

URGENT FIELD SAFETY NOTICE

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

**Attention: Operating Room Manager, Endoscopy Department, Risk Management and
Reprocessing Units**

	Model Name	Affected LOT Numbers
Forceps/Irrigation Plug (Isolated Type)	MAJ-891	All

Dear Healthcare Professional,

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 labeled 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 (8404056 2-0), 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)

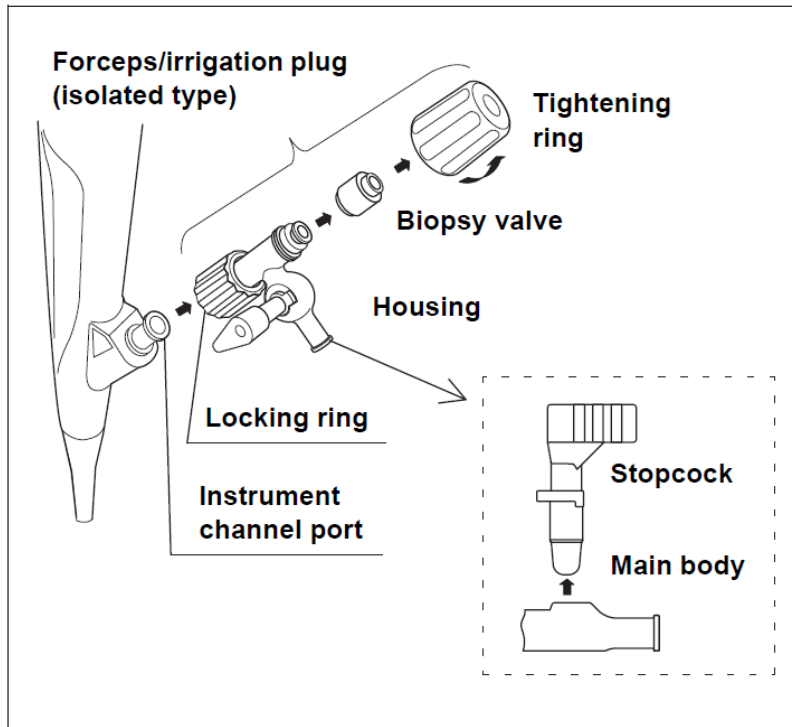



Figure 1: How to detach and disassemble the MAJ-891 from the instrument channel port prior to cleaning, disinfection and sterilization

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected MAJ-891. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this Field Safety Notice.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN and the referenced MAJ-891 reprocessing instructions.
3. Please note on the enclosed FSN Reply Form that you have received, understood, and followed this information. Kindly also indicate the quantity of required MAJ-891 Instruction for Use (IFU) hard copies on the Reply Form.

Note: Please note that the most current language version of the MAJ-891 Instruction for Use are available on the following Olympus webpage: www.olympus-europa.com.

When opening the webpage select 'Medical Systems', select 'Contact & Support', click on the magnifying symbol (), select 'Instruction Manual' and search for the relevant model (e.g. 'MAJ-891').

4. Send the completed Reply Form back to your Olympus representative ([xxx]) latest by [XXXX] regardless of whether you have any affected inventory at your facility.
5. If you have further distributed the products listed, identify your customers, forward them this Field Safety Notice, appropriately document your notification process and let us know the end-customer feedbacks accordingly.



This Field Safety Notice pertains to the above-referenced models only.

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

Olympus regrets any inconveniences caused by this Field safety Corrective Action fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at [phone number] or at [e-mail address] for any additional information concerning this matter.

Sincerely,



**Attachment 1:
Model names 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-240	EVIS CYSTOVIDEOSCOPE OLYMPUS CYF TYPE 240
	CYF-240A	EVIS CYSTOVIDEOSCOPE OLYMPUS CYF TYPE 240A
	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-5R	OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5R
	CYF-V	VISERA CYSTOVIDEOSCOPE OLYMPUS CYF TYPE V
	CYF-VA	VISERA CYSTOVIDEOSCOPE OLYMPUS CYF TYPE VA
	CYF-V2	VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2
	CYF-V2R	VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2R
	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
	CYF-VHR	CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHR
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-P6R	URETERO-RENO FIBERSCOPE OLYMPUS URF-P6R
	URF-P7	URETERO-RENO FIBERSCOPE OLYMPUS URF-P7
	URF-P7R	URETERO-RENO FIBERSCOPE OLYMPUS URF-P7R
	URF-V	URETERO-RENO VIDEOSCOPE OLYMPUS URF TYPE V
	URF-V2	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V2
	URF-V2R	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V2R
	URF-V3	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3
	URF-V3R	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3R

Items	Model Name	Device Description
Choledochoscope	CHF-B260	EVIS LUCERA VERSATILE SMALL DIAMETER VIDEOSCOPE OLYMPUS CHF TYPE B260
	CHF – BP260	EVIS LUCERA VERSATILE SMALL DIAMETER VIDEOSCOPE OLYMPUS CHF TYPE BP260
	CHF-B290	EVIS LUCERA ELITE CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF-B290
	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 CHOLEDOCHO FIBERSCOPE OLYMPUS CHF TYPE P60
	CHF-V	CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF TYPE V
	CHF-V2	CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF-V2
	CHF-240	EVIS CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF TYPE 240
	CHF-B001	EVIS EXERA TRANSDUODENAL CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF B001
	CHF-B160	EVIS EXERA ULTRATHIN VIDEOSCOPE OLYMPUS CHF TYPE B160
	CHF-B160-1	TRANSDUODENAL CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF TYPE B160-1
	CHF-BP160	EVIS EXERA ULTRATHIN VIDEOSCOPE OLYMPUS CHF TYPE BP160
	CHF-B260-1	TRANSDUODENAL CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF-B260-1
	CHF-B260(-S)	EVIS LUCERA ULTRATHIN VIDEOSCOPE OLYMPUS CHF TYPE BP260
	CHF-Y0002	CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF TYPE Y0002
	CHF-XP260	EVIS LUCERA CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF TYPE XP260
Hysteroscope	HYF-1T	OES HYSTEROFIBERSCOPE OLYMPUS HYF TYPE 1T



REPLY FORM – QIL 154-009

URGENT FIELD SAFETY NOTICE	
RE: Reprocessing Recommendations for Forceps/Irrigation Plug (Isolated Type) MAJ-891	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[Date]	
Model name	Quantity of MAJ-891 IFU hard copies required
MAJ-891	

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.

Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity to follow the MAJ-891 reprocessing instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to XXXX latest by XXXX.