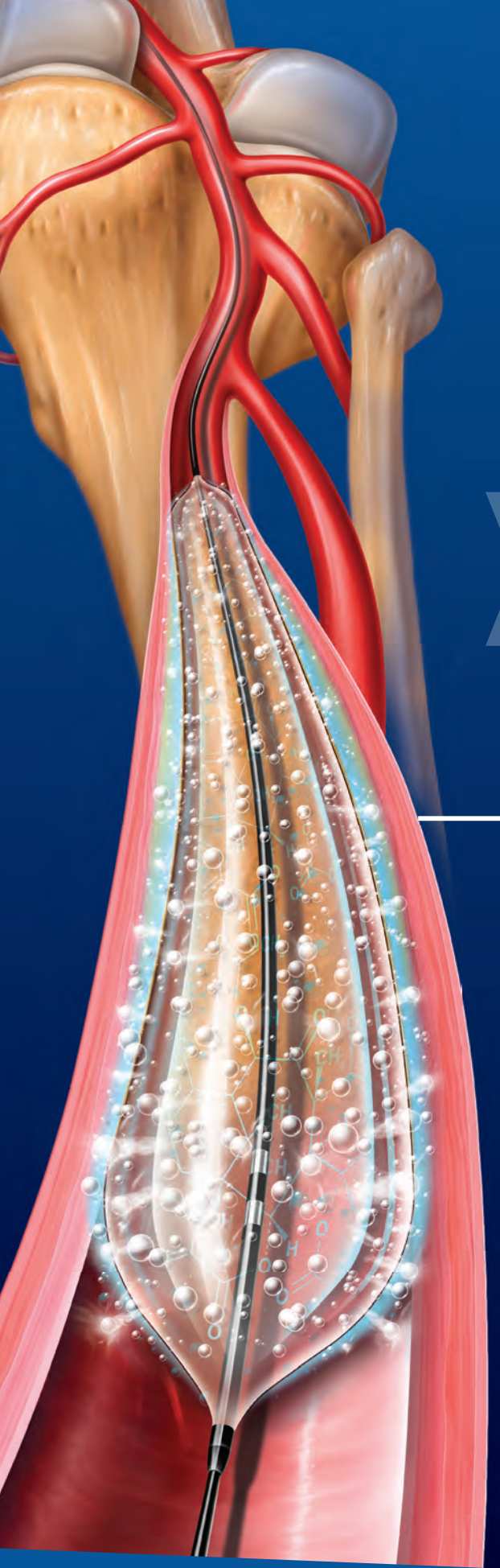


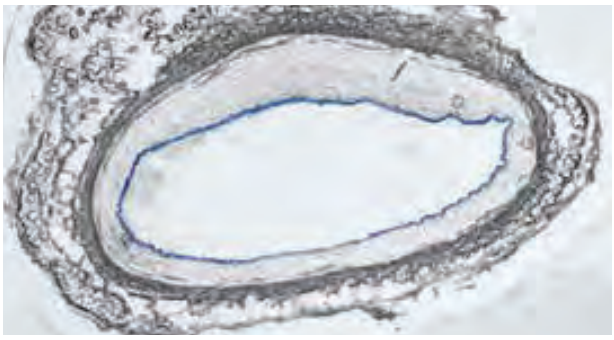
Go Further With **Lutonix™ 014** Drug Coated Balloon PTA Catheter

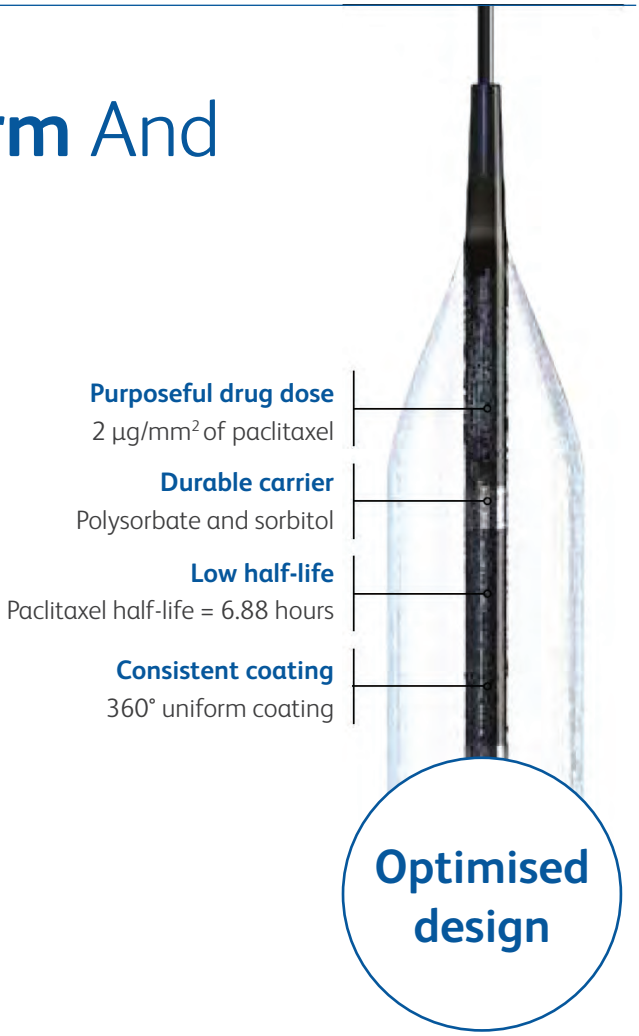
LUTONIX™ 014
Drug Coated Balloon PTA Catheter

BD

Low Profile With **Uniform** And **Durable Coating**

The LUTONIX™ 014 DCB has a **consistent coating** enabling 360° paclitaxel treatment at the target vessel. With a purposeful dose and appropriate excipient, the formulation **allows for effective transfer of drug to the vessel wall** while minimising downstream effects.

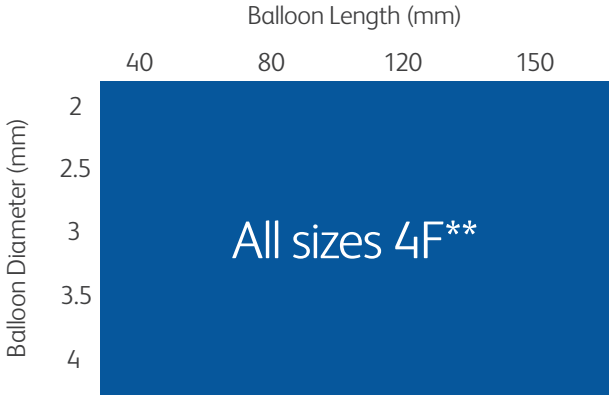




Product Performance

Utilising Ultraverse™ 014 technology as the base catheter, Lutonix™ 014 DCB provides **excellent pushability and trackability.** Our low 4F portfolio **allows for small entry profile and alternative access sites.**

Lutonix™ 014 DCB also features the GeoAlign™ Marking System which **increases procedure efficiency and decreases fluoroscopy exposure*.**



27% reduction in fluoroscopy time

* The GEOALIGN™ Marking System provides an approximation that may not be an exact representation of the distance traveled intravascularly and should be confirmed under fluoroscopy.
** All sizes available in 150 cm catheter lengths.

The Lutonix™ 014 DCB demonstrated non-inferior safety and DCB patients had 73.7 more days before first TLR and fewer reinterventions through 6 months in a rigorous Level 1, randomised 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%

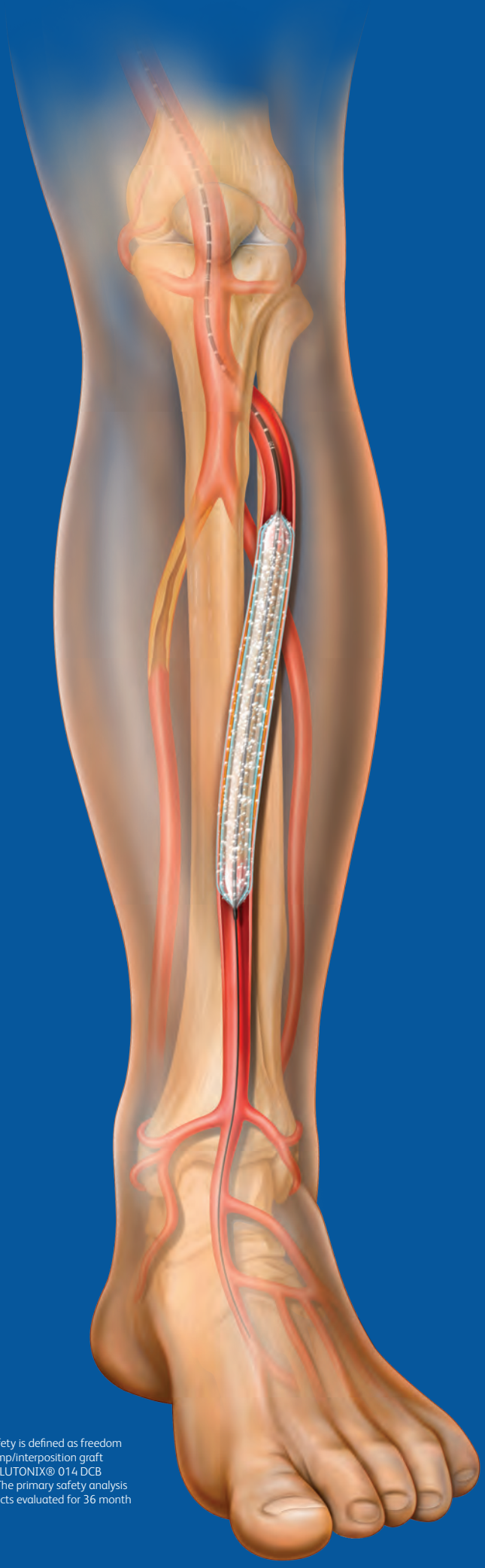
PTA 95.3%

6 month efficacy*

DCB

73.7

MORE DAYS BEFORE FIRST TLR



LUTONIX™ 014

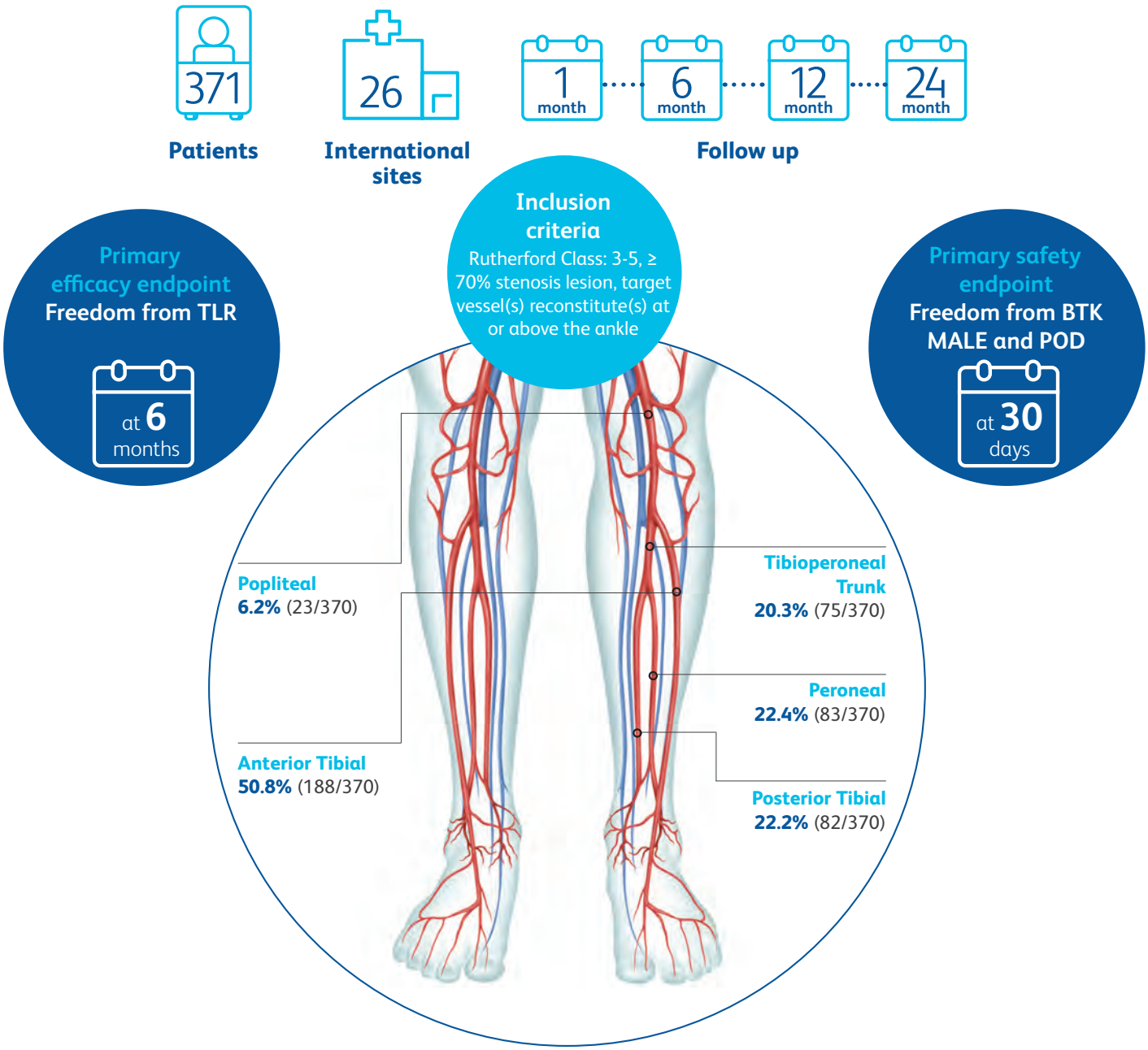
Drug Coated Balloon PTA Catheter

*As of July 2019 in the U.S. Percentages reported are derived from Kaplan-Meier analyses at 180 days. 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 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. The primary safety analysis for non-inferiority for DCB vs. PTA was met with a p-value of <0.001. As of January 2019, 52% (230/442) of subjects evaluated for 36 month follow-up. No statistical difference in All Cause Death (P=0.542

The Lutonix BTK Real-World Global Registry

The primary objective of the Lutonix Global Registry was to **demonstrate safety** and assess the clinical use and outcomes of the Lutonix™ DCB for treatment of **below-the-knee arteries** in a heterogeneous patient population in real world clinical practice.

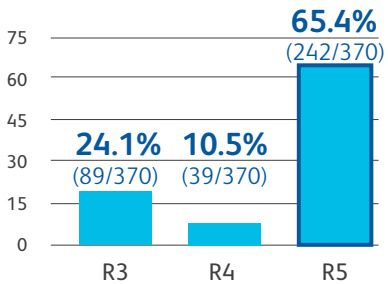
Registry Overview



Selected Demographics (DCB)

Risk Factors, % (n/N):		
Diabetes	**63.9%**	(237/371)
Dyslipidemia	**62.8%**	(233/371)
Hypertension	**87.1%**	(323/371)
Smoking (current)	**12.9%**	(48/371)
Smoking (former)	**38.5%**	(143/371)

Rutherford Category



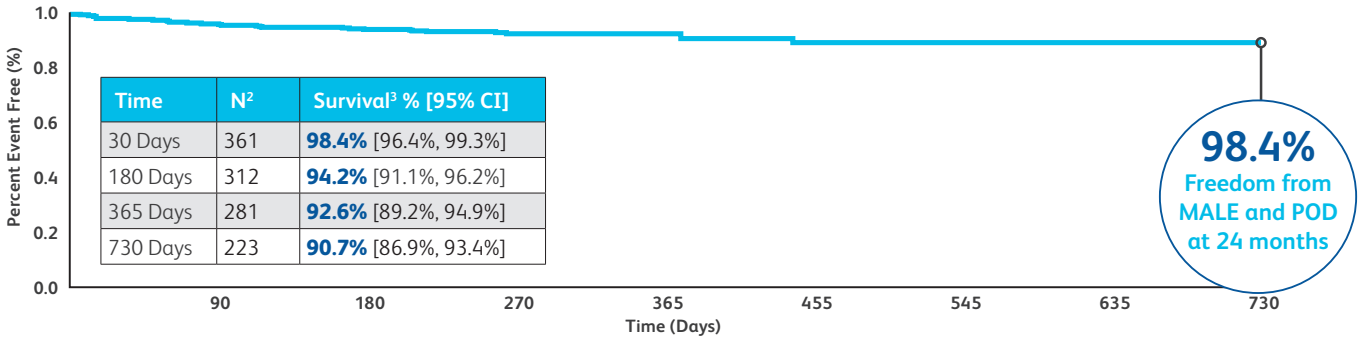
Baseline Angiographic Data (DCB)

Mean RVD, mm (n)	**2.7 ± 0.52 mm**	367
Any calcification, % (n/N)	**68.4%**	(242/354)
Severe calcification, % (n/N)	**20.5%**	(73/356)
Mean target lesion length, mm (n)	**121 ± 98.7**	(370)

Effective And **Safe** At 24 Months

Primary Safety[1]

Freedom from TVR, major index limb amputation, and device and all cause death

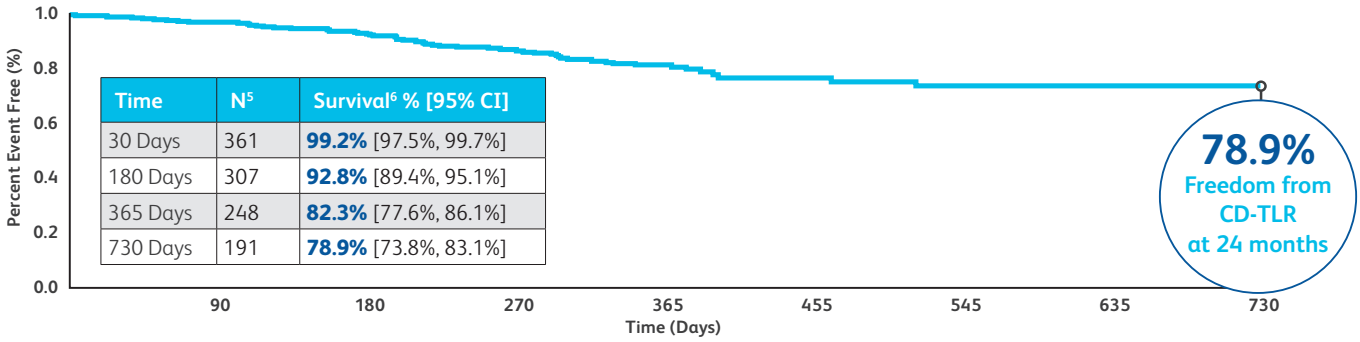


Time	N[2]	Survival[3] % [95% CI]
30 Days	361	**98.4%** [96.4%, 99.3%]
180 Days	312	**94.2%** [91.1%, 96.2%]
365 Days	281	**92.6%** [89.2%, 94.9%]
730 Days	223	**90.7%** [86.9%, 93.4%]

98.4%
Freedom from MALE and POD at 24 months

Primary Efficacy[4]

Freedom from clinically driven TLR



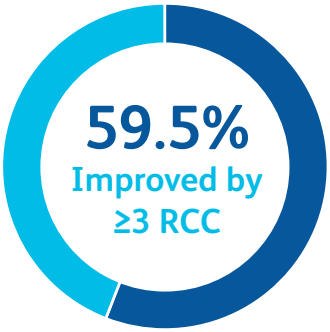
Time	N[5]	Survival[6] % [95% CI]
30 Days	361	**99.2%** [97.5%, 99.7%]
180 Days	307	**92.8%** [89.4%, 95.1%]
365 Days	248	**82.3%** [77.6%, 86.1%]
730 Days	191	**78.9%** [73.8%, 83.1%]

78.9%
Freedom from CD-TLR at 24 months

Freedom from:	Survival% [95% CI]
All cause death	80.5% (n=61) (75.7%, 84.5%)
Major amputation	93.4% (n=60) (88.6%, 95.6%)
Reintervention for Thrombosis/ Thrombolysis	89.1% (n=57) (84.9%, 92.1%)
Reintervention for Distal Embolization	100% (n=61) (NA,NA)
TVR	74.6% (n=48) (67.4%, 80.4%)
Unexpected device or drug related event	100% (n=61) (NA, NA)

24 month data

Rutherford improvement



LUTONIX™ 014
Drug Coated Balloon PTA Catheter

150 cm Catheter Length			
Order code	**Balloon Diameter (mm)**	**Balloon Length (mm)**	**Sheath Size (F)**
9020515200040	2	40	4F
9020515200080		80	4F
9020515200120		120	4F
9020515200150		150	4F
9020515250040	2.5	40	4F
9020515250080		80	4F
9020515250120		120	4F
9020515250150		150	4F
9020515300040	3	40	4F
9020515300080		80	4F
9020515300120		120	4F
9020515300150		150	4F
9020515350040	3.5	40	4F
9020515350080		80	4F
9020515350120		120	4F
9020515350150		150	4F
9020515400040	4	40	4F
9020515400080		80	4F
9020515400120		120	4F
9020515400150		150	4F

Norminal pressure: 6 ATM
RBP: 15 ATM

Intended use/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™ 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.
- 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

1 General Precautions

- The safety and effectiveness of using more than 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 non-controllable allergies to contrast agents.

2 Use in Conjunction with Other Procedures

The safety and effectiveness of the Lutonix™ Catheter used in conjunction with other drug eluting stents or drug coated balloons in the same procedure or following treatment failure has not been evaluated.

3 Device Handling Precautions

- Do not immerse the Lutonix™ Catheter in a saline bath. Replace any device where the balloon has come into contact with fluids prior to use.
- The coated balloon portion should be handled with dry sterile gloves whenever possible prior to use.
- The balloon protector should stay in place during preparation of the Lutonix™ Catheter and not be removed until just prior to placing over guidewire.
- If difficulty is encountered while removing the balloon protector, a new Lutonix™ Catheter should be utilized. Removing the balloon protector by force can cause a kink in the catheter shaft and lumen constriction may occur, affecting inflation/deflation of the balloon.

4 Device Use/Procedure Precautions

- To ensure therapeutic drug delivery:

  Never inflate the Lutonix™ Drug Coated Balloon prior to reaching the target lesion.

  The Lutonix™ Catheter should be advanced to the target site as fast as possible (i.e. ≤ 30 seconds) and immediately inflated to appropriate pressure to ensure full wall apposition (balloon to artery ratio of ≥ 1:1). If the time to deployment of the Lutonix™ Catheter exceeds 3 minutes, the catheter requires replacement with a new unit.
- Maintain balloon inflation for a minimum of 2 minutes (120 seconds). The balloon may remain inflated as long as is required by the standard of care to achieve a good angioplasty outcome.
- Appropriate vessel preparation, such as predilatation, is recommended to achieve optimal DCB results.
- After insertion, do not over-tighten the hemostatic adaptor (if used) around the Lutonix™ Catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.
- Always advance and retrieve the Lutonix™ Catheter under negative pressure.
- The Lutonix™ Catheter should always be manipulated under fluoroscopic observation when in the body.
- Do not continue to use the Lutonix™ Catheter if the shaft has been bent or kinked.
- Whenever possible, the Lutonix™ Catheter should be the final treatment of the vessel; however, post-dilatation is allowed with another PTA catheter or the previously used Lutonix™ catheter.

5 Pre- and Post-Procedure Antiplatelet Regimen

Dual antiplatelet therapy should be administered according to current medical standards pre-procedure and for a minimum of 4 weeks after the intervention. Prolonged antiplatelet therapy can be given at the discretion of the physician.

1. 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 at 30 days. Treatment with LUTONIX™ 014 DCB resulted in a freedom from primary safety event rate of 98.3% (354/360). Interim Data as of January 2019.
2. Subjects ongoing without an event at the beginning of the visit window
3. Primary safety response estimate based on Kaplan-Meier estimate
4. Primary Efficacy was defined as freedom from clinically-driven target lesion reintervention (TLR) at 6 months. Treatment with LUTONIX™ 014 DCB resulted in a freedom from primary efficacy event rate of 90.0% (289/321). Interim Data as of January 2019.
5. Subjects ongoing without a TLR failure at the beginning of the visit window
6. TLR-Free response estimate based on Kaplan-Meier estimates

BD Switzerland Sarl, Terre Bonne Park – A4, Route De Crassier, 17, 1262 Eysins, Vaud. Switzerland.

bd.com

CE 2797