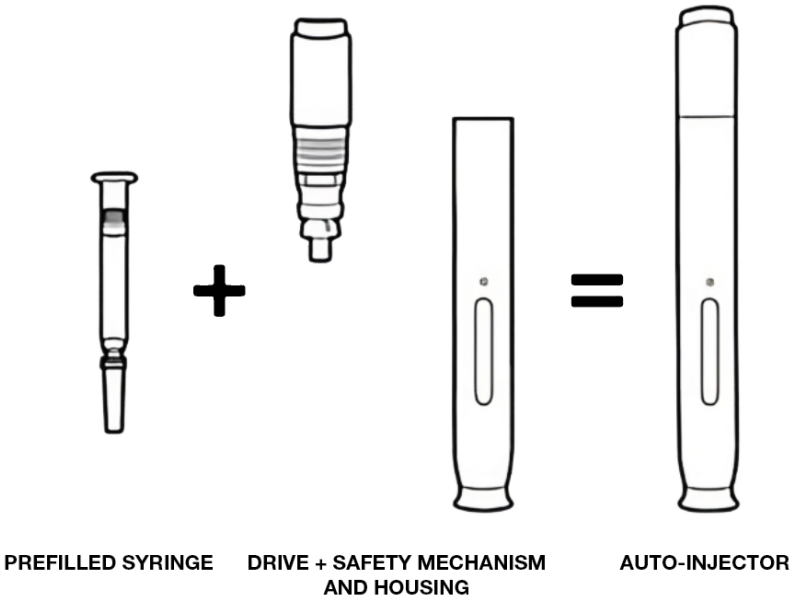


Figure 10 - Typical composition of auto-injector device. Adapted from Shire (2015).

As of today, there are more than 80 different autoinjector devices commercially available that are used to administer around 50 different drugs (Thompson et al., 2013). These numbers continue to grow as more autoinjector platforms enter the market. See for example Figure 11 showcasing a series of 14 disposable auto-injectors produced by the original equipment manufacturer(OEM) *Owen Mumford*. With estimates indicating the sale of hundreds of millions of disposable auto-injectors annually, this poses significant concern for the environmental impact that all this medical waste creates (Gerner et al., 2020). Currently, the typical product journey for most auto-injectors follows a linear path: they are manufactured, used, and disposed of as medical sharps waste, ultimately destined for incineration (see Figure 12). A study found, however, that in many instances used self-injectors can end up in regular municipal waste as a result of improper disposal, posing a significant health risk to society due to the injectors ending up in landfill (Montoya et al., 2021).

Figure 11 - 14 examples of the various auto-injectors from OEM Owen Mumford (Thompson et al., 2013).

Figure 12 - The current linear product journey of disposable auto-injectors

At the start of this thesis, J&J expressed interest in applying CE principles to their medical self-injectors. The main self-injector types used by J&J are safety syringes and auto-injectors. In consultation with J&J, the focus was placed on applying CE principles to auto-injectors, based on the reasoning that insights gained from the more complex auto-injectors could also benefit the simpler safety syringes. It is anticipated that the findings might be applicable across the entire product category of self-injectors.

3.1.2. Auto-injector Regulations

While auto-injectors are regulated by various international bodies, such as the FDA and EMA, to ensure their safety and effectiveness, these regulations were not fully considered in this project. Compliance with standards like ISO 13485 and ISO 11608-5, which cover quality management and functional requirements for auto-injectors, will become relevant in later stages of the product's development. For this thesis, the focus remained on a concept design without adhering to these regulatory guidelines. MacNeill et al. (2020), show how medical legislation and regulations can even act as barriers for a circular economy for medical disposable devices and as such may need to be challenged and revisited in the future. This is, however, out of scope for this project.

3.1.3. Trends and Developments for Auto-Injectors

This chapter explores the current market trends and developments within the healthcare sector concerning auto-injectors. A focus has been made on technological and sustainability advancements. The healthcare sector has been experiencing a significant demand for auto-injector devices, driven by the rising prevalence of chronic diseases and a shift towards home-based healthcare. Within this evolving landscape, sustainability and technological innovation have emerged as crucial factors influencing the development of new auto-injectors. By understanding these market trends, this chapter aims to provide insights into the future direction of auto-injector development and highlight potential opportunities for enhancing the sustainability and functionality of these devices.

Usability and Safety

Perhaps the most widespread trend within the auto-injector market is the continuous improvement in usability and safety. Significant advancements continue to be made to optimize usability and safety, including the development of foolproof and convenient two-step mechanisms and the implementation of mandatory needle safety features such as retracting needle covers (Weinhold et al., 2018). These innovations highlight the market's commitment to patient-centricity and safety, ensuring that auto-injectors are easy to use, reduce the risk of needle-stick injuries, and help combat needle phobia. See Figure 13 for an overview of some examples of popular features that illustrate this trend.

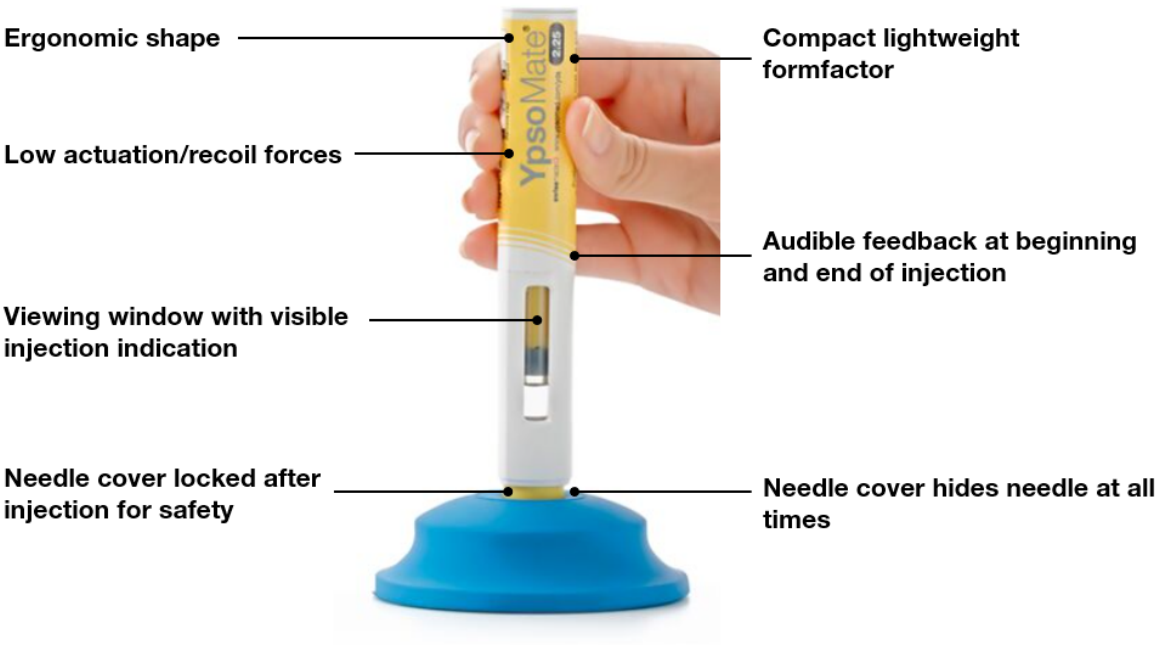


Figure 13 - Popular usability and safety features for auto-injectors. (Whelton, 2023)

Simplified Injectors

A trend that was observed surrounding sustainability in the auto-injector market was the introduction of simplified low part count injectors. Haselmeier developed a concept for the Piccoject auto-injector in 2022, with only 8 parts (Figure 14)(Metzmann et al., 2022). The Piccoject demonstrates a potential for simpler auto-injector designs. While this simplicity could theoretically support circular strategies, the Piccoject remains a single-use disposable injector not designed for circularity.

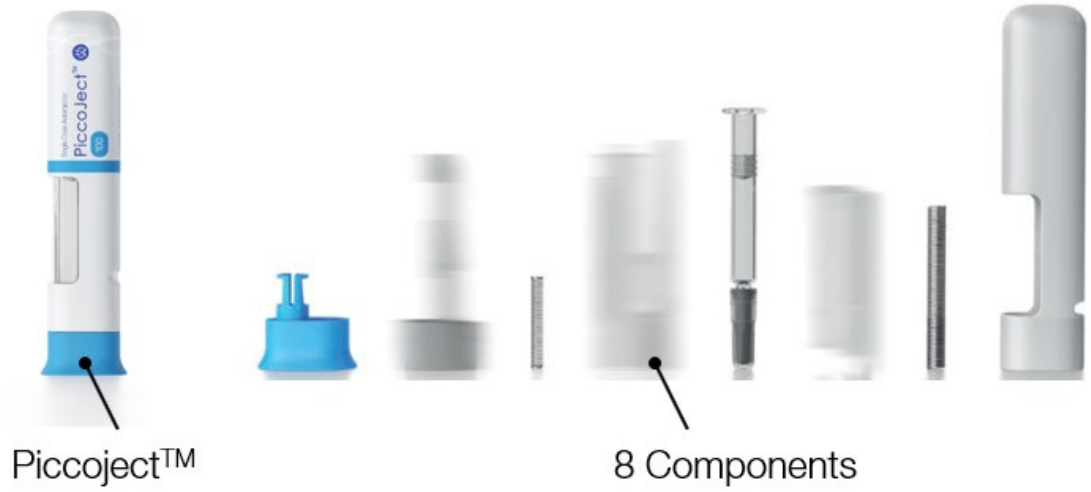


Figure 14 - Piccoject Injector and its 8 components (some components are still under development and are blurred) (Metzmann et al., 2022)

Biobased plastics

Some device manufacturers are experimenting with the use of biobased plastics in auto-injector designs as an alternative to the currently widely used petroleum-based plastics (see

Figure 15). Biobased plastics are sourced from renewable resources like sugarcane and therefore have the potential to reduce the environmental impact compared to petroleum-based plastics (Palmer-Felgate, 2024). However, the use of biobased plastics also brings its own challenges, such as inferior mechanical properties, difficulties with recycling, and significant costs (Abe et al., 2021). While biobased plastics offer potential carbon reduction benefits at first glance, merely replacing petroleum-based plastics with biobased ones without addressing the single-use nature of the devices only offers marginal environmental improvements. The full impact potential of bioplastics depends on addressing these challenges. The auto-injectors need to be redesigned around their new mechanical properties and for integrating the devices into revised recycling systems to accommodate these biobased materials.

Figure 15 – Eco-inject auto-injector made with biobased plastics (Palmer-Felgate, 2024).

Connectivity and Data-centricity

The integration of connectivity and data-collection options into auto-injectors is another significant trend observed in the auto-injector market (see Figure 16). These connected injector devices enable real-time tracking of medication usage and adherence by connecting with the patients mobile device, providing valuable data to healthcare providers for personalized treatment plans and timely interventions (Austin, 2023). Connectivity features can also offer patients additional guidance for their treatment in the form of real-time instructions, reminders and alerts to aid patient compliance and self-management.

However, the introduction of electronic components or add-on devices also raises concerns about e-waste, as their disposal would contribute significantly to environmental pollution (WHO, 2023). Balancing improved patient care with the environmental impact of electronic waste is a crucial consideration to be made in developing connected auto-injectors. Opportunities may exist in applying smart data-enabled solutions without electronics, such as using QR identifier codes, to reduce e-waste concerns.

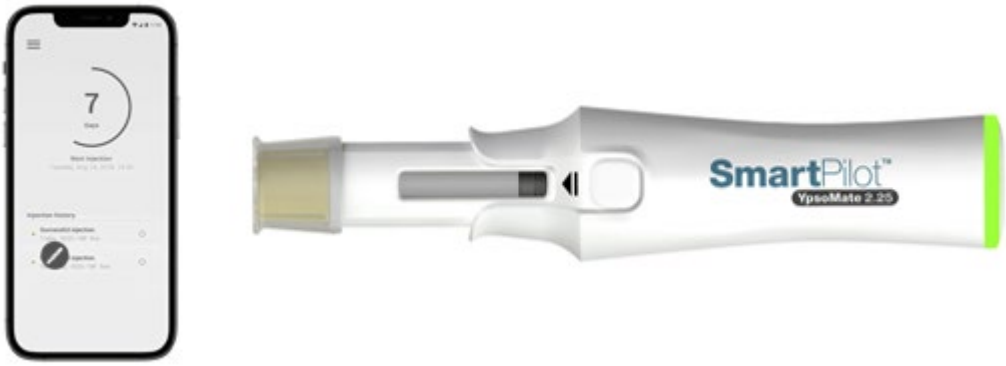


Figure 16 - Ypsomate SmartPilot Add-on device (Ypsomed, n.d.)

Hybrid reusable auto-injectors

The trend of hybrid reusable electronic auto-injectors often accompanies the integration of connectivity (see Figure 17). The benefits of these electronic injectors include greater control over the injection process, allowing for variable injection speed and force. Hybrid reusable devices are advantageous because they eliminate the need to discard the entire device after each injection. However, these devices also pose concerns regarding e-waste generation and may include additional usability steps that are unsuitable for patients with dexterity issues, making them inappropriate for all patients. Despite their benefits, the disposable cassettes still generate significant medical waste, with each cassette weighing roughly half of a typical auto-injector (Fraenkel et al., 2021). However, integrating such hybrid devices into a circular system where the cassettes components could be collected and reused or recycled might prove an interesting opportunity.

Furthermore, it was found that hybrid devices potentially complicate the use scenario by adding additional steps for use for the patient. Cassettes need to be reloaded and devices need to be kept fully charged to be ready for use at all times. In terms of safety and usability, it was therefore found that hybrid reusable injectors were inferior compared to pre-loaded injectors in this regard (Simpson, 2020). With the low frequency of injection for patients, use steps need to be carefully considered to avoid risk of incorrect or failed injections (Frew, 2011;Weinhold et al., 2018).

Figure 17 - Phillips-Medisize Aria electronic hybrid reusable injector and blue disposable injector cassette (Fraenkel et al., 2021)

Needle-free Injectors

Needle-free injection technology (NFIT) is an innovation that has long been dreamt up for the auto-injector market (see Figure 18). NFIT offers the potential for needleless drug delivery and therefore reduces the risk of needle stick injury and removes the classification of hazardous waste from the syringe. Despite ongoing research and development, the feasibility of this technology remains limited in the home-use injectable market due to significant technical challenges. One major complication is the variable viscosity of drugs, which makes it difficult to achieve consistent delivery without a needle (Ravi et al., 2015). Additionally, the fragility of some biological compounds poses a problem, as they cannot withstand the high injection forces required for needle-free systems. Consequently, while perhaps promising for the future, needle-free injection technology is not yet a viable alternative in the auto-injector market.

Figure 18 - The Portal Needle-free Injector Concept (Portal Instruments, n.d.)

System-level Developments for Auto-injectors

At a system level there are also some sustainability trends in the auto-injector industry that were observed. These include the development of take-back programs for used devices, facilitating return logistics and enabling companies to deploy further circular strategies. Novo Nordisk initiated this concept, for example, with their Returpen and Johnson & Johnson followed shortly after with their own program, SafeReturns (Novo Nordisk, n.d.; Johnson & Johnson, 2021). Additionally, it was found that collaborations within the pharmaceutical supply chain are becoming more common, exemplified by initiatives like the Alliance to Zero, which aims to accelerate the development of circular solutions in the industry (Alliance to Zero, n.d.). These trends both highlight a growing focus on sustainability and collaboration to address environmental impacts.

Auto-injector Circularity Developments at Johnson & Johnson

As this project was conducted in partnership with Johnson & Johnson (J&J), a close look was taken at the specific developments they have made concerning auto-injectors. J&J founded in 1886 and headquartered in the USA, is currently one of the world's biggest pharmaceutical companies. As such a large company and in line with its mission, J&J is committed to exploring its role in accelerating sustainability efforts in the healthcare sector. Within the auto-injector sector, Johnson & Johnson has implemented two significant initiatives aimed at advancing circular economy practices.

Firstly, J&J has launched SafeReturns, an injector return program currently operational in seven countries (including the United States and Switzerland), with plans for expansion into other regions. SafeReturns allows patients to send back their used injectors via mail. This program was designed as a first step in enabling a circular system for auto-injectors by facilitating the collection of used injectors and creating an opportunity for future development of recycling and remanufacturing (Johnson & Johnson, 2021).

Additionally, Johnson & Johnson is in the process of developing and deploying a pilot project focused on automating the disassembly of collected injectors (Figure 19) (Johnson & Johnson, 2021). This initiative aims to explore technological solutions for enabling circular strategies around component reuse and recycling within the company's operations, aligning with its broader sustainability objectives.

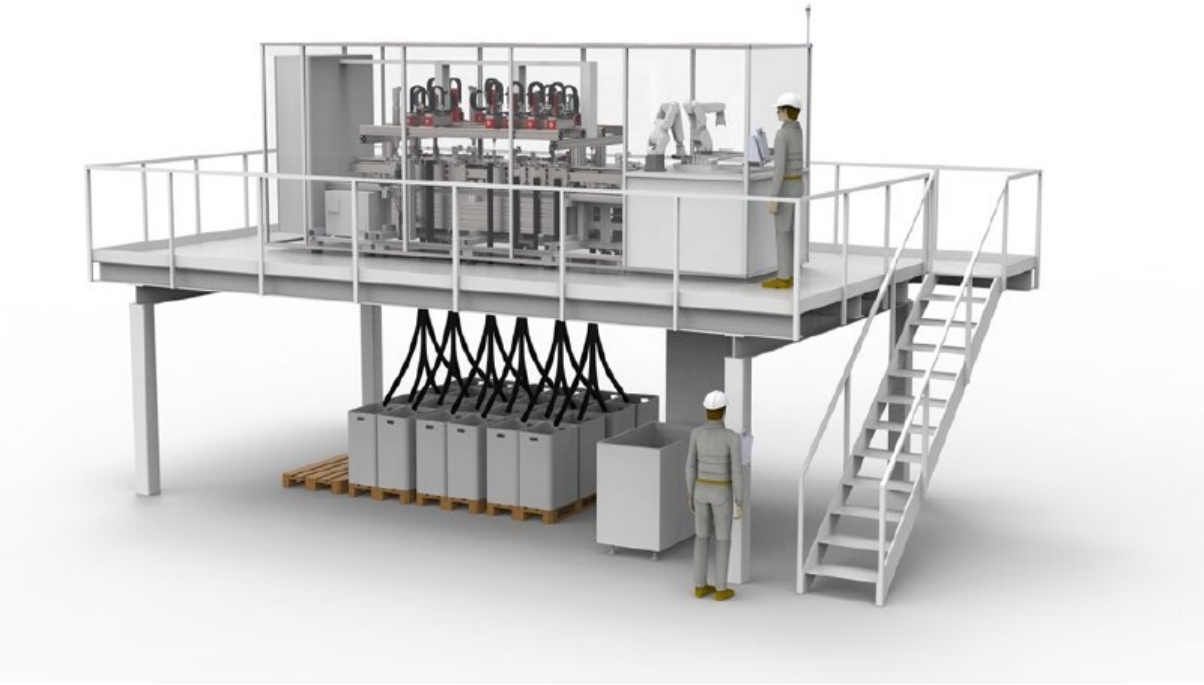


Figure 19 - Disassembly-line under development by J&J (Gysel, 2023)

Trends take-aways

Within the auto-injector industry trends were observed at both a product and system level. It was found that safety and usability of the devices is of paramount importance and significant advancements have been made in this area. Furthermore, the theme of sustainability was found to be making strong traction in the industry and many sustainable product developments are being made. However, these sustainable product developments alone have minimal impact on the system as a whole, often still failing to consider the product's end-of-life. Integrating the product developments into systemic developments, such as J&J's take-back scheme and designing injectors to fit into this circular system, may prove advantageous to enhance the sustainability of future auto-injectors. It is therefore essential to consider redesigning auto-injectors to align with the circular system being created. Lastly it was also observed that circular systems require a diverse set of competencies and that new partnerships will need to be created if such systems are to be realised.

3.2. The circular economy

This thesis aims to apply circular economy principles to the design of a self-injector in an attempt to minimise their contribution to medical waste. For clarity, as there are a plethora of different circular economy definitions, the definition of the circular economy used in this thesis is explained briefly here. The definition used here is based on the definition provided by the Ellen MacArthur Foundation (EMF), which states the circular economy is a resource efficient system where materials never become “waste” but instead are ideally recirculated at their highest value to society. (Ellen MacArthur Foundation, 2022). The model by EMF distinguishes between non-regenerative technical material cycles and regenerative biological material cycles, this thesis focuses on the technical cycles as these are most relevant for auto-injectors.

The economic model of today’s world is rooted in a linear economy, commonly referred to as the "take-make-waste" model (Ellen MacArthur Foundation, 2023). This model has fundamental limitations as it relies on the continuous extraction of finite resources, their conversion into products, and eventual disposal in the form of “waste”. To this day, even in the most ambitious countries, most of this waste is either incinerated or landfilled (Ritchie et al., 2023). This linear system is inherently unsustainable as our planet’s resources are finite. Therefore, the EMF states that “waste” is a human construct that should rather be labelled as mismanagement of finite resources.

The circular economy is a regenerative model that aims to eliminate waste altogether by closing material and product loops through design. This is done through processes such as product life extension and material recovery strategies that reuse waste in the system. According to den Hollander (2017), a linear economy produces waste through means of obsolescence, defined as a point in time at which a product loses its perceived value from the point-of-view of its user, leading to the product being discarded and its value being removed from the economic system.

There are several forms of obsolescence defined in literature including but not limited to:

- functional obsolescence (i.e. a product is physically worn out and can no longer perform its intended function)
- aesthetic obsolescence (i.e. a product has lost its aesthetic appeal)
- technological obsolescence (i.e. a product’s has become outdated through introduction of newer technologies)
- legal obsolescence (i.e. a product has become illegal due to new regulations)
- logistical obsolescence (i.e. a product is mismanaged within its environment)

The list goes on but for the medical field, an important form of obsolescence is hygienic obsolescence (i.e. a product has been made unsterile and poses a risk of infection and thereby a risk to human-life) (Kane et al., 2017). Figure 20 shows how hygienic obsolescence affects the value of a disposable auto-injector after it has been used by the patient.

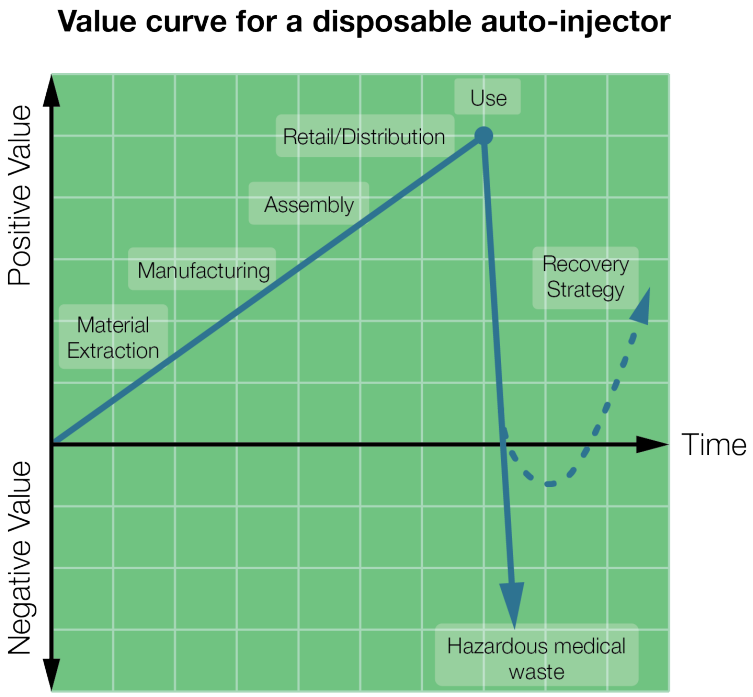


Figure 20 - The value of an auto-injector during its product life adapted from Haffmans (2019).

Important to note is that a product's state of obsolescence is reversible depending on the severity of obsolescence either at product or material level. In a circular economy, 'obsolete' products should not result in waste but rather should be reinjected into the economy through means of a recovery process (Hollander et al., 2017). This can be done by either extending the product life (e.g. through repair or remanufacturing) or by salvaging materials (e.g. through recycling).

Walter Stahel (2010) suggests to preserve value and energy by saying: "Do not repair what is not broken, do not remanufacture something that can be repaired, do not recycle a product that can be remanufactured. Replace or treat only the smallest possible part in order to maintain the existing economic value of the technical system." This is referred to as the 'inertia' principle. Bocken et al. have visualised this principle in the value hill. The principle compares the climbing of a hill to the energy that is used and the value that is created during the steps of the production of a product. This value is at its highest when the product is ready to be used (see Figure 21). Once the product is deemed "waste", the destruction of the product results in a loss of all the embedded value and energy.

Therefore replacing only the smallest possible part preserves most of the existing economic value of the product. This uses the smallest amount of energy. On the value hill this can be seen as a small step to the top requiring less energy than climbing the hill once more. For example, making an analogy with a bicycle, if the bicycle can be repaired and brought back to functionality this costs less energy and preserves more value than recycling the whole bicycle or its components to build it up again from scratch.

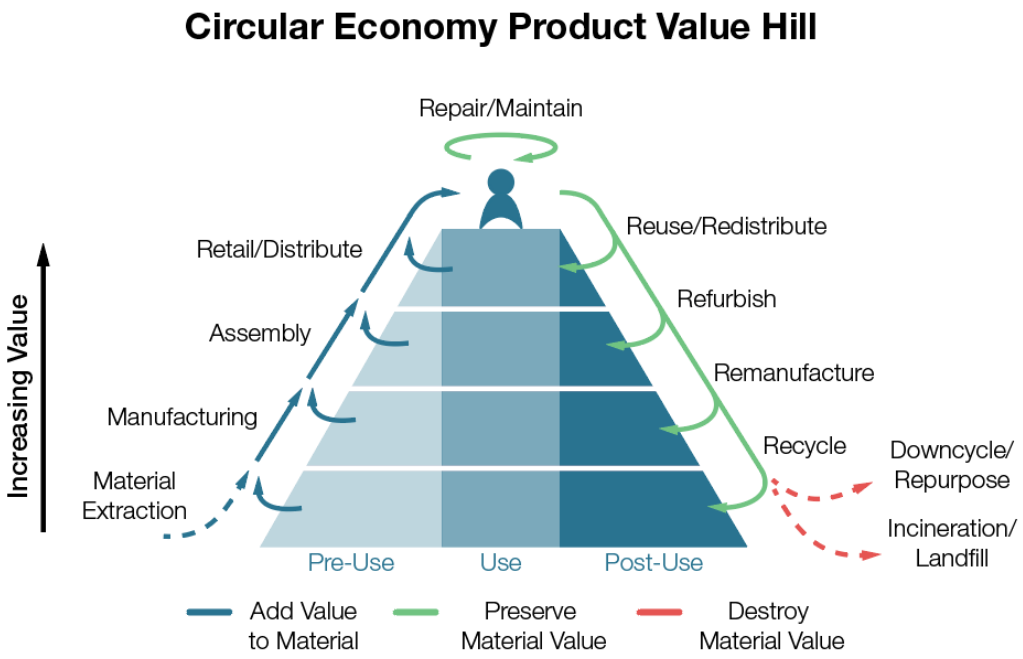


Figure 21 - Value Hill adapted from Achterberg et al. (2016)

Kane et al. (2017), show that when assessing 'circularity' in the medical technical industry, it is important to understand how medical products arrive at the classification of obsolescence in order to deploy adequate recovery methods. Often the effectiveness of specific recovery methods is dependent on the product category they are applied to. For example, for a single-use injector the needle is a hygienically critical component that makes recovery of the entire product uneconomic due to the high cost of sterilisation and low value of the needle. Analysis of obsolescence can be used as a starting point for finding the barriers and opportunities for circular recovery of single-use injectors. Literature has shown that design of products can have a positive influence on the ease of recovery when the End-of-Life of a product is considered early in the design phase (Bakker et al., 2019;Haffmans et al., 2019).

3.3. Circular economy principles for auto-injectors

Applying circular economy principles to any field comes with its unique challenges. However, as previously mentioned, what sets the medical industry apart from many other fields is it's rigorous commitment to personal safety. Healthcare's primary objective is to prioritise patient health above all else. The healthcare ethos and oath to "First, do no harm" underlines the inherent risk to human health that arises when treating patients (WHO, 2023). In order to ensure the safe practice of healthcare, stringent regulations are put in place and any medical device or procedure being put on the market is subject to comply with these regulations (MacNeill et al., 2020).

This focus on personal safety and the accompanying strict regulations make the application of circular economy principles in the healthcare industry particularly challenging. Additional challenges arise as regulations are not always the same for different regions (KPMG, 2023).

Several studies have been conducted in order to shed light on the challenges of circular economy principles in the healthcare sector. With widely cited research, Kane et al. (2017) appears a front runner in identifying and categorising the barriers as well as the opportunities for circular economy for medical devices. The barriers for medical devices (a.o. self-injectors) found in literature can be categorised into the following: safety, regulatory, financial, technical, social and environmental support structure (Kane et al., 2017; Hoveling et al., 2023). This chapter identifies the barriers for circular economy specific for auto-injectors that are currently present.

3.3.1. Barriers to circular economy principles for single use medical devices

The healthcare industry's strong "safety-first" culture coupled with an abundance of low cost virgin materials has led to the predominant use of disposable medical devices (Heinemann et al., 2022). The perception is that it is safer to dispose of used medical devices as medical waste rather than to decontaminate and reuse devices and that this should reduce infection risk (MacNeill, 2020). Kane et al. identified a specific type of obsolescence relevant to the medical sector, namely "hygienic obsolescence". Kane et al. define hygienic obsolescence when "a medical product is effectively rendered 'obsolete' after each use on a single patient, and can only be recovered when sterilization or disinfection processes are applied to render it hygienic once again."

Global standards and requirements for sterilization and disinfection follow the "Spaulding Scale" (see Figure 22). The scale categorises products into three different risk classes based on medical device invasiveness: "Critical", "Semi-Critical" and "Non-critical". The risk classification that a particular medical device falls into determines the level of decontamination required for safe use in medical procedures. Auto-injectors with their contained syringe and needle are classified as "critical" devices, however, as is shown in Chapter 3.3.1 when looking at a component level, the majority of the device is actually "Non-critical". See Appendix A for an overview of the guidelines on methods for decontaminations.

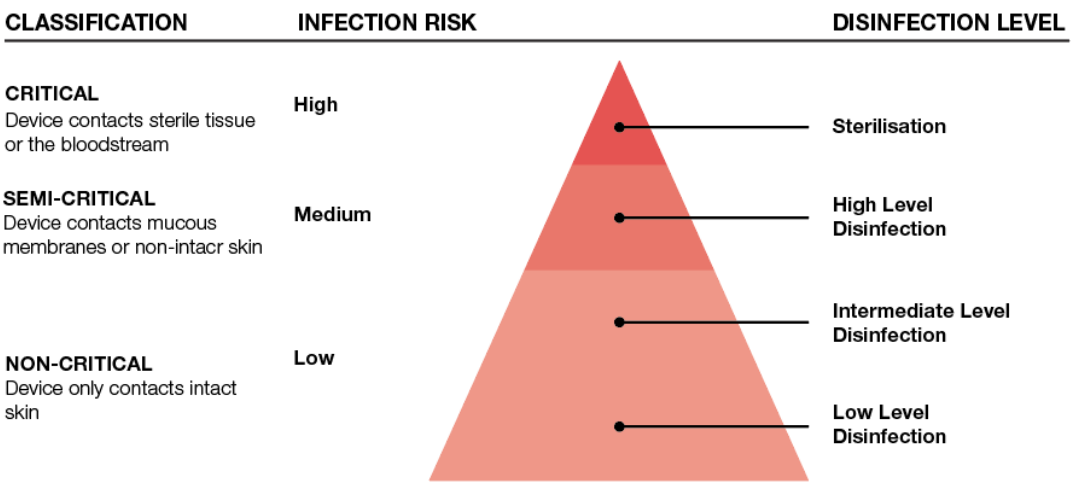


Figure 22 - Spaulding Scale adapted from Nanosonics UK (n.d.)

Apart from hygienic criticality, Kane et al. also mention the impact a medical product's value has on the recovery strategies that are viable. The authors further went on to identify a framework for different recovery strategies for medical products in a circular economy based on the product's hygienic criticality and economic value (see Figure 23). Kane et al. concluded for high-value, high-criticality devices design for reprocessing. For low-value, low-criticality items and for low-value, high-criticality items, design for separation and for recycling. Lastly high-value, low-criticality devices should be designed for refurbishment.

Typically, auto-injectors low-cost plastic construction makes them a low value product. According to Kane et al. a combination of high-criticality and low-value is a particularly difficult area of medical products to fit into a circular economy. MacNeill et al. (2022), further go on to state that due to their low complexity and difficulty of cleaning, syringes and needles might be most suitably recovered through recycling and that this product category will remain at least partially disposable in the foreseeable future. However, given the extremely large size of the global market for auto-injectors this is worth further exploring for circular design innovations.

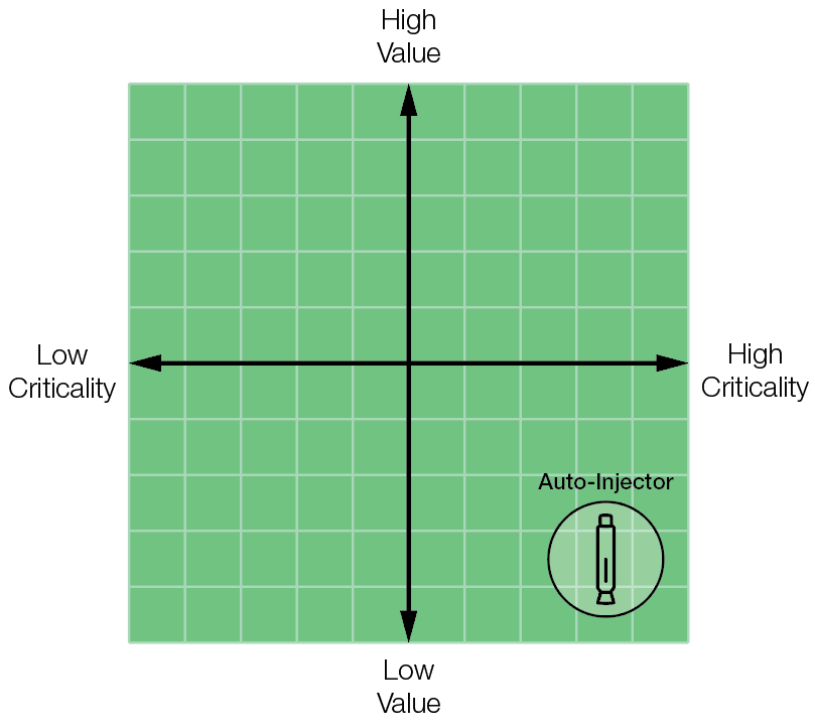


Figure 23 - Matrix for circular medical products by Kane et al. (2017) with Auto-Injector position.

The different barriers to circular economy principles in the medical field found in literature are shown below in Table 2. A selection has been made on barriers applicable to single-use disposable medical devices and specifically the implications for the design of an auto-injector.

Table 2 - Barriers to circular economy principles for single-use medical devices and implications for auto-injector design.

Category	Barriers	Implications for Study
Safety	1. (Perceived) increase in infection risk for patient due to insufficient decontamination compared to new devices (MacNeill et al., 2020) 2. Reprocessing a device for reuse must follow the same strict regulations for infection risk as a new device (Hoveling et al., 2023) 3. Risk to staff of cross-contamination during waste handling (World Health Organisation, 2015) 4. Concern of reduced performance or product failure due to effects of decontamination on the device (Kane et al., 2017)	1. Design for Safe handling, Design for Decontamination, Design for Trust 2. Out of Scope 3. Design for Safe handling 4. Device needs to resist decontamination effects
Regulatory	1. Strict regulations for medical waste handling, transport and disposal (MacNeill, 2020) 2. Strict regulations for medical device design and reprocessing and accompanying liability (MacNeill, 2020)	1. Out of Scope 2. Out of Scope
Financial	1. Cost of implementing recovery strategies (i.e. necessary infrastructure and logistics, quality assurance, regulatory compliance) (Rizos et al., 2021) 2. Business-as-usual incentives maximising bulk sale of single-use disposable devices to maximise profits (Hoveling et al., 2023) 3. High capital investments required for manufacturers to support systemic change to business models (MacNeill et al., 2020) 4. High (upfront) cost of reusable devices (Hoveling et al., 2023)	1. Out of Scope 2. Out of Scope 3. Out of Scope 4. Out of Scope
Technical	1. Devices are not designed for optimal integration into circular business models (Hoveling et al., 2023) 2. Low cost disposable devices often not designed for effective cleaning and decontamination. (Kane et al., 2017) 3. Decontamination effects on material degradation (Kane et al., 2017;van Straten, 2022) 4. Difficulty in validating device functionality after reprocessing (MacNeill, 2020)	1. Design for appropriate recovery strategies 2. Design for decontamination 3. Design for decontamination 4. Out of scope
Social	1. Reluctance to use reprocessed devices due to perceived infection risk (MacNeill et al., 2020) 2. Inherent resistance to systemic change (eco-system) (Hoveling et al., 2023;Jain, 2022)	1. Design for Trust 2. Out of Scope
Environmental Support Structure	1. Increased complexity of (reversed) supply-chain required for reprocessing (Kane et al., 2017) 2. Difficulty in accessing and reclaiming used products (Rizos et al., 2021) 3. Extra steps for manufacturer or reprocessor to meet regulatory requirements for reprocessed devices (MacNeill et al., 2020) 4. Require industry-wide collaboration and communication (MacNeill et al., 2020)	1. Out of Scope 2. Out of Scope 3. Out of Scope 4. Out of Scope

These are the barriers for circular economy for disposable medical devices that were found in literature. These barriers can be further split into two categories, namely systemic barriers and barriers that arise due to the design of the product. As this thesis looks at the design of an auto-injector for integration in a circular economy only the barriers that translate into product design requirements have been selected for further consideration in the later ideation and conceptualisation phase.

3.3.2. Opportunities

The previous sub chapter identifies some of the barriers that are present for disposable medical devices to a circular economy, however, literature also identifies opportunities (enablers) that are present.

Kane et al. (2017) state that many devices are not *entirely* "critical" or "non-critical" as in many cases only a portion of the "critical" device enters the patient's body. Safe and effective separation of the product's components would open up innovative solutions and allow these elements to be treated with appropriate recovery strategies (see Figure 24). For example, different elements can be reused, reprocessed or recycled. Kane et al. mention an example of a company that produces medical shavers with a reusable handle and disposable blades. They also state that design innovations for critical low-value medical products may be best targeted at the equipment and infrastructure required for recovery rather than the products themselves.

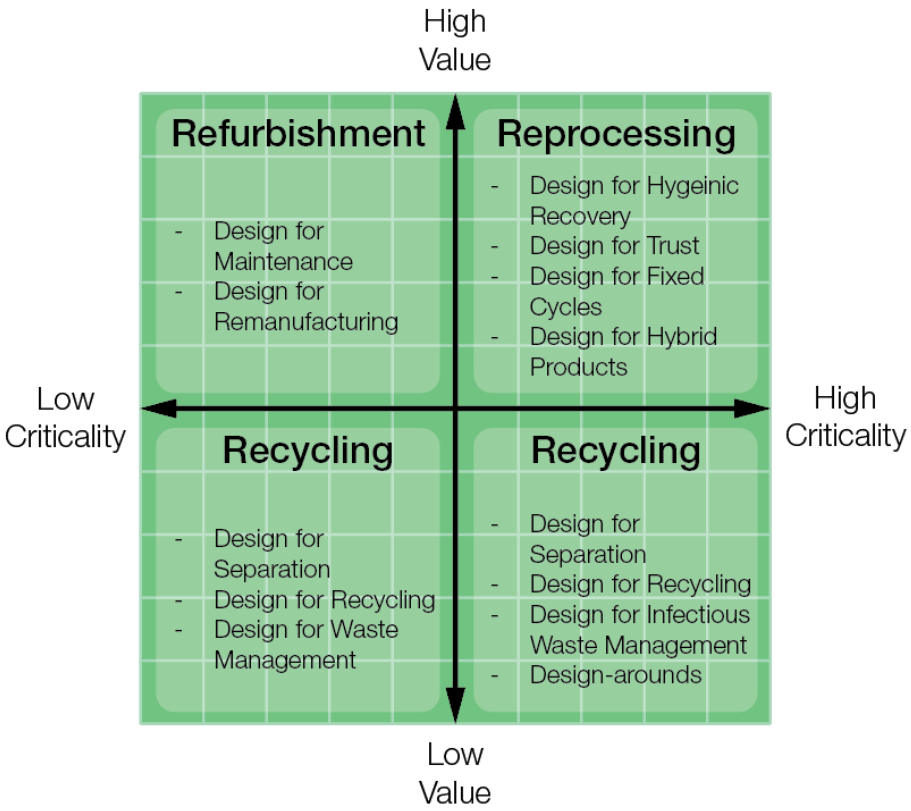


Figure 24 - Design Framework by Kane et al. (2017)

Guidelines already exist for the handling of low-critical low-value medical products. In this study, the focus is on the opportunities for circular economy of high-critical low-value auto-injectors. A first step towards preparing guidelines for designers for single-use medical devices including auto-injectors is found in Table 3. For completeness, the same list of categories are

used as in Table 2. It should be noted that the most relevant categories for this study are *Safety* and *Technical*.

Table 3 - Opportunities for circular design strategies for single-use medical devices including auto-injectors

Category	Opportunities
Safety	1. Design for effective and safe product hygienic recovery (cleaning and decontamination) (Kane et al., 2017) 2. Design for separation of "critical" and "non-critical" components: hybrid device. (Kane)
Regulatory	1. Design to track the number of sterilisation cycles and impact on device (van Straten, 2022) 2. Design for safe handling and transportation of used medical devices (Kane et al., 2017) 3. Design for standardisation (materials, logistics and reprocessing) (Hjorth, 2022; Bovea et al., 2018)
Financial	1. Introduce a service-based business model (Stahel) 2. Increase value of the medical device to finance recovery strategies into a viable business model (Kane et al., 2017). 3. For low-cost components optimise for decontamination and recycling via economies of scale (Kane et al., 2017) 4. Design for a limited number of use cycles rather than indefinite (Kane)
Technical	1. Design durable components/products that are able to survive the required circular product journey (Kane et al., 2017) 2. Select materials that are suitable for a circular product journey (Kane et al., 2017) 3. Design products for effective disassembly and reassembly (Kane et al., 2017) 4. Design for modularisation and simplification (Kane et al., 2017) 5. Introduce experimental demonstrative pilot projects to prove technical feasibility (Jain, 2022) 6. Design for quality control of post-use products and components (Hjorth, 2022; van Straten, 2022) 7. Design for uniformity of materials (mono-material) (Kane et al., 2017)
Social	1. Improve trust in reusable sterilised devices. (MacNeill, 2020)
Environmental Support Structure	1. Design for forward and reverse logistics/supply chain (e.g. packaging) (Kane et al., 2017) 2. Design to track, label and document use cycles as well as supply chain cycles. (van Straten, 2022) 3. Introduce experimental demonstrative pilot projects to prove supply-chain feasibility (Jain, 2022)

Development of the circular economy in the medical sector is still in its infancy. For example, it was observed that recycling of medical products into new medical products has not yet been implemented although technical feasibility has been demonstrated (van Straten, 2022).

3.4. Context Conclusions

In summary, developments in the auto-injector industry have been observed at both the product and system levels. The market for auto-injectors is growing rapidly due to a global rise in chronic diseases. Auto-injectors offer clear benefits for patient self-management of diseases and by reducing strain on the healthcare system. Currently, disposable single-use injectors dominate the market primarily due to their clear usability and safety benefits for patients. Disposable auto-injectors contribute significantly to the generation of medical waste. Research by Kane et al. (2018) categorise auto-injectors as the most difficult medical product category

for circular strategies being that they are low-economic value products with a high level of hygienic criticality. Kane et al. go on to identify that a valuable opportunity for this category of medical product is to design for separation of components in order to be able to treat the different risk-level waste accordingly.

Patient safety and usability have been identified as key factors for the successful adoption of new auto-injectors. Additionally, while there are ongoing developments towards more sustainable products, these efforts often neglect the product's end-of-life considerations. Integrating systemic developments, such as J&J's take-back scheme and designing injectors to fit into a circular system, may enhance the sustainability of future auto-injectors. An opportunity therefore exists to redesign injectors to better align with accompanying circular systems being created, like the one being developed by J&J. Other market players are also forming partnerships, such as the Alliance-to-zero, to accelerate the development of these circular systems, leveraging a diverse set of competencies. Visit Table 3 for a full list of the circular design opportunities for auto-injectors.

4. Analysis of the Case-study product: Ypsomate

This chapter presents an analysis of the case study product, the Ypsomate auto-injector (Figure 25). The analysis begins with a description of the product, its typical use case, and its functional features. It then proceeds with a detailed review of the disassembly process, providing a closer look at the product's architecture and the components found within it. Following an understanding of the case-study product's features and internal workings, the Circular Product Design assessment by Bovea et al. (2018) is applied to assess the original product in terms of design for the circular economy. This baseline scoring provides a basis for identifying areas of improvement in the redesign.

Figure 25 - The Ypsomate 2.25ml

4.1. Product Description

The Ypsomate 2.25ml auto-injector was selected as a case study product for analysis as it is an injector widely used in the industry including by Johnson & Johnson and as such was available for analysis. This injector is part of a product platform of injectors developed by the Swiss-based company Ypsomed (see Figure 26). Ypsomed produces hundreds of millions of Ypsomates each year (Jost, 2022). The Ypsomate stands out due to its stringent focus on patient safety and its user-friendly, easy-to-use design (Niedermann, 2019). Ypsomate injectors are used for the self-treatment of several chronic diseases, including multiple sclerosis, rheumatoid arthritis, migraine and obesity.

Figure 26 - The Ypsomate auto-injector platform (from left to right: 1ml, 2.25ml, Pro, 5ml)

While there may be slight differences in the number and size of components among the different Ypsomate auto-injectors, the design of these injectors is comparable. Ypsomed supplies the use of their auto-injectors to various pharmaceutical companies, producing the devices and fine-tuning their design to align with the specific requirements of the pharmaceutical drugs. Subsequently, the pharmaceutical companies are responsible for filling the auto-injectors with the appropriate drugs. This linear product production journey, which involves multiple stakeholders in order to supply the filled auto-injector to patients, follows the path outlined in Chapter 3.1.1 and illustrated in Figure 12.

4.1.1. Product Features

The Ypsomate auto-injector is a 2-step auto-injector. This category refers to the simple two-step procedure required to operate the device. These steps are illustrated in Figure 27. The first step involves removing the safety cap, which uncaps the hidden needle and deactivates the safety lock. This action prepares the auto-injector for use. The second step requires pressing and holding the needle-cover against the skin, which triggers the spring-driven mechanism to commence the injection. Audible clicks cue the start and completion of the injection, and the viewing window shows the plunger rod has delivered the full dose. After the injection, the needle cover locks over the needle to prevent accidental needle stick injuries. For a detailed description of the user experience with the Ypsomate, refer to Appendix C, which includes a storyboard outlining all the steps from obtaining the device to its disposal.

Figure 27 - The simple two steps of Ypsomate 2.25ml use

The Ypsomate is designed specifically with features for treating chronic diseases that require injections ranging from every two weeks to every few months (Gysel, 2023). The Ypsomate has two main areas of user-friendly functionality. The device is built with simplicity and ease of use in mind. Its features include straightforward use steps and a safety mechanism that locks the needle after use. Additionally, the needle is covered from sight at all times, a feature that has been proven to reduce needle phobia and can improve comfort and reduce the perceived pain of injection (Frew, 2011).

4.2. Product Architecture

A manual disassembly of the Ypsomate 2.25ml was performed to inspect the internal components of the device and to assess their accessibility (see Figure 28 & Figure 29). It was found that the injector consisted of several subassemblies containing a total of 20 components. These include a prefilled syringe, a driving mechanism, a needle-safety mechanism, and housing. Additionally, an overview of the different sub-assemblies and their functions are presented in Table 4.

Figure 28 - Photo of the destructive disassembly process and some of the required tools.

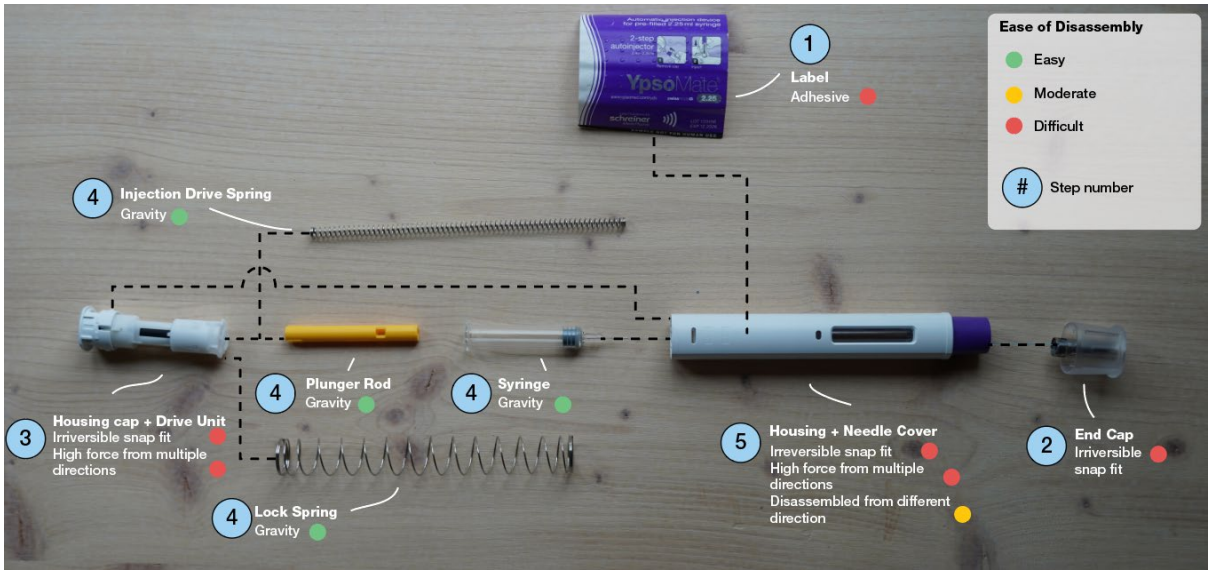


Figure 29 - Overview of Ypsomate 2.25ml disassembly with subassemblies

Table 4 - Individual subassembly functions

Subassembly/Component	Function
Label	Provide patient information about contents and injector
Injection Drive Spring	Provide driving force for the injection
Housing cap + Drive Unit	Trigger drive spring release and lock needle cover after use
Plunger rod	Transfer drive spring force to plunger
Syringe + Needle	Contain and preserve drug + inject through human skin
Housing + Needle cover	Protect internal components, provide ergonomic shape to hold, hide the needle, activate driving mechanism when pressed, block needle after use
End cap	Keep the needle sterile until use, provide ergonomic chape to remove cap

The disassembly process revealed the complexity and arrangement of the device's components, which is crucial for evaluating its current circularity potential as well as opportunities for redesign. Effective separation of components and materials is vital for several circularity strategies, including recycling and remanufacturing(Feenstra et al., 2021;Hjorth et al., 2022). An overview of the components has been made which can be found in Figure 30.

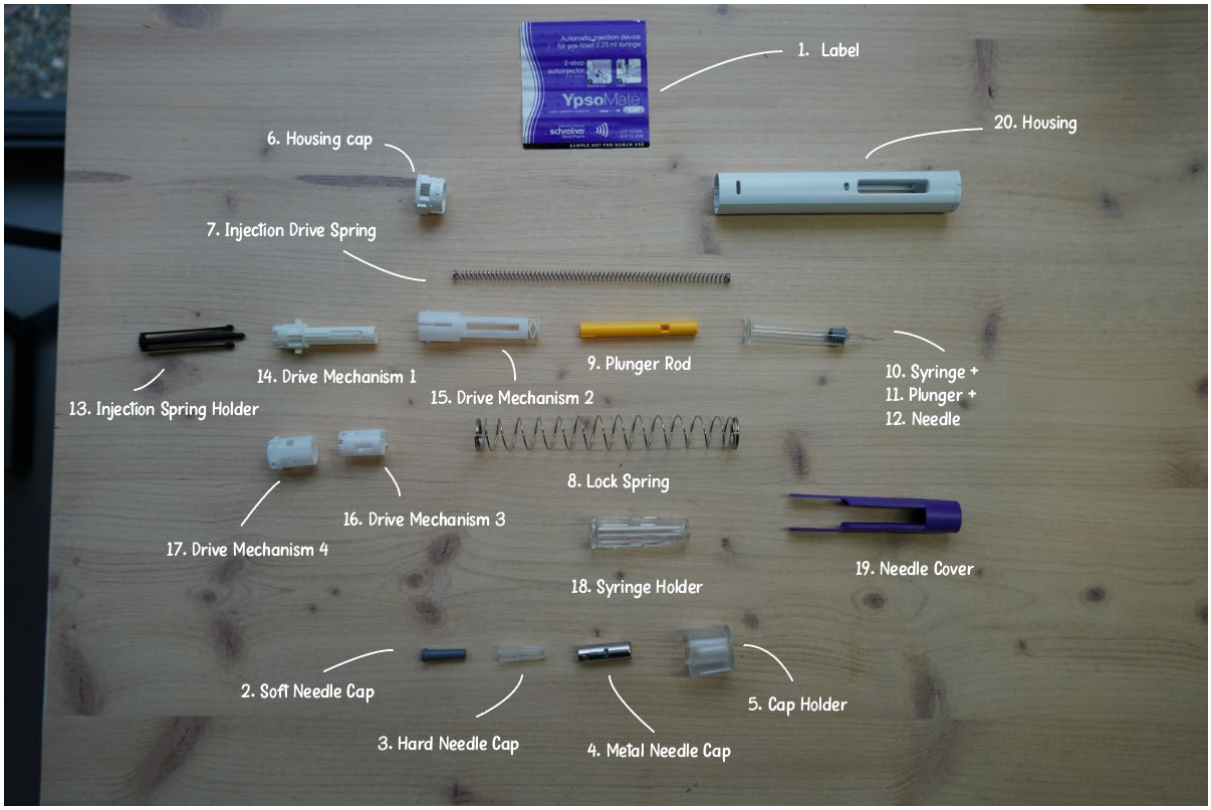


Figure 30 - Overview of all components of the Ypsomate 2.25ml

A rough overview of the materials has been laid out in a Bill of Materials (BoM) in Table 5 (Schuringa, 2023). The BoM also identifies the criticality rating of the individual components based on the Spaulding scale as previously explained in Chapter 3.3. Doing this shows

Table 5 - Bill of Materials Ypsomate 2.25ml

Part Number	Part Name	Material	Spaulding Scale	Justification Spaulding rating
1	Label	Laminated paper	Non-Critical	Can come into contact with intact human skin
2	Soft Needle Cap	Elastomer	Critical	Can come into contact with the critical needle.
3	Hard Needle Cap	Plastic type 1	N/A	Does not come into contact with patient
4	Metal Needle Cap	Stainless steel	N/A	Does not come into contact with patient
5	Cap Holder and Grip	Engineering plastic type 1	Non-Critical	Can come into contact with intact human skin
6	Housing Cap	Engineering plastic composite type 1	Non-Critical	Can come into contact with intact human skin
7	Injection Drive Spring	Stainless steel	N/A	Does not come into contact with patient
8	Lock Spring	Stainless steel	N/A	Does not come into contact with patient
9	Plunger Rod	Engineering plastic type 2	Semi-Critical	Can come into contact with medicine on inside of syringes
10	Syringe	Medical grade borosilicate glass	Critical	Contains critical medicine
11	Plunger	Elastomer	Critical	Comes into contact with critical medicine
12	Needle	Stainless steel	Critical	Enters the human body
13	Injection Spring Holder	Engineering plastic composite type 2	N/A	Does not come into contact with patient
14	Drive Mechanism 1	Engineering plastic composite type 3	N/A	Does not come into contact with patient
15	Drive Mechanism 2	Engineering plastic type 2	N/A	Does not come into contact with patient
16	Drive Mechanism 3	Engineering plastic type 2	N/A	Does not come into contact with patient
17	Drive Mechanism 4	Engineering plastic type 2	N/A	Does not come into contact with patient
18	Syringe Holder	Engineering plastic type 1	Non-Critical	Can come into contact with intact human skin
19	Needle Cover	Engineering plastic type 2	Non-Critical	Can come into contact with intact human skin
20	Housing	Engineering plastic composite type 1	Non-Critical	Can come into contact with intact human skin

4.2.1. Disassembly process

It is of interest to note, that the disassembly process was particularly difficult to perform by hand. Excessive force and precision was required to dismantle the device resulting in the permanent damage of small intricate components. The use of steel prongs and screw drivers was necessary to disengage irreversible snap-fits and a work bench vice was required to force open the housing cap (Part 6). In conclusion, it was evident that the Ypsomate was not designed with disassembly in mind. To further investigate trends for injector design in the industry, a total of 4 injectors from different manufacturers were disassembled. All these disassemblies found similar use of a variety of materials (polymers, glass, metals, composites) with irreversible joints (see Appendix D). This supports the finding that for current self-injectors separation of materials or components at their end-of-life is not optimised.

As suggested by Kane et al. (2017), a distinction was made at the component level of the device in terms of hygiene criticality and value (see Figure 31). Following the design framework

shown in Figure 24 explained in Chapter 3.3.2, it can be concluded that designing for the separation of components could allow for different recovery strategies and varying decontamination requirements for different batches of components. Effective separation of the most valuable component, the borosilicate glass syringe (Nr.10), would also provide significant value. Borosilicate glass is a valuable material that experienced shortages during the COVID-19 pandemic (Ganti, 2022). A circular economy for this material alone could greatly enhance material supply resilience.

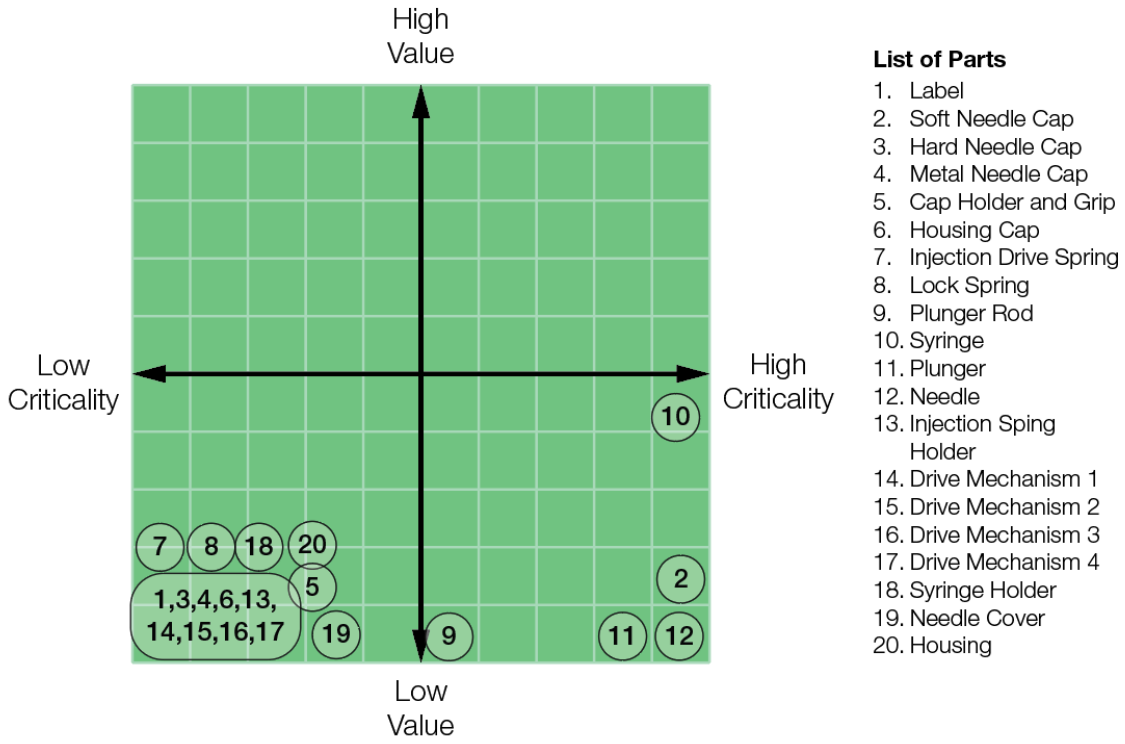


Figure 31 - Criticality-value matrix (Kane et al., 2017) on component level for the Ypsomate 2.25ml

4.3. Circular Product Design Assessment

Following the analysis of the Ypsomate's features and architecture in the previous sections, the Ypsomate's circular product design (CPD) improvement potential was assessed using the CPD assessment tool developed by Bovea et al. (2018). This tool was chosen for several reasons. Firstly, the authors provide a comprehensive list of 46 tangible CPD guidelines derived from extensive literature research, which can be used to evaluate the original product in terms of design for the circular economy. Secondly, the tool emphasizes the five different circular strategies and offers a method to assess which strategies are relevant for the product through a relevance assessment. Finally, by combining the guidelines with relevant strategies, the tool helps identify areas for improvement in the redesign of the Ypsomate.

The CPD assessment tool by Bovea et al. (2018) served as a general framework for this study but was adjusted where necessary to better fit the specific case of the Ypsomate. Figure 32 outlines how the tool was applied in this study. For a detailed explanation of the method, see Appendix E.

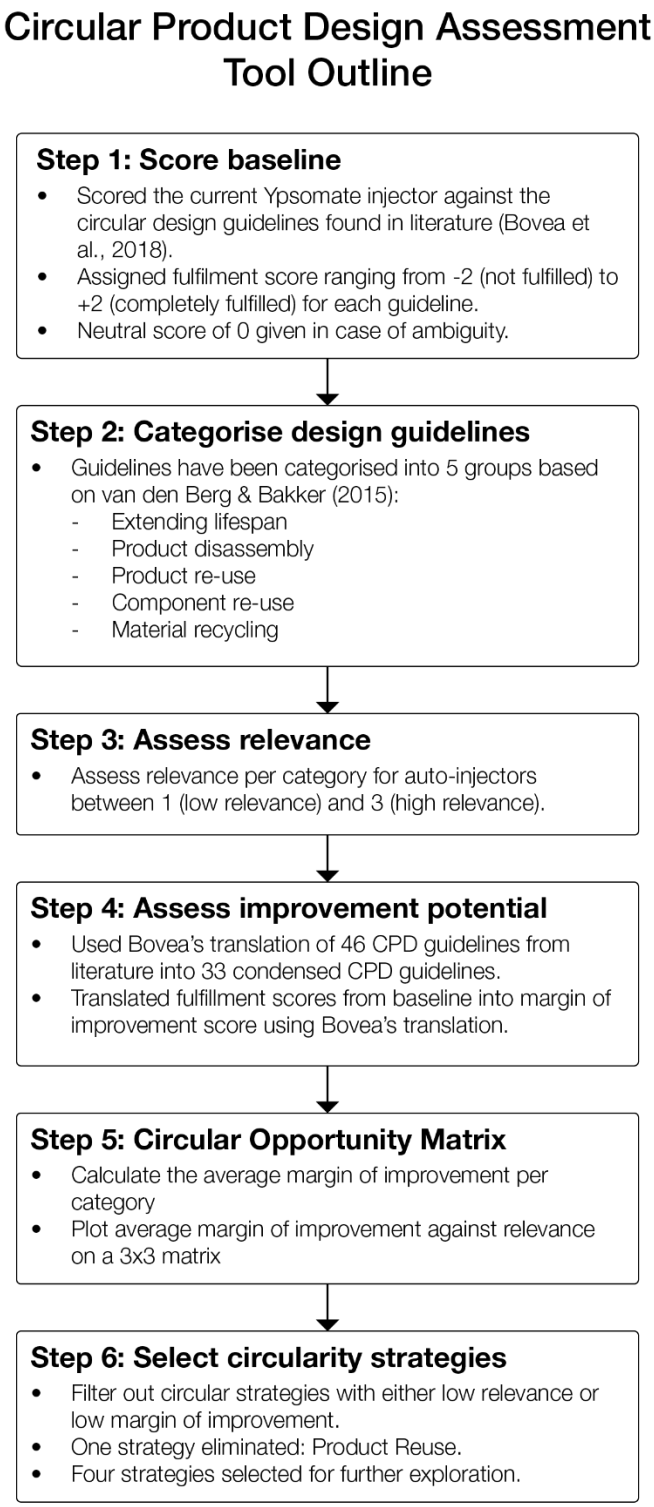


Figure 32 - Outline of the CPD assessment tool by Bovea et al. (2018) as used in this project.

Applying the CPD assessment tool led to the creation of a 3x3 opportunity matrix, where the relevance of circularity strategies was plotted against the average improvement potential for the Ypsomate within each category to identify the most significant areas for circular improvement (see Figure 33).

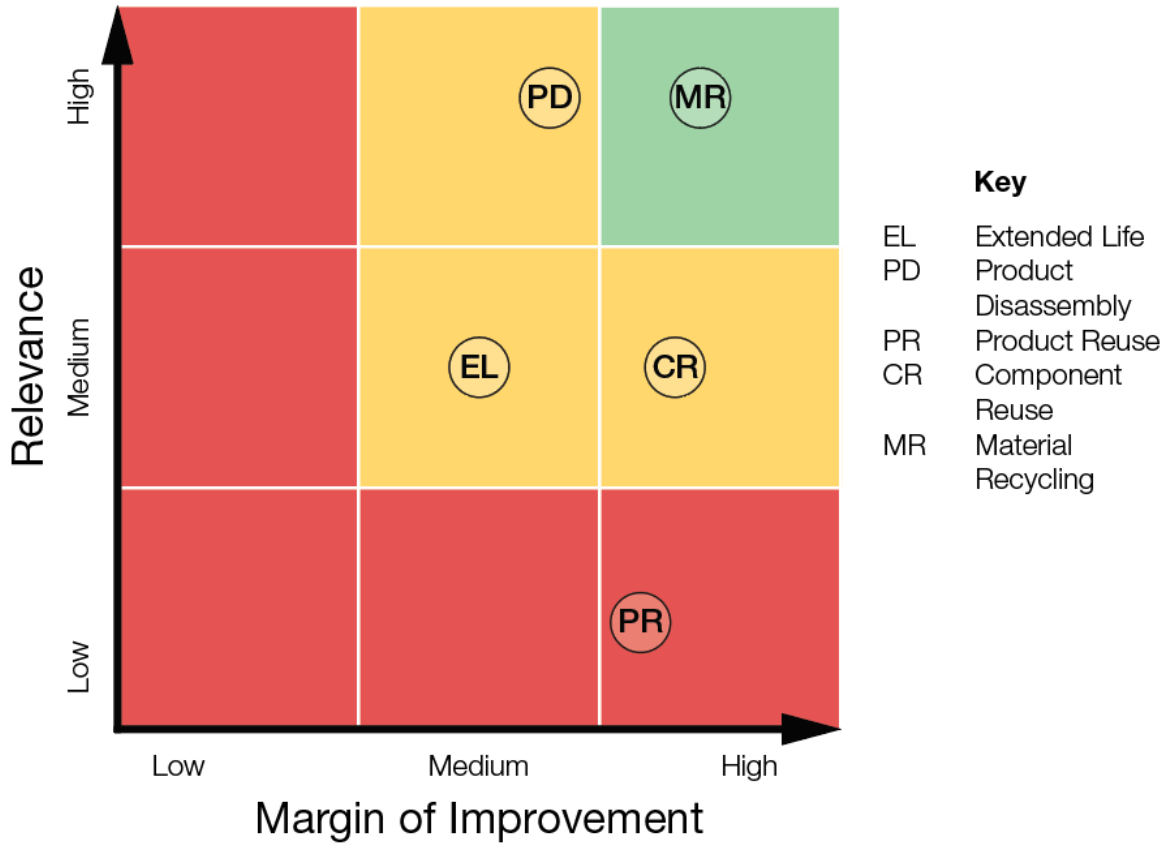


Figure 33 - Circular Product Design Opportunity Matrix for Ypsomate

The results of the CPD assessment tool identified four areas of significant circular opportunity: Material Recycling, Product Disassembly, Component Reuse, and Extended Life. Component Reuse, also known as Remanufacturing, is referred to as such from this point on. These four circular product design strategies have been used as starting points for design ideation and are presented in the following chapter

4.4. Chapter Conclusions

The analysis of the Ypsomate auto-injector has highlighted important aspects of its design, functionality, and improvement potential for circular design. The Ypsomate is an industry-leading device used for self-treatment of a wide range of chronic diseases due to it's safe and easy-to-use design. The analysis of the disassembly process and internal components revealed that the Ypsomate was not designed with possible End-of-life reprocessing in mind. The disassembly process required a lot of force and precision, indicating that the device is not designed for easy separation of materials or components. This makes applying circular recovery strategies such as recycling and remanufacturing difficult.

Furthermore, applying Kane et al.'s design framework at the component level uncovered opportunities for design for disassembly. Specifically, separating hygiene-critical components (such as the syringe and needle) would enable the application of appropriate decontamination

techniques for both critical and non-critical components. This separation would facilitate the recycling or reuse of these components.

Finally, the Circular Product Design (CPD) assessment tool by Bovea et al. (2018) identified several opportunities to enhance the Ypsomate for circular product design. The most valuable circular strategies identified were: Design for Material Recycling, Design for Disassembly, Design for Component Reuse, and Design for Extended Life. These strategies will be further explored in subsequent chapters to develop a more sustainable auto-injector design.

5. Redesign Ypsomate for a Circular Economy

This chapter presents ideation solutions for the four circularity strategies selected in the previous chapter to redesign the currently disposable single-use Ypsomate autoinjector. These strategies include: Design for Recycling, Design for Disassembly, Design for Remanufacturing, and Design for Product Life Extension. The ideation for these strategies presented in this chapter was based on the analysis of the context around the auto-injector landscape (Chapter 3) and the analysis of the Ypsomate case-study product (Chapters 4).

The redesign process began with establishing a set of general design requirements for the Ypsomate. This was followed by a brief literature review on existing design guidelines for the four circular strategies. Subsequently, ideation sessions were conducted, involving discussions and brainstorming with designers, engineers, product owners, circular design experts, and fellow design students. This collaborative approach ensured a diverse set of perspectives, facilitating the generation of early concepts for each strategy.

This chapter concludes by selecting the most promising strategy for further concept elaboration and detailing, providing the foundation for a detailed conceptual design that aims to integrate the Ypsomate into a circular economy.

5.1. General design requirements for a redesigned auto-injector

The first step in the redesign process was to combine the conclusions and findings from previous chapters to form general requirements for a redesigned Ypsomate. This analysis led to the formulation of specific design recommendations that address the critical factors influencing the potential success of the redesigned auto-injector. These requirements focus on enhancing user desirability, ensuring technical feasibility, and maintaining business viability. Ensuring that the redesign fulfils these requirements will increase the likelihood of its success and provide a strong basis for the further application of circular strategies. It is crucial to balance these requirements with circular product design guidelines to create a successful and sustainable circular product.

The general design requirements for a redesigned Yposmate are as follows:

Desirability for Users

1. Safety:
    a. The auto-injector must be at least as safe as the current Ypsomate, ensuring:
        i. The needle is hidden before, during, and after use to prevent accidental needle stick injuries.
        ii. An automatic locking needle cover or shield engages after injection to prevent reuse.
        iii. All materials in contact with the drug or patient are biocompatible and non-toxic.
        iv. The needle and syringe are protected from damage, contamination, and tampering until use.
2. Usability:
    a. The auto-injector must be at least as user-friendly as the current Ypsomate, incorporating:
        i. Easy 2-step activation (remove cap and press to inject).

   ii. An ergonomic design that can be operated with one hand, accommodating users with limited dexterity.
   iii. User feedback through visual or audible cues.
   iv. A small and lightweight design for easy transport and storage.
3. Trust:
   a. The auto-injector must evoke trust in its users by:
      i. Featuring a high-quality, clean appearance to improve patient confidence.
      ii. Ensuring the needle is hidden at all times to reduce needle phobia.

Technical Feasibility

1. Manufacturing Scalability:
   a. The auto-injector must be suitable for scalable automated production to ensure consistent quality and to meet global demand.
2. Durability in Design and Materials:
   a. The auto-injector must be robust and reliable, capable of performing across typical environmental conditions throughout its use phase.

Business Viability

1. Cost-Effective Production:
   a. The auto-injector must be suitable for financially competitive scaling to meet the demand for hundreds of millions of units per year.
   b. Production costs (materials, manufacturing, transport, etc.) must be covered by a competitive value proposition.
2. Supply Chain Efficiency:
   a. The auto-injector must integrate into a financially competitive supply chain, ensuring the delivery of injectable drug doses at the right place, time, and quantity.
3. Sustainable Business Model:
   a. The auto-injector must offer a financially sustainable value proposition to allow J&J to remain competitive.

The likelihood of success for the redesigned auto-injector is largely dependent on using these requirements as a foundation for the design, ensuring that the redesign fulfils the critical requirements of the current design. Balancing these design requirements with design guidelines for circularity enhances the chances of creating a high-quality, safe, and functional auto-injector that can be effectively integrated into a circular economy.

5.2. Ideation: Design for Recycling

The first design direction focuses on Design for Recycling. Design for Recycling is one of the lower value recovery strategies within the value hill model, meaning that most of the embodied energy and value in the product is lost (Kirchherr et al., 2017). However, material recovery through recycling still reduces emissions compared to primary production and landfill or incineration. A critical aspect to the success of Design for Recycling is the extent to which contained materials can be separated from one another, the reduction in number of materials and the use of materials with existing recycling streams (van Straten et al., 2023; van den Berg, 2015).

While the ideal outcome of a well-functioning circular economy is to reuse everything at its highest value to society, it is inevitable that products will eventually reach the end of their

functional life. This state of obsolescence necessitates consideration of less energy-efficient yet valuable material recovery methods (den Hollander et al., 2017).

From the list circular product design guidelines for recycling from Bovea et al. (2018) a shortlist was made based on the most significant improvement potential for the Ypsomate. The shortlist includes:

1. Promote pure mono-material designs.
2. Use high quality recyclable materials.
3. Design components to be easily separable based on material type.
4. Design components and materials to be identifiable.

These guidelines were used to generate solution concepts while trying as best as possible to respect the original functional design of the Ypsomate (see Figure 34).

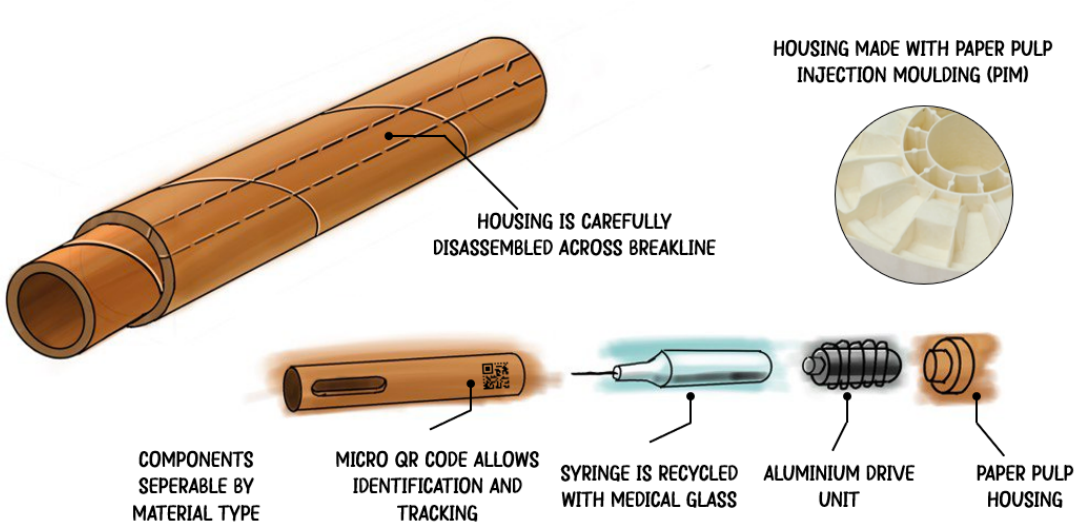


Figure 34 - Product idea for Design for Recycling Ypsomate

The main design features of the design for recycling concept are:

1. The concept features a highly recyclable paper pulp body. Pulp Injection Moulding (PIM) is a production technique used to make complex shapes from a paper based material with plastic-like properties with the advantage of it being highly recyclable (Nissha, n.d.).
2. The concept uses pure mono-materials that can be separated based on material.
3. The concept is design to be easily taken apart via break-line opening on the side of the device to access the components on the inside after use.
4. Once opened, the syringe and needle as well as the aluminium driving unit are easily separated from the rest of the device allowing 4 separate material streams to be easily recycled.
5. The concept features a micro QR code that ensures that the device can be identified and therefore allows the contained components to be traced.

5.3. Ideation: Design for Disassembly

Disassembly of a product is one of the crucial first steps in circular design strategies. The extent to which a product can be disassembled determines its usable lifetime or the lifetime of the contained materials. A product that is easy to disassemble is easy to repair, remanufacture and recycle. Within disassembly a distinction can be made between the non-destructive and

destructive disassembly of a product. For all cases except design for recycling, non-destructive disassembly is of utmost importance to allow reuse of components (Abuzied et al., 2020;Hjorth et al., 2022).

An important factor for the Ypsomate when designing for disassembly is who will interact with the device. While a disassembly-line should have easy access to the internal components, a patient or healthcare provider should not. This ensures that while patients are able to effectively use the device, it's delicate potentially hazardous internal components remain inaccessible to unauthorised users for safety reasons.

The following shortlist of circular design guidelines for disassembly was made based on the most significant improvement potential for the Ypsomate:

1. Design for automated disassembly.
2. Use easily accessible reusable fasteners.
3. Minimize the type of fasteners and therefore the number of tools to be used for disassembly.
4. Design and size components for easy handling of fasteners and parts.
5. Facilitate the quick access of most critical parts.

Ideating on these guidelines led to the following product idea (see Figure 35).

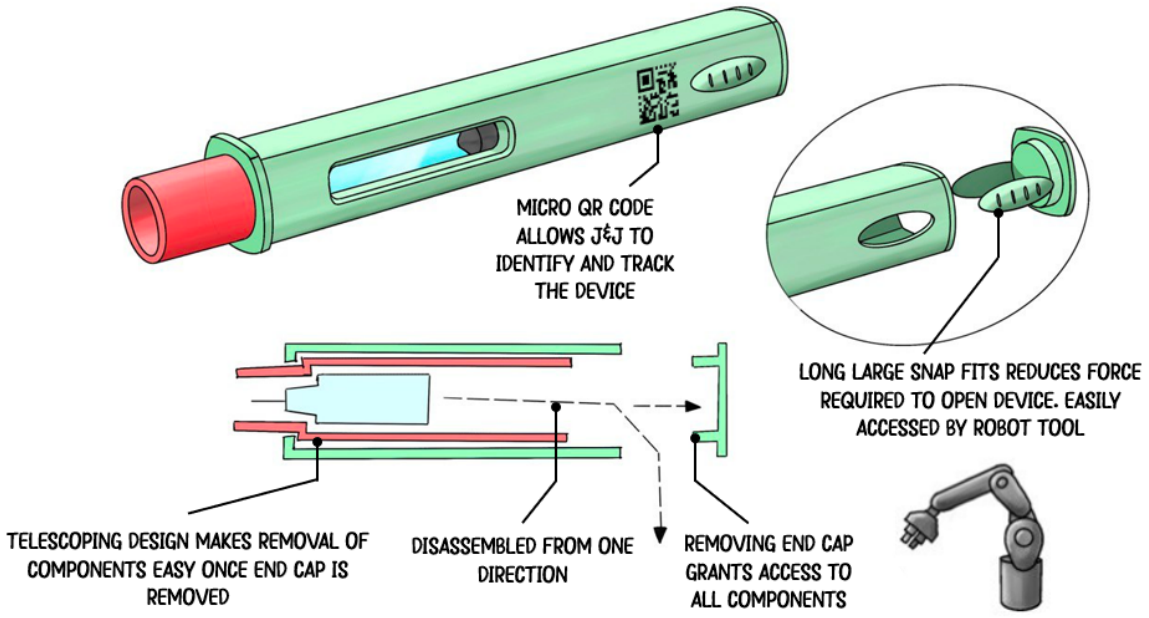


Figure 35 – Product idea for Design for Disassembly Ypsomate

The main features of the concept for design for disassembly are:

1. The concept uses large reversible snap fit fasteners that are easily accessible from the outside of the device.
2. The concept only uses snap fit fasteners. These are released when pressed in by a robot arm tool from the outside, release of these snap fits releases all contained components
3. The concept components and joints have been sized for easy handling by a robot.

4. Once the end cap is removed the concepts components (including critical syringe) are all easily removed in one direction.
5. The components in the concept are all removed in one linear direction to prevent reorientation of the device and save time during disassembly.

5.4. Ideation: Design for Remanufacture

Designing a product for remanufacturing is to design it in such a way that it's components can be reused (in combination with new or other reused components) in order to assemble a new product of equal functionality to the original (van Straten et al., 2023). Remanufacturing offers environmental benefits by significantly reducing the need for energy and material consumption compared to producing new products. Additionally, it helps prevent used components from ending up in landfills.

When designing for remanufacturing it is important to take into account the potential differences in lifespan of different components and to design for easily separable modules that cluster components based on lifetime (Bovea et al., 2018).

The following shortlist of circular design guidelines for remanufacture was made based on the most significant improvement potential for the Ypsomate:

1. Design for modular components
2. Design for non-destructive easily separable components
3. Design components from robust high-quality materials.
4. Design components to withstand reprocessing including cleaning or decontamination.

Ideating on these guidelines led to the following product idea (see Figure 36).

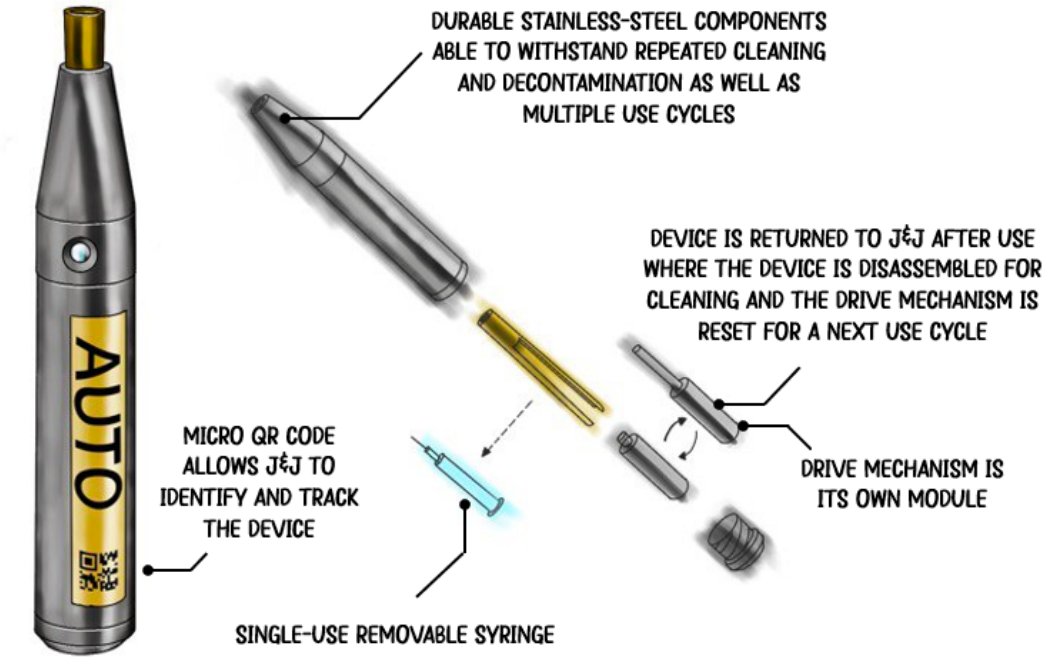


Figure 36 – Product idea for Design for Remanufacturing Ypsomate

The main features of the concept designed for remanufacture are:

1. The concept body and drive unit is made of highly robust stainless steel, chosen to withstand the decontamination process and repeated use for many life cycles.
2. The concept has made the drive unit a removable module whose mechanism can be reset, allowing it to be reused in its entirety when reassembled.
3. The concept is designed with reusable fasteners to allow easy non-destructive separation of components that can be individually reprocessed for reuse.

5.5. Ideation: Design for Extension of Lifespan

This circular strategy of extending life-span is a holistic circular design strategy that looks at a system level to optimise the use of resources in such a way that prevents the need for withdrawal of new resources for making new products to fulfil the same need (CIRCit Norden, 2020). This strategy is sometimes referred to as future-proofing by making products last longer and reducing the need for new products, this leads to reduced manufacturing volumes and the requirement of new business model innovation for circularity (van Straten et al., 2023, van den Berg et al., 2015). Think of for example *Nespresso* who started selling small elegant coffee machines with prepackaged recyclable coffee capsules to deliver customers a highly convenient quality espresso at home. The aluminium in the disposable coffee capsules is recollected and recycled to make new coffee capsules.

The following shortlist of circular design guidelines for extension of lifespan was made based on the most significant improvement potential for the Ypsomate:

1. Design for timeless use:
    a. Ensure safety across the entire extended life of the product
    b. Use materials of high quality which last longer and can be recycled
    c. Design for traceability of components and materials
2. Design for adaptability:
    a. Consider product service systems by rethinking the value proposition surrounding the product taking into account future outlook of the market.
3. Design for upgrading:
    a. Think of a disposal plan for exchanged components to ensure the contained materials can be recycled.

Ideating on these guidelines led to the following product idea (see Figure 37).

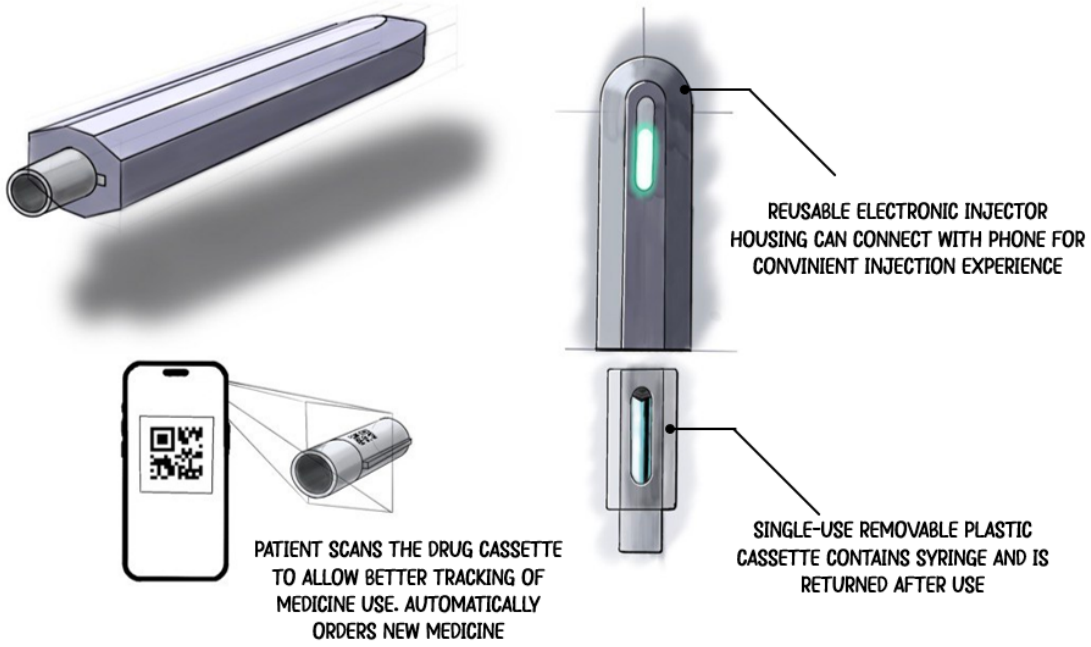


Figure 37 – Product idea for Design for Extended Life Ypsomate

The main features of the concept designed for remanufacture are:

1. The concept features a hybrid model design with a reusable housing laced with digital features like a resettable electronic drive mechanism as well as single-use drug cassettes that contain the syringe.
2. The single-use cassettes are made of recyclable plastic and are returned with a service to receive a new batch of medicine. This convenient service ensures patients always have enough medicine and also ensures the used cassettes are returned for recycling.
3. The cassettes feature unique identification QR codes that help patients keep track of their medicine use and allows J&J to identify their cassettes.

5.6. Evaluation of Ideas

During the ideation of the circular design strategies applied to the Ypsomate, it was observed that the design guidelines for the four different strategies have significant correlations. For example the following design guidelines were considered important for all four strategies:

1. Design for modular product construction.
2. Design for non-destructive separation of components.
3. Design with durable and recyclable materials able to function as intended over multiple product lifecycles but also suitable for recycling at eventual end-of-life.
4. Design for the easy identification of products, components and materials.

It was found that the design guidelines for Design for Disassembly had the most correlation with the guidelines for the other three design strategies. See Appendix F for the full list of 46 guidelines found from literature and their overlap between the four strategies (Bovea et al., 2018). It was therefore concluded that design for disassembly could be viewed as an enabler for the other three strategies. This conclusion was further supported in literature by van Straten et al. (2023) who stated that "*Design for disassembly is one of the fundamental principles to use across all of these design concepts. The effectiveness of design for disassembly*

determines the product lifecycle and the level of waste prevention." Discussions with design experts from the client company Johnson & Johnson further supported decision making for concept selection and it was therefore decided to continue detailed concept development of the Design for Disassembly injector. This aligns with J&J's sustainability vision for a circular product system in which self-injectors are returned and disassembled to enable remanufacture or recycling.

6. Detailed Concept Design

Building on the ideation presented in Chapter 5, this chapter provides an overview of the detailed concept development for an Ypsomate auto-injector designed for disassembly. During ideation, it was found that design for disassembly was an enabling factor for implementing any of the other three circularity strategies for the Ypsomate. To illustrate this shared design challenge, a hypothetical product journey was sketched in Figure 38, depicting the activities in this proposed circular system for an auto-injector. This circular product journey for both remanufacturing and recycling flows highlights the importance of several circular design enablers that each pose their own challenges for success of these strategies. These enablers include: collection logistics, disassembly, sorting and quality control. Collection of the injectors to initiate the return logistics is a design challenge that J&J is already looking into with their *SafeReturns programme*, but this thesis will continue by delving into the challenge of designing an auto-injector for disassembly.

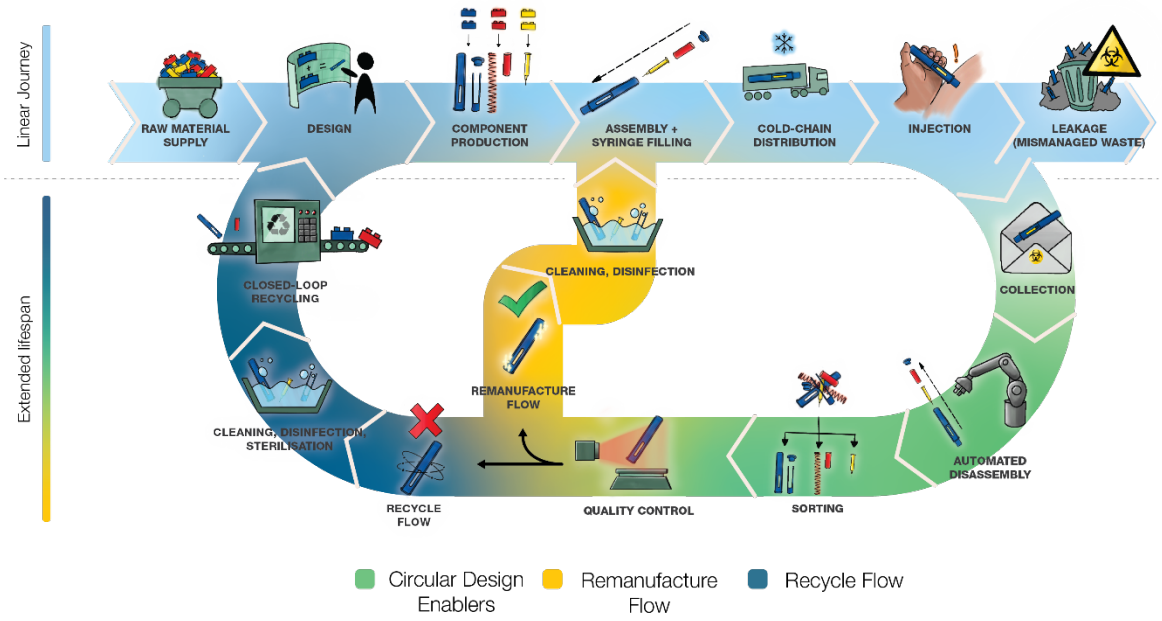


Figure 38 – Proposed hypothetical circular product journey for the Ypsomate

The steps and design features required for the circular product journey of the Ypsomate after the collection phase are outlined in Figure 39 and Figure 40. Analysing the newly proposed product journey helped identify areas of design improvement necessary for the redesigned product.

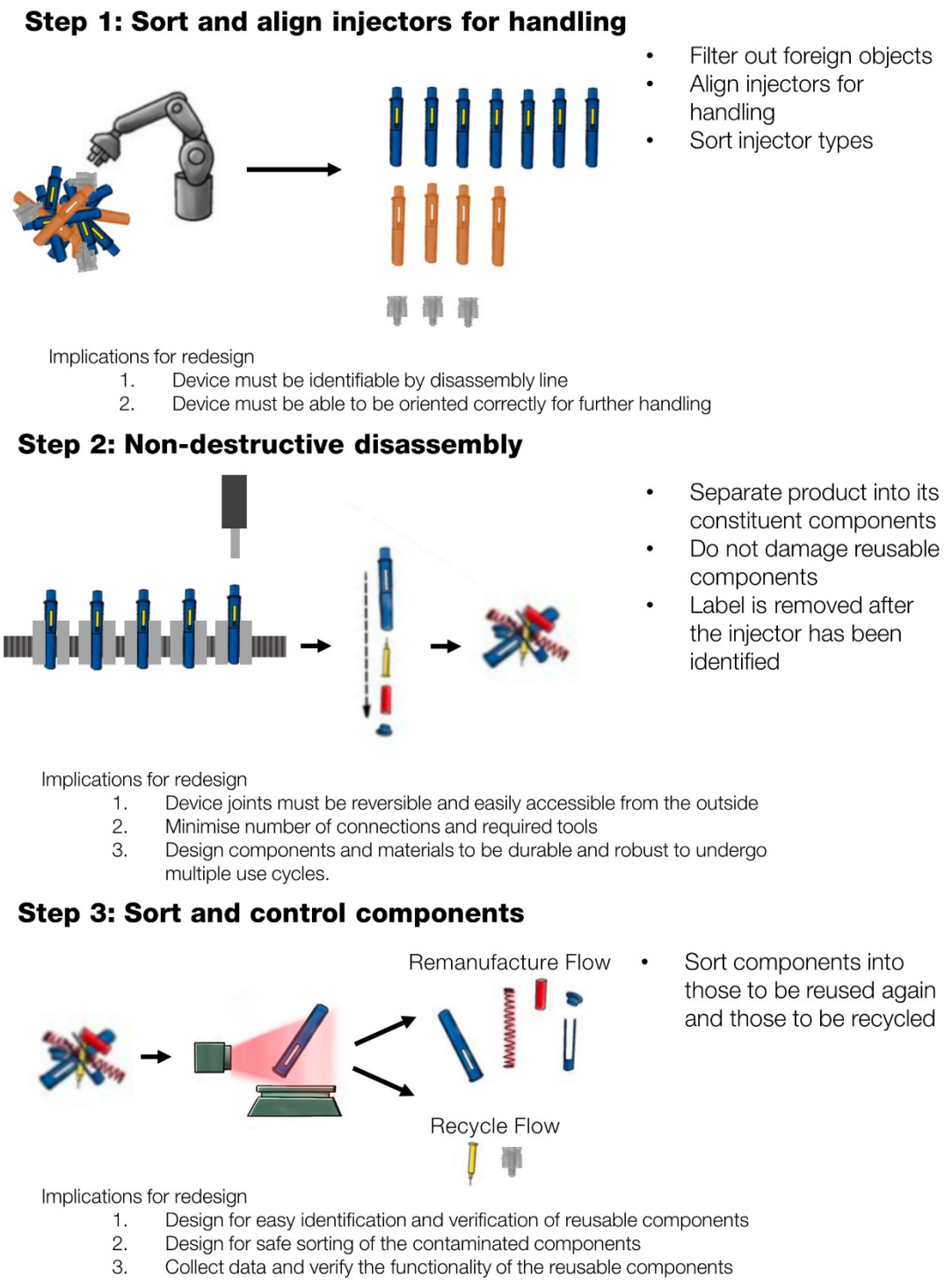


Figure 39 - Steps 1 through 3 of the proposed circular product journey for the Ypsomate after the collection phase.

Step 4: Clean and decontaminate parts

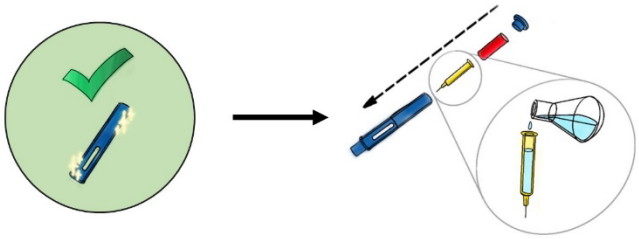
- Decontaminate reusable and recycle parts according to Spaulding scale

Implications for redesign

1. Components should be designed with cleaning in mind and materials should be chosen based on resistance to cleaning
2. Design components to be shaped for easy cleaning. (No hard to clean areas)

Step 5: Parts ready for Remanufacture

- After reprocessing and quality control, remanufactured components are combined and reassembled with new components into new injectors, ready for refilling.

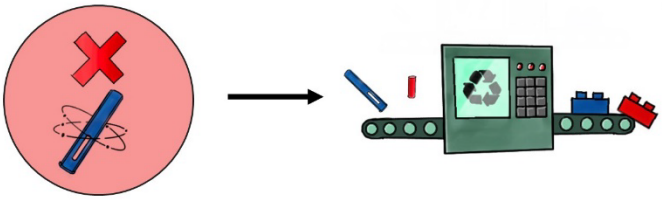


Implications for redesign

1. Components should be designed to be robust and to withstand the required reprocessing
2. Utilise the design of separable modules to speed up disassembly and reassembly

Step 5: Parts ready for Recycling

- After quality control, components unfit for remanufacture are sorted based on material type and recycled into material for new parts



Implications for redesign

1. Limit material use to materials of high quality suitable for recycling. Preferably as few different materials as possible to make recycling economically feasible.
2. Components or subassemblies must be separable based on compatible material type.

Figure 40 - Steps 3 through 6 of the circular product journey for the Ypsomate up until remanufacture and recycling.

6.1. Design for Disassembly

Extensive literature has examined the elements that contribute positively to Design for Disassembly (DFD) (Abuzied et al., 2020). However, there are unique aspects of the circular model proposed for J&J and the Ypsomate that distinguish it from typical scenarios discussed in research.

6.1.1. Non-Destructive vs. Destructive Disassembly

Literature differentiates between non-destructive and destructive disassembly. Non-destructive disassembly is crucial for preserving the value of individual components. The ability to disassemble without damaging parts ensures that components can be reused, thereby maintaining their value within the circular economy. Destructive disassembly is typically suitable only for recycling and is considered a last resort (Tolio et al., 2017). However, Van Straten et al. (2023) argue that even for recycling, non-destructive disassembly is preferred as it allows for more efficient sorting of materials.

6.1.2. Automation of Disassembly

Literature highlights the challenges of automating disassembly processes, especially when the assembly details of the device are unknown (Hjorth et al., 2022). However, in this scenario, J&J will oversee the disassembly process through a direct partnership with the Original Equipment Manufacturer, Ypsomed. This partnership allows for the collaborative creation of a highly effective and efficient closed-loop system. J&J will have precise knowledge of the disassembly procedures as well as the specific components and materials used in the auto-injector, facilitating optimal recycling and reuse. With hundreds of millions of auto-injectors used annually, automated disassembly is crucial for scalability. Additionally, it is particularly desirable in our system to ensure safety and minimize the risk of needle stick injuries.

6.1.3. Reframed Design Challenge

Based on the key findings that non-destructive disassembly is crucial for implementing circularity strategies for the Ypsomate and that automation of this process is vital for safety and scalability, the design challenge was reframed.

Initial design goal:

To redesign the Ypsomate for integration into a circular system in which the product as well as components and materials are recirculated, and the value of the device is maintained.

Reframed design goal:

To redesign the Ypsomate auto-injector to facilitates non-destructive automated disassembly to allow reuse and recycling of components.

6.2. Detailed Embodiment Design: MediLoop Injector

The development and detailing of the injector concept involved a thorough examination of existing design guidelines, insights from expert discussions, and iterative brainstorming sessions. This chapter outlines the specific design features and mechanisms that enable non-destructive automated disassembly. For clarity, the embodiment design of the redesigned concept was given the name *MediLoop* and is referred to as such from this point on. The MediLoop is depicted in Figure 41 and it's components in Figure 42. Note that although the concept resembles the Ypsomate, it was 3D modelled from scratch based off the dimensions of the original device. Due to the complexity of the *driver module* this sub-assembly was considered out of scope as it was too intricate to remodel and prototype. Design suggestions have been made for this component and a placeholder model has been used.

Figure 41 - MediLoop Circular Auto-injector Concept

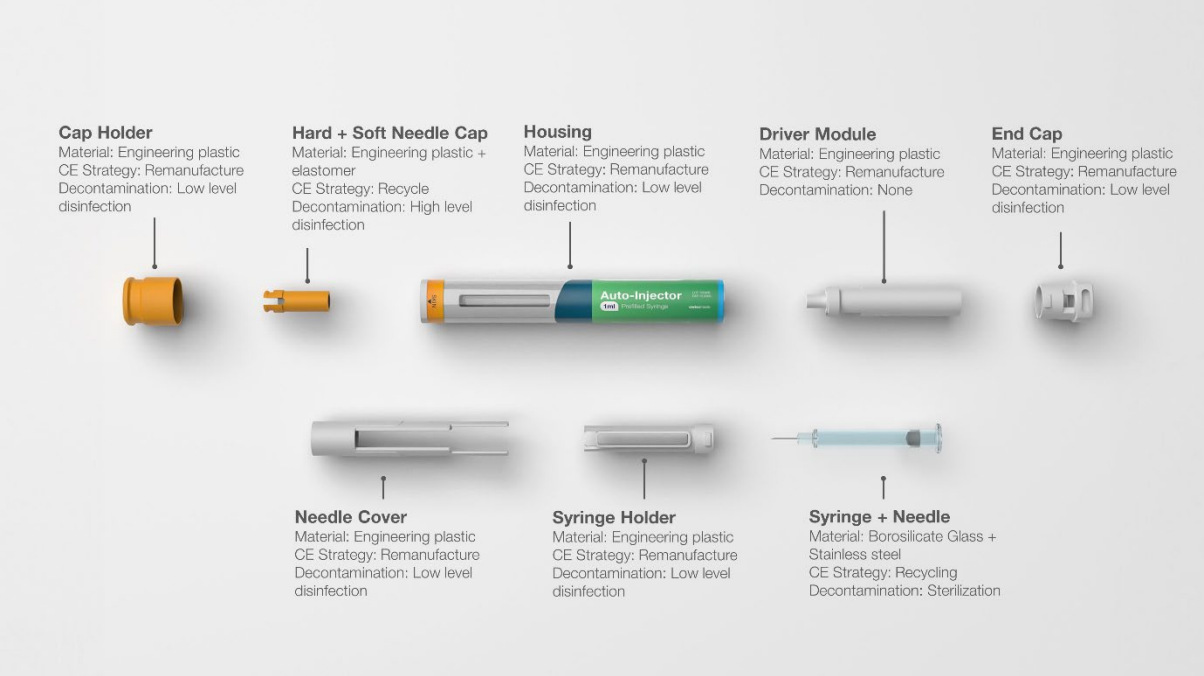


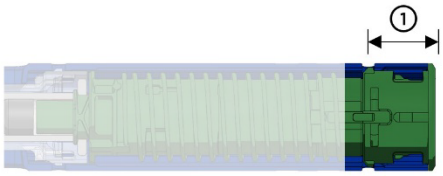
Figure 42 - Overview of the components in the MediLoop

6.2.1. Design Features and Mechanisms

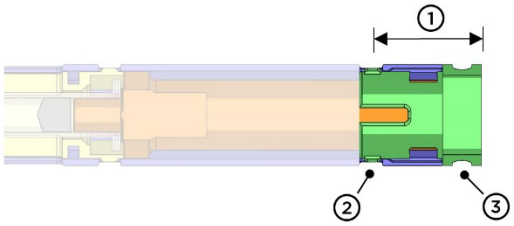
This sub-chapter presents the design improvements and mechanisms incorporated into the MediLoop auto-injector. The following figures (Figure 43,Figure 44,Figure 45) illustrate the modifications made to the Ypsomate, highlighting the advancements aimed at facilitating non-destructive automated disassembly.

Housing Cap

Current



Redesign

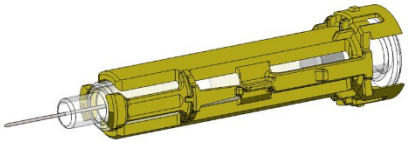


Improvements

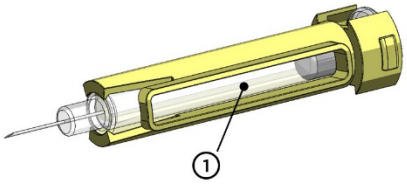
1. The housing cap has been redesigned to make the snap fits larger and the lever arms longer, thereby reducing the pressure and force required to disengage the snap fits and preventing damage.
2. Increased size of the snap fits make them more easily accessible from the outside.
3. The housing cap now features a new notch that facilitates the removal of the label.

Syringe Holder

Current



Redesign



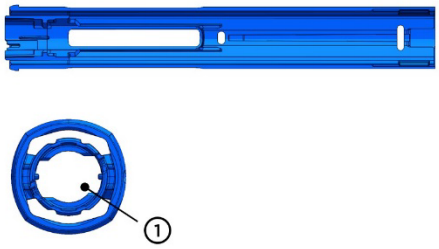
Improvements

1. Syringe holder now includes a direct window to the syringe this means the syringe holder no longer needs to be made from transparent PC, reducing the number of materials in the device.
2. To retain the shatter protection provided by the old syringe holder, the label is now made larger and transparent to prevent shattered glass from falling out of the device in the unlikely case of a syringe break.

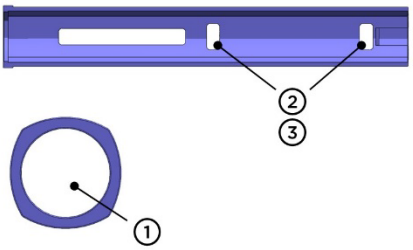
Figure 43 - Redesign Housing cap and Syringe holder

Housing

Current



Redesign

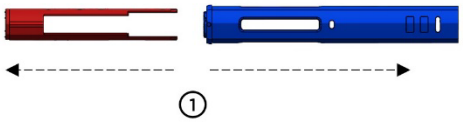


Improvements

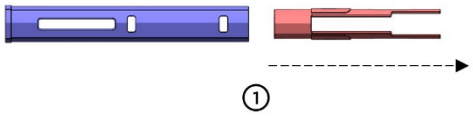
① The redesigned housing is now hollow which allows components to be easily removed in one linear motion from one direction.
② Access to snap fits has been made easier by increasing their size
③ Only one type of snap fit is used.
④ Telescoping parts grant easy access to all components.

Needle Cover

Current



Redesign

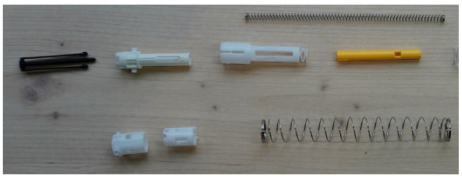


Improvements

① Needle cover redesigned to allow assembly and reassembly from one direction instead of two in current model.

Driving Mechanism

Current



Redesign

Improvements

① Driving mechanism redesigned as a mono-material module that can be reset after each use. The current driving mechanism consists of 6 different materials.

Figure 44 - Redesign Housing, Needle cover and Driving Mechanism

Label

Current

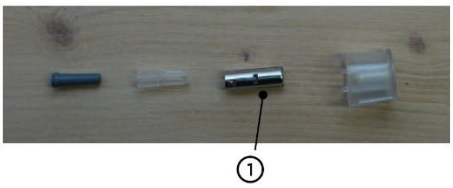
Redesign

Improvements

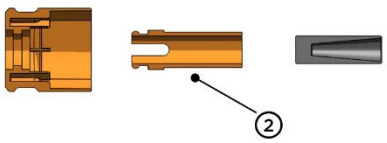
1. The label is now attached via shrink wrap instead of an adhesive on the device, preventing the need to remove residue from a used housing component.
2. Label made of recyclable transparent plastic instead of laminated paper.
3. Label now covers the entire housing to act as barrier for the syringe inside in case of accidental fracture.
4. Micro QR code added as identifier for tracking the device during its product journey

End Cap

Current



Redesign



Improvements

1. The end cap is redesigned without the need of a stainless-steel cover
2. The end cap now has a removable soft needle cover to allow reuse of part of the cover and recycling of the rest.

Figure 45 - Redesign Label and End cap

6.2.2. Disassembly Tool

Next to redesigning the device, the tool for disassembling the injector was also conceptualised. Figure 46 shows the design and workings of this tool. Figure 47 shows the sequence of removal of components during the automated disassembly process.

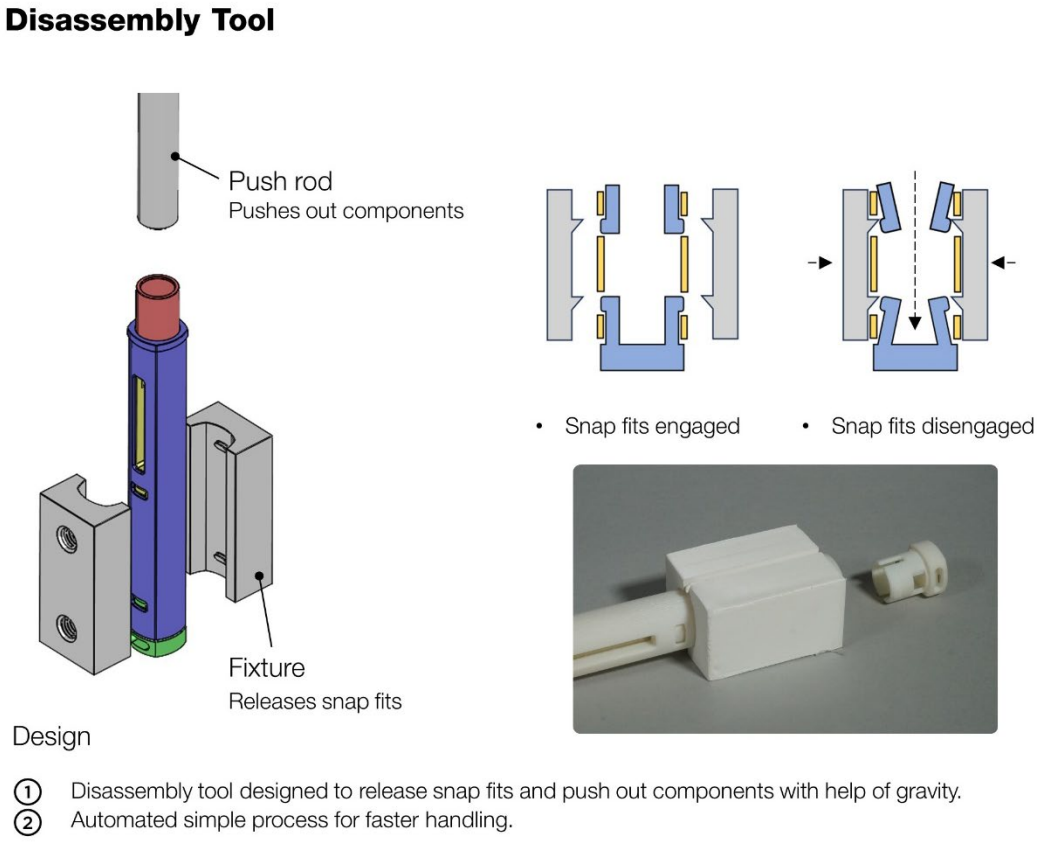


Figure 46 - The disassembly tool design for the MediLoop

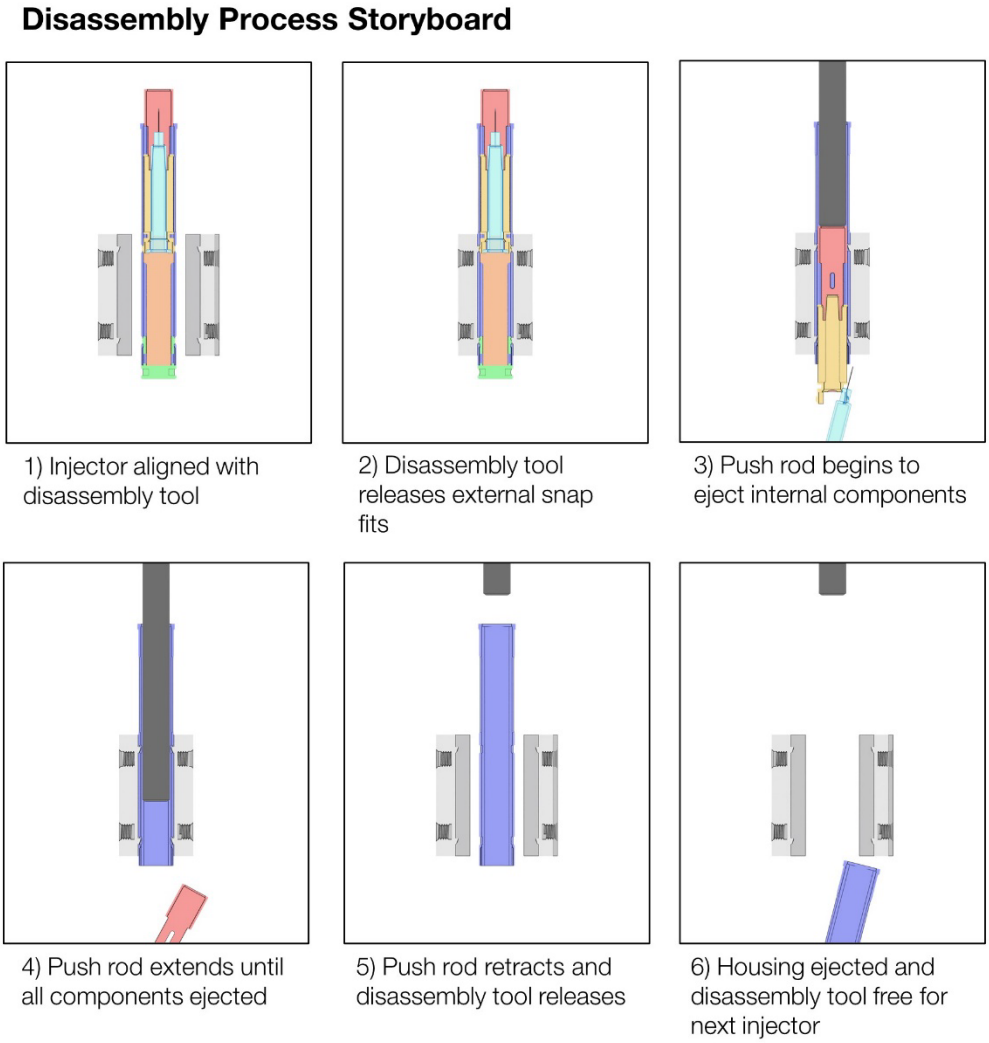


Figure 47 - Disassembly sequence storyboard

6.2.3. Rapid Prototyping

To validate the functionality and sizing dimensions of the detailed concept, low-fidelity physical prototypes were made during the design process. Initially, the intricate details of the auto-injector model did not lend themselves well to run-of-the-mill FDM printing. Therefore, a more advanced 3D printer, namely a MultiJet Fusion printer, was eventually used. MultiJet Fusion printing was able to achieve a much finer resolution than FDM printing, at the cost of reduced structural properties and delicate prints. This allowed for the validation of dimensional properties, but unfortunately, meant the prototyped components could not fully be tested for function. A photo of the final prototype can be seen in Figure 48 and a photo of all the mock-up iterations can be seen in Figure 49.

Figure 48 - The final aesthetic prototype of the redesigned auto injector.

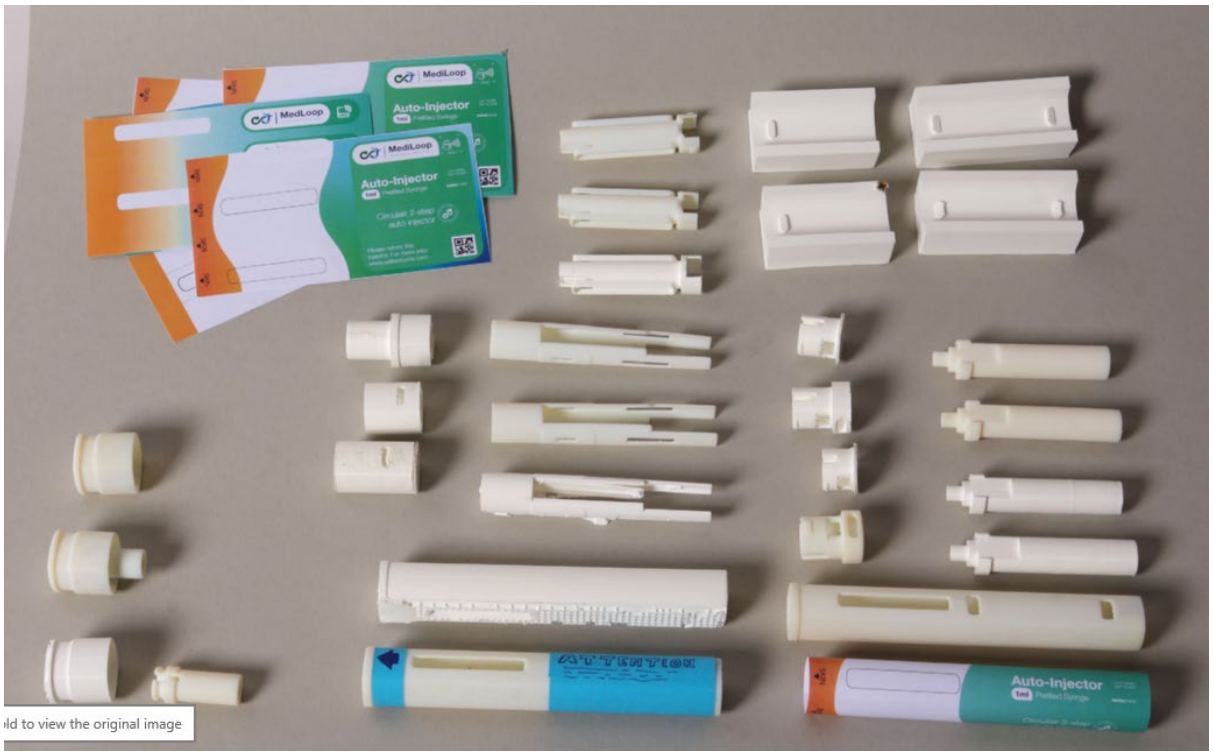


Figure 49 - Prototype iterations

6.3. Evaluation of MediLoop

To summarise the findings from this detailed conceptualisation, the application of circular design guidelines from literature to the Ypsomate auto-injector led to the development of a prototype injector, the MediLoop. Designing for the design goal “To design an Ypsomate auto-

injector concept that facilitates non-destructive automated disassembly to allow reuse and recycling of components." led to the redesign of a new auto-injector that is able to be non-destructively disassembled using a prototype disassembly tool. The main design improvements are outlined as follows and can also be seen in Figure 50:

1. Designed the injector for automated disassembly to improve safety for handlers and increase scalability potential for the circular process.
2. Designed easily accessible reusable joints and connections to increase efficiency of disassembly and reassembly.
3. Designed a simple fixture to aid in disassembly, speeding up disassembly.
4. Designed injector with reduced number of connections to decrease the number of disassembly steps required.
5. Designed injector with one type of snap fit and friction fit to improve disassembly efficiency.
6. Eliminated the need for injector reorientation to reduce time and effort of disassembly.
7. Injector designed for quick access to critical syringe and needle.
8. Designed removable label to aid in identification of injector along product journey.

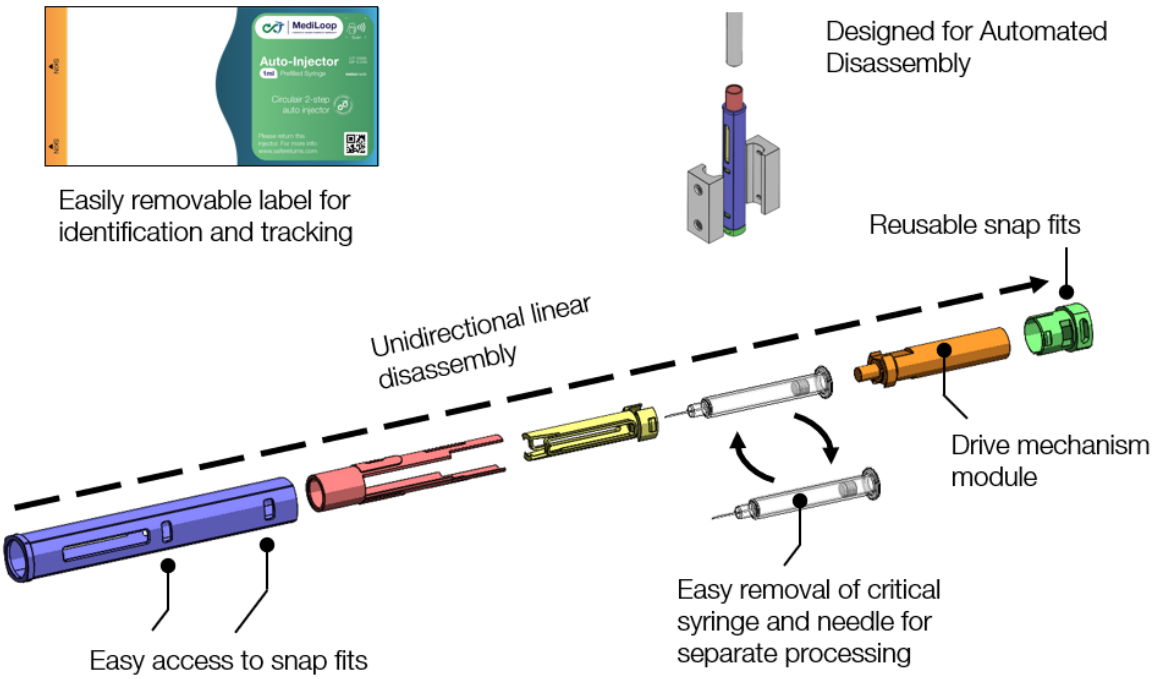


Figure 50 - Visual summary of the design improvements in the MediLoop concept

For completeness, the MediLoop concept was subsequently tested and scored against circular design guidelines from Bovea et al. (2018) that were presented in Chapter 4.3. Only the guidelines that received a relevance score of 3 (high relevance) are listed here to compare the improvement for fulfilment of CPD guidelines of MediLoop to the original Ypsomate injector (see Table 6). For a full list of the CPD guidelines comparison with justifications see Appendix G. The results showed significant improvement for the MediLoop compared to the Ypsomate.

Table 6 - Fulfilment of most relevant CPD guidelines for Ypsomate compared to MediLoop redesign.

	Circular Design Guideline	Ypsomate	Redesign
1	Create a modular design	0	1
2	Locate unrecyclable parts in areas easy to remove	-2	2
3	Minimise number of components	-1	-1
7	Improve the ratio between the labour required to retrieve components and their value	0	2
8	Avoid moulding or fusing incompatible materials	-2	1
9	Consider the use of an active disassembly	-2	2
10	Use standardised joints	-2	1
11	Prioritise latching to screws and joints	2	2
13	Minimise types of connectors	2	2
14	Use fasteners rather than adhesives	2	2
15	Make joints visible and accessible	-1	2
16	Use fasteners that are easy to remove	-2	2
17	Minimise the number of joins and connections	0	2
18	Minimise the number of tools and use pull/push processes	1	2
20	Use materials with a low environmental impact	-1	1
21	Use thin walls with nerves (plastics)	2	2
22	Use components made of pure materials	-2	2
23	Minimise the number of different materials	-2	2
24	Avoid secondary finishes and coatings	0	0
25	Use recycled and recyclable materials	-1	2
26	Use materials resistant to cleaning processes for components to to be reused	-2	2
27	Reduce the material content and energy required in the manufacturing process	0	-1
29	Minimise the use of toxic or hazardous materials	2	2
30	Use unplated metals for recycling	2	2
31	Use low alloy metals for recycling purposes	2	2
32	Use cast irons for recycling purposes	2	2
33	Use components and materials with verified reliability	0	0
34	Do not combine components that have different life spans	-2	0
38	Use components sized for easy handling	-1	2
39	Maximise the accessibility of components	-2	2
40	Avoid dismantling parts from opposite directions	-2	2
41	Simplify the product structure	0	2
	Total Score	**-10**	**48**

Comparing the MediLoop concept to the original Ypsomate revealed significant improvements in fulfilling the relevant CPD design guidelines, particularly those concerning product disassembly. However, one guideline, Guideline 27 on reducing material usage, scored lower in the redesigned product. This is because the redesigned injector is slightly larger than the original Ypsomate to accommodate reusable fasteners. Although not validated, a more developed functional model may also show slightly increased material usage due to the need for more robust components to survive multiple use cycles. This, however, requires further investigation. The following sub-chapters will evaluate the desirability, feasibility, viability, and circularity of the redesigned concept.

6.3.1. Evaluation of Desirability

Following the context and product analysis presented earlier in this project, it was identified that safety, usability, and trust are crucial factors for the desirability of auto-injectors from a patient's perspective.

Safety and Usability

The MediLoop concept fulfils safety and usability requirements by building on the well-established features of the Ypsomate. These features include a needle-safety mechanism that hides the needle at all times and locks it after use, preventing accidental needle-stick injuries. Additionally, the simple use steps and ergonomic design of the Ypsomate are retained in the MediLoop, ensuring ease of use for patients.

Patient Trust

Patient trust is essential for the adoption of the MediLoop concept. Kane et al. (2017) highlighted that patient perceptions and trust are significant barriers to implementing reusable medical devices. The MediLoop addresses this issue by incorporating replaceable labels that refresh the device's appearance and conceal any marks from previous use, thereby maintaining a clean, new look. While this design feature aims to build patient trust, further patient interviews and testing are necessary to evaluate its effectiveness. However, this was beyond the scope of this project.

6.3.2. Evaluation of Feasibility

Non-destructive Disassembly

The MediLoop demonstrates the feasibility of designing an auto-injector for non-destructive disassembly, allowing components to be separated without damage. This separation enables the reuse or recycling of components and allows distinct decontamination processes for hygiene-critical and non-critical components.

Durable Recyclable Materials

The current Ypsomate contains 20 components made from 13 different materials. Even if these components could be separated into their material streams, managing 13 recycling streams would be costly. Therefore, reducing the number of material streams to, for example, one plastic, one metal, and one glass stream, is preferable. In the MediLoop demonstrator prototype, only one type of plastic was used. However, this is an unfair comparison since the prototype is non-functional and cannot withstand the forces required for injection. Future studies should identify a durable mono-material plastic suitable for all plastic parts in the MediLoop injector to enhance recycling possibilities.

Tracking Product Life-cycles

Literature review indicated that circular product journeys could degrade devices (van Straten et al., 2023). Therefore, designing devices for validation and identification is crucial. The MediLoop concept addresses identification through the use of QR codes, allowing J&J to track individual devices throughout their product journeys. Given the project’s timeframe, further elaboration on the validation phase was beyond the scope and should be explored in future studies.

Decontamination

Decontamination of critical components is essential for enabling their reuse or recycling. While sterilizing the needle and syringe for reuse is likely too costly and undesirable due to needle dulling, these components can be recycled, as the heat required to melt glass sterilizes the material. According to the Spaulding scale (Chapter 3.3), light disinfection is sufficient for the remaining components to enable reuse. Further studies are needed to detail these processes.

6.3.3. Evaluation of Viability

Low-cost Production

The MediLoop concept is designed to use manufacturing processes similar to those of the Ypsomate. This should ensure that production remains cost-effective and competitive.

Efficient Supply Chain

The MediLoop is designed for automated disassembly, reducing the risk of needle-stick injuries and enabling scalable processing. Features such as accessible joints, telescoping parts, and

unidirectional disassembly accelerate the disassembly process. However, the MediLoop was not tested alongside the disassembly robot under development by J&J. Future studies should explore the disassembly of the MediLoop under real-world conditions. It will be important for efficiency of the system that the disassembly is not time-intensive.

Collaboration

Literature indicates that implementing circular systems is complex and requires diverse expertise (Rizos et al., 2021). Competencies in return logistics, disassembly, and reprocessing are important. Collaborating with industry partners can help J&J effectively realise a circular system for their injectors.

Standardization

As discussed in Chapter 3.2, all products eventually reach an irreversible obsolescence state, at which point only their material value remains. For the MediLoop auto-injector, designed for easy component and material separation, recycling is then a possible recovery strategy. Minimizing the number of materials used at the product level is crucial to making recycling financially viable, as individual recycling streams can be costly. With many different self-injectors on the market, including at least eight used by J&J, standardising materials across devices could facilitate collective recycling efforts. Furthermore, developing a system for return logistics, disassembly, and reprocessing requires significant investment. Standardising or collaborating with multiple suppliers on injector design elements for integration with the disassembly robot could be beneficial for J&J, though further viability studies are needed.

Regulation

Although only briefly touched upon in this report, regulation poses a significant barrier to implementing circularity strategies for auto-injectors and therefore also for MediLoop. With good reason, strict safety and hygiene standards are required for medical devices. Overcoming these regulatory barriers is crucial for the successful adoption of any of the proposed strategies. Proof-of-concept studies, like this one, play a vital role in demonstrating the feasibility of a circular system and can potentially influence regulatory bodies to adopt more flexible frameworks. However, further validation of the safety and efficacy of reused or recycled components is necessary. For successful implementation, comprehensive testing is required to ensure that reused materials do not compromise patient safety and meet regulatory requirements.

6.3.4. Evaluation of Circularity

Remanufacture and/or Recycling

This project demonstrates an auto-injector designed for disassembly. While design for disassembly is a crucial step, it is not a complete circular strategy and requires complementary strategies like Design for Remanufacturing or Design for Recycling. Further research is needed to determine which of these strategies is more suitable or if a combination of strategies is possible. Future studies should also consider effects of further redesign on the important desirability, feasibility, and viability requirements for auto-injectors outlined in this report.

Quantifying Environmental Impact

To provide a sustainable alternative to disposable auto-injectors, the MediLoop concept should undergo an environmental impact assessment. This assessment should compare waste reduction and quantify emission reductions. Future studies should evaluate the overall environmental impact of the entire circular system, including return logistics, disassembly, and

reprocessing, to ensure the proposed system reduces environmental impact compared to the current linear model. Although the current J&J disassembly plant is in Switzerland, exploring the deployment of local recovery facilities could minimize the environmental impact of long supply chains.

6.4. Key findings

In summary, successful integration of circular economy strategies for auto-injectors was found to depend on the following requirements:

1. The design shall not compromise the safety of patient or anyone in direct contact with the product or system.
2. The design shall not compromise the functionality or usability of the original product.
3. The design shall consider the entire life-cycle of the product (including End-of-Life) within a circular system.
4. The design shall enable non-destructive disassembly for separation of (critical) components and materials
5. The design shall make cleaning or decontamination easy for critical components
6. The design shall enable the validation of sterility, functionality, and material quality of the components for reuse or closed-loop recycling.
7. The design shall allow identification and tracking of products and their components within the circular system.
8. The design of product and system shall be scalable to meet market demand for millions of injectors per year.

7. Conclusions and Recommendations for Future Study

This thesis explored how auto-injectors can be redesigned to fit into a circular economy (CE). This project was assigned by pharmaceutical company Johnosn & Johnson that have already started development on a circular system for self-injectors with the launch of takeback schemes and innovating on a disassembly robot. Through discussion with the client and university, the Ypsomate auto-injector was selected as a case study product for redesign as this model is widely used in industry and technical information was available via J&J. This project was intended as a technical feasibility study with the aim to make circular design principles for auto-injectors more tangible for J&J. The research questions were as follows:

RQ2 How might we redesign the Ypsomate for integration into a circular system?

- **RQ2.1 What are the current barriers and opportunities for circular economy for disposable self-injectors?**
- **RQ2.2 What circular design strategies are most opportunistic for the Ypsomate auto-injector?**
- **RQ2.3 How might we apply the potential circular strategies in a redesign of the Ypsomate and its circular system?**

The project followed a creative problem-solving approach which involved an extensive exploration of the auto-injector and circular economy context through literature research, expert interviews and a field visit to the client's innovation development site in Switzerland. This is where the disassembly robot is being developed and deployed. Exploration of context revealed several trends in industry including a strong focus on patient safety and usability of devices. In addition, sustainability developments were found to be making strong traction in the industry as many sustainable product developments are being made. An important observation was that end-of-life design considerations for auto-injectors have so far been underexplored. J&J's developments on a system level (i.e. the whole value chain) therefore appear amongst the industry leading innovations towards a circular economy.

The most important barriers for auto-injector integration into a circular economy were found in combining safety considerations with reuse strategies. Auto-injectors are low-value medical devices with high hygiene criticality, making them difficult to reuse or recycle and thus costly to apply circular strategies. It is widely known that hygiene critical components such as the syringe and needle could introduce infection risks. For this reason, many countries have strict regulations in place which in themselves are considered CE barriers.

As a result, the most important opportunity was found in enabling the safe and cost-effective separation of the hygiene critical from the non-critical components. It was found that separating critical and non-critical components would reduce the amount of reprocessing required.

Following an assessment of the CE barriers and opportunities for auto-injectors, an in-depth product analysis of the case study product, Ypsomate was performed. This analysis involved applying Bovea et al. (2018) Circular product design framework to identify the most relevant circular strategies. These were found to be Design for Recycling, Design for Disassembly, Design for Component reuse and Design for Extended life. The next step was to generate design ideas for each category together with product owners, design engineers and fellow students.

After ideation it was concluded that Design for Disassembly was the most opportunistic CE strategy for the Ypsomate. With consideration for the design context a specific opportunity was found within automated non-destructive disassembly as this is an essential element in enabling the application of circular strategies such as component reuse and recycling.

In the next phase, the initial idea was further conceptualised into the MediLoop redesign followed the development of a physical prototype for proof-of-concept. By embodying design guidelines for disassembly of auto-injectors it was shown that it is technically feasible to make a significant improvement in the auto-injectors CE strategies for end-of-life recovery.

It was observed that the successful development of auto-injectors for a circular economy depends significantly on considering both system-level and product-level design aspects. Truly "sustainable" products cannot exist in isolation; their sustainability appears to be inherently linked to their ability to fit into a supporting ecosystem. Therefore, effective CE integration should take a holistic design approach that encompasses the entire lifecycle of the product, including its interactions with various stakeholders and systems.

7.1. Limitations and Recommendations for Future work

Although the focus of this project was on technical feasibility, it was found that the desirability and viability of a potential circular system must also be considered for its successful implementation. For example, during the extensive search for circular economy barriers for medical products, social barriers such as patient trust and required behavioural changes were identified as critical factors. These barriers must be further examined in future studies to increase patient acceptance of circular economy strategies, such as the presence of small traces of product use, and to determine how to influence the return rate of auto-injectors.

In terms of viability, the whole system needs to be considered for cost-effectiveness and scalability. Implementation of a circular system was found to require a diverse set of competencies and collaboration between industry players will therefore be fundamental. Additionally, further studies will need to determine the overall environmental impact from all steps involved in the circular system (return logistics, disassembly, reprocessing, etc.) in order to measure and quantify absolute improvements in emission and waste generation.

Some technical limitations of the system exist as product use-cycles through the system slowly degrade the auto-injector quality. Future research should explore the number of cycles that the different parts of the injectors can handle without presenting risk to the function of the product. It is expected that product use-cycle tracking and/or quality assurance techniques will play an important role in the feasibility of a circular system for auto-injectors.

7.2. Key learnings

To conclude, three key requirements were identified for successful integration of circular economy strategies for medical auto-injectors:

1. The design shall not compromise the safety of patient or anyone in direct contact with the product or system.
2. The design shall not compromise the functionality or usability of the original product.
3. The design shall consider the entire lifecycle of the product (including End-of-Life) within a circular system.

This master thesis has worked towards achieving its aim by making circular design principles for disposable self-injection devices more tangible for Johnson & Johnson. Through an extensive analysis and redesign of the Ypsomate auto-injector, the project has provided valuable insights and recommendations that might contribute to the transition towards a more sustainable healthcare industry. The findings and proposed circular strategies highlight the potential for integrating circular economy principles into medical device design, offering potential for reducing environmental impact and promoting sustainable practices.

8. Reflection

Now you've read through my thesis report you've seen the full culmination of a graduation project worth of work, but what you don't see is the journey of how I got there. An unknowing ambitious student started on this long journey, blissfully unaware of all the challenges he would face along the way. I selected this project because I have a fascination for the worlds wicked problems, especially the circular economy and the healthcare industry. I was always deeply intrigued by the complexity of designing for circularity and the large amount of challenges that are present when implementing CE in healthcare. But where a master thesis allows full individual freedom in selecting a direction, at times I lost myself a little in the complexity of this project.

During my time as a design student, I quickly became aware of my ability to make things and that these things often take shape in the form of products and objects. These products often serve a function and can also have a direct impact on the lives of people they touch. But I also realized that these things at some point reach the end of their functional existence and become waste. There needs to be another way, I thought. During my studies I followed many courses discussing the possible benefits of the circular economy and always thought to myself "Why is nobody implementing this, this makes so much sense. Good for people, planet and profit!? Let's go!".

When starting work on this complex topic, I continuously felt the urge that I needed to get a better grasp of the context surrounding CE, the medical world and specifically self-injectors if I wanted any success in designing a suitable CE solution. But I eventually realised there would always be more research to uncover and at some point with research, enough is enough. When I finally did feel I had good understanding of the playing field, I had so many design requirements to consider that I was a bit overwhelmed. Through discussing with my mentors, this project has therefore taught me the importance of scoping down a problem and also leaving requirements behind in order to think more freely and creatively.

Overall, I am proud of how far I have come with this project in the time I've had to work on it. By being thrown in the deep, I've learnt more about myself and who I am as a designer than any other point in my studies. I've learned I need to surround myself with a team of likeminded individuals and that CE is very complex system, with many parts that need to work together. I've learned that this is more about collaborating together and working together on a problem than it is about technical feasibility. And that if we achieve this, truly ground breaking systems are possible.

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Appendix A

Table 7 - Methods for disinfection and sterilization of patient care items and environmental surfaces (Rutula, 2013)

Process	Level of microbial inactivation	Method	Examples (with processing times)	Health care application (examples)
Sterilization	Destroys all microorganisms, including bacterial spores	High temperature Low temperature Liquid immersion	Steam (~40 min), dry heat (1-6 hr depending on temperature) Ethylene oxide gas (~15 hr), hydrogen peroxide gas plasma (28-52 min), ozone (~4 hr), hydrogen peroxide vapor (55 min) Chemical sterilants[†]: >2% glut (~10 hr); 1.12% glut with 1.93% phenol (12 hr); 7.35% HP with 0.23% PA (3 hr); 8.3% HP with 7.0% PA (5 hr); 7.5% HP (6 hr); 1.0% HP with 0.08% PA (8 hr); ≥0.2% PA (12 min at 50°C-56°C)	Heat-tolerant critical (surgical instruments) and semicritical patient care items Heat-sensitive critical and semicritical patient care items Heat-sensitive critical and semicritical patient care items that can be immersed
High-level disinfection (HLD)	Destroys all micro-organisms except high numbers of bacterial spores	Heat automated Liquid immersion	Pasteurization (65°C-77°C, 30 min) Chemical sterilants/HLDs[†]: >2% glut (20-45 min); 0.55% OPA (12 min); 1.12% glut with 1.93% phenol (20 min); 7.35% HP with 0.23% PA (15 min); 7.5% HP (30 min); 1.0% HP with 0.08% PA (25 min); 400-450 ppm chlorine (10 min); 2.0% HP (8 min); 3.4% glut with 26% isopropanol (10 min)	Heat-sensitive semicritical items (eg, respiratory therapy equipment) Heat-sensitive semicritical items (eg, GI endoscopes, bronchoscopes, endocavitary probes)
Intermediate-level disinfection	Destroys vegetative bacteria, mycobacteria, most viruses, most fungi but not bacterial spores	Liquid contact	EPA-registered hospital disinfectant with label claim regarding tuberculocidal activity (eg, chlorine-based products, phenolics, improved hydrogen peroxide exposure times at least 1 min)	Noncritical patient care item (blood pressure cuff) or surface with visible blood
Low-level disinfection	Destroys vegetative bacteria, some fungi and viruses but not mycobacteria or spores	Liquid contact	EPA-registered hospital disinfectant with no tuberculocidal claim (eg, chlorine-based products, phenolics, improved hydrogen peroxide, quaternary ammonium compounds-exposure times at least 1 min) or 70%-90% alcohol	Noncritical patient care item (blood pressure cuff) or surface (bedside table) with no visible blood

Appendix B

Please find here the calculation made for the comparison between amount of auto-injector waste relative to the weight and volume of the Eiffel tower.

Eiffel tower weight = 10100 tons = 9162 tonnes (https://www.toureiffel.paris/en/the-monument/key-figures)

Approximate weight of an auto-injector = 40 grams (https://yds.ypsomed.com/en/injection-systems/auto-injectors/ypsomate.html)

Estimate for number of auto-injectors sold per year globally = 500 million (https://www.ondrugdelivery.com/paving-the-way-to-zero-carbon-emission-combination-products-insights-from-the-ypsomate-zero-case-study/)

Typical density of plastics (common material used for auto-injectors) = 1,000 kg/m3 (https://hudsonriverpark.org/app/uploads/2020/06/Plastic-Density-Table.pdf)

Typical density of steel (building material of eiffeltower) = 7850 kg/m3

Global yearly auto-injector weight = 40 grams x 500 million = 20 000 tonnes

20,000 / 9,162 = 2.18 Eiffel towers in weight

Ratio steel to plastic density = 7850 / 1000 = 7.85

2.18 x 7.85 = 17.13 Eiffel tower in volume

Appendix C

Story board of Ypsomate user journey

1) User receives box with injector either by mail or by collecting at a pharmacy.

2) User stores box with injector in fridge.

3) According to schedule, user removes box with injector from fridge to prepare for injection.

4) User removes the injector from the packaging. Packaging disposed of with paper waste.

5) User checks medicine for irregularities.

6) User lets injector warm up to room temperature by leaving the injector out for 30 mins

7) User prepares supplies for injection: Alcohol swab, Cotton ball or gauze, Band-Aid, Sharps disposal container.

8) User selects injection area: either thigh or abdomen.

9) User cleans the injection area with alcohol swab.

10) User removes needle cap.

11) User places injector against injection area.

12) User pushes and holds injector against injection site and waits for audible feedback. After last click user waits an additional 5 seconds

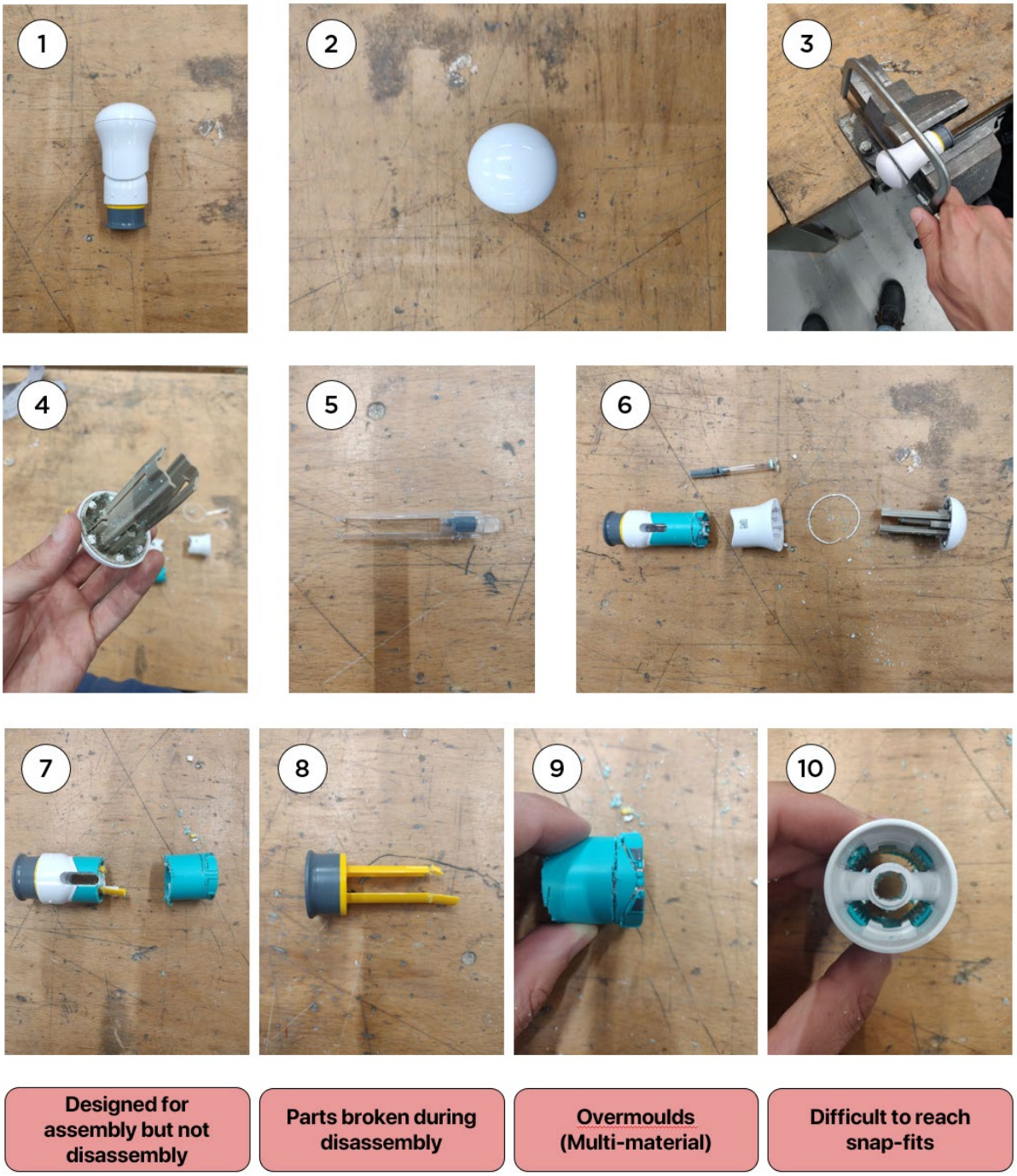
13) User cleans injection area with a cotton ball when finished.

14) User disposes of injector in sharps bin or in SafeReturns package

15) User returns sharps bin and contents to pharmacy or via SafeReturns.

Appendix D

Disassembly of the OnePress auto-injector.



Appendix E

The method by Bovea et al. (2018) starts by identifying 46 CPD guidelines derived from an extensive literature review. For this study, the Ypsomate was assessed against each guideline, with fulfilment scores ranging from -2 (not fulfilled) to 2 (completely fulfilled), and 0 for neutral fulfillment. Some guidelines were non-applicable to the Ypsomate and have been greyed out. The baseline assessment shows which circular design guidelines the product already scores well on and which could use improvement (see *Table 8*). Justifications are provided for each fulfilment score.

Table 8 - CPD assessment Ypsomate 2.25ml

#	Circular Design Guideline	Fulfilment Score	Justification
1	Create a modular design	0	The injector makes use of some subassemblies that could in theory be replaced separately from one another. However, it is clear that these sub assemblies have not been designed to be separated from one another.
2	Locate unrecyclable parts in areas easy to remove	-2	Difficult to recycle parts are rigorously embedded in the injector. Separating materials for recycling is therefore a big challenge.
3	Minimise number of components	-1	Competitor products use fewer components
4	Ensure resistance to dirt accumulation	2	Housing is sealed thoroughly, protecting the internals from dirt
5	Use standardised components	-1	Apart from the prefilled syringe there are no standard components
6	Minimise product varients	-2	Many variants available though with somewhat comparable designs and materials used
7	Improve the ratio between the labour required to retrieve components and their value	0	Once open, the high value medical syringe does come out easily. However, this is made intentionally difficult.
8	Avoid moulding or fusing incompatible materials	-2	Incompatible materials fused in for example the medical syringe and needle. Use of composites. Also sometimes overmoulds are used in certain variants.
9	Consider the use of an active disassembly	-2	No use of active disassembly. In fact disassembly seems to be made purposefully difficult.
10	Use standardised joints	-2	No use of standardised joints. Each injector uses its own designed snap fits.
11	Prioritise latching to screws and joints	2	Only used friction fits and snap fits.
12	Unify screw heads		Not applicable.
13	Minimise types of connectors	2	Only used friction fits and snap fits.
14	Use fasteners rather than adhesives	2	Only the label is attached with adhesives
15	Make joints visible and accessible	-1	Joints are visible but very difficult to access. High force and precision required.
16	Use fasteners that are easy to remove	-2	Some irreversible snap fits used. High force and precision required to remove joints.
17	Minimise the number of joins and connections	0	No indication that number of joints or connections was minimised.
18	Minimise the number of tools and use pull/push processes	1	Only push/pull processes use. However, various tools are required with use of high force.
19	Use inseparable joints for components made of the same or a compatible material		This guideline is only applicable for design for recycling and conflicts with guidelines for remanufacture. It has been deemed not applicable. A better guideline would be to make components out of the same material ***if*** inseparable.

20	Use materials with a low environmental impact	-1	13 materials used including scarce borosilicate glass as well as a mix of engineering plastics and stainless steel.
21	Use thin walls with nerves (plastics)	2	Injector uses thin walled parts
22	Use components made of pure materials	-2	Composites used
23	Minimise the number of different materials	-2	13 materials used in total
24	Avoid secondary finishes and coatings	0	Syringe uses silicone coating and plastics are likely treated with additives but unable to verify.
25	Use recycled and recyclable materials	-1	Materials are in theory recyclable but not recycled.
26	Use materials resistant to cleaning processes for components to to be reused	-2	Materials are resistant to cleaning but not heat intensive sterilisation.
27	Reduce the material content and energy required in the manufacturing process	0	No indication.
28	Ensure the identification of materials using material code marks	-2	No material markings or identifiers.
29	Minimise the use of toxic or hazardous materials	2	No indication. Assumption is made that all parts are non hazardous.
30	Use unplated metals for recycling	2	Stainless steel used.
31	Use low alloy metals for recycling purposes	2	Stainless steel used.
32	Use cast irons for recycling purposes	2	Stainless steel used.
33	Use components and materials with verified reliability	0	No indication.
34	Do not combine components that have different life spans	-2	Injector is single use and no consideration is made for combining components with different life spans.
35	Avoid using parts that require frequent replacement	-2	Injector is single use. Nothing can be said about frequency of replacement. The entire device has to be replaced after one use.
36	Minimise length of cables and wires		Not applicable.
37	Minimise weight of components	0	No indication that parts are excessively heavy.
38	Use components sized for easy handling	-1	Small components used can be difficult to sort or handle. Consider combining small components in sub assembly with mono material. However, most components should be easy to handle.
39	Maximise the accessibility of components	-2	Injector not designed to allow components to be easily accessible
40	Avoid dismantling parts from opposite directions	-2	Injector disassembled from two directions. Rotation required during disassembly.
41	Simplify the product structure	0	No indication effort has been made to simplify the product structure.
42	Build monitoring equipment into the system		Not applicable.
43	Ensure that the fewest possible technicians are required to perform a maintenance task		Not applicable. Disassembly will be automated.
44	Position components that often need to be maintained closely and in easily accessible place	-1	Injector is disposable. Not applicable.

45	Eliminate the need for special disassembly procedures	-2	Difficult disassembly procedure is required to take apart the device. Can not be done without damaging and breaking opent the device.
46	Use simple and standardised tools	-2	Special tools required to release snap fits to take apart device
	Total Score	**-20**	

The next step in the method involves translating the 46 CPD guidelines from literature into Bovea et al.'s 33 condensed circular economy design guidelines. Once converted, the 33 condensed guidelines are categorised using the CE principles proposed by the Ellen MacArthur Foundation and grouped into 5 circularity strategies defined by van den Berg & Bakker (2015).

- Extended life
- Disassembly
- Product reuse
- Component reuse
- Material recycling

After grouping the guidelines into categories, the degree of relevance of each circularity strategy for auto-injectors, assigning relevance scores from 1 (low relevance) to 3 (high relevance). Table 9 provides argumentation for the relevance scores per category.

Table 9 - Degree of relevance per circular design category for Ypsomate

Circular Design Category	Relevance Score	Argumentation
Extending lifespan	2	The Ypsomate is a consumable product with a very brief functional lifespan (once the drug is delivered the injector is redundant). For hygiene and safety reasons, extending the lifespan of an auto injector is not suitable. However, solutions might be found for hybrid products with partially reusable elements.
Disassembly	3	The Ypsomate is a complex technical product with many parts of various materials. Disassembly is highly relevant to separate material streams and enables different circular solutions for the different components. For example, disassembly enables components to be cleaned and decontaminated appropriately, a step essential for the reuse of either parts or materials in medical products.
Product Reuse	1	Full product reuse of the Ypsomate is not feasible because the syringe and needle can not be sufficiently cleaned and the needle becomes dull after use.
Component Reuse	2	Apart from the syringe and needle, most components are not damaged during use and could potentially be used again with minimal cleaning and decontamination.
Material Recycling	3	Due to the amount of high quality materials in the product and the short life span of the product combined with the volume of production recycling of materials is considered highly relevant.

Following on, the margin of improvement (MoI) must be assessed per guideline. This was achieved by translating the fulfilment scores from the baseline score into MoI scores. Low fulfilment scores equates to a high MoI score. For the justifications for these scores refer to Table 8. In the case of multiple baseline scores going into reformed guidelines (see Table 8, Column 3), an average improvement score was used. MoI scores range from 1 (low margin of improvement to 3 (high margin of improvement).

Table 10 - Circular design opportunity assessment for Ypsomate

Circular design guidelines group	Code	Circular Design guidelines	Design guidelines from Error! Reference source not found.	Degree of Margin of Improvement	Degree of Relevance	Level of circularity improvement (MI x R)
Extension of life span	EL1	Timeless design	6	2	2	4
	EL2	Adaptability	1,43	2	2	4
	EL3	Upgrading	1, 5, 41, 43	2	2	4
Disassembly (Connectors)	DC1	Use standardised joints	10, 12, 16, 18, 48	3	3	9
	DC2	Use joints than can be disassembled rather then fixed joints	7, 11, 14, 16	2	3	6
	DC3	Use screws with the same metrics	7, 10, 12	1	3	3
	DC4	Minimise type of joints	7, 13	1	3	3
	DC5	Use easily accessible joints	7, 15, 41	3	3	9
	DC6	Minimise the number of joints	7, 17	2	3	6
	DC7	Minimise the number of tools to be used	7, 18	2	3	6
	DC8	Use standardised tools	10, 48, 49	3	3	9
Disassembly (Structure)	DS1	Adopt modular designs	1, 43, 45	2	3	6
	DS2	Minimise the number of components	3, 43	3	3	9
	DS3	Be able to quickly identify disassembly joints	7, 15, 41	3	3	9

	DS4	Minimise length of wires and cables	38	1	3	3
	DS5	Size components to make their handling easier	23, 39, 40	2	3	6
	DS6	Facilitate the accessibility of essential components (for their potential reuse/recycling)	2, 7, 41, 47	3	3	9
	DS7	Avoid the disassembly of parts in opposite directions	42	2	3	6
	DS8	Design to make disassembly automatic	9	3	3	9
Product Reuse	PR1	Design to avoid dirt from accumulating	-	2	1	2
	PR2	Use materials that overcome cleaning processes	4, 28	1	1	1
	PR3	Minimise the use of parts that require frequent repairs/replacements	35, 37	3	1	3
	PR4	Use components with a similar life span	36	3	1	3
	PR5	Incorporate systems to monitor failing components	44	3	1	3
Components Reuse	CR1	Use standardised components	5	3	2	6
	CR2	Minimise variations in the appliance	6, 45	2	2	4
Material Recycling	MR1	Use materials compatible for recycling	8, 30, 32	3	3	9
	MR2	Unify materials in the components joined by fixed joints	8, 20	3	3	9
	MR3	Use materials with a low environmental impact (recyclable/low energy content/etc.)	21, 27, 29, 33, 34	2	3	6

	MR4	Promote monomaterial designs	8, 20, 25	3	3	9
	MR5	Avoid using surface treatments	24, 26, 32	2	3	6
	MR6	Label materials	30	3	3	9
	MR7	Minimise using hazardous materials	24, 26, 31	2	3	6

In order to assess the most valuable circular strategies for Ypsomate, a 3x3 opportunity matrix was used. This matrix plotted the degree of relevance against the average improvement potential within each category to identify the most significant areas for circular improvement (see Figure 51).

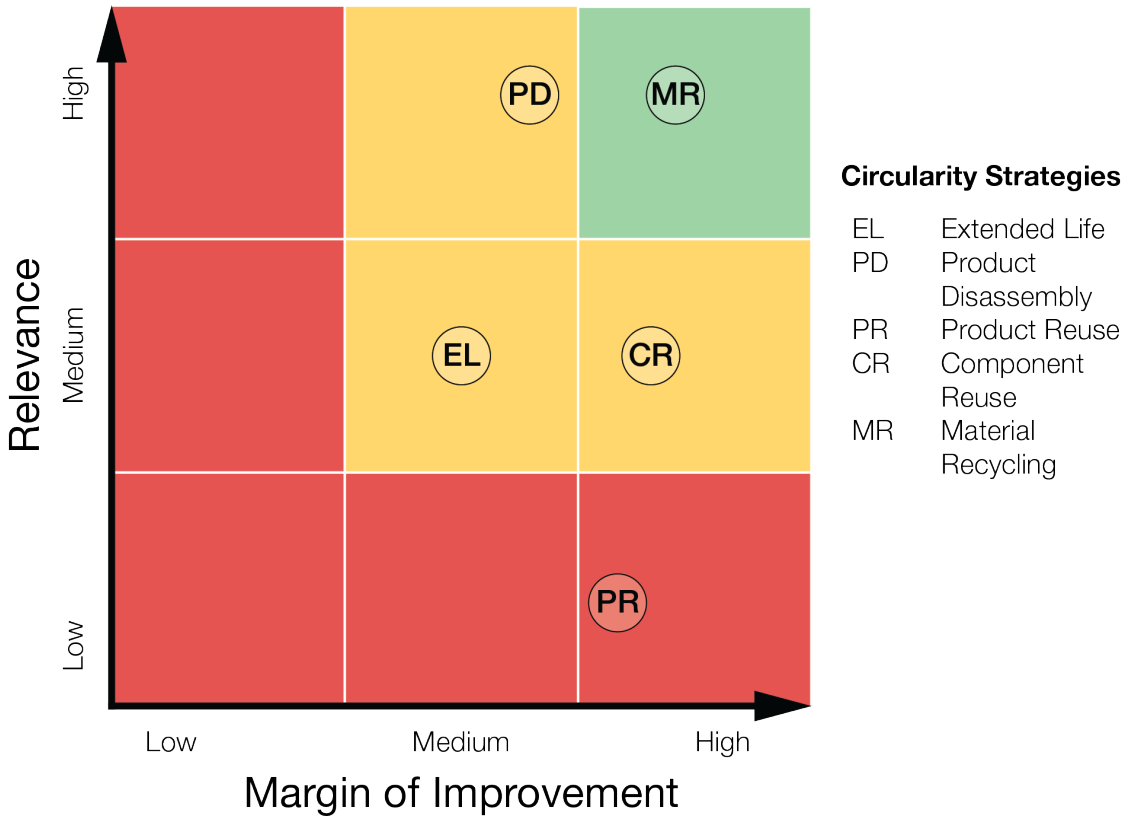


Figure 51 - Circular Product Design Opportunity Matrix for Ypsomate

Appendix F

Bovea made their own translation of 46 CPD guidelines into circular strategies but this translation was at times found to be rather arbitrary. It was decided to reassess this by discussing with other design engineers and combining an assessment by van Straten et al., (2023). This led to the following table, which lists Bovea et al. (2018) circular design guidelines reevaluated for relevance to the four selected circular strategies from Chapter 4.3. As can be seen, Design for Disassembly has the most overlap with other circular design strategies and can therefore be considered an enabler for the other three circular strategies.

Table 11 - List of Bovea et al. 46 circular design guidelines and relevance for selected circular design strategies for Ypsomate.

#	Guideline	Recycling	Disassembly	Remanufacture	Extended Life
1	Create a modular design	✓	✓	✓	✓
2	Locate unrecyclable parts in areas easy to remove	✓	✓		
3	Minimise number of components	✓	✓	✓	
4	Ensure resistance to dirt accumulation	✓	✓	✓	✓
5	Use standardised components	✓	✓	✓	
6	Minimise product variants	✓	✓	✓	✓
7	Improve the ratio between the labour required to retrieve components and their value	✓	✓	✓	
8	Avoid moulding or fusing incompatible materials	✓	✓		
9	Consider the use of an active disassembly	✓	✓	✓	✓
10	Use standardised joints	✓	✓	✓	✓
11	Prioritise latching to screws and joints	✓	✓	✓	✓
12	Unify screw heads	✓	✓	✓	✓
13	Minimise types of connectors	✓	✓	✓	✓
14	Use fasteners rather than adhesives	✓	✓	✓	✓
15	Make joints visible and accessible	✓	✓	✓	✓
16	Use fasteners that are easy to remove	✓	✓	✓	✓
17	Minimise the number of joins and connections	✓	✓	✓	✓
18	Minimise the number of tools and use pull/push processes	✓	✓	✓	✓
19	Use inseparable joints for components made of the same or a compatible material	✓			
20	Use materials with a low environmental impact	✓			
21	Use thin walls with nerves (plastics)	✓			
22	Use components made of pure materials	✓			
23	Minimise the number of different materials	✓			
24	Avoid secondary finishes and coatings	✓			
25	Use recycled and recyclable materials	✓			

26	Use materials resistant to cleaning processes for components to be reused	✓	✓	✓	✓
27	Reduce the material content and energy required in the manufacturing process	✓		✓	
28	Ensure the identification of components and materials using material code marks	✓	✓	✓	✓
29	Minimise the use of toxic or hazardous materials	✓		✓	✓
30	Use unplanted metals for recycling	✓			
31	Use low alloy metals for recycling purposes	✓			
32	Use cast irons for recycling purposes	✓			
33	Use components and materials with verified reliability	✓	✓	✓	✓
34	Do not combine components that have different life spans				✓
35	Avoid using parts that require frequent replacement				✓
36	Minimise length of cables and wires				
37	Minimise weight of components	✓	✓	✓	
38	Use components sized for easy handling	✓	✓	✓	✓
39	Maximise the accessibility of components	✓	✓	✓	✓
40	Avoid dismantling parts from opposite directions	✓	✓	✓	✓
41	Simplify the product structure	✓	✓	✓	✓
42	Build monitoring equipment into the system			✓	✓
43	Ensure that the fewest possible technicians are required to perform a maintenance task				
44	Position components that often need to be maintained closely and in easily accessible place		✓	✓	✓
45	Eliminate the need for special disassembly procedures	✓	✓	✓	✓
46	Use simple and standardised tools	✓	✓	✓	✓

Appendix G

Table 12 shows the fulfilment scoring of both the Ypsomate and the MediLoop redesign as well as the relevance scoring for the full list of CPD guidelines from Bovea et al. (2018). The table also includes justifications for the scoring for the MediLoop. For justifications of the scoring for relevance of guidelines or for scoring of the Ypsomate see Appendix E.

Table 12 - CPD guidelines from Bovea et al. (2018) with scoring applied to Ypsomate and MediLoop redesign with relevance scores and justifications

	Circular Design Guideline	Ypsomate	Redesign	Relevance	Justification
1	Create a modular design	0	1	3	The drive unit is now a separable module
2	Locate unrecyclable parts in areas easy to remove	-2	2	3	All parts now easily separable
3	Minimise number of components	-1	-1	3	Simplification of device out of scope for this project. Could be possible in future
4	Ensure resistance to dirt accumulation	2	2	1	Housing is sealed thoroughly, protecting the internals from dirt
5	Use standardised components	-1	-1	2	Only the syringe is a standard component but it could interesting for future study to see if for example the drive unit could become a standard component in other injectors
6	Minimise product varients	-2	0	2	Out of scope
7	Improve the ratio between the labour required to retrieve components and their value	0	2	3	Once open internal components are easily released.
8	Avoid moulding or fusing incompatible materials	-2	1	3	Except for the syringe and needle, only mono material parts
9	Consider the use of an active disassembly	-2	2	3	Disassembly process automated
10	Use standardised joints	-2	1	3	Two identical snap fit joints accessible from outside.
11	Prioritise latching to screws and joints	2	2	3	Only snap fits used.
12	Unify screw heads				N/A
13	Minimise types of connectors	2	2	3	Only snap fits and friction fits used.
14	Use fasteners rather than adhesives	2	2	3	No adhesives used accept in label
15	Make joints visible and accessible	-1	2	3	Joints are all accessible from the outside by special tool
16	Use fasteners that are easy to remove	-2	2	3	Fasteners are easily accessible and low force to disengage
17	Minimise the number of joins and connections	0	2	3	Only necessary joints used
18	Minimise the number of tools and use pull/push processes	1	2	3	Only push/pull processes used and two tools
19	Use unseparable joints for components made of the same or a compatible material				N/A as this removes possibility of remanufacturing
20	Use materials with a low environmental impact	-1	1	3	All materials are recyclable
21	Use thin walls with nerves (plastics)	2	2	3	Injector uses thin walled parts
22	Use components made of pure materials	-2	2	3	Only mono-material parts used
23	Minimise the number of different materials	-2	2	3	Reduced number of materials
24	Avoid secondary finishes and coatings	0	0	3	Mediloop should not use additives in it's materials but exact material composition is out of scope for this study
25	Use recycled and recyclable materials	-1	2	3	All materials now separable and recyclable. No more composites to be used.
26	Use materials resistant to cleaning processes for components to to be reused	-2	2	3	Due to removal of hygiene critical components, components can now be cleaned and appropriately decontaminated
27	Reduce the material content and energy required in the manufacturing process	0	-1	3	In order for all parts to perform their function correctly the device actually increased in size
28	Ensure the identification of materials using material code marks	-2	2	1	Materials can be identified as the product can be tracked full circle.
29	Minimise the use of toxic or hazardous materials	2	2	3	No hazardous materials used
30	Use unplated metals for recycling	2	2	3	Stainless steel
31	Use low alloy metals for recycling purposes	2	2	3	Stainless steel
32	Use cast irons for recycling purposes	2	2	3	Stainless steel
33	Use components and materials with verified reliability	0	0	3	Out of scope for this study. Quality testing should be performed on parts and materials to ensure reliability
34	Do not combine components that have different life spans	-2	0	3	Going from a device designed for single use to potentially multiple use cycles per component testing of the individual life cycles will need to be performed
35	Avoid using parts that require frequent replacement	-2	-1	1	Due to hygiene & safety reasons the syringe needs to be replaced after each use.
36	Minimise length of cables and wires				N/A
37	Minimise weight of components	0	-1	1	robustness.
38	Use components sized for easy handling	-1	2	3	Component handling has been optimised with automated disassembly in mind.
39	Maximise the accessibility of components	-2	2	3	Components easily accessible
40	Avoid dismantling parts from opposite directions	-2	2	3	Parts dismantled in one linear direction
41	Simplify the product structure	0	2	3	Assembly and Disassembly is now done from one direction (Linear)
42	Build monitoring equipment into the system				N/A
43	Ensure that the fewest possible technicians are required to perform a maintenace task				N/A
44	Position components that often need to be maintanined closely and in easily accessible place	-1	2	1	Although not for maintenance, hygiene critical parts (e.g. the syringe and needle) are now easily accessible
45	Eliminate the need for special disassembly procedures	-2	2	3	Simple disassembly process
46	Use simple and standardised tools	-2	2	3	Simple tooling used