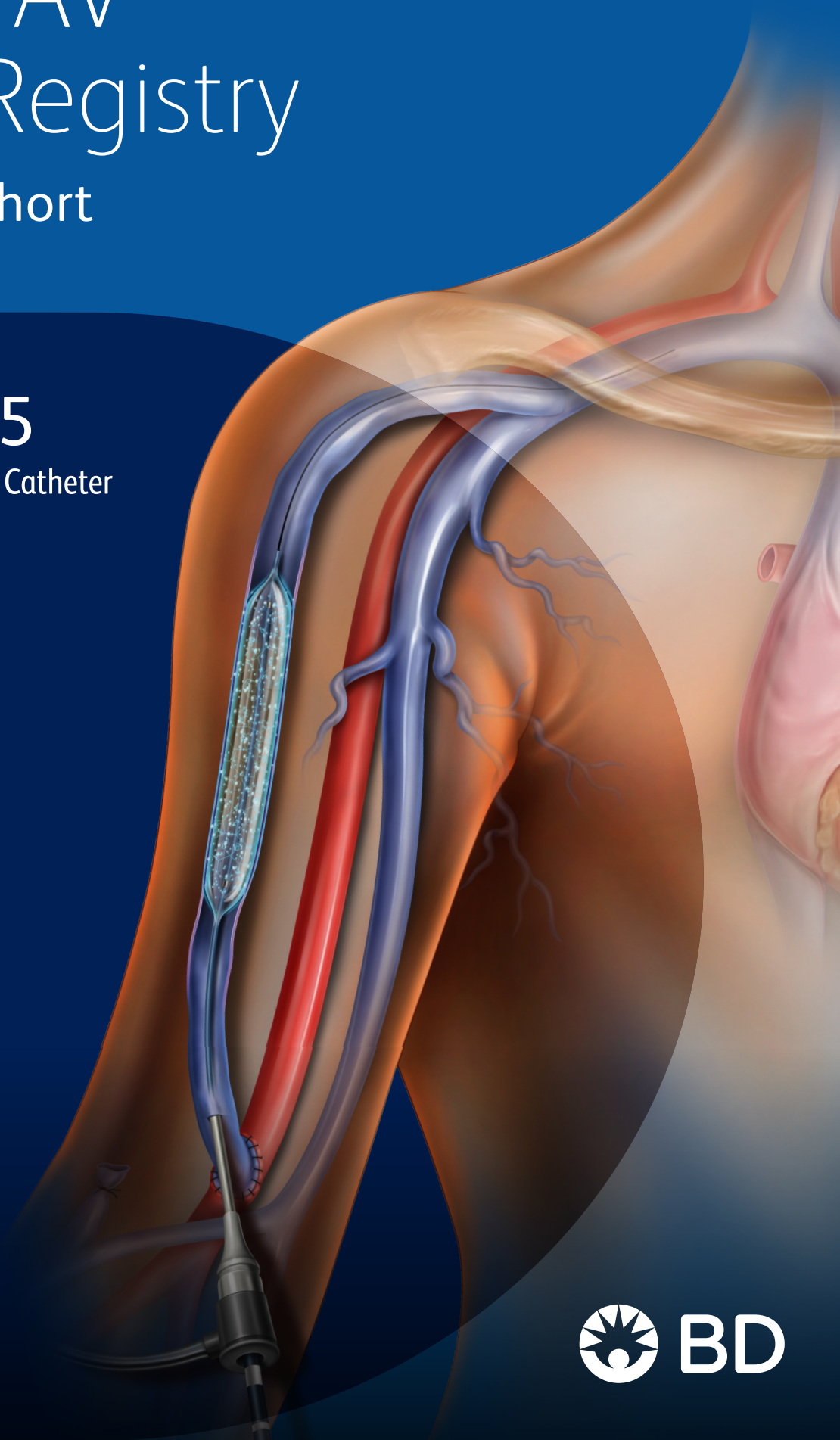
Lutonix AV Global Registry

AV Fistula Cohort

Lutonix™ 035

Drug Coated Balloon PTA Catheter



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Lutonix AV Global Registry AV Fistula Cohort[1]

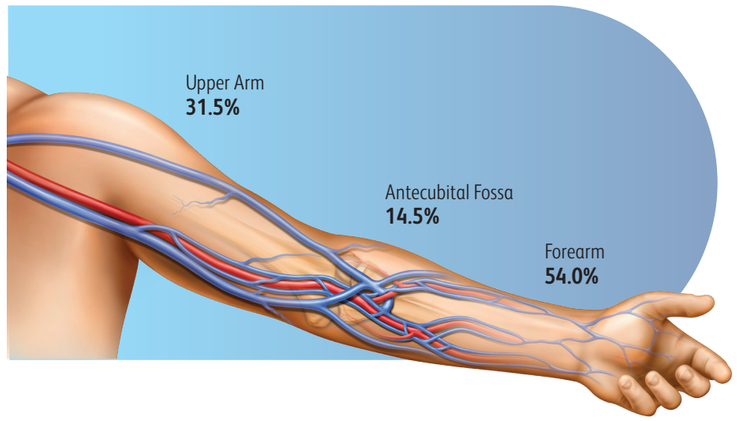
The Lutonix AV Global Registry was a prospective, multi-center, single-arm, real-world registry that assessed the safety and effectiveness of Lutonix™ 035 DCB in a real-world setting.

The **Lutonix AV Fistula Cohort** included subjects from the Lutonix AV Global Registry who met the Lutonix AV IDE Trial eligibility criteria.[1]

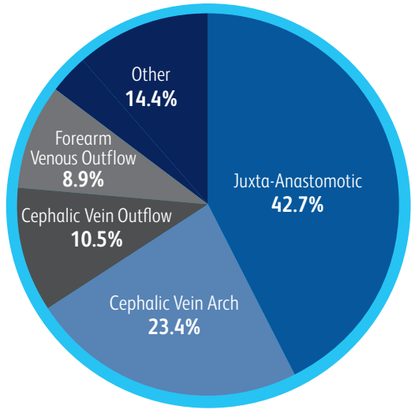
Lutonix AV Fistula Cohort Overview

Patients/Sites	124 patients at 18 international sites
Primary Effectiveness Endpoint	Target Lesion Primary Patency (TLPP) at 6 months
Primary Safety Endpoint	Freedom from serious adverse events involving the AV access circuit through 30 days
Key Inclusion Criteria	Target lesion located from anastomosis to axillosubclavian junction, ≥50% stenosis, reference vessel diameter of 4-12 mm
Follow Up	12 months

Fistula Locations



Target Lesion Location

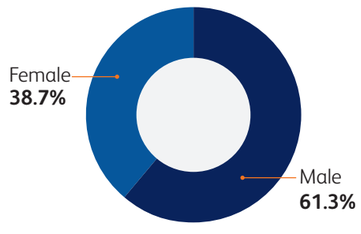


Demographics

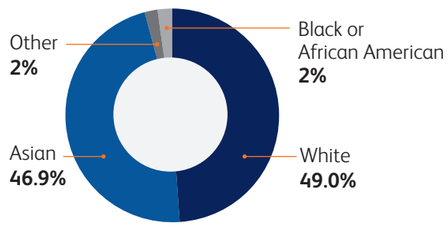
Age (years), Mean

67.7

Gender



Race[2]



Measurable Outcomes

Primary Endpoints

94.9%
Primary Safety Endpoint at 30 Days

85.1%
Target Lesion Primary Patency at 6 months

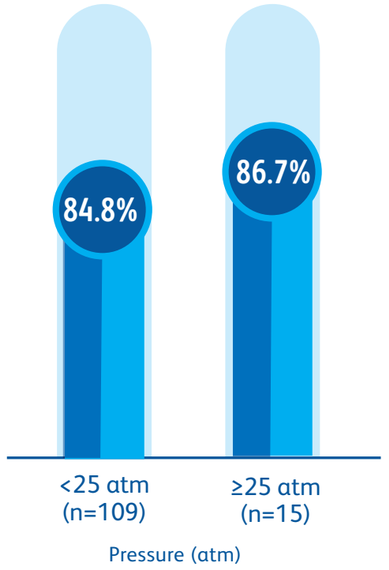
Reinterventions

At 6 months
74%
of patients remained free from CD-TLR at the target lesion

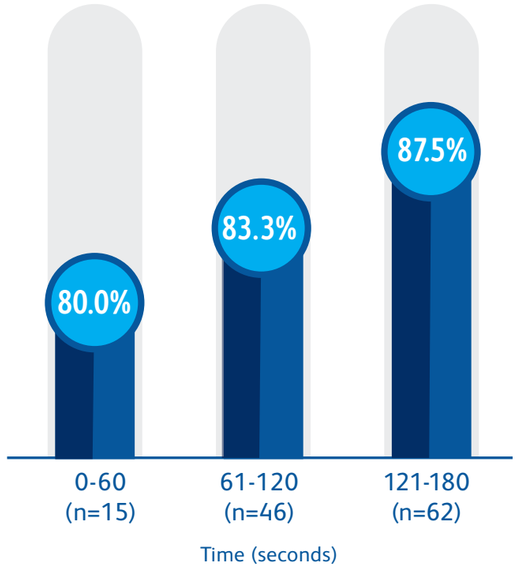
Target Lesion Primary Patency by Procedural Technique

Higher target lesion primary patency rates were observed with greater vessel preparation pressure and longer Lutonix™ 035 DCB inflation times.

6-month TLPP by **Vessel Preparation Pressure**
(pre-dilatation balloon)



6-month TLPP by **Inflation Time**
(drug-coated balloon)



Lutonix™ 035

Drug Coated Balloon PTA Catheter

Diameter (mm)	Length (mm)	RBP (atm)	Sheath Profile	Shaft Length	
				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	☐ LX3575540V	
	60	12	5F	☐ LX3575560V	
	80	12	5F	☐ LX3575580V	
	100	12	5F	☐ LX35755100V	
6	40	12	5F	☐ LX3575640V	
	60	12	5F	☐ LX3575660V	
	80	12	5F	☐ LX3575680V	
	100	12	5F	☐ LX35756100V	
7	40	12	5F	☐ LX3575740V	
	60	12	5F	☐ LX3575760V	
	80	10	5F	☐ LX3575780V	
	100	10	5F	☐ LX35757100V	
8	40	10	6F	☐ LX3575840V	☐ LX35100840V
	60	10	6F	☐ 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

[1]Post Hoc Analysis, Lutonix AV Fistula Cohort, a subset of the Lutonix Global AV Registry. Primary efficacy endpoint was target lesion primary patency, defined as the interval following treatment until freedom from a clinically driven re-intervention of the target lesion or access thrombosis, through 6 months. Primary safety endpoint defined as freedom from localized or systemic serious adverse events through 30 days that reasonably suggests the involvement of the AV access circuit. At 6 months, 92 of the 124 (74.2%) subjects had no clinically-driven reintervention of the target lesion or access thrombosis. Data on file. BD. Tempe, AZ.

Lutonix AV IDE Trial. At 6 months, treatment with Lutonix™ 035 DCB resulted in a target lesion patency rate of 71.4% versus 63.0% with standard PTA alone. Target lesion primary patency defined as freedom from 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. At 30 days, treatment with Lutonix™ 035 DCB was associated with 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. Trerotola SO, Saad TF, Roy-Chaudhury P. The lutonix av randomized trial of paclitaxel-coated balloons in arteriovenous fistula stenosis: 2-year results and subgroup analysis. *J Vasc Interv Radiol*. 2020;31(1). doi:10.1016/j.jvir.2019.08.035.

Percentages reported are derived from Kaplan-Meier analyses for both the Lutonix Global AV Registry, Lutonix AV Fistula Cohort and Lutonix AV IDE Trial.

[2] One limitation of the Lutonix AV Global Registry is that the subjects who met the Lutonix AV IDE eligibility criteria (the AV Fistula Cohort) are primarily White (49%) or Asian (46.9%) and thus are not entirely reflective of a U.S. patient population. Please consult product instructions for use for additional details.

The Lutonix™ 035 Drug Coated Balloon PTA 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: 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).

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 · Steal Syndrome · 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 respective product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions. Lutonix™ DCB is $\mathrm{R}_{\mathrm{X}\ \mathrm{Only}}$

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