PRE-STERILIZED SPINE IMPLANTS

Technical Report

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Medacta International

PRE-STERILIZED SPINE IMPLANTS - TECHNICAL REPORT

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A NEW TREND OF IMPLANTS: STERILE, SINGLE PACKAGED AND BARCODED

To prevent any concerns related to reprocessed implants, all Medacta Products are pre-sterilized and ready for implantation, which offers a multitude of benefits to the surgeon and the hospital.

Pre-sterilized implants eliminate the risks of reprocessing:

- Contamination in the OR
- Transfer of liability
- Unproven cleaning
- Material corrosion
- Cost of sterilization

The FDA mandates obligatory tracking of both lot and reference numbers of all implants.

Medacta offers a solution to this because pre-packaged sterile implants provide traceability for each implant that goes in every patient.

The Medacta implants are provided in individual boxes, sterile, with double packaging allowing for 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 every box.

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

The barcode conveniently summarizes all of this information in an easy to process format.

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

1 IMPLANTS LIABILITY

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

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

2 FULL TRACEABILITY

All Medacta implants are bar-coded, by part and lot number, using standard bar codes GS1.

3 COST EFFECTIVENESS

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

Time and resources in 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.

4 STERILIZATION METHOD

Sterile double 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 reprocessed spinal implants open during the entire case, the risk for contamination pre, peri and post implantation is virtually non-existent.

Manufacturing of sterile implants by Medacta takes place in a clean environment in compliance with ISO14644: 2015 Class 7, a FDA recognized standard. Implants are sterilized using Gamma rays.

In a final validation step, specific tests are implemented to demonstrate implants cleanliness and sterilization:

- Sterility test according to ISO 11737-2
- Bioburden test according to ISO 11737-1
- Cytotoxicity test according to ISO 10993-5 and USP<87>
- Systemic toxicity test according to ISO 10993-11
- Pyrogen test according to USP <151> and Endotoxin test according to EP2.6.14
- Determination of residues level as per ASTM F2459-12

5 ISSUES RELATED TO NON-STERILE IMPLANTS

«[...] Using up old stock would simply prolong what we now recognize as suboptimal clinical practice.»[1]

To ensure safety and compliance, Medacta, 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.

«The cost and risk associated to infection can be mitigated by ensuring appropriate implant sterilization»

Infection rates in spinal surgery range between 1% and 15%, causing significant patient morbidity and resulting in significant additional costs to the hospital[2]. Working with devices that are clean and free of contamination is paramount to prevent surgical wound infections.

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 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].

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

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.

«[...] anyone who reprocesses a device bears full responsibility for its safety and effectiveness.»

6 TRANSFER OF LIABILITY

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[4]".

In the case of non-sterile products being prepared for multiple surgeries, the verification that each device has not been re-used is never possible, and therefore liability may be questioned and patient safety endangered.
In addition to that, the responsibility for cleaning and sterilization processes, performed repeatedly, lies entirely with the health-care provider.

7 LACK OF COMPLIANCE

Potential consequences of multiple reprocessing cannot be assessed by the final user, who is not equipped to carry out the final checks that are listed in the product manufacturing process. Therefore, the device being implanted may have been damaged by chemical or mechanical factors during the reprocessing/multiple shipping phases and such damages will go undetected.

As in the vast majority of cases the batch number of a non-sterile implant is NOT transcribed on the patient record, the hospital will hardly be able to connect a batch number with the patients that received those implants. Therefore, in case of a batch recall, the number of patients who will need to be recalled may be much larger, as all patients implanted with a certain reference number (not a batch number) should be examined or treated as per recall instructions.

8 UNPROVEN CLEANING

Despite sterilization, the endotoxins retain biological activities: A significant concern is the ability to properly sterilize the implants.

The caddies 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 caddy is cleaned through an automated washer, cleaning and rinsing of each individual implant becomes challenging.

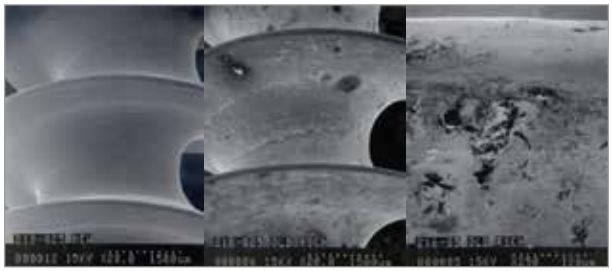
Recent studies documented that, despite sterilization, the endotoxins retain biological activities .

Biological and chemical residues will retain their immunogenicity after sterilization.

«[...] 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 electrochemical 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 likely.



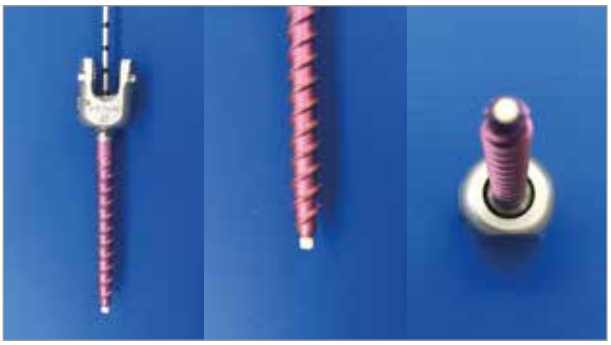
Microscopic images of a new, unprocessed screw (left image) alongside 2 images of screws that have undergone reprocessing on numerous occasions (images taken at 2 different magnifications).

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

There is no guideline available for the shipment of the implant sets, 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 OR occurs after the tray is opened.

Although set coverage significantly reduced the contamination, it does not completely eliminate the risk[5].



Example of a cannulated pedicle screw containing bone after reprocessing

9 ASSOCIATED COSTS

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

The implant trays are checked at different stages after reprocessing prior to OR use. This time-consuming practice often result 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.

10 CONCLUSION

Postoperative infections and their costly consequences call for a deeper understanding of risk prevention.

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 implant surface.

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.

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[3] Schultz,Janet.Monitoring and Load Release for Implants Sterilized by Steam Within Healthcare Facilities. Managing Infection Control. Jan 2004.

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[5] Implant contamination during spine surgery. Jesse E. Bible, MD, MHSa, Kevin R. O'Neill, MDa, Colin G. Crosby, MDa, Jonathan G. Schoenecker, MD, PhDa, Matthew J. McGirt, MDb, Clinton J. Devin, MDa. The Spine Journal 13 (2013) 637-640.

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