

PRODUCT CATALOGUE

from ACCESS
to CLOSURE



PUSHING BOUNDARIES

 **TERUMO**
INTERVENTIONAL
SYSTEMS



Angiographic Catheter

An angiographic or diagnostic catheter is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guidewire or a catheter into the target site. The OUTLOOK 4 Fr (1.40mm) has a large lumen to allow contrast media to be injected at high flow rates and is designed towards exhibit good torque control.¹

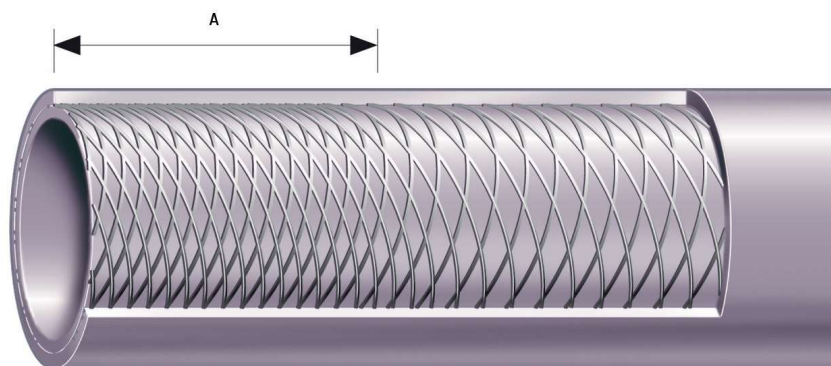
The catheter inserter on the pigtail catheter, can be used to straighten the catheter tip for easier insertion into the sheath. After catheter insertion, it can be peeled off the catheter. Fixed, strain relief, prevents the catheter from kinking at its proximal end.¹

Product Characteristics

- Double-braiding with variable pitch offers proximal support and increased flexibility at the distal end of the catheter, to promote a smooth catheter engagement in all kinds of anatomies.¹
- The wall structure permits flow rates up to 23 ml/sec (saline) and a maximum pressure limit of 1200 psi (8274 kPa)¹
- The Tiger and BLK curves enable angiography of right and left coronary arteries using either radial or brachial approach - The single catheter concept decreases procedure and fluoroscopy time²

¹ Terumo Instructions for Use, Outlook catheter.

² Kim S-M et al. Int J Cardiovasc Imaging 2006;22:295-303.



A Flexible

General specifications

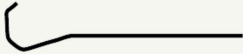
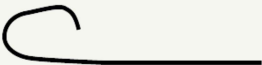
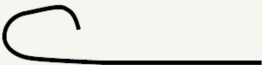
Guidewire Compatibility - Diameter	0.038 in / 0.97 mm
Inner Diameter Of The Shaft	0.041 in / 1.03 mm
Outer Diameter Of The Shaft	1.4 mm / 4 Fr
Pressure Limit	1200 psi

Item specifications

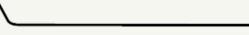
Shape	Side Holes	Length	Code
-	0	30 cm	RQ-ADD4103M
-	0	40 cm	RQ-ADD4104M
-	0	100 cm	RQ-4AR2000M
-	0	100 cm	RQ-4TR5000M
-	0	100 cm	RQ*4AL1000M
-	0	100 cm	RQ-4AL2000M
-	0	100 cm	RQ-BA14110M
-	0	100 cm	RQ-4TR4000M
-	0	100 cm	RQ-4ARJP00M
-	0	100 cm	RQ-4AR1000M
-	0	100 cm	RQ*4AL2000M
-	0	100 cm	RQ-4AL3000M
-	0	100 cm	RQ-BA24110M
-	0	100 cm	RQ-4AL1000M
-	1	100 cm	RQ-4TR3510M
-	1	100 cm	RQ*4TR3510M
-	1	100 cm	RQ*4TR4010M
-	1	100 cm	RQ-4TIG110M

Please quote above item reference codes when placing an order

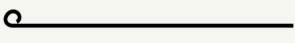
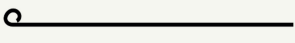
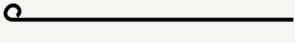
Item specifications

Shape	Side Holes	Length	Code
-	1	100 cm	RQ-4TR4010M
 Radial 4	1	100 cm	RQ-4BLK410M
 Vertebral	0	100 cm	RQ-BH14110M
 Judkins Left 3,5	0	100 cm	RQ*4JL3500M
 Judkins Left 3,5	0	100 cm	RQ-4JL3500M
 Judkins Left 4	0	100 cm	RQ*4JL4000M
 Judkins Left 4	0	100 cm	RQ-4JL4000M
 Judkins Left 5	0	100 cm	RQ-4JL5000M
 Judkins Left 5	0	100 cm	RQ*4JL5000M
 Judkins Left 6	0	100 cm	RQ-4JL6000M
 Multipurpose 2.5	0	100 cm	RQ-4MP2500M

Item specifications

Shape	Side Holes	Length	Code
 Multipurpose 4.0	0	100 cm	RQ-4MP4100M
 Multipurpose 4.0	2	100 cm	RQ-4MP4020M
 Cobra Middle	0	80 cm	RQ-AB54108M
 Internal Mammary	0	100 cm	RQ-4BPJP00M
 Internal Mammary	0	100 cm	RQ-4BPIR00M
 Bypass Judkins Left	0	100 cm	RQ-4BPJL00M
 Bypass Judkins Right	0	100 cm	RQ-4BPJR00M
 Radial L-40	0	100 cm	RQ-4HL4000M
 Radial R-40	0	100 cm	RQ-4HR4000M
 Radial-IMA	0	110 cm	RQ-4BPIP01M
 Mini Cath-Standard 60° Angle	0	20 cm	RQ*BHA4102M

Item specifications

Shape	Side Holes	Length	Code
 Judkins Right 2.5	0	80 cm	RQ-4CR2508M
 Judkins Right 3.5	0	100 cm	RQ-4JR3500M
 Judkins Right 3.5	0	100 cm	RQ*4JR3500M
 Judkins Right 4	0	100 cm	RQ-4JR4000M
 Judkins Right 4	0	100 cm	RQ*4JR4000M
 Judkins Right 5	0	100 cm	RQ-4JR5000M
 Judkins Right 5	0	100 cm	RQ*4JR5000M
 Straight Pigtail	4	65 cm	RQ-4SP504GM
 Straight Pigtail	8	65 cm	RQ-4SP008GM
 Straight Pigtail	8	90 cm	RQ-4SP0089M
 Straight Pigtail	8	110 cm	RQ*4SP0081M

Please quote above item reference codes when placing an order

Item specifications

Shape	Side Holes	Length	Code
 Straight Pigtail	8	110 cm	RQ-4SP0081M
 Mini Cath-Standard	0	20 cm	RQ*BH94102M
 Mini Cath-Standard	0	30 cm	RQ*BH94103M
 Vertebral (Soft Tip)	0	100 cm	RQ-BHA4110M
 Angled Pigtail 145°	8	110 cm	RQ-4AP4581M
 Angled Pigtail 155°	8	110 cm	RQ-4AP5581M

RADIFOCUS® *Optitorque*®

Angiographic catheter



An angiographic or diagnostic catheter is intended for use in angiographic procedures.¹ It delivers radiopaque media and therapeutic agents to selected sites in the vascular system.¹ It is also used to lead a guidewire or a catheter into the target site.¹

Radifocus® Optitorque®, a complete line of coronary diagnostic catheters with optimum torque control and precise placement for smooth angiographic procedures.

Product Characteristics

- *High-torque design, precised manipulation¹*
- *The Tiger and BLK curves enable angiography of right and left coronary arteries using either radial or brachial approach - The single concept decreases procedure and fluoroscopy time²*

¹ Terumo data on file. Reference RF55GB-0805MD-15(0805)E. Measurement of distal rotation angle relative to the proximal rotation angle – comparison single mesh catheters vs Radifocus Optitorque.

² Kim S-M et al. Int J Cardiovasc Imaging 2006;22:295-303.

General specifications

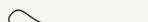
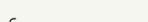
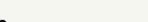
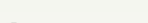
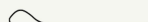
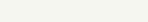
Guidewire Compatibility - Diameter

0.038 in / 0.97 mm

Item specifications

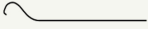
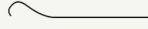
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4 Fr 1.4 mm	20 cm	0.041 in 1.03 mm	-	750 psi	0	RH-BH94102M
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	-	750 psi	0	RH-AE4410GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	-	750 psi	6	RH-4ST016GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 J-Curve Large	750 psi	0	RH*AD4410GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 Shepherd Hook 1.0 cm	750 psi	0	RH*AC4410GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 Shepherd Hook 1.0 cm	750 psi	0	RH-AC4410GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 Cobra 2 Middle	750 psi	0	RH-AB5410GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 Cobra 2 Middle	750 psi	0	RH*AB5410GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 J Curve Large	750 psi	0	RH-AD4410GM

Item specifications

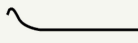
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4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 Cobra 1 Small	750 psi	0	RH-AB4410GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 Cobra 1 Small	750 psi	0	RH*AB4410GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 J-Curve Small	750 psi	0	RH*AD6410GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 Straight Pigtail	750 psi	6	RH-4SP006GM
4 Fr 1.4 mm	65 cm	0.041 in 1.03 mm	 J Curve Middle	750 psi	0	RH-AD5410GM
4 Fr 1.4 mm	80 cm	0.041 in 1.03 mm	-	750 psi	0	RH-AE44108M
4 Fr 1.4 mm	80 cm	0.041 in 1.03 mm	 Cobra 2 Middle	750 psi	0	RH-AB54108M
4 Fr 1.4 mm	80 cm	0.041 in 1.03 mm	 Cobra 2 Middle	750 psi	0	RH*AB54108M

Please quote above item reference codes when placing an order

Item specifications

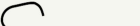
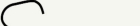
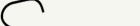
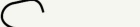
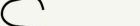
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4 Fr 1.4 mm	80 cm	0.041 in 1.03 mm	 Cobra 3 Large	750 psi	0	RH-AB64108M
4 Fr 1.4 mm	80 cm	0.041 in 1.03 mm	 Cobra 3 Large	750 psi	0	RH*AB64108M
4 Fr 1.4 mm	80 cm	0.041 in 1.03 mm	 Cobra 1 Small	750 psi	0	RH-AB44108M
4 Fr 1.4 mm	80 cm	0.041 in 1.03 mm	 Cobra 1 Small	750 psi	0	RH*AB44108M
4 Fr 1.4 mm	80 cm	0.041 in 1.03 mm	 Straight Pigtail	750 psi	6	RH-4SP0068M
4 Fr 1.4 mm	90 cm	0.041 in 1.03 mm	-	750 psi	0	RH-4ST0109M
4 Fr 1.4 mm	90 cm	0.041 in 1.03 mm	 Straight Pigtail	750 psi	6	RH-4SP0069M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH*BA14110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH-4BPJP00M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH*BA24110M

Item specifications

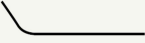
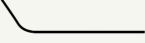
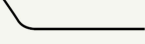
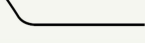
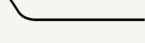
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4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH-4AL2000M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH-BA24110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH-BA34110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH*BB14110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH-BB14110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH*BB24110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH*BA34110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH-BB24110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	-	750 psi	0	RH-BA14110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Bentson Hanafee Wilson 2	750 psi	0	RH*BE24110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Vertebral	750 psi	0	RH*BH14110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Vertebral	750 psi	0	RH-BH14110M

Please quote above item reference codes when placing an order

Item specifications

Outer Diameter	Length	Inner Diameter	Shape	Pressure Limit	Side Holes	Code
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Bentson Hanabee Wilson 1	750 psi	0	RH*BE14110M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Bentson-Hanabee- Wilson 1	750 psi	0	RH-BE14110M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 MANI	750 psi	0	RH-BG14110M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Judkins Left 3,5	750 psi	0	RH*4JL3500M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Judkins Left 3,5	750 psi	0	RH-4CL3500M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Judkins Left 4,0	750 psi	0	RH*4JL4000M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Judkins Left 4	750 psi	0	RH-4CL4000M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Judkins Left 5	750 psi	0	RH*4JL5000M

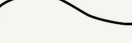
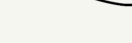
Item specifications

Outer Diameter	Length	Inner Diameter	Shape	Pressure Limit	Side Holes	Code
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Judkins Left 5	750 psi	0	RH-4CL5000M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Multipurpose 2.5	750 psi	2	RH-4MP2520M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Multipurpose 2.5	750 psi	2	RH*4MP2520M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Multipurpose 3.0	750 psi	2	RH*4MP3020M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Multipurpose 3.0	750 psi	2	RH-4MP3020M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Multipurpose 3.5	750 psi	2	RH-4MP3520M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Multipurpose 4.0	750 psi	2	RH*4MP4020M
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Multipurpose 4.0	750 psi	2	RH-4MP4020M

Item specifications

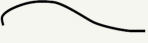
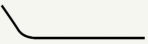
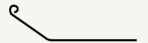
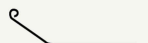
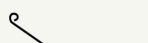
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4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Newton Technique 1	750 psi	0	RH-BC14110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Internal Mammary	750 psi	0	RH-4BPIN00M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Internal Mammary	750 psi	0	RH*4BPIN00M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Amplatz Left Large	750 psi	0	RH-4AL3000M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Amplatz Left Small	750 psi	0	RH-4AL1000M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Amplatz Left Small	750 psi	0	RH*4AL1000M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Amplatz Right Middle	750 psi	0	RH-4AR2000M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Amplatz Right Middle	750 psi	0	RH*4AR2000M

Item specifications

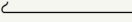
Outer Diameter	Length	Inner Diameter	Shape	Pressure Limit	Side Holes	Code
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Amplatz Right Small	750 psi	0	RH-4AR1000M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Bentson-Hanafee- Wilson 2	750 psi	0	RH-BE24110M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Judkins Right 3.5	750 psi	0	RH*4JR3500M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Judkins Right 3.5	750 psi	0	RH-4CR3500M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Judkins Right 3.5	750 psi	0	RH*4CR3500M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Judkins Right 4	750 psi	0	RH*4JR4000M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Judkins Right 4	750 psi	0	RH-4CR4000M
4 Fr 1.4 mm	100 cm	0.041 in 1.03 mm	 Judkins Right 4	750 psi	0	RH*4CR4000M

Please quote above item reference codes when placing an order

Item specifications

Outer Diameter	Length	Inner Diameter	Shape	Pressure Limit	Side Holes	Code
4 Fr 1,4 mm	100 cm	0,041 in 1,03 mm	 Judkins Right 5	750 psi	0	RH-4CR5000M
4 Fr 1,4 mm	110 cm	0,041 in 1,03 mm	-	750 psi	0	RH-ABP4111M
4 Fr 1,4 mm	110 cm	0,041 in 1,03 mm	-	750 psi	6	RH-4ST0161M
4 Fr 1,4 mm	110 cm	0,041 in 1,03 mm	 Multipurpose 3.5	750 psi	2	RH-4MP3521M
4 Fr 1,4 mm	110 cm	0,041 in 1,03 mm	 Straight Pigtail	750 psi	6	RH*4SP0061M
4 Fr 1,4 mm	110 cm	0,041 in 1,03 mm	 Straight Pigtail	750 psi	6	RH-4SP0061M
4 Fr 1,4 mm	110 cm	0,041 in 1,03 mm	 Angled Pigtail 145°	750 psi	6	RH*4AP4561M
4 Fr 1,4 mm	110 cm	0,041 in 1,03 mm	 Angled Pigtail 145°	750 psi	6	RH-4AP4561M
4 Fr 1,4 mm	110 cm	0,041 in 1,03 mm	 Angled Pigtail 155°	750 psi	6	RH-4AP5561M

Item specifications

Outer Diameter	Length	Inner Diameter	Shape	Pressure Limit	Side Holes	Code
4 Fr 1.4 mm	110 cm	0.041 in 1.03 mm	 Angled Pigtail Round Type 155°	750 psi	4	RH*4APR241M
4 Fr 1.4 mm	110 cm	0.041 in 1.03 mm	 Angled Pigtail Round Type 155°	750 psi	4	RH-4APR241M
5 Fr 1.7 mm	65 cm	0.047 in 1.2 mm	-	1000 psi	0	RH-AED510GM
5 Fr 1.7 mm	65 cm	0.047 in 1.2 mm	-	1000 psi	0	RH-AE4510GM
5 Fr 1.7 mm	65 cm	0.047 in 1.2 mm	 Shepherd Hook 0.8 cm	1000 psi	0	RH-AC3510GM
5 Fr 1.7 mm	65 cm	0.047 in 1.2 mm	 Shepherd Hook 1.0 cm	1000 psi	0	RH-AC4510GM
5 Fr 1.7 mm	65 cm	0.047 in 1.2 mm	 Cobra 2 Middle	1000 psi	0	RH-AB5510GM
5 Fr 1.7 mm	65 cm	0.047 in 1.2 mm	 Cobra 2 Middle	1000 psi	0	RH*AB5510GM
5 Fr 1.7 mm	65 cm	0.047 in 1.2 mm	 J Curve Small	1000 psi	0	RH-AD6510GM

PRODUCT SPECIFICATIONS

Radifocus® Optitorque®

Size	I.D.	Flow rate	Pressure limit
	Shaft	Saline	
4 Fr	1.03 mm	19 ml/sec	750 psi
5 Fr	1.20 mm	32 ml/sec	1000 psi

Outlook™

Size	I.D.	Flow rate	Pressure limit
	Shaft	Saline	
4 Fr	1.03 mm	23 ml/sec	1200 psi

ORDERING INFORMATION

				RADIFOCUS OPTITORQUE CATH.		OUTLOOK CATH.
				Item code by size		
Tip shape	Shape name	Side holes	Length	4 Fr/1.40 mm	5 Fr/1.70 mm	4 Fr/1.40 mm
Visceral Shapes						
	Cobra small	0	65cm	RH-AB4410GM	RH-AB4510GM	-
	Cobra Middle	0	65cm	RH-AB5410GM	RH-AB5510GM	-
	J Curve Small	0	65 cm	RH-AD6410GM	RH-AD6510GM	-
	J Curve Middle	0	65 cm	RH-AD5410GM	RH-AD5510GM	-
	Simmons/Sidewinder 1	0	65 cm	RH-AE4410GM	RH-AE4510GM	-
	Simmons/Sidewinder (type S-J)	0	65 cm	-	RH-AED510GM	-
	Shepherd Hook 1.0 cm	0	65 cm	RH-AC4410GM	RH-AC4510GM	-
	UFE 19 cm	0	80cm	-	RH-AUB510BM	-
Cerebral Shapes						
	Simmons/Sidewinder 1	0	100 cm	RH-BA14110M	-	RQ-BA14110M
	Simmons/Sidewinder 2	0	100 cm	RH-BA24110M	RH-BA25110M	RQ-BA24110M
	Simmons/Sidewinder 3	0	100 cm	RH-BA34110M	RH-BA35110M	-
	Hinck headhunter 1	0	100 cm	RH-BB14110M	RH-BB15110M	-
	Bentson-Hanabee-Wilson 1	0	100 cm	RH-BE14110M	-	-
	Bentson-Hanabee-Wilson 2	0	100 cm	RH-BE24110M	RH-BE25110M	-
	Mani	0	100 cm	-	RH-BG15110M	-
	Vertebral	0	100 cm	RH-BH14110M	RH-BH15110M	RQ-BH14110M
	Vertebral (Soft Tip)	0	100 cm	-	RH-BHB5110M	RQ-BHA4110M
Flush Catheters						
	Straight Pigtail	6	65 cm	RH-4SP006GM	RH-5SP006GM	-
	Straight Pigtail	8	65 cm	-	-	RQ-4SP008GM
	Straight Pigtail	6	80 cm	RH-4SP0068M	-	-
	Straight Pigtail	8	90 cm	-	-	RQ-4SP0089M
	Straight Flush	6	65 cm	RH-4ST016GM	-	-
Bolia Mini Cath						
	Mini-Cath Standard	0	20 cm	RH-BH94102M ¹	-	RQ-BH94102M
	Mini-Cath Standard	0	30 cm	-	-	RQ-BH94103M
	Mini-Cath Standard 60° angle	0	20 cm	-	-	RQ-BHA4102M

1. This item may have additional lead time. Please contact your Terumo representative for more information.

Units per box: 5 pcs

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 INTERVENTIONAL
 SYSTEMS

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

Registration No.: ID 60148413 0001

Report No.: 21228437 006

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

Product Identification: Outlook
(see attachment for products included)
Replaces Certificate, Registration No.: ID 60102567 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: 2020-04-07

Date: 2020-04-07

Notified Body



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

Doc. 1/2, Rev. 0

Attachment to Certificate

Registration No.: ID 60148413 0001
Report No.: 21228437 006

Manufacturer: Terumo Corporation
 44-1, 2-chome, Hatagaya
 SHIBUYA-KU, TOKYO 151-0072
 JAPAN

Angiographic Catheter Outlook

<Thoracic use>

Product code:

Character number:

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

Character number	Characters & Meaning											
1-2	Product type RQ: Outlook											
3	Destination *: for worldwide excluding Japan											
4	Outer diameter of catheter Character : 4 5 Size: Fr. (mm) : 4 (1.40) 5 (1.70)											
5-8	Indication of tip configuration: four digits are specified for each tip shape/Tip curve length											
9	Number of side holes Character : 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, J Number : 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 52											
10	Length Character : 4 E 5 F 6 G 7 H 8 I 9 Length (cm): 40 45 50 55 60 65 70 75 80 85 90 Character : J 0 K 1 L 2 N P Q R S Length (cm): 95 100 105 110 115 120 125 130 135 140 145 Character : T Length (cm): 150											
11	Spare : 0~9, A~Z If unnecessary, omitted											
12	Language for labeling M: Multi-language											

Date: 2020-04-07



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

Attachment to Certificate

Registration No.: ID 60148413 0001
Report No.: 21228437 006

Manufacturer: Terumo Corporation
 44-1, 2-chome, Hatagaya
 SHIBUYA-KU, TOKYO 151-0072
 JAPAN

Scope: Angiographic Catheter Outlook

<Visceral and cerebral use>

Product code: R Q ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
 Character number: 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters & Meaning
1-2	Product type RQ: Outlook
3	Destination *: for worldwide excluding Japan
4	Indication of catheter use A: Abdominal & Peripheral (Visceral use) B: Cerebral use
5-6	Indication of tip configuration/number of side holes: two digits are specified for each tip shape
7	Catheter size O.D. 4: 4 Fr. (1.40 mm)
8	Availability of stopcock 1 : without stopcock
9-10	Catheter Length Characters : 04 0E 05 0F 06 0G 07 0H 08 0I 09 Length (cm): 40 45 50 55 60 65 70 75 80 85 90 Character : 0J 10 1A 11 1B 12 1C 13 1D 14 1E Length (cm): 95 100 105 110 115 120 125 130 135 140 145 Character : 15 Length (cm): 150
11	Languages used for the indications M: Multilanguage :
12	Special product indication : alphanumeric digit to distinguish from standard items

Date: 2020-04-07



DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**

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

being the manufacturer of:

RADIFOCUS Optitorque

Angiographic Catheter

Product : Angiographic Catheter

declare that the above products of **Class III** 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, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60114893 0001) under the supervision of TÜV Rheinland LGA Products GmbH, 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, February 10, 2020

(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION

Appendix A - List of Code Number Structure

R H +/* □ □ □ □ □ □ □ □ □ □ □ □
1 2 3 4 5 6 7 8 9 10 11 12

1) Thoracic use

Position	Meaning of indication		
1 – 2	Product type RH : Radifocus® Optitorque™		
3	Destination * : for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) + / * : for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co., Ltd)		
4	Catheter size O.D. (indication on labelling) 4 : 4 Fr. (1.40 mm) 5 : 5 Fr. (1.70 mm) 6 : 6 Fr. (2.00 mm)		
5 – 8	Indication of tip configuration : these four digits are specific for each tip shape		
	Four digits	Tip shape	Tip curve length
	AL10	AMPLATZ LEFT	Small
	AL20	AMPLATZ LEFT	Middle
	AL30	AMPLATZ LEFT	Large
	AP45	Angled Pigtail	145°
	AP55	Angled Pigtail	155°
	AP65	Angled Pigtail	165°
	APR2	Angled Pigtail	Round Type 155°
	AR10	AMPLATZ RIGHT	Small
	AR20	AMPLATZ RIGHT	Middle
	AR30	AMPLATZ RIGHT	Large
	ARJP	AMPLATZ RIGHT Type JP	Small
	ARR5	AMPLATZ MODIFIED Type NTR r5	-
	ARRC	AMPLATZ MODIFIED Type NTR	-
	BL35	Jacky Radial	3.5 cm
	BL40	Sarah Radial	4.0 cm
	BLK4	Radial BLK	4.0 cm
	BPIG	LIMA	-
	BPIM	Internal Mammary (Round tip)	-
	BPIN	Internal Mammary	-
	BPIR	Internal Mammary	-
	BPJL	Bypass Judkins Left	-
	BPJP	Internal Mammary Type JP	-
	BPJR	Bypass Judkins Right	-
	BPRB	Radial Internal Mammary Type RB	-
	BU35	BACKUP LEFT	3.5 cm
	CAS1	CASTILLO 1	Small
	CAS2	CASTILLO 2	Middle
	CL35	JUDKINS LEFT	3.5 cm
	CL40	JUDKINS LEFT	4.0 cm
	CL45	JUDKINS LEFT	4.5 cm
	CL50	JUDKINS LEFT	5.0 cm
	CL60	JUDKINS LEFT	6.0 cm
	CR35	JUDKINS RIGHT	3.5 cm
	CR40	JUDKINS RIGHT	4.0 cm
	CR45	JUDKINS RIGHT	4.5 cm
	CR50	JUDKINS RIGHT	5.0 cm

Position	Meaning of indication																																																											
	CR60	JUDKINS RIGHT										6.0 cm																																																
	FJ10	Amplatz Right Modified										-																																																
	JL35	JUDKINS LEFT										3.5 cm																																																
	JL40	JUDKINS LEFT										4.0 cm																																																
	JL50	JUDKINS LEFT										5.0 cm																																																
	JL60	JUDKINS LEFT										6.0 cm																																																
	JR35	JUDKINS RIGHT										3.5 cm																																																
	JR40	JUDKINS RIGHT										4.0 cm																																																
	JR50	JUDKINS RIGHT										5.0 cm																																																
	JR60	JUDKINS RIGHT										6.0 cm																																																
	MP25	Multipurpose										2.5cm																																																
	MP30	Multipurpose										3.0cm																																																
	MP35	Multipurpose										3.5cm																																																
	MP40	Multipurpose										4.0cm																																																
	PL15	Baby Judkins Left										1.5cm																																																
	PL20	Baby Judkins Left										2.0cm																																																
	PL25	Baby Judkins Left										2.5cm																																																
	PL30	Baby Judkins Left										3.0cm																																																
	PR15	Baby Judkins Right										1.5cm																																																
	PR20	Baby Judkins Right										2.0cm																																																
	PR25	Baby Judkins Right										2.5cm																																																
	PR30	Baby Judkins Right										3.0cm																																																
	RD30	3D-Right Modified										3.0cm																																																
	RD40	3D RC										4.0cm																																																
	SAL1	AL 1										small																																																
	SAL2	AL 2										middle																																																
	SL35	JUDKINS LEFT										3.5cm																																																
	SL40	JUDKINS LEFT										4.0cm																																																
	SL50	JL 5.0										5.0cm																																																
	SP00	Straight Pigtail										-																																																
	SP02	Straight Pigtail										Small Loop																																																
	ST01	Straight (without soft tip)										-																																																
	TIG1	TIG										4.0cm																																																
	TIG2	Radial TIG 4.5										4.5cm																																																
	TR35	Radial TIG II 3.5										3.5 cm																																																
	TR40	Radial TIG II 4.0										4.0cm																																																
	TR45	Radial TIG II 4.5										4.5 cm																																																
	TR50	Radial TIG II 5.0										5.0 cm																																																
9	Number of holes: Character: 0 1 2 3 4 5 6 7 8 9 J K L T Number: 0 1 2 3 4 5 6 7 8 9 52 20 50 4 (special side holes)																																																											
10	Catheter length : <table><tr><td>Character</td><td>4</td><td>E</td><td>5</td><td>F</td><td>6</td><td>G</td><td>7</td><td>H</td><td>8</td><td>I</td><td>9</td></tr><tr><td>Length (cm)</td><td>40</td><td>45</td><td>50</td><td>55</td><td>60</td><td>65</td><td>70</td><td>75</td><td>80</td><td>85</td><td>90</td></tr><tr><td>Character</td><td>J</td><td>0</td><td>K</td><td>1</td><td>L</td><td>2</td><td>N</td><td></td><td></td><td></td><td></td></tr><tr><td>Length (cm)</td><td>95</td><td>100</td><td>105</td><td>110</td><td>115</td><td>120</td><td>125</td><td></td><td></td><td></td><td></td></tr></table> * The maximum catheter length for the following tip shapes is 100 cm: 3D-Right Modified and 3D RC												Character	4	E	5	F	6	G	7	H	8	I	9	Length (cm)	40	45	50	55	60	65	70	75	80	85	90	Character	J	0	K	1	L	2	N					Length (cm)	95	100	105	110	115	120	125				
Character	4	E	5	F	6	G	7	H	8	I	9																																																	
Length (cm)	40	45	50	55	60	65	70	75	80	85	90																																																	
Character	J	0	K	1	L	2	N																																																					
Length (cm)	95	100	105	110	115	120	125																																																					
11	Braid cut length Q: 60 mm (For products whose braid cut length is not 60mm, the product code consists of 11 characters and the 11th character denotes the language for labeling.)																																																											
12	Languages used for the indications M: Multilanguage																																																											

2) Visceral and cerebral use

Position	Meaning of indication		
1 – 2	Product type RH : Radifocus® Optitorque™		
3	Destination *: for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) + / *: for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co., Ltd)		
4	Indication of catheter use A: Visceral use B: Cerebral use		
5 – 6	Indication of tip configuration: these two digits together with digit 4 makes an unique code specific for each tip shape and number of side holes		
	Two digits	Tip shape	Side holes
Visceral (A in position 4)			
AF	AAF	-	6
B4	Cobra1 (C1)	Small	None
B5	Cobra2 (C2)	Middle	None
B6	Cobra3 (C3)	Large	None
BI	Cobra1 (C1)	Small	1
C3	SHEPHERD HOOK	0.8cm	None
C4	SHEPHERD HOOK	1.0cm	None
D1	J Curve	7.0cm	None
D4	J Curve	Large	None
D5	J Curve	Middle	None
D6	J Curve	Small	None
E4	SIDEWINDER	1	None
E5	SIDEWINDER	2	None
E6	SIDEWINDER	3	None
EC	MESENT	-	1
ED	SIDEWINDER Type: S-J	1	None
F1	Mikaelsson (1)	-	None
G1	RLG	-	None
G3	RH	-	None
G4	RS	-	None
G9	YASHIRO TYPE	-	None
GF	RH Modified	-	None
M7	Straight	-	None
R9	RH CK TYPE	-	None
UB	UFE Type 1	19 cm	None
ZX	Straight	-	8
Cerebral (B in position 4)			
A1	Simmons/Sidewinder 1	Sim1	None
A2	Simmons/Sidewinder 2	Sim2	None
A3	Simmons/Sidewinder 3	Sim3	None
B1	Hinck Headhunter 1	H1	None
B2	HEADHUNTER	3	None
B3	HEADHUNTER	4	None
C1	NEWTON TECHNIQUE	1	None
C2	NEWTON TECHNIQUE	2	None
C3	NEWTON TECHNIQUE	3	None
E1	Bentson-Hanafee-Wilson 1	JB1	None
E2	Bentson-Hanafee-Wilson 2	JB2	None
G1	Mani	-	None

	H1	Vertebral	-	None							
	H8	Vertebral	-	2							
	H9	Vertebral Bolia Mini Cath	-	None							
	K9	Sliding Curve	-	None							
	L1	BERENSTEIN	BL1	None							
	R5	Hinck Headhunter 1	Short tip	None							
	R7	MEDULLAR II	Middle	None							
	R8	MEDULLAR I	Small	None							
	R9	MEDULLAR III	Large	None							
7	Catheter size O.D. (indication on labelling) 4 : 4 Fr. (1.40 mm)5 : 5 Fr. (1.70 mm)										
8	Availability of stopcock 1 : without stopcock										
9 - 10	Catheter length										
	Character	02	03	04	05	06	0G	07	0H	08	0I
	Length (cm)	20	30	40	50	60	65	70	75	80	85
	Character	09	0J	10	1A	11	1B	12	1C		
	Length (cm)	90	95	100	105	110	115	120	125		
11	Languages used for the indications M: Multilanguage										

DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
Interleuvenlaan 40,
3001 Leuven, Belgium

being the manufacturer of:

RADIFOCUS® OPTITORQUE™

Product: Catheter for Angiography
(See Appendix A for related product codes)

declare that the above product of Class III is in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.1 (a) of the Directive, relating to the "Full Quality Assurance System" set out in Annex II, and by certification of Annex II.3 (Registration No: HD 60134707 0001) and Annex II.4 (Registration No: ID 60149181 0001), under the supervision of TÜV Rheinland LGA Products GmbH as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 27.09.2021

(place and date of issue)



M.J. Aerts
VP Regulatory and Vigilance

TERUMO EUROPE N.V.

Appendix A – Related product codes

The product code is composed of 11 digits maximum and explained as follows:

Thoracic use

1	2	3	4	5	6	7	8	9	10	11
R	H	Radifocus Optitorque								
Production site		-	Terumo Europe							
Catheter size O.D.		4	4 Fr. / 1.40 mm							
		5	5 Fr. / 1.70 mm							
		6	6 Fr. / 2.00 mm							
Indication of tip configuration							Tip Shape		Tip curve length	
			A	L	1	0	Amplatz Left		Small	
			A	L	2	0	Amplatz Left		Middle	
			A	L	3	0	Amplatz Left		Large	
			A	P	4	5	Angled Pigtail 145°		5.5 cm	
			A	P	5	5	Angled Pigtail 155°		5.5 cm	
			A	P	6	5	Angled Pigtail 165°		5.5 cm	
			A	P	R	2	Angled Pigtail Round Type 155°		2.0 cm	
			A	R	1	0	Amplatz Right		Small	
			A	R	2	0	Amplatz Right		Middle	
			A	R	3	0	Amplatz Right		Large	
			A	R	J	P	Amplatz Right Type JP		Small	
			A	R	R	5	Amplatz Modified Type NTR r5		-	
			A	R	R	C	Amplatz Modified Type NTR		-	
			B	L	K	4	Radial BLK		-	
			B	P	I	M	Internal Mammary (Round tip)		-	
			B	P	I	N	Internal Mammary		-	
			B	P	I	R	Internal Mammary (short tip)		-	
			B	P	J	L	Bypass Judkins Left		-	
			B	P	J	P	Internal Mammary type JP		-	
			B	P	J	R	Bypass Judkins Right		-	
			B	P	R	A	Internal Mammary Type RA		-	
			B	P	R	B	Internal Mammary Type RB		-	
			B	R	5	5	Hinck Headhunter 1 (short tip)		-	
			B	U	3	5	Backup Left		3.5 cm	
			C	A	S	1	Castillo		Small	
			C	A	S	2	Castillo		Middle	
			C	A	S	3	Castillo		Large	
			C	L	2	5	Judkins Left		2.5 cm	
			C	L	3	5	Judkins Left		3.5 cm	
			C	L	4	0	Judkins Left		4.0 cm	
			C	L	4	5	Judkins Left		4.5 cm	
			C	L	5	0	Judkins Left		5.0 cm	
			C	L	6	0	Judkins Left		6.0 cm	
			C	R	2	5	Judkins Right		2.5 cm	
			C	R	3	5	Judkins Right		3.5 cm	
			C	R	4	0	Judkins Right		4.0 cm	
			C	R	4	1	Judkins Right		4.0 cm	
			C	R	4	5	Judkins Right		4.5 cm	
			C	R	5	0	Judkins Right		5.0 cm	
			C	R	6	0	Judkins Right		6.0 cm	
			H	L	4	0	Radial L-40		4.0 cm	
			H	R	4	0	Radial R-40		4.0 cm	
			J	L	3	5	Judkins Left (Original Shape)		3.5 cm	

1	2	3	4	5	6	7	8	9	10	11
				J	L	4	0	Judkins Left (Original Shape)		4.0 cm
				J	L	5	0	Judkins Left (Original Shape)		5.0 cm
				J	R	3	5	Judkins Right (Original Shape)		3.5 cm
				J	R	4	0	Judkins Right (Original Shape)		4.0 cm
				J	R	5	0	Judkins Right (Original Shape)		5.0 cm
				J	R	6	0	Judkins Right (Original Shape)		6.0 cm
				K	T	4	0	Modified JL-4.0 Type KT		4.0 cm
				M	P	1	5	Multipurpose		1.5 cm
				M	P	2	5	Multipurpose		2.5 cm
				M	P	3	0	Multipurpose		3.0 cm
				M	P	3	1	Multipurpose (3.0 cm) Type EL GAMAL I		Small
				M	P	3	5	Multipurpose (3.5 cm)		3.5 cm
				M	P	4	0	Multipurpose (4.0 cm)		4.0 cm
				M	P	4	1	Multipurpose (4.0 cm) Type EL GAMAL II		Medium
				S	P	0	0	Straight Pigtail		-
				S	P	G	1	Straight Pigtail		Large
				S	T	0	0	Straight (with soft tip)		-
				S	T	0	1	Straight (without soft tip)		-
				S	A	L	1	Amplatz Left (short tip)		Small
				S	A	L	2	Amplatz Left (short tip)		Middle
				S	A	R	1	Amplatz Right(short tip)		Small
				S	A	R	2	Amplatz Right (short tip)		Middle
				S	L	3	5	Judkins Left (Original A Type)		3.5 cm
				S	L	4	0	Judkins Left (Original A Type)		4.0 cm
				S	R	4	0	Judkins Right (Original A Type)		4.0 cm
				T	I	G	1	Brachial Type		4.0 cm
				T	R	3	5	Radial TIG II 3.5		3.5 cm
				T	R	4	0	Radial TIG II 4.0		4.0 cm
			T	R	4	5	Radial TIG II 4.5		4.5 cm	
			T	R	5	0	Radial TIG II 5.0		5.0 cm	
Number of side holes								0 ~ 9	0 to 9 side holes	
Catheter length								6	60 cm	
								G	65 cm	
								7	70 cm	
								8	80 cm	
								9	90 cm	
								0	100 cm	
								1	110 cm	
Languages used for the indications								Multi-language		M

Visceral and cerebral use

1	2	3	4	5	6	7	8	9	10	11		
R	H	RadiFocus Optitorque										
Production site		-	Terumo Europe									
Indication of catheter use & structure		A	Visceral use									
		B	Cerebral use									
Indication of tip configuration					Tip shape				Tip curve length		Side holes	
			A in position 4									
			A	2	Renal				-	None		
			B	4	Cobra 1 (C1)				Small	None		
			B	5	Cobra 2 (C2)				Middle	None		
			B	6	Cobra 3 (C3)				Large	None		
			B	P	Headhunter				9.5 cm	None		
			C	3	Shephard Hook				0.8 cm	None		
			C	4	Shephard Hook				1.0 cm	None		
			D	1	J Curve				7.0 cm	None		
			D	4	J Curve				Large	None		
			D	5	J Curve				Middle	None		
			D	6	J Curve				Small	None		
			E	4	Sidewinder				1 cm	None		
			E	5	Sidewinder				2 cm	None		
			E	6	Sidewinder				3 cm	None		
			E	D	Sidewinder Type S-J				1 cm	None		
			F	1	Mikaelsson (1)				-	None		
			P	C	BPH				19 cm	None		
			U	B	UFE				19 cm	None		
			B in position 4									
			A	1	Simmons/ Sidewinder 1				Sim 1	None		
			A	2	Simmons/ Sidewinder 2				Sim 2	None		
			A	3	Simmons/ Sidewinder 3				Sim 3	None		
			B	1	Hinck Headhunter 1				H1	None		
			B	2	Hinck Headhunter 3				H3	None		
			B	3	Headhunter				4	None		
			C	1	Newton Technique				1	None		
			C	2	Newton Technique				2	None		
			C	3	Newton Technique				3	None		
			E	1	Bentson-Hanafee-Wilson 1				JB1	None		
			E	2	Bentson-Hanafee-Wilson 2				JB2	None		
			G	1	Mani				-	None		
			H	1	Vertebral				-	None		
H	8	Vertebral				-	2					
H	9	Vertebral				Bolia Minicath	None					
H	B	Vertebral (short tip)				-	None					
L	1	Berenstein				BL1	None					
R	5	Hinck Headhunter 1 (short tip)				H1	None					
R	7	Medullar II				Middle	None					
R	8	Medullar I				Small	None					
R	9	Medullar III				Large	None					
Outer diameter of catheter					4	4 Fr. / 1.40 mm						
					5	5 Fr. / 1.70 mm						
Indication of stopcock							1	Without two-way stopcock				
Catheter length							0	2	20 cm			
							0	G	65 cm			

1	2	3	4	5	6	7	8	9	10	11
								0	7	70 cm
								0	8	80 cm
								0	9	90 cm
								1	0	100 cm
								1	1	110 cm
Languages used for the indications								Multilingual		M

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145252 0001

Report No.: 12031336 018

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

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-23

Date: 2019-12-23



Notified Body

M. Aihara
M.Sc. M. Aihara

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

Doc. 1/2, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Products included:

- Blood Bags
- Blood Donor Set
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet



Notified Body

Mai'hara

Date: 2019-12-23

M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Products included:

- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer

Notified Body

M. Aihara

M.Sc. M. Aihara



Date: 2019-12-23

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

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

Scope: Design and Development, Manufacture, Distribution and Service of

- Angiographic Catheter and Accessories
- Anti-adhesion System
- Balloon Dilatation Catheter
- Blood Collection/Transfusion Device and Accessories
- Blood Glucose Monitoring system
- Cartridge Injection System
- Catheter Introducer and Accessories
- Electronic Sphygmomanometer
- Electronic Thermometer
- Embolization Prosthesis and Accessories
- Endoscopic Vessel Harvesting System
- Extracorporeal Circulation Device and Accessories
- Falloposcopic Tuboplasty Device and Accessories
- Guide Wire and Accessories
- Guiding/Micro Catheter and Accessories
- Infusion Pump
- Infusion Set and Accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1485480-1

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

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- Left-Ventricular Assist System
- Needle
- Open-heart surgery devices and Accessories
- Oral Care Device and Accessories
- Peritoneal Dialysis Device and Accessories
- Pneumatically-powered Massager
- Prefillable Syringe
- Pulse Oximeter
- Radial Artery Hemostasis Device and Accessories
- Stent System
- Syringe
- Syringe Infusion Pump
- Syringe with Needle
- Thrombus Removal Device
- Tube Catheter and Accessories
- Urine test strip
- Vascular Closure Device
- Vascular Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



Michiaki Aihara
Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1485480-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Terumo Corporation 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo 151-0072 Japan	Aspects related to Design and Development, Manufacture, Distribution and Service.
/02	c/o Terumo Corporation - Tokyo office 3-20-2, Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Aspects related to Design and Development and activities related to corporate management processes.
/03	c/o Terumo Corporation, Shonan Center 1500, Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Aspects related to Distribution and activities related to customer communication processes.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29