Boston Scientific
Advancing science for life™

ELUVIA™ Drug-Eluting Vascular Stent System

Superior Results in the first head-to-head DES SFA Trial[1]

OBJECTIVE:

Evaluate the safety and effectiveness of the Boston Scientific Corporation ELUVIA™ Drug-Eluting Vascular Stent System for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 140 mm in length.

IMPERIAL TRIAL DESIGN:

Global multi-center, 2:1 randomization against Cook Medical's Zilver™ PTX™ Stent, controlled, single-blind, non-inferiority trial; core lab adjudicated

- 465 (RCT) patients across 64 sites
- **Primary Endpoints:**

  Safety: Major Adverse Events defined as all causes of death through 1 month, Target Limb Major Amputation through 12 months and/or Target Lesion Revascularization (TLR) through 12 months.

  Efficacy: Assess primary vessel patency* at 12 months post-procedure.

- Primary patency, freedom from TLR, ankle-brachial index (ABI), Rutherford classification and stent fracture rate evaluated
- Eligible patients with chronic, symptomatic (Rutherford categories 2, 3 or 4) lower limb ischemia and stenotic, restenotic or occlusive lesions in the native superficial femoral artery or proximal popliteal artery
- Degree of stenosis ≥ 70% (visual angiographic assessment)
- Vessel diameter ≥ 4 mm and ≤ 6 mm
- Total lesion length ≥ 30 mm and ≤ 140 mm
- 5-year follow-up

BASELINE CHARACTERISTICS:

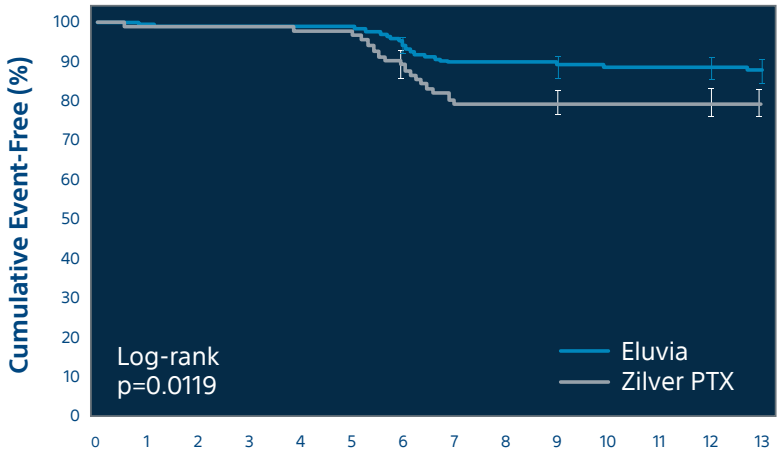
Patient Demographics	Eluvia (n=309)	Zilver PTX (n=156)
Age (Years)	68.5±9.5	67.8±9.4
Male Gender	66.0%	66.7%
Diabetes Mellitus	41.7%	43.6%
History of Smoking	86.1%	84.0%
Hypertension	82.2%	85.3%
Hyperlipidemia	76.3%	75.6%
Coronary Artery Disease	50.8%	45.2%

Lesion Characteristics	Eluvia (n=309)	Zilver PTX (n=156)
Reference Vessel Diameter (mm)	5.0±0.8	5.1±0.8
Target Lesion Length (mm)	86.5±36.9	81.8±37.3
Severely Calcified	40.1%	32.3%
Percent Diameter Stenosis	80.7±16.5	80.8±16.4
Total Occlusions	31.2%	30.3%
Extending into Distal SFA	66.3%	65.4%
Extending into PPA	18.0%	12.7%

12-MONTH PRIMARY PATENCY RESULTS:

Eluvia demonstrated a **statistically significant difference in primary patency** compared to Zilver PTX at 12 months in the IMPERIAL Trial.

IMPERIAL TRIAL 12-Month PRIMARY PATENCY RATES K-M Estimate*



Eluvia (n=309)
88.5%

Zilver PTX (n=156)
79.5%

*Defined as a binary endpoint determined to be patent when the 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.

1. 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™ Stent, single-blind, non-inferiority design; independent core lab adjudication. Superiority determined in a post hoc analysis that was specified prior to unblinding. 12-Month Primary Patency rate of 86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX arm (p-value = 0.0144).

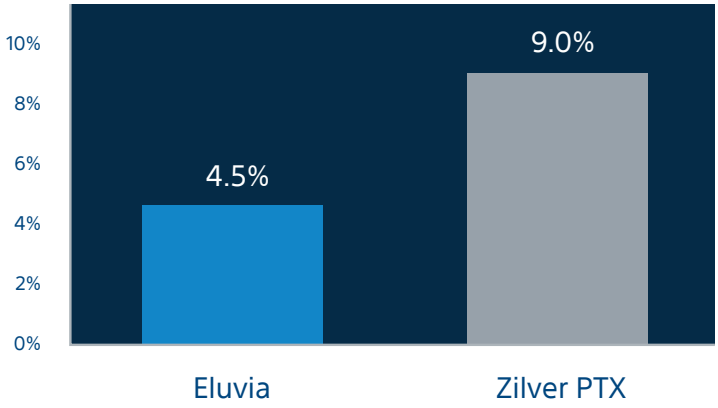
Randomized Controlled Trial | 12-month results

12-MONTH SAFETY RESULTS:

- 95.1% of Eluvia patients were free of Major Adverse Events at 12 months (vs. 91.0% of Zilver PTX patients)
- Eluvia demonstrated half the target lesion revascularization rate (TLR) of Zilver PTX at 12 months (4.5% vs. 9.0%)

	Eluvia	Zilver PTX	p-value
12-month MAE	4.9%	9.0%	0.0975
All Causes of Deaths at 1 Month	0.0%	0.0%	Undefined
Target Limb Major Amputation	0.3%	0.0%	1.0000
Target Lesion Revascularization	4.5%	9.0%	0.0672

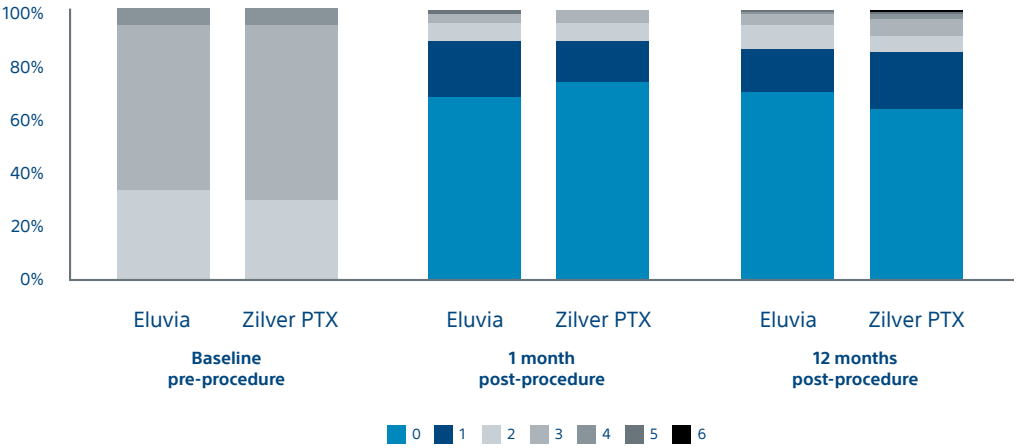
CLINICALLY-DRIVEN TLR RATE | 12 MONTHS



PATIENT OUTCOMES:

- 85.8% of Eluvia patients presented with no or minimal claudication (Rutherford 0-1) at 12 months (vs. 84.5% of Zilver PTX patients)
- 89.6% of Eluvia patients had improvement by at least 1 Rutherford category compared with baseline without the need for TLR (vs. 83.1% of Zilver PTX patients)

RUTHERFORD CATEGORY



ELUVIA® DRUG-ELUTING VASCULAR STENT SYSTEM

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The ELUVIA Drug-Eluting Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters (RVD) ranging from 4.0-6.0 mm and total lesion lengths up to 190 mm. **CONTRAINDICATIONS:** • Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive an ELUVIA Drug-Eluting Stent. It is unknown whether paclitaxel will be excreted in human milk, and there is a potential for adverse reaction in nursing infants from paclitaxel exposure. • Patients who cannot receive recommended anti-platelet and/or anti-coagulant therapy. • Patients judged to have a lesion that prevents proper placement of the stent or stent delivery system. **WARNINGS:** • The delivery system is not designed for use with power injection systems. • Only advance the stent delivery system over a guidewire. • The stent delivery system is not intended for arterial blood monitoring. • In the event of complications such as infection, pseudoaneurysm or fistula formation, surgical removal of the stent may be required. • Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent. • It is strongly advised that the treating physician follow the Inter-Society Consensus (TASC II) Guidelines recommendations (or other applicable country guidelines) for antiplatelet therapy pre-procedure to reduce the risk of thrombosis. Post-procedure dual antiplatelet therapy is required for a minimum of 60 days. **PRECAUTIONS:** • Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures. • The stent is not designed for repositioning. • Once the stent is partially deployed, it cannot be "recaptured" or "reconstrained" using the stent delivery system. • The stent may cause embolization from the site of the implant down the arterial lumen. • This product should not be used in patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy. • Persons with a known hypersensitivity to paclitaxel (or structurally-related compounds), to the polymer or its individual components (see details in Primer Polymer and Drug Matrix Copolymer Carrier section), nickel, or titanium may suffer an allergic response to this implant. • Persons with poor kidney function may not be good candidates for stenting procedures. **PROBABLE ADVERSE EVENTS:** Probable adverse events which may be associated with the use of a peripheral stent include but are not limited to: • Allergic reaction (to drug/polymer, contrast, device or other) • Amputation • Arterial aneurysm • Arteriovenous fistula • Death • Embolization (air, plaque, thrombus, device, tissue, or other) • Hematoma • Hemorrhage (bleeding) • Infection/Sepsis • Ischemia • Need for urgent intervention or surgery • Pseudoaneurysm formation • Renal insufficiency or failure • Restenosis of stented artery • Thrombosis/thrombus • Transient hemodynamic instability (hypotensive/hypertensive episodes) • Vasospasm • Vessel injury, including perforation, trauma, rupture and dissection • Vessel occlusion Probable adverse events not captured above that may be unique to the paclitaxel drug coating: • Allergic/immunologic reaction to drug (paclitaxel or structurally-related compounds) or the polymer stent coating (or its individual components) • Alopecia • Anemia • Gastrointestinal symptoms • Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage or necrosis • Myalgia/Arthralgia • Peripheral neuropathy There may be other potential adverse events that are unforeseen at this time. 92306016 A.1

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