



March X, 2019  
Olympus reference: QIL 151-010

## 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. 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 customers can continue to use the MAJ-209 suction valves identified [in this letter](#) 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.

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] 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.
- b) Inspect your inventory for the MAJ-209 and identify any of the specified lot numbers.
- c) Implement the handling instructions in your facility and ensure you train your personnel on the handling instructions.
- d) Indicate on the enclosed questionnaire that you have received this notification.
- 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 151-010

<b>OLYMPUS URGENT FIELD SAFETY NOTICE HANDLING INSTRUCTIONS FOR THE OLYMPUS MAJ-209 SINGLE-USE SUCTION VALVE</b>
<b>[Name &amp; Address of Hospital/Medical Facility]</b>
<b>[Dept/Attn]</b>
<b>[Date]</b>

I herewith acknowledge the receipt of your Field Safety Notice (FSN) as well as the “Addendum to the Instruction for Use of the MAJ-209”.

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 understand the necessity of this additional handling information.

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

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

Position \_\_\_\_\_

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

## Addendum to the Instruction for Use of the MAJ-209 Handling instructions for preventing the breakage of MAJ-209

Model Name	Instruction for Use	Affected LOT No.	
		LOT No. on the carton box	LOT No. on the sterile pack
MAJ-209 Single-Use Suction Valve	Article No.: 028987	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. Which movement of the MAJ-209 suction valve tube has to be avoided in order to prevent valve breakage?**

- An upward lifting of the suction valve's main body pipe away from the endoscopes has to be avoided.



**II. How can users control the situation?**

- The user can control the situation and avoid breakage by following the three movement rules described below:



**1**

Attaching and detaching the suction tube only with pushing- /pulling-force in direction of the suction valve.



2

With attached suction tube: While using rotation movement **avoid pulling the attached tubing**. Assure to have **sufficient tube length** available in order to avoid pulling forces to the suction valve's main body pipe.



3

Disconnect the suction valve after the procedure with a clock-wise turn and slight pressure on the suction valve's main body pipe in direction of the scope (contrary movement to the one that would lead to breakage).

### III. How can the broken MAJ-209 valve be removed from the bronchoscope?

- In order to allow removal of the remaining suction body, for example a small screw-driver or scissor can be inserted into the ruptured tube opening of the suction valve. A clock-wise turn will then remove the broken valve from the bronchoscope/other endoscopes.



- Please take measures to ensure a quick removal of a broken valve can be done and have sufficient quantities (at least one) of the MAJ-209 available for replacement.

This document is to be retained with the Instructions for Use of the MAJ-209.