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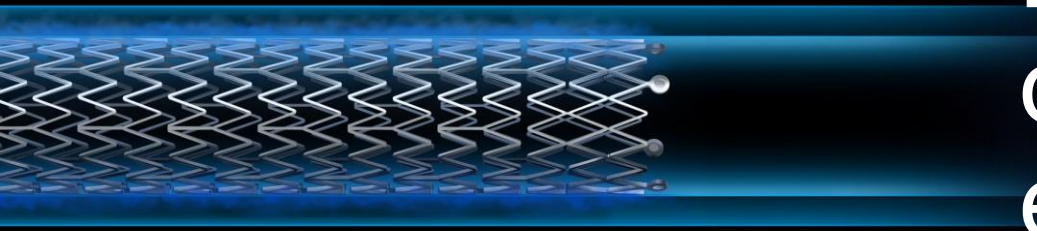
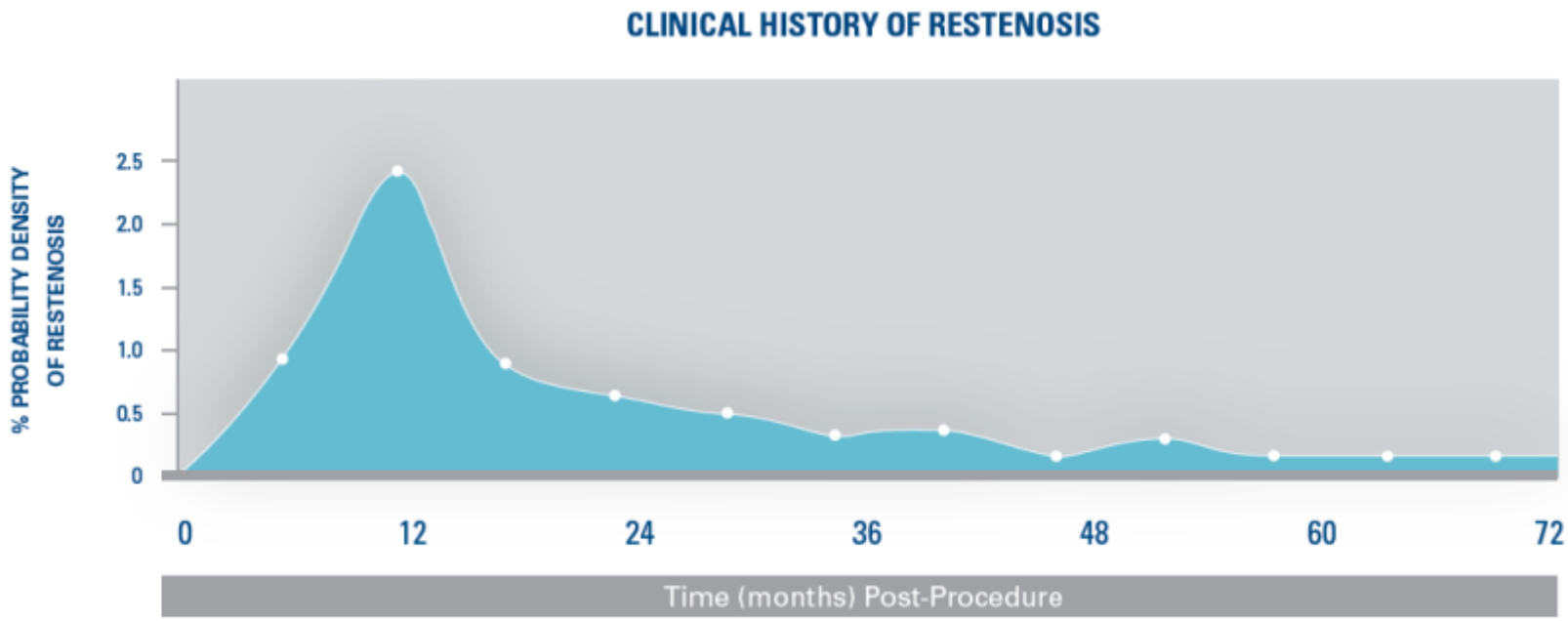
ELUVIA™
Drug-Eluting Stent



Economical Value and Impact of a Polymer-coated, Paclitaxel-eluting Stent Eluvia™

Chang-Hwan Yoon, MD/PhD
Seoul National University Bundang Hospital

Clinical Probability of Restenosis Following SFA Stenting



- Timing of SFA restenosis is longer than coronary stenting, which predominantly occurs within 6 months after stenting
- Factors for restenosis in the SFA include the number of runoff vessels, severity of lower limb ischemia, and length of diseased segments

Eluvia Only Therapy to Provide Sustained Drug Release

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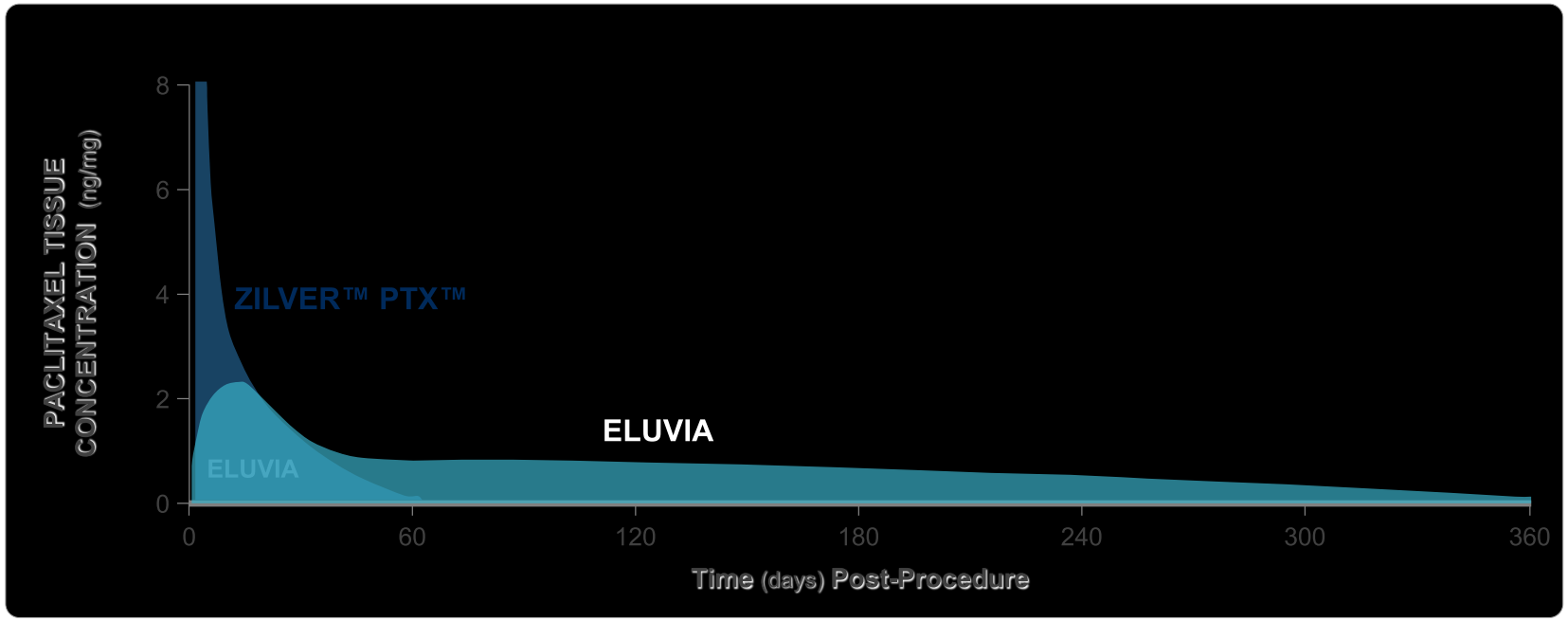
DRUG RELEASE OVER TIME



The Eluvia™ Stent System was designed to sustain drug release when restenosis is most likely to occur

Eluvia™ System Design: Mechanical Considerations

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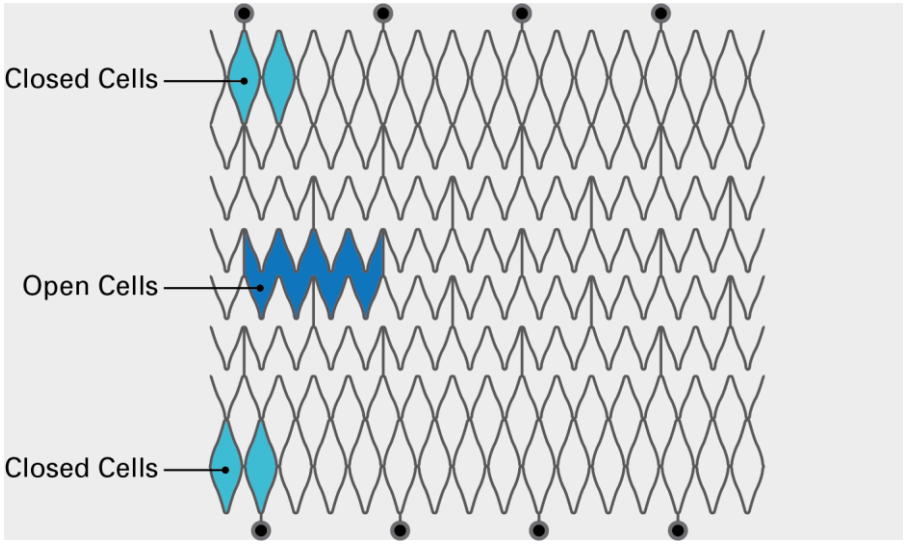
Innova Stent Designed for the SFA to optimize:

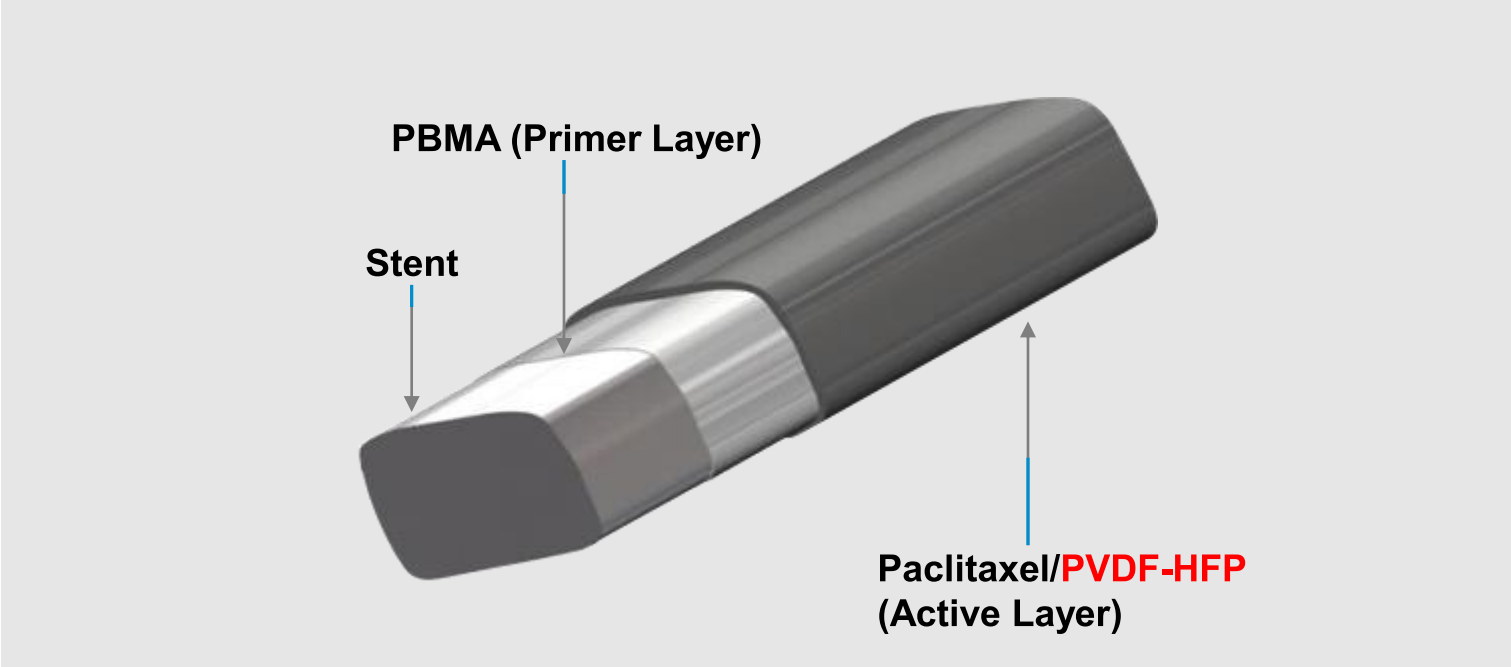
- Radial strength
- Flexibility
- Fracture resistance

While providing uniform scaffolding for optimal drug delivery



Eluvia™ Coating Design

- **Primer Layer** (PBMA)**:** Promotes Adhesion of Active Layer to Stent
- **Active Layer** (PTx, PVDF-HFP) **– Controls Release of Paclitaxel**



Poly Butyl Methac- rylate (**PBMA**)
Poly(vinylidene fluoride-co-hexafluoropropylene) (PVDF-HFP)

Eluvia DES RCT Results At-A-Glance

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		1 Year		2 Years		3 Years	
		Eluvia DES	Control	Eluvia DES	Control	Eluvia DES	Control
EMINENT[1] RCT, multicenter, global 2:1 vs BMS (n=775)	**Primary Patency (K-M Estimate)**	**85.4%**	**76.3%** (BMS) ★ **p=0.0087**	EMINENT Follow-up through 5 Years			
	Reintervention (CD-TLR)	8.5%	10.6% (BMS) p=0.3256				
IMPERIAL[2,3] RCT, multicenter, global 2:1 vs Zilver® PTX®, (n=309)	**Primary Patency (K-M Estimate)**	**92.1%**	**81.8%** (ZilverPTX) ★ **p=0.0094**	83.0%	77.1% (ZilverPTX) p=0.1008	IMPERIAL Follow-up through 5 Years	
	Reintervention (CD-TLR)	4.5%	9.0% (ZilverPTX) p=0.0672	**12.7%**	**20.1%** (ZilverPTX) ★ **p=0.0495**		

*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.
**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.

1. EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021
2. Intention to treat. IMPERIAL Head-to-Head RCT. 2-Year results presented by Osamu Iida, MD. VIVA 2019
3. Gray WA, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1

★ Statistically Significant

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Durable and Consistent Results Across Real-World Studies

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First-in-Human Trials and Real World Data

		Independent Studies			
		MAJESTIC[1] (n=57)	Münster Registry[2] (n=130)	Auckland All-comers Registry[3] (n=51)	DESAFINADO[4] (n=64)
Primary Patency (K-M estimate)**	12 months	**96.4%**	**90%**	**94.0%***	**84%**
	24 months	**83.5%**	**71%**	**93.8%***	NA
Study design		Single arm, multicenter trial	Single center retrospective registry	Single center registry	Single center retrospective registry
Lesion length (mm)		70.8 ± 28.1	194	105.4	193 ± 128
Occlusion (%)		46%	74%	53%	48%

*Observed rate.

First ever FIM data for Eluvia demonstrating polymeric PTX yields exceptional primary patency rates

CLI in nearly 1/3 of patients

Consistent and reproducible primary patency results at 1 and 2 years in real world lesions

Over 75% of patients with Diabetes and CLI.

**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.

1. Müller-Hülsbeck S, et al. Cardiovasc Intervent Radiol. 2017;40(12):1832-1838.
2. Stavroulakis, JACC Cardiovasc Interv. https://doi.org/10.1016/j.jcin.2021.01.026
3. Holden, A. Single Centre Long-Term Experience with the Boston Scientific Eluvia DES in Femoro-popliteal Artery Occlusive Disease. LINC 2020.
4. Kum, S. DES for SFA/Pop 12 Month Results of the DESAFINADO Registry. LINC 2020.

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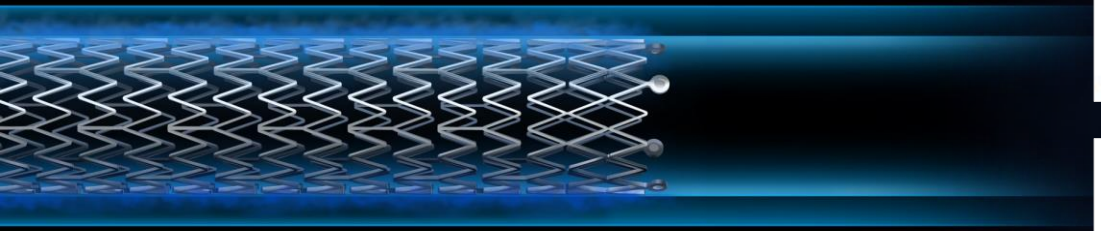

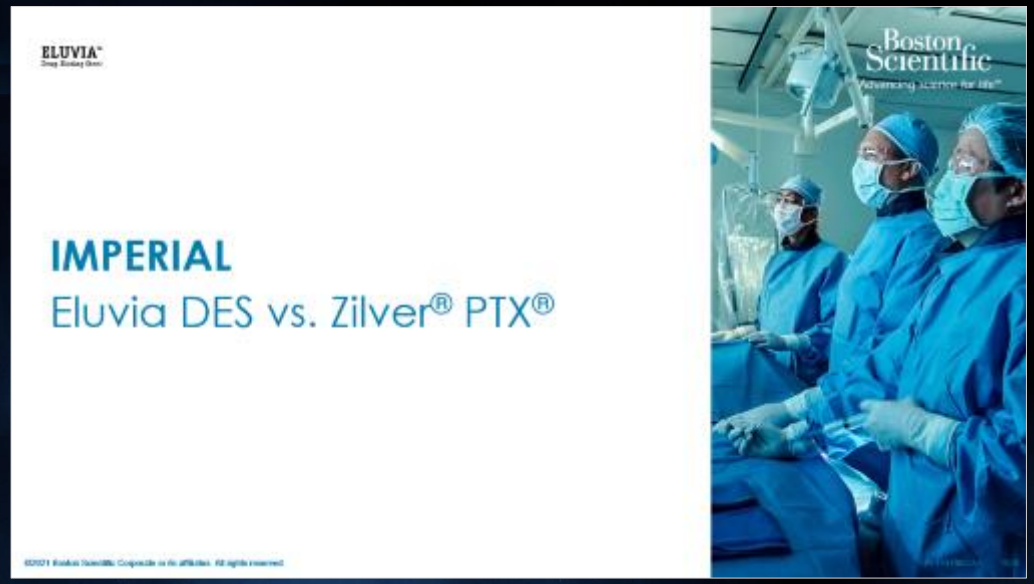

ELUVIA™
Drug-Eluting Stent

EMINENT

Eluvia DES vs. Bare Metal Stents

EMINENT RCT

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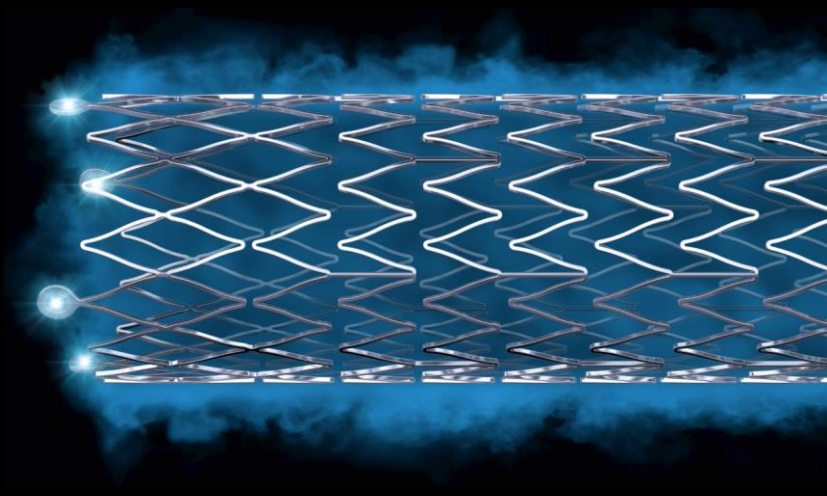
EMINENT is the largest randomized controlled trial (2:1) comparing Eluvia™ Drug-Eluting Vascular Stent System to self-expanding bare metal stents (BMS) for SFA/PPA

At 1-Year, Eluvia DES demonstrated:

- **Superior effectiveness** over BMS[1] and
- **A statistically significant** greater rate of **primary sustained clinical improvement** without reintervention



1. EMINENT Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against commercially-available Self-Expanding Bare Nitinol Stents, single-blind, superiority design; independent core lab adjudication. 12-Month Primary Patency rate of 83.2% in the Eluvia arm vs. 74.3% in the Bare-Metal Stenting arm (p-value = 0.0077). EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

EMINENT Trial Design and Endpoint

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Primary Investigators	**Prof. Dr. Yann Gouëffic** Vascular Surgeon (Paris, France) **Prof. Dr. Giovanni Torsello** Vascular Surgeon (Münster, Germany)
Study Design	RCT (Eluvia DES vs Bare Metal Stent) • 2:1 randomized • Single-blind • Superiority trial
Patients	N=775 Eluvia N=508 vs BMS N=267
Primary Endpoint	12-Month Primary Patency
Investigational Centers	58 study centers in 10 European Countries

EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

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EMINENT Study Devices

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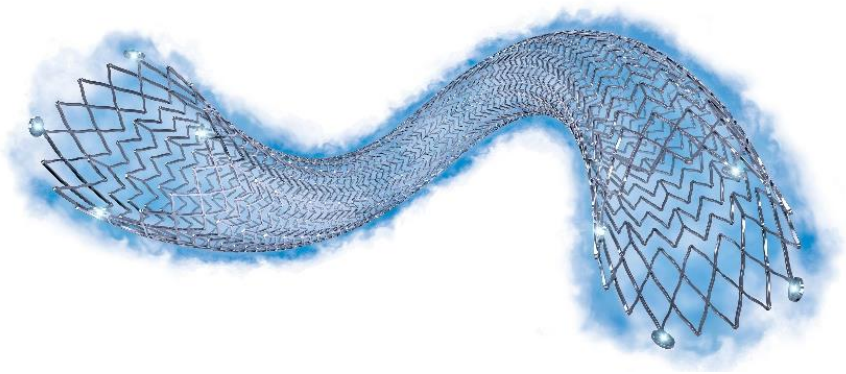
ELUVIA Drug-Eluting Stent
N=508



VS

Bare Metal Stents (BMS)
N=267

Innova™ Vascular Self-Expanding Stent	(Boston Scientific)
Supera™ Peripheral Stent	(Abbott)
LifeStent™ Vascular Stent	(Bard)
EverFlex™ Self-Expanding Peripheral Stent	(Covidien/Medtronic)
S.M.A.R.T® Flex Vascular Stent and S.M.A.R.T. CONTROL® Vascular Stent	(Cordis/Cardinal)
Pulsar®-18	(Biotronik)
Compete® SE Vascular Stent	(Medtronic)

EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

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Baseline Patient Characteristics

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EMINENT Trial Details:

- 775 (RCT 2:1) patients across 58 centers in 10 European countries
- Rutherford category 2, 3, or 4
- Degree of stenosis ≥ 70% (visual angiographic assessment)
- Vessel diameter ≥ 4 mm and ≤ 6 mm
- Total lesion length ≥ 30 mm and ≤ 210 mm

	Baseline Characteristics	ELUVIA DES (n=508)	CONTROL (n=267)	p-value
Demographics	Age (years)	68.9 ± 8.7	68.9 ± 9.1	0.9739
	Male Gender	71.5%	67.4%	0.2431
	Diabetes Mellitus (medically-treated)	31.9%	32.6%	0.8440
	History of Smoking (current/previous)	36.0%/39.6%	36.0%/41.6%	0.9849/0.5884
Lesion	Percent Stenosis (%)	86.6 ± 15.2	85.5 ± 15.3	0.3629
	Total Occlusions	42.3%	39.9%	0.5372
	Total Stented Length (mm)	105.8 ± 48.4	109.2 ± 49.8	0.3858
	Target Lesion Length (mm)	75.6 ± 50.3	72.2 ± 47.0	0.3815
	Moderately Calcified	21.6%	26.0%	0.1849
	Severely Calcified	30.3%	31.1%	0.8122

EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

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Superior Effectiveness I Statistically Significant Primary Patency with Eluvia

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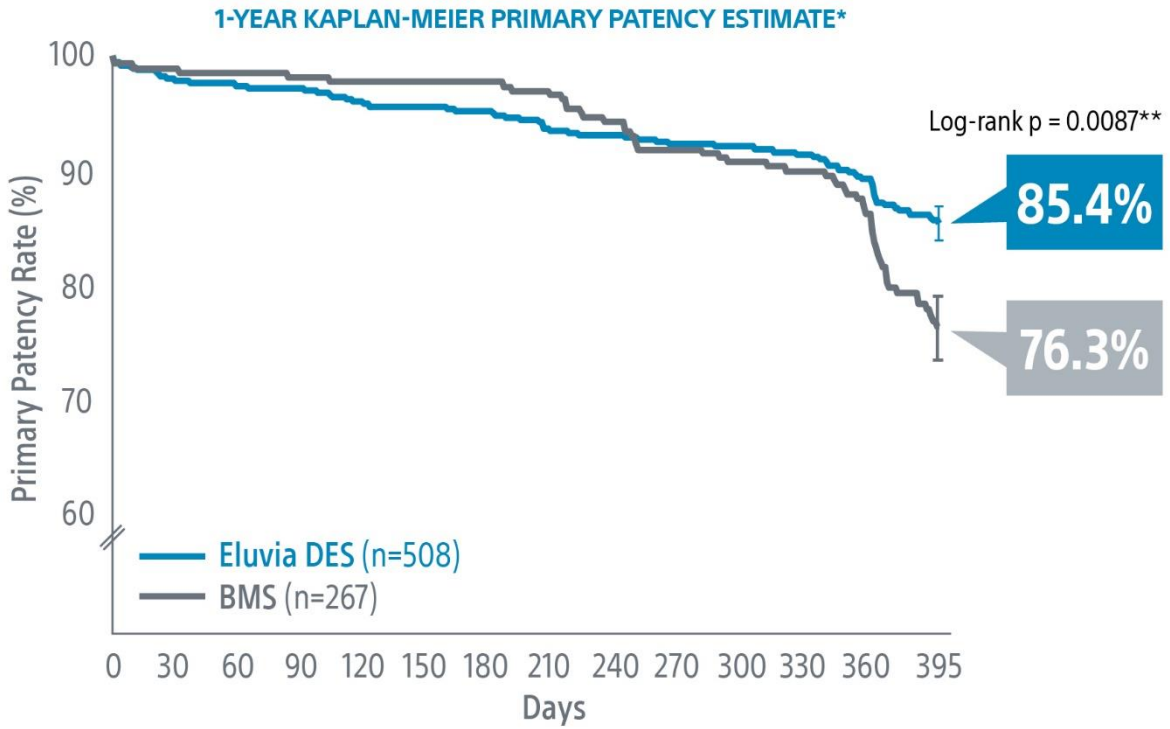
Eluvia DES demonstrated **superiority over BMS**[1] with a statistically significant primary patency through 1-Year



*Kaplan-Meier Estimate: Primary patency defined as core-lab assessed duplex ultrasound peak systolic velocity ratio (PSVR) ≤ 2.4 at 12 months in the absence of clinically-driven TLR or bypass of the target lesion.
**Log-rank p-value compares the entire K-M curves from time point zero to day 395 (full 1-year follow-up window)
1. EMINENT Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against commercially-available Self-Expanding Bare Nitinol Stents, single-blind, superiority design; independent core lab adjudication. 12-Month Primary Patency rate of 83.2% in the Eluvia arm vs. 74.3% in the Bare-Metal Stenting arm (p-value = 0.0077).
EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Sustained Clinical Improvement | Improvement in Rutherford Score

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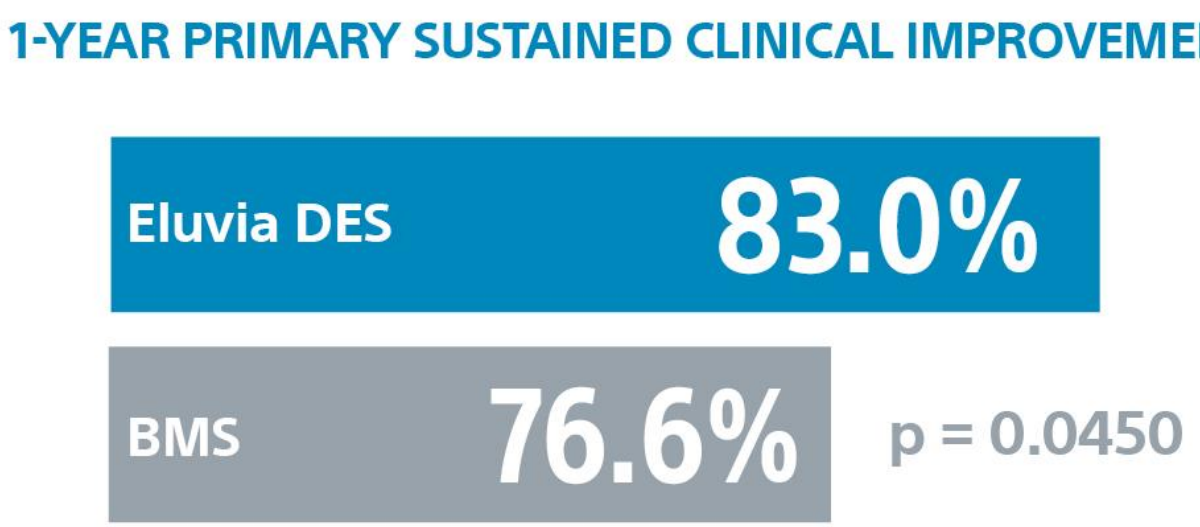
Eluvia DES demonstrated a **statistically significant greater rate of primary sustained clinical improvement** without reintervention over BMS through 1-Year



***In EMINENT, primary sustained clinical improvement was defined as an improvement (decrease) by at least 1 Rutherford category, without TLR.
EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Safety I Similar Major Adverse Events Among Eluvia and BMS

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No significant differences in CEC-adjudicated major adverse event rates.
No significant difference in all-cause death through 1-Year.

12-Month Major Adverse Event Rates	ELUVIA DES (n=492)	BMS (n=273)	p-value
All Death, Major Amputation, TLR	11.8% (56/474)	11.8% (31/263)	0.9912
All-Cause Death at 12 Months	2.7% (13/474)	1.1% (3/263)	0.1528
Target Limb Major Amputation	0.2% (1/474)	0.0% (0/263)	1.0000
Clinically-Driven Target Lesion Revascularization	8.4% (40/474)	10.6% (28/263)	0.3212

As-treated. Major adverse events adjudicated by the Clinical Events Committee. P values from Chi-square test or two-sided Fisher's exact test.

EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

EMINENT Conclusions

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Eluvia demonstrated superior effectiveness and sustained clinical improvement over BMS through 1-Year.

- Eluvia demonstrated superiority over BMS with a statistically significant primary patency through 1-Year (85.4% vs 76.3%; p=0.0087)
- Eluvia demonstrated a statistically significant greater rate of primary sustained clinical improvement without reintervention over BMS through 1-Year (83.0% vs 76.6%; p=0.0450)
- No significant differences in CEC-adjudicated major adverse event rates. No significant difference in all-cause death between Eluvia DES and bare metal stents through 1 year. (2.7% vs 1.1%; p=0.1518)

1. EMINENT Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against commercially-available Self-Expanding Bare Nitinol Stents, single-blind, superiority design; independent core lab adjudication. 12-Month Primary Patency rate of 83.2% in the Eluvia arm vs. 74.3% in the Bare-Metal Stenting arm (p-value = 0.0077).
EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

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ELUVIA™
Drug-Eluting Stent

IMPERIAL

Eluvia DES vs. Zilver® PTX®

IMPERIAL is the world's first Head-to-Head DES SFA Trial

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Enabling direct objective comparison of a real-world patient mix

Trial Design			Patient Characteristics	
Eluvia randomized vs. Cook's Zilver® PTX®	All DCB and Zilver PTX FDA-approval trials randomized vs. PTA or BMS	465 subjects at 64 sites worldwide	40% severely calcified (4-5x higher than IN.PACT and Lutonix FDA-approval trials)	31% of lesions total occlusions 42% diabetics

Eluvia demonstrated **superior 1-Year primary patency**[1] compared to Zilver PTX

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.
- 1-Year Primary Patency rate of **86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX arm** (p-value = 0.0144).
- Trial data published in the Lancet. (Gray WA, Lancet. 2018 Sep 24. pii:S0140-6736(18)32262-1).

1. 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). Gray WA, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1. Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

IMPERIAL Clinical Study Overview

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Primary Investigators	Global: William A. Gray, MD European: Stefan Müller-Hülsbeck, MD		
Study Design	**RCT (Eluvia DES vs Zilver PTX)** • 2:1 randomized • Single-blind • Non-inferiority trial	**Long Lesion Sub-study (Eluvia)** • Single arm • Lesion Length 140 mm – 190 mm	**Pharmacokinetic Sub-Study (Eluvia)** • Single-arm
Patients	N=465 Eluvia N=309 vs Zilver PTX N=156	N=50	N=13
Investigational Centers	65 study centers: US, Canada, New Zealand, Belgium, Germany, Austria, Japan		

Gray WA, et al. Lancet. 2018;392(10157):1541-1551.

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IMPERIAL Study Devices

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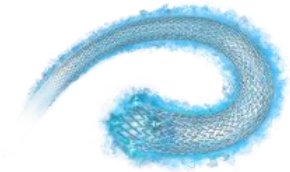

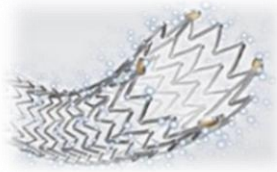

	ELUVIA™ DES Boston Scientific		Zilver® PTX® Cook Medical	
Stent Platform	Innova		Zilver Flex	
Material	Nitinol		Nitinol	
Polymer	Biostable Fluorinated Polymer Matrix (PROMUS polymer)		None	
Drug Dose Density	Paclitaxel, 0.167 µg/mm^2		Paclitaxel, 3 µg/mm^2	
Deployment	Self-expanding		Self-expanding	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

BSC Data on file. Zilver PTX DFU

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Superior Effectiveness I Statistically Significant Primary Patency with Eluvia

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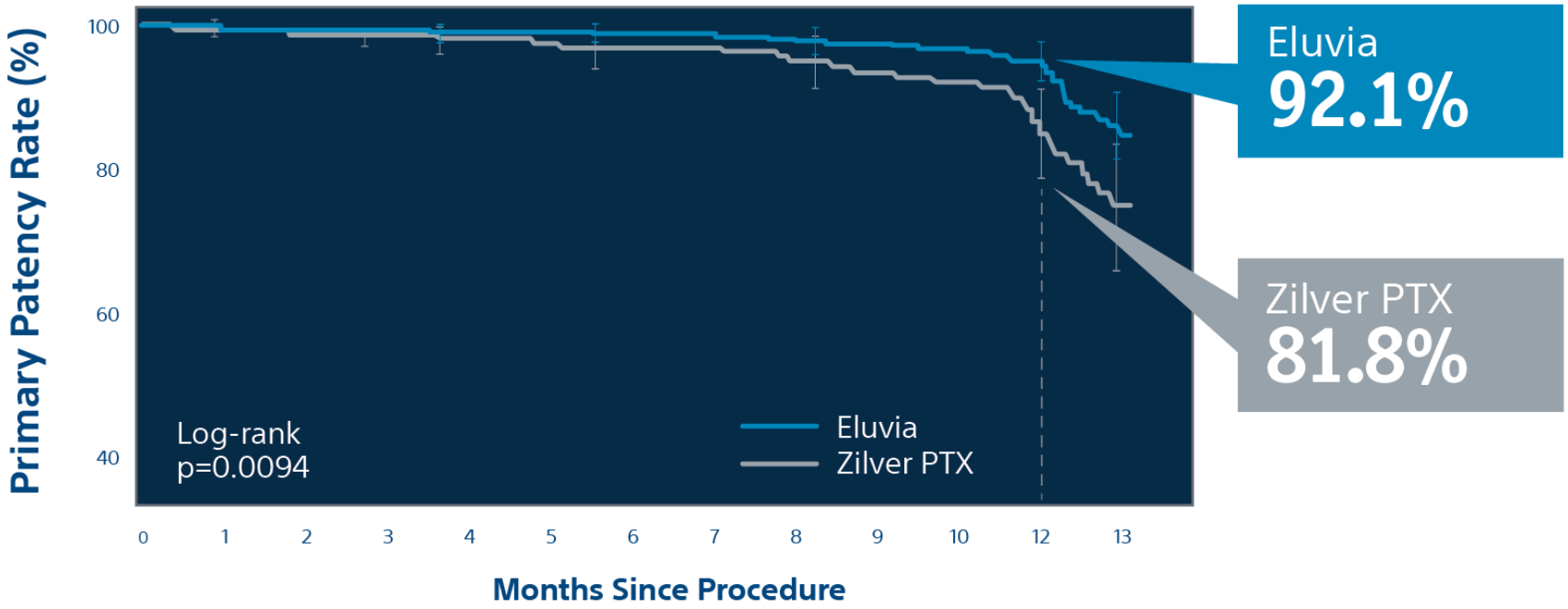
Eluvia DES demonstrated **superiority over Zilver PTX[1]** with a statistically significant primary patency through 1-Year



Eluvia also achieved **the highest primary patency** reported in any SFA DE Pivotal Trial at 1-Year

1. 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). Gray WA, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1.

*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.

**Log-rank p-value compares the entire K-M curves from time zero to full one year follow-up window.

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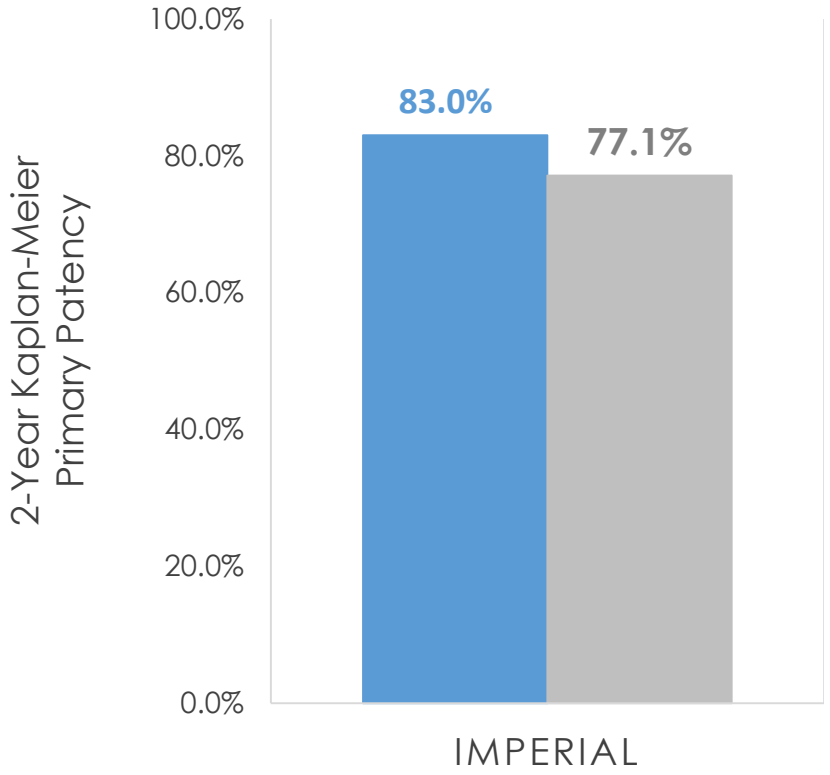
Effectiveness I Highest 2-Year Primary Patency for DES



	Eluvia	Zilver PTX
Lesion Length	8.7 cm	8.2 cm

Intention to Treat. Adapted from Iida, O VIVA 2019 Presentation. Kaplan-Meier Estimate.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Effectiveness I Durable, Consistent Results in Complex Lesions at 2 Years

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IMPERIAL TRIAL 2-YEAR CLINICAL RESULTS Excellent Patient Follow-up at 24-Months (~90%)	**IMPERIAL RCT**[2] (n = 309)	**IMPERIAL Long Lesions**[2,3] (n = 56)	**Diabetic Subgroup** (n = 116)	**Severe / Moderate Calcium Subgroup** (n = 193)	**CTO Subgroup** (n = 96)
Study Design	RCT, multicenter, global	Single arm, multicenter, global	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global
24-month primary patency rate**	**83.0%**	**77.2%**	**85.7%**	**85.0%**	**76.4%**
Lesion length (mm)	86.5	162.8	87.0	89.9	94.4
Severe calcification	40%	28%	46%	n/a	n/a
Total occlusions	31%	32%	25%	n/a	100%
	Highest primary patency ever reported at 2 years*	**Highly durable outcomes in ~16cm lesions at 2 years**	TLR (12%) in line with overall cohort and **low stent thrombosis rate** (0.9%)	Remarkable primary patency and **<10% TLR** in **heavy calcium**	**Highly durable outcomes in CTOs at 2 years**

*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.
**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.
2. In IMPERIAL RCT, Eluvia K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p =0.1008
Diabetic Subgroup Analysis = Medically Treated Diabetes

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Drug-Eluting Data In Perspective
Kaplan-Meier Primary Patency at 2-Years

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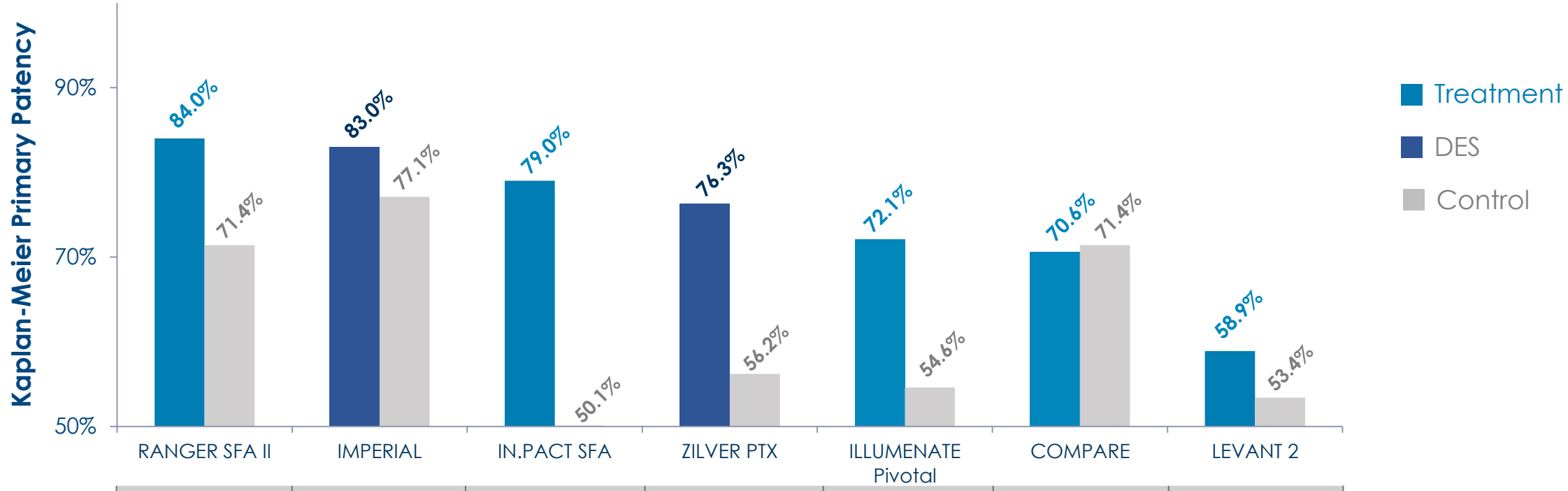

Treatment vs. Control	Ranger vs. PTA	Eluvia vs. Zilver PTX	IN.PACT Admiral vs. PTA	Zilver PTX vs. BMS	Stellarex vs. PTA	Ranger vs. In.Pact	Lutonix vs. PTA
Mean lesion length (cm)	8.3	8.7	8.9	6.6	8.0	12.3	6.3

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

References:
- Dake et al (2016). Circulation. 2016;133:1472-1483; TASC C/D: Zilver PTX Instruction for use (Aug 2019)
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- COMPARE Clinical Trial 24-Month Results presented by Sabine Steiner, MD. LINC 2021
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- RANGER II SFA 2 Year Reults Presented at VIVA 2021 by Ravish Sachar, MD

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Long Lesion Sub-study 2-Year Patency in Perspective*

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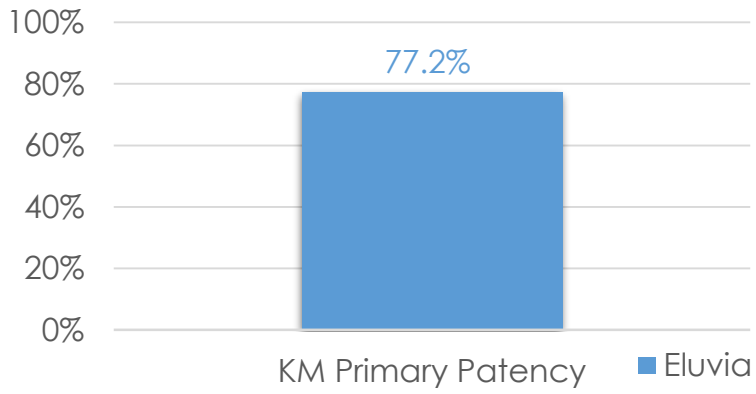
LONG LESION SUB-STUDY 24-MONTH OUTCOMES[1] with Eluvia

Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: Outcomes of the Single-Arm IMPERIAL Long Lesion Sub-study of the Eluvia Drug-Eluting Stent

Lesion Characteristics	IMPERIAL Long Lesion
Lesion Length	16.2 cm
Mod/Sev Calcium	70%
Chronic Total Occlusion (CTO)	32%
Diabetics	40%

2-yr KM Primary Patency

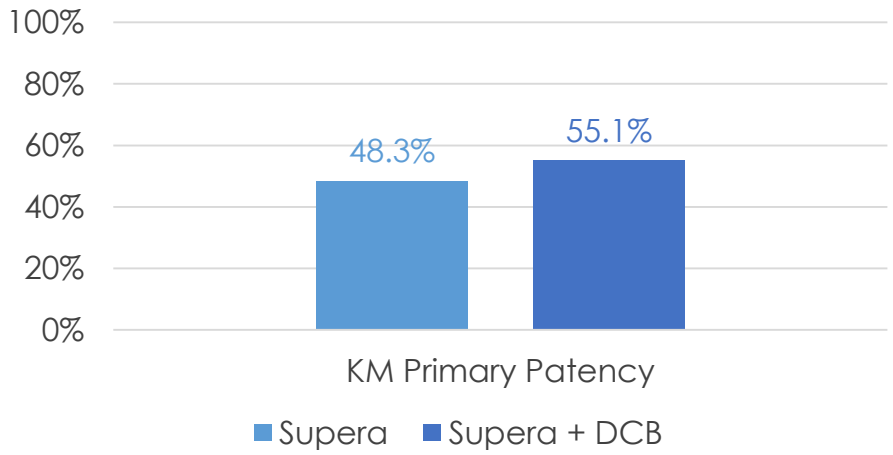


RAPID TRIAL 24-MONTH OUTCOMES[2] with Supera and DCB

Drug coated balloon supported Supera stent versus Supera stent in intermediate and long-segment lesions of the superficial femoral artery: 2-year results of the RAPID Trial

Lesion Characteristics	RAPID
Lesion Length	15.8 cm
Mod/Sev Calcium	Not Reported
Chronic Total Occlusion (CTO)	>70%
Diabetics	~30%

2-yr KM Primary Patency



*Results from different clinical investigations are not directly comparable. Information provided for educational purposes only

1. Vermassen, F. VIVA Late-Breaking Clinical Trials June 2020
2. de Boer, Sanne et al (2019). Drug coated balloon supported Supera stent versus Supera stent in intermediate and long-segment lesions of the superficial femoral artery: 2-year results of the RAPID Trial. The Journal of cardiovascular surgery. 60. 10.23736/S0021-9509.19.11109-3.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Effectiveness I Low Repeat Interventions at 2 Years

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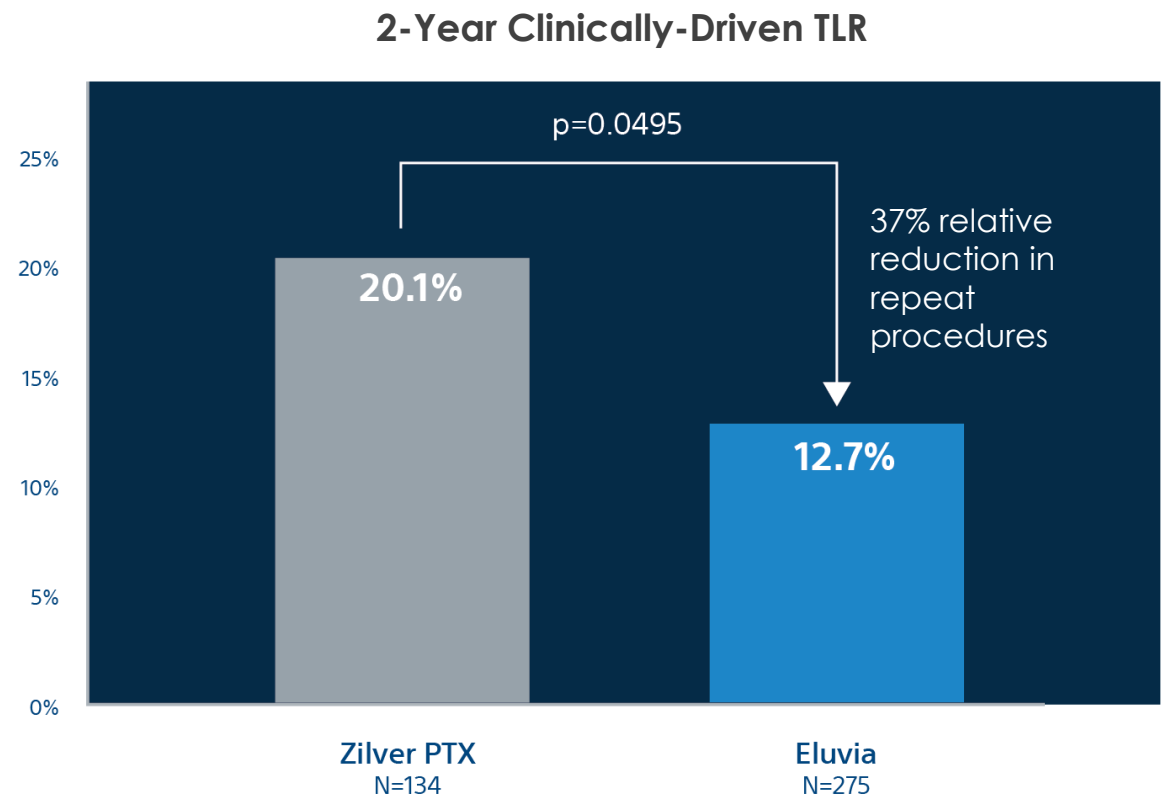
ELUVIA had **statistically significant fewer repeat procedures compared to ZILVER PTX**[1] at 2-Years



1. Intention to treat. Iida O, VIVA 2019. RCT, randomized controlled trial; TLR, target lesion revascularization.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Effectiveness I Low Repeat Interventions at 2 Years

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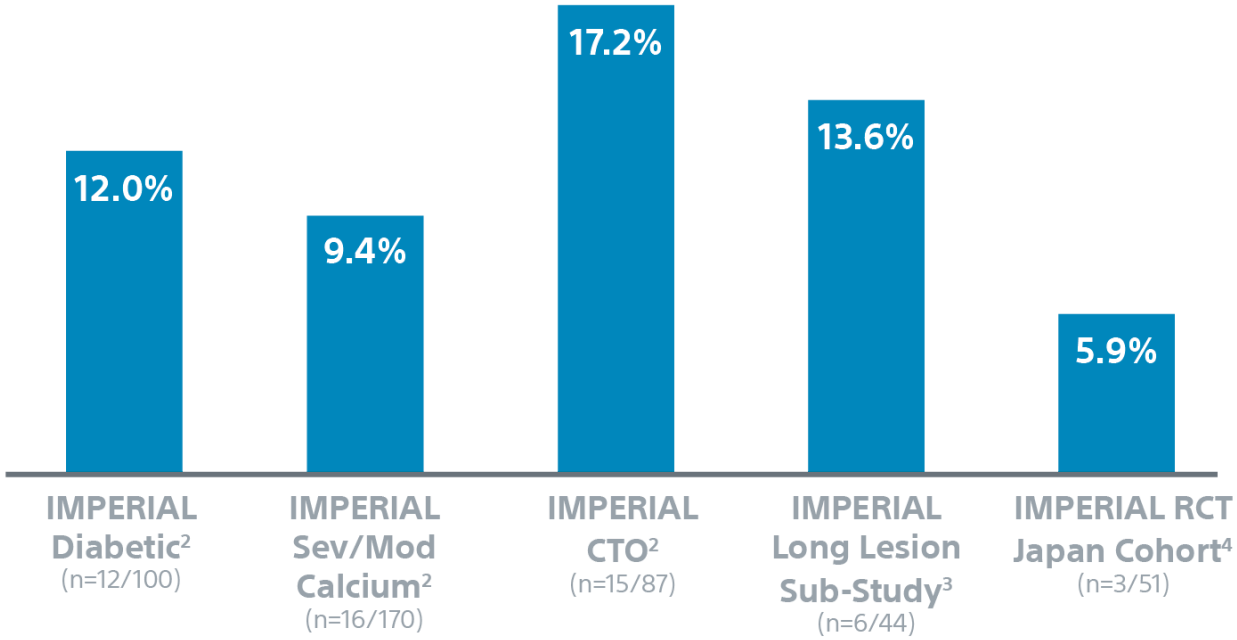
Eluvia demonstrated consistently low CD-TLR at 2-Years in challenging SFA disease

Exceptional Outcomes at 2 Years: Reduction[1] in Repeat Procedures



1. RCT, As-Treated Clinically-Driven TLR at 2-years: 20.1% for Zilver PTX vs. 12.7% for Eluvia (p=0.0495). 2. Intention to treat. A target lesion revascularization will be considered clinically-driven if it occurs within 5 mm proximal or distal to the original treatment segment with diameter stenosis ≥50% by quantitative angiography (QA) and the subject has recurrent symptoms (≥ 1 change in Rutherford Classification or associated with decreased ABI/TBI of ≥20% or ≥0.15 in the treated segment. TBI allowed in cases of incompressible vessels.
2. Gray, W. 2 year Outcomes from the IMPERIAL Randomized Head to Head Study of Eluvia DES and Zilver PTX. LINC 2020.
3. Vermassen, F. VIVA Late-Breaking Clinical Trials June 2020.
4. Iida, O. IMPERIAL Head to Head Randomized Study of Eluvia and Zilver PTX. Two-Year Outcomes & Japanese Patients. JET 2020.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Safety I Low All-Cause Mortality* 2-Years

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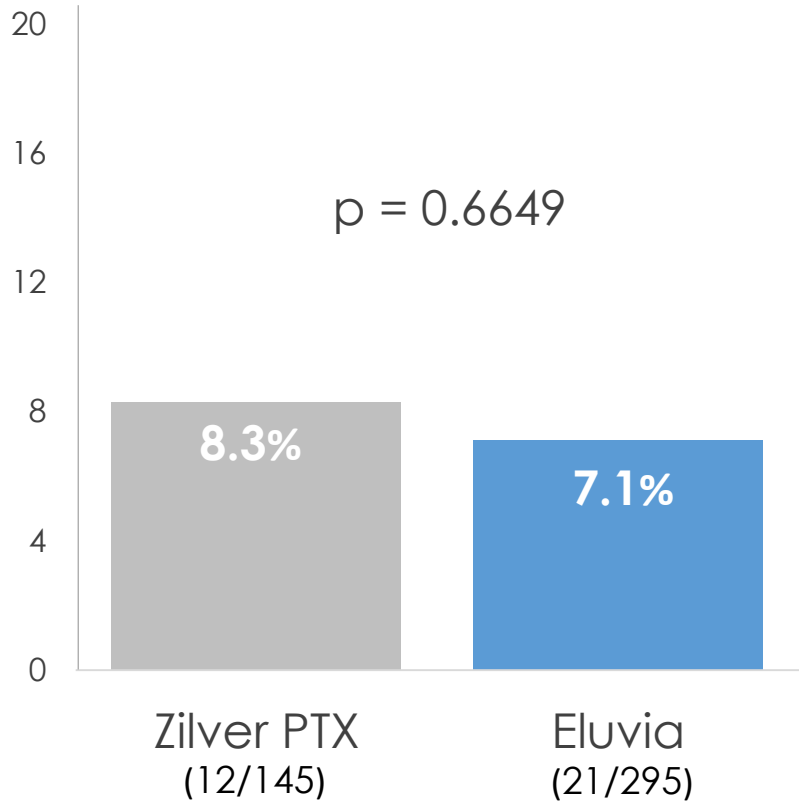
All-cause mortality was within range expected for symptomatic PAD and no differences were observed between both therapies**



Intention to treat. Adapted from Iida, O, VIVA 2019 Presentation
*CEC-adjudicated all-cause mortality
**Amputation Rates, Mortality, and Pre-operative Comorbidities in Patients Revascularised for Intermittent Claudication or Critical Limb Ischaemia: A Population Based Study Baubeta Fridh, E. et al. European Journal of Vascular and Endovascular Surgery, Volume 54 , Issue 4 , 480 – 486

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

IMPERIAL Conclusions

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At 1 and 2-Years, Eluvia DES demonstrates remarkable longer-term durability in patients with complex SFA disease.

- Superiority over Zilver PTX[1] with a statistically significant primary patency through 1-Year.
- Highest 2-year primary patency rate for a DES (83.0% KM estimate) in SFA disease.
- Statistically significantly lower clinically-driven TLR rate at 2 years for Eluvia vs Zilver PTX (12.7% vs 20.1%; p=0.0495).
- Eluvia demonstrated consistently low CD-TLR at 2 years in challenging SFA disease (Calcium, CTO, Diabetic, Long Lesions).
- No difference in all-cause mortality for Eluvia 7.1% vs. 8.3% for Zilver PTX (p=0.6649) at 2 years. Mortality rate within range expected for symptomatic peripheral arterial disease.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Korean National Health Insurance Service

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"인공혈관 수가 낮다"며 '고어' 철수...3살 민규의 위태로운 생명

Low price and too much quality-related request for artificial arterial graft of GORE → Gore retreated from Korean market

김민제 기자 十구독

등록 :2019-03-07 05:00 수정 :2019-03-07 09:28

소아용 인공혈관 독점업체 '고어'
의료수가 낮다며 한국에서 철수
병원 재고 떨어지자 수술 못 해
복지부 "원하는 가격 다 주겠다"
공급 재개 요청에도 고어 무응답

This baby could not undergo cardiac surgery.

'고어(Gore)'사의 인공혈관이 없어 선천성심장병 수술을 받지 못한 양민규(3)군.

사회 많이 보는 기사

1. 지하철 시위 미참여 한국장총, 다시 "이준석 대표 사퇴해야"
2. "구속될 듯하면 차키 주세요" 법원앞 주차장 고단한 사연들
3. 오늘도 삭발..."이준석 대표, 일주일 동안 휠체어 함께 타보자"
4. 법무·검찰 고위간부 재산 평균 20억원...법무부 한동훈·검찰 노정연 '1위'
5. 4일부터 '10인·12시' 거리두기 완화...오미크론은 '긴 꼬리' 유행

한겨레와 친구하기

3 years journey for Eluvia Premium Price has definitely not been easy, but all the teamwork has paid off

- Well-Prepared Success : Opportunities come only to those who are ready
- Try some NEW things Together with the team to become the best HEGA in Korea

Eluvia Korean Budget Impact Model : **The First BIM in Korea** by Korea-AP HEGA collaboration

Eluvia Reimbursement April 2017 Same price with Zilver PTX

Ministry of Health and Welfare

J-group re-evaluation announcement Jan 2020

BSK Premium price application submitted under re-evaluation Mar 2020

HIRA Value appraisal committee Oct 2020

First Discussion on BIM with KR-AP HEMA, PI @ Danang, VN **Feb 2019**

- ✓ ***Let's try something new together for Eluvia!!***
- ✓ *Do we really need the E-BIM in Korea?*
- ✓ *Why should we try?*
- ✓ *Korean physicians may dislike the BIM*
- ✓ *Are we wanting the premium price of Eluvia?*

Clinical expert, Prof. SW Park engagement Contract Dec 2019

- ✓ ***First cross-border engagement*** *with Korean physician for* ***health economic data generation***

Finalize the model and submit to ISPOR Mar 2020

- ✓ *Decision made for* ***premium price application under re-evaluation***

Korea BIM abstract publication via ISPOR Sept 2020

- ✓ ***BIM abstract, CMS add-on payment submitted to HIRA before the committee***

BUDGET IMPACT ANALYSIS OF THE ELUVIA DRUGELUTING STENT FOR PERIPHERAL ARTERY DISEASE IN KOREA

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- Objectives: Lower-limb peripheral arterial disease (PAD) is a common manifestation of systematic atherosclerosis leading to significant morbidity and mortality. In Korea, drug-eluting stent (DES) implantation is the standard of care for treatment of PAD, however, different DES products are associated with different rates of total lesion revascularisation (TLR) and subsequent healthcare resource use. This study aimed to estimate the financial savings realised when selecting a paclitaxel-eluting DES (Eluvia) over a paclitaxel-coated DES (Zilver PTX) for treatment of PAD in Korea at the population-level.
- Methods: **A 5-year budget-impact analysis** was conducted to estimate the cost savings associated with the use of Eluvia compared with Zilver-PTX from the Korean National Health Insurance System perspective. Two-year efficacy and safety data were sourced from the IMPERIAL randomised controlled trial which compared Eluvia and Zilver PTX in patients with lower-limb PAD. Episodic cost and epidemiology data relating to endovascular percutaneous and surgical interventions, DES prices and volume, were collected from Korea's Health Insurance Review and Assessment (HIRA) service, using relevant K-ICD10 codes; and were validated externally. Yearly growth in procedures was informed by historical trends. Trial results at 12-24 months were applied to each year's incident population (with no projections) and associated costs in order to calculate the number of TLRs and hospital readmissions.

Park SW, Ariyaratne TV, Peacock A, Deltetto I, Yoo SJ, Jung SJ, Taylor C

BUDGET IMPACT ANALYSIS OF THE ELUVIA DRUGELUTING STENT FOR PERIPHERAL ARTERY DISEASE IN KOREA

Boston Scientific
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- Results: The analysis estimated a total of 8,416 patients with lower-limb PAD will be treated with DES from 2020-2024. Assuming 100% of these patients will be treated with Eluvia compared with Zilver PTX, potential savings of₩5,489 million (wUSD 4.5 million) was estimated to the Korean payer. Potential savings were primarily driven by the fewer TLRs with Eluvia compared with Zilver PTX (1,190 vs. 2,035) over the 5-year period.

- Conclusions: The Eluvia DES is a cost-saving option for lower-limb PAD treatment in Korea, owing to the reduced TLRs and hospital readmissions compared with Zilver PTX.

As a result, Eluvia acquired 10% price premium over competitor product in South Korea (From Nov. 2021)

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Official announcement

약물방출 PTA STENT(PREMOUNTED TYPE)

J5238021	ELUVIA DRUG ELUTING VASCULAR STENT	전규격	1EA	BOSTON SCIENTIFIC CORPORATION	니켈-타이타늄 합금, 파클리탁셀 등	보스톤사이언티픽코리아	1,234,410	1,317,170	11/1/2021	상한금액 조정 및 가치평가 10% 가산

Premium price

Detail

	Before	Medical device re-evaluation assessment	Eluvia premium Price (based on BIM)	Price Gap
	*Same price* *KRW 1,234,410* *(USD 1,114)*[1]	*-3% applied for both products* *KRW 1,197,378* *(USD 1,081)*	*+10% premium* *KRW 1,317,170* *USD (1,189)*	*KRW 119,792* *(USD 108)*
			*N/A*	

1. *Standard exchange rate: 1 USD = KRW 1,108 applied*

ELUVIA™ Drug-Eluting Vascular Stent System

Boston Scientific
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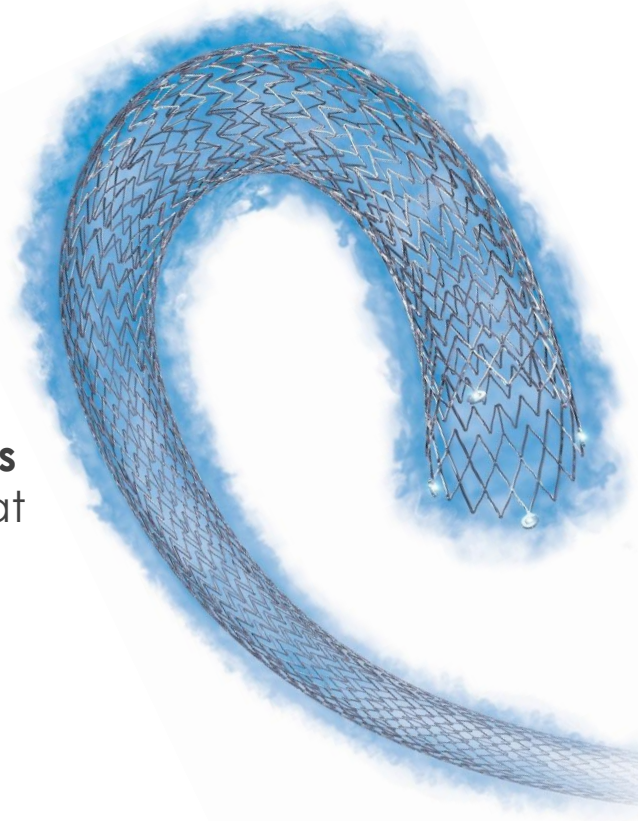
A New Standard of Care in SFA Stenting

No SFA stent has performed better at 2-Years.
No matter the lesion complexity.
No matter the patient.[1,2]

Eluvia demonstrated a statistically significant **superior primary patency at 1-Year over BMS**[3] and **Zilver PTX**.[4]

Eluvia demonstrated **statistically significant fewer repeat procedures compared to Zilver PTX** at 2-Years.[5]



1. 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. 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.
2. In IMPERIAL RCT, Eluvia K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p =0.1008. Diabetic Subgroup Analysis = Medically Treated Diabetes
3.EMINENT Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against commercially-available Self-Expanding Bare Nitinol Stents, single-blind, superiority design; independent core lab adjudication. 12-Month Primary Patency rate of 83.2% in the Eluvia arm vs. 74.3% in the Bare-Metal Stenting arm (p-value = 0.0077).
4. 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).
5. Intention to treat. IMPERIAL Head-to-Head RCT. 2-Year results presented by Osamu Iida, MD. VIVA 2019