

EC Design-Examination Certificate
Directive 93/42/EEC Annex II, Section 4
Medical Devices

Registration No.: ID 60156558 0001

Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Product

Identification: Radifocus Guide Wire

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60116055 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2024-05-26

Effective Date: 2021-05-14

Date: 2021-05-14

Notified Body



Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:
Report No.:**

**ID 60156558 0001
21262067 005**

Manufacturer:

**Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan**

Radifocus Guide Wire

Product code system

(1) Radifocus Guide Wire M without radiopaque tip marker

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

Position	Indication & Meaning
1-2	Product name RF: Radifocus Guide Wire M (Non-Shapeable Type) RE: Radifocus Guide Wire M(Shapeable Type)
3	Destination: *: for worldwide excluding Japan
4	Core wire flexibility G: Standard, H: Half stiff, P: Stiff

Date: 2021-05-14



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Radifocus Guide Wire

Position	Indication & Meaning																																																	
5	Tip configuration A: Angled/standard type, B: 3mm J-angled/standard type, C: 6mm J-angled/standard type, E: Double-angled/standard type, K: Angled/Shapeable type L: Straight/Shapeable type N: 2mm J-angled/standard type, R: 1.5mm J-angled/standard type S: Straight/standard type, F: Angled/High Flex type J: Straight/High Flex Type V: 2mm J-angled/Super Flex type																																																	
6-7	Outer diameter of guide wire Character18 Diameter in Stiff core type: 0.020" / 0.51 mm inch/mm Other core types: 0.018" / 0.46 mm Character25323538 0.025" / 0.032" / 0.035" / 0.038" / 0.64 mm 0.81 mm 0.89 mm 0.97 mm																																																	
8-9	Guide wire length <table><tr><td>Indication</td><td>05</td><td>07</td><td>08</td><td>12</td><td>15</td><td>18</td><td>20</td><td>22</td><td>26</td></tr><tr><td>Length (cm)</td><td>50</td><td>70</td><td>80</td><td>120</td><td>150</td><td>180</td><td>200</td><td>220</td><td>260</td></tr><tr><td>Indication</td><td>30</td><td>35</td><td>40</td><td>45</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Length (cm)</td><td>300</td><td>350</td><td>400</td><td>450</td><td></td><td></td><td></td><td></td><td></td></tr></table>										Indication	05	07	08	12	15	18	20	22	26	Length (cm)	50	70	80	120	150	180	200	220	260	Indication	30	35	40	45						Length (cm)	300	350	400	450					
Indication	05	07	08	12	15	18	20	22	26																																									
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Length (cm)	300	350	400	450																																														
10	Flexible part length in the distal tip <table><tr><td>Indication</td><td>1</td><td>3</td><td>5</td><td>8</td></tr><tr><td>Length (cm)</td><td>1 (short taper)</td><td>3 (normal taper)</td><td>5 (long taper)</td><td>8 (long long taper)</td></tr></table>										Indication	1	3	5	8	Length (cm)	1 (short taper)	3 (normal taper)	5 (long taper)	8 (long long taper)																														
Indication	1	3	5	8																																														
Length (cm)	1 (short taper)	3 (normal taper)	5 (long taper)	8 (long long taper)																																														
11	Languages used for labelling M: Multi language																																																	

Date: 2021-05-14



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Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product Code System

(2) Radifocus Guide Wire M without radiopaque tip marker (Standard type)

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

Position	Indication & Meaning							
1-2	Product name RF: Radifocus Guide wire M							
3	Destination +/*: for worldwide excluding Japan							
4	Core wire flexibility G: Standard H: Half Stiff P: Stiff							
5	Tip configuration A: Angled/standard type, S: Straight/standard type							
6-7	Outer diameter of guide wire							
	Indication	18		18		25		
	Diameter (inch/mm)	0.018'' /0.46 mm (other core types)		0.020'' /0.51 mm (stiff core type)		0.025'' /0.64 mm		
		32 0.032'' /0.81 mm		35 0.035'' /0.89 mm		38 0.038'' /0.97 mm		
8-9	Guide wire length							
	Indication Length (cm)	05 50	08 80	12 120	15 150	18 180	22 220	26 260

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Japan

Radifocus Guide Wire

Product Code System

(2) Radifocus Guide Wire M without radiopaque tip marker (Standard type)

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

10	Flexible part length in the distal tip				
	Indication Length (cm)	1 (short taper	3 (normal taper)	5 (long taper)	8 (long long taper)
11	Languages used for labelling M: Multi-language				

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Radifocus Guide Wire

Product Code System

(3) Radifocus Guide Wire M with radiopaque tip marker

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

Position	Indication & Meaning			
1-2	Product name RF: Radifocus Guide Wire M(with radiopaque Tip Marker)			
3	Destination * : for worldwide excluding Japan			
4	Radiopaque marker R: with radiopaque gold tip marker			
5	Tip angle A: 45°, B: 70°			
6-7	Outer diameter of guide wire			
	Indication	10	14	16
	Diameter (inch/mm)	0.011'' / 0.28 mm	0.014'' / 0.36 mm	0.016'' / 0.41 mm
8-9	Guide wire length 18 : 180 (cm)			
10	Flexible part length in the distal tip 8 : 8 (cm) (long long taper)			
11	Accessory supplied with the guide wire T: Torque device			
12	Languages used for labelling M: Multilanguage			



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Japan**

Radifocus Guide Wire

Product Code System

(4)Radifocus Guide Wire GT

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

Position	Indication & Meaning									
1-2	Product name RG: RADIFOCUS GUIDE WIRE GT									
3	Destination * : for worldwide excluding Japan									
4	Type G: Tip not shapeable									
5	Tip configuration: A: 45° angled, B : 70° angled, C: 3.0 mm J-angled, E: 90° angled, J: 1.5 mm J-angled K: Double-angled (110°+ 160°), Q: 15° angled, V: Double-angled (90°+ 90°), W: Double-angled (90°+ 150°), X : Double-angled (135°+ 150°)									
6-7	Outer diameter of guide wire									
	Indication Diameter (inch/mm)	12 0.012'' /0.30 mm	14 0.014'' /0.36 mm	16 0.016'' /0.41 mm						
8-9	Guide wire length 15 : 150 (cm) , 18 : 180 (cm) , 20 : 200 (cm)									
10	Flexibility S: Standard, F: Floppy									
11	Angled tip length									
	Indication	H	J	K	L	N	P	R	None (Standard)	
	Angle tip length (mm)	2	3	5	6	7	8	9	4	
	For products whose angled tip length is 4 mm or is not 2, 3, 5, 6, 7, 8, 9 mm, the code number consists of 11 characters and the 11th character indicates the language for labelling.)									
12	Language for labelling M: Multi-language									

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