NewsLetter
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More Details on：www.microport.com.cn

Email：ir@microport.com
Tel (021) 38954600
Fax (021) 50801305

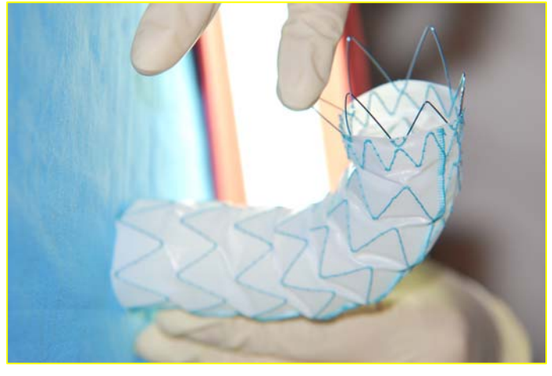
MicroPort Completed FIM for Two EP Products

On July 16th, 2011, Microport EP MedTech Co. Ltd. successfully completed the first-in-man clinical studies of the Columbus™ 3D electrophysiological mapping system and VoyagerTM irrigated RF ablation catheter at Beijing Anzhen Hospital of the capital Medical University.

The clinical studies enrolled 10 patients with paroxysmal atrial fibrillation, who underwent the pulmonary vein isolation by RF catheter ablation under the guidance of the 3D Electrophysiological Mapping System. Linear ablations were performed at the isthmus after pulmonary vein isolation, with 100% acute pulmonary vein isolation success rate. No pulmonary vein stenosis was found during the immediate postoperative retrograde pulmonary vein angiography; and no complication occurred during or after the ablation procedures. This first-in-man clinical study paves the way for the upcoming large scale multi-center clinical trial.

Two MicroPort Medical Products Successfully Registered in Philippines

Registration for Hercules Thoracic Stent-Graft System and Hercules Bifurcated Stent-Graft system in Philippines were approved by the Bureau of Food and Drugs in January and April respectively. The products are intended for the treatment of aortic aneurysm repair.



MicroPort Successfully Hosted Symposiums on PCI for Complex Diseases in Philippines

On April 25th, MicroPort hosted two symposiums on PCI for complex diseases in Manila Doctors Hospital and St. Luke's Medical Center-Global City in the Philippines. Professor Shaoliang Chen, vice president of the Nanjing Cardiovascular Hospital, was invited to perform a live surgery demonstration. Two complex PCI cases were completed during the day, with Firebird2 drug-eluting stents implanted successfully.

The symposiums and results of the live surgery demonstration perfectly demonstrated the excellent trackability and flexibility of Firebird2 which not only bolstered the local doctors' confidence, but enhanced product awareness and popularity.

Endovascular Treatment for Acute Stanford B-Type ADs with Domestic Stent Grafts Is both Safe and Effective

Recently, Mr. Mier Jiang, Director of the department of vascular surgery of the Shanghai 9th People's Hospital published a research paper called <Endovascular Repair of Acute Stanford B-Type Aortic Dissections with Domestic Stent Graft in China: Early and Mid-Term Results> in <Surgery Today> (official journal of the Japan surgical society).

Data from all 51 patients who presented with acute aortic dissections (ADs, Stanford B type) between April 2004 and May 2009 and underwent endovascular interventions with domestic stent graft were retrospectively reviewed. All patients were followed up for from 1 to 48 months. 41 MicroPort stents were used including 11 Aegis-T and 30 Hercules-T. There was no strut failure or surgical conversion in any of the patients with a 4-year survival rate of 92.16%, which proved that endovascular treatment for acute Stanford B-type ADs with domestic stent grafts is both safe and effective, while also demonstrating an acceptable survival rate and mid-term clinical outcomes.

Hot Discussions on Thoracic Endovascular Aortic Repair

On March 17, MicroPort and the Department of Cardiology, Chinese PLA (People's Liberation Army) General Hospital co-organized an advance thoracic endovascular aortic repair (TEVAR) course. The wonderful expert lectures, on-site surgery, vivid simulation of medical equipment and case analysis attracted around 20 experts in the field of vascular surgery from Brazil and Venezuela. Professor Wei Guo, Director of the Department of Cardiology, Chinese PLA General Hospital and Ms. Zhenghua Miao, MicroPort Peripheral Product Sales Vice President also attended the meeting.

Three on-sight surgeries were conducted including one endovascular repair of abdominal aortic aneurysms and two endovascular repair of the thoracic aorta, in which MicroPort's Hercules Tubular Aortic Stent-Graft System and Hercules Bifurcated Stent-Graft System were adopted. The experts were favorably impressed by the products for their excellent flexibility and trackability.

501 Newton Rd., ZJ Hi-Tech Park
Shanghai 201203, P. R. China

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The Three Industry Standards That MicroPort Participated in Drafting Officially Issued

Recently, the State Food and Drug Administration (SFDA) published an announcement that 69 industry standards for medical device that have already been approved will come into effect from July 1st, 2012. MicroPort participated in drafting one mandatory standard and two recommended industry standards including YY0778-2010 <Radiofrequency Ablation Catheter>, YY/T 0807-2010 <ASTM F2394-07 Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System>, and YY/T 0808-2010 <ASTM F2477-2007 Standard Test Methods for in vitro Pulsatile During Testing of Vascular Stents>.

Trademark and Patent Issuing Information

Recently, five MicroPort trademarks have been registered upon approval by Trademark Office of State Administration for Industry & Commerce (SAIC)of the PRC, including the trademark of "定向", "Castor", "CLADO", "Firehawk" and "火鹰". In addition, two patents for "equipment for cutting heart valve leaflets" and “a balloon catheter device” have been granted the patent right for utility model by State Intellectual Property Office (SIPO) of the PRC .

3-Year Follow-Up Result of FIREMAN

FIREMAN is the first clinical research of using domestic drug-eluting stents to treat complex coronary artery disease. It was started in 2006, and had already completed a 3-year follow-up by September 2010, which covered MACE, TLR/TVR, in-stent thrombosis and stroke, and especially the analysis of the related factors causing in-stent thrombosis, as well as analysis of different subgroups of patients divided by the age, sex, diabetes or hyperlipidemia history and so on. The follow-up results, which are beneficial to the further understanding of using domestic drug-eluting stents to treat complex coronary artery disease, showed that the cumulative cardiac death rate was 1.7%, the incidence of MI, TVR and MACE was 1.4%, 5% and 7.1% respectively, and the thrombosis rate was 0.39%.

12-Month Follow-Up Result of Focus

FOCUS is currently the largest international pre-approval multicenter clinical-registered research which was started in 2009, with a total of 5084 patients selected. The follow-up result obtained 6 months after the launch of Firebird2 Rapamycin-eluting CoCr Stent in China showed that the cumulative cardiac death rate was 0.63%, the incidence of MI, TVR and MACE was 1.07%, 0.3% and 1.8% respectively, and the thrombosis rate was 0.61%.

The Clinical Studies of FIM

FIM of Firehawk is a clinical research project of the new-generation drug-eluting stents with 20 patients selected prior to commercialization, according to which the rate of clinical surgical success was 100%, the one-month follow-up rate was 100%, the four-month angiographic follow-up rate was 95%, and the OCT follow-up rate was 70%. The angiographic follow-up and OCT follow-up results indicated an in-stent lumen loss of 0.13±0.18mm, and 0.16±0.07mm respectively, with 0 TLR incidence and a stent-coverage ratio as high as 96.2%.

The Patient Enrollment in FIRE2 – DIABETES Clinical Trial Completed

On July 16, 2011, MicroPort completed enrollment of 1000 patients in its FIRE2 – DIABETES (Efficacy and Safety of Firebird2 Cobalt-Chromium Alloyed Sirolimus-Eluting Stent in Treatment of Complex Coronary Lesions in Diabetes) clinical trial. Meanwhile, the clinical follow-up for 30 days, 6 months and a year respectively, are already underway according to schedule. FIRE2 – DIABETES is an international multi-center prospective clinical registry research which involved over 40 research centers all over the world. All of the implanted stents were Firebird2 cobalt-chromium alloyed sirolimus-eluting stents. The findings of the research will provide scientific basis for the efficacy and safety of the products in treatment of complex coronary lesions in diabetes.

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