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 15th 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 THEI 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** (please indicate if a complete or opened box are still available (e.g. 3 x complete, 1x opened). If no affected EndoTherapy products will be returned please insert 0)

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	98K,99K,9XK

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.
	N5407330	NM-610U-0423	01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK
Injection Needle	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
	N5408130	NM-610U-1826	01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK
EBUS-TBNA Aspiration Needle	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
	N5432430	NA-201SX-4022	95V,96V,97V,98V,99V,9XV,9YV,9ZV,01V,02V,03V,04V,05V,06V,07V,08V,09V,0XV
TBNA Aspiration Needle	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
	N2369930	NA-601D-1519	01K,02K,03K,04K,05K,06K,07K,08K,09K,0XK,98K,99K,9XK,9YK,9ZK
Guide Sheath Kit	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
	N3042130	K-204	01K,02K,03K,04K,05K,06K,07K,08K,09K,95K,96K,97K,98K,99K,9XK,9YK,9ZK
Guiding Device	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