# Devices Report

**Report ID: 2024/002/026/601/060**

Medicines & Healthcare products Regulatory Agency

## Administrative information

**To which NCA(s) is this report being sent?**
MHRA

**Date of this report**
2024-02-26

**Type of Report**
Initial

**Reference assigned by the manufacturer**
FSN 001/24

**FSCA reference number assigned by NCA**
2024/002/026/601/060

**Incidence reference number assigned by NCA**
-

**Name of the co-ordinating NCA Competent Authority (if applicable)**
-

## Information on the submitter of the report

**Submitter of report**
Manufacturer

## Manufacturer information

**Manufacturer Organisation name**
HMC Premedical spa

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## Authorized representative information

**Authorised representative Organisation name**
HMC Medical UK Limited

**Contact Name**
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## National Contact Point Information

**National contact point organisation name**
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**Name of the contact person**
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Blackrod, Bolton

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## Medical Device Information

**Class**
MDD Class IIb

**Nomenclature system (preferable GMDN)**
GMDN

**Medical device nomenclature code**
64616

**Nomenclature text**
ENFit double-lumen polyurethane “Replogle” tube

**Commercial name/brand name/make**
ENFit double-lumen polyurethane “Replogle” tube

**Model**
NF02L

**Catalogue/Reference number**
NF02L

**Serial number(s)**
-

**Lot/batch number(s)**
19I09004 21F18002 23C03045 23C03046

**Device manufacturing date**
-

**Device expiry date**
-

**Notified body (NB) ID number(s) (if applicable)**
-

**Details of additional devices/ accessories involved in the incident**
-

**Software version (if applicable)**
-

## Description of FSCA

**Background information and reason for the FSCA**

The hospital reported that there was a problem with location of the irrigation holes in the ENFit 10fr double Lumen Replogle Tube with a neonate patient. When the tube was in situ in the patient, and saline was administered for irrigation, the saline came out of the first hole in the tube, which is (roughly) 7cm from the end of the tube . The patient that required the tube has an oesophageal atresia 9.5cm down from her mouth meaning that the tube was only inserted to 9.5cm. The result was that the saline came out (roughly) 3cm away from her mouth which was likely above the epiglottis and a huge risk of aspiration. This also meant that the patient secretions were not loosened and blocked the suction holes.

**Description and justification of the action (corrective / preventive)**

The defective sample is not available for investigation. Since the device was put on the market, we have never received similar complaint. From the feedback received from the hospital, the appropriate procedure was followed for the use of the device. The reporter identified a difference in the position of the holes in the device, compared with the competitor device (Cardinal Health Replogle Tube). The position of the holes on the competitor device is closer to the end of the tube the first hole being roughly 2cm from the end of the tube. We cannot eliminate the possibility that the location of the holes on the tube contributed to the complications experienced by the patient. Without access to the tubes subject to the complaint but based on the available information from the reporter it is not possible to exclude the possibility that the design of this device resulted in the complications the patient experienced. For this reason, the decision has been taken to initiate a recall. The product will be placed in quarantine, and the recall notice will be issued. The product will be withdrawn from the market and no new batches of the product will be placed on the market.

**Advice on actions to be taken by the distributor and the user**

Users should contact Medicina who will arrange collection and destruction of the batches specified.

**Progress of FSCA, together with reconciliation data**

-

**Time schedule for the implementation of the different actions**

Subject to approval of draft FSCA by MHRA, notifications to all customers in territory can be sent within 5 working days of approval, follow-up every 7 working days thereafter

**Attached Please Find**

Field Safety Notice (FSN) in English

**FSN status**

Final FSN

**Attachments**

| File Name |
| --- |
| FSN 001/24 |

**All EEA, Great Britain, candidate countries and Switzerland**

-

**Distribution (Multiple choice)**

-

**Other Countries (including Northern Ireland)**

-

## Comments

**Comments**

Incident also reported MHRA code 2024/002/026/601/052.