Boston Scientific
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ELUVIA™ Drug-Eluting Vascular Stent System

2-year results from IMPERIAL, the world's 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
- 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)	IMPERIAL Long Lesion Sub-Study[3] (n = 50)
Study Design	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global	Single arm multicenter, global
24-month primary patency rate**	**83.0%**	**85.7%**	**85.0%**	**76.4%**	**77.2%**
Lesion length (mm)	86.5	87.0	89.9	94.4	162.8
Severe calcification	40%	46%	n/a	n/a	28%
Total occlusions	31%	25%	n/a	100%	32%
	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**	**No stent thrombosis despite long, heavily calcified lesions[4]**

* 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. Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

** 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).

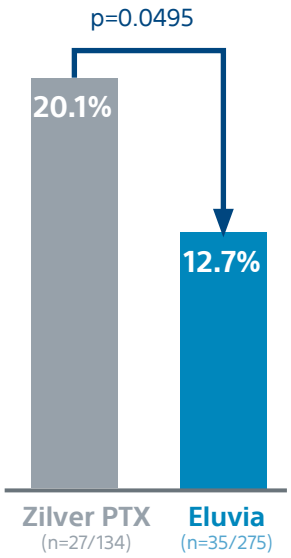
2. In IMPERIAL RCT, Eluvia K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p=0.1008.

3. Vermassen, F. VIVA Late-Breaking Clinical Trials June 2020.

4. 70% of IMPERIAL Long Lesion Sub-study lesions were Severe/Moderate Calcium

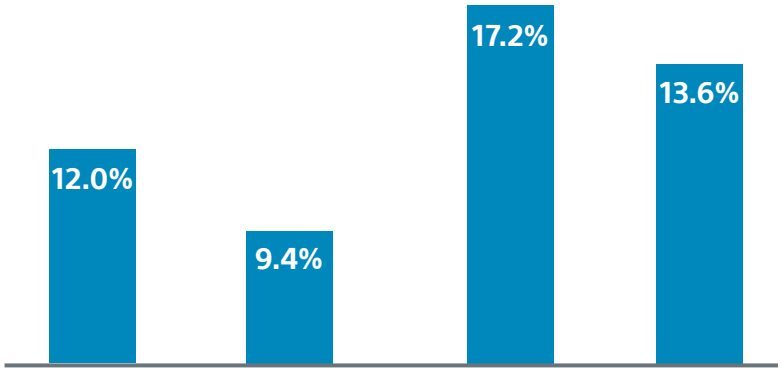
2-Year Results: In IMPERIAL RCT, Eluvia demonstrated a **statistically significant reduction in TLR** vs. Zilver PTX at 24 months

CLINICALLY-DRIVEN TLR RATE



IMPERIAL RCT

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



IMPERIAL Diabetic (n=12/100)

IMPERIAL Sev/Mod Calcium (n=16/170)

IMPERIAL CTO (n=15/87)

IMPERIAL Long Lesion Sub-Study (n=6/44)

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.

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