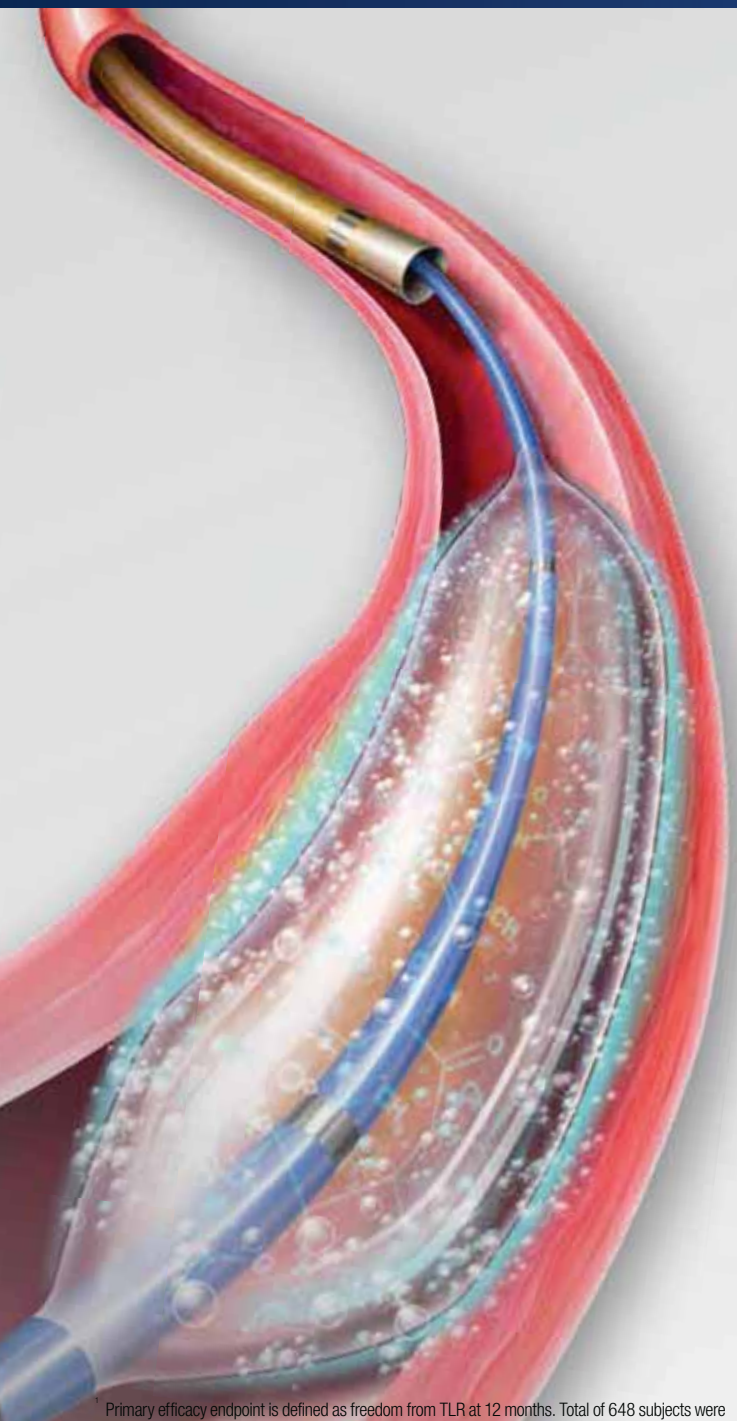
90.3% Freedom from TLR at 24 Months[1]
The LUTONIX® Global SFA Real-World Registry



The primary objective of the Global SFA Real-World Registry was to demonstrate safety and assess the clinical use and outcomes of the LUTONIX® DCB in a heterogeneous patient population in **real world clinical practice.**

Registry Statistics	
Patients	691
Sites / Countries	38 / 10
Selected Demographics	
Diabetes (n/N)	39.5% (273/691)
Rutherford Category	
Grade 2	20.6% (142/689)
Grade 3	66.9% (461/689)
Grade 4	7.4% (51/689)
Grade 5 & 6	1.6% (11/689)
Angiographic Data	
Target Lesion Length (mm) mean ± SD (n)	101.2 ± 84.2 (685)
Calcification (n/N)	50.2% (238/474)
Total Occlusion (n/N)	31.2% (214/686)
Most Distal Lesion Location (n/N)	
SFA	70.0% (483/690)
Proximal Popliteal	16.8% (116/690)
Mid Popliteal	10.1% (70/690)
Distal Popliteal	3.0% (21/690)

PRIMARY ENDPOINTS

Freedom from TLR[1]	
at 12 Months	**94.1%**
at 24 Months	**90.3%**
30 Day Safety[2]	**99.4%**

[1] 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 month 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 lesion in both SFA and popliteal.

[2] The primary safety endpoint is defined as Freedom at 30 days from TVR, major index limb amputation, and device- and procedure-related death (VIVA safety endpoint). Please refer to the LUTONIX® 035 IFU for complete data sets and more detailed LUTONIX® 035 DCB clinical information, including with regard to the LUTONIX® DCB Global SFA Registry and the LEVANT 2 global, prospective, randomized, pivotal study.

LUTONIX® 035 | 5F
Drug Coated Balloon PTA Catheter

LUTONIX® 035 Drug Coated Balloon PTA Catheter | 5F

75 cm Catheter Length .035" Guidewire Compatible				
Diameter (mm)	Length (mm)	RBP † (ATM)	Sheath Profile (F)	Product Codes
4	40	12	5F	LX35754405F
	60	12	5F	LX35754605F
	80	12	5F	LX35754805F
	100	12	5F	LX357541005F
5	40	12	5F	LX35755405F
	60	12	5F	LX35755605F
	80	12	5F	LX35755805F
	100	12	5F	LX357551005F
6	40	12	5F	LX35756405F
	60	12	5F	LX35756605F
	80	12	5F	LX35756805F
	100	12	5F	LX357561005F
7	40	12	5F	LX35757405F
	60	12	5F	LX35757605F

Nominal Pressure*	
4, 5 mm	6 ATM
6, 7 mm	7 ATM

† RBP (Rated Burst Pressure): the pressure at which Bard has 95% confidence that 99.9% of the balloons will not burst at or below upon single inflation.

* Nominal pressure: the pressure at which the balloon reaches its labeled diameter.

130 cm Catheter Length .035" Guidewire Compatible				
Diameter (mm)	Length (mm)	RBP † (ATM)	Sheath Profile (F)	Product Codes
4	40	12	5F	LX351304405F
	60	12	5F	LX351304605F
	80	12	5F	LX351304805F
	100	12	5F	LX3513041005F
	120	12	5F	LX3513041205F
	150	12	5F	LX3513041505F
5	40	12	5F	LX351305405F
	60	12	5F	LX351305605F
	80	12	5F	LX351305805F
	100	12	5F	LX3513051005F
	120	12	5F	LX3513051205F
	150	12	5F	LX3513051505F
6	40	12	5F	LX351306405F
	60	12	5F	LX351306605F
	80	12	5F	LX351306805F
	100	12	5F	LX3513061005F
	120	12	5F	LX3513061205F
	150	12	5F	LX3513061505F
7	40	12	5F	LX351307405F
	60	12	5F	LX351307605F

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

LUTONIX® 035 Drug Coated Balloon PTA Catheter

Indications for Use: The LUTONIX® 035 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 300 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

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)** 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 if product damage is evident. **3)** 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. **4)** 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. **5)** Use the recommended balloon inflation medium of contrast and sterile saline (≤50% contrast). Never use air or any gaseous medium to inflate the balloon. **6)** This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds. **7)** The safety and effectiveness of the LUTONIX® Catheter have not been established for treatment in cerebral, carotid, coronary, or renal vasculature. **8)** The safety and effectiveness of using more than four LUTONIX® drug coated balloons (i.e., a maximum drug coating quantity of approximately 15.1 mg paclitaxel) in a patient has not been clinically evaluated.

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.

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 • Amputation/loss of limb • Aneurysm or pseudoaneurysm • Arrhythmias • Embolization • Hematoma • Hemorrhage, including bleeding at the puncture site • Hypotension/hypertension • Inflammation • Occlusion • Pain or tenderness • Pneumothorax or hemothorax • Sepsis/infection • Shock • 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: 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. $R_{X\ Only}$

BPV/LTNX/0616/0081(2)

BARD

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