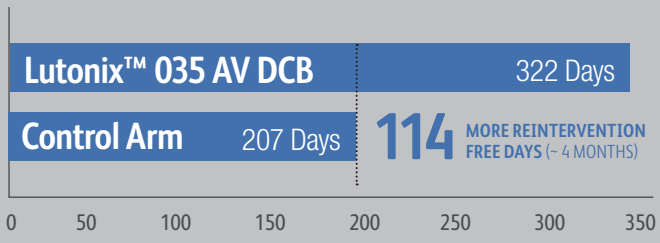
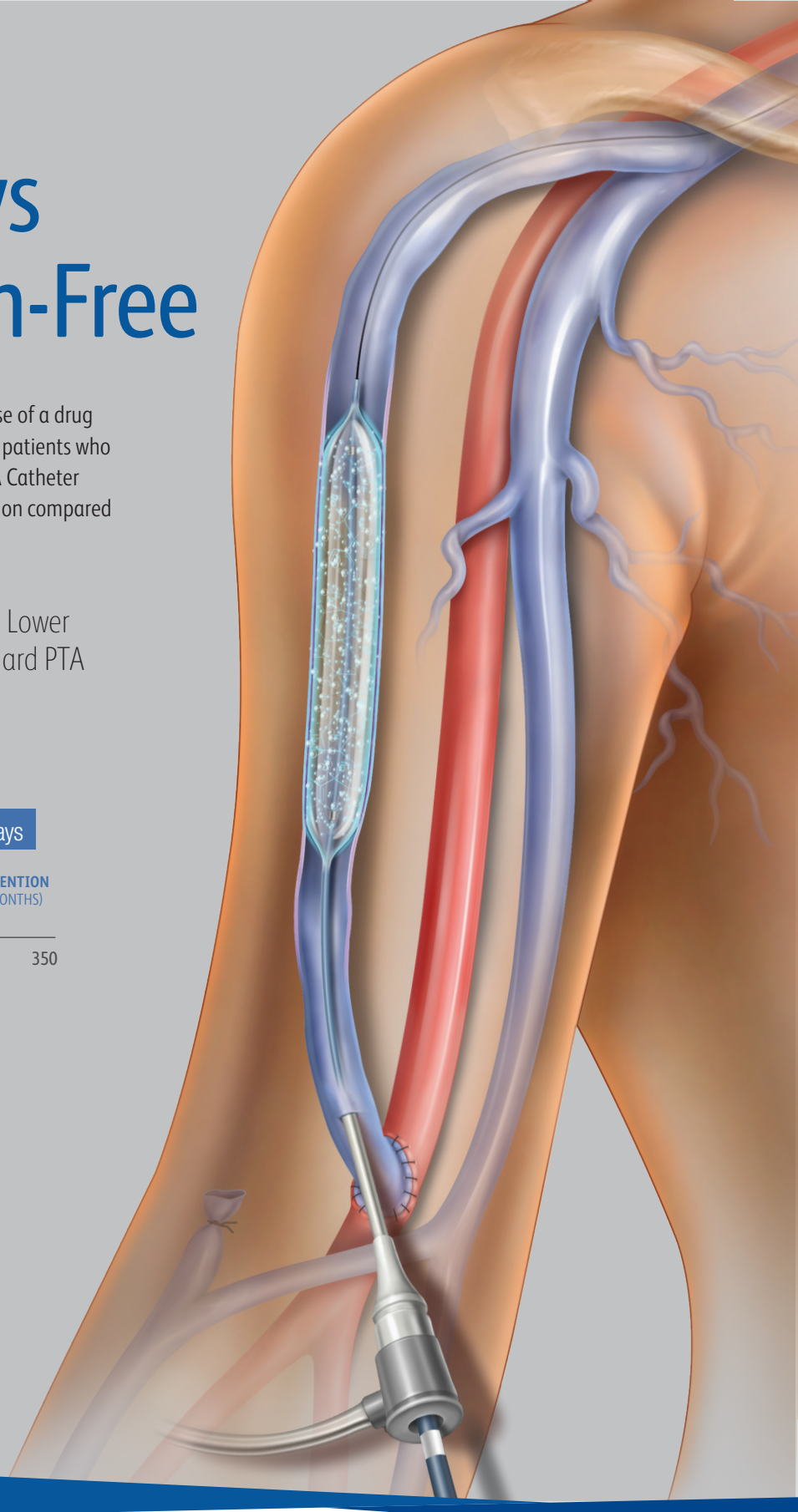
114 More Days Reintervention-Free

The Lutonix AV Clinical Trial was the first to evaluate the use of a drug coated balloon in dysfunctional AV fistulae. At 24 months, patients who were treated with a Lutonix™ 035 Drug Coated Balloon PTA Catheter went an average of 322 days before needing a reintervention compared to 207 days when treated with PTA alone*.

- **Broadest Size Offering** for AV DCBs†
- **Lowest Profile AV DCB** with All Sizes 7F or Lower
- **More Intervention-Free Days** than Standard PTA

Lutonix AV IDE Clinical Trial
Time to First Reintervention





Lutonix™ 035

Drug Coated Balloon PTA Catheter

*Lutonix™ AV Clinical Trial data on file. N=285. At 6 months, treatment with Lutonix™ 035 DCB resulted in a primary patency rate of 71.4% versus 63.0% with PTA alone. Primary patency defined as ending with a clinically driven re-intervention of the target lesion or access thrombosis. The primary effectiveness analysis for superiority of DCB vs. PTA was not met with a one sided p-value of p = 0.0562. Mean time to TLPP event for subjects with an event was longer for DCBs (321.8 vs. 207.4 d; p<0.0001). At 30 days, treatment with Lutonix™ 035 resulted in a freedom from primary safety event rate of 95.0% versus 95.8% with PTA alone. Primary safety defined as freedom from localized or systemic serious adverse events through 30 days that reasonably suggests the involvement of the AV access circuit. The primary safety endpoint for non-inferiority for DCB vs. PTA was met with one-sided p-value of p = 0.0019. Percentages reported are derived from Kaplan-Meier analyses.

† On the U.S. Market, as of February 2020

BD

Lutonix™ 035

Drug Coated Balloon PTA Catheter

Balloon Diameter (mm)	Balloon Length (mm)	RBP (atm)	Sheath Profile	Shaft Length		
				40 cm	75 cm	100 cm
4	40	12	5F		☐ LX3575440V	
	60	12	5F		☐ LX3575460V	
	80	12	5F		☐ LX3575480V	
	100	12	5F		☐ LX35754100V	
5	40	12	5F	☐ LX3540540V	☐ LX3575540V	
	60	12	5F	☐ LX3540560V	☐ LX3575560V	
	80	12	5F	☐ LX3540580V	☐ LX3575580V	
	100	12	5F	☐ LX35405100V	☐ LX35755100V	
6	40	12	5F	☐ LX3540640V	☐ LX3575640V	
	60	12	5F	☐ LX3540660V	☐ LX3575660V	
	80	12	5F	☐ LX3540680V	☐ LX3575680V	
	100	12	5F	☐ LX35406100V	☐ LX35756100V	
7	40	12	5F	☐ LX3540740V	☐ LX3575740V	
	60	12	5F	☐ LX3540760V	☐ LX3575760V	
	80	10	5F		☐ LX3575780V	
	100	10	5F		☐ LX35757100V	
8	40	10	6F	☐ LX3540840V	☐ LX3575840V	☐ LX35100840V
	60	10	6F	☐ LX3540860V	☐ LX3575860V	☐ LX35100860V
	80	10	6F		☐ LX3575880V	☐ LX35100880V
	100	10	6F		☐ LX35758100V	☐ LX351008100V
9	40	11	7F		☐ LX3575940V	☐ LX35100940V
	60	11	7F		☐ LX3575960V	☐ LX35100960V
	80	10	7F		☐ LX3575980V	☐ LX35100980V
10	40	10	7F		☐ LX35751040V	☐ LX351001040V
	60	10	7F		☐ LX35751060V	☐ LX351001060V
12	40	10	7F		☐ LX35751240V	☐ LX351001240V
	60	10	7F		☐ LX35751260V	☐ LX351001260V

Nominal Pressure
4, 5, 7x80, 7x100, 8, 9, 10, 12 mm = 6 atm
6, 7x40, 7x60 mm = 7 atm

REPRESENTATIVE NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

Lutonix™ 035 Drug Coated Balloon PTA Catheter

Indications for Use: The Lutonix™ Catheter is indicated for percutaneous transluminal angioplasty (PTA), after pre-dilatation, for treatment of stenotic lesions of dysfunctional native arteriovenous dialysis fistulae that are 4 mm to 12 mm in diameter and up to 80 mm in length.

Contraindications: 1) Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children over the next 2 years. 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. **2)** Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.

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. **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 after the "Use by" date. **3)** Do not use if product damage is evident. **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 as this may cause air emboli in case of balloon burst. **7)** This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds as this may cause allergic reaction (difficulty in breathing, skin rash, muscle pain).

Precautions: General Precautions: 1) The Lutonix™ Catheter should only be used by physicians trained in peripheral vascular percutaneous interventional procedures. **2)** Consideration should be given to the risks and benefits of use in patients with a history of non-controllable allergies to contrast agents. **3)** The safety and effectiveness of the LUTONIX® Catheter have not been established for treatment in cerebral, carotid, coronary, or renal vasculature. **4)** The safety and effectiveness of using multiple Lutonix® drug coated balloons that deliver greater than 7.6 mg paclitaxel in a patient has not been clinically evaluated.

Potential Adverse Events: Potential adverse events which may be associated with a PTA balloon dilation procedure include, but are not limited to, the following: • Additional intervention • Allergic reaction to drugs or contrast medium • Aneurysm or pseudoaneurysm • Arrhythmias • Embolization • Hematoma • Hemorrhage, including bleeding at the puncture site • Hypotension/hypertension · Inflammation • Loss of permanent access • Occlusion • Pain or tenderness • Sepsis/infection · Shock • Stroke • Thrombosis • Vessel dissection, perforation, rupture, or spasm

Although systemic effects are not anticipated, refer to the Physicians' Desk Reference for more information on the potential adverse events observed with paclitaxel.

Potential adverse events, not described in the above source, which may be unique to the paclitaxel drug coating include, but are not limited to, the following: • Allergic/immunologic reaction to the drug coating (paclitaxel) • Alopecia • Anemia • Blood product transfusion • Gastrointestinal symptoms • Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis • Myalgia/Arthralgia • Myelosuppression • Peripheral neuropathy

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

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