Pantera LEO

Fast-Exchange PTCA catheter

English

STERILE EO

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Description

The Pantera LEO fast-exchange PTCA catheter (hereinafter Pantera LEO PTCA catheter) is designed for dilatation of stenotic segments in coronary arteries and for post dilatation of coronary stents. The dilatation balloon is designed to inflate to a known diameter and length at recommended inflation pressures (refer to Compliance Chart on page 2). There are two radiopaque markers, one at the proximal end and one at the distal end of the cylindrical part of the balloon, to facilitate fluoroscopic visualization and positioning of the catheter. The proximal end of the catheter has a single female Luer-Lock port to inflate/deflate the balloon. The working length of Pantera LEO PTCA catheter is 145 cm. The proximal shaft of the catheter is a hypotube and the distal portion of the catheter is a flexible shaft. The surface of the catheter is coated as described in **Table 1** below:

Segment (mm)	Coating type
Balloon [Ø 2.0 – 5.0]	Hydrophobic
Distal shaft	Hydrophilic
Proximal shaft	Hydrophobic

Table 1: Coating surfaces of the Pantera Leo catheter sizes

The guide wire lumen starts at the catheter tip and ends at the guide wire exit port, 34 cm from the distal end. The Pantera LEO PTCA catheter is compatible with guide wires of 0.014" (0.36 mm) diameter and guiding catheters with an inner diameter ≥ 0.056" (1.42 mm). To indicate when the catheter tip exits from the guiding catheter, shaft exit markers are located on the hypotube 92 cm (brachial technique) and 102 cm (femoral technique) from the distal end of the Pantera LEO PTCA catheter. To facilitate the catheter handling, a "click-in" hypotube fastener has been applied to the catheter hub; this should be used when the catheter is stored on the preparation table.

Caution: This fastener is intended to hold only the hypotube section of the catheter, the distal shaft should not be held by the "click-in" fastener.

How Supplied

Sterile. Non-pyrogenic. Device is sterilized with ethylene oxide. DO NOT use if the package is opened or damaged, or if any information provided is obscured or damaged.

Contents

- One (1) Pantera LEO PTCA catheter in a sealed, peel open pouch.
- One (1) Instructions for Use Manual.
- One (1) Compliance Chart.

Storage

Store in a dark, dry location between 10°C and 40°C/ 50°F and104°F.

Indications

The Pantera LEO PTCA catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion and for post dilatation of coronary stents.

Contraindications

All general contraindications for percutaneous transluminal coronary angioplasty (PTCA) are contraindications for this device.
Contraindications for this device and percutaneous transluminal coronary angioplasty (PTCA) in general are:

- Lesions that cannot be reached or treated with the system.
- Target vessel unprotected left main coronary artery.
- Coronary artery spasm in the absence of a significant stenosis.

Furthermore, all procedure-related contraindications as described in the national and international guidelines of the respective medical associations apply.

Warnings

- This device is designed and intended for single use only. DO NOT resterilise and/or reuse. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure. BIOTRONIK will not be responsible for any direct, incidental or consequential damages resulting from resterilisation or reuse.
- DO NOT use the catheter if the outer or the inner package is damaged or opened.
- Use prior to the "use by" date.
- DO NOT expose the catheter to organic solvents, e.g., alcohol.
- Use only an appropriate balloon inflation medium (e.g., 50:50 mixture by volume of contrast medium and saline). Never use air or any gaseous medium to inflate the balloon.
- When the catheter is in the body, it should be manipulated under high-quality fluoroscopy.
- DO NOT torque the catheter more than one (1) full turn.
- DO NOT advance or retract the catheter unless the balloon is fully deflated under vacuum. If strong resistance is met during manipulation, stop the procedure and determine the cause of the resistance before proceeding. Advancement by force may result in damage to the vessel and/or laceration or separation of the guide wire or dilatation catheter. This may necessitate recovery of fragments.
- Balloon pressure should not exceed the Rated Burst Pressure (RBP). Use of a pressure monitoring device is mandatory to prevent over-pressurization.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the original diameter of the vessel proximal and distal to the stenosis.

Precautions

- Prior to procedure, the 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.
- PTCA placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Only physicians thoroughly trained and educated in the performance of PTCA should use the catheter system.
- Exercise care during handling to reduce the possibility of accidental breakage, bending or kinking of the catheter shaft.
- Ensure that the guide wire exit port remains inside the guiding catheter at all times. Guide wire exit port is indicated on the label.
- Appropriate anticoagulant, antiplatelet and vasodilatation therapy should be administered to the patient.
- Use only guide wires with a 0.014" (0.36 mm) diameter. When using two guide wires, care should be taken when introducing, torquing and removing one or both guide wires to avoid entanglement or spiralling. Caution should be applied not to damage the Pantera LEO PTCA catheter with the second guide wire during the advancement and the retrieval.
- Use guiding catheters with an inner diameter ≥ 0.056" (1.42 mm).
- The hypotube fastener is intended to hold only the hypotube section of the catheter; the distal shaft should not be held by the "click-in" fastener.
- Do not use the Pantera LEO PTCA catheter if a vacuum can not be held, as this indicates a system failure.

Potential Adverse Events/Complications

Possible adverse events associated with PTCA procedure include, but are not limited to:

- Cardiac events: Myocardial infarction or ischemia, abrupt closure of coronary target vessel, restenosis of treated vessel, cardiogenic shock, angina, tamponade, perforation or dissection of coronary artery or aorta, cardiac perforation, emergency cardiac surgery, pericardial effusion, aneurysm formation.
- Arrhythmia events: Ventricular tachycardia, ventricular fibrillation, atrial fibrillation, bradycardia.
- Balloon catheter events: Failure to reach or cross the lesion, inflation difficulties, rupture or pinhole of the balloon, deflation difficulties, withdrawal difficulties, embolization of catheter material.
- Respiratory events: Acute pulmonary edema, congestive heart failure, respiratory insufficiency or failure.
- Vascular events: Access site hematoma, hypotension/ hypertension, pseudoaneurysm, arteriovenous fistula formation, retroperitoneal hematoma, vessel dissection, rupture or perforation, intimal tear, vessel recoil and restenosis, thrombosis or occlusion, vasospasm, peripheral ischemia, distal embolization (air, tissue debris, thrombus).
- Neurologic events: Permanent (stroke) or reversible (TIA) neurologic event, femoral nerve injury, peripheral nerve injury.
- Bleeding events: Access site bleeding or hemorrhage, hemorrhage requiring transfusion or other treatment.
- Allergic reactions to contrast media, antiplatelets, anticoagulants.
- Death.
- Infections.

Directions for use

Select an appropriate Pantera LEO PTCA catheter for the target vessel. The inflation diameter of the balloon must not exceed the diameter of the coronary artery or bypass graft proximal or distal to the stenosis. If the stenosis cannot be crossed with the desired dilatation catheter, a smaller diameter PTCA catheter can be used to predilate the lesion.

PTCA catheter preparation

01. Take the protection ring with the catheter out of the package and place it onto a sterile field.
02. Gently pull out the catheter from the protection ring.
03. Remove the balloon protector and the stylet.

Pre-flush guide wire lumen

04. Connect a syringe containing sterile saline to an appropriately sized flushing needle.
05. Apply the needle into the distal tip of the catheter and flush the guide wire lumen.
06. Remove the syringe and the flushing needle.

Purge air from the catheter

07. Connect a 3-way stopcock to the Luer-Lock of the catheter.
08. Prepare and remove air from the inflation/deflation device according to manufacturer's recommendations and instructions.
09. Attach the inflation/deflation device containing 3 ml of balloon inflation medium to the stopcock.

Warning: Use only an appropriate balloon inflation medium (e.g., 50:50 mixture by volume of contrast medium and saline). Never use air or any gaseous medium to inflate the balloon.

10. Open the stopcock so that the fluid path between the catheter and the inflation/deflation device is established.
11. Pull the plunger of the inflation/deflation device and aspirate air from the catheter for at least 30 seconds.

Caution: DO NOT use the Pantera LEO PTCA catheter if a vacuum cannot be held, as this indicates a system failure.

12. Close the stopcock so that the fluid path to the catheter is closed and evacuate all air from the inflation/deflation device through the stopcock.
13. Repeat steps 10-12 if necessary, to ensure air contained in the balloon and inflation lumen are removed. Release the inflation/deflation barrel to normal pressure.
14. Open the stopcock and set the system aside for use.

Insertion technique

15. Attach a hemostatic valve to the Luer-port of the guiding catheter positioned within the vasculature.
16. Position the guide wire under fluoroscopy, in accordance with PTCA techniques.
17. Back load the proximal end of the guide wire, into the distal tip of the PTCA catheter until it exits at the guide wire exit port 34 cm from the distal tip.
18. Carefully insert the PTCA catheter through the hemostatic valve.
19. Advance the PTCA catheter through the guiding catheter using fluoroscopic guidance to determine when the catheter tip approaches the distal tip of the guiding catheter.

Note: The two proximal exit markers may be used to approximate when the PTCA catheter has reached the distal end of the guiding catheter.

20. Advance the PTCA catheter into the target vessel and following the guide wire toward the lesion.

Note: The radiopaque balloon markers facilitate balloon positioning within the lesion.

Warning: If strong resistance is met during manipulation, stop the procedure and determine the cause of the resistance before proceeding. Advancement by force may result in damage to the vessel and/or laceration or separation of the guide wire or the PTCA catheter. This may necessitate recovery of fragments.

Balloon inflation

21. Inflate the balloon to dilate the lesion using standard PTCA techniques.

Warning: Do not exceed a total of 16 inflations.

Warning: DO NOT exceed RBP.

Warning: To reduce the potential for vessel damage, the inflated diameter of the balloon must not exceed the original diameter of the vessel proximal and distal to the lesion.

22. If a significant stenosis persists, inflate the balloon again increasing pressure gradually until the lesion fails to improve.
23. After each inflation, assess the distal coronary blood flow by arteriography through the guiding catheter.

Balloon deflation

24. Deflate the balloon in accordance with the standard PTCA procedures. Apply negative pressure to the balloon for at least 40 seconds before carefully pulling the PTCA catheter out of the target vessel.
25. Pull the completely deflated PTCA catheter into the guiding catheter.

Catheter removal/Exchange procedure

26. Loosen the hemostatic valve.
27. Hold the guide wire and hemostatic valve in one hand, while grasping the PTCA catheter shaft in the other hand.
28. Maintain the guide wire position in the coronary artery by keeping the guide wire stationary, and begin pulling the dilatation catheter out of the guiding catheter.

Note: Monitoring the guide wire position under fluoroscopy is highly recommended during the exchange.

29. Pull on the catheter until the guide wire exit port is reached. Carefully remove the flexible, distal portion of the PTCA catheter off the guide wire while maintaining the guide wire position across the lesion. Close the hemostatic valve.

Note: In case of difficulties during catheter removal, remove the entire system at once, i.e., the guiding catheter, the guide wire and the PTCA catheter simultaneously.

30. Completely remove the PTCA catheter from the guide wire.
31. If required, prepare and introduce the next PTCA catheter to be used, as previously described or following the indications of the manufacturer.

Note: Inspect the PTCA catheter integrity immediately upon removal from the patient.

32. After use dispose the product and packaging in accordance with hospital, administrative and/or local government policy.

Warranty/Liability

The product and each component of its system (hereinafter "the product") have been designed, manufactured, tested and packaged with all reasonable care. However, BIOTRONIK has no control over the conditions under which the product is used and a disturbance of the intended function of the product may occur for various reasons. In this respect, the warnings in this product publication/ instructions for use are expressly to be considered as an integral part of this Disclaimer and provide more detailed information. For this reason, BIOTRONIK disclaims all warranties, expressed or implied regarding the product, including but not limited to, any warranty of merchantability or fitness for a particular purpose of the product. Product descriptions or user guidelines in publications do not constitute any expressed representation or any expressed or implied warranty. BIOTRONIK is not liable for any direct, incidental or consequential damages or medical expenses caused by any use, defect, failure or malfunction of the product whether the claim is based on contract, warranty, tort or otherwise. This does not apply in the case of intention or in the case of gross negligence of legal representatives or executive staff of BIOTRONIK. In commercial transactions relating to merchants, the liability is limited to the compensation of typical damages; compensation for any untypical or incidental damage is excluded. These limitations of liability and warranty are not intended to contravene any mandatory provisions of law applicable in the respective country. If any clause of the Disclaimer is considered by a competent court to be invalid or to be in conflict with the applicable law, the remaining part of it shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause which best reflects BIOTRONIK's legitimate interest in limiting its liability or warranty without infringing any mandatory provisions of applicable law. No person has any authority to bind BIOTRONIK to any warranty or liability regarding the product.

Symbol legend

STERILE EO	Sterilized using ethylene oxide	NP	Nominal pressure
	Do not reuse	RBP	Rated burst pressure
	Caution	LOT	Batch code
	Keep dry	REF	Catalogue number
	Keep away from sunlight		Use by
	Temperature limitation		Consult instructions for use
STERILIZE	Do not resterilize		Manufacturer
	Do not use if package is damaged		Date of Manufacture
NC	NC means non-compliant and relates ro radial balloon expansion which remains minimal between nominal and rated burst pressure		

Compliance Chart

	Inflation Pressure		Balloon Diameter (mm)										
	atm	(kPa)	2.0	2.25	2.5	2.75	3.0	3.25	3.5	3.75	4.0	4.5	5.0
	6	(608)	1.93	2.16	2.41	2.65	2.89	3.12	3.36	3.57	3.85	4.38	4.86
	8	(811)	1.95	2.18	2.43	2.68	2.92	3.15	3.40	3.61	3.89	4.41	4.90
	10	(1216)	1.96	2.21	2.45	2.70	2.94	3.19	3.43	3.66	3.92	4.44	4.93
	12	(1216)	1.98	2.23	2.48	2.73	2.97	3.22	3.47	3.70	3.96	4.47	4.97
NP	**14**	**(1419)**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.25**	**3.50**	**3.75**	**4.00**	**4.50**	**5.00**
	15	(1520)	2.01	2.26	2.51	2.76	3.01	3.27	3.52	3.77	4.02	4.52	5.02
	16	(1621)	2.02	2.27	2.52	2.77	3.03	3.28	3.54	3.80	4.04	4.53	5.04
	17	(1723)	2.03	2.28	2.54	2.79	3.04	3.30	3.55	3.82	4.06	4.55	5.05
RBP	**18**	**(1824)**	2.04	2.30	2.55	2.80	3.06	3.32	3.57	3.84	4.08	**4.56**	**5.07**
	19	(1925)	2.05	2.31	2.56	2.81	3.07	3.33	3.59	3.87	4.10	4.58	5.09
RBP	**20**	**(2027)**	**2.05**	**2.32**	**2.57**	**2.83**	**3.09**	**3.35**	**3.61**	**3.89**	**4.12**	4.60	5.11
	21	(2128)	2.06	2.33	2.58	2.84	3.10	3.37	3.62	3.92	4.14	4.61	5.12
	22	(2229)	2.07	2.34	2.60	2.85	3.11	3.38	3.64	3.94	4.16	4.63	5.14

NP	**In vitro testing has shown that the balloons will reach their nominal size at given Nominal Pressure.**
RBP	**In vitro testing has shown that with 95% confidence, 99.9% of the balloons will not burst at or below Rated Burst Pressure. DO NOT exceed RBP.**

Sizes

	Balloon Diameter (mm)										
Balloon Length (mm)	2.0	2.25	2.5	2.75	3.0	3.25	3.5	3.75	4.0	4.5	5.0
8	X	X	X	X	X	X	X	X	X	X	X
12	X	X	X	X	X	X	X	X	X	X	X
15	X	X	X	X	X	X	X	X	X	X	X
20	X	X	X	X	X	X	X	X	X	X	X
30	X	X	X	X	X	X	X	X	X	X	X

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