

Medical Instrumentation Industry: With Emphasis on Medtronic

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This industry sector analysis was performed by Dr. Shankar while pursuing his Executive MBA at FAU, in 2000

A. EXECUTIVE SUMMARY

Medtronic's mission is to provide lifelong solutions for people with chronic disease. The company, which was started in a garage in 1949, has had a respectable first 40 years of existence. In the 1990s, however, under the direction of a new CEO, Medtronic's growth exploded. Medtronic, long known for its medical innovations, is today nothing short of a medical miracle itself to the Wall Street, which considers it the "Microsoft of medical devices." Its earnings over the past ten years have increased at an annualized rate of 26% while the market capitalization has increased 80 fold to \$61 billion. Medtronic is a vertically integrated company, with a dominant position in the cardiovascular field. In order to keep up its torrid pace, it has gone on a buying binge over the past three years, swallowing medical device companies both in the cardiovascular field and beyond. For a company that grew from within earlier, this is a major change in strategy that has come at considerable expense, because of the uncertainty of the acquired technology, cultural challenges, lack of product synergy from the acquisitions, the battle of the giants, and the buying power that is concentrated in the hands of a few HMOs. However, grow it must. We provide certain key insights here, based on our own expertise and experiences in commercializing cardiovascular devices

B. INDUSTRY ANALYSIS

C.1. Industry Structure

The medical products industry manufactures systems for monitoring, recording, analyzing, diagnosing, assisting, and modifying the body's normal and abnormal functioning. Here, our focus will be primarily on the surgical and assistive devices in the cardiovascular area, the central focus of Medtronic. Many of the companies in this domain do have diversified holdings and synergy is rarely evident.

The U.S and the industrialized western world is growing old and age brings about a rapid increase in heart ailments. In the U.S., about 64% of growing number of people over age 65 suffer from some chronic heart condition and/or hypertension (high blood pressure) [Frie97, Cens99]. There are about 49 million Americans of all ages with these chronic conditions. Further, in age groups of 45 and above, heart diseases far outnumbered other causes of hospitalization – at 4 million patients, both men and women, and 25% of all

hospitalizations. Annually, a million Cardiac catheterizations are performed on men patients in the U.S., by far the leading surgical procedure. This is only exceeded by assisted delivery for women, at 2.5 million deliveries per year. Among the diagnostic and other nonsurgical procedures, angiocardiology and arteriography, which are used as exploratory aids to determine the need for heart surgery, led with 1.7 million such procedures (versus a total of 17.5 million procedures for all diagnostic modalities). Finally, a sad statistic – about a million Americans die every year due to atherosclerosis, the cause behind heart attacks and strokes. Balloon angioplasty and bypass surgery are two major methods of assisting patients with near-fatal poor circulation of blood to the heart. Stent has been the next battleground [McLe99]. They are tiny medical scaffolds that keep diseased or damaged arteries open up so that blood can flow.

Heart arrhythmia (irregular and chaotic heart rhythms) is yet another major area, with about half a million pacemakers implanted every year. The two major product categories here are: Pacemakers and implanted defibrillators. Implanted defibrillators require very small currents to shock the heart back to normal rhythm and thus avoids the need for heavy equipment, trauma, and possibility of large skin burns. These internal defibrillators, ridiculed until recently, have become a standard assist device, having saved many lives.

On related fronts, there are pharmaceutical drug companies which make drugs to reduce blood pressure, to relieve pressure in the chest (“Angina”), to dissolve the plaques in the arteries, and to reduce cholesterol in the blood. Recently, Gene Chip technology has been shown to be viable [Affy00]. In the Gene chip, one can compare a person’s DNA sequence against known blue prints for a disease gene. It may be possible to detect the disease at an early stage when the treatment modality may be simpler. Gene therapy may find application there. Research has moved in yet another direction: today, many researchers believe that inflammation is the cause of plaque buildup in arteries. It was shown recently that an enzyme related to inflammation (and vascular endothelial injury) was elevated in women prone to high degree of the atherosclerosis disease.

Thus, it is clear that, in addition to the more traditional methods, of pharmacological and surgical interventions, other modalities may evolve soon: genetic, molecular, hormonal, and neurohormonal (release of the chemical via brain stimulation).

C.2 Strategic Group Map

For this, we chose to divide the group strictly based on their product lines in the cardiovascular area. A successful company, as per our reasoning, needs alliances across the four levels of diagnosis (Early, Intermediate, Advanced, Debilitating) and five types of intervention (preventative, pharmaceutical, surgical, genetic therapy, and combinational). We provide a table below that attempts to provide a picture of how the different products fit together. Interestingly, new ideas turn up, especially in the area of combinational intervention schemes, that have the potential to do the least harm and to be used at the earliest possible moment so the body can “repair” itself and overcome its own fallibility.

We list the following companies in this matrix:

Preventative – Johnson & Johnson, Affymetrix, Vasocor Inc

Pharmaceutical - Baxter International, Eli Lilly, Merck, Pfizer, Mylan Labs.

Surgical – Medtronic, Guidant, C.A. Bard, St. Jude Medical, Johnson & Johnson

Genetic –Genzyme

Combined – Potential exists at Medtronic, Baxter-Edward Life Sciences, Lilly-Guidant, to explore combined therapies. At Medtronic, they may be able to develop neurohormonal systems (that can use brain stimulation to provide a much finer control of the heart’s functionality). The others could combine drug and engineering interventions, so neither is large enough to cause side effects. Other collaborations may evolve.

Table 1: Strategic Group Map

Intervention / Diagnosis	Preventative: Exercise/Diet	Pharmaceutical Drugs	Surgical	Gene Therapy	Combined
Early Onset	Vasocor, Affymetrix		Not undertaken	Genzyme	Vasocor-Affymetrix?
Intermediate	Johnson & Johnson, HP	Merck, Pfizer,	risk/benefit analysis – not good	Not enough known now	Baxter-Edward L, Lilly-Guidant?
Advanced	May not be useful	Lilly, Johnson & Johnson	Guidant, Medtronic	May not be useful	Worth Exploring
Debilitating	Insufficient Information	Merck, Mylan,	Medtronic, Guidant, Bard, St. Jude Medical	Did not complete the search	Worth Exploring
Comments	Low profit, Very Large Market	Medium profit, Large Market	High profit, Medium Market	Very high profit, Small Market	Enormous benefits. Tradeoffs for profit - possible

C.3 Firm's Competitive Position

Medtronic is synonymous with pacemakers and the company has achieved an outstanding pace of innovation. About 70% of its revenues come from products introduced within the past two years. Many analysts consider this the best medical-device company in the world [McLe99].

Medtronic is right in the middle of the cardiovascular industry, quite literally, more closely aligned with the surgical and nonsurgical procedures, both to help people live longer with their cardiovascular disease. Some of these assist/diagnostic devices are as follows: Catheters Stents; Pacemakers; and Implanted defibrillators [Medt00]. Medtronic does not market products for early detection and/or monitoring of the disease. It also does not produce drugs to control the disease. We use the word "disease" to refer to all the possible cardiovascular diseases.

Much of its growth in the past ten years has come from its single-minded focus on cardiovascular disease. While many major pharmaceutical companies continued to develop drugs to control the various ailments, and found their profits there, some of these companies (such as Eli Lilly) and consumer companies (such as Johnson and Johnson and Hewlett Packard) did attempt to address the needs for medical devices as part of their conglomerates. Medical devices were considered less important than drugs in the fight to overcome heart ailments, given the historical role of antibiotics and drugs elsewhere. Medtronic with its better focus, agility, and long history of medical device innovations, was in position in early 90s as interest in surgical procedures peaked and implantable devices became feasible, thanks to a concurrent trend in the electronic field. Today, the jury is out as to which is a better method, given the side effects of the drugs and the restenosing of the "repaired/replaced" artery. Stents are the latest in that fight to keep the arteries open. This is an enormously risky business with fortunes and market shares fluctuating rapidly as various companies try to come up with a still better stent. The concentrated buying power of few HMOs and hospital chains indeed makes this a very risky proposition [Medt00]. Risky as it is, it is also very lucrative, for it may be the difference between living and dying for the patient.

Thus, it was inevitable that Medtronic would try to establish itself in this field of stents. Medtronic acquired stent-maker, and leader in the market (30% market share of the \$1.9 billion-a-year market), Arterial Vascular Engineering, in January 1999 at a hefty price tag of \$4.3 billion, only to see the market share plunge, when competitors brought out superior stents [McLe99]. A Paine Webber analyst estimates that this acquisition has cost Medtronic shareholders \$10 billion in purchase price and lost market value. Note that this acquisition was in its area of expertise. Medtronic believed that a complete portfolio of products (in the cardiovascular area) would make it more competitive from the hospitals' point of view. At present, Guidant is the market leader in stents, with sales of \$700 million this year [Burt00]. Johnson & Johnson holds some of the basic stent patents, and has had a long-standing suit against Guidant for patent infringement. It was recently reported that Guidant and Johnson & Johnson have agreed to develop an alliance that would permit Guidant to use the latter's stent technology, while the latter will buy

Guidant's balloon catheters [Burt00]. Their alliance will impact the most promising market of congestive heart failure (see below).

Medtronic also spent \$4.7 billion to acquire five other major companies during the past year, primarily financed by its high-priced stock [Medt00, McLe99]. Medtronic now supplies devices and surgical tools for everything from spinal operations to ear, nose, and throat procedures. Its foray into these unrelated fields is questionable, though one can claim shared resources in terms of electronic technology. But, we do not consider that a major synergy. Besides, most hospital income (20% revenue and 50% profits) come from cardiac care, as is evident from the numbers given above. Perhaps it is a diversification strategy to reduce risk. But as the text describes it, shareholders are better off diversifying on their own. Lack of synergy and massiveness of these acquisitions (purchases at 8 to 10 times the annual sales) does not bode well for the company.

Medtronic is extending both in the cardiovascular area and these other areas. A neurological product to control tremors in Parkinson's disease has been developed. FDA approval is pending, mainly because this involves a brain implant similar to the electronic heart implants and Medtronic is charting a new path here. In the cardiovascular area, congestive heart failure (CHF) is the next major opportunity to conquer. In CHF, for a variety of reasons, the heart becomes unable to pump blood effectively. It is the major cause of cardiovascular hospitalizations and is the only form of heart disease that is on the rise. Both Medtronic and Guidant will file soon products for FDA approval [McLe99]. This has the potential for doubling or even trebling the cardiac rhythm management market in five years, from the current \$4.5 billion a year market. Guidant's electrical devices used for CHF are already in use in Europe. Guidant recently started discussion with Johnson & Johnson to access their CHF-pertinent technology (Called the Contak, licensed from Impulse Dynamics, NV). The companies involved believe that the current electrical technology of Medtronic and Guidant can only help 40% of the patients, and Contak has the potential of doubling the market, since it may increase the strength of the heart beat in patients with CHF [Burt00].

Guidant, the main competitor to Medtronic, perhaps strategically well placed to outgrow Medtronic, has another ace up its sleeve: It was spun off of Eli Lilly in 1994 [Valu00]. Guidant, with its emphasis on "Complete Disease Management," is well set to include pharmaceutical drugs in the overall treatment plan [Guid00]. Medtronic is still going it alone and has a complete focus on delivering solutions only based on medical products. Medtronic recently joined Johnson & Johnson, GE's Medical Systems, Baxter International, and Abbot Laboratories in announcing plans to develop an Integrated Internet to support hospital purchases [Wins00]. It is clear that Medtronic is focused on supporting the hospitals quite exclusively, and may use this Internet site to identify missing products that it can develop, so it can become an "indispensable" supplier to hospitals. However, when it comes to treatments and preferences in the health care sphere, heart overrules the brain and emotional decisions are made. In the high risk, high return area of advanced cardiovascular surgery, cost is not an object, and mere ability to "plug the holes" in the product portfolio may not be sufficient to be the chosen one for the high profit areas.

D. ENVIRONMENTAL SCAN

D.1 Opportunities

- Many big pharmaceutical and other medical devices companies have spun off their investments in the cardiovascular field. They were simply unable to keep up the innovation pace set by a few leaders there, Medtronic, Guidant, Johnson & Johnson (which uses a highly decentralized innovative organization), and HP, and a few others. Baxter has spun off their cardiovascular division [Valu00] to gain in flexibility. Both Medtronic and Guidant seems to have the best electronic and medical technology infrastructure and have integrated the two well. St. Jude Medical, despite many cardiovascular product introductions has not been much of a challenger for the other two. C.R. Bard Inc., is a \$2 billion capitalization company which seems to have faced too many court cases on their products recently. There are several smaller companies, such as Arrhythmia Research Tech, and recent spinoffs, such as Edwards Life Sciences (from Baxter International), are not major players yet [Valu00, Dail00].
- Few start-ups can survive on their own. The entry barriers are too steep. Start-ups without the financial and infrastructural support (miniaturization, clinical trials, hospital contact networks, and FDA approval processes) of the big companies will wither way. On the other hand, big companies invariably lose their ability to innovate, as they get bigger. Both Eli Lilly and Baxter International spun off their cardiovascular product companies into separate companies – Guidant and Edwards Life Sciences, respectively [Valu00]. Seek out good ideas, both within and without, and fund them.
- Bioinformatics is the study and use of DNA and gene databases that are rapidly accumulating around the globe. Genechips [Affy00] and Genetic testing may take the initiative from all “macro” or functional therapy and support modalities, since one potentially has the opportunity to catch the disease in its early stages. The intermediate level of intervention techniques that might evolve will be some combination of genetic testing and early support modalities. A simple example: use of jaw expanders used to push the jaw out so there is no crowding of teeth as children get older and get new teeth. Early X-rays will catch this situation. This avoids surgical interventions later on. An appropriate cardiovascular technology might be: Early markers for heart disease coupled with systems for preventive cardiology.
- Cardiovascular disease, while in decline in the Western World, is rapidly becoming a major threat in the rest of the world. That is a much bigger market, and of course, faces many well-established companies such as Siemens in dueling for supremacy. About 43% of Medtronic income comes from non-US sales, however, limited to Japan and Eastern Europe.
- Controlled release of drugs coupled with electrophysiology (that is the pacing and defibrillation, the strong suits of Medtronic) may pave the way for new early

treatments. An internal defibrillator requires very small amount of energy when compared to the external defibrillator. In a similar fashion, any drug delivered directly to the site of need will need significantly smaller dose. This may have fewer side effects and may actually help the body adapt and cope on its own, in the longer run.

D.2 Threats

- Era of specialists is over. You need to educate the general physician to become a good specialist. There is tremendous difference at the websites of the two leading companies, with Guidant out-serving Medtronic [Medt00 and Guid00]
- There is increased and concentrated buying power. Medical committees and HMOs are making the decision. These entities will seek lower prices, integrated and modular solutions, and are, by nature, deliberative and slow.
- An informed patient is a doctor's best friend. By extension, this patient is also the best friend of the medical industry. Slight him or her and pay for the consequences, whether it is the industry's fault or not. Inform him or her and you have a community ally who may lobby for you.
- It is a battle of the giants and they face concentrated buying power. Swings in market share can be significant. As with the pharmaceutical industry, a new radical product from a competitor can upset the balance sheet significantly. And one can never rest on one's laurels.
- Gene therapy, which has been lately shown to be ineffective, may still evolve and pose a major threat. There may not be a need for such chronic assist devices if we can manipulate the genes to reduce or reverse the effects of an abnormal or modified gene.
- Johnson & Johnson, Baxter, and Guidant all have unique alliances with pharmaceutical divisions/parent entities [Valu00]. New combined therapies may evolve. Medtronic is still going it alone. It can develop synergy between its cardiovascular unit and neurostimulation unit. However, this is far fetched, and may not be easily palatable to FDA. Medtronic's FDA application for certain brain implants has moved at a very slow pace.

E. COMPANY

E.1 Strengths

- One of the 100 Best Companies to work for in America. But then, all its major competitors are also ranked in the same top 100! [Bran99].
- A vertically integrated company with state-of-the-art facilities
- A tradition of close collaboration with medical doctors and other professionals.
- High entry barrier. The company spends 11.5% of sales for research and development and has reduced the cost of goods sold from 31% in 1995 to 25% in 1997.

- Rapid innovator. It received 110 patents in the U.S. in 1997. This is significantly lower than high technology companies. However, medical products are harder to come by – much work on human and/or animal subjects is needed.
- A technology leader. Their latest defibrillator has 13 million transistors versus 7 million transistors for Pentium II. The company has its own chip fabrication facility [Medt00, McLe99].
- About 43% of revenues come from international operations. The company operates as a global enterprise in over 120 countries throughout the world. Most of its competitors have similar attributes [Hugu99, Medt00].
- Ranked 190th in the 300 most profitable companies in American Business. The company is recommended for long-term investment by many value-oriented mutual fund managers [Hoov00, Hugu99].

E.2 Weaknesses

- Diversification beyond its traditional domain of cardiovascular products into neurophysiological, renal, and other medical areas. No sharing of resources, other than the sales force is evident. However, these other fields will benefit from the cutting edge electronic technology infrastructure that Medtronic has built up. Other “big” companies can perhaps gain the same or better advantage by teaming up with companies that specialize in those domains. However, a PC company like IBM will not be able to reorient itself to develop products that are biocompatible. But a long-term relationship can build that expertise.
- No exclusive focus on cardiovascular disease. Cardiovascular disease and mortality due to it far outpaces every other disease and non-disease causes of death. Though the developed world has seen a significant decrease in the mortality, still it ranks as the #1 killer in the western world. Well-to-do people in third world countries have adopted much of the western life style and are seeing increased risk due to heart disease. With such exclusive focus, the company would be able to develop products for the various groups (pediatric, women, and men), various stages of the disease (healthy, early and asymptomatic, symptomatic, and advanced/impaired stages) and various types of modification modalities (drug, diet, exercise, radiation, etc.) . Such a focus will be consumer and patient friendly. The company will have to either develop horizontal integration (via start-ups) or develop alliances with companies with complementary strengths.
- No support for patients. The focus is strictly on the hospitals and the medical doctors. Patient may incidentally be a “housing” for their products. Patients and their families who come to Medtronic for help will be sorely disappointed. No public relations seems to have been undertaken on any aspect of maintaining good health and avoiding diseases. Being a good-neighbor is important. Focused solely on interventional, not preventative measures, almost seems to want that the status-quo continue. Most likely it will, but the public relations generated and a few lives saved in the process, might avoid many bigger problems, such as litigation happy attorneys.

- A self-focused and self-laudatory website, perhaps reflective of its culture [Medt00]. In comparison, Guidant website attempts to educate the patient and the medical doctor {Guid00}. We once again wonder: To the company, Is a person a dollar sign or a symbol of life to be cherished? To be fair, Medtronic has an excellent record of helping a large number of patients who otherwise could not have been helped. For example, Lauren is a one year child with a Medtronic pacemaker that keeps her alive [Laur00]. But you would find no mention of such feats at their website.
- No tie-in with a drug company. Many slow release drug delivery mechanisms are being developed, especially as pertinent to diabetes treatment. We envision a trend that will mix and match electrical and chemical treatments that are better optimized than either.
- Operationally, the company has had slower annual growth (17%) when compared to recent past (26%) and cash flow (down to \$450 million in 1999 from \$685 the previous year).

F. RECOMMENDED CHANGES IN STRATEGY

- **Involve the public.** *Compare with Guidant. Medtronic does not care whether the public knows it exists or not. Higher chance of product liability cases; Patients won't demand to see the Medtronic products; Easy for the stock to get battered if the earnings turn south; Ignores a very important feedback mechanism to create new products. Home health products will build goodwill and actually may increase the number of patients seeking medical attention earlier – because of a better informed patient.*
- **Branch out into Preventative Cardiology.** *Cardiovascular disease is the Number 1 killer in the US and Western World. The baby boomers are getting older, in the age range of heart attacks and strokes. They need help to live longer and will pay the top price for that. Surgical and invasive procedures are fine, but Medtronic is in an unique position to show its Social Responsibility by encouraging more preventative methods and developing methods to monitor oneself in that regard, either at home or at sports places, without the need for medical personnel. Perhaps its bread and butter products will suffer – since heart attacks may be reduced. But there will be new products that will evolve. Surgical intervention are not being reimbursed at the old levels and are being questioned as modalities of choice. This suggestion is similar to “Open Architecture” concept of Sun Micro Systems.*
- **Get out of the ENT business.** *Or at least, spin them off as a majority owned company. There is no synergy with the core business, other than that committees are making decisions at hospitals and they may want to look to one supplier for all their needs. IT is unlikely that this will happen. But Medtronic can provide that*

one-stop shop center concept by developing an alliance with others. They just did that – Internet site for hospital purchases.

- **Invest in more start-ups.** *They are close to a monopoly in the medical devices domain. That is not good – eventually, self-imposed discipline will be compromised and innovation will suffer. Start ups in Internet and Software can beat a Microsoft, but the entry barriers are very high here – a new product may take 12 to 15 years to reach the market after sufficient R&D has been completed (as happened in my research licensed out to a commercial entity). As the text book says, they should invest in more startups. They seem to be focused on swallowing other big companies – and of course, that brings its own cultural shocks and unknown product risks, as happened with Arterial Vascular Engineering. Better to put seed money in their own empowered employees and other notable ideas.*
- **Segment the market.** *Traditionally cardiovascular disease has been a male-dominated disease. Most of the major studies have focused on Men only. However, the disease is indeed a major killer disease for women as well. Defining a niche over Women's cardiovascular health problems may give a significant advantage over the long run. First, the company would be considered women friendly. Second, focus will inevitably help develop products that are more appropriate for women – not just convenient and acceptable. Third, knowledge gained from healthy women who age slower, speaking from a cardiovascular perspective, may help address the problems in the men's domain sooner before the problems become irreversible.*
- **Extend to Pediatric health care.** *Pediatric hypertension is on the rise – kids are getting stressed out earlier and have poorer dietary habits than their parents had as kids a generation ago. Run a PR campaign and contribute to their knowledge of health. They are the ones who will grow up to become the next generation medical professionals. Catch them young, as Apple has done, and Microsoft is doing.*
- **Seek synergy in product development.** *Look for cross-functionality in the CNS (central nervous system) and CV (cardiovascular) domains. Could brain stimulation help control the heart functions? Would that be in some way better? Or bring that in anyway since nature intended that there be checks and balances in the system? That is, Is it better to evolve a chronic disease treatment that considers the connection between the body, brain, and mind?*
- **Get ready for class action suits and malpractice suits.** *Build in recording and monitoring devices into the implanted systems to ascertain proper usage of the device. This will act as a deterrent and avoid frivolous suits.*
- **Scan the competition and university research for new ideas.** *There is a strong need to be on the alert for developments by competitors. Simply innovating,*

oblivious to the surroundings, won't do, especially in this field. Reverse engineer and learn as much as you can about the competitors' products. Look for trends. We have no proof that they do not do this.

- **Aggressively expand in the third world countries.** *Clearly, this is a long-term strategy. As these countries grow more westernized and the cardiovascular illness risk increases, Medtronic will already be in place. We believe that the US companies are significantly better at cost effective delivery of advanced technology medical solutions, when compared to European companies such as Siemens AG and Royal Philips Electronics.*
- **Invest more in Research and Development.** *Explore synergy between its cardiovascular and neurophysiology divisions. Explore synergy between drug and electrical modalities of treatment. As an example, slow release of plaque dissolving drugs may be placed close to the site of treatment, instead of being delivered orally.*

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