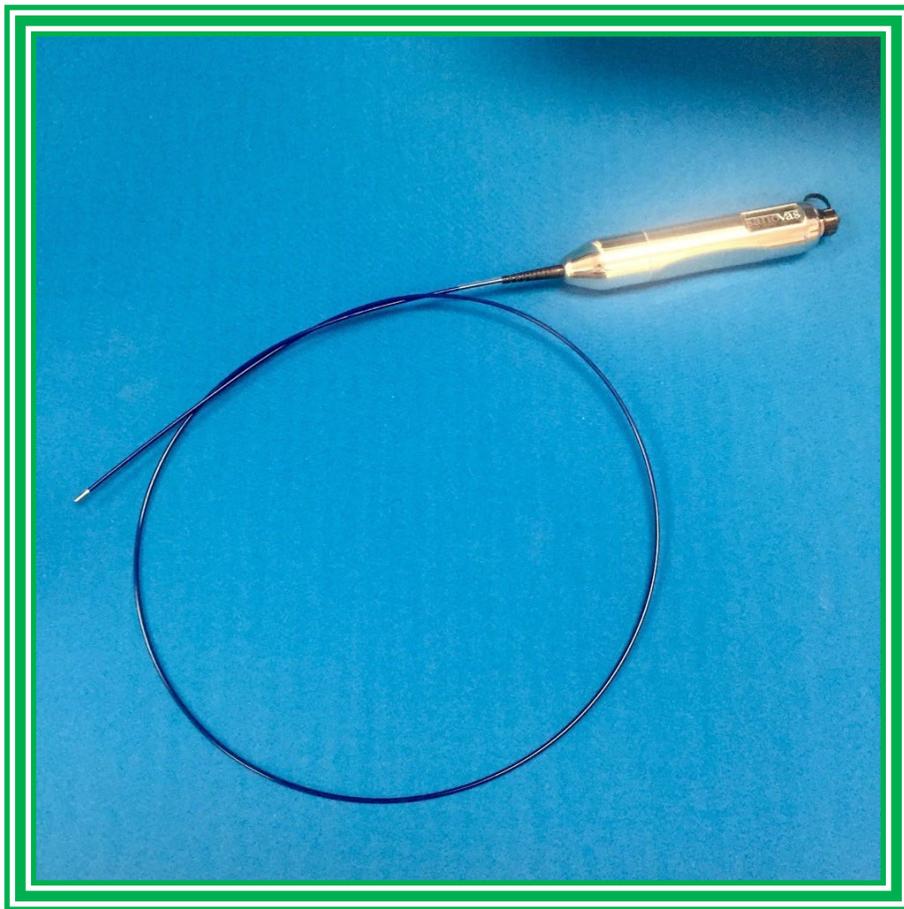




Instrument Inspection System

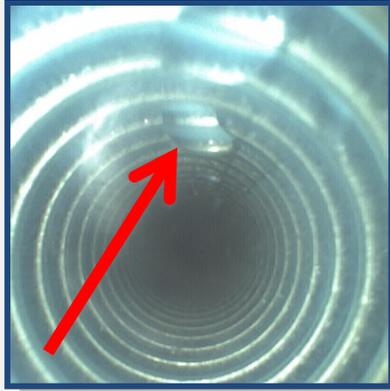


“Always be Patient Ready”

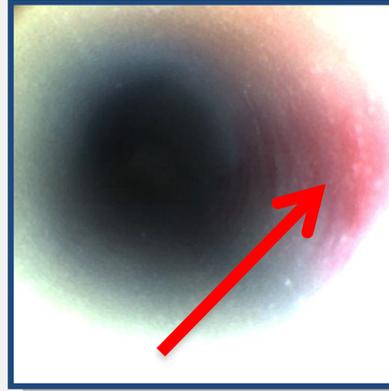


ARE YOUR INSTRUMENTS PATIENT READY?

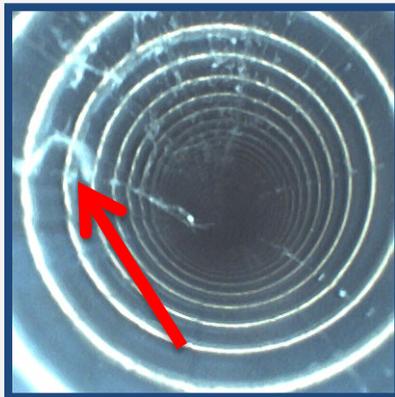
A total of 36 inspections were done on colonoscopes and gastroscopes with the SteriView™ Inspection Scope, during which the facility staff altered their reprocessing protocol slightly to overcome findings of retained fluids in biopsy channels. These findings were noted in spite of compliance with facility policies and procedures on reprocessing that included air drying and hanging in a dedicated cabinet.



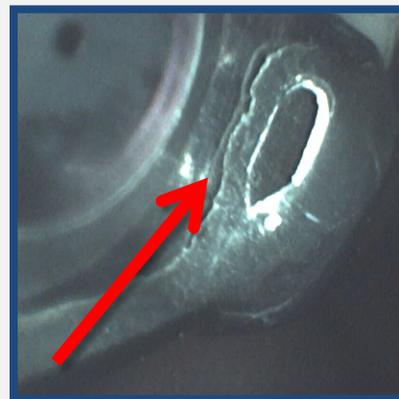
NOT Patient Ready



Colonoscope
NOT Patient Ready



Gastroscope with channel
“shredding” NOT Patient Ready



ERCP scope air/water nozzle
defect? NOT Patient Ready

Published studies are now emerging that show inspection of surgical and endoscopic instrumentation yields significant findings advantageous to infection control and detection of mechanical damage, **any and all of which can have serious impact on patient safety!**

In an independent study¹ conducted at the University of Minnesota Medical School demonstrated:

- 71% failed to meet the criteria for patient-ready endoscopes
- 29% harbored viable bacteria
- Contamination was highest in gastroscopes
- Damaged was detected in 9 of 17 scopes examined

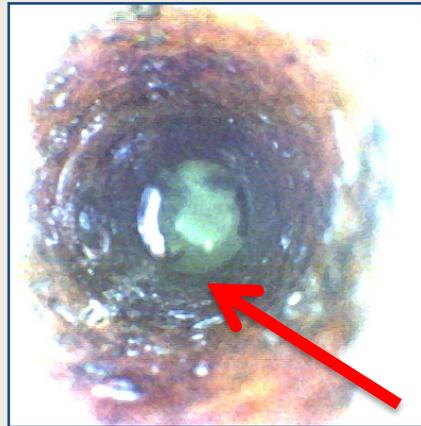
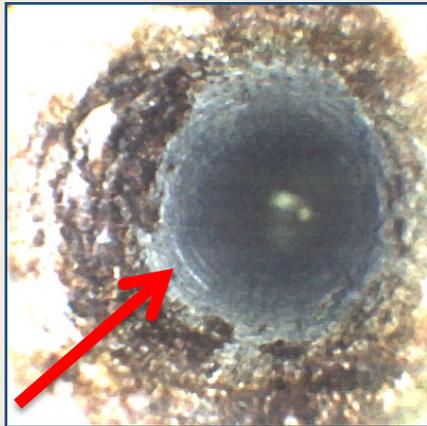
A subsequent study² demonstrated:

- Gastroscopes had higher ATP levels than colonoscopes.
- Borescope examinations of endoscope lumens revealed defects requiring repair.
- Microbial growth was found on approximately half of “patient-ready” endoscopes.
- Internal damage and residual fluid may foster contamination and biofilm formation.

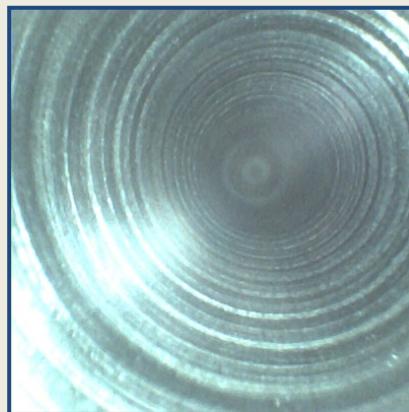
A Surgical Case Study

A series of inspections was done in early 2016, independent of any support from SteriView personnel. The lead Reprocessing Technician used the system continuously for three months, most immediately finding a number of defects inside the center's arthroscopy shaver handpieces.

There was remarkable and significant internal damage due to corrosion in all of the handpieces owned by the center. Images were taken and taken to the Clinical Manager, who presented them to the Board of Directors. The decision was made to contact the manufacturer, who promptly replaced all of the units with new ones.



Arthroscopy shaver hand -piece with significant internal corrosion
NOT Patient Ready



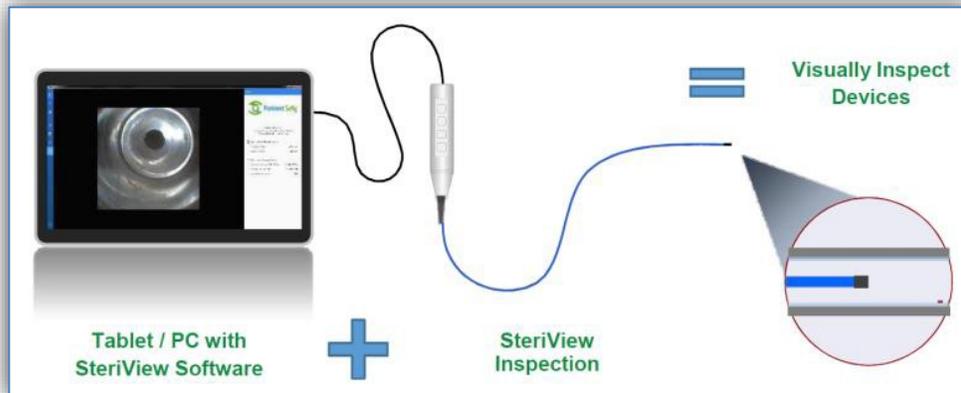
Patient Ready!

This ASC now uses the SteriView™ Inspection System routinely, as part of ongoing Quality Assurance and Process Improvement, keying on its role in verifying cleanliness as well as mechanical condition of all its lumened instrumentation. Digital imaging and file management have found use in preparation for regulatory auditing by CMS and JCAHO. This center now has a digital catalog of their reusable instruments, with time and date stamp and organized into digital folders, on a Sanovas SteriView™ laptop.

Sources:

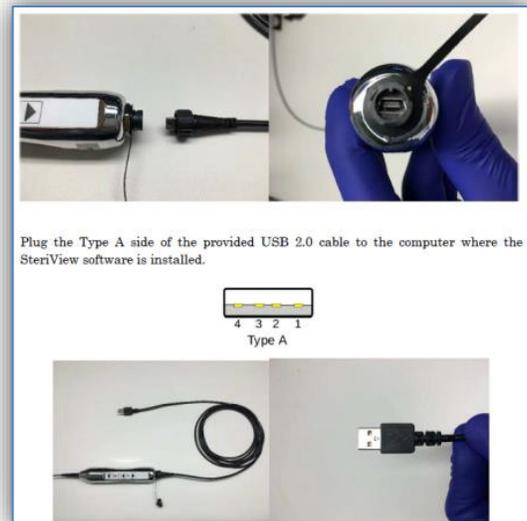
1. Residual contamination found on endoscopes in an ambulatory surgery center, Ofstead, et al; research poster, AORN 2016
[http://www.aornjournal.org/article/S0001-2092\(16\)30166-1/abstract](http://www.aornjournal.org/article/S0001-2092(16)30166-1/abstract)
2. Assessing residual contamination and damage inside flexible endoscopes over time, Ofsted et al; AJIC; 9/7/2016
[http://www.ajicjournal.org/article/S0196-6553\(16\)30701-5/fulltext](http://www.ajicjournal.org/article/S0196-6553(16)30701-5/fulltext)

SteriView™ Inspection System (mic)



Camera System

- The mic comes in 2 diameters. 1.8mm and 2.3mm OD.
- The length of the mic is 110cm.
- The mic is a fully digital image and not fiberoptic.
- The mic insertion tube can detach from the handle.
- It allows you to interchange sizes with one handle.
- It allows you to clean the insertion tube in an AER-Automatic Endoscope Reprocessor if necessary. Insertion tube and camera head can be cleaned with a Sanicloth.



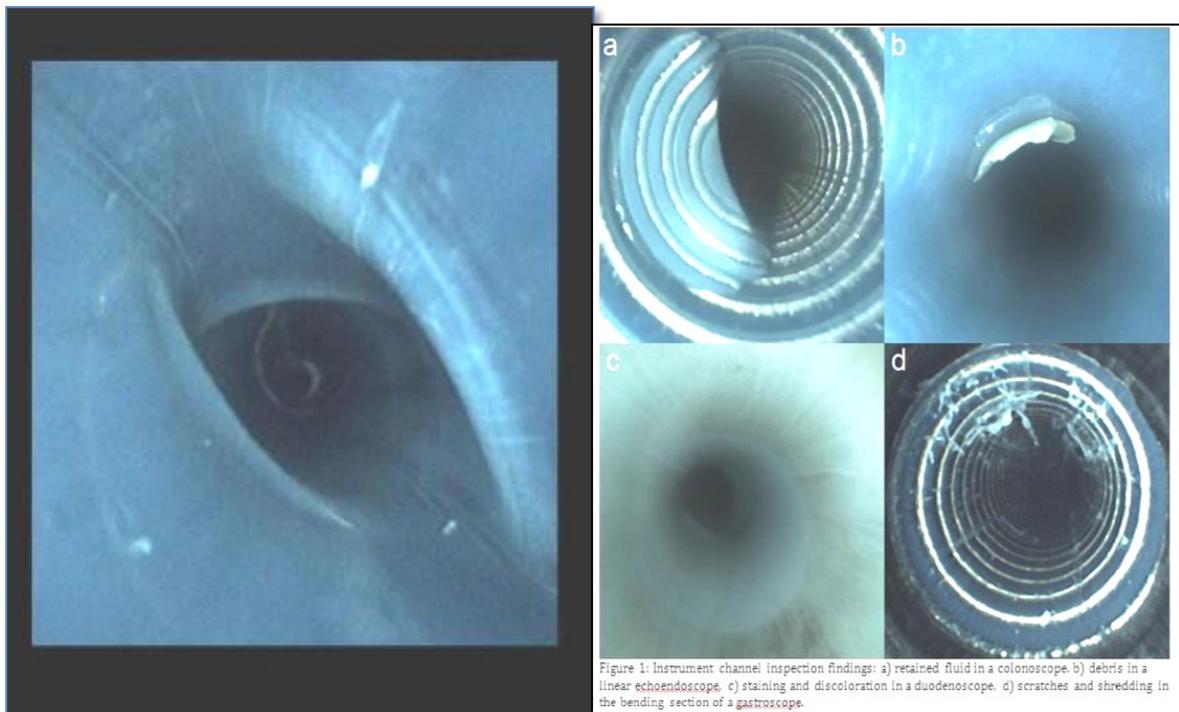
Computer System

- The mic can be purchased with a Surface Pro tablet computer or ship with the software on a USB key to be installed on your own computer.
- Images and video can be taken from either the camera head or from the computer/touchscreen computer.
- All images and videos can be cataloged by scope with references images.

- All images and videos are auto date and timed stamped.
- The mic connection is via standard USB.

The image

- The native image is 400x400 pixels. With our interpolation algorithm it scales to 800x800 pixels.
- Fully digital image.
 - No white out glare like you would see with a fiberoptic scope.
 - Less breakage than with a fiber optic bundle.



The Company

- The mic is distributed through TRICOR-Systems, Dri-Scope Aid®.
- The warranty is 1 year.
- Repairs on the camera are repair-replace.
- Loaners are available upon request.



Product Specifications

- active array size: 400 x 400
- minimum exposure time: 72.15 μ s
- frame rate:
 - 160 Kpixel (400x400): 30 fps
- scan mode: progressive
- max S/N ratio: 36.8 dB
- dynamic range: 65.8 dB @ 4x gain
- sensitivity: 1000 mV/Lux-sec
- color mosaic: RGB Bayer pattern
- pixel size: 1.75 μ m x 1.75 μ m
- lens size: 1/18"
- diagonal field of view (FOV): 120°
- f no.: 5.0
- focal length: 0.418 mm

- **AORN** - “personnel should use lighted magnification for the inspection and inspect internal channels using an endoscopic camera or borescope (i.e., a device used to inspect the inside of an instrument through a small opening or lumen of the instrument).
- **SGNA** - “Visual inspection is recommended to make sure the endoscope is visibly clean (AAMI, 2015; Rutala et al., 2008)...Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris) (FDA, 2009; AAMI, 2015
- **ASGE** - “Visually inspect both endoscopes and reusable accessories frequently in the course of their use and reprocessing, including before, during and after use, as well after cleaning and before high-level disinfection.”
- **ANSI/AAMI** - Referred to above, ST 79; “After completing 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.” There’s additional discussion about using methods to measure residues not detectable using visual inspection.
- **AAMI ST91** - “Cleaning verification is performed following cleaning to verify the effectiveness of a cleaning process prior to disinfection...should include visual inspection...testing of the cleaning efficacy of mechanical equipment...monitoring of key cleaning parameters”
- **CMS** - the ASC Infection Control Audit Tool discusses visual inspection and compliance with manufacturers’ IFUs. Another resource for CMS audits required drying of reusable instrumentation after reprocessing, which you *cannot verify without an inspection scope*.
- **Instrument manufacturers** are starting to mandate use of “endoscopic cameras” or “endoscopes” to inspect their devices internally. Examples are found in IFUs from Stryker and Arthrex.

Contact:

For information, details on these studies, or a demonstration at your facility.
