AngioSculpt®

Competitive overview and objections
Overview - Other “Speciality” Balloons

**Cutting Balloon – Boston Scientific**
- Relatively stiff device
- Difficult to deliver in complex lesions
- Limited lengths & low rated burst pressure
- Risk of vessel perforation

**ScoreFlex – Orbus Neich (Fx Mini-Rail)**
- Inconsistent “non-slip”
- Unpredictable “scoring” wire location
- No studies documenting incremental benefit prior to stenting
Cutting Balloon

Atherotomes (razor blades)
Cutting Balloon Limitations

• Relatively stiff device
• May be difficult to deliver in complex lesions
• Limited lengths (6, 10, 15 mm)
• Low rated burst pressure (10 atm)
• Risk of perforation in complex lesions/bifurcations ≥2%
Cutting Balloon

• Uses process of Atherotomy to dilate de novo A & B lesions (IFU Indications)

• 3 atherotome blades score the plaque creating inflation sites for crack propagation and larger luminal dimensions

• Fewer dissections than POBA (25% vs 39%, REDUCE I Trial)

• (ISR) CB vs POBA: 11.8% vs. 19.1% (Reduce III Trial)

• Non-compliant balloon
Limitations of Boston Scientific Cutting Balloon

• IFU
  – only use in de novo A & B lesions (not complex lesions)
  – Avoid usage in coronary arteries with heavily calcified lesions, excessive tortuosity (not good deliverability)
  – Lesions are limited to discrete(<=15mm) and tubular 10mm in length
  – Can only inflate to 10ATM

• 25% dissection in small vessels (Reduce I Trial)

• Slippage (6.6% Rescut Trial)
Interface with Stents: AngioSculpt v. Cutting Balloon

AngioSculpt
(Helical Scoring Element with rectangular scoring edge)

Cutting Balloon (Longitudinal cutting blades with triangular sharp point)
Contact interface with Stents: AngioSculpt v. Cutting Balloon

AngioSculpt

- Stent
- Scoring Element 0.135mm Wide Edge

Cutting Balloon

- Stent
- Cutting Blade 0.03mm Wide Edge

Report on file at AngioScore
Contact Interface with Stents: AngioSculpt® Vs Cutting Balloon

- **AngioSculpt Strut:** Flat surface contact
- **Cutting Balloon Blade:** Sharp edge

The *Cutting Balloon* surface contact with the coating of DES may be prone to cut the polymer and increase the likelihood of delamination.
Coating Integrity of DE Stents

Delamination that is correlated with the location of the Cutting Balloon blades
## Cutting balloon RBP 10 atm

<table>
<thead>
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<th>Pressure (atm)</th>
<th>Balloon Diameter (mm)</th>
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## Cutting Balloon Vs AngioSculpt

<table>
<thead>
<tr>
<th>Cutting Balloon</th>
<th>AngioSculpt</th>
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</thead>
<tbody>
<tr>
<td>• Longitudinal Artherotomes</td>
<td>• Helical laser cut and electropolished nitinol scoring element</td>
</tr>
<tr>
<td>• Low RBP</td>
<td>• High RBP</td>
</tr>
<tr>
<td>• Higher dissection rate although less than POBA</td>
<td>• Lowest dissection rate</td>
</tr>
<tr>
<td>• Risk of perforations &lt;2%</td>
<td>• 0% perforations</td>
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</tbody>
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AngioSculpt is more deliverable, more flexible, can be inflated to higher pressures, and is safer.
Safe Cut / Score Flex

Safe Cut / Score Flex – Orbus Neich (Fx Mini-Rail)

- Inconsistent “non-slip”
- Unpredictable “scoring” wire location
- No studies documenting incremental benefit prior to stenting
- Previous version marketed by Guidant which is now AVD called the FX mini rail was discontinued
High Pressure Balloons

• Several studies demonstrated that higher pressures are frequently not enough to offset the high impedance of a diseased artery

• “Unfortunately there is no guarantee that simple high pressure post dilatation will result in final optimal stent deployment

Objections

- Price
- Deliverability
- Lack of Clinical data / evidence based medicine
- It's just another cutting balloon
- I don’t have any suitable patients
- Cannot use in heavy calcification
Objection - Price

AS is not a mainstream product (limited impact on budget)

Used in challenging cases where there is no better alternative (Surgery more expensive)

Potential to minimise the use of stents (reduced need for bail out stenting due to lower rate of dissections)

Note:

Generally AS is priced at a similar level to CB.

Much less expensive than Rotoblator
Objection - Deliverability

- AS is more bulky than a standard PTCA balloon
- Behaves and tracks like more a stent rather than a PTCA balloon
- Will deliver 90% of the time (primary procedural success)
- Will deliver 98% of the time (total procedural success – Manage a physicians expectations. Example. In direct stenting sometimes they need to pre-dilate)
- But AS is more deliverable than a Cutting balloon

The advantage is better angiographic outcome - simple
Objection – Clinical data

• AS is not a stent and there is no drug delivery eliminating the need for long term F/U

• Results are immediate due to the mechanical effect of a focused force angioplasty. If a standard balloon will not dilate a resistant lesion and a better angiographic outcome is achieved with AS… do you really need clinical data?

• Future products in pipeline include a drug delivery AS. AngioScore is not J&J or Abbott with resources and future product developments may make any further data gathered now redundant
Objection – It’s another cutting balloon

- This rationale is understood….. Many people may say this……but…. AS does so much more
- It is used in more clinical indications
- More deliverable/trackable
- Much Safer – less dissections and zero perforations
- Can be inflated to higher pressures
- Semi compliant allowing to tailor AS to vessel size
- Better re-wrap allowing for multiple inflations
Objection – I don’t have any suitable patients

- How do you treat?
- Mid size segment RCA?
- ISR
- Calcification
- Etc etc
Objection Heavy calcification

• Do not fall into the trap that AS can treat excessively heavy calcification
• Only Rotablator can treat this plaque effectively
• Rotablator does not leave a tidy angiographic result
• Use AS in conjunction with Rotablator to tidy up afterwards
510(k) Cleared for Balloon Dilatation of Lesions in Infrapopliteal Arteries.
Not for Use in the Coronary or Neuro-Vascular System.
Caution: Investigational Device for Coronary Use.
Limited by United States Law to Investigational Use in Coronary Applications.
CE Mark Granted for Coronary and Peripheral Applications.