NC TREK RX & OTW

Coronary Dilatation Catheters

CAUTION

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

INDICATIONS

The NC TREK RX & OTW Coronary Dilatation Catheters are indicated for:

a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion

b) balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with
ST-segment elevation myocardial infarction

c) balloon dilatation of a stent after implantation (balloon models 2.00 mm – 5.00 mm only)

Note: Post-deployment stent expansion testing was performed on the bench with the MULTI-LINK VISION and MULTI-LINK ULTRA stents. All stents should be deployed in accordance with the manufacturer's indications and instructions for use.

CONTRAINDICATIONS

The NC TREK RX & OTW Coronary Dilatation Catheters are not intended to be used:

- in an unprotected left main coronary artery;
- to treat coronary artery spasm in the absence of a significant stenosis.

WARNINGS

This device is intended for one time use only. DO NOT resterilize and / or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

Percutaneous transluminal coronary angioplasty (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.

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.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of *in vitro* testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent overpressurization.

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 while 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 before proceeding.

Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked; this may result in the shaft breaking. Instead, prepare a new catheter.

Do not torque the catheter more than one (1) full turn.

Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60 – 85%, and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment, and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and / or damage / separation of the catheter.

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.

PRECAUTIONS

Note the “Use by” date specified on the package.

Inspect all product prior to use. Do not use if the package is open or damaged.

This device should be used only by physicians trained in angiography and PTCA, and / or percutaneous transluminal angioplasty (PTA).

Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

If the surface of the NC TREK RX or OTW Coronary Dilatation Catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.

Do not reinsert the NC TREK RX or OTW Coronary Dilatation Catheter into the coil dispenser after procedural use.

Applies to NC TREK RX Only:

The design and construction of these catheters do not provide the user with distal pressure monitoring capability.

With 4.5 mm and 5.0 mm balloon dilatation catheters, some increased resistance may be noted upon insertion or withdrawal into or out of the guiding catheter. Choosing a larger guiding catheter size may minimize this.

Applies to NC TREK OTW Only:
The safety and effectiveness of this PTCA balloon catheter for the treatment of in-stent restenosis (ISR) has not been established.

ADVERSE EFFECTS

Possible adverse effects 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