



Urgent: Medical Device Product Recall Notice

**Device: TREO® Abdominal Stent-Graft System
Certain Lots Manufactured to Date**

May 08, 2023

Dear Valued Customer/Distributor,

Attention: All those implanting or managing affected patients

The purpose of this notice is to inform you that Terumo Aortic is voluntarily recalling specific lots of the Terumo Aortic TREO® Abdominal Stent-Graft Systems due to a potential issue with the affected products incorrectly containing a different-sized graft than expected. The TREO® Abdominal Stent-Graft System is a modular endovascular system designed to treat infrarenal abdominal aortic and aorto-iliac aneurysms.

Terumo Aortic has an investigation underway related to this issue and is currently working to determine the root cause and will take appropriate corrective action. Terumo Aortic has conducted an internal investigation and tracked the affected lots to a narrow time frame resulting from a specific manufacturing event detailed in the table below.

The potential hazard of dimension discrepancies between the package and the actual stent-graft is the risk of implanting an oversized or undersized device that may not fit the patient's anatomy; therefore, not addressing the therapeutic goals aimed by the physician. To date, Terumo Aortic has not received any reports of adverse events related to this issue. There is no safety concern for patients that have already been treated successfully using product from these lots. Patients should be managed according to standard clinical practice. There are no specific patient monitoring instructions related to this Field Safety Corrective Actions that are recommended beyond the existing follow-up schedule.

Actions to be taken by the Customer/User:

1. Examine your inventory to confirm whether you have any affected product and immediately quarantine all impacted items.
2. Complete the attached **Acknowledgement Form**. It may be that you no longer have any physical inventory on site. Completing the form will allow us to update our records and will also negate the need for us to send any further communications on this matter.
 - a. Therefore, please complete the form even if you no longer have any affected product in your physical inventory.
 - b. Note: Terumo Aortic authorizes its customers to utilize electronic signatures and email delivery as a means of submitting necessary documents.
3. Return all affected product to a Terumo Aortic sales representative.

4. Retain a copy of the signed **Acknowledgement Form** and this Field Safety Notice in the event of a compliance audit of your facility's documentation. The names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.
5. Please inform Terumo Aortic of any adverse events concerning the use of the affected product.
 - a. Please comply with any local laws or regulations concerning the notification of adverse events to your local distributor or Competent Authority if appropriate.

If you have any questions regarding this recall, please contact your local sales representative or taustreolabels@terumoaortic.com.

Product and Distribution Information

See Table in Attachment 2 below for the affected product list.

TMC is committed to providing our customers with high-quality, effective medical devices. We take this commitment seriously and understand that on rare occasion, corrective actions such as this recall may be necessary to uphold that commitment.

Thank you for choosing to do business with TMC and we apologize for any inconvenience this action may cause you.

Transmission of this Notice

Forward this notice to all those who need to be aware within your organization such as risk managers and hospital administration, as well as any organization where the potentially affected product has been transferred. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

This correction is being made with the knowledge of the Food and Drug Administration. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Enclosures:

Attachment 1: Customer Acknowledgement Form

Attachment 2: Affected Product List

May 08, 2023

URGENT: MEDICAL DEVICE RECALL

CUSTOMER ACKNOWLEDGMENT FORM

Customer Name
Street Address
City, State, Zip Code

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@terumoaoartic.com.

Affected Product List

Posting Date	Final Catalog	Final Lot#
4/27/2021	28-L2-11-080S	B210123087
4/27/2021	28-L2-15-120U	2104230365
4/27/2021	28-S2-13-080S	B210427155
4/27/2021	28-L2-15-120U	2104230371
4/27/2021	28-L2-17-100U	2104230448
4/27/2021	28-L2-13-080U	2104260081
4/27/2021	28-L2-15-080U	2104120114
4/27/2021	28-L2-13-080U	2104260083
4/27/2021	28-L2-13-080U	2104260082
4/27/2021	28-S2-13-080U	2104270154
4/27/2021	28-S2-13-080S	B210427156
4/27/2021	28-L2-17-100U	2104230449
4/27/2021	28-L2-17-100U	2104230444
4/27/2021	28-S2-13-080S	B210427157
4/27/2021	28-L2-17-100U	2104230459
4/27/2021	28-L2-15-120U	2104230370
4/27/2021	28-L2-15-120U	2104230366
4/27/2021	28-L2-15-120U	2104230364
4/27/2021	28-L2-15-120U	2104230363
4/27/2021	28-L2-15-120U	2104230372
4/27/2021	28-L2-15-120U	2104230369
4/27/2021	28-L2-15-120U	2104230368
4/27/2021	28-L2-17-100U	2104230450
4/27/2021	28-L2-15-120U	2104230367
4/27/2021	28-L2-13-080U	2104260085
4/27/2021	28-L2-20-100U	2104230399
4/27/2021	28-L2-20-100U	2104230394
4/27/2021	28-L2-13-080U	2104260084
4/27/2021	28-L2-13-080S	B210426086
4/27/2021	28-L2-13-080U	2104260087
4/27/2021	28-L2-20-100U	2104230391
4/27/2021	28-L2-20-100U	2104230392

4/27/2021	28-L2-20-100U	2104230395
4/27/2021	28-L2-20-100U	2104230401
4/27/2021	28-L2-20-100U	2104230398
4/27/2021	28-L2-20-100U	2104230403
4/27/2021	28-L2-20-100U	2104230406
4/27/2021	28-L2-20-100U	2104230404
4/27/2021	28-L2-20-100U	2104230409
4/27/2021	28-L2-20-100U	2104230408
4/27/2021	28-L2-20-100U	2104230412
4/27/2021	28-L2-20-100U	2104230411
4/27/2021	28-L2-20-100U	2104230400
4/27/2021	28-L2-20-100U	2104230396
4/27/2021	28-L2-20-100U	2104230390
4/27/2021	28-L2-20-100U	2104230405
4/27/2021	28-L2-20-100U	2104230402
4/27/2021	28-L2-20-100U	2104230407
4/28/2021	28-L2-13-080S	B210426080
4/28/2021	28-L2-13-080S	B210426079
4/28/2021	28-L2-17-100U	2104230447
4/28/2021	28-L2-17-100U	2104230446
4/28/2021	28-CMP-2734-L4	2104290063
4/28/2021	28-L2-17-100U	2104230445
4/28/2021	28-CMP-2802-L1	2104290061
4/28/2021	28-L2-17-100U	2104230443
4/28/2021	28-L2-17-100U	2104230442
4/28/2021	28-CMP-2789-L2	2104290076
4/28/2021	28-L2-17-100U	2104230441
4/28/2021	28-L2-17-100U	2104230437
4/28/2021	28-L2-17-100U	2104230435
4/28/2021	28-CMP-2802-L2	2104290066
4/28/2021	28-L2-17-140U	2104270162
4/28/2021	28-L2-17-100S	B210423433
4/28/2021	28-L2-17-140S	B210423477
4/28/2021	28-L2-15-100S	B210417056
4/28/2021	28-L2-15-100U	2104170055

4/28/2021	28-L2-15-100S	B210417054
4/29/2021	28-L2-15-100U	2104170053
4/29/2021	28-L2-11-100S	B210109120
4/29/2021	28-L2-17-140U	2104260077
4/29/2021	28-L2-17-140U	2104260078
4/29/2021	28-L2-13-160S	B210417186
4/29/2021	28-L2-24-080S	B210423424
4/29/2021	28-L2-24-080U	2104230422
4/29/2021	28-L2-13-120U	2104230470
4/29/2021	28-L2-13-120U	2104230469
4/29/2021	28-L2-24-080S	B210423425
4/29/2021	28-L2-13-120U	2104230468
4/29/2021	28-L2-13-120U	2104230472
4/29/2021	28-L2-24-080U	2104230421
4/29/2021	28-L2-13-120U	2104230471
4/29/2021	28-L2-20-140S	B210427160
4/29/2021	28-L2-20-140S	B210427167
4/27/2021	28-B2-26-080U	2104230262
4/27/2021	28-B2-26-080U	2104230258
4/27/2021	28-B2-26-080U	2104230275
4/27/2021	28-B2-26-080U	2104230260
4/27/2021	28-C2-28-040U	2104230337
4/27/2021	28-C2-28-040S	B210423338
4/27/2021	28-B2-26-080U	2104230264
4/27/2021	28-B2-26-080U	2104230259
4/27/2021	28-C2-28-040S	B210423335
4/27/2021	28-C2-28-040S	B210824336
4/27/2021	28-B2-26-080U	2104230266
4/27/2021	28-A1-28-100S	B210419093
4/27/2021	28-A1-24-100S	B210413288
4/27/2021	28-A1-26-100S	B210419042
4/27/2021	28-A1-24-100S	B210413292
4/27/2021	28-A1-22-100S	B210413330
4/27/2021	28-A1-24-100S	B210413291
4/27/2021	28-A1-26-100S	B210419039

4/27/2021	28-C2-26-040U	2104230316
4/27/2021	28-C2-26-040S	B210423317
4/27/2021	28-C2-26-040S	B210423318
4/27/2021	28-C2-26-040S	B210423319
4/27/2021	28-C2-26-040U	2104230314
4/27/2021	28-A1-26-100S	B210419040
4/27/2021	28-A1-24-100S	B210413290
4/27/2021	28-A1-22-100S	B210413329
4/27/2021	28-C2-28-040U	2104230336
4/27/2021	28-B2-26-080U	2104230263
4/27/2021	28-B2-26-080U	2104230272
4/27/2021	28-B2-26-080U	2104230257
4/27/2021	28-B2-26-080U	2104230261
4/27/2021	28-B2-26-080U	2104230273
4/27/2021	28-B2-26-080U	2104230274
4/27/2021	28-B2-26-080U	2104230265
4/28/2021	28-B2-30-080U	2104230187
4/28/2021	28-B2-28-080U	2104230124
4/28/2021	28-B2-28-080S	B210423141
4/28/2021	28-B2-30-080U	2104230196
4/28/2021	28-B2-28-080S	B210423137
4/28/2021	28-A1-36-100S	B210419171
4/28/2021	28-B2-30-080U	2104230199
4/28/2021	28-B2-26-080U	2104230270
4/28/2021	28-A1-33-100S	B200305246
4/28/2021	28-A1-33-100S	B210413345
4/28/2021	28-A1-36-100S	B210414006
4/28/2021	28-B2-26-080U	2104230281
4/28/2021	28-B2-26-080U	2104230268
4/28/2021	28-B2-26-080U	2104230267
4/28/2021	28-B2-26-080U	2104230269
4/28/2021	28-B2-26-080U	2104230278
4/28/2021	28-B2-30-080U	2104230186
4/28/2021	28-B2-26-080U	2104230279
4/28/2021	28-B2-30-080U	2104230184

4/28/2021	28-B2-30-080U	2104230185
4/28/2021	28-B2-30-080U	2104230200
4/28/2021	28-B2-30-080U	2104230201
4/28/2021	28-B2-30-080U	2104230193
4/28/2021	28-B2-30-080U	2104230198
4/28/2021	28-B2-30-080U	2104230192
4/28/2021	28-B2-30-080U	2104230191
4/28/2021	28-B2-30-080U	2104230194
4/28/2021	28-B2-30-080U	2104230197
4/28/2021	28-B2-26-080U	2104230280
4/28/2021	28-B2-26-080U	2104230271
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4/28/2021	28-B2-28-100U	2104230154
4/28/2021	28-B2-28-100U	2104230164
4/28/2021	28-B2-28-100U	2104230165
4/28/2021	28-B2-28-100U	2104230166
4/28/2021	28-B2-28-100U	2104230167
4/29/2021	28-B2-24-080U	2104230229
4/29/2021	28-C2-24-055S	B210423216
4/29/2021	28-C2-30-040S	B210423346
4/29/2021	28-C2-26-055U	2104170180
4/29/2021	28-B2-24-080U	2104230230
4/29/2021	28-B2-24-080U	2104230233
4/29/2021	28-B2-24-080U	2104230236
4/29/2021	28-B2-36-120S	B201112209
4/29/2021	28-B2-24-080U	2104230232
4/29/2021	28-B2-24-080U	2104230226
4/29/2021	28-C2-22-055U	2104170101
4/29/2021	28-B2-28-080U	2104230138
4/29/2021	28-B2-28-080U	2104230135
4/29/2021	28-B2-30-100U	2104260091
4/29/2021	28-B2-36-100U	2104170130

4/29/2021	28-B2-24-080U	2104230235
4/29/2021	28-B2-36-100U	2104170128
4/29/2021	28-B2-24-080U	2104230244
4/29/2021	28-B2-24-080U	2104230228
4/29/2021	28-B2-36-100U	2104170132
4/29/2021	28-B2-36-100U	2104170133
4/29/2021	28-B2-24-080U	2104230231
4/29/2021	28-B2-36-100U	2104170131
4/29/2021	28-B2-28-080U	2104230143
4/29/2021	28-B2-36-100U	2104170134
4/29/2021	28-B2-24-080U	2104230234
4/29/2021	28-B2-28-080U	2104230136
4/29/2021	28-B2-30-080U	2104230183
4/29/2021	28-B2-28-080U	2104230139
4/29/2021	28-B2-30-080U	2104230182
4/29/2021	28-B2-28-080U	2104230125
4/29/2021	28-B2-28-080U	2104230142
4/29/2021	28-B2-30-080U	2104230189
4/29/2021	28-C2-24-070S	B210423305
4/29/2021	28-B2-30-080U	2104230188
4/29/2021	28-C2-24-070S	B210423304
4/29/2021	28-B2-30-080U	2104230195
4/29/2021	28-B2-30-080U	2104230190
4/29/2021	28-C2-22-055U	2104170100
4/29/2021	28-C2-24-070S	B210423306
4/29/2021	28-C2-24-070S	B210423303
4/29/2021	28-C2-28-070U	2104230342
4/29/2021	28-C2-24-055S	B210423215
4/29/2021	28-C2-26-070S	B210423328
4/29/2021	28-C2-24-055U	2101130271
4/29/2021	28-C2-24-070S	B210423307
4/29/2021	28-C2-26-070S	B210423330
4/29/2021	28-C2-26-070S	B210423331
4/29/2021	28-C2-26-070S	B210423333
4/29/2021	28-C2-28-070U	2104230341

4/29/2021	28-C2-28-070U	2104230339
4/29/2021	28-C2-26-070S	B210423332
4/29/2021	28-C2-28-070U	2104230340
4/29/2021	28-C2-24-055S	B210423214
4/29/2021	28-C2-30-040S	B210423348
4/29/2021	28-B2-24-080U	2104230227
4/29/2021	28-C2-30-040U	2104230347
4/29/2021	28-B2-36-120S	B210423202
4/29/2021	28-C2-30-040S	B210423345