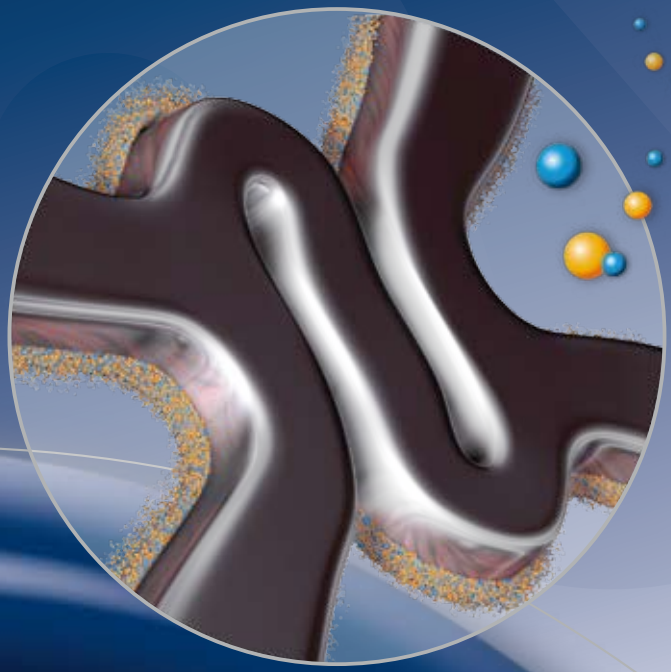
BioMatrix Flex™

THE ABLUMINAL BIODEGRADABLE POLYMER DES

From a DES to a BMS*



BIOSENSORS
INTERNATIONAL

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THE ABLUMINAL BIODEGRADABLE POLYMER DES

From a DES to a BMS*

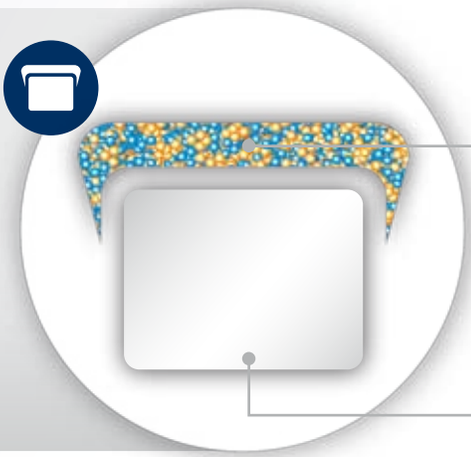
Abluminal biodegradable coating

No drug carrier or drug inside the stent:

– Early BMS-like endothelial coverage[1]

– More targeted drug release

– Reduced systemic exposure



PLA biodegradation and BA9™ drug elution

from a DES

Abluminal coating absorbed after 6-9 months*

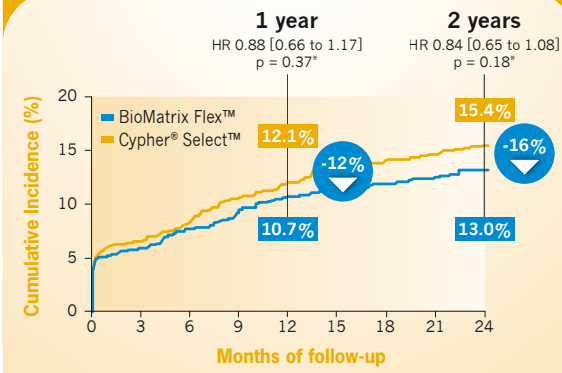
to a BMS*

Proven safety of a DES with an abluminal biodegradable polymer

Confirmed safety

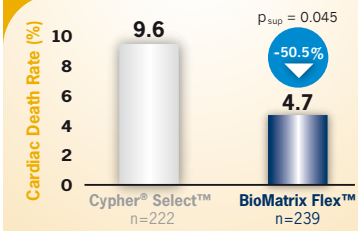
- With a 16 % reduction in MACE compared to the Cypher® Select™ stent at 2 years in LEADERS[2]
- With no late or very late stent thrombosis in STEALTH I out to 4 years[4]

MACE (Cardiac Death, MI or TVR) at 2 years[2]



*p = values for superiority

Significant Reduction in Cardiac Mortality in Complex Patients at 2 Years[3] – Syntax Score High (>16)



LEADERS post-hoc analysis

Mortality benefit

The BioMatrix Flex™ stent reduces the cardiac death rate by 50.5 % compared to the Cypher® Select™ stent at 2 years[3]

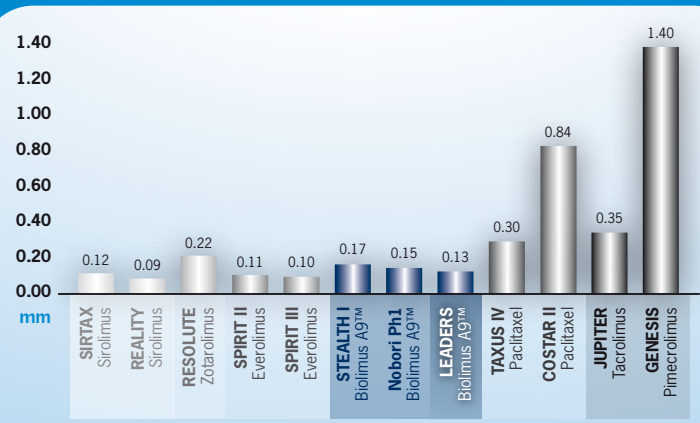
Proven efficacy of the Biolimus A9™ drug

Low Late Loss

- Lower level of late loss achieved in the LEADERS trial with the BioMatrix Flex™ stent at 9 months compared to the Cypher® Select™ stent[8]

In stent late loss in LEADERS = 0.13 mm[8]

In-Stent Late Luminal Loss at 9 months[9]

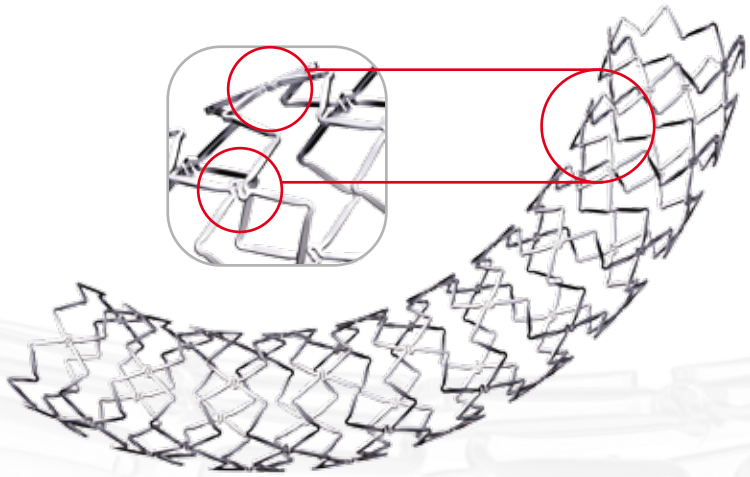


For descriptive purposes only – RCTs with different protocols should not be compared

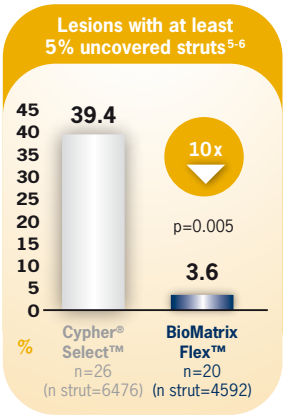
Enhanced deliverability** with advanced stent design

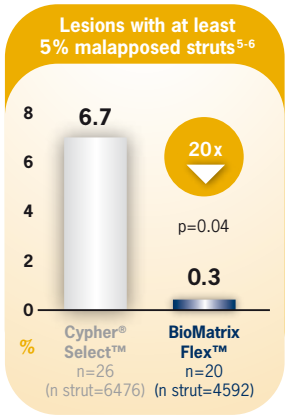
Improved flexibility[10]

The curved connectors combined with the Quadrature Link™ design give the Juno™ stent platform improved flexibility, while preserving stent security and vessel scaffolding



** Deliverability defined as a combination of flexibility, trackability and pushability





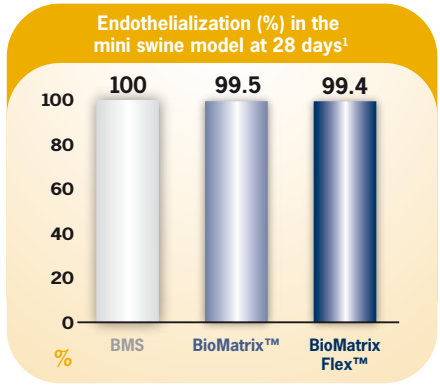
Superior strut coverage

10 times better strut coverage of the BioMatrix Flex™ stent than the Cypher® Select™ stent at 9 months[5-6]

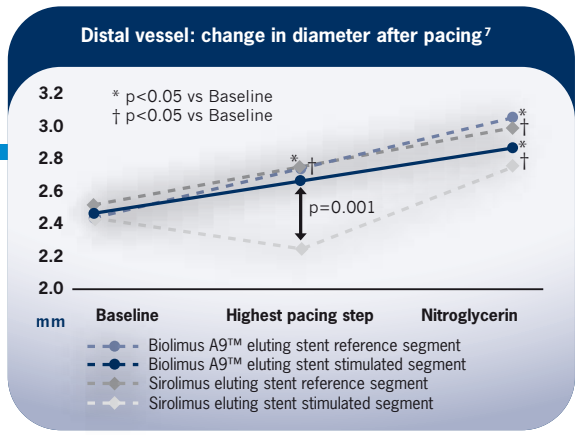
- The BioMatrix Flex™ stent achieves 96.4 % of near to complete strut coverage

Superior stent apposition

More than 20 times better stent apposition of the BioMatrix Flex™ stent than the Cypher® Select™ stent at 9 months[5-6]

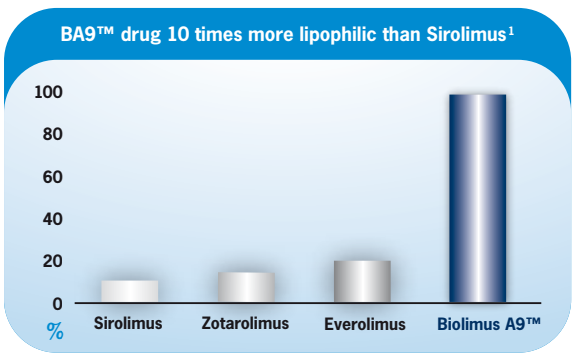


In the animal model, the BioMatrix Flex™ stent achieves a similar level of re-endothelialization compared to its bare metal stent platform



BA9™ drug / Biodegradable PLA technology demonstrates preserved vasomotion[7]

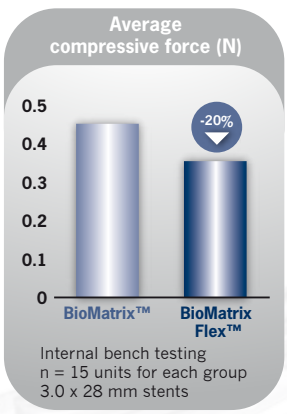
- Abnormal vasomotion (vasoconstriction) was observed for the sirolimus eluting stent group after high pacing stimulation, while normal vasomotion (vasodilatation) was observed in the BA9™ eluting stent group



Highest lipophilicity of the common limus drugs[1]

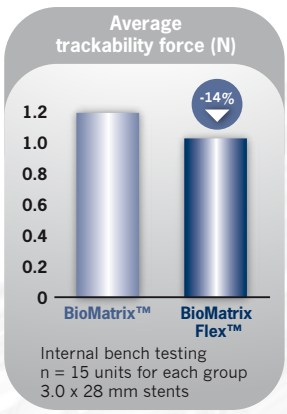
- Minimizes systemic exposure and reduces the drug circulating in the bloodstream
- Due to high lipophilicity, the drug is rapidly absorbed by tissue

Improved flexibility[10]

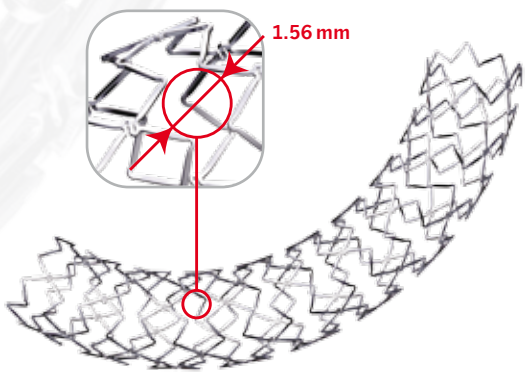


Less force needed to bend the BioMatrix Flex™ stent for improved deliverability**

Improved trackability[10]



Less force needed with the BioMatrix Flex™ stent to navigate through tortuous vessels for improved deliverability**



Larger side branch access[10]

- Improved initial cell opening to facilitate the side branch access

Taking the LEAD in DES Clinical Excellence

Our trials gather clinical data for this technology from a wide range of patients, including those with single de novo lesions, multiple vessel disease, acute coronary syndromes, bifurcations, left main, small vessels and extreme long lesions.

Trial		n	Planned FU	Status	Comparator
STEALTH PK		27	1 yr	Completed	Single Arm
STEALTH I		120	5 yrs	5 yrs FU completed	Gazelle™ (BMS)
BEACON I		292	1 yr	Completed	Single Arm
LEADERS		1707	5 yrs	2 yrs FU completed	Cypher® Select™ (DES)
BEACON II		497	5 yrs	30 d FU available	Single Arm
e-BioMatrix	**PMS** **PMR**	1122 4000	5 yrs	PMS Enrollment Completed PMR Currently enrolling	Single Arm
e-BioMatrix India	**PMD** **PMR**	1000 4000	5 yrs	Currently enrolling	Single Arm

From "Single de Novo"

To "Real World"

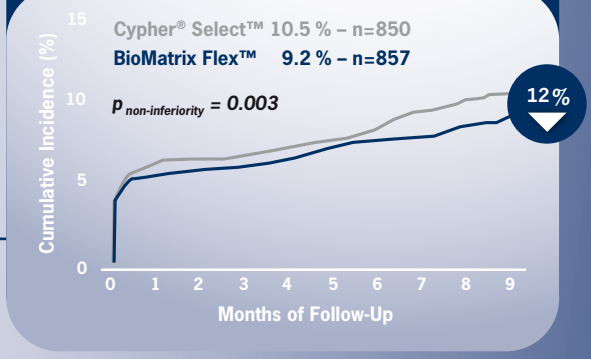
STEALTH PK n=27
Single Arm Registry, Pharmacokinetics
Primary Endpoint: Biolimus A9™ drug concentration at 30 days and 6 months

STEALTH I n=120
Randomized Multicenter Clinical Trial – BioMatrix™ vs Gazelle™ (2:1)
Primary Endpoint: In-Stent Late Loss at 6 months
Results: 0.09 vs 0.48 mm ($p < 0.01$)

BEACON I n=292
Multicenter Single Arm Registry
Primary Endpoint: TVR at 6 months
Results: 2.1 %

LEADERS n=1707
Randomized Multicenter All-Comers Clinical Trial
BioMatrix Flex™ vs Cypher® Select™
Primary Endpoint: CV death, MI, clinically-indicated TVR at 9 months
Results:

Primary Endpoint
Cardiac Death, MI or TVR at 9 months[8]

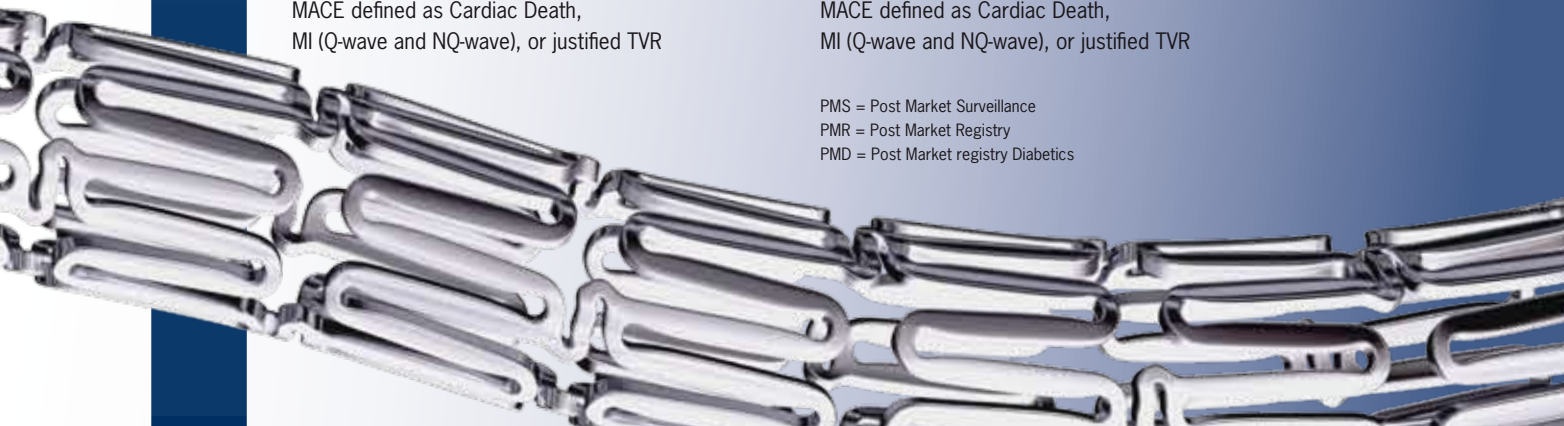


BEACON II n=497
Multicenter Single Arm Post Market Registry
Primary Endpoint: MACE at 12 months
MACE defined as Cardiac Death, Ischemic Driven MI (Q-wave and NQ-wave) and Ischemic Driven TLR (PTCA and CABG)

e-BioMatrix n=+5000
Multicenter Single Arm Post Market Registry
PMS: n=1122
PMR: n=4000
Primary Endpoint: MACE at 12 months
MACE defined as Cardiac Death,
MI (Q-wave and NQ-wave), or justified TVR

e-BioMatrix India n=5000
Multicenter Single Arm Post Market Registry
PMD: n=1000
PMR: n=4000
Primary Endpoint: MACE at 12 months
MACE defined as Cardiac Death,
MI (Q-wave and NQ-wave), or justified TVR

PMS = Post Market Surveillance
PMR = Post Market Registry
PMD = Post Market registry Diabetics



BIOMATRIX FLEX™

THE ABLUMINAL BIODEGRADABLE POLYMER DES

Ordering Information

	Stent Length (mm)					
Stent Diameter (mm)	**8**	**11**	**14**	**18**	**24**	**28**
2.25	BMX-2208	BMX-2211	BMX-2214	BMX-2218	BMX-2224	BMX-2228
2.50	BMX-2508	BMX-2511	BMX-2514	BMX-2518	BMX-2524	BMX-2528
2.75	BMX-2708	BMX-2711	BMX-2714	BMX-2718	BMX-2724	BMX-2728
3.00	BMX-3008	BMX-3011	BMX-3014	BMX-3018	BMX-3024	BMX-3028
3.50	BMX-3508	BMX-3511	BMX-3514	BMX-3518	BMX-3524	BMX-3528
4.00	BMX-4008	BMX-4011	BMX-4014	BMX-4018	BMX-4024	BMX-4028

Biosensors International Group, Ltd. licenses its proprietary BA9™ drug and PLA technology to Terumo Corporation (Nobori®), Devax, Inc. (AXXESS™) and Xtent, Inc. (XTENT®).

STEMI + ACS INDICATIONS DIABETICS

* In vivo testing in porcine model demonstrates abluminal coating is absorbed after 6 to 9 months – Data on file at Biosensors Intl

1. Data on file at Biosensors Intl
2. Klauss, V., LEADERS, 2-year Clinical Follow-Up, oral presentation, TCT 2009
3. Wykrzykowska, J., oral presentation, Late Breaking Trial Session, EuroPCR 2010
4. Grube, E., Safety and Performance Evaluation of Biosensors Biolimus A9™ Eluting Stent (BioMatrix™) STEALTH I: a 4-year safety follow-up, e-poster, TCT 2008 – The BioMatrix™ stent was used in the STEALTH I clinical trial
5. Di Mario, C., OCT: Differences between biodegradable and durable polymers – Insights from the LEADERS trial, oral presentation, TCT 2008
6. Barlis, P. et al., An optical coherence tomography study of a biodegradable vs. durable polymer-coated limus-eluting stent: a LEADERS trial sub-study; European Heart Journal (2010) 31, 165-176
7. Hamilos, M. et al. on behalf of the Nobori Core investigators, Differential Effects of Drug-Eluting Stents on Local Endothelium-Dependent Coronary Vasomotion, J Am Coll Cardiol 2008 51:2123-2129
8. Windecker, S. et al., Biolimus-eluting stent with biodegradable polymer versus Sirolimus-eluting stent with durable polymer for coronary revascularization (LEADERS): a randomised non inferiority trial; The Lancet 2008; 372 No. 9644: 1163-1173
9. Windecker, S. et al., NEJM 2005; Morice, M.-C. et al., JAMA 2006; Serruys, P.W. et al., EuroIntervention 2006; Stone, G.W. et al., JAMA 2008; Costa, M. et al., Am J Card 2006; Chevalier, B. et al., EuroIntervention 2006; Ostojic, M. et al., EuroIntervention 2008; Stone, G.W. et al., NEJM 2004; Krukoff, M.W., JACC 2008; Verheye, S. et al., ACC/SCAI 2008
10. Compared to the BioMatrix™ stent platform – Internal bench testing – Flexibility and trackability: n=15 in each group, 3.0x28 mm stents – Side branch access: n=2 in each group, 3.0x28 mm/3.0x18 mm stents – Bench test results may not necessarily be indicative of clinical outcomes

BioMatrix Flex™ Drug Eluting Stent System is CE approved.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

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