Deliver More with the Only 018 DCB*

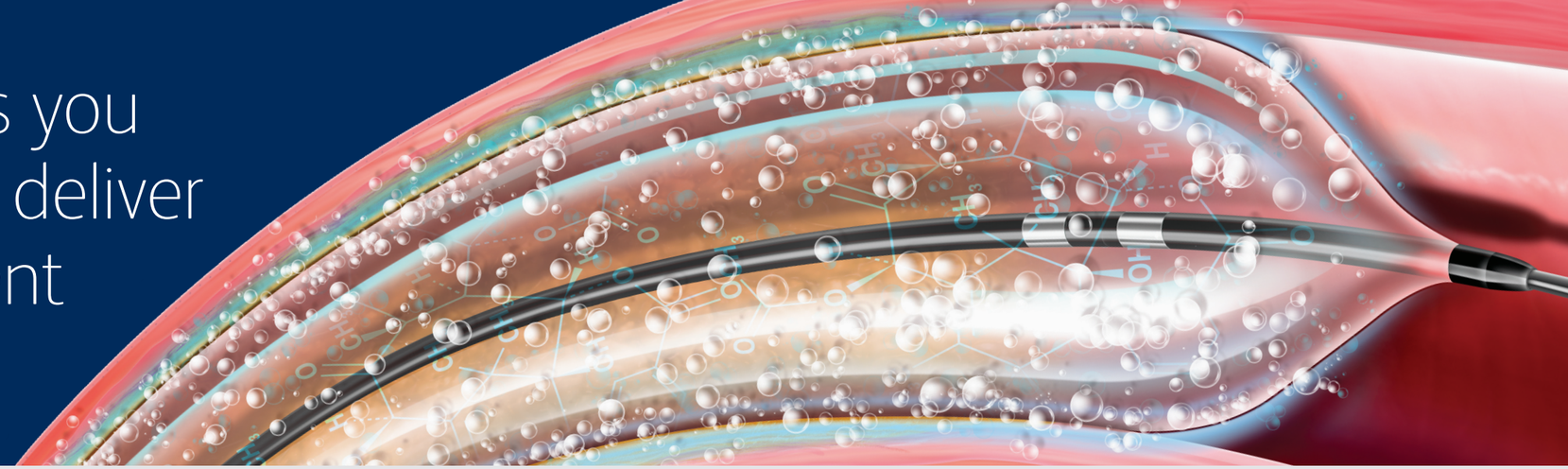
Lutonix™ 018

Drug Coated Balloon PTA Catheter

* As of February 2020

BD

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 0.018")
- Reduce guidewire exchanges
- Enable alternative access

Longest DCB Available* - Lengths up to 300 mm

Balloon Length (mm)

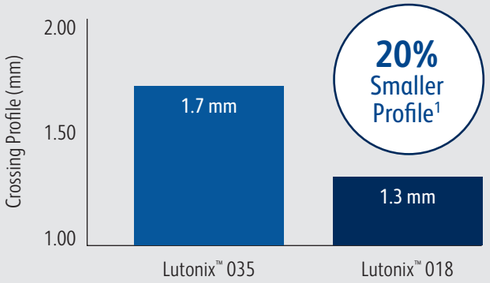
Balloon Diameter (mm)	40	60	80	100	150	220	**300**
4	4F	4F	4F	4F	4F	4F	**5F**
5	5F	5F	5F	5F	5F	5F	**5F**
6	5F	5F	5F	5F	5F	5F	**5F**
7	5F	5F	5F	5F	5F	5F	

ALL SIZES 5F OR LESS

More Crossability

With a crossing profile **20% lower than the lowest profile 035 DCB**[1], Lutonix™ 018 was builit to:

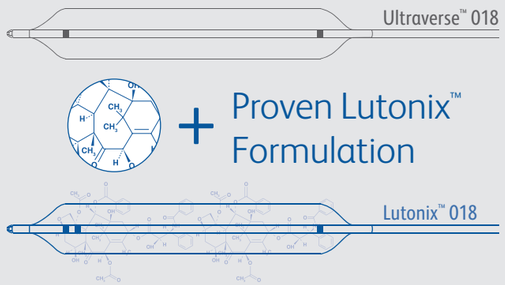
- Cross tight lesions
- Navigate tortuous anatomy
- Reliably deliver drug to complex lesions



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 Long Term Efficacy

The Lutonix™ 018 DCB utilizes the same **proven drug coating formulation** as the Lutonix™ 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%

90.3%
Freedom from TLR at 24 Months[2]

Diameter (mm)	Length (mm)	Sheath Profile	100 cm Catheter Length
4	40	4F	☐ LX181004404F
	150	4F	☐ LX1810041504F
	220	4F	☐ LX1810042204F
	300	5F	☐ LX1810043005F
5	40	5F	☐ LX181005405F
	150	5F	☐ LX1810051505F
	220	5F	☐ LX1810052205F
	300	5F	☐ LX1810053005F
6	40	5F	☐ LX181006405F
	150	5F	☐ LX1810061505F
	220	5F	☐ LX1810062205F
	300	5F	☐ LX1810063005F
7	40	5F	☐ LX181007405F
	150	5F	☐ LX1810071505F

Diameter (mm)	Length (mm)	Sheath Profile	130 cm Catheter Length
4	40	4F	☐ LX181304404F
	60	4F	☐ LX181304604F
	80	4F	☐ LX181304804F
	100	4F	☐ LX1813041004F
	150	4F	☐ LX1813041504F
	220	4F	☐ LX1813042204F
	300	5F	☐ LX1813043005F
5	40	5F	☐ LX181305405F
	60	5F	☐ LX181305605F
	80	5F	☐ LX181305805F
	100	5F	☐ LX1813051005F
	150	5F	☐ LX1813051505F
	220	5F	☐ LX1813052205F
	300	5F	☐ LX1813053005F
6	40	5F	☐ LX181306405F
	60	5F	☐ LX181306605F
	80	5F	☐ LX181306805F
	100	5F	☐ LX1813061005F
	150	5F	☐ LX1813061505F
	220	5F	☐ LX1813062205F
	300	5F	☐ LX1813063005F
7	40	5F	☐ LX181307405F
	60	5F	☐ LX181307605F
	80	5F	☐ LX181307805F
	100	5F	☐ LX1813071005F
	150	5F	☐ LX1813071505F
	220	5F	☐ LX1813072205F

I authorize the purchase of these products.

PHYSICIAN NAME

PHYSICIAN SIGNATURE

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

* As of January 2020; on the US market

[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

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 arteriovenous dialysis fistulae that are 4 mm to 7 mm in diameter and up to 80 mm in length.

Contraindications: The Lutonix™ Catheter is contraindicated for use in: **1)** Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy (SFA). **2)** Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children over the next to two years. 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. **3)** Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.

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 device exposure Inadequate information is available to evaluate the potential mortality risk associated with the use of paclitaxel-coated devices for the treatment of other diseases/conditions, including this device indicated for use in arteriovenous dialysis fistulae. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients. See Section 10.1 for further information. **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 resterilize. Risks of reuse in another patient, reprocessing, or resterilization include: **4a)** Compromising the structural integrity of the device and/or device failure which, in turn, may result in 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. To prevent over-pressurization, use of a pressure monitoring device is recommended. **6)** Use the recommended balloon inflation medium of contrast and sterile saline (≤50% contrast). 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 dilatation procedure include, but are not limited to the following: · Additional intervention · Allergic reaction to drugs, excipients or contrast medium · Amputation/loss of limb (SFA) · Aneurysm or pseudoaneurysm · Arrhythmias · Embolization · Hematoma · Hemorrhage, 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 · Steal 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. ℞ only

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