May Cover Story

Silver Cross spins gold lining into sterile processing operations progress

INSIDE THE CURRENT ISSUE

People & Opinions

Are you meeting the current manufacturers’ requirements?

Instruction for Use (IFU) on verifying cleanliness of your lumened surgical instruments.

by Jahan Arizi, BS, CBET

A quick Google search for “dirty surgical instruments” yields hundreds of thousands of hits. It has been five years since the issuing of alerts by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Association for the Advancement of Medical Instrumentation (AAMI), and many other organizations to the challenges related to cleaning the internal channels of medical devices. Despite this, however, most hospitals are still unable to verify the cleaning of surgical instruments with lumens.

A look back — July 7, 2009, FDA sent a safety alert to health care institutions stating that:

- FDA has become aware of instances in which pieces of tissue have remained within certain arthroscopic shavers, a device used in some orthopedic surgical procedures, even after the cleaning process was believed to have been completed according to the manufacturer’s instructions. Reports submitted to FDA suggested that the tissue retained was not evident to the naked eye ... because retained tissue in these devices can compromise the entire sterilization process.

- Consider inspecting the inside of the devices following cleaning to ensure that they have been cleared of any tissue or fluids. There may be multiple ways to accomplish this. As one example, the facility that brought this situation to our attention uses a 3mm video scope to inspect the channels of the shaver hand piece.

We know that the FDA’s safety alert was initiated based on a CDC investigation into cross-contamination at hospitals. The CDC found two probable sources — deep inside a hand-held arthroscopic shaver, used to shave away bone and tissue during orthopedic surgery; and inside a long, metal tube called an inflow/outflow cannula, used both to irrigate and suction the surgical site. During the investigation, surgical tools were inspected with a tiny video camera revealing human tissue and bone stuck inside a metal tube called an inflow/outflow cannula, used both to irrigate and suction the surgical site. During the investigation, surgical tools were inspected with a tiny video camera revealing human tissue and bone stuck inside the cannula, used both to irrigate and suction the surgical site.

One may look at these surgical instruments which have been cleaned using the manufacturer-recommended IFU and make an assumption that they are free of debris.

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Worth Repeating

“Surgical smoke creates a serious workplace hazard, resulting in increased respiratory illness. Looking back, we’ll wonder how the archaic practice of exposing staff and patients to harmful substances for hours at a time in a confined environment could ever have been accepted.”

Jill Skoczen, Marketing Manager, Megadyne Medical Products Inc.

“With today’s ASCs being asked today to perform the same types of surgeries found in acute care facilities there cannot be a difference in infection prevention. ASCs have to find a way to be more efficient.”

Dave Billman, COO, Innovative Sterilization Technologies LLC.

“The upfront expense to properly protect and organize instruments can easily be justified by the reduction of instrument repair and replacement within the first year. As you start to add up the expense of needing to repair or replace instruments in those sets it becomes obvious for the need to keep them protected from damage.”

Marcus Super, Director of IntruSafe, Sales and Marketing, Summit Medical

“Some critics will have their opinion no matter what, but we make an attempt to work hand-and-hand whenever possible and to remove the silos between departments when possible.”

Jim Tyrrell, SPD Manager, Silver Cross Hospital, New Lenox, ILz

“Critical Care nurses and Supply Chain professionals need to be respectful of the value each brings to the table when it comes to making sure we have the right products to take care of our patients. We each have our area of expertise, but neither of us understands the total package necessary to make the best decisions. Partnership is key.”

Mary Bylone, R.N., MSM, CNML,
left in an arthroscopic shaver.\(^2\)

One important lesson learned from the CDC investigation is that debris inside lumened surgical devices is a pervasive threat to patient safety. In the past, it has been thought that perhaps what we can’t see can’t hurt us, but we now know that the "ostrich" approach to patient safety is one destined for failure.

**If it isn’t clean, it will never be sterile**

In 1996, Michele Alfa, Ph.D., informed us that there was already a growing concern about the effectiveness of decontamination technique for reusable medical instrumentation in healthcare facilities. Studies at that time had already shown the ability of sterilization technologies, which under normal conditions achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt.\(^3\)

Cleaning is the removal of foreign material (e.g., soil, residue and organic material) from objects and is normally accomplished by using water with detergents. Thorough cleaning is required before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces or inside the lumen of instruments interfere with the effectiveness of these processes. Also, if soiled materials dry or bake onto the instruments, the removal process becomes more difficult and the disinfection or sterilization process less effective or ineffective. Surgical instruments should be presoaked or rinsed. This will prevent drying of blood, allowing for easier removal from instruments.

Sterile processing professionals understand the importance of cleaning and many feel they do not have the tools or the time to follow the instructions for use (IFU). Many professionals feel the incident with the shaver described above was the tipping point, demonstrating not only the importance of cleaning but also the importance of verifying a medical device is indeed clean after reprocessing.

**Survey of professionals**

The 2014 IAHCSMM annual meeting had a workshop that focused on site and surface inspection. The attendees were asked to fill out a simple survey on how they clean and inspect orthopedic shavers.
The chart above shows the results.

This survey showed that even with new IFU’s stressing the importance of visually inspecting shavers with some type of scope, only 7 percent of the people taking the survey are doing this important step.

While the survey was of a small sample size, it does correlate with what was presented at the FDA workshop in 2011 by Smith & Nephew Endoscopy. That study showed sterile processing staff are not following the IFU by conducting visual inspection on each medical device. 4

It is important to point out that it is not just shavers. It is really any lumen device, as was well documented in the AORN Journal article "Uphill Grime: Process Improvement in Surgical Instrument Cleaning." 5

**Advancements in the area of visual inspection**

At a minimum, all instruments should be individually inspected and be visibly clean prior to high-level disinfection or sterilization. Medical device manufacturer Stryker’s IFU for shavers indicates “use of endoscopic camera and endoscope is necessary to see the inner surface of the lumen.” 6

Are we confident that following manufacturer-recommended IFU has removed all debris from lumened surgical instruments?

Is there debris inside the instrument that cannot be visualized by the naked eye?

Could the retained debris inside surgical instruments cause cross-contamination?

It is not just the lumens. It is now the ability to inspect and document almost any surface of a medical device. Products, like a simple bench based camera, give the sterile processing professional the ability to look at the box lock area or the fine tips of a scissor. The closer inspection will allow them to check for burrs or nicks they might not see with the naked eye. The sterile processing professionals’ customer, the surgeon, uses a microscope (or simple loupe) to perform surgery. They are seeing medical devices up close under...
Troubleshooting a distal tip of an ERCP Scope

First line of defense

Sterile processing professionals need to be properly in­serviced, be equipped with the right tools, and have enough time to ensure they are properly following a device’s IFU. Inspection tools like the ones discussed here are available and should be used to help reduce the chance of dirty instruments being used on the next patient. The sterile processing professional is one of the first lines of defense for the patient. When you think about it, the job description should include the duty of “safety officer” because that is what they do: clean, inspect, assemble and get the medical device ready to be used in a safe manner.

Sterile processing professionals will find support for having the right tools for inspecting medical devices in the IFUs of the medical device and guidance documents from various standards groups, including the "The Source of Sterile Processing" AAMI/ANSI ST 79 which states: "Inspection using magnification might identify residues more readily than the unaided eye. Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures (see Annex D for available methods)."

So the question each facility needs to ask is, why am I not inspecting these devices properly each time? Without doing so each time, I may be putting the next patient at risk.

Designing scopes, tools for verifiable cleaning

As recent news headlines have tragically demonstrated, arthroscopic shavers are not the only medical devices that pose a challenge to effective reprocessing. In several healthcare facilities across the country (and counting) life threatening infections associated with Endoscopic Retrograde Cholangiopancreatography (ERCP) scopes and antibiotic resistant bacteria, including carbapenem-resistant Enterobacteriaceae (CRE), have been reported. This has happened at some of the leading institutions in the country, including UCLA, University of Pittsburgh, Virginia Mason, Advocate Lutheran and Cedar Sinai. If these events have occurred there, they most surely are occurring elsewhere. As with the arthroscopic shavers, a significant part of the issue is device design that represents a real challenge to effective cleaning. As with the shavers, tools need to be developed and used to verify that effective cleaning and reprocessing have occurred. Tools such as lighted magnifiers for inspection and reagent tests designed to detect residual organic soil are key to help verify cleaning.

These are the kinds of tools the Food and Drug Administration (FDA) alluded to when recommending using quality assessment tools (See FDA Safety Communication for details. Updated Information for Healthcare Providers Regarding Duodenoscopes http://t.co/LEi4F5IOihd). Furthermore, ECRI is now recommending microbial surveillance testing of flexible endoscopes, including culturing (ECRI Institute Recommends Culturing Duodenoscopes as a Key Step to Reducing CRE Infections [Hazard Report], https://www.ecri.org/resource-center/Pages/Superbug.aspx). A relatively new tool in the market is a quick and easy method to detect gram-negative bacteria that might exist in an ineffectively reprocessed scope. The advantage of a test like this is it is specific to the kind of bacteria most often associated with serious infections (such as CRE), but is quick (10 minutes) and as it does not require any special training or skills, can be conducted by reprocessing personnel.

1. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm170639.htm


5. DOI: http://dx.doi.org/10.1016/j.aorn.2012.03.018.


Jahan Azizi, BS, CBET, has over 28 years’ experience in Biomedical Engineering. As the Clinical Engineer Consultant for the University of Michigan Health System Office of Clinical Safety, Jahan’s responsibilities included investigating and analyzing potential professional liability claims and incidents related to medical equipment; and advising and training medical staff in assessing, resolving and preventing incidents of risk to patient. Retired in 2014 from the University of Michigan, he is currently the Director of Regulatory Affairs for Heart Sync Inc., a medical device manufacturer. He has presented on patient safety and equipment issues to the Association for the Advancement of Medical Instrumentation (AAMI), the American Society for Testing of Materials (ASTM), and the FDA's MedSun reporting group, and has published in AAMI Horizons and AORN Journal.