

Date: August XX, 2023

Olympus Reference: QIL FY24-EMEA-14-FY24-OMSC-12

URGENT FIELD SAFETY NOTICE

Recall - Market removal of Disposable EMR KIT and Distal Attachments

DISPOSABLE EMR KIT: K-001, K-002, K-003, K-004, K-011, K-012

Lot: please refer to Attachment 1

Distal Attachment (Please refer to Attachment 1): MH-462, MH-463, MH-464, MH-465, MH-466, MH-483, MH-587, MH-588, MH-589, MH-590, MH-591, MH-592, MH-593, MH-594, MH-595, MH-596, MH-597, MH-598, MAJ-289, MAJ-290, MAJ-291, MAJ-292, MAJ-293, MAJ-294, MAJ-295, MAJ-296, MAJ-297, MAJ-663, MAJ-664, MAJ-665, MAJ-666

Lot: please refer to Attachment 1

Attention: Endoscopy Department, Risk Management Department

Dear Health Care Practitioner,

Olympus has become aware of an issue that requires your attention. This letter pertains to the DISPOSABLE DISTAL ATTACHMENT included in DISPOSABLE EMR KIT and Distal Attachment referenced above. The DISPOSABLE DISTAL ATTACHMENT has been designed to be attached to the distal end of the endoscope. It is to be used in combination with electrosurgical snares for endoscopic mucosal resection within the gastrointestinal tract. The distal attachment is also suitable for use in maintaining a suitable depth in the endoscopic field of view. The Distal Attachment has been designed to be attached to the Distal End of an Olympus endoscope to facilitate endoscopic therapy.

The products referenced above contain di-2-ethylhexyl phthalate (DEHP). Olympus has previously announced on the labeling that the product contains DEHP.

Since Olympus has confirmed that alternative products can be provided, Olympus has decided to ask our customers to cease using the subject products and to further remove them.

Risk to Health

In general, potential patient harms associated with the use of plastic products containing DEHP include: chemical exposure, hypersensitivity/allergic reaction, endocrine disruption, reproductive and developmental toxicity and carcinogenicity. Long term DEHP toxicity may occur if a distal attachment inadvertently becomes a retained foreign body with resultant leaching over time. Olympus has not received any reports of these harms occurring from the use of our products.

Action steps to be taken by the end user:

Olympus has determined based upon our distribution records that your facility is in possession of one or more affected devices with a Lot number shown in Attachment 1. Olympus requires you to take the following actions:

1. Immediately assess any product you have to identify the product number with affected lot listed in this communication, **cease use of product and quarantine any affected product**. The image below depicts the area where the lot number is identified. The lot# is on the Carton box and Pack. Please refer to the Attachment 2 for the identification of the subject products.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN.
3. If you have further distributed this product, identify your customers, and forward them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.
4. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative **XX.XX.XXXX** latest by **XX.XX.XXXX**.
5. Your local Olympus representative will contact you to arrange return and appropriate reimbursement. Olympus will issue a Return Material Authorization to return any affected product at no charge to you. Olympus will issue a credit to your facility for your affected product.

Olympus requests that you report complaints, including patient physical condition suspected to be affected by DEHP, to Olympus. Please report complaints to **[local facility complaint reporting contact]**. **[If applicable:]** Adverse events experienced with the use of this product may also be reported **[local competent authority]** by **[method]**.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me at **[phone number]** or **[e-mail address]**.

Sincerely,

[SIGNATORY]
[Contact Name]

Attachment 1 – affected devices

1) Disposable EMR Kit

Material ID	Model number	Description	Lot Number
025846	K-001	K-001 EMR KIT UGI	0XI, 0YI, 12I, 14I, 15I, 16I, 17I, 26K, 27K, 28K, 29K, 2XK, 2YK, 2ZK, 31K, 32K
025847	K-002	K-002 EMR KIT UGI	0XI, 0YI, 12I, 13I, 14I, 16I, 17I, 27K, 2XK, 2YK, 2ZK
025848	K-003	K-003 EMR KIT UGI	0XI, 0YI, 12I, 13I, 14I, 15I, 16I, 17I, 25K, 26K, 27K, 28K, 29K, 2XK, 2YK, 2ZK
025849	K-004	K-004 EMR KIT UGI	16I, 17I, 26K
N2485230	K-011	K-011 disposable EMR-Kit	0XI, 15I, 17I
N2485330	K-012	K-012 disposable EMR-Kit	16I, 17I

2) Distal Attachment

Material ID	Model Number	Description	Lot Number
028933	MH462	MH462#EMR-1 MUCOSAL RES. CAP,5	All lot
028938	MH463	MH463#EMR-2 MUCOSAL RES. CAP,5	All lot
028942	MH464	MH464#EMR-5 MUCOSAL RES.CAP,5P	All lot
028941	MH-465	MH-465#EMR-4 RESECTIONCAP 5 PC	All lot
028940	MH466	MH466# EMR-3 MUCOSAL RES.CAP,5	All lot
028948	MH-483	MH-483#MUCOSAL RESECTION	All lot
028548	MH-587	MH-587# DISTAL ATTACHMENT	All lot
028549	MH-588	MH-588# DISTAL ATTACHMENT	All lot
028550	MH-589	MH-589 DISTAL ATTACHMENT	All lot
028551	MH-590	MH-590# DISTAL ATTACHMENT	All lot
028552	MH-591	MH-591# DISTAL ATTACHMENT	All lot
028553	MH-592	MH-592# DISTAL ATTACHMENT	All lot
028554	MH-593	MH-593# DISTAL ATTACHMENT	All lot
028555	MH-594	MH-594# DISTAL ATTACHMENT	All lot
028556	MH-595	MH-595# DISTAL ATTACHMENT	All lot
028557	MH-596	MH-596# DISTAL ATTACHMENT	All lot
028558	MH-597	MH-597# DISTAL ATTACHMENT	All lot

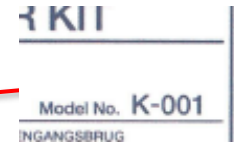
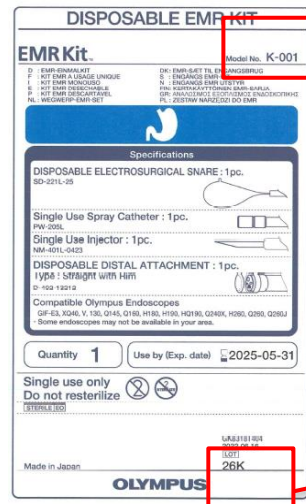
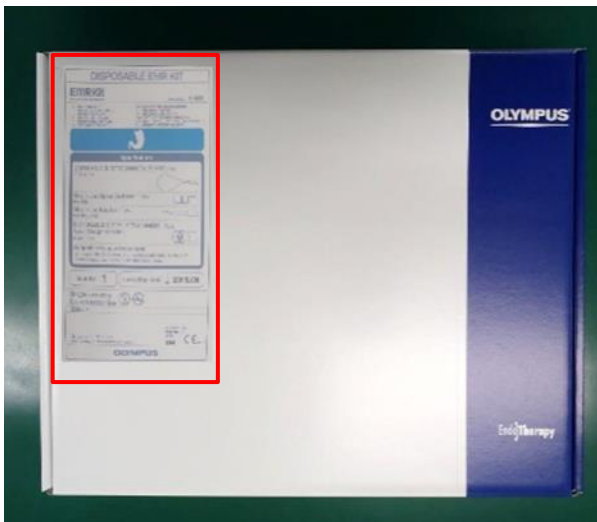
028559	MH-598	MH-598# DISTAL ATTACHMENT	All lot
028965	MAJ-289	MAJ-289 DISTAL ATTACHMENT	All lot
028966	MAJ-290	MAJ-290 DISTAL ATTACHMENT	All lot
028967	MAJ-291	MAJ-291 DISTAL ATTACHMENT	All lot
028968	MAJ-292	MAJ-292 DISTAL ATTACHMENT	All lot
028969	MAJ-293	MAJ-293 DISTAL ATTACHMENT	All lot
028970	MAJ-294	MAJ-294 DISTAL ATTACHMENT	All lot
028971	MAJ-295	MAJ-295 DISTAL ATTACHMENT	All lot
028972	MAJ-296	MAJ-296 DISTAL ATTACHMENT	All lot
028973	MAJ-297	MAJ-297 DISTAL ATTACHMENT	All lot
026694	MAJ-663	MAJ-663 DISTAL ATTACHMENT	All lot
026695	MAJ-664	MAJ-664 DISTAL ATTACHMENT	All lot
026696	MAJ-665	MAJ-665 DISTAL ATTACHMENT	All lot
026697	MAJ-666	MAJ-666 DISTAL ATTACHMENT	All lot

Attachment 2 – Identification of the subject product

1) Disposable EMR Kit

- You can find the product name and Lot number on the carton box.

Carton box

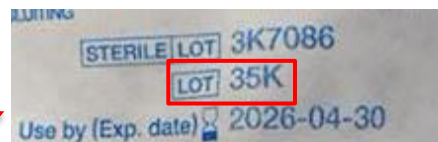
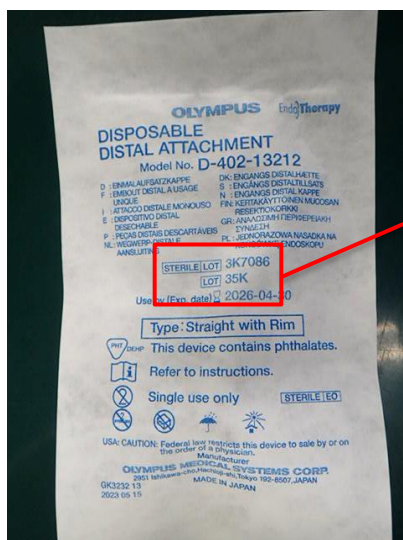


Model No.

Lot

- You can find the product name and Lot number on the sterile pack.

Sterile Pack

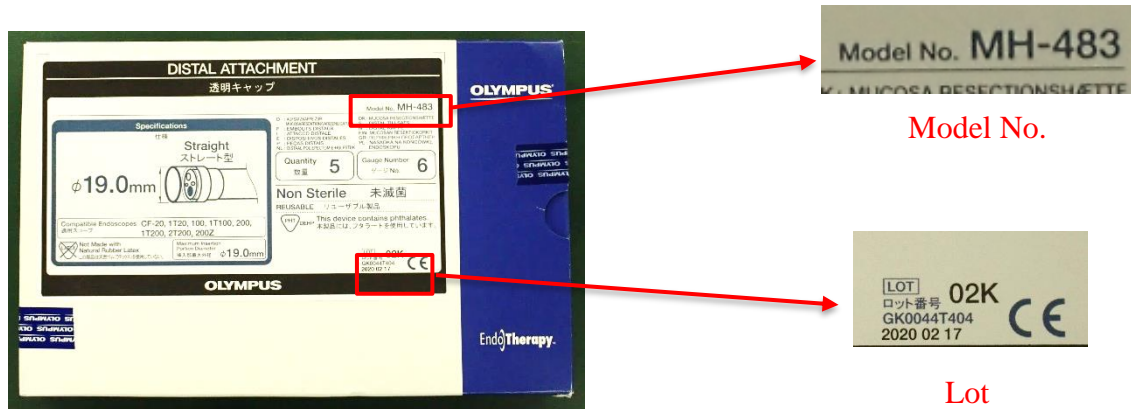


Lot

2) Distal Attachment

- You can find the product name and Lot number on the carton box.

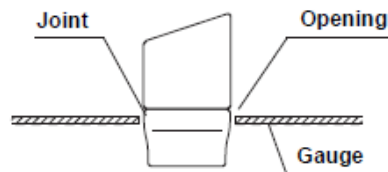
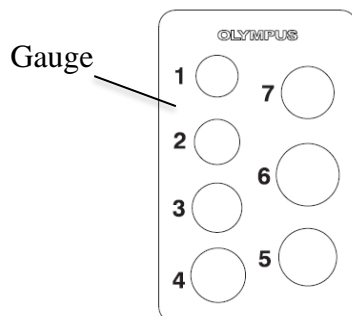
Carton box


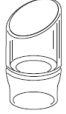










- If identification information cannot be obtained from the carton box, please check the type and size of the product using the Gauge(*1).






(*1)





The Gauge provided in the standard set has seven Openings in it, each number is inscribed with an order of 1, 2, 3, 7, 4, 5, 6 which starts from the smallest to the largest in diameter. These numbers match the Gauge Numbers of the following Tables. Fit the Distal Attachment into the Gauge using the above mentioned order (smallest to largest). By passing the Joint of the Distal Attachment through the Gauge find the smallest and passable Gauge Number for the Distal Attachment. Then find the type of the Distal Attachment by confirming the shape of the distal part of the attachment.











Gauge number	1				
Model No.	MH-462	MH-587	MH-593	MAJ-289	MAJ-295
Shape					
Type	Straight	Oblique	Straight with Rim	Oblique with Rim	Wide Opening Oblique with Rim





Gauge number	2				
Model No.	MH-463	MH-588	MH-594	MAJ-290	MAJ-296
Shape					
Type	Straight	Oblique	Straight with Rim	Oblique with Rim	Wide Opening Oblique with Rim

Gauge number	3				
Model No.	MH-464	MH-589	MH-595	MAJ-291	MAJ-297
Shape					
Type	Straight	Oblique	Straight with Rim	Oblique with Rim	Wide Opening Oblique with Rim

Gauge number	4			
Model No.	MH-465	MH-590	MH-596	MAJ-292
Shape				
Type	Straight	Oblique	Straight with Rim	Oblique with Rim

Gauge number	5			
Model No.	MH-466	MH-591	MH-597	MAJ-293
Shape				
Type	Straight	Oblique	Straight with Rim	Oblique with Rim

Gauge number	6			
Model No.	MH-483	MH-592	MH-598	MAJ-294
Shape				
Type	Straight	Oblique	Straight with Rim	Oblique with Rim

Gauge number	7			
Model No.	MAJ-663	MAJ-664	MAJ-665	MAJ-666
Shape				
Type	Straight	Oblique	Straight with Rim	Oblique with Rim



REPLY FORM – QIL FY24-EMEA-14-FY24-OMSC-12

OLYMPUS URGENT FIELD SAFETY NOTICE Market removal of Disposable EMR KIT and Distal Attachment		
[Name & Address of Hospital/Medical Facility]		
[Dept/Attn]		
[Date]		
[Inventory information]		
Model Name	Lot Numbers	Quantity

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to XXXXX <mailto:>latest by XXXX.