URGENT: MEDICAL DEVICE CORRECTION

InstaClear Sheath

Product Name: InstaClear Sheath
Model/Catalog Number: See Appendix
Lot Number/UDI-DI: See Appendix

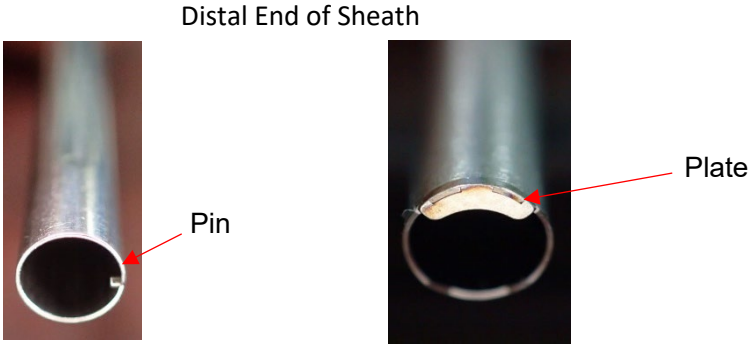
Date: May 1, 2024

Attention: ENT Department, Risk Management Department

Dear Healthcare Professional.

Olympus is writing to inform you of a Field Corrective Action on the Olympus InstaClear Sheath models listed in the attached Appendix. These products are intended to be used with rigid rod endoscopes in order to maintain clear visualization of endoscopic procedures without having to remove the scope from the surgical site. The device is indicated for use during routine diagnostic procedures and during endoscopic sinus surgery.

Reason for Action:
Olympus is taking this corrective action after investigating a complaint for an InstaClear Sheath (Model # LCS4K30BTOL) in which the plate on the distal end of the sheath broke off during a procedure. Olympus has received sixty-seven (67) complaints across all sheath models related to breakage or damage to the pin or plate at the distal end of the InstaClear Sheath since the product was launched in 2016. Four (4) complaints were reported as serious injuries. The image of the pin and plate is below.



In an effort to maximize patient safety and mitigate any immediate and potential risk to patient health, Olympus is notifying users of these complaints and is providing the attached labeling Addendum with updated instructions for sheath installation and setup. The Addendum includes new Warnings to inspect the InstaClear Sheath upon removal from the patient to determine if there are any missing components and to immediately retrieve any fragments retained within the patient.

Risk to Health:
The pin or plate breaking off the tip of the InstaClear sheath can lead to potential patient harms. Increased force when applying the sheath to the rigid scope can damage the pin or plate and increase the risk of dislodging the

pin or plate from the sheath. This may lead to a delay in initiating a procedure or a foreign body (broken pin or plate) in the patient, potentially requiring imaging and prolonged operative time to locate and remove the broken piece. Additionally, tissue injury or bleeding could occur due to exposed sharp edges. A broken piece remaining in the patient could potentially lead to an inflammatory reaction (granuloma), or infection.

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 Medical Device Correction Action as well as the attached labeling "Addendum".
2. Inspect your inventory and identify any devices with the model names specified above. Please check all areas of the hospital to determine if any of these devices remain in inventory. Add a copy of the enclosed addendum with your remaining inventory. This is not a product removal action. You may continue to use the products, but in accordance with the attached labeling addendum.
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification and addendum.
4. If you have further distributed this product, identify your customers, and forward them this notification.
5. Access the Olympus recall portal to indicate that you have received this notification.
    a) Go to https://olympusamerica.com/recall
    b) Enter the recall number "0445"
    c) Complete the form as instructed and include your account ID number

Olympus requests you to report any complaints, including breakage of the InstaClear Sheath pin or plate, to the 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 at Cynthia.Ow@olympus.com

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas

OLYMPUS

Appendix: InstaClear Sheath Medical Device Correction Instruction for Use Addendum Affected Products and Product Lots

Product Name	Model/Catalog Number	Lot Number(s)	UDI-DI
INSTACLEAR SHEATH, OLY 0degree 4K ULTRA	LCS4K00UNOL	All	Not Listed
INSTACLEAR SHEATH, OLY 45degree 4K BOT	LCS4K45BTOL	All	Not Listed
INSTACLEAR SHEATH, OLY 45degree 4K TOP	LCS4K45TPOL	All	Not Listed
INSTACLEAR SHEATH, OLYMPUS 0 DEGREE SCOP	LCS1500UNOL	All	00821925040137
INSTACLEAR SHEATH, OLYMPUS 30 DEGREE BOT	LCS1530BTOL	All	00821925040151
INSTACLEAR SHEATH, OLYMPUS 30 DEGREE TOP	LCS1530TPOL	All	00821925040144
INSTACLEAR SHEATH, OLYMPUS 30d, 4K BOTT	LCS4K30BTOL	All	Not Listed
INSTACLEAR SHEATH, OLYMPUS 30d, 4K TOP	LCS4K30TPOL	All	Not Listed
INSTACLEAR SHEATH, OLYMPUS 45 DEGREE BOT	LCS1545BTOL	All	00821925040175
INSTACLEAR SHEATH, OLYMPUS 45 DEGREE TOP	LCS1545TPOL	All	00821925040168
INSTACLEAR SHEATH, OLYMPUS 70 DEGREE BOT	LCS1570BTOL	All	00821925040199
INSTACLEAR SHEATH, OLYMPUS 70 DEGREE TOP	LCS1570TPOL	All	00821925040182
INSTACLEAR SHEATH, OLYMPUS 70d, 4K BOTT	LCS4K70BTOL	All	Not Listed
INSTACLEAR SHEATH, OLYMPUS 70d, 4K TOP	LCS4K70TPOL	All	Not Listed
INSTACLEAR SHEATH, STORZ 30 DEGREE BOT	LCS1830BTST	All	00821925040083
INSTACLEAR SHEATH, STORZ 30 DEGREE TOP	LCS1830TPST	All	00821925040076
INSTACLEAR SHEATH, STORZ 45 DEGREE BOT	LCS1845BTST	All	00821925040106
INSTACLEAR SHEATH, STORZ 45 DEGREE TOP	LCS1845TPST	All	00821925040090
INSTACLEAR SHEATH, STORZ 70 DEGREE BOT	LCS1870BTST	All	00821925040120
INSTACLEAR SHEATH, STORZ 70 DEGREE TOP	LCS1870TPST	All	00821925040113
LENS CLEANER SHEATH FOR 4MM X 180MM STOR	LCS1800UNST	All	00821925040069

April 16, 2024

InstaClear™ Lens Cleaner Revisions

The Instructions for Use (PN0024666) and Insert (PN0022808) for your InstaClear Lens Cleaner have been updated. Below is a summary of the changes.

What has Changed:

A. Console IFU (main system manual), PN0024666:

1. Section 3.1 Indications for Use, page 6. The following warning has been added.

WARNING

- Not intended for use beyond the sinuses.

2. Section 5.4 Sheath Connection, page 19. Additional information (noted in blue) has been added to the Caution statement.

CAUTION

Do not force the sheath hub all the way to the lightpost as a gap between the sheath hub and lightpost should be seen. If a gap is not visible, damage to the distal end may occur. After sliding the sheath over the scope, inspect the sheath distal end to ensure it is not damaged, loose, bent, or broken, and nothing protrudes from the end.

3. Section 6.3 Procedure After Use, page 26. Additional heading and warning paragraph has been added to this section.

After Surgery

WARNING

- Inspect devices immediately upon removal from the patient. If there are any signs of damage or missing components, inspect the operative field for any retained fragment. If found, immediately remove from patient.

B. Sheath IFU (1 page leaflet), PN0022808

1. Section “Indications for Use” section has been added from the system manual.

Intended to clear the end of a rigid rod endoscope in order to maintain clear visualization of endoscopic procedures without having to remove the scope from the surgical site. The device is indicated for use during routine diagnostic procedures and during endoscopic sinus surgery.

WARNING! Not intended for use beyond the sinuses.

2. Section “Intended User”: Three additional Caution statements have been added.

CAUTION! Before use, inspect the outer surfaces of the sheath for any rough surfaces or sharp edges which may cause harm.

CAUTION! Do not force the sheath hub all the way to the lightpost as a gap between the sheath hub and lightpost should be seen. If a gap is not visible, damage to the distal end may occur.

CAUTION! After sliding the sheath over the scope, inspect the sheath distal end to ensure it is not damaged, loose, bent, or broken, and nothing protrudes from the end.

3. Section “InstaClear CONSOLE AND FOOTPEDAL”. Additional heading and warning paragraph has been added.

After Surgery

WARNING! Inspect devices immediately upon removal from the patient. If there are any signs of damage or missing components, inspect the operative field for any retained fragment. If found, immediately remove from patient.

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