3211-01

Crosstella™ RX

PTA Balloon Dilatation Catheter

TERUMO

Apr 2021

PM-05583

REF Catalogue number	SN Serial number	LOT Lot number
Use by	Do not reuse	Do not resterilize
Do not use if package is damaged	Consult instructions for use	Keep dry
Keep away from sunlight	STERILE EO Sterilized using ethylene oxide	Contents
Manufacturer	Manufacturing site	P Pressure
NP Nominal Pressure	RBP Rated Burst Pressure	Balloon Diameter
<L> Balloon length	RX Rapid Exchange	Rx ONLY CAUTION : Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

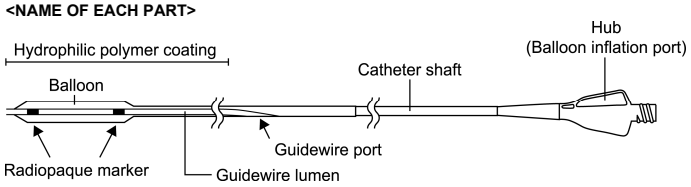
[PRODUCT DESCRIPTION]

Crosstella RX is a Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter for peripheral indications. Crosstella RX is a rapid exchange (RX) type and the maximum diameter of the compatible guidewire is 0.018 inches (0.46 mm).

The distal section of this catheter consists of a balloon and dual lumen shafts (co-axial). The outer lumen is used for inflation and deflation of the balloon with contrast medium diluted with saline solution. The inner lumen (the guidewire lumen; from the distal tip to the guidewire port) is for inserting a compatible guidewire to facilitate advancing the catheter through the stenotic lesion or stent to be dilated. The proximal section is a single lumen shaft with a single luer port hub for connecting an inflation/deflation device. Inside the balloon, two radiopaque markers, which indicate the working length of the balloon, are placed to guide the physician for positioning the balloon properly in the targeted lesion under fluoroscopy. Crosstella RX is available in various balloon sizes by its diameter and length at recommended inflation pressures (Nominal pressure). Upon inflation, the balloon diameter varies according to the inflating pressure. The balloon compliance chart of Crosstella RX is provided in Table 1 at the end of this Instructions for Use. In the sterilization package, the device is equipped with the protective materials, a balloon protective tube and a stylet, which are to be removed before use. The balloon protective tube is placed over the balloon folded in a low profile and the stylet is inserted into the guidewire lumen to prevent collapsing the catheter shaft. The catheter's distal tip is tapered to facilitate the catheter's advancing into the stenotic lesion or stent. The surface of catheter is partially coated with hydrophilic polymer coating which generates lubricity when wet.

The flushing needle is provided as an accessory of this device for flushing and filling the guidewire lumen with heparized saline.

<NAME OF EACH PART>



Sterile and non pyrogenic in an undamaged and unopened blister pouch. This device is sterilized by ethylene oxide.

Recommended guidewire diameter:
Maximum diameter: 0.018"(0.46mm)

Recommended inflation pressure and maximum inflation pressure
Nominal pressure: 8atm
Rated burst pressure: 14atm

[INDICATIONS]

The Crosstella RX PTA balloon dilatation catheter 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.

Note: The verification test for stent post-dilatation of Crosstella RX was conducted using Complete® SE Vascular Stent System (Medtronic, Inc), S.M.A.R.T.® CONTROL® Vascular Stent System (Cordis Corporation) .

[CONTRA-INDICATIONS]

1. Patients who have developed anastomotic stenosis within one month after AV shunt construction.
2. Patients having lesions which communicate with a pseudoaneurysm.
3. Patients who are pregnant.
4. Patients who cannot tolerate antiplatelet therapy or anticoagulant therapy.

[WARNINGS AND PRECAUTIONS]

[Warnings]

1. This device is for single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, the biocompatibility and the physical integrity of the device.
2. Do not use if the product or the unit packaging has been damaged.
3. Do not inflate the balloon exceeding the diameter of the blood vessel proximal and distal to the stenotic lesion.
4. Do not inflate the balloon to a pressure exceeding the rated burst pressure.
5. Do not use this catheter in the central circulatory system.

[Precautions related to procedures]

1. Do it carefully and slowly to remove this device out of the carrier tube and to remove protection parts from this device, Careless handling may damage the balloon and/or the catheter shaft of this device to impair balloon inflation and/or deflation.
2. Inflate the balloon with the contrast medium diluted with saline in the ratio of 1:1 (hereafter, inflation fluid). No gaseous medium such as air should be used for inflation. (Balloon may be inflated irregularly.)
3. 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.)
4. In case of serious stenotic lesions such as calcified lesions, the blood vessel can not be dilated fully. Do not apply a pressure exceeding the rated burst pressure in such a case. (The balloon may burst and the debris may remain inside the body.)
5. As for the medical devices used in conjunction with this catheter, follow the instructions for use of such devices. (When the balloon catheter is used for post-dilatation of stent during peripheral stent placement procedure, refer to the manufacturer's instructions for use.)
6. For insertion into stent, withdrawal from stent or in-stent dilatation of the balloon, proceed with caution under fluoroscopy. (Doing so without fluoroscopy may damage this catheter or injure the blood vessel.)
7. Do not attempt to pass the Crosstella RX PTA balloon dilatation catheter through a smaller sized introducer sheath than indicated on the label. Refer to product labeling.

[Precautions during usage]

1. Use the device immediately after the sterile package is opened.
2. The entire procedure should be carried out aseptically.
3. This catheter should be used only by physicians skilled in percutaneous vascular therapy.
4. Select the catheter with appropriate balloon size (balloon diameter, balloon length) according to the following (procedures) criteria.
   1) The inflated balloon diameter shall not exceed the inner vessel diameter proximal and distal to the lesion.
   2) The length of the inflated balloon shall not exceed the length of the lesion to be treated.
   (Inappropriate catheter selection may lead to acute vascular occlusion.)
5. Use this catheter only when emergency surgery can be performed at any time.
6. The physician in charge of the procedure should determine the duration and number of balloon inflations based on his/her past experiences.
7. Heparinized saline should be infused for anti-coagulation while this balloon catheter is inserted in the blood vessel.
8. Never inflate the balloon or advance the guidewire with the catheter bent or kinked.

9. Manipulate the catheter carefully in the blood vessel verifying the location and movement of its tip under fluoroscopy or DSA (Digital Subtraction Angiography) monitoring.
10. Always inflate the balloon while observing its inflation state under fluoroscopy. Inflate the balloon carefully while verifying its movement with the radiopaque markers. If any abnormality is found such as a little resistance, immovable catheter during manipulation or kinked distal tip of the guidewire, the procedure should be discontinued immediately and this catheter should be removed slowly together with the guidewire.
11. Do not insert or remove the catheter rapidly. (Operating rapidly may damage the catheter or injure the vascular intima.)
12. Do not move the catheter with the balloon inflated. (Moving the catheter with the balloon inflated may result in balloon burst or catheter shaft breakage.)
13. Do not inflate or deflate the balloon rapidly in the blood vessel. (Rapid inflation or deflation may damage the blood vessel or cause the balloon to burst resulting in the debris left inside the body.)
14. Do not use an injector (automatic injection device) for inflating the balloon.
15. Precautions should be taken to prevent any damage to the catheter by a surgical knife or scissors.
16. If any abnormality such as strong resistance is experienced while manipulating the catheter, the procedure should be discontinued immediately. The cause should be verified and appropriate measures should be taken. (Continuing the operation with excessive force may result in damage to the catheter or in vascular wall injury.)
17. Always pay attention to the patient's condition and monitor the body temperature, pulse, and breathing. When any abnormality is found, discontinue the use of the catheter immediately or take appropriate measures for the patient's condition on the discretion of the physician.
18. After use dispose the catheter as medical waste according to hospital procedures.
19. Do not use agents containing organic solvents or oleaginous contrast media. Contact with these agents may lead to damage of the catheter.
20. While manipulating this catheter, do not twist or rotate the catheter.
21. While inserting this device into the blood vessel or removing this device from the blood vessel, make sure that the balloon is completely deflated. (A device with larger and longer balloon requires a longer deflation time.)
22. If resistance is felt during post procedural withdrawal of this device, it is recommended to withdraw the entire system together with the introducer / guide sheath.
23. Always use the catheter along a guide wire inserted into the guide wire lumen.

[Operational Instructions]

Materials typically required for PTA with the Crosstella RX PTA balloon dilatation catheter include:

- Guidewire(s) of appropriate diameter and length
- Appropriate introducer/guide sheath and dilator set
- Vial of contrast medium
- Vial of sterile saline
- Inflation device with manometer
- Luer-lock syringe
- Three-way stopcock

[Operation method or instructions for use]

1. Selection of the catheter

Prior to use, verify the blood vessel inner diameter proximal and distal to the stenotic lesion under fluoroscopy, and select the catheter with appropriate balloon size. If two sizes are applicable to the diameter verified, select the smaller size.

2. Preparations

1) After aseptically removing the catheter from the package container, remove the protective materials from the catheter.
2) Replace the air in the balloon and balloon inflation lumen with inflation fluid according to the following procedures.
   a) Attach the inflation device (not included in this kit) filled with the inflation fluid onto the balloon inflation port.
   b) After applying negative pressure for approximately 10 seconds to the inflation device, direct the catheter shaft tip downward and release the negative pressure slowly to allow the fluid to fill the balloon and balloon inflation lumen and to expel the air.
   c) When any air is found in the balloon and balloon inflation lumen, repeat the procedure b) until the air is expelled completely.
   d) Detach the inflation device from the balloon inflation port and remove air from the cylinder of the inflation device.
   e) Reattach the inflation device onto the balloon inflation port and maintain negative pressure. Verify that the air no longer returns into the syringe.
3) Flush the guidewire lumen with heparinized saline using the flushing needle and fill the lumen with the heparinized saline.
4) Immerse the entire Crosstella RX PTA balloon dilatation catheter in saline.

3. Insertion and inflation of the balloon catheter

Prior to use, please check if this catheter is compatible to the guide catheter (not included in this kit), the introducer sheath (not included in this kit), and the guidewire (not included in this kit) by the following table.

Catalogue number	Balloon diameter (mm)	Compatible sheath (Fr/mm)	Maximum diameter for the guidewire (inch/mm)
BD-F20020MR ～ BD-F60200ER	2mm,2.5mm,3mm, 4mm,5mm (excluding 120mm, 150mm, 200mm Balloon Length), 6mm (20mm, 40mm Balloon Length)	4Fr/1.35mm	0.018 inch (0.46mm)
	5mm (120mm,150mm,200mm Balloon Length),6mm (excluding 20mm,40mm Balloon Length)	5Fr/1.66mm	

When using the catheter inserted in the introducer sheath or guide catheter

1) When using the catheter in the guide catheter, loosen the hemostatic valve while keeping it tight enough to prevent blood leakage.
2) Gradually insert the catheter, with the balloon deflated completely, into the introducer sheath or guide catheter over the guidewire and advance to the distal periphery of the lesion. Under fluoroscopy, advance the catheter slowly to make its radiopaque marker in the balloon reach the target site.
3) Under fluoroscopy, verify the position of the radiopaque marker in the balloon and determine the dilatation site.
4) Attach the inflation device securely to the balloon inflation port.

5) Inflate the balloon gradually to the target diameter verifying the inflation pressure and dilate the stenotic lesion (for inflated balloon diameters, consult the balloon compliance chart provided in Table 1. at the end of this Instructions for Use).

4. Removal of the catheter
   1) After applying negative pressure to deflate the balloon completely, remove the catheter.
5. Re-insertion of the catheter
   1) If a re-insertion of the removed catheter with deflated balloon is required, ensure the balloon is completely deflated and folded before re-inserting it into the patient's blood vessel. On re-insertion use the catheter as per "Insertion and inflation of the balloon catheter" section herein.
   2) If any resistance is encountered while re-inserting the catheter, stop advancing it and carefully remove it out of the patient's blood vessel. Prepare to use a new Crosstella RX in accordance with the procedures provided above in this section of this Instruction for Use.

[Complications]

Device Failures:

・Balloon rupture
・Insufficient inflation / deflation of the balloon
・Breakage of the balloon and / or the catheter shaft
・Difficulty in removing the device
・Leakage of inflation fluid

Adverse Events:

・Local or systemic infections
・Local internal bleeding or hematoma
・Intimal rupture
・Vascular dissection
・Vascular perforation
・Vascular rupture
・Aneurysm
・Arrhythmia
・Acute vascular occlusion
・Venous thromboembolism
・Vasospasm
・Formation of pseudoaneurysm
・Arteriovenous fistula
・Bleeding requiring transfusion
・Allergic response to the contrast media / renal failure
・Ache or pressing pain
・Death
・Embolism
・Endocarditis
・Fever
・Hypertension / Hypotension
・Inflammation
・Myocardial Infarction
・Sepsis
・Shock
・Stroke
・Transient Ischemic Attack

[Storage and expiration date]

1. Store in a cool, dry, dark place. Avoid exposure to water, direct sunlight.
2. The expiration date is indicated on the box. Do not use after the expiration date.

[Package]

1 set/box

[Name and address of manufacturer]

Manufacturer : 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

Table 1. Crosstella RX Balloon Compliance Chart

Pressure (atm)	Balloon Diameter (mm)					
	2.00	2.50	3.00	4.00	5.00	6.00
8	2.05*	2.49*	3.02*	4.00*	5.04*	5.93*
10	2.10	2.55	3.09	4.08	5.17	6.06
12	2.15	2.61	3.16	4.17	5.29	6.18
14	2.20**	2.66**	3.24**	4.26**	5.42**	6.30**
16	2.25	2.72	3.31	4.36	5.57	6.42

* Nominal pressure
** Rated Burst Pressure