SAPPHIRE II PRO Coronary Dilatation Catheter

CORONARY DILATATION CATHETER

INSTRUCTIONS FOR USE

ENGLISH

CE 2797

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

DEVICE DESCRIPTION

The Sapphire II PRO Coronary Dilatation Catheter is designed to allow easy exchange of the catheter using a standard length 0.014 inch guidewire. Balloon diameters range from 1.0mm to 4.0mm. The balloon is made of the semi-compliant material, 1.0mm to 1.5mm balloons have a rated burst pressure of 16 atmospheres and 1.75mm to 4.0mm balloons have 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. The proximal shaft allows superior proximal pushability with a smooth transition to a distal shaft composed of an outer tube, an inner tube and a balloon. Two radiopaque platinum/iridium marker bands are located within the balloon segment with the exception of 1.0mm to 1.5mm balloons which incorporate a centrally positioned single marker band. The guidewire enters the catheter tip and advances coaxially out the distal Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard length guidewire. Two marker 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.

HOW SUPPLIED

Contents	One (1) Sapphire II PRO Coronary Dilatation catheter, one (1) Re-wrap tool, one (1) securement clip, one (1) flushing needle.
Sterile	Sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is open or 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 PRO Coronary Dilatation Catheter is contraindicated in the following patient types:

- 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 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.
- 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.
- Balloon pressure should not exceed the rated burst pressure (RBP) indicated on the package. The RBP is based on 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. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use By" date specified on the package.
- This device is designed and intended for single use only. DO NOT reprocess, resterilize and/or reuse. Reuse of single-use devices creates a potential risk of patient or user infections. Reuse may lead to impairment of functional performance. Infections and/or limited performance of the device may lead to injury, illness or death of the patient.

PRECAUTIONS

- Do not reinsert the PTCA catheter into the coil dispenser after procedural use.
- 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 being used.
- The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. After the procedure, anticoagulant therapy should be continued for a period of time as determined by the physician.
- The design and construction of these catheters do not provide the user with distal pressure monitoring capability.
- Discard all disposable devices used during this procedure per local requirements for medical device waste disposal.
- Do not use oil-based contrast medium, organic solvents or alcohols; there is a possibility of catheter leak, damage or lubrication loss.

POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS

Potential complications and adverse effects due to the use of this product include, but are not limited to, the following:

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

MATERIALS REQUIRED

- Arterial Sheath
- Femoral or brachial guiding catheter in the appropriate size and configuration
- Hemostatic valve(s)
- Contrast medium diluted 1:1 with normal saline
- Sterile heparinized normal saline
- 20 cc Luer-lock syringe
- Inflation device
- Guidewire diameter not to exceed 0.014"; see product label
- Guidewire introducer
- Guidewire torque device

PREPARATION FOR USE

Prior to use, examine all equipment carefully for defects. Examine the dilatation catheter for bends, kinks, or other damage. Do not use any defective equipment.
Prepare equipment to be used following manufacturer's instructions or standard procedure.
Complete the following steps to prepare the PTCA catheter for use:

1. Remove the protective mandrel from the catheter tip.
2. Slide the protective sheath off the balloon.
3. Flush the guidewire lumen of the PTCA catheter.
4. Attach the syringe with heparinized normal saline to the flushing needle packaged with the catheter; gently insert the needle into the tip of the catheter and flush the guidewire lumen with heparinized normal saline until fluid is seen exiting the guidewire port.
5. Prepare an inflation device with the recommended contrast medium according to the manufacturer's instructions.
6. Evacuate air from the balloon segment using the following procedure:
7. Fill a 20 cc syringe or the inflation device with approximately 4 cc of the recommended contrast medium.
8. After attaching the syringe or inflation device to the balloon inflation lumen, orient the dilatation catheter with the distal tip and the balloon pointing in a downward vertical position.
9. Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter.
10. Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.
11. Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the dilatation catheter. Maintain negative pressure on the balloon until air no longer returns to the device.
12. Slowly release the device pressure to neutral.
13. Disconnect the 20 cc syringe (if used) and connect the inflation device to inflation port of the dilatation 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. Otherwise complications may occur.

INSTRUCTIONS FOR USE

1. Insert a guidewire through the hemostatic valve that is on the guiding catheter, following the manufacturer's instructions.
2. Advance the guidewire carefully into and through the guiding catheter. Withdraw the guidewire introducer, if used.
3. Attach a torque device to the guidewire, if desired. Under fluoroscopy, proceed with accepted PTCA techniques to advance the guidewire to and across the lesion.
4. Backload the distal tip of the dilatation catheter onto the guidewire ensuring that guidewire exits the catheter at approximately 25 cm proximal to the balloon.
5. Advance the dilatation catheter over the guidewire until it approaches the hemostatic valve.
6. Open the hemostatic valve. Insert the dilatation catheter while maintaining guidewire position and tighten the hemostatic valve. To facilitate insertion, the balloon must be fully deflated to negative pressure.
7. Tighten the hemostatic valve to create a seal around the dilatation catheter without inhibiting movement of the dilatation catheter. This will allow continuous recording of proximal coronary artery pressure.

Note: It is important that the hemostatic valve be closed tightly enough to prevent blood leakage around the dilatation catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon or restricts guidewire movement.

8. Advance the dilatation catheter until the appropriate proximal marker aligns with the hemostatic valve hub. This indicates that the dilatation catheter tip has reached the guiding catheter tip.
9. Advance the dilatation catheter over the guidewire and into the stenosis. Continue under fluoroscopy and use the radiopaque marker band(s) to position the usable (dilating) section of the balloon within the stenosis.

Note: When using the dual wire technique, a dual hemostatic valve should be used and care taken when introducing, torquing and removing one or both wires to avoid entanglement. Guidewires should not be rotated more than 180 degrees in either direction during the dual wire procedure. It is recommended that one wire be completely withdrawn from the patient before removing additional equipment.
Caution: If any resistance is felt, do not advance the guidewire or the dilatation catheter by force. Before proceeding, determine the cause under high resolution fluoroscopy. Advancement by force may result in damage to the vessel and/or laceration or separation of the guidewire or the dilatation catheter. This may necessitate recovery of fragments.

10. Continue the procedure using accepted coronary angioplasty technique to dilate the stenosis. Note: Do not exceed the rated burst pressure printed on the package label. Maintain negative pressure on the balloon between inflations.

Caution: The balloon may slip out of the lesion when inflated because of the hydrophilic coating. Inflate the balloon carefully under the guidance of high resolution fluoroscopy so that the balloon does not change position in the lesion.

11. Withdraw the deflated PTCA catheter and guidewire into the guiding catheter. Using a technique of choice, remove the PTCA catheter, guidewire and guiding catheter from the vasculature. Discard the PTCA catheter, guidewire, and guiding catheter.

Caution: Removal of the dilatation catheter should be done after loosening the hemostatic valve.

12. The catheter may be coiled once using the securement clip provided in the package (attached to the bottom left of the compliance card). Care should be taken not to kink or bend the shaft upon placement or removal of the clip. Only the proximal shaft should be secured with the securement clip; it is not intended for the distal end of the catheter.
13. The balloon may be re-folded once (after expansion) using the balloon re-wrap tool provided in the package (attached to the upper right of the compliance card). The stylet should be used concurrently to support the guidewire lumen and care should be taken not to damage the balloon upon placement or removal of the re-wrap tool.

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. 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 guidewire lumen is reached. Carefully pull back 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 valve onto the guidewire to hold it securely in place.
6. Prepare the next dilatation catheter to be used, as previously described in the Preparation For Use section.
7. Back load another dilatation catheter onto the guidewire as previously described under the Instructions For Use Section, Step 4, and continue the procedure accordingly.

REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

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OrbusNeich Medical (Shenzhen) Co., Ltd
1 Jinkui Road
Futian Free Trade Zone
Shenzhen 518038
China

EC REP
Quality First International OÜ
Laki 30
12915 Tallinn
Estonia

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	
Guiding Catheter	
Contents (numeral represents quantity of units inside)	1
Keep Dry	
Keep Away from Sunlight / Heat	
EU Authorized Representative	EC REP
Manufacturer	
Conformity to the Council Directive 93/42/EEC Concerning Medical Devices	CE 2797

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