

MED DEVICE MONTHLY

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

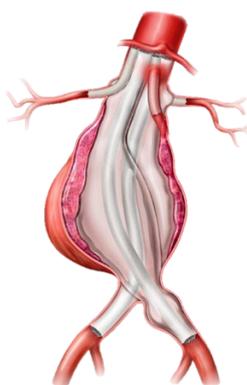


ENDOLOGIX LLC: BREAKTHROUGH VASCULAR DEVICE

Endologix LLC has been granted Breakthrough Device Designation from the FDA for its ChEVAS (Chimney EndoVascular Aneurysm Sealing) System.

The FDA Breakthrough Devices Programme allows patients better access to medical devices that may provide a more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases, with breakthrough devices receive priority review.

The ChEVAS System is an investigation endovascular abdominal aortic aneurysm (AAA) sealing therapy designed to combine the Nellix 3.5 endograft with parallel visceral stents to enable treatment of patients with juxtarenal, pararenal and suprarenal AAA.

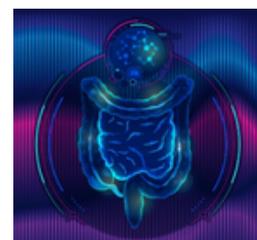


Suono Bio Enhancing Drug Delivery with Ultrasound

Suono Bio, founded by two MIT professors and alumnus, is using technology to boost the treatment of gastrointestinal tract disorders.

Suono Bio is the culmination of more than three decades of discoveries made in MIT labs by researchers including schoellhammer and fellow Suono co-founders Robert Langer, who

It can often be difficult to get drugs to reach disease sites along the gastrointestinal tract, which spans the mouth, esophagus, stomach, small and large intestinal tract.



THE NEUROTECH STARTUP THAT BEAT ELON MUSK IN THE BRAIN CHIP RACE

Last week, the FDA granted the neurotech startup Synchron a groundbreaking approval to conduct more ambitious experiments and test its neural implant in human paralysis patients, setting it on the path to eventually become the first brain implant to get commercial approval.

That puts it ahead of Elon Musk's neural implant venture, Neuralink, which in spite of over \$360 million in funding — nearly an order of magnitude more than the amount raised by Synchron — has yet to convince the FDA that it's ready to make the jump from its highly-publicized tech demonstrations in animals to the actual human experimentation that Musk claims will allow users to connect their brains to AI and cure their neurological conditions.

Synchron's ultimate goal is to snake stents up your jugular vein and into the vasculature that supplies your brain with oxygen, permanently implanting a distributed series of sensors that it calls the Stentrode to constantly record your entire brain's activity. A far less invasive procedure than Musk's Neuralink has planned: laser-drilling holes through volunteers' skulls and threading them with metal wires.





WEARABLE THERAPEUTIC DEVICE TO COMBAT NAUSEA

This user-controlled device prevents and treats nausea associated with pregnancy, anxiety, hangovers, physician-diagnosed migraines, chemotherapy, and works as an adjunct to antiemetics in treating post-operative nausea.

Reliefband's FDA-cleared Device is a drug-free therapy and an effective solution that uses pulses to prevent nausea and vomiting before it begins while also being effective after symptoms have already occurred.

This device uses a highly specific waveform, frequency, and intensity to stimulate the median nerve on the underside of the wrist. This activity uses the body's neural pathways to block waves of nausea produced by the stomach.



Bio-inspired, blood repelling tissue glue could seal wounds rapidly

Hemostasis is a lingering critical problem - failure to stop bleeding and associated complications is still the 1st cause of mortality in the military and 2nd cause of death in the civilian sectors in the U.S. (before the COVID-19 pandemic),

In response, MIT engineers have designed a strong, biocompatible glue that can seal injured tissues and stop bleeding - inspired by the sticky substance that barnacles use to cling to rocks. Barnacles glue contains not only adhesive proteins but also lipid (or oil) rich components that can clean contaminants from the target surface to aid the adhesion formation.

This new paste can adhere to surfaces even when they are covered with blood and can form a tight seal within about 15 seconds of application. Such glue could offer a much more effective way to treat traumatic injuries and to help control bleeding during surgery.

MED TECH: CERTIFICATIONS

FDA Clears Boston Scientific's EXALT Model-B Bronchoscope

Boston Scientific has received U.S. FDA clearance for the EXALT Model B Single-Use Bronchoscope, designed for use in bedside procedures within the intensive care unit (ICU) and operating room (OR).

The EXALT Model B Bronchoscope can be used for a range of bronchoscopy procedures such as secretion management, airway intubation, percutaneous tracheostomy, double-lumen endotracheal tube placement, and biopsies.



Acutus Medical's Software Receives FDA Clearance and CE Mark

Acutus has received both U.S. FDA and European CE Marking for their new Medical Software, AcQMap 8. The technology is designed to enable imaging, visualization, planning, and ablation all in one system.

AcQMap 8 introduces seamless integration of Acutus' AcQBlate FORCE Sensing Ablation Catheter and System into the AcQMap® High-Resolution Imaging and Mapping System, enabling a complete end-to-end cardiac ablation procedure with the AcQMap system.



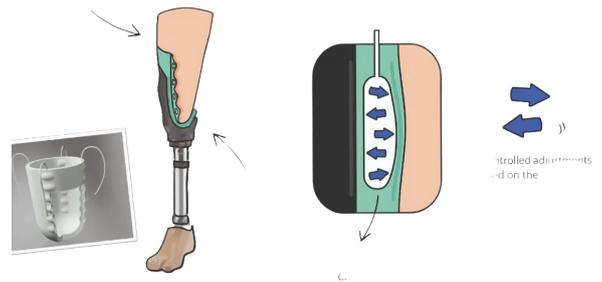


DEVICE SPOTLIGHT: Unhindr's AI-Powered Custom-Fitted Wearable Sleeve

UK startup Unhindr develops an AI-Powered custom-fitted wearable sleeve, addressing the issue of inflexible prosthesis. Unhindr's CEO, Ugur Tanriverdi, along with Co-founder and Chief Scientific Officer, Firat Güder, and Chief Technology Officer, Guglielmo Senesi, are developing Roliner, a wearable sleeve that uses an AI algorithm to adapt to a person's fitting needs throughout the day.

The technology is currently being developed with a team of amputee advisors to help deliver a comfortable prosthesis and is supported by clinical research led by Dr. Joseph Shalhoub, a vascular surgeon at St Mary's Hospital and honorary senior lecturer at Imperial College London. The early-stage adaptive robotics company has just won £500,000 in Innovate UK funding to grow and scale their adaptable AI prosthetic device.

Additionally, the Mayor of London had also announced Unhindr as the winner of the Mayor's 2020 Entrepreneur Health Award, and the company has been selected as one of the 15 most innovative startups in Europe by the European Institute of Innovation and Technology of the European Union in partnership with GE Healthcare, Cap Digital, and Imperial College London.



TOP 3 UK MED-DEVICE START-UPS

Here are some of the exceptional UK startups and companies 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 best United Kingdom based Medical Device startups and companies who are showcasing a variety of approaches to innovation within their sectors.



GyroGear: GyroGear is developing a wearable smart-glove technology to increase hand stability, reducing hand tremors in Parkinson's and essential tremor patients. Developed by an ex-NHS doctor, engineers, and expert clinicians, the GyroGlove works by using GyroScopes, which have applications in aviation and electronics, to counter any input of force in any direction swiftly and proportionately and stabilise the hands.



4D Biomaterials: 4D Medicine Ltd, is set to commercialise a new class of 3D printing materials – liquid resins that can be printed into solid 3D scaffolds to help patients recover from major medical procedures more quickly. The company has secured a £197k grant from Innovate UK and a pre-seed investment of £281k from SFC Capital to develop a range of implantable medical devices that will improve patient quality of life by accelerating healing and recovery after surgeries.



QV Bioelectronics: Manchester-based QV Bioelectronics are a pioneering medical device startup developing the first-of-its-kind electric field therapy implant to treat the most common and aggressive type of brain tumours has recently bagged £735K in an oversubscribed seed funding round in order to advance the development of its innovative GRACE implant.