The New Requirements For Cleaning Validation*

Of Surgical Instruments

*"It's all about reducing morbidity and mortality caused by contaminated instruments."

James Schneiter
President
America’s MedSource, Inc.
Scope Of The Problem

- According to the CDC, 2 million hospitalized patients contract a Hospital Acquired Condition (HAC), or “Never Event” (because it should never happen) each year in the U.S., and:
  - HACs cause or contribute to the death of 99,000 patients annually
  - **270 deaths daily (82 from surgical infections)**
  - Mortality figure is greater than the number of deaths attributed to AIDS, breast cancer and motor vehicle accidents **combined**
  - In 2010, the CDC estimated that HACs added over $25 billion per year to the cost of healthcare.
According to the CDC, Surgical Infections:

- **Cost $57,000 per occurrence** to resolve a deep organ surgical infection
- **Add 11 extra days** of hospitalization
- Increases chance of being placed in the ICU by **60%**
- **Five times** more likely to be readmitted to the hospital
- **Twice the incidence of mortality**
- Surgical infections occur in 2-5% of clean extra-abdominal surgeries and **20% of intra-abdominal surgeries**
- **Result in approximately 30,000 deaths annually**
According To The CDC’s “Guideline For The Prevention Of Surgical Site Infection, 1999”

- “Among surgical patients, **SSIs were the most common nosocomial infection**, accounting for 38% of all such infections.”

- “When surgical patients with SSIs died, 77% of the deaths were reported to be related to the infection, and **the majority (93%) were serious infections involving organs or spaces accessed during the operation.**”

- “Advances in infection control practices include improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis. **Despite these activities, SSIs remain a substantial cause of morbidity and mortality among hospitalized patients.**”
CDC’s “Guideline For The Prevention Of Surgical Site Infection, 1999” (Cont.)

• “PATHOGENESIS: Microbial contamination of the surgical site is a necessary precursor of SSI. Sources of SSI pathogens include contaminated surgical instruments.”

• “Microorganisms may contain or produce toxins and other substances that increase their ability to invade a host, produce damage within the host, or survive on or in host tissue.”

• “Many gram-negative bacteria produce endotoxins, which stimulates cytokine production. In turn, cytokines can trigger the systemic inflammatory response syndrome that sometimes leads to multiple system organ failure.”

• “One of the most common causes of multiple system organ failure in modern surgical care is intra-abdominal infection.”
“Do you know what is inside of the instruments that you put inside of your patients?”
BIOBURDEN

• Bioburden is the quantitative estimation of the number of viable microorganisms on a surgical instrument or medical device before decontamination and sterilization.

• Surgical infections are preventable by proper cleaning and decontamination of surgical instruments. Thorough cleaning is required to remove all organic soil and bioburden (microorganisms) from soiled instruments to ensure proper sterilization.

• Bertha Litski once said, "A contaminated instrument used in surgery is as dangerous as a loaded gun."

• If instruments are not thoroughly cleaned, sterilization may not occur. Failure to remove bioburden will not only affect the functionality of the instrument (difficult to open and close), it will also interfere with the sterilization process thus increasing a patient’s risk of contracting a surgical infection.
Cut-Away of Conventional Laparoscopic Instrument Filled With Bioburden
“Biofilms can be composed of gram-positive or gram-negative bacteria, and species most frequently isolated from medical devices include gram-positive Enterococcus faecalis and Staphylococcus aureus, and the gram-negative Escherichia coli, Klebsiella pneumoniae and Pseudomonas aeruginosa. The bacteria can originate from patients' own skin, from the hands of healthcare workers, or from other external sources in the environment. **Biofilm is known to be tenacious as well as highly resistant to antimicrobial treatment inside of surgical instruments.**”

“The mechanisms of device-related infections are still not completely understood even though ‘the tendency of foreign bodies to predispose patients to infection has been recognized since the 14th century,’ asserts one team of researchers.”

“According to researchers at the Centers for Disease Control and Prevention (CDC), microbial biofilms develop when microorganisms adhere to a submerged surface and produce extracellular polymers that facilitate adhesion to a surface that may be inert, nonliving material or living tissue.”

“**Battling Biofilm**” Infection Control Today, Kelly Pyrek, Sept. 1, 2002
The History Behind the Push

For Surgical Instrument Cleaning Validation

• "Healthcare facilities must start to demand from their instrument suppliers Cleaning and Sterilization documentation that has been validated by an independent testing laboratory utilizing AAMI’s protocol." (Jennifer Schraag, Infection Control Today, May 2006, “Designed To Kill?”).

• Natalie Lind, CRCST, CCSMC, ACE, pointed out in her article “Reprocessing Specialty Instruments” (Infection Control Today, June 2000) that, “Improperly processed instruments pose a significant threat to patient outcomes. Failure to process instruments correctly can lead to nosocomial infections. Ideally, reprocessing considerations should be addressed before an instrument is selected and purchased. Part of the overall purchase decision should be the instrument’s cleaning and sterilization validation.”
“Effective cleaning, disinfection, and sterilization is a very real challenge for the millions of insidious pathogens that could be lurking in a surgical instrument. Add to that challenge a resistant prion, and the sterile processing department (SPD) has a real fight on their hands.” (Jennifer Schraag, Infection Control Today, May 2007, “CJD Presents Myriad Challenges to the SPD”).

In the April 2001 AORN Journal, Romona Conner states, “Decontamination is the first and most important step in the sterilization process. Inadequate cleaning of organic debris may result in retained organisms and make the sterilization process ineffective.”

Linda Clement, a consultant in sterile processing warns, “Be sure the vendor understands you are asking for more than just cleaning instructions. You must have the independent laboratory verification that those instructions actually work for cleaning the instrument.” (Infection Control Today, November 2002).
Dennis Maki, MD, head of the Infectious Diseases Department at the University of Wisconsin Medical School, emphasizes, “When sales representatives make claims about how well their product works, ask to see their documentation – clinicals, independent laboratory testing, etc. If the manufacturer can’t document its claims, why would you use that product with your patients?” (Infection Control Today, November 2002, Ann Hewitt, RN, BSN, MM).

In her article, "Infection Control Challenges With Laparoscopic Instruments," Ann Hewitt, RN, BSN, MM, states, “Due to the design of internal lumens and channels in many laparoscopic instruments, it is impossible to access the entire surface area that needs cleaning. Squared off corners, dead spaces and rough edges all provide nooks and crannies for the deposit of tissue, blood, mucous or other bio-burden. Devices that you know are damaged, corroded, bent or constructed with inaccessible surfaces (i.e., no flush ports) that come into contact with patient tissue should not be used on patients.” (Infection Control Today, November 2002).
If your facility’s instruments have design flaws, the healthcare team may follow all proper handling and reprocessing procedures; that is, they may be ‘doing things right’ and still be using contaminated instruments. ‘Doing the right thing’ means your team will take every available step to prevent the infection of a vulnerable patient, including eliminating undocumented, non-cleanable instruments. The potential to reduce surgical site infections lies within your power.” (Ann Hewitt, RN, BSN, MM, Infection Control Today, November 2002).
CMS’s 10 Categories of “Never Events”

1. Foreign Object Retained After Surgery
2. Air Embolism
3. Blood Incompatibility
4. Stage III and IV Pressure Ulcers
5. Falls and Trauma
   - Fractures
   - Dislocations
   - Intracranial Injuries
   - Crushing Injuries
   - Burns (including electrical burns caused by defective insulation on a laparoscopic instrument)
   - Electric Shock
Laparoscopic Burns and RADEL® Insulation

According to its manufacturer, RADEL® is:

1. An excellent material to use with electro-surgical instruments due to its exceptional insulating properties. The failure of conventional insulation on laparoscopic instruments is the number one cause of painful, dangerous and costly patient burns incurred during a laparoscopic procedure.

2. Able to withstand the stress and high temperatures of repeated cycles in a steam autoclave with no loss of dimensional stability. Conventional insulations can shrink and pull back from the distal end of the instrument after repeated steam sterilization cycles, greatly increasing the risk of a patient burn or infection.

3. A high temperature, lightweight, polyphenylsulfone material with outstanding impact resistance.

4. Highly resistant to hydrolysis when exposed to hot water or steam. Hydrolysis is the chemical reaction that can cause a breakdown of the polymers used in conventional insulations, resulting in 'pinholes' in the insulation. These pinholes increase the potential of a dangerous surgical infection or serious patient burn.

*RADEL® is a registered trademark of the Union Carbide Corporation, NY, NY
CMS’s 10 Categories of “Never Events” (continued):

6. Manifestations of Poor Glycemic Control
   – Diabetic Ketoacidosis
   – Nonketotic Hyperosmolar Coma
   – Hypoglycemic Coma
   – Secondary Diabetes with Ketoacidosis
   – Secondary Diabetes with Hyperosmolarity

7. Catheter-Associated Urinary Tract Infection (UTI)

8. Vascular Catheter-Associated Infection
CMS’s 10 Categories of “Never Events” (continued):

9. **Surgical Site Infection** Following:
   - Coronary Artery Bypass Graft (CABG) – Mediastinities
   - Bariatric Surgery
     - Laparoscopic Gastric Bypass
     - Gastroenterostomy
     - Laparoscopic Gastric Restrictive Surgery
   - Orthopedic Procedures
     - Spine, Neck, Shoulder, Elbow

10. **Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)**
    - Secondary Diabetes with Ketoacidosis
    - Secondary Diabetes with Hyperosmolarity

Payment was discontinued by CMS and Private Insurance Carriers on October 1, 2008 for these 10 “Never Events”.

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Both of these shafts are coated with bio-burden, greatly increasing the risk of patient infection.
Hospital Solutions To “Never Events”

• Require from every vendor documented clinical data and/or independent laboratory validation of the efficacy and safety of their products or services.

• Partner with healthcare vendors who can provide patient safety solutions.

• Actively seek out products that prevent “Never Events” and not just products that simply cost less. A cost/benefit analysis must be a part of every product selection decision.

• Actively research new products and new technologies that have been documented and/or validated to reduce or eliminate “Never Events.”
HHS “Hospital Compare” website lists rates of surgical complications, infections and other problems

• Medicare has begun publishing patient safety ratings for thousands of hospitals as the first step toward paying less to institutions with high rates of surgical complications, infections, mishaps and potentially avoidable deaths.

• The new data, available on Medicare's Hospital Compare website, evaluate hospitals on how often their patients suffer complications (i.e., surgical infections).

• The new data on patient safety moves Medicare further along toward its ultimate goal, which is to base payments on the actual medical outcomes for patients. To rate hospitals, Medicare is comparing them to the national rates for medical complications and hospital acquired conditions.

• This new evaluation system was directed by last year's healthcare law, which set up new "value-based purchasing program" that will begin in October 2014.
Hospital Compare

Where do you want to find a hospital?

**Search Information**

**Location** - ZIP Code or City, State

e.g. 10009 or New York, NY

**Search type**

- General
- Medical Conditions
- Surgical Procedures

Find Hospitals

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Hospital Spotlight

Click on the new Patient Safety Tab during your hospital search to see new information on Hospital Acquired Conditions and Serious Complications and Deaths.

In January, Medicare will report new measures for heart attack care and surgical care. Also, for the first time, we will be reporting information on central line infections from the Centers for Disease Control's National Healthcare Safety Network.

You can now visit Medicare’s Hospital Value Based Purchasing Program page and learn more about future measures.

You can now get information on Mortality and Readmission Measures for approximately 150 Veterans Administration Hospitals.

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Additional Information

- View a list of Hospital Compare Contacts
- Download the Hospital Compare Database (Data Last Updated: October 13, 2011)
Number and Location of Microorganisms

“All other conditions remaining constant, the larger the number of microbes, the more time a germicide needs to destroy all of them. Spaulding illustrated this relation when he employed identical test conditions and demonstrated that it took 30 minutes to kill 10 B. atrophaeus (formerly Bacillus subtilis) spores but 3 hours to kill 100,000 Bacillus atrophaeus spores. This reinforces the need for scrupulous cleaning of medical instruments before disinfection and sterilization.”
FACTORS AFFECTING THE EFFICACY OF DISINFECTION AND STERILIZATION (Pg33)

• “Reducing the number of microorganisms that must be inactivated through meticulous cleaning increases the margin of safety when the germicide is used according to the labeling and shortens the exposure time required to kill the entire microbial load. Researchers also have shown that aggregated or clumped cells are more difficult to inactivate than mono-dispersed cells.”

• “Medical instruments that have crevices, joints, and channels are more difficult to disinfect than are flat-surface equipment because penetration of the disinfectant of all parts of the equipment is more difficult. Only surfaces that directly contact the germicide will be disinfected, so there must be no air pockets and the equipment must be completely immersed for the entire exposure period.

• Manufacturers should be encouraged to produce equipment engineered for ease of cleaning and disinfection.”
The Joint Commission

Accreditation Program: Hospital
National Patient Safety Goals
Effective January 1, 2011
In addition to what is happening in the surgical suite, recent changes to CMS guidance have prompted accreditation organizations such as Joint Commission to update their positions on steam sterilization. Here is what the Joint Commission has to say:

“Based on discussions with experts in the field, professional and governmental organizations, the Joint Commission has decided to refocus its survey efforts on all of the critical processes included in sterilization. If a complete and effective process of sterilization is used, it will be considered an effective sterilization method. Therefore, surveyors will review the critical steps of disinfection and sterilization to determine if the process is appropriate. Surveyors will, among other activities:

* Observe instruments from the time they leave one operating room to when they are returned to the next

*Ask healthcare workers to provide the manufacturer's instructions for instrument sterilization and to describe and demonstrate how instruments are being cleaned and decontaminated according to those written instructions.
* Observe the cleaning of instruments. Rinsing is rarely enough to properly remove soil from instruments; **meticulous cleaning is needed**.

* Verify that staff members are wearing appropriate personal protective equipment.

* Observe the sterilization process. **The surveyor will ask for the manufacturer's instructions for the following items: the sterilizer, wrapping or packaging, and the instruments.**

* Review sterilization logs. Surveyors will ask about parametric, chemical and biological indicators."

This new CMS landscape requires healthcare facilities to be vigilant about all their processes and procedures. For this reason, **it is important for surgical staff to have a thorough working knowledge of surgical instrument reprocessing best practices** and an understanding of the role each of them plays in the process.
Point-of-use preparation:

Some typical point-of-use shortcuts that have been observed in operating rooms are: not unlocking instruments; not disassembling instruments; not wiping off gross material and body fluids during procedures; not moistening or pre-treating instruments before transporting them for sterile processing; and not returning instruments to their proper containers.

Point-of-use preparation does not replace the cleaning process; it begins the cleaning process. Gross soil and bioburden should immediately be removed with sterile water at the back table or side stand. This is the first step for patient and staff safety. For the most efficient, effective and safe cleaning and decontamination, surgical personnel should also:

Follow the manufacturer's cleaning instructions for point-of-use cleaning
Observed decontamination shortcuts such as not having the manufacturer's instructions available for reference [i.e., wall chart], not disassembling the instruments and devices, thinking that rinsing under water is a substitute for decontamination, not using the proper cleaning chemicals (compatible enzymes and detergents with proper dilution rates), not using the proper cleaning brushes, and not rinsing and drying washed devices thoroughly enough to remove all chemical residue can potentially expose the next patient to contaminates.

Where an instrument is cleaned and how it is prepared for sterilization is of the utmost importance.....it does matter! **Failure to properly clean an instrument may permit residual organic material, inorganic matter and lubricants to hinder the disinfection and/or sterilization process.** The ANSI/AAMI ST79:2010 Section 7; *Cleaning and other decontamination processes* document details the requirements for the entire cleaning process, from the point of use through the sterilization of the medical device prior to its next use.
Background

• In recent years, there has been a significant advance in knowledge and technology involved in reprocessing reusable medical devices. Additionally, there has been an evolution towards more complex reusable medical device designs that are more difficult to clean and disinfect or sterilize. The revision of this guidance reflects scientific advances in this area. Under FDA labeling regulations, 21 CFR Part 801, a device must have adequate directions for use, which include instructions on preparing a device for use. Instructions on how to reprocess (i.e., clean and disinfect or sterilize) a reusable device are critical to ensuring a reusable device is appropriately prepared for its next use.
FDA’s Draft Guidance for Industry and FDA Staff - Processing/ Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

• Criterion 2. All reprocessing instructions for reusable devices should advise users to thoroughly clean the device.

• In general, the effectiveness of each step in the reprocessing of a reusable medical device will influence the effectiveness of subsequent steps. The fact that adequate reprocessing depends upon the thoroughness of cleaning emphasizes the importance of ensuring the instructions to the user result in thorough cleaning.

• The cleaning step should be described in the labeling as part of an overall reprocessing regimen. You should evaluate the rigor of the cleaning step in terms of its ability to eliminate organic soil from the device. The effectiveness of the cleaning step in making the device ready for the next patient will influence the effectiveness of subsequent processes, including any terminal processing.
VII. Validation of Reprocessing Methods in Accordance with the Quality System Regulation

Manufacturers must validate the design (including reprocessing instructions) of reusable devices and reprocessing procedures associated with reuse in accordance with the Quality System regulation (21 CFR Part 820) to make certain the device can be effectively reprocessed over its use life.

For devices that are subject to design controls under 21 CFR 820.30, labeling (e.g. reprocessing instructions) must be considered during design validation to assure user needs and intended uses are met. The human factors methods used should ensure that the characteristics of the user population and operating environment are considered. (21 CFR 820.30(g))

Cleaning and sterilization processes require process validation which provides a high degree of assurance that a device will consistently meet predetermined specifications. (21 CFR 820.75)
Reprocessing

2011 Summit
Priority Issues from the AAMI/FDA
Medical Device Reprocessing Summit
AAMI REPROCESSING 2011 SUMMIT

• “We share the common bond of being passionate about patient safety and improving patient outcomes.”

• “Healthcare organizations which have experienced challenges associated with reusable medical devices, including the Veterans Administration, Tulane medical Center and Victoria General Hospital, join countless other hospitals and surgical centers in joining our recommitment to solving these old frustrations and issues because of their desire to prevent future patient events.”

• “We encourage you to use this post-summit publication in your own organizations, professional associations, standards committees, task force meetings, and the like. This is not an AAMI or FDA ‘to do’ list. It is a multi-stakeholder ‘to do’ list, and every organization and person that impacts reprocessing has an important role in the follow-up activities.”

Mary Logan, AAMI President and Pamela Scott, Senior Science Advisor, FDA
“Every patient undergoing a medical procedure has a basic expectation that the environment and instruments of care will be clean and safe. In recent years, that expectation has been shaken by reports of patients put at risk of serious infection from reusable medical devices that were inadequately cleaned, sterilized, or disinfected—the domain known as reprocessing.”

“The clarion themes that emerged from the summit should serve as a call to action for all stakeholders with roles to play in improving patient safety in reprocessing reusable medical devices.”
Seven Clarion Themes

1. Gain consensus on “how clean is clean” and on adequate cleaning validation protocols for reprocessing reusable medical devices.
2. Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.
3. Pay early, iterative, and comprehensive attention to reprocessing requirements throughout the device design process.
4. Make human factors and work environment factors priorities when developing reprocessing requirements.
5. Improve information collection and sharing to broaden the use of best practices in reprocessing.
6. Improve reprocessing competencies by strengthening training, education, and certification.
7. Create a greater sense of urgency and understanding throughout the healthcare community about the consequences of inadequate reprocessing.
AAMI REPROCESSING 2011 SUMMIT

Things your organization can do right now to improve your reprocessing:

“Nothing and disinfection/sterilization of reusable are separate, equally important processes that must be performed before each patient use according to the device manufacturers’ written instructions for use (IFU). For information go to www.fda.gov/MedicalDevices/Safety.

“Have the IFU as well as all cleaning implements and equipment required by the IFU readily available in all the reprocessing areas.”

“Create a multidisciplinary committee to review the priority issues and set a plan for solving them throughout the organization. The following areas should be represented: OR, Infection Prevention and Control, healthcare technology management, endoscopy, risk management, quality, safety, education and materials management.”

“Central sterile processing should be included in purchasing decisions for medical devices, to provide input on whether the device can be reprocessed appropriately.”

Reserved
“As a patient, I want every reprocessed device to be in the same condition as when it was new, so there is no possibility of adverse effects.”

—A summit participant

“The risk to patient safety underlies every challenge and priority action. The Centers for Medicare & Medicaid Services (CMS) have begun to quantify that risk. In a study by CDC and CMS conducted in three states, more than one in four (28%) ambulatory surgery centers had infection control deficiencies associated with device reprocessing.”

“The Joint Commission also expanded its survey of the critical steps and the integrity of the medical device cleaning, disinfection and sterilization process.”
“In addition to co-hosting this summit, the FDA is already taking steps that will help manufacturers produce safer reusable devices. We have issued a draft guidance for manufacturers of reusable devices that provides greater clarity on how to scientifically validate the reprocessing instructions that are part of the device labeling, and we are working with our partners in the development of standards, guides and other reports that update processes, materials, test methods, design, and acceptance criteria for cleaning reusable medical devices.”

— William H. Maisel, Deputy Center Director for Science and Chief Scientist, Center for Devices and Radiological Health, FDA
The general procedure for validation (measuring cleaning efficacy) can be described as including the following steps:

- Soil the device

- Allow soil to simulate worst-case conditions (e.g., allow soil to penetrate lumens, allow soil to dry)

- Clean the device according to the manufacturer’s IFU

- Extract the cleaned device with elution fluid or other solvents, or measure soil directly on the device (i.e., the radionuclide method for cleaning validation)

- Test the extracted fluid for residual soil

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“Theoretically, if a device is truly impossible to clean, it should never end up on hospital shelves.”

The FDA, as part of its medical device clearance process [510(k) approval], are finally requiring device manufacturers to verify that their cleaning instructions actually work to clean the device.

Few in the industry, however, believe the regulation works. Instead of testing their instruments in the real world of hospitals, industry veterans say, manufacturers usually hire independent labs to evaluate their cleaning instructions (IFUs) under perfect conditions.
NELSON LABORATORIES, INC.

QAU AUDIT STATEMENT

[X] USFDA (21 CFR PART 58)    [ ] USEPA (40 CFR PART 160)

CLEANING EVALUATION OF THE ROSS 'CLEAR FLUSH' LAPAROSCOPIC GRASPER

Study Director: Final Report Dated:

Russell W. Lee, B.S. 17 Jan 2005

1. The test was conducted in accordance with the USFDA or USEPA Regulations as noted above. All laboratory results pertaining to this study are recorded in Nelson Laboratories' Data File Number 281216.
2. In accordance with the Good Laboratory Practice Regulations, the Sample Contamination phase(s) of this study was inspected by the Quality Assurance Unit on: 12 Jan 2005. The findings of the inspection(s) were reported to Management and to the Study Director on: 14 Jan 2005.

3. The Quality Assurance Unit has reviewed this report and has determined that the methods and standard operating procedures are accurately described, and that the reported results accurately reflect the raw data.

4. The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study:

   Emily Mitzel                      Dr. Jerry Nelson
   Russell Lee                       Jeff Hills
   Steven Jensen                     Nick Workman
   Sara Toole

QUALITY ASSURANCE: Brandy Miles    DATE: 18 Jan 2005
INTRODUCTION:

This report describes the evaluation of the recommended cleaning procedures for POSS Laparoscopic Grasper from POSS Instruments. The devices were contaminated with blood soil (BLSO) containing Geobacillus stearothermophilus, ATCC #7953. Bioburden extractions were performed to determine the number of viable organisms present on one positive control device prior to cleaning. Three test devices were contaminated, cleaned, and an additional bioburden assay was performed on each device to determine the bioload reduction.

PROCEDURES:

Cleaning Procedure:

*Culture Preparation*: BLSO was inoculated with the test organism from a stock spore suspension maintained at 2-8°C. A standard plate count was performed on the inoculated BLSO to determine the initial titer of the test organism.

*Sample Contamination*: The devices were immersed in inoculated BLSO and allowed to remain in contact with the BLSO for 15 minutes. The soiled devices were placed into a clean pan, covered with a towel dampened with purified water (PURW), and allowed to sit for 30 minutes to simulate the wait time between contamination and cleaning. The instrument jaws and black rubber caps were open during contamination.
Positive Control Recovery: The positive control device was tested using the bioburden method described below. The extraction efficiency was determined by repeating the bioburden test procedure for a total of four consecutive extractions on the positive control.

Cleaning Procedure: In a clean metal pan, the enzymatic detergent Enzol™ was prepared according to the manufacturers recommendations. Fifty cc of the detergent were flushed through the flush port of each device. The flushes were repeated until the solution was clear.

The enzymatic detergent Enzol™ was prepared in an ultrasonic water bath according to the manufacturers recommendations. The devices were sonicated for ten minutes. The black lumen rubber seal and the jaw position were open during cleaning.

The devices were removed from the sonicator and placed into the metal pan that contained the enzymatic detergent. With a soft bristle brush, the devices were manually cleaned while immersed in the cleaning solution. Particular attention was given to crevices and other hard-to-clean areas.
The devices were thoroughly rinsed under lukewarm, running tap water for one minute. Fifty cc of tap water was flushed through the flush port of each device. The flushes were repeated until the water was clear.

The devices were dried with a clean, soft cloth. The flush ports were dried with compressed air until all the water was removed.

The devices were inspected for visible soil and found to be clean.

**Bioburden Testing:** The positive control and cleaned devices were tested for bioburden by, immersing in peptone Tween® and shaking manually 100 times to extract the organisms present. Aliquots of the extract fluid were diluted where appropriate, and plated onto soybean casein digest agar (SCDA) or filtered through a 0.45 μm membrane and placed onto SCDA. Plates were incubated at 55-60°C for 24 ± 3 hours and colonies were enumerated.

**Calculations:** For the positive control, the percent efficiency was obtained by dividing the number of organisms recovered in the first extraction by the total number of organisms recovered from the product. The positive control titer and recovered counts from cleaned devices were corrected for the extraction efficiency.

The percent reduction in bacterial counts was calculated using the following formula:
% Reduction = \frac{\text{Initial Population} - \text{Final Population}}{\text{Initial Population}} \times 100\%

Where: Final population = Corrected number of organisms recovered from the cleaned devices
Initial population = Corrected positive control titer

Log reductions were calculated using this formula:

\text{Log Reduction} = \text{Log U} - \text{Log C}

Where: U = Corrected positive control titer
C = Corrected number of organisms recovered from the cleaned devices

RESULTS:

The results of the cleaning evaluation are summarized in Table 1. Each device was inoculated and cleaned individually, and some variability is expected between devices. The BLSO and positive control titers are listed at the bottom of the table. The extraction efficiency and cleaning reduction values are based on a high inoculum to simulate worst case. Percentages may vary with samples contaminated at a lower level.

The cleaned devices were free of visible soil.
### TABLE 1. Cleaning Results

<table>
<thead>
<tr>
<th>DEVICE IDENTIFICATION</th>
<th>CORRECTED COUNTS PER UNIT</th>
<th>PERCENT REDUCTION</th>
<th>LOG$_{10}$ REDUCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$3.9 \times 10^1$</td>
<td>99.974%</td>
<td>3.6</td>
</tr>
<tr>
<td>2</td>
<td>$9.2 \times 10^1$</td>
<td>99.937%</td>
<td>3.2</td>
</tr>
<tr>
<td>3</td>
<td>$1.4 \times 10^2$</td>
<td>99.903%</td>
<td>3.0</td>
</tr>
<tr>
<td>Average</td>
<td>$9.1 \times 10^1$</td>
<td>99.938%</td>
<td>3.3</td>
</tr>
</tbody>
</table>

BLSO Titer: $1.7 \times 10^5$ CFU/mL

Corrected Positive Control Titer: $1.0 \times 10^5$ CFU/device

Extraction Efficiency: 33.8%
REFERENCES:


ANSI/AAMI ST35-2003: Good Hospital Practice: Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings. ANSI/AAMI.

Steps You Can Take To Reduce Patient Risk

- Require from every vendor documented clinical data and/or independent laboratory validation of the efficacy and safety of their products or services.

- Partner with healthcare vendors who can provide patient safety solutions.

- Only use instruments who’s IFUs have been validated to ensure clean, sterile, moisture-free instruments on every reprocessing cycle. If a vendor can’t provide validation on their instruments, find a vendor that can.

- Ensure that your laparoscopic instruments have superior insulation (i.e., Radel) to minimize the risk of patient burns.

- Actively research new products and new technologies that have been documented and/or validated to reduce or eliminate “Never Events.”
Will you join in the fight to reduce patient morbidity and mortality by requiring cleaning validation from your instrument vendors?

Patients are counting on you everyday!