Senri

PTA balloon dilatation catheter

Low Profile PTA Balloon combining Finesse and Pushability. Senri is a Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter for peripheral indications. It is designed specifically for the dilatation of stenosis in arteries, veins, or artificial blood vessels in regions other than cephalic, cervical and cardiac vessels.

Product Characteristics

Low profile semi-compliant balloon, hydrophilic coated

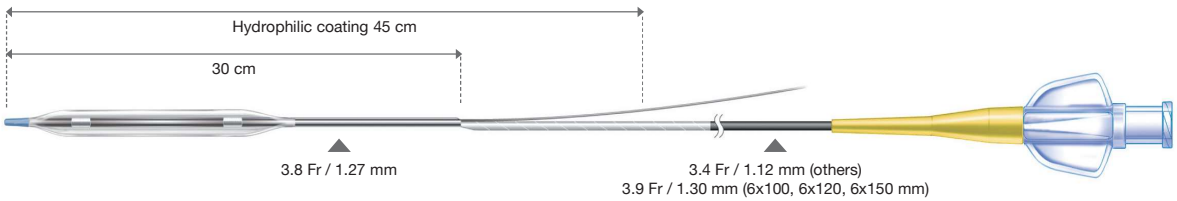
- *Featuring an extremely low crossing profile, by a 3-folded (ø3.0-6.0mm) and 4-folded (ø7.0-8.0mm) balloon with high flexibility for successful crossability and superior trackability.*
- *The distal 45 cm catheter segment is hydrophilic coated for swift and easy navigation, even through complex anatomy.*

Dedicated shaft design

- *Combines the pushability of a stainless steel hypotube shaft with the kink resistance of a polymer shaft, even for cross-over procedures in sharp angulated bifurcations.*
- *Maintains very fast deflation times.*

Broad range of sizes

- *Balloon diameters from 2-8mm and lengths up to 150mm - suitable for a great variety of peripheral interventional procedures.*



General Specifications

Balloon material	Polyamide
Balloon folding	2 mm to 6 mm balloons: 3-folded - 7 mm and 8 mm balloons: 4-folded
Maximum guidewire	0.018" (0.46 mm)
Effective catheter length	150 cm
Nominal pressure	8 atm / 811 kPa
Rated burst pressure	Ø 2-7 mm: 14 atm / 1419 kPa Ø 8 mm: 12 atm / 1216 kPa

Minimum sheath size / Minimum guiding catheter

Balloon diameter (mm)	Compatible sheath (Fr / mm)	Compatible guide catheter (Fr / mm)
2, 3, 4, 5, 6x40 mm	4 Fr / 1.33 mm	6 Fr / 2.0 mm
6 mm (excl. 6x40 mm), 7 mm	5 Fr / 1.67 mm	7 Fr / 2.33 mm
8 mm	6 Fr / 2.0 mm	8 Fr / 2.67 mm

Item Specifications

Balloon diameter (mm)	Balloon length (mm)					
	40	60	80	100	120	150
2	BD-S2040L	BD-S2060L	BD-S2080L	BD-S20100L	BD-S20120L	BD-S20150L
3	BD-S3040L	BD-S3060L	BD-S3080L	BD-S30100L	BD-S30120L	BD-S30150L
4	BD-S4040L	BD-S4060L	BD-S4080L	BD-S40100L	BD-S40120L	BD-S40150L
5	BD-S5040L	BD-S5060L	BD-S5080L	BD-S50100L	BD-S50120L	BD-S50150L
6	BD-S6040L	BD-S6060L	BD-S6080L	BD-S60100LH	BD-S60120LH	BD-S60150LH
7	BD-S7040L	BD-S7060L	BD-S7080L	—	—	—
8	BD-S8040L	BD-S8060L	—	—	—	—

Please quote above item reference codes when placing an order

IS616/46GB06161T1

KANEKA
MEDICAL
PRODUCTS

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:	**Senri** **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 13 of the Device Documentation of Senri (No: MEG-TDA1/13)
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. SR091279
11. Place, Date of Issue:	Osaka, Japan (Place) 2021-09-13 (Date (yyyy-mm-dd))
12. Signature:	K. Sanaka Kazuaki Sanaka (QMS Management representative)

Attachment

Catalogue No.	Balloon Diameter (mm) <La>	Balloon Length (mm) <Lb>	Effective length (cm) <Lc>
BD-S2040M	2.00	40	90
BD-S2060M	2.00	60	90
BD-S2080M	2.00	80	90
BD-S20100M	2.00	100	90
BD-S20120M	2.00	120	90
BD-S20150M	2.00	150	90
BD-S3040M	3.00	40	90
BD-S3060M	3.00	60	90
BD-S3080M	3.00	80	90
BD-S30100M	3.00	100	90
BD-S30120M	3.00	120	90
BD-S30150M	3.00	150	90
BD-S4040M	4.00	40	90
BD-S4060M	4.00	60	90
BD-S4080M	4.00	80	90
BD-S40100M	4.00	100	90
BD-S40120M	4.00	120	90
BD-S40150M	4.00	150	90
BD-S5040M	5.00	40	90
BD-S5060M	5.00	60	90
BD-S5080M	5.00	80	90
BD-S50100M	5.00	100	90
BD-S50120M	5.00	120	90
BD-S50150M	5.00	150	90
BD-S6040M	6.00	40	90
BD-S6060M	6.00	60	90
BD-S6080M	6.00	80	90
BD-S7040M	7.00	40	90
BD-S7060M	7.00	60	90
BD-S7080M	7.00	80	90
BD-S8040M	8.00	40	90
BD-S8060M	8.00	60	90
BD-S6060MH	6.00	60	90
BD-S6080MH	6.00	80	90
BD-S60100MH	6.00	100	90
BD-S60120MH	6.00	120	90
BD-S60150MH	6.00	150	90
BD-S7040MH	7.00	40	90
BD-S7060MH	7.00	60	90
BD-S7080MH	7.00	80	90
BD-S8040MH	8.00	40	90
BD-S8060MH	8.00	60	90
BD-S2040L	2.00	40	150
BD-S2060L	2.00	60	150

Attachment

Catalogue No.	Balloon Diameter (mm) <La>	Balloon Length (mm) <Lb>	Effective length (cm) <Lc>
BD-S2080L	2.00	80	150
BD-S20100L	2.00	100	150
BD-S20120L	2.00	120	150
BD-S20150L	2.00	150	150
BD-S3040L	3.00	40	150
BD-S3060L	3.00	60	150
BD-S3080L	3.00	80	150
BD-S30100L	3.00	100	150
BD-S30120L	3.00	120	150
BD-S30150L	3.00	150	150
BD-S4040L	4.00	40	150
BD-S4060L	4.00	60	150
BD-S4080L	4.00	80	150
BD-S40100L	4.00	100	150
BD-S40120L	4.00	120	150
BD-S40150L	4.00	150	150
BD-S5040L	5.00	40	150
BD-S5060L	5.00	60	150
BD-S5080L	5.00	80	150
BD-S50100L	5.00	100	150
BD-S50120L	5.00	120	150
BD-S50150L	5.00	150	150
BD-S6040L	6.00	40	150
BD-S6060L	6.00	60	150
BD-S6080L	6.00	80	150
BD-S7040L	7.00	40	150
BD-S7060L	7.00	60	150
BD-S7080L	7.00	80	150
BD-S8040L	8.00	40	150
BD-S8060L	8.00	60	150
BD-S6060LH	6.00	60	150
BD-S6080LH	6.00	80	150
BD-S60100LH	6.00	100	150
BD-S60120LH	6.00	120	150
BD-S60150LH	6.00	150	150
BD-S7040LH	7.00	40	150
BD-S7060LH	7.00	60	150
BD-S7080LH	7.00	80	150
BD-S8040LH	8.00	40	150
BD-S8060LH	8.00	60	150

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

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

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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TÜV SÜD Product Service

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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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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