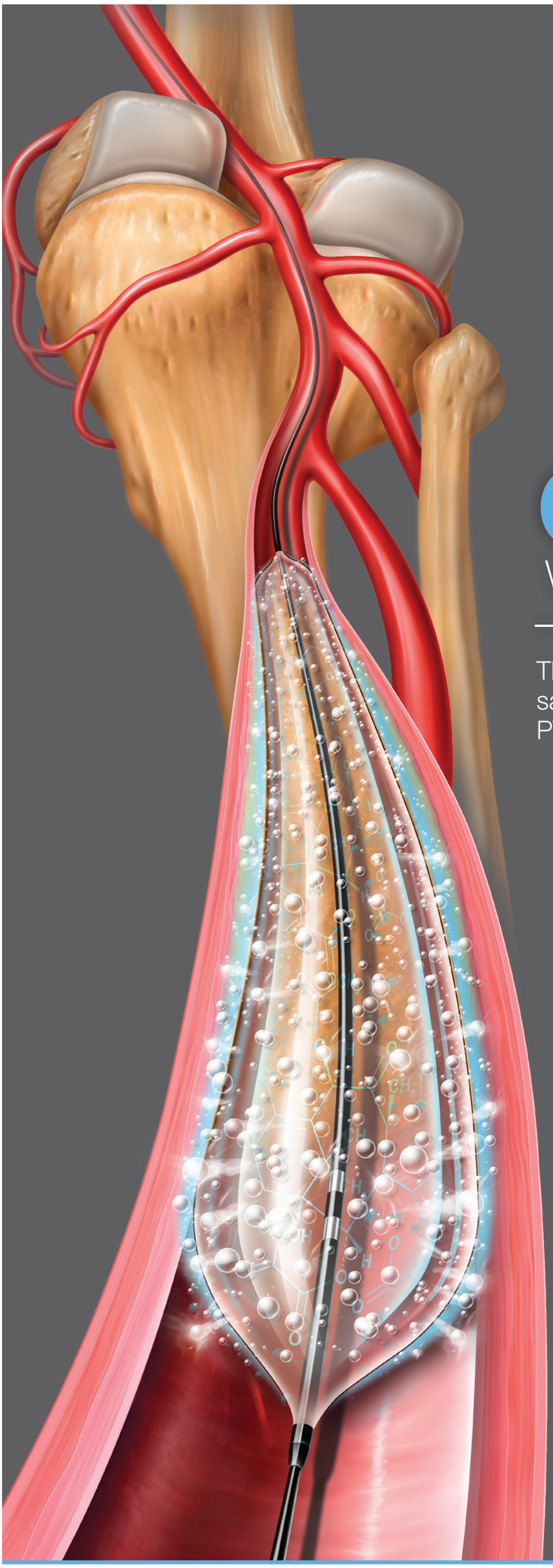

# Go Further

## With the LUTONIX® 014 DCB

The LUTONIX® 014 DCB demonstrated non-inferior safety and 20.7% improved primary patency over PTA* in a rigorous Level 1, Randomized Clinical Trial.

The LUTONIX® 014 product line features:

- All 4F sheath compatibility
- Dual distal marker bands
- GEOALIGN® Marking System

6 Month Safety*

DCB 97.8%

PTA 95.3%

6 Month Efficacy*

DCB 85.3%

PTA 70.7%

**LUTONIX® 014**

Drug Coated Balloon PTA Catheter

* Lutonix BTK IDE Clinical Data on File. Primary Efficacy is defined as freedom from composite of above-ankle amputation, target lesion occlusion, and clinically-driven target lesion revascularization. As 6 months, treatment with LUTONIX® 014 DCB resulted in a primary efficacy rate of 73.7% (196/266) versus 63.5% with PTA alone (87/137). The primary effectiveness analysis for superiority of DCB vs. PTA was not met with a p-value of 0.0273. At 30 days, treatment with LUTONIX® 014 DCB resulted in a freedom from primary safety event rate of 99.3% (283/285) versus 99.4% (154/155) for PTA alone. Primary Safety is defined as freedom from composite of all-cause death, above-ankle (index) amputation or major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis) of the index limb involving a below-the-knee. The primary safety analysis for non-inferiority for DCB vs. PTA was met with a p-value of <0.001. Percentages reported are derived from Kaplan-Meier analyses.

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# LUTONIX® 014

## Drug Coated Balloon PTA Catheter

### LUTONIX® 014 DCB PTA Catheter Product Codes

| Diameter (mm) | Length (mm) | Rated Burst Pressure* | Sheath Profile | 150 cm Catheter Length |
|---|---|---|---|---|
| 2 | 40 | 15 | 4F | ☐ 9020515 200040 |
| | 80 | 15 | 4F | ☐ 9020515 200080 |
| | 120 | 15 | 4F | ☐ 9020515 200120 |
| | 150 | 15 | 4F | ☐ 9020515 200150 |
| 2.5 | 40 | 15 | 4F | ☐ 9020515 250040 |
| | 80 | 15 | 4F | ☐ 9020515 250080 |
| | 120 | 15 | 4F | ☐ 9020515 250120 |
| | 150 | 15 | 4F | ☐ 9020515 250150 |
| 3 | 40 | 15 | 4F | ☐ 9020515 300040 |
| | 80 | 15 | 4F | ☐ 9020515 300080 |
| | 120 | 15 | 4F | ☐ 9020515 300120 |
| | 150 | 15 | 4F | ☐ 9020515 300150 |
| 3.5 | 40 | 15 | 4F | ☐ 9020515 350040 |
| | 80 | 15 | 4F | ☐ 9020515 350080 |
| | 120 | 15 | 4F | ☐ 9020515 350120 |
| | 150 | 15 | 4F | ☐ 9020515 350150 |
| 4 | 40 | 15 | 4F | ☐ 9020515 400040 |
| | 80 | 15 | 4F | ☐ 9020515 400080 |
| | 120 | 15 | 4F | ☐ 9020515 400120 |
| | 150 | 15 | 4F | ☐ 9020515 400150 |

.014 Guidewire Compatible
Nominal Pressure: 6 ATM
* RBP (Rated Burst Pressure): the pressure at which BD has 95% confidence that 99.9% of the balloons will not burst at or below upon single inflation


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**LUTONIX® 014 Drug Coated Balloon PTA Catheter**

**Indications for Use:** The LUTONIX® 014 Drug Coated Balloon Catheter is intended for use as a PTA catheter to dilate stenotic or obstructive vascular lesions in the lower extremities, for the purpose of improving limb perfusion and decreasing the incidence of restenosis.

**Contraindications:** The LUTONIX® 014 Catheter is contraindicated for use in: · Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy. · 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. · Pediatric patients. The safety and effectiveness of the LUTONIX® Catheter in pediatric patients has not been established. · Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system. · This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds.

**Warnings:** · Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged or opened prior to intended use. · Do not use if product damage is evident. · Do not use after the "Use By" date. · 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. · 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. · Use the recommended balloon inflation medium of contrast and sterile saline (≤ 50% contrast). Never use air or any gaseous medium to inflate the balloon. · The safety and effectiveness of the LUTONIX® Catheter have not been established for treatment in cerebral, carotid, coronary, renal vasculature or mesenteric arteries.

**Precautions:** · 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. · The LUTONIX® Catheter should only be used by physicians trained in percutaneous interventional procedures. · Consideration should be given to the risks and benefits of use in patients with a history of noncontrollable 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 · Latrogenic 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 package insert for indications, contraindications, hazards, warnings, precautions, and instructions for use.** $R_{x\ Only}$ BD, the BD logo, Bard, GeoAlign, and Lutonix are trademarks of Becton, Dickinson and Company or its affiliates. 
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