

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

M. Aihara

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

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										

PRODUCT SPECIFICATIONS

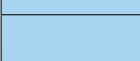
Radifocus® Optitorque®

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
6 Fr	1.30 mm	37 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	6 Fr/2.00 mm	4 Fr/1.40 mm
Cardiology							
	Amplatz Left AL-1	0	100 cm	RH-4AL1000M	RH-5AL1000M	RH-6AL1000M	RQ-4AL1000M
	Amplatz Left AL-2	0	100 cm	RH-4AL2000M	RH-5AL2000M	RH-6AL2000M	RQ-4AL2000M
	Amplatz Left AL-3	0	100 cm	RH-4AL3000M	RH-5AL3000M	RH-6AL3000M	RQ-4AL3000M
	Amplatz Right AR-1	0	100 cm	RH-4AR1000M	RH-5AR1000M	RH-6AR1000M	RQ-4AR1000M
	Amplatz Right AR-2	0	100 cm	RH-4AR2000M	RH-5AR2000M	RH-6AR2000M	RQ-4AR2000M
	Amplatz Right AR-3	0	100 cm	-	RH-5AR3000M	-	-
	Amplatz Right AR-JP	0	100 cm	-	RH-5ARJP00M	-	RQ-4ARJP00M
	Amplatz Modified ModNTR	0	100 cm	-	RH-5ARRC00M	-	-
	Judkins Left CL-3.5 or JL-3.5	0	100 cm	RH-5CL3500M	-	RH-6CL3500M	RQ-4JL3500M
	Judkins Left CL-4.0 or JL-4.0	0	100 cm	RH-5CL4000M	-	RH-6CL4000M	RQ-4JL4000M
	Judkins Left CL-4.0	0	110 cm	-	RH-5CL4001M	-	-
	Judkins Left CL-4.5	0	100 cm	-	RH-5CL4500M¹	RH-6CL4500M	-
	Judkins Left CL-5.0 or JL-5.0	0	100 cm	RH-5CL5000M	-	RH-6CL5000M	RQ-4JL5000M
	Judkins Left CL-6.0 or JL-6.0	0	100 cm	-	RH-5CL6000M	RH-6CL6000M	RQ-4JL6000M
	Judkins Right CR-2.5	0	80 cm	-	-	-	RQ-4CR2508M
	Judkins Right CR-3.5	2	80 cm	-	RH-5CR3528M	-	-
	Judkins Right CR-3.5 or JR-3.5	0	100 cm	RH-4CR3500M	RH-5CR3500M	RH-6CR3500M	RQ-4JR3500M
	Judkins Right CR-3.5	2	110 cm	-	RH-5CR3521M	-	-
	Judkins Right JR-4.0	0	100 cm	-	-	RH-6JR4000M	-
	Judkins Right CR-4.0 or JR-4.0	0	100 cm	RH-4CR4000M	RH-5CR4000M	-	RQ-4JR4000M
	Judkins Right CR-4.0	0	100 cm	-	-	RH-6CR4100M	-
	Judkins Right CR-4.5	0	100 cm	-	-	RH-6CR4500M	-
	Judkins Right CR-5.0 or JR-5.0	0	100 cm	RH-4CR5000M	RH-5CR5000M	RH-6CR5000M	RQ-4JR5000M
	Multipurpose MP-2.5	2	100 cm	RH-4MP2520M	RH-5MP2520M	-	-
	Multipurpose MP-2.5	0	100 cm	-	-	-	RQ-4MP2500M
	Multipurpose MP-3.0	2	100 cm	RH-4MP3020M	-	-	-
	Multipurpose MP-3.5	0	100 cm	-	RH-5MP3500M	RH-6MP3500M	-
	Multipurpose MP-3.5	2	100 cm	RH-4MP3520M	-	-	-
	Multipurpose MP-3.5	2	110 cm	RH-4MP3521M	-	-	-
	Multipurpose MP-4.0	2	100 cm	RH-4MP4020M	RH-5MP4020M	RH-6MP4020M	RQ-4MP4020M
	Multipurpose MP-4.0	0	110 cm	-	RH-5MP4001M	-	-
	Multipurpose EI Gamal 2	0	100 cm	-	-	-	RQ-4MP4100M
	Straight ST	6	65 cm	RH-4ST016GM	-	-	-
	Straight ST	0	90 cm	RH-4ST0109M	-	-	-
	Straight ST	6	110 cm	RH-4ST0161M	-	-	-
	Internal Mammary IM	0	100 cm	RH-4BPIN00M	RH-5BPIN00M	RH-6BPIN00M	-
	Internal Mammary IM-Round Tip	0	100 cm	-	RH-5BPIM00M	-	-
	Internal Mammary IM-Short tip	0	100 cm	-	RH-5BPJ00M	-	RQ-4BPJ00M
	Internal Mammary IM-JP type	0	100 cm	RH-4BPJP00M	RH-5BPJP00M	-	RQ-4BPJP00M
	Bypass BP-JL	0	100 cm	-	RH-5BPJL00M	RH-6BPJL00M	RQ-4BPJL00M
	Bypass BP-JR	0	100 cm	-	RH-5BPJ00M	RH-6BPJ00M	RQ-4BPJ00M
	Straight Pigtail PIG-Small	4	65 cm	-	-	-	RQ-4SP504GM
	Straight Pigtail PIG	6	65 cm	RH-4SP006GM	RH-5SP006GM	-	-
	Straight Pigtail PIG	8	65 cm	-	-	-	RQ-4SP008GM
	Straight Pigtail PIG	6	80 cm	RH-4SP0068M	-	-	-
	Straight Pigtail PIG	6	90 cm	RH-4SP0069M	-	-	-
	Straight Pigtail PIG	8	90 cm	-	-	-	RQ-4SP0089M
	Straight Pigtail PIG	6	110 cm	RH-4SP0061M	RH-5SP0061M	RH-6SP0061M	-
	Straight Pigtail PIG	8	110 cm	-	-	-	RQ-4SP0081M
	Angled Pigtail PIG-145°	6	110 cm	RH-4AP4561M	RH-5AP4561M	RH-6AP4561M	-
	Angled Pigtail PIG-145°	8	110 cm	-	-	-	RQ-4AP4581M
	Angled Pigtail PIG-155°	6	110 cm	-	RH-5AP5561M	RH-6AP5561M	-
	Angled Pigtail PIG-155°	8	110 cm	-	-	-	RQ-4AP5581M
	Radial Tiger I	1	100 cm	-	RH-5TIG110M	RH-6TIG110M	RQ-4TIG110M
	Radial Tiger I	1	110 cm	-	RH-5TIG111M	-	-
	Radial Tiger II-3.5	1	100 cm	-	-	-	RQ-4TR3510M
	Radial Tiger II-4.0	0	100 cm	-	RH-5TR4000M	RH-6TR4000M	RQ-4TR4000M
	Radial Tiger II-4.0	1	100 cm	-	-	-	RQ-4TR4010M
	Radial Tiger II-4.0	0	110 cm	-	RH-5TR4001M	-	-
	Radial Tiger II-4.5	0	100 cm	-	RH-5TR4500M	-	-
	Radial Tiger II-5.0	0	100 cm	-	RH-5TR5000M	RH-6TR5000M	RQ-4TR5000M
	Radial BLK	1	100 cm	-	RH-5BLK410M	RH-6BLK410M	RQ-4BLK410M
	Radial BLK	1	110 cm	-	RH-5BLK411M¹	-	-
	Radial Tiger I	1	100 cm	-	RH-5TIG110M	RH-6TIG110M	RQ-4TIG110M
	Radial Tiger I	1	110 cm	-	RH-5TIG111M	-	-

1. This device may have additional lead time. Please contact your local Terumo contact for more information.

Units per box: 5 pcs

PRODUCT SPECIFICATIONS

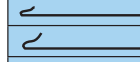
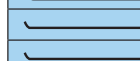
Radifocus® Optitorque®

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

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	-
		0	80 cm	RH-AB44108M	RH-AB45108M	-
	Cobra Middle	0	65cm	RH-AB5410GM	RH-AB5510GM	-
		0	80 cm	RH-AB54108M	RH-AB55108M	RQ-AB54108M
	Cobra Large	0	80 cm	RH-AB64108M	RH-AB65108M	-
	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 2	0	80 cm	RH-AE44108M	RH-AE55108M	-
	Simmons/Sidewinder (type S-J)	0	65 cm	-	RH-AE0510GM	-
	Shepherd Hook 1.0 cm	0	65 cm	RH-AC4410GM	RH-AC4510GM	-
	UFE 19 cm	0	80cm	-	RH-AUB5108M	-
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						Units per box: 5 pc
	Mini-Cath Standard	0	20 cm	RH-BH94102M¹	-	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 additionnal lead time. Please contact your Terumo representative for more information.



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RADIFOCUS® *Optitorque*®

A complete line of angiographic catheters, designed for easy manipulation.

- **Easy manipulation**

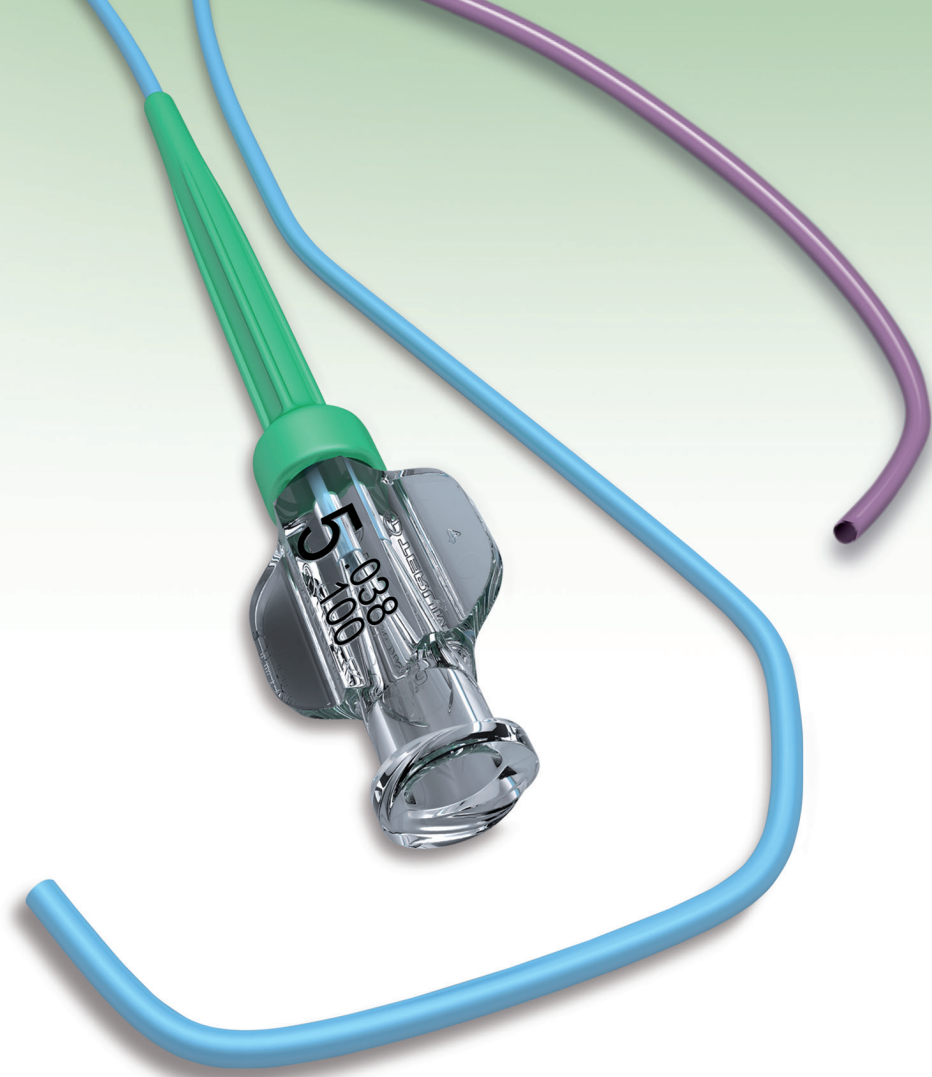
The double-braided stainless steel mesh technology provides good torque control (1:1) and catheter stability.

- **Reduced injection time**

The catheter's ultra-thin wall creates a large lumen thereby increasing flow of the contrast media and reducing injection time¹.

- **A full range of shapes**

Dedicated shapes for cardiology and peripheral procedures.

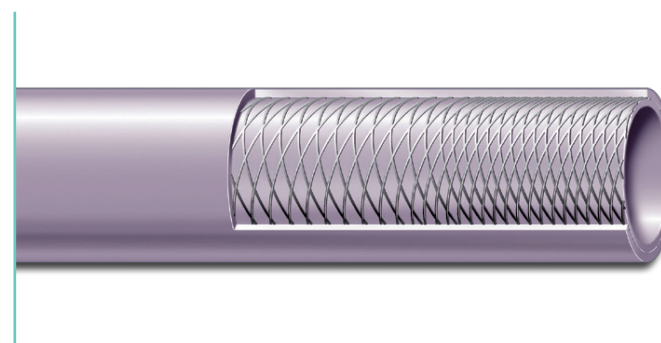


Outlook™

The dedicated 4 Fr Outlook catheter facilitates performance through a small diameter.

- **Smooth catheter engagement**

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.



- **High pressure limits**

The ultra-thin wall structure permits smaller outer and larger inner diameter enabling flow rates up to 23 ml/sec (Saline), and a maximum pressure limit of 1200 psi/8274 kPa.



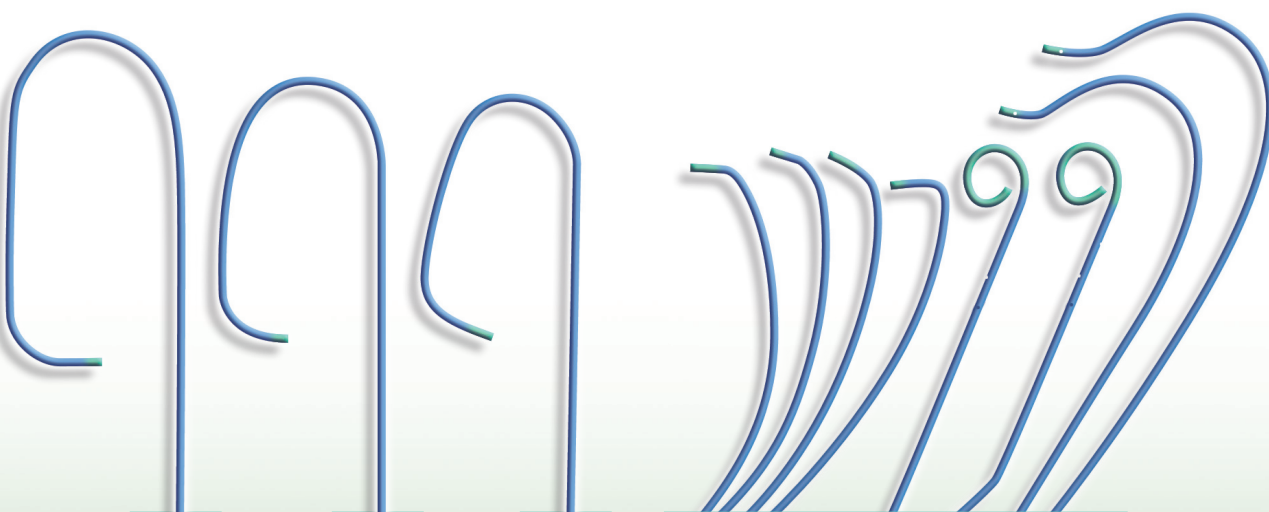
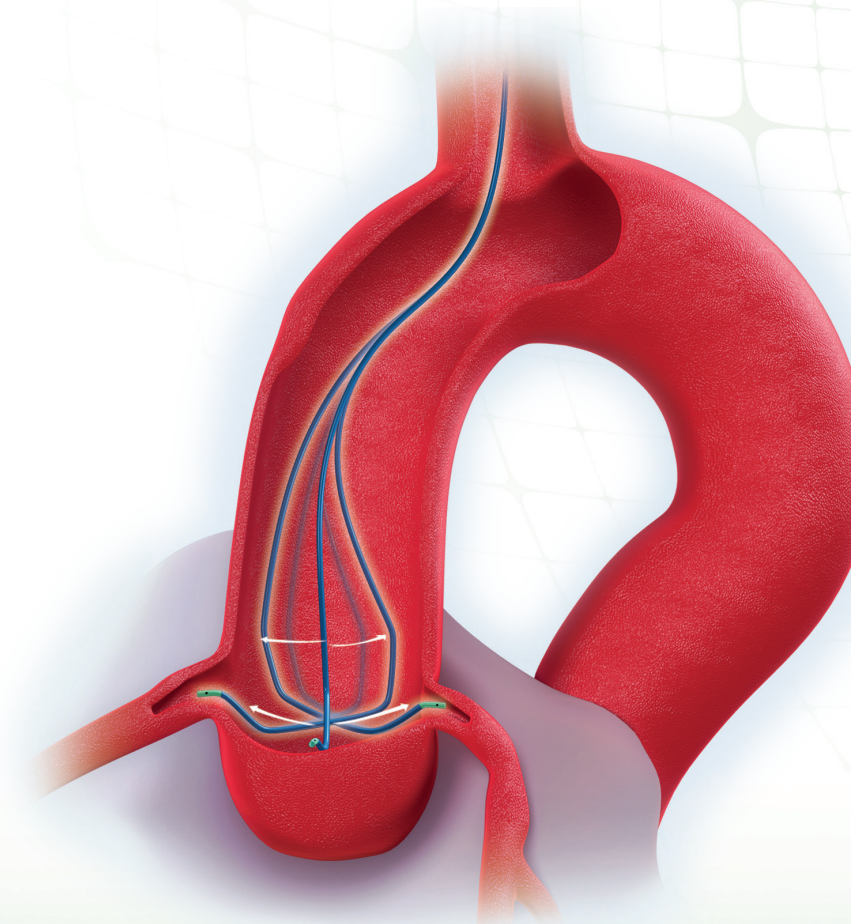
OUR DEDICATION TO **TRANSRADIAL PROCEDURES**

Radial Shapes

The Tiger and BLK curves enable angiography of right and left coronary arteries using either radial or brachial approach. The single catheter concept, eliminating the catheter exchange step, provides both procedural and cost efficiencies¹.

- **Single catheter concept for coronary interventions**

- › **Eliminates** catheter exchange step.
- › **Shortens** procedure and fluoroscopic time¹.
- › Engages with a **simple** clockwise rotation to enhance ease of use¹.



1. Seong-Man Kim et al, 2005. Novel Diagnostic Catheter specifically designed for both coronary arteries via the right transradial approach. The International Journal of Cardiovascular Imaging. 2005, 10.007/s10554-005-9029-8. A prospective, randomised trial of Terumo Tiger II vs Cordis Judkins Catheters.



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...										
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Productatorul	Reprezentant	Ordin	Data	Cod vamal
		Optitorque				Terumo				
DM000051684	CATERET DE DIAGNOSTIC PENTRU ANGIOGRAFIE	RADIFOCUS® OPTITORQUE®			Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.P5-01.Rg04-52	19-02-2018	
DM000125119	CATERET PENTRU ANGIOGRAFIE	RADIFOCUS® OPTITORQUE®	ANGIOGRAPHIC CATHETER		Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.P5-01.Rg04-163	19-06-2018	

✓ ☐ `Consozimit(NameMake) , 'Optitorque' ) И Consozimit(Productatorul) , 'Terumo'`