Abstract
Currently, there are two orthopedic implant types: (1) Sterile implants (e.g., joint prostheses) are distributed in a ready-for-use sterile fashion, and (2) nonsterile implants (e.g., plates, screws, Schanz pins, intramedullary rods) are processed by a healthcare facility’s central sterile service department (CSSD).

The current study evaluated processed implants for presence of coagulase-negative staphylococci, which was observed in 30% of the cortical screws, spongy screws, and Schanz pins (37 total samples) processed by a CSSD. Some samples were resistant to antimicrobial agents, thereby demonstrating that risk exists in the current methods used in the processing of nonsterile implants. Also of important note, nonsterile implants are commonly loaned worldwide. Loaned implantable materials should not be processed in the same manner as materials routinely prepared in the CSSD, as it is not possible to know the quality of the cleaning performed before the materials are returned to the loaning company. It is not uncommon for hospitals to receive loaned materials with organic residues.

Most surgical site infections (SSIs) in orthopedics are associated with the presence of implantable materials. Evidence indicates that prosthesis infections actually are biofilm-correlated infections that are highly resistant to antibiotic treatment and host immune responses. Orthopedic implants may be commercialized in two ways, as determined by the manufacturer: (1) Sterile implants (e.g., joint prostheses) are distributed in a ready-for-use sterile fashion, and (2) nonsterile implants (e.g., plates, screws, Schanz pins, intramedullary rods) are processed by a healthcare facility’s central sterile service department (CSSD).

The latter type of orthopedic implants are considered loaned and usually are packaged with surgical instruments in trays, with intended and perceived use on many different patients throughout the lifetime of the implants. The implantable pins and screws described in this article are loaned instruments, meaning that they have been transported between the supplier and a variety of hospitals to which they have been loaned for use.

Healthcare facilities routinely borrow specialty surgical instruments and implants worldwide to provide needed inventory without the burden of purchasing specific and expensive materials. Specific implants may require specialized surgical instruments to be implanted, thereby requiring a large amount of items in a facility’s inventory, resulting in burdens related to storage space and cost. Also, due to constantly changing technology, many healthcare facilities are challenged to keep their equipment inventories updated.

The facility described in this article (a 153-bed intermediate care hospital) receives numerous loaned sets of nonsterile orthopedic implants each month. When these sets arrive from the loaning company, they are considered contaminated and are delivered directly to the decontamination area for processing. Schanz, or stabilization, pins are among the most frequent nonsterile implants received by the CSSD at the facility. They are used to fix the tubular external fixator, which is used for temporary fracture stabilization and osteosynthesis implants.

An unexpected and unusual increase in infection in orthopedic surgery cases (39% superficial, 37% osteomyelitis, 24% deep incisional) was observed at the study facility. Three patients had no implants, five had manufacturer-sterilized prosthesis, and 48...
patients had implants processed by the CSSD of the hospital, including Schanz pins, plates, screws, Kirchner wires, and intramedullary rods.

Considering the possibility of biofilm contamination in these processable implants, this study sought to assess the sterility of Schanz fixation pins and screws processed in a CSSD.

Methods
Cortical screws, spongy screws, and Schanz pins received by the CSSD were used as samples in this study. These items were received in the decontamination room, where they were fully inspected, then cleaned immediately in a washer disinfector (105M; Cisabrasile, Joinville, Brazil) with a programmed cycle that included a three-minute cold prewash without detergent. This was followed by two cleaning phases at a temperature of 40°C for five minutes with enzymatic detergent (Luckzyme; Luckmann, São José, Brazil), and two rinses with cold water and consecutive thermal disinfection with demineralized water at a temperature of 93°C/199.4°F for 10 minutes. To ensure the efficacy of the processes, the performance of the washer disinfector was checked by commercially available tests.

After visual inspection and preparation, the materials were steam sterilized (420-640 Series; Cisabrasile) in a validated prevaccum 134°C cycle for five minutes based on the manufacturer’s instructions for use (IFU). The process was monitored by type 6 chemical indicator and a three-hour reading biological indicator. After sterilization, in the laboratory, the sets were opened in a laminar flow hood with aseptic technique. The samples were randomly removed with a sterilized forceps by a researcher wearing full surgical gowning (sterilized long-sleeved apron and gloves, mask, and cap).

A total of 37 samples of cortical screws, spongy screws, and Schanz pins were inoculated into a test tube containing thioglycollate (Difco, Franklin Lakes, NJ), which is used for sterility testing and rapid cultivation of anaerobic and aerobic microorganisms. The thioglycollate was selected because of its ability to support good growth of a broad variety of organisms. To release any biofilm that potentially was adhering to the surfaces, the tubes were sonicated (Enge Solutions) for five minutes and agitated for 30 seconds in vortex (Vortex-Genie 2);
Scientific Industries, Bohemia, NY). The samples were blinded in relation to the companies that loaned the implantable materials during laboratory analysis; therefore, it was not possible for researchers to discover the group to which the samples belonged, thereby avoiding potential bias.

The samples were incubated for 14 days at 36°C ± 2°C/96°F ± 2°F. Macroscopic observation of the turbidity in the culture medium, which is an indication of microbial growth, was conducted on a daily basis.

**Results**

From the fifth day of incubation, growth of coagulase-negative staphylococci (CoNS) was observed in 30% of the 37 inoculated samples. In the antibiotic sensitivity analysis, five CoNS samples showed resistance to erythromycin, penicillin, sulfamethoxazole, and trimethoprim.

**Conclusion**

As a result of the macroscopic aspect of the contamination in the culture media (i.e., coming from samples to the surface), the growth of CoNS in the samples provided strong evidence of the existence of biofilms in the analyzed materials. Identifying resistance to antimicrobials reinforces this possibility, which indicates the presence of risk in the current practice of processing implantable materials in the CSSD.

The ability of CoNS, which has been described as the main pathogen responsible for orthopedic infections, to form biofilms in both implants and instruments has been shown to result from the extracellular polysaccharides they produce. Residual biofilm in orthopedic surgical instruments already has been considered to be responsible for an outbreak of CoNS. The same microorganism was isolated in patients of another outbreak, in which the instruments used presented organic matter remains. An outbreak of *Pseudomonas aeruginosa* also was associated with failures in the processing of orthopedic surgical instruments, with organic matter identified in the instruments. Of important note, the formation of biofilms and their density gain is directly proportional to the time that a health-related product remains dirty and wet.

The International Organization for Standardization (ISO) standard, ISO 17664:2017, recommends that manufacturers commercializing nonsterile implants should provide IFUs for processing. The standard also states that those responsible for processing must strictly follow the IFUs and be aware that they are responsible for the risks inherent in material processing. Implants supplied under nonsterile conditions are subject to the same requirements that are applicable to implants supplied under sterile conditions.

To avoid cross-contamination, it is further recommended that implants should not be cleaned with other health products. However, loaned materials are delivered to hospitals without any written guidance on how to perform the cleaning process. In addition, some packs containing implants have no appropriate confirmation that they are suitable for the cleaning equipment used in the CSSD. Therefore, facility staff are left to rely on common sense in determining the cleaning process.

This study reinforces the existence of risk in processing implants, as well as serves as a call to action on the part of manufacturers and regulatory agencies to rethink the way these materials are commercialized.

**Disclaimer**

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References


