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PERIPHERAL INTERVENTIONS

Product Catalogue



7. Drug-Eluting Technologies

ELUVIA™

Drug-Eluting Vascular Stent System

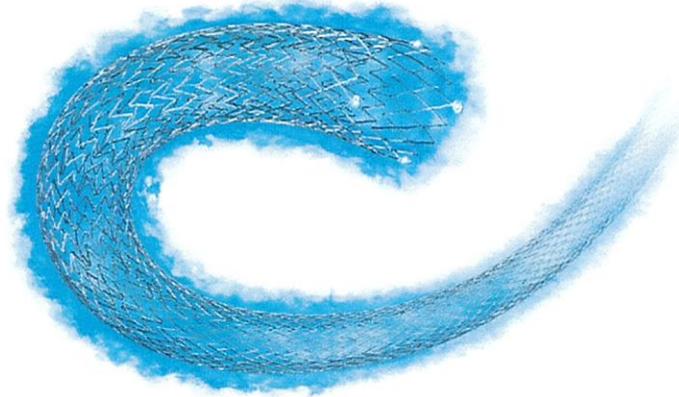
- The ELUVIA™ Stent System delivers unprecedented results in the SFA through its unique sustained drug release. ELUVIA is the only polymer-based peripheral paclitaxel device that provides controlled, localized, and sustained delivery of the lowest drug dose, optimizing the amount delivered to the tissue while minimizing downstream particulates. ELUVIA has demonstrated excellent efficacy and safety results in the IMPERIAL RCT and EMINENT RCT.

Sustained Drug Release

- The only SFA treatment option that sustains drug release for 12 months, when restenosis is most likely to occur
- Proven polymer implanted in 10 million lesions² since 2007

Optimized Stent Platform

- Optimized for flexibility, strength and fracture resistance
- Triaxial delivery system for precise deployment



Stent Length (mm)	Stent diameter (mm)				Minimum sheath size
	6		7		
	Delivery system working length (cm)				
	75	130	75	130	
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)

GW compatibility 0.035" / 0.89 mm
Over-the-Wire

¹ Müller-Hulsbeck S. Presented at CIRSE 2016. Represents actual freedom from TLR rate. Kaplan-Meier estimated freedom from TLR is 91.3%. Data on file at Boston Scientific.
² Data on file at Boston Scientific. Represents total global sales of the PROMUS (Boston Scientific) and XIENCE (Abbott) series of stents since 2007.

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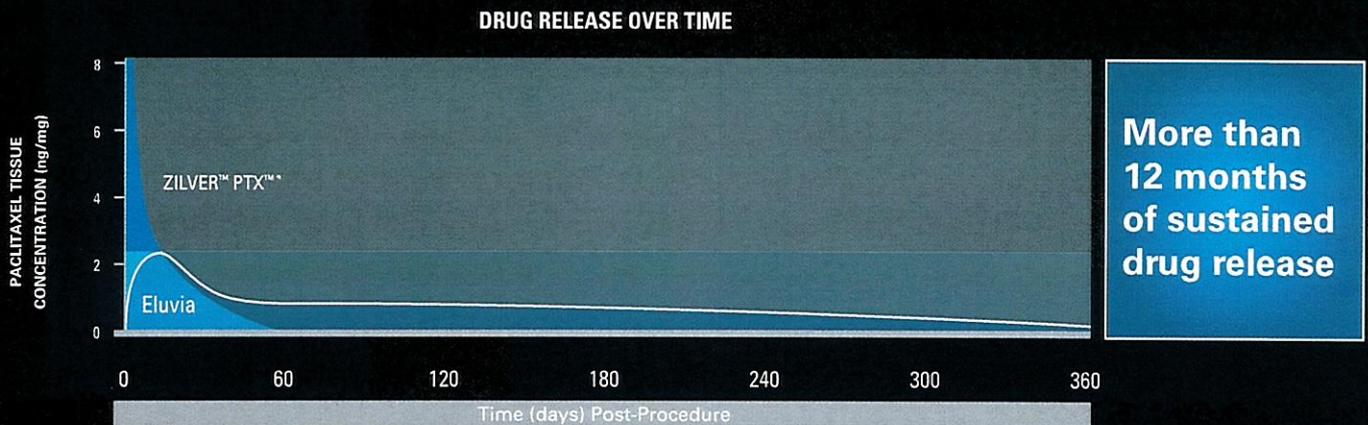
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The Solution: Sustained Drug Release

The Eluvia™ Stent, with Sustend™ drug-delivery technology, is designed to deliver paclitaxel when restenosis is most likely to occur.

Polymer-based technology with proven biocompatibility¹

- Implanted in more than 10 million vessels since 2007
- More than 20,000 patients studied in clinical trials

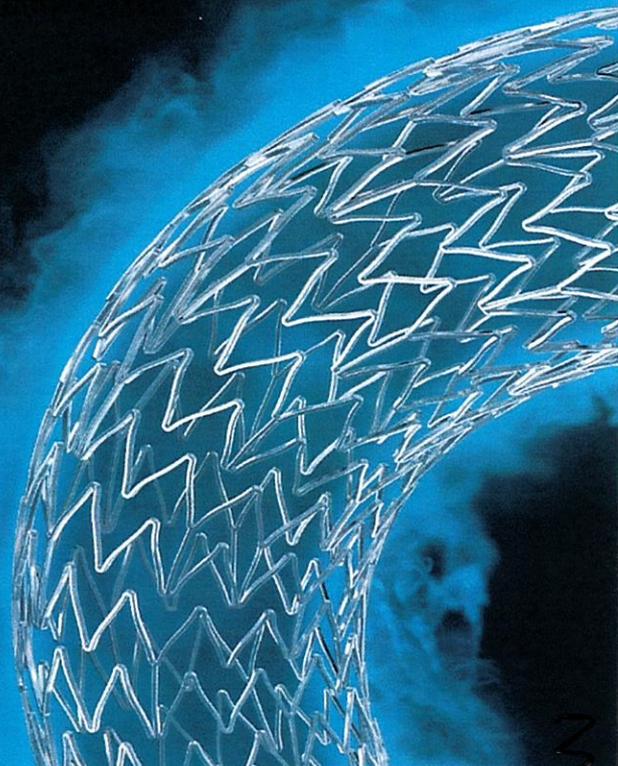


* Based on pre-clinical PK analysis. Data on file at Boston Scientific. Dake MD, et al. J Vasc Interv Radiol. 2011;22(15): 603-610.

Built on the Innova™ Stent platform, designed to optimize:

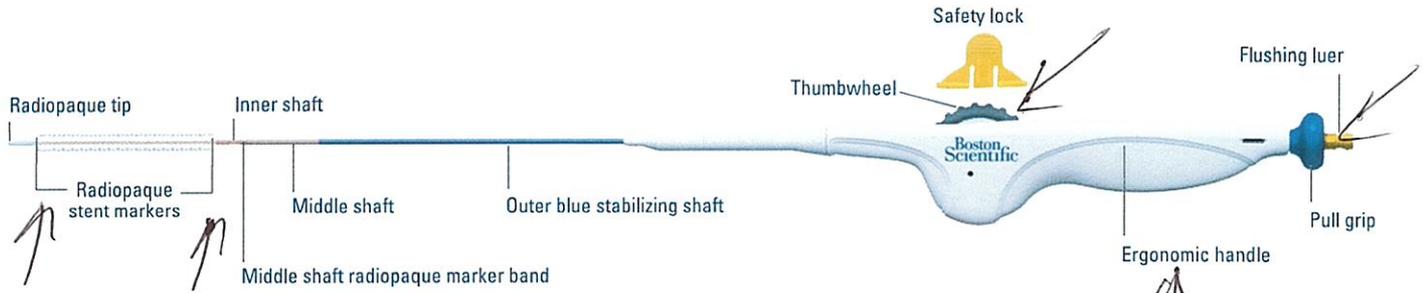
- Flexibility
- Radial strength
- Fracture resistance

While providing uniform scaffolding for drug delivery.



ELUVIA™ Drug Eluting Vascular Stent System

Triaxial delivery system for more precise and predictable stent placement



Stent Length (mm)	Stent diameter (mm)				Sheath Compatibility (F / mm)
	6		7		
	75	130	75	130	
40	H74939295600470	H74939295600410	H74939295700470	H74939295700410	6 / 2.0
60	H74939295600670	H74939295600610	H74939295700670	H74939295700610	6 / 2.0
80	H74939295600870	H74939295600810	H74939295700870	H74939295700810	6 / 2.0
100	H74939295601070	H74939295601010	H74939295701070	H74939295701010	6 / 2.0
120	H74939295601270	H74939295601210	H74939295701270	H74939295701210	6 / 2.0
150	H74939295601570	H74939295601510	H74939295701570	H74939295701510	6 / 2.0

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. This material is not for use or distribution in France. Eluvia is a registered or unregistered trademark of Boston Scientific Corporation or its affiliates. All other trademarks are property of their respective owners.

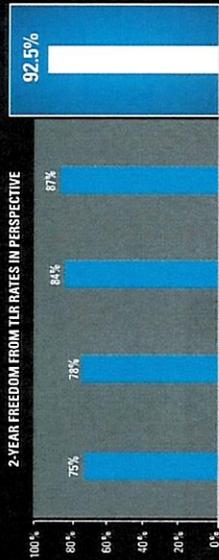
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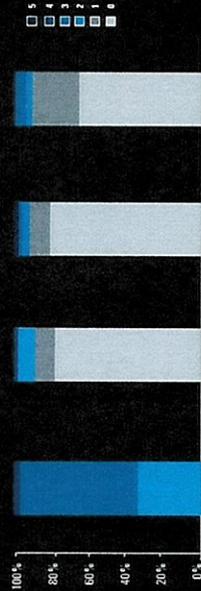
4

Highest reported Freedom from TLR rate at 2 years



Study	TLR Rate (%)
RESILIENT (LIFESTAR [®])	25%
RESILIENT (LIFESTAR [®])	17%
RESILIENT (LIFESTAR [®])	25%
RESILIENT (LIFESTAR [®])	45%
RESILIENT (LIFESTAR [®])	37%
RESILIENT (LIFESTAR [®])	46%

RUTHERFORD CATEGORY (MAJESTIC TRIAL)

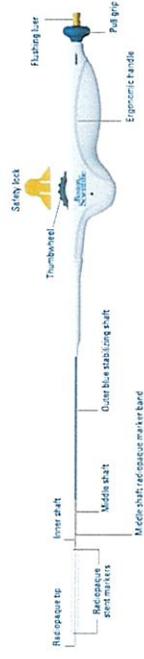


91% OF PATIENTS HAD NO OR MINIMAL CLAUDICATION AT 2 YEARS

1. Resilient Study: A Study of the Efficacy and Safety of the Resilient Drug-Eluting Vascular Stent System in Patients with Peripheral Artery Disease (PAD).
 2. Resilient Study: A Study of the Efficacy and Safety of the Resilient Drug-Eluting Vascular Stent System in Patients with Peripheral Artery Disease (PAD).
 3. Resilient Study: A Study of the Efficacy and Safety of the Resilient Drug-Eluting Vascular Stent System in Patients with Peripheral Artery Disease (PAD).
 4. Resilient Study: A Study of the Efficacy and Safety of the Resilient Drug-Eluting Vascular Stent System in Patients with Peripheral Artery Disease (PAD).
 5. Resilient Study: A Study of the Efficacy and Safety of the Resilient Drug-Eluting Vascular Stent System in Patients with Peripheral Artery Disease (PAD).

ELUVIA[™] Drug-Eluting Vascular Stent System

Triaxial delivery system for more precise and predictable stent placement



Stent Length (mm)	Stent diameter (mm)		Minimum sheath size
	6	7	
75	H74939295600410	H74939295700470	6F (1.67mm)
130	H74939295600610	H74939295700670	6F (1.67mm)
190	H74939295600810	H74939295700870	6F (1.67mm)
250	H74939295601010	H74939295701070	6F (1.67mm)
310	H74939295601210	H74939295701270	6F (1.67mm)
370	H74939295601510	H74939295701570	6F (1.67mm)

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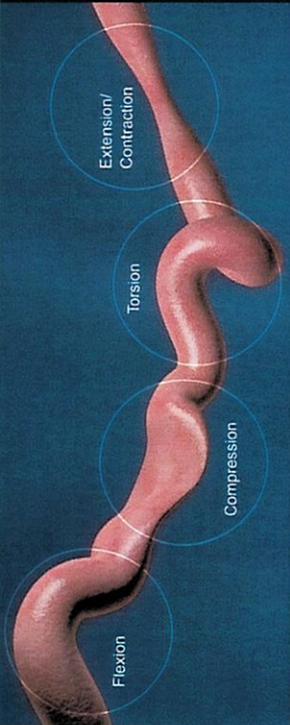
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 BSI/ELUVIA

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The Challenge: A Harsh SFA Environment



Significant mechanical forces in the SFA prolong the response to injury and make the SFA susceptible to restenosis.

CLINICAL HISTORY OF RESTENOSIS



Kid, G. et al. Catheterization and Cardiovascular Interventions. 2011; 78(1): 47

The Solution: Sustained Drug Release

The Eluvia™ Stent, with Sustend™ drug-delivery technology, is designed to deliver paclitaxel when restenosis is most likely to occur.

Polymer-based technology with proven biocompatibility¹

- Implanted in more than 10 million vessels since 2007
- More than 20,000 patients studied in clinical trials



Built on the Innova™ Stent platform, designed to optimize:

- Flexibility
- Radial strength
- Fracture resistance

While providing uniform scaffolding for drug delivery.

*Based on pre-clinical PK analysis. Duration: 60 days. Data from: ScienceDirect. Davis KD, et al. J Vasc Interv Radiol. 2011;22(10):1493-1499

The Outcome: UNPRECEDENTED Results in the SFA

MAJESTIC CLINICAL TRIAL

TRIAL OVERVIEW

- Core lab adjudicated single-arm, multicenter trial (n=57)
- 65% of lesions severely calcified
- 46% total occlusions
- 71 mm average lesion length

2-YEAR RESULTS

- 92.5%** Freedom from TLR
- 91%** patients with minimal or no claudication

0 STENT FRACTURES



1. M. J. et al. J Vasc Med Biol. 2011;23(1):1-11

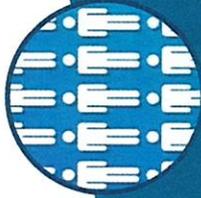
ELUVIA™ Drug-Eluting Vascular Stent System
In-Service presentation

More than 20 years of experience working with polymer + paclitaxel stents

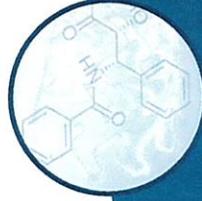
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20+ years of experience using paclitaxel in the coronary and peripheral arteries



More than **6 million** patient implants worldwide



4 generations of coronary paclitaxel-eluting stents and the next-generation **Eluvia DES**



Published 5-year data showing **similar all-cause mortality** between coronary paclitaxel-eluting stents compared to bare metal stents

Data from Level-1 Randomized Trials with 2,797 patients showed no difference in mortality at 5 years with Boston Scientific's paclitaxel-eluting coronary stent compared to bare metal stents*

*Stone GW, et al. JACC Cardiovasc Interv. 2011;4(5):530-542.



Product Overview



The ELUVIA™ Stent System delivers unprecedented results in the SFA through its unique Sustained Drug Release

Unprecedented,
Consistent Results

Eluvia demonstrated Superiority¹ in the first head-to-head DES SFA trial (IMPERIAL) 12 month Primary Patency (Kaplan-Meier): **92,1% (Eluvia)**; 81,8% (Zilver PTX); p-value=0.0094.

87% Primary Patency at 12 months in 200mm lesions (Münster Registry) with nearly half the patients had CLI²

Sustained Drug
Release

The only SFA treatment option that **sustains drug release beyond 1 year**

Optimized Stent
Platform

Optimized for **flexibility, strength and fracture resistance**
Triaxial delivery system for precise deployment
Built on the proven **Innova platform**



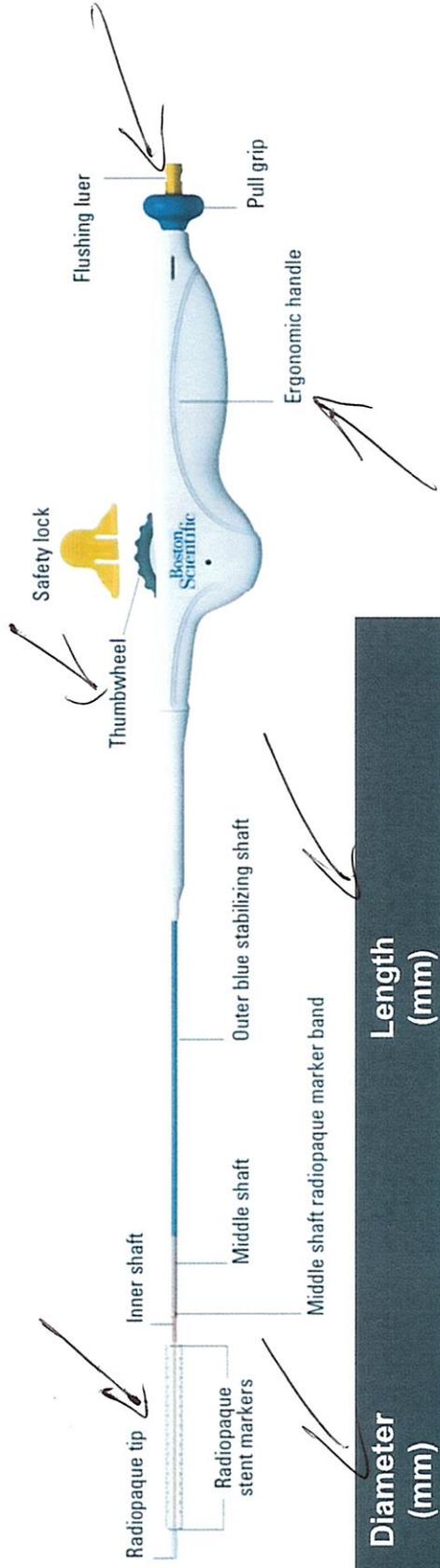
1. Superiority determined in Post Hoc Superiority Analysis. 12-Month Primary Patency rate of 86.8% in the Eluvia arm (n=309) vs. 77.5% in the Zilver PTX (n=156) arm (p-value= 0.0144)
2. Muller-Hulsbeck, S., et al. CVIR, 2017 Dec;40(12):1832-1838.
3. Gray W. Presented at TCT 2018. Kaplan-Meier estimated primary patency.
4. Bisdas, T Presented at LINC 2018



Product Specifications

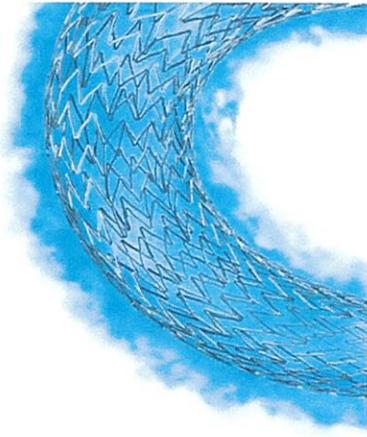


Boston Scientific



Diameter (mm)	Length (mm)		
6	40	60	80
7	40	60	80

Working length	130 cm
Sheath compatibility	6F (2 mm) (across all sizes)
	0.035" (0.89 mm) guidewire compatible



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Triaxial delivery system for precise stent delivery

Blue outer stabilizing shaft

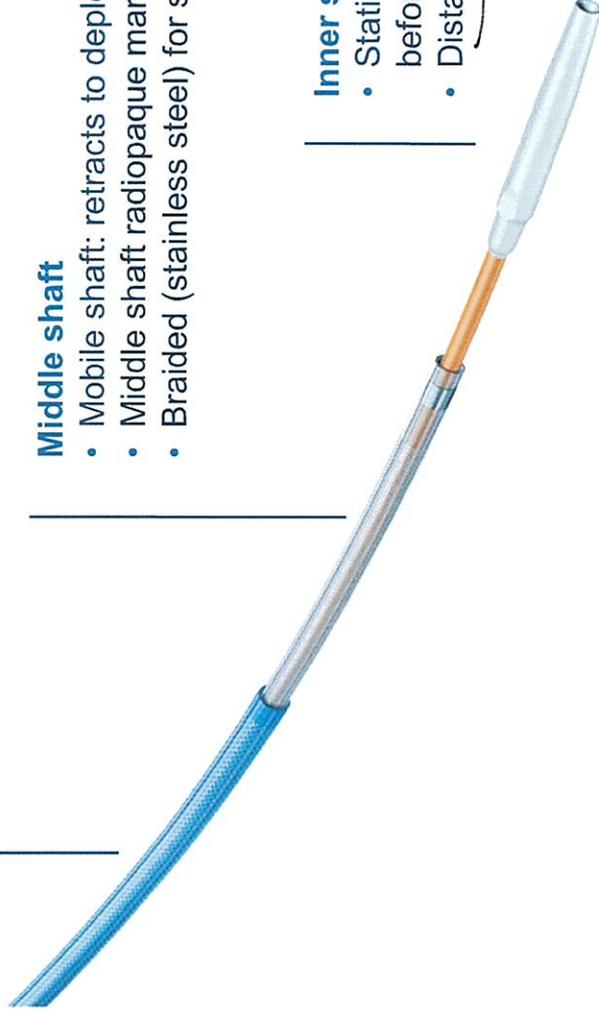
- Stationary shaft: designed to provide controlled, accurate placement
- Can be pinned in place to maintain position of the stent during deployment
- Braided (stainless steel) for strength and kink resistance

Middle shaft

- Mobile shaft: retracts to deploy stent
- Middle shaft radiopaque marker band provides visual feedback during deployment
- Braided (stainless steel) for strength and kink resistance

Inner shaft

- Stationary shaft: Provides framework to support stent before deployment
- Distal tip is radiopaque



Polymer Selection



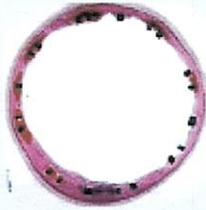
Multiple factors were considered in selecting an optimal polymer for Eluvia.

Biocompatible

PROMUS Polymer:

PBMA-PVDF

- 100k clinical patients
- Over 20M WW implants

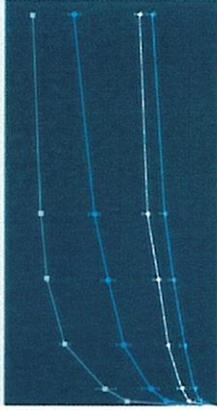


Durable

Durable coating during deployment/fatigue testing



Tunable



Deployable



1. Datta et al. Friction-Induced Nanopores on the Surface of the PROMUS Eluvia Stent. *ACS Nano*, 2013. <https://doi.org/10.1021/nl302498g>.
2. Datta et al. Eluvia Stent for the Treatment of Coronary Artery Disease. *ACS Nano*, 2013. <https://doi.org/10.1021/nl302498g>.

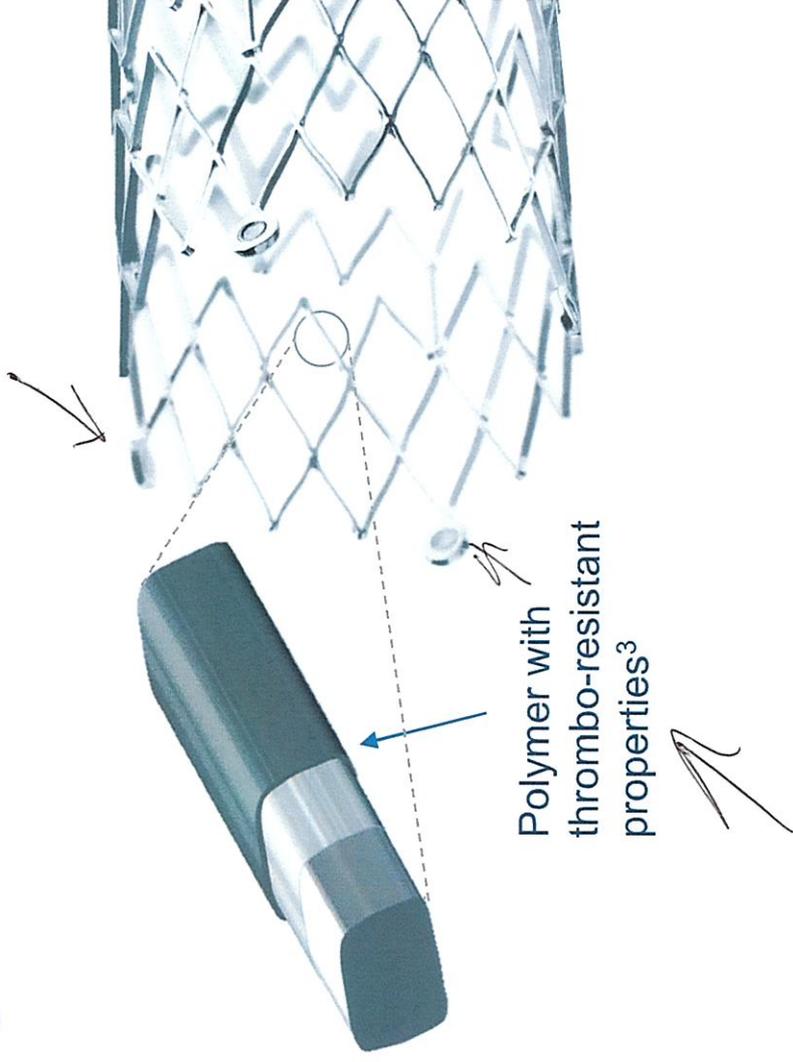
The most proven polymer for the Eluvia DES



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.

- Implanted in more than **20 million** vessels¹.
- More than **100,000 patients** studied in clinical trials².
- Eluvia evaluated in nearly **500 patients** in clinical studies.



Eluvia received CE Mark in Feb 2016 and FDA Approval in Sep 2018.
1. Data on file at Boston Scientific. Represents total implantations of the PROMUS, Boston Scientific and XIENCE Abbott stents since 2007.
2. Data on file at Boston Scientific. Represents total implantation of patients studied in the PROMUS and XIENCE series of clinical trials.
3. M. W. H. et al. Expert Review of Medical Devices. 2017; 10(10):1389-1444. doi:10.1586/1744-4440.2017.1303646.

Biology of the Restenotic Cascade in the SFA



The harsh SFA environment continues to elicit a response to injury long after an interventional treatment.

BIOLOGY OF RESTENOSIS



- 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

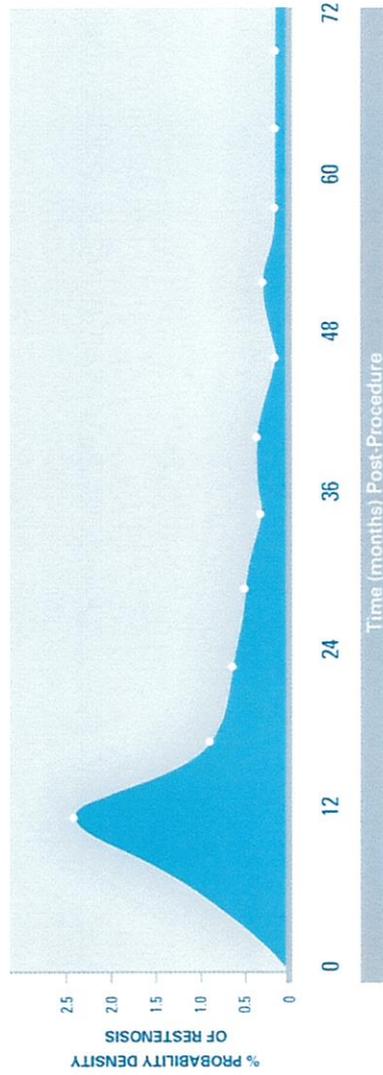
Forrester et al. JACC. 1991; 7:56-769.

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Sustained Drug Release to match the restenotic process in the SFA

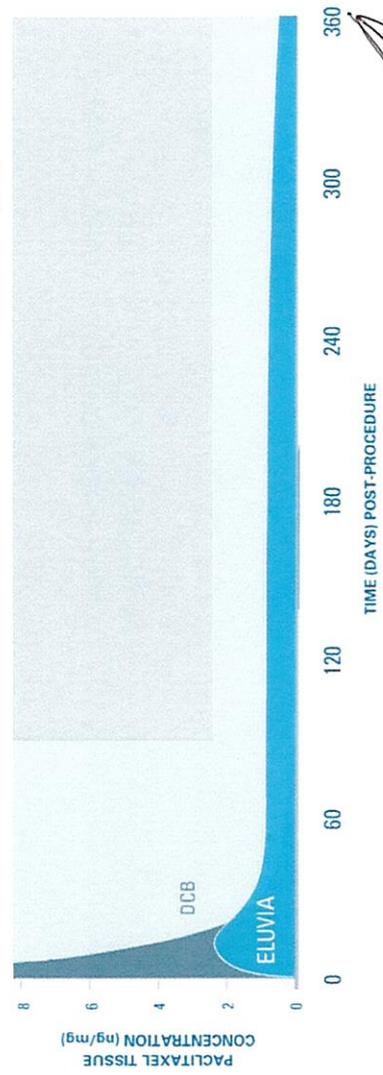


CLINICAL HISTORY OF RESTENOSIS IN NITINOL STENTS¹



Timing of SFA restenosis is longer compared to coronary stenting which predominantly occurs within 6 months after stenting²

DRUG TISSUE CONCENTRATIONS OVER TIME³



Eluvia sustained drug release beyond one year to match restenosis in the SFA.

1. Iida, O. et al. Catheterization and Cardiovascular Interventions. 2011; 78:611-617.
 2. Kimura T, et al. N Engl J Med. 1996;334:561-567.
 3. Based on preclinical pharmacokinetic analysis for Zilver PTX (Duke MD, et al. J Vasc Interv Radiol. 2011;22(5):603-610); IN.PACT Pacific, Lutonix and Ranger DCBx (Gongora CA, et al. JACC Cardiovasc Interv. 2015 Jul;8(8):1115-1123. doi: 10.1016/j.jcin.2015.03.020.); and Eluvia (Müller-Hülberck S. Expert Opin Drug Deliv. 2016;Oct;5:1-6.)

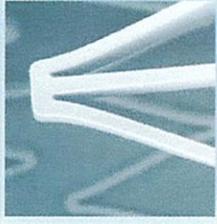
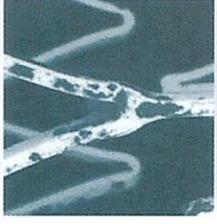
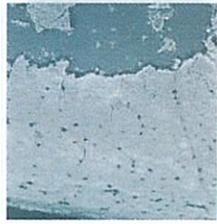
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Highly controlled paclitaxel delivery via a polymer-based system



Polymer-based drug delivery provides the most efficient way to

- Achieve remarkable clinical results with the **lowest drug dose**
- Significantly **minimize downstream particulates**
- **Sustain drug tissue concentrations** to match the restenotic process

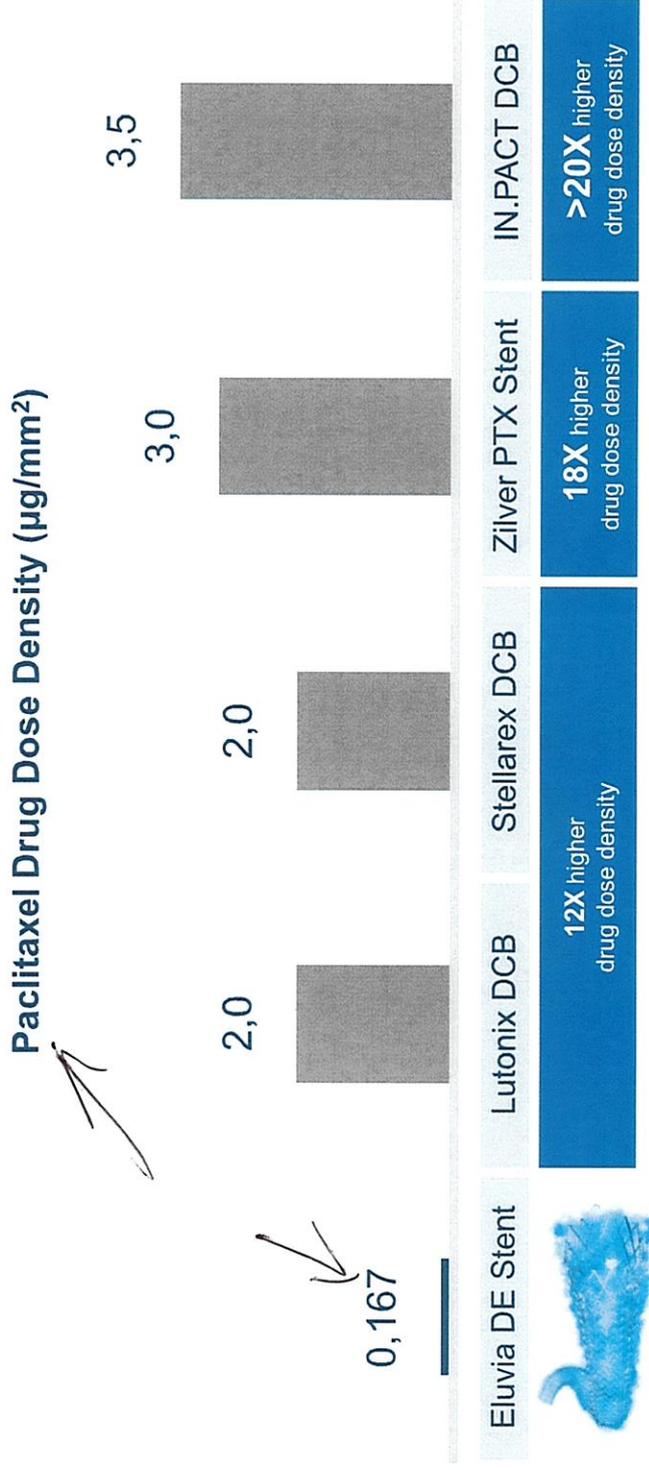
	Eluvia™	Zilver™ PTX™	IN.PACT™ DCB
Drug Delivery Design	Polymer-based delivery	No carrier	Excipient-based delivery
Drug Dose Density¹	0.167 µg/mm²	3.0 µg/mm ²	3.5 µg/mm ²
Average Downstream Particulates (≥ 10µm)²	411	10,523	977,333
Drug remaining after delivery through a simulated artery³ or after hydration⁴			
Duration of Drug Tissue Concentrations⁵	12-15 months	56 days	~60-90 days

1. Data from Eluvia, Zilver PTX, and IN.PACT Directions for Use.
 2. Data on file at Boston Scientific. Simulated, non-infectious model under clinically relevant flow conditions.
 3. Eluvia and Zilver PTX, viewed through scanning electron microscopy, 100 magnification.
 4. IN.PACT is prepared in phosphate buffered saline at 37°C and the carrier was rinsed at 300X.
 5. Basilio et al. *Cell Transplantation*. 2015;24(10):2015-2020. Miller-Hall et al. *J Vasc Med Biol*. 2015;27(5):165-172. Dwyer et al. *J Vasc Med Biol*. 2015;27(5):165-172. Miller-Hall et al. *JACC Cardiovasc Interv*. 2015;7(10):1115-1123. doi: 10.1016/j.jcin.2015.03.020.

Lowest drug dose density among all peripheral paclitaxel-based technologies



Boston Scientific's Drug-Eluting Technologies are designed to optimize drug transfer to bring patients the **best clinical outcomes with the lowest possible drug dose**



Data from Eluvia, Lutonix, Stellarex, Zilver PTX, and IN.PACT Directions for Use.

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CE 0344

Eluvia showed similar particulate loss compared to a bare metal stent



Downstream particulates collected with a polycarbonate filter
6 x 120 mm devices

Eluvia

EverFlex BMS

Zilver PTX

IN.PACT DCB



Device Particulate Counts $\geq 10\mu\text{m}$

411

446

10,523

977,333

IMPERIAL Study Devices



	Eluvia™ DES Boston Scientific	Zilver® PTX® Cook Medical
Stent Platform	Innova	Zilver Flex
Material	Nitinol ←	Nitinol
Polymer	Biostable Fluorinated Polymer Matrix (PROMUS polymer)	None
Drug Dose Density	Paclitaxel, 0.167µg/mm ² ←	Paclitaxel, 3 µg/mm ²
Deployment	Self-expanding ←	Self-expanding
Sizes	Diameter 6-7 mm	Diameter 6-8 mm
	Length 40-150 mm	Length 40-120 mm

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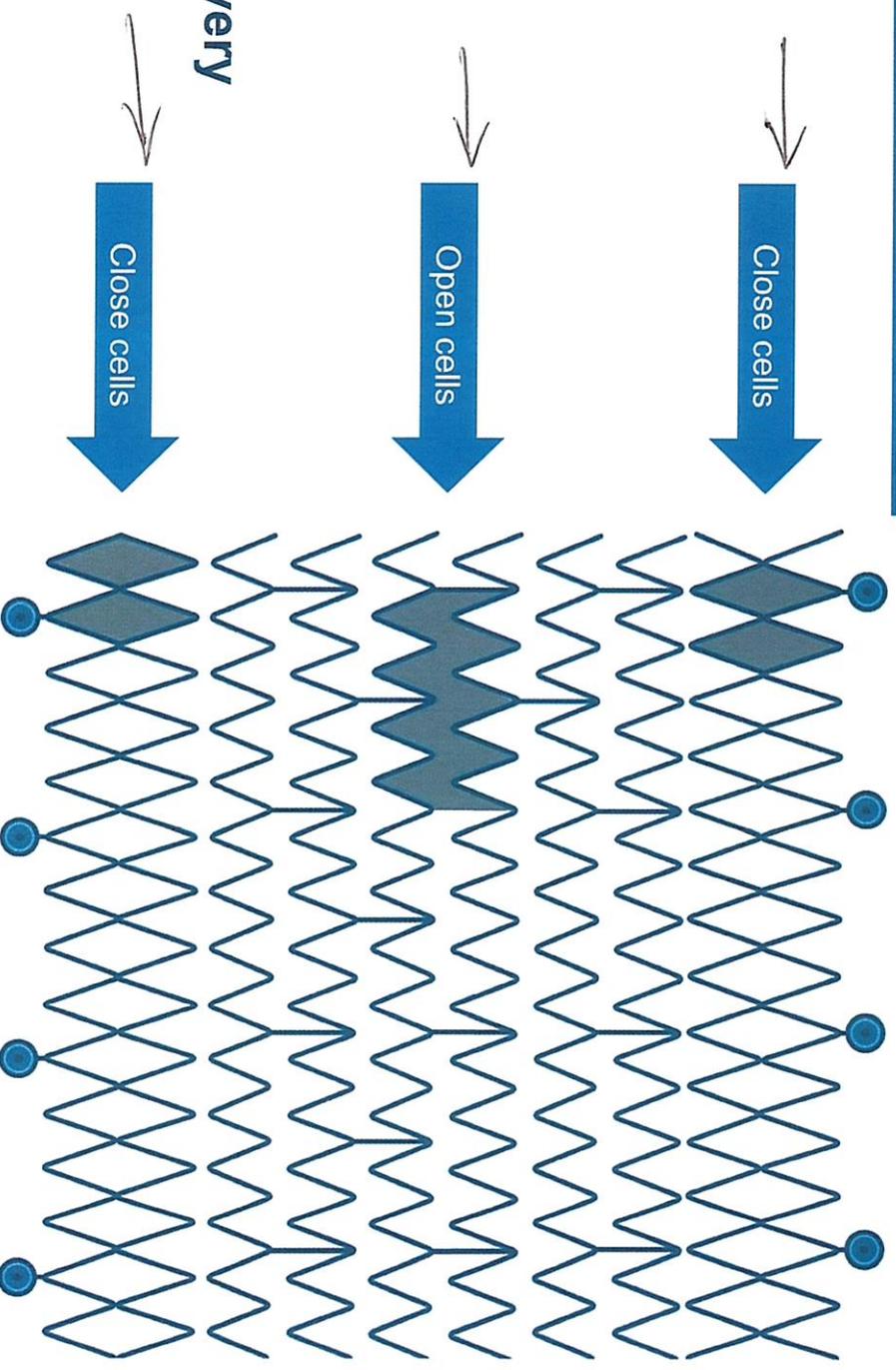
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Stent Design

The ELUVIA™ Drug-Eluting Stent is built on the INNOVA™ Stent Platform

Designed to optimize:

- Flexibility
- Radial strength
- Fracture resistance



While providing uniform scaffolding for drug delivery

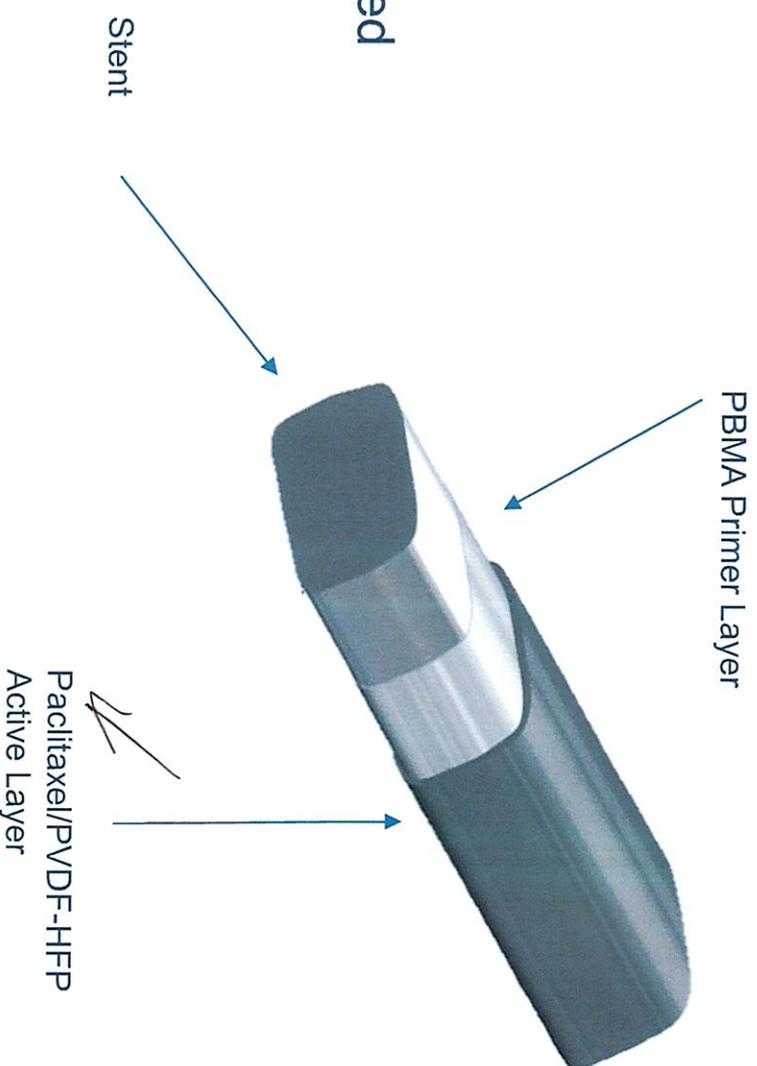
1. Data on file at Boston Scientific. Represents total global sales of the PROMUS (Boston Scientific) and XIENCE (Abbott) stents since 2007.
2. Data on file at Boston Scientific. Represents total population of patients studied in the PROMUS and XIENCE series of clinical trials.

SUSTEND™ Polymer-Based Drug Delivery

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Proven biocompatibility and safety

- Implanted in more than 10 million vessels¹ since 2007
- More than 20,000 patients² studied in clinical trials



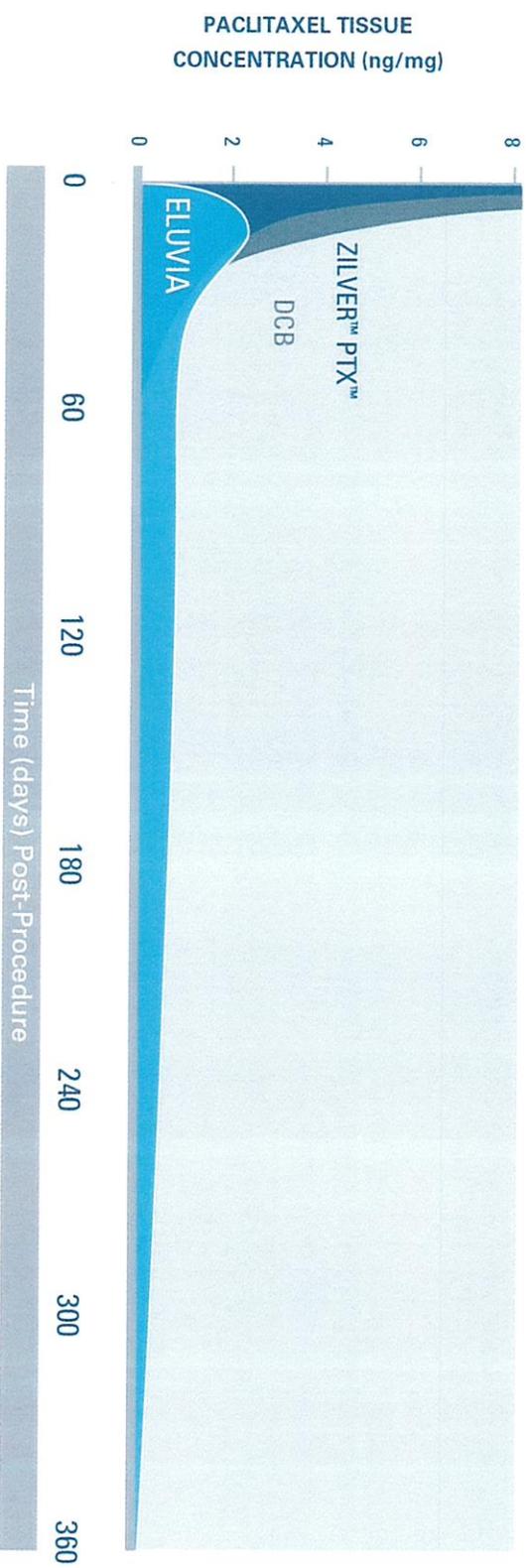
1. Data on file at Boston Scientific. Represents total global sales of the PROMUS (Boston Scientific) and XIENCE (Abbott) stents since 2007.
2. Data on file at Boston Scientific. Represents total population of patients studied in the PROMUS and XIENCE series of clinical trials.

Sustained Drug Release to Reduce Restenosis



→ The ELUVIA™ stent system was designed to sustain drug release when restenosis is most likely to occur

DRUG TISSUE CONCENTRATIONS OVER TIME



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.

Designed for intuitive handling and deployment

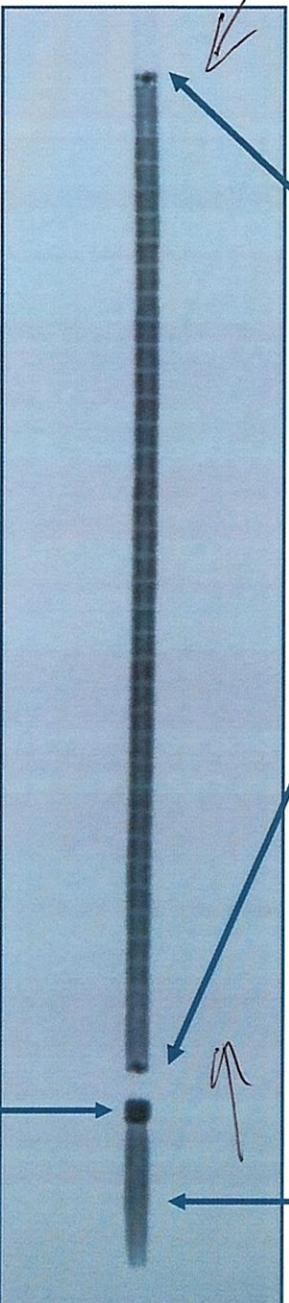


Delivery System Design

Excellent visibility under fluoroscopy

Proximal and Distal Stent Markers

- Four tantalum markers at each end of the stent



Middle Shaft Radiopaque Marker Band

- Moves during deployment as middle shaft retracts and stent deploys

Inner Shaft Radiopaque Tip

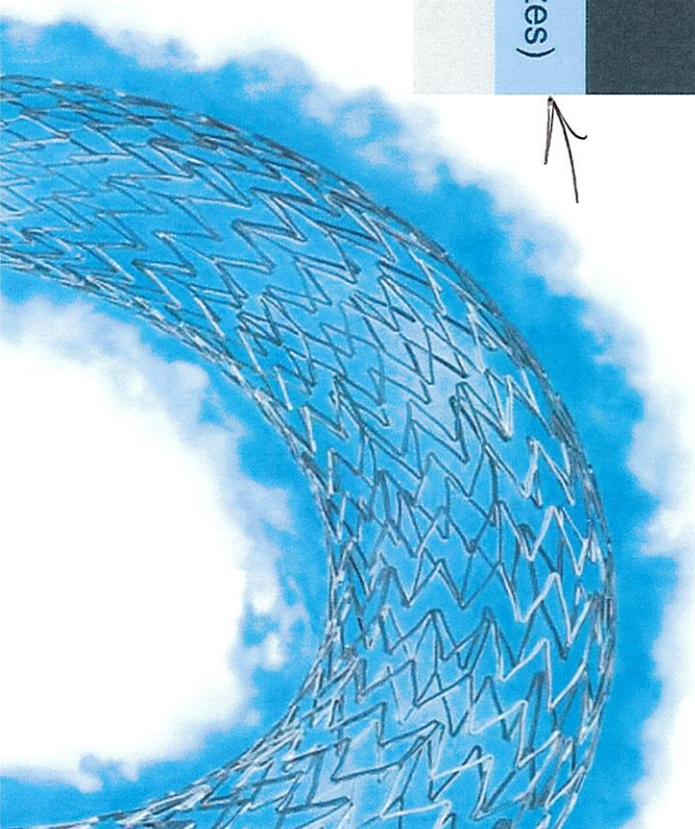
- Marks distal end of stent delivery system

Product Specifications

Boston
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Diameter (mm)	Length (mm)					
6	40	60	80	100	120	150
7	40	60	80	100	120	150

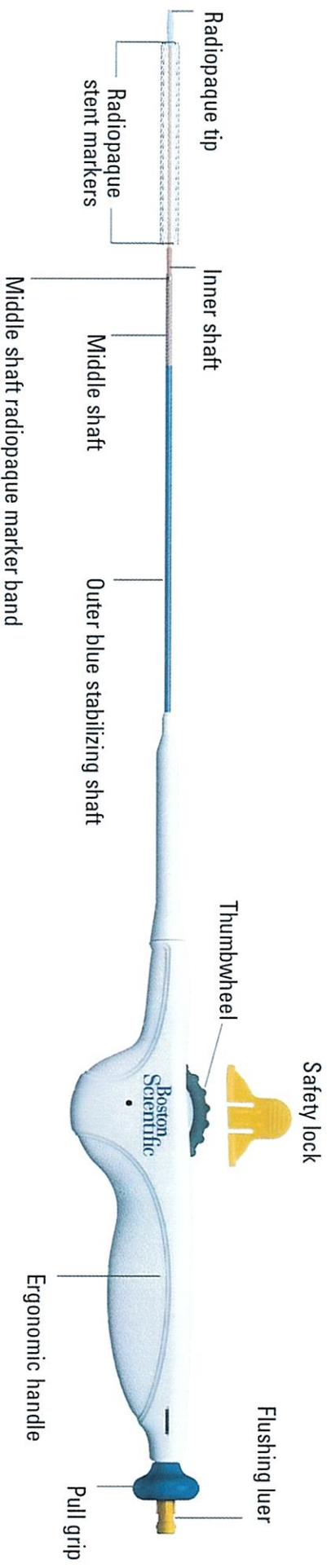
Working lengths	75 and 130 cm
Sheath compatibility	6F (2 mm) (across all sizes)
0.035" (0.89 mm) guidewire compatible	



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Product Specifications

System Components



Total system length (tip to hub)		
	75 cm system	130 cm system
All stent lengths	105 cm	160 cm