

Metacross[®]

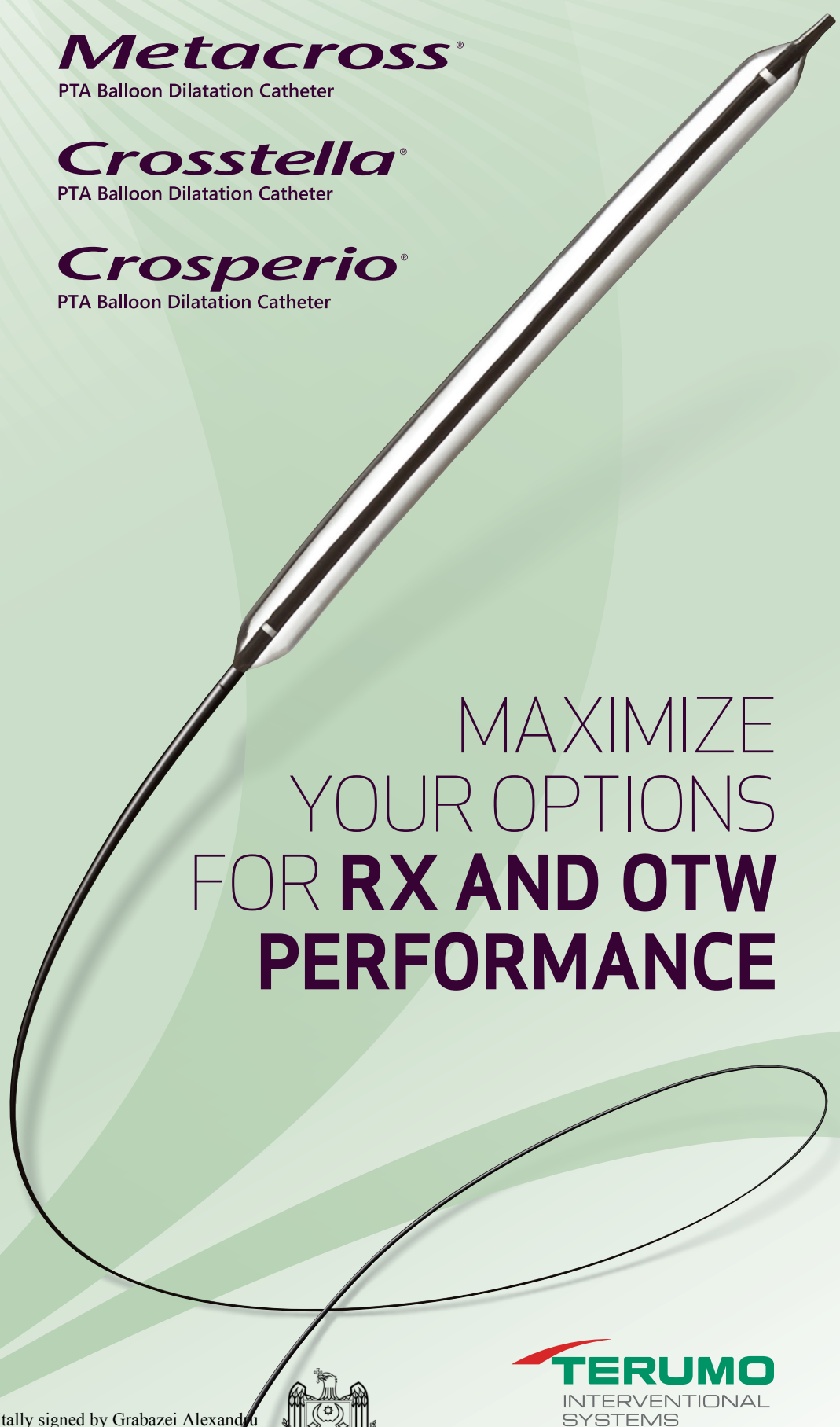
PTA Balloon Dilatation Catheter

Crosstella[®]

PTA Balloon Dilatation Catheter

Croserio[®]

PTA Balloon Dilatation Catheter



MAXIMIZE
YOUR OPTIONS
FOR **RX AND OTW**
PERFORMANCE



CHOOSE FROM A FULL LINE OF RX AND OTW OPTIONS

Designed for optimal performance

METACROSS® PTA Balloon Dilatation Catheter (0.035")

CROSSTELLA® PTA Balloon Dilatation Catheter (0.018")

CROSPERIO® PTA Balloon Dilatation Catheter (0.014")

Providing end-to-end performance with less effort and more options, our rapid exchange (RX) and over-the-wire (OTW) PTA balloon dilatation catheters let you choose the optimal solution for you and your patients.

- 3 guidewire sizes available (0.014", 0.018", and 0.035")¹⁻⁶
- Smaller balloon profiles help ease crossability^{7,*}
 - Supports re-crossability within the same procedure¹⁻⁶
- Well-designed shaft and stiff tapered core wire engineered for maximizing pushability[†]
 - Effective transition of force from proximal to distal end



Catheter	Guidewire Compatibility (in)	Usable Shaft Length (cm)	
Metacross® RX	0.035	135	
Metacross® OTW	0.035	65/90/135	
Crosstella® RX	0.018	150	Pro
Crosstella® OTW	0.018	150	
Crosporio® RX	0.014	150	
Crosporio® OTW	0.014	65/150	

* Diameter range: METACROSS® RX/OTW (3-12 mm); CROSSTELLA® RX/OTW (2-6 mm); CROSPERIO® RX/OTW (1.5-4 mm).

† RX design feature.

‡ METACROSS® RX/OTW PTA Balloon Catheter illustrations shown.

PUSHING BOUNDARIES

Terumo Interventional Systems is **committed to your success** with innovative procedural solutions and ongoing support for your most challenging cases.

We are relentlessly seeking new ways to help you apply effective solutions and achieve **better outcomes for more patients.**



CHOOSE FROM A FULL LINE OF RX AND OTW OPTIONS

Designed for optimal performance

- METACROSS®** PTA Balloon Dilatation Catheter (0.035")
- CROSSTELLA®** PTA Balloon Dilatation Catheter (0.018")
- CROSPERIO®** PTA Balloon Dilatation Catheter (0.014")

Providing end-to-end performance with less effort and more options, our rapid exchange (RX) and over-the-wire (OTW) PTA balloon dilatation catheters let you choose the optimal solution for you and your patients.

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† RX design feature.

‡ METACROSS® RX/OTW PTA Balloon Catheter illustrations shown.

Catheter	Guidewire Compatibility (in)	Usable Shaft Length (cm)	Shaft Diameter		Proximal Tapered	Proximal Marker (mm)	Center (mm)	Distal Marker (mm)	Distal Tapered (mm)	Distal (mm)
Metacross® RX	0.035	135	Proximal 3.9 Fr (1.30 mm)	Distal 5.7 Fr (1.90 mm)	1.7	1.7	1.6	1.7	1.4	1.02
Metacross® OTW	0.035	65/90/135	5 Fr compatible: 5.4 Fr (1.80 mm) 6/7 Fr compatible: 5.7 Fr (1.90 mm)		1.7	1.7	1.6	1.7	1.4	1.07
Crosstella® RX	0.018	150	Proximal 3.4 Fr (1.12 mm) or 4.1 Fr (1.35 mm)	Distal 4 Fr (1.32 mm)	1.28	1.32	1.28	1.36	1.29	0.62
Crosstella® OTW	0.018	150	4 Fr compatible: 3.9 Fr (1.30 mm) 5 Fr compatible: 4.3 Fr (1.43 mm)		1.19	1.30	1.26	1.30	1.01	0.58
Crosperio® RX	0.014	150	Proximal 3.5 Fr (1.16 mm)	Distal 3.5 Fr (1.16 mm)	0.85	0.85	0.82	0.86	0.83	0.47
Crosperio® OTW	0.014	65/150	3.8 Fr (1.28 mm)		0.90	0.87	0.81	0.83	0.76	0.46

RAPID EXCHANGE: BETTER HANDLING BY DESIGN

Achieve optimal results with Rapid Exchange

- Enables faster, more convenient exchange of devices
- Supports the use of shorter guidewires
- Encourages procedural efficiency, reducing fluoroscopy time and radiation dose
- Optimizes control, allowing a single operator to mitigate lost wire position

Metacross® RX

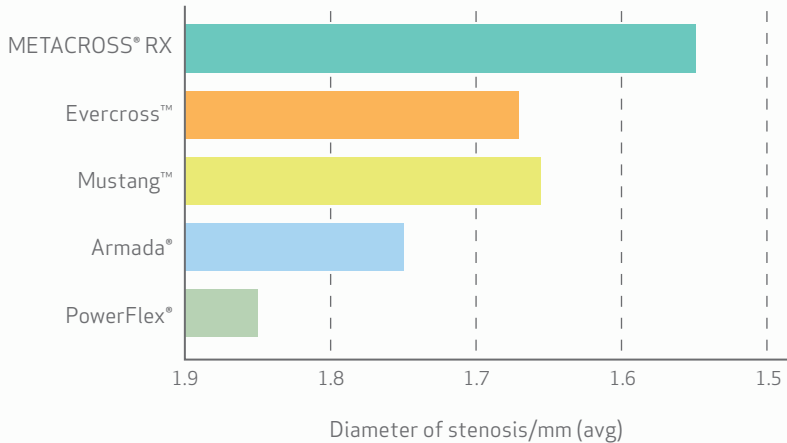
PTA Balloon Dilatation Catheter

ENGINEERED FOR PERFORMANCE

Excellent crossability with innovative catheter design⁷

- Designed to provide best-in-class pushability⁷
- Larger diameter proximal shaft⁷
- Smallest balloon profile among tested semi-compliant balloons⁷

METACROSS® RX has excellent crossability compared to select competitors



Sample size: METACROSS® RX n=10, competitors n=5; size used for comparison: 6 mm x 40 mm.

METACROSS® RX

CROSSTELLA® RX

CROSPERIO® RX

▲
See inserts for ordering information.

Metacross®

PTA Balloon Dilatation Catheter

Crosstella®

PTA Balloon Dilatation Catheter

Crosperio®

PTA Balloon Dilatation Catheter



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Indications

CROSPERIO® RX PTA Dilatation Balloon Catheter, CROSPERIO® OTW PTA Dilatation Balloon Catheter, CROSSTELLA® RX PTA Dilatation Balloon Catheter, CROSSTELLA® OTW PTA Dilatation Balloon Catheter, METACROSS® RX PTA Dilatation Balloon Catheter, and METACROSS® OTW PTA Dilatation Balloon Catheter are intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native and synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

RX ONLY. Refer to the product labels and package insert for complete warnings, precautions, potential complications, and instructions for use.

References:

1. METACROSS® RX IFU, January 2016.
2. METACROSS® OTW IFU, March 2016.
3. CROSSTELLA® RX IFU, February 2016.
4. CROSSTELLA® OTW IFU, May 2016.
5. CROSPERIO® RX IFU, March 2016.
6. CROSPERIO® OTW IFU, March 2016.
7. Data on file.

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 **TERUMO**
INTERVENTIONAL
SYSTEMS

Metacross® RX

PTA Balloon Dilatation Catheter

ORDERING INFORMATION

METACROSS® RX 0.035" PTA Balloon Dilatation Catheter – 135 cm								
BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)							
	20	40	60	80	100	120	150	200
3	BD-L30020CR	BD-L30040CR	BD-L30060CR	BD-L30080CR	BD-L30100CR	BD-L30120CR	BD-L30150CR	BD-L30200CR
4	BD-L40020CR	BD-L40040CR	BD-L40060CR	BD-L40080CR	BD-L40100CR	BD-L40120CR	BD-L40150CR	BD-L40200CR
5	BD-L50020CR	BD-L50040CR	BD-L50060CR	BD-L50080CR	BD-L50100CR	BD-L50120CR	BD-L50150CR	BD-L50200CR
6	BD-L60020CR	BD-L60040CR	BD-L60060CR	BD-L60080CR	BD-L60100CR	BD-L60120CR	BD-L60150CR	BD-L60200CR
7	BD-L70020CR	BD-L70040CR	BD-L70060CR	BD-L70080CR	BD-L70100CR	BD-L70120CR	BD-L70150CR	BD-L70200CR
8	BD-L80020CR	BD-L80040CR	BD-L80060CR	BD-L80080CR	—	—	—	—
9	BD-L90020CR	BD-L90040CR	BD-L90060CR	BD-L90080CR	—	—	—	—
10	BD-LX0020CR	BD-LX0040CR	BD-LX0060CR	BD-LX0080CR	—	—	—	—
12	BD-LX2020CR	BD-LX2040CR	—	—	—	—	—	—

6Fr

7Fr



Metacross® OTW

PTA Balloon Dilatation Catheter

ORDERING INFORMATION

METACROSS® OTW 0.035" PTA Balloon Dilatation Catheter – 65 cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)							
	20	40	60	80	100	120	150	200
3	BD-L30020SW	BD-L30040SW	BD-L30060SW	BD-L30080SW	BD-L30100SW	BD-L30120SW	BD-L30150SW	BD-L30200SW
4	BD-L40020SW	BD-L40040SW	BD-L40060SW	BD-L40080SW	BD-L40100SW	BD-L40120SW	BD-L40150SW	BD-L40200SW
5	BD-L50020SW	BD-L50040SW	BD-L50060SW	BD-L50080SW	BD-L50100SW	BD-L50120SW	BD-L50150SW	BD-L50200SW
6	BD-L60020SW	BD-L60040SW	BD-L60060SW	BD-L60080SW	BD-L60100SW	BD-L60120SW	BD-L60150SW	BD-L60200SW
7	BD-L70020SW	BD-L70040SW	BD-L70060SW	BD-L70080SW	BD-L70100SW	BD-L70120SW	BD-L70150SW	BD-L70200SW
8	BD-L80020SW	BD-L80040SW	BD-L80060SW	BD-L80080SW	—	—	—	—
9	BD-L90020SW	BD-L90040SW	BD-L90060SW	BD-L90080SW	—	—	—	—
10	BD-LX0020SW	BD-LX0040SW	BD-LX0060SW	BD-LX0080SW	—	—	—	—
12	BD-LX2020SW	BD-LX2040SW	—	—	—	—	—	—

5Fr

6Fr

7Fr

METACROSS® OTW 0.035" PTA Balloon Dilatation Catheter – 90 cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)							
	20	40	60	80	100	120	150	200
3	BD-L30020MW	BD-L30040MW	BD-L30060MW	BD-L30080MW	BD-L30100MW	BD-L30120MW	BD-L30150MW	BD-L30200MW
4	BD-L40020MW	BD-L40040MW	BD-L40060MW	BD-L40080MW	BD-L40100MW	BD-L40120MW	BD-L40150MW	BD-L40200MW
5	BD-L50020MW	BD-L50040MW	BD-L50060MW	BD-L50080MW	BD-L50100MW	BD-L50120MW	BD-L50150MW	BD-L50200MW
6	BD-L60020MW	BD-L60040MW	BD-L60060MW	BD-L60080MW	BD-L60100MW	BD-L60120MW	BD-L60150MW	BD-L60200MW
7	BD-L70020MW	BD-L70040MW	BD-L70060MW	BD-L70080MW	BD-L70100MW	BD-L70120MW	BD-L70150MW	BD-L70200MW
8	BD-L80020MW	BD-L80040MW	BD-L80060MW	BD-L80080MW	—	—	—	—
9	BD-L90020MW	BD-L90040MW	BD-L90060MW	BD-L90080MW	—	—	—	—
10	BD-LX0020MW	BD-LX0040MW	BD-LX0060MW	BD-LX0080MW	—	—	—	—
12	BD-LX2020MW	BD-LX2040MW	—	—	—	—	—	—

5Fr

6Fr

7Fr

METACROSS® OTW 0.035" PTA Balloon Dilatation Catheter – 135 cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)							
	20	40	60	80	100	120	150	200
3	BD-L30020CW	BD-L30040CW	BD-L30060CW	BD-L30080CW	BD-L30100CW	BD-L30120CW	BD-L30150CW	BD-L30200CW
4	BD-L40020CW	BD-L40040CW	BD-L40060CW	BD-L40080CW	BD-L40100CW	BD-L40120CW	BD-L40150CW	BD-L40200CW
5	BD-L50020CW	BD-L50040CW	BD-L50060CW	BD-L50080CW	BD-L50100CW	BD-L50120CW	BD-L50150CW	BD-L50200CW
6	BD-L60020CW	BD-L60040CW	BD-L60060CW	BD-L60080CW	BD-L60100CW	BD-L60120CW	BD-L60150CW	BD-L60200CW
7	BD-L70020CW	BD-L70040CW	BD-L70060CW	BD-L70080CW	BD-L70100CW	BD-L70120CW	BD-L70150CW	BD-L70200CW
8	BD-L80020CW	BD-L80040CW	BD-L80060CW	BD-L80080CW	—	—	—	—
9	BD-L90020CW	BD-L90040CW	BD-L90060CW	BD-L90080CW	—	—	—	—
10	BD-LX0020CW	BD-LX0040CW	BD-LX0060CW	BD-LX0080CW	—	—	—	—
12	BD-LX2020CW	BD-LX2040CW	—	—	—	—	—	—

5Fr

6Fr

7Fr

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Crosstella® RX

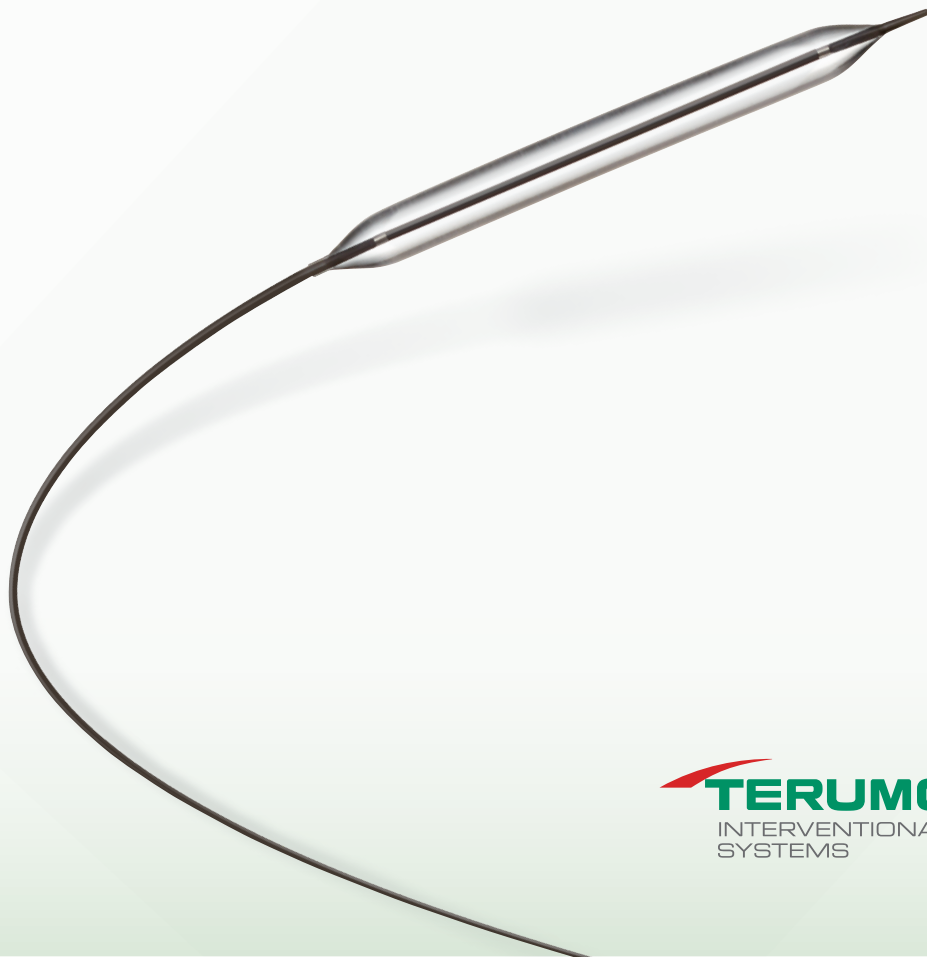
PTA Balloon Dilatation Catheter

ORDERING INFORMATION

CROSSTELLA® RX 0.018" PTA Balloon Dilatation Catheter – 150 cm								
BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)							
	20	40	60	80	100	120	150	200
2	BD-F20020LR	BD-F20040LR	BD-F20060LR	BD-F20080LR	BD-F20100LR	BD-F20120LR	BD-F20150LR	BD-F20200LR
2.5	BD-F25020LR	BD-F25040LR	BD-F25060LR	BD-F25080LR	BD-F25100LR	BD-F25120LR	BD-F25150LR	BD-F25200LR
3	BD-F30020LR	BD-F30040LR	BD-F30060LR	BD-F30080LR	BD-F30100LR	BD-F30120LR	BD-F30150LR	BD-F30200LR
4	BD-F40020LR	BD-F40040LR	BD-F40060LR	BD-F40080LR	BD-F40100LR	BD-F40120LR	BD-F40150LR	BD-F40200LR
5	BD-F50020LR	BD-F50040LR	BD-F50060LR	BD-F50080LR	BD-F50100LR	BD-F50120LR	BD-F50150LR	BD-F50200LR
6	BD-F60020LR	BD-F60040LR	BD-F60060LR	BD-F60080LR	BD-F60100LR	BD-F60120LR	BD-F60150LR	BD-F60200LR

4Fr

5Fr



Crosstella® OTW

PTA Balloon Dilatation Catheter

ORDERING INFORMATION

CROSSTELLA® OTW 0.018" PTA Balloon Dilatation Catheter – 150 cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)							
	20	40	60	80	100	120	150	200
2	BD-F20020LW	BD-F20040LW	BD-F20060LW	BD-F20080LW	BD-F20100LW	BD-F20120LW	BD-F20150LW	BD-F20200LW
2.5	BD-F25020LW	BD-F25040LW	BD-F25060LW	BD-F25080LW	BD-F25100LW	BD-F25120LW	BD-F25150LW	BD-F25200LW
3	BD-F30020LW	BD-F30040LW	BD-F30060LW	BD-F30080LW	BD-F30100LW	BD-F30120LW	BD-F30150LW	BD-F30200LW
4	BD-F40020LW	BD-F40040LW	BD-F40060LW	BD-F40080LW	BD-F40100LW	BD-F40120LW	BD-F40150LW	BD-F40200LW
5	BD-F50020LW	BD-F50040LW	BD-F50060LW	BD-F50080LW	BD-F50100LW	BD-F50120LW	BD-F50150LW	BD-F50200LW
6	BD-F60020LW	BD-F60040LW	BD-F60060LW	BD-F60080LW	BD-F60100LW	BD-F60120LW	BD-F60150LW	BD-F60200LW

4Fr

5Fr



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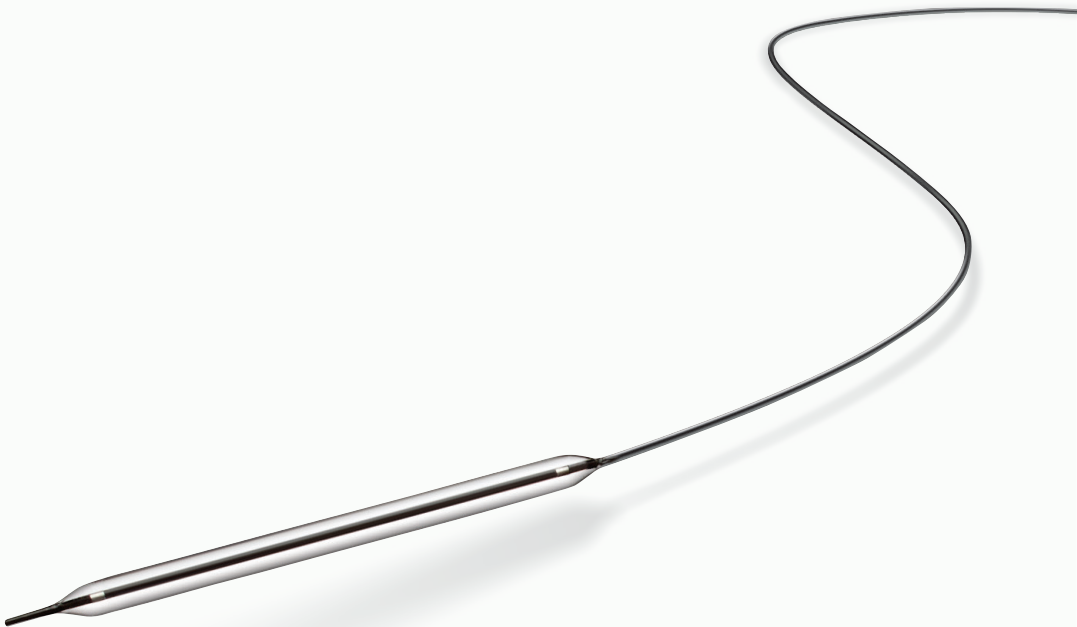
Crosperio® RX

PTA Balloon Dilatation Catheter

ORDERING INFORMATION

CROSPERIO® RX 0.014" PTA Balloon Dilatation Catheter – 150 cm						
BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)					
	20	40	80	120	150	200
1.5	BD-B15020LR	BD-B15040LR	BD-B15080LR	BD-B15120LR	—	—
2	—	BD-B20040LR	BD-B20080LR	BD-B20120LR	BD-B20150LR	BD-B20200LR
2.5	—	BD-B25040LR	BD-B25080LR	BD-B25120LR	BD-B25150LR	BD-B25200LR
3	—	BD-B30040LR	BD-B30080LR	BD-B30120LR	BD-B30150LR	BD-B30200LR
3.5	—	BD-B35040LR	BD-B35080LR	BD-B35120LR	BD-B35150LR	BD-B35200LR
4	—	BD-B40040LR	BD-B40080LR	BD-B40120LR	BD-B40150LR	BD-B40200LR

4Fr



Crosprio® OTW

PTA Balloon Dilatation Catheter

ORDERING INFORMATION

CROSPERIO® OTW 0.014" PTA Balloon Dilatation Catheter – 65 cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)					
	20	40	80	120	150	200
1.5	BD-B15020SW	BD-B15040SW	BD-B15080SW	BD-B15120SW	—	—
2	—	BD-B20040SW	BD-B20080SW	BD-B20120SW	BD-B20150SW	BD-B20200SW
2.5	—	BD-B25040SW	BD-B25080SW	BD-B25120SW	BD-B25150SW	BD-B25200SW
3	—	BD-B30040SW	BD-B30080SW	BD-B30120SW	BD-B30150SW	BD-B30200SW
3.5	—	BD-B35040SW	BD-B35080SW	BD-B35120SW	BD-B35150SW	BD-B35200SW
4	—	BD-B40040SW	BD-B40080SW	BD-B40120SW	BD-B40150SW	BD-B40200SW

4Fr

CROSPERIO® OTW 0.014" PTA Balloon Dilatation Catheter – 150 cm

BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)					
	20	40	80	120	150	200
1.5	BD-B15020LW	BD-B15040LW	BD-B15080LW	BD-B15120LW	—	—
2	—	BD-B20040LW	BD-B20080LW	BD-B20120LW	BD-B20150LW	BD-B20200LW
2.5	—	BD-B25040LW	BD-B25080LW	BD-B25120LW	BD-B25150LW	BD-B25200LW
3	—	BD-B30040LW	BD-B30080LW	BD-B30120LW	BD-B30150LW	BD-B30200LW
3.5	—	BD-B35040LW	BD-B35080LW	BD-B35120LW	BD-B35150LW	BD-B35200LW
4	—	BD-B40040LW	BD-B40080LW	BD-B40120LW	BD-B40150LW	BD-B40200LW

4Fr

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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 024736 0061 Rev. 01

Manufacturer:

KANEKA Corporation

3-18, 2-Chome, Nakanoshima, Kita-ku

Osaka-city, OSAKA

530-8288 JAPAN

Product Category(ies): Peripheral angioplasty balloon catheter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

JNQ235039027

Valid from:

2020-05-11

Valid until:

2024-05-26

Date,

2020-05-11

Christoph Dicks

Head of Certification/Notified Body



Certificate

No. Q5 024736 0069 Rev. 02

Holder of Certificate:

KANEKA

KANEKA Corporation

3-18, 2-Chome, Nakanoshima, Kita-ku
Osaka-city, OSAKA
530-8288 JAPAN

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Medical Device for Selective Blood or Plasma Component Adsorption, Catheter Intervention, Surgical or Neurosurgical Drainage, Cerebral Shunt, Vacuum Extraction Delivery, Cell Separation / Harvesting, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology.
Production and Distribution of Blood Flowmeter and Inflation Device.
Distribution of Plasma Separator, Blood Tubing Lines and Apheresis Unit.
Design and Development, Production and Distribution of In-vitro Diagnostic Products for Genetic-testing.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 024736 0069 Rev. 02

Report No.: JN1459484

Valid from: 2021-03-01

Valid until: 2023-08-31

Date, 2021-02-10

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 024736 0069 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): **KANEKA Corporation**
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA,
530-8288 JAPAN

Design and Development, Production and Distribution of Medical
Devices for Selective Blood or Plasma Component Adsorption,
Catheter Intervention, Surgical or Neurosurgical Drainage,
Cerebral Shunt, Vacuum Extraction Delivery, Cell Separation /
Harvesting, Endoscopic Intervention, Ophthalmology, Vascular /
Neurovascular Embolization and Cardiac Electrophysiology
Production and Distribution of Blood Flowmeter and Inflation
Device

Distribution of Plasma Separator, Blood Tubing Lines and
Apheresis Unit

Design and Development, Production and Distribution of In-vitro
Diagnostic Products for Genetic-testing

KANEKA Corporation Osaka Plant
5-1-1, Torikai-Nishi, Settsu-city, OSAKA, 566-0072 JAPAN

Design and Development, Production and Distribution of Medical
Devices for Selective Blood or Plasma Component Adsorption,
Catheter Intervention, Surgical or Neurosurgical Drainage,
Cerebral Shunt, Vacuum Extraction Delivery, Cell Separation /
Harvesting, Endoscopic Intervention, Ophthalmology and Vascular
/ Neurovascular Embolization

Production and Distribution of Blood Flowmeter and Inflation
Device

Distribution of Plasma Separator, Blood Tubing Lines and
Apheresis Unit

Production and Distribution of In-vitro Diagnostic Products for
genetic-testing

KANEKA Corporation Takasago Plant
1-8, Miyamae-cho, Takasago-cho, Takasago, Hyogo, 676-8688
JAPAN

Design and Development, Production and Distribution of In-vitro
Diagnostic Products for genetic-testing

Certificate

No. Q5 024736 0069 Rev. 02

Facility(ies):

KANEKA Medix Corporation Kanagawa Plant
225-1, Aza Deguchi, Yamakita, Yamakita-machi,
Ashigara-Kami-gun, KANAGAWA, 258-0113 JAPAN

Production and Distribution of Medical Devices for Catheter Intervention, Surgical or Neurosurgical Drainage, Cerebral Shunt, Vacuum Extraction Delivery, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology

KANEKA Medix Corporation Osaka Office
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA,
530-8288 JAPAN

Sales Office

KANEKA MEDICAL VIETNAM CO., LTD.
35 VSIP Street 6, Vietnam - Singapore Industrial Park,
An Phu Ward, Thuan An City, Binh Duong Province, VIETNAM

Production of Catheter Intervention, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology

KANEKA Corporation Tokyo Office
12-32, 1-Chome, Akasaka, Minato-ku, Tokyo, 107-6028 JAPAN

Sales Office

KANEKA Medix Corporation Tokyo Office
12-32, 1-Chome, Akasaka, Minato-ku, Tokyo, 107-6028 JAPAN

Sales Office

KANEKA Medix Corporation Tokyo Logistics Center
3-2-52, Yashio, Shinagawa-ku, Tokyo, 140-0003 JAPAN

Distribution of all products

Kaneka Medical Tech Corporation Ina Factory
7108-1 Nishiminowa, Ina-shi, Nagano, 399-4501 JAPAN

Production and Distribution of Medical Devices for Endoscopic Intervention and Ophthalmology

Certificate

No. Q5 024736 0069 Rev. 02

Facility(ies):

Kaneka Medical Tech Corporation Okaya Factory
2-6-16 Kohan, Okaya-shi, Nagano, 394-0034 JAPAN

Design and Development, Production and Distribution of Medical
Devices for Endoscopic Intervention, Ophthalmology and Cardiac
Electrophysiology

-/-

DECLARATION OF CONFORMITY

1. Manufacturer: **KANEKA Corporation**
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city,
OSAKA 530-8288, JAPAN
2. European representative: **KANEKA PHARMA EUROPE N.V.**
Nijverheidsstraat 16, 2260 Westerlo-Oevel, BELGIUM
3. Product: **Metacross RX**
PTA Balloon Dilatation Catheter
4. Catalogue No.: see Attachment
5. Classification: Class IIa, Rule 6 of annex IX of the MDD 93/42/EEC
6. Conformity assessment route: Annex II excluding Section 4 of the MDD 93/42/EEC applied

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATIONS OF CONFORMITY. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

7. Standard applied: See the List of Applied Standards in Chapter 7A of the Device Documentation of Metacross RX (No: MEG-TDA1a/07)
8. Notified body: TÜV SÜD Product Service GmbH (Identification No. 0123)
Ridlerstrasse 65 D-80339 München, Germany
9. EC Certificate: G1 17 04 24736 061

10. Start of CE-marking: **LOT No. SP068159**

11. Place, Date of Issue: Osaka, Japan 2018-06-04
Place Date (yyyy-mm-dd)

12. Signature:



K. Sanaka
Kazuaki Sanaka (QMS Management Representative)

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
Metacross RX	BD-L30020MR	3.0	20	900
Metacross RX	BD-L30040MR	3.0	40	900
Metacross RX	BD-L30060MR	3.0	60	900
Metacross RX	BD-L30080MR	3.0	80	900
Metacross RX	BD-L30100MR	3.0	100	900
Metacross RX	BD-L30120MR	3.0	120	900
Metacross RX	BD-L30150MR	3.0	150	900
Metacross RX	BD-L30200MR	3.0	200	900
Metacross RX	BD-L40020MR	4.0	20	900
Metacross RX	BD-L40040MR	4.0	40	900
Metacross RX	BD-L40060MR	4.0	60	900
Metacross RX	BD-L40080MR	4.0	80	900
Metacross RX	BD-L40100MR	4.0	100	900
Metacross RX	BD-L40120MR	4.0	120	900
Metacross RX	BD-L40150MR	4.0	150	900
Metacross RX	BD-L40200MR	4.0	200	900
Metacross RX	BD-L50020MR	5.0	20	900
Metacross RX	BD-L50040MR	5.0	40	900
Metacross RX	BD-L50060MR	5.0	60	900
Metacross RX	BD-L50080MR	5.0	80	900
Metacross RX	BD-L50100MR	5.0	100	900
Metacross RX	BD-L50120MR	5.0	120	900
Metacross RX	BD-L50150MR	5.0	150	900
Metacross RX	BD-L50200MR	5.0	200	900
Metacross RX	BD-L60020MR	6.0	20	900
Metacross RX	BD-L60040MR	6.0	40	900
Metacross RX	BD-L60060MR	6.0	60	900
Metacross RX	BD-L60080MR	6.0	80	900
Metacross RX	BD-L60100MR	6.0	100	900
Metacross RX	BD-L60120MR	6.0	120	900
Metacross RX	BD-L60150MR	6.0	150	900
Metacross RX	BD-L60200MR	6.0	200	900
Metacross RX	BD-L70020MR	7.0	20	900
Metacross RX	BD-L70040MR	7.0	40	900
Metacross RX	BD-L70060MR	7.0	60	900
Metacross RX	BD-L70080MR	7.0	80	900
Metacross RX	BD-L70100MR	7.0	100	900
Metacross RX	BD-L70120MR	7.0	120	900
Metacross RX	BD-L70150MR	7.0	150	900
Metacross RX	BD-L70200MR	7.0	200	900
Metacross RX	BD-L80020MR	8.0	20	900
Metacross RX	BD-L80040MR	8.0	40	900
Metacross RX	BD-L80060MR	8.0	60	900
Metacross RX	BD-L80080MR	8.0	80	900
Metacross RX	BD-L90020MR	9.0	20	900
Metacross RX	BD-L90040MR	9.0	40	900
Metacross RX	BD-L90060MR	9.0	60	900
Metacross RX	BD-L90080MR	9.0	80	900
Metacross RX	BD-LX0020MR	10.0	20	900

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
Metacross RX	BD-LX0040MR	10.0	40	900
Metacross RX	BD-LX0060MR	10.0	60	900
Metacross RX	BD-LX0080MR	10.0	80	900
Metacross RX	BD-LX2020MR	12.0	20	900
Metacross RX	BD-LX2040MR	12.0	40	900
Metacross RX	BD-L30020CR	3.0	20	1350
Metacross RX	BD-L30040CR	3.0	40	1350
Metacross RX	BD-L30060CR	3.0	60	1350
Metacross RX	BD-L30080CR	3.0	80	1350
Metacross RX	BD-L30100CR	3.0	100	1350
Metacross RX	BD-L30120CR	3.0	120	1350
Metacross RX	BD-L30150CR	3.0	150	1350
Metacross RX	BD-L30200CR	3.0	200	1350
Metacross RX	BD-L40020CR	4.0	20	1350
Metacross RX	BD-L40040CR	4.0	40	1350
Metacross RX	BD-L40060CR	4.0	60	1350
Metacross RX	BD-L40080CR	4.0	80	1350
Metacross RX	BD-L40100CR	4.0	100	1350
Metacross RX	BD-L40120CR	4.0	120	1350
Metacross RX	BD-L40150CR	4.0	150	1350
Metacross RX	BD-L40200CR	4.0	200	1350
Metacross RX	BD-L50020CR	5.0	20	1350
Metacross RX	BD-L50040CR	5.0	40	1350
Metacross RX	BD-L50060CR	5.0	60	1350
Metacross RX	BD-L50080CR	5.0	80	1350
Metacross RX	BD-L50100CR	5.0	100	1350
Metacross RX	BD-L50120CR	5.0	120	1350
Metacross RX	BD-L50150CR	5.0	150	1350
Metacross RX	BD-L50200CR	5.0	200	1350
Metacross RX	BD-L60020CR	6.0	20	1350
Metacross RX	BD-L60040CR	6.0	40	1350
Metacross RX	BD-L60060CR	6.0	60	1350
Metacross RX	BD-L60080CR	6.0	80	1350
Metacross RX	BD-L60100CR	6.0	100	1350
Metacross RX	BD-L60120CR	6.0	120	1350
Metacross RX	BD-L60150CR	6.0	150	1350
Metacross RX	BD-L60200CR	6.0	200	1350
Metacross RX	BD-L70020CR	7.0	20	1350
Metacross RX	BD-L70040CR	7.0	40	1350
Metacross RX	BD-L70060CR	7.0	60	1350
Metacross RX	BD-L70080CR	7.0	80	1350
Metacross RX	BD-L70100CR	7.0	100	1350
Metacross RX	BD-L70120CR	7.0	120	1350
Metacross RX	BD-L70150CR	7.0	150	1350
Metacross RX	BD-L70200CR	7.0	200	1350
Metacross RX	BD-L80020CR	8.0	20	1350
Metacross RX	BD-L80040CR	8.0	40	1350
Metacross RX	BD-L80060CR	8.0	60	1350
Metacross RX	BD-L80080CR	8.0	80	1350

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
Metacross RX	BD-L90020CR	9.0	20	1350
Metacross RX	BD-L90040CR	9.0	40	1350
Metacross RX	BD-L90060CR	9.0	60	1350
Metacross RX	BD-L90080CR	9.0	80	1350
Metacross RX	BD-LX0020CR	10.0	20	1350
Metacross RX	BD-LX0040CR	10.0	40	1350
Metacross RX	BD-LX0060CR	10.0	60	1350
Metacross RX	BD-LX0080CR	10.0	80	1350
Metacross RX	BD-LX2020CR	12.0	20	1350
Metacross RX	BD-LX2040CR	12.0	40	1350
Metacross RX	BD-L30020ER	3.0	20	2000
Metacross RX	BD-L30040ER	3.0	40	2000
Metacross RX	BD-L30060ER	3.0	60	2000
Metacross RX	BD-L30080ER	3.0	80	2000
Metacross RX	BD-L30100ER	3.0	100	2000
Metacross RX	BD-L30120ER	3.0	120	2000
Metacross RX	BD-L30150ER	3.0	150	2000
Metacross RX	BD-L30200ER	3.0	200	2000
Metacross RX	BD-L40020ER	4.0	20	2000
Metacross RX	BD-L40040ER	4.0	40	2000
Metacross RX	BD-L40060ER	4.0	60	2000
Metacross RX	BD-L40080ER	4.0	80	2000
Metacross RX	BD-L40100ER	4.0	100	2000
Metacross RX	BD-L40120ER	4.0	120	2000
Metacross RX	BD-L40150ER	4.0	150	2000
Metacross RX	BD-L40200ER	4.0	200	2000
Metacross RX	BD-L50020ER	5.0	20	2000
Metacross RX	BD-L50040ER	5.0	40	2000
Metacross RX	BD-L50060ER	5.0	60	2000
Metacross RX	BD-L50080ER	5.0	80	2000
Metacross RX	BD-L50100ER	5.0	100	2000
Metacross RX	BD-L50120ER	5.0	120	2000
Metacross RX	BD-L50150ER	5.0	150	2000
Metacross RX	BD-L50200ER	5.0	200	2000
Metacross RX	BD-L60020ER	6.0	20	2000
Metacross RX	BD-L60040ER	6.0	40	2000
Metacross RX	BD-L60060ER	6.0	60	2000
Metacross RX	BD-L60080ER	6.0	80	2000
Metacross RX	BD-L60100ER	6.0	100	2000
Metacross RX	BD-L60120ER	6.0	120	2000
Metacross RX	BD-L60150ER	6.0	150	2000
Metacross RX	BD-L60200ER	6.0	200	2000
Metacross RX	BD-L70020ER	7.0	20	2000
Metacross RX	BD-L70040ER	7.0	40	2000
Metacross RX	BD-L70060ER	7.0	60	2000
Metacross RX	BD-L70080ER	7.0	80	2000
Metacross RX	BD-L70100ER	7.0	100	2000
Metacross RX	BD-L70120ER	7.0	120	2000
Metacross RX	BD-L70150ER	7.0	150	2000

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
Metacross RX	BD-L70200ER	7.0	200	2000
Metacross RX	BD-L80020ER	8.0	20	2000
Metacross RX	BD-L80040ER	8.0	40	2000
Metacross RX	BD-L80060ER	8.0	60	2000
Metacross RX	BD-L80080ER	8.0	80	2000
Metacross RX	BD-L90020ER	9.0	20	2000
Metacross RX	BD-L90040ER	9.0	40	2000
Metacross RX	BD-L90060ER	9.0	60	2000
Metacross RX	BD-L90080ER	9.0	80	2000
Metacross RX	BD-LX0020ER	10.0	20	2000
Metacross RX	BD-LX0040ER	10.0	40	2000
Metacross RX	BD-LX0060ER	10.0	60	2000
Metacross RX	BD-LX0080ER	10.0	80	2000
Metacross RX	BD-LX2020ER	12.0	20	2000
Metacross RX	BD-LX2040ER	12.0	40	2000
R2P Metacross RX	BD-P30020ER	3.0	20	2000
R2P Metacross RX	BD-P30040ER	3.0	40	2000
R2P Metacross RX	BD-P30060ER	3.0	60	2000
R2P Metacross RX	BD-P30080ER	3.0	80	2000
R2P Metacross RX	BD-P30100ER	3.0	100	2000
R2P Metacross RX	BD-P30120ER	3.0	120	2000
R2P Metacross RX	BD-P30150ER	3.0	150	2000
R2P Metacross RX	BD-P30200ER	3.0	200	2000
R2P Metacross RX	BD-P40020ER	4.0	20	2000
R2P Metacross RX	BD-P40040ER	4.0	40	2000
R2P Metacross RX	BD-P40060ER	4.0	60	2000
R2P Metacross RX	BD-P40080ER	4.0	80	2000
R2P Metacross RX	BD-P40100ER	4.0	100	2000
R2P Metacross RX	BD-P40120ER	4.0	120	2000
R2P Metacross RX	BD-P40150ER	4.0	150	2000
R2P Metacross RX	BD-P40200ER	4.0	200	2000
R2P Metacross RX	BD-P50020ER	5.0	20	2000
R2P Metacross RX	BD-P50040ER	5.0	40	2000
R2P Metacross RX	BD-P50060ER	5.0	60	2000
R2P Metacross RX	BD-P50080ER	5.0	80	2000
R2P Metacross RX	BD-P50100ER	5.0	100	2000
R2P Metacross RX	BD-P50120ER	5.0	120	2000
R2P Metacross RX	BD-P50150ER	5.0	150	2000
R2P Metacross RX	BD-P50200ER	5.0	200	2000
R2P Metacross RX	BD-P60020ER	6.0	20	2000
R2P Metacross RX	BD-P60040ER	6.0	40	2000
R2P Metacross RX	BD-P60060ER	6.0	60	2000
R2P Metacross RX	BD-P60080ER	6.0	80	2000
R2P Metacross RX	BD-P60100ER	6.0	100	2000
R2P Metacross RX	BD-P60120ER	6.0	120	2000
R2P Metacross RX	BD-P60150ER	6.0	150	2000
R2P Metacross RX	BD-P60200ER	6.0	200	2000
R2P Metacross RX	BD-P70020ER	7.0	20	2000
R2P Metacross RX	BD-P70040ER	7.0	40	2000

Attachment

Name as per device label	Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
R2P Metacross RX	BD-P70060ER	7.0	60	2000
R2P Metacross RX	BD-P70080ER	7.0	80	2000
R2P Metacross RX	BD-P70100ER	7.0	100	2000
R2P Metacross RX	BD-P70120ER	7.0	120	2000
R2P Metacross RX	BD-P70150ER	7.0	150	2000
R2P Metacross RX	BD-P70200ER	7.0	200	2000
R2P Metacross RX	BD-P80020ER	8.0	20	2000
R2P Metacross RX	BD-P80040ER	8.0	40	2000
R2P Metacross RX	BD-P80060ER	8.0	60	2000
R2P Metacross RX	BD-P80080ER	8.0	80	2000

DECLARATION OF CONFORMITY

1. Manufacturer: **KANEKA Corporation**
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA
530-8288, JAPAN
2. European representative: **KANEKA PHARMA EUROPE N.V.**
Nijverheidsstraat 16, 2260 Westerlo-Oevel, BELGIUM
3. Product: **Metacross OTW**
PTA Balloon Dilatation Catheter
4. Catalogue No.: see Attachment
5. Classification: Class IIa,
Rule 6 of annex IX of the MDD 93/42/EEC
6. Conformity assessment route: Annex II excluding Section 4 of the MDD 93/42/EEC applied

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

7. Standard applied: See the List of Applied Standards in Chapter 7A of the Device Documentation of Metacross OTW (No: MEG-TDA1b/05)
8. Notified body: TÜV SÜD Product Service GmbH (Identification No. 0123)
Ridlerstrasse 65 D-80339 München, Germany
9. EC Certificate: G1 17 04 24736 061

10. Start of CE-marking: **LOT No. SP068161**

11. Place, Date of Issue: Osaka, Japan 2018-06-04
Place Date (yyyy-mm-dd)

12. Signature: K. Sanaka
Kazuaki Sanaka (QMS Management Representative)



Attachment

Model: Metacross OTW

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
BD-L30020SW	3.0	20	65
BD-L30040SW	3.0	40	65
BD-L30060SW	3.0	60	65
BD-L30080SW	3.0	80	65
BD-L30100SW	3.0	100	65
BD-L30120SW	3.0	120	65
BD-L30150SW	3.0	150	65
BD-L30200SW	3.0	200	65
BD-L40020SW	4.0	20	65
BD-L40040SW	4.0	40	65
BD-L40060SW	4.0	60	65
BD-L40080SW	4.0	80	65
BD-L40100SW	4.0	100	65
BD-L40120SW	4.0	120	65
BD-L40150SW	4.0	150	65
BD-L40200SW	4.0	200	65
BD-L50020SW	5.0	20	65
BD-L50040SW	5.0	40	65
BD-L50060SW	5.0	60	65
BD-L50080SW	5.0	80	65
BD-L50100SW	5.0	100	65
BD-L50120SW	5.0	120	65
BD-L50150SW	5.0	150	65
BD-L50200SW	5.0	200	65
BD-L60020SW	6.0	20	65
BD-L60040SW	6.0	40	65
BD-L60060SW	6.0	60	65
BD-L60080SW	6.0	80	65
BD-L60100SW	6.0	100	65
BD-L60120SW	6.0	120	65
BD-L60150SW	6.0	150	65
BD-L60200SW	6.0	200	65
BD-L70020SW	7.0	20	65
BD-L70040SW	7.0	40	65
BD-L70060SW	7.0	60	65
BD-L70080SW	7.0	80	65
BD-L70100SW	7.0	100	65
BD-L70120SW	7.0	120	65
BD-L70150SW	7.0	150	65
BD-L70200SW	7.0	200	65
BD-L80020SW	8.0	20	65
BD-L80040SW	8.0	40	65

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
BD-L80060SW	8.0	60	65
BD-L80080SW	8.0	80	65
BD-L90020SW	9.0	20	65
BD-L90040SW	9.0	40	65
BD-L90060SW	9.0	60	65
BD-L90080SW	9.0	80	65
BD-LX0020SW	10.0	20	65
BD-LX0040SW	10.0	40	65
BD-LX0060SW	10.0	60	65
BD-LX0080SW	10.0	80	65
BD-LX2020SW	12.0	20	65
BD-LX2040SW	12.0	40	65
BD-L30020MW	3.0	20	90
BD-L30040MW	3.0	40	90
BD-L30060MW	3.0	60	90
BD-L30080MW	3.0	80	90
BD-L30100MW	3.0	100	90
BD-L30120MW	3.0	120	90
BD-L30150MW	3.0	150	90
BD-L30200MW	3.0	200	90
BD-L40020MW	4.0	20	90
BD-L40040MW	4.0	40	90
BD-L40060MW	4.0	60	90
BD-L40080MW	4.0	80	90
BD-L40100MW	4.0	100	90
BD-L40120MW	4.0	120	90
BD-L40150MW	4.0	150	90
BD-L40200MW	4.0	200	90
BD-L50020MW	5.0	20	90
BD-L50040MW	5.0	40	90
BD-L50060MW	5.0	60	90
BD-L50080MW	5.0	80	90
BD-L50100MW	5.0	100	90
BD-L50120MW	5.0	120	90
BD-L50150MW	5.0	150	90
BD-L50200MW	5.0	200	90
BD-L60020MW	6.0	20	90
BD-L60040MW	6.0	40	90
BD-L60060MW	6.0	60	90
BD-L60080MW	6.0	80	90
BD-L60100MW	6.0	100	90
BD-L60120MW	6.0	120	90
BD-L60150MW	6.0	150	90
BD-L60200MW	6.0	200	90

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
BD-L70020MW	7.0	20	90
BD-L70040MW	7.0	40	90
BD-L70060MW	7.0	60	90
BD-L70080MW	7.0	80	90
BD-L70100MW	7.0	100	90
BD-L70120MW	7.0	120	90
BD-L70150MW	7.0	150	90
BD-L70200MW	7.0	200	90
BD-L80020MW	8.0	20	90
BD-L80040MW	8.0	40	90
BD-L80060MW	8.0	60	90
BD-L80080MW	8.0	80	90
BD-L90020MW	9.0	20	90
BD-L90040MW	9.0	40	90
BD-L90060MW	9.0	60	90
BD-L90080MW	9.0	80	90
BD-LX0020MW	10.0	20	90
BD-LX0040MW	10.0	40	90
BD-LX0060MW	10.0	60	90
BD-LX0080MW	10.0	80	90
BD-LX2020MW	12.0	20	90
BD-LX2040MW	12.0	40	90
BD-L30020CW	3.0	20	135
BD-L30040CW	3.0	40	135
BD-L30060CW	3.0	60	135
BD-L30080CW	3.0	80	135
BD-L30100CW	3.0	100	135
BD-L30120CW	3.0	120	135
BD-L30150CW	3.0	150	135
BD-L30200CW	3.0	200	135
BD-L40020CW	4.0	20	135
BD-L40040CW	4.0	40	135
BD-L40060CW	4.0	60	135
BD-L40080CW	4.0	80	135
BD-L40100CW	4.0	100	135
BD-L40120CW	4.0	120	135
BD-L40150CW	4.0	150	135
BD-L40200CW	4.0	200	135
BD-L50020CW	5.0	20	135
BD-L50040CW	5.0	40	135
BD-L50060CW	5.0	60	135
BD-L50080CW	5.0	80	135
BD-L50100CW	5.0	100	135
BD-L50120CW	5.0	120	135

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (cm)
BD-L50150CW	5.0	150	135
BD-L50200CW	5.0	200	135
BD-L60020CW	6.0	20	135
BD-L60040CW	6.0	40	135
BD-L60060CW	6.0	60	135
BD-L60080CW	6.0	80	135
BD-L60100CW	6.0	100	135
BD-L60120CW	6.0	120	135
BD-L60150CW	6.0	150	135
BD-L60200CW	6.0	200	135
BD-L70020CW	7.0	20	135
BD-L70040CW	7.0	40	135
BD-L70060CW	7.0	60	135
BD-L70080CW	7.0	80	135
BD-L70100CW	7.0	100	135
BD-L70120CW	7.0	120	135
BD-L70150CW	7.0	150	135
BD-L70200CW	7.0	200	135
BD-L80020CW	8.0	20	135
BD-L80040CW	8.0	40	135
BD-L80060CW	8.0	60	135
BD-L80080CW	8.0	80	135
BD-L90020CW	9.0	20	135
BD-L90040CW	9.0	40	135
BD-L90060CW	9.0	60	135
BD-L90080CW	9.0	80	135
BD-LX0020CW	10.0	20	135
BD-LX0040CW	10.0	40	135
BD-LX0060CW	10.0	60	135
BD-LX0080CW	10.0	80	135
BD-LX2020CW	12.0	20	135
BD-LX2040CW	12.0	40	135