

FLEX Catheter: A Novel Device Facilitating in the Preparation of Vessels for Angioplasty.

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Disclosure

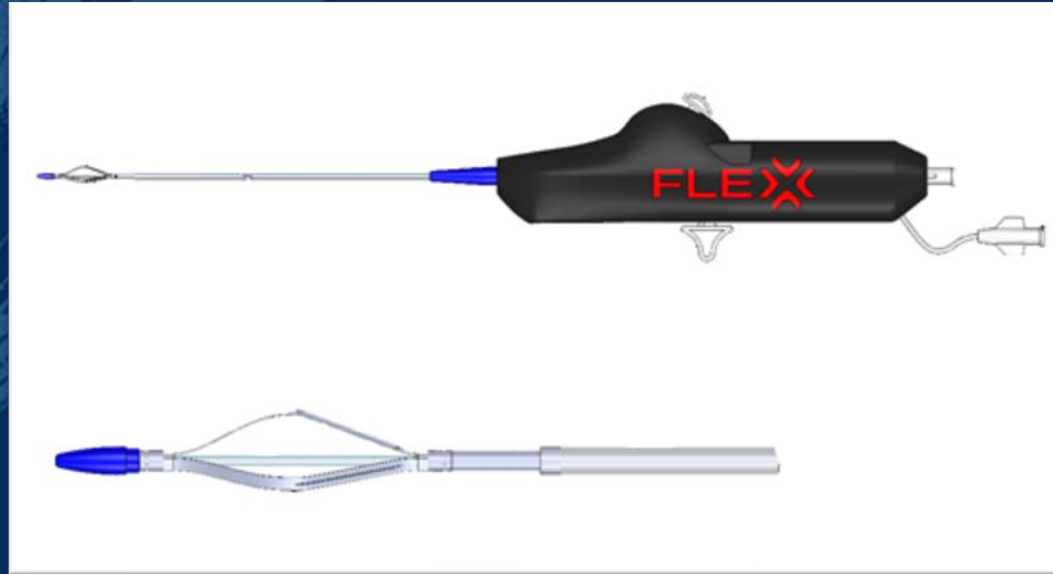
Speaker name: Louis Lopez

I do not have any potential conflict of interest

Vessel Prep with FLEX Catheter

- Increases Lumen Gain
- Improves Vessel Compliance
- Facilitates Drug Distribution
 - Atherotomes Create Longitudinal Channels
 - Increases Surface Area for Drug Uptake
- Minimizes Adverse Events
 - Dissections
 - Decreases Stenting
 - Embolization
 - Perforations

FLEX Catheter®



Sheath Size

6 French

Wire Compatibility

.014 and .018

Catheter Length

40cm and 120cm

3 Atherotomes (Proximal)

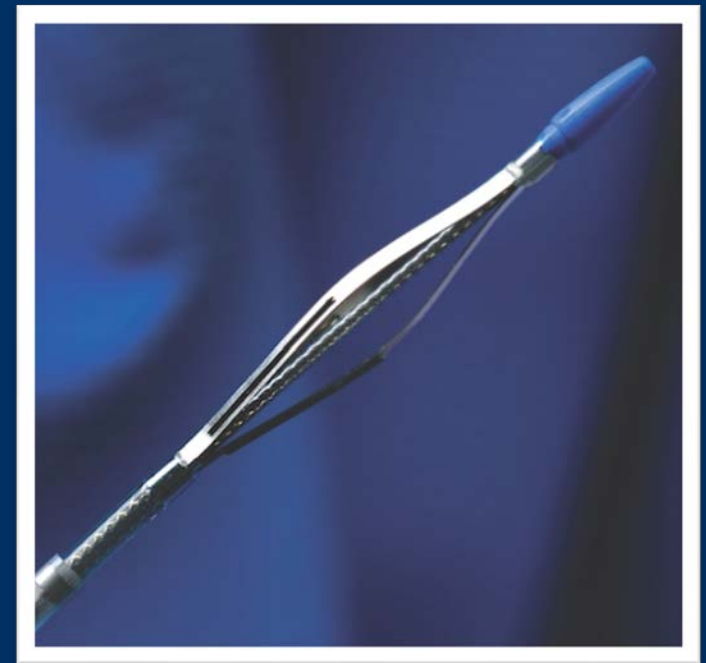
0.01" in Height

FDA / CE Mark Indication

Facilitate Dilatation of Stenoses of
Femoropopliteal and AVF/AVG

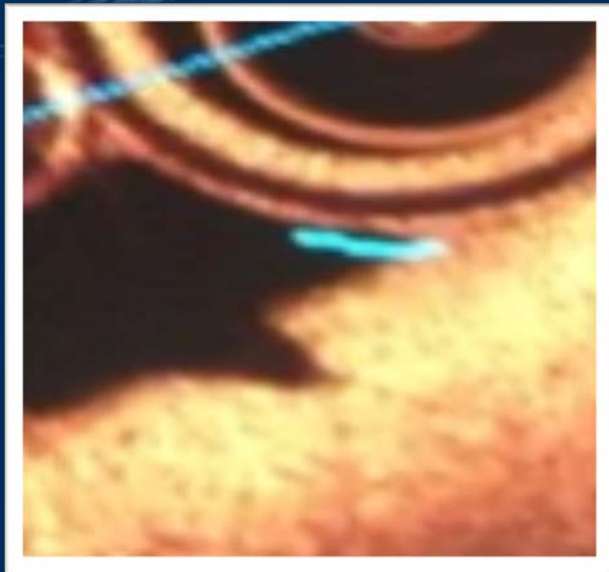
FLEX Catheter®

- 3 Skid Plates with A Proximal Atherotome
- Controlled Depth Micro-Incision
- Basket Expands by a Actuation Button
- Retrograde Pull-Back
- Rotation Control
- Dynamic Scoring® Technology
- A One Size Fits All Device.

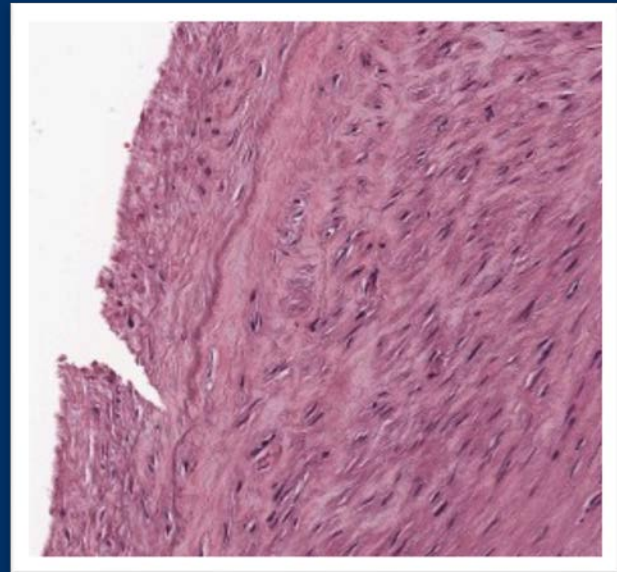


Dynamic Scoring[®] Technology

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



OCT Image of Micro-Incision



Histology of Micro-Incision
(Cadaveric Human SFA)

Clinical Data

- Multi-Center Acute Real World Data
- 51 Operators in 32 Hospital Systems
- December 2015 to October 2017
- Voluntarily Provided Case Reports
- 237 Femoropopliteal Lesions
- Procedure:
 - FLEX → Angioplasty

Lesion Characteristics	
In-Stent Restenosis	8% (n=20)
Chronic Total Occlusion	43% (n=103)
Average Lesion Length (mm)	136
Range of Lesion Length (mm)	2 – 350
Moderate / Severe Calcification	51% (n=122)
Average Age	72

Procedural Data

	Mean (Range)
Pre-Existing Stenosis	92%
Post FLEX Stenosis	68%
Post FLEX Luminal Gain	24%
DCB Use	73% (n=174)
Opening Balloon Pressure (atm)	4 (2 – 12)
Maximal Balloon Pressure (atm)	9 (4 – 18)
Post Procedure Residual Stenosis	9%
Post Procedure Luminal Gain	83%

Results

Technical Success	98.7%
FLEX Treated Lesion Prior to Angioplasty	100%
Vessel Perforation Occurrences	0
Distal Emboli	0
Minimal Vessel Dissection	5% (n=13)
Flow-Limiting Dissection	0
Provisional Stent Use	19% (n=45)
Average Luminal Gain Post Procedure	86.2%

Case Studies

Case 1: VMG99



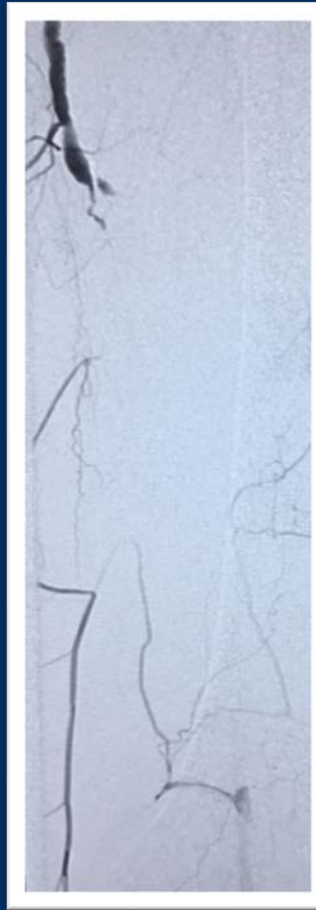
Pre- Angiogram

Procedure Details	
In-Stent Restenosis / Chronic Total Occlusion	
Treatment Location:	Right Femoral
Vessel Diameter:	6 mm
Lesion Length:	135 mm
Calcification:	None
Vessel Prep Device:	FLEX Catheter
DCB Treatment:	6 x 150 (1 Minute Inflation)

Case 1: VMG99

Procedural Results

Pre Stenosis	100%
Post FLEX Stenosis	70%
Luminal Gain Post FLEX	30%
Post DCB Stenosis	10%
DCB Opening Pressure (atm)	3
DCB Maximal Pressure (atm)	8
Dissection	None



Pre-Angiogram



Post FLEX



Post DCB

Case 2: VMG194



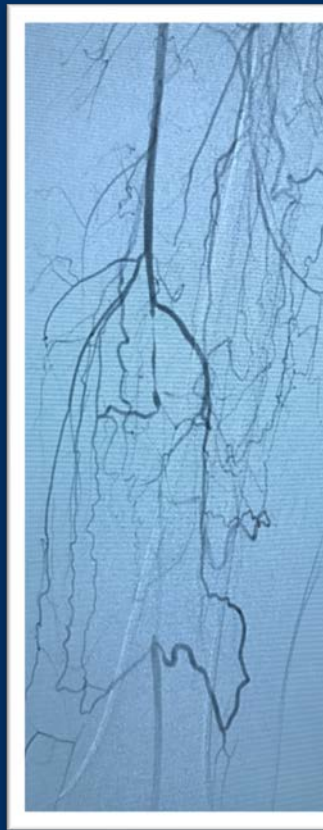
Pre- Angiogram

Procedure Details	
Treatment Location:	Left Femoral
Vessel Diameter:	4 mm
Lesion Length:	120 mm
Calcification:	Severe
Vessel Prep Device:	FLEX Catheter
DCB Treatment:	4 x 120 (3 Minute Inflation)

Case 2: VMG194

Procedural Results

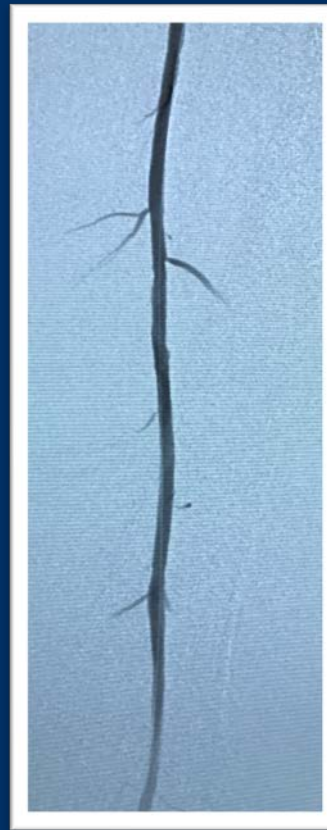
Pre Stenosis	100%
Post FLEX Stenosis	70%
Luminal Gain Post FLEX	30%
Post DCB Stenosis	0%
DCB Opening Pressure (atm)	3
DCB Maximal Pressure (atm)	8
Dissection	None



Pre-Angiogram



Post FLEX



Post DCB

Conclusion

- The FLEX Catheter[®] Safely Treats Complicated Femoropopliteal Lesions with a High Degree of Technical Success.
- Successfully Achieves Luminal Gain Post FLEX Without Flow-Limiting Dissection, Emboli, or Perforations.
- Low Opening Balloon Pressures (approx. 4 atm) Suggest Significant Improvement in Vessel Wall Compliance with FLEX use.
- Lower Dissection Rate After FLEX use Lowers the Necessity of Stenting.

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