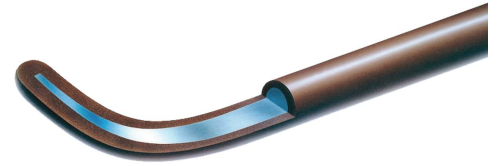


RADIFOCUS® *Guidewire M* STANDARD



Guide Wire

Indicated for use for standard angiography in coronary and peripheral territories, catheterization, embolization, peripheral angioplasty and stenting (with or without an exchange wire), and subintimal angioplasty in small, standard or large proximal or distal vessels.

Product Characteristics

Radifocus® Guidewire M Standard type is a Nitinol hydrophilic guidewire covered with polyurethane containing tungsten and a hydrophilic polymer coating (M Coat™).

- Radiopaque polyurethane jacket
- One-piece construction
- Rounded, tapered tip

General specifications

| | |
|----------------------------|--|
| Distal Curve | Angled, Double Angulation (Bolia), J Angled (1.5 mm), J Angled (3 mm), Straight / Straight mm |
| Hydrophilic Coating | "M" Polymer |
| Radiopaque Jacket | Polyurethane Layer Containing Tungsten |

Item specifications

| Guidewire Diameter - Outer Diameter | Length | Flexible Length | Core Material | Code |
|--|---------------|------------------------|----------------------|-------------|
| 0.018 in 0.46 mm | 50 cm | 30 mm | Nitinol | RF-GA18053M |
| 0.018 in 0.46 mm | 80 cm | 30 mm | Nitinol | RF*GS18183M |
| 0.018 in 0.46 mm | 150 cm | 30 mm | Nitinol | RF*GS18153M |
| 0.018 in 0.46 mm | 150 cm | 30 mm | Nitinol | RF-GA18153M |
| 0.018 in 0.46 mm | 150 cm | 30 mm | Nitinol | RF-GS18153M |
| 0.018 in 0.46 mm | 150 cm | 30 mm | Nitinol | RF*GA18153M |
| 0.018 in 0.46 mm | 180 cm | 30 mm | Nitinol | RF*GA18183M |
| 0.018 in 0.46 mm | 180 cm | 30 mm | Nitinol | RF-GA18183M |
| 0.018 in 0.46 mm | 180 cm | 30 mm | Nitinol | RF-GS18183M |
| 0.018 in 0.46 mm | 220 cm | 30 mm | Nitinol | RF-GA18223M |
| 0.018 in 0.46 mm | 260 cm | 30 mm | Nitinol | RF-GS18263M |
| 0.018 in 0.46 mm | 260 cm | 30 mm | Nitinol | RF*GA18263M |
| 0.018 in 0.46 mm | 260 cm | 30 mm | Nitinol | RF-GA18263M |
| 0.018 in 0.46 mm | 260 cm | 30 mm | Nitinol | RF*GS18263M |
| 0.025 in 0.64 mm | 50 cm | 30 mm | Nitinol | RF-GA25053M |
| 0.025 in 0.64 mm | 120 cm | 30 mm | Nitinol | RF-GA25123M |
| 0.025 in 0.64 mm | 120 cm | 30 mm | Nitinol | RF-GS25123M |
| 0.025 in 0.64 mm | 150 cm | 30 mm | Nitinol | RF-GA25153M |
| 0.025 in 0.64 mm | 150 cm | 30 mm | Nitinol | RF-GS25153M |
| 0.025 in 0.64 mm | 150 cm | 30 mm | Nitinol | RF*GS25153M |
| 0.025 in 0.64 mm | 150 cm | 30 mm | Nitinol | RF*GA25153M |
| 0.025 in 0.64 mm | 180 cm | 30 mm | Nitinol | RF*GA25183M |
| 0.025 in 0.64 mm | 180 cm | 30 mm | Nitinol | RF-GA25183M |
| 0.025 in 0.64 mm | 180 cm | 30 mm | Nitinol | RF-GS25183M |
| 0.025 in 0.64 mm | 260 cm | 30 mm | Nitinol | RF-GS25263M |
| 0.025 in 0.64 mm | 260 cm | 30 mm | Nitinol | RF*GA25263M |
| 0.025 in 0.64 mm | 260 cm | 30 mm | Nitinol | RF-GA25263M |
| 0.025 in 0.64 mm | 260 cm | 30 mm | Nitinol | RF*GS25263M |
| 0.032 in 0.81 mm | 120 cm | 30 mm | Nitinol | RF-GA32123M |
| 0.032 in 0.81 mm | 120 cm | 30 mm | Nitinol | RF-GS32123M |
| 0.032 in 0.81 mm | 150 cm | 30 mm | Nitinol | RF-GS32153M |
| 0.032 in 0.81 mm | 150 cm | 30 mm | Nitinol | RF*GA32153M |
| 0.032 in 0.81 mm | 150 cm | 30 mm | Nitinol | RF*GS32153M |
| 0.032 in 0.81 mm | 150 cm | 30 mm | Nitinol | RF-GA32153M |
| 0.032 in 0.81 mm | 180 cm | 30 mm | Nitinol | RF-GA32183M |
| 0.032 in 0.81 mm | 180 cm | 30 mm | Nitinol | RF-GS32183M |

Please quote above item reference codes when placing an order

Item specifications

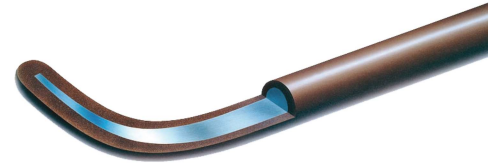
| Guidewire Diameter - Outer Diameter | Length | Flexible Length | Core Material | Code |
|--|---------------|------------------------|-----------------------|-------------|
| 0.032 in 0.81 mm | 180 cm | 30 mm | Nitinol | RF*GA32183M |
| 0.032 in 0.81 mm | 260 cm | 30 mm | Nitinol | RF*GA32263M |
| 0.032 in 0.81 mm | 260 cm | 30 mm | Nitinol | RF-GS32263M |
| 0.032 in 0.81 mm | 260 cm | 30 mm | Nitinol | RF-GA32263M |
| 0.032 in 0.81 mm | 260 cm | 30 mm | Nitinol | RF*GS32263M |
| 0.035 in 0.89 mm | 50 cm | 30 mm | Nitinol | RF-GA35053M |
| 0.035 in 0.89 mm | 80 cm | 30 mm | Nitinol | RF*GA35083M |
| 0.035 in 0.89 mm | 80 cm | 30 mm | Nitinol | RF-GA35083M |
| 0.035 in 0.89 mm | 120 cm | 30 mm | Nitinol | RF-GS35123M |
| 0.035 in 0.89 mm | 120 cm | 30 mm | Nitinol | RF*GA35123M |
| 0.035 in 0.89 mm | 120 cm | 30 mm | Nitinol | RF-GA35123M |
| 0.035 in 0.89 mm | 150 cm | 10 mm | Nitinol | RF-GA35151M |
| 0.035 in 0.89 mm | 150 cm | 10 mm | Nitinol | RF-GS35151M |
| 0.035 in 0.89 mm | 150 cm | 30 mm | Nitinol | RF*GA35153M |
| 0.035 in 0.89 mm | 150 cm | 30 mm | Nitinol | RF*GB35153M |
| 0.035 in 0.89 mm | 150 cm | 30 mm | Nitinol | RF*GS35153M |
| 0.035 in 0.89 mm | 150 cm | 30 mm | Nitinol | RF*GR35153M |
| 0.035 in 0.89 mm | 150 cm | 30 mm | Stiff Tapered Nitinol | RF*PS35153M |
| 0.035 in 0.89 mm | 150 cm | 50 mm | Nitinol | RF-GA35155M |
| 0.035 in 0.89 mm | 150 cm | 50 mm | Nitinol | RF*GA35155M |
| 0.035 in 0.89 mm | 150 cm | 50 mm | Nitinol | RF-GS35155M |
| 0.035 in 0.89 mm | 150 cm | 80 mm | Nitinol | RF-GA35158M |
| 0.035 in 0.89 mm | 150 cm | 80 mm | Nitinol | RF*GA35158M |
| 0.035 in 0.89 mm | 150 cm | 80 mm | Nitinol | RF-GS35158M |
| 0.035 in 0.89 mm | 150 cm | 80 mm | Nitinol | RF*GS35158M |
| 0.035 in 0.89 mm | 180 cm | 10 mm | Nitinol | RF-GA35181M |
| 0.035 in 0.89 mm | 180 cm | 10 mm | Nitinol | RF-GS35181M |
| 0.035 in 0.89 mm | 180 cm | 30 mm | Nitinol | RF-GS35183M |
| 0.035 in 0.89 mm | 180 cm | 30 mm | Nitinol | RF*GR35183M |
| 0.035 in 0.89 mm | 180 cm | 30 mm | Nitinol | RF*GS35183M |
| 0.035 in 0.89 mm | 180 cm | 30 mm | Nitinol | RF*GA35183M |
| 0.035 in 0.89 mm | 180 cm | 30 mm | Stiff Tapered Nitinol | RF*PS35183M |
| 0.035 in 0.89 mm | 180 cm | 50 mm | Nitinol | RF*GE35185M |
| 0.035 in 0.89 mm | 180 cm | 80 mm | Nitinol | RF*GA35188M |
| 0.035 in 0.89 mm | 180 cm | 80 mm | Nitinol | RF*GE35188M |
| 0.035 in 0.89 mm | 220 cm | 30 mm | Nitinol | RF-GA35223M |

Please quote above item reference codes when placing an order

Item specifications

| Guidewire Diameter - Outer Diameter | Length | Flexible Length | Core Material | Code |
|--|---------------|------------------------|-----------------------|-------------|
| 0.035 in 0.89 mm | 220 cm | 30 mm | Nitinol | RF-GS35223M |
| 0.035 in 0.89 mm | 220 cm | 30 mm | Nitinol | RF*GA35223M |
| 0.035 in 0.89 mm | 260 cm | 10 mm | Nitinol | RF-GA35261M |
| 0.035 in 0.89 mm | 260 cm | 10 mm | Nitinol | RF-GS35261M |
| 0.035 in 0.89 mm | 260 cm | 30 mm | Nitinol | RF*GS35263M |
| 0.035 in 0.89 mm | 260 cm | 30 mm | Nitinol | RF-GS35263M |
| 0.035 in 0.89 mm | 260 cm | 30 mm | Nitinol | RF*GR35263M |
| 0.035 in 0.89 mm | 260 cm | 30 mm | Nitinol | RF*GA35263M |
| 0.035 in 0.89 mm | 260 cm | 30 mm | Stiff Tapered Nitinol | RF*PS35263M |
| 0.035 in 0.89 mm | 300 cm | 30 mm | Nitinol | RF*GA35303M |
| 0.035 in 0.89 mm | 300 cm | 30 mm | Nitinol | RF*GS35303M |
| 0.035 in 0.89 mm | 300 cm | 30 mm | Nitinol | RF-GA35303M |
| 0.035 in 0.89 mm | 400 cm | 30 mm | Nitinol | RF*GS35403M |
| 0.035 in 0.89 mm | 400 cm | 30 mm | Nitinol | RF*GA35403M |
| 0.035 in 0.89 mm | 450 cm | 30 mm | Nitinol | RF*GA35453M |
| 0.035 in 0.89 mm | 450 cm | 30 mm | Nitinol | RF*GS35453M |
| 0.038 in 0.97 mm | 150 cm | 10 mm | Nitinol | RF-GS38151M |
| 0.038 in 0.97 mm | 150 cm | 10 mm | Nitinol | RF-GA38151M |
| 0.038 in 0.97 mm | 150 cm | 30 mm | Nitinol | RF*GS38153M |
| 0.038 in 0.97 mm | 150 cm | 30 mm | Nitinol | RF*GA38153M |
| 0.038 in 0.97 mm | 150 cm | 30 mm | Nitinol | RF-GS38153M |
| 0.038 in 0.97 mm | 150 cm | 30 mm | Stiff Tapered Nitinol | RF*PS38153M |
| 0.038 in 0.97 mm | 180 cm | 30 mm | Nitinol | RF*GA38183M |
| 0.038 in 0.97 mm | 180 cm | 30 mm | Nitinol | RF-GS38183M |
| 0.038 in 0.97 mm | 180 cm | 30 mm | Nitinol | RF*GS38183M |
| 0.038 in 0.97 mm | 180 cm | 30 mm | Nitinol | RF-GA38183M |
| 0.038 in 0.97 mm | 220 cm | 30 mm | Nitinol | RF-GA38223M |
| 0.038 in 0.97 mm | 260 cm | 30 mm | Nitinol | RF*GS38263M |
| 0.038 in 0.97 mm | 260 cm | 30 mm | Nitinol | RF*GA38263M |
| 0.038 in 0.97 mm | 260 cm | 30 mm | Nitinol | RF-GA38263M |
| 0.038 in 0.97 mm | 260 cm | 30 mm | Nitinol | RF-GS38263M |

RADIFOCUS® *Guidewire M* STIFF



Guide Wire

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

Product Characteristics

Radifocus® Guidewire M Stiff type is a stiff Nitinol hydrophilic guidewire covered with polyurethane containing tungsten and an hydrophilic polymer coating (M Coat™) for good torque control and shape memory as well as high stiffness and resistance.

- Radiopaque polyurethane jacket
- One-piece construction
- Rounded tapered tip

General specifications

| | |
|----------------------------|--|
| Core Material | Stiff Tapered Nitinol |
| Hydrophilic Coating | "M" Polymer |
| Radiopaque Jacket | Polyurethane Layer Containing Tungsten |

Item specifications

| Guidewire Diameter - Outer Diameter | Length | Flexible Length | Distal Curve | Code |
|-------------------------------------|--------|-----------------|-------------------|-------------|
| 0.018 in 0.46 mm | 180 cm | 30 mm | Angled | RF*PA18183M |
| 0.02 in 0.51 mm | 150 cm | 30 mm | Angled | RF-PA18153M |
| 0.02 in 0.51 mm | 260 cm | 30 mm | Angled | RF-PA18263M |
| 0.020 in 0.51 mm | 260 cm | 30 mm | Angled | RF*PA18263M |
| 0.025 in 0.64 mm | 150 cm | 30 mm | Angled | RF-PA25153M |
| 0.025 in 0.64 mm | 150 cm | 30 mm | Angled | RF*PA25153M |
| 0.025 in 0.64 mm | 150 cm | 30 mm | Straight | RF-PS25153M |
| 0.025 in 0.64 mm | 180 cm | 30 mm | Angled | RF-PA25183M |
| 0.025 in 0.64 mm | 260 cm | 30 mm | Angled | RF*PA25263M |
| 0.025 in 0.64 mm | 260 cm | 30 mm | Angled | RF-PA25263M |
| 0.035 in 0.89 mm | 80 cm | 30 mm | Angled | RF*PA35083M |
| 0.035 in 0.89 mm | 80 cm | 30 mm | Angled | RF-PA35083M |
| 0.035 in 0.89 mm | 80 cm | 30 mm | Straight | RF-PS35083M |
| 0.035 in 0.89 mm | 150 cm | 10 mm | Angled | RF-PA35151M |
| 0.035 in 0.89 mm | 150 cm | 30 mm | Angled | RF*PA35153M |
| 0.035 in 0.89 mm | 180 cm | 30 mm | Angled | RF*PA35183M |
| 0.035 in 0.89 mm | 180 cm | 30 mm | J Angled (1.5 mm) | RF*HR35183M |
| 0.035 in 0.89 mm | 180 cm | 30 mm | J Angled (2.0 mm) | RF*HN35183M |
| 0.035 in 0.89 mm | 180 cm | 30 mm | Straight | RF-PS35183M |
| 0.035 in 0.89 mm | 180 cm | 80 mm | Angled | RF*PA35188M |
| 0.035 in 0.89 mm | 260 cm | 30 mm | Angled | RF*PA35263M |
| 0.035 in 0.89 mm | 260 cm | 30 mm | Angled | RF-PA35263M |
| 0.035 in 0.89 mm | 260 cm | 30 mm | Straight | RF-PS35263M |
| 0.035 in 0.89 mm | 300 cm | 30 mm | Angled | RF*PA35303M |
| 0.035 in 0.89 mm | 300 cm | 30 mm | Angled | RF-PA35303M |
| 0.035 in 0.89 mm | 300 cm | 30 mm | J Angled (1.5 mm) | RF*HR35303M |
| 0.038 in 0.97 mm | 80 cm | 30 mm | Straight | RF-PS38083M |
| 0.038 in 0.97 mm | 150 cm | 30 mm | Angled | RF*PA38153M |
| 0.038 in 0.97 mm | 150 cm | 30 mm | Angled | RF-PA38153M |
| 0.038 in 0.97 mm | 150 cm | 30 mm | Straight | RF-PS38153M |
| 0.038 in 0.97 mm | 180 cm | 30 mm | Angled | RF*PA38183M |
| 0.038 in 0.97 mm | 180 cm | 30 mm | Angled | RF-PA38183M |
| 0.038 in 0.97 mm | 180 cm | 30 mm | Straight | RF-PS38183M |
| 0.038 in 0.97 mm | 260 cm | 30 mm | Angled | RF-PA38263M |

Please quote above item reference codes when placing an order

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS Guide Wire M

Product : Catheter Guide Wire

declare that the above products of **Class III** 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, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60116055 0001) under the supervision of TÜV Rheinland LGA Products GmbH, 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

RADIFOCUS GUIDEWIRE M Product code system

1) Without radiopaque tip marker

Standard type

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

| Character number | Denotation | | | | | | |
|------------------|--|--|-----------|---------------------|-----------|---------------------|-----------|
| 1-2 | Product name | RADIFOCUS GUIDE WIRE M | | | | | |
| 3 | Destination | * : for export | | | | | |
| 4 | Core wire flexibility | G : Standard H : Half stiff P : Stiff | | | | | |
| 5 | Tip configuration | A : Angled B : J-angled (3mm) C : J-angled (6mm) E : Double-angled N : J-angled (2mm) R : J-angled (1.5mm) S : Straight | | | | | |
| 6-7 | Outer diameter of guide wire | 18 | | | | 25 | |
| | | stiff-core type: 0.020" | | | | | |
| | | other core types: 0.018" | | | | | |
| | | 32 0.032" | | 35 0.035" | | 38 0.038" | |
| 8-9 | Guide wire length | 05 | 07 | 08 | 12 | 15 | 18 |
| | | 50 cm | 70 cm | 80 cm | 120 cm | 150 cm | 180 cm |
| | | 22 | 26 | 30 | 35 | 40 | 45 |
| | | 220 cm | 260cm | 300cm | 350cm | 400 cm | 450 cm |
| 10 | Flexible part length in the distal tip | 1 : 1cm (short taper) 3 : 3cm (normal taper) 5 : 5cm (long taper) 8 : 8cm (long long taper) | | | | | |
| 11 | Languages used for the indications | M : Multilanguage | | | | | |

High Flex Type

R F *

1 2 3 4 5 6 7 8 9 10 11

| Character number | Denotation | | | | | | | | | | |
|------------------|--|--|-----------|-----------|-----------|-----------|-----------|-----------|-----------|--|--|
| 1-2 | Product name | RADIFOCUS GUIDE WIRE M | | | | | | | | | |
| 3 | Destination | *: for export | | | | | | | | | |
| 4 | Core wire flexibility | G : Standard H : Half stiff | | | | | | | | | |
| 5 | Tip configuration | J : Straight F : Angled | | | | | | | | | |
| 6-7 | Outer diameter of guide wire | 18 | 25 | 32 | 35 | 38 | | | | | |
| | | 0.018" | 0.025" | 0.032" | 0.035" | 0.038" | | | | | |
| 8-9 | Guide wire length | 12 | 15 | 18 | 22 | 26 | 30 | 40 | 45 | | |
| | | 120cm | 150cm | 180cm | 220cm | 260cm | 300cm | 400cm | 450cm | | |
| 10 | Flexible part length in the distal tip | 3 : 3cm (normal taper) | | | | | | | | | |
| 11 | Languages used for the indications | M : Multilanguage | | | | | | | | | |

Super-Flex Type

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

| Character number | Denotation | | | | |
|------------------|--|------------------------|--------|--------|--------|
| 1-2 | Product name | RADIFOCUS GUIDE WIRE M | | | |
| 3 | Destination | *: for export | | | |
| 4 | Core wire flexibility | G : Standard | | | |
| 5 | Tip configuration | V : J-angled (2mm) | | | |
| 6-7 | Outer diameter of guide wire | 35: 0.035" | | | |
| 8-9 | Guide wire length | 15 | 18 | 20 | 22 |
| | | 150 cm | 180 cm | 200 cm | 220 cm |
| 10 | Flexible part length in the distal tip | 1 : 1cm (short taper) | | | |
| 11 | Languages used for the indications | M : Multilanguage | | | |

Shapeable Type (E Type)

R E * □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

| Character number | Denotation | | | | | |
|------------------|--|----------------------------|--------|--------|--------|--------|
| 1-2 | Product name | RADIFOCUS GUIDE WIRE M | | | | |
| 3 | Destination | *: for export | | | | |
| 4 | Core wire flexibility | G : Standard | | | | |
| 5 | Tip configuration | L : Straight K : Angled | | | | |
| 6-7 | Outer diameter of guide wire | 18 | 25 | 32 | 35 | 38 |
| | | 0.018" | 0.025" | 0.032" | 0.035" | 0.038" |
| 8-9 | Guide wire length | 12 | 15 | 18 | 22 | 26 |
| | | 120cm | 150cm | 180cm | 220cm | 260cm |
| 10 | Flexible part length in the distal tip | 3 : 3cm (normal taper) | | | | |
| 11 | Languages used for the indications | M : Multi-language | | | | |

2) With radiopaque tip marker

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

| Character number | Denotation | | | |
|------------------|--|----------------------------------|-----------|-----------|
| 1, 2, 4 | Product name | RADIFOCUS GUIDE WIRE M | | |
| 3 | Destination | *: for export | | |
| 5 | Tip configuration (Angled) | A : 45° B : 70° | | |
| 6-7 | Outer diameter of guide wire | 10 | 14 | 16 |
| | | 0.011" | 0.014" | 0.016" |
| 8-9 | Guide wire length | 18 : 180cm | | |
| 10 | Flexible part length in the distal tip | 8 : 8cm (long long taper) | | |
| 11 | Accessory supplied with the guide wire | T : Torque device | | |
| 12 | Languages used for the indications | M : Multilanguage | | |

RADIFOCUS GUIDEWIRE M manufactured by TVC Product code system

Standard type

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

| Position | Meaning of indication | | | | | | |
|----------|------------------------------------|--|-----------|------------------|-----------|------------------|-----------|
| 1-2 | Product type | RADIFOCUS GUIDE WIRE M | | | | | |
| 3 | Destination | + / * for worldwide excluding Japan | | | | | |
| 4 | Core wire flexibility | G : Standard H : Half stiff P : Stiff | | | | | |
| 5 | Tip configuration | A : Angled S : Straight | | | | | |
| 6-7 | Outer diameter of guide wire | 18 | | | 25 | | |
| | | stiff-core type: 0.020" / 0.51 mm other core types: 0.018" / 0.46 mm | | | | | |
| | | 32 | | 35 | | 38 | |
| | | 0.032" / 0.81 mm | | 0.035" / 0.89 mm | | 0.038" / 0.97 mm | |
| 8-9 | Guide wire length | 05 | 07 | 08 | 12 | 15 | 18 |
| | | 50 cm | 70 cm | 80 cm | 120 cm | 150 cm | 180 cm |
| | | 22 | 26 | | | | |
| | | 220 cm | 260cm | | | | |
| 10 | Flexible part length in distal tip | 1 : 1cm (short taper) 3 : 3cm (normal taper) 5 : 5cm (long taper) 8 : 8cm (long long taper) | | | | | |
| 11 | Languages used for the indications | M : Multilanguage | | | | | |

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

**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

M. Aihara

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

Date: 2019-12-23

Notified Body


M.Sc. M. Aihara



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



Michihara

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

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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. |

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