Use of the Flexible Inspection Scope (FIS) for Inspection of Flexible Endoscopes and Other Instruments

Product Code: FIS-005

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The Flexible Inspection Scope is a type of video borescope that includes a distal tip composed of a light source and camera lens at the end flexible shaft that comes in various lengths and sizes. A borescope is a piece of equipment used to inspect the inside of an instrument through a small opening (lumen/channel) found on that instrument. The Healthmark Flexible Inspection Scope is intended for inspection of any medical or surgical instrumentation preferably after cleaning, and prior to disinfection or sterilization. It may be used on the outside or inside surfaces of instruments including those such as arthroscopy routers, shavers, reamers, flexible endoscopes and other lumened items.

According AAMI ST91 [1], healthcare facilities should establish a comprehensive quality assurance and safety program to monitor all aspects of endoscope processing. This program should incorporate both visual inspections and testing of the equipment to identify conditions that may affect the cleaning or disinfecting processes.

Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes. Use of enhanced visualization methods, including inspection with a borescope, such as the Flexible Inspection Scope (FIS), is being incorporated into current standards and recommendations.

Visual inspection of the equipment should include the following:

- Residual organic soil
- Cracks and other damage to the instrument
- Integrity of fiber optic bundles
- Use of magnification

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Both ST91 and AORN Endoscope Reprocessing Guidelines [2] state to consider inspection with borescope. According to ST91, "Inspection using magnification and additional illumination might identify residues more readily than the unaided eye… tools such as **video borescopes** of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices…the use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning..."

According to AORN VII.c.1., "Internal channels of flexible endoscopes may be inspected using an endoscopic camera or **borescope.** [2: High Evidence] Endoscopic cameras and borescopes penetrate the lumen and allow for improved visual inspection."

In AAMI ST79 [3] Visual inspection is described as a verification of the Cleaning process. Section 7.6.4.5 states the following:

- After completing the cleaning process, personnel should visually inspect each item carefully to detect any visible soil.
- Inspection using magnification and light borescopes might identify residues not observable by 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).

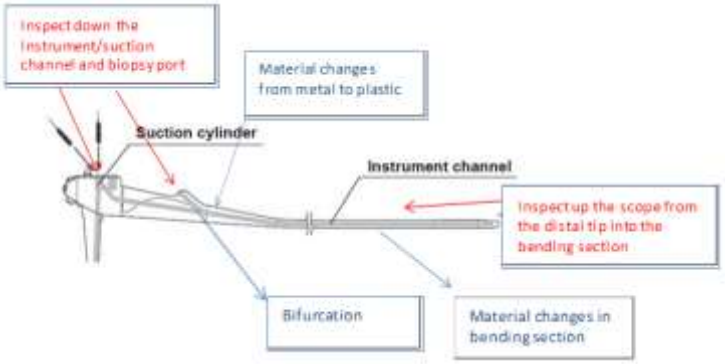
Also, the IAHCSMM Endoscope Reprocessing Manual [4] from 2017 states the following: "The most important areas for inspect on are the lumens that run through the endoscope. Lumens pose a cleaning challenge because of their narrow structure that prevents visualization during the cleaning; 'therefore, it is important to always check lumens for cleanliness after cleaning. Visual inspection of lumens can be accomplished using a borescope, a small flexible fiberoptic device that enables visualization of otherwise inaccessible areas within endoscope lumens."

According to the SGNA POSITION STATEMENT on Management of Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting[5], "A comprehensive quality control program for reusable medical devices should be implemented and include, but not limited to the following:

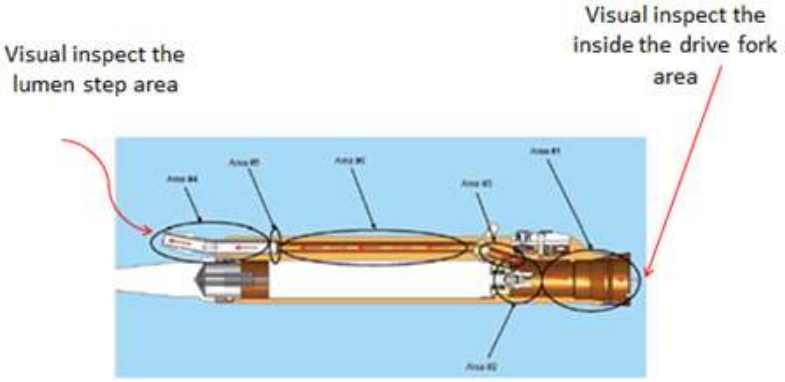
a. Visual inspection and equipment testing to identify conditions that may affect the cleaning or disinfection process. Damaged reusable items should be removed from use. Follow facility protocol for returning device.
b. Procedures for monitoring the useful life of medical devices that include visual inspection, scheduled maintenance, and removal of equipment from use based on manufacturer's guideline.

Areas to inspect:

1. **Endoscopes**: There are many areas in an endoscope which can be inspected with the FIS including instrument suction channel, channel openings/valve housings, distal tip, forceps elevator recess on endoscopes. Here are some other suggested areas that might be considered for inspection on a flexible endoscope:



2. **Shavers:** Areas to inspect include the following:



IFU Support for using a Flexible Inspection Scope:

1. Arthrex Hand Piece [6]: The IFU states the following, "Check the device for visible soil. It is recommended that the cannulation be inspected with an illuminated, magnifying scopes. Clean the device using the guidelines for manual cleaning if any soil is visible…".

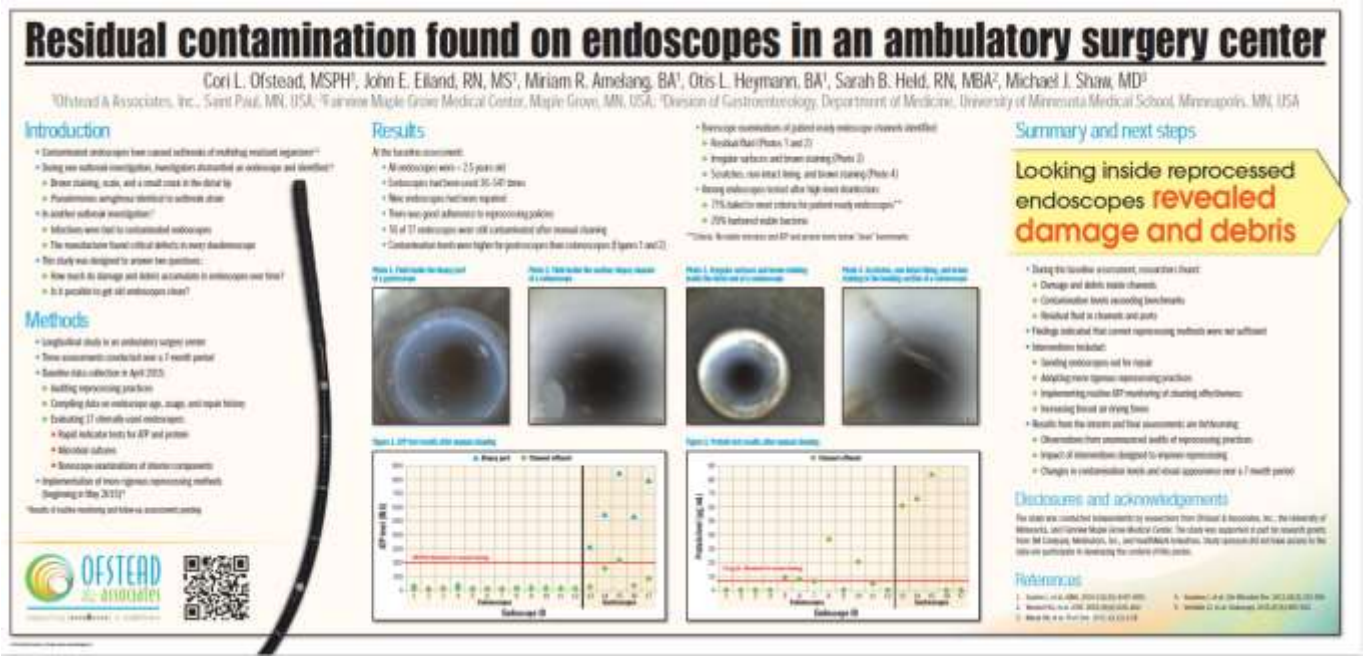
2. STRYKER Shaver Hand Piece [7]: The IFU states the following, "Visually inspect the hand piece, including all internal surfaces, for remaining soil. Use an endoscopic camera and endoscope if necessary to see the inner surface of the lumen. If soil remains, repeat the manual cleaning procedure, focusing on those areas…".

In an FDA Safety Communication [8], "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 handpiece."

Study data:

1. In a recent study conducted by Ofstead and Associates [9], the Flexible Inspection Scope was used to inspect endoscopes in a healthcare facility. During this study there was good adherence to published reprocessing steps, however, upon inspection of the interior components of endoscopes with a FIS, borescopic examination revealed the following:
   - Residual fluid
   - Irregular surfaces and brown staining
   - Scratches, non-intact lining, and brown staining

Therefore, by examining inside the reprocessed endoscopes, the study revealed both damage and debris retained inside the channels of the inspected scopes. Inspections revealed damage and debris inside channels and residual fluid in channels and ports. These findings indicated that current reprocessing methods were not sufficient to result in properly reprocessed endoscopes. By identifying these findings, the facility was able to implement additional measures to ensure that endoscopes were being reprocessed to a higher standard of care.



2. In another publication by Ofstead and Associates [11], the Flexible Inspection Scope was used to inspect GI endoscopes in a Healthcare facility over time. During the study, it was found that most GI endoscopes had irregularities upon inspection. Specifically, examination with the flexible inspection scope demonstrated scratches, discoloration, debris and fluid inside the endoscope channels.

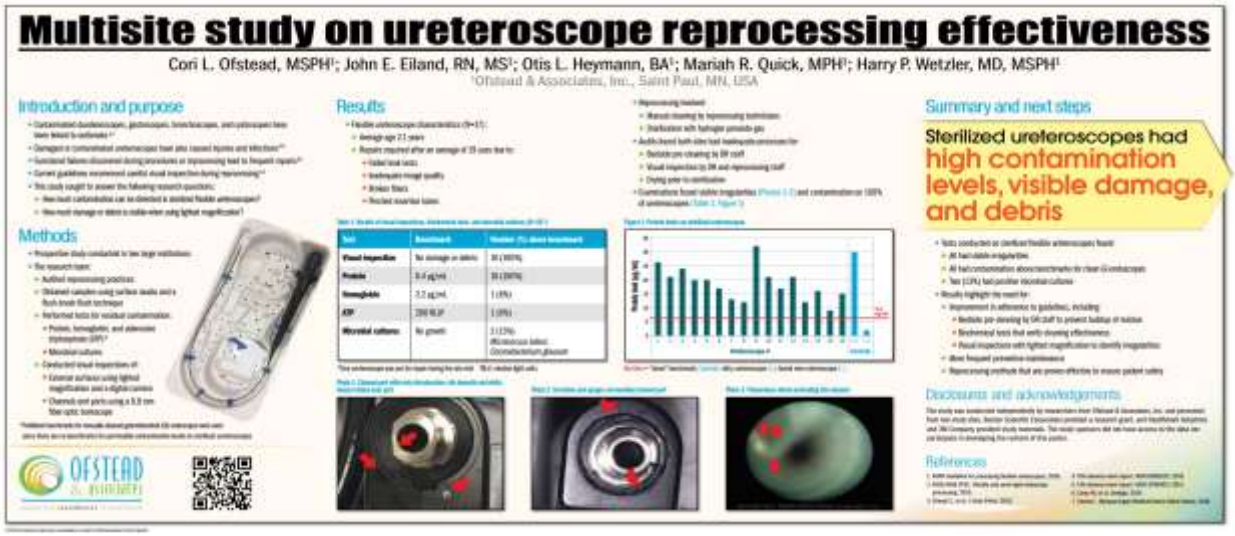
   Therefore, by performing inspection with this borescope, researchers were able to identify endoscopes that needed repair and had critical defects. These findings support use of enhanced visual inspection by use of a borescope, such as the Flexible Inspection Scope.

   In a recent study entitled, "Inspection of Endoscope Instrument Channels After Reprocessing Using a Prototype Video Camera: A Pilot Study [12]," authored by Thaker et al., it was determined that an inspection program with a video camera device showed that internal damage and/or discoloration of the instrument channel appears to occur frequently, even in newer endoscopes. Also, the study demonstrated that video inspection of the endoscope channel may be useful to audit reprocessing performance and to identify damaged endoscopes.

3. Ofstead and associates presented the study below at the AORN 2017 Conference[12]. In this study, it was found that sterilized ureteroscopes had high levels of visible

irregularities, debris, damage and contamination upon inspection with a flexible inspection scope.

4. Ofstead and associates presented the study below at the AORN 2017 Conference[13]. In this study, it was found that sterilized ureteroscopes had high level of visible irregularities, debris, damage and contamination upon inspection with a flexible inspection scope.



5. A poster submitted to IAHCSMM for exhibit at the 2018 national conference entitled, "How to get to visually clean: Site and Surface Inspection" detailed the process and requirements for inspecting various types of instruments for residual debris and damage. It recommended that the facility must decide what instruments should be inspected, how often, and with what while keeping in mind current standards and guidelines on the topic. The poster displayed several photos of internal inspection of instruments showing both residual debris and damage that would not qualify the instrument as clean and functional. [14]

6. A recent article in HPN by M.A. Drosnock elaborated on the inspection step for instruments[15] and stated that removal of soil and inspection of the instrument for residual debris or damage are critical steps in assessing the quality of reprocessing and whether the item is fit to move on in the process. Items that are deemed to be in disrepair should be taken out of service immediately and those that show signs of having residual soil in or on them either by cleaning verification test or by visual

inspection, should be re-cleaned and re-tested until they pass both the inspection and verification tests.

7. The CMS ASC Infection prevention surveyor worksheet and the CMS Survey and Cert Worksheets state that surveyor should be looking for the following steps to be performed in facilities.
    a. In section 3.A.6 it is stated, "Flexible endoscopes are inspected for damage and leak tested as part of each reprocessing cycle". [16]
    b. Also, in section 3.B.5, the worksheet reads, "Items are thoroughly pre-cleaned according to the manufacturer's instructions and visually inspected for residual soil prior to sterilization." [17]

Example photos demonstrating internal endoscope channels/areas:

Fig. 1 FIS set up with computer

Fig. 2 Internal Channel

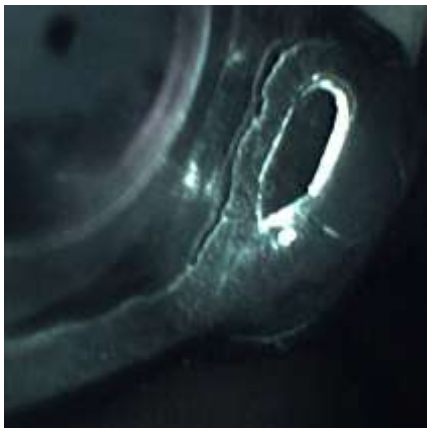


Fig. 3 Crack in weld at water jet

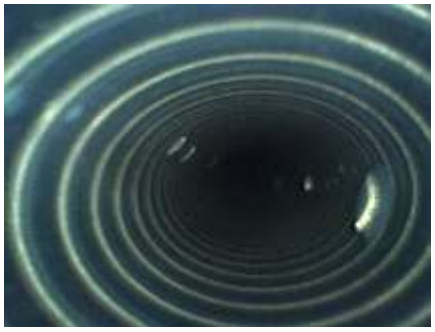


Fig. 4 Water in Channel

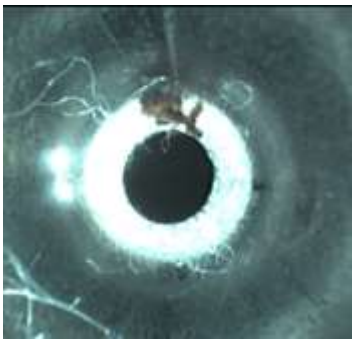


Fig. 5 Debris in Channel

Example photos of internal suction and shaver lumens:

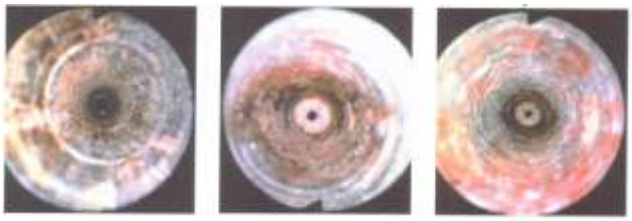


Fig. 6 Suction lumens

Fig. 7 Shaver Inspection

Fig. 8 Debris inside shaver

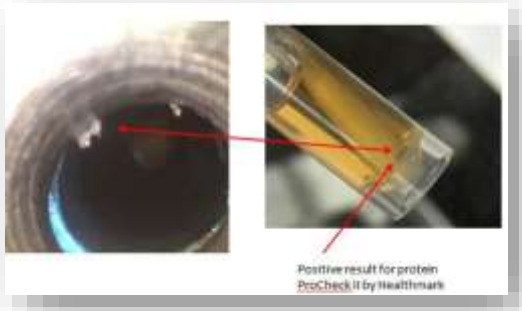


Fig. 9 Shaver debris which tested positive for protein

Conclusion:

Therefore, to summarize, the Flexible Inspection Scope (FIS) is a useful tool for inspection of flexible endoscopes, arthroscopy routers, shavers, reamers, flexible endoscopes and other lumened instruments. Use of the FIS borescope provides the end-user a simple verification test to inspect the instrument suction channel, channel openings, distal tip, forceps elevator recess on endoscopes and the internal lumens on other instruments to determine if there are any signs of damage, retained debris and/or moisture remaining in the channel.

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