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Advancing science for life™

**ELUVIA™** Drug-Eluting Vascular Stent System

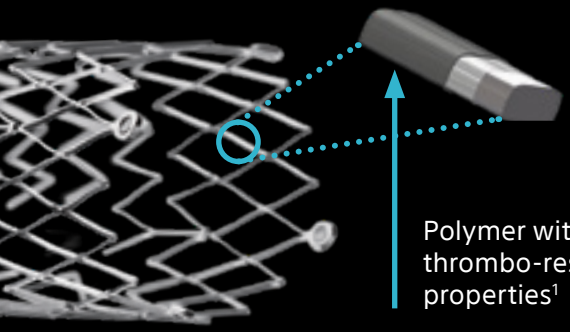
# Sustained Release. Superior Results.

IMPERIAL Trial: A global randomized controlled multi-center trial with 2:1 randomization of the ELUVIA™ Drug-Eluting Stent against Cook Medical's Zilver™ PTX™ Stent, single-blind, non-inferiority design; independent core lab adjudication. Superiority determined in a post hoc analysis that was specified prior to unblinding. 12-Month Primary Patency rate of 86.8% in the ELUVIA arm vs. 77.5% in the Zilver PTX arm (p-value = 0.0144).

# Lowest drug dose delivered by the world's most proven polymer

## Polymer-based technology with proven biocompatibility

The ELUVIA Stent uses the same fluoropolymer as the PROMUS™ and XIENCE™ coronary stents which have a proven history of safety in the body.

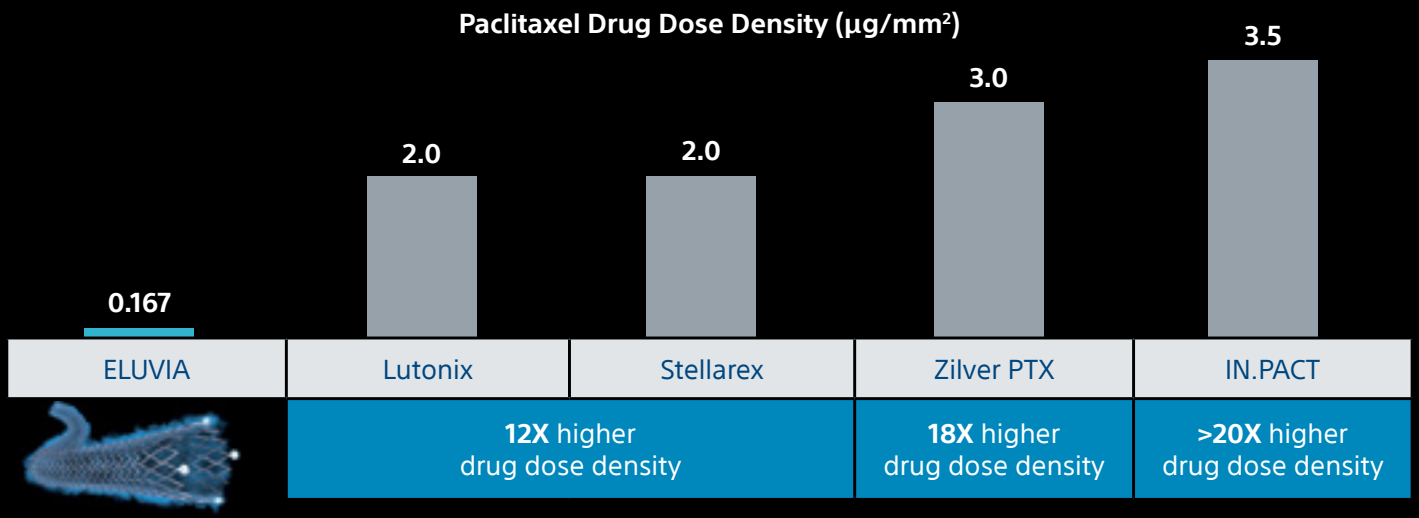


Polymer with thrombo-resistant properties[1]

**20 Million+**
Implants[2]

**100,000+**
Patients Studied in Clinical Trials[3]

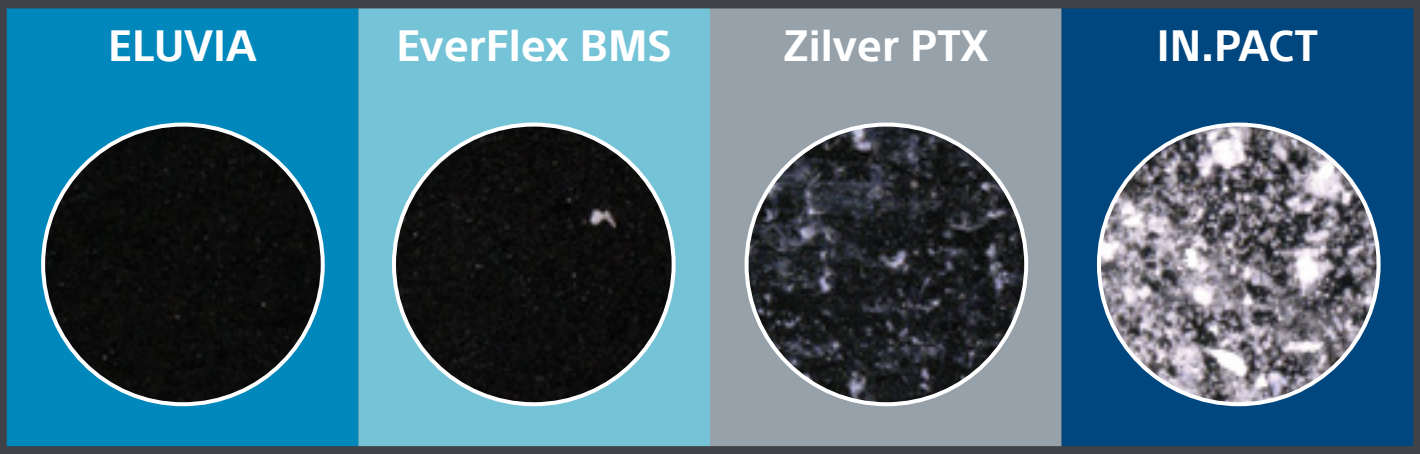
## ELUVIA has the lowest drug dose density of any drug-eluting SFA technology[4]




1. Mori H, et al. Expert Review of Medical Devices. 2017. doi:10.1080/17434440.2017.1363646.
2. Data on file at Boston Scientific. Represents total global sales of the PROMUS (Boston Scientific) and XIENCE (Abbott) stents since 2006.
3. Data on file at Boston Scientific. Represents total population of patients studied in the PROMUS and XIENCE series of clinical trials.
4. Data from ELUVIA, Lutonix, Stellarex, Zilver PTX and IN.PACT Directions for Use.

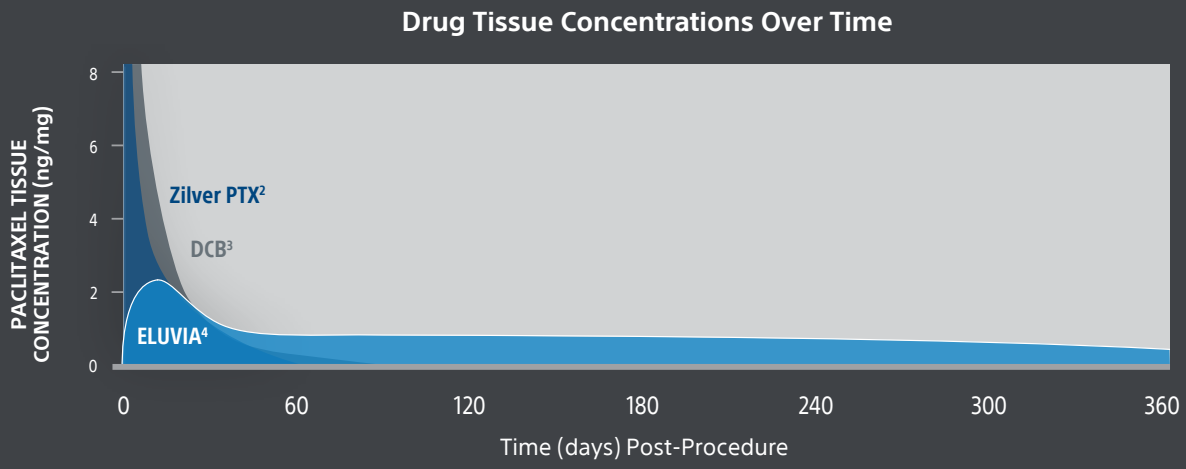
# Highly controlled drug delivery, sustained to match the restenotic process

## ELUVIA's polymer ensures targeted delivery of the drug to the lesion and minimizes downstream particulates




Downstream particulates collected with polycarbonate filter[1]
ELUVIA showed similar particulate loss compared to a bare metal stent

## ELUVIA's polymer sustains drug tissue concentrations beyond 12 months




Restenosis following nitinol stenting peaks at about 12 months in the SFA[5]

1. Devices were tested in simulated-use conditions with fluid recirculation. Media was collected using 5 µm pore size filters and imaged at 50x magnification.
2. Based on preclinical pharmacokinetic analysis for Zilver PTX. Dake MD, et al. J Vasc Interv Radiol. 2011;22(5):603-610.
3. Based on preclinical pharmacokinetic analysis for three drug-coated balloons (IN.PACT Pacific, Lutonix, Ranger). Gongora CA, et al. JACC Cardiovasc Interv. 2015 Jul;8(8):1115-1123. doi: 10.1016/j.jcin.2015.03.020.
4. Based on preclinical pharmacokinetic analysis for ELUVIA. Müller-Hülsbeck S. Expert Opin Drug Deliv. 2016 Oct 5:1-6.
5. Iida, O. et al. Catheterization and Cardiovascular Interventions. 2011; 78:611-617.

# Remarkable and consistent clinical efficacy in the most challenging SFA lesions

## IMPERIAL is the first and only randomized trial comparing a low-dose polymeric drug-eluting stent to a high-dose non-polymeric drug-coated stent

ELUVIA™ **92.1%** VS ZILVER™ PTX™ **81.8%**

**Statistically Significant***
Kaplan-Meier Estimate[1]

## One-year primary patency results in complex lesions

| | IMPERIAL RCT[2] (n=309) | IMPERIAL Long Lesions[3] (n=50) | IMPERIAL Diabetic Subgroup Analysis[4] (n=116) | IMPERIAL Severe/Moderate Calcium Subgroup Analysis (n=193) | IMPERIAL CTO Subgroup Analysis (n=96) | Münster Registry (n=62) |
|---|---|---|---|---|---|---|
| **Study Design** | RCT, multicenter, global | Single arm multicenter, global | RCT, multicenter, global | RCT, multicenter, global | RCT, multicenter, global | Single-center registry |
| **12-month primary patency rate[1]** | **92.1%** | **91.0%** | **95.2%** | **92.5%** | **86.4%** | **87.0%[5]** |
| **Lesion length (mm)** | 86.5 | 162.8 | 87.0 | 89.9 | 94.4 | 200 |
| **Severe calcification** | 40% | 28% | 46% | n/a | n/a | 42%[6] |
| **Total occlusions** | 31% | 32% | 25% | n/a | 100% | 79% |
| | Statistically significantly **higher primary patency** vs. Zilver PTX | Remarkable primary patency in **long lesions** | Statistically significantly **lower TLR and (3.7%) stent thrombosis rate (0.9%)** vs. Zilver PTX | Remarkable primary patency and **2.8% TLR** in **heavy calcium** | Low TLR (1.9%) and **stent thrombosis rate** (2.2%) | **CLI in nearly half** of patients |

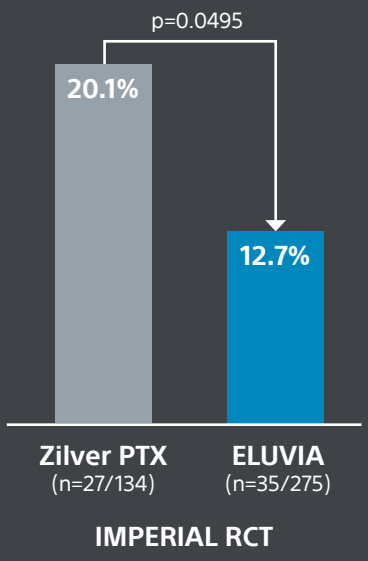
Adapted from Holden, A LINC 2020 Presentation.

*Kaplan-Meier Primary Patency Estimate through 1-year (including follow-up window) was statistically significant with a p-value of 0.0094.

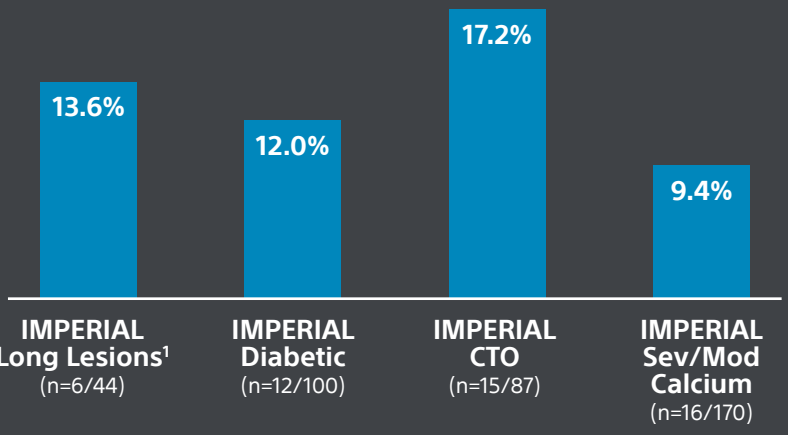
1. Kaplan Meier Estimate; Primary patency as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is ≤ 2.4 at the 12-month follow-up visit, in the absence of clinically-driven TLR or bypass of the target lesion.
2. In IMPERIAL RCT, ELUVIA K-M Primary Patency was 92.1% vs. 81.8% for Zilver PTX at 12 months.
3. Golzaar, J. et al, Journal of Endovascular Therapy, Jan 2020. https://doi.org/10.1177/1526602820901723.
4. In IMPERIAL Diabetic Subgroup, ELUVIA K-M Primary Patency was 95.2% vs 81.5% for Zilver PTX at 12 months.
5. PSVR < 2.0.
6. Moderate and severely calcified.

# Consistent and Durable Clinical Outcomes at 2 Years

Statistically significant reduction in CD-TLR with Eluvia at 2 years vs. Zilver PTX

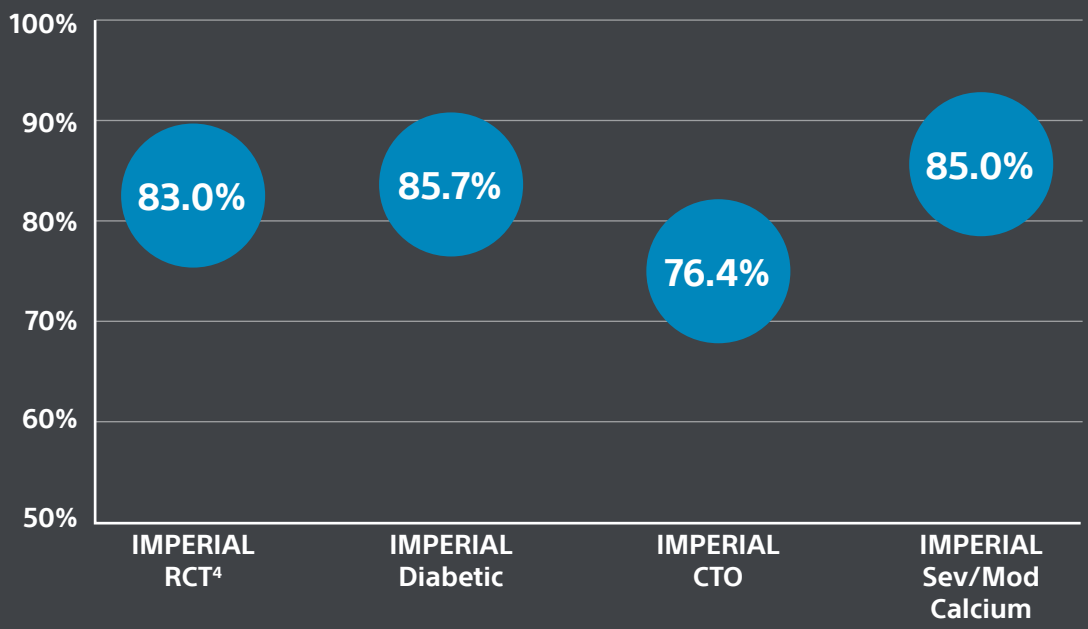



Consistently low 2-year CD-TLR in Challenging SFA Disease




## ELUVIA Demonstrated the Highest Ever 2-Year Primary Patency in an SFA Pivotal Trial for DES or DCB[2]

2-Year Kaplan-Meier Primary Patency Estimate[3]




In IMPERIAL RCT, CEC adjudicated all-cause mortality rate at 2 years for ELUVIA was 7.1% (21/295) vs. 8.3% (12/145) for Zilver PTX.

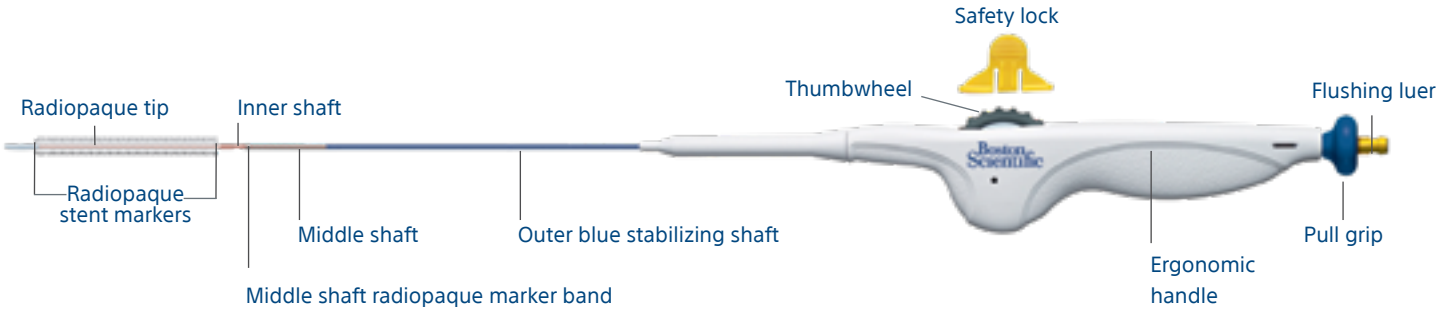
IMPERIAL RCT CD-TLR data is intention to treat and adapted from Iida, O. VIVA 2019 presentation.

1. Long Lesion TLR is as-treated as presented at FDA Panel 2019. All other TLR data sets adapted from Gray, W. LINC 2020 Presentation, are intention to treat.
2. Highest-two year primary patency based on 24-month Kaplan-Meier estimates reported for IMPERIAL, IN.PACT SFA, ILLUMENATE, LEVANT II and Primary Randomization for Zilver PTX RCT.
3. Intention to treat. Kaplan-Meier estimate utilizing time-to-event of clinically-driven TLR up to 730 days and Duplex Ultrasound data at 24 months. 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. Adapted from Gray, W, LINC 020 Presentation.
4. In IMPERIAL RCT, ELUVIA K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p=0.1008.

# ELUVIA™

Drug-Eluting Vascular Stent System

## Triaxial delivery system for more precise and predictable stent placement




## Stent diameter (mm)

| | | 6 | | 7 | | |
|---|---|---|---|---|---|---|
| | | Delivery system working length (cm) | | | | |
| | | 75 | 130 | 75 | 130 | Minimum sheath size |
| Stent Length (mm) | 40 | H74939295600470 | H74939295600410 | H74939295700470 | H74939295700410 | 6F (2.0 mm) |
| | 60 | H74939295600670 | H74939295600610 | H74939295700670 | H74939295700610 | 6F (2.0 mm) |
| | 80 | H74939295600870 | H74939295600810 | H74939295700870 | H74939295700810 | 6F (2.0 mm) |
| | 100 | H74939295601070 | H74939295601010 | H74939295701070 | H74939295701010 | 6F (2.0 mm) |
| | 120 | H74939295601270 | H74939295601210 | H74939295701270 | H74939295701210 | 6F (2.0 mm) |

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