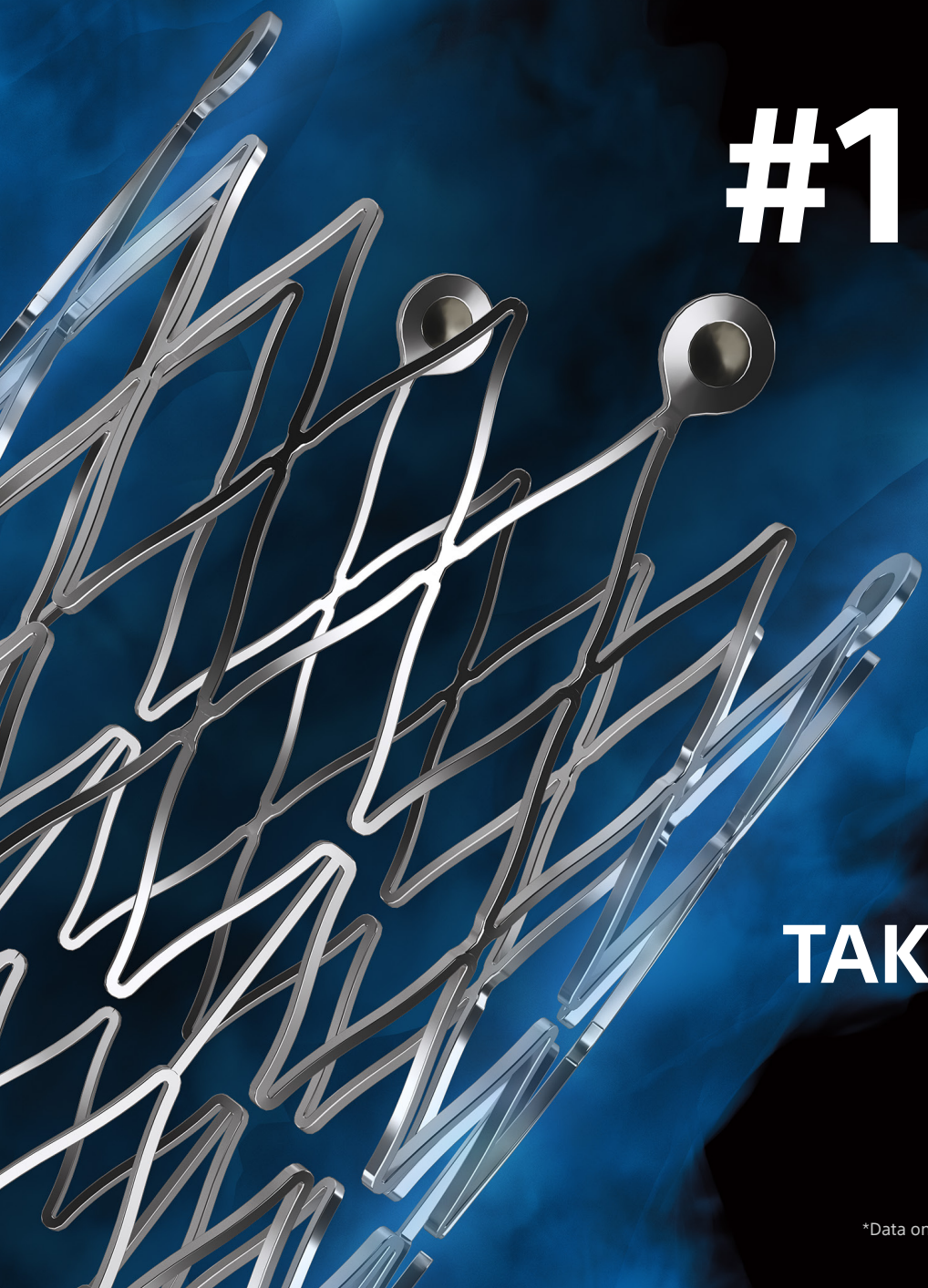
Boston Scientific
Advancing science for life™

ELUVIA™ Drug-Eluting Vascular Stent System

The standard of care in SFA stenting.



#1 Eluvia is the most-implanted SFA stent.*

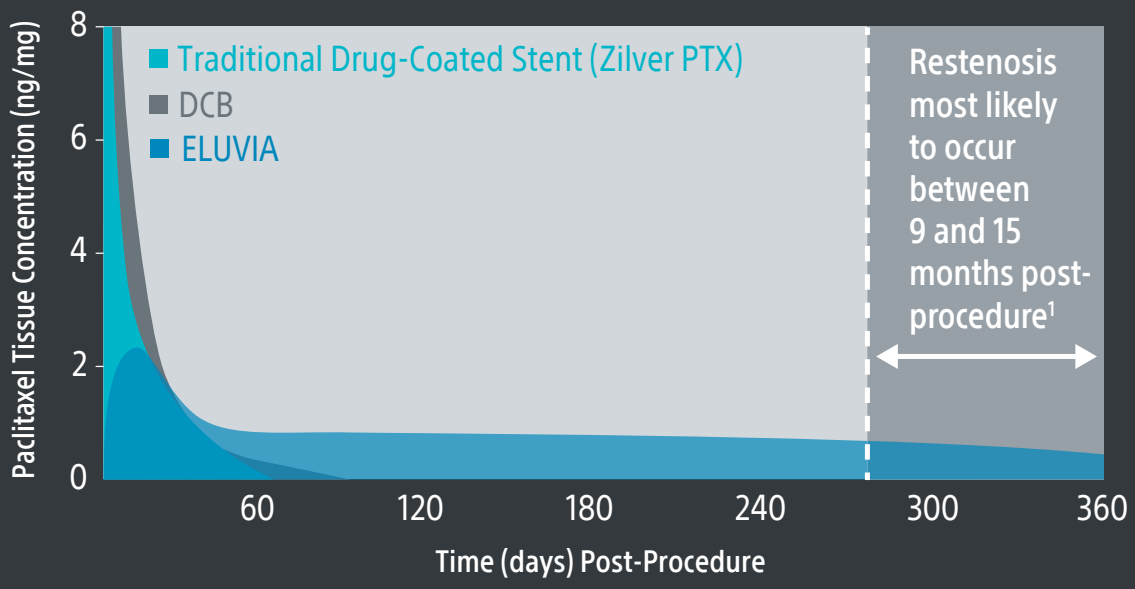
TAKE THE FIGHT TO PAD.

*Data on file at Boston Scientific. DRG US hospital market data, June 2024

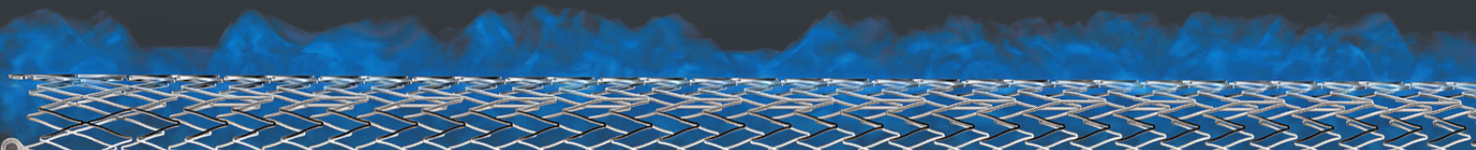
Engineered for the challenges of the SFA.

Eluvia drug-eluting stent is designed with over two decades of elution engineering experience at Boston Scientific. It is the only DES designed to efficiently deliver drug to the target lesion for over a year, when restenosis is most likely to occur in the SFA.

ONLY ELUVIA DES OFFERS **SUSTAINED DRUG RELEASE** TO MATCH THE SFA RESTENOTIC CASCADE[1]



ELUVIA DES HAS THE **LOWEST DRUG DOSE** DENSITY OF ANY PTX THERAPY[2]

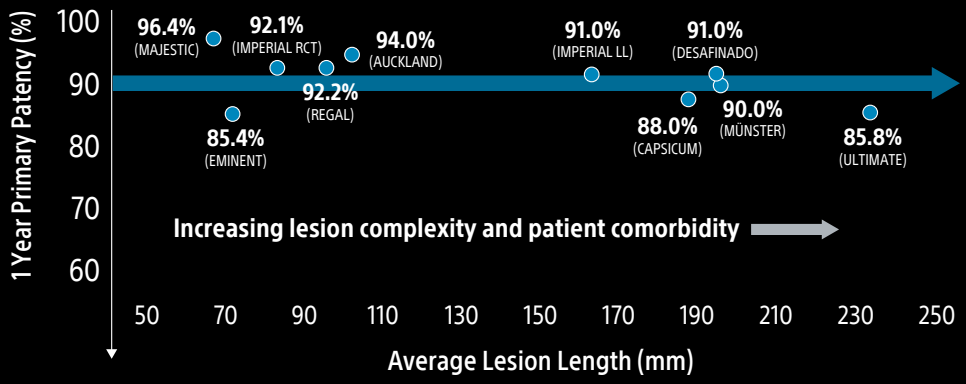


The standard of care in SFA stenting.

Eluvia DES has demonstrated exceptional and consistent outcomes in multiple randomized control trials and real-world registries in even the most challenging complex lesions.

HIGHEST PRIMARY PATENCY

1-Year K-M primary patency rate and lesion length[3]

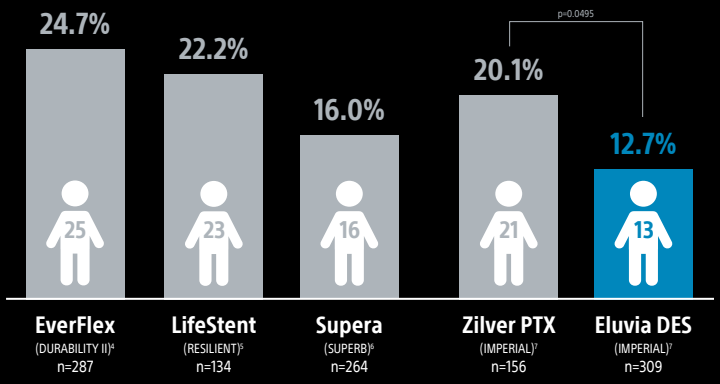


~90% Primary Patency at 1 Year

THE LOWEST REVASCULARIZATION RATE OF ANY SFA STENT

2-Year clinically-driven TLR

Number of patients requiring reintervention within 2 years



Eluvia shows 20-50% reduction in repeat procedures compared to competitive stents[4]

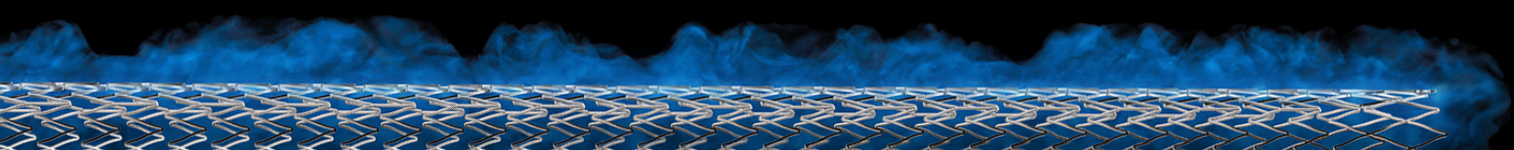
Nearly 9 out of every 10 Eluvia patients did not require a reintervention within 2 years[4]

SUSTAINED LONG-TERM RESULTS

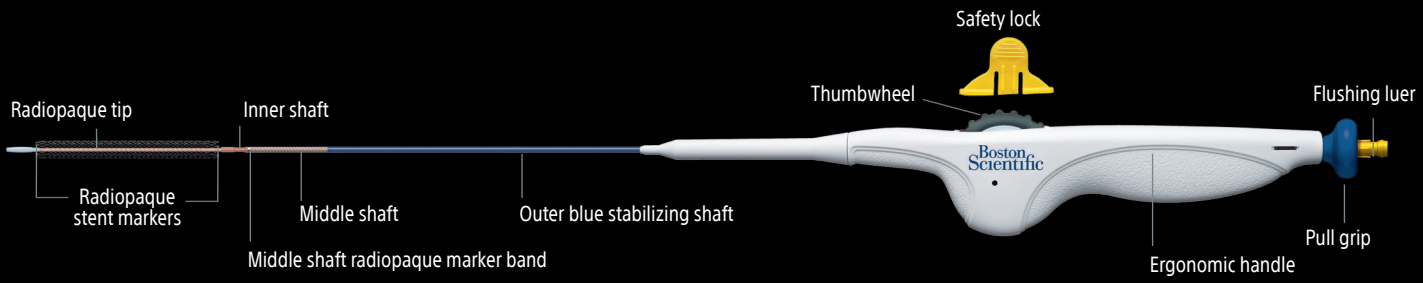
5-Year clinically-driven TLR

Münster registry recorded
79% freedom from CD-TLR at 5 years[8]

Nearly 8 out of every 10 patients did not require a reintervention at 5-years[8]



ELUVIA™ Drug-Eluting Vascular Stent System



		Stent diameter (mm)		
		6	7	
		Delivery system working length 130 cm		Minimum sheath size
Stent Length (mm)	40	H74939294600410 08714729876571	H74939294700410 08714729876694	6F
	60	H74939294600610 08714729876588	H74939294700610 08714729876700	6F
	80	H74939294600810 08714729876595	H74939294700810 08714729876717	6F
	100	H74939294601010 08714729876601	H74939294701010 08714729876724	6F
	120	H74939294601210 08714729876618	H74939294701210 08714729876731	6F
	150	H74939294601510 08714729876625	H74939294701510 08714729876748	6F

1. Iida, O. et al. Catheterization and Cardiovascular Interventions. 2011; 78:611-617. Kimura T, et al. N Engl J Med 1996,334-:561-567. Based on pre-clinical PK analysis for Zilver PTX. (Dake MD, et al. J Vasc Interv Radiol. 2011;22(5):603-610); IN.PACT Pacific, Lutonix and Ranger DCBs (GongoraCA, et al. JACC Cardiovasc Interv. 2015 Jul;9(8):1115-1123. doi: 10.1016/j.jcin.2015.03.020.); and Eluvia (Müller-Hülsbeck S. Expert Opin Drug Deliv.2016 Oct 5:106.) Data on file at Boston Scientific.
2. Drug Dose Data from Eluvia DES, Zilver PTX, Lutonix 018 DCB, Lutonix 035 DCB, Stellarex 035 DCB, Surveil 035 DCB and Ranger DCB Instructions for Use. Data on file at Boston Scientific.
3. Müller-Hülsbeck S, et al. Cardiovasc Intervent Radiol. 2017;40(12):1832-1838. Gouëffic Y, et al. Circulation. 2022;146(21):1564-1576. Gray WA, LINC 2020. Lansink W, LINC 2023. Holden A, LINC 2020. Golzar J, et al. J Endovasc Ther. 2020;27(2): 296-303.Iida O, et al. Vasc Med. Published online Mar 8, 2024. Kum S, et al. Vasc Med. 2021;26(3):267-272. Stavroulakis K, et al. JACC Cardiovasc Interv. 2021;14(6):692-701. Ichihashi S, et al. Eur J Vasc Endovasc Surg. 2022;64(4):359-366.
4. Rocha-Singh KJ, et al. Catheter Cardiovasc Interv. 2015;86(1):164-170. Laird et al (2012) Endovasc Ther. 2012; 19:1-9; Severe Calcification: Laird et al (2010) Circ Cardiovasc Interv. Garcia et al (2017) Catheterization and Cardiovascular Interventions 89:1259-1267 (2017). Müller-Hülsbeck S, et al. Cardiovasc Intervent Radiol. 2021;44(3):368-375.
5. Laird et al (2012) Endovasc Ther. 2012; 19:1-9; Severe Calcification: Laird et al (2010) Circ Cardiovasc Interv.
6. Garcia et al (2017) Catheterization and Cardiovascular Interventions 89:1259-1267 (2017).
7. Müller-Hülsbeck S, et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44(3):368-375. doi:10.1007/s00270-020-02693-1
8. Torsello, G.F. et al. Cardiovasc Intervent Radiol 47, 177-185 (2024).

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 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 4.0-6.0 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. **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 D.2

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