

# The Medical Devices Supply Chain

## Introduction

While looking out the window of her office, seeing the snow pile up in the parking lot of the Medical Technologies Corporation (MTC) headquarters in Collegeville, Pennsylvania, Chris Evert, the Chief Supply Chain Officer continued to ponder her dilemma, convinced that there might not be a simple solution to the problem he was asked to solve. Last week, at the MTC Board of Directors meeting, he was told flat-out that he had to come up with costs savings large enough to cover the newly-imposed Affordable Care Act (ACA) Medical Device Excise Tax of 2.3% of revenue. The surgical devices that the firm sells puts them squarely into the focus of this tax, and after taxes, 2.3% of sales translated into over 10% reduction in MTC's profits. This would ensure that no one in the corporation would get their annual bonus, or worse, lay-offs might be considered. Her CFO, Peter Sampras, had pointed directly at him and made it clear that he had to come up with major cost savings and it was obvious that there was no way around this.

## Background

The United States is the largest medical device market in the world with an aggregate market size of around \$110 billion in 2014; expected to reach \$133 billion by 2016. Overall, there are more than 6,500 medical device manufacturers, most of them small and medium-sized and more than 80 percent of them have fewer than 50 employees. The sector employs almost half a million people directly and indirectly almost 2 million more. Most of the jobs in this industry require a highly-skilled workforce. In general, medical device firms are located throughout the country, however, there are larger concentrations in regions known for other high-tech, such as Silicon Valley and Boston's route 128. Table 1 shows the general categories of medical devices.<sup>i</sup>

### *The U.S. Medical Device Industry*

Medical devices are essential healthcare products in many hospital surgical departments. This generally protects the manufacturers from volatile swings in revenue, but these products also carry high price tags, which makes them somewhat vulnerable to economic downturns. Recently, technological advances, the legislative expansion of healthcare access, the improving economy, and hospitals' desire to increase revenue through service line expansions have positively influenced demand for medical devices. In addition, the aging US population has further contributed to growth, due to the high

incidence of health issues requiring medical devices within the elderly population. The Affordable Care Act (ACA) implemented an excise tax on medical devices (2.3% of revenues) which is expected to drag down average industry profit margins, (8.8% of revenue in 2015) unless the industry finds a way to dampen the impact of the legislation. The major market segmentation is shown in Exhibit A.

Manufacturers in the Medical Devices supply chain have typically had a weaker bargaining position in price negotiations with large hospital buying groups, known as Group Purchasing Organizations (GPO). In addition, the relationship between device manufacturers and their hospital clients is partially mediated by third-party medical surgical distributors. Most large manufacturers, such as MTC, rely heavily on distributors to supply their products to hospitals via GPO contracts which provide hospitals with access to the manufacturers' products. On the other hand, smaller medical device manufacturers are often shut out of the market when a larger competitor has secured exclusive contracts. In exchange, these GPO customers often have advantages in pricing negotiations by consolidating their purchases through a sole (single) source. Increasingly, hospital customers of medical device manufacturers are joining larger GPOs to enhance their purchasing power. Therefore, in the last five years, the size of transactions has become larger, more complex and to a greater degree, transactions are based on long-term contracts. The power balance is shifting to the customers and this presages significant pricing pressures and increases the use of preferred vendors.<sup>ii</sup>

### *The Medical Devices (Medical Surgical) Distributors*

The Medical Supplies Wholesaling industry is the link in the Medical Devices supply chain between manufacturing companies and healthcare providers. The industry was hit hard in the recession of 2009, which caused a decline in physician visits, and subsequent medical procedures. Nonetheless, the industry has shown resilience and growth potential, as the number of doctors' office visits declined a further 2.8% in 2010. After the recession, as the economy improved, growth has rebounded, especially among patients who lost their employment, and along with that their insurance coverage, and had to delay elective surgical procedures. Accordingly, overall revenue in the industry has grown in line with the slowly recovering economic environment. The average revenue is projected to increase at an annual rate of 4.8% over the next five years. The major cause of this growth is the increased activity in the medical sector overall, which can be attributed to the ACA extending healthcare coverage to tens of millions of previously uninsured Americans. More specifically, the average revenue increase in the medical device distribution industry is predicted to be 7.6% in 2015, however margins in this tier are razor thin (as low as 2%). In addition to revenue growth, the medical surgical distribution industry is undergoing significant consolidation. Over the coming five years, the number of companies is expected to decline on average by 0.6%. Consequently, larger firms have the ability to better negotiate pricing and provide a one-stop solution to customers nationwide. While the number of firms is on the decline, the

total number of people employed in the industry has increased over the past five years providing further evidence for rising demand.<sup>iii</sup>

The medical device tax, specified in the ACA, will require medical device manufacturers to pay a 2.3% excise tax and will likely cause manufacturers to increase the price of goods sold to medical surgical distributors. However, medical surgical distributors will not be able to pass all the tax hikes on to healthcare providers; therefore, industry profit growth is expected to be stunted through the coming years. Moreover, the Centers for Medicare and Medicaid Services (CMS) continues to revise and adapt durable medical device supplier standards, which were first implemented in late 2008. These standards were a major departure from the previously low level of CMS oversight. Now, meeting these supplier standards is a prerequisite for manufacturers in the industry so they can receive payment for products that are covered by Medicare. Initially 26 requirements were imposed on suppliers that wished to participate in the Medicare program. The most significant stipulation requires that all suppliers become accredited by a recognized independent organization.

### *The Major Hospital Systems in the United States*

Hospitals are the primary provider of healthcare in the United States. Overall, hospitals are expected to generate almost one trillion dollars in revenue in 2015. Revenue growth is expected to average about 4% per year, including growth of 4.4% in 2015. While volume and revenue may be increasing, hospitals face unprecedented financial uncertainty given a major shift in reimbursement methodology from a historically volume-oriented (fee-for-service) approach to a more value-oriented system which links hospital reimbursement to patient outcomes. This financial focus on patient outcomes (and health management) is driving an increased emphasis on coordination among healthcare providers in the downstream healthcare delivery supply chain. As a result, this traditionally fragmented industry sector has just begun consolidating, creating large hospital systems known as integrated delivery systems or networks. The hospital provider industry is quite decentralized as no firm accounts for more than 5.0% of industry revenue, and the four largest firms combined account for less than 10.0% in 2015. However, the picture changes when industry concentration is examined at the regional level. For example, the Hospital Corporation of America, mainly located in Florida and Texas, controls between 20% and 40% of the market in the areas in which it operates. Similarly, Universal Health Services seeks dominance in growth markets and focuses on medium-sized cities of up to 500,000 people, thereby avoiding larger cities with more competitors. Another player, Community Health Systems, has also focused on markets outside metropolitan areas, and a large proportion of their hospitals are in markets where they have no competitors at all.<sup>iv</sup> The major growth drivers of volume are the broadened insurance coverage brought by the ACA, the sinking unemployment rate that increased not only insurance coverage but also consumer disposable income, and the aging population. Summarizing, hospital providers are under

pressure to do more with less (provide equal or higher value of services at the same or lower total costs).

Given the conditions described above, innovation has received considerable and increasing attention among major hospitals in search of new revenue streams. The ACA legislation also created the Center for Medicare and Medicaid Services (CMS) Innovation Center<sup>v</sup>. Through this Center, \$10 billion has been allocated to support hospitals in developing new technologies and innovative models that improve patient care. Plainly stated, the Innovation Center was established for the purpose of developing and testing new innovations to reduce (CMS) program expenditures, while maintaining or enhancing the quality of care (CMS, 2012). In addition to regulatory pressures, hospitals are experiencing increased competition and have come to understand the need to embrace innovation to improve performance. The increased focus on innovation is evidenced in that over one million patients annually receive care from providers participating in the Innovation Center initiatives<sup>v</sup>. The Innovation Center's project portfolio has attracted participation from a broad array of healthcare organizations and focuses on an array of innovations from service delivery models to technology. People may not typically think about hospitals as 'innovators', but consider the Cleveland Clinic, which has a commercialization arm that "turns the breakthrough inventions of Cleveland Clinic employees into patient-benefiting medical products"<sup>vi</sup> Through a variety of methods including direct equity investment and licensing agreements, "66 companies have been enabled by Cleveland Clinic technology and expertise"<sup>vi</sup>. The Cleveland Clinic is active in technology development, having transacted nearly 450 licenses and over 2,200 patent applications, securing 525 issued patents.

### *Medical Device Tax*

One of the most important environmental factors affecting the industry was the recently introduced Medical Device excise tax. This tax has been heavily criticized by the Republican side of the Congress.<sup>vii</sup> The ACA has imposed a 2.3% tax on medical device revenues, which is unlike other corporate levies, for example income tax, which is paid on profits. Such a tax can have a disastrous effect on some businesses, especially ones which have already lower profitability. In addition, since companies require FDA approval to sell their products, some medical device manufacturers require years of investments until they become profitable, and the tax would prolong the time until a new firm would reach profitability. On the other side of the political spectrum, there is a strong sentiment that the law is necessary to fund the ACA and that medical device manufacturers are profiting from the new health care law, and as such should fund it. There is a major disagreement on the number of jobs that might be lost due to such a tax, with the industry already claiming reduced spending on Research and Development. One estimate predicts that the total loss of jobs will reach about 195,000 in the supply chain over the next five years. On the other hand, the Congressional Research Service predicts that job

losses will be relatively minor and the introduction of the tax should have an insignificant effect on the final price of health care if at all.<sup>viii</sup> The specific stipulations of the Medical Device Excise Tax is shown in Exhibit B.

## The Medical Devices Supply Chain at MTC

The Medical Devices supply chain for MTC consists of several major players: Manufacturers, Medical Surgical Distributors and/or Third Party Logistics (3PL) Firms, and Hospitals. The flow of products from the manufacturing plant to the hospital operating room usually takes devices through a lengthy path. The manufacturers assemble the products usually in lots of 7,200 per week. Each surgical kit contains hundreds of individual parts that may be used by the surgeon. Often, it is not possible to predict which items will be needed in an individual surgical case. In addition, the number of surgical kits used varies dramatically (see Exhibit C). One issue is Inventory Management and specifically if the six months of supply is too large. This is something that should be analyzed. Part of the sales representative's function is to show the surgeon which devices to use. In addition, if the surgeon is using a new kit, the sales representative will show him or her how to use it with a patient.

After assembly, the surgical kits are sterilized. While other manufacturers do this in-house or let the distributor handle sterilization altogether, MTC uses an off-site sterilization service provider. Some manufacturers even enable the product to be sterilized by their distributor, but then have to ensure this step is completed in order to satisfy their own Quality Assurance department. When sterilized off-site, the surgery kits are then sent back to the manufacturer, before they are shipped out to the next tier in the supply chain. The one-way transit time from the manufacturer to the sterilization provider is on average 48 hours and the sterilization takes usually 24 hours. There are two choices on how a manufacturer can route its products, either to a medical surgical distributor or by using their own 3PL. Using a 3PL allows the manufacturer to control their product all the way to the final customer, but there are several efficiencies that can be gained by using a distributor. Amongst the advantages, manufacturers have is that they are not responsible for the inventory and they can reduce their inventory outstanding and they can recognize revenue much quicker.

The distributors or 3PLs usually perform two functions: at the first level, they provide a central distribution function, and at the second level, to pre-position inventory near the hospital at a branch or loaner office location. In some cases the second level distribution is performed by the salesperson themselves. They often carry trunk stock in their company-provided vehicles. This increases the amount of inventory in the supply chain significantly. The transfer of inventory typically occurs on a weekly basis, but emergency replenishments are possible as needed to fill demand. Another issue is the

use of RFID tags, which are used to streamline the supply chain. The tags may be attached to the products at either the first or the second-tier distribution points.

Some manufacturers route devices through multiple DCs. For example, devices flow to a Central Distribution Center, then to a Regional Distribution Center before being delivered to a health system's central supply distribution center or individual hospitals. Others, like MTC, utilize loaner offices and branch offices rather than regional distribution centers. Their devices often are delivered directly to the Operating Room by sales representatives, bypassing Central Receiving and hospital storage facilities (Central Supply / Materials Management). Unused instruments and devices are shipped back into the distribution network, where the kits are replenished, re-sterilized and shipped back to another hospital.

## The Key Decision-Makers in the Medical Devices Supply Chain

The major objective of MTC's management team is to satisfy the requirements of the firm's investors and maintain and increase profitability of the firm overall. The medical device tax is a serious impediment to this mandate. Peter Sampras and the rest of the senior leadership are willing to make considerable changes to the supply chain to increase efficiency to the point that they do not have adverse effects. They believe that the current system is working well, but they also know that something has to be done.

Evert views the sales representatives as adding value in a fragmented way. While they maintain the relationships with the surgeons, who are generally viewed as the major driver of which surgical kit to use, they are also highly-trained individuals, who spend considerable time in the operating rooms assisting the surgeons during cases. They are compensated very well and their commissions add substantial cost to the product, but they also provide a competitive advantage through their relationships with the surgeons, which is of immeasurable value. The average sales representative earns a total salary of around \$300,000, with some top earners receiving more than \$1,000,000 per year. John McEnroe, the vice president of sales does not want to see the model changed at all, but he knows there are many of his colleagues that believe the solution to the profitability issue is to remove sales representatives entirely.

The intermediaries in the supply chain, medical surgical supply distributors, rely on the fact that hospitals prefer buying from one large distributor that carries a full line of medical supplies. While a manufacturer could build a distribution network with the help of a specialized 3PL, they have to overcome the fact that hospitals prefer working with distributors. But if they were able to lower the selling cost enough to warrant a change, they might be able to convince the hospitals to switch.

Hospital Group Purchasing Organizations (GPOs) bundle the purchases of their hospital members which enable them to reduce their costs. The group pools the negotiating and buying power of multiple health care providers which helps hospitals purchase supplies at a lower cost. These organizations can leverage the large combined spend and match the power of large dominant manufacturers of medical supplies. The major objective of these groups is to reduce cost, and any changes that can lower the costs of products will be welcome.

Surgeons have an important position in the medical devices supply chain because they are powerful decision-makers in the supply chain. If a doctor believes that a certain surgical device or kit should be used, they can make the case to the hospital administration to purchase it for their surgical cases regardless of whether or not the SKU is on the GPO contract. These are known as Physician Preference Items (PPIs). It is generally known that about 80% of surgeries are scheduled routine surgeries, using standard surgical kits. The remaining 20% of cases require special kits and often the advice of the sales representative. In general, the surgeons prefer working closely with their sales representatives for the first few surgeries, until they master the intricacies of the new device.

Finally, there are hospital administrators, who are responsible for managing costs for the hospital. As discussed, in light of the new ACA, there is strong pressure for hospitals to lower costs. Given the reduced and redesigned reimbursement methodologies facing hospitals, pressure to reduce costs has never been greater. Hospital administrators have to balance the requirements of the surgeons, who have to receive all the tools necessary to perform their surgical cases with the overall financial well-being of the entire organization. The hospital administration has a number of challenges, some of which are outlined in the New Jersey Commission on Rationalizing Health Care Resources 2008 report (p. 118) which reads, "...Physicians have the primary role in determining what resources are utilized within the hospital... Yet the hospital is financially liable for many of these decisions and currently has few tools at its disposal to address overutilization of resources by physicians. The Commission heard a presentation from a consultant where costs for similar risk patients with a similar diagnosis varied by a magnitude of five depending on the physician caring for the patient within a given hospital." For these reasons, medical device manufacturers have historically aggressively marketed to physicians with the aim of indirectly influencing hospital purchases through their physician champions. Today, hospitals are implementing cross-functional value analysis teams or committees often lead by the hospital's supply chain function and comprised of physicians, business managers, and clinical staff to evaluate suppliers (and GPO) contracts and approve/deny requests for 'off-contract' purchases. The percentage of 'on-contract' purchases has become an important supply chain metric in leading hospitals.



## Current Industry Issues

The major medical device manufacturers, such as Medtronic, have broadened their product portfolio and expanded their international operations. In addition, there is a lot of publicity around 3D printing changing the medical devices industry. In a recent New York Times article, it was reported that 3D printed limbs can not only provide customized solutions to patients and doctors, but it can provide them at a much lower cost than traditional prosthetics.<sup>ix</sup> The other major advantage from a supply chain perspective is that inventory management becomes significantly easier because surgical kits could be printed on-demand and customized to the actual needs of the patient. Although the technology is still in its infancy, it could have a very significant effect on the current competitive landscape.

An important factor in the industry is consolidation. In addition, the industry went through a number of strategic acquisitions in recent years. Most significantly, in June 2014, Medtronic announced plans to acquire Covidien in a deal that will create the largest medical device manufacturer in the world. Another facet in the Medtronic-Covidien merger is the fact that it has been called a tax inversion deal. As the Wall Street Journal reported: “The deal, which could be announced Monday, would be structured as a so-called tax inversion, according to one of the people. In such deals, acquirers buy companies domiciled in countries with lower corporate tax rates than their own as a means of reducing their overall rate. Covidien is based in Ireland, which is known for having a relatively low tax rate: its main corporate tax rate is 12.5%. In the U.S., home to Medtronic, the 35% rate is one of the world’s highest.”<sup>x</sup> Other firms could also start considering this option as tax inversion can dramatically reduce the expenses of the firm.

## Next Steps

After getting her marching orders at the MTC Board of Director’s meeting, Chris Evert moved quickly. He conducted a working session with their major distributor, Bishop Health, on how to streamline the relationship and save cost; hoping to make up most of the loss in revenues caused by the tax. Her counterpart, Stefanie Graf, the Director of Purchasing at Bishop, offered up several strategies. First, they both agreed, that if the law would get repealed, that would be the easiest way out. So, one strategy might be to ramp up their lobbying efforts, especially in the Republican-controlled Congress, and hope for a legislative change. The impact of this change would eventually change the landscape of the overall industry, however in the short run, the entire ACA was working its way through the judicial branch in the U.S. courts and the challenges brought by the various cases might even get argued in front of the Supreme Court in 2015. But this would essentially be just hoping for the problem to fix itself, but inaction is not something they cannot afford.



As Evert returned to her office after a day of meetings, he wondered what the supply chain for MTC should look like. There were several issues with the current supply chain, as he saw it. First, the off-site sterilization was adding not only time to the supply chain, but also introducing multiple touch points and the need for more transportation. Second, because of the multiple touch points throughout the supply chain, transportation and warehousing were controlled by multiple companies, which created potential safety issues. Third, and for many the most pressing issue, was the issue of sales representatives themselves. Sales representative commissions were adding direct cost to the final product. By some estimates, sales, general, and administrative expenses accounted for around 45% of revenue in 2014 and the largest driver was these sales commissions. While having a representative call on surgeons certainly seemed like a logical idea, a number of people in the firm argued for the elimination of this type of sales model. Although there might be a sales advantage, it just seemed to Evert that the practice of carrying inventory into the operating room seemed quite outdated and inefficient. The financial statements for MTC are shown in Exhibit D.

Another option that Medical Technologies was considering was to move away from the Distributor model to a direct model, by using a Third Party Logistics (3PL) provider. Changing channels was not an easy option, but the advantage would be that MTC could increase the sales price they received since they would sell at retail versus wholesale. It would, however require MTC to take responsibility for the activities that the distributor was once performing. Another requirement would be to convince the powerful hospital group purchasing organizations (GPOs) to add their products directly to their catalog without going through a distributor. This would not be an easy task either and it is questionable what impact it would have on their competitive position.

Finally, Evert tackled the issue of why the salespeople commanded such very high compensation. The model was skewed towards performance, as sales compensation consisted primarily of high commissions, however this did cut deeply into the profits of the firm. John McEnroe, the Vice President of Sales was livid when they met to talk about the sales model. McEnroe told Evert point blank that he didn't understand what it took to sell the company's products and that nobody else in the industry was using a different model. Some of their competitors are in a very strong financial position, as shown in Exhibit D, while others were struggling. The question is how to take advantage of possible weaknesses, while not opening up their own. He suggested that Evert take a look at the input prices and rationalize the distribution network. Evert was not necessarily convinced, but he knew that any changes to the sales representative model would require a solid financial analysis.

Another popular method of improving efficiency is implementing low unit of measure (LUM) Lean/JIT systems between distributors and hospitals. "Distributors are more willing to shift from the traditional bulk model of shipping inventory in full-case quantities of use. Distributors in essence assume

responsibility for holding inventory and replenishing individual locations. The hospital is still responsible for placing the purchase orders but they are transmitted by individual departments, and the material is delivered directly to the ward, bypassing the storage room. Under this model, inventory expenses can be more aligned with clinical demand”.<sup>xi</sup> This and other changes would have to happen with the consent of the hospitals value analysis teams (VATs) or committees (VACs) which include physicians, business managers, clinical managers, and other leaders to make policy decisions.

The placement of RFID tags in the field warehouses or offices had also been problematic as that had created an additional step in the workflow of the supply chain. However, in considering this, it brought up the broader issue of where specific tasks in the supply chain should be performed. It is questionable whether each task is performed at the best location in the supply chain. Inventory management in the medical device industry at large is a serious impediment to efficiency. Devices are stored in several locations throughout the network of the manufacturer, 3PLs, distributors, and at various locations in the hospitals, for example operating rooms, and surgical pods. This however, makes inventory tracking and control significantly more difficult. In addition, the inventory management systems in hospitals are often inadequate for maintaining consistently efficient levels of supply.

The fact that most surgical kits are hand-carried into the operating room had long troubled Evert. Similarly to other medical supplies, the surgical kits could be stored in “smart kiosks” at the hospital locations, which would enable them to effectively control the inventory and it would reduce the need for the hospital to carry the inventory themselves. A member of the surgical staff could then check out and pay for the kit when necessary and it would remove a lot of touch points. In emergencies, there would be a button to press to bypass the checkout process, however most procedures were scheduled and inventory should remain accounted for, if the hospital staff would follow the protocol for checking out the product. In addition, kiosk distribution would enable the manufacturer to have complete visibility into the “last mile” of the supply chain. Sales representatives would only be required to maintain the relationship with the surgeons and worry less about inventory control. Evert was not sure of the barriers that he would encounter, but she was sure that her colleague John McEnroe would fight him as hard as he could and the reaction of the hospitals would remain unclear as well. Regardless of the solution Evert recommends for MTC, there is a lot of work ahead of him.

## Exhibits

### *Exhibit A: Overview of the Medical Device Industry*

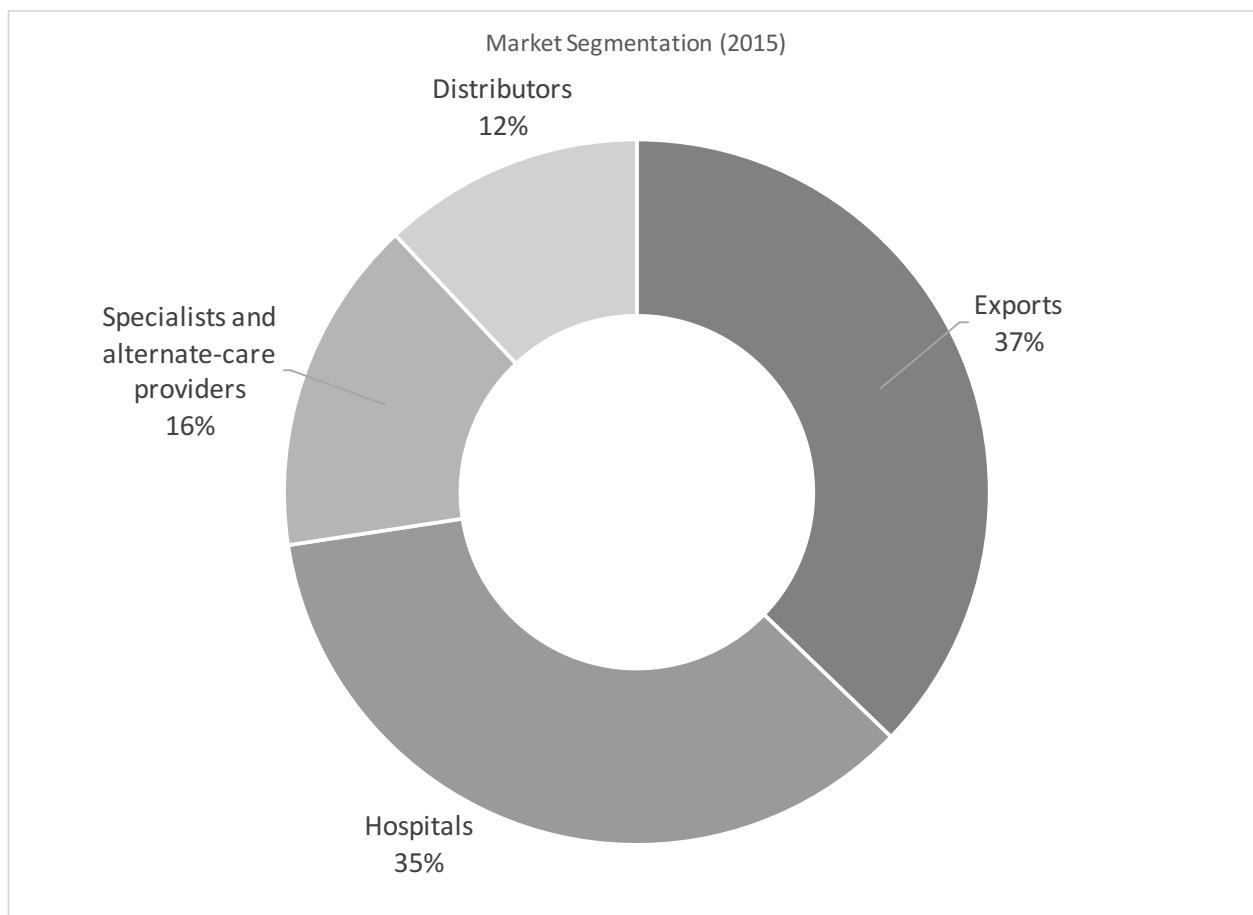
**Table 1: Medical Device Categories.**

<b>Electro-medical equipment:</b>	Includes a variety of powered devices, such as pacemakers, patient-monitoring systems, MRI machines, diagnostic imaging equipment (including informatics equipment), and ultrasonic scanning devices.
<b>Irradiation apparatuses:</b>	Includes X-ray devices and other diagnostic imaging, as well as computed tomography equipment.
<b>Surgical and medical instruments:</b>	Includes anesthesia apparatuses, orthopedic instruments, optical diagnostic apparatuses, blood transfusion devices, syringes, hypodermic needles, and catheters.
<b>Surgical appliances and supplies:</b>	Includes artificial joints and limbs, stents, orthopedic appliances, surgical dressings, disposable surgical drapes, hydrotherapy appliances, surgical kits, rubber medical and surgical gloves, and wheelchairs.
<b>Dental equipment and supplies:</b>	Includes equipment, instruments, and supplies used by dentists, dental hygienists, and laboratories. Specific products include dental hand instruments, plaster, drills, amalgams, cements, sterilizers, and dental chairs.

### **Main markets for medical device manufacturers**

- Hospitals and clinics (partly through GPOs)
- Specialists and alternate-care providers
- Third-party healthcare providers and Distributors
- Exports

**Figure 1: Expected Major Market Segmentation in 2015**



*Exhibit B: Medical Device Excise Tax*

On Dec. 5, 2014, the IRS issued final regulations on the new 2.3 percent medical device excise tax that manufacturers and importers will pay on sales of certain medical devices beginning Jan. 1, 2015. In addition, the IRS issued Notice 2012-77, which provides interim guidance regarding the determination of sale price and other issues related to the tax.

The IRS developed the final regulations in consultation with technical experts at the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services, and after carefully reviewing numerous public comments.

Generally, under the final regulations, a “taxable medical device” is a device that is listed as a device with the FDA under section 510(j) of the Federal Food, Drug and Cosmetic Act, and 21 CFR part 807, pursuant to FDA requirements. If a device is not listed as a device with the FDA but the FDA determines that the device should have been listed as a device, the device will be deemed to be listed as a device with the FDA as of the date the FDA notifies the manufacturer or importer in writing that corrective action with respect to listing is required.

The new tax does not apply to sales of eyeglasses, contact lenses, and hearing aids. The new tax also does not apply to the sale of any other devices that are of a type generally purchased by the general public at retail for individual use (the retail exemption).

In general, the final regulations provide a facts-and-circumstances approach to evaluating whether a type of device qualifies for the retail exemption. Specifically, the final regulations suggest factors to consider in evaluating whether a particular type of device qualifies for the retail exemption. The factors enumerated in the final regulations are non-exclusive; additional factors may be relevant to determining whether a given type of device qualifies for the retail exemption.

The final regulations also identify several categories of medical devices that qualify for the retail exemption (the retail exemption safe harbor). The retail exemption safe harbor includes devices in the FDA's online in vitro diagnostics (IVD) Home Use Lab Tests (Over-the-Counter Tests) database, devices that the FDA describes as "OTC" or "over the counter" in certain official FDA classification or product code headings or descriptors, and a number of devices that qualify as durable medical equipment, prosthetics, orthotics or supplies for which payment is available on a purchase basis under the Medicare Part B payment rules.

The medical device excise tax applies to manufacturers and importers and generally does not apply to individual consumers.

Sales of taxable medical devices for further manufacture or export may be made tax free if certain registration and other requirements are met.

*Exhibit C: Surgical Kits Inventory and Shipments*

Month	January	February	March	April	May	June	July	August	September	October	November	December
2013												
Starting	120,816	125,871	120,415	132,696	125,386	124,197	135,897	121,361	141,836	129,436	131,764	127,822
Shipped	26,203	33,738	18,977	40,057	33,429	18,070	47,283	1,852	42,170	30,419	32,223	22,894
Production	31,258	28,281	31,258	32,747	32,240	29,770	32,747	22,327	29,770	32,747	28,281	20,839
Ending	125,871	120,415	132,696	125,386	124,197	135,897	121,361	141,836	129,436	131,764	127,822	125,767
2014												
Starting	125,767	131,395	126,075	139,201	132,010	130,192	144,269	129,639	149,643	138,731	141,597	136,333
Shipped	27,135	34,962	19,637	41,514	34,581	18,685	48,953	1,838	43,675	31,457	33,346	23,677
Production	32,763	29,642	32,763	34,323	32,763	32,763	34,323	21,842	32,763	34,323	28,082	23,402
Ending	131,395	126,075	139,201	132,010	130,192	144,269	129,639	149,643	138,731	141,597	136,333	136,058

*Exhibit D: Medical Technologies Corporation Financials*

**Table 2: Medical Technologies Corporate Income Statement**

	2010	2011	2012	2013	2014
Revenue	\$ 4,437.18	\$ 4,831.20	\$ 5,482.62	\$ 5,713.62	\$ 5,953.86
Cost of Goods Sold	\$ 1,441.44	\$ 1,508.76	\$ 1,855.26	\$ 1,835.46	\$ 1,964.82
<b>Gross Profit</b>	<b>\$ 2,995.74</b>	<b>\$ 3,322.44</b>	<b>\$ 3,627.36</b>	<b>\$ 3,878.16</b>	<b>\$ 3,989.04</b>
Research, development and engineering expenses	\$ 221.76	\$ 260.04	\$ 304.92	\$ 310.86	\$ 353.76
Selling, general and administrative expenses	\$ 1,653.96	\$ 1,786.62	\$ 2,079.00	\$ 2,287.56	\$ 2,683.56
Intangible amortization	\$ 23.76	\$ 38.28	\$ 80.52	\$ 81.18	\$ 91.08
Other	\$ 44.22	\$ 81.84	\$ 50.16	\$ 49.50	\$ 31.68
	<b>\$ 1,943.70</b>	<b>\$ 2,166.78</b>	<b>\$ 2,514.60</b>	<b>\$ 2,729.10</b>	<b>\$ 3,160.08</b>
Operating income	\$ 1,052.04	\$ 1,155.66	\$ 1,112.76	\$ 1,149.06	\$ 828.96
Other income (-expense)	\$ 19.80	\$ (14.52)	-	\$ (23.76)	\$ (29.04)
Earnings before income taxes	\$ 1,071.84	\$ 1,141.14	\$ 1,112.76	\$ 1,125.30	\$ 799.92
Income taxes	\$ 341.22	\$ 300.96	\$ 225.06	\$ 268.62	\$ 135.96
<b>Net earnings</b>	<b>\$ 730.62</b>	<b>\$ 840.18</b>	<b>\$ 887.70</b>	<b>\$ 856.68</b>	<b>\$ 663.96</b>

Note: all numbers in \$millions unless otherwise noted

**Note on Income Taxes:**

The effective income tax rate on earnings was 17.0%, 23.9% and 20.2% in 2014, 2013 and 2012, respectively. The effective income tax rate for 2014 includes income tax benefits relating to favorable audit resolutions in multiple jurisdictions. The effective income tax rate for 2013 includes the net impact of effective settlement of all tax matters through 2005 relating to two foreign subsidiaries, and adjustment of the estimate of foreign tax credits to the amount shown on the tax return as filed. The effective income tax rate for 2011 includes the net impact of the settlements with the IRS as described above.

The American Taxpayer Relief Act of 2012 (the Act) was signed on January 2, 2013. The Act provided numerous tax provisions for corporations including an extension of the research tax credit and an extension of certain provisions for companies with significant international operations. The provisions originally expired at December 31, 2011 but were retroactively extended through December 31, 2013. In 2013 we recorded tax benefits of \$13 related to the 2012 research tax credit and other provision of the Act.



**Table 3: Medical Technologies Corporation Balance Sheet**

	<b>2013</b>	<b>2014</b>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$934.65	\$897.13
Marketable securities	\$1,936.30	\$1,769.47
Accounts receivables	\$958.10	\$1,017.06
<b>Inventories</b>		
Raw Materials	\$135.34	\$152.09
Work in process	\$47.57	\$56.95
Finished goods	\$664.64	\$743.70
<b>Total inventories</b>	<b>\$847.55</b>	<b>\$952.74</b>
Deferred income taxes	\$543.37	\$589.60
Prepaid expenses and other current assets	\$239.19	\$358.45
<b>Total current assets</b>	<b>\$5,459.16</b>	<b>\$5,584.45</b>
<b>Property, plant and equipment</b>		
Land, buildings and improvements	\$418.75	\$459.62
Machinery and equipment	\$1,076.69	\$1,213.37
<b>Total property, plant and equipment</b>	<b>\$1,495.44</b>	<b>\$1,672.99</b>
Less allowance for depreciation	\$860.28	\$948.72
<b>Net property, plant and equipment</b>	<b>\$635.16</b>	<b>\$724.27</b>
<b>Other assets</b>		
Goodwill	\$1,435.14	\$2,575.48
Other intangibles, net	\$954.08	\$1,332.63
Other	\$364.48	\$330.98
<b>Total</b>	<b>\$8,848.02</b>	<b>\$10,547.81</b>
<b>LIABILITIES AND SHAREHOLDER EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$192.96	\$210.38
Accrued compensation	\$312.89	\$358.45
Income taxes	\$46.90	\$87.77
Dividend payable	\$67.67	\$77.05
Accrued expenses and other liabilities	\$625.78	\$1,029.79
Current maturities of debt	\$10.72	\$16.75
<b>Total current liabilities</b>	<b>\$1,256.92</b>	<b>\$1,780.19</b>
Long-term debt, excluding current maturities	\$1,169.82	\$1,835.13
Other liabilities	\$661.29	\$871.00
<b>Shareholders' equity</b>		
Common stock, \$0.10 par value		
Authorized:	\$25.46	\$25.46
Additional paid-in capital	\$735.66	\$777.20
Retained earnings	\$4,912.44	\$5,103.39
Accumulated other comprehensive income	\$86.43	\$155.44
<b>Total shareholder equity</b>	<b>\$5,759.99</b>	<b>\$6,061.49</b>
<b>Total liabilities and shareholder equity</b>	<b>\$8,848.02</b>	<b>\$10,547.81</b>

Note: all numbers in \$millions unless otherwise noted

*Exhibit D: Medical Device Competitors*

**Table 4: Medtronic Inc. (US segment) – financial performance**

Year	Revenue		Operating Income	
	(\$ million)	(% change)	(\$ million)	(% change)
2010-11	8,872.00	-2.9	2,421.20	-6.2
2011-12	8,828.00	-0.5	2,524.30	4.3
2012-13	9,059.00	2.6	2,695.90	6.8
2013-14	9,209.00	1.7	2,349.60	-12.8
2014-15	9,611.80	4.4	2,179.80	-7.2
2015-16	10,501.20	9.3	2,450.50	12.4

Note: all numbers in \$millions unless otherwise noted

**Table 5: General Electric Company (US medical device and diagnostics segment) – financial performance**

Year	Revenue		Operating Income	
	(\$ million)	(% change)	(\$ million)	(% change)
2010	7,560.40	2.1	1,123.90	0.4
2011	8,091.10	7.0	1,254.20	11.6
2012	8,315.00	2.8	1,291.80	3.0
2013	8,274.10	-0.5	1,348.40	4.4
2014	8,191.40	-1.0	1,327.00	-1.6
2015	8,125.60	-0.8	1,350.10	1.7

Note: all numbers in \$millions unless otherwise noted

**Table 6: Johnson & Johnson (US industry-relevant segment) – financial performance**

Year	Revenue		Operating Income	
	(\$ million)	(% change)	(\$ million)	(% change)
2010	3,343.70	3.6	1,124.30	6.8
2011	3,240.70	-3.1	661.60	-41.2
2012	3,212.70	-0.9	841.90	27.3
2013	3,135.10	-2.4	578.90	-31.2
2014	2,736.30	-12.7	652.20	12.7
2015	2,850.90	4.2	705.00	8.1

Note: all numbers in \$millions unless otherwise noted unless otherwise noted

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