TriReme Medical

Chocolate® PTCA Balloon Catheter

INSTRUCTION FOR USE

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

DEVICE NAME

Chocolate® Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Catheter

DEVICE DESCRIPTION

The Chocolate® PTCA Balloon Catheter is a "rapid-exchange" balloon dilatation catheter with an atraumatic tapered tip. The product family consists of 0.014" system that is compatible with 0.014" guidewire. The overall catheter length is approximately 140cm.

The distal end of the catheter has a semi-compliant balloon that expands to known diameters (refer to compliance chart) at specific pressures. The balloon is constrained by a nitinol constraining structure (CS) which provides fast deflation and uniform re-wrap. Upon deflation, the CS is removed from the vessel along with the balloon catheter. The balloon is available in multiple sizes and contains radiopaque markers to assist with positioning (refer to catalog numbers). The proximal end of the device is a common PTCA catheter design of a polymer shaft connected to a hypotube with a plastic hub and strain relief. The hub has one port used to inflate the balloon.

The Chocolate® PTCA Balloon Catheters are supplied STERILE and intended for single use.

HOW SUPPLIED

Sterile: Sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is open or damaged.

Contents: Each package contains one (1) Chocolate® PTCA Balloon Catheter.

Product Shelf Life: One (1) year

STORAGE: Store in a dry, cool place.

INDICATIONS FOR USE

The Chocolate® PTCA Balloon Catheter is intended for balloon dilatation of the stenotic portion of coronary artery for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Coronary artery spasm in the absence of significant stenosis.
- Post dilatation of balloon expandable stents or crossing through deployed stents and/or stent struts.

WARNINGS

- Do not use in the presence of a freshly deployed stent.
- The Chocolate® PTCA Balloon Catheter has not been tested for the treatment of in-stent restenosis and post-dilatation of stents or advancement through stents or synthetic vascular grafts.
- STERILE product, to be used one time only. Re-sterilizing or re-using may compromise the structural integrity of the device and may create a risk of contamination which, in turn, may result in health risks to patients.
- The inflated diameter of the balloon should correspond to the diameter of the vessel for treatment.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support.
- The catheter should be used under fluoroscopic guidance. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. Do not advance against resistance without first determining the cause of the resistance and taking appropriate action.
- Balloon pressure should never exceed the rated burst pressure (RBP). Exceeding the RBP may result in balloon rupture and CS failure.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the Chocolate® PTCA Balloon Catheter prior to the "Use By" date specified on the package.

PRECAUTIONS

- Ensure the balloon size and device functionality are suitable for the intended procedure.
- The device should only be used by trained physicians.
- Use appropriate anticoagulant and vasodilator therapy during and after the procedure.
- Do not pre-inflate prior to use. Prepare as directed in the Balloon Catheter Preparation section.
- Catheter should not be rotated in one direction more than three (3) turns during use. Alternate the rotating direction if additional rotation is needed.

POTENTIAL COMPLICATIONS / ADVERSE EFFECTS

The following complications may result from a balloon dilatation procedure, but may not be limited to:

- Abrupt closure
- Allergic reaction to medication or contrast medium
- Arrhythmias, including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- Arterio-venous fistula
- Coronary artery dissection or perforation
- Need for revascularization
- Death
- Emboli (air, tissue, thrombi, material from device(s) used in the in the procedure)

- Emergency coronary artery bypass graft surgery
- Emergency percutaneous coronary intervention
- Acute myocardial infarction
- Heart failure
- Hemorrhage or hematoma. Need for blood transfusion
- Hypotension/hypertension
- Infection, local or systemic
- No/slow reflow of treated vessel
- Pericardial effusion, tamponade
- Pseudo-aneurysm
- Restenosis of the vessel
- Stable or unstable angina
- Stroke/cerebrovascular accident/TIA
- Surgical repair of vascular access site
- Thrombosis

PREPARATION FOR USE

Note*: Do not expose the catheter to organic solvents (e.g., alcohol).*
Note: *Do not use if there is evidence that the integrity of the package has been compromised.*

1. Carefully remove the product from the sterile packaging. Examine carefully for defects. Examine the catheter for bends, kinks or other damage. Do not use any defective device. Do not use if the sterile barrier is damaged.
2. Remove the protective balloon cover and stylet, discard.
3. Prepare an inflation device with the recommended contrast medium according to the manufacturer's instructions.
4. Evacuate air from the balloon segment using the following procedure:
   a. Fill a 20cc syringe or the inflation device with approximately 4cc of contrast medium.
   b. Attach a stopcock to the catheter hub (inflation lumen).
   c. Connect the syringe or inflation device to the stopcock and open to the inflation lumen, orient the dilatation catheter with the distal tip and the balloon pointing in a downward position.
   d. Apply negative pressure and aspirate. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter. Close the stopcock.
   e. Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.
   f. Remove all air from the syringe of inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the dilatation catheter. Open stopcock and maintain negative pressure on the balloon until air no longer returns to the device.
   g. Slowly release the device pressure to neutral.
   h. Disconnect the 20cc syringe (if used) and connect the inflation device to the inflation port of the dilatation catheter without introducing air into the system.

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

PROCEDURE

Insertion

1. Insert a 0.014" guidewire through the hemostatic valve following the manufacturer's instructions. Under fluoroscopy, position the guidewire just past the tip of the guiding catheter or across the stenosis according to accepted PTCA techniques.
2. Backload the distal tip of the dilatation catheter onto the guidewire ensuring that the guidewire exits the notch located approximately 25cm proximal to the balloon.

   Note: When back loading the dilatation catheter onto the guidewire, the dilatation catheter should be supported. In advancing the dilatation catheter into the guiding catheter, manually support the dilatation catheter and firmly grasp the proximal shaft. Shaft diameter differences should be taken into consideration when opening and tightening the hemostatic valve and upon withdrawal of the dilatation catheter.
3. Advance the dilatation catheter over the guidewire until it approaches the hemostatic valve. Open the hemostatic valve. Insert the dilatation catheter while maintaining guidewire position and tighten the hemostatic valve.

Positioning & Deployment

4. Advance the dilatation catheter over the guidewire and to the stenosis. Use the radiopaque markers on the balloon for positioning.
   Note: Do not advance against resistance. When resistance is felt while crossing the lesion, slightly pull back the catheter and try to advance again. If resistance persists, DO NOT force passage.
5. Inflate the balloon to desired diameter per compliance chart to perform PTCA per standard procedure. The diameter of the balloon should correspond to the diameter of the vessel for treatment.
6. Fully deflate the balloon by applying negative pressure. Maintain negative pressure between inflations and while withdrawing the catheter.

Withdrawal

7. Withdraw the deflated dilatation catheter and guidewire from the guiding catheter through the hemostatic valve. Tighten the hemostatic valve.

EXCHANGE PROCEDURE TECHNIQUE

The Chocolate® PTCA Balloon Catheter has been specifically designed for rapid, single operator balloon exchanges. Perform dilatation catheter exchange according to standard practice.

EXPLANATIONS OF SYMBOLS USED IN LABELING

	Attention. See Instructions for Use		Maximum Guidewire Diameter
	Do not resterilize	GUIDE	Recommended Guide Catheter
	For one use only	NP	Nominal Pressure
	Do not use if package is damaged	RBP	Rated Burst Pressure
REF	Catalog Number	Non-Pyrogenic	Non-Pyrogenic
LOT	Lot Number	STERILE EO	Sterilized using ethylene oxide gas
	Use By		Manufacturer

CE 0124

EC REP

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