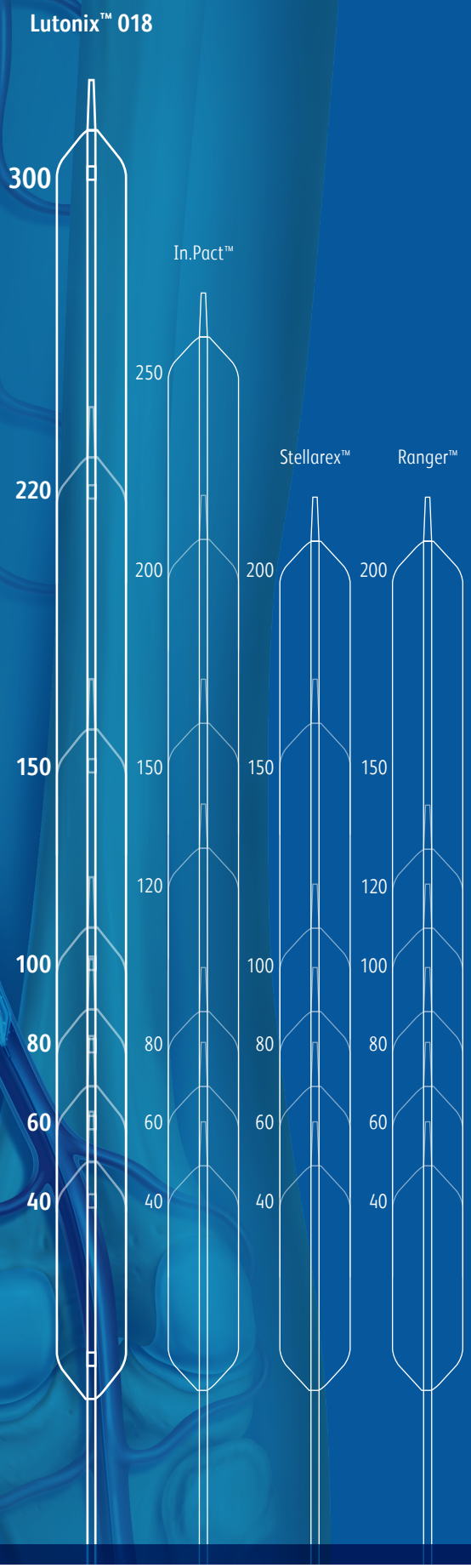
The First & Only 300 mm DCB*

Treat your long femoropopliteal lesions with the longest DCB on the U.S. Market. Proven safe and effective in an IDE trial†, global registry, and an independent analysis‡, Lutonix™ DCB has the broadest size offering and the lowest profile of all U.S. DCBs, with all sizes 5F or lower.

90.3%
Freedom from TLR
at 24 Months in the Lutonix Real-World Registry**



Lutonix™ 018

Drug Coated Balloon PTA Catheter

* As of November 2020 on the U.S. market.

** 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. Device studied was Lutonix™ 035 Drug Coated Balloon PTA Catheter.

† LEVANT 2 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™ resulted in a freedom from primary safety event rate of 86.7% with PTA alone (p=0.185). Primary safety defined as composite of freedom from all-cause perioperative death and freedom at 1 year in the index limb from amputation (STK or BTK), reintervention, and index-limb related death. Kaplan-Meier analyses for safety and effectiveness were pre-specified. Device studied was Lutonix™ 035 Drug Coated Balloon PTA Catheter.

‡ Analysis conducted by an independent clinical research organization, Syntactx LLC for which it was compensated by BD. 173 deaths in LEVANT 1 and LEVANT 2 (including patients form Continued Access arm of LEVANT 2), with 151 occurring in Lutonix™ 035 DCB patients (14.0%) and 22 in PTA patients (10.4%). Data on file. Bard Peripheral Vascular, Inc. Tempe, AZ. Device studied was Lutonix™ 035 Drug Coated Balloon PTA Catheter.

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 300 mm in length in native superficial femoral or popliteal arteries with reference vessel diameter of 4-7 mm. 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.

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.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions. $R_{x\ only}$

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