



First Patient Treated with BIOTRONIK's DREAMS Scaffold



Initial clinical evaluation of newest unique bioabsorbable magnesium scaffold for the treatment of vascular disease treatment takes place

It was announced today that BIOTRONIK, a principal producer of cardio- and endovascular medical technology, has reached a new highlight in the therapy evolution for coronary artery disease patients.

In the frame of the clinical study BIOSOLVE-II conducted by Prof. Dr. Michael Haude of Germany's Lukaskrankenhaus in Neuss, the BIOTRONIK DREAMS (Drug Eluting Absorbable Metal Scaffold) was successfully implanted in the first patient.

DREAMS is a bioabsorbable scaffold uniting the superior mechanical advantages of a metallic stent with a reliable bioabsorption profile. This serves to open vessels and keep them from re-clogging while bypassing the long-term shortcomings of everlasting metal stents.

During a patient's life, permanent stents cage the vessel segment while this new design - made of a bioabsorbable magnesium alloy, which is coated with a bioabsorbable polymer matrix and an anti-proliferative Limus drug - is devised to be eventually absorbed, thus leaving the vessel naturally restored.

The BIOSOLVE-I study gave BIOTRONIK precious insight into the clinical workings of the first generation of DREAMS. Building on these findings the BIOSOLVE-II trial is an upcoming, multi-center clinical trial assessing the safety and efficiency of DREAMS in its improved design. It will be used for regulatory approval of the product and include about 120 patients from 8 countries who will receive follow-up investigations carried out at 1, 6, 12, 24, and 36 months. The primary endpoint is in-segment late lumen loss (LLL).

Following successful implantation of the first DREAMS scaffold in a rather challenging lesion with significant calcification Prof. Haude was impressed with the effortlessness of deliverability and vessel adaptability. "The acute performance was similar to a contemporary drug-eluting stent, but offering the advantage of uncaging the vessel in the long run." Haude commented.

BIOTRONIK President Vascular Intervention Dr. Daniel Buehler is confident that this innovative treatment will prove its efficiency based on the promising clinical data for this new generation of bioabsorbable magnesium and concluded "BIOTRONIK has refined the technology based on physicians' input to deliver the optimal balance between vessel scaffolding, absorption profile, and drug elution characteristics".

Source: [BIOTRONIK](#)

14 October 2013

Published on : Thu, 17 Oct 2013