

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION

44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

RADIFOCUS Introducer II

Product : Catheter Introducer

declare that the above products of **Class IIa** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :

TERUMO EUROPE N.V.

Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see Appendix A

Tokyo, July 27, 2023

(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION

Appendix A - List of Code Number Structure

□	□	*	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11	12

Character number	Characters & Meaning
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath.
3	Destination *: for export
4	Kit contents A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel ^{*1} , (Guide inserter ^{*2}) B : Sheath, Dilator, Mini guide wire, (Guide inserter ^{*2}) C : Sheath, Dilator E : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), (Guide inserter ^{*2}) G : Sheath, Dilator, Mini guide wire, Scalpel ^{*1} (Guide inserter ^{*2}) H : Dilator J : Sheath, Dilator, Scalpel ^{*1} K : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (metallic needle), Scalpel ^{*1} , (Guide inserter ^{*2}) L : Sheath, Dilator, Syringe, Entry needle (SurfloFlash), Scalpel ^{*1} M : Sheath, Dilator, Entry needle (SurfloFlash), Scalpel ^{*1} N : Sheath, Dilator, Mini guide wire, Syringe, Scalpel ^{*1} , (Guide inserter ^{*2}) P : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), (Guide inserter ^{*2}) Q : Dilator, Mini guide wire, (Guide inserter ^{*2}) R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter ^{*2}) S : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), Scalpel ^{*1} , (Guide inserter ^{*2}) W : Mini guide wire ^{*1} : not contained in the export specifications ^{*2} : contained when the mini guide wire has an angled tip or a J tip.

Character number	Characters & Meaning																																																																	
5-6	Sheath Size (w/o hydrophilic polymer coating) Characters: 40 50 55 60 65 70 75 80 85 90 10 11 00 Size: 4.0 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 10.0 11.0 no sheath Sheath Size (with hydrophilic polymer coating) Characters: F4 F5 F6 F7 Size: 4.0 5.0 6.0 7.0																																																																	
7	Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm) Standard Type (the items with their product code starting with RS*) <table><tr><td colspan="2" rowspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr><tr><td>0.018"</td><td>0.021"</td><td>0.025"</td><td>0.035"</td><td>0.038"</td></tr><tr><td rowspan="4">Type of scalpel and tray</td><td>b-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">Standard</td></tr><tr><td>a-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr><tr><td>b-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">With adapter</td></tr><tr><td>a-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr><tr><td colspan="2">Entry needle size</td><td>22G × 1"</td><td>22G × 1"</td><td>20G × 2"</td><td>18G × 2 1/2"</td><td>16G × 2 1/2"</td><td rowspan="2"></td></tr><tr><td colspan="2">metallic needle size</td><td>---</td><td>---</td><td>---</td><td>18G × 2 3/4"</td><td>18G × 2 3/4"</td></tr></table>													Mini guide wire diameter/ Dilator inner diameter					Type of Surflo	0.018"	0.021"	0.025"	0.035"	0.038"	Type of scalpel and tray	b-type	A	D	G	K	N	Standard	a-type	B	E	H	L	P	b-type	C	F	J	M	Q	With adapter	a-type	V	W	X	Y	Z	Entry needle size		22G × 1"	22G × 1"	20G × 2"	18G × 2 1/2"	16G × 2 1/2"		metallic needle size		---	---	---	18G × 2 3/4"	18G × 2 3/4"
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Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM): <table><tr><td colspan="2" rowspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr><tr><td>0.018"</td><td>0.021"</td><td>0.025"</td><td>0.035"</td><td>0.038"</td></tr><tr><td rowspan="4">Type of scalpel and tray</td><td>b-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">With adapter</td></tr><tr><td>a-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr><tr><td>b-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">Standard</td></tr><tr><td>a-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr><tr><td colspan="2">Entry needle size</td><td>22G × 1"</td><td>22G × 1"</td><td>20G × 2"</td><td>18G × 2 1/2"</td><td>16G × 2 1/2"</td><td rowspan="2"></td></tr><tr><td colspan="2">metallic needle size</td><td>---</td><td>Metallic Entry Needle improved product 21G × 1 2/5"</td><td>Metallic Entry Needle improved product 20G × 1 2/5"</td><td>18G × 2 3/4"</td><td>18G × 2 3/4"</td></tr></table>														Mini guide wire diameter/ Dilator inner diameter					Type of Surflo	0.018"	0.021"	0.025"	0.035"	0.038"	Type of scalpel and tray	b-type	A	D	G	K	N	With adapter	a-type	B	E	H	L	P	b-type	C	F	J	M	Q	Standard	a-type	V	W	X	Y	Z	Entry needle size		22G × 1"	22G × 1"	20G × 2"	18G × 2 1/2"	16G × 2 1/2"		metallic needle size		---	Metallic Entry Needle improved product 21G × 1 2/5"	Metallic Entry Needle improved product 20G × 1 2/5"	18G × 2 3/4"	18G × 2 3/4"
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Character number	Characters & Meaning
8-9	Length of sheath 05 ~: 50 mm ~
10	Type of mini guide wire A: Plastic, Angled B: Plastic, Angled, 4mm of tip cut E: Straight E F: Flex, Angled H: Short tapered, short angle J: Plastic, 3mm J K: Stiff, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight V: Plastic, 1.5mm J-angle Y: Flex, Straight
11	Packaging Q: Tray package (Multi-language) R: Pouch package (Multi-language)
12	Reserved 1: With scalpel. 5: Inner diameter of dilator at distal end: 0.038", Outer diameter of mini guide wire: 0.035" Z: Entry needle: 20Gx2"→20Gx1 1/4" Length of mini guide wire: 80cm→45cm, scalpel contained. W: Entry needle: 20Gx2"→20Gx1 1/4", scalpel contained.

Appendix A - List of Code Number Structure

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 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters & Meaning					
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath					
3	Destination + / * : Manufactured by TVC for worldwide excluding Japan					
4	Kit contents A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel* ¹ , (Guide inserter* ²) B : Sheath, Dilator, Mini guide wire, (Guide inserter* ²) C : Sheath, Dilator R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle), (Guide inserter* ²) *1: not contained in the export specification *2: contained when the mini guide wire has an angled tip or a J tip.					
5-6	Sheath Size (Fr) (w/o hydrophilic polymer coating)					
	Characters	40	50	60	70	80
	Size	4.0	5.0	6.0	7.0	8.0
	Sheath Size (Fr) (with hydrophilic polymer coating)					
	Characters	F5	F6			
	Size	5.0	6.0			
7	Mini guide wire OD, Dilator ID, Size of Enrtty needle (length of projecting portion of dilator is 25mm) Standard Type (the items with their product code starting with RS*)					
		Mini guide wire diameter/ Dilator inner diameter			Type of Surflo	
		0.025”	0.035”	0.038”		
	Type of scalpel and tray	G	K	N	Standard	
	Entry needle size	20G×2”	18G×2 1/2”	16G×2 1/2”		
	Metallic needle size	---	18G×2 3/4”	18G×2 3/4”		
	Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM*)					
		Mini guide wire diameter/ Dilator inner diameter			Type of Surflo	
		0.021”	0.025”	0.035”		
	Type of scalpel and tray	---	G	---	With adapter	
		F	J	M	Standard	
	Entry needle size	---	20G×2”	---		
Metallic needle size	Metallic Entry Needle improved product 21G×1 2/5”	Metallic Entry Needle improved product 21G×1 2/5”	---			
8-9	Length of sheath 00 : no sheath					

	05~ : 50mm~ ~
10	Type of mini guide wire A: Plastic, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight H: Short tapered, short angle
11	Packaging Q: Tray package (Multi-language #, Chinese) R: Pouch package (Multi-language #, Chinese)
12	Reserved 1: With scalpel. 5: Inner diameter of dilator at distal end: 0.038", Outer diameter of mini guide wire: 0.035" Z: Entry needle: 20Gx2" → 20Gx1 1/4" Length of mini guide wire: 80cm → 45cm, scalpel contained. W: Entry needle: 20Gx2" → 20Gx1 1/4" , scalpel contained.