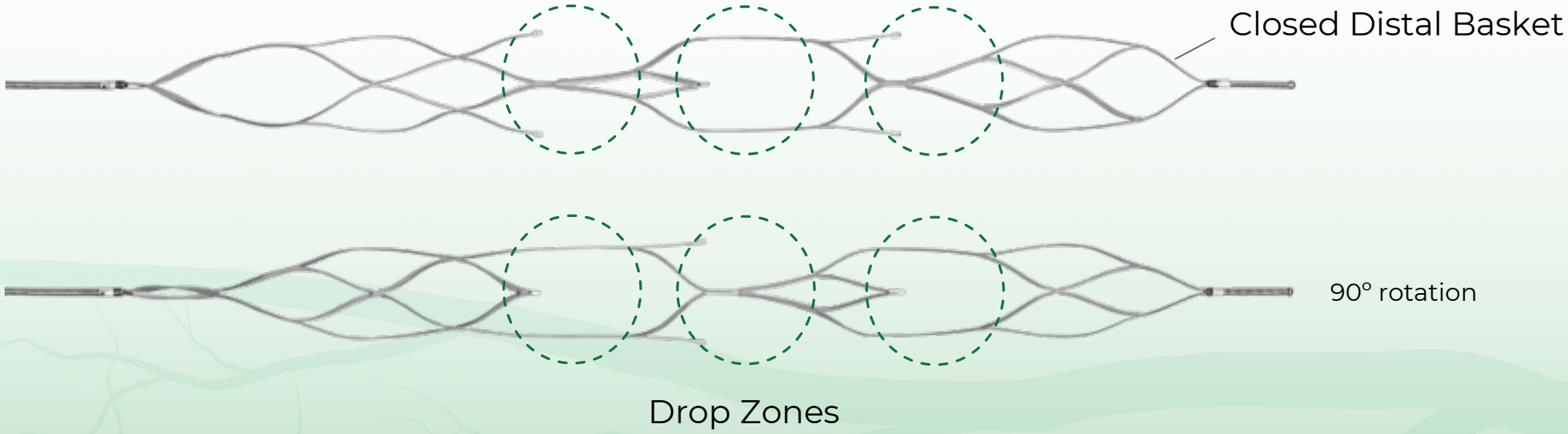
PVASC TRAINING: PAD

#DoTheDropZone with ALL CLOT TYPES

PVASC THROMBECTOMY SYSTEM

pVasc's unique Drop Zone™ technology **captures** and **extracts** thrombo-emboli



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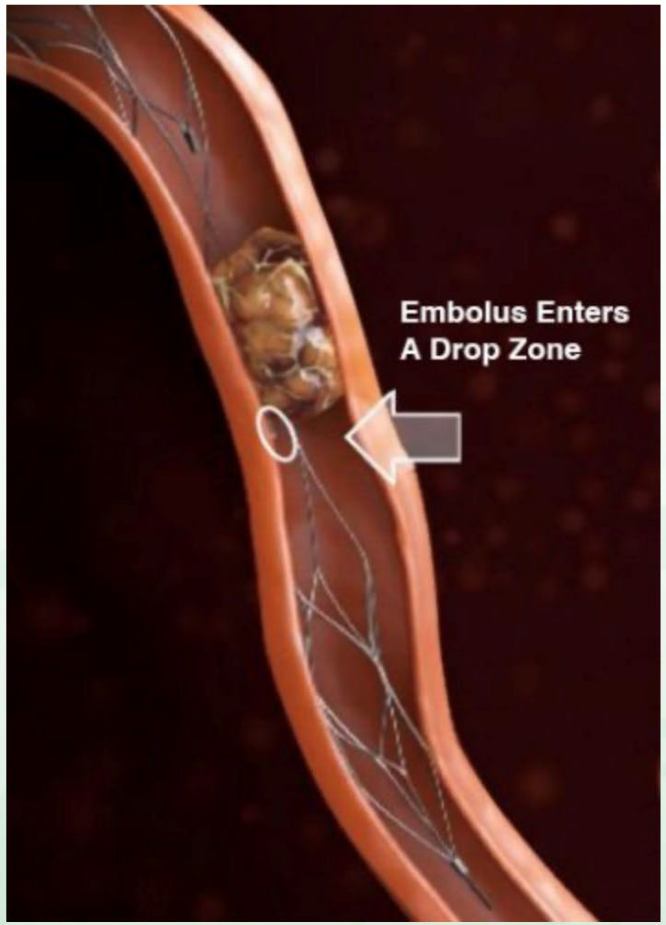
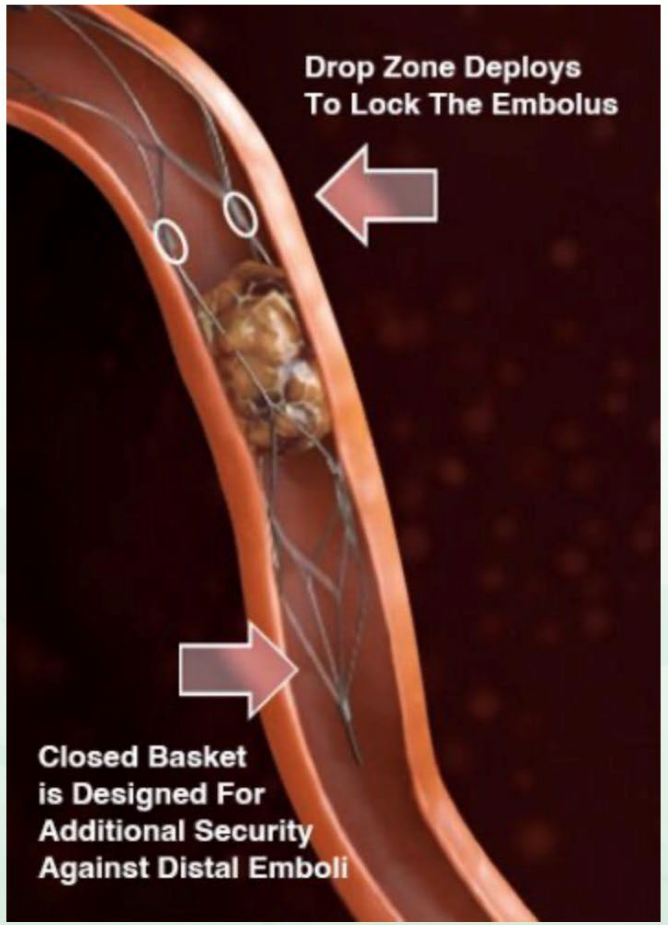


TRAP

Drop Zone traps embolus to capture it inside the device lumen.



LOCK AND REMOVE

Embolus is locked for secure removal.

PVASC THROMBECTOMY SYSTEM

- pVasc device is designed to capture the full range of occlusions from soft, acute clot to organized, chronic emboli in the proximal to distal peripheral arteries

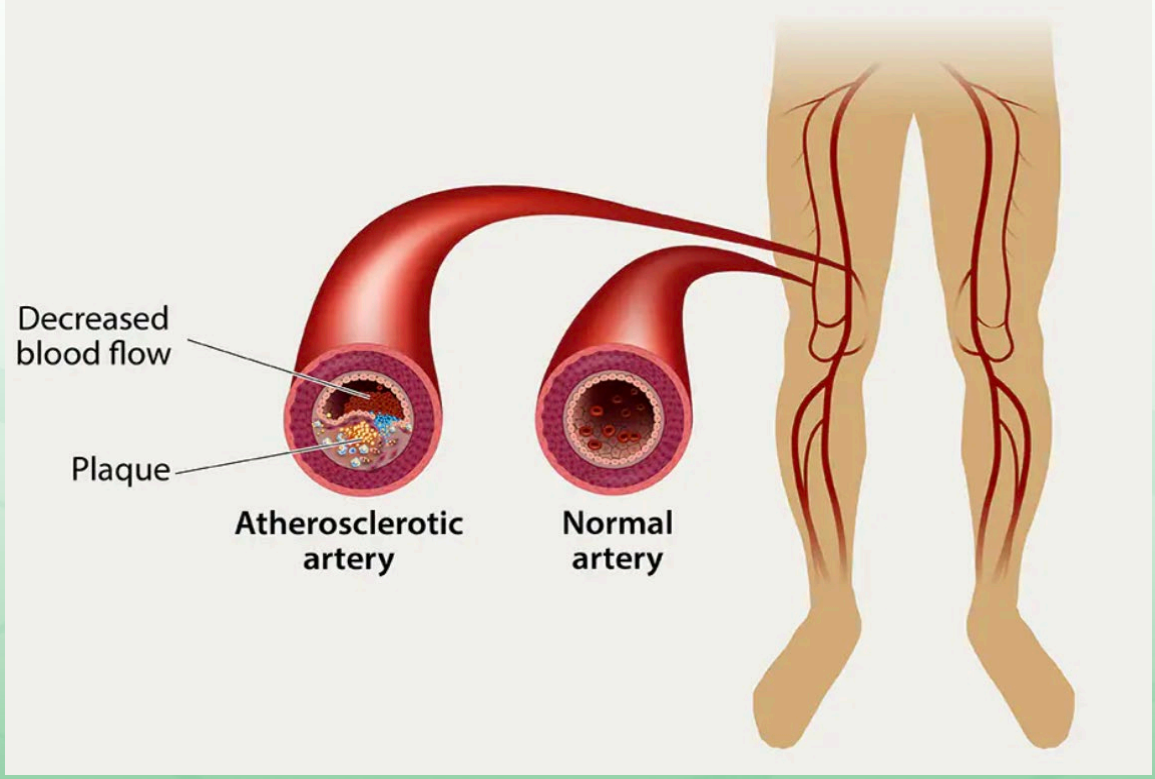
PVASC THROMBECTOMY SYSTEM

- Designed for proximal to distal arteries 6 to 2 mm in diameter
- Simple
  - Streamlined handling
  - Optimized navigability
  - Easy to set up - no capital equipment required
- Versatile
  - Use alone before/with adjunctive therapies as needed
  - Working time not limited by concern of blood loss

PAD AND THE ROLE FOR PVASC

PERIPHERAL ARTERIAL DISEASE (PAD)

- Narrowing or blockage of the arteries, resulting in reduced blood flow to the limbs
- Caused by atherosclerosis, the buildup of fatty plaque
- Affects > 12 million Americans and 200 million individuals worldwide[1]
- Risk Factors
  - Age
  - Diabetes
  - Smoking
  - High cholesterol
  - High blood pressure
  - Chronic kidney disease
  - Family history

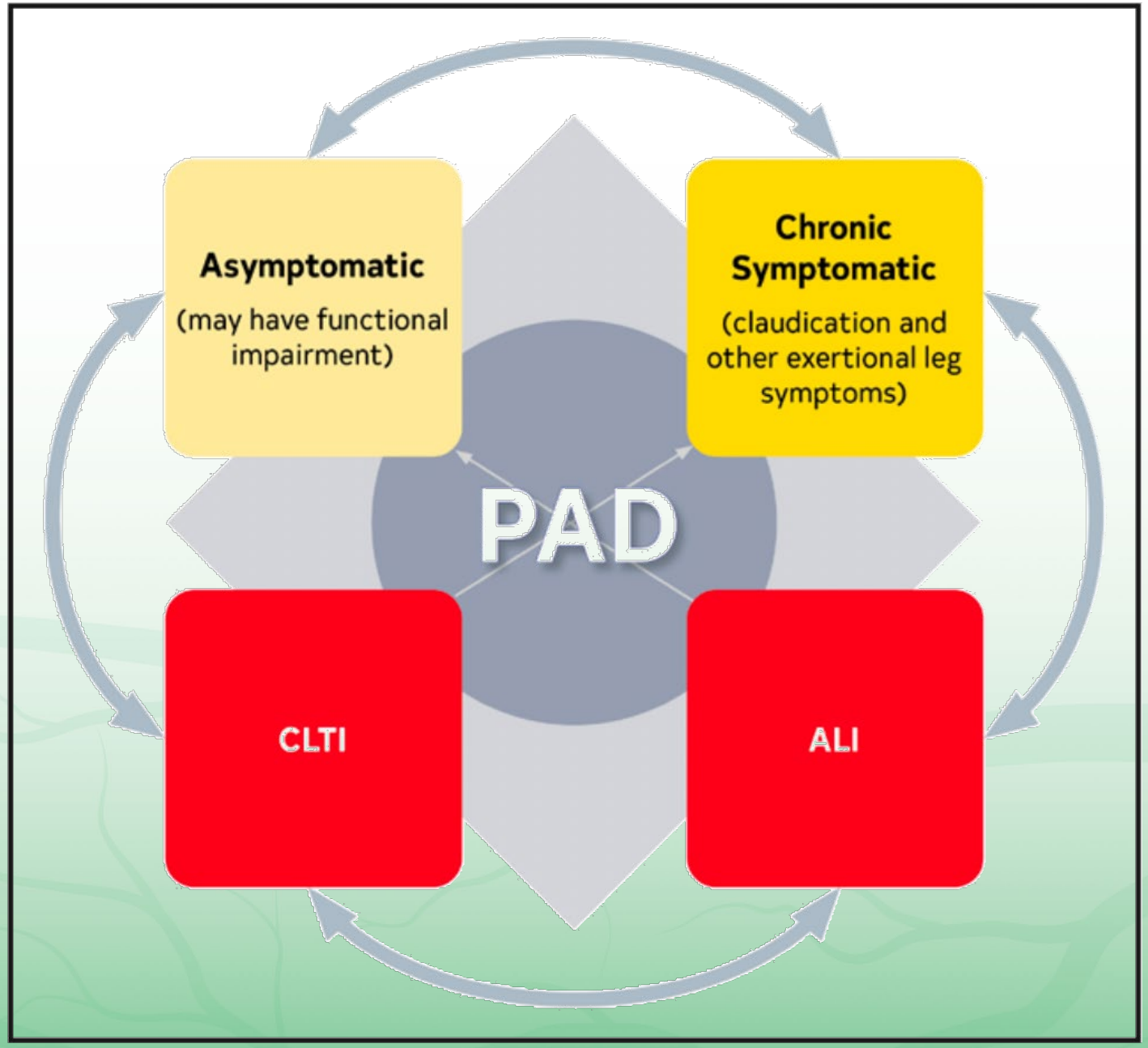


1 Allison MA, Armstrong DG, and Goodney PP, et al.. Health Disparities in Peripheral Artery Disease: A Scientific Statement from the American Heart Association. https://doi.org/10.1161/CIR.0000000000001153

PERIPHERAL ARTERIAL DISEASE (PAD)

- Increased risk of amputation, heart attack, stroke, and death[1]
- Approximately 185,000 amputations are performed annually in the US with more than 2 million people living with an amputation[2]
- Nearly half of people 65 and older who had a limb amputated because of PAD died within a year of surgery according to AHA statistics[3]
- Most common type is lower-extremity PAD (i.e. legs and feet)[4]
- Upper-extremity PAD (i.e. arms, hands, and fingers) affects about 10% of patients[4]

1 AHA. New roadmap to lower the risk of amputation in peripheral artery disease. 5/14/2024 https://www.heart.org/en/news/2024/05/14/new-roadmap-to-lower-the-risk-of-amputation-in-peripheral-artery-disease
2 AHA. Microvascular Disease Increases Amputation in Patients with Peripheral Artery Disease. 2/20/2020. https://www.ahajournals.org/doi/10.1161/ATVBAHA.119.312859
3 AHA. New roadmap to lower the risk of amputation in peripheral artery disease. 5/14/2024 https://www.heart.org/en/news/2024/05/14/new-roadmap-to-lower-the-risk-of-amputation-in-peripheral-artery-disease
4 https://www.heart.org/en/health-topics/peripheral-artery-disease/about-peripheral-artery-disease-pad
CDC https://www.cdc.gov/heart-disease/about/peripheral-arterial-disease.html



STAGES OF PAD

DISEASE PROGRESSION

	Asymptomatic
Prevalence	20-59% of PAD patients
Symptoms	None but may have functional impairment
Treatment	Lifestyle/diet changes; medication

STAGES OF PAD

DISEASE PROGRESSION

	Asymptomatic	**Chronic Symptomatic** (Intermittent Claudication)
Prevalence	20-59% of PAD patients	Up to 80% of PAD patients
Symptoms	None but may have functional impairment	Fatigue, discomfort, pain brought on by walking and relieved by rest
Treatment	Lifestyle/diet changes; medication	Exercise, lifestyle changes, medication, and revascularization if prior options do not improve symptoms (ACC 2024 Guidelines)

STAGES OF PAD

DISEASE PROGRESSION

	Asymptomatic	**Chronic Symptomatic** (Intermittent Claudication)	**Critical Limb Ischemia (CLI)**
Prevalence	20-59% of PAD patients	Up to 80% of PAD patients	Between 11-20% of PAD patients
Symptoms	None but may have functional impairment	Fatigue, discomfort, pain brought on by walking and relieved by rest	• Symptoms >/= 14 days • Chronic pain at rest, nocturnal recumbent pain, or ischemic skin lesions that may include ulcers or gangrene
Treatment	Lifestyle/diet changes; medication	Exercise, lifestyle changes, medication, and revascularization if prior options do not improve symptoms (ACC 2024 Guidelines)	Revascularization to prevent permanent damage, i.e. amputation, through surgery (endarterectomy, bypass) or endovascular therapies (balloon angioplasty, stenting, atherectomy, lithotripsy)

STAGES OF PAD

DISEASE PROGRESSION

May not result from CLI but often is

	Asymptomatic	Chronic Symptomatic (Intermittent Claudication)	Critical Limb Ischemia (CLI)	Acute Limb Ischemia (ALI)
Prevalence	20-59% of PAD patients	Up to 80% of PAD patients	Between 11-20% of PAD patients	• 1.7% among patients with symptomatic PAD
Symptoms	None but may have functional impairment	Fatigue, discomfort, pain brought on by walking and relieved by rest	• Symptoms >/= 14 days • Chronic pain at rest, nocturnal recumbent pain, or ischemic skin lesions that may include ulcers or gangrene	• Symptoms < 14 days • Sudden decrease in limb perfusion causing an immediate threat to limb viability • Pale skin, slow pulse, cold skin, numbness/tingling in limbs, limb paralysis
Treatment	Lifestyle/diet changes; medication	Exercise, lifestyle changes, medication, and revascularization if prior options do not improve symptoms (ACC 2024 Guidelines)	Revascularization to prevent permanent damage, i.e. amputation, through surgery (endarterectomy, bypass) or endovascular therapies (balloon angioplasty, stenting, atherectomy, lithotripsy)	Emergency procedure to prevent permanent damage, i.e. amputation

ALI is key target and CLI in certain

ALI TREATMENT MOVING FROM SURGERY TO ENDOVASCULAR THERAPY…

- Revascularization (endovascular or surgical, including CDT) is indicated to prevent amputation in patients with a salvageable limb, Class 1 Level A (ACC/AHA 2024 Guidelines)
- Surgical embolectomy performed via arterial cut down and a Fogarty balloon was the historical primary treatment
- Endovascular approaches emerged with CDT (intra-arterial catheter directed thrombolysis) 20 years ago showing similar limb salvage rates with surgery
- Contemporary CDT experience reports[1]:
  - 80 – 90% technical success rate
  - 84% amputation free survival at 30 days and 75% at 1 year
  - BUT hemorrhage at 8-10%

1. ESVS 2020 Clinical Practice Guidelines on the Management of Acute Limb Ischaemia

…EVOLVING TO MODERN THROMBECTOMY IN ALI

- CDT has lengthy time to flow restoration (>24 hrs) and thrombectomy may be required
  - Rutherford 2a (limb marginally threatened): CDT is recommended as an alternative to surgery, Class 1, Level A (ESVS 2020 Guidelines)
  - Rutherford 2b (limb immediately threatened): CDT may be considered if initiated promptly and may be combined with percutaneous aspiration or thrombectomy, Class 2b, Level B (ESVS 2020 Guidelines)
- Growing trend away from CDT to thrombectomy in both Rutherford 2a and 2b
  - PEN Stride Study: 54.6% presented with Rutherford 2a and 34.5% Rutherford 2b

1. ESVS 2020 Clinical Practice Guidelines on the Management of Acute Limb Ischaemia

ALI PATIENTS HAVE COMPLICATED HEALTH HISTORIES

Cardiovascular history and risk factors	
Angina	8.4 (10/119)
Atrial fibrillation	21.0 (25/119)
Coronary artery disease	32.8 (39/119)
Heart failure	12.6 (15/119)
Hypertension	86.6 (103/119)
Hyperlipidemia	84.0 (100/119)
Other history	
Cancer	21.0 (25/119)
Renal failure/ insufficiency	10.1 (12/119)
Diabetes mellitus	37.8 (45/119)
Tobacco use within last 10 years	53.8 (64/119)

PEN STRIDE Study JVS 10/2023

MANY HAD PRIOR PROCEDURES

Vascular history	
Chronic limb ischemia	47.1 (56/119)
Prior revascularization of affected limb	53.8 (64/119)
Endovascular[b] (includes balloon and stent)	42.9 (51/119)
Surgical[b] (includes endarterectomy, bypass graft, and graft revisions)	47.9 (57/119)
Bypass graft	22.7 (27/119)
Autogenous graft	3.4 (4/119)
Prosthetic graft	19.3 (23/119)
Amputation of the contralateral limb	4.2 (5/119)
Amputation of the ipsilateral limb, below tarsometatarsal joint	5.9 (7/119)

→ Organized chronic occlusions

→ Challenging access? Potential re-occlusions?

→ Challenging access? Potential re-occlusions?

PEN STRIDE Study JVS 10/2023