A Step Ahead in SFA Treatment

LUTONIX® 035 | 5F

Drug Coated Balloon PTA Catheter

BD

BARD

has joined BD

Enhance Your SFA Treatment Algorithm

The LUTONIX® 035 Drug Coated Balloon PTA Catheter is both a **proven**, **effective stand-alone treatment option**, as well as an **enhancement to any treatment algorithm**.

The LUTONIX® 035 Drug Coated Balloon PTA Catheter is based upon **PTA technology**, and is similarly **versatile and easy to use**.

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Maximizing Efficacy Without Compromising Safety

A drug coated balloon (DCB) is comprised of three main components: a balloon, a drug, and a carrier.

The drug coating of the LUTONIX® 035 is designed to **inhibit restenosis** in the arterial wall while allowing the lumen to **restore and reendothelialize**.

DRUG

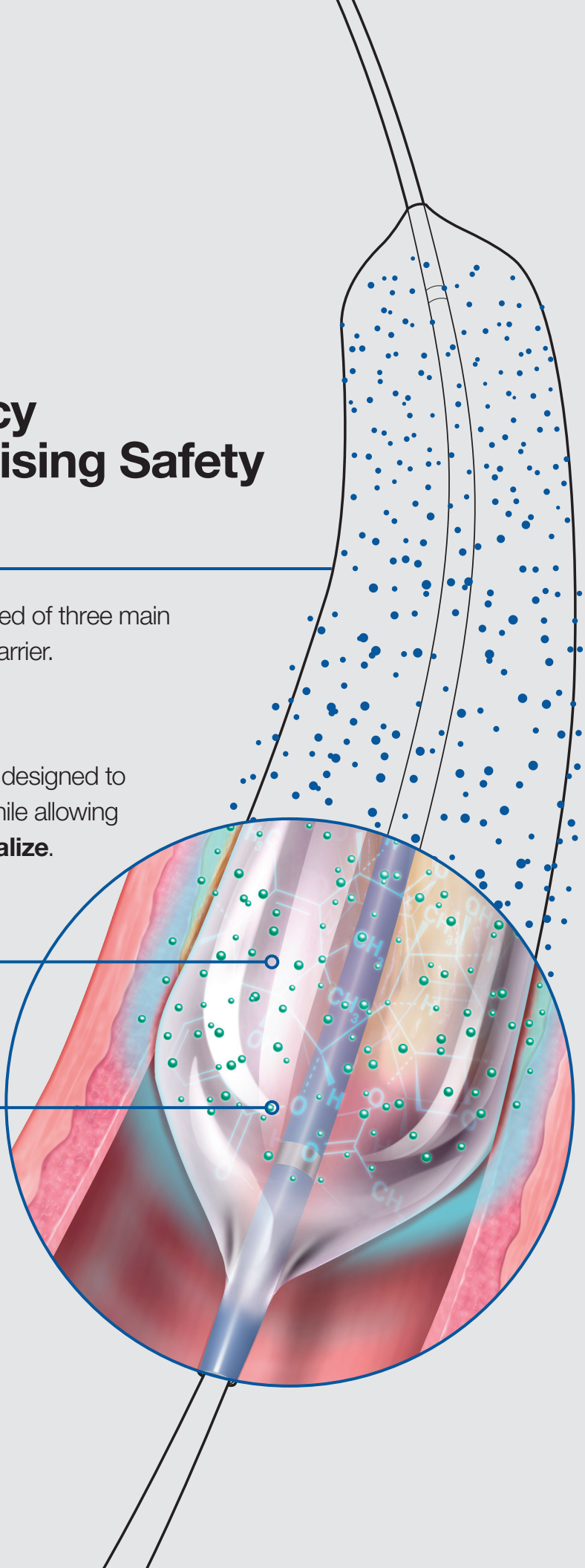
LUTONIX® 035 DCB drug dose of paclitaxel is 2 µg/mm^2

+ CARRIER

Polysorbate and sorbitol

= COATING

Facilitate therapeutic drug retention and release of drug at the treatment site

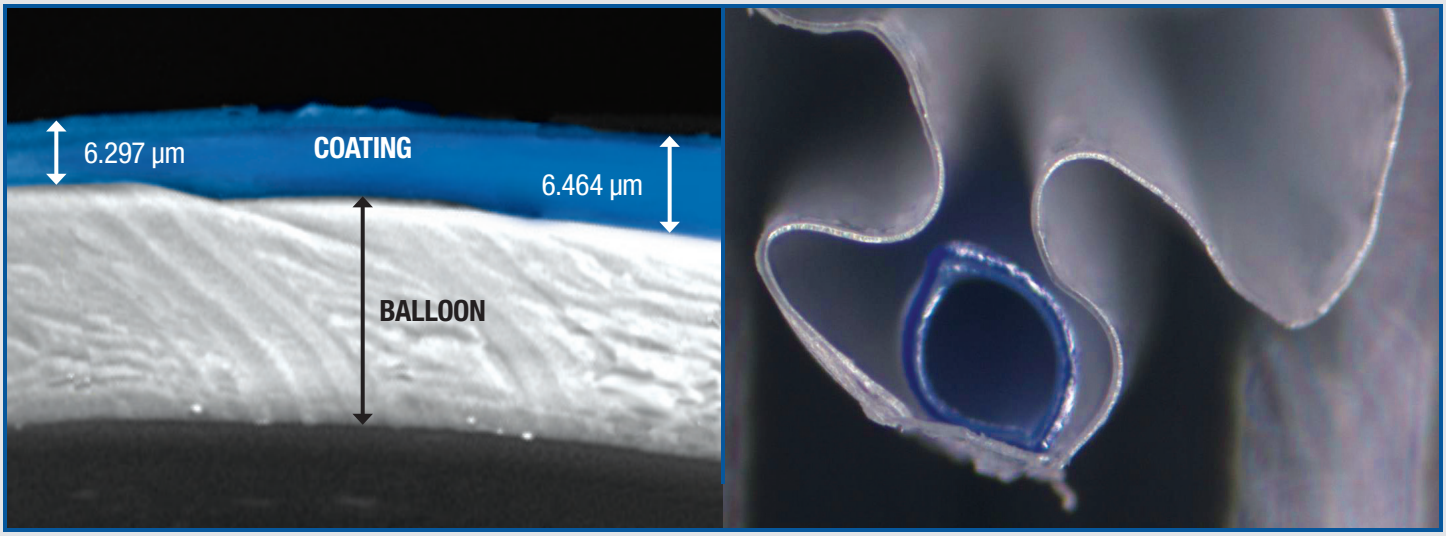


OPTIMIZED DESIGN

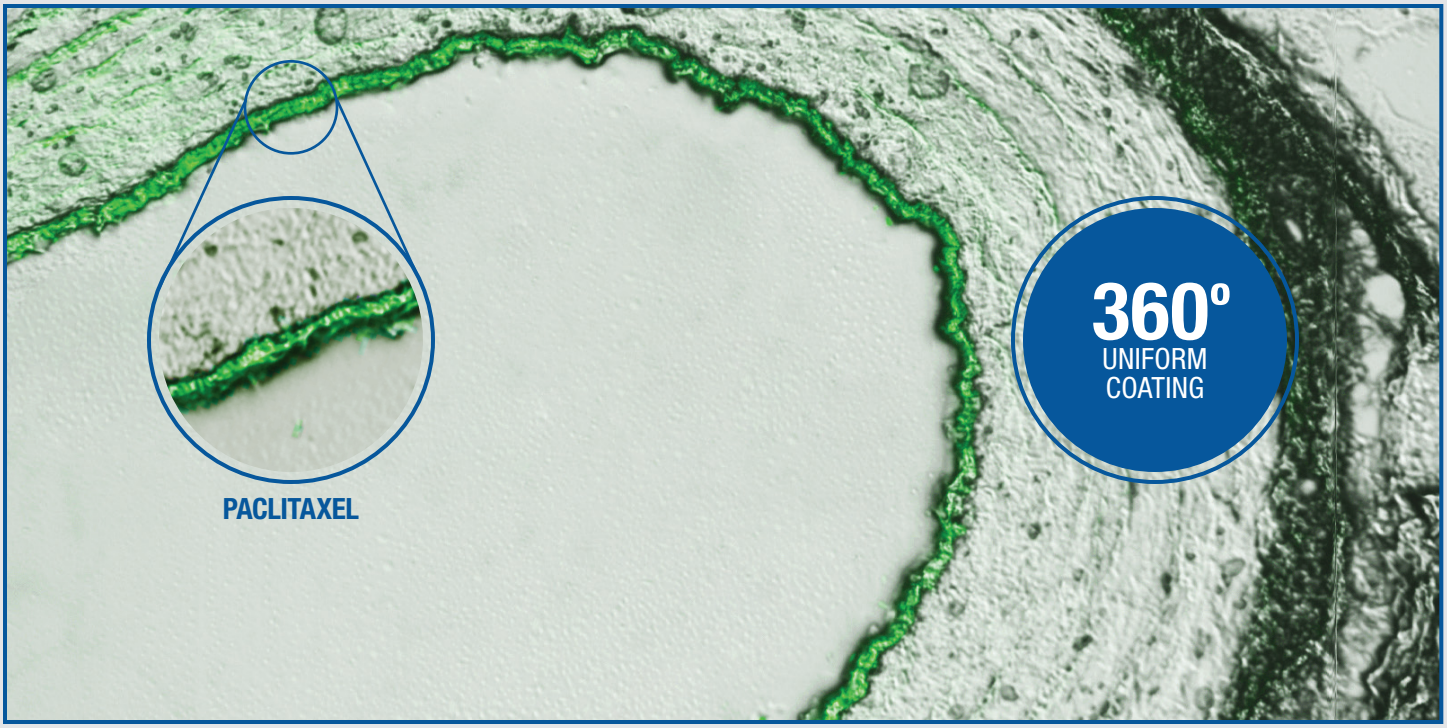
Uniform & Durable Coating

The LUTONIX® 035 DCB demonstrated a consistent coating resulting in:

- **360°** of paclitaxel coating at the target vessel[4]
- **6.46 µm** coating thickness
- **4% drug dose variability** across the length of the balloon



LUTONIX® 035 balloon and coating cross sections

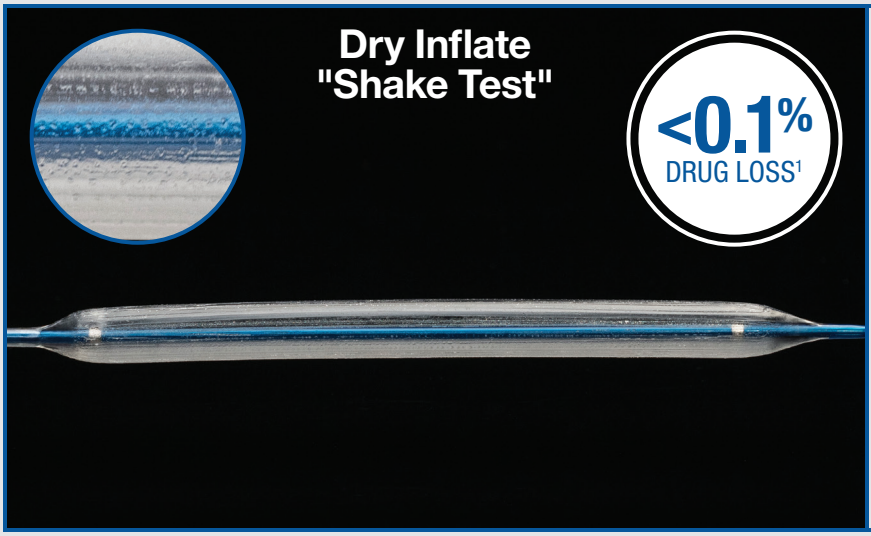


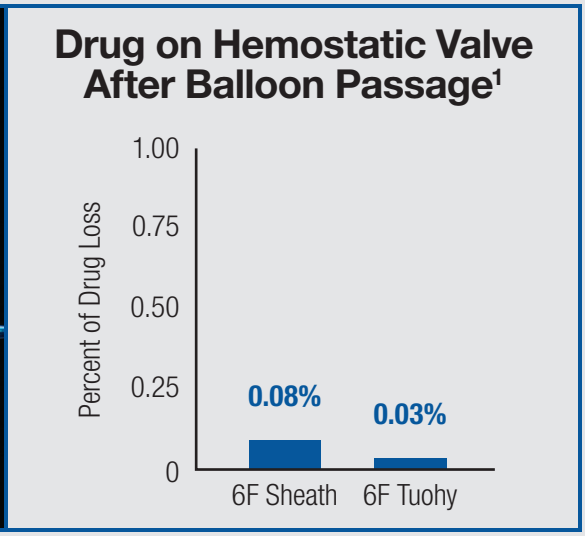
Uniform delivery in-vivo at 1 hour (animal arterial cross section after 30 seconds of inflation)

PROVEN SAFETY

Safe During Prep & Handling

The LUTONIX® 035 DCB coating formulation is designed to **limit drug flaking** during preparation and handling, **minimizing unnecessary drug exposure to staff and patients**. In a dry inflate "shake test", the LUTONIX® 035 DCB showed a <0.1% drug loss during prep.[1]





Dedication to Pre-Clinical Research

The pre-clinical animal work of Renu Virmani, MD, studied the effects of both **1X** and **4X** the therapeutic dose of paclitaxel.

Data showed **no significant distal embolic or downstream drug effects** from the LUTONIX® 035 DCB formulation, **even at 4X the dose**.[3]

LUTONIX® 035 demonstrated a **sustained presence of paclitaxel** in the arterial wall through **30 days**, with demonstrated pharmacological effects up to **90 days**.

ZERO
DOWNSTREAM
DRUG EFFECTS[3]

RIGOROUS TESTING

Proven in a Level 1 Clinical Trial

The LEVANT 2 clinical trial was the **first U.S. IDE trial approved** by the FDA to evaluate the use of a DCB for the treatment of PAD in the SFA and popliteal arteries. **LEVANT 2 raised the bar for scientific rigor in PAD trials** and was designed to **reduce bias** in the results in order to accurately and scientifically assess and compare the long-term performance of the treatment modalities alone.

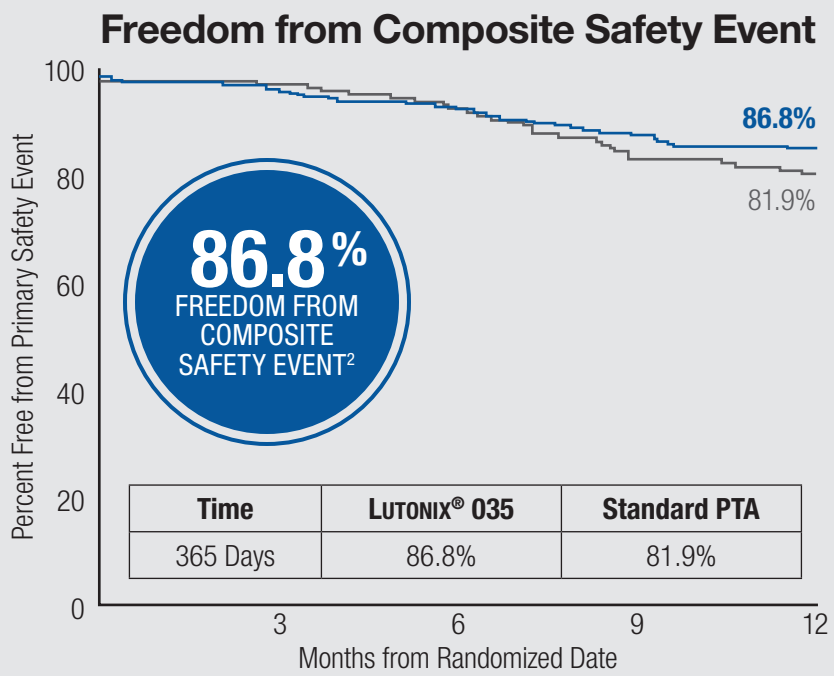
CLINICAL TRIAL DESIGN

Trial Design	365 Days
Patients Enrolled	476 Patients at 54 Global Sites
Treatment Area	SFA and Popliteal (P1, P2, P3) Arteries
Inclusion Criteria	Rutherford 2-4 De Novo or Restenotic Lesions
Lesion Type	Length ≤ 150 mm Diameter 4-6 mm ≥ 70% Stenosis No In-Stent Restenosis

CHALLENGING PATIENT DEMOGRAPHIC:

- 43.4% Diabetics
- 70.6% Rutherford 3 & 4
- 59.2% Calcified Lesions
- 20.6% Total Occlusions

Established Safety Record Comparable to PTA[2]



Time	LUTONIX® 035	Standard PTA
365 Days	86.8%	81.9%

LUTONIX® 035 DCB demonstrated a safety profile that is **consistent with PTA** with **no rare adverse events** up to 24 months and **no** unanticipated **safety events** due to device or drug in over 1,000 patients.[2]

Low rates of thrombosis **0.4%** at 12 months*, **similar to PTA**.

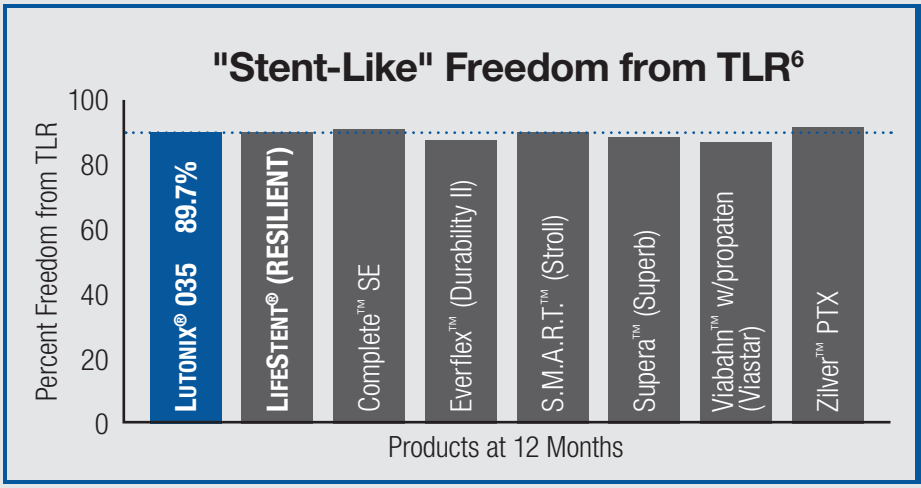
* 1/285

ENHANCED OUTCOMES

Sustained Improvement at 12 Months

Patients treated with a DCB reported **less pain and the ability to walk further** at 12 months compared to patients treated with PTA alone.[5] **9 out of 10** patients treated with LUTONIX® 035 DCB did not require reintervention within one year.

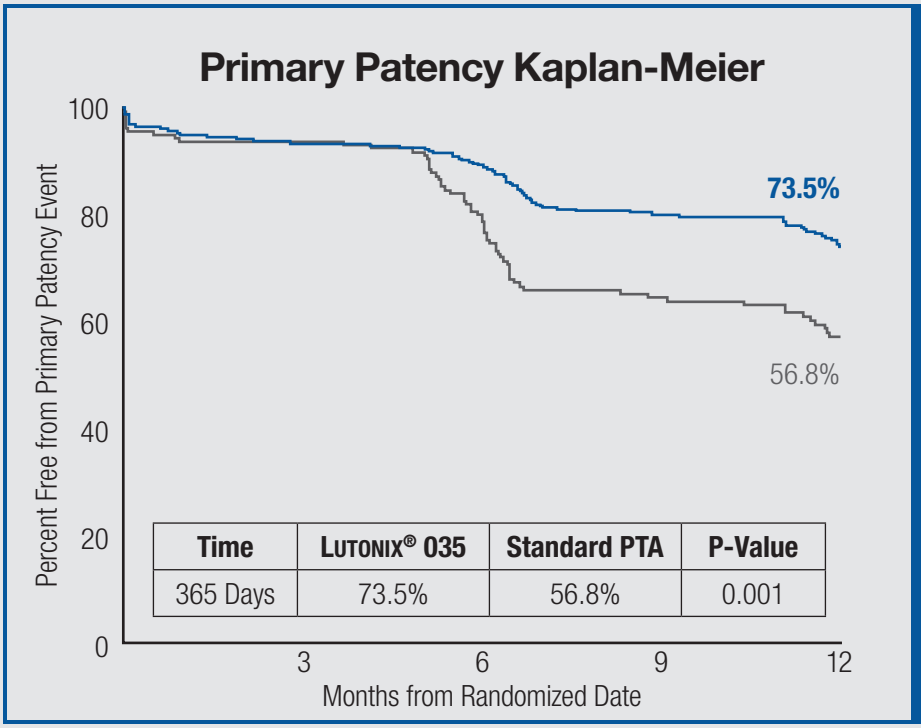
88.2%
RUTHERFORD SUSTAINED IMPROVEMENT[2]



89.7%
FREEDOM FROM TLR[2]

Consistent with the current stent freedom from TLR rates.[6]

29.4% Improved Primary Patency over PTA at 12 Months[2]



Time	LUTONIX® 035	Standard PTA	P-Value
365 Days	73.5%	56.8%	0.001

73.5%
PRIMARY PATENCY[2]

LUTONIX® 035 DCB demonstrated a **statistically significant superior primary patency rate** at 12 months compared to PTA.[2]

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[1] Bench test data on file. Bench results may not be indicative of clinical performance. Different test methods may yield different results.

[2] LEVANT 2 clinical trial data on file. N=476. At 12 months, treatment with LUTONIX® 035 resulted in a primary patency rate of 73.5% versus 56.8% with PTA alone (p=0.001). Primary patency defined as absence of binary restenosis defined by DUS PSVR >2.5 and freedom from Target Lesion Revascularization (TLR). At 12 months, treatment with LUTONIX® 035 resulted in a freedom from composite safety event rate of 86.8% versus 81.9% with PTA alone. Primary safety defined as composite of freedom from all-cause Perioperative death and freedom at 1 year in the index limb from Amputation (ATK or BTK), Reintervention, and Index-limb related death. Percentages reported are derived from Kaplan-Meier analyses (not pre-specified).

[3] Virmani preclinical animal data on file. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.

[4] Based on pre-clinical testing. May not be indicative of actual clinical performance.

[5] Patients self-reported pain and walking distance in a questionnaire at 12 months in LEVANT 2. N=397 (DCB = 264, PTA =133). Patients were blinded to their original treatment modality.

[6] Circ Cardiovasc Interv 2010;3:267-276, Circ Cardiovasc Interv 2011;4:495-504, J Vasc Surg 2013;53:73-83, SSED for Complete SE Vascular Stent System., SSED for SMART Control and SMART Vascular Stent Systems., J Am Coll Cardiol 2013;62:1320-7. TLR is defined as Target Lesion Revascularization. This was a secondary endpoint in the LEVANT 2 trial. Reported stent TLR rates are from Kaplan-Meier analyses at 12 months. Values are public, published data for SFA stents released in the past five years. These data are not from head-to-head clinical studies.

LUTONIX® 035 Drug Coated Balloon PTA Catheter

Indications for Use: The LUTONIX® 035 Drug Coated Balloon Catheter is intended for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature and for the treatment of obstructive lesions and decreasing the incidence of restenosis. In addition, the LUTONIX® 035 Drug Coated Balloon Catheter is intended for PTA of native dialysis fistulae or synthetic grafts, opening narrowing and immature fistulae, to improve blood flow, and decreasing the incidence of restenosis.

Contraindications: The LUTONIx® Catheter is contraindicated for use in: 1) Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy. 2) 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. 3) Pediatric patients. The safety and effectiveness of the LUTONIX® Catheter in pediatric patients has not been established. 4) Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system. 5) This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds.

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 if product damage is evident. 3) Do not use after the "Use By" date. 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: - 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. 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 (s:50% contrast). Never use air or any gaseous medium to inflate the balloon.7) The safety and effectiveness of the LUTONIx® Catheter have not been established for treatment in cerebral, carotid, coronary, renal vasculature or mesenteric arteries.

Precautions: 1) The safety and effectiveness of using more than two Lutonix® drug coated balloons (i.e., a maximum drug coating quantity of approximately 7.6 mg paclitaxel) in a patient has not been clinically evaluated. 2) The Lutonix Catheter should only be used by physicians trained in percutaneous interventional procedures.3) Consideration should be given to the risks and benefits of use in patients with a history of non-controllable allergies to contrast agents.

Potential Adverse Events: Potential adverse events which may be associated with a peripheral balloon dilatation procedure include: • Additional intervention • Allergic reaction to drugs, excipients or contrast medium • Aneurysm or pseudoaneurysm • Arrhythmias • Embolization • Hematoma • Hemorrhage, including bleeding at the puncture site • Hypotension/hypertension • Iatrogenic arteriovenous fistula formation • Inflammation • Occlusion • Pain or tenderness • Pneumothorax or hemothorax • Sepsis/infection • Shock• Stroke • Thrombosis • Vessel dissection, perforation, rupture, or spasm

Potential adverse events that may be unique to the LUTONIX® Catheter paclitaxel drug coating:

Allergic reaction to drug coating
There may be other potential adverse events that are unforeseen at this time.

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

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