

Microeconomics of Competitiveness

Minnesota Medical Device Cluster

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Executive Summary

Since the invention of the pacemaker and formation of Medtronic, Inc. in 1949, Minnesota has enjoyed the benefits created by a critical mass of medical device firms that were created or chose to locate within the state. Economic reliance on this industry can be seen in the location quotient, a measure of employment in an industry in comparison with the broader United States. Minnesota's medical device industry has a very high location quotient of 3.5, indicating that Minnesota's proportion of workers in this industry is much higher than elsewhere in the country.

Competition among states to attract the medical device industry has become much fiercer in recent years. As a result, the Minnesota medical device industry has been losing momentum to other states. It is more important than ever that regional leaders become more proactive than reactive and that the "business as usual" approach is put to rest.

This report applies analysis tools developed by Michael Porter to understand and diagnose the medical device cluster in Minnesota. Internet research and information gained through interviews with industry participants is used heavily in the report.

The most critical issue identified during analysis is that bold progress is needed now. Much analysis has already been performed on this industry in Minnesota and key recommendations have already been made. However, critical stakeholders still do not speak with one regional voice. Other issues include burdensome regulatory requirements that lengthen time to market for new products, difficult access to capital for startup firms, and uncertainty around how recent federal healthcare reform will reshape the industry.

In response to the most critical issue found, the vision set forth in this report is to *spark cultural change in the Minnesota medical device industry*. Specifically, cluster participants must understand the imperative for change, realize the value of speaking with one regional voice, and acknowledge the benefit to the overall cluster of fostering startup companies within Minnesota. Cultural change in this cluster will be recognized by robust partnerships between business, government, and academia, best in class trade associations in which prominent leaders of industry steer strategic decisions and action, and energetic movement toward a more entrepreneurial risk-taking culture.

This report recommends short, medium, and long-term action steps for achieving each aspect of cultural change. The most important recommendation in the report is for the cluster to align with one voice on a strategic direction, the outcomes expected, and specific actions to be taken.

The medical device cluster in Minnesota has been a great boon to economic health in the region over the past several decades. In order to ensure that the medical device industry continues to be major contributor to Minnesota's economy, action must be taken now to preserve and grow the cluster.

Introduction

The medical device industry in Minnesota has been a topic of interest for regional government for many years. Much analysis has already been performed on this industry in this region and numerous recommendations have resulted from the large body of work that already exists. This report applies analysis tools developed by Michael Porter to understand and diagnose the medical device cluster in Minnesota. A heavy reliance is placed on information gained from industry participants and from internet research.

History of the Cluster in the Twin Cities

Minnesota shares a rich history in the manufacturing and development of medical devices. The Minnesota medical device cluster is home to many well-known industry leaders such as Boston Scientific, 3M, and Medtronic. These companies have reaped the benefits of being surrounded by small and medium sized firms by doing a number of acquisitions over the years. As a result of the mere presence of large cardiac device firms, it may appear that the cluster specializes in cardiac devices. However, the cluster is diverse as it contains firms specializing in medical supplies, hearing aids, and nerve stimulation. Evidence would also suggest that a radiology cluster is developing in Eagan, Minnesota.

Historically, the Minnesota medical device cluster has also been home to ground-breaking research. World renowned researcher Dr. Doris Taylor's work at the University of Minnesota in cell therapies and biological engineering continues to draw attention to the Minnesota medical device community. As the cluster evolves, her research will continue to impact the region. The University of Minnesota will continue to play a substantial role in the cluster.

Timeline of Major Events

1949 – Medtronic is founded by Earl Bakken and Palmer Hermundslie as a partnership to service electronic medical equipment.

1950 – The Variety Club Hospital located at the University of Minnesota becomes the first hospital in the United States to be totally devoted to heart patients.

1954 - University of Minnesota cardiac surgeons perform the first open-heart surgeries using cross-circulation, a risky procedure where a parent was connected with tubes to his or her child to provide oxygenated blood during surgery.

1957 – Medtronic develops the first wearable, external, battery-operated pacemaker at the request of University of Minnesota surgeon C. Walton Lillehei.

1972 – The bileaflet mechanical heart valve is developed at the University of Minnesota.

1972 – Cardiac Pacemakers is founded.

1972 – American Medical Systems founded by Dr. Brantley Scott, et al.

1973 – American Medical Systems unveils first inflatable penile prosthesis implant.

1976 – Manny Villafana establishes St. Jude Medical Inc. to develop and market a series of innovative heart valves.

1977 - First implant of St. Jude Medical mechanical heart valve.

1978 - Siemens-Elema introduces the first single-chip pacemaker, significantly reducing pacemaker size and improving reliability.

1982 – St. Jude Medical receives approval from the U.S. Food and Drug Administration to market its mechanical heart valve in the United States.

1984 – Medical Alley, a nonprofit trade association supporting the state’s health care industry, is formed.

1984 - The US Food and Drug Administration approves the 3M/House single-channel cochlear implant.

1985 – American Medical Systems is purchased by Pfizer.

1991 – Minnesota’s biotechnology association is formed, MNBIO.

1994 – Acumen Healthcare begins to develop medical device support software.

1998 – American Medical Systems is purchased from Pfizer by Warburg Pincus.

2004 – Medtronic unveils the world’s first digital pacemaker.

2005 – Medtronic surpasses the \$10 billion dollar revenue mark.

2005 – Medical Alley and MNBio merge to become LifeScience Alley.

2007 – Boston Scientific and Guidant reach an agreement to merge. This creates a new \$27 billion dollar company.

2007 - Received Japanese approval of St. Jude Medical's first heart failure products in Japan.

2008 – Dr. Doris Taylor of the University of Minnesota creates a working rat heart from baby rat stem cells.

Cluster Definition

Industry Definition

Though significant research on medical device clusters has been performed at state and national levels, defining this dynamic and rapidly changing industry is difficult. NAICS and SIC codes and other traditional classifications and measures have been unable to historically track firms or account for changing product boundaries within the medical device industry. According to the UMass Donahue Institute's Economic and Public Policy Research unit, "companies are anonymous and company product mix data is not recorded in government economic data. The anonymity requirement obscures growth dynamics and the neglect of product information obscures cluster boundaries and dynamics¹." For example, a firm that manufactures computer components and also manufactures imaging systems for computer tomography (CT) medical devices would be classified under a non-medical technology code if the CT systems are not its major activity.

For the purposes of this report, a recent definition of the cluster by the BioBusiness Alliance of Minnesota (BBAM) and the Minnesota Department of Employment and Economic Development (DEED) is used. The definition states that "the medical device market consists of all instruments, apparatuses, implements, implants, in vitro reagents, or component parts or accessories that are used to prevent, diagnose, treat, or cure diseases."²

According to BBAM, the medical device industry can be divided into multiple segments, including:

- Cardiovascular
- Orthopedics
- Ophthalmology
- General surgery
- Neurological products
- In vitro diagnostics
- Imaging

Geographic Scope: Minnesota

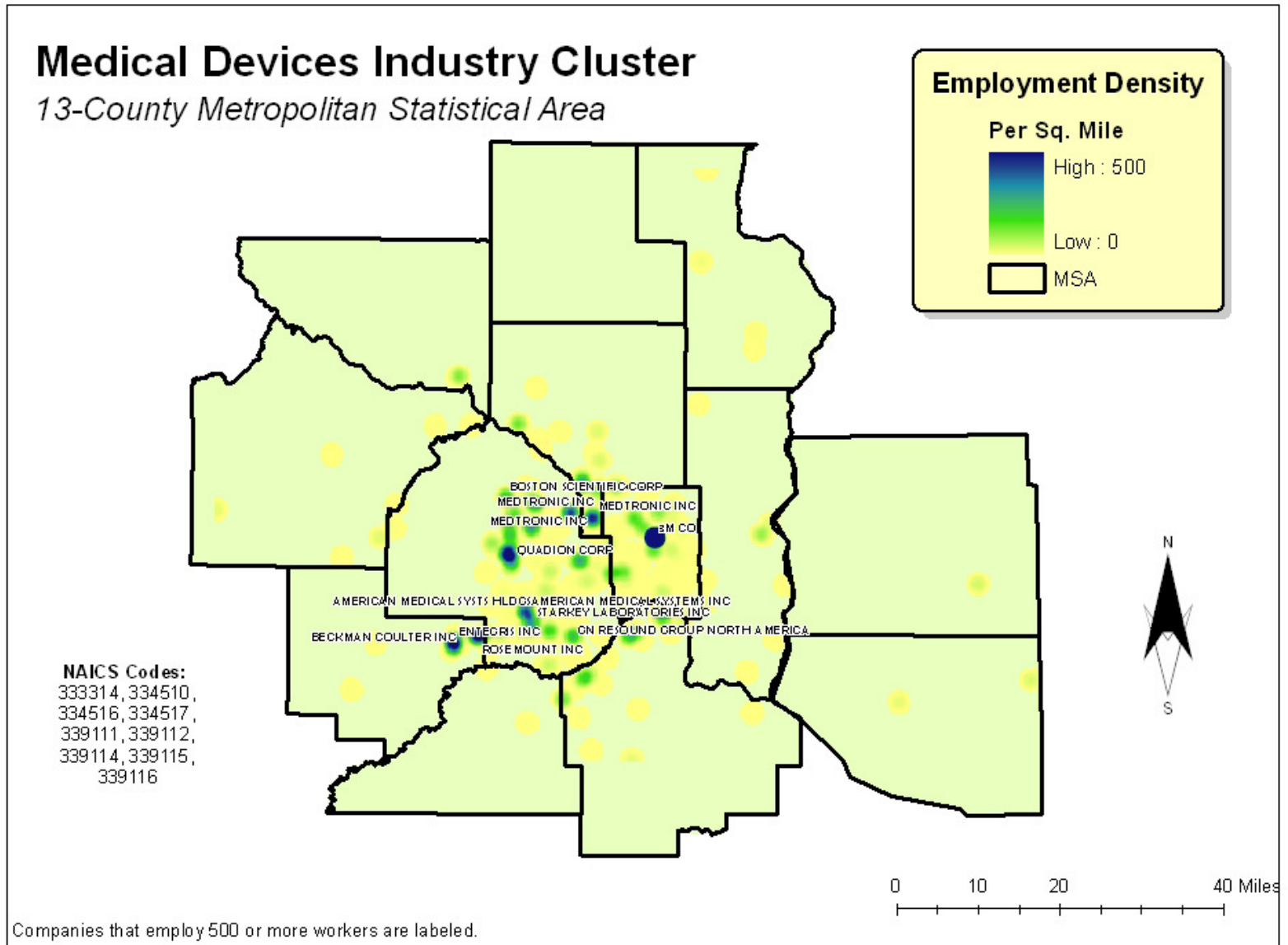
Using Quarterly Census of Employment and Wages, DEED advances the cluster definition with industry statistics and geographical boundaries. The cluster is concentrated mainly in the Twin Cities metropolitan region and in particular, in Hennepin, Ramsey and Anoka counties³ (see Figure 1). In fact, in 2007, more than 85 percent of the cluster employment was in the Twin Cities metro area, specifically in Hennepin, Ramsey, and Anoka counties.

¹ Corporate Report Factbook 2007, Dun and Bradstreet

² Destination 2025: Focus on the Future of the Medical Device Industry 2009, Deloitte Consulting & the BioBusiness Alliance of Minnesota

³ Minnesota's Medical Device Cluster 2008, Minnesota Department of Employment and Economic Development

Figure 1



Source: 2009 2nd Quarter InfoUSA

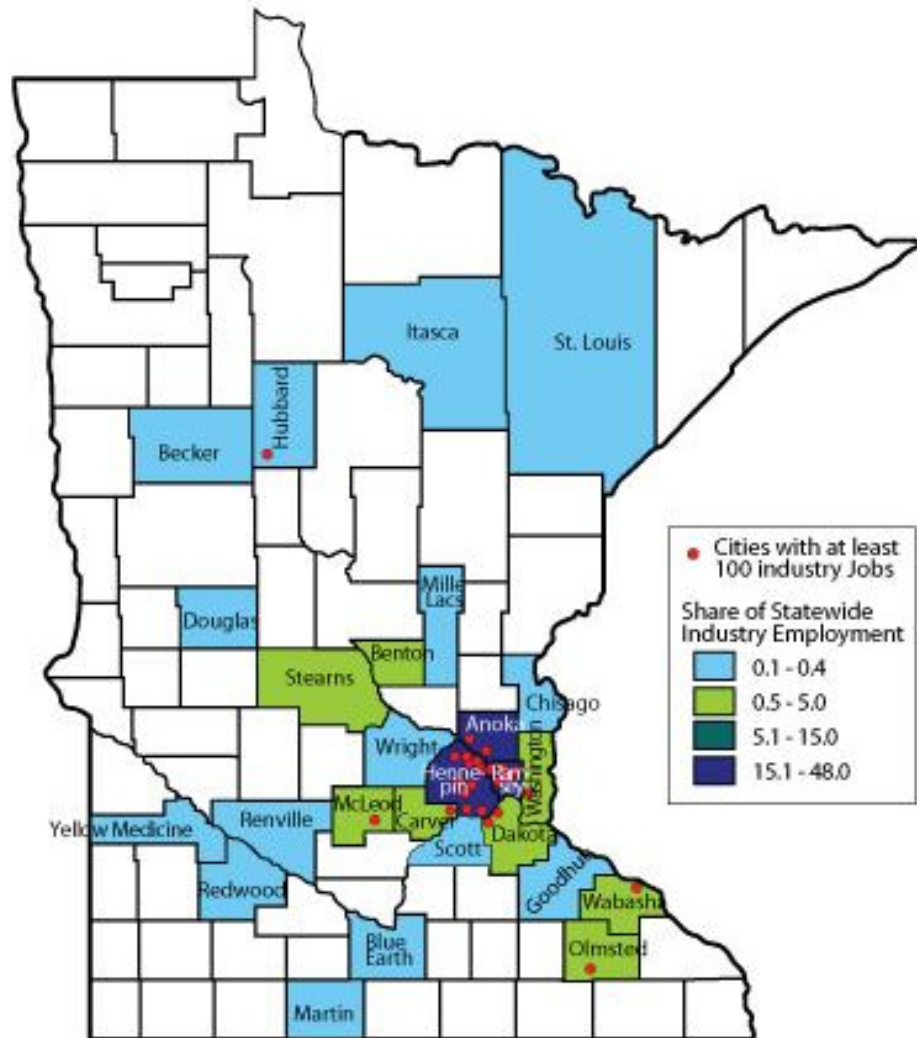
Prepared by DEED LMI (AR) on Oct 19, 2009.

Figure 2 expands the cluster analysis to show the statewide distribution of industry employment. Though jobs are largely confined to areas near the metro region, it is evident there are pockets of employment in other cities and regions throughout the state.

Outside the metro region, Rochester, home of the Mayo Clinic, is an important contributor and node of the medical device cluster. The Mayo Clinic is Minnesota's largest employer and one of the largest medical research campuses in the United States, with more than 32,000 employees in Rochester and another 13,000 employees who work for the Mayo Health System. Of course, while many of these employees are not employed in the medical device industry, the vast numbers demonstrate the size and scope of the Mayo Clinic.

Figure 2

Medical Devices Industry Employment Distribution



Source: DEED Labor Market Information Office ALMIS 2006 Annual Employment Data.

Economic Scope: Minnesota

Research by DEED offers several indicators as to the importance of the medical device industry for the state of Minnesota:

First, there are roughly 29,351 workers in this industry, accounting for 1.4 percent of total jobs in Minnesota⁴. The five largest medical device firms in Minnesota alone (Medtronic, 3M, Boston Scientific, St. Jude Medical, and American Medical Systems) generate more than \$22 billion in sales⁵.

Second, the location quotient, which is a measure of the proportion of employment in the industry in Minnesota in comparison with the United States, shows that a heavy proportion of workers in this industry are located in Minnesota. As defined by DEED, the Minnesota medical device cluster has a location quotient of 3.5. In general, a number more than 1.2 is a relevant quotient that would mean that the proportion of workers in the industry is much greater in Minnesota than elsewhere.

Third, in 2006 Minnesota ranked second in the United States for the number of people employed in medical device manufacturing, only less than California and more than Massachusetts. Moreover, the industry gained 23.8 percent employment between 2000 and 2006 when all the other states were losing employment.

Fourth, Minnesota ranked second (after California) for the number of medical device patents registered between 2001 and 2005. Minnesotan companies obtained 2,341 patents, an important indicator of progress of an industry heavily dependent on technological innovation.

Fifth, wages are very high for at least two of the most important sub-clusters: electro-medical device and surgical appliance manufacturing. For Minnesota based electro-medical device companies, wages paid are 8.3 percent higher than in the U.S. For Minnesota based surgical appliance manufacturing companies, wages are 40.9 percent higher than in the U.S.⁶

Finally, Minnesota is one of the largest exporters of medical device technologies to the nation and to the world. Minnesota companies generated more than \$2.1 billion of exports in the “Miscellaneous manufacturing” category (NAIC 339), making it the seventh largest exporter. Though this category also includes toys, jewelry, and musical instruments, it still indicates significance for the medical device industry.

⁴ Prescription for Success 2008, Rachel Hillman and Jennifer Ridgeway

⁵ Corporate Report Factbook 2007, Dun and Bradstreet

⁶ Minnesota’s Medical Device Cluster 2008, Minnesota Department of Employment and Economic Development

Stakeholder Analysis

There are many important stakeholders that are part of the medical device cluster:

Stakeholder	Importance of Stakeholder	Influence of Stakeholder
Medical Device Companies	HIGH	HIGH
Doctors and Medical Staff	HIGH	HIGH
Regulatory Community	HIGH	HIGH
Investors	HIGH	HIGH
Colleges and Universities	HIGH	MODERATE
Hospitals	HIGH	MODERATE
Suppliers	HIGH	MODERATE
Distributors	HIGH	LOW
Trade Associations	HIGH	LOW
Policymakers	MODERATE	MODERATE

Five Forces Analysis

Using Michael Porter's Five Forces Model, the following will examine the medical device industry in the Twin Cities. Strong forces in this model indicate an industry in which it is more difficult to compete successfully.

Threat of Entry = **STRONG**

Barriers to entry in the medical device space are high for several reasons:

- There are many regulatory and clinical requirements that a company must meet before launching a new product. The result of these requirements is that the lead time to market for a new medical device product is typically very long and requires a company to maintain R&D funding for longer than in many other industries.
- Companies entering the industry typically need to make costly capital investments in order to ramp up manufacturing capabilities.
- Product distribution usually occurs via direct sales personnel who build strong relationships with physicians.
- Some companies have built strong brand identities around quality and innovation, resulting in less likelihood that hospitals will choose another company's product.
- Most companies have strong technology protection through patents.
- Access to early stage capital for startup companies in the region is often difficult to obtain.

Although some barriers to entry are high, other factors lower the barrier to entry in the region and increase the likelihood of new companies starting within the cluster. Examples of factors which lower the barrier to entry are the following:

- A very strong regulatory and clinical infrastructure exists in Minnesota, which helps companies overcome the many requirements for new products. By leveraging this infrastructure, new entrants to the market can get a product to market faster by hiring experienced regulatory and clinical professionals.
- Brand identities of some large, established companies in the cluster have been tarnished due to product recalls and safety advisories. These impaired reputations may cause customers to scan the field for alternatives, making it easier for new companies to gain a foothold.
- Multiple patent infringement lawsuits have been successful recently, resulting in sizeable penalty fees and large legal costs for all parties involved. These burdensome legal costs and settlements have consumed cash at established medical device companies, leaving them with less cash to pursue new product development and, in turn, leaving space for new entrants to innovate.
- The medical device industry has an entrepreneurial track record in the Twin Cities. This track record and the presence of experienced entrepreneurs increase the possibility that new companies will be created within the cluster.

New medical device products must conform to strict documentation and data rules before they will be approved by the FDA. Since a change in leadership at the FDA after the Obama administration took office, the FDA is exhibiting increased oversight. These rules

for documentation and data require a lot of manpower and time to meet, but a mitigating factor in the Twin Cities region is the presence of a strong regulatory and clinical infrastructure. Multiple universities in Minnesota offer courses in medical device related topics, and St. Cloud State University offers a Masters degree in Regulatory Affairs and Services. LifeScience Alley, a trade association in Minnesota, offers a lot of valuable seminars and learning experiences in topics that can help companies keep their employees current on the regulatory environment. And, lastly, the large numbers of trained regulatory and clinical professionals in the region hold a wealth of knowledge and experience that aids companies in processing their regulatory submissions as quickly as possible.

Most medical device startup companies spend large amounts of capital in order to get their factories running. Many companies need to build controlled environment areas to ensure that their products are built under the right environmental conditions, such as specific temperatures or pressures. Capital equipment purchases are also needed in order to produce prototype and commercial builds of new products. This initial cash outlay definitely increases the difficulty for new entrants to the market.

Distribution channels for many medical device companies are well established. Most companies distribute through direct sales personnel who interact personally with physicians and other personnel at the hospitals that they serve. The distribution channel is simple in concept, but takes time for competitors to imitate because of the personal relationships sales reps develop with the physicians that they serve. The time required increases switching costs to the doctor if he must build a new relationship with another sales rep if he switches to a product from a different company. On the other hand, when a sales rep switches to a company that he previously competed with, large portions of revenue are often taken with them to their new company because the physician prefers to continue working with the same sales rep rather than build a new relationship.

Some larger medical device companies have built strong brand loyalty to their products, which means that a physician will be unlikely to choose a competitor's product unless there are overwhelming reasons to do so. Sometimes this brand loyalty comes from a company's track record with quality or customer service, and sometimes it comes from a regular pipeline of innovative product offerings. Some companies have seen their brand reputations dented recently been due to product issues. Tarnished brands increase the opportunity for other companies to take market share because physicians and hospitals may be more inclined than usual to consider alternative products.

Once a medical device company is established, it usually enjoys strong protection of its technology via patents. However, in recent years there have been many costly patent infringement lawsuits that have cost all companies involved a lot of time and money. Often these cases are settled out of court to reduce the expense of ongoing legal fees. The increasing costs of patent lawsuits may diminish the overall value of a company's patent portfolio.

Minnesota's policies to incent investment in early stage companies have not been as aggressive as other states that court medical device companies. This fact is a danger to continued growth and competitiveness in the cluster. For example, the angel investor tax credit in Wisconsin has enticed some startup companies to locate there rather than in the Twin Cities. Minnesota recently passed an angel investor tax credit, which is a great step forward. Minnesota needs to continue to promote entrepreneurial endeavors through policies and resource support at the state level.

The history of successful medical device startups in the Twin Cities means that there are many seasoned entrepreneurial professionals in the area who may continue to start or build new companies or who can mentor other entrepreneurs who decide to take the plunge. The Twin Cities' medical device industry may be shifting to more of a medium to large company cluster than a smaller company cluster. If the shift is indeed happening, or if it proceeds too far, the benefits that an entrepreneurial history provides will be lessened.

Overall, the threat of entry is strong because there are numerous barriers to entry. The barriers have mitigating factors, but are still formidable.

Substitute Products: MEDIUM

In order for a product to be a viable substitute, it must fulfill the same function as the product which it is substituting.

Today, substitute products exist for some types of medical devices but not all. For example, physicians may choose to treat a disease condition with pharmaceuticals rather than a device even if the device is clinically indicated. Pharmaceutical substitution is common in the cardiac rhythm management space, which is strong in Minnesota. Sometimes pharmaceutical substitution is done because a patient refuses to get an implanted device, but more often the physician does not recommend it or make the referrals necessary to assess the patients need for a device.

Looking into the future, there is a significant threat that genomics, proteomics, and / or biological breakthroughs could radically alter the medical device industry by giving patients effective treatment options that do not require a medical device.

Substitute products face the same barriers to entry that medical devices face, particularly with respect to long lead times to market and initial capital outlays. These barriers to entry will not stop substitute products from evolving, but will make the emergence of new substitutes more gradual than if the barriers to entry were lower.

The overall force of substitute products is medium in the medical device industry because even though there are substitutions happening for some products, the demand for the products in general is strong and growing.

Buyer Power: STRONG

Buyers of medical devices are usually hospitals or physicians. The purchasing landscape has changed considerably in the last few years and continues to evolve. This force is strong for two key reasons - buying power is becoming more and more consolidated in the industry, and medical reimbursement policies are evolving.

Individual physicians have significant influence over the products and brands they use. However, as health care costs rise, more hospitals are requiring physicians to implant only products and brands that are covered in pricing contracts negotiated by their central purchasing departments. Another purchasing trend is that more hospitals are sharing pricing information with each other, driving all of their negotiated prices lower.

When more than one company offers a similar product, the products are usually close enough that either would effectively treat the patient's condition. This drives 'supermarket buying' where hospitals state a low price they are willing to pay and wait until one of the companies agrees to provide products at that price. Typically, one of the companies bidding for the business agrees to the price, which then results in continued price erosion for all companies as that pricing information becomes transparent throughout the industry.

The Centers for Medicare and Medicaid Services (CMS) determines the dollar amount that the government will pay for any given treatment, procedure, or device under the governmental insurance programs. Most non-governmental insurers adopt the same reimbursement levels within their groups, which means that CMS reimbursement decisions have enormous power to affect the medical device industry. This power is growing as reimbursement policy focuses more on cost effectiveness rather than just safety and efficacy.

As for the threat of backward integration by buyer groups, there is little threat that hospitals or physicians will themselves become medical device producers because of the barriers to entry and because they want to stay focused on their core value proposition which is not producing medical devices.

Overall, the force of buyers on the industry is strong due to undifferentiated products, the strengthening of block purchasing patterns, and stricter reimbursement practices.

Supplier Power: MEDIUM

Supplier power can be strong in an industry for two main reasons: switching costs and forward integration. Switching costs are the costs to a medical device producer that are incurred when it switches from one supplier to another. If the costs of moving from one supplier to another are low, then switching costs are low and vice versa. Forward integration occurs when a supplier decides to become a direct competitor in the market that it serves. In other words, when a supplier forward integrates it will produce and sell not only a portion of the medical device, but the actual device itself.

The primary suppliers to this industry are component and equipment manufacturers. Manufacturing equipment suppliers do not pose much threat to the industry, either from switching costs or from forward integration.

Component suppliers are difficult to classify as a group because there are hundreds of component suppliers to the medical device industry. For some types of components, there are multiple suppliers who do not pose a threat to the industry. But other suppliers produce critical, complex components, such as lithium batteries. This second group of suppliers poses a threat due to high switching costs and potential forward integration. These key suppliers often understand well the regulatory hurdles to get new products approved; if they are manufacturing one of the most complex elements in a medical device product, they could reasonably forward integrate if they wished to challenge the established companies.

Overall, the force of suppliers on the industry is medium. This conclusion is reinforced by the evidence of multi-year contracts with suppliers. When supplier power is strong in an industry, contracts are typically non-exclusive and short-term.

Existing Rivalry: STRONG

There are many firms in the medical device industry competing head to head with each other for the same market. Low product differentiation in some key markets strengthens the rivalry, as do low switching costs by hospitals and strategic confusion about where the industry will land after the dust settles with medical reimbursement, regulatory, and genomic/biologic challenges.

Rivalry often decreases during times of lower growth, but in the Twin Cities the rivalry appears to remain strong. This may be due to fierce price competition as companies try to retain as much business as they can in an economic downturn.

Currently, this industry is also facing uncertainty due to health care reform. With such ambiguity in the near and distant future, many companies do not know how product regulations and approvals will be affected, how their prices will be compared with other alternatives, or how policies will shape reimbursement rates.

Overall, this force is strong especially because of the strategic confusion. It is difficult to predict what the industry will look like in the future or how firms will react to the changing dynamics within the industry.

External Forces: STRONG

Several external forces exert a significant effect on this industry, such as government involvement through both regulatory agencies and reimbursement policies. Health care costs in the United States are on an unsustainable path. The recently passed health care reform bill did not change the fact that health care costs consume an extremely high percentage of GDP. These unsustainable costs could have a considerable impact on the cluster's long term viability and growth, depending on how the government ultimately decides to address the cost burden.

Technological changes also pose a real risk of major influence on this industry, specifically advances in genomics, proteomics, and biologic products.

Given the likelihood and impact of multiple external forces on this industry, this force is quite strong in this industry.

Five Forces Summary

All forces in this industry are strong or medium, with no forces being low. In summary, this industry is difficult to enter and difficult to prosper in since most of the forces have considerable strength. A firm's strategy for sustained competitive advantage must be quite good to succeed long-term in this industry.

Diamond Model Analysis

The following examination of the medical device industry in Minnesota utilizes Michael Porter's Diamond Model.

Factor Conditions = STRONG

Factor conditions are attributes of a given region that affect the ability for an industry to succeed there. Basic factors that affect multiple life sciences industries, including medical device companies are:

- There are many workers in Minnesota, specifically in the Twin Cities, skilled in professions that benefit the cluster. Examples include engineers, technicians, clinical staff, regulatory professionals, manufacturing assemblers, and more.
 - Some companies have located in the Twin Cities specifically because of worker experience with active implantables (devices with electronic subsystems, or 'brains', which can dynamically respond to patient input).
 - Coloplast moved subsidiary companies to the Twin Cities in part because of the region's proven legal knowledge in the medical device space.
- The University of Minnesota and the Mayo Clinic in Rochester, Minnesota have a solid history of support and interaction with the medical device cluster. For example, the "University has a rich legacy in the cardiovascular sciences, including a leading role in the development of the wearable battery-powered pacemaker,"⁷
- There is a strong regulatory and clinical infrastructure in Minnesota. Many firms have demonstrated that they can successfully write complex regulatory submissions that get approved, or can design effective clinical studies. This knowledge benefits the entire cluster as employees move between companies during their career.

Demand Conditions = WEAK

Demand conditions in the medical device cluster in Minnesota were historically strong and provided advantage to the medical device cluster's emergence. For example, Earl Bakken and Dr. C. Walton Lillehei were open heart surgery pioneers at the University of

⁷ <http://www.mmf.umn.edu/bulletin/2008/winter/medschoolnews/bakken.cfm>

Minnesota Medical School⁸ and the Mayo Clinic's prestige drew patients from across the nation. The University of Minnesota was also instrumental in early clinical trials of pacemakers. These original demand conditions are very likely the reason why cardiovascular devices play such a prominent role of Minnesota's medical device cluster.

Over the past few decades, demand conditions in Minnesota have changed significantly to the point where Minnesota no longer possesses an advantage in this aspect over other geographies. Evidence of this change can be seen by clinical trials that are nationwide or even exclusively outside of the United States.

As Minnesota's medical device industry looks into the future, new demand conditions may be created through novel, world-changing innovations. For example, Dr. Doris Taylor at the University of Minnesota is a pioneer in cardiac regeneration and is renowned for her accomplishments. Her prestige may drive new demand conditions that could benefit the medical device cluster as well as other related clusters.

Firm Rivalry = STRONG

Rivalry in the Minnesota medical device cluster is intense. There are hundreds of firms that participate in the cluster, ranging from component manufacturers to producers of finished devices and from trade associations to the regulatory agencies that work closely with the producers. Many firms make products that compete directly with each other, resulting in frequent head to head races for market share. As Minnesota's companies strive for sustainable competitive advantage, it is important to remember Michael Porter's mandate that competing firms must 'run the same race faster' *as well as* 'run a different race'.

As indicated by Porter, strong local competition results in all local companies becoming more competitive globally. This occurs because local rivalry forces companies to find competitive edge beyond the natural local factor conditions. This competitive edge, in turn, drives increased global prominence. Therefore, strong local rivalry can actually help spur a cluster forward. This dynamic seems to hold true for all of the major Minnesota medical device companies, which have significant global presence either through market presence, global subsidiaries, or both.

Supporting Industries = STRONG

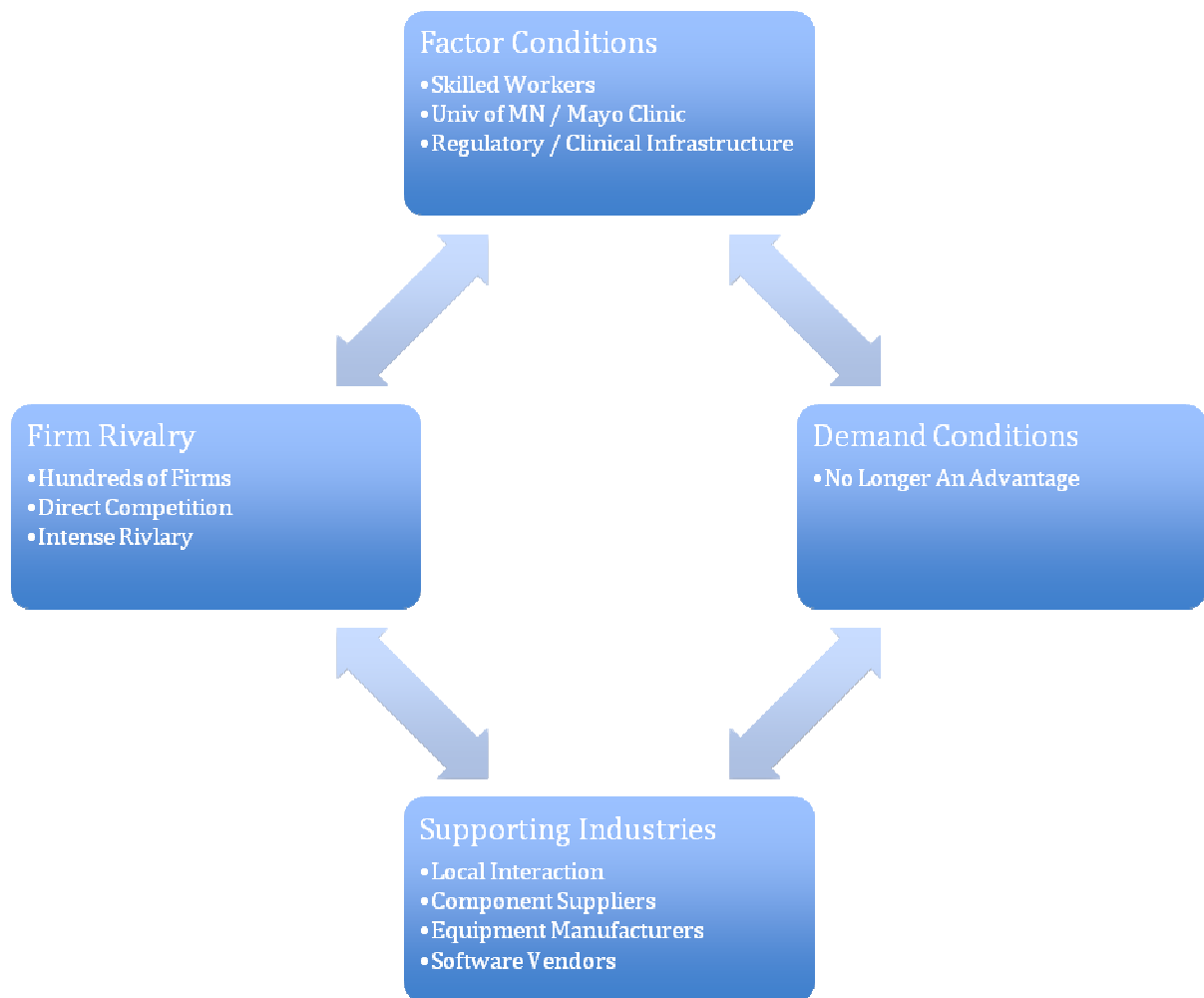
There are numerous suppliers to the medical device cluster located in the Twin Cities area. The proximity of key suppliers entices companies to grant more business locally because they can interact more personally with the suppliers, even to the point of partnering closely with suppliers during the product development lifecycle. Suppliers include component suppliers, equipment manufacturers / integrators, software vendors, etc. Of course, a larger localized industry also leads to an increase other types of businesses in the regulatory, legal, and purchasing fields.

⁸ <http://www.medtronic.com/about-medtronic/our-story/our-first-pacemakers/index.htm>

Diamond Model Summary

All parts of the diamond positively impact the Minnesota medical device cluster, with the exception of Demand Conditions (see Figure 3). It makes sense that the Diamond is strong because the medical device cluster in Minnesota is strong. But what seems missing from the diamond model is consideration of the trend of the cluster. Specifically, the cluster may not be thriving to its maximum potential for the region and may actually be stagnating.

Figure 3



Critical Issues

Based on analysis and review of previous cluster evaluations, the most critical issue for the Minnesota medical device cluster is actionable movement forward. Enough analyses have been done and it is now the time to act. This message was clearly indicated throughout the interviews and it is evident from the multiple industry analysis reports that are available. In order to explain this issue more fully, a brief review of the work that has been completed follows.

The North Star Rising Science and Technology Economic Development Commission of Minnesota (NSR) have proposed legislation to spur economic development. The legislation proposed ten key actions and would have been funded through a ten year bonding investment. The legislation did not pass in its original form. Instead, Minnesota set up another commission within DEED to study the issues. After two years of further study, a report came out in January 2010 with recommendations quite similar to the original NSR ideas.

The Bio Business Alliance of Minnesota (BBAM), which is 50% funded by the state of Minnesota, spent over one million dollars to produce analysis and recommendations for six life sciences areas, including the medical device area. Their report, called Destination 2025, came out only one year ago.

There are several medical device industry cluster reports that have been produced over the years. Most of them are at least several years old, but they include many of the same themes as later reports.

Industry participants indicated that they are growing weary of repeating the same analyses with little or no action resulting. In order to keep entrepreneurs and key opinion leaders engaged in economic development for the medical device industry, some significant action steps need to be taken to demonstrate that the state and region are serious about future growth.

There are other critical issues that need attention in the cluster:

- New product approvals must go through a significant regulatory journey before they are cleared by the FDA. Oversight by the FDA has increased since the Obama administration took office, resulting in frequently longer approval cycles. The FDA has also announced that it will be making significant changes in its 510(k) and Pre-Market Approval (PMA) types of regulatory submissions.
 - "In order to market a medical device in the U.S., manufacturers must go through one of two evaluation processes: Premarket notification [510(k)], unless exempt, or premarket approval (PMA), a much more involved process. Most medical devices are cleared for commercial distribution in the U.S. by the premarket notification [510(k)] process."⁹

⁹ <http://www.gxpanjvt.com/ivtnews/templates/IVTNews.aspx?articleid=1239&zoneid=18>

- Access to capital for early stage companies in the Twin Cities has been a challenge. Other states have for a long time had more enticing incentives for early stage companies than Minnesota, such as angel investor tax credits. Minnesota recently passed a similar tax credit, which is a great step forward. But the fact that it took Minnesota approximately seven years to pass the tax credit does not bode well for timely future actions.
- The health care reform bill in Washington includes a sizeable 'innovation tax' to help pay for the bill. This tax significantly impacts medical device companies. Some CEO's of large companies have gone on record saying that they will need to lay off thousands of employees in order to cover the costs of the incremental tax and maintain their expected profitability for shareholders. The uncertainty this tax over the last year has led to more caution and less risk-taking by many companies in the industry.

Vision

Before recommending an action plan for the medical device cluster, it is important to describe a clear vision for the cluster. The goal of a vision statement is to galvanize people toward a common future. Vision statements can inspire people to achieve defined objectives, even if they are stretch objectives, provided the vision outlines an easy to understand image of a desired state. The vision is critical for development of the action plan because only actions that directly move the cluster toward the vision should be recommended.

Our vision is to:

Spark cultural change in the Minnesota medical device industry

Specifically, the cultural change that needs to be sparked is for cluster participants to:

- Understand the imperative for change in order to preserve and grow the strong medical device industry that exists today in Minnesota.
- Realize the value to all participants of speaking and acting with one regional voice in order to attract and retain medical device companies in the area. In order to speak with one voice, a crisp and aligned strategy must exist that cascades directly to the messages given and collective actions taken by the cluster.
- Acknowledge the benefit to the overall cluster of fostering startup companies in the region.

Much analysis has been done on this cluster in the past, but the cluster participants are still not working together to the degree that is needed in order to preserve and grow the existing cluster over time. Minnesota has enjoyed the benefits created by a critical mass of medical device firms that have been created here or have chosen to locate within the state. As competition amongst states to attract this industry becomes fiercer, it is more important now than ever that regional and state leaders become more proactive than reactive. Interview feedback was consistent that Minnesota has pursued a 'business as usual' approach and has not done enough to proactively spur development in the cluster, while other states in the nation have taken specific steps to lure medical device companies to their region. Minnesota must become bolder in its economic development strategy for the benefit of the region.

Cultural change in this cluster will be recognized by the following:

- Robust partnerships between business, government, and academia moving forward together toward one common vision.
- Best in class trade associations that are recognized by all as contributing significantly to forward progress and in which prominent leaders of industry steer strategic decisions and actions.
- Energetic movement toward a more entrepreneurial risk-taking culture.

Cultural change in any group is much easier said than done. Chris Argyris and Peter M. Senge wrote about the 'ladder of inference' that describes how culture is created or

changed.¹⁰ In a nutshell, the ladder of inference says that people's experiences create their opinions and beliefs. The opinions and beliefs in turn lead to actions based on those beliefs. A collection of actions by a group of people defines the culture of that group. So, in the case of the medical device cluster, the combined set of actions by cluster participants defines the culture of the cluster.

In order to spark cultural change and fulfill the vision, new experiences for the participants in the cluster and for the institutions that impact the cluster must be created. The action plan needs to focus on small victories that will create positive new experiences in the cluster, as well as on longer-term actions that will help the cluster thrive in the future. The action plan will include a roadmap to demonstrate small wins within the next year and build momentum for cultural change.

Robust Partnerships – Common Vision

We must call attention to the fact that the medical device industry is crucial and valued in Minnesota. Minnesota leaders, including mayors and the governor, must become a “drum” so that all companies – both large and small – feel and know that they are valued in Minnesota. This political unison must understand the importance of the industry and have the information and ability to create a unified voice. Leadership must be on the same page and momentum must be sustained. Nothing is more disheartening to industry leaders than volatile initiatives that stall or do not deliver measurable progress.

Leaders in industry must themselves become more active in preserving and growing the cluster. Currently, there is not a unified voice from the industry for economic development strategies or pro-medical device policies. Trade associations have tried to fill this gap, but many key cluster leaders are not directly involved in the efforts making the results less impactful.

Academia should also more actively engage with the medical device cluster. The educational community should meet regularly with industry leaders to tailor their research and curriculum to reflect the evolving nature of the cluster.

Best in Class Trade Associations

Trade associations like LifeScience Alley and the BioBusiness Alliance of Minnesota are important to the health of the medical device industry in Minnesota and have been a major component of the industry's success thus far. Nurturing smaller businesses leads to innovation and can lead to national prominence. Trade associations previously acted as a catalyst for innovation and technological discovery in the Minnesota medical device industry. However, as companies grow larger and business becomes more competitive, collective brainstorming and collaboration have fallen off. Trade associations are no longer seen by many industry participants as a catalyst for innovation.

Risk-Taking Culture

Many agree that the state of Minnesota is sorely missing the environment needed to foster risk-taking and encourage early stage companies. Innovation exists, but the financiers,

¹⁰ <http://www.solonline.org/pratool/ladder.html>

especially in the medical device field, are not very willing to invest in companies because the medical device startup risk is high and the time for return on investment is long due to regulatory and clinical requirements.

It is imperative that Minnesota foster a stronger entrepreneurial, risk-taking environment in order to preserve the existing cluster and improve it over time. One local medical device entrepreneur characterized the situation by saying, “Minnesota thinks the medical device industry is the goose that will keep laying the golden egg”. Unfortunately, this is likely not the case. According to the Destination 2025 report by the BioBusiness Alliance of Minnesota, Minnesota heavily depends on the medical device industry for a significant portion of its economic health. However, as the cardiovascular market matures, the cluster growth is slowing and, in some cases, even shrinking. Action is needed now.

Action Plan

Many believe that Minnesota has lost the culture to embrace those who are willing to take risks to create new companies. Given that a large part of the Minnesota economy is built around the medical device industry, an industry highly dependent on innovation, this is especially alarming. Therefore, the vision for the cluster is to spark cultural change that will actively encourage the growth and innovation of the medical device cluster in Minnesota.

With a clear vision in place, an action plan is presented that is meant to drive goals to realization and, ultimately, to create a more diversified and vibrant medical device industry within the state of Minnesota.

The goals needed to achieve the vision are, again:

- Robust partnerships between business, government, and academia moving forward together toward one common vision.
- Best in class trade associations that are recognized by all as contributing significantly to forward progress and in which prominent leaders of industry steer strategic decisions and actions.
- Energetic movement toward a more entrepreneurial risk-taking culture.

The recommended action steps are divided into three sections:

- Short-Term Action Steps
- Medium-Term Action Steps
- Long-Term Action Steps

Short-term action steps are meant to be easily accomplished by existing organizations without the need for new partnerships or other social infrastructure. These tasks can be accomplished in under six months with little to no costs. These tasks can also be labeled as “small victories”, helping the industry to gain momentum and propel it forward in the right direction. Medium-term action steps may require the creation of new partnerships, the creation of new organizational infrastructure, or the expansion of existing structure. These steps will likely cost more and may take up to two years. Long-term action steps are the broadest and will likely require commitments from the highest levels of state government. These steps are more complex and costly but are also the most expansive in terms of state direction. We believe long-term action steps will likely take a minimum of two years to initiate.

A series of tables below summarize the recommended actions to achieve the vision. After the tables is a comprehensive discussion of each action step and associated impact.

In addition to this report, there are already several well-crafted, and recent, comprehensive reports that analyze the medical device / bioscience cluster(s) within Minnesota and recommend specific actions for economic development. What is lacking is coordinated and unified action. One of the difficulties of this project has been identifying

new and innovative approaches to revitalizing Minnesota's medical device cluster. Therefore, the primary recommended action in this report is for the key stakeholders to join together and work toward common strategic objectives. The specific strategic objectives that the unified cluster would work toward will most likely include new actions recommended by this report or actions from previous reports.

Additional reports with many deserving recommendations include the following:

- Science and Technology Economic Development Project Committee - "Recommendations For a Minnesota Science & Technology Initiative" - January 2010
- BioBusiness Alliance of MN & Deloitte Consulting - "Destination 2025 - Minnesota's Medical Device Industry: A Vision for the Future" - January 2009
- BioBusiness Alliance of MN & Deloitte Consulting - "Destination 2025 - Minnesota's Biologic and Biopharmaceutical Industry: A Vision for the Future" - January 2009
- Minnesota North Star Rising Plan - (Submitted to MN Legislature – March 2009)
- Department of Employment and Economic Development - "Microeconomics of Competitiveness: Minnesota's Medical Devices Cluster" - February 2008

Short-Term Actions						
Category	Proposed Owner	Action Item	Impact Toward Vision	Proposed Resources	Potential Timeline	Comments
Robust Partnerships	BBAM	Align key stakeholders on the strategic direction, desired outcomes, and action plan for the cluster	Builds a common vision and plan	<ul style="list-style-type: none"> ▪ DEED ▪ LSA ▪ Industry participants ▪ Universities 	2010	Broad alignment toward a vision and action plan does not exist today in the cluster.
	Public Policy Makers	Create the Minnesota Science and Technology Authority (MSTA)	Promotes collaboration in the cluster and fosters entrepreneurs	<ul style="list-style-type: none"> ▪ DEED ▪ LSA ▪ Industry participants 	2010	Governmental leaders and industry participants need to be vocal about the need for this authority and the benefits it will bring to this cluster.
	U of M OTC	Continue to build commercialization track record at U of M's OTC	Spurs innovation and med tech startups	<ul style="list-style-type: none"> ▪ DEED Office of Science & Technology (OST) ▪ Entrepreneurs 	2010 and ongoing	

Short-Term Actions						
Category	Proposed Owner	Action Item	Impact Toward Vision	Proposed Resources	Potential Timeline	Comments
	BBAM	Create and promote a regional brand for the cluster	Markets the region to attract and retain companies	<ul style="list-style-type: none"> ▪ LSA ▪ DEED 	2010	Regional competitiveness in the cluster requires a crisp cluster brand that can be easily communicated and understood.
	DEED OST	Create a database of new market analysis information	Validates viability of a new product idea	<ul style="list-style-type: none"> ▪ Entrepreneurs 	2010	
Best in Class Trade Associations	LSA	Lobby MN to pass investment tax credits similar to neighbor states	Promotes innovation	<ul style="list-style-type: none"> ▪ LSA ▪ Industry participants 	2010	Complete! On April 1 st , 2010, MN signed into law new angel investor and R&D tax credits with the goal of encouraging innovation.
	LSA	Aggregate business resources into a consolidated reference library.	Creates efficiency for entrepreneurs	<ul style="list-style-type: none"> ▪ Government agencies ▪ Mayors ▪ Entrepreneurs 	2010	Would help cut red tape and establish a relationship between industry and regional government.
Risk-Taking Culture	LSA	Influence the FDA 510(k) and PMA reform through targeted lobbying	Accelerates new product development	<ul style="list-style-type: none"> ▪ Mayors ▪ Industry leaders 	2010	The FDA has announced reform to the PMA and 510(k). Changes are expected by September of 2010.

Medium-Term Actions						
Category	Proposed Owner	Action Item	Impact Toward Vision	Proposed Resources	Potential Timeline	Comments
Robust Partnerships	St. Cloud State University	Expand St Cloud State University's regulatory degree program	Prepare regulatory professionals to meet business needs	<ul style="list-style-type: none"> ▪ St Cloud State ▪ Industry participants 	2011-2012 academic year	
Best in Class Trade Associations	LSA and / or BBAM	Start a trade association branch dedicated to medical devices.	More focused to drive results faster	<ul style="list-style-type: none"> ▪ Industry participants 	2011	The existing trade associations' broad focus on life sciences may take away focus from growing the medical device sector.
	LSA or BBAM	Fund an economic study of the cluster	Demonstrates value of cluster to strategic decision-makers	<ul style="list-style-type: none"> ▪ Industry participants ▪ DEED 	2010-2011	Study results could be used for lobbying, investor pitches, and to attract additional entrepreneurs.
	MSTA	Develop a mentor program for med tech startups	Spurs innovation and med tech startups	<ul style="list-style-type: none"> ▪ Industry participants 	2010-2011	Pair med tech startup companies or entrepreneurs with successful med tech companies to act as mentors.

Medium-Term Actions						
Category	Proposed Owner	Action Item	Impact Toward Vision	Proposed Resources	Potential Timeline	Comments
Risk-Taking Culture	LSA	Lobby for a repeal of the new federal medical device excise tax	Repeal will encourage more companies to take risks on innovation	▪ Industry leaders	2011	The tax will disproportionately hurt the MN economy due to our economy's specialization in medical device technology.
	U of M	Pilot an open lab course and internships with startup companies	Encourage student risk-taking that may later translate into innovation.	▪ Industry participants	2012	Nurture scientific curiosity in students with the goal of enticing some of them to pursue entrepreneurial careers.

Long-Term Actions						
Category	Proposed Owner	Action Item	Impact Toward Vision	Proposed Resources	Potential Timeline	Comments
Robust Partnerships	MN	Study the economic benefits of redeveloping a transportation corridor between the Twin Cities, Rochester, and St. Cloud	Brings the Mayo Clinic more directly back into the sphere of the cluster	<ul style="list-style-type: none"> ▪ Mayo clinic ▪ DEED ▪ Industry participants ▪ LSA ▪ BBAM 	2011-2012	Many in the medical device field believe there is a growing disconnect between Rochester- and Twin City-based medical device industries.
	MN	Recommend the possibility of building an NIH center of excellence in MN	Promotes innovation	<ul style="list-style-type: none"> ▪ DEED ▪ U of M ▪ Industry Participants ▪ LSA ▪ BBAM 		Federally funded research facilities are proven to significantly affect local and state economies. They also strengthen local connections with the federal government.

Long-Term Actions						
Category	Proposed Owner	Action Item	Impact Toward Vision	Proposed Resources	Potential Timeline	Comments
Best in Class Trade Associations	LSA or BBAM	Develop programs in partnership with academic programs	Promotes innovation	<ul style="list-style-type: none"> ▪ Universities ▪ Industry participants 	2010-2011	Get graduate students involved with medical device companies and trade associations early in their careers to increase innovation by bringing in new perspectives and backgrounds.
Risk-Taking Culture	Industry	Take a leadership position to 'bend the health care cost curve'	Would establish MN as a leader in cost effective med tech, in addition to innovation	<ul style="list-style-type: none"> ▪ Government agencies ▪ Trade associations 		MN may have an advantage over other states because of its managed care model.

Short-Term Action Descriptions

These short-term action items will provide small wins that will build momentum in the cluster and set the stage for the medium-term and long-term actions that will come next. In order to achieve the vision of cultural change within the cluster, small victories must be demonstrated in order to provide for the cluster participants new experiences that will in turn shape their beliefs and actions toward the cluster.

Robust Partnerships

Align on strategic direction, outcomes, and action plan for the cluster

This action is crucial action is perhaps the most important. Every other recommended action will likely remain only an idea unless there is coordinated progress in a common direction. If action is taken on only one recommendation, this needs to be the one. This action can be short-term due to the amount of analysis already completed on the medical device cluster.

The decision-makers who will pick the strategic direction, outcomes, and final list of actions should be leaders in the cluster with a track record for action rather than analysis and discussion. Explicit outcomes and actions should be agreed upon, with milestones and measurable success criteria for each.

We believe that BBAM would be the best agency to lead the strategy alignment, outcomes, and action plan because of its proven history of strategy development for the medical device cluster. Participants in this action must include leadership from trade associations, key governmental groups, relevant university departments, and companies large, medium, and small. Failure to involve strong leaders from all these groups will result in continued lack of a unified voice and action plan for the cluster.

The strategy chosen should neither be too broad nor too narrow. One option is for the strategy to emphasize one or two sub-sectors within the cluster that hold a great deal of promise for future growth. For example, diabetes related devices might be chosen due to the huge and increasing number of people being treated, or drug delivery might be chosen due to the strong trend toward combination devices.

The outcomes that are selected should include clear roles for the main participant groups in the cluster. For example, LSA could be tasked with overall networking and communication throughout the cluster. BBAM could be chartered with creating metrics of success, benchmarking, and monitoring Minnesota's performance to the metrics over time, in addition to its role as overall strategic coordinator for the cluster.

Create the Minnesota Science and Technology Authority (MSTA)

Recently, the Minnesota Science and Technology Economic Development Project Committee recommended the establishment of the Minnesota Science and Technology

Authority (MSTA). The MSTA would develop and implement comprehensive science and technology economic development strategy for the state by:

- coordinating public and private efforts to procure federal funding for research and development
- promoting contractual relationships between businesses that receive federal grants and prime contractors and Minnesota-based subcontractors
- working with higher education institutions and nonprofits to promote collaborative efforts to respond to federal funding opportunities
- developing a framework for Minnesota companies to establish sole-resource relationships with federal agencies
- providing grants and financial assistance to eligible recipients

The MSTA currently awaits action by the House Finance Committee to move further toward reality. The MSTA's strategy for the state will be broad across all science and technology areas. BBAM has a proven track record of strategy development for the medical device cluster. In order to ensure sufficient attention to the strategy for the medical device cluster, it is recommended that BBAM remain the owner of the cluster strategy development, outcomes, and actions and that BBAM and MSTA work closely together to ensure strategic alignment.

Creation of the MSTA will be a great thing for Minnesota because a state agency with the power and explicit charter to drive economic development will be very helpful to coordination and collaborations within the medical device cluster. MSTA would be the logical choice to determine the best use of additional funding that the cluster might receive for use in economic development activities.

Continue to build on OTC's track record

Another example of a negative widespread belief is that the University of Minnesota is perceived as poor at translating research into dollars.¹¹ "But that criticism is getting old, or at least it should be. Under Jay Schrankler and Doug Johnson, the school's tech transfer program has made enormous strides."¹² The process for evaluating technology for transfer at the Office for Technology Commercialization has been improved and involves experienced industry managers, as well as industry veterans who advise companies in their early stages. Biomedical technologies are on of three focus areas in which the Office of Technology Commercialization is focusing.

Regional Brand

Regional competitiveness in the cluster requires a crisp cluster brand that can be easily communicated and understood. In recent years, many industry participants have been frustrated at the lack of progress in the sector and the fragmented silos between key groups in the sector. The experiences that have been created with stakeholders have led to negative beliefs about the sector, including beliefs that the sector is in decline or near

¹¹ <http://www.startribune.com/business/17284174.html>

¹² <http://www.medcitynews.com/2009/12/kudos-to-university-of-minnesota-tech-transfer/>

decline and that little to no progress is being made to preserve the industry. This belief seems fairly widespread and drives actions (or lack of actions) by the cluster members. Beliefs such as these will likely persist unless there is a concerted effort to achieve a common understanding of the state of the cluster and future plans. Once the cluster participants align on the strategy, concise talking points should be created and promoted both within the cluster, in order to spur entrepreneurship, and beyond the region in order to attract additional companies from outside the area.

Specific beliefs discovered in the diagnostic phase include multiple statements about DEED being too passive and not engaged enough in supporting new companies in the startup phase. In fact, in May, 2008, the new Office of Science and Technology was created within DEED and offers a host of expertise and services for startups like those in the medical device cluster.

During interviews, one entrepreneur said that "a holistic, organic set of interconnections" to support entrepreneurs was needed. For example, he noted that when he was seeking help applying for a grant in Wisconsin, the Wisconsin Entrepreneurs' Network steered him to "an awesome grant writer" in Madison. A few years ago, looking for similar help in Minnesota, "I couldn't get any names," he said. As part of the SBIR/STTR program at the new Office of Science and Technology, an entrepreneur can receive funding to have portions of a startup's federal grant applications written. Some services like these have recently been added to the Minnesota landscape and need more active promotion in order to best foster an entrepreneurial climate in Minnesota.

New Market Analysis Database

Startup companies need access to accurate and recent market data. This data is available at considerable cost through companies such as Frost & Sullivan. Minnesota could enable entrepreneurs and keep their costs down by creating a repository of new market data that entrepreneurs could use to build their business plans and to seek funding for their ventures.

Best in Class Trade Associations

Investment tax credits

A key recommendation was to pass investment tax credits in Minnesota comparable to those available in neighboring states. Minnesota took a step in the right direction with the recent passing of a bill that provides tax credits for angel investments. The bill will provide \$50 million in tax credits over the next five years in the form of a 25% tax credit for angel investors up to \$125,000 per year per investor. In addition, the bill provides an increase in the first tier of Minnesota's Research and Development Tax Credit from 5% to 10%.

Though the passing of the recent tax credits for early stage funding in Minnesota is essential if the State wishes to remain competitive, Minnesota should do more than simply "keep up" with its neighbors. We must also take bold, new steps.

Aggregate business resources

Obstacles to starting a successful med tech company are not always financial, but are sometimes governmental. Properly navigating an increasingly murky set of regulations and statutes is essential for success, not to mention the fact that public programs to help entrepreneurs all have distinct web sites that can be difficult to find. Trade associations have the resources to aggregate information about programs, resources, and municipal contacts that are available to startup companies in order to ease their startup burden and provide efficiencies. Providing this type of information has the potential to save significant time and frustration for innovators wanting to branch out on their own for the first time.

Risk-Taking Culture

Influence PMA and 510(k) reform at the FDA

The FDA has announced that changes are coming to both the PMA and 510(k) submission types in September, 2010. These changes could significantly impact the product development strategies and barriers to entry in the medical device cluster. The cluster needs to understand the impact of the proposed changes and influence the federal process with a unified voice.

Medium-Term Action Descriptions

Robust Partnerships

Expand St. Cloud State Masters in Regulatory Affairs and Services

Multiple interviewees mentioned the importance of programs like St. Cloud State's new masters degree program in regulatory affairs. The program is quite new, but the feedback is already pointing toward accelerating its growth by expanding the cohort size.

Best in Class Trade Associations

Dedicated cluster branch in a trade association.

A number of interviewees discussed very significant value that the trade associations LifeScience Alley and BioBusiness Alliance of Minnesota bring to the cluster. However, many also expressed dissatisfaction with how the trade associations have evolved. Interestingly, the reasons for dissatisfaction varied and the sub-themes were not strong. For example, one entrepreneur that we spoke with stated, "The track record and focus of BBAM is not strong. BBAM is too broadly focused." Another contact stated that LifeScience Alley has injected too many consultants looking for business into their educational programs. Yet another stated that the trade associations were filling an important niche, but were not a major force within the cluster because the executives of

large companies rarely participate in association events. Several others were very happy with the programs and services offered by both organizations.

The recommendation is to create a branch within one of the existing trade associations that is focused solely on the medical device cluster in order to ensure focus on this aspect of the life sciences in Minnesota. Ideally, this would be part of an existing trade association rather than a new one in order to encourage the strength of the main trade associations and to make it easier for the branches to collaborate and for the cluster to speak with one voice. The dedicated trade association arm would need to heavily involve industry leaders, from both big and small companies. The opinions of these leaders should weigh heavily on the strategic actions of the dedicated arm. Physicians and health care providers also need to be an integral part of this branch of the trade association.

Fund cluster economic study

Policymakers possess significant power and influence over economic policies relevant to the medical device industry in Minnesota. Funding an economic study of the cluster would serve to educate policymakers about the possible effects of legislation related to the medical device industry. The results of the study could also be used for lobbying, to publicize industry success and positive economic impact on the Minnesota economy, and for entrepreneurs to better position new product developments.

Mentor program for startups

Experienced firms and entrepreneurs will help startups avoid making the same mistakes they did as a startup. This program could be run by a trade association, or possibly through DEED's Office of Science and Technology.

Risk-Taking Culture

Lobby for repeal of the medical device excise tax

Due to the recent passage of President Obama's healthcare reform package the medical device industry in Minnesota faces the challenges accompanied with a \$20 billion dollar excise tax on medical devices levied over a 10 year period. This tax will cover all product classes with the exception of retail products like contact lenses and diabetes supplies. It is still unclear which devices will fall under the provision of the tax. The excise tax combined with healthcare reform ushers in a new era of uncertainty to the Minnesota medical device industry.

In the past, Minnesota medical device companies have failed to supply a unified voice for the purpose of expressing their dissatisfaction with policies or the lack of policies essential to the growth and health of the medical device industry in Minnesota. Furthermore, many within the general public do not understand the impacts this tax will have on their local economy. For many supporters, this tax is seen as a "tax on the rich, big businesses." The negative impact on innovation, and potentially jobs, is not recognized by the mainstream.

The medical device cluster must band together with their lobbying trade associations to fight for the repeal of this new tax.

Pilot curriculum changes

There is a philosophy in risk culture. If the universities would spring more “crazy scientists”, there will be more innovators, more homegrown companies, and new products. The industry needs more people to add real value, not just process data.

The recommendation is for the University of Minnesota to pilot a curriculum change for science and engineering students. Specifically, to require either an open lab course or an internship at a startup company for all science and engineering degrees. Either of these curriculum options would allow the students to experience risk and possible failure first hand with the ultimate goal of enticing some of the students to pursue more innovative and entrepreneurial careers.

Additionally, students should be encouraged to experiment more within the safety of their academic labs. Though the rigid processes they learn are essential, a course where the student completely designs his or her own lab experiment would be helpful in further developing curiosity and the ability to critically think for one’s self. The open lab course would have minimal guidance from a professor; the student would be tasked with creating value by identifying important questions or problems and then answering them through research and experimentation in the lab.

Long-Term Action Descriptions

Robust Partnerships

Study economic benefits of transportation corridor to Rochester

Many in the cluster believe that industries based in Rochester are not as integrated into the Twin Cities-based medical device cluster as they were in the past and, furthermore, that this disconnect is growing. Rochester is home to the Mayo Clinic (Minnesota’s largest employer), the Biotechnology Center, and the newly-established University of Minnesota-Rochester campus, so it is imperative that transportation links between the Twin Cities and Rochester be improved in order to maximize the economic impact of the medical device work being done in each region.

Though it was not in the scope of this analysis to determine whether Rochester-based companies were becoming more detached from Twin Cities-based companies, it is understandable that enhanced connections could improve the overall health of the cluster. Therefore, it is recommended that Rochester be linked to the Twin Cities by commuter rail. This link could come in the form of a stop on the proposed Twin Cities – Chicago high-speed passenger rail link or by the creation of a separate commuter rail line. Likewise, it is also recommended that improved transportation connections to Saint Cloud be lobbied for.

Recommend an NIH Center of Excellence in MN

Lobby for bringing federal dollars and laboratory facilities to Minnesota. Federally funded laboratories and jointly managed federal-university partnership facilities have been proven to have a significant economic impact on state and local economies. Federal research facilities provide jobs and research dollars while acting as a catalyst for crossover collaborations between universities and government that conduct advanced research. These facilities are also intrinsically linked to the state education system in which they reside and provide substantial intangible benefits to the community. Federal research facilities are essential for technology transfer and the development of private companies within many industries.

Specifically, a Center of Excellence is a center of expertise that can be relied on to explore and understand the needs and interests of communities, businesses, government agencies, non-profits, and industries. Such a Center could “help solve knowledge and skill-related problems, to provide avenues for new, well-trained workers or act as a source for upgrading an existing workforce, to involve students in research activities, to find answers to technical questions, and to promote applied research in particular fields.”¹³

Though the NIH Center of Excellence would not likely lead to more device sales, its presence could increase productivity by improving health outcomes and could attract additional device companies to locate in Minnesota. Our recommendation is that this Center of Excellence would focus on research and outcomes that will ‘bend the health care cost curve’, a concept discussed in more detail below, in order for the NIH and Minnesota to capitalize on the expertise that the region has to offer.

Best in Class Trade Associations

Develop programs in partnership with academia

Place graduate students in internship programs exposing them to medical device work, in order to provide the next generation of innovators with career contacts and real life experience. This program could increase the probability that students will stay in Minnesota and contribute to the cluster.

Another benefit of this action would be that companies would be able to do more research with lower overhead cost, since interns typically cost a company far less than a regular employee would.

Risk-Taking Culture

Take a leadership position to 'bend the health care cost curve'

In the United States, standard short-term methods to address the rising healthcare costs, like reducing prices, are not sufficient to succeed long-term. Legislation and industry

¹³ <http://www.pc.ctc.edu/coe/mission.htm>

action should support the necessary changes and improvements in healthcare by reforming payment systems, regulations, and institutions that currently prevent patients from consistently getting the best quality care at the lowest cost.

This strategy consists of three parts:

- First, all stakeholders in the system need better information and tools to be more effective.
- Second, provider payments should be redirected towards rewarding improvements in quality and reductions in cost growth as well as providing support for health delivery technologies that save money while emphasizing disease prevention.
- Finally, patients should be given greater support for improving their health and lowering overall health care costs, including incentives to improve measureable health goals related to the reduction of preventable health conditions.

The medical device industry has a substantial role to play in this strategy. Technological advances in medical devices have the potential to reduce costs and improve care. Societal preference towards healthier lifestyle options and preventative strategies could place significant pressure on the market to revamp medical treatments.

Substantial political capital has already been spent reforming health insurance markets. Government has also restricted subsidy programs to create competition among these markets as well as instituted near-universal participation in insurance markets through national healthcare reform.

By changing the trajectory of rising healthcare costs, Minnesota could take a leadership position in ‘bending the cost curve’ by leading changes in the industry that are likely to come about at some point anyway. By doing so, Minnesota has the opportunity to position its medical device industry at the vanguard of an industry shift and to solidify its position as a leader in the field.

Specifically, the Minnesota medical device strategy that is developed should outline bold, long-term actions that could be taken to drive healthcare costs down at the same time as benefiting the area’s economic goals. One recommended action would be to devote the NIH center of excellence to the study and experimentation of devices, procedures, methods, and processes that deliver efficacious and cost effective medical care.

Conclusion

The medical device industry in Minnesota continues to be strong, but has not been as proactive as other states in preserving and growing the sector in order to provide ongoing economic benefits to the region.

The Five Forces analysis shows that all forces in the industry are strong or medium. This is a difficult industry to participate in, but Minnesota has demonstrated a decades long ability to prosper in medical devices. This track record can be leveraged for future growth that other regions without an established medical device presence will have difficulty

imitating. The Diamond Model shows that all parts of the diamond, except Demand Conditions, positively impact the cluster.

Combining the implications of the diamond with the proven leadership in this sector, Minnesota is positioned well to leap its medical device industry ahead of other states. In order to do so, Minnesota must spark cultural change by starting with proactively defining a strategy for success that all stakeholders align to and then driving actions toward the strategy.

The medical device cluster in Minnesota has been a great boon to economic health in the region over the past several decades. In order to ensure that the medical device industry continues to be major contributor to Minnesota's economy, action must be taken now to preserve and grow the cluster.

Appendix A: Acronyms

Definition of Commonly Used Acronyms	
DEED	Department of Employment & Economic Development
LSA	Life Science Alley
BBAM	Bio Business Alliance of Minnesota
U of M	University of Minnesota
OTC	Office for Technology Commercialization
FDA	Federal Drug Administration
PMA	Pre Market Approval (FDA Submission Type)
510(k)	FDA Submission Type
NIH	National Institutes of Health
MSTA	Minnesota Science and Technology Authority
R&D	Research and Development
GDP	Gross Domestic Product

Bibliography

Science and Technology Economic Development Project Committee -
"Recommendations For a Minnesota Science & Technology Initiative" - January 2010

BioBusiness Alliance of MN & Deloitte Consulting - "Destination 2025 - Minnesota's
Medical Device Industry: A Vision for the Future" - January 2009

BioBusiness Alliance of MN & Deloitte Consulting - "Destination 2025 - Minnesota's
Biologic and Biopharmaceutical Industry: A Vision for the Future" - January 2009

Minnesota North Star Rising Plan - (Submitted to MN Legislature – March 2009)

Department of Employment and Economic Development - "Microeconomics of
Competitiveness: Minnesota's Medical Devices Cluster" - February 2008

<http://www.semnrail.org/whysupport.html>

<http://en.wikipedia.org/wiki/Biologic>

<http://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Consumers/default.htm>

<http://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Industry/default.htm>

<http://www.medcitynews.com/2010/02/angel-investment-tax-credit-in-minnesota-the-burden-of-proof/>

https://www.lifesciencealley.org/advocacy/angel_investor_tax_credit.aspx

<http://www.accountingweb.com/blogs/brianstrahle/state-and-local-tax-360/minnesota-research-and-development-credit-now-applies-pas>

<http://www.earthtimes.org/articles/show/angel-investor-tax-credit-signed-by-minnesota-governor,1231231.shtml>

<http://atr.org/believe-minnesota-passes-pro-growth-tax-a4738#>

<http://www.medcitynews.com/2010/04/angel-tax-bill-becomes-law/>

<http://www.minnesotamedicine.com/PastIssues/May2007/FacetoFaceMay2007/tabid/1776/Default.aspx>

http://www.eurekaalert.org/pub_releases/2010-02/uom-uom021610.php

<http://www.medcitynews.com/2010/01/can-miromatrix-regenerate-minnesotas-medical-industry-an-exclusive-interview-with-dr-doris-taylor-and-miromatrix-ceo-rob-cohen/>

<http://speakingoffaith.publicradio.org/programs/2009/stem-cells/>

http://www.nytimes.com/2008/01/14/health/14heart.html?_r=1&ref=us

- http://minnesota.publicradio.org/collections/special/columns/polinaut/archive/2010/03/the_medical_dev.shtml

- <https://www.lifesciencealley.org/default.aspx>

http://www.collaborative.net/about_us/index.cfm

<http://biobusinessalliance.org/>

- <http://www.healthcarefinancenews.com/news/minnesotas-reforms-lead-way-toward-accountable-care-model>

<http://www.minnesotahealthinfo.org/>

- <http://www.massdevice.com/news/fda-make-510k-changes-september>

<http://www.gxpanjvt.com/ivtnews/templates/IVTNews.aspx?articleid=1239&zoneid=18>

- http://www.positivelyminnesota.com/Business/Get_Help_from_Our_Experts/Office_of_Science_Technology/index.aspx

<http://www.matr.net/article-29306.html>

- <http://www.warf.org/index.jsp>

http://en.wikipedia.org/wiki/Wisconsin_Alumni_Research_Foundation

<http://wan.mediasite.com/mediasite/Viewer/?peid=e4f0ef0e-34e0-49ca-9712-5ccb89d7ca47>

<http://discovery.wisc.edu/discovery>

- <http://www.mmf.umn.edu/bulletin/2008/winter/medschoolnews/bakken.cfm>

<http://www.medtronic.com/about-medtronic/our-story/our-first-pacemakers/index.htm>

<http://www.ahc.umn.edu/education/med/index.htm>

- <http://www.research.umn.edu/techcomm/about.htm>

<http://www.techconnect.org/Summit2009/expo/exhibitors.html?id=18>

- <http://www.startribune.com/business/17284174.html>

<http://www.medcitynews.com/2009/12/kudos-to-university-of-minnesota-tech-transfer/>

-

<http://www.mndaily.com/2010/02/16/technology-commercialization-research-revenue>

-

<http://www.mdc.umn.edu/about.html>

http://www.mpo-mag.com/news/2008/06/26/university_of_minnesota_opens_new_medical_devices_center

-

<http://www.stcloudstate.edu/ras/about.asp>

-

<http://www.time.com/time/nation/article/0,8599,1973135-3,00.html#ixzz0kBNaFH1D>

http://www.mdiec.org/files/HUBS_Survey_Results.pdf

<http://www.mbbnet.umn.edu/scmap/biotechmap.html>

<http://www.massmedic.com/docs/umassacm04.pdf>
<http://www.mpo-mag.com/articles/2006/07/top-medical-device-companies-report>

http://www.massbio.org/economic_development/the_massachusetts_supercluster

-

http://www.positivelyminnesota.com/Data_Publications/Economic_Trends_Magazine/October_2008_Edition/Medical_Devices_Manufacturing_Prescription_for_Success.aspx

<https://www.lifesciencealley.org/default.aspx>

<http://www.biobusinessalliance.org/>

<http://www.tcbmag.com/factfinder/bigbook/publicly-tradedmedicaldevicemanufacturers-top20.aspx>

http://www.manta.com/mb_43_D1_24/medical_equipment_device/minnesota

-

<http://www.startribune.com/business/20919269.html>

<http://twincities.bizjournals.com/twincities/stories/2009/09/14/daily12.html>

<http://www.massdevice.com/news/jp-morgan-analyst-says-device-makers-tax-might-not-be-deep-originally-feared>

http://www.medicaldevicedaily.com/servlet/com.accumedia.web.Dispatcher?next=cd_d_articleSample&article=11