



January 31, 2018

**RE: Information Regarding the Procedure for Performing a Presoak in Detergent Solution for Cases of Delayed Reprocessing and Excessive Bleeding**

Dear Health Care Professional,

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 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 appropriate Instructions for Use/Reprocessing Manual provided by Olympus.

The Olympus manuals state the maximum amount of time 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 the time indicated in the manual. 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.

See below for the maximum amount of time Olympus endoscopes can be left to soak in detergent solution during the Presoaking/Delayed Reprocessing procedure. This information can also be found in each endoscope's reprocessing manual.



The following endoscopes can be soaked for a maximum of 1 hour (per soak):

BF-1T180	BF-P180	CYF-5	ENF-L3
BF-1T60	BF-P190	CYF-5A	ENF-P2
BF-1TH190	BF-P60	CYF-5R	ENF-P3
BF-1TQ180	BF-Q180	CYF-V2	ENF-P4
BF-3C160	BF-Q180-AC	CYF-V2R	ENF-T3
BF-3C40	BF-Q190	CYF-VA2	ENF-XP
BF-40	BF-UC160F-OL8	CYF-VH	LF-2
BF-6C240	BF-UC180F	CYF-VHR	LF-DP
BF-H190	BF-XP160F	URF-V2	LF-GP
BF-MP160F	BF-XP190	URF-V2R	LF-P
BF-MP60	BF-XP60	URF-P5	LF-T
BF-N20	BF-XT160	HYF-V	LF-TP
BF-P160	BF-XT40	HYF-XP	

The following endoscopes can be soaked for a maximum of 10 hours (per soak):

CF-2T160I	GIF-1TH190	PCF-H180AI
CF-2T160L	GIF-1TQ160	PCF-H180AL
CF-H180AI	GIF-2T160	PCF-H190DL
CF-H180AL	GIF-2TH180	PCF-H190I
CF-H180DL	GIF-H180	PCF-H190L
CF-HQ190I	GIF-H180J	PCF-PH190I
CF-HQ190L	GIF-H190	PCF-PH190L
CF-Q160S	GIF-HQ190	PCF-Q180AI
CF-Q160ZI	GIF-N180	PCF-Q180AL
CF-Q160ZL	GIF-Q160Z	PCF-S
CF-Q180AI	GIF-Q180	PJF-160
CF-Q180AL	GIF-XP160	SIF-100
GF-UC140P-AL5	GIF-XP180N	SIF-Q140
GF-UCT140-AL5	GIF-XP190N	SIF-Q180
GF-UCT180	GIF-XQ40	TGF-UC180J
GF-UE160-AL5	GIF-XTQ160	TJF-Q180V
GF-UM160	JF-140F	PEF-V
		SIF-100



The following endoscopes can be soaked for a maximum of 2 hours (per soak):

ENF-VT2

The following endoscopes should be soaked “until debris is loosened” (per soak):

URF-P6

URF-P6R

**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).

Sincerely,

Olympus