Selethru™ PTCA Balloon Dilatation Catheter（KPTCA Series）

Instruction for Use

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Ver. T00

Contents

Caution: Carefully read all instructions prior to use. Failure to observe all warnings and precautions may result in complications.

Device Description

The Selethru™ PTCA balloon dilatation catheter（KPTCA Series) is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter. The device is mostly composed of integrated shaft system and a balloon located near the distal tip. The proximal of the integrated shaft is polymer coated stainless steel tube. The steel construction is designed to optimize proximal push ability with a smooth transition to a distal shaft. The distal shaft is a double lumen tubing integrated by two single lumen plastics tubing. One of the lumen is for the guidewire passage and another for the inflated passage. A hydrophilic coating is applied to the outside surface of the distal shaft to reduce friction force with the vascular wall. The balloon material allows dilatation with precise control of balloon diameter and length.
This device have two radiopaque iridium-platinum marker bands located within the balloon segment. The marker bands are designed to aid in positioning the balloon in the stenosis. Two marked sections are located on the hypotube shaft to indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. The catheter is compatible with 5F or larger guiding catheters. The guidewire passage accepts a standard 0.014 inch guidewire to get through. The design of this dilatation catheter does not incorporate a lumen for distal dye injection and distal pressure measurements.

Supply, Storage and Expiry date

Contents	One (1) PTCA balloon dilatation catheter.
Sterile	Sterilized with ethylene oxide gas. Nor-pyrogenic.
Storage	Store in a dry, dark, cool place.
Expiry date	The shelf life of the PTCA balloon dilatation catheter is 2 years

Indications

The Selethru™ PTCA Balloon Dilatation Catheter（KPTCA Series) is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

Contraindications

The use of the PTCA Balloon Dilatation Catheter is contraindicated in the following patient type:

- 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:

- The catheter is only sterilized with ethylene oxide gas and non-pyrogenic, do not use if the package is opened, damaged or broken.
- This devices is designed and intended for single use only. Do not resterilize or reuse it. Reuse of device or non-sterile device may result in patient infection.
- To reduce the potential for vessel damage, the inflate diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA should only be performed at hospitals, and the catheter system is to be used only by physicians thoroughly trained in the performance of PTCA.
- 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 rate burst pressure (RBP) indicated on the package label for each balloon. 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 burst at or below their RPB. To prevent over-pressurization, use a pressure-monitoring.
- 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 and no resistance is felt. If there is resistance, 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.
- 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.
- Use the catheter prior to the “Use By” date specified on the package and labels.
- The device will not fit any introducer sheath smaller than 5F.

Precautions

- This product should be used only by physicians with experience in angiography and percutaneous transluminal coronary angioplasty (PTCA).
- Inspect the products carefully prior to use. Do not use if the package is open or damage.
- It is possible to rinse the guide wire lumen in a sterile/isotonic saline solution.
- Prior to angioplasty the balloon 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.
- Do not inflate the balloon prematurely. The recommended inflation pressure of the balloon must not be exceeded. It is also recommended that a pressure gauge is used to measure the inflation pressure.
- During the procedure, provide appropriate anticoagulant and coronary vasodilator therapy to the patient as needed. Anticoagulant therapy should be continued for a period of time as determined by the physician after the procedure.
- If the surface of the dilatation catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.
- The inflated diameter of the balloon should correspond to the lumen of the coronary artery, never use a balloon with a larger diameter.
- Care should be taken not to apply excessive force during preparation or use, as this may damage the device.

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
- Acute vessel closure
- Total occlusion of a coronary artery
- Dissection of the coronary vessel
- Arterial perforation
- Arterial rupture
- Vessel trauma requiring surgical repair or re-intervention
- Restenosis of prior treated target vessel segment
- Hematoma
- Hemorrhage
- Angina pectoris
- Arrhythmia, including ventricular fibrillation
- Drug reaction, allergic reaction to contrast medium
- Hypotension
- Hypertension
- Infections

- Coronary artery spasm
- Arterio-venous fistulas
- Embolism
- Embolization or fragmentation of thrombotic or atherosclerotic material
- Pseudoaneurysm
- Cerebral circulatory disorders
- General bleeding
- Thrombus formation
- Ischaemia
- Palpitations
- Emergent Coronary Artery Bypass Graft Surgery (CABG)
- Vascular complication which necessitate a surgical interventions

Materials Required

- Sterile heparinized normal saline
- Hemostatic valve(s)
- Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery
- 60% contrast medium diluted 1:1 with normal saline
- Inflation device
- 20cc Luer-lock syringe (optional)
- Appropriately-sized guide wire (diameter not to exceed the maximum guide wire for the dilatation catheter; see product label)
- Guide wire torque device
- Guide wire introducer
- Primary flushing tool

Preparation for Use

Prior to use, it is essential to examine all equipment carefully for defects. Examine the dilatation catheter for bends, kinks, or other damage. Do not use if the package is open or damaged, or the product is damaged.

Prepare equipment to be used following manufacture's instruction or standard procedure. Complete the following steps to prepare the PTCA catheter for use:

1. Take out the device from the packaging and gently withdraw the dilatation catheter from the protection ring.
2. Remove the stylet from the distal tip of the dilatation catheter, slide the protective sheath off the balloon.
3. Flush the PTCA balloon dilatation catheter. Attach a syringe filled with heparinized normal saline to the flushing tool, gently insert the flushing tool into the distal end of the catheter, and

inject heparinized normal saline into the lumen. Follow this procedure for subsequent flushing. Flush solution should be seen coming out of the guide wire port.

Note: Submerge the balloon in sterile heparinized normal saline during balloon preparation to activate the coating.

4. Prepare an inflation device with the recommended contrast medium according to the manufacturer's instructions.
5. Purge air from catheter inflation lumen using the following procedure:
   a) Fill a 20cc syringe or the inflation device with approximately 4cc of the recommended contrast medium.
   b) After attaching the syringe or inflation device to the balloon inflation lumen, orient the catheter with the distal tip and the balloon pointing in a downward vertical position.
   c) Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter.
   d) Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.
   e) 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.
   f) Slowly release the device pressure to neutral.
   g) 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 contrast medium (diluted 1:1 with normal saline) prior to inserting into the body (repeat steps 5a through 5g, if necessary). Otherwise, complications may occur.

Instructions for Use

Note: Percutaneous introduction techniques and arteriotomy are both suitable when using introduction sets and guide wires.

1. Insert a guiding catheter fitted with a hemostatic adapter using standard technique. If necessary the guide wire lumen can be irrigated with physiological saline solution.
2. Insert a guide wire through the hemostatic valve following the manufacturer's instructions. Advance the guide wire carefully into and through the guiding catheter.
3. Attach a torque device to the guide wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.
4. Carefully introduce the balloon-tipped catheter over the proximal end of the guide wire until it approaches the hemonstatic valve. Open the hemonstatic valve insert the dilatation catheter while maintaining guide wire position and tighten the hemonstatic valve. To facilitate insertion, the balloon must be fully deflated to negative pressure.
5. 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 guide wire movement.

6. Slide the PTCA catheter forwards the lesion, position the usable section of the balloon across the lesion using the balloon radiopaque markers as reference points.

   Note: When using the dual wire technique, a DUOSTART (or equivalent) Dual Hemostatic Valve should be used and care taken when introducing, torqueing, and removing one or both wire to avoid entanglement. Guide wire should not be rotated more than 180 degrees in either direction during the dual wire procedure. It is recommended that one wire be completely withdraw from the patient before removing additional equipment.
7. Inflate the balloon to perform PTCA per standard procedure. Maintain negative pressure on the balloon between inflations. The inflation should be kept for a period of at least 30 seconds.
8. **Note: Do not exceed the rated burst pressure (RBP)** printed on the package label. The RBP and compliances of PTCA catheter are list in the table 1.
9. Withdraw the deflated dilatation catheter and guide wire from the guide catheter through the hemostatic valve. Tighten the hemostatic valve.
10. Dispose of the catheter per institutional standard for biohazardous materials.

Table 1. PTCA dilatation catheter compliance

Balloon Size	Pressure (atm-kPa)						
	6-608●	8-811	10-1013	12-1216	14-1419	16-1621▲	18-1824
1.00	1.00●	1.03	1.06	1.08	1.10	1.12▲	1.14
1.25	1.25●	1.29	1.33	1.37	1.40	1.43▲	1.46
1.50	1.50●	1.54	1.58	1.62	1.66	1.70▲	1.74
2.00	2.00●	2.04	2.08	2.12	2.16	2.20▲	2.24
2.25	2.25●	2.30	2.35	2.40	2.44	2.48▲	2.54
2.50	2.50●	2.55	2.60	2.65	2.70	2.75▲	2.80
2.75	2.75●	2.81	2.87	2.93	2.99	3.05▲	3.10
3.00	3.00●	3.07	3.14	3.21	3.28	3.35▲	3.41
3.25	3.25●	3.32	3.39	3.46	3.53	3.60▲	3.67
3.50	3.50●	3.58	3.66	3.73	3.80	3.87▲	3.94
4.00	4.00●	4.08	4.16	4.24	4.32	4.40▲	4.47

● Nominal Pressure ▲Rate Burst Pressure (Do not exceed Rate Burst Pressure)

Exchange Procedure Technique

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

1. Loosen the hemostatic valve.
2. Hold the guide wire and hemostatic valve in one hand, while grasping the balloon shaft in the other hand.
3. Maintain guide wire 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 opening in the guide wire lumen is reached. Carefully inch the flexible, distal portion of the balloon catheter off the guidewire while maintaining the guidewire position across the lesion.
5. Slide the distal tip of the dilatation catheter out of the hemostatic valve, and tighten onto the guide wire to hold it securely in place. Completely remove the dilatation catheter from the guide wire.
6. Prepare the next dilatation catheter to be use, as previously described in the Preparation For Use section.
7. Backload another dilatation catheter onto the guide wire as previously described under the instruction For Use Section, Step 4, and continue the procedure according.

References

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

Graphical Symbols for Medical Device Labeling

1		Manufacturer
2		Serial number
3		Batch code
4		Catalogue number
5		Date of manufacture

6		Sterilized using Ethylene Oxide
7		Do not reuse
8		Consult instructions for use
9		Keep away from sunlight
10		Keep dry
11		Do not use if package is damaged
12		Do not resterilize
13		Use by

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