

August X, 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	88H	H8807 to H8816
		89H	H8901 to H8917
		8XH	H8X01 to H8X22
		8YH	H8Y01 to H8Y21
		8ZH	H8Z01 to H8Z19
		91H	H9101 to H9106

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) Return your inventory of the above mentioned lot numbers to your local Olympus organization at XXXXXX to get a free of charge replacement in return. Indicate on the enclosed questionnaire that you have received this notification as well as the quantities per LOT number you are going to return to Olympus for replacement.
- e) Send the completed form back to your Olympus representative (xxx)
- f) If you have further distributed this product, identify your customers, forward them this [FSN] including the attachments, and appropriately document your notification process.
- g) If you want to return affected products to Olympus, please contact your local Olympus representative at XXXX to discuss the timeline of receiving a replacement product.

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 at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.

Sincerely,



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 returned to Olympus (please indicate if a complete box or single valves are returned)	LOT No. to be returned to Olympus	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 return to Olympus immediately.

Name (Signature) _____

Name (Print) _____

Position _____

Please fax this completed reply form to Olympus at [contact number] latest by XXXX