Rev 1: September 2018

FSN Ref: Manufacturer's ref number FSCA Ref: 2247858-02-22-2021-001C

Date: 23 Feb 2021

Urgent Field Safety Notice
RelayPlus and Relay 85

For Attention of: Relay Distributors

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	RelayPlus is an endovascular device intended to treat fusiform aneurysms and saccular aneurysms / penetrating atherosclerotic ulcers in the descending thoracic aorta. The RelayPro Stent-Graft, 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.
1.	2. Commercial name(s)
	RelayPlus Thoracic Stent Graft System (RelayPlus) and RELAY Thoracic Stent-Graft with Transport Delivery System (Relay 85)
1.	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
1.	5. Device Model/Catalogue/part number(s)*
	See Appendix
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	All
1.	8. Associated devices
	None

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	There is no defect or malfunction of the RelayPlus device itself. Discrepancies were noted in the OUS RelayPlus Instructions for Use (LSPEC-2844-5850, Rev D, LSPEC-2844-1642, Rev J) within Table 2 that lists the target landing zones. The proximal landing zones listed are correct however there are errors in the distal landing zone. After further review, it was also noted that 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). There is no defect or malfunction of the Relay85 device itself. Upon review of the Relay85 IFU (LSPEC-2844-5848 Rev C, LSPEC-2844-1110 Rev L), it was also noted that the landing zone recommendations are correct, however the only error is that the recommendations are not listed for graft sizes 30-38mm.
2.	2. Hazard giving rise to the FSCA*
	The potential Hazard of following the incorrect guidelines in the IFU for the target distal landing zone is a Type Ib endoleak and resultant intervention to correct. Regarding the sheath size, vessel access could be impacted.
	3. Probability of problem arising

2.	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.
2.	4. Predicted risk to patient/users
	These risks are categorized with maximum severity levels of 3 with potential harms including 'Delay of procedure – Serious' and 'Blood loss – Serious'. The maximum occurrence level is also listed as 3. This severity/occurrence level results in an acceptable risk level for the failure mode.
2.	5. Further information to help characterise the problem
	To assess the likelihood of the occurrence of a hazard related to the distal landing zone discrepancy in the IFU, Clinical Evaluation Report for the Relay family of devices was consulted. This report compiles up-to-date clinical data results from internal clinical studies and published literature for the Relay family of devices and relevant competitive products. Table 60 in the RPT presents specific data related to Type Ib endoleaks and suggests Type Ib endoleaks at 30 day follow up also appeared similar among patients that received Relay devices (1.3%) versus competitor devices (1.8%). This was higher than the early Type Ib endoleak rate reported in TEVAR meta-analyses and large studies. Data on Type Ib endoleaks throughout follow up was not well reported in the literature. Among competitor studies, throughout follow up Type Ib endoleak rate increased to 3.2% (2/64) at 2 years post-procedure but later follow up was not reported. For Relay meanwhile, Type Ib endoleaks remained at 0% throughout follow up. Because the type of endoleak may not be differentiated (Ia versus Ib) in publications, all Type I endoleaks were also reviewed (Table 58 of RPT-0003) and again RelayPlus rates were lower as reported in publications versus competitor devices at 2 year follow-up. In a review of internal complaints for the history of RelayPlus commercialization, three complaints specifically attributed to Type Ib endoleaks were reported. 1)TAA-0234, Date Received May 13, 2016: this report was from Japan (the US product is approved in Japan, the OUS IFU would not have been provided); 4 months post-implant, an endoleak was noted. The distal end appeared infolded with a Type Ib endoleak. A competitive device was used during a re-intervention to treat the endoleak. 2)TAA-0381, Date Received July 20, 2018: this case occurred in the US. Three RelayPlus were used to treat an aneurysm and there was no endoleak observed. Upon follow-up CTA, the patient was found to have a Type Ib endoleak. 3)TAA-0472, Date Received June 4, 2019: this case occurred in Japan (the US product is approved in Japan, the OUS IFU would hot have been provided); after implanting two RelayPlus, the physician noted an endoleak and decided to implant a 3rd device distally assuming it was a Type Ib. The endoleak did not resolve and considered this was not a Type Ib.None of the reported Type Ib endoleaks occurred in regions where the discrepant distal landing zone requirements were listed in the IFU. Regarding the error in the sheath sizes listed, the listing of 22Fr rather than 23Fr for the 22 – 26mm sizes would be the ones of concern as the actual diameter would be greater than the value cited in the IFU. Three RelayPlus complaints have been reported involving a 22, 24 or 26mm x 250mm RelayPlus devices.1)TAA-0472 listed above. 2) TAA-0489, Date Received August 27, 2019: Issues were noted in the packaging upon receipt of the device at the Terumo Japan facility, this was an internal complaint. 3) TAA-0507, Date Received October 31, 2019: this case occurred in the US; prior to the procedure, the physician went through a product demo and his hand slipped on the device and he cut his finger. There was no report of access issues in these complaints and they occurred in Japan or the US, not in a region with the discrepant IFU. For the Relay85, there were two complaints that were deemed probable Type Ib endoleaks: 1) TAA-0214 and TAA-0222: Numerous complaints were filed for endoleaks by one physician and hospital in China in 2016. Although the physician was identified as an experienced user of the Relay device, several complaints were filed with suspected Type III or IV endoleaks. Upon examination of each complaint at Bolton, TAA-0214 and TAA-0222 were deemed most likely Type Ib or possibly Type Ia for TAA-0222.

2.	6. Background on Issue
	Discrepancy noted internally during review of IFU artwork LSPEC-2844-5850 Rev D on February 5th. There is no associated field issue or complaint. Subsequent to that review, an error was noted in LSPEC-2844-5848 Rev C, the IFU for the Relay85.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	**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) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety March 19, 2021
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	April 16, 2021
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. 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.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**Global Risk Assessment, GRA-0018, List of Catalogue and UDI Numbers**
4.	10. Name/Signature	**Megan Indeglia, Senior Director Regulatory Affairs**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.