Radifocus® Guide wire M Non-Vascular type – Guide wires

Enlarge image

Radifocus® Guide wire M Non-Vascular type are standard and stiff Nitinol hydrophilic guide wires covered with polyurethane and hydrophilic coating for non-vascular procedures (endourology).

Indicated for use for non-vascular procedures such as Endoscopic and Urologic applications (drainage, endoprothesis placement, and embolization), catheterization and exchange procedures in normal, tortuous and narrow, and tight and stenotic ducts (bile and pancreatic ducts).

Product Characteristics

- Extra flexible & non traumatic tapered tip: increased flexibility, smooth and safe navigation through ducts.
- Extra hydrophilic (“M” polymer coating): smooth navigation through both catheters and ducts, providing time savings to user.
- Polyurethane radiopaque jacket: smooth surface to minimize adhesion to the wire, soft and atraumatic navigation. Includes tungsten for higher visibility.
- Super elastic Nitinol alloy core: excellent shape memory, greater flexibility, increased control in difficult cases. Prevents kinking for an easier and faster catheter placement.
- One-piece construction: improved steering control, true one-to-one torque transmission, easier, faster and safer navigation through both catheter and ducts.
- Rounded end: decreased likelihood of duct trauma, smoother wire insertion.

General Specifications

Core material	Standard or stiff Nitinol
Radiopaque jacket	Polyurethane layer containing tungsten
Hydrophilic coating	“M” polymer
Guide wire diameters	0.020” (0.51 mm) / 0.025” (0.64 mm) / 0.032” (0.81 mm) / 0.035” (0.89 mm)
Guide wire lengths	150 cm / 260 cm / 400 cm / 450 cm
Distal flexible length	30 mm
Distal curves	Straight / 45° angled
Units per box	5

Item Specifications

Shaft	Outer diameter	Length	Flexible length	Distal curve	Item reference
Standard	0.035” / 0.89 mm	150 cm	30 mm	Angled	NV-GA35153M
Standard	0.035” / 0.89 mm	150 cm	30 mm	Straight	NV-GS35153M
Stiff	0.035” / 0.89 mm	150 cm	30 mm	Angled	NV-PA35153M
Stiff	0.035” / 0.89 mm	150 cm	30 mm	Straight	NV-PS35153M
Standard	0.032” / 0.81 mm	260 cm	30 mm	Angled	NV-GA32263M
Standard	0.035” / 0.89 mm	400 cm	30 mm	Angled	NV-GA35403M
Standard	0.032” / 0.81 mm	400 cm	30 mm	Angled	NV-GA32403M
Standard	0.035” / 0.89 mm	260 cm	30 mm	Angled	NV-GA35263M
Standard	0.035” / 0.89 mm	450 cm	30 mm	Angled	NV-GA35453M
Standard	0.032” / 0.81 mm	260 cm	30 mm	Straight	NV-GS32263M
Standard	0.032” / 0.81 mm	400 cm	30 mm	Straight	NV-GS32403M
Standard	0.035” / 0.89 mm	260 cm	30 mm	Straight	NV-GS35263M
Standard	0.035” / 0.89 mm	400 cm	30 mm	Straight	NV-GS35403M
Standard	0.035” / 0.89 mm	450 cm	30 mm	Straight	NV-GS35453M
Stiff	0.020” / 0.51 mm	450 cm	30 mm	Angled	NV-PA18453M
Stiff	0.025” / 0.64 mm	450 cm	30 mm	Angled	NV-PA25453M
Stiff	0.035” / 0.89 mm	260 cm	30 mm	Angled	NV-PA35263M
Stiff	0.035” / 0.89 mm	400 cm	30 mm	Angled	NV-PA35403M
Stiff	0.020” / 0.51 mm	450 cm	30 mm	Straight	NV-PS18453M
Stiff	0.025” / 0.64 mm	450 cm	30 mm	Straight	NV-PS25453M
Stiff	0.035” / 0.89 mm	260 cm	30 mm	Straight	NV-PS35263M
Stiff	0.035” / 0.89 mm	400 cm	30 mm	Straight	NV-PS35403M

Please quote above item reference codes when placing an order.
Other code numbers are available on special demand. For any further information, please contact your local Terumo representative.

TÜVRheinland®

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

Registration No.: ID 60116053 0001

Report No.: 21262066 001

Manufacturer:

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Product Identification:

Radifocus Guide Wire M

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60042797 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: 2021-12-20

Effective Date: 2016-12-21

Date: 2016-12-19

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: ID 60116053 0001
Report No.: 21262066 001

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

Scope: Radifocus Guide Wire M

Product Code System

Radifocus Guide Wire M

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

Position	Indication & Meaning
1 - 2	Product group: RF : Radifocus
3	Manufacturing site: -: TERUMO Europe N.V.
4	Core wire flexibility: G : Standard P : Stiff
5	Tip configuration: A : Angled S : Straight
6-7	Outer diameter of guide wire

Indication	18	25	32	35	38
Diameter (inch)	0,018" (0,020)*	0,025"	0,032"	0,035"	0,038"
(mm)	0,46 mm (0,51 mm)*	0,64 mm	0,81 mm	0,89 mm	0,97 mm

* for stiff-core type

8-9 Guide wire length:

Indication:	05	08	12	15	18	22	26	30	40	45
Length (cm)	50	80	120	150	180	220	260	300	400	450

10 Flexible part length:

Indication:	1	3	5	8
Length (cm)	1	3	5	8

11	Languages used for indication: M : Multi-language
12	Special product indication: alphanumerical digit to distinguish from standard items

Date 19.12.2016

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS® GUIDE WIRE M

Product: **Guide Wire 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 60116053 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 12 digits maximum and explained as follows:

1	2	3	4	5	6	7	8	9	10	11	12
R	F	RadiFocus									
Production site		-	Terumo Europe N.V.								
Core wire flexibility			G	Standard							
			P	Stiff							
Tip configuration				A	Angled						
				S	Straight						
Outer diameter of guide wire					1	8	0.018" / 0.46 mm				
					1	8	0.020" / 0.51 mm (only for stiff type)				
					2	5	0.025" / 0.64 mm				
					3	2	0.032" / 0.81 mm				
					3	5	0.035" / 0.89 mm				
					3	8	0.038" / 0.97 mm				
Guide wire length							0	5	50 cm		
							0	8	80 cm		
							1	2	120 cm		
							1	5	150 cm		
							1	8	180 cm		
							2	2	220 cm		
							2	6	260 cm		
							3	0	300 cm		
							4	0	400 cm		
							4	5	450 cm		
Flexible part length									1	1 cm	
									3	3 cm	
									5	5 cm	
									8	8 cm	
Languages used for indication										M	Multi-language
Special product indication: alphanumerical digit to distinguish from standard items											X

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® Prüfzertifizierungsstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

has established and applies a quality management system for medical devices for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-12-08
Certificate Registration No.:	SX 60134689 0001
An audit was performed. Report No.:	21240046 013
This Certificate is valid until:	2021-12-07

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

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.

Servicing of active medical devices.

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 2/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

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

Scope:

additional sites included:

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

Activities: Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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

Activities: Design and development, manufacture and sterilization of extra corporeal circuits for open heart surgery and ancillary devices

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 3/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

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

Scope:

additional sites included:

Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices:

Terumo Europe N.V.
Terumo Interventional Systems - EMEA (TIS-EMEA)
Interleuvenlaan 40, 3001 Leuven, Belgium

Terumo Europe N.V., Terumo Cardiovascular Europe, Middle East & Africa (TCV-EMEA)
Ludwig-Erhard-Straße 6, 65760 Eschborn, Germany

Terumo Europe N.V., Terumo Medical Products EMEA (TMP-EMEA)
Interleuvenlaan 40, 3001 Leuven, Belgium

Terumo Europe N.V., Diabetes Management EMEA (DM-EMEA)
Interleuvenlaan 40, 3001 Leuven, Belgium

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

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

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Doc. 4/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

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

Scope:

additional sites included:

Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnotic medical devices:

Terumo Deutschland GmbH
Ludwig-Erhard-Straße 6, 65760 Eschborn, Germany

Terumo Deutschland GmbH, Zweigniederlassung Switzerland
Bodenäckerstrasse 3, 8957 Spreitenbach, Switzerland

Terumo Deutschland GmbH, Zweigniederlassung Austria
Liebermannstrasse F10-301, 2345 Brunn am Gebirge, Austria

Terumo Europe España SL
Avda. Juan Carlos I, Nº13-7 Planta, Edificio Torre La Garena
28806 Alcalá de Henares (Madrid), Spain

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

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Doc. 5/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

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

Scope:

additional sites included:

Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnotic medical devices:

Terumo Europe N.V., Emerging Market Division
Interleuvenlaan 40, 3001 Leuven, Belgium

Terumo Italia S.r.l.
Via Paolo di Dono 73, 00142 Roma, Italy

Terumo France S.A.S.
Bâtiment Renaissance, 3 rond-point des Saules,
78280 Guyancourt, France

Terumo Sweden AB
Sven Källfets gata 18,
426 71 Västra Frölunda, Sweden

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 6/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

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

Scope:

additional sites included:

Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnotic medical devices:

Terumo Europe UK Ltd.
Otium House, 2 Freemantle Road, Bagshot Surrey GU19 5LL, UK

Terumo Poland Sp. Zoo
Wisniowy Business Park budynek D, ul. 1 Sierpnia 6
02-134 Warszawa, Poland

Terumo Europe N.V., Benelux Sales Division
Interleuvenlaan 40, 3001 Leuven, Belgium

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 7/7, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134689 0001
Report No.: 21240046 013

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

Scope:

additional sites included:

Marketing and distribution of active and non-active medical devices:

Terumo Europe N.V., Terumo Pharmaceutical Solutions
Interleuvenlaan 40, 3001 Leuven, Belgium

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth