Live Case Presentations, Data, and Diagnostics as CLI Meeting Continues

CHICAGO, August 13, 2015 — This morning at the start of day 2 of the Amputation Prevention Symposium, Thomas Zeller, MD, director of the Department of Angiology at Universitaets-Herzzentrum, Freiburg-Bad Krozingen, in Bad Krozingen, Germany, gave a keynote speech on his experience with and data for drug-eluting technologies.

“Professor Zeller saw the need for data to support a way to treat CLI patients,” said course co-director Jihad A. Mustapha, MD, as he introduced the talk. “He has paved the way for many of us. Research initiated by professor Zeller opened the door to therapies that would otherwise not be available to CLI patients.” Zeller described the latest data supporting the use of drug-eluting balloons (DEB) in the lower limbs.

“Is short-term contact of the drug-eluting balloon drug as effective as a drug-eluting stent? The data tell us it is,” said Zeller. He expressed confidence in the future benefit of DEB for CLI therapy, with the caveat that many factors must be taken into account and investigated, including the excipient, the balloon platform, the antirestenotic drug dose, and the balloon coating process. Dr. Zeller discussed results of the LEVANT II study as well as the IN.PACT Admiral above-the-knee studies, which had positive results. On the other hand, IN.PACT DEEP showed negative results below the knee.

“Unfortunately this affects our strategy for CLI patients,” said Zeller, who added that this raised concerns about the safety of paclitaxel use in patients with ischemic wounds. Possible reasons for the negative results in the DEB group included the varying coating technologies and the different plastic materials from one balloon studied to the next. He called for further research on efficacy of DEB in tibial arteries, studying claudicants only with no wounds.

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D. Christopher Metzger, MD, presented two live cases remotely from Kingsport, Tenn., in which he demonstrated orbital atherectomy; stenting, and alternative access techniques for complex cases. During the case presentations, faculty also shared tips on device and equipment selection. Course co-director Larry J. Diaz-Sandoval, MD, spoke about a trend toward miniaturization of equipment, which he said now enables use of a greater variety of devices in the tibial arteries.

Concurrent sessions took place in the general session room as well as in breakout sessions for the vascular tech workshop as well as the Save a Leg, Save a Life Foundation “SALSAL at AMP” programming. This programming was new to the AMP meeting to support a multidisciplinary approach to CLI care.

“A multidisciplinary approach has become a part of our everyday practice,” said Mustapha in his opening remarks. “We want you to know what happens before, during, and after revascularization.”

The exhibit hall had its grand opening on day 2, welcoming more than 40 exhibitors who engaged attendees in discussion of their products available for peripheral vascular procedures. Exhibitors also hosted attendees at a programming was new to the AMP meeting to support a multidisciplinary approach to CLI care.

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AMP continues Friday, August 14, with a focus on data and multidisciplinary care.

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CO₂ Angiography vs Contrast Angiography

An interview with Larry J. Diaz-Sandoval, MD, Director, Endovascular & Vascular Medicine Fellowship, Metro Health Hospital, Wyoming, Michigan; Assistant Professor Medicine, Michigan State University, Grand Rapids, Michigan.

In which patients do you consider the use of CO₂ instead of contrast media?

Patients that I consider for CO₂ use are patients with baseline renal insufficiency, those with a history of anaphylactic reactions to iodinated contrast media, and especially those with critical limb ischemia (CLI). Patients with CLI tend to have multiple comorbidities, including advanced kidney insufficiency, and they are frequently afraid of the prospect of undergoing a procedure, which may damage their remaining kidney function so that they end up needing dialysis. Although CO₂ has been around for a long time, it wasn’t until recently that it has gained acceptance, as operators have become more familiar with its use and technique.

How has the equipment surrounding CO₂ use advanced?

I am currently working on a study with colleagues from Italy. An Italian company has created an automatic injector of CO₂ called the Angiodroid. One of the limitations for the use of CO₂, especially in CLI, is that you often get fragmented images. The quality of the pictures (especially below the knee) is not great. This has been used as a reason not to use CO₂ in patients with CLI.

Typically in CLI patients, we find multilevel and multivessel disease, meaning they can have disease compromising the iliac segment as well as the femoropopliteal segment, and then the below-the-knee segment. When you inject CO₂ into the aorta, the amount that reaches below-the-knee levels is minimal and the quality of the image becomes degraded. In order to improve the images, we have learned to use selective techniques, which means that we advance a catheter to the closest area of interest and inject in that particular area. However, most operators still use hand injections. With hand injections, as you are injecting and there is less gas left in the syringe, the force you are applying on the plunger doesn’t change; therefore, the injection is more efficient at the beginning and then too fast towards the end.

It is difficult to correct how much pressure you are actually applying. The automatic injector has the ability to grade, in a precise fashion, the amount of CO₂ that is delivered. In our study, we have also found that the amount of pressure that needs to be utilized should be relatively constant and about 20 mmHg higher than the patient’s systolic blood pressure. When you inject at a higher pressure, as the CO₂ goes into the artery it causes a rapid distension of the adventitia. Patients feel pain and then they move, and when there is motion, there is also image degradation. The “sweet spot” is about 20 mmHg higher than the patient’s systolic blood pressure.

It is our hope that devices such as this will eliminate one of the biggest obstacles we see in the referral pattern in our practices, which is that often physicians do not want to refer their patients to be treated for significant peripheral arterial disease or CLI, because they are concerned about their patient’s kidneys. This will be an important tool in our armamentarium that will provide our patients with a much-needed benefit.

Have the images you have obtained using the automated CO₂ injector been adequate?

In our study, we had multiple, experienced operators look at images blindly, and studied the coefficient of inter-observer variability (kappa coefficient). It was amazing that the percentage of agreement between several experienced operators was rather high.

It is going to be very interesting to see how the automatic CO₂ injector is going to work, because now we can get images of the pedal arterial tree. We can see the dorsalis pedis, plantar branches, and pedal arch, with an excellent resolution. I have a feeling this is going to be groundbreaking.

Do you have any final take-home advice for interventionists?

Interventionists need to become familiar with CO₂ and they need to become familiar with the use of techniques available for everybody. Even if you use CO₂ with manual injection, you can help your patients by decreasing the total amount of contrast that they may need during an intervention. In our institution, we also use ultrasound-guided interventions, which in conjunction with CO₂ allows us to decrease the amount of dye used during peripheral vascular interventions.

Dr. Diaz reports no conflicts of interest regarding the content herein.
**Noteworthy News**

**Drs. Mustapha and Diaz-Sandoval Publish Editorial on US-Guided Tibiopedal Access in JIC**

In an editorial commentary in *The Journal of Invasive Cardiology* (JIC), J.A. Mustapha, MD, and Larry J. Diaz-Sandoval, MD, discuss a study published in the June issue of JIC. In the study, “Feasibility and Safety of Routine Transpedal Arterial Access for Treatment of Peripheral Artery Disease,” Kwan et al conclude that the routine use of a transpedal approach for the treatment of PAD may be feasible as well as safe. The authors also conclude that pedal artery access may avoid many complications associated with the traditional femoral approach. Drs. Mustapha and Diaz-Sandoval warn that a strategy of puncturing one or two tibiopedal arteries may not be necessarily recommended as a “routine” approach in patients with end-stage renal disease and diabetes:

“The study by Kwan et al represents the first published study looking at routine US-guided tibial pedal arterial access for the invasive diagnosis and treatment of patients with a wide spectrum of PAD symptoms, and their results echo the previously reported findings of feasibility and safety of this technique when performed exclusively among patients with CLI,” write Mustapha and Diaz-Sandoval. “It also provides us with evidence that the natural evolution process is finally taking place in the infrapopliteal space. The first-ever guidelines for the use of peripheral interventions in the infrapopliteal segment were published only recently, demonstrating the lack of available high-quality data to guide interventions in this arterial segment. As Kwan et al notice, there is still a large amount of work to be done. Ultimately, prospective and multicenter studies (likely registries) should probably be performed to further validate this strategy and its adequacy as a default approach.”

**LEVANT 2 Data Published in NEJM**

Results from the LEVANT 2 study were published in June in *The New England Journal of Medicine*. Results demonstrated superior primary patency for Lutonix 035 Drug-Coated Balloon PTA Catheter (Lutonix DCB; Bard PV) over standard percutaneous transluminal angioplasty (PTA), as well as safety consistent with standard PTA balloons. The Lutonix DCB is coated with paclitaxel and utilizes standard mechanical dilatation to revascularize the femoropopliteal arteries. The LEVANT 2 pivotal study is a global, prospective, single-blind, randomized, 54-site study (42 sites in the United States and 12 in Europe) that enrolled all patients under one protocol, comparing Lutonix 035 DCB with standard PTA. The Lutonix 035 DCB was the first drug-coated balloon approved by the US Food and Drug Administration (FDA) in October 2014.

Kenneth Rosenfield, MD, section head of Vascular Medicine and Intervention at Massachusetts General Hospital and LEVANT 2 principal investigator, said in a press release, “LEVANT 2 followed a rigorous blinding protocol, which was designed to reduce bias in the results. In addition to superiority in primary patency, the paclitaxel-coated balloon used in the study also demonstrated sustained improvements in Rutherford category from baseline to 12 months, and improved patient-reported walking distance scores.”

**EXCITE ISR Proves Durability at 12 Months**

Twelve-month data from the EXCITE ISR clinical trial were presented by Craig Walker, MD, at New Cardiovascular Horizons (NCVH) in New Orleans in May. The EXCimer Laser Randomized Controlled Study for Treatment of Femoropopliteal Arteries above the Knee In-Stent Restenosis (EXCITE ISR) is a first-of-its-kind large multicenter prospective randomized trial ever conducted for the treatment of femoropopliteal in-stent restenosis (ISR).

Results of the landmark study show that Spectranetics’ laser atherectomy devices used with PTA are safer and more effective than PTA alone for treating femoropopliteal ISR. Turbo-Tandem and Turbo-Elite are the only indicated atherectomy devices cleared by the FDA to treat femoropopliteal ISR. Critical 12-month results include significantly less residual stenosis and need for bail-out stenting with Turbo-Tandem, 92.9% procedural success rate using Turbo-Tandem with PTA vs 81.7% with PTA alone (P<.01), primary safety endpoint major adverse events (MAEs) rates at 30 days 5.4% vs 20.8% with PTA alone (P<.001), primary efficacy endpoint freedom from target lesion revascularization through 6 months 78.3% vs 58.9% with PTA alone (P=.002), and excimer laser atherectomy with adjunctive PTA associated with a 43% reduction in TLR through 12 months.

**Centers for Medicare & Medicaid Services Holds MEDCAC Meeting**

On July 22, 2015, the Centers for Medicare & Medicaid Services (CMS) convened a panel of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). The panel examined existing interventions for the Medicare population and address areas where evidence gaps exist for lower-extremity peripheral artery disease (PAD), including asymptomatic PAD, intermittent claudication, and critical limb ischemia. The committee vice chair was Peter Bach, MD, Attending Physician & Director, Center for Health Policy and Outcomes, Memorial Sloan-Kettering Cancer Center. Panel members voted on specific questions to advise CMS on coverage for PAD interventions. A full list of panel members and speakers is available at http://www.cms.gov/medicare-coverage-data-base/details/medcac-meeting-details.aspx?MEDCACId=70.
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A recent study suggests that shifting to an endovascular-first treatment strategy for critical limb ischemia (CLI) could result in superior limb salvage rates, fewer major amputations, and shorter lengths of hospital stay. Yet, despite advances in endovascular and surgical revascularization techniques, limb morbidity remains high. Treatment of CLI comes with inherent challenges for the clinician—the condition is associated with high rates of morbidity and mortality, and patients are typically poor candidates for surgery.

The hands-on ultrasound-guided tibio-pedal access and intervention workshop with cadaveric models at this year’s Amputation Prevention Symposium (AMP) is designed to arm endovascular specialists with the most advanced tools and techniques and the latest scientific data to help them meet these challenges and give them the best opportunity to improve outcomes and quality of life for patients with CLI.

“AMP is about improving and refining your endovascular lower extremity skills,” says George Pliagas, MD, FACS, FRCS, a vascular surgeon with Premier Surgical Associates in Knoxville, Tenn., who serves as faculty for the workshop. “For first-time attendees, it introduces them to the realm of critical limb ischemia and its multitudes of treatment,” he says. “For the experienced endovascular specialists, it allows them the opportunity to interact with experienced faculty and pick up new tips and techniques that are not available at any other venue.”

Pliagas began treating vascular patients 25 years ago and sees a broad spectrum of vascular problems on a daily basis—from aortic to peripheral and venous disease. His special interest lies with the use of hybrid techniques that combine endovascular and open surgery to tackle challenging vascular presentations. Because the instructors for the cadaveric lab come from various disciplinary backgrounds, they can offer workshop participants the advantage of a broader wealth of clinical knowledge and experience from their individual specialties.

Advanced discussions will take place during the course so that attendees will understand the indications for pedal access, and the ancillary procedures that can be used to ensure superior outcomes. Faculty will provide insight into the anatomy of accessing tibial vessels, and walk attendees through a step-by-step educational process that will introduce them to the scope of pedal access. They will highlight the advantages of pedal access in certain clinical instances and also address complications of pedal access and how to avoid them.

An anatomic display of lower limb vasculature in cadaveric models will allow workshop participants to dissect the course of the vessels being accessed, thus, offering them a 3-dimensional understanding. “The cadaver lab is a phenomenal opportunity for attendees to improve their abilities without placing their patients at risk while they learn,” says lab instructor Robert Vorhies, MD, a board-certified vascular and endovascular surgeon with Cox Health Systems in Springfield, Mo. “Working with cadaveric models also allows the attendee to focus completely on the technique of ultrasound-guided vascular access without the pressures of clinical practice, such as time constraints, patient comfort, staff scrutiny, sedation management, and so on.”

Vorhies has 10 years of experience working in a community practice at a Level 1 regional referral center. He works with two other partners who have similar training and, together, they perform more than 1,000 peripheral interventions a year in the hybrid operating room and catheterization lab settings, including both open and complex percutaneous peripheral revascularizations for CLI.

He and the other faculty will first demonstrate and then provide hands-on training, sharing tips and tricks for successful access, crossing, and intervention. They will explain a stepwise approach in utilizing ultrasound guidance to gain tibiopedal access in the patient with CLI.

“Ultrasound-guided access is a key element of expanding limb salvage opportunities,” Vorhies says. This includes the needle and wire manipulations under ultrasound, as well as tips for inserting sheaths and devices. More advanced attendees can attempt catheter-to-catheter wire transfer under direct ultrasound guidance. The faculty will review specific instances where this technique is best utilized either as a stand-alone technique or in combination with other access options.

“Attendees are very appreciative of the opportunity to utilize cadaveric models because it simulates the conditions they face on a daily basis in the lab and allows for detailed explanation of the technique at hand,” Pliagas says. “It allows for refinement of the technique for some and, for others, it gives them the confidence to attempt this technique in order to salvage a lower extremity at risk for amputation.”

Participants will receive up-to-date instruction on the use of various devices, catheters, and wires that can be utilized from a pedal approach. The workshop will cover a series of techniques to help cross lower extremity pathology and will also tackle the concepts of snaring tibial wires, and the rendezvous support catheter technique.

Improvements in existing wires, catheters, and devices will be demonstrated so that the attendees understand how technology has facilitated this new approach. The devices used in this workshop are all readily available and should already be familiar to most attendees. This includes a standard small ultrasound machine and probe, micro-puncture access kit, 4 Fr sheath, and several standard wires and catheters.

They will be given the opportunity to actually use all of this equipment so they feel comfortable with this skill.”

Continued on page 10
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GeoAlign® Markers serve as a simple-to-use, non-radiopaque ruler on the catheter shaft. The GeoAlign® System is featured on both the UltraVerse® 035 PTA Catheter and Lutonix® 035 DCB. The GeoAlign® System is designed to facilitate repeatable catheter alignment at the lesion and increase procedure efficiency by minimizing fluoroscopy exposure.*

* GeoAlign® Markers are not a replacement for fluoroscopy. When the catheter is exposed to the vascular system, the location of the balloon should be confirmed while under high quality fluoroscopic observation. Animal study (repeat PTA in swine artery) was performed by 3 physicians who tested the Lutonix® 035 DCB (no drug) and the UltraVerse® 035 PTA Catheter, both with GeoAlign® Markers, to POBA with no GeoAlign® Markers (n=112, test n = 96, control n = 16). Animal data on file. Bard. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.

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Critical Limb Ischemia: CLI Diagnostics and Interventions

Written by a multidisciplinary panel of internationally recognized professionals, this book offers expert perspectives on techniques and technologies to overcome multilevel, multivessel complex peripheral vascular disease. Leading experts share tips and tricks to simplify the complexity of CLI revascularization and conquer vast unmet patient needs in CLI therapy. This textbook emphasizes outcomes research coupled with promising new device innovation to include low-profile devices and drug-eluting technologies that are changing the course of therapy for critical limb ischemia.

Jihad A. Mustapha, MD, FACC, FSCAI, is an internationally acclaimed interventional cardiologist who is well known for his groundbreaking work in critical limb ischemia (CLI). As a passionate advocate for CLI education, therapy and amputation prevention, he has been instrumental in advancing CLI therapy on a global level. In this book, he has successfully assembled an expert team of authors from the world’s leading centers to summarize the current best practices for the diagnosis and treatment of CLI.

For more information or to order, please visit www.CLIDiagnosticsandInterventions.com
A Closer Look at Chronic Total Occlusions and Complex Lesions

Reported in up to 40% of patients with symptomatic peripheral artery disease (PAD), chronic total occlusions (CTOs) are frequently encountered during endovascular interventions. Interest among interventionalists in treating CTOs and complex lesions has grown considerably, as rapid advances in dedicated equipment and techniques to tackle these challenging blockages have emerged over the past decade. The result has been a high rate of procedural success and low rate of complications.

While many factors influence procedural success in CTOs, the clinician’s skill set and familiarity with the available technology is paramount. This year’s Amputation Prevention Symposium features hands-on workshops for CTOs and complex lesions designed to expose physicians to the latest CTO crossing devices. The workshops’ expert faculty have considerable experience with the CTO crossing devices and devices used for complex lesions. They will be able to share with attendees their practical experiences with each device, the mechanism of action of the device and tips and tricks when using the device.

“We are very aware that the standard instructions guiding the use of each device may not address the physician’s individual questions and concerns,” says Fadi Saab, MD, FASE, FACC, FSCAI, who serves as director of the workshops. “The workshops are designed to be the translational piece bridging the gap between the concept and clinical application.”

An endovascular interventionalist, Saab has more than a decade of experience in cardiology and cardiovascular medicine; is an active faculty member at Metro Health Hospital in Wyoming, MI., and is a clinical assistant professor of medicine at the Michigan State University School of Medicine. His main practice revolves around treating patients with advanced peripheral vascular disease and critical limb ischemia (CLI), and he is heavily experienced in CLI, amputation prevention, and ultrasound-guided tibial pedal access.

“We constantly find new clinical situations where CTO devices can offer significant advantages,” Saab says. “This is evident especially with tibial disease and the need for low-profile devices.” Faculty will discuss which device to use in a particular clinical scenario as well as the clinical applicability of each of the devices. For example, a physician who treats patients with tibial and plantar CTOs can discuss with each faculty expert how to employ the appropriate CTO device with his or her patients. The faculty will also share difficult clinical scenarios they’ve encountered, and they will highlight situations where the use of a particular device may be contraindicated or not helpful.

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Faculty will discuss the applicability of re-entry devices like the Outback LTD re-entry catheter (Cordis) and the Pioneer catheter (Medtronic) and will also highlight additional low-profile re-entry devices like the OrRoad re-entry catheter system (Boston Scientific) and Enter re-entry system (Covidien).

“In planning our CTO and complex lesions workshops, we also recognized the importance of support catheters and wires,” Saab says. “Pedal loop reconstruction is the new frontier in the management of CLI patients.” So faculty will also discuss the applicability of support catheters like the Navistar (Terumo Medical), CX1 (Cook Medical), and the Quick-Cross (Spectranetics).

By the end of the workshop, Saab says attendees will be able to operate and troubleshoot the majority, if not all, of the devices. “We want them to see how the device can fit in their daily routine,” he says. “Furthermore, by increasing the success rate of crossing the CTO, the physician will save time and achieve higher patient satisfaction.”

References
Cadaver Lab  
Continued from page 6

The addition of the SALSAL track along with the traditional AMP track makes this a multidisciplinary conference supporting the goal of limb preservation in patients with diabetes. The combination allows attendees to gain up-to-date knowledge and techniques needed to support a multidisciplinary approach in preventing amputations and restoring function in diabetic patients with PAD. This appeals not only to vascular interventionalists but also to podiatric surgeons and wound care specialists.

- CHARLES ANDERSEN MD, FACS  Madigan Army Medical Center

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2. Venugopala S, Patel MR, Jones WS. Limb ischemia: cardiovascular diagnosis and management from head to toe. Can J Cardiol. 2015;31(7):611

Faculty Talk

The AMP meeting is on the cutting edge of educating providers with current concepts; this year adding a wound track will only further enhance that cutting-edge forward thinking.

- DONALD E. MRDJENOVICH, DPM, CWS, FACCWS  
Central PA Podiatry Associates, PC

Indications for Use
The IN.PACT Admiral Paclitaxel-Coated PTA Balloon catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, of de novo or restenotic lesions up to 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4.7 mm.

Contraindications
The IN.PACT Admiral DCB is contraindicated for use in:
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- 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 whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings
- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP (14 atm [1419 kPa]) is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.

- The safety and effectiveness of implanting multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 20,691 µg of paclitaxel in a patient has not been clinically evaluated in the IN.PACT SFA Trial.

Precautions
- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient’s exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events.

Potential Adverse Events
Adverse events that may occur or require intervention include, but are not limited to the following: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous AV fistula; death; dissection; embolization; fever; hematoma; hemorhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.

Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.

Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthritis; myelosuppression; peripheral neuropathy.

Refer to the Physician’s Desk Reference for more information on the potential adverse events observed with paclitaxel. There may be other potential adverse events that are unforeseen at this time. Please refer to appropriate product Instructions for Use for a detailed list of indications, warnings, precautions and potential adverse events. This content is available electronically at www.manuals.medtronic.com.

CAUTION: Federal (USA) law restricts the use of this device to sale by or on the order of a physician.
**Warnings**

- 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.
- Patients with known allergies or sensitivities to paclitaxel or its excipients.
- Patients judged to have a lesion that prevents complete predilatation, of de novo or restenotic lesions up to 180 mm long, requiring inflation from reference vessel diameters of 4-7 mm.
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries may be dilated intraprocedurally.
- The extent of the patient's exposure to the drug coating is dependent on the delivery system and/or creation of a reflux zone. The potential adverse events observed with paclitaxel. There may be other potential adverse events that are unforeseen at this time.

**Precautions**

- The use of this product carries the risks associated with the delivery system and/or creation of a reflux zone; local infection at access site; local or distal hypotension/hypertension; inflammation; ischemia or infarction; dissection; embolization; fever; hematoma; hemorrhage; aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; amputation/loss of limb; arrhythmias; arterial and/or venous ulceration; arteriovenous fistula; arteriovenous malformation; allergic/immunologic reaction; alopecia; myalgia/arthralgia; myelosuppression; peripheral neuropathy.
- The safety and effectiveness of the IN.PACT Admiral DCB used in the treatment of a specific lesion are not known if the lesion cannot be crossed by the delivery system and/or creation of a reflux zone.
- Assess risks and benefits before treating patients with a history of vascular complications, and/or bleeding events.

**Contraindications**

- The IN.PACT Admiral DCB is contraindicated for use in:
  - Patients with known allergies or sensitivities to paclitaxel or its excipients.
  - Patients judged to have a lesion that prevents complete predilatation, of de novo or restenotic lesions up to 180 mm long, requiring inflation from reference vessel diameters of 4-7 mm.

**Indications for Use**

- The IN.PACT Admiral Paclitaxel-Coated PTA Balloon catheter is indicated for percutaneous transluminal angioplasty, after predilatation, of de novo or restenotic lesions up to 180 mm long, requiring inflation from reference vessel diameters of 4-7 mm.

**Potential Adverse Events**

- Abrupt vessel closure; balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to deliver the device and/or create a risk of contamination of the device, and whether there is a potential for adverse reaction in nursing mothers. Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

**For distribution in the USA only.**

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

**Rx only.**
Finally, an SFA Standard.

A PROVEN PRIMARY THERAPY FOR THE TREATMENT OF SFA DISEASE

INCOMPARABLE CLINICAL OUTCOMES IN THE SFA
IN.PACT Admiral demonstrates positive, consistent outcomes across a broad range of patient populations.

PROVEN PRIMARY THERAPY IN SFA DISEASE
IN.PACT Admiral has demonstrated a low provisional stenting rate, minimizing the need for durable implants.

DIFFERENTIATED DCB DESIGN INTENDED TO MAXIMIZE SAFETY AND EFFICACY
95.7% primary safety composite, proving superior safety to standard PTA.

IN.PACT SFA Trial - Now Published††

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† IN.PACT SFA Trial: n=331 (n=220 DCB arm, n=111 PTA arm)
† Defined as freedom from device- and procedure-related death at 30 days and freedom from target limb major amputation and CD-Tvr at 12 months.

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