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
- IMPERIAL demonstrated that Eluvia is non-inferior for both the primary safety and efficacy endpoints (Primary Endpoint Cohort n = 396) and improved upon those results in the Post Hoc Superiority Analysis with the full patient cohort (n=465).
- 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:

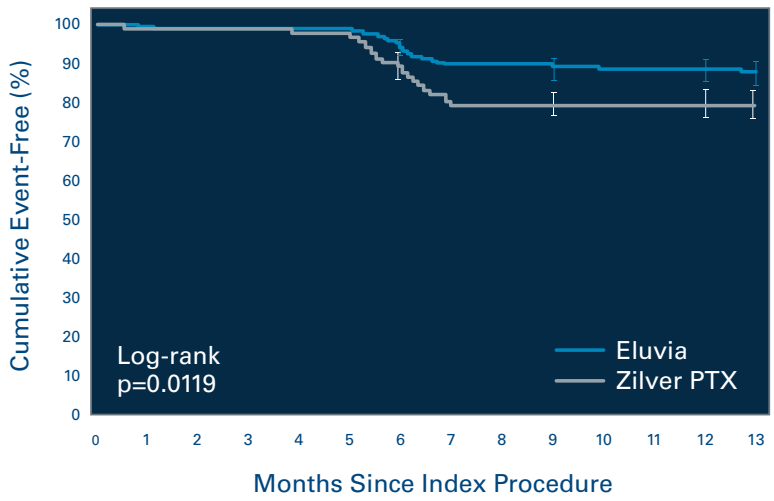
Patient Demographics	Eluvia (n=309)	Zilver PTX (n=156)
Age (Years)	68.5±9.5	67.8±9.4
Male Gender	66.0%	66.7%
Diabetes Mellitus	41.7%	43.6%
History of Smoking	86.1%	84.0%
Hypertension	82.2%	85.3%
Hyperlipidemia	76.3%	75.6%
Coronary Artery Disease	50.8%	45.2%

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.

KAPLAN-MEIER PRIMARY PATENCY RATES



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. Superiority determined in Post Hoc Superiority Analysis. 12-Month Primary Patency rate of 86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX arm (p-value = 0.0144). **CAUTION:** Eluvia is an investigational device. Limited by US law to investigational use only. Not available for sale.

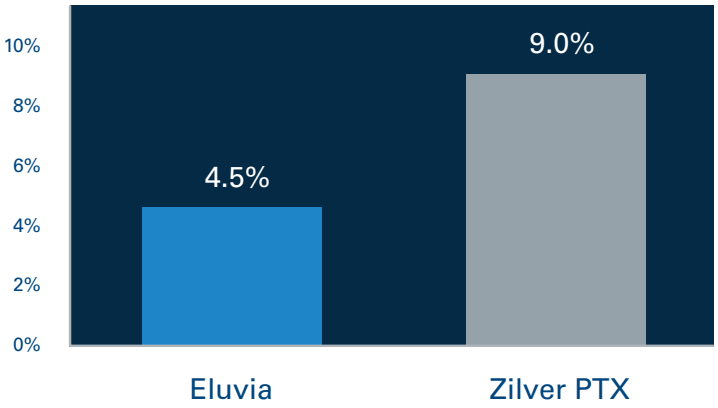
Randomized Controlled Trial | 12-month results

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

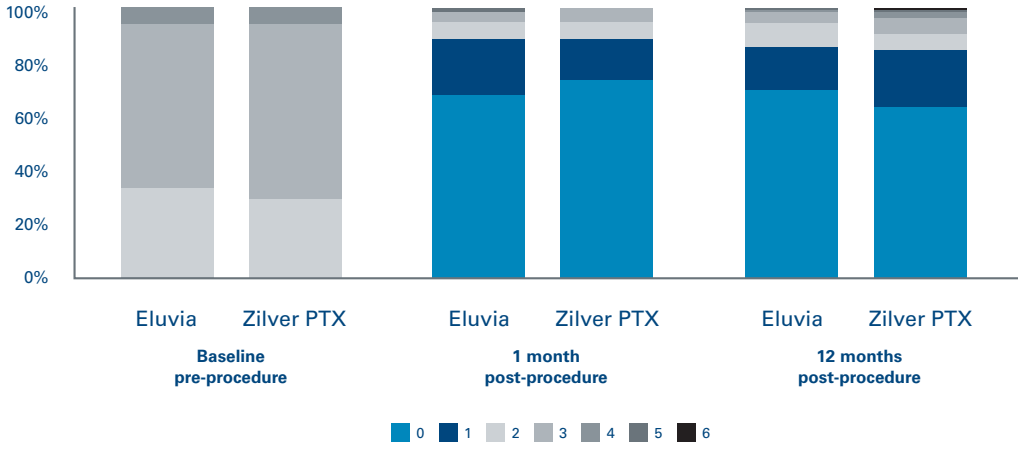
CLINICALLY-DRIVEN TLR RATE | 12 MONTHS



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



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