XO Score: A Novel Scoring Sheath for Treatment of Complex Lesions and BTK CTO’s

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Disclosure

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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(s)

☐ I do not have any potential conflict of interest
PAD Patients

- **Advanced Age**
  - 40.3M 65+yrs old in U.S.\(^{(1)}\)
  - 85+ age group is fastest growing in U.S.\(^{(1)}\)

- **Diabetes**
  - Up to 26M in U.S.\(^{(2)}\)
  - Diabetes is fastest growing health problem in U.S.\(^{(3)}\)

- **Kidney Disease**
  - Up to 31M in U.S. \(^{(4)}\)
  - Diabetes is leading cause of kidney disease\(^{(2)}\)

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1. The Older Population: 2010 (2010 U.S. Census Briefs; C2010BR-09)
3. Diabetes Fact Sheet from American Diabetes Association
Treating Calcific Plaque: Balloon Angioplasty

Angiosculpt scoring balloon catheter by Angioscore

Flextome cutting balloon catheter by Boston Scientific

Chocolate PTA catheter by TriReme
XO SCORE® Diamond Sheath

Proprietary Rotostrut™ Design
(18) Flat low-profile blades rotate up and out during inflation to score then rotate back during balloon deflation

Local Infusion
Infuse or aspirate at the lesion site during and after inflation

Over the Wire (OTW) Compatible with .014”, .018”, .035” guidewires

Radiopaque Catheter Body
Visibility under x-ray fluoroscopy

Uses Standard PTA Balloon
2mm - 12mm diameter balloons
20 - 120mm long balloons
75 - 150cm long shafts
Balloon Not Included

Low-Profile Flexible Shape-Memory Metal Alloy Exoskeleton
Ultra-thin one-piece 65μ walls from proximal hub to distal scoring or cutting section

Tapered Distal Tip
Low 3 – 4 French crossing profile

XO SCORE™ is shown for educational purposes only and is not FDA or CE Mark cleared at this time.
XO SCORE Diamond flexible inflation with 10cm PTA inside porcine femoral arteries

XO SCORE Diamond under low-dose fluoroscopic x-ray. Basic angioplasty balloon visible under the XO SCORE Shell.

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XO SCORE Pushability Testing (Sheath is a Metal Alloy)

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XO SCORE Lesion Crack Testing (Less Barotrauma)

40% lower than PTA

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Evidence of uniform circumferential scoring with controlled depth using XO Diamond 10

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XO SCORE: Infusion (Biologics)

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Conclusion

XO SCORE: Cross and Score

1. Cross lesion with any 0.014”, 0.018”, or 0.035” wire.
2. Track XO Score over the wire.
3. Preload or Insert over-the-wire PTA balloon into the proximal XO Score and advance the balloon to target site.
   - XO Score 5F OD with 4F+ID for PTA balloons compatible with 4F sheaths
   - XO Score 6F OD with 5F+ID for PTA balloon compatible with 5F sheaths
   - XO Score Rapid-exchange under development.
4. Inflate and deflate as needed.
5. Infuse as needed.

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XO SCORE ANIMATION LINK: https://youtu.be/CUFY9Ei0kVM
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