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ICD-10-PCS Code Request for Insertion of Sustained Release Drug-Eluting Stent(s) of Above the Knee Arteries

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Peripheral Arterial Disease

- PAD affects over 8.5 million Americans[1]
- PAD prevalence among Medicare beneficiaries: 10-14%[2] or an estimated 6 million+ beneficiaries
- 56,300 Inpatient Medicare PAD primary or secondary diagnosis discharges[3]

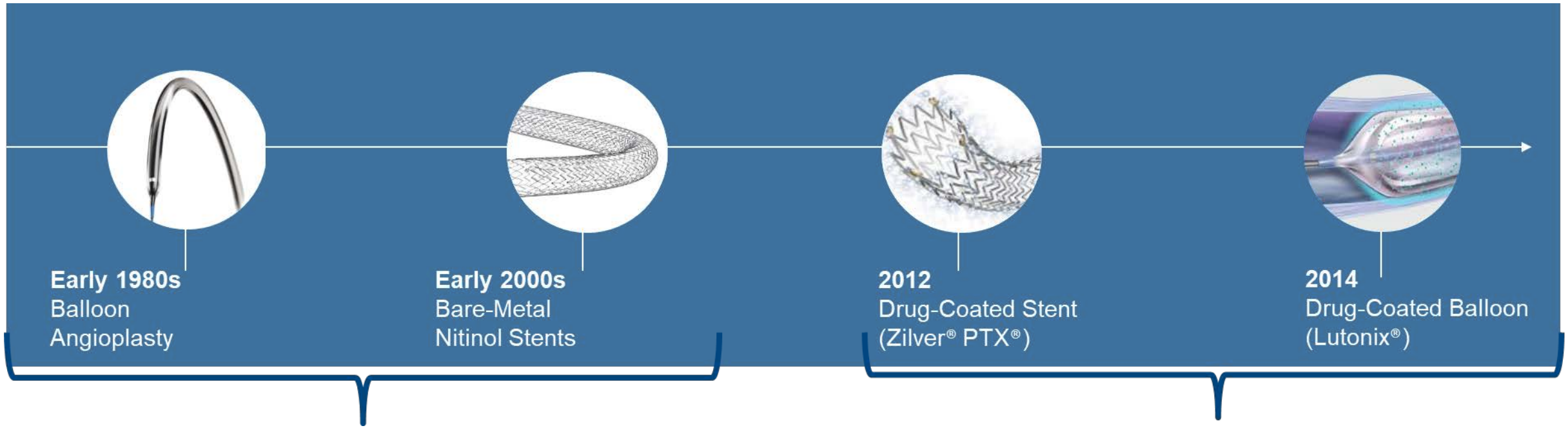
Claudication is pain and/or cramping in the leg due to inadequate blood flow to the muscles, typically felt while walking.

Image sourced from cardiologyconsultantsorlando.com

- Patients with claudication are often treated with endovascular procedures, including stenting.
- 11,086 Inpatient Medicare PAD revascularization femoral/popliteal stent procedure discharges in FY2017

Sources: 1. American Heart Association, Peripheral Artery Disease (PAD) Resources
2. Kalbaugh CA et al. J Am Heart Assoc. 2017 May 3;6(5).
3. Definitive Healthcare (2018). 2017 Centers for Medicare and Medicaid Services (CMS) Medicare Standard Analytical Files (SAF). Retrieved from https://www.definitivehc.com/
4. FY17 Medicare Provider Analysis and Review files

Treatments for PAD

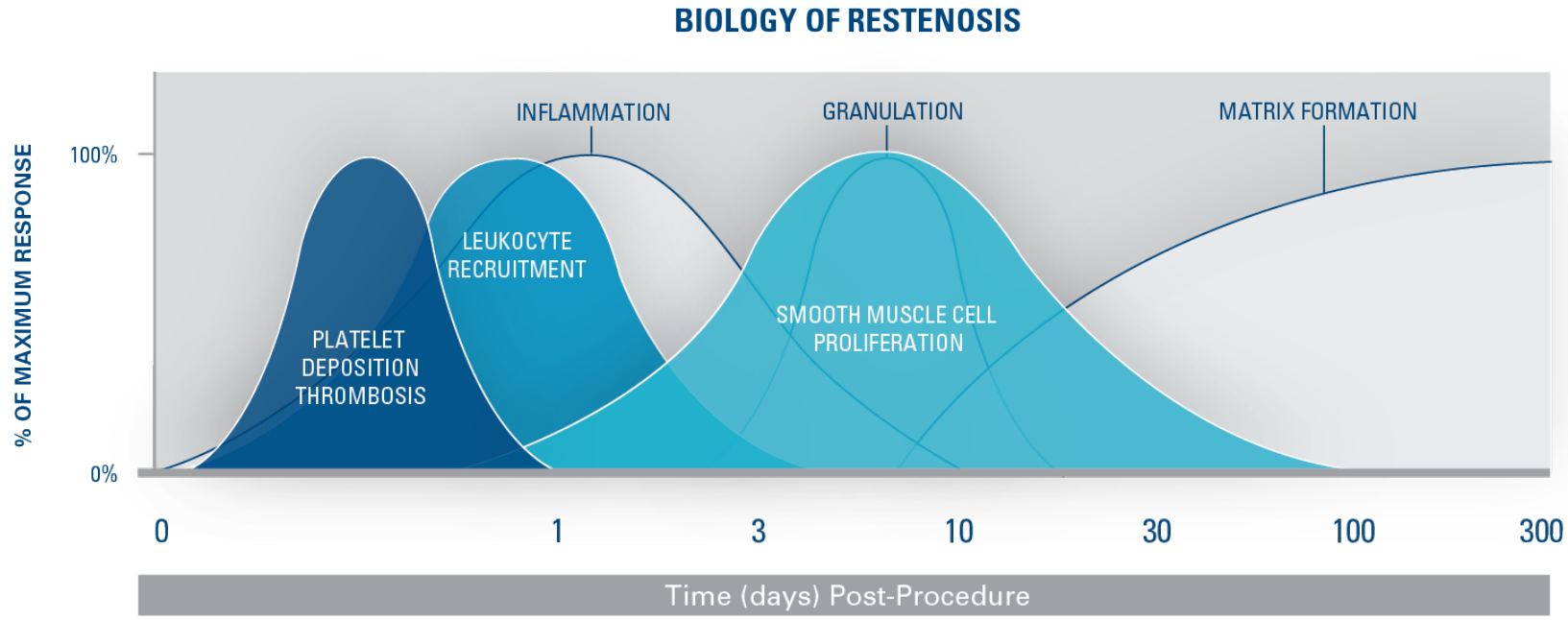


Early technologies lacked anti-restenotic drug and therefore had higher reintervention rates

First generation drug coated technologies only deliver anti-restenotic drug over the first 60 days

Zilver PTX is a registered trademark of Cook Medical. Image sourced from Cook website.
Lutonix is a registered trademark of CR Bard, Inc. Image sourced from Bard website.

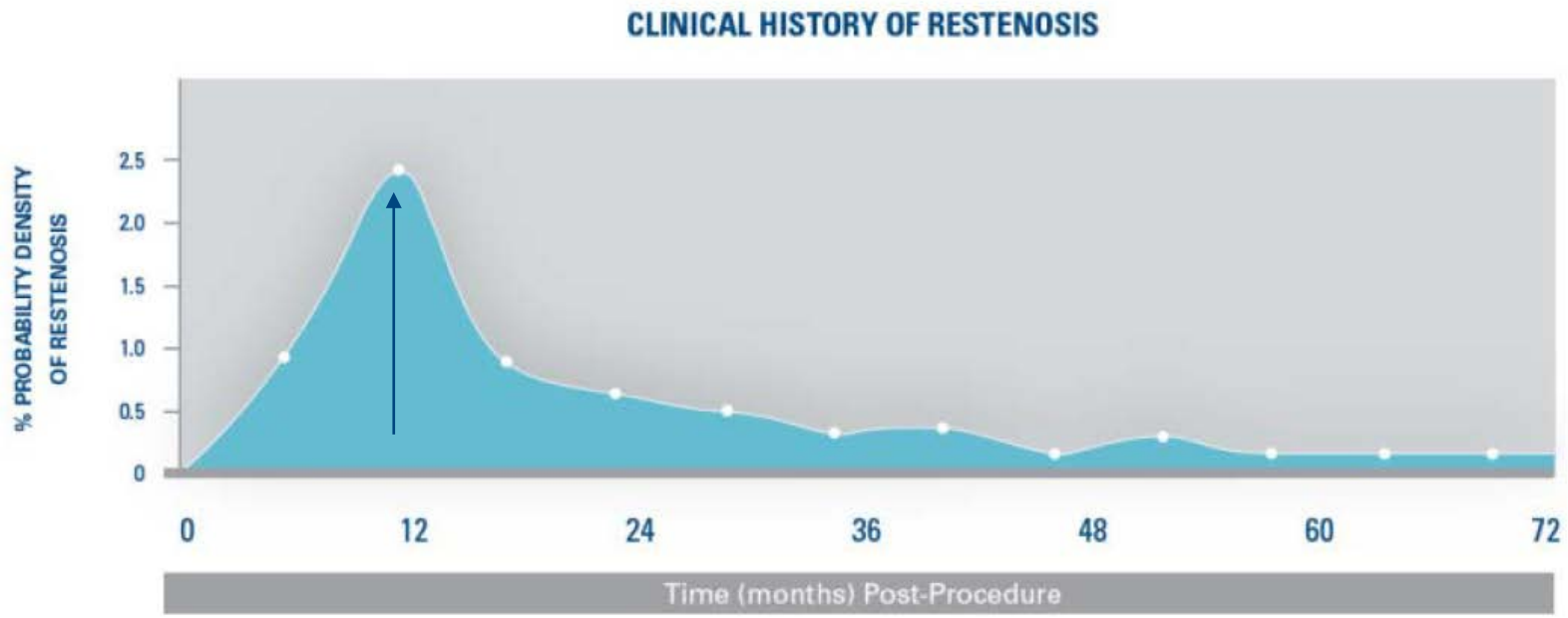
The Goal: Inhibit Restenotic Cascade



- Smooth muscle cell proliferation can continue for up to 100 days or longer after stent implantation
- Extracellular matrix formation can continue well beyond 300 days

Sources: Forrester et al. *JACC* 1991; 758-769.

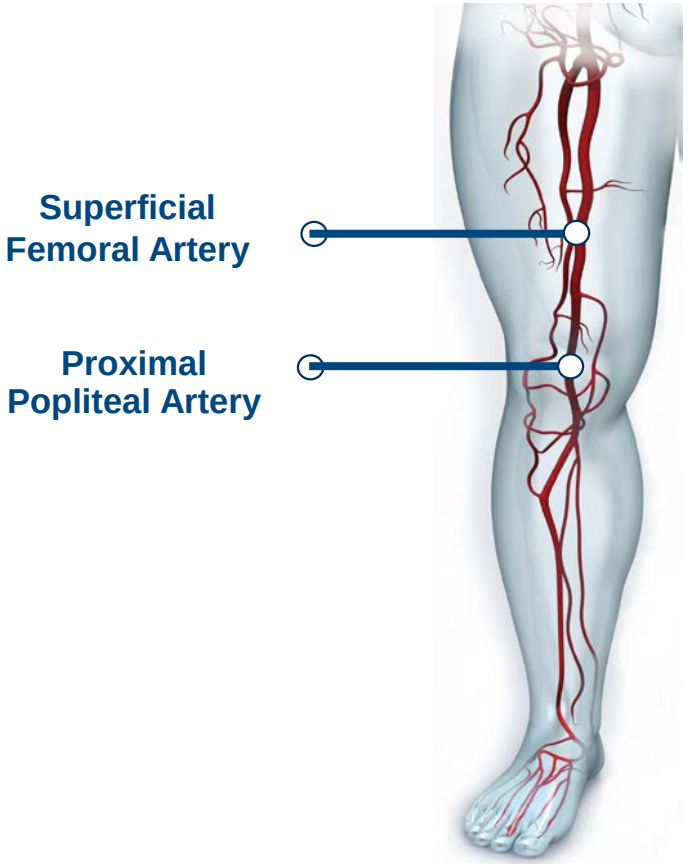
The SFA is Highly Susceptible to Restenosis:
Need longer effective duration of anti-proliferative



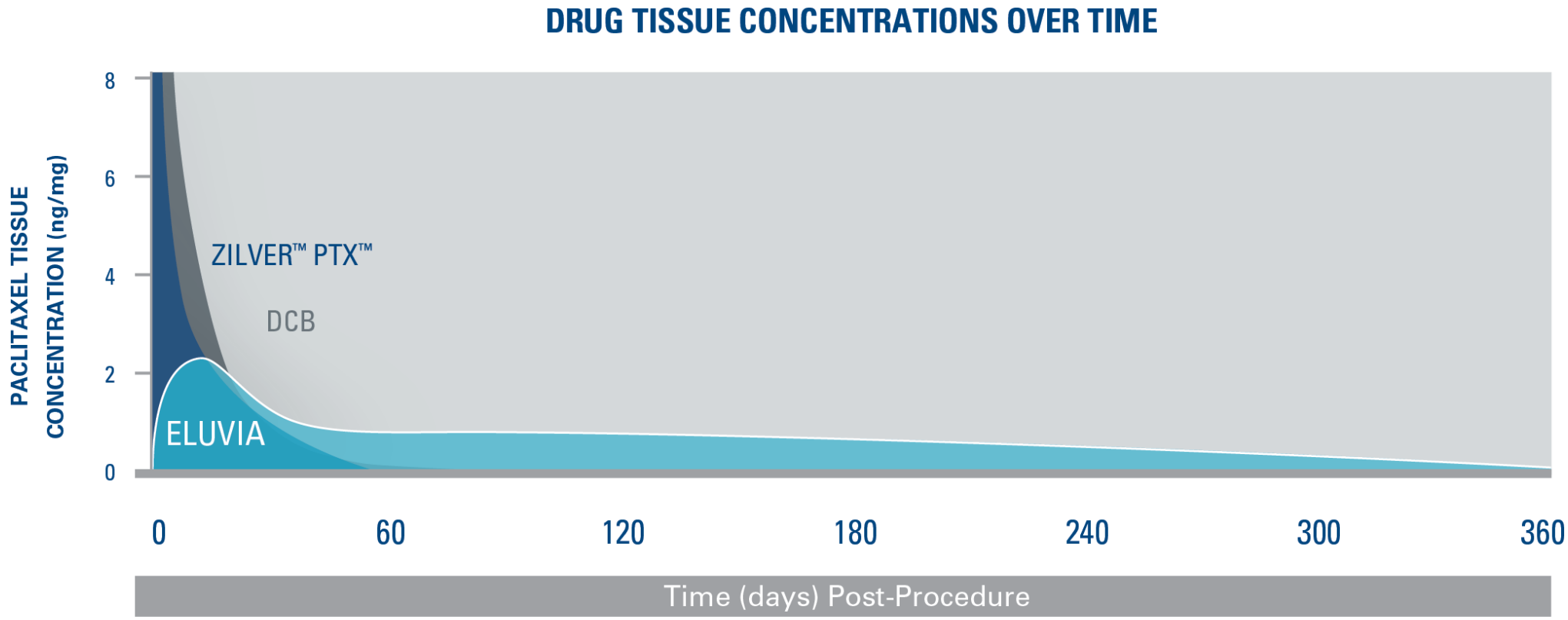
- Interventional treatment elicits a healing process from the artery, increasing the risk for restenosis.
- The SFA is exposed to mechanical forces such as bending and twisting, prolonging the healing process.
- This extended healing process increases the timespan during which restenosis is likely to occur.

Sources: Forrester et al. *JACC* 1991; 758-769; Iida, O. et al. *Catheterization and Cardiovascular Interventions*. 2011; 78:611-617;
Kimura T, et al. *N Engl J Med* 1996; 334:561-567

Eluvia™ Drug-Eluting Vascular Stent System



Eluvia™: The First and Only FDA-Approved Device with Sustained Drug Release to Match the SFA Restenotic Cascade



Sources: Based on pre-clinical PK analysis. Data on file at Boston Scientific; Dake MD, et al. J Vasc Interv Radiol. 2011;22(5):603-610

IMPERIAL Pivotal Randomized Controlled Trial
Overview

Purpose: 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 up to 140 mm in length.

Clinical Hypothesis: A drug-eluting stent with sustained drug release over one year will improve patency.

Trial Design

Global, multi-center trial consisting of:

- 465 subjects at 64 investigational sites worldwide
- A prospective, multicenter, 2:1 randomization against the Zilver® PTX® stent, controlled, single-blind, non-inferiority trial (RCT)
- Superiority analysis of primary patency in the full-analysis cohort was a prespecified post-hoc analysis
- Core lab adjudicated

Primary Endpoints

Safety:

- Major Adverse Events defined as all causes of death through 1 month, Target Limb Major Amputation through 12 months and/or Target Lesion Revascularization (TLR) through 12 months.

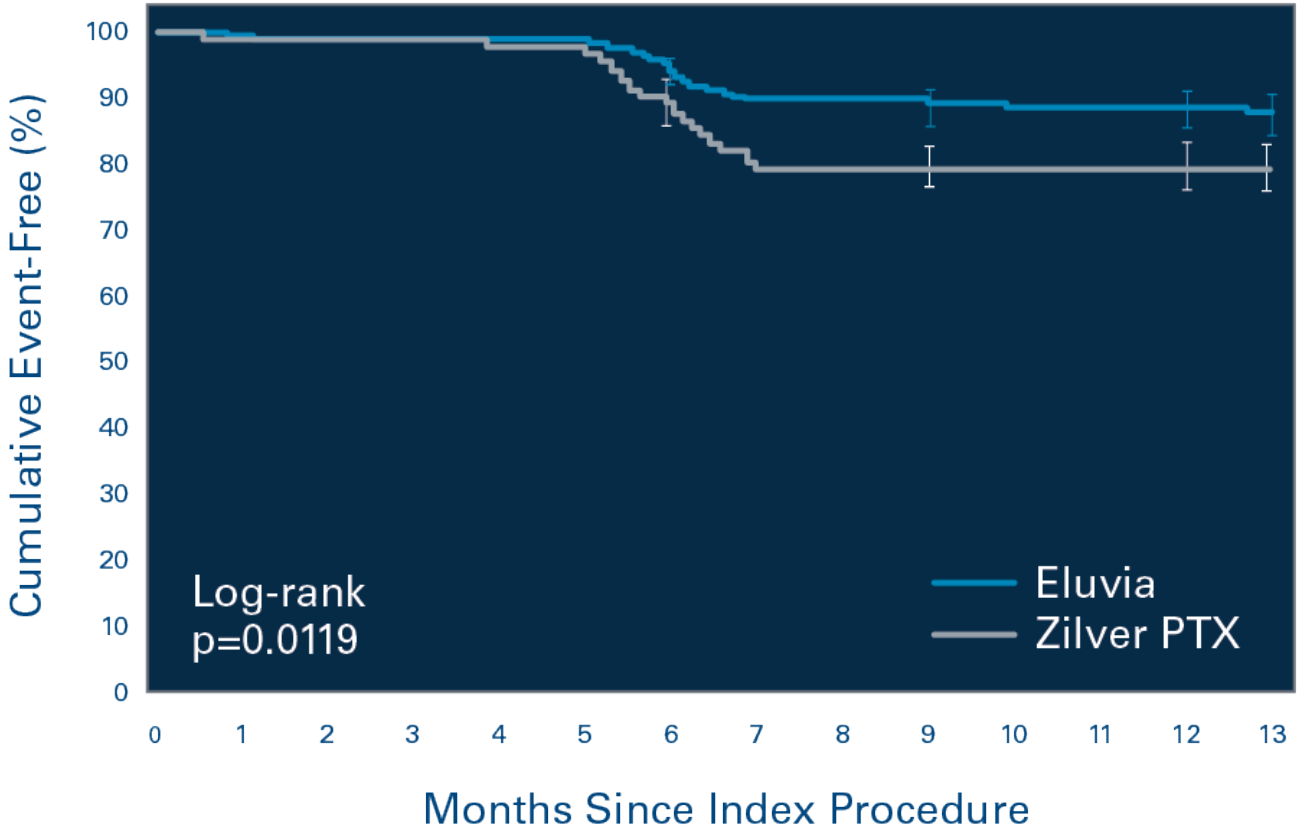
Efficacy:

- Assess primary vessel patency at 12 months post-procedure.

Sources: Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet. 2018 Sep 24.

IMPERIAL Trial: First Head-to-Head Trial with Paclitaxel Stents

Eluvia™ Achieved Superiority vs. Zilver® PTX®*



Eluvia (n=309)
88.5%

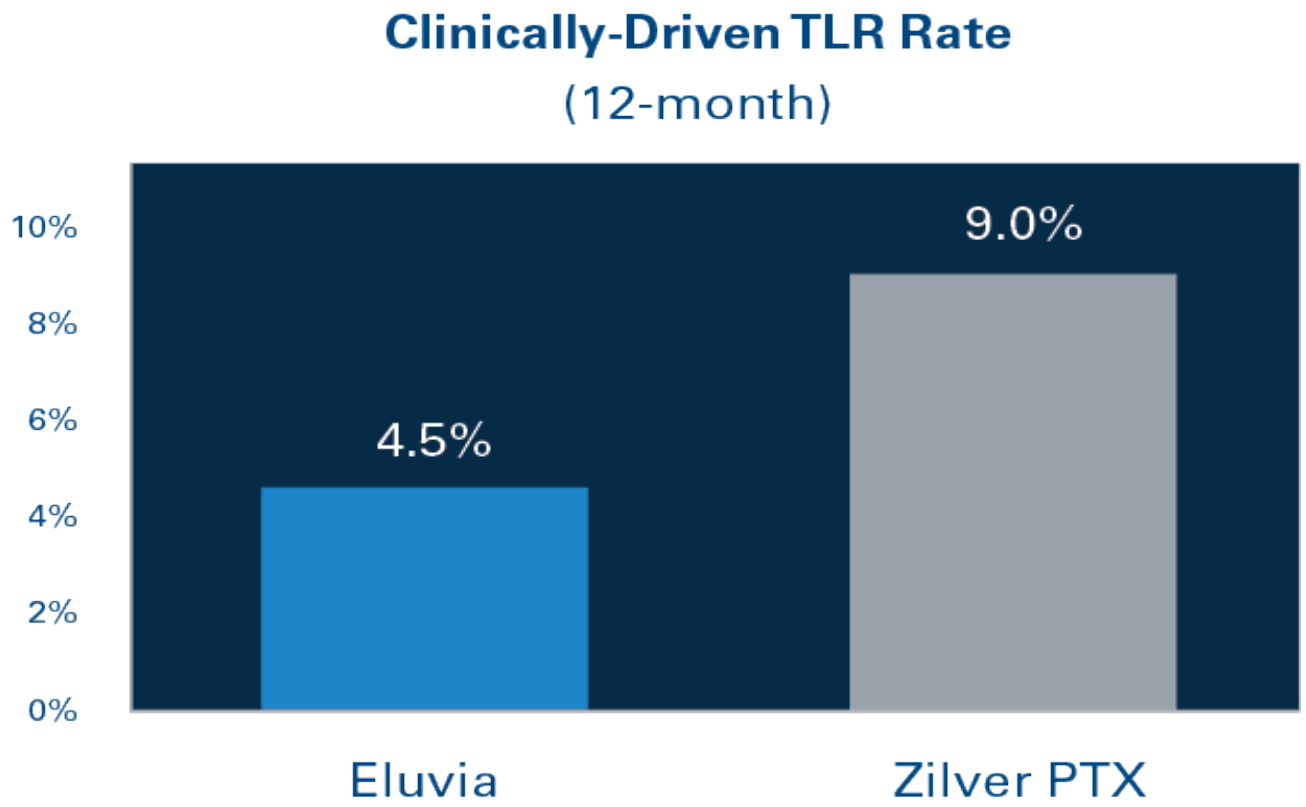
Zilver PTX (n=156)
79.5%

(Kaplan-Meier Estimate)

*Superiority determined in a pre-specified post-hoc superiority analysis. Twelve month primary patency rate of 86.8% in the Eluvia™ arm vs 77.5% in the Zilver® PTX® arm (p-value = 0.0144).

Sources: Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet. 2018 Sep 24.

IMPERIAL Trial
Eluvia™ Patients Had Half the Rate of Reintervention



p value = 0.0672

Sources: Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet. 2018 Sep 24.

IMPERIAL Trial

Similar Functional Outcomes, but Eluvia™ Had Half the Reinterventions

these improvements for the Zilver® PTX® group were associated with twice as many TLRs.

	Eluvia™	Zilver® PTX®
Improvement by at least 1 Rutherford category compared to baseline – without TLR	89.6%	83.1%
EQ-5D index values at 12 months	0.8	0.8

Sources: Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet. 2018 Sep 24.

IMPERIAL Trial
Analysis of Hospitalization & Device-Related Complications

	Eluvia™	Zilver® PTX®
Hospital Readmission Rate at 12 Months	3.9%	7.1%
Device-Related Adverse Events	8.1%	14.1%
Average Number of Days in Hospital Post-Index Procedure		
TLR/Total Vessel Revascularization (TVR)	2.8	7.1
Procedure/Device-Related Adverse Events	2.7	4.5

Patients treated with Eluvia™ had a lower rate of device-related complications than patients treated with Zilver® PTX®

Sources: Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet. 2018 Sep 24.

Thank you