



August 22, 2019  
Olympus reference: QIL 152-005

## URGENT FIELD SAFETY NOTICE

### HANDLING INSTRUCTIONS FOR THE OLYMPUS MAJ-209 SINGLE-USE SUCTION VALVE

Attention: Operating Room Manager and Risk Management Department

Model Name	Description	LOT No. on the carton box	LOT No. on the sterile pack
MAJ-209	MAJ-209 Single-Use Suction Valve	<b>88H</b>	<b>H8807 to H8816</b>
		<b>89H</b>	<b>H8901 to H8917</b>
		<b>8XH</b>	<b>H8X01 to H8X22</b>
		<b>8YH</b>	<b>H8Y01 to H8Y21</b>
		<b>8ZH</b>	<b>H8Z01 to H8Z19</b>
		<b>91H</b>	<b>H9101 to H9106</b>

Dear Health Care Practitioner:

Olympus has become aware of a matter that requires your attention regarding the above-referenced LOT numbers of the 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.

Please note that this second Field Safety Notice (FSN) is related to the first Field Safety Notice issued in March 2019 (Olympus reference: QIL 151-010).

As you may remember, Olympus initiated a first Field Safety Corrective Action (QIL 151-010) shortly after receiving a complaint of a MAJ-209 breaking during a patient procedure that then got stuck in the endoscope’s suction cylinder. This resulted in an extended patient procedure and prolonged patient exposure to anesthesia. While no patient injury has been reported to date, a breakage of the MAJ-209 influences the fluid suction capability and could result in a potential vision decrease for the user and a possible procedure interruption.

Olympus thoroughly reviewed the recent complaint history of the MAJ-209 and determined that a change of the molding supplier led to the increased number of events. Meanwhile, the assessment showed that even those moldings do not break as long as they are used in accordance with the instructions. Hence, we reminded users that they can continue to use the MAJ-209 suction valves only in accordance with the Instruction for Use for MAJ-209 and the instructions within the addendum provided within the last FSCA.

In addition, Olympus ramped up the manufacturing capacities of the former molding supplier for a counter measured MAJ-209 Single-Use Suction Valve. As of today, and as a mere, additional precautionary measure, Olympus is enabled for a proper and timely replacement of the remaining affected lots in the field. We are now notifying our customers accordingly and ask them to return all remaining affected devices to Olympus.



Actions to be taken by the user:

Our records indicate that your facility has purchased one or more of these devices. Olympus requests your facility take the following immediate actions:

- a) Carefully read the content of this [FSN].
- b) Inspect your inventory for the MAJ-209 and identify any of the specified lot numbers.**
- c) Scrap your inventory of the above mentioned lot numbers to get a credit note in return.**
- d) Indicate on the enclosed questionnaire that you have received this notification as well as the quantities per LOT number you are going to scrap.
- e) Send the completed reply form as well as the disposal confirmation back to your Olympus representative (ra@olympus-mea.com )**
- f) If you have further distributed this product, identify your customers, forward them this [FSN] including the attachments, and appropriately document your notification process.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation.

If you require additional information or on-site support, please do not hesitate to contact Olympus directly ra@olympus-mea.com .

Sincerely,

Iman Ibrahim  
Regional Quality Assurance and Regulatory Affairs Manager Middle East & Africa  
Olympus MEA FZ-LLC  
Registration No. 93456 (Dubai Creative Clusters Authority)  
Dubai Science Park - Nucleotide Complex - Dubai - United Arab Emirates  
P.O. Box: 33607 Dubai  
United Arab Emirates

Phone: +971 56 524 0079  
E-Mail: iman.ibrahim@olympus-mea.com



REPLY FORM – QIL 152-005

OLYMPUS URGENT FIELD SAFETY NOTICE					
HANDLING INSTRUCTIONS FOR THE OLYMPUS MAJ-209 SINGLE-USE SUCTION VALVE					
[Name & Address of Hospital/Medical Facility]					
[Dept/Attn]					
[Date]					
Quantities still available on stock (please indicate if a complete box or single valves are still available. If no stock is available please insert 0)	Quantities to be scrapped (please indicate if a complete box or single valves are scrapped)	LOT No. to be scrapped	LOT No. on the carton box	LOT No. on the sterile pack	
			88H	H8807 to H8816	
			89H	H8901 to H8917	
			8XH	H8X01 to H8X22	
			8YH	H8Y01 to H8Y21	
			8ZH	H8Z01 to H8Z19	
			91H	H9101 to H9106	

I herewith acknowledge the receipt of your Field Safety Notice (FSN).  
 Further I confirm that I have trained the responsible personnel on the actions required in the FSN for the MAJ-209 and transferred the information to all affected departments on which this action may have an impact. I confirm that I have no more affected LOTs on site besides the above mentioned quantities which I'll scrap and report to Olympus immediately.

Name (Signature) \_\_\_\_\_

Name (Print) \_\_\_\_\_

Position \_\_\_\_\_

Please return this completed reply form to Olympus by September 15<sup>th</sup>, 2019