BIÇAKCILAR
Touching Lives One Device at a Time

MARKETWATCH

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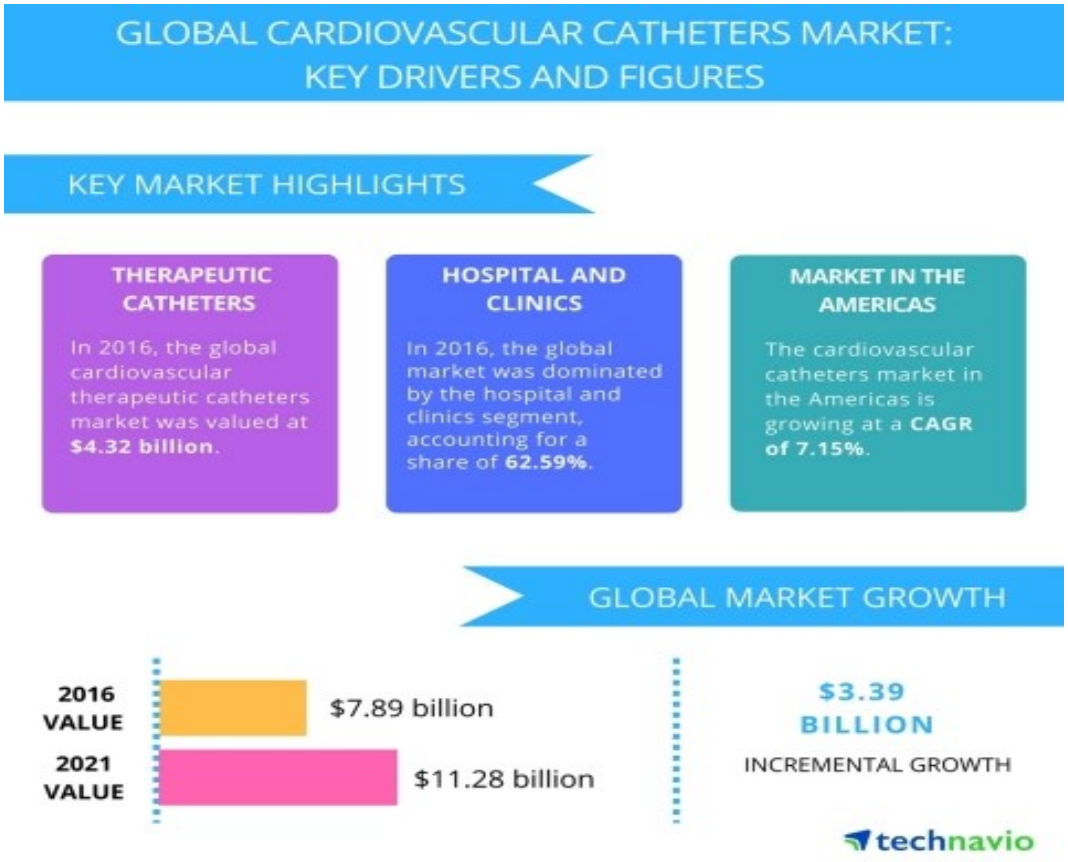
In this issue…Top Trends in the Cardiovascular Catheters Market by Technavio



The top three emerging trends driving the global cardiovascular catheters market according to Technavio research analysts are:

- **Business strategies to emerge in the market**: Stryker reprocesses single-use medical devices such as cardiovascular therapeutic and diagnostic catheters through its department named Stryker Sustainability Solutions. Though reprocessed single-use cardiovascular catheters can arise questions on their medical safety, the products are processed and sterilized in such a way, which decreases the chances of infection.

- **Increase in M&A:** M&A helps large companies to increase their product portfolio, and for small companies, it increases the chance to penetrate the market. It increases market competitiveness, which thrives companies to focus on the development of innovative products in the market.

- **Integration of robotic cardiac catheter system and hybrid operating room equipment :** Hybrid ablation is a growing market trend, which is at the clinical research stage. It combines surgery and catheter ablation to treat AF. To increase the precision of the surgery and improve efficacy, the adoption of robotic-assisted surgery is increasing in the market.

In this issue… Siemens Healthineers introduces new heart attack diagnostic tests

Siemens Healthineers has introduced two new assays for quick diagnosis of acute myocardial infarction or heart attack, following approval from the US Food and Drug Administration (FDA). The High-Sensitivity Troponin I assays (TnIH) for the Atellica IM and ADVIA Centaur XP/XPT in-vitro diagnostic analysers are designed to detect low cardiac troponin I levels in serum or plasma.

Said to demonstrate 99% precision, the assays can also identify small changes in a patient's troponin level because of repeat testing."According to Siemens, the TnIH assays leverage the company's technology with three new monoclonal antibodies and are set to provide better patient care with high-sensitivity cardiac troponin detection."

Early diagnosis is critical as the heart muscle starts dying within 30-60 minutes following the blockage of blood flow to the heart.

Since dying heart muscle releases troponin into the bloodstream, the compound is considered as an indicator of a heart attack.

Out of the more than eight million visits to emergency departments in the US, only 5.5% lead to serious diagnoses such as heart attacks. The new assays are expected to support testing initiatives by using data to correctly triage patients early or rule out myocardial infarctions.

Zuckerberg San Francisco General Hospital and Trauma Center, Clinical Chemistry and Toxicology chief Alan Wu said: "If we can do a more efficient job at triaging patients to receive the proper level of care and to discharge the patients who do not need to stay in the emergency department, this will have a tremendous economic advantage for our healthcare system."

According to Siemens, the TnIH assays leverage the company's technology with three new monoclonal antibodies and are set to provide better patient care with high-sensitivity cardiac troponin detection. The Siemens portfolio for troponin detection additionally includes Atellica IM, ADVIA Centaur, Dimension EXL and Dimension Vista TNIH assays that are also designed to detect lower troponin levels.

DePuy Synthes introduces Concorde Lift interbody implant

DePuy Synthes, a division of Johnson & Johnson Medical Devices Companies, has introduced the new Concorde Lift Expandable Interbody Device in the US for the treatment of degenerative disc disease. The implant is part of the company's new Unleash MIS TLIF (Transforaminal Lumbar Interbody Fusion) Procedural Solution designed for minimally invasive spine surgery.This procedural system additionally comprises the Concorde Clear MIS Discectomy Device and the Viper Prime System for percutaneous pedicle screw insertion.

"The implant is part of the company's new Unleash MIS TLIF (Transforaminal Lumbar Interbody Fusion) Procedural Solution designed for minimally invasive spine surgery."It is intended to simplify certain stages of minimally invasive spine surgery and increase its efficiency. DePuy Synthes Spine worldwide president Nadav Tomer said: "This Unleash Solution delivers a new offering to help reduce the complexity associated with minimally invasive spine surgery while reducing costs and OR footprint.

"DePuy Synthes is committed to innovating the tools and technology required to serve more patients globally in a range of care settings by delivering disruptive procedural solutions that improve outcomes supported by real-world clinical and economic evidence." Concorde Lift can be implanted during a spinal fusion surgery, where the degenerated disc is replaced with the device in order to restore the disc height amongst the two spinal vertebrae. The implantation is preceded by the degenerated disc-clearing process using Concorde Clear MIS Discectomy Device, which is said to require fewer instrument passes and removes more disc material.

Viper Prime System is used during the last stage of the procedure to combine various instruments into a single screw inserter tool, thereby allowing insertion of the percutaneous pedicle screw in a single instrument pass. Together, the Unleash MIS TLIF devices are expected to minimise surgical complexity, enhance patient outcomes and reduce costs.

In this issue… Hologic launches initiative for affordable access to diagnostic tests

Hologic has launched a new initiative to enhance access to its molecular tests intended for the diagnosis of certain infectious diseases in approximately 50 countries, including African and Southeast Asian regions. The new Hologic Global Access Initiative will be carried out in alliance with the Clinton Health Access Initiative (CHAI) and the UK-backed MedAccess.

It focuses on offering affordable testing for human immunodeficiency virus (HIV), hepatitis B and C (HBV and HCV) and human papillomavirus (HPV) infections. "Hologic said that the program optimizes overall lab systems efficiency, minimises instrument downtime and reduces stockouts and waste, thereby supporting Integrated Diagnostics Consortium objectives."

Set to be rolled out in August this year, the initiative features single, all-inclusive pricing without any upfront costs or capital expenditure. The programme will aim to improve access to the company's automated molecular testing platform called Panther system, which is suitable for centralised as well as decentralised labs.

Panther system can deliver up to 320 results in eight hours and can be run with Aptima HIV-1, HCV and Quant assays. The Aptima HPV assay to detect 14 high-risk HPV types related to cervical cancer can also be run on this platform.

Hologic Diagnostic Solutions division president Tom West said: "Through this initiative in partnership with the global public health community, we're determined to make an even greater impact in countries with limited resources and help reduce the burden of global infectious diseases, especially HIV."

The initiative is said to be in line with UNAIDS' 90-90-90 goal, which aims to have 90% of people living with HIV diagnosed by 2020, 90% diagnosed patients will get sustained antiretroviral treatment, and 90% of those on antiretroviral therapy will have viral suppression.

Hologic added that the programme optimises overall lab systems efficiency, minimises instrument downtime and reduces stockouts and waste, thereby supporting Integrated Diagnostics Consortium objectives.

Deals this week July 27, 2018

OrthoSpin Ltd has raised $3m in a financing round from US-based investment firm Johnson & Johnson Innovation – JJDC Inc. Based in Israel, OrthoSpin is focused on the development of a robotic external fixation system to improve patient care. The company plans to use the funds towards clinical trials.

Thornhill Medical has raised funds through a series A financing round from China-based investment firm Shanghai Yonghua Investment Management Co Ltd. Based in Canada, Thornhill Medical manufactures novel healthcare products. The company plans to use the funds towards working capital, clinical development, and to expand its footprint and sales in the international market.

CeQur will acquire a worldwide license for the insulin delivery system OneTouch Via. The device is expected to be launched by CeQur in 2019, pursuant to the transfer of manufacturing equipment. Based in Switzerland, CeQur is engaged in the manufacture of insulin delivery devices, while Calibra Medical is a US-based developer of three-day, wearable, on-demand bolus insulin-delivery device.

Boston Scientific Corporation has entered an agreement to acquire Claret Medical Inc for $270m. The acquisition will add Claret's sentinel cerebral embolic protection system to Boston's product portfolio. The system is used to protect the brain in patients who are undergoing transcatheter aortic valve replacement (TAVR).

Abbott Begins U.S. Pivotal Trial for the Tendyne Mitral Valve Replacement System

Abbott announced it has initiated a pivotal clinical study in the U.S. of its Tendyne Transcatheter Mitral Valve Replacement (TMVR) system for the treatment of mitral regurgitation. The trial will evaluate the safety and efficacy of the treatment in patients suffering from mitral regurgitation (MR), known as a leaky heart valve. The investigational Tendyne device is the first and only mitral valve replacement that can be repositioned and fully retrieved, allowing the surgeon to precisely place the device during implantation, which could improve patient outcomes. Since the approval of the MitraClip device in 2008, Abbott has led the development of minimally invasive solutions for difficult-to-treat mitral regurgitation, and the Tendyne device is designed to offer a new treatment option for MR patients requiring a minimally invasive replacement valve.

The study, called SUMMIT, will enroll up to 1,010 patients at 80 sites in the U.S., EU and Canada to evaluate if treatment with the Tendyne TMVR system is safe and effective for patients suffering from severe MR. Jason Rogers, M.D., professor and director of interventional cardiology at U.C. Davis Medical Center in Sacramento, Calif., and Gorav Ailawadi, M.D., professor of surgery and chief of cardiac surgery at the University of Virginia, are co-principal investigators of the study, which will evaluate a composite endpoint of death, cardiovascular hospitalization, stroke or reoperation at one year. The first several patients in the trial were treated at Ascension's Via Christi Hospital St. Francis in Wichita, Kan. and the West Virginia University Heart and Vascular Institute in Morgantown, W.Va.

Mitral regurgitation is a debilitating, progressive and life-threatening disease in which the heart's mitral valve does not close completely, causing blood to flow backward and leak into the left atrium of the heart. The condition can raise the risk of irregular heartbeats and stroke, and if left untreated, could ultimately lead to heart failure and death. Nearly one in 10 people over the age of 75 have moderate to severe MR1, which is often difficult to diagnose. Abbott's MitraClip is the leading approved device to repair a leaking mitral valve, but there are currently no approved minimally invasive therapies to replace the mitral valve.

The Tendyne valve may provide a life-saving treatment option for MR patients by replacing their native mitral valve without open-heart surgery to reduce their heart failure symptoms. The device is a tri-leaflet, bioprosthetic valve available in multiple sizes, and is stabilized by a pad and a tether mechanism that holds the pad in place where it's been implanted inside the native valve. As the first and only repositionable and fully retrievable replacement valve, Tendyne can conform to a broad range of anatomies, which may allow for better outcomes and procedural ease-of-use.

"The mitral valve is known for its complex anatomy and, as a result, managing mitral regurgitation can be challenging, especially in elderly or frail patients for whom there are limited to no treatment options," said Bassem M. Chehab, M.D., medical director of Via Christi's structural heart program, who implanted the first patient in the study with the Tendyne valve. "I'm encouraged by promising early results from the global study and excited about the potential for the Tendyne device to advance the field of transcatheter mitral valve replacement in the U.S. by providing another option for MR patients needing a minimally invasive alternative."

Abbott recently shared data at EuroPCR, the annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), that showed positive results from the first 100 patients treated in a global study of the Tendyne device. Results showed that, at 30 days, patients treated with Tendyne had a significant reduction in symptoms of MR and low mortality rates.

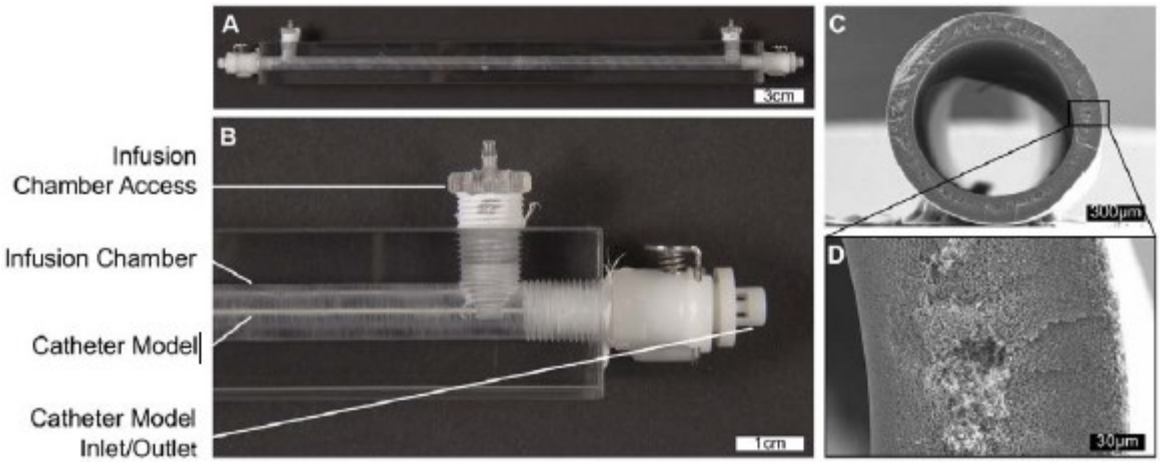
"Transcatheter mitral valve replacement represents a new frontier in treating people whose valve does not close properly and who would benefit from a replacement valve instead of repair," said Michael Dale, vice president of Abbott's structural heart business. "Abbott established the market for minimally invasive mitral valve repair with MitraClip, showing the safety and viability of a non-surgical repair and paving the way for other catheter-based devices to treat structural heart diseases. Our scientists and engineers are building on our expertise to advance transcatheter mitral valve replacement with our Tendyne technology to provide a needed treatment option."

Technique Keeps Blood from Touching Catheter's Surface to Make Dialysis Safer

Central venous catheters, such as those used during dialysis, have a nasty tendency of getting fouled up with proteins and bacterial deposits. Not only do the catheters end up having a short lifetime, patients are exposed to the potential for serious infections. At Draper, a research and development firm, a team has developed a way of keeping proteins from settling onto the insides of catheters, thereby avoiding a myriad of complications that can result from dirty catheters.

The method is called water-infused surface protection (WISP) and it results in a layer of pure, blood-free fluid gliding on the inside surface of the catheter. Because no blood actually comes in contact with the catheter, protein buildup is prevented. Additionally, any proteins that do somehow end up sticking to the catheter are quickly pushed away by the stream.

The Draper researchers believe that in addition to obvious benefits, the new catheter technology will lead to easier delivery of antibiotics, anti-coagulants, and thrombolytic drugs directly through a central venous catheter.



Accu-Chek Solo Tube-Free Insulin Micropump Cleared in Europe

Marketwatch

BIÇAKCILAR, Corporate Marketing

Wearables + Telephone Coaching Didn't Improve Peripheral Arterial Disease Symptoms

Wearables have the potential to improve our health. They can be reminders that we're not moving enough throughout the day, and they can be useful tools for doctors to monitor the fitness progress of their patients. However, in the Journal of the American Medical Association, McDermott and her colleagues recently reported that their trial of prescribing a home-based exercise program using a wearable activity monitor (FitBit Zip) plus telephone coaching over nine months, did not improve patients' lower extremity peripheral arterial disease (PAD), when compared to typical care that had no onsite sessions, active exercise, nor coaching.

Many studies have already shown that supervised treadmill exercise as a treatment for patients with peripheral arterial disease significantly improves symptoms. Furthermore, combining supervised exercises with home exercises gives patients even bigger improvements. However, these supervised programs require patients to visit an exercise center three times a week. This can be difficult for patients and so many choose to not participate.

Therefore, the goal of this study was to assess the feasibility of a home-based exercise program to achieve fitness improvements, by supervising patients using wearable activity trackers, and coaching them through weekly or monthly telephone calls. The researchers studied a total of 200 PAD patients who were 70.2±10.4 years old on average. 99 were randomized to the exercise intervention group, and 101 were randomized to the usual care group.

McDermott and colleagues found that at the end of the nine month study, there was no difference in the six minute walk distance between the patients that had exercise intervention and the patients that had usual care. (The six minute walk distance is a standardized test that measures the severity of a patient's PAD; longer walk distances indicate less disease.) Patients with the intervention had a non-significant increase in their walk distance from 330.5±100.2m to 333.4±115.1m, and the patients with usual care saw a non-significant increase in their walk distance from 336.2±96.6m to 348.2±98.1m; essentially, the intervention did nothing. The study's secondary subjective measures of PAD also showed no differences between the groups. Curiously, one of the questionnaires that allowed patients to report their pain during activity showed that patients with usual care actually improved more and had less pain than patients with exercise intervention.

The study had several limitations. Perhaps most significant were the weekly or monthly coaching sessions that took out immediate feedback, and that only 79% of scheduled telephone coaching sessions were actually made, which could be insufficient for significant results. Regardless, the study presented strong evidence for a lack of efficacy of applying wearables and technology to improve fitness to reduce disease.

As we move towards tele-health, more technologies will attempt to solve health problems from the comfort of a patient's home. We can imagine a world where we Skype a doctor and they order a few blood tests to be processed by a home Theranos-like unit, and then they prescribe medications and exercise routines and track healing progress using wearables and more blood tests. One day, it'll probably be that way. For now, however, it's still worth it to visit the doctor and follow their guidance and care plans in person.