November 6, 2012

RE: Guidelines for Returning Olympus Flexible Endoscopes for Repair

Dear Healthcare Practitioner:

The purpose of this letter is to provide guidance to customers on our requirements when returning Olympus flexible endoscopes to service centers for repair.

All flexible endoscopes must be rendered safe to handle prior to being returned to Olympus for repair. To accomplish this, **all flexible endoscopes must be cleaned AND high-level disinfected or sterilized prior to shipment to a service center for repair.** In addition, Olympus requires that the cleaning AND high-level disinfection or sterilization process be verified prior to initiation of repair. To expedite repair of your flexible endoscope, please complete the Equipment Service Request Form (available at *www.olympusamerica.com* in the repair service section) and include it with your flexible endoscope. If a flexible endoscope is received without a completed Equipment Service Request Form, Olympus will contact the customer to verify proper reprocessing prior to initiating repair. Flexible endoscopes that have not been cleaned AND high-level disinfected or sterilized will be returned to the customer without being repaired.

The following information provides guidance on how to reprocess damaged flexible endoscopes to render them safe to handle. Damaged endoscopes that are still watertight should be reprocessed according to instructions provided in the Olympus reprocessing manual. However, if the endoscope has developed a leak, routine reprocessing may lead to further damage. Therefore, Olympus has developed special guidelines for flexible endoscopes that have failed leakage testing.

The key to preventing further damage to a leaking endoscope is to provide positive pressure to the endoscope during all phases of the reprocessing cycle by connecting the endoscope to the maintenance unit (Olympus model MU-1) or light source. This will ensure that the endoscope is pressurized throughout the entire reprocessing cycle and will help to prevent fluid from entering the endoscope.

A leak in the endoscope will be indicated by a continuous series of bubbles emerging from a location on the endoscope. Before removing the endoscope from the water, identify and make note of the location of the leak. With the maintenance unit or light source still turned on and the leakage tester still connected, remove the endoscope from the water. If the maintenance unit or light source is turned off while the endoscope is immersed, water may invade the internal spaces and further damage the endoscope.

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Mandatory Manual Cleaning

1. 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. Wrapping the tape too tightly may result in damage to the endoscope. For leaks detected in other locations (e.g., internal channel), proceed with the instructions provided below.

2. Fill a basin with detergent solution at the temperature and concentration recommended by the detergent manufacturer. Use a basin that is at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.

3. Insert the leakage tester connector into the output socket of the maintenance unit or the light source and turn the maintenance unit or the light source ON. Set the light source's airflow regulator switch to "HIGH" or "3".

4. Connect the leakage tester's connector cap to the venting connector of the water-resistant cap. For 190-series endoscopes, the leakage test connects directly to the lightguide connector.

5. Immerse the endoscope in the detergent solution.

6. Perform manual cleaning according to the instructions provided in the reprocessing manual. Minimize unnecessary flexion of the insertion tube and universal cord during cleaning.

Mandatory High-Level Disinfection or Sterilization

1. Sterilization:

Following manual cleaning, the preferred method of rendering a leaking endoscope safe to handle is ethylene oxide 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 instructions provided below.

Sterilization in a STERRAD sterilization system is also an acceptable alternative practice provided the endoscope is listed as materially compatible with the STERRAD sterilization system. Those endoscope models which are compatible with STERRAD sterilization may be sterilized using the normally recommended STERRAD model, cycle and conditions (e.g., check booster requirements) as long as the following requirements are met: 1) The endoscope has been properly cleaned and dried, and 2) Fluid has not invaded the endoscope. Retained fluid will cause the STERRAD cycle to abort and may contribute to additional repairs.

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2. Manual High-Level Disinfection:

   a. Fill a basin with disinfectant solution at the temperature and concentration recommended by the disinfectant manufacturer. Use a basin that is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to allow the endoscope to be completely immersed.
   b. Insert the leakage tester connector into the output socket of the maintenance unit or the light source and turn the maintenance unit or the light source ON. Set the light source’s airflow regulator switch to “HIGH” or “3”.
   c. Connect the leakage tester’s connector cap to the venting connector of the water-resistant cap (140/160/180-series) or endoscope directly (190-series).
   d. Immerse the endoscope in the disinfectant solution.
   e. Perform the high-level disinfection procedure described in the endoscope’s reprocessing manual. Minimize unnecessary flexion of the insertion tube and universal cord during reprocessing.

3. 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. As a result, Olympus recommends performing the manual high-level disinfection procedure on leaking endoscopes.

   However, some AERs are designed to maintain positive pressure to the internal cavities of the endoscope in order to prevent fluid invasion during the reprocessing cycle. 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.

If you have any additional questions, please contact your local Olympus sales representative or the Olympus Technical Assistance Center at 1-800-848-9024 (United States). Thank you.

Sincerely,

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