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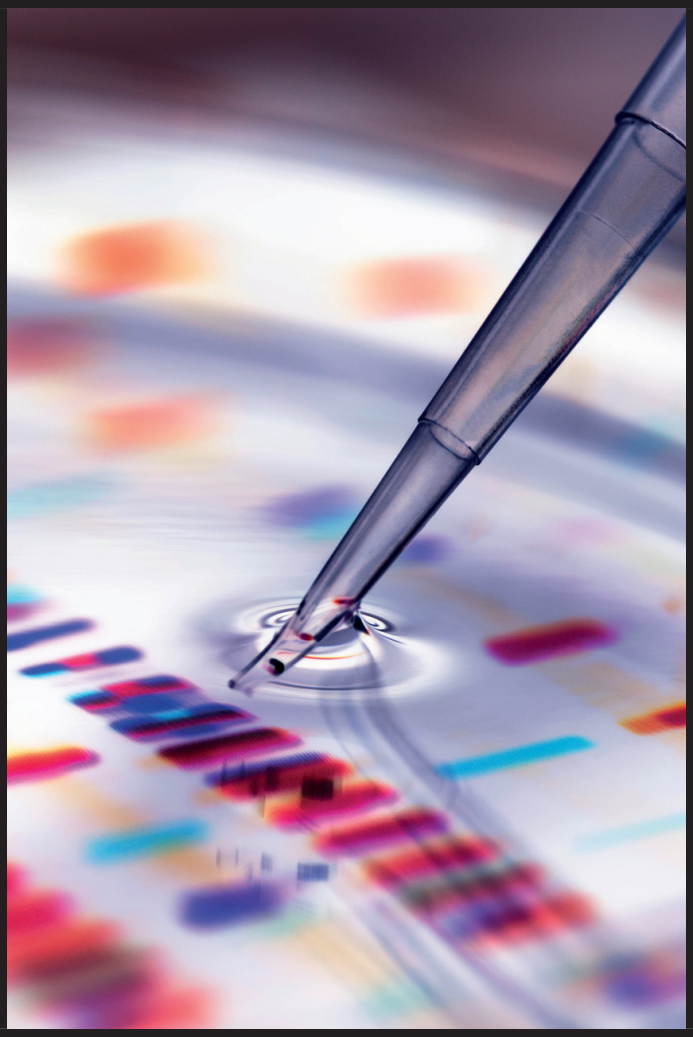

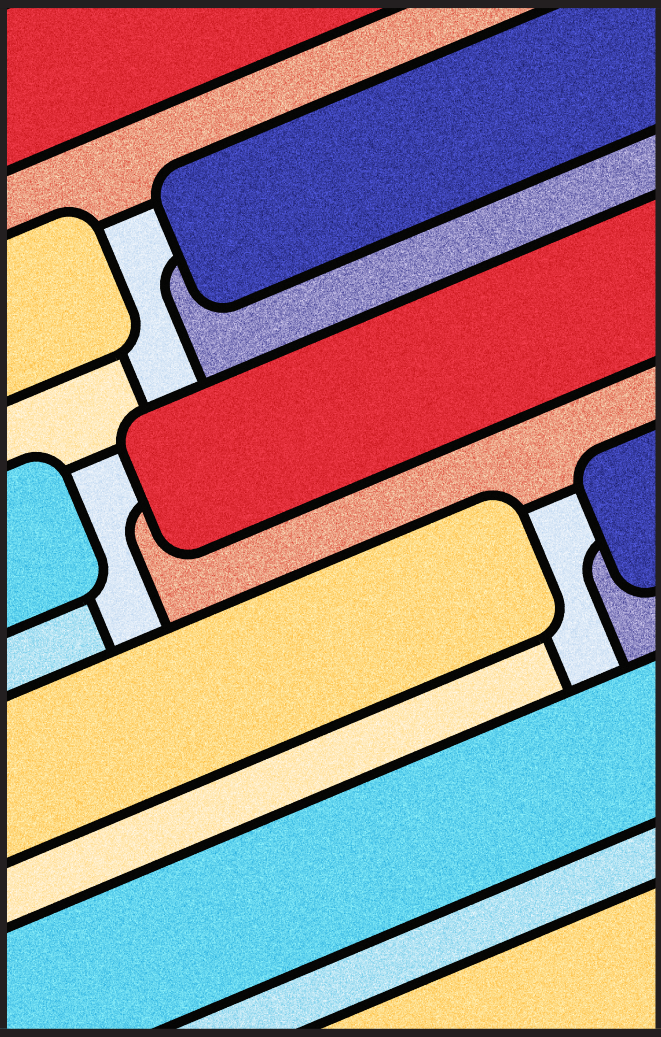

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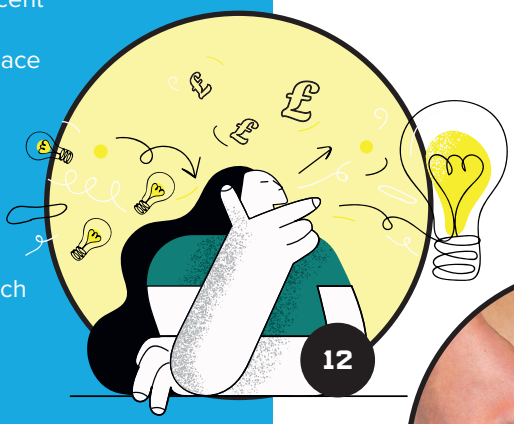

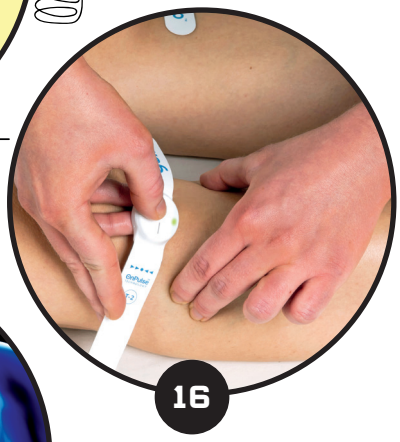

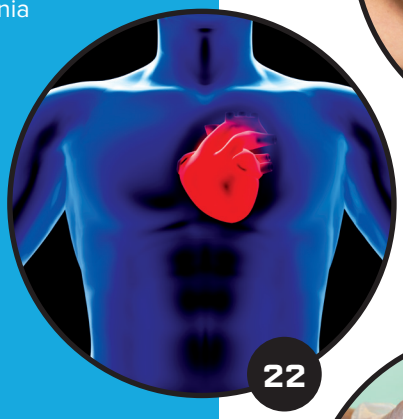

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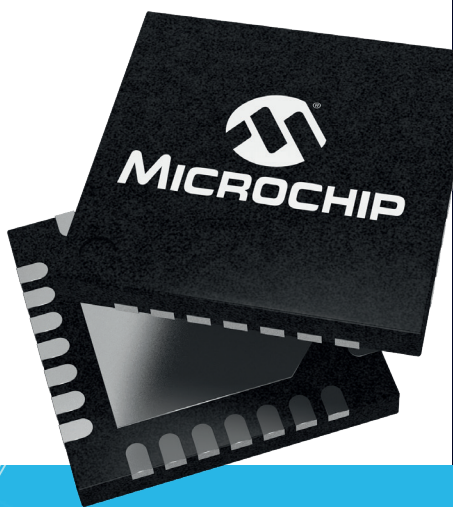

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FROM THE EDITOR

A proper antibody testing roll-out can keep the COVID wolf from the door

As I write this, the situation in the UK is looking a little precarious again, and if we were to endure another winter of harsh restrictions, it would feel like a huge kick in the teeth for many who have sacrificed so much. Put aside the selfish aspect of thinking about one's freedoms, with deaths still at more than 100 a day despite a government doing victory laps about its admittedly commendable vaccination programme, there is a strong argument for more measures to be put in place.

Politically, this dividing line seems to fall on masks, social distancing, and home working measures to make the R rate more manageable to handle so the NHS doesn't fall over this winter and prevent the grave knock-on effects that can have on other aspects, such as routine operations being cancelled and the backlog caused by COVID-19 so far. The government's method of handling a crisis which has seen over 140,000 people sadly pass away because of the disease, is to bet its house on the booster programme, and encouraging those who have yet to have either of their two jabs to come forward. Both aspects make sense, but there have been warnings that vaccination alone will not get us out of this particular rut – as has been evidenced in Israel previously and currently in mainland Europe – and the good work of a quick rate of vaccination can be undone if there are no other mitigations put in place. It seems the government has left the pitch in this regard.

Regular readers of this column and listeners to The MedTalk Podcast will know that I have not been the greatest fan of the government's response – mainly because I feel they have left it too late to act and it's cost the lives of loved ones, and on a personal note, I feel that it put someone very close to me in hospital and fearing for their life.

But here, I propose a measure that can form part of the solution. We know that the government has procured a vast number of doses that can vaccinate the UK population several times over. Currently those eligible for a booster is similar to those who were in first in line to receive the vaccine following its roll-out; the clinical vulnerable and those over a certain age – in this case the over 50s, though soon to be over 40s – as well as those working in the clinical and social care setting.

I feel a larger scale roll-out of antibody testing is needed to allow the population the opportunity to regularly test their levels of immunity, whether this be via clinical appointments (remote or otherwise) or home testing in a similar way we can obtain lateral flow tests for the virus. Surely this is something that the public can get on board with in a bid for normal life and little disruption?

This would allow for us to account for the differing levels of immunity within the population, regardless of age and if people are immunosuppressed, targeting those who are most in need of a third vaccination – therefore helping drive down transmission. Currently we have a policy that could see vaccinations being unused. To avoid that happening, I am somewhat sympathetic for a temporary measure of asking people to come forward for a third jab once a threshold of the priority groups have been vaccinated anyway.

Vaccinations have rightly been billed as a weapon for us all to return to normal in a worry-free environment, but that can only be done if more pragmatic measures run in parallel.

Citadel Health awarded £15.9m contract to future proof Wales national pathology services

A £15.9 million contract has been awarded to Citadel Health to provide new technology to NHS Wales, which will bring together the management of end-to-end patient testing for every discipline across Wales.

This investment by NHS Wales aims to modernise and transform pathology services, with better care, faster and more targeted treatments, and improved health outcomes for patients.

Pathology underpins 95% of all clinical pathways and 70% of all diagnoses in Wales. With the pressure on testing services brought about by the COVID-19 pandemic and the challenges of treating a growing and ageing population, often with multiple coexisting conditions, the need for a modern pathology network has never been greater.

The Evolution vLab Laboratory Information Management System (LIMS) software will replace the current three separate systems, to create a single, modern pathology network that connects every clinician, lab and hospital in Wales with a complete patient test management solution, all via a single login.

Once live, the system will manage the more than 35 million test requests that are processed each year by 21 NHS Wales pathology labs, and support every hospital, clinic, and GP nationwide.

With Citadel Health's solution integrated with NHS Wales Welsh Clinical Portal, laboratories, hospitals, and clinicians will have faster access to real-time pathology

WOUND CARE APP ALLOWS FOR HOME ASSESSMENT

Global technology company Healthy.io has launched its wound care app in Wales, allowing patients to have their wounds assessed and monitored from the comfort of their own home.

The eight-month project, currently being rolled out in Swansea Bay University Health Board across Swansea Bay and Neath Port Talbot, is financed by Welsh Government's Digital Solutions Fund (DSF) that is coordinated by Digital Health Ecosystem Wales (DHEW). The project has already reached 30 patients in between the period of the 11th and 26th of October, with 36 individual wounds being digitally monitored and nine wound types identified by 18 clinicians using the service.

Wound care services account for a significant amount of NHS Wales' annual budget, costing £330 million, which is 6% of its total. Improperly assessing wounds can also lead to unnecessary follow up visits and outpatient appointments, causing capacity issues and delays for patients accessing services.

Healthy.io's Digital Wound Management Solution allows district nurses to travel to patients as part of regular check-ups and scan wounds with an app that can be integrated into existing software on smartphones and tablets.

These are then shared onto a secure digital portal that can be accessed by clinical staff to remotely assess and monitor wound progression over time, as well as providing digital consultation services.

This solution prompts early detection of static wounds, allowing for earlier intervention and a reduction in unnecessary suffering. By using a digital wound management solution, clinicians are also able to bring patients in on their wound healing journey which, in other areas, has not only helped to engage patients in their care, but also had a positive effect on wellbeing. Healthy.io's Digital Wound Management Solution also benefits clinical staff and healthcare services by reducing the administrative burden and streamlining work through a simplified and consistent recording and assessment process.

This proven technology is already well established in England, at trusts such as Livewell in the southwest. Swansea Bay University Health Board has joined these organisations that are helping drive better patient outcomes and improve health system efficiencies through digital transformation. Healthy.io delivered face-to-face training to onboard and engage with healthcare staff to ensure a two-way dialogue was established from the beginning.

Katherine Ward, chief commercial officer and UK managing director of Healthy.io, said: "We are delighted to bring our Digital Wound Management Solution to the clinicians at Swansea Bay University Health Board, marking our first site in NHS Wales. Traditional wound care management is time and resource-intensive for clinicians as well as often challenging for patients. By making routine wound monitoring digital, we help already-burdened healthcare professionals make better clinical decisions and support patients in having their care managed closer to home."

information across every discipline at their fingertips.

Stephen Lynch, executive general manager at Citadel Health said: “The COVID pandemic has placed unprecedented demands on clinical testing services worldwide, reinforcing the case for investment and transformation of digitally enabled healthcare systems to meet evolving needs.

“For clinicians and patients alike, getting test results as quickly and accurately as possible is essential to allow them to make timely decisions about treatments and ultimately provide the best possible outcomes.

“Our cutting-edge technology provides a unified pathology workflow to help people now, and into the future, as new tests and services are developed to meet growing demands. We’re proud to be working with NHS Wales - an organisation that is leading the way in digital transformation of healthcare in the UK - we are delighted to be working alongside them on this journey.”

VISTAMED TO CREATE 100 NEW JOBS IN CARRICK-ON-SHANNON FACILITY

VistaMed, a Freudenberg Medical company and CDMO for complex extrusions, finished catheters, and medical devices for minimally invasive applications, has announced that it will create 100 new jobs at its facility in Carrick-on-Shannon in Co. Leitrim.

Tanaiste and minister for enterprise trade & employment Leo Varadkar TD said: “I’m really pleased to see that VistaMed is expanding in Leitrim and will be recruiting 100 people over the next two years. This significant expansion demonstrates VistaMed’s continued commitment to Carrick-on-Shannon, where it was founded and underscores Ireland’s position as a global hub for the world’s leading medtech companies. I wish the team every success with this new expansion.”

The company’s products have evolved in terms of form and complexity since its foundation, offering product design, development, component manufacturing including labelling, packaging, and sterilisation support for customers. The company produces a range of catheter-based products used in diagnostic or therapeutic procedures such as cardiology, electrophysiology, peripheral stent delivery systems, urology, endoscopy, neurology, and pain management.

Patrick Mulholland, managing director of VistaMed, said: “This latest jobs announcement is in direct response to the strong demand for development and manufacturing capabilities in VistaMed from existing and new customers. This is an exciting time in the continued development of our company, many of the devices we develop offer exceptional opportunities for engineers to gain experience working with the most innovative products to come on the market.”

Gearing up for 2022?

After a return in September 2021, you won’t have long to wait until the next edition of Med-Tech Innovation Expo will return on 8-9 June 2022 at the NEC in Birmingham, bigger and better than ever before.

Co-located with TCT 3Sixty, Med-Tech Innovation Expo is the number one event for medical device supply chain intelligence in the UK and Ireland, taking place alongside other manufacturing shows including Manufacturing Expo, Engineering Expo, Design Engineering Expo, and Maintec.

Our floorplan is starting to fill up as exhibitors increase their presence on the show floor following a successful return despite the challenges of the COVID-19 pandemic.

At the show, Mark Turner, managing director of Medical Engineering Technologies, said: “Good to be here in Birmingham, good to meet the crowds and the people who are our real customers face-to-face. It hasn’t happened for some time now. So, really good to have some good conversations and get some projects started.”

Jennifer Driver, supplier development specialist for The West Group, who have increased their presence on the show floor for next year added: “It’s a great way to visit potential suppliers, existing suppliers. It’s nice to do the networking as well. In the medical industry there’s no limits so there’s always something new on the horizon.”

A call for speakers is out and exciting plans are taking shape on our conference stages as talks, debates and panel sessions are planned across many subjects including supply chain strategy, adoption of minimally invasive devices, artificial intelligence, plus many more.

There’s also the opportunity for those at the show to get their message out prior to June by working closely with Med-Tech Innovation News, offering you a full, 360-degree holistic view of the medical device supply chain industry.

This is via our website with over 600,000 users a year, 8,000+ social media followers, over 17,000 e-newsletter subscribers, the latest addition to our stable with The MedTalk Podcast discussing the latest news and issues in life sciences, and, of course, Med-Tech Innovation magazine. Joining the Med-Tech Innovation community for, and ahead of, June opens several avenues for you to connect to your customers: in print, online, audio, and face-to-face.

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LIL-LETS REPLACES PLASTIC APPLICATOR TAMPON

Lil-lets has announced that as part of its sustainability mission, it will no longer manufacture its plastic applicator tampon, as of November 2021.

The company will replace the product with a new design as it has unveiled its reusable tampon applicator.

The tampon applicator can be cleaned between uses and has been designed with comfort in mind.

It has been designed to be slimline and smooth, with a rounded tip for easy insertion. It's also got a lid, to load your tampon into the applicator without having to touch any of the insertion tube.

Environmental activist Ella Daish said: "It's fantastic to see a major brand like Lil-Lets really leading the change in the period industry by not only removing plastic applicators from their products, but also stepping into the reusable market with their applicator!

"We need more companies to follow their lead in taking steps that are better for people and the planet."

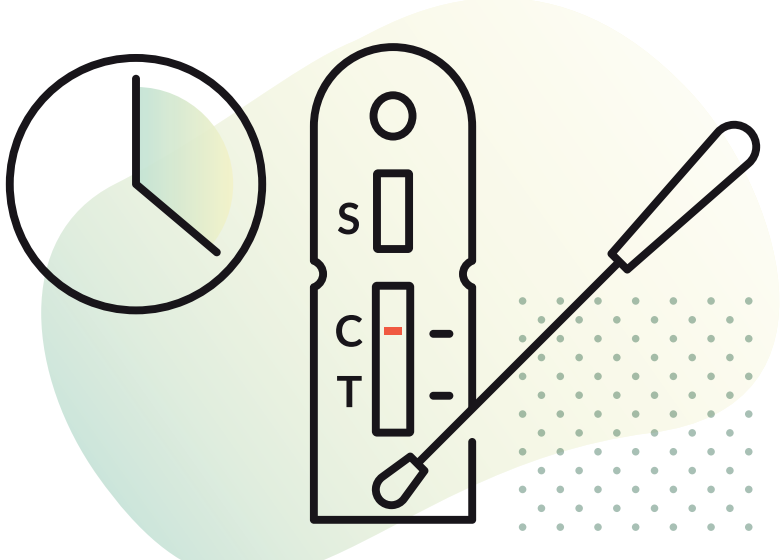
Image credit Lil-lets

SureScreen's lateral flow tests rolled out across universities

Surescreen's COVID-19 lateral flow device (LFD) is now being rolled out to universities across England.

The test is the first British-made assisted LFD device to be validated in a laboratory by Public Health England (PHE) and will provide a qualitative yes/no result in under 15 minutes. The test was developed with help from Omega Diagnostics in Scotland, who are responsible for part of the assembly process.

Jenny Harries, the chief executive of the UK Health Security Agency (UKHSA), said: "Testing – along with vaccines – is one of our first lines of defence against COVID-19, and in the months ahead, rapid tests will keep fortifying these defences, as thousands of university students use them to check whether they are infectious and likely to transmit the virus, all at lightning speed."



3P Innovation presented with two Queen's Awards for Enterprise

3P innovation, a Midlands-based engineering and custom automation company was presented with its two Queen's Awards for Enterprise (2020 and 2021) by Her Majesty's Lord Lieutenant of Warwickshire, Mr. Tim Cox.

The High Sheriff of Warwickshire – Lady Willoughby De Brooke, The Mayor of Warwick – Councillor Richard Edgington and a few of their customers were in attendance. The event comprised of a tour of 3P's facilities, live demos of some of their equipment and a networking session right after the awards ceremony and high tea.

The company was awarded with a Queen's Awards for Enterprise in Innovation in 2020 and a Queen's Award for International Trade in 2021. Internationally recognised, these are the UK's most prestigious business awards, which date back to 1966.

Commenting on this success, Dave Seaward, founder and engineering director at 3P said: "The future is looking bright at 3P. These awards recognise the hard work of all our employees and the pride we take in developing our people. We were honoured and humbled to be presented with these royal awards. We look forward to continued development of our highly skilled staff who design and develop market-leading automation for our clients."

3P innovation works collaboratively with global pharma and medical device businesses to help develop their new products, devices and production processes. This exporting manufacturer can design and manufacture sophisticated and heavily regulated automation.

Before the pandemic, there was little public interest into the manufacture of asthma inhalers, injection pens, vaccines, PPE or diagnostic tests – this is 3P's expertise. Having helped develop equipment to make existing cancer treatments, 3P's engineers are also active in the exciting 'cell & gene' sector, which could lead to cures for cancer in the very near future.

What's happening with value-based procurement?

Oli Hudson, content director at Wilmington Healthcare, looks at the phrase of the moment in procurement circles – what does it actually mean for medtech?

OPINION

One complaint about the NHS that many medtech suppliers I have worked with over the years maintain is the service's obsession with short term cost over long-term value.

It is an issue that at least some parts of the NHS seem to share, hence the current vogue for ideas of value-based procurement (VBP).

The idea of Value-Based Healthcare has been doing the rounds for at least ten years, originating with the Right Care programme of Sir Muir Grey in the early 2010s, when it made a connection between the resources used and outcomes achieved, focussing on unwarranted variation and waste reduction.

VBP now has a definition accepted by academics and NHS Supply Chain that stresses two things: a purchasing process that "generates opportunities to release capacity", and that it should "deliver tangible, measurable benefits that make a positive impact on patient care, and increase efficiency."

An NHS England board paper in 2017 explored how CCGs could benefit from a value-based rather than cost-based approach. In 2019, it sidestepped into the world of procurement - with NHS Supply Chain appointing a VBP lead – Brian Mangan – and commissioning a report into how the approach could benefit systems.

The report's release was supressed for most of the course of the pandemic. When it came, it found three critical success factors:

- clinical support and engagement - critical to the adoption of VBP
- a need for common understanding of value between buyers and suppliers
- assurance from suppliers to substantiate claims aid VBP adoption for NHS trusts.

If properly understood by both the NHS and suppliers, then, could VBP offer promise to both sides for the future?

The NHS from April 2022 will be divided into 42 integrated care systems; integrated bodies of purchasers – involving local authorities, former clinical commissioners, and hospital trusts as providers – and are given a new duty to arrange services in the best interests of patients, taxpayers, and the population.

The current legislation means three things to note. It requires hospitals to work together as place-based partnerships to secure contracts, meaning they can look at the spread of resources with a wider lens, and not be forced to compete for and conserve resources. Place based partnerships are likely to tender collectively and engage more generally in joint procurement.

These services will be paid for by a block budget, rather than activity-based payments, giving providers some leeway over day-to-day cost pressures. In the future, contracts are likely to be paid for by a block/blended approach, meaning trusts have a secure baseline of funding but also incentives to achieve value and/or outcomes.

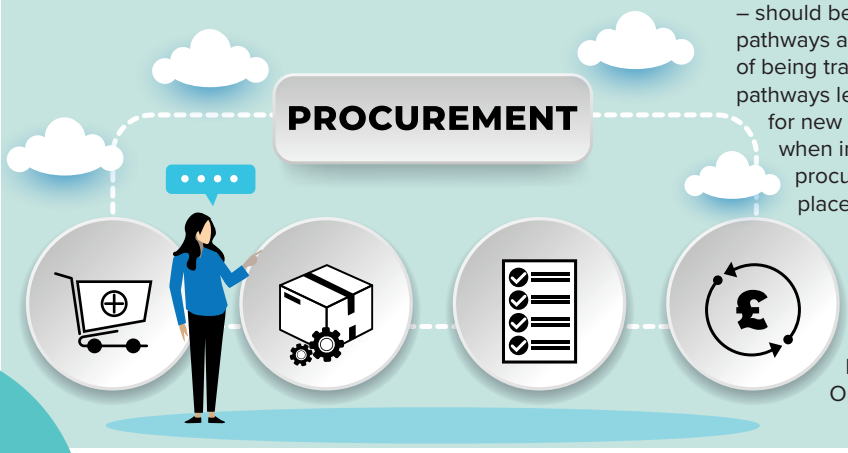
The legislative proposals shift their emphasis from cost to value. Taken in the round, the time is riper for VBP than at any stage in the past decade.

NHS Supply Chain's report concluded that clinical support and engagement were essential for VBP – and this is another synergy with the new Health and Care Bill. The legislation also stresses that leading the charge for transformation in a given 'place' – a locale of 300,000 to 500,000 people – should be clinicians. All pathways are in the process of being transformed. New pathways lead to a need for new technology, when imaginative new procurement can take place.

A piece in HSJ of 21 October covered a collaboration by the South London Cardiac Operational Delivery Network (ODN) and NHS Supply Chain. The project brought together cardiologists from the five centres in a "clinical council" to improve procurement of percutaneous heart stents, featuring evidence about the various stents on offer obtained by surgeons in real time.

The process led to the number of suppliers being cut from 12 to two, and to projected savings of 30% of the total spend on the devices across the five trusts. The spend on stents was projected to go from £4.5 million per year to around £3.2 million per year. Other examples of this kind of project are available in NHS Supply Chain's own VBP project report and findings. 13 pilots are being taken forward as a result of the review, in capital equipment, cardiology, endoscopy and endourology, ward based consumables, and wound care.

When trying to influence local procurement, particularly the use of a new device in a novel clinical pathway, clinical engagement must be sought. Suppliers must ensure their aims align with those of the target system, place, and pathway. Also, all claims proposing a value for systems, involving those patients and the costs (or savings) involved in them should be readily available and based on fully costed business cases – and should be understood and valued by the clinicians medtech has engaged with to further the innovation. If these three areas are focussed on, VBP could prove a useful concept for medtech.



CLINICAL ASSISTANCE TOOLS:
THE NEXT GENERATION OF PATIENT CARE

Kevin Bambury, co-founder of ONCOassist, writes about the new medtech developments that improve the patient journey while providing relief to HCP's workflow.

When we started ONCOassist, we were motivated by one simple problem. Clinicians were spending too much time trying to find the tools and information they needed to make an informed decision. We heard stories of oncology clinicians queuing to get access to computers, printing off reference material which were then brought to patients' bedsides to help with decision making. Highly trained clinicians were spending too much time on something other than caring for patients. This seemed like an inefficient process in our digital age and one we were primed to solve.

By focussing on bringing all the key tools and information oncology clinicians use daily into one platform, we have developed ONCOassist into an app used by oncology HCPs globally. We estimate nearly 45% of oncology HCPs globally now use ONCOassist, even after other apps that similarly assist clinical decision making have emerged. All are putting the needs of clinicians and their patients at the centre of what they do. From the very beginning, we felt user feedback and engagement was a key part of our development strategy, we focussed on surveying our users, meeting them at conferences and engaging via emails. The information we garnered was critical to helping us grow and remain at the forefront of their needs. Even to this day, our mission statement is to help oncology professionals globally make more informed decisions. This is something we remind ourselves of every day.

Over the same time, we have been able to watch other companies with similar focusses on assisting clinicians and their patients emerge and grow; below are some examples.

SALASO HEALTH

Salaso health allows clinicians to send evidence-based exercise programs to their patients to help them with their recovery. These are provided in the form of crisp, easy to follow videos which patients can follow from the comfort of their own home. This assists clinicians by giving them a platform from which to guide and monitor their patients, while empowering patients to manage their own recovery with the help of their clinician. Just like ONCOassist, Salaso Health focusses on the needs of the clinician and their patient.

SWIFT QUEUE

Swift Queue was founded to streamline appointment booking in healthcare systems around the world. Their online booking platform takes the burden of managing patients in the waiting room away from the clinical care team and allows them to focus on what they are best at. Again, the focus was on solving a common clinical challenge and leveraging technology to make what was an inefficient process streamlined.

MEDXNOTE

A third company that is assisting clinicians and growing quickly is Medxnote. They provide clinicians with the right clinical data, at the right time, by connecting your hospital IT systems with chatbots. Medxnote is integrated with the existing healthcare IT infrastructure and sends key information to clinicians from these disparate systems, when and where it is needed.

For anyone developing a product in healthcare, I urge you to talk to users and find ways to engage with them regularly, whether it be via digital means or in person. This is critical prior to launch, but also after launch. It's a complex space and products that are developed need to be constantly evolving.

THE IRISH MEDTECH ECOSYSTEM

In navigating a complex regulatory environment, the community at the Western Gateway building in UCC was key, as was the regulatory affairs centre of excellence in Dundalk IT. We got commercial support from the Ignite programme in UCC as well as mentors provided by Enterprise Ireland and the UCC Ignite programme.

Finally, we were very fortunate that the Irish oncology community via ICORG (now Cancer Trials Ireland) were willing to engage and give us feedback on how ONCOassist could be improved to help them in their day-to-day lives as oncology clinicians.

IAN BOLLAND SAT DOWN WITH MICHAEL ANSTEY AND ROBERT TANSLEY, PARTNERS AT CAMBRIDGE INNOVATION CAPITAL (CIC), TO LEARN MORE ABOUT ITS INVOLVEMENT IN LOCAL LIFE SCIENCE COMPANIES, AND ITS STRATEGY FOR INVESTMENT.

PICK OF THE BUNCH

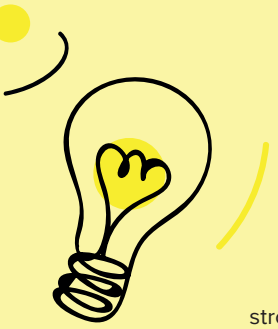
CIC is a venture capital firm driven by an initiative from the University of Cambridge. Though independent of the university, Anstey highlighted that the company is in a privileged position within the technology ecosystem in the area, and isn't just limited to life sciences, but described medical deVices, diagnostics, and therapeutics as a key pillar for CIC's investments.

Explaining more, Anstey said: "Our objectives and our goal is to provide growth capital to IP rich, knowledge intensive companies that have a direct link to the Cambridge ecosystem. That direct link could be a spin-out from the University but the other could be a company that has a meaningful presence in the Cambridge ecosystem.

"The common thread of all our companies is this knowledge-rich, IP-intensive nature of companies, but in terms of sectors we invest broadly. We invest in life sciences and healthcare companies, that of course includes therapeutics – both platform and single assets – but it also very much includes medical devices and diagnostics."

Though CIC is independent of the University, there is an element of interdependence. The University of Cambridge has a subsidiary called Cambridge Enterprise, and CIC works closely with the seed funding strand of the organisation, as it inherits the pre-emption, follow-on investment rights in university seed fund investments. CIC is provided with the right to co-invest with university seed funds and has access to information on university IP generation.

"We directly benefit from the investments that Cambridge



Enterprise does by taking on the pre-emption rights of the University in the follow-on rounds. The University's deal flow is incredibly strong and gets stronger every year. At the same time, Cambridge Enterprise looks to us for growth and for growth capital. This is not a situation where CIC is the only investor in Cambridge University spin-outs. We are one investor but often the lead investor, and often the catalyst to rounds that come together in these follow-on rounds."

There have been several success stories to emerge from CIC's investments in Cambridge affiliated companies – notably CMR Surgical following the development of its lightweight, versatile and flexible Versius surgical robotics system which is now competing with Intuititive's Da Vinci system. Sense Biodetection has also been able to launch a new class of diagnostic product – an instrument-free molecular test that combines the performance of laboratory testing with the benefits of disposable immunoassays. Pre-pandemic its focus was flu, but it managed to pivot its offering to COVID-19 following the outbreak, and is currently looking at entering other disease areas.

Tansley explains that CIC was set up to provide capital and support for companies to grow and fulfil their potential and acknowledged that medtech and diagnostics have not been able to traditionally attract the capital to compete on a global scale.

"The observation in Cambridge was there was a good seed fund, but there was that chasm of financing to actually be able to scale a company to become competitive globally.

"In the last seven or eight years we've invested over £200 million but our 32 companies have attracted over £1.5 billion of co-invest. So, how do we affect the wider organisation? I think part of it is crystallising the access to capital to allow earlier stage businesses to attract the capital they require for them to potentially grow. We're not the only investor but because we're on the ground and know the companies intimately, we're able to catalyse that additional investment which is required from these companies.

"The disadvantage that medtech and diagnostics have had could be because of factors including low levels of reimbursement in the U.S. and Europe in particular, and the requirement for companies to exit in order to access the sizeable distribution and marketing networks associated with large companies."

Tansley continues: "Often the distribution costs for medtech and diagnostics are huge and for small companies it is very difficult for them to build up the network to achieve it themselves therefore exits to larger companies is an important pathway.

"What we've seen is a consolidation of a number of large medtech companies, through M&As, so the potential number of medtech acquirers of new companies is reduced and that inevitably creates a buyers' market, which again suppresses the potential returns.

"CIC only focusses on products which are truly innovative, truly differentiated because I think that's the only way you will get that reimbursement and attract the attention of acquirers. I think that is the trend, it pushes everything towards innovation because you need to have that differentiated position.
"If we can do anything, and I wouldn't want to overstate our role in it, perhaps it would open people's eyes to their potential and if they have that ambition, share that ambition. We're not alone and we're just one element in that. It's just one small element but I think that we're ambitious and it feeds into our companies as well."

Anstey feels that CIC can also take a hands-on approach with companies and the diverse set of experiences within the firm allows them to provide advice to commercialise innovations, building upon the world-leading science behind the products within the ecosystem.

He added: "In my previous career I was advising multinational medtech companies on reimbursement, regulatory strategy, on going to market, on product launch. The reality is you can have a fantastic product but without thoughtful consideration of those very certain aspects it'll never succeed and there won't be a viable company there. Some of the value we do bring is helping companies navigate that path and prioritisation of reimbursement, regulatory pathway, go to market strategy and commercial launch."

CIC only focusses on products which are truly innovative, truly differentiated because I think that's the only way you will get that reimbursement and attract the attention of acquirers

THE GREAT ENABLER:

How packaging is aiding ophthalmic and combination product breakthroughs

Olivia Gebhart, segment marketing manager pharma, Amcor Flexibles, comments on recent innovations in the ophthalmologic space, and the role of packaging.

Whether it is using daily or frequent-replacement lenses, wearing contact lenses is an everyday routine for many. And it's easy to see why: they're simple, effective and provide a convenient method of vision correction without the hassle of eyeglasses. And they're only getting better. Today, innovations in corrective lenses, lenses that can treat dry eye, or lenses that can even treat astigmatism are all current viable options, and we continue to see regular developments in the space. Even though contact lens usage dropped slightly during the pandemic, advances in this area haven't slowed down. In fact, the attention that COVID-19 placed upon personal hygiene – in particular, handwashing and avoiding touching the face – is something that has always been a major topic for contact lens users and manufacturers but also for the primary packaging providers.

Eyes are one of the most sensitive parts of the human body - the human cornea is one of the most densely innervated tissues. This not only makes the eyes vulnerable to pain, but also to infection and other issues that can be caused by poor hygiene for example when using contact lenses. As a result, and already long before consumers need to exhibit good hygiene practices when putting in the contact lens, the packaging of the lens needs to ensure sterility so that users can feel confident and safe to use them.

How do manufacturers ensure sterility in contact lens packaging? Firstly, lenses are generally packaged in a plastic bowl sealed to a peelable lidding foil. After the manufacturing of the lens, placing it in the bowl, flushing with saline solution and sealing it with the flexible lidding material, the final airtight pack is being steam sterilised.

Sterilisation of the final contact lens blister pack is not easy. The lens itself as well as the primary packaging material – bowl and lidding - need to be able to withstand the steam sterilisation process without the functionality being compromised. For the primary packaging this means that its integrity is being kept until the point of use to ensure patient safety.

As there are new innovations coming to the market such as contact lenses that contain, in addition to their corrective features, also Active Pharmaceutical Ingredients (API), the demands to the packaging even increase. Beyond the ability to withstand steam sterilisation and thereby keeping excellent peel-properties for a hassle-free consumer experience, the primary packaging now also needs to ensure that the right level of API arrives at the point of use and that there is no migration or interaction between packaging material and the API.

One recent innovation in pharmaceutical packaging can answer to this new demand. It is a flexible film lidding solution, that can withstand steam sterilisation, also prevents drug uptake into the packaging as well as ensuring smooth peel-properties.

This development goes a long way in enabling further innovation for combination products, that consist of a medical device and an API, beyond contact lenses. It highlights the importance of close collaboration between drug and packaging manufacturer in particular in the development of combination devices, where many different factors may be interlinked. An early on collaboration can make all the difference in combining drug and material specific knowledge and ultimately leading to greater innovation and providing a better solution for patients and consumers.

REGULATION & APPLICATION:

BRINGING DEVICES TO MARKET

Rachel Fallon, CTO Sky Medical, outlines the challenges and regulatory hurdles faced when adopting medtech devices into global healthcare systems.

Transforming a technology into a compliant and commercially viable medical product is one of the biggest challenges in modern healthcare. Adopting medtech devices into different medical settings requires time, money, resources, data and – crucially – backing from clinicians within the system. Commercial success relies on companies managing collaboration between multiple critical business functions - including research and development, regulatory, manufacturing, and clinical - to deliver a solution that has regulatory approval for use on patients and delivers better clinical outcomes more cost effectively.

UNDERSTANDING THE MARKET

A commercially viable medical device needs to demonstrate both real-world clinical and economic evidence of success. In an ideal world, products need to deliver both a better outcome for patients and a more cost-effective solution for healthcare systems.

To provide the relevant levels of evidence required for regulatory approval is a long and complicated process. It relies on first demonstrating the validity of a medical concept, identifying the key clinicians that are likely to become early adopters of the technology and working with them to arrange studies that demonstrate the impact of the device on real life patients. Even when regulatory approvals have been achieved, companies must continue patient studies to ensure the ongoing validity of data. Bringing medical products to market is therefore a process that can take place over years. It relies on the goodwill of already overstretched clinicians to champion new ways of addressing medical issues, as well as rock solid evidence of positive patient outcomes.

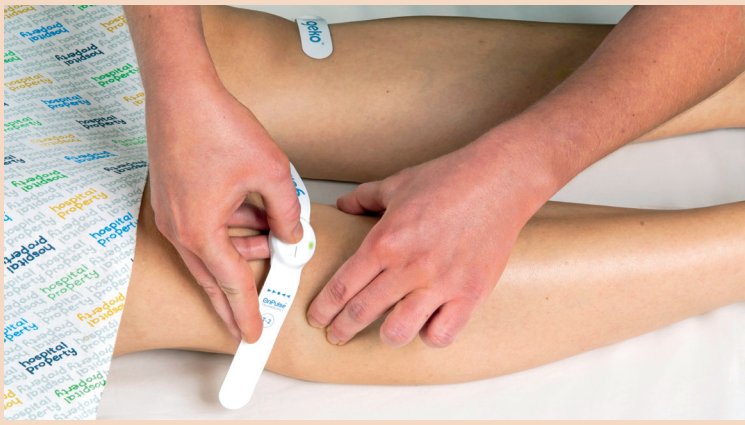
MULTIPLE APPLICATIONS – MULTIPLE STUDIES

Medtech devices can be particularly successful when applicable to multiple medical conditions – we call such devices 'platform technologies.' For example, Sky Medical's own geko device increases the rate of blood flow in patients with limited mobility for whatever reason. This has applications for patients in hospital (unable to move when recovering from operations) as well as for immobile patients in the home environment. The device is therefore potentially applicable to a range of conditions that can be improved through increased blood flow, such as VTE and chronic wound care.

These kinds of devices can be hugely beneficial for healthcare systems. The wider the possibilities of application, the more impact a device could potentially have. However, this does not mean the route to regulatory success is any less complicated or onerous.

NAVIGATING REGULATORY HURDLES

Every application for each different use needs to be considered as requiring its own patient data. Proving that a medtech device improves blood flow to address one medical condition is not applicable to other scenarios. Clinical and economic evidence is needed to support each different indication



where the device could be beneficial to the patient. Likewise regulatory approval will need to be achieved for each different clinical application.

For medtech devices that incorporate electronics and batteries, devices have a further complication of needing to comply with not only clinical regulation but also regulation around electrical safety, environmental legislation, and biocompatibility.

Because regulatory legislation varies from country to country, medtech companies also must consider that regulation will vary in every country. Additionally, the regulatory environment regularly changes.

HOW REGULATION CAN IMPACT MANUFACTURING

This can have a direct impact on the manufacturing, distribution and supply chain challenges that companies face; each country supplied may need specific regulatory compliance statements within or on the packaging. This makes it much harder to quickly shift stock from one country to another and may require additional investment in supplies. Excess stock can be a major cash drain, and this is further exacerbated because medtech companies need to ensure there is always a steady and reliable supply of devices to service the needs of patients.

For these reasons, close and regular communication between the commercial, finance and manufacturing teams is essential. This includes keeping a watch on lead times for product components and device assembly, together with a rolling sales forecast for product by territory. It is also clearly important to invest in the manufacturing process to ensure every device is high quality and reliable.

COLLABORATION LEADS TO SUCCESSFUL INNOVATION

Close collaboration ensures businesses can make informed decisions that will help to roll out medical devices across healthcare systems more successfully. Having a multi-disciplined team equipped with the relevant knowledge and collaboration skills across research and development, regulatory and manufacturing is a pre-requisite to bringing a device successfully to market. This is as much a communications challenge as a clinical one – if you can create an environment where business functions can collaborate, you will have a space built to encourage innovation.

> ***The wider the possibilities of application, the more impact a device could potentially have. However, this does not mean the route to regulatory success is any less complicated or onerous***

ARE REGULATIONS KEEPING PACE WITH FEMTECH?

Sophie McGrath, partner at Goodwin, considers if the regulations surrounding women's health and femtech devices are fit for purpose.

The women's health and wellness industry has expanded exponentially in recent years and is expected to be worth $65 billion by 2027. Driving this growth are companies focussed on developing technology aimed at addressing women's health and wellbeing across a range of areas, including reproductive, sexual, and mental health. These companies are often aimed at bridging the gender gap in women's healthcare, resulting from, among other things, the underrepresentation of women in clinical trials and research and the design of healthcare systems.

While the issues presented by the gender gap are not new, they have become a focal point because of the intersection of several economic, demographic and market factors. Demand has increased for products and services from women who are looking for optionality in their healthcare and demanding alternatives. This has coupled with a commercial awareness of the market size and its purchasing power, with women directing 83% of all consumption in the USA. As a result, venture capital investment has increased. In August 2021, following a $110 million series D funding round, Maven became the first women's health start-up to reach a valuation of over $1 billion. Women's healthcare is also increasingly a focus of government attention; earlier this year, the Department of Health and Social Care announced its intention to develop a new women's health strategy, requesting input from women to help create a set of priorities to put women back at the centre of their own health and wellbeing.

This shift in focus has intersected with a changing healthcare landscape increasingly concentrated on personalisation and digital healthcare solutions, exemplified by the growth and development of wearable technologies and the establishment of departments such as NHSX in 2019. COVID-19 has accelerated this progression towards digital, which necessitated a move towards remote healthcare through web-based applications during national lockdowns. The expansion of digital services has fuelled the growth of women's healthcare platforms and applications, which are often focussed on the provision of remote healthcare.

One critical factor to consider in the continued expansion of the women's health and wellness industry is the legal and regulatory framework in which these technologies are being developed. There is no separate regulatory regime for female-focussed technology and these developments therefore fall within frameworks applicable to remote access healthcare and medtech more generally. This raises the question of whether the existing regulatory environment can achieve the right balance between ensuring that women receive products and services that are safe and fit for purpose, while eliminating unnecessary or disproportionate obstacles to continued innovation in an underserved space.

In the USA, the growth of remote healthcare has faced regulatory obstacles resulting from restrictive and conflicting state laws in crucial areas. These restrictions have temporarily been waived because of the COVID-19 pandemic and the declaration of a public health emergency ("PHE") on 31 January 2020. This waiver has increased access to remote healthcare, which can be provided to new and existing patients via third party applications and has incentivised healthcare professionals participating in Medicare who can be reimbursed for remote services at the same rate as in-person visits. Alongside state-wide relaxations, remote health utilisation in the US has risen to levels 38 times higher than before the pandemic, allowing female-focussed companies in the remote healthcare space to grow and broaden their audience. While the PHE is a temporary measure and it is unclear if more permanent relaxations of existing regulation will be put in place, developments in this area will impact continued innovation and access in women's healthcare.

Innovation in Britain faces different legal challenges because of regulations that do not clearly reflect the new application-based digital environment. For example, the MHRA regulates technologies which are classified as a "medical device," which also covers web-based applications. The regulatory framework maintains a distinction between regulated devices or software that is intended to provide a diagnosis, control conception and/or which is used to administer medication and unregulated applications intended to monitor health and wellbeing or provide general advice. New female-focussed technologies may test the validity of these distinctions; for example, it is unclear whether an application that tracks a person's basal body temperature and is intended to facilitate conception will be subject to existing medical device regulation.

These are some of the potential pitfalls in existing legal and regulatory regimes and how these interact with the development of technology centred on women's healthcare solutions. A continued focus by lawmakers and regulators on women's health strategies in connection with increased collaboration with innovators and investors will ensure the industry's potential is maximised in the years to come.

UPDATING MESH MATERIAL:
THE TISSUE MATRIX

Tela Bio explains the alternative to mesh that can be used in hernia repair procedures.

With an estimated 20 million repaired each year worldwide, hernias are common and represent a major source of disability and morbidity in patients. Today, mesh is used in almost 90% of hernia procedures to prevent a recurrence. But it's the "how" and "with what material" used in hernia repair procedures that may mean the difference between a potential surgical complication and a smooth recovery. With healthcare resources already stretched thin due to COVID-19, it's critical that each patient and their provider select the right hernia reinforcement material, based on the patient's needs and clinical research.

PLASTIC MESH USED TODAY

A significant advancement in the surgical treatments of hernias came in the 1950s after the invention of a permanent synthetic polymer-based mesh. The reinforced strength provided by this advancement meant overall fewer revision surgeries. In fact, in a 2004 prospective, randomised controlled trial published in the Annals of Surgery, the authors demonstrated a 10-year cumulative incisional hernia recurrence rate of 63% for suture repairs with no mesh reinforcement and a 32% recurrence rate for repairs using permanent synthetic mesh. While permanent synthetic mesh materials have been used safely in most procedures over the years, the application of these types of mesh has been associated with serious complications, which include mesh contracture, adhesions, fistulae, and others. Many of these related complications can be attributed to the prolonged foreign body exposure inherent to the amount, density, and type of permanent synthetic polymer in the mesh implant. Despite these potential complications, surgeons continue to choose polymeric meshes for most hernia repairs due to long-standing clinical experience, their relatively low cost, and ability to withstand intra-abdominal wall pressures, helping to reduce the risk of reherniation.

LIMITATIONS OF BIOLOGIC MESH

Biologic materials are an alternative to synthetic materials due to their inherently lower inflammatory response and resilience, particularly for high-risk patients. Harvested from xenogeneic or allogeneic organs, the extracellular matrix (ECM) creates a scaffold for remodelling once processed to remove cells and DNA from the tissue. However, quality can vary, depending upon processing methods. In addition, while these materials show promise, unfortunately, they are expensive and due to the retention of the protein elastin, may weaken over time.

NEXT-GEN MATERIAL

If neither fully synthetic nor fully biologic meshes are ideal, what is the answer? A more recently developed material used in hernia repairs is a reinforced tissue matrix called OviTex.

The new material, consisting of polypropylene or polyglycolic acid polymer, interwoven within layers of xenograft tissue, has shown promise as a suitable alternative both preclinically and clinically.

OviTex Reinforced Tissue Matrix creates a three-dimensional scaffold, interweaving low levels of polymer suture throughout layers of ovine (sheep) forestomach (rumen)-derived ECM. This construction creates a permeable, tissue-based scaffold that allows fluids and cells to flow throughout the device enabling neovascularisation and functional tissue remodelling as demonstrated in multiple preclinical models. The polymer enhances the strength of the layers of biologic tissue providing overall compliance comparable to that of the human abdominal wall, which is critical in offloading tension of the sutured hernia repair during the acute healing phase.

Utilising input from over 100 general and plastic surgeons, OviTex's embroidered design of OviTex is interwoven through layers of biologic material in a "lockstitch" pattern, creating an embroidered construction. This offers a technology intended to surpass the performance of all existing hernia repair and abdominal wall reconstruction mesh products.

The biologic material in OviTex, derived from ovine rumen, serves as the natural building block, is optimised to reduce foreign body response, and enable functional tissue remodelling. The interwoven polymer fibres provide additional reinforcement, along with improved handling and load-sharing capability to support natural abdominal wall function. The polymer fibre is available in resorbable or permanent variations and comprises less than 5% of the final product.

OviTex Reinforced Tissue Matrix aims to combine the benefits of biologic material and polymer reinforcement to provide a more natural hernia repair.

Recently published in the journal Polymers, an early clinical assessment of OviTex Reinforced Tissue Matrix described a decrease in chronic postoperative inguinal pain, improvement of preoperative hiatal hernia symptoms, and a lower incidence of recurrence compared to use of synthetic mesh in a more challenging ventral hernia repair population.

THE FUTURE OF HERNIA REPAIR

Hernia mesh material is overdue for an update and now is the time for healthcare providers and patients to consider alternatives to long-standing hernia mesh options. While the healthcare system and resources have been stretched thin and overworked during the pandemic, it is critical that providers understand the drawbacks of plastic mesh and the limitations of biologics. Considering a next-gen hernia reinforcement material may help address patient concerns surrounding permanent synthetic mesh and decrease the foreign body exposure while facilitating functional tissue remodelling.

THE JOURNEY FROM 'ART TO PART'...

and how to avoid the many pitfalls

Graham Webster, director at Plastic-IT, discusses the injection moulding route on making a high-quality part for medical devices.

On the face of it, the process of injection moulding is apparently simple – make a mould, force some molten plastic into it and let it cool, open the mould and ship the product. However, those reading this will know that is an oversimplification – so how complex is it?

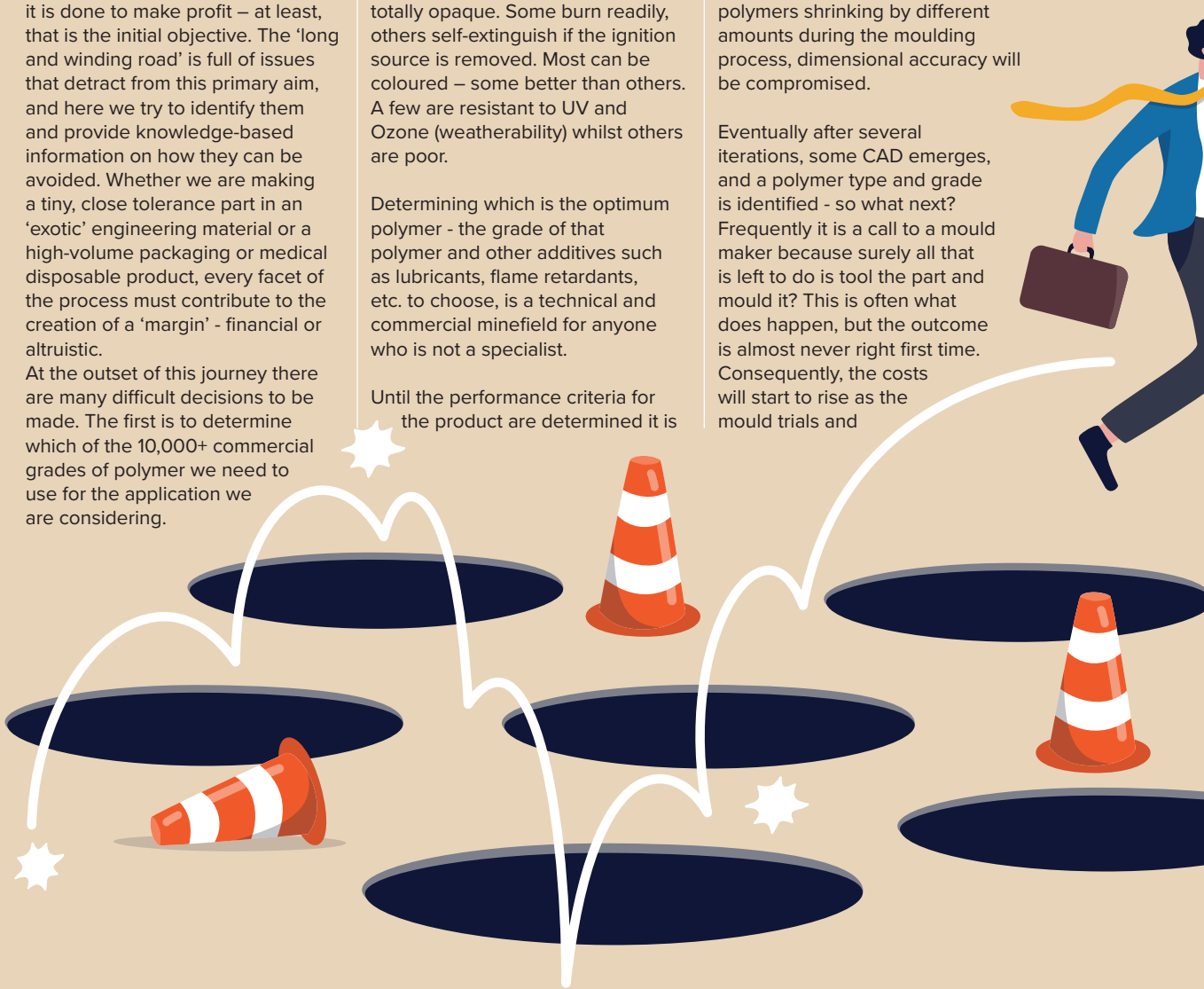
First let's look at why we use this process – which is now the largest manufacturing method in the world. The common denominator is that it is done to make profit – at least, that is the initial objective. The 'long and winding road' is full of issues that detract from this primary aim, and here we try to identify them and provide knowledge-based information on how they can be avoided. Whether we are making a tiny, close tolerance part in an 'exotic' engineering material or a high-volume packaging or medical disposable product, every facet of the process must contribute to the creation of a 'margin' - financial or altruistic.
At the outset of this journey there are many difficult decisions to be made. The first is to determine which of the 10,000+ commercial grades of polymer we need to use for the application we are considering.

All injection mouldable thermoplastics will melt at between roughly 90°C and 400°C so generally they can't compete with metals on a heat basis. Most are good as electrical insulators whereas metals are mostly good conductors. Thermoplastics may be very stiff especially when combined with reinforcing fibres of glass or carbon (19,000MPa - 60% Glass filled polyamide 6) or very flexible and even elastic. Some are completely transparent and others totally opaque. Some burn readily, others self-extinguish if the ignition source is removed. Most can be coloured – some better than others. A few are resistant to UV and Ozone (weatherability) whilst others are poor.

Determining which is the optimum polymer - the grade of that polymer and other additives such as lubricants, flame retardants, etc. to choose, is a technical and commercial minefield for anyone who is not a specialist.

Until the performance criteria for the product are determined it is impossible to specify the polymer type and grade. Consequently, designing the geometry of the part for its fit, function and aesthetics, must be done in concert with choosing the polymer. This should be the expertise area of the product designer but as has been illustrated, it is a complex task that few people can take on with certainty. Once a mould is made there is some opportunity to mould different materials for evaluation but due to the likelihood of these polymers shrinking by different amounts during the moulding process, dimensional accuracy will be compromised.

Eventually after several iterations, some CAD emerges, and a polymer type and grade is identified - so what next? Frequently it is a call to a mould maker because surely all that is left to do is tool the part and mould it? This is often what does happen, but the outcome is almost never right first time. Consequently, the costs will start to rise as the mould trials and



If you had a crystal ball that would tell you the six numbers in next Saturday's lottery, you would surely use it. CAE tools, expertly used, are just like crystal balls

subsequent mould rework cycle develops.

The better way is to prototype it. Today additive manufacturing can produce a 3D object direct from the CAD in a polymer something 'similar' to the injection moulded intention. However, it delivers little more from a production engineering perspective because at this point there has been no evaluation as to whether the geometry can be satisfactorily moulded. To do this we turn to a CAE moulding simulation product such as Moldflow.

In comes another knowledge-based technology that baffles the majority. You may be surprised to discover that the technology has been around for more than 40 years. In skilled hands it will simulate the total moulding process and determine the final sizes and shape of the part post moulding by using the CAD model and a very comprehensive data base of polymers. If you had a crystal ball that would tell you the six numbers in next Saturday's lottery, you would surely use it. CAE tools, expertly used, are just like crystal balls – telling you precisely how well the CAD would mould – without having to make a mould.

Due to the aforementioned complexity of developing a toolable geometry (that satisfies fit and function requirements in an economically viable polymer that can be moulded), NOT taking advantage of science-based

predictions from a CAE tools in 2021 is madness.

Frequently we see this application of CAE referred to as a DFM report whereas of course 'Design for Manufacturability' (DFM) is, by definition, a 'design process' and not an error checking process to be used just before steel is cut and performed by the mould maker.

For a moment let us revert to understanding the product development process. It is unlikely that the exact Widget that we are wanting to make as an injection moulded part has not been made before, so there can be no pre-existing knowledge of the detail of its manufacturability at the outset.

It is impractical to expect one person to be knowledgeable in so many diverse technologies, so it is best to be a collaborative process of teaming together experts in their field as early in the project's life as possible. Instead of this being a serial process, today with CAD, CAE and on-line meetings the iterative process of getting from Art to Part can now easily be a true team effort. The process must start from the product designer as it is normal here that the brief or requirement is distilled form the end user.

These are always 'fit and function' specifications and probably also aesthetic ones too. The minimisation of cost is also a pre-requisite. Today the process should be one of collaboration between the product designer, the materials expert, the tooling engineer, and the manufacturing engineer who also take data, advise, and feedback from CAE engineers who can evaluate strength, dimensional accuracy and mouldability. 30 years ago, the term "Concurrent Engineering' was coined; today it's called Concurrent Knowledge based Part Production or CKPP for short. It is a specific methodology following concurrent engineering concepts specifically for plastic injection moulding. When adopted, the outcome is parts right first time at optimum cost in the shortest time frame.

Shouldn't this be the methodology that you adopt on every project?

HOW THE AI IN HEALTH AND CARE AWARD HELPED TO ADVANCE ARRYTHMIA DIAGNOSES

Glyn Barnes, director of strategic marketing at iRhythm, reflects on the effect the AI in Health and Care Award has had on industry, the company itself, and patients.

n September 2020, iRhythm was named a winner of the AI in Health and Care Award (managed by the Accelerated Access Collaborative, in partnership with NHSX and the National Institute for Health Research), announced at London Tech Week by the then-health secretary Matt Hancock. Across four phases, £140 million of funding was made available for the AI Award. This supports both the financing of implementation of these novel technologies and the provision of educational support for clinicians. Our Zio XT service was selected in round one of the process and combines a wearable cardiac monitoring device with a proprietary AI algorithm to detect a range of arrhythmias. Continuous ECG data is collected by a small device worn by the patient, for up to fourteen days. This is then uploaded to our proprietary AI software to provide a fast and accurate assessment and ultimately, a patient report to help clinicians make a rapid diagnosis.

All recipients of funding from the AI In Health and Care Award will tell you the same thing – that it has enabled creative and innovative products to improve NHS workflows and patient outcomes throughout NHS England's healthcare system. Especially from a Zio XT perspective, the Award has enabled patients to have quicker but still accurate diagnoses while continuing to go about their day-to-day life with little disruption. This NHSX programme has fast-tracked the progress of Zio and many other novel technologies.

The AI Awards have given healthtech innovators the freedom to develop within the national healthcare space. One aim of the programme is to assist in the NHS' Long Term Plan to:

- Improve outcomes for cardiovascular patients by early detection and management of conditions such as atrial fibrillation (AF)

- Assist the ambition to expand virtual clinics and remote care, not only enabling efficient access to care for hard-to-reach patient populations, but also speeding-up the overall process of diagnosis and treatment.

To reach these objectives, iRhythm has been able to work with selected sites, including Barts Health NHS Trust in London, East Kent Hospitals University NHS Foundation Trust, Liverpool Heart and Chest Hospital (LHCH), Gloucester Hospital, University Hospital Southampton NHS Foundation Trust and North Bristol NHS Trust. The award has supported the implementation of Zio and ensured secondary care systems can take advantage of the benefits the service presents. One of the most significant results of the Zio service is the dramatic reduction in waiting lists for ambulatory ECG testing. Furthermore, sites are also seeing a significant reduction in more costly procedures such as implantable loop recorders which typically cost around £1,500 per patient.

Not only has the AI Award given the selected healthtech innovators the ability to establish themselves within the sector, but it is also providing technologies that enable patients to be seen and/or monitored more quickly and therefore, diagnosed, and treated more quickly than before. This will lead to an improvement in outcomes. Without receiving funding from the AI in Health and Care Award, the introduction of these new technologies would have taken significantly longer, and some may not have reached the patient at all. Undoubtedly, the backlog of patients waiting to receive urgent care is one of the greatest challenges facing the UK's National Health Service.

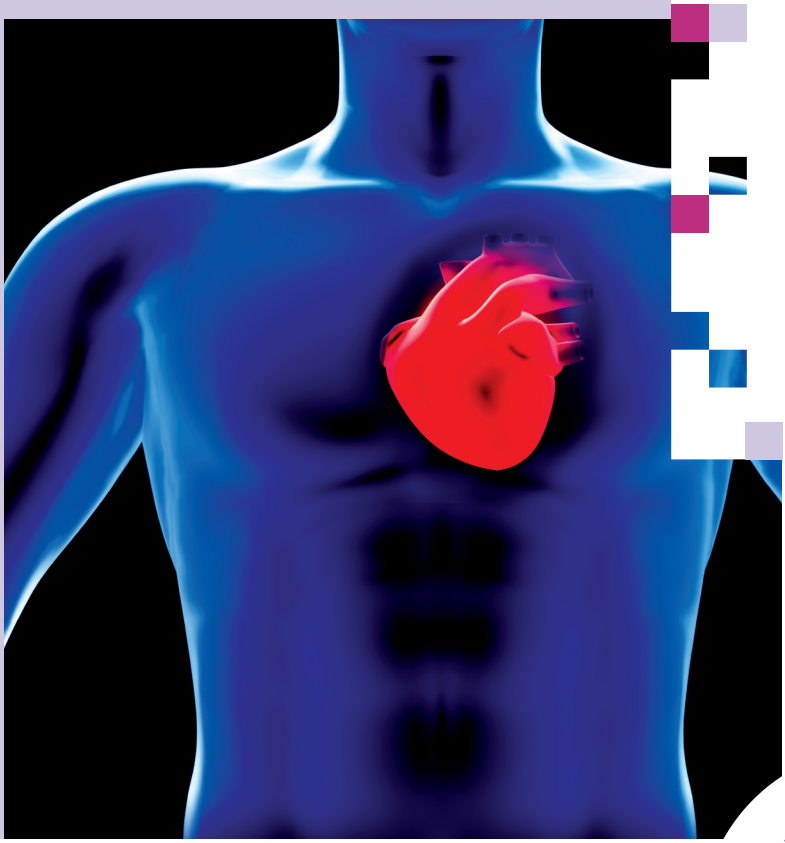
The funding from the AI Awards has meant that we in iRhythm have the necessary resources to help establish Zio XT as the leading light in this particular niche. The new health secretary Sajid Javid warned in July that hospital waiting lists could reach 13 million in the coming months, so technology such as ours will play a big part in combating that concern. For example, initial outcomes have shown that the introduction of Zio XT at Liverpool Heart and Chest Hospital helped to reduce patient waiting times from approximately eight weeks, to around one in a very short space of time.

Reflecting on the impact of Zio, Tony Shannon, non-invasive lead cardiac physiologist at LHCH, said: "Without the assistance of iRhythm and the funding it received via the AI Awards, the pandemic could well have resulted in further increased waiting lists at LHCH, anywhere up to 20 weeks."

We would recommend any healthtech company that is looking to make an impact in the NHS landscape and develop into a widely adopted provider of healthcare solutions, should apply for round four funding via the AI in Health and Care Award, which will open in 2022.

Without a doubt, the UK is home to some of the most cutting-edge and life-changing medical devices. This is, in-part, thanks to the NHS' commitment to become a world leader in the use of AI and machine learning. During the pandemic, the NHS showed that innovative technologies could improve services for the better, in a speedy yet safe manner.

The Award has – and will continue to – ensure that companies can accelerate their innovations, and potentially not have to wait many years to move from clinical trials to widespread adoption.



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TOO MUCH TOO SOON

Chris Froud and **Alexander Ford** senior associates and patent attorneys at European intellectual property firm, Withers & Rogers, explain why there is such a thing as filing IP and patent applications too early.

Companies are often advised to file patent applications at an early stage to prevent competitors from copying their inventions and beating them to market. However, those developing solutions specifically for medical applications, such as surgical robots, could lose years of market exclusivity by taking this approach. Instead, they should learn lessons from drug developers and adapt their intellectual property (IP) strategy accordingly.

It's rare to find an area of medicine that doesn't use technology for something. As advancements are made, more innovations are being introduced to the field, such as a growing use of surgical robots.

In robotically assisted surgery, rather than applying surgical tools directly to a patient by hand in the traditional manner, a surgeon directs a surgical robot to carry out the procedure. The surgeon uses a remote manipulator or computer control to guide surgical tools held by the robot's end effector, which carries out the procedure. By improving stability and precision, these robots reduce the chance of human error during challenging surgeries and are less invasive than traditional open surgery.

The first procedure assisted by a surgical robot was carried out in 1985. However, it wasn't until 2000, when Intuitive Surgical launched the Da Vinci Surgical System, that this technology became more mainstream. For years, Intuitive were the market leaders in this field, but recently new players have entered the space, such as CMR Surgical, the creator of the Versius minimal access suturing tool. Although the company is a relative newcomer in this field, it is making a big impact in the UK.

The more common robot-assisted surgery becomes, the more innovation activity is likely to take place. R&D activity in this field is growing rapidly, which means innovators would normally seek patent protection at an early stage to secure their slice of the market. Usually, this approach would be recommended by IP professionals, however it might not be the best choice for medtech innovators.

In pharmaceuticals, achieving market and regulatory approval for new drugs can take up to 20 years, so it's possible for a patent to have expired before the product is ready to go to market. As such, drug developers would typically keep their innovations secret for as long as possible. With this approach, they can maximise the period of exclusivity during which they can commercialise their innovations once the drugs are approved and market ready. Medtech innovators should consider doing likewise.

Surgical robots must also complete an approval process before they are introduced to the mainstream market, which can take several years. As patents provide 20 years of exclusivity, this could mean the patent is only useful for a portion of its lifetime if it is granted while the product is still going through the approval process. In some cases, it could even be about to expire by the time that the product reaches peak sales, opening the door for competitors. Pharmaceutical innovators have the option of supplementary protection certificates (SPCs), which extend the life of the patent beyond 20 years, but this is currently not the case for medtech companies.

Rather than filing for a patent as soon as the idea is formed, medtech innovators should consider keeping the invention a trade secret while the approval process is ongoing. While there are risks attached, this approach should ensure that information regarding the product is protected throughout the approval process and could help to optimise the commercial rewards that might result when the product is brought to market. If the approval process for a new product takes three years, and a patent is filed on completion, the innovator will have a total of 23 years of exclusivity to make the most of.

It is also important to consider that patents contain a wealth of technical detail that is made public once they are allowed to publish. If an innovator files for a patent on their surgical robot, and then market and regulatory approval is denied after the patent has published, all this technical detail will be out in the public domain for competitors to take advantage of. Once the innovation has been refined and is ready for the approval process again, the original patent may no longer cover the refined product. Although the patent can be revised, it may not be as broad as if it was filed after approval, leaving the innovator in a weaker position commercially.

Choosing not to file for patent protection at an early stage does come with the risk of someone else developing the same innovation and filing first. For medtech innovators, IP strategies need careful consideration - balancing the complexities of a crowded marketplace with making the most of any commercial benefits.

AUTOMATING THE FIXTURING PROCESS

Mike G John CEng IMechE, head of engineering at industrial metrology supplier The Sempre Group, explains the importance of fixtures in the medical device industry.

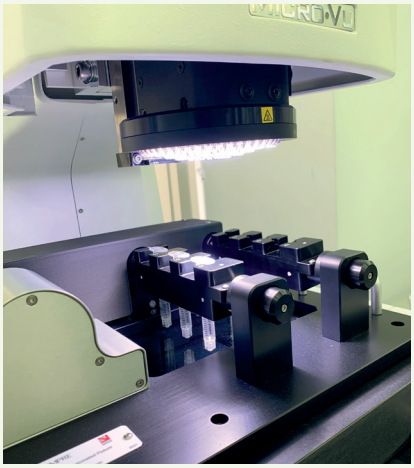
According to the McKinsey Center for Government, a medical device manufacturer experiences an average 10% drop in share price after a single, major product recall event. Remaining compliant is key to avoiding recalls, so providing ridged support during medical device quality testing stops unwanted movement and ensures testing is compliant.

The importance of fixtures can't be overstated, and neither can the benefits delivered by automated metrology, which can remove thousands of manual interventions from even a simple manufacturing process. This produces significant cash savings and allows operators to focus on more profitable tasks.

Medical device manufacturers understand the importance of a reliable manufacturing process, which is fully compliant with industry regulations, such as the biocompatibility regulation ISO 10993. Naturally, this compliance must include the fixtures that secure the components during quality testing to ensure ISO/IEC 17025, which requires competent testing and calibration, throughout the whole manufacturing process.

When measuring small, intricate components, Original Equipment Manufacturers (OEMs) get the most accurate results quickly when the part under inspection is secured. Fixtures, for example, are key when inspecting medical components because they provide 360-degree access and keep them in place without exerting too much pressure and damaging the part. This is particularly important when using a touch probe as it requires access to all areas of the component for visual inspection and internal tactile probing.

These fixtures must also have an operator friendly design, especially in the medical industry, so parts can only be secured in one specific way, using methods like 'Poka-Yoke'. These techniques can guarantee the measurements of components conform to the same standard as when it was qualified.



CHOOSING A FIXTURE

OEMs have two choices of fixture, static or automated. Manual fixtures require operators to physically turn the fixture between each measurement, which can be a very time-intensive process. Both techniques have their place, but automated fixturing can deliver considerable benefits where it is suitable.

Consider the example of a medical device manufacturer making vials. The manufacturer uses a static fixture with four fixtures or 'spars', which require turning individually three times each measurement cycle. As a result, the operator must make twelve actions to complete one batch.

The manufacturer plans to run ten different batches, so the operators must carry out 120 operations to complete quality testing. The time-intensive process is intensified further when the manufacturer produces ten different vials that require individual quality testing, creating 1,200 actions for the operator. Ultimately, the manufacturer must employ more operators to fulfil the manual requirements of testing and avoid bottlenecks during production.

Fortunately, automated fixtures take out the time-consuming process of manually turning the spar between measurements. The automated fixture integrates a high precision rotary indexer that automatically turns the parts. The operator does not have to wait for the measurements to take place, so can carry out jobs that require human intervention, such as data analysis.

BESPOKE FIXTURING SOLUTIONS

Manufacturers will not always be able to find an off-the-shelf solution that suits their application. If the part has a complex geometry, like a hip joint, it can become unstable in a standard modular fixturing system, which will alter the accuracy of the measurement.

In these circumstances OEMs can work with a fixturing provider to create a bespoke solution that securely holds the part, reducing the risk of human error and improving accuracy. A specialist fixturing provider can also create bespoke solutions to ensure the process is compliant with medical regulations. Sourcing external expertise provides manufacturers with the R&D, testing and production skills that avoid the risk and time-consuming process of designing the fixtures in-house.

Creating a bespoke automated fixture is only a small part of the metrology process. OEMs can further reduce lead times installing robotic arms to pick and place medical parts on the fixture, further removing the need for manual intervention.

Metrology providers can also integrate automated SPC software with the fixturing process to automatically measure the part and store the data in a single, centralised data collection point. Engineers can review real-time data at any point in the production process and analyse it to prove compliance and accuracy. The software also automatically produces first article inspection (FAI) reports at the click of a button that manufacturers can share with stakeholders.

Contacting a metrology one stop shop allows OEMs to have an end-to-end turnkey solution to their metrology process. Metrology providers can assess quality testing needs and make recommendations, create the required fixtures, validate the parts based off industry regulations and deliver, calibrate, and install the technology and software.

Medical components must be vigorously inspected to avoid recalls and ensure medical device companies have reliable components.

A quicker ROAD TO RECOVERY

Dave Walsha, sales manager at precision drive system supplier EMS, looks at how micromotors are advancing rehabilitation equipment.

According to the World Health Organisation (WHO), over two billion people are living with a health condition that benefits from rehabilitation. Innovations in rehabilitation engineering are giving patients with once debilitating health conditions independence and higher quality of life.

The process can include helping patients find ways to improve how they move around, such as through physiotherapy, altering their environment and supporting them with mobility aids.

Mobility aids such as wheelchairs, lifts and prosthetics provide patients with support and assistance that allows them to perform activities they would otherwise be unable to. For instance, a stair lift can enable a patient with arthritis to ascend and descend stairs, thus allowing them to live in a house with multiple floors.

To attain the force needed to physically support a patient, many mobility aids are driven by powerful, high precision micromotors, with powered prosthetics and exoskeletons at the forefront of rehabilitation engineering.

PRECISION PROSTHETICS

The earliest practical prosthesis discovered is a wooden toe from Egypt, which is around 3,000 years old. Prosthetics have come a long way since then, now being made from advanced materials, such as carbon fibre, and some even being robotic. Thanks to advances in engineering, over 45,000 people in England are benefiting from lower limb prosthetics alone.

Prosthetics need several qualities to perform as closely as possible to natural limbs. If the prosthetic is robotic, it must be lightweight to reduce strain for the user and to provide greater comfort for the wearing body part.

It's important that the powering motors are small to avoid making the prosthetic bulky, allowing it to perform agile movements and look closer to the typical human form. It also helps the prosthetic limb fit into smaller spaces, such as when reaching for an item in a full kitchen cupboard.

The motorised prosthetic must perform with precision and variable functionality. For example, the same limb must be able to forcefully pull open a door or hold an egg securely without cracking it. The motors must be highly accurate to ensure the prosthetic executes its actions correctly, such as pressing a lift button on target. It's also important that the powering motors are quiet, so the prosthetic remains relatively inconspicuous, and the user isn't constantly disturbed by unnecessary noise.

EXCEPTIONAL EXOSKELETONS

However, motorised wearable devices are not just for those who require a prosthetic limb. For patients who have lost mobility due to a spinal cord injury, rehabilitation exoskeletons can be a revolutionary part of their recovery process.
While wheelchairs provide patients with increased mobility, independence, and quality of life, they do have some drawbacks. For instance, patients who spend long periods in a wheelchair in the same position can develop other health conditions, such as osteoarthritis and pressure ulcers.

Because of these issues, physiotherapy is required to keep the body moving, but typically relies on the support of multiple healthcare professionals, crutches, and a treadmill, and is a difficult process for all involved. Rehabilitation exoskeletons offer an alternative to get the patient moving, and offer greater independence, mobility and quality of life benefits than using a wheelchair alone.

Many exoskeletons can be fitted and operated entirely by the patient. The patient's body is strapped into the exoskeleton, which has a series of sensors and motors to coordinate movement, with a powering battery pack worn on the patient's back. Some models also require the use of crutches, whereas others do not.

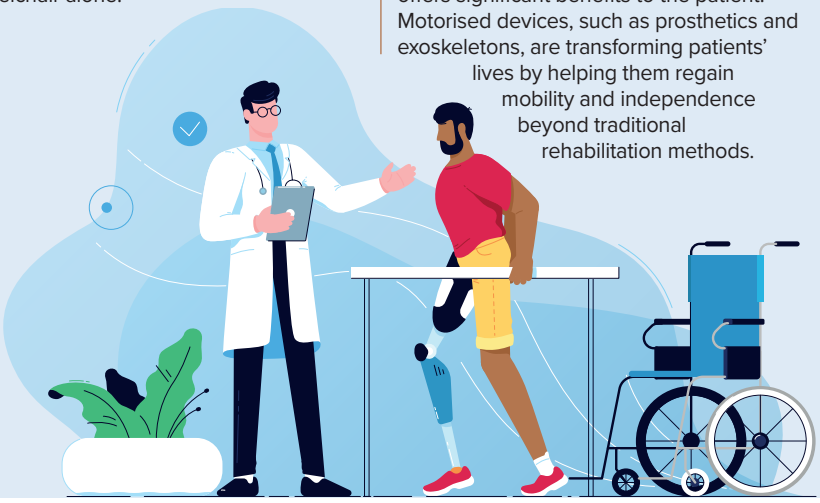
The motors are a crucial element of a rehabilitation exoskeleton, being responsible for driving the patient's movements and supporting their gait. The motor systems must be precise to replicate human movement and offer the optimal amount of torque and motion control.

Fine speed control is vital in exoskeleton systems to ensure the user can perform a variety of movements, from walking at pace to carefully navigating a steep incline. Being able to work under load is also important for tasks such as descending a staircase or sitting down.

ADVANCED ENGINEERING

Design engineers must select high performance, reliable motors that meet the demands of rehabilitation equipment. EMS is the sole UK supplier of FAULHABER motors, which are all made in a precision manufacturing process. The FAULHABER BXT series, used for rehabilitation equipment, has a flat construction which helps keep prosthetics and exoskeletons streamlined in design.

Rehabilitation is a demanding process but offers significant benefits to the patient. Motorised devices, such as prosthetics and exoskeletons, are transforming patients' lives by helping them regain mobility and independence beyond traditional rehabilitation methods.



MEET THE STARTUP:

PITCH PERFECT:

GIVING THE BEST START IN LIFE

After winning Pitch@Med-Tech Innovation Expo, **James Carpenter**, CEO of SurePulse, gave us his reaction, and told us a little bit more about his company.

First, congratulations on winning Pitch@Med-Tech Innovation – without sounding too cliched, how did it feel?
It was great - it's always gratifying and a huge honour to win an award. I felt proud for the whole team who are working away behind the scenes so hard and have had to face some real challenges over the past couple of years. Also, I was delighted that the judges picked up on what is the essence of our vision at SurePulse, the importance of innovation from the very first moments of a baby's life when every second counts. That sort of feedback really energises me and makes me want to get back to work to continue trying to make a difference!

Give us a broad overview of SurePulse, where did the idea behind the company come from?
SurePulse was born out of a collaboration between the Faculties of Engineering and Medicine at the University of Nottingham. The technology was originally being developed for monitoring the heart rate of miners working underground, and one of the Nottingham neonatologists happened to see it in a presentation and said that such a wireless approach might be very useful for the Delivery Room. Our vision to improve vital signs monitoring for newborn babies was established and then followed several years of technology and product development and clinical trials. SurePulse was spun-out of the University in 2014.

You outlined in your presentation about the potential errors in correctly identifying and recording vital signs in newborns. Tell us more about how your product range addresses those challenges?
Existing vital sign monitoring solutions do not meet clinicians' satisfaction in the Delivery Room. They are often not accurate enough or quick enough in providing a reliable heart rate, and this means that newborn babies can be over-treated (if the assessed heart rate is lower than the actual heart rate) or under-treated (if the assessed heart rate is higher than the actual heart rate). Either can result in clinical interventions that are inappropriate and can result in the baby needing to stay in hospital for longer than necessary or, sometimes even harm to the baby.

This is for a variety of reasons. Pulse oximeters are positioned on the wrist or ankle where perfusion (blood flow) is compromised, and so take a while for a heart rate to be shown; ECG is the 'gold standard' for heart rate monitoring in newborn babies and usually performs well (when available), however electrodes are fiddly to apply to wet vernix-covered skin, and can cause delays if they fall off, and occasionally in preterm babies with fragile skin there can cause skin damage; the stethoscope is the fall-back in most situations in hospitals across the UK and heart rate assessment using the stethoscope has been shown to be fairly unreliable in the resuscitation of newborn babies as it relies on mental calculations in a highly stressful environment.

SurePulse's patented optical sensor is integrated into a soft cap which can be rapidly applied to the baby's head at birth (preterm babies will usually have a wooly cap put on anyway to keep them warm). This positions the sensor on the forehead where blood perfusion is maintained, even during physiological compromise. These advantages enable SurePulse to provide a fast and accurate heart-rate signal wirelessly, giving clinicians and healthcare providers the right information at the right time, when every second counts.

I was delighted that the judges picked up on what is the essence of our vision at SurePulse, the importance of innovation from the very first moments of a baby's life when every second counts

How does your product cater for babies of different sizes? Particularly with a premature birth who would be smaller than a baby born at full term?
The caps come in five sizes and will fit babies from about 24 weeks gestational age (full-term is 37 weeks) to 42 weeks gestational age. Feedback from parents, midwives and nurses is fantastic about the caps - the design means that they are easy to put on, very comfortable for the baby and keep them warm (this is something that was validated in one of the clinical trials). Also, there is less waste potential for the NHS - the materials that we use for the SurePulse Cap means that we have reduced the size range to five. Many other medical hats for newborns have 12 or more different sizes.

Give our readers an idea of your presence in the medical setting in the UK?
As well as on-going clinical trial work at the Nottingham University Hospitals NHS Trust, we are now conducting a large-scale beta trial at Manchester University Hospitals NHS Foundation Trust, one of the largest trusts in the UK. We are also anticipating expanding this to two more NHS hospitals in the next month.

Tell us about the future. What else is coming down the track in terms of products and the business itself?
We've just received our FDA 510(k) clearance for the US market which is really exciting. The US is the world's largest healthcare market and has a huge population and 3.8 million births every year (it's about 750,000 in the UK). We are currently meeting with potential importers, distributors, and sales channel providers as well as neonatologists in the US to establish our first clinical sites. With CE and FDA approval under our belt we have major commercial opportunities in Europe and the US to realise over the next few years and alongside that, we are developing future vital signs monitoring solutions and clinical trials are due to start next year.

Opening the book:

How genome sequencing aids newborn screening

Ian Bolland caught up with **Chris Hughes**, managing director UK & Ireland of PerkinElmer, to discuss how its genome sequencing technology is used in newborn babies.

Many parents will be familiar with the heal prick test following a child's birth and there is a good chance that PerkinElmer's technology has been behind it. Newborn screening is currently based on biochemical testing on the instruction of a healthcare professional as a dry blood spot is analysed.

Hughes described the biochemical testing and genome sequencing done on newborns as "opening the book" on the child that is being screened.

Currently, in the UK, PerkinElmer's sequencing performs nine different tests:

- sickle cell disease (SCD)
- cystic fibrosis (CF)
- congenital hypothyroidism (CHT)
- phenylketonuria (PKU)
- medium-chain acyl-CoA dehydrogenase deficiency (MCADD)
- maple syrup urine disease (MSUD)
- isovaleric acidaemia (IVA)
- glutaric aciduria type 1 (GA1)
- homocystinuria (HCU)

The current criteria followed by the UK for screening conditions is based on the stipulations of the Wilson and Jungner criteria advocated by the World Health Organisation (WHO), amongst which include: the condition should be adequately understood; there should be facilities for diagnosis and treatment available; and clinical management of the condition should be optimised in all healthcare providers. The number of conditions screened for varies per country (and follow different criteria) but PerkinElmer's newborn screening solutions can identify more than 50 congenital disorders.

Whole genome sequencing, on the other hand, offers an additional layer of screening to test for a wide range of genetic markers for several rare and otherwise difficult to detect disorders.

Explaining PerkinElmer's process, Hughes said: "Blood spots are very robust, it's something that Perkin Elmer is very good at, but we are the people who are best placed to sequence from their dry blood spot because it isn't as easy as it sounds. Most people will be going for saliva or DNA extracted from blood.

"First, we need to extract the DNA from the sample, so we've got an instrument there called chemagens, essentially a sample comes into an instrument, uses magnetic beads to suck the DNA onto these magnetic beads and bind them to them."

From there magnetic rods take the beads out of the sample and within the same instrument it is washed several times just to increase the quality of the sample you've got. After extracting the DNA out of the sample needs to be prepared for sequencing.

Hughes continues: "We have a kit of, essentially, a suite of reagents which will chop the DNA up into the fragments you need for sequencing and the liquid handling.

"Once it's prepared, we've got instruments which are checking for the amount of DNA, something that we call victor nivo, and then the quality of the DNA you've got. Sequencing is the most expensive part of the process, so you want to make sure that you've got enough of it and what you do have is of high quality."

"From there we are going into the sequencer, which is owned by

sequencing company Illuminar, and PerkinElmer operates its pieces of equipment, essentially at the end of the lab process. The data has tellers using artificial intelligence and machine learning to interpret the data, but this is done under the supervision of the human eye so anything that comes about matches with the clinical presentation."

With individuals becoming more accustomed to testing at home throughout the pandemic, Hughes feels that this genome sequencing technology feeds into the idea of the strategy towards public health coming from a more preventative angle to battling certain diseases and conditions, rather than reactive – and cites the example seen in professional football in recent years.

"You've got a population now that's used to the idea of diagnostic testing because I don't know how many COVID tests that you've had but many will have multiple for their children as well. The whole point of whole genome sequencing is you get all the information, so you can be screened for diseases not that we'd just be looking for at point of birth.

"You're probably familiar with Fabrice Muamba, and other people who have collapsed on football pitches, that's a genetically inherited heart condition. Essentially if we screen the population for that we'd have less incidents where seemingly healthy people can have real problems out of the blue."

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