**ELUVIA™ Drug-Eluting Vascular Stent System**

**Triaxial delivery system for more precise and predictable stent placement**

<table>
<thead>
<tr>
<th>Delivery system working length (cm)</th>
<th>Stent diameter (mm)</th>
<th>Minimum sheath size</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>6</td>
<td>6F</td>
</tr>
<tr>
<td>60</td>
<td>7</td>
<td>6F</td>
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<tr>
<td>80</td>
<td>7</td>
<td>6F</td>
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<tr>
<td>100</td>
<td>7</td>
<td>6F</td>
</tr>
<tr>
<td>120</td>
<td>7</td>
<td>6F</td>
</tr>
</tbody>
</table>

**Consistent and Durable Clinical Outcomes at 2 Years**

Statistically significant reduction in CD-TLR with Eluvia at 2 years vs. Zilver PTX

Consistently low 2-year CD-TLR in Challenging SFA Disease

- **Zilver PTX** (n=27/134) 20.1%
- **Eluvia** (n=16/170) 12.7%

Consistently low 2-year CD-TLR in IMPERIAL Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against Cook Medical's Zilver™ PTX™

**IMPERIAL RCT CD-TLR data** is intention to treat and adapted from Iida, O. VIVA 2019 presentation

In IMPERIAL RCT, CEC adjudicated all-cause mortality rate at 2 years for Eluvia was 7.1% (21/295) vs. 8.3% (12/145) for Zilver PTX.

**Highest two-year primary patency** based on 24-month Kaplan-Meier estimates reported for IMPERIAL, IN.PACT SFA, ILLUMENATE, LEVANT II and Primary Randomization for Zilver PTX RCT.

**Primary patency** defined as duplex ultrasound PSVR ≤2.4, in the absence of restenosis, ulceration, amputation, or death.

**2-Year Kaplan-Meier Primary Patency Estimate**

- **IMPERIAL RCT** 83.0%
- **Diabetic** 85.7%
- **CTO** 76.4%
- **Sev/Mod Calcium** 85.0%

**Sustained Release. Superior Results.**

**Adverse Events**

- **Eluvia** is a registered or unregistered trademark of Boston Scientific Corporation or its affiliates. All other trademarks are property of their respective owners.

**Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.**

**OPERATOR'S INSTRUCTIONS:**

- Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

**Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only.**

**CONTRAINDICATIONS:**

- **Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive an ELUVIA Drug-Eluting Stent.**

**PRECAUTIONS:**

- **Stenting across a bifurcation or side branch**

**ADVERSE EVENTS:**

- **Term adverse events** are unintended and unintended negative clinical events that occur at any time in a patient receiving the stent and are not necessarily causally related to the stent.

**PROBABLE ADVERSE EVENTS:**

-**Embolic events**

**ASSESSMENT:**

- **Eluvia** is an embolic event with a lower mean arterial pressure or triggering event.

- **Hematoma**

- **Infection/Sepsis**

- **Ischemia**

**INTERVENTION:**

- **Eluvia** is an embolic event with a lower mean arterial pressure or triggering event.

**PROBABLE ADVERSE EVENTS:**

- **Hematoma**

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- **Ischemia**

**INTERVENTION:**

- **Eluvia** is an embolic event with a lower mean arterial pressure or triggering event.

**DEFINITIONS:**

- **Eluvia** is an embolic event with a lower mean arterial pressure or triggering event.

- **Hematoma**

- **Infection/Sepsis**

- **Ischemia**

**INTERVENTION:**

- **Eluvia** is an embolic event with a lower mean arterial pressure or triggering event.

**RECOGNIZING ELUVIA™ STENT FRACTURE:**

- **Eluvia** is an embolic event with a lower mean arterial pressure or triggering event.

**DOCUMENTATION:**

- **Eluvia** is an embolic event with a lower mean arterial pressure or triggering event.
Eluvia has the lowest drug dose density of any drug-eluting SFA technology. Polymer-based technology with proven biocompatibility: The Eluvia Stent uses the same fluoropolymer as the PROMUS™ and XIENCE™ coronary stents which have a proven history of safety in the body.

Eluvia’s polymer ensures targeted delivery of the drug to the lesion and minimizes downstream particulates. The low drug dose density of Eluvia results in lower tissue concentrations, which can help reduce the risk of stent thrombosis. Downstream particulates collected with polycarbonate filter: Eluvia showed similar particulate loss compared to a bare metal stent.

Polymer with thrombo-resistant properties: Eluvia’s polymer sustains drug tissue concentrations beyond 12 months.

Remarkable and consistent clinical efficacy in the most challenging SFA lesions:

IMPERIAL is the first and only randomized trial comparing a low-dose polymeric drug-eluting stent to a high-dose non-polymeric drug-coated stent. One-year primary patency results in complex lesions: Eluvia’s polymer has demonstrated statistically significant improvements in primary patency compared to other stent technologies.

**Highly controlled drug delivery, sustained to match the restenotic process:**

Eluvia’s polymer sustains drug tissue concentrations beyond 12 months. Drug Tissue Concentrations Over Time.

**Lowest drug dose delivered by the world’s most proven polymer**

Polymer-based technology with proven biocompatibility: The Eluvia Stent uses the same fluoropolymer as the PROMUS™ and XIENCE™ coronary stents which have a proven history of safety in the body.

**Data from Eluvia, Lutonix, Stellarex, Zilver PTX and IN.PACT Directions for Use.**

- **2.** Data on file at Boston Scientific. Represents total global sales of the PROMUS (Boston Scientific) and XIENCE (Abbott) stents since 2006.
- **3.** Data on file at Boston Scientific. Represents total population of patients studied in the PROMUS and XIENCE series of clinical trials.
- **4.** Paclitaxel Drug Dose Density (μg/mm²).
- **5.** PSVR < 2.0
- **6.** Moderate and severely calcified.

**Data from Boston Scientific.**

- **5.** Iida, O. et al. Catheterization and Cardiovascular Interventions. 2011; 78:611-617.
- **6.** Statistically Significant; Primary patency as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is ≤ 2.4 at the 12-month follow-up visit, in the absence of clinically-driven TLR or bypass of the target lesion.

**One-year primary patency results in complex lesions:**

**Statistically Significant**

**ELUVIA™ Zilver™ PTX™**

92.1% vs 81.8%

Kaplan-Meier Estimate

**Remarkable and consistent clinical efficacy in the most challenging SFA lesions**

**Drug Tissue Concentrations Over Time**

**Downstream particulates collected with polycarbonate filter:**

Eluvia showed similar particulate loss compared to a bare metal stent.

**20 Million+ Implants**

**100,000+ Patients Studied in Clinical Trials**

**12X higher drug dose density**

**8X higher drug dose density**

**Statistically Significant**

Kaplan-Meier Estimate

**Adapted from Holden, A LINC 2020 Presentation**

**Remarkable**

Highly controlled drug delivery, sustained to match the restenotic process.

**Statistically Significant**

Kaplan-Meier Estimate through 1-year (including follow-up window) was statistically significant with a p-value of 0.0094.

**Based on post hoc analysis for Eluvia comparing to Zilver PTX.**

**4.** Paclitaxel Drug Dose Density (μg/mm²).

**5.** PSVR < 2.0