

# Glidesheath Slender®

## Transradial Introducer Sheath



*Glidesheath Slender offers the smallest option for procedures requiring 5, 6, and 7 Fr sheaths<sup>1</sup>. The proprietary thin-wall technology reduces the outside diameter of the introducer sheath by 1Fr while maintaining a larger inner-diameter equivalent.*

### *Product Characteristics*

- Thin wall leading to a 1Fr reduction in outer diameter.
- A smaller diameter sheath reduces the arteriotomy size, to enhance post-procedure hemostasis<sup>2</sup>.
- Easy insertion and removal with proprietary Terumo M Coat™ hydrophilic coating.
- Designed towards minimise mechanical irritation to the artery.
- Less penetration resistance than conventional sheaths.<sup>2, 3</sup>

1 Saito S et al. Catheter Cardiovasc Interv 1999;46:173-178

2 Rao S et al. Eur Heart J 2012;33:2521-2526

3 Saito S et al. Catheter Cardiovasc Interv 2002;56:328-332

## Item specifications

Outer Diameter	Sheath Length	Entry Needle - Diameter	Entry Needle - Length	Entry Needle - Type	Mini Guidewire - Type	Mini Guidewire - Diameter	Mini Guidewire - Length	Code
5 Fr	10 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	45 cm	RM*RS5J10PQ
5 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	45 cm	RM*ES5J10SQ
5 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	45 cm	RM*ES5J10PQ
5 Fr	10 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	45 cm	RM*RS5F10PQ
5 Fr	10 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	45 cm	RM*ES5F10SQ R
5 Fr	10 cm	22 G 0.7 mm	35 mm	Metallic Entry Needle	Spring	0.018 in 0.46 mm	45 cm	RM*RS5C10PQ
5 Fr	16 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	80 cm	RM*ES5J16HQ S
5 Fr	16 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	80 cm	RM*RS5J16PQ
5 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	80 cm	RM*ES5J16SQ
5 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	80 cm	RM*ES5J16PQ
5 Fr	16 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	80 cm	RM*RS5F16PQ
5 Fr	16 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	80 cm	RM*ES5F16SQ R
6 Fr	10 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.025 in 0.64 mm	45 cm	RM*ES6J10HQ S
6 Fr	10 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	45 cm	RM*RS6J10PQ
6 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	45 cm	RM*ES6J10SQ
6 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	45 cm	RM*ES6J10PQ
6 Fr	10 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	45 cm	RM*RS6F10PQ
6 Fr	10 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	45 cm	RM*ES6F10SQ
6 Fr	10 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	45 cm	RM*ES6F10HQ R
6 Fr	10 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	45 cm	RM*ES6F10SQ R
6 Fr	10 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	45 cm	RM*ES6F10HQ
6 Fr	10 cm	22 G 0.7 mm	35 mm	Metallic Entry Needle	Spring	0.018 in 0.46 mm	45 cm	RM*RS6C10PQ
6 Fr	16 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.025 in 0.64 mm	80 cm	RM*ES6J16HQ S
6 Fr	16 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	80 cm	RM*ES6J16PQ
6 Fr	16 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	80 cm	RM*RS6J16PQ
6 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	80 cm	RM*ES6J16SQ
6 Fr	16 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	80 cm	RM*RS6F16PQ
6 Fr	16 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	80 cm	RM*ES6F16SQ
6 Fr	16 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	80 cm	RM*ES6F16HQ
6 Fr	16 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	80 cm	RM*ES6F16HQ R
6 Fr	16 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	80 cm	RM*ES6F16SQ R
7 Fr	10 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.025 in 0.64 mm	45 cm	RM*ES7J10HQ S
7 Fr	10 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	45 cm	RM*RS7J10PQ
7 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	45 cm	RM*ES7J10SQ
7 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	45 cm	RM*ES7J10PQ

*Item specifications*

Outer Diameter	Sheath Length	Entry Needle - Diameter	Entry Needle - Length	Entry Needle - Type	Mini Guidewire - Type	Mini Guidewire - Diameter	Mini Guidewire - Length	Code
7 Fr	10 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	45 cm	RM*RS7F10PQ
7 Fr	10 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	45 cm	RM*ES7F10SQ R
7 Fr	16 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.025 in 0.64 mm	80 cm	RM*ES7J16HQS
7 Fr	16 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	80 cm	RM*RS7J16PQ
7 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	80 cm	RM*ES7J16SQ
7 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	80 cm	RM*ES7J16PQ
7 Fr	16 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	80 cm	RM*RS7F16PQ
7 Fr	16 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	80 cm	RM*ES7F16SQ R

# RADIFOCUS® *Introducer II* STANDARD KIT

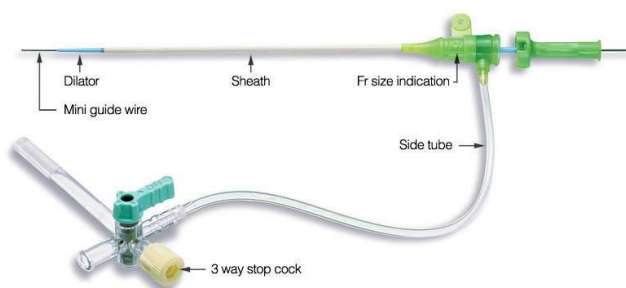
Introducer Sheath



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

## 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
- **Wide variety of kit variations providing all elements for quick vessel access:** 4 - 11 Fr sheaths, 5 - 25 cm lengths, Surflash or micro puncture metal needle



## Available Kits

- **A Kit** contains sheath, dilator, plastic mini guidewire and plastic IV catheter (entry needle)
- **B Kit** contains sheath, dilator, plastic or spring mini guidewire
- **C Kit** contains sheath and dilator
- **R Kit** contains sheath, dilator, spring mini guidewire and metallic entry needle

## A Kit

### General Specifications

Sheath length	10 cm
Mini guidewire	Plastic Straight and Angled 0.025" (0.64 mm) for 4 Fr, 0.035" (0.89 mm) for all others 45 cm
Entry needle	Plastic IV Catheter - 18G x 2 1/2" (1.2 x 64 mm), except for 4 Fr : 20G x 2" (0.9 x 51 mm), 2.5 ml syringe is included
Guidewire compatibility	0.025" (0.64 mm) for 4 Fr 0.035" (0.89 mm) for all others
Packaging	Tray

### Item Specifications

Inner diameter	Mini guidewire type	
	45 cm angled	45 cm straight
4 Fr	RS+A40K10AQ	RS+A40G10SQ
5 Fr	RS+A50K10AQ	RS+A50K10SQ
6 Fr	RS+A60K10AQ	RS+A60K10SQ
7 Fr	—	RS+A70K10SQ
8 Fr	—	RS+A80K10SQ
9 Fr	—	RS*A90K10SQ
10 Fr	—	RS*A10K10SQ
11 Fr	—	RS*A11K10SQ

Please quote above item reference codes when placing an order



## B Kit

1<sup>st</sup> Type in tray with plastic mini guidewire

### General Specifications

Sheath length	10 cm and 25 cm
Mini guidewire	Plastic Straight and Angled 0.025" (0.64 mm) or 0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others 45 cm for 10 cm sheath and 80 cm for 25 cm sheath
Guidewire compatibility	0.025" (0.64 mm) or 0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others
Packaging	Tray

### Item Specifications

Inner diameter	Guidewire compatibility	Sheath length 10 cm		Sheath length 25 cm
		Mini guidewire type		
		45 cm angled	45 cm straight	80 cm angled
4 Fr	0.025" (0.64 mm)	—	RS+B40G10SQ	—
4 Fr	0.035" (0.89 mm)	RS+B40K10AQ	RS+B40K10SQ	—
5 Fr	0.038" (0.97 mm)	RS+B50N10AQ	RS+B50N10SQ	RS+B50N25AQ
6 Fr	0.038" (0.97 mm)	—	RS+B60N10SQ	RS+B60N25AQ
7 Fr	0.038" (0.97 mm)	—	RS+B70N10SQ	RS+B70N25AQ
8 Fr	0.038" (0.97 mm)	—	RS+B80N10SQ	RS+B80N25AQ
9 Fr	0.038" (0.97 mm)	—	RS*B90N10SQ	RS*B90N25AQ
10 Fr	0.038" (0.97 mm)	—	RS*B10N10SQ	RS*B10N25AQ
11 Fr	0.038" (0.97 mm)	—	RS*B11N10SQ	RS*B11N25AQ

Please quote above item reference codes when placing an order



**B Kit***2<sup>nd</sup> Type in tray with spring mini guidewire***General Specifications**

<b>Sheath length</b>	10 cm
<b>Mini guidewire</b>	Spring, J-type 0.035" (0.89 mm) and 0.038" (0.97 mm) 45 cm
<b>Guidewire compatibility</b>	0.035" (0.89 mm) or 0.038" (0.97 mm)
<b>Packaging</b>	Tray

**Item Specifications**

Inner diameter	Guidewire compatibility	
	0.035" (0.89 mm)	0.038" (0.97 mm)
4 Fr	RS+B40K10MQ	—
5 Fr	RS+B50K10MQ	RS+B50N10MQ
6 Fr	RS+B60K10MQ	RS+B60N10MQ
7 Fr	RS+B70K10MQ	RS+B70N10MQ
8 Fr	RS+B80K10MQ	RS+B80N10MQ
9 Fr	RS*B90K10MQ	RS*B90N10MQ
10 Fr	RS*B10K10MQ	RS*B10N10MQ
11 Fr	RS*B11K10MQ	RS*B11N10MQ

Please quote above item reference codes when placing an order

*3<sup>rd</sup> Type in pouch with spring mini guidewire***General Specifications**

<b>Sheath length</b>	10 cm
<b>Mini guidewire</b>	Spring J Angled 0.035" (0.89 mm) for all items
<b>Guidewire compatibility</b>	0.035" (0.89 mm) for 4Fr items 0.038" (0.97 mm) for all other items
<b>Packaging</b>	Pouch

**Item Specifications**

Inner diameter	Item reference
4 Fr	RS*B40K10MR
5 Fr	RS*B50N10MRD
6 Fr	RS*B60N10MRD
7 Fr	RS*B70N10MRD
8 Fr	RS*B80N10MRD
9 Fr	RS*B90N10MRD
10 Fr	RS*B10N10MRD
11 Fr	RS*B11N10MRD

Please quote above item reference codes when placing an order

**C Kit****General Specifications**

<b>Sheath length</b>	10 cm and 25 cm
<b>Guidewire compatibility</b>	0.025" (0.64 mm), 0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others
<b>Packaging</b>	Pouch

**Item Specifications**

Inner diameter	Guidewire compatibility	Sheath length	
		10 cm	25 cm
4 Fr	0.025" (0.64 mm)	RS+C40G10NR	—
4 Fr	0.035" (0.89 mm)	RS+C40K10NR	RS+C40K25NR
5 Fr	0.038" (0.97 mm)	RS+C50N10NR	—
6 Fr	0.038" (0.97 mm)	RS+C60N10NR	RS+C60N25NR
7 Fr	0.038" (0.97 mm)	RS+C70N10NR	RS+C70N25NR
8 Fr	0.038" (0.97 mm)	RS+C80N10NR	RS+C80N25NR
9 Fr	0.038" (0.97 mm)	RS*C90N10NR	—
10 Fr	0.038" (0.97 mm)	RS*C10N10NR	—
11 Fr	0.038" (0.97 mm)	RS*C11N10NR	—

Please quote above item reference codes when placing an order

**R Kit****General Specifications**

<b>Sheath length</b>	10 cm
<b>Mini guidewire</b>	Spring, J-type 0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others 45 cm
<b>Entry needle</b>	Metallic entry needle - 18G x 2 3/4" (1.2 x 70 mm)
<b>Guidewire compatibility</b>	0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others
<b>Packaging</b>	Tray

**Item Specifications**

Inner diameter	Item reference
4 Fr	RS+R40K10MQ
5 Fr	RS+R50N10MQ
6 Fr	RS+R60N10MQ
7 Fr	RS+R70N10MQ
8 Fr	RS+R80N10MQ
9 Fr	RS+R90N10MQ

Please quote above item reference codes when placing an order

# RADIFOCUS® *Introducer II*

## TRANSRADIAL KIT

Introducer Sheath

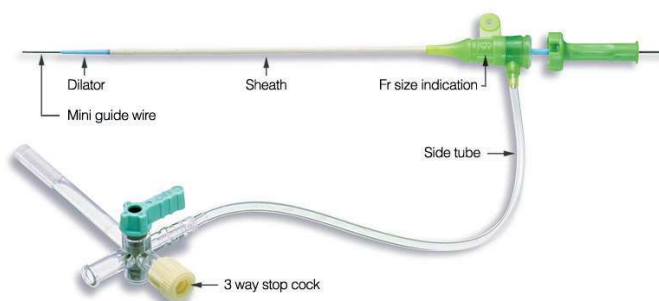


*Introducers are intended to be inserted percutaneously into a vessel to facilitate the entire interventional procedure.*

*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.

## Solution Nr. 2

### Radifocus® Introducer II M Coat™, Introducer Kit with hydrophilic M Coating

- Dilator internal tip diameter equals to mini guidewire external diameter
- Retrieving the M Coat™ sheath requires only half the force compared to conventional uncoated sheaths

#### Available Kits

- **M Coat™ A Kit** contains sheath, dilator, plastic mini guidewire and plastic IV catheter (entry needle), 2.5 cc syringe
- **M Coat™ R Kit** contains sheath, dilator, spring mini guidewire and metallic entry needle

#### M Coat™ A Kit

#### General Specifications

Sheath length	10 cm, 16 cm and 25 cm
Sheath coating	Hydrophilic M Coat™
Mini guidewire	Plastic Straight 0.025" (0.64 mm) 45 cm for 10 cm sheath and 80 cm for 16 cm and 25 cm sheath
Entry needle	Plastic IV Catheter - 20G x 1 ¼" (0.9 x 32 mm) , 2.5 ml syringe is included
Guidewire compatibility	0.025" (0.64 mm)
Packaging	Tray

#### Item Specifications

Inner diameter	Sheath length		
	10 cm	16 cm	25 cm
5 Fr	RM*AF5J10SQW	RM*AF5J16SQW	RM*AF5J25SQW
6 Fr	RM*AF6J10SQW	RM*AF6J16SQW	RM*AF6J25SQW

Please quote above item reference codes when placing an order

#### M Coat™ R Kit

#### General Specifications

Sheath length	10 cm, 16 cm and 25 cm
Sheath coating	Hydrophilic M Coat™
Mini guidewire	Spring Straight 0.021" (0.53 mm) and 0.025" (0.64 mm) 45 cm for 10 cm sheath, 80 cm for 16 cm and 25 cm sheath
Entry needle	Metallic entry needle 21G x 1 2/5 (0.8 x 36 mm) 20G x 1 2/5 (0.9 x 36 mm)
Guidewire compatibility	0.021" (0.53 mm) and 0.025" (0.64 mm)
Packaging	Tray

#### Item Specifications

Inner diameter	Guidewire compatibility	Sheath length		
		10 cm	16 cm	25 cm
5 Fr	0.021" (0.53 mm)	RM*RF5F10PQ	RM*RF5F16PQ	RM*RF5F25PQ
5 Fr	0.025" (0.64 mm)	RM*RF5J10PQ	RM*RF5J16PQ	RM*RF5J25PQ
6 Fr	0.021" (0.53 mm)	RM*RF6F10PQ	RM*RF6F16PQ	RM*RF6F25PQ
6 Fr	0.025" (0.64 mm)	RM*RF6J10PQ	RM*RF6J16PQ	RM*RF6J25PQ

Please quote above item reference codes when placing an order

# RADIFOCUS® *Introducer II*

## PEDIATRIC KIT

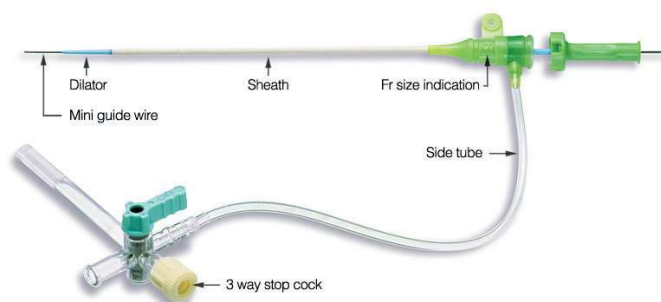
Introducer Sheath



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

### 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
- **Nitinol super elastic mini guidewire** enables smooth insertion and removal



### Available Kits

- **A Kit** contains sheath, dilator, plastic mini guidewire and plastic IV catheter (entry needle), 2.5 cc syringe
- **B Kit** contains sheath, dilator and plastic mini guidewire



A Kit

### General Specifications

Sheath length	5 cm and 7 cm
Mini guidewire	Plastic Straight 0.025" (0.64 mm) 45 cm
Guidewire compatibility	0.025" (0.64 mm)
Entry needle	Plastic IV catheter - 20G x 2" (0.9 x 51 mm), 2.5 ml syringe is included
Packaging	Tray

### Item Specifications

Inner diameter	Sheath length	
	5 cm	7 cm
4 Fr	—	RS+A40G07SQ
5 Fr	RS*A50G05SQ	RS+A50G07SQ
6 Fr	RS*A60G05SQ	RS+A60G07SQ

Please quote above item reference codes when placing an order



B Kit

### General Specifications

Sheath length	7 cm
Mini guidewire	Plastic Straight 0.025" (0.64 mm) 45 cm
Guidewire compatibility	0.025" (0.64 mm)
Packaging	Tray

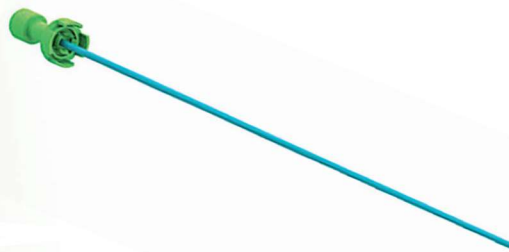
### Item Specifications

Inner diameter	Sheath length	Item reference
4 Fr	7 cm	RS+B40G07SQ
5 Fr	7 cm	RS+B50G07SQ
6 Fr	7 cm	RS+B60G07SQ

Please quote above item reference codes when placing an order

# RADIFOCUS® OBTURATOR

Introducer Sheath



An obturator supports the wall of the indwelling introducer sheath without a catheter in place.

## Product Characteristics

- Snap-on connection to sheath hub
- High flexibility and kink-resistance
- Color coded
- Made of polypropylene with a rounded tip

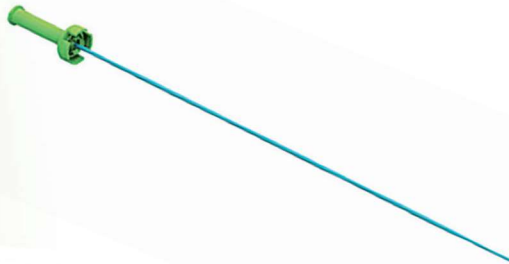
## Item Specifications

Compatible Introducer Sheath size	Length	
	10 cm	25 cm
4 Fr	XX*RF050410M	—
5 Fr	XX*RF050510M	XX*RF050525M
6 Fr	XX*RF050610M	XX*RF050625M
7 Fr	XX*RF050710M	XX*RF050725M
8 Fr	XX*RF050810M	XX*RF050825M
9 Fr	XX*RF050910M	—

Please quote above item reference codes when placing an order

# RADIFOCUS® VESSEL DILATOR

Introducer Sheath



A vessel dilator facilitates the pre-dilatation of puncture site.

## Item Specifications

Outer diameter	Length	Guidewire compatibility	
		0.035" (0.89 mm)	0.038" (0.97 mm)
4 Fr	15.5 cm	RF*VD40K10M	—
5 Fr	15.5 cm	RF*VD50K10M	RF*VD50N10M
6 Fr	15.5 cm	RF*VD60K10M	RF*VD60N10M
7 Fr	15.5 cm	RF*VD70K10M	RF*VD70N10M
8 Fr	15.5 cm	RF*VD80K10M	RF*VD80N10M
9 Fr	15.5 cm	RF*VD90K10M	RF*VD90N10M
10 Fr	15.5 cm	RF*VD10K10M	—
11 Fr	15.5 cm	RF*VD11K10M	—

Please quote above item reference codes when placing an order

## DECLARATION OF CONFORMITY

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

being the manufacturer of:

### **RADIFOCUS<sup>®</sup> 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		
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		



## 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





## Appendix A - List of Code Number Structure

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

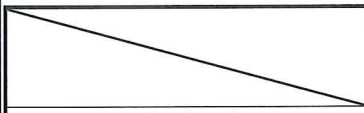
Character number	Characters & Meaning
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath.
3	Destination *: for export
4	Kit contents A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel <sup>*1</sup> , (Guide inserter <sup>*2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

Character number	Characters & Meaning																																																																			
5-6	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																																																																			
7	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"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td>Type of Surflo</td></tr><tr><td colspan="2"></td><td>0.018"</td><td>0.021"</td><td>0.025"</td><td>0.035"</td><td>0.038"</td><td></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 rowspan="2"></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></tr></table>												Mini guide wire diameter/ Dilator inner diameter					Type of Surflo			0.018"	0.021"	0.025"	0.035"	0.038"		Type of scalpel and tray	a-type	A	D	G	K	N	Standard	b-type	B	E	H	L	P	a-type	C	F	J	M	Q	With adapter	b-type	V	W	X	Y	Z	Entry needle size		22G×1"	22G×1"	20G×2"	18G×2 1/2"	16G×2 1/2"		metallic needle size		---	---	---	18G×2 3/4"	18G×2 3/4"
		Mini guide wire diameter/ Dilator inner diameter					Type of Surflo																																																													
		0.018"	0.021"	0.025"	0.035"	0.038"																																																														
Type of scalpel and tray	a-type	A	D	G	K	N	Standard																																																													
	b-type	B	E	H	L	P																																																														
	a-type	C	F	J	M	Q	With adapter																																																													
	b-type	V	W	X	Y	Z																																																														
Entry needle size		22G×1"	22G×1"	20G×2"	18G×2 1/2"	16G×2 1/2"																																																														
metallic needle size		---	---	---	18G×2 3/4"	18G×2 3/4"																																																														
*Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM*): <table><tr><td colspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td>Type of Surflo</td></tr><tr><td colspan="2"></td><td>0.018"</td><td>0.021"</td><td>0.025"</td><td>0.035"</td><td>0.038"</td><td></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 rowspan="2"></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></tr></table>													Mini guide wire diameter/ Dilator inner diameter					Type of Surflo			0.018"	0.021"	0.025"	0.035"	0.038"		Type of scalpel and tray	a-type	A	D	G	K	N	With adapter	b-type	B	E	H	L	P	a-type	C	F	J	M	Q	Standard	b-type	V	W	X	Y	Z	Entry needle size		22G×1"	22G×1"	20G×2"	18G×2 1/2"	16G×2 1/2"		metallic needle size		---	Metallic Entry Needle improved product 21G×1 2/5"	Metallic Entry Needle improved product 20G×1 2/5"	18G×2 3/4"	18G×2 3/4"
		Mini guide wire diameter/ Dilator inner diameter					Type of Surflo																																																													
		0.018"	0.021"	0.025"	0.035"	0.038"																																																														
Type of scalpel and tray	a-type	A	D	G	K	N	With adapter																																																													
	b-type	B	E	H	L	P																																																														
	a-type	C	F	J	M	Q	Standard																																																													
	b-type	V	W	X	Y	Z																																																														
Entry needle size		22G×1"	22G×1"	20G×2"	18G×2 1/2"	16G×2 1/2"																																																														
metallic needle size		---	Metallic Entry Needle improved product 21G×1 2/5"	Metallic Entry Needle improved product 20G×1 2/5"	18G×2 3/4"	18G×2 3/4"																																																														

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

Character number	Characters & Meaning									
1, 2	Product name RS: Introducer kit									
3	Destination + / *: Manufactured by TVC for worldwide excluding Japan									
4	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.									
5-6	Sheath Size (Fr) (w/o hydrophilic polymer coating)									
	Characters	40	50	60	70	80				
	Size	4.0	5.0	6.0	7.0	8.0				
7	Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)									
			Mini guide wire diameter/ Dilator inner diameter		Type of Surflo					
0.025"			0.035"				0.038"			
	Type of scalpel and tray		G		K		N		Standard	
	Entry needle size		20G×2"		18G×2 1/2"		16G×2 1/2"			
	metallic needle size		---		18G×2 3/4"		18G×2 3/4"			
8-9	Length of sheath 00 : no sheath0 5~ : 50mm~									
10	Type of mini guide wire A: Plastic, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight									
11	Packaging Q: Tray package (Multi-language #, Chinese) R: Pouch package (Multi-language #, Chinese)									
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.									



**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**

*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**

Doc. 1/2, Rev.0

**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



**Notified Body**

*Mai'hara*

**Date:** 2019-12-23

**M.Sc. M. Aihara**

**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**

*M. Aihara*

**M.Sc. M. Aihara**



**Date: 2019-12-23**



# Certificate

**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



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



# Certificate

**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



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



# Certificate

**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



*Michiaki Aihara*

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



# 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



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>

Digitally signed by Grabazei Alexandru

Date: 2020.04.09 15:34:39 EEST

Reason: MoldSign Signature

Location: Moldova



TÜV Rheinland and LGA are registered trademarks. Utilization and application requires prior approval.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/7, Rev. 0

**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**



**Date:** 2018-12-03



*[Signature]*  
**Dipl.-Ing. (FH) D. Wiedemuth**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 2/7, Rev. 0

**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**



**Date:** 2018-12-03

**Dipl.-Ing. (FH) D. Wiedemuth**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 3/7, Rev. 0

**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



**Date:** 2018-12-03

**Certification Body**



*D. Wiedemuth*  
**Dipl.-Ing. (FH) D. Wiedemuth**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 4/7, Rev. 0

**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  
diagnostic medical devices:

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

Terumo Deutschland GmbH, Zweigniederlassung Switzerland  
Bodenackerstrasse 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, N°13-7 Planta, Edificio Torre La Garena  
28806 Alcalá de Henares (Madrid), Spain

**Certification Body**



**Date:** 2018-12-03

  
**Dipl.-Ing. (FH) D. Wiedemuth**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 5/7, Rev. 0

**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  
diagnostic 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

**Certification Body**



**Date:** 2018-12-03

  
**Dipl.-Ing. (FH) D. Wiedemuth**



**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  
diagnostic 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

**Certification Body**



**Date:** 2018-12-03

  
**Dipl.-Ing. (FH) D. Wiedemuth**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 7/7, Rev. 0

**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

**Certification Body**



**Date:** 2018-12-03

  
**Dipl.-Ing. (FH) D. Wiedemuth**

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

**Registration No.:** HD 60106290 0001

**Report No.:** 21240046 001

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

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

Replaces Approval, Registration No.: HD 60035711 0001

**Expiry Date:** 2020-12-07

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:** 2015-12-08

**Date:** 2015-12-08

Notified Body

Dipl.-Ing. D. Meier

**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 60106290 0001  
**Report No.:** 21240046 001

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

**Products:**

- Syringes
- Needles
- Administration sets
- Blood collecting systems
- Angiographic-interventional catheter systems
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles
- Blood collecting systems

**Date:** 2015-12-08

**Notified Body**

**Dipl.-Ing. D. Meier**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 2/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HD 60106290 0001  
**Report No.:** 21240046 001

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

**Additional sites included:**

TERUMO EUROPE N.V.  
European Distribution Center  
Brikkovenstraat 48  
3600 Genk, Belgium


**Scope:** Warehouse operations and distribution of medical devices

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

**Scope:** Design and development, manufacture of extracorporeal circuits for open heart surgery and ancillary circuits

**Date:** 2015-12-08

**Notified Body**

  
**Dipl.-Ing. D. Meier**

