

MARKETWATCH

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MEDICAL DEVICE INDUSTRY BEYOND THE 1ST Q F 2018

While the Frost & Sullivan report anticipates China taking a bigger step forward in the future for medical devices, the population will continue to grow, possibly to 9.7 billion by 2050, from a current 7.6 billion in 2018 according to the United Nations. Meaning the current medical device companies will have to exponentially expand to address the growing populations needs.

FDA IN FOCUS

The action plan acknowledges the amount of patients that have been helped with advancements of medical devices. It focuses on five areas: establishing a patient safety net, exploring regulatory options, developing safer devices, advancing medical device cybersecurity, and integrating the Center for Devices and Radiological Health regulatory process.

While the “FDA’s use of real-world evidence” will support regulatory decision-making for medical devices to lower the cost from incentives, the report said. Inevitably there will be more costs associated with developing medical devices, either in R&D or cybersecurity updates. While investors may be curious if sales will be lower than expected if this causes products to be more expensive, it also guarantees the consumers will have a better, and safer product.

3D PRINTING AND MEDICAL DEVICES

VentriPoint focuses on an ultrasound system to analyze the heart with a 3D image of the heart. It’s able to analyze all four cardiac chambers making it equivalent to the capabilities of an MRI. The company had 158 percent growth over 2017 to get a spot of the Venture 50 list.

LIFEPLUS ANNOUNCES WORLD’S FIRST NON-INVASIVE CONTINUOUS BLOOD GLUCOSE MONITORING WEARABLE

LifePlus Inc. today announced that it has entered the multi-billion-dollar smart medical wearables category with the introduction of Lifeleaf - the world’s first non-invasive continuous blood glucose monitoring multi-sensor wearable device. In addition to blood glucose monitoring, the patent-pending multi-sensor device non-invasively monitors heart rate, blood pressure, respiration rate and oxygen saturation

NEXT GENERATION STENT RETRIEVER DEVICE USED TO TREAT ISCHEMIC STROKE

CERENOVUS, part of the Johnson & Johnson Medical Devices Companies, announced today it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for EMBOTRAP II Revascularization Device, a next generation stent retriever used to capture and remove life-threatening blood clots from the brain following an ischemic stroke.

In this issue...

Latest Market Overview on Global Device Market

The medical device industry is facing its own unique challenges and market opportunities. The industry for medical devices is, in most parts of the world, heavily regulated. Medical devices require approval for reimbursement and have prices that, in many cases, are negotiated by group purchasing organizations and governments. Medical device company are constantly researching and investing in product development to produce the innovations that are key to driving market success. Despite the market's many challenges, medical devices benefit from servicing an enlarging elderly population worldwide. **Medical devices also rank among the first priorities of emerging nations, whose economies and amounts spent on healthcare are increasing.**

Kalorama estimates the global medical device market at \$389 billion dollars. This means a large opportunity for hundreds of companies offering solutions that can improve patient outcomes and reduce hospital stays.

40+ Specific Medical Device Markets (in terms of growth)

Anesthesia Monitors	Electrosurgical Devices	Spine Implants
Blood Collection	Endoscopes (excluding gastro)	Stethoscopes
Blood Gas Analyzers	Gastric Banding/Bariatric	Sutures, Staples, Staplers
Blood Pressure Monitors	Gastro Endoscopes	Traditional Surgical Instruments (scalpels, forceps, retractors, scissors)
Cannual Respiratory	Glucose Tests	Ultrasound
Catheters	Hip Implants	Vascular Closure Devices
Computed Tomography	Hypodermic Syringe	
Coronary Stents	Infusion Pumps	
CPAP Machines		

1. United States	10. India	18. Chile
2. Japan	11. Brazil	19. Malaysia
3. Germany	12. Switzerland	20. Poland
4. China	13. Mexico	21. Indonesia
5. France	14. Turkey	22. South Africa
6. United Kingdom	15. South Korea	23. Vietnam
7. Italy	16. Sweden	
8. Spain	17. Singapore	
9. Canada Australia		

Country-Level Medical Device Markets

The medical device market, in terms of revenues, is not even half as large as the global pharmaceutical market, though it sees many more transactions. This is due to pricing, as in volume terms there are more units sold in the device market. However, growth prospects in medical devices in the aggregate are more promising than in the current pharmaceutical industry, challenged by patent.

How Artificial Intelligence Is Changing Medical Devices

An industry expert talks about the dramatic impact that artificial intelligence (AI) is having on the medical device field.

Machine learning and artificial intelligence (AI) have long been heralded as the future of transformative technologies. From diagnostic and imaging technologies to therapeutic applications and robotics, the potential for machine learning and AI technologies reaches almost every corner of the medtech world. So, what does that mean for the development and application of next-gen medical devices?

Dave Saunders is the chief technology officer of Galen Robotics, an emerging surgical robotics company that specializes in a new line of robotic technologies that provide a cooperatively controlled surgical platform. The company aims to provide robot-assisted technologies that can extend increased precision and unprecedented tool stabilization to microsurgery procedures.

Saunders has personally overseen the evolution of more than 40 different internet-based products from inception to market since 1991 and has led product development programs for virtual machine clustering and computer-vision-guided surgical tools. He'll also be speaking at MD&M East in June where he'll be covering the topic of "How Artificial Intelligence Has Changed Everything for Medical Devices."

"We're already seeing AI and machine learning being applied to diagnostics and other areas, so inroads are being made. AI and machine learning for surgical devices might be a bit further out though. Currently we don't have a clear path from the FDA for approval in this area, and training for AI and machine learning is also a bit more difficult for something like a surgical robot than, say, facial recognition or other more prominent uses of AI. We're getting there, but a lot more work is needed. "

"I think it's opening a lot of doors and making complex analysis more possible in a wide range of applications. A great rule of thumb from Dr. Andrew Ng of Stanford is that anything a human can "think through" in a second or less is a possible candidate for AI or machine learning. This rule of thumb isn't perfect, but it does provide for a short list that can help technologists and product managers see where devices might benefit from applied AI and machine learning.

"Some of these things are being applied now, so patients could already be benefitting from AI and machine learning systems and not even know it. A bit down the road could be smart-vitals monitoring with wearable devices. Based on readings, medications could be adjusted in real time, or emergency services could be alerted if a combination of vitals shows that something is wrong. You may not want your phone to automatically dial 911 if your heart rate is elevated, but there could be a combination of readings which do indicate an urgent problem. These are the kinds of things that AI and machine learning systems could help us better understand about the human body as more data is gathered and analyzed by the wearables we already have today. "





Emergo Survey: Tempered Growth Expectations for Medical Device Markets in 2018

Medical device manufacturers' growth expectations for markets worldwide have decreased for 2018 compared to previous years due to various regulatory and economic factors, a recent survey shows.

Emergo's Global Medical Device Industry Outlook for 2018 included responses from nearly 4,000 participants on which markets they expect to yield the most growth this coming year. As in the 2017 survey, companies anticipate higher growth opportunities in the US and Europe than other markets. However, growth expectations for all markets have fallen since Emergo's last survey in 2017.

Double-digit decreases for US, European growth expectations

Although 41% of survey respondents anticipate strong European market growth in 2018, 51% of our 2017 respondents expressed similar expectations. US market growth expectations saw an even more dramatic decline: Whereas 60% of 2017 respondents saw the US as a high-growth market, only 43% of our 2018 participants see significant growth opportunities there this year.

In Europe, the effects of implementing the new Medical Devices Regulation (MDR) and In-Vitro Diagnostics Regulation (IVDR) have no doubt affected manufacturers' near-term expectations in the world's second-largest market. The complexities of the new Regulations as well as new, stricter requirements for Notified Bodies have created near-term challenges for companies seeking and renewing CE Marking in Europe.

Responses to a separate question in our 2018 survey provide further context for firms' lower performance expectations for Europe. When asked how closely they understand the upcoming MDR and IVDR, more than half of all companies reported only a basic understanding of the new Regulations and how they will affect European regulatory compliance. (Less than 30% of firms cited strong understanding of the MDR and IVDR.)

No similar massive regulatory overhauls have recently occurred in the US, but other factors in that market help explain lower expectations for 2018:

The return of the Medical Device Excise Tax (MDET), which had been set to take effect after a two year moratorium in early 2018 while our survey was being conducted (yet another two-year moratorium has since delayed MDET implementation again).

Ongoing efforts to limit the scope of the Affordable Care Act (Obamacare), Medicaid and other federal healthcare funding systems, which may impact manufacturers' reimbursement arrangements and contribute to overall uncertainty in terms of US FDA compliance.

FDA application fees under the Medical Device User Fee Amendments of 2017 (MDUFA IV) increased by more than 30% for many types of registrations, including a major increase of 125% for 510(k) premarket notification submissions. (510(k) registrants with sales of less than \$100 million may qualify for lower small-business user fees, however.)

BRIC and emerging market expectations also tempered

Respondents' expectations for emerging markets such as Brazil, China and India also decreased between 2017 and 2018 surveys, but at much lower rates than those for the US and Europe:

3 Value-Selling Tips To Improve Your Medical Device Sales Strategies

A successful medical device sales business of the future is one that provides stakeholders with both clinical and economic information.

There are three succinct ways healthcare buyers differentiate their services to patients: **care, access and cost**. This means your medical device sales person must know how to create a dialogue around solid solutions and favorable outcomes rather than focus on slick product features.

The following are three key tips for creating medical device sales strategies that focus on proven value-selling techniques:

Tip #1: Align Our Value Proposition With Target Healthcare Buyers

As healthcare buyers compete against each other to lower costs and improve their services, the best way to get their attention is by providing valuable information that directly supports their value proposition. If you offer a prospect a useful webinar or free report, for example, it should contain a compelling value proposition that benefits the prospect's business. **(Let us do this and I can help you...we need to sound like experts in the market)**

When we understand the business and financial impact of a new value proposition, we're better able to make smart adjustments to our value-selling process.

Tip #2: Emphasize The Economic Impact Of Our Medical Device

Today, we must show healthcare buyers how our medical device is going to help them solve internal issues of costly inefficiencies to generate an immediate return on investment.

Once we've laid the foundation for how our products and services drive ROI, our sales efforts can use this economic argument to their advantage. This healthcare sales strategy is accomplished by identifying specific value elements for each individual prospect or customer.

Tip #3: Ground Your Value-Selling Claims In Supporting Data

Whether healthcare buyers are competing in terms of better care, improved access, lower costs or some combination of these elements, they're looking for proof that your medical device solution delivers the edge they need. When it comes to providing this proof in such a complex system, analytics are key to demonstrating value.

To build a competitive medical device sales model around value selling, we need a platform for capturing, analyzing and managing sales data. A CRM system is designed to help sales teams develop more informed and engaged relationships between salespeople and healthcare buyers.

As these major changes are taking place in the field of medical device sales, many companies are likely to struggle when adapting to a value-selling approach. This shift may be particularly challenging for companies that have long competed on price alone or by selling premium, innovative products.

This can be done and we also have been establishing the CRM system. Let us work together on integrating these strategies on the CRM platform and get comfortable with the value proposals as we plan for 2020.

Developing a Strategic Selling Process

Consistency and persistence is the goal as we sell medical devices. Eighty percent of sales require five follow-ups according to Hubspot report. When formulating our team's selling process, we need to have a clear vision of our product and how it stands out from other medical devices.

When doing consultations and building customer relationships, be sure to feature products in a hands-on or creative way so that customers can fully experience what they are anticipating to buy. Medical devices can be complex and tricky to understand, so it's important to have a clear explanation of your product. This strategy is especially important as we build the portfolio with new products.

The time to be prepared for the new portfolio is now. Customers should walk away feeling like they will be missing out if they don't purchase our device.