Boston Scientific
Advancing science for life™

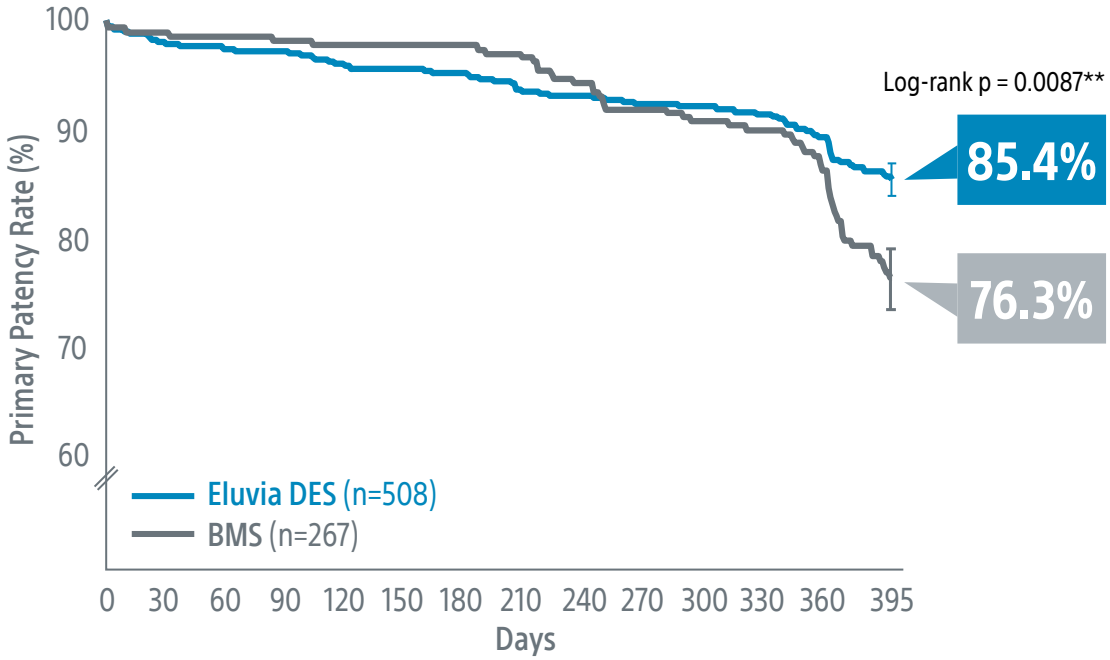
EMINENT CLINICAL TRIAL[1]

EMINENT is the largest randomized controlled trial (2:1) comparing Eluvia™ Drug-Eluting Vascular Stent System to self-expanding bare metal stents (BMS) for SFA/PPA
EU multi-center; superiority trial; core lab adjudicated

SUPERIOR EFFECTIVENESS:

Eluvia demonstrated **superiority over BMS[2]** with a **statistically significant primary patency** of **85.4% versus 76.3%** through 1-Year

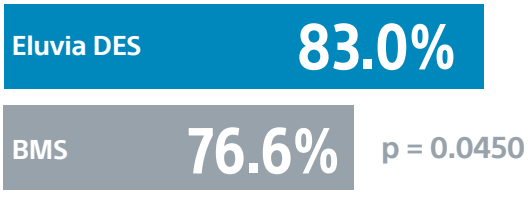
1-YEAR KAPLAN-MEIER PRIMARY PATENCY ESTIMATE*



SUSTAINED CLINICAL IMPROVEMENT:

Eluvia demonstrated a statistically significant greater rate of sustained clinical improvement without reintervention over BMS through 1-Year

1-YEAR PRIMARY SUSTAINED CLINICAL IMPROVEMENT***



*Kaplan-Meier Estimate: Primary patency defined as core-lab assessed duplex ultrasound peak systolic velocity ratio (PSVR) ≤ 2.4 at 1-year 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 point zero to day 395 (full 1-year follow-up window)
***In EMINENT, primary sustained clinical improvement was defined as an improvement (decrease) by at least 1 Rutherford category, without TLR.

1. EMINENT RCT 1-Year results presented by Yann Gouëffic, MD. VIVA 2021
2. EMINENT Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against commercially-available Self-Expanding Bare Nitinol Stents, single-blind, superiority design; independent core lab adjudication. Primary Endpoint: 1-Year Binary Primary Patency rate of 83.2% in the Eluvia arm vs. 74.3% in the Bare-Metal Stenting arm (p-value = 0.0077).

EMINENT TRIAL DETAILS:

- 775 (RCT 2:1) patients across 58 centers in 10 European countries
- Rutherford category 2, 3, or 4
- Degree of stenosis ≥ 70% (visual angiographic assessment)
- Vessel diameter ≥ 4 mm and ≤ 6 mm
- Total lesion length ≥ 30 mm and ≤ 210 mm

BASELINE CHARACTERISTICS	ELUVIA DES (n=508)	CONTROL (n=267)	p-value
Age (Years)	68.9 ± 8.7	68.9 ± 9.1	0.9739
Male Gender	71.5%	67.4%	0.2431
Diabetes Mellitus (medically-treated)	31.9%	32.6%	0.8440
History of Smoking (Current/Previous)	36.0%/39.6%	36.0%/41.6%	0.9849/0.5884
Percent Stenosis (%)	86.6 ± 15.2	85.5 ± 15.3	0.3629
Total Occlusions	42.3%	39.9%	0.5372
Total Stented Length (mm)	105.8 ± 48.4	109.2 ± 49.8	0.3858
Target Lesion Length (mm)	75.6 ± 50.3	72.2 ± 47.0	0.3815
Moderately Calcified	21.6%	26.0%	0.1849
Severely Calcified	30.3%	31.1%	0.8122

CONTROL STENT USAGE (n=294)

- **Innova**™ Vascular Self-Expanding Stent (Boston Scientific)
- **Supera**™ Peripheral Stent (Abbott)
- **LifeStent**™ Vascular Stent (Bard)
- **EverFlex**™ Self-Expanding Peripheral Stent (Covidien/Medtronic)
- **S.M.A.R.T.**® Flex Vascular Stent and **S.M.A.R.T. CONTROL**® Vascular Stent (Cordis/Cardinal)
- **Pulsar**®**-18** (Biotronik)
- **Complete**® **SE** Vascular Stent (Medtronic)

1-YEAR SAFETY RESULTS

No significant differences in Major Adverse Event (MAE) rates or All-Cause Death between **patients treated with Eluvia DES vs. BMS** through 1-Year.

	ELUVIA DES (n=492)	BMS (n=273)	p-value
All Death, Major Amputation, TLR	11.8% (56/474)	11.8% (31/263)	0.9912
All-Cause Death at 12 Months	2.7% (13/474)	1.1% (3/263)	0.1528
Target Limb Major Amputation	0.2% (1/474)	0.0% (0/263)	1.0000
Clinically-Driven Target Lesion Revascularization	8.4% (40/474)	10.6% (28/263)	0.3212

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 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. Potential 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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To order product or for more information contact customer service at 1.888.272.1001

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