

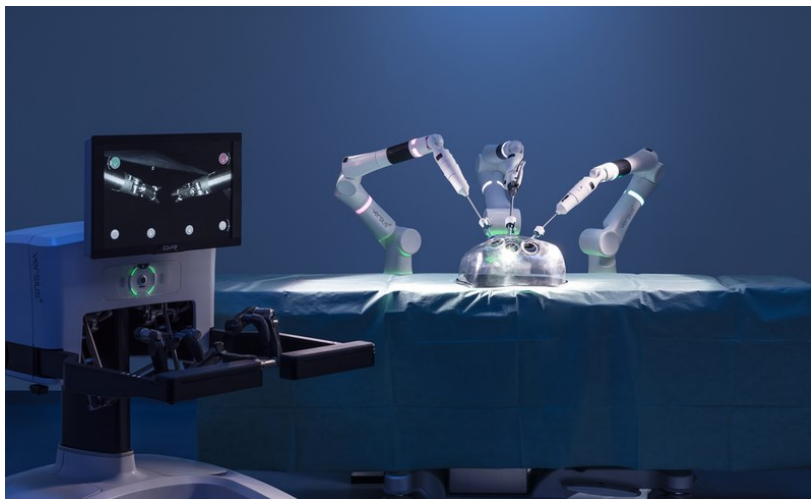
MARKETWATCH

Weekly News Bulletin– Issue No.25

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In this issue... **CMR Surgical unveils surgical robotic system Versius**

Sept 6, 2018



UK-based medical equipment maker CMR Surgical has unveiled a next-generation surgical robotic system, called Versius, to provide a portable option for minimal access surgery. The robotic system is designed to address the complexities and offer improved access during minimal access surgeries.

“According to CMR Surgical, the new surgical robotic system bio-mimics the human arm and offers freedom of port placement with benefits of small fully-wristed instruments.” Versius comes with a small form and individually cart-mounted arms, which enable its transportability between operating rooms and hospitals. The portability is said to also allow easy setup and patient access.

According to CMR Surgical, the new surgical robotic system bio-mimics the human arm and offers freedom of port placement with benefits of small fully-wristed instruments. In addition, Versius features 3D HD vision, easy instrument control and various options for working positions. CMR Surgical CEO Martin Frost said: “We believe Versius represents a paradigm shift in surgery. The ground-breaking design, coupled with genuine affordability, means that patients everywhere have the potential to benefit from the advantages of minimal access surgery.” According to Accuray Research, the current \$4bn global annual revenues of robot-assisted minimal access surgery market are estimated to reach \$20bn by 2025.

Draper's Wireless Brain Implant to Make New Therapies Possible

Draper, an engineering firm in Cambridge, MA, has developed a tiny wireless neuromodulation device that may be small enough to implant into the interior of the cranium right against the brain. Current brain stimulators are placed, like pacemakers, under the skin in the chest, with electric leads reaching out through the vasculature into the brain. This limits the areas of the brain where neurostimulation can be delivered and the leads can have a variety of issues that either limit their effectiveness or create additional problems for the patient. Draper claims that its new device is about 20 times smaller than current devices with similar capabilities. Their prototype isn't a product yet, but it has all the necessary components for advanced, multi-channel simultaneous recording and neurostimulation. It consists of so-called Gemstones that are wirelessly powered and offer 32 channels of recording and stimulation. They can be grouped into larger devices to offer more channels, with Draper so far putting four together to get 128. The Gemstones also have processing capability, so if one detects certain brain signal signatures, it can tell others to begin delivering their stimulation signals.



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In this issue... Disposable diagnostics: fighting antimicrobial resistance in the field



Dr Maria Daniela Angione of Trinity College Dublin has developed an electronic chip intended for use as part of a disposable diagnostic tool. Now undergoing preclinical trials, it could quickly detect bacterial infections and help address the growing problem of antimicrobial resistance. Antimicrobial resistance is one of the defining healthcare challenges of our times. As more bacteria become resistant to the drugs designed to treat them, we face the possibility of a return to a pre-antibiotic age of infectious disease.

Already, some 700,000 deaths each year are being attributed to antimicrobial resistance, a figure that could surge to 10 million by 2050 if the situation isn't rectified. We are seeing the likes of drug-resistant hospital infections (such as MRSA and *C. difficile*), multi-drug-resistant pneumonia, and a barely treatable strain of gonorrhoea. This is clearly a complex problem, with no

straightforward solution. However, one key piece of the puzzle will be minimising inappropriate antibiotic use. At present, antibiotics are prescribed far more than they ought to be. The Center for Disease Control and Prevention (CDC) estimates that up to half of antibiotic use in humans, and much of antibiotic use in animals, is unnecessary and inappropriate. Improving 'antibiotic stewardship' (i.e., being responsible about how they're taken) would make everyone safer.

"There is a clear need for rapid detection of viruses and bacteria." Unfortunately, the issue is compounded by a lack of rapid diagnostic tests. Since traditional culture-based tests can take days to return results, antibiotics are often prescribed before the patient has a definitive diagnosis. Oftentimes, this means they end up taking antibiotics for non-bacterial infections. As Dr Maria Daniela Angione, a researcher at Trinity College Dublin, explains, rapid detection is important for several reasons – not just for reducing antimicrobial resistance, but also for controlling the spread of disease.

"The current tests to identify bacterial infection require cell cultures, or they are based on immunoassay tests or PCR, which are extremely time consuming and require access to specialist facilities," she says. "In the primary care setting, the gold standard for urinary tract infections for example is still cell culture, which takes three days for the bacteria identification. It's a long time if you require a rapid answer." She adds that, while there are currently a few techniques available for rapidly detecting infections, their usage is hampered by price. "They are based on an antigen detection test, but they are quite expensive and require specialised equipment," she says. "So there is a clear need for rapid detection of viruses and bacteria. Ideally this should be low cost and applicable at the point of care, or without the assistance of highly trained medical personnel."

DIY diagnosis: using disposable tools for rapid, accurate detection of bacteria- Angione is currently working on a device that could dramatically improve the situation. Specifically, she has developed an electronic chip that will be integrated into a sensing platform and used as a disposable diagnostic tool.

"The first barrier that I see is related to the patients – they may have some expectations when they go to the GP, and clinicians might be reluctant to update their traditional approach that has been in use for so many years," she says. "Also, the pharmaceutical companies need to produce new antibiotics but they have little funding to invest in this area. So it's not just the development of the technology that is a challenge." All this said, she holds high hopes for the future, pointing out that the device's advantages speak for themselves. As it uses integrated circuits and low-cost electronic components, it is not only sensitive but cheap and easy to make. This means it could be suitable for use in remote, low-income settings – not to mention available in the pharmacy. "It could facilitate diagnosis and enable a targeted therapeutic plan at an early stage of bacterial or viral infection, reducing the healthcare cost," she explains. In the short term, she's hoping to work together with industry and clinicians to source more funding. "Of course it's a long process, but there are a few opportunities so I'm hoping to get more funding and to develop tools to validate the technology, bringing it to the market as soon as possible," she says. "We hope that this interest will generate the support required to advance the technology to a point of commercialization in the next five years."

Inside Costa Rica's super-sized medical device sector



In 2017, medical devices became Costa Rica's top export, surpassing the agricultural sector for the first time in the country's history. With more than 70 medical device companies operating in Costa Rica, how has this small nation managed to develop such a successful and fast-growing medical technology sector?

For developing nations, perhaps the foremost principle driving sustainable economic success is diversification. Diversified economies are more resilient against downturns and less vulnerable to shock changes in the commodities markets. For an effective demonstration of the dangers of relying too much on a single sector, one need look no further than the economic meltdown of oil-dependent Venezuela, where crashing oil prices have sparked hyperinflation, food shortages and civil unrest. One country that has clearly gotten the message on the benefits of diversification is Costa Rica, the Central American nation of five million inhabitants that Organisation for Economic Co-operation and Development (OECD) secretary-general Ángel Gurría praised as "a development success story" during the presentation of the OECD's latest economic survey of the country in April this year.

Only a few decades ago, Costa Rica was principally known for its agricultural exports of products such as fruits, coffee and sugar, but since the late 90s, the country has made great strides in educating its workforce and nurturing new high-tech and service-based sectors, including consumer electronics, finance and tourism.

"We needed to make sure that we found, as a country, an industry that we knew was going to be a very stable industry in terms of growth," says Madrigal. "We knew that with the forecast of the medical device and healthcare industry, this was an industry that would clearly prove to be very stable. So we started working on a strategy to promote, leveraging Baxter's experience in the country, and start attracting a number of other companies along the same path as Baxter." Jumping forward to 2018, the progress of the medical device sector in Costa Rica is impressive. Medical equipment exports from Costa Rica have tripled since 2007, says Madrigal, and last year the life sciences industry overtook agriculture to become the country's top export, with a combined export value of just under \$3bn comprising 27% of Costa Rica's outgoing trade. The country is second only to Mexico as a medical device exporter in Latin America.

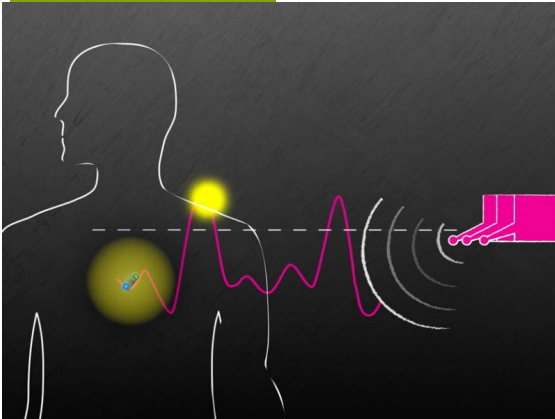
Over the years, the Costa Rican medical device industry has itself expanded and diversified, with growing sophistication in the devices manufactured locally. "We used to be pretty much just disposables, and today we have a very good balance between disposables, medical and surgical instruments, therapeutic devices, and now we're going into diagnostic equipment," Madrigal notes. "Cardio medical devices are by far the largest export in the country, but we have orthopaedics, we have diagnostic equipment, we have endoscopy, neuromodulation, infusion systems, optics – so we really have diversified. We typically say that we cover the whole body."

Today's medical device sector in Costa Rica is made up more than 70 companies, including major multinational players, such as Baxter, Medtronic, Allergan, Boston Scientific and Hologic. Other factors are related to Costa Rica's high standards of education, which has boosted the country's pool of skilled labour, perfect for a highly regulated industry that must conform to exacting quality measures. Costa Rica has even established – in conjunction with the University of Minnesota – Latin America's first Master's degree in medical devices. "Costa Rica has dedicated at least 8% of our GDP to education," says Madrigal. "That has led to having the ideal labour force that is highly educated, that is easily trainable, and that understands the demands of the medical device industry." Costa Rica also benefits from its geographic location, with strong links to the US and Europe, as well as generally high fluency in English in the population, which explains the heavy presence of US-originating companies in the market. "

Adjusting to a digital future- Each year, CINDE organises the Life Sciences Forum Costa Rica to bring the industry together and discuss the prevailing issues and opportunities in medical equipment and technology. This year's event will take place in October – so what is on the sector's mind this year? As is par for the course in virtually any industry in the 21st century, digital dominates the discussion. "

"Looking to the future, Madrigal says the country expects to increase its annual medical device export value from around \$3bn now to \$5bn by 2020, an ambitious goal that might well be achievable on the evidence of the sector's soaring rise so far. "We have been working on understanding the global incentives that are given in competitive countries, and we are working on potentially visualising to the government some incentives that are more on the innovation side," Madrigal says. "

Wireless charging: the breakthrough medical devices are waiting for?



Miniature implants hold the possibility for drug delivery, continuous monitoring and personalised treatment wrapped up in a compact in vivo device. Now, researchers at MIT and their colleagues, have developed a new system that can wirelessly power and communicate with medical implants inside the body, a huge step in realising their potential. Personalised implants could drastically change the way medical treatments are given and received, but issues surrounding the invasiveness of such devices have hindered research. To reduce the impact these have on the body, researchers from the Massachusetts Institute of Technology (MIT) have collaborated with scientists from Harvard Medical School and Brigham and Women's Hospital in the US to create a tiny battery-less implant, which can be powered from outside the body. The hope is that by eliminating the need for batteries, implantable devices could be made much smaller and less invasive. The researchers believe that their new technology, called In Vivo Networking (IVN), could revolutionise the design of medical devices and unlock a new frontier of better drug delivery, monitoring and personalised treatments.

How does it work?

The implants used in the collaborative study are roughly the size of a grain of rice and can be placed deep within the body where they are powered by radio frequency (RF) waves.

During animal testing, the researchers demonstrated that these waves are capable of powering devices located 10cm deep in tissue, from a distance of 1m.

Such implants have various applications and so their use in treatment would depend on what a patient required. For instance, the miniature implants could release drugs directly into a region of body on a controlled time frame, or could be placed in other areas to provide stimulation when necessary.

Senior author of the wireless charging study Professor Fadel Adib explains the challenges his team faced: "Our goal was to wirelessly power and communicate with tiny devices implanted deep within the human body.

"The key challenge in realising this goal is that wireless signals attenuate significantly as they go through the human body. This makes the signal that reaches the implantable sensors too weak to power it up."

The researchers addressed the weak nature of radio waves inside the body by using numerous antennas to emit signals at marginally different frequencies. These waves then overlapped and integrated during travel and the overlapping of high points generated enough energy to power an implant. The wireless tech is also capable of powering more than one device at a time, which could be useful should a patient require simultaneous treatment in several areas of the body.

Despite the challenges, the implants have been successfully tested inside various living mammals, but particularly in swine models. During these swine tests the device was implanted under the pig's skin, as well as 10cm-deep in the animal's stomach. The research team believe that when the implants can finally be tested in humans they could be life-changing for patients suffering from numerous diseases.

What impact could the technology have?

"In vivo networking can enable many applications, like performing controlled drug delivery to treat diseases like malaria or Alzheimer's when placed inside smart pills, measuring the condition of organs and tissues – such as pressure, glucose, gut microbiome – and sending data to the outside world; and treating diseases like Parkinson's or epilepsy when integrated with deep brain stimulators," says Adib. Brigham and Women's Hospital assistant professor Giovanni Traverso has also highlighted other potential medical implications of the device. In an earlier interview with Digital Trends he said: "The incorporation of [this] system in ingestible or implantable device could facilitate the delivery of drugs in different areas of the gastrointestinal tracts. "Moreover, it could aid in sensing of a range of signals for diagnosis, and communicating those externally to facilitate the clinical management of chronic diseases."

August's top news stories

MIT researchers develop in-body GPS system to track tumours

Researchers at the Massachusetts Institute of Technology (MIT) have developed an in-body GPS system, called ReMix, which can identify the location of ingestible implants inside the body via low-power wireless signals. The team expects that such implants can be used to track tumors by monitoring even slight movements. In the future, the implants may also help in dispensing drugs to a specific area in the body. "The in-body GPS system is based on a wireless technology that MIT previously developed to detect heart rate, breathing and movement." ReMix is being developed by MIT's Computer Science and Artificial Intelligence Laboratory (CSAIL) in alliance with Massachusetts General Hospital (MGH). The in-body GPS system is based on a wireless technology that MIT previously developed to detect heart rate, breathing and movement.

NHS, Microsoft and BHF partner to create UK defibrillator map

The NHS, Microsoft and the British Heart Foundation (BHF) have entered a partnership in which they plan to create a UK defibrillator map with the aim of saving thousands of patients from a fatal cardiac arrest. The companies say they have a shared ambition to make the devices readily available for every out-of-hospital cardiac arrest. This is in response to figures showing that public-access defibrillators are used in less than 3% of out-of-hospital cardiac arrests because their location is unknown to bystanders even though they could significantly increase survival chances. The BHF says this is leading to a needless loss of lives, as 999 call handlers are unable to direct bystanders to their nearest defibrillator. The new defibrillator map will encompass detailed locations of defibrillators across the UK so that these directions can be given. It will also offer maintenance tips to those in charge of the devices.

Boston Scientific to challenge Medtronic in the cryoablation market

Boston Scientific announced an agreement to acquire Cryterion Medical, a company developing a cryoablation platform to treat atrial fibrillation (AF). Medtronic is currently the only player in the cryoablation market with its Arctic Front Cryoablation System. With Boston's upcoming entrance into the market, Medtronic will face tough competition within the electrophysiology space.

With the increasing incidence of AF, the electrophysiology market is expected to grow rapidly over the next few years. Radiofrequency (RF) ablation is still the preferred treatment choice, but cryoablation has gained momentum through successful clinical trial results that showed similar patient outcomes to patients treated using RF ablation catheters, as well as the fact that cryoablation is potentially safer and has fewer post-procedural complications. Furthermore, the cryoballoon is much simpler to use compared to the RF ablation technique, which requires "precise mapping and point-by-point ablation".

Medtronic's strong presence in the electrophysiology market is driven by its dominance within the cryoablation space, where it is a pioneer of cryoablation technology. However, outside of cryoablation, Boston Scientific's presence has been much stronger than Medtronic's in both the ablation and diagnostic spaces since the acquisition of C.R. Bard's electrophysiology business in 2013. With Boston Scientific having a strong product portfolio in RF ablation and diagnostic catheters, Medtronic's growth in the electrophysiology market is somewhat limited due to its comparatively weaker portfolio outside of cryoablation. Medtronic faces limitations in growth due to the higher cost of the cryoablation system and the complexity around producing the catheters, which need to be built by hand.