



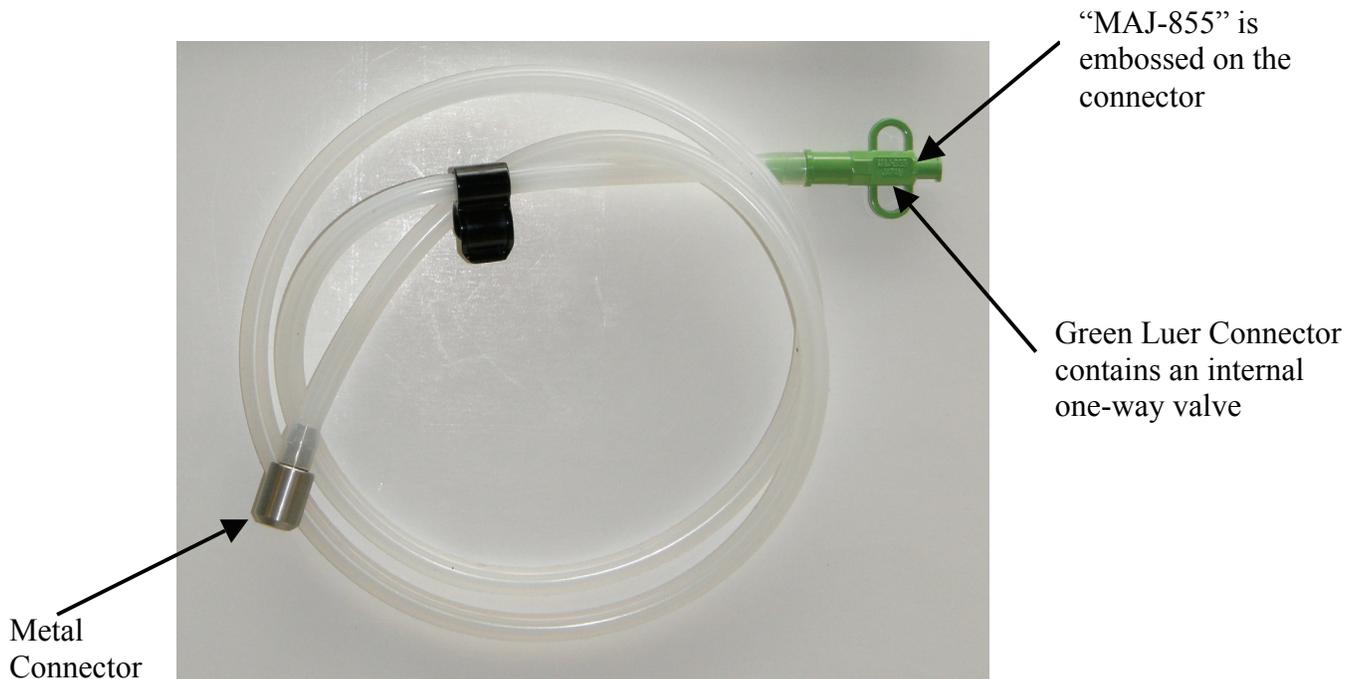
February 11, 2009

IMPORTANT SAFETY NOTICE

Dear Olympus HealthCare Practitioner:

It has come to our attention that some customers may be inadvertently neglecting to appropriately reprocess the MAJ-855 Auxiliary Water Tube. This notice is to remind you that the MAJ-855 Auxiliary Water Tube **must be reprocessed each time it is used in an endoscopy procedure, regardless of whether the auxiliary water feeding function was used during the procedure or not.** Olympus is not aware of any injuries that have occurred as a result of this reported breach in reprocessing.

The MAJ-855 Auxiliary Water Tube is pictured below and can be positively identified by the model name (“MAJ-855”) embossed on the green Luer connector. This connector contains a one-way valve that prevents fluid from flowing backward through the tube and prevents water from freely flowing out of the distal end (metal connector) of the tube when disconnecting a syringe or pump from the green Luer connector.



MAJ-855 Auxiliary Water Tube

OLYMPUS AMERICA INC.

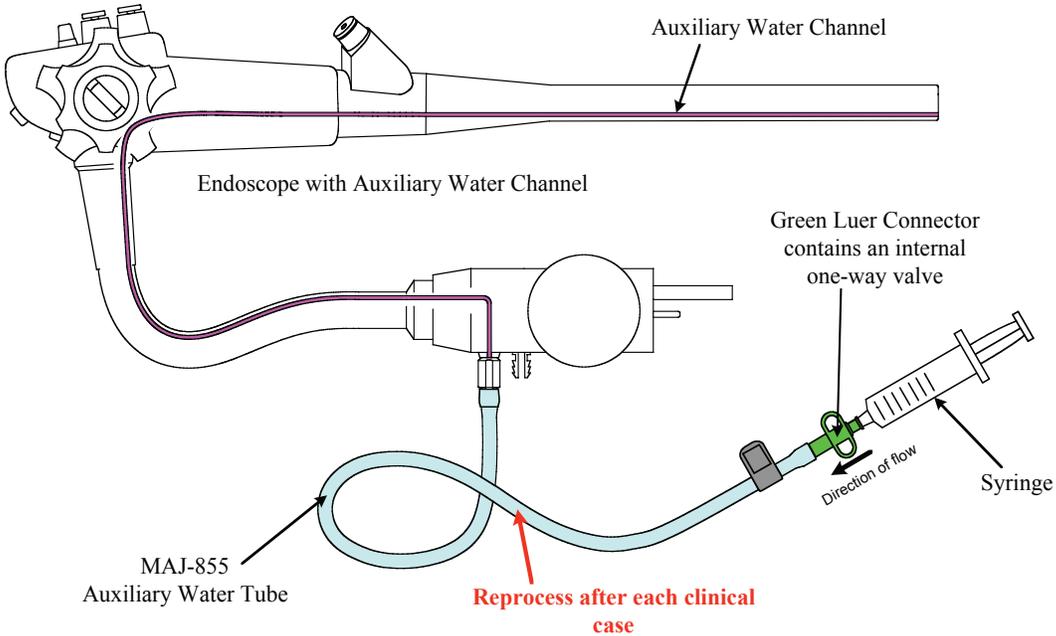
3500 CORPORATE PARKWAY, PO BOX 610, CENTER VALLEY, PA 18034-0610
TELEPHONE (484) 896-5000

The MAJ-855 Auxiliary Water Tube is an accessory provided as a standard set item with each new 160-series and 180-series OLYMPUS endoscope that has an Auxiliary Water Channel. An Auxiliary Water Channel is found on the following OLYMPUS 160/180-series endoscopes.

160 Series		180 Series	
CF-Q160L	CF-Q160I	CF-H180AI	CF-H180AL
CF-Q160S	CF-Q160AL	CF-Q180AI	CF-Q180AL
CF-Q160AI	GIF-2T160	PCF-H180AI	PCF-H180AL
GIF-XTQ160	GIF-1TQ160	PCF-Q180AI	PCF-Q180AL

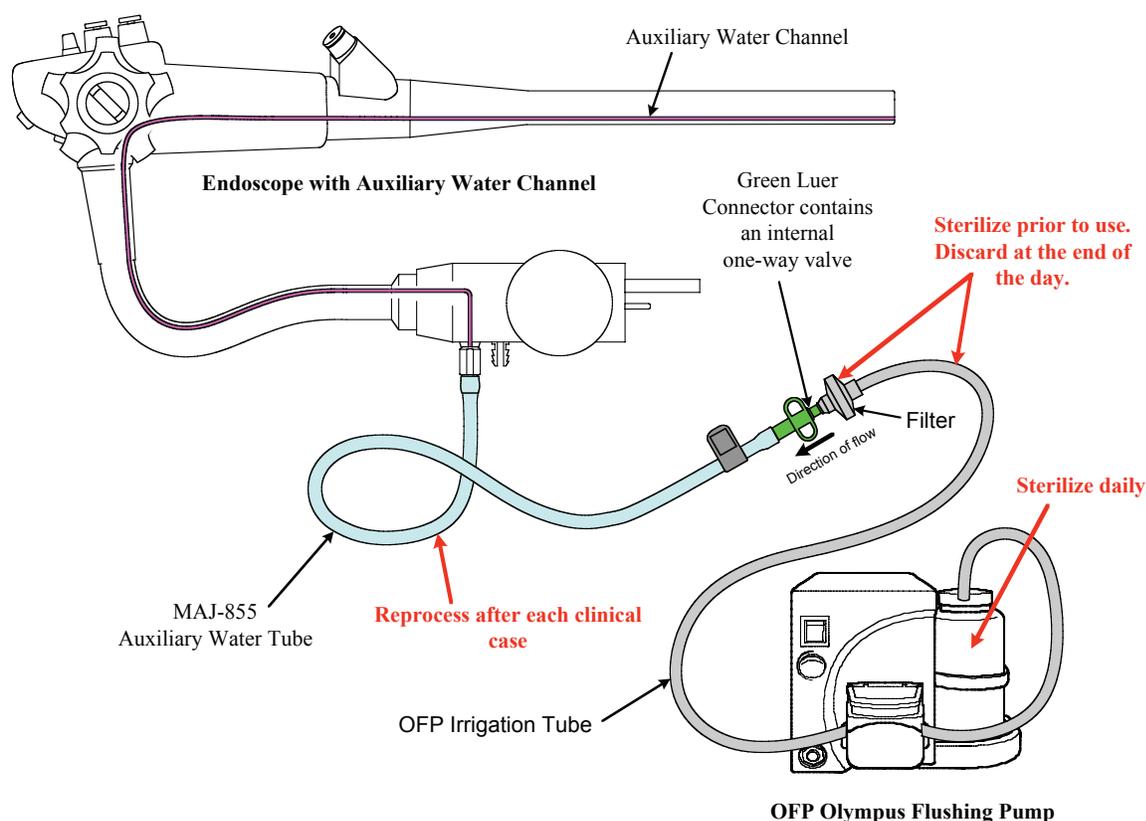
The MAJ-855 Auxiliary Water Tube is used during patient exams to flush sterile water through the auxiliary water channel to wash the endoscopic field of view. Sterile water for washing the mucosa can be provided either manually by use of a syringe or automatically via a flushing pump.

The following diagram illustrates the connections for manually flushing sterile water through the auxiliary water channel via a syringe. The water flush travels through the auxiliary water channel, a small dedicated tube within the endoscope, and then exits the distal tip of the instrument in a forceful stream.



Setup for Manually Feeding Water via Syringe

Alternatively, as shown in the following diagram, the MAJ-855 can be connected to the tubing of a flushing pump to automatically flush sterile water through the auxiliary channel of the endoscope for mucosal washing.



Setup for Automatically Feeding Water via OFP Pump

The MAJ-855 Auxiliary Water Tube must be reprocessed prior to first use and following each use (i.e., after each patient exam). Whenever an MAJ-855 Auxiliary Water Tube is connected to an endoscope for clinical use, it must be reprocessed before reuse on a subsequent patient, regardless of whether the auxiliary water feeding function was used during the procedure or not.

The one-way valve in the green Luer connector of the MAJ-855 is important for the safe and effective use of this accessory. The one-way valve prevents fluid from flowing backward through the tube and prevents water from freely flowing out of the distal end (metal connector) of the tube when disconnecting a syringe or pump from the green Luer connector. Do not modify this tube or change its connector(s). The connector is not intended to be removed for reprocessing.

In addition to its use during clinical procedures, the MAJ-855 is also used to reprocess 160-series and 180-series endoscopes that contain auxiliary water channels. When the MAJ-855 is used to manually reprocess an endoscope with an auxiliary water channel, the MAJ-855 will be reprocessed along with the endoscope itself.

However, if the endoscope is reprocessed in an automated endoscope reprocessor (AER), and the MAJ-855 is not used to connect the endoscope to the AER, the MAJ-855 must be reprocessed as a separate item.

The MAJ-855 is compatible with all high-level disinfectants that are compatible with Olympus endoscopes, as well as steam sterilization.

Note that if the Olympus OFP Flushing Pump is used, both the Filter and Irrigation Tube for the OFP must be sterilized prior to first use. They can then be used for multiple endoscopy procedures throughout one day without the need for re-sterilization between patient examinations. However, they must be discarded at the end of the day. The OFP Fluid Container must be sterilized daily.

ADDITIONAL INFORMATION

If you require additional information about the proper steps to reprocess Olympus endoscopes or accessories, please contact our Technical Assistance Center (TAC) at 1-800-848-9024, option 1. The Olympus TAC can assist in answering questions on reprocessing and obtaining additional copies of Reprocessing Manuals for Olympus endoscopic equipment.

Olympus offers an extensive curriculum of educational programs for endoscopy, with specific courses on endoscope reprocessing for both nurses and reprocessing specialists. Please visit our website at www.olympusuniversity.com or call the Olympus Registration help desk at 1-800-231-0016 to obtain more information.

Additionally, Olympus has a webpage dedicated to reprocessing information for Olympus endoscopy equipment. Please visit our website at www.olympusamerica.com/msg_section/cds/index.asp.

Sincerely,

Olympus America Inc.