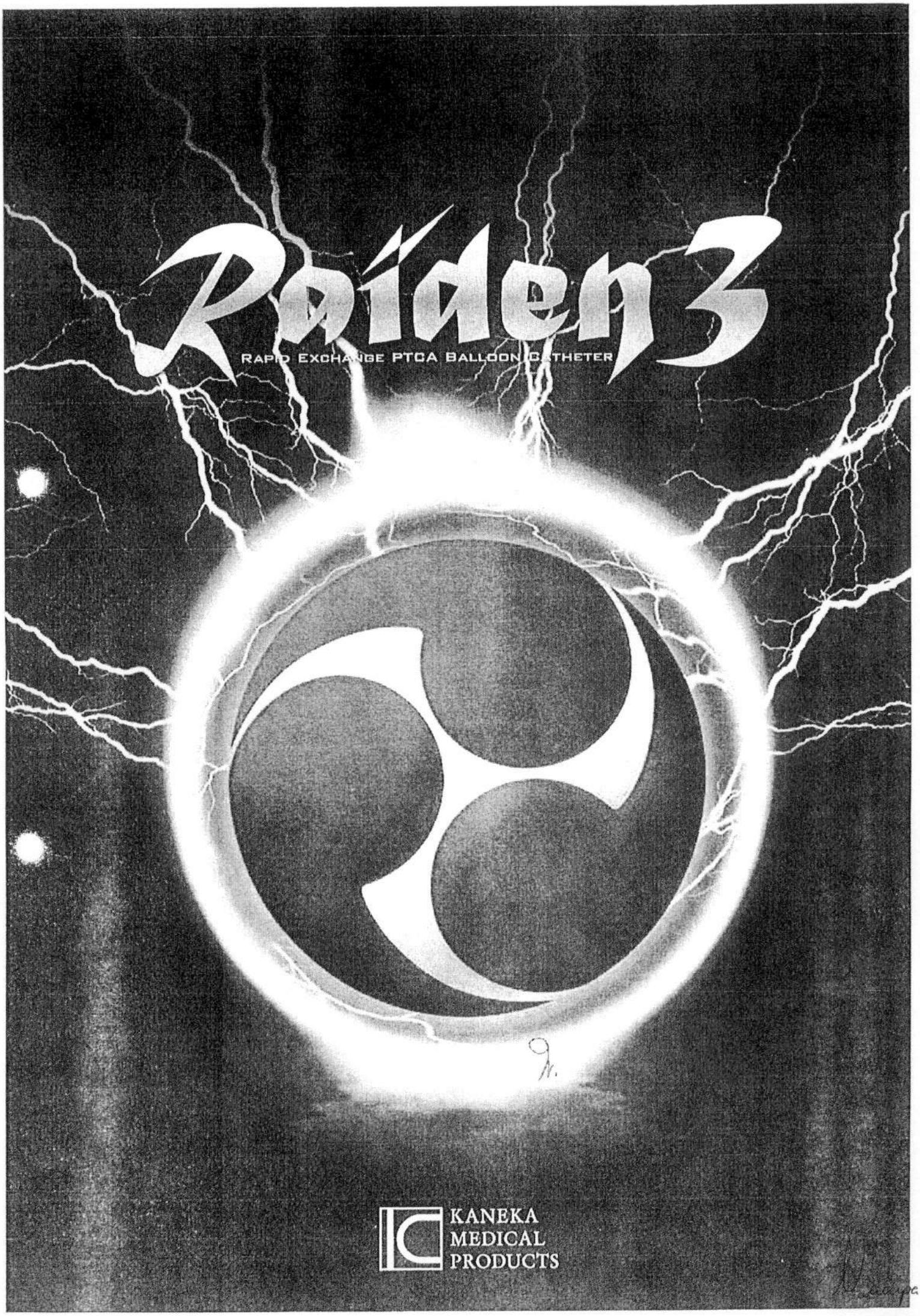
Raiden3
RAPID EXCHANGE PTCA BALLOON CATHETER
KANEKA
MEDICAL
PRODUCTS

Raiden 3

1. Challenge

Product lineup with the balloons of Ø1.50mm and Ø1.75mm for our challenge to cross tight lesions

2. Evolution

Higher crossability with new hydrophilic coating, low balloon profile and improved shaft specifications

(In comparison with data of our existing products.)

3. Confidence

Preserving dilatation accuracy even after repetitive inflation/ deflation — RBP: 22atm for the balloons of Ø2.25 - 4.00mm

RBP: 20atm for the balloons of Ø1.50, 1.75, 2.00, 4.25 and 4.50mm.

Balloon Compliance

Balloon Diameter (mm)	Pressure (atm [x10^{5}Pa])										
	2	4	6	8	10	12	14	16	18	20	22
1.50	1.33	1.37	1.40	1.44	1.47	1.50	1.52	1.55	1.58	1.60	
1.75	1.55	1.60	1.63	1.68	1.72	1.75	1.77	1.81	1.84	1.87	
2.00	1.72	1.78	1.84	1.90	1.96	2.00	2.03	2.05	2.08	2.11	
2.25	1.94	1.99	2.07	2.14	2.20	2.25	2.29	2.33	2.35	2.38	2.42
2.50	2.21	2.27	2.35	2.40	2.46	2.50	2.54	2.58	2.62	2.66	2.71
2.75	2.37	2.43	2.51	2.60	2.68	2.75	2.82	2.87	2.91	2.94	2.97
3.00	2.63	2.70	2.77	2.86	2.93	3.00	3.05	3.09	3.13	3.16	3.19
3.25	2.87	2.96	3.05	3.13	3.20	3.25	3.30	3.34	3.37	3.40	3.45
3.50	3.08	3.17	3.26	3.36	3.44	3.50	3.56	3.61	3.65	3.68	3.72
3.75	3.29	3.39	3.49	3.59	3.68	3.75	3.81	3.86	3.90	3.94	3.99
4.00	3.50	3.61	3.72	3.83	3.92	4.00	4.06	4.11	4.15	4.20	4.26
4.25	3.67	3.83	3.97	4.09	4.17	4.25	4.31	4.36	4.41	4.47	
4.50	3.86	4.04	4.20	4.31	4.41	4.50	4.56	4.62	4.67	4.73	

■ Nominal: Nominal Pressure
■ RBP: Rated Burst Pressure
*Do not inflate the balloon to a pressure that exceeds the RBP.

Shaft Outer Diameter (Proximal)	2.1Fr / 0.70mm
Radiopaque Markers	one in the middle (Balloon Diameter: 1.5, 1.75mm) two (Balloon Diameter over 2.0mm)
Catheter Effective Length	1,460mm
Compatible Gudewire Diameter	0.014 inches

Product Specifications

Catalogue Number	Balloon Diameter (mm)	Balloon Length (mm)	Shaft Outer Diameter (Distal) (Fr/mm)
RD3-8-150	1.50	8	2.5/0.84
RD3-8-175	1.75	8	2.5/0.84
RD3-8-200	2.00	8	2.5/0.84
RD3-8-250	2.50	8	2.6/0.86
RD3-8-300	3.00	8	2.6/0.86
RD3-8-350	3.50	8	2.7/0.90
RD3-8-400	4.00	8	2.7/0.90
RD3-10-200	2.00	10	2.5/0.84
RD3-10-225	2.25	10	2.6/0.86
RD3-10-250	2.50	10	2.6/0.86
RD3-10-275	2.75	10	2.6/0.86
RD3-10-300	3.00	10	2.6/0.86
RD3-10-325	3.25	10	2.6/0.86
RD3-10-350	3.50	10	2.7/0.90
RD3-10-375	3.75	10	2.7/0.90
RD3-10-400	4.00	10	2.7/0.90
RD3-10-425	4.25	10	2.7/0.90
RD3-10-450	4.50	10	2.7/0.90
RD3-13-200	2.00	13	2.5/0.84
RD3-13-225	2.25	13	2.6/0.86
RD3-13-250	2.50	13	2.6/0.86
RD3-13-275	2.75	13	2.6/0.86
RD3-13-300	3.00	13	2.6/0.86
RD3-13-325	3.25	13	2.6/0.86
RD3-13-350	3.50	13	2.7/0.90
RD3-13-375	3.75	13	2.7/0.90
RD3-13-400	4.00	13	2.7/0.90
RD3-13-450	4.50	13	2.7/0.90

Catalogue Number	Balloon Diameter (mm)	Balloon Length (mm)	Shaft Outer Diameter (Distal) (Fr/mm)
RD3-15-200	2.00	15	2.5/0.84
RD3-15-225	2.25	15	2.6/0.86
RD3-15-250	2.50	15	2.6/0.86
RD3-15-275	2.75	15	2.6/0.86
RD3-15-300	3.00	15	2.6/0.86
RD3-15-325	3.25	15	2.6/0.86
RD3-15-350	3.50	15	2.7/0.90
RD3-15-375	3.75	15	2.7/0.90
RD3-15-400	4.00	15	2.7/0.90
RD3-15-425	4.25	15	2.7/0.90
RD3-15-450	4.50	15	2.7/0.90
RD3-20-200	2.00	20	2.5/0.84
RD3-20-225	2.25	20	2.6/0.86
RD3-20-250	2.50	20	2.6/0.86
RD3-20-275	2.75	20	2.6/0.86
RD3-20-300	3.00	20	2.6/0.86
RD3-20-325	3.25	20	2.6/0.86
RD3-20-350	3.50	20	2.7/0.90
RD3-20-375	3.75	20	2.7/0.90
RD3-20-400	4.00	20	2.7/0.90
RD3-20-425	4.25	20	2.7/0.90
RD3-20-450	4.50	20	2.7/0.90
RD3-30-250	2.50	30	2.6/0.86
RD3-30-300	3.00	30	2.6/0.86
RD3-30-350	3.50	30	2.7/0.90
RD3-30-400	4.00	30	2.7/0.90

Do not re-use | STERILE EO Sterilized using ethylene oxide | Consult instructions for use

Manufacturer

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CE 0123

Ref No.E107-216 Date Nov.2019 2000 CO

KANEKA MEDICAL PRODUCTS

KANEKA Corporation

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

Technical File Summary of Raiden 3

A. INTENDED USE

Raiden 3 is intended to be used for dilating the stenosis lesion in the coronary artery when performing percutaneous transluminal coronary angioplasty.

B. TECHNICAL DATA

B.1. Balloon

Feature/ parameter	Specification/ descriptions
Design	Rx Hilarcam Rapid Exchange
Distal section	Tapered and rounded
Entry profile*	0.43mm (0.0169 inch)
Deflation time*	<13s
Nominal pressure	1.2MPa
Rated balloon pressure	2.0MPa for balloon diameter of ≤2.00mm and ≥4.25mm 2.2MPa for balloon diameter in the range of 2.25mm≤ and ≤4.00mm
Balloon diameter range	1.50-4.50mm (0.0590 – 0.177 inch)
Radiopaque markers	1 marker for balloon diameter of ≤1.75mm 2 markers for balloon diameter of ≥2.00mm
Balloon folds	Small size balloons (<φ2.0mm): 2 pleats Large size balloons (≥φ2.0m): 3 pleats
Balloon shoulder	30°

* These values are reference purpose only, and are not guaranteed.

B.2. Catheter

Feature/ parameter	Specification/ descriptions
Effective length	1460mm (57.480 inch)

B.3. Others

Feature/ parameter	Specification/ descriptions
Hydrophilic coating	Polyurethane, polyethylene glycol
Inner coating	None
GW compatibility	0.36mm (0.0142 inch)

C. MATERIAL

C.1. Balloon

Part description	Material
Balloon	Nylon 12 copolymer

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C.2. PTCA Catheter

Part Description	Material
Balloon	Nylon 12 copolymer
Radiopaque marker	Platinirldium alloy
Guidewire passage tube	Polyethylene Nylon 12 copolymer
Catheter shaft	Nylon 12 copolymer Nylon 12 Stainless steel Polytetrafluoroethylene
Strain relief	Nylon 12 copolymer
Coating	Polyurethane Polyethylene glycol
Adhesive	Polyurethane Cyanoacrylate
Hub	Styrene-butadiene copolymer
Pigment	Pigment Yellow 95 Phthalocyanine Blue Pigment Violet 19 Titanium Oxide Carbon Black

D. COMPLIANCE TABLE (For balloon)

Balloon Diameter (mm)	Pressure (atm)/(kPa)										
	2 203	4 405	6 608	8 811	10 1013	12 1216	14 1419	16 1621	18 1824	20 2027	22 2229
1.50	1.33	1.37	1.40	1.44	1.47	1.50	1.52	1.55	1.58	1.60	-
1.75	1.55	1.60	1.63	1.68	1.72	1.75	1.77	1.81	1.84	1.87	-
2.00	1.72	1.78	1.84	1.90	1.96	2.00	2.03	2.05	2.08	2.11	-
2.25	1.94	1.99	2.07	2.14	2.20	2.25	2.29	2.33	2.35	2.38	2.42
2.50	2.21	2.27	2.35	2.40	2.46	2.50	2.54	2.58	2.62	2.66	2.71
2.75	2.37	2.43	2.51	2.60	2.68	2.75	2.82	2.87	2.91	2.94	2.97
3.00	2.63	2.70	2.77	2.86	2.93	3.00	3.05	3.09	3.13	3.16	3.19
3.25	2.87	2.96	3.05	3.13	3.20	3.25	3.30	3.34	3.37	3.40	3.45
3.50	3.08	3.17	3.26	3.36	3.44	3.50	3.56	3.61	3.65	3.68	3.72
3.75	3.29	3.39	3.49	3.59	3.68	3.75	3.81	3.86	3.90	3.94	3.99
4.00	3.50	3.61	3.72	3.83	3.92	4.00	4.06	4.11	4.15	4.20	4.26
4.25	3.67	3.83	3.97	4.09	4.17	4.25	4.31	4.36	4.41	4.47	-
4.50	3.86	4.04	4.20	4.31	4.41	4.50	4.56	4.62	4.67	4.73	-

Nominal Pressure
Rated Burst Pressure

Manager

E. FINAL DEVICE - REQUIREMENTS

No.	Items	Specification	Test methods and identification
1	Appearance (Surface)	No adhesive substance, abnormality impairing use, or coating liquid is seen on the outside surface of the catheter.	As specified in ISO10555-1
2	Corrosion resistance	No signs of corrosion in metal parts.	As specified in ISO10555-1
3	Peak tensile force	Not less than 5 N - Between the balloon and the distal shaft - Between the distal shaft and the middle shaft - Between the middle shaft and the proximal shaft - Between the proximal shaft and the hub	As specified in ISO10555-1
4	Recommended dilating pressure (NP: Nominal Pressure)	1.2 MPa	As specified in ISO10555-4
5	Maximal dilating pressure (RBP: Rated Burst Pressure)	2.0 MPa (Balloon diameter: 1.50 – 2.00 mm) (Balloon diameter: 4.25 – 4.50 mm) 2.2 MPa (Balloon diameter: 2.25 – 4.00 mm)	As specified in ISO10555-4
6	Diameter of the largest guidewire	0.36 mm (0.014 inch)	As specified in ISO10555-4
7	Hubs	Compliance with ISO594-1 and ISO594-2	As specified in ISO594-1 and ISO594-2.
8	Radio-detectability	The radiopaque markers are located in the designated sites.	As specified in ISO10555-1, 4
9	Distal tip	The edge is tapered and rounded.	As specified in ISO10555-1
10	Biocompatibility test	Free from biological hazard.	Choose the tests specified in ISO10993-1 and perform individual tests as specified in ISO10993.
11	Sterility assurance	Sterility assurance level (SAL): 10^{-6}	As specified in ISO11135 or an equivalent or stricter standard

12	Residual EO, ECH	Compliance with ISO10993-7	One catheter is shredded into approximately 2 cm pieces. After the pieces are put into sealable bottle, distilled water is added until whole of the pieces are immersed in the distilled water. Then, the sample is shaken for 24 hours using constant temperature reservoir which is set at 37°C, and perform the gas chromatography.
13	Endotoxin	Endotoxin level: Less than 0.5 EU/mL	Perform the test as specified in "Endotoxin Test" in JP.

F. APPLIED STANDARDS

Standard	Title
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971:2007	Medical devices - Application of risk management to medical devices
ISO 10555-1:2013 /Amd1:2017	Intravascular catheters – Sterile and single-use catheters - Part 1: General requirements
ISO 10555-4:2013	Intravascular catheters – Sterile and single-use catheters - Part 4: Balloon dilatation catheters
ISO 10993-1:2009 /Cor 1:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO10993-7:2008 /Cor 1:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
ISO 10993-18:2005	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
ISO 11135:2014	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
EN 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
ISO 11607-1:2009, including Amd 1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2006, including Amd 1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications
ISO 15223-1:2016	Medical devices. Symbols to be used with medical devices labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer with medical devices
ISO 14644-1:2015	Cleanrooms and associated controlled environments. - Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments. - Part 2: Monitoring to prove evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices

G. PRE-CLINICAL STUDIES

G.1. Engineering tests

Based on test results listed below, it has been concluded that Raiden 3 conforms to all requirements of ISO 10555-1:2013 and ISO 10555-4:2013 and is clinically safe to use.

ISO 10555-1:2013 and ISO 10555-4:2013 tests conducted on Raiden 3:

Radio-detectability test

Biocompatibility test

Surface test

Corrosion resistance test

Peak tensile force test

Freedom from leakage test

ISO594-1 and ISO594-2 conformity test (Hubs)

Distal tip test

Designation of nominal size test

Balloon rated burst pressure test

Balloon fatigue test

Deflation time test

Balloon compliance test

G.2. Laboratory tests

The in vitro performance assessment was performed for demonstrating the clinical efficacy of Raiden 3 in all product lineups. It has been concluded that Raiden 3 has equivalent or better performance than the similar medical device and that the anticipated risks are tolerable, based on the results of the series of evaluation relating to clinical use. Therefore, the design of Raiden 3 is judged acceptable and clinically usable without any specific problem.

Performance tests conducted on Raiden 3:

Guidewire sliding performance test

Crossability performance test

Trackability performance test

Kissing Balloon Technique performance test

G.3. Biocompatibility

The biological safety of Raiden 3 was evaluated in accordance with ISO 10993-1:2009. The results of relevant biological safety tests showed that the components of Raiden 3 had enough biocompatibility. We concluded that all risks associated with biological hazards of Raiden 3 were acceptable.

Biocompatibility tests conducted on Raiden 3:

Cytotoxicity test

Skin sensitization test

Irritation test

Acute toxicity test

Pyrogenicity test

Thrombogenesis test (Antithrombotic nature)

Hemolytic toxicity test

G.4. Medicinal Substances

Not applicable. Raiden 3 does not incorporate a medical substance.

G.5. Devices Containing Biological Material

Not applicable. Raiden 3 does not incorporate a material of animal or human origin.

G.6. Sterilization

Raiden 3 is sterilized by Ethylene Oxide gas, under condition shown in the below table. The procedure of validation and routine control of sterilization is conformed to ISO 11135:2014. We judged that Raiden 3 including accessory conforms to ISO10993-7:2008/Cor 1:2009.

Table Overview of sterilization condition

Sterilization method	Ethylene oxide sterilization
Institution performing the validation	KANEKA Corporation Osaka Plant
Applicable standard	ISO 11135:2014
SOP for sterilization validation	OQSC1014-2
Sterility assurance	Sterility assurance level (SAL): 10^{-6} Assurance method: The device is validated for sterility by checking SAL records.
Standard sterilization parameters	(1) EOG concentration (initial): 500 - 900 mg/L (2) Temperature: 45 - 55°C (3) Humidity: 40 - 70%RH (4) Pressure during sterilization: 0.09 - 0.11 MPa (5) Sterilization time: 6.0 - 6.5 hours

Based on the test results listed below, the sterility assurance level has been confirmed to be 10^{-6}.

Sterilization validation tests conducted on Raiden 3:

Physical performance qualification

Microbiological performance qualification

PCD validation

Checking of the heat treatment condition and the product qualification

G.7. Packaging Qualification

We conducted our packaging validation and gap analysis and we evaluated the conformity of our packaging to ISO11607-1: 2009, including Amd 1:2014 and ISO 11607-2:2006, including Amd 1:2014. As a part of the packaging validation, we conducted the aging tests and shipment simulation tests. As a result, we concluded tha Raiden 3 maintained the packaging integrity within shelf life (3 years).

G.8. Shelf Life

Real time aging test for Raiden 3 was performed and time-dependent impacts on the catheter body and packaging material of Raiden 3 were evaluated. As a result of the test data derived from worst-case size of Raiden 3. we confirmed that there were no deterioration of the catheter body and packaging material of Raiden 3. It is concluded that Raiden 3 can be used effectually and safely within the shelf life for 3 years.

Accelerated aging tests conducted on Raiden 3:

Radio-detectability test

Appearance test

Distal tip test

Catheter nominal size test

Balloon nominal size test

Repeated inflation test

Peak tensile strength test

Sterilization bag end seal strength

Evaluation on sterilization bag appearance, non-leaching, and odourless

Sterilization bag end seal permeability test

Label test

G.9. Software Verification and Validation Studies

Not applicable. Raiden 3 does not incorporate software.

G.10. Usability Engineering

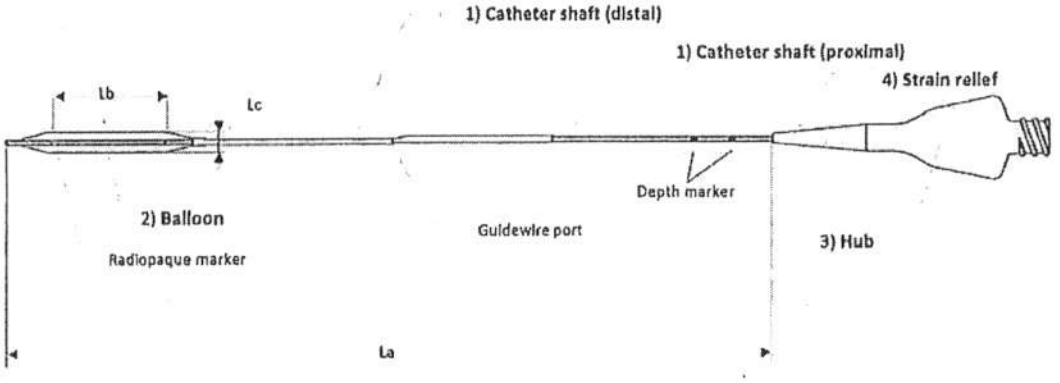
We evaluated the usability of Raiden 3 according to our internal procedure conformed to IEC 62366-1:2015 and gap analysis. As a result, the design of Raiden 3 was assessed acceptable and complies with IEC 62366-1:2015.

G.11. Animal Studies

Not applicable. No animal testing was performed aside from biocompatibility studies.

H. DIAGRAM

Raiden 3, a rapid-exchange typed PTCA balloon dilatation catheter, consists of 1) Catheter shaft, 2) Balloon, 3) Hub, and 4) Strain relief. Packaging materials of Raiden 3 are 5) Balloon protection tube, 6) Balloon core, 7) Carrier tube, 8) Accessories housing materials and 9) Compliance chart (Balloon pressure – outer diameter cross-reference table). These elements are sold as one package and aren't separately provided to customers.



La; effective length, Lb; balloon length, Lc; balloon diameter

Figure Diagram of Raiden 3

KANEKA MEDICAL PRODUCTS

KANEKA Corporation

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

I. ARTICLE CODES

Identifier	Brief Description of Item						
	Balloon diameter (mm) <Lc>	Balloon length (mm) <Lb>	Effective length (mm) <La>	Shaft outer diameter			Crossing profile (mm/inch)
				Distal (Fr/mm)	Guidewire port (Fr/mm)	Proximal (Fr/mm)	
RD3-8-150	1.50	8	1460	2.5/0.84	2.6/0.88	2.1/0.70	0.69/0.0272
RD3-8-175	1.75	8	1460	2.5/0.84	2.6/0.88	2.1/0.70	0.73/0.0287
RD3-10-200	2.00	10	1460	2.5/0.84	2.6/0.88	2.1/0.70	0.73/0.0287
RD3-10-225	2.25	10	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.76/0.0299
RD3-10-250	2.50	10	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.79/0.0311
RD3-10-275	2.75	10	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.81/0.0319
RD3-10-300	3.00	10	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.85/0.0335
RD3-10-325	3.25	10	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.91/0.0358
RD3-10-350	3.50	10	1460	2.7/0.90	2.9/0.98	2.1/0.70	0.94/0.0370
RD3-10-375	3.75	10	1460	2.7/0.90	2.9/0.98	2.1/0.70	0.96/0.0378
RD3-10-400	4.00	10	1460	2.7/0.90	2.9/0.98	2.1/0.70	1.04/0.0409
RD3-10-425	4.25	10	1460	2.7/0.90	2.9/0.98	2.1/0.70	1.06/0.0417
RD3-10-450	4.50	10	1460	2.7/0.90	2.9/0.98	2.1/0.70	1.06/0.0417
RD3-15-200	2.00	15	1460	2.5/0.84	2.6/0.88	2.1/0.70	0.73/0.0287
RD3-15-225	2.25	15	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.76/0.0299
RD3-15-250	2.50	15	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.79/0.0311
RD3-15-275	2.75	15	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.81/0.0319
RD3-15-300	3.00	15	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.85/0.0335
RD3-15-325	3.25	15	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.91/0.0358
RD3-15-350	3.50	15	1460	2.7/0.90	2.9/0.98	2.1/0.70	0.94/0.0370
RD3-15-375	3.75	15	1460	2.7/0.90	2.9/0.98	2.1/0.70	0.96/0.0378
RD3-15-400	4.00	15	1460	2.7/0.90	2.9/0.98	2.1/0.70	1.04/0.0409
RD3-15-425	4.25	15	1460	2.7/0.90	2.9/0.98	2.1/0.70	1.06/0.0417
RD3-15-450	4.50	15	1460	2.7/0.90	2.9/0.98	2.1/0.70	1.06/0.0417
RD3-20-250	2.50	20	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.79/0.0311
RD3-20-275	2.75	20	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.81/0.0319
RD3-20-300	3.00	20	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.85/0.0335
RD3-20-325	3.25	20	1460	2.6/0.86	2.6/0.88	2.1/0.70	0.91/0.0358
RD3-20-350	3.50	20	1460	2.7/0.90	2.9/0.98	2.1/0.70	0.94/0.0370
RD3-20-375	3.75	20	1460	2.7/0.90	2.9/0.98	2.1/0.70	0.96/0.0378
RD3-20-400	4.00	20	1460	2.7/0.90	2.9/0.98	2.1/0.70	1.04/0.0409
RD3-20-425	4.25	30	1460	2.7/0.90	2.9/0.98	2.1/0.70	1.06/0.0417
RD3-20-450	4.50	30	1460	2.7/0.90	2.9/0.98	2.1/0.70	1.06/0.0417

KANEKA MEDICAL PRODUCTS

KANEKA Corporation

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

Date: June 15, 2020

T. Miyata

Takeaki Miyata

Manager

Regulatory Affairs & Quality Assurance Team

Medical Devices Solutions Vehicle

KANEKA Corporation

KANEKA CORPORATION

แบบ บ.น.ท 1

รับรองบางส่วน
หนังสือรับรองประกอบการนำเข้าเครื่องมือแพทย์
สำนักงานคณะกรรมการอาหารและยา
กระทรวงสาธารณสุข

หนังสือเลขที่ JPN 6400314

12 มกราคม 2564

ได้พิจารณาหนังสือรับรองการขาย/หนังสือรับรองการขายและหนังสือรับรองระบบคุณภาพการผลิตแล้ว ถูกต้องตามประกาศกระทรวงสาธารณสุข (ฉบับที่ 34) พ.ศ. 2549 แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. 2531

ชื่อผู้นำเข้า : บริษัท ดีทแฮล์ม เคลเลอร์ โลจิสติกส์ จำกัด

ชื่อผู้ผลิต : KANEKA CORPORATION OSAKA PLANT (JAPAN)

หนังสือฉบับนี้ใช้ประกอบกับ ☑ หนังสือรับรองการขายเลขที่ 5758

ประเทศ Japan

☑ หนังสือรับรองระบบคุณภาพการผลิตเลขที่ Q5 024736 0069 Rev. 01

สามารถใช้ประกอบการนำเข้าเครื่องมือแพทย์จนถึงวันที่ 25 กุมภาพันธ์ 2568

สำนักงานคณะกรรมการอาหารและยา

กระทรวงสาธารณสุข

ผู้อนุญาต

เงื่อนไข

1.เมื่อปรากฏว่าประเทศผู้ผลิตหรือประเทศเจ้าของผลิตภัณฑ์ห้ามขาย หรือมีการยกเลิกการรับรองระบบคุณภาพการผลิตของเครื่องมือแพทย์รายการใดตามที่ระบุไว้ในหนังสือรับรองฉบับนี้ให้ถือว่าการรับรองเครื่องมือแพทย์ดังกล่าวเป็นอันยกเลิก

2. ห้ามนำเลขที่หนังสือไปประกาศโฆษณา

3. ห้ามโฆษณาว่าได้ผ่านการรับรองจากสำนักงานคณะกรรมการอาหารและยา

4. ห้ามโฆษณาเครื่องมือแพทย์ก่อนได้รับความเห็นชอบจากสำนักงานคณะกรรมการอาหารและยา

5. สำนักงานคณะกรรมการอาหารและยา ขอสงวนสิทธิ์ที่จะยกเลิก/เพิกถอนหนังสือรับรองประกอบการนำเข้าเครื่องมือแพทย์ฉบับนี้ หากผู้นำเข้าไม่ดำเนินการให้เป็นไปตามกฎกระทรวงกำหนดหลักเกณฑ์วิธีการ และเงื่อนไข การจดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ที่ออกตามพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. 2551 เมื่อกฎกระทรวงดังกล่าวมีผลบังคับใช้แล้ว

หมายเหตุเพิ่มเติม

ข้อมูลที่ผู้ประกอบการบันทึกเข้ามาทั้งหมดถือเป็นความรับผิดชอบของผู้ประกอบการ

เอกสารแนบท้ายหนังสือเลขที่ JPN 6400314

เลขที่หนังสือรับรองระบบคุณภาพการผลิต

ชื่อผู้ผลิต KANEKA CORPORATION OSAKA PLANT (JAPAN) ประเทศ Japan

ISO เลขที่ Q5 024736 0069 Rev. 01

สำนักงานคณะกรรมการอาหารและยา กองควบคุมเครื่องมือแพ

รายการนำเข้าผลิตภัณฑ์เครื่องมือแพทย์ ตามหนังสือรับรองเลขที่ JPN 6400314

วันที่อนุมัติ 12/1/2564 วันที่หมดอายุ 25/2/2568

ความหมายของรหัส Owner

1 รหัส 52577 ชื่อเจ้าของ/ผู้ผลิตต่างประเทศ KANEKA CORPORATION (JAPAN) ประเทศ Japan

ความหมายของรหัส manucd

1 รหัส 52580 ชื่อเจ้าของ/ผู้ผลิตต่างประเทศ KANEKA CORPORATION OSAKA PLANT (JAPAN) ประเทศ Japan

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
52577	52580	Q5 024736 0069 Rev. 01	RD3-8-150	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000137
52577	52580	Q5 024736 0069 Rev. 01	RD3-8-175	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000138
52577	52580	Q5 024736 0069 Rev. 01	RD3-8-200	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000139
52577	52580	Q5 024736 0069 Rev. 01	RD3-8-250	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000141
52577	52580	Q5 024736 0069 Rev. 01	RD3-8-300	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000143
52577	52580	Q5 024736 0069 Rev. 01	RD3-8-350	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000145
52577	52580	Q5 024736 0069 Rev. 01	RD3-8-400	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000147

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
52577	52580	Q5 024736 0069 Rev. 01	RD3-10-200	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000150
52577	52580	Q5 024736 0069 Rev. 01	RD3-10-225	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000151
52577	52580	Q5 024736 0069 Rev. 01	RD3-10-250	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000152
52577	52580	Q5 024736 0069 Rev. 01	RD3-10-275	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000153
52577	52580	Q5 024736 0069 Rev. 01	RD3-10-300	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000154
52577	52580	Q5 024736 0069 Rev. 01	RD3-10-325	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000155
52577	52580	Q5 024736 0069 Rev. 01	RD3-10-350	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000156
52577	52580	Q5 024736 0069 Rev. 01	RD3-10-375	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	Kaneka PTCA Catheter CO-R6, Raiden 3	1	10685	47732	6452580000157