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ELUVIA™ Drug-Eluting Vascular Stent System

87.9% Primary Patency in the IMPERIAL Long Lesion Sub-Study (162.8 mm lesion length)[1]

OBJECTIVE: To evaluate the safety and effectiveness of the Eluvia Drug-Eluting Vascular Stent System for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions >140 mm and ≤ 190 mm in length.

TRIAL DESIGN: A 50 subject concurrent, non-blinded, non-randomized, single arm (Eluvia) long lesion sub-study.

Key Eligibility Criteria

- Chronic, symptomatic lower limb ischemia defined as Rutherford categories 2, 3 or 4.
- Stenotic, restenotic or occlusive lesion(s) located in the native SFA and/or PPA.
- Degree of stenosis ≥ 70% by visual angiographic assessment.
- Vessel diameter ≥ 4 and ≤ 6 mm
- Patent infrapopliteal and popliteal artery, i.e., single vessel runoff or better with at least one of three vessels patent (<50% stenosis) to the ankle or foot with no planned intervention.

Primary Safety Endpoints

The primary safety endpoint assesses the 12-month MAE-free rate.

Primary Effectiveness Endpoint

The primary effectiveness endpoint assesses the 12-month primary patency.

BASELINE CHARACTERISTICS:

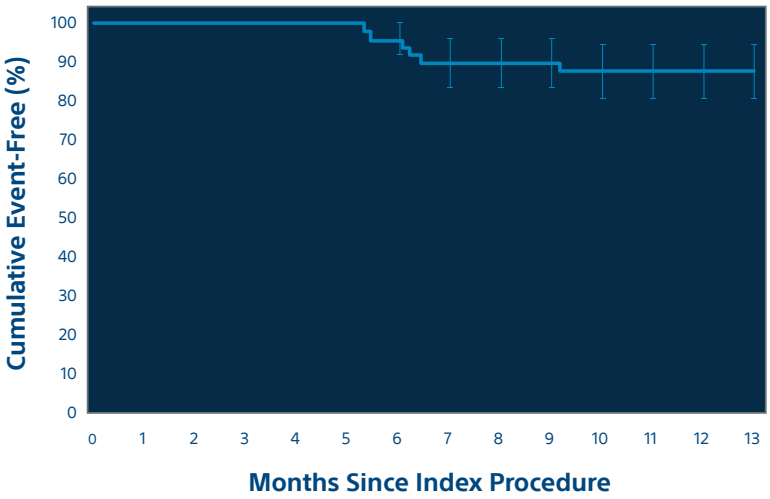
Patient Demographics	Eluvia (n=50)
Age (Years)	68.2±8.9
Male Gender	64.0%
Diabetes Mellitus	40.0%
History of Smoking	84.0%
Hypertension	92.0%
Hyperlipidemia	82.0%
Coronary Artery Disease	56.0%

Lesion Characteristics	Eluvia (n=50)
Target Lesion Length (mm)	162.8±34.7
Reference Vessel Diameter (mm)	4.7±0.7
Moderate Calcification	42.0%
Severely Calcified	28.0%
Percent Diameter Stenosis	81.9±15.0
Total Occlusions	32.0%
Extending into Distal SFA (including proximal popliteal)	76.0%
Stented Segment Length (mm)	193.3±28.9

12-MONTH PRIMARY PATENCY RESULTS:

Eluvia demonstrated **87.9% primary patency** in the IMPERIAL Long Lesion Sub-Study.

IMPERIAL TRIAL 12-Month PRIMARY PATENCY RATE K-M Estimate*



Eluvia
87.9%

* Defined as a binary endpoint determined to be patent when the 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.

IMPERIAL Long Lesion Sub-Study | 12-month results

12-MONTH SAFETY RESULTS:

- 93.5% of patients were free of Major Adverse Events at 12 months

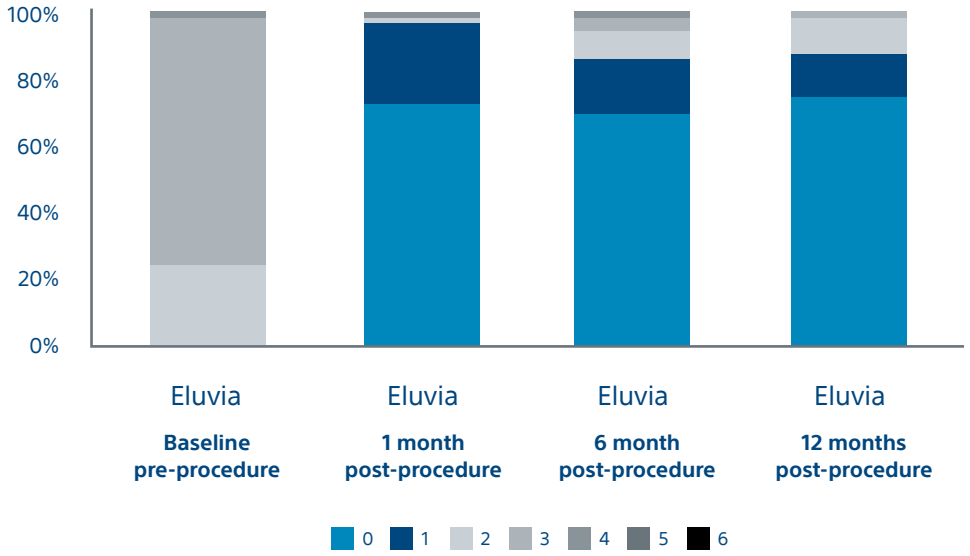
	Eluvia (n=50)
12-month MAE	6.5%
All Causes of Deaths at 1 Month	0.0%
Target Limb Major Amputation	0.0%
Target Lesion Revascularization	6.5%
Stent Thrombosis	0.0%

6.5% TLR
in 162.8 mm Lesions

PATIENT OUTCOMES:

- 87.2% of Eluvia patients presented with no or minimal claudication (Rutherford 0-1) at 12 months
- 91.5% of Eluvia patients had improvement by at least 1 Rutherford category compared with baseline without the need for TLR

RUTHERFORD CATEGORY



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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