FSN2026-003

Bolton Medical Inc.
799 International Parkway
Sunrise, FL 33325, USA

T. +1 954-838-9699
terumoaortic.com

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

Device:	**Relay®Plus Thoracic Stent Graft System** **Relay®Pro Thoracic Stent Graft System** **TREO® Abdominal Stent-Graft System**

Dear Valued Customer,

The purpose of this letter is to notify consignees that Bolton Medical Inc., operating as Terumo Aortic, is conducting a voluntary medical device recall (removal) of all **Relay®Plus, Relay®Pro and TREO® Stent-Graft Systems** within expiry due to potential endotoxins present on the delivery system. Refer to Appendix 1 for a full list of products impacted.

Description of the Problem:

Through an internal review, elevated endotoxins on the delivery systems has been identified. The current testing shows ~1% of the units have the risk of endotoxin levels above the specification.

Risk to Health:

Endotoxin is a pyrogen that can create reactions from fever to more serious and rarely potentially life-threatening outcomes, including sepsis, septic shock, organ failure, and death.

Since 2023, 26 complaints have been received related to fever, infection, inflammation, and sepsis. Four of these complaints included the outcome of death. This represents a rate of 0.07%. As the etiology of an infection or inflammatory response can be related to circumstances unrelated to the procedure or device, the root cause of the complaints were not necessarily tied to this issue but cannot be ruled out at this time.

Despite the likelihood that any endotoxin would be cleared from the body within hours to days, the risk of an inflammatory response, which is most commonly acute, may persist for a period of time. We would recommend close observation for signs of inflammation (outlined) during the initial hospitalization and provider follow up at regular intervals as is routinely performed post implant, especially in high-risk patient populations such as those with significant comorbidities or are immunocompromised. Of course, if such symptoms are identified, routine evaluation and assessment for other, more common causes, such as infection or post implant syndrome is recommended and treatment should follow standard medical practice for the symptoms. Monitor for:

- Fever, chills, malaise
- Nausea, vomiting, diarrhea
- Hypotension (low blood pressure)
- Respiratory distress
- Coagulopathy (clotting abnormalities)
- In severe cases: sepsis, multi-organ dysfunction

Actions To Be Taken by Customer:

1. **Immediately discontinue use of the Relay Plus, Relay Pro, and Treo**.
2. Isolate affected inventory to prevent future use.
3. If devices have been transferred to another facility, please provide them with a copy of this notification and instruct them to follow the actions in this section.
4. Complete Appendix 2 the number of units in your control to be returned to Terumo. **The form is required even if you do not have product on hand.**
5. Contact **vascutek_customer_services@terumoaortic.com** to initiate the return process.
6. Return affected product with a copy of Appendix 2 to:

Goods in
Terumo Aortic
Newmians Avenue
Inchinnan Business Park
Renfrewshire
PA4 9RR

Corrective Action:

Bolton Medical is currently conducting a thorough root cause investigation to determine the source of endotoxin. Once a root cause is identified, appropriate corrective action will be taken to ensure new product does not have an endotoxin risk. One potential source has been identified at a supplier and corrective action has already been implemented. Additional corrective actions will be implemented based on full root cause investigation to eliminate all potential sources of endotoxin.

Please be assured that we take the safety and quality of our products very seriously and remain committed to supporting you with high-quality products. If you have additional questions, please reach out to your **Terumo Aortic Representative** or contact us at **Market_Actions-TMC@terumomedical.com**.

On behalf of Bolton Medical, Inc.

Kimberly Feitl
Vice President, Quality

Appendix 1: Recalled Product List

Material	EAN / GTIN

MEDICAL DEVICE RECALL NOTICE (Removal)

Please return completed form to <Local Recall Email> and include a copy with the device returns.

Appendix 2: Recall Notice Acknowledgement Form
FSN2026-004

Account Information:

Customer Name:	
Customer Address:	
Customer Telephone Number:	
Customer e-mail Address:	

To be completed by the customer:

Quantity of Product in My Facility:	
Quantity of Product Being Returned:	
Lot #s included:	

By signing below, I acknowledge:

- Receipt of the recall notice and confirm that I understand the contents.
- I have communicated the information to users in my organization or other organizations I transferred products to.
- All products in my facility have been isolated and are being returned.

Name (Print):	
Signature:	
Date:	