Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL08-13 March 31, 2008

Item: Improper reprocessing of flexible endoscope biopsy valves

Specific Incident: A VA medical center noted that their semi-disposable (i.e., reusable to an extent; limited use) biopsy valves (Olympus part number MB-358) for their colonoscopes (Olympus Model CF-180AL) and esophago-gastro-duodeno (EGD) scopes (Olympus Model GIF-H180) were not being reprocessed properly. The caps of the semi-disposable biopsy valves were not opened up (see the figures in Attachment 1), and hence were not cleaned, brushed, and disinfected or sterilized according to the manufacturer's instructions. This resulted in the presence of bioburden on the semi-disposable biopsy valves. The facility has since switched to use of disposable biopsy valves for their flexible endoscopes.

NOTE: While the Specific Incident section references a specific manufacturer's flexible endoscopes and biopsy valves, THIS PATIENT SAFETY ALERT APPLIES TO ALL COLONOSCOPES, EGD, AND ULTRASOUND SCOPES THAT HAVE BIOPSY VALVES, REGARDLESS OF MANUFACTURER OR MODEL.

General Information: Biopsy valves cover the biopsy port of flexible endoscopes used for various endoscopic procedures. While disposable biopsy valves are most often used for bronchoscopes, other flexible endoscopes (e.g., colonoscopes, EGD scopes, ultrasound scopes) may have reusable (i.e., reusable to an extent; semi-disposable; limited use) biopsy valves. The reusable biopsy valves must be opened up for cleaning and reprocessed according to the flexible endoscope manufacturer's instructions.

Actions: Chief of SPD (or designee) must ensure the following actions are carried out by close of business Tuesday, April 8, 2008:

1. All personnel who reprocess flexible endoscopes have read this Patient Safety Alert and the attachment.

   NOTE: Ensure you have identified all areas in your facility that reprocess flexible endoscopes, 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. As requested by VA Central Office, in an email from Odette Levesque on March 14, 2008, if you have not already done so, check the cleaning and reprocessing processes that you have in place for flexible endoscopes. If you identify any similar issue(s) in terms of failure to adequately clean or reprocess flexible endoscopes or their accessories, report them in an Issue Brief through your Network Office to VA Central Office, if you have not done so already.

3. Consider use of disposable biopsy valves rather than reusable valves. If you switch to disposable biopsy valves or make a plan to do so, ensure they are suitable for the particular flexible endoscope (i.e., obtain written confirmation of suitability from the flexible endoscope manufacturer). Note that reusable biopsy valves may be needed based on suitability to the specific type of flexible endoscope being used and procedure being performed.

4. If you continue to utilize reusable biopsy valves:

    a. Ensure that reprocessing personnel follow manufacturer's instructions for reprocessing all portions of the flexible endoscope, which includes removing biopsy valves from the endoscopes and ensuring that reusable biopsy valves are opened up (e.g., caps flipped open) and properly cleaned, brushed, and disinfected or sterilized according to manufacturers instructions.

    b. Ensure that locally-developed Standard Operating Procedures (SOPs) exist for reprocessing flexible endoscopes that follow manufacturer's instructions. Ensure also, that as part of the SOPs, that reusable, reprocessed biopsy valves are visually inspected and not released for use if any debris (e.g., potential bioburden) is found. In addition, the biopsy valves must be inspected for damage and discarded if there is any evidence of damage.

Add'l Information: Guidance – regarding notification of any patients that may have been exposed to pathogens as a result of possible improper reprocessing – is not addressed in this Patient Safety Alert. Such guidance could potentially be provided in a separate communication.

Source: VA Medical Center

Contacts: Bob Osburn, National SPD at (214) 857-4190,
Lelia Thomas-Lakey, National SPD/ID at (713) 794-7973, or
Tom Mize, National SPD/ID at (513) 487-6022.

Attachments: 1) Figure of reusable closed and open biopsy valves.

ATTACHMENT 1: **Figure of reusable closed and open biopsy valves.**

Biopsy valve in closed position Biopsy valve in open position

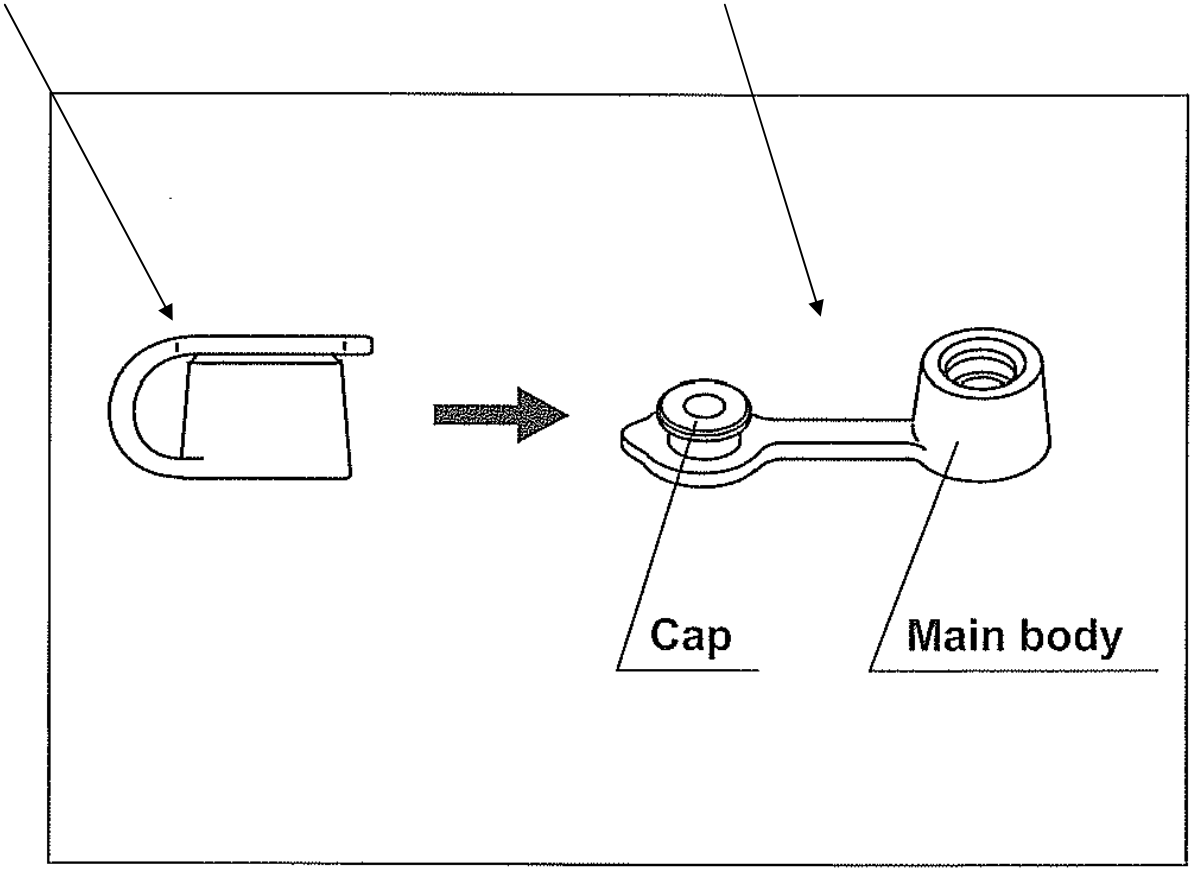

Figure courtesy of Olympus (from their Olympus EVIS EXERA II GIF/CF/PCF Type 180 Series Reprocessing Manual).