Boston Scientific
Advancing science for life™

ELUVIA™ Drug-Eluting Vascular Stent System

IMPERIAL CTO Subgroup Analysis: Remarkable and Consistent Primary Patency, Even in Challenging Lesions

OBJECTIVE: This subgroup analysis provides clinical data on 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 in **Chronic Total Occlusions (CTOs).**

CTO BASELINE CHARACTERISTICS:

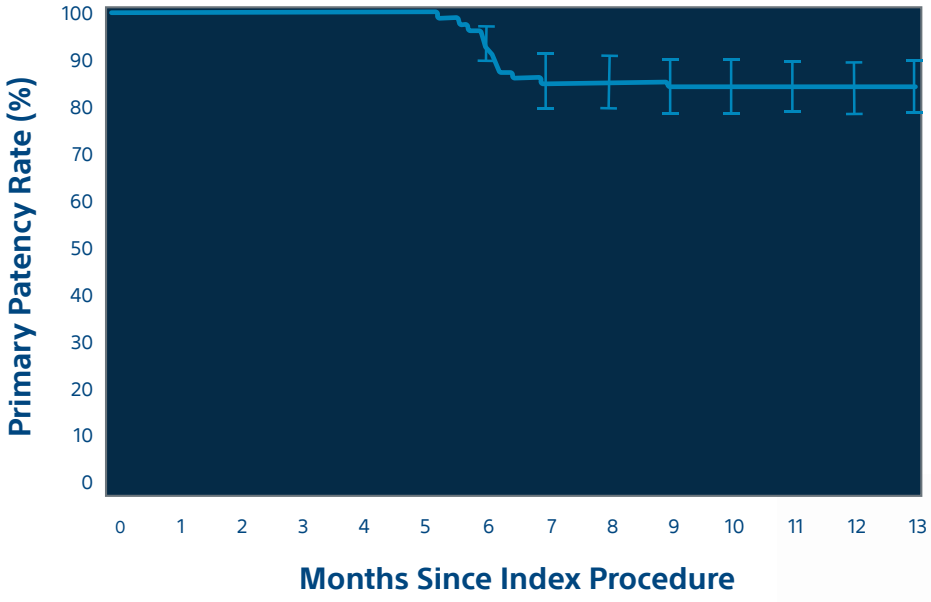
Patient Demographics	Eluvia (n=96)
Diabetes Mellitus	30.2%
History of Smoking	84.4%
Hypertension	71.9%
Coronary Artery Disease	40.0%

Lesion Characteristics	Eluvia (n=96)
Target Lesion Length (mm)	94.4±34.3
Reference Vessel Diameter (mm)	4.9±0.8
Percent Diameter Stenosis	100.0±0.0

12-MONTH PRIMARY PATENCY & SAFETY RESULTS for CTOs:

Eluvia demonstrated **83.9% primary patency in chronic total occlusions** in the IMPERIAL CTO Subgroup.*

12-MONTH KAPLAN-MEIER ESTIMATE PRIMARY PATENCY RATE**



83.9%
Eluvia

* Versus 90.6% in the non-CTO arm of the IMPERIAL subgroup.
**Kaplan Meier Estimate; 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.

IMPERIAL CTO Subgroup Analysis | 12-month results

12-MONTH SAFETY RESULTS:

	Eluvia (n=96)
12-month MAE	7.9%
Target Limb Major Amputation	0.0%
All Causes of Deaths at 1 Month	0.0%
Clinically-driven TLR	7.9%
Stent Thrombosis	2.2%

7.9% TLR

2.2% STENT THROMBOSIS

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**: • 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 A.1**

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

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