

**URGENT: MEDICAL DEVICE ADVISORY NOTICE**  
**MAJ-891 Forceps/Irrigation Plug (Isolated Type)**

Product Name	Model/Catalog Number	Lot Number(s)	UDI
<i>Forceps/Irrigation Plug (Isolated Type)</i>	<i>MAJ-891</i>	<i>All</i>	<i>04953170063114</i>

Date: December 18, 2024

Attention: Endoscopy Department, Surgical Department, Risk Management

Dear Healthcare Professional:

Olympus is sending an advisory notice 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), 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.**

**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), and hysteroscopes (HYF series), although it should be noted that 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 in 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.**

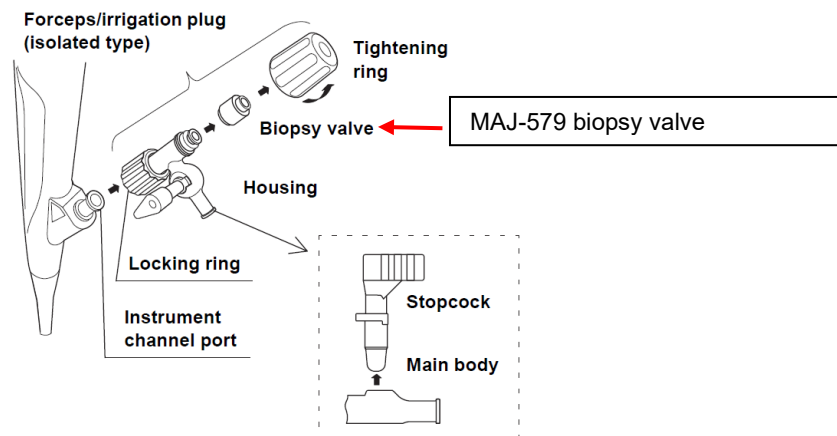


Figure 1 – MAJ-891 Forceps/Irrigation Plug

**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 MAJ-891 was previously discontinued in 2022 for the US market and the compatibility table below lists the available alternative devices to the MAJ-891 for Olympus cystoscopes (CYF series) and ureteroscopes (URF series), or hysteroscopes (HYF series). There are currently no alternative Olympus irrigation plugs for use with CHF and HYF endoscopes. 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 plug manufacturer.

If you have any questions regarding suitable alternatives to the MAJ-891, contact our Technical Assistance Center (TAC) at 1-800-848-9024, option 1, or your Olympus Sales Representative. **Please refer to Attachment 1 for a full listing of scope models and alternative devices.**

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

**\*Please contact our Technical Assistance Center to check the seal-port available in your country.**

**\*\*If available in your country.**

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 and Resources:**

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.

If you require additional information regarding the proper steps to reprocess MAJ-891, Olympus provides the following resources:

- You can contact our Technical Assistance Center (TAC) at 1-800-848-9024, option 1. The TAC department can assist in answering questions on MAJ-891 cleaning and reprocessing and obtaining additional copies of the MAJ-891 instructions and supplemental educational materials, including a wall chart for MAJ-891 cleaning and reprocessing.
- Olympus has a webpage dedicated to reprocessing information for Olympus urology equipment. Please visit our website at <https://medical.olympusamerica.com/urology-reprocessing-training>.
- Olympus America has dedicated field personnel, called Endoscopy Support Specialists (ESS), that visit customer sites to assess and observe customer reprocessing methods and provide reprocessing training and education. If you would like an ESS to visit your facility to review and train on the MAJ-891 cleaning and reprocessing instructions, please request a site visit by calling our TAC department at 1-800-848-9024, option 1.
- Olympus America offers an extensive program of educational programs for endoscopy, with specific courses on endoscope reprocessing for both nurses and reprocessing specialists. Please visit our website at <https://continuum.olympusprofed.com>.

### **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. Use alternative devices to the MAJ-891, according to the compatibility table above.
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this letter. Specifically, please ensure that all reprocessing personnel are completely knowledgeable and thoroughly trained on the MAJ-891 reprocessing instructions.
4. Olympus requests that you acknowledge receipt of this letter through our web portal:
  - a. Go to <https://olympusamerica.com/recall>
  - b. Enter the recall number "0465"
  - c. Complete the form as instructed.

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. Refer to the "Training and Resources" section above for additional resources.
6. If you have further distributed this product, identify your customers, and forward them this letter.

Olympus requests you to report any complaints, including incidents of infection, to our Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail [Cynthia.Ow@Olympus.com](mailto:Cynthia.Ow@Olympus.com).

Sincerely,

*Cynthia Ow*

Cynthia Ow  
Field Corrective Actions Lead, Americas

**Attachment 1 – Olympus Endoscopes compatible with the MAJ-891 and  
Compatible Alternative Devices to MAJ-891**

Scope Series	Model Number	Model Name	Compatible with MAJ-2092	Compatible with BPS-Y
Cystoscope (CYF Series)	CYF-240	CYF-240 Flexible Video CystoNephroscope	No	Yes
	CYF-5	CYF-5 CYSTOSCOPE EVOLUTIONI	Yes	Yes
	CYF-5A	N3627870 CYF-5A CYSTOSCOPE E	Yes	Yes
	CYF-5R	CYF-5R Flex CystoNephro Fiberscope Rever	Yes	Yes
	CYF-V2	CYF-V2 VISERA Cysto-Nephro v	Yes	Yes
	CYF-V2R	CYF-V2R Flex CystoNephro Videoscope Rev	Yes	Yes
	CYF-VA2	CYF-VA2 VISERA Cysto-Nephro Videoscope	Yes	Yes
	CYF-VH	CYF-VH HD Flex CystoNephro Videoscope	Yes	Yes
	CYF-VHA	CYF-VHA HD FlexCystoNephroVideoscope Asp	Yes	Yes
	CYF-VHR	CYF-VHR HD FlexCystoNephroVideoscope Rev	Yes	Yes
Ureterscope (URF Series)	URF-P5	N3627930 OLA URF-P5 URF-P5 FLEXIBLE URET	Yes	Yes
	URF-P6	URF-P6 SUPER-SLIM FLEXIBLE FIBEROPTIC UR	Yes	Yes
	URF-P6R	URF-P6R SUPER-SLIM FLEXIBLE FIBEROPTIC U	Yes	Yes
	URF-P7	URF-P7 Flex Uretero Fiberscope	Yes	Yes
	URF-P7R	URF-P7R Flex Uretero Fiberscope	Yes	Yes
	URF-V	URF-V EndoEYE Flexible Ureteroscope	Yes	Yes
	URF-V2	URF-V2 SLIM FLEXIBLE VIDEO URETEROSCOPE	Yes	Yes
	URF-V2R	URF-V2R SLIM FLEX VID URETERO SCOPE, REV	Yes	Yes
	URF-V3	URF-V3 URETEROSCOPE, FLEX, VIDEO, STD	Yes	Yes
	URF-V3R	URF-V3R URETEROSCOPE, FLEX, VIDEO, REV	Yes	Yes
Choledochoscope (CHF Series)	CHF-P20Q	CHF-P20Q CHOLEDOCHOINEPHRO CYS TOFIBERSCOPE	No	No
	CHF-CB30L	CHF-CB30L TRANSLAPAROSCOPIC CHOLEDOCHOSCOPE	No	No
	CHF-BP30	CHF-BP30 OES CHOLEDOCHOFIBER	No	No
	CHF-P60	CHF-P60 OES CHOLEDOCHOSCOPE	No	No
Hysteroscope (HYF Series)	HYF-1T	OES HYSTEROFIBERSCOPE OLYMPUS HYF TYPE 1T	No	No