

## Industry Overview

### Healthcare systems - opportunities for SpineSonics

#### Trends in the US healthcare system

The average economic price tag of healthcare systems is 8.9% of GDP in OECD countries, while in the US healthcare expenditure is doubled at 16.9% (OECD, 2015). The correlation of healthcare expenditure and net income in OECD countries indicate healthcare expenditure of about 10% of net income ( $R^2=0.78$ ). The US healthcare system stands out with the highest healthcare expenditure, reaching 20% of income per capita (OECD, 2014). The size of the US population combined with the high level of healthcare expenditure and the existence of top notch medical schools and hospitals collaborate to generate the primary market for medical devices in the world. Notably, reimbursement policy in the US has recently shifted with the introduction of the Affordable Health Care Act (also known as Obamacare). Increasing of reimbursement coverage in the US could accelerate the rate of spinal fusions in the US. On the other hand, American providers are now expected to provide higher value of healthcare per dollar spent. Tightening of reimbursement may curb the high annual growth in spinal fusion, and provide an opportunity for low-cost surgical navigation. Blue Cross and Blue Shield of North Carolina, for example, excluded lumbar spinal fusion for disc degeneration indications and introduced a three month non-surgical treatment before surgery for spinal fusion, resulting in a 30% decrease in spinal fusions (Lee, 2014). In addition, the Affordable Health Act introduced a 2.3% sales tax on medical devices, a tax that may reduce the sales of some medical devices. However, since most healthcare products are inelastic goods, the sales tax is not expected to have a negative impact on sales volume. Importantly, the desire to increase the value of spine surgeries for patients and reduce spending for payers will create new business opportunities for innovative medical device companies such as SpineSonics.

#### Emerging Healthcare Markets

Outside the US, the largest market of spinal fusion in a single country is in Japan and China (Global Data, 2014). In contrast to the projected slow growth in the US market, growth in emerging economies is faster, in accordance with rising life-spans and rising healthcare expenditures. The spinal fusion market in China will grow from \$226 million in 2013 to \$665 million by 2020, at an impressive Compound Annual Growth Rate (CAGR) of 16.66%, making China the fastest growing spinal fusion market in the world (Global Data, 2014). The number of surgical procedures in China is expected to triple from approximately 46,000 in 2013 to an estimated 146,000 in 2020. The global market share of China will rise from 5% in 2013 to 10% in 2020. High growth rate of spinal fusion could be also evident in other emerging healthcare systems, such as India, and Southeast Asia, but access to these data is limited.

The high rates of growth in emerging healthcare systems are appealing to many medical device companies. In addition, the strategic focus of SSM on a low-cost solution to spinal navigation may become successful in less privileged healthcare systems. However, despite the faster growth rates in spinal fusions in emerging markets, higher total number of spinal surgeries, higher expenditure rates and geographical and cultural proximity to Canada makes the US the primary destination market for SSM, at least for now. Regardless of the marketing strategy, regulatory approval for a foreign medical device in China requires a home country approval first. This adds another reason to concentrate the initial efforts on FDA approval and postpone introduction to China to later stages.

### **Trends in the medical device industry**

Medical device manufacturers, together with healthcare providers and pharmaceutical companies are channeling scientific discoveries from the lab into the clinic. The global medical device industry is growing dramatically with an expected CAGR of 6.1% (Reuters,2012).The medical device market in Canada was estimated at \$6.4 billion in 2012, representing about two percent of the global medical device market of \$327 billion (Industry Canada, 2013). The Canadian medical device industry, excluding medical imaging, employed 35,000 employees in about 1,500 corporations, mostly small and midsize enterprises averaging 23 employees per company (MEDTEC, 2015). Worldwide, there are 27,000 medical device firms employing 1 million people, or 37 employees per company on average (Industry Canada, 2013). Comparing the relative share of the Canadian medical device market (2%) and the relative Canadian employment in medical devices (3.5%) suggests that Canada punches above its weight in the global medical device industry.

In contrast to the aggregation of pharmaceutical companies in increasingly large multibillion dollar multinational corporations, the medical device industry is more fragmented. The fragmentation of the medical device industry can be attributed to a lower barrier of entry and quicker product development cycles. Almost billion dollar R&D investment over a decade is required for the approval of a pharmaceutical drug, and the success rate of drug approval is about one in ten. In contrast, medical device approval is shorter, less complicated, and thus much cheaper. Within about a year, an FDA approval can be obtained. The large investment in pharmaceutical R&D erects a large barrier for entry, and thus limits the number of companies which can bring a new drug to the market. In the medical device industry, on the other hand, the smaller R&D costs lower the entry barrier and enable market entry of smaller entities. In the context of spinal navigation, big and expensive imaging systems, such as MRI and CT machines are an exception, as these technologies require larger R&D budgets and are typically developed by large multinational corporations such as GE, Siemens and Toshiba.

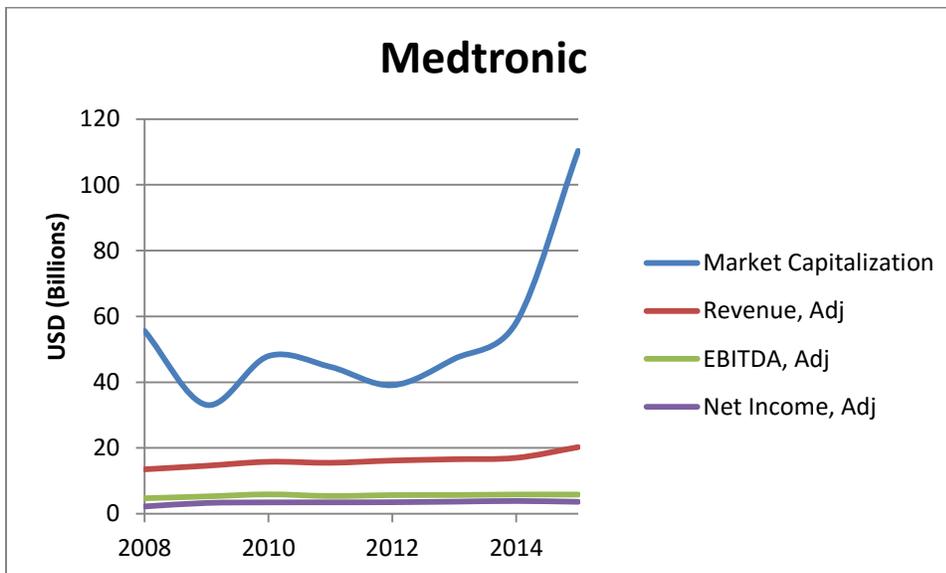
Different concentration of customers in the medical device industry is also likely to contribute to the fragmentation of this industry. Pharmaceuticals are prescribed to patients by

many physicians, and thus big pharma require a large and expensive sales force. In contrast, buyers of medical devices are often hospitals and outpatient clinics, representing doctors and nurses as end-users of the technology. The concentration of sales in hospitals and even multi-hospital aggregates can be supported by smaller sales teams, these are more affordable for small and mid-size enterprises.

Despite the general fragmentation trends in the medical device industry, M&A activities have intensified in recent years and several large multinational corporations with more than \$10 billion in revenues have emerged. Medtronic, Stryker and Johnson and Johnson (JNJ) are among the large medical device makers, and each one of these corporation has a significant stake in the spinal fusion market of surgical instruments and surgical navigation devices.

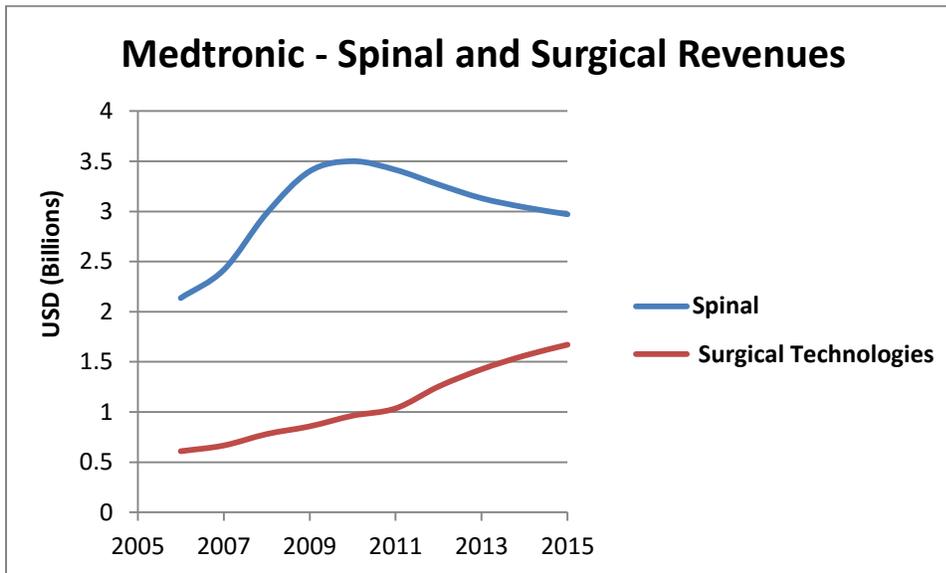
### Medtronic

Headquartered in Minnesota, Medtronic is the largest global medical device company, with a market cap of over \$100 billion (**Figure 2**). Revenues for Medtronic are steadily growing with a CAGR of 6.75% over the last four years. Profit margins are very healthy at slightly above 20% (**Figure 2**), similar to the profit margins of big pharma. At the beginning of 2015, cash and stock acquisition of Covidien for \$50 billion solidified the status of Medtronic as a global leader in the medical device industry. In 2012, Medtronic acquired China’s Kanghui Holdings for \$816 million, providing a strong beachhead for Medtronic in emerging Asian healthcare markets (Global Data, 2014). About half of Medtronic’s revenues are generated from cardiac devices, such as pacemakers. Medtronic is a market leader in surgical instrumentation for spinal fusions, including pedicle screws and rods. The annual spinal revenues in Medtronic reach \$3 billion, or 14% of total revenues. Surgical technologies yield \$1.7 billion, or 8% in revenue for Medtronic (Bloomberg Terminal).



**Figure 2.** Financial indicators at Medtronic (2008-2015). Data Source: Bloomberg Terminal.

Spine revenues for Medtronic have increased with a CAGR of 13% from 2006 to 2010, peaking at \$3.5 billion. Interestingly, the revenues of Medtronic from its spinal division are actually decreasing from \$3.5 billion in 2010 to \$3 billion in 2015 (**Figure 3**). The reason for this decline could be related to the slowdown in the number of new spinal fusion cases in the US since 2010 (**Figure 1**). Medtronic has reported slow growth in its US spinal revenues and high growth in its Asian sales (**Appendix 1**), but the Asian market is not big enough to compensate for the decline in the US market. In addition, Medtronic is facing an increased price pressure from its domestic competitors in the high margin surgical instrument market. Importantly, in contrast to the decline in spinal revenues, Medtronic is experiencing a steady growth of 12% CAGR in revenues from its surgical technologies division, grossing \$1.6B in revenues in 2015 (**Figure 3**). Medtronic is manufacturing intraoperative fluoroscopy units (the C-arm and the newer O-arm) and a compatible optic navigational system (StealthStation®). The sales of the O-arm accounts almost doubled from 150 units in 2011 to 350 in 2014 (**Appendix 1**).

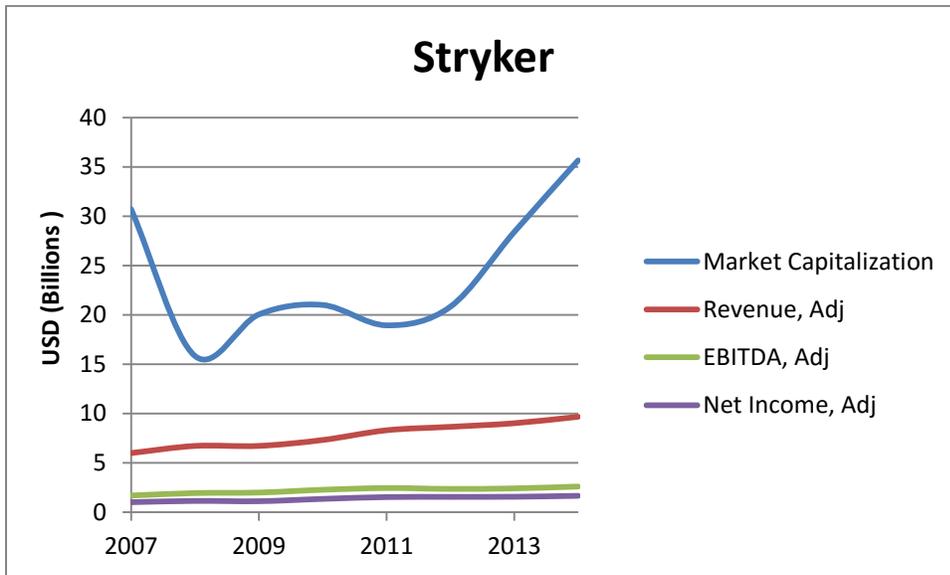


**Figure 3.** Spinal and Surgical technologies revenues in Medtronic (2006-2015). Data Source: Bloomberg Terminal

### Stryker

Stryker is headquartered in Kalamazoo, Michigan, and its market valuation reach \$35 billion, position it among the large medical device corporations. Over the last three years, Stryker has enjoyed consistent profit margins of 17%, slightly lower than profit margins in Medtronic. Fuelled by natural growth and a series of small acquisitions, the growth of revenues in Stryker was consistent at 5% over the last three years (**Figure 4**), slightly lower than growth in rival Medtronic. In addition, a higher price-earning ratio (P/E) for Stryker in comparison with Medtronic, indicates a higher risk perception for Stryker. Hip and knee surgeries contribute to

43% of revenues in Stryker, spine instruments contribute 18% of revenues, and surgical tools, including robotic arms for hip replacement contribute 39% of revenues. This segmentation emphasizes the importance of smart surgical tools and navigation devices in modern medical device companies. Stryker does not develop imaging equipment per se, but its surgical navigation software can integrate with existing CT modalities and ‘smart’ surgical tools to allow pre-operative planning. The ultrasound technology developed by SpineSonics could be integrated with the Stryker imaging Software to allow safer procedures for patients and surgeons.

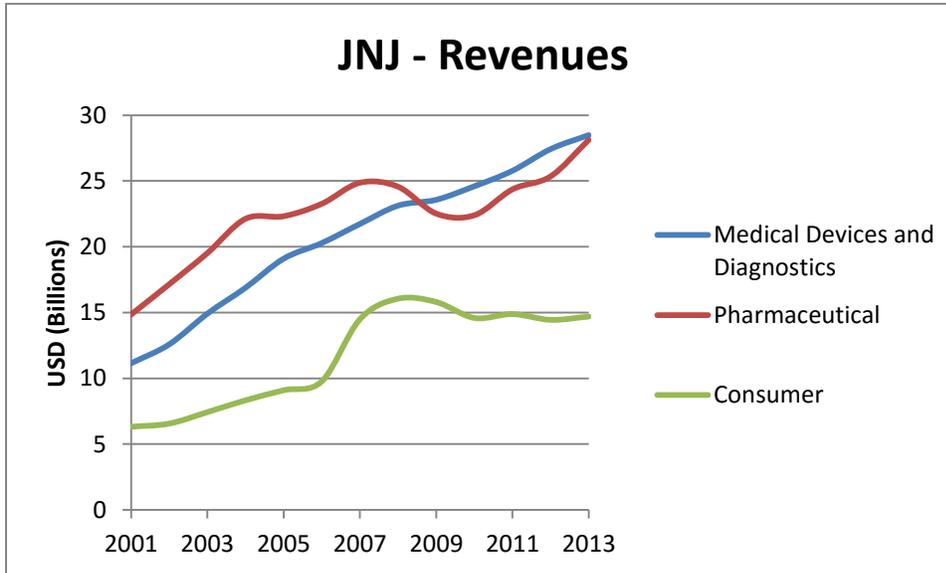


**Figure 4.** Financial indicators at Stryker (2007-2014). Data Source: Bloomberg Terminal.

### Johnson and Johnson (JNJ)

With a market cap of \$273 billion, JNJ is a healthcare industry global giant, uniquely combining pharmaceuticals, medical device and consumer products with strong brand recognition. Medical devices and pharmaceuticals contribute an equal 40% share to its revenue, and the rest are sales of consumer products (**Figure 5**). With \$28 billion in revenues from medical devices, JNJ is a global leader in the medical device industry. On the pharmaceutical side of its business, JNJ is ranked fifth in the US pharmaceutical market with \$14 billion in sales, while in Canada it is ranked first with \$1.9 billion in sales. JNJ is ranked seventh in the global pharmaceutical industry, with \$28 billion in annual pharmaceuticals sales around the world. Seventy five years of history brought JNJ to become one of the most diverse healthcare companies in the medical device and pharmaceutical industry. Interestingly, pharmaceuticals revenues in JNJ are more volatile (**Figure 5**), likely as results of patent expiration of blockbuster drugs and strong competition from generics. In contrast to pharmaceuticals declining shares in JNJ revenues (from 45% to 40%), the share of medical device revenues in JNJ is steadily growing over the last decade from 30% to 40%. JNJ market position can be described as broad scope with multiple sources of income in diverse fields. JNJ enjoys strong brand recognition despite its broad repertoire of products and differentiations. Particularly in its medical device division, JNJ can be

seen more as a holding company, with many medical device products managed independently. JNJ is therefore a decentralized array of more than 270 subsidiaries around the world operating under the JNJ umbrella (Global data, 2014). The subsidiaries are completely owned by JNJ and their financial reports are consolidated.



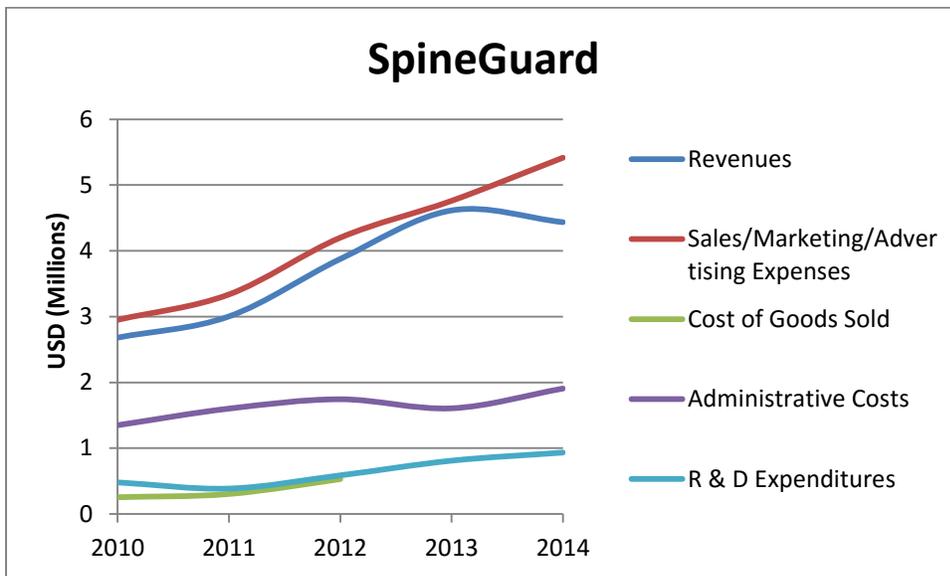
**Figure 5.** Revenues in JNJ (2001-2013). Data Source: Bloomberg Terminal.

### SpineGuard

SpineGuard is a small company that was co-founded in 2009 by Pierre Jérôme and Stéphane Bette, former executives at Medtronic and SpineVision. The main product of SpineGuard is PediGuard, invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. The PediGuard utilizes electrical impedance to alert spine surgeons when the pedicle bone is breached. The product was FDA and CA approved. The company claims that use of the PediGuard reduces pedicle perforations by three fold and reduces pedicle screw placement time by 15%. Using the PediGuard in conjunction with X-ray fluoroscopy can reduce radiation exposure by 30% (Chaput et al., 2012). In 2014, SpineGuard reported full-year revenue of €4,436k compared with €4,615k for the full-year 2013. In 2014 a decline in sales was noted, with 6,063 PediGuard units sold compared with 6,308 in 2013, including 3,212 in the United States (53% of SpineGuard revenue is from the US). The price of one disposable PediGuard unit is thus about \$800. The company has not been profitable yet (**Figure 6**), and its 2014 losses were 4.5 million Euros. The revenues of SpineGuard in the first quarter of 2015 were 1.5M Euros. Projecting annual revenues of six million Euro, will not suffice to bring the company to profitability with its current rate of spending. Large marketing expenses in SpineGuard are 6.7 fold higher than spending on research and development. SpineGuard will likely increase marketing and sales spending to attempt to accelerate growth in US sales. SpineGuard was also granted regulatory approval in China in June 30, 2015. The

company also reported strong growth in sales in Europe and Latin America; France (+21%), Germany (+73%), Switzerland (+43%) and other Latin American countries (+30%).

Electrical impedance as utilized by SpineGuard is limited in scope to warning for severe breaches of the bone. The surgical probe provided by SpineGuard does not provide directional information to guide surgeons in the insertion of the probe, and therefore is sold as an accompanying product to CT navigation systems with the intention of reducing X-ray exposure by shortening use-time of CT. This consideration is likely limiting the market penetrance of SpineGuard. Furthermore, electrical impedance sensing is limited to the surgical probe itself, and a breach of the bone by a pedicle screw is not monitored by the probe. SpineGuard is addressing this limitation by developing a next generation product of so-called ‘smart-screws’, extending electrical impedance sensing with a specially crafted hollow screws. A European patent (1781198) was filed in 2005 and granted in the beginning of 2015 for the hollow screw, and might enable SpineGuard to enhance its portfolio, once the hollow screw gains regulatory approval.



**Figure 6.** Financial indicators at SpineGuard (2010-2014). Data source: Bloomberg terminal.

**Conclusions –survival of medical device startups among giant corporations**

Revenues and profits are steadily growing in the medical device industry, indicating an attractive industry. The rising market valuations for medical device companies Medtronic and Stryker (Figure 2 and 4, P/E of 29 and 42, respectively) reflect investors’ appetite towards the medical device industry and high expectation for increasing revenues and high profitability.

Geographical segmentation of sales in these companies indicate that about half of sales revenues

are generated in the US and the rest are spread across the globe, emphasizing the importance of penetrating the US medical market for the success of SpineSonics. Changes in reimbursement policies in the US brought by the Affordable Care Act in 2010 are likely to pressure medical device companies to embrace design-for-value concepts (Chilukuri et al., 2012) to better align technologic innovation and economic benefits. This trend could reward innovative small companies and contribute to further fragmentation in the medical device industry. In contrast, waves of M&A, particularly in the spinal fusion market favour the emergence of large entities. In 1998 JNJ acquired Depuy and in 2011 JNJ merged with Synthes to create a large portfolio of orthopedic instruments under the brand name Depuy Synthes, controlled by JNJ. Medtronic is also growing by acquisitions, with the Kanghui acquisition in 2012 and the Covidian acquisition in 2015. Before the Covidian acquisition the two companies acquired six of the 18 medical device deals in 2014 (Noris & Peralta, 2015), and it will be interesting to watch the appetite of the merged giant for smaller acquisitions. Fostering relations between SpineSonics and a large industrial partner could support investment and collaboration at the early stages of product development. Following regulatory approval, a rapid scale-up in sales can be achieved with an existing sales and marketing infrastructure supported by a large industrial partner.