

[REDACTED], 03.02.2026

## **Urgent Field Safety Notice**

concerning

**E-tegra Stent Graft System  
E-nside TAAA Multibranch Stent Graft System  
E-vita OPEN NEO**

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Dear valued customer,

With this letter we would like to inform you that JOTEC GmbH has decided to issue a voluntary, preventive Field Safety Corrective Action (FSCA) by means of a Recall and a Field Safety Notice (FSN) to rule out any potential errors during the scanning of the packaging process and ensure patient safety. The description and justification of the planned action can be found in the following section.

### **Address**

Clinical users, responsible person in the area of purchasing and logistics, dealers/distributors

### **Details on affected devices**

E-tegra Stent Graft System with the following LOT numbers:

- 1573926
- 1573928
- 1576034

E-nside TAAA Multibranch Stent Graft System with the following LOT numbers:

- 1573949
- 1573955
- 1573959

E-vita OPEN NEO with the following LOT numbers:

- 1573978
- 1573997
- 1573998
- 1573999
- 1574002
- 1574004
- 1575125
- 1575152

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## **Background information and reason for the FSCA**

After the ERP system was changed in the company, a security feature was introduced in the packaging process via the ERP system. The ERP system scans to check whether the production batch matches the label on the outer sterile bag and the label on the outer carton. If these three labels do not match, the ERP system issues an error message as required. If, for example, an error message is received during the second scan, the third label can still be scanned, and if it matches the first label, the error message disappears and the status remains "OK" in the ERP system.

Due to the packaging process, it is possible that no error messages were generated. However, the scanned data is not stored. As a result, we cannot currently say with 100% certainty that there were no discrepancies during the packaging process. Consequently, we cannot completely rule out the possibility that a product of a different size may be included in the product box, as shown on the label on the product box. The new ERP system was introduced on 07.01.2026.

## **Advice on action to be taken by the user / customer**

According to our documentation, your institution has received affected products from us. Therefore, JOTEC GmbH asks you to proceed as follows:

1. Please remove all products affected by this recall from your stock and quarantine the products. The products must not be used anymore.
2. If you have affected products within your stock, a Sales person will come to you to bring you a replacement device and pick up the affected product. Please confirm this in using the reply letter.
3. If you don't have affected products and they were still used, please confirm this using the reply letter.

## **Transmission of this Field Safety Notice**

This notice needs to be passed on to all those who need to be aware within your organization. If you have transferred products to any other organization, please forward a copy of this notice to the organization or inform the contact person stated in this notice.

Please maintain awareness of this notice and resulting action until the procedure has been finished.

## **Contact person**

[Redacted]

[Redacted]

[Redacted]

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