



MED DEVICE MONTHLY

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



National stroke month: JNJ introduce new FPE device

DEVICE OF THE MONTH: Orthopaedic Development

With it being national stroke month, it is apt that we look at a ground-breaking technology in the stroke device field that is highly successful in achieving First-Pass Effect (FPE).

Earlier this month THINK Surgical and OrthoDevelopment announced an exciting milestone, receiving FDA clearance for use of the TSolution OneTotal Knee Application and BKS Trimax.

Johnson & Johnson's Cerenovous Embotrap Revascularisation Device has achieved FPE in a trial which looked at patients with disabling strokes who underwent mechanical thrombectomy.

The collaboration enhances each company's expertise in the field of orthopaedic device design and active robotic surgery, this innovative merger provides the only commercially available active robotic system for total knee replacement that supports an open implant library, giving surgeons a choice of implant options.

FPE is the ability to open the occluded or clotted brain arteries on the first attempt, after a patient has suffered an ischemic stroke. Patients who achieved FPE had significantly higher rates of regaining clinical functional independence

The procedure leads to fewer nursing costs, reduction in the use of critical care facilities, and greater use of standard hospital care; therefore, on top of better patient outcome there are significant savings in the costs associated with hospitalisation

CEO Profile - Roland Rott



As of April 2021, Roland Rott is CEO & President of GE Healthcare's \$3B Global Ultrasound Business, after 9 successful years at the company. Following his time at Leopold-Franzens University, Rott began his career by setting up a student start-up that became a leading system integrator in West-Austria.

Ensuing the acquisition of his company by Exact Software, he remained in this company holding progressively more senior positions culminating in MD of EMEA & APAC. In 2011, Roland put his expertise to use in the med-tech industry, joining as general manager of IT at Ultrasound at GE, and then general manager of global women's health in 2014, and VP & GP of Women's health in 2019.

After 9 years of developing his proficiency in various units of the company, he acquired his position as CEO, leading strategic direction and the global team in areas of Women's Health, General Imaging, Point of Care, Primary Care, and Cardiovascular Ultrasound



THE RISE OF ROBOTICS IN HOSPITALS

Surgical robotics sector boosted by hospital spending in Q1 of 2021. With spending on capital equipment increasing, this indicates a stronger outlook for surgical robotics procedures.

As procedures are returning to normality following the pandemic, hospital finances are significantly healthier than they were following past economic downturns which bodes well for sales of Stryker's Mako robotic platform for knee and hip surgery, as well as Intuitive Surgical's Da Vinci robots; which in particular saw particularly strong demand in the U.S., China, France and the U.K during this first quarter.

Medtronic struggle to shake spinal fusion lawsuit

A whistleblower lawsuit accusing Medtronic of fraudulently marketing devices before FDA clearance for several spinal fusion devices can proceed, the U.S. 9th Circuit Court of Appeals has ruled.

The plaintiffs alleged that Medtronic violated the Anti-Kickback Statute by providing rebates to hospitals to buy the devices and paying physicians for costs related to business development events for the devices. The court also rejected Medtronic's argument that the False Claims Act was not the proper vehicle for bringing a claim of fraud against the FDA.

Allergan Aesthetics \$550 million deal



RESONIC

Allergan Aesthetics struck a \$550 million deal to acquire Soliton for its newly launched tattoo removal and cellulite treatment. Carrie Strom, president of Global Allergan Aesthetics, said in a statement that "there is a huge unmet need to address cellulite, and effective treatments have been elusive and frustrating for consumers."

The device, Resonic, uses high-frequency sound waves to fade tattoos and drive short-term improvements in the appearance of cellulite.

2 IMPRESSIVE MED-TECH START UPS TO WATCH IN 2021



ABLE HUMAN Motion is an exciting Barcelona-based device start-up, founded in 2018. They are the world's first manufacturer of robotic exoskeletons, improving the quality of life for individuals with disabilities. Their innovative lower-body exoskeleton is the first home-use product globally, and their advanced technology aims to empower every person in a wheelchair, by providing better mobility and greater independence.



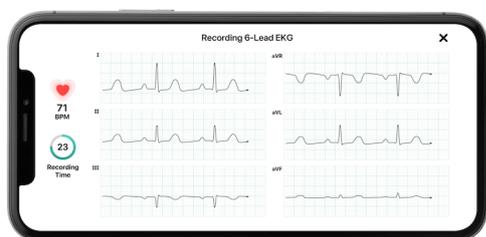
GRAIL is a Silicon Valley start-up, founded in 2016 with a strong trajectory for success within the next decade. They're transforming cancer care through their innovative, safe, and effective blood test device which detects multiple types of cancer at an early stage. Most of these cancers cannot be detected through current screening paradigms making this a crucial development in pinpointing their location in the body – at a time where treatment is far more likely to succeed.



THE LESS-INTRUSIVE DEVICE AIDING MENTAL HEALTH PATIENTS

An innovative response to the COVID-19 pandemic is the **KardiaMobile 6L**, manufactured by **AliveCor**. It is a small wireless device that is quicker and less intrusive, alternative to ECG's for patients using certain antipsychotic medications, providing readings in 30 seconds in the comfort of the patient's home.

The device is placed on the patient's knee and remotely records the ECG via Bluetooth onto the professional's Trust-approved smartphone or tablet. The reading can then be emailed to the patient's clinical team as a PDF.



UKCA, NEW STANDARDS FOR MED DEVICES IN THE UK?

With the post-Brexit environment now being a reality for the UK Med Device industry, new guidelines are being implemented and the United Kingdom Conformity Assessment confirmed a replacement of their CE mark.

The government's existing regulatory authority, the Medicines and Healthcare Products Regulatory Agency (MHRA) will take over responsibilities that were previously those of the European Union. As of the 30th of June, the UKCA mark will be an enforceable regulatory requirement for medical device products to be sold in the UK.



Boston's digital home monitoring system

Following the pandemic, digital transformation is becoming a priority for many med device companies. Boston Scientific has demonstrated this through the development of its new monitoring system, the MyLATTITUDE app.

The app enables patients to independently obtain answers to common questions about their LATITUDETM NXT implanted device, allowing them to supervise patients' heart conditions from home

NHS'S MEDTECH BACKLOG FROM COVID

NHS surgeries are facing an unprecedented surge in demand after the COVID-19 pandemic eases. The backlog, according to the BMA, is potentially costing the NHS between £4 -5.4 billion to work through.

Some of this additional activity is likely to be outsourced to private hospitals, particularly high-volume flows such as hip and knee replacements. This brings private hospitals into the Medtech stakeholder map as far as NHS pathways are concerned.