
SAFETY
FIRST

Increasing the Margin of Safety in Flexible Endoscope Processing:

A Focus on Visual Inspection

BY KEVIN ANDERSON, MBA, BSN, RN, CNOR, CRCST, CIS, CHL, CER, CLINICAL EDUCATION SPECIALIST—HEALTHMARK INDUSTRIES

Certified Endoscope Reprocessor (CER) lessons provide members with ongoing education focusing on the maintenance and handling of endoscopes. These lessons are designed for CER recertification but can be of value to any CRCST.

Earn Continuing Education Credits

Online: Visit www.myhspa.org for online grading.

By mail: Mailed submissions to HSPA will not be graded or granted a point value (paper/pencil grading of the CER Lesson Plans is not available through HSPA or Purdue University). HSPA accepts only online submissions.

Scoring: Each online quiz with a passing score is worth 2 contact hours toward your CER recertification (6 points) or CRCST recertification (12 points).

More information: HSPA provides online grading services for any of the Lesson Plan varieties. **Note: Purdue University ONLY provides grading services for the CRCST and CIS lessons. Please do not send the CER or CHL lessons to Purdue for grading. Direct any questions about online grading to HSPA at 312.440.0078.**

LEARNING OBJECTIVES

1. Review recommendations for visual inspection of flexible endoscopes using the unaided eye
2. Learn the importance of designing a space to comply with and execute visual inspection
3. Identify ways to implement more effective visual inspection within the flexible endoscope reprocessing workflow

For decades, flexible endoscopes have been useful for diagnosing and treating millions of patients. They are also expensive hospital-owned assets that have evolved in complexity and capability. Flexible endoscopes are an effective tool for modern medicine, but the devices can pose a great danger to patients if they are not properly cared for and processed.

On the heels of the Association for the Advancement of Medical Instrumentation's (AAMI's) updated industry standard ANSI/AAMI ST91:2021 *Flexible and semi-rigid endoscope processing in health care facilities*, there are many changes and additions to the recommendations for processing flexible endoscopes. It is easy to see the changes and become overwhelmed with trying to fit all of the new practices into one's day-to-day workflow or standard operating procedures (SOPs). With complex processes, it can be helpful to focus on one step at a time—working to design the process, workflow, training and competency verification around each step before moving to the next. While there are many changes and updates to the new ST91:2021 document, this lesson plan focuses on the visual inspection step with the unaided eye.

Objective 1: Review recommendations for visual inspection of flexible endoscopes using the unaided eye

Those who have worked in a fast-paced endoscopy area know the challenges and constraints often felt by processing technicians. With flexible endoscopes especially, it can be easy to miss steps in the process, often without even realizing it. The inspection step is one that can be easily overlooked amid the hustle of a busy endoscopy suite. One primary indicator that the inspection process is not being prioritized lies within the layout of the decontamination area. Often, this area lacks a dedicated space for performing inspection.

Another telltale sign observed in many endoscopy areas is the presence of damaged endoscopes hanging in a storage cabinet and presented as "patient ready." (See **Figure 1**) It is critical to raise awareness about the types of damage that can readily be detected with the unaided eye—but doing so requires both proper training and technicians who purposefully and diligently seek to detect damage or other defects.

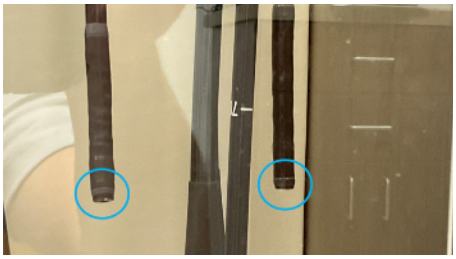

Figure 1: Damaged glue joints on the bending section

Sterile Processing (SP) technicians and leaders should aim to inspect endoscopes at every opportunity. The earlier problems are detected, the better the chance of preventing potential problems and reducing patient risks down the line. Although recognizing the importance of routine and ongoing inspection is beneficial, it is also helpful to determine a specific time and process for visually inspecting flexible endoscopes. Manufacturers' instructions for use (IFU) may offer inspection recommendations, but not all will include specific directions for the critical inspection step. In the absence of those instructions, the latest version of ST91 can deliver valuable guidance. ST91:2021 places the visual inspection step after manual cleaning, rinsing, drying and channel purge. This is an ideal time in the process to perform visual inspection. If debris is found, the manual cleaning process should be repeated. (See **Figure 2**) If damage is detected, technicians should remove the device from service and follow their facility's policy for repairs.

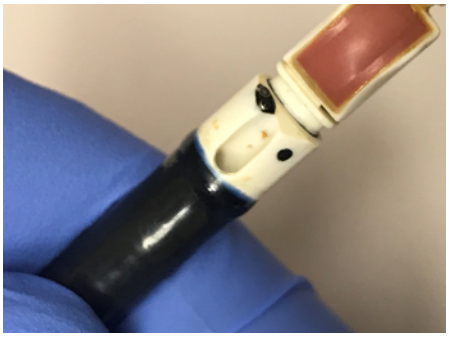

Figure 2: Debris present on biopsy channel of EUS endoscope

What should technicians look for during visual inspection? ST91:2021 states that technicians should inspect for both residual debris (Section 7.1.2) and the presence of damage (Section 7.2.2). Most flexible endoscopes are opaque and dark in color, and their bending sections can increase cleaning challenges and the risk of retained residual debris. During inspection, it is essential to look for discoloration around the lenses in the distal tip, discoloration or debris at the end of the channels, and discoloration that becomes pronounced around the white markings along the insertion tube.

Inspecting for damage is equally important. It is prudent for technicians to become familiar with the various types of damage for flexible endoscopes. This damage can include:

- Cracks or broken seals on the various lenses.
- Chips or cracks in the distal end cap. (See **Figure 3**)
- Damaged or missing adhesive at the distal end or on the bending section's glue joints.
- Tearing, peeling or scratching on the surface of the insertion tube.
- Dents along the insertion tube or the light guide tube (caused by crushing).
- An insertion tube that angulates when stored vertically. While using an endoscope, it is normal for the practitioner to angulate the device to safely navigate the patient's anatomy. When flexible endoscopes hang vertically in storage, however, they should not angulate. They should hang straight down.

The best way for technicians to learn proper inspection processes and practices is to perform inspection during training and ongoing competency programs. For a point of reference, technicians may also review ST91:2021 Annex E.

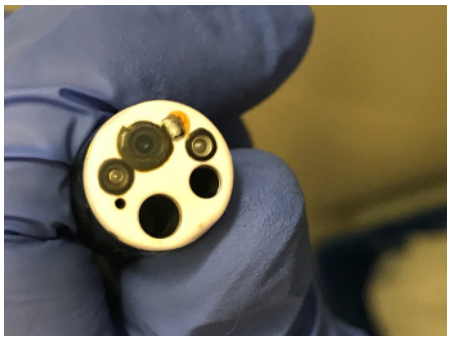

Figure 3: Damaged distal end cap

When checking flexible endoscopes for damage, each instrument's accessories should not be overlooked. Some accessories may be disposable and discarded after each procedure. Other accessories, however, are commonly reused. One such accessory that requires careful inspection is the soaking cap. The purpose of the soaking cap is to protect the endoscope's electronic components, and it features a seal around it that is subject to wear and tear over time. If the seal becomes compromised, it is possible to have fluid invasion during the cleaning process. Consistent, diligent inspection of the soaking cap and other accessory

components is critical to the safe function of the endoscope.

Objective 2: Learn the importance of designing a space to comply with and execute visual inspection

It is common for flexible endoscope processing departments to lack designated inspection areas. Often endoscope inspection areas are retrofitted for the task, meaning that an area was not originally designed for this process. Furthermore, as standards and guidelines are updated, requirements change; therefore, the need to revise the physical inspection space may be a serious concern.

Whether facilities are planning for a renovation of the current endoscope reprocessing area or seeking a more simplified reorganization of the space, it is essential that the space feature a designated location for visual inspection. Enough space should be allocated to rest an entire endoscope on a table without over coiling it and causing damage. It can be helpful for processing professionals to use their largest endoscope to help ensure the table is adequately sized. Also, the inspection space should be adjacent to the areas where previous steps in the processing cycle are performed to keep the process flow unidirectional. *Note: It is important to maintain proper distance or barriers to prevent cross-contamination of cleaned endoscopes.*

Consider designating and labeling the area specifically for visual inspection. Other enhanced methods of inspection may occur there as well. While this lesson specifically addresses unaided visual inspection, enhanced inspection with lighted magnification or borescopes can also occur in this designated space.

Lighting is another key factor to consider when designing the inspection area. Adequate lighting aides proper visual inspection; therefore, reprocessing professionals should consult with SP leaders and Facilities Management staff if lighting-related concerns are present in the inspection area and other spaces throughout the Sterile Processing department (SPD). ST91:2021 includes guidance regarding how much light should be provided in this space (i.e., between 500 and 1,000 lux for general inspection, and between 1,000 and 2,000 lux for detailed inspection). Every person's vision differs (sometimes considerably), so proper lighting in all processing areas is an essential visual inspection aide.

Objective 3: Identify ways to implement more effective visual inspection within the flexible endoscope reprocessing workflow

To further assist in the development of an effective visual inspection process, it is crucial to assess training for all individuals who reprocess flexible endoscopes. Providing technicians with real-life examples of what they should be looking for during inspection can be highly beneficial. Annex E of ST91:2021 contains useful reference photographs that could effectively be incorporated into departmental training.

Documenting one's findings can help reinforce the visual inspection step and the importance of the inspection process. Documentation can be done in a simple logbook or a computer-based document and may include a checklist for the type of damage found (i.e., internal or external damage and the location of the damage on the endoscope). Because flexible endoscope damage can vary significantly in real-world situations, it is also beneficial to take photographs of damaged endoscopes. These images may be captured in the SPD at the time the damage is detected during inspection, or photographs may be requested and obtained from the endoscope repair company. Bear in mind, however, that unless proper documentation is recorded during inspection within the SPD, it may be difficult to identify defects that will lead the device to be sent for repair. Also, repair vendors may not photographically capture all damage present on endoscopes, so diligent documentation within the endoscope inspection area is beneficial.

Conclusion

Flexible endoscopes have historically been considered safe and effective diagnostic tools, but technicians must be aware of potential damage that can occur with these complex devices. Visual inspection is a critical step for proactively identifying damage, defects and potential processing problems that can jeopardize patient safety.

Technicians should be provided with foundational visual inspection training to build their competence and confidence and allow for more methodical and effective implementation of current industry standards for flexible endoscope processing. The SP team should be aware of the updates in ST91:2021 to further ensure quality practices that will help promote safety and positive patient outcomes. Incorporating additional inspection processes and tools, such as lighted magnifiers and borescopes, and ensuring that adequate space and lighting are provided to assist with inspection are also important to help technicians identify damage, defects and bioburden within a flexible endoscope.

RESOURCE

ANSI/AAMI ST91:2021 *Flexible and semi-rigid endoscope processing health care facilities.* Available for purchase at https://www.aami.org.