Glidewire Advantage®

Peripheral guidewire

Radifocus® Glidewire Advantage™ are hybrid extra-stiff Nitinol hydrophilic guidewires covered with polyurethane containing tungsten and an hydrophilic polymer coating (M Coat) for peripheral procedures.

Indicated for use for standard angiography procedures in peripheral territories, catheterization, embolization, peripheral angioplasty and stenting (with or without exchange wire) in narrow and tortuous vessels.

Product Characteristics

- *Super elastic Nitinol core: excellent shape memory, greater flexibility, increased control in difficult cases. Prevents kinking for an easier and faster catheter placement.*
- *Dual hybrid structure which allows 2 jobs with one wire: cross the lesion and support the interventional device delivery. No wire exchange, lower complications risk, shorter procedure and fluoroscopy time.*
- *Extra stiff proximal core shaft with spiral PTFE polytetrafeuoroethylene coating: provide sufficient device support and very smooth sliding characteristics even in complex anatomies.*
- *25 cm distal part: standard Terumo Radifocus® hydrophilic guidewire, smooth surface minimizing blood adhesion. Allows soft atraumatic navigation and delivery to the lesion. Exclusive Terumo M Coat polymer: smooth distal navigation (no friction) through catheter and vessels (time savings to user).*
- *Proximal and distal shafts connected seamlessly with unique DuoCore™ fusing technology for a smooth transition and navigation through vessels.*
- *Rounded end: decreased likelihood of vessel trauma, smoother wire insertion.*
- *High visibility of the tip due to the distal gold marker (for 0.014" and 0.018").*

General Specifications

Core material	Nitinol
Proximal part	155 cm / 235 cm / 275 cm spiral PTFE coated shaft
Distal radiopaque jacket	25 cm Polyurethane layer containing tungsten
Distal hydrophilic coating	"M" polymer (M Coat®)
Guidewire diameter	0.014" (0.36 mm) / 0.018" (0.46 mm) / 0.035" (0.89 mm)
Guidewire lengths	180 cm / 260 cm / 300 cm
Distal flexible length	Tapered 10 mm or 50 mm
Distal hydrophilic coated plastic part length	25 cm

Item Specifications

Product code	Shaft	Tip coil marker	Wire diameter	Overall length	Proximal spiral PTFE coating length	Distal hydrophilic coated length	Flexible tip length (taper)	Tip figure
RA*FA14181CM	Extra stiff	Yes	0.014" / 0.36 mm	180 cm	155 cm	25 cm	1 cm	Angled
RA*FA14301CM	Extra stiff	Yes	0.014" / 0.36 mm	300 cm	275 cm	25 cm	1 cm	Angled
RA*FS14301CM	Extra stiff	Yes	0.014" / 0.36 mm	300 cm	275 cm	25 cm	1 cm	Straight
RA*FA18181CM	Extra stiff	Yes	0.018" / 0.46 mm	180 cm	155 cm	25 cm	1 cm	Angled
RA*FA18301CM	Extra stiff	Yes	0.018" / 0.46 mm	300 cm	275 cm	25 cm	1 cm	Angled
RA*FS18301CM	Extra stiff	Yes	0.018" / 0.46 mm	300 cm	275 cm	25 cm	1 cm	Straight
RA*CA35185CM	Extra stiff	No	0.035" / 0.89 mm	180 cm	155 cm	25 cm	5 cm	Angled
RA*CA35265CM	Extra stiff	No	0.035" / 0.89 mm	260 cm	235 cm	25 cm	5 cm	Angled
RA*CS35185CM	Extra stiff	No	0.035" / 0.89 mm	180 cm	155 cm	25 cm	5 cm	Straight
RA*CS35265CM	Extra stiff	No	0.035" / 0.89 mm	260 cm	235 cm	25 cm	5 cm	Straight

Please quote above item reference code when placing an order

IS616/43GB0616ITI

TERUMO

No.DOC-DQ010-0800

Rev.10

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS Glidewire Advantage

Guide Wire

Product : Catheter Guide Wire

declare that the above products of **Class IIa** 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, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), 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

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 15:36:52 EEST
Reason: MoldSign Signature
Location: Moldova

Appendix A －List of Code Number Structure

□ □ ＊ □ □ □ □ □ □ □ □ □

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

Character number	Character & Meaning	
1,2	Product name	RA : Radifocus Glidewire Advantage
3	Destination	＊ : export
4	Specifications of core wire	B : (distal) Ni-Ti/HALF STIFF ＋ (proximal)Ni-Ti C : (distal)Ni-Ti/STIFF ＋ (proximal)Ni-Ti F : (distal) Tip coil marker / Ni-Ti/STIFF ＋ (proximal)Ni-Ti G : (distal)Tip coil marker /Ni-Ti/STIFF ＋ (proximal) Stainless Steel
5	Tip configuration	A : angled type B : angled type S : straight type
6,7	O.D. of product	35 : φ0.89mm(0.035”) 18 : φ0.46mm(0.018”) 14 : φ0.36mm(0.014”)
8,9	Overall length	18 : 180cm 26 : 260cm 30 : 300cm
10	Length of flexible portion at distal end	1 : 1cm 3 : 3cm 5 : 5cm
11	Length of hydrophilic coating	C : 25cm 3 : 30cm
12	Language for labeling	(blank): export M7 M: export M26

Terumo Europe NV
Emerging Market Division

Researchpark Haasrode 1520
Interleuvenlaan 40
3001 Leuven, Belgium
Tel.: +32 16 38 13 08
Fax: +32 16 38 16 01

www.terumo-europe.com

To: Whom It May Concern

Ref: 2021/038/IS/MI

Leuven, 02 April 2021

Letter of Authorization

We, company-manufacturer **Terumo Europe N.V. (Belgium),** with a manufacturing facility located at Interleuvenlaan 40, 3001, Leuven, Belgium, being a truly official representative of company-manufacturer Terumo Corporation (Japan) with manufacturing facilities located worldwide, hereby appoint following company (hereinafter - "Company"):

FCPC "DataControl" SRL
20 Melestiu Street, MD-2001,
Chisinau, Republic of Moldova,

to be our official representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. of following medical products and devices manufactured and/or distributed by us:

Accuforce PTCA dilatation catheter (RX)
Angio-Seal Evolution Vascular Closure Device
Angio-Seal VIP Vascular Closure Device
Azur Detachment Controller
Azur Peripheral Coil System
Climber Guiding Catheter
Crosperio RX PTA Balloon Dilatation Catheter
Crosstella OTW PTA Balloon Dilatation Catheter
Destination Guiding Sheath
Eliminate Aspiration catheter
FemoSeal Vascular Closure System
Finecross MG Coronary Micro-Guide catheter
Glidesheath Slender Hydrophilic Coated Introducer Sheath
Heartrail II Guiding Catheter
HydroPearl Compressible Microspheres for Embolisation
LifePearl Drug-elutable microspheres for embolisation
Metacross® OTW PTA Balloon Dilatation Catheter
Metacross® RX PTA Balloon Dilatation Catheter
Navicross Support Catheter
Occlusafe Temporary Occlusion Balloon Catheter
Outlook Angiographic Catheter
Progreat Micro Catheter System
Radifocus Glidecath Angiographic Catheter
Radifocus Guide Wire GT with Gold Coil
Radifocus Guide Wire M
Radifocus Guide Wire M Non-Vascular

RADIFOCUS® Glidewire Advantage™
RADIFOCUS® Glidewire Advantage™ Track
Radifocus Obturator
Radifocus Torque Device
Radifocus Vessel Dilator
Radifocus OPTITORQUE Angiographic Catheter
Radifocus Introducer II (Transradial Kit)
Radifocus Introducer II
Roadsaver Carotid Artery Stent
Runthrough® NS Extension Wire PTCA Guide Wire
Runthrough® NS PTCA Guide Wire
Ryujin Plus OTW PTCA dilatation catheter (OTW)
Ryujin Plus PTCA dilatation catheter (RX)
Senri® PTA Balloon Dilatation catheter
Tercross® PTA Dilatation Catheter (OTW)
Ryurei PTCA Dilatation Catheter
TR Band Radial Artery Haemostasis Band
Ultimaster Sirolimus eluting coronary stent system
Ultimaster Tansei Sirolimus eluting coronary stent system

Hereby the Company is authorized to ensure that state registration (re-registration) of the abovementioned products is obtained and maintained in accordance with the legislation of Republic of Moldova.

For this purpose, the company can perform all acts, including but not limited: to submit, confirm, receive all necessary documents, including registration certificates, to reply to inquiries, questions or other communications from authorized institutions, after consultation with Regulatory department of Terumo Europe N.V, to conduct any field actions which may be necessary, in accordance with legislation of Republic of Moldova.

Registration certificates must be issued on the name of Terumo Europe N.V.

This authorization letter is valid for a period of 12 /twelve/ months from the date of issue, unless revoked earlier by Terumo Europe N.V.

For and behalf of Terumo Europe N.V.:

Fien Aerts
VP Regulatory & Vigilance
Terumo Europe NV

TERUMO
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 LEUVEN, BELGIUM

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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.

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 15:36:54 EEST
Reason: MoldSign Signature
Location: Moldova

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:

- 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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2019-12-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.0

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-12-23

M.Aihara

M.Sc. M. Aihara

Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Michiaki Aihara
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 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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Michiaki Aihara
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 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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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