Biosensors Clinical Trial Program

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	3 yrs FU completed	Cypher® Select™ (DES)
BEACON II		497	5 yrs	30 d FU available	Single Arm
e-BioMatrix	**PMS** **PMR**	1000 4000	5 yrs	PMS Enrollment Completed PMR Currently enrolling	Single Arm
e-BioMatrix India	**PMD** **PMR**	1000 4000	5 yrs	Currently enrolling	Single Arm

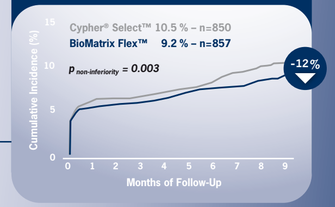
From "Single de Novo"

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 %

Primary Endpoint
Cardiac Death, MI or TVR at 9 months[6]



To "Real World"

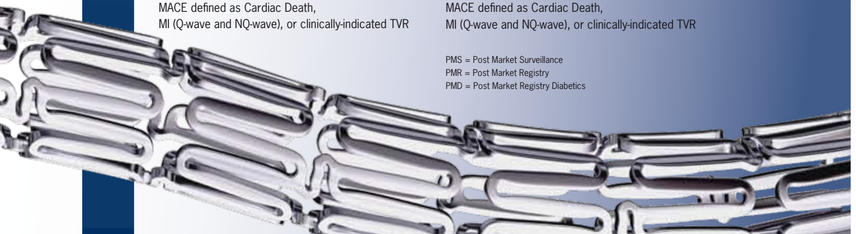
LEADERS n=1707
Randomized Multicenter All-Comers Clinical Trial
BioMatrix Flex™ vs Cypher® Select™
Primary Endpoint: CV death, MI, clinically-indicated TVR at 9 months
Results:

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

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

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



BioMatrix THE ABLUMINAL BIODEGRADABLE POLYMER DES Flex™

Ordering Information

AVAILABLE NOW
LONG LENGTHS

	Stent Length (mm)							
Stent Diameter (mm)	8	11	14	18	24	28	33 NEW!	36
2.25	BMX-2208	BMX-2211	BMX-2214	BMX-2218	BMX-2224	BMX-2228	NA	NA
2.50	BMX-2508	BMX-2511	BMX-2514	BMX-2518	BMX-2524	BMX-2528	BMX-2533	BMX-2536
2.75	BMX-2708	BMX-2711	BMX-2714	BMX-2718	BMX-2724	BMX-2728	BMX-2733	BMX-2736
3.00	BMX-3008	BMX-3011	BMX-3014	BMX-3018	BMX-3024	BMX-3028	BMX-3033	BMX-3036
3.50	BMX-3508	BMX-3511	BMX-3514	BMX-3518	BMX-3524	BMX-3528	BMX-3533	BMX-3536
4.00	BMX-4008	BMX-4011	BMX-4014	BMX-4018	BMX-4024	BMX-4028	NA	NA

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

The BioMatrix Flex™ stent is indicated in diabetics, STEMI and ACS patients for stent lengths up to 28 mm.

* 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. Serruys, P. W., oral presentation, TCT 2010
3. Windecker, S., oral presentation, TCT 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. 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
6. 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
7. 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
8. Compared to the BioMatrix™ stent platform – Internal bench testing – Flexibility and trackability: n=15 in each group, 3.0x28mm stents – Side branch access: n=2 in each group, 3.0x28mm/3.0x18mm 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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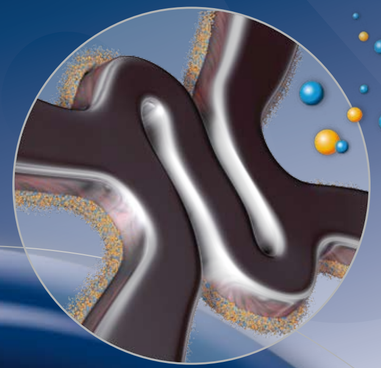
BioMatrix THE ABLUMINAL BIODEGRADABLE POLYMER DES Flex™

From a DES to a BMS*

STEMI + ACS INDICATIONS DIABETICS



BIOSENSORS INTERNATIONAL

BioMatrix FLEX™

THE ABLUMINAL BIODEGRADABLE POLYMER DES

From a DES to a BMS*

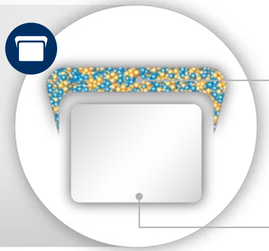
Abluminal biodegradable coating

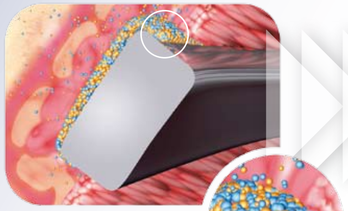
No drug carrier or drug inside the stent:

– Early BMS-like endothelial coverage[1]

– More targeted drug release

– Reduced systemic exposure





PLA biodegradation and BA9™ drug elution

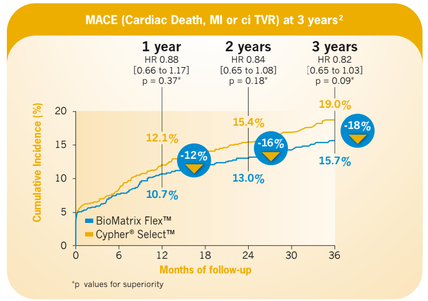
Abluminal coating absorbed after 6-9 months*

from a DES **to a BMS***

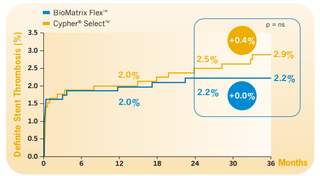
Proven safety of a DES with an abluminal biodegradable polymer

Confirmed safety and efficacy
out to 3 years in an "All-Comers" population

- With an 18 % reduction in MACE compared to the Cypher® Select™ stent at 3 years in LEADERS[2]
- With a strong trend in favor of BioMatrix Flex™

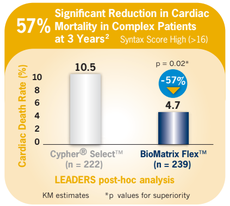


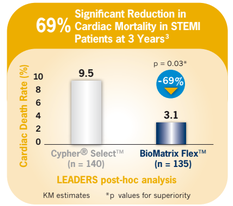
Confirmed safety with no additional definite VLST for BioMatrix Flex™ from 2 to 3 years[2]



- 0.2% cumulative VLST at 3 years
- No VLST in native coronary arteries

Significant Cardiac Mortality Benefit





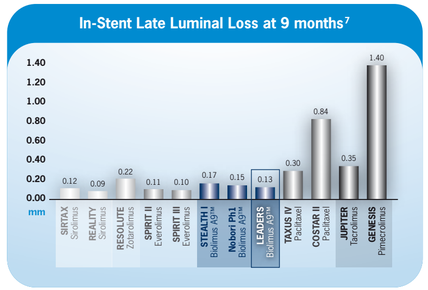
BioMatrix Flex™ shows a significant reduction in cardiac death in complex patients (STEMI and Syntax High [>16]) at 3 years

Proven efficacy of the Biolimus A9™ drug

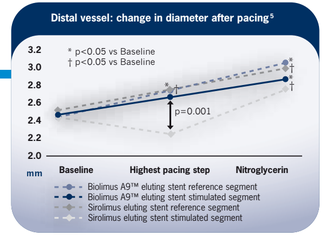
Low Late Loss

- Lower level of late loss achieved in the LEADERS trial with the BioMatrix Flex™ stent at 9 months compared to the Cypher® Select™ stent[6]

In stent late loss in LEADERS = 0.13 mm[6]

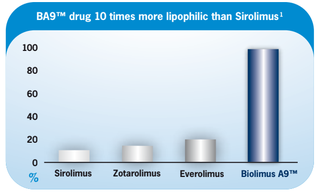


For descriptive purposes only – RCTs with different protocols should not be compared



BA9™ drug / Biodegradable PLA technology demonstrates preserved vasomotion[5]

• 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



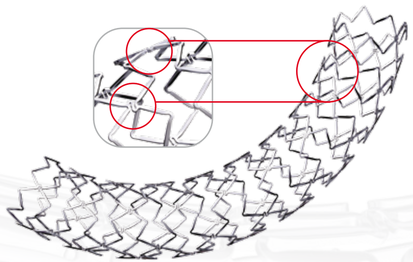
Highest lipophilicity of the common limus drugs[1]

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

Enhanced deliverability** with advanced stent design

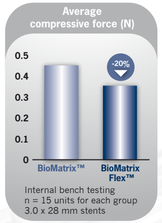
Improved flexibility[8]

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



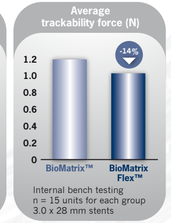
** Deliverability defined as a combination of flexibility, trackability and pushability

Improved flexibility[8]

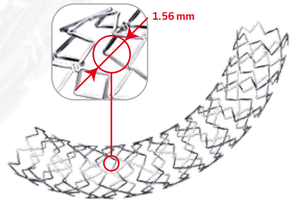


Less force needed to bend the BioMatrix Flex™ stent for improved deliverability**

Improved trackability[8]



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



Larger side branch access[8]

- Improved initial cell opening to facilitate the side branch access