**BIOTRONIK AG**
**Ackerstrasse 6**
**CH-8180 Bülach**
**Switzerland**

# INSTRUCTIONS for Distributors

## Voluntary Field Safety Corrective Action

Document-Identification:

REC 000_052_857 A

### Product: Fortress Introducer Sheath System

Dear Distributor,

The device manufacturer *Contract Medical International GmbH (dba Heraeus Medevio)* is initiating a Voluntary Field Safety Corrective Action to withdraw units from one specific lot of its Fortress Introducer Sheath System from the market.

The manufacturer identified some units within **Lot Number 800989** of the Fortress Introducer System, 6F Straight 45cm, that were labeled with an incorrect inner pouch label. Specifically, the Reference (REF) number, Unique Device Identifier - Device Identifier (UDI-DI), and device representation scheme correspond to the 4F version of the device, instead of the 6F version included in the pouch. However, correctly labeled products of the same Lot can be used safely and are not impacted by this Field Safety Corrective Action.

This Voluntary Field Safety Corrective Action affects **only** certain products out of the one lot of the Fortress listed in the Field Safety Notice **and not** any other Fortress lots.

**We kindly ask you to read and follow the instructions stated below, for handling this Voluntary Field Safety and Corrective Action.**

**Instructions:**

1. Read the full instructions in the **Field Safety Notice**.
    - Fill out and sign the *Distributor Acknowledgement Form*.
    - Send the signed form to **cnf.vi@biotronik.com** within **2 working days** of receiving this message.
    - Make sure everyone in your organization who needs to know is informed.

2. **STOP** immediately the shipping of the affected Fortress lot.
3. Identify without any delay all sub-distributors (if applicable) and customers that have received affected devices. Inform us immediately if you delivered products from the affected Fortress lot to any sub-distributors.
4. Bring immediately the enclosed Field Safety Notice with the attached *Effectiveness Check* in Attachment I to the attention of each of your customers identified in step 3. Make sure that each customer receives, reads and understands the Field Safety Notice.
5. Make sure customers follow the instructions in the Field Safety Notice.
   They must complete and send the filled out *Effectiveness Check Form* to:
   mailto:medevioregulatoryaffairs@heraeus.com
   mailto:cnf.vi@biotronik.com

   Important: **Even if the outer box label is correct, the label on the pouch inside might still be wrong!**

6. If a customer reports that they have products with incorrect pouch labels, remove those products from the hospital without delay. Check that the number written on the *Effectiveness Check Form* matches the number of products you removed. Collect all the retrieved stock from all the hospitals at your main office.
7. Remove all remaining stock of the affected Fortress lot — including: items in car trunks, stock held by sales reps and stock at sales offices, if applicable. Collect everything at your **main office**.
8. Fill out and sign the *Distributor Confirmation of Closure* when you have concluded the Field Safety Corrective Action in your country. Send the signed form to **cnf.vi@biotronik.com.**
9. Label the shipment and shipping documents with this reference: CAPA 2025-0035.

   Send all affected products you have collected back to:

   BIOTRONIK AG, Ackerstrasse 6, 8180 Bülach, Switzerland.

   Important: Keep a copy of all documents for your records and include the original *Effectiveness Forms* and the *Distributor Confirmation of Closure* in the package.

**Attention!**
Return all affected Fortress products in one single shipment — do not send multiple shipments. Use FedEx for the return**.** Bill the shipment to the recipient using **FedEx account number: 218353304.**

In addition to these instructions, please observe the applicable local legislation including any obligation of the distributor to report this Voluntary Field Safety Corrective Action to your National Competent Authority. If you receive questions from your Competent Authority regarding this Voluntary Field Safety Corrective Action, please forward it to Complaint Management using the contact e-mail below.

**All actions must be performed without delay!** We appreciate your sense of urgency retrieving the affected Fortress lot by this Voluntary Field Safety Corrective Action.

**Contacts:**

For questions in relation to the execution of this Field Safety Corrective Action, the Field Safety Notice, or Competent Authority requests please contact BIOTRONIK AG Complaint Management:

Contact: cnf.vi@biotronik.com

For questions in relation to return shipments, custom concerns and replacements please contact BIOTRONIK AG Corporate Sales Support:

Contact: vicss@teleflex.com

Thank you for your professionalism, cooperation and efforts in this task.

Kind regards,

Marcel Schäfer
Sr. Director Regulatory Affairs & Post Market Surveillance

Attachments:
- Field Safety Notice with *Attachment I – Effectiveness Check*
- *Distributor Acknowledgement Form*
- *Distributor Confirmation of Closure*