Pilot Study of the FLEX™ Plaque Modification catheter in peripheral arterial disease

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Disclosure

Speaker Name: Dr. John Pigott

I have the following potential conflicts of interest to report:

☐ Consulting

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

✓ Other

☐ I do not have any potential conflict of interest
FLEX™ Plaque Modification Catheter

- Vessel Prep/Plaque Modification Catheter
- 6 Fr Sheath Compatible
- 0.018/0.014 Wire Compatible
- 120cm Working Length
- One Size Fits all for SFA/Popliteal
- One Size Fits all for BTK(pipeline)
- Tri-element Atherotome interacts with vessel wall at sub 1 ATM
- Design delivers Linear DYNAMIC Scoring
FLEX™ Plaque Modification Catheter
Linear Dynamic Vessel Preparation

Low pressure interaction with vessel wall, results in:

- Decreased incidence and grade of dissection
- Decreased need for Stenting
- Ideal vessel preparation for DCB
First in Man Clinical Study

- 2 centers
- 12 Patients
- 17 Fem-Pop Lesions

Lesion lengths:
- 1-15cm (5, 6, 8, 10, 15)
- Ave length 6.3 CM

Lesion types:
- 2 Chronic Total Occlusion
- Eccentric / Long
- Moderate Calcium

- 100% Technical Success
  - No perforations
  - No embolization
  - No thrombosis
  - Wide patency
  - 100% lesion cross

- At 30 Days
  - Improved ABI
    (p < 0.001)
  - Significant Rutherford Classification Improvement
    (p = 0.004)
Case Performed in University Herzzentrum Bad Krozingen, Germany

- Left SFA
- 3cm Chronic Total Occlusion
- .018 Glidewire Advantage was used to cross occlusion

Treatment
- FLEX Plaque Modification Catheter
- 3x80 PTA
- 6x80 DCB
- 5x40 Supera Stent
FLEX Vessel Prep
Mid SFA CTO

CTO  Post FLEX  Post PTA/DCB  Post Stent
Conclusion

• Early clinical cases in challenging arterial anatomy demonstrates an extremely safe device.

• FLEX reveals 100% technical success in cases to date.

• At less than one third the cost of atherectomy devices FLEX is a cost effective plaque modification/vessel preparation device.
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