Crosperio® RX

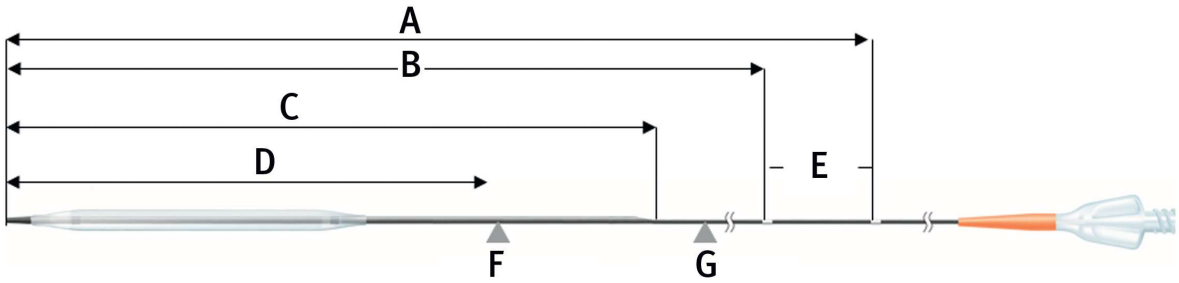
PTA Balloon Dilatation Catheter

Crosperio RX is a Percutaneous Transluminal Angioplasty (PTA) balloon dilatation catheter for peripheral indications. It is 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 or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

Product Characteristics

- *Stiff core wire provides better pushability to reach and cross very distal target lesions[1]*
- *Very small balloon profile and hydrophilic coating facilitates successful lesion access and crossing for below-the-knee and below-the-ankle interventions[1]*

1 Tested against selected RX competitors. Data on file. Terumo Corporation-CROSPERIORX Product Information.



A 100 cm
B 90 cm
C Guidewire lumen length: 30 cm/40 cm
D Hydrophilic coating: 28 cm /38 cm
E Depth markers
F 3.5 Fr/1.16 mm
G 3.5Fr/1.16mm

General specifications

Maximum Guidewire	0.014 in / 0.36 mm
Minimum Sheath Size	4 Fr
Nominal Pressure	8 atm
Rated Burst Pressure	14 atm
Usable Shaft Length	150 cm

Guidewire lumen length 40 cm only for Balloon length 200 mm
Hydrophilic coating 28 cm only for Balloon length 20 -150 mm
Hydrophilic coating 38 cm only for Balloon length 200 mm

Digitally signed by Grabazei Alexandru
Date: 2022.01.10 10:59:44 EET
Reason: MoldSign Signature
Location: Moldova

IS803/6GB1219KAV

Item specifications

Balloon Diameter	Balloon Length	Code
1.5 mm	20 mm	BD-B15020LR
1.5 mm	40 mm	BD-B15040LR
1.5 mm	80 mm	BD-B15080LR
1.5 mm	120 mm	BD-B15120LR
2 mm	40 mm	BD-B20040LR
2 mm	80 mm	BD-B20080LR
2 mm	120 mm	BD-B20120LR
2 mm	150 mm	BD-B20150LR
2 mm	200 mm	BD-B20200LR
2.5 mm	40 mm	BD-B25040LR
2.5 mm	80 mm	BD-B25080LR
2.5 mm	120 mm	BD-B25120LR
2.5 mm	150 mm	BD-B25150LR
2.5 mm	200 mm	BD-B25200LR
3 mm	40 mm	BD-B30040LR
3 mm	80 mm	BD-B30080LR
3 mm	120 mm	BD-B30120LR
3 mm	150 mm	BD-B30150LR
3 mm	200 mm	BD-B30200LR
3.5 mm	40 mm	BD-B35040LR
3.5 mm	80 mm	BD-B35080LR
3.5 mm	120 mm	BD-B35120LR
3.5 mm	150 mm	BD-B35150LR
3.5 mm	200 mm	BD-B35200LR
4 mm	40 mm	BD-B40040LR
4 mm	80 mm	BD-B40080LR
4 mm	120 mm	BD-B40120LR
4 mm	150 mm	BD-B40150LR
4 mm	200 mm	BD-B40200LR

Please quote above item reference codes when placing an order

IS803/6GB1219KAV

kaneka

DECLARATION OF CONFORMITY

1. Manufacturer:	**KANEKA Corporation** 3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA 530-8288, JAPAN
2. European representative:	**KANEKA MEDICAL EUROPE N.V.** Nijverheidsstraat 16, 2260 Westerlo-Oevel, BELGIUM
3. Product:	**Crosperio 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 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 Crosperio RX (No: MEG-TDA1c/08)
8. Notified body:	TÜV SÜD Product Service GmbH (Identification No. 0123) Ridlerstrasse 65 D-80339 München, Germany
9. EC Certificate:	G1 024736 0061 Rev.01
10. Start of CE-marking:	**LOT No. SR091368**
11. Place, Date of Issue:	Osaka, Japan (Place) 2021-09-17 (Date (yyyy-mm-dd))
12. Signature:	K. Sanaka Kazuaki Sanaka (QMS Management Representative)

Attachment

Model: Crosperio RX

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
BD-B15020MR	1.5	20	900
BD-B15040MR	1.5	40	900
BD-B15080MR	1.5	80	900
BD-B15120MR	1.5	120	900
BD-B20020MR	2.0	20	900
BD-B20040MR	2.0	40	900
BD-B20080MR	2.0	80	900
BD-B20120MR	2.0	120	900
BD-B20150MR	2.0	150	900
BD-B20200MR	2.0	200	900
BD-B25020MR	2.5	20	900
BD-B25040MR	2.5	40	900
BD-B25080MR	2.5	80	900
BD-B25120MR	2.5	120	900
BD-B25150MR	2.5	150	900
BD-B25200MR	2.5	200	900
BD-B30020MR	3.0	20	900
BD-B30040MR	3.0	40	900
BD-B30080MR	3.0	80	900
BD-B30120MR	3.0	120	900
BD-B30150MR	3.0	150	900
BD-B30200MR	3.0	200	900
BD-B35020MR	3.5	20	900
BD-B35040MR	3.5	40	900
BD-B35080MR	3.5	80	900
BD-B35120MR	3.5	120	900
BD-B35150MR	3.5	150	900
BD-B35200MR	3.5	200	900
BD-B40020MR	4.0	20	900
BD-B40040MR	4.0	40	900
BD-B40080MR	4.0	80	900
BD-B40120MR	4.0	120	900
BD-B40150MR	4.0	150	900
BD-B40200MR	4.0	200	900
BD-B15020LR	1.5	20	1500
BD-B15040LR	1.5	40	1500
BD-B15080LR	1.5	80	1500
BD-B15120LR	1.5	120	1500
BD-B20020LR	2.0	20	1500
BD-B20040LR	2.0	40	1500
BD-B20080LR	2.0	80	1500
BD-B20120LR	2.0	120	1500
BD-B20150LR	2.0	150	1500
BD-B20200LR	2.0	200	1500

Article number	Balloon diameter (mm)	Balloon length (mm)	Effective length (mm)
BD-B25020LR	2.5	20	1500
BD-B25040LR	2.5	40	1500
BD-B25080LR	2.5	80	1500
BD-B25120LR	2.5	120	1500
BD-B25150LR	2.5	150	1500
BD-B25200LR	2.5	200	1500
BD-B30020LR	3.0	20	1500
BD-B30040LR	3.0	40	1500
BD-B30080LR	3.0	80	1500
BD-B30120LR	3.0	120	1500
BD-B30150LR	3.0	150	1500
BD-B30200LR	3.0	200	1500
BD-B35020LR	3.5	20	1500
BD-B35040LR	3.5	40	1500
BD-B35080LR	3.5	80	1500
BD-B35120LR	3.5	120	1500
BD-B35150LR	3.5	150	1500
BD-B35200LR	3.5	200	1500
BD-B40020LR	4.0	20	1500
BD-B40040LR	4.0	40	1500
BD-B40080LR	4.0	80	1500
BD-B40120LR	4.0	120	1500
BD-B40150LR	4.0	150	1500
BD-B40200LR	4.0	200	1500

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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A4 / 07.17

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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

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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

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

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

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