YpsoMate Refill

Concept design of a reusable self-injection device for the circular economy.

Master Thesis
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Integrated Product Design

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Msc. Graduation Thesis
April 2023

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Fig. 1: (Top) Injecting myself with an YpsoMate autoinjector.

Fig. 2: (Bottom) In the past 4 years, I have discarded over 60 autoinjectors.

0.1 | Preface

Over the past four years, I have injected myself monthly with an autoinjector to prevent migraine attacks (Fig. 1). Therefore, I have first-hand experience with the issue that this thesis aims to solve: autoinjector waste. Fig. 2 shows that I generated a significant amount of autoinjector waste in the past four years. Unfortunately, this waste is not unique to me, as it is estimated that 150 million autoinjectors are discarded worldwide each year, contributing to environmental pollution through incineration or landfilling (Filipova & Owen Mumford, 2019).

This thesis introduces a reusable autoinjector, The YpsoMate Refill, to reduce CO2e emissions and waste related to self-injection devices. So taking care of my health does not mean sacrificing the environment.

Enjoy reading!

Emma Linders

0.2 | Acknowledgments

I would like to thank all the amazing people that I worked with during this project.

I want to thank JC, my chair, for his unlimited enthusiasm and guidance during the project. Every meeting left me with a head full of new ideas.

Thank you, Sjoerd, for the interesting discussions and the sharp questions that helped me reflect on what I was doing. I always walked out of our meetings with a smile.

To Sebastian, Marion, and the entire Alliance to Zero, I could not have asked for a better client to work with. From answering all my detailed questions, inviting me to Switzerland (and providing me with an extensive itinerary of must-sees), and giving me the opportunity to present to the entire Alliance in Delft.

Wilfred, thanks for the support from the beginning when brainstorming about possible graduation topics. Your practical advice about my process and the technical details kept me sharp and focused during this project.

I am also grateful for Jos, Daniël & Daniël, Michiel, Martin, and my other colleagues at npk design, who gave me a great place to work and were always up for brainstorming.

I would also like to thank Joris from the Applied Labs, Peter from npk design, and the staff at the PMB for supporting me with building the prototypes.

Thanks, Coffee ** group, for all the breaks without coffee, the morning updates if the only nice room with windows was still available, and the good energy and support at the faculty.

Thanks to my Industrial Design friends, Het Scheve Huisje, Zuidwal, high school friends, climbing buddies, family, and parents for the fun activities, distractions, and entertainment to get my mind off my graduation topic.

Finally, a special thanks to Lars for all the brainstorming sessions, hugs, late-night deadline support, cooking and doing the dishes for the past month without complaining, and planning an amazing Morocco trip with me to look forward to during my graduation project.

0.3 | Executive summary

This thesis proposes the YpsoMate Refill concept design: an autoinjector that can be refilled at a Refill Hub to reduce its environmental impact. After five reuses, it has a 60% lower CO2e impact than the single-use YpsoMate. The concept design aims to inspire the non-profit Alliance to Zero in their journey towards a sustainable pharmaceutical sector.

0.3.1 Moving from a wasteful linear life to a circular life cycle

The YpsoMate autoinjector is a popular and convenient self-injection device used for various conditions, but its single-use design generates a significant amount of waste and CO2 emissions. To turn this wasteful linear life cycle (Fig. 3) into a circular one (Fig. 4), this report analyses current autoinjectors on their ease of disassembly and their environmental impact, using tools like HotSpot Mapping, Disassembly Maps, and Life Cycle Assessments.

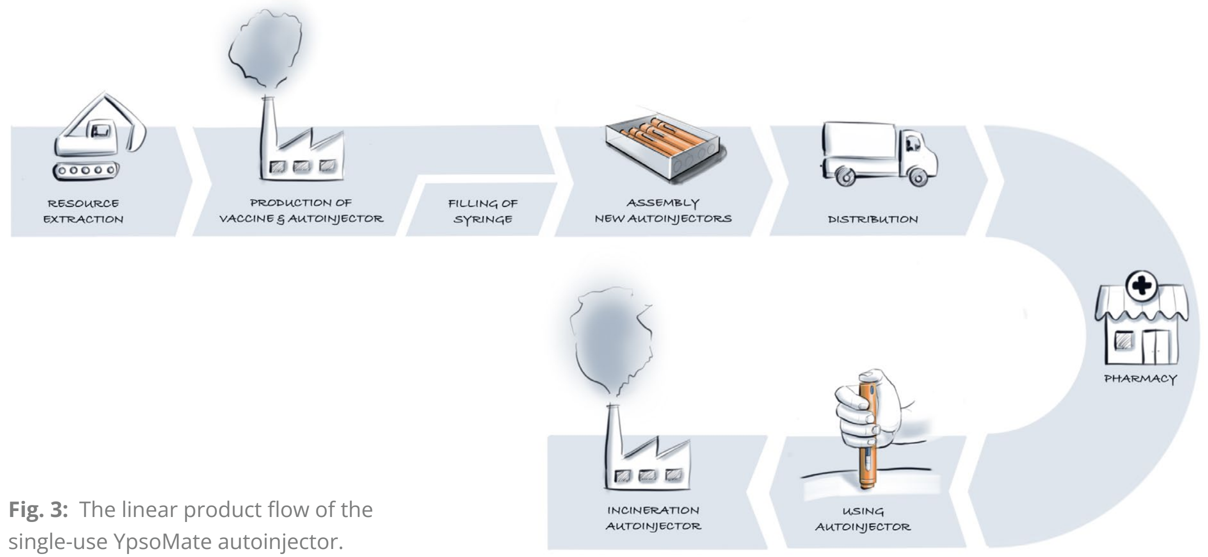

Fig. 3: The linear product flow of the single-use YpsoMate autoinjector.

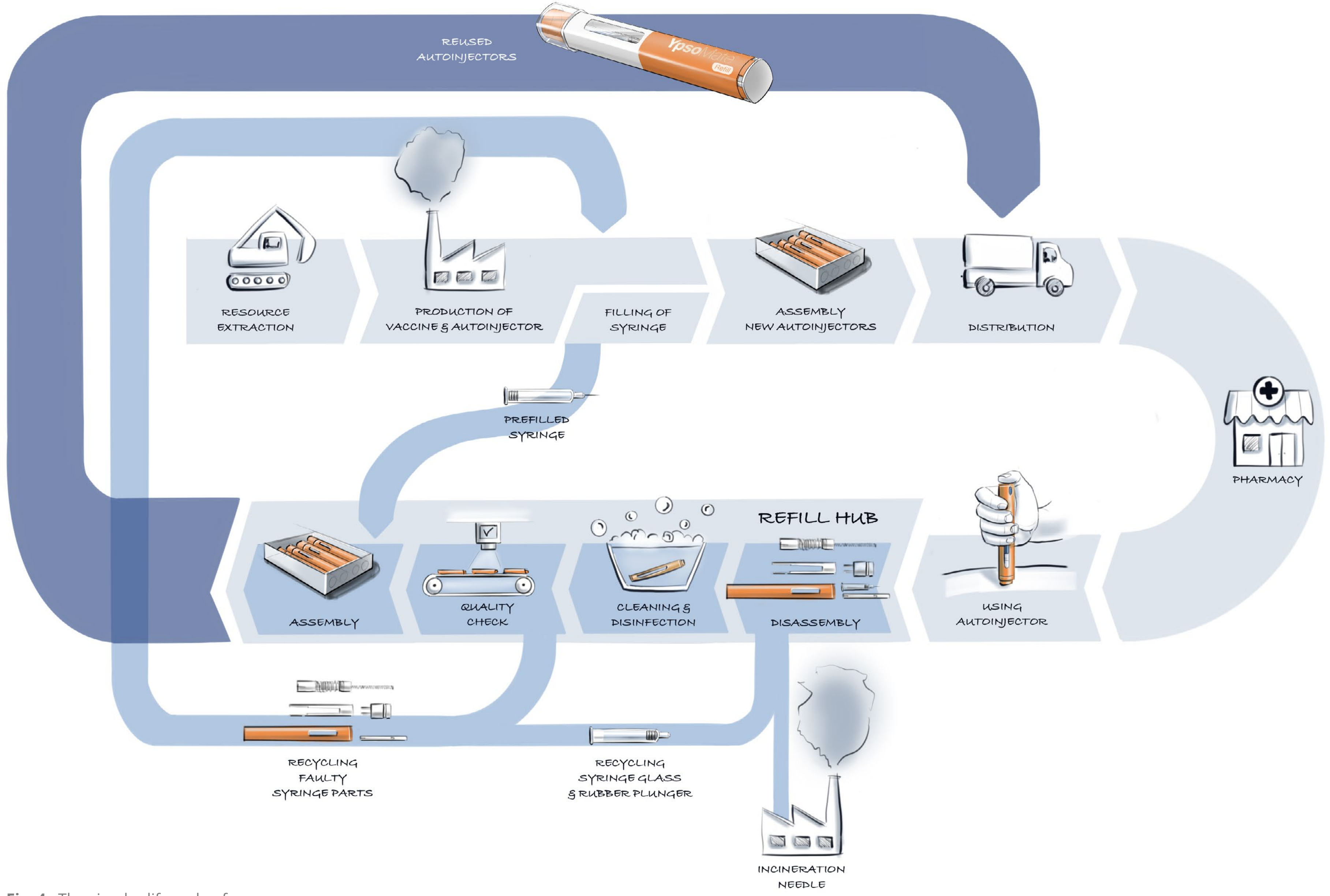

Fig. 4: The circular life cycle of the YpsoMate Refill concept.

0.3.2 The YpsoMate Refill reduces, reuses and recycles its parts

The project's outcome is a visionary concept design for transitioning autoinjectors into the Circular Economy – the YpsoMate Refill. The proposal includes interventions to **reduce** the part count from 19 to 17 to minimize CO2e emissions. Moreover, it contains a new product architecture that enables quick and easy automated dis- and reassembly for **reuse** (Fig. 5). Additionally, the use of a limited amount of commonly recycled bio-based plastics supports **recycling** at the end of life.

The circular product life cycle (Fig. 5) involves returning the used autoinjector at a Refill Hub, where it undergoes automated disassembly, disinfection, replacement of the prefilled syringe, a rigorous quality check, and reassembly. Finally, it is sealed with a new medicine-specific label to provide patients with a fresh and trustworthy product.

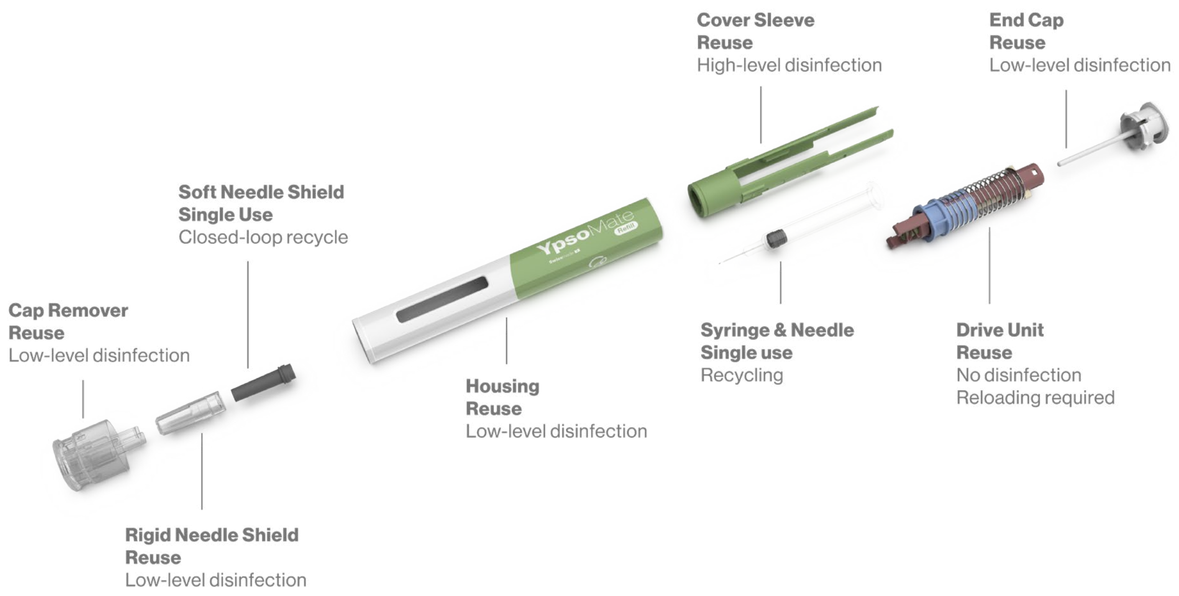

Fig. 5: The final disassembly step of the YpsoMate Refill.

0.3.3 65% less CO2e after 5 reuses

A Life Cycle Assessment (LCA) confirms that even if the YpsoMate Refill is not reused, its environmental impact is approximately 25% lower (excluding the use-phase) than the single-use YpsoMate (Fig. 6). This is thanks to the use of bioplastics and its reduced part count. Moreover, the LCA shows that the YpsoMate Refill emits approximately 50% less CO2e than the single-use YpsoMate after one reuse (two use-cycles) and approximately 65% after five reuses.

However, then CO2e reduction flattens as the environmental impact of reusable parts decreases to a minimum, while the CO2e emissions from single-use parts and the reuse process remain constant Therefore, the optimal number of reuses for an autoinjector part seems to be around five times, reducing the CO2e impact by approximately 60% compared to the current single-use YpsoMate 1.0 mL, while the likelihood of part failure remains low due to the limited reuse count. To achieve this reuse count, a high return rate is crucial, thus motivating patients to return their used autoinjectors is essential.

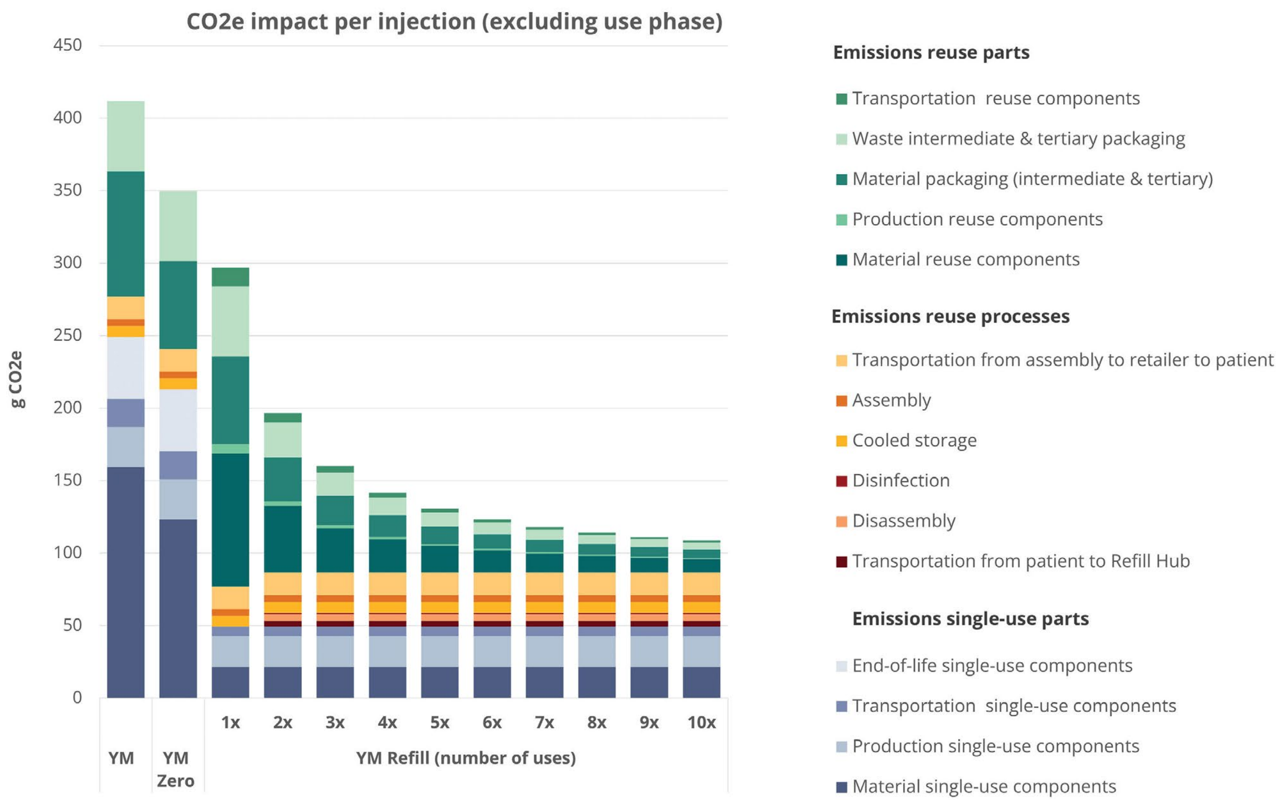

Fig. 6: The environmental impact of the YpsoMate Refill for different reuses counts compared to the single-use YpsoMate 1.0 mL and the YpsoMate Zero.

0.3.4 Easy to dis- and reassemble

Compared to the single-use YpsoMate, the YpsoMate Refill is much easier to dis- and reassemble. While I had to break parts of the single-use YpsoMate during disassembly, the YpsoMate Refill features reusable connections. Due to its subassemblies, it requires only three steps to reach any part in the YpsoMate Refill, in comparison to nine steps for the single-use YpsoMate. Moreover, the entire device can be disassembled in eight tasks, compared to the twenty-one tasks required for the single-use YpsoMate.

0.3.5 A sustainable alternative to single-use autoinjectors

In conclusion, the YpsoMate Refill concept (Fig. 7 & Fig. 8) offers a sustainable, convenient, and safe alternative to single-use autoinjectors. It aims to inspire the non-profit Alliance to Zero in their journey towards a sustainable pharmaceutical sector and provides patients with the opportunity to take care of their health without harming the environment.

Fig. 7: The certified reuse icon aims to increase the patients' trust in the reused autoinjector.

Fig. 8: The autoinjector can be returned in this box to the Refill Hub via post, home pick-up or at the local pharmacy.

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1. Project introduction

Currently, the dominating design is an wasteful single-use autoinjector. However, the healthcare sector is increasingly aware of the importance of sustainability. This chapter introduces the graduation project by discussing the shift towards a sustainable healthcare sector and autoinjectors. It also introduces the companies involved in this project: Alliance to Zero, Ypsomed, TU Delft and npk design.

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1.1 | Problem statement

1.1.1 Unsustainable healthcare

If the global health care sector were a country, it would be the fifth-largest greenhouse gas emitter on the planet (Kraliner et al., 2020). Even though the aviation industry gets more scrutiny for its negative environmental impact, the healthcare sector emits almost twice as much CO2 (aviation: 2,4% (Timperley, 2019)). By contributing to 4,4% of the global net greenhouse gas emissions and toxic air pollutants (Kraliner et al., 2020), the healthcare sector is jeopardizing its mission to protect people's health.

The linear use of medical products negatively impacts the environment, by generating a large hazardous waste stream of products that are produced in energy-intensive processes.

1.1.2 Wasteful autoinjectors

This graduation project focuses on reducing the environmental impact of a specific product in this healthcare environment: a YpsoMate autoinjector. Autoinjectors are used to self-inject drugs safely and conveniently in emergencies such as anaphylaxis (severe allergic reaction), migraine and epileptic seizures or for chronic conditions like psoriasis, multiple sclerosis and rheumatoid arthritis (Vijayaraghava, 2012). These injectors are optimized for ease of use, administering the injection one-handed by pushing a button or placing the device onto the skin. (Global Autoinjectors Market, 2016)

The first autoinjectors were introduced in the market in the 1980s to treat anaphylaxis, but from 2006 onwards they were used more widely for managing chronic diseases (Simpson, 2020). Since then, the market has been growing rapidly. More than 20 pharmaceutical companies have developed nearly 80 autoinjectors until today. Of the around 50 approved drug-autoinjector combinations on the market, 62% are disposable autoinjectors (Roy et al., 2021).

This currently dominating single-use autoinjector design has the benefit that it decreases the risk of contamination and inappropriate re-use. Moreover, companies generate a steady revenue stream through the continuous sales of disposable autoinjectors, without the high costs associated with product reprocessing and sterilisation of used injectors (Fraenkel & Sørensen, 2021).

However, this comes with a cost to the environment. Circa 150 million autoinjectors are used worldwide yearly (Filipova & Owen Mumford, 2019). These single-use items generate a large hazardous waste stream of over 10,875 tons* yearly that ends up in landfill or incineration.

* According to Gerner (2022), the sales of YpsoMate 1.0 mL and YpsoMate 2.25 are evenly divided. Therefore, I assumed that 50% of the 150 million autoinjectors worldwide are 1.0 mL and 50% 2.25 mL. Furthermore, for the estimate, I took the waste per injection estimated by Fraenkel and Sorensen (2021): 1.0 mL autoinjector: 65g waste, 2.25 mL autoinjector: 80g waste. The exact amount of waste differs per brand and device. This results in the following calculation: (weight 1.0 mL*0.5 + weight 2.25 mL*0.5)* autoinjectors used yearly = (0.065kg * 0.5 +0.080kg * 0.5) * 150 million = 10,875 million kg = 10,875 ton

1.1.3 Sustainable autoinjectors

The autoinjector market is currently changing in favour of sustainable autoinjectors (Simpson, 2020), driven by increasing demand from patients and shareholders for eco-friendly devices. (Fraenkel et al., 2022). User studies of Philips showed that patients prefer a sustainable autoinjector, as long as it was comparable to other autoinjectors concerning precision and safety (Hudson - Farmer, 2021). Pharmaceutical companies are also recognizing the benefits of offering sustainable options, not only to differentiate themselves from competitors but also to comply with evolving regulations (chapter 2.4) (Simpson, 2020).

This shift towards sustainable healthcare is also reflected in the Paris agreement and Green Deal. In reaction, The Dutch Green Deal on Sustainable Healthcare 3.0 sets a target of a 55% reduction in emissions by 2030 (Government of the Netherlands, 2022).

This mentality shift is also visible when looking at the developments in the autoinjector industry. For example, Ypsomed (2022) developed the YpsoMate Zero (Fig. 11), which is an autoinjector made of biobased plastics. Johnson & Johnson (Gysel, 2022) and Novo Nordisk (PenCycle, n.d.) are launching take-back schemes for recycling used pens and autoinjectors.

Fig. 11: The YpsoMate Zero autoinjector (Ypsomed, 2022)

Reusable autoinjectors

Pharma companies are not only looking into recycling autoinjectors, but they are also extending their lifespan. Philips (Fig. 12), Jabil (Fig. 13) and DaliMed (Fig. 14) are releasing autoinjectors on the market that can be refilled by patients. Fig. 12 shows how the patient can replace a single-use cartridge while reusing the autoinjector main body.

However, there are multiple disadvantages to letting the patient refill the autoinjector:

- Refill adds extra steps which can harm the ease of use. Patients use autoinjectors non-frequently, often once or twice a month. This means that it takes longer for them to build a routine and remember how to use the autoinjector. Extra steps complicate the use of the autoinjector, creating space for mistakes and thus inadequate medicine administration. A study by Andre et al. (2017) shows that patients prefer the two-step autoinjectors (88.9% chose this as their first choice) over patient-refillable devices (1.9% first choice), because they are easier to use.
- A large patient group of autoinjectors are people with multiple sclerosis and rheumatoid arthritis. (Vijayaraghava, 2012) Since their hand movement can be limited, these extra refill steps can be challenging. Refilling the autoinjector themselves is less suitable for these patients.
- Medicines administered via an autoinjector can be expensive. For example, the preventative migraine medicine Aimovig costs €500 per injection (Zorginstituut Nederland, 2022). Mistakes during refills could waste valuable medicine.

To address these concerns, the Alliance to Zero and Ypsomed asked me to explore the idea of refilling autoinjectors away from the patient, at a Refill Hub. This way, the patient experience remains unchanged, while reducing waste and environmental impact. One autoinjector could be reused by multiple patients, reducing material and energy use.

Fig. 12: Philips Aria (Philips, 2022)

Fig. 13: Qfinity by Jabil (Jabil, n.d.)

Fig. 14: Flexi-Q by DaliMed (DaliMed, n.d.)

1.2 | Involved companies

The Alliance to Zero is a non-profit association consisting of eight pharma companies. These companies are further discussed in chapter 2. Their ambition is to facilitate the transition of the pharmaceutical sector towards net zero emissions. To further explore this topic, they initiated multiple graduation projects at the TU Delft. These projects aim to redesign an auto-injector device manufactured by Ypsomed, known as the YpsoMate, to align with the principles of the circular economy. My project focuses on prolonging YpsoMate's use stage through third-party refill.

Ypsomed is a Swiss-based company making self-medication devices, including auto-injectors. As a member of the Alliance to Zero, the company aims to achieve net-zero operational CO2 emissions by 2030. Also, Ypsomed aims to achieve net-zero CO2 emissions across its entire value chain by 2040 (Ypsomed, 2022).

To help them get a step closer to this goal, I designed the "YpsoMate Refill". This is an auto-injector concept that could be refilled at a designated Refill Hub and then sent to a new patient.

Throughout this graduation project, my main contact was Sebastian Gerner, the President of the Alliance to Zero and Ypsomed's Corporate Sustainability Manager. I also had the opportunity to visit Ypsomed's headquarters and factory in Bern (Switzerland) and evaluate my concepts with their experts.

The Alliance to Zero launched this graduation project in collaboration with professor Jan-Carel Diehl from the faculty of Industrial Design Engineering. The project was placed under the guidance of the Circular Medical Delft Design Lab. This is a collaborative platform dedicated to innovation in medical design for the circular economy.

npk design was involved in this graduation project as a third-party mentor. They guided me in the design process with their valuable practical knowledge of sustainable and medical product design. npk design is a product design agency based in Leiden, the Netherlands. They specialize in creating innovative and sustainable solutions for various industries, including healthcare and biotechnology.

1.3 | Scope

This graduation project proposes a concept design for the YpsoMate Refill. This is a two-step autoinjector designed for the pharmaceutical company Ypsomed, that can be refilled at a Refill Hub after each use to increase its lifespan. This decreases its waste and thus energy and material use, while keeping the ease of use and comfort optimal.

The main focus of this graduation project is on the product embodiment of a third-party refillable autoinjector for the circular economy.

Since 80% of a product's environmental impact is determined in its design phase (EU Science Hub, n.d.), the product architecture can significantly impact the CO_2 and waste footprint. Additionally, this thesis proposes a product-service system that facilitates third-party refills of YpsoMates.

However, my master, interests and learning goals focus more on product embodiment. Therefore, the refill service around the YpsoMate Refill gets less priority and is developed on a higher concept level.

The final deliverables stated below reflect this scope.

1.3.1 Final deliverables

- An analysis of the current state of YpsoMate autoinjectors regarding the circular economy with a focus on refill.
- A concept redesign of a third-party refillable YpsoMate: the YpsoMate Refill.
- A proof-of-concept prototype of the YpsoMate Refill concept.
- A proposal for a product-service system that facilitates third-party refills of YpsoMates.
- A comparison of the proposed YpsoMate Refill concept to the single-use YpsoMate and the YpsoMate Zero in terms of environmental impact and ease of disassembly.

Design goal

Design of the YpsoMate Refill autoinjector concept, which facilitates third-party refill and fits in the circular economy to reduce CO2e emissions and waste.

1.4 | Research questions

To reach the project goals described in the previous chapter, I researched the questions in Table 1.

Table 1: Main research questions and sub-questions, listed next to the chapters that answers them.

Main research question	ID	Sub-question	Chapter
1. What is the current state of autoinjectors regarding the circular economy, particularly concerning refillability?	RQ1.1	How do patients currently use autoinjectors and what opportunities and challenges does this present for designing a refillable YpsoMate autoinjector?	3.1
	RQ1.2	What are the current industry standards for safety, hygiene, comfort, and cost-effectiveness in autoinjectors?	3.2
	RQ1.3	What are the potential regulatory and certification challenges facing the development of circular economy autoinjectors?	3.3
	RQ1.4	What circular design strategies are most applicable to the development of the YpsoMate Refill?	4
	RQ1.5	What is the current market landscape for autoinjectors and what sustainable alternatives exist?	5.1
	RQ1.6	What is the environmental impact of the current YpsoMate autoinjectors throughout their lifecycle and where are opportunities for improvement?	5.2
	RQ1.7	How easily can current autoinjectors be disassembled and reassembled?	5.3
	RQ1.8	How durable and reliable is YpsoMate, and which components must be sterilized to maintain reliability?	5.4
	RQ1.9	What is the current state of standardization and upgradability of the YpsoMate autoinjectors?	5.5
	RQ1.10	How well does the current YpsoMate align with high-value recycling principles?	5.6
	RQ1.11	Is YpsoMate resource efficient?	5.7
	RQ1.12	How well does YpsoMate align with principles of regeneration and reducing harmful substances?	5,8
	RQ1.13	What is the current supply chain for autoinjectors and what challenges and opportunities does this present for the implementation of a refill stream?	6

Main research question	ID	Sub-question	Chapter
2. How can the product-service system of the YpsoMate autoinjector be modified to accommodate third-party refills?	RQ2.1	How can the design of the YpsoMate autoinjector be modified to accommodate third-party refills?	6 & 7
	RQ2.2	What would a service system for refilling YpsoMate autoinjectors look like?	6 & 7
3. How does the YpsoMate Refill concept compare to the single-use YpsoMate and YpsoMate Zero in terms of environmental impact and ease of disassembly?	RQ3.1	What is the environmental impact of the YpsoMate Refill concept?	8.1
	RQ3.2	What is the ease disassembly of the YpsoMate Refill concept?	8.2

1.5 | Approach & method

In this graduation project, I used the Creative Problem Solving method to structure my design process (van Boeijen et al., 2014). I selected this method because it helps to understand and redefine design problems to come up with innovative solutions.

Fig. 15 shows an overview of my design process and the methods I used. was not a linear process, but involved revisiting steps. required back and forth between steps. For example, to accurately define the key design problems, I conducted a Life Cycle Assessment on my initial concept design. This analysis helped me identify areas within my design that could be optimized to reduce the environmental impact further.

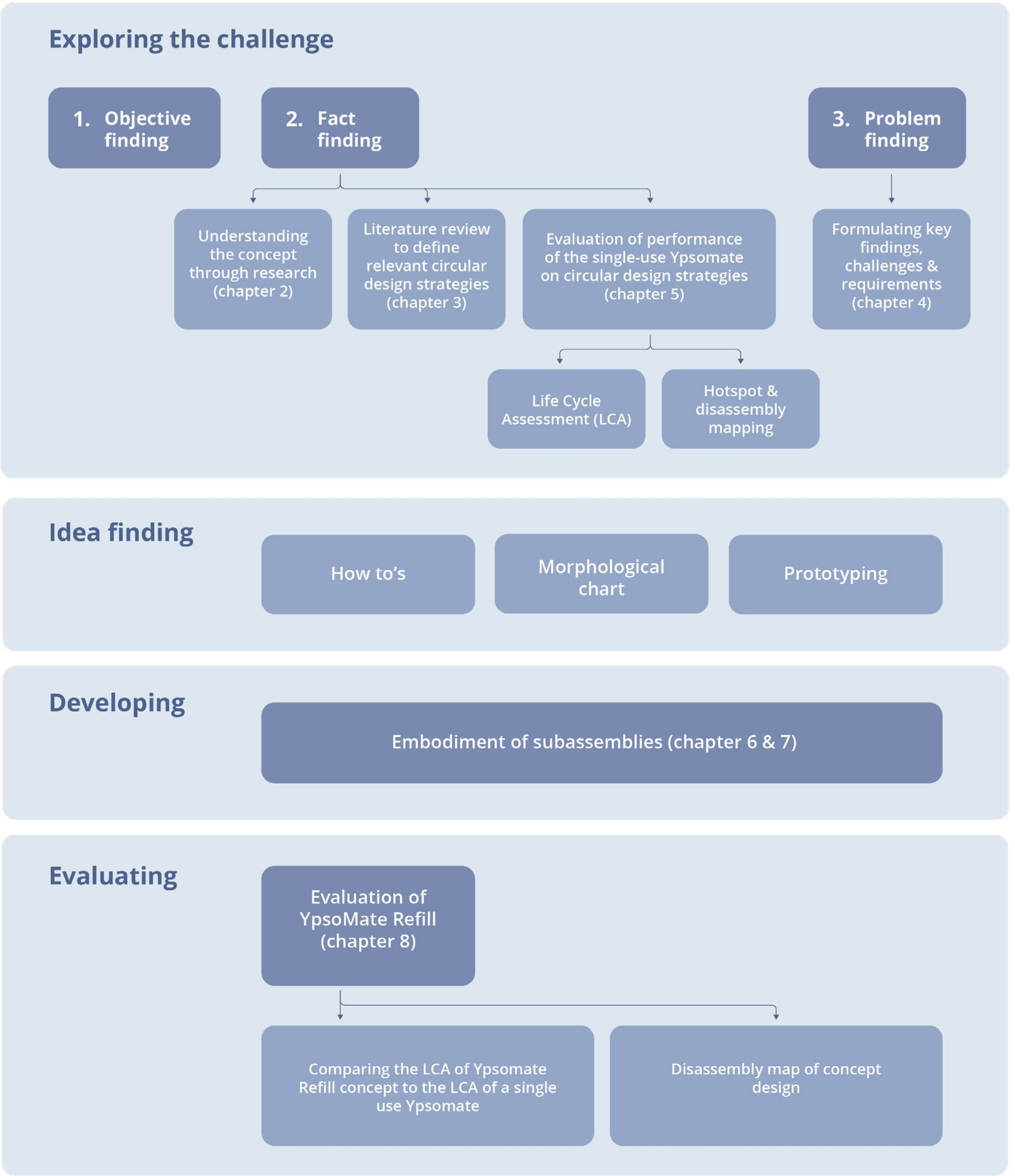

Fig. 15: My design process structure and used methods, according to the framework of the Create Problem Solving method (Boeijen et al., 2014).

Part 1 Analysis

2. Context

This chapter outlines the context of the project. It discusses the use of autoinjectors, its features, functions and regulations. The chapter also looks into the market of (sustainable) autoinjectors and the YpsoMate supply chain.

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2.1 | Autoinjector use

2.1.1 Use applications

YpsoMate autoinjectors are used to conveniently self-inject medicine for the treatment of (chronic) diseases, such as rheumatoid arthritis, multiple sclerosis, oncology, obesity, premenstrual dysphoric disorder, psoriasis, migraine, obesity, etc (Gerner, 2022). Ypsomed does not produce autoinjectors for severe allergic reactions. Other companies, such as EpiPen, cover these users.

2.1.2 Advantages & disadvantages of autoinjectors

Autoinjectors have gained popularity in the treatment of chronic diseases since 2006 (Simpson, 2020) due to their numerous benefits over manual injections that require a nurse to administer the injection or training of the patient.

One advantage of autoinjectors is that they are easy to use and enable self-administration. This eliminates the need for a hospital visit, thus reducing transportation CO_2e emissions and reducing the workload of nurses (Metzmann et al., 2022). Additionally, the autoinjector ensures patient safety as the patient never sees the needle, reducing their anxiety (Kozubski, 2010).

However, autoinjectors come with a few drawbacks, such as being more expensive than manual injections and generating a large waste stream (Vijayaraghavan, 2020).

This thesis addresses the waste problem by introducing a reusable autoinjector, the YpsoMate Refill.

Takeaways

- Autoinjectors are a safe and convenient tool for self-injection.
- However, they generate a large waste stream.
- This thesis tackles this problem by introducing a reusable autoinjector.

2.1.3 Intended use

The YpsoMate offers the convenience of only

1. The patient pulls off the cap to remove the needle shield from the prefilled syringe (Fig. 17).
2. The patient pushes the autoinjector onto the skin to trigger the injection (Fig. 18).

Research by Andre et al. (2017) shows that patients find two-step autoinjectors, such as the YpsoMate, easier to use compared to three-step autoinjectors, where a button must be pressed to activate the injection. The simplicity of the YpsoMate design makes it easy for patients to use, even for those who may have difficulty with more complex devices.

However, in reality, there are more use steps involved in a YpsoMate injection. Appendix A shows the autoinjector patient journey.

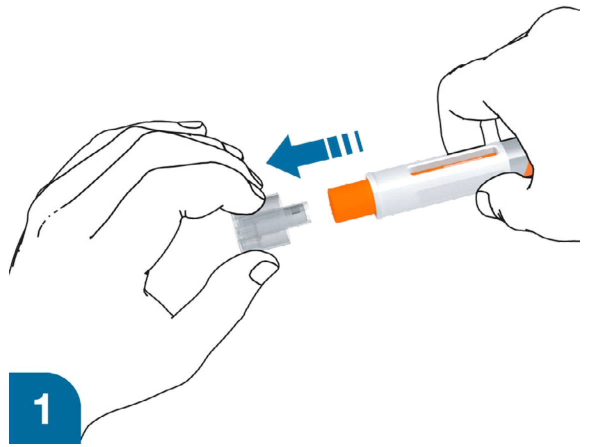


Fig. 17: Step 1 - Remove the cap from the YpsoMate (YpsoMate – the 2-step Autoinjector, n.d.).

Fig. 18: Step 2 - Push the YpsoMate on the skin to start the injection (YpsoMate – the 2-step Autoinjector, n.d.).

2.1.4 Unintended use

It is important to take unintended use scenario's into account, since patients do not always use it as expected.

To explore these unintended use scenario's, I conducted a survey with five participants (Appendix B), who use different types of autoinjectors, such as insulin, EpiPen, rheumatoid arthritis, and migraine. Through Instagram stories, I asked the question: "How do you use/ handle/ transport your injection pen?" Through literature research, I found more unintended use scenarios.

Autoinjectors stored in the fridge have fewer changes of scratching

The insulin, migraine and rheumatoid arthritis autoinjector should be stored in a cool place. Therefore, they often have a fixed storage place, such as a fridge at home.

The EpiPen does not have to be cooled and is often carried close to the user, so adrenaline can be administered in case of a serious allergic reaction. Thus the EpiPen does not have a fixed storage space but is stored in pockets and bags. This provides more options for accidental misuse. However, Ypsomed does not produce EpiPens, so these misuse scenarios are not relevant to the YpsoMate Refill redesign.

Results

The results showed that the following unintended actions can impact the possibilities for the reuse of the autoinjector:

- Dropping the injection before and/ or after use (P1 & P5).
- Scratching the EpiPen during transportation (Schreiner MediPharm, 2020).
- Drowning the autoinjector (EpiPen) in a washing machine, after leaving it behind in worn clothing (McCray et al., 2020).
- Taking the autoinjector off the skin before the injection is finished (P5).
- Not bringing the sharp waste bin with autoinjector back to the pharmacy, so the autoinjectors lie at home for years (P1).
- Disposing of the autoinjector into the general waste bin instead of the sharp disposal container.

However, using an autoinjector past its "use by" date, accidental injection (Rimler, 2020) and not cooling the autoinjector while travelling (P1 & P2) do not have an impact on the reuse scenario. Therefore, these unintended actions will not be further discussed in this report.

P3 and P4 mentioned no unintended use. They keep the autoinjector in a box in the fridge (Fig. 19) till they need to use it and then quickly dispose of it after use (Fig. 20).

Key Takeaways

The YpsoMate autoinjector can be misused. Since it is mainly stored in the fridge and only used for a minute during the injection, the impact of misuse on the autoinjector is lowered. These are misuse scenarios relevant to YpsoMate:

- Dropping the autoinjector on the floor
- Drowning it in water
- Scratching it during transportation or after use.
- Not finishing the injection, which leaves medicine in the syringe.
- Not disposing the autoinjector properly, so it would not reach the refill stream.

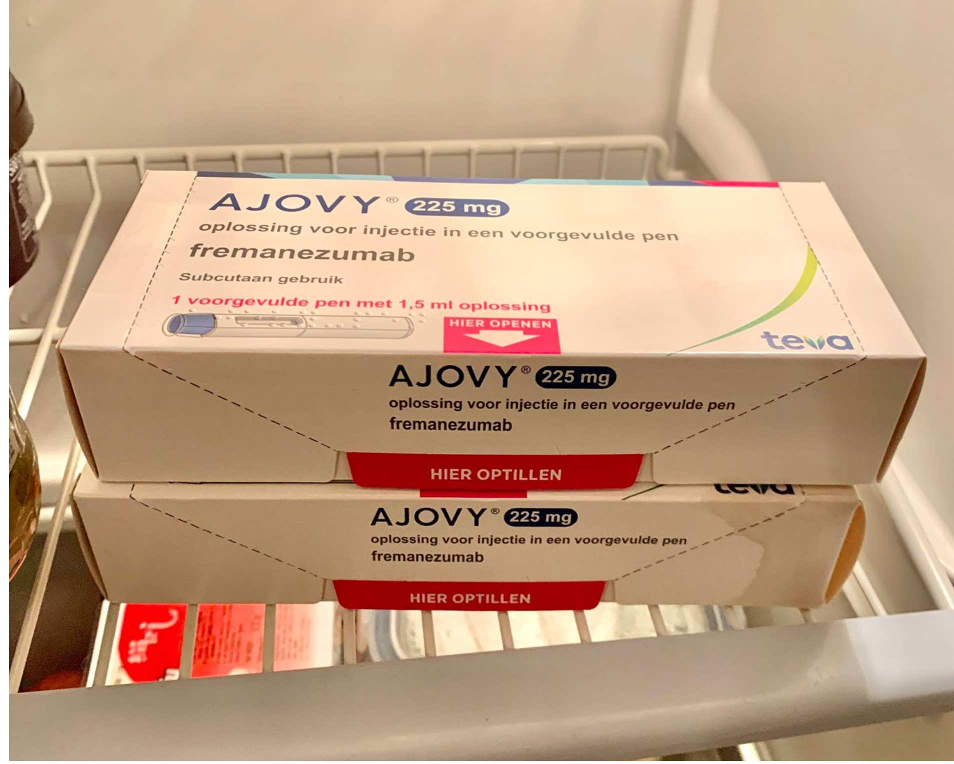


Fig. 19: The autoinjector (Ajovy migraine medicine) is stored in a cardboard box inside the fridge to keep the medicine cooled.

Fig. 20: After use, the patient is supposed to put the YpsoMate autoinjector in a sharp waste bin and bring it to the pharmacy when full.

2.2 | Autoinjector features

2.2.1 Subcutaneous injection

The YpsoMate injects into the subcutaneous tissue with a needle depth of 5 - 8 mm. Subcutaneous tissue is the layer of fat located between the skin and the muscle (Fig. 21).

Medication administered through this method is often absorbed more slowly than if injected into a vein, sometimes over a period of 24 hours. (Case-Lo, 2018)

Subcutaneous injections can be administered in the upper arm, abdomen and thigh (Fig. 22). The thigh and abdomen are the most common injection sites (YpsoMate – Quick Guide, n.d.) as they are easily accessible and have a thicker layer of subcutaneous tissue.

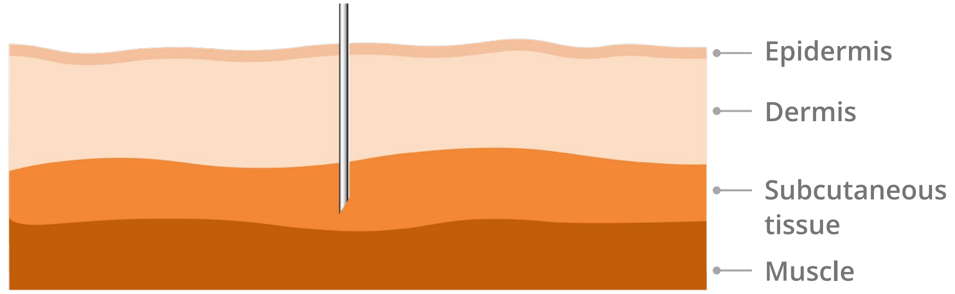


Fig. 21: The subcutaneous tissue is tissue between the fatty skin and the muscle. (Case-Lo, 2018).

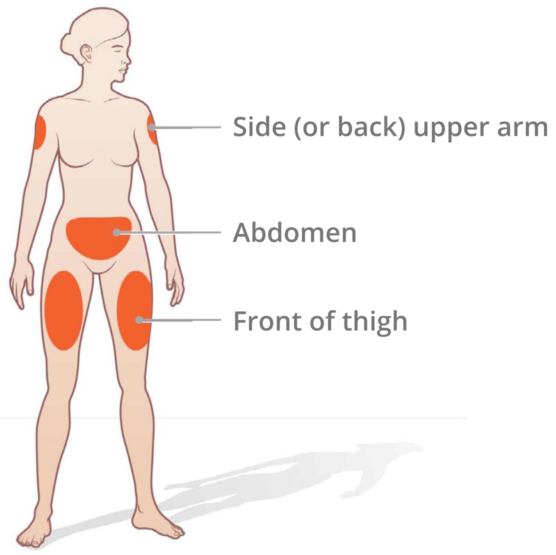


Fig. 22: Subcutaneous injection sites (Case-Lo, 2018).

2.2.2 YpsoMate features

The YpsoMate platform offers a variety of autoinjector options for drug volume, connectivity, and sustainability (Fig. 23). The platform is designed with ease of use and comfort in mind, as well as safety and cost-effectiveness.

The YpsoMate autoinjectors have the following features:

Safety

- Needle shielding before, during, and after use to prevent accidental needle stick injuries.
- A unique square shape that prevents the autoinjector from rolling off tables or other flat surfaces.

Ease of use & Comfort

- A simple two-step injection process, with no additional button-activated steps required.
- A typical injection time of ten seconds.
- Ergonomic, compact housing for good grip and control.
- Audible confirmation “clicks” at the start and completion of the injection to increase patient confidence.
- A large viewing window allows patients to observe the injection progress.

Takeaways

- The YpsoMate autoinjector is designed with ease of use, comfort and patient safety in mind.
- These features should be integrated into the YpsoMate Refill concept design.

Fig. 23: Different YpsoMate autoinjectors (Ypsomed, n.d.)

2.2.3 Autoinjector feature trends

The autoinjector market is continuously evolving, with new trends emerging in the areas of sustainability, connectivity, platform design for different drugs and volumes, and needle-free injections. Appendix C shows an in depth analysis of these trends. In summary, the following trens are emerging in the autoinjector market:

- ***Sustainability*** gets more attention with recycling programs, reusable autoinjectors (Fig. 25), and biomaterials.
- ***Connected autoinjectors*** can help with medication management, but adds electronic waste to the injector (Fig. 24 & Fig. 26).
- Companies are developing ***versatile autoinjector platforms*** that can accommodate a wider range of drugs and volumes.
- ***Motor-driven autoinjectors*** offer the ability to tailor the motor force for different drugs, but also have drawbacks such as the need for battery charging and higher environmental impact.
- The University of Twente is developing laser-driven ***needle-free injections*** that have the potential of reducing waste (needles) and pain. However, it could take up to ten years before this technology is market ready.

This thesis centers around the sustainability trend as it aligns with the concept of reuse. Additionally, it explores the connected autoinjector trend by examining the RFID tag of the YpsoMate. Moreover, the YpsoMate Refill is an autoinjector platform that can be used by various pharmaceutical companies.

Sebastian Gerner expressed a lack of interest in motor-driven autoinjectors and needle-free injections. Therefore, this thesis does not delve further into these topics.

Takeaways

- This thesis examines the emerging trends of sustainability, connectivity, and versatile autoinjector platforms

Fig. 24: Through LEDs, the SmartPilot communicates when the drug has reaches room temperature and is ready for injection.

Fig. 25: The Philips Aria has a screen-based user interface and can be connected to a phone (Phillips-Medisize, 2022).

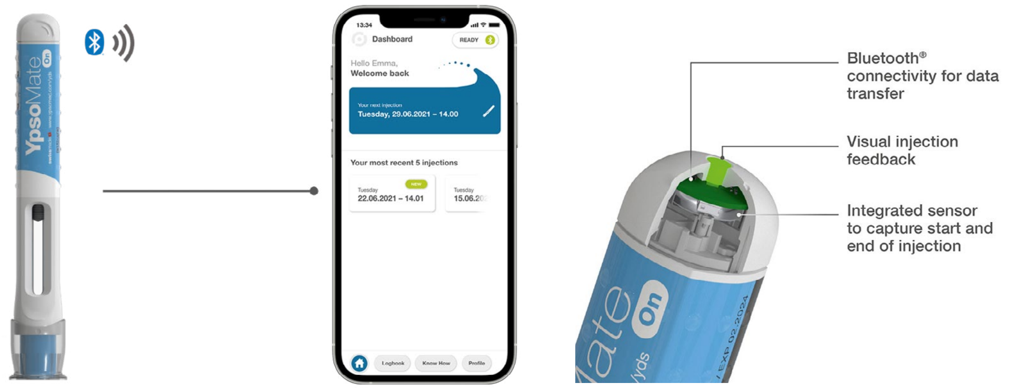


Fig. 26: The YpsoMate On can be connected to a phone (YpsoMate On, n.d.).

2.3 | YpsoMate Product architecture

The YpsoMate product architecture is complicated, with many parts working together to deliver the injection safely, comfortably, and effectively. This chapter aims to give an understanding of how the YpsoMate works.

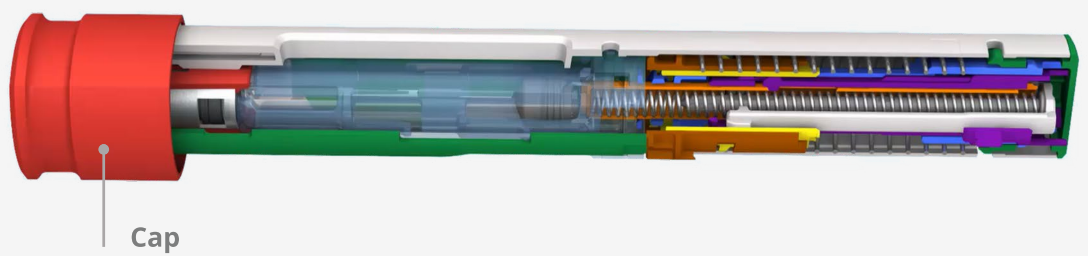


Fig. 27: Ypsomed (n.d.)

2.3.1 Working principle

The following steps explain how the YpsoMate delivers an injection (Fig. 27, Fig. 28, Fig. 29)

1. Remove the cap

The cap locks the injection from being activated. Therefore, the patient first removes the cap.

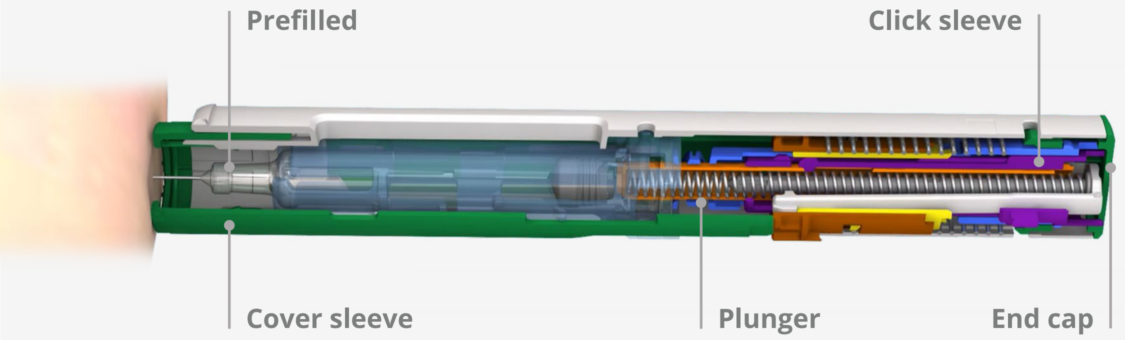


Fig. 28: Ypsomed (n.d.)

Fig. 29: Ypsomed (n.d.)

2. Trigger the injection

The patient then pushes the cover sleeve of the device against the skin, which triggers the spring-powered mechanism in the Drive unit. that pushes the plunger down in the prefilled syringe. This starts the injection, where the plunger pushes the medicine via the syringe through the needle into the skin. At the start of the injection, the click sleeve of the Drive unit slams into the end cap, producing the sound of the start click. This indicates to the user that the injection

3. End of Injection

When the injection is finished, the Drive unit produces an end-click sound to indicate to the user that the injection has ended. When the patient lifts the autoinjector off the skin, the cover sleeve moves down and locks itself in this position. This prevents the patient from reaching the needle again to avoid needle stick injuries.

2.3.2 YpsoMate parts

Fig. 30 shows the parts that YpsoMate consists of. In this chapter, I refer to the numbers indicating parts in this image. Appendix D contains a functional analysis of the YpsoMate parts.

The product architecture of a two-step autoinjector includes several key components that work together:

- ***Housing:*** The plastic housing (nr. 19) provides a comfortable grip for the patient to hold the autoinjector and protects the medication. The housing has a certain thickness to handle the high forces of the spring-powered mechanism.
- ***Needle***: The needle (nr. 15) is made of stainless steel and is glued into the prefilled syringe (nr.14). It is shielded before and after use to prevent accidental needle stick injuries. The needle does not move during the injection. Instead, the cover sleeve moves up when pushed against the skin, exposing the needle, and allowing it to enter the skin.
- ***Prefilled Syringe:*** The prefilled syringe contains the medication and a rubber plunger (nr. 16). It is placed inside the housing and protected by a plastic syringe protector (nr. 17). This protector ensures that in case of breakage, the glass does not reach the patient.
- ***Drive unit:*** The Drive unit is the spring-powered mechanism that is responsible for delivering the medication. The patient triggers this injection by pushing the cover sleeve onto the skin, causing the holding pin (nr. 11) to release the injection spring (nr. 5. This spring pushes the plunger rod (nr. 9) and plunger down in the prefilled syringe, injecting the medicine through the needle into the skin.
- ***Cover sleeve:*** The cover sleeve (nr. 18) is the safety mechanism that hides the needle from the patient before and after the injection. After the injection, it locks via snap-fits in the Drive unit, preventing the patient from reaching the needle again.
- ***Cap:*** The cap (nr. 1,2 & 3) is the safety mechanism that prevents the injection from being activated until the device is pressed against the skin. It also protects the needle with a soft (nr. 2) and rigid needle shield (nr. 1).
- ***Label:*** The label (nr. 4) contains the medicine-specific information, the brand and how to use the autoinjector. It is glued around the housing and hides the snap-fits that close the housing.

YpsoMate 1.0 mL

1. Rigid needle shield
2. Soft needle shield
3. Cap remover
4. Label
5. Injection spring
6. Cover sleeve spring
7. Outer Telescopic lock sleeve
8. Inner Telescopic lock sleeve
9. Plunger rod
10. End cap
11. Holding pin
12. Click Sleeve
13. Mechanic holder
14. Syringe
15. Needle
16. Plunger
17. Syringe holder
18. Cover sleeve
19. Housing

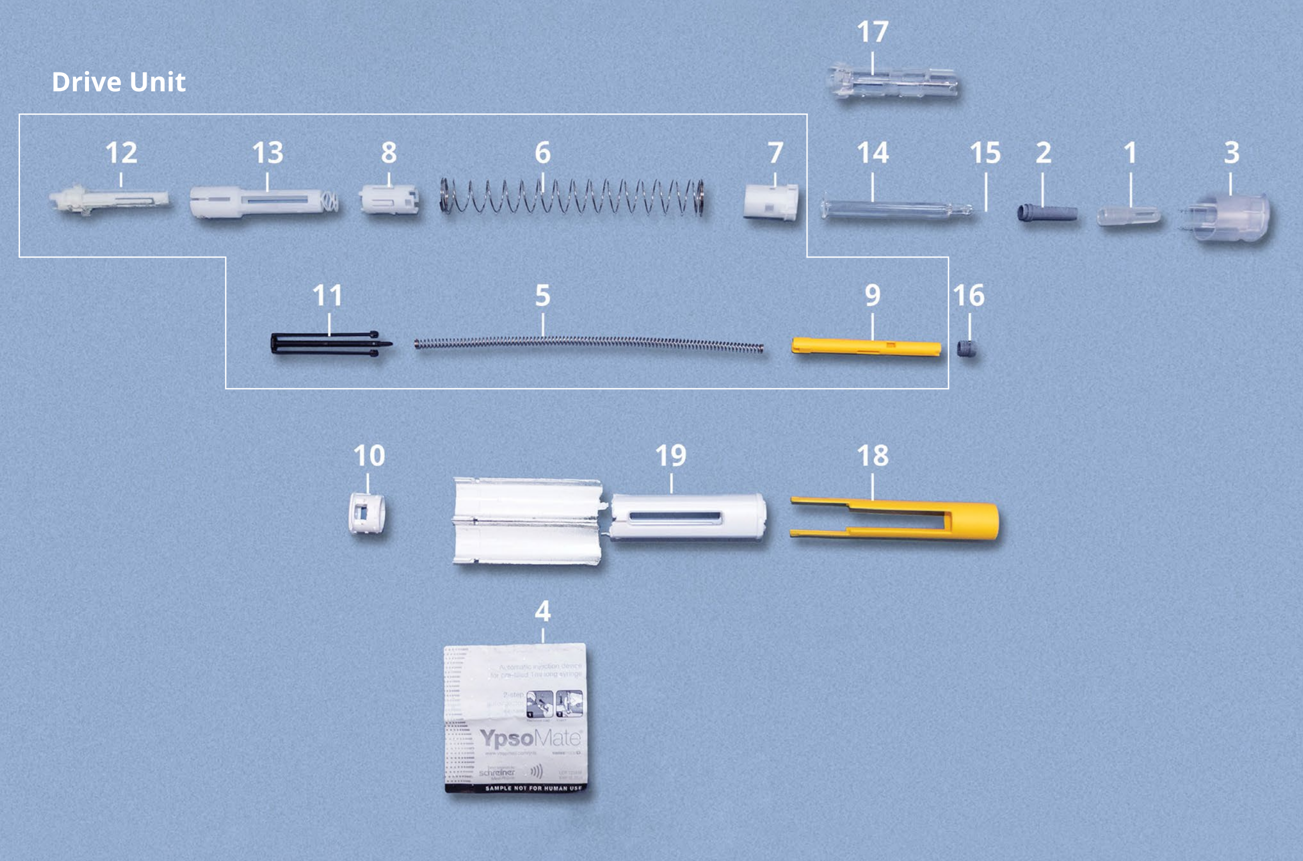


Fig. 30: YpsoMate parts. The order of the numbers might seem random, but is related to the disassembly map in chapter 5.

2.4 | Regulations & norms

2.4.1 Autoinjector regulations

Autoinjector devices are regulated by various governmental agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). This ensures their safety and effectiveness. To meet these regulations, manufacturers must comply with various standards and guidelines for design, manufacturing, testing, and labeling, as well as completing clinical trials (Richter, 2011). Additionally, regulations and norms for autoinjector devices may vary by country and region. Manufacturers must adhere to the guidelines of the countries in which they plan to market the device. Two important international standards for the development and production of autoinjector devices are ISO 13485 and ISO 11608-5.

ISO 13485 is the medical device industry's standard for quality management (ISO 13485:2016, 2016). It outlines requirements for a quality management system to ensure that medical devices are safe and effective for their intended use.

ISO 11608-5, on the other hand, specifies the requirements and test methods (Fig. 31) for the functional and dimensional characteristics of autoinjectors (ISO 11608-5:2022, 2022). This ensures that the device can accurately deliver medication and can withstand normal wear and tear.

It is important to note that for the concept design of the YpsoMate Refill, these regulations and norms are not yet relevant. Therefore, the norms will not be considered in this graduation project. However, as the design progresses and moves into later stages of development and engineering, adherence to these regulations and norms will become crucial for the successful marketability of the product.

Fig. 31: A machine conducts sequential tests on the YpsoMate autoinjectors to check that it adheres to the ISO 11608-5 standard.

2.4.2 Regulations that shape a potential circular future for autoinjectors

The European Union's Green Deal initiative aims to promote sustainable practices and reduce the environmental impact of various industries. To achieve this goal, the EU has implemented various legislation, such as the Sustainable Products Initiative (European Commission, 2020), the Extended Producer Responsibility (European Commission, 2014) through Eco-Modulation (European Commission, 2022), the Plastic Tax (WTS Global, 2022) and the Waste Framework Directive (European Commission, n.d.). The Waste Framework Directive establishes a hierarchy of waste management options, in which waste and reuse are preferred (Fig. 32). This fits the scope of the YpsoMate Refill concept. However, none of the mentioned legislation currently applies to infected medical products, such as autoinjectors.

Fig. 32: Prevention of waste and reuse are preferred options in the waste hierarchy according to the Waste Framework Directive (European Commission, n.d.).

2.4.3 Regulations that shape a potential circular future for autoinjectors

Even though none of the current regulations around sustainability apply to contaminated autoinjectors, companies like Ypsomed are proactively designing sustainable products in anticipation of future regulations in this field. S. Rieder and T. Koch (n.d.) from Rytec Circular made a "worst-case scenario" for current single-use YpsoMate autoinjectors (Fig. 33). It shows possible upcoming regulatory, economical, and societal influences which could force Ypsomed to become more sustainable.

2.4.4 Regulations for electronic autoinjectors

The integration of electronics into autoinjectors to create connected devices introduces new regulatory obligations, such as compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE). This directive includes an EU proposal from 2020, which bans certain toxic substances in batteries (European Commission, 2020). It also makes it mandatory for producers to guarantee the collection of used batteries for recycling. This regulation is also applicable to medical devices, such as autoinjectors.

To comply with these regulations, manufacturers of autoinjectors have several options. They can design a reusable device (YpsoMate SmartPilot) or a reusable unit that has an easy-to-separate battery (Earl, 2022). Another option is to customize autoinjector labels to add radio frequency identification (RFID) tags for connectivity with a phone (Schreiner, n.d.). This way the connected autoinjector does not require a battery. All these options aim to make the devices more sustainable and less impactful to the environment.

Takeaways

- ISO 13485 and ISO 11608-5 provide strict norms for autoinjector testing and quality management. These are not relevant to the concept design of the YpsoMate Refill but should be taken into consideration in a later development stage.
- There are no regulations yet for non-electronic autoinjectors. However, Rytec Circular (n.d.) expects upcoming EU regulations (Fig. 33).
- Autoinjectors containing a battery should follow the WEEE regulation.

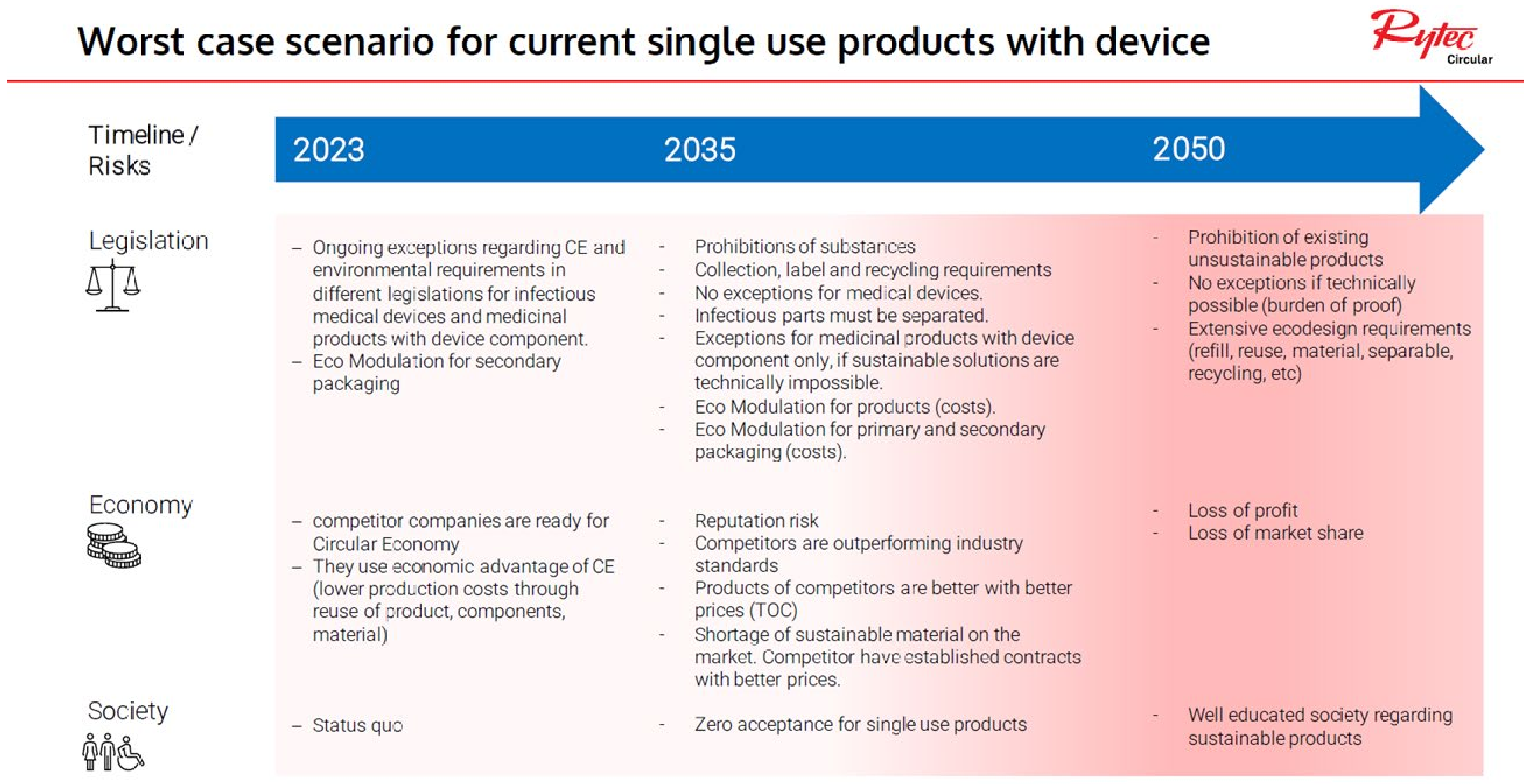


Fig. 33: Possible upcoming regulatory, economical, and societal influences that could force the YpsoMate autoinjector to become more sustainable (Rieder & Koch, n.d.)

2.5 | Autoinjector market

2.5.1 Growth in global market

The autoinjector market is growing rapidly. The European autoinjector market, which is the focus of this thesis, is estimated to be growing at a rate of 16% from 2022 to 2027. Therefore, the market is estimated to be worth 1.76 billion USD by 2027 in comparison to 0.83 billion USD in 2022.

Reasons for this growth are an increase in chronic diseases and the use of home healthcare, the growth of the biologics industry, technological advancements and the approval of more self-injection devices. (Strategic Market Research, 2021)., including;

There are currently more than 20 pharmaceutical companies that have developed nearly 80 autoinjectors. Of the around 50 approved drug-autoinjector combinations, 62% are disposable single-use autoinjectors (Roy et al., 2021). These offer proven delivery platforms for a wide variety of drugs. The other 38% are reusable autoinjectors (Fig. 34), which are often electronic and form a niche of bespoke systems for single drugs and individual pharma companies (Scrase & Philips Medisize, 2021).

Takeaways

- The autoinjector market is growing due to an increase in home healthcare, chronic diseases, a variety of drugs and connected devices.
- The current dominating design (62%) is single-use disposable autoinjectors.

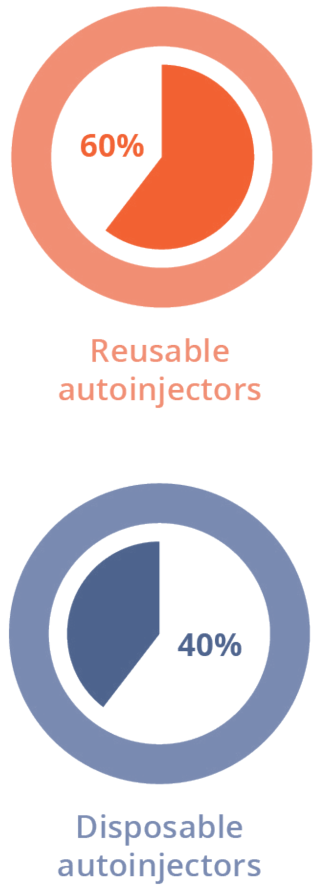


Fig. 34: Sixty percent of the approved drug-sutoinjector combinations are single-use (Roy et al., 2021).

2.5.2 Ypsomed's market involvement & competitors

Ypsomed is a significant player in the global autoinjector market, with a market share of approximately 50% (Gerner, 2022). According to Sebastian Gerner (2022), Corporate Sustainability Manager at Ypsomed, Ypsomed's main competitor in the field of autoinjectors is SHL Medical. Other competitors include Haselmeier and Owen Mumford (Knowledge Sourcing Intelligence LLP, 2019).

In 2022, Ypsomed produced tens of millions YpsoMate autoinjectors, with an equal division between the 1.0 mL and the 2.25 mL versions. Ypsomed estimates to produce hundreds of millions autoinjectors by 2030 (Gerner, 2022), This makes it even more important to launch sustainable autoinjectors on the market, to limit the harmful environmental impact of the increasing production.

According to Gerner (2022), the main market of the YpsoMate autoinjector is fragmented over Europe, in the U.S. and Japan, even though they are also active in Asia (India & China). This thesis focuses on the European autoinjector market.

Takeaways

- Ypsomed estimates to produce hundreds of millions YpsoMate autoinjectors in 2030, making it even more important to make these sustainable.
- This thesis focusses on the European autoinjector market.

2.5.3 Competitors in the Sustainable Autoinjector Market

The sustainable autoinjector market is a rapidly growing area within the overall autoinjector market (Simpson, 2020) driven by increasing awareness of sustainability in the healthcare sector, regulatory pressures, and consumer demands (Patel & Sheridan, 2021). To improve the sustainability of autoinjectors, companies are taking several measures.

Reusable Autoinjectors

Philips (Fig. 37 & Fig. 38) and Jabil (Fig. 35) are among the companies developing reusable autoinjectors, reducing the need for disposable devices and associated waste. However, both of these autoinjector require battery charging, since they can connect to a phone and a are motor-driven.

Therefore, there is a gap in the market for non-electronic, spring-powered autoinjectors that can be refilled at specialized hubs, creating an opportunity to develop sustainable devices accessible to patients who may not have the physical capability to perform the refill movements, such as those with MS or rheumatoid arthritis. This thesis explores this opportunity.

Autoinjector Recycling

Johnson and Johnson (Gysel & Johnson & Johnson, n.d.) and Novo Nordisk (PenCycle, n.d.) have launched take-back schemes to recycle autoinjectors.

Supply Chain Optimization

SHL Medical has optimized its supply chain to improve the efficiency of production and transportation processes. Additionally, the company uses solar energy to reduce CO2 emissions.

Reduced Part Count

The PiccoJect autoinjector (Fig. 36) from Haselmeier is a disposable, single-use autoinjector aiming to minimize its impact by reducing the part count and optimizing component wall thickness (Metzmann & Muenzer, 2022). This approach helps Haselmeier reduce material use and, thus, its environmental footprint.

Takeaways

- The sustainable autoinjector market is experiencing rapid growth due to rising awareness, regulatory pressure, and consumer demands.
- Measures to improve the sustainability of autoinjectors include recycling and reusing them, optimizing the supply chain, and reducing the part count.
- These measures served as inspiration for the development of the YpsoMate Refill concept.

Fig. 35: The Qfinity reusable autoinjector platform (Jabil, n.d.)

Fig. 36: The PiccoJect has a reduces part count to save CO2e emissions (Haselmeier, n.d.).

Fig. 37: Reusable Philips Aria prototype (Philips-Medisize, 2023)

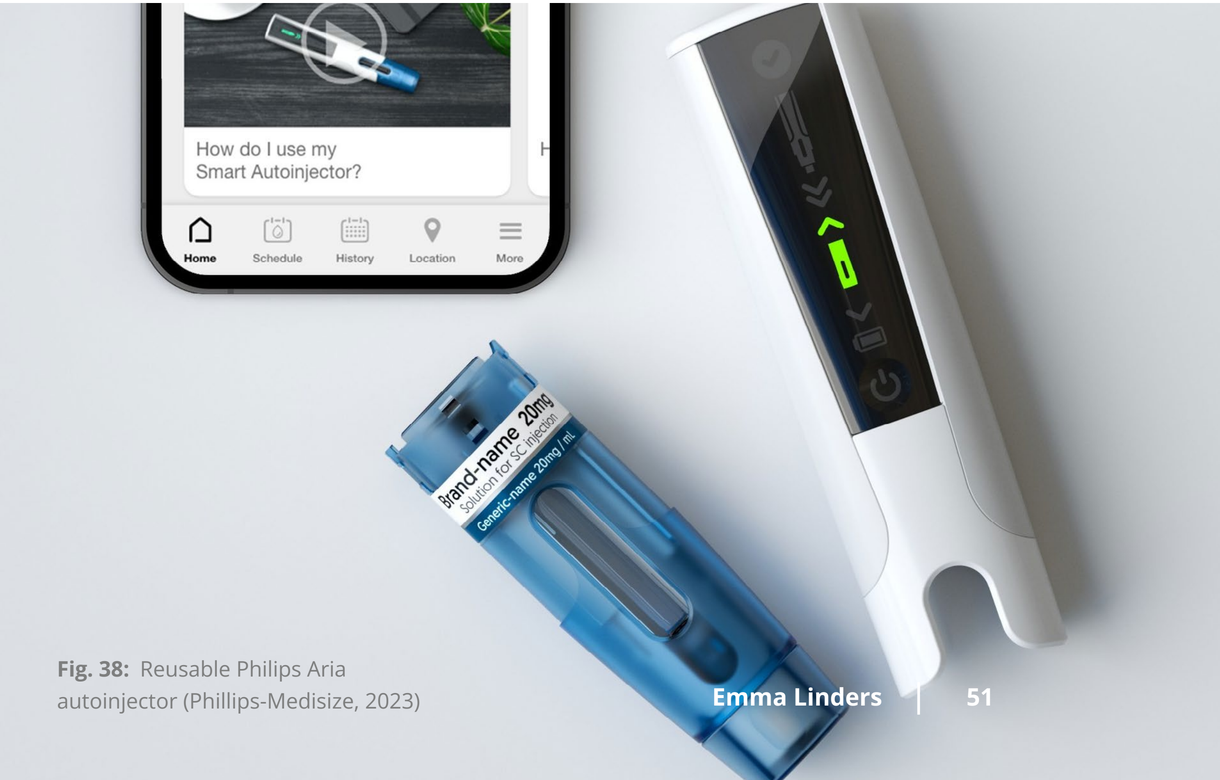


Fig. 38: Reusable Philips Aria autoinjector (Phillips-Medisize, 2023)

2.5.4 Stakeholders in the sustainable autoinjector market

The stakeholder map (Fig. 39) for the sustainable autoinjector market depicts the interests and level of influence of stakeholders concerning sustainability. The arrows illustrate the influence of stakeholders on each other, except for those of lawmakers (government) who impact each stakeholder through new regulations. While the placement of each stakeholder on the map is based on estimates, it provides valuable insights into the market's dynamics.

Ypsomed is actively developing sustainable autoinjectors, but the adoption of these devices for drugs lies with pharmaceutical companies, making them critical players with significant influence.

Takeaway

- Ypsomed is committed to developing sustainable autoinjectors, but the pharmaceutical companies responsible for developing the drugs are crucial players in ensuring these devices are used.

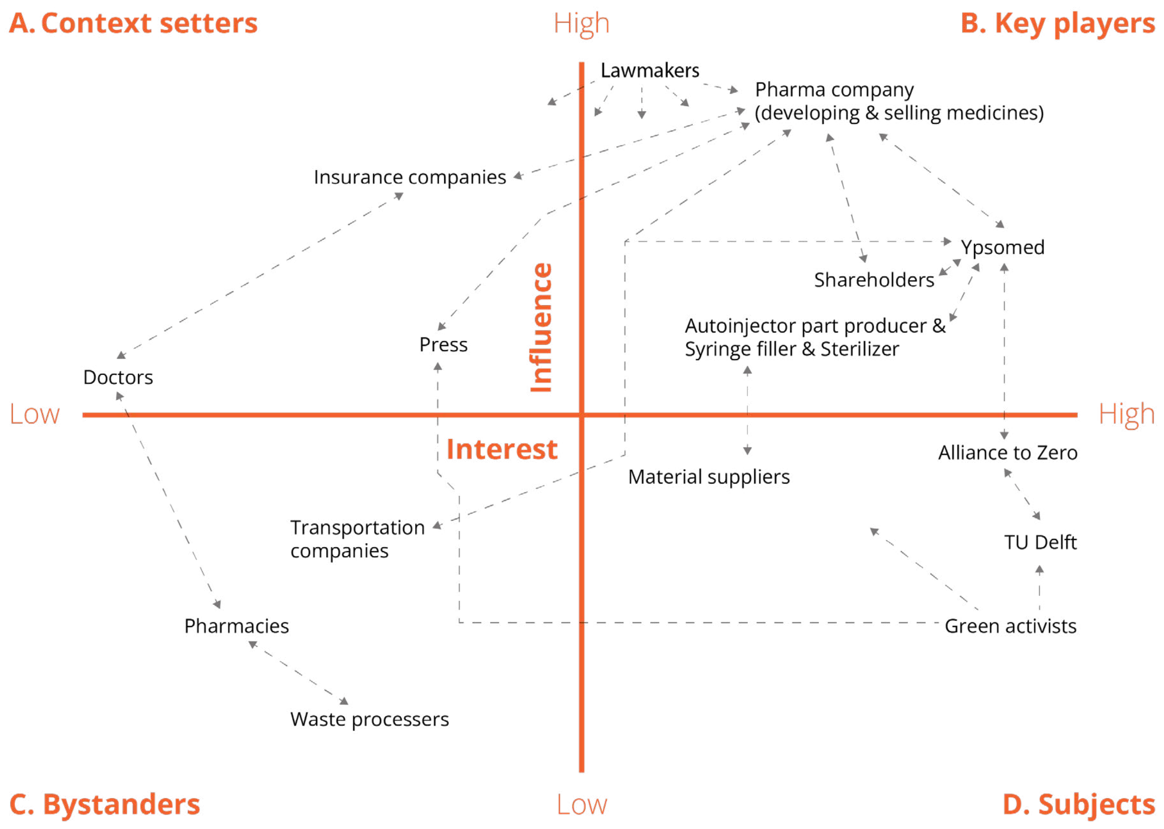


Fig. 39: Stakeholder map of the YpsoMate autoinjector.

2.6 | Supply chain YpsoMate

Currently, the supply chain of a YpsoMate autoinjector is linear. Fig. 40 shows a simplified version of this chain, which ends at incineration.

However, in reality, the production of the YpsoMate autoinjector involves a complex supply chain of companies that produce different parts. To create a more sustainable supply chain, these companies have united in the Alliance to Zero. Appendix E gives an in depth overview of this supply chain.

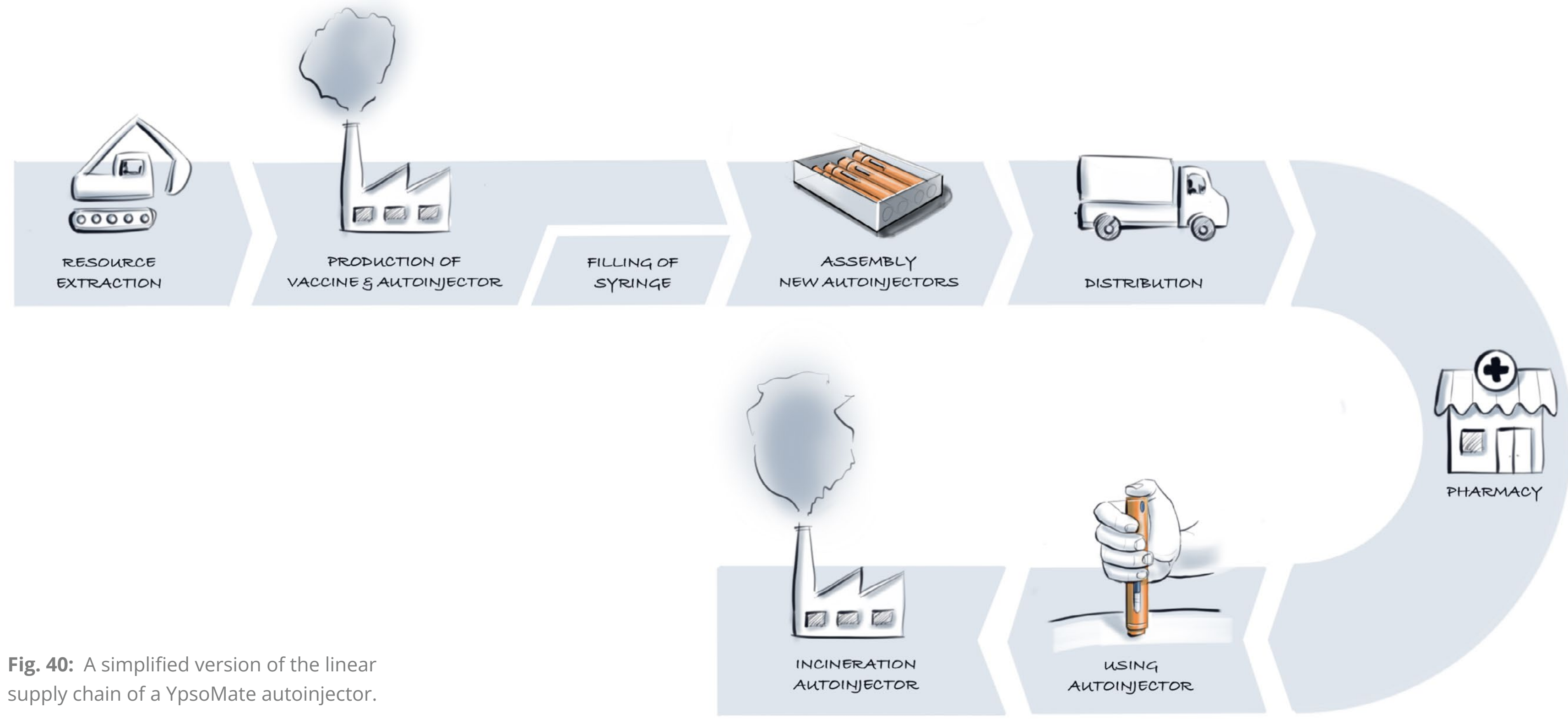


Fig. 40: A simplified version of the linear supply chain of a YpsoMate autoinjector.

2.6.1 Production YpsoMate

The list below and Fig. 41 summarize the involvement of Alliance to Zero companies in the supply chain of the YpsoMate autoinjector:

- **SCHOTT Pharmaceutical Systems** produces and sterilizes the glass syringe.
- **Datwyler** produces the rubber plunger and the soft and rigid needle shield.
- **Ypsomed** produces all the injection moulded parts, such as the housing, Drive unit, and cap. It also assembles the autoinjector parts into subassemblies, which are then send to Sharp.
- **Schreiner** produces the label.
- **Körber** prints and cuts the secondary packaging boxes that the patient receives
- **Sharp** receives all the autoinjector parts and subassemblies from the companies mentioned above and assembles, labels and packages the YpsoMate autoinjector.

Takeaway

- The production of an YpsoMate autoinjector involves a complex supply chain of companies in Germany, Switzerland and Belgium.

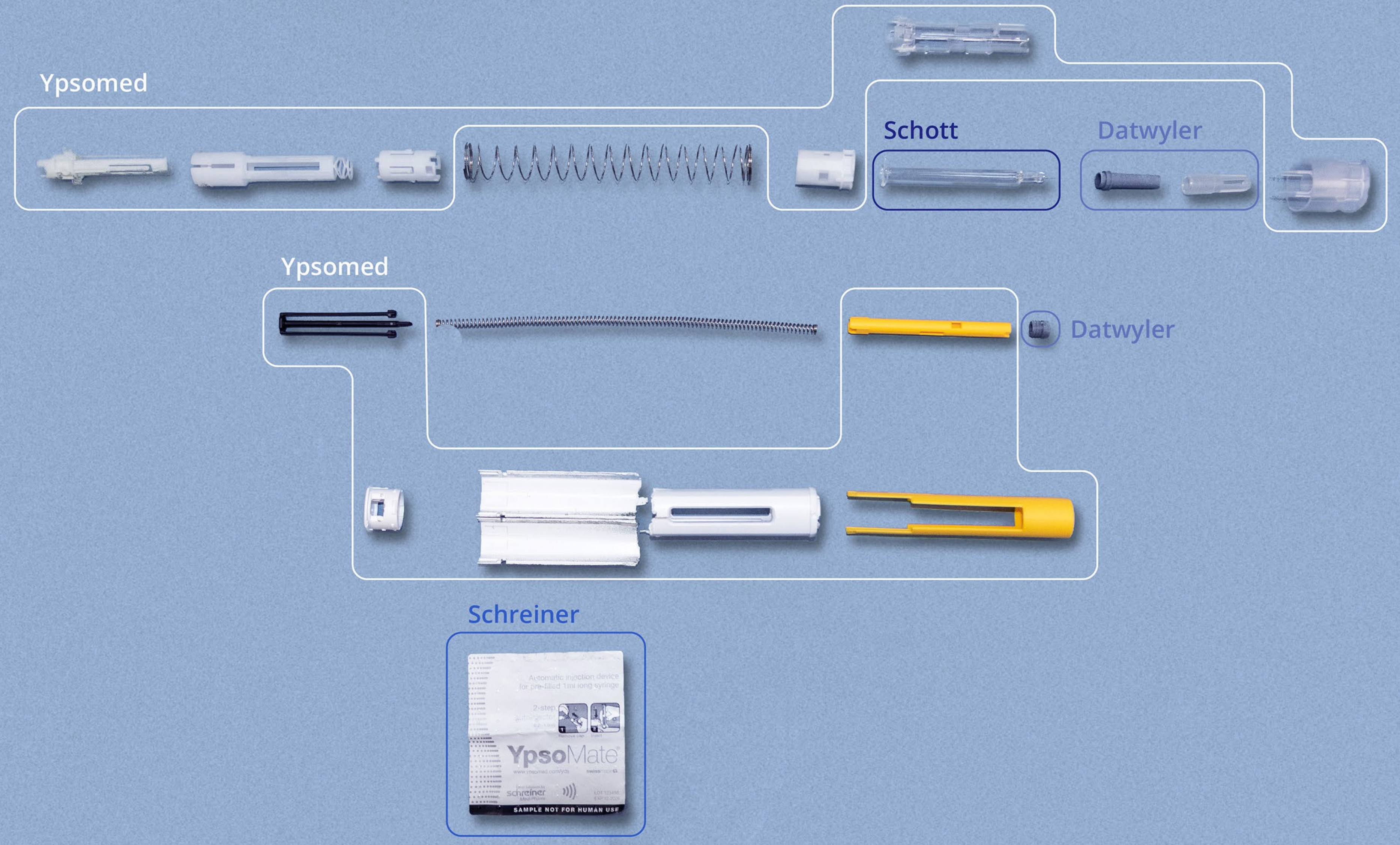


Fig. 41: An overview of the YpsoMate parts linked to the company that produces them. If a part is not linked to a company, it is produced by an company outside the Alliance to Zero

2.6.2 Reverse logistics autoinjectors

Reverse logistics for refilling autoinjectors would involve collecting used devices, disassembling them, cleaning, and disinfecting the contaminated parts, and conducting a quality check before reassembling them into fully functional autoinjectors. Currently, a specific reverse logistics system for refilling autoinjectors does not exist. However, this chapter examines existing logistics that could be relevant and adapted for refilling autoinjectors.

Collecting used autoinjectors

Currently, companies such as Novo Nordisk (PenCycle, n.d.) (Fig. 44) and Johnson & Johnson (Safe Returns, n.d.) implementing programs for collecting used autoinjectors. Both achieve a 50% return rate of used autoinjectors (Novo Nordisk, n.d.; Johnson & Johnson, n.d.).

Novo Nordisk launched take-back services for used pen injectors in the UK, Brazil, France, the US, China, Japan, Germany and Italy. Here, they collect used pen injectors through pharmacies (Fig. 42), pre-paid post boxes, or home collection (Fig. 43). Novo Nordisk found that convenience, trustworthiness, and flexibility were key priorities for patients, while safety and simplicity were key for pharmacists.

Fig. 42: Collection box for used pen injectors at a pharmacy (Novo Nordisk , 2022).

Fig. 43: Return box for pen injectors (PenCycle, n.d.).

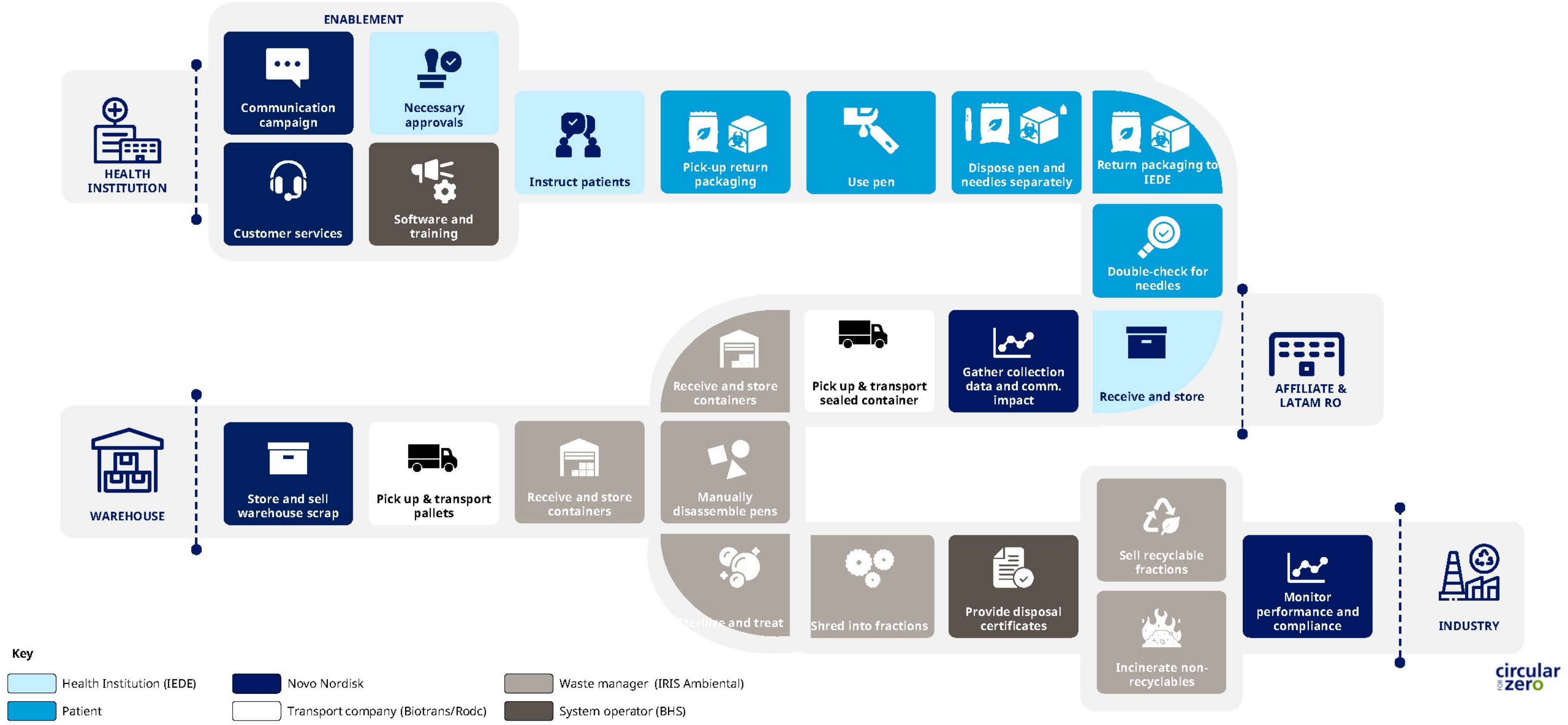


Fig. 44: Novo Nordisk PenCycle logistics (Jensen, 2022)

Dis- and reassembly

Ypsomed possesses both an in-house assembly line and expertise in assembly. Additionally, Johnson & Johnson is developing a disassembly and recycling machine (Fig. 45 & Fig. 46) for autoinjectors from various brands, including the YpsoMate 1.0 mL, YpsoMate 2.25 mL, and YpsoMate Pro. Gerner (2022) indicates that Ypsomed sees this as a beneficial strategy that pharmaceutical companies, such as Johnson & Johnson, set up a disassembly and recycling hub. They use autoinjectors from different brands (Ypsomed, SHL Medical). By combining the disassembly and recycling of autoinjectors from different brands, they can generate a larger return stream and allow for economies of scale. This could be an efficient and cost-effective strategy in the long run.

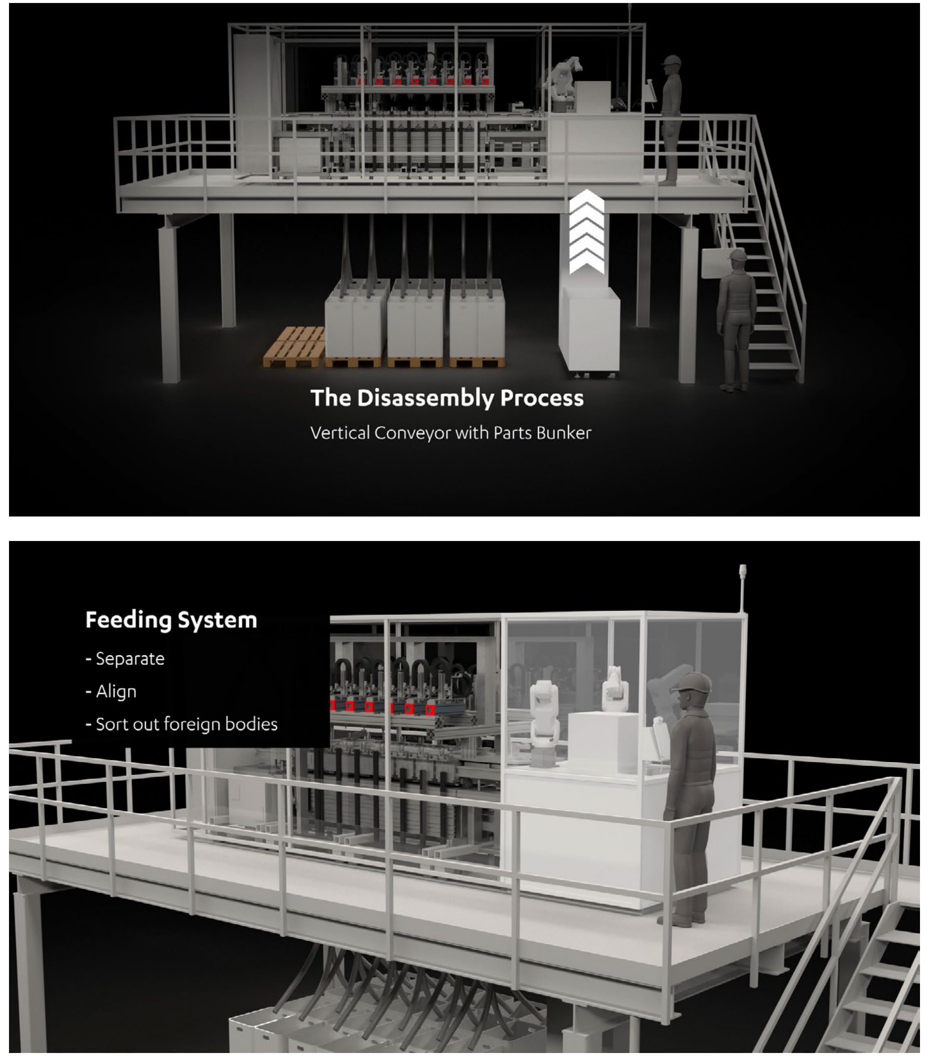


Fig. 45: Renders of an autoinjector disassembly & recycling system (Johnson & Johnson, 2022).

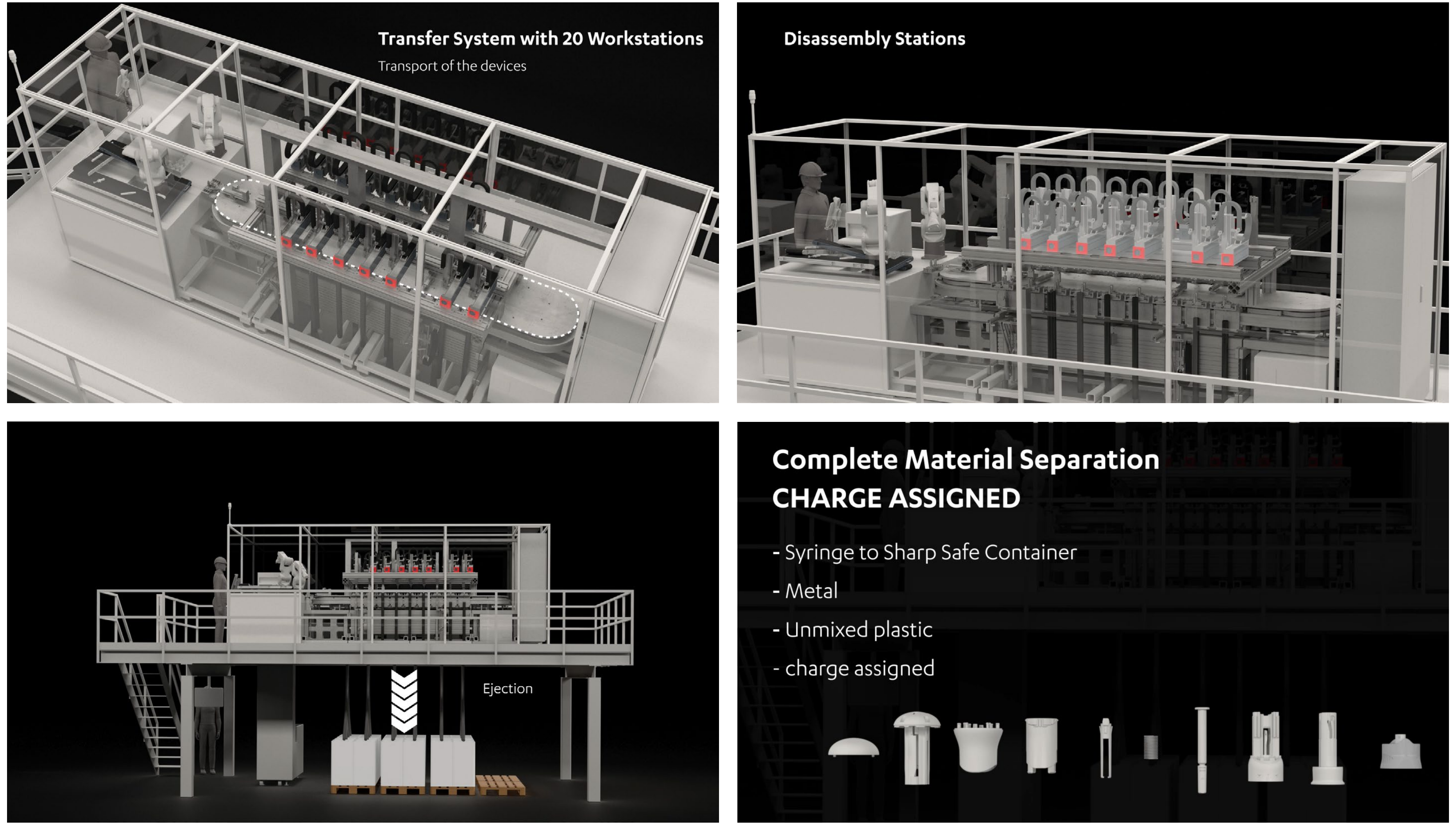


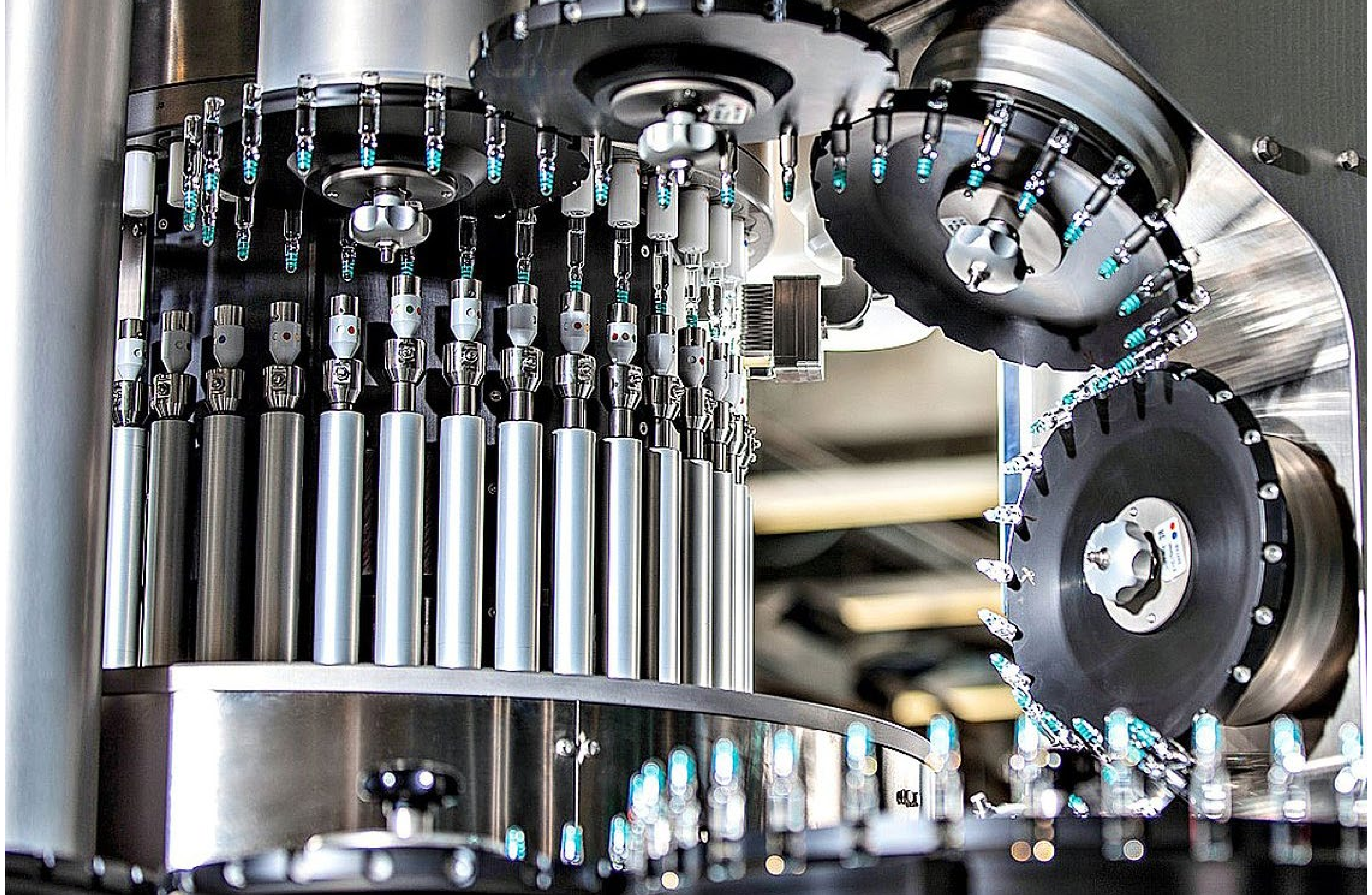
Fig. 46: Renders of an autoinjector disassembly & recycling system (Johnson & Johnson, 2022).

Quality check

During my visit to the Ypsomed factory in Burgdorf, I observed that the quality check process for their autoinjectors is destructive and not automated. This method involves testing the device to its limits using testing equipment, after which the autoinjector is discarded. Since only a small percentage of an autoinjector batch is checked, the destruction of the devices is acceptable.

In a refill scenario, more autoinjectors likely need to be tested to guarantee quality after reuse. This raises the challenge of finding a way to check the quality of used autoinjector parts without destroying them. One potential solution is to use camera inspection to detect scratches and breakages, as this method is already used for prefilled syringes (Fig. 47) (Körber, n.d.). Other technologies should also be explored to ensure that autoinjectors can be reused safely.

Fig. 47: Automatic quality inspection of Prefilled Syringes via a camera, high voltage, and laser (Körber, n.d).



Takeaways

- Existing pen and autoinjector return programs include collection through pharmacies, pre-paid post boxes and home collection.
- The current return rate in pen and autoinjector take-back schemes is 50%.
- Johnson & Johnson is developing disassembly and recycling hubs for YpsoMate autoinjectors and other brands.
- Current autoinjector quality checks are destructive. Non-destructive checks should be explored to ensure the safety of reused autoinjector parts.

3. Circular design

This chapter explores the role of refillable autoinjectors in the circular economy, and how circular design strategies can be used to enhance their sustainability. Additionally, it presents various circular business models that can be applied to the autoinjector industry.

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3.1 | Circular economy definition

The goal of this master thesis is to redesign an autoinjector that fits into the circular economy, with a focus on reuse. Therefore, this chapter explores the circular economy.

As an alternative to the linear take-make-dispose economy, a circular economy is an industrial system that is restorative or regenerative by intention and design. (Ellen MacArthur Foundation, 2012).

By analysing 114 definitions of a circular economy, Kirchherr et al. (2017, p.229) defined the circular economy as the following;

"an economic system that replaces the 'end-of-life' concept with reducing, alternatively reusing, recycling and recovering materials in production/distribution and consumption processes. It operates at the micro level (products, companies, consumers), meso level (eco-industrial parks) and macro level (city, region, nation and beyond), with the aim to accomplish sustainable development, thus simultaneously creating environmental quality, economic prosperity and social equity, to the benefit of current and future generations. It is enabled by novel business models and responsible consumers."

In summary, "in a circular economy the value of products and materials is maintained for as long as possible; waste and resource use are minimised, and resources are kept within the economy when a product has reached the end of its life, to be used again and again to create further value" (European Commission, 2015).

The circular economy aims to design out waste. In reality, a perfect circular economy is impossible, because there will always be some leakage of materials. But striving towards a circular economy could help to limit the harmful environmental impact of our society.

The EU Circular Economy Action plan (European Commission, 2020) describes the shift towards a circular economy as necessary to create new sustainable advantages, protect businesses from future potential resource scarcity, and boost the economy. New legislation (chapter 2.4) is compelling companies to adapt to the circular economy (Sehnem et al., 2019)

Takeaways

- In the circular economy, product and material value is maintained as long as possible.

3.2 | Resource cycles

The circular economy's aim is to eliminate waste by creating a continuous flow of materials, as shown in the butterfly diagram (Fig. 49, Ellen MacArthur Foundation, 2014). There are two cycles: the technical and biological, which reuse, refurbish, and recycle products and materials, or return biodegradable materials to nature.

The diagram shows a hierarchy, with tighter cycles being preferable to outer ones due to their ability to save material, energy, and reduce greenhouse gas emissions, water usage, and toxic substances.

Moreover, circling longer is preferred, since this keeps the value potential of products, components and materials using them longer. (Ellen MacArthur, 2012)

Takeaway

- "The greenest product is the one that already exists, because it doesn't draw on new natural resources to produce." (Donahoe, cited in Bocken et al., 2014)

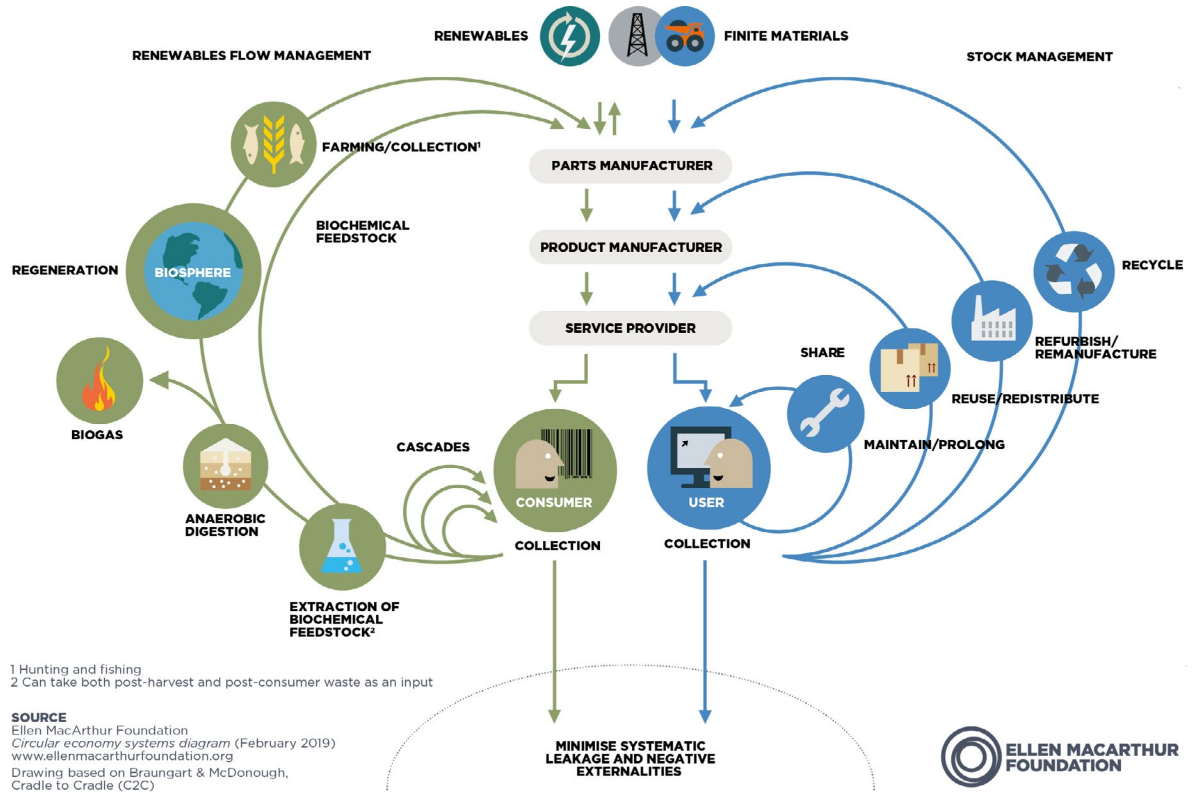


Fig. 49: Circular economy systems diagram – butterfly diagram (Ellen MacArthur Foundation, 2014)

3.3 | Value hill

Achterberg et al. (2016) proposes the value hill model to emphasize the importance of maintaining products at their highest value. The red line in Fig. 50 represents the value hill of linear products like autoinjectors. The product's value increases with each pre-use step, but once it reaches its peak, it is discarded and incinerated after one use, resulting in wasted energy, material, and potential.

However, Fig. 50 also shows an alternative to the linear value hill. By incorporating the 9R framework (Potting et al., 2017), products can be reused, refurbished, repurposed, and recycled to maintain their high value for as long as possible.

Takeaways

- Currently, the YpsoMate has a linear value hill.
- The value should be maintained by incorparating the 9R framework.

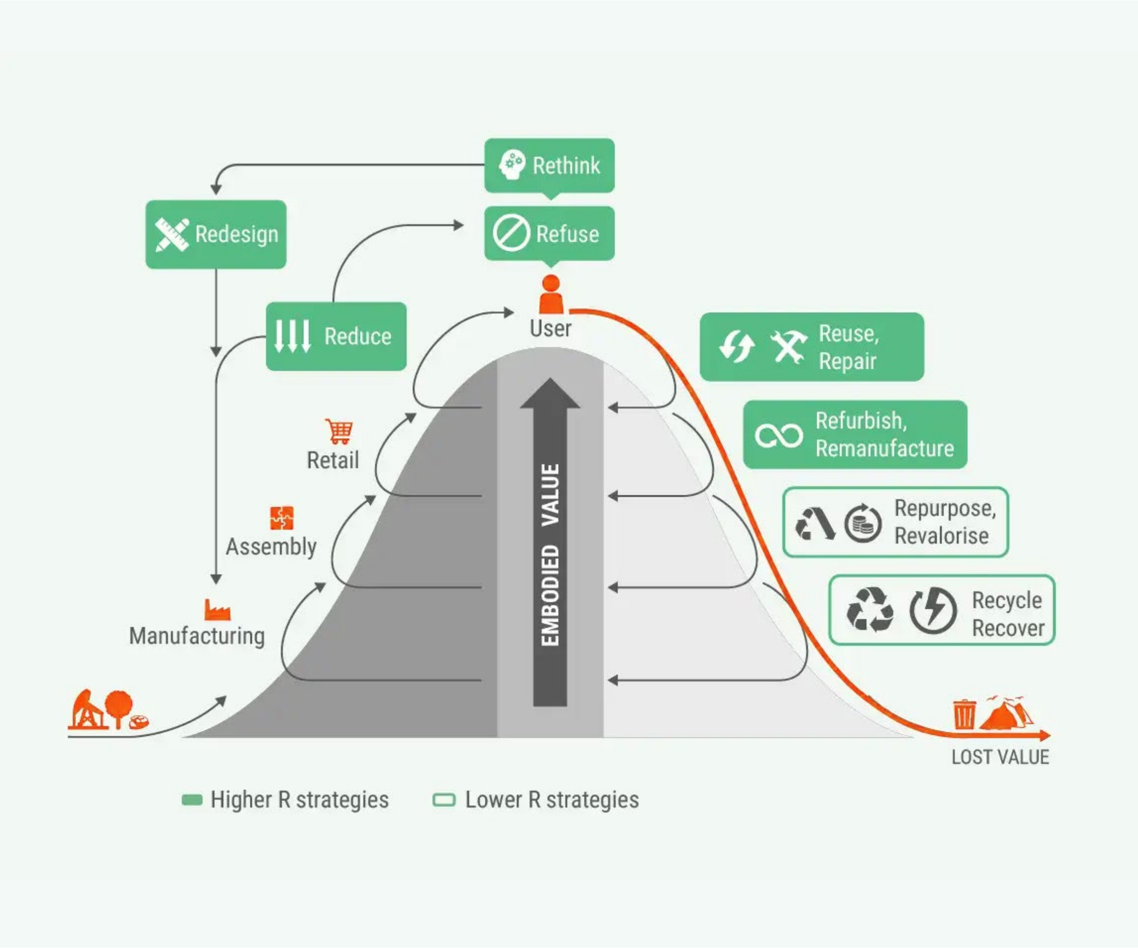


Fig. 50: Adapted Value Hill Model to include the 9R Framework (Metabolic, 2021)

3.4 | Circular product design strategies

Eighty percent of a product's environmental impact is determined in the design phase (European Commission, 2012).

This means that designers can lower this impact by applying circular product design strategies.

Table 2 on the next pages shows a collection of these strategies from Bocken et al. (2016), Bakker et al. (2014), Flipsen (2020) and (Institute of Design Research Vienna et al., 2021). Bocken et al. (2016) and the Ypsomed Ecodesign Guidelines. Fig. 51 links these strategies to the principles of reducing, reusing, recycling and regenerating (Konietzko et al., 2020).

Chapter 5 evaluates the YpsoMate autoinjector based on these product design strategies.

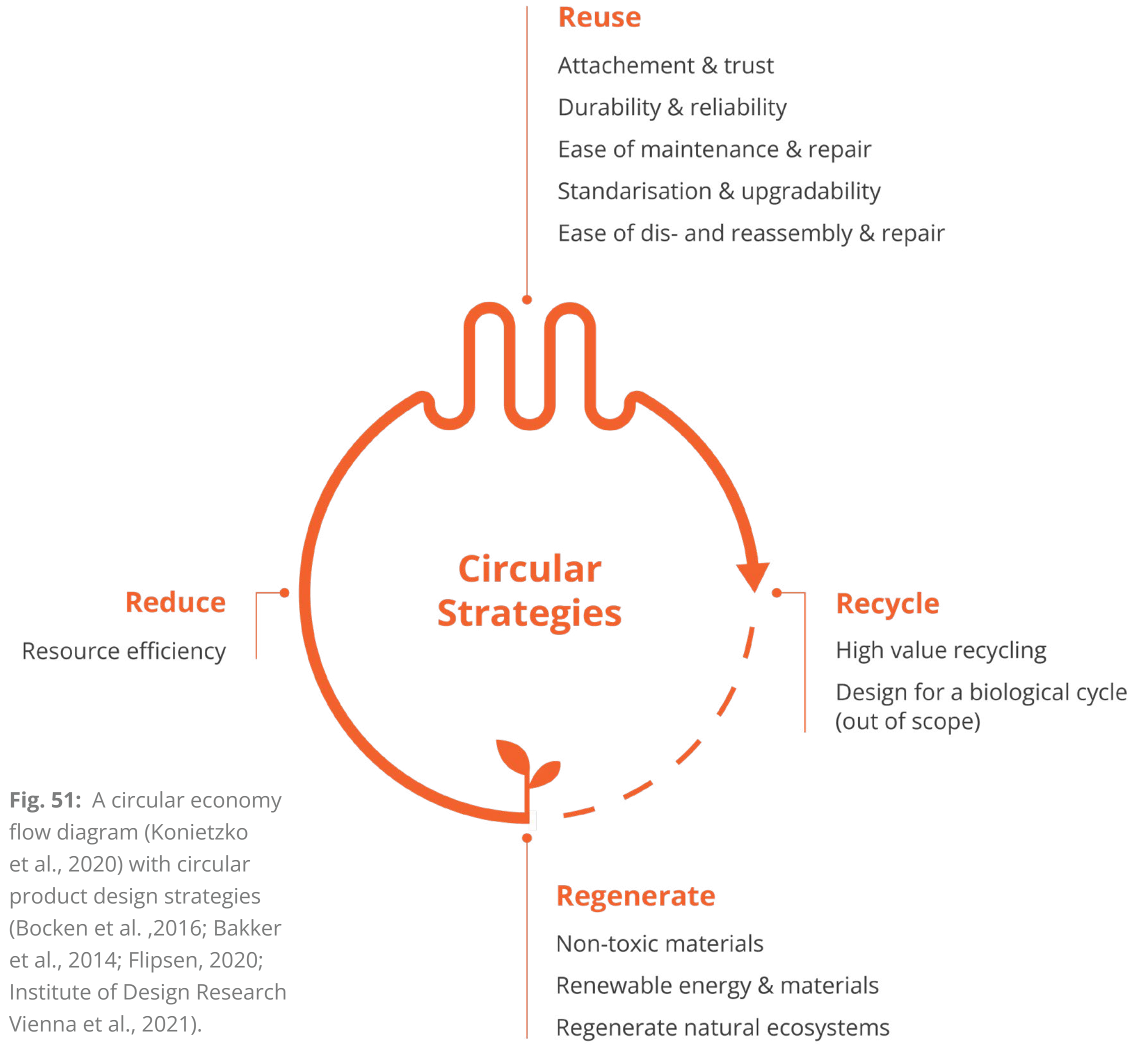
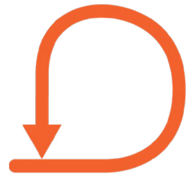


Fig. 51: A circular economy flow diagram (Konietzko et al., 2020) with circular product design strategies (Bocken et al. ,2016; Bakker et al., 2014; Flipsen, 2020; Institute of Design Research Vienna et al., 2021).

Table 2: A collection of circular product design strategies to slow, close and narrow resource flows.

Design strategy	Sub-strategy	Impact on design
Regenerate *Make resource flows clean* 	**Make clean**	• Use non-toxic materials. • Use renewable energy & materials. • Regenerate natural ecosystems.
Reduce *Narrow resource loops* 	**Design for resource efficiency**	• The amount of material and parts in a product is decreased. • Locally available materials are used. • Recycled or renewable materials are used. • A product's energy consumption is limited
Reuse *Extend the time materials spend in use before being disposed of.* 	**Design for attachment and trust**	Design for attachment is less relevant for the autoinjector since the patient uses it only once and then sends it back to the producer. Design for trust is relevant because the patient should trust the reused autoinjector to use it comfortably.
	Design for durability & reliability	• Materials are resistant to wear. • Structural design is resistant to damage.
	Design for ease of maintenance and repair	• Spare parts are available. • Parts that are likely to fail are easily accessible (low disassembly depth & time). • Reusable fasteners (no glue). • Since the autoinjector is a safety-critical product, it should be easily repairable by the producer, but not by the patient.
	Design for standardization & upgradability	• A minimum number of components is used in a wide range of product variants. • A modular design allows for upgrades of parts.

Design strategy	Sub-strategy	Impact on design
Reuse	**Design for dis- and reassembly**	The disassembly depth and time are decreased through: • Reusable visible fasteners are used for easy de- and reattachment. • Surfacing: the number of steps needed to reach a critical part is decreased. • Clumping: parts are grouped into sub-assemblies that can be easily taken out to reach critical parts. • The amount of parts is decreased. • Disassembly is automated or as efficient as manufacturing.

Design strategy	Sub-strategy	Impact on design
Recycle *Increase the number of materials that are recirculated instead of disposed of.*	**Design for a technological cycle: high-value recycling**	• A limited amount of recyclable mono-materials is used, so no composites. • Shredding separates materials in uniform (large) pieces, so no fixed connections with e.g. glue. • Electronics are easily removable. • Contaminated assemblies are encapsulated and easily separable. • A list of all materials contained in the product is available to make recycling easier (material passport). • Materials harmful to human health or the environment are minimized/excluded.
	Design for a biological cycle (out of scope)	• Materials are biodegradable. This is not relevant to project since the goal is to make the product long-lasting for reuse. Biodegradable materials make more sense for fast-moving products, such as single-use products (Haffmans et al., 2018).

3.5 | Circular business model strategies

Transitioning from a linear to a circular economy means moving away from the “sell more, sell faster” business model to circular business models. This chapter explains the circular business models as described in the book ‘Products that last’ (Bakker et al., 2014). The YpsoMate Refill uses the access model, as described in chapter 6.

3.5.1 The classic long-life model

This model creates revenue through the sales of a high-quality long-lasting product. For the autoinjector market, there is no example of this business model, since autoinjectors cannot be reused indefinitely without replacing the needle and medicine syringe.

3.5.2 Hybrid model

Patient-refillable autoinjectors, such as the Philips Aria, are examples of a hybrid model. Philips sells injection cartridges with a short lifespan, which are used together with a high-quality durable refillable autoinjector.

3.5.3 The gap exploiter model

This model feeds on value gaps in the existing system without proposing anything new. In the autoinjector market, an example could be companies that earn money by recycling the autoinjectors and selling the materials (even though this is currently not happening).

3.5.4 Access model

The access model creates revenue by providing the user with access to a product, while the provider keeps ownership of the product. (Bakker et al., 2014) This business model is most suitable for the away-from-patient refillable YpsoMate. Ypsomed keeps the ownership of the autoinjector but lends it to patients, who return it after a single-use. This business model is further explored in chapter 6 & 7.

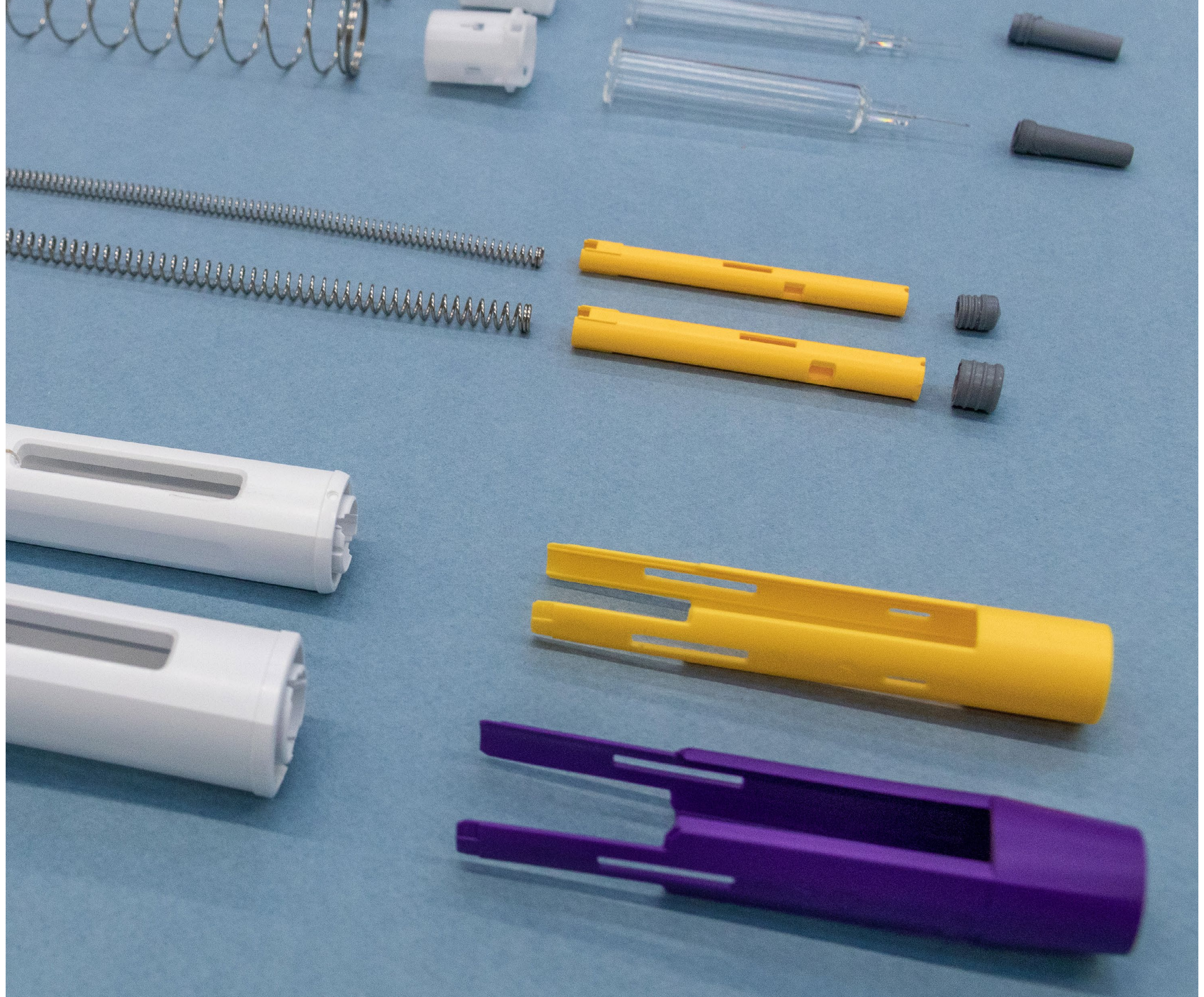
3.5.5 Performance model

Getting an injection at the doctor is an example of a performance model (Fig. 52). Users are not interested in the product (the injection), but only in the result and quality of the service (being vaccinated).

Fig. 52: Getting an injection at the doctor is an example of a performance model.

4. Key findings

This chapter summarizes the key findings of the previous chapter 2 and the upcoming chapter 5. It shows how the current single-use YpsoMate autoinjector performs in relation to the circular design strategies outlined in chapter 3. Moreover, this chapter connects the key findings to the requirements for the design phase (chapter 6 & 7).



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4.1 | Introduction Key Findings

This chapter presents a summary of the key research findings from chapter 2 and the upcoming chapter 5, and relates them to the requirements of the YpsoMate Refill concept. The key findings answer the first research question:

What is the current state of autoinjectors regarding the circular economy, particularly concerning refillability?

To accomplish this, I used the circular economy framework and circular strategies discussed in chapter 3 (Fig. 55).

Using the circular strategies as a guide, I evaluated the current single-use YpsoMates to identify areas for improvement. My analysis revealed that there is significant room for improvement to make the YpsoMate more compatible with the circular economy.

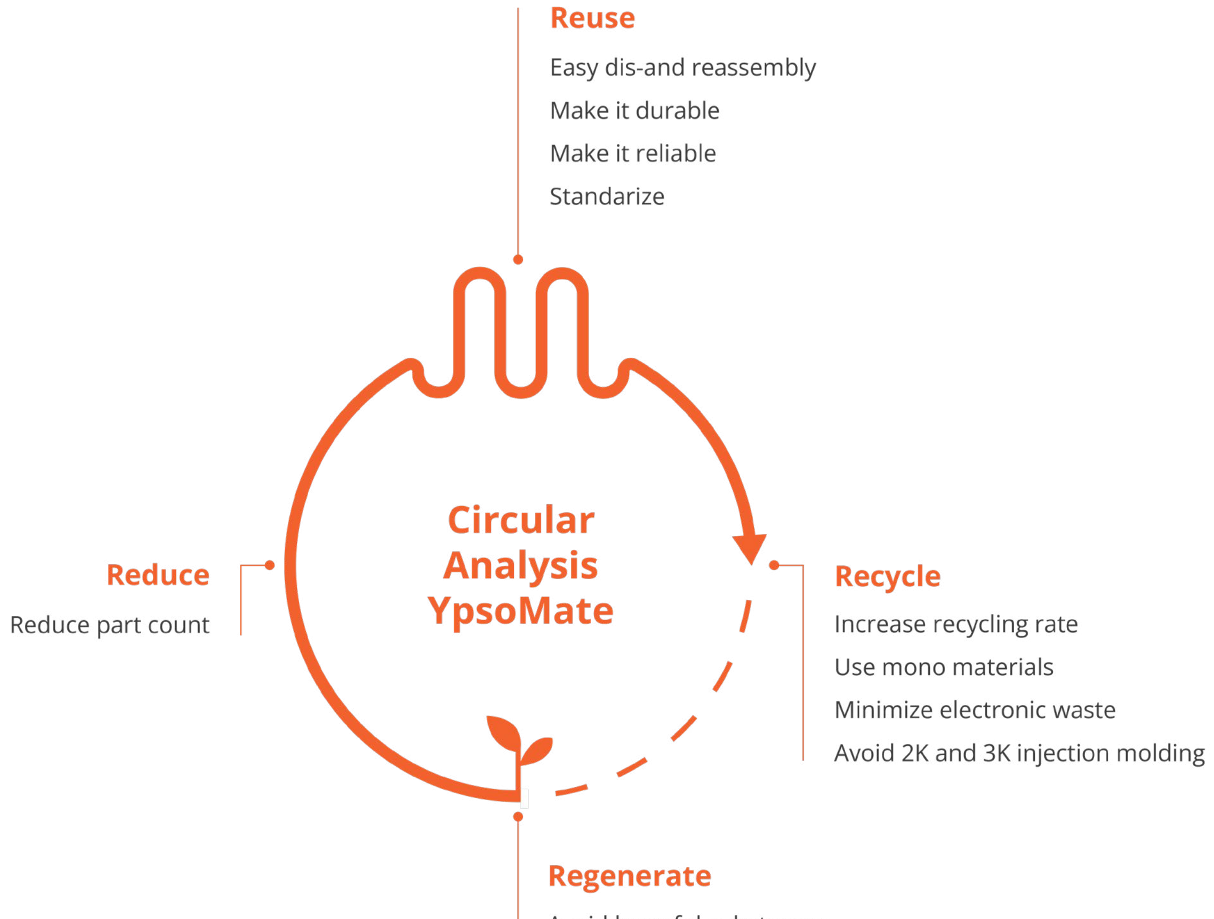


Fig. 55: The circular analysis insights of the single-use YpsoMates

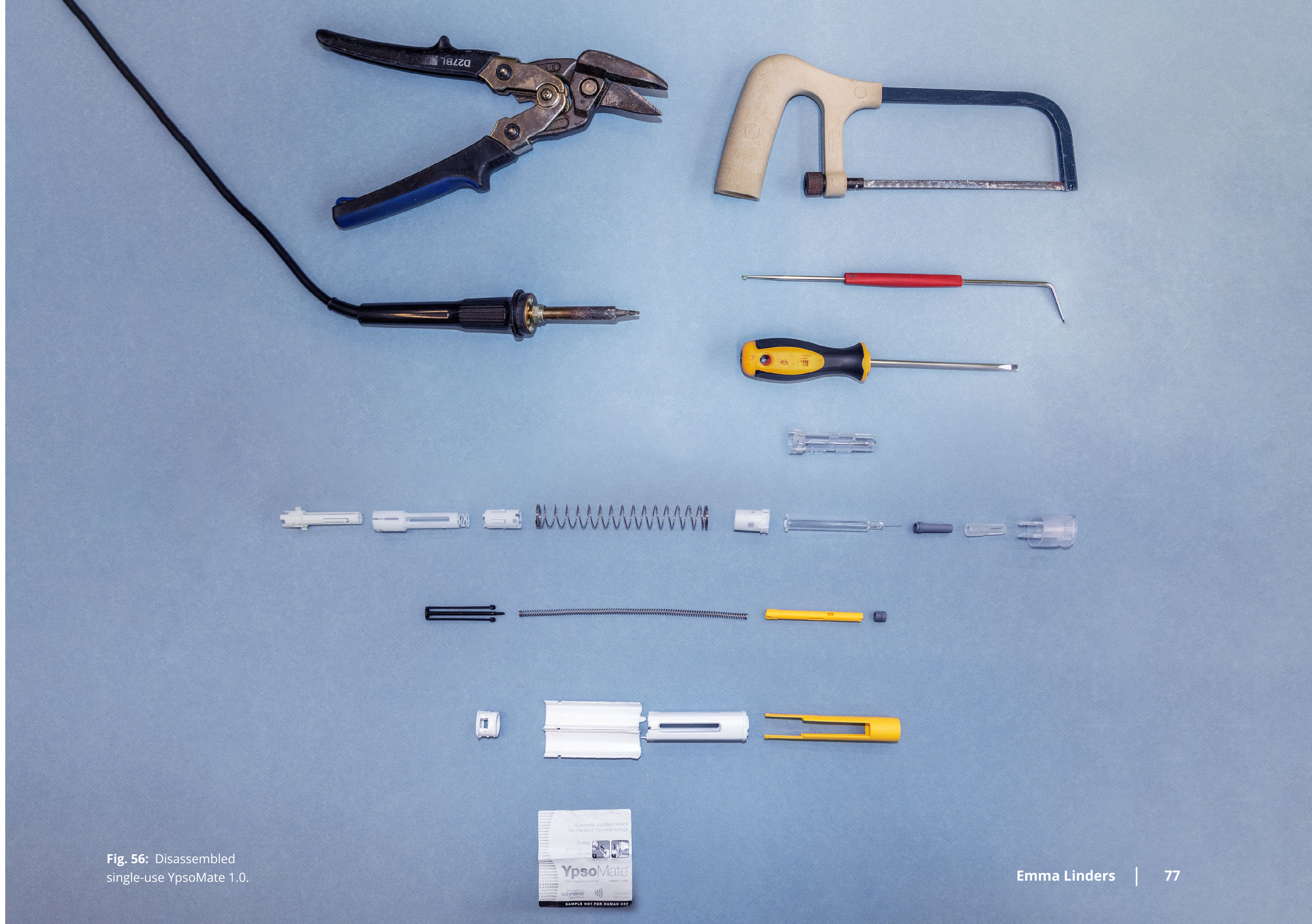
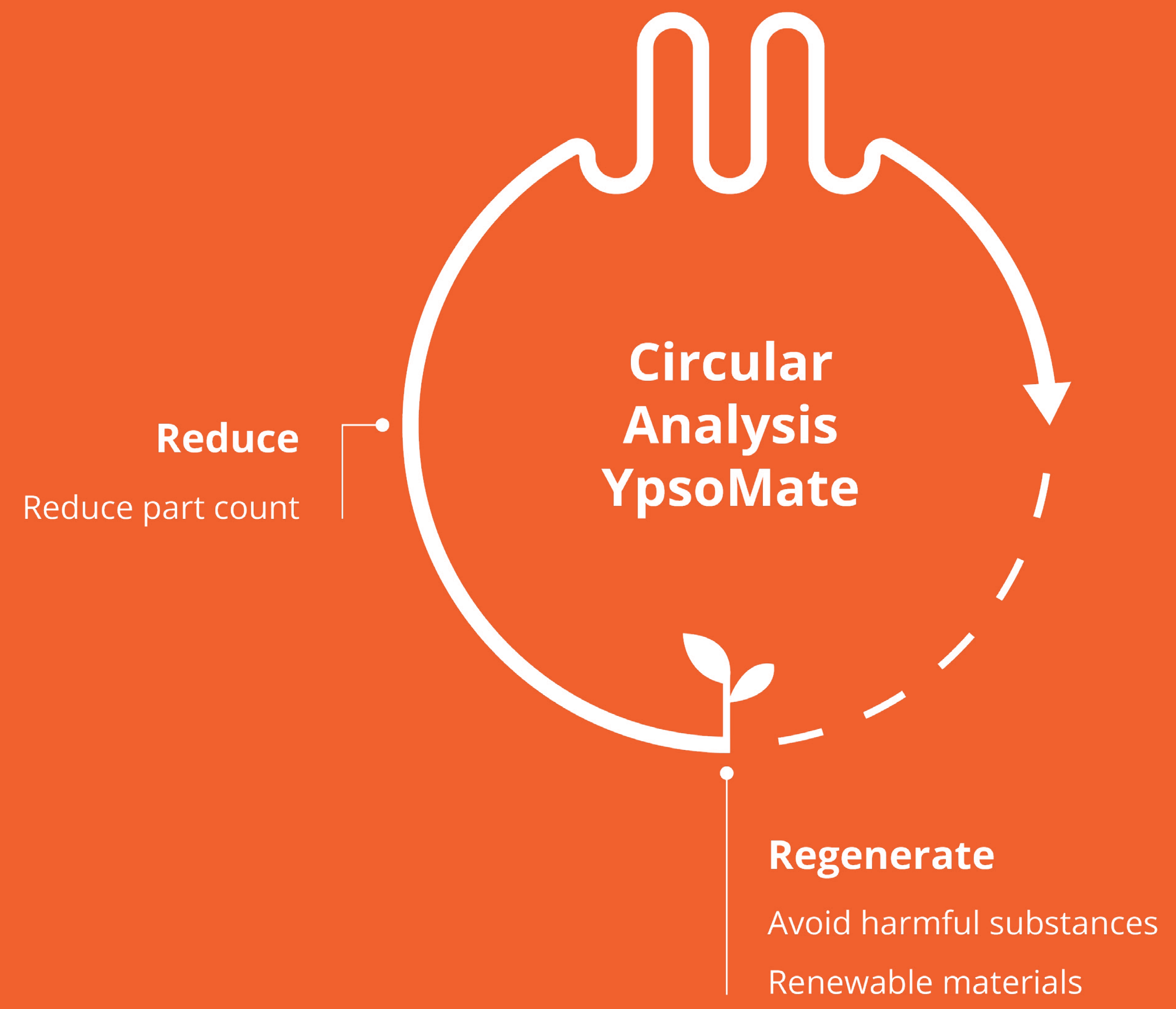


Fig. 56: Disassembled single-use YpsoMate 1.0.

Circular strategy A

Regenerate & Reduce



4.2 | Regenerate (RG)

Table 3: Regenerate insights and requirements based on the analysis of chapter 5.

Category	Insight	ID	Requirement
Avoid harmful substances	• The syringe, needle and plunger are sterilized with EO gas, which is a harmful substance for the environment.	RG1	Avoid environmentally harmful substances.
Renewable materials	• The single-use YpsoMate is made of virgin materials, while the YpsoMate Zero consists mainly of bioplastics	RG2	Use biobased plastics if possible.

4.3 | Resource efficiency (RE)

Table 4: Resource efficiency insights and requirements based on the analysis of chapter 5.

Category	Insight	ID	Requirement
Reduce part count	The YpsoMate 1.0 mL consists of 19 parts, which all add to the total CO2e impact of the autoinjector (Fig. 57).	RE1	Reduce the number of parts to the necessary functions.

Fig. 57: The YpsoMate autoinjector contains 19 parts.

Circular strategy **B**

Reuse

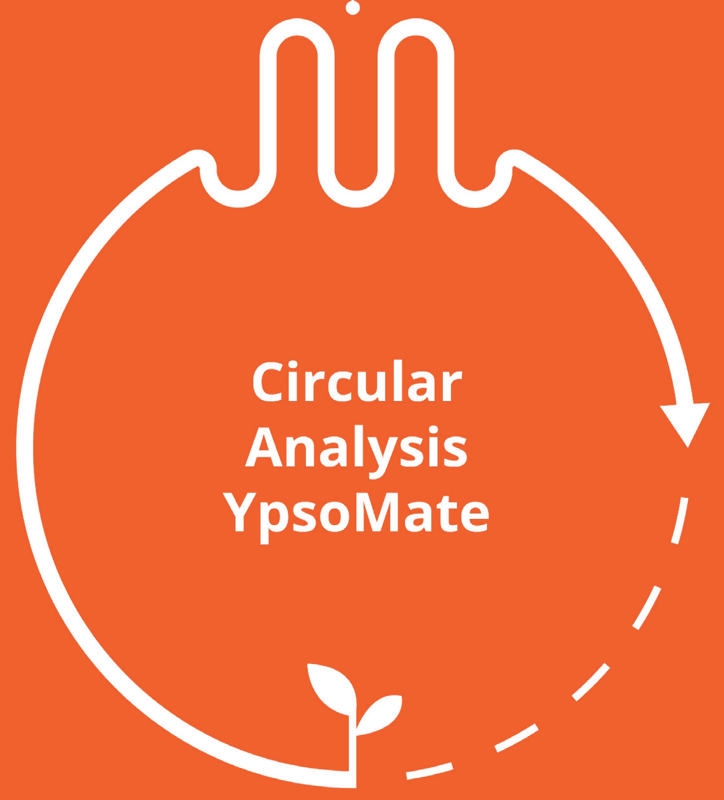
Reuse

Easy dis-and reassembly

Make it durable

Make it reliable

Standarize



4.4 | Ease of (dis)assembly (EoD) & repair

Table 5: Ease of (dis)assembly & repair insights and requirements based on the analysis of chapter 5.

Category	Insight	ID	Requirement
Reduce disassembly steps	It takes 18 steps and 19 minutes to disassemble a YpsoMate autoinjector (Fig. 58).	EoD1	Decrease the number of disassembly steps.*
		EoD2	Disassemble into subassemblies for immediate reuse, disinfection and recycling streams.
Reusable fixtures	To disassemble the YpsoMate, I needed to break parts (housing & mechanic holder).	EoD3	Apply reusable fasteners that are easily accessible for automated disassembly, but hard to access by the patient.

* Improvements refer to the single-use YpsoMate 1.0 mL as a baseline product.

Fig. 58: I needed to cut open the housing to remove the cover sleeve and syringe protector.

4.5 | Durability (D)

Table 6: Durability insights and requirements based on the analysis of chapter 5.

Category	Insight	ID	Requirement
Preventing damage during use	Patients could scratch or drop the housing during use.	D1	Minimize visual imperfections (scratches) on the outside of the YpsoMate.
		D2	The YpsoMate autoinjector withstands Ypsomed's drop-tests.*
		D3	When choosing materials, aim for durable ones with a low CO_2 impact and a high recycling rate.
Preventing damage during dis- & reassembly.	Disassembly may cause wear and tear to parts (Fig. 59 & Fig. 60).	D4	Disassembly is limited to parts that need to be disposed of, disinfected or replaced.

* I will not test this during this graduation project, since it is out of scope, but it is a requirement for the final YpsoMate autoinjector and should be evaluated by Ypsomed.

Fig. 59: The plastic spring broke of the Click Sleeve during manual disassembly.

Fig. 60: I scratched the polycarbonate housing on purpose with a sharp stainless steel part. These scratches do not occur during normal use.

4.6 | Reliability

Table 7: Reliability insights and requirements based on the analysis of chapter 5.

Category	Insight	ID	Requirement
Patient safety	Patient safety and high quality drug administration are the most important features of an autoinjector.	R1	Patient safety & high quality drug administration above all else.
Sterilisation & disinfection	In the current single-use YpsoMate. the needle, syringe and rubber plunger are sterilized. The other parts do not require sterilization or disinfection, because they are newly produced in a clean factory.	R2	Sterilize or disinfect parts of the reused autoinjector according to the Spaulding Classification (Fig. 61).
		R3	Contaminated critical parts are easy to separate without contaminating other parts.
Trust	In order for the YpsoMate Refill to be a success, patients should feel safe to use it and trust it.	R4	Patients trust the reused autoinjector.

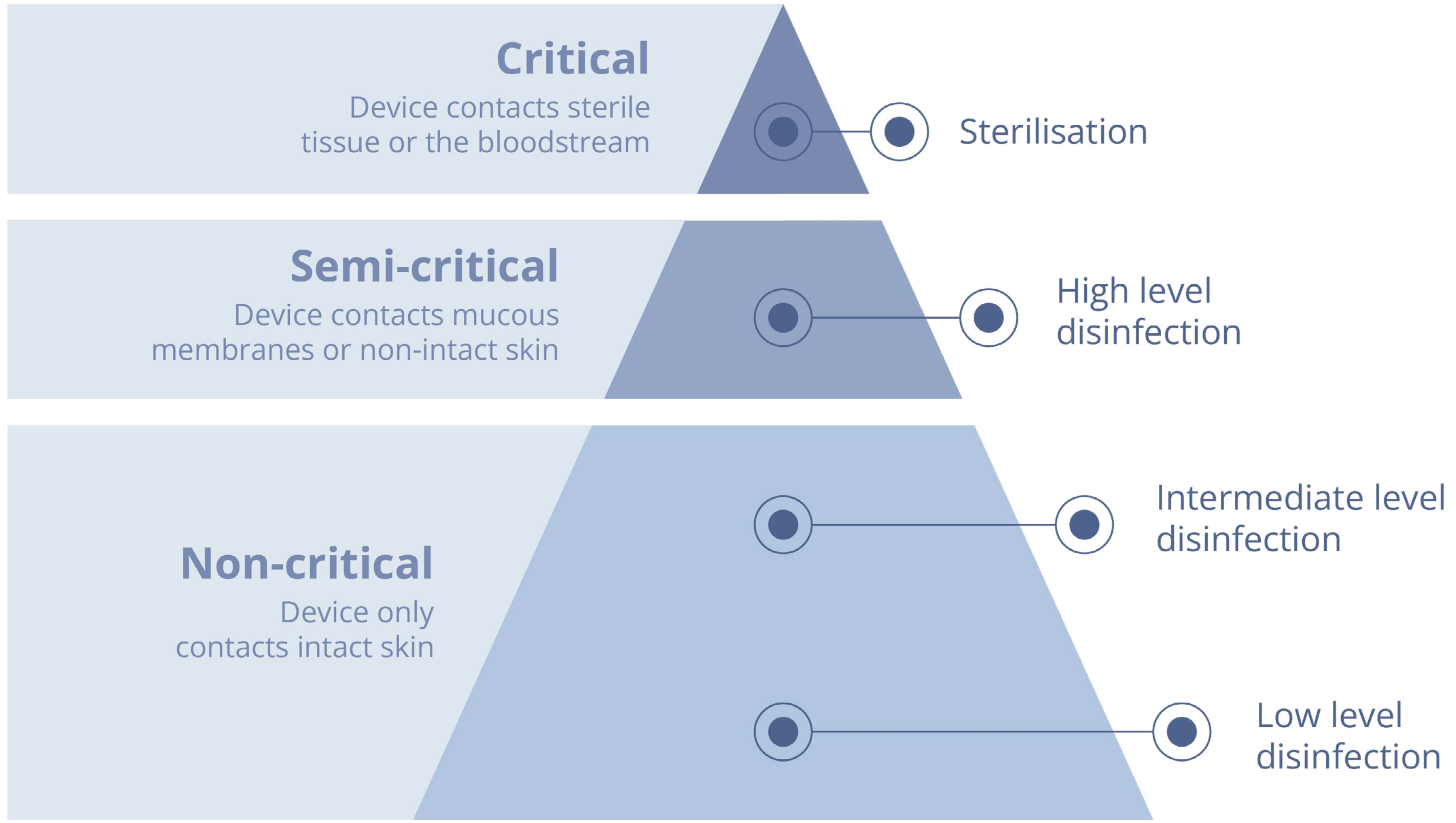


Fig. 61: The Spaulding classification (1967) for sterilization & disinfection

4.7 | Standardization (S)

Table 8: Standardization insights and requirements based on the analysis of chapter 5.

Category	Insight	ID	Requirement
Limit customization to large reusable batches	Currently, pharma companies can customize the plunger rod color, cover sleeve color, label, housing and needle size of YpsoMate's (Fig. 62).	S1	Limit customization single use parts and/ or to batches large enough for their own reuse stream.

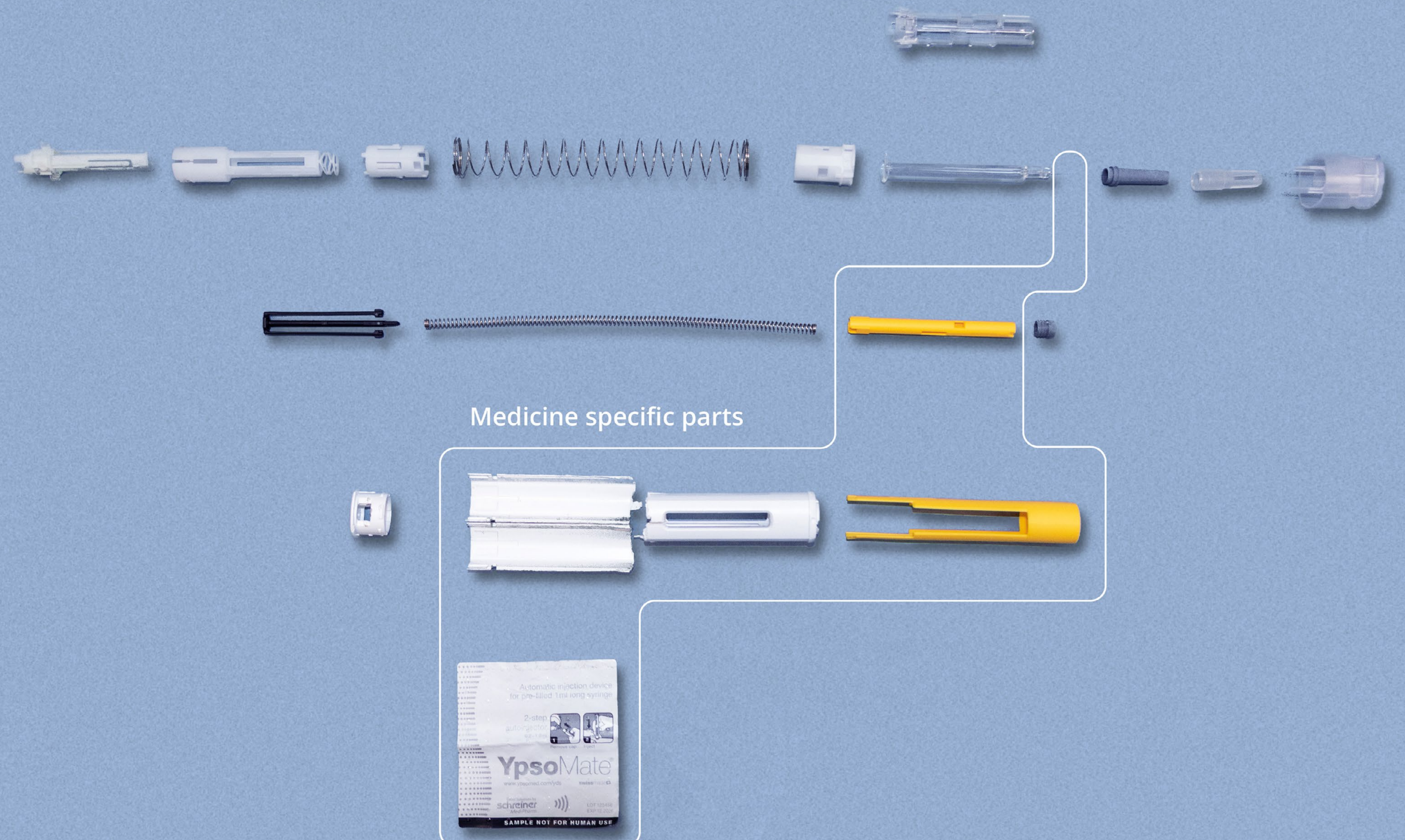
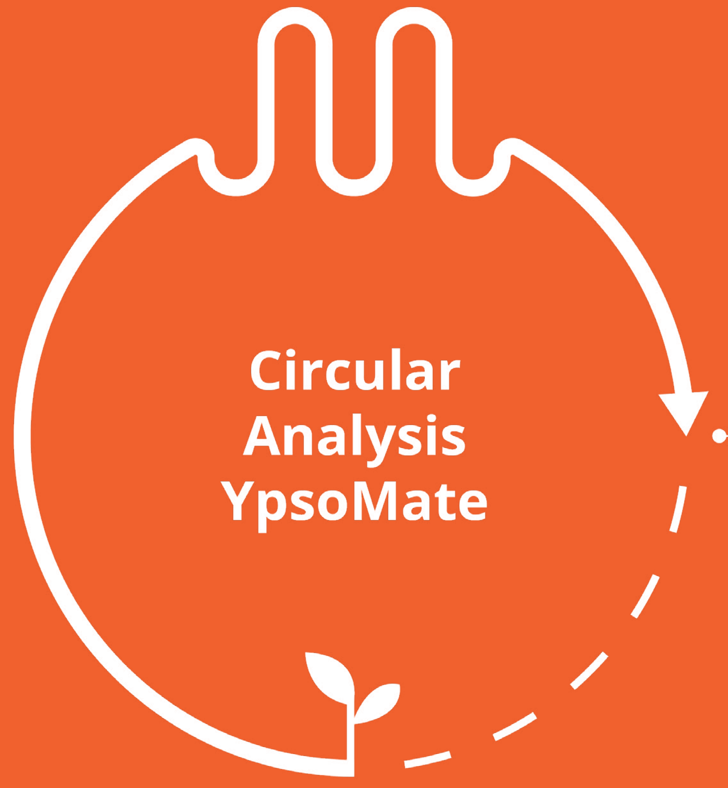


Fig. 62: The plunger, cover sleeve, label, housing and syringe can be customized by the client.

Circular strategy C

Recycle



Recycle

Increase recycling rate

Use mono materials

Minimize electronic waste

Avoid 2K and 3K injection molding

4.8 | High value recycling (HR)

Table 9: High value recycling insights and requirements based on the analysis of chapter 5.

Category	Insight	ID	Requirement
Increase recycling rate	Incineration of YpsoMates causes 10,8% of its total CO2e footprint (South Pole, 2022).	HR1	Increase the recycling rate of YpsoMate.
Mono-materials	YpsoMate consists of 6 different plastics, of which 3 are mixed or reinforced. This makes recycling difficult.	HR2	Reduce the variety of plastics in the autoinjector to commonly recycled mono-materials.*
Eliminate fixed connections	YpsoMate parts made of different materials are inseparable with shredding, due to a label glued onto the housing.	HR3	Make different materials fully separable by eliminating fixed connections.
Minimize electronic waste	Some YpsoMate's have an NFC tag inseparably laminated into the label, creating electronic waste (Fig. 64).	HR4	Make electronics easily separable for reuse and recycling.
Avoid 2K and 3K injection molding	2K and 3K injection molding is used for customized housings (Fig. 63). This makes different materials inseparable and thus non-recyclable.	HR5	Avoid 2K and 3K injection molding.

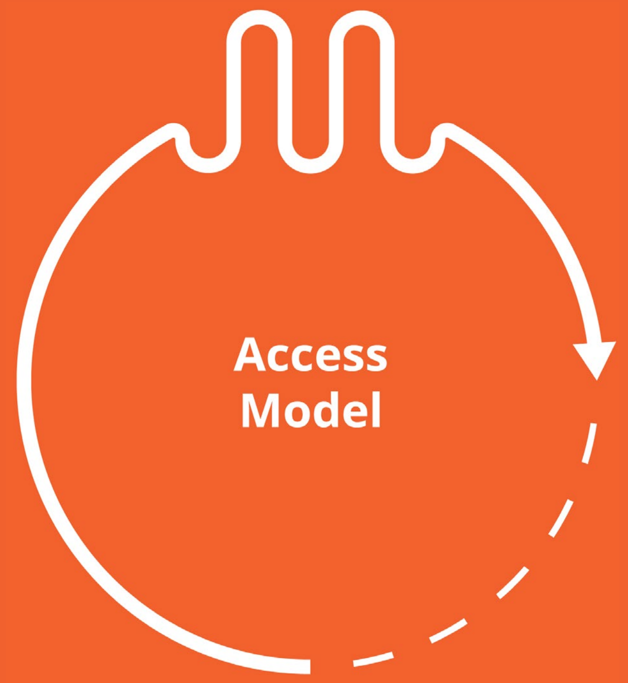
* Improvements refer to the single-use YpsoMate 1.0 mL as a baseline product.

Fig. 63: A customized cap with a 2K injection molded silicone housing cannot be separated entirely during recycling.

Fig. 64: A label with a laminated NFC tag inside it is glued around the housing of the YpsoMate. This makes separating materials very hard

Circular business model

Access model



4.9 | Access model (AM)

Table 10: Access model insights and requirements based on the analysis of chapter 2.

Category	Insight	ID	Requirement
Automated refill system	Manual disassembly of autoinjectors with sharp needles is considered unsafe/ unethical by the Alliance to Zero (Gerner, 2022) and is to expensive.	AM1	A utomate dis- and reassembly, disinfection and refill of YpsoMate autoinjectors.
Placement of Refill Hub(s)	YpsoMate is distributed all over the world, but the main market is the U.S., Japan and fragmented over Europe.	AM2	The emissions of a refill system are lower than the emissions of a single-use autoinjectors.
Size of refill system	YpsoMate's market is expected to grow from tens of million autoinjectors in 2022 to a hundreds of million autoinjectors in 2030 (Gerner, 2022).	AM3	The refill system can process hundreds of millions autoinjectors a year.

Fig. 65: A semi-automated assembly line of YpsoMate autoinjectors (Ypsomed, 2022)

5. Assessment of current autoinjectors

This chapter assesses current autoinjectors' ease of disassembly and their environmental impact. The ease of disassembly is evaluated by using Disassembly Map and Hotspot Mapping tools. The environmental impact is determined with a Life Cycle Assessment.

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5.1 | Introduction

This chapter examines the possibilities of integrating the existing single-use YpsoMate into the circular economy. It addresses the challenges and opportunities for designing a refillable version of the YpsoMate. The chapter also highlights the necessary improvements required before third-party refills of YpsoMates can be made possible.

Chapter 5.2 compares the Life Cycle Assessment of the single-use YpsoMate 1.0 mL to the YpsoMate Zero.

Sections 5.3 to 5.8 delve deeper into the YpsoMate autoinjector, evaluating it against the circular product design strategies discussed in chapter 4, including resource efficiency (5.3), regeneration (5.4), ease of disassembly & repair (5.5), durability & reliability (5.6), standardization & upgradability (5.7) and high value recycling (5.8).

5.2 | Life Cycle Assessment

This chapter looks at the life cycle of a single YpsoMate autoinjector and the YpsoMate Zero (Fig. 66) and the environmental impact of the different stages and parts.

Multiple Life Cycle Assessments

I conducted a comprehensive analysis of the environmental impact of the YpsoMate 1.0 mL autoinjector by combining the findings of three Life Cycle Assessments (LCA). South Pole (2022) performed the initial LCA for the Alliance to Zero, which was then reviewed by Carnstone (2022) to identify opportunities for reducing its carbon footprint. In parallel, Ypsomed (unpublished) conducted an LCA to compare the YpsoMate to the YpsoMate Zero. I used the South Pole LCA with the revisions made by Carnstone as the primary source. However, this LCA does not specify the impact of the autoinjector parts produced at Ypsomed separately. For this, I used data from the Ypsomed LCA (unpublished). The graphs in this chapter present the outcome of integrating these three LCAs into a single analysis."

Fig. 66: The single-use YpsoMate 1.0 mL (left) and the YpsoMate Zero 1.0 mL (right)

Scope

The LCA of South Pole evaluates the environmental impact of a single-use YpsoMate 1.0 mL autoinjector including packaging, used by a customer in Germany. The analysis covers the entire life cycle, from cradle to grave (Fig. 67), and measures the impact in terms of carbon dioxide equivalent (CO2e). CO2e is a metric used to combine the emissions of different greenhouse gases based on their global warming potential (Eurostat, n.d.). The LCA does not include the impact of the medicine inside the autoinjector.

Reasons for this are that the Alliance to Zero has no control over vaccine production and YpsoMates contain varying medicines. Additionally, data on the carbon footprint of medicine production is difficult to obtain.

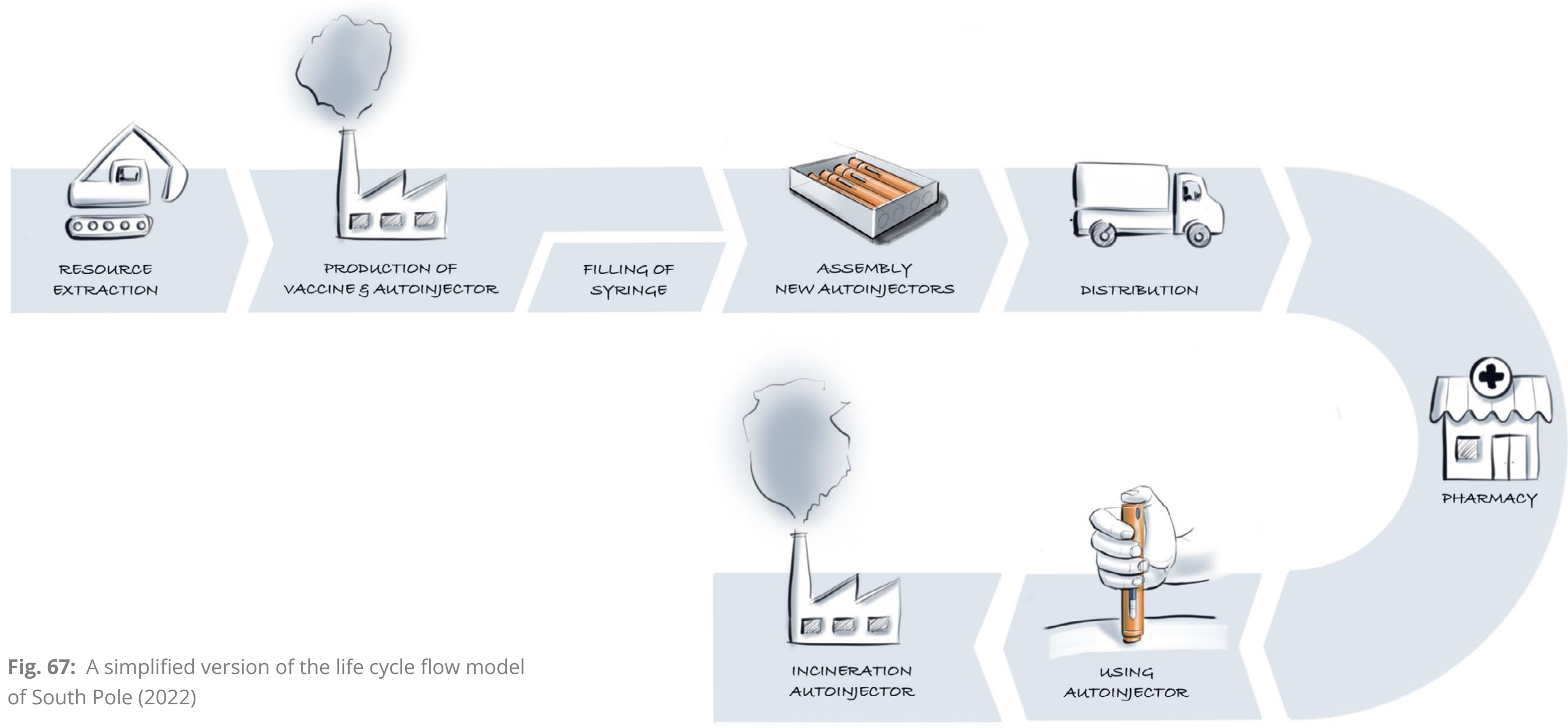


Fig. 67: A simplified version of the life cycle flow model of South Pole (2022)

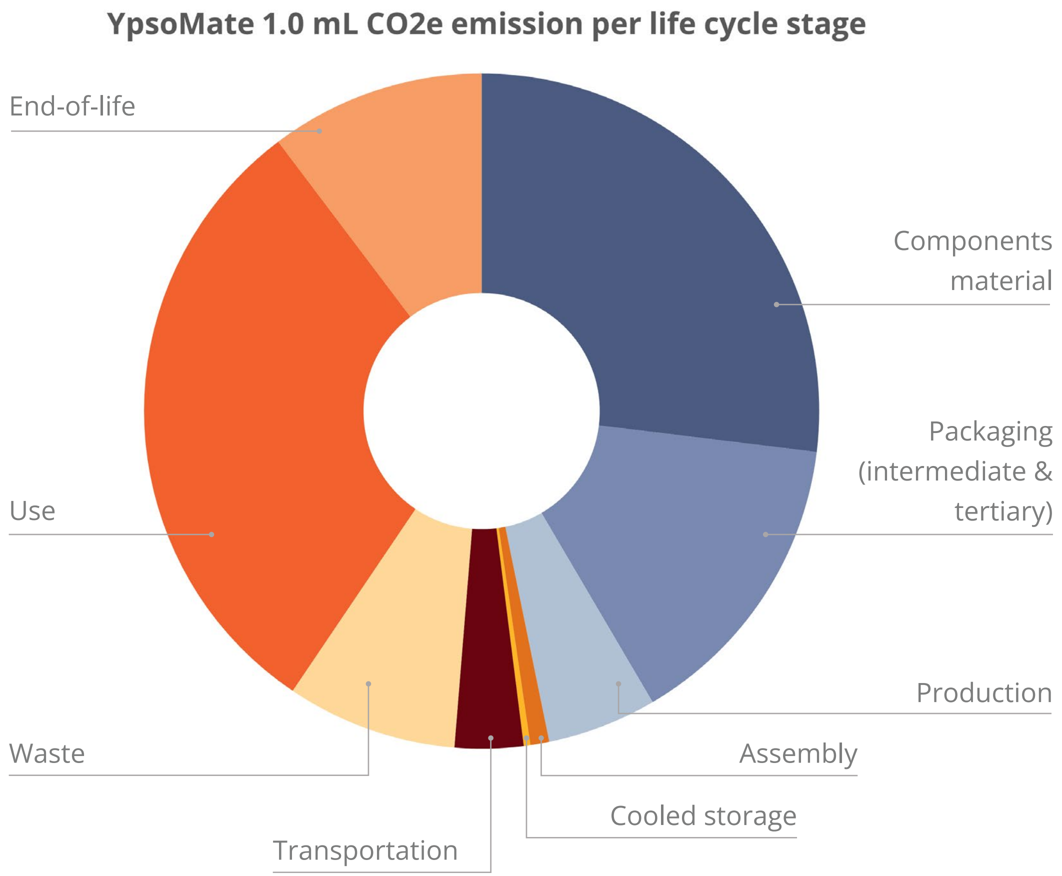
5.2.1 Results Life Cycle Assessment YpsoMate 1.0 mL

Emissions per Life Cycle Stage

The YpsoMate 1.0 mL has an approximate total emissions of 600 gCO2e. Fig. 68 shows that two stages contribute significantly two these emissions:

- **Linearity in the supply chain:** The YpsoMate material, packaging material, and end-of-life make up approximately 50% of emissions. Switching to a circular system, like the YpsoMate Refill concept, could significantly reduce this impact. The Ypsomed Zero already reduces these emissions by using bioplastics and recycled PET for packaging.
- **Use phase:** This stage is a large contributor to the CO2e emissions (30%), which includes pickup from the pharmacy by the user and cooled storage at home. However, South Pole recommends validating their assumption that 56% of the patients drive 5 km by car to pick up solely one autoinjector. It might not be a realistic scenario. Some pharmacies, such as the St. Antonius Hospital in the Netherlands (2022), are delivering autoinjectors to patients' homes via (electric) bike couriers. This lowers the carbon emissions from cars and provides an extra service to patients.

Fig. 68: Emissions per stage of the product life cycle. Values based on LCA's of South Pole (2022), Carnstone (2022) and Ypsomed (unpublished).



Emissions per part

Fig. 69 shows the CO2e emissions (g) needed to produce and dispose of an autoinjector part. This includes YpsoMate materials, part production and end-of-life (European scenario: 53% incineration, 47% landill). I excluded the use, assembly and transportation phases because they do not apply to one part, but to the entire autoinjector or assemblies. I also excluded the tertiary packaging and waste, because Ypsomed and the other producers are working on reducing these impacts. Therefore, the data on this is already outdated.

The part with the highest carbon impact is the housing since it emits approximately 70 gCO2e. The part with the lowest impact is the needle, which emits less than 0.1 gCO2e, due to its low weight of 0,01 kg.

Takeaways

- Linearity of the supply chain (YpsoMate material, packaging material and end-of-life) accounts for approximately 50% of the autoinjector's total CO2e emissions. This could be reduced by switching to a circular system like the YpsoMate Refill concept.
- The use phase (autoinjector pick-up from pharmacy, cooled storage at home) accounts for 30% of YpsoMate's total CO2e emissions. This is due to the assumption that 56% of the patients drive 5 km by car to pick up one autoinjector, that should be validated. In the meantime, pharmacies in the Netherlands are switching to home-delivery of medicines with (electric) bikes, to reduce carbon emissions associated with driving to the pharmacy (Antonius Ziekenhuis, 2022).
- The housing has the highest CO2e impact (approx. 70 gCO2e) among all autoinjector parts, while the needle has the lowest (less than 0.1 gCO2e).

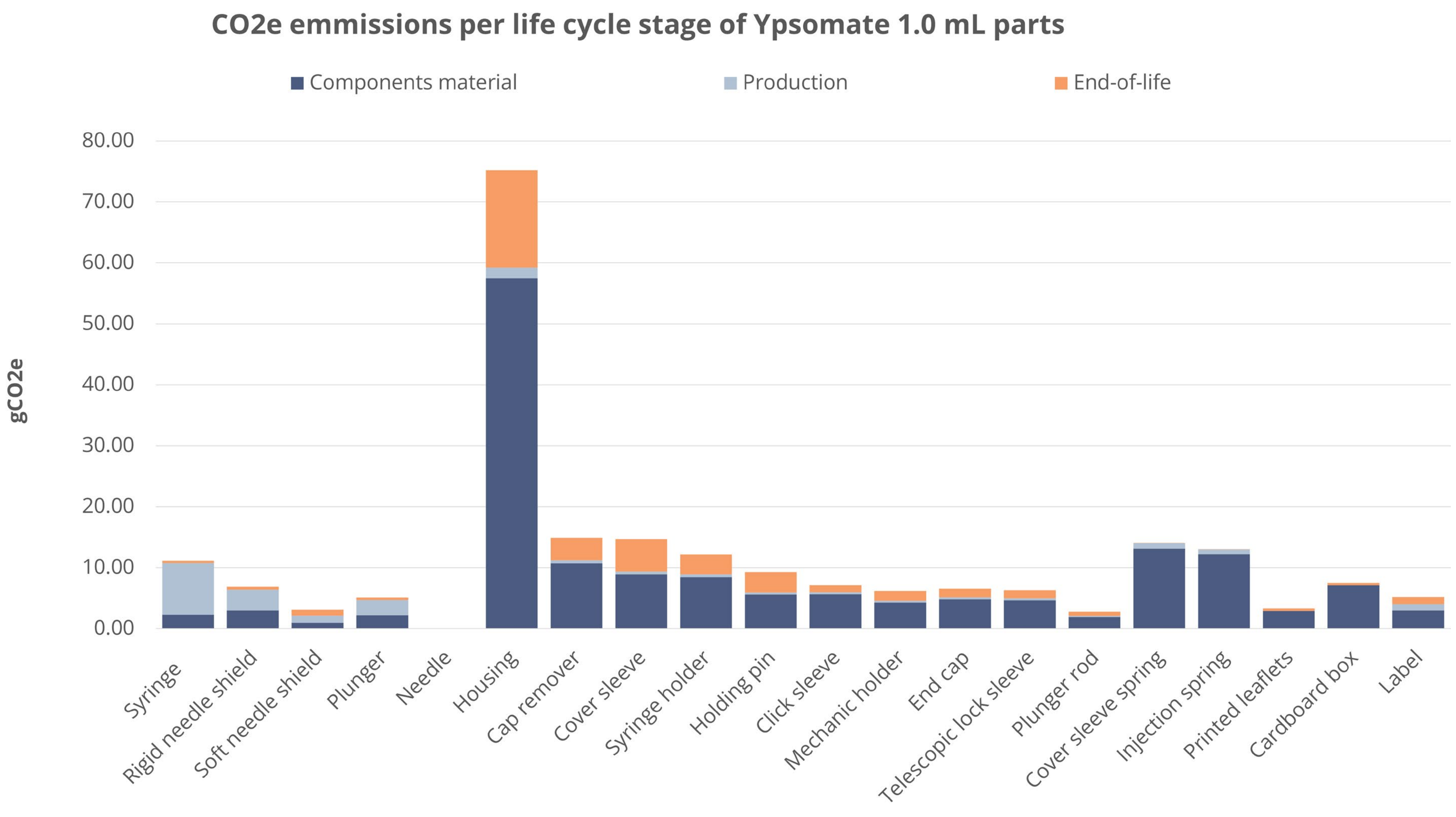


Fig. 69: CO2e emissions per life cycle stage of YpsoMate 1.0 mL parts. Values based on LCA's of South Pole (2022), Carnstone (2022) and Ypsomed (unpublished).

5.2.2 CO2e impact YpsoMate Zero

Ypsomed developed the YpsoMate Zero autoinjector to reduce the carbon emissions associated with their previous models. Even though it is a single-use autoinjector, the YpsoMate Zero aims to be the first carbon-emission-free autoinjector on the market. To achieve this, Ypsomed has implemented various sustainable measures, including the use of bioplastics, the use of recycled PET (rPET) packaging trays and offsetting any remaining carbon footprint.

A Life Cycle Analysis (LCA) conducted by Ypsomed shows a 10% reduction in carbon footprint as a result of these measures, as seen in Fig. 70. The rest of the emissions are removed through carbon offsetting.

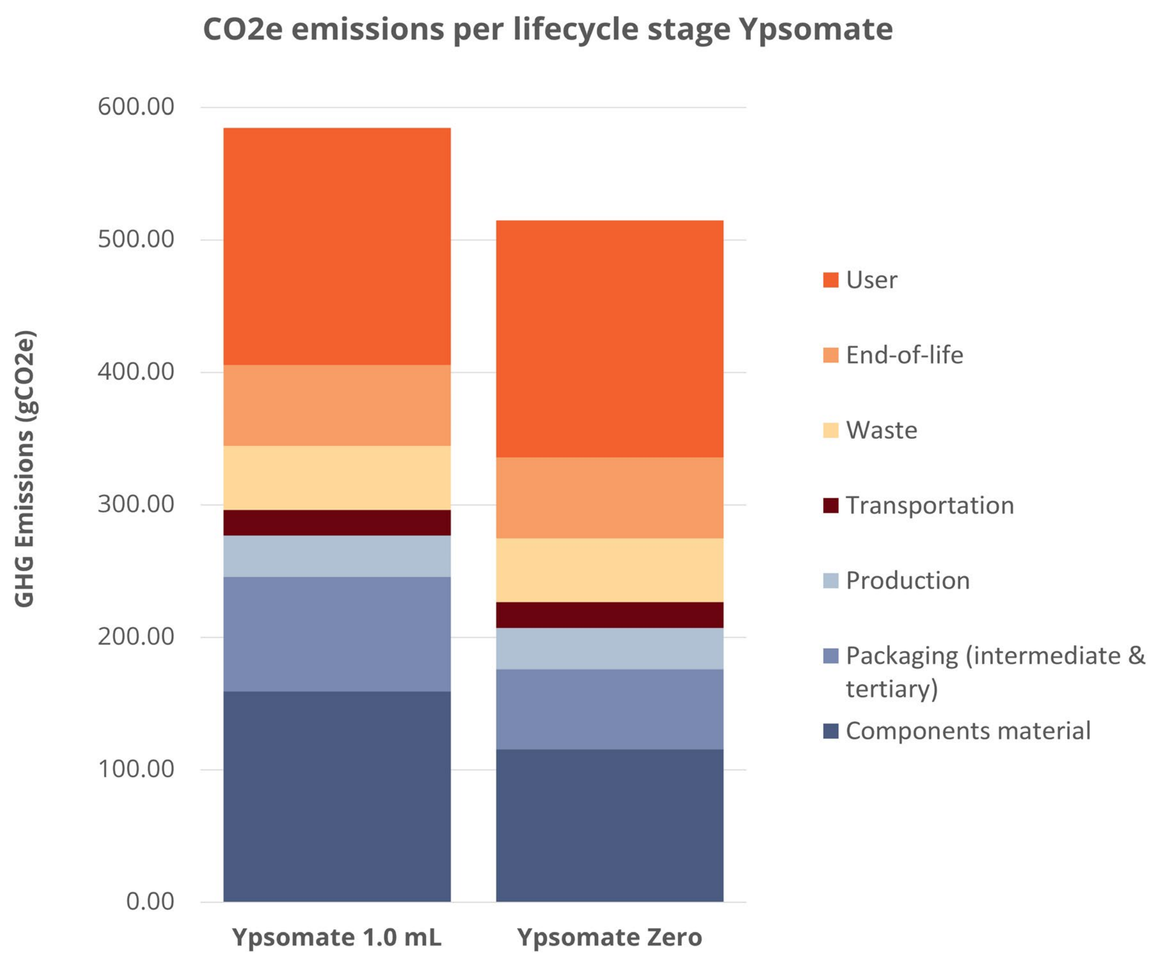


Fig. 70: LCA of the YpsoMate 1.0 mL and the YpsoMate Zero 1.0 mL measured in gCO2e.

Carbon offsetting

After switching to biobased plastic parts and rPET packaging, there is 70% of YpsoMate's initial carbon footprint left. To offset this remaining environmental impact, Ypsomed participates in a reforestation program (Ypsomed, n.d.). However, it is worth noting that carbon offsetting (Fig. 71) is a controversial method since the promised CO2 impact is often lower than promised. South Pole, the company where Ypsomed purchased its carbon offsets, is currently embroiled in a scandal regarding the sale of fraudulent carbon offsets (Crezee & Gijzel, 2023). This could mean that the YpsoMate Zero emissions are higher than claimed. Experts such as Ecochain (2021) advise that companies should prioritize reducing their emissions first.

My YpsoMate Refill concept could help to reduce the remaining 70% carbon impact and thus minimize the need for carbon offsetting.

Takeaways

The YpsoMate Zero reduces the carbon footprint of the YpsoMate by 31% through:

- Replacing virgin plastic with chemically identical bioplastic autoinjector parts. This is also interesting for my YpsoMate Refill concept.
- Using recycled PET packaging trays.

Ypsomed offsets the remaining 70% by participating in a reforestation program.

Fig. 71: Poorly calculated carbon offsetting can lead to more CO2 emissions instead of CO2 reduction (Crezee et al., 2023).

5.3 | Resource efficiency

In 1998, von Weizsäcker et al. wrote the influential book “Factor Four”. It aimed to inspire companies to apply resource efficiency measures. Twenty-four years later, this is still a relevant circular design strategy, as it aims to narrow resource flows, by using fewer resources to achieve the same goal.

5.3.1 Packaging

Within the YpsoMate production process, the consultancy Carnstone (2022) found the opportunity to reuse and reduce the packaging around the autoinjectors. Fig. 72 & Fig. 73 shows that autoinjector(s) (parts) are packaged in single-use plastic trays.

To lower the carbon footprint of the packaging, Ypsomed already replaced the PET trays with recycled PET trays. They are also looking into reusing the trays.

I will not focus further on improving the resource efficiency of the packaging. The reasons for this are that my focus is on redesigning the autoinjector itself and the Alliance to Zero is already improving the environmental impact of the packaging.

Fig. 72: (Top) The YpsoMate autoinjectors are shipped to Sharp in single-use PET trays, and single-use cardboard boxes.

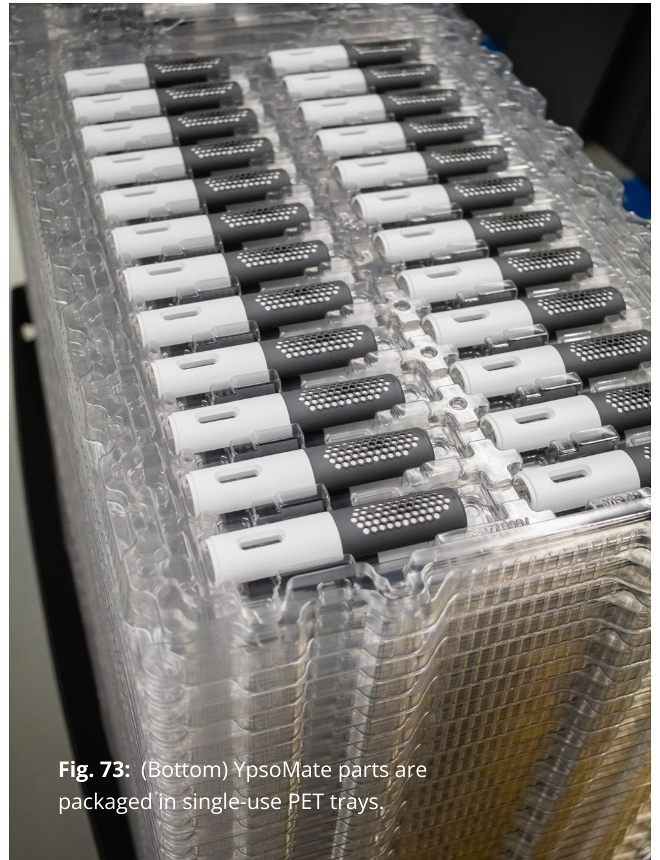


Fig. 73: (Bottom) YpsoMate parts are packaged in single-use PET trays.

5.3.2 YpsoMate parts

The ingle-use YpsoMate 1.0 mL consists of 19 parts (Fig. 74). These parts work together in a complex way to mechanically push out the medicine and shield the needle afterwards while providing auditive feedback (a click).

Engineers at Ypsomed are working on a new autoinjector with a reduced part count and only the essential functions, to increase resource efficiency and make it simpler, cheaper and more sustainable. However, decreasing the number of parts means getting rid of certain features, such as the beginning and end click. Ypsomed’s engineers are ideating on new ways to communicate the beginning and end of an injection.

This provides an interesting design challenge: reducing the part count in a YpsoMate autoinjector.

Takeaways

- Ypsomed is aiming to reduce and reuse the packaging around the autoinjector to increase resource efficiency. For me, this is out of scope.
- An interesting design challenge is to reduce the number of parts in the YpsoMate.

Fig. 74: The YpsoMate autoinjector contains 19 parts.

5.4 | Regeneration

To become circular, firms need to regenerate their material and energy flows. This includes using non-toxic material, switching to renewable energy and regenerating natural ecosystems (Konietzko et al., 2020). This chapter analyses the steps taken to regenerate nature during the YpsoMate's production process.

5.4.1 Reduce harmful substances

During the production of the YpsoMate autoinjector, the harmful Ethylene Oxide (EO) gas is used for sterilization.

EO gas sterilization

The syringe and needle (Fig. 75) and the rubber plunger are sterilized with Ethylene Oxide (EO) gas. The advantages of EO gas sterilization are (Steris, n.d.):

- EO gas sterilization is suitable for plastics that cannot be exposed to heat, moisture or radiation.
- Products can be sterilized in their final packaging since the EO gas permeates the sealed films and cardboard packaging.

However, there is a backlash against EO gas sterilization, because it is a toxic gas that can harm the environment and human safety (Australian Government, n.d.). In response, companies such as Steris have developed less harmful EO gas sterilization methods by reducing the amount of EO sterilant. Still, not using EO gas at all would be the most sustainable option.

I recommend that Datwyler and SCHOTT explore alternative sterilization methods that prioritize sustainability, such as using Hydrogen Peroxide (discussed further in chapter 6). As a first step, switching to sustainable EO gas sterilization would be a good start while investigating the feasibility of Hydrogen Peroxide as a viable alternative.

Takeaway

I would advise SCHOTT and Datwyler to look at sustainable EO gas sterilization or other more environmentally friendly sterilization methods (Hydrogen Peroxide) for the syringe, needle and plunger.

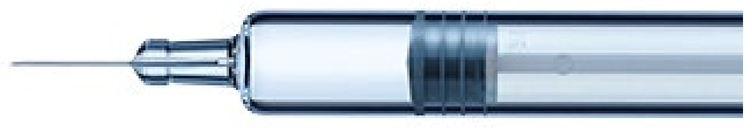


Fig. 75: The needle, syringe and plunger are sterilized with EO gas (Steris, n.d.).

5.4.2 Renewable energy

The companies producing the YpsoMate autoinjector are switching to renewable energy instead of fossil fuels (Fig. 75) (Ypsomed, 2022). This could decrease the carbon footprint of production and assembly.

5.4.3 Renewable materials

The Ypsomed Zero uses biobased plastics made from non-food crops and waste. This reduces the dependency on fossil based plastics and reduces the CO2e footprint.

Takeaway

- Companies producing the YpsoMate autoinjector are switching to solar energy.
- Ypsomed switched to biopolymers for their YpsoMate Zero.

Fig. 76: Installation of solar panels (Blake, 2016).

5.5 | Ease of disassembly & repair

Design for dis- and reassembly is a strategy that can increase material and component reuse (Crowther, 1999). Dis- and reassembly is vital for the YpsoMate refill scenario, so the autoinjector can be cleaned, refilled, repaired and reused.

To evaluate the ease of dis- and reassembly, this chapter compares the YpsoMate autoinjectors to autoinjectors from other brands (Fig. 77) via a HotSpot analysis (Flipsen, 2020) and disassembly maps (De Fazio et al., 2021).

To visualize the disassembly steps, I made disassembly maps showing the routes towards the target components (De Fazio et al., 2021). This method assesses the ease of disassembly based on four parameters: disassembly depth/sequence, type of tools, fastener reusability/reversibility and disassembly time. Chapter 5.5.8, 5.5.9 and 5.5.10 show the disassembly maps of the autoinjectors.

5.5.1 HotSpot parts

To determine the target components (Fig. 78) that should be easy to reach during disassembly, I used the HotSpot Mapping tool (Flipsen et al., 2020). This tool classifies critical parts (HotSpots) as parts that have a high failure rate, a high economic value and/or a high environmental impact. However, the priority parts with a high failure rate are hard to determine for the YpsoMate. Since it is a single-use product, there is no data and knowledge about which parts break easily. Therefore, Fig. 78 does not specify which parts have a high failure rate.

Environmental & Economic HotSpots

The HotSpot mapping tool flags parts that belong to the 80th percentile or higher as economically critical. This is the case for the two stainless steel springs and the housing due to their high material value. Sebastian Gerner (2023) from Ypsomed confirmed that these are the most expensive parts.

To determine which parts get a high environmental impact indicator, I used the LCA discussed in the previous 5.1. According to Flipsen et al., 2020), parts that fall into the 80th percentile or higher are flagged with an environmental indicator (Fig. 78). The housing impact is the highest with approximately 70 gCO2e, but the cap remover, cover sleeve and the two springs are also considered environmental HotSpots.

The disassembly map indicates these HotSpots are indicated with a black environmental and economic indicator icon (Fig. 78). I only applied these tags to the YpsoMate autoinjector disassembly map, as this is the product I plan to redesign and have LCA data for.

YpsoMate 1.0 mL

GlaxoSmithKline (gsk) - Imigran

Novartis - Aimovig

Fig. 77: I disassembled three different autoinjectors.

YpsoMate part name	Environmental HotSpot	Economic HotSpot
Housing	X	X
Cover sleeve spring	X	X
Injection spring	X	X
Cap remover	X	
Cover sleeve	X	

Fig. 78: YpsoMate Parts that are environmental and economic HotSpots fall in the 80th percentile or higher (Flipsen, 2020).

5.5.2 Disassembly map structure

Fig. 79 explains the structure of the disassembly map.

Building blocks

The disassembly map features two key elements: parts and activities. Parts are depicted by a part number in a gray circle, which is connected to the part list. Activities are placed inside rounded rectangles that communicate information about the type of fastener, the tool used and the number of tasks to perform. The color of the rounded rectangle is depended on the type of tool.

To enhance the readability of the disassembly map, I used fewer abbreviations for the tools and connections in comparison to earlier disassembly maps (De Fazio, 2021; Steffner, 2021; Vermaat, 2020).

Linear and parallel disassembly

The disassembly map uses two different sequences: linear and parallel disassembly.

- In ***linear sequences***, one part (B) can only be removed after another part (A) has been disassembled first.
- In ***parallel sequences***, multiple parts can be disassembled at the same time. For instance, parts A and B can be removed in any order.

I applied a constant grid for the disassembly sequences, as suggested by Steffner (2021). This makes it easier to compare different disassembly maps and count the disassembly depth.

Parallel sequences in the product architecture are preferred over linear sequences as they make disassembly easier and faster. Parallel sequences reduce the disassembly depth, allowing multiple tasks to be performed at once and requiring fewer steps to reach a specific part (De Fazio, 2021.)

And/or relationships

Fig. 79 shows that to remove part C, first parts A and B need to be removed. The order in which parts A and B are removed does not matter.

Subassemblies

Some parts can be removed as subassemblies, which consist of multiple parts that remain connected to each other after being taken apart from the main assembly. These subassemblies can be further disassembled at a later stage.

Penalties

Penalties highlight challenges in the disassembly process. The disassembly map shows these penalties with an icon in an orange circle next to a task. There are the following penalties (De Fazio, 2021; Flipsen, 2020) :

- ***Time intensive:*** marks activities that take longer than 30 seconds to perform. As an improvement on previous disassembly maps (De Fazio, 2021; Steffner, 2021; Vermaat, 2020), the indicator shows the time it takes to perform the action. This way, you get a better sense of scale.
- ***Force intensive:*** indicates activities that require the use of both hands or substantial forearm strength (over 20N).
- ***High precision:*** marks activities that require a tool that needs to be positioned with high precision.
- ***Non-reusable fastener:*** indicates fasteners that become damaged during the disassembly process and can thus not be reused.
- ***Obstructed access:*** indicates when the access to a fastener is blocked.

Other disassembly maps (De Fazio, 2021; Steffner, 2021; Vermaat, 2020) include a penalty for uncommon tools. This is important for products that are disassembled by customers since they likely have limited tools available. However, for the YpsoMate Refill scenario, where the autoinjectors are disassembled in a factory, uncommon tools are useful. This means that users cannot easily disassemble the autoinjector, but a factory can. Therefore, this is not a penalty in the disassembly maps of the autoinjectors.

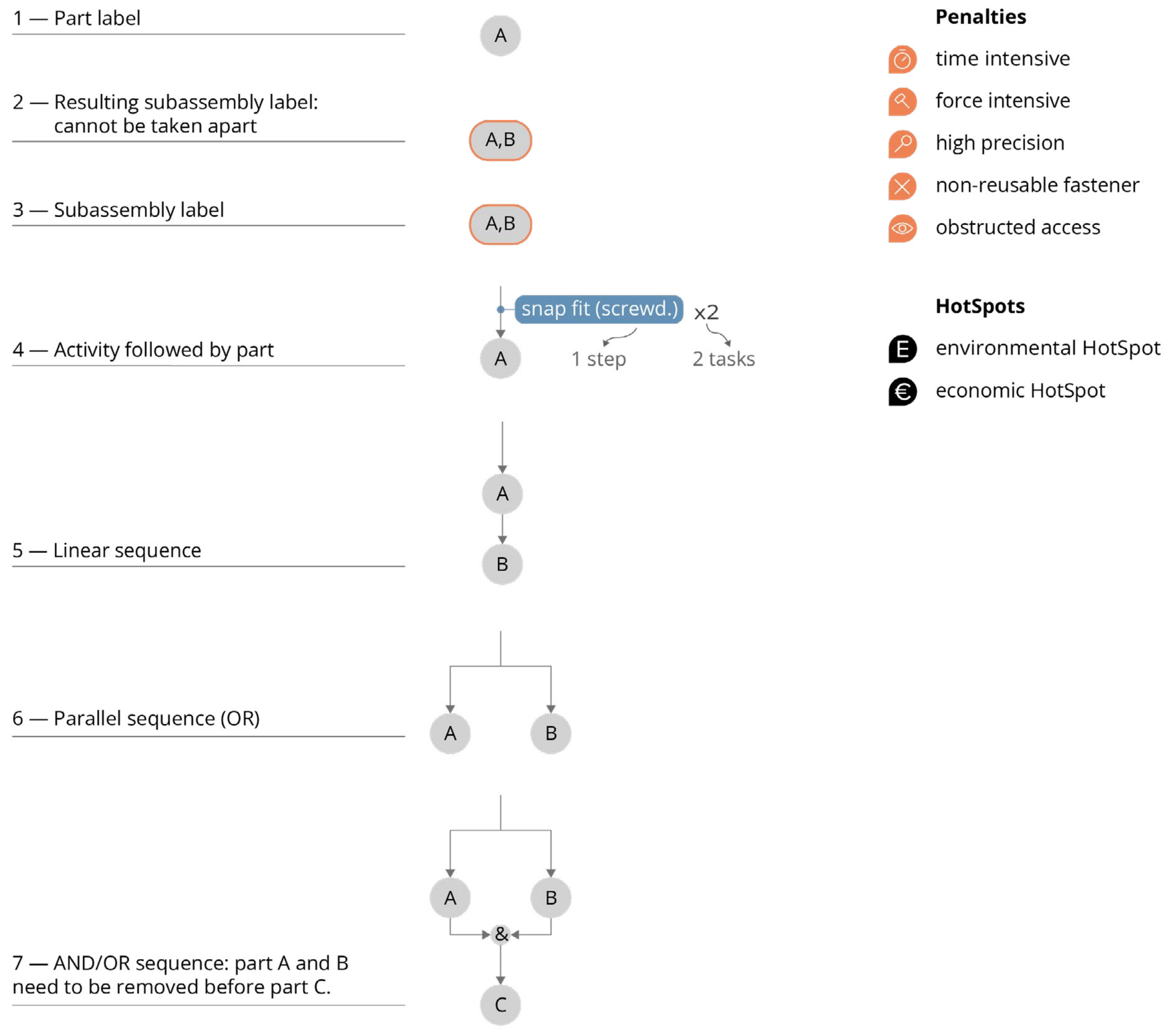


Fig. 79: The structure of the disassembly map. Based on an image of Steffner (2021).

5.5.3 Disassembly depth & sequence

Despite having the least number of parts (19) among the disassembled autoinjectors, the YpsoMate autoinjector required the most steps and tasks to take apart (Fig. 81). It also had the highest maximum part depth (Fig. 80), indicating a more sequential process compared to others. This meant that fewer tasks could be done in parallel, which slowed down the disassembly process. For example, it took seven steps to reach the syringe and needle.

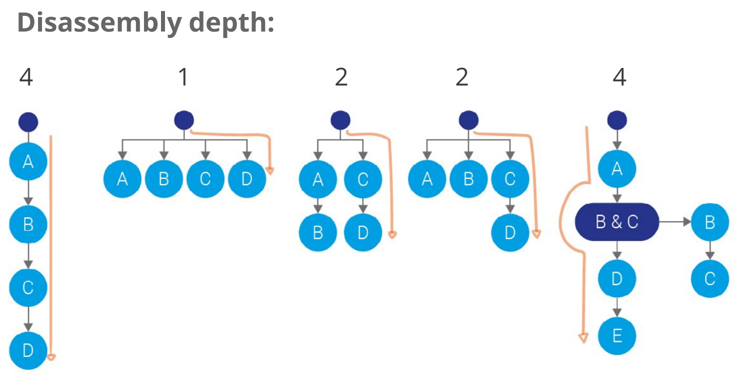


Fig. 80: Explanation of the disassembly depth. Image from Vermaat (2020)

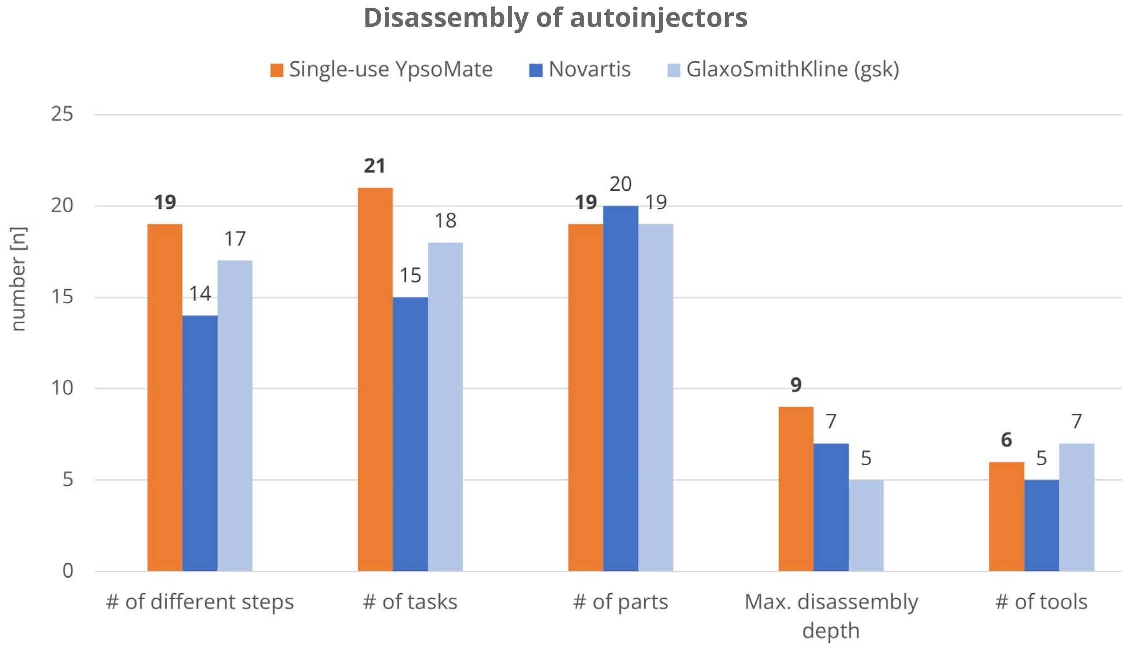


Fig. 81: The number of steps, tasks, parts, part depth and tools needed to disassemble the different autoinjectors.

5.5.4 Penalties

Table 11 shows the penalties the YpsoMate autoinjector got. The penalties force intensive and high precision have limited impact on the YpsoMate Refill concept, as the disassembly and reassembly will be automated. However, penalties for time-intensive, non-reusable fasteners, and obstructed access hinder the reuse options and should be improved in the Ypsomate Refill design.

The upcoming subchapters highlight Ypsomate parts that got penalties for time, non-reusable fasteners, and obstructed access and compares them to other autoinjectors that perform poorly or exceptionally in these areas.

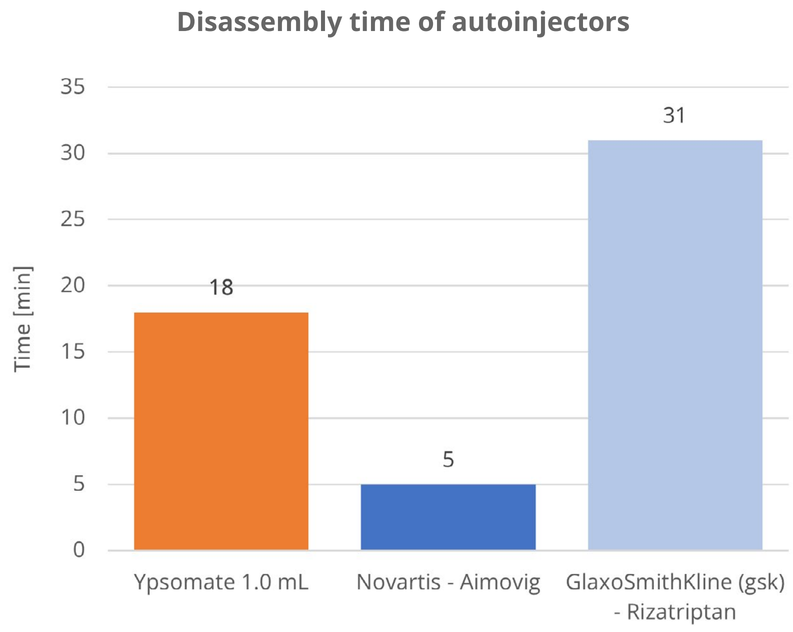


Fig. 82: The disassembly time of various autoinjectors. The measurements include the time required to figure out how to take the autoinjector apart, including any trial and error. It's expected that the disassembly time will decrease with experience and repetition.

Autoinjector type	Time intensive	Force intensive	High precision	Non-reusable fastener	Obstructed access
YpsoMate 1.0 mL	2	3	7	5	2
Novartis	0	2	3	4	3
GlaxoSmithKline	2	5	2	5	3

Table 11: Penalties of the three autoinjectors. The highest penalties are highlighted in orange.

5.5.5 YpsoMate 1.0 mL

It took 18 minutes to disassemble the YpsoMate autoinjector. This is mainly due to the removal of the housing with a saw and cutting pliers.

Fig. 83:

Label

The *label was glued* to the housing and could not be reused after removing it (Fig. 83).

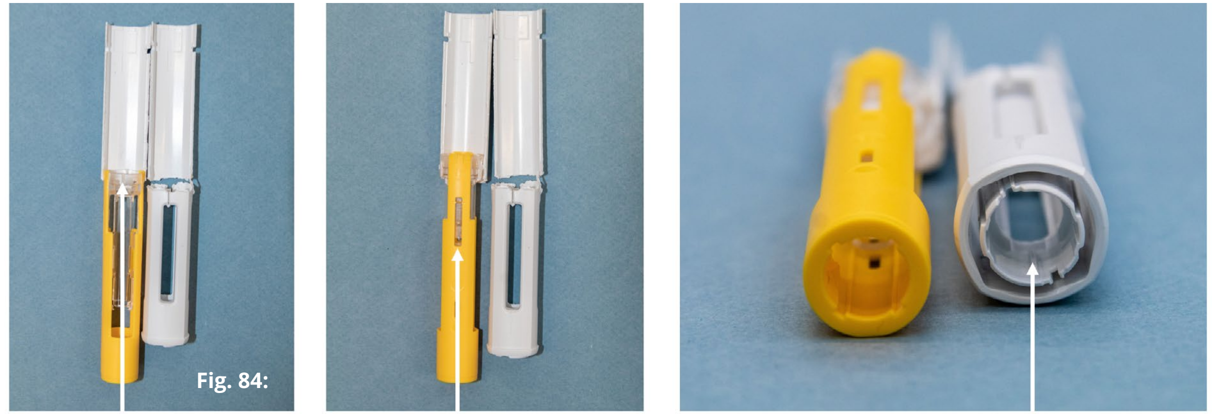


Fig. 84:

Snapfit connecting syringe holder to housing

Connection between cover sleeve and syringe holder

The housing is sandwiched between the cover sleeve and syringe holder, so it needed to be cut open.

9 min.

Housing, cover sleeve & syringe protector

It took me 9 minutes to separate the housing from the cover sleeve and the syringe holder. Fig. 84 shows that the syringe holder was attached with snap-fits to the cover sleeve, but those two parts are sandwiched between the housing. Therefore, I had to ***cut*** and ***saw open*** the housing (Fig. 85) to reach the snap-fits on the syringe holder to separate the parts from each other. This was a destructive and time-consuming method.

Fig. 85: I had to cut open the housing to seperate it from the cover sleeve and the syringe holder.

Fig. 86:

Fig. 87:

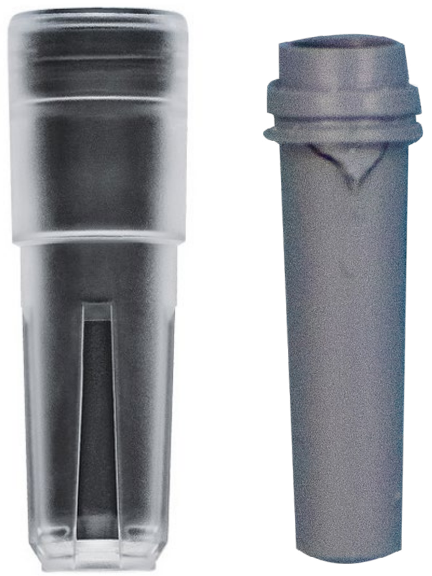


Fig. 88:

2 min.

End cap & mechanic holder

The ***end cap*** was connected to the ***mechanic holder*** with snap-fits that strongly kept it in place (Fig. 86). The only way I could separate the parts was by ***melting away the snap-fits*** of the mechanic holder with a soldering iron, so the end cap could slide over them.

Soft needle shield

I removed the ***soft needle shield*** from the rigid needle shield using a scriber. However, the rubber of the soft shield ***tore*** because it was clamped tightly (Fig. 87).

Needle & syringe

In all three autoinjectors, the ***needle is glued*** into the syringe (Fig. 88), so they can only be separated by breaking the needle off. However, I did not try this due to the potential danger of glass shattering.

5.5.6 Novartis button-activated autoinjector

The Novartis autoinjector had the quickest disassembly time of 5 minutes. This was thanks to its easy-to-open housing that could be separated by pulling the two housing parts apart (which required some force). Upon opening the housing, the parts fell out into subassemblies (Fig. 89). This sped up the disassembly process since the housing did not have to be cut open to access inner parts. It also decreased the part depth and decreased the disassembly time, since parts could be taken apart in parallel. Creating subassemblies that can easily be removed from the housing would be a great strategy for the YpsoMate Refill concept to speed up the dis- and reassembly process.

However, the cap remover could not be removed from the rigid needle shield, resulting in penalties a 'non-reusable fastener penalty for the device.

Fig. 89: After opening the housing, the Novartis autoinjector fell apart into subassemblies. This sped up the disassembly process.

5.5.7 GlaxoSmithKline (gsk) reusable autoinjector

The gsk reusable autoinjector (Fig. 90) had the longest disassembly time of 31 min. This is primarily due to the removal of the housing, which took 24 minutes. The housing was made of hard, brittle plastic and could only be separated by breaking it apart using a saw and combination pliers. I resorted to melting the housing open with a soldering iron (Fig. 90). Therefore, these parts get penalties for using an obstructed, non-reusable fastener that is time-consuming to open.

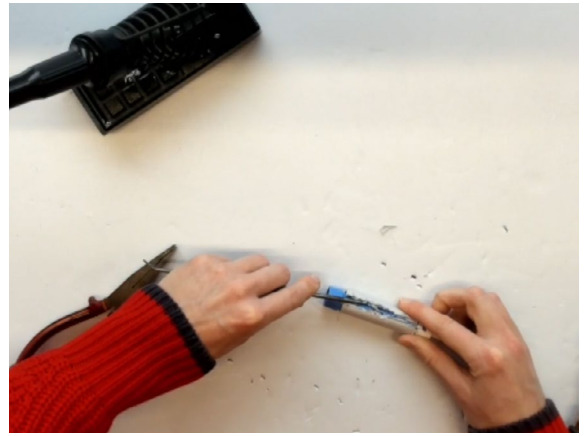


Fig. 90: To remove the housing, I broke it open by melting the plastic with a soldering iron.

Takeaways

- The disassembly of the YpsoMate autoinjector took 18 minutes to complete.
- Despite having fewer parts compared to the Novartis and GlaxoSmithKline autoinjectors, the YpsoMate required the most steps to disassemble.
- The sequential nature of the YpsoMate's disassembly process slows it down. By organizing parts into easily detachable subassemblies, the disassembly could be more efficient and quicker
- The YpsoMate has five non-reusable fasteners, so it cannot be reassembled.

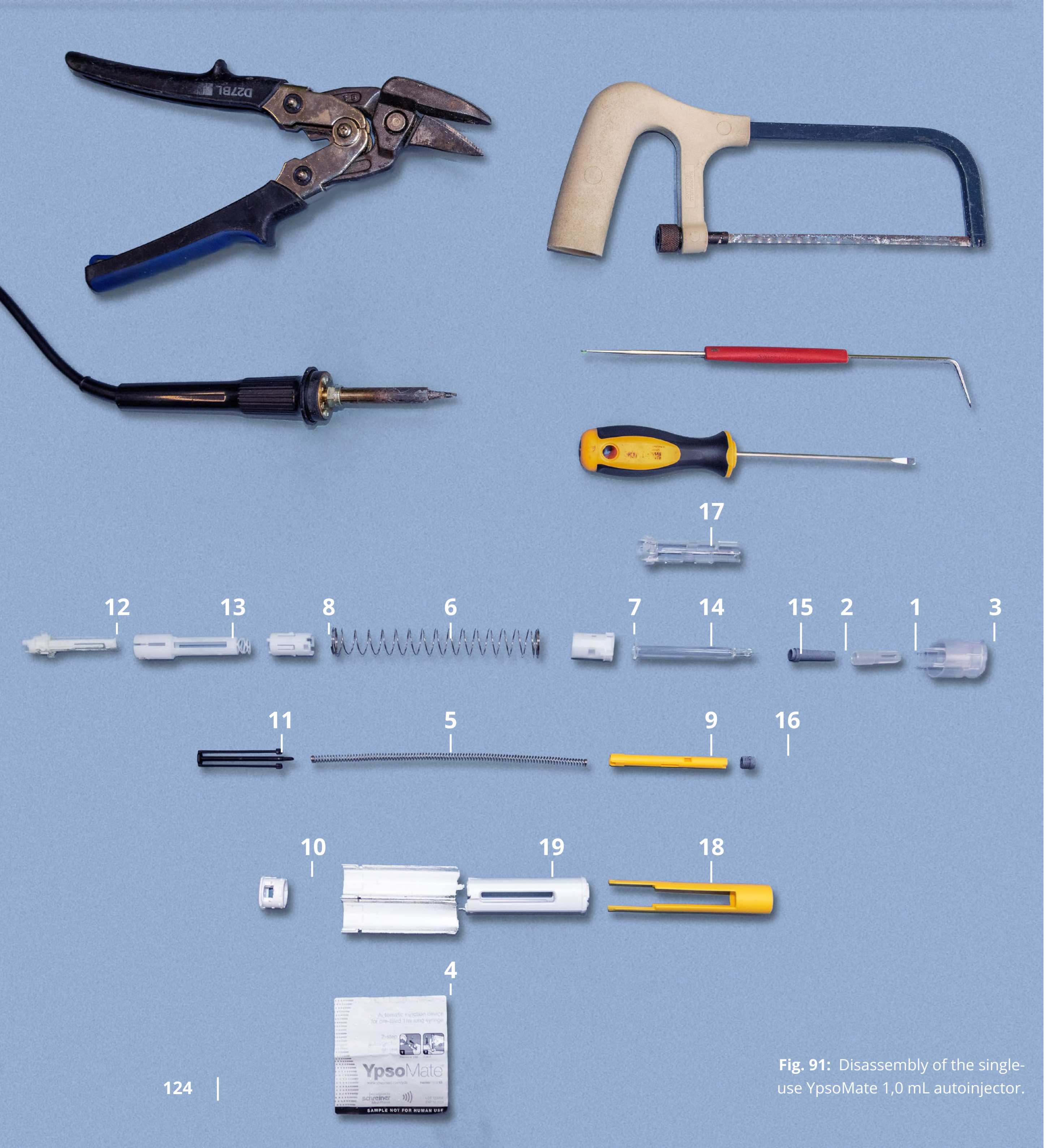


Fig. 91: Disassembly of the single-use YpsoMate 1,0 mL autoinjector.

5.5.8 YpsoMate 1.0 mL

1. Rigid needle shield
2. Soft needle shield
3. Cap remover
4. Label
5. Injection spring
6. Cover sleeve spring
7. Outer Telescopic lock sleeve
8. Inner Telescopic lock sleeve
9. Plunger rod
10. End cap
11. Holding pin
12. Click Sleeve
13. Mechanic holder
14. Syringe
15. Needle
16. Plunger
17. Syringe holder
18. Cover sleeve
19. Housing

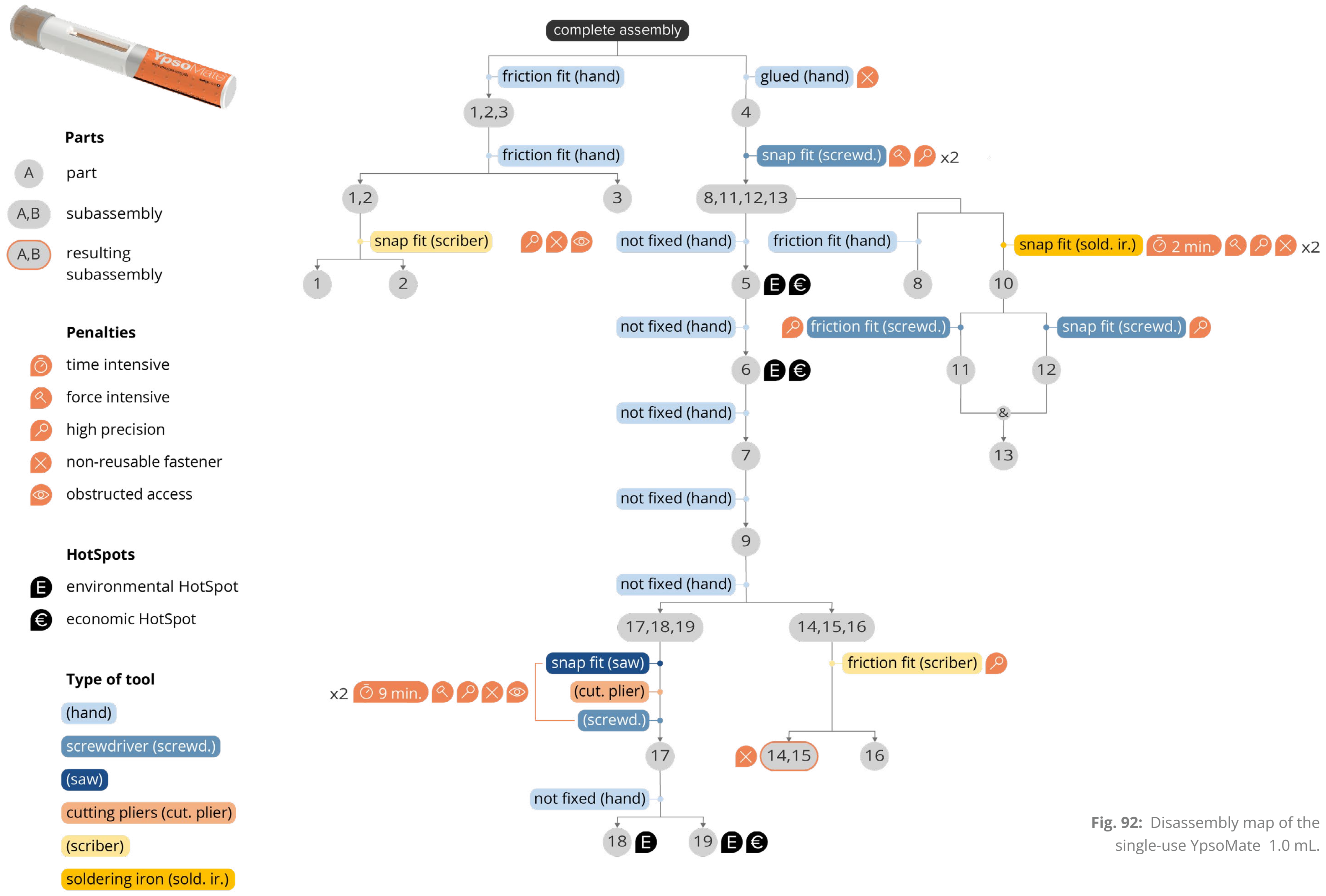


Fig. 92: Disassembly map of the single-use YpsoMate 1.0 mL.

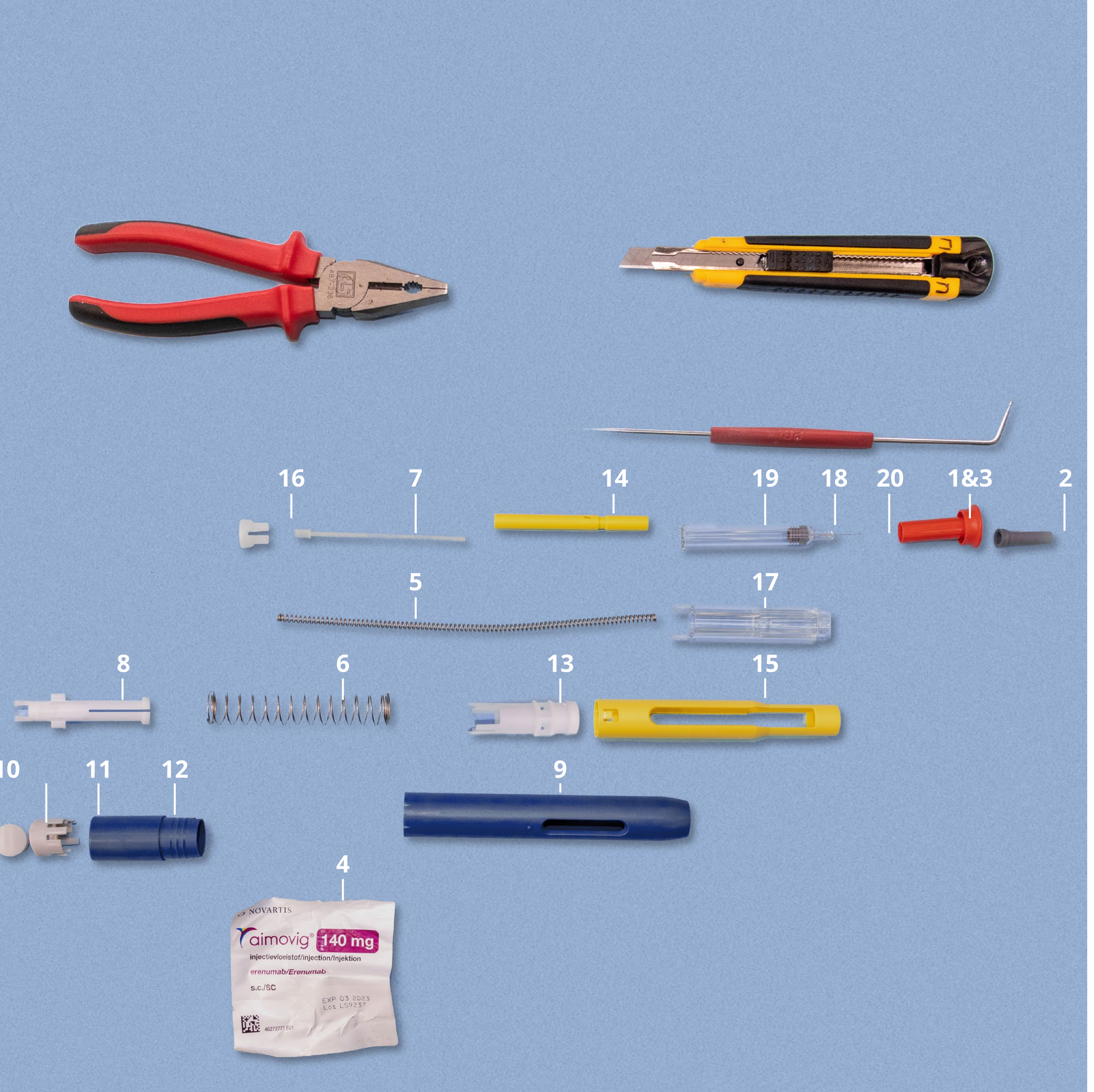


Fig. 93: Disassembly of the single-use Novartis autoinjector.

5.5.9 Novartis - Aimovig

1. Rigid needle shield
2. Soft needle shield
3. Cap remover
4. Label
5. Injection spring
6. Cover sleeve spring
7. Holding pin
8. Mechanic holder
9. Housing bottom
10. Button
11. Button holder
12. Housing top
13. Cover sleeve holder
14. Plunger rod
15. Cover sleeve
16. Plunger rod holder
17. Syringe holder
18. Plunger
19. Syringe
20. Needle

Parts

A part

A,B subassembly

A,B resulting subassembly

Penalties

time intensive

force intensive

high precision

non-reusable fastener

obstructed access

Type of tool

(hand)

screwdriver (screwd.)

combination pliers (comb. plier)

(scriber)

(knife)

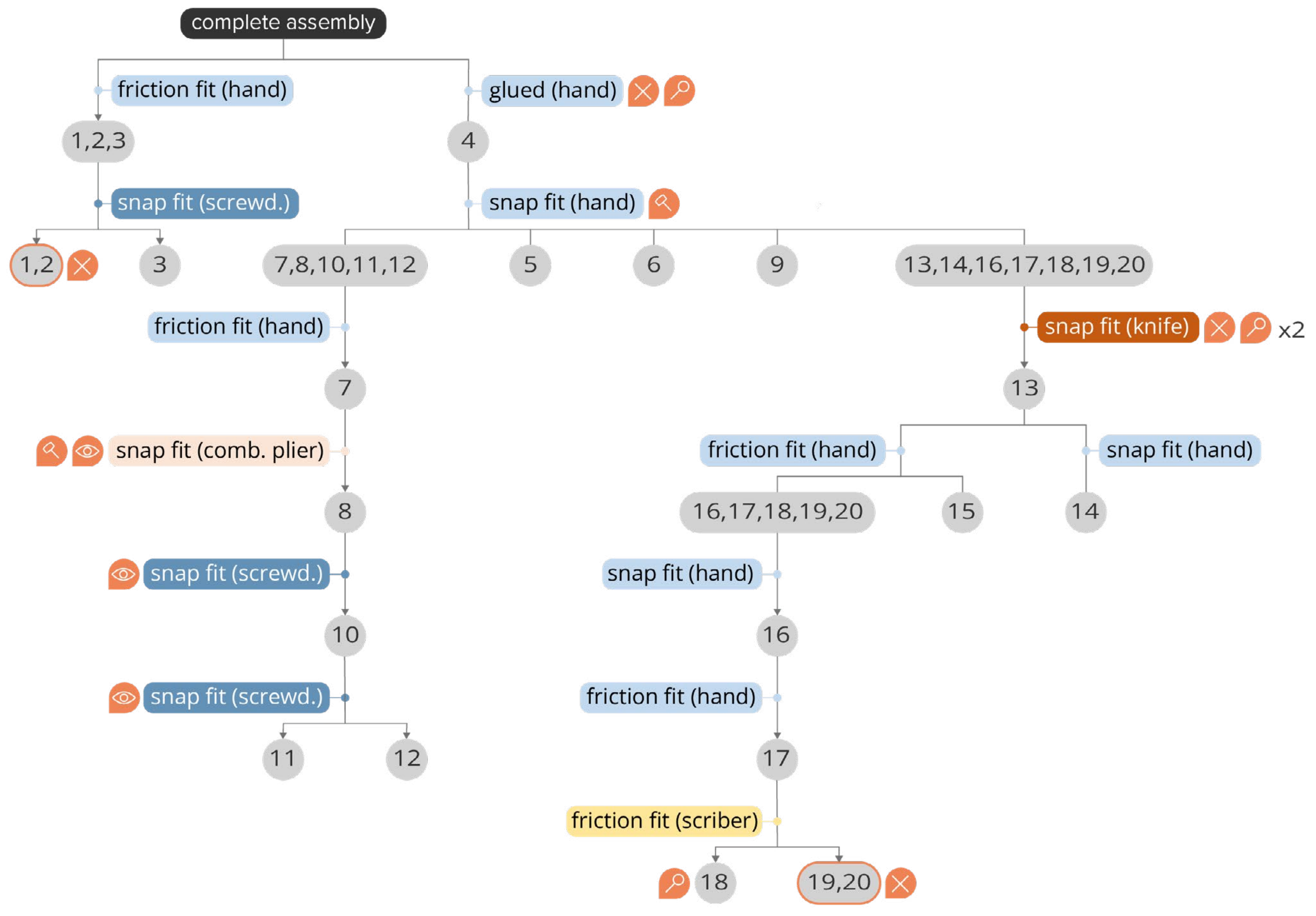


Fig. 94: Disassembly map of the single-use Novartis autoinjector.

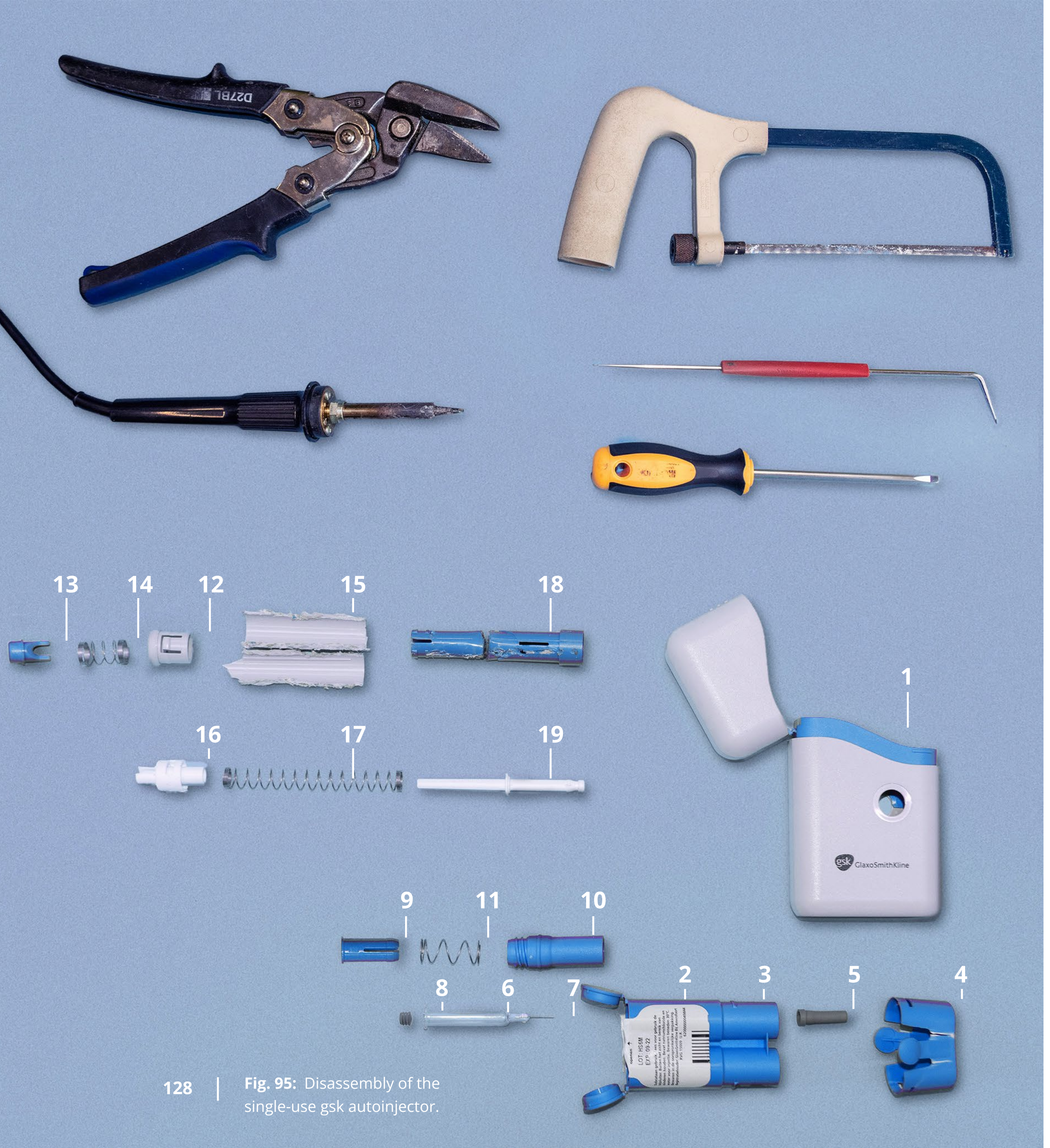


Fig. 95: Disassembly of the single-use gsk autoinjector.

5.5.10 GlaxoSmithKline (gsk) - Imigran

1. Storage box*

Cartridge

2. Label
3. Housing cartridge
4. Cap cartridge
5. Soft needle shield
6. Syringe
7. Needle
8. Plunger
9. Syringe holder
10. Cover sleeve
11. Cover sleeve spring

Autoinjector

12. Button holder
13. Button
14. Button spring
15. Housing grey
16. Plunger holder
17. Injection spring
18. Housing blue
19. Plunger rod

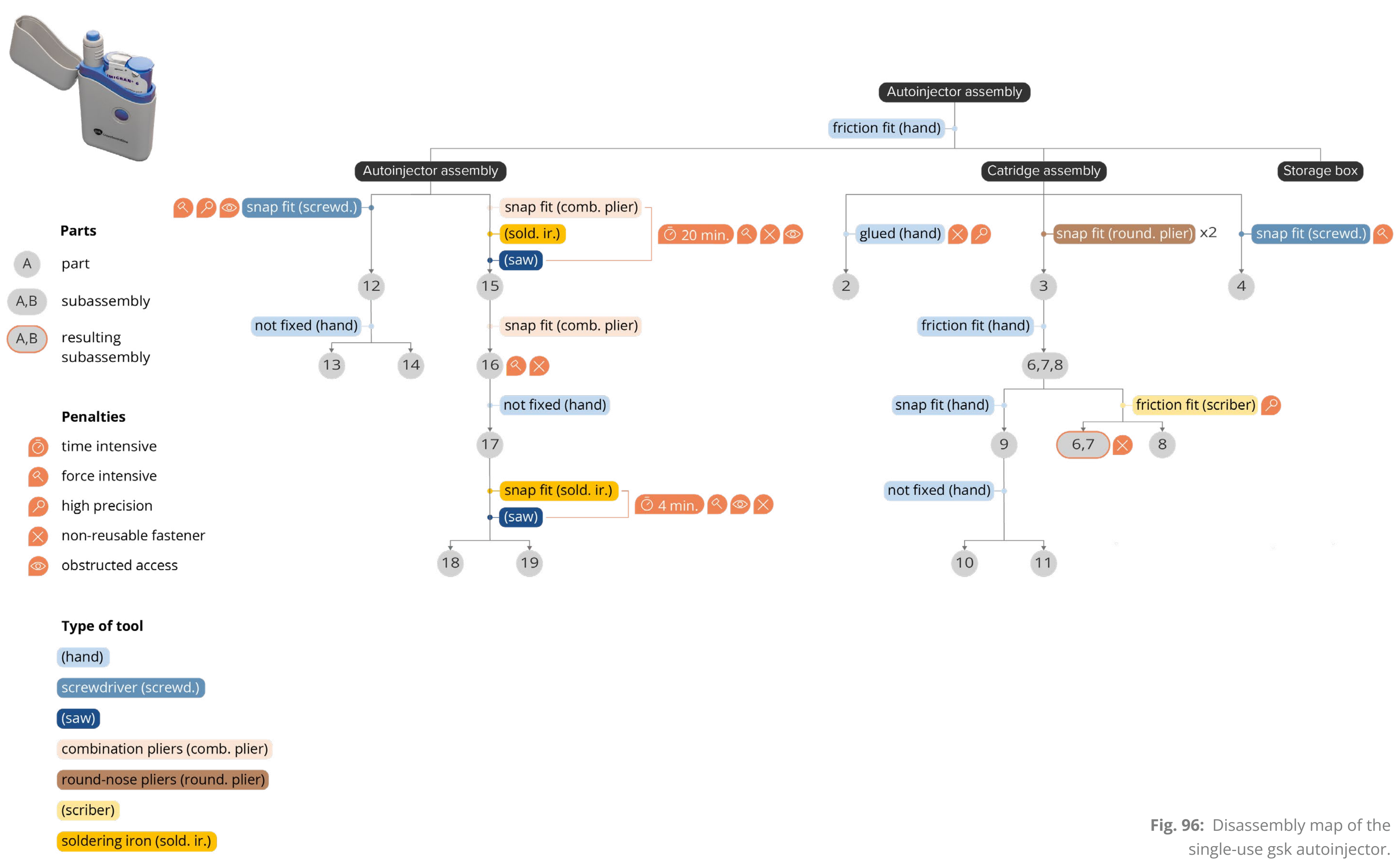


Fig. 96: Disassembly map of the single-use gsk autoinjector.

* Even though this storage box consists of multiple parts, I did not take it apart, because it is not relevant for this project.

5.5.11 Ease of maintenance & repair

Design for maintenance and repair is a circular strategy to extend product life (Bocken et al., 2016).

Maintenance is "the performance of inspection and/or servicing tasks to retain the functional capabilities of a product". (Linton et al., 2005, p. 1814)

Repair is about "restoring a product to a sound/ good condition after decay or damage." (Linton et al., 2005, p. 1813)

Currently, all YpsoMate autoinjectors are single-use products. Therefore, the autoinjectors are not repaired and maintained. This chapter evaluates if it would be possible to maintain and repair the YpsoMates in case they would be used multiple times in a reuse scenario.

Ease of disassembly

For ease of maintenance and repair, parts that have a high risk and impact of failure must be easy to replace (Flipsen et al., 2020). Therefore, ease of disassembly is key. The previous chapters showed that it is impossible to disassemble the YpsoMate without breaking parts. This makes maintenance and repairs impossible.

Risk of failure

Data on the need for maintenance and the risk of failure of YpsoMate parts are not available. Since it is currently a single-use product, engineers at Ypsomed do not know which parts are likely to fail after multiple uses. This makes it harder to prioritize the accessibility of parts based on the risk of failure. Tests would have to be conducted to generate data about the risk of failure of parts. Marianna Escobar is going to research this during her thesis, so this is out of scope for this thesis.

Impact of failure

It is also hard to prioritize parts based on the impact of failure. The failure of any part can harm the safety of the patient and the functioning of the autoinjector. For example, a broken cap can bend the needle and make it unhygienic. Any broken element in the Drive unit harms the injection. The housing keeps all parts together and should therefore not break. And like this, each part has a high impact when failing. Therefore, all components seem to be equally important based on their risk of failure and the impact of failure. Marianna Escobar is going to look further into this.

Takeaways

- Data about the risk of failure of YpsoMate parts does currently not exist because it is a single-use product. Tests should be conducted to establish this data to optimize the design.
- All parts in the YpsoMate have a high impact when failing and should therefore be thoroughly checked before reuse.

5.6 | Durability & reliability

This chapter evaluates the physical durability and reliability of the current YpsoMate autoinjector while taking reuse into account. A durable product can take the wear and tear without breaking down (Bocken et al., 2016). Reliability refers to "designing for a high likelihood that a product will operate throughout a specified period without experiencing a chargeable failure when maintained in accordance with the manufacturer's instructions." (Bocken et al., 2016, p. 310).

5.6.1 Physical durability

Durability during use

Patients may damage the YpsoMate during or after use, by dropping, scratching, drowning, bending or breaking it (as discussed in the chapter 2.1.3 about extreme usecases). The YpsoMate housing protects the inside parts from damage. The housing is made of Polycarbonate (PC), a stiff, hard, tough and rigid plastic (Granta Edupack, 2022). Thus, the PC housing protects the autoinjector against damage if the patient drops the autoinjector.

However, PC is not well suited for patients carrying the autoinjector with them at all times, since it easily scratches (Vickers Hardness is 18 - 20 HV (Granta Edupack, 2022)) and could yellow after long-term exposure to UV light (British Plastics Federation, 2022). Yet, patients using the YpsoMate often do not carry the autoinjector with them, since the medicines need to be refrigerated (see chapter 4.1.3). Still, these limitations of the Polycarbonate housing need to be considered when redesigning the autoinjector for reuse, since the housing should look reliable after multiple uses.

Takeaway:

- The PC housing is drop-resistant, but not scratch and UV-resistant.

Durability during dis- and reassembly

While taking the autoinjector apart, I broke the plastic spring of the Click Sleeve because I applied too much pressure (Fig. 97). However, automated disassembly would have a lower chance of applying too much force and thus damaging drive unit parts. Still, taking the drive unit apart increases the chances of damaging it. Since the drive unit does not need cleaning according to the Spaulding Scale (chapter 4), it can stay together during refill to prevent wear and tear.

This also raises the question if the drive unit parts need to be thicker to be more durable. I evaluated the drive unit parts with an engineer at npk design (Beljon, 2022) and we concluded that making the drive unit parts thicker is not necessary. If the yield strength of these parts is not exceeded during dis- and reassembly, the parts do not wear down/ break. With automated dis- and reassembly, the robots can apply a specific force to prevent exceeding the yield limits of the materials. Making the snap-fits thicker can even make the parts more prone to breaking (Beljon, 2022).

Takeaways

- The drive unit can stay together during refill to prevent wear and tear.
- The current drive unit parts will not break if the disassembly machines stay below their materials' yield strength. Thus, it is not a priority to optimize the parts for reuse.

Fig. 97: The plastic spring broke of the Click Sleeve during manual disassembly.

5.6.2 Emotional durability

Design for emotional durability refers to "a situation where users and products flourish within long-lasting empathic partnerships." (Chapman, 2005, p. 75)

For the YpsoMate Refill, this definition is not usefull, since it is a product that the patient only uses once, so there is no long-lasting relationship, Therefore, I use the term emotional durability to describe the patient's perception of the reused autoinjector as durable and reliable.

Even if the autoinjector is physically durable, if it appears worn down, the emotional durability is low, and the patient may not to use it.

Therefore, ensuring that the autoinjector maintains its appearance and functionality is crucial for enhancing its emotional durability and increasing patient satisfaction and trust.

5.6.3 Reliability

Since medicine effectiveness and safety are key in the medical sector, the autoinjector's reliability is extremely important. Since the YpsoMate parts are newly produced in a clean environment, the majority of the parts do not require sterilization or disinfection. Only the parts that come into contact with the medicine or enter the bloodstream, such as the needle, glass syringe, and rubber plunger, are sterilized to ensure that all microorganisms are killed (South Pole, 2022).

When reusing the autoinjector, some parts will require disinfection to guarantee patient safety. Chapter 6.3.2 looks into the sterilization and disinfection requirements and methods for the refillable YpsoMate.

5.7 | Standardization & upgradability

Design for standardization and compatibility is a circular strategy to prolong the lifespan of parts and subassemblies. It is about creating products with parts that fit other products as well (Bakker et al., 2014). This chapter evaluates the standardization and compatibility between YpsoMate autoinjectors.

5.7.1 Platform strategy

To speed up the time to market for pharmaceutical companies aiming to release a new medicine, YpsoMate uses a platform strategy (Fig. 99) (Ypsomed, n.d). This means that Ypsomed initiates new platform development, such as the development of a new autoinjector, independently from customers. When a company wants to release a new drug on the market, Ypsomed can offer them a fully developed autoinjector. The client can then customize the design.

This means that most YpsoMate autoinjectors on the market contain similar parts, sharing internal mechanisms and square housing. However, customers often customize colors and sometimes housing shapes to make them more ergonomic for certain patient groups. The next chapter discusses the different platforms Ypsomed offers.

5.7.2 Variation between YpsoMate platforms

Ypsomed produces five types of YpsoMate autoinjectors (Fig. 98), which they call YpsoMate platforms.

Three of those variations cater to different vaccine volumes, namely: 1.0, 2.25 and 5.5 mL. Then there are two variations of the 1.0 mL autoinjector: a connected version (YpsoMade Smart) and a sustainable version (YpsoMate Zero).

The parts of the YpsoMate 1.0 mL and the YpsoMate Zero are similar in size since they both contain 1.0 mL of injection fluid. The 2.25 mL autoinjector has the same parts as the 1.0 mL autoinjector, but every part is bigger (Fig. 100). This is due to the stronger spring force needed and the larger syringe. The YpsoMate 5.5 mL has a different housing design and the internal parts are likely also different, due to the high forces needed to inject the large volume of injection fluid.

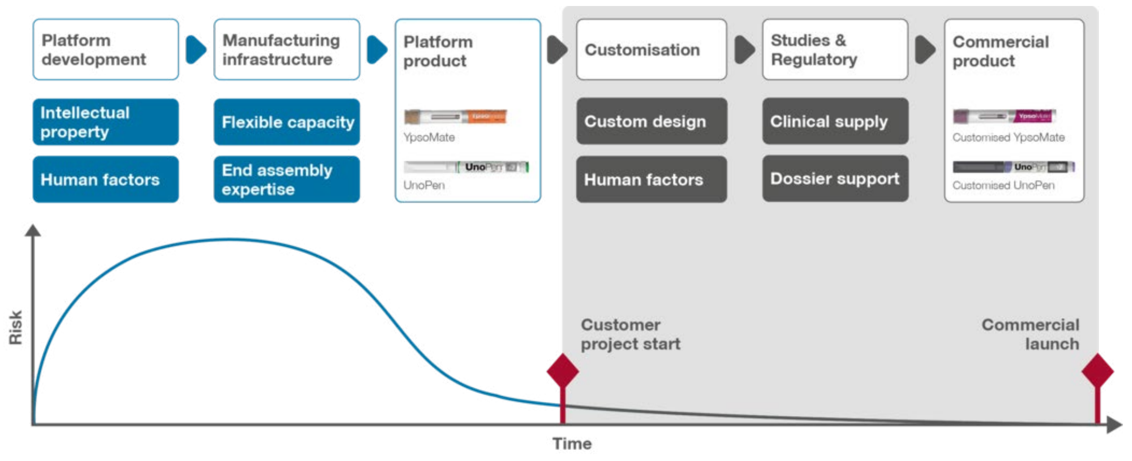
Together with Sebastian Gerner from Ypsomed, I decided to focus on the 1.0 mL autoinjector. Since the redesign principles of the 1.0 mL YpsoMate can be translated to the 2.25 and 5.5 mL autoinjectors.

Takeaways

- The YpsoMate Zero and YpsoMate 1.0 mL parts are interchangeable and compatible.
- The parts of the YpsoMate 1.0 mL/ Zero and the YpsoMate 2.25 and 5.5 mL are different in size and thus not compatible.
- This means that Ypsomed would need different refill streams for the 1.0, 2.25 and 5.5 mL autoinjectors.
- My redesign focuses on the YpsoMate 1.0 mL/ Zero, since the redesign principles can be translated to the other sizes.

Fig. 98: Different YpsoMate autoinjector versions (Ypsomed, 2022).

Fig. 99: YpsoMate platform strategy (Ypsomed, n.d.)



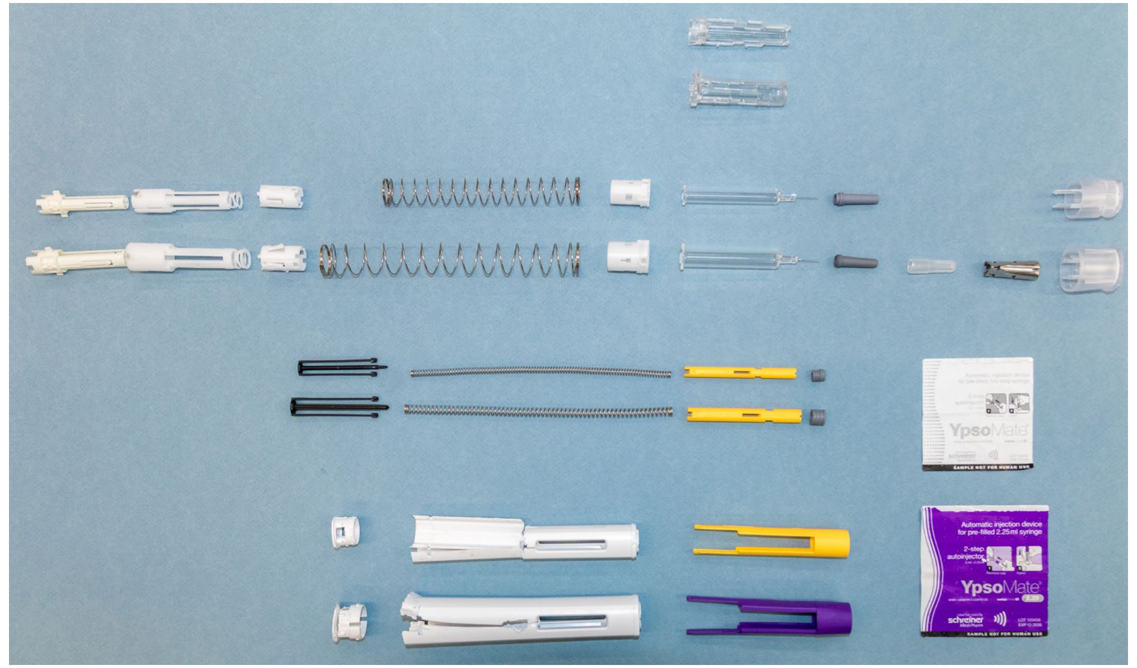


Fig. 100: d.) Differences in part size between the YpsoMate 1.0 mL and the YpsoMate 2.25 mL.

5.7.3 Customization & upgrades within a YpsoMate platform

Within the YpsoMate 1.0 mL line, there are variations in parts depending on the medicine and company.

The following parts are medicine/ company specific (Fig. 102):

- Plunger rod (color)
- Cover sleeve (color)
- Housing (shape & size can be customized upon request, but this is less common).
- Needle (size)
- Label (color, company name, medicine, dose, serial number, expiration date.)

These medicine specific parts make it more difficult to have an efficient refill stream. It means that autoinjector parts of different medicines and companies are not compatible.

Customized housing

Fig. 101 shows a customized housing. A customized larger housing to provide an ergonomic grip for patients with rheumatoid arthritis is placed around a standard housing. This housing around a housing adds a lot of plastic (waste) to each autoinjector. But it provides Ypsomed with the benefit to customize autoinjectors fast and cheap. Moreover, for ergonomic and/ or cosmetic reasons, Ypsomed uses 2K and 3K injection molding. This results in products consisting of inseparable different plastics. This limits recycling.

Takeaways

- Currently, the plunger rod, cover sleeve, housing, needle and label vary between companies and medicines.

Fig. 101: A larger customized housing is clicked around a standardized housing.

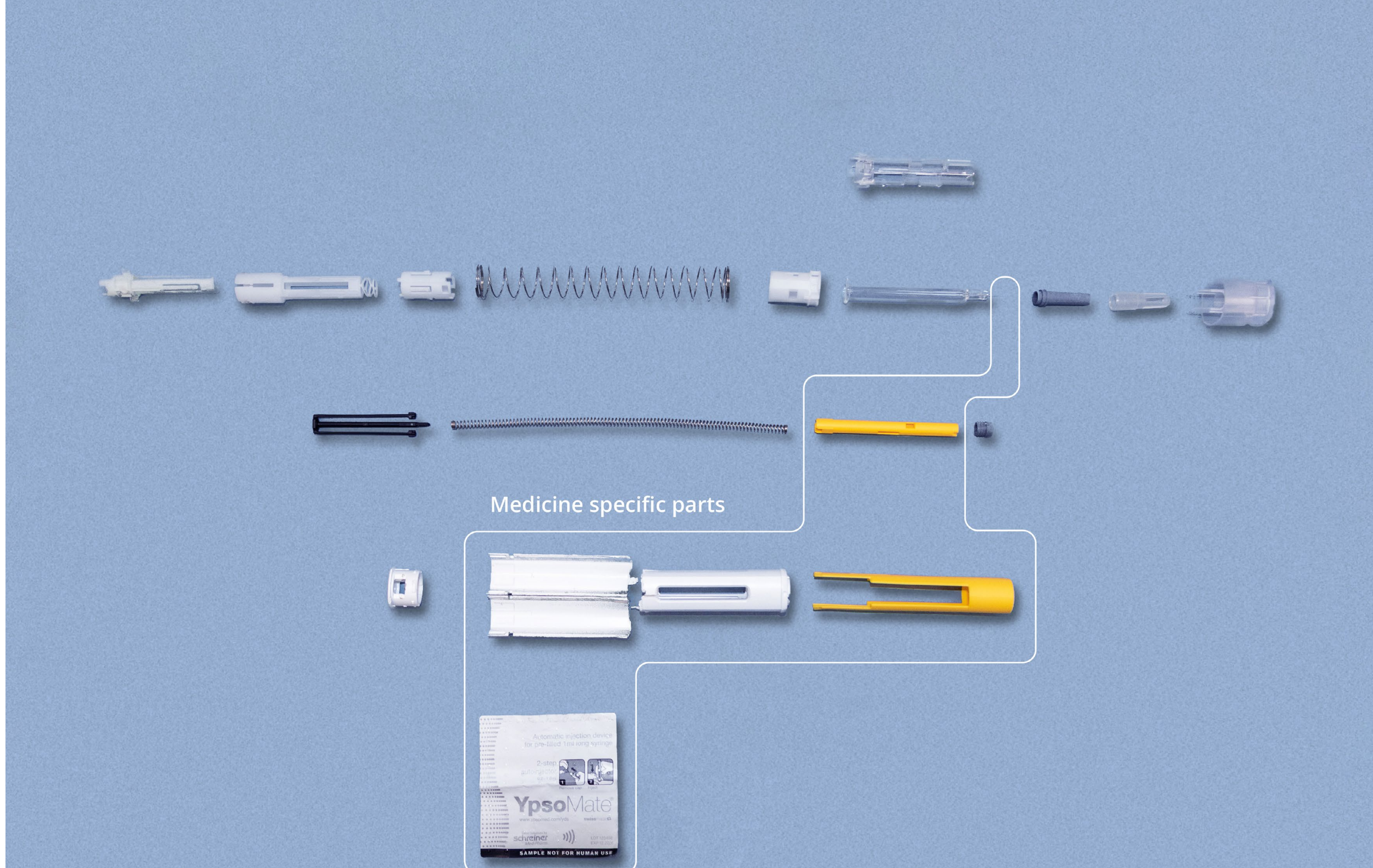


Fig. 102: The plunger, cover sleeve, label and housing can be customized by the client (a Pharma company).

5.8 | High value recycling

A step towards the circular economy is closing resource loops. This can be done by designing for a technological cycle, meaning that "materials can be safely and continuously recycled into new materials and products. (Boulding, 2003). For a continuous closed loop, it is important that recycling maintains the material properties (Bocken et al., 2015).

5.8.1 Recycling take-back schemes

The healthcare company Novo Nordisk launched a Take-Back scheme for insulin pens in the UK and Denmark in 2021 to enable recycling (Fig. 104). Patients can bring their used pens back to their pharmacy or mail them back to Novo Nordisk. (PenCycle, n.d.). At a Novo Nordisk facility in Denmark, the pens are disassembled and sorted by material for recycling. In collaboration with a Danish Design firm, the plastic is recycled into chairs (Fig. 104) and the glass from the insulin vials is melted down to create lamps. (Nielsen, 2020)

Johnson & Johnson is also working on a Safe Returns program for autoinjector recycling (Gysel, 2022). However, there are no take-back schemes (yet) that recycle autoinjectors and turn them into new autoinjectors.

Johnson & Johnson (n.d.) is also developing a machine that could recycle YpsoMate autoinjectors after use.

Takeaway

- Companies are developing take-back schemes to recycle autoinjectors.

Fig. 103: (Top) This insuline pen can be recycled in the Take-Back scheme (PenCycle, n.d)

Fig. 104: (Bottom) A chair made of plastic from recycled insuline pens (Novo Nordisk, 2020)

5.8.2 Recyclability of the YpsoMate

Incinerated after one use

Currently, all YpsoMate autoinjectors are incinerated or landfilled (depending on the country) after one-time use, since it is classified as infected medical waste (Gerner, 2022). A LCA from SouthPole (2022) shows that this incineration causes approximately 10% of the total CO2e emissions of a YpsoMate autoinjector. Even if there would be a take-back scheme for the YpsoMate, it would be hard to recycle the current design. The upcoming subchapters discuss the reasons for this.

Label glued to housing

There is a label glued around the housing (Fig. 105), containing medicine-specific information. The label hides snap-fits, thus making it harder for patients to open the housing.

However, the glue makes the housing and label inseparable via shredding, Unless the label is soaked off, shredding the autoinjector results in a mixed waste stream of housing plastic (PC & 10% ABS) and label plastic (PP).

NFC tag inseparable from label

Some autoinjectors contain an NFC tag to connect them to the YpsoMate SmartPilot. The YpsoMate SmartPilot is a device that can be connected to a smartphone, to monitor medicine adherence (YpsoMate, 2022).

However, the NFC tag is laminated into the label (Fig. 105). This makes them inseparable from each other, creating a mixed waste stream of electronics and plastics that cannot be recycled. This is against the advice of the Ypsomed Ecodesign guidelines (2022), which state that electronics should be easily separable.

Fig. 105: A label with a laminated NFC tag inside it is glued around the housing of the YpsoMate.

Part	Material
1. Rigid needle shield	PP
2. Soft needle shield	Rubber
3. Cap Remover	PC
4. Label	PP
5. Injection spring	Stainless steel
6. Cover sleeve spring	Stainless steel
7. Outer telescopic lock sleeve (TLS)	POM
8. Inner TLS	POM
9. Plunger rod	POM
10. End cap	PC/ 10% ABS
11. Holding pin	PA + 60% GF
12. Click Sleeve	PBT + 30% GF
13. Mechanic holder	POM
14. Syringe	Glass
15. Needle	Stainless steel
16. Plunger	Rubber
17. Syringe holder	PC
18. Cover sleeve	POM
19. Housing	PC/ 10% ABS

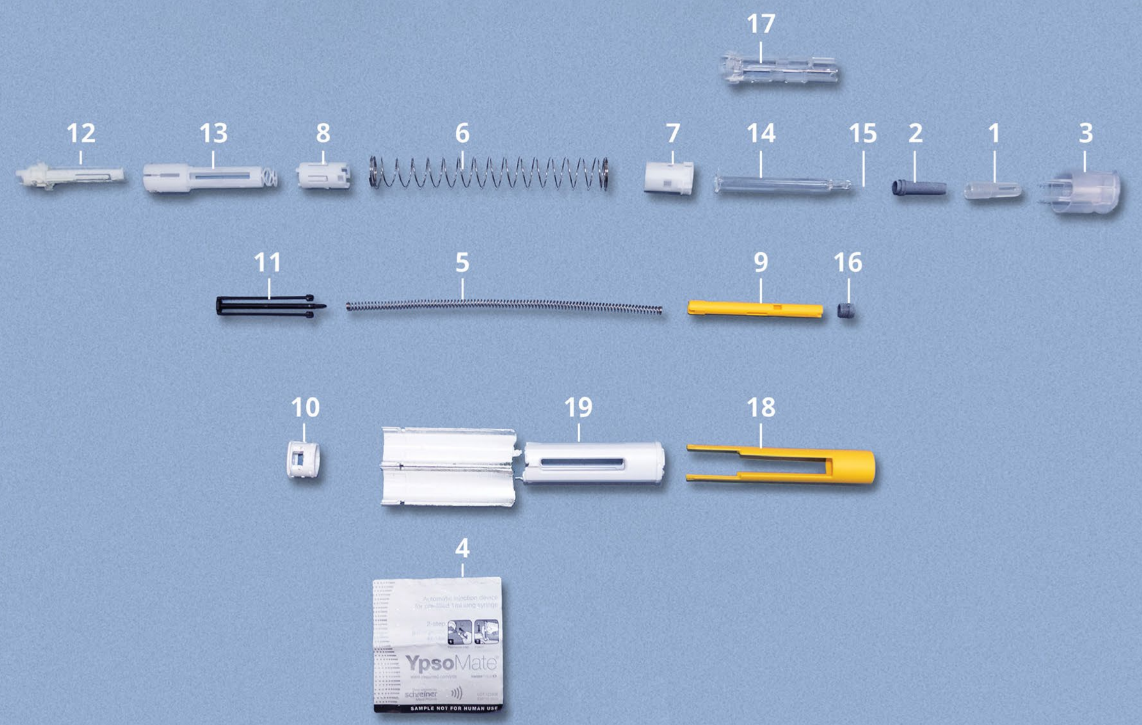


Fig. 106: The single-use YpsoMate autoinjector with parts and materials.

Large variety of plastics

Fig. 106 shows that the YpsoMate contains six different plastics, alongside rubber, glass and stainless steel. Separating these different types of plastic asks for more precise recycling, making it more difficult and expensive. Therefore, the Ecodesign guidelines of Ypsomed (2022) advise limiting the variety of plastics in a device and making entire assemblies of one material.

Reinforced and mixed plastics

For recycling, mono-materials are preferred, so the Ypsomed Ecodesign guidelines (2022) advise against making the housing out of PC with 10% ABS. Engineers at Ypsomed are looking into making the housing from PP. This is a weaker plastic than PC but has the advantage of being a commonly recycled mono-material (Granta Edupack, 2022)

Two parts in the drive unit (Fig. 107, 11: holding pin & 13: click sleeve) are made of plastic reinforced with glass fiber, to make them stronger. For example, the holding pin is reinforced, since it holds the heavily loaded injection spring in place.

A disadvantage of reinforced plastic composites is that they can only be downcycled (Granta Edupack, 2022). Therefore, Ypsomed's Ecodesign Guidelines (2022) advise to avoid reinforced plastics.

2K & 3K injection moulding

Pharma companies can customize their housing to consist of multiple plastics, such as hard plastic and silicone (Fig. 107). This silicone can provide extra grip but is also often done for aesthetic reasons. Ypsomed uses 2K and 3K injection molding to create these housings. This results in products consisting of inseparable different plastics. This limits recycling.

Fig. 107: A customized cap with a 2K injection molded silicone label.

Takeaways

Even if there would be a take-back scheme for the YpsoMate, it would be hard to recycle the current design. It is difficult to separate the autoinjector in different streams of mono-materials, due to the use of ;

- a large variety of plastics
- reinforced plastics
- a label glued onto the housing
- an NFC tag is inseparably laminated into the label
- 2K and 3K injection moulding

Part 2
Design

6. YpsoMate Refill

This chapter introduces the YpsoMate Refill concept design. YpsoMate refill is an autoinjector that fits into the circular economy. Instead of being incinerated after one-time-use, the autoinjector is sterilized and refilled at a Refill Hub. This way, one autoinjector can be reused by many different patients, to reduce waste, CO_2 emissions and energy use.

The chapter discusses the product journey of the YpsoMate Refill and highlights the changes in comparison to the single-use YpsoMate. The next chapter 7 dives deeper into the redesign that is needed for this circular product journey.

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6.1 | YpsoMate Refill: a first step towards a circular autoinjector

The YpsoMate Refill (Fig. 109) design exemplifies Ypsomed's first Ecodesign Guideline, "Rethink." Unlike conventional autoinjectors that are discarded after use, the YpsoMate Refill allows patients to use an autoinjector while the device's ownership remains with the pharmaceutical company, which expects patients to return it for reuse (Fig. 110). This access model approach is more sustainable than typical single autoinjectors (Fig. 109) because it significantly reduces waste by refilling the autoinjector.

After being returned to a Refill Hub, the YpsoMate Refill undergoes a thorough quality check to ensure that all components are fit for reuse. Any single-use or damaged parts are recycled, while reusable parts are cleaned, disinfected, and reloaded. The housing receives a fresh label, and a new prefilled syringe is inserted.

By reusing the same autoinjector for multiple patients, the YpsoMate Refill concept helps to the reduce environmental impact and waste of self-injections.

This innovative design aligns with Ypsomed's commitment to promoting sustainability while guaranteeing patients' safety and comfort. Overall, the YpsoMate Refill represents a first step towards a circular future for autoinjectors.

Takeaway

- The YpsoMate Refill follows a circular product journey.

Fig. 108: The YpsoMate Refill concept

YpsoMate 1.0 mL & YpsoMate Zero: linear product life

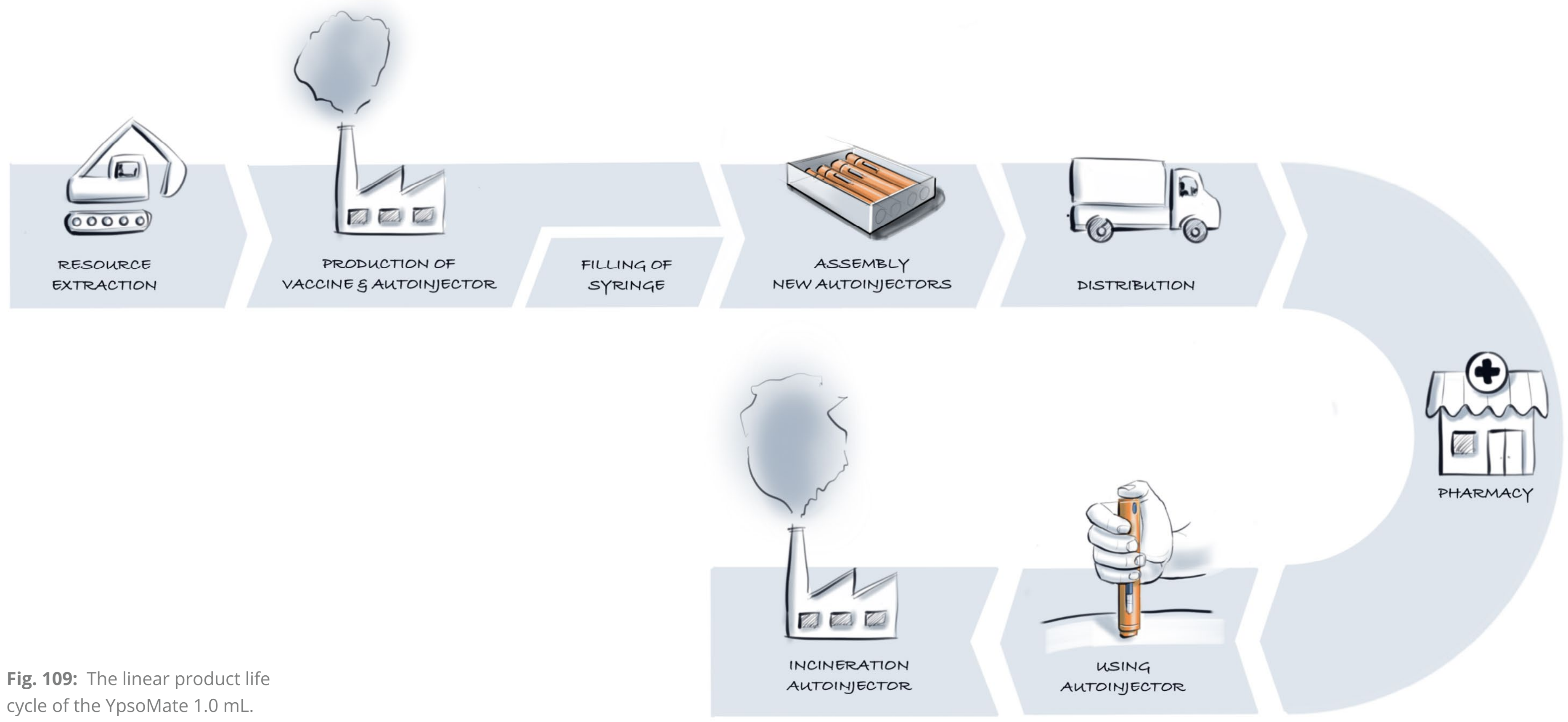

Fig. 109: The linear product life cycle of the YpsoMate 1.0 mL.

YpsoMate Refill: circular product life

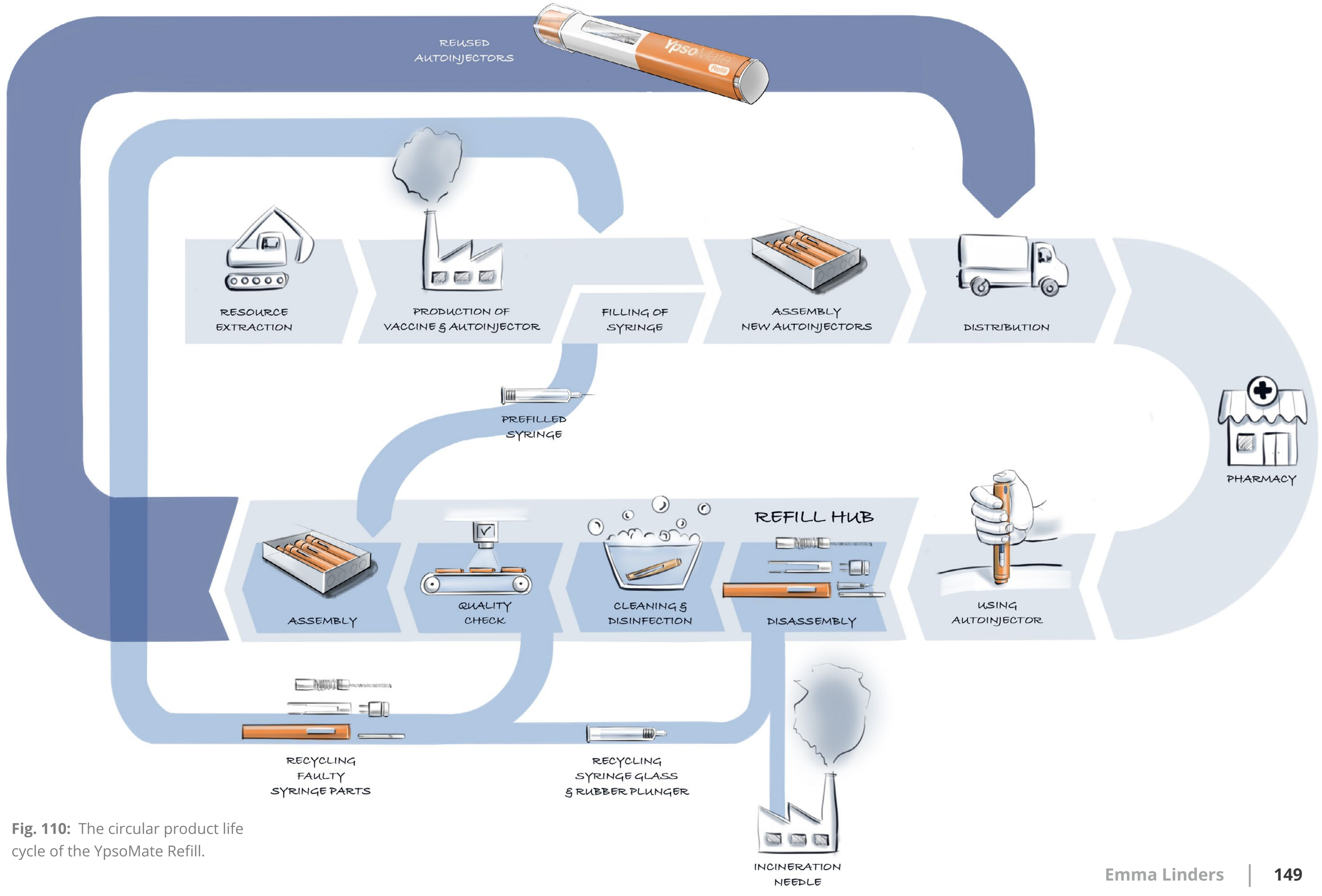

Fig. 110: The circular product life cycle of the YpsoMate Refill.

6.2 | Patient experience

6.2.1 Unboxing the YpsoMate Refill

The YpsoMate Refill introduces a new packaging box design (Fig. 112) that not only reduces packaging waste but also promotes sustainable autoinjector usage. The redesigned packaging design aims to convey a sense of quality and sustainability to patients, motivating them to return the used autoinjector to the Refill Hub. This chapter compares the current YpsoMate 1.0 mL packaging to the redesigned YpsoMate Refill packaging.

Current Single-Use YpsoMate Packaging

When a patient receives the single-use YpsoMate 1.0 mL via home delivery, the autoinjector box is double packaged inside a delivery box that is often larger than necessary Fig. 111. This results in increased packaging waste and transportation emissions since it means that fewer boxes can fit within a truck.

Fig. 111: The current single-use YpsoMate is delivered inside a box in a box

Redesigned YpsoMate Refill Packaging

The YpsoMate Refill packaging features a single delivery box that securely houses the autoinjector (Fig. 114), reducing packaging waste. The box is made of unbleached recycled cardboard, which not only reduces the environmental impact but also captures the patient's attention and emphasizes the sustainable nature of the autoinjector. Inside the box, patients can find more information about the YpsoMate take-back scheme (Fig. 113).

The goal of the YpsoMate Refill packaging is to create a unique unboxing experience that communicates to patients that the autoinjector is a high-quality product that should be reused, not thrown away.

Fig. 112: The YpsoMate Refill arrives in this box, which saves packaging waste.

Fig. 113: The instructions show the patient how to return the autoinjector after use.

Fig. 114: The YpsoMate Refill is securely protected inside the box.

6.2.2 Using the YpsoMate Refill autoinjector

Familiar and easy to use

The YpsoMate Refill autoinjector is just as simple to use as the single-use YpsoMate, as shown in Fig. 115 and Fig. 116. The Refill model closely resembles its single-use counterpart, making it easy for patients to adapt to. Because the injection experience remains unchanged, patient evaluations of the redesign were deemed unnecessary.

Building Patient Trust in the YpsoMate Refill Autoinjector

To differentiate the YpsoMate Refill as a refillable autoinjector, an icon on the end cap and label (Fig. 117) captures patients' attention.

This "certified reuse" icon indicates the device's reuse history and aims to reinforce patients' confidence in its safety and quality.

According to the research of Novo Nordisk (n.d.), trust is a key priority for patients.

Patients can also find additional information inside the packaging box on the device's rigorous testing and quality checks, which aim to further boost their confidence in the autoinjector's reliability and safety.

To maintain the device's appearance, a new label enclosing the housing conceals any scratches, creating a fresh look and aesthetic hygiene.

However, to evaluate the effectiveness of these trust-building measures, interviews with patients are necessary to assess their attitudes toward reusing an autoinjector. Yet, such tests are beyond the scope of this graduation project.

Takeaways

- The YpsoMate Refill has the same easy use steps as the single-use version.
- The "certified reuse" icon aims to reinforce patients' trust.
- A new label makes the autoinjector look fresh and reliable.

Fig. 115: Step 1 - Remove the cap from the YpsoMate Refill.

Fig. 116: Step 2 - Push the YpsoMate Refill on the skin to start the injection.

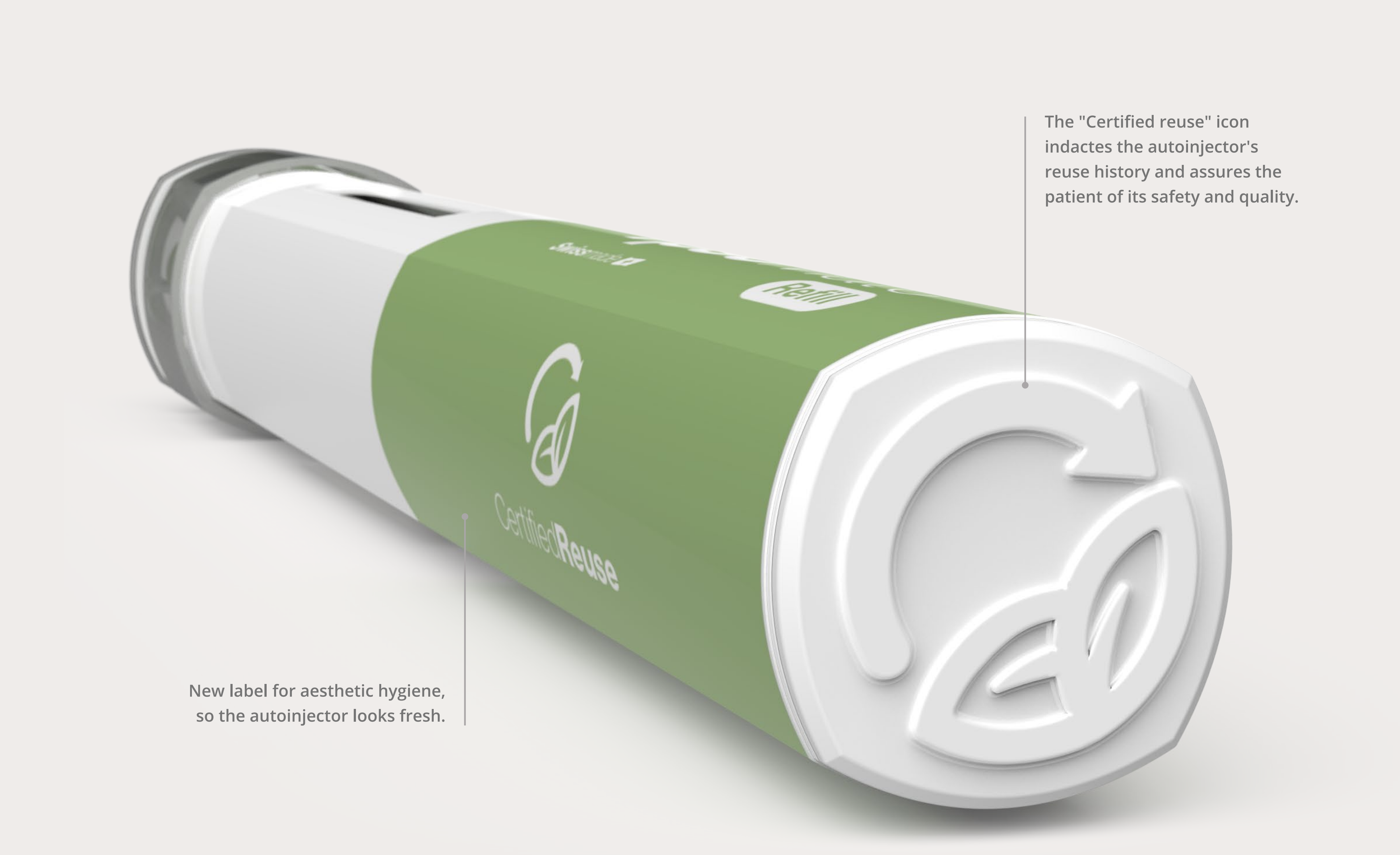

Fig. 117: The end cap has a "Certified Reuse" icon that indicates the device's reuse history and aims to reinforce patient confidence in its safety and quality.

6.2.3 Returning the YpsoMate Refill

Convenience and flexibility are crucial in motivating patients to return their autoinjectors (Novo Nordisk, n.d.).

Therefore, patients can return their YpsoMate Refill via various methods, including bringing it back to the pharmacy, via home collection, or pre-paid post boxes. The pre-paid post box is the same box that the patient received the autoinjector in, minimizing packaging waste. Patients can simply remove their address sticker to uncover the Refill Hub's address and use the same box to return the autoinjector.

Fig. 118: The patient can return the used autoinjector via a pre-paid post box.

6.3 | Refill Hub

This chapter provides an overview of the disassembly, disinfection, quality check, and assembly process of the YpsoMate Refill at the Refill Hub (Fig. 119). Upon arrival, the YpsoMate undergoes disassembly and the reusable parts are carefully disinfected. Afterwards, all components undergo a quality check to ensure that they are in excellent condition. Any single-use or damaged parts are recycled, and finally, a new prefilled syringe is inserted into the housing, which is then wrapped in a fresh label.

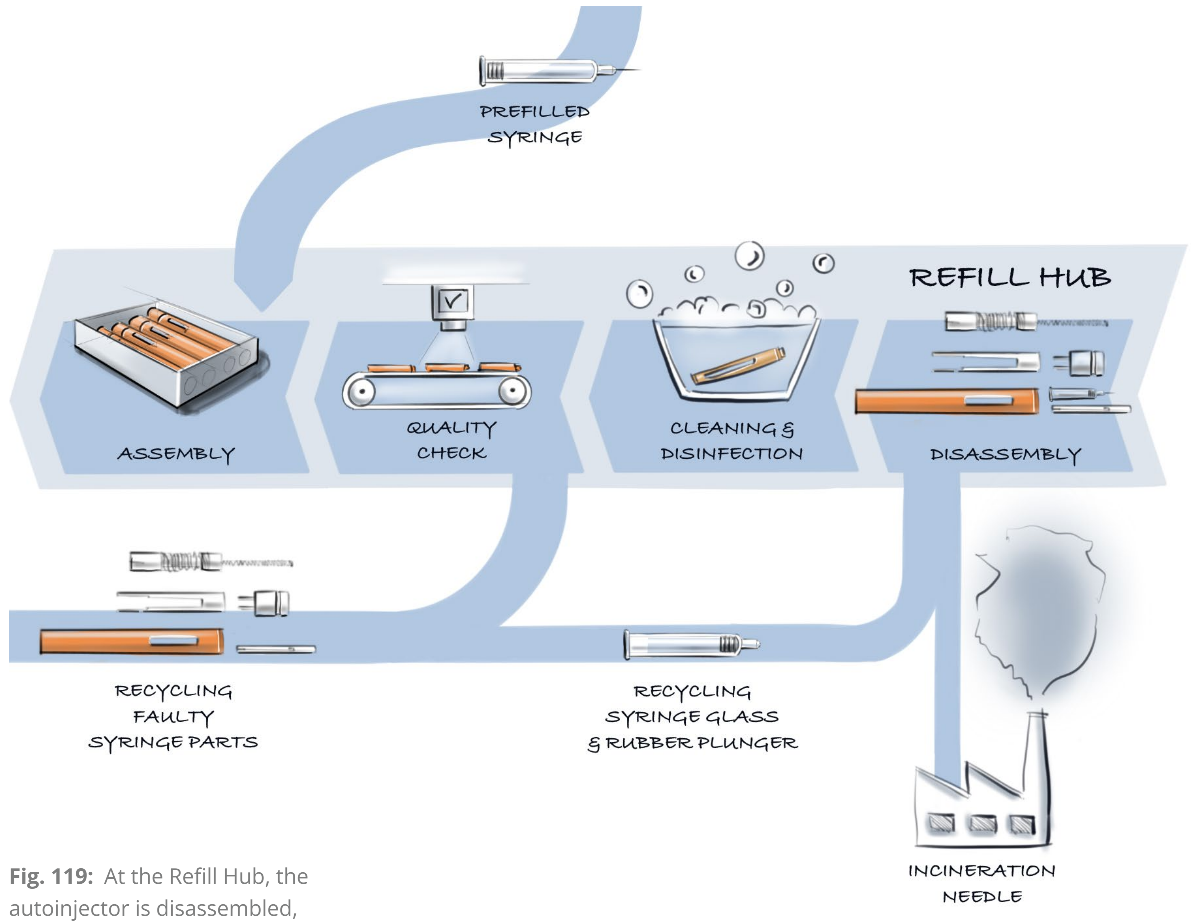

Fig. 119: At the Refill Hub, the autoinjector is disassembled, disinfected, checked and reassembled.

6.3.1 Disassembly

To make refilling and cleaning easy, the YpsoMate Refill is designed with reusable connections and can be easily disassembled and reassembled. Fig. 120 till Fig. 123 show the disassembly steps.

1. A machine punctures the label to open the snap-fits of the end cap to remove the drive unit, syringe, and cover sleeve.
2. Simultaneously, the cap is disassembled into the cap remover and the rigid & soft needle shield.
3. The syringe slides out of the drive unit.
4. The cover sleeve slides out of the housing.
5. The end cap is separated from the drive unit.
6. The drive unit is reset and reloaded.
7. The label is soaked off the housing.

To speed up the process, most of these steps can be done simultaneously. Moreover, only parts that require disinfection are disassembled, so the drive unit remains intact.

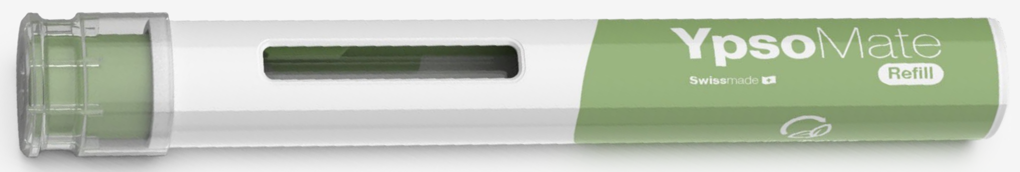

Fig. 120: Step 1

Fig. 121: Step 2

Fig. 122: Step 3

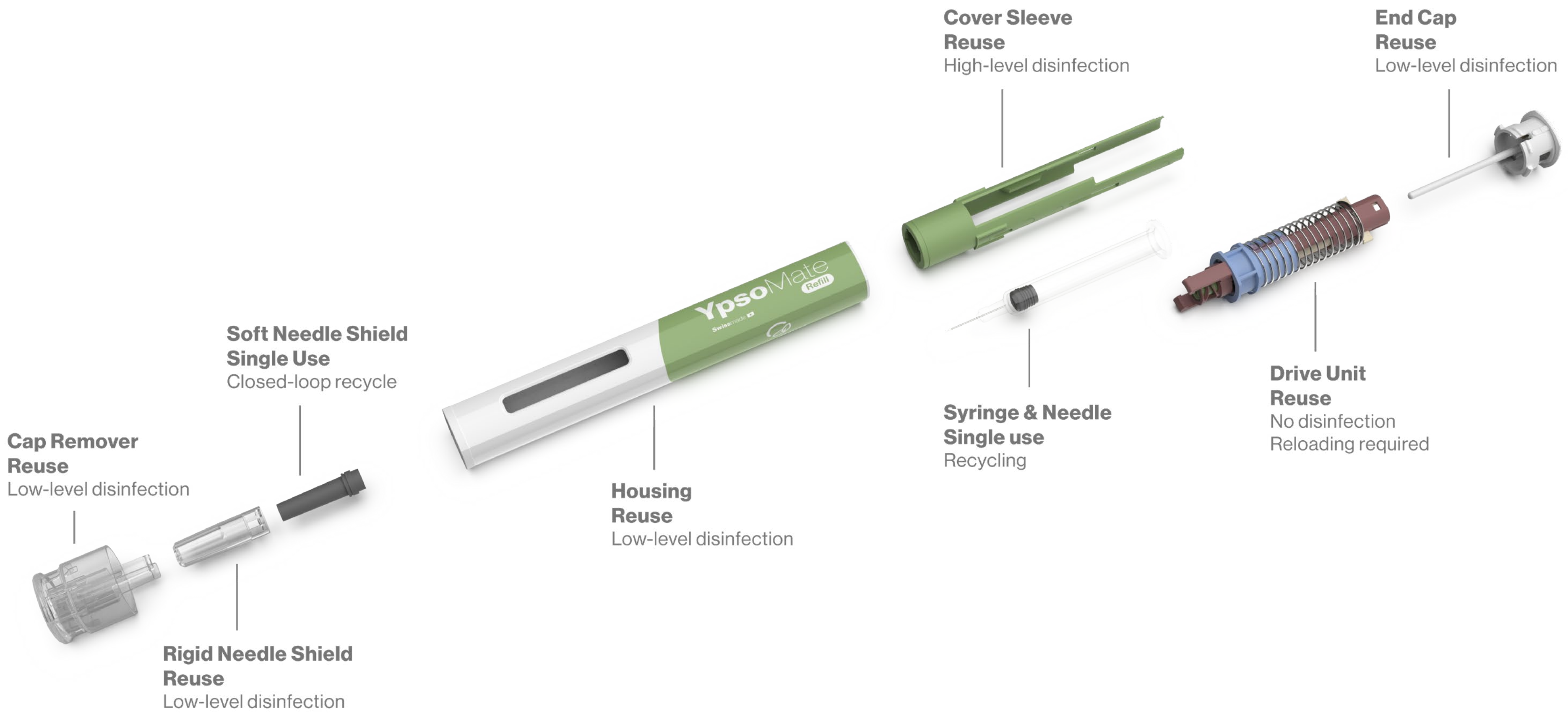

Fig. 123: Step 4

6.3.2 Disinfection

Sterilization single-use YpsoMate

In the current single-use YpsoMate, all parts are produced in clean environments. Therefore, only the parts that come into contact with the medicine or enter the bloodstream, such as the needle, syringe, and plunger are sterilized to ensure the safety of the autoinjector (South Pole, 2022).

Sterilization & disinfection YpsoMate Refill

However, when the used YpsoMate Refill is returned to the Refill Hub after use, some parts are contaminated. To determine if sterilization or disinfection is required before reuse, I used the Spaulding classification framework (Fig. 124) (Spaulding et al., 1968). This framework forms the basis of international medical device disinfection guidelines (Nanosonics, 2022). I classified the Ypsomate autoinjector parts as follows (Fig. 125):

Sterilization

The needle, syringe, plunger, and soft needle shield must be sterilized, as these parts come into contact with the bloodstream. However, as specified before and further elaborated in chapter 7, these parts will not be reused but recycled instead, due to other considerations. Therefore, no used parts need to be sterilized between injections.

High-level disinfection

The cover sleeve requires a high-level of disinfection, as it may touch the puncture wound after injection.

Low-level disinfection

The housing, end cap, cap remover, and rigid needle shield require low-level disinfection, as these parts could come into contact with intact skin when the patient holds the autoinjector and removes the cap.

No cleaning/disinfection needed

The Drive-Unit is encapsulated by the housing and does not come into contact with the patient's skin. Therefore, it does not require cleaning or disinfection. The plunger rod may raise some concerns as it may contain medicine residue from the syringe wall. However, the plunger rod never comes into contact with the medicine that is injected into the patient, since the medicine is shielded by the rubber plunger. Therefore, it is not critical that the plunger rod is cleaned between injections. This is beneficial, as it allows the Drive-Unit to stay together between reuses.

This classification of autoinjector parts should be reviewed by a medical specialist to ensure the safety of the device.

Takeaway

- The Spaulding Scale indicates which YpsoMate parts need high and low-level disinfection. Fig. 125 shows an overview of these parts.

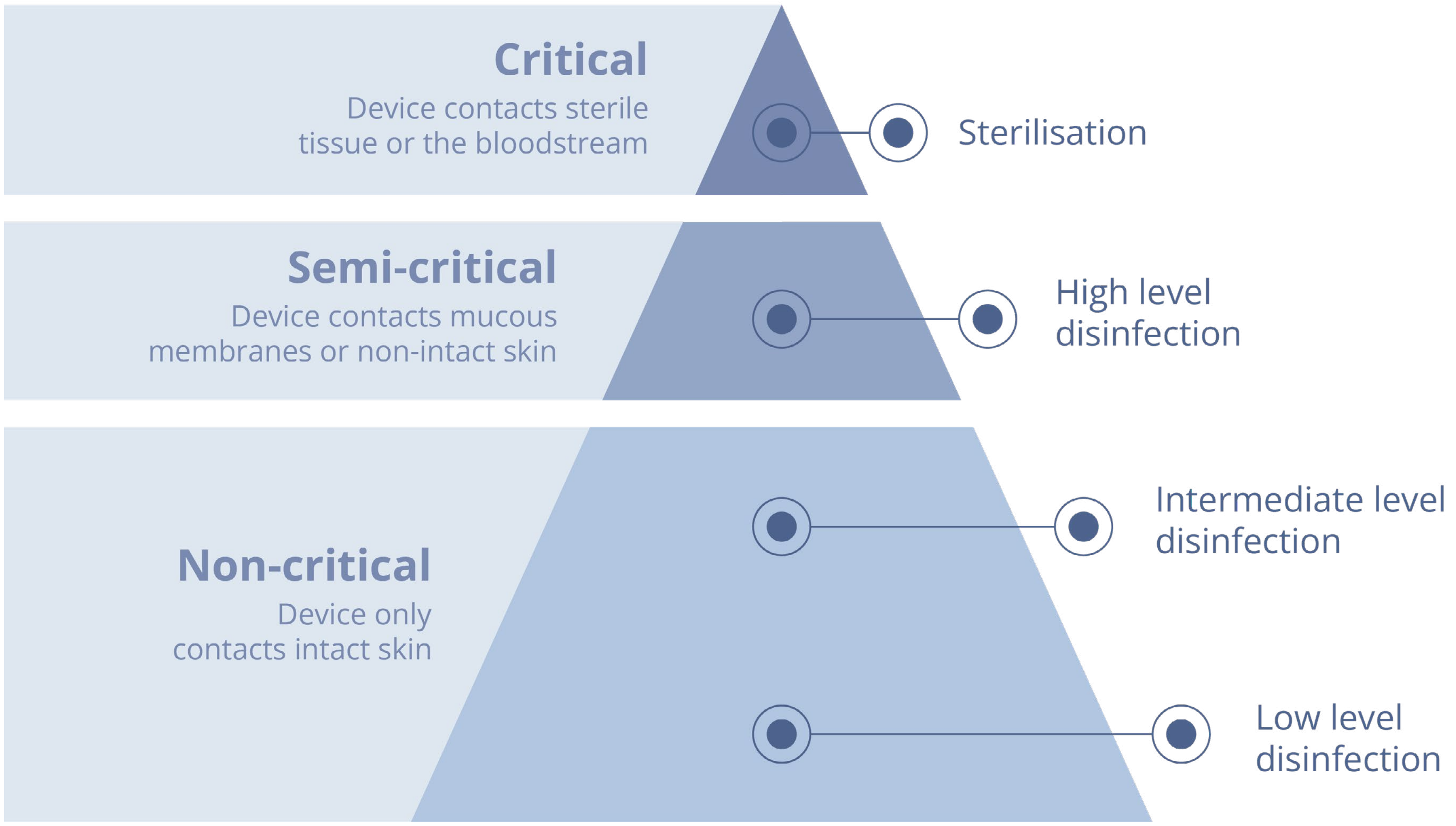

Fig. 124: Spaulding Classification (Nanosonics, 2022).

Disinfection process

Effective disinfection of medical devices requires thorough cleaning and drying before beginning the disinfection process. Appendix F gives an overview of different disinfection methods is, along with their advantages, disadvantages, environmental impact, and compatibility with different materials.

High-level disinfection for YpsoMate cover sleeve

The cover sleeve of the YpsoMate autoinjector may come into contact with non-intact skin after the injection, making high-level disinfection necessary. A sustainable and effective method for disinfecting the polycarbonate cap is to use gas or liquid hydrogen peroxide. This method produces water and oxygen as by-products, making it environmentally friendly (Rutala & Weber, 2013; Gill, 2021).

Low-level disinfection for other YpsoMate components

The end cap, housing, cap remover, and rigid needle shield of the YpsoMate autoinjector require low-level disinfection and are made of polycarbonate (PC). A common and safe method for low-level disinfection of PC is to use a solution of water and a mild detergent, followed by thorough rinsing to remove any remaining detergent or dirt. It is important to avoid using methyl alcohol for disinfection, as it can discolor and crack the PC (Rutala & Weber, 2013).

Takeaways

- Hydrogen peroxide is a sustainable high-level disinfection method.
- Avoid using methyl alcohol for PC disinfection, as this can discolor and crack the material.

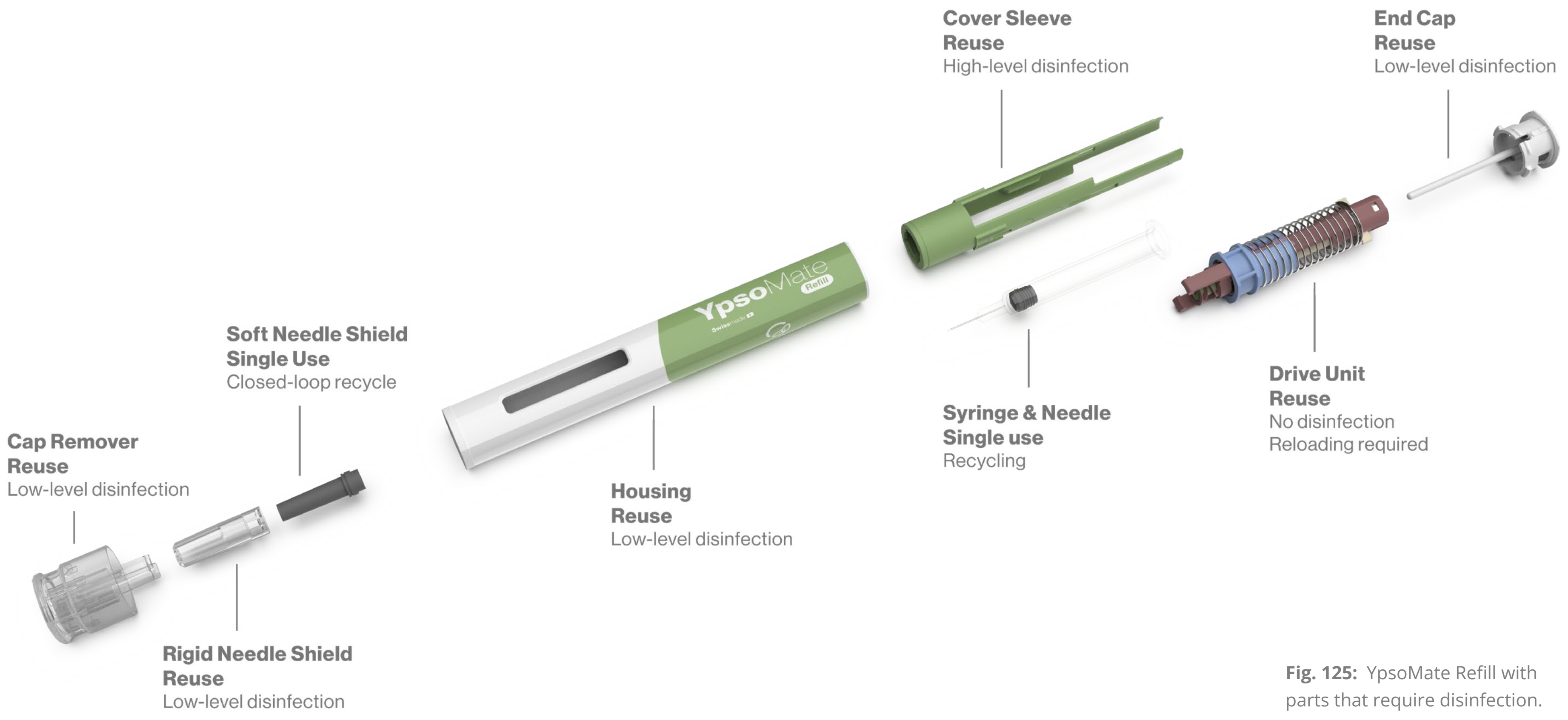

Fig. 125: YpsoMate Refill with parts that require disinfection.

6.3.3 Quality check

After disassembly and disinfection, the parts and Drive-Unit subassembly undergo a quality check to ensure their structural integrity for another reuse cycle. However, the current quality checks used for the single-use YpsoMate autoinjectors are not suitable for the YpsoMate Refill parts. The following paragraphs explain the reasons and propose an alternative method for testing the quality of used parts.

Quality check for single-use YpsoMate

The current quality checks for the single-use YpsoMate autoinjectors are destructive (Fig. 126) and not automated since only a few parts of each batch are tested to guarantee the quality of the entire batch. However, this method cannot be used for the YpsoMate Refill since each part has had a different lifetime, and destroying the parts during the quality test would render them unusable. Therefore, an alternative method is needed to test the quality of the used parts.

Fig. 126: A destructive quality check of an YpsoMate autoinjector at the Ypsomed factory in Burgdorf, Switzerland.

Quality check for YpsoMate Refill

To determine how often the YpsoMate Refill parts can be reused, tests should be conducted to create reuse guidelines. Then, the parts could be traced to determine how often they can still be reused. Tracing could be done by adding a serial number to a part or assembly or via RFID tags (this does not have a preference, since it adds electronic waste).

However, tracing does not provide information if the patient dropped the autoinjector or if the part has been exposed to extreme temperatures or other conditions that could affect its integrity. Therefore, quality checks with cameras are also needed to detect broken parts and scratches. Artificial Intelligence could potentially help with analyzing these camera images to automate the process (Pahl, 2020).

Even though this chapter provides an initial idea for the quality check of reuse parts, this should be further investigated. Fortunately, Mariana Osorio Escobar, the new graduation student for the Alliance to Zero, will be looking into this.

Broken parts are recycled

Together with the single-use parts, the parts that do not pass the quality check are recycled to minimize waste and reduce the environmental impact of the YpsoMate Refill. The YpsoMate Refill contains only mono-materials, which increases the recycling possibilities. The next chapter 7 discusses this in more detail.

Takeaways

To ensure the quality of reused YpsoMate parts, this combination of methods could be used;

- Tracing parts
- Camera quality checks for scratches and broken parts
- Quality testing to create a database on how often parts can be reused and how they look after a certain amount of reuses.

6.3.4 Reassembly

The reassembly process involves putting the disinfected and quality-checked parts back together in reverse order to disassembly, with the addition of a new prefilled syringe. Once the assembly is complete, the housing is sealed with a new label containing medicine specific information. This label ensures that the autoinjector looks fresh and clean. This label also conceals the snap-fits of the end cap to prevent patients from attempting to open the device.

7. Detailed Design

This chapter provides a detailed overview of the design process for transforming the YpsoMate single-use autoinjector into the sustainable YpsoMate Refill concept. The design process follows the principles of the circular economy, with a focus on reducing material consumption, promoting reuse, and recycling materials to lower the CO2e footprint and waste.

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7.1 | YpsoMate Refill requirements

7.1.1 Introduction

Table 12 & Table 13 show the requirements the YpsoMate Refill concept needs to fit. I divided them into two types of requirements: product architecture requirements (Table 12) and sustainability requirements (Table 12). The requirements contain no hard numbers (yet) since this is a conceptual project with a time to market of five to fifteen years (2030 - 2040).

Product architecture requirements

Table 12 shows the YpsoMate Refill product architecture requirements. These are based on the product architecture analysis in chapter 2 and are requirements already in use in the current YpsoMate autoinjectors.

Sustainability requirements

Table 13 shows YpsoMate Refill's sustainability requirements. These requirements help the YpsoMate to fit into the circular economy. They are based on takeaways of chapter 3,4 and 5.

7.1.2 Product architecture requirements

Table 12: Product architecture requirements of the YpsoMate Refill concept.

Category	ID	Requirement
Prefilled syringe	PS1	The patient can check that the syringe is intact before injection.
Needle	N1	Shield the needle before, during and after use to avoid accidental needle stick injuries.
	N2	Protect the needle during transportation and storage, so it cannot bend.
Injection	I1	The patient starts the injection by pushing the autoinjector onto the skin.
	I2	There is support offered on the skin around the needle.
Feedback and information	FI1	The autoinjector communicates the medicine type, dosage, producer, expiration date and usage.
	FI2	It is an option to connect the autoinjector to the SmartPilot add-on to transform it into a fully connected smart product system.
	FI3	There is multimodal feedback at the beginning and end of the injection.
Housing	HO1	The autoinjector does not easily slip from the hand during use.
	HO2	The housing keeps the components of the autoinjector together.
	HO3	The autoinjector cannot be (easily) taken apart by the patient.
	HO4	The autoinjector does not roll easily from e.g. a table.

7.1.3 Sustainability requirements

Table 13: Sustainability requirements of the YpsoMate Refill concept.

Category	ID	Requirement
Resource efficiency	RE1	Reduce the number of parts to the necessary functions.
Ease of disassembly & repair	EoD1	Decrease the number of disassembly steps.*
	EoD2	Disassemble into sub-assemblies for immediate reuse, disinfection and recycling streams.
	EoD3	Apply reusable fasteners that are easily accessible for automated disassembly, but hard to access by the patient.
Durability	D1	Minimize visual imperfections (scratches) on the outside of the YpsoMate.
	D2	The YpsoMate autoinjector withstands Ypsomed's drop-tests.**
	D3	When choosing materials, aim for durable ones with a low CO2 impact and a high recycling rate.
	D4	Disassembly is limited to parts that need to be disposed of, disinfected or replaced.
	D5	Know the Product health before (distributing for) reuse.
Reliability	R1	Patient safety & high-quality drug administration above all else.
	R2	Sterilize or disinfect parts of the reused autoinjector according to the Spaulding Classification.
	R3	Contaminated critical parts are easy to separate without contaminating other parts.
	R4	Patients trust the reused autoinjector.
Standardization	S1	Limit customization single use parts and/ or to batches large enough for their own reuse stream.
High-value recycling	HR1	Increase the recycling rate of YpsoMate.
	HR2	Reduce the variety of plastics in the autoinjector to commonly recycled mono-materials.*
	HR3	Make different materials fully separable by eliminating fixed connections.
	HR4	Make electronics easily separable for reuse and recycling.
	HR5	Avoid 2K and 3K injection moulding.
Regenerate	RG1	Avoid environmentally harmful substances.
	RG2	Use biobased plastics if possible.
Access Model	AM1	Automate dis- and reassembly, disinfection and refill of YpsoMate autoinjectors.
	AM2	The emissions of a refill system are lower than the emissions of single-use autoinjectors.
	AM3	The refill system can process hundreds of millions autoinjectors a year.

* Improvements refer to the YpsoMate 1.0 mL as a baseline product.

* This thesis does not test this, but it is a requirement for the final YpsoMate autoinjector and should be evaluated by Ypsomed.

7.2 | Reduce

To minimize material consumption and lower CO2e emissions, the YpsoMate Refill (Fig. 127) has a reduced part count of 17 instead of 19 compared to the single-use YpsoMate autoinjector (Fig. 129).

I achieved this by integrating the syringe holder and holding pin functions into other parts. This chapter discusses the design changes made to eliminate the syringe holder and holding pin.

Fig. 127 and Fig. 129 show and overview of the parts in the single-use YpsoMate and the YpsoMate Refill.

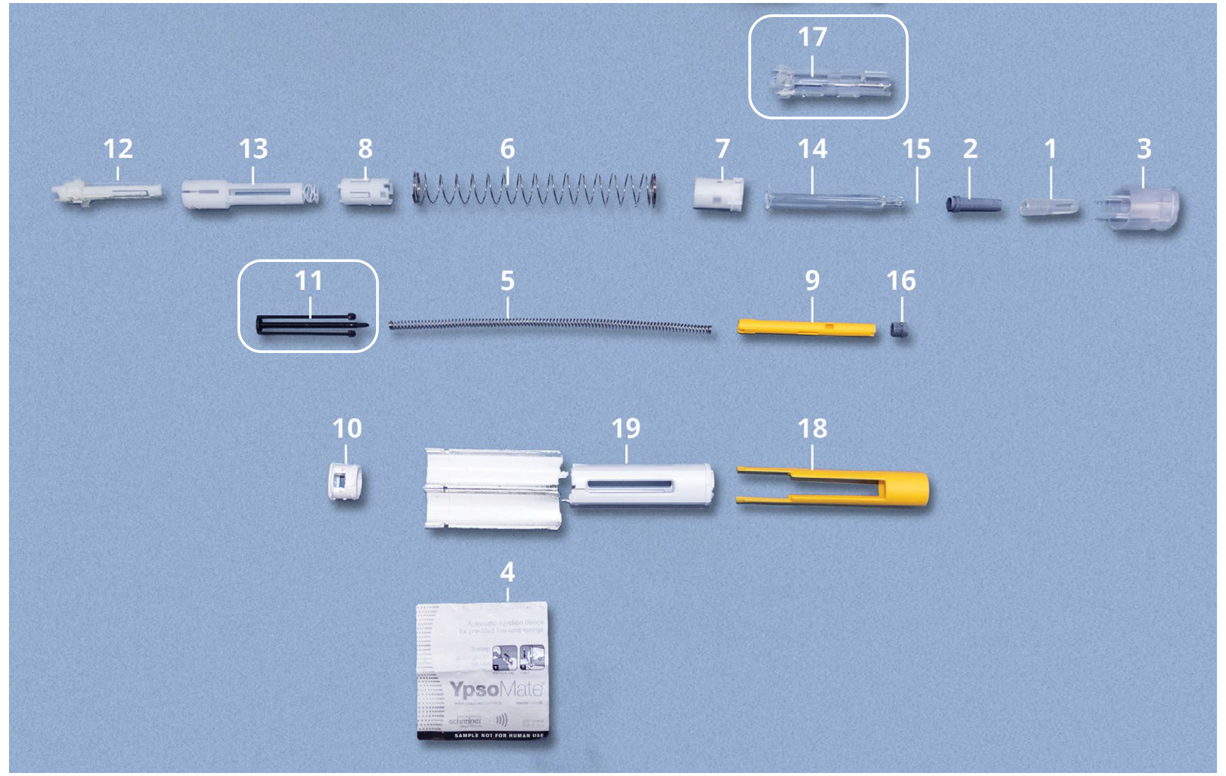


Fig. 127: Exploded view of the YpsoMate 1.0 mL. The YpsoMate Refill design eliminates nr. 11, the holding pin, and nr. 17, the syringe holder.

7.2.1 YpsoMate parts

1. Rigid needle shield
2. Soft needle shield
3. Cap remover
4. Label
5. Injection spring
6. Cover sleeve spring
7. Outer Telescopic lock sleeve
8. Inner Telescopic lock sleeve
9. Plunger rod
10. End cap
11. **Holding pin**
12. Click Sleeve
13. Mechanic holder
14. Syringe
15. Needle
16. Plunger
17. **Syringe holder**
18. Cover sleeve
19. Housing

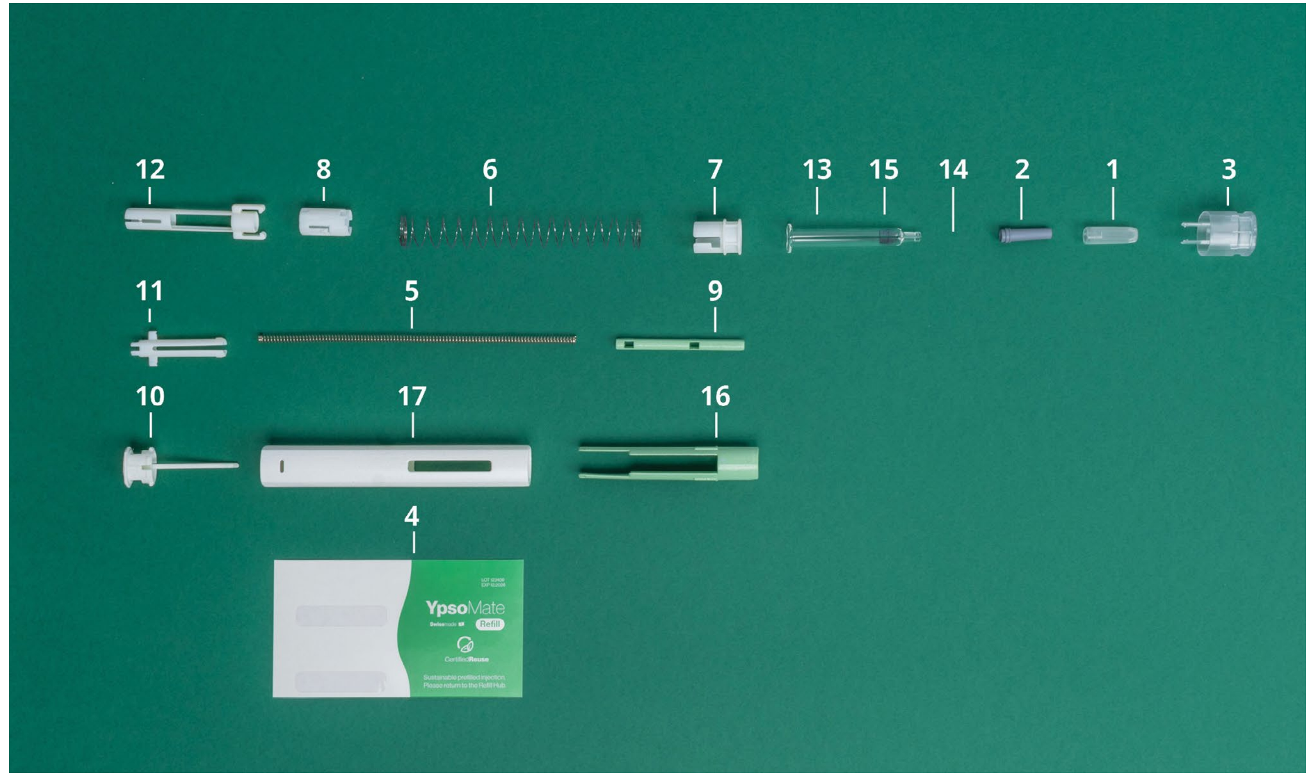


Fig. 128: Exploded view of the YpsoMate Refill concept design.

7.2.2 Eliminating the syringe holder

Single-use YpsoMate

The syringe holder in the single-use YpsoMate (Fig. 129) has several functions, but it scratches easily and would thus be a single-use part. To reduce its environmental impact, the YpsoMate Refill eliminates the syringe holder, replacing its function as described in the next paragraphs.

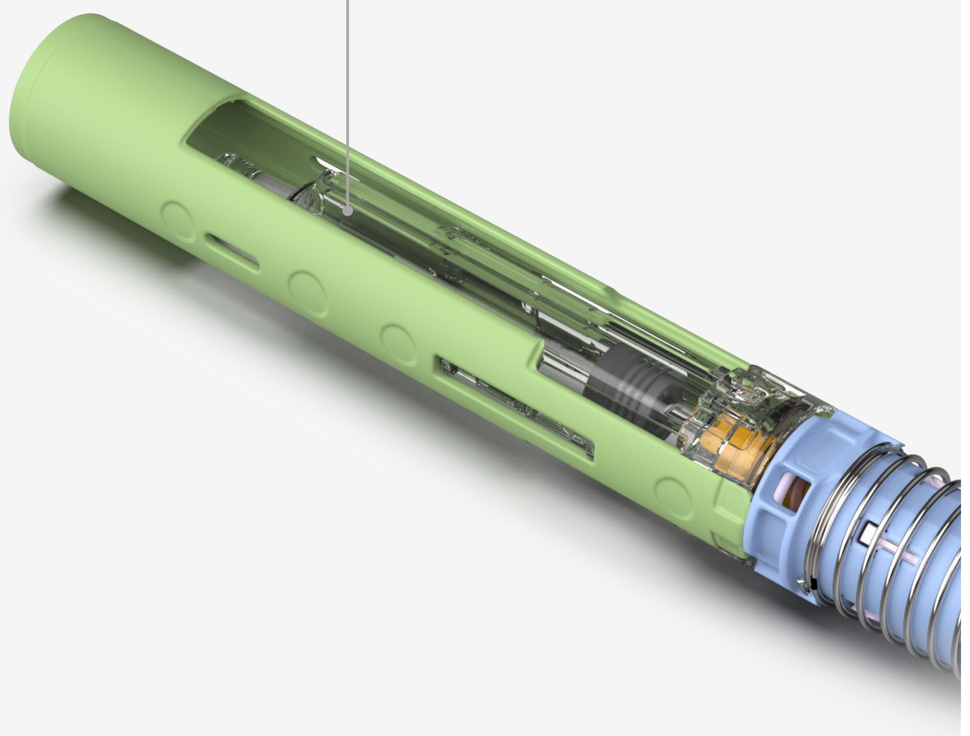


Fig. 129: The syringe holder in the single-use YpsoMate keeps the syringe in place.

YpsoMate Refill

The YpsoMate Refill integrates the following functions of the syringe holder in other parts:

Preventing the syringe from breaking:

In the YpsoMate Refill, the syringe is recessed in the housing, so the chances of an object bumping into it and breaking it are low (Fig. 130).

Moreover, a transparent part of the label (Fig. 131) closes the viewing window, to protect the syringe and prevent dirt from entering the housing.

Lastly, the syringe is already made of strong glass that does not break easily according to Ypsomed engineers.

Fig. 130: The YpsoMate Refill has the syringe recessed in the housing to protect it.

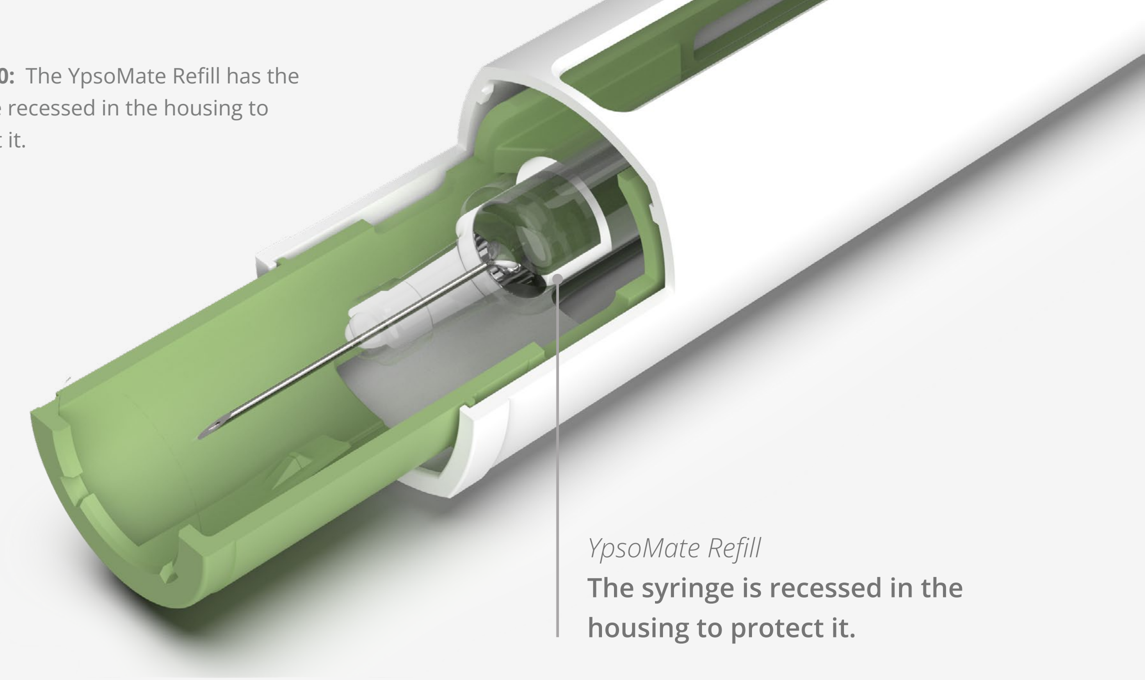


Fig. 131: The label of the YpsoMate Refill covers the viewing window to protect the syringe and prevent dirt from entering.

Keeping the syringe in position:

The YpsoMate Refill syringe is held in place by the arms of the mechanical holder (Fig. 132) and the protrusions in the cover sleeve (Fig. 133).

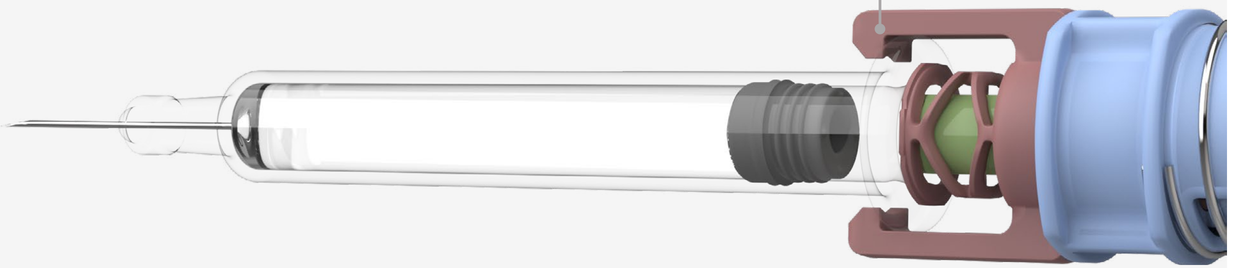


Fig. 132: In the YpsoMate Refill, the arms of the mechanic holder keep the syringe in place.

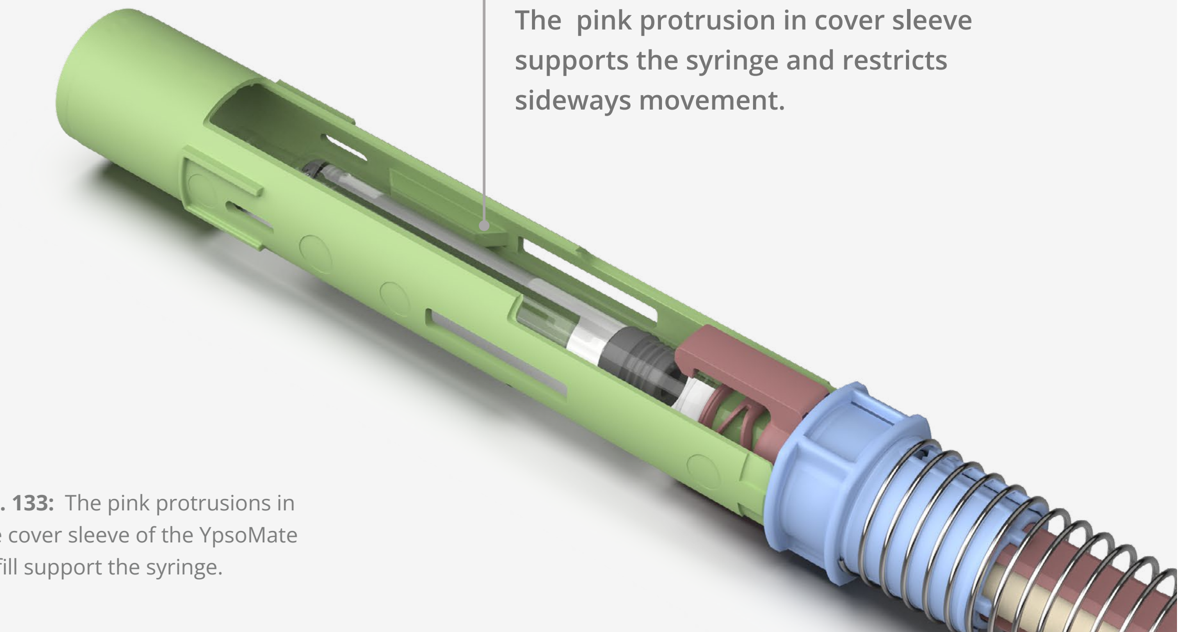


Fig. 133: The pink protrusions in the cover sleeve of the YpsoMate Refill support the syringe.

Limiting movement of the cover sleeve:

The YpsoMate Refill housing features a small lip that blocks the ridge on the cover sleeve, to prevent it from falling out of the housing (Fig. 134). This design does not only keep the cover sleeve in place but also facilitates easy disassembly by allowing the sleeve to slide out of the back of the housing.

In contrast, when taking apart the single-use YpsoMate, I had to cut the housing open (Fig. 135). The root of the problem was a structure inside the housing that was wedged between the cover sleeve and the syringe holder. Fortunately, the YpsoMate Refill resolves this issue by removing the inner housing structure and the syringe holder, thereby simplifying the disassembly process.

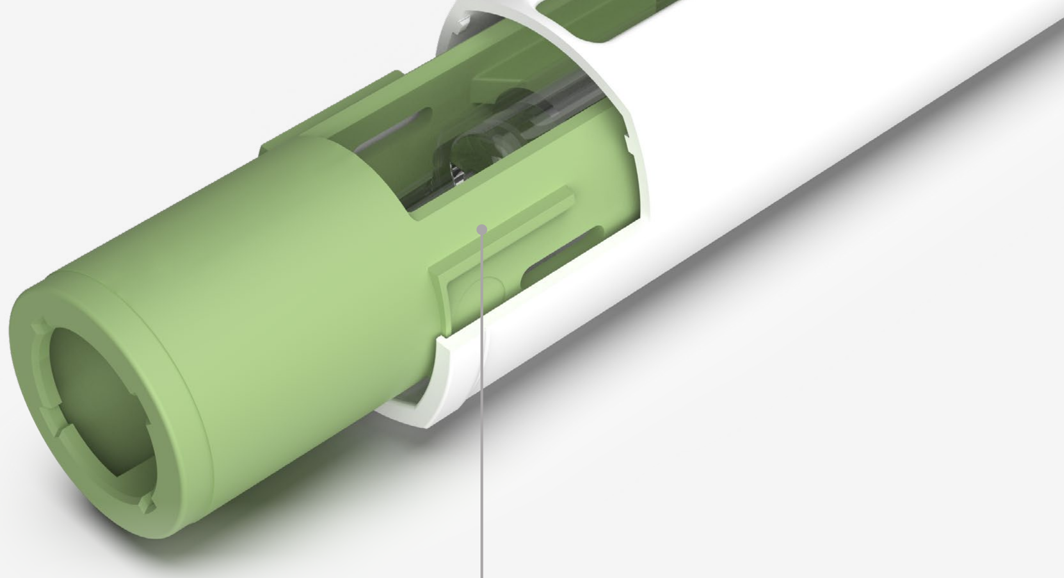


Fig. 134: The YpsoMate Refill cover sleeve can easily be removed.

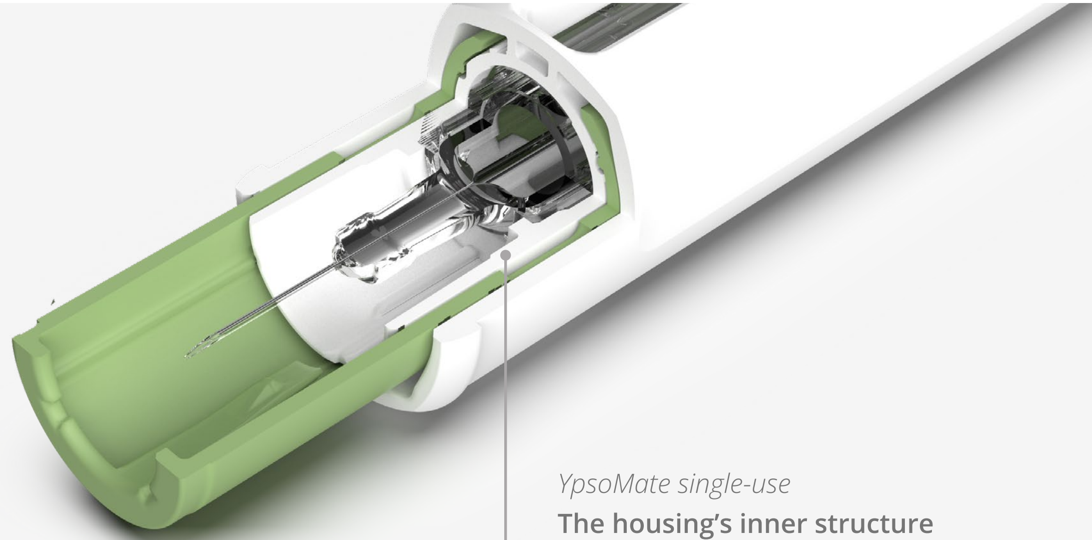


Fig. 135: The inner housing structure of the single-use YpsoMate blocks the cover sleeve.

Ideation & prototyping

In the ideation phase, I considered closing the viewing window in the housing by making the housing out of transparent plastic (Fig. 136).

However, this would increase CO2e emissions by adding extra material to the housing. Thus, I covered the viewing window with a transparent label instead. This solution protects the syringe and prevents dirt from entering the housing, while adding less material and less CO2e.

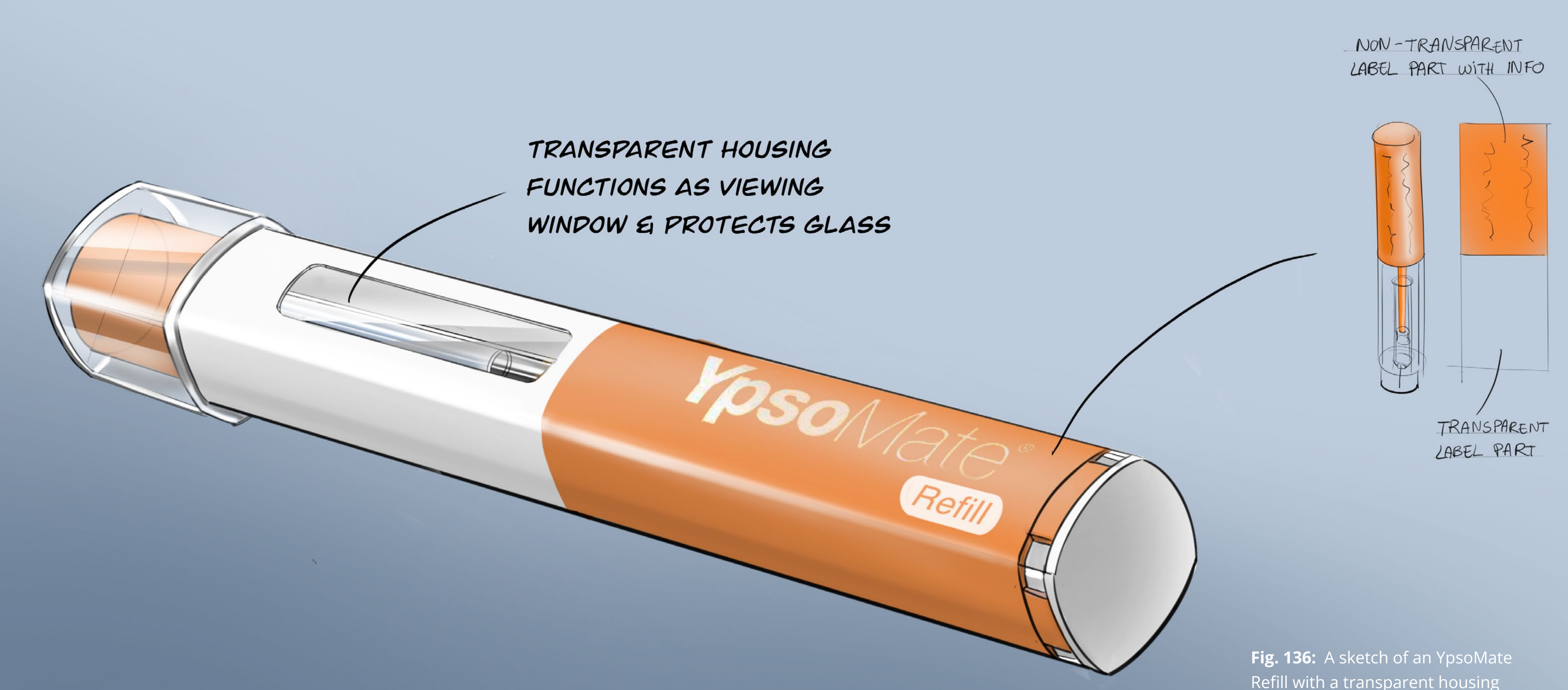


Fig. 136: A sketch of an YpsoMate Refill with a transparent housing with a closed viewing window to protect the syringe.

Fig. 137 illustrates the other options I explored to integrate the functions of the syringe holder into other parts. Ultimately, I chose the solutions mentioned earlier because they added the least complexity to the disassembly of the autoinjector and were compatible with the current assembly line. For instance, I considered opening the housing from the side instead of the back to access the inner parts. However, this would require Ypsomed to modify all its assembly machines and processes, resulting in a significant investment. Hence, I rejected this option and prototyped the options shown in Fig. 138 & Fig. 139. These worked well.

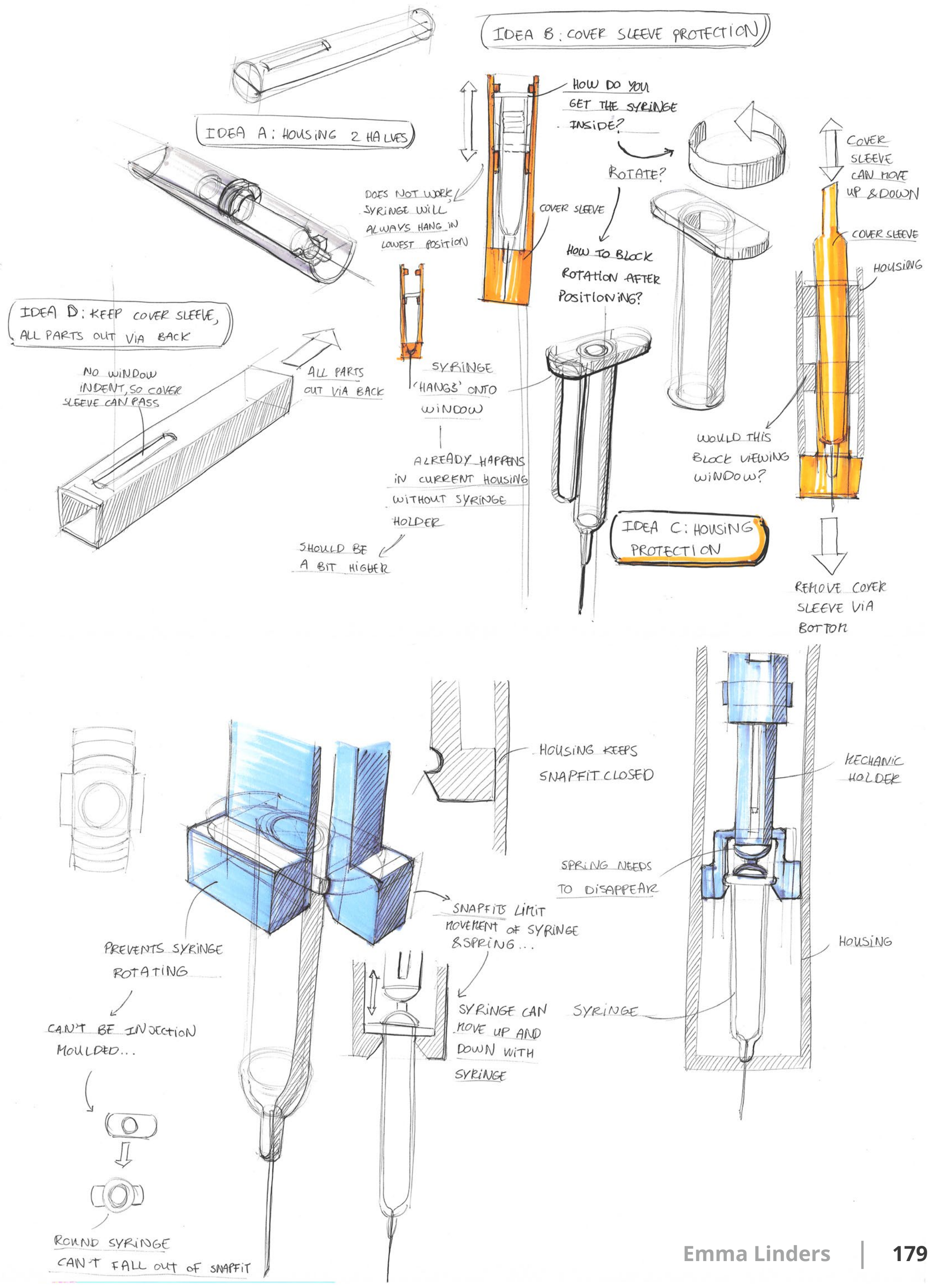


Fig. 137: Sketches to explore the options of integrating the syringe holder functions into other parts.

Fig. 138: The arms of the mechanic holder keep the syringe in place.

Fig. 139: The cover sleeve ridges ensure that is does not fall out of the housing.

7.2.3 Eliminating the holding pin

Functions of holding pin in the single-use YpsoMate

The holding pin plays a critical role in ensuring the plunger rod remains loaded with the injection spring before use (Fig. 140 & Fig. 141). However, since autoinjectors can sit idle in patients' homes for prolonged periods, the holding pin must withstand the spring force over an extended time. To reinforce it, a glass-filled plastic composite is used, but this material is difficult to recycle, contrary to the YpsoMate Refill's objective of reducing composite use to enhance recycling.

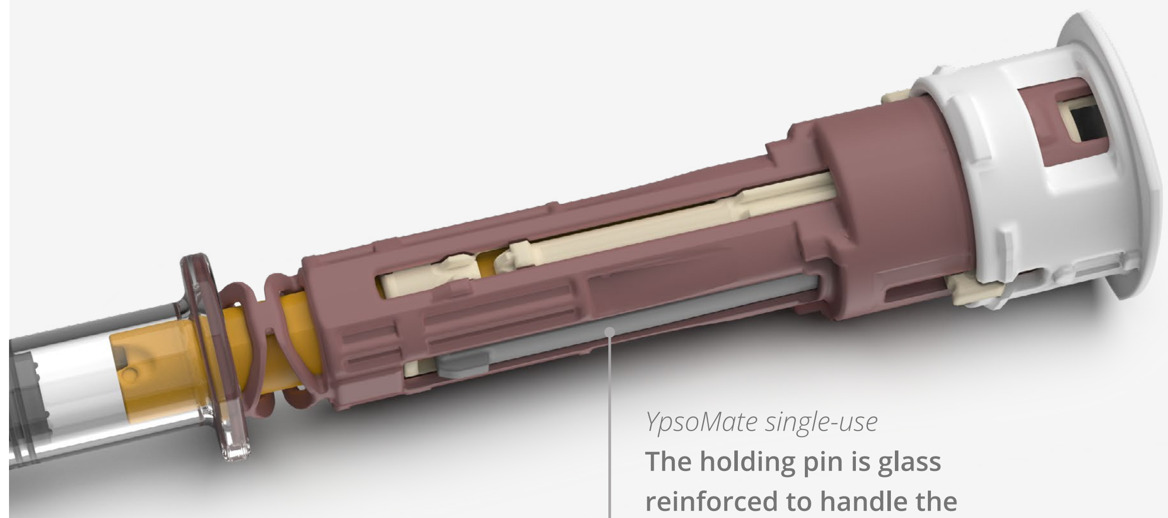


Fig. 140: The holding pin in the single-use YpsoMate keeps the injection spring in a loaded position.

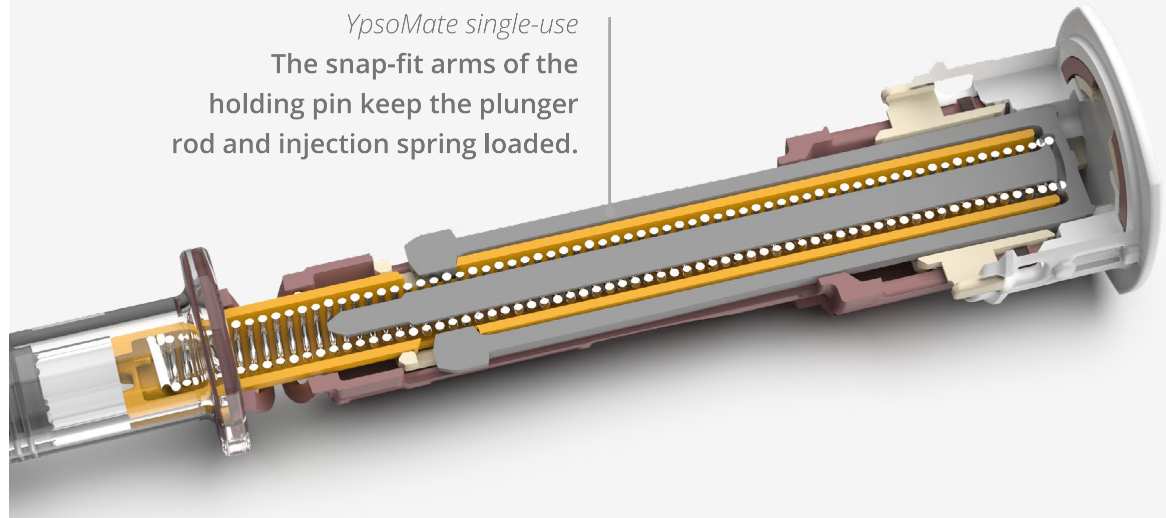


Fig. 141: Cross section of the holding pin, the plunger rod and the injection spring.

YpsoMate Refill: Integrating the functions of the holding pin in the end cap and click sleeve

Therefore, the YpsoMate Refill design eliminates the holding pin and instead integrates its function into the click sleeve and the end cap.

In the YpsoMate Refill, the end cap has a pin that keeps the injection spring in place (Fig. 142). The arms of the click sleeve keep the plunger rod with the injection spring loaded (Fig. 143, Fig. 144 & Fig. 145).

The click sleeve in the single-use YpsoMate 1.0 mL also requires glass reinforcement for added strength. To eliminate the need for this reinforcement, I modified the snap-fit arms by curving them, making them wider and shorter, to enhance their strength. However, to confirm their strength without reinforcement, a finite element method analysis is required, which is beyond the scope of this graduation project.

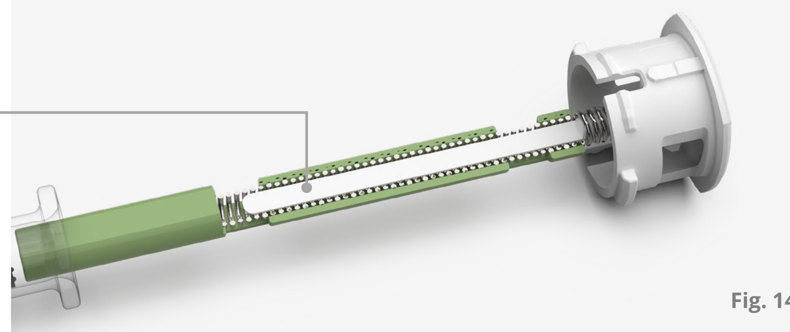


Fig. 142

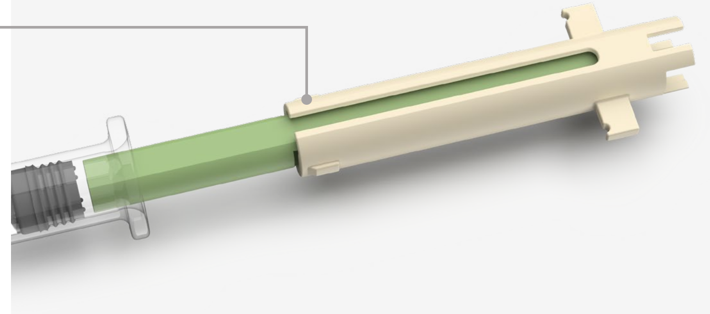


Fig. 143

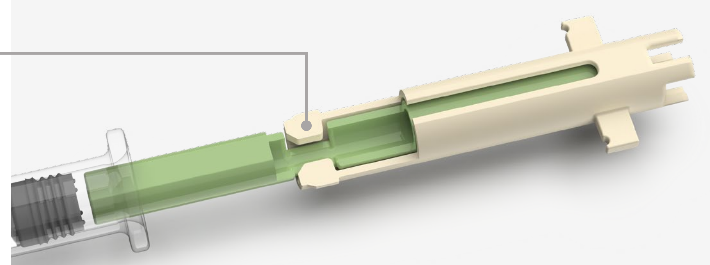


Fig. 144

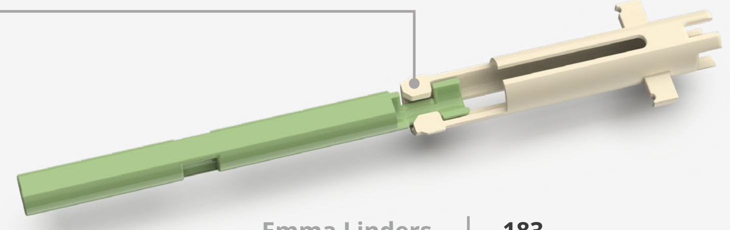


Fig. 145

7.3 | Reuse

The YpsoMate Refill concept focuses on part reuse to reduce CO_2e emissions. With reusable connections, dis- and reassembly are effortless. To speed up the disassembly, only parts requiring disinfection are separated, so the Drive unit stays together.

Out of the 17 parts that make up the YpsoMate Refill, 12 are safe to reuse following quality checks (Fig. 146).

However, the remaining 5 parts are single-use due to either containing medicine-specific information or the reuse process requiring too much energy.

This chapter outlines the disassembly steps and the design changes needed to create reusable connections. Additionally, it explains why certain parts are single-use.

7.3.1 Disassembly steps

1. A machine punctures the label to open the snap-fits of the end cap to remove the drive unit, syringe, and cover sleeve.
2. Simultaneously, the cap is disassembled into the cap remover and the rigid & soft needle shield.
3. The syringe slides out of the drive unit.
4. The cover sleeve slides out of the housing.
5. The end cap is separated from the Drive unit.
6. The Drive unit is reset and reloaded.
7. The label is soaked off the housing.
8. The RFID tag's patient data is deleted in the case of a smart autoinjector.

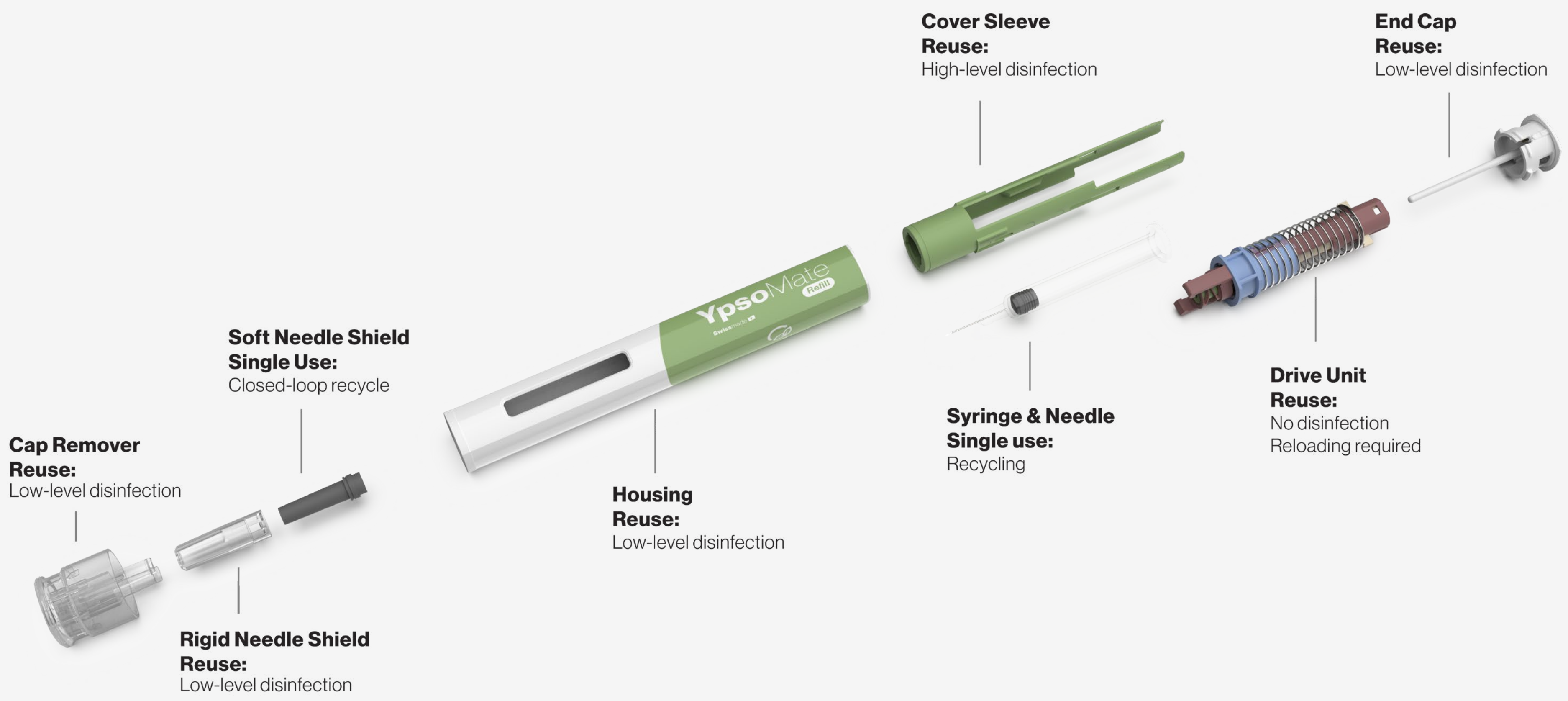


Fig. 146: 12 out of 17 YpsoMate Refill parts can be reused after a quality check and disinfection.

Disassembly step 1: Open the housing by removing the end cap

To disassemble the YpsoMate Refill, a machine starts by opening the housing through the end cap (Fig. 147). The machine presses the snap-fits inwards, which perforates the label. This process lifts out the end cap along with the attached drive unit and syringe. While the end cap snap-fits can be easily opened with machines in the Refill Hub, patients, it is challenging for patients as it requires applying a high simultaneous force on both snap-fits. Furthermore, the snap-fits are covered by the label to discourage patients from attempting to open them.

Fig. 147: Opening the YpsoMate Refill housing via the end cap.

Ideation

During the ideation phase, I explored alternative methods to open the housing, such as using a screw thread (Fig. 149) or unclamping and pulling on the cover sleeve (Fig. 148). With feedback from Ypsomed engineers and after assessing prototypes, I ultimately decided to maintain the same opening mechanism as the current single-use YpsoMate, by pushing in snap-fits at the end cap.

I chose to stick with the existing design as it is more difficult for patients to open compared to the screw thread and cover sleeve options. Additionally, Ypsomed already possesses a tool to open these snap-fits, which can potentially be developed into an automatic disassembly

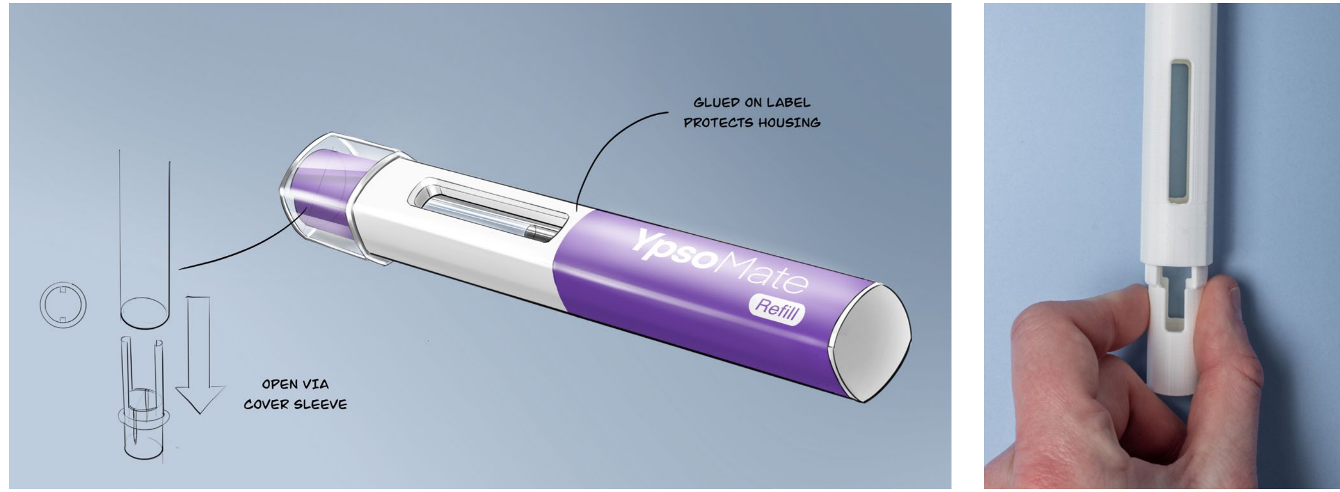


Fig. 148: Idea of opening the housing at the cover sleeve instead of via the end cap.

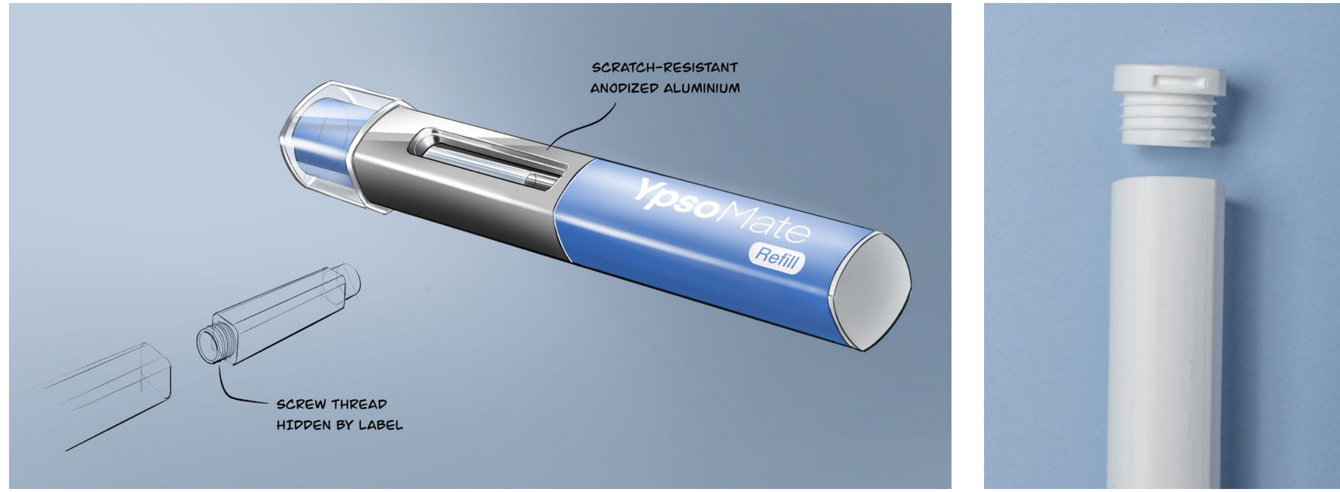


Fig. 149: Idea of opening the housing by rotating a hidden screw thread.

Step 2:
Disassemble the cap

A machine removes the cap and disassembles it into the cap remover, the rigid & soft needle shield (Fig. 150). This was already possible in the single-use YpsoMate, so no design changes were required.

Step 3:
Remove the syringe from the drive unit

As previously described in chapter 7.2, the arms of the mechanical holder keep the syringe securely in place. When the drive unit is taken out of the housing, the syringe can slide out of its arms (Fig. 151).

It is not necessary to separate the syringe, plunger, and needle since they will be shredded for recycling.

Step 4:
Slide the cover sleeve out of the housing

As discussed in the previous chapter 7.2, the cover sleeve design changed, so it can easily slide out of the back of the housing during disassembly (Fig. 152).

Fig. 150: The disassembly of the cap required no design changes.

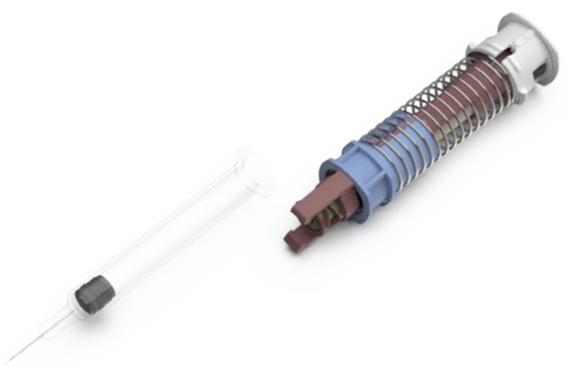


Fig. 151: The syringe slides out of the arms of the mechanic holder to be recycled.

Fig. 152: The cover sleeve slides out of the back of the housing.

Step 5:
Separate the end cap from the drive unit

The second step of the disassembly process involves separating the end cap from the drive unit. It is important to do so as the end cap requires disinfection while the drive unit does not. In the case of the single-use YpsoMate, I had to melt away the snap-fits with a soldering iron to disconnect the end cap from the mechanical holder (Fig. 153 & Fig. 154).

However, for the YpsoMate Refill, I improved the snap-fits by making them reusable (Fig. 155 &Fig. 156). This allows for easy disconnection of the end cap from the mechanical holder as a machine can simply push the snap-fits inwards.

YpsoMate single-use
I melted the snap-fit away to seperate the end cap from the mechanic holder (photograph of result).

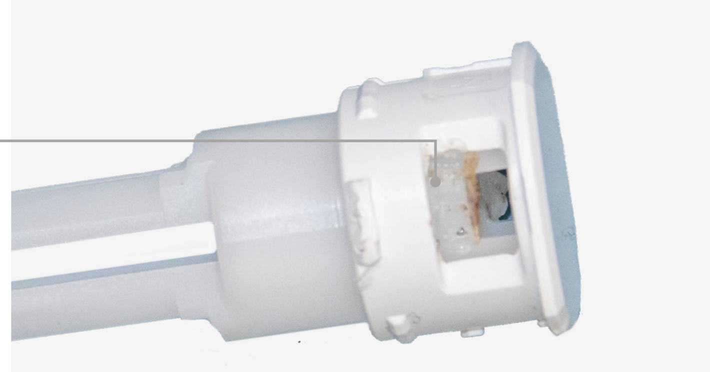


Fig. 153

YpsoMate single-use
This non-reusable snap-fit makes dis- and reassembling the end cap impossible.

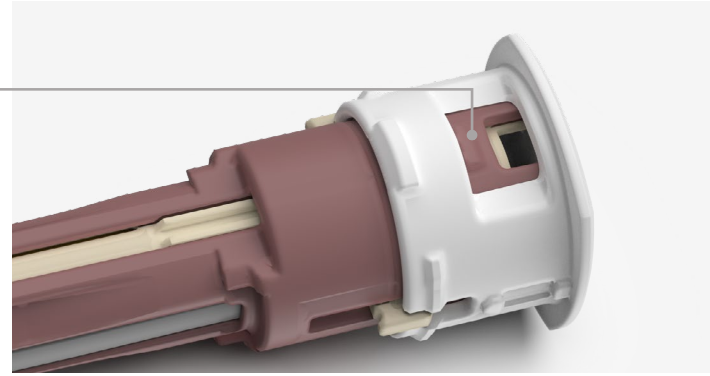


Fig. 154

YpsoMate Refill
A machine pushes this reusable snap-fit inwards to separate the end cap.

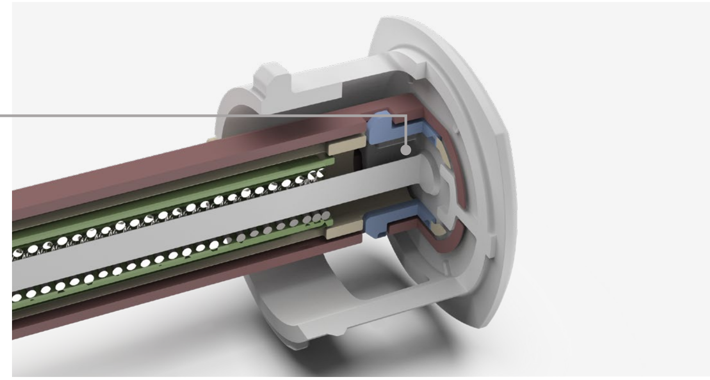


Fig. 155

YpsoMate Refill
The snap-fit is easily accesible once the end cap is out of the housing.

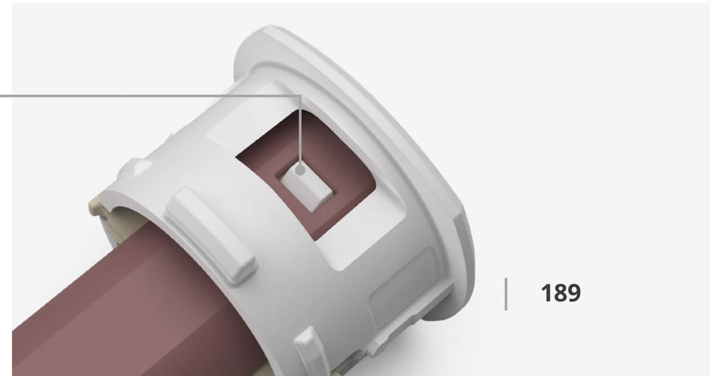


Fig. 156

Step 6:
Reset & reload the drive unit

Reload

During the injection, the injection spring pushes down the plunger rod to inject the medicine. To reload the injection spring, a machine pushes the plunger rod back into the drive unit (Fig. 157. & Fig. 158)

Reset

Once the injection is complete, the drive unit automatically pushes the cover sleeve down, ensuring that the needle is not accessible to the patient. However, before administering the next injection, the drive unit must be reset to remove this cover sleeve block.

For the single-use YpsoMate, the entire drive unit must be disassembled and reassembled to reset and reload the device. To speed up this process, I changed the design of the drive unit, so it can stay together during the resetting and reloading (Fig. 159 till Fig. 162).

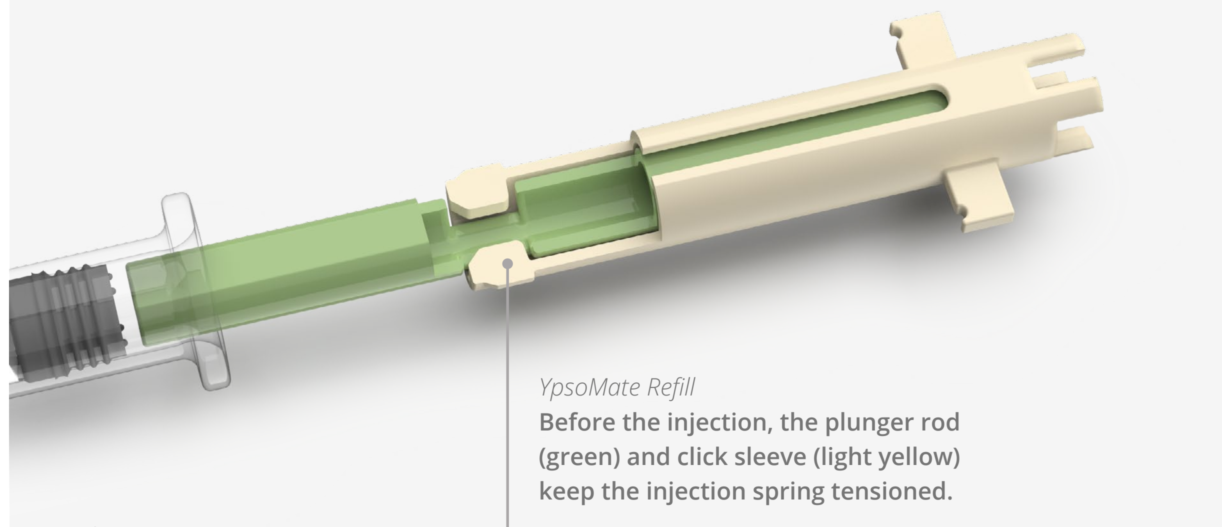


Fig. 157

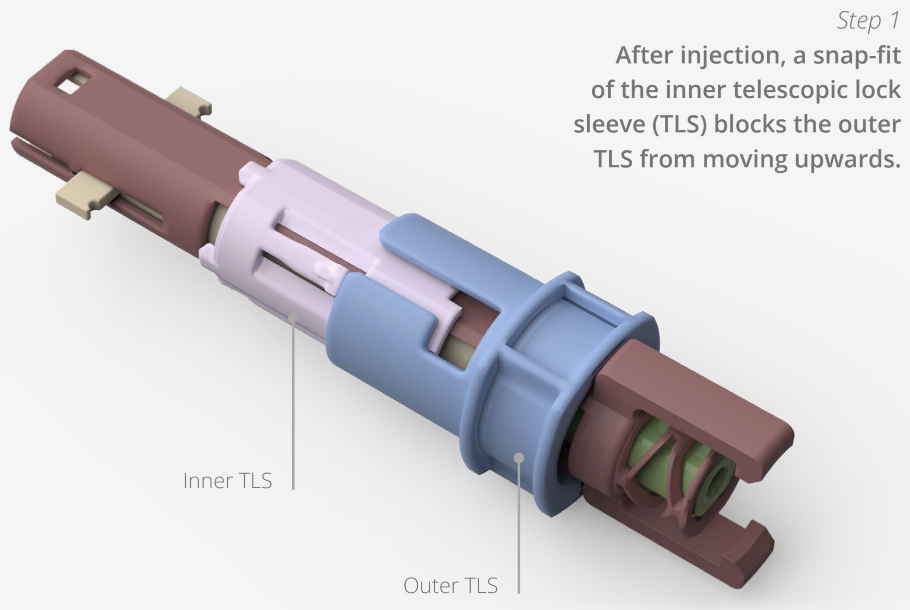


Fig. 159

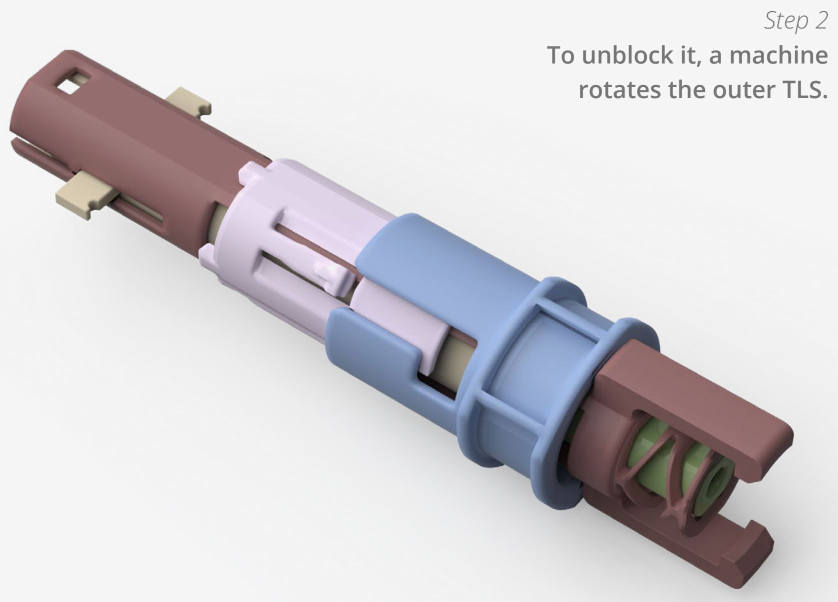


Fig. 160

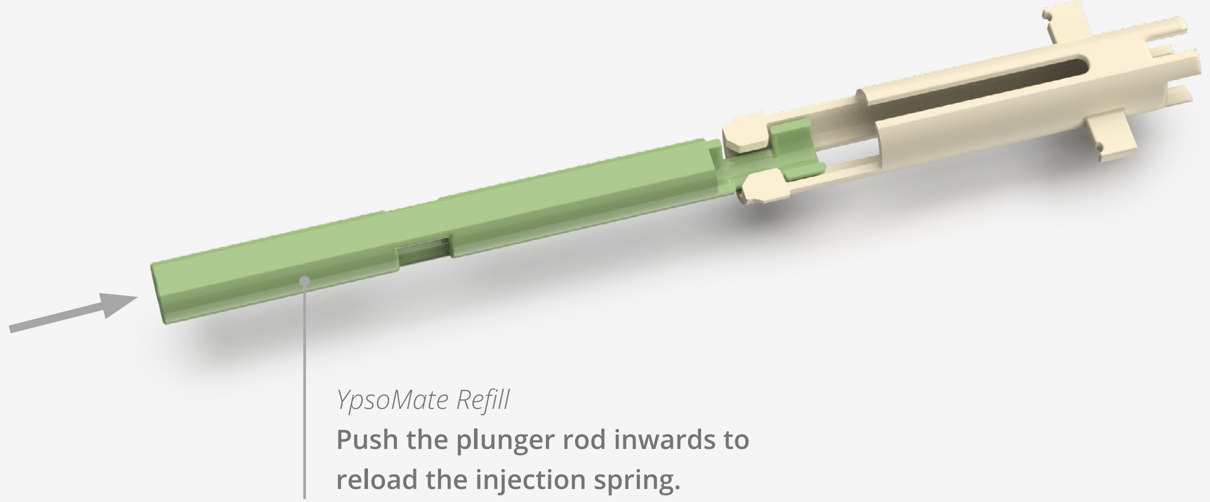


Fig. 158

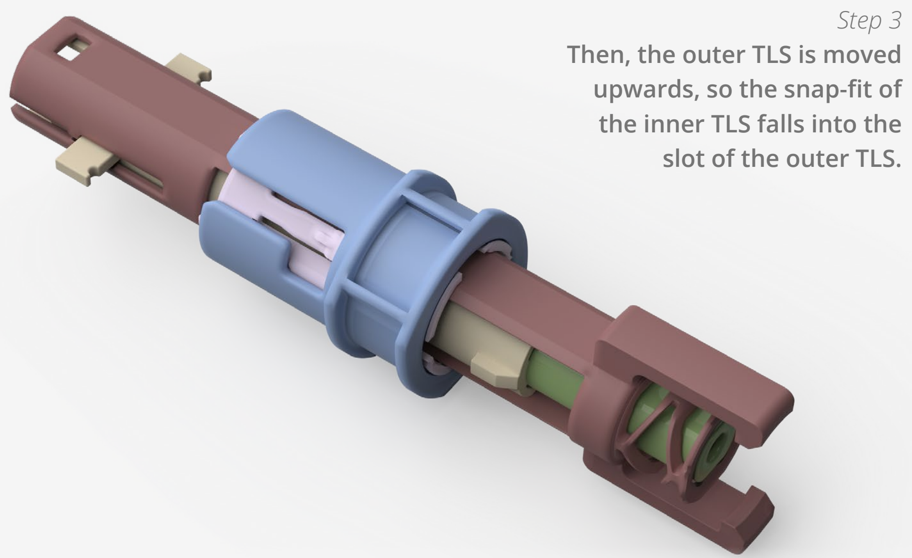


Fig. 161

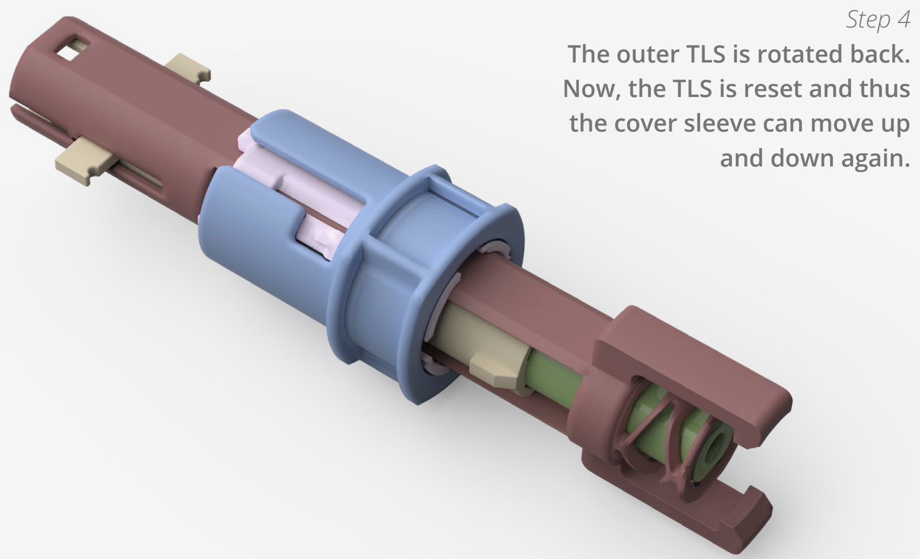


Fig. 162

Ideation & prototyping

Reload

One of the ideas I explored during ideation was to keep the plunger attached to the click sleeve after injection using tiny hooks. However, prototypes showed that this approach was not effective. Therefore, I prototyped the other option described in the previous pages, which worked well (Fig. 164).

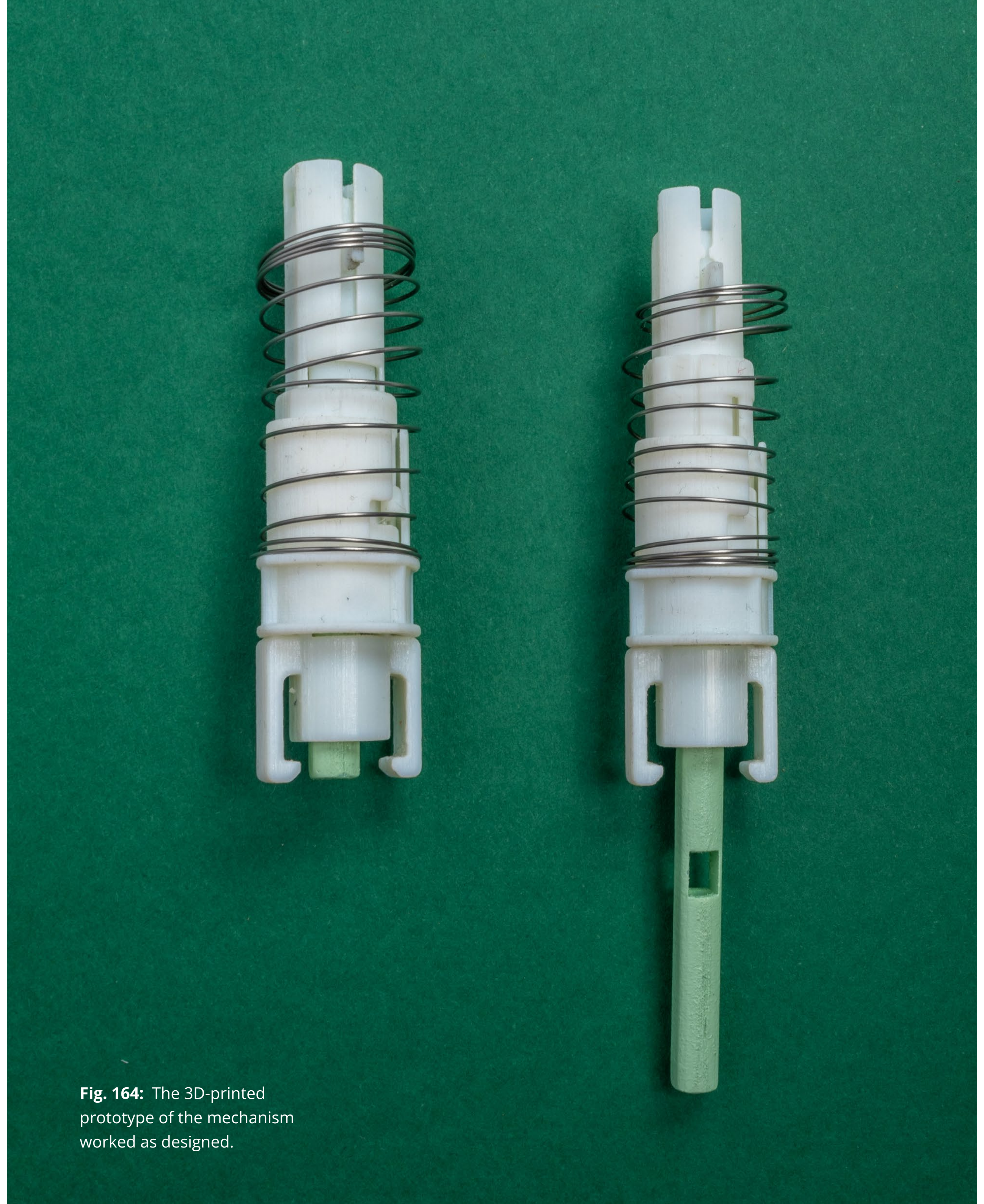


Fig. 164: The 3D-printed prototype of the mechanism worked as designed.

Reset

I also considered resetting the telescopic lock sleeve by pressing its snap-fits inward. However, this was not practical due to the presence of the cover sleeve spring, which obstructed access to the snap-fits. Therefore, I decided to adopt a solution that involved rotating the sleeve to reset it (Fig. 166).

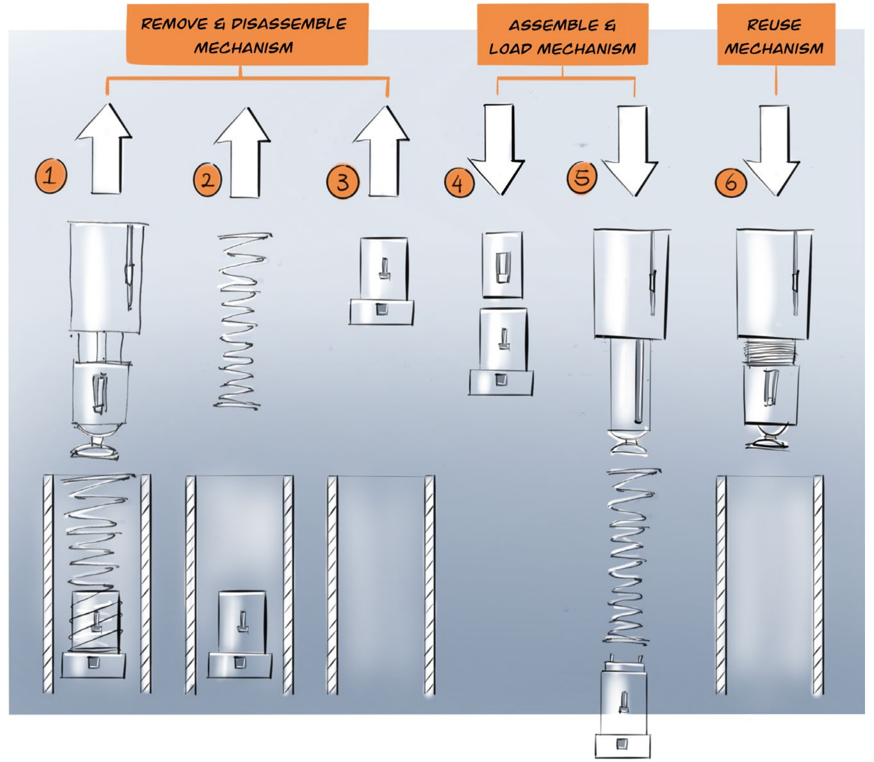


Fig. 165: The drive unit of the single-use YpsoMate needs to be fully disassembled to be reset and reloaded.

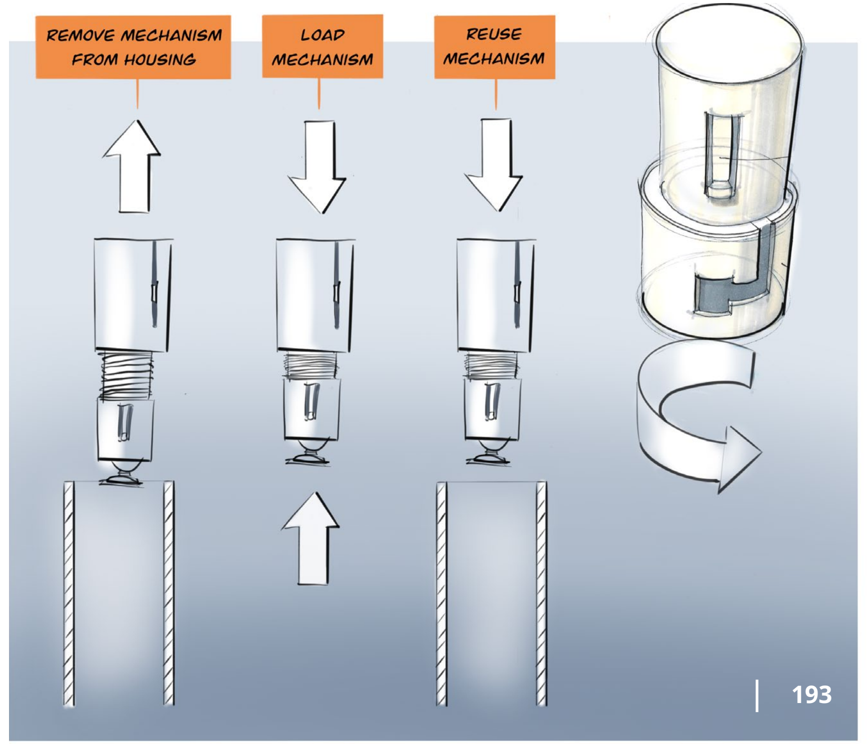


Fig. 166: The redesigned drive unit can be reset without disassembling it to make the process more efficient.

Step 7:
Wash the label off the housing

The next step of the YpsoMate Refill disassembly process involves removing the label from the housing (Fig. 167). While this was a challenging task for the single-use YpsoMate due to the label being firmly glued on, the YpsoMate Refill label is fixed to the housing with a wash-off adhesive. This type of adhesive dissolves in water, allowing for easy removal of the label using conventional industrial cleaning methods. As a result, the process does not leave any residual glue on the housing (Herma, n.d.; UPM Raflatac, n.d.).

Fig. 167: The label can be soaked off the housing, since it is glued with wash-off adhesive.

Ideation

In the ideation phase, I searched for ways to attach labels to autoinjector housings without using glue (Fig. 168). However, the solutions I came up with did not stop the label from rotating. The label should remain fixed to the housing since loose labels decrease patients' trust in the autoinjector (Ypsomed, n.d.).

Shrink-wrap labels were a possible solution to fix the label without glue, but they are difficult to remove and limit recycling (Boretech, n.d.). Using paper labels reduces CO2e impact, but there is a risk of the label fading if it gets wet. After considering various options, gluing the plastic label with wash-off adhesive seems the best solution, as it provides a secure attachment that is easy to remove in a factory setting.

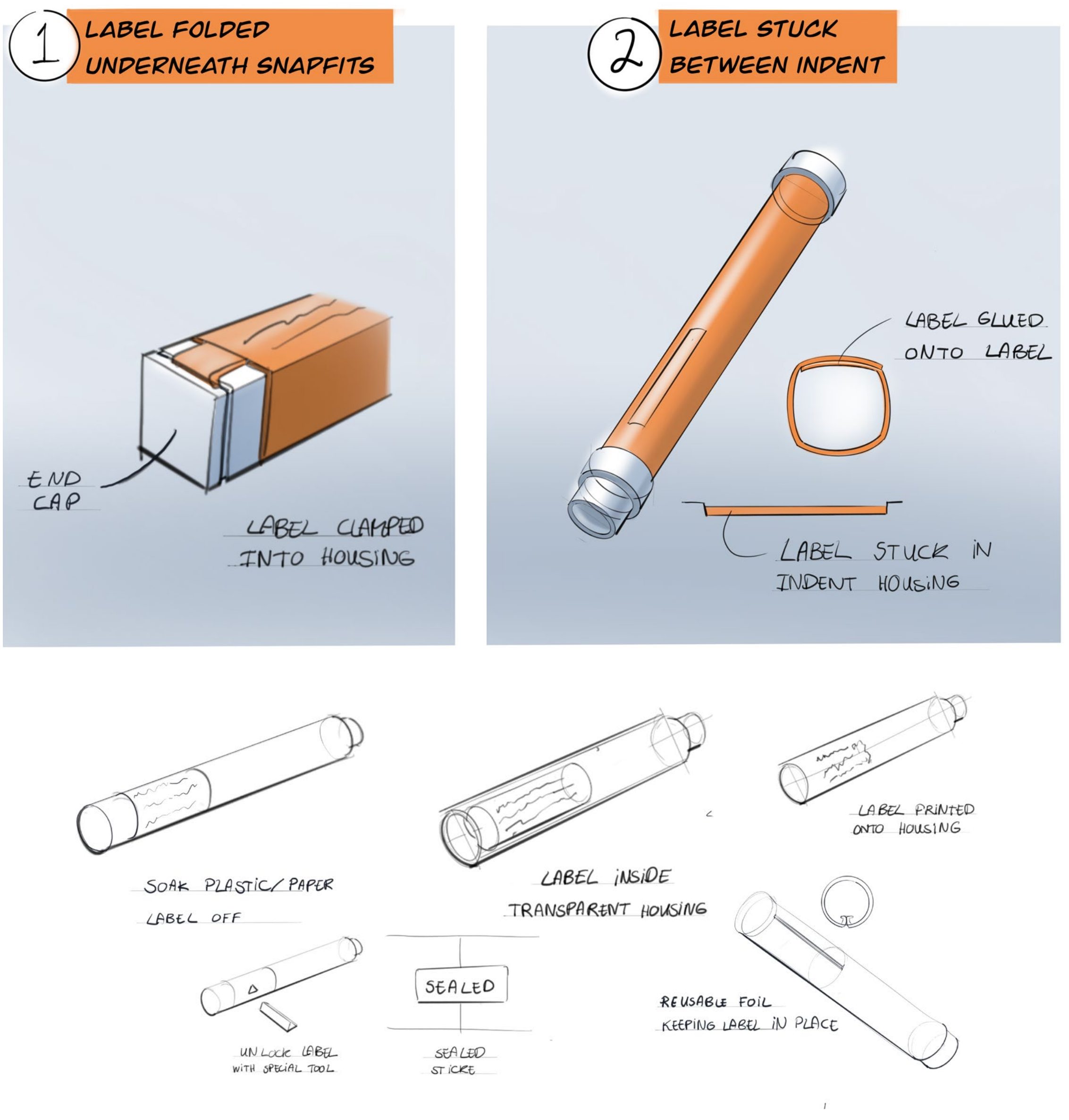


Fig. 168: Ideation to attach the label without glue.

Step 8: Delete patient data from RFID tag

Removing the patient data from the RFID tag is only relevant for smart autoinjectors equipped with an RFID tag, which allows patients to track their injections using their smartphones. By resetting the patient data, the RFID tag is safe to use by another patient (Honeywell, 2015). Still, it still tracks the number of reuse cycles, which is beneficial for the quality check,

In the single-use YpsoMate, the RFID tag is laminated into the label. However, the goal of the YpsoMate Refill is to reuse the RFID tag to limit electronic waste. Since the label is a single-use item in the YpsoMate Refill, the RFID tag would be thrown away after each use. Yet, since the calculated impact in the LCA of chapter 8 is low and RFID tags are only used in a limited amount of YpsoMates, this had not my priority.

During the redesign, I positioned the RFID tag on the Drive Unit (Fig. 169), which does not require disinfection, to prevent damage to the tag. However, Kurt Kugler from Schreiner (the producer of labels with RFID tags) raised the concern during the final presentation to the Alliance to Zero that the stainless steel spring surrounding the tag might interfere with the signal. This should be tested to validate it.

As there was not enough time to improve the design before graduation, I suggest exploring alternative positions for the RFID tag. An option would be to place it in a small plastic casing that can be easily inserted into the housing and removed during disassembly. This approach would avoid the need for disinfection of the RFID tag. I recommend further exploring this possibility.

Takeaways

- A limited number of YpsoMates use RFID tags to connect them to patients' phones.
- The YpsoMate Refill aims to reuse these tags to reduce electronic waste.
- Kurt Kugler from Schreiner indicated that the current placement of the RFID tag on the Drive Unit might not work due to the spring interfering the signal.
- Further testing is required, and alternative placements should be explored.

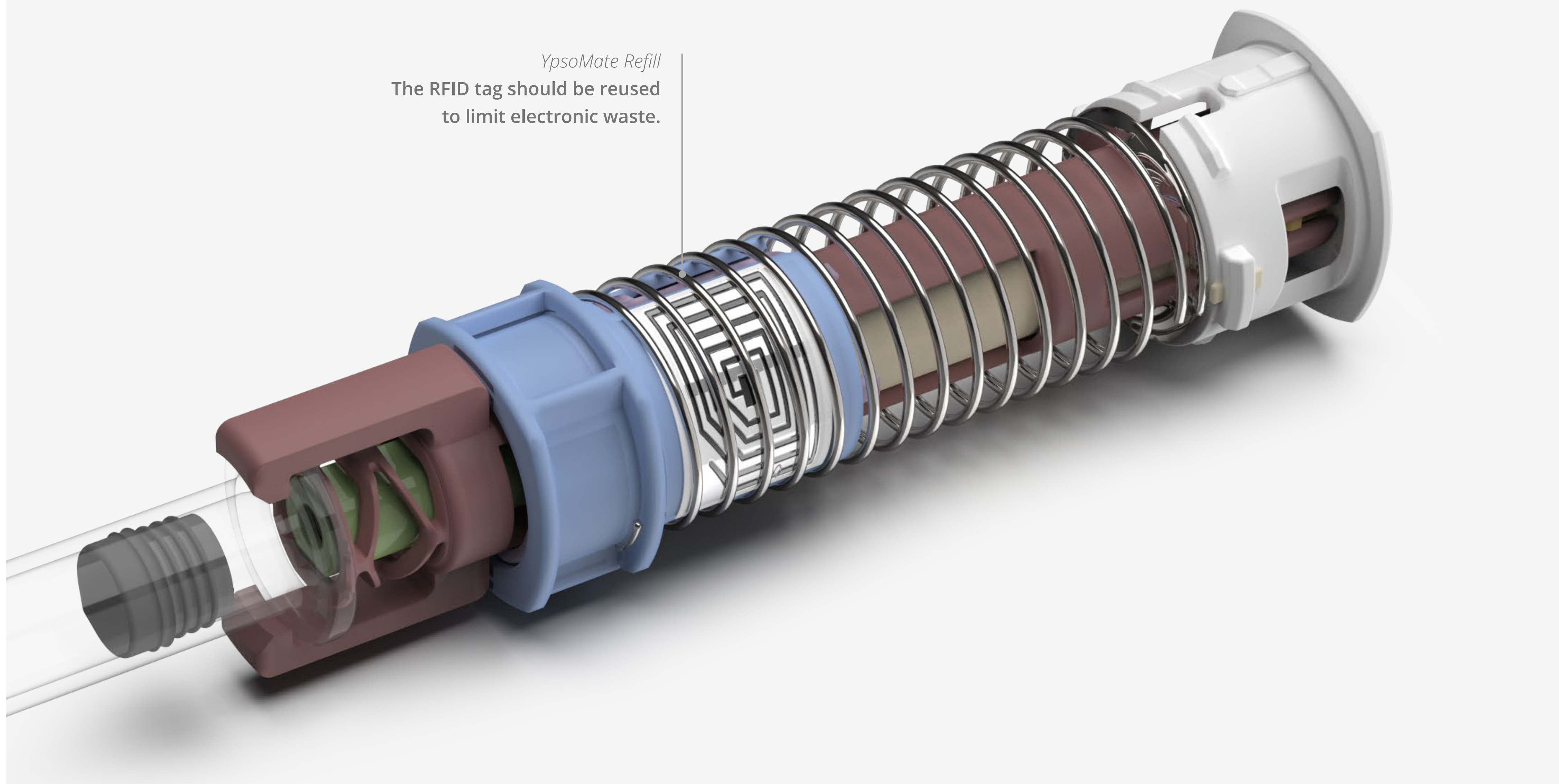


Fig. 169: The RFID tag signal might be blocked my the spring.

7.3.2 Durability

To ensure that the autoinjector parts are durable enough for reuse, it is important to design them with a realistic reuse count in mind.

The Life Cycle Assessment in the next chapter reveals that reusing parts approximately five times is an ideal balance. This approach reduces the total CO2e impact by approximately 60% compared to the single-use YpsoMate, while minimizing the likelihood of part failure due to the limited reuse count. Therefore, the parts do not need to be over-engineered for hundreds of life cycles, which would only add material, thus increasing the environmental footprint.

Currently, there is no data available on how well the single-use YpsoMate parts perform when being reused. More research is required, and graduation student Mariana Escobar will look into this.

Considering that the autoinjector is typically only reused five times, I decided not to modify the current material properties and thicknesses of the parts. According to engineers at npk design, the snap-fits currently used will not break, provided that their material yield stress is not exceeded during dis- and reassembly. This can be easily ensured by programming the forces of the dis- and reassembly machines correctly.

However, during the disassembly of the existing single-use autoinjector, I discovered that some drive unit parts, such as the spring in the mechanic holder, are susceptible to breaking. To prevent wear and tear from dis- and reassembly, the drive unit has a new design that can be reset and reloaded without disassembling it.

Takeaways

- Reusing the YpsoMate parts five times seems to be the sweet spot.
- It reduces the CO2e impact by approximately 60% while minimizing the likelihood of part failure.
- Due to this low reuse count, it is not necessary to make the parts out of stronger and more durable materials. Using e.g. aluminum would only increase the CO2e emissions.
- To prevent wear and tear in the drive unit during dis- and reassembly, the drive unit stays together.

Ideation

In the ideation phase, I considered the possibility of using more scratch-resistant anodized aluminum for the housing (Fig. 170). However, aluminum has higher CO2e emissions during production, and since the autoinjector is only likely to be reused five times, the additional CO2 emissions of aluminum are not justifiable. Moreover, aluminum is more expensive than polycarbonate. Therefore, the YpsoMate Refill concept solves the issue of potential scratches on the polycarbonate housing by covering the entire housing with a label that is replaced after each reuse. This way, the single-use label scratches instead of the reusable housing.

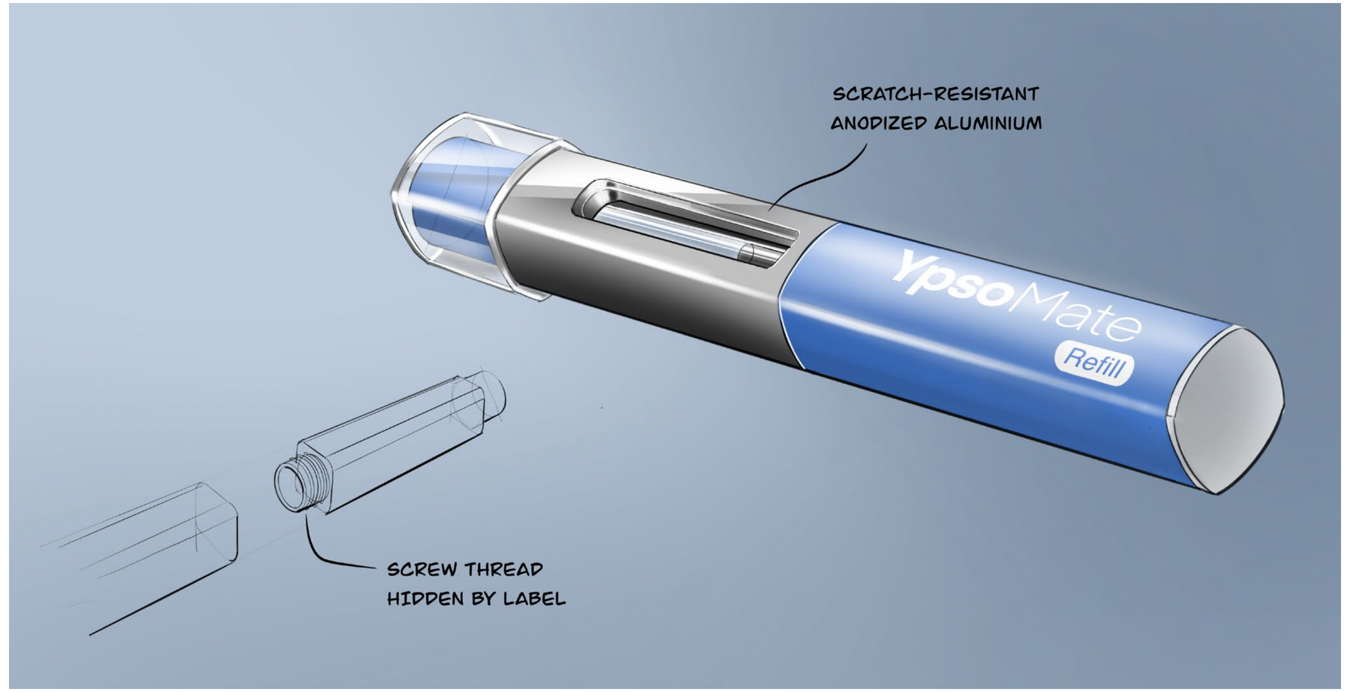


Fig. 170: Idea for an aluminum housing.

7.3.3 Single-use parts

Of the 17 YpsoMate Refill parts, 12 can be reused. However, five parts are single-use because they are medicine-specific, damaged, or require more energy and effort to reuse than to recycle. This chapter explains why the soft needle shield, the label and the subassembly of the syringe with the needle and plunger are single-use items, and how they are recycled to minimize their environmental impact.

Takeaways:

- 12 out of 17 YpsoMate Refill parts are reusable.
- The syringe, plunger, needle, label, and soft needle shield are single-use parts because they are medicine-specific, damaged, or require more energy and effort to reuse than to recycle.
- These single-use parts are recycled to lower their environmental impact.

The soft needle shield

The soft needle shield (Fig. 171) is designed for single-use only, as it provides a sterile environment for the needle. The needle punctures the rubber during use, making it unsuitable for reuse.

Fig. 171: The soft needle shield is punctured by the needle and provides a sterile environment (SCHOTT, n.d.).

Label

The label on the YpsoMate Refill is intended for single-use as it contains medicine-specific information (Fig. 172). Moreover, the label helps conceal any scratches on the autoinjector to maintain its appearance. Therefore, a new label is required for each use.

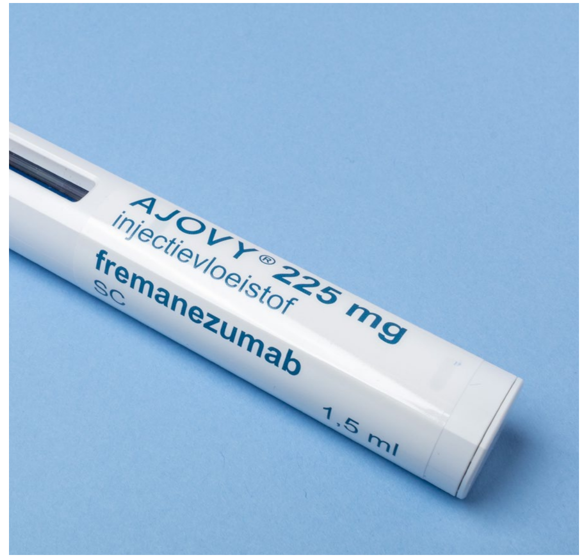


Fig. 172: The label is single-use, because it contains medicine specific information

Needle

The needle is difficult to reuse as it requires resharpening (Fig. 173), cleaning, sterilization, and separation from the syringe before and after each use. Hence, Arne Kloke from the syringe manufacturer SCHOTT recommends using a new needle for each injection. The production of the needle has a low carbon footprint of only 0.02g CO2e due to its lightweight of 0.01g (South Pole, 2022). Therefore, using a new needle for each injection has a minimal environmental impact.

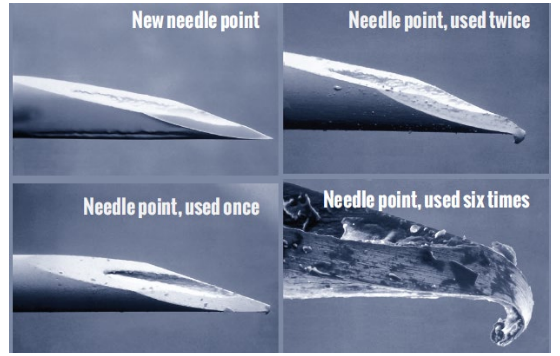


Fig. 173: The needle point deforms after multiple uses (Dickinson, 2003).

Syringe

The syringe (Fig. 174) is a single-use part because it requires more energy and effort to reuse than to recycle. Removing the needle from the syringe requires heat, and the lubricating silicone layer on the syringe is damaged during the injection. To ensure that the silicone layer is of equal thickness, it needs to be removed and reapplied before the next injection (Kloke, 2022). However, the removal process requires a solvent bath, which is harmful to the environment (McLaren, 2022). Therefore, recycling the glass syringe seems like a better option than reusing it. Glass can be recycled without degrading its quality (Dyer, 2014), and SCHOTT is exploring opportunities to recycle used glass.

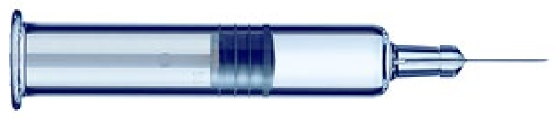


Fig. 174: The syringe is coated with a silicone layer that limits reuse (SCHOTT, n.d.).

Plunger

Similar to the syringe, the plunger (Fig. 175) is a single-use part because of the Omni-Flex coating that is damaged after a single-use. Reusing the plunger requires removing the coating in a non-sustainable solvent batch before reapplication. Moreover, the plunger is difficult to remove from the syringe in an automated process, making shredding for recycling a more energy-efficient option.

Fig. 175: The rubber plunger is coated with an OmniFlex coating that limits reuse (Datwyler, n.d.).

7.4 | Recycle

The autoinjector parts cannot be reused indefinitely, because they might not meet the quality standards after many reuses or are single-use.

YpsoMate Refill parts should be recycled instead of incinerated to lower the environmental footprint. This chapter describes the design changes made to optimize recycling, such as using mono-plastics and limiting the use of RFID tags.

7.4.1 Mono-materials

To optimize the YpsoMate autoinjector for recycling, I recommend getting rid of glass-reinforced materials. Chapter 7.2 describes the optimized click sleeve snap-fit arms that are strong enough to eliminate the need for glass reinforcement. Moreover, I recommend using a limited amount of commonly recycled materials, as suggested by Meike Schurringa (2023).

To further reduce its environmental impact, the YpsoMate Refill autoinjector incorporates biobased plastic components, similar to the YpsoMate Zero. These bioplastics can be recycled after use since they are chemically identical to virgin plastics (Borealis, n.d.)

Fig. 176 shows an overview of the materials used in the single-use YpsoMate and the recommended material changes for the YpsoMate Refill.

Takeaways

- The YpsoMate Refill consists of mono-materials to optimize recycling at the end-of-life.
- It also consists of bioplastics to reduce the environmental impact further.

Part	Material
1. Rigid needle shield	Bio-PC
2. Soft needle shield	Rubber
3. Cap Remover	Bio-PC
4. Label	Bio-PP
5. Injection spring	Stainless steel
6. Cover sleeve spring	Stainless steel
7. Outer telescopic lock sleeve (TLS)	Bio-PC
8. Inner TLS	Bio-PC
9. Plunger rod	Bio-PC
10. End cap	Bio-PC
11. Click Sleeve	Bio-PBT
12. Mechanic holder	Bio-PC
13. Syringe	Glass
14. Needle	Stainless steel
15. Plunger	Rubber
16. Cover sleeve	Bio-PC
17. Housing	Bio-PC

Fig. 176: The YpsoMate Refill concept proposes using a limited amount of commonly recycled materials and bioplastics.

7.4.2 Reduce the use of Radio Frequency Identification (RFID) tags

To improve the recyclability of the YpsoMate autoinjector, it is essential to reduce the use of Radio Frequency Identification (RFID) tags (Fig. 177). Although these tags enable communication with the YpsoMate Smart Pilot and patients' smartphones, they are challenging to recycle even if they are separated from the other materials. This is because the antennas on the RFID tag need to be manually removed before recycling, which is too labor-intensive for most recycling facilities (Evreka, 2022). As a result, RFID tags are not commonly recycled.

Takeaway

- I recommend reducing the use of RFID tags, because they are not commonly recycled.

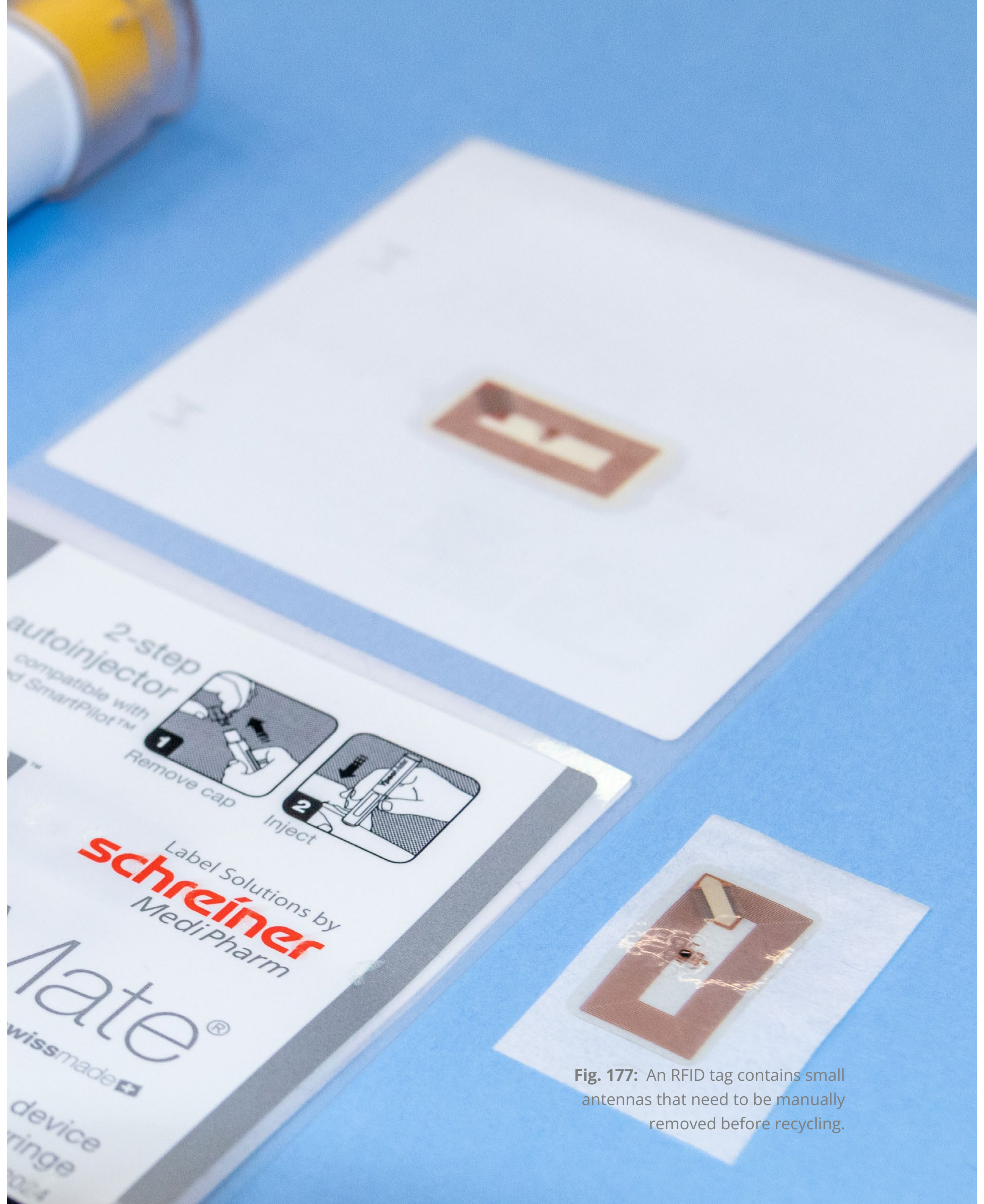


Fig. 177: An RFID tag contains small antennas that need to be manually removed before recycling.

7.5 | Prototyping

To test the functionality of the mechanisms I created, I made 3D printed prototypes. Initially, I used FDM printing, but the small parts lacked the necessary level of detail. Thus, I switched to a MultiJet Fusion 3D printer, which produced good results.

After several iterations, the prints fit together seamlessly, and the mechanisms operated as intended. Unfortunately, due to the fragility of the MultiJet Fusion prints, I was unable to subject the parts to the load of the springs. Therefore, I could not verify the full functionality of the mechanism, but the prototype serves as an effective visual model for communicating my design (Fig. 178).

Takeaway

- Fig. 178 shows an aesthetic prototype. The mechanism is not fully functional, because the 3D-printed parts are to brittle to handle the spring forces.

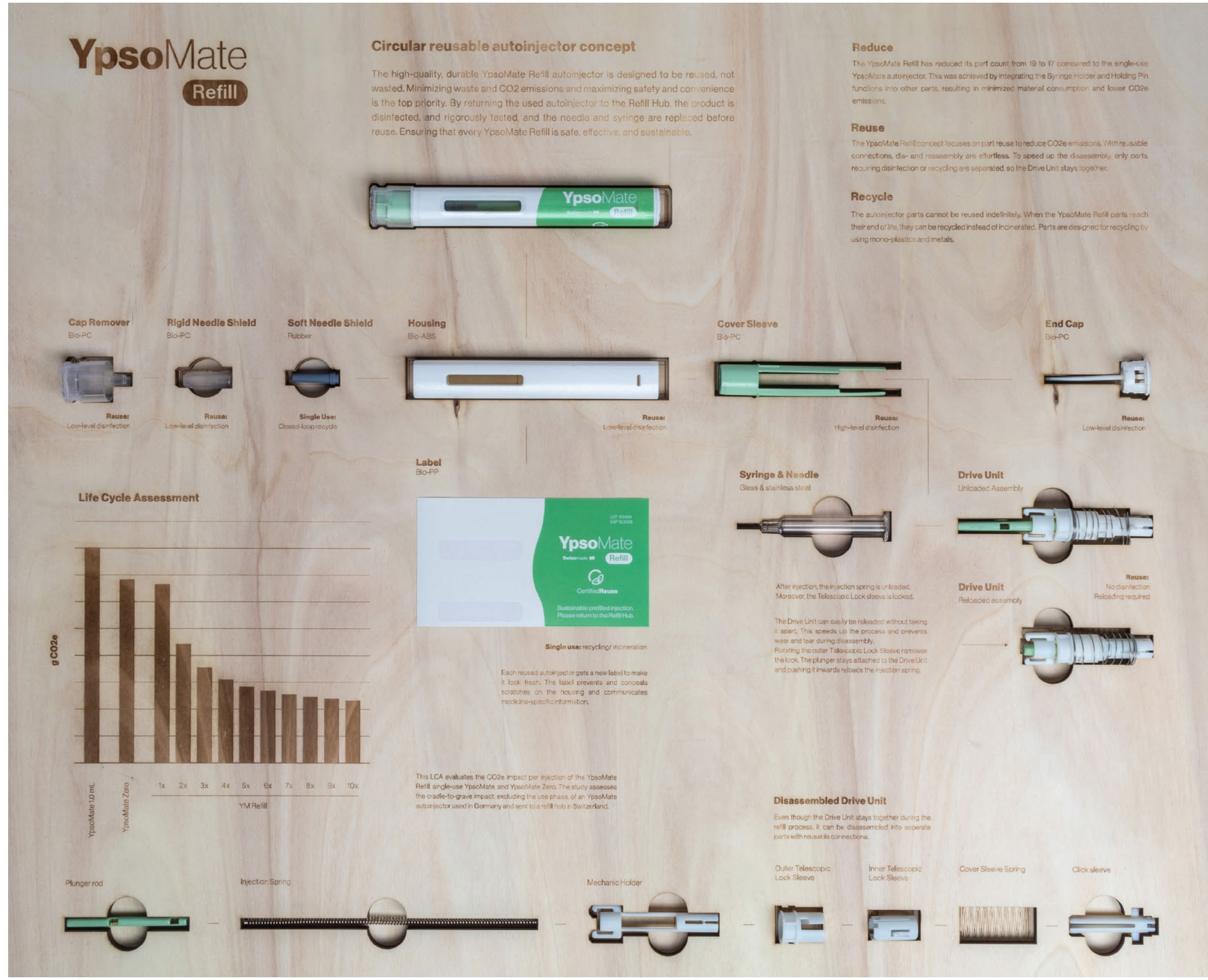
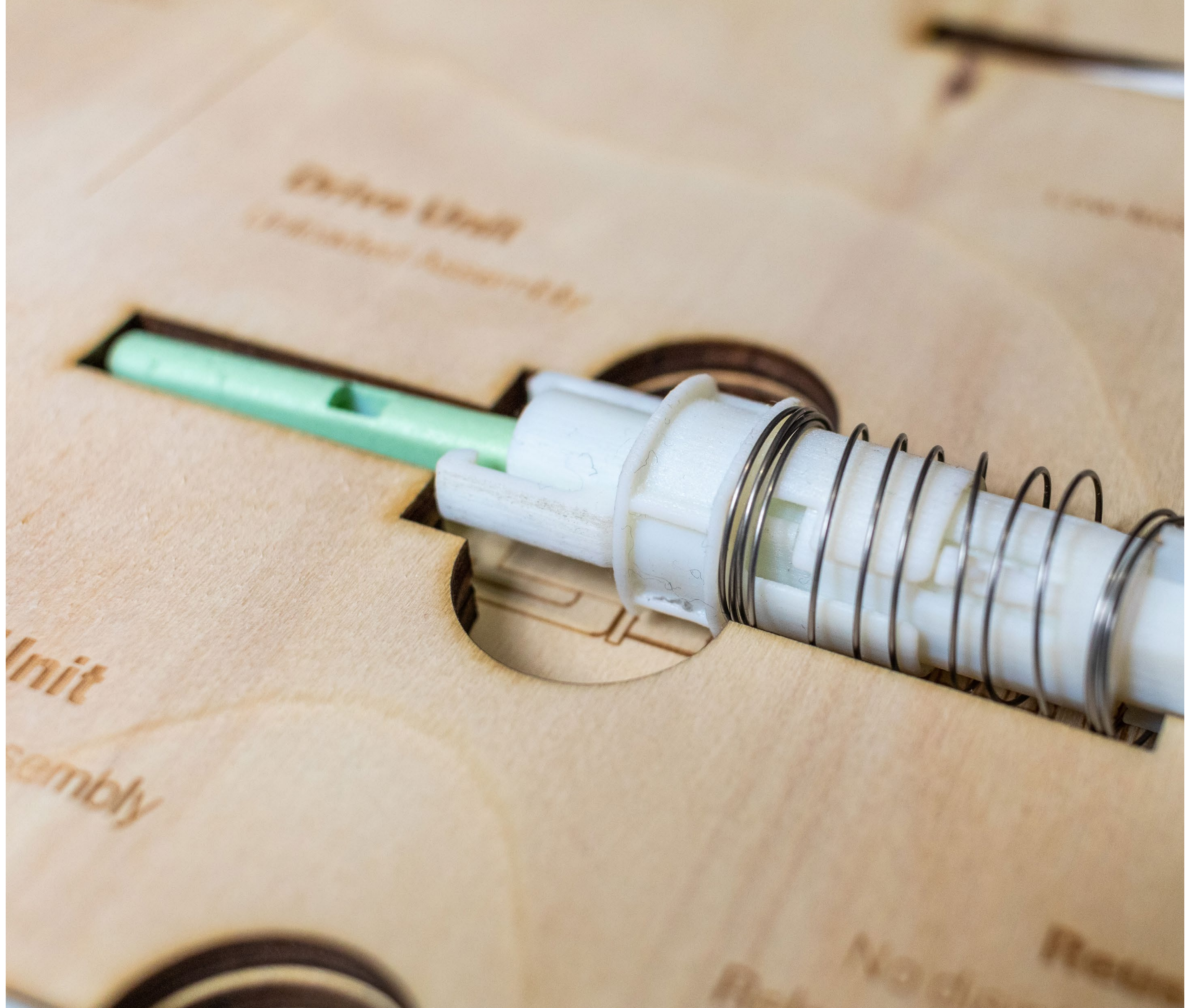


Fig. 178: To present the prototype to the Alliance to Zero, I laser printed a wooden sheet with an exploded view of the YpsoMate Refill concept.

Part 3
Evaluate

8. Concept validation

This chapter looks into the third research question: How does the YpsoMate Refill compare to the single-use YpsoMate and YpsoMate Zero in terms of environmental impact and ease of disassembly? To evaluate this, chapter 8.1 presents a Life Cycle Assessment of the YpsoMate Refill. Chapter 8.2 shows the disassembly map of the YpsoMate Refill and compares this to the single-use YpsoMate



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8.1 | Life Cycle Assessment (LCA)

8.1.1 Introduction

To assess the environmental impact of the YpsoMate Refill concept, this chapter conducts a fast-track Life Cycle Assessment (LCA) of the YpsoMate Refill. The LCA compares the YpsoMate Refill to the single-use YpsoMate and the YpsoMate Zero, providing insights into the environmental impact of each product. Nadine Kaufmann, an LCA expert at Ypsomed, reviewed the LCA assumptions, and confirmed that my th assumptions seem valid. Moreover, Kaufmann conducted a similar LCA for a different refill concept and arrived at similar conclusions as this study.

However, since this is a fast track LCA with a considerable number of assumptions, this chapter does not mention specific numbers for the CO2e impact, but offers approximations instead.

Fig. 179: The LCA evaluates the environmental impact of the YpsoMate Refill concept.

8.1.2 Scope of the analysis

This fast-track Life Cycle Assessment (LCA) compares the environmental impact (CO2 equivalent) of the YpsoMate Refill with the single-use YpsoMate 1.0 mL and YpsoMate Zero autoinjectors (Fig. 181). I obtained the data for this LCA from LCA's conducted by South Pole (2022), Carnstone (2022), and Ypsomed (2020), and I combined this data with information from the Ecoinvent V3.8 and Idemat 2022 database to calculate the impact of the YpsoMate Refill.

Chapter 5 discusses how the YpsoMate Zero incorporates bio-plastics, an optimized supply chain, and recycled PET packaging trays. I applied these same measures to the YpsoMate Refill design, using the YpsoMate Zero LCA as the starting point for the YpsoMate Refill LCA. Additionally, I assumed that the YpsoMate Refill materials are recycled at their end-of-life, as shown to be feasible by Meike Schurringa (2023). To calculate the impact of recycling, Nadine Kauffman advised me to use the cut-off method, which involves subtracting the CO2e emissions of incineration from the material impact (Williams & Eikenaar, 2022). The LCA results for a scenario where the parts are incinerated at their end-of-life, instead of recycled, can be found in Appendix G.

Takeaway

- This LCA compares the CO2e impact from cradle to grave of the single-use YpsoMate 1.0 mL (Fig. 181) and YpsoMate Zero (Fig. 182) to the reusable YpsoMate Refill autoinjector.
- I assumed that the YpsoMate Refill uses bioplastics, and optimized supply chain, recycled PET packaging trays and that the materials are recycled at their end-of-life.

Fig. 180: The LCA compares the single-use YpsoMate 1.0 and the YpsoMate Zero to the YpsoMate Refill concept.

YpsoMate 1.0 mL & YpsoMate Zero: linear product life cycle

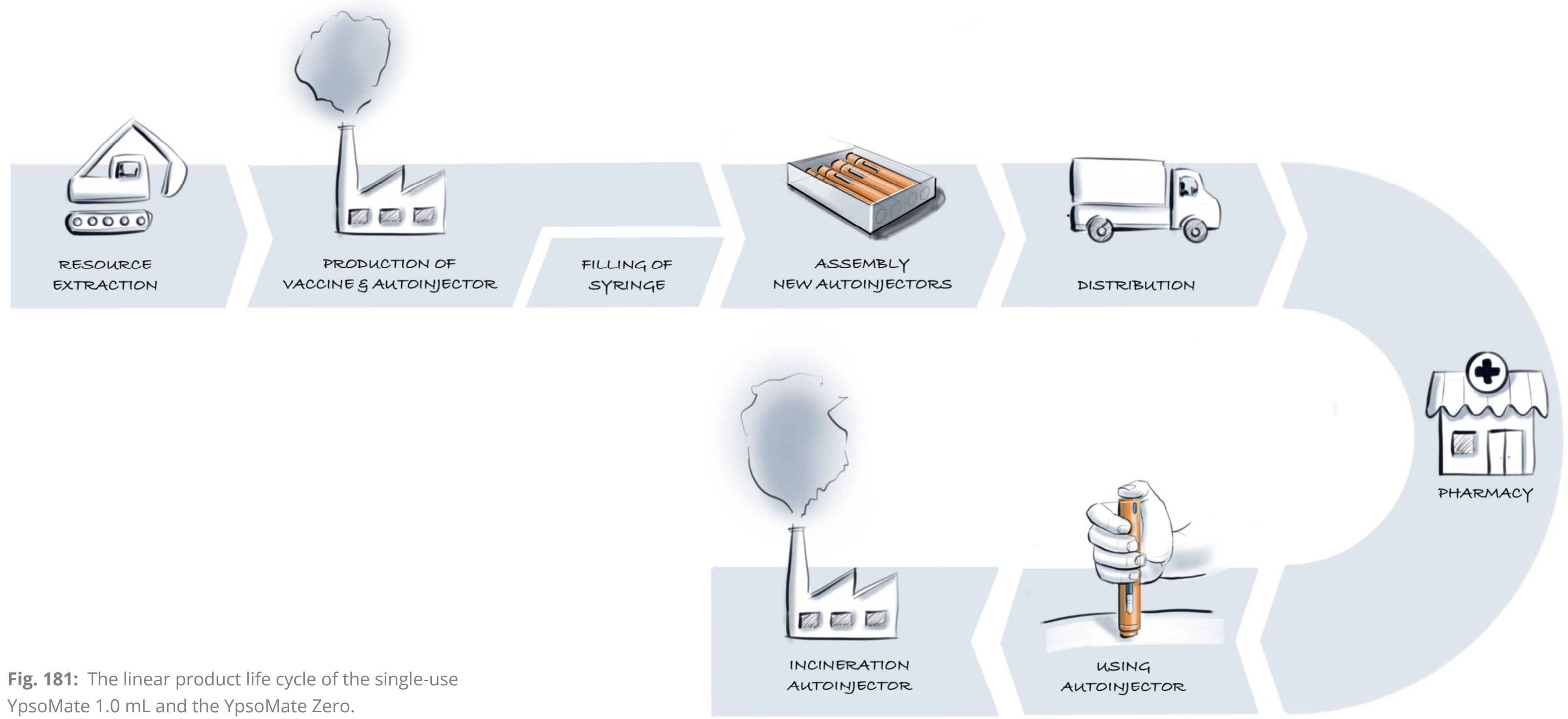


Fig. 181: The linear product life cycle of the single-use YpsoMate 1.0 mL and the YpsoMate Zero.

YpsoMate Refill: circular product life cycle

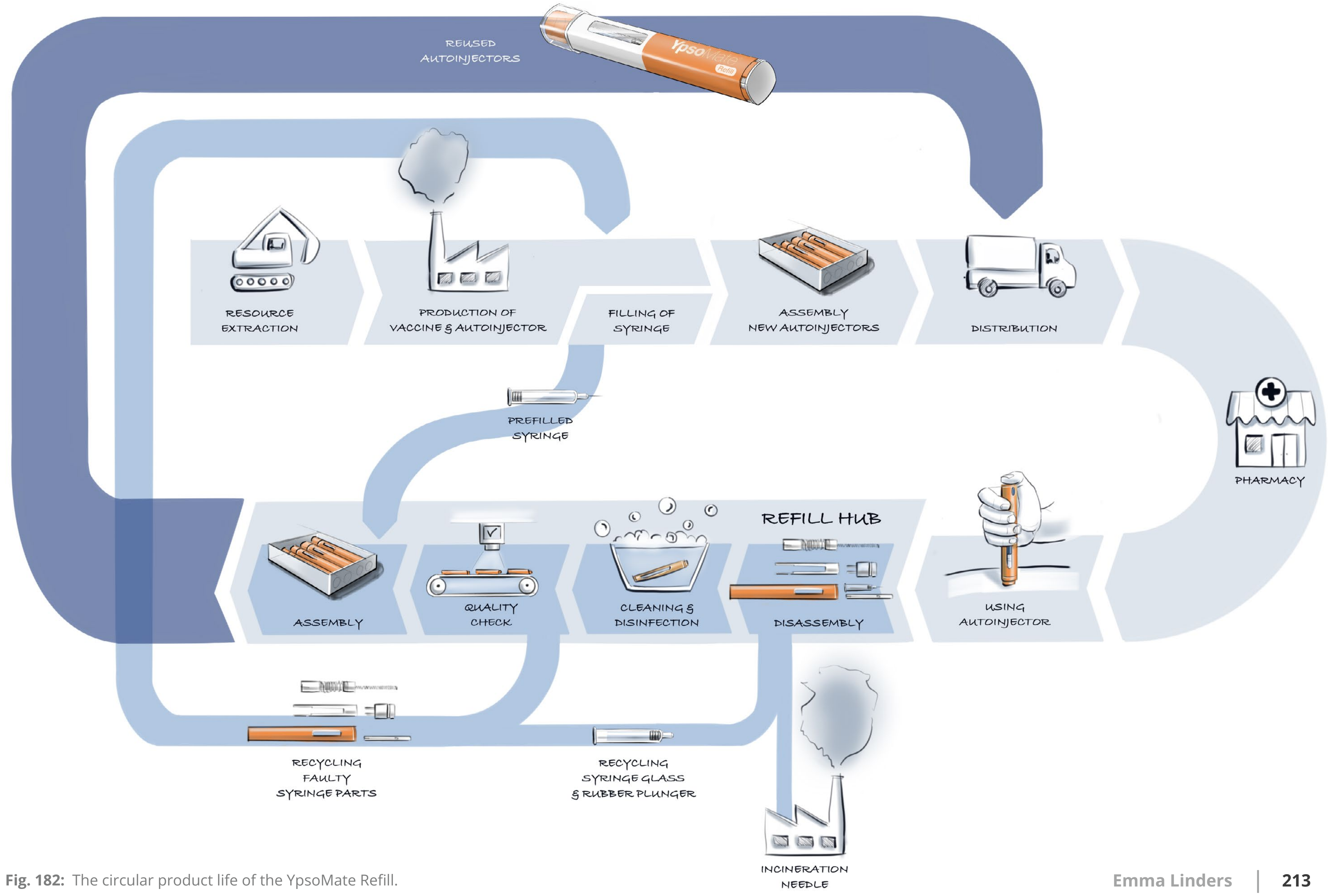


Fig. 182: The circular product life of the YpsoMate Refill.

8.1.3 Single-use and reuse parts

Chapter 6 explains that 12 out of 19 YpsoMate Refill parts are reused (Fig. 183). In my LCA, I assumed that not only the autoinjector parts but also the intermediate and tertiary packaging will be reused. This type of packaging is used for transporting the autoinjector parts within the factory and between production partners. The Alliance to Zero is exploring reusing the tertiary packaging, so this is a valid assumption.

Takeaways

- In the YpsoMate Refill LCA calculations, the syringe and needle, soft needle shield, plunger, label, printed leaflets and cardboard box are single-use parts.
- The other YpsoMate Refill parts and the intermediate and tertiary packaging are reused.

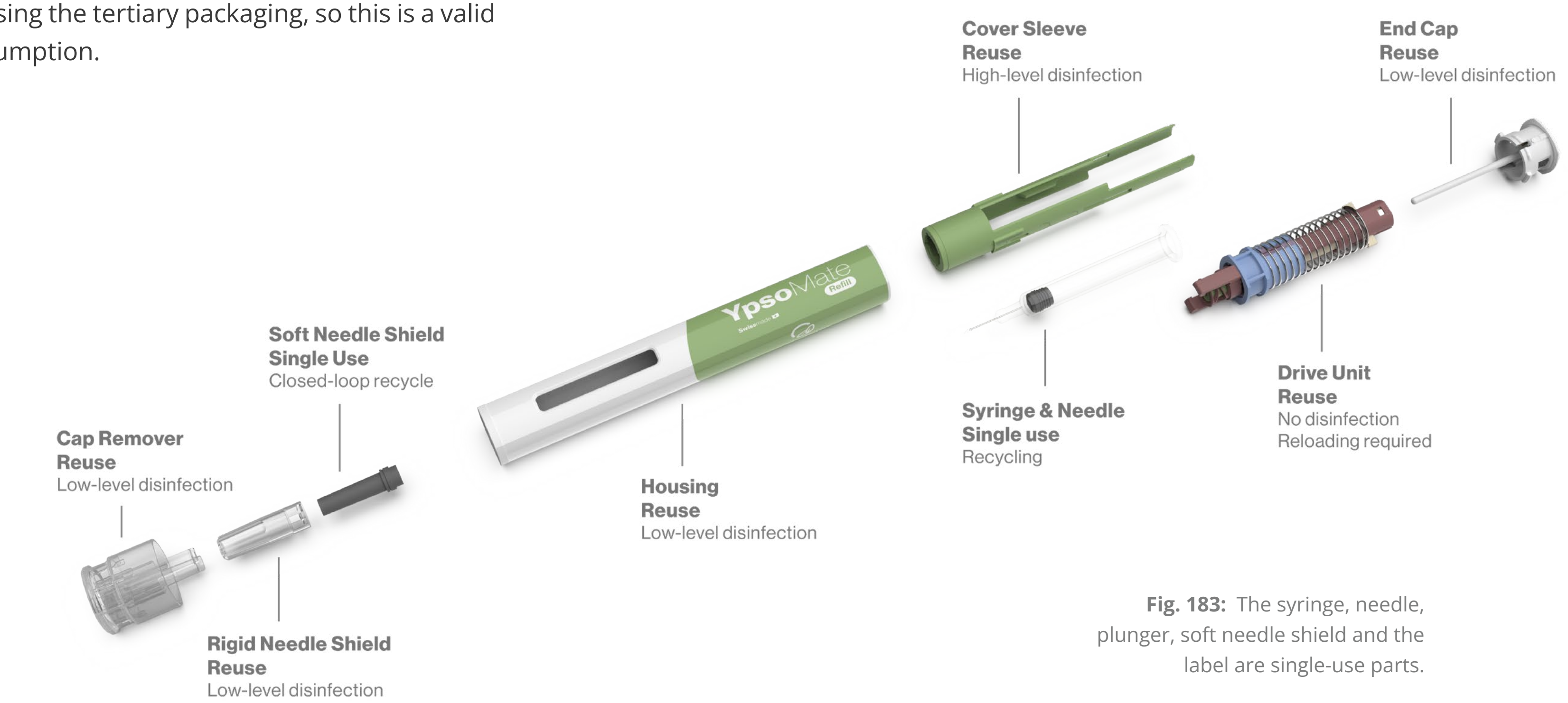


Fig. 183: The syringe, needle, plunger, soft needle shield and the label are single-use parts.

8.1.4 CO2e impact per injection

Fig. 185 illustrates the CO2e impact per injection (excluding the use phase) of the YpsoMate (YM) Refill compared to the single-use YpsoMate 1.0 mL and YpsoMate Zero. The graph indicates that even when used only once, the YpsoMate Refill has approximately a 25% lower CO2e impact than the single-use YpsoMate 1.0 mL and 15% lower than the YpsoMate Zero. This is due to its reduced part count since there is no syringe holder and no holding pin, the use of bioplastics and recycling the materials at its end-of-life.

When the YpsoMate autoinjector is reused once, the CO2e emissions decrease by approximately 50% compared to a single-use YpsoMate and 45% compared to a single-use Ypsomate Zero (percentages calculated exlcluding the use-phase). These percentages decreases further to approximately 65% (YpsoMate) and 60% (YpsoMate Zero) CO2e reduction after five uses. However, as shown in the graph, the CO2e reduction flattens after more than five uses because the impact of the reuse parts becomes minimal, while the impact of the single-use parts and processes for reuse remains the same.

To further reduce the CO2e impact of the YpsoMate Refill, the impact of the single-use parts and processes for reuse should be minimized.

Five times reuse appears to be a sweet spot, reducing the CO2e impact with approximately 65% in comparison to the single-use YpsoMate, while the likelihood of a part failure is low due to the limited reuse count.

Increasing the reuse count from five times to ten times only results in an additional 5% reduction in CO2e impact, but the chances of a part failure increase.

Calculation

To calculate the emissions per injection as shown in Fig. 185, I used the following formula:

Emissions per injection = (emissions reuse parts / amount of injections) + (emissions reuse processes - 1) + emissions single-use parts

Takeaways

- Even without reusing the YpsoMate Refill, it has a 25% lower CO2e impact (excl. use) than the single-use YpsoMate, due to less parts, bioplastics and recycling the materials at its end-of-life.
- Reusing parts five times appears to be a sweet spot. This reduces the total CO2e impact with approximately 65% in comparison to the single-use YpsoMate 1.0 mL (excl. use), while the likelihood of a part failure is low due to the limited reuse count
- Increasing the reuse count from five times to ten times only results in an additional 5% reduction in CO2e impact, but the chances of a part failure increase.

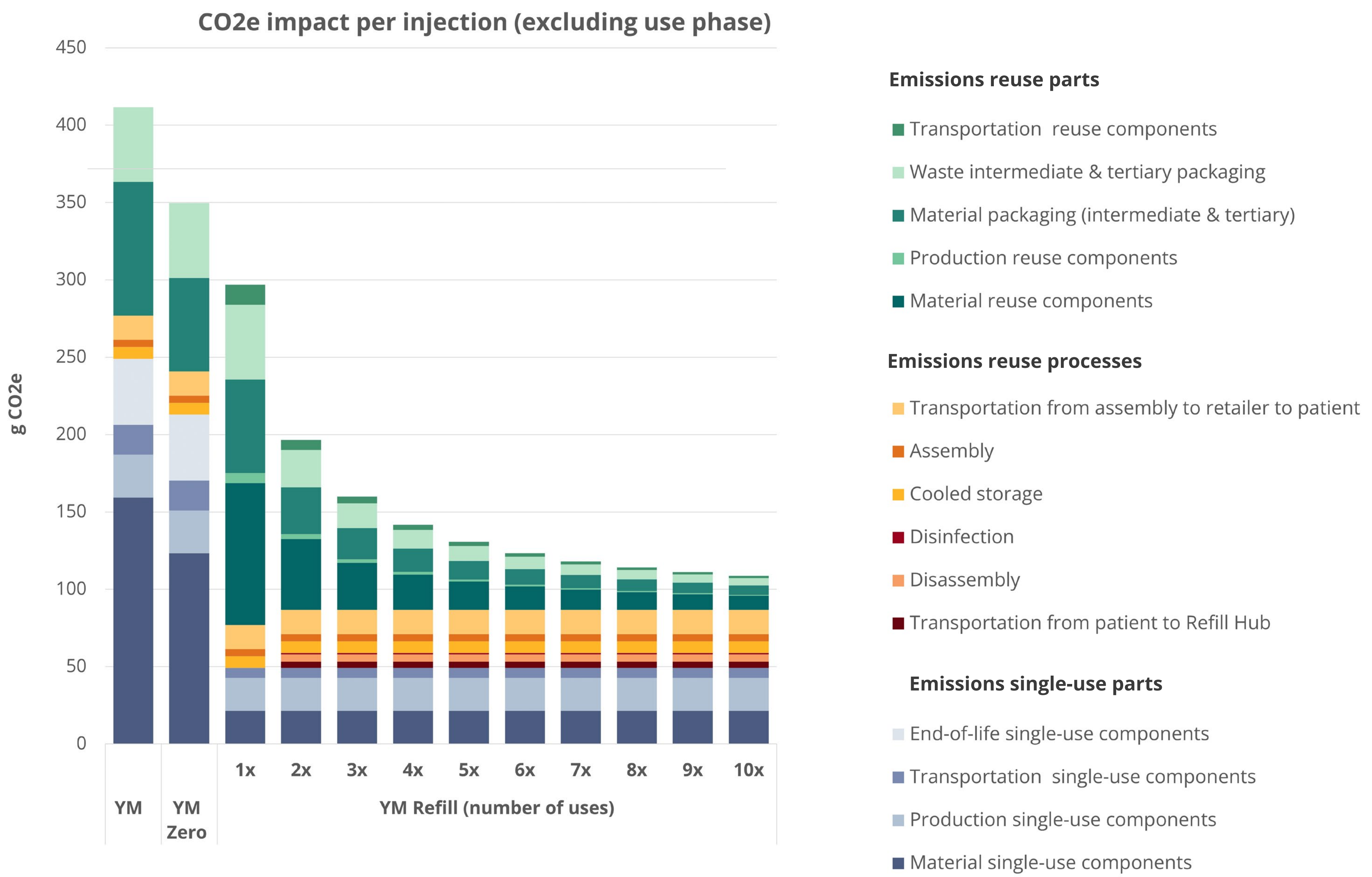


Fig. 184: The CO2e emissions (g) of the single-use YpsoMate (YM) 1.0 mL and YpsoMate Zero (excl. the use phase) compared to the CO2e (g) emissions of the YpsoMate Refill over multiple reuses.

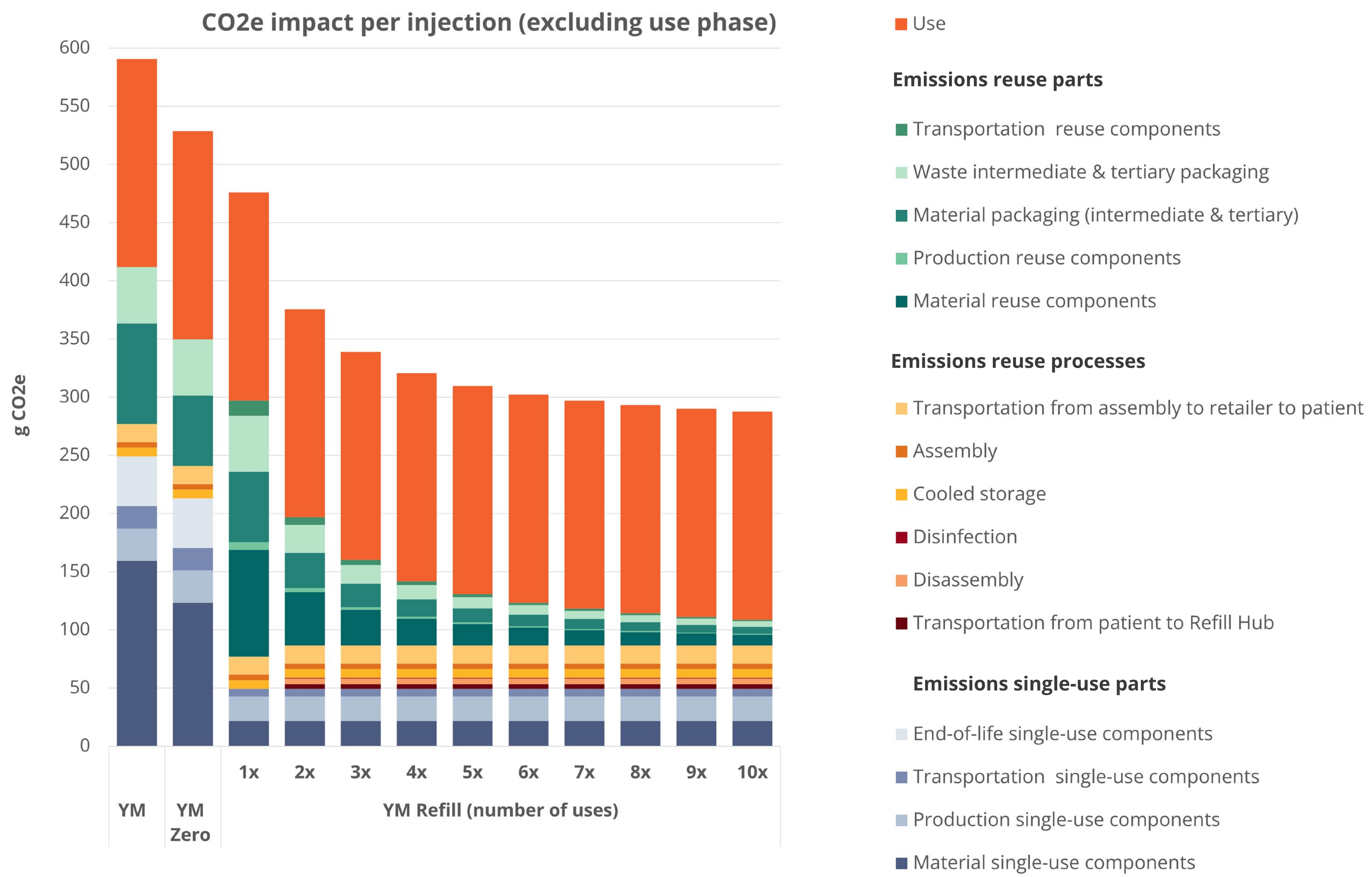


Fig. 185: The CO2e emissions (g) of the YpsoMate 1.0 mL and the YpsoMate Zero (including the use phase) in comparison to the CO2e (g) emissions of the YpsoMate Refill over multiple reuses.

Impact of the use phase

Fig. 186 illustrate the CO2e impact per injection, including the use phase, of the YpsoMate Refill in comparison to the single-use YpsoMate 1.0 mL and YpsoMate Zero.

It reveals that the use phase contributes significantly with 180 g CO2e per injection.

This high impact is primarily based on the assumption by South Pole (2022) that 56% of patients travel 5 km by car to pick up a single autoinjector. To mitigate this impact, it would be worthwhile to explore alternative delivery options such as delivering the autoinjectors to patients' houses using (electric) bike couriers. The St. Antonius Hospital in the Netherlands (2022) is already using this strategy to reduce carbon emissions from cars and provide an additional service to patients.

Takeaways:

- The use phase emits 180 g CO2e per injection.
- This could be reduced by preventing that patients travel by car to the pharmacy, e.g. by home-delivering autoinjectors with electric bikes.

8.1.5 Extra CO2e- emissions due to reuse processes

There are extra processes required to reuse YpsoMate Refill autoinjectors, including disassembly, disinfection and transportation between the patient and the Refill Hub. The following paragraphs describe the extra CO2e emissions these processes add to each reuse cycle.

Disassembly

The process of disassembling the used autoinjector has an impact of approximately 5 g CO2e. To calculate this impact, I assumed that the impact of disassembly is similar to the impact of assembly, as calculated in the LCA conducted by South Pole (2022). I validated this assumption with Nadine Kaufmann.

Disinfection:

As outlined in chapter 6, the cap remover and cover sleeve require disinfection before reuse, while the housing and end cap need cleaning. This results in an environmental impact of approximately 1 g CO2e. Since the impact of specific disinfection processes is not available, I assumed that the environmental impact of disinfection is equal to the impact of sterilization. However, this assumption should be further validated to get a more accurate LCA, since the impact value seems really low. However, Kaufmann also calculated this value and came to the same low number.

Transportation between the patient and Refill Hub

The transportation of the autoinjector from the patient to the Refill Hub has an impact of approximately 5 g CO2e. For this calculation, I assumed that the patient lives in Frankfurt (Germany), since this is the scope of the LCA of South Pole (2022) and Carnstone (2022).

Moreover, I assumed that the Refill Hub is located near the Ypsomed factory in Burgdorf, Switzerland. However, in reality, the placement of the Refill Hub should be carefully considered based on multiple factors, such as the patient's location and the production facilities. It is not economically viable to place a Refill Hub in every city, as there will not be enough autoinjectors to reuse, which would result in a high cost and environmental impact of the Refill Hub compared to the CO2e savings of reusing the autoinjector. A balance should be found between having multiple Refill Hubs on each continent to keep the transportation distance to patients low while receiving enough autoinjectors to benefit from the economy of scale and refill on a large scale.

Lastly, the calculation is based on the assumption that the autoinjector is transported with a non-cooled truck to the Refill Hub.

Takeaways:

The reuse of YpsoMate Refill autoinjectors requires the following extra processes in comparison to single-use autoinjectors:

- Disassembly of used autoinjectors has a low impact of approx 5 g CO2e.
- Disinfection also has a low impact of approx. 1 g CO2e.
- Transportation for a patient living in Frankfurt (Germany) to a Refill Hub positioned next to Ypsomed in Burgdorf (Switzerland) emits approx. 5 g CO2e. This increases if the patient lives further away.

8.1.6 Return rate

To achieve the CO2e emission savings discussed earlier, patients should return their autoinjectors for reuse. Novo Nordisk's PenCycle and Johnson & Johnson's return program reported a 50% return rate. However, Arne Kloke, a member of Alliance to Zero, believes that this rate may not reflect the return rate of a more established system over time. The Alliance to Zero estimates a return rate of 15% to 25%.

In contrast, Health Beacon is currently achieving an impressive return rate of 90% for used autoinjectors. This can be attributed to their diligent tracing process, coupled with proactive reminders to patients via a postal box for return after use.

Fig. 186 highlights the impact of varying return rates on the percentage of returned autoinjectors after multiple uses. For instance, with a return rate of 90%, if a hundred autoinjectors are distributed, less than 10 of these autoinjectors remain in use after seven cycles. Similarly, a return rate of 50% indicates that less than 10 of the autoinjectors are still in use after four cycles, while a return rate of 20% yields this same outcome after only two cycles. It is important to note that the graph does not account for potential wear and tear in the parts of the autoinjector that may render it non-reusable

However, with productions of hundreds of millions of YpsoMate's in 2030, even with a low return rate, the YpsoMate Refill has the potential to make a significant impact, underscoring the importance of promoting sustainable healthcare practices by encouraging patients to return used autoinjectors for proper disposal and recycling.

To increase the CO2e emissions savings of the YpsoMate Refill, the focus should be on increasing the return rate.

Johnson & Johnson (n.d.) has already conducted an extensive research on how to increase the return rate. The findings indicate that making people aware of the sustainable benefits of returning the product is more motivating than offering a monetary reward.

Takeaways

- The return rate return of YpsoMate Refill autoinjectors plays a crucial role in achieving CO2e emission savings. Therefore, to increase these savings, the focus should be on increasing the return rate.
- With a return rate of 50% (found in a Novo Nordisk Pilot), less than 10% of the YpsoMate Refill autoinjectors are left after four reuse cycles. This 10% could be tens of millions of YpsoMates by 2030.
- With a return rate of 20% (estimate of the Alliance to Zero), 10% of the YpsoMate Refill autoinjectors are left after two reuse cycles.

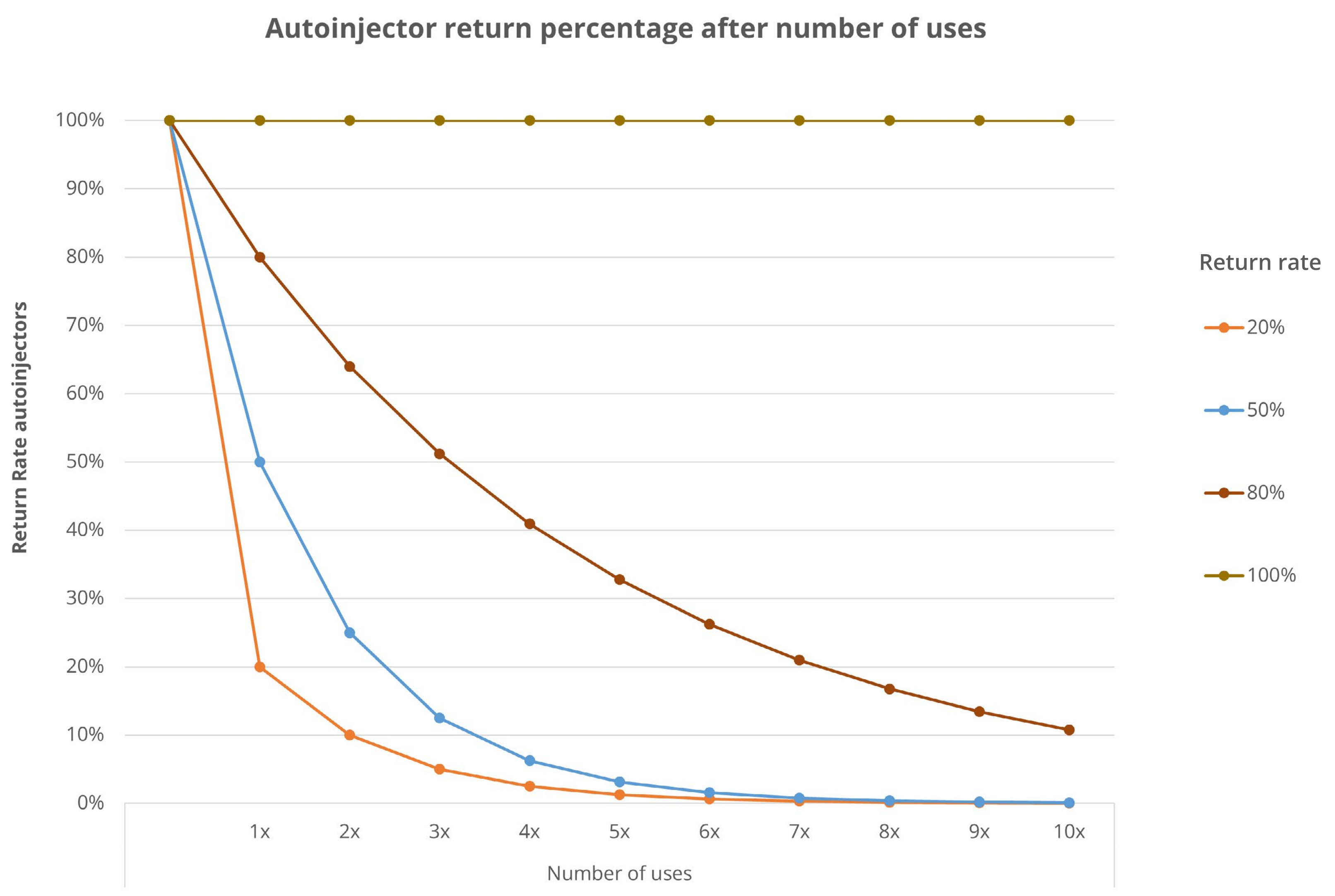


Fig. 186: The autoinjector return percentage after a number of uses for certain return rates.

8.2 | Ease of disassembly

This thesis aims to improve the ease of disassembly of the YpsoMate autoinjector. This chapter demonstrates the achievement of this goal by comparing the disassembly map (De Fazio et al., 2021) of the YpsoMate Refill to those of the single-use YpsoMate, single-use Novartis and reusable GlaxoSmithKline (gsk) autoinjectors.

8.1.7 Disassembly of the YpsoMate Refill

To disassemble the YpsoMate Refill, a machine can reset and reload the Drive Unit without dismantling it, as explained in chapter 6.

Therefore, the Drive Unit appears as a resulting subassembly (Fig. 187) in the disassembly map shown in Fig. 190.

However, if a Drive Unit part breaks, it is possible to take apart the Drive Unit and salvage certain components for reuse, such as the springs. The disassembly map in Fig. 192 shows this scenario.

When comparing the ease of disassembly of the YpsoMate Refill to the single-use YpsoMate, this chapter uses the scores of the disassembly map where the Drive Unit remains intact. This is because it is the most typical scenario, as the Drive Unit only needs to be taken apart if a part breaks.

Additionally, the disassembly map of the YpsoMate Refill accounts for an automated disassembly process, which employs a "machine" as the tool for each disassembly step. In contrast, the disassembly map for the single-use YpsoMate, which I personally dismantled, displays tools such as hand, screwdriver, and pliers.

Since the YpsoMate Refill will undergo automated disassembly, I could not determine the disassembly time since manual disassembly time is incomparable to that of a machine. As a result, the ease of disassembly comparison did not consider disassembly time. Nonetheless, I assume that the disassembly time will be short, as the YpsoMate Refill has an efficient disassembly process where steps can be done in parallel.

Fig. 187: The Drive Unit as a resulting subassembly

8.2.1 Disassembly depth & sequence

Table 14 illustrates a great improvement in the disassembly process of the YpsoMate Refill concept design, with only eight disassembly steps compared to 19 steps for the single-use YpsoMate. Moreover, the YpsoMate Refill has fewer disassembly tasks and steps than the other analyzed autoinjector.

Additionally, the YpsoMate Refill has a maximum disassembly depth (Fig. 188) of only three, while the single-use YpsoMate has a depth of nine. This means that any part can be accessed in only three disassembly steps. The low disassembly depth is due to the autoinjector being disassembled into subassemblies, which can be taken apart in parallel to speed up the process.

The following example demonstrates the impact of this low disassembly depth. In the single-use YpsoMate, six parts and subassemblies need to be removed before reaching the prefilled syringe, which should be quickly removed to avoid cross-contamination. In contrast, the YpsoMate Refill requires the removal of only one subassembly to access the prefilled syringe.

Disassembly depth:

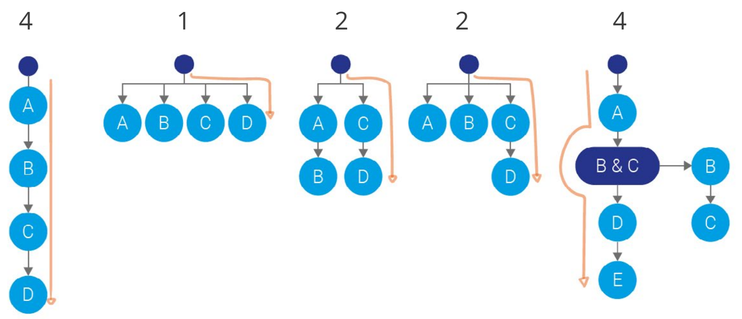
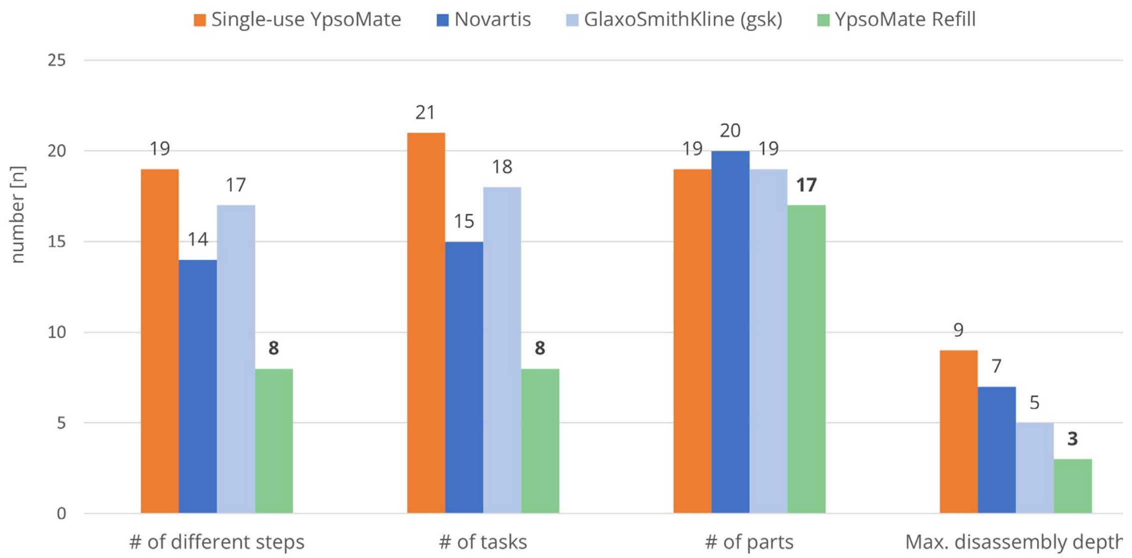


Fig. 188: Explanation of the disassembly depth. Image from Vermaat (2020)

Table 14: The disassembly of autoinjectors in numbers

Disassembly of autoinjectors



8.2.2 Penalties

The disassembly map assigns penalties to tasks that are time or force intensive, require high precision, involve non-reusable fasteners or have obstructed access. However, for the YpsoMate Refill, the penalties for force-intensive and high-precision tasks have limited impact, as the disassembly and reassembly process is automated. In fact, they can even be an advantage, making it difficult for patients to open the autoinjector while remaining easy for a machine.

Table 15 highlights the YpsoMate Refill's improvements in disassembly penalties, with no penalties for time-intensive, non-reusable fastener, or obstructed access tasks.

In comparison, the single-use YpsoMate received two time-intensive, five non-reusable fastener, and two obstructed access penalties.

Although the YpsoMate Refill does receive penalties for force-intensive and high-precision tasks, as previously discussed, this is actually beneficial in preventing patients from opening the autoinjector.

Takeways

- It requires only three steps to reach any part in the YpsoMate Refill, in comparison to nine steps for the single-use YpsoMate.
- The YpsoMate Refill gets no penalties for time intensive, non-reusable fastener and obstructed access, while the single-use YpsoMate has nine of those penalties.
- The YpsoMate Refill can be disassembled in eight tasks, compared to twenty-one tasks required for the single-use YpsoMate.

Autoinjector type	Time intensive	Force intensive	High precision	Non-reusable fastener	Obstructed access
Single-use YpsoMate	2	3	7	5	2
Novartis	0	2	3	4	3
GlaxoSmithKline	2	5	2	5	3
YpsoMate Refill	0	2	3	0	0

Table 15: Penalties of the autoinjectors. The highest penalties are highlighted in orange.

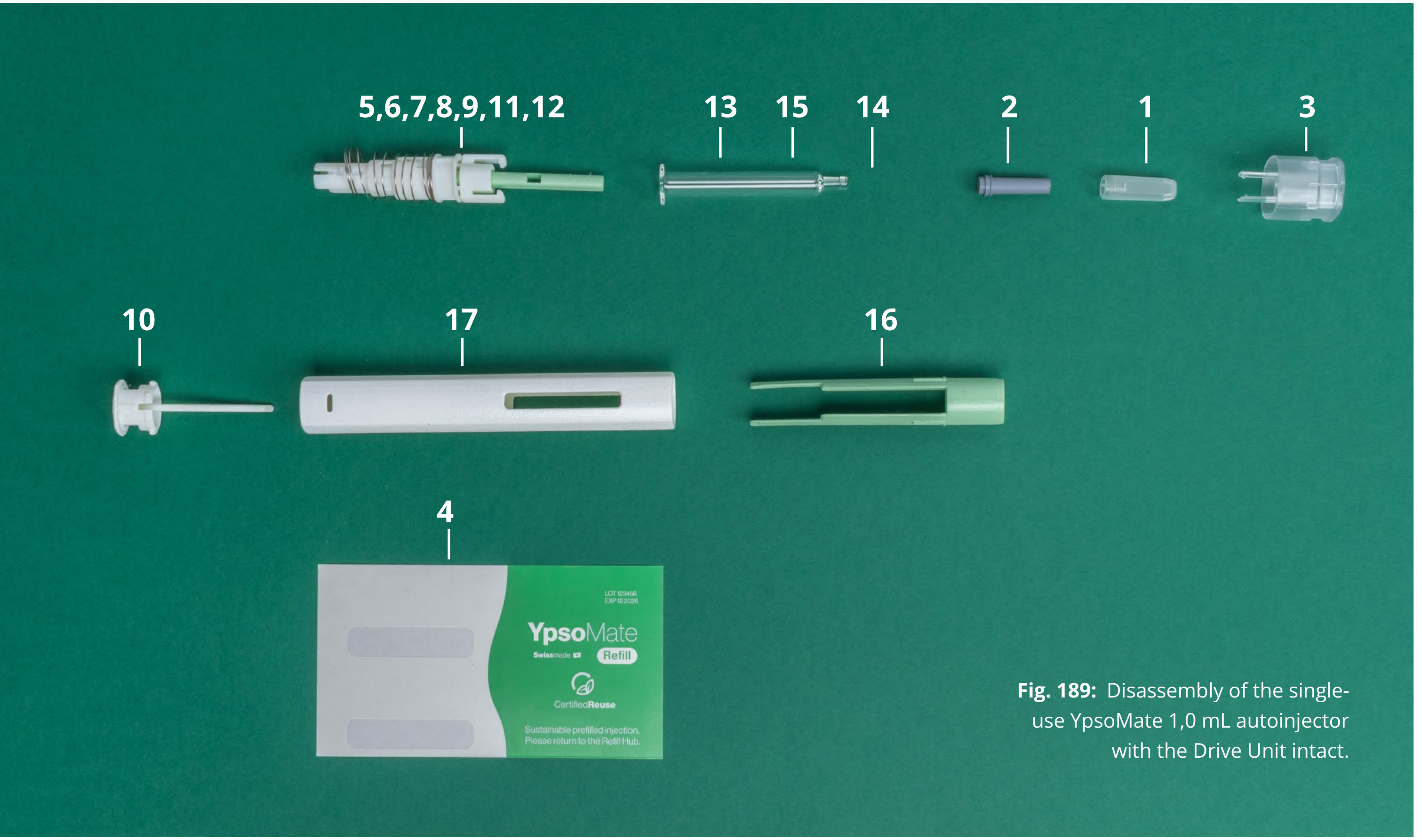


Fig. 189: Disassembly of the single-use YpsoMate 1,0 mL autoinjector with the Drive Unit intact.

8.2.3 YpsoMate Refill: Drive Unit intact

1. Rigid needle shield
2. Soft needle shield
3. Cap remover
4. Label
5. Injection spring
6. Cover sleeve spring
7. Outer Telescopic lock sleeve
8. Inner Telescopic lock sleeve
9. Plunger rod
10. End cap
11. Click Sleeve
12. Mechanic holder
13. Syringe
14. Needle
15. Plunger
16. Cover sleeve
17. Housing

Parts

A part

A,B subassembly

A,B resulting subassembly

Penalties

force intensive

high precision

HotSpots

environmental HotSpot

economic HotSpot

Type of tool

machine

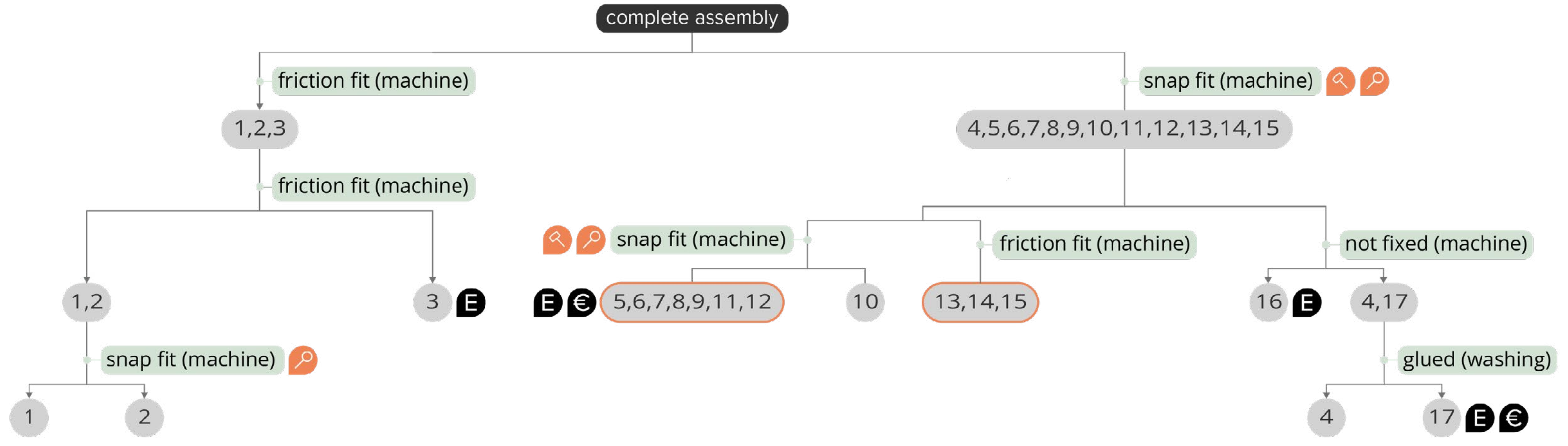


Fig. 190: Disassembly map of the single-use YpsoMate 1.0 mL.

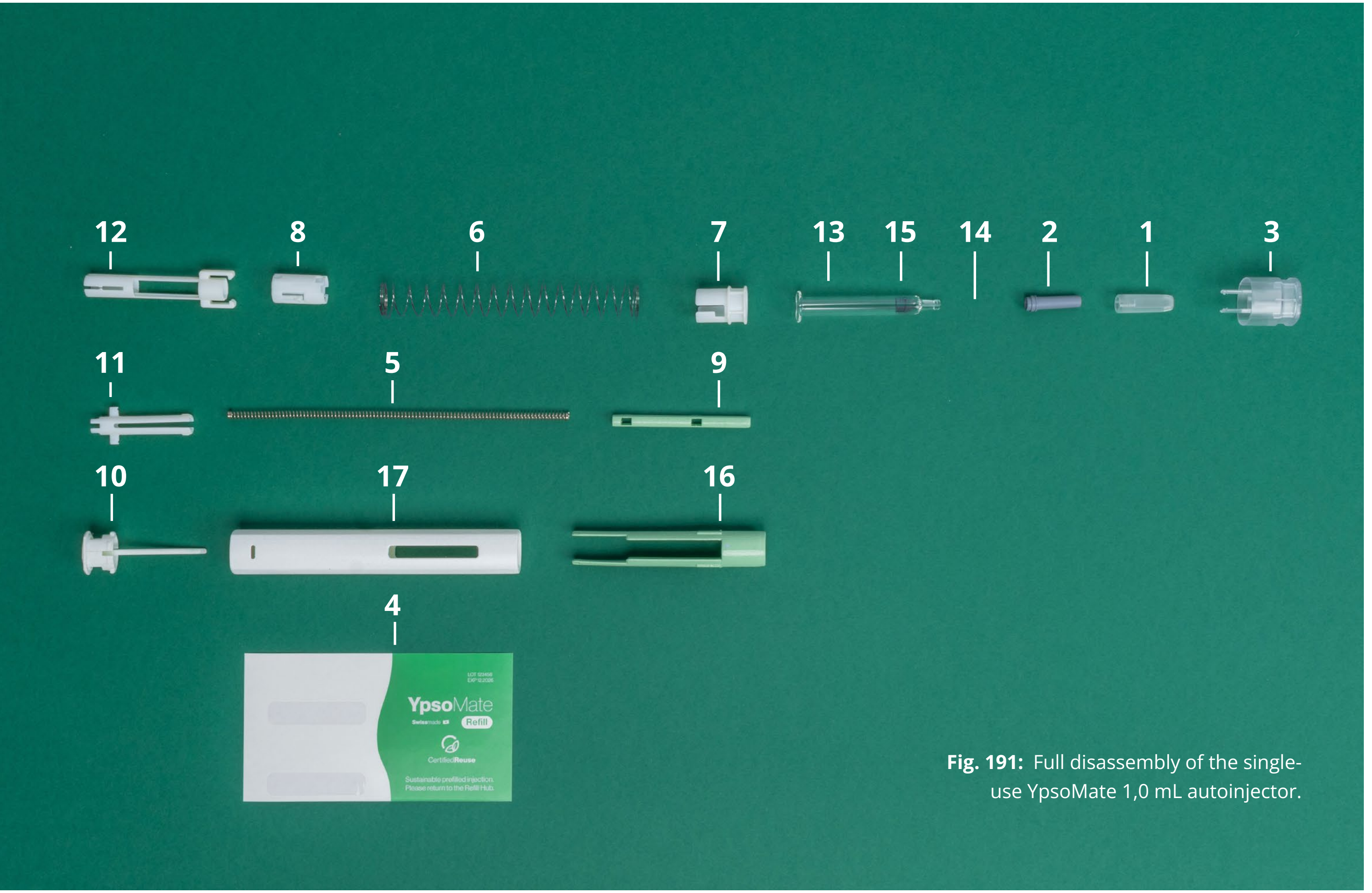


Fig. 191: Full disassembly of the single-use YpsoMate 1,0 mL autoinjector.

8.2.4 YpsoMate Refill: Drive Unit Disassembled

1. Rigid needle shield
2. Soft needle shield
3. Cap remover
4. Label
5. Injection spring
6. Cover sleeve spring
7. Outer Telescopic lock sleeve
8. Inner Telescopic lock sleeve
9. Plunger rod
10. End cap
11. Click Sleeve
12. Mechanic holder
13. Syringe
14. Needle
15. Plunger
16. Cover sleeve
17. Housing

Parts

A part

A,B subassembly

A,B resulting subassembly

Penalties

force intensive

high precision

HotSpots

E environmental HotSpot

€ economic HotSpot

Type of tool

machine

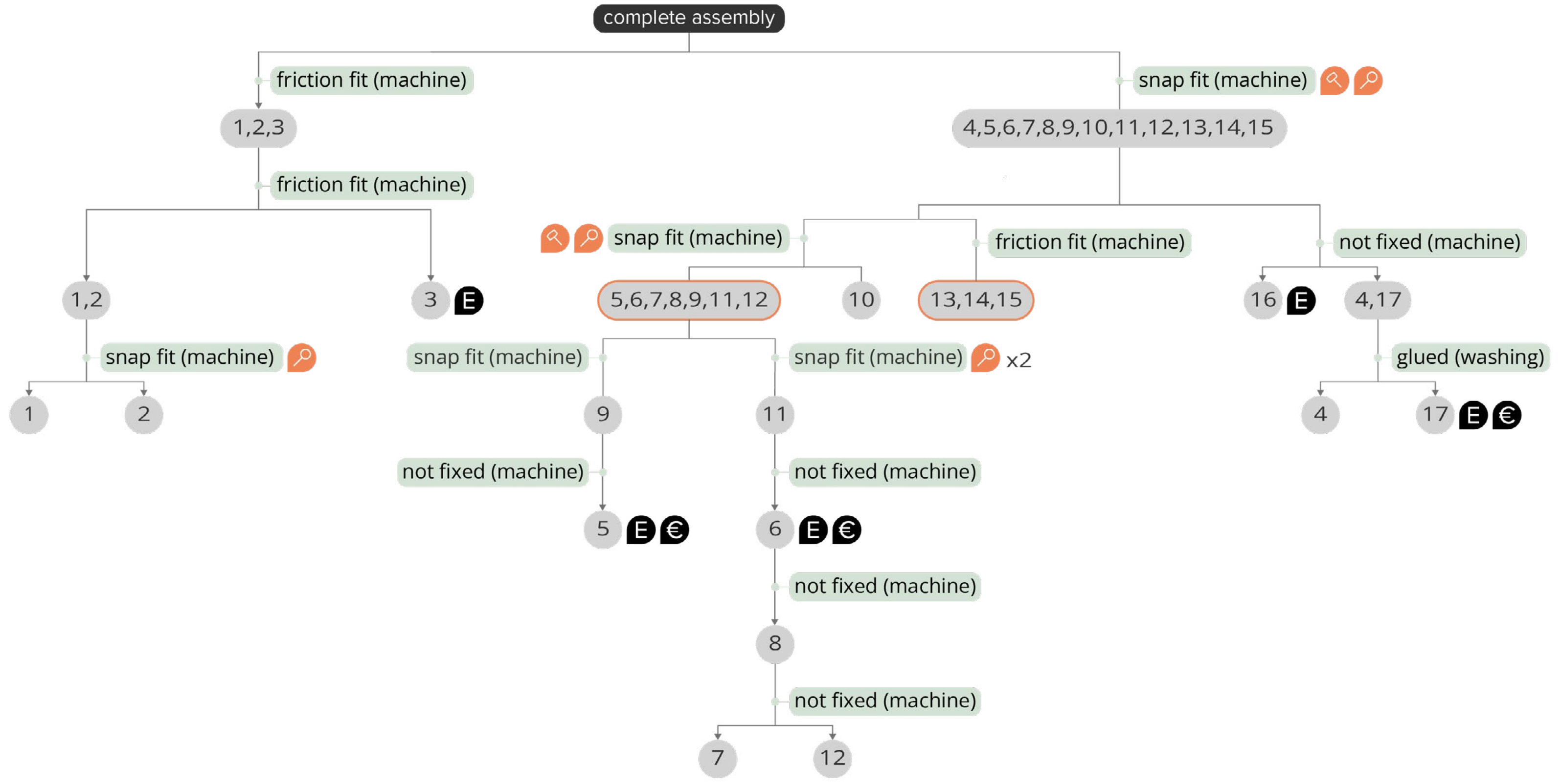
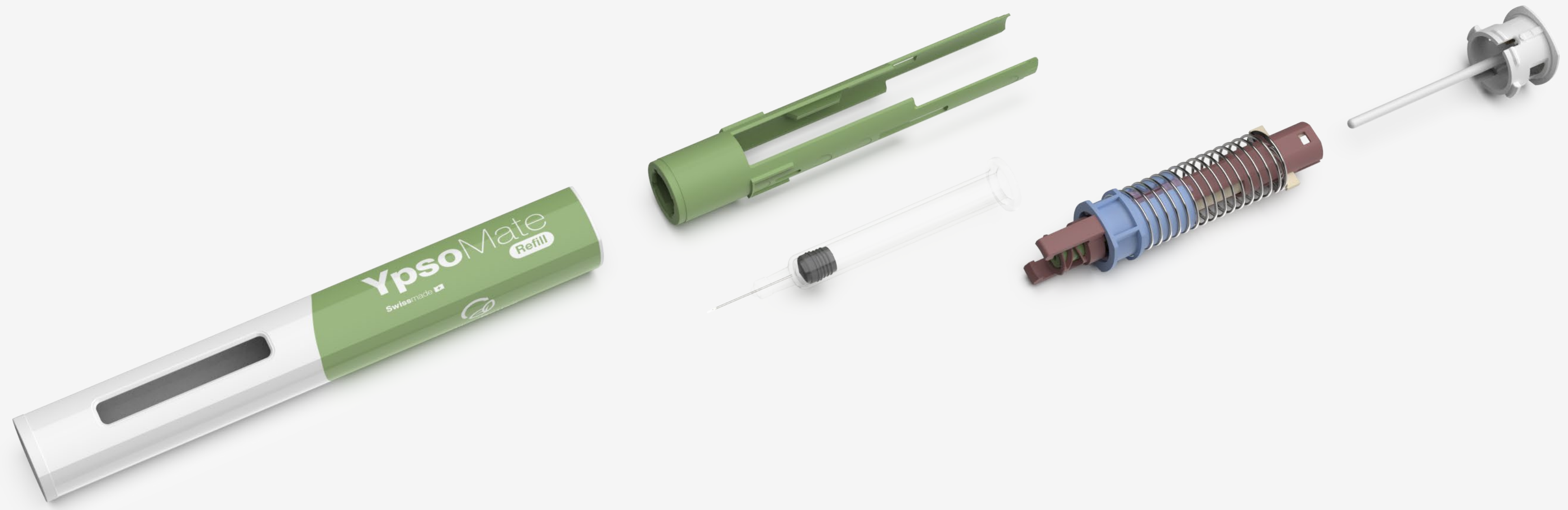


Fig. 192: Disassembly map of the single-use YpsoMate 1.0 mL.

9. Conclusion

This chapter recaps the design proposals for the YpsoMate Refill. Moreover, it proposes a set of recommendations and provides a personal reflection.



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9.1 Conclusion

9.1.1 Research Problem

YpsoMate is a popular self-injection device used by patients with conditions such as migraine, psoriasis, multiple sclerosis, and rheumatoid arthritis. Although it is a convenient and easy-to-use device that saves patients a trip to the hospital, it generates a considerable amount of waste and CO2e emissions because it is incinerated after a single-use (Fig. 193).

In 2030, Ypsomed expects to produce millions of autoinjectors annually, resulting in 8800 tonnes of waste. If you put the yearly wasted autoinjectors end to end, they would encircle the world seven times. Additionally, these autoinjectors emit approximately 120,000 tonnes of CO2e yearly, equivalent to 173,000 people flying from Europe to Australia and back. Nearly 50% of these CO2 emissions are caused by the linearity of the supply chain, including the resource extraction, production, and incineration of the autoinjectors.

To address these environmental problems, this thesis introduces the YpsoMate Refill: a concept design of an autoinjector that can be refilled at a Refill Hub to reduce waste and CO2e emissions. Moreover, this thesis answers the following research questions:

1. What is the current state of autoinjectors regarding the circular economy, particularly concerning refillability?
2. How can the product-service system of the YpsoMate autoinjector be modified to accommodate third-party refills?
3. How does the YpsoMate Refill concept compare to the single-use YpsoMate and YpsoMate Zero in terms of environmental impact and ease of disassembly?

9.1.2 Methods

To answer the first research question, I applied circular design strategies from Bocken et al. (2016), Bakker et al. (2014), Flipsen (2020), DeFazio et al. (2020) and the Institute of Design Research Vienna et al. (2021) to assess the circularity of the current YpsoMate and the YpsoMate Zero. Additionally, I conducted a Life Cycle Assessment to determine the CO2e emissions. I also used the HotSpot and Disassembly Mapping tools to evaluate the ease of disassembly.

To address the second research question, I implemented the Creative Problem Solving method (Van Boeijen et al., 2014) to transform my research findings into design challenges that could be addressed with innovative solutions. I developed and refined the YpsoMate Refill concept through sketching, prototyping (Fig. 194), and evaluations with among others Ypsomed engineers.

For the third research question, I used Life Cycle Assessments, Hotspot, and Disassembly Mapping to compare the environmental impact and ease of disassembly of the YpsoMate Refill to the current YpsoMate and the YpsoMate Zero.

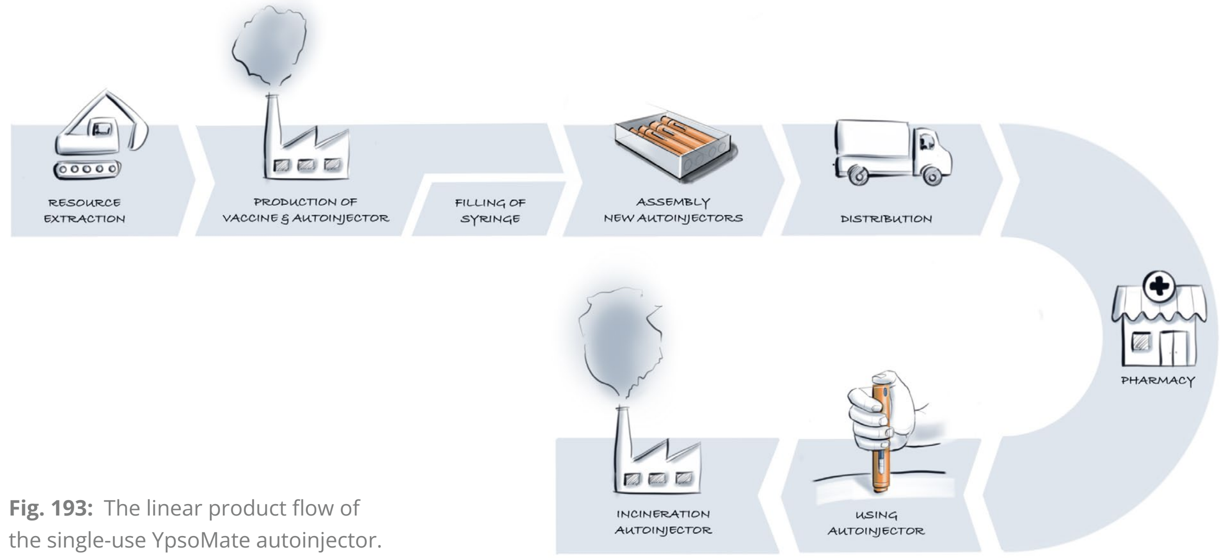

Fig. 193: The linear product flow of the single-use YpsoMate autoinjector.

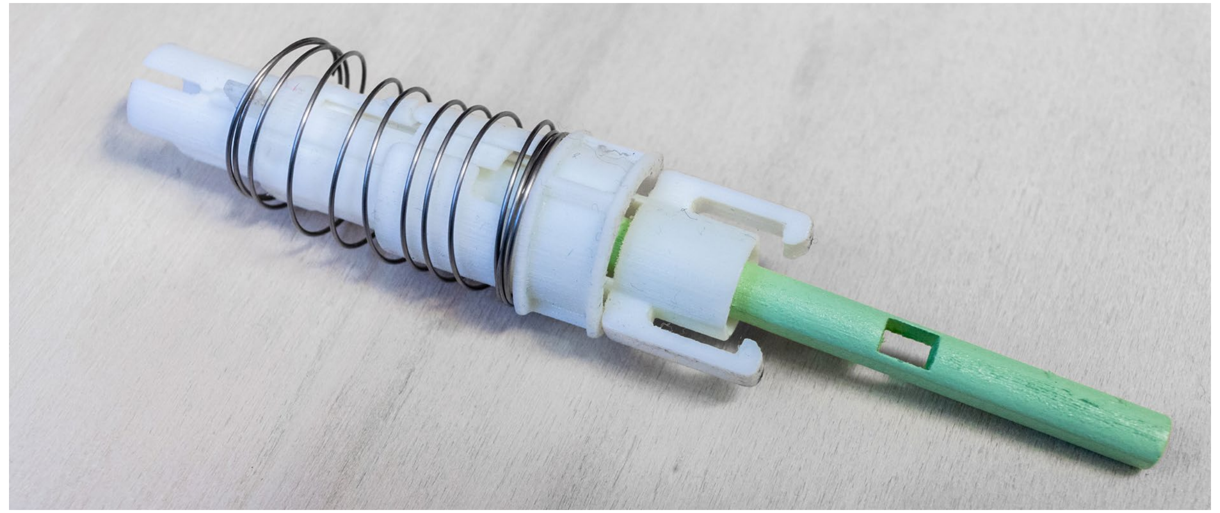

Fig. 194: The prototype of the drive unit showed that the mechanicsm works as expected.

9.1.3 Findings

This chapter groups the findings of the thesis based on the research question they answer.

RQ1: A sustainability evaluation of current autoinjectors

Product complexity & part count

The current YpsoMate is a highly complex product, consisting of 19 parts, which contribute to the device's CO2e emissions. The multitude of parts also increases the likelihood of failure, thus limiting the reuse potential.

Reusability challenges

Neither the current YpsoMate nor the YpsoMate Zero is designed for reuse. Parts cannot be easily reused, because disassembly requires breaking certain parts (Fig. 196). The linear disassembly process is time-consuming since tasks cannot be done in parallel.

Recycling limitations

Due to their classification as contaminated medical waste, used autoinjectors are typically incinerated or landfilled, with no parts being recycled. Furthermore, the variety of materials used, including glass-reinforced parts, limits potential recycling options.

Industry developments

Companies such as Novo Nordisk, Johnson & Johnson, and Health Beacon have taken steps to establish take-back programs and automated disassembly hubs to create a circular autoinjector system. Novo Nordisk and Johnson & Johnson currently have a 50% return rate, while Health Beacon achieved an impressive 80% return rate. These initiatives demonstrate the willingness of both industry and patients to create a more sustainable autoinjector system.

Fig. 196: Breaking the housing open to disassemble the single-use YpsoMate.

RQ2 - Design of a product-service system of the YpsoMate Refill

This thesis presents the YpsoMate Refill concept (Fig. 197) as a solution for accommodating third-party refills. The design incorporates modified parts that facilitate easy dis- and reassembly while reducing the part count from 19 to 17 to minimize CO2e emissions. Additionally, the use of a limited amount of commonly recycled bio-based plastics supports a circular product life.

In this circular product life cycle (Fig. 198), the patient can return their used autoinjector at their local pharmacy, via home collection, or pre-paid post boxes (Fig. 200). Once the autoinjector arrives at the Refill Hub, machines disassemble it in a few simple steps that can be done in parallel (Fig. 199). The contaminated parts are disinfected, and the prefilled syringe is replaced with a new one to ensure sterility. All parts undergo a meticulous quality check, the Drive Unit is reset, and the injection spring is reloaded for another injection cycle. The parts are then reassembled, and the housing is sealed with a new medicine-specific label to give the autoinjector a fresh, clean look.

The refilled autoinjector is now ready to be used by another patient, making the YpsoMate Refill design a sustainable, convenient, and safe alternative for single-use autoinjectors.

Fig. 197: The YpsoMate Refill autoinjector.

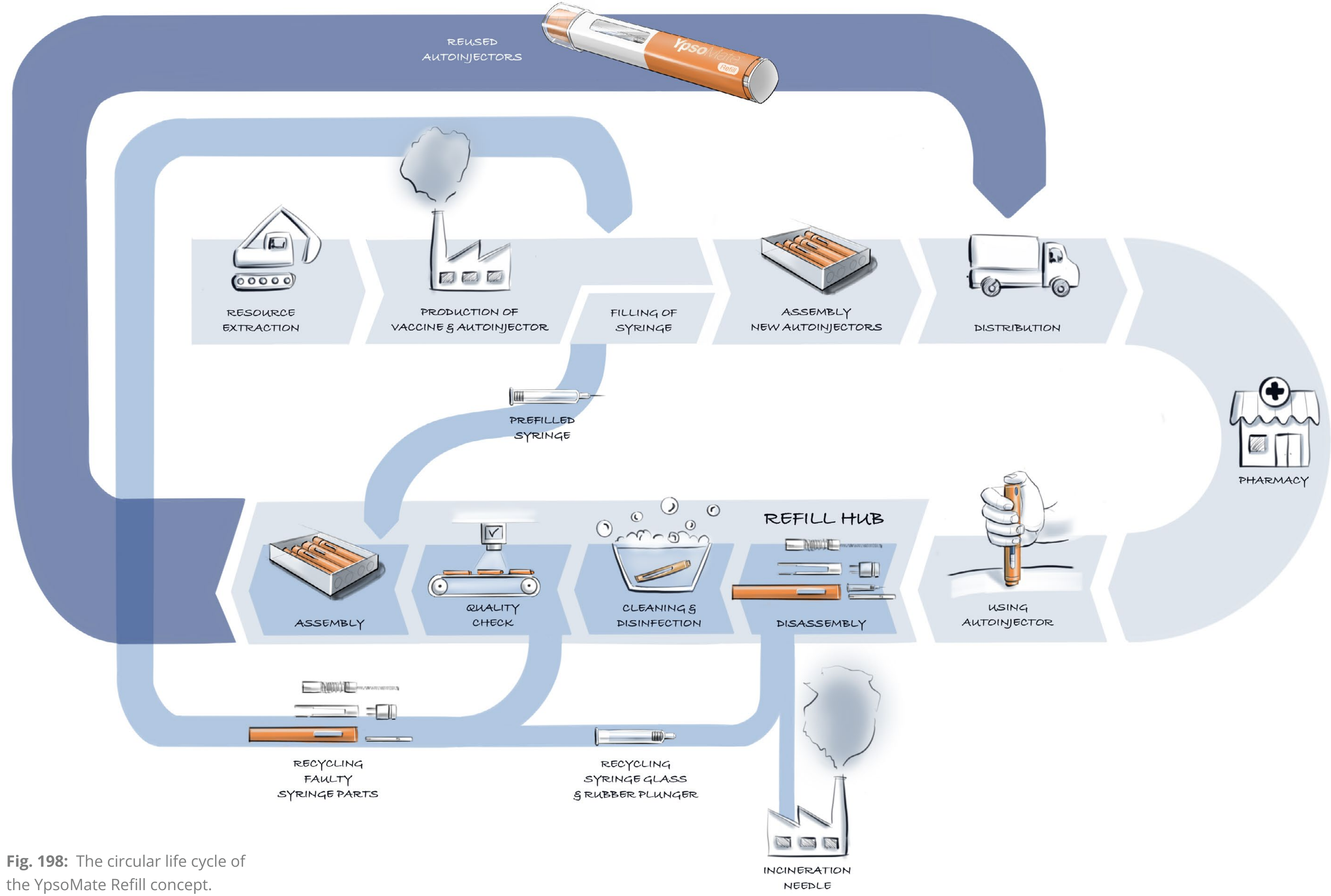

Fig. 198: The circular life cycle of the YpsoMate Refill concept.

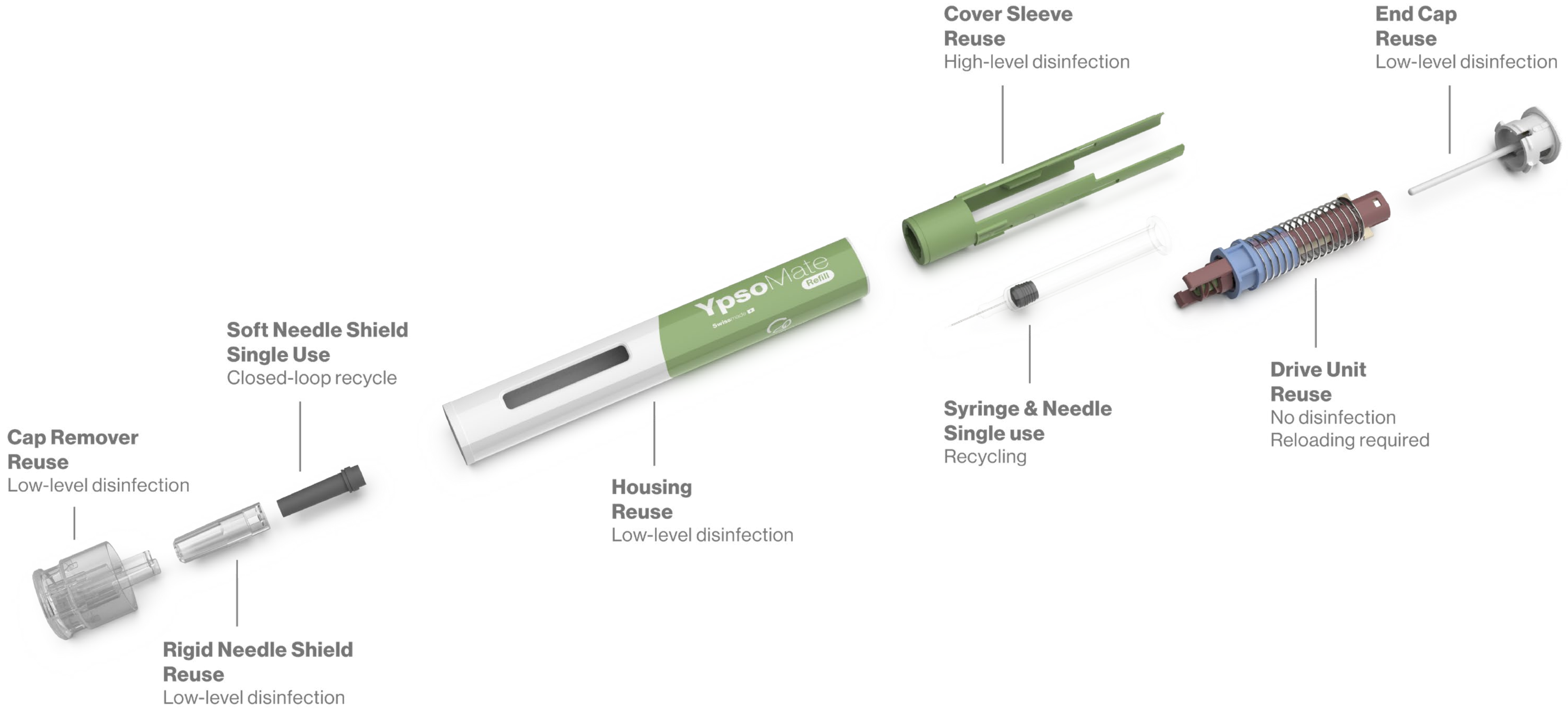

Fig. 199: The YpsoMate Refill can be easily disassembled in an automated process.

Fig. 200: The patient can return the YpsoMate Refill to the Refill Hub in this box.

RQ3: Evaluation of YpsoMate Refill concept in comparison to the single-use YpsoMate

60% CO2e reduction after 5 reuses

The YpsoMate Refill has a 25% lower CO2e impact than the single-use YpsoMate 1.0 mL in the Life Cycle Assessment (LCA). This is due to the use of bioplastics and the reduced part count.

The assessment (Fig. 201) points out that the use phase has a relatively high impact on the total CO2e emissions. This is because South Pole (2022) assumed that 56% of patients travel 5 km by car to pick up a single autoinjector. To mitigate this impact, it is worth exploring alternative delivery options such as delivering the autoinjectors to patients' homes via (electric) bike couriers.

As shown in Fig. 201, after one reuse, the YpsoMate Refill emits approximately 50% less CO2e than the single-use YpsoMate. The reduction increases to approximately 65% after five reuses. However, the graph also demonstrates that the CO2 reduction flattens after multiple reuses as the CO2e impact of the reusable parts becomes minimal, while the impact of CO2 emissions related to the reuse process and single-use items remain constant. These include transportation, dis- and reassembly, disinfection, and the materials and production of single-use parts. This indicates that reusing parts indefinitely is not only physically impossible but also does not make sense from a CO2e emission perspective since CO2e reductions become minimal.

Moreover, if 80% of patients return their used autoinjector, only 10% of those autoinjectors are returned to the Refill Hub after ten use cycles. Therefore, it is statistically unlikely that the same autoinjector is reused more than ten times.

Therefore, the optimal number of reuses for an autoinjector part seems to be around five times. This reduces the CO2e impact by approximately 65% compared to the current single-use YpsoMate 1.0 mL, while the likelihood of part failure remains low due to the limited reuse count.

Easy of dis- and reassembly

Compared to the single-use YpsoMate, the YpsoMate Refill is much easier to dis- and reassemble. While I had to break parts of the single-use YpsoMate during disassembly, the YpsoMate Refill features reusable connections. A machine can take the YpsoMate Refill apart into subassemblies, that can be disassembled in parallel. This results in a maximum disassembly depth of three steps, compared to the single-use YpsoMate's disassembly depth of nine.

This means that any part can be accessed in just three simple disassembly steps, which is a great improvement. Additionally, the YpsoMate Refill Drive Unit can be reloaded without disassembly. Therefore, the entire device can be disassembled in eight tasks, compared to the twenty-one tasks required for the single-use YpsoMate. This streamlined process speeds up the dis- and reassembly process, making it more efficient.

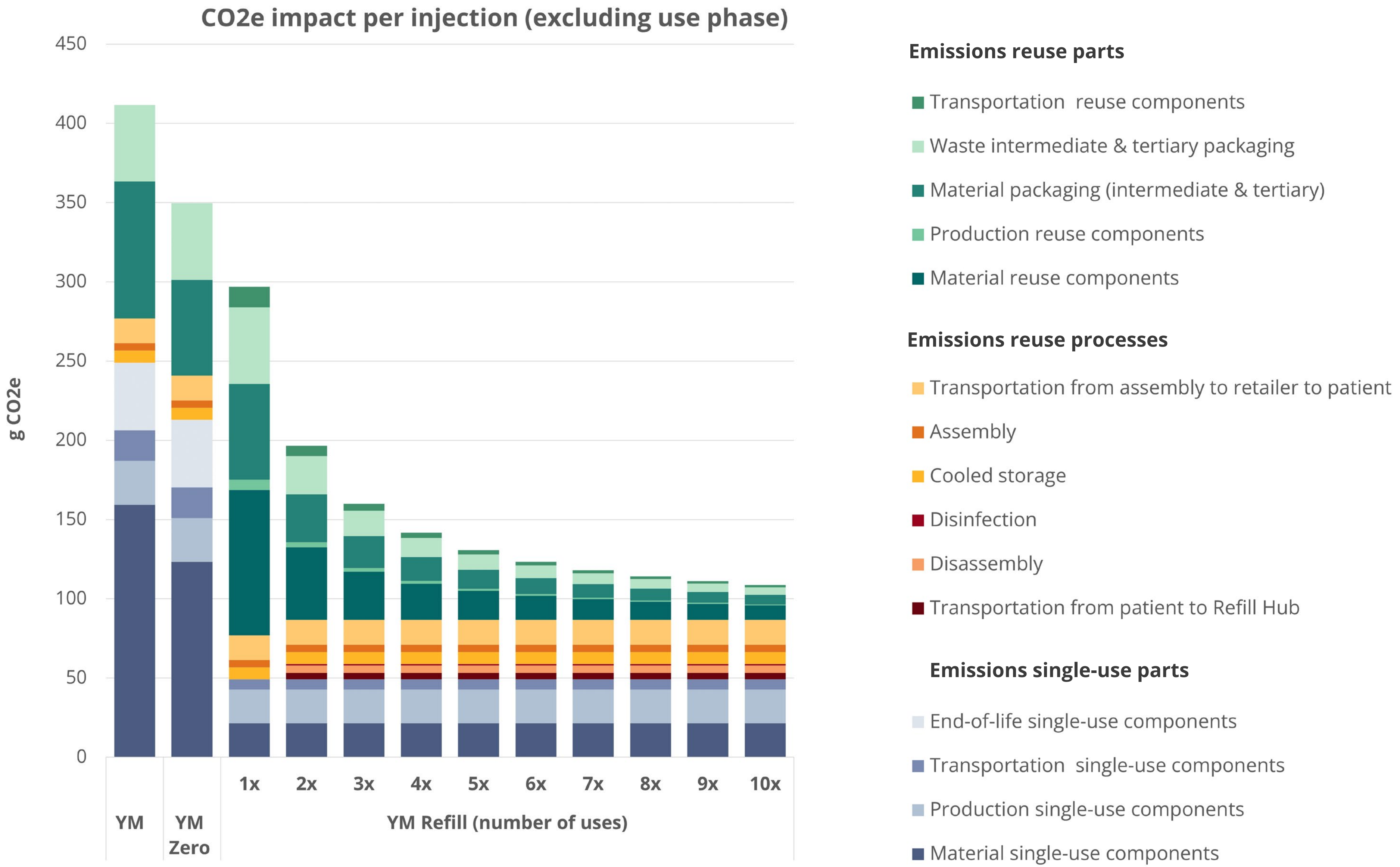

Fig. 201: The environmental impact of the YpsoMate Refill for different reuses counts compared to the single-use YpsoMate 1.0 mL and the YpsoMate Zero.

9.2 Implications

The findings of this thesis could have several implications for the environment, the pharmaceutical industry, patients, and circular academic theories.

9.2.1 Environment

Firstly, the thesis shows that refilling autoinjectors at a Refill Hub can be a promising strategy to reduce the environmental impact of these devices, by lowering CO_2e emissions and waste. The redesigned single-use YpsoMate for third-party refill presents a new direction for the Alliance to Zero to explore further, aligning with their vision to create a pharmaceutical sector with net-zero emissions.

9.2.2 Alliance to Zero

Secondly, the YpsoMate Refill design introduces the companies of the Alliance to Zero to circular design strategies that might be unfamiliar to them. These strategies offer the companies tools to explore how to reduce their environmental impact and could be applied to other products than autoinjectors.

9.2.3 Patients

Thirdly, the YpsoMate Refill concept gives patients the opportunity to safeguard their health through self-injections, while not burdening the environment. The patients' preference for more sustainable healthcare options is not adequately addressed in the current single-use dominated autoinjector market (Fraenkel et al., 2022). The YpsoMate Refill concept can fill this market gap and provide patients with a sustainable, convenient, and safe option for self-injection.

9.2.4 Academia

Lastly, this thesis has academic value since it applies existing circular product design strategies to a case study. This thesis can inspire and guide future designers by providing them with practical examples of how to design circular medical products. It also provides researchers who have written papers on circular strategies (Bocken et al., 2016; Bakker et al., 2014; Flipsen, 2020; De Fazio et al., 2021) with insights into how their theories can be applied in a design process.

In conclusion, the implications of this thesis could extend beyond the design of the YpsoMate Refill, and they have the potential to create value for the environment, pharmaceutical industry, patients, and the academic world.

9.3 Limitations & recommendations for future research

In any research, limitations are inevitable and this thesis is no exception. This chapter discusses the limitations and provides recommendations for future research to address them.

9.3.1 Limited scope: focus on refill by a third party

In response to Alliance to Zero's request, this thesis focuses on the YpsoMate autoinjector's refill process by a third party. The scope does not include self-refilling by patients at home, as Ypsomed is already working on an autoinjector designed for that purpose. The goal of the third-party-refill YpsoMate is to keep autoinjector use as simple as possible for patients. This could be especially beneficial for patients that lack the hand mobility to refill the autoinjector, such as patients with Rheumatoid Arthritis and Multiple Sclerosis (MS).

In future research, it would be interesting to compare third-party refills to self-refill by patients. While self-refilling may increase the risk of misuse and complexity for patients, it eliminates the action of returning the used autoinjector. With self-refill, there is no risk of patients failing to return used autoinjectors, as is the case with third-party refill. Thus, the autoinjector is more likely to be reused, increasing environmental savings. This should be further investigated.

9.3.2 Return rate

High return rates for used autoinjectors are crucial for achieving significant environmental impact, as reusing them reduces the need for new production. While Johnson & Johnson (n.d.) and Novo Nordisk (n.d.) have a return rate of 50%, Health Beacon achieved an impressive return rate of 90% (Briggs, 2023). To further improve return rates and reach the level of success seen by Health Beacon, I recommend conducting additional research on the most effective methods for motivating patients to return their used autoinjectors.

9.3.3 Design for manufacturing

To bring the YpsoMate Refill concept to market, it needs to be designed for manufacturing. Currently, it is a concept design optimized for 3D printing, resulting in for example some components having excess wall thicknesses. Moreover, it should be checked if the geometries are suitable for injection molding. The click sleeve's strength without glass reinforcement also requires further evaluation through a Finite Element Analysis and testing. While out of scope for this thesis, I recommended further iterations and prototyping to get the design production ready.

9.3.4 Injection volume & customization

The YpsoMate autoinjector is available in three different drug volumes: 1.0 mL, 2.25 mL, and 5.5 mL (uncommon). Moreover, currently, pharmaceutical companies ordering the YpsoMate autoinjectors can customize the colors of the cover sleeve and plunger rod, and if deemed necessary, the housing shape (Fig. 202). This provides a challenge for the reuse system since this means that there will be multiple reuse streams of different autoinjector part sizes and colors. As agreed with the Alliance to Zero, the scope of this thesis focused on the YpsoMate 1.0 mL, but the logistics of having multiple reuse streams should be considered in further research.

Fig. 202: A customized autoinjector housing is clicked around a standardized housing.

9.3.5 Refill Hub with dis- & reassembly, quality check & disinfection

Due to the time constraint of the thesis and the focus on the product redesign, I gave less priority to the development of the Refill Hub system. While the thesis suggests a general procedure for disassembly, disinfection, quality check, and reassembly at a Refill Hub, a more in-depth solution for these actions could be explored in future research. Fortunately, graduation student Marianna Escobar is going to look into this.

Dis- & reassembly

Although the YpsoMate is designed for easy dis- and reassembly, machines to facilitate this process need to be developed. The Alliance to Zero should investigate this matter, but it is not expected to be a significant challenge since Ypsomed already possesses large assembly machines and expertise in this area.

Quality check

While the thesis provides recommendations for the quality check process, such as tracing parts and subassemblies, it also emphasizes the need for further research to determine the lifespan of each part. Currently, Ypsomed lacks data on the durability and probability of failure of the autoinjector parts. Fortunately, Marianna Escobar is researching how often parts can be reused.

Disinfection

This thesis employs the Spaulding Scale to classify which parts require high or low-level disinfection. However, this classification should be aligned with existing regulations about hygiene and safety. Additionally, the impact of disinfection on the structural integrity of the parts needs to be researched, as this can affect their lifespan.

Location of the Refill Hub

For the Life Cycle Assessment, this thesis assumed that the Refill Hub would be located in Burfdorf, Switzerland, near the Ypsomed factory. However, further research is necessary to determine the appropriate number of Refill Hubs and their suitable locations to cater to the YpsoMate patient group. It should consider factors such as patient proximity and group size. The goal is to strike a balance between having multiple Refill Hubs on each continent to minimize the transportation distance to patients and receiving enough autoinjectors to benefit from the economy of scale.

9.3.6 Life Cycle Assessment (LCA)

To accurately compare the environmental impact of YpsoMate Refill to YpsoMate and YpsoMate Zero, I combined LCA data from South Pole, Carnstone, and Ypsomed. Although this is not a conventional approach, it provided me with more precise results than estimating the data myself. However, the LCA has limitations despite being evaluated by sustainability expert Nadine Kaufmann. Therefore, future research should validate the LCA values. There are several limitations to the LCA outcome that should be taken into consideration.

First, the location of the Refill Hub impacts the CO2e emissions, and I assumed it would be located in Burfdorf, Switzerland. To improve the accuracy of the LCA calculation, the exact location of the Refill Hub should be determined. Moreover, the LCA assumes that the patient lives in Frankfurt, Germany. Naturally, the impact of transportation increases when the patient lives further away from the Refill Hub.

Secondly, due to a lack of data from suppliers, I estimated the environmental impact of RFID tags by assuming they were equivalent to a passive electronic component. While I calculated their environmental impact to be around 7 grams CO2e due to their low weight of 0.1 grams, concerns were expressed by Alliance to Zero members that the actual impact of RFID tags might be higher. Therefore, this estimate should be confirmed with data from RFID tag suppliers.

Moreover, the calculation of the emissions savings due to recycling should be validated. Also, the LCA does not take into account parts breaking down and needing to be replaced.

Finally, the LCA only considered the environmental impact of YpsoMate 1.0 mL, while the emission savings from reusing YpsoMate 2.25 mL could be even greater due to its larger size.

9.3.7 Regulations

Although the Alliance to Zero did not require regulations and norms to be taken into account for this thesis, it is important to note that this does create limitations. Future research should investigate the potential impact of (upcoming) legislation on the feasibility of third-party autoinjector refill options and how the design can meet the safety requirements.

9.3.8 Patient, doctor & healthcare insurance

Research by Novo Nordisk indicates that trust is a key priority for patients. This thesis proposes interventions to enhance patients' trust in the reused autoinjector, such as a "certified reuse" icon that confirms that each component has undergone rigorous testing before reuse, and a fresh label that makes each autoinjector look as good as new. However, due to time constraints, this thesis did not evaluate the impact of these interventions on patients. Future research could explore how patients perceive reused autoinjectors and identify interventions that enhance their trust.

Furthermore, the success of the YpsoMate Refill depends not only on patients but also on the prescribing doctor and the health insurance provider covering the autoinjector. It is worth investigating whether sustainability is a unique selling point for them to adopt the YpsoMate Refill.

Fig. 203: The "certified reuse" icon aims to enhance patients trust by indicating that the autoinjector's quality is checked.

9.3.9 Conclusion of limitations & recommendations

In conclusion, while this thesis has its limitations, it has successfully achieved the goal of proposing an inspiring design concept for the YpsoMate Refill (Fig. 203). Despite the limitations in the Life Cycle Assessment, it is evident that the YpsoMate Refill has a lower CO2e impact than both the single-use YpsoMate and the YpsoMate Zero. Future research can further strengthen the concept by providing more detailed information on the Refill Hub system, optimizing the design to meet regulatory requirements, validating patient trust in the reused autoinjector, and improving the return rate. By addressing these areas, the YpsoMate Refill has the potential to lead the autoinjector market toward a more sustainable future.

9.4 Personal reflection

During the past half year, I had the opportunity to work on an incredibly interesting project. I would like to share some of my thoughts on the process:

9.4.1 Designing for myself? Or keeping my bias out?

Till now, I have always designed for other people and user groups. This project was the first time that I could design a solution for a problem that has annoyed me for years: the autoinjector waste piling up in my drawer. I try to live sustainably; eat vegetarian, and travel by train, but still this essential need to take care of my health harms the environment.

While being in the target group made the project easier, I also had to ensure that my personal experience didn't stand in the way of designing a good product. To reduce this bias, I spoke with patients to understand how they use their autoinjectors and explore the extreme use cases the autoinjector should endure.

Since the project mainly focused on product design and less on the customer experience (just keep it as simple as possible), I believe my personal experience did not hinder the design process.

9.4.2 Radical vs. Innovative

During the project, I faced the challenge of balancing my wild, out-of-the-box ideas with practical, achievable ones. At first, I had big dreams of designing housing that resembled plant roots, which would save material and still be sturdy. But as I delved deeper into the project, I realized that I needed to rein in my ideas a bit to make them more realistic, yet still push boundaries.

The Alliance to Zero expert and Ypsomed engineers were helpful, giving me detailed feedback on why some of my concepts were impossible. This had as result that halfway through the project, my concepts were so feasible that the changes I made were almost unnoticeable. Fortunately, Wilfred, Sebastian, Sjoerd, and JC challenged me to think bigger and push the boundaries a bit more.

And I'm proud to say that my hard work paid off. I was able to create the YpsoMate Refill concept, which is radical enough to reduce autoinjector CO_2e emissions by at least 60%. Still, it seemed so feasible that most of the Alliance to Zero partners wanted to bring the concept to production after my presentation. This was a real boost, and it showed me that it's possible to make something both radical and achievable.

9.4.3 Complexity at its core

Initially, I thought that a self-injection device would be simple - just a spring and a needle, right? However, as soon as I dismantled the YpsoMate autoinjector, I realized how wrong I was. This project challenged me to understand every detail of the complicated mechanism and redesign it. Fortunately, Sebastian, Ypsomed, Marion, and all the Alliance to Zero partners were extremely helpful in providing me with the insights I needed. I realize how unique this is that a normally guarded pharmaceutical industry openly shared all their knowledge with me.

After understanding the mechanisms and redesigning them, I ran into the next challenge: the Life Cycle Assessment. At the TU Delft, we only get to see a glimpse of Fast Track LCA's. This time, I got a detailed and comprehensive LCA as a twenty-five-page Excel sheet. Even though all this data was a gold mine for my YpsoMate Refill LCA, I still had to dig through it. This was challenging and frustrating at times, but I learned a lot.

Lastly, I had to explain my elaborate project to people who were not as involved in it as I was. After my greenlight meeting, I realized that I needed to work on explaining the detailed design changes I made in a more understandable way. I found myself apologizing for the complexity of the project, which made me realize that I needed to simplify my explanations. So, I created clear renders and visualizations and presented my work to multiple audiences until I felt confident that people understood my complex redesign. Because let's face it, a design is only good if people can understand it!

9.4.4 Sustainability as my driver

Throughout my studies, sustainability has always been a driver for me. It adds an extra layer of complexity that makes projects more challenging but also more rewarding. I look forward to developing my sustainable knowledge further during my professional career. But first, I'm going to enjoy the beautiful nature in Morocco to get a reminder of what we are doing these sustainable projects for.

Thank you for tagging along on my graduation journey!

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