

LEADERS 2-YEAR RESULTS

BIOMATRIX
THE ABLUMINAL BIODEGRADABLE POLYMER DES **FLEX**™

LEADERS "All-Comers" RCT Design

(PI: S. Windecker, Co-PI: P. Serruys)

Limus Eluted from A Durable versus ERodable Stent Coating

Randomized (1:1), Single-Blind, Multi-Center Study

"Real World": SVG, De Novo or Restenotic Coronary Artery Lesions, Chronic Stable Angina, Silent Ischemia, Acute Coronary Syndromes

BioMatrix Flex™
n = 857

Cypher® Select™
n = 850

10 Sites in Europe

Primary Endpoint:
Non-inferiority for cardiac death, MI, or clinically indicated TVR at 9 months

Clinical Follow-Up

9 mo 98.8%

1 yr 97.6%

2 yr 97.0%

LEADERS

met its primary endpoint¹
Relative reduction of MACE of 12%

BioMatrix Flex™
proves low Late Loss¹

In-Stent Late Loss at 9 months
0.13 mm BioMatrix Flex™
vs. 0.19 mm Cypher® Select™

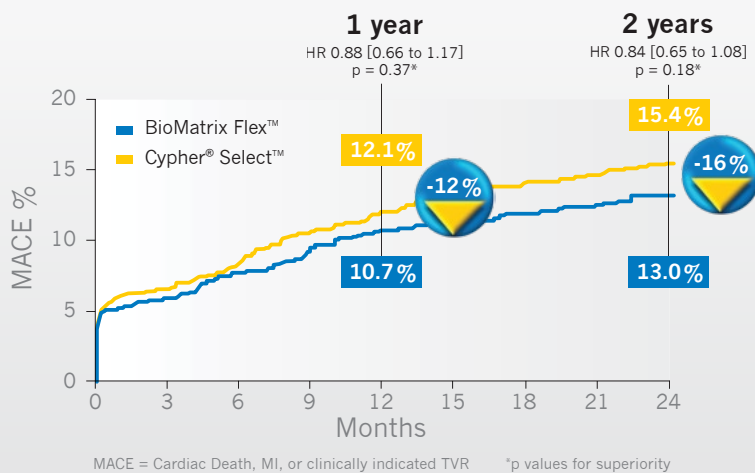
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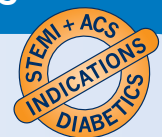
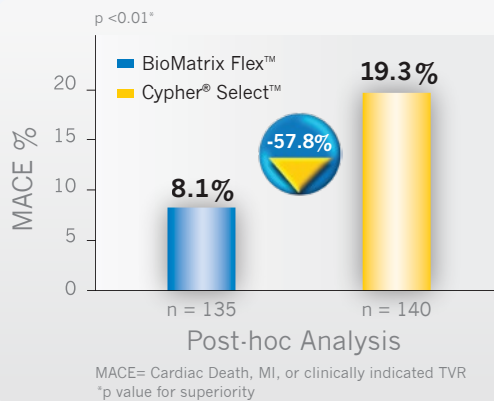
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Proven safety and efficacy of the BioMatrix Flex™ stent confirmed out to 2 years in an "All-Comers" population²



The cumulative incidence of MACE continues to diverge over time in favor of the BioMatrix Flex™ stent compared to the Cypher® Select™ stent.

Proven superiority of the BioMatrix Flex™ stent in STEMI patients at 2 years²



Statistically significant reduction of MACE in STEMI patients



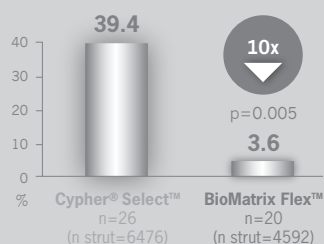
Lower rate of very late stent thrombosis with the BioMatrix Flex™ stent compared to the Cypher® Select™ stent in an “All-Comers” population

BIOMATRIX
THE ALUMINUM BIODEGRADABLE POLYMER DES **FLEX™**

LEADERS OCT Sub Study at 9 months³

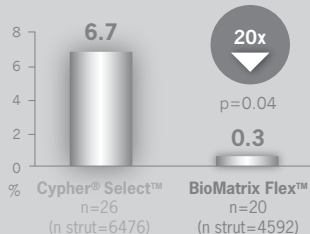
Superior strut coverage with the BioMatrix Flex™ stent compared to the Cypher® Select™ stent

Lesions with at least 5% uncovered struts⁴



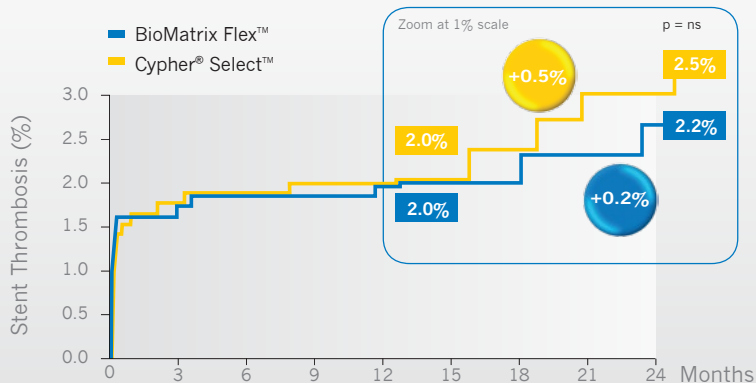
Superior stent apposition with the BioMatrix Flex™ stent compared to the Cypher® Select™ stent

Lesions with at least 5% malapposed struts⁴



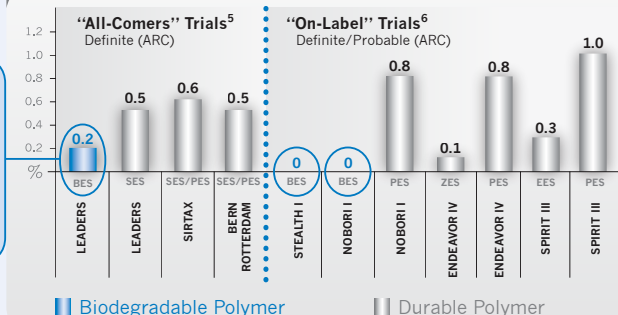
Signs of safety benefits for the BioMatrix Flex™ stent beyond 1 year²

Definite Stent Thrombosis - Very Late Stent Thrombosis (VLST) per ARC definition



In the BioMatrix Flex™ group, VLST were limited to SVGs, which are excluded from the “On-Label” trials reported for the 1st generation of DES using durable polymers.

Very Late Stent Thrombosis in perspective



The VLST rate of the BioMatrix Flex™ stent is the lowest as reported in the “All-Comers” multicenter RCTs⁷.

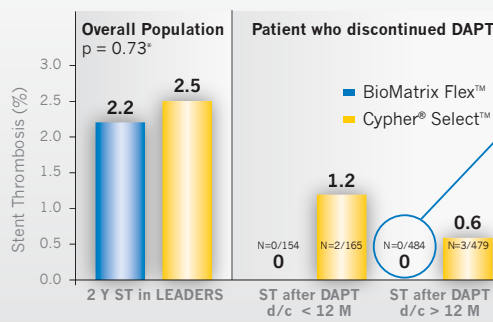
For descriptive purposes only - RCTs with different protocols should not be compared

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 - Bern/Rotterdam: Wenaweser, P. et al., Incidence and correlates of drug-eluting stent thrombosis in routine clinical practice: 4-year results from a large 2-institutional cohort study; J Am Coll Cardiol 2008;52:1154-1140
- “On-label” trials
 - STEALTH I: Grube, E., Safety and Performance Evaluation of Biosensors Biolimus A9™ Eluting Stent (BioMatrix™) STEALTH I: a 3-year safety follow-up, e-poster, TCT 2007
 - Nobori I: Chevalier, B. et al., Nobori I Long term results: 2 years phase 1&2 and 3 years phase 1, EuroIntervention
 - Endeavor IV: Leon, M.B., Zotarolimus-eluting Stent update, ACCI2 2009; The DES Summit, March 27-30, 2009; Orlando, FL
 - SPIRIT III: Stone, G.W. et al., Randomized Comparison of Everolimus-Eluting and Paclitaxel-Eluting Stents, Circulation 2009;119:680-686
- Based on currently available published data of randomized clinical trials in “All-Comers” population

No VLST after dual anti-platelet therapy discontinuation with the BioMatrix Flex™ stent²

Effect of DAPT Discontinuation



No VLST after DAPT discontinuation was observed in the BioMatrix Flex™ group. Between 12 and 24 months, nearly 500 “All-Comers” patients were off DAPT.

