

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

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Disclosure

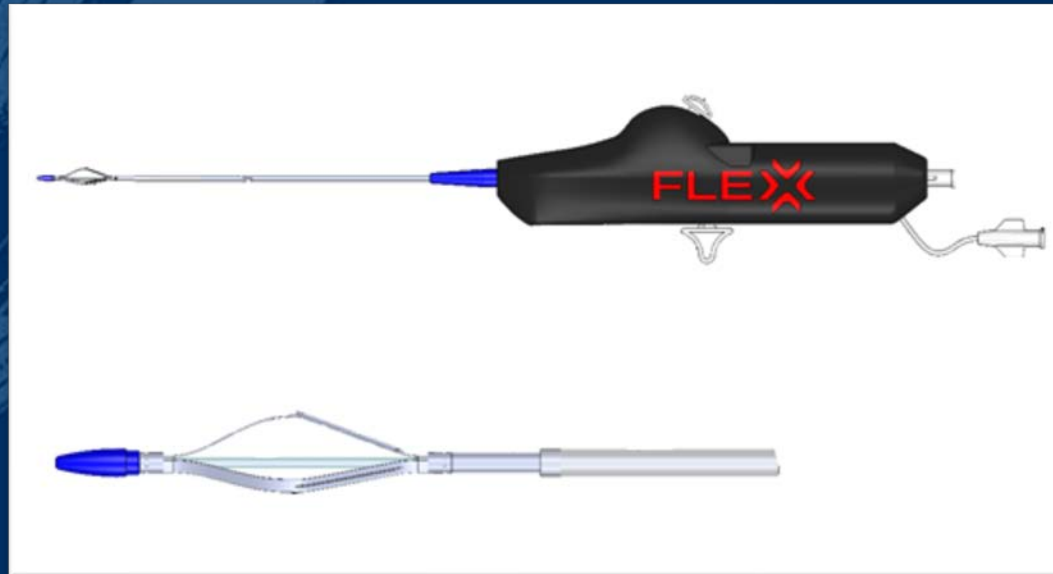
Speaker name: Louis Lopez

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)

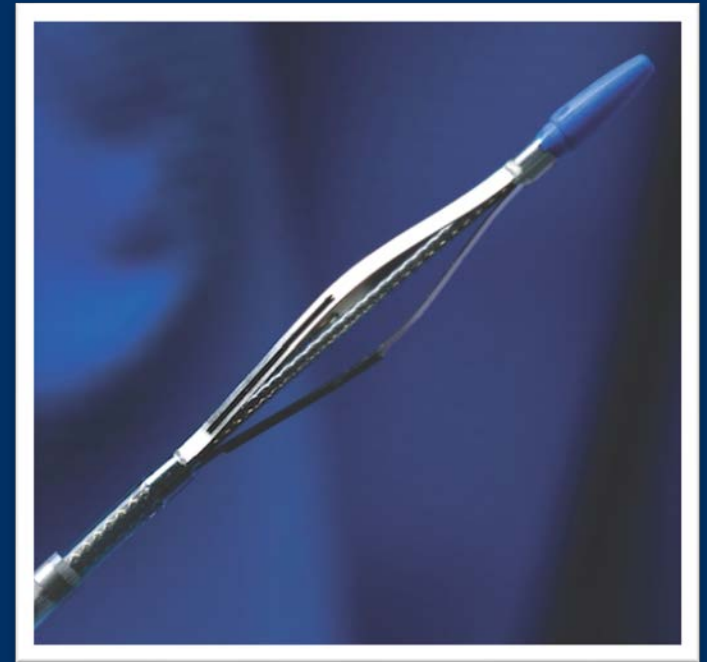
0.01” in Height

FDA / CE Mark Indication

Facilitate Dilatation of Stenoses of
Femoropopliteal and AVF/AVG

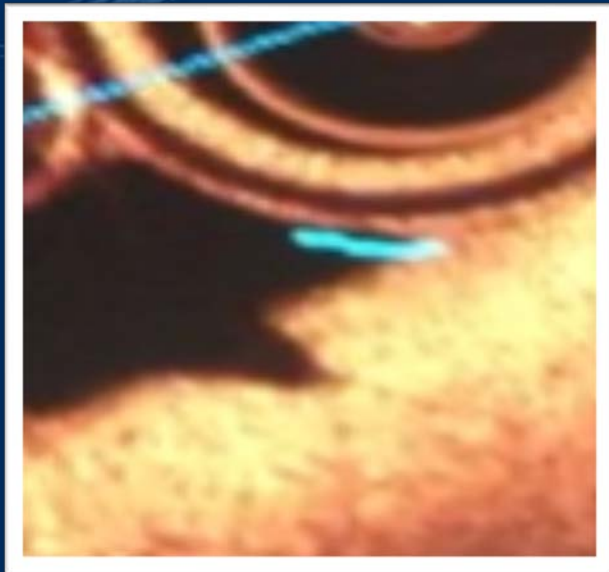
FLEX Catheter®

- 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.

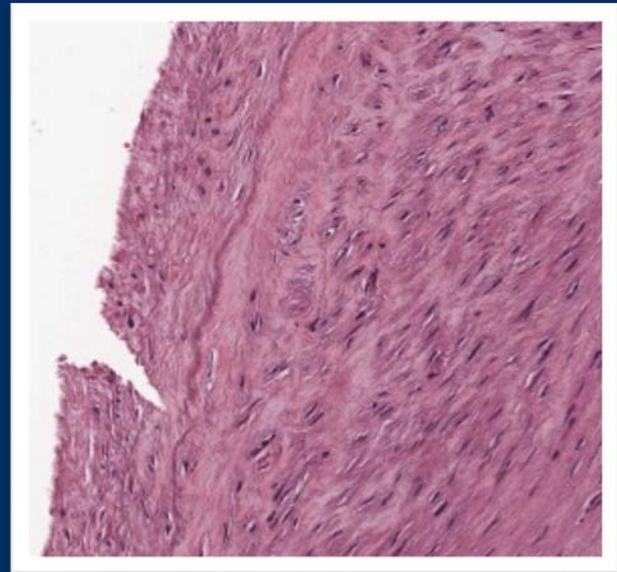


Dynamic Scoring[®] Technology

- 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



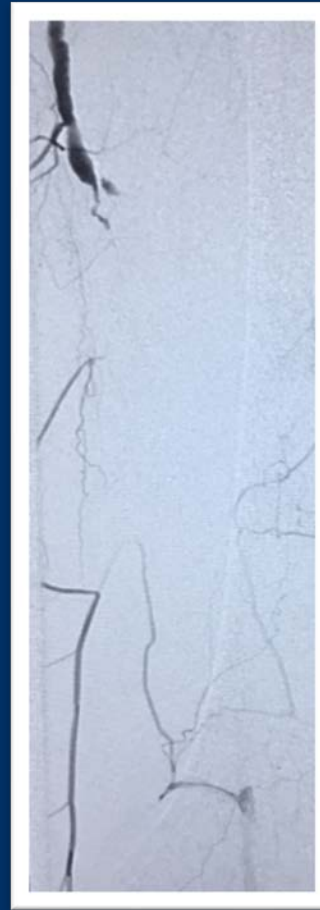
Pre- Angiogram

| 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



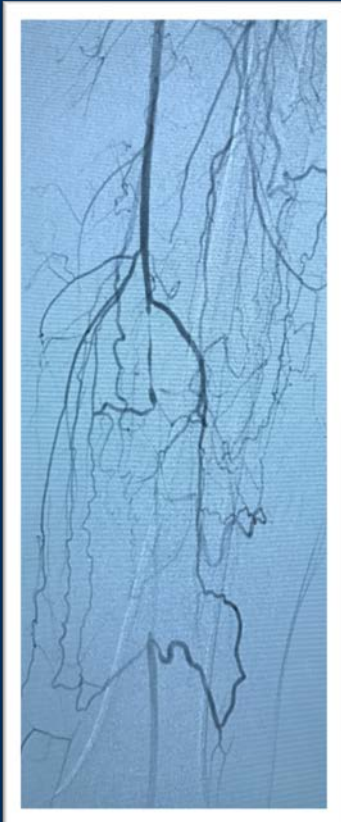
Pre- Angiogram

| 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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