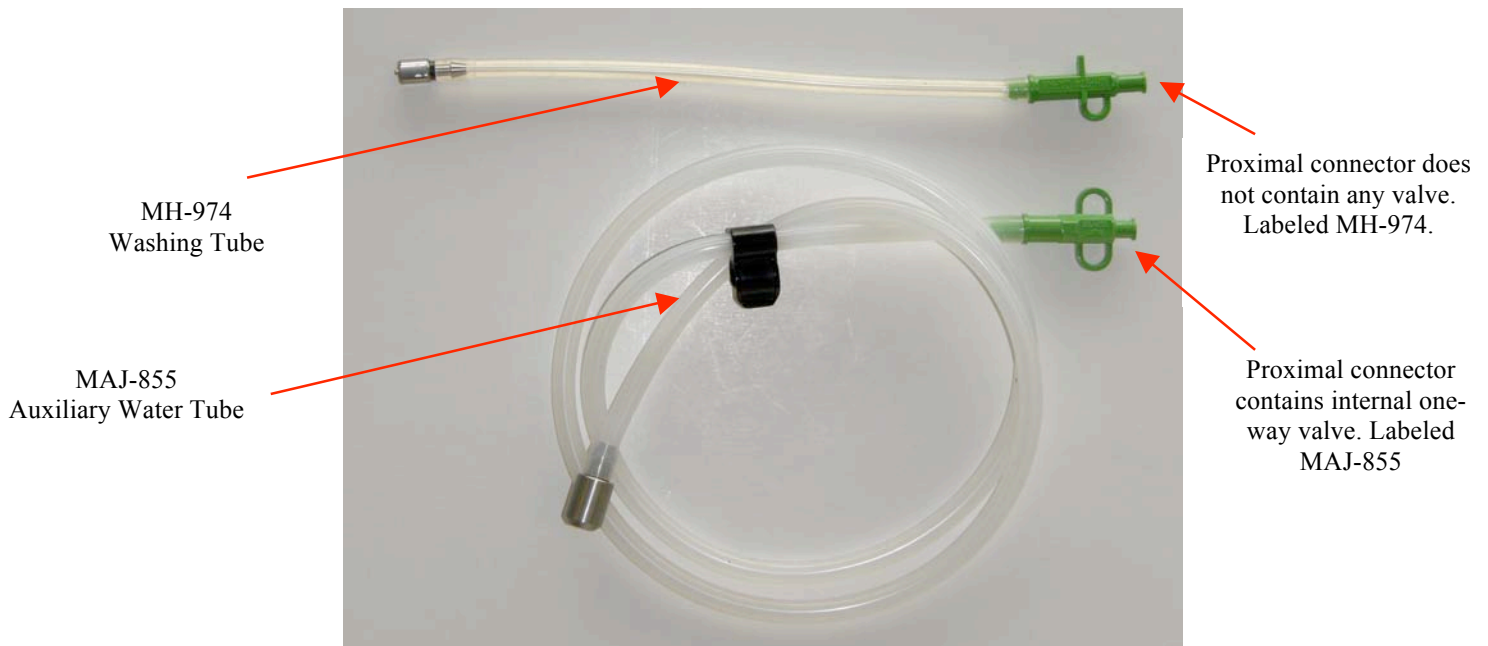


--- Important Safety Notice ---

January 26, 2009

On December 22, 2008 the Department of Veterans Affairs National Center for Patient Safety issued a Patient Safety Alert entitled “Improper set-up and reprocessing of flexible endoscope tubing and accessories”. (This document can be accessed at <http://www.patientsafety.gov/alerts.html>.) This alert was issued in response to an event involving Olympus endoscopy equipment in use at a Department of Veterans Affairs Hospital. From the onset of this report, Olympus America Inc. has worked closely with the Department of Veterans Affairs National Center for Patient Safety to review the events leading up to the publication of this alert.

Olympus would like to remind our customers of the proper use of the OLYMPUS accessory parts mentioned in this alert. These devices are pictured below.



As evidenced in the photograph, the tubes are quite different in appearance. The MH-974 is approximately 10 inches in length whereas the MAJ-855 is approximately 4 feet in length.

Function

- The MH-974 Washing Tube is designed for EVIS160/140 endoscopes that have an elevator wire channel and for EVIS 140/240 endoscopes that have an auxiliary water channel. The MH-974 is used in the reprocessing room to flush reprocessing fluids through the elevator wire channel and auxiliary water channel during endoscope reprocessing. The MH-974 is also used to flush sterile water through the auxiliary water channel during patient exams in the endoscopy room. The water must be injected manually via a syringe.
- The MAJ-855 Auxiliary Water Tube is used during patient exams to flush sterile water through the auxiliary water channel to wash the endoscopic field of view. The water may be injected manually via a syringe or a flushing pump. The MAJ-855 also is used to flush

reprocessing fluids through the auxiliary water channel during endoscope reprocessing. The one-way valve in the proximal connector of the MAJ-855 prevents backflow of fluids from the auxiliary water channel of endoscope into the flushing pump tubing. The above one-way valve also prevents water from flowing out of the proximal connector of the MAJ-855 when disconnecting the syringe or the flushing pump tubing from the MAJ-855.

Reprocessing

- The MAJ-855 Auxiliary Water Tube and MH-974 Washing Tube must be reprocessed prior to first use and following each use during a patient exam.
- **The MAJ-855 Auxiliary Water Tube and MH-974 Washing Tube must be reprocessed after every patient exam, regardless of whether or not auxiliary water flushing was performed during the patient exam.**
- The MAJ-855 Auxiliary Water Tube is often used with the OLYMPUS OFP Flushing Pump. The OFP irrigation tube, filter and fluid container of the OFP must be sterilized prior to the first patient use. The OFP tubing and filter can be used in multiple patient exams throughout one day without the need for re-sterilization between patient exams but must be discarded at the end of the day.

Only accessories specified by Olympus can be used with Olympus endoscopes.

Do not modify any accessory or use with an unspecified model of endoscope, or for an unspecified use.

Table 1. MAJ-855 and MH-974 specifications

Tube	Application	Intended use	Reprocessing frequency for MAJ-855/MH-974
MAJ-855 Auxiliary Water Tube	EVIS180/160 endoscopes with an auxiliary water channel	Auxiliary water flushing using a syringe or flushing pump	After each patient exam
		Reprocessing the auxiliary water channel	
MH-974 Washing Tube	EVIS160/140 endoscopes with an elevator wire channel	Reprocessing the elevator wire channel	When reprocessing the endoscope
	EVIS140/240 endoscopes with an auxiliary water channel	Auxiliary water flushing using a syringe	After each patient exam
		Reprocessing the auxiliary water channel	

Olympus would like to remind our users that all OLYMPUS medical devices are accompanied by instructions for use which detail the device features, proper care and reprocessing. Olympus strongly encourages customers to read and fully familiarize themselves with the device's instructions prior to its use and to follow recognized industry practices.