

Reference: 2021-001M

2nd August 2021

URGENT - FIELD SAFETY NOTICE

To all users of Olympus Forcep/Irrigation Plug (Isolated Type) MAJ-891

Re: Reprocessing Recommendations for Forceps/Irrigation Plug (Isolated Type) MAJ-891

Dear Customer,

Olympus is implementing a Field Corrective Action for the device listed below. The affected model and batch number is listed below.

Model Number	Model Description	Batch Number
MAJ-891	Forceps/Irrigation Plug (Isolated Type)	All

Olympus Medical Systems Corporation (“Olympus”) is writing to remind you of important reprocessing instructions for the Forceps/Irrigation Plug (Isolated Type) model MAJ-891 (“MAJ-891”).

The MAJ-891 is attached to the instrument channel port of certain Olympus endoscopes, including cystoscopes (CYF series), ureteroscopes (URF series), choledochoscopes (CHF series), and hysteroscopes (HYF series), to allow both irrigation and the use of endo-therapy accessories.

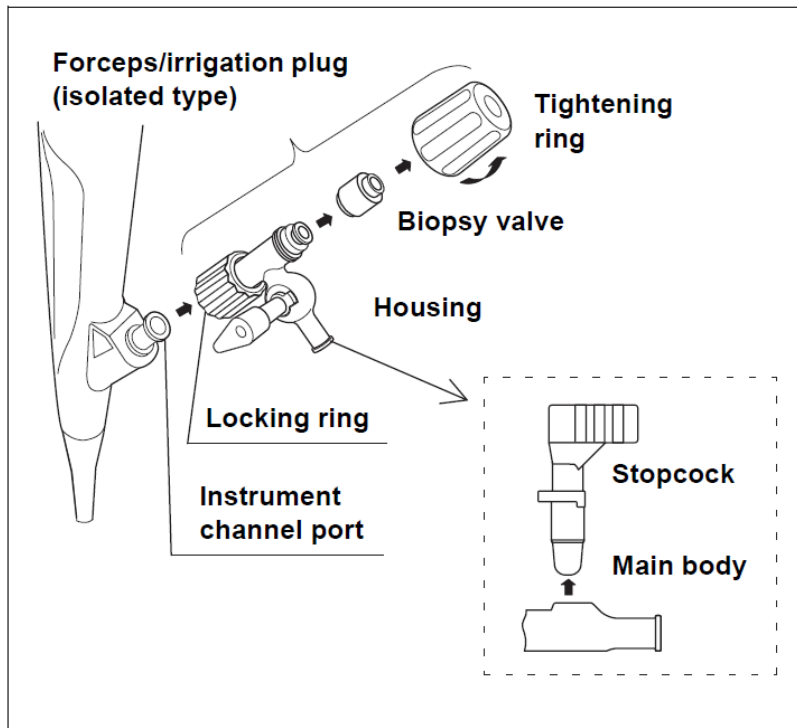
Please refer to Attachment 1 for the model names of the Olympus endoscopes with which the MAJ-891 may be used as an accessory.

Reprocessing Reminder

Olympus is investigating potential causes and contributing factors relating to reported infection and contamination complaints associated with the MAJ-891. Although Olympus has determined that the risk of infection is low based on available data, Olympus’ investigation revealed a potential risk of patient infection due to inadvertent retention of biomaterial when the reprocessing procedure applicable to the MAJ-891 is not performed as instructed, such as not completely removing and disassembling MAJ-891 during reprocessing. Therefore, Olympus is reminding customers to follow the labelled instructions when reprocessing MAJ-891.

Improper and/or incomplete reprocessing can present an infection control risk. Accordingly, it is important to closely follow the instructions for use for reprocessing the MAJ-891, including disassembling the MAJ-891 as instructed.

Please also ensure that all reprocessing personnel are completely knowledgeable and thoroughly trained on the reprocessing instructions in the MAJ-891 instructions, especially ensuring that the MAJ-891 is detached from the instrument channel port and disassembled before it is cleaned, disinfected, or sterilized. (see Figure 1)



(Figure 1)

If you require additional information about the proper steps to reprocess MAJ-890, there are numerous ways to obtain this information:

- You can contact our Olympus Representative who can assist in answering questions on MAJ-891 reprocessing and/or obtaining additional copies of the reprocessing manuals.
- Olympus can also provide reprocessing training and education. If you would like Olympus to visit your facility to review and train on the cleaning and reprocessing process, please approach our Olympus Representative.

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. Please read through carefully the enclosed information and share this notice to any healthcare professional from your organization as appropriate.
2. Complete and return the 'Response Form' to Olympus.

Olympus regrets any inconvenience caused 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 for enquiries

Regulatory Affairs Department

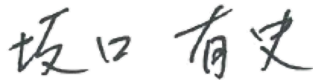
Email : mes-ra.oml@olympus.com

Tel : (603) 7886 9188

Fax : (603) 7887 2833

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,



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Yuji Sakaguchi

Managing Director

Olympus (Malaysia) Sdn. Bhd.

Attachment 1

Model name of the Olympus endoscopes sold that use the MAJ-891 as an accessory.

Items	Model Name	Device Description
Accessory	MAJ-891	Forceps/Irrigation Plug (Isolated Type) MAJ-891
Cystoscopes	CYF-4	OES Cystofiberscope Olympus CYF-4
	CYF-4A	OES Cystofiberscope Olympus CYF-4A
	CYF-5	OES Cystonephrofiberscope Olympus CYF-5
	CYF-5A	OES Cystonephrofiberscope Olympus CYF-5A
	CYF-V2	VISERA Cysto-Nephro Videoscope Olympus CYF Type V2
	CYF-VA2	VISERA Cysto-Nephro Videoscope Olympus CYF Type VA2
	CYF-VH	Cysto-Nephro Videoscope Olympus CYF-VH
	CYF-VHA	Cysto-Nephro Videoscope Olympus CYF-VHA
Ureteroscope	URF-P3	OES Uretero-Reno Fiberscope Olympus URF Type P3
	URF-P5	OES Uretero-Reno Fiberscope Olympus URF Type P5
	URF-P6	Uretero-Reno Fiberscope Olympus URF-P6
	URF-P7	Uretero-Reno Fiberscope Olympus URF-P7
	URF-V	Uretero-Reno Videoscope Olympus URF Type V
	URF-V2	Uretero-Reno Videoscope Olympus URF-V2
	URF-V3	Uretero-Reno Videoscope Olympus URF-V3
Choledochoscope	CHF-BP30	OES Transduodenal Choledochofiberscope Olympus CHF Type BP30
	CHF-CB30L	OES Choledochofiberscope Olympus CHF Type CB30L
	CHF-P20Q	OES Choledochofiberscope Olympus CHF Type P20Q
	CHF-XP20	OES Choledochofiberscope Olympus CHF Type XP20
	CHF-P60	OES Choledochofiberscope Olympus CHF Type P60
	CHF-V	Choledochofiberscope Olympus CHF Type V
Hysteroscope	HYF-1T	OES Hystero-fiberscope Olympus HYF Type 1T



Response Form

Please send the complete and signed Response Form to Regulatory Affairs Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs
Fax/Email : (603) 7887 2833 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.: _____
Date : _____
Ref : 2021-001M

URGENT - FIELD SAFETY NOTICE

Re: Reprocessing Recommendations for Forceps/Irrigation Plug (Isolated Type) MAJ-891

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 the affected devices, which I will adhere to the reprocessing instructions.

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date