BIÇAKCILAR
Touching Lives One Device at a Time

MARKETWATCH

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In this issue…Industry In Brief

May 28, 2018

Singapore to change law to enable better access to medical devices

The Health Sciences Authority (HSA) of Singapore has revealed plans to upgrade its regulatory legislation in order to ensure improved access to select low-risk medical devices (MDs) and standalone mobile applications. The authority also intends to offer more clarity on current policies and requirements for telehealth and high-risk devices involving changes to appearance or anatomy.

To be effective from 1 June 2018, the enhancements target various operational and emerging business models in the industry. They are intended to enable access and innovations as well as protect the health and safety of patients. “The Health Sciences Authority of Singapore expects that by reducing the time-to-market, consumer access to lower risk medical devices will be faster.”

Messe Stuttgart confirms new medical show as Medtec Europe heads to Nuremberg

Following news that UBM is combining its Medtec Europe event with MT-Connect, and re-locating to Nuremberg in 2019, previous host Messe Stuttgart has announced the launch of T4M. The new trade show will take place from 7 to 9 May 2019 at Messe Stuttgart.

What’s so smart about medical device packaging?

The group has been working on a new concept which would use audio messaging to communicate instructions – with the prompts being triggered by touch-sensitive paper technology. The group says that there’s a real clinical need for this, because poorly understood instructions can lead to drugs and devices being misused, potentially endangering the patient. ntelligent ink has certainly seen increasing usage in medical applications, but I expect that the coming years will propel advanced printed electronics to the fore of medical device packaging. It’s happening already. The August Faller Group for example recently announced a prototype of a ‘counting device’ – a folding carton for medicine which uses an e-paper display and electronic controls. The user just has to press a button on the display each time he/she takes a pill, and the packaging can track their dose. Another prototype from the firm, currently just called ‘Medical Prescription’ keeps track of the amount of pills and connects to a smartphone app via bluetooth, which in turn sends the signal to order a repeat prescription. All of this is great news for medical device manufacturers. Smart packaging creates added value in the form of a closer bond with the patient – a rapidly emerging trend in the age of digital health. But smart packaging is not without a couple of significant drawbacks. Predictably, cost is the main one. Added value is all well and good, but if it can’t be achieved cheaply, it adds cost that some won’t be able to afford. What’s more, smart packaging, as it evolves, will likely incorporate more and more elements, with increasing levels of functionality being added in. This means more components, more adhesives, more inks – all of which detract from the green credentials of the packaging in question. It’s not a huge problem at the moment – printed electronics don’t currently add too much foreign material into the waste stream. But it’s a key thing to consider as our ideas about smart packaging continue to evolve.

In this issue… Eight ways that industry 4.0 is impacting medical device manufacturers

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1 – **Reducing errors-** Industry 4.0 technologies can be implemented across the whole manufacturing process, but quality control is perhaps the step with the most potential for improvement. Using sensor technology, manufacturers can quickly identify the source of the problem, and thus reduce unplanned downtime.

2 – **Monitor and improve performance-** Predictive maintenance technologies can save time and avoid costly breakdowns in the long term – all from a one-off investment in technology. Algorithms and machine learning, such as those used by GE's Brilliant Manufacturing software, can now anticipate when – and why – a machine is likely to fail. Jennifer Bennett, general manager for GE Digital's manufacturing software initiatives explained: "Manufacturers are challenged to decide what to build, how to build it, where and when to build it, and how to efficiently maintain it. We believe that the key to optimising the full product life cycle from design to service is through analytics of data that has been traditionally locked inside corporate silos."

3 – **Go paperless-**Going paperless could signal an improvement in regulatory conformance. Robert Kavanagh, business development executive at Irish medical device manufacturing specialist Seabrook Technology says: "Taking a look at the recent FDA figures on Non-Compliance Observations, it is clear that production and process controls are a key source of issues. In our experience, over 50% of non conformances are a result of errors on paper, rather than problems with the product."

4 – **Track and trace-** Raumedic is one of the major players in the medical device field to take steps towards going digital with its manufacturing systems. Last year the group selected software provider Guardus Solutions to design a new manufacturing execution system (MES) for its existing machinery as well as future investments. As a result, products from Raumedic can be tracked all the way back to the raw material and can also be cross-linked, managed and documented from the time of their development to their delivery.

5 – **Bolder designs-**Design trends like miniaturisation create opportunities for the medical device sector – but they also create challenges for manufacturers. Using advanced scanning and technology processes, manufacturers can produce more complex and intricate designs.

6 – **Inventory control -**Industry 4.0 may be capable of increasing outputs – but more output means more raw materials and supplies coming into the plant. Luckily, technology could hold the key to this as well. Gelston Howell, senior vice president, marketing at medical device manufacturer Sanmina says: In the past, managing inventory was manually transacted in an enterprise resource planning system, such as Oracle or SAP. With the implementation of industry 4.0 technologies and the use of machine-to-cloud communication, inventory management has moved from manual to automatic transactions, enabling real-time inventory control.

7 – **Customisation-** Personalised medicine could be a game-changer in healthcare delivery – but it will have an impact on those manufacturers who aren't geared up to deliver on the promise. 3D printing is one option, but older manufacturing methods can also be adapted with advanced product lifecycle management (PLM) software. For example, Siemens now offers a PLM platform that creates an automated image to implant process.

8 – **Scalability -** Adopting Industry 4.0 tech can help future-proof OEMs for future expansion. B. Braun Medical recently made the switch to a digital manufacturing system. Francisco Almada Lobo, CEO of critical manufacturing said of the move: "Critical manufacturing is committed to B. Braun's success, both in our project execution approach and our flexibility to meet all of their long-term needs. We will use a joint project team to configure our system and build the competence to maintain it for the foreseeable future. We are confident that we will help B. Braun Medical Industries become a global benchmark for advanced and innovative medical manufacturing."

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Reprocessed single-use devices forecast for growth

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New research from Coherent Market Insights has found that single-use medical device reprocessing is gaining in popularity as it helps to reduce hospital waste and allows for major cost savings.

For instance, US healthcare provider Kaiser Permanente reportedly saves $11 million per annum by reprocessing certain single-use devices. Non-profit environmental group Practice Green Health, is quoted as saying that single-use medical device reprocessing prevented the entry of 10,000 tonnes of medical waste into the waste stream from 1997–2007, via the re-processing of an estimated 50 million devices.

Coherent's research states that hospitals potentially stand to reduce the cost associated with medical devices by 50%.

However the findings report that the Asia Pacific, Europe and South America regions have historically been lacking in regulatory standards, which is a restraining factor for the growth of the reprocessing market.

The European Union is looking to address the matter, however, and the upcoming European medical device regulations (MDR) set out the minimum requirements for the reprocessing of single-use medical devices. According to a fact sheet issued by the European Union, under the new rules reprocessing may only take place when authorised under national law and in accordance with the provisions of the medical devices regulation.

When reprocessing is allowed, the entity that wants to reprocess the device must assume the same obligations as a manufacturer. However, a different regime is applied in the case of reprocessing by health institutions and by third parties on the request of health institutions.

Making EIT's (European Institute of Innovation and Technology) wildcard initiative work

Thomas Prock, partner at Marks and Clerk, looks at the EU's new 'wildcard' initiative, which will back high-risk medical device ideas.

Certain health problems bring with them a level of risk and complexity that can make investment in their solutions difficult. These problems require blue sky thinking and public/private cooperation. In a similar vein EIT Health, an offshoot of the European Institute of Innovation and Technology, recently announced that it would make €4 million of funding available for 'wildcard' medtech ideas which utilise emerging technologies like AI and big data or tackle urgent health challenges including antimicrobial resistance.

So, what can medtech innovators and entrepreneurs do to make wildcard ideas and inventions investable?

Underpinning all successful innovation is intellectual property (IP). IP takes many forms, ranging from the well-known such as patents and trade marks, to the less well known, such as know-how and database rights. One thing investors will be looking for when considering the potential of a new product, will be reassurance that those behind the product have a developed sense of how their IP portfolio and strategy will continue to support the business as it develops. The strategic use of IP protection can give a company a competitive edge, helping de-risk the business in the eyes of investors. IP will also prevent third party imitation of your products, thus preserving your market and preventing competition from third parties. Beyond this, and especially in cases where an invention truly fits the description of 'wildcard', the lack of prior art (pre-existing knowledge that might limit the scope of a patent in a more established industry) means that well drafted IP might confer not just protection for your invention, but also the opportunity to licence your innovation to others, creating lucrative revenue streams and enabling access to new markets.

Having an effective IP strategy is critical for companies of all sizes, even if – in the case of pre-investment companies – it can only be implemented at some future time. Demonstrating an understanding of the opportunities offered by IP and prioritising the IP that needs to be protected first, will be key to attracting investment.

Another key question for emerging medtech companies and entrepreneurs will be, who in the company owns the knowledge inherent in the business? Most of the knowledge and skill within small companies is concentrated within the memories of the small number of individuals who founded the business. This is both a blessing and a curse. The upside is that corporate knowledge is easily accessible and admin is minimised. As companies grow however, a lack of clear policies and documentation can lead to disputes. For example, if a founder member of the team leaves, he or she might take their knowledge with them unless there is some agreement to the contrary. There's no one size fits all approach to IP and developing the right portfolio and strategy is a bespoke process. Engaging in this process early on however will put an emerging enterprise on sure footing, and make wildcard innovations all the more investable.

Top 4 orthopedic medical device market trends

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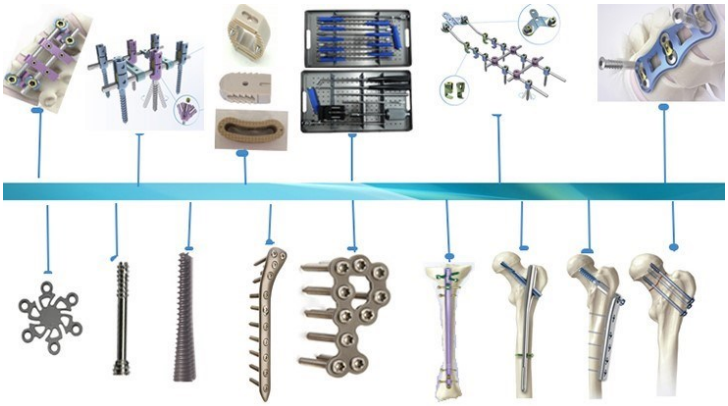
Cleveland, Ohio – Orthopedic devices play a crucial role in providing pain relief, improving mobility, and enhancing the quality of life of the patients suffering from musculoskeletal disorders. These medical devices and procedures used in orthopedics keep on evolving in the light of changing consumer needs. Technological advancements and integration of digital technologies has also triggered the changes in demand pattern as far as the patients and healthcare professional are concerned.

Maintaining qualified team of professionals is becoming increasingly vital for the healthcare institutes owing to the rapid technological advancements. It is essential for the manufacturers to keep in mind the safety, comfort, and convenience of the consumers. Affordability is another factor that plays a key role in the overall growth of the market for orthopedic devices. Incorporation of cutting-edge trends have revolutionized the field of orthopedics over the last few years. For instance, medical fabrics and wearable medical devices.

Trends in orthopedic devices
Here are some of the major trends observed in the way manufacturing, distribution, and sales of orthopedic devices work:

Cost control – Expanding regulatory requirements and stringency in terms of the government mandates have pushed manufacturers towards making careful decisions when it comes reducing cost-drivers that do not add value to the devices. Mitigating regulatory expenses and supply chain charges is vital for the companies to reduce the cost of instruments. As a result of these prerequisites, some of the top manufacturers in the orthopedic devices market are focused on commoditization in terms of devices, delivery systems, and instruments. Rising investments in cost effective designs and compliant designs is expected to encourage manufacturers to reduce to the cost of orthopedic medical devices and make them easily available for the majority of consumers in need.

Technological advancements – As per the researchers, minimally invasive surgeries are gaining prominence as they cause less pain, scarring, and hospital stay. The increased accuracy rate of these surgeries is a revelation for the instrument manufacturers who want to incorporate this technique while developing orthopedic devices. Apart from that, advanced techniques like computer-aided surgeries, robotics, and



3D printing are being adopted for the patient outcome and precision. High demand for these surgical procedures and latest technologies reflects on the changing manufacturing trends in the market for orthopedic devices. The orthopedic supply chain is in constant need for devices that can reduce the impact and improve accuracy while cutting into the bones, small or large. 3D printing and manufacturing – Healthcare sector is adopting 3D printing at an astonishing pace. Irrespective of ethical and technological changes, major manufacturers are adopting 3D printing in regenerative medicine, tissue engineering, bio-printing, and other advanced processes.

Product innovations – Reduced procedure time seems to be one of the primary requirements from patients as well as healthcare professionals. Growing demand for orthopedic procedures from geriatric population makes it essential for advanced and highly accurate products. Advanced technology makes these devices simple, user-friendly, and accurate. The toughest part here is to develop devices that have all these features and yet can be available at affordable prices. This remains one of the major challenges for the top players operating in the global orthopedic devices market. As per the researchers, a rise in research and development and investments in collaborations for enhanced product portfolio can be expected in near future.