VOLCANO

Decide, guide, treat and confirm: The Philips Volcano CLI solution

innovation + you

601-0100.109/LC

PHILIPS

Critical Limb Ischemia Affects the Lives of Many Patients

- There are an estimated **2 million** people in the United States that have **CLI**, including undiagnosed patients.[1]
- **Diagnosed CLI** currently affects roughly **1 million** Americans.[2]
- **54%** of patients with CLI may receive amputation as their primary procedure.[2]
- Hospital costs associated with amputation totaled more than **$8.3 billion** in 2009.[3]

1. The SAGE Group reports that in 2007 approximately 2.8 million people in Western Europe suffered from critical limb ischemia [press release]. Atlanta, GA: SAGE Group. Oct. 20, 2008. http://thesagegroup.us/press%20releases/PressReleaseCLI%20W%20Eu08.html
2. Goodney PP, Travis LL, Nallamothu BK, et al. Variation in the use of lower extremity vascular procedures for critical limb ischemia. Circ Cardiovasc Qual Outcomes. 2012;5(1):94-102.
3. HCUP Nationwide Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP). Rockville, MD: Agency for Healthcare Research and Quality; 2009.

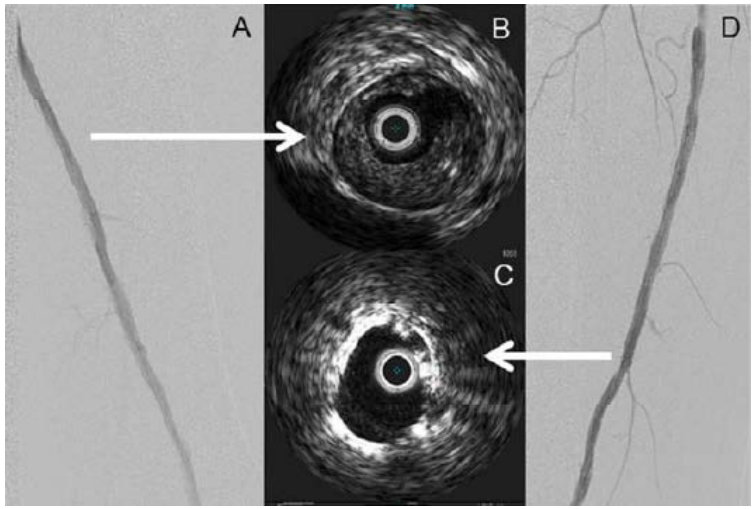
PHILIPS

Decide: IVUS Reference Data Can Assist Your Patient Therapy Choice

IVUS Provides You More Detailed Info Than Angio Alone

- IVUS aids your procedure by providing information:
  - To assess plaque morphology
  - To determine the location and extent of calcium
  - To assist in your choice of patient therapy

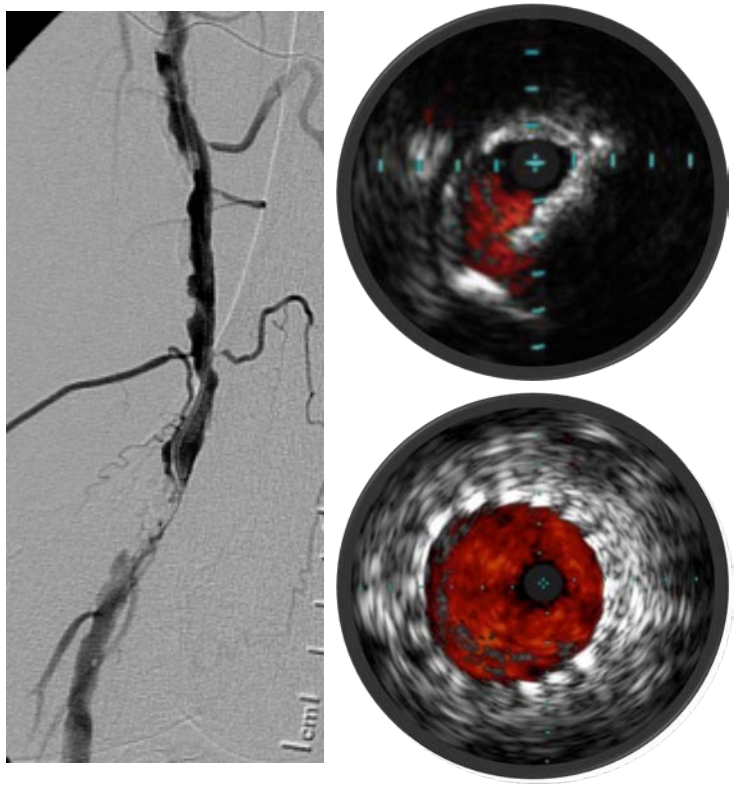
- Angio alone doesn't give the same level of detail about lesion morphology and geometry.



PHILIPS

How Does Data Affect Your Treatment Choice?

- Study data suggests that determination of overall vessel diameter and interpretation of plaque morphology by angiography are discordant from IVUS-derived data.[1]
- Grading of calcification was moderate to severe in 40% by angiography but in only 7% by IVUS ($p < .05$).[1]
- The location and extent of calcium within the vessel can be key to choosing which therapy is most suitable for the patient.[2]



1. Arthurs et. al. Evaluation of peripheral atherosclerosis: A comparative analysis of angiography and intravascular ultrasound imaging. J Vasc Surg. 2010 Apr;51(4):933-8; discussion 939. doi: 10.1016/j.jvs.2009.11.034. Epub 2010 Jan 15.
2. Lee JT, Fang TD, White RA. Applications of intravascular ultrasound in the treatment of peripheral occlusive disease. Semin Vasc Surg. 2006 Sep;19(3):139-44.

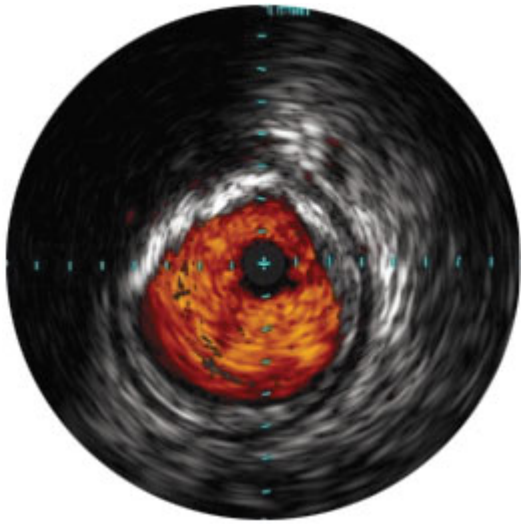
PHILIPS

Guide: IVUS Can Assist Your Treatment Strategy

Assessing Therapy Completeness and Device Sizing

- IVUS can aid you in assessing completeness of therapy.
  - Based on post-treatment IVUS, you may be able to better assess effectiveness and completeness of treatment, and if adjunctive therapy is needed.

- IVUS guides therapy by providing information helpful for device sizing.



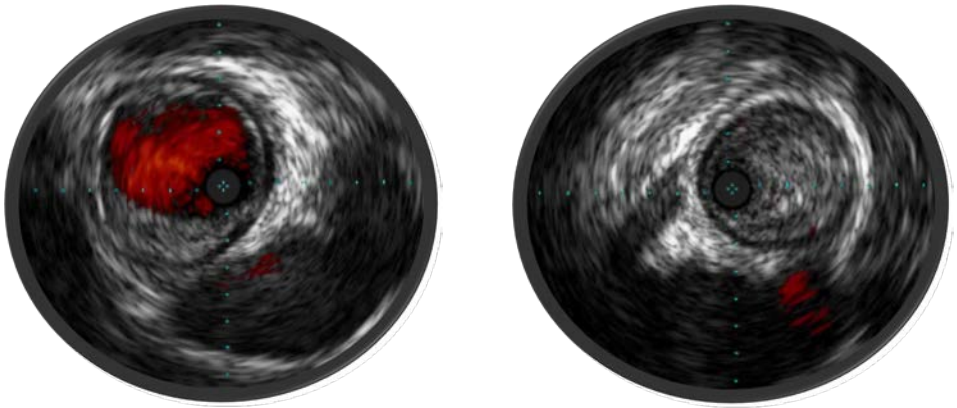
Results not predicting future outcomes.
IVUS images obtain from actual cases with consent from the clinician.
Data on file at Philips Volcano.

PHILIPS

IVUS Guidance and Outcomes Data

- IVUS utilization during lower extremity peripheral vascular procedures was independently predictive of lower **Amputation rates** (OR = 0.59; 95% CI, 0.45-0.77; p <.001).[1]
- Study data has suggested that IVUS use was associated with significantly higher primary patency rates than no IVUS use in femoropopliteal stenting (90 ± 2% primary patency at 1 year in IVUS guided group versus 72 ± 3% in the angio guided group, p <0.001).[2]

IVUS Images Pre and Post Phoenix Atherectomy[3]



1. Panaich et, al, Intravascular Ultrasound in Lower Extremity Peripheral Vascular Interventions: Variation in Utilization and Impact on In-Hospital Outcomes From the Nationwide Inpatient Sample (2006–2011). J Endovasc Ther 2016 Feb 4;23(1):65-75. Epub 2015 Dec 4.
2. Iida O, et. al. Efficacy of Intravascular Ultrasound in Femoropopliteal Stenting for Peripheral Artery Disease With TASC II Class A to C Lesions. J Endovasc Ther. 2014 Aug;21(4):485-92.
3. Results not predictive of future outcomes. IVUS images obtained from actual cases with consent from the clinician. Data on file at Philips Volcano.

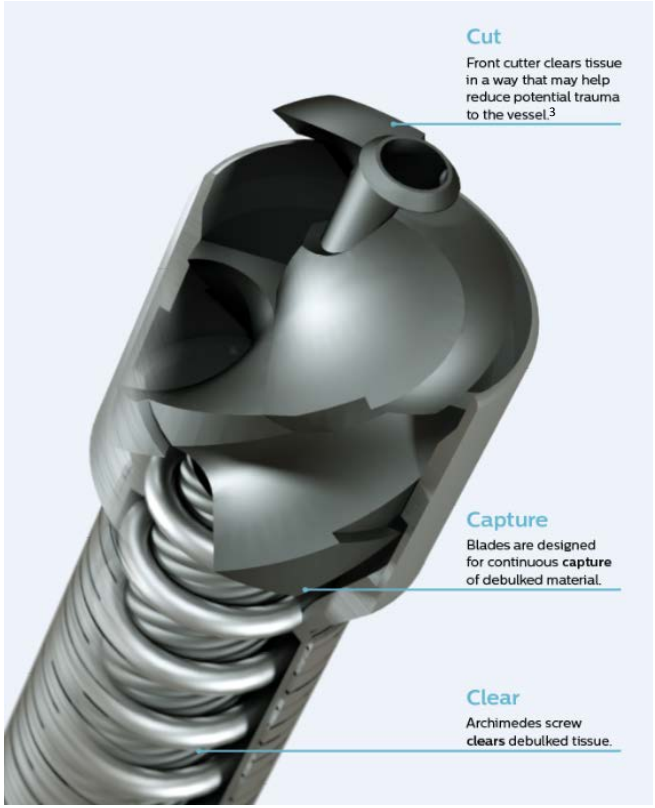
Treat: Phoenix Atherectomy System Is a Hybrid Solution For Treating Your Patients

Phoenix Atherectomy System Family of Products: Hybrid Design[1]

Versatility: Phoenix effectively treats a broad range of tissue types, from soft plaque to calcified arteries, for lesions both above and below the knee.[2]

Center mass cutter: Clears tissue in a way that may help reduce potential trauma to the vessel. Design of the Phoenix cutter head allows debulked tissue be continuously captured, resulting in a <1% rate of distal embolization.[3]

Cut, capture and clear mechanism of action: Front cutter clears tissue, blades continuously capture debulked material, which is then removed by the Archimedes screw.



1. Directional cutting ability only available with Phoenix 2.4mm deflecting catheter
2. The Phoenix atherectomy 1.8 mm tracking catheter is indicated for vessels 2.5 mm in diameter or above. The Phoenix atherectomy 2.2 mm tracking and 2.4 mm deflecting catheters are indicated for vessels 3.0 mm in diameter or above. While the 1.8 mm and 2.2 mm tracking catheters are indicated for femoral, popliteal, or distal arteries located below the knee, the Phoenix 2.4 mm deflecting catheter is indicated for femoral and popliteal only.
3. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD.

PHILIPS

Phoenix Atherectomy System Family of Products: Hybrid Design

- Hybrid atherectomy is a new category of atherectomy
  - Not rotational or directional
  - It combines the benefits of existing atherectomy systems to a unique atherectomy solution that allows physicians to tailor treatment to patients

*Directional cutting ability only available with Phoenix 2.4mm deflecting catheter

PHILIPS

Phoenix Atherectomy System-
The Next Generation of Atherectomy

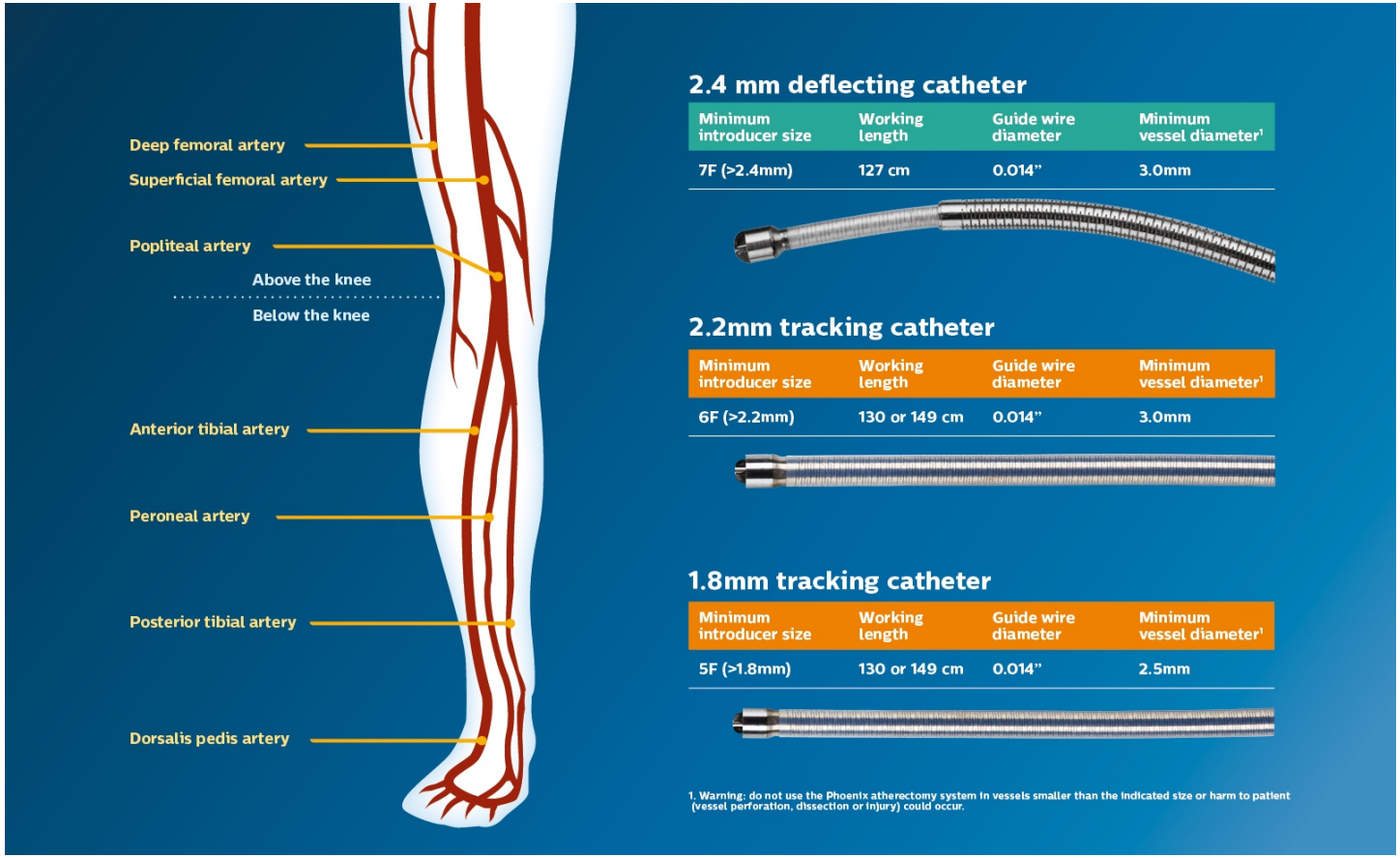
- The first hybrid atherectomy system available –
- Combines the benefits of existing atherectomy systems to tailor the treatment for each patient.

	Hybrid	Directional	Laser	Orbital	Rotational
Front cutting for direct lesion access	✓		✓	✓	✓
Plaque removal	✓	✓			✓
Directional cutting ability*	✓	✓			
Single insertion	✓		✓	✓	✓
No need for capital equipment	✓	✓			

*Available with Phoenix 2.4 deflecting catheter.

PHILIPS

Phoenix Hybrid Atherectomy System Family of Products: Treats Above and Below the Knee*



*The Phoenix atherectomy 1.8 mm tracking catheter is indicated for vessels 2.5 mm in diameter or above. The Phoenix atherectomy 2.2 mm tracking and 2.4 mm deflecting catheters are indicated for vessels 3.0 mm in diameter or above. While the 1.8 mm and 2.2 mm tracking catheters are indicated for femoral, popliteal, or distal arteries located below the knee, the Phoenix 2.4 mm deflecting catheter is indicated for femoral and popliteal only.

PHILIPS

Phoenix Hybrid Atherectomy System Family of Products: Help Address Clinical Concerns[1]

Clinical Concern	Phoenix Design	Safety Data[2]
Vessel Injury	Over the wire, center mass cutter that clears tissue in a way that may help reduce potential trauma to the vessel	1.9% Perforation 0.9% Dissection*
Distal Embolization**	Continuous capture and clearance of debulked material into the catheter	<1% distal embolization 0% use of distal protection

*grade C or greater
**requiring intervention

1. Directional cutting ability available with the 2.4mm Phoenix deflecting catheter only
2. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD

PHILIPS

Phoenix Hybrid Atherectomy System Family of Products: Effectiveness

- EASE trial data confirms Phoenix's ability to effectively treat a broad range of tissue types, from soft plaque to calcium, for lesions both above and below the knee.[1,2]
- Offering of 3 catheters diameters has been shown to effectively treat most peripheral vasculature.[2]
  - 1.8 and 2.2mm (non-deflecting) are suited for treating small vessels or highly stenosed lesions.
  - 2.4mm (deflecting) is suited for larger vessels or eccentric lesions.[3]

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD.
2. Phoenix Atherectomy device is indicated for vessels 2.5mm in diameter and above
3. 2.4mm Phoenix Atherectomy device is indicated for vessels above the knee

PHILIPS

Phoenix Hybrid Atherectomy System
Family of Products: Ease of Use

- Single insertion- no need to remove and clean out debulked material.
- Battery-powered handle operated. No capital equipment or additional procedural accessories required.
- Low profile, front cutting design allows for direct lesion access without having to first pass a nosecone.[1]

1. Phoenix Atherectomy Device is indicated for vessels 2.5mm and above

PHILIPS

EASE Study Overview[1]

- Prospective, single arm, multi-center, FDA-approved IDE study in US and Germany
- Lower limb atherectomy with or without adjunctive treatment
- Follow-up at 30 Days and 6 Months
- Independent adjudication of adverse events
- 105 total patients, 123 lesions enrolled

Endovascular Atherectomy Safety and Effectiveness
(EASE) Study

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD 600-0100.153/001

PHILIPS

EASE Study Overview[1]

- Co-primary endpoints:
  - Acute debulking with ≤50% residual stenosis (technical success)
  - 30-day major adverse events (safety)
- National Principal Investigators
  - Dr. Tom Davis at St. John's Detroit
  - Dr. Jim McKinsey at Columbia Presbyterian NY
- All 3 sizes of Phoenix catheters were included in trial
  - 7F (deflecting), 6F, and 5F

Endovascular Atherectomy Safety and Effectiveness
(EASE) Study

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD 600-0100.153/001

PHILIPS

EASE Trial Data: Target Lesion Characteristics[1]

Variable	n = 123
Distal RVD (mm)	3.52 ± 0.7 (2.5, 3.5, 4.5)
Lesion Length (mm)	34.0 ± 29.8 (3, 20,100)
Baseline RCC	
0	0
1	0
2	26 (25%)
3	45 (43%)
4	7 (7%)
5	27 (26%)
6	0

33% CLI

- Patients with varying degrees of arterial disease were treated
  - 33% of patients had CLI
  - 26% of patients had active tissue loss as they were RCC 5

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD

PHILIPS

EASE Trial Data: Target Lesion Characteristics[1]

Variable	n = 123
ATK	59 (47.9%)
SFA	35 (28.5%)
Popliteal	24 (19.5%)
BTK	64 (52.0%)
AT	21 (17.1%)
TPT	14 (11.4%)
PT	18 (14.6%)
Per	11 (8.9%)
Patent Tibial Vessels	
Single or less	44 (42%)

- The Phoenix catheter was used to treat above and below the knee

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD

PHILIPS

EASE Trial Data: Procedural Information[1]

Variable	N=123
Pre-Treatment with PTA	1 (0.8%)
Distal Protection Used in Treatment of Target Lesions	0 (0%)
Bailout Stent Required	1 (0.8%)
Handle Run Time	5.9 + 4.7 mins (0.5, 4.6, 25.0)

- Distal protection was not used for any of the patients
  - Trial results showed <1% distal embolization

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD

PHILIPS

EASE Trial: Safety and Effectiveness Endpoints[1]

Primary Endpoint Attainment	
Effectiveness: Technical Success	117/123 (95.1%) Target Performance Goal: >86%
Safety: 30-Day MAE	6/105 (5.7%) Target Performance Goal: <20%
MAE Composite at 30 Days	
Abrupt Closure	0
Clinically Driven TLR	1 (0.9%)
Perforation	2 (1.9%)
Grade C or greater Dissection	1 (0.9%)
Distal emboli req interv	1 (0.9%)
Unplanned Toe Amputation	3 (2.9%)
Unplanned BTK Amputation	0
Unplanned ATK Amputation	0

- The Phoenix Atherectomy System met safety and effectiveness endpoints
- Unplanned toe amputations:
  - A single subject had three (3) MAE events, including: a flow-limiting dissection and an emboli, each requiring intervention; also, an unplanned toe amputation occurred within the 30-day follow-up and a Rutherford-Becker Classification of 5[1]

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD

PHILIPS

Rutherford Class Improvement Durability Over Time[1]

Variable	30D (n=104)	6M (n=98)
Rutherford Class Change from Baseline at Visit		
≥ -1	76/102 (74.5%)	78/97 (80%)
No Change	26/102 (25.5%)	16/97 (16%)
+ 1	0 (0.0%)	2/97 (2%)
+2	0 (0.0%)	1/97 (1%)
>2+	0 (0.0%)	0 (0.0%)

Kaplan-Meier Patency Estimates at 6 months:

Freedom from TLR	88.0%
Freedom from TVR	86.1%

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD

PHILIPS

Summary[1]

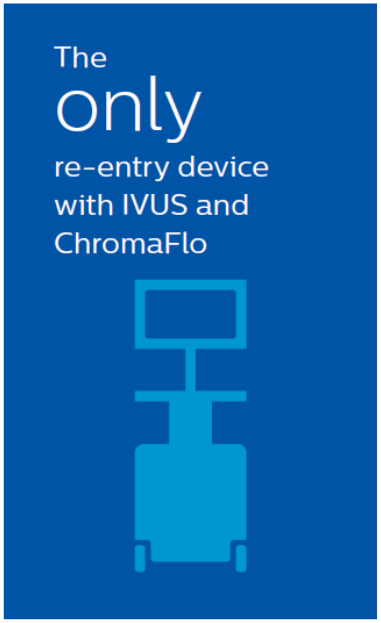
- Based on study data and our initial experience, the Phoenix System is a safe and effective atherectomy solution for the peripheral vasculature
- EASE met pre-defined performance goals in safety and effectiveness with sustained improvement at 6 months
  - Post-market Phoenix Registry is currently underway
- Phoenix cuts, captures and clears debulked material with a single catheter insertion
- May offer ability to debulk arteries that may not have been previous candidates for atherectomy due to front-cutting mechanism and low profile.

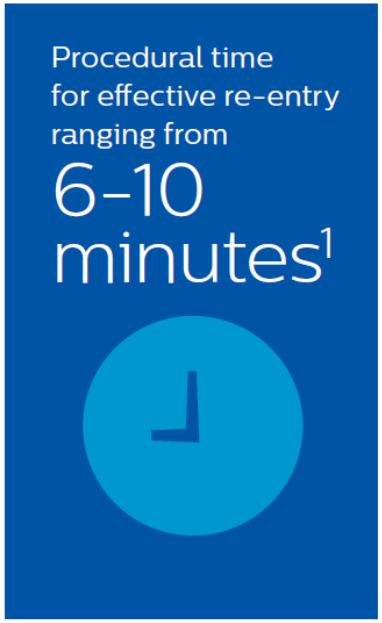
1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD

Treat: Pioneer Plus IVUS-Guided Re-entry Catheter for True Lumen Return

Pioneer Plus:
IVUS-guided clarity to true lumen re-entry

Pioneer Plus is the only IVUS-guided re-entry catheter delivering quick, confident and controlled true lumen re-entry.[3]



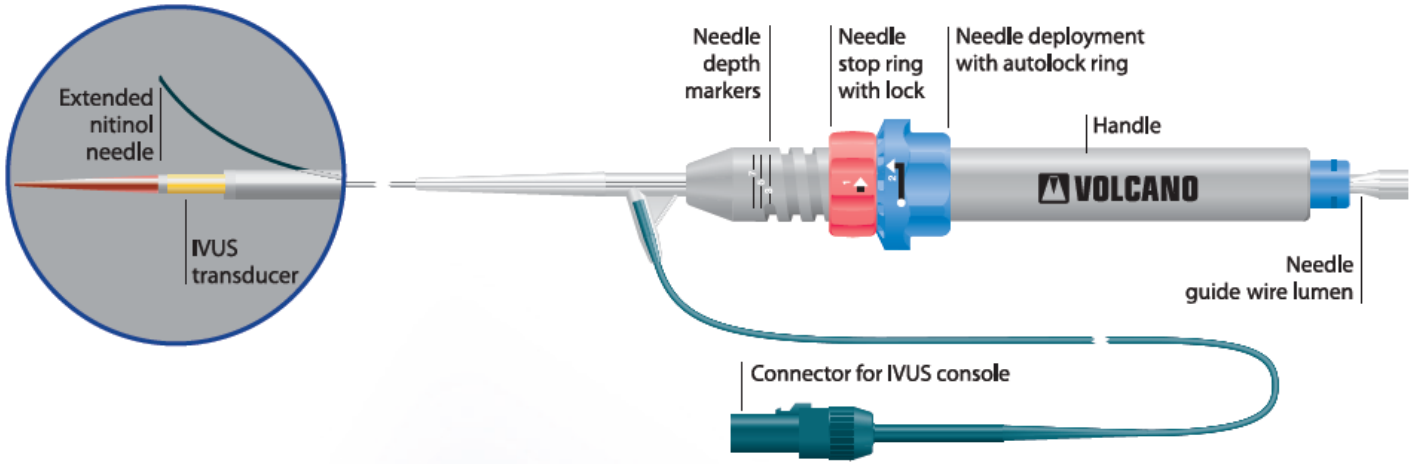


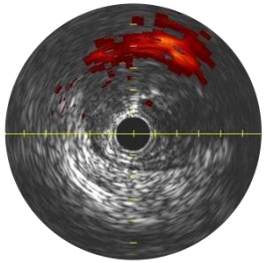
1. Saket R., Razavi, M., Padidar A., et al. Novel Intravasular Ultrasound-Guided Methods to Create Transintimal Arterial Communications: Initial Experience in Peripheral Occlusive Disease and Aortic Dissection. J Endovasc Ther. 2004; 11: 274-280.
2. Al-Ameri, H et al. Peripheral Chronic Total Occlusions Treated with Subintimal Angioplasty and a True Lumen Re-Entry Device. Journal of Invasive Cardiology. 2009; 21(9): 468-472.
3. Saket et al., Novel Intravascular Ultrasound-Guided Method to Create Transintimal Arterial Communications, J Endovascular Therapy, 11:274–280, 2004. Krishnamurthy et al., Intravascular ultrasound-guided true lumen reentry device for recanalization of unilateral chronic total occlusion of iliac arteries: technique and follow-up. Ann Vasc Surg. 24:487-97, 2010.

PHILIPS

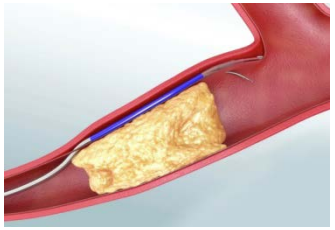
.

Pioneer Plus:
Identify true lumen with speed and precision





The integrated 64-element, phased array IVUS transducer (20 MHz) provides easy visualization of true lumen with the help of ChromaFlo



Adjustable nitinol needle (24G) includes 3 depths (3mm, 5mm & 7mm) designed for easier penetration

PHILIPS

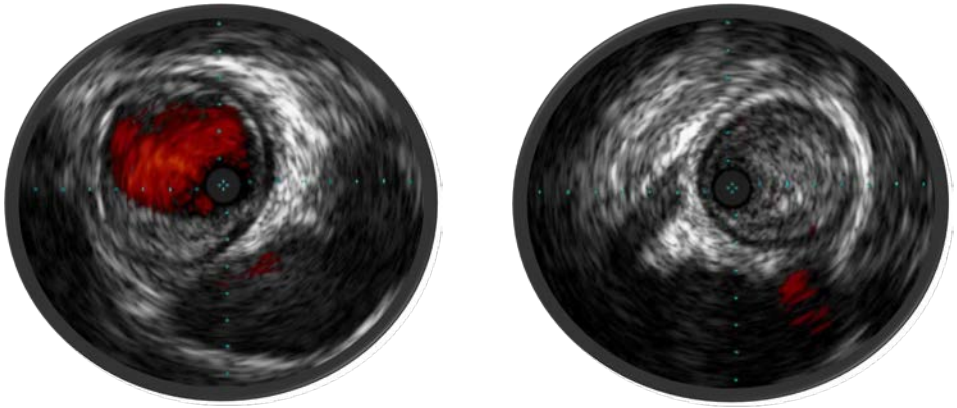
Confirm: IVUS Data Can Support Outcomes Assessment

IVUS Guidance Is Associated with Better Outcomes

- Research suggests that IVUS guided peripheral interventions result in better outcomes than angio guided interventions (90 ± 2% vs. 72 ± 3% p<0.001).[1]

- Research suggests that IVUS is able to provide evidence that a significant portion of the plaque has been removed during atherectomy procedures.[2]

IVUS Images Pre and Post Phoenix Atherectomy[3]

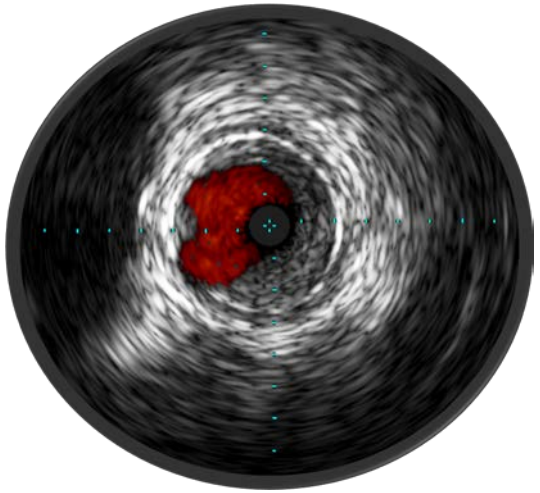


1. Ida O, et. al. Efficacy of Intravascular Ultrasound in Femoropopliteal Stenting for Peripheral Artery Disease With TASC II Class A to C Lesions. J Endovasc Ther. 2014 Aug;21(4):485-92.
2. Lee et al. Applications of Intravascular Ultrasound in the Treatment of Peripheral Occlusive Disease. Semin Vacs Surg 19:139-144 2006
3. Results not predicting future outcomes. IVUS images obtain from actual cases with consent from the clinician. Data on file at Philips Volcano.

Confirming Your Results

- IVUS can aid you in assessing completeness of therapy.
  - Based on post treatment IVUS, you may be able to better assess effectiveness and completeness of treatment, and if adjunctive therapy is needed.

- Study data has reported that gray scale IVUS showed 68% of study patients had >70% residual stenosis after “successful” endovascular interventions were confirmed by angiograms.[1]



Results not predictive of future outcomes.
IVUS images obtained from actual cases with consent from the clinician. Data on file at Philips Volcano.

1. Hitchner E, Zayed M, Varu V, Lee G, Aalami O, Zhou W. A prospective evaluation of using IVUS during percutaneous superficial femoral artery interventions. *Ann Vasc Surg* 2015;29(1):28-33.

PHILIPS


PHILIPS