

MarketWATCH NEWS

Corporate Marketing & Strategy @ Bicakcilar

In this issue:

1. Acquisition Summary
2. Cerus Endovascular secures CE Mark for new microcatheter
3. Catch your breath: a device that spots critical Covid-19 cases
4. Cloud technology: How it can protect your manufacturing process
5. Even after Covid-19, the pandemic's health effects may linger
6. Eko receives NIH grant for AI-based heart disease detection study
7. Caption Health raises

Reference: <https://www.medicaldevice-network.com/market-data/>
<https://www.med-news.comtechnews.com/>

Acquisition Summary

◆ **Creo Medical acquires healthcare products supplier Albyn Medical**

UK-based Creo Medical Group has announced the acquisition of Albyn Medical, a Spain-based manufacturer of gastroenterology, urology and endoscopy products, for an equity value of €24.8m.

◆ **Artio Medical acquires medical device company Flow Forward**

Artio Medical has acquired US-based medical device company Flow Forward Medical in a stock-for-stock merger transaction.

◆ **Siemens Healthineers to acquire Varian Medical for \$16.4bn**

Germany-based medical device company Siemens Healthineers has signed an agreement to acquire US-based radiation oncology treatment solutions provider Varian Medical Systems in a \$16.4bn deal.

◆ **Medtronic to buy French spinal implant maker Medicea**

Medtronic has signed a deal to acquire Medicea, a French manufacturer of patient-

Cerus Endovascular secures CE Mark for new microcatheter

Cerus Endovascular has received CE Mark approval for the CerusEndo MC 021 microcatheter, which enables physicians to access tortuous neuro vasculature and deliver therapeutic devices to intended targets.

The CerusEndo MC 021 microcatheter, which has already secured the US Food and Drug Administration (FDA) approval, is the company's first microcatheter to obtain European regulatory approval.

CerusEndo MC 021 microcatheter offers improved proximal support by providing better deliverability and responsiveness in physicians' hands. It is available in multiple distal flexible profiles.

Cerus Endovascular president Stephen Griffin said: "We remain committed to meeting the ever-increasing needs of the interventional neuroradiologist community, and with that in mind, our team has clearly identified a range of increased performance demands required of a go-to intracranial access microcatheter.

"As a result, we have expanded our key 021 platform so that it can deliver a wider range of devices than it was originally designed for, including stents, braided flow diverters and stentriever, for treatment of both hemorrhagic and ischemic strokes. In particular, the 021 ensures predictable stability and control when delivering larger and braided devices through the device lumen."

The company expects to begin the commercial sales of the newly CE-Marked product in the fourth quarter of this year.



In April, Cerus Endovascular secured CE Mark for the Neqstent Coil Assisted Flow Diverter device designed for the treatment of intracranial aneurysms.

Catch your breath: a device that spots critical Covid-19 cases

Amid the Covid-19 crisis, Cambridge Respiratory Innovations has been working to scale up production of its flagship capnometer. Natalie Healey speaks to CEO James Whitticase to find out more about the tech, and the challenges for a small company looking to make a dent in a global challenge. James Whitticase certainly didn't have a pandemic in mind when he took over the reins of start-up Cambridge Respiratory Innovations last September. But, while many people brushed off reports of a deadly pneumonia of unknown cause in Wuhan, China at the start of the year, he grew anxious. He had a feeling the then-mysterious infection wasn't going to be contained. He then started to wonder if his company might be able to help should his worst fears be realised. N-Tidal has an unlikely origin story. It's the brainchild of two founding directors, engineer Julian Carter and physician John Altrip who stumbled upon a commercial air conditioning unit with impressive sensitivity. They wondered if they could make a similarly sensitive device to monitor carbon dioxide at a patient's mouth. Collecting this data from normal breathing could provide new insights into an individual's lung function, they reasoned.



In the breath

The purpose of the lungs is to supply blood with oxygen and remove carbon dioxide from it. Therefore, measuring carbon dioxide levels in the breath is an indicator of how well these organs are working. Traditionally, measuring the gas breathed out is achieved via a diverted breath sample.

You breathe into a face mask, it takes your breath down the tube, and then you have a little sensor somewhere down that tube that measures carbon dioxide," Whitticase says. "But it does it really crudely. By doing it straight from the mouth, it's very accurate, very sensitive and collects a huge amount of data."

By measuring patients' normal breathing at rest, the handheld N-Tidal device transmits respiratory data in real-time via 3G mobile phone networks to a cloud-based software platform. Originally developed for conditions such as chronic obstructive pulmonary disease and asthma, the same principles can apply to Covid-19. It can tell doctors how badly the disease is impacting the lungs.

Used on coronavirus wards, respiratory readings could be produced without doctors needing to supervise the data capture. And the information may provide intensive care units with a picture of a patient's evolving clinical condition, helping doctors to identify patients who are deteriorating by picking up on subtle clues in their breathing that might otherwise be missed.

"We should help the team identify who to step up into an intensive care environment, who to keep on the general ward, and potentially who we could send home with a device so the team could still watch them," says Whitticase.

Importantly for a highly contagious virus, the data captured from N-Tidal is a non-aerosol-generating process. Plus, the design incorporates two replaceable parts which form a single user, disposable breath pathway. These are separate from the rest of the device and can be easily replaced between users.

Whitticase had not foreseen the device being used by NHS trusts though. Before Covid-19 hit, the route to market for N-tidal was likely to be pharmaceutical companies, so research teams could use the device to assess the efficacy of COPD drugs in development. That all changed when it became clear the novel coronavirus was going to be a major crisis.

Knowing when to jump

But making such a major business pivot isn't easy. Although N-Tidal had been manufactured and was ready to be shipped, the accompanying software wasn't suitable for hospitals. It had been built for pharmaceutical companies and clinical trials, rather than doctors. Luckily, a prototype clinical monitoring system was already in development. Cambridge Respiratory Innovations originally had a launch date in mind for it of late 2021.

"As soon as Covid hit China, we started working on it and by the time it got into Europe, we repurposed the whole company's focus on clinical dashboards to support doctors with the Covid challenge," reveals Whitticase.

Finances were another hurdle. The company was just embarking on a seed funding round, but the money wasn't there at the start of the year. Quick cash was needed to ramp up supply for the increased demand of the devices.

Cloud technology: How it can protect your manufacturing process

Exceptionally high standards and demands rest on everything from data management to workplace efficiency. Offering new solutions to old problems, such as streamlining fax transmissions through online faxing, cloud-based solutions can transform your manufacturing operation in several ways:



cloud-based solutions can transform your manufacturing operation in several ways:

Comprehensive access

The production and manufacturing of healthcare products require a lot of important documentation, tools, systems and software. These are located in one of two places: As a specific file or executable program on a computer, held in physical form in a physical location

Remote work has been shown to have numerous benefits for the manufacturing industry, with over half of employees in the sector seeking more flexible work options. But current practices don't facilitate such demand — and the low figure of just 9% of manufacturing organisations offering such flexibility attests to this. What's worse, if you are unable to reach the location of the required file or system — perhaps somebody else is using the computer for a more urgent task, or what you need is housed on another site — you may find tasks become impossible to complete.

Effective work within healthcare manufacturing requires the removal of these kinds of limitations — and that is exactly what cloud technology does.

Cloud technology offers instant use of files, software and other solutions from multiple access points. As long as the technology is compatible with a device — be it a computer, tablet, smartphone, etc. — you can use it wherever you are. You don't need to travel to a specific location or have accessibility limited to one place. By incorporating cloud technology into your manufacturing process, you sever restrictive ties associated with location-based accessibility and ensure task completion.

Avoid internal IT problems

Cloud-based technology, however, offers a reprieve from such disastrous situations. All elements are managed externally by developers, whose sole purpose is to ensure their particular cloud product remains active and supported. So, the risk of experiencing IT problems reduces drastically. By accessing their systems through online portals, you remove all your internal responsibility of keeping your IT processes operating smoothly. Instead, it is entirely in the cloud developer's control. The result is this: providing your network connection remains stable, you'll very rarely experience anything in the way of IT nightmares. If IT problems are something you find occur regularly, the introduction of cloud-based technology can drastically reduce workplace downtime.

Avert disaster

A true workplace disaster is something you never want to experience. When something goes majorly wrong, it doesn't matter where in your organisation the problem started; it can have massive ramifications for your entire operation. Cloud-based technology cannot reduce the risk of every potential major problem that could befall a healthcare manufacturer. But it does have plenty of potential to support better practices that can minimise the chance of experiencing one widespread and particularly damaging disaster:

Loss of data

Loss of data can occur due to all manner of problems, from intentional theft to misplacement of physical files. The causes may be different, but the outcome is the same — major consequences in terms of:

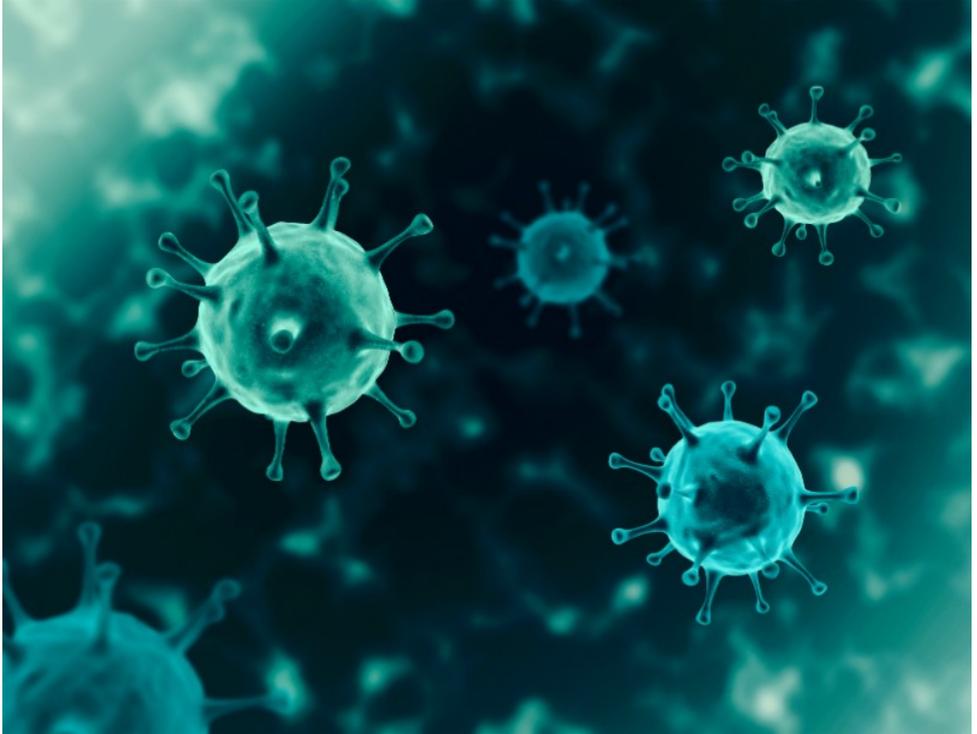
Downtime caused by re-acquiring data or slowdowns caused by an inability to access important files and documentation

Potential legal and financial ramifications of breaching data protection compliance laws relating to any healthcare clients you may have.

Even after Covid-19, the pandemic's health effects may linger

We have all dreaded it, and far too many of us have experienced it. Coughing, shortness of breath, fever. These are all symptoms of the most important health crisis of our time: Covid-19. Fortunately, this will all be over when we find a vaccine. Right?

Unfortunately, there is a growing cause for concern that Covid-19 may have long-term health effects on those who are infected, even long after they are cured. The long-term effects vary wildly. There have been reports of scar tissue forming on the



lungs, damage to heart tissue and more vague reports of long-term fatigue, joint pain or chest pain. This is completely discounting the long-term mental health effects Covid-19 will have as well.

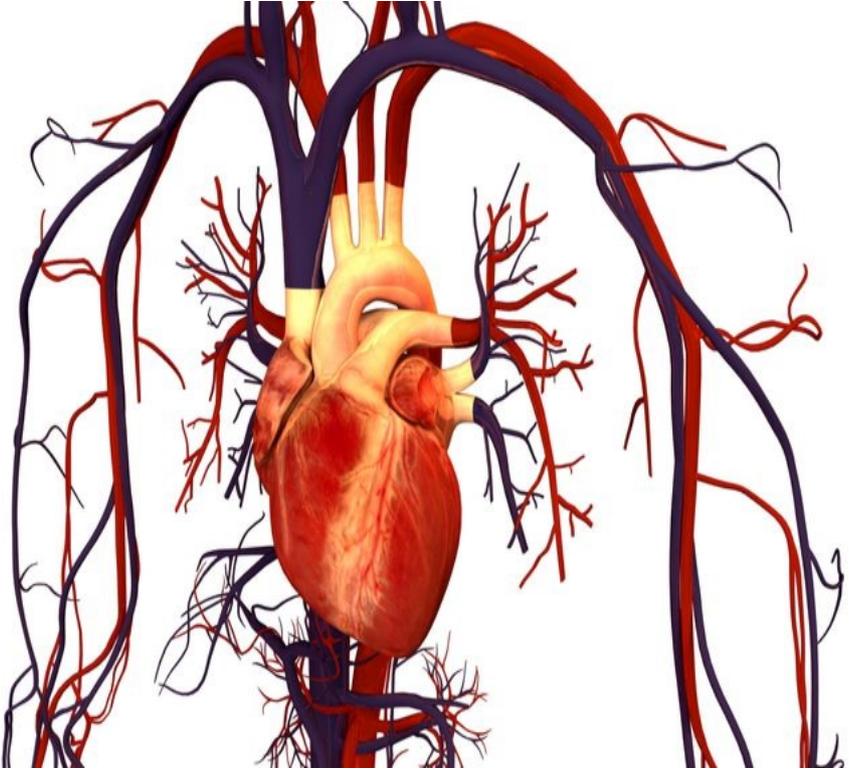
While the results are not yet iron-clad, there is enough evidence to give us pause. With SARS and MERS, Covid-19's two predecessors and genetic 'cousins,' studies that conducted follow-ups with survivors of these pandemics have also found fatigue, depression and muscle pain even months after patients recovered from their initial infection. Covid-19 seems to be no different with preliminary reports suggesting similar outcomes.

Why then is this the case? Isn't Covid-19 a purely respiratory virus? If so, then shouldn't the damage be contained to the respiratory tract? Unfortunately, it seems that Covid-19 like SARS and MERS is a full-body infection. Older studies of SARS showed that the mechanism that SARS used to enter the body's system was through the ACE2 receptor pathway. This means that wherever in the body there are ACE2 receptors, SARS could potentially enter.

Unfortunately for us, Covid-19 is able to abuse this same receptor, and doubly damning seems to be the fact that the ACE2 receptor is found throughout the body. It is found in the gastrointestinal tract, the capillaries of the body and the heart, among other places. This has led to increased formation of blood clots, heart attacks, and in very few extreme cases, a need for surgical removal of the gut. These may also be long-term issues that will plague Covid-19 victims for the remainder of their lives.

This is why containment is still so important, even during this late stage in this pandemic. Every person who is infected with the virus may become a person with a chronic heart, lung or gastrointestinal issue for decades to come.

Eko receives NIH grant for AI-based heart disease detection study



US-based digital health company Eko has received a \$2.7m Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH).

The grant will support the company's ongoing study with Northwestern Medicine Bluhm Cardiovascular Institute that aims to validate algorithms for pathologic heart murmurs and valvular heart disease screening.

Cardiovascular disease is considered to be a leading cause of mortality in the US. Due to the challenges in detecting hearing murmurs with traditional stethoscopes, valvular heart disease often goes undetected.

The study intends to help clinicians to identify patients with heart disease without the use of screening tools such as echocardiograms, which are only available at speciality clinics.

Ekochief medical officer Adam Saltman said: "This SBIR award from the NIH underscores our vision to provide world-class cardiovascular care at the patient's point of care.

"Our mission is to change how cardiovascular disease is diagnosed, and as one of the first centres in the country to study AI and cardiovascular disease Northwestern is an ideal partner to help us reach our goal."

Eko and Northwestern initiated their collaboration in March last year.

In a separate development, Canon Medical Systems USA has received 510(k) clearance for its Advanced intelligent Clear-IQ Engine (AiCE) for the Vantage Oriion 1.5T MR system.

The technology uses a deep-learning algorithm to differentiate true signal from noise and suppress the noise while facilitating advanced signal, image reconstruction and seamless workflow.

Meanwhile, another US MedTech company Integra LifeSciences has obtained the Food and Drug Administration (FDA) clearance for a specific neurosurgery indication for its CUSA Clarity Ultrasonic Surgical Aspirator System.

The indication enables CUSA Clarity to be used in neurosurgery for resection of tumours, ranging from soft to firm consistencies. This includes the removal of primary and secondary malignant and benign brain and spinal tumours, as well as meningiomas and gliomas.

Last year, Integra LifeSciences acquired neurosurgical devices maker Arkis Biosciences.

Caption Health raises \$35m for ultrasound technology commercialization



Medical artificial intelligence (AI) company Caption Health has raised \$35m in a Series B financing round to develop and commercialise its Food and Drug Administration (FDA)-cleared, AI-guided ultrasound technology.

Led by the company's existing investor DCVC, the round was joined by new investors Atlantic Bridge and Edwards Lifesciences, along with existing investor Khosla Ventures.

Caption Health plans to use the capital to ramp up its commercial operations and form new partnerships in addition to funding its AI technology platform expansion efforts.

The Caption AI platform, which includes Caption Guidance and Caption Interpretation, is designed to perform ultrasound and obtain diagnostic-quality images.

The platform enables healthcare providers to perform ultrasound and obtain diagnostic-quality images without specialised training. It is expected to help clinical decision-making and save costs and time for medical institutions.

Caption AI was granted expedited clearance by the US FDA after receiving urgent requests from clinicians at leading hospitals across the country during the Covid-19 pandemic, the company noted.

The company is planning to add new clinical capabilities to expand the use of Caption AI in additional care settings.

Caption Health CEO Charles Cadieu said: "This capital will enable us to scale our collaborations with leading research institutions, regional health systems and other providers by making ultrasound available where and when it is needed – across departments, inside and outside the hospital.

"As the world's first and only AI-guided ultrasound technology, our goal is to enable all clinicians, regardless of prior experience, to capture diagnostic-quality ultrasounds."

Caption AI software is fully integrated with a Terasonu Smart 3200T Plus portable ultrasound system, which offers a range of clinical applications such as lung, vascular and abdominal scanning.