A safer, easier, cost effective solution for spinal implant management is possible.
IMPLANT REPROCESSING IS ASSOCIATED WITH:

- FDA REGULATIONS
- RISKS
- LIABILITY
- TRACEABILITY
## Summary

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1. References

The following articles are referenced in this document:


- Single-Use Screws and Plates. Joanna Ford (R&D Officer, SMTL), Graham Yarlett (HSDU Manager, Royal Glamorgan Hospital), Gill Bailey (Contracts Officer, WHS), & Pete Phillips (Director, SMTL) Epub http://www.medidex.com/research/788-single-use-screws-and-plates.html


2. Executive Summary

Infection rates in spinal surgery range between 1% and 15%, causing significant patient morbidity and resulting in important additional costs to the hospital. Working with devices that are clean and free of contamination is paramount to prevent surgical wound infections. However, a rapid look at the current practice by most implant vendors in the US calls into question the general adherence to this basic requirement.

The concerns raised by the use of reprocessed implants have motivated countries such as Australia and Scotland to specifically address the problem, recommending the use of single use, pre-sterilized implants. In Scotland, the deadline for the conversion to prepackaged sterile implants was December 31st, 2007.

As the Scottish Health Department points out, “most orthopedics units use (...) small orthopedics implants which have been repeatedly reprocessed in racks or trays (...). We suspect many of these devices have been recirculating for many years. Using up old stock would simply prolong what we now recognize as suboptimal clinical practice.”

To ensure safety and compliance, Spineart, a spinal device company with its origin in Switzerland, has offered sterile single packaged barcoded implants for almost 10 years. Using sterile packaged implants is a safer, simpler and cost-effective solution to mitigate the risk of infection.

Sterile implants meet compliance requirements, including unwanted transfer of liabilities.


3. Infections

Implants are foreign bodies retained within the surgical wound, therefore representing a threat of infection. Implants require particular care in terms of sterilization practice and quality control process.

Any microorganisms present on the device at the time of implantation will remain in the system, although infections associated with implants may not be evident for up to a year after procedure.

In addition, the placement of an implant often means the removal of tissue, with interruption of blood supply and significant manipulation of the tissues immediately adjacent to the implant, creating an area potentially favorable for microorganisms to multiply, further increasing the risk of infection. Furthermore, because there is interrupted blood supply, antibiotics cannot easily reach the microorganisms that may cause a clinical infection.

Often, the infection is not curable with the implant in place and removal may be required, placing an additional risk of severe permanent injury for the patient\(^3\).

4. Risks of reprocessing

Most often, the single-use spinal implant trays are loaned and delivered as non-sterile, requiring processing to make them ready for use.

The lifecycle of an implant has many steps, each of them adding potential risk factor for contamination.

The lifecycle of an implant has many steps, each of them adding potential risk factor for contamination.
The practice used for re-processing (or re-sterilization) of medical implants raises several concerns.

**Transfer of liability**

There are a number of legal concerns associated with re-processed implants.

Outside of the United States, the United Kingdom’s Medicines and Healthcare Products Regulatory Agency states: “The reuse of single-use devices has legal implications: anyone who reprocesses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness.”

No clear guidance is provided to define the term *reuse*, although the term single-use indicates that reprocess should not take place under any circumstances.

**Lack of compliance**

Another relevant concern related to reprocessed implants is the lack of traceability. It is not possible to trace back the history of the implants (for example: manufacture date, how many times it has been reprocessed, where and how many times it has been shipped.)

If, for example, a device is subjected to a recall, it is not possible for the healthcare provider to know which patient has been implanted with the incriminated batch. Practically, this means that every implanted patient will be reached and monitored, irrespective of the lot number of the implant used on them.

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Risks of reprocessing

Unproven cleaning

A significant concern is the ability to properly clean the implants.

The racks that hold the implants are not designed to enable optimal cleaning but more to facilitate the selection of the size in the OR. Therefore, when the rack is cleaned through an automated washer, cleaning and rinsing of each individual implant becomes challenging.

Recent studies documented that, despite sterilization, the endotoxins retain biological activities.

Biological and chemical residues will retain their immunogenicity after sterilization.

Despite sterilization, the endotoxins retain biological activities.

Example of tray showing residues post-reprocessing

[6] Reprocessing of Implantable Screws and Plates in Orthopedic Tray Sets

Risks of reprocessing

Corrosion

Once an implant arrives to a healthcare facility, it is not possible to know how many times it has been reprocessed. However, repeated sterilization cycles may ultimately have an impact on the surface of the implant.

The reprocessing of non-sterile implants involves a certain level of mechanical (abrasion and/or fretting) and electrochemically corrosion (contact with solutions and other metals).

Although little research has been published on the topic, there is the possibility that repeated cycles of sterilization already started the corrosion process prior to implantation, thus making metal fracture and subsequent implant failure more likely8.

Risks of reprocessing

Contamination

As previously mentioned, often the implant sets are provided to the healthcare facility on a loaner basis.

There is no guideline available for the shipment of the implant sets and often, between surgeries, the sets travel in the car of the sales representative. The implant sets are therefore continuously exposed to hazardous contamination and ultimately the hospital is responsible for the cleanliness and sterility.

A recent study based on 105 consecutive surgical cases, has shown that contamination of implants in the OR occurs after the tray is opened.

Although set coverage significantly reduced the contamination, it does not completely eliminate the risk.

The implant sets are exposed to hazardous contamination and the hospital is responsible for the sterility.

Example of a cannulated pedicle screw containing bone after reprocessing

Risks of reprocessing

Costs

The costs associated with reprocessing are often ‘hidden’ and transferred by the vendor to the healthcare facility.

The financial cost of the implant sets’ reprocessing is difficult to estimate as it varies from one center to another. However, the cost of the actual reprocessing is only a part of the financial burden ascribed to the healthcare facility.

The implant trays are checked at different stages after reprocessing prior to OR use. This time consuming practice often results in trays returned from the OR for being considered non-compliant. A non-compliant implant set at the time of the surgery may result in important costs in the form of delays and cancellations.

Moreover, post-operative infections are considered “Never Events” by Centers for Medicare & Medicaid Services (CMS) and as such might not be reimbursed by Medicare.

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Moreover, post-operative infections [...] might not be reimbursed by Medicare.
5. A new Generation of Implants: Sterile, Single Packaged, and Barcoded

To prevent any concerns related to reprocessed implants, Spineart is providing since 2005 an entire range of sterile spinal implants.

**What are the advantages of pre-sterilized implants?**

- NO contamination risk from reprocessing
- NO more transfer of liability
- NO risk of material corrosion
- FULL traceability and compliance
- Cost savings

The Spineart implants are provided in individual boxes, sterile, with double packaging allowing a compliant transfer from a non-sterile to sterile area within the operating room.

Along with the implant in its sterile double packaging, Instructions For Use (IFU) and stickers with reference, lot numbers and barcodes are provided inside the box.

Spineart implant: packaged in double pouch; IFU and stickers labels with barcodes are inside the implant package.
Sterile, Single Packaged, and Barcoded

The outer box incorporates a wide label with a clear image of the implant, reference, size and quantity, lot number and expiration date.

The barcodes conveniently summarize all that information in an easy to process format.

The box is covered in an external wrap to provide additional evidence of any tempering with the packaging.

External labeling with visual, references, size, quantity, lot number, expiration date and barcodes.
Sterile, Single Packaged, and Barcoded

**No liability**

As the healthcare facility is not involved in reprocessing, there is no more transfer of liability from the vendor to the hospital with regards to implant sterility and integrity.

In terms of potential claims arising from insurance companies or patients as a consequence of surgical wound infection, the use of sterile implants is also becoming critical in order to demonstrate that the healthcare provider made use of every available technology to reduce the risk for the patient.

**Full traceability**

All Spineart implants are barcoded, by part and lot number, using standard barcodes and 2D barcodes.

With hospitals moving to Electronic Medical Records (“EMR”), such as Epic, Spineart is the only spine company with implants that can be scanned into any EMR system as they are implanted, removing human error.

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Image of label sticker provided with the Spineart individually packaged sterile implant.
Sterile, Single Packaged, and Barcoded

**Cost effectiveness**

Sterile single packaged barcoded implants are alleviating the healthcare facility of the financial burden and time necessary for the reprocessing.

Time and resources at the sterilization department are freed allowing more efficient and better quality service for the rest of the reusable instrumentation.

The association of barcoding with an effective hospital tracking system ensures that only the implants used will be billed.

**Sterilization method**

Sterile single packaged implants are wrapped in sealed packaging and do not require washing and steam sterilization prior to use. Each implant used in procedure is taken out of its packaging only seconds before being implanted. Unlike for reprocessed spinal implants in implant racks, the risk for contamination pre, peri and post implantation is virtually non-existent.

Manufacturing of sterile single packed implants by Spineart takes place in a clean room in compliance with ISO14644: 2004 Class 7, an FDA recognized standard. Implants are sterilized using Gamma rays.

In a final validation step, specific tests are implemented to demonstrate implant cleanliness, cytotoxicity according to ISO 10993-5, systemic toxicity according to ISO 10993-11, pyrogen testing according to European Pharmacopeia, and various determination of residues level such as total organic carbon, total hydrocarbon and heavy metals.
6. Conclusion


Within this context, the use of reprocessed implants raises several concerns.

One of the first questions is whether the supplier has validated that the implant sets can be safely reprocessed hundreds of times and if so, what are the consequences for the integrity of the surface of the implant.

In addition, before and during the surgery the implants are exposed to hazardous contamination; even after the sterilization, it is well documented that endotoxins retain their biological activity. Biological and chemical residues will retain their immunogenicity after sterilization.

The lack of traceability of implant batch may result in time-consuming practices and a number of legal concerns that are associated with the responsibility for the sterilization of the implant.

Working with prepackaged, sterile implants offers demonstrated advantages in terms of safety, implant integrity, traceability, liability and cost saving.