# Pumping up circularity

## Design for the reusability of endovascular inflators

MSc. Thesis Report
**Pablo Yániz González**

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MSc. Graduation Thesis
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# Executive summary


**Towards a Circular Economy for Endovascular Inflators: Introducing POMPA**

Inflators play a crucial role in interventional radiology and cardiology to restore blood flow to obstructed veins. Given the high-risk nature of these procedures, inflators must be sterile. Consequently, they are designed for only single-use. This practice results in the annual incineration of around 100.000 inflators annually in the Netherlands, contributing to approximately 62500 kg of $CO_2$-eq emissions.

Our research, employing literature review, Hot-Spot and Disassembly maps, interviews and observations identified key barriers to reuse of the current inflators. These devices are designed for single-use, applying materials that cannot withstand decontamination and lacking the ability to be disassembled. In addition, parts are fixed together to reduce the chances of failure during the procedure.

This master's thesis proposes a circular model for endovascular inflators, focusing on the reuse of valuable components within healthcare institutions while disposing of the rest. POMPA. POMPA is a circular redesign of the inflators. It aims to make inflators easy and safe to use, disassemble, decontaminate, reassemble and reuse. POMPA adopts materials suitable for decontamination and redesigns the architecture of inflators to achieve complete dis- or reassembly of the product in less than a minute without compromising its functions and performance.

The new system and product-level interventions enable the decontamination and reuse of key components for about 1000 patient procedures. POMPA has a lower environmental and economic impact than current single-use inflators after just nine uses.

In conclusion, POMPA offers a sustainable, convenient, and safe alternative to single-use inflators. This conceptual solution has many features that can be further explored and improved, but for now, it is intended to be a first step towards more circular inflators and to inspire similar innovation change in other medical devices.

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# 01
# INTRODUCTION

This chapter provides an introduction to the project, including the general existing problem it seeks to address and the response to that problem that motivated the project. It also defines the scope of the project, formulates an objective and the research questions guiding the exploration. Finally, it briefly describes the parties involved and the project approach.

## 1.1. Problem statement

According to the Rijksinstituut voor Volksgezondheid en Milieu (RIVM) (Steenmeijer et al., 2022), the Dutch healthcare sector is a major contributor to the national environmental burden. It is responsible for 7% of the national carbon footprint, 8% of water use, 13% of resource use, 7% of land use, and generating 4% of the nation's volume of waste. This contributes substantially to climate change and ecosystem degradation, with direct consequences for public health both now and in the future (Steenmeijer et al., 2022).

To address these challenges, the Dutch government, healthcare institutions, and MedTech industry are working together under the Green Deal 3.0 to promote sustainability in the sector and reduce its negative environmental impact. The Green Deal 3.0 (Rijksoverheid & Ministerie van Volksgezondheid Welzijn en Sport, 2024) outlines five principal targets (Rijksoverheid & Ministerie van Volksgezondheid Welzijn en Sport, 2024):

1. Promoting health to decrease care needs,
2. Increasing the sector's knowledge and awareness of its environmental and climate impacts,
3. Minimising pharmaceutical pollution in ground and surface water,
4. Reducing direct CO2 emissions from buildings, energy, and transport by 55% by 2030 (compared to 2018), with a goal of climate neutrality by 2050,
5. Cutting primary raw material consumption by 50% by 2030 (relative to 2016) and achieving full circularity in care by 2050, guided by R-strategies (see Table 1).
6. **By 2026, the aim is for at least 20% of medical devices to be reusable**, which requires collaboration to develop sustainable alternatives, encourage circular market demand, and implement sustainable procurement practices. Furthermore, by 2030, unsorted residual waste should not exceed 25% of all healthcare waste, as this is typically destined for incineration.

## 1.2. Scope and goal

The fifth target of the Green Deal 3.0 is of particular importance for the interventional radiology (IR) departments, as single-use devices (SUDs) constitute the second largest contributor (accounting for 41%) to the departments' greenhouse gas emissions (Chua et al., 2021). The IR department of the Leiden University Medical Center (LUMC) started this project centred on developing a more circular alternative to current inflators to address this target.

Inflators are SUDs frequently employed in various departments of hospitals, not only IR. Also in interventional cardiology (IC), gastroenterology, and urology, among others. While the core characteristics of inflators in these fields are broadly similar, there are essential differences in the pressure they must withstand and measure, as well as in their fluid capacity. Consequently, this project focuses on inflators used in interventional cardiology and radiology.

The R-strategies relevant to the development of a circular alternative for these inflators are detailed in Table 1, ordered by their potential to reduce environmental impact. Given the essential role of these devices in clinical practice, their established efficacy, and their align-

**Circular economy**



Linear economy

| | R-STRATEGY | DEFINITION |
|---|---|---|
| Smarter product use and manufacture. Narrow the loop. | Refuse (Design) | Make the device redundant by abandoning its function or offering the same function in a radically different, more sustainable device. |
| | Rethink (Design) | Make device use more intensive by considering its usage, functions and systems. |
| | Reduce (Design) | Increase efficiency in device manufacturing or use by consuming fewer natural resources and materials. |
| Expand lifespan of products and its parts. Slow the loop. | **Reuse (Technical)** | Reprocess and reintroduction of a discarded device for another patient, provided it remains in good condition and functional. This process may also involve maintenance and repair to prolong the device's lifespan. |
| | Remanufacture (Technical) | Restore a discarded device and bring it up to date or use parts of a discarded product in a new product with the same function. The high-quality standards for medical devices. |
| | Repurpose (Technical) | Use discarded device or its parts in a new device with a different function. |
| Useful application of materials. Close the loop. | Recycle (Technical) | Process materials to obtain the same (high grade) or lower (low grade) quality. |
| | Renew (Bio-cycle) | Dissolve or break down materials into nature. |
| | Recover energy (Waste) | Incineration of materials with energy recovery. |

Table 1. *Hierarchical list and definition of the R-strategies, following Hoveling et al.'s (2024) adaptation to healthcare-specific terminology of the original definitions of R-strategies by Potting et al. (2017). Hoveling et al. (2024) consider repair and maintenance as an intrinsic part of reuse, merge remanufacture and refurbishment because of the high-quality standards in the sector, and introduce 'renew' as an alternative to the technical cycles.*

ment with the preferences of healthcare professionals, the project has a primary focus on the technical strategies (reuse, remanufacture, repurpose, and recycle), with an initial focus on reuse.

To ensure the effective implementation of these strategies within the healthcare setting, it is crucial to propose them together with a redesign of the product's use and post-use system. The high safety standards and time-critical nature of healthcare environments often prevent the successful implementation of changes in practice (Steenmeijer et al., 2022).

Therefore, the initial goal of the project is as follows:

**Design a proof-of-principle prototype to validate a new circular product journey for inflators used in Interventional Radiology and Cardiology procedures.**

## 1.3. Research questions

The following research questions guided the analysis part of the project to reach the initial project goal. They are arranged in four topics, that correspond to the chapters where these questions are answered:

### Chapter 2. Context and usage

| | |
|---|---|
| RQ2.1 | What are inflators? |
| RQ2.2 | What procedures are they used for? |
| RQ2.3 | How many inflators are currently used per year? |
| RQ2.4 | What is the current market landscape for inflators and what sustainable alternatives or trends exist? |
| RQ2.5 | How are inflators used during procedures? |
| RQ2.6 | What are inflators' main functions and features? |
| RQ2.7 | How is the end of life of current inflators? |

### Chapter 3. Decontamination and reprocessing

| | |
|---|---|
| RQ3.1 | What level of decontamination is required for each component of inflators to maintain reliability for the following usage? |
| RQ3.2 | What does current legislation indicate about the reprocessing of inflators? |
| RQ3.3 | How does the decontamination process, from one patient to the next, look like? |
| RQ3.4 | What cleaning and sterilisation methods are available? |
| RQ3.5 | Which of those methods could be suitable for inflators? How would the materials and mechanisms of current inflators perform during decontamination? |

### Chapter 4. Assessment of current inflators

| | |
|---|---|
| RQ4.1 | How are inflators structured? What are the main subassemblies? |
| RQ4.2 | What is the disassembly and reassembly experience of current inflators? |
| RQ4.3 | How durable and reliable is an inflator and what are its critical components if reused? |
| RQ4.4 | What are inflators' most valuable components? |

### Chapter 5. Circular journeys

| | |
|---|---|
| RQ3.1 | What are the best reprocessing possibilities for inflators? |
| RQ3.2 | What circular strategies are best for those reprocessing possibilities? |
| RQ3.3 | How would the circular reprocessing journeys for inflators look like? |

## 1.4. Involved parties

**TU Delft**

Este proyecto es el trabajo final del TU Delft master's program Integrated Product Design. Jan-Carel Diehl (chair) y Bas Flipsen (mentor) han guiado, ofrecido apoyo y su design expertise constantemente. Numerosos otros empleados de la universidad también han contribuido con su expertise y su tiempo, como profesorado y trabajadores del PMB. Además, TU Delft ha facilitado los recursos, por ejemplo los softwares o las 3d printing facilities y materiales.

**LUMC**

Como iniciadores del proyecto y clientes, desde el departamento de Interventional Radiology han compartido conocimientos sobre el contexto y el uso, han guiado el proyecto, han facilitado contactos y han ayudado a la investigación. Además, otros departamentos como el Central Sterilisation Department o el Design and Prototyping hub han colaborado compartiendo su expertise en distintas áreas centrales del proyecto.

**npk design**

npk design was involved as a third-party mentor. They offered guidance in the design process and evaluation with their practical knowledge of sustainability, medical product design, and engineering.

## 1.5. Approach

This project has used the double diamond method to structure the research and design process. The journey can be divided into a first phase of discovery and exploration, in which literature research, semi-structured interviews, observational studies, hotspot and disassembly mapping among other methods were applied. The next phase, 'define', drew out the insights and structured the project requirements. Again, an explorative development phase, in which concepts were developed and prototyped, and finally a critical and evaluative phase, which delivered a final solution.

# 02
# CONTEXT

In this chapter, the product around which the thesis revolves is introduced, along with its features and an analysis of its context, distribution, usage, and disposal.

## 2.1. What are inflators?

*RQ2.2. What procedures are they used for?*

An inflator is a device or system of instruments with a medical purpose designed for the controlled absorption and injection of fluids at high pressures with both rapid and precise fluid movements, while simultaneously monitoring pressure levels. The terms 'inflator', 'inflation device', and 'indeflator' are often used interchangeably in the field.

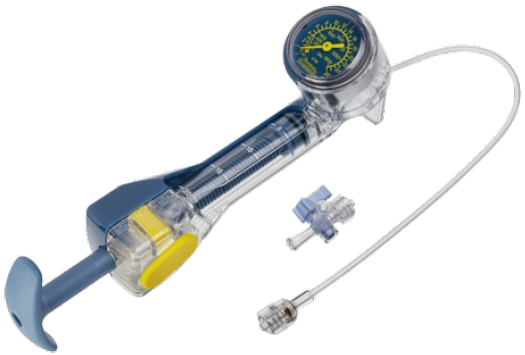


Figure 1. *Example of a currently used inflator* (Boston Scientific EMEA, 2024).

Figure 2. *Inflator being used during a balloon angioplasty*. Adapted from Manos Brilakis (2020).

**Takeaways 2.1**

- Inflators operate with fluids.
- Inflators allow two types of plunger movements: fast and precise.
- Inflators are used at high pressures and measure the pressure in the system.

## 2.2. Medical fields where inflators are used

*RQ2.2. What procedures are they used for?*

*This section aims to introduce the recent origin of the use of inflators, the main endovascular procedures for which they are used, and the other departments in which they are employed.*

The development of inflators gained significant momentum in the 1970s and 1980s during the early years of interventional radiology. This discipline was born in January 1964, when Charles Dotter performed the first percutaneous transfemoral catheter dilatation, later known as percutaneous transluminal angioplasty (PTA), to treat a stenosis in the superficial femoral artery of an 82-year-old woman (see Figure 3). Dotter's technique at the time improved the blood flow using a guide wire to advance series of coaxial Teflon catheters with gradually increasing diameters across the stenosis. The success of this technique led to its application in other areas of the body. Substantial innovations came with the introduction of balloon catheters in 1973, followed by Andreas Grüntzig's first successful coronary balloon dilation, the first ever percutaneous transluminal coronary angioplasty (PTCA) (Rösch et al., 2003). Together with the balloon-tipped catheters came the first inflators.

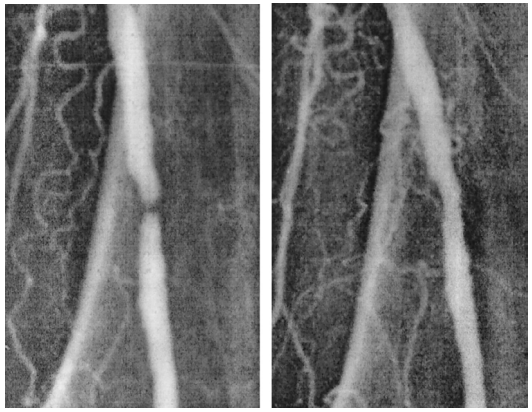


Figure 3. *The after (left) and before (right) of the first PTA, performed on January 16, 1964 by Charles Dotter* (Rösch et al., 2003).

These pioneering procedures were developed to address stenosis, which refers to the abnormal narrowing of blood vessels or other tubular structures in the body. Chhabra et al. (2025) and the NHLBI and NIH (2024) explain how, in the context of arteries, stenosis is often caused by atherosclerosis, a disease in which plaque made up of cholesterol, fat, blood cells, and other elements, builds up against the arterial walls, narrowing them down and reducing the amount of blood that gets to the upcoming tissues.

Atherosclerosis can be treated with PTA, the procedure developed by Dotter. Commonly known as balloon angioplasty or simply angioplasty, it is a minimally invasive medical procedure that employs a balloon-tipped catheter to compress the plaque and dilate the stenosis. The intervention completed by Grüntzig, PTCA, is a specific angioplasty procedure for the arteries of the heart usually performed by interventional cardiologists, and in case it is performed with a stent, as represented from Figure 4 to Figure 7, it is named Percutaneous Coronary Intervention (PCI).

Over time, inflators have evolved in design and functionality, expanding their applications across various medical departments. Today, they are widely used not only in interventional cardiology (IC), interventional radiology (IR), and peripheral vascular interventions, but also in gastroenterology, urology, otolaryngology (ENT), nephrology, and vertebral procedures, among others (Atrion Medical, 2024).

## 2.3. Figures

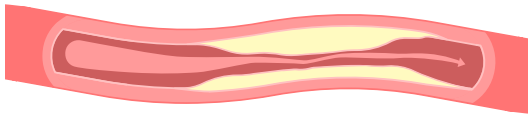


Figure 4. *Plaque build-up in the artery causes the arteries to narrow and block blood flow.* Adapted from Boston Scientific Corporation (2025).

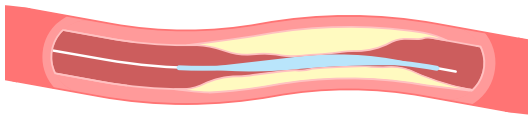


Figure 5. *An inflatable balloon-tipped catheter with a stent is introduced through the skin in extremities until the narrowed area.* Adapted from Boston Scientific Corporation (2025).

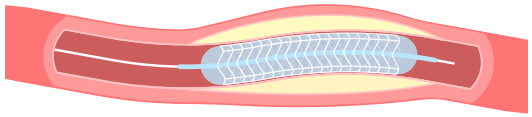


Figure 6. *The balloon is inflated pressing the plaque against the arterial wall and dilatating the artery.* Adapted from Boston Scientific Corporation (2025).

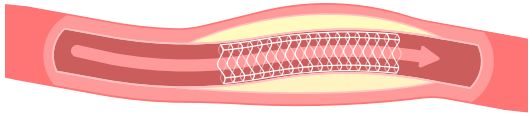


Figure 7. *The balloon is removed, normalising blood flow and leaving the stent to keep the artery open.* Adapted from Boston Scientific Corporation (2025).

*RQ2.3. How many inflators are currently used per year?*
*RQ2.4.What is the current market landscape for inflation devices?*

*Section 2.3 depicts the growth of the inflators market. It also provides actual and estimated quantities of inflators used in the LUMC and in the Netherlands per year. These data will be of interest for further environmental analysis.*

According to the World Health Organization [WHO] (2024), the proportion of global population over 60 years will almost duplicate, increasing from 12% in 2015 to 22% in 2050. This ageing demographic trend is predicted to lead to an expansion in the demand for inflators, as the incidence of diseases necessitating their use, including cardiovascular, urological, and pulmonary conditions, is also expected to rise. This anticipated growth is further supported by analyses from MarketsandMarkets (2019) and SNS insider (2025), which highlight the increasing adoption of minimally invasive procedures and the projected rise in the number of hospitals and clinics offering these procedures in emerging markets. They valued the inflators market at USD 600 million in 2024, with projections indicating growth to almost USD 1 billion by 2032.

Despite the projected growth in the inflator market, precise figures on the annual usage of inflators remain unclear. Available data indicate that 37,987 inflators were used in the Netherlands for interventional cardiology in 2022 alone (Hart & Vaatcijfers & Nederlandse Hart Registratie, 2023). At the LUMC, annual usage approximates 1,975 devices, distributed across the departments of interventional cardiology (±1,100), interventional radiology (±275), and gastroenterology (±600).

| | Netherlands | LUMC |
|---|---|---|
| Interv. Cardiology | 37987 | 1100 |
| Interv. Radiology | 9497* | 275 |
| Gastroenterology | 20720* | 600 |
| Total | 68204* | 1975 |
| **Total including other departments** | **100000*** | 2900* |

Table 2. *Figures for inflators used in the Netherlands and within the LUMC. Values that are estimations are marked with the symbol *. "Other departments" include peripheral vascular interventions, urology, ENT, nephrology, and vertebral procedures.*

An initial estimate of national consumption, derived from extrapolating LUMC usage data to the Dutch healthcare system as a whole, is presented in Table 2. This suggests a total annual usage of approximately 70,000 single-use inflators. If other departments in which inflators are used (such as peripheral interventions, urology, ENT, nephrology, and vertebral procedures) are considered, it is reasonable to estimate that at least 100,000 inflators are used each year in the Netherlands.

**Takeaways 2.2, 2.3**

- Inflators are used in multiple medical departments, including Interventional Radiology and Cardiology.
- The inflators market is growing.
- It could be estimated that 100000 single-use inflators are used per year in the Netherlands.

Figure 8. *Primary and secondary packagin and Instructions for Use included per Boston Scientific Ecore 40 device.*

## 2.4. Usage procedure

*RQ2.5. How are inflators used during procedures?*

*The goal of this section is to describe how inflators are used during procedures, specifically during IR and IC interventions, and to provide a list of steps for preparing, using, and disposing of an inflator.*

The use of an inflator occurs within a broader procedural context, which includes tasks like preparing and decontaminating the Operating Room (OR) for surgery (Figure 9 shows how the OR looks during an angioplasty procedure), positioning the patient, administering anaesthesia, puncturing the chosen vessel with a needle (in the cases of IR or IC), inserting a guidewire, placing a sheath, injecting contrast dye, advancing the guidewire until the obstruction, inserting a catheter, etc. However, this section focuses specifically on the actions that directly involve the inflator and define its usage. The steps for preparing, using and disposing of the device are depicted in Figure 10 and listed below.

The inflator cannot be used straight from the packaging (see Figure 8 for the amount of

packaging used for Boston Scientific Encore 40); it requires preparation before use (steps 1 to 7, as listed below and represented in Figure X) in accordance with the balloon dilatation catheter manufacturer's instructions.

For preparation, a stopcock valve is usually included in the device's packaging to purge the air out of the system and ensure that only a liquid sterile mixture of saline and contrast agent inflate the balloon, but it is not always used as the Instructions for Use (IFU) sometimes even include it only as a recommendation (see Atrion Medical (2020) or Merit Medical Systems (2021) for example), or do not even mention its usage (for instance Merit Medical Systems (2020a)). In hospital observations, skilled nurses completed the first six preparation steps in about 50 seconds (without using the stopcock valve).

Once preparation is finished and the balloon is placed in the area of the patient where the stricture is, it can be inflated and deflated with the liquid (steps 8 and 9) following the catheter manufacturer's directions for maximum inflation pressure – the balloon could burst inside the body if that pressure is exceeded. Depending on the procedure it is used for, the in-


Figure 9. *Operating room during a balloon pulmonary angioplasty procedure* (Nebraska Medicine Nebraska Medical Center, 2023).

flator could be used by the doctor or physician (for example during IR and IC interventions), or the nurse (e.g. gastroenterology).

It is usual to inflate the balloon gradually, avoiding reaching the maximum pressure specified for the balloon at the first inflation so as not to overload the walls of the blood vessel or organ to be dilated. No blood can flow through those vessels while dilated, so Taylor & Stout (2002) indicate that each blockage due to the inflation cannot last longer than 20 to 60 seconds to ensure enough oxygen supply to the rest of the tissues. For that reason, O'Donnell (1995) and Taylor & Stout (2002) highlight some additional desirable features for inflators: monitoring the inflation time between inflations, and recording and showing historical information regarding the duration and intensity of past inflations and deflations.

It is also common for the intervention to require several balloons to be inflated, from smaller to larger, to resolve the stricture progressively. In this case, multiple balloon-tipped catheters with different balloon sizes may be used, which requires repeating steps 7 (attaching the catheter to the inflator system) to 10 (detaching and disposing of it) several times before the procedure is completed and the inflator is finally disposed of (step 11). If a new catheter is connected and no more saline-contrast solution is left in the syringe barrel, steps 2 to 10 need to be repeated to inflate the new balloon. Consequently, the duration of the procedure while the inflator is involved can last from a few minutes to almost half an hour.

As an overall feedback from conversations with doctors, physicians, and nurses from various departments, they like how current inflations are used, their working principle, how they feel and their simplicity. Each one of them might have their preferences regarding specific features like the ergonomics of the knob. But overall, the consensus is that they would not want to compromise the current features for sustainability.

### Steps list

Next are the steps for preparing and using an inflator that features an actuator-controlled lock mechanism. This comprehensive sequence, synthesised from the IFUs of the devices examined in Appendix A, is structured into three phases: preparation for use in surgery, use in surgery, and disposal. In the preparation phase described here, the stopcock is used to purge the air out of the system, and the catheter is connected to the stopcock. However, as highlighted earlier, the IFUs differ on whether to use the stopcock during the preparation phase. Some IFUs describe alternative preparation routes, either omitting the stopcock or altering the order of steps, while still ensuring an airless and tightly connected pathway between the liquid in the syringe barrel and the balloon-tipped catheter.

#### Preparation for use in surgery

1. Extract the device from its packaging(s).
2. Prepare a solution of contrast medium and normal saline. The inflator package can be used as a sterile container to pour the solution into. Check balloon catheter instructions for recommendations, if any, for specific mixture requirements.
3. Release the lock mechanism with the actuator and manually advance the piston via the knob forward to the 0 (zero) mL position.
4. Submerge the male luer lock adapter into

## PREPARATION FOR USE IN SURGERY

Time ≈ 1 minute

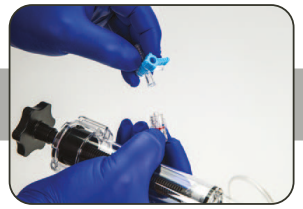
**01** Upack from the sterile package

**02** Prepare contrast and saline solution

**03** Advance the piston to the 0 mL position

**04** Submerge the tube in solution, aspirate

**05** Attach the stopcock valve to the luer lock



**06** Purge the air in the system

**07** Attach the catheter to the stopcock valve

## USE IN SURGERY

**08** Rapid inflation: operate the actuator, push the piston knob

Precise inflation: release the actuator, turn the knob clockwise

**09** Rapid deflation: operate the actuator pull back the piston knob

## DISPOSAL

**10** Detach the catheter and throw it away

**11** Throw away the inflation device

Figure 10. *Schematic representation of the usage procedure. When* n *catheters are used, repeat highlighted steps in orange* n *times*. Figures adapted from Micro-Tech Endoscopy (n.d.).

the prepared contrast solution. With the lock mechanism released, aspirate an appropriate volume of contrast solution within the syringe. Release the actuator.

5. Install the stopcock onto the luer lock. Adjust the valve to establish an open fluid path to the syringe.
6. While holding the device upright, purge the air from the syringe and connecting tube by advancing the piston. If necessary, tap the syringe lightly to remove all entrapped air within the system.
7. Create a fluid-to-fluid tight connection between the male and female luer lock connectors of the device or stopcock and catheter respectively.

**Use in surgery**

8. To rapidly inflate the balloon, operate and hold the actuator while slowly pushing the piston knob forward. Next, to get to the desired pressure with precision, release the actuator and gradually turn the piston knob clockwise to inflate and (if necessary) counterclockwise to deflate.
9. To rapidly deflate the balloon, operate and hold the actuator and then pull back on the piston knob. The lock mechanism can hold the piston in negative pressure if the actuator is released.

**Disposal**

10. Once the balloon has been successfully used and deflated, the catheter can be withdrawn from the patient and thrown away. Disconnect it from the inflator.
11. Once the procedure is completed, throw away the device.

**Takeaways 2.4**

- Inflators during IR and IC interventions are used by the doctor or physician. In other procedures, it is the nurses who operate them.
- Inflators require approximately one minute of preparation before they can be used to inflate/deflate the balloon.
- Inflators pump a liquid mixture into the balloon. There can be no air inside the closed catheter-inflator system.
- The balloon may rupture if the indicated pressure is exceeded (this does not usually happen).
- Desirable features inflators could have: monitoring the inflation time between inflations, and the duration and intensity of past inflations.
- The mechanism of the inflator locks the plunger in place and holds the system pressure. A precise movement is achieved by turning the plunger knob. By operating the actuator, a fast movement can be achieved.
- Practitioners like current inflators' experience and they would not compromise it for sustainability.

## 2.5. Functions and features

*RQ2.6. What are inflators' main functions and features?*

*This section includes an analysis of inflators to find their common functions and features. To do this, a simple deconstruction of inflators allows for a component and function-based perspective analysis.*

### Inflators' parts

The project focuses on inflators used in IR and IC. They generally cost around 30€ and include:

- a syringe barrel (1),
- a threaded plunger (2),
- an o-ring or similar (3),
- a lock mechanism module (4),
- a pressure gauge (5),
- a high-pressure tube (6) with a luer-lock connector,
- and a stopcock valve (7) that can be connected to the luer-lock adapter.

The design and connections of these components might vary between models, sometimes resulting in additional parts. This deconstruction of the inflators is depicted in Figure 11, which shows the various components on a real inflator, and in Figure 12 schematically, where the pressure gauge is also divided into a pressure sensing unit (5.1) and a display unit (5.2) following Taylor and Stout's (2002) analysis of the physical separation of the gauge.


Figure 11. *Typical parts of an inflator.* Adapted from Micro-Tech Endoscopy (2025).

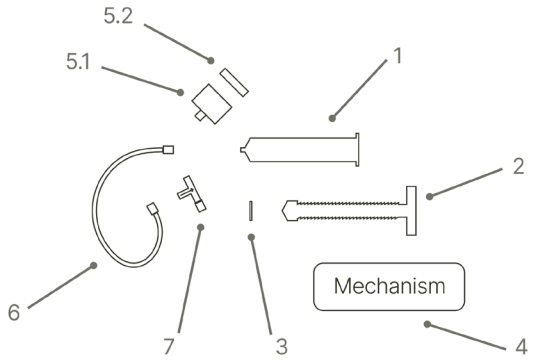



Figure 12. *Schematical exploded representation of the typical parts of an inflator.*

### Takeaways 2.5

- Endovascular inflators have at least seven components, which may be more depending on how the connections and the lock mechanism are solved.

### Pressure

Appendix A reviews some of the most significant inflators on the market. Those devices specified for angioplasty procedures (used in IR and IC) are highlighted in yellow. They can register at least 30 atm. Some of Merit's devices can even measure 35 and 40 atm, and Atrion's QL series offers a model with a maximum pressure of 40 atm and another configuration of 55 atm. Inflators designed to measure pressures of 40 or higher atmospheres are specifically engineered for use in particular-

ly complex cases that are out of the scope of this project, such as those involving severely calcified, long, stenotic, or resistant fibrotic lesions (Boston Scientific Corporation, 2020b). According to a cardiologist at LUMC (P1) (personal communication, November 6, 2024), the maximum pressure necessary to inflate the balloons used during angioplasty procedures is 28 atm. For this reason, their department's inflator tender requirements specify that these items must reach at least 28 atm (Programma van Eisen INDEFLATORS, 2024).

Pressures of 28 atm or higher are achieved when the piston or plunger is moved inwards in the barrel, applying force to the liquid. The saline-contrast solution is confined within the fixed volume of the inflator, stopcock, and balloon-tipped catheter. Liquids are highly resistant to compression, generally considered 'incompressible', meaning they maintain their volume under pressure. This property allows the force applied to the liquid to be transmitted equally throughout the system, following Pascal's principle.

As pressure increases, the balloon deforms (inflates), pressing against the plaque and dilating the artery. The balloon's expansion is filled by the liquid, which is transferred from the barrel as the plunger advances. This process could continue until either the rated burst pressure of the balloon is reached or a component fails, causing a leak.

To maintain system integrity, the barrel walls, plunger, gauge, tubing, stopcock, and catheter must be engineered to withstand internal pressures of more than 28 atm. They are designed with a safety factor to provide a margin for unexpected pressure spikes during the procedure, to account for potential alterations in manufacturing and material properties, and to ensure that they remain safe even if a safety measure (e.g. a visual alert for maximum pressure in the manometer) fails. Chadwick et al. (2014) highlight that inflators should withstand pressures that exceed about 50 atm. Critical points of potential failure are the connections between components, which must remain liquid-tight to prevent leaks or bursts. For instance, the device connects to the catheter via standardised luer-lock connections to transfer the liquid solution. O-rings or similar seals on the plunger tip and on the manometer's connection play a crucial role in ensuring these unions remain sealed under high pressure.

**Takeaways 2.5**

- Endovascular inflators register pressures of at least 28 atm and withstand at least 50 atm as a safety factor.
- Connections between components and o-rings or similar are vital for liquid-tight connections.

### Pressure gauges

The main function of pressure gauges in the inflator's system is to monitor the pressure within the balloon. This is done to make sure that enough pressure is being applied to inflate the balloon, compress the plaque that creates the narrowing, and not exceed the balloon pressure limits specified by the manufacturer (O'Donnell, 1995).

Inflators most commonly use analogue bourdon tube pressure gauges (see Figure 13). Bourdon tube medical pressure gauges with a CE certification can cost between USD 1,5 and 4. For those prices, the case can be ABS, the lens PC, the dial plate aluminium, and the bourdon tube and connector brass (Focus Technology, 2025).

Bourdon tube pressure gauges have a C-shaped tube inside. This tube connects to the exterior. The inflation liquid (represented in blue in Figure 14) can enter the pressure gauge up to the end of the tube. When pressure increases in the system, the forces deform the tube into a more open C-shape. This movement of the tube is mechanically transmitted to the gauge dial (Instrupaedia, 2018).

Other pressure gauge types include diaphragm, capsule, and bellows pressure gauges. Diaphragm pressure gauges have an elastic diaphragm that ensures the separation between the interior of the gauge and the process medium and transfers the pressure to the dial. As shown in Figure 15, the liquid is only in contact with the exterior wall of the diaphragm. Capsule pressure gauges use more than one diaphragm. Bellows pressure gauges use a bellow-like system inside a housing. The liquid enters the housing and compresses the bellows (Instrupaedia, 2018).

Pressure gauges can also have a sensor that converts the measured pressure into an electrical signal. Almost every sensor measures pressure with a diaphragm system (Instrupaedia, 2018). A digital pressure gauge includes such a sensor, plus an electronic module that reads the signal generated, transforms it, and displays it on a digital screen. The survey of interventional radiologists conducted by Geertse et al. (2023) revealed that 34 out of the 42 participants (81%) preferred an analogue pressure reading. Whilst their familiarity with other types of reading and the basis for their preference are unclear, it is worth noting that none favoured a digital dial for the device, and that three participants (7%) preferred visualising the system pressure on the room's dis-


Figure 13. *CE-certified analogue bourdon tube pressure gauge for medical use* (Focus Technology, 2025).

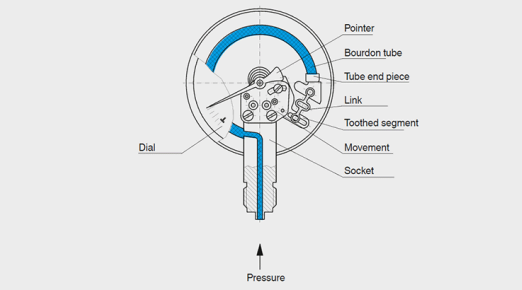



Figure 14. *Interiors of a bourdon tube pressure gauge, in which a blue liquid has reached up to the closed end of the tube* (WIKA, 2025).

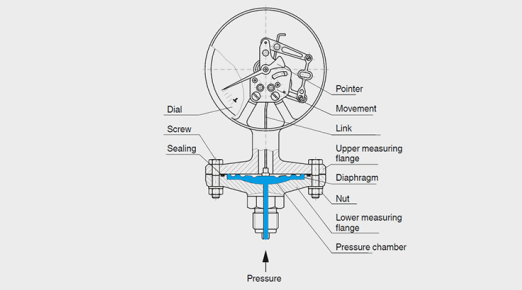



Figure 15. *Interiors of a diaphragm pressure gauge. The liquid does not go inside the gauge* (WIKA, 2025).

play screen, alongside the images of the balloon inside the patient's body.

A pressure transmitter, instead of displaying the readings directly, transmits them to a display unit that is physically separated from the sensing unit. Taylor and Stout (2002) highlight that it is awkward for the physicians operating the syringe to constantly alternate their attention from the syringe to the display unit. Also, cables used to transmit the pressure are bulky and easily lead to a cluttered OR. Therefore, a physical separation between the sensing and display units is not preferred.

Regarding what is necessary for inflators, the sensor should be accurate, and the display should be easy to read (P1, personal communication, November 6, 2024). Most pressure gauges have a luminescent dial to ensure proper readability in normal and low-light conditions to facilitate this experience.

### Takeaways 2.5

- Inflators usually use bourdon tube pressure gauges. The liquid medium goes inside these gauges.
- Bourdon tube pressure gauges cost USD 1,5 – 4.
- Other types of measuring pressure systems include using a diaphragm, in which the liquid does not go inside, a capsule, and bellows.
- Pressure transmitters and digital pressure gauges use a sensor and either transmit the measured pressure or directly display it. Analogue pressure gauges are preferred over digi-tal or transmitters.
- Accuracy and readability are highly valued. A luminiscent dial helps with readability.

**Barrel capacity, transparency, and dispensing**

The inflators in Appendix A highlighted in yellow for angioplasty procedures have a fluid capacity of 20 to 30 mL (see Figure 16 for an example), with one exception being an Atrion QL configuration that only displays markings on the barrel from 0 to 10 mL. Some of these devices' barrels have additional capacity beyond the final millilitre marking. A barrel with a capacity bigger than the volume required to inflate a single balloon is essential for the following reasons:

- Air can also be absorbed while filling the inflator with the saline and contrast solution. However, it should not be used to inflate the balloon. Therefore, after purging the air from the system there will always be some of the barrel volume left unused. Consequently, the capacity of the syringe must account for a part of its volume not housing the required liquid for the balloon. This is further detailed in the procedural overview in section 2.4.
- Furthermore, multiple balloon-tipped catheters might be employed within the

same surgical procedure. If sufficient contrast and saline solution remains in the barrel, only steps 7 to 10 (detaching the previous catheter, attaching a new one, and using the inflator) of the usage procedure (section 2.4) will need to be performed. Otherwise, steps 2 to 10 will have to be operated and the procedure will take more time. Thus, it is essential to have a barrel with substantial capacity and, at least, a transparent part showing if there is enough liquid to inflate the next balloon or if the liquid should be refilled before use with the new catheter.

Figure 16. *Detail of the Boston Scientific Ecore 40 inflator. The barrel has consistent markings up to 20 mL of capacity, and then less detailed indications up to 25 mL. This gives enough extra capacity after the 20 mL required for angioplasty. Beyond that 25 mL mark there is still some barrel volume left.*

Geertse et al. (2023) conducted a survey among interventional radiologists. 37 of those 42 respondents (88%) considered it important for the syringe barrel to be transparent to see if there is air or blood (it can be a sign of balloon rupture) in it. The rest of the reasons were related to checking the mixing of the contrast and saline solution if done directly in the syringe (10%), and verifying that the balloon is emptying during deflation by seeing the liquid fill the barrel (10%).

A cardiologist at LUMC (P1) (personal communication, November 6, 2024) also highlighted that the syringe barrel should be transparent to ensure that no air bubbles could be accidentally injected into the balloon. Additionally, he considered that the mL markings should be clearly visible for accurate measurement. However, of the 42 respondents to the Geertse et al. (2023) survey, almost 60% think the volume does not need to be readable. In fact, only 15% look at the volume of the barrel while inflating and deflating the balloon, and they do so while checking the pressure. Most of them (73%) only look at the pressure, and 12% look at the pressure plus the x-ray image.

For fluid dispensing reference, Merit Medical System's Monarch® (2020c) and Blue Diamond™ (2021) indicate a dispensing ratio of around 0,45 mL (± 0,07 mL) of fluid for each 360º clockwise turn of the syringe plunger handle, while their DiamondTOUCH™ (2020b) dispenses 0,57ml (± 0.10mL) per full rotation.

For consistent fluid dispensing, syringes commonly have coatings of materials like silicone oil on the inner surface of the barrel and the plunger tip. This creates a hydrophobic layer that reduces contact and potential interaction between the syringe and the fluid while improving the sealing and the smoothness of the movement between the plunger and the barrel (Reuter & Petersen, 2012). Alternative solutions to achieve similar low-friction movement without leakage and to reduce reliance on coatings include using polytetrafluoroethylene (PTFE, commonly known as Teflon) for the plunger tip or machining the barrel lumen and plunger to high precision.

There is no documented information on coatings used in the products analysed in Appendix A apart from the Medallion syringe used

in the Viper dilation syringe-gauge assembly (Merit Medical OEM, 2024). However, unless an inflator utilises PTFE or is manufactured with high-precision machining, it is generally assumed to have coatings, as elastomers naturally exhibit a slight stickiness (Reuter & Petersen, 2012).

### Takeaways 2.5

- Endovascular inflators have a marked fluid capacity of at least 20 mL, with the total fluid capacity being a few millilitres more.
- The barrel of inflators should be transparent enough to ensure that there is no blood or air inside the system.
- Markings indicating fluid capacity are not used by most practitioners. Therefore, the vol-ume does not need to be readable.
- Inflators dispense at around 0,45 mL to 0,57ml (± 0.10mL) per full rotation of the plunger handle.
- The barrel of inflators is assumed to have a silicone coating.

**Ergonomics. Barrel and knob.**

Some devices have a syringe-like shape, that of an elongated tube or barrel with a plunger, and two main ways of holding them have been observed. One hand is always grabbing the plunger knob, while the other could be either at the top of the device grabbing the manometer (see Figure 17), or ready to operate the actuator by the end of the syringe body (see Figure 18). Other products like Everest by Medtronic and the Mastro series by Demax have a shape that indicates to the personnel how to grab it (see Figures 19 and 20).

Figure 17. *B. Braun's Winged Locking Inflation Device being hold by the manometer during a PCI procedure.*

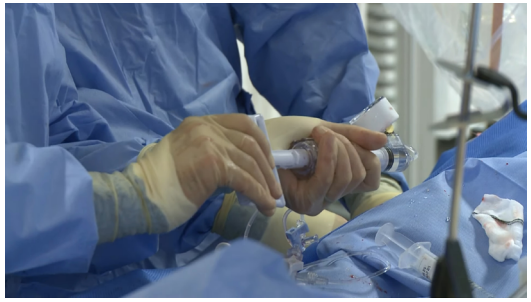


Figure 18. *Merit Medical System's inflation device being hold by the end of the syringe body during a PCI procedure.*

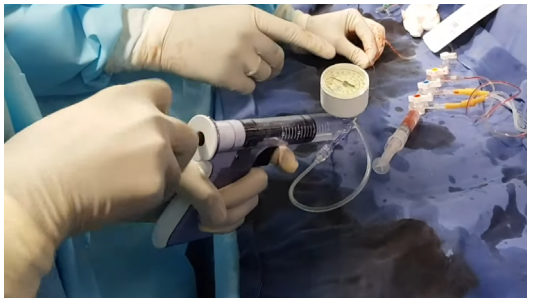


Figure 19. *Medtronic's Everest inflation device being grabbed as a gun.*

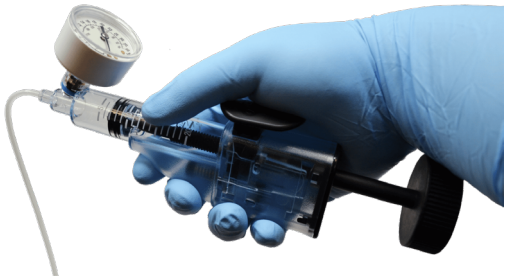


Figure 20. *Demax's Mastro is designed so that the shape of the hand fits the shape of the product, making it intuitive how to hold and operate the mechanism* (Demax, 2020).

There are different design possibilities for the plunger knob. Some devices, like Boston Scientific's Encore 26 and Merit's inflators, feature a flat handle, whereas others, such as Atrion's QL series (Figure 21) and Medtronic's Everest (Figure 22), have a round or semi-round knob.

Round knobs allow for more gradual turns and therefore pressure control, reducing the need for large wrist rotations, such as 180° turns, which may potentially cause wrist discomfort or strain. Round knobs are also a preference for (P1) (personal communication, November 6, 2024) and a requirement in the Programma van Eisen INDEFLATORS (2024). Moreover, some knobs such as the one of the Everest inflator have a ridged design, which enhances the grip. Recent innovations by Merit Medical Systems (2024a) include a smaller handle that is almost 20% easier to turn.

### Takeaways 2.5

- There is no defined way of holding inflators, and practitioners tend to hold them in the way that is most comfortable for them.
- Round knobs help with controlling the pressure and are preferred. A ridged design or simi-lar that enhances the grip is also important.

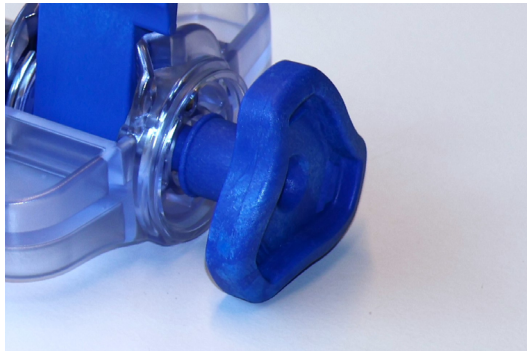


Figure 21. *Atrion's QL series semi-round handle.*

Figure 22. *Medtronic's Everest round handle.*

**Lock mechanism**

The interaction between the lock mechanism and the threaded plunger enables both fast and coarse or slow and precise fluid absorption and injection. The locking mechanism typically has two positions, controlled by an actuator such as a push button, lever, or trigger. In its idle position, the threaded plunger engages with a threaded nut in the lock mechanism, allowing precise rotational movements for controlled advancement and retraction. When the lock is released, the plunger can move longitudinally for quicker adjustments.

As a force is applied to advance the plunger in the barrel, it acts a force upon the liquid, building pressure in the system. This pressure also acts on the plunger face, generating an axial force that tries to push the plunger backwards. The friction between the threads of the plunger and the lock mechanism prevents the plunger from moving, though minimal pressure loss (fractions of an atmosphere) may occur at very high pressures. The threaded engagement and material strength of the lock mechanism must be strong enough to prevent slipping or failure under this force.

Automated lock mechanisms were explored in the 90s (O'Donnell, 1995). The proposed solutions were not perfect. An automated mechanism such as those proposed might make sense if it could be reused, but it is complicated by the need for it to be sterile. It would be cumbersome and involve a lot of waste, whether it is located inside or outside the sterile area of the OR.

The cardiologist P1 (personal communication, November 6, 2024) indicates that the locking mechanism should be intuitive, convenient, and user-friendly. He also highlights that it should not be too hard to press or operate the actuator, as it is slightly more difficult to press it with gloves, and the displacement of the actuator is preferred to be long rather that a short motion. Recent innovations by Merit Medical Systems (2024a) include reducing the force needed to activate the pressure relief mechanism of the BIG60 ALPHA™ Inflation Device by almost half when pressurised, and by almost two thirds at no pressure.

**Takeaways 2.5**

- Lock mechanisms have a half nut that engages with the threaded plunger in its idle position. This interaction allows precise movements and holds the pressures. The pressing or sliding action on the actuator disengages the threads, allowing quick movements of the plunger.
- The plunger should not be able to leave the barrel. Otherwise, at high pressures, it will exit at high speed.
- The actuator should be intuitive, convinient, and user friendly.

### High-pressure tubing

According to Merit Medical Systems (2024b), high-pressure tubing must be both clear and elastic. A transparent tube is crucial to detect and prevent air bubbles from being injected into the patient's body, and elasticity allows to reduce strain on the conduit. Radiology departments typically prefer flexible polyurethane hoses, while cardiology departments opt for more rigid polyvinyl chloride (PVC) alternatives. Merit Medical Systems (2024b) supplies ethylene oxide (EtO) -sterilised high-pressure tubes with multiple customization options, including material selection (flexible braided polyurethane, co-extruded nylon/polyurethane, or rigid PVC – see Figure 23), lengths spanning from 25 cm to 183 cm, and burst pressures typically at 83 bar (81.9 atm). These tubes are also available with inner diameters of 1.8 mm or 2.2 mm and are equipped with luer connectors that can also withstand these high pressures.

**Takeaways 2.5**

- High-pressure tubing must be clear and elastic.

## 2.6. Supply and disposability

*RQ2.7. How is the end of life of current inflators?*

*Here it is discussed how inflators are delivered and should be treated until the end of their life according to the indications of the manufacturers.*

Inflators (excluding handles like the Alliance II Handle) are typically distributed in sterile conditions, whether for use in IR, IC, or procedures in other departments involving contact only with intermediate-risk areas of the body. All reviewed inflators are sterilised using EtO, as detailed in Appendix A.

Once adequately decontaminated, the device must be handled using aseptic techniques to prevent redecontamination before it reaches the OR (Rutala et al., 2024). Neither the package nor the product can get damaged. The manufacturers indicate not to use and immediately return the product if the contents or the sterile package are damaged or if the package is open (Boston Scientific Corporation, 2023), as it cannot be validated anymore that the product is free of microorganisms and it could lead to the transmission of infections. When the package is opened during surgery, contamination of inflators may occur in multiple ways. Their surfaces are exposed to cross-contamination. For instance, this could happen when they are operated with contaminated gloves or when fluids are splashed onto their surfaces. The inflation fluid could also be considered a source of contamination (Taylor & Nelson, 2000), as the contrast could make the components fail (Medtronic, 2016). Therefore, as a general norm, once the sterile barrier is broken, before or during surgery, the product is considered contaminated.

After usage, inflators could either be disposed of as biohazardous waste or reprocessed for additional use with a different patient. All inflators analysed are for single use only and are indicated not to be reused, reprocessed, or re-sterilised, as that might generate a risk of cross-infection, compromise the structural integrity of the device, and potentially cause it to fail (Boston Scientific Corporation, 2023; Medtronic, 2016; Atrion Medical, 2020). These brands assume no responsibility for their products if their indications on reuse, reprocessing, and re-sterilising are not followed – they would no longer be liable for them according to the Regulation (EU) 2017/745 (2017) and to the Volksgezondheid Welzijn en Sport (2025). Some brands indicate proper disposal according to accepted medical practices and applicable laws and regulations (Atrion Medical, 2020; Boston Scientific Corporation, 2023). Some others even recommend destroying the devices (Merit Medical Systems, 2023; Vedkang, 2018). The LUMC takes this biohazardous waste that cannot be reused or recycled to a modern waste plant in Amsterdam where it is incinerated to produce heat and energy (LUMC, n.d.).

**Takeaways 2.6**

- Current inflators are EtO sterilised, even if sterility is not required.
- Inflators get contaminated during usage. Therefore, they are considered biohazardous waste and cannot be reused, remanufactured, repurposed or recycled if they are not reprocessed before.
- Current inflators are single use and disposed of. After usage at the LUMC they are incinerated.

# 03

# DECONTAMINATION AND REPROCESSING

This chapter explores the existing methods of decontamination and the steps a medical device goes through for safe reprocessing.

## 3.1. Decontamination levels

*RQ3.1. What level of decontamination is required for each component of inflators to maintain reliability for the following usage?*

*While this section does not directly respond to research question 3.1, it presents terms like "contamination" and "decontamination" and explains the Spaulding classification, which are necessary to respond to RQ3.1.*

Inanimate objects and living matter are contaminated when they have actual or potential contact with pathogenic microorganisms (Occupational Safety and Health Administration [OSHA], 1991). Ensuring that medical devices do not transmit infectious pathogens and therefore spread infections is fundamental (Rutala et al., 2024). Huys (2011) refers to the "decontamination" of a medical device as reducing the contamination to an "acceptable level" to prevent infection. The WHO and PAHO (2016) and the OSHA (1991) define this acceptability as when the devices or surfaces are safe to handle, whether for further processing, immediate use, or disposal.

There are three levels for reducing contamination or bioburden with physical or chemical

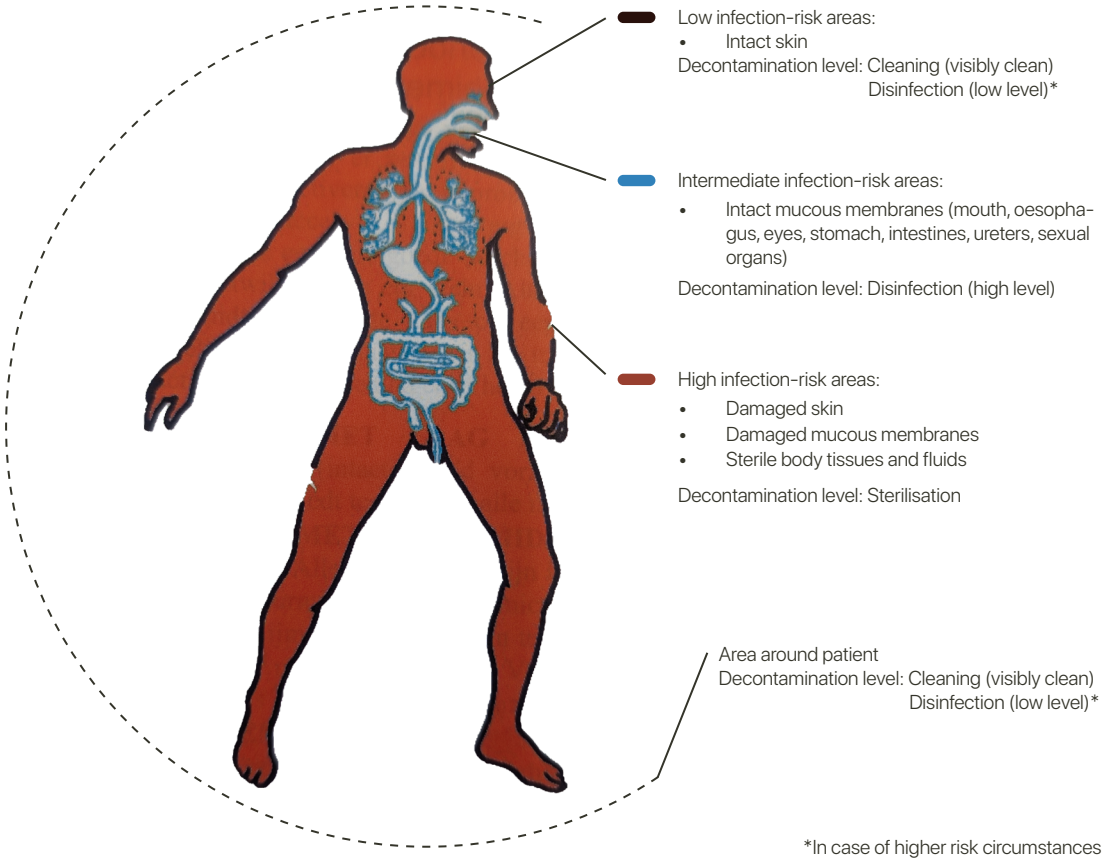



Figure 23. *Recommended levels of decontamination for medical instruments in contact with areas around and of the body with a low (non-critical), intermediate (semi-critical), and high (critical) risk of infection.* Adapted from Huys (2011).

tools: cleaning, disinfection, and sterilisation. The acceptable bioburden level and the method applied in each situation are chosen depending on the patient's risk of developing an infection. The main factor for the choice is the area of application around, on, or in the body according to the Spaulding classification (see Figure 23). In case of specific circumstances with increased risk, the expected bioburden and the patient's general health status should also be taken into consideration to reduce even more the biological load to a level for safe use (Huys, 2011).

As shown in Figure 23, disinfection of medical instruments is adequate to ensure that no pathogens will risk the patient's health when the procedure involves only contact with intact mucous membranes, which entails an intermediate risk of infection. In case devices may interact with high-risk areas – damaged skin or mucous membranes, or sterile body areas such as blood – sterilisation becomes necessary (WHO & PAHO, 2016; Rutala et al., 2024; Huys, 2011).

## 3.2. Required decontamination levels for inflators

*RQ3.1. What level of decontamination is required for each component of inflators to maintain reliability for the following usage?*

*This section explains how the two different use cases of inflators directly define their decontamination levels.*

Inflation devices are usually distributed in sterile conditions. Depending on the use case, they can be considered intermediate-risk (semi-critical) or high-risk (critical) equipment and therefore require high-level disinfection (in case no specific circumstances increase the risk of infection) or sterilisation respectively.

Interventional radiology or cardiology procedures with inflators require a completely sterile field, as they involve working with high infection-risk parts of the body – punctured skin, blood, vessels... As a consequence, inflation devices for this usage must be packed and sterilised to create a sterile barrier that maintains sterility until opened in the OR (Huys, 2011).

A second use case can be exemplified with the utilisation of an inflator during a stricture

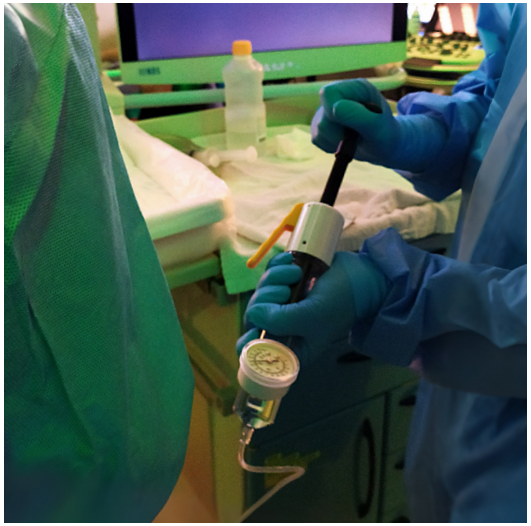


Figure 24. *Vedkrang inflation device used during an endoscopic retrograde cholangiopancreatography (ERCP) and stricture dilatation procedure at the LUMC.*

dilatation procedure for gastroenterology (see Figure 24) or urology, where there is no risk of contact with damaged sterile body fluids, organs, or tissues, and there is no penetration with non-intact skin or mucous membranes. Existing gateways in the body, such as the mouth, are used to gain access to the stricture. The inflator could then be cleaned and disin-

Figure 25. *Alliance™ II System. Syringe/gauge assembly in the blue tray where it is supplied, and handle with which it is used* (BostonScientificEndo, 2015).

fected for later reuse (WHO & PAHO, 2016; Rutala et al., 2024; Huys, 2011). However, some parts of the device come into contact with the saline and contrast solution, a sterile liquid that usually does not touch any part of the patient – only if the maximum inflation pressure indicated for the balloon was surpassed and the balloon bursted inside the patient. These parts are the interior of the barrel of the syringe, the plunger or piston tip, the manometer or pressure transducer, and the high-pressure tube including the luer-lock connectors. They could be sterilised before usage for extra safety reasons (U. van der Velden, personal communication, November 12, 2024; Taylor & Nelson, 2000). The Alliance™ II System seen in Figure 25 serves as an illustrative example of a device for this use case with some parts sterilised and others disinfected. It features a single-use syringe/gauge assembly supplied EtO sterilised in a sealed tray, and a reusable handle supplied non-sterile. The handle can be wiped with cleaned water and disinfecting solution such as 2% glutaraldehyde, as it does not contact the sterile solution (Boston Scientific Corporation, 2020a). The inflators analysed in Appendix A that are not for high infection-risk areas of the body and are still delivered sterile could be disinfected only.

**Takeaways 3.1, 3.2**

- Inflators for IR and IC use need to be sterilised as they involved working with high infection-risk areas of the body.
- Inflators for the rest of the departments, even though also sterilised, do not need such level of decontamination.

## 3.3. Reprocessing of single-use devices

*RQ3.2. What does current legislation indicate about the reprocessing of inflators?*

*Here, the term "reprocessing" is introduced and current legislation is explored to see the possi-bilities of reprocessing inflators.*

The Regulation (EU) 2017/745 (2017), the WHO and PAHO (2016), and Rutala et al. (2024) refer to reprocessing as the series of steps a contaminated and/or used medical devices must go through for safe additional use on a patient. These may include cleaning, inspecting and testing, restoring the device's technical and functional safety, disinfecting, packaging, labelling, sterilisation, and storing.

The Medical Device Regulation (MDR), Regulation (EU) 2017/745 (2017), leaves the decision on reprocessing and further use of single-use devices (SUD) on the national laws. In the Netherlands, it is permitted under the conditions set out in the MDR (Volksgezondheid Welzijn en Sport, 2025). These conditions include reprocessing and using SUD within healthcare institutions and by an

external reprocessor when requested by the institution (the SUD must be returned to that same healthcare institution after reprocessing) as far as safety and performance are not compromised and are equivalent to that of the original device, and specific requirements are met regarding risk management, procedures validation, product release and testing, quality management system, reporting incidents and traceability (Regulation (EU) 2017/745, 2017; Volksgezondheid Welzijn en Sport, 2025).

The Volksgezondheid Welzijn en Sport (2022) prohibits reprocessing in some cases, essentially eliminating the risk of infection through prions with Creutzfeldt-Jakob disease. None of these cases are relevant to inflators, except that devices cannot be reprocessed if they have already been reprocessed by another entity or through another process.

Therefore, reprocessing current inflators released to the market in agreement with the MDR (or with Directive 93/42/EEC if released before 26 May 2021) is allowed in the Netherlands if the process is demonstrated by scientific evidence to be safe (Regulation (EU) 2017/745, 2017). As indicated in the IFU of inflators, manufacturers do not consider reprocessing to be safe for their single-use inflators. However, devices determined to be single-use by their manufacturers can also be reprocessed if sufficient scientific evidence of safety is brought by a third party. This is sometimes a matter of legal responsibilities and R-strategies (remanufacture) are applied to single-use devices without the need of a complete redesign of the product and introduction to the market a new device.

**Takeaways 3.3**

- Reprocessing of single-use devices is allowed in the Netherlands, but in the case of inflators, manufacturers do not consider this to be safe, and without other scientific evidence re-processing is not applicable.

## 3.4. Reprocessing of reusable devices

*RQ3.2. What does current legislation indicate about the reprocessing of inflators?*

*Following on from the research in the previous section, the possibilities for reprocessing reusable inflators according to the legislation are explored here.*

Reprocessing reusable medical devices is allowed according to both European and Dutch legislation. As per the Ministerie van Volksgezondheid Welzijn en Sport (2020), applicable Dutch legislation no longer regulates the reprocessing in the Netherlands as many standards and guidelines have been developed in recent decades and implemented in practice. In Dutch hospitals there must be an expert in the field responsible for the reprocessing of reusable invasive medical devices, who follows the current standards and guidelines, and who is responsible for the presence of procedures for cleaning, disinfecting and/or sterilising medical devices under the specifications provided by the manufacturer applicable to the medical device.

The Regulation (EU) 2017/745 (2017) indicates what to include in the IFU of medical

products to be supplied by the manufacturer. Regarding reusable devices, appropriate and validated methods for reprocessing should be specified, as well as how to identify that the instrument should not be reused anymore, for instance degradation or maximum number of reuses allowed. The MDR also requires reusable devices to have a Unique Device Identifier (UDI) carrier on the device itself, permanent and readable throughout the lifetime of the device, to have the necessary data about the product, manufacturer, etc. incorporated on it. It could be a RFID (Radio-Frequency Identification) tag or a QR code laser engraved, for example.

As shown in Appendix A, no reusable inflators have been found in the market. The closest thing is the Alliance Handle (a complicated external mechanism used to push and pull the plunger of a syringe), but it is not applicable to the procedures performed in interventional radiology and cardiology. A reusable inflator for IC and IR could be developed and launched to the market, integrating features like the UDI carrier, so that it could be reprocessed.

**Takeaways 3.4**

- Reprocessing of reusable inflators would follow Dutch legislation, if there were any.
- A reusable inflator would have to carry a permanent and readable Unique Device Identifier.

## 3.5. Reprocessing process

*RQ3.3. How does the decontamination process, from one patient to the next, look like?*
*RQ3.4.What cleaning and sterilisation methods are available?*

*This section goes into detail on what decontamination options are available and what steps need to be taken up to sterilising a medical device. Lessons are drawn from each phase from a product perspective.*

### Cleaning

The WHO and PAHO (2016) and Rutala et al. (2024) defend that the first and most important step for reprocessing medical instruments is to clean them. If this step was overlooked, the previously mentioned materials remaining on device surfaces might impede the action of disinfection and/or sterilisation agents, thus affecting their efficacy. This is because microorganisms are protected in the dirt and some chemical products are ineffective in contact with organic matter or other chemicals. Decontamination should start as soon as possible, or dried gross soil will be more difficult to remove. They even recommend a pre-clean-

ing step at the point of use after the operation, where reusable devices should be separated from the rest of the disposables, get the gross soil removed from their surfaces and be kept moist until they arrive at the decontamination department.

These authors define cleaning as removing visible soil, organic, and inorganic material from objects and surfaces using water together with chemical detergent or enzymatic agents, either manually or mechanically. The cleaning agents must be checked for dilution ratio, water temperature, contact time, and compatibility with the materials to be cleaned. Enzymatic cleaners help remove organic debris from the surfaces, while chemical agents, also called detergents, dissolve fat and protein materials. The latter are neutral or slightly alkaline (pH 8 – 10,8) and can be corrosive. The process they describe is illustrated in the subsection "Decontamination steps" in figures 26 to 32 and consists of the following steps:

1. Pre-cleaning (Figure 26).
   As described previously, decontamination should start at the point of use by soaking, spraying, or wiping the gross soil off the surfaces of the instruments, sometimes with the aid of the appropriate cleaning agents.

2. Device preparation (Figure 27).
   Once the soiled devices arrive at the cleaning area or room, they should be prepared so that cleaning agents, disinfectants, and sterilants can reach every surface of the products. Assemblies, screws, hinges, sharp bends, serrations, and blind, long and narrow lumens are some design factors that might restrict the flow and reduce the efficacy of the agents. Therefore, hinged or jointed items must be opened before mechanical procedures, and complete disassembly of the products which consist of multiple pieces is a must. All these pieces should be kept close together throughout the process to allow future reassembly. Any tools used for the disassembly should also be properly decontaminated together with the device. Hinged instruments are defined by Lipscomb et al. (2006) as those which have a box joint. Examples of reusable hemostatic forceps and needle holder with box lock hinges can be seen in Figures 33 and 34.

3. Manual cleaning (Figures 28 and 29).
   This includes using water and cleaning products while submerging, brushing, rinsing, flushing, and drying the medical articles. Some items also need lubrication before sterilisation. Products with long, narrow lumens are difficult to clean, which challenges the reprocessing. They might require appropriate brushes (soft, long and wide enough) and a forced flow of the detergent agent through the tube. This is why the WHO and PAHO (2016) strongly recommend not decontaminating problematic items such as catheters and tubing and considering them single-use. The tools used during the cleaning process should also be disinfected at the end of the day.

4. Mechanical cleaning (Figures 30 and 31).
   Cleaning should be enough to prepare the devices for disinfection or sterilisation. However, its effectiveness can currently only be validated in real-time by visually inspecting the surfaces for soil remains. Although this affects both manual and mechanical cleaning, mechanical cleaning presents certain advantages in this

**Decontamination steps for medical devices requiring terminal sterilisation, focusing on the cleaning stage**

**01** PRE-CLEANING

Figure 26. *Pre-cleaning at the point of use* (Steelco S.p.A., 2024).

**02** DEVICE PREPARATION

Figure 27. *Preparing the devices at the cleaning room: opening of hinged products and disassembling devices of multiple parts* (Medewerker Centrale Sterilisatie, n.d.).

**03** MANUAL CLEANING.
rinsing, brushing, and drying

Figure 28. *Rinsing with a pressurised shower* (Gerlitz, 2015).

Figure 29. *Brushing to remove the soil.*

**04** (OPTIONAL) MECHANICAL CLEANING.
ultrasonic cleaning, washing disinfecting...

Figure 30. *Mechanically cleaning with an ultrasonic cleaner.*

Figure 31. *Mechanically cleaning with a washing disinfector. The machines are accessible from the cleaning and the packaging rooms* (GPR, 2024).

**05** POST-CLEANING. INSPECTION

Figure 32. *Visually validating the cleaning and disinfection process and checking their functionality* (Falk et al., 2023).

**06** PACKAGING
**07** STERILISATION

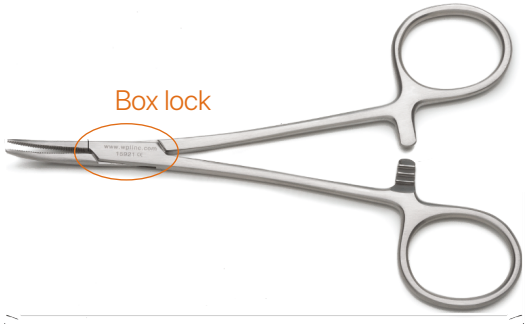



Figure 33. *Box lock in hemostatic forceps*. Edited from World Precision Instruments, 2025).

Figure 34. *Box lock detail in Mayo-Hegar carb bite needle holder* (Ebay, n.d.).

regard. It is therefore highly recommended to combine manual with mechanical cleaning, with manual cleaning as an essential preliminary step to mechanical cleaning.

These advantages include that the mechanical equipment is usually automated, which may increase productivity and effectiveness (certain machines can more easily access difficult-to-clean areas), minimise staff exposure to risks, and deliver products following a parametric release process, providing controlled and consistently reliable results.

Mechanical cleaning can be performed with ultrasonic cleaners, washer-disinfectors, cart washers, and washer sterilisers.

- The ultrasonic cleaner uses cavitation and implosion (plus detergent) to remove the soil from the products, even from difficult parts like serrations, hinges or lumens. For that to happen, the water has to be between 27ºC and 43ºC, and the devices must be pre-cleaned, open, submerged, and filled with water. They will have to get rinsed and dried afterwards.
- The washer-disinfectors, as the name suggests, clean and disinfect the products. They do so by pre-rinsing (no manual pre-rinse is needed), washing with cleaning agents, lubricating, disinfecting by flushing with hot (around 90ºC) water, and drying the articles, which must have their hinges fully open, must be disassembled, and cannot be stacked on top of each other (hence assemblies and hinged or jointed devices take up more space).
- Cart washers share functional similarities with washer-disinfectors, but they cannot wash the items with enzymatic agents nor lubricate them. They are typically employed to clean and disinfect specific products, like containers for surgical instruments.
- Washer sterilisers are modified steam sterilisers that combine washing, disinfecting, steam sterilising, and drying.

5. Post-cleaning. Inspection and function testing (Figure 32).
   On-the-spot validation of the effectiveness of the cleaning (and of the disinfec-

tion, if a washer disinfector or cart washer is used) is essential to ensure that no materials remain on the product affecting the efficacy of disinfection or sterilisation, depending on the decontamination level required. As stated before, this is done by visually inspecting the items. If there was any visible dirt, the article should return to the cleaning area to start the process again. Critical areas, like joints or serrations, should be thoroughly inspected.

In addition, the devices must be verified to function correctly at some point in the reprocessing journey before they reach the operating theatre. After cleaning, products will be disinfected or packaged and sterilised. Then they should be handled properly to prevent redecontamination before their reuse. Therefore, this function testing task is performed now that they have been thoroughly cleaned of all soil. For instance, it includes checking the smooth movement of hinges, the tightness of screws, and the sharpness of scissors. Furthermore, multi-part instruments should be assembled to verify that all components are present and functioning correctly. Any articles that are damaged, incomplete, or malfunctioning should be reported.

### Takeaways 3.5

- Every surface of the devices must be possible to decontaminate.
- The materials of a reprocessable device must be resistant to submersion in water.
- The materials must be compatible with the reprocessing agents. Therefore, they should be resistant to slightly alkaline detergents.
- Product shapes should facilitate mechanical cleaning, as parametric release is preferred.
- Products should not have shadowed areas.
- A complete disassembly of multi-part devices prior to cleaning is needed. Post-cleaning reassembly is necessary to verify the correct functioning of devices. Tools used for the disassembly also need to be decontaminated. Therefore, the design of multi-part products should be avoided. Or at least, the dis- and re-assembly steps and number of parts re-duced, as more steps take more paid time of workers, and more parts take more space in the disassembly chain and more possibilities of components getting lost. Also, manual dis- and re-assembly should be prioritised. Or at least, common tools should be possible to use for the complete (dis)assembly.
- Blind, long and narrow lumens must be avoided.
- Screws, hinges, sharp bends, and serrations should be avoided as an extra safety factor, even though ultrasounds can ensure proper decontamination. Opening hinges and in-specting these features takes extra time for workers.
- Necessary lubrication should be applied before sterilisation.

### Disinfection

The WHO and PAHO (2016) and Rutala et al. (2024) define disinfection as the thermal or chemical destruction of many or all microorganisms, excluding bacterial spores, on inanimate objects. While disinfection is not a required step for reprocessing devices intended for terminal sterilisation (such as those used in IR and IC procedures), it is sometimes incorporated into the cleaning process, particularly in mechanical systems like washer-disinfectors. Proper cleaning ensures that sterilisation can effectively eliminate all microorganisms, including spores, without the need for an intermediate disinfection step.

Inflators are also used in intermediate-risk procedures that do not require sterilisation. In such cases, certain components may only require high-level disinfection instead of sterilisation. It can be achieved (after pre-cleaning and cleaning) through thermal disinfection using hot water (e.g., in washer-disinfectors) or chemical disinfection, which involves immersing the item completely in a germicidal solution for a specified time. Afterwards, the device must be rinsed with sterile water, thoroughly dried to prevent microbial growth, and stored for future use, adhering to the expiration date determined by the disinfectant used. It is essential to follow the manufacturer's instructions when selecting a chemical disinfectant. Some disinfectants, for instance, may damage or corrode product surfaces due to incompatibility with certain materials (WHO & PAHO, 2016; Rutala et al., 2024).

#### Takeaways 3.5

- If the scope were to design for reuse of inflators used in intermediate risk operations, they should be adapted for thermal or chemical disinfection rather than sterilisation.

### Sterilisation

Sterility refers to the state of being free from viable microorganisms and sterilisation to the process of rendering a product sterile (European Committee for Standarization [CEN], 2024; WHO & PAHO, 2016; Rutala et al., 2024). The absolute sterility of an item that has undergone sterilization cannot be assured. Instead, the sterility of processed items must be expressed as the probability of a microorganism surviving on or within the item. For an article to be considered sterile, that probability has to be equal to or less than 1×10−6, which is assured by validating and monitoring the sterilisation process (CEN, 2024; Rutala et al., 2024).

After the inspection and function testing phase of the cleaning, instruments should be prepared for sterilisation by being arranged in trays or baskets to facilitate their use in the OR, e.g. products to be used in the same procedure should be arranged in the same tray. Some considerations have to be taken into account during tray assemblies. For instance, hinged articles should be opened. Moreover, multi-part instruments had been assembled during the inspection, and they should be dis-

assembled for sterilisation unless the manufacturer's guidelines specify the opposite (WHO & PAHO, 2016; Rutala et al., 2024).

Single items or trays should then be packed before sterilisation. Medical devices undergo sterilisation in their final packaging, a process known as terminal sterilisation (CEN, 2018), to ensure they remain uncontaminated until their next use in the operating room. This packaging forms a sterile barrier system that needs to be both compatible with the sterilisation method and sufficiently durable to withstand damage while effectively blocking microorganisms and moisture. There are multiple packaging types and materials, so the appropriate one for the items, sterilisation method, and manufacturer's instructions should be chosen. Packages should have on the outside a chemical indicator to monitor the process and an identification (WHO & PAHO, 2016; Rutala et al., 2024). According to the Volksgezondheid Welzijn en Sport (2022), this identification should indicate the components packed, mention that they are sterile, include an identifying code that relates them to the sterilisation batch, and add the time and month until which they will be suitable for usage, a statement remarking that they can only be used after sterilisation, and the sterilisation method.

There are multiple validated methods available for sterilisation. Rutala & Weber (2023) classify them into physical agents that use heat (e.g. steam, dry heat) or irradiation (gamma rays, e-beam, x-rays), and chemical agents that use poisoning via gas (e.g. EtO, nitrogen dioxide, chlorine dioxide), vapours (hydrogen peroxide, peracetic acid), or liquids (such as peracetic acid and glutaraldehyde) to eliminate microorganisms. Chemical agents sterilisation should be limited to those products for which no alternative method is available (Huys, 2011).

The WHO and PAHO (2016), Rutala et al. (2024), and Huys (2011) highlight steam, specifically pre-vacuum steam, as the preferred method of sterilisation for medical devices with a critical risk of infection that are resistant to heat, steam, pressure, and moisture. As per the WHO and PAHO (2016) and Rutala et al. (2024), most reusable medical devices are made of heat-stable materials.

For heat-sensitive instruments (e.g. those made of plastics) EtO has been used since the 1950s. The Gamma Industry Processing Alliance and the International Irradiation Association (2017) indicate that EtO is the most common sterilisation method of single-use medical devices. It accounts for approximately 50% of medical device sterilisation, the remaining being 40,5% gamma radiation sterilisation, 4,5% e-beam, and the last 5% a variety of other methods. However, (Huys, 2011) dictates that EtO should only be used when there are no other alternatives. He highlights that it is not used anymore in Dutch hospitals and there are only a few companies in the Netherlands that offer EtO sterilisation.

Some medical devices cannot withstand heat or are not suitable for sterilisation by irradiation. For this group of materials, chemical methods can be used. Poisoning (intoxication) of a living organism can be caused by both gases and liquids. Gas sterilisation should be limited to those products for which no alternative method is available. Because it is a highly toxic substance, EtO is a hazard to the environment and its use should therefore be kept to an absolute minimum. Because of all the complications, it can be said that EO is a sterilisation method that should only be used when there

are no other alternatives. In Dutch hospitals, this method is not used anymore. There are a few specialised companies in the Netherlands that offer EtO sterilisation. In general, these are large installations for bulk sterilisation (Huys, 2011). The United States Environmental Protection Agency recently applied measures to reduce EtO concentrations for sterilisation and therefore its emissions by 80%, so the members of the Association of Medical Device Reprocessors (AMDR) are considering Vaporised Hydrogen Peroxide (VHP) as an alternative to EtO for some products (AMDR, 2024). The advantages and disadvantages of this alternative, as well as other methods of sterilisation, are outlined in the following overview. These are based on Rutala & Weber (2023), Huys (2011), WHO and PAHO (2016), and Rutala et al. (2024).

| | Steam | Irradiation (Gamma, electron beam) |
|---|---|---|
| ADVANTAGES | • **Preferred method of sterilisation.**<br>• **Nontoxic to patient, staff, environment.**<br>• **Inexpensive.**<br>• Cycle easy to control and monitor.<br>• Least affected by organic/inorganic soils among sterilization processes listed.<br>• Rapidly microbicidal. Rapid cycle time, 3 to 18 minutes depending on the sterilisation temperature (121° - 134°C). **Readily available.**<br>• Penetrates packaging, device lumens.<br>• Microbicidal efficacy data.<br>• Long history of safe and effective use. | • **Fastest sterilisation methods.**<br>• Compatible with most medical materials, especially e-beam.<br>• **Products can be processed in final packaging**, as radiation penetrates it.<br>• Require atmospheric pressure and higher ambient temperature.<br>• Microbicidal efficacy data.<br>• Long history of safe and effective use.<br>• No residue on sterilized products.<br>• No regulated emissions. |
| DISADVANTAGES | • **Unsuitable for heat-sensitive instruments (also harmful for them)**, anhydrous materials, and for wood.<br>• Microsurgical instruments damaged by repeated exposure.<br>• May leave instruments wet, causing them to rust.<br>• Potential for burns.<br>• Chrome stainless steel surgical blades and other related devices have developed pitting and dulling of the cutting edges after multiple sterilization cycles. **Steam corrodes sharp instruments.**<br>• Safe use of steam sterilizers requires a sound knowledge of their requirements. Not all settings have this expertise. | • **Ionizing radiation affects all polymer's physical and chemical properties.**<br>• **Individual plastics must be assessed.**<br>• Common plastics such as polyvinyl chloride, acetals, Teflon (polytetrafluoroethylene) and polypropylene must be avoided.<br>• Adverse effects on glues and adhesives.<br>• **Gamma radiation**<br>**Requires a nuclear reactor, which is expensive. Involves industrial bulk production** of medical devices, such as syringes.<br>Source replenishment (Cobalt-60) and requalification required.<br>Licensing, installation, security and radioactive waste disposal are challenging.<br>Cannot be used for devices with batteries.<br>• **E-beam has limited penetrating capability** and is not suitable for products with challenging product geometries and regions of high-density materials. It also requires shielding. |

| | Ethylene Oxide (EtO) | Hydrogen Peroxide (Gas Plasma, Vaporized, or with ozone) | Vaporised peracetic acid |
|---|---|---|---|
| ADVANTAGES | • **Penetrates device lumens, medical packaging.**<br>• **Products can be processed in sealed, final packaging.**<br>• Simple to operate and monitor<br>• **Best materials compatibility profile** of all sterilization technologies. Compatible with most medical materials and FDA cleared for over 55,000 medical devices.<br>• Microbicidal efficacy data.<br>• Long history of safe and effective use.<br>• Can sterilize products with electronic components and batteries. | • **Safe** environment and health care personnel (water and oxygen end products, **no toxic waste**).<br>• **Cycle time is 28-75 minutes. Aeration is short or not needed. Fast compared to EtO.** Some cycles are faster than steam.<br>• Used for heat- and moisture-sensitive items, as **process temperature <50 °C**.<br>• Easy installation, operation, monitoring.<br>• Compatible with most medical devices.<br>• Only requires electrical outlet.<br>• Microbicidal efficacy data.<br>• Able to sterilize electronic components and batteries. | • Used for heat sensitive items.<br>• **Compatible with most plastics.**<br>• **Potential for in-house sterilisation.** |
| DISADVANTAGES | • **Only to be used when there are no other alternatives.**<br>• **Requires long aeration time** to remove its residue. Lengthy cycle/aeration time (1-4 hours of sterilisation time plus 1 day to several weeks of degassing time).<br>• **ETO is toxic, a carcinogen, flammable, and explosive.** Can be highly reactive with other chemicals.<br>• Requires monitoring of the work areas and of discharge into the environment.<br>• **Expensive compared to steam.**<br>• ETO emissions regulated by states/countries. Catalytic cell removes 99.9% of ETO and converts it to $CO_2$ and $H_2O$.<br>• Incompatible with some materials, e.g. silicone.<br>• Sterilization chamber size from 4.0-7.9 $ft^3$ total volume (varies with model type).<br>• ETO 1 ppm TWA-employee exposure.<br>• Liquids generally not recommended. | • Cellulose (paper, cardboard), linens, powders and liquids cannot be processed.<br>• Sterilization chamber size from 1.8-9.4 $ft^3$ total volume (varies with model type). **Small chamber limits devices sterilized at one time.** Scalability or chamber size challenging.<br>• **Low penetration power.**<br>• **Restrictions based on lumen internal diameter and length** (see manufacturer's recommendations). Certain models of sterilizers require "boosters of $H_2O_2$ to sterilise lumens.<br>• Sensitive to small changes in process parameters (eg, temperature).<br>• Requires synthetic packaging (polypropylene wraps, polyolefin pouches).<br>• $H_2O_2$ 1 ppm TWA-employee exposure.<br>• Does not have linear inactivation.<br>• **Very few single-use medical devices (34) have been FDA validated.** | • Poor penetration power; can penetrate primary packaging (Tyvek) but not end packaged medical products<br>• Not compatible with cardboard<br>• Surface sterilant<br>• Incompatible with some plastics, water and oxygen<br>• Limited experience on medical devices, must be evaluated for compatibility, product performance, microbial efficacy, residuals, large chambers/scalability and product aesthetics<br>• **FDA listed as a novel sterilization**<br>• Limited scientific literature<br>• **Very few single-use medical devices (7) have been validated** |

| | Chlorine dioxide | Formaldehyde gas or low temperature steam formaldehyde (LTSF) |
|---|---|---|
| ADVANTAGES | • **Used for heat sensitive items (sterilisation at 15º to 40ºC).**<br>• Does not damage electronics or batteries.<br>• Primary use for chlorine dioxide is decontamination (eg, room, building), treating water systems, disinfecting food.<br>• Rapid aeration.<br>• Non-carcinogenic, non-teratogenic. | • Fast compared to EtO. Sterilisation time 40-180 min. Process time several hours.<br>• Cost per cycle relatively low.<br>• Compatible with certain medical devices.<br>• Absence of toxic waste.<br>• Easy installation. |
| DISADVANTAGES | • Poor penetration power; can penetrate primary packaging (Tyvek) but not end packaged medical products (cardboard boxes).<br>• Surface sterilant.<br>• Incompatible with some plastics, water and oxygen.<br>• Limited experience, must be evaluated for compatibility, product performance, microbial efficacy, residuals, large chambers/ scalability and product aesthetics.<br>• Not discussed as a novel technology by the FDA as they **do not have a history of safe and effective use** as demonstrated by ample scientific literature or 510(k)s clearances.<br>• **Very few single-use medical devices (5) have been validated** | • Known to be a toxic, irritating and allergenic chemical.<br>• Suspected carcinogen and mutagenic.<br>• Tight environmental controls are recommended for safe use - not to exceed 0.75 ppm (8 hours) or 2 ppm (15 minutes).<br>• Incompatible with moisture-sensitive materials (operating temperature of 70 - 75ºC).<br>• Papers and woven cloths not compatible.<br>• **Several countries have discouraged the use of LTSF, including the Netherlands.** |

### Takeaways 3.5

- Devices are packed before sterilisation. They will remain packed until their next use in the OR.
- Some sterilisation methods, like steam, require multi-part instruments to be sterilised disassembled. Thus they once again must be disassembled. They will have to be assembled for use once the package is opened at the OR by the nurse or physician responsible. If a tool is required for the assembly, the tool will have to be sterilised together with the device. These just add up to the reasons why ease of dis- and reassembly is of utmost importance.
- Steam is the preferred method of sterilisation. It is non-toxic, inexpensive, and has a quick cycle. However, it is not suitable for heat-sensitive materials (121º - 134º) and corrodes sharp instruments.
- Otherwise, irradiation methods should be explored for compatibility.
- Otherwise, and as a last option, chemical sterilisation could be explored. Few devices have been validated for methods other than EtO. $H_2O_2$ is a promising but limited technique.

### Long, narrow lumens

Geometries such as long, narrow lumens that were difficult to clean are also challenging for the disinfection and sterilisation processes. Huys (2011) highlights that air can get trapped inside lumens during steam sterilisation. This is represented in Figures 35 and 36. Areas only in contact with hot air will not get sterilised, so air needs to be removed before injecting the steam. According to U. van der Velden (personal communication, November 12, 2024), lumens of steam re-sterilisable devices have to follow a diameter-to-length ratio equal to or greater than 1 to 1500 mm. The experimental results obtained by van Doornmalen (2013) on steam sterilisation of 3 mm wide tubes with one open end under relaxed and optimistic boundary conditions indicate that lengths above 200 mm and 400 mm respectively do not achieve the minimum steam concentration required for surface sterilisation. He demonstrated that the length of the lumen is the most important parameter for the efficacy of steam sterilisation. Rutala et al. (2024) compiled data on the effectiveness of low-temperature sterilisation technologies on 3, 2, and 1 mm wide lumens. They presented how non-properly cleaned devices with serum and salt greatly impact the microbicidal action, and that the diameter of the lumen can also have a significant impact on H2O2 sterilisation.

#### Takeaways 3.5

- Blind, long and narrow lumens could affect cleaning and/or steam sterilisation. However, the dimensions defining these lumens are far from the dimensions of the syringe, even high-pressure tubes, or other components of the inflators that could be attempted to be reprocessed.

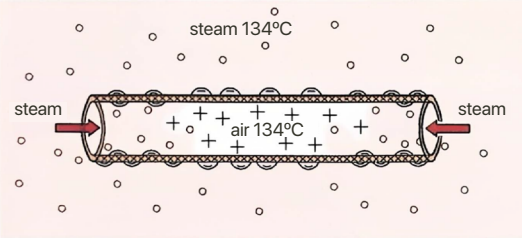



Figure 35. *Air trapped by steam entering an object with both sides open.* Adapted from Huys (2011).

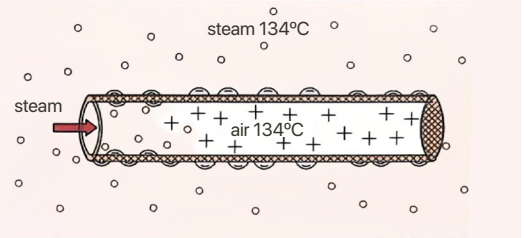



Figure 36. *Air trapped by steam entering an object with one side open.* Adapted from Huys (2011).

# 04

# ASSESSMENT OF CURRENT INFLATORS

This chapter evaluates current inflators' ease of disassembly and their environmentally and economically valuable parts. Selected inflators are disassembled and their architecture is analysed.

## 4.1. Assessment approach

*RQ4.3. How durable and reliable is an inflator and what are its critical components if reused?*

*This chapter of the research focuses on the disassembly and structure of the products, and is supported by the use of two design tools. Here, it is explained why the disassembly was done and the value of these tools for the research.*

The ease of disassembly and reassembly of The ease of disassembly and reassembly of products is crucial for enabling Circular Economy strategies like reuse, repair, remanufacturing, repurposing, and recycling (Hoveling et al., 2024). As discussed in the previous chapter, disassembly and reassembly are necessary in the context of medical devices to ensure decontamination and safe reuse. In the case of steam sterilisation, for example, the sterilisation department staff must assemble and disassemble the devices once, and then the nurses or physicians assemble them for use in the OR and disassemble them again when they have finished using them. Disassembly is typically manual, with the possibility (not preferred) of utilising certain tools. Therefore, it should be as easy and fast as possible. A product that takes more time to disassemble implies more money to be paid for the staff's time.

Since it is of utmost importance, the ease of disassembly of some inflators is assessed in this chapter using Hotspot Mapping (Flipsen et al., 2020) and Disassembly Map (De Fazio et al., 2021) tools. These tools also help evaluate which are the priority and most valuable parts of the devices analysed.

Flipsen et al. (2020) developed the Hotspot Mapping method for optimising product disassembly by identifying its critical parts (the ones that should be accessible for repair, remanufacture or recycling) and highlighting the factors that facilitate or limit the disconnection of these parts. For this method, they define critical parts as those that have functional and maintenance priority (priority parts), in addition to a high environmental and economic value (valuable parts). It is difficult to determine which are the priority parts of inflators, as they are single-use devices (SUD) and there is no data on the failure rate of their parts. They are designed to be used only once, so they have no critical parts for reuse or repair. Thus, only valuable parts are considered in this evaluation of the products.

The Disassembly Map gives a quick overview of the product's structure, the tools, tasks, task intensity, and sequence needed to disconnect the parts, which and where are priority and valuable parts, as well as the penalties or tasks that limit the ease of disassembly. It facilitates the comparison of the disassembly of different products (De Fazio et al., 2021).

The approach to disassembly involved performing a gentle dismantling (non-destructive) to the extent possible, followed by non-reversible methods to obtain all components separately and evaluate their criticality.

**Takeaways 4.1**

- No information is available on the durability and reliability of inflators. Due to their single-use nature, no critical parts for repair can be defined from among their current components.

## 4.2. Products assessed

*The section briefly describes the characteristics of the selected products for the assessment.*

Six manufacturers were approached to evaluate their products and five devices (see Table 1) were obtained that represented the current market in terms of pressure measurement, fluid capacity ranges, lock mechanisms, shape, and ergonomics. These devices are:

- The Encore™ 26 Inflation Device by Boston Scientific Corporation. It was previously used in the IR department at LUMC for angioplasty procedures before being replaced due to cost considerations. It can measure pressures up to 26 atm and has a fluid capacity of 20 mL. The quick-release mechanism is released by pressing a button on the right side of the device. The plunger has a flat knob at its distal end.
- The Encore™ 40 Inflation Device, manufactured by Atrion Medical and distributed by Boston Scientific Corporation. It belongs to the QL® Inflation Devices series by Atrion Medical (2024), that offers configurable inflators with a maximum pressure range of 15 to 40 atm and a capacity of 15 to 60 mL. Other brands like Cook Medical, B. Braun, BD, and Integra LifeSciences Corporation also offer similar models in their product portfolios. The Encore 40 has a working range of 0 to 40 atm and a barrel capacity of 60 mL (Boston Scientific Corporation, 2024). It incorporates a triangular-shaped knob on the plunger and a quick-release mechanism with a nut element that engages the threads of the plunger when rotated crosswise to the syringe.
- The Everest Disposable Inflation Device by Medtronic, which is currently used in LUMC's IR and IC departments. It supports pressures up to 30 atm and contains 60 mL. It features a gun-style ergonomic design, a trigger-based quick-release mechanism, and a rounded plunger knob.
- The Vedkang™ Balloon Inflator by Vedkang Medical, used in the Endoscopy department at LUMC, offers a 60 mL barrel and a pressure gauge measuring up to 12 atm. It uses a longitudinal knob and a lever mechanism to control rapid or precise inflation movements. This lever mechanism is also used in products distributed by other brands such as B Braun, BD, and Taeyeon Medical.
- The Alliance™ II Integrated Inflation/Litho Handle by Boston Scientific Corporation. This product is used with a single-use sterile syringe-gauge assembly (12 atm of maximum pressure and 50 mL of fluid capacity) for balloon dilatation purposes. It has two features: First, it facili-tates an ergonomic grip during the inflation and deflation process. Second, it incorporates a mechanism that enables controlled dilatation of the balloon. The working principle of the mechanism is similar to that of a caulking gun. It integrates a directional control mechanism, enabling the user to switch between forward and backwards motion with ease. The handle is provided non-sterile and can be reused once disinfected.

  The sample analysed was provided by the endoscopy department of the LUMC and had been in use for several years up to the loan date. It still performed adequately and was being used in medical procedures. However, it should be mentioned that the turning action of the directional switch offered a higher resistance compared to the smoothness of turning observed in new products (BostonScientificEndo, 2015), as well as an intense noise.

| |  |  |  |  |  |
|---|---|---|---|---|---|
| **BRAND** | BSC | BSC | Vedkang | BSC | Medtronic |
| **PRODUCT** | Encore™ 26 | Encore™ 40 | Vedkang | Alliance™ II Handle | Everest |
| **USAGE** | Balloon dilatation, endoscopy, urology | Balloon dilatation | Does not say | Balloon dilatation, endoscopy, urology | Balloon dilatation |
| **MAX. PRESSURE (atm)** | 26 | 40 | 15 | | 30 |
| **FLUID CAPACITY (mL)** | 20 | 60 | 60 | | 20 |
| **MANOMETER** | Analog | Analog | Analog | | Analog |
| **LOCK MECHANISM** | Finger latch | Lock lever | Lever | Similar to caulk gun | Actuator as trigger |
| **STERILISATION** | EtO | EtO | EtO | High-level disinfection | EtO |
| **SINGLE-USE** | Yes | Yes | Yes | Reusable | Yes |
| **REFERENCE** | BSC (2023) | Atrion Medical (2020) | Vedkang (2018) | Atrion Medical (2020) | Medtronic (2016) |
| **OTHER** | Previously used in IR department at LUMC | Patents and manufactured by Atrion Medical | | To be used together with Alliance™ Syringe | Gun-style ergonomic design. Currently used in IR and IC departments at LUMC |

Table 3. *Products assessed and their features.*

## 4.3. Disassembly results. Product by product

*RQ4.1. How is the product structured? What are the main subassemblies?*
*RQ4.2. What is the disassembly and reassembly experience of current inflators?*
*RQ4.4. What are inflators' most valuable components?*

*This section explains the disassembly experience with inflators and the main learnings from their architecture. It shows the structure and the most valuable parts of various products.*

### Encore™ 26

The Encore™ 26 was the only inflator that could be completely disassembled without destroying any components or connections. Figure 39 lists its parts. This does not imply that it did not present challenges. The product is encased in a two-piece housing, one blue (1) and the other transparent (9). These two pieces are joined with snap-fits featuring a 90° retaining angle. This union secures both the manometer (5) and the lock mechanism comprising (2), (3), (8), and (10). Figure 37 illustrates how four hands and six tools were simultaneously required to separate this housing and access the remaining components.

Another difficult aspect of the disassembly process was separating the actuator (8) from the half-nut (10). They were joined too tightly together and compressing against each other the transparent casing (9). This squeezing together of the casing makes the half-nut (10) immobile in its position relative to the walls of the casings (9 and 1). This detail is crucial to maintain the integrity and functionality of the device under high-pressure conditions: when the plunger (11) engages the threads of the half nut (10) and transmits to it the forces derived from the high pressure, the half nut distributes the force to the rest of the structure.

Figure 38 is the moment when the actuator was separated (8) from the half nut (10) and the casing (9). It was necessary to apply pressure simultaneously to two distinct parts of the actuator (8) to create a small gap through which a spudger could be inserted to provide leverage.

Both challenges, as well as the critical parts of the product, are highlighted in the disassembly map of the Encore™ 26, in Figure 39. All the

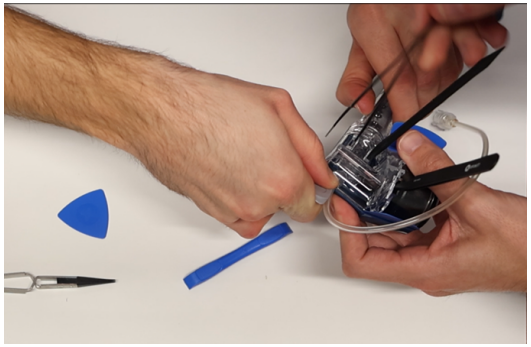
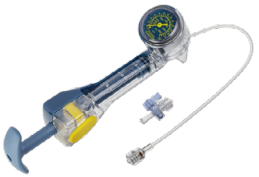
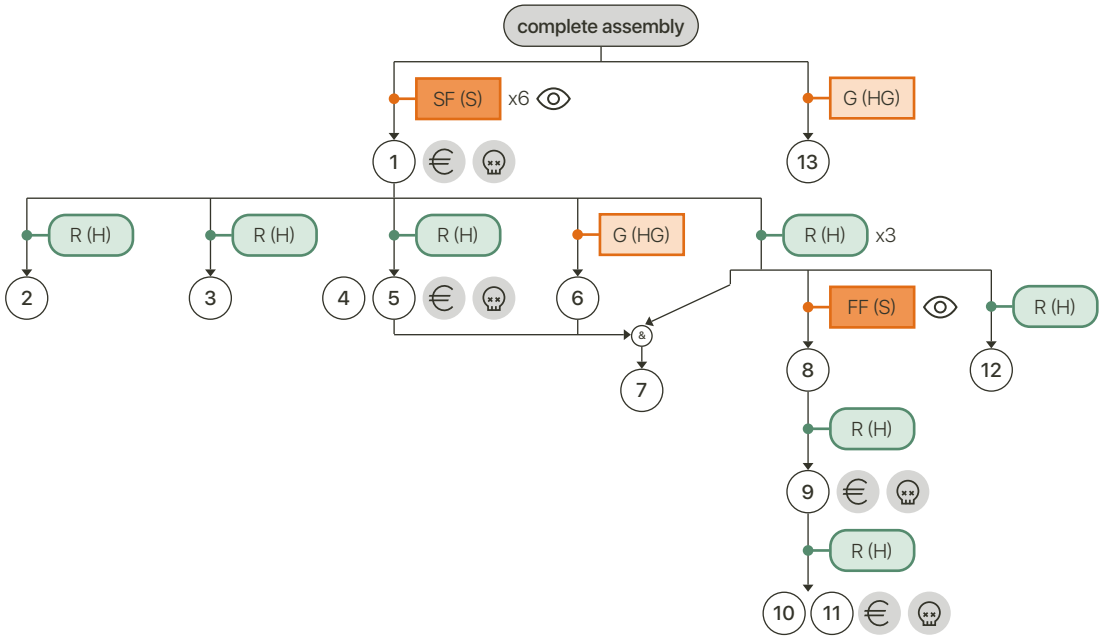


Figure 37. *Dismantling the casing (1, 9) of the Encore™ 26. Four hands and six tools had to be used at the same time to succeed.*

Figure 38. *Separating the actuator (8) from the half-nut (10) of the Encore™ 26. The gap to introduce the spudger was so small that I ended up hurting myself.*

## Disassembly map
## Encore™ 26 Inflation Device






**Parts**

| | |
|---|---|
| 1 | Part |
| A | Subassembly |

**Type of tool**

| | |
|---|---|
| (H) | Hand |
| (HG) | Heat Gun |
| (S) | Spudger |

**Abbreviations**

| | |
|---|---|
| SF | Snap-Fit |
| FF | Friction-Fit |
| R | Remove |
| G | De-glue |

**Part list**

1. Blue case
2. Spring
3. Spring
4. O-ring
5. Manometer
6. High-pressure tube
7. Barrel
8. Actuator
9. Transparent case
10. Half-nut
11. Plunger
12. O-ring
13. Luer connector

**Penalties**

- Product manipulation
- Low visibility/identifiability
- Uncommon tool
- Non-reusable connector

**Target components**

- Environmental indicator
- Economic indicator

**Motion type and force intensity**

| | Low | Mid | High |
|---|---|---|---|
| Hand | | | |
| Single motion tool | | | |
| Multiple motion tool | | | |

Figure 39. *Disassembly map of the Encore™ 26.*

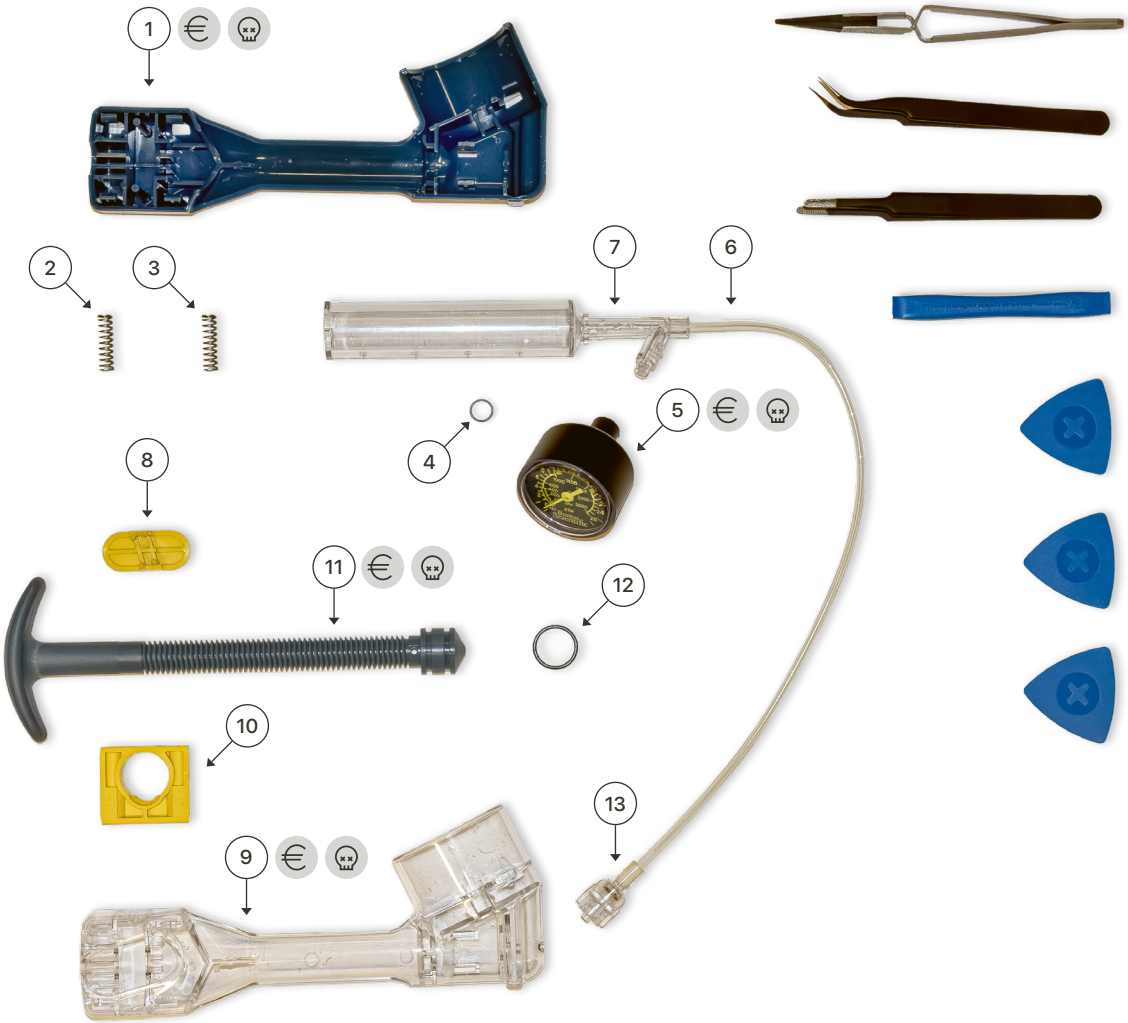



Figure 40. *Disassembled Encore™ 26 inflator. The parts are numbered following the part list included in Figure 39, and the environmental and economic hotspots are highlighted.*

parts and the tools used for the disassembly are shown in Figure 40.

Another observation about this product is that the springs (2, 3) in their resting position inside the device were compressed by the casings (1, 9). And when pressing the actuator (8), they were compressed further. This compression, in turn, pushes the half nut (10) to constantly engage its threads with the plunger (11) and ensures that the plunger (11) cannot be moved by the user or the internal pressures without releasing the lock mechanism.

### Takeaways 4.3

- Encore 26 can be disassembled, but does not fall within the boundaries of a reprocessable product. It requires two people at the same time and many different tools to achieve the disassembly.
- Encore 26 uses 90º angle snap-fits for a secure connection that withstands the high pressures, but it does not allow for easy disassembly.
- The springs were pre-compressed in their resting position, to make the half nut constantly engage with the plunger.

### Encore™ 40

The disassembly of the Encore™ 40 was more complicated. Davis & Kanner (2004) include the assembly process of the QL® series in their patent, so the first approach was to follow these steps in reverse. Figure 43 shows the assembly process they describe using the language of the Disassembly Map method. The assembly process of this product incorporates two critical steps that make the complete disassembly unfeasible. These irreversible connections are highlighted and categorised as a new penalty type in Figure 43. The steps in question are as follows:

- Piston and plunger integration: The piston of the plunger (6) is initially placed inside the barrel (1) before the nut assembly (A) is mounted onto the barrel. When mounted, the nut assembly reduces the diameter of the barrel's rear aperture and traps the piston within the barrel. In the final assembly phase, the plunger (12) is inserted into the barrel and attached to the plunger. This attachment cannot be undone because it is inaccessible inside the barrel. Consequently, the plunger becomes irremovable from the barrel unless the nut

Figure 41. *Final dissassembly destructive method used for the Encore™ 40: a saw machine. As can be observed, this destructive method produces quite a lot of debris, which probably slightly influences the weighting of the parts for economic and environmental assessment.*

assembly is first dismantled. What makes it worse is that the nut assembly cannot be disassembled with the plunger in there.

- Nut Assembly Fixation: The nut assembly is permanently fixed to the barrel with a friction-fitted metallic pin (11). This connection also permanently secures the plunger within the barrel structure.

The disassembly started destructively, by breaking some parts of the nut assembly so that the plunger with the piston had enough space to leave the barrel. However, this did not lead to any results, and the product was cut in two with a band saw. The cutting in half is shown in Figure 41.

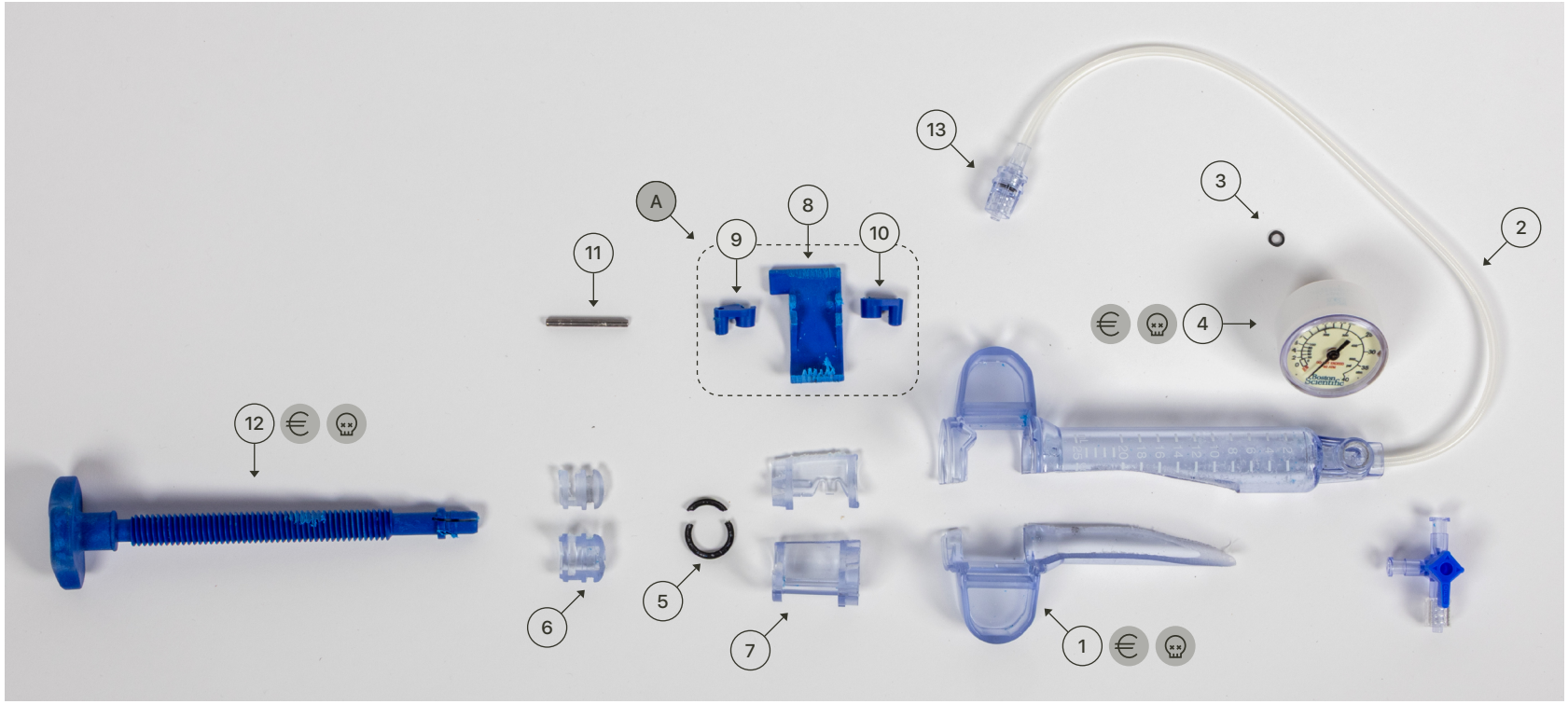



Figure 42. *Disassembled Encore™ 40 inflator. The parts are numbered following the part list included in Figure 43, and the environmental and economic hotspots are highlighted.*

## Assembly map
## Encore™ 40 Inflation Device

### Parts

1 Part

A Subassembly

### Type of tool

(H) Hand
(A) Applicator

### Abbreviations

SF Snap-Fit
FF Friction-Fit
P Position
G Glue
Sc Screw

### Part list

1. Barrel
2. High-pressure tube
3. O-ring manometer
4. Manometer
5. Piston o-ring
6. Piston
7. Carrier member
8. Nut member
9. Link member
10. Link member
A. Nut assembly
11. Pivot pin
12. Plunger
13. Luer connector

### Motion type and force intensity

Low Mid High

Hand

Single motion tool

### Penalties

Product manipulation

Low visibility/identifiability

Uncommon tool

Non-reusable connector

Irreversible connection

### Target components

Environmental indicator

Economic indicator

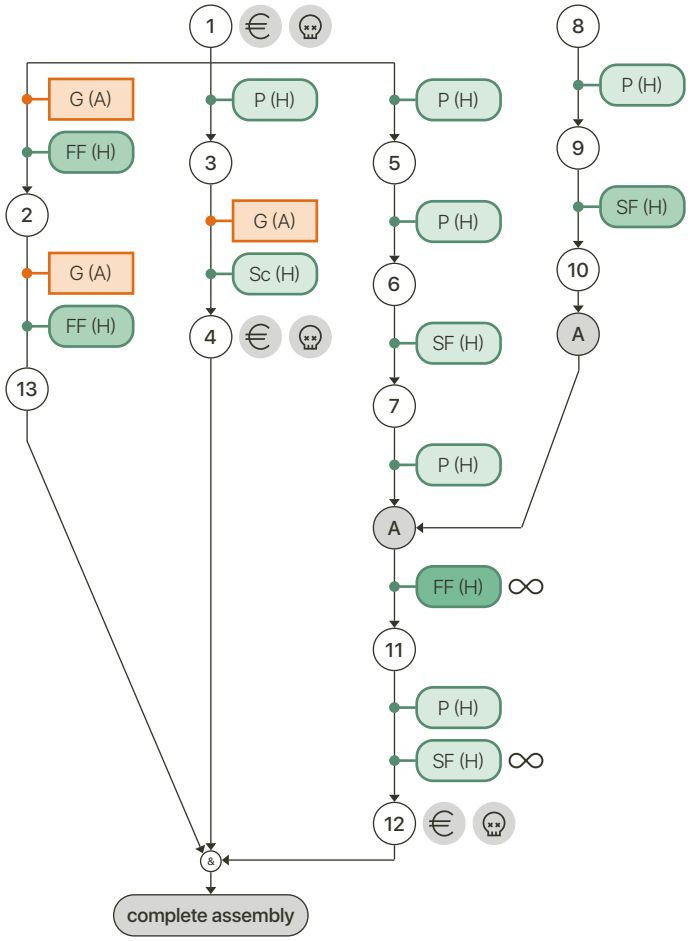



Figure 43. *Assembly map of the Encore™ 40 inflator.*

This device was interesting to study. It is the only inflator observed to have a quick-release mechanism that does not use springs. Springs in other devices move the half nut relative to one axis, up and down, for example, to engage and disengage it from the plunger. Instead, the Encore™ 40 locks and unlocks the plunger to the half-nut by rotating the half-nut relative to the longitudinal axis of the barrel, as in a conventional overcentre mechanism. The progressive rotational movement of the half nut (8) and the link members (9, 10) during use of this mechanism with respect to the pivot pin (11) is shown in Figure 46. Here, the half nut (8) rotates from a disengaged position with the plunger (12) on the left, to an engaged position on the right. Figures 44 and 45 help to understand where these schematic shapes come from.

As the vertical axis of the half nut (9) approaches the centre of rotation (the pivot pin, 11), the half nut (9) begins to graze against the plunger (12), and rotational resistance is generated. When the vertical axis and the centre of rotation coincide, the resistance is at its maximum. Once past the point of rotation (right engaged position in Figure 46), the half

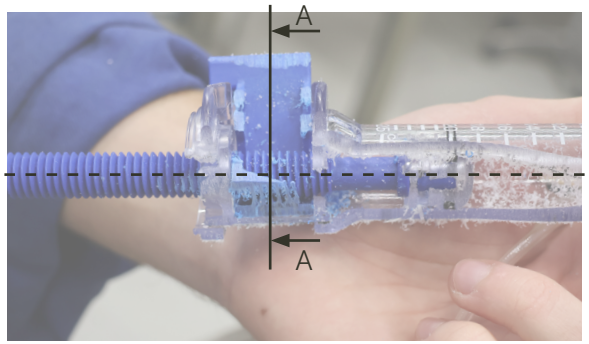



Figure 44. *Lateral view of the Encore™ 40 inflator mechanism (after partially destroyed with the saw machine) with a cut section. The longitudinal axis of the barrel crosses the image.*

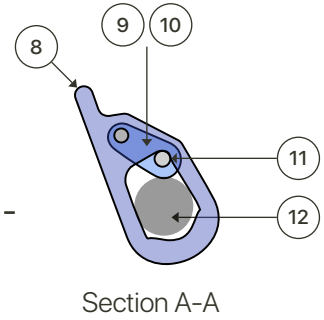



Figure 45. *Section view of the overcentre mechanism of the Encore™ 40. The numbers represent the nut member (8), the link members (9 and 10), the pivot pin (11), and the plunger (12).*

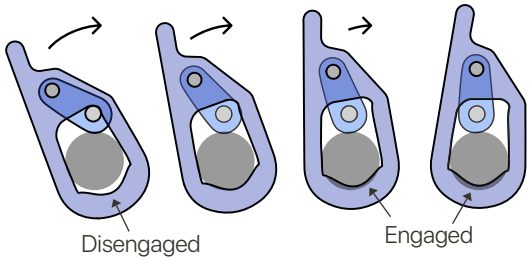



Figure 46. *Progressive rotational movement of the half nut (8) and link members (9 and 10) of the Encore™ 40 with respect to the pivot pin (11), from a disengaged to an engaged position.*

nut (9) and plunger (12) are still in contact, still engaged, but not grazing as much. Therefore, an engaged position is achieved from which it is difficult to get out of.

### Takeaways 4.3

- The Encore™ 40 is impossible to disassemble following a gentle or non-destructive approach. Its assembly process included two irreversible steps (assembly inside the barrel and a tight fit) to make sure the plunger would not be able to leave the barrel.
- Its lock mechanism does not include springs. Instead, it has an overcentre mechanism in which the half nut rotates between two secured positions to engage and disengage from the plunger.

**Everest**

This inflator also presented significant challenges during disassembly. It has structures assembled with snap-fits of a 90° retaining angle. However, this time the snap-fits are impossible to disconnect because some large connection areas of the device are also glued together. Figure 47 indicates where the snap-fits and the glued area of the device are, and Figure 48 shows how the glued parts that make up the handle of the "barrel" were dismantled. It was impossible to disassemble it without damaging or sawing the attached components.

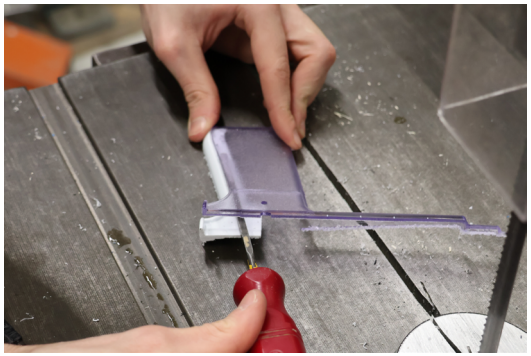


Figure 48. *Trying to break through the glued parts with a flat blade screwdriver.*


Figure 47. *Snap-fits and glued area of the device.*

Figure 49 shows the inflator after being cut in half with the sawing machine. The Everest, completely disassembled, can be seen in Figure 50, which includes a list of all components numbered and the environmental and economic hotspots of the device obtained with the HotSpot mapping tool.

Ryan (1992) explains the design of the Everest, the operation of its locking mechanism, and names the materials used for most of its parts. This is the only product for which there is information about its materials. For this reason, Table 5 provides a basic analysis of the Everest's energy, environmental and economic impact.

The locking mechanism of the device works by transforming the horizontal movement of the actuator, in this case a trigger (5), into a vertical movement of the half-threaded nut (7). This is possible because the half nut (7) rests and slides on an inclined surface of the trigger (5). When the trigger (5) is actuated horizontally, it causes a threaded half nut (7) inside the device to move downwards and no longer engage with the threaded plunger (12). The plunger (12) can then move freely down the barrel.

Figure 49. *Everest inflator after being sawed in two halves.*

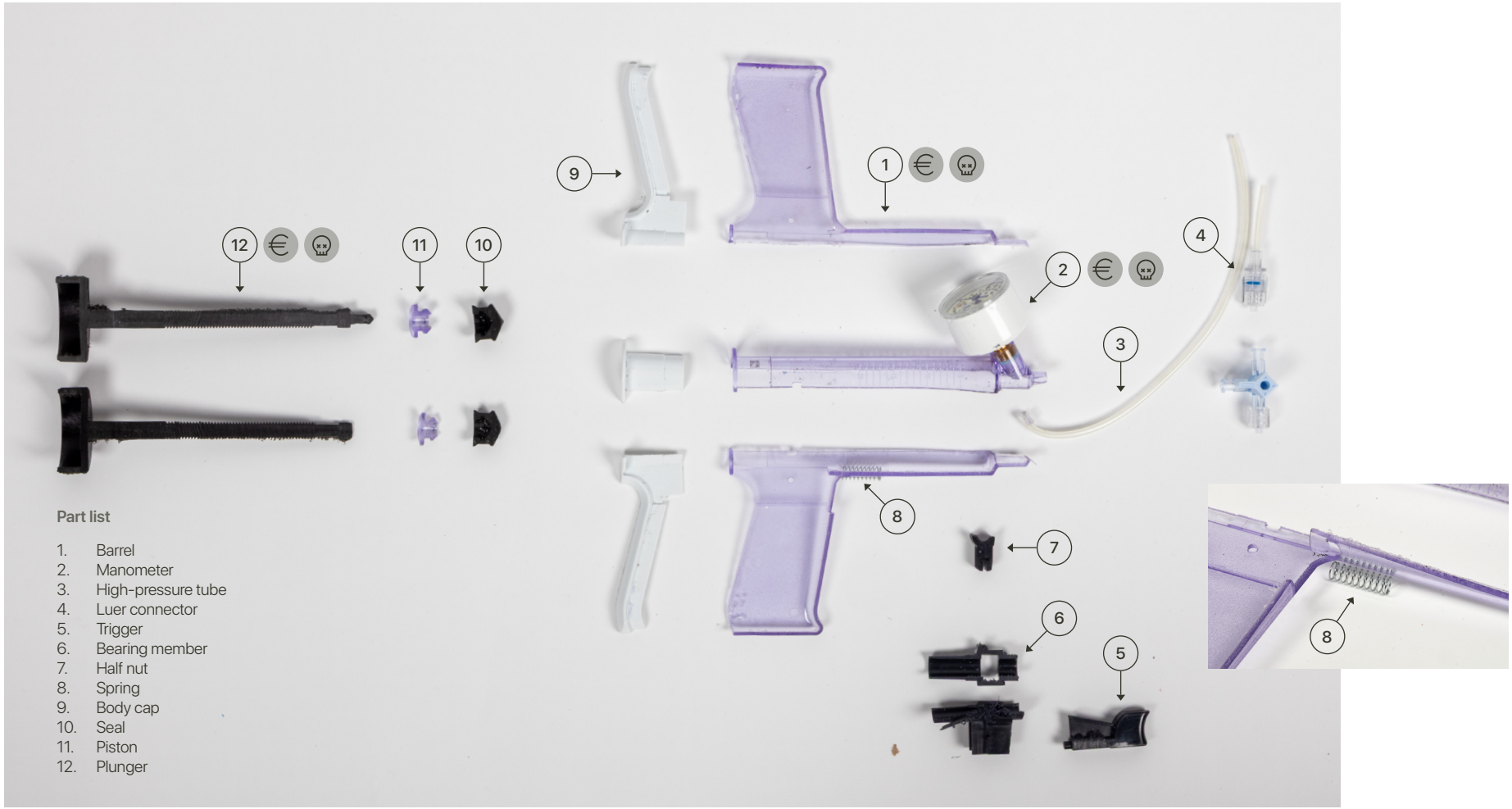



Figure 50. *Disassembled Everest inflator. A part list is included. The parts are numbered and the environmental and economic hotspots are highlighted.*

### Takeaways 4.3

- The Everest inflator cannot be disassembled using a gentle or non-destructive method. It uses 90º angle snap-fits and glue to connect its components in a safe way that endures the high pressures.
- This device also uses a spring system to ensure that the actuator has only one stable position, to which it will return if it is not kept actuated.
- This product was granted a patent in 1992. The industry has been operating for more than 30 years on the basis of the same inflators, without significant improvements regarding sustainability.

### Vedkang™

The Vedkang™ only exhibited three visible or palpable connection points (in addition to the manometer): three threaded rods. However, no further disassembly was possible beyond unscrewing these. Consequently, the disassembly process ultimately involved cutting it in half with a saw. The process is shown in Figure 51, and the result of the disassembly can be seen in Figure 52, which includes a part list and count.

The function of the threaded rods (7, 8, 9) is not fully understood. It can be assumed that they are there to reinforce the connection between the half nut housing (10) and the barrel (1). But after removing the rods and dividing the inflator into several parts, the housing (10) and the barrel (1) were still permanently glued together.

This inflator uses an additional component (18) that covers part of the plunger (17). When the plunger (17) is fully inserted into the barrel (1), this component (18) collides with the housing (10) before the sealing element (15) touches the inner end of the barrel (1). Thereby it is understood to have the function of stopping the plunger (17) before the sealing element (15) is damaged.

Figure 51. *Vedkang™ going through a second sawing cycle after separating the actuator.*

Another highlight of this inflator is the plunger (17). It is made of a stainless steel 304 rod covered with nylon (PA6). The other inflators analysed only need a nylon plunger to operate at higher pressures. Therefore, the reason for using the SS rod is not clear.

The actuator of the Vedkang is a button (6). It pivots on a pin (5) and fits on the upper surface of the half nut (13). When the button (6) is pressed, it rotates and engages with the half nut (13). The half nut (13) is compressed inside the barrel (1) between the rear wall of the housing (10) and a stopper (14) at the front. The rotational movement can therefore only be transformed into a vertical movement of the half nut (13), which disengages the plung-

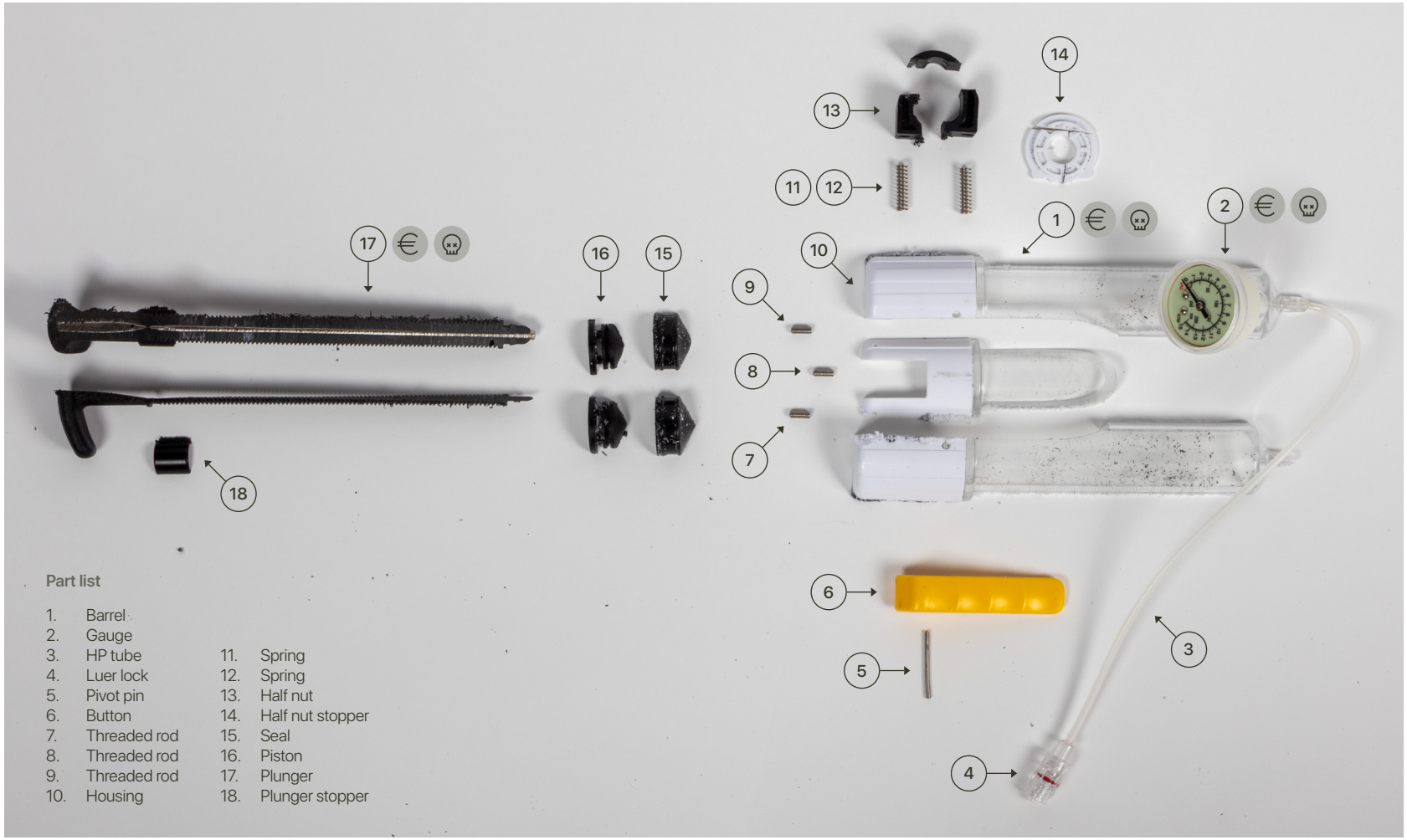



Figure 52. *Disassembled Vedkang inflator. A part list is included. The parts are numbered and the environmental and economic hotspots are highlighted.*

er (17) and allows it to move freely inside the barrel (1). The springs (11, 12) give the half nut a sole stable position.

### Takeaways 4.3

- It is necessary to break the Vedkang to gain access to its interior components because glue has been used to assemble it.
- It is the inflator that withstands the least pressure of the four and requires the most parts. Not all of its design decisions have been understood.
- The locking mechanism uses springs and a rotating actuator. The rotational movement of the actuator then has to be translated into vertical movement.

**Alliance™ II Handle**

Alliance™ is a system of two devices, a syringe with a gauge and a handle, that has the mechanism separated from the barrel and plunger. The handle integrates a mechanism that enables controlled dilatation of the balloon. Figure 53 shows the handle disassembled, plus the syringe as a single unit.

Given the complex composition of this product, which has 31 components (without taking into account the syringe), and considering that it cannot be sterilised—not only due to the instructions given in the IFU, but also because of the impracticality of reprocessing a product with such a multitude of parts that would require meticulous control during repeated disassembly and reassembly cycles—this product is not analysed for redesign. Consequently, the identification of critical and valuable components for this particular device is not necessary.

## 4.4. General disassembly results

*RQ4.2. What is the disassembly and reassembly experience of current inflators?*
*RQ3.5. Which of those cleaning and sterilisation methods could be suitable for inflators? How would the materials and mechanisms of current inflators perform during decontamination?*

*This section compiles the most important insights extracted from the disassemblies and adds some overall learnings.*

### Takeaways

- The inflators have 12 components (Everest and Encore 40), 13 components (Encore 26), and 18 components (Vedkang). This is not counting the stopcock valve. Because the stopcock valve comes in the box with the inflator but disassembled, and sometimes it is not used during the procedure. Surprisingly, the device that has to withstand the least pressure is the one that has the most parts to function.
- The four inflators analysed allow for fast and precise movements of the plunger inside the barrel by having a threaded

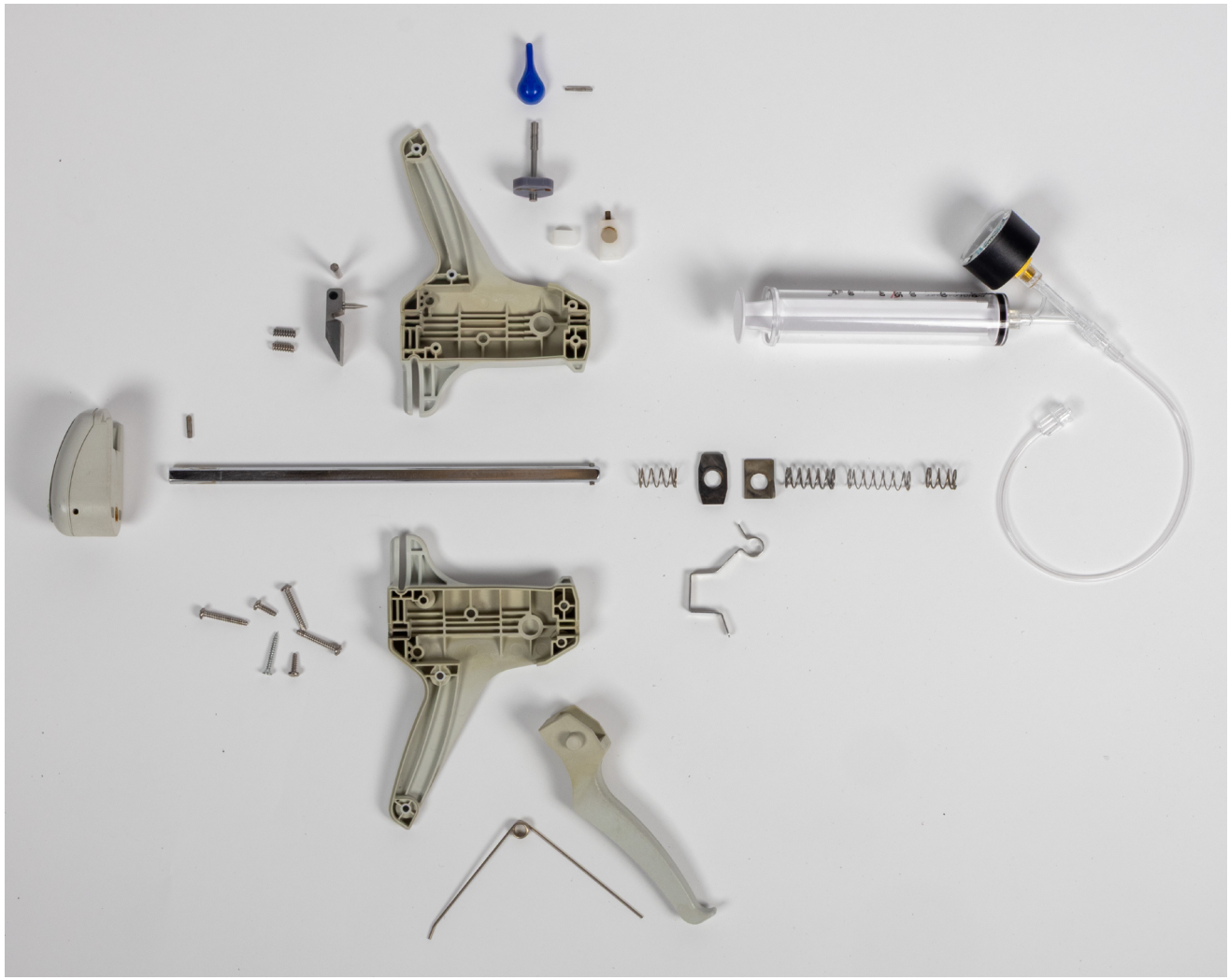


Figure 53. *Alliance™ II Integrated Inflation/Litho Handle disassembled, together with the syringe.*

plunger and a half nut. The half nut can only move in one direction and has one or two defined positions to engage and disengage with the plunger.

- Key observations from these disassemblies reveal that inflators share common design features: The lock mechanism must be tightly connected to the barrel to withstand the pressure transmitted by the plunger. Manufacturers have addressed this requirement by developing barrel-mechanism systems that are either impossible or extremely difficult to separate. Also, the connections used do not allow the plungers to leave the barrel while in use, as this would lead to failure.
- For current inflators to be reprocessable and align with circularity strategies, disassembly adapted to the working conditions of physicians, nurses, and sterilisation staff and, by extension, the separation of the barrel, plunger, and mechanism components, is essential. Therefore, a redesign of inflation devices that contemplates these challenges could consider, for example, alternatives for connection points between these three components and innovative locking mechanisms that can be easily separated for reprocessing.
- Inflators use thermoplastics that are not suitable for the high temperatures of a mechanical cleaning process with washer disinfectors (for parametric release). They are also not suitable for steam sterilisation.
- Therefore, the current inflators cannot be reprocessed for technical R-strategies such as reuse, repair, remanufacture, repurpose, or recycle.

## 4.5. Hotspots

*RQ4.4. What are inflators' most valuable components?*

*As explained in the initial section of this chapter, only parts with high economic and environmental value are considered critical and, therefore, classified as hotspots or target components in this analysis. According to the method proposed by Flipsen et al. (2020), the criticality of parts is determined by their placement in the 80th percentile or higher within economic and environmental parameters.*

Among the four inflators examined, three components stand out as the most valuable: the pressure gauge, the barrel and the plunger. These parts son las que mayor impacto tendrían si se les aplicasen R-strategies. These parts would have the greatest impact if R strategies were applied to them. Therefore, these are where a redesign activity should focus, while the rest of the components could remain disposable.

In the case of the Encore 26, the polycarbonate barrel is not directly considered a hotspot. The two casings, which compress the

barrel and connect it to the other parts of the inflator, are. In other devices, this function is mainly achieved by the glue that binds all parts to the barrel. If we consider that part of the barrel's function is to have the locking mechanism and the pressure gauge firmly attached to the same body, it can be understood that the casing of the Encore 26 is an extension of the barrel.

# 05
# CIRCULAR JOURNEYS

Circular reprocessing paths and their consequences for the redesign of inflation devices are analysed in this chapter.

## 5.1. Circular strategies

*RQ5.1. What are the best reprocessing possibilities for inflators?*
*RQ5.2. What circular strategies are best for those reprocessing possibilities?*

*Not all of the R strategies presented at the beginning of this report can be attempted to be applied to inflator redesign in the course of this project. This section defines and explains those that need to be focused on in order to develop a system and product level solution.*

This project explores circular product journeys that could maintain the value of inflators, their components, or materials in the economy for as long as possible. It focuses on technical circular strategies, following a priority order—reuse, remanufacturing, repurposing, and recycling—based on their circular potential as defined by Hoveling et al. (2024). The following sections present two circular journeys for inflators, one emphasising reuse, the other focusing on remanufacture, both including terminal sterilisation.

As per Hoveling et al. (2024), reusing in a medical context involves reprocessing and reintroducing a discarded device for another patient, provided it remains in good condition and functional. This process may also involve maintenance and repair to prolong the device's lifespan. Remanufacturing, on the other hand, entails restoring a discarded device to current standards or integrating its components into a new device with the same functionality.

Both reusable and single-use medical devices can be reprocessed either within a healthcare institution or through an external provider. Each option has different requirements and implications, such as scale, transportation logistics, device control and monitoring, and turnaround time between uses. An important factor to consider is that reusable products have a determined number of cycles they can be used for. Reprocessing allows for a product with components tested for longer and shorter cycles. Then, when one of the parts cannot be reprocessed anymore, the rest can still be used to form a new product. Additionally, different sterilisation methods are more suitable for different settings—steam sterilisation is typically used in-house, whereas methods like EtO and irradiation are more common in large-scale industrial sterilisation.

The circular pathways presented in the following sections consider inflators as hybrid equipment. This term refers mainly to reusable items, with small single-use components (Rizan et al., 2022; Hoveling et al., 2024). This is in case it is interesting for future redesign not entirely reprocessing them and keeping some components as disposable parts.

For hybrid devices, reprocessing only some components of a system requires nurses to as-semble in the OR the final device consisting of the reprocessed parts and some newly pro-duced pieces. This assembly can also be completed during reprocessing, becoming a remanu-factured product instead. Third-party reprocessors, including the original manufacturer, can facilitate this process to improve efficiency and ease of use. This pathway of remanufacturing to restore the device to a 'like-new' state before returning it to the OR is the second circular journey explored in this chapter.

## 5.2. In-house reprocessing

*RQ5.3. How would the circular reprocessing journeys for inflators look like?*

*This section shows the in-house reprocessing journey, within the healthcare institution. Then, it reviews which of the sterilisation methods are suitable and which is best for this journey.*

As part of this project, a visit to the Central Sterilisation Department (CSD) at LUMC allowed for an in-depth understanding of the reprocessing workflow for reusable medical instruments in the Netherlands. This workflow is shown in Figure 54. The reprocessing occurs in three distinct areas within four hours. Instruments arrive from the OR in transport carts and enter the cleaning or soiled area, where both the carts and the devices' UDI carriers are scanned to track the start of the decontamination process. In this room cleaning is performed manually, with an ultrasonic cleaner, and using washer-disinfectors. These last machines take in the instruments from the soiled room and return them clean and disinfected through another opening into the clean area.

In the clean area, staff verify the washer-dis-


* Requires nurses to reassemble devices at the OR
** Devices are also disinfected at the CSD of the LUMC during the cleaning procedure

Figure 54. *In-house reprocessing journey.*

infector process, rescan each instrument, and visually inspect them for residual contaminants. Products that still have organic or inorganic material on their surfaces are returned to the soiled area. Functional tests of the products ensure that they work properly. If they have any damage or do not perform as expected, they are sent to be repaired. After the evaluation of the products, they are grouped and assembled into trays for the upcoming surgery. The trays are then packaged, labeled for sterilisation, and placed into autoclaves, which—like the washer-disinfectors—have two doors: one facing the clean area and another leading to the sterile storage zone. Once sterilised, the chemical indicators of the devices are checked, as well as the autoclave's process, and the instruments are stored under optimal conditions until their next use.

The autoclaves are for steam sterilisation. The LUMC also used to have hydrogen peroxide gas plasma sterilisation for a few specific products, but not anymore. In section 3.4 "Reprocessing of reusable devices" advantages and disadvantages of hydrogen peroxide as a sterilant are assessed. While it is safe and can be used for heat- and moisture-sensitive materials like plastics, not many devices have been validated for this sterilant, lumen sterilisation might be a challenge, and the chamber sizes are typically smaller than the ones of the autoclaves. Vaporised peracetic acid is highlighted as another method with potential for in-house sterilisation. It has some limitations (apart from the fact that only seven medical devices have been validated for this method of sterilisation). For instance, it has low penetration power and is a surface sterilant, thus hindering the reprocessing of devices with lumens such as the indeflator. Therefore, steam sterilisation is still the preferred method for this pathway, even if it presents some challenges, e.g. on heat-sensitive materials.

The CSD of the LUMC collaborates with Van Straten Medical B.V. to get their products repaired. Their facilities were also visited. They are shipped to Van Straten Medical once cleaned. There, they inspect and repair them to make sure that they work properly (Figure 54 shows part of the workshop they have, where the manual repairing is done). Afterwards, they are cleaned in a washer disinfector and delivered back to the LUMC, where they can join the reprocessing chain at the clean room.

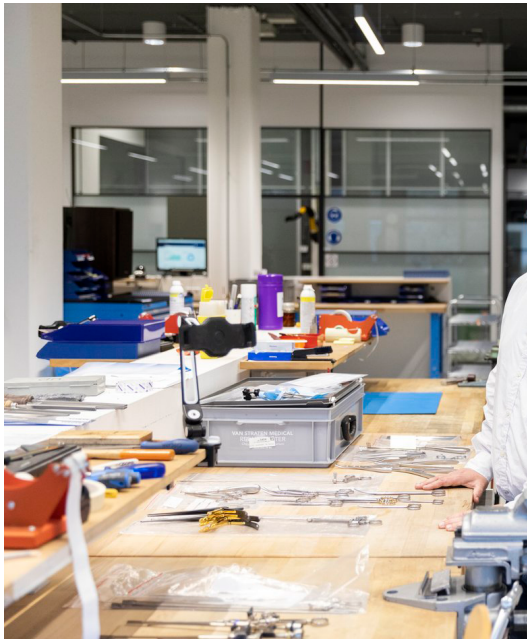


Figure 55. *Workshop space at Van Straten Medical B.V. for manual repair of medical products.*

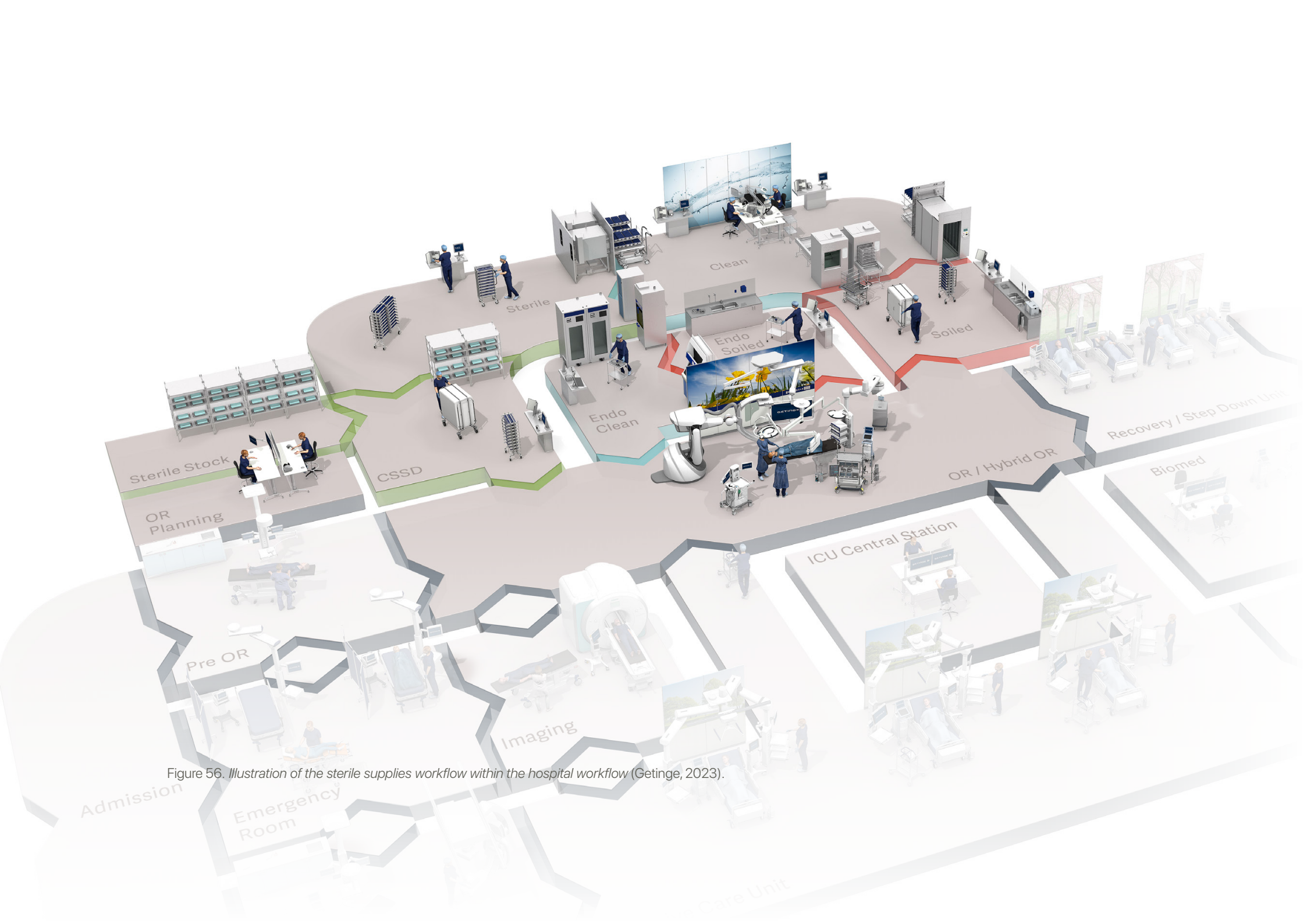



Figure 56. *Illustration of the sterile supplies workflow within the hospital workflow* (Getinge, 2023).

The facility employs Getinge 86-series washer-disinfectors, high-capacity steam sterilisers, and an instrument tracking system by Getinge. Figure 56 illustrates the CSD layout and its linear decontamination workflow.

Reprocessing medical devices in healthcare settings using steam sterilisation has notable pros and cons. An important consideration is the scale of this approach. Data from the first chapter suggests that more than 2900 inflators would undergo reprocessing each year at LUMC. Table 4 summarises the information.

**In-house steam sterilisation for reusable medical device reprocessing**

| ADVANTAGES | DISADVANTAGES |
|---|---|
| • Steam sterilisation is the most widely used method in healthcare facilities and the preferred choice in reprocessing guidelines due to its safety, non-toxicity, affordability, quick processing time, and extensive history of use (further details in Section 4.3).<br>• Reduces transport emissions and costs since all processes occur within the healthcare facility (except for repairs and maintenance if needed).<br>• Requires only primary packaging, eliminating the need for additional cardboard packaging.<br>• Overall, the facility has to deal with fewer products that come from the exterior and depends more on itself. | • Steam sterilisation also has some disadvantages (full list in Section 4.3). It is not compatible with heat-sensitive materials like plastics and may cause micropitting, minor damage, or corrosion.<br>• Requires devices to be disassembled before autoclaving, meaning nurses must reassemble them before use in the OR.<br>• If repairs and maintenance are outsourced, an extra cleaning phase is necessary.<br>• The capacity of the healthcare facility and the adaptation of their personnel to work with new reusable devices are other aspects to take into account. |

Table 4. *Advantages and disadvantages of in-house reprocessing. Considering that it is steam sterilisation, as discussed previously it is preferred and more common in healthcare facilities. And that it is reusable devices. Healthcare institutions will always follow the manufacturer's instructions. Also, it makes no sense to consider single-use devices for this comparison if the goal is to end up introducing a new device to the market.*

## 5.3. External reprocessing

*RQ5.3. How would the circular reprocessing journeys for inflators look like?*

*Before, in-house was explored. Here, the possibility of a third party reprocessor is also considered.*

External reprocessing refers to outsourcing medical device reprocessing to a third party before returning them for another use in healthcare facilities. As mentioned in the previous section, LUMC's CSD collaborates with Van Straten Medical for instrument repair and maintenance. Van Straten Medical also offers full reprocessing services for hospitals without suitable facilities, receiving contaminated products, decontaminating them, and returning them for reuse. While the process is similar to in-house reprocessing, transportation costs rise, and monitoring becomes more complex since devices leave the healthcare premises. Healthcare institutions prefer to reprocess reusable devices themselves whenever possible.

External reprocessing not only applies to reusable devices. It can also involve the remanufacturing of single-use devices. As explained by Hoveling et al. (2024) and Vanguard AG

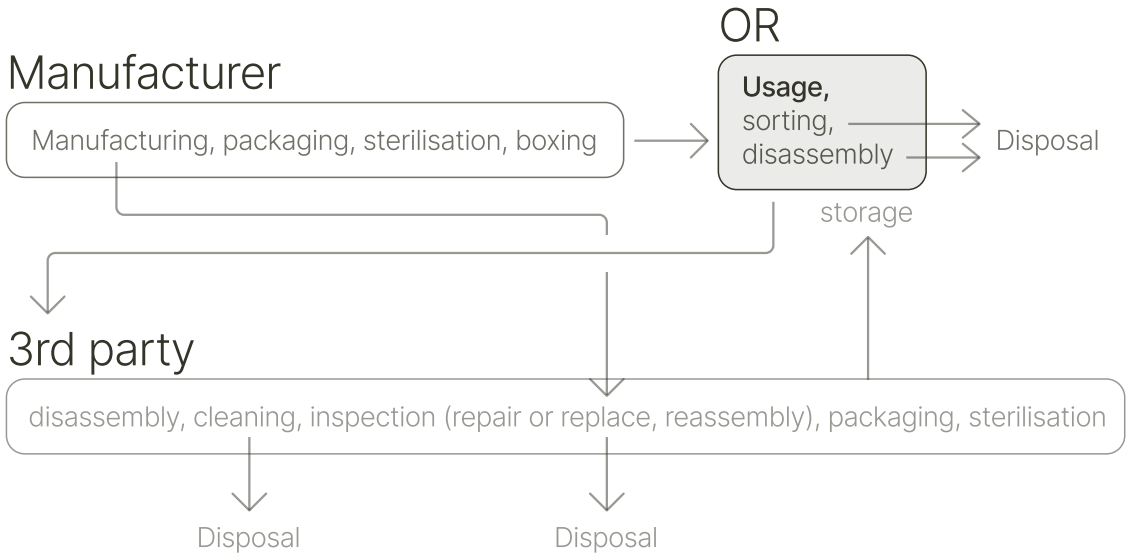



Figure 57. *External reprocessing journey.* Based on Vanguard AG (2025) and Stryker (2024).

(2025), these used products undergo remanufacturing to restore them to a 'like-new' state or to integrate some of their components into new products. This process has different requirements and implications for inflators compared to external reprocessing reusable devices.

Vanguard AG (2025) and Stryker (2024) summarise a detailed remanufacturing procedure for SUDs, which inspired the product journey illustration on Figure 57. This process consists of the following steps:

1. Point of use pre-cleaning. Devices should be cleaned of gross soil and kept moist to prevent it from drying on their surfaces.
2. Inspection & Tracking: Upon arrival, devices are checked for damage or non-reprocessable conditions and assigned a laser-marked unique tracking number. This is similar to LUMC's CSD, where reusable instruments are also laser-marked to indicate that they are already part of the reprocessing system of the hospital.
3. Cleaning: Devices are disassembled, precleaned, washed and disinfected, dried, visually inspected to validate cleanness, and reassembled.
4. Function Testing and Replacement: A mechanical function test is conducted to validate every movement and function of the device, and if necessary, certain components are replaced (as seen in Stryker's reprocessed case studies by Deschamps & Gaudreault (2023)).
5. Packaging & Sterilisation: Products are sealed in Tyvek sterilisation bags (primary packaging), undergo low-temperature sterilisation, have the sterilisation method validated through microbiological testing, and then are placed in secondary packaging (boxing) before being returned to healthcare institutions.

While Vanguard AG (2025) does not specify sterilisation methods, Deschamps and Gaudreault (2023) report that four out of five reprocessed SUDs by Stryker were sterilised with EtO, while the fifth used hydrogen peroxide. The Association of Medical Device Reprocessors (2024) supports using the same sterilisation method as the OEM to maintain substantial equivalency. In the case of inflators, this would be EtO, even though it is highly recommended not to be used by the guidelines and recent policies are trying to reduce its usage.

**Evaluation**

The two remarkable aspects of this circular journey evaluated are that it enables large-scale industrial sterilisation and low-temperature terminal sterilisation methods. Regarding the scale of what this reprocessing could be, the analysis in the first chapter showed that in the Netherlands slightly less than 40000 inflation devices are used for two interventional cardiology procedures per year. A third party can specialise in the reprocessing of certain products and offer these services to several healthcare institutions at the same time.

On the other hand, by not reprocessing within the healthcare institution, the possibility to carry out poisonous and toxic methods such as EtO, or to test the possibilities of new methods such as VHP, can be assessed.

This circular journey also facilitates usage at the OR, since the reprocessed parts of the product are combined and assembled to new disposable components before sterilisation. Therefore, unlike reprocessing with steam, remanufactured inflation devices could arrive to the OR assembled.

This possibility also has some drawbacks. For instance, transport costs and emissions are expected to be higher, controlling and monitoring the devices that leave the hospital is more complicated, and remanufacturing would require spare parts from the manufacturer for replacement or producing those parts independently.

This information is summarised in Table 5.

**External medical device reprocessing**

| ADVANTAGES | DISADVANTAGES |
|---|---|
| • Large-scale reprocessing, suitable for collaborating with multiple healthcare institutions.<br>• The third party can get more specialised in the reprocessing of such a device.<br>• Possibility of low-temperature sterilisation. Even though they are not preferred.<br>• Less work at the OR to assemble everything.<br>• The healthcare institution is no longer responsible for the reprocessing. | • Not focused on steam sterilisation, which is the preferred option for sterilisation by experts.<br>• Higher transport costs and emissions.<br>• Complicated to control and monitor if it depends on an external company. |

Table 5. *Advantages and disadvantages of external reprocessing.*

## 5.4. Journey selection

*RQ5.1. What are the best reprocessing possibilities for inflators?*
*RQ5.2. What circular strategies are best for those reprocessing possibilities?*

*This section aims to choose among the possibilities and give a concrete answer to the research questions to facilitate the next phases of the project.*

Deciding which reprocessing route offers the most effective path toward circular inflation devices is not as straightforward as comparing advantages and disadvantages. A comparative analysis based on economic and environmental factors could provide valuable insights, but it would fail to capture the full complexity of how each approach shapes product design constraints.

Each reprocessing route imposes unique requirements on the redesign of inflation device, impacting material selection, component geometries, assembly and disassembly steps, and the extent to which parts are reprocessed or discarded. These aspects fundamentally alter the product system, as each circular pathway is deeply intertwined with the product's envisioned design.

Given this interdependence, a meaningful comparison between the two circular product-journey systems can only be conducted once their technical feasibility and design implications are thoroughly explored. Moreover, each scenario involves different stakeholders in the reprocessing chain, each with their own incentives, interests, and operational constraints that may favor one approach over the other.

However, this project is limited in time, and although it would be interesting to explore the different routes to a certain level of depth in the development of the concepts, this is beyond the possibilities of the project.

Therefore, to decide on which circular journey and circular strategy to focus on, special relevance is given to the advantages of steam sterilisation from the point of view of safety, sustainability, economics, and how well adapted the current healthcare institutions are to reprocess products with this method. This sterilisation method defines that the project focuses on the redesign for in-house reuse of inflators.

# 06
# VISION AND REQUIREMENTS

This chapter summarises the decisions made based on the research, how those adapt to the initial goal of the project, and the requirements to comply

## 6.1. Vision

The research conducted has led to the decision to focus on redesigning inflators for in-house reuse via steam sterilisation. The project will involve the development of a proof-of-principle prototype for a hybrid inflator, enabling the most valuable components—namely, the manometer, barrel, and plunger—to be reused following reprocessing, while the remaining parts will be discarded. Components designated as single-use include the high-pressure tube, stopcock valve, and O-rings or comparable gaskets.

Feedback from physicians and nurses indicates a strong preference for a user experience closely resembling that of current inflators; consequently, the new device will also incorporate a lock mechanism that engages with a threaded plunger. The lock mechanism itself will be redesigned to allow for disassembly and reassembly, overcoming the limitations of current devices, which are single-use due to their non-detachable construction.

By developing a device with these characteristics, the project aims to validate a new circular product journey for inflators employed in Interventional Radiology and Cardiology.

## 6.2. Requirements

**Requirements to operate safely and provide an experience similar to that of current inflators in the operating room:**

1.1. The materials used for the device must be biomedical and medical grade or biocompatible.

1.2. The device must be able to monitor pressure.

1.3. The pressure measurements must be easy to read.

1.4. The pressure gauge should be luminescent (wish)

1.5. The device must be able to measure at least 28 atm.

1.6. The device must withstand at least 50 atm.

1.7. The device must dispense fluid at a similar ratio to current devices (0,45 to 0,57 mL per full rotation of the handle).

1.8. The device must provide both fast and precise movements of the plunger, sliding and threading it in or out of the barrel.

1.9. The plunger must be threaded.

1.10. The device must have a threaded component (half nut) that engages with the plunger.

1.11. This threaded component must be able to move only within two positions.

1.12. The barrel must be transparent.

1.13. The barrel's transparency should be enough to check it has any air bubbles or blood inside.

1.14. The barrel's transparency should allow checking if there is enough liquid for the inflation of another balloon.

1.15. The barrel must be lubricated prior to use.

1.16. The barrel must have liquid-tight connections for the high-pressure tube and manometer.

1.17. The plunger must have a sealed fit into the barrel.

1.18. The plunger cannot be able to leave the barrel while in use.

1.19. The plunger should have a rounded or semi-rounded knob (wish).

1.20. The actuator should be intuitive, convenient, and user-friendly (wish).

1.21. The actuator should be equally comfortable to operate for both left-handed and right-handed users (wish).

1.22. The material for the barrel, plunger, and mechanism module must have a Young's modulus greater than X.

1.23. The material for the barrel, plunger, and mechanism module must have an ultimate tensile strength greater than X.

1.24. Disposable components must be sterile.

**Requirements to be reprocessed:**

2.1. The device should be intuitive to assemble and disassemble.

2.2. The device must be easy to assemble and disassemble.

2.3. The device should require few steps only for assembly and disassembly.

2.4. The assembly of the device must be secure for use during the procedure so that it does not get disassembled while using it.

2.5. The physician or nurse should be able to complete the preparation for use in surgery steps in less than two minutes.

2.6. Assembly should be completed in less than one minute.

2.7. Dis- and reassembly should be possible to perform without tools (wish)

2.8. The device must have excellent compatibility with fresh water

2.9. The device must have excellent compatibility with weak alkalis

2.10. The device must have excellent compatibility with steam sterilisation

2.11. The device must have enough free surface area to carry the UDI.

2.12. Reusable components must have enough surface area to have an individual identifier.

2.13. Every surface of the reusable components must be possible to decontaminate.

2.14. Reusable components should not have shadowed areas so that the decontamination agents can reach everywhere and staff can visually inspect the device (wish).

2.15. Reusable components should facilitate both manual and mechanical cleaning (wish).

2.16. Hinges, sharp ends, and additional serrations or screws to the threaded plunger and half nut should be avoided. Moving parts should have space in between them to allow the de-contamination agents to pass between them (wish).

2.17. Blind, long, and narrow lumens must be avoided.

2.18. The number of small parts should be minimal so as not to lose them (wish).

**Sustainability requirements:**

3.1. The most valuable components (manometer, barrel and plunger) should be reused (wish).

3.2. The reusable components should be optimised to last for more reprocessing cycles (wish).

3.3. The materials chosen for the reusable components of the device should be possible to re-cycle (wish).

# 07
# CONCEPT EXPLORATION

This chapter describes the exploration and evaluation of solutions for the target parts of a reusable inflator.

## 7.1. Target parts. Approach

This chapter focuses on the exploration of reusable steam sterilisable possibilities that can withstand high pressures for the pressure gauge, cylinder, plunger and locking mechanism. The first step is to explore the possibilities available on the market for each of these critical components.

The pressure gauges are complex parts whose redesign would be beyond the scope of this project. For the redesign of the barrel, the plunger and the parts that would make up the lock mechanism, it is interesting to carry out a study of the materials compatible with the circular journey through which they would have to pass.

## 7.2. Pressure gauges

In Chapter 2, the principal types of pressure gauges were described, including their measurement mechanisms—such as the Bourdon tube and diaphragm (see Figure 58)—and whether they operate via analogue dials or digital sensors.

A review of products from leading manufacturers in the food and pharmaceutical sectors revealed that, while some companies offer hygienic and decontaminable gauges, these are intended for industrial use and rely on Clean In Place (CIP) and Sterilisation In Place (SIP) systems. These methods focus exclusively on cleaning the gauge surfaces that contact the measured fluid, with diaphragm-based gauges commonly employed to avoid internal contamination. In the context of endovascular procedures, however, it is essential that all surfaces, including the exterior, are fully sterilised—a standard not achieved by CIP and SIP alone.

Only a few manufacturers provide autoclavable pressure gauges capable of withstanding pressures up to 40 atmospheres. For instance, WIKA's steam-sterilisable analogue manometers (PG43SA-C, PG43SA-D, and PG43SA-S)

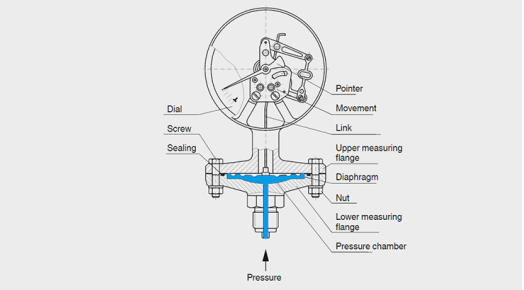



Figure 58. *Interiors of a diaphragm pressure gauge. The liquid does not go inside the gauge* (WIKA, 2025).

Figure 59. *Tri-Clamp connector used for pressure gauges with diaphragms*.

use diaphragm seals and robust materials such as polysulfone and stainless steel (WIKA, 2023), but their maximum pressure ratings are 10, 16, and 16 atmospheres, respectively, with the PG43SA-S priced between €578.47 and €912.17, depending on how they are connected (WIKA, 2024).

Anderson-Negele's EM and ASHCROFT's 1032 Sanitary Pressure Gauge models are capable of measuring up to 40 bar, are steam-sterilisable, comply with 3A sanitary standard 74, and can be used with a standard Tri Clamp 1½" connection weighing 450 g (see Figure 59 for the connector). Figures 60 and 61 provide visual and dimensional details: the EM gauge has a 90 mm round dial and an overall height exceeding 100 mm, with the Tri Clamp connection measuring 50.5 mm in diameter (Anderson-Negele, 2022). The 1032 gauge has a 98 mm round dial and a total height of 140 mm.

The EM gauge itself costs approximately €585. For that price, Anderson-Negele is not able to give the specific number of cycles which the device can handle (personal communication, May 2, 2025).

By contrast, disposable gauges are far lighter (typically 50 g or less), with a 40 mm face and a 10 mm threaded connection. Accordingly, the Anderson-Negele solution would likely result in a significant and probably adverse change to the user experience for clinical and sterile services staff.

Baumer Electric (2017) developed the PBMH autoclavable pressure transmitter, which could also fit the requirements of this exploration of pressure gauges. However, they give indications about how sensitive the diaphragm

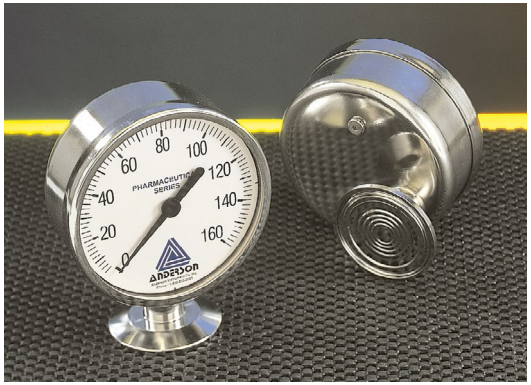



Figure 60. *Anderson-Negele EM model pressure gauge.*

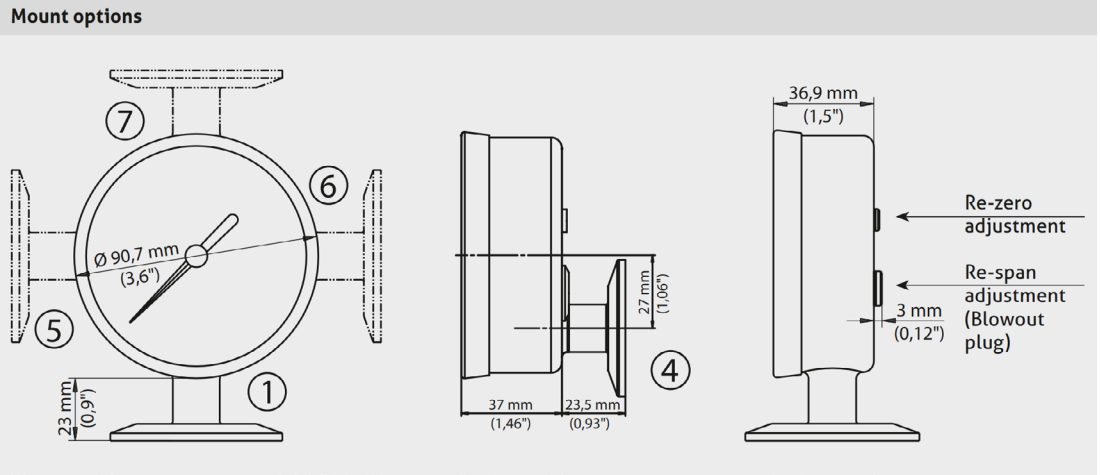



Figure 61. *Anderson-Negele EM model pressure gauge mount options and dimensions.*

solution is. The diaphragm could get damaged if it were touched with solids or direct water jets. Damage to the diaphragm would probably mean that the gauge cannot be used anymore. Maybe sending it back to Baumer for their repair would be a possibility. But this part would be too critical for the reprocessing journey of a device at the healthcare institution. It would have to be constantly assembled and disassembled, passed from one tray to another, transported around the hospital, and then decontaminated with the utmost care. Anderson-Negele (personal communication, May 2, 2025) also indicates that the diaphragm is the most fragile component and, even if the gauge is suitable for the application, care would have to be taken when handling it.

In conclusion, for these prices, dimensions and with so much sensitivity in the diaphragm, autoclavable pressure gauges are not a viable option for inflators. Instead, single-use pressure gauges will have to be used for redesign.

## 7.3. Syringes (barrel and plunger)

This section aims to see if there are syringes on the market that meet the requirements of the project. A syringe is composed of a barrel and a plunger, plus usually a gasket or o-ring. A transparent syringe, reusable by steam sterilisation, used in the medical field, capable of withstanding more than 30 atm and with a capacity greater than 20 mL could be used to incorporate it partially or completely in the redesign of the inflators.

There are syringes with lower capacity that meet the rest of the requirements (Hamilton Company, 2025b). There are borosilicate glass and polymethylpentene (PMP) syringes with the required capacity, but which do not withstand such high pressures (Poulten & Graf, 2025; Hamilton Company, 2025; Ardes, 2014). And there are stainless steel syringes that only do not meet the requirement of being transparent (Cetoni, 2017; Harvard Apparatus, n.d.). But there are no syringes that meet all the requirements.

The Cetoni (2017) syringe design is particularly noteworthy for its facilitation of disassembly and O-ring replacement (refer to Figures 62 and 63). The plunger is separated into three parts: the plunger body, which ends in a threaded section; the piston tip, which accommodates the O-rings and contains a female thread for attachment to the plunger; and a sleeve positioned between the plunger and piston to secure the O-rings. Furthermore, a mounting aid is used to ensure the O-ring is uniformly fitted onto the piston.

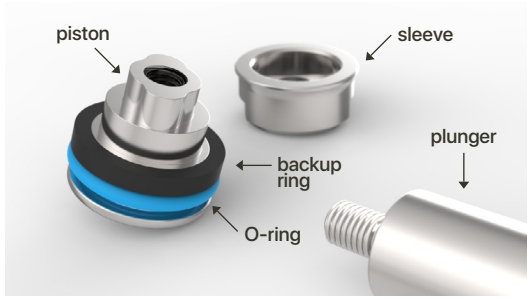



Figure 62. *Three components of Cetoni's (2017) plunger, plus the O-rings.*

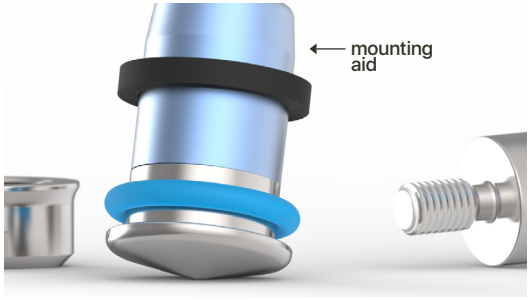



Figure 63. *Three components of Cetoni's (2017) plunger, plus the O-rings.*

## 7.4. Material compatibility. Barrel

This design is optimised to avoid damaging the O-rings during the repeated assembly and disassembly required for reprocessing, as the FKM Viton O-rings used in their syringes are resistant to steam sterilisation.

For reusable inflator designs, it will be necessary to frequently remove and replace a single-use O-ring. Thus, a design that minimises damage to both the plunger and the O-ring, requires few additional tools, and maintains O-ring performance is of particular interest. For example, O-rings can be removed with any plastic or metal spatula (as long as it has rounded edges, so it won't cut into the O-ring or the plunger).

As there are no existing barrels in the market suitable for the chosen circular journey, the barrel is to be redesigned to propose a reusable barrel option that aligns with this circular journey. Then, a new material has to be chosen for the barrel that must demonstrate a level of performance during use that is at least equivalent to, if not exceeding, that of the polycarbonate barrels currently utilised in inflators, while facilitating repeated reprocessing for use with different patients and compatibility with the cleaning and sterilisation techniques. Polycarbonate is not considered appropriate for the intended reusable product pathway due to its limited resistance to steam sterilisation.

The performance of existing barrels is influenced by factors including material selection, thickness, geometry, and manufacturing technique, with current barrels produced from injection-moulded polycarbonate. Any candidate material should exhibit Young's modulus and tensile strength values at least equal to those of polycarbonate, ensuring reliable performance under operational pressures and minimising the risk of mechanical failure.

A high Young's modulus ensures minimal deformation under pressure, maintaining barrel geometry and preventing leaks due to ovalisation. Tensile strength defines the maximum stress the material can withstand before breaking; the barrel must endure internal pressure without rupture or leakage, noting that rupture in a liquid-filled barrel would not result in explosive failure, unlike with air.

Material comparison was conducted using the Level 3 Bioengineering database from Granta EduPack 2024 R2 (Granta Design, 2024), which catalogues 57 polycarbonate compositions, some blended with other materials (e.g., glass fibre, carbon fibre, PTFE, silicone, stainless steel fibre), often resulting in opacity.

Filtering was performed based on biomedical suitability, medical grade (USP Class VI, ISO 10993), resistance to ethylene oxide sterilisation, and transparency, as detailed in Table 6.

Only three thermoplastics with a polycarbonate base met all criteria: "PC (copolymer, heat resistant)", "PC + Polyester transparent amorphous (impact modified)", and "PC + PPC (Unfilled)". The latter two are blends. Manufacturers generally cite only polycarbonate as the material for their barrels, suggesting the use of "PC (copolymer, heat resistant)". This materi-

al is the most prevalent in the database (204 tradenames), is the only one with FDA-approved and registered medical devices, and demonstrates the best mechanical properties, with the highest average Young's modulus and only a slightly lower ultimate tensile strength than "PC + PPC (Unfilled)". Consequently, the average values of Young's modulus and tensile strength for "PC (copolymer, heat resistant)" are adopted as the constraints for evaluating candidate materials for the redesigned barrel.

The polycarbonate under consideration exhibits an average Young's modulus of 2.3 GPa and an average tensile strength of 62.8 MPa. The complete technical data sheet for this material is provided in Appendix X. It is also noted therein that the polycarbonate demonstrates excellent compatibility with ethylene oxide (EtO) sterilisation, while its resistance to steam sterilisation is only marginal, as classified within the scale of poor < marginal < good < excellent.

Another relevant aspect of this circular product journey, as reflected in Table 7, is the material's durability against weak alkalis, since the chemical agents or detergents employed in

| ATTRIBUTE | CONSTRAINTS | EXPLANATION |
|---|---|---|
| Biomedical materials | Yes | Used in medical applications, including medical devices. Compatible with the human body and manufactured under clean conditions. |
| Medical grades (USP Class VI, ISO 10993) | Yes | ASTM or ISO medical standard for the material.<br>Or used in FDA-approved implantable medical device.<br>Or certified for biocompatibility by compliance with ISO 10993-1 or USP (United States Pharmacopoeia) Class VI. |
| Transparency | Transparent | Very good transparency though may be inherently tinted. |
| Sterilisability (EtO) | Good | Usually satisfactory: multiple sterilisation cycles normally possible; one or more problems for unsuitability with EtO may need to be controlled. |
| | Excellent | Nearly always satisfactory: no problems for unsuitability usually apply. |

Table 6. *Selection criteria to filter out the polycarbonate used in inflators.* Data extracted from Granta Design (2024).

cleaning are mildly alkaline and may corrode certain materials. The polycarbonate in question possesses merely acceptable resistance to immersion in weak alkalis, implying that additional protective measures may be required during each cleaning cycle.

Consequently, the polycarbonate currently utilised for inflator barrels is considered unsuitable for the envisioned circular product pathway. Table 7 outlines the selection criteria applied to identify suitable materials for the barrel.

After filtering the database according to these constraints, only six materials out of 4339 candidates emerge as potential solutions: three ceramics — "Alumina (99.9%) (translucent)", "Alumina bio-ceramic", and "Zirconia bio-ceramic" — and three thermoplastics — "PEI (unfilled)", "PPSU (unfilled)", and "PSU (extrusion and injection moulding)".

Table 8 presents a comparative analysis of these six materials, using "PC (copolymer, heat resistant)" as the reference. The materials are evaluated based on parameters previously employed in Table 7, as well as additional criteria such as price, environmental indicators,

| ATTRIBUTE | CONSTRAINTS | EXPLANATION |
|---|---|---|
| Biomedical materials | Yes | Used in medical applications, including medical devices. Compatible with the human body and manufactured under clean conditions. |
| Medical grades (USP Class VI, ISO 10993) | Yes | ASTM or ISO medical standard for the material. Or used in FDA-approved implantable medical device. Or certified for biocompatibility by compliance with ISO 10993-1 or USP (United States Pharmacopoeia) Class VI. |
| Young's modulus | Higher than 2,3 GPa | Average value of PC copolymer, heat resistant. |
| Tensile strength | Higher than 62,8 MPa | Average value of PC copolymer, heat resistant. |
| Transparency | Transparent | Very good transparency though may be inherently tinted. |
| Water (fresh) | Excellent | Resistance to submersion in fresh water. Excellent means no degradation in material performance is expected after long term exposure. |
| Weak acids | Excellent | Resistance to submersion in weak alkalis (pH between 7 and 10). Excellent means no degradation in material performance is expected after long term exposure. |
| Sterilisability (steam autoclave) | Excellent | Nearly always satisfactory: typically >100 sterilization cycles. |

Table 7. *Selection criteria to filter out what materials are feasible for the barrel.* Data extracted from Granta Design (2024).

end-of-life considerations, and usage in existing medical devices. No significant differences were observed among the materials regarding environmental indicators for the production of virgin and typical grade materials; thus, only data on virgin grade production are included. Environmental indicators related to polymer moulding are most pertinent for thermoplastics, given that injection moulding is the prevailing and likely optimal manufacturing method for new barrels.

All six candidate materials surpass polycarbonate in both Young's modulus and tensile strength, indicating their viability for surgical performance without failure. However, the data provided by Granta Design (2024) do not permit the ceramic options to be considered as practical alternatives.

### Ceramics

Ceramics are notable for their extraordinary mechanical properties, which in some cases exceed those of stainless steel 316L. For instance, alumina (99.9%) possesses a Young's modulus 170 times greater than that of polycarbonate, while zirconia exhibits an ultimate tensile strength 12 times higher.

These ceramics also have a lower environmental footprint and embodied energy than polycarbonate during primary production. Alumina (99.9%) alone allows for functional recycling, and the database documents the use of zirconia and alumina bio-ceramic in orthopaedic and dental applications.

Nevertheless, the cost of ceramics is substantially higher than that of polycarbonate and more cost-effective alternatives such as PEI and PSU, with zirconia being twice as expensive as PSU and aluminas more than three times as costly.

Moreover, ceramics exhibit significantly greater density — 3.4 times for aluminas and 5.1 times for zirconia — potentially impacting ergonomics, comfort, and performance in surgical use.

Furthermore, ceramic processing involves multiple stages, including shaping, sintering, and secondary processing such as grinding or machining. Granta Design (2024) only provides data on the environmental impact and energy consumption of grinding, which are extremely high and diminish the advantages of ceramics' primary production impact. The lack of comprehensive processing data impedes a fair comparison with thermoplastics and prevents ceramics from being considered viable alternatives for the barrel.

### Thermoplastics

The Harris profile depicted in Figure 64 offers a visual representation of the data in Table 8. Unlike standard Harris profiles, where parameters are ordered by weight, this profile follows the sequence described in Table 8 for improved cross-referencing. The image, therefore, requires careful interpretation.

Overall, the Harris profile reveals that PPSU performs least favourably, being the most expensive, with less impressive mechanical properties and an embodied energy higher than the other thermoplastics. PSU emerges as the most advantageous, being slightly less expensive than PEI and possessing marginally lower embodied energy, though both exceed that of polycarbonate. PSU is only inferior to PEI in terms of the number of sterilisation cy-

| | PC (copolymer, heat resistant) | Alumina (99.9%) (translucent) | Alumina bio-ceramic | Zirconia bio-ceramic | PEI (unfilled) | PPSU (unfilled) | PSU (extrusion and injection molding) |
|---|---|---|---|---|---|---|---|
| **General information** | | | | | | | |
| Biomedical materials | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| **Price** | | | | | | | |
| Price (EUR/kg) | 3,2 | 37,3 ⇧ | 34 ⇧ | 20,6 ⇧ | 14,3 ⇧ | 49,6 ⇧ | 10,8 ⇧ |
| **Physical properties** | | | | | | | |
| Density (kg/m^3) | 1160 | 3990 ⇧ | 3950 ⇧ | 5870 ⇧ | 1270 ⇧ | 1290 ⇧ | 1240 ⇧ |
| **Mechanical properties** | | | | | | | |
| Young's modulus (GPa) | 2,3 | 393 ⇧ | 390 ⇧ | 208 ⇧ | 2,96 ⇧ | 2,34 ⇧ | 2,69 ⇧ |
| Tensile strength (MPa) | 62,8 | 284 ⇧ | 514 ⇧ | 798 ⇧ | 96,5 ⇧ | 69,6 ⇧ | 99,1 ⇧ |
| **Optical, aesthetic and acoustic properties** | | | | | | | |
| Transparency | Transparent | Transparent | Transparent | Transparent | Transparent | Transparent | Transparent |
| **Healthcare & food** | | | | | | | |
| Medical grades? (USP Class VI, ISO 10993) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Sterilizability (steam autoclave) | Marginal | Excellent ⇧ | Excellent ⇧ | Excellent ⇧ | Excellent ⇧ | Excellent ⇧ | Excellent ⇧ |
| **Critical materials risk** | | | | | | | |
| Contains >5wt% critical elements? | No | Yes ⇩ | Yes ⇩ | No | No | No | No |
| **Processing properties** | | | | | | | |
| Polymer injection molding | Excellent | | | | Acceptable ⇩ | Acceptable ⇩ | Acceptable ⇩ |
| **Durability** | | | | | | | |
| Water (fresh) | Excellent | Excellent | Excellent | Excellent | Excellent | Excellent | Excellent |
| Weak alkalis | Acceptable | Excellent ⇧ | Excellent ⇧ | Excellent ⇧ | Excellent ⇧ | Excellent ⇧ | Excellent ⇧ |
| **Environmental indicators - primary production** | | | | | | | |
| Climate change (CO2-eq), primary production (virgin grade) (kg/kg) | 5,18 | 2,81 ⇩ | 2,81 ⇩ | 4,39 ⇩ | 11,1 ⇧ | 12,7 ⇧ | 10,2 ⇧ |
| Embodied energy, primary production (virgin grade) (MJ/kg) | 114 | 52 ⇩ | 52 ⇩ | 61,7 ⇩ | 207 ⇧ | 233 ⇧ | 191 ⇧ |
| **Environmental indicators - processing** | | | | | | | |
| Polymer molding energy (MJ/kg) | 21,7 | | | | 28,3 ⇧ | 27 ⇧ | 25,6 ⇧ |
| Polymer molding CO2 (kg/kg) | 1,63 | | | | 2,12 ⇧ | 2,02 ⇧ | 1,92 ⇧ |
| Polymer molding water (l/kg) | 16,4 | | | | 19,6 ⇧ | 19 ⇧ | 18,3 ⇧ |
| Grinding energy (per unit wt removed) (MJ/kg) | 14,6 | 161 ⇧ | 228 ⇧ | 66,8 ⇧ | 24,3 ⇧ | 10,8 ⇩ | 30,6 ⇧ |
| Grinding CO2 (per unit wt removed) (kg/kg) | 1,09 | 12,1 ⇧ | 17,1 ⇧ | 5,01 ⇧ | 1,82 ⇧ | 0,81 ⇩ | 2,3 ⇧ |
| **Recycling and end of life** | | | | | | | |
| Recycle | ✓ | ✓ | ✗ | ✗ | ✓ | ✓ | ✓ |
| Functional recycle | ✗ | ✓ | ✗ | ✗ | ✗ | ✗ | ✗ |
| Combust for energy recovery | ✓ | ✗ | ✗ | ✗ | ✓ | ✓ | ✓ |
| **Links** | | | | | | | |
| FDA Approved Examples | 1 | 0 | 8 | 1 | 0 | 0 | 0 |
| Medical Devices | 5 | 0 | 10 | 8 | 0 | 1 | 1 |

Table 8. *Comparison of the six possible materials for the redesign of the barrel, relative to the PC, based on data from Granta Design (2024). The numerical values are given in averages. A 10% change from the PC data is highlighted in orange.*

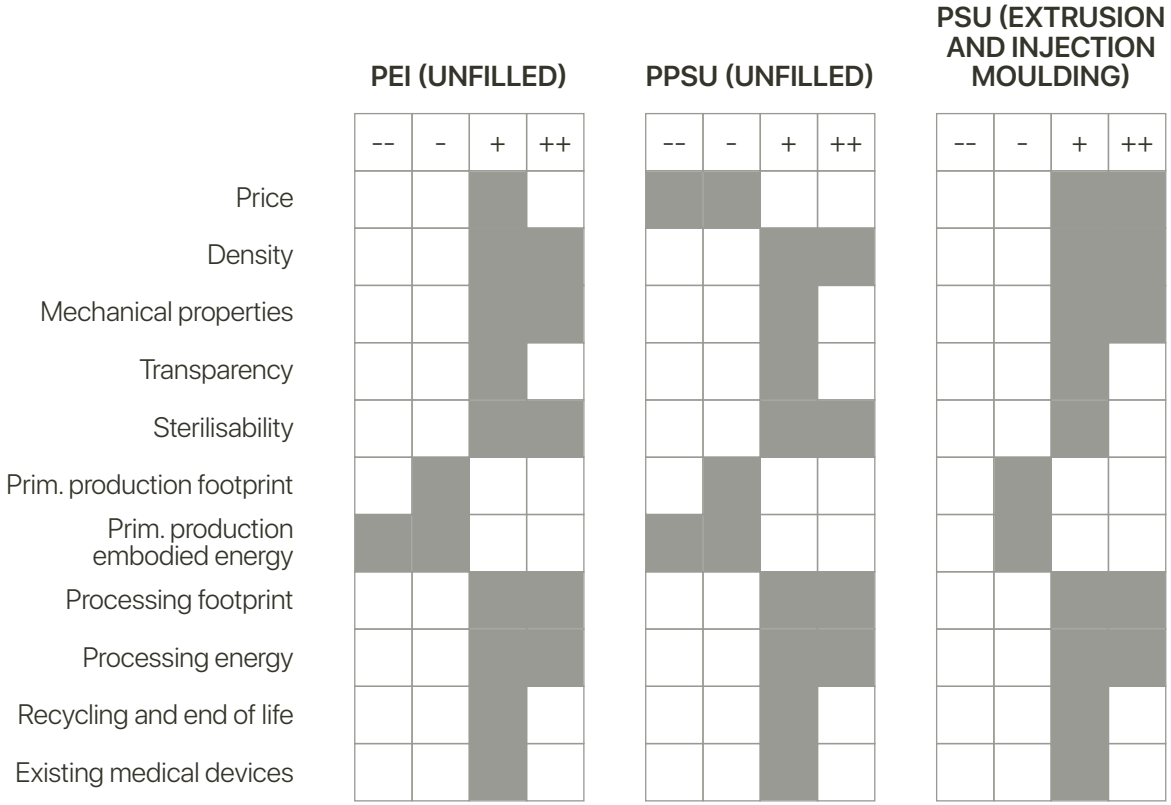



Figure 64. *Harris profile comparison of the three possible thermoplastics for the redesign of the barrel, relative to the PC, based mainly on data from Granta Design (2024), with extra sources to assess the transparency and sterilisability. The importance of the parameters is not reflected in their vertical arrangement. This arrangement is defined to follow a structure similar to that in Table 8.*

cles it can withstand. PEI performs comparably to PSU in most respects.

Although Table 8 indicates that only PSU and PPSU are used in medical products (e.g., surgical trays), PEI is also employed for the Indusbello Sterilisation Tray (SABIC, 2016), as shown in Figure 65.

Both PEI and PPSU excel in their ability to endure over 1,000 steam sterilisation cycles without degradation. PEI ULTEM™ resins, including HU1000, HU1004, and HU1010, are biocompatible, unfilled, and stable after more than 1,000 cycles at 134°C (SABIC, 2023; SABIC, 2025), with the base material being transparent amber (though it can also be fully transparent). Figure 66 illustrates the tinted appearance of HU1010, which intensifies with wall thickness.

Radel® PPSU resists over 1,000 cycles without significant loss of mechanical properties (Solvay, 2017), though the transparent grade R-5000 is amber-tinted and undergoes noticeable colour change (Solvay, 2014). In comparison, Udel® PSU withstands 500 cycles, but exhibits significant changes in its proper-

ties (Solvay, 2017; 2018), and transparent versions such as P-1700 NT11 show even greater colour change than PPSU (Solvay, 2018).

PEI and PPSU are thus better aligned with the project objective of enhancing circularity through redesign for reuse and extended service life, as they tolerate more sterilisation cycles than PSU. Selecting a barrel material with higher cycle tolerance is essential to avoid limiting the product's lifespan. As PEI outperforms PPSU in other parameters, polyetherimide (unfilled) is identified as the optimal sustainable alternative for the inflator barrel.

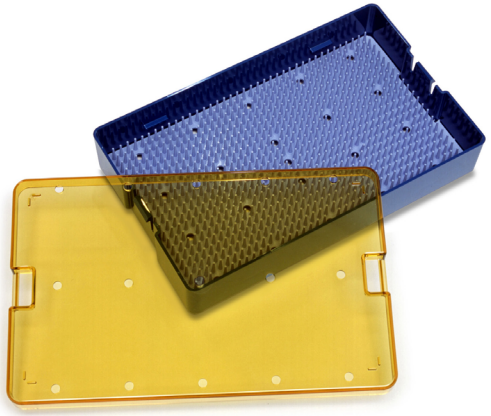


Figure 65. *Indusbello Sterilization Tray, that uses PEI ULTEM™ HU1004 resin* (SABIC, 2016).

Figure 66. *Transparency of a product using PEI ULTEM™ HU1010 resin* (CNDO ENGINEERING LIMITED, n.d.).

## 7.5. Material compatibility. Plunger and mechanism

For the rest of the parts of the device (the plunger and lock mechanism), which do not have the limitation of transparency but still have to withstand the high pressures generated, metals are chosen a priori, specifically Stainless Steel 316L.

The end of life of metallic surgical devices is normally determined by wear and damage due to the surgical use for which they are intended (Ambler, 2023). Most reusable surgical instruments are made of stainless steel, specifically stainless steel 316L, because of the combination of its great mechanical properties, corrosion resistance, ease of cleaning, availability, and cost-effectiveness (Ford & Phillips, 2014; Xavier et al., 2022; (Newson, 2002).

316L stainless steel has a Young's modulus almost 100 times higher than PC and tensile strength almost 10 times higher. In terms of price, 316L stainless steel is about twice as expensive as PC. Using SS 316L for the plunger can make not only the product last by withstanding the pressure, but also its threads can withstand the rough encounters with the threads of the half nut.

The weight of the stainless steel could pose an ergonomic problem for doctors or nurses. It could also bring qualities to the product such as robustness and transmit safety. Once the prototypes have been developed, it will be possible to check whether the weight is a limitation and other materials such as PEEK, other thermoplastics or other metals will have to be sought to reduce the weight without compromising the mechanical properties of the parts, the pressure they can withstand, or the number of steam sterilization cycles they can withstand.

For all these reasons, it is decided to think about what a reusable inflator could look like considering the plunger and possibly the mechanism to be made of stainless steel.

## 7.6. Ideation and conceptualisation

The ideation phase started with the objective of exploring solutions to two distinct issues.

The first issue concerned the optimal method for attaching the lock mechanism module to the barrel, with considerations including ease of assembly and disassembly, minimisation of component count for improved cleanability, and the capacity to endure substantial mechanical loads. Four potential approaches were identified: threaded connections, bayonet fittings, snap-fits, and clamps.

Upon preliminary assessment, snap-fits were disregarded. Achieving the required flexibility for secure engagement would be impractical with metals if they also had to be thick to resist the pressure.

Clamps were also considered unsuitable due to the complexity introduced by multiple small components and the associated time required for assembly, even though this method might offer superior security.

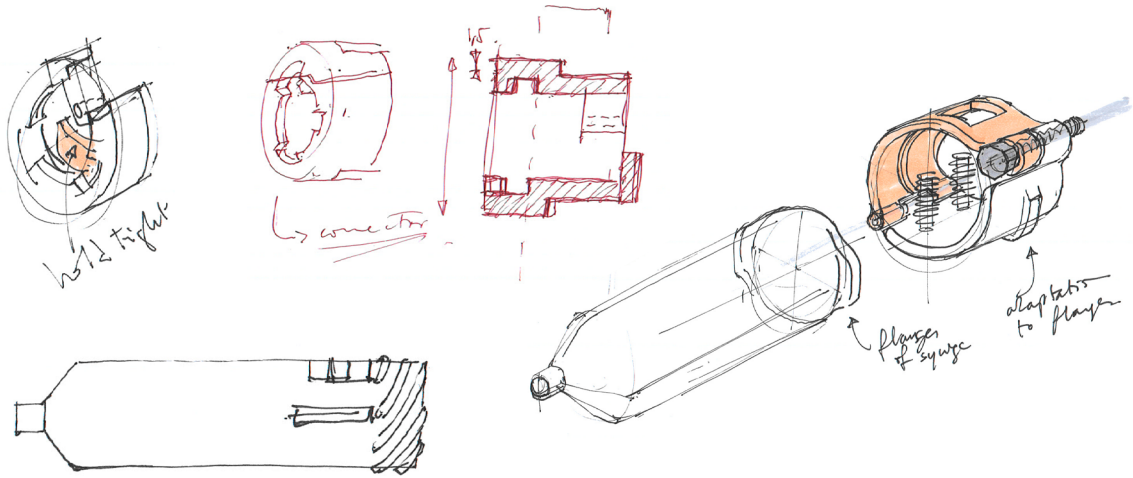


Figure 68. *Some ideation sketches regarding the first issue: connectors.*

For all these reasons, it is decided to think about what a reusable inflator could look like considering the plunger and possibly the mechanism to be made of stainless steel.

The second issue involved the development of quick-release mechanisms that would facilitate straightforward assembly and disassembly, while ensuring the half nut could only move between two predetermined positions. An additional design constraint was the exclusion of springs, as their diminutive size would prevent the application of traceability codes required for the decontamination process.

Figure 68 shows ideation sketches of a bayonet connector, a clamp system, and a threaded barrel.

Figures 69, 74, and 78 show sketches that explore three concepts on how to build such mechanisms.

**Concept 1. Overcentre mechanism**

This concept is inspired by the Encore 40 or QL inflator. It tries not to use springs by having an overcentre mechanism with components that can be assembled and disassembled. Figure 70 once more shows the working principle of an overcentre mechanism, as developed for the Encore 40. It includes a half nut that can be rotated relative to the longitudinal axis of the barrel, a connector that engages with the barrel and limits the movement of the half nut, a pivoting element that allows the half nut to rotate with respect to the connector, and a threaded plunger.

Three ways of assembling this solution were explored. These three versions focus on reducing the number of parts that the disassembly can start with, as that could lead to more ways to have failures in the disassembly. The three versions are presented in Figure 71.

The chosen version to evaluate this concept against concepts 2 and 3 only has one way to start the disassembly, connecting the connector to the barrel. The pivoting axis is trapped between the connector and the half nut. And it reduces the amount of material used compared to the other two versions. Figures 72 and 73 show this final version chosen and its main components disassembled.

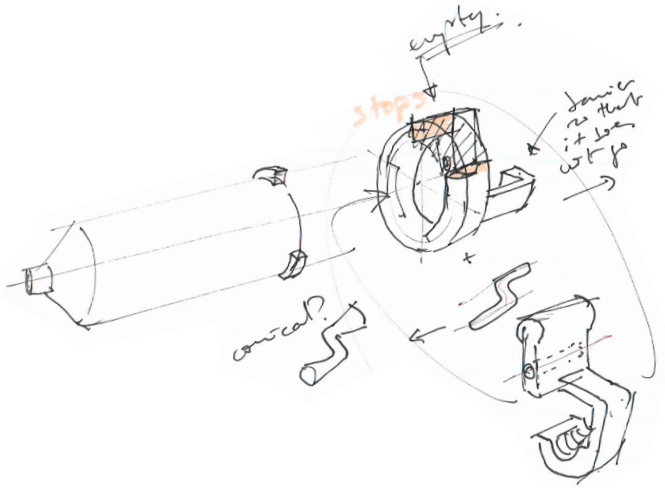


Figure 69. *Ideation sketch of Concept 1, inspired in the Encore 40 or QL inflator.*

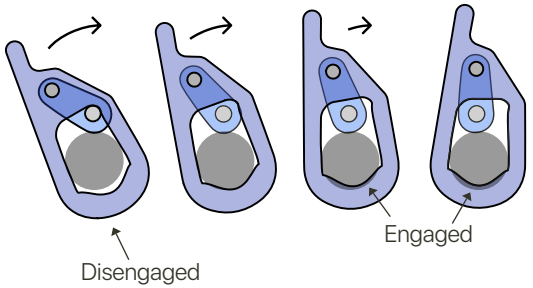



Figure 70. *Overcentre mechanism working principle as designed for the Encore 40. It allows progressive rotational movement of the half nut and link members with respect to the pivot pin, from a disengaged to an engaged position.*

Figure 71. *Three working versions of Concept 1 that can be disassembled.*

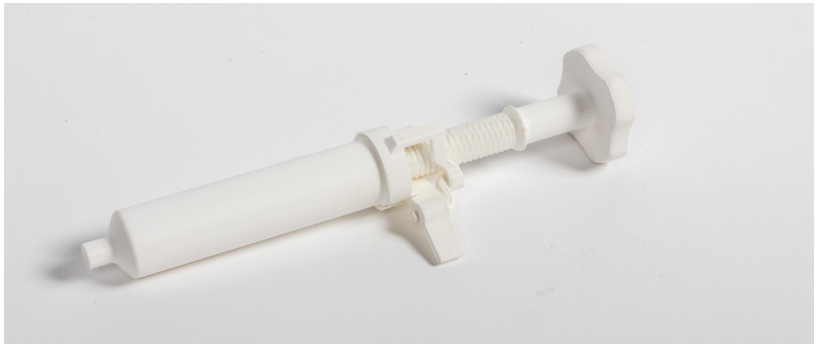


Figure 73. *Chosen version of Concept 1, assembled.*

Figure 72. *Chosen version of Concept 1, disassembled. The lock mechanism needs three parts to be connected to the barrel and work properly.*

### Concept 2. Gearshift mechanism

This concept sparked thanks to two thoughts: how not to use springs and instead have a guided system that would allow the user to move the actuator into defined positions only. And how to translate horizontal movement into vertical movement of the half nut, so that it can engage and disengage easily. Both thoughts became interdependent while developing this concept. It proposes a mechanism that is actuated by sliding a stick, similar to a gearshift, through a guided configuration of possible positions.

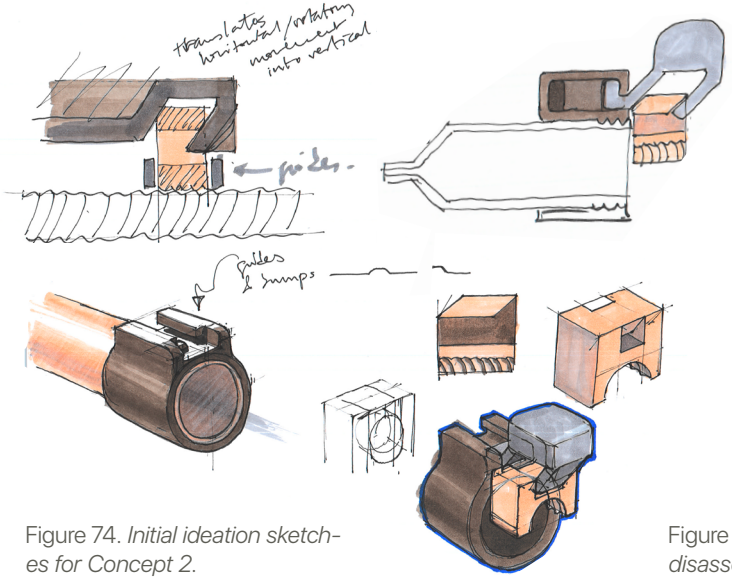



Figure 74. *Initial ideation sketches for Concept 2.*

Figure 75. *Concept 2 disassembled. The lock mechanism is designed using three parts only.*

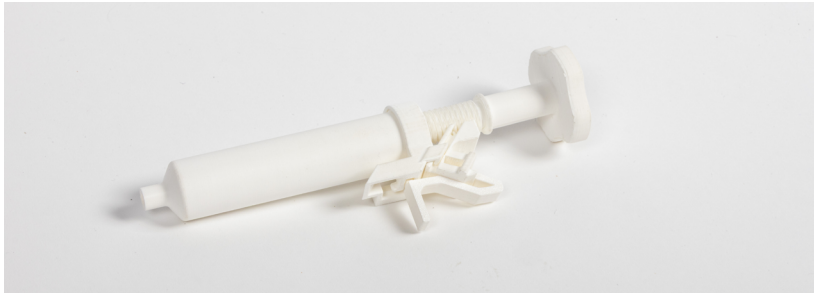


Figure 76. Final version of *Concept 2, assembled, as used for the evaluation of the concepts.*

Figure 77. Details of the concept.

Figure 78. *Concept 2 disassembled. The lock mechanism is designed using three parts only.*

### Concept 3. Spring mechanism

This concept uses springs and proposes a similar interaction with a button to be pressed to the experience of the Encore 26 inflator. The main considerations for this concept were how to restrict the movement of the half nut, whether or not to divide the half nut in half, to allow for better assembly, and whether or not to change the shape of the barrel to have the half nut assembled inside. After iterations were made with springs, a final version of this concept for the evaluation was developed with a flat spring. This spring was introduced as a way of reducing the risk of losing small springs throughout the reprocessing. Also, the flat spring was developed so that it could be press-fitted and secured with an extra pin to the half nut, thereby reducing the number of parts needed for the concept. Finally, the connector to the barrel is assembled after the half nut, and allows the plunger to go into the barrel with its piston assembled.

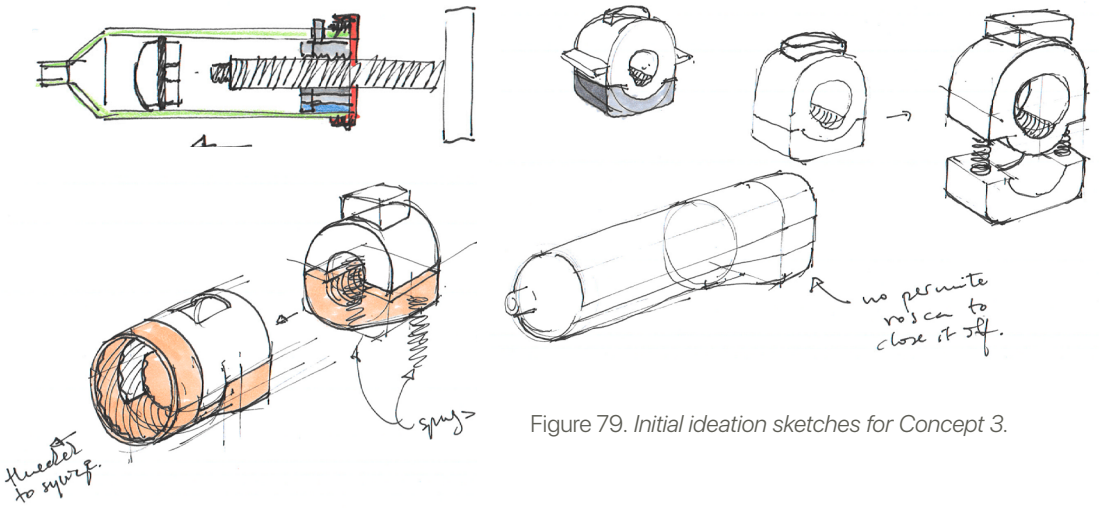



Figure 79. *Initial ideation sketches for Concept 3.*

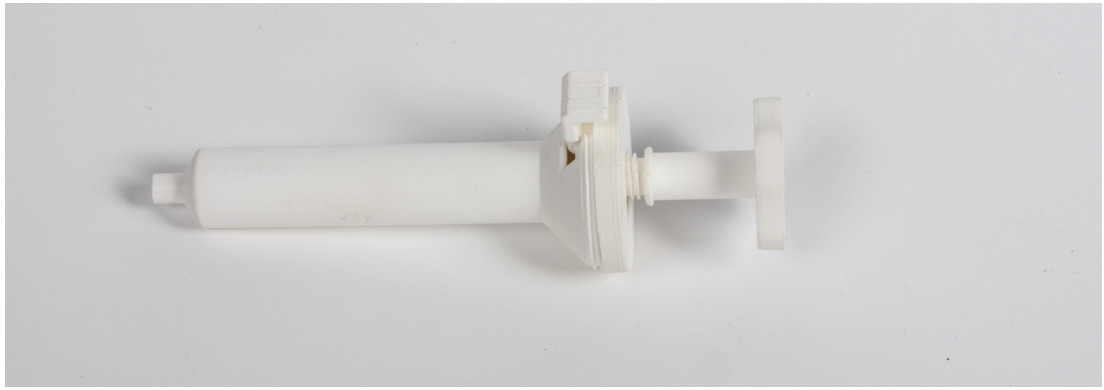


Figure 80. Final version of *Concept 3, assembled, as used for the evaluation of the concepts.*

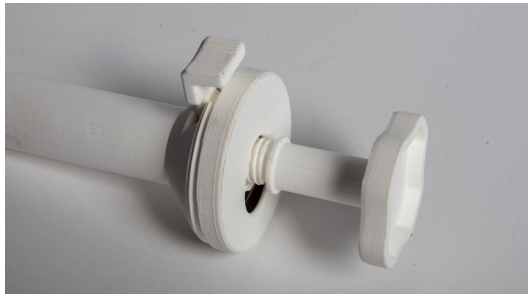


Figure 81. Details of the concept.

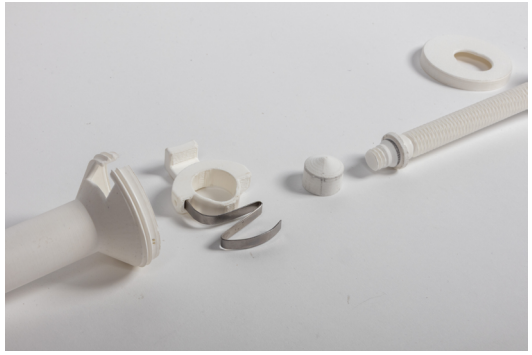


Figure 83. Details of the concept.

Figure 82. *Concept 2 disassembled. The lock mechanism is designed using two parts only.*

## 7.7. Concept evaluation

These concepts were evaluated using three parameters: ease of use, ease of assembly and disassembly, engineering feedback, and reprocessing feedback. It would have also been interesting to evaluate them based on pressure simulations using CAD models to determine if the concepts passed the 50 atm of pressure requirement. Basic environmental and economic performances based on the embodied footprint and the prices of the materials could have also helped to have a better argument for what concept to choose. However, time was limited in this project, and the rest of the parameters provided a clear preferred solution. The pressure resistance is a critical requirement, but it was considered that, thanks to the materials chosen, the concepts could be able to withstand the pressure. Also, the shapes and thicknesses could have been forever optimised to have a fair comparison between the concepts.

### Ease of use and ease of assembly and disassembly

The evaluation of the concepts on ease of use and ease of assembly and disassembly was performed with a total of 6 fellow students. The assembled concepts were presented to the participants.

They were asked for intuitiveness of the working principles, on a scale from 1 to 5 (1. Would struggle with instructions, 2. Can't find out. Would need instructions, 3. Don't know. Play around and guess, 4. Not sure with your guess, 5. Confident with your guess). Intuitiveness is important for the ease of use, to have the nurses and physicians be able to operate the products without much need for instructions. The participants were able to see and grab the concepts, but not interact with their mechanism.

Concept 3 (spring) performed as the most intuitive with almost all fives (4,8 on average). Some participants said that covering the internal workings of the mechanism made it look simpler, easier to understand and use. Then, concept 1 (overcentre) got an average of 3,7 out of 5, and concept 2 (gearshift) got an average of 3,3 out of 5. Concept 2 (gearshift) was often referred to as a labyrinth. Comments said it looked complex and too much like if done from a mechanical engineering perspective. About concept 1 (overcentre), participants

Figure 84. Concept 1 (overcentre) being evaluated with a student on ease of dis- and reassembly, and ease of use.

could guess that something would move, but it was not clear what to move, how to move, or how it would move.

After that, it was explained to them how each concept was disassembled and assembled while performing the assembly and disassembly. This tried to simulate the Instructions for Use explanation that nurses, physicians, and staff from the sterilisation departments would have with them when facing disassembly and reassembly. After each concept was presented, the participants were asked to dis- and reassemble the devices five times. It was performed that many times in order to see a learn-

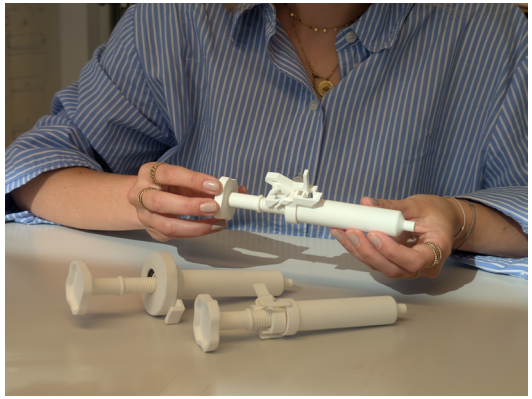


Figure 85. Concept 2 (gearshift) being evaluated with a student on ease of dis- and reassembly, and ease of use.

Figure 86. Concept 3 (springs) being evaluated with a student on ease of dis- and reassembly, and ease of use.

ing curve. Time and the number of instructions given were recorded while the participants performed the assemblies and disassemblies. Only one instruction was once given for the first disassembly of one of the participants of concept 3 (spring).

A clear learning curve could be seen overall. However, because of the level of prototyping of the concepts, each concept had problems, and participants sometimes struggled more to complete their tasks on the fourth time than the first time, for example. The components were 3d printed and tolerances had yet to be perfectly optimised. This was taken into account when evaluating the struggles of participants.

Problems with concept 1 (overcentre) included that it was not straightforward how to do it. Parts could be assembled the opposite way, and it would not work. The order of the assembly was also not straightforward. And fitting the half nut with the pivoting axis and the connector at the same time, while the threaded plunger added friction to the task, was quite complex. Feedback from most participants was aligned, highlighting these problems and saying that if the product was not used that often, the learning curve would not be that accelerated, and there would be more struggles over time because it did not follow the design philosophy o poke-yoke.

Difficulties with concept 2 (gearshift) also included that it had possible wrong ways of assembling it and it was not that straightforward. The complex shape and looks made it difficult to remember how to assemble the parts. Sliding was not that smooth, partially because of the 3d printing tolerances.

Struggles with concept 3 (springs) included a too-long thread to connect the mechanism to the barrel, and the spring of the half nut had to be pre-compressed when introduced into the barrel, which made it jump out of its place sometimes while assembling or disassembling.

The fastest in disassembly was concept 2 (gearshift) with an average disassembly of 10,3 seconds. Then it was concept 1 (over-

centre) with 10,8 seconds and finally concept 3 (springs) 13,6 seconds. Concept 1 (overcentre) achieved the fastest disassembly time once, 4 seconds.

The fastest in assembly was concept 2 (gearshift) with an average assembly of 17,9 seconds. Then it was concept 3 (springs) with 18,6 seconds, and finally concept 1 (overcentre) 18,9 seconds. The fastest time achieved for the reassembly was with concepts 1 and 2 at 8 seconds.

As can be seen, the three concepts obtain similar time results. The difference between their averages is three seconds for disassembly and one second for assembly. In general, the three concepts more than meet the requirements 2.5 and 2.6 on the times that assembly and disassembly should take.

Finally, participants rated the ease of use of the concepts. All participants rated concept 3 (springs) as the easiest to use, with a 5 out of 5 (on a scale from very hard to very easy). Concepts 1 and 2 both had a 3 out of 5 on average.

Concept 3 was not the fastest, but it was the most straightforward, with fewer possible problems that could happen throughout the process. In comparison, for example, some comments on concept 1 (overcentre) said that it felt like a struggle because of how precise it needed to be. Concept 2 (gearshift) was also criticised because the parts that had to fit together were too small and the participants had to aim

**Engineering and reprocessing evaluation**

The engineering evaluation was conducted with a biomedical professor, engineers from the design and prototyping department of the LUMC, and an engineer from npk design. The reprocessing evaluation was conducted with an expert in sterilisation from the LUMC. Here are some comments received while assessing them, which also focus on usage. Their rating of the concepts is directly shown in Figure 87, the Harris profile.

Overall, concept 3 (springs) outperformed the other two. Because of its simplicity and how clean it is. It was said that it conveys the usage interaction clearly, that it speaks for itself what has to be done for interaction. Engineers also described it as the most promising.

The experts highlighted that the components of concept 2 (gearshift) had many angles and sharp edges, which could make it difficult for production and for usage with gloves on. It also had shadowed areas, and these are to be avoided when thinking about mould constructions and about cleaning, even though shadow areas should not be a problem with proper manual cleaning. How it translates the movement was said not to be the most efficient, because one part has to translate the movement into another one in an angled way, and friction comes into play. Also, by having three parts to make the movement, tolerances will make the concept have a less perfect fit.

Concept 1 (overcentre) was also criticised for the play it leaves for tolerances. It was said to need to be more robust, and the cut on the connector that allows the assembly of the half nut was pointed out as negative for its performance. Its parts are small, easy to lose, and to assemble upside down. The connector is hard

to make, even with casting. A big problem this concept has is that the way it is assembled (threading it in or bayonet, both solutions include rotation) and the way it is operated (rotate the half nut with respect to the barrel) are the same types of movements. Therefore, it could be disassembled unintentionally while used at the OR.

**Results**

Figure 87 shows the comparison of these three concepts with a Harris profile, in which the ratings given by the experts and participants are included. It is easy to see that concept 3 (springs) performs the best in these parameters. This is why the final concept proposal is an improved version of concept 3.

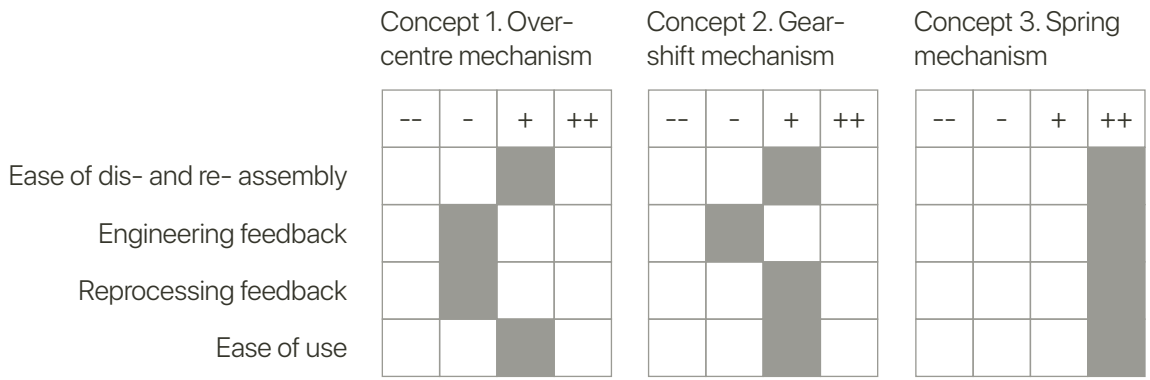



Figure 87. Evaluation of the concepts using the Harris profile tool.

# 08

# POMPA.
# DESIGN PROPOSAL

This chapter presents Pompa, the final design that aims to respond to the selected circular journey, and compares its impact to current inflators.



# 8.1. Pompa. Towards circular inflators

Pompa is the final product design proposal of the project.

Pompa is a hybrid inflator for high-risk procedures in interventional cardiology and radiology that allows its five most critical components (barrel, plunger and locking mechanism module) to be reused for 1000 cycles and the remaining four less critical parts to be discarded. It offers physicians and nurses an experience similar to that of current inflators, as it includes a mechanism with a similar operating principle to that used in current inflators. It is designed so that all its components can be easily assembled and disassembled in less than one minute, without greatly affecting the surgery preparation experience. The ease of disassembly and the materials used enable in-house reprocessing with steam sterilisation for reuse.

Figure 88. Pompa's lock mechanism being actuated.

## 8.2. Adapted for reusability

Five components of Pompa have been designed to be reusable in-house with steam sterilisation, while the rest are disposable components. This hybrid lifecycle is represented in Figure 89.

The reusable components use PEI for the barrel, Nitinol for the spring (assembled together with the barrel), and stainless steel for the plunger, the piston, the connector, and the half nut. These materials have excellent compatibility with fresh water, soft alkalis, and steam sterilisation and, theoretically, could withstand up to 1000 reprocessing cycles.

Pompa is also easy to decontaminate, as a previous iteration of the concept was validated by the sterilisation expert. This new and final version, in comparison to the one used for the evaluations, integrates a superelastic nitinol spring that is tightly fitted to the barrel and does not need to be disassembled. This technology is simple, easy to clean, requires a smaller half nut and barrel, and is already integrated into another reusable medical product that received the CE validation (Horeman, 2020). Figure 90 shows a detail of Pompa, in which the half nut (golden colour) can be seen hanging on top of the thin nitinol rod.

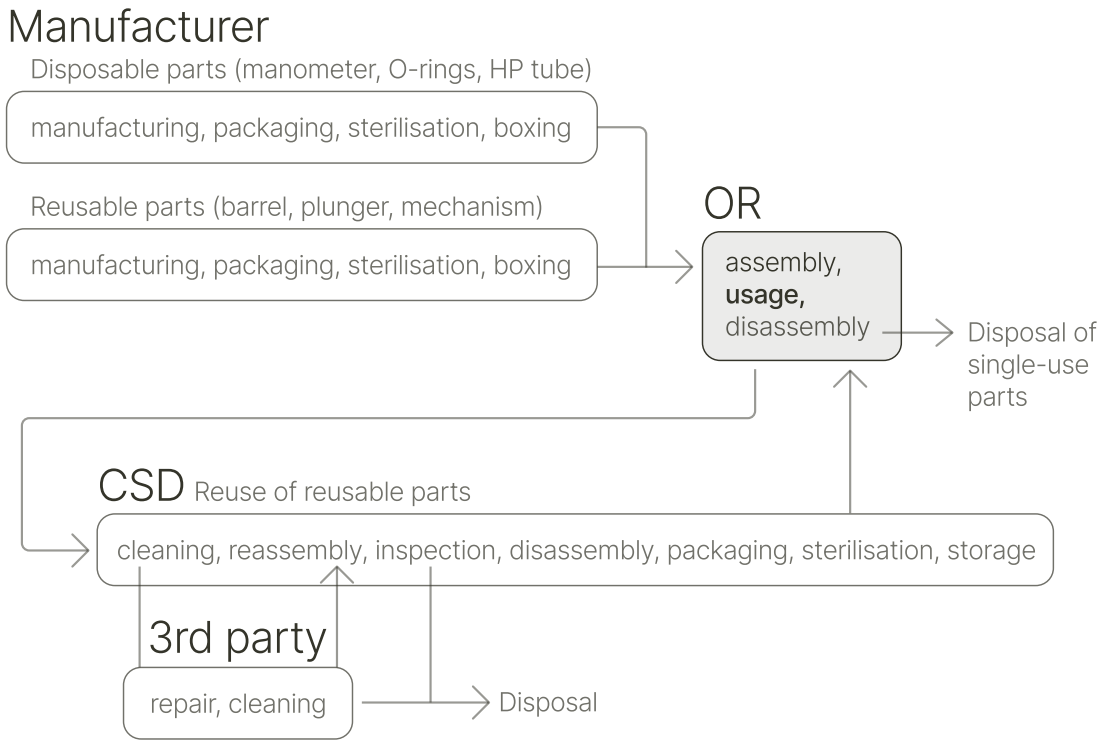



Figure 89. *In-house reprocessing journey adapted for Pompa.*

## 8.3. Ease of (dis)assembly

Pompa is adapted for reusability because it is easy to disassemble and reassemble. It uses only 9 components (disposable inflators at least used 12), five of which are reused and are big enough for reprocessing. It also reduces the number of steps for dis- and reassembly: 8, instead of 11 required for the Encore 26 or 16 to assemble the Encore 40.

It has been validated with other students to be fast, easy, and intuitive to dis- and reassemble without the need of any tools. The reusable components of the evaluated version of Pompa had an average disassembly time of 13,6 seconds and an average assembly time of 18,6 seconds. In total, with the single-use disposable parts, this final prototype has quickly been tested to fulfil assembly and disassembly in less than 1 minute.

The whole product disassembled is shown in Figure 91. Figures 92 to 99 show the assembly steps.

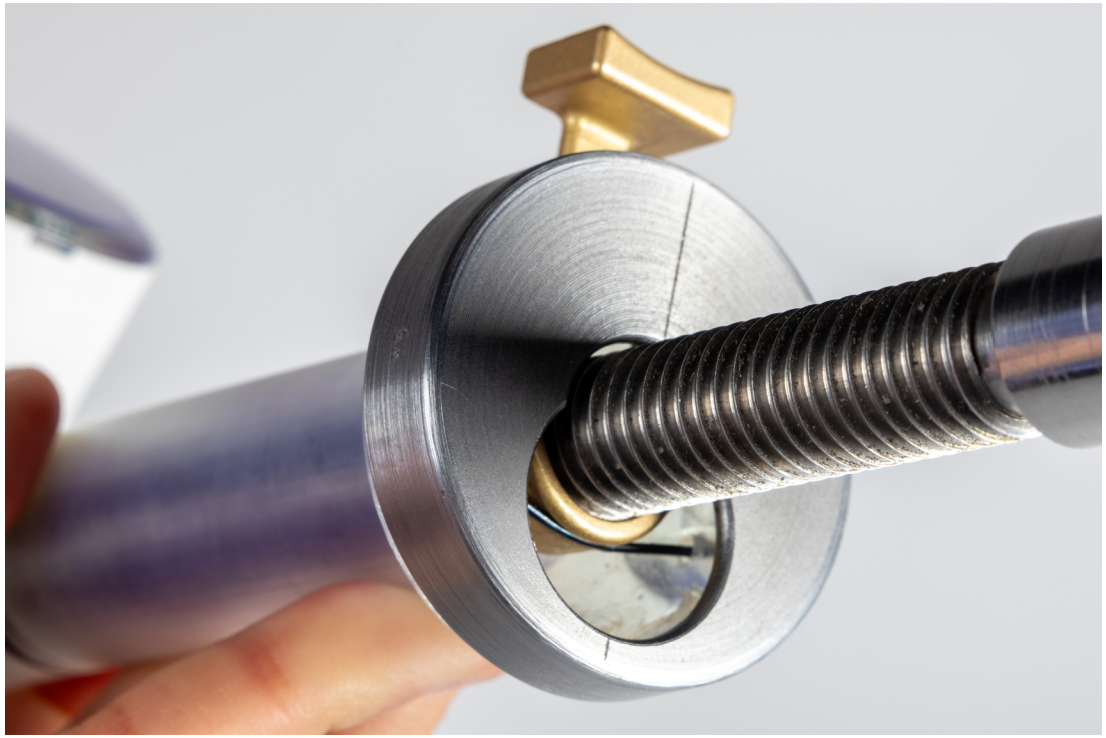


Figure 90. *Detail of the lock mechanism of Pompa. The half nut is placed on top of a thin and superelastic nitinol rod, which acts as a spring. The assembly of the half nut precompresses the spring, so the half nut is constantly being pushed to engage with the plunger.*

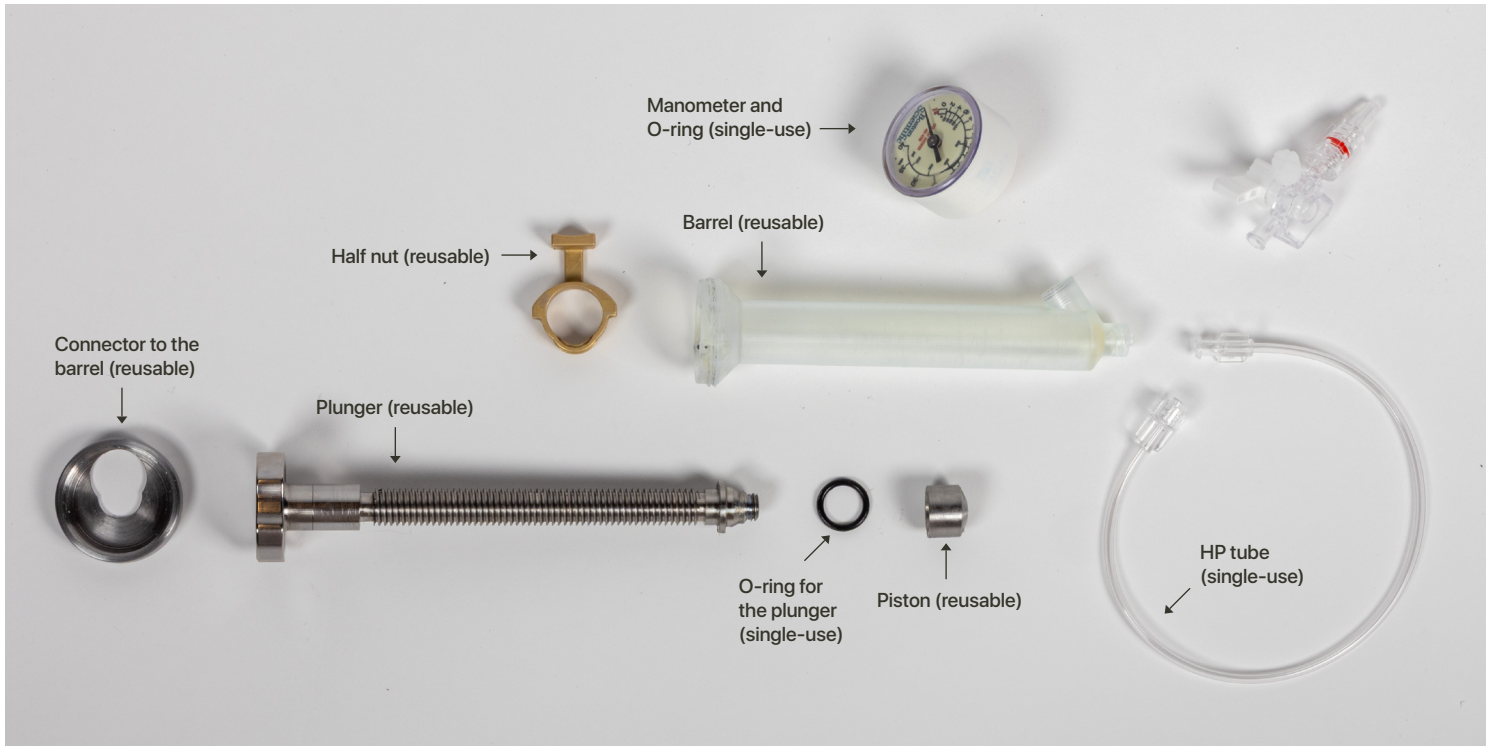



Figure 91. *Detail of the lock mechanism of Pompa. The half nut is placed on top of a thin and superelastic nitinol rod, which acts as a spring. The assembly of the half nut precompresses the spring, so the half nut is constantly being pushed to engage with the plunger.*

**Assembly steps: 8**

Figure 92. *1. Thread in the luer lock connectors of the high-pressure tube and the barrel.*

Figure 93. *2. Insert the O-ring and thread in the manometer for a liquid-tight connection.*

Figure 94. *3. Place the O-ring to in the plunger. Expand it uniformly.*

Figure 95. *4. Thread in the piston.*

Figure 96. *5. Place the plunger inside the connector.*

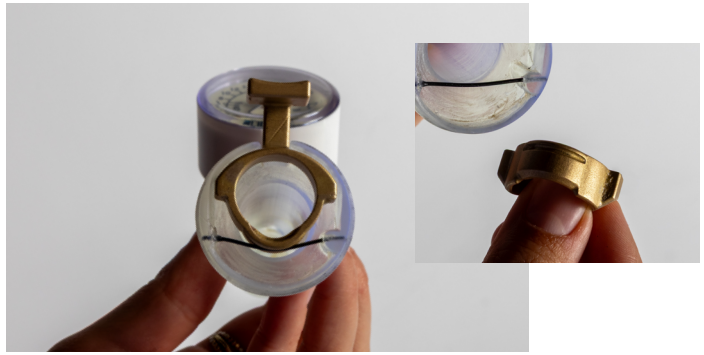


Figure 97. *6. Fit the half nut inside the barrel. The nitinol rod should fit into the groove of the half nut.*

Figure 98. *7. While pressing the half nut, push the plunger inside the barrel.*

Figure 99. *8. Thread the connector into the barrel and it is ready to operate.*

## 8.4. Design details

To make everything disassemblable, the barrel has three connection points. At its front it has a male luer lock connector thread for liquid-tight connection with the HP tube.

It has an NPT thread to connect with the manometer. The NPT thread, together with an O-ring, also creates a liquid-tight connection.

At its rear, the half-nut fits into the barrel (the barrel has a small opening for this purpose) and the connector encloses it inside the barrel when it is threaded into the barrel. The connector and the walls of the barrel make sure the half nut can only be displaced vertically, as required to operate the lock mechanism.

At the beginning of the concept development, some prototypes were produced to make sure that the dispensing ratio was the same as in current inflators: the dimensions of the thread of the Encore 26 was used for Pompa, as it was the only product that had not been destroyed during the disasssemblies.

The plunger needs to move smoothly within the barrel. Current inflators use silicone oil lubricant to achieve this. Steam-compatible lubricants for Pompa can also be added to the barrel before the sterilisation cycle to achieve a similar performance each time.

The threads of the half nut and the plunger are not conventional. In order to produce them in stainless steel and brass, npk design (and especially Peter Hiep) were of great help. They developed a cutting tool that would lathe the plunger's thread (see Figures 100, 101, 102).

Obviously, all these design details could not have been refined without many iterations. Figure 103 shows all the prototypes produced throughout the project. Each was developed with a new idea, a new concept or improvement to test.

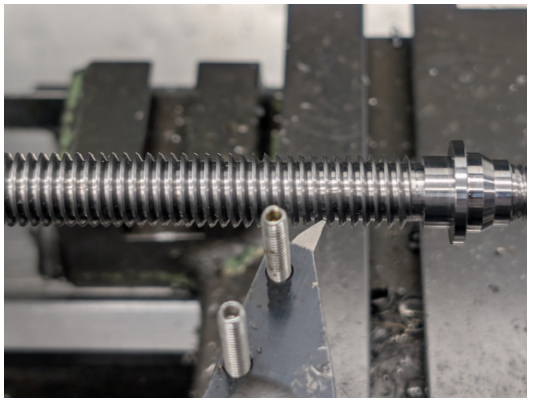


Figure 100. *The cutting tool, at its firts position to do part of the thread.*

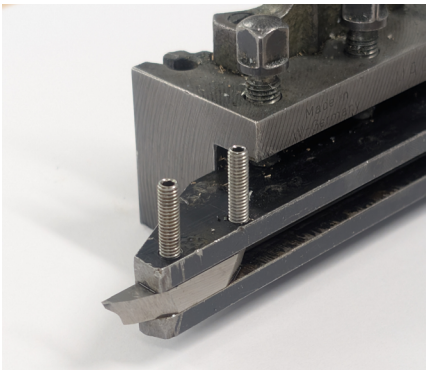


Figure 101. *Special cutting tool developed by npk design specifically for this thread on the plunger.*

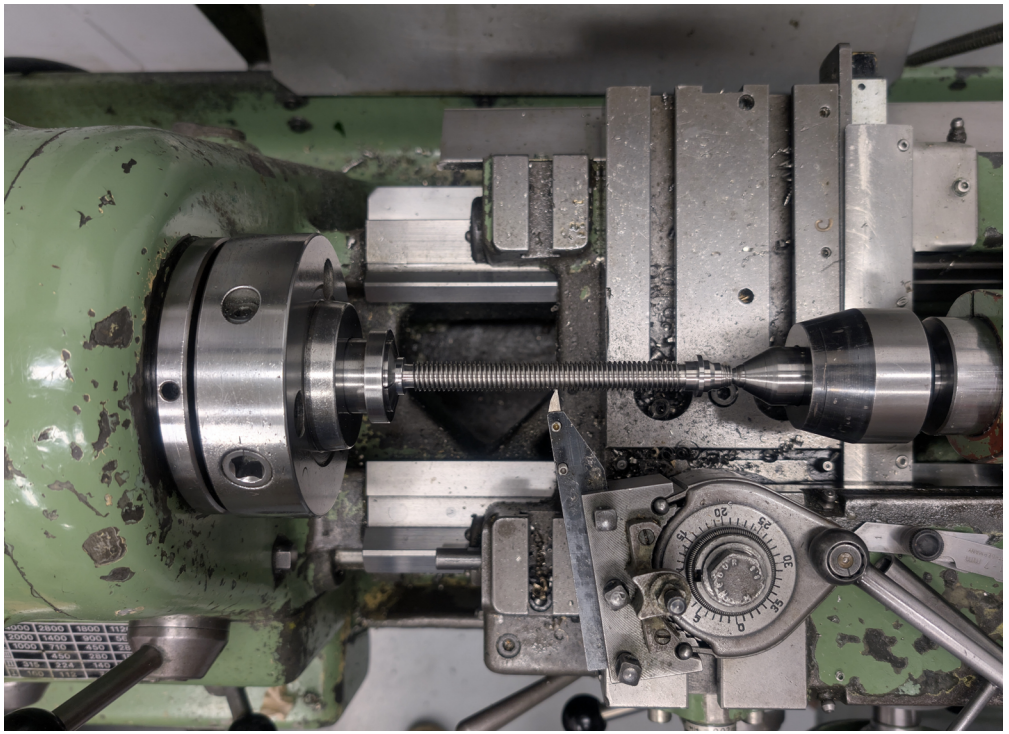


Figure 102. *The cutting tool, at its second position (angled) to cut the other part of the thread.*

Figure 103. *All prototypes produced throughout the project.*

## 8.5. Sustainability and economic validation

This project proposes a new circulability strategy for endovascular inflators and redesigns an inflator adapted to this strategy so that its critical or most valuable parts are reused. It is interesting to make a comparative study of the environmental impact and costs of this solution compared to current inflators to validate the proposed solution. The only inflator for which there is data on the materials used is the Everest.

Table 9 shows a comparison between the Pompa components that are reused and the Everest inflator components that have the same functions: the barrel, the plunger and piston, and the mechanism module. The components that are single-use for Pompa are not included because there is a lack of information on material properties of some of them, such as the material of the O-ring in the luer lock or the materials used for the pressure gauge and their percentages of weight.

This comparison only uses data about the materials and does not include any data on manufacturing, transport, or use. It would be interesting to carry out a more detailed analysis of these aspects in the future in order to have a more realistic comparison.

From the results of the table we can compare both products and see that, just comparing the impact of the materials of the reusable parts of Pompa and its equivalents in Everest:

After 2 uses, Pompa has lower embodied energy than the Everest inflator.

After 3 uses, Pompa produces less waste and has a lower carbon footprint than the Everest inflator.

After 9 uses, Pompa is more cost effective.

**After 9 uses, Pompa has a better impact than current inflators. And it still has 991 reuse cycles left.**

| | Number | Part | Material | Weight (g) | Embodied energy (MJ) | Carbon footprint (CO2-eq) (kg) | Cost (EUR) |
|---|---|---|---|---|---|---|---|
| EVEREST | 1 | Barrel | PC (copolymer, heat resistant) | 70,5 | 8,1 | 0,37 | 0,25 |
| | 2 | Trigger | POM (copolymer) | 3,7 | 0,32 | 0,012 | 0,0085 |
| | 3 | Bearing member | PA6 (25% glass fiber) | 4,9 | 0,53 | 0,034 | 0,016 |
| | 4 | Half nut | PA6 (25% glass fiber) | 1 | 0,11 | 0,007 | 0,0033 |
| | 5 | Spring | SS ANSI 304L, annealed | 1 | 0,047 | 0,0042 | 0,0057 |
| | 6 | Body cap | ABS (extrusion) | 16 | 1,6 | 0,059 | 0,04 |
| | 7 | Piston | PC (copolymer, heat resistant) | 1,1 | 0,13 | 0,0057 | 0,0038 |
| | 8 | Plunger | PA6 (25% glass fiber) | 22,7 | 2,4 | 0,16 | 0,074 |
| | Total Everest | | | 119,9 | 13,237 | 0,652 | 0,401 |
| POMPA | 1 | Barrel | PEI (unfilled) | 23,5 | 4,9 | 0,26 | 0,37 |
| | 2 | Half nut | SS ANSI 316L, annealed | 18,3 | 1,4 | 0,12 | 0,24 |
| | 3 | Connector | SS ANSI 316L, annealed | 35,3 | 2,3 | 0,19 | 0,34 |
| | 4 | Piston | SS ANSI 316L, annealed | 14,5 | 0,98 | 0,083 | 0,16 |
| | 5 | Plunger | SS ANSI 316L, annealed | 226 | 15 | 1,3 | 2,4 |
| | 6 | Spring | Nickel-titanium alloy wire, annealed, austenitic | 0,5 | 0,19 | 0,012 | 0,018 |
| | Total Pompa | | | 318,1 | 24,77 | 1,965 | 3,528 |

Table 9. *Comparison between Everest and Pompa. Regarding the data on Everest, these are the materials introduced in Granta in order to make the comparison. They are an estimate that tries to be as close as possible to what is described in the product patent. There, Ryan (1992) specifies that the syringe is polycarbonate, the trigger is an acctal such as Delrin™, the bearing member, half nut, and plunger are glass filled nylon, the spring has no information on what type of stainless steel it is, and the body cap says it may be made of PC or ABS. It doesn't look like the same material as the syringe, so it was decided for ABS in the comparison. The weights may not be as accurate as they should be because the product was shredded with a saw in order to analyse it and particles were lost.*

# 09
# DISCUSSION

This last chapter discusses the added value of the project, the limitations it faced, and some recommendations for future progress.

## 9.1. Contributions

This research endeavoured to challenge the prevailing single-use culture of endovascular inflator design within interventional cardiology and radiology. The core objective was to reconcile the seemingly opposing forces of functionality, safety, and urgent environmental responsibility. While these domains often present contradictory demands in the medical context, where functionality traditionally favours disposal and sustainability demands retention, this project shows that it is possible to overcome this false dichotomy through innovative design thinking and systematic circular integration.

The work presented here evaluates the changes in the product's lifecycle with different designs, achieving solutions that have the lowest environmental impact while maintaining all requirements necessary for its use in the medical context. For this, it explores disassembly and decontamination processes to adapt a product design that was seemingly already established in a manner that achieves the new requirements of sustainability strategies while also producing a great economic impact. By doing this, the research presents a successful example of how sustainability is to be applied to the medical industry.

The assignment also uncovers significant opportunities for further research. Potential research pathways that stem from the results provided here can extend to both theoretical considerations on what are the most useful approaches to reassessing sustainability for medical products, as well as practical studies that extend similar exercises to other single-use products.

## 9.2. Limitations and recommendations

Due to the limited timeframe available for this project, a comprehensive evaluation of the proposed solution against all specified requirements could not be accomplished. The ability to withstand high pressures remains a critical requirement for use in surgery. Although the mechanical properties of the selected materials suggest that Pompa would be able to withstand such loads, it is recommended that detailed simulations and physical testing be performed to confirm and refine the design's performance under such conditions.

A thorough sustainability and economic analysis that included the full lifecycle of the product and its disposable elements was not possible. It is recommended that at least a basic analysis be performed in all phases of the life cycle.

User testing with end-users was also not conducted; it is recommended that clear instructions for use be developed and that the comprehensibility of assembly and disassembly steps be validated with target users.

Ergonomic evaluation has been limited to

replicating the conditions of existing inflators. Therefore, aspects such as the plunger knob size and the increased weight associated with metallic components need further investigation. If weight proves problematic, alternative materials should be considered, provided they maintain the required mechanical properties and sterilisation durability. However, it is known that increased weight may be perceived positively, as it could convey robustness and durability, attributes valued in reusable medical instruments.

It is further recommended to explore the adaptability of the device for use in departments beyond interventional radiology and cardiology, as other clinical areas have different requirements regarding barrel volume and pressure tolerance. Redesigning the product for these specific contexts could enable greater reusability, improved disassembly, and cost reductions.

The liquid-tightness of the manometer and barrel connection should be evaluated. If having an O-ring is not enough and is revealed to be problematic, it is suggested to adopt a disposable hemostasis valve with a pre-attached manometer to ensure sealing and reduce assembly steps.

It is also recommended that the acceptability and adaptability of the proposed system in international contexts be investigated.

Finally, once the design has been refined, further optimisation should be carried out to ensure regulatory compliance and manufacturability.

## 9.3. Disclaimer for AI use

This thesis made use of AI tools, such as ChatGPT and Perplexity, to help improve language, carry out quick initial research, organise ideas. All content and conclusions remain the author's own, and critical analysis was conducted independently.

# 10
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# APPENDIX