

MED DEVICE MONTHLY

"The RW Search Company Newsletter on the latest Med-Tech developments"



Miach Orthopaedics Initiates Post-Market Study for BEAR® Implant

A privately held company dedicated to developing bio-engineered surgical implants for connective tissue restoration, this month announced the first patient has been treated in the company's BEAR III study of the BEAR® Implant – the first medical technology to clinically demonstrate that it enables healing of a patient's torn anterior cruciate ligament (ACL).

BEAR III is a single-arm, multi-center cohort study enrolling 250 patients, all of whom will receive the BEAR Implant and will be followed for 10 years.



Boston Scientific announces €30m medtech investment in Cork

Boston Scientific has announced a €30 million investment in its Cork facility to accelerate the development and manufacturing of minimally invasive medical technologies that treat patients suffering from cancer and peripheral arterial diseases. This announcement is expected to generate 70 new jobs over the next three years.

Speaking on the announcement, Tánaiste and Minister for Enterprise, Trade and Employment Leo Varadkar said "Ireland is globally recognised as a centre of excellence for the Life Sciences and this investment is a real vote of confidence in us and our capacity. I wish the team the very best with their plans."

THIS MONTHS TOP CARDIAC DEVICES

With World Heart Day being on the 29th September, it's important to remember heart disease and stroke are the world's leading cause of death claiming 18.6 million lives each year. We thought it was apt to round up some of the FDA cleared platforms contributing to the general effort of reduction of the disease

Biotronik PK Papyrus Covered Coronary Stent System: Biotronik's PK Papyrus-covered coronary stent is a balloon-expandable covered stent that is implanted into a coronary artery using a balloon catheter delivered system designed to treat coronary artery perforations or tears in heart blood vessels. It is positioned at the sight of a coronary artery perforation and the balloon is inflated to expand the covered stent, press it against the coronary artery wall and seal the perforation while allowing for normal blood flow.



Boston Scientific HeartLogic Heart Failure Diagnostic: Boston Scientific's HeartLogic is a personalised remote heart failure diagnostic and monitoring device. Boston Scientific designed the device to provide weeks of advance notice to detect early signs of worsening heart failure. It uses physiologic sensors with high sensitivity and low-alert burden to predict heart failure decompensation.



CVRx Barostim Neo: CVRx's Barostim Neo is a heart failure neuromodulation device. CVR-x designed the device to improve systems in patients with advanced heart failure who are not suited for other heart failure devices by electrically activating the baroreflex to reduce sympathetic activity and increase parasympathetic activity.





THIS MONTH IN M & A

Memic to merge with SPAC at more than \$1 billion valuation

Israeli medical device company Memic Innovative Surgery, which has developed a robotic-assisted surgery solution, announced on Friday that it has reached an agreement to merge with MedTech Acquisition Corporation, a publicly traded special purpose acquisition company (SPAC) focused on medical technology.

The combined company is set to have an estimated pro-forma equity value of more than \$1 billion.

GE Healthcare agrees to acquire BK Medical for \$1.45bn

GE Healthcare has agreed to acquire BK Medical from Altaris Capital Partners in an all-cash purchase worth \$1.45bn.

The transaction, which is expected to close in 2022, subject to review by the relevant regulatory authorities, will strengthen GE's \$3bn ultrasound business and help the company expand beyond pre-and post-operative diagnostic ultrasound.

THIS MONTH IN CERTIFICATIONS

ENDOSOUND EndoSound Vision System

The FDA granted breakthrough status to the EndoSound Vision System, an add-on device for flexible upper gastrointestinal video endoscopes. Adding the device to an endoscope creates an endoscopic ultrasound system capable of performing procedures such as fine needle biopsies without the elevator mechanism linked to the risk of infection.



NOVOCURE NovoTTF-200T System

Novocure received breakthrough status for the cancer treatment device when FDA decided its NovoTTF-200T System gave the designation aimed at first-line treatment of patients with unresectable or metastatic liver cancer.

The designation covers the use of the device, which emits electric fields to disrupt cancer cell division, in combination with Roche's oncology drugs Avastin and Tecentriq.



MICROTRANSPONDER Vivistim Paired VNS

MicroTransponder's breakthrough-designated stroke rehabilitation system. The device consists of an implantable pulse generator that stimulates the vagus nerve to improve the effectiveness of rehabilitation therapy.



IMPEDIMED SOZO® Digital Health Platform

Impedimed received breakthrough status for a device for measuring the volume of fluid to remove from renal failure patients during dialysis. The device uses bio impedance spectroscopy to measure body water.



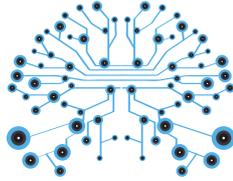
MicroTransponder plans to make the device available in parts of the U.S. by the end of the year, before expanding nationally in 2022.

ImpediMed is pitching the approach as more accurate than the current method, which uses weight scales that cannot account for muscle loss. Removing too much or too little fluid can have negative health outcomes such as low blood pressure.



How Is the FDA Considering Regulation of AI and Machine Learning Devices?

With the rise of AI applications in Med Tech, there has been a growing demand for a system to regulate AI/machine learning-based software as medical devices.



The U.S. Food and Drug Administration (FDA) has now issued the “Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan” from the Center for Devices and Radiological Health’s Digital Health Center of Excellence.

The Action Plan is a direct response to stakeholder feedback to the April 2019 discussion paper, “Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device” and outlines five actions the FDA intends to take.

NEUROLOGY TECH: Flow Neuroscience

Swedish health tech Flow Neuroscience has raised \$9 million in a Series A round, with the funding is expected to be used to further develop existing depression treatments as well accelerate expansion into the US market via clinical trials and FDA approval. To date, the startup has raised a total of \$11.6 million.

The headset delivers tDCS to the forehead which, according to the company, reverses neural activity imbalances in the frontal lobe observed in people with depression. The device pairs with a smartphone app that guides the user through a 6-week wellness program.



START-UPS TO WATCH THIS MONTH

Here are some of the exceptional startups that RW Search has pinpointed this month, who are taking a variety of approaches to innovating the medical device industry, all well worth a follow. We showcase three of our top picks for the medical device companies who are pioneering within their sectors.



Reperio: A Portland, Oregon-based medical device startup founded by Travis Rush and Matt Wallington. The company developed an FDA-approved "health kit" that can be used to test various health metrics such as cholesterol, glucose, blood pressure, resting heart rate and other important health indicators. This year, Reperio Health earned \$6M in seed funding from the investors: Caduceus Capital Partners, Rogue Venture Partners, Liquid 2 Ventures, and G Ventures.



ZygoFix: another medical device startup from Israel, known for its medical device called zLOCK - a 3D-printed, screwless implant which serves as an alternative to painful spinal fusion surgery. Founded by medical device entrepreneurs Uri Arnin and Yizhar Floman, ZygoFix raised \$2M in seed funding from Trendlines Group, Agriline, Israel Innovation Authority, and other private investors in March 2021.



Oxular: A medical device startup from the United Kingdom, and a leading company in therapeutic devices to treat retinal diseases. Founded by David Fellows and Thomas Cavanagh, the company recently received a \$37M investment in a venture round from Forbion Capital Partners.