



December 2, 2014

RE: Information Regarding the Procedure for Performing a Presoak in Detergent Solution for Cases of Delayed Reprocessing and Excessive Bleeding for use with Olympus Flexible Endoscopes

Dear Health Care Practitioner:

This letter is in response to your recent inquiry regarding delayed reprocessing of Olympus flexible endoscopes.

The standard Olympus procedure for reprocessing flexible endoscopes is labeled for and intended to be performed without time delays. Continuous reprocessing through the steps indicated in the Olympus endoscope manual ensures that patient fluids and debris do not begin to dry and harden on the endoscope external surfaces and within the endoscope channels.

If reprocessing has been delayed after endoscope precleaning, resulting in patient fluid or debris drying onto the surface of the endoscope, the standard reprocessing procedure may not be effective. In this case, the endoscope should be reprocessed according to the instructions provided in the endoscope manual for “Presoak for Excessive Bleeding and/or Delayed Reprocessing”. This procedure has been included in most flexible endoscope manuals and should be performed as an additional reprocessing step after precleaning and leakage testing, but prior to Manual Cleaning.

Standard Reprocessing Procedure

1. Precleaning
2. Leakage Testing
3. Manual Cleaning
4. Disinfection or Sterilization
 - a. Manual Disinfection
 - b. Automated Disinfection
 - c. Sterilization

Delayed Reprocessing Procedure

1. Precleaning
2. Leakage Testing
3. **Presoak for Delayed Reprocessing**
4. Manual Cleaning
5. Disinfection or Sterilization
 - a. Manual Disinfection
 - b. Automated Disinfection
 - c. Sterilization

Olympus has performed cleaning validation studies that included a one-hour delay between precleaning and manual cleaning, and between manual cleaning and high-level disinfection or OER-Pro reprocessing. Precleaning should always be performed at bedside immediately after the patient procedure according to the instructions provided in the endoscope manual.

Following precleaning, the endoscope should be transported to the decontamination area to undergo leakage testing, manual cleaning, and terminal high-level disinfection or sterilization. In the event that there is more than a one-hour delay between precleaning and manual cleaning, or manual cleaning and OER-Pro reprocessing or high-level disinfection, the endoscope should be reprocessed according to the instructions in the revised endoscope reprocessing manual for



GI-180 series endoscopes or the GI-series 190 endoscopes following the section for “Presoaking the Endoscope”.

In this revised manual it is stated to allow the endoscope to soak in the detergent solution until the debris is loosened. Do not immerse the endoscope in the detergent for more than 10 hours. In order to avoid unnecessary long-term submersions, Olympus recommends that the facility develop a process to track the time from the end of the patient procedure to initiation of the precleaning process and also from the completion of precleaning to initiation of manual cleaning in order to determine whether the extended soak procedure should be utilized.

Also, please note that when determining how long of an extended soak to perform for a flexible endoscope, if debris has loosened on the external surface of endoscope, then the conditions on the inside of the channels should be same as on the surface since the channels are manually filled with detergent solution. Therefore, if the debris on the external surface is confirmed to have been loosened by visual inspection, then the appropriate soak time has been achieved.

WARNING

The procedure described in “Presoak for Excessive Bleeding and/or Delayed Reprocessing” is not intended for routine reprocessing. Since the endoscope is soaked for an extended period of time during this procedure, it should be utilized only when necessary. Routine, prolonged soaking of flexible endoscopes may result in damage to the instrument.

If you have any additional questions, please contact your local Olympus sales representative, the Olympus Technical Assistance Center at 1-800-848-9024 (United States) or 1-800-387-0437 (Canada).

Thank you.

Sincerely,

A handwritten signature in black ink that reads "Mary Ann Drosnock". The signature is written in a cursive, flowing style.

Mary Ann Drosnock, MS, CIC, CFER, RM (NRCM)
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