

# The Value of Lumen Inspection

# See What You Have Been Missing

RECENT NATIONAL MULTIcenter survey found that 70% of instrument lumens inspected with a small-diameter endoscope had foreign matter in the lumens. Cleaning instrument lumens has always been a challenge; it is difficult to clean what you cannot see. We can speculate it is clean, but we cannot be certain unless the lumens are visually inspected.

Until recently, technology didn't exist to visually inspect inside instrumentation. Now, there are small-diameter, flexible waterproof endoscopes as small as 1 mm designed for Central Service (CS)/Sterile Processing Departments (SPDs) to visually inspect the lumens of instruments. To be sterile, the inside of the instruments must be as clean as the outside.

There are many documented surgical site infections caused by dirty instrument lumens. In 2009, a series of dirty arthroscopic shaver hand piece lumens was clinically documented as the cause of multiple surgical site infections.<sup>2</sup> This situation prompted the U.S. Food and Drug Administration (FDA) to issue a Patient Safety News reiterating the need for facilities using arthroscopic shavers to consider inspecting the inside of the devices after cleaning to ensure that they have been cleared of any tissue or fluids.<sup>3</sup>

## A CLEARER PICTURE

Today, Stryker and Arthrex's arthroscopic shaver hand piece Instructions for Use (IFU) recommend the use of an endoscope to inspect the inner surface of the lumen.<sup>4</sup> This was recently reiterated in the October 6, 2014, FDA Medical Safety and Alert document that mentioned inspecting the inside of the devices and using an endoscope to inspect the channels of the shaver handpiece.<sup>5</sup> The value of lumen inspection was shown in the multi-center inspection survey that found 81% of the shaver hand pieces inspected (76/94) had foreign matter in them.

Visual inspection of instruments has always been the standard of care. ANSI/ AAMI ST79 – 7.5.5, *Verification of the cleaning process* states "After the cleaning process, personnel should visually inspect each item carefully to detect any visible soil. Inspection using magnification might identify residues more readily than the unaided eye." All lumen inspection systems on the market offer magnification.

Today's small-diameter endoscopes are designed to allow technicians a quick and easy way to visually inspect the inside of cannulated instrumentation. Technology now has allowed for the diameter of the endoscopes as small as 1mm, allowing inspection of very small lumens. Hospitals using SPD lumen inspection endoscopes are finding blood, tissue, bone, brush fibers, human hair, bone cement, and unidentifiable debris in their cannulated instruments.

What can be found hiding inside surgical instruments after the cleaning process was documented in 2011 at the Workshop on Medical Device Cleanliness. The University of Michigan inspected the lumens of 494 suction tubes and 15 arthroscopic shavers with an endoscope. Every inspected instrument (100%) had foreign matter in the lumens.<sup>6</sup>

# NATIONAL MULTI-CENTER INSTRUMENT LUMEN INSPECTION SURVEY 71 HOSPITALS PARTICIPATED

Instrument Category	# of inst.	Dirty	%
Arthroscopic Shavers	94	76	81%
Suction Tubes	480	348	73%
Orthopedic Cannulated Instruments	141	101	72%
Laparoscopic Instruments	112	75	67%
Miscellaneous Cannulated Instruments	22	13	59%
Flexible Endoscopes	9	4	44%
Robotic Instruments	11	2	18%
Total	860	613	70%





The 2015 Multi-Center Lumen
Inspection Survey inspected 860
instruments in 71 hospitals nationwide.
The survey used 1mm and 2mm SPD
lumen inspection endoscopes to inspect
an array of cannulated instruments.
Arthroscopic shaver hand piece lumens,
suction tubes and cannulated orthopedic
instruments represented the highest
percentage of instruments to not pass
inspection. Without the SPD endoscope,
the technician would not have found the
foreign matter.

As minimally invasive procedures require more complex, lumened instrumentation, it is becoming more difficult to confirm cleanliness. The 1mm and 2mm endoscopes fit down the lumens of the da Vinci® EndoWrist® Instruments¹, drill guides, laparoscopic instruments, flexible reamers, and most cannulated instruments.

There are also lumen inspection endoscopes designed to inspect flexible endoscopes, such as duodenoscopes, gastroscopes, bronchoscopes, and colonoscopes. These lumen inspection endoscopes are 700 mm in length to allow inspection of the complete working channels. It takes less than a minute to visually inspect a flexible endoscope to confirm it is effectively cleaned. CS/SPD staff can also visually inspect the elevator on duodenoscopes.

Hospitals are also using the SPD lumen inspection systems to confirm that loaner trays are clean. Because hospitals do not know how the loaner trays were cleaned and processed, it is critical to inspect the outside and the inside of the instrumentation before they are sterilized and used.

Most SPD lumen inspection endoscopes are waterproof. This is essential as many inspections happen immediately following the cleaning process, and lumens can still have water in them. When using a 700mm-long SPD lumen inspection system, water will still be found in the lumens after they come out of the automated washers. This is also true with all cannulated stainless steel instruments.

There are two types of SPD lumen inspection systems on the market today. The first is a direct view where the technician visually inspects the instrument by looking directly into the eyepiece of the endoscope. This is a cost-effective system for hospitals that lack a computer at every workstation. There are also camera-view systems that connect to a computer, so the technician can view the image of the lumen on the computer monitor. All camera-view systems on the market can record video and pictures to document the cleanliness of the instrument or the foreign matter that is found.

## IN CONCLUSION

The ultimate goal of Central Service/ Sterile Processing is to provide clean and sterile instruments. Today, many institutions are using SPD lumen inspection systems to educate not only the CS/SPD professionals, but also the



Camera view lumen inspection system inspecting a dirty duodenoscope

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surgical staff. By documenting dirty instrument lumens, managers can help CS/SPD staff to understand the value of following industry standards and IFU.

Increasingly, CS/SPD and Operating Room directors are using these devices to show OR staff why they should follow the AST and AORN guidelines of flushing instrumentation during the procedure, and to intraoperatively soak the lumen instrumentation in sterile water if it is not going to be used again.

There are many challenges in today's SPD departments. The biggest challenge is to consistently supply the OR with clean instruments. With today's lumen inspection systems, departments can now visually confirm that the insides of instruments are as clean as the outside, and improve the standard of care. •

### REFERENCES

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