CIRCULAR CARE IN PRACTICE

REUSE AND REMANUFACTURING AS A KEY TO SUSTAINABLE HEALTHCARE

The healthcare sector faces growing pressure. Not only are healthcare costs rising, but the environmental impact and use of scarce raw materials are a cause for concern. In the Netherlands, healthcare accounts for around 12% of national raw material consumption and 7% of CO_2 emissions. To make healthcare future-proof, it is important to extend product life cycles and reduce waste.

Reuse plays a key role in this, ranging from sterilisation at the Central Sterilisation Department (CSA) to remanufacturing (the technical reprocessing of instruments).

The *High-Quality Medical Instrument Reuse* (HHMI) project is investigating how these strategies can be applied in practice and which design principles need to be considered.

From sterilisation to reprocessing

For decades, hospitals have relied on the CSA to clean and sterilise medical instruments after use. However, over the past twenty years, more and more high-quality instruments, such as surgical staplers and ultrasonic scalpels (Figure 1), have been marketed as single-use products. Infection prevention, convenience, time savings, and a favourable business model have ensured the current model remains in place.

The result: reliable and efficient care, but instruments made from high-quality materials end up in the waste stream after a single use. Because sterilisation is not always technically or legally possible, hospitals often lack alternatives. In some cases, remanufacturing offers a solution. Where CSA stops, reprocessing continues: instruments are dismantled, checked, repaired and revalidated outside the hospital. This creates a product that can be safely reused without compromising on quality or functionality.

The HHMI project

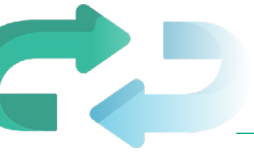
The RAAK-MKB project on the reuse of high-quality medical instruments, led by Saxion University of Applied Sciences' Industrial Design research group, is investigating how medical devices can be made suitable for reuse – both through redesign and reprocessing. The focus extends beyond product design to the entire system: logistics, cleaning, quality assurance, and validation.

A broad group of public and private partners is involved, including Medisch Spectrum Twente (MST), the Association of Experts in Sterile Medical Devices (VDSMH), Santeon, Logic Medical, R-Solution, Oceanz, Implican, Vanguard A.G., First15 and Wittenburg Group.

Practical cases

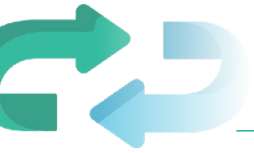
The project takes a practical approach to learning. By working real-world cases, we gain generic insights into the reuse and reprocessing of medical instruments.

Implican is developing a reusable intestinal anastomosis device (used to connect two sections of intestine) based on an innovative healing technique. The focus here is on iterative design with attention to sterilisability and user experience.



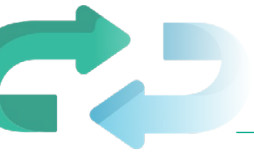
How can reusability be integrated into medical device development?

Vanguard A.G. is investigating how the collection of single-use devices can be scaled up to a robust process to enable large-scale reprocessing.



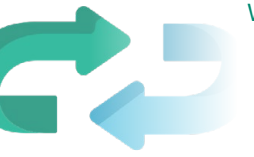
What is needed to collect existing single-use devices for reprocessing?

First15 supplies emergency medical kits and is investigating within HHMI the extent to which their innovative tourniquet is suitable for multiple use.



How can you assess whether an existing product is suitable for reuse?

Wittenburg Group focuses on circular plastics that can withstand sterilisation and reprocessing, so that high-quality materials can be reused in the healthcare chain.



What properties are required for multiple sterilisation of plastics and in which medical instruments can these be applied?

In all cases, user research is essential. The involvement of surgeons, surgical assistants, CSA staff and purchasers is crucial in order to map out the context surrounding the circularity of medical instruments.

Challenges surrounding the reprocessing of instruments

Vanguard is an international company that repurchases used single-use instruments, cleans and reprocesses them, and reintroduces them as CE-marked products This extends the lifespan of high-quality materials while saving hospitals both purchasing and waste disposal costs.

Various **life cycle assessments** show that this also pays off ecologically. A Fraunhofer UMSICHT study (Schulte et al., 2021) showed that reprocessing electrophysiology catheters scores better than new production in 13 of the 16 impact categories, with more than 50% less climate impact. A follow-up study (Meister et al., 2022) showed CO_2 emissions per use are up to 60% lower with reductions of 57% over the total lifespan.

With the introduction of the Medical Device Regulation (MDR), remanufacturing was formally recognized and regulated at the European level. Depending on the category, a remanufacturer may be treated as an external service provider (CS remanufacturing) or as a full manufacturer (CE remanufacturing).

While this provides a clear framework, it also creates significant hurdles. Extensive documentation requirements and a structural shortage of **Notified Bodies** – the independent organizations that certify medical devices – result in high costs, long delays, and uncertainty. As a consequence, technically proven and ecologically valuable solutions often fail to scale.

Vanguard actively works to overcome these barriers: by investing in certification processes, sharing evidence from practice, and engaging with hospitals and regulators, the company helps demonstrate that remanufacturing can be safe, sustainable, and cost-effective. Yet the speed of adoption still depends heavily on national choices under Article 17 of the MDR, which vary across Europe.

Initial results

The initial results of this research can be summarised in two areas: the **opportunities and barriers** that determine the context of circular care, and the **design guidelines** that provide direction for the development of future-proof medical instruments.

Opportunities and barriers

> Technical and system innovations must go hand in hand. Without regulatory adjustments and greater certification capacity, the potential of remanufacturing in healthcare will remain largely untapped.

> It is important to note that reuse and remanufacturing are complementary and not competing. Together, they form a necessary backbone for circular healthcare practice.

> Multiple value is an important advantage: reuse and remanufacturing not only save on hospital waste costs, but can also be more financially beneficial in the long term and reduce dependence on raw materials.

> An adapted product alone is not enough. The entire system must adapt: return logistics, quality control, capacity at CSAs and operational processes must be adjusted. With the rise of single-use (disposable) instruments, CSA capacity has generally been scaled down. It also appears that different stakeholders have divergent interests. Whereas purchasers and insurers focus primarily on costs, CSA employees emphasise cleanability.

> Small, modular steps are achievable. Early adopters such as MST and Erasmus MC play a crucial role in building trust and paving the way for others.

> **Circular care not only contributes to making the healthcare sector more sustainable, but also to the broader social transition to a circular economy.**

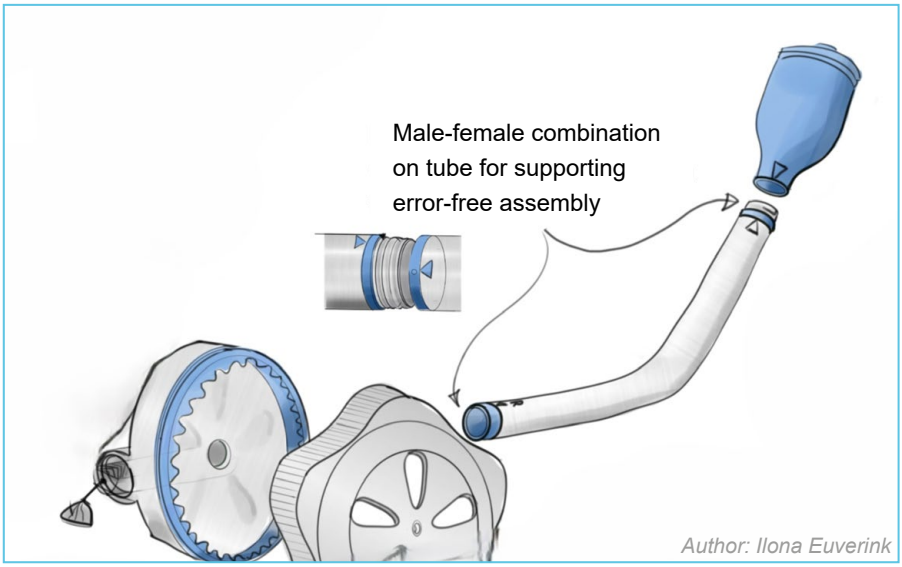
Design guidelines

Sterilisable and sustainable use of materials: materials must be suitable for repeated use without loss of quality.

Cues for foolproof assembly: components must be intuitively correct to assemble in order to reduce the risk of incorrect assembly in the CSA department, which causes delays and possibly even dangerous situations in the operating theatre (Figure 2).

Minimise the impact on CSA capacity: instruments should be designed to be modular and dismantlable, or equipped with sufficient flow openings, so that all surfaces are effectively accessible for mechanical cleaning and steam penetration during sterilisation. Dimensions and geometry must match the standardised dimensions of CSA baskets and trays to ensure compatibility with existing cleaning and logistics processes.

User involvement of all users from the outset: design choices must be in line with practice and increase acceptance among end users. For example, involve the CSA department from the outset in considering the cleanability of the device. Simple but fundamental choices for certain materials can sometimes be decisive in determining whether a product is suitable for reuse or not.



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Towards a circular ecosystem

Every reused instrument has a positive effect on raw material scarcity, the enormous waste mountain and the carbon footprint of the healthcare sector. Circular care not only contributes to making the healthcare sector more sustainable, but also to the broader social transition to a circular economy.

Redesigning instruments for reuse and reprocessing single-use devices are part of a larger transformation in healthcare. The potential is significant: many medical products are still not designed with reuse in mind. The HHMI project demonstrates that, with collaboration and smart design, real progress is possible.

Knowledge sharing and collaboration are essential to further strengthening this ecosystem. Only in this way can healthcare be made sustainable and future-proof. ■

The invitation for an exploratory meeting is open; this project started in August 2024 and will run until August 2026.

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This project has been made possible in part by a RAAK-MKB grant from the National Coordination Point for Applied Research SIA.