BioMatrix Flex™

LEADERS

LEADERS: a foundation for the future

Raising the bar

Around ten years ago, early clinical data was beginning to show that, in combining Biolimus A9™ with a biodegradable polymer, Biosensors had developed potentially ground-breaking technology in the form of BioMatrix Flex™. In order to provide convincing evidence of the patient benefits that this conferred, an equally ground-breaking clinical trial was required.

Unlike any previous trial, this study would involve a direct comparison of BioMatrix Flex with the gold standard durable-polymer DES, include the majority of patients types routinely seen in daily practice, and incorporate clinical endpoints. Ideally, it would also be independently analyzed by the investigators.

From these requirements, LEADERS (**L**imus **E**luted from **A** **D**urable versus **ER**odable **S**tent coating) was born!

A landmark protocol

- Protocol independently designed by the study investigators
- Head-to-head randomized study between BioMatrix Flex and the gold standard Cypher® Select™
- 1700 patients from ten European centers
- To include "all comers", i.e. all patients requiring a DES
- Primary endpoint was non-inferiority for incidence of MACE (Major Adverse Cardiac Events) at nine months.*
- Additional clinical follow-up conducted annually out to five years.

A series of notable firsts

- **First head-to-head randomized clinical study (RCT) between two limus-eluting stents**
- **First RCT between two stents to involve an "all-comers" patient population**
- **First RCT between two stents to be independently monitored and assessed by its investigators**

Results from LEADERS

Primary endpoint successfully met: 9 month data published in *The Lancet* in 2008[1]. 9.2% of patients given BioMatrix Flex and 10.5% of patients given Cypher Select experienced a clinical adverse event that could be included in the primary composite endpoint, thus demonstrating non-inferiority of BioMatrix Flex.

Continually improving outcomes for BioMatrix Flex-treated patients observed in the one[2], two[3], three[4], four[5] and five-year results.

The four-year results, published in *The Lancet* in 2011[5], reinforced the long-term clinical benefits of BioMatrix Flex. Compared with Cypher Select, it significantly reduced the risk of cardiac events, which was associated with the reduced risk of very late stent thrombosis (VLST). This was the first time that a DES with biodegradable polymer had been shown to improve clinical outcomes compared to a DES with durable polymer.

The final report from LEADERS has recently been presented at TCT 2012. This confirms that BioMatrix Flex improves clinical outcomes compared with Cypher Select for up to five years.

"Thus, BioMatrix Flex has become the Gold Standard in biodegradable technology."

* MACE is a clinical composite of cardiac death, myocardial infarction, or clinically-indicated target vessel revascularization (TVR).

References:

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LEADERS is a Biosensors International study. www.clinicaltrial.gov - NCT00389220.

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11134-000-EN - Rev.01