

## MicroPort Pioneer Balloon Dilatation Catheter Received CFDA Re-registration Certificate

Recently, Pioneer balloon dilatation catheter developed and manufactured by MicroPort received CFDA re-registration certificate.

#### Columbus<sup>TM</sup> Three-dimensional EP Navigation System Received CE Certificate

Recently, Columbus  $^{TM}$  Three-dimensional EP Navigation System received CE certificate. MicroPort EP Medtech is preparing to launch its electrophysiology (EP) products into the international market.

#### Hercules<sup>TM</sup>-B Bifurcated Stent-graft and Delivery System Honored with 2013 National Key New Project

Recently, MicroPort's Hercules<sup>TM</sup>-B Bifurcated Stent-graft and its delivery system were honored with 2013 National Key New Project. It is the 5th consecutive years in which MicroPort has receive the certificate.

## Hercules™ Balloon Dilatation Catheter Received CFDA Certificate

Recently, Hercules<sup>TM</sup> Balloon Dilatation Catheter received certificate from China Food and Drug Administration (CFDA). Hercules<sup>TM</sup> Balloon Dilatation Catheter literary filled the gap in the domestic-made large balloon market and broke the dependence on the foreign-made products.

### MicroPort Cronus<sup>TM</sup> Surgical Stent Graft System Received Re-registration

Recently, Cronus™ Surgical Stent Graft System received re-registration from China Food and Drug administration (CFDA).

#### MicroPort Received Re-registration for GnRH Infusion Pump

Recently, La Fenice® GnRH Infusion Pump received re-registration from Shanghai Food and Drug Administration (SFDA).

#### MicroPort Foxtrot PTCA Balloon Dilatation Catheter Received CE Certificate

Recently, Foxtrot PTCA balloon dilatation catheter received CE certificate from DEKRA Certification B.V. The product approval further signals the Company's globalization strategy.



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## MicroPort Pioneer Balloon Dilatation Catheter Received CFDA Re-registration Certificate

Recently, Pioneer balloon dilatation catheter developed and manufactured by MicroPort received CFDA re-registration certificate.

MicroPort's Pioneer is a balloon dilatation catheter featured with a fast switching system and excellent traceability and tracking performance. It is used during a minimally invasive non-surgical procedure commonly known as Percutaneous Transluminal Coronary Angioplasty (PTCA). The product provides further solutions for doctors and physicians during various surgeries treating complex lesions. One of the advantages of Pioneer is that any two Pioneer catheters with different specification can be perfectly matched and connected within the 6F guiding catheter. Pioneer is the first product that MicroPort introduced in China. Through the continuous product improvements, Pioneer has achieved the implant growth rate more than 30% in the past years.

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## Columbus<sup>TM</sup> Three-dimensional EP Navigation System Received CE Certificate

Recently, Columbus<sup>TM</sup> Three-dimensional EP Navigation System ("Columbus<sup>TM</sup>") developed by Shanghai MicroPort EP MedTech Co., Ltd. ("MicroPort EP Medtech") and AnchorTM External Reference Patch received CE certificate. MicroPort EP Medtech is preparing to launch its electrophysiology (EP) products into the international market.

Columbus<sup>TM</sup> is indicated for the diagnosis and treatment of complex arrhythmia diseases. Complex arrhythmia diseases mainly include supraventricular tachycardia, atrial fibrillation, atrial flutter, atrial tachycardia, premature ventricular contractions and

ventricular tachycardia. The intricate electrocardiogram reading and difficult procedure make the treatment of diseases further complicate.

The Columbus<sup>TM</sup> processes the localization information of the catheter and then generates three-dimensional model of heart chambers. After the model is combined with **ECG** reading, the further detailed electroanatomical model is generated. Compared with the traditional procedure which uses catheter ablation under X-ray fluoroscopy, ColumbusTM provides a comprehensive image solution that combines cardiac electrical mapping with anatomy structure for physicians to better treat patients with complex arrhythmias. Furthermore. the use of Columbus<sup>TM</sup> greatly reduces the exposure to X-ray for patients and physicians during the procedures.

Dr. Yiyong Sun, president of MicroPort EP MedTech commented, "In addition to typical functions offered by competitors' products, Columbus<sup>TM</sup> provides real time display of the deflected portion of the ablation catheter. By incorporating multi-channel EP recording functions, Columbus<sup>TM</sup> provides physicians with benefit of real-time observation and analysis of intraoperative electrical signal change. The receipt of CE registration of Columbus<sup>TM</sup> is a great advancement of MicroPort EP business."

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## Hercules<sup>™</sup>-B Bifurcated Stent-graft and Delivery System Honored with 2013 National Key New Project

Recently, MicroPort's Hercules™-B Bifurcated Stent-graft and its delivery system were honored with 2013 National Key New Project. It is the 5th consecutive years in which MicroPort has receive the certificate.

Hercules<sup>TM</sup>-B Bifurcated Stent-graft and the delivery

501 Newton Rd., ZJ Hi-Tech Park Shanghai 201203, P. R. China http://www.microport.com Email: <u>ir@microport.com</u>
Tel: (86) (21) 38954600
Fax: (86) (21) 50801305



# Newsletter

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system are indicated for endovascular treatment of abdominal aortic aneurysm. The applicable indications and ranges include the infrarenal AAAs in which the landing zone is more than 15mm. Hercules<sup>TM</sup>-B Bifurcated Stent-graft is the second generation of AAA (abdominal aortic aneurysm) stent which is based on the technology of first generation product: Aegis. The improved stent structure, performance and the delivery system combined with full range of product specifications provide physicians and doctors with even more choices.

Hercules<sup>TM</sup>-B Bifurcated Stent-graft system consists of two major components: the main body (aorto-iliac bifurcated component) and a contralateral limb. During the surgery, those two components are being delivered separately into the human body through respective bilateral femoral artery and being connected as a whole at the lesion area. The deployment of bifurcated stent graft serves as an artificial vessel wall. It is a specially woven fabric tube (graft) supported by flexible wire frame (stent) that physicians use to create a new path for blood flow in the patient's aorta, reducing pressure on the aneurysm and the risk of rupture.

"Currently, MicroPort's Hercules<sup>TM</sup>-B **Bifurcated** Stent-graft system has about 15% of domestic market share in the field and it is being exported to various countries including Philippines, Argentina, Brazil and others." Ms. Zhenghua Miao, General Manager of MicroPort Endovascular (Shanghai) Co., Ltd. said, "In to the conventional similar products, Hercules<sup>TM</sup>-B provides ease of access with its low profile, hydrophilic delivery system and anti-leakage structure to better accommodate a broad range of aortic anatomies. empowering physicians offer endovascular aortic repair (EVAR) to more AAA patients than ever before."

The National Key New Project refers to those that are developed for the first time in China or the innovative products that have outstanding performance among the similar products. Products recognized by the program generally have significant improvement in structure, material or technology compared with old products, and remarkably improve the product performance or extend functions. It's an important recognition from the government and milestone achievement for the company.

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## Hercules<sup>TM</sup> Balloon Dilatation Catheter Received CFDA Certificate

Recently, Hercules™ Balloon Dilatation Catheter, independently developed by MicroPort and its subsidiary MicroPort Endovascular (Shanghai) Co., Ltd., received certificate from China Food and Drug Administration (CFDA). Hercules™ Balloon Dilatation Catheter literary filled the gap in the domestic-made large balloon market and broke the dependence on the foreign-made products. The device effectively addresses the endoleak during the endovascular treatment for the aortic aneurysm or dissection.

An aneurysm or dissection occurs when a segment of the vessel becomes weakened. The pressure of the blood flowing through the vessel creates a bulge or tear at the weak spot, much as an overinflated inner tube can cause a bulge in a tire. The bulge or tear usually starts small and grows as the pressure continues. Aneurysms or dissections are dangerous because they can rupture, causing internal bleeding. Endovascular aneurysm repair (or endovascular aortic repair) (EVAR) is a type of endovascular surgery used to treat an aortic aneurysm (AAA) or dissection.

Hercules™ Balloon Dilatation Catheter is mainly used for post-release stent expansion which allows the stent graft to fully fit the shape and contour of human blood vessels to prevent endoleak which is characterized by persistent blood flow within the aneurysm sac or false lumen following endovascular aneurysm repair (EVAR). This device used in combination with aortic stent graft offers a total solution for physicians and surgeons for





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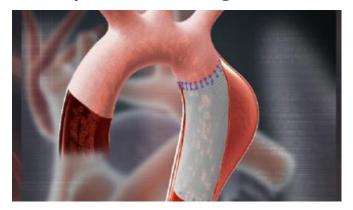
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treating aortic aneurysm or dissection.

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## MicroPort Cronus<sup>TM</sup> Surgical Stent Graft System Received Re-registration



Recently, Cronus<sup>™</sup> Surgical Stent Graft System, independently developed by MicroPort and its subsidiary MicroPort Endovascular (Shanghai) Co., Ltd., received re-registration from China Food and Drug administration (CFDA).

Cronus™ Surgical Stent Graft System is mainly used in thoracic surgery for aortic dissection in DeBakey type I and type III. Cronus Surgical Stent Graft System is modified vascular graft prosthesis, specifically designed for one-stage repair in complex thoracic aortic disease through median sternotomy in an elephant trunk like fashion. The device achieves the combination of surgical and interventional approaches while avoiding the weaknesses associated with the individual method. The encouraging low prevalence of morbidity and mortality has made the surgery for complex thoracic aortic disease more convenient and achievable. The device is one-of-a-kind in the world and currently has 100% market share.

Since 2003 in which it was first used in the surgery in China, Cronus™ Surgical Stent Graft System has been successfully applied and utilized for 10 years. According to statistics, "Aortic Arch Stent Surgical Replacement Operation" reduces the overall mortality rate from 20% to 4.34%; in addition, currently more

than 100 hospital started performing such surgical procedure and the procedure rate reached more than 2,000 annually. Furthermore, the devices has been adopted in other countries and up till now, the total procedures reached more than 8,000 worldwide.

Cronus<sup>™</sup> Surgical Stent Graft System has been widely recognized within the industry. The device greatly improved the quality of surgical treatment of aortic dissection.

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## MicroPort Received Re-registration for GnRH Infusion Pump



Recently, La Fenice® GnRH Infusion Pump, independently developed by MicroPort Lifesciences Co., Ltd. which is a subsidiary of MicroPort group, received re-registration from Shanghai Food and Drug Administration (SFDA). Compared to the previous generation of the product, the new La Fenice® GnRH Infusion Pump added various featues and functionalities such as vibration alarm, pictorial descriptions in the user manual, in which to meet the requirements of laws and regulations.

GnRH Infusion Pump is used for the treatment of Idiopathic HypogonadotropicHypogonadism (IHH) which is also known as Kallmann Syndrome. In recent years, China's infertility prevalence rate has risen to 12.5%, including male's morbidity of Kallmann Syndrome is about 1/2000, the female is about 1/10000. Although our country for the diagnosis of such disorders has been in the leading level in the world, but

501 Newton Rd., ZJ Hi-Tech Park Shanghai 201203, P. R. China http://www.microport.com Email: <u>ir@microport.com</u>
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it has been the lack of appropriate therapy. It is the first pulsatile GnRH infusion pump in China, which fills the market blank of domestic similar products.

Equipped with pulse infusion via micro pumptechnology, GnRH infusion pump stimulates hypophysis to excrete Follicle-Stimulating Hormone (FSH)/ luteinizing hormone (LH) by simulating pulse excretion of human gonadotropin-releasing hormone(GnRH) in order to make patients recover from abnormally physiological regulated function. This treatment can promote and maintain the development of secondary sex characteristics, restore fertility, improve adult growth hormone deficiency, increase bone density, reduce the risk of cardiovascular events.

Presently, MicroPort has been promoting GnRH infusion pump therapy thoughout the China. Besides Shanghai Ruijin Hospital, MicroPort has successfully built the promotional centers in various large state-owned hospitals in Hebei, Henan, Xinjiang, Shaanxi, Guangdong, Guangxi, Beijing, Qingdao and other provinces.

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### MicroPort Foxtrot PTCA Balloon Dilatation Catheter Received CE Certificate

Recently, Foxtrot PTCA balloon dilatation catheter, independently developed by Shanghai MicroPort Medical (Group) Co., Ltd., received CE certificate from DEKRA Certification B.V. The product approval further signals the Company's globalization strategy.

Foxtrot PTCA balloon dilatation catheter is used for balloon dilatation of the stenotic portion of a coronary artery for the purpose of improving myocardial perfusion. It is also indicated for post-delivery expansion of balloon-expandable stents. Studies have shown that the degree of stent apposition in the lesion area is directly related to the pressure exerted on the balloon during the implant. Nowadays, it has become a

Tel:

Email: ir@microport.com

(86) (21) 38954600

(86) (21) 50801305

common practice using high pressure balloon to increase the effectiveness and uniformed stent expansion.

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