Boston Scientific
Advancing science for life™

IMPERIAL RCT SUMMARY

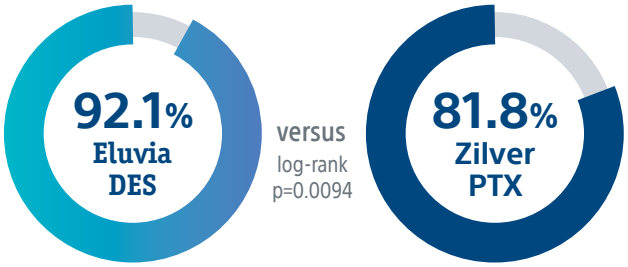
The world's first head-to-head DES SFA Trial, evaluating Boston Scientific Corporation's Eluvia™ Drug-Eluting Vascular Stent System and Cook Medical's Zilver™ PTX™ Stent

Sustaining strong results through five years

The results of the IMPERIAL RCT show that Eluvia Drug-Eluting Stent (DES) is clinically effective and safe in treating patients with symptomatic SFA disease both in the short-term during the height of restenosis risk, and long-term out to five years.

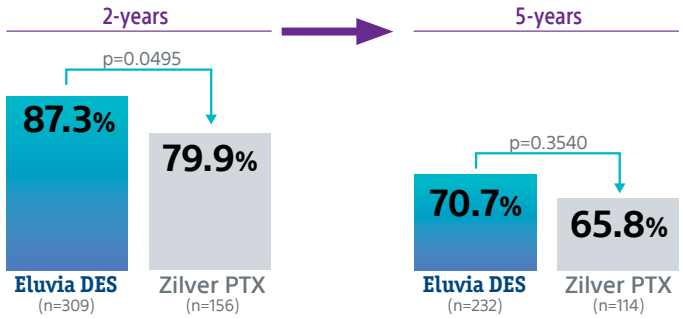
Eluvia DES demonstrated superiority over Zilver PTX[1] with a statistically significant primary patency through 1-Year

IMPERIAL RCT 1-YEAR RESULTS
K-M Primary Patency



Eluvia DES showed lower revascularization rates than Zilver PTX through 5 years[2] with statistical significance[3] at 2-Years

FREEDOM FROM CD-TLR RATES

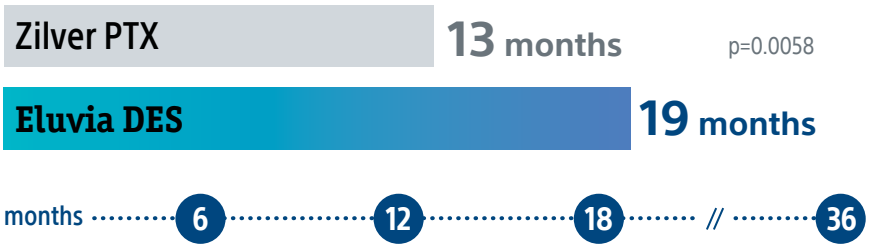


Durable, consistent outcomes in long and complex lesions

IMPERIAL TRIAL 2-YEAR CLINICAL RESULTS
Excellent Patient Follow-up at 24-Months (~90%)

	IMPERIAL RCT[4] (n = 309)	IMPERIAL Long Lesions[5,6] (n = 56)	Diabetic Subgroup[7,8] (n = 116)	Severe/ Moderate Calcium Subgroup[8] (n = 193)	CTO Subgroup[8] (n = 96)
Study Design	RCT, global multicenter	Single arm, global multicenter	RCT, global multicenter	RCT, global multicenter	RCT, global multicenter
24-month primary patency rate*	**83.0%**	**77.2%**	**85.7%**	**85.0%**	**76.4%**
Lesion length (mm)	86.5	162.8	87.0	89.9	94.4
Severe calcification	40%	28%	46%	n/a	n/a
Total occlusions	31%	32%	25%	n/a	100%
	Highest primary patency ever reported at 2 years**	Highly durable outcomes in ~16cm lesions at 2 years	TLR (12%) in line with overall cohort and low stent thrombosis rate (0.9%)	Remarkable primary patency and <10% TLR in heavy calcium	Highly durable outcomes in CTOs at 2 years

Eluvia DES patients on average avoided reintervention 6 months longer than Zilver PTX patients at 3-Years[2†]



IMPERIAL TRIAL 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 140mm 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
- 5-year follow-up
- Degree of stenosis ≥ 70% (visual angiographic assessment)
- Vessel diameter ≥ 4mm and ≤ 6mm
- Total lesion length ≥ 30mm and ≤ 140mm

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%

Lesion Characteristics	Eluvia (n=309)	Zilver PTX (n=156)
Target Lesion Length (mm)	86.5±36.9	81.8±37.3
Severely Calcified	40.1%	32.3%
Total Occlusions	31.2%	30.3%
Extending into Distal SFA	66.3%	65.4%

* Intention to treat. Kaplan-Meier estimate utilizing time-to-event of clinically-driven TLR up to 730 days and Duplex Ultrasound data at 24 months. Primary patency defined as duplex ultrasound PSVR ≤2.4, in the absence of clinically-driven target lesion revascularization or bypass of the target lesion, as assessed by the DUS core lab.
**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.
† Among patients who underwent a CD-TLR within 3 years of the index procedure

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). Gray WA, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1.
2. Gray W. 5-year Results from the IMPERIAL Randomized Study of Eluvia and Zilver PTX Drug-eluting Stents and Long Lesion Substudy for Femoropopliteal Artery Disease; CRT 2023, Washington DC Feb 27, 2023.
3. Intention to treat. Iida O, VIVA 2019. RCT, randomized controlled trial; TLR, target lesion revascularization.
4. In IMPERIAL RCT, Eluvia K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p=0.1008.
5. Golzaar, J. et al, Journal of Endovascular Therapy, Jan 2020. https://doi.org/10.1177/1526602820901723.
6. Vermassen, F. VIVA Late-Breaking Clinical Trials June 2020.
7. In IMPERIAL Diabetic Subgroup, Eluvia K-M Primary Patency was 95.2% vs. 81.5% for Zilver PTX at 12 months. Diabetic = Medically Treated Diabetes.
8. Dr. Gray LINC presentation -2. Gray, W. 2 year Outcomes from the IMPERIAL Randomized Head to Head Study of Eluvia DES and ZilverPTX. LINC 2020.

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 "Instructions 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 indicated for improving 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 mm - 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** Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications. STERILE – DO NOT RESTERILIZE – SINGLE USE ONLY • 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. **POTENTIAL ADVERSE EVENTS** Potential 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 D.4**

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