

# Late-Breaking Trials: Embargoed Until 9:30 AM PST

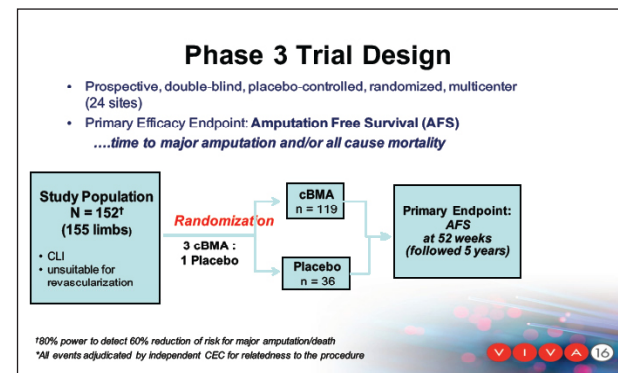
HIGHLIGHTS FROM TODAY'S TRIAL PRESENTATIONS.

## MOBILE CLINICAL TRIAL: MARROWSTIM PAD KIT FOR THE TREATMENT OF CRITICAL LIMB ISCHEMIA (CLI) IN SUBJECTS WITH SEVERE PERIPHERAL ARTERIAL DISEASE (PAD) (MOBILE CLINICAL TRIAL RESULTS)

Presenter: Michael P. Murphy, MD

The phase 3 MOBILE (MarrowStim Treatment of Limb Ischemia in Subjects With Severe Peripheral Arterial Disease) clinical trial is a prospective, double-blind, placebo-controlled, randomized, multicenter study that sought to determine if autologous bone marrow-derived progenitor cells could decrease major amputation in patients with critical limb ischemia. The primary endpoints were assessment of treatment-related adverse events and defined as time to major amputation or all-cause mortality (amputation-free survival). This is the first phase 3 trial in the United States in cell therapy. It enrolled 152 patients (155 limbs treated) at 24 sites. The rationale and design of this trial was based on a previous

phase 1 trial and used a 3 (treatment) to 1 (placebo) randomization scheme; stratification of randomization was also based on Rutherford score and presence of diabetes.



## SAFETY AND PERFORMANCE OF THE SHOCKWAVE LITHOPLASTY SYSTEM IN TREATING CALCIFIED PERIPHERAL VASCULAR LESIONS: 6-MONTH RESULTS FROM THE TWO-PHASE DISRUPT PAD STUDY

Presenter: Prof. Thomas Zeller, MD

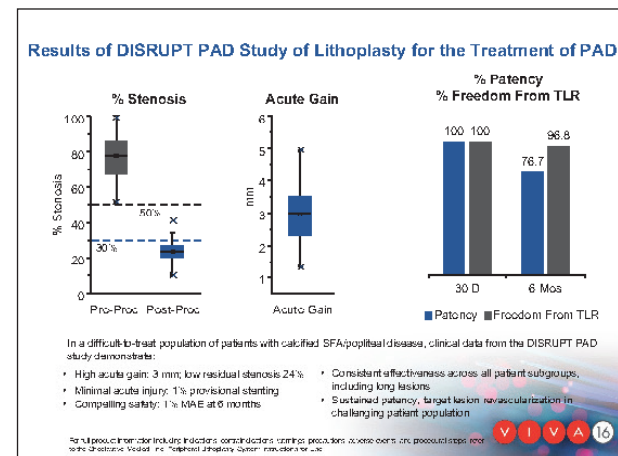
Lithoplasty technology integrates the calcium-disrupting power of lithotripsy with the familiarity and simplicity of balloon-based interventional devices. Built on a traditional balloon catheter platform, lithoplasty devices (Shockwave Medical) use the intermittent pulsatile mechanical energy of lithotripsy to disrupt both superficial and deep calcium while minimizing soft tissue injury and an integrated balloon to dilate lesions at low pressures, restoring blood flow.

The DISRUPT PAD study is a single arm, two-phase multicenter study that enrolled 95 patients with symptomatic calcified femoropopliteal lesions ≤ 15 cm in length. The primary safety endpoint was freedom from major adverse events (MAE) through 30 days. Procedural

success, the primary performance endpoint, was defined as < 50% residual diameter stenosis, with or without adjunctive balloon angioplasty therapy. Key secondary endpoints include target lesion revascularization and vessel patency defined as freedom from > 50% restenosis.

The ongoing positive results of the DISRUPT PAD study demonstrate that the lithoplasty technology is a promising treatment for patients with calcified peripheral artery disease, a difficult-to-treat population.

Clinical data from the study demonstrate compelling safety, consistent procedural success across all patient subgroups (including moderate and severe calcium), high acute gain, and minimal acute vessel injury. Midterm results show sustained patency, target lesion revascularization, and functional improvement through 6 months. There were no major amputations, perforations, thrombus, or distal embolization events. There was 100% procedural success with average residual stenosis of 24% and acute gain of 3 mm. Only one stent (1%) was implanted to treat a flow-limiting dissection. Vessel patency was 77% at 6 months as assessed by duplex ultrasound.



Target lesion revascularization was only 3% at 6 months. Note that the lithoplasty system holds CE Marking. It is not available in the United States.

## IN.PACT SFA RANDOMIZED TRIAL: DRUG-COATED BALLOONS SHOW SUPERIOR 3-YEAR OUTCOMES VERSUS ANGIOPLASTY

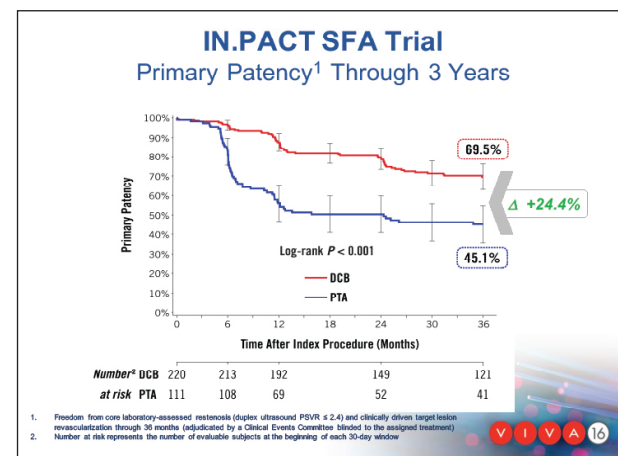
Presenter: Prakash Krishnan, MD

IN.PACT SFA is an independently adjudicated, prospective, multicenter, randomized, single-blinded trial that enrolled 331 patients with symptomatic (Rutherford 2–4) femoropopliteal lesions. Patients were randomly assigned in a 2:1 ratio to treatment with the In.Pact Admiral drug-coated balloon (DCB) (Medtronic) or percutaneous transluminal angioplasty (PTA). Study assessments included primary patency, defined as freedom from clinically driven target lesion revascularization (CD-TLR) and duplex-derived restenosis; major adverse events, including target vessel revascularization (TVR); and functional outcomes (EQ-5D questionnaire, walking impairment questionnaire, and 6-minute walk test) were evaluated through 3 years.

At 3 years, patients treated with the In.Pact Admiral DCB demonstrated significantly superior primary patency when compared to PTA (69.5% vs 45.1%;  $P < .001$ ). The

rates of CD-TLR were 15.2% for DCB and 31.1% for PTA ( $P = .002$ ), with time to first event significantly longer for the DCB group ( $542.9 \pm 278.2$  days vs  $302.9 \pm 213$  days;  $P < .001$ ). There were no device- or procedure-related deaths and no major amputations in either group through 3-year follow-up. The rate of thrombosis was low (2% DCB vs 4.9% PTA;  $P = .283$ ). Both groups showed similar functional assessment results at 3 years, although DCB patients achieved this level of function with 48% fewer reinterventions.

In this multicenter randomized trial, the In.Pact Admiral DCB was shown to have superior long-term patency and low reintervention rates when compared to angioplasty. To date, this is the only DCB to show durable treatment effect through 3 years, supporting its continued use as a first-line treatment for symptomatic femoropopliteal disease.



# Late-Breaking Trials: Embargoed Until 9:30 AM PST

HIGHLIGHTS FROM TODAY'S TRIAL PRESENTATIONS.

## VIRTUS ILIOFEMORAL VENOUS STENTING US IDE STUDY

Presenter: Stephen Black, MD

VIRTUS is a prospective, multicenter, single-arm, non-randomized global study. The objective of the study is to assess the safety and efficacy of the Vici venous stent system (Veniti, Inc.) in achieving patency of the target venous lesion in patients with clinically significant, chronic, nonmalignant occlusion of the iliofemoral venous tract. A total of 200 patients are being enrolled in clinical centers worldwide: 30 feasibility subjects and 170 pivotal.

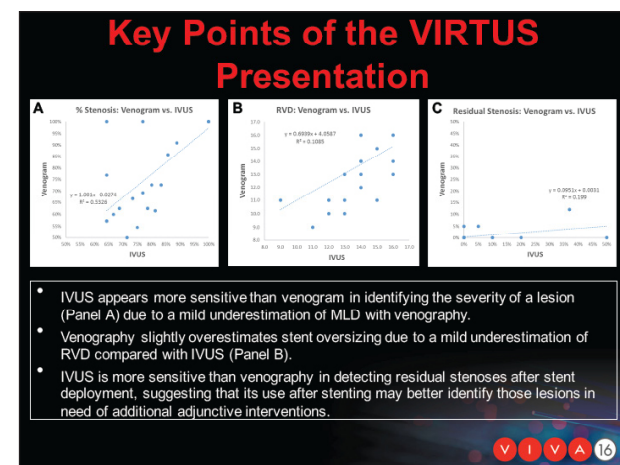
Inclusion criteria of the study include symptomatic patients who are assessed by venogram and intravascular ultrasound (IVUS) and are  $\geq 18$  years of age. Exclusion criteria were patients whose vein diameters are not within limits stated in the current Vici venous stent instructions for use and also those who have had any previous surgical or endovascular procedure of the target vessel.

Subjects' follow-up intervals include 30 days, 6 months,

12 months, and yearly thereafter up to 5 years after the index procedure. Baseline assessments include but are not limited to medical history, laboratory testing, chronic venous insufficiency questionnaire, venous clinical severity score, venogram, and IVUS.

Although venography has a long history in the diagnosis of venous disease, data suggest IVUS may be better to define lesion severity. In the VIRTUS feasibility cohort analyzed, preprocedure venogram and IVUS measurements of minimum luminal diameter (MLD) were highly correlated. Post-stent percentage stenosis was not highly correlated between venography and IVUS. The degree of stent oversizing was greater by venogram than IVUS. Venography is important for guiding appropriate stent deployment, although IVUS may be more accurate for assessing the severity of a lesion and for proper venous stent sizing.

VIRTUS subjects will continue to be followed, and more data will be analyzed and presented as they become available.



## DRUG-COATED BALLOON TREATMENT FOR PATIENTS WITH INTERMITTENT CLAUDICATION: INSIGHTS FROM THE IN.PACT GLOBAL FULL CLINICAL COHORT

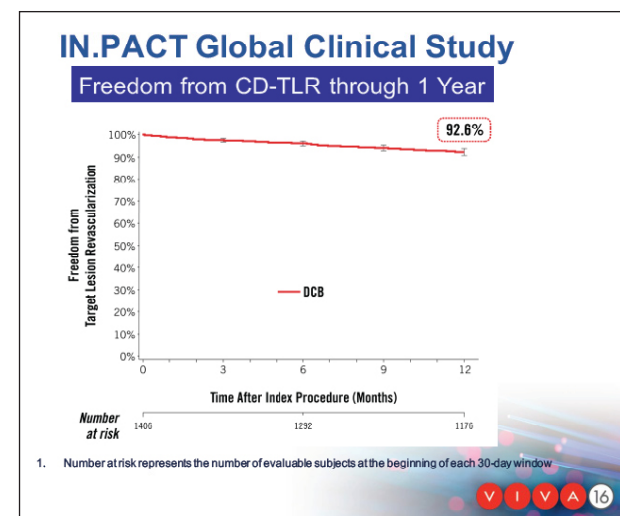
Presenter: Michael R. Jaff, DO

IN.PACT Global is an independently adjudicated and monitored multicenter, international, prospective, single-arm study designed to expand the clinical evidence of the In.Pact Admiral drug-coated balloon (DCB) (Medtronic) in the treatment of real-world patients with symptomatic (Rutherford 2–4) femoropopliteal peripheral artery disease (PAD). A total of 1,406 patients were treated with the In.Pact Admiral DCB and analyzed as part of the consecutively enrolled clinical cohort. A subset of the clinical cohort subjects, referred to as the imaging cohort, were required to undergo duplex ultrasound imaging at 12 months and at the time of any reintervention within 12 months to assess target lesion patency. The imaging cohort consisted of three prospectively prespecified subgroups, and data for the subjects in each

group have been previously presented: de novo in-stent restenosis ( $n = 131$ ), long lesion  $\geq 15$  cm ( $n = 157$ ), and chronic total occlusion  $\geq 5$  cm ( $n = 126$ ). Twelve-month outcomes from the entire clinical cohort are presented herein.

The mean age of subjects in the clinical cohort was  $68.6 \pm 10.1$  years, and 67.8% were male. The mean lesion length was  $12.09 \pm 9.54$  cm, including 18% in-stent restenosis, 35.5% total occlusions, and 68.7% calcified lesions. The primary effectiveness endpoint, freedom from clinically driven target lesion revascularization (CD-TLR) within 12 months, was 92.6%. The primary safety outcome, a composite of freedom from device- and procedure-related mortality through 30 days and freedom from major target limb amputation and clinically driven target vessel revascularization within 12 months, was 92.1%. The rates of major target limb amputations and thrombosis within 12 months were 0.2% and 2.9%, respectively.

These results confirm safety and effectiveness of the In.Pact Admiral DCB in femoropopliteal lesions. To our knowledge, this is the largest clinical evaluation of real-



world patients treated with DCBs to date.

## TODAY'S LATE-BREAKING TRIAL PRESENTATION SCHEDULE

- 8:10 AM Valiant US-IDE 3-Year Results
- 8:22 AM LIFE Registry Final Results
- 8:34 AM AVF Interventions—Traditional Surgical vs Novel Endovascular Approach
- 8:46 AM MAJESTIC 2-Year Results and Subgroup Analysis
- 8:58 AM DEB SFA-Long Study 2-Year Results

All trial presentations are 7 minutes, with 2 minutes for questions.