Expanding Your **Options** With The Addition Of **018 DCB**

The LUTONIX® 018 DCB brings the performance of the LUTONIX® drug coating technology to an 018 platform. LUTONIX® 018 offers a comprehensive size matrix to **treat femoropopliteal lesions without the need to exchange to an .035" wire.**

LUTONIX® 018

Drug Coated Balloon PTA Catheter

Balloon Diameter (mm)	Balloon Length (mm)						
	40	60	80	100	120	150	220
4	4F	4F	4F	4F	4F	4F	4F
5	5F	5F	5F	5F	5F	5F	5F
6	5F	5F	5F	5F	5F	5F	
7	5F	5F	5F	5F			

BD

LUTONIX® 018
Drug Coated Balloon PTA Catheter

1. Data on file. Bard Peripheral Vascular, Inc. Tempe, AZ. 4 x 220 mm LUTONIX® 035 DCB N=25, 4 x 220 LUTONIX® 018 DCB N = 30. Bench test results may not necessarily be indicative of clinical performance. Different tests may yield different results.
2. Primary efficacy endpoint is defined as freedom from TLR at 12 months. Total of 648 subjects were evaluable for the primary efficacy endpoint analysis. The 12 month TLR Free rate by subject counts at 12 months was 93.4%. The Kaplan-Meier estimates TLR-Free survival was 94.1% at 12 months and 90.3% at 24 months. TLR-Free survival by lesion location was 94.7% (n=483) for SFA, 92.9% (n=86) for popliteal, and 92.3% (n=121) for patients with lesions in both SFA and popliteal. Data on file, Bard Peripheral Vascular, Inc.

LUTONIX® 018 Drug Coated Balloon PTA Catheter

1. INTENDED USE / INDICATIONS FOR USE

The Lutonix® 018 Drug Coated Balloon Catheter is intended for Percutaneous Transluminal Angioplasty (PTA) in the femoropopliteal artery and for the treatment of obstructive lesions and decreasing the incidence of restenosis.
In addition, the Lutonix® 018 Drug Coated Balloon Catheter is intended for PTA of native dialysis fistulae or synthetic grafts to improve blood flow and decrease the incidence of restenosis.
The Lutonix® 018 Drug Coated Balloon Catheter is intended for treatment up to 290 mm in lesions length or approximately a total drug coating quantity of 7.6 mg paclitaxel per patient.

2. CONTRAINDICATIONS

The Lutonix® Catheter is contraindicated for use in:
- Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy.
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and there is a potential for adverse reaction in nursing infants from paclitaxel exposure.
- Pediatric patients. The safety and effectiveness of the Lutonix® Catheter in pediatric patients has not been established.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.
- This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds.

3. WARNINGS

- A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.
- Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged or opened prior to intended use.
- Do not use if product damage is evident.
- Do not use after the "Use By" date.
- The Lutonix® Catheter is for use in one patient only; do not reuse in another patient, reprocess or resterilise. Risks of reuse in another patient, reprocessing, or resterilisation include:
  — Compromising the structural integrity of the device and/or device failure which, in turn, may result in patient injury, illness or death.
  — Creating a risk of device contamination and/or patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to patient injury, illness or death.
- Do not exceed the Rated Burst Pressure (RBP) recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over-pressurisation, use of a pressure monitoring device is recommended.
- Use the recommended balloon inflation medium of contrast and sterile saline (≤ 50% contrast). Never use air or any gaseous medium to inflate the balloon.
- The safety and effectiveness of the Lutonix® Catheter have not been established for treatment in cerebral, carotid, coronary, renal vasculature or mesenteric arteries.

4. PRECAUTIONS

4.1 General Precautions
- The Lutonix® Catheter should only be used by physicians trained in percutaneous interventional procedures.
- Consideration should be given to the risks and benefits of use in patients with a history of non-controllable allergies to contrast agents.

4.2 Use in Conjunction with Other Procedures
The safety and effectiveness of the Lutonix® Catheter used in conjunction with other drug eluting stents or drug coated balloons in the same procedure or following treatment failure has not been evaluated.

4.3 Device Handling Precautions
- Do not immerse the Lutonix® Catheter in a saline bath. Replace any device where the balloon has come into contact with fluids prior to use.
- The coated balloon portion should be handled with dry sterile gloves whenever possible prior to use.
- The balloon protector should stay in place during preparation of the Lutonix® Catheter and not be removed until just prior to placing over guidewire.
- If difficulty is encountered while removing the balloon protector, a new Lutonix® Catheter should be utilised. Removing the balloon protector by force can cause a kink in the catheter shaft and lumen constriction may occur, affecting inflation/deflation of the balloon.

4.4 Device Use/Procedure Precautions
- The Lutonix® Catheter should always be manipulated with adequate visualisation technique when in the body.
- Appropriate vessel preparation, such as predilatation, is recommended to achieve optimal DCB results. Successful pre-dilation is defined as of ≤ 30% residual stenosis.
- Always advance and retrieve the Lutonix® Catheter under negative pressure.
- After insertion, do not over-tighten the hemostatic adaptor (if used) around the Lutonix® Catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.
- To ensure therapeutic drug delivery:
  — Never inflate the Lutonix® Drug Coated Balloon prior to reaching the target lesion.
  — The Lutonix® Catheter should be advanced to the target site as fast as possible (i.e. ≤ 30 seconds) and immediately inflated to appropriate pressure to ensure full wall apposition (balloon to vessel ratio of ≥ 1:1). If the deployment of the Lutonix® Catheter exceeds 3 minutes, the catheter requires replacement with a new unit.
- Maintain balloon inflation for a minimum of 2 minutes (120 seconds). The balloon may remain inflated as long as is required by the standard of care to achieve a good angioplasty outcome.
- Do not continue to use the Lutonix® Catheter if the shaft has been bent or kinked.
- Whenever possible, the Lutonix® Catheter should be the final treatment of the vessel; however, post-dilatation is allowed with another PTA catheter or the previously used Lutonix® catheter. Best outcomes are obtained when the final % diameter stenosis is 0 – 20%.

4.5 Pre- and Post-Procedure Antiplatelet Regimen
If applicable, dual antiplatelet therapy should be administered according to current medical standards pre-procedure and for a minimum of 4 weeks after the intervention. Prolonged antiplatelet therapy can be given at the discretion of the physician.

SFA & Popliteal Drug Coated Balloon Product Codes

Diameter (mm)	Length (mm)	Sheath Profile		100 cm Catheter Length
4	40	4F	☐	9111410400040
	60	4F	☐	9111410400060
	80	4F	☐	9111410400080
	100	4F	☐	9111410400100
	120	4F	☐	9111410400120
	150	4F	☐	9111410400150
	220	4F	☐	9111410400220
5	40	5F	☐	9111410500040
	60	5F	☐	9111410500060
	80	5F	☐	9111410500080
	100	5F	☐	9111410500100
	120	5F	☐	9111410500120
	150	5F	☐	9111410500150
	220	5F	☐	9111410500220
6	40	5F	☐	9111410600040
	60	5F	☐	9111410600060
	80	5F	☐	9111410600080
	100	5F	☐	9111410600100
	120	5F	☐	9111410600120
	150	5F	☐	9111410600150
7	40	5F	☐	9111410700040
	60	5F	☐	9111410700060

Diameter (mm)	Length (mm)	Sheath Profile		130 cm Catheter Length
4	40	4F	☐	9111413400040
	60	4F	☐	9111413400060
	80	4F	☐	9111413400080
	100	4F	☐	9111413400100
	120	4F	☐	9111413400120
	150	4F	☐	9111413400150
	220	4F	☐	9111413400220
5	40	5F	☐	9111413500040
	60	5F	☐	9111413500060
	80	5F	☐	9111413500080
	100	5F	☐	9111413500100
	120	5F	☐	9111413500120
	150	5F	☐	9111413500150
	220	5F	☐	9111413500220
6	40	5F	☐	9111413600040
	60	5F	☐	9111413600060
	80	5F	☐	9111413600080
	100	5F	☐	9111413600100
	120	5F	☐	9111413600120
	150	5F	☐	9111413600150
7	40	5F	☐	9111413700040
	60	5F	☐	9111413700060
	80	5F	☐	9111413700080
	100	5F	☐	9111413700100

I authorise the purchase of these products.

PHYSICIAN NAME	PHYSICIAN SIGNATURE	REPRESENTATIVE'S NAME	CONTACT PHONE NO.

CE 2797

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

 BPV/LTNX/1118/0275a(1)

BD