LUTONIX® 035 | 5F

Drug Coated Balloon PTA Catheter

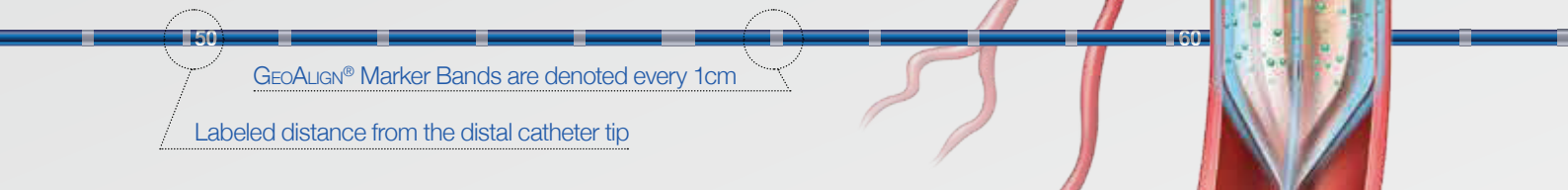
The 5 French LUTONIX® 035 DCB is designed to minimize the size of the access site.

- Lengths: 40, 60, 80, 100, 120, 150 mm
- Diameter: 4-6 mm up to 150 mm

7 mm * 40 - 60mm
8 mm * 40 - 60mm
9 mm * 40 - 60mm
10 mm * 40 - 60mm
12 mm * 40 mm

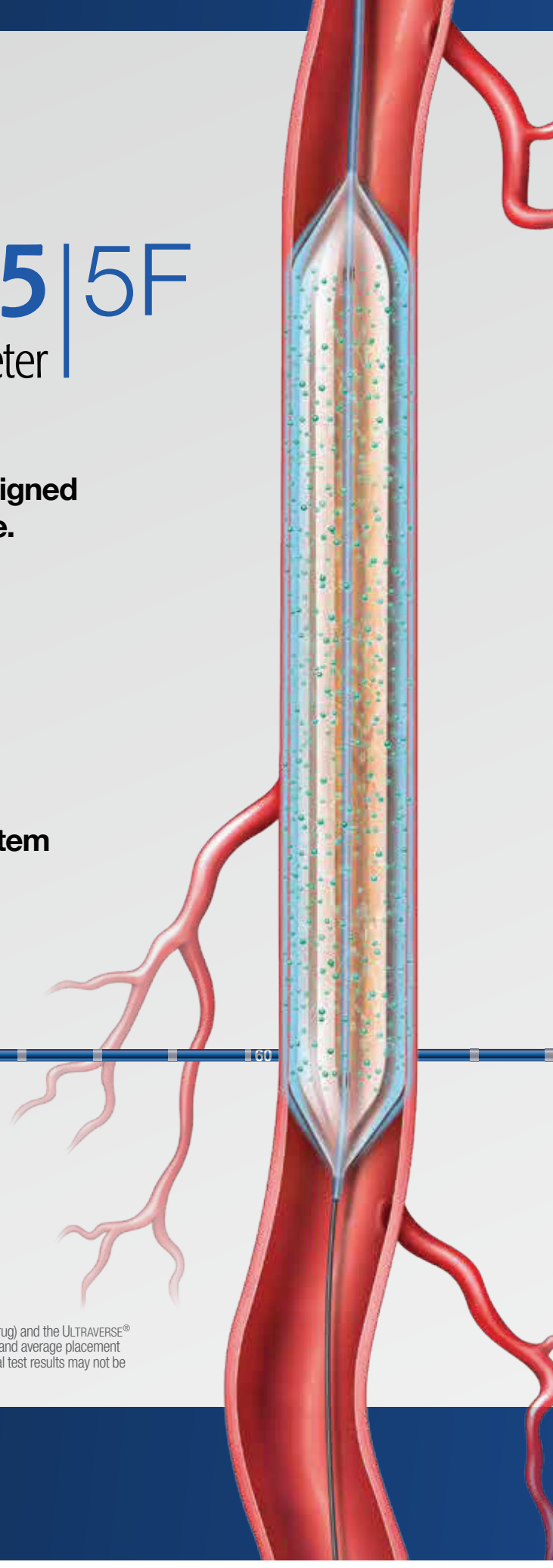
Features the GEOALIGN® Marking System

- Designed to mitigate geographic miss
- 27% average reduction in fluoroscopy time in pre-clinical study*



GEOALIGN® Marker Bands are denoted every 1cm

Labeled distance from the distal catheter tip



* Animal study (repeat PTA in swine artery) was performed by 3 physicians who tested the LUTONIX® 035 DCB (no drug) and the ULTRAVERSE® 035 PTA Catheter, both with GEOALIGN® Markers, to POBA with no GEOALIGN® Markers (n=112, test n = 96 (with and average placement time of 66 seconds), control n = 16 (with an average placement of 90 seconds)). Animal data on file. Bard. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.

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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.

Lutonix® 035 Drug Coated Balloon PTA Catheter

Intended Use/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.

General Precautions: 1) 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. **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.

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 • Iatrogenic 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 inserts for indications, contraindications, hazards, warnings, precautions and instructions for use.

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