

Relay Plus Customers

Date: 23 Feb 2021

Urgent Field Safety Notice: RelayPlus and Relay 85 Instructions for Use (IFU) Update

Information on Affected Devices*	
1. Device Type(s)	
RelayPlus and Realy85 are endovascular devices intended to treat fusiform aneurysms and saccular aneurysms / penetrating atherosclerotic ulcers in the descending thoracic aorta. The stent-grafts, once placed in the aorta, provides an alternative conduit for blood flow while excluding the lesion. The system consists of a sterile implantable stent-graft and single-use delivery system.	
2. Commercial name(s)	
RelayPlus Thoracic Stent Graft System (RelayPlus) and RELAY Thoracic Stent-Graft with Transport Delivery System (Relay 85)	
3. Unique Device Identifier(s) (UDI-DI)	
See Appendix 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)	
See Appendix 1	

Reason for Field Safety Corrective Action (FSCA)	
1. Description of the product problem	
There is no defect or malfunction of the RelayPlus or Relay 85 device itself. Discrepancies were noted in the RelayPlus Instructions for Use within Table 2 that lists the target distal landing zones. The proximal landing zones listed are correct however there are errors in the distal landing zone, where recommendations were not listed for graft sizes 30-38 for the Relay 85 device. Additionally, a few of the cited French sizes in Table 1 for the delivery system outer sheath size required update (there is no actual impact to the product, they were all entry errors in the IFU).	
2. Hazard giving rise to the FSCA	
The potential Hazard of following the incorrect guidelines in the IFU for the target distal landing zone could be Type Ib endoleak and resultant intervention to correct. Regarding the sheath size, vessel access could be impacted, however, the likelihood is very low.	
3. Probability of problem arising	
There is very low likelihood that the physician would solely use the IFU in order to determine the distal landing zone requirements and corresponding sheath size.	
4. Predicted risk to patient/users	
Per internal risk management documentation, the risks are categorized with a severity levels of 3 (Serious) with potential harms including 'Delay of procedure' and 'Blood loss'. The occurrence level is also listed as 3 (Moderate, occasional failure). This severity/occurrence level results in an acceptable risk level for the failure mode. However, as there is no defect to the product (only a discrepant IFU) the overall risk to a patient is significantly lower than the documented risk above. Physicians receive training and guidance for device selection prior to use and there have been no reported complaints for these issue in the geographic area where the discrepant IFUs have been utilized.	
5. Further information to help characterise the problem	
The potential harm of following the incorrect guidelines in the IFU for the target distal landing zone could be a Type Ib endoleak and resultant intervention to correct. Regarding the sheath size, vessel access could be impacted, however the likelihood is low as there have been no reported Type Ib endoleaks or related access issues in regions where the incorrect guidance is listed in the IFUs. The IFUs will be updated to correct the landing zone lengths and other identified discrepancies (Appendix 3). Appendix 2 contains copies of the training and planning materials related to the distal landing zone to share with the physicians.	
6. Background on Issue	
Discrepancy noted internally during review of the RelayPlus IFU. There is no associated field issue or complaint. Subsequent to that review, an error was noted in the IFU for the Relay85.	

Type of Action to mitigate the risk	
1. Action To Be Taken by the User <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input checked="" type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)	
2. By when should the action be completed?	Update Instructions for Use should be in devices manufactured after 16 April 2021.
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 as there is no defect to the device. 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)	Yes
5. Action Being Taken by the Manufacturer <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None	
6. By when should the action be completed?	April 16, 2021
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: Training Material Appendix 3: Updated IFU Appendix 4: Reply Form
6. Name/Signature	

REPLY FORM

Affected Product: RelayPlus and Relay 85 Thoracic Stent-Graft Systems
(References 28-M3#####S and 28-M1#####S); all lots
manufactured to date

Issue Description: See **Medical Device Safety Correction Notice** (dated 23 February 2021)
regarding discrepancies noted in the RelayPlus and Relay 85 Instructions for
Use for the target distal landing zones.

Field Action No.: 2247858-02-22-2021-001C

Required Actions by April 30, 2021:

- Review the Training Slide and Updated IFU for proper distal landing zone requirements
- Return this **completed/signed (esignature acceptable)** form to Julie Bourassa via email

Hospital Name _____

Name (Please Print):	Signature:
Title:	Email:
Phone Number:	Date:

Please E-MAIL to Julie Bourassa at:

E-mail: j.bourassa@terumoaortic.com