Aperta NSE Coronary Dilatation Catheter

1. Warnings

1.1 Intravascular manipulation of the product should be carefully performed under fluoroscopy. Movement of the product distal tip or operation without confirming its location may result in possible damage to the product.

1.2 Should any product resistance and abnormality in product tip movement and location occur during operation, immediately cease usage and confirm cause under fluoroscopy. Continued use may result in damage to the product.

1.3 With the guide wire exit port of the product placed beyond the tip of a guiding catheter, care should be taken for eliminating any slack in the guide wire to the guide wire exit port when retracting the product into the guiding catheter. The product or the guide wire may become inoperable or incur damage.

1.4 To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate to the vessel just proximal or distal to the stenosis.

1.5 Carefully remove the product from the protective hoop and remove the stylet and the balloon protector from the product ensuring that no damage to the product is incurred. Damage to the balloon or the balloon lumen may cause balloon inflation/deflation failure or affect functionality.

1.6 When inserting and/or retrieving the product, use a gauze doused in heparinized saline to wipe the guide wire and remove any foreign particles from surface. Contaminant may cause damage to the product or the guide wire.

1.7 Care should be taken when using the product on lesions with multiple stents implanted such as Y stenting, T stenting, culotte stenting and crush stenting (including bifurcated lesions). The protruding elements may potentially become entangled on the stent. Such condition may result in damage to the product.

1.8 Care should be taken when using the product in distal sections of drug eluting stents. There are reports of extremely delayed coating of neointima with drug eluting stents.

1.9 The product should only be manipulated while fully deflated. Operating while inflated may cause damage to the product.

1.10 The product should only be used in facilities capable of performing emergency coronary artery bypass grafting (CABG) as a provision against complications that may cause injury or serious complications that could prove to be life threatening.

1.11 Do not use any products comprising organic solvent, fat-based emulsions or oil to prevent damage to the product such as hub and protruding elements and/or hydrophilic coating deterioration.

1.12 PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

1.13 Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of in vitro testing. At least 99.9% of the balloon (with a 95% confidence) will not burst at or below their RBP. Use a pressure gauge to prevent over-inflation of balloon.

1.14 During insertion and withdrawal from a stent, proceed with caution under fluoroscopy (doing so without fluoroscopy may damage this catheter or injure the blood vessel).

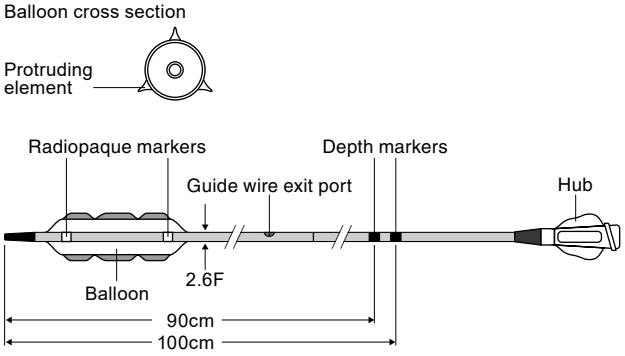
2. Intended User

Interventional cardiologists who have acquired the technique of PTCA/PCI.

3. Device Description

The product is a rapid exchange (RX) percutaneous transluminal coronary angioplasty (PTCA) balloon catheter. The elements and balloon of this product are comprised of a single material and help treat lesions that are difficult to dilate by concentration of the dilating force. The elements are spaced 120° parallel to the shaft. Two radiopaque markers inside the balloon indicate the length of the balloon and guide proper positioning in the lesion. The distal section of the catheter (2.6F) is comprised of a dual-lumen shaft; the outer lumen is for balloon dilatation, and the inner lumen allows for rapid exchange of 0.014" or smaller guidewires. The area from the catheter tip to the guide wire exit port is coated with a hydrophilic coating. The proximal shaft contains catheter insertion depth markers at 90cm and 100cm, and the proximal hub enables balloon inflation and deflation using a standard balloon inflation device. The device is available in eight balloon diameters ranging from 2.0 to 4.0mm. The nominal inflation pressure is 14atm and the rated burst pressure is 24atm. The balloon compliance chart is provided at the end of this Instructions for Use. The device is packaged sterile with a balloon protector and stylet that are removed prior to use.

<Product Diagram>



Recommended inflation pressure (NP: Nominal Pressure) 14atm (14×10^2kPa)
Maximum inflation pressure (RBP:Rated Burst Pressure) 24atm (24×10^2kPa)
Maximum compatible guide wire outer diameter 0.014inch (0.36mm)
Minimum compatible guiding catheter ID: 0.058inch (1.47mm)

<Material>

Nylon resin, polyethylene, polyether block amide, stainless steel, polyurethane, polyvinylpyrrolidone

<Components>

Flush device, catheter clip, rewrap tool / 1 unit each

4. Intended Purpose

The purpose of the use of the product is to dilate atherosclerotic obstructed segments of coronary arteries that are difficult to dilate by regular POBA (plain old balloon angioplasty) to improve coronary artery flow.

5. Indications

The product is indicated for balloon dilatation of the stenotic portion of the coronary artery, for the purpose of improving myocardial perfusion. The product is intended to be used in vessels with a reference vessel diameter of 2.00-4.00mm.

6. Patient Target Population

Patients who have significant coronary stenosis with evidence of myocardial ischemia and have a coronary artery suitable for a balloon diameter of 2.00-4.00mm in percutaneous transluminal angioplasty, as determined by the physician (including pregnant patients).

7. Clinical Benefits

The product's first priority is to improve the patient's ischemic condition of the coronary artery that causes angina pectoris and myocardial infarction, which leads to symptom relief. In addition, maintaining the patency of the improved lesion is the primary purpose of PTCA/PCI. The product is a PTCA balloon catheter that is intended to dilate a stenosis that is difficult to dilate with POBA and achieve revascularization. The product is expected to be fully dilated with the protruding elements to prevent balloon slip and control dissection during dilation.

8. Contraindications

8.1 The product is sterilized, is not re-usable and must not be resterilized. Resterilization and/or reuse could result in infection or degradation of product characteristics such as balloon size, shaft strength or lubricity and could result in failure of the product during use.

8.2 Vasculature spasm without significant stenosis.

8.3 Lesions in left main trunk without protection by collateral blood flow, bypass or any other method.

8.4 Lesions located in bifurcation beyond stent struts.

8.5 Lesion located distal to a freshly implanted stent.

8.6 Lesions with stent damage.

9. Precautions

9.1 Precautions Prior to Use

9.1.1 Refer to attached documents of all pharmaceuticals and medical devices used in relation to the target lesion and procedure.

9.1.2 Confirm specifications of the product and other devices used in relation to the target lesion and procedure.

9.1.3 Do not use the product if the packaging or contents are damaged or contaminated. Especially take care not to damage protruding elements.

9.1.4 All product use should be undertaken in a sterile environment.

9.1.5 The sterile barrier system is the pouch. Only the contents in the pouch are provided aseptically.

9.1.6 When used for a pregnant patient (or potential for being pregnant), the effects of X-rays on the fetus should be considered.

9.2 Precautions During Use

9.2.1 Care should be taken when using the guide wire or the flush device to ensure that any damage to the product does not occur.

9.2.2 Do not use air when performing the balloon inflation. There is potential to cause complications associated with air embolization.

9.2.3 To avoid coagulation of blood within the guide wire lumen, thereby affecting the operations of the product, be sure to adequately flush the lumen with heparinized solution and do not use the product for an extended period of time.

9.2.4 When the balloon can not be concentrically inflated, take care that the balloon movement does not occur. Balloon movement during inflation may cause damage to vessel.

9.2.5 The fixed valve should be closed in order that the balloon positioning is fixed during inflation. Balloon movement during inflation may cause damage to vessel.

9.2.6 When closing the hemostatic valve, be sure not to impede the operation of guide wire or the inflation/deflation line of the balloon.

9.2.7 Should the product incur kinking to the shaft, do not continue to use or attempt to repair. Damage to the product may occur.

9.2.8 When placing a number of devices into patient, operate the product and other devices carefully in order to prevent entanglement. If resistance is felt during procedure, confirm cause of resistance. Damage to the product or other devices may occur.

9.2.9 Check the product for abnormality such as damage, loosening of connected sections or leakage of chemical solutions on a regular basis.

9.2.10 Once the balloon has been inflated, do not re-wrap the balloon by use of the balloon protector. Damage to the balloon may occur.

9.2.11 Administer appropriate anticoagulants and vasodilators during the procedure.

9.2.12 Care should be taken during insertion or inflation within a stent or a hard lesion such as calcified lesions. Damage to the product may occur.

9.2.13 Do not rotate the product within the vasculature. Rotating may result in damage to the product.

9.2.14 The physician in charge of the procedure should determine the duration and number of balloon inflations based on his/her past experiences.

9.2.15 Dispose of the product as medical waste and take measures to prevent the possible spread of infection.

10. Adverse Events

Possible adverse events include, but are not limited to, the following:

- Acute myocardial infarction
- Arrhythmia (including ventricular fibrillation, bradycardia, tachycardia)
- Arterial spasm
- Arteriovenous fistula
- Coronary artery dissection, perforation, rupture, or injury
- Death
- Hemorrhage or hematoma
- Hemorrhagic complications
- Hypo / hypertension
- Infection
- Ischemia caused by long duration inflation
- Nausea or vomiting
- Palpitation
- Reaction (e.g., medicinal reaction or allergic reaction to contrast media)
- Restenosis following angioplasty
- Stroke, air embolization, distal embolization
- Thrombosis
- Total occlusion of the coronary artery or bypass graft
- Unstable angina

11. Materials Required

The following materials should be prepared for use:

- Guiding catheter
- Guide wire
- Hemostatic valve
- Syringe
- Inflation device
- 3-way stopcock

12. Instructions for Use

12.1 Preparation

12.1.1 Inspect and confirm each device for correct functionality.

12.1.2 Remove the product from the packaging (remaining in the protective hoop).

12.1.3 Carefully remove the product from the protective hoop.

12.1.4 Carefully remove the balloon protector and the stylet. Confirm that there is no damage to the product.

NOTE: Inflation and deflation of the balloon shall not be performed prior to use (unlike the preparation for a conventional PTCA balloon catheter).

12.1.5 Immerse the entire shaft of the product in heparinized saline.

12.1.6 Using the flushing device or the flushing needle, remove air from the guide wire lumen by flushing with heparinized saline through the product tip (tip of the guide wire lumen).

12.1.7 Connect the stopcock to the product hub (balloon inflation port), and secure the stopcock lever in the “off” position for the channel to the balloon.

12.1.8 Prime an inflation device with appropriate amount of diluted contrast media (contrast : heparinized saline = 1:1). Connect it to the stopcock and flush the port of stopcock with contrast media.

12.1.9 Turn the stopcock lever to open the flow channel between the product and the inflation device, and with the inflation device tip facing downward, aspirate for 20-30 seconds.

12.1.10 With the inflation device tip facing downward, cease aspiration and confirm that the product lumen is devoid of air.

12.1.11 Repeat the above process until the product is completely devoid of residual air/bubbles.

12.1.12 Removing all residual air from the inflation device, again deflate the balloon and maintain the condition.

*Do not allow air or liquid to enter the balloon in order to preserve the balloon folding functionality and the protruding elements.

12.2 Insertion of Product

12.2.1 Follow the package insert for each medical device and complete preparation of the devices prior to insertion of the product.

12.2.2 Cross the target lesion with the guide wire and confirm its entry into the distal vasculature.

12.2.3 With the balloon completely deflated, carefully insert the tail end of the guide wire into the distal tip of the product and advance the product to the target lesion.

12.3 Balloon Inflation

12.3.1 Confirm position of the balloon in relation to the target lesion and close the hemostatic valve, locking balloon into place.

12.3.2 Inflate the balloon to the nominal inflation pressure for appropriate length of time and deflate the balloon using the inflation device.

12.3.3 Perform multiple inflations as deemed necessary.

12.3.4 Upon completion of dilatation, ensure the balloon is completely deflated, return the product to within the guiding catheter and evaluate improvement to stenotic site via angiography.

12.3.5 Should adequate expansion not be achieved at this time, further improvement may be attained by increasing inflation pressure or length of time (see compliance chart).

12.4 Removal of Product

After complete deflation of the balloon, carefully remove the product while ensuring that the guide wire remains in location.

12.5 Rewrap Tool (reference)

The rewrap tool is used for re-wrapping the balloon folds. When undertaking re-wrapping using the rewrap tool included as an accessory, follow the procedure described below.

12.5.1 Insert the stylet through the side of the rewrap tool that does not have a flare.

12.5.2 With the balloon held in negative pressure, insert the stylet into the guide wire lumen.

12.5.3 Being careful not to damage product, use fingers to gently roll the balloon wrapping. Looking directly at the fold from the tip, the folds are wrapped in a clock wise direction.

12.5.4 Carefully insert the balloon body into the rewrap tool. In order to avoid damaging product do not rotate product or tool during insertion.

12.5.5 While inside the rewrap tool, apply low inflation pressure and slowly reduce pressure.

12.5.6 Under negative pressure, carefully remove rewrap tool and stylet.

12.5.7 Visually confirm condition of product (including balloon).

13. Storage Method, Shelf Life and Sterilization

13.1 Storage Method

13.1.1 Store the product in a room temperature location not exposed to high temperature and humidity or direct sunlight and take proper precautions to ensure the product does not contact water.

13.1.2 Avoid inclinations, vibrations and impacts (including during transportation) and store in a safe, stable environment.

13.1.3 Do not store near chemicals or in areas where the device may be exposed to gases.

13.2 Shelf Life

Use this product before the date of “Use By” shown on the package label.

13.3 Sterilization Method

The product package has been sterilized by exposure to Ethylene Oxide Gas (EtO) and not intended to be re-sterilized.

14. Product Warranty Disclaimers and Limitation of Remedies

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15. References

The physician should consult current medical practice literature on balloon dilatation, such as that published by ACC/AHA.

16. Reporting Adverse Events

Any incidents shall be reported to the manufacturer and the competent authority of your State.

Manufacturing Site

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Japan

Manufacturer

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Japan

Symbols

- Catalogue number : REF
- Batch code : LOT
- Use by :
- Do not reuse :
- Do not resterilize :
- Consult instructions for use :
- Sterilized using ethylene oxide : STERILE EO
- Keep dry :
- Keep away from sunlight :
- Do not use if package is damaged :
- Manufacturer :
- Date of manufacture :
- Balloon diameter :
- Balloon length :

Compliance Chart of Aperta NSE

Inflation Pressure		Balloon Diameter (mm)							
atm	kPa	2.00mm	2.25mm	2.50mm	2.75mm	3.00mm	3.25mm	3.50mm	4.00mm
4	4x10²	1.78	2.02	2.27	2.45	2.70	2.95	3.18	3.50
5	5x10²	1.81	2.05	2.30	2.50	2.73	2.98	3.23	3.55
6	6x10²	1.84	2.08	2.33	2.55	2.76	3.01	3.26	3.60
7	7x10²	1.86	2.11	2.36	2.59	2.79	3.04	3.29	3.65
8	8x10²	1.88	2.13	2.38	2.63	2.82	3.07	3.32	3.70
9	9x10²	1.90	2.15	2.40	2.65	2.85	3.10	3.35	3.75
10	10x10²	1.92	2.17	2.42	2.67	2.88	3.13	3.38	3.80
11	11x10²	1.94	2.19	2.44	2.69	2.91	3.16	3.41	3.85
12	12x10²	1.96	2.21	2.46	2.71	2.94	3.19	3.44	3.90
13	13x10²	1.98	2.23	2.48	2.73	2.97	3.22	3.47	3.95
14	**14x10²**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.25**	**3.50**	**4.00**
15	15x10²	2.02	2.27	2.52	2.77	3.02	3.27	3.52	4.02
16	16x10²	2.04	2.29	2.54	2.79	3.04	3.29	3.54	4.04
17	17x10²	2.06	2.31	2.56	2.81	3.06	3.31	3.56	4.06
18	18x10²	2.08	2.33	2.58	2.83	3.08	3.33	3.58	4.08
19	19x10²	2.09	2.35	2.60	2.85	3.10	3.35	3.60	4.10
20	20x10²	2.10	2.36	2.62	2.87	3.12	3.37	3.62	4.12
21	21x10²	2.11	2.37	2.64	2.89	3.14	3.39	3.64	4.14
22	22x10²	2.12	2.38	2.66	2.91	3.16	3.41	3.66	4.16
23	23x10²	2.13	2.39	2.68	2.93	3.18	3.43	3.68	4.18
24	**24x10²**	**2.14**	**2.40**	**2.70**	**2.95**	**3.20**	**3.45**	**3.70**	**4.20**
25	25x10²	2.15	2.41	2.72	2.97	3.22	3.47	3.72	4.22
26	26x10²	2.16	2.42	2.74	2.99	3.24	3.49	3.74	4.24
27	27x10²	2.17	2.43	2.76	3.01	3.26	3.51	3.76	4.26

Nominal Pressure Rated Burst Pressure (Do not exceed)

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