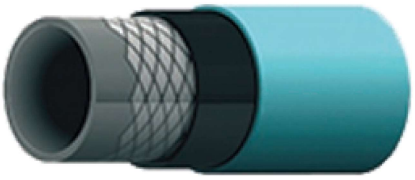
RADIFOCUS®



Angiographic Catheter

Radifocus Angiographic Catheter is a 5 Fr angiographic catheter 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.

Product Characteristics

- *Polyamide surface, rounded tip and one-piece body structure.*
- *Internal metallic mesh braid.*
- *Radiopaque surface.*
- *High pressure resistance (up to 1000 psi/6895 kPa).*
- *Various type shapes available.*

General specifications

Catheter Material	Polyamide
Guidewire Compatibility - Diameter	0.038 in / 0.97 mm
Hydrophilic Coating	Polyamide
Inner Diameter	0.043 in / 1.1 mm
Mesh Braid Material	Stainless Steel
Pressure Limit	1000 psi / 6895 kPa

Digitally signed by Grabazei Alexandru
Date: 2022.02.03 16:33:32 EET
Reason: MoldSign Signature
Location: Moldova

IS803/31GB1219KAVIII

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	65 cm	Femoral - Cerebral Shape	 Vertebral	0	RF-EH1500GM
5 Fr 1.7 mm	65 cm	Femoral - Ventricular Shape	-	6	RF-FG1500GM
5 Fr 1.7 mm	65 cm	Femoral - Ventricular Shape	 Straight	6	RF-FK1500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	-	0	RF-DD4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	-	0	RF*DD4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	-	0	RF-DD6500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	-	0	RF-DD5500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Shepherd Hook 0.8 cm	0	RF-DC3500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Shepherd Hook 1.0 cm	0	RF*DC4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Shepherd Hook 1.0 cm	0	RF-DC4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 2 Middle	0	RF-DB5500GM

Please quote above item reference codes when placing an order

IS803/31GB1219KAVIII

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 2 Middle	2	RF-DB2500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 2 Middle	2	RF*DB2500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 3 Large	0	RF-DB6500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 3 Large	2	RF-DB3500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 1 Small	0	RF-DB4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 1 Small	2	RF-DB1500GM
5 Fr 1.7 mm	65 cm	Femoral- Visceral Shape	-	0	RF-DE4500GM
5 Fr 1.7 mm	80 cm	Femoral - Ventricular Shape	-	6	RF-FG15008M
5 Fr 1.7 mm	80 cm	Femoral - Ventricular Shape	 Straight	6	RF*FK15008M
5 Fr 1.7 mm	80 cm	Femoral - Ventricular Shape	 Straight	6	RF-FK15008M

Please quote above item reference codes when placing an order

IS803/31GB1219KAVIII

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	0	RF-DAC5008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	0	RF-DA25008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	0	RF*DG35008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	0	RF-DAB5008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	2	RF*DA15008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	2	RF-DA15008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	4	RF*FL15008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Straight	0	RF*DI15008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 2 Middle	0	RF*DB55008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 2 Middle	0	RF-DB55008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 3 Large	0	RF-DB65008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 3 Large	0	RF*DB65008M

Please quote above item reference codes when placing an order

IS803/31GB1219K-AVIII

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 1 Small	0	RF-DB45008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 1 Small	0	RF*DB45008M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EJ15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EB35010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EB15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EC25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EC45010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EA15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EA25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EA35010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EC25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EB15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EB25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EJ15010M

Please quote above item reference codes when placing an order

IS803/31GB1219KAVIII

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EC35010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EA15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EA25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EB25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EC45010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EA35010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Vertebral	0	RF-EH15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Vertebral	0	RF*EH15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Vertebral	2	RF-EH45010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Bentson-Hanafee-Wilson 1	0	RF-EE15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 MANI	0	RF*EG15010M

Please quote above item reference codes when placing an order

IS803/31GB1219KAVIII

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 MANI	0	RF-EG15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Newton technique 1	0	RF-EC15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Bentson-Hanafee- Wilson 2	0	RF-EE25010M
5 Fr 1.7 mm	100 cm	Femoral -Cerebral Shape	-	0	RF-EA45010M
5 Fr 1.7 mm	110 cm	Femoral - Ventricular Shape	-	6	RF-FG15011M
6 Fr 2.0 mm	80 cm	Femoral - Visceral Shape	-	4	RF*FL16008M

Please quote above item reference codes when placing an order

IS803/31GB1219KAVIII

EC Certificate

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

Registration No.: HD 60134707 0001

Report No.: 21240046 017

Manufacturer:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products: (see attachment for products and additional sites included)

Replaces Certificate, Registration No.: HD 60106290 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.

Notified Body

Effective Date: 2020-04-21

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

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.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products included:

- Syringes
- Needles
- Administration sets
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires
- Introducer for vascular access
- Angiographic Catheters
- Guidewire for Angiography

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:
- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüfstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

additional sites included:

Terumo Europe N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium

Terumo Europe UK
3 Unity Grove, Knowsley Business Park South
Knowsley, Merseyside L34 9GT, United Kingdom

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüf- und Zertifizierungsstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

EC Design-Examination Certificate

Directive 93/42/EEC Annex II, Section 4

Medical Devices

Registration No.: ID 60148569 0001

Report No.: 21228431 007

Manufacturer:

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

Product Identification:

Radifocus Glidecath

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60102630 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: 2020-04-21

Date: 2020-04-21

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

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 Certificate
Registration No.: ID 60148569 0001
Report No.: 21228431 007

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

Angiographic Catheter Radifocus Glidecath

Product code:	R	F	*	□	□	□	□	□	□	□	□	□
Character number:	1	2	3	4	5	6	7	8	9	10	11	12

Character number	Characters & Meaning
1-2	Product name RF: Radifocus
3	Destination * : for export
4	Applied region: **X:** Renal & Visceral, **Y:** Cerebral (for single braided) **Z:** Renal & Visceral, **W**: Cerebral (for double braided)
5-6	Indication of tip configuration: these two digits together with digit 4 makes an unique code specific for each shape and number of side holes
7	Outer diameter of catheter: Indication: **4** **5** Diameter (Fr/mm): 4 (1.40) 5 (1.70)
8	Indication of two-way stopcock 1 : without two-way stopcock
9-10	Catheter length

Character :	**02**	**0C**	**03**	**0D**	**04**	**0E**	**05**	**0F**	**06**	**0G**	**07**
Length (cm):	20	25	30	35	40	45	50	55	60	65	70
Character :	**0H**	**08**	**0I**	**09**	**0J**	**10**	**1A**	**11**	**1B**	**12**	**1C**
Length (cm):	75	80	85	90	95	100	105	110	115	120	125
Character :	**13**	**1D**	**14**	**1E**	**15**						
Length (cm):	130	135	140	145	150						

Notified Body
TÜVRheinland
Dipl.-Ing. S. Pane

Date 2020-04-21

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: ID 60148569 0001
Report No.: 21228431 007

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

Angiographic Catheter Radifocus Glidecath

Product code:	R	F	*	□	□	□	□	□	□	□	□	□
Character number:	1	2	3	4	5	6	7	8	9	10	11	12

Character number	Characters & Meaning
11	Hydrophilic coating length Character : **1** **2** **3** **4** **5** **6** **7** **8** **9** **F** **G** Length (cm): 1 2 3 4 5 6 7 8 9 20 25 Character : **H** **I** **J** **K** **L** Length (cm): 30 35 40 45 50 The eleventh character is omitted for all catheters with hydrophilic coating length of 15 cm.
12	Language for labeling **M** = Multilanguage **A** = Multilanguage (sold in USA)

Notified Body

Date 2020-04-21

Dipl.-Ing. S. Pane

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS® ANGIOGRAPHIC CATHETER

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 60106290 0001) and Annex II.4 (Registration No: ID 60114889 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, 15.01.2019
(place and date of issue)

M.J. Aerts
VP Quality and Regulatory Affairs
TERUMO EUROPE N.V.

Appendix A – Related product codes

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

1	2	3	4	5	6	7	8	9	10	11
R	F	RadiFocus								
Production site		-	Terumo Europe							
Indication of catheter use & structure			D	Renal & Visceral use						
			E	Cerebral						
			F	Cardiac						
Indication of tip configuration						Tip shape			Tip curve length	Side holes
				D in position 4						
				A	1	Femoral-Visceral RENAL			-	2
				A	2	Femoral-Visceral RENAL			-	None
				A	4	Femoral-Visceral Cobra Kimoto Type			Small	None
				A	7	Modified RENAL			-	None
				A	8	Femoral-Visceral Cobra			Small	1
				A	B	Femoral-Visceral RENAL Right (small curve)			-	None
				A	C	Femoral-Visceral RENAL Left			-	None
				B	1	Femoral-Visceral COBRA			Small	2
				B	2	Femoral-Visceral COBRA			Middle	2
				B	3	Femoral-Visceral COBRA			Large	2
				B	4	Femoral-Visceral COBRA			Small	None
				B	5	Femoral-Visceral COBRA			Middle	None
				B	6	Femoral-Visceral COBRA			Large	None
				B	7	Femoral-Visceral Cobra			Small	2
				B	8	Femoral-Visceral Cobra			Middle	2
				B	9	Femoral-Visceral Cobra			Large	2
				C	1	Femoral-Visceral Shepherd Hook			0.8 cm	2
				C	2	Femoral-Visceral Shepherd Hook			1.0 cm	2
				C	3	Femoral-Visceral Shepherd Hook			0.8 cm	None
				C	4	Femoral-Visceral Shepherd Hook			1.0 cm	None
				C	6	Femoral-Visceral Shepherd Hook			1.2 cm	None
				C	7	Femoral-Visceral Shepherd Hook			CJ1	None
				C	8	Femoral-Visceral Shepherd Hook			CJ2	1
				D	3	Femoral-Visceral J Curve			Small	2
				D	4	Femoral-Visceral J-Curve			1	None
				D	5	Femoral-Visceral J-Curve			2	None
				D	6	Femoral-Visceral J-Curve			3	None
				D	8	Femoral-Visceral J Curve			4 cm	None
				E	1	Femoral-Visceral Sidewinder			1	2
				E	2	Femoral-Visceral Sidewinder			2	2
				E	3	Femoral-Visceral Sidewinder			3	2
				E	4	Femoral-Visceral Sidewinder			1	None
				E	5	Femoral-Visceral Sidewinder			2 cm	None
				E	6	Femoral-Visceral Sidewinder			3 cm	None
				F	1	Femoral-Visceral Mikaelsson			1	None
				F	2	Femoral-Visceral Mikaelsson			2	None
				F	3	Femoral-Visceral Mikaelsson			3	None
				G	1	Femoral-Visceral RLG			-	None
				G	2	Femoral-Visceral RDP			-	None
				H	1	Femoral-Visceral Shepherd Hook Modified			15.0 mm	1
				H	2	Femoral-Visceral Shepherd Hook Modified			17.5 mm	1

1	2	3	4	5	6	7	8	9	10	11	
Indication of tip configuration (continued)				**H**	**3**	Femoral-Visceral Shepherd Hook Modified				20.0 mm	1
				H	**4**	Femoral-Visceral Shepherd Hook Modified				30.0 mm	1
				L	**1**	Femoral-Visceral JA				1	None
				N	**3**	Femoral-Visceral Hook T				3	1
				N	**6**	Femoral-Visceral Hook R				-	1
				N	**8**	Femoral-Visceral Hook				AGC	None
				N	**9**	Femoral-Visceral Kyuudai Type				-	-
				O	**1**	Femoral-Visceral Hirai Type				-	None
				O	**4**	Femoral-Visceral Hook 10				-	None
				O	**5**	Femoral-Visceral Nagatomi Type				1	None
				O	**6**	Femoral-Visceral Nagatomi Type				2	None
				P	**1**	Femoral-Visceral LG				-	None
				P	**4**	Femoral-Visceral Yamawaki-R				-	None
				Q	**1**	Femoral-Visceral GT				1	None
				Q	**2**	Femoral-Visceral GT				1	2
				Q	**7**	Femoral-Visceral NCC				-	None
				S	**1**	Femoral-Visceral Hiramatsu				1	None
				S	**7**	Femoral-Visceral Shepherd Hook KT Type				-	1
				S	**8**	Femoral-Visceral Shepherd Hook KK Type				-	1
				T	**1**	Femoral-Visceral J Curve				Large	1
				T	**7**	Femoral-Visceral J Curve Short tip				Large	None
				V	**2**	Femoral-Visceral LAV				55 mm	None
				E in position 4							
				A	**1**	Femoral-Cerebral Simmons				1	None
				A	**2**	Femoral-Cerebral Simmons				2	None
				A	**3**	Femoral-Cerebral Simmons				3	None
				A	**4**	Femoral-Cerebral Simmons				4	None
				B	**1**	Femoral-Cerebral Headhunter				1	None
				B	**2**	Femoral-Cerebral Headhunter				3	None
				B	**3**	Femoral-Cerebral Headhunter				4	None
				B	**4**	Femoral-Cerebral Hilal Modified Headhunter				H1H	None
				B	**6**	Femoral-Cerebral Hilal Modified Headhunter				H5H	None
				B	**7**	Femoral-Cerebral Hilal Modified Headhunter				H6H	None
				B	**8**	Femoral-Cerebral Hilal Modified Headhunter				H1P	None
				C	**1**	Femoral-Cerebral Newton Technique				1	None
				C	**2**	Femoral-Cerebral Newton Technique				2	None
				C	**3**	Femoral-Cerebral Newton Technique				3	None
				C	**4**	Femoral-Cerebral Newton Technique				4	None
				C	**5**	Femoral-Cerebral Newton Technique				5	None
				C	**9**	Femoral-Cerebral K Special				-	None
				D	**1**	Femoral-Cerebral Harwood-Nash				1	None
				E	**1**	Femoral-Cerebral Bentson-Hanafee-Wilson				1	None
				E	**2**	Femoral-Cerebral Bentson-Hanafee-Wilson				2	None
				E	**3**	Femoral-Cerebral Bentson-Hanafee-Wilson 3				JB3	None
				E	**9**	Femoral-Cerebral Kameyana				-	None
				F	**1**	Femoral-Cerebral Kerber				-	None
				F	**8**	Femoral-Cerebral Bentson-Hanafee-Wilson 2 Modified				JB2	None
				G	**1**	Femoral-Cerebral Mani				-	None
				H	**1**	Femoral-Cerebral Vertebral				-	None
				H	**4**	Femoral-Cerebral Vertebral				-	2
				J	**1**	Femoral-Cerebral Hinck				1	None
				J	**2**	Femoral-Cerebral Hinck				2	None
				K	**1**	Femoral-Cerebral Niigata Type				1	None
				K	**2**	Femoral-Cerebral Niigata Type				2	None

1	2	3	4	5	6	7	8	9	10	11
Indication of tip configuration (continued)				**L**	**1**	Femoral-Cerebral Berenstein			-	None
				L	**3**	Femoral-Cerebral Berenstein Komonji Type			-	2
				F in position 4						
				G	**1**	Femoral-Ventricular Pigtail			-	6
				K	**1**	Femoral-Ventricular Straight			-	6
Outer diameter of catheter						**5**	5 Fr. / 1.70 mm			
Indication of stopcock							**0**	Without Two-way stopcock		
Catheter length								**0**	**G**	65 cm
								0	**7**	70 cm
								0	**8**	80 cm
								0	**9**	90 cm
								1	**0**	100 cm
								1	**1**	110 cm
Packaging indication								Multilingual		**M**

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope: Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories.

Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices.

Installation and serving of active medical devices.

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.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o TERUMO EUROPE N.V. Interleuvenlaan 40 3001 Leuven Belgium	Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories. Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices. Installation and serving of active medical devices
/02	c/o Terumo Europe UK 3 Unity Grove Knowsley Business Park South Merseyside, Knowsley L34 9GT United Kingdom	Design and development, manufacture and sterilization of extra corporeal circuits for open heart surgery and ancillary devices

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The scope of certification also covers the following sites:

/03	c/o Terumo Deutschland GmbH Ludwig-Erhard-Str. 6 65760 Eschborn Germany	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/04	c/o Terumo France S.A.S. Bâtiment Renaissance, 3 rond-point des Saules 78280 Guyancourt France	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/05	c/o Terumo Italia S.r.l. Via Paolo di Dono 73 00142 Roma Italy	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/06	c/o Terumo Europe España SL Avda. Juan Carlos I, N°13-7 Planta 28806 Alcalá de Henares (Madrid) Spain	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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3001 Leuven
Belgium

The scope of certification also covers the following sites:

/07	c/o Terumo Europe UK Ltd. Otium House 2 Freemantle Road Bagshot Surrey GU19 5LL United Kingdom	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/08	c/o Terumo Europe N.V. Benelux Sales Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/09	c/o Terumo Sweden AB Sven Källfets gata 16 SE-426 71 Västra Frölunda Sweden	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/10	c/o Terumo Deutschland GmbH Zweigniederlassung Switzerland Bodenäckerstrasse 3 8957 Spreitenbach Switzerland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/11	c/o Terumo Europe N.V. European Distribution Center Brikkenovenstraat 48 3600 Genk Belgium	Storage and distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/12	c/o Terumo Europe N.V. Terumo Interventional Systems EMEA (TIS-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/13	c/o Terumo Europe N.V. Terumo Cardiovascular Europe Middle East & Africa (TCV-EMEA) Ludwig-Erhard-Straße 6 65760 Eschborn Germany	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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Belgium

The scope of certification also covers the following sites:

/14	c/o Terumo Europe N.V. Terumo Medical Products EMEA (TMP-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/15	c/o Terumo Europe N.V. Diabetes Management EMEA (DM-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/16	c/o Terumo Europe N.V. Terumo Pharmaceutical Solutions Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices and active implantable medical devices
/17	c/o Terumo Deutschland GmbH Zweigniederlassung Austria Liebermannstrasse F10-301 2345 Brunn am Gebirge Austria	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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The scope of certification also covers the following sites:

/18	c/o Terumo Europe N.V. Emerging Market Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/19	c/o Terumo Poland Sp. Zoo Wisniowy Business Park budynek D ul. 1 Sierpnia 6 02-134 Warszawa Poland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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