

Reference: 2024-008M

18 December 2024

URGENT - FIELD SAFETY NOTICE

To user of **Olympus Forceps/Irrigation Plug (Isolated Type)**

Model Numbers: MAJ-891

Lot Numbers: All

Re: Olympus to Provide Reprocessing Instruction and Lists of Available Alternative Devices to MAJ 891

Attention: **Endoscopy Department & Risk Management**

Dear Health Care Provider:

Olympus is writing to inform you of a Field Corrective Action pertaining to 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), hysteroscopes (HYF series), and ventriculoscopes (VEF 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.

Reason for Action:

Olympus’ investigation into reported infection and contamination complaints associated with the MAJ-891 revealed a potential risk of patient infection due to inadvertent retention of biomaterial when the reprocessing procedure for the MAJ-891 is not performed as instructed, such as not disconnecting the MAJ-891 from the endoscope and disassembling it before reprocessing. In the period of August 1, 2021 to May 1, 2024, Olympus identified one-hundred and twenty (120) serious injuries and one (1) death reported due to infection following procedures in which the MAJ-891 was used with a cystoscope (CYF scope). Investigation by Olympus indicates that there was improper reprocessing in most of these infection cases. Olympus has not received any infection-related complaints for cases where the MAJ-891 was used with other compatible endoscopes including ureteroscopes (URF series), choledochoscopes (CHF series), hysteroscopes (HYF series), and ventriculoscopes (VEF series), although it should be noted that the risk of infection as a result of improper reprocessing is also applicable to these endoscopes.

Due to the risk of infection that may result from improper MAJ-891 reprocessing, alternatives to the MAJ-891 should be used instead. A list of Olympus alternative irrigation plugs that can be used with certain Olympus scopes is listed below.

If no alternative for the MAJ-891 is available, it is important to closely follow the reprocessing instructions for both the endoscope(s) and the MAJ-891 Forceps/Irrigation Plug, **especially detaching the MAJ-891 from the instrument channel port of the endoscope and disassembling before it is cleaned, disinfected or sterilized** (Reference Figure 1 below, depicting proper disassembly of the MAJ-891). The reprocessing instructions for the MAJ-891 can be found in Chapters 5 through 7 of the MAJ-891 Instructions for Use (IFU). **Users should also inspect the biopsy valve (MAJ-579), used as illustrated below in the MAJ-891, for damage or deformation and replace the biopsy valve if damage is identified, as instructed in the IFU. A damaged or deformed biopsy valve may impact the reprocessing efficacy.**

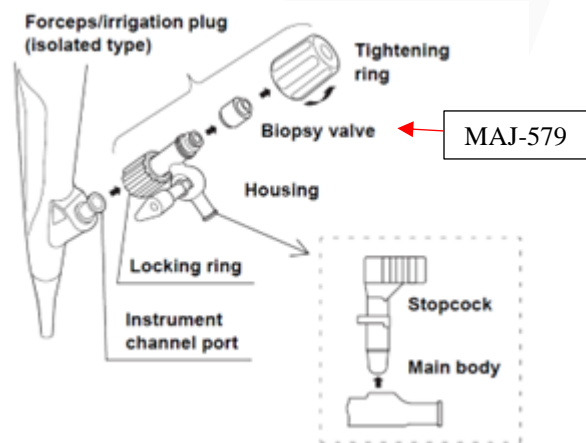


Figure 1

Risk to Health:

The potential harm of improper and/or incomplete reprocessing of the MAJ-891 Forceps/Irrigation Plug is exposure to a contaminated device. This exposure could result in patient injury including infection, urinary tract infection, or sepsis, and, in some cases, could result in death. These harms may require inpatient hospitalization/monitoring, and treatment with oral or intravenous antibiotics.

Alternative Devices to the MAJ-891:

The compatibility table below lists the available alternative devices to the MAJ-891 for Olympus cystoscopes (CYF series) and ureteroscopes (URF series). There are currently no alternative Olympus irrigation plugs for use with choledochoscopes (CHF series), hysteroscopes (HYF series), or ventriculoscopes (VEF series). Use an alternative scope in those situations or a non-Olympus irrigation plug provided it has been validated for use with the Olympus scope by the irrigation plug manufacturer.

If you have any questions regarding suitable alternatives to the MAJ-891, contact your Olympus Sales Representative.

Please refer to Attachment 2 for a full listing of scope models and alternative devices.

Scope Series	Compatible Alternative Devices to MAJ-891
Cystoscope (CYF)	Luer-Split + Seal-Port model MAJ-2092; Adjustable Biopsy Port Seal Y-Adapter model BPS-Y
Ureteroscope (URF)	Luer-Split + Seal-Port model MAJ-2092; Adjustable Biopsy Port Seal Y-Adapter model BPS-Y
Choledochoscope (CHF)	There are currently no alternative Olympus irrigation plugs compatible with Olympus CHF scopes.
Hysteroscope (HYF)	There are currently no alternative Olympus irrigation plugs compatible with Olympus HYF scopes.
Ventriculoscope (VEF)	There are currently no alternative Olympus irrigation plugs compatible with Olympus VEF scopes.

The MAJ-2092 is a single device that does not require disassembly for reprocessing. In contrast, the MAJ-891 consists of multiple components and requires further disassembly after being removed from the scope before reprocessing. If this step is overlooked, the reprocessing may not be effective. The BPS-Y is a single-use alternative device to the MAJ-891 and is replaced after each use, so the risk of contamination due to improper reprocessing is not applicable for this device.

Training

Olympus will contact you to schedule a mutually beneficial time for an Olympus Field Representative to visit your facility and review the contents of this letter. If no alternatives are available, Olympus will also review the reprocessing instructions for the MAJ-891 Forceps/Irrigation Plug and the compatible endoscopes.

Actions Required:

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

1. Carefully read the content of this letter.
2. For information, there is the risk of infection that may result from improper reprocessing of the MAJ-891 and compatible endoscopes.
3. Use alternative devices to the MAJ-891 according to the compatibility table.
4. Where there are currently no alternative Olympus irrigation plugs for use such as with the CHF, HYF and VEF endoscopes, the customer should use an alternative scope in those situations or a non-Olympus irrigation plug provided it has been validated for use with the Olympus scope by the irrigation plug manufacturer.
5. Olympus will contact you to schedule a mutually beneficial time for an Olympus Field Representative to visit your facility and review the contents of this letter and the MAJ-891 reprocessing instructions.
6. If you have further distributed this product, identify your customers and forward them this letter.
7. Olympus requests that you acknowledge receipt of this letter and return the 'Response Form' to us.

Olympus requests that you report any complaints, including incidents of infection and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

Contact for enquiries.

Regulatory Affairs and Quality Assurance Department

Email : mes-ra.oml@olympus.com

Tel : (603) 7650 8990

Fax : (603) 7650 8999

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

Yours sincerely,

Hideki Nagai

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Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd.

Attachment 1 – Olympus Endoscopes compatible with the MAJ-891

Scope Series	Model Number	Model Name
Cystoscope (CYF Series)	CYF-240	CYF-240 Flexible Video CystoNephroscope
	CYF-240A	CYF-240A FLEXIBLE CYSTOSCOPE
	CYF-5	CYF-5 CYSTOSCOPE EVOLUTIONTI
	CYF-5A	N3627870 CYF-5A CYSTOSCOPE E
	CYF-5R	CYF-5R Flex CystoNephro Fiberscope Rever
	CYF-V2	CYF-V2 VISERA Cysto-Nephro v
	CYF-V2R	CYF-V2R Flex CystoNephro Videoscope Rev
	CYF-VA2	CYF-VA2 VISERA Cysto-Nephro
	CYF-VH	CYF-VH HD Flex CystoNephro Videoscope
	CYF-VHA	CYF-VHA HD FlexCystoNephroVideoscope Asp
	CYF-VHR	CYF-VHR HD FlexCystoNephroVideoscope Rev
Ureteroscope (URF Series)	URF-P5	N3627930 OLA URF-P5 URF-P5 FLEXIBLE URET
	URF-P6	URF-P6 SUPER-SLIM FLEXIBLE FIBEROPTIC UR
	URF-P6R	URF-P6R SUPER-SLIM FLEXIBLE FIBEROPTIC U
	URF-P7	URF-P7 Flex Uretero Fiberscope
	URF-P7R	URF-P7R Flex Uretero Fiberscope
	URF-V	URF-V EndoEYE Flexible Urete
	URF-V2	URF-V2 SLIM FLEXIBLE VIDEO URETEROSCOPE
	URF-V2R	URF-V2R SLIM FLEX VID URETERO SCOPE, REV
	URF-V3	URF-V3 URETEROSCOPE, FLEX, VIDEO, STD
	URF-V3R	URF-V3R URETEROSCOPE, FLEX, VIDEO, REV
Choledochoscope (CHF Series)	CHF-P20Q	CHF-P20Q CHOLEDOCHOINEPHRO CYS TOFIBERSC
	CHF-CB30L	CHF-CB30L TRANSLAPAROSCOPIC CH OLEDOCHOS
	CHF-BP30	CHF-BP30 OES CHOLEDOCHOFIBER
	CHF-P60	CHF-P60 OES CHOLEDOCHO
	CHF-V	CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF TYPE V
	CHF-V2	CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF-V2
	CHF-B260	TRANSDUODENAL CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF-B260
	CHF-BP260	EVIS LUCERA ULTRATHIN VIDEOSCOPE OLYMPUS CHF TYPE BP260
	CHF-XP260	EVIS LUCERA CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF TYPE XP260
	CHF-B290	EVIS LUCERA ELITE CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF-B290
Hysteroscope (HYF Series)	HYF-1T	OES HYSTEROFIBERSCOPE OLYMPUS HYF TYPE 1T
Ventriculoscope (VEF Series)	VEF-V (For JP only)	OLYMPUS VEF TYPE V

Attachment 2 – Compatible Alternative Devices to MAJ-891

Scope Series	Model Number	Compatible with MAJ-2092					Compatible with BPS-Y*				
		OCA	OEKG	OCS M	OCAP	OJ	OCA	OEK G	OCS M	OCA P	OJ
Cystoscope (CYF Series)	CYF-240	No	No	No	No	No	Yes	Yes	NA	Yes	NA
	CYF-240A	No	No	No	No	No	Yes	Yes	NA	Yes	NA
	CYF-5	Yes	Yes	No	Yes	Yes	Yes	Yes	NA	Yes	NA
	CYF-5A	Yes	Yes	No	Yes	Yes	Yes	Yes	NA	Yes	NA
	CYF-5R	Yes	NA	NA	NA	NA	Yes	Yes	NA	Yes	NA
	CYF-V2	Yes	Yes	No	Yes	Yes	Yes	Yes	NA	Yes	NA
	CYF-V2R	Yes	NA	NA	NA	NA	Yes	Yes	NA	Yes	NA
	CYF-VA2	Yes	Yes	No	Yes	Yes	Yes	Yes	NA	Yes	NA
	CYF-VH	Yes	Yes	No	Yes	Yes	Yes	Yes	NA	Yes	NA
	CYF-VHA	Yes	Yes	No	Yes	Yes	Yes	Yes	NA	Yes	NA
CYF-VHR	Yes	Yes	NA	NA	NA	Yes	Yes	NA	Yes	NA	
Ureterscope (URF Series)	URF-P5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	NA
	URF-P6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	NA
	URF-P6R	Yes	Yes	NA	Yes	NA	Yes	Yes	NA	Yes	NA
	URF-P7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	NA
	URF-P7R	Yes	Yes	NA	Yes	NA	Yes	Yes	NA	Yes	NA
	URF-V	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	NA
	URF-V2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	NA
	URF-V2R	Yes	Yes	NA	Yes	NA	Yes	Yes	NA	Yes	NA
	URF-V3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	NA
	URF-V3R	Yes	Yes	NA	Yes	NA	Yes	Yes	NA	Yes	NA
Choledochoscope (CHF Series)	CHF-P20Q	NA	NA	NA	No	No	No	No	No	No	No
	CHF-CB30L	No	No	No	No	No	No	No	No	No	No
	CHF-BP30	No	No	No	No	No	No	No	No	No	No
	CHF-P60	N(Y2)	N(Y2)	No	N(Y2)	N(Y2)	No	No	No	No	No
	CHF-V	NA	N(Y2)	No	N(Y2)	N(Y2)	No	No	No	No	No
	CHF-V2	NA	NA	Yes	Yes	Yes	No	No	No	No	No
	CHF-B260	NA	NA	NA	NA	No	No	No	No	No	No
	CHF-BP260	NA	NA	NA	NA	No	No	No	No	No	No
	CHF-XP260	NA	NA	NA	NA	No	No	No	No	No	No
CHF-B290	NA	N(Y2)	NA	N(Y2)	N(Y2)	No	No	No	No	No	
Hysteroscope (HYF Series)	HYF-1T	No	No	No	No	No	No	No	No	No	No
Ventriculoscope (VEF Series)	VEF-V	NA	NA	NA	NA	No	No	No	No	No	

The BPS-Y is not intended for use when performing high-frequency cauterization. Use the MAJ-2092 when performing high-frequency cauterization.

Response Form

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

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.: _____
Date : _____
Ref : 2024-008M

URGENT - FIELD SAFETY NOTICE

Re:Olympus to Provide Reprocessing Instruction and List of Available Alternative Devices to MAJ-891

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

- I DO NOT have affected product remaining. Product has been condemned or discarded.
- I DO have the affected product, which I will adhere to the reprocessing instruction of MAJ-891

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date

2024-008M FSN Customer Letter

Final Audit Report

2024-12-19

Created:	2024-12-18 (Australian Western Standard Time)
By:	Seo Ching Yeoh (seoching.yeoh@olympus.com)
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