



## Neuroanatomical studies

## Value based healthcare: Maximizing efficacy and managing risk with spinal implant technology



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## ABSTRACT

**Objective:** The aim of this work is to investigate the efficiency of the perioperative processing of pedicle screw systems (PSS) prior to and after fusion surgery for conventional systems compared to an innovative value-based system.

**Methods:** This literature and application-based evaluation of efficacy compares a single-use PSS to conventional systems which require re-sterilization. The literature review focuses on sterilization factors, perioperative factors and surgical site infection (SSI) with particular consideration of liability, logistics and costs. An economic benefit simulation considers operating room (OR) time savings and resulting costs regarding preoperative OR preparation, intraoperative OR handling and postoperative OR disposal, and sterilization costs.

**Results:** According to literature, re-sterilizable surgical instruments shows severe contamination after sterilization and reprocessed pedicle screws foreseen may demonstrate corrosion, contamination, deterioration and damage. In addition to the reprocessing costs, the re-sterilization of devices causes indirect expenses due to surgery delays, cancellations and infection treatments. Economic simulation shows average savings per case of 1.167€ for percutaneous and 983€ for open surgery, and of 21 min OR time for a terminally sterilized PSS. Considering also tray sterilization, the average cost savings amount 1.415€ per case.

**Conclusions:** To evaluate the benefits of disposable instruments compared to re-sterilizable systems, process-oriented comparative analyses are required. For the specific setting of spinal fusion surgery, single-use implants and instruments, streamlined instrumentation and optimized operative techniques have the potential to save costs due to significantly decreased expenses for processing, logistics, decreased rates of contaminated instruments, less OR delays, and potentially lower revision and SSI rates.

## 1. Introduction

Health expenditure has risen steadily and considerably in recent decades. Since 2009 average health spending as a share of GDP (gross domestic product) was relatively stable at about 8.8% across all OECD countries. The United States spent the highest share of GDP on health at 17.1% in 2017 with annular growth rates between 1.2% and 4.9% within the last five years [1]. Interestingly, only a rather small proportion of the increase in health expenditure for all OECD countries, namely less than 10%, can be explained by demographic change. On average, income effects play the most important role (> 50%), followed by residual effects including medical and technological innovation with individual variations for each member state [2]. New, value-based healthcare concepts are an important step to ensure that the population continues to receive the best possible medical care in the future. Innovative technologies must focus on both costs and clinical outcome.

In 2011 spinal fusion surgery was the procedure with the highest aggregate hospital costs (12,837 million US\$; 7.1%) with mean costs of 27,600 US\$ per hospital stay in the United States [3]. The gold standard for surgical treatment of various indications requiring fusion of the thoracolumbar spine is posterior instrumentation using pedicle screws.

For a typical mono-segmental fusion, four pedicle screws including locking screws and two rods are implanted. A complex set of instruments and various screw options in different dimensions are offered by manufactures to accomplish this task. These pedicle screw systems (PSS) consist of three to five or, depending on the case, up to 10 trays. Preparing these complex systems prior to and after surgery involves numerous processes that have to be evaluated in terms of time expenditure, logistics, patient safety and total costs. The aim of this work is to evaluate the perioperative processing of PSSs in terms of efficiency for conventional systems that require re-sterilization and an innovative value-based single-use system.

**Abbreviations:** GDP, Gross Domestic Product; LCA, Life Cycle Assessment; OECD, Organisation for Economic Co-operation and Development; OR, Operating Room; PSS, Pedicle Screw System; SSI, Surgical Site Infection; TKA, Total Knee Arthroplasty

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Fig. 1. Single-use instrument kit.

## 2. Methods and materials

The single-use PSS under investigation (Neo Pedicle Screw System™, Neo Medical S.A., Villette, Switzerland) comprises a variety of screw sizes, rod sizes, and instruments. They are all delivered sterile and ready to use. Instruments are made from high performance polymers and are provided in sterile instrument kits for posterior fixation of the non-cervical spine (Fig. 1). Pedicle screws are made from titanium alloy and delivered pre-mounted on a screw extender including a tissue dilator (Fig. 2). All screws are designed to be used either polyaxial or monoaxial, they are cannulated and fenestrated, and are pre-mounted on screw extenders with a continuous thread to be used as reduction screw, or alternatively as standard low profile screw head. The rods are made from titanium alloy as well and delivered sterile. The system can be used via an open, minimally invasive (mini-open) or percutaneous posterior approach.

This disposable implant system is said to be designed to make spine fusion surgery faster, safer and simpler through a consequent integration of surgical technique, implant and instrument design, thus potentially reducing overall costs for the hospital [4]. Each surgical step being meticulously optimized and designed to maintain surgical flexibility, the procedure may increase efficiency and reduce operating room (OR) time. For comprehensive information on conventional and single-use PSSs see Table 1

This literature and application based evaluation of efficiency focuses on sterilization factors, perioperative factors and surgical site infections (SSI) in terms of liability, logistics and costs.

Economic benefit simulation is based on the author's hospital data. One-minute operating room time is valued in our hospital at a cost of 50€ (staff 60%, material 20%, resources ex. Electricity 20%) which is in line with data from other German hospital performing complex surgery [5,6]. Cleaning, disinfection and sterilization cost of 82€ per tray based on our hospital internally calculated cross-charging fees defined by the Controlling department. For pre-, intra- and postoperative OR handling time, a series of 20 spinal fusion surgeries was documented. In 10 cases the single-use system under investigation with/without a cage was used and in 10 cases a reusable control system (CD HORIZON® SOLERA™ System and CD HORIZON® LONGITUDE™ System, Medtronic, Dublin, Ireland) with TSPACE® Transforaminal Lumbar Interbody Fusion System (Aesculap AG, Tuttlingen, Germany). All fusions including cages were transforaminal (TLIF). The conventional systems were specially reduced and customized for our center, to an average of five trays instead of nine. Surgeries were performed in open (control system: four trays) and percutaneous (control system: six trays) technique and were normalized to five screws, which was the average screw number. All



Fig. 2. Single-use screw kit.

**Table 1**  
Conventional vs. single-use PSS.

	Conventional	Single-use
No. of trays	Up to 7	1
No. of instruments	60+	5
Weight	≤70 kg/155lbs +	1 kg/2.2 lbs
Screw inventory	200+	14

activities were carried out by the same experienced nurse.

For preoperative handling, time recording started at the moment when the sterile nurse was informed about the surgical procedure until the moment when the pedicle screw system was prepared for the surgery. This includes the following steps: bringing the material from the storage room to the OR, opening and unpacking the PSS/cages, and preparing the tables and pushing them to the side to cover the patient.

In order to exclude procedure-dependent periods, only the following two steps were recorded for intraoperative handling: 1) Time between the moment the surgeon tells the nurse what screw size and design is needed and the moment he or she holds it in the hand. For resterilizable screws, this includes searching for the screw, reading the reference and lot number to the unsterile jumper for documentation purposes, assembling the screw on the screwdriver and passing it to the surgeon. For the single-use system, this includes opening the screw kit corresponding to the right size required sliding the screwdriver in the pre-assembled screw and passing it to the surgeon. 2) Time between the moment when all screws are inserted in the pedicles and the rods are inserted in the head of all screws until all screws are finally tightened and all instruments including screw extensions are removed.

For postoperative handling, the time period started when the nurse breaks sterility to clean and re-pack the instruments in the trays. For resterilizable systems this includes re-packing to the sterilization trays and closing until the trays are closed and ready to be sent to the sterilization department. For the single-use system it ends when all products are in the trash bin.

Set up of the instrumentation in the OR is shown in Fig. 3 (conventional reusable system, including tray for disc preparation), and in Fig. 4 (single-use PSS system).

## 3. Results

Reprocessing of conventional PSSs includes numerous steps that need to be performed according to legal and manufactures' requirements such as decontamination, inspection, washing, completion, re-assembly, packing, labeling, sterilization, drying and storage. Reprocessing affects mechanically complex implants and instruments with narrow cavities, interfaces and recesses. Less commonly used implant sizes undergo multiple sterilization procedures before final implantation.



Fig. 3. Conventional reusable system set up in the OR room.



Fig. 4. Set up in OR room of the single-use system.

### 3.1. Sterilization factors

A double-blind study to evaluate possible contamination of 23 re-sterilizable surgical instruments found signs of contamination in at least one of the sample regions for all instruments. The majority of instruments (56%) showed severe contamination and only 9% displayed low-level contamination [7]. Thiede et al. [8] monitored the practice of reprocessing at 14 hospitals in Germany and found the following: in 57% the washer-disinfectors and in 50% the sterilizers were obsolete or not suitable for performing a validated process, in 57% basic qualification of staff was not completed and in 79% visual inspection was not performed correctly. All proofed reprocessing units demonstrated a lack of validated reprocessing processes in all sub-steps. The authors concluded that cost savings by reducing quality, low importance of the reprocessing unit in hospitals, and insufficient frequency of monitoring by the relevant authorities are the main causes of poor reprocessing performance. Other studies evaluated pedicle screws obtained from reprocessed implant sets in clinical circulation for the presence of residual nonmicrobial contaminants and/or foreign material and found corrosion, carbohydrate, fat and soap on screws foreseen for implantation. The authors showed that implants that have not been thoroughly cleaned may be associated with impractical cleaning and inspection methods envisioned by the manufacturers. The steps required by manufacturers take 15 times longer than real-time processing does [9]. The results are in line with that of McAuley et al. [10], who studied the effects of repeated reprocessing on single-use screws in screw caddies. These sets were reprocessed on average up to 600 times per annum. Visual proof showed contamination and corrosion of screws in screw caddies. There is evidence that exposure to an increased number of reprocessing cycles leads to increased rates of contamination, corrosion, deterioration and/or damage. Furthermore, it has been shown that bacterial contamination is significantly higher for re-sterilized devices in comparison to new unused instruments after 72 h into a culture medium [11]. Agarwal et al. [12] found in 30–56% of all surgeries contamination in unused trays 4 h after being opened.

### 3.2. Perioperative factors

Approximately 20% of elective surgical case cancellations are caused by facility related factors with highest cancelation rates in surgical specialties that require specialized equipment such as orthopedic surgery [13]. Agarwal et al. [12] evaluated the logistics, costs, and potential adverse effects associated with the current practice of reprocessing medical devices. The following costs and resources were found: initial sterilization \$75 per tray for 100% of non-sterile implants, preoperative delay due to incomplete set/contamination/wet load \$187.5 per hour in 44.4% of all surgeries the delay was > 1 h, total reported OR delays due to incomplete set/contamination/wet load \$10–30 per min in 5.5% of cases, training of employee in sterilization processing department \$41,414 per employee, routine risk analysis \$175 daily to weekly, readmission for surgical site infection (SSI) \$4500

per day in 5.5% of all cases. Assuming 500 surgeries per year and using two implant trays per case, the authors calculated total cost of \$174,374 per year, excluding costs related to SSI and instruments. The authors' conclusion of their work is that the use of terminally sterilized devices is an efficient way for hospitals to decrease their costs for re-processing, associated OR delays and SSI treatment possibly originated from the device because manufacturers are required by law to use standard validated cleaning and sterilization techniques.

### 3.3. Surgical site infection

SSI causes significant burdens to affected patients, hospitals and economic health care systems. There is evidence to indicate that the SSI rate after thoracolumbar spinal surgery is more at the upper end of a range between 4.2% and 13.8% as cited in the literature [14,15]. According to a study conducted in the US, SSI extended the duration of hospital stay by 9.7 days and increased costs by more than \$20,000 per case for various indications [16].

In Europe, the treatment of patients with SSI costs on average approximately twice as much and lasts about twice as long relative to uninfected patients. Broex et al. [17], were able to allocate the majority of the increased costs to an extended stay in hospital, but they also found in their study a negative impact on patient outcomes, increased morbidity and mortality as well as decreased health-related quality of life. The authors highlighted the need for renewed efforts to reduce the financial burden of SSI.

Although SSI is to be considered a multifactorial event, prolonged surgery time was found by Pull ter Gunne et al. to be an independent significant risk factor for deep infection [18]. An increased exposure of the implant to the surroundings increases the risk of contamination, possibly resulting in screw loosening [19]. A prospective bi-centric study comparing single-use instrumentation in posterior lumbar fusion to re-processable instrumentation in the same field of application suggests that single-use instrumentation can reduce SSI to acceptable rates of about 2% [15].

### 3.4. Economic simulation

Pre-, intra- and postoperative OR handling times and the resulting cost savings for the implant system under investigation and the control system are displayed in Table 2.

At the author's site 30% of all surgeries are performed percutaneously and 70% in open technique. Consequently, using the single-use system saves on average 1.038€ and 21 min OR time per case in comparison to the reusable control system. If the costs for tray sterilization are also taken into account, the savings even amount to 1.415€ on average.

Table 2

Pre-, intra- and postoperative OR handling time and cost savings.

	Single-use	Conventional	Time saving	Cost saving
<i>Mean preoperative OR preparation</i>				
– percutaneous	55 sec	365 sec	310 sec	258€
– open	60 sec	405 sec	345 sec	288€
<i>Mean intraoperative OR handling</i>				
– percutaneous	95 sec	835 sec	740 sec	617€
– open	95 sec	575 sec	480 sec	400€
<i>Mean postoperative OR disposal</i>				
– percutaneous	30 sec	380 sec	350 sec	292€
– open	40 sec	395 sec	355 sec	296€
<i>Total mean OR handling</i>				
– percutaneous	180 sec	1580 sec	1400 sec	1.167€
– open	195 sec	1375 sec	1180 sec	983€

#### 4. Discussion

In order to be able to finance the best possible medical care in the future, innovative concepts are required that do not only focus on clinical results and direct expenses, but also optimize entire processes from an organizational and economic point of view. So-called value-based implant systems are expected to show good clinical outcome, to improve the efficiency of the entire perioperative process, to minimize risks for users and patients and so lead to significant financial cutbacks. The time and cost savings discussed herein using a single-use PSS in comparison to a conventional reusable and re-sterilizable PSS can be essentially attributed to three factors: 1) sterile packaging of instrumentation and screw kits, 2) universally streamlined instruments and implants and 3) meticulously optimized operative technique.

As shown by literature, sterile single-use instruments and implants significantly reduce the risk of contamination, corrosion, deterioration and damage. They avoid costs and resources in hospitals for handling, storage and reprocessing, reduce the rate of OR cancelation and delay, and help to decrease SSI which in turn can lead to the need of further healthcare. Disregarding the financial burden caused by SSI, the savings calculated in this study using a single-use PSS amount to an average of 1.415€ and 21 min OR time per spinal fusion surgery.

Bouthors et al. [20] calculated in their prospective, randomized, single-center study on open or minimally-invasive 1- to 2-level lumbar spinal fusion surgery savings for perioperative pure processing of 181€ per surgery when using a single-use device in comparison to a reusable one consisting of 3 trays. For reusable devices seven different processing steps were identified and for single-use devices five steps. Each processing step was evaluated on the basis of personnel costs, consumption costs and hospital waste costs. However, depreciation costs of the sterilization unit, costs for infrastructure and other hidden costs have not been taken into account, underestimating the processing costs of reusable devices. According to Schaer et al. [21] associated costs for reusable instruments account for about 56% of the total costs. Furthermore, the study identified significantly different mean perioperative processing times with 176 min (range: 109–248 min) in the reusable group and 33 min (range: 22–59 min) in the single-use group. The results confirmed that savings are essentially attributed to the absence of pre-disinfection, sterilization and instrument assembling. Another interesting aspect is the high variability of processing times, which is caused by different experience and qualification of the personnel. Considering this fact Thiede et al. [8] found that in practice 65% of the staff do not have a completed basic qualification, the reesterilization of the instruments unnecessarily results in increased contamination risks and higher time expenditure leading to higher costs. Bouthors et al. [20] mentioned further time delays and consequently increased costs, which, however, were not further specified in the study, that arose due to the absence of the reusable system at the time of surgery in 10% (2/20) of cases. According to Bouthors et al. single-use set availability can be of clear advantage especially in trauma departments. But also the lower weight and reduced SSI risk of disposable devices are advantageous. Other authors [22], who performed activity based costing analysis and cost-effectiveness analysis for lumbar arthrodesis with reusable and disposable kits, confirmed the above mentioned findings in principle regarding patient's safety, hospital in-house logistics, set availability and cost savings, however with comparatively lower cutbacks.

Sterile-packed single-use instruments are also used in Total Knee Arthroplasty (TKA). A literature based cost model study [23] investigating the logistical and economic advantages of sterile single-use instruments for TKA confirmed significant median cost savings of \$994 per case (interquartile range \$759–\$1231). Instrument unavailability has also not been accounted for in this model. The authors summarized that single-use instrumentation has the potential to support time and cost efficiency while improving process reliability and predictability. OR overtime can dramatically be reduced by the use of disposable

instruments allowing for higher case numbers. Other authors confirmed increased efficiency and less instrument-related costs due to single-use instruments in TKA [24,25], but not for laparoscopic surgical instruments [21] or distal radius plating [26].

The opponents refer to increased environmental pollution caused by disposable instruments that end up in the garbage after each surgery [21]. According to Soroceanu et al. [27], the monthly costs for waste associated with spine surgery are on average \$17680 at their department of Orthopaedic surgery. A recent study compares the environmental impacts of a conventional reusable loaner set of surgical instruments for lumbar fusion to a streamlined disposable set using Life Cycle Assessment (LCA) [28]. Leiden et al. report a 75% overall benefit for the application of the single-use set with savings ranging from 45% to 85% for the individual impact categories (energy use, resource consumption, emissions of greenhouse gases, acidification potential and particular matter) and an aggregated single score indicator (18 impact categories contributing to human health, ecosystem quality and resource availability). According to the study results, the main environmental impact for the single-use set is caused during production and for the reusable set during sterilization with the greatest effect due to energy consumption for washing and steam sterilization. Transport and waste have only a minor influence on the LCA of both systems with higher environmental burden for the reusable system due to sterile sheets made of polypropylene for tray wrapping in comparison to various types of plastic for packing and single-use instruments of the disposable system. The authors describe possible improvements by switching from loaner to consignment systems and from steam sterilization to <sup>60</sup>Co gamma sterilization, while the environmental impact for the reusable system remains higher and no break even can be achieved. Further savings could be achieved by reducing the number of instruments to be sterilized, e.g. through smaller modular instrument kits and by increasing the efficiency of surgeries due to reduced OR times.

This literature and simulation based analysis of efficiency has some limitations, mainly due to the complexity of the processes and the lack of universal costs, which are to a large extent user and health system dependent. On one hand, the costs and time measures, but also the organizational structures vary from hospital to hospital and from country to country. For instance, costs for reesterilization depend mainly on the number of instruments and trays to be sterilized and therefore vary significantly from PSS to PSS. Possible intraoperative time savings depend, among other things, on the surgical technique used. Personnel costs and reimbursement in the health sector vary from country to country, and from hospital to hospital. Furthermore, indirect expenses such as depreciation costs, expenses for maintenance and repair, energy, water or general consumables like soap etc. are difficult or impossible to allocate to individual process steps. According to literature reviews sterilization costs range from \$31 to \$100 per tray [23] and OR costs from \$22 to \$133 per minute with an average OR fee of \$62 or \$66 under consideration of anesthesiology [29]. Goldberg et al. mention operational and staff wage differences and differing accounting methods as a cause. Also Siu et al. [30] concluded from their systematic review of reusable versus disposable laparoscopic instruments that operative costs, hidden costs and sterilization methods vary greatly between studies. The relatively small number of cases performed with the new technique is a limitation of this study, and further process-oriented research is required to compare the efficiency of disposable instruments with that of reusable instruments using standardized economical methods. Clinical studies, single-center and multicentric, are ongoing to confirm the safety and efficacy of the single-use system, but also randomized multicentre clinical studies are needed.

#### 5. Conclusion

In order to evaluate the benefits of disposable instruments compared to re-sterilizable instruments, a pure comparison of acquisition

costs is not sufficient. Rather, process-oriented value-based comparative analyses are required.

The present study shows, that for the specific setting of spinal fusion surgery, sterile packed single use implants and instruments, streamlined instrumentation and optimized operative techniques have the potential to give added value to both patients and healthcare suppliers. This includes direct cost savings due to decreased rates of damaged or contaminated implants and instruments, and less processing-related OR delays, resulting in more efficient OR utilization, and potentially in lower revision and SSI rates as well. Terminally sterilized implants and instruments can help hospitals to significantly decrease their costs for processing and reduce in-house logistics and storage capacities while improving the environmental impact.

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### Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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