Eluvia's guiding design principles

- Unique SFA environment
- Strong, fracture-resistant stent
- Elution profile that matches the disease process
- Durable, biocompatible coating

Environmental Differences: Mechanical Environment

Newer stents are highly durable, long term data shows impact on patency

Timing of disease progression much longer in the SFA vs. coronary artery

- Clinical History of Restenosis

Coronary Drug Eluting Stent polymers have been shown to be biocompatible with good safety profile

Technology Differences: Polymer Selection

<table>
<thead>
<tr>
<th>Stent</th>
<th>Polymer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolute Integrity™ (MDT)</td>
<td>BioLinx</td>
</tr>
<tr>
<td>Xience™ (ABT)</td>
<td>Fluorinated Polymer (PBMA – PVDF)</td>
</tr>
<tr>
<td>Promus™ (BSC)</td>
<td>Fluorinated Polymer (PBMA – PVDF)</td>
</tr>
</tbody>
</table>
Design considerations due to technology differences between coronary artery vs. SFA

Environmental Differences
- Mechanical Environment
- Pathological Differences
- Disease Progression

Technology Differences
- Balloon Expandable vs. Self-Expandable
- Polymer Selection
- Elution Profiles

Eluvia™: mechanical design
Optimization of force, fracture resistance, and flexibility ensures design addresses mechanical environment.

Eluvia™: coating design
- Primer layer (PBMA) Promotes adhesion of active layer to stent
- Active layer (PTx/PVDF-HFP) Controls release of Paclitaxel

Sustained drug release to reduce restenosis

MAJESTIC study: first Eluvia human experience (n=57)

Considerations for DES study design in 2015
- Should include updated control
  - BMS
  - DCB
  - Atherectomy + DCB
  - DES
- Selected lesions tested
  - Should include longer lesions
  - Should include calcified lesions
**Optimal Study Design for DES in 2015**

- DES vs DES
- Allows direct comparison of outcomes
  - Same inclusion exclusion criteria
  - Same study parameters (endpoints, follow-up, etc)
- Eliminates noise from other treatments
- H2H is favorably looked upon by the physician community
- Compare to already proven safe and efficacious device with long term data

**Boston Scientific Global Pivotal Study**

**IMPERIAL Trial**

**Clinical Study Overview**

- **Title**: To evaluate the safety and effectiveness of the ELUVIA Drug-Eluting Vascular Stent System (ELUVIA Stent) for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 140 mm in length.
- **Primary Investigators**
  - Global: William A. Gray, MD
  - European: Prof. Dr. med Stefan Müller-Hülsbeck
- **Objective**: The IMPERIAL Global Pivotal Study will evaluate the safety and efficacy of the ELUVIA Drug-Eluting Vascular Stent System (ELUVIA Stent) for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 140 mm in length.
- **Endpoints**
  - **Primary Safety**
    - Major Adverse Cardiac Events (MACES) rate defined as:
      - All-cause death through 1 month
      - Target lesion revascularization (TLR) through 12 months
      - Target vessel revascularization (TVR) through 12 months
  - **Primary Efficacy**
    - Avascular restenosis (AVR) defined as:
      - All-cause death through 1 month
      - Target lesion revascularization (TLR) through 12 months
      - Target vessel revascularization (TVR) through 12 months

**Study Design**

- A prospective, multicenter, 2:1 randomized (ELUVIA vs Zilver PTX), controlled, single-blind, non-inferiority trial (RCT).
- A randomised trial comparing the ELUVIA drug-eluting stent versus Zilver PTX stent – which has proven safety and efficacy in the SFA.
- The IMPERIAL study design promises directly comparable data with favorable long term data.

**Boston Scientific Global Pivotal Study**

**IMPERIAL Study Stents**

**Zilver PTX**

- **Product Image**
- **Stent Platform**: Zilver Flex Innova
- **Material**: Nitinol
- **Drug**: Paclitaxel
- **Polymer Matrix**: Biostable

**Eluvia™ DES**

- **Product Image**
- **Stent Platform**: Zilver PTX
- **Material**: Nitinol
- **Drug**: Paclitaxel
- **Polymer Matrix**: Biostable

**Conclusion for Eluvia DES**

- The IMPERIAL Global Pivotal Study will evaluate the safety and efficacy of the ELUVIA Drug-Eluting Vascular Stent System (ELUVIA Stent) for treating SFA and/or PPA.
- Longer lesions, up to 140 mm, will be treated with the Eluvia stent.
- The goal of the study is to prove non-inferiority to the Zilver PTX stent – which has proven safety and efficacy in the SFA with favorable long term data.
- The IMPERIAL study design promises directly comparable data for DES treatment in the SFA.