Investor Newsletter

Issue 06 2024

MicroPort®

MicroPort® Releases Latest Clinical Study Results for Firehawk® at EuroPCR 2024

MicroPort®, along with its various business units and associated companies, participated in this year's EuroPCR, which was held in Paris, France. During the conference, MicroPort® showcased its integrated solutions in the coronary intervention field and innovative products in structural heart diseases, electrophysiology, and extracorporeal life support. Furthermore, MicroPort® shared its products' latest clinical study advancements with approximately 12,000 experts and scholars worldwide, attracting numerous attendees for discussions and interactions.

At EuroPCR 2024, MicroPort® displayed several integrated solutions including Firehawk®, Firehawk Liberty™ Rapamycin Target Eluting Coronary Stent Systems, Firefighter™ PTCA, Firefighter™ NC PTCA, VitaFlow Liberty® Transcatheter Aortic Valve and Retrievable Delivery System, MOBYBOX® ECMO System, PathBuilder® Room Septum Puncture Needles, adjustable bend sheath sets, intracardiac guide sheaths and accessories, attracting numerous attendees for discussions and interactions.

Noting these successes, MicroPort® will continue integrating the technology and experience of leading experts from different countries to help hundreds of millions worldwide live better and longer lives.

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MicroPort® Coronary's Intravascular Piezoelectric Guidewire System Enters "Green Path" in China

Recently, MicroPort® RotaPace's Intravascular Piezoelectric Guidewire System gained NMPA approval for entry into the special review procedures for innovative medical devices (the "Green Path"). This system was co-developed by a team led by Academician Junbo Ge from Zhongshan Hospital, Fudan University.

As a co-developer, Academician Ge stated, "Close collaboration between physicians and engineers is essential throughout the innovation process. The Intravascular Piezoelectric Guidewire System transforms innovative concepts into practical solutions, creating 'tunnels' through hard calcified CTO lesions to aid in crossing occlusions. We hope this will significantly benefit coronary heart disease patients and contribute to the global advancement of medical care."

Dr Bin Yue, President of MicroPort® Coronary, remarked, "To overcome the challenge in chronic total occlusion percutaneous coronary intervention (CTO-PCI), we partnered with Academician Ge, professor Jianying Ma and others to conduct countless trials and explorations. This approval marks the second active device from MicroPort® Coronary to enter the 'Green Path'. In the future, MicroPort® Coronary will continue driving technological innovation, focusing on the development of high-end innovative medical devices to provide high-quality, accessible solutions for coronary heart disease."

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MicroPort® CardioFlow's Mitral Valve Collaboration Partner 4C Medical Receives FDA Breakthrough Device Designation for AltaValve™

Recently, AltaValve™, a transcatheter mitral valve replacement (TMVR) system developed by 4C Medical, has been granted two Breakthrough Device designations by the Food and Drug Administration (FDA). These designations specifically target treatment indications for moderate to severe or severe mitral regurgitation (MR) and moderate/severe MR with moderate/severe mitral annular calcification.

The AltaValve™ system is the only fully retrievable low-profile TMVR system globally, poised to offer the world's first atrial-only fixation MR treatment solution upon its market release. Its innovative design maximally avoids the challenges of mitral annular anchoring present in existing TMVR technologies helping to protect cardiac structures during the procedure, reduce the risk of left ventricular outflow tract obstruction or damage, and enhance clinical outcomes.

The Breakthrough Device designations from the FDA reflect the unique achievements and leading position of the AltaValve™ system in the field of interventional MR treatment. An early feasibility study has shown positive results, and confirmatory clinical trials are expected to commence globally by the end of 2024 to support CE marking and FDA approval.

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MicroPort® MedBot™ Receives Approval for Its Toumai® Robot in the EU

On 7 May 2024, MicroPort® MedBot™'s Toumai® Laparoscopic Surgical Robot received CE MDR certification from the EU, approving its use in urologic, general, thoracic, and gynecological endoscopic surgeries. This approval confirms the robot's stability, clinical efficacy, safety, and technological innovation.

The Toumai® robot features the world's first force-sensing component for laparoscopic surgery robots. It is designed with a multi-layer safety architecture that enables real-time protective sensing and automatic locking when the head is disengaged. Its advanced imaging system offers a 10x optical magnification high-definition view, enabling glasses-free 3D imaging. With seven degrees of freedom, the surgical arm system stabilizes the surgeon's physiological tremor, providing wrist-like articulation in surgical instruments surpassing human hands' flexibility, precision, and stability.

To date, Toumai® has been used in over 90 medical institutions worldwide, completing nearly 3,000 multi-disciplinary clinical surgeries, including almost 200 remote surgeries using 5G technology. According to Dr Chao He, President of MicroPort® MedBot™: "Receiving CE certification marks a new milestone in our global strategy. We will seize this opportunity to continually expand our international presence, meet clinical needs with high-quality medical robotic solutions, and improve the accessibility of surgical robot technology to make surgery easier, safer, and less invasive."

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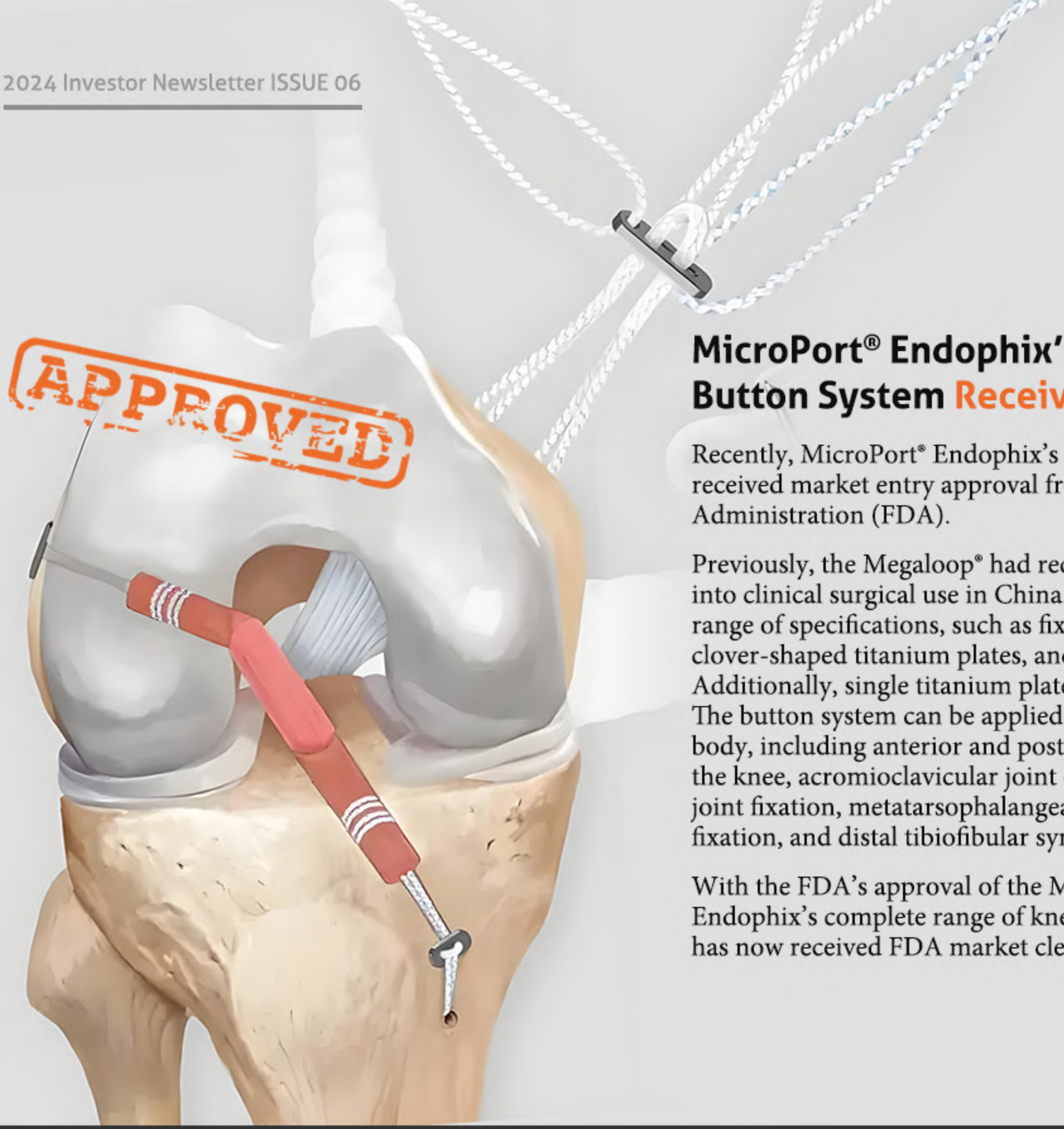

MicroPort® Endophix's Megaloop® Button System Receives FDA Approval

Recently, MicroPort® Endophix's Megaloop Button System (Megaloop®) received market entry approval from the U.S. Food and Drug Administration (FDA).

Previously, the Megaloop® had received NMPA approval and had been put into clinical surgical use in China. This series includes a comprehensive range of specifications, such as fixed and adjustable loop titanium plates, clover-shaped titanium plates, and adjustable dual titanium plates. Additionally, single titanium plates paired with adjustable coils are available. The button system can be applied to a variety of indications throughout the body, including anterior and posterior cruciate ligament reconstruction of the knee, acromioclavicular joint dislocation fixation, wrist carpometacarpal joint fixation, metatarsophalangeal and tarsometatarsal joint dislocation fixation, and distal tibiofibular syndesmosis fixation.

With the FDA's approval of the Megaloop® Button System, Endophix's complete range of knee ligament repair solutions has now received FDA market clearance.

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