

Eurocor announces the completion of the Freeway Stent Study

- **FREEWAY™ drug-eluting balloon for treatment of stenotic or occluded lesions in the SFA or proximal popliteal arteries**
- **12 Months follow-up of last patient completed**

Bonn, Germany – March 30th 2017 - Eurocor, an international specialist in medical DEB - technology, services and solutions, today announced the completion of the Freeway Stent Study.

The Freeway Stent Study was lead-managed by Prof. Dr. Josef Tacke, Klinikum Passau, Germany. The multicenter, open, prospective randomized study investigated the prevention of restenosis in the treatment of Superficial Femoral Artery (SFA) or Popliteal artery (PI-segment) lesions in the legs. The study examined whether implantation of a Nitinol stent followed by post-dilatation with a drug-eluting balloon (DEB) FREEWAY™ is advantageous to Nitinol stenting and post-dilatation by a plain old balloon angioplasty (POBA). The study was conducted in 13 sites in Germany and Austria. 204 patients suffering from *de novo* lesions that needed to be stented were enrolled and randomized in a 1:1 ratio. Patients have been followed at 6 and 12 months.

The 6 Months results

Final 6 months results of the Freeway Stent Study have been presented at CIRSE (Cardiovascular and Interventional Radiological Society of Europe) congress 2016, Barcelona, Spain. The results show a significant better primary patency for the DEB arm compared to the POBA arm (91.4 % vs. 74.4 %, respectively; $p = 0.003$) at follow-up, analyzed by an independent and blinded corelab. The results also show a very low target lesion revascularization (TLR) rate of only 4.1 % after treatment with FREEWAY™ DEB, whereas the POBA group shows a TLR rate of 9.0 %. These findings go along with a significant improvement in Rutherford classification (94.4% vs. 84.3%, respectively; $p = 0.027$) and a significant improvement in Ankle-Brachial-Index (ABI Index) at follow-up.

Prof. Dr. Josef Tacke commented: “In-stent restenosis is a serious problem in the SFA and PI-segment. The 6 months results of our study have shown, that Drug-eluting balloons are a good and desirable option to prevent restenosis in patients that need to be stented. After the very positive results at 6 months we are now looking forward to the 12 months results of the study.”

About FREEWAY™

Eurocor’s second-generation drug-eluting technology PTA balloon FREEWAY™ has been developed as an alternative to the limitations of existing therapeutic options for PAD e.g. restenosis after POBA or stenting. The product provides good crossability, trackability and pushability and can be used where the use of other therapies is limited by the occurrence of high restenosis rates, anatomical challenges and stent fractures.

The coating makes the difference – FREEWAY™ uses a special homogenous coating

Eurocor’s DEB technology utilizes a homogenous drug coating, which is released when the balloon is expanded. This inhibits the proliferation of smooth muscle cells, and may prevent restenosis by disturbing microtubule formation and thereby inhibiting cell division and migration. Paclitaxel is applied in a final concentration of 3 µg/mm² to the surface of the balloon.

FREEWAY™ features

- Clinically proven robust coating, with no drug loss on the way to target.
- Balloon lengths of 20 - 150 mm for Ø 2.0-8.0 mm with different shaft lengths
- Excellent catheter flexibility with tapered, hydrophilic shafts and low tip entry profiles
- New high pressure FREEWAY™ AV shunt balloon for improved patency in dialysis access

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About Eurocor:

Eurocor is a rapidly growing European Life Sciences Technology Corporation specializing in the research, development and manufacture of cardiovascular and endovascular products. Eurocor provides interventional physicians with innovative coronary stent technologies and special cardiovascular and endovascular devices, manufactured in Bonn. Products are indicated for minimally invasive cardiovascular and peripheral surgery and comply with biological and biomechanical principles to offer highly flexible, adaptable solutions. Extensive research and development, close clinician collaboration, outstanding quality standard philosophy and global scientific alliances lead to optimization of clinically effective technologies. Eurocor has designed an innovative method for balloon catheter drug delivery with high patient compliance. One heartbeat ahead® – with innovative products such as DIOR® and FREEWAY™.

Eurocor GmbH is a wholly owned subsidiary of Opto Eurocor Healthcare Limited and is part of the Opto Circuits Group.

For more information, please visit eurocor.de and optocircuits.com.