



سندد بثقة  
Moving Forward  
with Confidence

رؤية عمان  
2040  
Oman Vision

To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (MOH)**  
**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**  
**Hospital Director (Al Nahda Hospital)**  
**Hospital Director (Al Massara Hospital)**  
**The Head of Medical Services in SQU Hospital**  
**The Head of Medical Services in Royal Oman Police**  
**The Head of Medical Services in Ministry of Defence**  
**The Head of Medical Services in The Diwan**  
**The Head of Medical Services in The Sultan's Special Force**  
**The Head of Medical Services in Internal Security Services**  
**The Head of Medical Services in Petroleum Development of Oman**  
**The Head of Medical Services in LNG Oman**  
**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No...77..... dated 20/4/22 Regarding Recall of  
DISPOSABLE GRASPING FORCEPS FG-51D, FG-55D from ( mrf: Olympus).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



Circular No. 77 / 2022

18-09-1443 H

20-04-2022

**Recall of DISPOSABLE GRASPING FORCEPS FG-51D, FG-55D from Olympus.**

Source	ConvaTec Company through their local agent.			
Product	DISPOSABLE GRASPING FORCEPS FG-51D, FG-55D .			
Manufacturer	Olympus.			
Local Agent	Muscat Pharmacy & Stores LLC.			
The affected products		Model Name	Affected LOT Numbers	Material Number
	DISPOSABLE GRASPING FORCEPS	FG-51D	ALL	N5402630 026740
	DISPOSABLE GRASPING FORCEPS	FG-55D	ALL	N5402930 026746
Reason	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.			
Action	<ol style="list-style-type: none"><li>1. 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.</li><li>2. Olympus will return any affected product at no charge to you.</li><li>3. Contact the local agent for remedial action.</li></ol>			
Product Picture				
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>			

Dr. Mohammed Hamdan Al Rubaia  
DIRECTOR GENERAL





Date: 4.4.2022  
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.

### 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.

# **OLYMPUS**

3. Contact Olympus at [ra@olympusmea.com](mailto:ra@olympusmea.com). 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.
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 [[ra@olympusmea.com](mailto:ra@olympusmea.com)] latest by [Monday 18.4.2022].

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.

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 [[ra@olympusmea.com](mailto:ra@olympusmea.com)] for any additional information concerning this matter.

Sincerely,

Iman Ibrahim  
Regional Head of Quality Assurance and Regulatory Affairs Middle East & Africa  
Healthcare, Industrial and Life Science Divisions  
Olympus MEA FZ-LLC, P.O. Box: 33607 Dubai  
Registration No. 93456 (Dubai Development Authority)  
Dubai Science Park - Laboratory Complex - Dubai - United Arab Emirates