The Standard Reusable Orthopaedic Depth Gauge: A Pilot Study of Residual Device Contamination Following Routine Cleaning

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Purpose: Surgical site infections (SSIs) are a serious issue in orthopaedic surgery, occurring in up to 4% of cases. One known etiology behind hospital-acquired SSIs is the use of contaminated reusable medical devices, particularly those with designs that make effective cleaning difficult, because proper cleaning is essential for effective sterilization. Several such design features, including rigid lumens and multiple parts, exist in orthopaedic depth gauges, which are routinely used in trauma surgery and regularly exposed to blood, bone, and tissue. The purpose of this study was to measure the cleanliness of orthopaedic depth gauges after standard cleaning and reprocessing.

Methods: Visual and chemical tests of device cleanliness were conducted on a random sample (n = 12) of orthopaedic depth gauges at a highly ranked Level I trauma center after they underwent the center's standard cleaning processes. The devices were visually inspected for soils, which could include rust, blood, bone, tissue, or other debris, with the naked eye and with a lighted, flexible 3.3-mm borescope. The devices were also tested for protein and hemoglobin residue, as well as with a combined test for carbohydrate, protein, and hemoglobin.

Results: Of the devices that were tested, 91.7% (11 devices) failed visual inspection, meaning visual evidence of soils was seen on or within the device. Notably, the small lumen of the device was smaller than the borescope, so it was impossible to visualize and, therefore, could have retained additional debris. Furthermore, 16.7% (2 devices) failed chemical tests for hemoglobin and those same 2 devices tested positive for protein.

Conclusion: Ultimately, all but one of the devices harbored soil. Of greater concern, 16.7% tested positive for protein and hemoglobin residue. These results suggest that the design of the orthopaedic depth gauge makes it challenging to clean properly. US Food and Drug Administration recommendations state that sterilization may not be effective if a device cannot be adequately cleaned. Moreover, other orthopaedic instruments with poorly cleaned lumens have caused serious infections. New methods to improve the cleanliness of depth gauges should be considered, which could include more effective cleaning protocols, a design that makes cleaning easier, or a single-use, disposable device.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.