BIÇAKCILAR
Touching Lives One Device at a Time

MARKETWATCH

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In this issue…Discreet catheters released to improve patient care

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Medical device company CompactCath announced the expansion of its intermittent urinary catheter line with two new devices.

The company's OneCath is available to both adults and children as a product designed to improve the lives of patients and help rising healthcare costs due to an affordable cost.

The second product, CompactCath Coudé combines the compact design of CompactCath, providing a smaller, easy to use, and discreet catheterisation experience unlike traditional catheters. The device's curved tip increases reach for patients to successfully drain their bladder. More so, CompactCath Coudé has been designed for easier insertion and is the first of its kind to feature the unique "Case Up, Tip Up" design, which simplifies the catheterisation process by reducing the need for visual dependency.

CEO of CompactCath, Naama Stauber Breckler, said: "Since launching the CompactCath brand, we've received overwhelming positive feedback from both users and clinicians, citing the catheter's non-touch insertion, discreetness, portability, and convenience as revolutionary in comparison to current catheters available in the marketplace.

We have also found that in addition to compact catheter solutions for active lifestyles, there is a rising need for affordable catheters that don't sacrifice quality for cost, especially for the uninsured, underinsured, and those with high deductibles, and that's why we created OneCath."

Dr. Daniel Hong, CompactCath's chief medical officer, said: "With traditional coudé catheters, it's difficult to know whether the tip is pointing in the right direction, which is crucial for proper insertion.

"We've alleviated this problem by simplifying the design of the catheter. As long as CompactCath Coudé is held in the vertical position, the tip will also be in the vertical, upright position, allowing for correct insertion and removal throughout the catheterization process. This creates a manageable and controllable procedure by greatly reducing discomfort and the risk of catheter associated trauma to the urethra. We have invented the first catheter which eliminates the need for a guide stripe as we commonly see on coudé catheters, simplifying the insertion process and allowing users to catheterize correctly and with confidence."

In this issue… Complying with labelling as EU MDR gets close

Sticking points

- **UDI applied in Europe**: UDI has its own dedicated section within EU MDR. The EU's guidelines are in line with the Global UDI initiative, as are the FDA UDI rules.; all labels must include PI (GTIN) and DI components as textual and barcoded content. Many companies have already solved the UDI challenge due to its requirement in the US. However, companies who do not ship to the US are at the beginning of the UDI journey.

- **More serial and lot numbers**: This change falls under the UDI remit. However, EU MDR requires more products to be serialised than FDA UDI. Every active implantable device must have its own unique serial number. Other implantable devices will require a serial or lot number. Making the shift from batch labelling to a world where individual products need to be married with the right label at the right time is challenging. It requires a data-led labelling system.

- **Highlight authorised EU representatives**: Every manufacturer whose registered place of business is outside the EU is required to have a licensed EU representative. Previously, details of that representative were included in the IFU. EU MDR requires companies to print that information – symbol, name and address – on the label.

- **Warnings & precautions must be on label**: This change will probably have the biggest impact. MDA mandates that all warnings relating to a device must be printed on the label. Previously, these were all included in the IFU. The choice of which warnings need to be included is left to the manufacturer. However, the criteria on which they should base those decisions remain unclear.

- **Label must indicate blood and tissue derivatives**: EU MDR provides regulation for medtech innovations not previously covered by MDD; i.e nanotechnology, the use of computer software or medicines. All devices that incorporate a medical substance or tissues/cells or their derivatives must clearly indicate this on the label.

- **Include reprocessing cycles**: This is another huge data challenge. Under EU MDR, labels for single-use devices that can be reprocessed must detail the maximum amount a device can be reprocessed as well as the number of times the individual device has been reprocessed to date. Manufacturers will need to integrate batch information from their ERP systems and identify data changes to the product definition. This requires capturing information that's not currently included in the labelling system. Some manufacturers are considering stopping reprocessing single-use devices altogether – a major strategic decision that illustrates the potential impact of EU MDR.

- **eIFUs (electronic Information for Use):** EU MDR also introduces requirements around electronic IFUs and the 'absorption of substances' that dictate changes in labelling processes. Manufacturers must clearly indicate that the instructions for use are supplied in electronic rather than in paper form. This information must be provided on the packaging for each unit and – in the case of fixed medical devices – on the device itself. Manufacturers must also provide information on how to access the instructions for use in electronic form, such as through the addition of a URL.

- **Medical Device symbol** : Under EU MDR, manufacturers of medical devices must now include a new field on their labels; a clear symbolic indication that the device is a medical device. Again, this requirement goes much further than MDD and further impacts the design, spacing and data inputs to medical device labels

- **Label spacing differences**: In order to address the fact that new mandatory content – such as the addition of warning & precautions - is almost certainly going to create congestion, the recent Final Ruling by the FDA no longer requires English text to appear alongside symbols in order to free up label space. This will be worth consideration as its impact will lead to potentially significant label redesign.

- **Gluing it all together**: Achieving compliance with EU MDR will naturally create labelling challenges for medical device companies. Companies therefore need to ensure their current labelling system is fit for purpose. But they need to do it soon. Although EU MDR will not be fully enforced until 2022, the birth of EUDAMED in 2020 means companies could be prevented from registering or re-registering products if they don't address associated labelling challenges ahead of its introduction. Failure to do so could mean companies can't market their products in Europe.

Australia Offers Wave of Potential for Pharma, Medical Device Manufacturers

Gathering momentum and power like a monster wave, Australia's life science sector is increasingly becoming a beacon for pharmaceutical and medical device manufacturers seeking regulatory approval for their products.

In recent years, Australia's regulatory agency, the Therapeutic Goods Administration (TGA), has made strides to become more accessible and user-friendly to pharmaceutical and medtech companies around the globe to make Australia a tempting market destination for their products. At the same time, Australian innovators are putting the world's largest island nation on the map with ground-breaking research, technologies and products that are making the world take notice. Another trend is that more and more medical device manufacturers are finding that they don't need CE mark (which signifies European regulatory approval of a product) credentials to access Australia's growing market potential due to Europe's evolving Medical Device Regulations (MDR). Instead, they're going directly to the TGA for their conformity assessment. In turn, the TGA has made a concerted effort to refine internal processes and systems, which have shortened the amount of time it takes manufacturers to navigate the many facets of the medical device registration process.

Top Medical Device Industry Trends in 2018: Atypical Medical Device Technology Will Become More Typical

- Documentation Must Be Comprehensive, Conclusive and Recorded
- Adopting New Devices Often Involves a Lag Time
- Risk Management Is a Top Priority

Conclusion

The surge of medical devices and related technologies continues to expand the medical device playing field. Advances in technology will compel companies in all sectors to elevate their efforts in exploring new innovations. However, the compliance landscape is complex and regulatory inspections continue to get more detailed and thorough. Traditional and nontraditional medical device companies alike are recommended to be equally thorough with their quality and risk management processes.

Regulatory agencies have high expectations for all players in medical device manufacturing.

3D printing in the medical field: four major applications revolutionising the industry

3D printing has many functions in a variety of industries, however, in the medical field it has four main applications. Allie Nawrat found out how this technology could be used to replace human organ transplants, speed up surgical procedures, produce cheaper versions of required surgical tools, and improve the lives of those reliant on prosthetic limbs.

Additive manufacturing, otherwise known as 3D printing, was first developed in the 1980s. It involves taking a digital model or blueprint of the subject that is then printed in successive layers of an appropriate material to create a new version of the subject.

It has been forecast that 3D printing in the medical field will be worth $3.5bn by 2025, compared to $713.3m in 2016. The industry's compound annual growth rate is supposed to reach 17.7% between 2017 and 2025.

There are four core uses of 3D printing in the medical field that are associated with recent innovations: creating tissues and organoids, surgical tools, patient-specific surgical models and custom-made prosthetics.

Bioprinting tissues and organoids

One of the many types of 3D printing that is used in the medical device field is bioprinting. Rather than printing using plastic or metal, bioprinters use a computer-guided pipette to layer living cells, referred to as bio-ink, on top of one another to create artificial living tissue in a laboratory.

These tissue constructs or organoids can be used for medical research as they mimic organs on a miniature scale. They are also being trialled as cheaper alternatives to human organ transplants.

Surgery preparation assisted by the use of 3D printed models

Another application of 3D printing in the medical field is creating patient-specific organ replicas that surgeons can be use to practice on before performing complicated operations. This technique has been proven to speed up procedures and minimise trauma for patients.

This type of procedure has been performed successfully in surgeries ranging from a full-face transplant to spinal procedures and is beginning to become routine practice.

"3D printing has been used to create patient-specific organ replicas that surgeons can be use to practice on before performing complicated operations."

3D printing of surgical instruments

Sterile surgical instruments, such as forceps, hemostats, scalpel handles and clamps, can be produced using 3D printers. Not only does 3D printing produce sterile tools, some are based on the ancient Japanese practice of origami, meaning they are precise and can be made very small. These instruments can be used to operate on tiny areas without causing unnecessary extra damage to the patient.

One of the main benefits of using 3D printing rather than traditional manufacturing methods to produce surgical instruments is the production costs are significantly lower.

Custom-made prosthetics using 3D printing

Marketwatch

3 Medical-Device Industry Trends Changing Design and Manufacturing

According to Katy George, McKinsey's expert in its operations practice and pharmaceutical and medical products, there's another important industry that's being shaped as well—medical devices.Medical devices are invasive by nature—they probe in and around the human body. They look around, they cut away disease, they repair damage. Others remain inside the body—a replaced hip, a stented artery, a new valve, a pacemaker. So combining the highest-of-standard design and performance characteristics for such important medical devices, the incredibly complicated business model of health care itself, and stiff regulatory requirements make for the one of the most complex and demanding of any manufactured products.Because of this complexity, George believes the medical-device industry is being forced to look at the entirety of its business model to embrace change in ways that other industries don't. That said, she also believes that the lessons learned will ultimately benefit all industries.

Here are three medical-device industry trends she believes are embracing and contributing to the dynamic change that is taking place in both design and manufacturing.

1. **Design, Manufacturing, and Sales Functions Will Converge in a Quest for Value**. George believes that the acceleration of design and manufacturing capabilities are feeding off the challenges embedded in the medical-device industry and are productively disrupting business models.

What we see the industry increasingly pivoting toward is what we would call a design-for-value orientation and much more cross-functional integration of the marketing or commercial functions," George says. She believes the old paradigm of engineers coming up with ideas alone in a lab, then passing on the creations to the marketing department to commercialize them, probably "has to be flipped on its head."

"**It's not just about cost reduction**," George says. "**It's actually about continuing to evolve the product design the right way.** It's very difficult in this industry compared to some others for a couple of reasons. One is that you have multiple customers: You are designing for the patient, for the physician, for the procurement officer of the hospital, for the payor, for the regulator. So it's very different from doing a market-research study with consumers on what you care about in your hair dryer." George believes that the medical-device industry has already been in transition toward a more integrated approach to design, manufacturing, and marketing, but current trends toward integrating design and business functions are making it easier to understand and respond to exact usage conditions and what needs of patients and physicians are truly worth paying for. In other words, designing innovation for value.

2. **3D Printing Has the Potential to Be a Highly Disruptive Force**. George is also excited about the potential of 3D printing. "The promise is big, but it hasn't been realized yet," she says. "It's still kind of playing at the edges. But it's already pretty core in some medical-product spaces," such as dental implants and other noninvasive devices like prosthetic limbs.

3. Eliminate Waste in the Health-Care Supply Chain. George sees vast opportunities for the partnership of great design and advanced manufacturing developments to significantly shorten and tighten up waste in the supply chain.