

The importance of vessel preparation before DCB to fight against CLTI recurrence

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting for BD
- 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.



Patient Medical History:

- S, M. 79 years old female, Diabetes, dyslipidemia, hypertension, Atrial Fibrillation, CAD, bilateral PAD. Previous coronary revascularization (PCI + CABG) and previous contralateral lower limb revascularization (PTA) + minor amputation.
- CLTI of the left foot. Rutherford 5; TcPO₂: 18 mmHg. WIFI score: 1,3,1.
- Superficial wounds of all the toes.

CAD--- Coronary Artery Disease

PCI---Percutaneous coronary intervention

CABG---Coronary artery bypass grafting

CLTI--- chronic limb- threatening ischemia

TcPO₂ ---Transcutaneous Partial Pressure of Oxygen

WIFI score--- Multivariable analysis of Wound, Ischemia, and foot Infection (**WIFI**) components and classification schemes.



Recorded Case

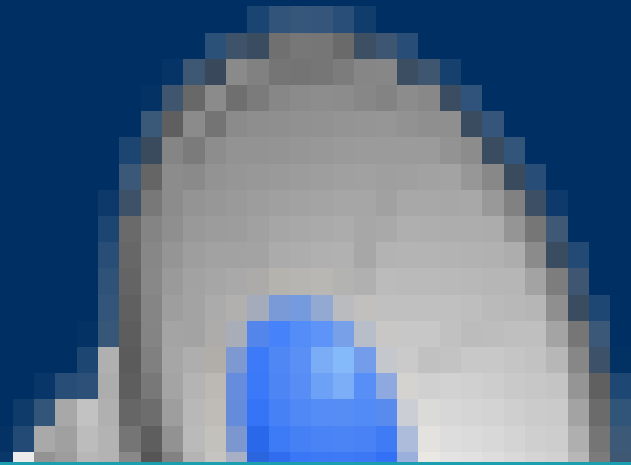


Conclusions

- HaloOne™ 6F and Long HaloOne™ 4F Sheaths were used in a “telescopic fashion” to help provide additional support, stability, and pushability to reach below knee lesions.
- UltraScore™ balloon was used to aid in crossing the calcified BTK-BTA lesions and provide pre-dilation/vessel preparation prior to DCB use.
- Lutonix™ Drug coated balloon was then successfully used clinical sequela

BTA---below-the-ankle
BTK– below-the-knee





THANK YOU VERY MUCH



Halo One™ Thin-Walled Guiding Sheath

Indications for Use: The Halo One™ Thin-Walled Guiding Sheath is indicated for use in peripheral arterial and venous procedures requiring percutaneous introduction of intravascular devices. The Halo One™ Thin-Walled Guiding Sheath is NOT indicated for use in the neurovasculature or the coronary vasculature.

Contraindications: There are no known contraindications for the Halo One™ Thin-Walled Guiding Sheath.

Warnings: **1)** Contents supplied STERILE using ethylene oxide (EtO). Non-pyrogenic. Do not re-use, reprocess or re-sterilize. This device is intended for single use only. **2)** Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. **3)** This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. **4)** Visually inspect the packaging to verify that the sterile barrier is intact. Do not use if the sterile barrier is opened or damaged. **5)** Use the sheath prior to the “Use By” date specified on the package. **6)** Do not advance the guidewire, sheath/dilator, procedural device, or any component if resistance is met, without first determining the cause and taking remedial action. **7)** Do not use a power injector through the sideport or the three-way stopcock. **8)** The Halo One™ Thin-Walled Guiding Sheath has not been evaluated for use in the neurovasculature or the coronary vasculature. **9)** After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations. **10)** Only advance or retract the sheath with the dilator inserted and only advance or retract the sheath and dilator while placed over a properly sized guidewire. **11)** Failure to deactivate the procedural device prior to removal through the sheath may cause damage to the sheath and may result in patient injury.

Precautions: **1)** The Halo One™ Thin-Walled Guiding Sheath shall only be used by trained physicians. Access procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment and / or ultrasound. **2)** Prior to beginning radial artery access, an assessment such as the Allen or Barbeau test should be performed to assess the presence/ adequacy of dual arterial circulation to the hand. Radial artery access is not recommended for patients with abnormal Allen or Barbeau test results or radial pulse, or insufficient dual arterial supply. **3)** Prior to beginning pedal access, physicians should assess the vascular anatomy to assure there is adequate antegrade flow at the level of the ankle. **4)** The minimum acceptable sheath French size is printed on the package label. Do not attempt to pass devices through a smaller size sheath introducer than indicated on the device label. **5)** The pouch should be inspected prior to opening to ensure the sterile barrier is not compromised. The device should be carefully removed and placed in the sterile field. The entire procedure from skin puncture or incision to sheath withdrawal must be carried out aseptically. **6)** Carefully inspect the sheath prior to use to verify that the sheath has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident. **7)** Careful attention must be paid to the maintenance of tight valve connections for duration of procedure to avoid blood leakage or the introduction of air into the system. Take remedial action if any excessive blood leakage is observed. **8)** Insert dilator into the center of the sheath valve. Forced insertion of the dilator which misses the center of the valve may cause damage and result in blood leakage. **9)** Advance or withdraw the sheath slowly. If resistance is met do not advance or withdraw until the cause of resistance is determined. **10)** When inserting, manipulating or withdrawing a device through the introducer always maintain the introducer position. **11)** Remove the dilator from the sheath slowly to avoid incomplete closing of the valve resulting in blood leakage. **12)** When using procedural devices close to the tip of the sheath care must be taken to ensure the active mechanism portion of the procedural device (e.g., balloon, stent zone, material removal section of atherectomy device) is not within the tip of the sheath. The radiopaque marker is located within 5 mm of the end of the tip but does not mark the true distal tip of the sheath. **13)** Before removing or inserting the interventional/diagnostic device through the sheath, aspirate blood from the 3-way stopcock to remove any fibrin deposition which may have accumulated in or on the tip of the sheath. **14)** Ensure to deactivate the procedural device prior to removal through the sheath. **15)** Take care when back loading the tip of the dilator over the guidewire to avoid damage to the dilator. **16)** Ensure the dilator is securely connected with the sheath prior to advancing otherwise only the sheath may advance into the vessel and the sheath tip may cause damage to the vessel. **17)** Ensure the dilator is in place within the sheath before advancing the sheath as otherwise damage may be caused to the vessel. **18)** Do not place sutures on the sheath tubing since this may restrict access/flow through the sheath. When puncturing, suturing or incising near the sheath be careful not to damage the sheath. Proper functioning of the sheath depends on its integrity. Care should be used when handling the sheath. **19)** If using fluid injection through the 3-way stopcock, ensure the dilator or procedural device is not in place at the same time. **20)** If resistance is felt during post-procedure withdrawal of the procedural device, it is recommended to remove the procedural device, guidewire, and sheath as a single unit. **21)** In order to activate the hydrophilic coating, it is recommended to wet the Halo One™ Thin-Walled Guiding Sheath with heparinized saline solution immediately prior to its insertion in the body. Failure to activate the coating may lead to sub-optimal trackability of the sheath. To maintain lubricity this surface must be kept completely wet. **22)** Proper functioning of the Halo One™ Thin-Walled Sheath depends on its integrity. Care should be used when handling the sheath. Damage may result from kinking, stretching, or forceful wiping of the Halo One™ Thin-Walled Guiding Sheath. Do not continue to use the sheath if the shaft has been bent or kinked.

Potential Adverse Effects: Potential adverse effects that may result from a percutaneous vascular procedure (directly or indirectly associated with the device) may include, but are not limited to: • Air embolism • Aneurysm or pseudoaneurysm • Arteriovenous fistula • Compartment Syndrome • Death • Embolism • Endocarditis • Hematoma • Hemorrhage, including bleeding at the puncture site • Intimal tear • Radial artery occlusion/spasm • Sepsis/infection/inflammation • Tissue necrosis • Thrombus formation • Vessel spasm, perforation or dissection • Potential systemic indirect/inherent adverse effects related to general endovascular procedures may include, but are not limited to: • Arrhythmias • Drug reactions, allergic reaction to contrast media • Hypotension/hypertension • Pain and tenderness

Ultrascore™ Focused Force PTA Balloon

Indications for Use: The ULTRASCORE™ Focused Force PTA Balloon is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post dilatation of balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

Contraindications: The ULTRASCORE™ Focused Force PTA Balloon is contraindicated: • Where there is the inability to cross the target lesion with a guidewire • For use in the coronary or neuro vasculature

Warnings: **1)** Contents supplied STERILE using ethylene oxide (EO). Non-Pyrogenic. Do not use if sterile barrier is opened or damaged. Do not reuse, reprocess or re-sterilize. Use the catheter prior to the “Use By” date specified on the package label. **2)** This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. **3)** Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. **4)** To reduce the potential for vessel damage or difficulty in deflating, the inflated diameter and length of the balloon should approximate the diameter and length of the vessel just proximal and distal to the stenosis. **5)** When the catheter is exposed to the vascular system, the location of the balloon should be confirmed while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Applying excessive force to the catheter can result in tip or catheter breakage, catheter kink, or balloon separation. **6)** Do not exceed the RBP recommended for this device. Balloon rupture or difficulty in deflation may occur if the RBP rating is exceeded. To prevent over pressurization, use of a pressure monitoring device is recommended. **7)** After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations.

Precautions: **1)** Carefully inspect the catheter prior to use to verify that catheter has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident. **2)** The ULTRASCORE™ Focused Force PTA Balloon should only be used by physicians experienced in the performance of percutaneous transluminal angioplasty. **3)** It is recommended to consider the use of anti-coagulants, anti-platelet agents, and/or vasodilators in conformance with the accepted standard of practice or institutional guidelines surrounding peripheral endovascular procedures. **4)** For ULTRASCORE™ .014" guidewire sizes only, in order to activate the hydrophilic coating, wet the ULTRASCORE™ balloon and catheter with sterile saline or wipe the balloon catheter with sterile saline saturated gauze immediately prior to its insertion in the body. Do not wipe the balloon catheter with dry gauze. **5)** The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size introducer sheath than indicated on the label. **6)** Use the recommended balloon inflation medium (25% contrast medium/75% sterile saline solution). Never use air or other gaseous medium to inflate the balloon. **7)** The ULTRASCORE™ Focused Force PTA Balloon should be used with caution for procedures involving calcified lesions, stents or synthetic vascular grafts due to the abrasive nature of these lesions. **8)** Fully evacuate the balloon prior to withdrawing the system. Larger sizes of ULTRASCORE™ Focused Force PTA Balloons may exhibit slower deflation times. **9)** If resistance is felt during post procedure withdrawal of the catheter through the introducer sheath, determine if contrast medium is trapped in the balloon with fluoroscopy. If contrast is present, push the balloon out of the sheath and then completely evacuate the contrast before proceeding to withdraw the balloon. **10)** If resistance is still felt during post procedure withdrawal of the catheter, it is recommended to remove the balloon catheter and guidewire/introducer sheath as a single unit. **11)** Do not continue to use the balloon catheter if the shaft has been bent or kinked. **12)** For ULTRASCORE™ .014" guidewire sizes only, prior to re-insertion through the introducer sheath, re-activate the hydrophilic coating, and clean the balloon catheter by wiping the balloon catheter with sterile saline saturated gauze and rinsing with sterile saline. Do not wipe the balloon catheter with dry gauze. **13)** GEOALIGN™ Marking System is designed to be used as an additional reference tool to accompany the interventionalist standard operation procedure. The use of fluoroscopic imaging is recommended following positioning of the catheter to the target lesion and prior to balloon deployment.

Potential Adverse Reactions: The complications that may result from a peripheral balloon dilatation procedure include: • 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 • Occlusion • Pain or tenderness • Pneumothorax or hemothorax • Sepsis/infection • Shock • Short term hemodynamic deterioration • Stroke • Thrombosis • Vessel dissection, perforation, rupture, or spasm

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: General 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

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