Top 10 Trends in Medical Devices in 2017

Bolt-on Acquisitions Continue to Rise

As market pressures have increased, the pace of consolidation in the medical device industry has been accelerating in the past five years. However, the game-changing megamergers may be behind us. The only milestone merger that happened in 2016 in medical technology ("medtech") was Abbott Laboratories’ acquisition of St. Jude for $25 billion. Other key multibillion-dollar deals so far this year have been Abbott's buyout of Alere for $5.8 billion, Canon's acquisition of Toshiba Medical Systems for $5.9 billion, and Johnson & Johnson’s acquisition of Abbott Medical Optics from Abbott Laboratories for $4.3 billion. While large, transformative transactions are rare, the trend towards strategic merger and acquisition (M&A) activities at a tuck-in level in medtech continued in 2016. In fact, medical device companies have demonstrated an increasing appetite for strategic “bolt-on” acquisitions that would fill their portfolio gaps and subsequently help them establish more comprehensive solutions or expand their geographical reach. For example, Thermo Fisher has been pursuing a steady M&A strategy in its life sciences business and secured a string of bolt-on deals in 2016 alone, including the acquisitions of biological analysis toolmaker Affymetrix; leading high-performance electron microscopy provider FEI; and a stem cell and reagent firm, MTI-GlobalStem.

Heading into 2017, although the new landscape favors large companies who can leverage economies of scale, GlobalData anticipates the calming of the high-profile M&A scene. Instead, the shift to strategic M&A activities at a tuck-in level will continue, as medical device companies start to reconsider their approach to dealing with execution and synergy capture. Moreover, the contribution of Asian buyers to M&A in Europe and the US is likely to increase, as Asian players continue to deepen and broaden their exposure to the global market.

Declining Venture Capital Will Limit Some Growth and Innovation

As risks inherent in medical device development continue to persist, more and more venture capital firms may continue to shy away from investing in the medtech sector in 2017.
GlobalData has observed a steady decline in the number of venture capital deals in the medtech space over the last three years. Despite the industry’s focus on innovation, venture capital funding remains elusive for emerging medical device companies in a variety of therapeutic areas. Uncertainties over the economy, especially stemming from seismic events, such as Britain’s impending exit from the European Union; stringent regulatory guidelines; and difficult reimbursement environments lead to investors becoming risk-averse. Moreover, clinicians tend to prefer pharmaceutical and conservative treatment options over device-based invasive interventions. An emphasis on long-term patient outcomes and healthcare expenditure will dissuade both clinicians and payers from favoring treatment options that entail a greater risk of complications.

Small and start-up medical device companies are particularly vulnerable to limited venture capital availability, which can cause crippling delays as they try to launch new products. This lack of funding can adversely affect the broader industry by putting a ceiling on growth and innovation. In the uncertain healthcare environment of 2017, small companies need to solidify their financial resources or be acquired by larger companies to ensure their products achieve market access.

**Value-Based Healthcare Will Become a Greater Priority**

To cope with rising costs, healthcare reimbursement is moving away from the traditional fee-for-service payment model, in which providers are reimbursed based on the number of procedures performed and patients treated. Instead, healthcare systems and insurers are transitioning into value-based care. In this system, hospitals and physicians are held responsible for the quality of care provided to their patients, and paid in a way that takes into account factors such as patient complications and re-operations, hospital acquired infections, and readmission rates. Reimbursement can be given in a bundled payment based on the expected cost of a particular care episode, and financial penalties can be administered for excessive costs. This transition presents a variety of challenges for payers and hospital groups, but also a number of hurdles for medical device companies seeking to maintain profitability in the ever-evolving healthcare landscape.

It will soon no longer be enough for medical device manufacturers to simply offer the best quality implant or most clinically successful instrumentation. Instead, companies will need to reevaluate their offerings and include a range of tools tailored towards physicians and hospital
groups, such as applications and services that help physicians monitor patient outcomes, guide hospitals towards cost savings, and assist in improving clinical outcomes. These collaborations with healthcare providers will deliver an edge to manufacturers willing to adapt to providers’ growing needs. Additionally, evidence-based care and treatment paradigms will increase in importance, as hospital purchasing groups seek to lower expenditures. In 2017, data exhibiting cost effectiveness and exceptional clinical outcomes will be paramount, and medical device manufacturers will need to focus efforts on generating effective data in a format that hospitals and physicians find useful.

**Novel Technologies Will Make a Splash in the US Cardiovascular Market**

2016 has seen some interesting cardiovascular technologies finally begin to make their way to the US. Two in particular stand out: coronary bioresorbable vascular scaffolds (BVSs) and peripheral drug-coated balloons (DCBs). Both have been marketed abroad for several years, particularly in Europe.

Coronary BVSs have been a notable technology for several years in Europe and will continue to be a closely followed story in the US in 2017. The experience of this technology in Europe has admittedly been mixed; early results in the GHOST-EU registry suggested a worrying stent thrombosis rate in some of the early patients implanted with the device. More recent data—particularly in the ABSORB III trial, the US pivotal trial used to achieve FDA approval a few months before the time of writing—have started to alleviate some concerns. However, the technology has not seen particularly robust uptake in Europe. Abbott Laboratories was likely hoping that its Absorb BVS would become more of a workhorse technology at this point. Nevertheless, between the ongoing US launch of the Abbott product and the commercialization of new BVS options in Europe, led by Elixir Medical, this is a dynamic market to watch.

2016 has also witnessed the introduction of peripheral DCBs into the US market. Lutonix, manufactured by CR Bard and co-distributed with Boston Scientific, and IN.PACT Admiral, developed by Medtronic, launched within months of each other. Both competitors have been dueling over market share ever since. GlobalData expects this market to flourish in 2017 as devices overcome reimbursement hurdles.
Robot-Assisted Procedures Will Flourish

Physicians and patients increasingly prefer minimally invasive procedures over open surgeries due to shorter operative times, lower post-operative complications rates, and quicker discharge times. The introduction of robot-assisted systems provides further impetus for the adoption of minimally invasive surgical procedures in the future. GlobalData estimates the current robotic surgical systems market (excluding ancillary instruments) to be close to $1 billion. This space is dominated by Intuitive Surgical, manufacturer of the da Vinci Surgical System, commonly used for laparoscopic procedures such as hysterectomies and prostatectomies. GlobalData expects to expand significantly over the next five years for a variety of reasons. Firstly, studies undertaken to evaluate robotic surgeries for numerous indications may yield promising results. If the results of these experiments prove substantial benefits of robotic surgery over conventional interventional procedures, support for the commercial use of these systems will multiply. Secondly, an increasing number of strategic partnerships between established medical device players and startup companies will advance the adoption of novel surgical systems. Examples of these partnerships include the strategic agreement between Medtronic and Israel-based Mazor Robotics in May 2016, as well as the formation of Verb Surgical, a joint venture from Johnson & Johnson and Verily initiated in late 2015.

GlobalData expects strategic partnerships to provide a stronger foundation to the growing market of robotic surgery systems in the long run. In the short term, particularly in 2017, GlobalData anticipates that clinical studies and regulatory clearances—primarily from the FDA—for these platforms will be on the rise. The development of more fully working prototypes will be an important milestone in the evolution of robotic surgical systems.

The New Trump Administration May Signal a Potential Boon for the US Medical Markets

Although the total impact on the market remains unclear, GlobalData expects that Donald Trump’s unexpected presidential win will be a boon for the global healthcare industry. Trump’s vision for healthcare includes a highly competitive, state-centric insurance market and increased infrastructure for affordable healthcare on the individual level. Proposals such as allowing deductible health insurance premiums from tax returns and creating specialized health saving accounts could encourage individuals to pay for medical care out-of-pocket, while block grants for Medicaid could lower the economic burden on the state level. However, repealing
even part of the Affordable Care Act could have chaotic effects on the market as millions of Americans on the plan lose their newly acquired insurance.

The biggest expected benefit for the global healthcare market is Trump’s proposal to grant overseas pharmaceutical companies entrance into the US market. Stocks in the pharmaceutical industry have already begun to soar after Trump’s win, and not without good reason. By removing barriers to entry into the US market, foreign companies will have access to one of the largest medical markets in the world. Although Trump has made several statements advocating for greater scrutiny of drug price increases, his policies ultimately center on promoting free trade and the determination of prices through supply and demand.

**Bariatric Specialties Will Witness Robust Advances in Minimally Invasive Surgery**

Within many medical device markets such as general surgery, cardiology, and orthopedic surgery, there has long been a trend towards less invasive procedures. This has resulted in an increase in the number of minimally invasive procedures over the past several years. In the field of general surgery, this trend is going one step further with an increase in the number of non-invasive procedures being developed. While minimally invasive procedures have helped to reduce the risk of infections and post-operative complications, non-invasive procedures further reduce the risk to patients by removing many of the risks of complication that come from incisions and the use of heavy anesthetics, and also reduce hospital stay times and therefore costs to the healthcare system. The field of bariatric surgery has been using minimally invasive procedures for several years and is now emerging in the field of non-invasive procedures since the introduction of gastric balloons. The use of gastric balloons is increasing globally, with significant growth in the US since receiving FDA approval in 2015. GlobalData expects this trend to continue through 2017, within the field of bariatric surgery and throughout other areas in general surgery.

**The Internet of Things Will Continue to Accelerate Healthcare Evolution**

The Internet of Things (IoT) is an emerging phenomenon where machines are embedded with sensors that allow them to relay data to each other with little to no human involvement. The resulting proliferation of “smart electronics” in phones and wearable devices creates a large dataset that could be parsed to detect diseases early, reduce public health risks, and improve
operational efficiencies in the healthcare industry. An often-cited use case for IoT in healthcare is remote monitoring and communication to keep track of patients as they move through a facility. While promising, IoT will witness slow adoption in healthcare due to regulations around patient data and the length of time it takes to determine the prognostic value of captured data.

GlobalData believes that 2017 will see healthcare insurance companies tapping into a different application of IoTs. With the preponderance of wearable devices and pricing pressures in healthcare, insurance premiums will be determined by a patient’s lifestyle as recorded on a smartwatch in a usage-based insurance model. This is predicated by car insurance companies, which use odometer readings, mileage aggregated from GPS data, and other driving patterns to determine the risk profile of a client. Although the system is not foolproof, healthcare insurance companies can implement an algorithm that uses daily exercise regimen, eating habits, and vital signs to determine pricing plans.

The concerns resulting from increased connectivity due to IoT demand better emphasis on security and privacy. Unlike current practice, where software companies and big conglomerates frequently lose client information to hackers, policies have to be in place to encrypt healthcare data and decentralize the database where possible using new technologies such as the Blockchain.

**Personalized Medicine Will Inch Closer to Revolutionizing Diagnosis and Treatment**

Recent technological advances have heralded a new age of personalized medicine, shifting away from the traditional practice of identifying therapies that target the majority of the population. Personalized medicine is the tailoring of treatment to a patient’s individual genetic profile, enabling an understanding of disease progression and response to certain treatments. This trend is being driven by improvements in genetic sequencing, such as the rise of next-generation sequencing, as well as advances in systems biology and pharmacology. Together, these technologies enable analysis of the clinical implications of a patient’s genetic profile, which GlobalData expects to be a continuing trend in 2017.

Conventionally, a randomized controlled trial is used to gather evidence applicable to a heterogeneous population; personalized medicine has the ability to meet some of the shortcomings of this approach, such as the potential for a certain gene to alter the outcome of a therapy. This was first seen to be the case in 2002, where a genetic link was found to cause a hypersensitivity reaction upon treatment with abacavir. Currently, cancer treatments are
being developed alongside companion diagnostics that are able to evaluate the effectiveness of the drug based on the patient’s genetic profile. Furthermore, personalized medicine enables clinicians to determine appropriate drug doses for patients. Determining ideal dosage of warfarin is often challenging due to its narrow therapeutic range, but advancements in personalized medicine have found links to three genes that can better predict patient response, enabling safer prescriptions. In addition to tailoring treatment, personalized medicine is able to identify a patient’s risk of developing certain diseases, including several cancers. The utility of personalized medicine at several major points in the course of a patient’s disease will make this a major trend in 2017, and has potential to revolutionize the diagnosis and treatment of disease.

An Emphasis on Home Care Will Rise

With the climbing costs of healthcare services and shortages of healthcare facilities and labor, cost-effective home care devices will be further increasing. Fueled by technological advances and increasing financial incentives, the number, range, and complexity of home care medical devices are surging. Complex therapeutic devices such as infusion pumps, ventilators, and dialysis machines will be used more often in the comfort of patients’ own homes or even be taken with them when they travel. Thanks to advanced wireless technology and powerful database tools, clinicians can oversee patients with the necessary data remotely. In addition to traditional home care devices, healthcare will begin to move into the palms of patients’ hands, providing healthcare management apps on smartphones or tablets, from health monitoring to disease diagnosis. This transformation represents a new challenge to the medical industry, as new entrants push aggressively to provide efficient and personalized solutions to fulfill clinical needs. Steep learning curves and ambiguous reimbursement for these devices may impact the market adoption, but these new care delivery models will likely continue to spread in 2017.