

FLEX Scoring Catheter Vessel Preparation Device

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Disclosure

Speaker name: Frank Arko, MD.

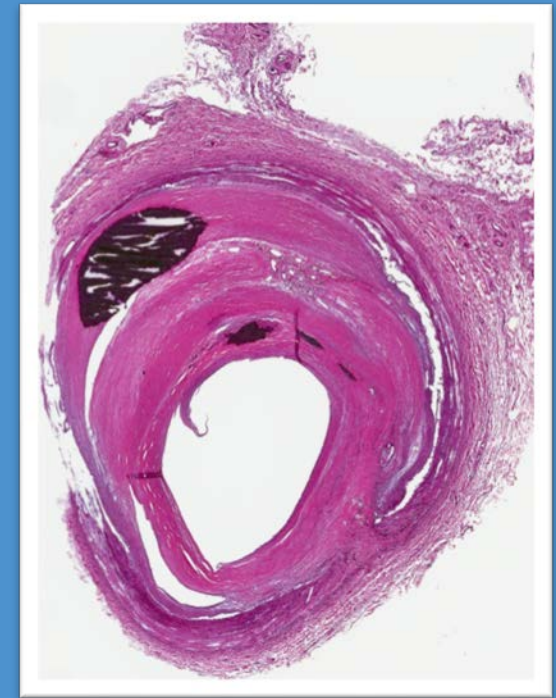
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- I have the following potential conflicts of interest to report:
 - Receipt of grants/research support: Medtronic, Gore, Penumbra
 - Consultant: Phillips, Gore, Medtronic, Penumbra.

Purpose of Vessel Preparation

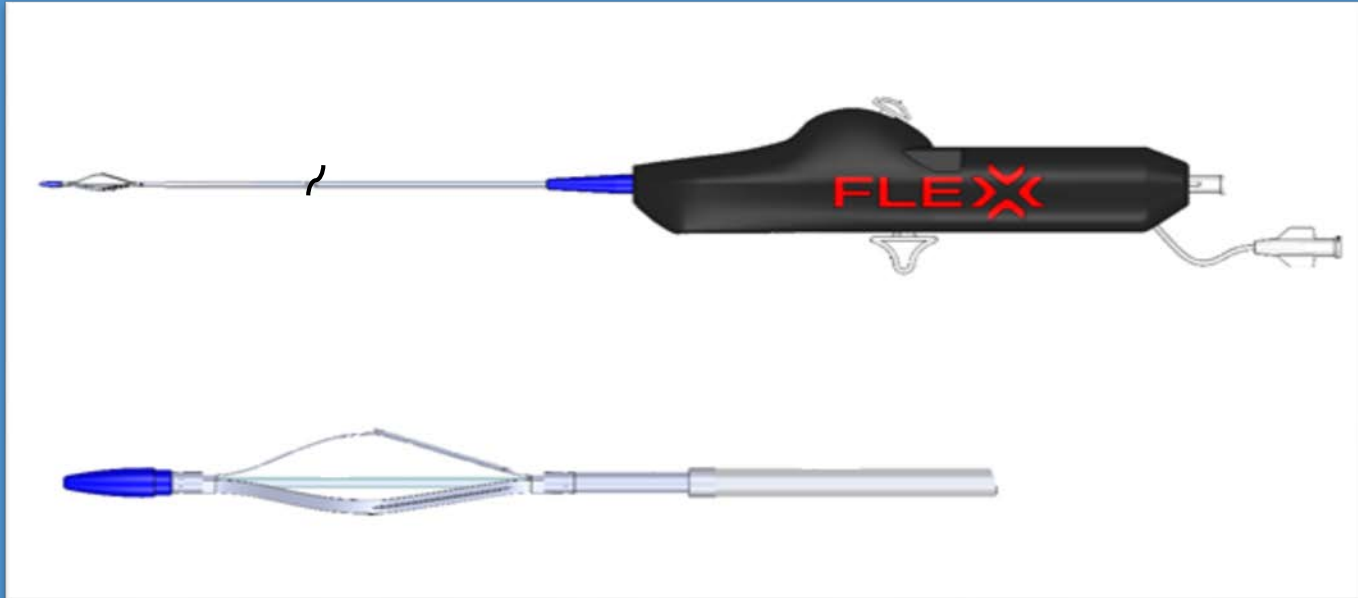
Creates a optimal environment for angioplasty:

- Improves Vessel Compliance - Lower Balloon Pressures for Lesion Effacement
- Increases Luminal Gain
- Facilitates Drug Distribution
- Minimize Adverse Events - Dissections, Embolization, Perforations
- Decreases the Need for Stenting



Calcified Atherosclerotic
Cadaver SFA Lesion

FLEX Scoring Catheter®



Sheath Size

6 French

Wire Compatibility

.014 and .018

Catheter Length

40cm and 120cm

3 Atherotomes (Proximal)

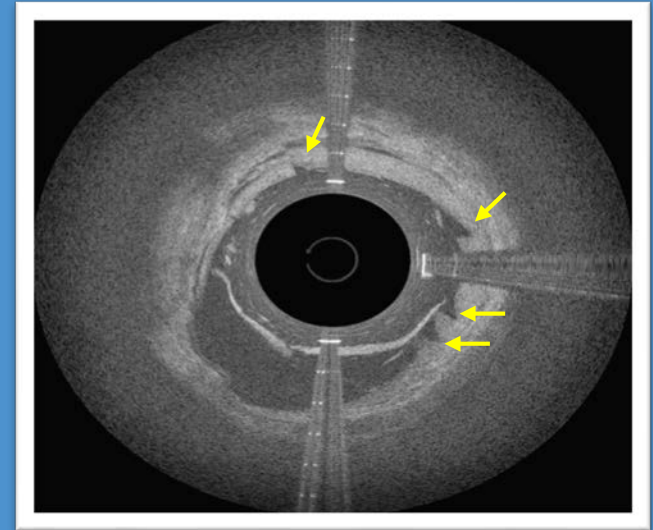
0.01" in Height

FDA / CE Mark Indication

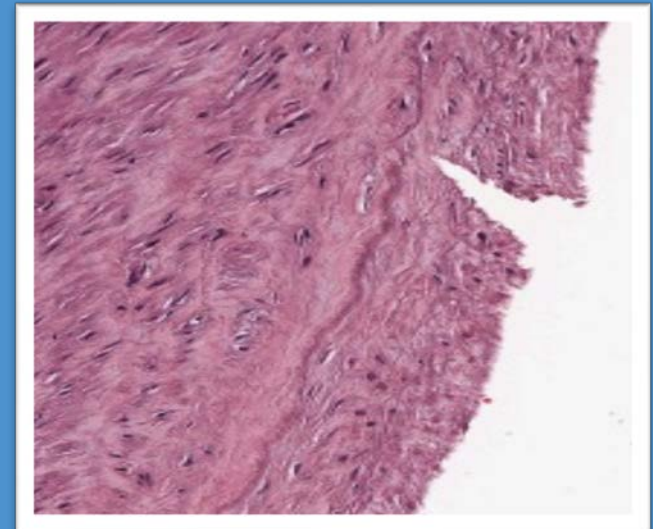
Facilitate Dilatation of Stenoses of
Femoropopliteal and AVF/AVG

FLEX Scoring Catheter

- 3 Proximal Atherotomes Mounted on Skids
 - Creates Longitudinal Channels
- Controlled Depth Micro-Incision
- Retrograde Pull-Back
- Rotation Control
- Dynamic Scoring® Technology
- A One Size Fits All Device.



OCT Image of Micro-Incision



Histology of Micro-Incision
(Cadaveric Human SFA)

Dynamic Scoring[®] Technology

- Precise Longitudinal Micro-Incisions
- Skid Surface Area Prevents Perforation
 - Atherotomes Interact with Vessel Surface at 1 atm
- Creates a Controlled Environment for Angioplasty
- Basket “Flexes” to Plaque Contour.



Case Study 1

Procedural Details

Treatment Location	SFA
Vessel Diameter (mm)	4
Lesion Length (mm)	80
Calcification	Mild
Vessel Prep Device	FLEX Catheter®
DCB Treatment	4 x 100 (3 Minute Inflation)



Pre- Angiogram

Case Study 1

Procedural Results

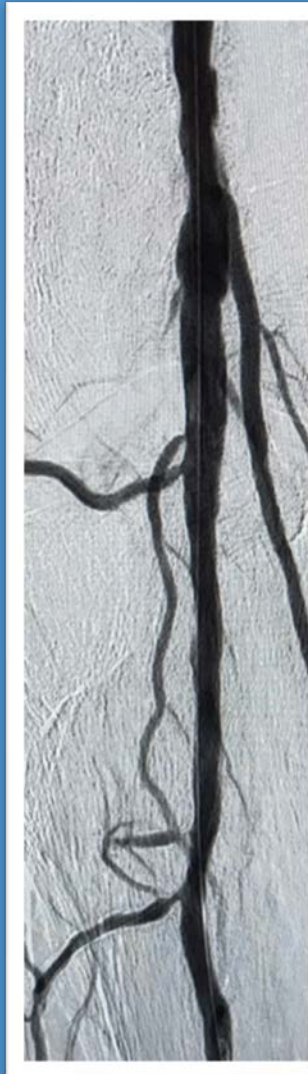
Pre Stenosis	100%
Post FLEX Stenosis	60%
Luminal Gain Post FLEX	40%
DCB Opening Pressure (atm)	6
DCB Maximal Pressure (atm)	12
Post DCB Stenosis	10%



Pre-Angiogram



Post FLEX

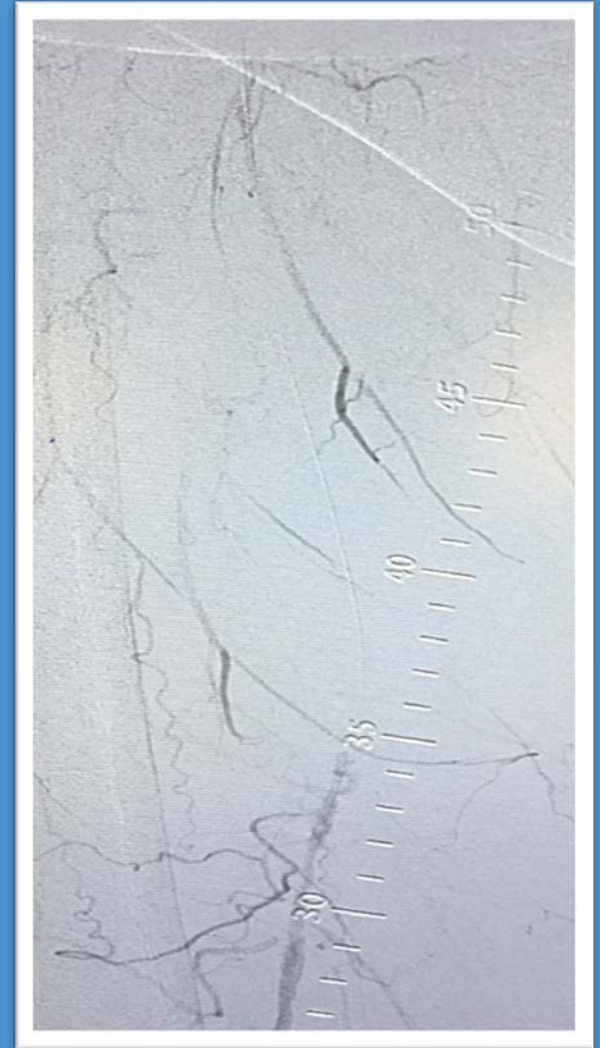


Post DCB

Case Study 2

Procedural Details

Treatment Location	SFA
Vessel Diameter (mm)	6
Lesion Length (mm)	160
Calcification	Mild
Vessel Prep Device	FLEX Catheter®
POBA Treatment	6 x 150 (3 Minute Inflation) x2



Pre- Angiogram

Case Study 2

Procedural Results

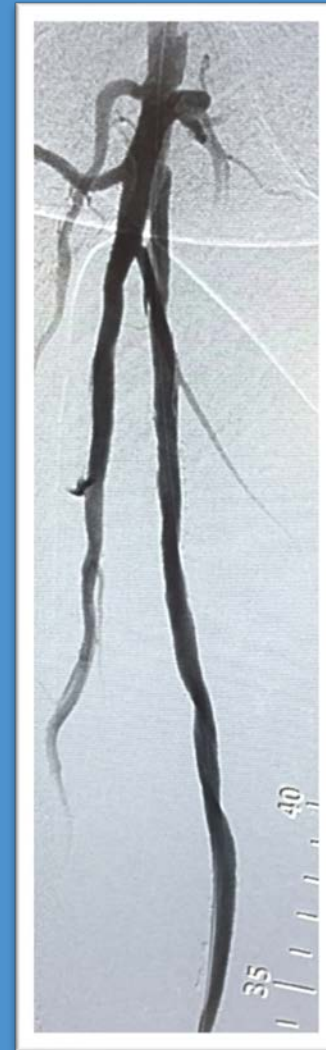
Pre Stenosis	100%
Post FLEX Stenosis	75%
Luminal Gain Post FLEX	25%
POBA Opening Pressure (atm)	6
POBA Maximal Pressure (atm)	12
Post POBA Stenosis	5%
Dissection	None



Pre-Angiogram



Post FLEX



Post POBA

Case Study 3

Procedural Details

Treatment Location	SFA
Vessel Diameter (mm)	5
Lesion Length (mm)	250
Calcification	Severe
Vessel Prep Device	FLEX Catheter®
DCB Treatment	5 x 150 (3 Minute Inflation) 5 x 120 (3 Minute Inflation)

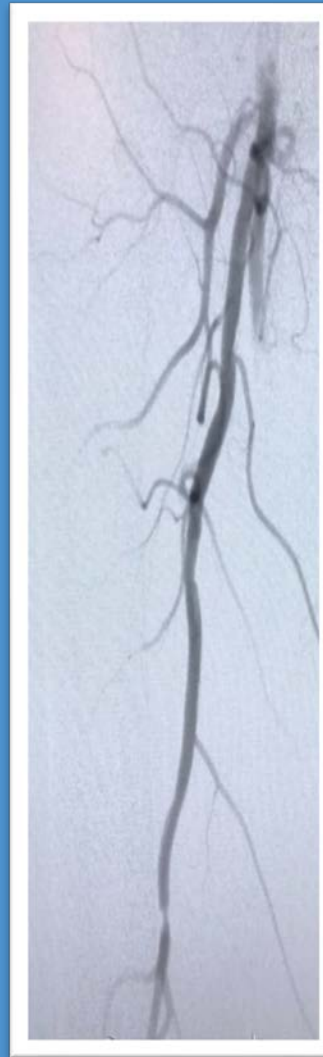


Pre- Angiogram

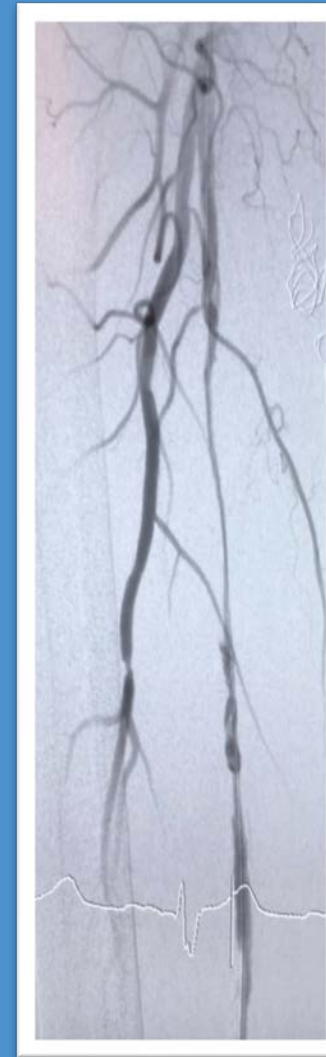
Case Study 3

Procedural Results

Pre Stenosis	100%
Post FLEX Stenosis	70%
Luminal Gain Post FLEX	30%
DCB Opening Pressure (atm)	5
DCB Maximal Pressure (atm)	8
Post DCB Stenosis	5%
Dissection	None



Pre-Angiogram



Post FLEX



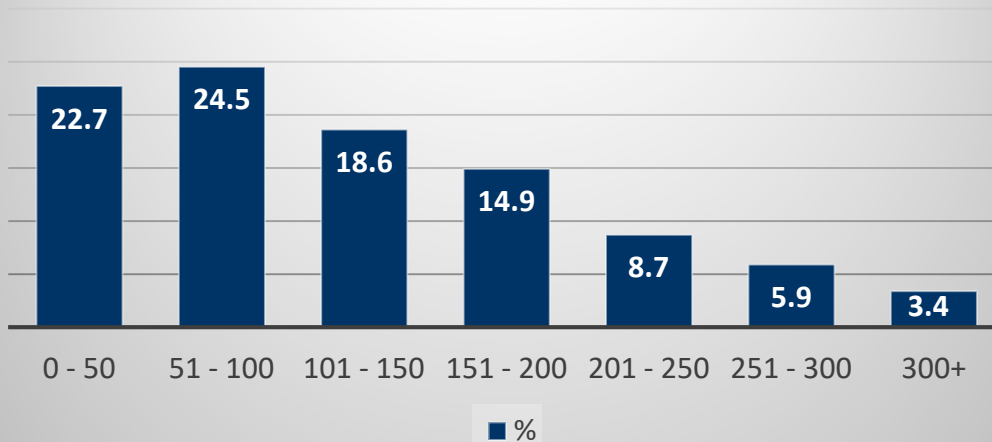
Post DCB

Post Market Clinical Data

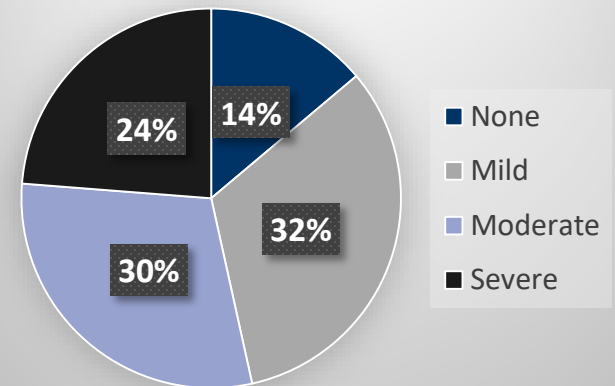
Post Market Real World Data
December 2015 – March 2018
80 Physicians
53 Institutes

Lesion Characteristics	
Number of Lesions Treated	322
Average Vessel Diameter (mm)	5.5 (1 – 15)
Average Pre-Stenosis (%)	92 (50 – 100)
Chronic Total Occlusions	44% (n= 140)
Average Lesion Length (mm)	131 (2 – 410)

Lesion Length (mm)



Calcification (%)



Procedural Data

	Average (Range)
Pre-Stenosis	92% (50 – 100)
Number of FLEX Passes	3.5 (1 – 8)
Post FLEX Luminal Gain	26% (0 – 15)
Balloon Opening Pressure (atm)	4.3 (2 – 12)
Maximal Balloon Pressure (atm)	9.0 (3 – 12)
FLEX + Angioplasty Residual Stenosis	9% (0 – 50)

Results

Technical Success	99%
Vessel Perforation	0%
Distal Embolization	0%
Minimal Vessel Dissection	5.3% (A=4.3%, B=1%)
Flow-Limiting Dissection	0%
Provisional Stent Use	19.9%
Bail-Out Stenting	0%
Average Luminal Gain Post Procedure	81.8%

Conclusion

- The FLEX Catheter® Safely and Effectively Treats Complex Femoropopliteal Lesions (Long, Calcified, CTOs)
- A High Degree of Technical Success is Achieved.
- Luminal Gain Post FLEX Attained Without Flow Limiting Dissection, Emboli, or Perforations.
- Low Opening Balloon Pressures Suggest Improvement in Vessel Wall Compliance After Vessel Preparation with the FLEX.
- A Low Dissection Rate After FLEX Use Translates to Less Stenting Required.

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