

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



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.:** ID 60156558 0001
Report No.: 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

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>							
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



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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 Character 18 Diameter in Stiff core type: 0.020" / 0.51 mm inch/mm Other core types: 0.018" / 0.46 mm Character 25 32 35 38 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									
	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					
10	Flexible part length in the distal tip									
	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									

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44-1, 2-chome, Hatagaya
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Japan

Radifocus Guide Wire

Product Code System

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

<input type="checkbox"/>	<input type="checkbox"/>	+/*	<input type="checkbox"/>							
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)

<input type="checkbox"/>	<input type="checkbox"/>	+/*	<input type="checkbox"/>							
1	2	3	4	5	6	7	8	9	10	11

10	Flexible part length in the distal tip				
	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				



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Radifocus Guide Wire

Product Code System

(3) Radifocus Guide Wire M with radiopaque tip marker

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>								
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	18
	Diameter (inch/mm)	0.011'' /0.28 mm	0.014'' /0.36 mm	0.016'' /.041 mm	0.018'' /046 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: Multi language				



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Japan

Radifocus Guide Wire

Product Code System

(4)Radifocus Guide Wire GT

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>									
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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