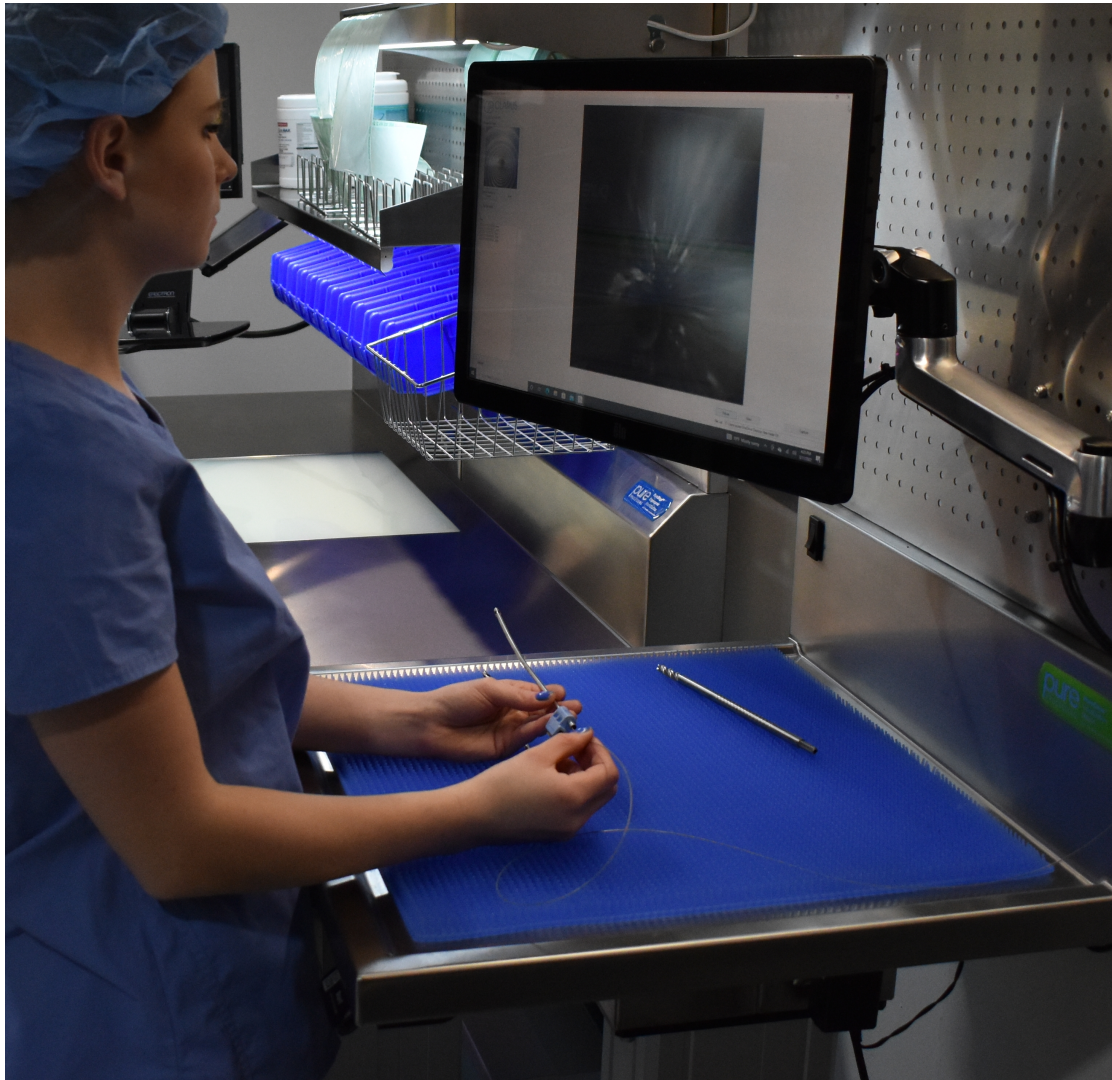


## The Case for Enhanced Internal Visual Inspection of Reusable Devices with Channels



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## Inspection Scope: Enhanced Internal Visual Inspection

Minimally invasive surgery offers patients a potentially better healthcare experience. The reusable devices used for these procedures are complex and delicate, making them difficult to clean and therefore challenging to disinfect or sterilize, since failed cleaning can lead to infection outbreaks. Regulatory standards bodies are starting to include recommendations for enhanced visual inspection of the inside surfaces of these devices, to help assure effective cleaning.

### MINIMALLY INVASIVE SURGERY

*“Endoscopic procedures provide life-saving diagnostic information, but do they put patients at unnecessary risk of deadly infection from cross contamination?”*

-Noronha [3]

Patients and surgeons prefer minimally invasive surgery (MIS) due to less trauma, quick recovery and short hospital stays [1]. Growth in the number of minimally invasive surgical procedures performed is expected to continue because of these desirable benefits [2].

### A CHALLENGE TO CLEAN

*“The endoscope itself is not dangerous, but the current cleaning process used between procedures leaves patients susceptible to infection and troubles many healthcare practitioners.”*

-Noronha [3]

MIS is performed with intricately designed endoscopes and robotics, and be accomplished through natural orifices or very small openings. However, there is a down side: **they are challenging to clean!**

Incomplete cleaning of these surgical instruments leaves surgical debris in the lumens, or other small internal spaces, which limits the effectiveness of disinfection or sterilization processes. Resulting infection outbreaks have caused devastating results:

Arthroscopic shavers: In an unidentified hospital in Texas, seven surgical site infections occurred after arthroscopic procedures in the spring of 2009 [4, 5].

Bronchoscopes: Numerous patients were exposed during multiple outbreaks caused by contaminated bronchoscopes [6, 7].

Duodenoscopes: Exposure to contaminated duodenoscopes was related to 39 infected patients at a northeastern Illinois hospital in 2013 [8, 9 & 10].

Gastrointestinal Endoscopes: Thirty outbreaks, involving 251 patients occurred, in the United States from 1974 to 2004 [6].

**Unfortunately, this is not an exhaustive list!**

*“...reprocessing is time consuming, labor intensive, expensive and, most importantly, susceptible to failure. Among the most problematic features of an endoscope are the luminal channels, which often become contaminated by endoscope accessories. The lumen are difficult to access and clean and can easily harbor pathogens through multiple reprocessing procedures.”* -Noronha [3]

*“Visual inspection is recommended to make sure the endoscope is visibly clean.” -SGNA [11]*

*“Inspect equipment surfaces for breaks in integrity that would impair either cleaning or disinfection/sterilization.” -CDC [12]*

*“Careful visual inspection should be conducted to detect the presence of any residual soil. Inspection using magnification and additional illumination will identify residues and/or damage more readily than the unaided eye.” -ANSI/AAMI ST91: 2021 [13]*

## ENHANCED INTERNAL VISUAL INSPECTION

Best practices for processing reusable devices include visually inspecting for debris and damage with magnification and additional lighting [11 & 12]. Until recently, visual inspection was limited to the external surfaces of the devices.

In response to the spread of infections by contaminated devices, government agencies, standards committees and medical societies are calling for visually inspecting the internal mechanisms and lumens. They advocate the use of inspection scopes for this purpose [11, 12 & 13].

The FDA recommends including instructions for visual inspection in all routine cleaning instructions [14]. Two manufacturers of arthroscopic shavers include internal visual inspection in their Instructions For Use (IFU):

Arthrex®: Check device for visible soil. It is recommended that the cannulation be inspected with an illuminated, magnifying scope. Clean the device using the guidelines for manual cleaning if any soil is visible [15].

Stryker®: Visually inspect the handpiece, including all internal surfaces, for remaining soil. Use an endoscope if necessary to see the surface of the lumen [16].

PureClear™ Inspection Scopes are specifically designed for enhanced visual inspection of the lumens and internal workings of arthroscopic shavers and endoscopes.

## ADVANTAGES OF INSPECTION SCOPES

PureClear™ Inspection Scopes:

- Add illumination for better viewing.
- Enable visual inspection of internal surfaces for debris and damage.
- Magnify the image for easier identification of debris and damage.
- Are available in several lengths and diameters appropriate for many different types of devices.
- Aid in training.
- Comply with manufacturers' instructions for use.

## EXAMPLES OF ENHANCED INTERNAL VISUAL INSPECTION

### TOSH *et al.* [4]

Tosh et al. reported that bioburden was discovered in the handpieces of several makes and models of arthroscopic shavers by endoscopic visual inspection, that was not found during routine inspection of these same devices at different locations within a Texas healthcare system.

They suggest that the problem of retained debris inside devices is not specific to one location or one manufacturer.

### OFSTEAD *et al.* [17]

Ofstead et al. performed internal visual inspections of 20 colonoscopes and gastroscopes, with a borescope at baseline, after 2 months, and at a final assessment at 7 months. All endoscopes had visible irregularities at final assessment, including fluid, discoloration and debris. Twelve (60%) endoscopes had microbial growth detected by cultured samples.

They concluded that their findings support the need for the type of routine internal enhanced visual inspection recommended in the latest guidelines.

### AZIZI [18]

Jahan Azizi inserted a surgical video camera into 350 surgery-ready suction tips. All contained blood, bone or tissue, and some were rusty. Aziz's team then reprocessed these suction tips and inspected them again with the surgical video camera. Seven suction tips were found debris free, 343 were not.

Azizi stated that there are many other difficult or impossible surgical instruments to clean.

## CONCLUSION

Cross infections caused by contaminated surgical devices can lead to serious illness and even death. It is now understood that debris inside devices makes it difficult or impossible to high-level disinfect or sterilize. Government agencies, standards committees and professional societies are advocating for enhanced internal visual inspection after cleaning, as a method to detect debris and damage, and before high-level disinfecting or sterilizing.

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