

**BAPTIST HEALTH SOUTH FLORIDA** 



# FLEX Vessel Prep<sup>™</sup> System: Acute Results in Complex Vessel Anatomy

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# **Faculty Disclosures**

### Constantino Pena MD, FAHA, FSCCT, FSIR:

- Consultant Philips Medical; Avanos; Cordis
- Scientific Advisory Boards Boston Scientific; VentureMed; Surmodics
- Investor: Cagent Medical; Integrity Spine
- Speaker: Abbott Medical; BD; Cook Medical; Sirtex; Penumbra

Brand names are included in this presentation for participant clarification purposes only. No product promotion should be inferred.



## **Vessel Preparation**

- Modulate a vessel in order to allow dilatation to its final diameter for definitive therapy
- Modify plaque to improve vessel compliance and reduce dissections
- Potentially improve diffusion of DCB therapy
- Goal: safe dilation of vessels to improve outcomes





## Flex Vessel Prep<sup>™</sup> System – Why FLEX First?

**Optimizes revascularization of** *long, complex lesions with micro-incisions* 

- Controlled plaque modification in mixed morphology and asymmetrical lesions
- Consistent, long, micro-incisions prepare vessels prior to DCB or other therapies
- Create pathways to enhance and potentially facilitate drug access to diseased vessels

#### Safe

- Predictable, controlled-depth micro-incisions -10/1000"
- Minimizes risk of dissection, perforation, and other complications

#### Easy to use

- Simple design treats long, complex lesions
- Retrograde pull-back with minimal user variation
- ➢ No vessel sizing needed

#### **Cost efficient**

- ➢ No capital equipment−
- Only one or two catheters (shaft length)
- ➢ Quick over-the-wire set-up, and use −



## **Designed for "Faster-Easier-Safer" Vessel Prep**

- 6Fr; .014" or .018" guidewire (OTW)
- 2 working lengths 40cm & 120cm (US and OUS)
- Reinforced braided shaft for enhanced deliverability & torque performance
- Atraumatic tip for enhanced trackability and crossing profile
- For use in the femoral and popliteal arteries and AV fistulas and grafts
- Treatment element profile 2mm to 7mm





## **FLEX Vessel Prep<sup>™</sup> System**





### **FLEX Micro-Incisions**

### Precise, controlled-depth in real-world plaque morphology













# SFA - FLEX + In.PACT Admiral (Paclitaxel)

CBSET Cadaver Study – Coated Drug in Micro-Incisions





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## FLEX Vessel Prep<sup>™</sup> System Acute Results in Complex Vessel Anatomy

- Multi-center, retrospective review
- 185 real-world cases in long (20cm+), moderate-severe calcific (69%) lesions
- CTOs (≥ 8cm) 100% baseline stenosis
- Included only lesions prepped with the FLEX VP<sup>™</sup> System prior to DCB or POBA
- Angiograms collected at baseline, post FLEX, and post procedure

|   | Mean (Range), N (%) |
|---|---------------------|
| Number of Cases                                 | 185                 |
| Age   | 72 (38 – 92)        |
| Male  | 111 (60%)           |
| Vessel Diameter (mm)                            | 5 (1 – 10)          |
| Lesion Length (cm)                              | 20.8 (10 – 41)      |
| Moderate Calcification                          | 56 (30%)            |
| Severe Calcification                            | 73 (39%)            |
| Baseline Stenosis, %                            | 100                 |
| Post FLEX Luminal Gain, %                       | 34 (0 – 100)        |
| Angioplasty Effacement Pressure (atm)           | 4 (2 – 10)          |
| No Dissections                                  | 177 (96%)           |
| Type A Dissections                              | 6 (3%)              |
| Type B Dissections                              | 2 (1%)              |
| Emboli, Perforations, Flow Limiting Dissections | 0 (0%)              |
| Provisional Stenting                            | 52 (28%)            |
| Residual Stenosis, %                            | 10 (0 – 80)         |



### **Key Results**





# **Case Studies**



# Case Study 1

- 71-year-old male
- Rutherford Class 5
- 3 FLEX Passes
- POBA + DCB

| Procedure Details       |        |  |
|-------------------------|--------|--|
| Lesion Length           | 155 mm |  |
| Pre-Procedure Stenosis  | 100%   |  |
| Post FLEX Stenosis      | 30%    |  |
| Luminal Gain Post FLEX  | 70%    |  |
| Post Procedure Stenosis | 0%     |  |





# Case Study 2

- 72-year-old female
- Rutherford Class 3
- 4 FLEX Passes
- POBA + DCB

| Procedure Details       |        |  |
|-------------------------|--------|--|
| Lesion Length           | 410 mm |  |
| Pre-Procedure Stenosis  | 100%   |  |
| Post FLEX Stenosis      | 50%    |  |
| Luminal Gain Post FLEX  | 50%    |  |
| Post Procedure Stenosis | 10%    |  |





## Conclusions

- FLEX VP System effectively modified real-world plaque, including CTOs in the SFA/popliteal arteries.
- FLEX VP System is a safe and appears to limit potential risks of dissection and perforation in CTOs.
- Post-FLEX sub-nominal inflation pressures demonstrate improved vessel compliance.
- Further studies are warranted to confirm reduction of long-term reinterventions rates.



