Leak Testing: An Essential Step in Flexible Endoscope Reprocessing and IFU Adherence

LEARNING OBJECTIVES
1. Understand the significance and purpose of leak testing flexible endoscopes
2. Discuss different types of leak tests and the time required to conduct them properly
3. Outline potential human factors and mechanical issues that may influence proper leak testing

Flexible endoscopes present one of the most difficult reprocessing challenges faced by Sterile Processing (SP) professionals today. With intricate designs and delicate components, these instruments are difficult to keep in optimal working order. While there are many variations of endoscopes, depending on their intended use, they all have one key commonality: sealed sections that should never be exposed to fluids. It is essential that an endoscope remain sealed and that it can be pressurized before each reprocessing; otherwise, it might never be known whether fluid invasion occurred—a situation that can place patient safety at risk.

Endoscope manufacturers’ instructions for use (IFU) are one of the best sources of information that note the dangers of fluid invasion. This lesson references many warnings and cautionary statements from major flexible endoscope manufacturers that demonstrate the importance of leak testing. One such example is, “Caution: Before proceeding to manual cleaning, always perform a leak test on the flexible endoscope. Leaking flexible endoscopes must not be used in medical procedures as they pose a patient safety risk.”

Objective 1: Understand the significance and purpose of leak testing flexible endoscopes
Every step of endoscope reprocessing is critical to ensure the device is safe for the next patient. It is essential that leak testing be viewed as the vital step it is and that the process is never skipped or rushed to save time. Note: With unrealistic turnover times in many facilities, some might assume or hope that flexible endoscopes are more durable than they are. Unfortunately, they can become easily damaged, which makes proper leak testing crucial. It has been said that, “It’s not what a test tells you when it passes, but what it tells you when it fails.” A failed leak test tells us the endoscope needs to be repaired and must be handled and cleaned carefully to avoid further damage. It also tells...
us the endoscope poses a risk to the patient until it is repaired.

An endoscope can fail a leak test for numerous reasons, such as a tear in the external sheathing, a hole in an internal channel, or sealant that is no longer fully intact and can no longer keep components joined together. Regardless of the cause, once any integrity damage occurs, the endoscope becomes susceptible to fluid invasion.

Leak testing is the first step listed under the reprocessing section in every flexible endoscope IFU. This demonstrates that the step is essential. Certain areas of flexible endoscopes should never be exposed to fluid of any kind, not the least of which includes blood and detergents. These delicate, sometimes metal, components are important to the endoscope’s function and should be sealed off from anything that can corrode and destroy them. Additionally, these areas are difficult, if not impossible, to reach, so once soiled, contamination and patient safety risks increase.

Objective 2: Discuss different types of leak tests and the time required to conduct them properly

Leak tests are performed either “wet,” with the endoscope fully submerged in water, “dry” with the endoscope out of the water, or in some cases, a combination of both (with a dry test performed, followed by a wet test). This begs the question: which is the best method? The answer lies within the IFU. Like all other steps in the process, the endoscopes manufacturer has validated a leak testing procedure. The steps and equipment needed to perform the test are written clearly in every IFU. The IFU may prescribe one type of testing, give an option to choose between them, or even require both. One example is, “Pump up the leakage tester until a pressure of 200 mmHg is reached. Fully articulate the distal tip 5 times in each direction using the control lever, then reduce the pressure by pressing the pressure release button until the pressure reaches 160 mmHg. While pressurized, submerge the entire flexible endoscope into a basin or sink containing a minimum of 10 L (2.6 gallons) of room temperature water (no detergent).”

Generally, dry leak tests consist of pressurizing an endoscope to a range and observing for a drop in the pressure on a gauge. This can be seen in the following instruction: “Press the hand pump until a pressure between 19 and 27 kPa is indicated on the pressure display. The pointer must be within the ‘green area’ on the pressure display.”

Wet leak tests typically consist of pressurizing the endoscope but then submerging it to observe for bubbles exiting the endoscope. One instruction reads, “During leakage testing, a continuous series of bubbles emerging from a location on the endoscope indicates a leak at that location. This means that water will be able to penetrate the inside of the endoscope.” During both types of testing, time to make observations must be provided. For both types, the minimum observation time is often at least 30 seconds, as the following manufacturer instruction reads: “While immersing the endoscope completely in the water and deflecting the bending section of the endoscope by turning the endoscope’s UP/DOWN and RIGHT/LEFT angulation control knobs, observe the endoscope for approximately 30 seconds to confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.”

As can be seen from this instruction, a leak test is more than just observation, however.

Both the dry and wet leak test call for manipulation of the distal tip of the endoscope. The materials/composition of flexible endoscope sheaths and control buttons have the potential to mask small leaks if they are not put through their full range of motion. The importance of these steps is reinforced in ANSI/AAMI ST91, Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities: “Massage video or remote switches in a circular manner to more readily detect holes in these components. Massage video or remote switches in a circular manner to challenge the integrity of these components while looking for bubbles.”

Also, it is important to ensure there are no additional steps required for the specific model of endoscope being tested, such as is outlined in the following instruction: “…moving the elevator control lever, observe the distal end of the endoscope for additional 30 seconds to confirm that air bubbles do not emerge continuously or intermittently from any location around the forceps elevator.” In this example, an additional 30 seconds is needed for this particular model of endoscope. Note: Often, leak testing procedures can involve 10 or more steps; however, it is important to remember that taking the time to perform all actions correctly will help ensure the endoscope has not become a risk to the next patient.

Objective 3: Outline potential human factors and mechanical issues that may influence proper leak testing

Regardless of the type of test, an IFU will stipulate that the focus of leak testing is to ensure fluids are unable to enter the sealed portions of the endoscope. An unfortunate reality, however, is that if processing professionals are not careful, the actual leak testing process can cause fluid invasion. Failure to inspect both the leak tester and the endoscope’s connection ports for fluid – and/or attaching or detaching the endoscope under the surface of the water – can allow fluid to enter the endoscope, as this instruction notes: “Do not attach/detach the leakage tester while immersing...”
the endoscope in the water. Attaching/detaching underwater could allow the water to enter the endoscope, resulting in endoscope damage.”

Other common errors that can lead to a poor leak test can include: not submerging the entire endoscope; not examining the entire length, including the control body and connection sections; improperly disconnecting the endoscope from the tester; over pressurizing the endoscope; adding detergent to the water before the test; not removing excess bubbles from the exterior of the endoscope; and not flushing out air that may have been trapped inside the endoscope’s channels. Because locating bubbles that are escaping the endoscope is the primary indicator of a leak in a wet test, these last three aforementioned errors will cause confusion in deciding whether or not the endoscope has an actual leak – a misinterpretation that can lead to a damaged endoscope remaining in service.

If a leak is detected, the endoscope should not be exposed to any fluids unless outward pressure is being maintained. This can be achieved by simply leaving the leak tester attached to continually push air through the endoscope. If the leak is more significant, some manufacturers recommend applying tape to the sheath to close the damage as much as possible, as is noted in the following instruction: “If the leak is detected and found on the exterior of the flexible endoscope and can be sealed with waterproof tape, do so and submit the flexible endoscope to a full manual cleaning then high-level disinfection or sterilization.” If, however, the leak is severe and there is no chance of maintaining pressure, the manufacturer should be contacted for directions on the next steps.

It is important to note that one manufacturer’s IFU states that reducing the amount of debris present on and in the endoscope should be performed by wiping with detergent solution, but not submerging the endoscope. This process cannot be considered a truly effective cleaning process, and the leaking endoscope should still be regarded as contaminated and handled as such. A typical statement is, “Warning: Since leaking flexible endoscopes cannot be effectively cleaned, high-level disinfected or sterilized, they must be handled and shipped as a contaminated device following your institution’s policies.” Each facility should have a defined policy to address how leaking endoscopes should be treated, and all staff should understand and follow that policy. This policy should address not only how the endoscope should be handled in the department but how it should be packaged when it leaves the facility. It must also address compliance with all state and federal regulations that apply to transporting biohazardous items.

Like all equipment, leak testers come with instructions for cleaning and verifying that they are still working properly. Preventive maintenance and calibration schedules must be followed; however, it is essential to follow the manufacturer’s IFU to determine whether the leak testers need to be tested before each use (many manufacturers do require it). Some verification procedures state to depress the pin on the tester and listen for air to be released from the unit; however, this is a subjective test. Many IFU state to “Depress the pin located inside the connector cap of the leakage tester and confirm that air is emitted from the connector cap with a whoosh sound.” While this does demonstrate that air is being released, it cannot tell if it is at the correct pressure. There are pressure ranges for effective leak testing and if the pressure from the tester drops or falls out of range, small leaks are not able to be detected (“Insufficient pressures may reduce the likelihood for accurate leak detection…”). A question to ask when considering this might be, “Is this the only way of verifying the tester is working and can I tell if the sound being heard is as loud as it was yesterday?” Another question might be, “How can a comparison be made from day to day if different staff members perform the test each day?” These types of questions are why objective alternatives should be sought to ensure the leak tester is functioning properly. Currently, there are commercially available products that allow staff to run the tester and view the pressure directly to determine the correct amount is being delivered. Use of these products should be considered as part of a facility’s quality management system.

**Conclusion**

With so much emphasis being placed on correct endoscope reprocessing in standards, guidelines and manufacturers’ IFU, it is essential to ensure that proper leak testing is being performed and that the practice is deemed a critical part of a facility’s infection prevention and quality control program.

**REFERENCES**

1. Karl Storz instruction manual; Flexible rhinolaryngo fiberscope models 11003 BC1, 11101 RP2, 11101 SK2 Z18438US-BD-08/2018
2. Olympus reprocessing manual CYF VHA GE9142 11
3. Olympus reprocessing manual; TJF Q190 RC4995 01
4. Olympus reprocessing manual BF type 160 series GE1034 22
6. ANSI AMMI ST91: Flexible and semi-rigid endoscope processing in healthcare facilities 2015