by Kevin Stephenson, co-owner SP Concepts

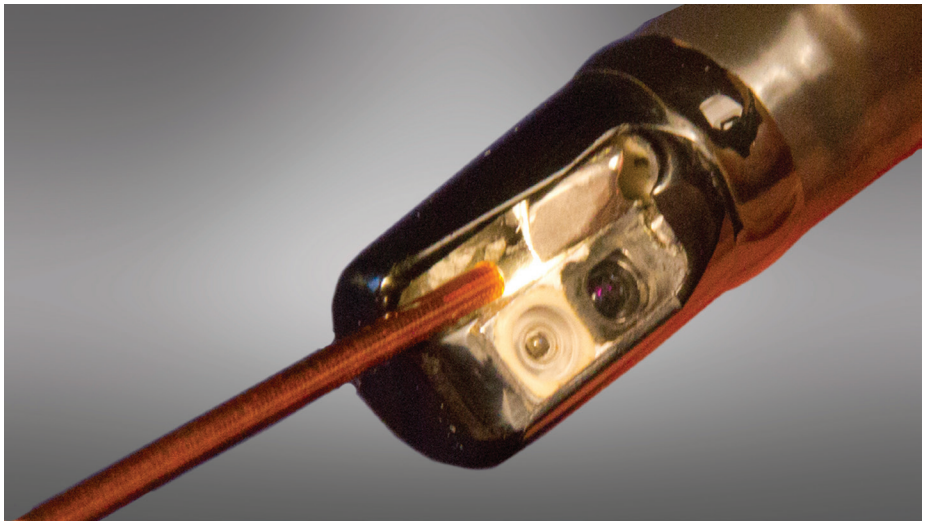
Visual Inspection of Flexible Endoscope Working Channels

See What You Have Been Missing

A RECENT MULTI-CENTER survey by SP Concepts[1] was conducted to visually inspect the working channels of flexible gastrointestinal endoscopes. The survey of 126 endoscopes in 41 hospital found that 59% of the inspected channels were still dirty after reprocessing. The survey was completed shortly after ECRI Institute named inadequate cleaning of flexible endoscopes before disinfection as the number one health technology hazard for 2016.[2]

The problem of cleaning a channel that one cannot see has always been a challenge for technicians. The technician can only assume that the working channel and suction ports are clean, but will not know with certainty until the endoscope is visually inspected.

Recent reports of infections from endoscopes that were later found to be contaminated has prompted the need for a more thorough visual inspection. The inspection scope in the multi-center survey allowed visual inspection of working channels and suction ports as small as 1 mm in diameter. Guidelines from the American National Standards Institute/ Association for the Advancement of Medical Instrumentation (ANSI/ AAMI), the Association of periOperative Registered Nurses (AORN), the Society of Gastroenterology Nurses & Associates Inc. (SGNA) and the Centers for Disease Control and Prevention (CDC) all recognize the value of visual inspection.



Magnified inspection of the elevator mechanism

SPECIFIC GUIDELINES THAT SUPPORT VISUAL INSPECTION

ANSI/AAMI ST91:2015 *Flexible and semi-rigid endoscope processing in health care facilities* states in 12.4.2: "*Tools such as video boroscopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices.*"[3]

In the Quality Assurance guideline of SGNA's 2016 *Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes*, it states that: *Visual inspection is recommended to make sure the endoscope is visibly clean (AAMI, 2015; Rutala, et al, 2008). It is not a guarantee that decontamination from manual cleaning is complete, but it can be considered a safety stop or "time out" to ensure the endoscope is visually clean before proceeding to the next step of high-level disinfection (HLD).*

a. Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris) (FDA, 2009; AAMI, 2015).

b. Use magnification and adequate lighting to help assist in visual inspection (AAMI, 2015).

c. Repeat manual cleaning step(s) if not clean[4]

Further, the *CDC Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing*, released in March 2015, recommends

Channel inspection with optional camera

the following for inspection and manual cleaning: *Ensure that the elevator mechanism located at the distal tip of the duodenoscope is thoroughly cleaned and free of all visible debris. The visible inspection is to be done with the elevator in the "open/raised" position, as well as with the elevator in the "closed/lowered" position to ensure there is no visible debris above or below the elevator mechanism. Consideration should be given to use of a magnifying glass (e.g., 10X) to improve detection of residual debris around the elevator mechanism.*[5]

MAGNIFICATION IDENTIFIES AREAS OF CONCERN

Using the new 1 mm and 2 mm waterproof scopes that are available on the market offers visual inspection as recommended in the CDC, ANSI/AAMI, AORN and SGNA guidelines. Visual inspection in this manner offers a quick and easy process to visually confirm that the working channels are free of foreign debris. A time study revealed that visual inspection of a working channel takes approximately one minute.

The types of foreign debris were not catalogued in the SP Concepts multi-center survey; however, the debris included tissue, fibers, blood, metal clips, brush bristles and other unidentified types of foreign matter. In addition, multiple endoscopes inspected still had significant fluid in the channels. One institution found fluid in two of their endoscopic retrograde cholangiopancreatography (ERCP) endoscopes five days after reprocessing.

Inspection scopes may be used with or without a camera. An economical direct view system does not need a camera. Direct visualization is achieved by looking through the eyepiece of the inspection scope. Use of a high-resolution digital camera attached to the inspection scope allows the technician to observe the inspection on a computer screen and document the findings with still and video images.

Inspection scopes offer magnification as recommended in ANSI/AAMI, SGNA, AORN and CDC guidelines.

CHANNEL INSPECTION REVIEW DATA			
Type of Scope	Dirty	Inspected	Percentage
Duodenoscopes	24	50	48%
Gastroscopes	24	37	65%
Colonoscopes	26	39	67%
All Flexible Endoscopes	74	126	59%

Inspection scopes have 9X magnification; however, using a digital camera increases magnification to 300X. The magnification is very useful in inspecting GI endoscope integrity (torn channel linings, chipped lenses, gasket cracks, etc.)

Inspection scopes are also useful for inspecting the outer surface and distal tips of flexible endoscopes. Visual inspection behind the elevator of an ERCP endoscope or in other difficult-to-see exterior places is easily conducted and is recommended by the CDC.

BRONCHOSCOPES, URETEROSCOPES AND CYSTOSCOPIES ALSO POSE CHALLENGES

The small working channels of flexible endoscopes have always been a challenge to clean. In 2014, the U.S. Food and Drug Administration (FDA) received 50 medical device reports (MDRs) that pointed to infections or device contamination associated with reprocessed flexible bronchoscopes (subsequently, these incidents led to additional investigation on this issue). In its September 17, 2015, safety communication, the FDA identified bronchoscopes as belonging to a subset of devices that poses a greater likelihood of microbial transmission and represents a high risk of infection if they are not adequately reprocessed.

The FDA safety communication recommended the implementation of a comprehensive reprocessing quality control program.[6] Using a 1 mm inspection scope to visually inspect the working channel can arguably enhance the quality control.

SURVEY RESULTS

An interesting finding in the multi-center SP Concepts survey is that ERCP endoscopes were statistically cleaner than the gastroscopes and colonoscopies tested. The findings may be, in part, due to the recent emphasis that has been put on ensuring ERCP endoscopes are clean.

CONCLUSION

ANSI/AAMI, AORN, SGNA and CDC guidelines all support visual inspection following the cleaning process. Inspection scopes as small as 1 mm in diameter, and with sufficient length, now exist to visually inspect the working channels and suction ports of flexible endoscopes. Using this technology to visually inspect the channels of 126 processed flexible endoscopes in 41 hospitals in the multi-center SP Concepts study yielded an overall rate of 59% that contained some form of foreign debris.

With today's inspection scopes as small as 1 mm, it is possible to inspect not only GI endoscopes, but also the small channels in bronchoscopes and ureteroscopes. Visual inspection of flexible endoscope channels using an inspection scope can be done quickly, easily and effectively, resulting in the potential for cleaner flexible endoscopes and lower risk of infection.

REFERENCES

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KEVIN STEPHENSON is co-owner of SP Concepts.