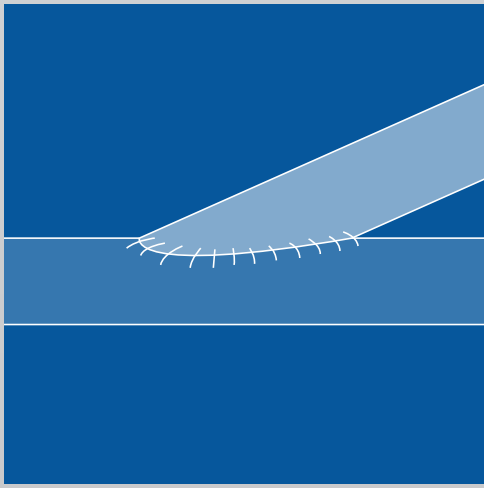
Lutonix DCB AV Global Registry



LUTONIX® 035
Drug Coated Balloon PTA Catheter

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Lutonix DCB AV Global Registry

The objective of the Lutonix DCB AV Global Registry was to demonstrate safety and assess the clinical use and outcomes of the LUTONIX® DCB for treatment of dysfunctional arteriovenous fistulae (AVFs) & arteriovenous grafts (AVGs) located in the arm in a heterogeneous patient population in **real world clinical practice**.

- ISR
- De novo lesions
- Restenotic lesions

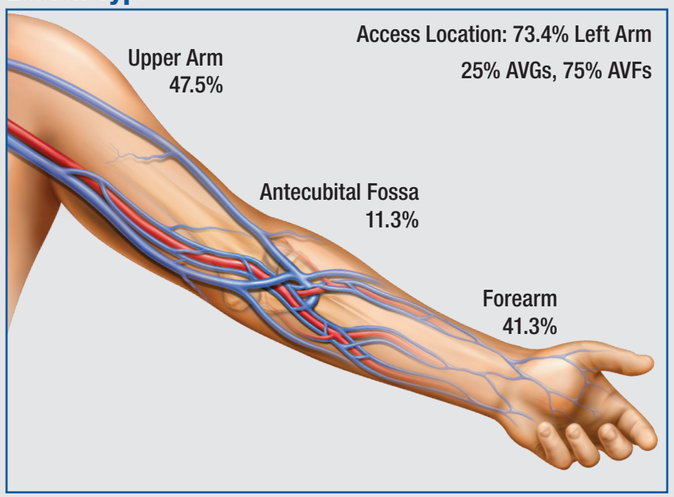
Study Design and Procedure

Trial Design	Prospective, Multi-Center, Single-Arm, Real-World Registry
Number of Patients/Sites	320 subjects with 391 lesions in 25 international centers
Key Inclusion Criteria	AVFs and AVGs located in the arm, **including central veins**, presenting with any clinical, physiological or hemodynamic abnormalities warranting angiographic imaging as defined in the K/DOQI guidelines
Primary Effectiveness Endpoint	Target Lesion Primary Patency (TLPP) - 6 months
Primary Safety Endpoint	Freedom from any serious adverse event(s) involving the AV access circuit through 30 days
Follow Up	12 months

Baseline Characteristics

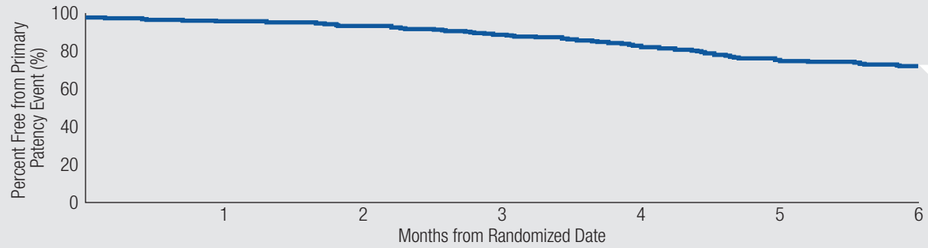
Baseline Characteristics	**AV Registry (N=320)**
Age (years), Mean ± SD (n)	67.3 ± 12.8 (320)
Median (min, max)	69.0 (32.0, 90.0)
Gender, % (n/N)	
Female	43.4% (139/320)
Male	56.6% (181/320)
Race, % (n/N)	
Asian	42.0% (102/243)
Black or African American	3.7% (9/243)
Other	2.1% (5/243)
White	52.3% (127/243)
Any Diabetes, %	41.9% (134/320)
Dyslipidemia, %	26.9% (86/320)
Hypertension, %	73.4% (235/320)

Lesion Type



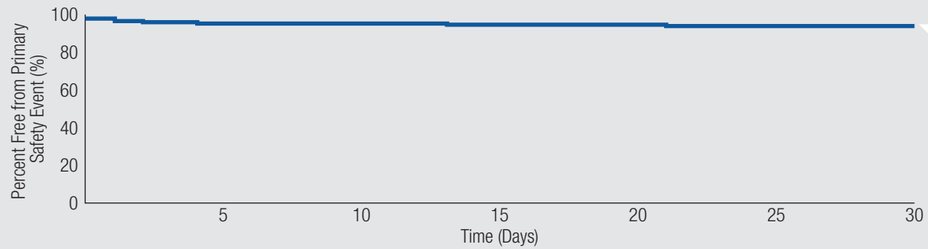
Primary Endpoints and Subgroups

Primary Endpoint: Patency (Kaplan-Meier at 6 Months)



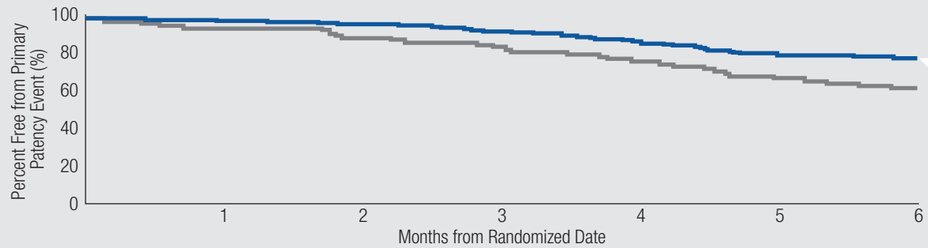
73.9%
TLPP AT 6 MONTHS IN REAL-WORLD TREATED LESIONS*

Freedom from Primary Safety Event (Kaplan-Meier at 30 Days)



96.1%
FREEDOM FROM PRIMARY SAFETY EVENTS AT 30 DAYS

Subgroups: TLPP by Access Type (Kaplan-Meier at 6 Months)



78.1%
TLPP IN FISTULA AT 6 MONTHS VS. 61.9% TLPP IN GRAFT

Exploratory Subgroup Analysis: Procedural Details TLPP at 6 Months

Variable	Level	TLPP at 6 Months	P-Value
Vessel Preparation	Yes	77.0%	0.0005
	No	48.6%	
Inflation Time	50-120 seconds	67.9%	0.0074
	120-180 seconds	79.8%	
	180-240 seconds	75.0%	

Lutonix Global AV Registry data on file. N=320. At 6 months, treatment with LUTONIX® 035 DCB resulted in a target lesion primary patency (TLPP) rate of 73.9%. By access type, treatment with LUTONIX® 035 DCB resulted in a TLPP of 78.1% for native fistulas only (240/320) and 61.9% for synthetic (graft) only (80/320). TLPP defined as the interval following index procedure intervention until clinically driven reintervention of the target lesion or access thrombosis. At 30 days, treatment with the LUTONIX® 035 DCB resulted in a freedom from primary safety event rate of 96.1%. Primary safety defined as freedom from any serious adverse event(s) involving the AV access circuit through 30 days. Percentages reported are estimated based on Kaplan-Meier estimates.

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. $\mathrm{R}_{\mathrm{X}\ \mathrm{Only}}$

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