Deliver More With
The Only 018 DCB*

LUTONIX® 018
Drug Coated Balloon PTA Catheter
Choose the DCB that gives you more of what you need to deliver safe and effective treatment to your patients.

more
Options with 018

The LUTONIX® 018 DCB is designed to:
- Perform over small guidewires (up to .018”)
- Reduce guidewire exchanges
- Enable alternative access

more
From a Leading Platform

LUTONIX® 018 was built on the proven ULTRAVERSE® 018 platform and features:
- Enhanced Pushability – Reinforced inner lumen provides axial strength
- Improved Visibility – Larger, dual distal marker bands on long lengths
- GEOALIGN® Marking System – Facilitates simple repeat catheter alignment at the lesion
more
Crossability

With a crossing profile 20% lower than the lowest profile 035 DCB\(^1\), LUTONIX\(^\circledR\) 018 was built to:

- Cross tight lesions
- Navigate tortuous anatomy
- Reliably deliver drug to complex lesions

The LUTONIX\(^\circledR\) 018 DCB utilizes the same proven drug coating formulation as the LUTONIX\(^\circledR\) 035 DCB, which demonstrated outstanding 24 month freedom from TLR in the following patient groups\(^2\):  
  - ISR Subgroup: 84.6%
  - Long Lesion Subgroup: 88.2%
  - All Patients: 90.3%


**LUTONIX® 018 Drug Coated Balloon PTA Catheter**

* As of December 2018, on the US market.


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 was 93.1% (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**

**Indications for Use:** The LUTONIX® 018 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 300mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7mm. The LUTONIX® 018 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, for treatment of stenotic lesions of dysfunctional native arteries and vein grafts with satisfactory pressure gradients. Additionally, it is used for the treatment of restenotic lesions of SFA and popliteal arteries. The drug coating includes paclitaxel (4 mg/mm), which is a potential for adverse reaction in nursing infants from paclitaxel exposure. 3) Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.

**Warnings:** 1) Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged or opened prior to intended use. 2) Do not use after 'Use by' date. 3) Do not use if product damage is evident. 4) The LUTONIX® Catheter is for use in one patient only; do not reuse in another patient, reprocess or sterilize. Risk of reuse in another patient, reprocessing or sterilization include: 1a) Compromising the structural integrity of the device and/or device failure which, in turn, may result in patient injury, illness or death. 2b) 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. 4b) 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. 5) Do not exceed the Rated Burst Pressure (RBP) recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. 6) To prevent balloon burst, use of a pressure monitoring device is recommended. 6) Use the recommended balloon inflation medium of contrast and sterile saline (≤50% contrast). 7) Never use air or any gaseous medium to inflate the balloon as this may cause air emboli in case of balloon burst. 7) This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds, as this may cause allergic reaction difficulty in breathing, skin rash, muscle pain.

**Precautions:** General precautions: 1) The LUTONIX® Catheter should only be used by physicians trained in percutaneous interventional procedures. 2) Consideration should be given to the risks and benefits of use in patients with a history of non-controllable allergies to contrast agents. 3) The safety and effectiveness of the LUTONIX® Catheter have not been established for treatment in cerebral, carotid, coronary, or renal vasculature. 4) For SFA application, the safety and effectiveness of using more than four Lutonix drug coated balloons or a maximum drug coating quantity of approximately 15.1 mg paclitaxel in a patient has not been clinically evaluated. 5) For AV Fistula application, the safety and effectiveness of using multiple Lutonix drug coated balloons that deliver greater than 7.6 mg paclitaxel in a patient has not been clinically evaluated. Potential adverse events which may be associated with a peripheral balloon dilation procedure include, but are not limited to the following: - Additional infection - Allergic reaction to drugs, excipients or contrast medium - Amputation/loss of limb (SFA) - Anemia or pseudoeuglobulinemia - Arthritis/Embolism - Embolism - Hematoma - Herniorrhage, including bleeding at the puncture site - Hypotension/hypertension - Inflammation - Loss of permanent access (AVF) - Occlusion - Pain or tenderness - Pneumothorax or hemothorax (SFA) - Sepsis/infection - Shock - Stroke Syndrome (AVF) - Stroke-Thrombosis - Vessel dissection, perforation, rupture, or spasm - Although systemic effects are not anticipated, refer to the Physicians’ Desk Reference for more information on the potential adverse events observed with paclitaxel.

**Potential adverse events, not described in the above source, which may be unique to the paclitaxel drug coating include, but are not limited to the following: - Allergic immunologic reaction to the drug coating (paclitaxel) - Alopecia - Anemia - Blood product transfusion - Gastrointestinal symptoms - Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) - Hepatic enzyme changes - Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis - Myalgia/Arthralgia - Myelosuppression - Peripheral neuropathy - Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions. F<sup>®</sup> © 2019 BD, BD, the BD logo, Bard, and Lutonix are the property of Becton, Dickinson and Company. All other trademarks are property of their respective owners. Illustrations by Mike Austin. Copyright © 2018. All Rights Reserved. Bard Peripheral Vascular, Inc. | www.bardpv.com | BD-10869

**I authorize the purchase of these products.**

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**PHYSICIAN SIGNATURE**

**REPRESENTATIVE’S NAME**

**CONTACT PHONE NO.**