



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

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| 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] |

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