MicroPort® EP Obtains CFDA Approval for EasyFinder™ 3D Steerable Curve Mapping Catheter

Shanghai MicroPort EP MedTech Co., Ltd. ("MicroPort® EP") recently obtained the regulatory approval from China Food and Drug Administration ("CFDA") for its in-house developed EasyFinder™ 3D Steerable curve mapping catheter.

The EasyFinder™ 3D catheter is indicated for use in cardiac electrophysiology studies. When used with Columbus™ 3D EP Navigation System ("Columbus™") and External Reference Patch, it provides precise location of the catheter curve in the body. EasyFinder™ 3D catheter has a high-torque shaft with a deflectable curve section. The tip deflection is controlled at the proximal end by a handle. The high-torque shaft also allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site.

President of MicroPort® EP Yiyong Sun said: "The CFDA approval of EasyFinder™ 3D Steerable curve mapping catheter signifies a major step forward for MicroPort® EP to provide a complete electrophysiological solution for arrhythmia patients with combinations of active and passive devices and equipment."
Firehawk® Gains
Launch Approval in Hong Kong Public Hospitals

On May 21, Firehawk® Rapamycin Target Eluting Coronary Stent System ("Firehawk"®) gained the approval from Hong Kong Hospital Authority, allowing it to enter in Hong Kong public hospitals. It is the first drug-eluting stent of MicroPort® that was granted launch approval in Hong Kong.

Firehawk® is the result of eight years of research and development of MicroPort® and it is the world’s first and only target-eluting stent ("TES"). It is a new-generation drug-eluting stent of MicroPort® for the treatment of coronary artery stenosis or occlusion after Firebird® Rapamycin-Eluting Coronary CoCr Stent System ("Firebird"®) and Firebird2® Rapamycin-Eluting Coronary CoCr Stent System ("Firebird2®"). Firehawk® adopts TES Technology platform, and its coating area is only 20% of the stent surface. Firehawk®’s drug is released over 90 days and its polymer is fully absorbed in nine months. Its average metal coverage rate is 14.0-16.1%. Firehawk® is the world’s lowest drug dosage stent, with only 1/3 dosage versus similar products while achieving the same efficacy.

Firehawk®’s Hong Kong launch marks a milestone in its market development. With its outstanding performance, it is expected that Firehawk® will provide more ideal cardiovascular treatment for local patients and help enhance the communication between cardiologists from Hong Kong and the mainland as well.
Firebird2® Gains Regulatory Approval in Taiwan

Taipei, China – Recently, MicroPort® received the regulatory approval from Taiwan Food and Drug Administration ("TFDA") for its in-house developed Firebird2®. It is the second drug-eluting stent of MicroPort® that successfully gained the regulatory approval in Taiwan, following Firehawk®.

Firebird2® is the second generation drug-eluting stent of MicroPort® for the treatment of coronary artery stenosis or occlusion. It is based on the new cobalt chromium alloy stent platform. It has good radial support force, excellent stent flexibility, and outstanding MRI compatibility.

With the increasing aging population, the incidence rate of coronary disease is constantly growing in Taiwan. According to statistics, there are around 30,000 PCI cases in the Taiwan market annually and the demand for coronary stent is rapidly increasing. As Firehawk® and Firebird2® both gained regulatory approval in Taiwan, MicroPort® further diversified its product offering in the local market. With its outstanding performance, it is expected that Firebird2® will provide more ideal cardiovascular treatment for the local patients.
Four MicroPort® Products Gain Regulatory Approval in Serbia

Recently, MicroPort® gained regulatory approval from the Ministry of Health in Serbia for four of its in-house developed cardiovascular products - Firehawk®, WALTZ™ CoCr Coronary Stent System ("WALTZ™"), Foxtrot™ NC PTCA Balloon Catheter ("Foxtrot™ NC"), and Foxtrot™ Pro PTCA Balloon Catheter ("Foxtrot™ Pro"). This is the first time for MicroPort® products to gain regulatory approval in Serbia.

The revolutionary third-generation drug-eluting stent ("DES") Firehawk® is the result of eight years of research and development of MicroPort® and it is the world's first and only target eluting stent. As the world's lowest drug dosage stent, Firehawk® combines the merits of the bare metal stent and DES. WALTZ™ is indicated for the treatment of coronary artery stenosis or occlusion. WALTZ™ has strong radial strength and excellent flexibility, crossability, trackability, and pushability to achieve the best surgical outcome. Foxtrot™ Pro is also indicated for pre-dilating the stenotic atherosclerotic lesions of coronary artery disease to facilitate the implantation of stent. Foxtrot™ NC is indicated for pre-dilation as well as post-dilation. It has excellent crossability, trackability and pushability.

With a population of seven million, Serbia has a growing market for cardiovascular products. After the four products gained regulatory approval in Serbia, MicroPort® further expands its overseas markets. In the future, MicroPort® will continue to bring in more high-quality medical devices to the Serbia market to benefit more local patients.
MicroPort® Displays Firehawk® in EuroPCR

On May 23, MicroPort® hosted a satellite meeting of "Firehawk": New Technology of DES and TARGET All-Comers Investigator Workshop at EuroPCR in Paris. Meanwhile, a live cases using Firehawk® to treat high-risk bifurcation disease was broadcasted at the conference.

On May 23, a live case in which Professor Kefei Dou, Professor Jie Qian and Professor Lei Song of Fuwai Hospital used Firehawk® to treat left main bifurcation and LAD/Diag bifurcation. The female patient, 54, suffered from exertional angina. The physicians adopted DK-Crush technique to successfully implant 4 Firehawk® stents into the lesion. The operation achieved successful result without malapposition, showing Firehawk® has excellent crossability for side branches and good performance in treating complicated lesion.

Dr. Andreas Baumbach of the St Bartholomew’s Hospital in London and Professor Niels Van Royen of VU University Medical Center in the Netherlands interpreted the 12-month result of its TARGET All-Comers ("TARGET AC") trial. The results of the TARGET AC trial demonstrated that vessels treated with the Firehawk® showed non-inferiority results when compared to vessels treated with the Xience family of drug eluting stents. The primary endpoint of non-inferiority for the Firehawk® stent compared to the Xience family stent was met with a 12-month TLF rate in the intent-to-treat population of 6.1 percent versus 5.9 percent, respectively (non-inferiority = 0.004). The primary QCA substudy endpoint of non-inferiority for the Firehawk® compared to the Xience family stent was met with an in-stent lumen late loss at 13-months in the per treat population of 0.17 ± 0.05 mm versus 0.11 ± 0.05 mm (P non-inferiority =0.024), respectively. This results further proved that Firehawk® can achieve the same efficacy with only 1/3 dosage versus similar products.

The revolutionary third-generation drug-eluting stent ("DES") Firehawk® is the result of eight years of research and development of MicroPort® and it is the world’s first and only target eluting stent. The TARGET AC trial is a prospective, multi-center, randomized controlled clinical trial consisting of entirely European based patients. This clinical study enrolled its first patient in December 2015 and completed enrollment of its last patient in October 2016. In total, there were 1,654 patients enrolled from 21 clinical study sites throughout Europe. In addition, the trial design included an OCT (Optical Coherence Tomography) sub-study consisting of 50 patients at three months post implantation and a QCA (Quantitative Coronary Angiography) sub-study consisting of 176 patients at 13 months.
MicroPort® Hosts "Firehawk® Challenging Hub-Meet the Best" Event in TCTAP

From April 28 to May 1, MicroPort® attended the 23rd Cardiovascular Summit TCTAP 2018 that integrates the newest interventional techniques and devices related to patient care in the coronary, peripheral and carotid arteries, as well as structural heart disease. During the conference, MicroPort® hosted "Firehawk Challenging Hub-Meet the Best" Event, to introduce Firehawk® Rapamycin Target Eluting Coronary Stent System ("Firehawk") to experts in attendance by lectures and case studies.

Professor Jie Qian of Fuwai Hospital of Chinese Academy of Medical Sciences said, Firehawk® features a 100% biodegradable PLA polymer and sirolimus drug combination, which ensures a steady and constant drug release rate and complete absorption of the polymer shortly after drug elution ends at nine months. He also introduced the global clinical study programs of Firehawk® - since the launch of TARGET FIM in 2009 following the first patient enrollment, the TARGET series studies enlarged its coverage from China to Europe, Southeast Asia, North America, and South America with nearly 17,000 patients enrolled in this large-scale global clinical studies.

In the conference, Professor Ruqiong Nie of Sun Yat-sen Memorial Hospital of Sun Yat-sen University, Professor Shaiful Azmi Yahaya of Institute Jantung Negara in Malaysia, Professor Yaojun Zhang of Xuzhou Third People’s Hospital, Professor Linda Lison of Pantai Indah Kapuk Hospital in Indonesia respectively shared case studies of Firehawk® and explained complex lesions like calcified lesion, CTO, bifurcation lesion, to the attendees. All of these experts spoke highly of Firehawk®’s excellent crossability.

Currently, MicroPort®’s new-generation drug-eluting stent Firehawk® and Firefighter™ PTCA Balloon Catheter ("Firefighter™") obtained regulatory approval in the South Korea market. In the future, MicroPort® will bring more high-quality and high-end medical device to South Korea to benefit local patients.
MicroPort® Endovascular Attends CICE 2018

MicroPort Endovascular (Shanghai) Co., Ltd. ("MicroPort® Endovascular") attended the CICE 2018 held in Sao Paulo, Brazil.

On April 16, Professor Chang Shu completed an operation using Hercules® Thoracic Stent-Graft System ("HT-LP") to treat thoracic aortic aneurysm with Professor Ferreira and his team. HT-LP with Low-Profile Delivery System reduces the requirement for the diameter of the entry vessel, the resistance in delivery and the damage to the artery. Meanwhile, the unique tip capture mechanism of bare stent can accurately control the proximal stent's position and shape. Postoperative angiography shows that the HT-LP stent graft was deployed in good shape and isolated the expanded aneurysm effectively without endoleak or movement.

During the CICE 2018, Professor Chang Shu conducted a live surgery with Professor Nasser in Jardim Cuiaba, in which they used MicroPort® Endovascular's Hercules® Bifurcated Stent Graft to treat a complex abdominal aortic aneurysm. After the deployment of Hercules® Bifurcated Stent Graft, the aneurysm was isolated effectively without endoleak or movement. The successful outcome fully demonstrated the efficacy and safety of the product, which was well received by experts in attendance.

In this event, MicroPort® Endovascular fully demonstrated the safety and efficacy of its products and successfully increased its brand awareness in overseas markets. In the future, MicroPort® Endovascular will continue to promote the development of aortic interventional treatment technologies through constant innovation and academic exchange events.
Tubridge® Displayed in WLNC

On April 27, a live case by Professor Jianmin Liu of Shanghai Changhai Hospital and his team using Tubridge® Vascular Reconstruction Device ("Tubridge®"), a product jointly developed by Shanghai Changhai Hospital and MicroPort NeuroTech (Shanghai) Co., Ltd. ("MicroPort® NeuroTech"), to treat V4 dissecting aneurysm, was broadcasted during the World Live Neurovascular Conference ("WLNC"). Tubridge® is the only "Shanghai-made" high-end product displayed in this year’s WLNC. This is also the first appearance of Tubridge® in an international congress.

Tubridge® is designed for the treatment of large and giant cerebral aneurysm. The device cures the cerebral aneurysm by effectively diverting the blood flow based on the hemodynamics, reducing the impact of blood flow to the cerebral aneurysm, and enabling the endothelial cells to grow along the stent struts and gradually repair aneurysmal neck. In March, Tubridge® gained the CFDA approval, which means more Chinese patients will benefit from this innovative technology. It is the fifth product of MicroPort® that obtained the CFDA approval through Green-Path.

As one of the most premier academic conferences in the field of neuro-interventional and cerebrovascular surgery, this year’s WLNC live broadcasted cases by hospitals of seven different countries.

Bo Peng, MicroPort® Chief Marketing Officer, who is also the Chairman of MicroPort® NeuroTech, said: "The launch of Tubridge® will further promote the development of domestically made high-end medical devices to benefit more patients. In the future, we will continue to provide high quality medical devices by constant innovation to benefit patients with cerebrovascular disease and make contribution to the development of neuro-interventional therapy in China."
MicroPort® Attends CCIF 2018

From April 19 to April 22, MicroPort® attended the 21th China Cardiovascular Interventional Forum (“CCIF 2018”) and hosted a case contest.

During the congress, the CCIF President Professor Yong Huo of Peking University First Hospital released the registration data of coronary heart disease interventional treatment in the Chinese mainland in 2017. According to the data, the total number of such treatment stood at 753,142 in 2017. Professor Huo said, the number experienced steady increase in 2017; on average 1.5 stents were used in each case, which remained unchanged from the previous years; the death rate of interventional treatment remained low; the percentage of radial artery approach continued to go up, showing that more physicians can master the technique; the percentage of PCI treatment of STEMI patients further increased, showing the effect of building more Chest Pain Centers; physicians in the district hospitals are playing an increasingly important role in coronary heart disease treatment with their enhanced PCI surgical skill.

On April 21, MicroPort® hosted a case contest with 14 cases involved in. In the end, Professor Xinyong Cai of Jiangxi Provincial People’s Hospital, Professor Hanbin Cui of Ningbo First Hospital, and Professor Bing Duan of Shijiazhuang First Hospital won the first place. Meanwhile, this case competition was live broadcasted via Dr. King studio and MicroPort® online platform, which attracted more than 1,500 audience to watch online. It provided opportunities for physicians in rural areas to learn more advanced technologies.

During the event, MicroPort® also carried out satisfaction survey activities during the conference. Experts showed high recognition of MicroPort®’s cardiovascular products such as Firehawk® and Firebird2®, and offered suggestions regarding product R&D.
MicroPort® Endovascular Attends Lijiang Vascular Surgery Intervention Treatment Summit

Guilin, China – From May 4 to May 6, MicroPort® Endovascular attended the Second Guangxi Guilin Lijiang Vascular Surgery Intervention Treatment Summit and hosted a satellite meeting.

On May 5, MicroPort® Endovascular hosted a satellite meeting on the clinical application of Castor® Branched Aortic Stent-Graft System ("Castor®").

Professor Peiyong Hou delivered a speech on endovascular reconstruction of aortic arch branches, in which he compared different techniques in reconstruction of aortic arch branches. He pointed out, branched Stent Graft does not change the original structure and conforms to the anatomy of aorta, which is the best choice for the endovascular reconstruction of LSA.

Professor XianLan Zhang introduced the tactics to use Castor® based on clinical cases. Professor Hongwei Huang shared the indications of Castor®. Professor Yugui Sun released the clinical data of Castor® which gained the approval from China Food and Drug Administration on June 25, 2017. Its pre-market clinical data show: The mortality rate in the hospital is 0%; the related mortality of the aortic dissection in 12 months is 0%; the incidence complication of the stent-related nervous system is 0%; and the incidence of neurological diseases is 5.48%.

Professor Hong Huang analyzed a case of Castor®.

Castor® is the first endovascular device used to preserve the branch artery while repairing the thoracic aorta. Its unique "unibody design" could accommodate diverse arch anatomy. The launch of Castor® marks a significant step forward in using endovascular repair to treat aortic arch. In the future, MicroPort® Endovascular will continue to innovate to develop more leading innovative products and further cultivate the market of aortic interventional treatment, so as to offer cost-effective medical solutions to save or reshape lives or improve the quality of life for patients.
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