Boston Scientific
Advancing science for life™

ELUVIA™ Drug-Eluting Vascular Stent System

2-year results from IMPERIAL, the world's first head-to-head DES SFA Trial[1]

Presented at LINC 2020

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

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%

2-Year Results: Eluvia demonstrated the **highest primary patency** ever reported in an SFA US Pivotal Trial for DES or DCB*

2-Year Durable and Consistent Results in Complex Lesions

	IMPERIAL RCT[2] (n = 309)	IMPERIAL Diabetic Subgroup Analysis (n = 116)	IMPERIAL Severe / Moderate Calcium Subgroup Analysis (n = 193)	IMPERIAL CTO Subgroup Analysis (n = 96)
Study Design	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global
24-month primary patency rate**	**83.0%**	**85.7%**	**85.0%**	**76.4%**
Lesion length (mm)	86.5	87.0	89.9	94.4
Severe calcification	40%	46%	n/a	n/a
Total occlusions	31%	25%	n/a	100%
	Highest primary patency ever reported 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**

* 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.

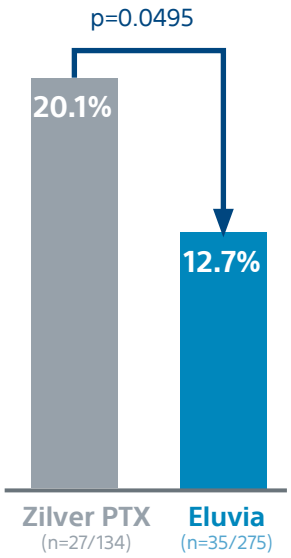
** Intention to treat. Kaplan-Meier estimate utilizing time-to-event of clinically-driven TLR up to 730 days and Duplex Ultrasound data at 24 months. Primary patency defined as duplex ultrasound PSVR ≤2.4, in the absence of clinically-driven target lesion revascularization or bypass of the target lesion,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

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).

2. In IMPERIAL RCT, Eluvia K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p=0.1008.

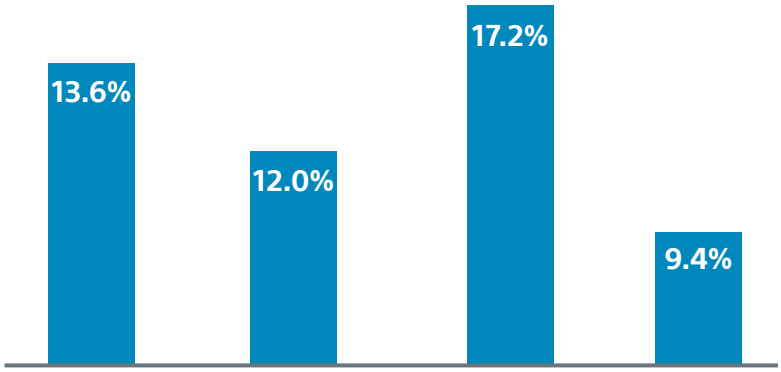
2-Year Results: In IMPERIAL RCT, Eluvia demonstrated a **statistically significant reduction in TLR** vs. Zilver PTX at 24 months

CLINICALLY-DRIVEN TLR RATE



IMPERIAL RCT

CONSISTENTLY LOW 2-YEAR CD-TLR IN CHALLENGING SFA DISEASE



24-MONTH SAFETY RESULTS*:

- 85.8% of Eluvia patients were free from Major Adverse Events at 24 months (vs. 79.9% of Zilver PTX patients)
- All-cause mortality for Eluvia was 7.1% (21/295) vs. 8.3% (12/145) for Zilver PTX (p=0.6649)

	Eluvia	Zilver PTX	p-value
24-month MAE	14.2%	20.1%	0.1236
All-Cause of Deaths at 1 Month	0.0%	0.0%	Undefined
Clinically-driven TLR	12.7%	20.1%	0.0495

*Intention to treat. Clinical Events Committee-adjudicated adverse events included major adverse events (MAE), all deaths, and stent thrombosis. MAEs defined as all causes of death through 1 month, target limb major amputation through 24 months, and target lesion revascularization through 24 months.

1. Long Lesion TLR is as-treated as presented at FDA Panel 2019. All other TLR data sets adapted from Gray, W. LINC 2020 Presentation, are intention to treat.

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:** A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients. See Section 8.1 of the DFU for further information. • 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 Carrie**r 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 B.3**

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Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

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