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%**

LUTONIX™ 035 | 5F
Drug Coated Balloon PTA Catheter

[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.

Subgroup Analysis of The LUTONIX™ Global SFA Real-World Registry

IN-STENT RESTENOSIS (ISR) SUBGROUP

Angiographic Data

Target Lesion Length (mm) mean ± SD (n)	154.4 ± 97.1 (89)
Calcification (n/N)	37.7% (26/69)
Total Occlusion (n/N)	28.1% (25/89)

ISR SUBGROUP RESULTS

Freedom from TLR at 24 Months[3]	
ISR	**85.5%**
ISR Calcification	**78.3%**
ISR Total Occlusion	**90.5%**

LONG LESION (LL) SUBGROUP

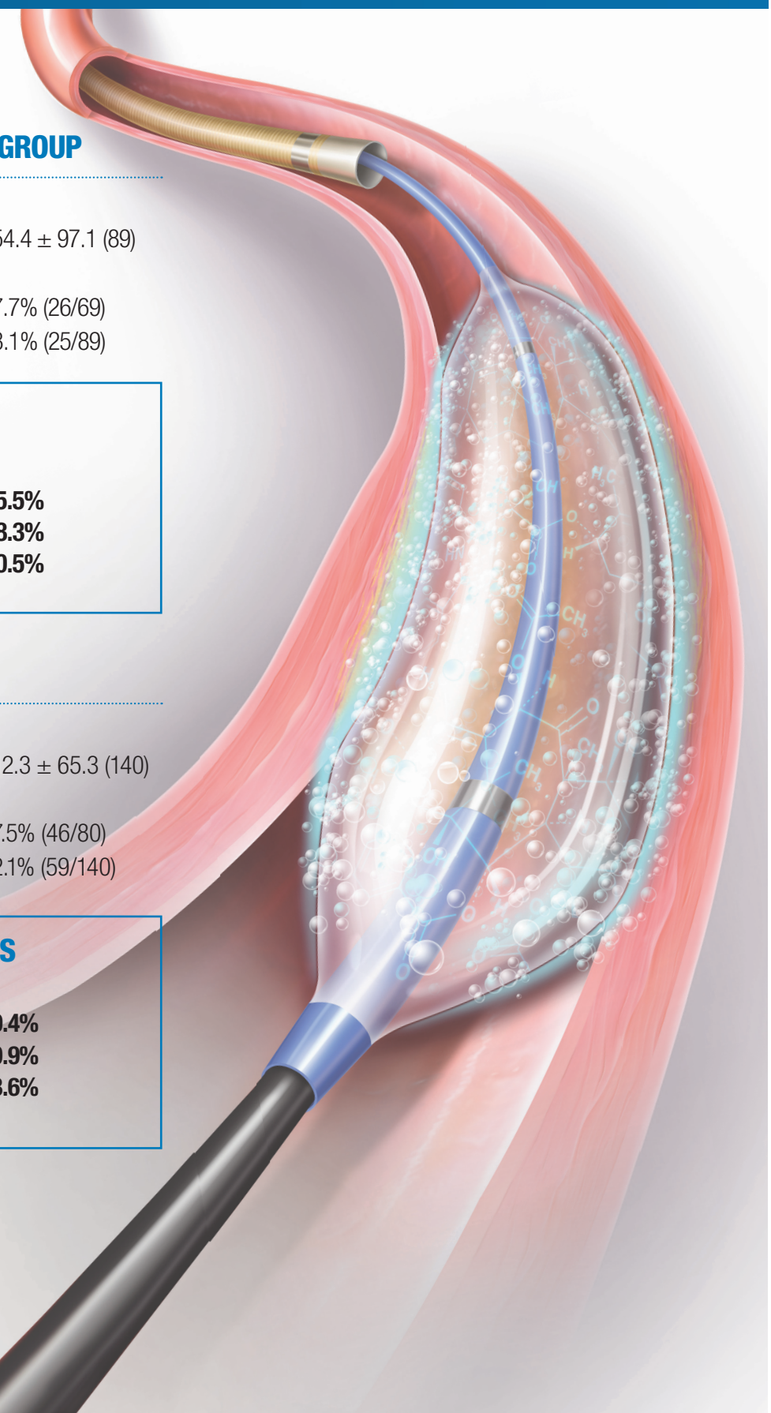
Angiographic Data

Target Lesion Length (mm) mean ± SD (n)	212.3 ± 65.3 (140)
Calcification (n/N)	57.5% (46/80)
Total Occlusion (n/N)	42.1% (59/140)

LONG LESION SUBGROUP RESULTS

Freedom from TLR at 24 Months[3]	
LL	**89.4%**
LL Calcification	**90.9%**
LL Total Occlusion	**93.6%**

[3] Kaplan Meier



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**
5	40	12	5F	9090475 500040
	60	12	5F	9090475 500060
	80	12	5F	9090475 500080
6	40	12	5F	9090475 600040
	60	12	5F	9090475 600060
	80	12	5F	9090475 600080
7	40	12	5F	9090475 700040
	60	12	5F	9090475 700060
8	40	12	7F	9090475 800040
	60	12	7F	9090475 800060
9	40	11	7F	9090475 900040
	60	11	7F	9090475 900060
10	40	11	8F	9090475 100040
	60	11	8F	9090475 100060
12	40	10	10F	9090475 120040

100 cm Catheter Length .035" Guidewire Compatible				
Diameter (mm)	**Length (mm)**	**RBP† (ATM)**	**Sheath Profile (F)**	**Product Codes**
4	40	12	5F	9090410 400040
	60	12	5F	9090410 400060
	80	12	5F	9090410 400080
	100	12	5F	9090410 400100
	120	12	5F	9090410 400120
	150	12	5F	9090410 400150
5	40	12	5F	9090410 500040
	60	12	5F	9090410 500060
	80	12	5F	9090410 500080
	100	12	5F	9090410 500100
	120	12	5F	9090410 500120
	150	12	5F	9090410 500150
6	40	12	5F	9090410 600040
	60	12	5F	9090410 600060
	80	12	5F	9090410 600080
	100	12	5F	9090410 600100
	120	12	5F	9090410 600120
	150	12	5F	9090410 600150

130 cm Catheter Length .035" Guidewire Compatible				
Diameter (mm)	**Length (mm)**	**RBP† (ATM)**	**Sheath Profile (F)**	**Product Codes**
4	40	12	5F	9090413 400040
	60	12	5F	9090413 400060
	80	12	5F	9090413 400080
	100	12	5F	9090413 400100
	120	12	5F	9090413 400120
	150	12	5F	9090413 400150
5	40	12	5F	9090413 500040
	60	12	5F	9090413 500060
	80	12	5F	9090413 500080
	100	12	5F	9090413 500100
	120	12	5F	9090413 500120
	150	12	5F	9090413 500150
6	40	12	5F	9090413 600040
	60	12	5F	9090413 600060
	80	12	5F	9090413 600080
	100	12	5F	9090413 600100
	120	12	5F	9090413 600120
	150	12	5F	9090413 600150

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.

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

Lutonix™ 035 Drug Coated Balloon PTA Catheter

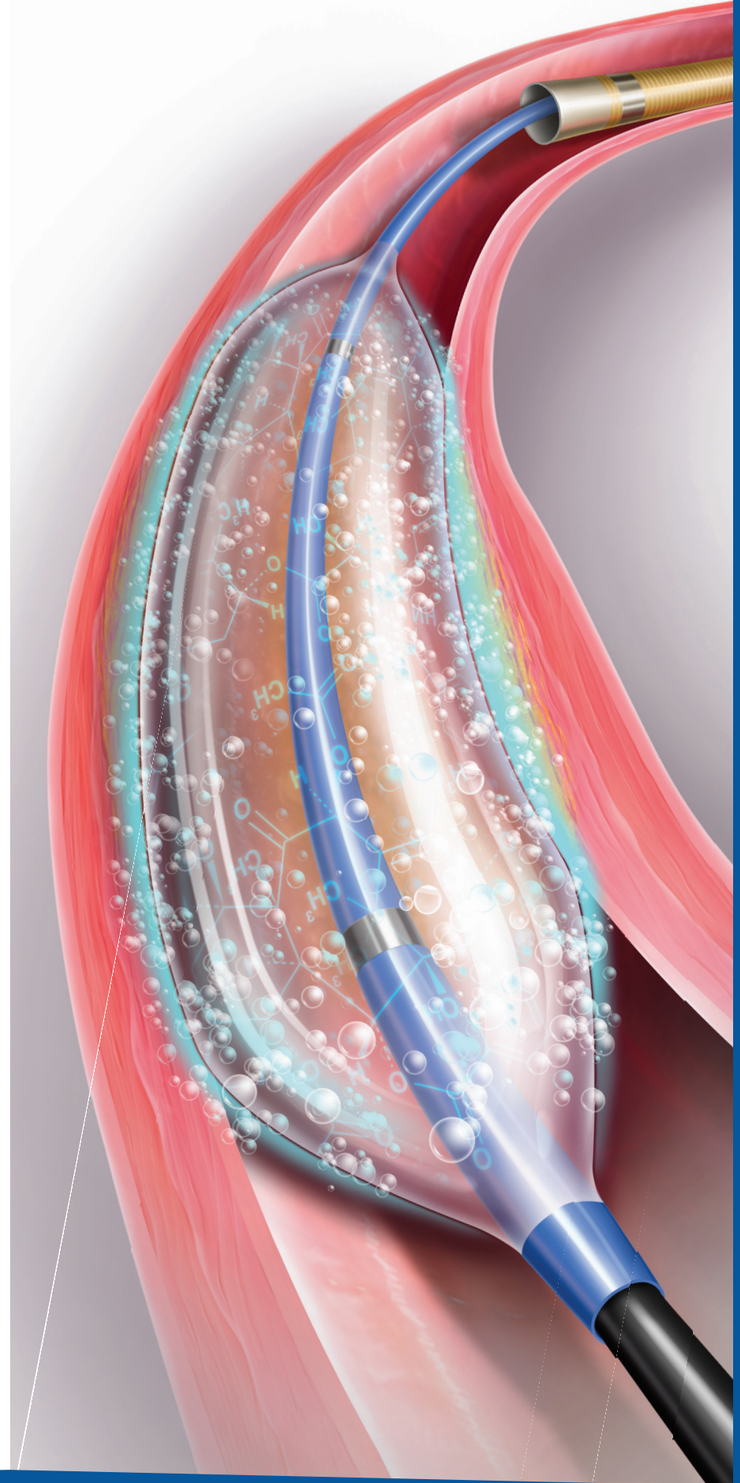
Indications for use: The Lutonix™ 035 Drug Coated Balloon Catheter is intended for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature and for the treatment of obstructive lesions and decreasing the incidence of restenosis. In addition, the Lutonix™ 035 Drug Coated Balloon Catheter 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 (≤ 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: General Precautions: 1) The safety and effectiveness of using more than 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. 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. **Device handling precautions:** 1) 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. 2) The coated balloon portion should be handled with dry sterile gloves whenever possible prior to use. 3)The balloon protector should stay in place during preparation of the Lutonix™ Catheter and not be removed until just prior to placing over guidewire. 4) If difficulty is encountered while removing the balloon protector, a new Lutonix™ Catheter should be utilized. 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. **Device use/procedure precautions:** 1)The Lutonix™ Catheter should always be manipulated with adequate visualization technique when in the body.2)Appropriate vessel preparation, such as predilatation, is recommended to achieve optimal DCB results. Successful pre-dilation is defined as of ≤ 30% residual stenosis.3) Always advance and retrieve the Lutonix™ Catheter under negative pressure.4) 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.5) 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.1) 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 2) Do not continue to use the Lutonix™ Catheter if the shaft has been bent or kinked. 3) 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%. 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.

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



LUTONIX™ Global SFA Real-World Registry

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LUTONIX™ 035 | 5F
Drug Coated Balloon PTA Catheter

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