FSN Ref: 2247858-05-01-2023-001R

TREO Customers Date: 12 May 2023

Urgent Field Safety Notice: TREO® Abdominal Stent-Graft System

1. Information on Affected Devices

1. Device Type(s)

The TREO® ABDOMINAL STENT-GRAFT SYSTEM (TREO) is a modular endovascular system designed to treat infrarenal abdominal aortic and aorto-iliac aneurysms in adult patients. The system consists of four types of implants, specifically a Main Bifurcated Stent-Graft, a Leg Extension Stent-Graft, a Proximal Cuff Stent-Graft and a Straight Iliac Extension Stent-Graft. Each stent-graft is preloaded into its own delivery system that is advanced under fluoroscopy to the location of the infrarenal aneurysm. The stent-graft is deployed at the intended location and creates a blood flow channel, excluding the aneurysm from blood pressure and flow.

2. Commercial name(s)

TREO® Abdominal Stent-Graft System

3. Unique Device Identifier(s) (UDI-DI)

See Attachment 1

4. Primary clinical purpose of device(s)

All TREO Stent-Graft Systems are indicated for the endovascular treatment of infrarenal abdominal aortic and aorto-iliac aneurysms in adult patients who have appropriate anatomy as described below:

- Adequate iliac or femoral access compatible with the required delivery systems
- Suprarenal neck angle of less than 45 degrees
- Infrarenal landing neck length of:
  - 10 mm or greater with an infrarenal angle of less than 60 degrees and an inside diameter of 17mm-32mm, or
  - 15 mm or greater with an infrarenal angle between 60 and 75 degrees and an inside diameter of 16mm – 30 mm
- Distal iliac landing neck of inside diameter:
  - 8 mm- 13 mm and a length of at least 10 mm or
  - >13 mm – 20 mm and a length of at least 15 mm

5. Device Model/Catalogue/part number(s)

See Attachment 1

2. Reason for Field Safety Corrective Action (FSCA)

1. Description of the product problem

Terumo has identified that, for the lots listed in Attachment 1, there is a potential for the package to contain a different-sized graft than expected.

2. Hazard giving rise to the FSCA

A single complaint was received reporting of technical issues during surgery. Preliminary investigation findings indicated that the box contained an incorrectly sized stent-graft. The stent-graft was approximately 20mm longer than the expected size printed on the carton label. However, it was possible to finalize the procedure successfully with no complications for the patient, and no adverse events related to this issue have been reported to date.

Per internal risk management documentation, using an incorrect device can potentially have significant impact to a patient. Although detection of an incorrect graft is likely, this would not occur until either after the procedure has commenced or the graft has been implanted. While the physician would likely be able to take corrective action to mitigate the incorrect device being implanted, there could be significant delay in the procedure as well as potential clinical effects, such as severe oversizing, branch artery coverage, or stent graft migration due to sequelae.

3. Probability of problem arising

The likelihood of this issue leading to harm is very low considering the discrepancy would likely be noted under fluoroscopy, and corrective action could be taken to prevent the incorrect device from being implanted. Alternatively, the treatment plan could be adjusted to account for the size discrepancy.

4. Predicted risk to patient/users

There were no reported harms in the one complaint reported for this issue. However, it is possible that an incorrect graft would not be noticed and could be implanted. Per internal risk management documentation, the worst-case risks are categorized with a severity level of 5 (Catastrophic) with potential harms including ‘vessel occlusion’ and ‘death’. The occurrence level is also listed as 2 (Low, relatively few failures).

5. Further information to help characterise the problem
The IFU includes steps that direct the clinician to check the stent-graft positioning under fluoroscopy both during and after the procedure. There are marker bands at both the proximal end of the main body device and the distal end of the contralateral limb of the main body device, making it possible for an incorrect length to be noticed during the implant procedure. Although the clinician is not specifically tasked with verifying the correct graft length, they are always aware of the location of the distal end of the stent-graft during the procedure. Therefore, an anomaly is likely to be noticed during these checks. While this may not prevent the implant from proceeding, it is likely to prevent an incorrect stent-graft from being implanted without being noticed and provide an opportunity for any additional measures to be taken. There is no safety concern for patients that have already been implanted successfully using product from these lots.
6. Background on Issue
See Section 2

Type of Action to mitigate the risk	
1. Action To Be Taken by the User ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☒ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU)	
2. By when should the action be completed?	Product Removal: As soon as possible, but no later than 30 days from FSN distribution. FSN Distribution: Beginning 12-May-2023 Customer Completion of Required Actions: 11-Jun-2023
3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No additional follow-up or review of patients' previous results is recommended as there is no defect to the device. Continual follow-up is the standard of care for patients receiving endovascular stent-grafts.	
4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
6. By when should the action be completed?	11-Jun-2023
7. Is the FSN required to be communicated to the patient /lay user?	No

General Information	
1. FSN Type	New
2. Further advice or information already expected in follow-up FSN?	No
3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
a. Company Name	Bolton Medical Inc

b. Address	799 International Parkway, Sunrise, Florida, USA 33325
c. Website address	www.Terumoaortic.com
4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
5. List of attachments/appendices:	Attachment 1: Affected Product List Attachment 2: Acknowledgment Form
6. Name/Signature	**Megan Indeglia, Global VP of Regulatory Affairs**

	Transmission of this Field Safety Notice
	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

May 12, 2023

URGENT: FIELD SAFETY NOTICE

CUSTOMER ACKNOWLEDGMENT FORM

Customer Name
Street Address
City, Zip Code, Country

We have read and understand the Field Safety Corrective Action letter issued by Terumo Aortic regarding the TREO® Abdominal Stent-Graft System. We have taken the appropriate action and disseminated this information to any affected staff, service, and/or facilities.

☐ We do not have affected product in our inventory.

☐ We have checked our inventory and will be returning the quantity indicated in the table below.

Catalog #	Lot #	Quantity Received	Quantity Used*	Quantity to be Returned

*Quantity Used includes products that were used, opened in error, returned to manufacturer as product complaints, or discarded.

Representative Name, Title/Position _____ Signature _____ Date _____

Within 30-days of receipt of this notice, please sign and return the completed form to:

taustreolabels@terumoaortic.com.