Dear Champion,

The purpose of this letter is to provide guidance on requirements related to the reprocessing of flexible endoscopes prior to shipment to service centers for repair of failed leak test.

Identifying the Leak

1. A leak in the endoscope will be indicated by a continuous series of air bubbles emerging from a location on the endoscope when performing the leak test.
2. Before removing the endoscope from the water, identify and make note of the location of the leak.
3. Remove the endoscope from the water while the endoscope is still pressurized. If the leak test is discontinued while the endoscope is still immersed, water may invade the internal space and further damage the endoscope.
4. Completely decompress the scope and blow out all channels with air.

Mandatory Manual Cleaning

1. The endoscope must be manually precleaned and high-level disinfected according to the manufacturer’s guidelines prior to shipping.
2. For a leak detected in the covering of the insertion tube, bending section, or universal cord, dry the leaking area thoroughly and wipe with alcohol. Carefully tape over the location of the leak with a piece of electrical tape prior to immersing the endoscope in detergent solution. Be careful not to tape too tightly as additional damage may result.
3. Re-pressurize the internal channels of the endoscope maintaining positive pressure. Maintaining this positive pressure will prevent fluid from entering the endoscope.
4. Fill a basin with an enzymatic solution at the temperature and concentration recommended by the enzymatic manufacturer. Use a basin large enough to allow the endoscope to be completely immersed.
5. Immerse in the enzymatic solution
6. Perform manual cleaning according to the scope manufacturer’s instructions provided in the Medical Instructions/Reprocessing Manual.
7. Rinse according to the manufacturer’s guidelines.
8. Minimize unnecessary flexing of the insertion tube and light guide cable during manual cleaning to prevent further damage.

Following manual cleaning, the manufacturer's guidelines state that the preferred method of rendering a leak positive endoscope safe to handle is ethylene oxide (EtO) sterilization. Ethylene oxide sterilization should be performed according to the instructions provided in the endoscope's reprocessing manual. If electrical tape was applied to a leak detected in the endoscope's external surface, remove the tape and wipe with 70% ethyl or isopropyl alcohol prior to ethylene oxide sterilization. If ethylene oxide sterilization is not possible, perform high-level disinfection or STERRAD sterilization according to the endoscope manufacturer's instructions. If EtO sterilization and/or STERRAD sterilization is not an option, scope manufacturer's recommend high-level disinfection.

High-Level Disinfection
Repeat steps 3-9 under Mandatory Manual Cleaning utilizing a high-level disinfectant approved to be safe and effective by the endoscope manufacturer.

Most scope manufacturer's recommend performing a manual high-level disinfection procedure on leaking endoscopes vs use of an Automated High-Level Disinfection.

Automated High-Level Disinfection
Automated Endoscope Reprocessors (AERs) circulate high-pressure fluid through the internal channels of the endoscope, which may result in fluid invasion and further damage to a leaking endoscope. Some AERs are designed to maintain positive pressure within the internal cavities of the endoscope in order to prevent fluid invasion during the reprocessing cycle. If using an AER, please check with the AER manufacturer to determine whether the AER:

1. Will develop fluid pressures within the endoscope that might cause additional damage
2. Can maintain sufficient positive internal air pressure within the leaking endoscope in question to permit a complete disinfection cycle to be performed
3. Check with your AER manufacturer to determine whether your AER is intended to reprocess leaking endoscopes, and whether positive pressure can be maintained during the disinfection cycle without aborting the cycle.

Now that the endoscope has been properly cleaned and high-level disinfected/sterilized, it is imperative to follow the repair companies shipping guidelines to expedite the repair. Contact the service center of the repair company of your choice to obtain an equipment/endoscope service request form. Most repair companies provide a loaner upon request while others provide a fast turnaround time that would negate the need for a loaner.

Alternative
In the event that sterilization or high-level disinfection is not an option, the endoscope should be considered contaminated. The endoscope should then be identified and shipped as a biohazard.

Containment of a flexible endoscope for biohazard shipment should be in a single use padded carton provided by the scope repair company. Enclose the contaminated endoscope in a 3ml red bag. Place all papers associated with the endoscope outside the red bag. It is recommended placing the box in a shipping carton as a third layer of protection. It is common for an additional cleaning fee to be added as a component of the repair fee.

When the endoscope is returned following the completed repair it must be reprocessed according to your protocol prior to patient utilization.

Requirements should either be emailed to Champions@sgna.org or faxed to 312-673-6694 as due. The following are the assignments for the next two weeks:

1. Complete the Education documentation grid for one activity
2. Review the SGNA Resources for Quality and Safety website.
3. Continue to develop and implement infection prevention education for your peers (total of 120 minutes)
4. Seek Opportunities to educate yourself on infection prevention topics (total of 180 minutes).

These bi-monthly emails will be archived for you to access as needed.

As always, SGNA is available for any questions or difficulties you may have.

Sincerely,
The SGNA Infection Prevention Work Group

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