The Sapphire II NC Coronary Dilatation Catheter is designed to allow easy exchange of the catheter using a diameter of 0.014 inch guidewire. Balloon diameters range from 1.75 mm to 5.0 mm. The balloon material is made of a minimally compliant ballast material distributed over the shaft. The proximal shaft of the catheter is composed of a female luer connector bonded to a PTFE coated stainless steel tube. The proximal shaft allows for superior pushability and smooth transition with a direct stent application. Two radiopaque platinum/iridium marker bands are located within the balloon segment. The guidewire enters the balloon shaft coaxially at the distal port, thereby allowing both coaxial guidance and rapid exchange of the catheter with a single standard guidewire. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

HOW SUPPLIED

Contents
- One (1) Sapphire NC Coronary Dilatation catheter, one (1) re-wrap tool, one (1) securing clip, one (1) flushing needle.
- Sterile
- Sterilized with ethylene oxide gas. Non-pyrogenic
- Do not use if the package is damaged.
- Storage
Store in a dry, dark, cool place.

INDICATIONS

For balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

The use of the Sapphire II NC Coronary Dilatation Catheter is contraindicated in the following patients and circumstances:
- Patients with an unprotected left main coronary artery.
- Patients with coronary artery spasm in the absence of a significant stenosis.

WARNINGS

When using this type of device, the following warnings should be observed:
- 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.
- PTCA in patients who are not appropriate candidates for coronary artery bypass graft surgery requires careful consideration, including evaluation of the potential hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- When the catheter is exposed to the vascular system, immediate use of a heparinized saline should be performed. Do not advance or retract the catheter unless the balloon is fully deflated under fluoroscopic control.
- If resistance is met during inflation, avoid forceful inflation.
- There may be no pressure response if balloon exchanges. To perform a dilatation catheter exchange:

1. Withdraw the deflated PTCA catheter and guidewire into the guiding catheter.
- Using a technique of choice, remove the PTCA catheter, guidewire and guidewire catheter from the vascular system. Discard the PTCA catheter, guidewire, and guidewire catheter.
- Removal of the dilatation catheter should be done after loosing the balloon:

1. The balloon may be collapsed once using the securment clip provided in the package (attached to the bottom left of the compliance card). Carry the catheter without the balloon while monitoring the wire position under fluoroscopy.
- The balloon may be collapsed once (after expansion) using the balloon re-seal tool provided in the package (attached to the upper right of the compliance card). The style should be used concurrent with the dilatation catheter to support the guidewire lumen and care should be taken not to damage the balloon upon removal or the securment clip.
- The PTCA catheter may be re-folded once (after expansion) using the balloon re-seal tool provided in the package.

EXCHANGE PROCEDURE TECHNIQUE

The PTCA catheter has been specifically designed for rapid, single-operator balloon exchanges. To perform a dilatation catheter exchange:

1. Loosen the hemostatic valve.
2. Advance the balloon catheter to the targeted lesion in one hand, while grasping the balloon catheter 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 out of the guiding catheter lumen, and then advance the balloon catheter over the guiding catheter onto the balloon.
5. Slip the balloon catheter over the guiding catheter, and then advance the balloon catheter onto the guiding catheter while maintaining the guidewire position under fluoroscopy.
6. Withdraw the deflated dilatation catheter out of the guiding catheter lumen, and then advance the balloon catheter onto the guiding catheter to enter the lesion.