MicroPort® EP Obtains CFDA Approval for Columbus® 3D EP Navigation System (2.0)


As the first domestic magnetic navigation system, Columbus® uses delicate catheters to map atriums and ventricles. With self-developed mapping/ablation catheters and reference patch from MicroPort® EP, system can show real-time 3D images of cardiac chambers after collecting and analyzing electrophysiological activities. Compared to Columbus® (1.0), the 2.0 model has more convenient and efficient clinical functions: (1) Rapid modeling; Real-time mapping (RTM); (2) Multi-catheter display, multiple positioning catheters can be displayed at the same time; (3) Multi-events recording, to view records of ablation events, stimulation events, and etc during produces; (4) Foot pedaling, to facilitate the physician’s operation.

Columbus® (1.0) gained the CE certificate in 2013, and it is the only domestically made 3D EP navigation system with the CE certificate. In 2016, Columbus® (1.0) was granted the CFDA approval. With the CFDA approval of Columbus® (2.0), it will provide more safe, effective, and affordable solution for patients with arrhythmias. As the only domestic company that provides a complete solution of cardiac EP treatment, MicroPort® EP will continue to strive for innovation and perfection to provide better arrhythmia solutions for patients and physicians.
MicroPort® CRM Announces PMDA Approval in Japan of PLATINIUM™ 4LV SonR® CRT-D

Clamart, France - On June 01, 2018, MicroPort® CRM, a business unit of MicroPort Scientific Corporation ("MicroPort®”), announced the approval by the Japanese Pharmaceutical and Medical Devices Agency ("PMDA") of PLATINIUM™ 4LV SonR CRT-D cardiac resynchronization device and the associated SonRtip™ lead featuring the innovative SonR technology.

The SonR system uses an innovative contractility micro-sensor embedded in the SonRtip lead to assess the patient’s left ventricular contractility and optimize the Cardiac Resynchronization Therapy ("CRT") response in heart failure patients. Based on the patient’s heart activity and needs, the algorithm automatically optimizes atrioventricular ("AV") delay and interventricular ("VV") delay settings – with the goal of improving the cardiac performance. Optimization is performed weekly at rest and during exercise which allows the therapy to be continuously adapted to the individual needs of each patient.

The safety and clinical effectiveness of MicroPort®’s proprietary SonR Cardiac Resynchronization system were evaluated in RESPOND-CRT study, a multi-center, randomized, two-arm, double-blinded, prospective trial enrolling more than 1,000 patients with advanced heart failure. Automatic optimization with SonR was compared to manual echocardiography guided optimization. The one-year data showed that the study met its primary safety and efficacy end points and demonstrated that SonR was associated with a 35% risk reduction in heart failure hospitalization2.

In addition, the study showed that the clinical outcomes were especially in favor of SonR in subgroups of patients less prone to respond to CRT. In patients with a renal dysfunction and a history of atrial fibrillation, SonR was associated with a 45% and 52% risk reduction in all-cause death or cardiovascular hospitalization respectively, and with a 38% risk reduction in all-cause death or HF hospitalization in patients with left bundle branch block and narrow QRS3.

"We've seen excellent long-term clinical results from the RESPOND CRT study on SonR optimization system.” said Benoit Clinchamps, MicroPort®, President of the CRM Business Unit. "Embracing MicroPort®’s commitment to advancing medical therapies to treat patients around the globe, we're pleased to bring this exclusive innovative technology for the benefit of Japanese patients who suffer from advanced heart failure."
MicroPort® Orthopedics Holds the Full Function, Faster® 2018 Didactic Conference

The Full Function, Faster® 2018 didactic conference, organized by MicroPort® Orthopedics, was recently held in London, Britain. The conference gathered more than 450 orthopedics specialists arriving from 35 different countries, with over 30 experts on total joint replacement from 20 countries delivering speeches. The conference comprised the sessions of fast recovery, peri-operative management, total hip replacement, SuperPath® Superior Percutaneously Assisted Total Hip ("SuperPath®"), total knee replacement and Medial-pivot Knee Replacement system ("Medial-pivot Knee") concept and technology, addressing post-operative fast recovery and patient satisfaction after the total joint replacement.

MicroPort® Orthopedics President Aurelio Sahagun delivered the opening speech of the conference. MicroPort® and MicroPort® Orthopedics continuously apply the most advanced orthopedic medicine, innovate in R&D, and are dedicated to the development of products improving patients' quality of life.

MicroPort® Orthopedics International Business Vice President Stefano Peverelli introduced the overall aims of the conference, which were to provide an academic exchange platform for joint surgeons around the world to discuss peri-operative management through the most advanced clinical research, focusing on patient satisfaction and fast recovery. Through this focused approach, the conference would lay a solid foundation for the promotion of new concepts and the development of new technologies.

The conference also used the occasion to proudly celebrate the 20th year anniversary of the Medial-Pivot Knee system, to which the conference dinner at London Tower was dedicated, with more than 400 guests and MicroPort® Orthopedics employees present. As one of the world's most established knee systems, MicroPort®'s Medial-Pivot design has witnessed more than 600,000 cases of implantation in the past 20 years. Its importance to the development of total knee replacement technologies has been confirmed in over 90 peer-reviewed publications on the basis of more than 15 years of clinical follow-up studies and the experience of clinical experts and patients.
MicroPort® CRM Holds the 12th Edition of New Horizons Scientific Conference

The 12th edition of the New Horizons Scientific Conference organized by MicroPort® CRM, was recently held in Paris. Angelo Auricchio, David Hayes, Francisco Leyva and Philippe Mabo, who are experts from Switzerland, the US, Britain and France respectively, were the joint chairpersons. Nearly 30 pacemaker electrophysiology and heart failure experts from over ten countries gave lectures. The conference attracted more than 250 cardiologists from nearly 20 countries to take part in exchanges, with the presence of Chinese physicians for the first time.

MicroPort® CRM President Benoit Clinchamps said in the opening remark that MicroPort® CRM has been engaged in the pacing sector for over four decades with a total of 1,100 patents or patent applications and over 1,000 employees globally. As a new subsidiary under MicroPort®, MicroPort® CRM will continue to be committed to innovation and R&D of more high-quality rhythm management products, and to commercialize high cost-performance-ratio medical solutions that can save and reshape patients’ lives or improve their quality of life.

The conference covered the topics of heart failure CRT’s pre-surgery patient choice, implantation technologies and after-surgery patient management in the forms of lectures, face-to-face discussions with the experts and debates. The conference provided a deeper knowledge of MicroPort® and MicroPort® CRM for the over 250 experts present from around the world. It also deepened their willingness for close cooperation with the corporations in the future.
MicroPort® Chairman and Chief Executive Officer Dr. Chang Zhaohua said, "MicroPort® will continue to sponsor New Horizons Scientific Conference, enhance communication with experts and physicians in the sector, and provide a bigger exchange platform for the R&D and business of cardiac rhythm management."

MicroPort® CRM develops, manufactures and markets products including defibrillators, cardiac resynchronization therapy devices and pacemakers for the diagnosis, treatment and management of heart rhythm disorders and heart failures, based on its legacy of more than one million patients implanted globally over nearly four decades. Among the products, Kora™ series are the world’s smallest full-body MRI conditional pacemakers, which make MRI scans no longer off-limits for pacemaker patients with the world’s first pacemaker technology capable of detecting an MRI field and automatically switching to asynchronous mode. Platinium Implantable Cardioverter Defibrillator (ICD) has the world's longest projected longevity of 14.3 years, giving the patients more durable and reliable safeguard. Platinium Cardiac Resynchronization Therapy Defibrillator (CRT-D) features the world's only SonR™contractility sensor for automatic CRT optimization, improving heart failure symptoms.

The New Horizons Scientific Conference is held by MicroPort® CRM with 12 editions so far. The conference builds a high-end platform for academic exchanges among global CRM and heart failure experts. It aims to make cardiac resynchronization therapy more popular, laying the solid groundwork for the promotion of new concepts and the application of new technologies.
MicroPort® Attends OCC 2018

On May 31, MicroPort® attended the 12th Oriental Congress of Cardiology ("OCC 2018") in Shanghai Expo Center and hosted a satellite meeting and a case contest. The OCC 2018 was hosted by Shanghai Medical Association and Chinese Society of Cardiology, focusing on the development and application of modern science in the field of cardiovascular diseases, while providing cardiologists a platform for academic exchange.

In the satellite meeting, Professor Bo Xu of Fuwai Hospital of Chinese Academy of Medical Sciences released the two-year clinical and imaging outcome of the FUTURE-I research, the First-In-Man ("FIM") study on Firesorb® Bioresorbable Sirolimus Target Eluting Coronary Scaffold System ("Firesorb®"). According to the result, the occurrence of the main endpoint in two years is zero, the occurrence of patient-oriented composite endpoint ("PoCE"), including death, myocardial infarction, and revascularization is 2.2%, and the occurrence of all-cause mortality, target vessel MI and stent thrombosis are all zero, which fully demonstrated the safety and efficacy of Firesorb®.

Professor Hui Gong of Jinshan Hospital of Fudan University delivered a report on "Physiological Pacing: New concept of the A2D mode". He pointed out, SafeR algorithm can realize A2D Physiological Pacing. The SafeR function of Rega™ Family Implantable Pacemakers developed by MicroPort Sorin CRM (Shanghai) Co., Ltd. ("MSC") can provide effective management for both SND and AVB patients by a more physiological therapy.

On June 2, Professor Bo Xu announced the primary endpoint data at 12 months and QCA angiography data at 13 months from its TARGET All-Comers ("TARGET AC") trial. The results of the TARGET AC trial demonstrated that vessels treated with the Firehawk® Rapamycin Target Eluting Coronary Stent System ("Firehawk®") showed non-inferiority results when compared to vessels treated with the Xience family of drug eluting stents. Such results further demonstrated that Firehawk® achieves the same efficacy with one third dosage versus similar products.

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MicroPort® Orthopedics Attends CAOS 2018

Recently, MicroPort® Orthopedics attended the 11th Annual Meeting of Chinese Association of Orthopaedic Surgeons (“CAOS 2018”) that focused on industries of joint, spine, trauma, and sport medicine. MicroPort® Orthopedics displayed its joint, spine and trauma product lines to demonstrate its branding ideology that "the Patient Always Comes First".

In this conference, MicroPort® Orthopedics displayed its Medial Pivot knee system, which caught wide attention from the attendees with its unique design. MicroPort® Orthopedics Medial Pivot knee was launched in 1998 with around 20 years' clinical history. Up to date, nearly 600,000 Medial Pivot knees have been implanted globally. The results demonstrate excellent clinical outcomes for both satisfaction (95%) and survivorship (98.8%) at 17 years. MicroPort® Orthopedics SuperPath® Micro-posterior Total Hip Arthroplasty (“SuperPath”™) also draw public attention with its "full function, faster" feature. As the world’s first total hip arthroplasty minimally invasive technique that facilitates a faster return to function for patients, SuperPath® causes incision as little as a 3-inch and ensures the maximum protection of soft tissue. Patients can walk as early as four hours after surgery. Recently a 103-year-old patient successfully received SuperPath® surgery in Zhengjiang First People's Hospital, which helped him to stand on his own feet the same day after the surgery.

MicroPort® Orthopedics also displayed its spine and trauma products including Wiltro Spinal Fixation System (“Wiltro”) and Bicera Bone Graft Substitute in its booth. Wiltro attracted wide attention with its unique guiding pin and guiding instruments.

During the conference, several senior orthopedic experts, including Professor Yan Wang of Chinese PLA General Hospital, visited MicroPort® Orthopedics booth and had in depth discussion with MicroPort® COO Glendy Wang and President of MicroPort® Orthopedics China Zixin Weng regarding product R&D and market development.
MicroPort® Orthopedics Attends CKS 2018

From June 1 to June 3, MicroPort® Orthopedics attended the Sixth Chinese Knee Society Conference ("CKS 2018") and displayed its Medial Pivot Knee System with unique design, which attracted wide attention from the attendees. The CKS 2018 was hosted by Chinese Medical Doctor Association and Chinese Association of Orthopedic Surgeons. Around 1,000 orthopedic surgeons were gathered in the congress to exchange ideas on the natural course of knee osteoarthritis, kinesiatrics, total knee/hip replacement, the application of smart instrument, and etc.

In the congress, MicroPort® Orthopedics hosted a satellite meeting on the design rationale and clinical application of medial pivot knee, and invited Professor Haishan Wu of Shanghai Ninth Hospital to give a lecture about "Patient Satisfaction – A Brief Analysis of the Design Rational of Medial Pivot Knee". Professor Wu explained in detail the importance of medial pivot design in restoring the natural knee structure based on the knee anatomy and the results of clinical studies. He said, the medial pivot knee design duplicates the movement of a natural knee and achieve the maximum restoration of the patient's knee function.

MicroPort® Orthopedics Medial Pivot Knee was launched in the US in 1998 with around 20 years' clinical history. Up to date, nearly 600,000 Medial Pivot Knees have been implanted globally. Several long-term studies have proved the advantages of medial pivot knee in total knee arthroplasty ("TKA"). The Knee has published a study evaluating long-term clinical and radiographic outcomes of the Medial-Pivot Knee System. The results demonstrate excellent clinical outcomes for both satisfaction (95%) and survivorship (98.8%) at 17 years. In the CKS 2018, MicroPort® Orthopedics staff enhanced the communication with physicians in the hope of keeping improving its products based on their clinical needs, and thereby to build a brand reflecting "the Patient Always Comes First".
MicroPort® Orthopedics Attends the First Edition of the Northeast Region Joint Surgery Summit Forum

From 8 June to 9 June, the first edition of the Northeast Region Joint Surgery Summit Forum was held at the Liaoning Province People’s Hospital. The forum was jointly held by China Health Promotion Foundation and Orthopedics Online, with Liaoning Province People's Hospital being the organizer and many domestic and foreign well-known experts in the field of joint surgery being present. Shanghai MicroPort®Orthopedics Co., Ltd. ("MicroPort® Orthopedics") attended and presented the Medial-Pivot Knee System, attracting the attentions of many well-known experts in the field.

As a cooperating corporation with the Liaoning Province People’s Hospital for the MicroPort® Joint Replacement Training Center, which is one of the hospital’s major medical projects, MicroPort® Orthopedics held a project-unveiling ceremony, which were attended by MicroPort® Scientific Corporation Chief Operation Officer Wang Gude and President of MicroPort® Orthopedics China Weng Zixin.

During the Master Rostrum session, Professor Qu Tiebing, delivered a speech on Medial-Pivot Concept and Patients' Satisfaction. Starting from the the Medial-Pivot Concept and combining it with a patient satisfaction survey, Professor Qu Tiebing went to the details of the important meaning of MicroPort® Orthopedics’ Medial-Pivot Knee design with regard to the restoration of a normal knee structure. Professor Bai Xizhuang, also delivered a speech together with Mr. Wang Huisheng on Clinical Application of Medial-Pivot Knees. Professor Bai Xizhuang and Mr. Wang Huisheng highlighted the highly bionic design of the Medial-Pivot knees and its outstanding performance in the respects of raising prosthesis survivorship and increasing the abrasion resistance of the prosthesis, which caused discussion among the audience. During the surgery live-streaming session, Professor Bai Xizhuang himself demonstrated a total knee replacement operation using MicroPort® Orthopedics EVOLUTION® Medial-Pivot Knee System. He also gave a detailed explanation of the process of the operation.
MicroPort Sorin CRM Commemorates the Clinical Application of the First Batch of Domestically made Rega® Family Pacemakers

Recently, MicroPort Sorin CRM, successfully held a series of events in Shanghai to commemorate the clinical application of the first batch of the Rega® Family Pacemakers on the sidelines of the 12th edition of the Oriental Cardiology Conference (OCC 2018).

MicroPort® Chief Technology Officer Dr. Luo Qiyi, said that MicroPort®’s development work in the cardiac rhythm management area in the earlier years, along with the setup of the joint venture MicroPort Sorin CRM and the recent acquisition of the CRM business of LivaNova, has made MicroPort® the only domestic corporation that owns the whole CRM product lines and all the related core technologies. It is not only an overarching measure for the globalization strategy of MicroPort®, but also a solid guarantee for the products’ domestic production and the replacement of foreign products in the cardiac rhythm management area.

MicroPort Sorin CRM Chief Executive Officer Dr. Wang Li, thanked in his speech the leaders of the society for their caring, support and help provided since the establishment of MicroPort Sorin CRM. He also thanked the clinical experts who were involved in the first batch of the implantations of the domestically made Rega® Family Pacemakers, as they firmly trusted the company and the products when the products were marketed.

Since the marketing of MicroPort Sorin CRM’s Rega® Family Pacemakers at the end of March this year, the products have treated nearly 100 patients at dozens of hospitals in China and received unanimous praises for its small size, longevity and excellent performance and outstanding quality from the physicians.
**MicroPort® Awarded as "Shanghai Brand"**

On June 7, a total of 53 enterprises were awarded as the first batch of "Shanghai Brand", and MicroPort® was the only healthcare company that was granted such honor with its star product Firehawk® Rapamycin Target Eluting Coronary Stent System ("Firehawk®"). The 53 listed enterprises cover 50 products and 36 services related with manufacturing, service, shopping and culture industries in Shanghai. The list was announced during the Shanghai Brand Certification Award Ceremony and 2018 World Accreditation Day. The attendees of the conference include Shanghai Deputy Mayor Kunlin Xu, Chief Engineer of Certification and Accreditation Administration of China Yumin Bo, Secretary-General of China National Accreditation Service for Conformity Assessment Jianhua Xiao, Deputy Secretary-General of Shanghai Municipal Government Jinshan Gu, Head of Shanghai Municipal Bureau of Quality and Technical Supervision Xiaolu Huang, President of Shanghai Brands International Certification Alliance Zhaozhe Xu. In the ceremony, Vice President of MicroPort® Corporate QA&QC Yong Li received the certification of "Shanghai Brand" on behalf of the company.

MicroPort® was awarded as "Shanghai Brand" with its new-generation drug-eluting stent Firehawk®. Firehawk® is the world’s first and only target-eluting stent ("TES"). It 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.

The certification of "Shanghai Brand" aims to cultivate high-end Chinese brands with international competitiveness. It recognizes high quality brands that meet the requirement of "leading brands, self-innovation, excellent quality, outstanding management and social responsibility".
Shanghai MicroPort Medical (Group) Co., Ltd.
Won A Patent Right Lawsuit Against NewMed Medical Co., Ltd.

On June 13, The Shanghai Intellectual Property Court delivered the first-instance judgment for the case of Shanghai MicroPort Medical (Group) Co., Ltd vs NewMed Medical Co., Ltd. and Yu Qifeng, Wang Haishan, Qin Tao, Liang Yuchen and Chen Jing over ownership of patent application and patent right disputes. The court ruled that the patent right for the utility model named Electropolishing Devices of the application number 201620366783.X and the patent application right for the invention named Electropolishing Devices of the application number 201610269615.3 should fall under the ownership of Shanghai MicroPort Medical (Group) Co., Ltd.

The plaintiff, namely Shanghai MicroPort Medical (Group) Co., Ltd ("The Group") has been engaged in the R&D, manufacturing and sales of high-end medical devices since 1998, and has been dedicated to technological innovation and breakthroughs. The Group has built up the ownership of over 3,100 patents or patent applications and created nearly 100 know-hows that are unique and never open to the public. The defendant of NewMed Medical Co., Ltd. ("NewMed Medical") was founded in March 2015, with the other defendants, namely Yu Qifeng, Qin Tao, Wang Haishan and Liang Yuchen, being former employees of The Group. Qin Tao, Wang Haishan and Liang Yuchen, who left The Group after February 2015, had owned the authority and opportunity to be in contact with the electropolishing technology and related devices. After leaving the Group, the three former employees filed patent applications about the technology, which is exclusively owned by The Group, in the name of NewMed Medical without the authorization of The Group, which seriously infringed on the legal rights of The Group. After learning the event, The Group filed a lawsuit at the Shanghai Intellectual Property Court to firmly defend its legal rights by judicial means. The Shanghai Intellectual Property Court has ascertained and established the facts that the technology had essentially existed at The Group before the departures of Qin Tao and Wang Haishan, while NewMed Medical failed to submit any evidence to support its argument that Yu Qifeng, the inventor, actually completed the invention of the technology at issue. Therefore, the rights basis of NewMed Medical for the patent and pending patent in disputes does not exist. The Shanghai Intellectual Property Court decided that the right of the patent and pending patent in disputes should be both owned by The Group.
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