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Touching Lives One Device at a Time

MARKETWATCH

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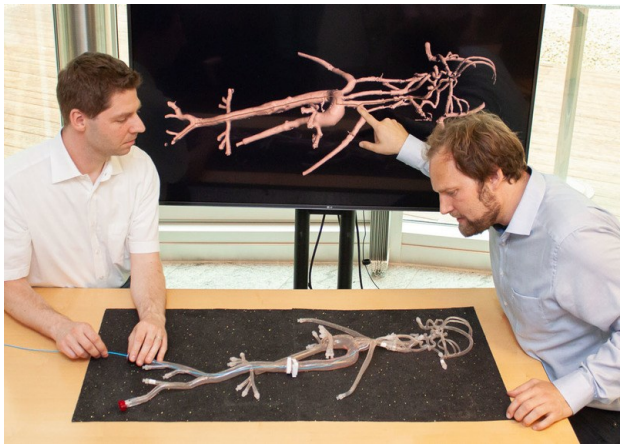
German researchers develop Intelligent Catheter Navigation system

Fraunhofer Institute for Digital Medicine MEVIS in Germany has developed a new catheter system called Intelligent Catheter Navigation (IntelliCath) to enable precise navigation through the vasculature.

Endovascular interventions involve the insertion of a thin, flexible wire for navigating a catheter into the blood vessels in order to apply stents or remove blood clots.

Patients have to undergo X-rays during the procedure to ensure accurate navigation of the catheter, exposing patients and doctors to radiation.



Fraunhofer MEVIS mathematician Dr Torben Pätz noted: “In addition, the X-rays merely show a 2D projection instead of a 3D image, which can sometimes impede precise localisation of the catheter.”

To address these challenges, the new catheter features an optical fibre with tiny ‘mirrors’. These mirrors reflect a portion of the light that changes colour when the fibre bends.

The change in colour can be measured by sensors and researchers will be able to obtain information on the intensity and direction of the vessel curvature.

Patients are also subjected to CT or MR imaging before the intervention procedure. This image data is used by software to create a 3D model of the vessel system which is displayed on a monitor.

During the procedure, real-time data from the fibre navigation can be fed into the model and the doctor will be able to see the monitor and view live navigation of the catheter through the vasculature in 3D.

Pätz added: “[Medical device companies] expend a great deal of technical effort into trying to reconstruct the shape of the entire catheter, which can be up to two meters long. Our algorithm, however, only needs a fraction of the data to localise the catheter in a known vascular system.”

When tested in a curved labyrinth made of silicone hoses, a prototype of the IntelliCath system was able to provide the live position of the catheter with precision of up to nearly 5mm.

The researchers plan to further assess the system on a full-body phantom of the human vascular system and a pig lung. A prototype for clinical trial is expected to be available by the end of next year.

The researchers are also working on an acoustic feedback to eliminate the need for doctors to constantly view the monitor.

Rolf Rihs Q&A: Automation solutions for the production of disposable medical devices

Rolf Rihs has been working at automation assembly manufacturer Mikron Automation for nearly 17 years. He speaks to Medical Device Network about the key requirements of the disposable devices industry and how his company meets these changing demands. He speaks to Medical Device Network about the key requirements of the disposable devices industry and how Mikron Automation meets these demands.

Rebecca Panks: What are the key requirements of the disposable devices industry and how do your solutions meet those needs?

Rolf Rihs: “I believe there are three key points to take into consideration. One is the regulatory side, especially the US Food and Drug Administration (FDA). The FDA is governing this market where there are clear guidelines, and these guidelines also have an impact on the automation side through the good automated manufacturing practice (GAMP5). If it is not the FDA, other regions apply. “With the regulatory requirements, Mikron has been building automation equipment for devices since the early 90s, so we have had long experience. In the meantime, we have also built the respective know-how to deal with all those regulatory rules. Our documentation is adapted to that and this is something not all automation suppliers can deliver. “The other thing that we have seen in recent years is generic drugs coming more and more into the market. That also has quite a strong impact on the industry of our customers and indirectly also on to us. “The impact is simple, it is just mathematics: You usually have one pharma company who owns the patent and dominates the market, but now there are suddenly more players. More players mean that the volume for each player is somehow diluted and it is unknown who will win which market share. “The last important point is, at the end of the day, health costs. Health costs are under pressure everywhere, and more and more health medications will come. This is very positive for the medical device manufacturers and also for us as automation suppliers.

“**RP: There is a trend in the medical device industry at the moment of personalised healthcare. Is this something that will affect your company?**

RR: “Sure, it will affect us but when we look at those requirements of customers coming to us, as we are an automation system supplier. So far, we have not seen that personalisation on the level of medical devices. The personalisation is more on the level of what the drug is in the device, or if it is a smart device how this device is linked to software and to personalisation on this level. “In other industries, there is this trend of personalisation also of physical products. But due to the regulatory restrictions of the medical industry, I don’t believe that in the near future personalised variants of the core functionalities of medical devices can be brought to the market. “Personalisation can be expected on the outside look and certainly on the software parameters of electronic medical devices, for example, pen injectors for diabetes patients.”

RP: Are there any further industry changes you have noticed?

RR: “There is one change: the war for talent. It is today not easier, or to put it another way, it is more complex to find really good people who can deal with all those challenges. But that is not just applied to us as automation system suppliers, you can call and ask anybody, you will have the same issues.

.“In a medical device, if the setting of a medical device is done wrong, this device could deliver the wrong result to the patient. So, they are really determined to ensure that nobody can access and the easiest way to secure that is to cut off all access.

AI surpasses humans in predicting heart attack and death

An algorithm has learned how to identify imaging patterns correlating to heart attack and death in cardiac patients and can predict the occurrence of these events with superior accuracy to human doctors, according to a study presented at 2019's International Conference on Nuclear Cardiology and Cardiac CT (ICNC) in Lisbon, Portugal.

In current medical practice, doctors will use risk scores to make treatment decisions for their cardiac patients. These are based on a series of variables like weight, age and lifestyle. However, they do not always have the desired levels of accuracy. A 2015 study published in Annals of Internal Medicine found that four of five standard risk scoring tests overestimated the risk of cardiovascular disease in a control group, which researchers suggested could lead to adverse outcomes such as the prescribing of statin therapies to patients who do not need them.

The study presented at ICNC was conducted at the Turku PET Centre in Finland. Researchers enrolled 950 patients complaining of chest pain, who underwent the centre's usual scanning protocol to check for coronary artery disease. Their outcomes were tracked for six years following their initial scans, over the course of which 24 of the patients had heart attacks and 49 died from all causes.

The patients first underwent a coronary computed tomography angiography (CCTA) scan, which yielded 58 pieces of data on the presence of coronary plaque, vessel narrowing and calcification. Patients whose scans were suggestive of disease underwent a positron emission tomography (PET) scan which produced 17 variables on blood flow. Ten clinical variables were also obtained from medical records including sex, age, smoking status and diabetes.

These 85 variables were then entered into an artificial intelligence (AI) programme called LogitBoost. The AI repeatedly analysed the imaging variables, and was able to learn how the imaging data interacted and identify the patterns which preceded death and heart attack with over 90% accuracy.

The predictive performance using the ten clinical variables alone was modest, with an accuracy of 90%. When PET scan data was added, accuracy increased to 92.5%. The predictive performance increased significantly when CCTA scan data was added to clinical and PET data, with accuracy of 95.4%.

Turku University Hospital postdoctoral researcher and study author Luis Eduardo Juárez-Orozco said: "The algorithm progressively learns from the data and after numerous rounds of analysis it figures out the high dimensional patterns that should be used to efficiently identify patients who have the event. The result is a score of individual risk.

"This should allow us to personalise treatment and ultimately lead to better outcomes for patients."

ICNC, which this year runs from Sunday 12 May to Tuesday 14 May, is co-organised by the American Society of Nuclear Cardiology, the European Association of Cardiovascular Imaging of the European Society of Cardiology, and the European Association of Nuclear Medicine (EANM).

Can the Apple 4 smartwatch save lives?

The smartwatch is the next step in wearables tech, after the smartphone; but can a smartphone save a life? The Apple Watch is in its fourth generation with the Apple Watch 4. The Apple Watch has multiple improvements over its predecessor, being larger, with more storage space, but possibly most importantly, has a built-in electrocardiogram (ECG).

The Apple Watch 3 has recently made headlines in a controversial heart study showing its potential use as a screening tool for heart arrhythmias. The Apple Watch 3 is equipped with a set of optical heart sensors to detect your heart rate during exercise.

Theoretically, this means that you could use this device to detect heart arrhythmias in users. Heart arrhythmias affect about 2.7 million people in the US, and contribute to an estimated 130,000 deaths each year.

The issue with heart arrhythmia is that it is a largely asymptomatic disease. Many people are not aware that they have the disease during the early stages, which is where the Apple Watch comes in. By detecting the users' heart rate, the watch should theoretically be able to detect spikes in the heart rate and alert the user appropriately.

In the Stanford-led study, users who reported arrhythmias had to apply a chest patch to verify the watches' results to validate its use as a screening tool in future. While there was a relatively low rate of concurrence (around 30–40%), this shows the Apple Watch has some value as a tool to spot early-onset heart arrhythmia patients.

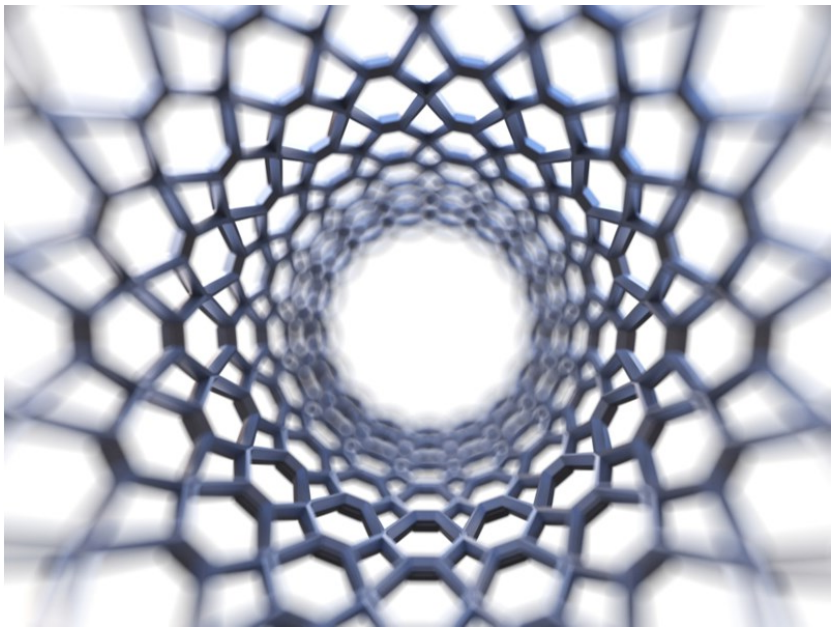
In an age of increasing tech and wearables adoption, tools like the Apple Watch may be useful to spot early-onset diseases that patients or GPs might otherwise miss, saving many lives in the process.

FDA warns against off-label use of Stryker's Wingspan stent

The US Food and Drug Administration (FDA) recently posted a safety warning stating that off-label use of Stryker's Wingspan stent system could increase the risk of stroke or death. This warning came on 25 April, shortly after results from a mandated post-market surveillance study were released.

Intracranial stents, 2019

The Wingspan stent has been tested in multiple clinical trials. The first was SAMMPRIS, a paradigm-shifting trial that tested percutaneous transluminal angioplasty and stenting (PTAS) using Stryker's Wingspan stent versus aggressive medical therapy alone in the treatment of patients with intracranial atherosclerotic disease (ICAD).



The SAMMPRIS trial concluded that aggressive medical management was superior to PTAS. Results from this trial led the FDA to severely narrow the indications of the Wingspan stent. It is now indicated for patients ages 22–80 years with a history of two or more strokes, with the most recent stroke having occurred more than seven days prior to the stenting procedure, and who have 70–99% stenosis in their intracranial artery. Patients should also have recovered well from their last stroke and have a modified Rankin score (a measurement of the degree of disability) of three or less.

The SAMMPRIS trial heavily influenced physicians' decision making in the treatment of ICAD patients in multiple countries including Australia, Canada, France, Italy, Portugal, Saudi Arabia, Spain, the UK, and the US.

In general, intracranial stenting is still performed in rare cases, but only when other forms of medical therapy have failed. To further understand the risks associated with this device, the FDA mandated the "Wingspan StEnt System PostmArket SurVEillance" (WEAVE) study, which has now been completed. In its recent safety warning, the FDA reported that patients who met the FDA-approved indications had a 2.6% combined rate of stroke or death, while patients who did not meet the FDA-approved indications had a 23.9% combined rate of stroke or death. These results lead the FDA to reiterate that only a select group of patients who fit the current indications and enrolment criteria for the WEAVE study may benefit from the use of Stryker's Wingspan stent for the treatment of ICAD.

Intracranial atherosclerotic disease treatment

Despite these negative results, Stryker's Wingspan stent still remains the only approved intracranial stent for the treatment of ICAD available on the US intracranial stenting market, which GlobalData estimated at $8.87 million in 2018. However, epidemiological considerations mean that ICAD is a much more prevalent disease in the Asia Pacific region, where it results in up to four times as many acute ischemic stroke cases. This heavy disease burden has resulted in a greater number of intracranial stenting procedures being performed, and markets with a higher potential for growth. While the Wingspan stent is available in China, MicroPort Scientific Corp has the dominant share in the market. Chinese sales of the APOLLO (MicroPort) stenting system are experiencing high levels of organic growth, driven by a number of factors including strong product promotion, industry-funded training programs for doctors and positive clinical trial data released in 2015.

Given the pre-existing negative public perception of the Wingspan stent due to the SAMMPRIS trial and the recent FDA warning, GlobalData expects that most intracranial stenting markets outside of Asia Pacific will remain steady or even decline in the foreseeable future. The usage of Stryker's Wingspan stent system, in particular, will likely decline in the face of added negative perception from the WEAVE trial.