# The Move to On-Demand Sterile Implants and Instruments: Eliminating Reprocessing Risks

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It is common practice among hospitals and surgical centers to re-sterilize unused metal implants, such as small plates and screws, hundreds and sometimes thousands of times before they are implanted in a patient.

Just how many times these metal implants undergo reprocessing procedures, and how they perform post-operatively, is cause for concern and discussion. How clean and reliable are they?

These questions are being increasingly raised by practitioners and health system administrators worldwide:

*"As I became more aware of the issues associated with implants that have been repeatedly reprocessed, I began to adopt the use of pre-sterile plates and screws into my surgical practice."*

*"Waiting for the hospital to sterilize implant trays can create long delays in my operative schedule. I appreciate the ability to use sterile on-demand devices immediately and have an increased peace of mind that any potential issues related to reprocessing are eliminated."*

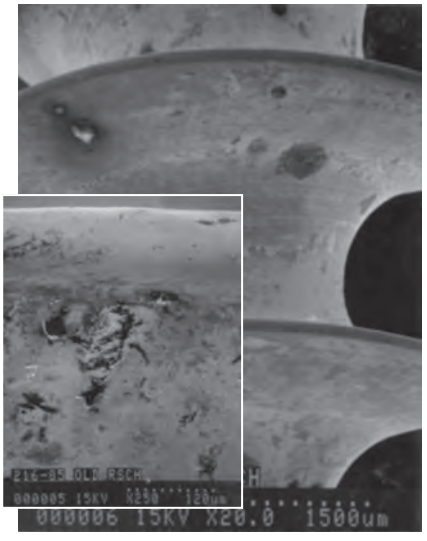
– Travis Hanson, MD
Foot & Ankle Orthopedic Surgery
Houston Methodist Orthopedics and Sports Medicine

Do pre-sterilized, single-use implants and instruments have distinct advantages over those that are repeatedly sterilized? What are the risks? And, what are the advantages of moving to on-demand pre-sterilized implants?

## KNOWN RISKS:

***Contaminants*** that remain post-sterilization – and can lead to inflammation -- are of obvious concern. While scrupulous cleaning to rid implants and instruments of all microorganisms and their possible pathogens before they enter an operating room is a routine procedure, inadequacies can occur if all areas of a device are not easily accessible. Even after cleaning, contaminants can unknowingly remain.

***Wear and fatigue*** are particularly important issues with all surgical implants. The sterilization procedure itself begins the intractable process of wear.



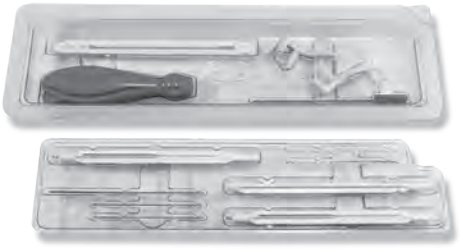
**Images of screw that has undergone re-processing on numerous occasions. Photo by Surgical Materials Testing Laboratory[2].**

Critical inspection of the cleaning and sterilization process, reveal unsettling findings related to contamination and implant morphology.

## STUDIES HAVE FOUND:

- **Cleaning followed by sterilization can result in altered surface morphology** as well as chemistry; implants that are re-washed and re-sterilized are not as clean and do not supply the same reliability as do new, never-before-opened, fresh implants.[1]
- **Repeated re-processing can increase the potential for cross-contamination** and leave devices inadequately decontaminated. This may damage or corrode the device potentially resulting in fatigue-induced failure.[2]
- **Organic residuals found on reprocessed screws and plates may stimulate an inflammatory response**. Re-running trays of screws and plates does leave a potential bioburden behind that could lead to potential complications.[3]
- **Visual proof… of contamination and corrosion caused by repeated reprocessing of single-use screws in screw caddies** … call for a change from the routine use of screw caddies to individually packaged and sterilized plates and screws.[4]

In response to these concerns, In2Bones, a global extremity company, designs and manufactures a full line of pre-sterilized implants for



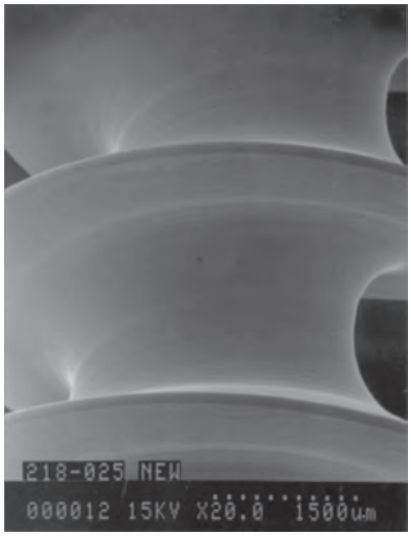
**In this example, the NeoSys Disposable Instruments set includes: Drivers, Handle, K-wire selection and Guides, Countersink and Depth Gauge.**

extremity surgery supplied together with single use, implant-specific instrumentation.

All implants are packaged pre-sterilized as part of the company's effort to provide innovative solutions that meet real clinical needs.

**ADVANTAGES OF PRE-STERILIZED DEVICES**: While health professionals await definitive clinical conclusions, they are already recognizing many advantages with pre-sterilized devices. Among them:

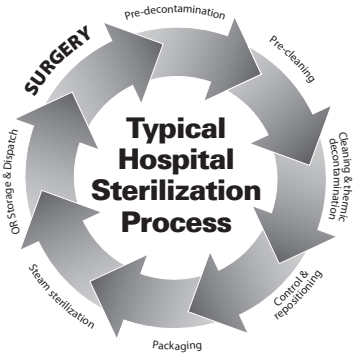
ELIMINATES CONTAMINATION AND WEAR RISKS: As noted previously, re-processed implants and instruments are subject to contamination, fatigue and wear risks[2]. Pre-sterilized devices put the burden of sterility on the device or instrument manufacturer.

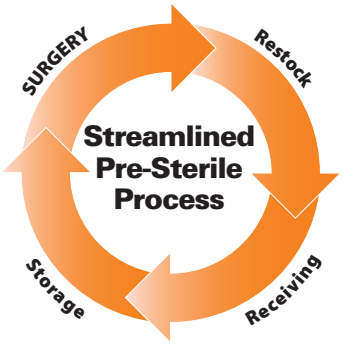



**Microscopical images of a new unprocessed screw. Photo by Surgical Materials Testing Laboratory[2].**

INTEROPERABILITY ADVANTAGES: Practitioners often work from multiple large trays of re-sterilized plates and screws. Too many trays crowd case carts and back tables. Pre-sterilized instrument kits are a quarter of the size of regular trays, and the surgical team uses only what is needed, cutting down on waste, minimizing contamination risk, while making the most of limited space in the O.R.

INTAKE AND PROCESSING EFFICIENCIES: Loaner tray intake guidelines require multiple steps and many hospitals require 48-72hour delivery before a scheduled procedure. Pre-sterilized implants and trays streamline this process on both the front and back end:




- No mislabeling or need to check trays for contents.
- Reduces inventory maintenance.
- Reduces check-in time and allows for convenient delivery.

REDUCED O.R. DELAYS: Any hint of contamination ensures instruments are returned for re-processing, potentially causing costly O.R. delays or cancellations. Pre-sterilized devices eliminate delays due to moisture in the tray, or an overlooked, contaminated instrument.

NURSING STAFF EFFICIENCIES: There is no doubt that data entry encroaches on staff workloads. Consider that every tiny plate and screw may soon require entry into a UDI database and in insurance claims. Pre-packaged, single use implants and instruments are already identified by UDI numbers eliminating the time required to search a supplier's cross reference UDI catalog in the surgical theater where patient care is the priority.

PROCESSING COST REDUCTION: All the expense involved in cleaning and sterilization should be factored into actual implant costs. Pre-sterilized on-demand implants may, at face value, have the perception of increased cost however, factoring in all the potential savings, the actual per-unit cost becomes less of an issue.

ELIMINATING THE ISSUE. FOCUSING ON SAFETY AND RELIABILITY AS PRIORITIES: While more definitive clinical study is required on the repeated reprocessing of medical implants and instruments, health professionals are finding more advantages than disadvantages to pre-sterilized devices. Considering a health system's need to prevent infection, reduce costs, and operate more efficiently, the switch to on-demand sterile implants and instruments makes for quality patient care and smart business.

**Example of a sterile plate and compression screw in sterile nested tubes including UDI compliant labels.**

1. Jung Hwa Park, Rene Olivares-Navarrete, Robert E. Baier, Anne E. Meyer, Rina Tannenbaum, Barbara D. Boyan, and Zvi Schwartz, "Effect of Cleaning and Sterilization on Titanium Implant Surface Properties and Cellular Response." Acta Biomaterialia, 2012 May 8(5): pp. 1966–1975. 2. Joanna Ford, R&D Officer, SMTL; Graham Yarlett, HSDU Manager, Royal Glamorgan Hospital; Gill Bailey, Contracts Officer, WHS; Pete Phillips, Director, SMTL, "Single-Use Screws and Plates," Surgical Materials Testing Laboratory's Medidex Medical Device Index, Feb 18, 2013. 3. Michelle J. Alfa (2012) "The 'Pandora's Box' Dilemma: Reprocessing of Implantable Screws and Plates in Orthopedic Tray Sets," Biomedical Instrumentation & Technology: Reprocessing, Vol. 46, No. sp12, pp. 55-59. 4. Terry McAuley (2016) "Reprocessing of Single-use Screws: A Study on the Effects of Repeated Reprocessing on Single-use Screws in Screw Caddies. Australasian College for Infection Prevention and Control 2016 Conference