OLYMPUS IRELAND
KeyMed House, Calmount Park, Ballymount, Dublin 12
Telephone: (01) 426 0100
e-mail: info@olympus.ie website: www.olympus.ie

DATE: 8 SEPTEMBER 2017

URGENT: FIELD SAFETY CORRECTIVE ACTION NOTICE
Action Identification Number: **252**
Type of Action: **Field Safety Corrective Action**

Affected products:

Model Number	Model Description	Lot Number(s)
A20975A	Working insert, with ramp, one way	13ZW, 149W, 14ZW, 159W, 15ZW, 162W, 168W
A20976A	Bridge, one way	146W, 147W, 148W, 149W, 14XW, 14YW, 14ZW, 151W, 152W, 153W, 154W, 155W, 156W, 157W, 158W, 159W, 15XW, 15YW, 161W, 162W, 163W, 164W, 165W, 167W, 168W, 16YW, 16ZW, 171W, 172W
A20977A	Bridge, two way	146W, 148W, 149W, 14XW, 14ZW, 151W, 152W, 153W, 154W, 155W, 156W, 158W, 159W, 15XW, 15YW, 161W, 162W, 163W, 164W, 165W, 166W, 167W, 168W, 169W, 16XW, 16ZW, 171W, 172W, 173W

Dear Customer

OLYMPUS is implementing a Field Safety Corrective Action ("FSCA") of the cystoscopy bridges and the working insert referenced above. Cystoscopy bridges and working inserts are used for endoscopic diagnosis and treatment in urologic applications.

OLYMPUS has initiated this FSCA 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 been observed. 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 require additional surgical treatment. Furthermore, the procedure can be prolonged resulting in extended anesthesia.

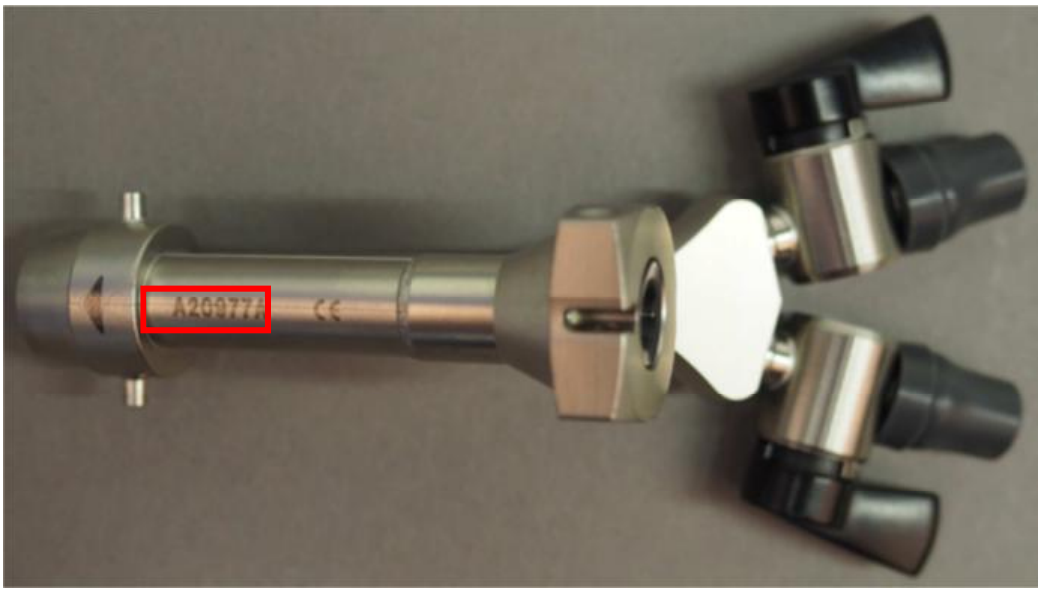
There has been no report about an adverse event or patient injury related to this issue. However, in an effort to prevent a potential risk to patient health, OLYMPUS is launching this action to provide its customers cystoscopy bridges and working inserts without adhesive. To achieve this, OLYMPUS will either rework the devices to remove the adhesive from the working channel or replace the devices completely. Please note that the lack of adhesive does not affect instrument passage.

Investigation results confirmed that these devices are safe to use until being reworked or replaced.

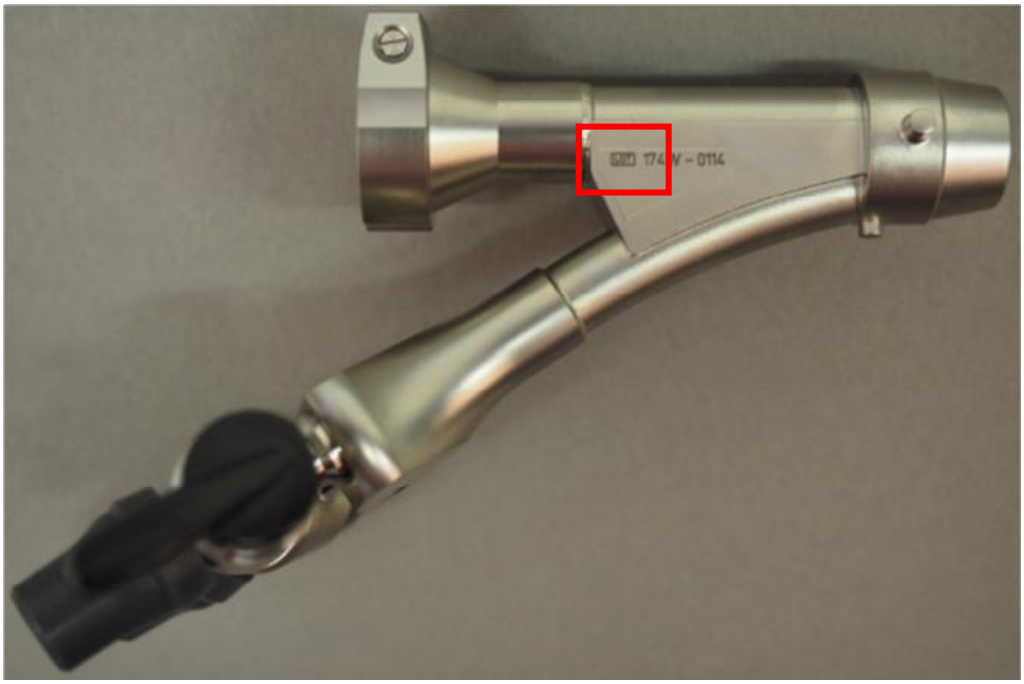
Action steps to be taken by the end user:

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. 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 the Olympus Helpdesk on 01 426 0100 to schedule the return of all your affected devices for rework/replacement.

3. Please note on the enclosed reply form that you have received this Field Safety Corrective Action Notice and include the quantity of any affected devices you have identified in your inventory and intend to return.

4. Please send the completed reply form by post, fax or a digitally scanned e-mail to:
   Ms Lynette Moran – Office Manager: Olympus Ireland
   Email: info@olympus.ie
   Fax: 01 426 0123

The national Competent Authority is aware of this action.

We appreciate your cooperation and apologise for any inconvenience this may cause. If you have any questions or would like further information, please do not hesitate to contact the Olympus Helpdesk on 01 426 0100.

Yours Sincerely

Robert Griggs

Quality and Regulatory Affairs General Manager

Enc. Field Safety Corrective Action Notice Reply Form

Date: 8 September 2017

URGENT: FIELD SAFETY CORRECTIVE ACTION NOTICE REPLY FORM

Affected Products:

Model Number	Model Description	Lot Number(s)
A20975A	Working insert, with ramp, one way	13ZW, 149W, 14ZW, 159W, 15ZW, 162W, 168W
A20976A	Bridge, one way	146W, 147W, 148W, 149W, 14XW, 14YW, 14ZW, 151W, 152W, 153W, 154W, 155W, 156W, 157W, 158W, 159W, 15XW, 15YW, 161W, 162W, 163W, 164W, 165W, 167W, 168W, 16YW, 16ZW, 171W, 172W
A20977A	Bridge, two way	146W, 148W, 149W, 14XW, 14ZW, 151W, 152W, 153W, 154W, 155W, 156W, 158W, 159W, 15XW, 15YW, 161W, 162W, 163W, 164W, 165W, 166W, 167W, 168W, 169W, 16XW, 16ZW, 171W, 172W, 173W

Please send the completed reply form by post, fax or a digitally scanned e-mail to:

Ms Lynette Moran – Office Manager: Olympus Ireland
Email: info@olympus.ie Fax: 01 426 0123

Dear Ms Moran

We have received the Field Safety Corrective Action Notice on the cystoscopy bridges and/or the working insert referenced above. I understand that I need to inspect my inventory and return any affected device(s) identified.

I will contact the Olympus Helpdesk on 01 426 0100 to schedule the return of all my affected devices for rework/replacement.

Choose either A or B:

A) _____ I checked my inventory and do NOT have any of the affected devices.

B) _____ I checked my inventory and I will return the following number of affected devices:

Model Number	Lot Number	Quantity

Name & Job Title: _____

Facility Name: _____

Address: _____

Post Code: _____ Telephone number: _____