



## Retained Bioburden On Surgical Instruments After Reprocessing: Are We Just Scraping the Surface?

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### ABSTRACT

*The design of medical devices, equipment, and instruments can provide ideal spaces for bioburden accumulation and subsequent development of surface biofilms, especially if compound hinges, gaps, channels, or lumens are present. Many outcomes related to the use of poor-quality instruments are likely to go unrecognized, especially if the result of an event is latent in a patient's course. To increase knowledge about the prevalence of reported events related to issues with surgical instruments, Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for acute care events associated with bioburden on surgical instruments reported from January 1, 2005, through December 31, 2015. Analysts then compared the results with Pennsylvania Health Care Cost Containment Council (PHC4) acute-care procedural denominator data from the same time frame. The results show an increase in the number of reported events over time, both in the number of reports per year and as a rate per 1,000 procedures. To combat the trend of increased bioburden prevalence, a quality improvement initiative in surgical instrument reprocessing may need to occur. The operating room and its patients depend on the reprocessing department; operating room services simply cannot exist without an adequate flow of clean and sterile surgical instruments and equipment. Efforts should be considered to unify departments and processes around the care and maintenance of mission-critical items, such as surgical instruments, devices, and equipment. (Pa Pat Saf Advis 2017 Jun; 14(2): 71-75.)*

### INTRODUCTION

Imagine a basic tool used for performing a task, such as a chisel. The chisel is a raw powerful tool that one strikes with a hammer, commonly used for removing large chunks of material. A chisel has a handle for stabilization, a striking surface, and a flat, angled cutting edge. Not complex or compound, the chisel nowadays is usually fabricated from a single piece of hard metal, is easy to wipe off and sharpen, and maintains its cutting edge for long periods of use, requiring little maintenance. Now, imagine a tool designed for cutting delicate objects, such as a small pair of scissors. The chisel has one cutting edge that moves in one direction, whereas scissors have two cutting edges that move in opposite directions, requiring the addition of a hinge pin. The scissors require sharpening of two indexing edges, lubrication of the hinge pin, and a specific interface with the operator through the two handles. As the precision of work increases, tools seem to become more complex and require more care for proper operation. Care and maintenance of complex tools, in turn, directly affects the quality of work when the tool is used.

The same principles can be applied to tools used for operations and procedures conducted on living beings. Tools evolve into *instruments* and *devices* as the complexity, delicateness, and success of a procedure increase, and their use directly influences a patient's real or perceived wellbeing. The straight Hibbs chisel, used in orthopedic surgery to remove large pieces of bone, is made of smooth, high-quality stainless steel; with no material gaps, channels, or overlaps, and it is easy to clean, disinfect, and maintain. Compare the Hibbs chisel to the Pratt-Smith hemostatic forceps (Pratt hemostat), with the Pratt's T-shaped, tube-like tip with precise, fine, serrated jaws, ratcheting handle, and smooth hinge action (see Figure 1). Based on its design and intended function (clamping delicate tissue) the Pratt hemostat has more nooks and crannies that are difficult to adequately reprocess and facilitate the accumulation of bioburden. Thus, the design of medical devices, equipment, and instruments may provide ideal spaces for bioburden accumulation, and subsequent development of biofilm, especially if compound hinges, gaps, channels, or lumens are present.

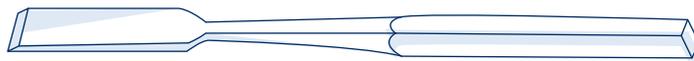
### Bioburden

Bioburden is “the degree of microbial contamination or microbial load; the number of microorganisms contaminating an object.”<sup>1</sup> Colloquial clinical use of the term bioburden includes both microscopic debris and debris that is visible to the naked eye and refers to tissue, body fluids, bacteria, or any other biologic material present on, or in, an instrument or device after use on, or in, a patient. Varying degrees of bioburden will be present on an object after use on a patient; the accumulation of bioburden on used equipment is unavoidable. Once bioburden is present on a surface, biofilm formation is not far behind.

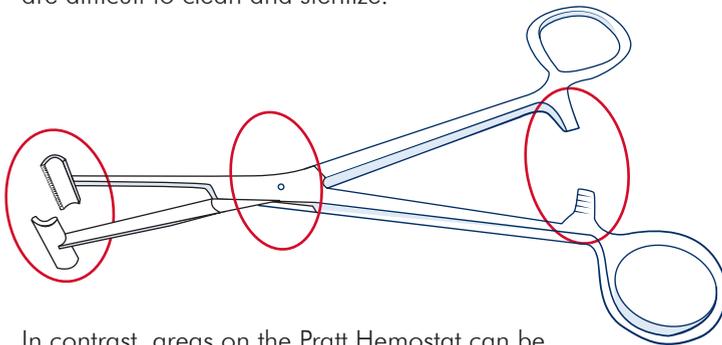
### Biofilm

Surface bioburden to any degree facilitates the formation of biofilm. Biofilm is “a slime-enclosed community of bacterial colonies that is very difficult to eradicate even with the most powerful antibiotics or sterilizing systems. Biofilms can occur on any body surface, on teeth (as dental plaque), medical equipment, medical tubing, contact lenses and elsewhere.”<sup>2</sup> It is important to note that biofilms can be visible to the naked eye in an aquatic or industrial environment, for example when pipes are fouled, but biofilms can also be microscopic and can develop on the surfaces of medical devices and equipment very rapidly (within minutes).<sup>3</sup>

**Figure 1. The Hibbs Chisel versus the Pratt Hemostat**



The Hibbs Chisel has no areas that are difficult to clean and sterilize.



In contrast, areas on the Pratt Hemostat can be difficult to clean and sterilize, especially if processed without using a stringer.

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### Healthcare-Associated Infection and Endotoxin

The published literature has examples of healthcare-associated infections (HAIs) linked to instruments and equipment that have been processed appropriately but, because of their design, have proved to be difficult to clean and disinfect or sterilize despite following the manufacturer’s cleaning instructions.<sup>4</sup> Furthermore, there is evidence of infection transmission when cleaning and sterilization procedures have not been adhered to, or where quality control has been poor.<sup>5</sup> Several researchers have also noted the risk of endotoxin presence on surgical instruments, which may contribute to orthopedic prostheses loosening.<sup>6,7</sup> The risk of complications and frequency of these types of events is difficult to determine; peer-reviewed literature addressing the topic is lacking. Many adverse outcomes related to the use of poor quality instruments are likely to go unrecognized, especially if the result of an event is latent in a patient’s course.

### METHODS

To help inform healthcare facilities about the prevalence of inadequate reprocessing of surgical instruments, Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database to identify acute-care event reports associated with bioburden on surgical instruments reported from January 1, 2005, through December 31, 2015. The end of 2015 was the last complete data set at the time of the query for all data sets. Analysts then compared the resultant trend identified within PA-PSRS data with Pennsylvania Health Care Cost Containment Council (PHC4)\* acute care procedural denominator data within the same time frame to account for potential artifact within

\* The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of health care, and increasing access to health care for all citizens. While PHC4 has provided data for this study, PHC4 specifically disclaims responsibility for any analyses, interpretations, or conclusions.

PA-PSRS data, in the event that increased volume reporting affected prevalence trends. The PHC4 acute care procedural denominator data report was produced using operating room revenue codes within a claim record to capture and count the number of operating room revenue codes per claim record thereby arriving at the denominator of inpatient claim records. PA-PSRS event reports include a free-text narrative section for reporters to augment the event report. Analysts also compared reports and narratives to discern any recurrent themes.

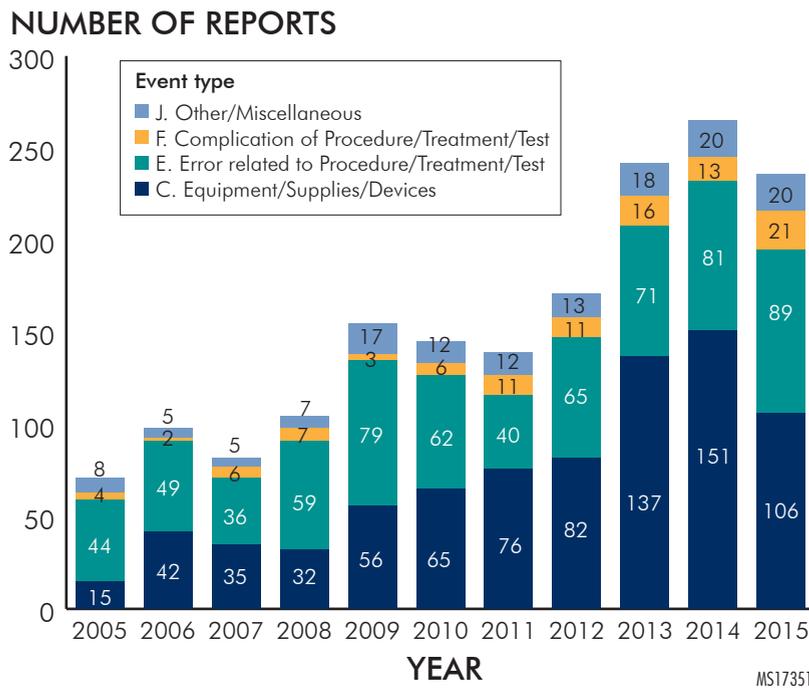
Authority analysts interviewed six individual operating room clinicians from four hospitals in different regions in Pennsylvania. The interviewees were informed that the Authority had received reports of surgical instruments with bioburden and or debris present after reprocessing that were for use in operating rooms. Interviewees were asked to describe rationales and possible explanations that they believed contributed to these events. Interviewees agreed to speak with the Authority on a guarantee of complete anonymity for themselves and their institutions. Interviews were conducted via phone and were structured in an open format without specific questions posed by the analyst.

### RESULTS

#### Quantitative Results

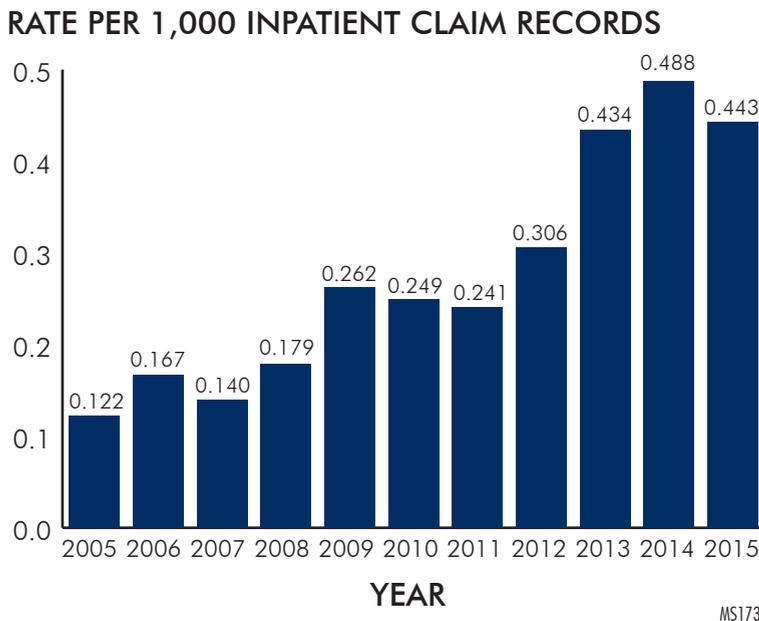
Figure 2 shows a general increase in the number of bioburden related events reported through PA-PSRS during the years 2005–2015. Figure 3 shows the rate of reported events per 1,000 inpatient claim records per year. Figure 3 mimics the trend identified in Figure 2 and demonstrates a general increase in bioburden prevalence per year, accounting for the number of patients. Figure 4 displays the rate of bioburden reports per 1,000 inpatient claim records by event type per year. Figure 4 further validates the initial trend of an increased bioburden prevalence over time isolated within PA-PSRS data.

Figure 2. Number of Bioburden Reports by Event Type



Note: Data submitted to the Pennsylvania Patient Safety Authority, 2005–2015.

Figure 3. Rate of Bioburden per 1,000 Inpatient Claim Records



Note: Data submitted to the Pennsylvania Patient Safety Authority, 2005–2015.

## Qualitative Examples

The following narratives from events reported through PA-PSRS are examples of the adverse impact ineffective cleaning and sterilization procedures can have in a clinical setting:\*

*Loaner instruments ran through washer decontaminator then wrapped and run through sterilizer. While setting up, staff noticed dried blood on the set.*

*While pushing bone graft into the instrument, a large piece of dried tissue from a previous case came out onto the field, contaminating the patient's bone graft and set-up.*

*Debris from a prior procedure dislodged from the endoscope and floated into the ventricle, unable to retrieve. Ventricle flushed and patient placed on antibiotics.*

*Laminectomy with local bone graft. Staff noted that a sterilized instrument pan containing spinal instruments was found to be contaminated with old bone and tissue from a previous case. The case was delayed.*

*Fragments of bone cement were observed in the patient's knee, and the surgeon had not used cement. The scrub nurse noticed the instrument impactor in the set had cement from a previous case on it. Wound class was changed from 1 to 2.*

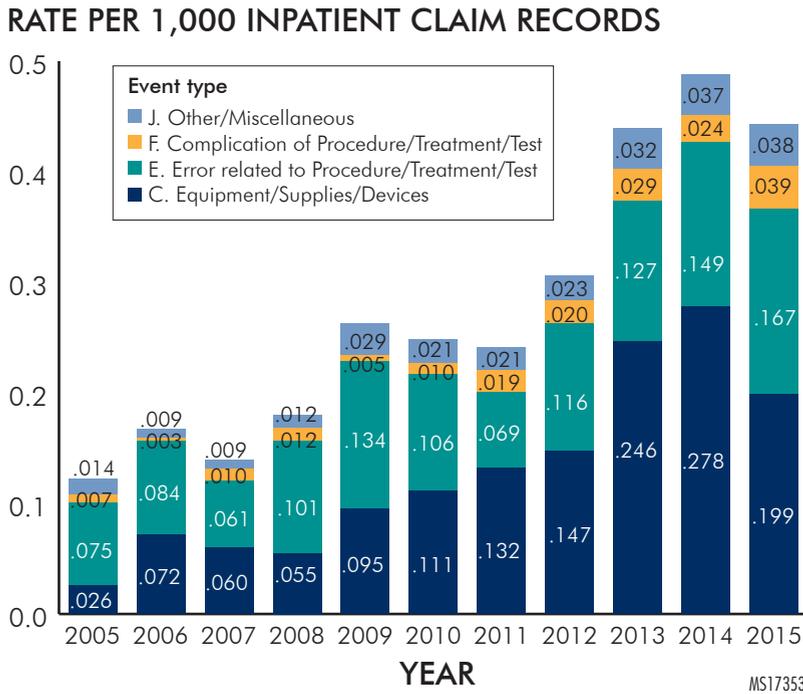
## Interview Results

The following problematic, common themes emerged during interviews with six individuals involved in surgical instrument reprocessing and use:

- Reprocessing staffing patterns not aligned with increases in surgical case loads

\* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

Figure 4. Rate of Bioburden per 1,000 Inpatient Claim Records, by Event Type



Note: Data submitted to the Pennsylvania Patient Safety Authority, 2005–2015.

- Unrealistic expectations related to reprocessing production pressure (demands for quicker turnaround of instruments)
- Subpar levels of surgical instrument stock
- Re-processors’ unfamiliarity with manufacturer’s instructions for use and care of instruments
- Operating room staff not consistently wiping, precleaning, or soaking instruments prior to sending for reprocessing
- Used surgical instrument trays sitting for prolonged periods of time before being sent for reprocessing
- The operating room and reprocessing departments treated as separate teams—a lack of cohesiveness between departments
- Lack of standardized training and education

- Poor workflow design in the reprocessing department
- Inconsistent auditing of process measures and quality indicators

When considering the quantitative and qualitative data, the explanations provided by the interviewees seem to deserve investigation for quality improvement because the prevalence of events shows an upward trend over time. All interviewees stated that their individual hospitals were aware of and actively addressing the issue of surgical-instrument reprocessing quality.

**LIMITATIONS**

Limitations of PHC4 data on the procedural denominator data report as per PHC4:<sup>8</sup>

“PHC4 data captures procedures that are performed per patient claim record. Also included on the claim record, when

applicable, are operating room revenue codes. The report was produced using operating room revenue codes within a claim record to capture and count the number of operating room revenue codes per claim record. One inpatient claim record may have one or more operating room revenue code associated with one or more procedures performed on the same day. For example, a hospitalized patient who had 6-procedures during the same day may have two operating room revenue codes reported/counted (one for general operating room service and another for minor operating room surgery).”

The analysts note the limitations of the PHC4 data collection method by using claim records and revenue codes. Thus, the bioburden rates per surgical procedure shown in Figure 4 might be lower than typical instrument bioburden prevalence per procedure in a clinical setting.

The Authority acknowledges that the interview data is of a limited nature and likely does not represent all conditions across Pennsylvania.

**DISCUSSION**

High-quality reprocessing of surgical instruments and equipment is a mission critical task. Although the interview evidence is limited, it must be considered that all interviewees noted some amount of separation and discordance between the operating room and reprocessing departments. The operating room and its patients depend on the reprocessing department; operating room services cannot exist without an adequate flow of quality surgical instruments and equipment. Efforts can be considered to unify departments and processes around the care and maintenance of mission critical items, such as surgical instruments, devices, and equipment.

As demonstrated by the examples of the Hibbs chisel and Pratt hemostat, surgical equipment comes in all shapes and sizes, with varying levels of complexity. Based on the design and complexity level, some instruments may be inherently easier to clean and subsequently disinfect or sterilize appropriately. Reprocessing and operating room staff need to have access to each instrument's instructions for use that include particular methods for cleaning, care, disinfection, sterilization, and maintenance. As noted in the results, there have been many reports of debris lodged on and inside instruments, especially those with gaps, lumens, and channels. Once debris dries inside or on an instrument surface, the instrument becomes increasingly difficult to clean; thus when *cleaning starts at the point of use* (in the operating room), removing debris at the point of reprocessing becomes more effective.<sup>9</sup>

Equipment design plays a vital role in determining how easily an effective, high-quality reprocessing method can be accomplished. There are examples in

the literature of infection transmission occurring after a device was processed according to the manufacturer's instructions, essentially due to device design that made adequate reprocessing difficult.<sup>4</sup> When purchasing equipment and instruments, the design and the entire use, reprocessing, and reuse cycle should be considered. An optimal approach would bring all users of an instrument to the table during the evaluation for purchase, to gather input on the features and design of the device. If reprocessing staff point out that the design of a device is problematic from a cleaning perspective, it may warrant evaluating equipment of a different design that can perform the same task. If there are no other alternatives, instructions about how to process the device need to be explored. For example, ultrasonic washers may be needed, or a facility may need to purchase more washers, adding time and cost to the process for a given piece of instrumentation. The Authority has a sample tool available, providing equipment-purchasing guidance in terms of integrating

equipment into the work place. The tool is available with an accompanying *Pennsylvania Patient Safety Advisory* article at <http://patientsafety.pa.gov/pst/Pages/PSAPatientSafetyTopicList.aspx>.

The data presented in this article scrapes the surface on a multitude of factors that affect the critical task of reprocessing surgical instruments and equipment. Quantitative, qualitative, and expert interview data have been compiled to provide insight into the complexity of a process that affects patient outcomes, patient satisfaction, staff satisfaction, workflow, finance, and other variables. The data and concepts presented herein are intended to give facilities a starting point for self-assessment of the reprocessing continuum, inclusive of all users and departments that interact with surgical instruments and equipment, to find quality-improvement opportunities.

## ACKNOWLEDGMENTS

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## NOTES

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