OLYMPUS

August 18, 2017

URGENT: MEDICAL DEVICE REMOVAL AND CORRECTIVE ACTION

Attention: Operating Room Manager

Regarding: Cystoscopy Bridges and Working Inserts - detaching fragments of adhesive

Model Number	Model Description	Lot Number(s)
A20975A	Working insert, with ramp, one way	13ZW to 172W
A20976A	Bridge, one way	146W to 172W
A20977A	Bridge, two way	146W to 174W

Dear Healthcare Practitioner:

Olympus America Inc. ("OAI") is implementing a medical device removal and corrective action associated with the cystoscopy bridges and working inserts identified by the model and lot numbers referenced above. These products were distributed from May 2014 through June 2017. Cystoscopy bridges and working inserts are used for endoscopic diagnosis and treatment in urologic applications.

OLYMPUS has initiated this action after receiving complaints about fragments of adhesive which detached from inside the working channel of the referenced cystoscopy bridge models. Cracking, chipping, missing pieces, and delamination of the adhesive have also been reported. Investigations have confirmed that this adhesive can detach during the intended use of the cystoscopy bridge or working insert (e.g., when inserting an instrument through the working channel). As a result, a fragment of the adhesive may fall inside the patient's bladder or urethra and will need to be retrieved. Although typically flushed out with irrigation fluid or passed naturally, the retrieval of large fragments of the adhesive could prolong the procedure or require additional surgical treatment.

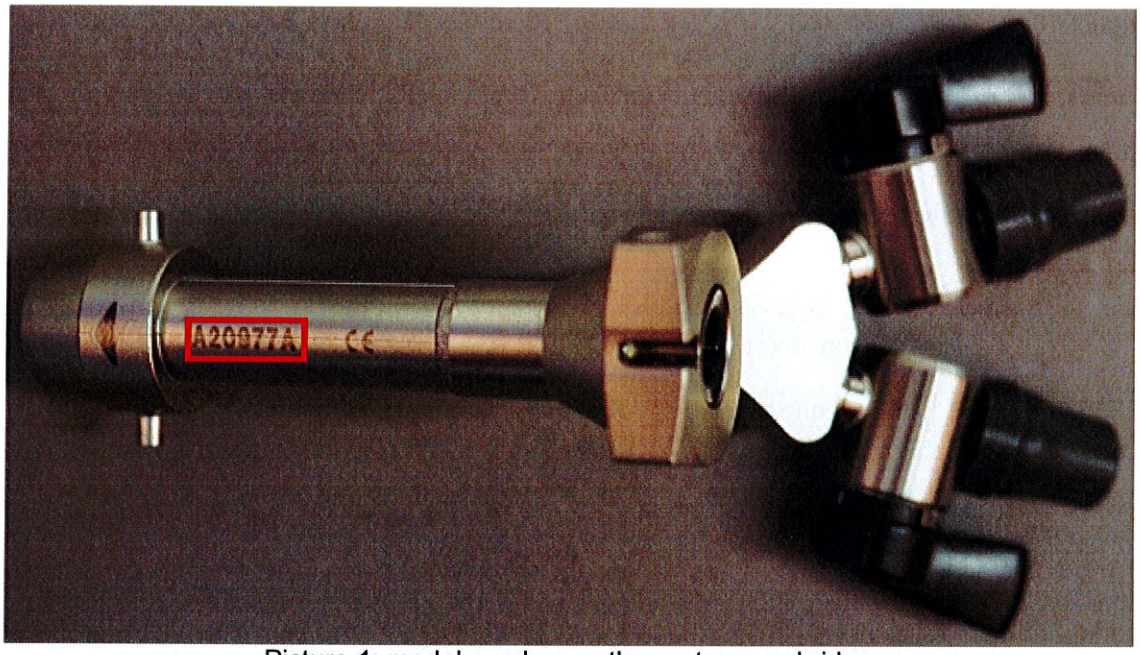
No patient injury has been related to this issue to date. However, in an effort to prevent a potential risk to patient health, OLYMPUS is undertaking this action to remove the existing products from the field and provide its customers with cystoscopy bridges and working inserts without adhesive. OLYMPUS will rework the cystoscopy bridges by removing the adhesive from the working channel, and will replace the working inserts. Please note that the lack of adhesive does not affect instrument passage.

Based on the manufacturer's investigation results and risk assessment, these devices are safe to use until reworked or replaced.

Action steps to be taken by the end user:

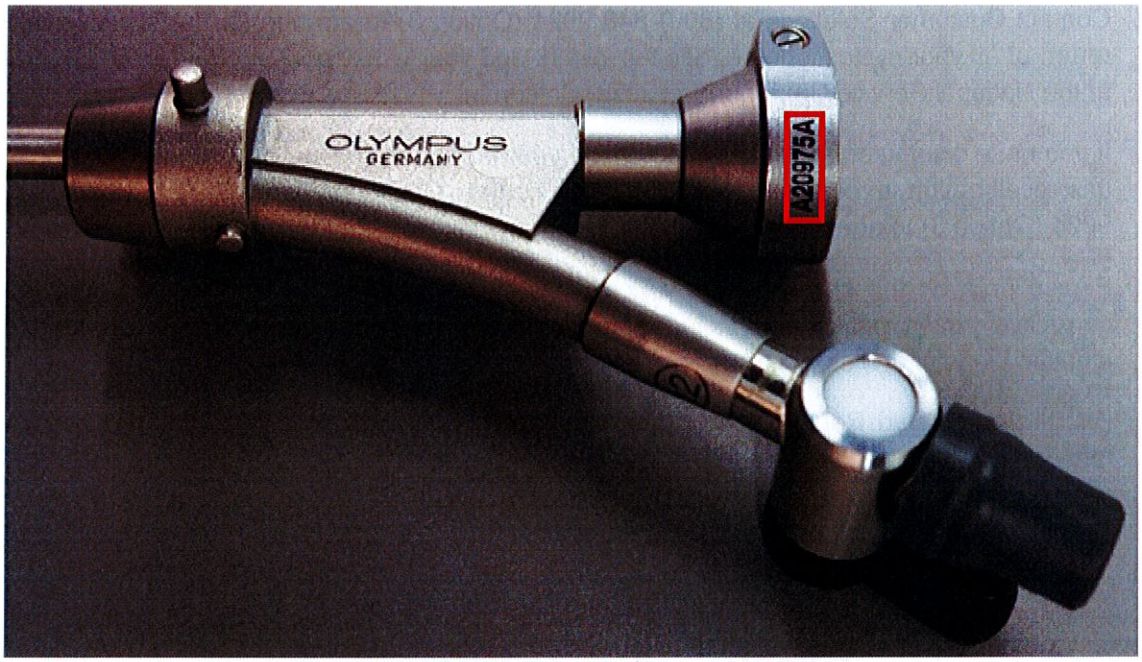
Our records indicate that your facility has purchased one or more of the affected cystoscopy bridge and/or working insert models with the lot numbers listed above. **OLYMPUS requires you to take the following actions:**

1. Inspect your inventory for the referenced devices and identify any of the specified model and lot numbers identified above. Please check all areas of the hospital to determine if any of these devices remain in inventory. The model and lot number can be found on the device as illustrated in the following pictures.

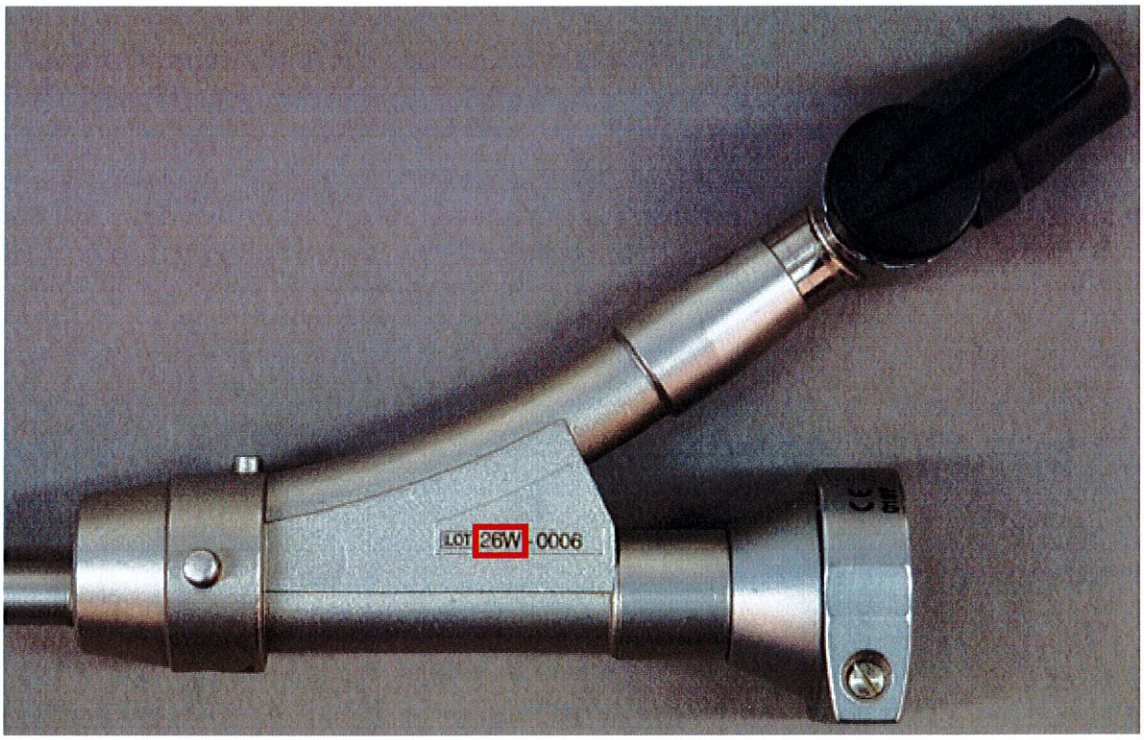


Picture 1: model number on the cystoscopy bridge

Picture 2: lot (LOT) number on the cystoscopy bridge



Picture 3: model number on the working insert



Picture 4: lot (LOT) number on the working insert

2. Contact Customer Solutions at (800) 848-9024 (Option 3) to arrange for the successive return of all your cystoscope bridges for rework and your working inserts for replacement at the National Service Center in San Jose, California.

3. If you have distributed these devices outside your facility, please notify your customers of this recall action immediately and have them contact Customer Solutions at (800) 848-9024 (Option 3) to arrange for return of the bridges and working inserts.

4. Please note on the enclosed Reply Form that you have received this medical device corrective action notice and include the quantity of any affected devices you have identified in your inventory and intend to return.

5. Fax the completed Reply Form to the Olympus Regulatory Affairs department at 484-896-7128.

The U.S. Food and Drug Administration is aware of this action.

OLYMPUS regrets any inconvenience this action may have caused and fully appreciates your prompt cooperation. If you have any questions or concerns, please do not hesitate to contact me directly at 484-896-5688 or at laura.storms@olympus.com.

Sincerely,

Laura Storms

Laura Storms
VP, Regulatory Affairs and Quality Assurance