



Full length article

Life cycle assessment of a disposable and a reusable surgery instrument set for spinal fusion surgeries

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ABSTRACT

The worldwide increasing wealth and increased life expectancy of humans has led to an increase in the number of medical procedures and surgeries. Surgeries are complex medical procedures which contribute to a significant share of the total environmental impact of the healthcare system. Among other important sources of environmental impacts from surgeries, material consumption due to required instrumentation accounts for up to 65 % of greenhouse gas emissions from surgeries. This study investigates how a disposable and a reusable surgery instrument sets for lumbar fusion surgeries contribute to the environmental impact and which system is more advantageous for the environment. For lumbar fusion surgeries, reusable and disposable instrumentation and implant sets are commercially available. Both sets are capable to support a one level lumbar fusion surgery. The reusable set is comprehensive and fully opened before the surgery, while the disposable system comes in a modular box system, and the boxes are opened on demand during the surgery. To compare the environmental impact of these different configurations, a comparative Life Cycle Assessment (LCA) was performed to assess the overall environmental impacts of both alternatives. One of the key findings is that the selected cleaning and sterilization process for reusable instruments is responsible for up to 90 % of the greenhouse gas emissions and decides which system is advantageous from an environmental perspective. Reducing the number of instruments to be cleaned and sterilized for a surgery should be the focus for future surgery instruments development from an environmental perspective.

1. Introduction

The life expectancy is increasing all over the world. From 2000–2015 the global life expectancy at birth increased by 5.5 years to 72 years. Parallel to this increase in the same time span, the current health expenditure globally increased from 5.4 % to 6.3 % of the world gross domestic product (World Health Organization, 2018). In particular, various studies from different countries showed that the number of lumbar instrumented fusion surgery increased: Since 1996 this kind of surgery has grown over 113 % in the USA with more than 122,000 surgeries annually (Deyo et al., 2005). A similar trend has been reported in the UK with 4036 in 2009/10 to more than 6547 surgeries annually in 2012/13 (Greenwood et al., 2015). For the time span between 2001 and 2010, Cortesi and colleagues reported a growing incidence rate from 11.5 to above 20, and the increasing average cost for a spinal fusion surgery increased from 4726 € to 9388 € in Italy (Cortesi

et al., 2017).

The expanding healthcare sector also results in an increasing environmental impact. For example the U.S. healthcare sector accounts for 8 % of the CO₂-equivalent emissions of the U.S., while hospitals are responsible for 39 % of the CO₂-equivalents of the US healthcare sector (Chung and Meltzer, 2009). Beside the contribution to the global warming, the amount of waste per patient is significant. From 0.76 kg per bed and day in India to 6 kg per bed and patient in Germany (Goyal and Bansal, 2016; Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege, 2007). As the worldwide wealth is increasing, it can be assumed that these numbers especially in low and middle income economies will escalate in the next years.

Operating theatres are the most resource intensive areas in hospitals (Practice Greenhealth, 2019). Recent studies showed that surgical instruments are, beside the HVAC system, the main driver in the environmental impact of surgical procedures and account for up to 65 %

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of the GWP (Thiel et al., 2015b; Campion et al., 2012). Therefore, reducing the environmental impact of surgeries by selecting instruments and implants with a reduced life cycle environmental impact might contribute to the reduction of the environmental impact of the whole healthcare system.

In Europe, manufacturers of medical implants for spinal fusions must prove the safety of their instruments by declaring conformity to class IIb of the EU Medical Device Directive (93/42/EEC). This requires a complex and time-consuming process to complete the conformity declaration (European Council, 1993). Currently, the reduction of the environmental burden is typically not considered during the conformity declaration process. Considering the environmental impact during the design phase of new medical products can contribute to reduce the environmental impact (Thiel et al., 2015a), and potentially reduce downstream human health impacts. However, the health and safety of the patient should have the highest priority in the design and use phase. Several design decisions like reducing the number of parts which need to be sterilized or selecting different safe sterilization processes do not influence the health and safety of the patients. Also the decision for disposable or reusable instruments does not necessarily influence the infection risk for patients (Sherman and Hopf, 2018).

State of research on comparative LCA of disposable and reusable surgical instruments

Surgeries require sterile instruments which are typically supplied in custom packs for a specific procedure. A variety of necessary instruments is supplied to the operating theatre in a custom pack which is opened during the surgery. Thiel and colleagues showed that the size of these custom packs has an influence on the environmental impact. Decreasing the size of the custom packs decreases the environmental impact (Campion et al., 2015; Thiel et al., 2017b). Further, it has been shown that especially in case of complex surgeries, a high number of surgical instruments remain and are disposed of unused (Zygourakis et al., 2016).

Various studies showed that the sterilization process is a critical process for the environmental footprint of sterile products. Pizzi and colleagues (Pizzi et al., 2014) and Rawlings and Pora (Rawlings and Pora (2009)) showed that using single use sterile process equipment for the biopharmaceutical production of monoclonal antibody leads to significant advantages in 18 studied midpoint impact factors. Thiel and colleagues (Thiel et al., 2017a) showed that in case of reusable instruments for cataract surgery, the sterilization process is one of the main impact factors. The main driver for the environmental impact of the multi-use system was the higher demand for steam, water and cleaning fluids. Another study, which only considers single surgical scissors, showed that the environmental impact for the reusable product is significantly lower (Ibbotson et al., 2013). Therefore, no general statement for disposable or against disposable surgical instruments can be made.

Instruments which are used within hospitals in developed countries are centrally collected and disposed. Strict regulations due to the infection danger through contaminations ensure that this waste is combusted in a hazardous waste incinerator (Berufsgenossenschaft für Gesundheitsdienste und Wohlfahrtspflege, 2019) or collected, cleaned and sterilized before it is mixed in a common waste stream (Reinhardt and Gordon, 1993).

Not all sterilization methods can be used for any materials. The most common methods are gamma irradiation for disposables and local steam sterilization in autoclaves for reusable instruments in hospitals. Both sterilization methods can harm the materials, so that the materials of surgical instruments must fit to the sterilization method (Massey, 2005; Harrell et al., 2018).

Derived on the state of research, the research question for this study is whether reusable or disposable surgical instrument sets for complex surgeries, here for single-level lumbar fusion surgeries, are advantageous from an environmental perspective. Also, the critical factors driving the environmental impact of sterile surgical instruments shall

be identified to allow conclusions for designing future sustainable surgical instruments.

2. Methodology

Life Cycle Assessment LCA is an internationally accepted and standardized method in DIN EN ISO 14040 (Deutsches Institut und für Normung, 2006). It considers environmental aspects and potential environmental impacts of a product or service throughout its whole life cycle – from raw material extraction through production and use up to final disposal. To conduct the LCA, the software tool Umberto NXT was used and the Ecoinvent 3.1 database was employed as the main life cycle inventory database. For critical processes, for example the energy demand for steam sterilization, power measurements were conducted. The selected impact categories are the cumulative energy demand (CED), abiotic depletion potential (ADP), global warming potential (GWP), acidification potential (AP) and particulate matter (PM). On the other hand, a single score indicator is used (ReCiPe Endpoint), which aggregates 18 different impact categories contributing to human health, ecosystem quality and resource availability. The use of individual impact categories and endpoints allows for a comprehensive analysis to ensure that the aggregated characteristic of endpoints does not hide specific negative impacts. All score indicators are calculated by the corresponding life cycle impact assessment methods (CML 2001 and ReCiPe 2008) integrated into Umberto NXT software.

3. System definition and life cycle inventory

The functional unit (FU) in this study is defined as the specific set of surgical instruments for the realization of single level lumbar fusion surgery (one surgery) including the implantation of four screws and two rods by means of a set of surgical instruments. The scope of this study encompasses the raw material extraction and production of the instrument sets, spare parts and packages, transportation, sterilization, use in hospital and final disposal, as shown in Fig. 1. The production site of the reusable set is Indiana/USA and the production site of the disposable set is Switzerland. Both are transported to the distribution point in Frankfurt/Germany and distributed to hospitals in Germany. It has been assumed that patients travel to a centrally located city within their metropolitan area for a spinal fusion. Based on eleven German metropolitan areas, in which 71 % of the German population live, an average distance from Frankfurt has been calculated. The distance to Frankfurt, calculated with the route planning function of Google Maps, has been weighted with the share of population living in a specific metropolitan area. The average of all eleven weighted distances is 3136 km, which represents the distance surgical instruments have to travel by lorry from the central distribution point Frankfurt.

According to the instructions of use from both manufacturers, the systems can be used nearly for the same indications. For the reusable system only one additional indication is given (curvatures, e.g. scoliosis).

To model the reusable set of surgical instruments, the Viper 2 surgical instruments and implants set from DePuy Synthes were used (DePuy Synthes: VIPER®, 2019). It encompasses six boxes including eleven trays with several instruments, screws and rods (left side of Fig. 2). Depending on the requirements of the lumbar surgery, only a part of the set is applied. The total weight is 45.5 kg per set. It is used for five years and discarded through a solid waste incineration process at the end of life. It is assumed that the conventional set is used for 60 lumbar fusion surgeries per year. Hence, 300 surgeries can be realized throughout the lifetime of one reusable set. To fulfill the functional unit of one surgery, only a three-hundredth of the weight of the reusable set is taken into account for production and disposal processes, but the total weight for the use phase. According to experience, 10 % of the instruments are lost per year. Beyond that, a loaner system for providing the surgical instruments is assumed for the base scenario. Thus,

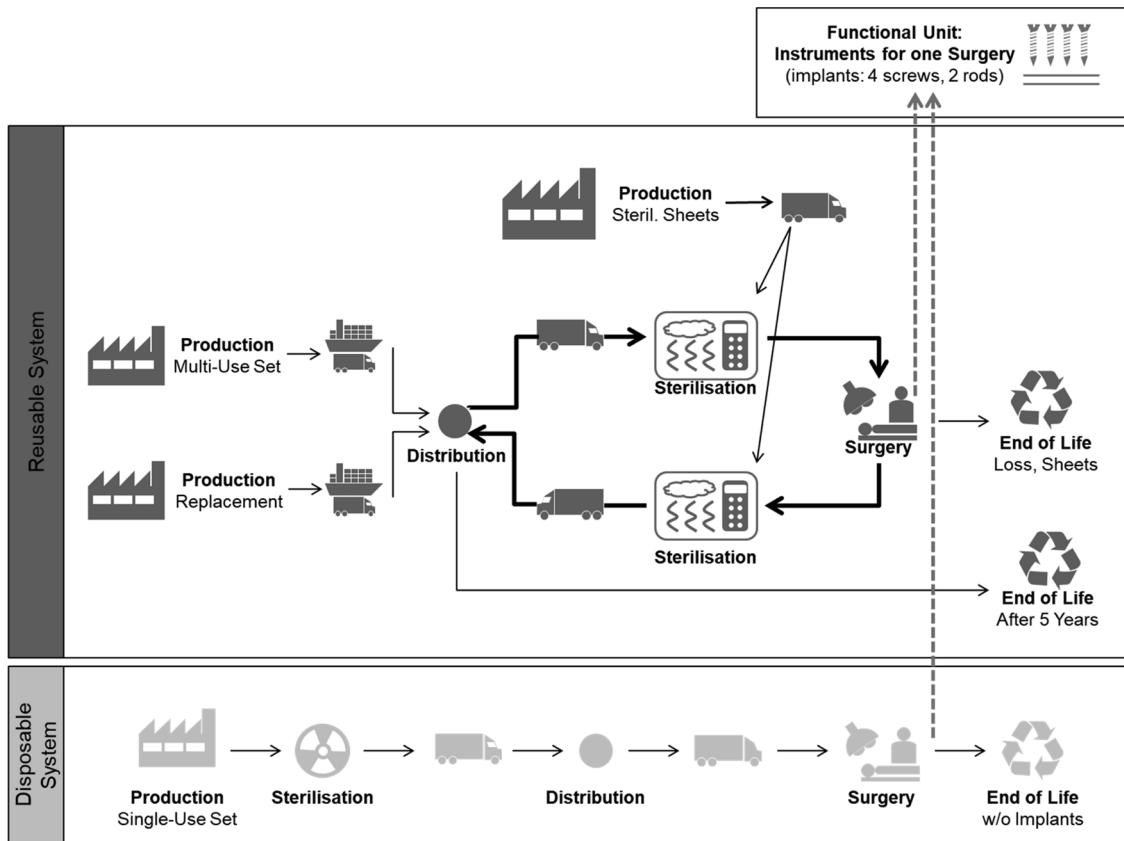


Fig. 1. Life cycle phases of reusable and disposable systems.

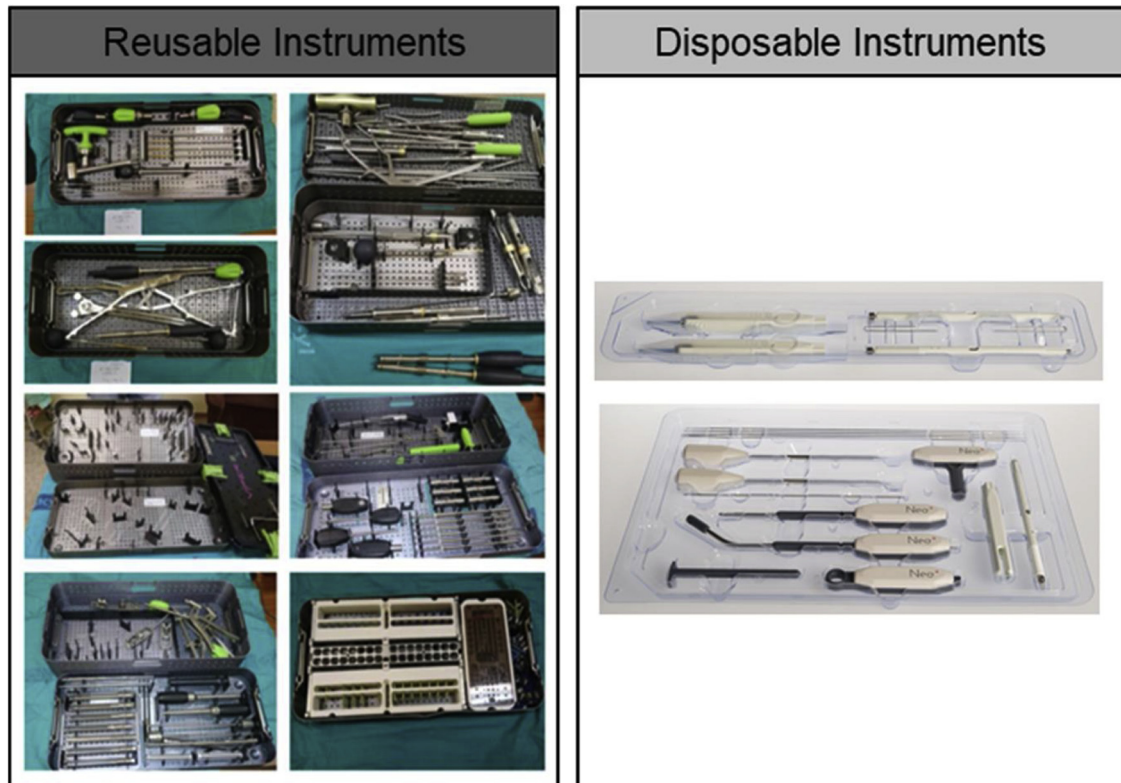


Fig. 2. Investigated instruments and implants set for lumbar fusion surgeries.

Table 1
Collected data and assumptions.

	Reusable product	Disposable product
Product set	6 boxes (incl. instruments, screws, rods) + additional screws	2 packages (p.) screws + nuts/screw extenders/screw drivers; 1p. rods; 1p. Instruments
Weight/set	44.885 + 0.580 = 45.465 kg/set	2*0.3985 + 0.080 + 1.094 = 1.971 kg/set
Application	Reusable (5 a, 60 OP/a) = > 300 OP/set	Single-use = > 1 OP/set
Loss	10 % of instruments / a = > 1.677 kg/a = 0.028 kg/OP	
Implants	4 screws + 2 rods = 0.083 kg/OP	
Sterilisation	Steam sterilisation 2x in hospital (before and after surgery) + steril sheets (1.4 kg/OP)	Gamma radiation (⁶⁰ Co) 1x (after production)
Production site	USA, Indiana	Switzerland, Muntelier
Distributor	Germany (Frankfurt)	Germany (e.g. Frankfurt)
Transportation	USA → Distributor: lorry (1100 km) + ship (6300 km) + lorry (500 km) Distributor → hospital: lorry (3136 km) Hospital → distributor: lorry (3136 km) Steril. sheets (Europe) → hospital: lorry (500 km)	Switzerland → central point → hospital: lorry (450 km + 3136 km)
End of life	Incineration	Incineration

the distributor provides the complete set of surgical instruments, which must be sterilized in hospital before the surgery. After the surgery, it is cleaned and sterilized again and sent back to the distributor. There, the set is checked and complemented before returning it to hospital. Steam sterilization is the typical sterilization method in this case and the dominating sterilization method in hospitals and accounted as gold standard (Stewart et al., 2009). Data collection for washing and steam sterilization was specific to a German hospital.

As disposable instruments and implants set, the Neo Pedicle Screw System from Neo Medical SA is used. It consists of one package with few instruments, one package with two rods and two packages with each two screws, nuts, screw extenders, and screw drivers. All parts of this single-use set are applied for a one level lumbar fusion surgery. The total weight is 2.0 kg per set. After manufacturing and packaging, the set is ⁶⁰Co gamma-sterilized, transported to the central distribution point Frankfurt and delivered to the hospitals. Here the whole set is used once for a one level lumbar fusion surgery. Screws and rods are implanted, packaging and instruments are discarded and incinerated as solid waste. The disposable system is a new development and served in modular packages, which clearly focusses on reducing the number of required instruments for the surgery and therefore allows using less instruments. An overview of the collected data and assumptions is given in Table 1 and an overview on the data sources in Table 2. Fig. 3 gives an overview on the transport routes within the functional unit.

4. Life cycle impact assessment

The outcome of the life cycle impact assessment for using the reusable set and the disposable set of surgical instruments are shown in Fig. 4 for the mentioned impact categories and the single-score indicator ReCiPe. They are displayed as percentage of the maximum value of each impact category. It is evident that the application of the disposable set of instruments results in an environmental advantage of approx. 45–85% against the reusable set in all impact categories. The aggregated single-score indicator depicts an overall benefit of 75 %. A deeper analysis of the process chain shows the contributions of production, sterilization, transportation and disposal to each impact

Table 2
Data sources.

	Reusable product	Disposable product
Production	Manufacturing process model based on weight, material and form of instruments / modelled with Ecoinvent manufacturing processes	
Transport	Based on calculated distances / modelled with Ecoinvent transport processes	
Sterilization	Based on measurements / modelled with Ecoinvent background data	Based on model / modelled with Ecoinvent background data
End of life	Incineration modelled with Ecoinvent waste incineration processes	

category, as shown in Fig. 4. It is obvious that the main environmental impact of the disposable set is generated in the production phase and that this share is always higher compared to the reusable set. But the major environmental impacts result from sterilization of the reusable set, mainly due to energy use for washing and steam sterilization. Transportation and disposal processes have minor impacts in both cases.

5. Sensitivity analysis

To investigate the robustness of this result and the influence of some assumptions, a sensitivity analysis was performed. Table 3 indicates the changes in the sensitivity analysis scenarios. Firstly, the number of usage cycles was increased from 60 to 100 times per year or rather from 300 to 500 surgeries in 5 years. And secondly, the application was changed from the loaner system to a consignment of the instruments by the hospital. Hence, instead of a double passage of sterilization before and after the lumbar surgery and repeated transportation between distributor and hospital, it is now assumed that the reusable set of surgery instruments is delivered to the hospital once and remains there. Only spare parts are delivered in addition. The efforts regarding sterilization and transportation are considerably reduced. Only an initial transport from distributor to hospital is required and only one sterilization process per surgery is needed, as shown in the upper part of Fig. 5. Thirdly, it has been assumed that the surgical instruments are only cleaned and disinfected in the hospital and the final sterilization is done in an external ⁶⁰Co gamma sterilization facility. The in-house cleaning and disinfection is still required to ensure the hygienic safety standards as the instruments are contaminated with blood and tissue after surgeries. It has been assumed that the external ⁶⁰Co gamma sterilization is located next to the distribution point so that no additional transports are required. A scenario in which only used instruments are reprocessed has not been considered as such a procedure would be accepted by health authorities and is not covered by the instructions for use. Damaged packages jeopardize the sterility for all instruments.

The result of the sensitivity analysis is shown in Fig. 6 for the single-

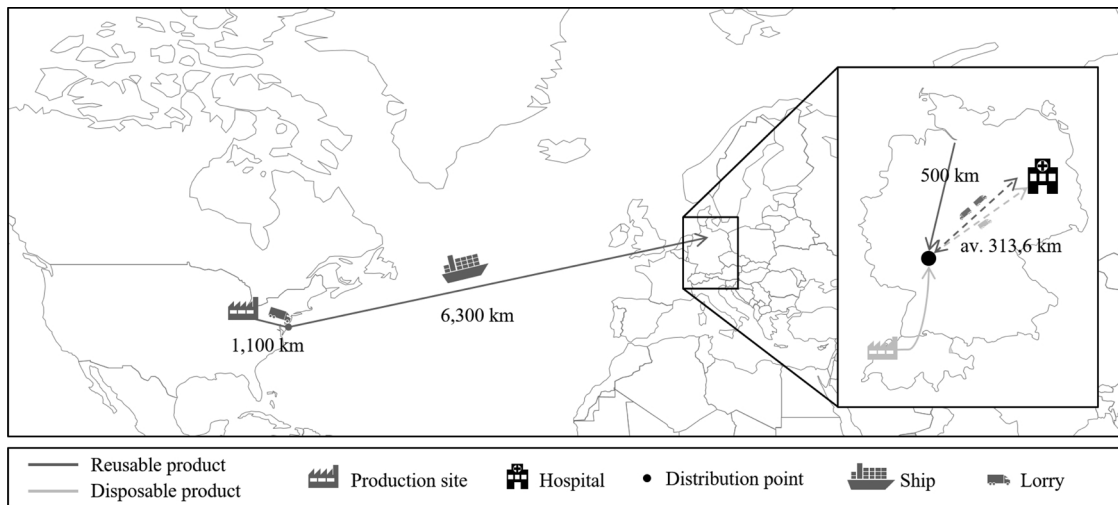


Fig. 3. Transport for reusable and disposable surgery instruments.

score indicator ReCiPe endpoints. The first option, increasing the number of surgeries per year, has a negligible effect on the entire environmental impact. But the second option, changing the logistics principle (from loaner to consignment system) and consequently dividing the number of sterilization cycles in halves, results in a serious reduction of environmental impacts. External ⁶⁰Co sterilization further reduces the environmental impact, but the environmental impact is still higher than for the disposable set. Further required transport increases the environmental impact and the impact for washing and disinfection within the hospital remains the same.

6. Discussion

This study showed that the energy demand for the steam sterilization of the reusable product has the highest impact on the eco-efficiency of the reusable surgical instruments. The negligible environmental impact of the ⁶⁰Co gamma radiation sterilization process leads to significant benefits for the disposable set. These results are also covered by other studies which indicated that the environmental impact of steam sterilization is considerably high (McGain et al., 2017).

A crucial aspect for the gamma sterilization with ⁶⁰Co are high safety standards during transporting and handling ⁶⁰Co (typically delivered in pencils). The building shell of the sterilization facility must be

2 m thick and a water basin of eight meters depth is required to store the pencils with ⁶⁰Co during maintenance (Sadle, 2013). In this study it has been assumed that the ⁶⁰Co is handled safely and no danger for the involved personnel can be expected. If this prerequisite is not fulfilled, for example in states with low safety standards for radioactive products, ⁶⁰Co sterilization can become a serious danger for the environment.

As steam sterilization is conducted locally in the hospitals, a high variety of products is sterilized at a relatively low automation degree. Various factors, as excessive weight of sterilization goods, low heat capacity and conductivity, heat transfer barriers or remaining air in the sterilization chamber can prevent a safe sterilization result (Maamari et al., 2016). Therefore, it is important to train the sterilization personnel and follow the recommendations from available guidelines to ensure a safe and good sterilization result (Reinhardt and Gordon, 1993).

Nevertheless, the sterilization is an important process to guarantee low infection rates and cannot be neglected. Due to the high safety standards for ⁶⁰Co gamma radiation sterilization, it is not possible to bring this sterilization process to hospitals and the materials of the reusable instrument set must be designed to withstand gamma radiation. A more promising approach to significantly decrease the energy demand for the sterilization would be to pack the reusable set into smaller modular boxes which are opened on demand. This allows

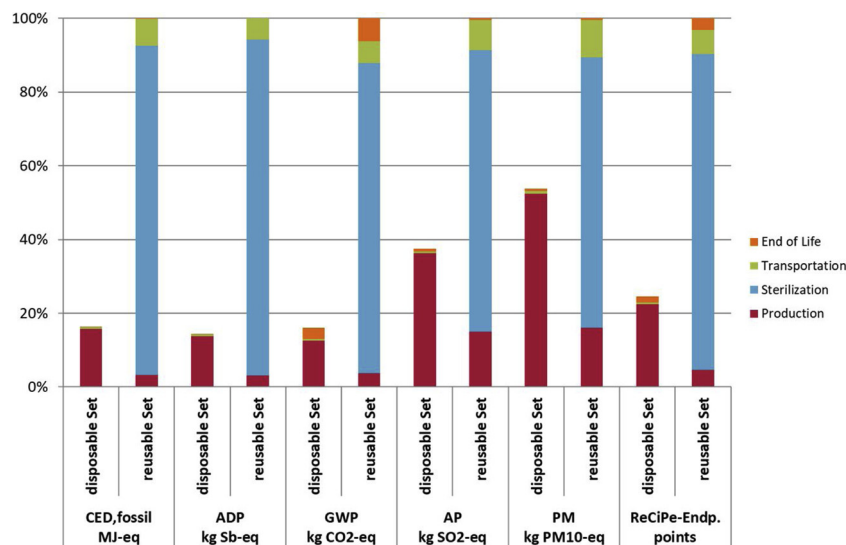


Fig. 4. Environmental impact per FU (set for one surgery) in percentage related to the reusable set.

Table 3
: Scenario Comparison.

Scenario	Changes
Disposable set	Base scenario
Reusable set, loaner, 300 s	Base scenario
Reusable set, loaner, 500s	The set is used for 500 times within 5 years.
Reusable set, consignment, 300 s	The reusable set is acquired by the hospital and not sent to the distributor between two surgeries. The set is used for 300 times within 5 years.
Reusable set, consignment, 500s	The reusable set is acquired by the hospital and not sent to the distributor between two surgeries. The set is used for 500 times within 5 years.
Reusable set, 60Co, 500s	The reusable set is cleaned within the hospital, sterilised externally with ⁶⁰ Co gamma radiation and used for 500 times within 5 years.

reducing the amount of instruments which need to be sterilized after one surgery and consequently reduces the environmental impact.

Increasing the number of use cycles further will only result in slight reductions of the environmental impact. Due to the high environmental impact of the cleaning, disinfection and sterilization process, the environmental impact of the reusable system will remain higher and no break-even can be reached.

Compared to the other life phases, the environmental impact from the end of life phase is relatively small. For all impact categories the reusable system has a higher negative environmental impact. The main driver for both systems is the combustion of plastic products. Plastic is used in case of the reusable system for sterile sheets, which are made of polypropylene. The single use system uses various types of plastic for packaging and the instruments. A reuse of these products is critical due to the contamination risk and the required cleaning and sterilization process.

Another aspect which should not be neglected is the required time for the surgery. Operating theatres are complex systems and their operation is associated with high cost and environmental burdens. A study showed that the energy and resource demand for the operating theatre causes up to 75 % of the CO₂-equivalents for one surgery (caesarean section) (Thiel et al., 2015b). Increasing the efficiency of surgeries by more efficient instruments and increasing the number of surgeries per day and operating theatre will decrease the environmental impact per surgery. In this case, a slightly not significant reduction of the surgery time (112 ± 39 for disposable and 127 ± 43 for reusable system) for posterior lumbar fusion is reported (Litrico et al., 2016). According to the manufacturer of the disposable system, the disposable system results in shorter surgery and preparation times due to the less complex system. Therefore, it can be assumed that the disposable system remains the one with a lower environmental impact if the scope will be expanded.

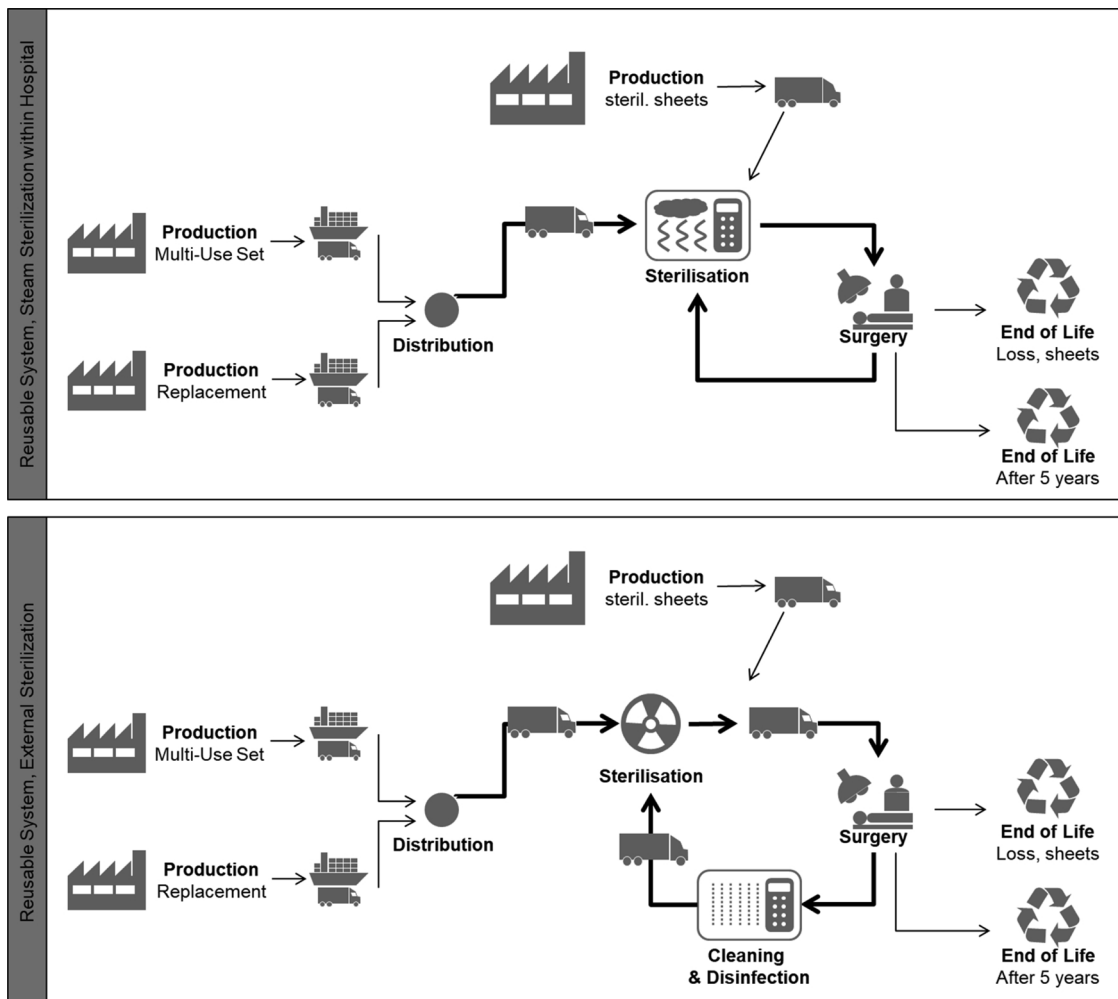


Fig. 5. Second and third additional scenarios for sensitivity analysis.

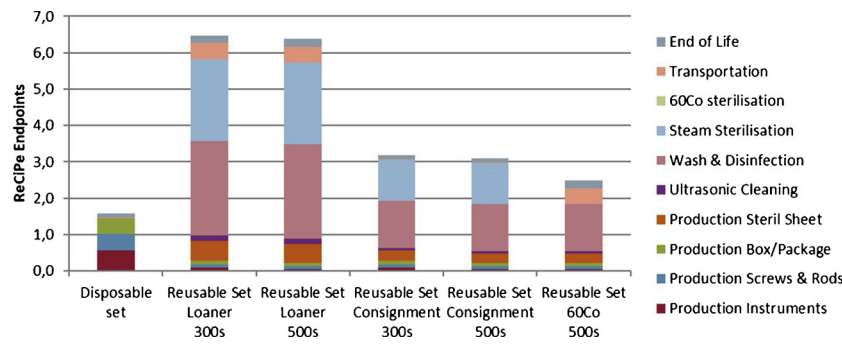


Fig. 6. Results of the scenarios from the sensitivity analysis.

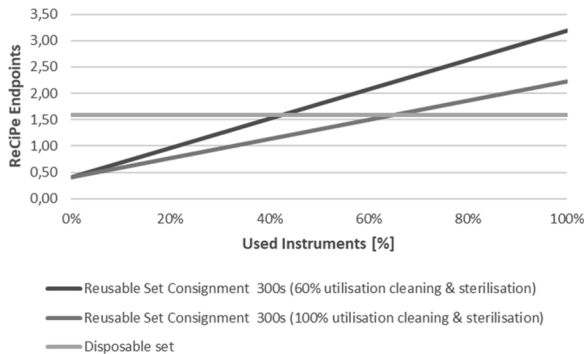


Fig. 7. ReCiPe Endpoints break-even analysis.

7. Implications

Based on this study it can be implicated that reusable products are not always better from an environmental perspective. A product design which leads to lower amounts of waste or parts to be cleaned is decisive. Therefore, this study shows the importance of the integration of a life-cycle perspective in the product development process.

If disposables are used, less energy is required for sterilization but more waste will be produced. A consistent waste management infrastructure in hospitals should be available to avoid these products ending up in landfills. Ideally, recycling routes which allow for preparing contaminated products will be developed for further reductions of the environmental impact.

For policy makers, these results show the importance of promoting the life cycle thinking approach. Simple statements that either reusables or disposables are better from an environmental perspective are critical. They can lead to wrong decisions as the situation is too complex. The integration of the life cycle engineering approach could become part of the conformity declaration as this is prepared during the product design phase.

To reduce the environmental impact and cost, surgery equipment manufacturers should pack their instruments kits into modular units which base on indications. Transferring the approach of using modular kits which are opened during the operation to the reusable instruments kit offers the chance to create a reusable set with a lower environmental impact and at lower cost. To achieve this, it is required that the hospital acquires the instrument set which is not send back to the distributor (Scenario reusable set, consignment, 300 s).

A further measure to decrease the environmental impact is the increase of the utilisation rate of the washing and disinfection as well as the steam sterilisation process from 60 % to 100 %. It has to be noted that an utilisation rate of 100 % in this process steps is typically not reached [this information was obtained from interviews with professionals in the field]. The utilisation of the ultrasonic cleaner for pre-cleaning the instruments is already at 100 % utilisation in the prior scenarios.

Fig. 7 shows that a break-even is reached at using 42.5 % of the instruments for the lower utilisation of cleaning and sterilisation process and at 65 % of the instruments for the 100 % utilisation rate. This means that in case less than 42.5 % respectively 65 % of the instruments are used, the reusable system is preferable. This shows the importance of high utilisation rates in central cleaning units and that modular packed instruments set lead to environmental and economic advantages. Further, modular kits allow to decrease the logistics efforts.

8. Conclusions and outlook

This paper investigated the environmental impact of a reusable and a disposable surgery instrument set for lumbar fusion surgeries with the implantation of four screws and two rods. An LCA was conducted and five impact categories and one single score indicator were used. The environmental impact of the disposable system was significantly lower in all studied impact categories and the single score indicator. The main reason for this is the high environmental impact of the steam sterilization process in hospitals and the big size of the reusable surgery instruments set. The investigation of further use scenarios confirmed this result.

A key implication for the development of future medical instrument and implant sets is that modular surgery sets which do not become fully unsterile upon opening single packages lead to significant environmental benefits. The gamma sterilization has environmental benefits in comparison to steam sterilization as no energy is required for the sterilization process itself. Nevertheless, it should not be neglected that using ⁶⁰Co for sterilization requires high safety standards to ensure that no radiation can leave the sterilization site.

Future work should investigate the environmental impact of different medical instruments and implant sets. If more compact and modular reusable systems are available, a break-even might be reached.

Declaration of Competing Interest

The research was done in the context of a research project funded by Neo Medical S.A. Neo Medical S.A. had no direct influence on the results of the study.

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