



Pennsylvania Patient Safety Reporting System

Patient Safety Advisory

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Bioburden on Surgical Instruments

Pennsylvania hospitals have submitted a number of reports to PA-PSRS describing cases in which sterilized surgical instruments have been contaminated with organic material from a prior procedure—something healthcare workers call “bioburden.” While most of these cases are recognized before the devices reach the patient, in some instances these soiled instruments have contaminated the sterile field.

These occurrences put patients at risk of surgical site infection (SSI), even if the instrument never touches the patient, because of the potential for contaminating the surgical field. Additionally, when contaminated equipment is recognized after a procedure has begun, precious operating time is lost, and the patient experiences prolonged anesthesia while properly sterilized equipment is obtained.¹

Background

Despite modern infection control practices, the incidence of SSIs remains high. SSIs have been estimated as the third most frequently reported type of healthcare-associated infection.² Despite advances in asepsis, environmental controls, and antimicrobial prophylaxis, SSIs continue to cause morbidity and mortality among surgical patients. Various explanations include an increase in the number of frail patients with chronic debilitating diseases who undergo surgery, increased utilization of implants and organ transplants, and the presence of antibiotic-resistant organisms.²

In July 2005, the Pennsylvania Health Care Cost Containment Council (PHC4) reported on hospital-acquired infections in the state, estimating that patients with SSIs had a mortality rate of 3.1%.³

Reports to PA-PSRS

Following are excerpts from reports submitted to PA-PSRS in which sutures, bone, or tissue have been discovered when instruments were unwrapped in the surgical field:

When placing the tissue protector on the drill, old dried blood and tissue came out.

Triple trocar was full of dried blood and smelled foul. Removed from sterile field.

Bone found in reamer prior to using it on patient. Bone was removed and reamer autoclaved. Equipment was not used on patient.

Suture remained on tunneler.

Particles of tissue were found in cannulated instrumentation.

These cases indicate problems of quality control in the form of failure to adequately clean and inspect instruments before sterilization.⁴⁻⁷

Adequate cleaning requires removal of all residue remaining on the instrument from previous use. Failure to remove debris interferes with disinfection and prevents sterilization.⁸⁻¹¹ Even sterilized foreign material left behind from a previous surgery becomes a foreign body inside the patient and will stimulate the patient’s defense mechanisms to reject or wall off this alien substance. Additionally, damage to instruments, such as corrosion, rust, or pitting, can occur from prolonged contact with organic material when cleaning is not thorough.^{1,12,13}

The level of disinfection or sterilization depends on the intended use of the instruments. The accepted gold standard is the Spaulding method (see Exhibit 1), by which medical instruments are categorized as critical, semicritical, or noncritical according to their intended use. This method has been in use for more than 35 years and guides decisions related to levels of disinfection and sterilization.^{9,11} However, all instruments, regardless of the category of use, require appropriate cleaning.

Surgical Instrument Preparation

Surgical instruments are processed in a multistep, prescriptive fashion.¹ Initially, instruments are cleaned either manually or with equipment, depending on the manufacturer’s recommendations. Instruments then undergo disinfection, removing most disease-causing organisms. Sterilization is the final step to kill all or-

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ganisms, including pathogens. Sterilization is effective only if all residual debris has been removed in the preceding steps.^{5,8-10}

Cleaning instruments, like cleaning dishes, is more difficult when material has dried. The objective is to remove debris before it has a chance to dry. Pre-cleaning may be done during the surgery or as soon as possible after the procedure.^{6,10,12,13} Methods include:

- Wiping the instrument with a lap or gauze sponge wet with sterile water during or after the procedure.
- Soaking the instrument in an enzymatic solution according to manufacturer recommendations after the procedure.⁸
- Flushing the instrument lumens with sterile water during or after the procedure.
- Using a nonfibrous sponge to wipe delicate microsurgical and ophthalmic instrument tips.¹³

The Association of periOperative Registered Nurses (AORN) suggests that sterile water be maintained in a sterile ring stand to separate it from sterile saline on the operating room back table. Sterile saline should not be used to clean instruments, as saline causes pitting and damage.^{1,12}

Instruments should be prepared for cleaning by separating all detachable parts. Complete disassembly is necessary to expose all surfaces during the mechanical action of cleaning, whether automated or manual. All movable parts should be disassembled. Instrument box locks, hinges, and joints should be opened.^{7,10} The lumens of cannulated instruments must be flushed with the cleaning solution and checked for soilage.

Manual and Mechanical Cleaning/Decontamination

The goal of cleaning is threefold: remove visible debris, remove invisible soilage, and eliminate as many microorganisms as possible.¹⁰ These tasks are completed in central supply by technicians who are often trained by the institution. Education is important to help ensure that the technician recognizes the significance of his/her contribution to an infection-free surgical outcome.^{8,14}

Meticulous cleaning is a prerequisite for disinfection and is essential to the integrity of sterilization.⁴⁻⁷ Cleaning begins with decontamination and removal of obvious debris. Typically, instruments are arranged in

Exhibit 1. Rational Approach to Disinfection and Sterilization

More than 35 years ago, Earl Spaulding developed a method to categorize medical instruments according to the amount of contact the instrument has with the body to determine the level or degree of disinfection and sterilization required.¹ There are three categories: critical, semicritical, and noncritical.

- **Critical objects** are items that penetrate soft tissue, bone, or the vascular system or through which blood flows, such as implanted medical devices, and should be sterile when used.
- **Semicritical items** are objects that touch mucous membranes or nonintact skin, such as endoscopes and respiratory therapy equipment, and require high-level disinfection (elimination of all microorganisms except high numbers of bacterial spores).
- **Noncritical items** are objects that contact intact skin, such as bedpans, blood pressure cuffs, and bedside tables. Low-level disinfection is required.^{2,3}

Notes

1. Rutala WA, Weber DJ. Disinfection and sterilization in health care facilities: what clinicians need to know. *Clin Infect Dis* 2004 Sep 1;39(5):702-9.
2. Rutala WA, Weber DJ. New disinfection and sterilization methods [online]. *Emerg Infect Dis* 2001 Dec [cited 2005 Jul 7]. Available from Internet: <http://www.cdc.gov/ncidod/eid/vol7no2/pdfs/rutala.pdf>.
3. Association for Professionals in Infection Control and Epidemiology. APIC guideline for selection and use of disinfectants. *Am J Infect Control* 1996 Aug;24(4):313-42.

trays. Hard-to-clean equipment may be soaked in an enzymatic solution or covered with spray, gel, or foam to initiate the decontamination process.

Various methods exist to ensure that instruments are decontaminated in readiness for sterilization.¹ Automated methods include washer/sterilizers, ultrasonic cleaners, and washer/decontaminators; as a last resort, devices may be cleaned manually. Manual cleaning using brushes is effective for instruments with lumens. The amount of friction or the number of brush strokes used during cleaning affects consistency of instrument cleanliness.⁸ In manual washing, the instruments are cleaned underwater to reduce the risk of employee exposure to potentially contaminated aerosols. Advantages of automated cleaning include decontamination consistency and protection of staff from exposure to organisms.

Mechanical cleaning is performed using several different types of equipment. Washer-sterilizers use mechanical action and detergent to remove residue. If instruments have crevices or are cannulated, preliminary irrigation and cleaning are necessary to ensure

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that all residue is removed before decontamination in the washer-sterilizer.

Automated cleaning with heat will bake any residual gross organic material onto the instruments, rendering them a challenge to sterilize.¹⁰ A washer-decontaminator can remove excess debris and eliminate the need for manual cleaning of instruments, but automation does not eliminate the need for inspection after they have been cleaned.

Ultrasonic cleaning uses high-frequency sound waves to penetrate and remove debris after the visible or gross residue has been rinsed off the instrument.¹⁰ It is most effective once the overt residue is removed, and it is effective on instruments with lumens or joints.⁸

Vigilance in verifying the removal of bioburden is of utmost importance to ensure sterilization. The term “bioburden” is often used to describe organic material on instruments^{15,16} but actually refers to the number of microorganisms contaminating an object.¹⁷ Properly cleaned nonlumen instruments have been demonstrated to contain a minimal number of organisms, which are not pathogenic.¹⁸

Inspection

Inspection is important to ensure that instruments are clean and disinfected, with no residue. Whenever any resistance or stiffness is noted in the movement of a part, the presence of residual debris should be suspected, and the instrument should be inspected accordingly.^{1,7} During inspection, staff should verify that teeth mesh, that equipment demonstrates proper tension, that ratchets work correctly, and that parts designed to move freely do so.⁷

In January 2002, AORN revised its “Recommended Practices for Cleaning and Caring for Surgical Instruments and Powered Equipment.” The goal of these practices is “to assist perioperative nurses in decontaminating, cleaning, maintaining, handling, storing, and/or sterilizing surgical instruments and powered equipment.”¹ Acknowledgment is given in the guideline to the innumerable specialized instruments and powered equipment that necessitate manufacturers’ guidance for cleaning.

AORN presents eight detailed recommended practices, which provide generalized direction for cleaning instruments.¹ The following is a synopsis of these practices:

1. Surgical instruments and powered equipment should be cleaned, handled, and used according to manufacturers’ instructions.
2. Instruments should be kept free of gross soilage during surgical procedures.
 - a) Instruments should be wiped with sponges moistened with sterile water to prevent corrosion, rusting, and pitting from dried blood and debris.
 - b) Lumened or cannulated instruments should be irrigated with sterile water. Saline causes instrument deterioration and should not be used.
3. Effective and timely decontamination of instruments should be performed in a manner that minimizes risk to those performing the task.
4. Surgical instruments with moving parts should be checked for function after cleaning. Lubrication may be indicated.
5. Instruments that have come in contact with prions (resilient protein substances) should be treated according to a specific prion-deactivation protocol. When changing policies the most recent updates related to prion deactivation should be obtained from the Centers for Disease Control and Prevention (CDC), the World Health Organization, and experts publishing new findings. Creutzfeldt-Jakob disease (CJD) is caused by a prion (see Exhibit 2). The following is a condensed version of the recommended practices for cleaning instruments when prion exposure is suspected:
 - a) Keep instruments moist before treating.
 - b) Clean instruments as soon as possible.
 - c) Keep instruments of similar tissue infectivity levels together.
 - d) Decontaminate instruments before processing:
 - Dispose of instruments that are impossible to clean or when cleaning is difficult and disposal is not cost-prohibitive.
 - When indicated, soak instruments for one hour in normal sodium hydroxide before cleaning and sterilizing.
 - Steam autoclave instruments at 132° to 134°C for 18 minutes in a prevacuum sterilizer or at 121°C for 60 minutes in a gravity displacement sterilizer.

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- e) Avoid using power drills or saws on highly infective tissue.
 - f) Note that disposable equipment is preferred and should be incinerated.
6. Surgical instruments should be visually inspected and prepared for storage or sterilization after decontamination; specifically, staff should consider:
- a) cleanliness and proper functioning
 - b) the presence of cracks, corrosion, pitting, burs, and nicks
 - c) sharpness of cutting edges
 - d) loose pins
 - e) wear and chipping of inserts and plated surfaces
 - f) any other defects.
7. Powered equipment and any attachments should be disassembled, decontaminated after use, lubricated, assembled, tested, and sterilized according to manufacturer instructions.
8. Policies and procedures regarding the care and cleaning of surgical instruments and powered equipment should be developed, re-

viewed at regular intervals, and made readily available in the practice setting.

See the published recommendations for details related to instrument and powered equipment cleaning and care when developing and/or revising policies.¹

Considerations for ensuring that surgical instruments remain free of debris include the following:

- Create an environment in which a team spirit is encouraged and infection prevention is a shared duty and begins with the responsibility of ongoing monitoring of the care of surgical equipment.^{7,8,10}
- Implement routine proactive efforts during and immediately after surgery to prevent soilage from drying on surgical instruments.
- Educate central supply staff on the principles of decontamination, disinfection, and sterilization.^{8,14}
- Maintain quality control by reviewing instrument management practices and reinforcing routine inspection of cleaned surgical instruments, especially those likely to have retained soilage.^{4,16}

To minimize the risk associated with a breakdown in

Exhibit 2. Prion Concerns

Effective reprocessing of surgical instruments is essential in the prevention of Creutzfeldt-Jakob disease (CJD), a prion disease that is a transmissible spongiform encephalopathy.^{1,2} CJD is a fatal disorder that more commonly occurs in older people, although vCJD (new variant Creutzfeldt-Jakob disease) occurs in younger people. Classic CJD is described as “insidious, taking up to 20 or more years for symptoms to appear, with death occurring within 5 to 14 months after symptoms present.”¹

While developing a test for assessing removal of protein from surgical instruments after cleaning, researchers in England discovered that alcohol strongly binds blood to stainless steel. Reports related to transmission of CJD between humans and chimpanzees indicate that the instruments were cleaned with alcohol-formaldehyde solutions.³ Therefore, when CJD is suspected, alcohol and formaldehyde should not be used to decontaminate surgical instruments used in neurosurgical cases.

The following strategies can help to reduce the risk of CJD transmission:

- Use disposable instruments in known CJD cases or in brain biopsy procedures if possible.^{1,4}
- Quarantine instruments used in neurosurgery until a diagnosis is available.¹
- Incinerate instruments that cannot be cleaned.¹
- Do not use flash sterilization.⁴
- Keep instruments moist to prevent drying of organic material.⁴

Notes

1. Exposure to Creutzfeldt-Jakob disease. *Jt Comm Perspect* 2001 Aug;21 (8):10-1.
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sterility, consider the following practices:

- Open sterile instruments on a separate stand, such as the ring stand, and inspect the contents to avoid the risk of contaminating other equipment or the surgical field. If contaminated instruments are found, the scrub nurse's gown and gloves can be changed without contaminating the supplies and other items in the sterile field.⁴
- If a soiled instrument is noted during the procedure, pass the instrument off the table and inform the surgeon so that prophylaxis can be provided.⁴

Look for new guidelines on processing practices to be released some time in the future. This will be the first revision since the 1985 release of CDC's "Guideline for Handwashing and Hospital Environmental Control." The new guidelines, which are in draft form as of February 2006, are intended to replace the section on sterilization and disinfection in the original guideline. The June 2002 issue of *OR Manager* contains highlights of the draft, which covers inactivation of pathogens such as those causing CJD, disinfection of equipment, decontamination of bone, endoscope disinfection, and new sterilization processes.¹⁹ The draft is no longer available on CDC's Web site and is in the process of comment review.²⁰

Notes

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An Independent Agency of the Commonwealth of Pennsylvania

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