# FIELD SAFETY NOTICE

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| **Commercial name of the affected product:** | Fortress Introducer Sheath System |
| **Date of related FSCA report:** | 15.07.2025 |
| **Type of action:** | Labelling Correction |

Date: 21 July 2025

Attention: Distributors and End Users in the hospital

Dear Sir or Madam,

we, Contract Medical International GmbH (dba Heraeus Medevio), Lauensteiner Straße 37, 01277 Dresden, Germany, with Single Registration Number: DE-MF-000007409, must inform you about the following issue concerning the Fortress Introducer Sheath System as described below.

**Details on affected device:**

| | | | |
|---|---|---|---|
| Product Name | Fortress Introducer Sheath System, 6F Straight 45cm | | |
| Model Number | 386594 | Lot Number | **800989 (only)** |

**Description of problem:**
We have identified that some units within Lot Number 800989 of the Fortress Introducer System, 6F Straight 45cm, may have been packaged with an incorrect pouch label. Specifically, the Reference (REF) number, Unique Device Identifier - Device Identifier (UDI-DI), and device representation scheme are of the 4F version of the device, rather than the packaged 6F version, see Figure 1.


Figure 1: Product Pouch Label with Incorrect REF number, UDI and Size

- ✓ The packed product and Lot number are correct - 6F
- ✓ Coloured part of the label is correct - Big font 6F print and colour is Green
- ✓ Compatible Guidewire size is correct - Same for 4F and 6 F
- ✓ The device length is correct - 45 cm
- ✓ The package quantity is correct - 1 piece
- ✓ Production and expiry date are correct
- ➢ **REF number and UDI are INCORRECT - they refer to the 4F version of the device**
- ➢ **The device description is INCORRECT – it refers to the 4F version of the device**
- ➢ **Device representation scheme is incorrect -4F has pre-shaped dilator, 6F does not**

**Harms:**
There have been no reports of adverse patient events related to this issue. However appropriate traceability of devices with the incorrect labelling information is affected.

As illustrated in Figure 1, the label includes color-coded printed information that correctly identifies the product as the 6F version. The color coding is clearly visible and aligns with the standard designation for this product size. The labelling error would therefore be identified before the procedure is performed. The probability of use of incorrect device size due to mismatching label is highly unlikely in well-regulated clinical settings due to:

- Standardized procedural protocols
- Color-coded sheath and catheter systems
- Pre-procedure checklists
- The users are well-trained in the catheterization procedures and aware of the clinical consequences.

**Advise on action to be taken by user:**
Our records indicate that the affected lot of the Fortress Introducer Sheath system was shipped to your facility.

Contract Medical International GmbH requests that the economic operators and customers who have received products from the affected lot, please verify if the labelling information on the received products are consistent. Figure 2 below, provides an example of the correct product pouch label where the labelling information and print content is consistent and matching with the devices from the delivered lot 800989:


Figure 2: Product Pouch Label with correct REF and size for lot 800989.

Contract Medical International GmbH requests to be contacted through the contact information listed below should you determine you have received a product with incorrect labelling for replacement.

Products from the affected lot that have correct labelling as indicated by Figure 2, are not impacted by this Field Safety Notice.

PLEASE ANSWER THE QUESTIONS ON PAGE 6 AND SEND THE ANSWERS TO:
medevioregulatoryaffairs@heraeus.com
cnf.vi@biotronik.com

**This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.**

**Please transfer this notice to other organizations on which this action has an impact.**

**Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of this action.**

**Contact reference person:**

Christelle Elson
Contract Medical International GmbH
Lauensteiner Straße 37
01277 Dresden
Germany

+49 351 2138888
**E-mail:** medevioregulatoryaffairs@heraeus.com

Christelle Elson
Christelle Elson (Jul 21, 2025 15:30 GMT+2)

Printed Name

Regulatory Affairs Manager

Position

# Attachment I – Effectiveness Check

**Please read the FIELD SAFETY NOTICE before answering.**
**Please read each question and indicate an answer.**

1. Did your firm receive the FIELD SAFETY NOTICE for Fortress Introducer Sheath System?
   YES☐ NO☐

2. Did your firm receive shipments of the product concerned in the FIELD SAFETY NOTICE?
   YES☐ NO☐

3. Do you currently have any units from Lot Number 800989 of the product referenced in this Field Safety Notice in your inventory or in use? (Please check inventories before answering and indicate quantity).
   YES☐, Quantity_____, NO☐

4. If the answer to question 3 is YES, please contact your local sales representative to arrange for the return and replacement of the product.

PLEASE RETURN THIS PAGE WITH YOUR SIGNATURE TO:
medevioregulatoryaffairs@heraeus.com
cnf.vi@biotronik.com

Name of person completing questionnaire: _____

Name of the Hospital/Institution: _____
Hospital Address: _____

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Date: _____