

RX NC Takeru[™]

PTCA Balloon Dilatation Catheter



March 2017

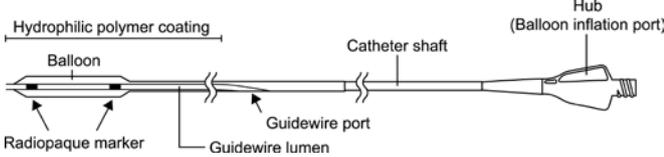
 Catalogue number	 Serial number	 Batch code
 Use by date	 Do not reuse	 Do not resterilize
 Do not use if package is damaged	 Consult instructions for use	 Keep dry
 Keep away from sunlight	 Sterilized using ethylene oxide	 Contents
 Manufacturer	 Manufacturing site	 Pressure
 Nominal Pressure	 Rated Burst Pressure	 Balloon Diameter
 Balloon length	 Rapid Exchange	 CAUTION : Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

[PRODUCT DESCRIPTION]

RX NC Takeru is a Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Dilatation Catheter. RX NC Takeru is a rapid exchange (RX) type and the maximum diameter of the compatible guidewire is 0.014 inches (0.36 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. RX NC Takeru 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 for RX NC Takeru is provided in Table 1 at the end of this Instructions for Use. In the sterilization package, the device is equipped with 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 advancing into the stenotic lesion or stent. The catheter's outer surface is partially coated with hydrophilic polymer to generate lubricity when wet.

<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 : 0.014" (0.36 mm)

Recommended inflation pressure and maximum inflation pressure

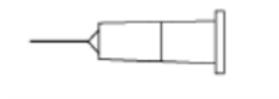
Nominal pressure (NP) : 12.0 atm (1216 kPa)

Rated burst pressure (RBP) : 20.0 atm (2027 kPa)

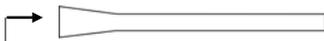
<Contents>

Quantity	Names of Device and Accessories
1	RX NC Takeru PTCA Balloon Dilatation Catheter
1	Flushing needle
1	Re-wrapping tool (for the models with the balloon diameters of 2.5 to 5.0 mm only)
1	Catheter clip

<Flushing needle>

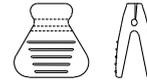


<Re-wrapping tool>



Entry for re-wrapping the balloon

<Catheter clip>



[INDICATIONS]

The RX NC Takeru PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion in the coronary artery or bypass graft stenosis for the purpose of myocardial perfusion. This product is also indicated for the post-delivery expansion of balloon expandable stents.

Note: The verification test for stent post-dilatation of RX NC Takeru was conducted using VeriFlex™ MONORAIL Coronary Stent System (Boston Scientific Corp.), Integrity Coronary Stent System (Medtronic Inc.), Revel™ Platinum Chromium Coronary Stent System (Boston Scientific Corp.), and XIENCE Xpedition® LL Everolimus Eluting Coronary Stent System (Abbott Vascular Inc.).

[CONTRA-INDICATIONS]

1. Unprotected left main trunk (LMT) of coronary artery.
2. Patients who have coronary artery spasm in the absence of a significant stenosis.
3. Patients who cannot tolerate antiplatelet therapy and/or anticoagulant therapy.
4. Patients who are pregnant or suspected for pregnancy.
5. Use for hand crimping of stent components and as a stent delivery system.

[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 to a diameter exceeding the diameter of the blood vessel just proximal and distal to the stenotic lesion.
4. Do not inflate the balloon to a pressure exceeding the rated burst pressure (RBP).
5. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
6. When the catheter is exposed to the vascular system, it should be manipulated under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance and resolve the problem before proceeding.
7. 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.

[Precautions related to procedures]

1. Use the catheter prior to the "Use Before" date specified on the package.
2. Carefully and slowly remove this device out of the carrier tube and remove the protective materials. Careless handling may damage the balloon and/or the catheter shaft and impair balloon inflation and/or deflation.
3. Inflate the balloon with the contrast medium diluted with saline at a ratio of 1:1. No gaseous medium such as air should be used for inflation. (Balloon may be inflated irregularly.)
4. Prior to use, expel all the air in the balloon and balloon inflation lumen and replace it with the inflation fluid. (In cases of incomplete air removal, balloon inflation state can not be observed under fluoroscopy.)
5. In case of serious stenotic lesions such as calcified lesions, the blood vessel cannot be dilated fully. Do not apply a pressure exceeding the rated burst pressure (RBP) even in such a case.

(The balloon may burst and the debris may remain inside the body.)

6. 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 a stent during a coronary stent placement procedure, refer to the manufacturer's instructions for use.)
7. 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.)
8. Do not attempt to pass the RX NC Takeru PTCA Balloon Dilatation Catheter through a smaller sized guiding catheter than indicated on the label. Refer to product labeling.
9. Do not use a larger sized guidewire than indicated on the label. Refer to product labeling.
10. Proceed with care to prevent the catheter from being kinked and collapsed when forming loops and bundle the catheter.
11. When using the catheter clip to secure the catheter, clip the stiffer, proximal end of the catheter. Do not clip the flexible, distal shaft of the catheter, or it may damage the catheter.
12. Proceed with care to prevent shaft kinking and collapse while removing the catheter clip (if the clip is used before insertion to a patient body). Carefully remove the catheter clip to unbundle the catheter so that the catheter shall not be kinked and collapsed.
13. The safety and effectiveness of this PTCA balloon catheter for the treatment of in Stent Restenosis (ISR) has not been established.

[Precautions during usage]

1. Use the device immediately after the sterile package is opened.
2. The entire procedure should be carried out aseptically.
3. The catheter system should be used only by physicians trained in percutaneous coronary intervention (PCI).
4. Select the catheter with appropriate balloon size (balloon diameter, balloon length) according to the following (procedures) criteria.
 - 1) The diameter of the inflated balloon shall not exceed the inner vessel diameter just 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 (20 inflations without stent and 10 inflations in-stent were verified by the performance bench test.).
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 with verifying the location and movement of its tip under fluoroscopy 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 and guidewire with the balloon inflated. (Moving the catheter and guidewire 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 guiding catheter.
23. Always use the catheter along a guidewire inserted into the guidewire lumen.
24. Do not immerse the catheter in hot water or chemicals such as disinfectants (This may adversely affect its function).

[Operational Instructions]

Materials typically required for PTCA with the RX NC Takeru PTCA Balloon Dilatation Catheter include:

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

[Operation method or instructions for use]

1. Selection of the catheter
Prior to use, verify the blood vessel inner diameter just 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 15 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 inflation device. (a syringe can be used in place of the inflation device for the procedures (a)-(e).)
- 3) Flush the guidewire lumen with heparinized saline and fill the lumen with the heparinized saline.
 - 4) If the balloon (with balloon diameter of 2.5 to 5.0 mm) is unintentionally dilated during above mentioned replacement of air from the catheter and flushing the guidewire lumen, use the re-wrapping tool so that the balloon is smoothly wrapped before the immersion of the catheter in saline.
 - 5) Immerse the entire RX NC Takeru PTCA Balloon Dilatation Catheter in saline for at least one minute before inserting it into the patient's blood vessel.
3. Insertion and inflation of the balloon catheter
- Prior to use, please check if this catheter is compatible to the guiding catheter (not included in this kit), and the guidewire (not included in this kit) by the following table.

Catalogue number	Balloon diameter (mm)	Compatible guiding catheter (Fr/mm)	Maximum diameter for the guidewire (inch/mm)
DC-RZ2006UA2	2.0 mm, 2.25 mm	5 Fr (1.4 mm)	0.014 inch (0.36 mm)
	2.5 mm, 2.75 mm		
	3.0 mm, 3.25 mm		
~ DC-RZ5030UA2	3.5 mm, 3.75 mm		
	4.0 mm	6 Fr (1.8 mm)	
	4.5 mm, 5.0 mm		

When using the catheter inserted in the guiding catheter

- 1) When using the catheter in the guiding catheter, loosen the hemostasis valve while keeping it tight enough to prevent blood leakage.
 - 2) After the guidewire advances to the distal periphery of the lesion under fluoroscopy, gradually insert the catheter, with the balloon deflated completely, into the guiding catheter over the guidewire to make its radiopaque marker(s) in the balloon reach the target site.
 - 3) Under fluoroscopy, verify the position of the radiopaque markers in the balloon and determine the dilatation site.
 - 4) Inflate the balloon gradually to the target diameter verifying the inflation pressure and dilate the stenotic lesion.
4. Removal of the catheter
- 1) After applying negative pressure to deflate the balloon completely, loosen the hemostasis valve.
 - 2) Grasp the guidewire and the hemostasis 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 hemostasis valve.
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 RX NC Takeru 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

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

- Acute myocardial infarction
- Arrhythmias, including ventricular fibrillation
- Arteriovenous fistula
- Coronary artery spasm
- Coronary vessel dissection, perforation, rupture, or injury
- Death
- Drug reactions, allergic reaction to contrast medium
- Embolism
- Hemorrhage or hematoma
- Hypo / hypertension
- Infection
- Restenosis of the dilated vessel
- Total occlusion of the coronary artery or bypass graft
- Unstable angina
- Emergency coronary artery bypass grafting
- Myocardial ischemia

[Storage and expiration date]

1. Store in a cool, dry, dark place. Avoid exposure to water, direct sunlight.

[Package]

1 set/box

[Name and address of manufacturer]

Manufacturer: KANEKA CORPORATION

Address: 3-18, 2 Chome, Nakanoshima Kita-ku, Osaka-city
530-8288 Japan
TEL No.: (+81)-(0) 6-6226-5256
FAX No.: (+81)-(0) 6-6226-5143

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Table 1. RX NC Takeru Balloon Compliance Chart

Pressure atm (kPa)	Balloon Diameter (mm)										
	2.0	2.25	2.5	2.75	3.0	3.25	3.5	3.75	4.0	4.5	5.0
12 (1216)	1.96*	2.22*	2.46*	2.73*	3.00*	3.22*	3.45*	3.73*	3.94*	4.53*	5.02*
14 (1419)	1.99	2.25	2.50	2.77	3.05	3.28	3.52	3.80	4.02	4.60	5.10
16 (1621)	2.02	2.28	2.54	2.80	3.08	3.32	3.57	3.86	4.08	4.66	5.17
18 (1824)	2.04	2.31	2.56	2.84	3.12	3.37	3.62	3.91	4.13	4.72	5.24
20 (2027)	2.06**	2.34**	2.59**	2.87**	3.16**	3.41**	3.67**	3.97**	4.18**	4.79**	5.31**
22 (2229)	2.09	2.36	2.62	2.90	3.20	3.45	3.72	4.02	4.24	4.85	5.39

* Nominal pressure

** Rated Burst Pressure