Reference: 2022-X001M

5th April 2022

URGENT: MEDICAL DEVICE RECALL
DISPOSABLE GRASPING FORCEPS FG-51D
(LOT NO: 8YK, 88K)

Attention: **Respiratory, Urology, General Surgery Department**

Dear Health Care Practitioner:

Olympus Medical Systems Corporation ("Olympus") has become aware of an issue that requires your attention. Olympus is writing to inform you of a voluntary recall (removal action) of DISPOSABLE GRASPING FORCEPS FG-51D ("FG-51D forcep") referenced above. This instrument has been designed to be used with Olympus endoscopes to retrieve foreign bodies, calculus or tissue specimens from the digestive tract, urinary tract, female reproductive tract, and respiratory organs.

Olympus has received complaints that the grasping portion of FG-51D can be difficult to open and close. Subsequent complaint investigation has confirmed that the FG-51D do not comply with Olympus standards for the force required to open and close the forceps.

Olympus has not received any reports or complaints of serious injury associated with this phenomenon.

Action(s) to be taken by end user:

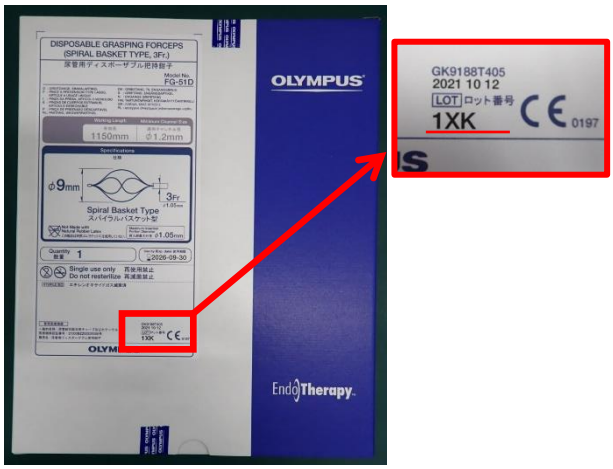
Our records indicate that you have purchased the affected product and we request you to take the following action(s):

1. Please read through carefully the enclosed information and share this notice to any healthcare professional from your organization as appropriate.

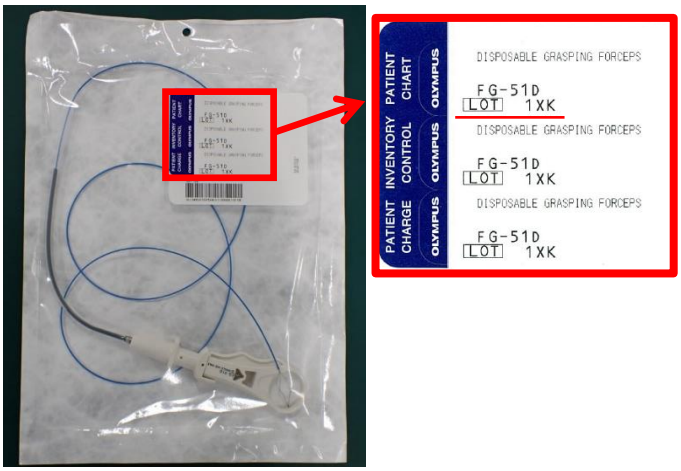
2. Immediately assess any product you have in stock to identify FG-51D forceps with affected lot numbers listed in this communication, cease use of product, and quarantine any affected product. The image below depicts the area on the label where the lot number is identified.

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Lot No. B-6-2, Level 6, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor
Tel: (603) 7886 9188 Fax : (603) 7887 2833

Carton box



Sterile pack



3. Complete and return the 'Response Form' to Olympus.
4. After analysis of your 'Response Form', an Olympus Representative will contact you on the recall procedure.

OLYMPUS regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact for enquiries
Regulatory Affairs Department
Email : mes-ra.oml@olympus.com
Tel : (603) 7886 9188
Fax : (603) 7887 2833

Yours sincerely,

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Yuji Sakaguchi
Managing Director
Olympus (Malaysia) Sdn. Bhd.

RESPONSE FORM

Medical Device Recall - Acknowledgement and Receipt

Response is required

[Name & Address of Hospital/Medical Facility]
[Dept/Attn]

PRODUCT NAME: DISPOSABLE GRASPING FORCEPS FG-51D

Please distribute this information to the appropriate personnel at your facility including surgeons who may have received the product which is the subject of this recall notice.

I have read and understand the recall instructions provided in the **5th April 2022** letter.

Yes ☐ No ☐

Any adverse incidents associated with recalled product?

Yes ☐ No ☐

If yes, please explain: _____

Check the applicable boxes below:

☐ I DO NOT have affected devices remaining. All have been used or discarded.

☐ I DO have the affected devices, which I will return to Olympus.
Lot Number: _____ Quantity to be Returned (UOM): _____

Name: _____

Designation: _____

…… ……

Signature & Company Stamp Date

Please send the completed and signed Response Form to Regulatory Affairs Department to
[Fax/Email : (603) 7887 2833 / mes-ra.oml@olympus.com]

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