

Patient Safety Alert

Veterans Health Administration Warning System Published by VA Central Office

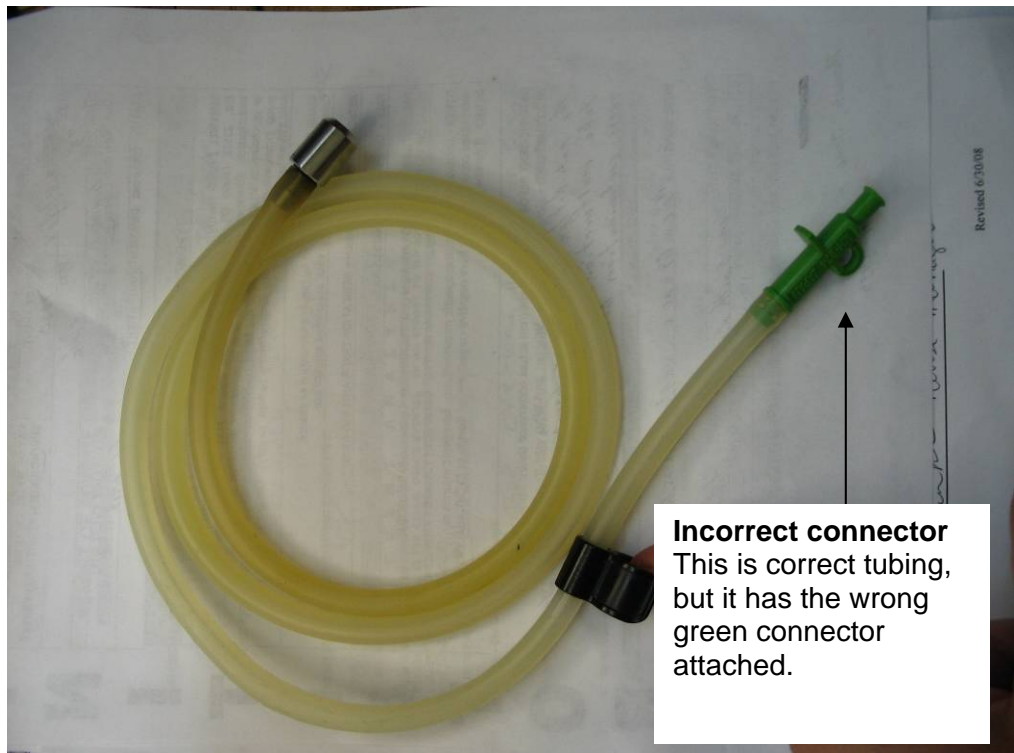
AL09-07

December 22, 2008

Item: Improper set-up and reprocessing of flexible endoscope tubing and accessories

Specific Incident: Correct tubing modified with an incorrect connector was used to attach an Olympus flexible endoscope to its irrigation source (Olympus Flushing Pump and accessories). This resulted in a backflow of body fluids into irrigation source tubing (where backflow should not occur) during an endoscopic procedure.

Specifically, during some endoscopic procedures, the facility used an Olympus Auxiliary Water Tube (MAJ-855) that was modified to have an Olympus Washing Tube (MH-974) connector attached instead of the connector intended to be used with the Olympus Auxiliary Water Tube (MAJ-855).



The Auxiliary Water Tube (MAJ-855) is required to connect the Auxiliary Water Port on the endoscope to the Olympus Flushing Pump (OFP) Filter (7501335), which is connected to the OFP Irrigation Tube (7501669). (See the photograph in Attachment 1, which depicts proper set-up of the equipment.) The MAJ-855's connector has a one-way valve and is a standard feature on the MAJ-855. The MAJ-855's one-way valve prevents backflow of body fluids from contaminating the

OFP Filter (7501335) and OFP Irrigation Tube (7501669). The Washing Tube's (MH-974) connector does not have a one-way valve.

While in the process of investigating the issue other problems were also discovered:

1. When the Olympus Auxiliary Water Tube (MAJ-855) with proper connector was used for clinical procedures, it was being reprocessed at the end of each day, instead of between each patient as required by the manufacturer's reprocessing instructions.
2. The OFP Irrigation Tube (7501669) and OFP Filter (7501355) were being reprocessed at the end of each day. The OFP Irrigation Tube (7501669) and OFP Filter (7501355), shown in the photograph in Attachment 2, are to be discarded at the end of each day per the manufacturer's instructions.

Improperly setting up (e.g., using incorrect connectors) and/or incorrectly reprocessing endoscopic tubing and accessories may place patients at risk from blood borne pathogens or other types of infections.

NOTE: While the Specific Incident and General Information sections of this Patient Safety Alert reference a specific manufacturer's endoscopic tubing and accessories, THIS PATIENT SAFETY ALERT APPLIES TO ALL FLEXIBLE ENDOSCOPIC TUBING AND ACCESSORIES, REGARDLESS OF MANUFACTURER OR MODEL.

General Information: Tubing design may have contributed to the reported event. Both of the tubings, while different in diameter and length, have green connectors. The green connector on the Washing Tube (MH-974) has one less wing than the green connector on the Auxiliary Water Tube (MAJ-855). See photographs of the tubings below, which show the connectors. NOTE: The manufacturer uses green connectors to indicate that the tubing is to be reprocessed, not discarded.



**Olympus
Washing
Tube
(MH-974)**

Its green
connector
has only 1
wing.



**Olympus
Auxiliary
Water Tube
(MAJ-855)**

Its green
connector with
one-way valve
has 2 wings.

Actions:

The Facility Director (or designee) will ensure that all of the following three actions are carried out by close of business January 7, 2009:

1. All personnel who perform procedures with flexible endoscopes and/or reprocess endoscopes and their tubing and accessories have read this Patient Safety Alert.

NOTE: Ensure you have identified all areas in your facility where reprocessing of flexible endoscopes occurs, which may include, but are not limited to the following: Ambulatory Surgery, Endoscopy, GI, GU, OR, Respiratory, SPD, Urology, and Clinics to include CBOCs.

2. For those facilities using the Olympus Flushing Pump and compatible endoscopes, ensure that:
 - a. the set-up shown in Attachment 1 is being consistently utilized. NOTE: In the photograph, the fluid flows from the Olympus Flushing Pump (located on the right) to the Olympus Endoscope (located on the left). Ensure that the OFP Irrigation Tube (7501669) is placed in the proper orientation through the OFP Cassette.
 - b. personnel who use and/or reprocess endoscopes and their tubing and accessories understand that:
 - i. they shouldn't modify, create, or enhance manufacturer tubings and accessories.
 - ii. the Olympus Auxiliary Water Tube (MAJ-855) is supplied non-sterile, and needs to be reprocessed before initial use and after each patient using steam sterilization (refer to the instruction manual for your particular endoscope).
 - iii. the OFP Filter (7501355) and OFP Irrigation Tube (7501669) are supplied non-sterile, must be sterilized prior to initial use, can be utilized all day, and must be

discarded at the end of each day, as per the manufacturer instructions.

- iv. the OFP Fluid Container (7501352) is supplied non-sterile, must be sterilized prior to initial use, can be utilized all day, and must be reprocessed using steam sterilization prior to next day's use (refer to the instructions for the Olympus Flushing Pump).

NOTE: If tubing and accessories from another manufacturer are used, they must be compatible with your particular Olympus products (flexible endoscope and flushing pump) and must be set-up and reprocessed or disposed of in accordance with the manufacturer's instructions. Note that the set-up and reprocessing instructions could differ from Olympus' set-up and reprocessing or disposal instructions.

3. Regardless of manufacturer or model of flexible endoscope,
 - a. confirm that you are using the proper tubing and accessories (in the correct sequence and orientation) when conducting clinical procedures with flexible endoscopes.
 - b. ensure that personnel who use and/or reprocess endoscopes and their tubing and accessories understand that they shouldn't modify, create, or enhance manufacturer tubing and accessories.
 - c. ensure that reprocessing personnel follow manufacturer's instructions for cleaning and reprocessing flexible endoscope's tubing and accessories. And, assure that any items that are single patient use are reprocessed (if reusable) or disposed of (if disposable) after each patient and that any items that are single day use are disposed of at the end of the day.
 - d. **if you identify any issues in terms of incorrect set-up during clinical procedures or failure to adequately clean or reprocess flexible endoscope tubing and accessories, report them in an Issue Brief through your Network Office to VA Central Office.**
 - e. ensure that locally-developed Standard Operating Procedures (SOPs) exist for reprocessing flexible endoscope tubing and accessories that are in accordance with the manufacturer's instructions, and provide access to the SOPs to all personnel who reprocess these flexible endoscope tubing and accessories. Document that personnel who reprocess flexible endoscope tubing and accessories have read the most current SOP(s) and have been evaluated for competency to reprocess flexible endoscope tubing and accessories.

Additional Information: If you don't have current instruction/use manuals for the Olympus Flushing Pump, the Olympus Auxiliary Water Tube (MAJ-855), and any other Olympus devices, contact Olympus to obtain a current version.

Guidance – regarding notification of any patients that may have been exposed to blood-borne pathogens as a result of possible improper equipment set-up or reprocessing – is not addressed in this Patient Safety Alert. Guidance will be offered in accordance with VHA Directive 2008-002, Disclosure of Adverse Events to Patients.

See also Patient Safety Alert AL08-13, regarding improper reprocessing of flexible endoscope biopsy valves:

<http://www.patientsafety.gov/alerts/FlexibleEndoscopeBiopsyValvesAL08-13.pdf>

Source: VA Medical Center

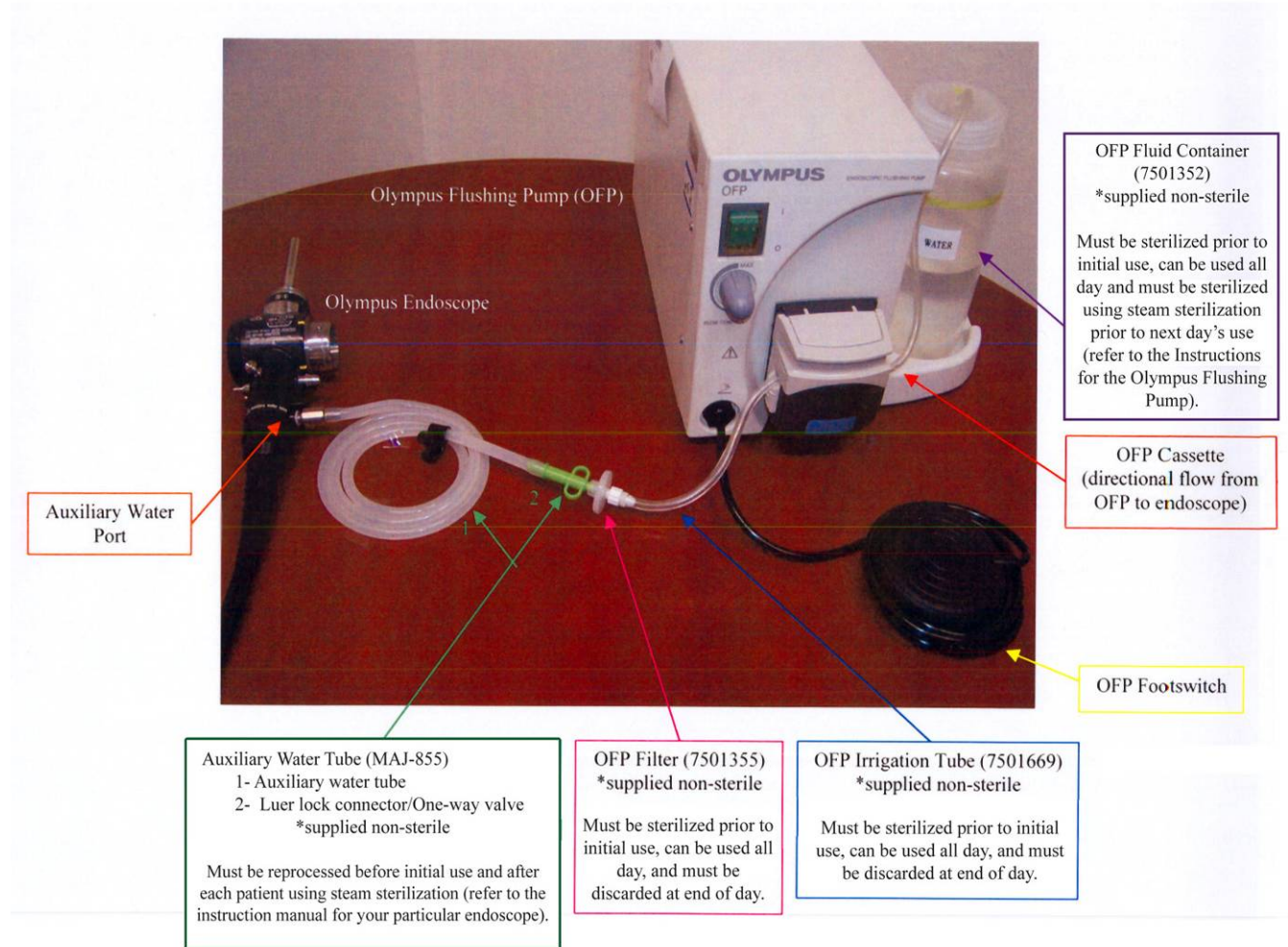
Attachments:

- 1) Photograph depicting correct set-up when using the Olympus Flushing Pump
- 2) Photograph showing the OFP Filter (7501355) and OFP Irrigation Tube (7501669)

Contacts: Olympus Regulatory Affairs, (800) 258-5187;
Dr. Gary Roselle, Director, National Infectious Diseases Program, (513) 475-6398;
Bob Osburn, Executive Manager for SPD, National Infectious Diseases Program, (202) 437-3958; or
Lori King, Biomedical Engineer, NCPS, (743) 930-5890.

ATTACHMENT 1

Photograph depicting the correct set-up using the Olympus Flushing Pump



ATTACHMENT 2

Photograph depicting the OFP Filter (7501355) and OFP Irrigation Tube (7501669)



OFP Filter
(7501355)

OFP Irrigation Tube (7501669)