FSN Ref: 2247858-12-06-2022-001R

Relay Pro Customers

Date: 6 Dec 2022

Medical Device Product Removal: RelayPro Labelling Discrepancy

Information on Affected Devices*
1. Device Type(s)
The RelayPro Thoracic Stent-Graft System is an endovascular device intended to treat thoracic aortic pathologies. Once placed in the aorta, the RelayPro Stent-Graft provides an alternative conduit for blood flow while excluding the lesion. The system consists of an implantable stent-graft and a delivery system. The stent-grafts are offered in a Bare proximal stent configuration and a Non-Bare Stent (or NBS) proximal configuration, referred to as RelayPro and RelayPro NBS respectively.
2. Commercial name(s)
The RelayPro Thoracic Stent-Graft System (Bare Stent Configuration) and The RelayPro Thoracic Stent-Graft System (NBS Configuration)
3. Unique Device Identifier(s) (UDI-DI)
See Attachment 1
4. Primary clinical purpose of device(s)
Treatment of aortic pathologies such as aneurysm, pseudoaneurysms, dissections, penetrating ulcers, and intramural hematoma, in adult patients
5. Device Model/Catalogue/part number(s)
Japan ['U' Codes]: approved November 29, 2021 US ['U' codes]: PMA P200045, approved August 5, 2021 EU (CE-marked countries, 'S' Codes): CE mark granted May 3, 2017

Reason for Field Safety Corrective Action (FSCA)	
1. Description of the product problem	
Terumo Aortic Sunrise has received two reports of incorrect stent-graft lengths in the Delivery System versus the size information printed on the pouch and carton label. One event was reported in Japan: the device was implanted and an extension device was used due to the incorrect size graft within the delivery system. The graft remains implanted. A second event was reported in France: this was detected during the procedure and prior to deployment of the graft. The graft was replaced with the correct size and the correct size device was successfully deployed. The procedure concluded successfully. After a thorough investigation, it has been determined that a labeling error has occurred at some point during the manufacturing process leading to discrepancies between the measurements shown on the label and the actual length of the device. The root cause of the labeling error has been determined to be lack of effective line clearance processes.	
2. Hazard giving rise to the FSCA	
The potential hazard of dimension differences between the label and the actual stent-graft is to deploy and implant an oversized or undersized device that would not fit patient's anatomy therefore not addressing the therapeutical goals aimed by the physician.	
3. Probability of problem arising	
There is a very low likelihood of this event occurring. For each of the 2 events reported, a corresponding alternate and incorrectly labeled device has been identified, both under Terumo Aortic control. As of October 31st, 2022, there have been 8,394 RelayPro and RelayPro NBS devices sold, and these are the only two cases of this type of product mismatch/mislabeling noted. This provides an occurrence score of 4/8394 or 0.048%. Additionally, there are numerous steps included in the IFU (Section 4.4 and 11.2 of 2844-8324 Rev. C for US/Japan (U part numbers), Section 9 of 2844-2100 Rev. C and 2844-2304 Rev. B for CE-marked product (S part numbers)) that the stent graft positioning should be checked under fluoroscopy during and after the procedure.	
4. Predicted risk to patient/users	

Per internal risk management documentation (RM-0229 Rev B), this would be an occurrence score of 2, meaning there are relatively few failures.

There are two risks associated with size discrepancies: a Length variance or a Diameter variance (severity 5).

Length variance: Whilst the clinician is not specifically tasked with checking that the correct graft length is being implanted, it is likely that any anomaly would be identified during the procedure under routine fluoroscopy and remedial measures taken to either extend the device if the implanted graft is shorter than expected or removed the device and replace with the correct size device. This would result in extended procedure time.

Diameter variance. An incorrect graft diameter would be difficult to identify by the physician. Variances in diameter can be either of the following: an under-sized diameter or an over-sized diameter.

Over sizing: Stent-Graft diameter would be larger than the diameter indicated on the label
Typically, a range of different diameter grafts are available and on hand for each procedure. Implanting an excessively large diameter could result in infolding of the graft and occlusion of the vessel.

Under sizing: Stent-Graft diameter would be smaller than the diameter indicated on the label:
A gap could occur between the stent graft and the native vessel, leading to the potential for stent graft migration. If the graft is significantly under-sized, the migration may happen right after the deployment. If the under-sizing is minimal, graft migration may not occur.

Diameter variances may be detected by the physician during the procedure and remedial actions taken if required. However, diameter variances may not be detected in all cases and stent graft migration may occur at a later time.

5. Further information to help characterise the problem

An analysis was performed on the two complaints received, including reviews of associated Device History Records (DHRs). The products were manufactured 4 months apart and there are different and unique circumstances associated with each complaint.

• For the first event reported from Japan, a temporary employee performed the pouch sealing process. Whilst the employee was fully trained and certified in the sealing and labeling operations, it appears that failure to follow established procedures for line clearance led to the error. The employee was not involved in the second event and has subsequently left the company.

• For the second event reported from France, an unusually high number of units were pouched (35) on the day the complaint unit was packaged. The established process and associated controls are designed to have a maximum of 30 units processed on a production shift. It is likely that a higher than usual number of units produced on a given day meant that a larger number of units than normal were in the pouching area, and a lack of proper line clearance led to the co-mingling. An analysis showed that this number of units is an anomaly, with only 18 total shifts in the past 2 years recording over 30 units pouched in a shift (see Attachment 1). Based on that information, it has been determined to bound any material that either (a) was prepared by the same operator, or (b) prepared on days where over 30 units were produced.

6. Background on Issue

Under the risk factors described above, 454 units must be quarantined and returned immediately to Terumo Aortic Sunrise for inspection.

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?	Effected units to be returned to manufacturer by February 3, 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 given the low risk. 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)	No
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?	Product removal to be completed by February 3, 2023. Modification to production will be completed in January.
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	Terumoaortic.com
4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
5. List of attachments/appendices:	Appendix 1: List of Catalog Codes and UDI Appendix 2: Reply Form
6. Name/Signature	**Megan Indeglia, Global Vice President Regulatory Affairs**