

The logo for LINC (Limb Inlet Neurovascular Catheter) features the letters 'LINC' in a white, sans-serif font. The letters are positioned over a stylized graphic of a hand or limb, rendered in dark blue with a red and yellow accent, suggesting a medical or prosthetic theme.

LINC

# Early Clinical Results of the FLEX Catheter<sup>®</sup> in the Treatment of Below the Knee Lesions

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# Disclosure

Speaker name: Jihad A. Mustapha

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I have the following potential conflicts of interest to report:

Consulting: Abbott Vascular, Bard Peripheral Vascular, Boston Scientific, Cagent Vascular, Cardiovascular Systems, Inc., Cook Medical, Medtronic, PQ Bypass, Spectranetics, Terumo Medical

# Background

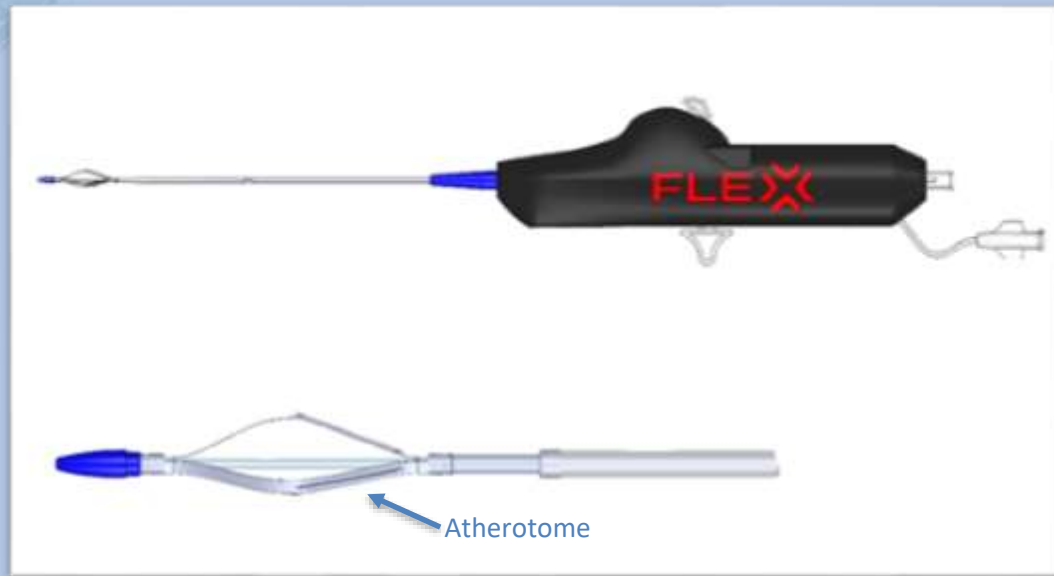
## Critical Limb Ischemia

- Tissue Loss / Nonhealing Wounds
- Increased Risk of Limb Loss
- Poor Quality of Life
- Amputation Rates
  - 30% at 1 year
- High Mortality Rates
  - 25% at 1 year.
  - 60% at 5 years.



# FLEX Catheter®

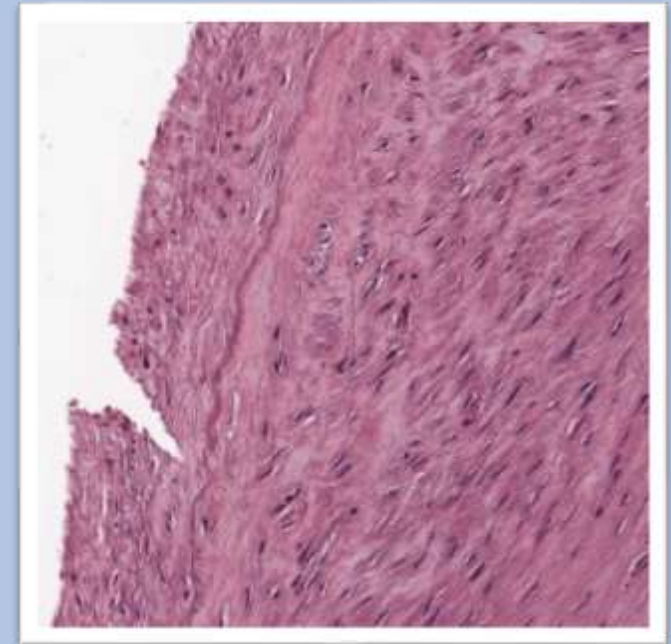
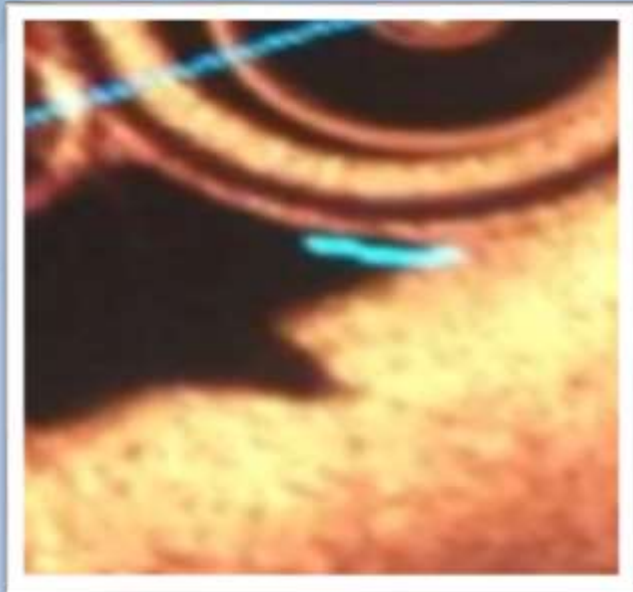
<b>Sheath Size</b>	6 French
<b>Wire Compatibility</b>	.014 and .018
<b>Catheter Length</b>	40cm and 120cm
<b>3 Atherotomes (Proximal)</b>	0.01" in Height
<b>Current FDA / CE Mark Indication</b>	Femoropopliteal and AVF/AVG



One Size Fits All  
Single Insertion Pull-Back Technique

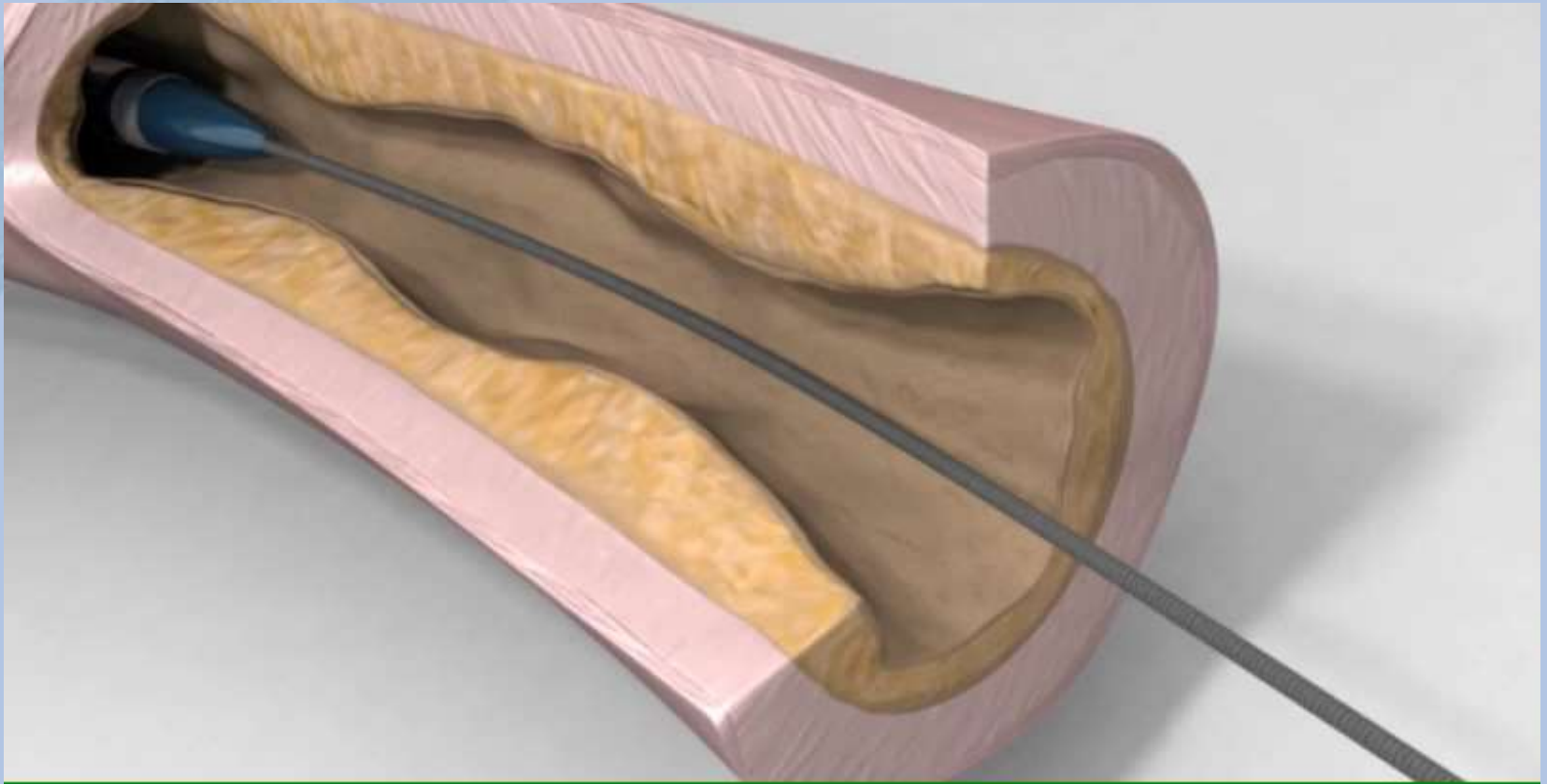
# Mechanism of Action


## Dynamic Scoring<sup>®</sup> Technology



- Precise Longitudinal Micro-Incisions
- Atherotomes Interact with Vessel Surface at 1 atm
- Facilitates an Increase in Vessel Compliance
- Creates a Controlled Environment for Angioplasty
- Basket “Flexes” to Plaque Contour.

# Vessel Prep





# Early Clinical Results of the FLEX Catheter in the Treatment of Below the Knee Lesions

# Clinical Data

- Multi-Center Acute Data
- 7 Operators in 7 Hospital Systems
- August 2016 to September 2017
- Voluntarily Provided Case Reports
- Procedure:
  - FLEX → Angioplasty
- 27 BTK Patients
  - Off Label Use

Lesion Location	
Popliteal	19%
AT	33%
PT	26%
Peroneal	22%
Lesion Characteristics	
Average Lesion Length (mm)	137.4
Lesion Length Range (mm)	40 – 300
Moderate/Severe Calcium	48%



# Procedural Data

	Mean (Range)
Pre-Existing Stenosis	92%
Chronic Total Occlusion Cases	52%
Post FLEX Stenosis	65%
Post FLEX Luminal Gain	27%
Opening Balloon Pressure (atm)	3 (2 – 5)
Maximal Balloon Pressure (atm)	7.8 (3 – 14)
Post Procedure Residual Stenosis	5.8%
Post Procedure Luminal Gain	86.2% (65 – 100)

# Results

Technical Success	100%
FLEX Treated BTK Lesion Prior to Angioplasty	100%
Vessel Perforation Occurrences	0
Distal Emboli	0
Vessel Dissection	0
Flow-Limiting Dissection	0
Provisional Stent Use	1 Case (3.7%)
Average Luminal Gain Post Procedure	86.2%



# Case Studies

# Case Study 1: VMG44

## Procedural Details

Rest pain and a shallow foot ulceration.

Treatment Location                      Popliteal to TPT

Vessel Diameter (mm)                      4.5

Lesion Length (mm)                      70

Calcification                      Severe

Vessel Prep Device                      FLEX Catheter®

DCB Treatment                      4 x 120 (2 Minute Inflation)



Pre- Angiogram

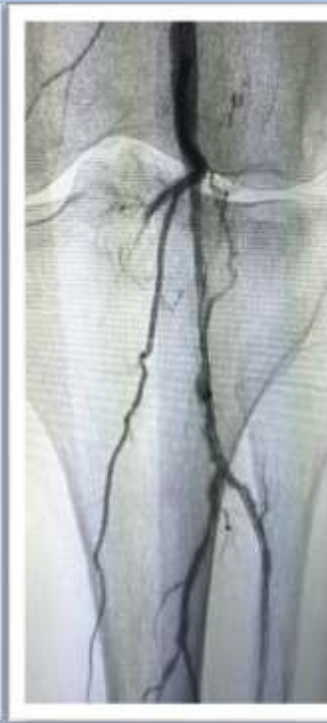
# Case Study 1: VMG44

## Procedural Results

Pre Stenosis	100%
Post FLEX Stenosis	40%
Luminal Gain Post FLEX	60%
Post DCB Stenosis	10%
DCB Opening Pressure (atm)	4
DCB Maximal Pressure (atm)	6
Dissection	None



Pre-Angiogram



Post FLEX



Post DCB

# Case Study 2: VMG89

Procedural Details	
Treatment Location	Peroneal
Vessel Diameter (mm)	3
Lesion Length (mm)	220
Calcification	Mild
Vessel Prep Device	FLEX Catheter®
POBA Treatment	3 x 120 (2 Minute Inflation)



Pre-Angiogram

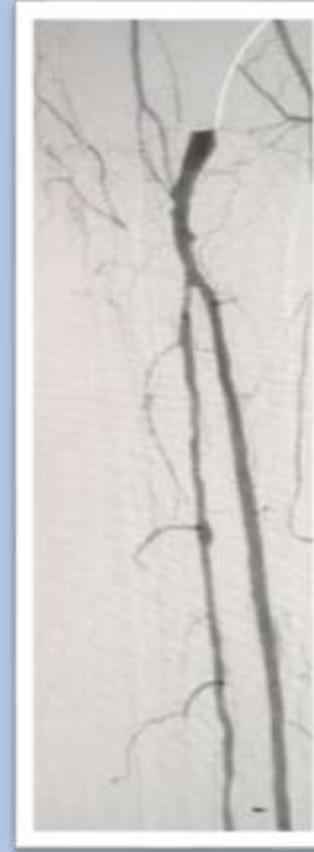
# Case Study 2: VMG89

## Procedural Results

Pre Stenosis	100%
Post FLEX Stenosis	60%
Luminal Gain Post FLEX	40%
Post DCB Stenosis	0
DCB Opening Pressure (atm)	3
DCB Maximal Pressure (atm)	9
Dissection	None



Pre-Angiogram



Post FLEX



Post POBA

# Conclusion

- 100% Technical Success in Achieving Luminal Gain Post FLEX Without Dissection Noted.
- Low Opening Balloon Pressures Suggest Significant Improvement in Vessel Wall Compliance with FLEX.
- The FLEX Catheter Provides a Useful Option for Treatment of BTK Lesions.
- Development of a Dedicated BTK-FLEX (5F sheath, 0.14 guidewire compatible, 150 cm catheter length) in Progress.



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