



Reference: 2017-003W

August 01, 2017

IMPORTANT FIELD SAFETY NOTICE

CYSTOSCOPY BRIDGES AND WORKING INSERTS (A20975A, A20976A, A20977A) – DETACHING FRAGMENTS OF ADHESIVES

Model Number	Model Description	Lot Number
A20975A	Working insert, with ramp, one way	Lot number 13ZW and higher
A20976A	Bridge, one way	Lot number 146W and higher
A20977A	Bridge, two way	Lot number 146W and higher

Table 1: List of affected cystoscopy bridges and working inserts

Dear Sir/Madam,

OLYMPUS is implementing a Field Safety Corrective Action (“FSCA”) for the cystoscopy bridges and the working insert referenced in *Table 1*. 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 affected cystoscopy bridge models. Cracking, chipping, missing pieces, and delamination of the adhesive have been observed. Investigation 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 customers with cystoscopy bridges and working inserts without adhesive. To achieve this, OLYMPUS will rework the cystoscopy bridges (Model No: A20976A and A20977A) by removing the adhesive from the working channel. As the working inserts (Model No: A20975A) cannot be reworked, these devices need to be replaced. Please note that the lack of adhesives does not affect instrument passage.

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

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Actions 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 referenced in *Table 1*.

OLYMPUS requires you to take the following actions:

1. Inspect your inventory for the affected devices and identify any of the specified model and lot numbers listed in *Annex A*. The model and lot number can be found on the device as illustrated in *Annex B*.
2. Contact your local Olympus representative to schedule the successive return of all affected devices for rework and/or replacement.
3. Please acknowledge on the enclosed "Response Form" that you have received this Field Safety Notice ("FSN") and include the quantity of affected devices you have identified in your inventory and intend to return.
4. Email the completed "Response Form" to the Regulatory Affairs Department at mes-ra.osp@olympus-ap.com.

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 us for additional information.

Contact for enquires

Olympus Singapore Pte. Ltd.

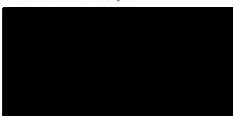
Regulatory Affairs Department

Email: mes-ra.osp@olympus-ap.com

Tel: 6833 4214

Fax: 6834 2438

Sincerely,



Loh E Thel

Deputy Division Manager

Medical Systems Business Division

Olympus Singapore Pte. Ltd.

cc: Chairman Medical Board and relevant Head of Departments



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Annex A: List of Affected Lot Numbers in the Region

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

Table 2: List of affected cystoscopy bridges and working inserts in the region

Annex B: Identification of Model Number and Lot Number on Device



Figure 1: Model number on the cystoscopy bridge



Figure 2: Lot number on the cystoscopy bridge

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Figure 3: Model number on the working insert



Figure 4: Lot number on the working insert