BIÇAKCILAR
Touching Lives One Device at a Time

MARKETWATCH

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In this issue…Stryker secures FDA pre-market approval for flow diverter

Medical technology company Stryker has secured pre-market approval from the US Food and Drug Administration (FDA) for the use of its Surpass Streamline Flow Diverter in treating unruptured large and giant wide-neck intracranial aneurysms.

The flow diverter has been designed as a small cobalt chromium braided stent for directing blood flow inside an intracranial artery, away from a weakened blood vessel sac or aneurysm. This blood flow diversion is meant to occlude the aneurysm over time, thereby decreasing the risk of rupture in the future. “Stryker’s flow-diverting stent is said to be equipped to address aneurysms in the neck region by reliably opening and delivering consistent mesh density for the occlusion and maintenance of perforator artery patency.”

Surpass Streamline, which is already marketed in other international countries, is the second such device to obtain the US regulatory approval. Stryker Neurovascular division president Mark Paul said: “The PMA approval of Surpass Streamline Flow Diverter in the US is an important milestone for the division.

“It expands our commercial footprint into the flow diversion market and reinforces our commitment to complete stroke care for patients suffering from cerebrovascular disease.” The treatment of unruptured aneurysms is considered more challenging due to their location and surrounding anatomy. Stryker’s flow-diverting stent is said to be equipped to address these aneurysms in the neck region by reliably opening and delivering consistent mesh density for the occlusion and maintenance of perforator artery patency.

The FDA approval is based on clinical outcomes obtained during the prospective, multi-centre SCENT investigational device exemption (IDE) clinical trial. According to the results, the trial met both primary and secondary endpoints, as well as demonstrated single stent efficacy with the Surpass Streamline Flow Diverter. SCENT IDE trial co-principal investigator Ricardo Hanel said: “The ability to resheath, reposition and recapture the device without losing distal wire position is a significant advantage for Surpass.”

Medtronic begins ECG Belt trial for heart failure therapy- 23 July 2018

Medtronic has started enrolment in a clinical trial intended to evaluate its ECG Belt Research System (ECG Belt) as a diagnostic to optimise cardiac resynchronisation therapy (CRT) for heart failure.

“The diagnostic tool will be applied during the implantation of a CRT device. The Belt will be externally wrapped around the patient’s chest and back to guide the left ventricular lead placement.” Medtronic Cardiac Resynchronization Therapy business vice-president and general manager Kweli Thompson said: “Our goal for this study is to give clinicians real-time insights to address each patient’s needs and to help optimise CRT for heart failure patients.”

The diagnostic tool will be applied during the implantation of a CRT device. The Belt will be externally wrapped around the patient’s chest and back to guide the left ventricular lead placement.

ECG Belt will be additionally used at follow-up visits to perform further optimisation of the device’s programmed settings.

In this issue… How sensing catheters are assisting surgical intervention

Cikautxo Medical OEM explains why more customers are seeking catheters with sensor technology built-in, and how this has impacted production

About 10% of the western population will, at a certain stage in their life, be taken to a catheterisation laboratory for angioplasty surgery (stent placement), treatment of an arrhythmia or a heart valve replacement. This percentage is increasing with an ageing population. Fortunately, most of these interventions can be carried out using minimally invasive procedures that are assisted by smart imaging and sensing catheters that are the 'eyes and ears' of the surgeon directly at the point of intervention.

The growing number of cables in the cath lab is rapidly becoming a problem. The interventionist increasingly has to deal with instruments that have electrical cables connected to them. These cables hamper the workflow, and can result in dangerous situations eg, when a cable hooks behind the rotating X-ray C-arm, or during an electrical cardioversion. Sensing smart catheters are consequently more and more demanded in the cath lab.

'Sensing' trends in catheters

To improve the success rate of the most important cardiovascular diseases but also for other type of surgeries, catheter manufacturers have started to add electronic sensing functionality to the instruments resulting in what is referred to as 'sensing' catheters. Here, different examples of catheters are distinguished based on their application disease. Some of the ongoing applications today are:

Urology: Foley Catheter Temperature Sensors enable clinicians to accurately monitor urinary output and bladder temperature in addition to facilitating urine drainage. Commonly used also to monitor a patient's body temperature during surgery.

Vascular: Vascular catheters with blood glucose measurement have the potential to become a standard of care for the management of blood glucose levels in the critical care units of the hospital. The near-continuous glucose measurements automatically transfer whole blood from a radial artery, peripheral vein, or central venous catheter to an external flow-through glucose sensor. A vascular catheter with this type of sensor acquires a fresh blood sample every five to 15 minutes, measures the concentration of blood glucose, and then flushes the sample back into the bloodstream using flush solution. Standardisation of blood sample acquisition, analysis, and calibration will increase the accuracy and precision of the blood glucose measurement, a major advantage of those catheters compared to routine clinical methods.

On-going therapy: A whole new class of implantable devices is being developed with the purpose of delivering local and on-going therapy. These 'electroceuticals' stimulate or block nerves directly addressing organs.

The 'sensing' catheters are contributing to Industry 4.0, where the Internet of Things (IOT) will also conquer the Internet of Medical Devices (IMD).

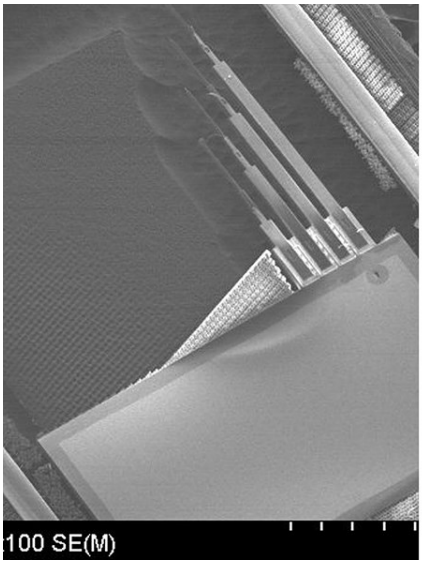
Manufacturing 'sensing' catheters

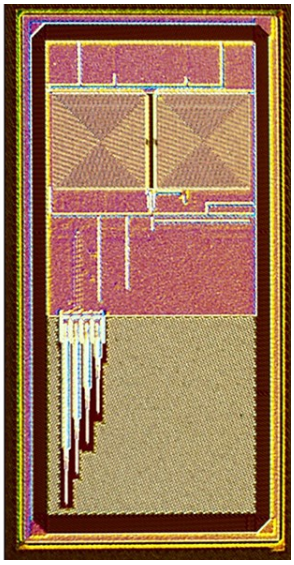
"Customers are increasingly demanding sensor integration in our OEM catheter manufacturing activity. We are embedding different types of sensors, from the most common ones like temperature or pressure sensors, up to the most difficult ones, like position systems.

"Sensors are very fragile components that need to be carefully manipulated during the assembly in the catheter. Intensive tests are also made to validate the correct sensing functionality after the product final assembly.

"Our sensor R&D centre, Ikerlan, located only a few miles from our cleanroom facilities, means we stay on top of the latest technologies in sensors, so we can help our customers to select the most appropriate solution for their needs," said Iker Principe, CEO, Cikautxo Medical OEM.

In this issue… Microscopic, Remotely Powered Implant to Read, Transmit Brainwaves from Inside Skull





Brain-computer interfaces and other technologies that rely on reading and stimulating the brain require electrodes to obtain and deliver signals, as well as a way to transmit those signals from within the brain. Electric wires have usually served as the method of connectivity, but they create serious challenges, including potential for infection, safety issues, and lack of discreetness. Wireless technologies have a lot of promise, but most approaches require a battery or another source of energy to power an implant to beam data back and forth from deep within the brain. Researchers at Purdue University have now developed a brain-reading implant that's incredibly small and that doesn't need any on-board batteries to power it. Instead, the device, which the researchers say is about the size of a piece of dust, relies on externally delivered electromagnetic waves to power it. It's conceptually similar to how wireless charging works in some modern smartphones. The implant was produced from a commercially available electronic chip that was modified to include microelectrodes.

The device is able to gather electric signals from a number of nerve endings at the same time. It can also be flexible, an important point for implants positioned within tissue resembling gelatin. A tiny antenna works as the energy harvester to power the system. "The main challenges are to operate such a wireless neural interface system with a small and flexible chip at very low power and yet high data rate," said Saeed Mohammadi, one of the researchers on the project. "We need a high data rate to be able to read signals from thousands of neurons using a single implant chip. At the same time, we need to operate the system at very low power for safety and size reasons.".

Latest Mergers and Acquisitions

23 July 2018

B. Braun to buy bloodlines business from NxStage Medical

Medical products developer B. Braun Medical has entered into an agreement to purchase a bloodlines business from medical technology company NxStage Medical.

23 July 2018

Boston Scientific to buy Claret Medical for up to $270m

Boston Scientific has entered into an agreement to purchase medical devices developer Claret Medical for an upfront cash payment of $220m.

How Medical Device Companies can Access the Latin American Market to Increase Sales and Achieve Long-Term Growth

Latin America is developing into that sizable, predictable part of the world market of medical devices. The region has developed into predictable, flourishing healthcare markets that would allow foreign manufacturers to have sustainable commercial operations. The Latin American market for medical devices and equipment is worth approximately an impressive US$30 billion. It always is difficult to enter a new market. Language barriers, cultural misunderstandings, excessive regulations and bureaucratic hurdles, and corruption all are contributing factors that can diminish success — or lead to defeat. Still, the risk can be worth the reward. According to Global Health Intelligence (GHI), deep epidemiological, demographic, and market shifts are taking place in Latin America and the Caribbean (LAC), and demand grew sharply for certain types of equipment between 2016 and 2017(3):

34 percent growth in electrocardiogram machines in Brazil, 104 percent growth in hemodialysis machines in Panama; 67 percent growth in infusion pumps in Guatemala;76 percent increase in X-ray machines in Costa Rica;24 percent growth in MRI machines in Mexico;41 percent growth in laparoscopic surgery equipment in Colombia;7 percent growth in CT scanners in Brazil;56 percent increase in ventilators in Guatemala;50 percent growth in linear accelerators in Argentina

Trends:

1 — **Don't Start In Brazil Or Mexico**

Most companies first enter the LAC region through its largest markets, Mexico or Brazil. However, these countries are costly and complicated pilot markets for a regional entry strategy. Brazil is Latin America’s most complicated, bureaucratic business environment, with onerous local regulations, a myriad of taxes to report, costly labor regulations and social taxes, a high cost of capital, expensive real-estate, poor infrastructure, crippling traffic, and a conflictive legal environment. Most foreign entries take about three times longer to reach positive returns in Brazil versus any other Latin American market. The Mexican market is far easier to enter than Brazil, but as a result, the competition is a lot fiercer. Mexico’s political class remains stuck in an age of bloated corruption. The smarter move may be to start in a mid-size or even small Latin American market — such as Colombia, Peru, Panama, Guatemala, or even Argentina — where the learning curve is less costly, and competition remains weak, but red tape is not too onerous.

2 — **Be sensitive To The Language And The Culture**

LAC has the third-largest economy in the world, by GDP, with a healthcare expenditure comparable to that of China or India(1). The region is home to over 600 million residents in over 30 countries, and almost all speak either Spanish or Portuguese. These languages are closely related to the point of general mutual intelligibility, resulting in a high localization return on investment for the foreign manufacturer expanding through the region.

3 — **Don't Award Market Exclusivity To A Single Distributor Or Agent**

Most LAC markets are highly centralized, with anywhere from 60-90 percent of wholesale activity centered in the capital city. However, three countries are not structured as such: Brazil, Colombia, and Mexico. In those markets, it is almost impossible to find a distributor with true national coverage and reach — though they might insist otherwise when you meet them at a trade show. You should consider engaging multiple distributors in a country, divided by region, sales channel, or client category. Exclusivity of any kind should be tied to minimal sales goals. It’s key to conduct due diligence when choosing a distributor in the LAC region. Many foreign manufacturers loosely choose their distributors at trade shows — relationships that usually end in disappointment when distributors don’t meet their sales quotas. You can’t afford to wait three years to determine whether your distributor was poorly chosen, and nothing inspires performance like competition. If you have multiple distributors in a market, and they are aware of one another’s performance, then your likelihood of success is high. If you are at the mercy of one distributor, your probability of underperformance is worrisomely high. LAC markets represent 9 percent of the world’s GDP and 10 percent of the global population(2). You should expect the region to capture no less than 9-10 percent of your company’s global sales. Distributor choice also affects your company’s regulatory strategy.

Continued... 5 Trends Propelling Latin America's Medtech Business

1. **Obesity And NCDs Expand**

The number of non-communicable diseases (NCDs) —also known as chronic diseases— that are often linked to lifestyle and daily habits, such as cardiovascular disease, cancer, chronic respiratory disease, and diabetes, have dramatically increased in Latin American and Caribbean countries. Comparisons of the prevalence of risk factors across the six World Health Organization (WHO) regions highlight the worrying state of health in the LAC region(4).

2. **Aging Population**

People in the LAC region are aging faster than the rest of the world. Some estimates say that by 2060 about 30 countries in the LAC region will have a greater proportion of older people than children under 155. Today there are 71 million people over the age of 60 in the LAC region; that number is expected to double by 2035 to over 214; an increase of more than 300 percent(3).

3. **The Population Is Getting Connected**

By 2020, more than a billion individuals across the LAC region will be connected to a mobile network; this is equivalent to about three-quarters of the region's population. There's been a regional surge in smartphone adoption in recent years. Today, smartphones account for about 60 per cent of the 690 million connections on mobile networks in the LAC region(6). The expansion of smartphone usage in Latin America is driving the growth of health apps and other areas, such as cybersecurity at hospitals, remote care/telemedicine, and home care. This will also drive demand for EMR systems and their associated cybersecurity solutions throughout the region(3).

4. **Hospitals Beef Up To Keep Up**

LAC hospitals are implementing electronic medical records (EMRs), picture archiving and communication systems (PACS), and radiology information systems (RIS)(3). Almost half of all the hospitals in the region have implemented EMRs. The EMR adoption is expected to grow at about 7.15% per year(7). This is particularly important for EMR, PACS, and RIS manufacturers since the adoption of EMRs usually drive the adoption or expansion of PACS and RIS technologies.

5. **Hospitals Need Tools To Track Costs And Increase Efficiencies**

Hospitals have logistics operations that continuously move large volumes of material among labs, pharmacies, pantries, and administrative units. While this logistics function has cost, quality, and safety implications, it is not likely core to hospitals' mission of providing patient care. Latin American hospitals face a challenge when it comes to creating cost efficiencies while running their logistics operations. Controlling costs requires the right tools and equipment, and that's where hospital suppliers can prove their worth by supplying the right software and tools(3).

Conclusion: The LAC region is made up of over 30 countries, which makes market penetration and regulatory compliance more complicated and labor-intensive. In the past, eager companies have struggled — and even failed — in this market due to their unfamiliarity with the local regulatory and cultural environment, which can prove to be a significant hindrance and potentially waste precious time and resources. Too many Medtech leaders fail to see the light at the end of the tunnel. The four major non-communicable diseases (cardiovascular disease, most cancers, diabetes and chronic respiratory diseases) will cause 81% of deaths in Latin America by 20308. Insufficient domestic Medtech production across the region leaves an open market for US and European exporters. Some LATAM countries have difficult-to-navigate processes that, despite a growing trend of foreign registrations, remain a challenging for many foreign companies. However, the regulatory landscape is changing in an attempt to bring state-of-the-art technologies to the people, although some LATAM countries offer expedited approval routes for devices already FDA-approved or CE-marked. Identifying the best-fit partners throughout the region — those with proven expertise in successfully navigating the LATAM market — is the ultimate key to success in this promising region.

Do Your Contract Manufacturer's Capabilities Support Your Manufacturing Regionalization Strategy?

Regionalized outsourcing strategies continue to grow in popularity. Gone are the days of shifting outsourcing to the lowest cost emerging market location. Today, most companies base sourcing strategies on a complex equation of factors driving total cost. When all these factors are considered, locating manufacturing within regions close to each end market often results in the greatest degree of responsiveness to market demand and lowest total cost. The underlying logic behind any regionalization strategy is that proximity to the end market reduces logistics costs and complexity; reduces raw material and finished goods shipping time; decreases finished goods safety stock requirements; and contributes to superior quality by minimizing unnecessary handling, transport and inspections. The question becomes: can the contract manufacturer your company selects enable your company to leverage the benefits of a regionalization strategy in your chosen end markets?

In this whitepaper, Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems highlights several areas to evaluate in determining whether or not a supplier's capabilities are likely to deliver lowest total cost of ownership (TCO).

If you are interested in reading the white paper, please click on the link:

https://directory.qmed.com/regionalized-outsourcing-strategies-continue-to-file087342.html

"THREE DAYS OF ACTIVE TRADING IS NOT CONSIDERED AN AEROBIC WORKOUT."