



January XX, 2020
Olympus reference: QIL 153-014
Online form reference: XYZ
Online form pin: XYZ

URGENT FIELD SAFETY NOTICE

RECALL OF CERTAIN OLYMPUS ENDOTHERAPY PRODUCTS DUE TO THE INTEGRITY OF STERILE PACKAGING

Attention: **Endoscopy Department, Risk Management Department**

| Affected Products and lot numbers | Manufacturing Date |
|-----------------------------------|---|
| See Attachment 1 | Prior to 15 th November 2020 |

Dear Healthcare Professional,

Olympus has become aware of an issue that requires your urgent attention. This letter pertains to the **integrity of the sterile packaging of certain Olympus EndoTherapy products**, which are supplied as sterile single-use devices. Please review Attachment 1 for a complete list of Olympus EndoTherapy products subject to this Field Safety Notice, as well as the affected Lot Numbers. Attachment 2 provides guidance to help your facility locate the manufacturing date and Lot Number of the devices currently in your possession.

Due to an anomaly in the packaging process of the devices and associated Lot Numbers listed in Attachment 1, it is possible that the sterility of these products is compromised due to a defective seal, which may allow a breach of the package's sterile barrier. This breach may be difficult to detect with the naked eye.

Olympus has not received any complaints of injury associated with defective packaging seals. However, it is possible that the use of non-sterile products may introduce microbes and potentially increase the risk of postoperative infection. To prevent this potential risk to patient health, Olympus requests that you immediately follow Steps 1-5 below.

Action steps to be taken by the end user:

Our records indicate that you have purchased one or more of the affected products. Olympus requires you to take the following actions:

1. Please inspect your inventory of Olympus EndoTherapy products to identify any of the specified Olympus models and Lot Numbers listed in Attachment 1. The manufacturing dates for all of these devices were on or before 15 November, 2020. The model number, Lot Number and the manufacturing date can be found on the box in which each device came. If you cannot find the manufacturing date due having disposed of a device's box, please inspect the lot number on the sterile pack as instructed in Attachment 2.
2. **Immediately cease any further use of any affected product you have, remove it from your inventory and quarantine it until it is shipped back to Olympus.**



3. Call your Olympus customer service representative at XXX-XXX-XXXX to obtain a Returned Goods Authorization so that you may return the product with no charge to you. Olympus will issue a credit or replacement to your facility for any returned products.
4. Please note on the enclosed questionnaire that you have received, understand, and have followed this information.
5. If you have further distributed the products listed in Attachment 1, identify your customers, forward them this Field Safety Notice including the attachments, appropriately document your notification process and let us know the end-customer feedbacks accordingly.

To access the online reply form please scan this QR code with your mobile phone and enter the data accordingly:

QR CODE HERE

Alternatively, please use this url: (URL LINK). Your unique reference to access the page securely is noted above.

Or scan and email your completed form response to olympusresponse@mktpoint.com

If you do not have access to a phone or computer, please fill out the form below and send using the envelope enclosed to the pre-printed address.

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

Olympus is aware that the implementation of these measures may cause inconvenience to you. However, we fully appreciate your prompt cooperation in addressing this situation and working with us to ensure your patients are treated only with the safe and effective Olympus products that you have come to rely upon.

In case of any questions, please do not hesitate to contact your local Olympus partner who will support you or make the necessary arrangements.

Yours sincerely,

Olympus Subsidiary/Distributor

Attachments:

1. List of affected products, models, and Lot Numbers.
2. Directions for locating manufacturing date and Lot Number on devices in your possession.



REPLY FORM – QIL 153-014 [customer ID]

| OLYMPUS URGENT FIELD SAFETY NOTICE | | | |
|---|------------|-----------------------------------|---|
| RECALL OF CERTAIN OLYMPUS ENDOTHERAPY PRODUCTS DUE TO THE INTEGRITY OF STERILE PACKAGING OF OLYMPUS ENDOTHERAPY PRODUCTS | | | |
| [Name & Address of Hospital/Medical Facility] | | | |
| [Dept/Attn] | | | |
| [Date] | | | |
| Article no. | Model name | LOT No. to be returned to Olympus | Quantities to be returned to Olympus <small>(please indicate if a <u>complete</u> or <u>opened</u> box are still available (e.g. 3 x complete, 1x opened). If no affected EndoTherapy products will be returned please insert 0)</small> |
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Dear Sirs,

Herewith we confirm the receipt of your Field Safety Notice. We understand the contents of this letter and have inspected our inventory of Olympus EndoTherapy products, have ceased using all affected products, and have quarantined the affected products that we located.

Name (Signature) _____
 Name (Print) _____
 Position _____

Please scan / email your completed paper form response to olympusresponse@mktpoint.com. Alternatively, use the envelope enclosed and send to the pre-printed address.

Attachment 1

| Product Category | Article Code | Model Name | Affected Lot No. |
|--------------------------------------|--------------|--------------|---|
| EUS-FNA Aspiration Needle | N1029120 | NA-200H-8022 | 93K,94K,99K |
| | N1053020 | NA-200H-8022 | 01K,02K,03K,04K,05K,06K,92K,93K,94K,95K,96K,97K,98K,99K,9XK,9YK,9ZK |
| ERCP Stone Extraction Balloon | N5383730 | B-V232P-A | 02V,03V,04V,05V,06V,07V,08V,09V,0XV |
| | N5383830 | B-V232P-B | 04V,06V,07V,08V,09V,0XV |
| | N5383930 | B-V242Q-A | 02V,03V,04V,05V,06V,07V,08V,09V,0XV |
| | N5384030 | B-V242Q-B | 9ZV,01V,02V,03V,04V,05V,06V,07V,08V,09V,0XV |
| | N5768130 | B-V233V-A | 04K,05K,06K,07K,08K,09K,0XK |
| ERCP Double Lumen Cannula | N2608930 | PR-V614M | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| Balloon Catheter | 026918 | B5-2Q | 01K,03K,04K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | 026922 | B7-2Q | 01K,02K,03K,06K,07K,08K,98K,99K,9XK,9YK,9ZK |
| Basket wire for Lithotripter | 026524 | MAJ-244 | 01K,02K,04K,05K,06K,07K,09K,92K,93K,94K,95K,97K,9XK |
| | 026527 | MAJ-247 | 01K,02K,03K,92K,93K,94K,97K,98K,99K,9XK,9YK,9ZK |
| Biliary Stent | N1798430 | PBD-203-0703 | 97K |
| | N1798530 | PBD-203-0704 | 04K |
| | N1798630 | PBD-203-0707 | 95K,96K,97K,98K,99K |
| | N1798730 | PBD-203-0710 | 01K,02K |
| Electrosurgical Knife -ITknife2 | N2613830 | KD-611L | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| Electrosurgical Knife - ITknife nano | N4468930 | KD-612L | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N4469130 | KD-612U | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| Electrosurgical Knife - Hookknife | N3046030 | KD-620QR | 01K,02K,03K,04K,05K,06K,07K,08K,98K,99K,9XK,9YK,9ZK |
| | N3046130 | KD-620UR | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N1080330 | KD-620LR | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| Electrosurgical Knife - TTknife | N2119630 | KD-640L | 01K,02K,03K,04K,05K,06K,07K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| Electrosurgical Knife - Dualknife | N3498730 | KD-650L | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N3498830 | KD-650Q | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N3498930 | KD-650U | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| Electrosurgical Knife - DualknifeJ | N5405030 | KD-655L | 01K,02K,03K,04K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5405130 | KD-655Q | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5405230 | KD-655U | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| Grasping Forceps to support ESD | N3636730 | LA-201 | 97K |
| | N3636830 | LA-202 | 01K,02K,92K,93K,94K,95K,96K,97K,98K,99K,9XK,9YK,9ZK |
| EMR Kit | N1072230 | K-010 | 04K,05K,06K,07K,08K,09K,92K,93K,94K,95K,96K,97K,98K,99K,9XK |
| Electrosurgical Snare | N3642430 | SD-210U-10 | 97V,98V,99V,9XV,03V,04V,05V,06V,07V |
| | N3642530 | SD-210U-15 | 97V,98V,99V,9YV,03V,04V,05V,06V,07V |
| | N3642630 | SD-210U-25 | 97V,98V,9YV,03V,04V,05V,06V,07V |
| | N4470430 | SD-221L-25 | 01K,02K,03K,04K,05K,07K,08K,09K,0XK,93K,95K,96K,97K,98K,99K,9XK,9YK,9ZK |
| | N1074530 | SD-230U-20 | 94K,95K |
| | N4471230 | SD-230U-20 | 97V,98V,99V,9XV,03V,04V,05V,06V,07V |
| | N3642730 | SD-240U-10 | 97V,98V,99V,9XV,03V,04V,05V,06V,07V |
| | N3642830 | SD-240U-15 | 97V,99V,9XV,9YV,03V,04V,05V,06V,07V |
| | N3642930 | SD-240U-25 | 97V,98V,99V,9YV,03V,04V,05V,06V,07V |
| | N5771330 | SD-400U-10 | 01K,92K,93K,99K,9XK,9YK,9ZK |
| | N5998230 | SD-400U-10 | 97V,98V,9XV,9YV,03V,05V,06V |
| | N5771430 | SD-400U-15 | 01K,02K,92K,93K,99K,9XK,9YK,9ZK |
| | N5998330 | SD-400U-15 | 97V,98V,03V,04V,06V |
| | Loop Cutter | N5781130 | FS-410U |

| Product Category | Article Code | Model Name | Affected Lot No. |
|------------------|--------------|---|---|
| Injection Needle | N3046830 | NM-400L-0421 | 03K,04K,05K,06K,98K,99K,9XK,9YK |
| | N3046930 | NM-400L-0421 | 01K,98K,99K,9XK,9YK,9ZK |
| | N5415930 | NM-400L-0421 | 01K,02K,03K,04K,05K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N5416030 | NM-400L-0423 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3047330 | NM-400L-0425 | 04K,05K,06K,07K,08K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5416130 | NM-400L-0425 | 01K,02K,03K,05K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3047130 | NM-400L-0523 | 01K,02K,03K,04K,05K,06K,07K,08K,98K,99K,9XK,9YK,9ZK |
| | N5416230 | NM-400L-0523 | 01K,02K,03K,05K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3047430 | NM-400L-0525 | 01K,98K,99K,9XK,9ZK |
| | N5416330 | NM-400L-0525 | 01K,04K,05K,07K,09K,98K,99K,9XK,9YK,9ZK |
| | N5416430 | NM-400L-0621 | 01K,02K,03K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N3047230 | NM-400L-0623 | 01K,04K,05K,06K,07K,08K,09K,9XK,9YK,9ZK |
| | N5416530 | NM-400L-0623 | 01K,02K,03K,05K,07K,08K,09K,99K,9XK,9YK,9ZK |
| | N3047530 | NM-400L-0625 | 01K,04K,07K,08K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5416630 | NM-400L-0625 | 01K,04K,05K,98K,99K,9XK,9YK,9ZK |
| | N5416730 | NM-400U-0323 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3047730 | NM-400U-0423 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5416830 | NM-400U-0423 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N5416930 | NM-400U-0425 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3047830 | NM-400U-0523 | 01K,02K,03K,04K,05K,06K,07K,98K,99K,9XK,9YK,9ZK |
| | N5417030 | NM-400U-0523 | 01K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3048130 | NM-400U-0525 | 01K,02K,03K,05K,06K,09K,0XK,98K,99K,9YK |
| | N5417130 | NM-400U-0525 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3047930 | NM-400U-0623 | 01K,03K,05K,06K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5417230 | NM-400U-0623 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3048230 | NM-400U-0625 | 01K,02K,03K,05K,06K,09K,98K,9XK,9YK |
| | N5417330 | NM-400U-0625 | 01K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3048330 | NM-400Y-0423 | 03K,04K,05K,07K,0XK,98K,9XK,9YK |
| | N5418030 | NM-400Y-0423 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N5417430 | NM-401L-0423 | 01K,02K,03K,04K,05K,06K,07K,08K,98K,99K,9XK,9YK,9ZK |
| | N3048730 | NM-401L-0425 | 01K,02K,03K,04K,05K,06K,07K,98K,99K,9XK,9YK,9ZK |
| | N5417530 | NM-401L-0425 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |
| | N3048530 | NM-401L-0523 | 01K,04K,98K,99K,9XK,9YK,9ZK |
| | N5417630 | NM-401L-0523 | 01K,02K,03K,04K,05K,06K,07K,08K,98K,99K,9XK,9YK,9ZK |
| | N3048830 | NM-401L-0525 | 98K,99K,9XK,9YK |
| | N5417730 | NM-401L-0525 | 01K,02K,03K,04K,05K,06K,07K,08K,98K,99K,9XK,9YK,9ZK |
| | N3048630 | NM-401L-0623 | 02K,03K,04K,06K |
| | N5417830 | NM-401L-0623 | 01K,02K,03K,04K,05K,06K,07K,08K,98K,99K,9XK,9YK,9ZK |
| | N5417930 | NM-401L-0625 | 01K,02K,04K,05K,06K,98K,99K,9XK,9YK,9ZK |
| | N5405330 | NM-600L-0421 | 01K,02K,03K,05K,07K,08K,98K,99K,9YK,9ZK |
| | N5405630 | NM-600L-0423 | 01K,02K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5405730 | NM-600L-0523 | 01K,02K,04K,06K,07K,09K,0XK,98K,99K,9YK,9ZK |
| N5406030 | NM-600L-0525 | 01K,0XK,9ZK | |
| N5405530 | NM-600L-0621 | 01K,03K,04K,08K,0XK,98K,9XK,9YK,9ZK | |
| N5406230 | NM-610L-0421 | 03K,04K,08K | |
| N5406530 | NM-610L-0423 | 01K,02K,03K,04K,05K,06K,07K,08K,0XK,98K,99K,9XK,9YK,9ZK | |
| N5406830 | NM-610L-0425 | 02K,03K,05K,07K,08K,0XK,98K,99K,9YK,9ZK | |
| N5407130 | NM-610L-0426 | 01K,02K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK | |
| N5406930 | NM-610L-0525 | 01K,02K,03K,04K,05K,0XK,98K,99K,9XK,9ZK | |
| N5407230 | NM-610U-0323 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK | |

| Product Category | Article Code | Model Name | Affected Lot No. |
|-----------------------------|--------------|---------------|---|
| Injection Needle | N5407330 | NM-610U-0423 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5407830 | NM-610U-0425 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5408330 | NM-610U-0426 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5407430 | NM-610U-0523 | 01K,02K,03K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5407930 | NM-610U-0525 | 01K,02K,03K,04K,05K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5407530 | NM-610U-0623 | 01K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N5408030 | NM-610U-0625 | 01K,02K,04K,06K,0XK,99K,9XK,9YK,9ZK |
| | N5407630 | NM-610U-1825 | 01K,02K,04K,05K,06K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| EBUS-TBNA Aspiration Needle | N5408130 | NM-610U-1826 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N2656630 | NA-201SX-4021 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,92K,93K,94K,95K,96K,97K,98K,99K,9XK,9YK,9ZK |
| | N1775830 | NA-201SX-4022 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,92K,93K,94K,95K,96K,97K,98K,99K,9XK,9YK,9ZK |
| | N1775930 | NA-201SX-4022 | 07K,08K,92K,93K |
| | N5432630 | NA-201SX-4021 | 95V,96V,97V,98V,99V,9XV,9YV,9ZV,01V,02V,03V,04V,05V,06V,07V,08V,09V,0XV |
| | N5432330 | NA-201SX-4022 | 95V,96V,97V,98V,99V,9XV,9YV,9ZV,01V,02V,03V,04V,05V,06V,07V,08V,09V,0XV |
| TBNA Aspiration Needle | N5432430 | NA-201SX-4022 | 95V,96V,97V,98V,99V,9XV,9YV,9ZV,01V,02V,03V,04V,05V,06V,07V,08V,09V,0XV |
| | N1880630 | NA-401D-1321 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N1880730 | NA-401D-1521 | 01K,02K,03K,04K,05K,06K,07K,08K,0XK,98K,99K,9XK,9YK,9ZK |
| | N1880830 | NA-411D-1321 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N1880930 | NA-411D-1521 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| Guide Sheath Kit | N2369930 | NA-601D-1519 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | N3041830 | K-201 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,95K,96K,97K,98K,99K,9XK,9YK,9ZK |
| | N3041930 | K-202 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,95K,96K,97K,98K,99K,9XK,9YK,9ZK |
| | N3042030 | K-203 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,95K,96K,97K,98K,99K,9XK,9YK,9ZK |
| Guiding Device | N3042130 | K-204 | 01K,02K,03K,04K,05K,06K,07K,08K,09K,95K,96K,97K,98K,99K,9XK,9YK,9ZK |
| | N5767130 | CC-220DR | 03K,04K,05K,06K,07K,08K,09K,0XK |
| Balloon Catheter | N3530530 | B5-2C | 01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK |
| | 026921 | B7-2C | 01K,02K,03K,04K,05K,06K,07K,08K,09K,98K,99K,9XK,9YK,9ZK |

Attachment 2

The image shows a detailed label for an Olympus medical device. The label is divided into several sections. At the top left, it indicates a quantity of 1. To the right, it specifies a use-by date of 2023-09-30. Below this, there are two crossed-out icons (a person and a recycling symbol) with the text 'Single use only' and 'Do not resterilize' in both English and Japanese. A 'STERILE EO' box indicates ethylene oxide sterilization. A person icon is next to the text 'TYPE BF applied part' and 'BF形装着部'. At the bottom left, there is a '管理医療機器' (Controlled Medical Device) section with general name, certification number, and sales name. On the right side, there are two red-bordered boxes with callout lines pointing to specific information: one for the manufacturing date (2020.11.16) and another for the lot number (0XK). The Olympus logo is at the bottom center.

Quantity 数量 1

Use by (Exp. date) 使用期限
2023-09-30

Single use only 再使用禁止
Do not resterilize 再滅菌禁止

STERILE EO エチレンオキサイドガス滅菌済

TYPE BF applied part
BF形装着部

管理医療機器
一般的名稱：単回使用高周波処置用内視鏡能動器具
医療機器認証番号：220ABBZX00223000号
販売名：ディスポーザブル高周波ナイフ KD-650

GK6907T403
2020.11.16

LOT ロット番号
0XK

CE 0197

OLYMPUS

Manufacturing date:
On or before 2020.11.15: Affected product

Lot number