MicroPort® Orthopedics Invited Professor Jimmy Chow Come to China to Carry Out SuperPath™ Academic Exchange Activities

The 17th Chinese Medical Association and the 10th Chinese Orthopedic Association (COA) International Academic Conference was held in Chongqing. As the world’s fourth largest orthopedic products manufacturer, MicroPort® Orthopedics participated in the conference and held a SuperPath® and EVOLUTION® satellite meeting, "MicroPort® Night" with new technology dissemination, shaft type knee series roadshow and many other activities.

Clinical Results of SuperPath® and EVOLUTION® Satellite Meetings

From November 19 to November 20, MicroPort® Orthopedics held satellite meetings at the Joint Hall and the Rehabilitation Hall during the conference. At the satellite meeting of the rehabilitation hall, Professor You Wang was invited to serve as chairman of the knee joint session and Professor Liu Yang was invited as chairman of hip joint session.

Professor Jimmy Chow, director of the Department of Orthopedics, at St. Luke’s Medical Center in the United States, presented a themed report at the meeting on "SuperPath": learning curve and clinical results of 7 years". About 400 doctors participated in the meeting. They discussed the clinical results of SuperPath® and its advantages. Dr. Chow has performed 1300 cases (including revision case) since 2008, with only 1% post-operative complication, average of 1.39 day length of stay in hospital, and over 60% of patients walking 4 hours after the surgery. According to Dr. Chow, he has operated on all his patients with SuperPath®, and the average BMI of his patients is 28.3 +/- 5.8 (heaviest 53).

Therefore, he considers that SuperPath® has the least restraints for patients to choose to have operations, among all contemporary hip MIS techniques. Through 1 day, 1 week and 1 month follow-up interviews on pain perception after surgery, they found that 70% of the patients perceive their pain level as zero by only taking oral pain management medicine, and without any medicines via analgesia pump or intravenous injection. This fact reveals that SuperPath® lowers patient pain perception after surgery by inter-operative protection of capsular, muscle and soft-tissue, so that patient may start physical therapy and speed up their joint functional recovery ASAP.
When comparing advantage of SuperPath® with DAA, Dr. Chow expressed that DAA is very “expensive” not only for its special operation table but also for a longer surgeon learning curve and higher complication rate which may frustrate the surgeons and their hospitals. SuperPath® is safe even for surgeons still in their learning curve because of its interchangeability to traditional approach during surgery, which facilitates SuperPath® as a technique for almost all hip surgeons.

In the session of knee joint, Professor Bae Dae Kyung, the former president of Korean Orthopedics Association, the founder of Korean Knee Society and the Korean Trauma Society, shared the design concept and clinical results of the EVOLUTION®. As the most influential expert in the field of internal shaft type of knee joint clinical application, Professor Bae Dae Kyung has rich experience in total knee arthroplasty, having operated more than 6000 knee surgeries.

Starting by talking about the kinematics of the knee joint, he then talked about the goal of the total knee arthroplasty, and emphasized the importance and necessity of the reconstruction of the knee joint kinematics and anatomy. He pointed out that the knee of the inner shaft, through the inside of the ball and socket joint surface, reconstructs lateral slide natural knee joint kinematics, which enables the patients to maintain high stability, and provides better mobility and proprioceptive at the same time. The long-term clinical follow-up results are superior, with no polyethylene wearing in 10 years of clinical follow-up results. For doctors and patients, it’s a very good solution.

On November 20, MicroPort® Orthopedics also held a symposium on SuperPath® for experts from China and America. During the symposium, Dr. Chow replied clinical questions from the attending surgeons. The participated experts said that this meeting provides a platform for in-depth exchanges for professionals. Doctors can communicate with Dr. Chow, one of the inventors of SuperPath® technique, face to face. It’s a good way to promote SuperPath®, the advanced technology, in China.
MicroPort® Orthopedics Medial Pivot Knee Roadshow China Tour-2015 COA

A MicroPort® Orthopedics Medial Pivot Knee Roadshow China Tour was held from November 15 to November 19. MicroPort® Orthopedics invited Dr. Bae Dae Kyung to share Medial Pivot Knee design rationale, surgical technique, and mid-long term clinical result. Meanwhile, Dr. Bae Dae Kyung demonstrated two surgeries during the China tour.

The roadshow covered Zhongda Hospital Southeast University, Dongyang People’s Hospital, Foshan Hospital of TCM, Guangzhou Orthopedic Hospital, and Third Affiliated Hospital of Guangzhou University of Chinese Medicine. Professor Bae Dae Kyung had his surgery demonstration at Dongyang and Foshan.

Prof. Bae shared presented medial pivot knee design rationale, how the prosthesis restores natural knee kinematics with its medial ball-in-socket for rotation and lateral path for sliding and roll-back. Meanwhile, the difference between medial pivot knee and traditional PS Knee were emphasized, especially the function and advantage of the medial pivot design without post-cam mechanism work to reduce poly ware and enhance knee stability. Prof. Bae demonstrated step-by-step the medial pivot knee surgical technique, including sequence of osteotomy and soft tissue balance, deformity correction and soft tissue balance for varus and valgus knee with flexion contracture patient and analysis of mid-long term clinical result from local center and multi-center study. According to Prof. Bae, medial pivot knee has been implanted in 1146 knee cases by 8 study centers, and result shows the survivorship reaches 97% after nine years follow-up. Prof. Bae emphasized several times that the goal of TKA is to restore fine joint function, range of motion and precise axial alignment. Such a goal requires a stable and wear resistant prosthesis. Medial pivot knee, with its socket articulation design and adequate tibia coverage (medial 97%, lateral 89%), has natural stability, less osteotomy and less wear, which lays the foundation of a successful TKA surgery.

In the roadshow, Professor Bae Dae Kyung discussed with many doctors about the internal axis of the knee joint, with the innovative design becoming a hot topic. The discussion also included the treatment of severe internal and external malformations, postoperative analgesia and hemostasis, rehabilitation management and other related content. To solve these problems, Professor Bae Dae Kyung gave detailed answers based on his own experience.

This time MicroPort® Orthopedics COA China roadshow not only introduced the design concept of the axis knee joint, popularized the knee prosthesis design trend, but also answered questions from domestic doctors on total knee arthroplasty. In the future, MicroPort® Orthopedics will continue to regularly carry out such activities, be committed to improve the level of domestic development, and provide a better solution for doctors and patients.
Release of New Products in "MicroPort® Night"

In the evening of November 19, the “MicroPort® Night” was held by MicroPort® Spine Trauma (Suzhou) Co., Ltd. (MicroPort® Spine Trauma). It’s a strategic partnership and new technology dissemination party. Strategic partners of the southwest region participated in the activities. More than 90 medical professionals and nearly 10 new contracted regional distributors from Sichuan, Chongqing, Guizhou and other provinces were invited to attend.

We released two new products -- Takin™ Spinal Internal Fixation System (Takin™) and PISCIS® Thoracic Lumbar Intervertebral Fusion Device System (PISCIS®). Takin™ is one kind of general spinal internal fixation system, applied to the thoracic, lumbar, sacral, iliac and spine anterior or posterior internal fixation. PISCIS® is made of PEEK-Optioma® material, which is suitable for a variety of surgical techniques, and thus makes it possible to maintain the intervertebral height, support vertebral body, restore the sagittal balance, and ultimately achieve fusion.

At the scene, many clinical experts had deep discussions on the instruments and the internal plant of MicroPort® Spine Trauma, and expressed their willingness of clinical practice. Professor Xianming Pan from Chengdu Military General Hospital said that people are looking forward to products which have high quality and reasonable prices. MicroPort® Spine Trauma can provide such kind of localization products. Manufacturing of these products is also a long term task to do in the field of Chinese Orthopedic.
The Registration Has Been Approved in Italy and South Africa for Reindeer™ Locking Compression Plate System

The Reindeer™ Locking Compression Plate System, which was produced by MicroPort® Spine Trauma based on its independent R & D, has been approved for registration in Italy and South Africa.

The Reindeer™ Locking Compression Plate System has precise anatomical design. It uses LCP combined-hole design and does not need to be bended during the operation. It can also be used for locking and unlocking screws. With the development of internal fixation, the application of locking plate has been expanded, and it can gradually be used in the treatment of limb fractures. The application of this new technology has improved the success rate of treatment for patients with high energy trauma.

Reindeer™ Locking Compression Plate System was introduced into the domestic market in 2014. Its approval of registration in Italy and South Africa this time indicates that MicroPort® Spine Trauma is actively exploring overseas markets for its locking plate series products, laying a solid foundation for the internationalization of MicroPort® Spine Trauma.
Annual Meeting of The Young Study Group of Joint Replacement

MPOJ participated in Annual Meeting of The Young Study Group of Joint Replacement as an exhibitor. Many surgeons attending this meeting have made energetic reports to the international society. This year, a session was held regarding the Medial Pivot Knee Design.
First Patient Enrolled in MicroPort's TARGET All Comer Clinical Trial in European for the Firehawk Rapamycin Target Eluting Coronary Stent System

MicroPort Scientific Corporation ("MicroPort") announced that the first patient was enrolled in the Firehawk® TARGET All Comer ("TARGET AC") clinical trial in Europe. This multi-center trial is designed to further assess the safety and effectiveness of the Firehawk® Rapamycin Target Eluting Coronary Stent ("Firehawk") for the treatment of atherosclerotic coronary lesions in an all comers, regardless of disease complexity and co-morbidities, real world population. Firehawk® is MicroPort’s proprietary, in-house developed, third generation Drug Eluting Stent ("DES") system and the Company received CE Mark approval for the Firehawk® in January 2015. The first patient was enrolled by a surgeon of Denmark.

TARGET AC is a prospective, multi-center, randomized controlled clinical trial. The study plans to enroll approximately 1,656 patients at up to 22 study sites throughout Europe including countries such as the United Kingdom, France, Spain, Italy, Belgium, the Netherlands, Poland, Germany, Austria and Denmark. Eligible patients with coronary artery disease will be randomized 1:1 to receive Firehawk® or Abbott’s Xience family of everolimus-eluting stents. The trial’s primary endpoint is the target lesion failure (TLF) rate at twelve months, and patients enrolled in the TARGET AC clinical trial will be followed up for up to five years.

"Firehawk® was designed to address the remaining limitations of current generation DES technology," said William Wijns, M.D., PhD, Cardiovascular Research Center, OLV Aalst, Belgium, and Principal Investigator of the study. "I am excited about its potential impact on patient care since the innovative groove design of the Firehawk® stent system has the potential to further reduce the risk of late adverse events and the need for device-mandated prolonged dual antiplatelet therapy, which is often associated with a higher risk of bleeding as well as increased patient treatment cost."
Clinical studies have shown that durable polymer coating technology may cause inflammation in the coronary artery. The Firehawk* stent abandons the need for a durable polymer coating technology and features instead a 100% biodegradable polyactic acid (PLA) polymer. Combined with sirolimus drug, Firehawk*’s biodegradable polymer and drug combination ensures a steady and constant drug release rate and complete absorption of the polymer shortly after drug elution ends at nine months. The stent itself has a proprietary design whereby tiny grooves have been etched on the outer surface of the stent. These grooves act as depository wells containing the polymer and drug combination, which allows Firehawk* to have a targeted release of the drug to the coronary vessel wall. This unique abluminal groove-filled design allows Firehawk* to overcome potential drawbacks experienced with other conventional drug eluting stents. In addition, in patients with complex lesions and complex PCI technique, Firehawk* overcomes concerns with the durability of the polymer coating in conventional DES. Because the polymer and drug combination are contained in the grooves of Firehawk* and not on the outer surface of the stent like conventional DES stents, the polymer coating is protected from abrasion or cracking due to crossing or re-crossing of the lesion during the procedure. Lastly, this targeted release design of Firehawk* allows it to provide the same level of clinical efficacy as a conventional DES while offering faster and more complete vessel healing after stent implantation, which could potentially reduce the duration of post-procedure dual antiplatelet therapy.

"The launch of the TARGET AC clinical trial in Europe is a tremendous milestone for MicroPort” said Mr. Qiyi Luo, Chief Technology Officer of MicroPort*. "We believe that the Firehawk* is potentially the best-in-class of the next generation DES to treat patients with coronary artery disease. We look forward to expanding on the body of clinical data that is already available to support the use of Firehawk* for patients in Europe.

"Firehawk* received China Food and Drug Administration (CFDA) approval in January 2014 and CE Mark approval in January 2015. The Firehawk* has been extensively studied in China in 1,261 patients through a comprehensive clinical program called TARGET, which includes TARGET First-in-Man (“TARGET FIM”), TARGET I RCT, TARGET I Long and TARGET II studies. These studies were required by the China FDA in order for Firehawk to obtain CFDA approval. The TARGET AC clinical trial builds upon the TARGET series study program. The Optical Coherence Tomography (OCT) data from the TARGET FIM trial demonstrated an early healing profile with an average of 96.2% strut coverage (new cell growth over stent struts) at four months, with a low rate of mal-apposed struts (0.1%) across the 14 stents analyzed. TARGET I RCT was a prospective, randomized trial evaluating the safety and efficacy of the Firehawk* stent for treating patients with single de novo coronary lesions compared with the Xience V everolimus-eluting stent. TARGET I demonstrated that the Firehawk* stent was non-inferior to the Xience V stent for the primary endpoint of in-stent late loss at nine months (0.13±0.24 mm vs. 0.13±0.18 mm, P<0.0001). Four-year follow-up results confirmed no definite/probable stent thrombosis and a reasonably low rate of target lesion revascularization (2.3% in Firehawk* group vs. 4.0% in Xience V group, P=0.33).
Firehawk® Indonesia’s Market-Entry Meeting

Recently, MicroPort® hosted a successful market-entry meeting for Firehawk® Rapamycin Target Eluting Coronary Stent System ("Firehawk") during the 7th Indonesia Society of Interventional Cardiology Annual Meeting (ISICAM-InaLive), making a positive first impression for Firehawk® to enter into Indonesia’s market.

The conference broadcast live two surgeries applying Firehawk®. Dr. Susenc and Dr. Yamin, Indonesian experts, operated the two complex lesion cases. Dr. Yamin used the Culotte technique for the treatment of bifurcation lesions. He implanted two Firehawk® stents during the operation. The postoperative results showed that two surgeries were successful, proving once again that Firehawk® is safe and effective in the treatment of complex diseases. Firehawk®’s excellent passing ability also was highly praised by the two experts.

Later at the Firehawk®’s market-entry meeting, MicroPort® invited Professor Shaoliang Chen, the vice president of the First Hospital of Nanjing City, the famous cardiac interventional expert, as the guest speaker. Together with Dr. Munawar, the chairman of the Indonesian Heart Association, Dr. Alkatiri, the Indonesian expert in the field of cardiac interventional, introduced the Firehawk® to the participants.

Dr. Munawar introduced the excellent performance and results of animal experiments with Firehawk®, highlighting the innovative technique of Firehawk®’s targeted elution. Professor Shaoliang Chen introduced a series of clinical research before the market-entry of Firehawk®. He also reported the latest 4 years’ clinical results of the Firehawk® Target I and Target II, which have proved their the effectiveness and safety of Firehawk®. In the end, Dr. Alkatiri shared his clinical experience of Firehawk® through the surgical cases, which gained much attention from the participating doctors.

These Firehawk® marketing activities also received attention and support from Dr. Munawar and Dr. Firman, the president of ISICAM-Inalive. They participated in the Firehawk® market-entry breakfast meeting, which was jointly organized by MicroPort® and PT. Otsuka Indonesia (PTOI), the Indonesian agent.

During the breakfast meeting, Yingqing Lin, MicroPort® vice president of international business and Mr. Sakiyama, the general manager of PTOI, gave two themed speeches to attendees. The speeches focused on “Firehawk®’s market-entry plan in Indonesia” and “How to promote the cardiac intervention in Indonesia through professional education and clinical trials”, which received positive feedback from participated doctors. They expressed the willingness of follow-up cooperation to promote the progress of the cardiac intervention in Indonesia. The local experts are full of expectations for and have confidence in the Firehawk®. All the marketing activities have laid a solid foundation in the Indonesian market for Firehawk®, and at the same time, a new chapter of the market development of Indonesia for MicroPort® was opened.
MicroPort® Completed the First Distant Interactive Surgery in the Field of Coronary Intervenotional Treatment

One PCI operation was operated in Kunshan Hospital of Traditional Chinese Medicine, Jiangsu Province. The operation was broadcasted in MicroPort® Cicada Auditorium, transmitted back to Shanghai MicroPort Medical (Group) Co., Ltd. ("MicroPort") via "MicroPort® Online" through the 4G wireless network.

Professor Weiyi Fang from Thoracic Hospital Affiliated to Shanghai Jiaotong University watched the operation live in the hall. Through audio and video interaction, professor Fang discussed the surgery with the surgical team of Kunshan Hospital of traditional Chinese Medicine. Professor Fang was giving guidance on operation strategy on-site, and he introduced the application techniques of coronary balloon and stent, including how to control the timing. The operation completed successfully. It was the first time MicroPort® used "MicroPort® Online Platform" to carry out a distant medical treatment in the field of coronary intervention collar, which was a milestone of significant importance.
The distant interactive guidance for the operation not only achieved the purpose of accurate treatment, but also shared the medical resources and medical staff. After surgery, professor Fang discussed with Dr. Zhaohua Chang, the chairman and CEO of MicroPort*, Mr. Bo Peng, the chief marketing officer, Mr. Lei Jiang, the vice president of marketing of the coronary artery, Dr. Chengyun Le, the vice president of planning and project management and Mr. Yi Sun, the senior director of IT department, regarding MicroPort*'s positive response to the national policy of supporting county level hospitals.

They hoped that the "MicroPort* Online" can continue to enrich the distant medical operation. MicroPort*'s mature medical resources will help to establish fixed-point centers around the county hospital, to set public platform to provide distant medical services, to promote the sustainable development of the level of intervention surgery in county level hospitals.

"MicroPort* Online" was officially launched in October 2015. It had already successfully distantly broadcasted a SuperPath™ surgical guidance carried out in Zhongshan Hospital Affiliated to Fudan University. This time the broadcast was still carried out via the 4G network mobile professional broadcast equipment, through the cloud server real-time to upload and download the signal of operation room's equipment, and to achieve audio and video interaction in broadcast mode.

The success of the operation means MicroPort* has already had the technical ability of online distant medical treatment. In the future, MicroPort* will continue to use the features of the techniques, promote the use of telemedicine in county level hospitals and increase the ability of medical services in primary hospital.
MicroPort® EP OptimAblate™ Cardiac RF Generator and OptimAblate™ Irrigation Pump Obtained CE Certification of EU

Independently researched and developed by Shanghai MicroPort EP MedTech Co (‘MicroPort® EP’), the OptimAblate™ Cardiac RF Generator and OptimAblate™ Irrigation Pump obtained the official CE Certification of EU.

OptimAblate™ Cardiac RF Generator is a device intended for RF ablation therapy of the human heart. It generates RF energy and continuously coordinates RF energy output, the temperature of the catheter’s tip electrode, and the tissue impedance during ablation therapy. When the RF energy heats the tissue, unwanted electrical pathways are interrupted or destroyed, thereby normal heart function restores. OptimAblate™ Irrigation Pump is a peristaltic pump designed to work with the OptimAblate™ RF Generator to deliver irrigation solution at specified flow rates to irrigated catheters for cooling purpose. The feature of double bubble detection of the pump ensures the safety and reliability of operations.

OptimAblate™ Cardiac RF Generator is designed to have a tilt angle display screen and high-definition touchscreen, and so is user friendly and straightforward to use. When linked with OptimAblate™ Irrigation Pump, it can display real-time data such as power, perfusion flow rate, temperature, impedance, and ablation duration. It also can provide various personalized consumer financial parameter settings and storage. This time, OptimAblate™ Cardiac RF Generator and OptimAblate™ Irrigation Pump received the official EU CE certification, indicating that MicroPort® EP cardiac RF generator products and irrigation pump series products make successful entry into these markets. It sets a solid foundation for the company to further develop the international market.

The “2015 Dunhuang EP tutorial Conference—Radiofrequency Ablation under 3D Navigation” was held in the First Hospital Affiliated to Lanzhou University. The Professional Committee of EP and Pacing of Gansu Medical Association and Heart Center of the First Hospital Affiliated to Lanzhou University hosted the conference. Professor Yansheng Ding, a famous domestic arrhythmia expert from the First Hospital of Peking University, was invited to attend the meeting as well as several cardiovascular disease experts within Gansu Province. MicroPort® EP participated in the meeting.

The meeting is chaired by Professor Zheng Zhang, director of First Hospital Affiliated to Lanzhou University. The status quo and future development of the treatment of atrial fibrillation were analyzed and the prospects of the future development of the 3D EP Navigation System in the treatment of arrhythmia were also presented. Subsequently, the experts communicated their views and experiences about the working theory of 3D EP Navigation System, a variety of applications in the treatment of arrhythmia and other issues of the application of the technology.

During the meeting, Professor Yansheng Ding had a first-hand experience by operating the MicroPort® EP Columbus™ 3D EP Navigation System (“Columbus™”) by himself. Dr. Qiang Li, Director of First Hospital Affiliated to Lanzhou University, gave comments besides him. As the first domestically developed 3D cardiac electrophysiology based on precise magnetic positioning technology, it is currently the only CE certified domestic system. Professor Ding gave a high evaluation and recognition of the Columbus™, looking forward to its application after enters into the market.

After the meeting, Dr. Qiang Li said that there are very large numbers of atrial fibrillation patients who would need radiofrequency ablation in Gansu Province. The 3D EP Navigation System is the kind of indispensable device for atrial fibrillation. The high price of import system and catheter products has been limiting many patients because of their economic capacity. MicroPort® EP Columbus™ System and ancillary products from the electrophysiology market undoubtedly bring more benefit to the patients with complex arrhythmia.
Product of MicroPort® EP
Completed First Clinical Case Observation

MicroPort® EP’s new product, the Cardiovascular Catheter Sheath and the Accessories, completed its first clinical case observation in the General Hospital of Shenyang Military Region. Compared with similar imported products, the surgeon’s evaluation of the product was very good.

The product is independently researched and developed by MicroPort® EP, and it's an essential for the catheter ablation of atrial fibrillation surgery, guiding radiofrequency catheter ablation and mapping catheter to a desired location in the surgery. This time’s clinical observation mainly studies the safety and effectiveness of the product, and the achievement indicates MicroPort® EP takes a step forward for providing a systematic solution for the treatment of complex arrhythmia.
Registration of Dongguan Kewei Occluder Series Products in Kazakhstan Approved

The first time registration in Kazakhstan of Dongguan Kewei Medical Instrument Co., Ltd.'s ("Dongguan Kewei") independently researched, developed and produced occluder series products was approved, including Atrial Septal Defect Occluder (ASD Occluder) and Conveying System, Ductus Arteriosus Occluder (PDA Occluder) and Conveying System, Ventricle Septal Defect Occluder (VSD Occluder) and Conveying System.

Dongguan Kewei ASD Occluder and Conveying System, PDA Occluder and Conveying System, VSD Occluder and Conveying System, can be applied to congenital atrial septal defect, interventional treatment of patent ductus arteriosus and ventricular septal defect. Through a conveying pipe, a crack resistance fluid plugging net rack is arranged in the lesion, effectively blocking the abnormal blood flow, enabling tissue defect finally being able to be repaired and reconstructed. Compared with the traditional surgery, the products will cause fewer traumas, less damage without tracheal intubation anesthesia, less pain, and shorter hospitalization time.

Previously, ASD Occluder, PDA Occluder, occluder with conveying system and VSD Occluder have won the CFDA registration certificate, and all occluder series products have entered in market. In addition, some of the occluder series products' registration in India and Russia had been approved. This time's approval of registration in Kazakhstan symbolized that Dongguan Kewei occluder products will officially enter the Kazakhstan market, laying the foundation to further explore the international market, and will bring health and good news for more overseas patients with congenital heart disease.