OLYMPUS

Reference: 2019-003M

20-Jun-2019

FIELD SAFETY NOTICE

Dear Sir/Madam,

OLYMPUS is implementing a Field Safety Corrective Action for the device listed below. The affected model and batch numbers are listed below.

Model No.	Description	Batch No.
MAJ-209	Single-Use Suction Valve	H8807 to H9106

Olympus has become aware of a matter that requires your attention. This Field Safety Notice pertains to the above-referenced Olympus MAJ-209 Single-Use Suction Valve ("MAJ-209"). The MAJ-209 has been designed to attach to the suction channel of bronchoscopes, cystoscopes, rhino-laryngoscopes and pleurascopes for aspirating fluid from the distal end of the endoscope through the instrument channel.

Olympus has initiated this action after receiving a complaint of a MAJ-209 breaking during a patient procedure and got stuck in the endoscope's suction cylinder. This resulted in an extended patient procedure and prolonged patient exposure to anesthesia. In addition, Olympus reviewed the recent complaint history of the MAJ-209 and has become aware of an increased number of reports of the MAJ-209 breaking off during a procedure, with the possibility of a piece of the suction valve remaining attached to the endoscopes. In the case of a breakage of the MAJ-209 the fluid suction capability is influenced resulting in a potential vision decrease for the user and a possible procedure interruption. After analyzing the available information about these events, Olympus has determined a change to the molding supplier led to the increased number of events.

Olympus has also determined that users can continue to use the MAJ-209 in accordance with the Instruction for Use for MAJ-209 and the instructions provided within the attached addendum. Olympus is notifying users of the possibility of the breakage, the proper handling of the MAJ-209, and how to disassemble a broken MAJ-209 from an endoscope, should a breakage occur. In the addendum attached to this letter you can find handling instructions for preventing the breakages of MAJ-209 and the required actions to remove a broken MAJ-209 from the endoscope.

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 in the process of manufacturing new products using a different molding supplier.

OLYMPUS SINGAPORE PTE LTD
Business Regn No. 198900566E
Business Address: 438B Alexandra Road, Alexandra Technopark Blk B, #03-07/12, Singapore 119968 Tel: (65) 6834 0010 Fax: (65) 6834 2438
www.olympus.com.sg

Action(s) to be taken by end user

Our records indicate that you have purchased the affected product(s) and we request you to take the following action(s):

1. Carefully read the content of this FSN as well as the attached "Addendum to the Instruction for Use of the MAJ-209" which describes the handling instructions for preventing the breakages of MAJ-209 and the required actions to remove a broken MAJ-209 from the endoscope.
2. Inspect your inventory for the MAJ-209 and identify any of the specified lot numbers, as specified in Annex A.
3. Implement the handling instructions in your facility.
4. Email the completed Response Form to the Regulatory Affairs Department at mes-ra.osp@olympus-ap.com, or you may return the completed form to your local Olympus representative.

OLYMPUS regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact information
Olympus Singapore Pte. Ltd.
Regulatory Affairs Department
Email : mes-ra.osp@olympus-ap.com
Tel : (+65) 6833 4214
Fax : (+65) 6834 2438

Sincerely,

[redacted]

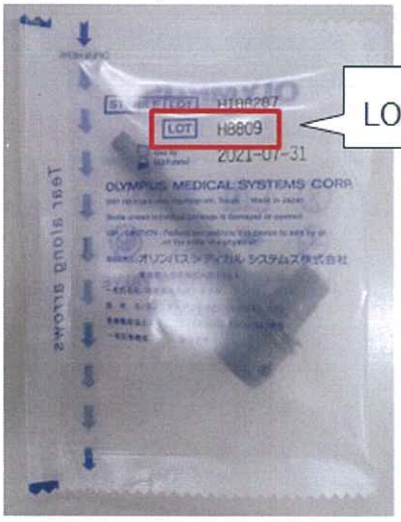
Loh E Thei
Division Manager
Medical Systems Business Division
Olympus Singapore Pte Ltd

Cc: Chairman Medical Board and relevant Head of Departments

Annex A

Model Identifier	Labeling on the carton box	88H	89H	8XH	8YH	8ZH	91H
MAJ-209	Labeling on the sterile pack	H8807	H8901	H8X01	H8Y01	H8Z01	H9101
		H8808	H8902	H8X02	H8Y02	H8Z02	H9102
		H8809	H8903	H8X03	H8Y03	H8Z03	H9103
		H8810	H8904	H8X04	H8Y04	H8Z04	H9104
		H8811	H8905	H8X05	H8Y05	H8Z05	H9105
		H8812	H8906	H8X06	H8Y06	H8Z06	H9106
		H8813	H8907	H8X07	H8Y07	H8Z07	
		H8814	H8908	H8X08	H8Y08	H8Z08	
		H8815	H8909	H8X09	H8Y09	H8Z09	
		H8816	H8910	H8X10	H8Y10	H8Z10	
			H8911	H8X11	H8Y11	H8Z11	
			H8912	H8X12	H8Y12	H8Z12	
			H8913	H8X13	H8Y13	H8Z13	
			H8914	H8X14	H8Y14	H8Z14	
			H8915	H8X15	H8Y15	H8Z15	
			H8916	H8X16	H8Y16	H8Z16	
			H8917	H8X17	H8Y17	H8Z17	
				H8X18	H8Y18	H8Z18	
				H8X19	H8Y19	H8Z19	
				H8X20	H8Y20		
				H8X21	H8Y21		
				H8X22			

Sterile pack ->



LOT : H8807 ~

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Response Form

Please send the complete and signed Response Form to Regulatory Affairs Department at:
mes-ra.osp@olympus-ap.com

To : Olympus Singapore Pte. Ltd., Regulatory Affairs Department
Fax : 6834 2438
From : _____ [Facility Name] Contact No. : _____
Date : _____
Ref : 2019-003M

FIELD SAFETY NOTICE

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

☐ I DO NOT have affected devices remaining. All have been used or discarded.

☐ I DO have unused inventory of affected devices. The handling instructions indicated in the "Addendum to the Instruction for Use of the MAJ-209" shall be implemented.

Model No.	Serial / Batch No.	Quantity to be Returned (UOM)
MAJ-209		

Name : _____
Designation : _____

_____ _____
Signature / Facility Stamp Date

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