Drug **C**oated **S**coring-**B**alloon for the treatment of **SB**s in complex coronary bifurcation lesions

Study Device (CE Marked and utilized as per IFUs)

- AngioSculpt PTCA platform*
- Rapid exchange
- Paclitaxel (3 µg/mm^2)
- NDGA (nordihydroguaiaretic acid)
- 4 diameters: 2.0, 2.5, 3.0, 3.5 mm
- 3 lengths: 10, 15, 20 mm
- Compliance range: 8-20 atm

*Based on AngioSculpt PTCA RX taper tip design

Study Device (CE Marked and utilized as per IFUs)

- Non-polymer based formulation of drug + excipient

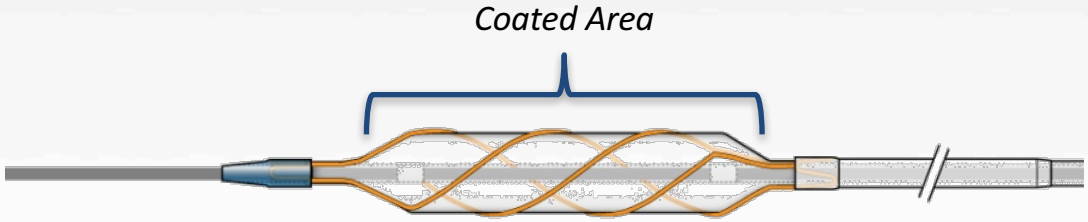
Paclitaxel

Surface concentration = 3 µg/mm2
Intended to inhibit restenosis

NDGA Excipient

Minimizes drug release until balloon inflation
Designed for homogeneous drug distribution to target vessel wall

- Coating is applied to working balloon surface, scoring element, and part of balloon cones



- Drug transfer from balloon to vessel wall requires minimum of 30 seconds inflation

Trial Synopsis:

Rationale:

- The combination of **drug-coating and scoring in the SB** may be an optimal **additional treatment** using the strategy of provisional T- Stenting in complex coronary bifurcation anatomies with **large side branches** and **with** significant **ostial disease length (≥ 5mm)**.
- These complex bifurcation lesions are considered by expert **consensus** to warrant a **2-stent technique** upfront.
- The **rationale** is to **limit the need for SB stenting**, based on: high acute luminal gain, low flow-limiting dissections rate, low elastic recoil and potential for enhanced drug uptake.

Trial Synopsis:

Study Design:

- Prospective, Single-Arm feasibility study
- 50 Patients
- 6-8 months angio follow up
- 12 months clinical follow up

Endpoints:

- **Primary Endpoint:**
  Clinical Success (Technical Success without periprocedural/within-discharge complications**)

- **Secondary Endpoint:**
  - Technical Success, defined as: residual stenosis ≤50%, without flow-limiting dissections confirmed by TIMI 3 flow and no SB stenting)
  - 6-8 months Angio Restenosis Rate
  - 6-8 months Late Lumen Loss
  - 12 months TLR
  - 12 months MACE

Inclusion Criteria:

- Medina X, X, 1
- SB Lesion diameter ≥ 2.25-2.5mm (by QCA evaluation)
- Pre-dilation of the SB required (Lesion length ≥ 5mm and/or difficult access to the SB, i.e. Ca++, wide angle > 70-80°)

Procedural Highlights:

Treatment at operator discretion/preference (NON-randomized):

Suggested strategy:

1. MB and SB wiring
2. Pre-dilation of SB (+/- MB)
    1. Provisional SB stenting if suboptimal SB result (SB stenosis >80% and/ or a flow limiting dissection) -> goto point 4.
3. SB treatment with Drug-Coated Scoring Balloon
4. MB treatment with DES
5. POT/KBI/POT or POT/Side/POT
6. End Procedure

    or

    Provisional SB stenting if suboptimal SB result (SB stenosis >80% and/ or a flow limiting dissection)

Backup

AGILITY Trial

«plain» AngioSculpt in complex True Bifurcations reduces dissections, stent rate and overall 9-month MACE vs. literature derived benchmarks of DES provisional T stenting

Study Design

- **Prospective, multi-center, single arm study**
- Assess **safety and efficacy** of ASC for the treatment of side branch (SB) stenosis in **true coronary bifurcations**
- PI: Dr. G. Weisz, Columbia University Medical Center
- **Primary endpoint**: Procedural success
- Angiographic Corelab
- Patients evaluated through their index hospitalization and followed up at the 30 days, 9 months intervals
- **9-month data published**

N = 93

Key Baseline Characteristics

Age	61.5y
Males%	72%
Diabetes	24.7%
Medina x / x / 1	92.5%*
Lesion length	17.4 (MV); 7.6 (SB) mm
RVD	2.78 (MV); 2.22 (SB) mm
%DS	67.3% (MV); 61.3% (SB)

*by Corelab evaluation

Procedural and 9-Month Results:

AngioSculpt was used in 97.8% of SB as primary therapy and 70.9% in MV (pre-dil before DES)

Primary Endpoint	
Procedural success	91.4%
Main Secondary Endpoints	
Final kissing balloon (FKB) without SB stent	16.3%
Bailout stenting of SB	10.9%
Other Key Secondary Endpoints	
Angiographic Success	93.5%
AngioSculpt used as primary therapy in SB	97.8%
AngioSculpt used to pre-dil MB	70.9%
9-Month MACE Rate	5.4%
9-Month TLR Rate	3.3%

See last slide for references