ELUVIA™ Drug-Eluting Vascular Stent System

12-month 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

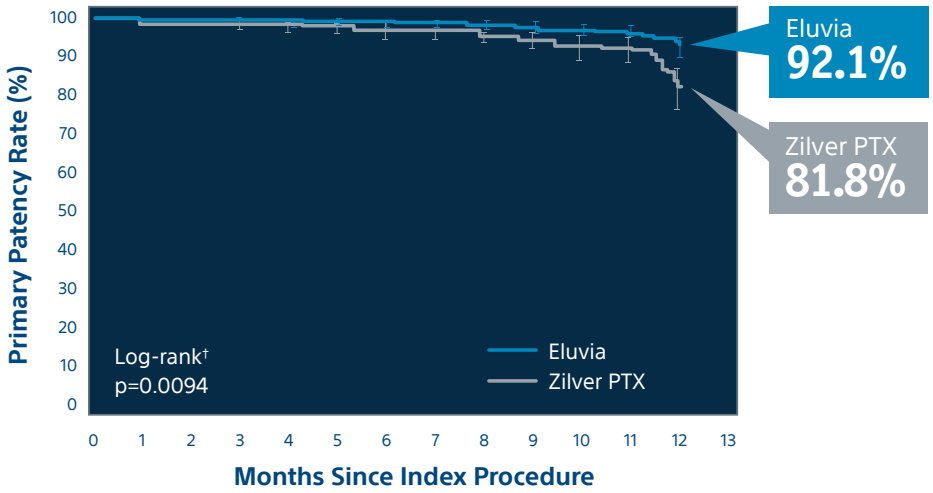
BASELINE CHARACTERISTICS:

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%

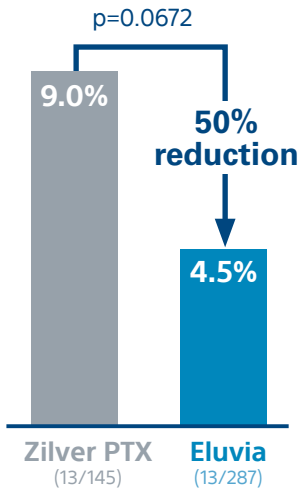
Lesion Characteristics	Eluvia (n=309)	Zilver PTX (n=156)
Target Lesion Length (mm)	86.5±36.9	81.8±37.3
Severely Calcified	40.1%	32.3%
Total Occlusions	31.2%	30.3%
Extending into Distal SFA	66.3%	65.4%

12-MONTH RESULTS: Eluvia demonstrated a **statistically significant difference in primary patency** and **half the TLR rate** vs. Zilver PTX at 12 months

PRIMARY PATENCY RATES K-M Estimate*



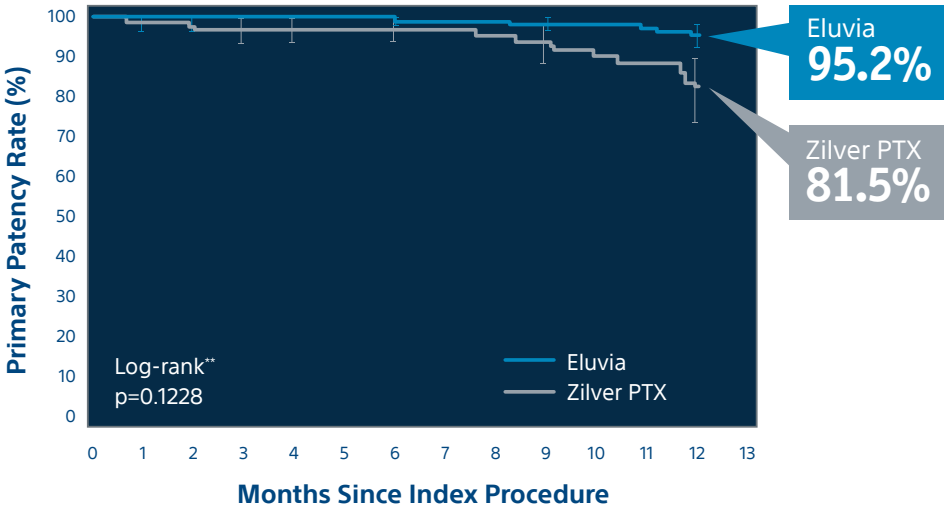
CLINICALLY-DRIVEN TLR RATE**



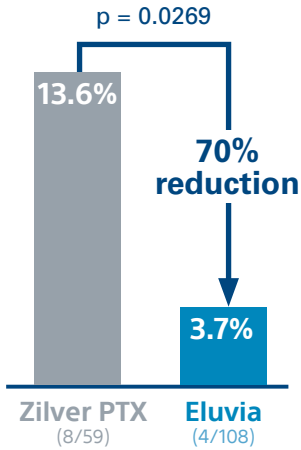
In IMPERIAL RCT and as reported in The Lancet, 1-year ITT, CEC adjudicated mortality rates were 2.1% (6/292) for Eluvia and 4.0% (6/150) for Zilver PTX (p=0.23).
*Kaplan Meier Estimate; Primary patency as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is ≤ 2.4 at the 12-month follow-up visit, in the absence of clinically-driven TLR or bypass of the target lesion.
** Gray, WA TCT 2018.
† Log-rank p-value compares the entire K-M curves from time zero to full one year follow-up window.
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).

IMPERIAL Diabetic^ Subgroup 12-Month Results: Eluvia demonstrated a **higher primary patency** and a statistically significant **TLR reduction of greater than 70%** in diabetic patients vs. Zilver PTX

PRIMARY PATENCY RATES
K-M Estimate*



CLINICALLY-DRIVEN TLR RATE[1]



12-Month Remarkable and Consistent Results in Complex Lesions

	IMPERIAL RCT[2] (n = 309)	IMPERIAL Long Lesions[3] (n = 50)	IMPERIAL Diabetic Subgroup Analysis[4] (n = 116)	IMPERIAL Severe / Moderate Calcium Subgroup Analysis (n = 193)	IMPERIAL CTO Subgroup Analysis (n = 96)	Münster Registry (n = 62)
Study Design	RCT, multicenter, global	Single arm multicenter, global	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global	Single-center registry
12-month primary patency rate*	**92.1%**	**91.0%**	**95.2%**	**92.5%**	**86.4%**	**87.0%[5]**
Lesion length (mm)	86.5	162.8	87.0	89.9	94.4	200
Severe calcification	40%	28%	46%	n/a	n/a	42%[6]
Total occlusions	31%	32%	25%	n/a	100%	79%
	Statistically significantly **higher primary patency**	Remarkable primary patency in **long lesions**	Statistically significantly **lower TLR (3.7%) and stent thrombosis rate (0.9%)**	Remarkable primary patency and **2.8% TLR** in **heavy calcium**	Low TLR (7.9%) and **stent thrombosis rate** (2.2%)	**CLI in nearly half** of patients

^Diabetes = medically-treated diabetic patients.
*Kaplan Meier Estimate; 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.
** Log-rank p-value compares the entire K-M curves from time zero to full one year follow-up window.
1. Intention to treat. Müller-Hülsbeck S, LINC 2019.
2. In IMPERIAL RCT, Eluvia K-M Primary Patency was 92.1% vs. 81.8% for Zilver PTX at 12 months.
3. Golzaar, J. et al, Journal of Endovascular Therapy, Jan 2020. https://doi.org/10.1177/1526602820901723
4. In IMPERIAL Diabetic Subgroup, Eluvia K-M Primary Patency was 95.2% vs. 81.5% for Zilver PTX at 12 months.
5. PSVR < 2.0.
6. Moderate and severely calcified.

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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