

Radifocus™ Guide Wire

M Non-Vascular

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Description

The RADIFOCUS™ Guide Wire M Non-Vascular is a standard and stiff Nitinol guidewire covered with polyurethane containing tungsten and a hydrophilic polymer coating (Mcoat™) for non-vascular procedures.

Intended to assist in the placement or exchange of devices during non-vascular procedures in endo-urology and for the cannulation or insertion of devices into the bile ducts and pancreatic duct.

Characteristics

- Rounded tip of Nitinol core combined with flexible tapered design ensure atraumatic navigation through the (non-vascular) vessels
- Nitinol core:

- Durable shape memory of super-elastic Nitinol core provides distal tip shape
- Balanced transition from tapered distal core to the more rigid proximal shaft for good crossability
- One-piece construction

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- Coating MCoat™:
 - Excellent durability of hydrophilic MCoat™ for sustained ease of navigation throughout the procedure
 - Terumo's MCoat™ superior lubricity combined with the most flexible distal tip ensure high trackability through any vasculature.

General specifications

Core material	Nitinol
Radiopaque jacket	Polyurethane layer containing tungsten
Hydrophilic coating	MCoat™
Guidewire diameters	0.018" (0.46 mm + 0.02 mm)* / 0.020" (0.51 mm + 0.01 mm)* / 0.025" (0.64 mm + 0.00 mm)* / 0.032" (0.81 mm + 0.00 mm)* / 0.035" (0.89 mm + 0.01 mm)* / 0.038" (0.97 mm + 0.02 mm)*
Guidewire lengths	80 cm / 120 cm / 150 cm / 180 cm / 260 cm / 400 cm / 450 cm
Distal flexible length	3 cm
Distal curves	Straight / Angled
Units per box	5

* Nominal OD + upper tolerance, reflecting Maximal OD.

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Product code	Wire type	Outer diameter	Length	Flexible tip length	Tip shape
NV-GS18153M	Standard	0.018" (0.46 mm + 0.02 mm)*	150 cm	3 cm	Straight
NV-GA18153M	Standard	0.018" (0.46 mm + 0.02 mm)*	150 cm	3 cm	45° Angled
NV-PA18153M	Stiff	0.020" (0.51 mm + 0.01 mm)*	150 cm	3 cm	45° Angled
NV-PS18453M	Stiff	0.020" (0.51 mm + 0.01 mm)*	450 cm	3 cm	Straight
NV-PA18453M	Stiff	0.020" (0.51 mm + 0.01 mm)*	450 cm	3 cm	45° Angled
NV-GS25153M	Standard	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	Straight
NV-GA25153M	Standard	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	45° Angled
NV-PA25153M	Stiff	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	45° Angled
NV-PS25453M	Stiff	0.025" (0.64 mm + 0.00 mm)*	450 cm	3 cm	Straight
NV-PA25453M	Stiff	0.025" (0.64 mm + 0.00 mm)*	450 cm	3 cm	45° Angled
NV-GS32153M	Standard	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	Straight
NV-GA32153M	Standard	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	45° Angled
NV-GS32263M	Standard	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	Straight
NV-GA32263M	Standard	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	45° Angled
NV-GS32403M	Standard	0.032" (0.81 mm + 0.00 mm)*	400 cm	3 cm	Straight
NV-GA32403M	Standard	0.032" (0.81 mm + 0.00 mm)*	400 cm	3 cm	45° Angled

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	Standard	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	45° Angled
NV-GA35083M	Standard	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	45° Angled
NV-PS35083M	Stiff	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	Straight
NV-GS35123M	Standard	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	Straight
NV-GA35123M	Standard	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	45° Angled
NV-GS35153M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	Straight
NV-GA35153M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	45° Angled
NV-PS35153M	Stiff	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	Straight
NV-PA35153M	Stiff	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	45° Angled
NV-GS35183M	Standard	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	Straight
NV-PS35183M	Stiff	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	Straight
NV-GS35263M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	Straight
NV-GA35263M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	45° Angled
NV-PA35263M	Stiff	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	45° Angled
NV-GS35403M	Standard	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	Straight
NV-GA35403M	Standard	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	45° Angled
NV-PS35403M	Stiff	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	Straight
NV-PA35403M	Stiff	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	45° Angled
NV-GS35453M	Standard	0.035" (0.89 mm + 0.01 mm)*	450 cm	3 cm	Straight
NV-GA35453M	Standard	0.035" (0.89 mm + 0.01 mm)*	450 cm	3 cm	45° Angled
NV-GS38153M	Standard	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	Straight
NV-PS38153M	Stiff	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	Straight
NV-PS38183M	Stiff	0.038" (0.97 mm + 0.02 mm)*	180 cm	3 cm	Straight

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Do you need more info about this product?

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Related products



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TR Band™

Radial Artery Compression Device

FemoSeal™

Vascular Closure System

Progreat™

Micro Catheter System

NaviCross™

Support Ca

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EU DECLARATION OF CONFORMITY

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

with Single Registration Number: **BE-MF-000001434**

being the manufacturer of:

RADIFOCUS™ Guide Wire M

Non-Vascular

Intended purpose: The RADIFOCUS Guide Wire M Non-Vascular is intended to assist in the placement or exchange of devices during non-vascular procedures in endourology and for the cannulation or insertion of devices into the bile ducts and pancreatic duct.

Basic UDI-DI: 5413206GWMNVTY

Related product codes: See Appendix A

declare that the above product of **Class IIa** is in conformity with applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 52.6 of the Regulation, relating to the “Conformity assessment based on a quality management system and on assessment of technical documentation” set out in Annex IX, and by certification of Annex IX.3 (EU quality management system certificate number HZ 1594584-1), 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.

This EU declaration of conformity is issued under our sole responsibility.

Leuven , 2023-07-04

(place and date of issue)



K. Verhaert
VP Quality, Regulatory & Vigilance
For and on behalf of TERUMO
EUROPE N.V.

Appendix A – Related product codes

- The product code is composed of 11 (or 12) digits maximum and explained as follows:

1	2	3	4	5	6	7	8	9	10	11	12
N	V	RADIFOCUS Guide Wire M Non-Vascular									
Production site		-	Terumo Europe N.V.								
Core wire flexibility		G	Standard type								
		P	Stiff type								
Tip configuration		A	Angled								
		S	Straight								
Nominal outer diameter of guide wire				1	8	0.018" / 0.46 mm (for standard type)					
				1	8	0.020" / 0.51 mm (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					
Nominal length of guide wire						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			
Flexible tip length						4	5	450 cm			
						3	3 cm				
Languages used for indication										M	Multi-language
Special product indication (Packaging variation)										1	

- List of product codes

Standard type - Angled	Standard type - Straight	Stiff type - Angled	Stiff type - Straight
NV-GA18153M	NV-GS18153M	NV-PA18153M	NV-PS18453M
NV-GA25153M	NV-GS25123M	NV-PA18453M	NV-PS25453M
NV-GA32153M	NV-GS25153M	NV-PA25153M	NV-PS35083M
NV-GA32263M	NV-GS32153M	NV-PA25453M	NV-PS35153M
NV-GA32403M	NV-GS32263M	NV-PA35153M	NV-PS35153M1
NV-GA35083M	NV-GS32403M	NV-PA35183M	NV-PS35183M
NV-GA35123M	NV-GS35123M	NV-PA35263M	NV-PS35263M
NV-GA35153M	NV-GS35153M	NV-PA35403M	NV-PS35403M
NV-GA35183M	NV-GS35183M	NV-PA38153M	NV-PS38153M
NV-GA35263M	NV-GS35263M		NV-PS38183M
NV-GA35403M	NV-GS35403M		
NV-GA35453M	NV-GS35453M		
NV-GA38153M	NV-GS38153M		

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III



Registration No.: HZ 1594584-1

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

EUDAMED Single
Registration No.: BE-MF-000001434

Products: Products of class IIa:

A010101 HYPODERMIC NEEDLES
A020199 SYRINGES - OTHERS
A010102 BUTTERFLY NEEDLES
U0601 UROLOGICAL GUIDEWIRES, HYDROPHILIC
G0399 DIGESTIVE ENDOSCOPY DEVICES – OTHER
C0504 ARTERIAL INTRODUCTION SETS
A010599 OPHTHALMOLOGY INJECTION NEEDLES AND KITS - OTHER

Authorised
representative(s): N/A

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 1142544-10

Effective date: 2023-06-20

Expiry date: 2026-12-31

Issue date: 2023-06-20



Sandor Juhasz
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,
Section 2 and 3 and Chapter III

Registration No.: HZ 1594584-1

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



Certificate history		
Revision:	Description:	Issue date:
1	First Issuance	2022-02-11
2	Update to include addition of 4 EMDN Codes to Products of Class IIa: U0601, G0399, C0504 and A010599 Note: Addition of U0601, G0399, C0504 codes per report no.: 3350367-530; and addition of A010599 code per report no.: 1142544-10	2023-06-20

Report No.: 1142544-10
Effective date: 2023-06-20
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