RADIFOCUS® Introducer II
TRANSRADIAL KIT

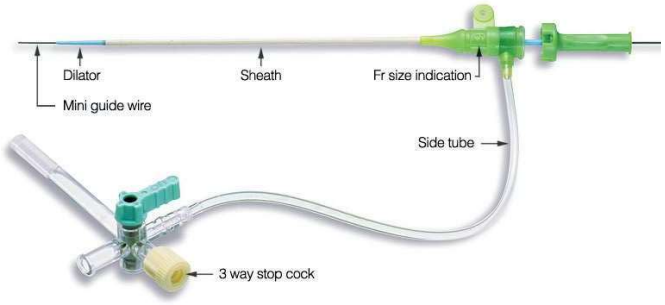
Introducer Sheath

Introducers are intended to be inserted percutaneously into a vessel to facilitate the entire interventional procedure.

Being a pioneer and a leader in vascular access, Terumo's goal is to offer complete solutions for transradial interventions with devices that minimize patient stress and optimize outcomes.

Product Characteristics

- *Total Integrated Fit (TIF) tip tapering: optimal tapering design at the tip of the sheath and dilator for smooth penetration*
- *Cross-cut hemostasis valve: effectively protects against blood reflux and air aspiration*
- *Thin radiopaque sheath with anti-kinking sleeve: for excellent catheter handling*
- *Snap-on / click-off dilator lock: prevents dilator back-out during insertion and allows one-hand unlocking*



Solution Nr. 1

Radifocus® Introducer II special transradial tapered Introducer Kit

- *Dilator internal tip diameter equals to mini guidewire external diameter*
- *Micro puncture metallic entry needle with short bevel (22G/21G/20G) equals to mini guidewire to minimize puncture site complications*

Available kits

R Kit contains sheath, dilator, spring mini guidewire and metallic entry needle.

General Specifications

Sheath length	7 cm and 10 cm
Mini guidewire	Spring Straight 0.018" (0.46 mm), 0.021" (0.53 mm) and 0.025" (0.64 mm) 45 cm
Entry needle	Metallic entry needle - 22G x 1 3/8 (0.7 x 35mm), 21G x 1 3/8 (0.8 x 35mm), 20G x 1 3/8 (0.9 x 35mm)
Guidewire compatibility	0.018" (0.46 mm), 0.021" (0.53 mm) and 0.025" (0.64 mm)
Packaging	Tray

Item Specifications

Inner diameter	Sheath length 7 cm			Sheath length 10 cm		
	Compatible with guidewire					
	0.018" (0.46 mm)	0.021" (0.53mm)	0.025" (0.64 mm)	0.018" (0.46 mm)	0.021" (0.53 mm)	0.025" (0.64 mm)
4 Fr	RT-R40A07PQ	RT-R40D07PQ*	RT-R40G07PQ	RT-R40A10PQ	RT-R40D10PQ	RT-R40G10PQ
5 Fr	RT-R50A07PQ	—	RT-R50G07PQ	RT-R50A10PQ	RT-R50D10PQ	RT-R50G10PQ
6 Fr	RT-R60A07PQ	—	RT-R60G07PQ	RT-R60A10PQ	RT-R60D10PQ	RT-R60G10PQ
7 Fr	—	—	—	—	RT-R70D10PQ	—

* This product may have additional lead time. Please contact your Terumo local representative.

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS® INTRODUCER II
(Transradial Kit)

Product: **Catheter Introducer**
(See Appendix A for related product codes)

declare that the above product of Class IIa 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), 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, 29.01.2020
(place and date of issue)

M.J. Aerts
VP Regulatory & Quality
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	**T**	Radifocus Introducer II Transradial Access									
Production site		**-**	Terumo Europe N.V.								
Indication of kit compostion			**R**	Sheath, Dilator, Spring guide wire and metallic entry needle							
Size of sheath in Fr				**4**	**0**	4 Fr					
				5	**0**	5 Fr					
				6	**0**	6 Fr					
				7	**0**	7 Fr					
Dilator I.D., distal tip length (difference of Dilator / sheath assembly), and type of metallic needle							Difference in length		Dilator I.D.		Metallic entry needle
							A		25		0.018"		22G x 35 mm
							D		25		0.021"		21G x 35 mm
							G		25		0.025"		20G x 35 mm
Length of the sheath							**0**	**7**	70 mm				
							1	**0**	100 mm				
Mini spring guide wire type									**N**	No guide wire			
									P	Straight, fixed core, uncoated, distal end flexible			
Packaging										**Q**	Tray pack (Multi language)		
Special product indication: alphanumerical digit to distinguish from standard items											**X**		

TERUMO

No.DOC-DQ010- 0245/DOC-DQ010-0821

Rev.19

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS Introducer II

Product : Catheter Introducer

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 15:34:34 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	Characters & Meaning
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath.
3	Destination *: for export
4	Kit contents A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) B : Sheath, Dilator, Mini guide wire, (Guide inserter[*2]) C : Sheath, Dilator E : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), (Guide inserter[*2]) G : Sheath, Dilator, Mini guide wire, Scalpel[*1] (Guide inserter[*2]) H : Dilator J : Sheath, Dilator, Scalpel[*1] K : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (metallic needle), Scalpel[*1], (Guide inserter[*2]) L : Sheath, Dilator, Syringe, Entry needle (SurfloFlash), Scalpel[*1] M : Sheath, Dilator, Entry needle (SurfloFlash), Scalpel[*1] N : Sheath, Dilator, Mini guide wire, Syringe, Scalpel[*1], (Guide inserter[*2]) P : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), (Guide inserter[*2]) Q : Dilator, Mini guide wire, (Guide inserter[*2]) R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter[*2]) S : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) W : Mini guide wire [*1]: not contained in the export specifications [*2]: contained when the mini guide wire has an angled tip or a J tip.

<table>
<tr><th>Character number</th><th>Characters & Meaning</th></tr>
<tr><td>5-6</td><td>Sheath Size (w/o hydrophilic polymer coating)
Characters: 40 45 50 55 60 65 70 75 80 85 90 10 11 00
Size: 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 10.0 11.0 no sheath
Sheath Size (with hydrophilic polymer coating)
Characters: F4 F5 F6 F7
Size: 4.0 5.0 6.0 7.0</td></tr>
<tr><td>7</td><td>Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
Standard Type (the items with their product code starting with RS*)
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.018”</td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td rowspan="4">Type of scalpel and tray</td><td>a-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">Standard</td></tr>
<tr><td>b-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr>
<tr><td>a-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">With adapter</td></tr>
<tr><td>b-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td colspan="2">Entry needle size</td><td>22G×1”</td><td>22G×1”</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td colspan="2">metallic needle size</td><td>---</td><td>---</td><td>---</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table>
Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM):
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.018”</td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td rowspan="4">Type of scalpel and tray</td><td>a-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">With adapter</td></tr>
<tr><td>b-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr>
<tr><td>a-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">Standard</td></tr>
<tr><td>b-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td colspan="2">Entry needle size</td><td>22G×1”</td><td>22G×1”</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td colspan="2">metallic needle size</td><td>---</td><td>Metallic Entry Needle improved product 21G×1 2/5”</td><td>Metallic Entry Needle improved product 20G×1 2/5”</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table></td></tr>
</table>

Character number	Characters & Meaning
8-9	Length of sheath 00 : no sheath 05～ : 50mm～
10	Type of mini guide wire A: Plastic, Angled B: Plastic, Angled, 4mm of tip cut E: Straight E F: Flex, Angled H: Short tapered, short angle J: Plastic, 3mm J K: Stiff, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight V: Plastic, 1.5mm J-angle Y: Flex, Straight
11	Packaging Q: Tray package (Multi-language) R: Pouch package (Multi-language)
12	Reserved 1: With scalpel. 5: Inner diameter of dilator at distal end: 0.038”, Outer diameter of mini guide wire: 0.035” Z: Entry needle: 20Gx2”→20Gx1 1/4” Length of mini guide wire: 80cm→45cm, scalpel contained. W: Entry needle: 20Gx1 1/4”, scalpel contained.

Appendix A - List of Code Number Structure

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

<table>
<tr><th>Character number</th><th>Characters & Meaning</th></tr>
<tr><td>1, 2</td><td>Product name
RS: Introducer kit</td></tr>
<tr><td>3</td><td>Destination
+ / ＊: Manufactured by TVC for worldwide excluding Japan</td></tr>
<tr><td>4</td><td>Kit contents
A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel, (Guide inserter*)
B : Sheath, Dilator, Mini guide wire, (Guide inserter*)
C : Sheath, Dilator
R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle), (Guide inserter*)
*: contained when the mini guide wire has an angled tip or a J tip.</td></tr>
<tr><td>5-6</td><td>Sheath Size (Fr) (w/o hydrophilic polymer coating)
<table>
<tr><td>Characters</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td></tr>
<tr><td>Size</td><td>4.0</td><td>5.0</td><td>6.0</td><td>7.0</td><td>8.0</td></tr>
</table></td></tr>
<tr><td>7</td><td>Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
<table>
<tr><td rowspan="2"></td><td colspan="3">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td>Type of scalpel and tray</td><td>G</td><td>K</td><td>N</td><td>Standard</td></tr>
<tr><td>Entry needle size</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td>metallic needle size</td><td>---</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table></td></tr>
<tr><td>8-9</td><td>Length of sheath
00 : no sheath0
5～ : 50mm～</td></tr>
<tr><td>10</td><td>Type of mini guide wire
A: Plastic, Angled
M: Spring, J
N: No mini guide wire contained.
P: Spring, Straight
S: Plastic, Straight</td></tr>
<tr><td>11</td><td>Packaging
Q: Tray package (Multi-language #, Chinese)
R: Pouch package (Multi-language #, Chinese)</td></tr>
<tr><td>12</td><td>Reserved
1: With scalpel.
5: Inner diameter of dilator at distal end: 0.038”,
Outer diameter of mini guide wire: 0.035”
Z: Entry needle: 20Gx2”→20Gx1 1/4”
Length of mini guide wire: 80cm→45cm, scalpel contained.</td></tr>
</table>

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle III

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

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