

10 medical device industry stories you need to know

December 27, 2019 By Chris Newmarker

1. Competition heats up in the robot-assisted surgery space

Medtronic (NYSE:MDT) this year unveiled its much-awaited Hugo RAS system, which the world's largest medical device company touts as more flexible and cost-effective than systems presently on the market. Medtronic's goal is to achieve U.S. 510(k) clearance in roughly two years.

Johnson & Johnson (NYSE:JNJ), meanwhile, announced that it was purchasing the remaining stake in Verb Surgical — following what J&J described as a successful strategic collaboration with the Alphabet (NSDQ:GOOGL) life sciences unit Verily. J&J's Ethicon subsidiary in February inked a \$3.4 billion deal to pick up surgical robotics pioneer Dr. Fred Moll's newest robotic surgical play, Auris Health, and its FDA-cleared Monarch platform. Meanwhile, the dominant player in the soft tissue robotic surgery space — **Intuitive Surgical** (NSDQ:ISRG) — isn't resting on its laurels. Its da Vinci SP robot for single-port surgery has a tube that is about an inch wide and delivers fully articulating instruments: three that can manipulate things and one that's a steerable endoscope. The robot is in the process of launching in the United States.

2. EPA moves closer to stricter regulation of medtech ethylene oxide sterilization

The EPA is requesting comment on available control technologies for reducing EtO emissions and on developments in practices, measurement, monitoring, processes and control technologies for the sterilant. With EtO currently the major method for sterilizing plastic medical device parts — and implementation of alternatives potentially years away — medical device companies could potentially face major extra costs going forward. Communities across the country have become alarmed over local sterilization plants using carcinogenic EtO.

3. Permanent repeal of the medical device tax

President Trump on Dec. 20 signed off on spending bills that included a permanent repeal of the 2.3% medical device excise tax, providing the medical device industry a win that it has sought for nearly a decade. The tax was part of the Affordable Care Act of 2010 and was one of a number of funding mechanisms meant to help pay for the health reform. But the medtech industry argued that the tax limited jobs and innovation.

Device companies over the years achieved temporary suspensions of the tax through Congress — but never an outright repeal, until now.

4. Just 18% of executive roles held by women

Less than a fifth of the executives at the 100 largest medical device companies are women, according to an analysis of Medical Design & Outsourcing's annual Big 100. And only three companies on the list have a female CEO: B. Braun Melsungen, Insulet and Paul Hartmann.

5. Federal court prepares for trial of former Theranos CEO Elizabeth Holmes

A federal judge has ordered the FDA and the Centers for Medicare & Medicaid Services to produce documents pertinent to the government's criminal case against former Theranos CEO Elizabeth Holmes and president Sunny Balwani, which is expected to go to trial in 2020.

Holmes and Theranos were once Silicon Valley darlings, with Holmes claiming that her company was set to revolutionize blood testing with technology that could analyze tiny amounts of blood. Investigative reporting, though, soon dismantled the claims Holmes was making about Theranos' technology, raising questions about whether she and others had misled investors. The downward spiral culminated in the 2018 shutdown of the company, with the SEC criminally charging Holmes and Balwani over what it described as a "massive fraud." Theranos has become so infamous in the public imagination that other companies seeking to innovate in the blood testing space now have a higher bar when it comes to proving their technology.



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6. The U.S.-China trade war

Under President Donald Trump, tariffs have become a go-to negotiating tactic with other countries, including close U.S. allies such as Canada and the European Union. In late May, Trump threatened to levy them against Mexico over illegal immigration; had he followed through, it could have been a serious situation for the U.S. medtech industry as many companies increasingly manufacture south of the border. No trade dispute, however, appeared to be as deep and long-lasting as the confrontation between the world's two largest economies. If the tariffs actually make a country great again, it might be Malaysia, Vietnam or Costa Rica, global medical device industry suppliers told Medical Design & Outsourcing over the summer.

7. Lack of preparation for MDR/IVDR

With only months to go before the EU's new Medical Device Regulation takes effect, many medical device companies are struggling to meet the deadline, and Europe's medtech trade association is accusing government authorities of dragging their feet.

Biotronik, meanwhile, announced in September that it was the first medtech manufacturer to receive MDR certification for a Class III (highest risk) medical device.

8. Leadership changes at FDA

The U.S. Senate recently confirmed Dr. Stephen Hahn — previously CMO at Houston's M.D. Anderson Cancer Center — as the new commissioner of the FDA. He's the first permanent commissioner of the agency since Dr. Scott Gottlieb resigned in April.

The FDA continues to look at ways to reform the medical device regulation process amid heightened media scrutiny, including including the International Consortium of Investigative Journalists' "Implant Files" articles and the Netflix documentary "Bleeding Edge." The agency, for example, has released draft guidances for the first four types of devices it will evaluate under its expedited Safety and Performance-Based Pathway to 510(k) clearance.

9. A robot revolution in the ortho surgery space

Stryker's success with its Mako robot-assisted surgery platform has other orthopedic device companies hastening to enter the space. Stryker's big competitors — Johnson & Johnson's DePuy Synthes business, Zimmer Biomet and Smith & Nephew — have either launched or are preparing to launch their own robots. And Medtronic has big plans for robot-assisted spine surgery.

10. Changes at the top

Omar Ishrak is preparing to retire from Medtronic's corner office next year. Geoff Martha, already promoted to company president this year, will become the new CEO. Read how Ishrak transformed Medtronic into the world's largest medtech operation.

Meanwhile, Miles White will step down from the CEO position at Abbott (NYSE:ABT) on March 31 after 21 years at the helm, but will remain with the company as executive chairman. Robert Ford, currently Abbott's president and COO, will become the company's 13th CEO. Medical Design & Outsourcing will have an article about White's legacy posting in early January.



Leapfrog names top hospitals for patient safety

Florida tops the list with the most across general, children's, rural and teaching hospitals – followed by California, Michigan and Virginia. Researchers collected data of approximately 13,000 individuals from three notable patient populations, including multiple ethnicities.

The Leapfrog Group has issued its annual list of top hospitals for quality and safety for 2019.

WHY IT MATTERS

Leapfrog, the national watchdog focused on health care safety and quality, recognizes hospitals that have demonstrated leading-edge quality and safety, as identified through the Leapfrog Hospital Survey.

The survey compares performance on national standards of patient safety, quality, efficiency and management structures that prevent errors – offering a comprehensive picture of how patients fare at individual institutions.

This data also enables hospitals to benchmark their progress toward The Leapfrog Group's standards and measure the care they deliver.

Among the factors considered in the survey: hospitals' ability to prevent infections, reduce C-sections, use technology to reduce medication errors and implement surgical volume standards for safety.

Fewer than 6% of all eligible facilities have attained top hospital recognition from Leapfrog.

THE LARGER TREND

Of the 120 Top Hospitals recognized in 2019, 55 are teaching hospitals, 37 are general hospitals, 18 are rural hospitals and 10 are children's hospitals.

Florida, California, Michigan and Virginia boast the greatest number of Top Hospitals, with nine or more hospitals in each of those states receiving the elite distinction.

ON THE RECORD

"Our Top Hospital award, one of the most prestigious in the U.S., recognizes hospitals for ensuring their facilities prioritize safety and quality in patient care," said Leah Binder, president and CEO of The Leapfrog Group.

"The standards achieved by Top Hospitals reflect the high expectations set by Leapfrog and its expert panels, which starts with a commitment to transparency. We also commend all hospitals that demonstrated this commitment by participating in the 2019 Leapfrog Hospital Survey."



ChristianaCare, Medtronic join on new project to target technologies, therapies

ChristianaCare will work with Medtronic on a five-year effort to innovate new value-based strategies, collaborating on new approaches to target therapies and technology-enabled intervention on the patients who will benefit most.

WHY IT MATTERS

Under the new agreement, Wilmington, Delaware-based ChristianaCare and Medtronic will have shared financial accountability to improve outcomes while reducing the cost of care, the organizations say.

Of the many technology initiatives being planned for the next five years, one of the first is focused on opioid-induced ventilatory impairment – a condition where opioids used for pain management can inhibit breathing and could cause respiratory distress unless clinicians intervene.

Medtronic and ChristianaCare will work to standardize an enhanced respiratory monitoring initiative to help address OIVI; the project will be designed to identify patients receiving opioids for pain management who are at high risk for OIVI and apply continuous monitoring technology to track breathing, and help alert the care team to abnormal trends.

Other initiatives will focus on new tech-enabled interventions to address chronic conditions such as heart failure and diabetes, officials say – enhancing ChristianaCare's ability to prevent or slow disease progression, reduce hospitalizations and lower overall cost of care for those and other diseases.

THE LARGER TREND

Both organizations hope the project will lead to significant and lasting improvements for health across Delaware and beyond, they say, noting that ChristianaCare's diverse patient population, gaining access to care across a broad array of healthcare settings, offers a valuable opportunity to scale new initiatives that could boost outcomes nationwide.

ON THE RECORD

"Together with Medtronic, we are aligning expertise and incentives to exponentially increase our ability to achieve optimal health — not just better care delivery," said Randall Gaboriault, M.S., chief digital and information officer and senior vice president, innovation and strategic development at ChristianaCare. "This collaboration will implement a new value chain, based on vested purpose, co-innovation, digital and data.«

"We recognize that creating healthier communities requires integrated care models, passion to improve the status quo, and an aligned purpose of helping patients live healthier and fuller lives," added Dr. John Liddicoat, executive vice president and president of the Americas Region at Medtronic. "This collaboration with ChristianaCare reinforces our joint commitment to healthcare innovation through value-based arrangements."



Medgadget's Best Medical Technologies of 2019

Electromagnetic Signals Slow Parkinson's, Treat Irritable Bowels, Improve Blood Pressure...

Buildup of β -amyloid plaques within the brain seems to be a cause of Alzheimer's disease. The MemorEM system from NeuroEM Therapeutics delivers transcranial electromagnetic treatment, or TEMT, to the brains of Alzheimer's patients targeting β -amyloid aggregates.

In animal studies, it was shown that TEMT does indeed prevent β -amyloid aggregates from forming and even disrupts existing conglomerations. In a study on eight patients who went through a treatment regimen, all but one showed either a pause or reversal in cognitive decline. If proven to work in larger groups of people, the treatment may become a common approach for dealing with **Alzheimer's** from the earliest stages.

A new device called IB-stim from Innovative Health Solutions received FDA clearance to treat **irritable bowel syndrome** (IBS) by manipulating the electrical signals reaching the brain.

It looks very similar to a hearing aid, but instead of processing sound, it uses three electrodes to deliver electrical impulses to the peripheral cranial nerve branches of the ear. These nerve bundles provide an efficient path into the regions of the brain that relate to pain perception. The artificial signals sent by the device seemingly disrupt signals coming from the gut, and the result is that there should be no sensation of pain.

Orchestra BioMed, a company out of New Hope, Pennsylvania, won the European CE Mark of approval for the Moderato implantable pulse generator which delivers Orchestra's unique BackBeat Cardiac Neuromodulation Therapy (CNT) to treat **hypertension**.

High blood pressure is typically treated using drugs, but BackBeat allows even existing cardiac implants to deliver therapy in a novel way by modulating the bioelectronic signals associated with blood pressure control.

Novel Hemodynamic Monitoring

Stents and blood flow diverters are now a common way to treat brain aneurysms, but whether these therapies actually help specific patients is hard to tell post treatment. Contrast enhanced angiography can do the job, but it is dangerous, inconvenient, and unpleasant to perform frequently. Researchers at Georgia Tech developed a sensor that can be built into currently available neural stents and flow diverters that can provide live hemodynamic information precisely from the spot that was treated.

The flexible sensor is a wireless device that can be printed to match the implant it will be attached to. As blood flows through the device, its capacitance slightly changes and this effect can be used to monitor blood flow perturbations down to .05 meters per second. It relies on inductive coupling to transmit its readings wirelessly to another device positioned outside the body.

Wireless Implant Controls Overactive Bladder Using Light

Collaborators from Washington University in St. Louis, the University of Illinois at Urbana-Champaign, and Northwestern University created a flexible wireless implant that senses the movements of an overactive bladder and delivers light to bring it under control.

Growing New Bones Inside Patients' Bodies

A team from Rice University printed a 3D bioreactor mold within which new bone can grow. It is made to be attachable to the rib bones of patients and can support stem cells and the formation of blood vasculature. The mold can be custom-made to the patient's own needs and after a few months of growth, the bioreactor can be explanted and the bone within transplanted to another part of the body. And that's that for 2019 and for the decade it was part of.

We very much look forward to the coming years and to the exciting and unexpected medical technologies that will surely be developed by bright minds around the world.

- **Probably the most important message as a summary of these technologies is that successful new medical device technologies always start with a problem that impacts the patient as the solution to the problem becomes the development.**



Operating Room Equipment Market Outlook to 2026 - Analysis on Anesthesia & Respiratory Devices, Patient Monitoring, Surgical Equipment, and Other Products

The global operating room equipment market was valued at USD 28,917.6 Mn in 2017 and is expected to reach **USD 48,165.1 Mn by 2026**, expanding at a CAGR of 5.9% from 2018 to 2026.

Over decades operating room has been constantly evolving to be an ideal operating room which **fulfills all the requirements & safety measures for patients and medical staff**. The incessant technological developments in the operating room equipment industry are expected to drive the overall market as the latest technologies are always the first choice for established chains of a hospital or ambulatory clinics.

Patient safety is one of the most important parts of operating room designing in which installment of each device and their position is decided based on medical requirements and specialties provided by the respective medical institution. However, increasing awareness related to early disease diagnosis for chronic diseases and supportive medical reimbursement policies are assisting the growth in a number of surgeries and critical disease diagnosis. Thus, overall aiding a substantial growth in increasing number of healthcare facilities that own operating rooms.

The key products present in operating rooms are anesthesia & respiratory devices, patient monitoring, surgical equipment, and other products. In the year 2017, anesthesia & respiratory devices dominated the market segment as these devices are an integral part of almost all types of surgeries and a recent surge in adoption of Anesthesia Information Management Systems (AIMS) is expected to maintain its dominance throughout the forecast period.

The importance of sterilization and single used accessories is mounting due to the rising prevalence of hospital-acquired infections which are one of the most life-threatening infections. Hence, accessories of anesthesia and respiratory devices that come in contact with patients are usually for single use.

In 2017, North America was identified as the largest operating room equipment market due to key drivers such as increasing awareness & prevalence related to chronic diseases, developed healthcare infrastructure & high accessibility towards modern operating room equipment, and an increasing number of ambulatory surgical centers. Outpatient hospital care centers are growing significantly in the United States due to cost-efficiency, a preferred destination for minimally invasive surgeries, and high accessibility compared to multispecialty hospitals.

Market Competition Assessment

The growth of operating room equipment is at a steady rate and major players present in this market are specifically focusing on providing technologically advanced, mobile, cost-efficient & multi-tasking equipment.

The key manufacturers present in this market are Philips Healthcare, Medtronic, Getinge AB, Stryker Corporation, Siemens Healthineers, Karl Storz GmbH & Co. Kg, GE Healthcare, Hill Rom (Trumpf Medical), STERIS plc, and Skytron among others.

Key Market Movements

- An increasing prevalence of chronic diseases coupled with mounting awareness related to disease diagnosis & treatment
- An increasing number of hospitals and ambulatory care centers is expected to assist the demand for operating room equipment
- Incessant advancement in the technologies of operating room equipment
- Multi-tasking equipment and smart devices are in high demand specifically for carrying out complex surgeries in the operating room

