Long DCB Lesion Case

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Disclosure

Speaker name: Gary M Ansel MD FACC

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I have the following potential conflicts of interest to report:

- ☒ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

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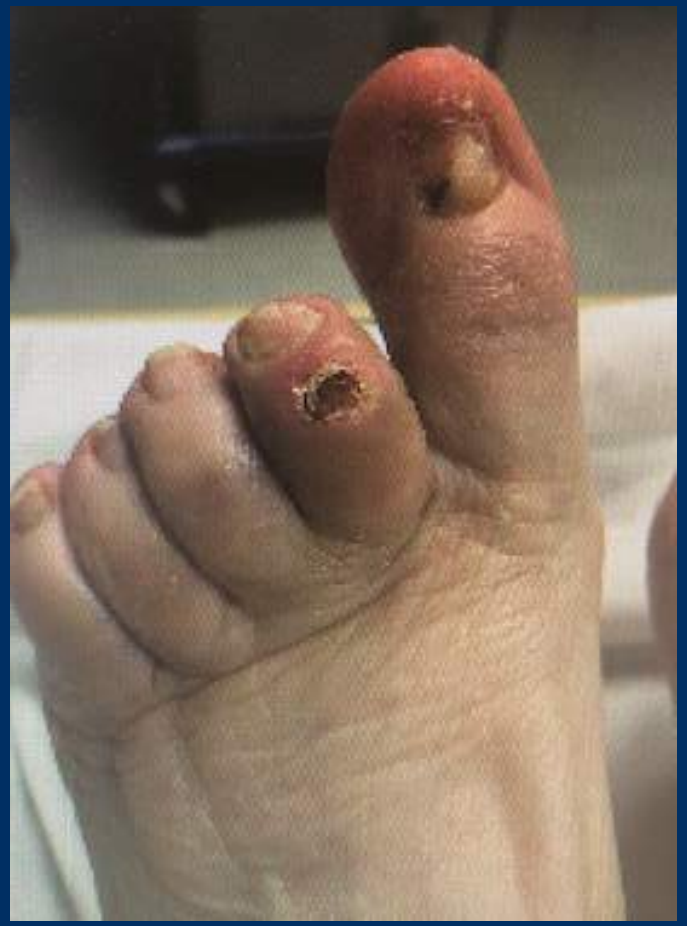
- The clinicians have been compensated by Becton, Dickinson and Company to participate in this presentation.

Complex Fempop Disease

- 82 y.o. female
- Presents with 2 mo hx of painful ulcer on toe
- PMHx
  - DM II
  - CAD
  - HTN
  - Hyperlipidemia
  - Hypothyroid
- Meds
  - Lipitor
  - Imdur
  - ASA
  - Lisinopril
  - Synthroid
  - Metoprolol

Noninvasive Studies and Clinical



Indication: Ulcer of skin

Clinical History and Risk Factors

History Notes:	Ulcer left 2nd toe.

Lower Arterial ABIs

Right:

Brachial Artery	144mmHg
ABI Posterior Tib	0.44
ABI Dorsalis Pedis	0.5

Left:

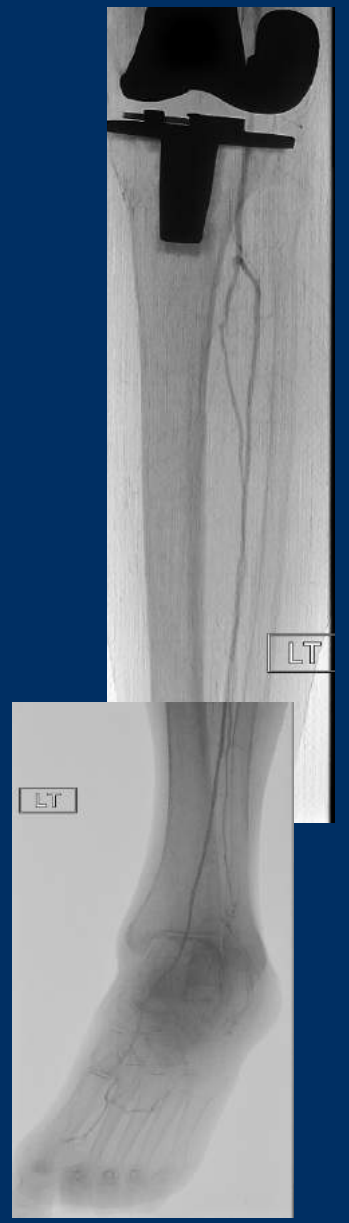
Brachial Artery	142mmHg
ABI Posterior Tib	0.44
ABI Dorsalis Pedis	0.44

Left Lower Extremity Arterial

	PSV Prox	PSV Mid	PSV Dis

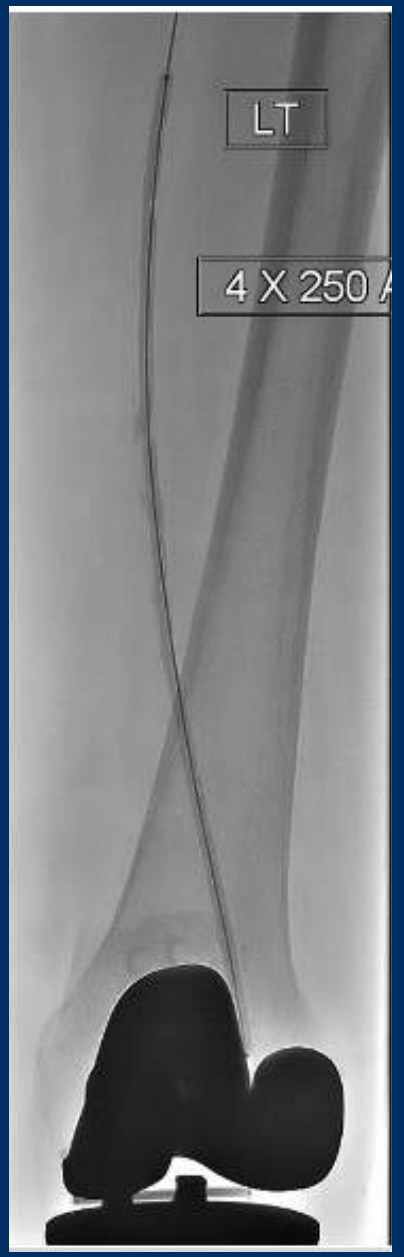
Pre-Procedure Angiogram

- **Rt common fem access**
- **Braided 7 fr sheath**
- **Crossed with .035 hydrophilic wire**

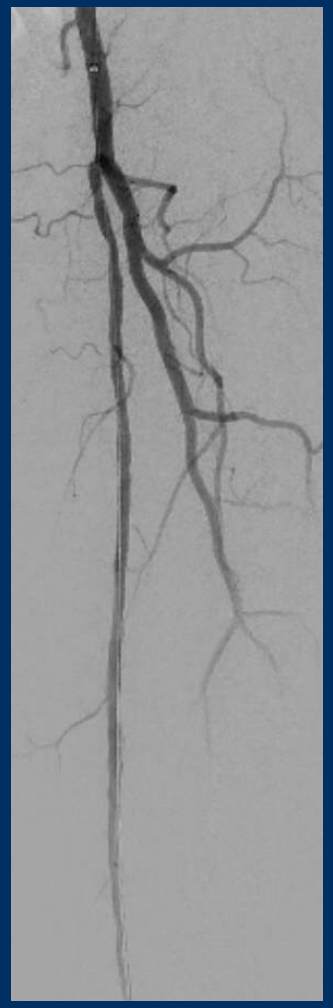


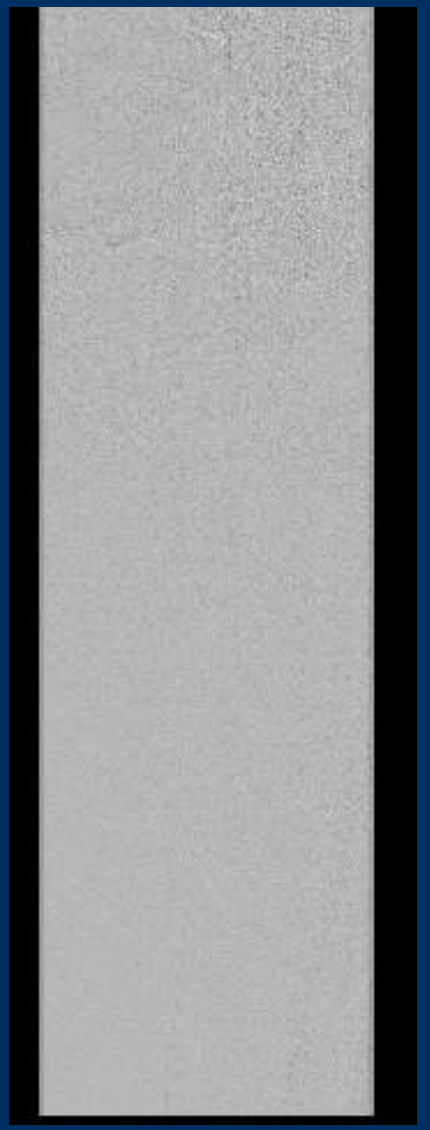
POBA Pre-dilation

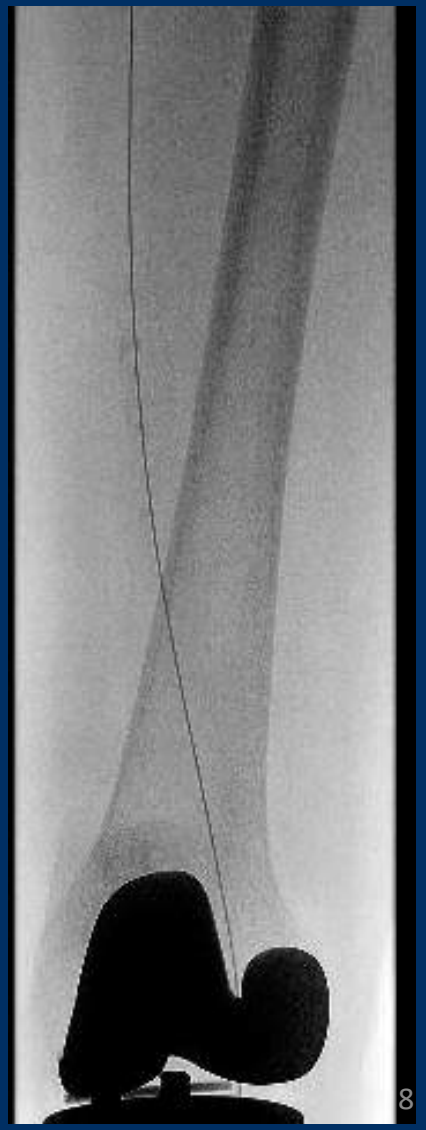
- PTA 2 minute each balloon inflation



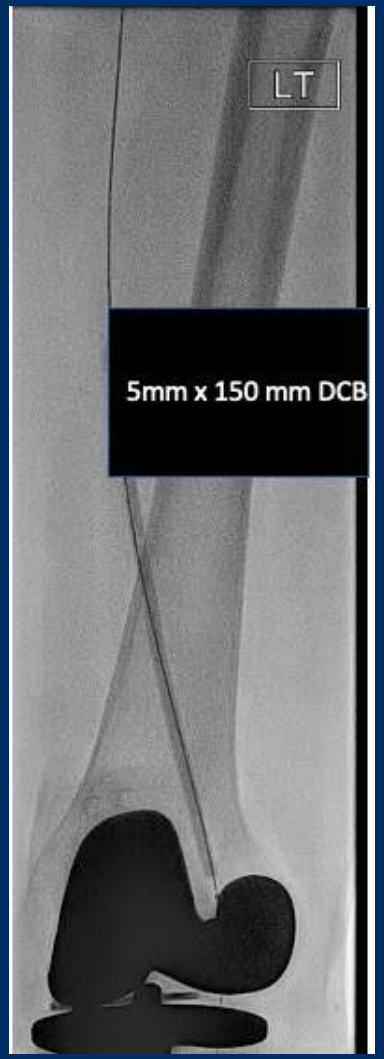
Post-POBA Angiogram



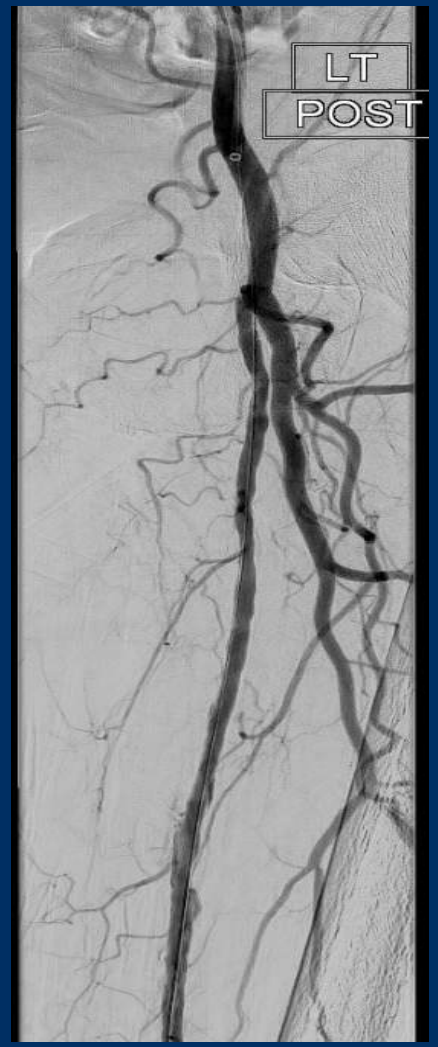


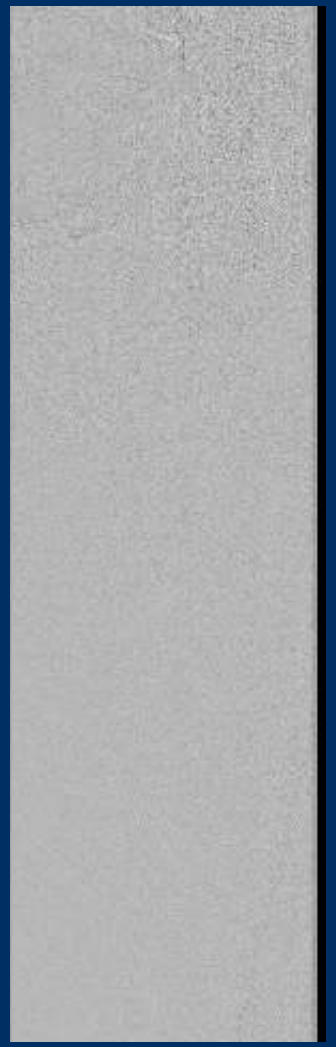


DCB

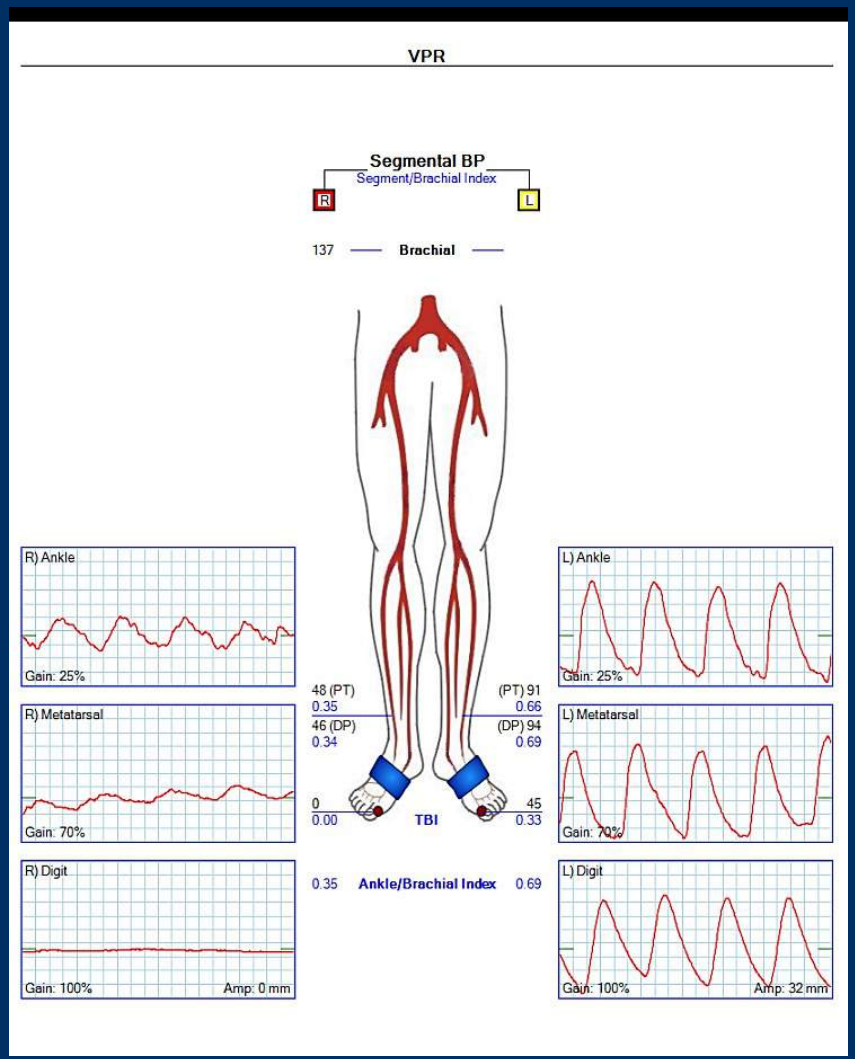


Post-Procedure Angiogram





Noninvasive Studies – Immediately Post



BD-33193

Clinical Follow up

- Rest pain resolved in 3 days
- Toe care with total resolution 9mo
- No restenosis at 12-mo

6 Months

[redacted] **Age:** 83 **Gender:** Female

Ref By:
Examined By:
Read By:

Date: 1/24/2018 4:20 PM
Room:

Segmental BP

Right			Left		
		Index			Index
Brachial:	137		**Brachial:**		
Ankle (PT):	48	0.35	**Ankle (PT):**	91	0.66
Ankle (DP):	46	0.34	**Ankle (DP):**	94	0.69
Digit:	0	0.00	**Digit:**	45	0.33

12 Months

Clinical History and Risk Factors	
Hypertension	Yes
Previous Angioplasty	Yes
Peripheral Art. Disease	Yes

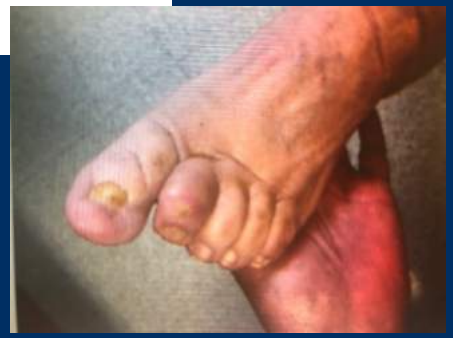
Lower Arterial ABIs

Right:
Brachial Artery 140mmHg
ABI Posterior Tib 0.57
ABI Dorsalis Pedis 0.61

Left:
Brachial Artery 138mmHg
ABI Posterior Tib 1.1
ABI Dorsalis Pedis 1.1

Left Lower Extremity Arterial

	PSV Prox (cm/s)	PSV Mid (cm/s)	PSV Distal (cm/s)	Stenosis	Doppler Waveform
Left External Iliac			186.78		Triphasic
Left Common Femoral			169.32		Triphasic
Deep Femoral			71.48		Triphasic



Q&A

LUTONIX™ DCB
Key Summary

- LUTONIX™ DCB 018 & 035 are indicated for SFA / ISR / Long Lesions / AV
- Only DCB portfolio on the U.S. Market** with:
  - Both 018 and 035 guidewire compatibility
  - 300mm balloon lengths
  - Sheath profile of ALL diameter sizes 5F or lower

** As of May 2021.

Thank you!

Lutonix™ 018 Drug Coated Balloon PTA Catheter

Indications for Use: The Lutonix™ 018 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 300 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm. The Lutonix™ 018 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, for treatment of stenotic lesions of dysfunctional native arteriovenous dialysis fistulae that are 4 mm to 7 mm in diameter and up to 80 mm in length.

Contraindications: The Lutonix™ Catheter is contraindicated for use in: · Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy (SFA). · Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children over the next to two 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. · Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.

Warnings: 1) 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 which is also 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. See Section 10.1 for further information. **2)** Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged or opened prior to intended use. **3)** Do not use after 'Use by' date. **4)** Do not use if product damage is evident. **5)** 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. **6)** 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. **7)** 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. **8)** 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: 1) The Lutonix™ Catheter should only be used by physicians trained in 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)** For SFA application, the safety and effectiveness of using more than four Lutonix™ drug coated balloons or a maximum drug coating quantity of approximately 15.1 mg paclitaxel in a patient has not been clinically evaluated. **5)** For AV Fistula application, 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 peripheral balloon dilatation procedure include, but are not limited to the following: • Additional intervention • Allergic reaction to drugs, excipients or contrast medium • Amputation/loss of limb (SFA) •Aneurysm or pseudoaneurysm • Arrhythmias • Embolization • Hematoma • Hemorrhage, including bleeding at the puncture site • Hypotension/hypertension • Inflammation • Loss of permanent access (AVF) • Occlusion • Pain or tenderness • Pneumothorax or hemothorax (SFA) • Sepsis/Infection • Shock • Steal Syndrome (AVF) • 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. Rx only

Lutonix™ 035 Drug Coated Balloon PTA Catheter

Indications for Use: The LUTONIX™ 035 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 300mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7mm.

Contraindications: · The LUTONIX™ Catheter is contraindicated for use in: Patients who cannot receive recommended 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. Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.

Warnings: 1) 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. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients. **2)** Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged or opened prior to intended use. **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. **7)** This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds. 8) The safety and effectiveness of the LUTONIX™ Catheter have not been established for treatment in cerebral, carotid, coronary, or renal vasculature. **9)** The safety and effectiveness of using more than four LUTONIX™ drug coated balloons or a maximum drug coating quantity of approximately 15.1 mg paclitaxel in a patient has not been clinically evaluated.

Precautions: **1)** The LUTONIX™ Catheter should only be used by physicians trained in 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.

Potential Adverse Events: Potential adverse events which may be associated with a peripheral balloon dilatation procedure include: •Additional intervention •Allergic reaction to drugs, excipients or contrast medium • Amputation/loss of limb •Aneurysm or pseudoaneurysm •Arrhythmias •Embolization •Hematoma •Hemorrhage, including bleeding at the puncture site •Hypotension/hypertension •Inflammation •Occlusion •Pain or tenderness •Pneumothorax or hemothorax •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: •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. ℞

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: 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 · Steal Syndrome ·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

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