Helix Balloon Dilatation Catheter

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.
OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS.
FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

1.0 Device Description

The Helix (Rx type) device is a coronary dilatation catheter designed for easy guidewire exchange. The catheter working length is 140cm. Balloon diameters range from ∅1.0mm to ∅4.0mm. The balloon material is made of a semi-compliant Pebax material for diameter 1.0mm to 4.0mm with a rated burst pressure of 14 atmospheres. The proximal shaft of the catheter is composed of a female luer connector bonded to a PTFE coated stainless steel tube with a wire. The proximal shaft joins with a smooth transition to a distal shaft composed of an outer tube of pebax/nylon and a tri-extrusion inner tube with a balloon laser welded to both tubes at the distal tip. Two radiopaque platinum/iridium marker bands are located within the balloon segment with the exception of balloon diameters less than 2.0mm which incorporate a centrally positioned single marker band. The inner tube accepts a standard 0.014 inch PTCA guide wire. The guide wire enters the catheter's tip and advances coaxially out the distal Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard length guide wire. Two marked sections of 5mm length each located on the proximal shaft indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

2.0 How supplied

Contents:	One (1) Balloon Dilatation Catheter
	One (1) Flushing Needle
	One (1) Re-wrap Tool
Sterile	sterilized with ethylene oxide gas. Non-pyrogenic.
Storage	Store in a dry, dark, cool place

3.0 Indications

The balloon dilatation 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

4.0 Contraindications

The catheter is contraindicated for use in:

- Unprotected left main coronary artery
- Coronary artery spasm in the absence of significant stenosis

5.0 Warnings

- For single patient, single procedure use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increase risk of inappropriate resterilization and cross contamination.
- Do NOT use the catheter if its package has been opened or damaged
- To reduce the potential for vessel damage in the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis
- 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.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do NOT advance or retract the catheter unless the balloon is fully deflated under vacuum as this can potentially result in damage to the vessel wall. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure indicated on the package label for each balloon. The rated burst pressure is based on the results of in vitro testing. Use of a pressure monitoring device is recommended to prevent over pressurization. PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium. To prevent the possibility of an air embolus, never use air or any gaseous medium to inflate balloon.
- Use the catheter prior to the "Use by" date (Expiration Date) specified on the package.

6.0 Precautions

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the procedure for which it is to be used
- The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty
- Appropriate anticoagulation, antiplatelet and vasodilator therapy should be administered to the patient
- When using two guide wires, care should be taken when introducing, torquing and removing one or both guide wires to avoid entanglement. It is recommended that one guide wire be completely withdrawn for the patient before removing any additional equipment

7.0 Adverse Events

Possible adverse effects include, but are not limited to the following

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

8.0 Materials to be used in combination with a balloon catheter include:

- Suitable guide wire, refer to label claim
- 20cc syringe for balloon preparation
- Suitable guiding catheter, refer to label claim
- 10cc or smaller syringe for manual dye injections
- Appropriate inflation medium (e.g. 50:50 sterile mixture of a contrast medium and saline)
- Pressure-indicating inflation device
- Hemostasis valve

9.0 Preparation for Use

- Select an appropriate balloon catheter for the target vessel
- Remove the device from the sterile packaging
- Prior to use, examine all devices carefully for defects. Examine the dilatation catheter for bends, kinks, or any other damage. Do NOT use any defective device.
- Remove the protective balloon stylet and balloon protector
- Using the flushing needle, flush the guidewire lumen with saline
- Balloon Purging, purge air from the catheter using a 20cc syringe filled with 2 to 3ml of the inflation medium with the balloon catheter pointing downward. Attach an inflation device to the balloon inflation port. Ensure that a meniscus of contrast medium is evident in both the catheter luer connector and the inflation device. Apply negative pressure with the inflation device. Do NOT attempt Pre-Inflation technique to purge the balloon lumen.

Caution: All air shall be removed from the balloon and displaced with contrast medium prior to inserting into the body. Otherwise complications may occur.

10.0 Instruction for Use

- Insertion Technique
  - Place the guiding catheter, with a hemostasis valve attached, in the orifice of the target coronary artery
  - Advance the guide wire through the guiding catheter to reach and cross the target lesion. Advance the distal tip of the balloon catheer over the proximal end of the guide wire. Ensure that the guide wire exits the balloon catheter throught the guide wire exit location
  - The hemostasis valve should be gradually tightened to control back flow. Excessive valve tightening may affect balloon inflation/deflation time as well as movement of the guide wire.
  - Track the balloon catheter over the wire to cross the lesion using the radiopaque marker(s) to locate the balloon across the lesion

- Balloon Inflation
  - Inflate the balloon to dilate the lesion using standard PTCA techniques
  - After each subsequent inflation, the distal blood flow should be assessed
  - If a significant stenosis persists, successive inflations may be required to resolve the stenosis. Do NOT exceed the rated burst pressure (see labeling)
  - Confirm the results with fluoroscopy
- Removing the Catheter
  - Apply negative pressure ot the inflation device and confirm that the balloon is fully deflated
  - Withdraw the balloon catheter into the guiding catheter while preserving guide wire position
  - After the deflated balloon dilatation catheter is withdrawn, it should be wiped clean with gauze soaked with sterile normal saline
  - Inspect the balloon catheter integrity
  - If reinserting the same balloon dilation catheter, flush the guide wire lumen of the balloon dilatation catheter using the flushing needle as described in the "Preparation for Use" section. Prior to reinsertion, the balloon dilatation catheter should be wiped clean with gauze soaked with sterile normal saline. The balloon may be refolded using the rewrap tool as described in the Re-Fold Tool as described in the "Re-Fold Tool" Section.
- Re-Fold Tool
  - This is an accessory component that allows the balloon to be rewrapped if required
    - ♦ Deflate the balloon by applying negative pressure to the inflation device and maintain under vacuum
    - ♦ Visually inspect the balloon to confirm that it is fully deflated
    - ♦ Remove the Re-fold Tool from Compliance Card
    - ♦ Load the non-flared end of the re-fold tool onto the stylet
    - ♦ Carefully load the stylet back through the distal tip of the catheter and past the proximal end of the balloon
    - ♦ While holding the catheter just proximal to the balloon, push the re-fold device over the balloon in a gentle twisting motion until the entire balloon is covered
    - ♦ Gently remove the re-fold device/stylet assembly
    - ♦ Inspect the balloon for any potential damage. Discard the balloon catheter if antere is any visual damage present on the balloon.

11.0 Reference

Physicians should consult recent literature on current medical practice on balloon dilatation, such as published by American College of Cardiology/American Heart Association.

12.0 Disclaimer of Warranty

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EXPLANATION OF SYMBOLS

Description	Symbol
Catalog Number	REF
Lot Number	LOT
Balloon Diameter	BALLOON ⌀
Balloon Length	BALLOON ⊢ ⊣
Sterilized Using Ethylene Oxide	STERILE EO
Use By	
Do Not Reuse	
Caution	
Consult Instructions For Use	
Do Not Resterilize	2 STERILIZE
Guiding Catheter	≥
Contents (numeral represents quantity of units inside)	1
Do not use if package damaged	
Conformity to the Council Directive 93/42/EEC Concerning Medical Devices	CE 2797

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