Fortis Ⅱ

CE 0123

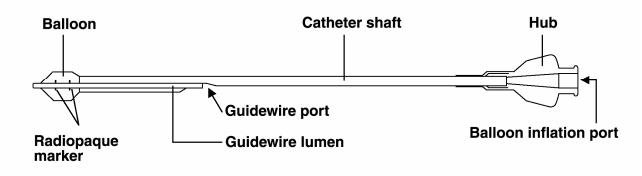
[Contraindications]

1. For single use only. Do not reuse, reprocess or resterilize.
2. These components are contraindicated in the following patients:
   - Patients with unprotected lesion in the left coronary trunk.
   - Patients with coronary artery spasm in the absence of significant stenosis.
3. Do not inflate the balloon exceeding the diameter of the blood vessel in the vicinity of the stenotic lesion. (The blood vessel may be damaged or ruptured.)
4. Do not inflate the balloon to a pressure exceeding the rated burst pressure. (The balloon may burst and the debris may remain inside the body.)
5. The catheter is contraindicated for hand crimping of stent components and as a stent delivery system.

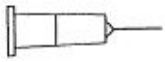
[Shape and structure]

1. Balloon catheter

<Representative schematics>



2. Flushing needle



NOTE

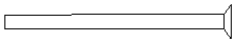
Flushing needle is used for priming guidewire lumen of Fortis Ⅱ.

3. Catheter clip

NOTE

Catheter clip is used for binding up catheter shaft of Fortis Ⅱ.

4. Balloon re-wrapper



NOTE

In case of re-insertion after removing out from the body, balloon may be inserted to balloon re-wrapper to make balloon wrap in slender shape.

[Indication for use]

1. Intended use

Fortis Ⅱ is intended to be used for dilating the stenotic lesion in the coronary artery when performing percutaneous transluminal angioplasty.

Recommended guidewire diameter

Maximum outer diameter: 0.014 inch (0.36mm)

Recommended guide catheter diameter

Minimum inner diameter: 1.5 mm

2. Indications

The Fortis Ⅱ (for CE marking) is indicated for patients suffering from coronary artery disease (CAD) such as myocardial infarction and angina pectoris.

[Operation method or instructions for use]

1. Preparations

1) After aseptically removing this catheter from the package container, detach the protective materials such as a blue balloon protective sheath.
2) Remove the air in the balloon and balloon inflation lumen according to the following procedures.
   (a) Attach the inflation device filled with diluted contrast media (hereinafter, the inflation fluid) onto the balloon inflation port (hereinafter, the inflation port), and place this catheter with the distal tip facing downward.
   (b) After applying the negative pressure using the inflation device for approximately 15 seconds, release the negative pressure gradually allowing the inflation fluid to fill the balloon and the balloon inflation lumen and to expel the air.
   (c) Repeat the procedures (b) to expel the air completely.
   (d) Remove the inflation device from the inflation port and expel all the air in the inflation device.
   (e) Reattach the inflation device to the inflation port and apply negative pressure. After checking that the air no longer returns to the inflation device, release the negative pressure gradually. (A syringe can be used in place of the inflation device for the procedures (a)-(e).)
   (f) Prior to inflation, immerse the balloon in saline for at least one minute. Inflate the balloon to the rated burst pressure specified and maintain that pressure for approximately 5 seconds.
   (g) If no abnormalities are found with the balloon, change the pressure to negative and deflate the balloon.
3) Flush the guidewire lumen with heparinized saline and fill the lumen with the saline.

2. Insertion and removal of the balloon catheter

1) Insert this catheter along the guidewire advanced to the distal end of the lesion. Under fluoroscopy, advance the catheter to make the radiopaque marker at the distal end of the catheter reach the target site. Balloon should be deflated during this procedure.

2) Determine the position of this balloon catheter and screw the haemostatic valve tight enough to prevent blood leakage.
3) Inflate the balloon to the appropriate pressure for the lesion.
4) When the procedure is finished, deflate the balloon completely and loosen the haemostatic valve.
5) After checking that the balloon is completely retracted into the guide catheter under fluoroscopy, remove this catheter.

3. Exchanging PTCA catheter

1) Loosen the haemostatic valve.
2) Grasp the guidewire and the haemostatic valve with one hand to prevent the dislocation of the guidewire from the position in the coronary artery. Grasp the handheld part of this balloon catheter with another hand and start pulling this catheter out of the guide catheter. The position of the guidewire should be monitored under fluoroscopy during this procedure.
3) Withdraw this balloon catheter gradually until its guidewire port comes out. While maintaining the position of the guidewire passing through the coronary artery lesion, pull this balloon catheter carefully out of the guidewire.
4) Close the haemostatic valve.
5) Referring to its package insert, prepare a rapid exchange catheter and insert it in place.

[Precautions related to procedures]

1. Prior to use, expel all the air in the balloon and balloon inflation lumen and replace it with the inflation fluid. (In case of incomplete air removal, balloon inflation state can not be observed under fluoroscopy.)
2. Prior to use, inflate the balloon with the rated burst pressure specified for each product and check that the balloon inflates and deflates appropriately.
3. Use the inflation fluid to inflate the balloon. No gaseous body such as air should be used for inflation.
4. Always immerse the balloon in saline for at least one minute before inflation as the strength of the balloon may sometimes decrease.
5. Do not move this catheter while the balloon is inflated in the blood vessel. (Moving the catheter with the balloon inflated may lead to blood vessel injury, balloon burst, and catheter breakage.)
6. The insertion and withdrawal of the catheter should be performed slowly with caution. (If this procedure is performed too fast, it may lead to kinking of or damage to the catheter shaft.)
7. As for the medical devices used in conjunction with this catheter, follow the package inserts of such devices.
8. Proceed with care to prevent PTCA dilatation catheter kinking and collapse when forming loops of catheter.
9. Proceed with care to prevent shaft kinking and collapse while removing the catheter clip.
10. Secure the PTCA dilatation catheter with the catheter clip at the stiffer, proximal end. Do not use the catheter clip on the flexible, distal shaft or catheters, it may damage the PTCA dilatation catheter.

[Precautions during usage]

[Important basic precautions]

1. This catheter may be used only by physicians skilled in percutaneous transluminal angioplasty.
2. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
3. Do not use if packaging is damaged.
4. Do not use agents containing organic solvents or oleaginous contrast media. Contact with these agents may lead to damage of the catheter.
5. Since PTCA procedure may induce dangerous complications, perform the procedure only after having prepared for emergency coronary artery bypass grafting (CABG).
6. Since serious complications might arise when using this catheter, operation should be done in the medical institution where emergency procedure can be executed.
7. The physician in charge of the procedure should determine the duration and number of balloon inflations based on his/her past experiences.
8. Heparinized saline should be infused for anti-coagulation while this balloon catheter is inserted in the blood vessel.
9. This catheter can only be inserted with the use of a guidewire. (Insertion of this catheter alone may lead to damage to the vascular wall or perforation of vessels.)
10. Operate the catheter carefully in the blood vessel verifying the location and movement of its tip under fluoroscopy.
11. Do not twist or turn this balloon catheter or the guidewire during operation. (The catheter may be tangled increasing the resistance.)
12. If abnormal or strong resistance is experienced during the operation, the cause for such abnormality or resistance should be verified and appropriate measures should be performed before proceeding. (If such abnormality or resistance is ignored and excessive force is applied, it may lead to damage of the vessels or to the catheter shaft breaking and remaining inside the body).
13. During usage, the catheter shaft should be replaced for any bend, break or kink. (If the catheter continues to be used and such occurrence is ignored, the catheter shaft may be damaged and remain inside body).
14. If a great resistance is encountered during insertion, movement, or pulling out of this catheter, it should be verified that the guidewire is not tangled. If so, the tangling

of the guidewire should be removed. (Since the guidewire lumen of this catheter is short, the guidewire may wind around the catheter shaft. In addition, while drawing this catheter back into the guiding catheter inside vessels, the wide-angle separation between the catheter shaft and guidewire may occur. Under this circumstance, a forced withdrawal may lead to damage to the guidewire or catheter.)

15. A catheter with any sign indicating damage should not be used.
16. Due to the lack of conductivity of twist forces, the catheter shaft should not be twisted (If twisted, the catheter shaft may be damaged and then remain inside the body).
17. Challenging lesions such as calcified or tortuous lesions may not be crossed with this catheter. The physician in charge of the procedure should determine whether this catheter is applicable based on his/her past experiences.
18. Precautions should be taken to prevent any damage to the catheter by the surgical knife or scissors.
19. During the usage of this catheter, the temperature, blood pressure, pulse, and respiration of patients should be monitored. In case of any abnormality, the procedure should be stopped or appropriate measures taken based on the physician's judgment.
20. After use, dispose of product and packaging in accordance with hospital, administrative and/or relevant national regulations.

[Adverse events]

Adverse events related to the product include, but are not limited to, infarction caused by occlusion of distal vessels or side branch, vasospasm, stripping of vascular endothelium, dissection of vascular intima, re-occlusion, vascular perforation, blood pressure fluctuation, stroke, shock, reaction to drugs, reaction to contrast media, renal insufficiency, transient ischemia, air embolism, thromboembolism, internal bleeding, hematoma, infection, etc. These adverse events may cause emergent coronary bypass surgery, myocardial infarction, re-stenosis, cardiac tamponade, hemorrhage, emergent brain surgery cerebral infarction, formation of vessel fistula, aneurysm, arrhythmia, and even death.

[Additional precautions]

1. Do not use if the product or package is believed to be damaged.
2. Use immediately after the sterile package is opened. Dispose as medical waste after use.

[Storage, care and expiration date]

1. Store in a cool, dark, and dry place avoiding exposure to water and direct sunlight, extreme temperature, or high humidity.
2. The expiration date is indicated on the box. Do not use after the expiration date.

[Package]

1 set (one primary packaging) / box

Contents)

1) Fortis Ⅱ (PTCA catheter) x 1
2) Flushing needle x 1
3) Catheter clip x 2
4) Balloon re-wrapper x 1

[Names and Addresses of Manufacturer, or Representative]

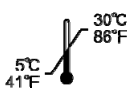
[Manufacturer]

Name: KANEKA CORPORATION
Address: 3-18, 2-Chome Nakanoshima, Kita-ku, Osaka-city, OSAKA, 530-8288 JAPAN
Tel. No.: (+81)-(0) 6-6226-5256
Fax No.: (+81)-(0) 6-6226-5143

[EC Representative]

Name: KANEKA PHARMA EUROPE N.V.
Address: Nijverheidsstraat 16, 2260 Westerlo-Oevel, BELGIUM
Tel. No.: (+32)-(0) 14-256-297
Fax No.: (+32)-(0) 14-256-298

[Description of symbols for use]

Symbol	Description
	Do not re-use
	Do not resterilize
	Sterilized using ethylene oxide
	Caution, consult accompanying documents
	Consult instructions for use
	Do not use if package is damaged
	Keep away from sunlight
	Keep Dry
	Temperature limitation