Total atherectomy solution for vessel preparation: Hybrid[1] atherecomy

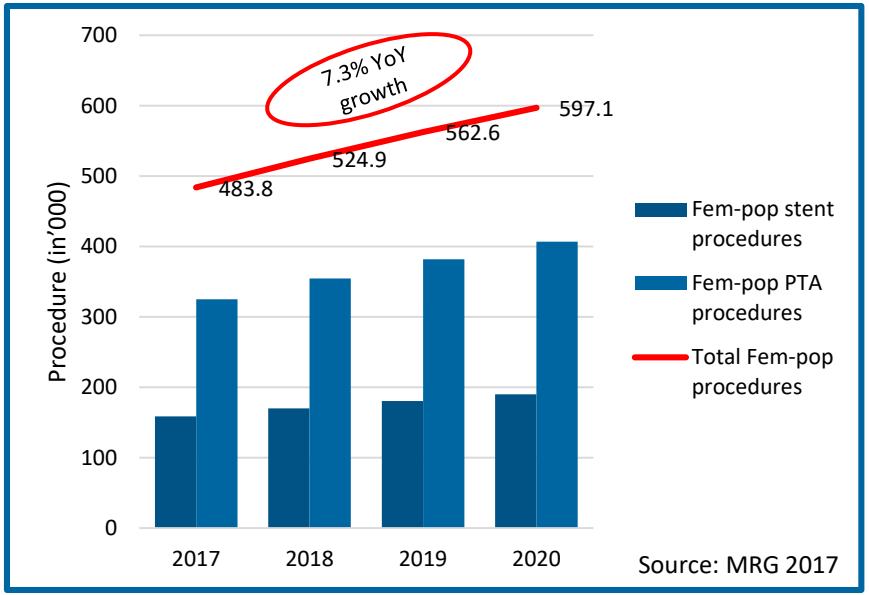
Joseph Griffin M.D

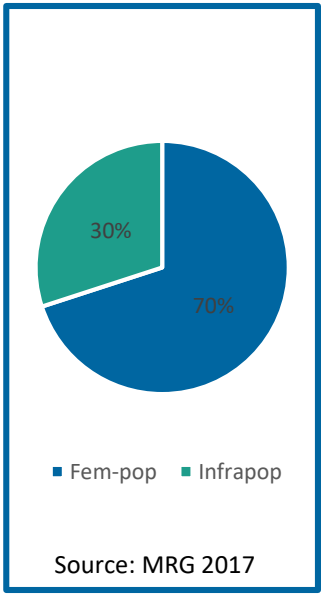
[1]Directional cutting ability only available with Phoenix 2.4mm deflecting catheter

Disclosures

Dr. Joseph Griffin has been compensated by Philips for his services in preparing and presenting this material for Philips' further use and distribution.

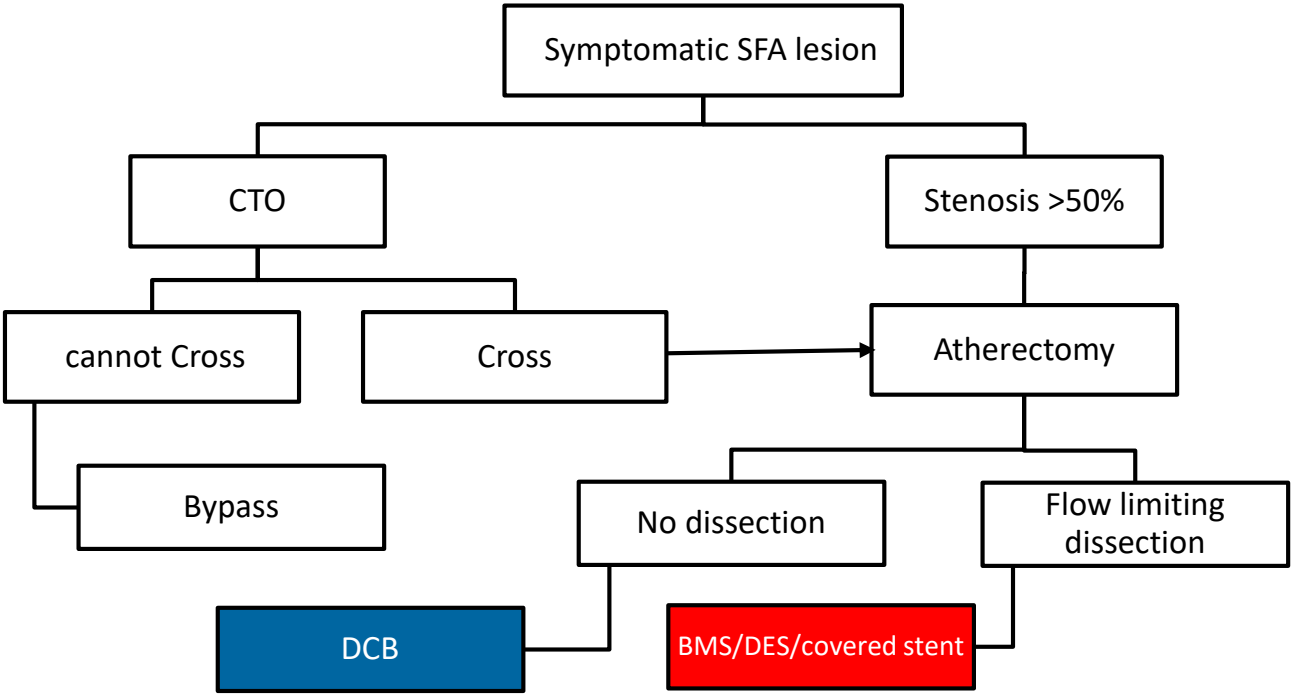
Total Fem-pop procedures in the US





- SFA stenting is growing but at slower pace
- DCB has helped increase the Fem-pop PTA procedures grow rapidly
- Total SFA procedure is growing at 7.3% year over year

My treatment algorithm for SFA



Phoenix hybrid[1] atherectomy- Safe[2]

1. Directional cutting ability only available with Phoenix 2.4mm deflecting catheter
2. Davis, Thomas et al., Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. Vascular. September 27, 2017, DOI: 10.1177/1708538117712383

Phoenix atherectomy system-
The next generation of atherectomy

- The first hybrid[1] atherectomy system available –
- Combines the benefits of existing atherectomy systems to tailor the treatment for each patient.

	Hybrid[1]	Directional	Orbital	Rotational
Front cutting for direct lesion access	✓		✓	✓
Continuous plaque removal	✓			
Directional cutting ability[1]	✓	✓		
Single insertion	✓		✓	✓
No need for capital equipment	✓	✓		✓

1. Directional cutting ability only available with Phoenix 2.4mm deflecting catheter

Phoenix: Hybrid[1] design

Hybrid[1] 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

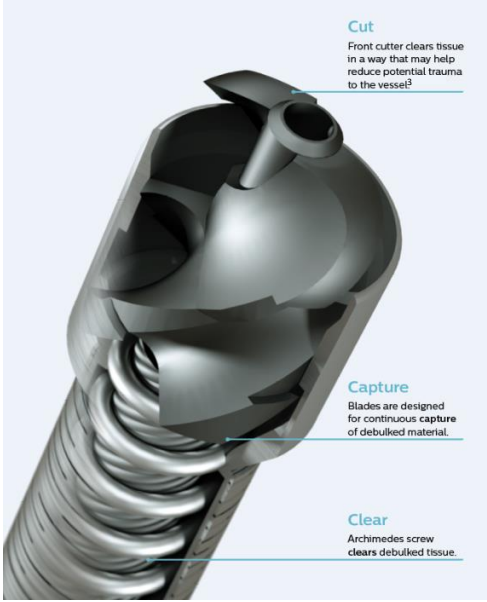
[1]Directional cutting ability only available with Phoenix 2.4mm deflecting catheter

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

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. Davis, Thomas et al., Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. Vascular. September 27, 2017, DOI: 10.1177/1708538117712383

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Phoenix hybrid[1] atherectomy- Ease of use

1. Directional cutting ability only available with Phoenix 2.4mm deflecting catheter

Phoenix hybrid[1] 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.[2]

1. Directional cutting ability only available with Phoenix 2.4mm deflecting catheter
2. Phoenix Atherectomy Device is indicated for vessel sizes 2.5mm and above

Phoenix hybrid[1] atherectomy system family of products: Ease of Use

Product Code	Min Introducer Size (Fr)	Crossing Profile (mm)	Working Length (cm)	Min Vessel Diameter (mm)	Max Guidewire Diameter (in)
P18130K	5 Fr	1.8 mm	130 cm	2.5 mm	0.014”
P18149K			149 cm		
P22130K	6 Fr	2.2 mm	130 cm	3.0 mm	
P22149K			149 cm		
P24130K	7 Fr	2.4 mm	130 cm	3.0 mm	
PD24127K	7 Fr	2.4 mm	125/127 cm	3.0 mm	0.014”

New

6 SKU’s – Total atherectomy solution

1. Directional cutting ability only available with Phoenix 2.4mm deflecting catheter

Phoenix hybrid[1] atherectomy-Effective

1. Directional cutting ability only available with Phoenix 2.4mm deflecting catheter

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

- **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

1. Davis, Thomas et al., Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. Vascular. September 27, 2017, DOI: 10.1177/1708538117712383

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**

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%)

1. Davis, Thomas et al., Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. Vascular. September 27, 2017, DOI: 10.1177/1708538117712383

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. Davis, Thomas et al., Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. Vascular. September 27, 2017, DOI: 10.1177/1708538117712383

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. Davis, Thomas et al., Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. Vascular. September 27, 2017, DOI: 10.1177/1708538117712383

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. Davis, Thomas et al., Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. Vascular. September 27, 2017, DOI: 10.1177/1708538117712383

Phoenix Registry Objective and Overview[1]

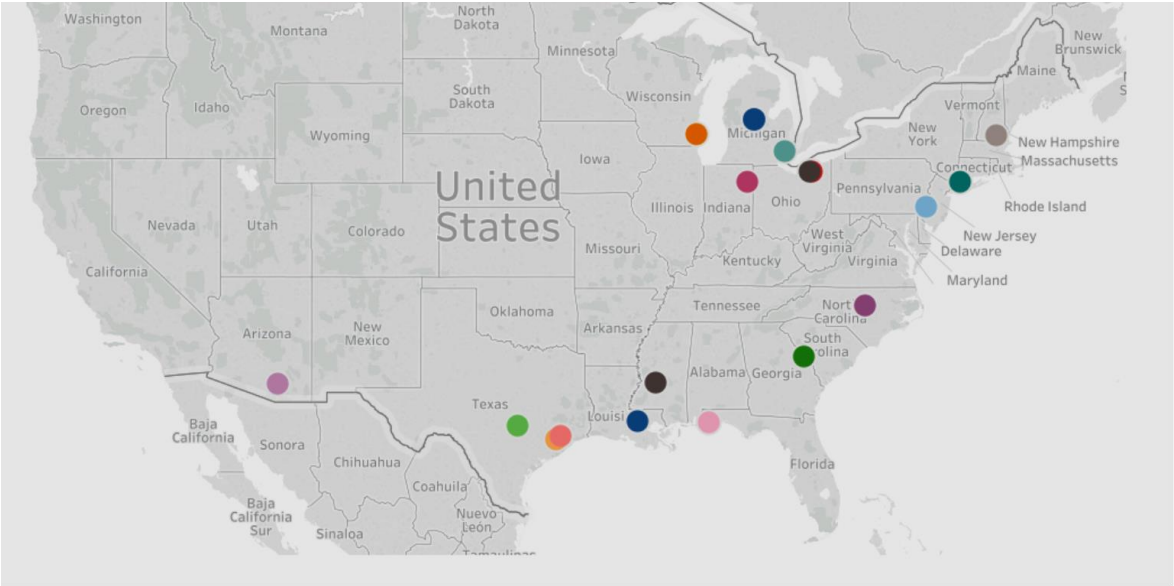
To evaluate the short and long-term clinical outcomes of patients treated with Phoenix atherectomy system for peripheral artery disease (PAD)

Post-approval, single arm observational registry

- Up to 600 subjects; all comers (Rutherford 2-6)
- 18 sites (US)
- On-label use with 1.8mm (5F), 2.2mm (6F), 2.4mm (7F) devices
- Follow-up: 30 Days; and 12 months (for CLI patients only)
- Primary Endpoints:
  - Safety – Device related complication
  - Efficacy – Procedural success
- Secondary Endpoints: TLR, TVR, Target Limb Amp, Wifi

1. Phoenix registry interim data presented by Dr Stilp at VIVA 2017

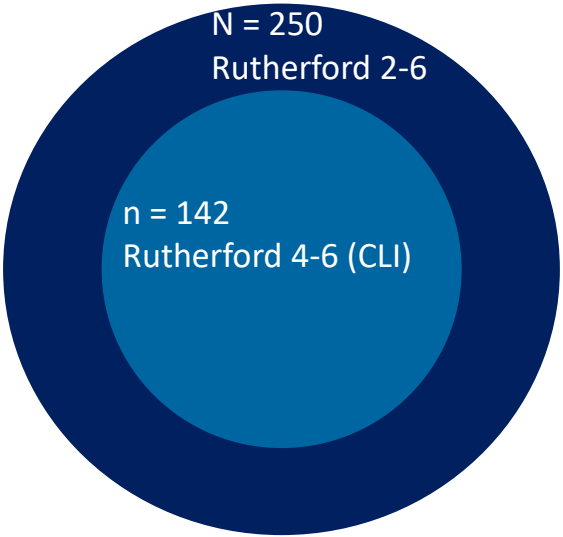
Phoenix Registry – Site location



18 sites across the US

Phoenix Registry interim results for 250 patients - All-comers[1]

	Number of patients	Rutherford category	Follow-up time
All comers	250	2 - 6	30 Days
CLI	142 (56.8%)	4 - 6	12 months



1. Phoenix registry interim data presented by Dr Stilp at VIVA 2017

Patient Baseline Demographics (N=250)[1]

Age	
Mean (SD)	70.6 (10.8)
Min, Max	34.4, 94.7
Gender	
Female	40.2% (103)
PAD Related History	
CAD Symptoms	30.4% (76)
CVA	12.4% (31)
HTN	94.8% (237)
COPD	19.2% (48)
Smoking	**69.6% (174)**
Diabetes	**59.6% (149)**

1. Phoenix registry interim data presented by Dr Stilp at VIVA 2017

Target Lesion Assessments[1]

Characteristics	Rutherford 2-3	CLI (4-6)	All-comers
Number of Patients	106	142	248*
Number of Lesions	142	190	332
Mean Length (mm)	86.2	114.2	102.2
Min Length (mm)	1	2	1
Max Length (mm)	600	460	600
Baseline Stenosis (%)	88.6%	90.4%	89.6%
Stenosis Min (%)	5	50	5
Stenosis Max (%)	100	100	100
Anatomical Location			
ATK	45.7%	25.8%	34.2%
BTK	54.3%	74.2%	65.8%
CTO	n/a	n/a	41.7%

- 248 out of 250 patients had valuable data for target lesion assessments

1. Phoenix registry interim data presented by Dr Stilp at VIVA 2017

Primary and secondary endpoints (All-comers)[1]

Primary End Points	
Effectiveness: Procedural Success (<=30% stenosis at the end of procedure)	99.0%
Safety: Adverse Events related to the device Perforation N=2 Dissection N=0 Distal Embolic Event N=0	1.2% (n=2)

Secondary End Points 30 Days (n=222)	
TLR	0.5%
Unplanned Amputations	0.9% (n=2)

30 Days Amputation Details

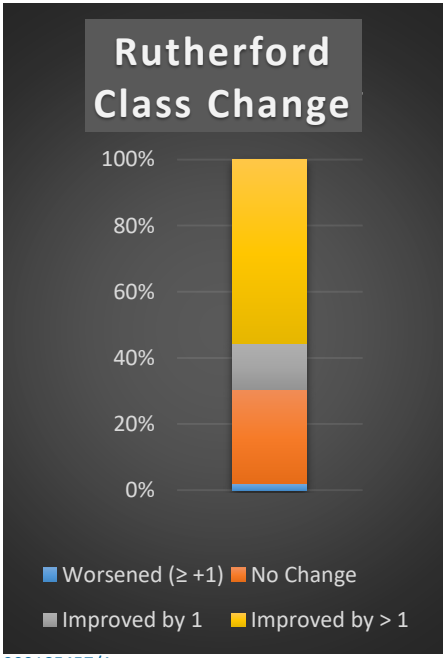
Amputation Type	Baseline Rutherford class	Tissue loss@ baseline
Metatarsal	5	minor
Metatarsal	5	minor

1. Phoenix registry interim data presented by Dr Stilp at VIVA 2017

Rutherford Category Changes at 30 Days[1]

98.1% had improvement or no change in RCC

Rutherford Class change from baseline	30 Days (n=222)
Worsened (≥ +1)	1.9%
No Change	28.5%
Improved by 1	14.0%
Improved by > 1	55.6%



1. Phoenix registry interim data presented by Dr Stilp at VIVA 2017

Wifi Classification Improvements at 30 Days[1]

Risk	Baseline	@ 30 days
High	4.6%	0.5%
Moderate	8.9%	3.0%
Low or Very low	86.5	96.5%

a, Estimate risk of amputation at 1 year for each combination

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	L	M	VL	L	M	H	L	L	M	H	L	M	M	H
W-1	VL	VL	L	M	VL	L	M	H	L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H	M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

b, Estimate likelihood of benefit of/requirement for revascularization (assuming infection can be controlled first)

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	VL	VL	VL	L	L	M	L	L	M	M	M	H	H	H
W-1	VL	VL	VL	VL	L	M	M	M	M	H	H	H	H	H	H	H
W-2	VL	VL	VL	VL	M	M	H	H	H	H	H	H	H	H	H	H
W-3	VL	VL	VL	VL	M	M	M	H	H	H	H	H	H	H	H	H
	f-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

fI, foot Infection; I, Ischemia; W, Wound.

1. Phoenix registry interim data presented by Dr Stilp at VIVA 2017

Primary and secondary endpoints: CLI Subgroup[1]

Primary Endpoint (n=142)	
Procedural Success (≤30% stenosis at the end of procedure)	99.2%

Secondary Endpoint		
	30 Days (n=125)	12 Months (n=30)
TLR	0.8%	6.7%
Unplanned Target Limb Amputation	7.6%	12.5% (n = 4)*

***12 Months Amputation Details**

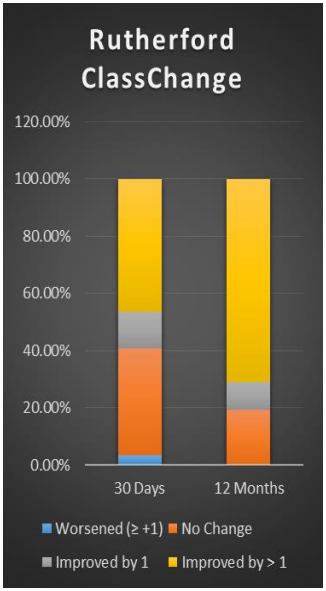
Amputation Type	Baseline Rutherford class	Tissue loss @ baseline
Metatarsal	6	Minor
AKA	6	Major
BKA	5	Minor
BKA	6	Extensive

1. Phoenix registry interim data presented by Dr Stilp at VIVA 2017

Rutherford Category Changes - CLI Subgroup[1]

RCC for CLI subgroup at baseline (n = 142)	
RCC	**Percentage (%)**
4	29.6
5	47.9
6	22.5

Rutherford Class Change from Baseline	30 Days (n=125)	12 months (n=31)
Worsened (≥ +1)	3.4%	0%
No Change	37.3%	19.4%
Improved by 1	12.7%	9.7%
Improved by > 1	46.6%	71%



100% had improvement or no change in RCC at 12 months

1. Phoenix registry interim data presented by Dr Stilp at VIVA 2017

Summary

- Phoenix hybrid[1] atherectomy system performance at this interim analysis of registry data is consistent with findings from the EASE study
- Interim results reveal similar safety and efficacy profile in the CLI population
- Acute Rutherford score improvements in CLI patients are consistent with general study population and continue in the long-term
- Interim data show durable improvements in CLI patients
- Phoenix hybrid[1] atherectomy system continues to be a viable vessel preparation solution in the treatment paradigm for all spectrums of PAD (Rutherford 2-6) which lead to clinical improvements

[1]Directional cutting ability only available with Phoenix 2.4mm deflecting catheter