

Field Safety Corrective Action: Product Recall

Product Codes: NF02L
Brands: ENFit Double Lumen Replogle Tube
FSN Ref: FSN-001/24, 2024/002/026/601/060
Date: 04/03/2024

Field Safety Corrective Action notice for certain batches of ENFit Double Lumen Replogle Tube

Immediate Attention

All users of ENFit Double Lumen Replogle Tube

Device Description

ENFit Double Lumen Replogle Tubes are used in Neonatal units to aspirate and irrigate fluids in conditions such as oesophageal atresia.



ENFit Double Lumen Replogle Tube

Reason for product recall

HMC and Medicina is voluntarily recalling the batches of the product listed below due to a potential design issue that has been established that has the potential to impact the health and safety of the patient. As a result of the investigation, the decision has been taken to initiate a recall.

Recalled Product Code, Description and Batch Numbers

Code	Description	Batches
NF02L	ENFit Double Lumen Replogle Tube 10FR	19I09004 21F18002 23C03045 23C03046

Action to be taken

- Please carefully read this Field Safety Notice and return the Acknowledgement Form
- Please do not use any of the batches of product listed on this notice
- If you have product to return, please complete the information on the Acknowledgement Form and our team will contact you for the material management
- Please distribute throughout your organisations and to relevant personnel
- If you have any questions or queries in relation to this notice, please contact us using the information below

Contact information regarding FSN

For Italy and Danmark	For All other countries
Emanuela Govi Complaints coordinator Email: emanuela.govi@hmcgroup.it Tel: +39 0535 22704	Shaista Patel QA/RA Administrator Email: quality.administrator@medicina.co.uk Tel: 01204 695050

Acknowledgement Form: FSN-001/24 Field Safety Corrective Action

Product Codes: NF02L

Brands: ENFit Double Lumen Replogle Tube

Please confirm you have received the notice by completing this form and returning it to us by post or email as soon as possible.

Acknowledgement

We confirm receipt of this Field Safety Notice FSN-001/24 and that this is received, read, and distributed to anyone it may concern within our organisation and/or to our customers (for distributors).

Organisation Name:	
Department:	
Representative Name and Signature:	
Date:	
Product to be returned:	Yes / No
Contact details to arrange return:	

Please return the Acknowledgement Form to:

For Italy and Danmark	For All other countries
Emanuela Govi Complaints coordinator Email: emanuela.govi@hmcgroup.it Tel: +39 0535 22704	Shaista Patel QA/RA Administrator Email: quality.administrator@medicina.co.uk Tel: 01204 695050