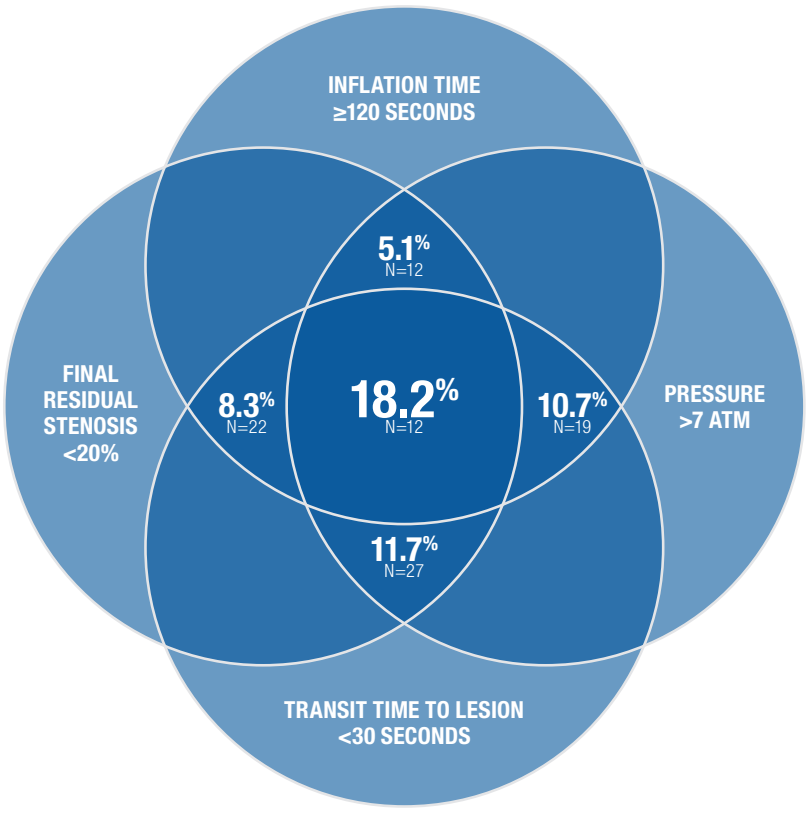
LUTONIX™ Procedural Techniques For Optimal Drug Delivery[1]

Observations from LEVANT 2 suggest that **12-month Primary Patency** may be positively influenced by the combination of the procedural techniques listed below:

- Transit time to lesion <30 sec.
- Balloon pressure >7 atm
- Balloon inflation time ≥120 sec.
- Final residual stenosis <20%
- Balloon sizing of ≥1:1 (full wall apposition)

Improved Primary Patency

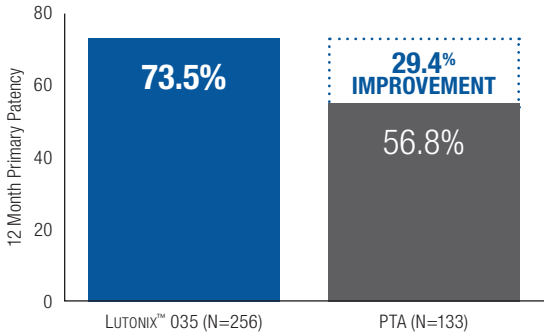
Observational post-hoc, subgroup analyses suggest that LUTONIX™ 035 DCB procedural techniques may affect 12-month Primary Patency. The diagram below shows the **percent increase** over the LEVANT 2 12-month Primary Patency of 73.5%.[1,2] Though 12-month Primary Patency is improved with 3 variables, it is optimal with 4 variables.



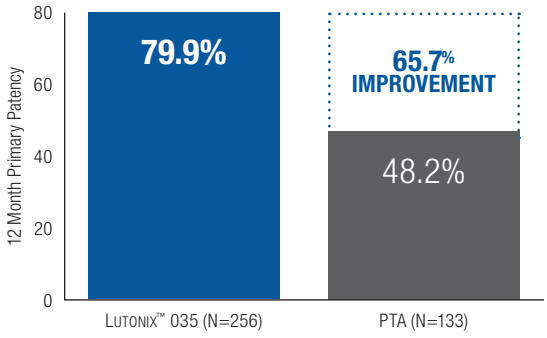
Balloon Sizing

A post-hoc subgroup analysis suggests that **full wall apposition** of the LUTONIX™ 035 DCB **positively impacted primary patency** results at 12 months.[2,3]

LEVANT 2 Clinical Trial
Average 0.9:1 Balloon-to-Artery Ratio[2]



LEVANT 2 Full Wall Apposition Subgroup
≥1.04:1 Balloon-to-Artery Ratio[2,3]



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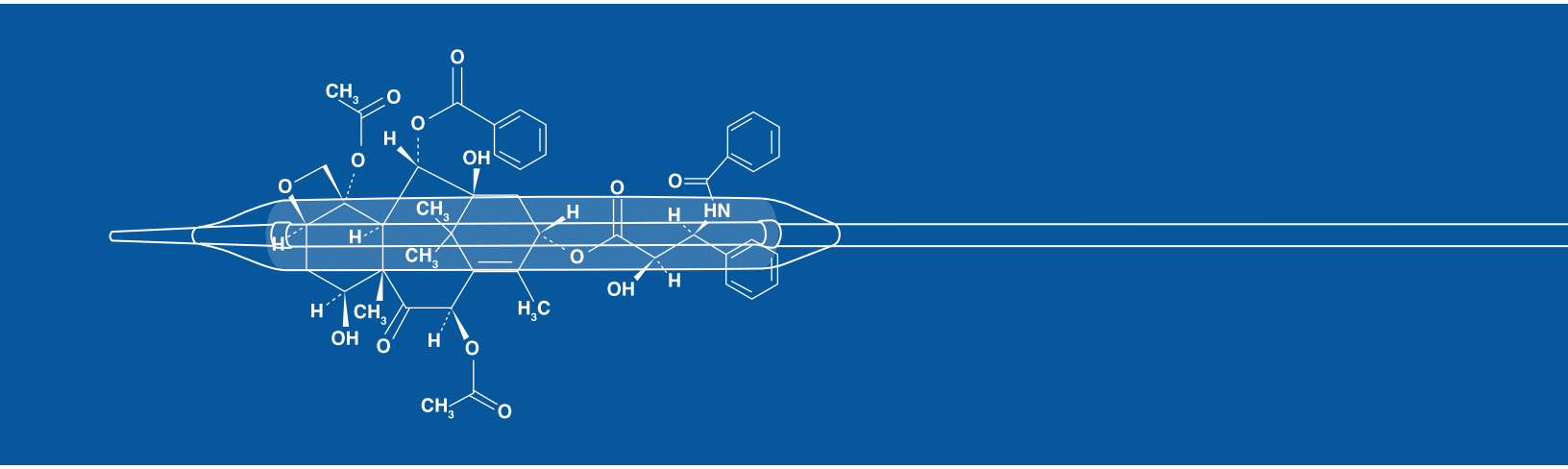
DATAPOINTS

LUTONIX™ 035 | 5F

Drug Coated Balloon PTA Catheter



[1] The data presented herein are observational only. Further confirmatory clinical evidence is required to support the conclusion that the combination of any of these procedural techniques would yield an improved primary patency result beyond the 12-month primary patency rate of 73.5% demonstrated in LEVANT 2.

[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). Numbers reported are Kaplan-Meier analyses, not pre-specified.

[3] A post-hoc subgroup analysis suggests the full wall apposition of the LUTONIX® 035 Drug Coated Balloon (minimum 1.04:1 balloon-to-artery ratio of the treatment device) showed increased primary patency of 79.9%. At 12 months, treatment with LUTONIX® 035 resulted in a freedom from primary safety event rate of 85.8% (balloon-to-artery ration <1). 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 relate death. Numbers reported are Kaplan-Meier analyses, not pre-specified. **Warning: Do Not Exceed Rated Burst Pressure.**

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

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