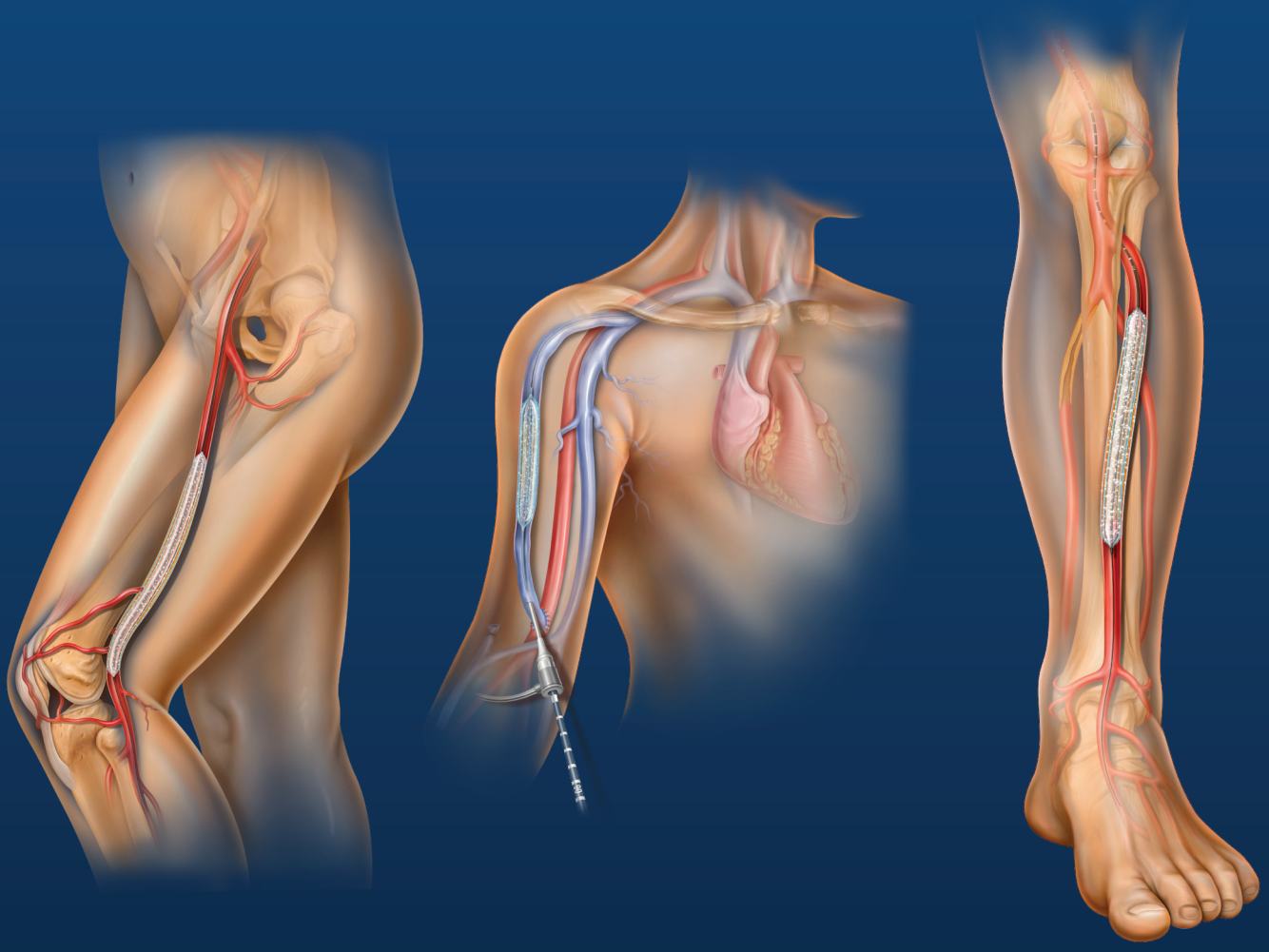
Leading with **evidence**



From **SFA** to **AV** to **BTK**

Lutonix™

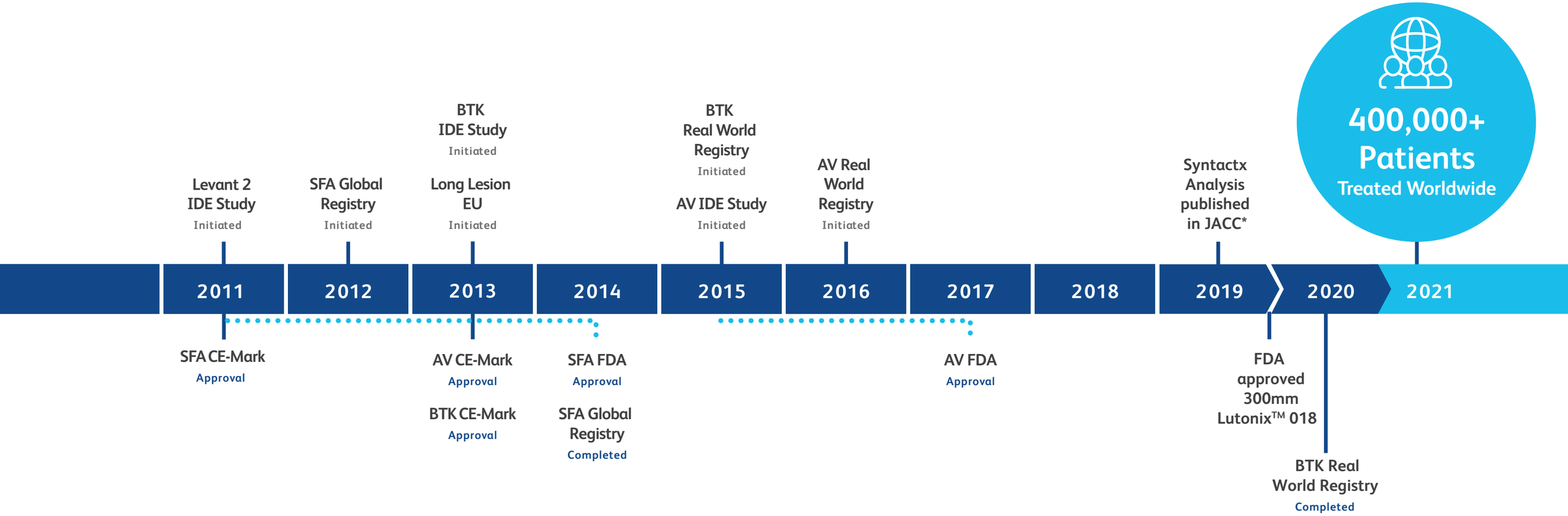
Drug Coated Balloon PTA Catheter

BD

First in clinical evidence

Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

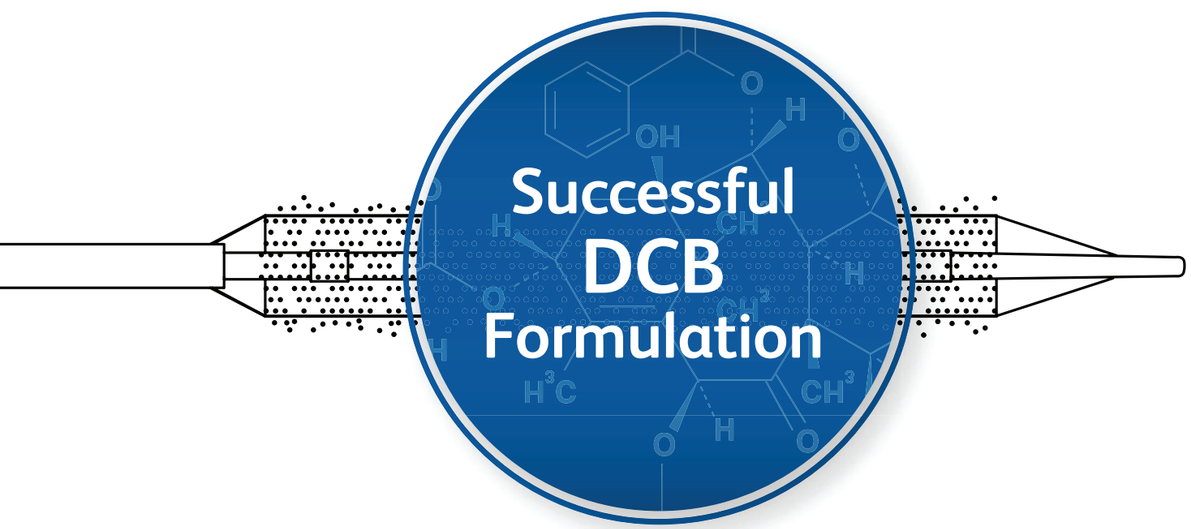
Lutonix™ has led the way in DCB innovation, starting with the first Global prospective randomised trial, making it the first FDA approved DCB in the US. This was followed by the first prospective randomised trial of Lutonix™ DCB in dysfunctional AV Fistulae. And then Lutonix™ studying the benefit and safety of DCB BTK in a prospective global randomised trial. Lutonix™ has continued to prospectively study DCB benefit in SFA, BTK and AV disease in Real World Registry settings.



* Independent Review of the LEVANT Clinical Program

Patient **safety** starts with the right coating

Coating uniformity + **Drug retention** + **Drug release** =



Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

Formulation matters

Rigorously evaluated formulation

>225 Carriers
Hundreds of carrier molecules screened

>250 Formulations
(Paclitaxel Dose + Carriers)
Over 45 pre-clinical studies completed

120 Coatings
Over 3,400 Devices Tested

Drug coated balloons use paclitaxel with differing carriers

Drug dose of paclitaxel is 2µg/mm²

Final optimised

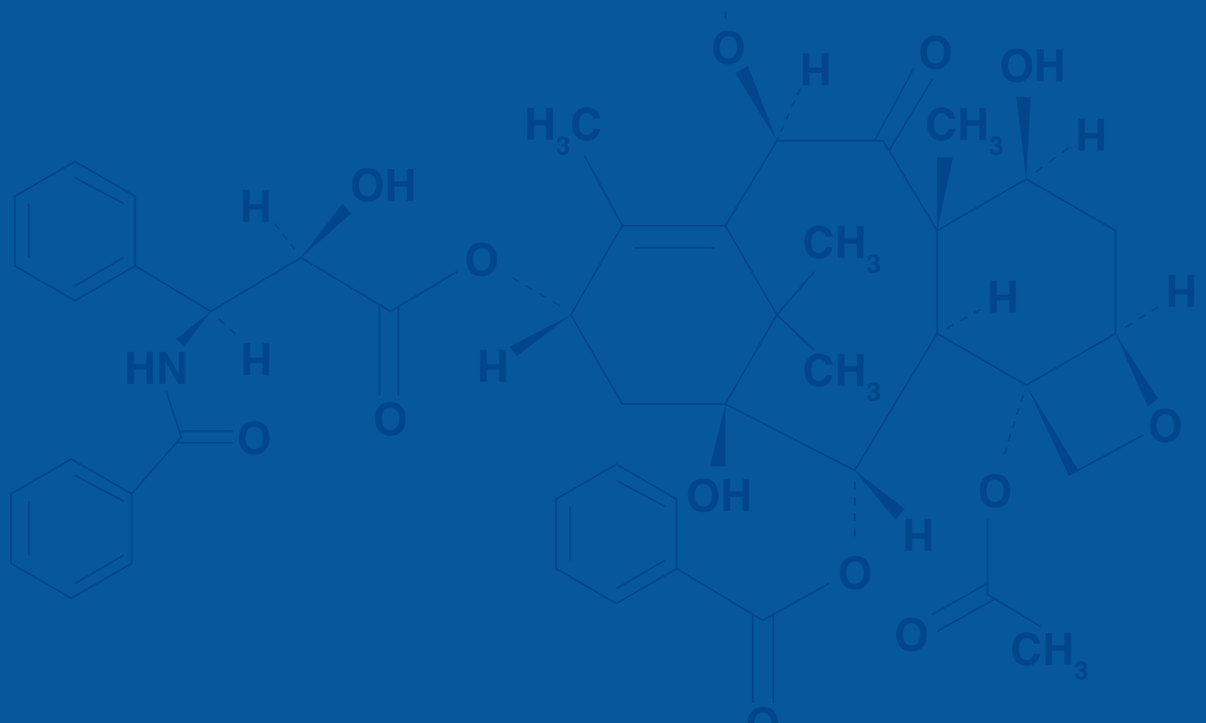
Lutonix™ DCB

Carrier of polysorbate and sorbitol

DCB coating differs depending on carrier and manufacturing process

Lutonix™ is **designed** to minimise downstream effects

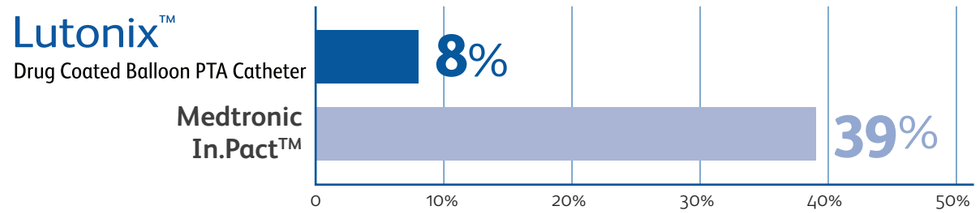
- **ZERO** preclinical evidence of downstream necrosis at 90 days[1]
- **ZERO** preclinical evidence of downstream crystalline material at 90 days[1]
- Coating formulation is designed to limit downstream effects



Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

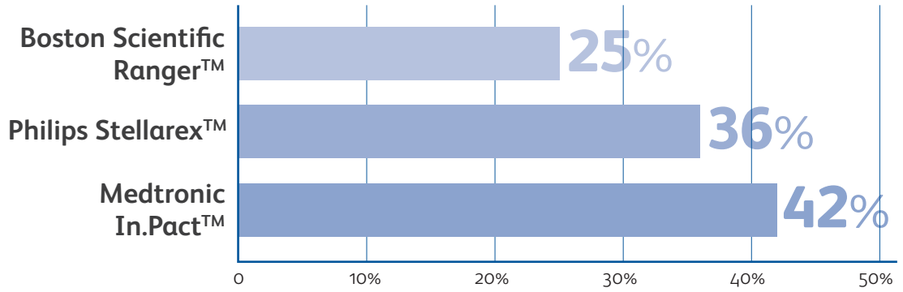
Pre-clinical testing has shown differences in downstream vascular changes among DCBs

Study I: Percentage of sections observed with vascular changes in downstream non-target tissue from arteries harvested at 28 days.[2]



Pre-Clinical head-to-head comparison of vascular changes (inflammation, smooth muscle cell necrosis, fibrinoid necrosis, nuclear pyknosis). 3X Balloons. 30 second inflation.

Study II: Percentage of sections observed with vascular changes in downstream non-target tissue from arteries harvested at 28 days.[3]



Pre-Clinical head-to-head comparison of vascular changes (inflammation, smooth muscle cell necrosis, fibrinoid necrosis, nuclear pyknosis). 3X Balloons. 1 minute inflation.

[2] Journal of Vascular and Interventional Radiology: Comparison of Particulate Embolization after Femoral Artery Treatment with In.Pact Admiral versus Lutonix™ 035 Paclitaxel-Coated Balloons in Healthy Swine. Limitations associated with this pre-clinical study include: Pathologic findings are limited to healthy swine and do not account for the fact that human PAD presents with co-morbidities; and transferring pre-clinical findings in healthy animal arteries to humans with peripheral arterial disease is complex, as lesions can be complicated by fibrosis, necrosis and calcification. This study was funded by Lutonix, Inc. (New Hope, Minnesota). Article available at: http://dx.doi.org/10.1016/j.jvir.2016.06.036. Kolodgie et al, JVIR D-15-01131R1. Preclinical results may not be indicative of clinical performance. Different test methods may yield different results.

[3] Journal of Vascular and Interventional Radiology: Comparison of Biological Effect and Particulate Embolization After Femoral Artery Treatment with Three Drug Coated Balloons in Healthy Swine Model. This study was funded by Lutonix, Inc. (New Hope, Minnesota). Article available at: https://doi.org/10.1016/j.jvir.2018.02.006. Torrii et al.

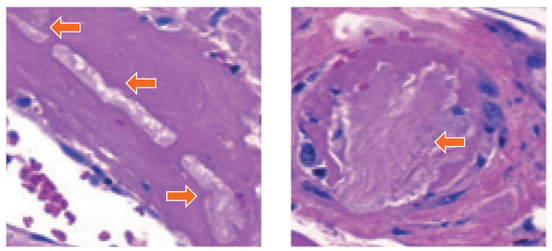
Pre-Clinical head-to-head comparison of downstream crystalline material[1,2]

Lutonix™ 035
Drug Coated Balloon PTA Catheter

ZERO

Crystalline material observed at 1x and 3x balloons

In.Pact™ Admiral DCB FreePac™ Coating



1x Balloon observed at 28 days

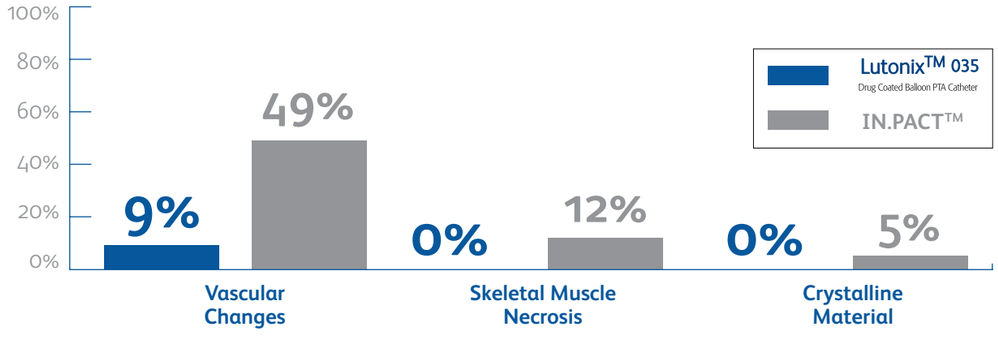
3x Balloon observed at 28 days

Comparison of Particulate Embolisation after Femoral Artery Treatment with IN.PACT™ Admiral versus Lutonix™ 035 Paclitaxel-Coated Balloons in Healthy Swine. Journal of Vascular and Interventional Radiology.

Frank D. Kolodgie, PhD, Erica Pacheco, MS, Kazuyuki Yahagi, MD, Hiroyoshi Mori, MD, Elena Ladich, MD and Renu Virmani, MD.

Arrows indicating crystalline material observed at 28 days. 1X and 3X Balloons.

Pre-clinical downstream arterial findings at 90 days[3]



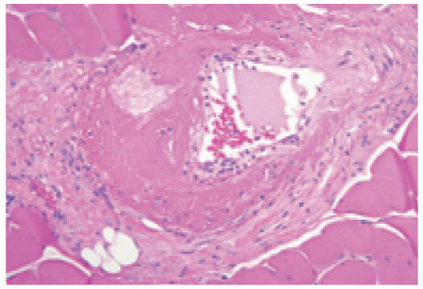
[1] Preclinical results may not be indicative of clinical performance. Different test methods may yield different results.

[2] Journal of Vascular and Interventional Radiology: Comparison of Particulate Embolization after Femoral Artery Treatment with In.Pact Admiral versus Lutonix™ 035 Paclitaxel-Coated Balloons in Healthy Swine. Limitations associated with this pre-clinical study include: Pathologic findings are limited to healthy swine and do not account for the fact that human PAD presents with co-morbidities; and transferring pre-clinical findings in healthy animal arteries to humans with peripheral arterial disease is complex, as lesions can be complicated by fibrosis, necrosis and calcification. This study was funded by Lutonix, Inc. (New Hope, Minnesota). Article available at: http://dx.doi.org/10.1016/J.jvir.2016.06.036. Kolodgie et al, JVIR D-15-01131R1.

[3] Virmani, Renu. "Comparison of Particulate Embolization after Femoral Artery Treatment with IN.PACT Admiral versus Lutonix™ 035 Paclitaxel-Coated Balloons in Healthy Swine." Journal of Vascular and Interventional Radiology, Elsevier, 15 Sept. 2016.

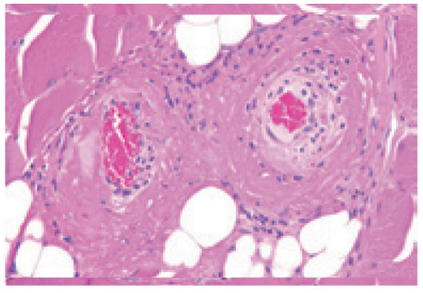
Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

Pre-clinical testing showed in.Pact™, Stellarex™ and Ranger™ DCBs each produced downstream crystalline material[1]



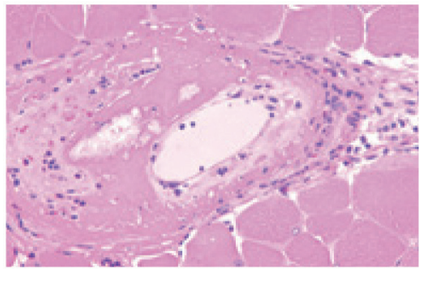
Medtronic In.Pact™

3.6-4.8%



Philips Stellarex™

2.4%



Boston Scientific Ranger™

1.2%

Percentage of sections observed with crystalline material in downstream non-target tissue from arteries harvested at 28 days. Pre-Clinical head-to-head comparison of downstream crystalline material. 3X Balloons. Data on file, Lutonix, Inc., New Hope, MN.

The first DCBwith proven performance in **SFA**[1]

- **85.4%** Primary Patency at 12 months for Real-World Registry
- Challenging patient demographic for Real-World Registry:
  - **43.4%** of patients were diabetic
  - **70.6%** of patients were Rutherford Category 3 and 4
  - **50.2%** of patients had calcified lesions

Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

SFA Real-World Registry **Freedom from TLR**

94.1% at 12 months[2]

90.3% at 24 months[2]

[2] LUTONIX Global SFA Real World Registry, n=691. Primary efficacy endpoint is defined as freedom from TLR at 12 months. TLR Free rate by subject counts at 12 months was 93.4% (⁶⁰⁵⁄₆₄₈). The Kaplan-Meier TLR-Free survival estimate was 94.1% at 12 months and 90.3% at 24 months. In the LEVANT 2 IDE Clinical Trial, treatment with Lutonix™ 035 DCB resulted in freedom from TLR rate of 87.7% at 12 months (²⁵⁵⁄₂₈₅) and a freedom from TLR rate of 82.0% at 24 months. Data on file, Bard Peripheral Vascular, Inc.

Global SFA Real-World Registry

Primary endpoints

30 day safety*

* (n/N = 681/685)

Freedom from target lesion revascularisation (TLR) at 24 months[1]

Secondary endpoints (at 24 months)[1]

All cause death, % (n/N)	5.9% (36/615)
Major index limb amputation, % (n/N)	0.9% (5/582)
Minor index limb amputation, % (n/N)	0.7% (4/580)
Reintervention for treatment of embolization to the distal vasculature, % (n/N)	0.7% (4/580)
Reintervention for treatment for thrombosis of the target vessel, % (n/N)	2.7% (16/583)

Lutonix™ 035 DCB demonstrated favourable efficacy and safety in real world patients.

Sub-group analysis (at 24 months)

Subgroup	Freedom from TLR, % (Kaplan-Meier)
Females	85.8%

Lutonix™ 035 DCB demonstrated efficacy in complex and challenging sub groups - calcified lesions, CTOs, in-stent Restenosis and long lesions (140-500 mm)

Subgroup	Freedom from TLR, % (n/N)
Calcified lesions	88.3% (174/197)
Chronic total occlusion	89.5% (162/181)
In-stent restenosis	85.5% (60/70)
Long lesions (140-500mm)	89.4% (95/106)

[1] In LEVANT 2 Clinical Trial at 12 months, treatment with Lutonix® DCB resulted in freedom from Target Lesion Revascularization rate of 89.7% (n=316, Kaplan-Meier), all cause death rate of 2.4% (7/290), major amputation rate of 0.3% (1/286), minor amputation rate of 0.0% (0/285), rate of reintervention for thrombosis and distal emboli 0.4% (1/285). Data on file.

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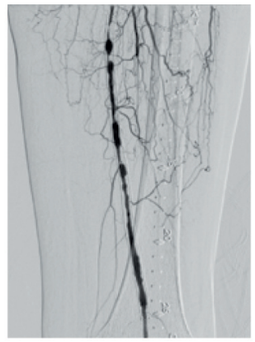
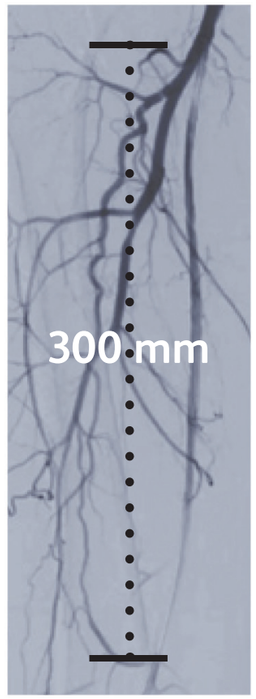
Lutonix™ Drug Coated Balloon PTA Catheter

Lutonix™ 035 SFA ISR randomised controlled trial



12 month primary endpoints (Interim results)[2]	Lutonix™ 035 DCB	PTA
Primary effectiveness	**66.2%** (N=31)	**49.6%** (N=8)
	33.5% Improvement over PTA	
Freedom from TLR (Secondary Endpoint)	**78.4%** (N=43)	**61.0%** (N=14)
	29.0% Improvement over PTA	
Safety	**72.6%** (N=40)	**61.0%** (N=14)

Lutonix™ 035 long lesion study (Europe)



Lutonix 035™ is now indicated for Long Lesions up to 300mm in the U.S.

Selected demographics

Baseline Angiographic data	Lutonix™ 035 DCB (N=118)
Lesion length	212.5 ± 68.3 mm
CTO	52.1%
Proximal SFA	51.3%
Mid SFA	35.9%
Distal SFA	14.5%
12 month primary endpoints (Interim results)[3]	Lutonix™ 035 DCB
Primary effectiveness	70.1%[4] (N=79)
Freedom from TLR (secondary endpoint)	87.4%[5] (N=97)
Safety	82.3% (N=92)

[2] Results are comprised of 82 randomized patients, from 20 sites, with 86.6% follow-up compliance through 12 months.

[3] Results are comprised of 118 patients, from 14 sites, with 89.0% follow-up compliance through 12 months. Follow-up through 36 months is ongoing.

[4] Primary effectiveness endpoint is primary patency defined as freedom from CEC-adjudicated clinicallydriven TLR and from core-lab adjudicated binary restenosis. Result is a Kaplan-Meier estimate.

[5] Result is a Kaplan-Meier estimate.

Extended time
to first reintervention

- **31.3%** fewer reinterventions in dysfunctional AV fistulae compared to PTA at 6 months
- Safety profile non-inferior to PTA
- **95.0%** freedom from primary safety event after 30 days

Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

71.4%

Primary patency at 6 months

+ 114 more

Reintervention free days at 24 months

30.0%

Improvement observed Vs. PTA at 24 months

[1] The Lutonix™ AV Clinical Trial was a prospective, multicenter, controlled study comparing the Lutonix™ 035 AV drug-coated balloon (DCB) to standard PTA for the treatment of dysfunctional AV fistulae. The study enrolled 285 patients (DCB: 141, PTA: 144) at 23 investigational sites in the U.S. from June 2015 to March 2016. The primary safety endpoint, freedom from serious adverse events involving the AV access circuit through 30 days, was 94.2% for the DCB group and 95.8% for the PTA group (proportional based analysis) while the primary efficacy endpoint, target lesion primary patency (TLPP) through 6 months, was 71.4% for the DCB group and 63% for the PTA group (Kaplan-Meier analysis at 180 days). Interim data, site reported, subject to change.

Level 1 clinical evidence for Dysfunctional AV Fistulae

Prospective, randomised, of Lutonix™ 035 DCB in Dysfunctional AV Fistulae

- 71.4% Primary patency at 6 Months
- 30.0% Improvement in primary patency over PTA at 24 months
- 95.0% Freedom from primary safety events at 30 days

Fistula locations

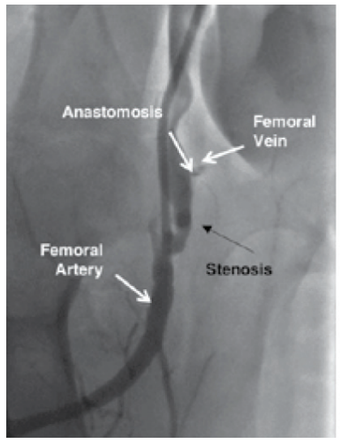
Upper arm:
DCB: 61.7% vs. PTA: 73.4%

Antecubital fossa:
DCB: 5.0% vs. PTA: 4.9%

Forearm:
DCB: 33.3% vs. PTA: 21.7%

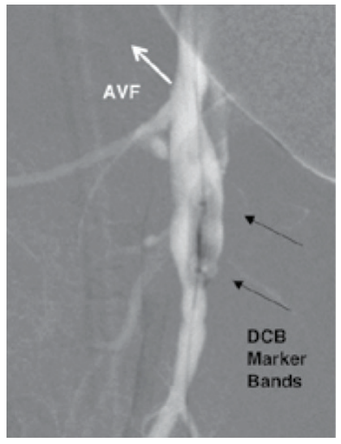
Pre-clinical Stenosed AVF Porcine Model[1]

Stenosed AV Fistula



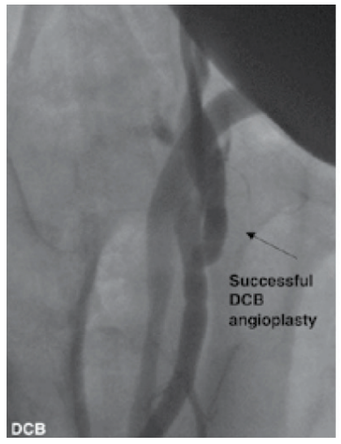
14 days post fistula creation, a stenosis is evident

Lutonix™ 035 DCB Treatment



The Lutonix™ 035 DCB is placed across the lesion and drug delivered

Post DCB Treatment



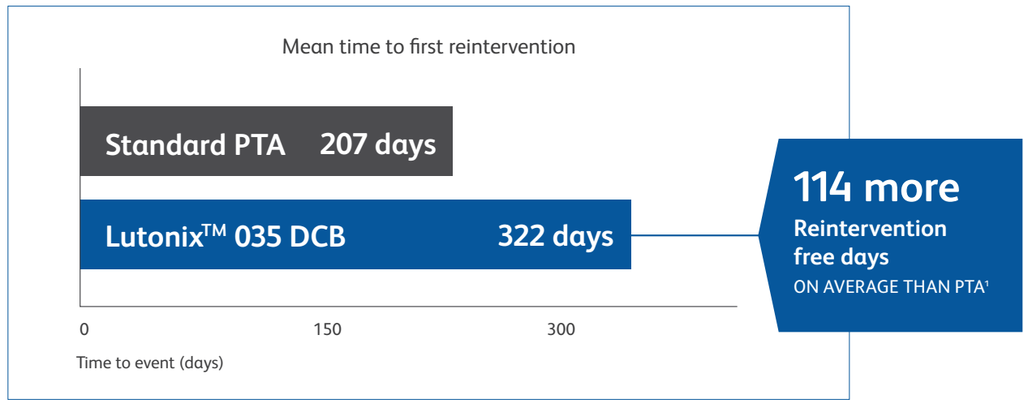
Post angioplasty, the effect of the drug and safety profile can be evaluated in the model

[1] Pre-clinical animal data on file. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.

Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

Reintervention-free days

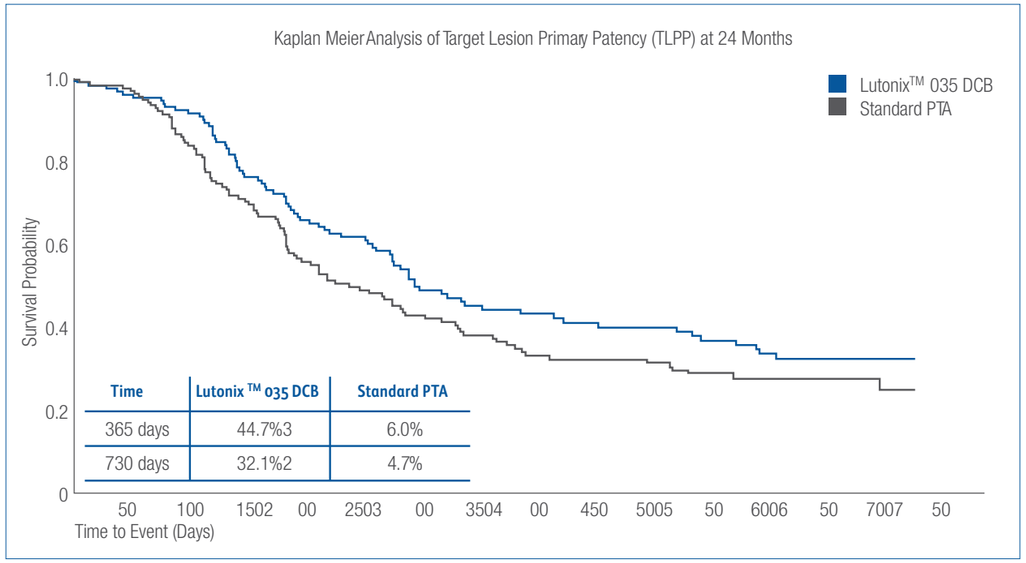
At 24 months, patients treated with a Lutonix™ 035 Drug Coated Balloon PTA Catheter went an average of **322 days before receiving a target lesion reintervention compared to 207 days** when treated with PTA alone.[1]



[2] 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. Number of interventions required to maintain TLP at 24 months were 195 in DCB arm versus 211 in the PTA arm. 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 localised 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 analysis. Interim data at 24 months, site reported, subject to change.

Target lesion primary patency: 12 and 24 months

30% improvement observed vs. PTA at 24 months



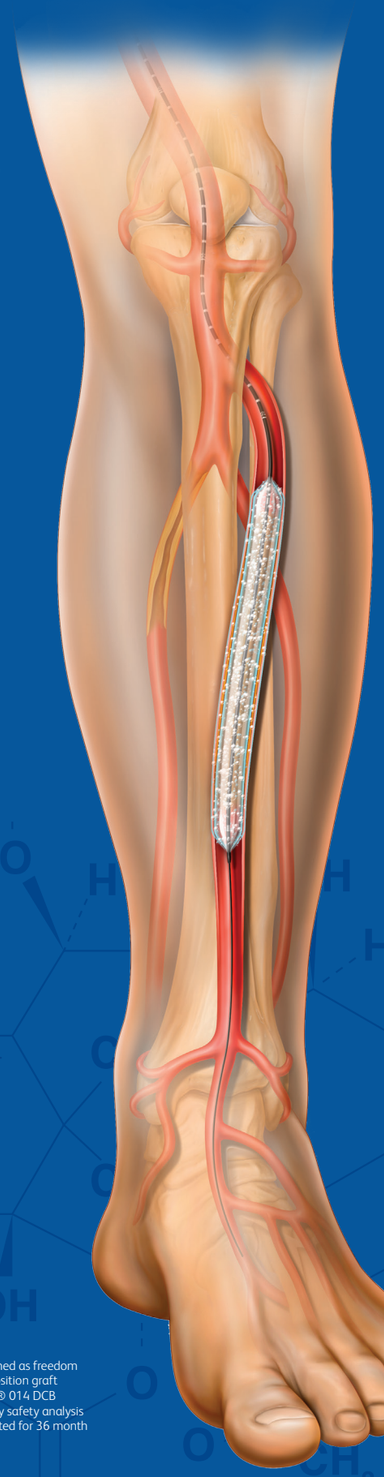
Time	Lutonix ™ 035 DCB	Standard PTA
365 days	44.7%3	6.0%
730 days	32.1%2	4.7%

The first **BTK** DCB in IDE clinical trial and real-world registry[1]

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

*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

Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

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

371 **Patients**

26 **International sites**

Follow up: 1 month, 6 month, 12 month, 24 month

Primary efficacy endpoint
Freedom from TLR
at **6** months

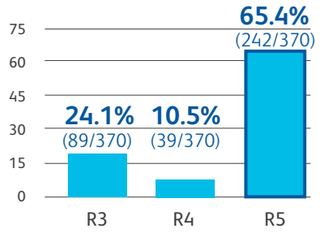
Inclusion criteria
Rutherford Class: 3-5, ≥ 70% stenosis lesion, target vessel(s) reconstitute(s) at or above the ankle

Primary safety endpoint
Freedom from BTK MALE and POD
at **30** days

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



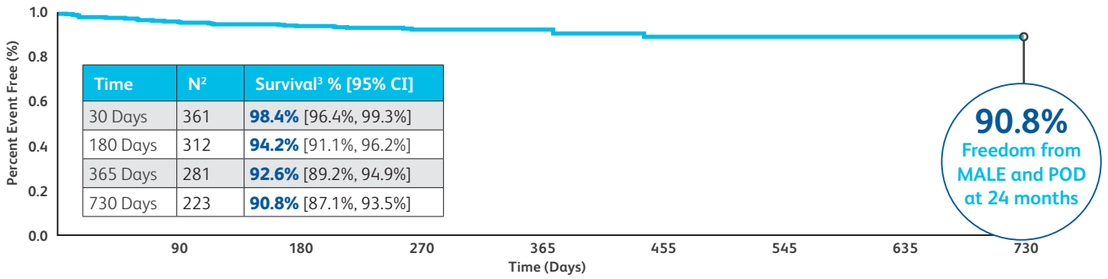
Baseline Angiographic Data (DCB)

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]

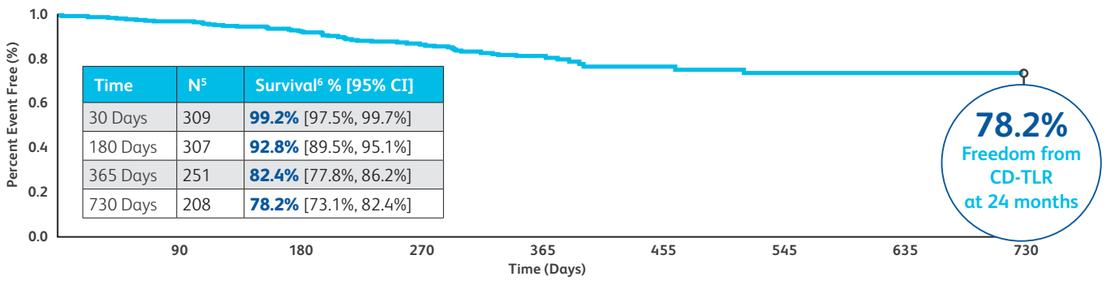
Freedom from TVR, major index limb amputation, and device and all cause death



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	**90.8%** [87.1%, 93.5%]

Primary Efficacy[4]

Freedom from clinically driven TLR

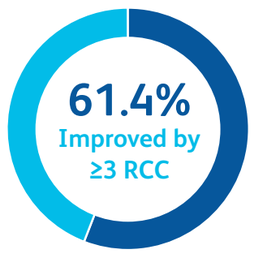


Time	N[5]	Survival[6] % [95% CI]
30 Days	309	**99.2%** [97.5%, 99.7%]
180 Days	307	**92.8%** [89.5%, 95.1%]
365 Days	251	**82.4%** [77.8%, 86.2%]
730 Days	208	**78.2%** [73.1%, 82.4%]

Freedom from:	Survival% [95% CI]
All cause death	80.8% (n=64) (76.2%, 84.7%)
Major amputation	93.5% (n=21) (90.1%, 95.7%)
Reintervention for Thrombosis/ Thrombolysis	88.9% (n=34) (84.8%, 92%)
Reintervention for Distal Embolization	100% (n=0) (NA,NA)
TVR	77.8% (n=48) (72.7%, 82.1%)
Unexpected device or drug related event	100% (n=0) (NA, NA)

24 month data

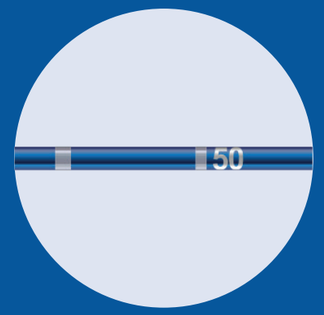
Rutherford improvement



Through 12 months

Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

Additional Product highlights:



The DCB with the **GeoAlign® Marking System** designed to help increase procedure efficiency and decrease radiation exposure by minimising fluoroscopy time.

4F/5F

The DCB with **all 5F[1] sheath profile sizes** for SFA minimising the size of the access site. Now offering sheath profile sizes **as low as 4F** for SFA, AV and BTK.

.035”
.018”
.014”

Expanding your options with the Lutonix™ 018 DCB and the Lutonix™ 014 DCB.

[1] Not all DCB sizes for Lutonix 035 are 4F compatible. Please refer to specifications sheet for sheath profile compatibility information.

Lutonix™ 035 Drug Coated Balloon PTA Catheter

75 cm Shaft Length					
Order code	Balloon Diameter (mm)	Balloon Length (mm)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Sheath Size (F)
9090475 500040	5	40	6	12	5
9090475 500060		60	6	12	5
9090475 500080		80	6	12	5
9090475 600040	6	40	6	12	5
9090475 600060		60	6	12	5
9090475 600080		80	6	12	5
9090475 700040	7	40	6	12	5
9090475 700060		60	6	12	5
9090475 800040	8	40	6	12	7
9090475 800060		60	6	12	7
9090475 900040	9	40	6	11	7
9090475 900060		60	6	11	7
9090475 100040	10	40	6	11	8
9090475 100060		60	6	11	8
9090475 120040	12	40	6	10	10
100 cm Shaft Length					
9090410 400040	4	40	6	12	5
9090410 400060		60	6	12	5
9090410 400080		80	6	12	5
9090410 400100		100	6	12	5
9090410 400120		120	6	12	5
9090410 400150		150	6	12	5
9090410 500040	5	40	6	12	5
9090410 500060		60	6	12	5
9090410 500080		80	6	12	5
9090410 500100		100	6	12	5
9090410 500120		120	6	12	5
9090410 500150		150	6	12	5
9090410 600040	6	40	6	12	5
9090410 600060		60	6	12	5
9090410 600080		80	6	12	5
9090410 600100		100	6	12	5
9090410 600120		120	6	12	5
9090410 600150		150	6	12	5
130 cm Shaft Length					
9090413 400040	4	40	6	12	5
9090413 400060		60	6	12	5
9090413 400080		80	6	12	5
9090413 400100		100	6	12	5
9090413 400120		120	6	12	5
9090413 400150		150	6	12	5
9090413 500040	5	40	6	12	5
9090413 500060		60	6	12	5
9090413 500080		80	6	12	5
9090413 500100		100	6	12	5
9090413 500120		120	6	12	5
9090413 500150		150	6	12	5
9090413 600040	6	40	6	12	5
9090413 600060		60	6	12	5
9090413 600080		80	6	12	5
9090413 600100		100	6	12	5
9090413 600120		120	6	12	5
9090413 600150		150	6	12	5

0.035” guidewire compatible

Units per case: 1

Leading with evidence from SFA to AV and BTK
Lutonix™ Drug Coated Balloon PTA Catheter

Lutonix™ 018 Drug Coated Balloon PTA Catheter

100 cm Catheter Length			
Order code	Balloon Diameter (mm)	Balloon Length (mm)	Sheath Size (F)
9111410400040	4	40	4
9111410400060		60	4
9111410400080		80	4
9111410400100		100	4
9111410400120		120	4
9111410400150		150	4
9111410400220		220	4
9111410500040	5	40	5
9111410500060		60	5
9111410500080		80	5
9111410500100		100	5
9111410500120		120	5
9111410500150		150	5
9111410500220		220	5
9111410600040	6	40	5
9111410600060		60	5
9111410600080		80	5
9111410600100		100	5
9111410600120		120	5
9111410600150		150	5
9111410700040	7	40	5
9111410700060		60	5

130 cm Catheter Length			
Order code	Balloon Diameter (mm)	Balloon Length (mm)	Sheath Size (F)
9111413400040	4	40	4
9111413400060		60	4
9111413400080		80	4
9111413400100		100	4
9111413400120		120	4
9111413400150		150	4
9111413400220		220	4
9111413500040	5	40	5
9111413500060		60	5
9111413500080		80	5
9111413500100		100	5
9111413500120		120	5
9111413500150		150	5
9111413500220		220	5
9111413600040	6	40	5
9111413600060		60	5
9111413600080		80	5
9111413600100		100	5
9111413600120		120	5
9111413600150		150	5
9111413700040	7	40	5
9111413700060		60	5
9111413700080		80	5
9111413700100		100	5

0.018” guidewire compatible

Units per case: 1

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	4
9020515200080		80	4
9020515200120		120	4
9020515200150		150	4
9020515250040	2.5	40	4
9020515250080		80	4
9020515250120		120	4
9020515250150		150	4
9020515300040	3	40	4
9020515300080		80	4
9020515300120		120	4
9020515300150		150	4
9020515350040	3.5	40	4
9020515350080		80	4
9020515350120		120	4
9020515350150		150	4
9020515400040	4	40	4
9020515400080		80	4
9020515400120		120	4
9020515400150		150	4

0.014” guidewire compatible

Units per case: 1

Lutonix™

Drug Coated Balloon PTA Catheter

The **DCB** with trials in **SFA, AV** and **BTK**

400,000+ Patients

Treated Worldwide

Lutonix™ 035 Drug Coated Balloon PTA Catheter

Indications for use: The Lutonix™ 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™ 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.

Lutonix™ 018 Drug Coated Balloon PTA Catheter

Indications for use: The Lutonix™ 018 Drug Coated Balloon Catheter is intended for Percutaneous Transluminal Angioplasty (PTA) in the femoropopliteal artery and for the treatment of obstructive lesions and decreasing the incidence of restenosis. In addition, the Lutonix™ 018 Drug Coated Balloon Catheter is intended for PTA of native dialysis fistulae or synthetic grafts to improve blood flow and decrease the incidence of restenosis.The Lutonix™ 018 Drug Coated Balloon Catheter is intended for treatment up to 290 mm in lesions length or approximately a total drug coating quantity of 7.6 mg paclitaxel per patient.

Lutonix™ 014 Drug Coated Balloon PTA Catheter

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: **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.

Precautions :
General Precautions **1)** 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. **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. 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.

Device Handling Precautions:

1) 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. **2)** The coated balloon portion should be handled with dry sterile gloves whenever possible prior to use. **3)**The balloon protector should stay in place during preparation of the Lutonix™ Catheter and not be removed until just prior to placing over guidewire. **4)** 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.

Device Use/Procedure Precautions:

1) The Lutonix™ Catheter should always be manipulated with adequate visualization technique when in the body .**2)** Appropriate vessel preparation, such as predilatation, is recommended to achieve optimal DCB results. Successful pre-dilation is defined as of ≤ 30% residual stenosis. **3)** Always advance and retrieve the Lutonix™ Catheter under negative pressure. **4)** After insert ion, 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. **5)** 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 vessel ratio of ≥ 1:1). If the deployment of the Lutonix™ Catheter exceeds 3 minutes, the catheter requires replacement with a new unit. **1)** 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 **2)** Do not continue to use the Lutonix™ Catheter if the shaft has been bent or kinked. **3)** 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. Best outcomes are obtained when the final % diameter stenosis is 0 – 20%.Pre- and Post-Procedure Antiplatelet Regimen. If applicable, 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

***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-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.**
Lutonix™ DCB Mortality Risk Analysis. In a meta-analysis published in December 2019 by Ouriel et al 1343 patients (1093 DCB and 250 PTA) from Lutonix drug coated balloons clinical studies [LEVANT 1, LEVANT 2, and LEVANT Japan] were assessed using Kaplan Meier analysis, the 2-year hazard ratio was 0.99 (95% confidence interval 0.25 - 3.95) in LEVANT 1, 1.40 (95% confidence interval 0.62 - 3.14) in LEVANT 2, and 0.32 (95% confidence interval 0.05 - 1.92) in the LEVANT Japan Clinical Trial. The 5-year hazard ratio after DCB angioplasty for the LEVANT 2 randomized trial was 1.60 (95% Confidence Interval 0.94 - 2.72), and 1.01 (95% confidence interval 0.68 - 1.52) in the aggregated LEVANT trials. Additional information regarding long-term outcomes can be found in Ouriel et al 2019. JACC Cardiovasc Interv. 2(24):2515-2524
The Lutonix™ 035 Drug and 018 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.

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

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