FSN2026-003 TAG Rev 01

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URGENT: MEDICAL DEVICE RECALL
(REMOVAL/FIELD SAFETY CORRECTIVE ACTION)

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 (including Custom Made devices)** 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 Distributor/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 **taukfsn2026-003boltonrecall@terumoaortic.com** to initiate the return process.

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:

taukfsn2026-003boltonrecall@terumoaortic.com.

On behalf of Bolton Medical, Inc.

Kimberly Feitl
Vice President, Quality

Appendix 1: Recalled Product List

Material	EAN / GTIN
-CMP- (All Custom Made Devices within expiry)	Various
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

Material	EAN / GTIN
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
28-M4-38-100-38S	00843576100084
28-M4-38-145-38S	00843576100213
28-N4-30-209-26S	00843576101456
28-B2-30-080S	08436045396754
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
28-M4-40-145-36S	00843576100589
28-N4-24-159-24S	00843576100961
28-B2-28-120S	08436045396907
28-L2-09-160S	08436045397461
28-L2-11-120S	08436045397331
28-B2-20-100S	08436045396785
28-B2-22-080S	08436045396716
28-B2-28-100S	08436045396822
28-B2-26-120S	08436045396891
28-B2-36-080S	08436045396778
28-L2-13-080S	08436045397201
28-M4-40-250-36S	00843576100787
28-B2-33-120S	08436045396921
28-L2-11-140S	08436045397409
28-M4-38-190-34S	00843576100671
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

Material	EAN / GTIN
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
28-B2-20-120S	08436045396860
28-B2-24-120S	08436045396884
28-B2-30-120S	08436045396914
28-N4-22-099-22S	00843576100824
28-B2-20-080S	08436045396709
28-B2-33-080S	08436045396761
28-L2-09-080S	08436045397188
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
28-S2-13-080U	00843576151963
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
28-L2-17-100S	08436045397294
28-L2-17-080S	08436045397225
28-L2-20-080S	08436045397232
28-S2-13-080S	08436045397553
28-S2-11-080S	08436045397546
28-C2-24-040S	08436045396969
28-B2-22-100S	08436045396792

Material	EAN / GTIN
28-C2-24-070S	08436045397126
28-M134200302485S	08436045390516
28-C2-33-040S	08436045397003
28-A1-26-100S	No EAN code
28-C2-22-040S	08436045396952
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
28-N4-32-209-32S	00843576101135
28-N4-42-204-38S	00843576101517
28-N4-36-154-36S	00843576101029
28-N4-34-209-34S	00843576101142
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
28-N4-40-154-36S	00843576101401
28-L2-20-140S	08436045397447
28-M130155262285S	08436045390394
28-N4-38-199-34S	00843576101494
28-N4-36-259-36S	00843576101289
28-M136145322485S	08436045390424
28-C2-36-040S	08436045397010
28-L2-09-120S	08436045397324
28-M142195382585S	08436045390554
28-M128155242285S	08436045390387
28-M132200282385S	08436045390509
28-B1-30-080S	8436045394439
28-B1-26-120S	8436045394576
28-B1-33-100S	8436045394521
28-B1-36-080S	8436045394453
28-B1-36-100S	8436045394538

Material	EAN / GTIN
28-B1-22-080S	8436045394392
28-B1-20-100S	8436045394460
28-C1-33-040S	8436045394682
28-C1-30-040S	8436045394675
28-B1-28-120S	8436045394583
28-B1-28-080S	8436045394422
28-L1-12-120S	No EAN code
28-L1-12-140S	No EAN code
28-L1-20-120S	No EAN code
28-L1-20-100S	No EAN code
28-L1-12-100S	No EAN code
28-L1-14-120S	No EAN code
28-M144200402585S	08436045390561
28-A1-30-100S	No EAN code
28-A1-24-100S	08436045397560
28-B1-22-100S	8436045394477
28-A1-28-100S	No EAN code
28-M144105442585S	08436045390110
28-A1-22-100S	No EAN code
28-A1-20-100S	08436045397560
28-M126155262285S	08436045390158
28-L2-24-080S	08436045397249
28-M126195262285S	08436045390288
28-M128195242285S	08436045390486
28-M130200262385S	08436045390493
28-M138145342485S	08436045390431
28-M136190322485S	08436045390523
28-M140145362585S	08436045390448
28-M138190342585S	08436045390530
28-M140195362585S	08436045390547
28-N4-38-199-38S	00843576101166
28-N4-34-209-30S	00843576101470
28-M124090242285S	08436045390011
28-N4-34-259-34S	00843576101272
28-C2-30-070S	08436045397157
28-N4-36-199-32S	00843576101487
28-N4-36-154-32S	00843576101388
28-N4-32-164-28S	00843576101364
28-M4-26-155-26S	00843576100152
28-N4-42-259-38S	00843576101616
28-A1-33-100S	No EAN code

Material	EAN / GTIN
28-N4-46-209-42S	00843576101531
28-N4-46-164-42S	00843576101432
28-N4-46-114-46S	00843576100947
28-N4-36-109-36S	00843576100893
28-M4-42-150-38S	00843576100596
28-N4-46-259-46S	00843576101333
28-N4-32-259-32S	00843576101265
28-M4-36-190-32S	00843576100664
28-N4-34-154-34S	00843576101012
28-N4-32-164-32S	00843576101005
28-N4-22-159-22S	00843576100954
28-M4-44-155-44S	00843576100244
28-M4-34-250-30S	00843576100756
28-M4-34-250-34S	00843576100459
28-M4-42-105-42S	00843576100107
28-M4-22-150-22S	00843576100138
28-M4-44-250-40S	00843576100800
28-N4-24-259-24S	00843576101227
28-N4-46-164-46S	00843576101074
28-C2-30-055S	08436045397072
28-N4-46-209-46S	00843576101203
28-C2-20-070S	08436045397102
28-P1-12-031S	08436045397669
28-N4-34-259-30S	00843576101579
28-P1-17-033S	08436045397683
28-N4-34-109-34S	00843576100886
28-N4-44-209-40S	00843576101524
28-N4-38-259-34S	00843576101593
28-N4-38-154-38S	00843576101036
28-M138100382485S	08436045390080
28-M4-38-250-38S	00843576100473
28-M4-46-105-46S	00843576100121
28-N4-38-109-38S	00843576100909
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
28-M122090222285S	08436045390004
28-M4-42-150-42S	00843576100237

Material	EAN / GTIN
28-M4-26-195-26S	00843576100282
28-M4-24-250-24S	00843576100404
28-N4-42-114-42S	00843576100923
28-N4-44-114-44S	00843576100930
28-M4-44-105-44S	00843576100114
28-P1-24-035S	08436045397706
28-M4-42-250-38S	00843576100794
28-N4-42-159-42S	00843576101050
28-P1-14-033S	08436045397676
28-M4-22-250-22S	00843576100398
28-M142150382585S	08436045390455
28-N4-36-259-32S	00843576101586
28-M4-24-190-24S	00843576100275
28-M4-22-190-22S	00843576100268
28-M4-28-155-24S	00843576100527
28-M4-30-250-30S	00843576100435
28-N4-22-199-22S	00843576101081
28-M4-46-200-42S	00843576100718
28-M4-30-200-26S	00843576100633
28-M4-28-195-24S	00843576100626
28-N4-40-204-36S	00843576101500
28-N4-26-204-26S	00843576101104
28-N4-24-199-24S	00843576101098
28-N4-44-164-44S	00843576101067
28-N4-44-209-44S	00843576101197
28-N4-44-259-44S	00843576101326
28-N4-22-259-22S	00843576101210
28-N4-30-259-30S	00843576101258
28-M4-36-250-32S	00843576100763
28-N4-40-259-40S	00843576101302
28-B2-22-120S	08436045396877
28-N4-44-259-40S	00843576101623
28-N4-40-259-36S	00843576101609
28-N4-38-259-38S	00843576101296
28-N4-44-164-40S	00843576101425
28-N4-26-259-26S	00843576101234
28-C2-36-070S	08436045397171
28-M4-24-150-24S	00843576100145
28-N4-42-259-42S	00843576101319
28-M4-32-250-32S	00843576100442
28-P1-20-035S	08436045397690

Material	EAN / GTIN
28-N4-38-154-34S	00843576101395
28-M4-22-190-40S	00843576128026
28-M4-40-190-22S	00843576135512
28-N4-22-190-40S	00843576139145
28-N4-40-190-22S	00843576146631
28-N4-40-204-40S	00843576101173
28-M4-44-155-40S	00843576100602
28-M4-46-155-42S	00843576100619
28-M126095262285S	08436045390028
28-N4-42-204-42S	00843576101180
28-M4-44-200-44S	00843576100374
28-M4-46-200-46S	00843576100381
28-N4-46-259-42S	00843576101630
28-N4-40-114-40S	00843576100916
28-C2-26-070S	08436045397133
28-S2-09-080S	08436045397539
28-M4-46-155-46S	00843576100251
28-C2-22-055S	08436045397034
28-C2-22-070S	08436045397119
28-P1-08-031S	08436045397645
28-M4-28-250-28S	00843576100428
28-M4-42-250-42S	00843576100497
28-M4-30-250-26S	00843576100732
28-N4-32-190-24S	00843576142961
28-N4-34-190-26S	00843576144040
28-N4-36-190-28S	00843576145047
28-N4-42-190-34S	00843576147829
28-N4-38-190-30S	00843576146020
28-N4-40-190-32S	00843576146969
28-N4-44-190-36S	00843576148604
28-N4-46-190-38S	00843576149304
28-M4-32-250-28S	00843576100749
28-N4-32-259-28S	00843576101562
28-M4-36-250-36S	00843576100466
28-M4-44-250-44S	00843576100503
28-M4-46-250-46S	00843576100510
28-M128095282285S	08436045390035
28-M122190222285S	08436045390264
28-M146200422685S	08436045390578
28-P1-10-031S	08436045397652
28-M4-44-200-40S	00843576100701

Material	EAN / GTIN
28-N4-28-259-28S	00843576101241
28-L1-10-160S	No EAN code
28-L1-20-140S	No EAN code
28-B1-33-080S	8436045394446
28-L1-24-140S	No EAN code
28-L1-10-100S	No EAN code
28-L1-10-080S	No EAN code
28-L1-10-140S	No EAN code
28-L1-14-140S	No EAN code
28-L1-24-100S	No EAN code
28-B1-24-080S	8436045394408
28-C1-28-040S	8436045394668
28-L1-17-100S	No EAN code
28-L1-14-080S	No EAN code
28-L1-08-100S	No EAN code
28-L1-08-180S	No EAN code
28-L1-17-120S	No EAN code
28-L1-14-100S	No EAN code
28-B1-28-100S	8436045394507
28-B1-36-120S	8436045394613
28-L1-12-080S	No EAN code
28-M322090222290S	08436045392237
28-M322150222290S	08436045392367
28-M322190222290S	08436045392497
28-M322250222390S	08436045392626
28-M324090242290S	08436045392244
28-M324150242290S	08436045392374
28-M324190242290S	08436045392503
28-M324250242390S	08436045392633
28-M326095262290S	08436045392251
28-M326155262290S	08436045392381
28-M326195262290S	08436045392510
28-M326250262390S	08436045392640
28-M328095282290S	08436045392268
28-M328155242290S	08436045392756
28-M328155282290S	08436045392398
28-M328195242290S	08436045392855
28-M328195282290S	08436045392527
28-M328250242390S	08436045392954
28-M328250282390S	08436045392657
28-M330095302290S	08436045392275

Material	EAN / GTIN
28-M330155262290S	08436045392763
28-M330155302290S	08436045392404
28-M330200262390S	08436045392862
28-M330200302390S	08436045392534
28-M330250262390S	08436045392961
28-M330250302390S	08436045392664
28-M332095322290S	08436045392282
28-M332155282290S	08436045392770
28-M332155322290S	08436045392411
28-M332200282390S	08436045392879
28-M332200322390S	08436045392541
28-M332250282490S	08436045392978
28-M332250322490S	08436045392671
28-M334100342390S	08436045392299
28-M334145302390S	08436045392787
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28-M336145322490S	08436045392794
28-M336145362490S	08436045392435
28-M336190322490S	08436045392893
28-M336190362490S	08436045392565
28-M336250322490S	08436045392992
28-M336250362490S	08436045392695
28-M338100382490S	08436045392312
28-M338145342490S	08436045392800
28-M338145382490S	08436045392442
28-M338190342590S	08436045392909
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28-M338250342590S	08436045393005
28-M338250382590S	08436045392701
28-M340105402490S	08436045392329
28-M340145362590S	08436045392817
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28-M340250402590S	08436045392718

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28-M342105422590S	08436045392336
28-M342150382590S	08436045392824
28-M342150422590S	08436045392466
28-M342195382590S	08436045392923
28-M342195422590S	08436045392596
28-M342250382590S	08436045393029
28-M342250422590S	08436045392725
28-M344105442590S	08436045392343
28-M344155402590S	08436045392831
28-M344155442590S	08436045392473
28-M344200402590S	08436045392930
28-M344200442590S	08436045392602
28-M344250402690S	08436045393036
28-M344250442690S	08436045392732
28-M346105462690S	08436045392350
28-M346155422690S	08436045392848
28-M346155462690S	08436045392480
28-M346200422690S	08436045392947
28-M346200462690S	08436045392619
28-M346250422690S	08436045393043
28-M346250462690S	08436045392749
28-N222099222290S	08436045393050
28-N222159222290S	08436045393180
28-N222199222290S	08436045393319
28-N222259222290S	08436045393449
28-N223164282390S	08436045393227
28-N223164322390S	08436045393210
28-N224099242290S	08436045393067
28-N224159242290S	08436045393197
28-N224199242290S	08436045393326
28-N224259242290S	08436045393456
28-N226104262290S	08436045393074
28-N226164262290S	08436045393203
28-N226204262290S	08436045393333
28-N226259262290S	08436045393463
28-N228104282290S	08436045393081
28-N228164242290S	08436045393579
28-N228164282290S	08436045393210
28-N228204242290S	08436045393678
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28-N228259242390S	08436045393777

Material	EAN / GTIN
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28-N230156432290S	08436045393326
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28-N230164262390S	08436045393227
28-N230164302290S	08436045393227
28-N230164302390S	08436045393227
28-N230209262390S	08436045393685
28-N230209302390S	08436045393357
28-N230259262390S	08436045393784
28-N230259302390S	08436045393487
28-N232104322390S	08436045393104
28-N232164282390S	08436045393593
28-N232164322390S	08436045393234
28-N232209282390S	08436045393692
28-N232209322390S	08436045393364
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28-N232259322490S	08436045393494
28-N234109342390S	08436045393111
28-N234154302390S	08436045393609
28-N234154342390S	08436045393241
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28-N234209342490S	08436045393371
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28-N234259342490S	08436045393500
28-N236109362490S	08436045393128
28-N236154322490S	08436045393616
28-N236154362490S	08436045393258
28-N236199322490S	08436045393715
28-N236199362490S	08436045393388
28-N236259322590S	08436045393814
28-N236259362590S	08436045393517
28-N238109382490S	08436045393135
28-N238154342490S	08436045393623
28-N238154382490S	08436045393265
28-N238190342590S	08436045393050
28-N238199342590S	08436045393722
28-N238199382590S	08436045393395
28-N238259342590S	08436045393821
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28-N240154402590S	08436045393272
28-N240204362590S	08436045393739
28-N240204402590S	08436045393401
28-N240259362590S	08436045393838
28-N240259402590S	08436045393531
28-N242114422590S	08436045393159
28-N242159382590S	08436045393647
28-N242159422590S	08436045393289
28-N242204382590S	08436045393746
28-N242204422590S	08436045393418
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28-N242259422590S	08436045393548
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28-N244164402590S	08436045393654
28-N244164442590S	08436045393296
28-N244209402590S	08436045393753
28-N244209442590S	08436045393425
28-N244259402590S	08436045393852
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28-N244259442690S	08436045393555
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28-N246164462690S	08436045393302
28-N246209422690S	08436045393760
28-N246209462690S	08436045393432
28-N246259422690S	08436045393869
28-N246259462690S	08436045393562

MEDICAL DEVICE RECALL NOTICE (Removal/Field Safety Corrective Action)

Please return completed form to taukfsn2026-003boltonrecall@terumoaortic.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:	
RGA #	

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:	