INSTRUCTION FOR USE

RISE™ NC

Non-Compliant PTCA Balloon Catheter

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1. DEVICE DESCRIPTION

Biosensors RISE™ NC, rapid exchange (RX) Non-Compliant (NC) Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Catheter, has an integrated shaft system and a balloon near the distal tip. The shaft has one lumen to inflate / deflate the balloon and a second lumen for the advancement on a guidewire.

1.1 Device components

- The distal shaft of the catheter is coated with hydrophilic coating.
- Two radiopaque platinum marker bands are located within the balloon segment to aid in its positioning within the targeted lesion.
- Two marked sections are located on the hypotube shaft at 90 cm and 100 cm from the distal tip.
- A female luer lock connector hub is located at the proximal end of the balloon catheter. This hub connects to the balloon inflation lumen.

Table 1: Device Description

Balloon Diameters (mm)	2.00 – 4.00	4.50
Balloon Length (mm)	8; 10; 12; 15; 20; 25	8; 10; 12
Catheter Working Length (cm)	142	
Balloon material	Nylon 12	
Balloon compliance	Non-compliant	
Guiding catheter compatibility	5F	
Guidewire inner lumen compatibility	0.014” PTCA guidewire	
Balloon Inflation: Nominal Inflation Pressure: Rated Burst Pressure:	 14 atm / 1419 kPa 20 atm / 2027 kPa	 14 atm / 1419 kPa 18 atm / 1824 kPa

Table 2: Product range available

Nominal expanded balloon diameter (mm)	Nominal unexpanded balloon length (mm)					
	8	**10**	**12**	**15**	**20**	**25**
2.00	NCB-20008	NCB-20010	NCB-20012	NCB-20015	NCB-20020	NCB-20025
2.25	NCB-22508	NCB-22510	NCB-22512	NCB-22515	NCB-22520	NCB-22525
2.50	NCB-25008	NCB-25010	NCB-25012	NCB-25015	NCB-25020	NCB-25025
2.75	NCB-27508	NCB-27510	NCB-27512	NCB-27515	NCB-27520	NCB-27525
3.00	NCB-30008	NCB-30010	NCB-30012	NCB-30015	NCB-30020	NCB-30025
3.25	NCB-32508	NCB-32510	NCB-32512	NCB-32515	NCB-32520	NCB-32525
3.50	NCB-35008	NCB-35010	NCB-35012	NCB-35015	NCB-35020	NCB-35025
3.75	NCB-37508	NCB-37510	NCB-37512	NCB-37515	NCB-37520	NCB-37525
4.00	NCB-40008	NCB-40010	NCB-40012	NCB-40015	NCB-40020	NCB-40025
4.50	NCB-45008	NCB-45010	NCB-45012			

2. INDICATIONS

The Biosensors RISE NC PTCA Balloon Catheter is indicated for:

- balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion
- post-delivery expansion of balloon expandable coronary stents.

3. CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Patients suffering from coronary artery spasms, in the absence of a significant stenosis.
- Off-label use (i.e.: outside of the approved indication for use).

4. WARNINGS

- Ensure that the packaging has not been damaged or opened as this may indicate a breach of the sterile barrier. Check the "Use by date" indicated next to the representative symbol on the labels and do not use a product that has reached or exceeded its labeled expiration date. The sterility and stability of the device cannot be guaranteed once the pouch has been opened and hence the device MUST be used promptly. Un-used devices should be returned to Biosensors International™[1] and should not be re-stocked.
- **This device is intended for single use only and must not be reused in another procedure.** DO NOT resterilize the device as this can compromise its performance, can lead to device failure and procedure complications with severe injury or patient death. Reuse, reprocessing and resterilization bear the risk of cross contamination and patient to patient infection.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery (CABG) can be quickly performed in the event of a potentially life-threatening or other serious complication.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. Use extreme caution and careful judgment in patients who have severe reaction to contrast agents that cannot be adequately pre-medicated.
- Do not exceed the rated burst pressure as indicated on product label. Use of pressures higher than specified on the product label may result in a rupture of the balloon with possible intimal damage and vessel dissection.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- 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 and no resistance is felt. If there is resistance, determine and address its cause before proceeding. Continuing to advance or retract the catheter against resistance may result in damage to the vessels, and in damage or separation of the catheter.
- Never apply extreme bending or twisting force to any section of the catheter, in order to prevent kinking, damage, or separation of the shaft. Do not use, or attempt to straighten, a catheter if the

[1] Please contact the Sales and Customer Service of your region or local distributor for return of goods

shaft has become bent or kinked; this may result in the shaft breaking. Instead, prepare a new catheter. Do not force motion of the balloon catheter against significant resistance.

- In the event of catheter damage / separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.
- The safety and efficacy of RISE NC PTCA Balloon Catheter has not been established for pediatric use.

5. PRECAUTIONS

- Only physicians who have received appropriate training and education should perform PTCA procedure and the risk/benefit of such procedure shall be assessed for each patients by the physician
- Prior to angioplasty, the balloon catheter should be examined to verify its integrity and ensure that its size is suitable for the specific procedure for which it is to be used. If the device is kinked it should not be used.
- During the procedure, provide as needed appropriate anti-coagulant and coronary vasodilator therapy to the patient. Continue this therapy for an appropriate period of time after the procedure.
- When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.
- After use, disposal of the device and of its packaging must be handled according to hospital policies and applicable laws and/or regulations.
- Do not expose delivery catheter to organic solvents, e.g. isopropyl alcohol. Such an exposure can degrade delivery catheter performance.

6. OPERATOR’S MANUAL

6.1 Inspection prior to use

Prior to use, inspect the sterile package integrity, do not use if it is damaged. Carefully examine the balloon catheter prior to use and particularly look at the balloon catheter to detect any bends, kinks, or other damage. Verify all equipment as well to be used during the procedure. Do not use any damaged equipment, damaged package, breached sterile pouch or expired product. Verify that the catheter size is suitable for the specific procedure for which it is intended.

6.2 Materials required

One or more of each of the following material are required for PTCA but not supplied with RISE NC PTCA Balloon Catheter:

- Arterial sheath and dilatator set
- Guiding catheter (femoral or brachial) in the appropriate configuration to select the coronary artery and with minimum inner diameter of 0.056”/1.42mm (5F compatible)
- Guidewire, 0.014 inch / 0.36 mm maximum diameter x 190 cm minimum length
- Guidewire torque device
- Inflation device with manometer
- Haemostatic valve(s)
- Three-way stopcock
- Luer-lock syringes 10 ml, 20 ml
- Sterile saline or heparinized sterile saline

- Contrast medium diluted 1:1 with normal saline

6.3 Balloon catheter and inflation device preparation

Prepare each equipment to be used following instructions of its manufacturer.

Complete the following steps to prepare the RISE NC PTCA Balloon Catheter for use:

1. Remove the balloon catheter from the package.
2. Remove the stylet and protective sheath from the distal end of the catheter.
3. Prepare the inflation device with an appropriate inflation medium (equivalent of 1:1 mixture of contrast medium and sterile saline).
4. Prepare the catheter for purging using the following procedure:
    a) Fill a luer-lock 20ml syringe or the inflation device with appropriate contrast medium (usually corresponds to 4ml of a 1:1 mixture of contrast medium and sterile saline). Do not use air or any gaseous medium to inflate the balloon catheter.
    b) Attach the syringe or inflation device to the inflation port of the balloon catheter, orient the balloon catheter with the distal tip and the balloon pointing in a downward vertical position.
    c) Apply negative pressure . Slowly release the pressure to neutral, allowing contrast to fill the shaft of the balloon catheter.
    d) Disconnect the syringe or inflation device from the inflation port of the balloon catheter.
    e) Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the balloon catheter.
    f) Maintain negative pressure on the balloon until air no longer returns to the device. If air is continuously aspirated (can be revealed by bubbles), verify that the balloon has no leaks by inflating the balloon with the inflation medium. Do not use the balloon catheter if there are any leaks.
    g) Slowly release the device pressure to neutral.
    h) Disconnect the luer-lock 20ml syringe (if used) and connect the inflation device to the inflation port of the balloon catheter without introducing air into the system.

CAUTION: All air must be removed from the balloon and displaced with contrast prior to inserting into the body, (repeat steps 4c through 4f, if necessary); otherwise, complications may occur.

6.4 Insertion and use

1. Prepare the vascular access site according to standard practice.
2. Flush and fill the guidewire lumen of the balloon catheter with heparinized normal saline.
3. Prior to using RISE NC PTCA Balloon Catheter device, ensure that a guiding catheter is in place and offers support for advancing the catheter into the vessel, and that the guidewire is adequately positioned through the lesion.
4. Insert the guidewire through the haemostatic valve on the guiding catheter, following the manufacturer's guidelines or standard practice. Under fluoroscopic guidance, carefully advance the guidewire into and through the guiding catheter to the target vessel, across the stenosis, and into a distal vessel. Attach a torque device to the guidewire, if desired. Under fluoroscopy, advance the guidewire to the desired vessel and then position the distal wire in the desired location.
5. Always advance RISE NC PTCA Balloon Catheter over a guidewire that is positioned through the target stenosis and into a distal section of the coronary artery.

6. Backload the guidewire into the distal tip of the balloon catheter guidewire lumen, and ensure that the guidewire exits the opening located approximately 20-22 cm proximal to the balloon.
7. Thoroughly aspirate and flush the hemostatic valve and the guiding catheter in preparation for introduction of the balloon catheter.
8. Advance the balloon catheter over the guidewire until it approaches the hemostatic valve of the guiding catheter. Loosen the haemostatic valve, insert the balloon catheter while maintaining the guidewire position and ensure the balloon is fully deflated; advance the balloon catheter into the guiding catheter and tighten the haemostatic valve to create a seal around the catheter. Caution should be taken not to over-tighten the hemostatic valve around the balloon catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon. The movement of the balloon catheter within the guiding catheter should not be restricted. If unusual resistance is felt, do not advance the catheter through the adapter.
9. Advance the balloon catheter until the appropriate proximal marker approaches the hub of the guiding catheter. Under fluoroscopy, continue to advance the balloon catheter over the guidewire and into the stenosis.
10. Verify the positioning of the balloon across the lesion prior to inflation, using the radio-opaque markers of the balloon for reference and inflate the balloon slowly to the appropriate pressure (do not to exceed 10 total inflations). Do not exceed the rated balloon burst pressure (refer to compliance card provided with the device and RBP mentioned in Table 1: Device Description).
11. After the lesion has been dilated and results confirmed by angiographic standard techniques, pull the plunger of the inflation device to create a vacuum, and control the deflation of the balloon under fluoroscopy.
12. After complete deflation, pull the balloon catheter back into the guiding catheter until complete removal.
13. If procedure is completed, remove the guiding catheter from the vessel and follow standard practice for management of the insertion site.

7. EXCHANGE PROCEDURE TECHNIQUE

The Biosensors RISE NC PTCA Balloon Catheter is a rapid exchange dilatation catheter. To perform such procedure, refer to following procedure:

1. Loosen the hemostatic valve.
2. Hold the guidewire and hemostatic valve in one hand, while grasping the balloon shaft in the other hand.
3. Maintain guidewire position in the coronary artery by holding the wire stationary and begin pulling the dilatation catheter out of the guiding catheter, while monitoring the wire position under fluoroscopy.
4. Withdraw the deflated dilatation catheter until the notch in the guidewire lumen is reached (marker indicates notch). Carefully inch the flexible, distal portion of the dilatation catheter out of the rotating hemostatic valve, while maintaining the guidewire's position across the lesion.
5. Slide the distal tip of the dilatation catheter out of the hemostatic valve and tighten onto the guidewire to hold it securely in place. Completely remove the dilatation catheter from the guidewire.
6. Prepare the next dilatation catheter to be used, as previously described in section 6.3. Balloon catheter and inflation device preparation.

7. Backload another dilatation catheter onto the guidewire, as previously described under the section 6.4 Insertion and use and continue the procedure accordingly.

8. POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with the use of a PTCA catheter in native coronary arteries, include but not limited to:

- Abrupt vessel closure or spasm
- Acute myocardial infarction
- Angina or unstable angina
- Aneurysm, pseudoaneurysm or arteriovenous fistula
- Arrhythmias, including ventricular fibrillation,
- Allergic reaction to anti-coagulation and/or anti-thrombotic therapy, contrast medium, or delivery system materials
- Hemorrhage or hematoma (in particular at puncture site)
- Cardiac tamponade/pericardial effusion
- Cardiogenic shock
- Dissection, perforation, rupture, or injury of the treated coronary artery
- Coronary thrombosis
- Emergency coronary artery bypass graft surgery (CABG)
- Death
- Embolism
- Hypotension/hypertension
- Infection and/or pain at insertion site
- Restenosis of dilated vessel
- Renal failure
- Stroke / Cerebrovascular accident
- Total occlusion of the coronary artery, bypass graft or side branches
- Thrombosis

9. REFERENCE

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by the American College of Cardiology and the American Heart Association (ACC/AHA) or European Society of Cardiology (ESC).

10. HOW SUPPLIED

STERILE, NON-PYROGENIC. This device is sterilized with ethylene oxide sterilization.
LATEX FREE. This device does not contain latex.
CONTENTS: One (1) RISE NC PTCA Balloon Catheter, one (1) Instruction for Use and one (1) compliance card.
STORAGE: Store in a cool, dark and dry place.
DISPOSAL: Dispose of device in accordance with local regulations.
NOTE: This product does not contain phthalates

11. SYMBOLS USED IN LABELING

	Legal Manufacturer		Keep away from sunlight or heat
	Date of Manufacture		Keep Dry
REF	Catalog number		Do not use if package is damaged or open
LOT	Batch code		Balloon Length
	Caution, consult accompanying documents		Balloon Diameter (at nominal inflation pressure)
	Do not re-sterilize		Maximum Guidewire Outer Diameter (OD)
	Do not reuse		Minimum Guiding Catheter Inner Diameter (ID)
STERILE EO	This product has been sterilized using Ethylene Oxide		Consult Instruction for use
	Use by date Do not use this device after the indicated date (Year-Month-Day)	RBP	Rated Burst Pressure
NP	Nominal Pressure		Non-pyrogenic

12. WARRANTY

Biosensors International warrants that its products are manufactured to the specifications set forth on its packaging, instructions for use and related literature.

This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Biosensors International neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.

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