OLYMPUS

Date: **XX.XX.XXXX**
Olympus reference: QIL 154-020

# URGENT FIELD SAFETY NOTICE

**RE: Recall for DISPOSABLE GRASPING FORCEPS FG-51D, FG-55D**

**Attention: Operating Room Manager, Endoscopy Department, Risk Management and Reprocessing Units**

| | Model Name | Affected LOT Numbers | Material Number |
|---|---|---|---|
| **DISPOSABLE GRASPING FORCEPS** | **FG-51D** | **All** | **N5402630 026740** |
| **DISPOSABLE GRASPING FORCEPS** | **FG-55D** | **All** | **N5402930 026746** |

Dear Healthcare Professional,

Olympus has become aware of an issue that requires your attention. This letter pertains to the DISPOSABLE GRASPING FORCEPS FG-51D, FG-55D ("FG-51D/55D forceps") referenced above.

These instruments have been designed to be used with Olympus endoscopes to retrieve foreign bodies, calculus or tissue specimens from the respiratory organs, digestive tract, urinary tract and female reproductive tract.

Olympus has received complaints that the grasping portion of FG-51D and FG-55D forceps can be difficult to open and close. Subsequent complaint investigation has confirmed that the FG-51D and FG-55D forceps do not comply with Olympus standards for force required to open and close the forceps. Olympus has not received any reports or complaints of serious injury associated with this phenomenon. Olympus requests you to report any patient injuries, including infections associated with any Olympus endo-therapy devices. Contact your **[Regions to add their local information]** to report complaints.

**Action steps to be taken by the end user:**

Our records indicate that your facility has purchased one or more of the affected FG-51D or FG-55D. Therefore, Olympus requires you to take the following actions:

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

2. Immediately assess any product you have in stock to identify FG-51D and FG-55D forceps, cease use of product and quarantine any affected product.

3. Contact your **[Olympus customer service representative at XXXXXXX].**
   *O*lympus 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.

4. 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 feedbacks 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 **[XXXXX]** latest by **[XX.XX.XXX].**

The DISPOSABLE GRASPING FORCEPS FG-51D, FG-55D ("FG-51D/55D") are currently in ship hold. For the availability of the device or alternative devices please contact to Olympus customer service representative.

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

Olympus regrets any inconveniences caused by this Field Safety Corrective Action and fully appreciates your prompt cooperation in addressing this situation.
Please do not hesitate to contact Olympus directly at **[phone number]** or at **[e-mail address]** for any additional information concerning this matter.

Sincerely,

# REPLY FORM – QIL 154-020

| **URGENT FIELD SAFETY NOTICE**<br>**Model name:** FG-51D and FG-55D |
|---|
| **[Name & Address of Hospital/Medical Facility]** |
| **[Dept/Attn]** |
| **[Inventory information (LOT Number and qty)]** |
| [**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 **XXXX** latest by **XXXX.**