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.

Complete Listing of Reference Numbers

RELAY Thoracic Stent-Graft with Transport Delivery System

#	REFERENCE NUMBER	GTIN		#	REFERENCE NUMBER	GTIN
1	28-M122090222285S	08436045390004		32	28-M136145362485S	08436045390202
2	28-M122150222285S	08436045390134		33	28-M136190322485S	08436045390523
3	28-M122190222285S	08436045390264		34	28-M136190362485S	08436045390325
4	28-M124090242285S	08436045390011		35	28-M138100382485S	08436045390080
5	28-M124150242285S	08436045390141		36	28-M138145342485S	08436045390431
6	28-M124190242285S	08436045390271		37	28-M138145382485S	08436045390219
7	28-M126095262285S	08436045390028		38	28-M138190342585S	08436045390530
8	28-M126155262285S	08436045390158		39	28-M138190382585S	08436045390332
9	28-M126195262285S	08436045390288		40	28-M140105402485S	08436045390097
10	28-M128095282285S	08436045390035		41	28-M140145362585S	08436045390448
11	28-M128155242285S	08436045390387		42	28-M140145402585S	08436045390226
12	28-M128155282285S	08436045390165		43	28-M140195362585S	08436045390547
13	28-M128195242285S	08436045390486		44	28-M140195402585S	08436045390349
14	28-M128195282285S	08436045390295		45	28-M142105422585S	08436045390103
15	28-M130095302285S	08436045390042		46	28-M142150382585S	08436045390455
16	28-M130155262285S	08436045390394		47	28-M142150422585S	08436045390233
17	28-M130155302285S	08436045390172		48	28-M142195382585S	08436045390554
18	28-M130200262385S	08436045390493		49	28-M142195422585S	08436045390356
19	28-M130200302385S	08436045392220		50	28-M144105442585S	08436045390110
20	28-M132095322285S	08436045390059		51	28-M144155402585S	08436045390462
21	28-M132155282385S	08436045390400		52	28-M144155442585S	08436045390240
22	28-M132155322385S	08436045390189		53	28-M144200402585S	08436045390561
23	28-M132200282385S	08436045390509		54	28-M144200442585S	08436045390363
24	28-M132200322385S	08436045390301		55	28-M146105462685S	08436045390127
25	28-M134100342385S	08436045390066		56	28-M146155422685S	08436045390479
26	28-M134145302385S	08436045390417		57	28-M146155462685S	08436045390257
27	28-M134145342385S	08436045390196		58	28-M146200422685S	08436045390578
28	28-M134200302485S	08436045390516		59	28-M146200462685S	08436045390370
29	28-M134200342485S	08436045390318				
30	28-M136100362385S	08436045390073				
31	28-M136145322485S	08436045390424				

RELAY Plus Thoracic Stent-Graft with Delivery System

#	REFERENCE NO.	GTIN	#	REFERENCE NO.	GTIN	#	REFERENCE NO.	GTIN
1	28-M3220902222290S	08436045392237	34	28-M3341003423905	08436045392299	67	28-M3422503825905	08436045393029
2	28-M3221502222905	08436045392367	35	28-M3341453023905	08436045392787	68	28-M3422504225905	08436045392725
3	28-M3221902222905	08436045392497	36	28-M3341453423905	08436045392428	69	28-M3441054425905	08436045392343
4	28-M3222502223905	08436045392626	37	28-M3342003024905	08436045392886	70	28-M3441554025905	08436045392831
5	28-M3240902422905	08436045392244	38	28-M3342003424905	08436045392558	71	28-M3441554425905	08436045392473
6	28-M3241502422905	08436045392374	39	28-M3342503024905	08436045392985	72	28-M3442004025905	08436045392930
7	28-M3241902422905	08436045392503	40	28-M3342503424905	08436045392688	73	28-M3442004425905	08436045392602
8	28-M3242502423905	08436045392633	41	28-M3361003623905	08436045392305	74	28-M3442504026905	08436045393036
9	28-M3260952622905	08436045392251	42	28-M3361453224905	08436045392794	75	28-M3442504426905	08436045392732
10	28-M3261552622905	08436045392381	43	28-M3361453624905	08436045392435	76	28-M3461054626905	08436045392350
11	28-M3261952622905	08436045392510	44	28-M3361903224905	08436045392893	77	28-M3461554226905	08436045392848
12	28-M3262502623905	08436045392640	45	28-M3361903624905	08436045392565	78	28-M3461554626905	08436045392480
13	28-M3280952822905	08436045392268	46	28-M3362503224905	08436045392992	79	28-M3462004226905	08436045392947
14	28-M3281552422905	08436045392756	47	28-M3362503624905	08436045392695	80	28-M3462004626905	08436045392619
15	28-M3281552822905	08436045392398	48	28-M3381003824905	08436045392312	81	28-M3462504226905	08436045393043
16	28-M3281952422905	08436045392855	49	28-M3381453424905	08436045392800	82	28-M3462504626905	08436045392749
17	28-M3281952822905	08436045392527	50	28-M3381453824905	08436045392442			
18	28-M3282502423905	08436045392954	51	28-M3381903425905	08436045392909			
19	28-M3282502823905	08436045392657	52	28-M3381903825905	08436045392572			
20	28-M3300953022905	08436045392275	53	28-M3382503425905	08436045393005			
21	28-M3301552622905	08436045392763	54	28-M3382503825905	08436045392701			
22	28-M3301553022905	08436045392404	55	28-M3401054024905	08436045392329			
23	28-M3302002623905	08436045392862	56	28-M3401453625905	08436045392817			
24	28-M3302003023905	08436045392534	57	28-M3401454025905	08436045392459			
25	28-M3302502623905	08436045392961	58	28-M3401953625905	08436045392916			
26	28-M3302503023905	08436045392664	59	28-M3401954025905	08436045392589			
27	28-M3320953222905	08436045392282	60	28-M3402503625905	08436045393012			
28	28-M3321552822905	08436045392770	61	28-M3402504025905	08436045392718			
29	28-M3321553222905	08436045392411	62	28-M3421054225905	08436045392336			
30	28-M3322002823905	08436045392879	63	28-M3421503825905	08436045392824			
31	28-M3322003223905	08436045392541	64	28-M3421504225905	08436045392466			
32	28-M3322502824905	08436045392978	65	28-M3421953825905	08436045392923			
33	28-M3322503224905	08436045392671	66	28-M3421954225905	08436045392596			