FSN2026-003

URGENT: MEDICAL DEVICE RECALL (R

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 your **Terumo Representative** to initiate the return process.

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.



Appendix 1: Recalled Product List

Material	EAN / GTIN
28-N4-30-209-30S	00843576101128
28-B2-24-080S	08436045396723
28-N4-30-164-26S	00843576101357
28-N4-28-104-28S	00843576100855
28-N4-28-164-24S	00843576101340
28-N4-30-164-30S	00843576100992
28-B2-26-080S	08436045396730
28-N4-26-164-26S	00843576100978
28-N4-28-164-28S	00843576100985
28-N4-30-104-30S	00843576100862
28-C2-20-055S	08436045397027
28-N4-28-204-28S	00843576101111
28-M4-36-145-32S	00843576100565
28-M4-30-095-30S	00843576100046
28-N4-30-259-26S	08435761001553
28-M4-34-145-34S	00843576100190
28-M4-36-145-36S	00843576100206
28-M4-32-155-32S	00843576100183
28-N4-28-259-24S	00843576101548
28-M4-40-195-36S	00843576100688
28-M4-28-250-24S	00843576100725
28-N4-28-204-24S	00843576101449
28-M4-34-100-34S	00843576100060
28-M4-32-200-28S	00843576100640
28-M4-38-190-38S	00843576100343
28-M4-36-190-36S	00843576100336
28-M4-40-195-40S	00843576100350
28-M4-32-200-32S	00843576100312
28-M4-36-100-36S	00843576100077
28-M4-32-095-32S	00843576100053
28-N4-24-099-24S	00843576100831
28-M4-40-145-40S	00843576100220
28-B2-28-080S	08436045396747
28-L2-13-120S	08436045397348
28-N4-26-104-26S	00843576100848
28-M4-34-145-30S	00843576100558
28-M4-34-200-30S	00843576100657
28-M4-38-145-34S	00843576100572

28-L2-09-140S	08436045397393
28-L2-15-120S	08436045397355
28-M4-30-155-30S	00843576100176
28-L2-15-160S	08436045397492
28-L2-13-160S	08436045397485
28-M4-34-200-34S	00843576100329
28-L2-15-080S	08436045397218
28-B2-24-100S	08436045396808
28-L2-13-100S	08436045397270
28-L2-13-140S	08436045397416
28-B2-26-100S	08436045396815
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28-M4-38-145-38S	00843576100213
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28-L2-15-100S	08436045397287
28-L2-15-140S	08436045397423
28-B2-36-100S	08436045396853
28-M4-28-095-28S	00843576100039
28-M4-22-090-22S	00843576100008
28-C2-30-040S	08436045396990
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28-N4-24-159-24S	00843576100961
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28-L2-09-160S	08436045397461
28-L2-11-120S	08436045397331
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28-B2-22-080S	08436045396716
28-B2-28-100S	08436045396822
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28-L2-13-080S	08436045397201
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28-B2-33-120S	08436045396921
28-L2-11-140S	08436045397409
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28-M4-40-250-40S	00843576100480
28-M4-40-105-40S	00843576100091
28-M4-38-250-34S	00843576100770
28-M4-30-200-30S	00843576100305
28-M4-28-155-28S	00843576100169
28-M4-30-155-26S	00843576100534

28-M4-24-090-24S	00843576100015
28-M4-26-095-26S	00843576100022
28-M4-28-195-28S	00843576100299
28-L2-11-160S	08436045397478
28-B2-33-100S	08436045396846
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28-B2-24-120S	08436045396884
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28-B2-33-080S	08436045396761
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28-B2-30-100S	08436045396839
28-L2-09-100S	08436045397256
28-C2-28-070S	08436045397140
28-C2-36-055S	08436045397096
28-L2-11-100S	08436045397263
28-L2-11-080S	08436045397195
28-B2-36-120S	08436045396938
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28-M134145302385S	08436045390417
28-L2-20-120S	08436045397379
28-S2-09-080U	00843576151949
28-S2-11-080U	00843576151956
28-L2-17-140S	08436045397430
28-L2-24-100S	08436045397317
28-N4-34-154-30S	00843576101371
28-N4-32-104-32S	00843576100879
28-X1-06-S-140X	00843576151819
28-L2-24-120S	08436045397386
28-L2-24-140S	08436045397454
28-L2-20-100S	08436045397300
28-L2-17-160S	08436045397508
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28-M134200302485S	08436045390516

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28-C2-28-040S	08436045396983
28-L2-17-120S	08436045397362
28-C2-33-055S	08436045397089
28-C2-33-070S	08436045397164
28-C2-26-040S	08436045396976
28-C2-24-055S	08436045397041
28-L1-17-140S	No EAN code
28-C2-28-055S	08436045397065
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28-N4-42-204-38S	00843576101517
28-N4-36-154-36S	00843576101029
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28-L2-24-160S	08436045397522
28-C2-20-040S	08436045396945
28-M132155282385S	08436045390400
28-L2-20-160S	08436045397515
28-N4-40-154-40S	00843576101043
28-M4-42-195-42S	00843576100367
28-C2-26-055S	08436045397058
28-A1-36-100S	No EAN code
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28-L2-20-140S	08436045397447
28-M130155262285S	08436045390394
28-N4-38-199-34S	00843576101494
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28-L2-09-120S	08436045397324
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28-M128155242285S	08436045390387
28-M132200282385S	08436045390509
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28-B1-26-120S	8436045394576
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28-B1-36-100S	8436045394538
28-B1-22-080S	8436045394392
28-B1-20-100S	8436045394460
28-C1-33-040S	8436045394682

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28-B1-28-120S	8436045394583
28-B1-28-080S	8436045394422
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28-N4-36-154-32S	00843576101388
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28-M4-26-155-26S	00843576100152
28-N4-42-259-38S	00843576101616
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28-N4-36-109-36S	00843576100893

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28-N4-32-259-32S	00843576101265
28-M4-36-190-32S	00843576100664
28-N4-34-154-34S	00843576101012
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28-C2-20-070S	08436045397102
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28-P1-17-033S	08436045397683
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28-N4-38-154-38S	00843576101036
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28-N4-36-199-36S	00843576101159
28-N4-42-159-38S	00843576101418
28-M4-46-250-42S	00843576100817
28-M4-42-195-38S	00843576100695
28-N4-32-209-28S	00843576101463
28-M4-32-155-28S	00843576100541
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28-M4-26-195-26S	00843576100282
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28-M4-42-250-38S	00843576100794
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28-P1-14-033S	08436045397676
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28-B1-36-120S	8436045394613
28-L1-12-080S	No EAN code
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28-M322150222290S	08436045392367
28-M322190222290S	08436045392497
28-M322250222390S	08436045392626
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28-M332200322390S	08436045392541
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28-N246259422690S	08436045393869
28-N246259462690S	08436045393562

MEDICAL DEVICE RECALL NOTICE (Removal)

Please return completed form to Market_Actions-TMC@terumomedical.com and include a copy with the device returns.

Appendix 2: Recall Notice Acknowledgement Form
FSN2026-003

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:	