Date: XX.XX.XXXX
Olympus reference: QIL FY24-EMEA-03-FY23-OMTA-35

URGENT FIELD SAFETY NOTICE

Recall of Single Use Repositionable Clip HX-202LR/HX-202UR

Attention: Endoscopy Department

Material ID	Material Description	Lot Number
N4508930	HX-202LR.A (EN)	25K, 26K, 27K, 28K
N4509030	HX-202LR.B (EN)	26K, 27K, 29K, 2YK
N4509130	HX-202UR.A (EN)	24K, 25K, 26K, 27K, 28K, 29K, 2XK
N4509230	HX-202UR.B (EN)	24K, 25K, 26K, 27K, 29K, 2XK, 2ZK, 31K, 32K

Dear Health Care Practitioner:

Olympus has become aware of an issue that requires your attention. This letter pertains to the Single Use Repositionable Clip HX-202LR and HX-202UR ("HX-202 LR/UR") referenced above. The HX-202 LR/UR have been designed to be used with an Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of endoscopic marking, hemostasis for mucosal/sub-mucosal defects < 3 cm, bleeding ulcers, arteries < 2 mm, polyps < 1.5 cm in diameter and diverticula in the colon and as a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

Olympus has become aware of increased complaints on clip deployment occurring during clinical procedures, leading to hazardous situations where clips fail to achieve their expected function or deploy incorrectly, potentially causing harms to patients. The complaints include reports that: 1.) the clip arm does not open when the user pushes the slider, 2.) the clip arm does not close when the user pulls the slider and 3.) the clip detaches from the target tissue earlier than expected, after being deployed in a procedure.

The issues described above can lead to hazardous situations in which the clips cannot achieve their intended purpose, namely: (1) approximate a tissue opening or defect, (2) provide hemostasis to a bleeding vessel or mucosa, or (3) serve as a marker for subsequent location identification. Patient harms associated with these hazardous situations include: absence of treatment (e.g. hemostasis not achieved), prolonged procedure (e.g. extended time to accomplish hemostasis), and unexpected medical interventions (e.g. additional clipping) being required to accomplish therapeutic purposes. Additionally, the issues described above can lead to mucosal injury/perforation, hemorrhage, and dehiscence of a previously approximated closure. The root cause of the issues described above is under investigation. Accordingly, we are instructing all customers to cease using the HX-clips with the lot numbers referenced above.

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 above. Olympus requires you to take following actions:

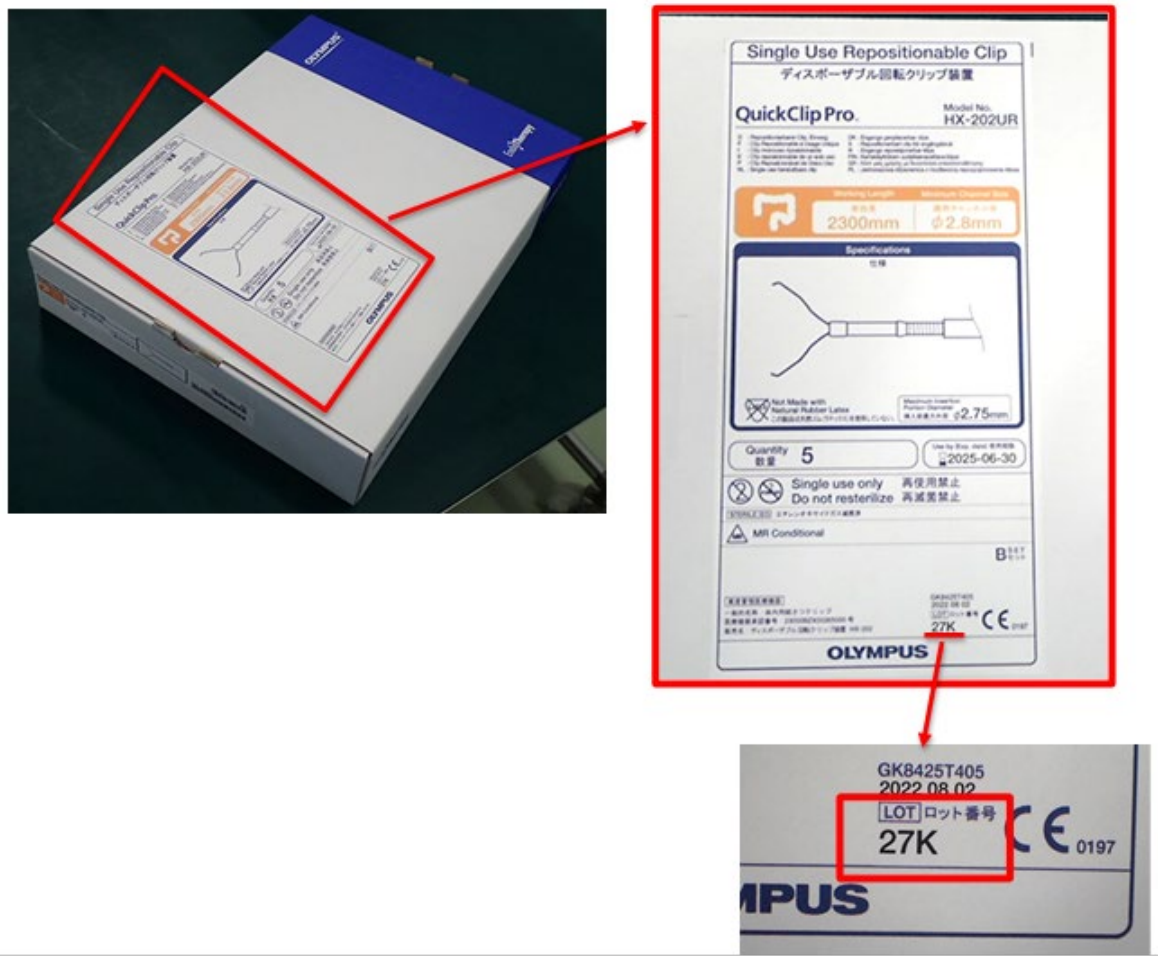
1. Carefully read the content of this Field Safety Notice.

2. Immediately assess any product you have to identify HX-202LR/UR with affected lot number 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.

Carton box

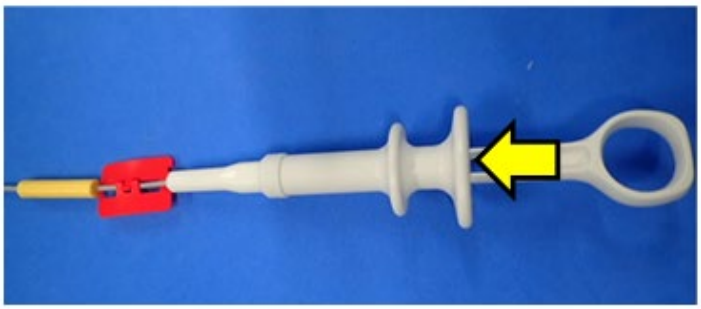
[SetA]

[SetB]



Pack

Handle



3. Contact your Olympus representative at [XXXXXXX]. 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 upon return of affected product.

4. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

5. 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 at [XXXXXXX] latest by [XX.XX.XXXX].

Olympus requests that you report complaints, including clip failure to deploy or premature clip deployment and adverse events, 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]

REPLY FORM – QIL FY24-EMEA-03-FY23-OMTA-35

FIELD SAFETY NOTICE
Recall of Single Use Repositionable Clip HX-202LR/HX-202UR

[Name & Address of Hospital/Medical Facility]

[Dept/Attn]

[Inventory information (Material and Lot Number(s) of Single Use Repositionable Clip HX-202LR/HX-202UR)]

Model	Lot Number

[Date]

Dear Sirs or Madams,

I herewith confirm 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. I understand the necessity to follow the steps.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to **[XXXXXXX]**