Shunmei®

LOACH

CE 2764

INSTRUCTION FOR USE

PTCA Balloon Dilatation Catheter

CAUTION

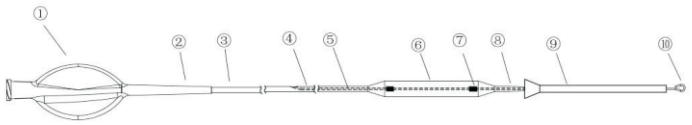
Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

PTCA balloon dilatation catheter is designed to allow rapid exchange of the catheter using a standard length 0.014 inch guidewire. Balloon diameters range from1.5mm to 4.0mm. The balloon material is made of a compliant material and balloons have a rated burst pressure of 16 atmospheres. The compliant material allows high pressure dilatation while maintaining precise control of the balloon diameter and length.

The PTCA balloon dilatation catheter is a sterile, single-use, non-pyrogenic and disposable device. The balloon has one (for ⌀1.5mm) or two (for ⌀1.75-4.0mm) radiopaque markers to aid in positioning the balloon in the stenosis and is designed to provide an expandable segment of known diameter and length at a specific pressure. The dilatation catheter is coated with hydrophilic coating, which is activated when wet.The proximal shaft of catheter is composed of a female luer connector (Hub) bonded to a PTFE coated stainless steel tube (Hypotube).

The target tissue of the PTCA Balloon Dilatation Catheter is coronary artery and the device contacts with blood. The device consists of 10 parts: hub, strain relief, hypotube,distal outer body, distal inner body, balloon, radiopaque marker band(s), catheter tip, balloon sheath, stylet (see **Figure 1**). no software and accessories.



①Hub ②strain relief ③Hypotube ④Distal Outer body ⑤Distal Inner body
⑥Balloon ⑦Radiopaque Marker Bands ⑧Catheter tip ⑨Balloon Sheath ⑩Stylet

Figure 1 Structure of PTCA Balloon Dilatation Catheter

INTENDED USE/ INDICATIONS

The PTCA balloon dilatation catheter is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

The catheter is contraindicated for use in:

- Unprotected left main coronary artery
- Coronary artery spasm in the absence of a significant stenosis
- Pregnancy

General surgical for PTCA applications contraindications:

- Coronary artery is stiff or calcified, eccentric stenosis
- Chronic total occlusive disease with severe calcification
- Multiple extensive diffuse lesions
- Patient with refractory heart failure (ejection fraction <35%)
- Severe (ventricular) arrhythmia

General surgical for PCI applications ontraindicatons:

- Hemorrhagic diseases
- Contrast agent allergy
- Those who are allergic to antiplatelet drugs and / or stent materials
- The target vessel diameter is less than 2.25mm
- Pre-expansion of severe calcified lesions is insufficient.
- Diseases with high complications and high mortality
- Diffusely diseased small-caliber artery or vein graft
- Other coronary conditions not amendable to PCI

WARNINGS

When using this type of device, the following warnings should be observed.

- This device is designed and intended for single use only. Do not reprocess, resterilize and/or reuse, as it can potentially compromise device performance and increase the risk of cross infection, which may lead to injury, illness or death of the patient.
- To reduce the incidence rate for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- 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 forcoronary 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 over pressurization.
- 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 it has become bent or kinked; this may result inthe catheter breaking.Instead, prepare a new catheter.
- The removal and dispose of the product should only be performed by surgeons who have received adequate training.
- Use the catheter prior to the “USE-BY DATE” specified on the package.

PRECAUTIONS

- Use the product in the period of validity specified on the package.
- This product is a kind of sterile non-pyrogenic product. Do not use if the package is damaged.
- Do not reinsert the catheter into the coil dispenser after procedural use.
- The usage and functions of this product must be known in details before using so as to ensure that its size is suitable for the specific procedure for which it is to be used, and to ensure safety and effectiveness in using.
- 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 surgeon.
- A manual pressure expansion device should be used, rather than an automatic expansion device.
- Purge the air and liquid inside the balloon before using.Do not use oil-based contrast medium, organic solvents or alcohols;there is a possibility of catheter leak, damage or lubrication loss.
- This device should be used only by surgeons trained in angiography of percutaneous transluminal coronary angioplasty.
- Discard all disposable devices used during this procedure per local requirements for medical device waste disposal.

POTENTIAL SIDE EFFECTS/ ADVERSE EVENTS

Adverse events or potential side effects associated with the use of the PTCA balloon dilatation catheter include, but are not limited to:

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

COMPLICATIONS

- Death
- Stroke
- Renal failure

HOW SUPPLIED

The PTCA balloon dilatation catheter is supplied sterilized by ethylene oxide gas and non-pyrogenic for single use only.

STORAGE

- Store the PTCA Balloon dilatation catheter in a clean, cool, dry and dark place to avoid extended exposure to light and moisture.
- Storage environment should be rat-proof and moth-proof in order to keep the integrity of package.
- Keep it from contacting corrosion gas.
- Storage temperature: 0°C to 40°C
- Storage humidity:≤ 80%

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) Prepare contrast medium (50:50 sterile mixture of a contrast medium and saline). Do not use the contrast medium which incorporates the components of Ethiodol, Lipiodol or same kind of agents.

2) Remove the stylet from the catheter tip; Slide the Sheath off the balloon.

3) Flush PTCA Balloon dilatation catheter: Attach a syringe filled with normal saline to the flushing tool, insert the flushing tool in the distal end of the catheter, and inject normal saline into the lumen. Follow this procedure for subsequent flushing.

4) Prepare an inflation device with the recommended contrast medium according to the manufacturer’s instructions.

5) Evacuate air from the balloon segment using the following procedure:

a. Fill a 20 cc syringe or the inflation device with approximately 4 cc of contrast medium.

b. 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.

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 20 cc 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 prior to inserting into the body, (repeat steps **5.a** through **5.g**, if necessary); otherwise, complication may occur.

6) Submerge the balloon in sterile normal saline during balloon preparation to activate the coating.

INSTRUCTIONS FOR USE

1) Insert a guide wire through the hemostatic valve following the manufacturer's instructions. Advance the guide wire carefully into and through the guiding catheter. When complete, withdraw the guide wire introducer, if used.

2) Attach a torque device to the guide wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel,then across the stenosis.

3) Back load the distal tip of the dilatation catheter onto the guide wire ensuring that the guide wire exits the notch (side hole of catheter).

Note: When back loading the dilatation catheter onto the guide wire, the dilatation catheter should be supported. In advancing the dilatation catheter into the guiding catheter,one's hand should support the dilatation catheter and firmly grasp the Hypotube. Shaft diameter differences should be taken into consideration when opening and tightening the hemostatic valve and upon withdrawal of the dilatation catheter.

4) Advance the dilatation catheter over the guide wire until it approaches the hemostatic valve. 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.

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) 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.

7) Advance the dilatation catheter over the guide wire and into the stenosis, continue under fluoroscopy and use the radiopaque marker bands to position the usable section of the balloon within stenosis.

8) 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.

9) Withdraw the deflated dilatation catheter and guide wire from the guiding catheter through the hemostatic valve. Tighten the hemostatic valve.

Caution: After the deflated balloon dilatation catheter is withdrawn, it should be wiped clean with gauze soaked with sterile, heparinized normal saline and stored. Prior to reinsertion, the balloon should be submerged in sterile, heparinized normal saline to reactivate the coating.

10) After the operation, the balloon dilatation catheter and other disposable device should be disposed according to local law.

EXCHANGE PROCEDURE TECHNIQUE

The balloon dilatation 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 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 guide wire lumen is reached. Carefully pull back the flexible, distal portion of the dilatation catheter out of the rotating hemostatic valve while maintaining the guide wire's position across the stenosis.

5) Slide the distal tip of the dilatation catheter out of the hemostatic valve,and tighten valve onto the guide wire 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 guide wire as previously described under the INSTRUCTION FOR USE section, step 3, and continue the procedure accordingly.

REPEAT APPLICAITONS

The product is applicable to repeat application. After the the product is applied to the patient, a few months or years later, some patients may have the same disease. When the doctor determines according to the patient's physical condition that the patient needs the same operation to treatment, this product can be used on these patients again.

JOINT USE DEVICES

Including Arterial Sheath, Guiding catheter, guide wire, syringe, Inflation device, Haemostasis valve.

CONFORMITY ASSESSMENT ROUTE

Annex II of MDD 93/42/EEC, including Section 4.

REFERENCES

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

DIFINITIONS

	Caution		Keep dry
LOT	Batch code		Non-pyrogenic
2 Sterilize	Do not resterilize		Do not use if package is damaged.
	Use-by date		Do not re-use
STERILE EO	Sterilized using ethylene oxide		Date of manufacture
REF	Catalogue number		Consult instructions for use
	Manufacturer		Keep away from sunlight
40℃ 0℃	Temperature limit	EC REP	Authorized representative in the European Community
CE	CE Marking	2764	Notified ID number
ϕ	Diameter		

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SM-IFU-PTCA(BDC)-001,A.6
Effective date: 2021.05.10