Table of contents

Introduction .................................................................................................................................................. 4

1. Executive summary ................................................................................................................................ 5

2. About this report .................................................................................................................................... 8

3. The medical device industry is a large and increasingly important contributor to a modern economy .................................................................................................................................. 11

4. Sweden’s medical device industry has a proud history, but the bar for success is rising and Sweden largely relies on aged inventions ........................................................................................... 15

5. Building a successful medical device industry requires purposeful collaboration between several stakeholders .......................................................................................................................... 31

6. Measured against international best practice, the Swedish environment for medical devices has important shortcomings .................................................................................................................. 45

7. Each stakeholder needs to take action to ensure a strong future for the industry ................................................................................................................................................ 55

Appendix .................................................................................................................................................... 65

Partners and sponsors to the project

- Carl Bennet AB
- CapMan
- Chalmers University of Technology
- Elekta AB
- Gambro AB
- Göteborg University
- Innovationsbron
- Karolinska Institutet (KI)
- Karolinska University Hospital
- Royal Institute of Technology (KTH)
- Sahlgrenska Academy
- VINNOVA

Project steering group

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Carl Johan Sundberg (Karolinska Institutet)
Introduction

The medical device industry is a very important industry for Sweden – on the basis of its contribution to gross domestic product (GDP) and employment. The industry’s innovations also elevate the level of healthcare provided in Sweden and the rest of the world.

As three of the medical device stakeholders in Sweden, we see great benefits in a closer collaboration between our own organizations and others (e.g., companies, government, financiers, and industry-network organizations). Primary benefits from our perspective would be a strengthened innovation environment and better healthcare.

Over the last few years in the Stockholm region we have made an effort through the creation of Centre for Technology in Medicine and Health (CTMH) to identify and initiate research, educational programs and industrial collaboration for development and improvement of clinical applications and processes in healthcare. Presented in this report is a case for further strengthening our efforts and, through collaboration with other stakeholders, increasing medical device innovation in Sweden. Key characteristics of our future collaboration in this area are high ambition, focus and action.

Even though we as initiators of this report view this from a Stockholm perspective we would like to stress the national relevance of this report.

We want to thank the steering group (Lars-Åke Brodin (ROYAL INSTITUTE OF TECHNOLOGY), Bertil Guve (ROYAL INSTITUTE OF TECHNOLOGY /CTMH), Lars Kihlström (KAROLINSKA UNIVERSITY HOSPITAL), Bo Norrman (KAROLINSKA INSTITUTET), and Carl Johan Sundberg (KAROLINSKA INSTITUTET)) and all the individuals who have contributed to this effort through funding, workshops, interviews and guidance. We look forward to an exciting journey together and to building on the momentum created during the creation of this report.

Peter Gudmundson, President of the Royal Institute of Technology

Birgir Jakobsson, CEO of Karolinska University Hospital

Harriet Wallberg-Henriksson, President of Karolinska Institutet

5 December, 2007
The medical device industry is large and fast growing, with very attractive benefits to a modern economy. Global sales amount to over USD 200 billion and continued strong growth is expected to be driven by the aging of the population, the increased burden of life-style related diseases, product innovation, growing wealth in developed nations and the expected expansion of healthcare in under-developed markets. From a national perspective, a strong medical device industry is a source of competitive advantage as it supports distinctive academic environments and creates high income, knowledge-intensive jobs. More importantly, the industry contributes to the improvement of health throughout the world through new healthcare solutions.

Sweden has a proud history in medical devices, based on groundbreaking innovations like the gamma knife, dental implants, the implantable pacemaker, and the dialysis machine. These and other innovations have helped build leading companies, as well as an industry that has been a strong contributor to the Swedish economy. From 1999 to 2005, the medical device industry in Sweden achieved consistent GDP contribution growth of 10% per year driven by employee growth of 4% per year and an overall productivity improvement far above most other industries.

But the bar for success in the global medical device arena is rising, and Sweden is still relying, for the bulk of its medical device revenues, on innovations that are 30 to 50 years old. More complex innovation, more stringent regulation, and increasing cost pressure in the healthcare system contribute to a more challenging environment for device companies. As the challenge to bring products to market and to achieve true differentiation increases, and as the customer landscape grows even more complex and demanding, the question is whether Sweden can keep pace with the best in the industry. Will Sweden see the creation of new global leaders and will existing leaders strengthen their positions through establishing new, attractive growth platforms?

While the Swedish industry continues to perform well, there are signs that Sweden may be losing some of the distinctiveness it has achieved in the past. Looking across the medical device industry today, a number of observations give cause for concern. It appears that Sweden is starting to lose some of its strength in the relevant research communities, and is struggling to turn good ideas into products and companies. The small and medium sized Swedish companies hold relatively limited potential to generate new global leaders. And, while Sweden has some large, global companies, it seems to be unable to maximize the value of these companies when it comes to building strong networks and innovation clusters in the country. Overall, the large companies are active in more slowly growing segments of the medical device market, and in some cases there is a risk of control and ownership becoming less Swedish.

What can be done better? Measured against international best practice cases, the current environment for medical device innovation and commercialization in Sweden has important shortcomings. An analysis of international success cases shows that building a strong medical device industry requires strong focus, real collaboration and long-term commitment from several key stakeholders: academic institutions, leading hospitals, government, financiers, network organizations and companies. There is no single formula for success, but drawing on these cases, four critical enablers stand out:

1) strong and aligned incentives
2) world class capabilities
3) active industry collaboration and networks
4) adequate funding for research and early commercialization. In addition, the existence or creation of a strong and sophisticated local home market has played an important role.

The incentive system in Sweden does not provide enough impetus for physicians and universities to do enough applied research and commercialize ideas. It is typically considered more academically rewarding to conduct basic medical research than applied research, and commercialization of
research output does not provide career benefits in the same way as in some other countries, such as the US. This translates into an insufficiently entrepreneurial culture. In terms of capabilities, the shortage is mainly related to customer-driven innovation and commercialization skills like international marketing and sales and reimbursement management. There is also a general scarcity of connectivity and networks in Sweden to facilitate collaboration projects, access the healthcare system, conduct cross-disciplinary R&D and support commercialization. It is noteworthy how little the stakeholders know about each other’s agendas, needs and assets. A shortage of funding has also played a role, especially the limited availability of medical technology-specific research and product development funding and early seed capital.

These issues are complex, and while many of them have been the subject of past scrutiny, relatively little action has been taken. However, much of what needs to be done does not require grand reforms, and is within the reach and influence of the key stakeholders. For each stakeholder, a clear set of actions are recommended.

**Technical and medical universities need to**

1. Emphasize medical technology innovation and make it a high priority on their strategic agendas, develop concrete strategic plans with priority research areas, appoint medical technology taskforces to deliver on the strategic plan and secure funding for research and collaboration
2. Map and market their research capabilities towards the industry and other academic institutions and develop intellectual property (IP) sharing models to simplify collaboration between stakeholders
3. Develop medical technology knowledge platforms, e.g., joint professorships, seminars on healthcare needs, awards for medical technology innovation based on cross-disciplinary collaboration
4. Develop and launch medical technology educational programs of relevance to the industry
5. Encourage and support research staff to focus on medical technology research and product development through a medical technology-targeted research fund
6. Encourage and support commercialization of research output through high-quality business programs and incubators

**University hospitals and county councils need to**

1. Work together to ensure that medical technology innovation is a high priority on their strategic agendas, develop concrete strategic plans with priority research areas, appoint medical technology taskforces to deliver on the strategic plan and secure funding for research and collaboration
2. Increase collaboration (product development, clinical research and testing, advisory boards) with, and outreach to, academia and industry and be transparent about clinical problems in need of medical technology solutions
3. Encourage hospital staff to focus on medical technology research, commercialization and clinical testing by including collaboration experience as criteria for appointing positions within the hospital, making funding available, creating prestigious innovation awards and making universities’ business programs available for hospital staff
4. Ensure that health economic priorities are set within county councils and communicated throughout the organization

**Companies need to**

1. Identify areas for innovations that can be sourced – and need to be sourced – from outside the company
2. Proactively reach out to academia and university hospitals in Sweden to explore what they have to offer in relation to these areas
3. Build business oriented connections with small and midsized companies to share knowledge in sales and marketing, regulatory and reimbursement issues
4. Engage in a Swedish “focus cluster”

**Government should consider**

1. Making available a significant medical technology-focused cluster fund and make investments subject to clear commercially viable investment criteria
2. Allocating funds for applied medical technology research with a needs-driven focus for which individual researchers can apply
3. Intentivizing academic institutions to motivate and support researchers in commercialization by, for example, providing additional funding for commercialization, and reviewing an option to include an additional regulated task for universities (i.e., commercialization of research output)
Although achievable, the sum of these actions represents a significant challenge. To move quickly to action, it is suggested that stakeholders should find a number of focus areas (“focus clusters”) for innovation and commercialization where there is natural energy to build on. These should be areas that represent significant unmet customer need and fit with the capabilities of the academic institutions, and where there is an existing and motivated large company which is willing to commit and invest. Candidates for such focus areas could be elderly care, a specific cancer segment, e-health or patient aids. The ambition level for Swedish leadership should be set very high in order to focus the agendas of all key stakeholders. Strong local networks need to be built to orchestrate the development and resource setting of these focus clusters. These networks can either be based on existing ones, like the Centre for Technology in Medicine and Health (CTMH) or they need to be built to suit the specific needs of each cluster.

* * *

Sweden has a strong foundation to build on in the medical device industry, but achieving the ambitious goals laid out in this report will require a level of collaboration and collective energy that is starkly different from today. Further analysis is of limited value, and action is of the essence.
In recent years, medical technology in Sweden has attracted more interest from politicians, venture capitalists, the media and other institutions than before. In early spring 2007, the Royal Institute of Technology (KTH) in Stockholm invited representatives of the Swedish medical technology industry, Karolinska Institutet (KI) and Karolinska University Hospital into dialogue. The aim was to discuss the challenges and potential of the Swedish medical technology environment. More specifically, attention was paid to the conditions necessary to create an efficient innovation process that includes the industry, the universities and the healthcare system. As a result of this discussion, KTH took the initiative to create the prerequisites for a major national study on the subject. During the spring of 2007 the vice president commissioned to the Centre for Technology in Medicine and Health, CTMH, (owned by KTH, KI and the Stockholm County Council) to lead the study. A steering group was created with representatives from KTH (School for Technology and Health), KI (Unit for BioEntrepreneurship) and Karolinska University Hospital (FoUU, Department for Research, Development and Education). The group gathered financiers and partners to the study and launched the study in the summer of 2007.

The scope of the work has been to identify and ignite action relevant to improving the possibilities and the climate for medical technology industry, research and healthcare in Sweden. As the report and its recommendations show, there are several actions that can and need to be taken by the institutions and companies. Not all solutions are complex. And there is a need for acting with a sense of urgency.
The major focus of this report has been to provide a holistic review of the Swedish medical device industry by drawing on experiences from the former and current situation, and national and international industry. The main questions addressed in the report are

• How has the Swedish medical device industry performed over the last five to fifteen years?
• What are best practice examples for creating a strong medical device industry?
• What lessons can be learned from these examples?
• What should Swedish stakeholders do to secure the future success of the industry?

Many excellent reports have been written over the last few years on how Sweden can improve its pharmaceutical/bio-technology/medical technology industry and research. This report differs from other reports in three ways

• First, it is focused solely on medical devices and diagnostics (for definition please see appendix)
• Second, it concludes that the existing industry is actually performing better than many reports have highlighted as there is a positive trend in GDP contribution, number of employees, productivity, and exports. Yet the report does highlight that the bar for success in the industry is going up and that Sweden lacks some key conditions, indicating that action is needed
• Third, the recommendations are focused on collaboration and what each stakeholder can do to contribute rather than solely relying on government intervention

The steering group for the project has consisted of representatives from KTH, KI and Karolinska University Hospital: Lars-Åke Brodin (KTH), Bertil Guve, chairman (KTH/CTMH), Lars Kihlström (Karolinska University Hospital), Bo Norrman (KI), and Carl Johan Sundberg (KI). The steering group has reported to the deputy president of KTH, Margareta Norell Bergendahl.

McKinsey & Company, an international management consulting firm, has supported the steering group in tasks of fact gathering and analysis by

• Conducting approximately 50 interviews with key stakeholders (CEOs of medical device companies, hospital CEOs, presidents of universities, researchers, etc.)
• Conducting 4 workshops with over 40 stakeholder representatives
• Interviewing international medical device experts to understand international cases

The ultimate objective has been to map out the current state of the Swedish medical device industry and outline recommendations for the future.

For questions regarding this report please contact Bertil Guve at the Centre for Technology in Medicine and Health (CTMH; KTH-KI-SLL). For a digital version of this report (PDF) please visit www.ctmh.se
The medical device industry is a large and increasingly important contributor to a modern economy

The medical device industry has seen strong growth in recent years, and has delivered innovations over the last 50 years that have improved the health and welfare of millions of people throughout the world.

**The global medical device industry – an explosion in innovation**

**1940s**
- External Defibrillator
- Intra-ocular lens
- Haemodialysis

**1950s**
- X-ray Angiography
- External Pacing
- Fixed rate implanted pacers
- Charnley Intramedullary hip
- Heart/lung bypass

**1960s**
- Solid state X-ray
- Mechanical Heart Valve
- Intra-Aortic balloon pump
- IPPV ventilators
- Artificial heart implant
- Fiber optic endoscopy
- CABG procedure

**1970s**
- High quality Ultrasound
- CT
- PTCA
- Diagnostic Electrophysiology
- Trans-cut. nerve stimulator
- Hollow fibre dialysis
- PTFE vascular grafts
- Pulse oximetry
- Skin staplers
- Radial Keratotomy

**1980 – 90s**
- Digital Subtraction Angiography
- MRI
- Nasal ventilation for sleep apnea
- Bone stimulation
- Implanted defibrillators
- Epilepsy ‘pacers’
- Coronary stenting
- Radioablation
- Endoscopic surgery
- Intravenous oxygen therapy
- Tissue growth factors
- Drug eluting stents
- Xeno-transplantation
- Artificial bone

**Note:** See appendix for explanation of abbreviations and definitions

**Source:** Interviews with medical device industry representatives
The global market for medical devices today is more than USD 200 billion and is estimated to grow by approximately 7% per year. It employs 800,000 individuals throughout the world (where of approximately 10,000 are in Sweden). While the US is home to the largest share of the industry, a number of other countries (e.g., Germany, Switzerland and Japan) account for a significant share, including Sweden. In addition, the medical device industry has delivered more shareholder value than many other industries over the last 15 years.

The medical device industry is projected to continue to achieve strong growth and to be a catalyst for substantial job creation. Two main factors fuel the industry’s growth. First, the ongoing demographic shift, with an aging population in developed countries, is likely to lead to increased demand for healthcare and healthcare-related products and services. Second, there is a growing importance of lifestyle-related diseases (weight-related conditions, type 2 diabetes, heart attacks, etc.), which in many cases increase the demand for both pharmaceuticals and medical devices. In addition to these two factors, increasing wealth in developed nations drives demand for advanced healthcare, with trends shifting towards growing importance of advanced diagnostics (e.g., imaging technologies) and minimally invasive technologies.

In the future, expansion of healthcare in under-developed markets is also likely to grow the medical device market. There are several important benefits of the medical device industry. In a globalized labor market, in which low-skilled work is increasingly subject to offshoring, countries will find that a complex and demanding industry like medical devices can be an important source of competitive advantage. The industry can also serve as a supporting mechanism for a thriving academic environment as well as create attractive high income jobs. Furthermore, there is a ripple effect, with every job in the industry supporting several other businesses in adjacent industries and thereby creating additional job openings. The Milken Institute, an American independent economic think tank, suggests in a study of the San Diego area that each job in the medical device industry creates 1.5 additional jobs in other industries. Applying this factor to the overall industry, over 2 million jobs are supported by the medical device industry globally.

However, as beneficial as these contributions to the overall economy may seem, the most obvious and most important benefit of the medical device industry is that it saves lives and helps cure and treat diseases.

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1 Opportunities in global medical devices and diagnostics, Health Research International, 2006
2 US Census Bureau annual survey of manufacturers; Eurostat annual detailed enterprise statistics; MHLW
3 Opportunities in global medical devices and diagnostics, Health Research International, 2006
4 Datastream
5 Opportunities in global medical devices and diagnostics, Health Research International, 2006
6 America’s Biotech and Life Science Clusters: San Diego’s Position and Economic Contributions, Milken Institute 2004
In Sweden, a number of stakeholders would benefit from the continued success of a strengthened medical device industry. *Universities* would gain a) a reason to develop world-class skills in core areas, b) potentially larger budgets from profit-sharing with focus clusters, as well as c) additional research funding through increased collaboration with industry.

*County councils and university hospitals* might gain additional funds through collaboration with industry on product development initiatives and clinical testing. These institutions would also benefit from a more innovative environment, which could lead to earlier treatment (through increased involvement in clinical trials) and better, more cost-efficient healthcare. Health technology would be added as part of the regional development engine. A conscious medical technology developing environment could help to stimulate a continuing quality improvement culture, which benefits patients immediately. Swedish hospitals could further strengthen their brand as being a source of key innovations. In addition, through increased focus on high-quality needs-driven research, directors of clinical departments would be able to attract clinicians with superior skills in research.

*Companies (domestic and foreign)* would have an opportunity to a) source the innovation and core world-class skills at Sweden’s universities and hospitals, b) test and develop products, and conduct clinical testing, in a more accessible and high-quality care environment, and c) develop closer relationships to researchers, clinicians and other companies that would facilitate their development and growth as well as secure easier access to new management talent.

The effect is that the *government* would enjoy not only a higher domestic employment in well-paying jobs (which will stimulate further job creation and generate more tax revenue) but also an improved research environment, which would benefit related industries and academic fields.

The final stakeholder group, *investors*, would also profit via a) new investment opportunities in medical technology as well as other industries and b) occasions to strengthen existing portfolio companies through a stronger medical technology network.

Given these benefits, the development of a strong and vibrant medical device industry should be actively encouraged by countries, companies, academia, investors, the healthcare system and private citizens.

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7 Interviews and workshops pursued during this effort
8 Medical device clusters focused on sub-segments, e.g., elderly care, driven jointly by key stakeholders (for further description, see chapter 7)
Sweden’s medical device industry has a proud history, but the bar for success is rising and Sweden largely relies on aged innovations.

Historically, the Swedish economy has benefited from the strength of the Swedish medical device industry. However, many of the innovations that represent the backbone of the industry today date back 30 to 50 years, which raises the question of whether Sweden can sustain and strengthen its position through a continued stream of innovation. The bar for success is rising and there are signs that Sweden is starting to lose some of the distinctiveness it has enjoyed in the past.

Sweden has a proud history

The Swedish medical device industry is a large (SEK 60 billion) and highly consolidated sector (five companies represent approximately 75% of revenues) – one which has achieved considerable success throughout the world. While Sweden accounts for less than 1% of the global market for medical devices, the Swedish medical device companies account for approximately 4% of the global market revenues. And in an industry dominated by US players, Sweden has two companies (Gambro and Getinge) on the global top-50 list.

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9 Review of medical device and diagnostic companies in Sweden based on data from Statistics Sweden, Odin, Swedish companies Registration Office, VINNOVA, Swedish Medtech and interviews. Revenue data from annual reports or Odin
10 Definition of Swedish companies in this report: Companies owned by a Swedish citizen or a Swedish company, companies listed on the Swedish stock exchange and companies originating from and with operations in Sweden and that currently are owned by any (domestic or foreign) private equity firm
11 Opportunities in global medical devices and diagnostics, Health Research International, 2006; The World Medical Market Report, Epsicom Business Intelligence, 2005
12 Opportunities in global medical devices and diagnostics, Health Research International, 2006
### Annual sales of Swedish companies by company and by industry segment

Sales from latest available year (2005 or 2006); 100% = SEK ~60 billion

#### Sales by company

- **Permobil**: 2%
- **Phadia**: 3%
- **Astra Tech**: 5%
- **Eka**: 7%
- **Nobel Biocare**: 9%
- **Mölndal Healthcare**: 12%
- **Gambro**: 26%
- **Getinge**: 23%
- **Other**: 13%

#### Sales by segment

- **Blood processing and therapy products**: 4%
- **Wound care**: 4%
- **Patient aids**: 4%
- **Surgical dressings, drapes**: 7%
- **Infection control**: 7%
- **Energy-based technologies**: 8%
- **Surgical tables, lights and fixed systems**: 12%
- **Dental**: 13%
- **Urology & Renal**: 26%
- **Other**: 14%

#### Note:

- Based on 316 identified companies (identified from Swedish industry, SNI codes 33.101, 73.103, 24.42, 35.43, 51.46, 51.871, interviews, trade organizations, VINNOVA, and patent publications). Financials from latest available year (2005-2006).
- Data from 2005. Revenues from Gambro Healthcare US that were divested in 2005 excluded. Revenues from remaining Gambro Healthcare (non-US clinics) that were divested in 2007 included (accounting for 13% of total revenues in 2005).
- Assuming 70% of AstraTech's revenues are in urology and renal and 30% are in dental.

#### Source:

- Statistics Sweden; Swedish Companies Registration Office; Odin; VINNOVA; Swedish Medtech; Interviews

### Top 50 global medical device and diagnostics companies, 2006

Revenues in USD billions

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<th>Rank</th>
<th>Company</th>
<th>Revenue (Billions)</th>
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<td>J&amp;J MD&amp;D (US)</td>
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<td>3</td>
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* Data from 2005 (includes non-US dialysis clinics)

#### Source:

- Company filings
The medical device industry has historically performed better than many other industrial sectors in Sweden (e.g., telecom, automotive, and pulp and paper) in GDP contribution growth, which was approximately 10% CAGR from 1999 to 2005 (compared to -6 to 5% for pharmaceuticals, automotive and pulp and paper).

This has been driven by an employee growth, which was approximately 4% CAGR (compared to -3% to 2% for the other industries) and strong productivity improvements of CAGR 11% over the same period. Currently approximately 10,000 people are employed in Sweden in the medical device industry of which a large share is employed by the top five Swedish companies and large global companies with operations in Sweden.

In addition, the Swedish medical device industry’s net exports have been fairly stable compared to many other countries and have been experiencing a slight overall increase.

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Note: Value add as share of GDP. Sample of companies included in respective industry: Pharmaceuticals: AstraZeneca, Pfizer, Recip; Automotive: Volvo, Scania, SAAB automobile; Pulp & Paper: StoraEnso, SCA, Billerud; Telecom: Ericsson, Flextronix, Powerwave technologies


Source: Statistics Sweden

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13 See appendix for explanation of CAGR
14 Statistics Sweden
15 Statistics Sweden
Employee growth of Swedish medical device industry compared to other industries

Note: Sample of companies included in respective industry: Pharmaceuticals: AstraZeneca, Pfizer, & Recip; Automotive: Volvo, Scania, SAAB automobile; Pulp & Paper: StoraEnso, SCA, & Billerud; Telecom: Ericsson, Flextronix, & Powerwave technologies

Source: Statistics Sweden

Selection of Swedish and foreign medical device companies in Sweden by employee number and type

Data as of November 2007

Note: a As defined in this report (see reference 10)  
b Both manufacturing and other  
c Both manufacturing, marketing & sales and other  
d Two different companies  
e Including 35–40 people in Finland

Source: Swedish Medtech; Interviews with company representatives; Corporate web sites; Annual reports
Productivity of Swedish medical device industry compared to other industries and average

Productivity, value add/hours worked

<table>
<thead>
<tr>
<th>Industry</th>
<th>Index, 100=1999</th>
<th>CAGR 1999–2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical devices</td>
<td>200</td>
<td>11.1%</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>164</td>
<td>10.3%</td>
</tr>
<tr>
<td>Sweden total</td>
<td>120</td>
<td>4.0%</td>
</tr>
<tr>
<td>Pulp &amp; paper</td>
<td>100</td>
<td>1.8%</td>
</tr>
<tr>
<td>Automotive</td>
<td>80</td>
<td>-3.3%*</td>
</tr>
<tr>
<td>Telecom</td>
<td>60</td>
<td>-17.5%**</td>
</tr>
</tbody>
</table>

* Not including sub suppliers
** 1999–2003, numbers past 2003 are not disclosed by Statistics Sweden
Source: Statistics Sweden; Swedish National Accounts

Swedish net exports of medical instruments compared to other countries

Net exports of medical instruments
USD millions

Source: United Nations Comtrade database
Sweden has a set of strong and unique prerequisites

Interviews with company representatives and workshops performed to support this effort reveal that the long-term competitiveness of the Swedish medical device industry has been enabled by two primary factors:

- **High quality healthcare system.** Sweden has a reputation for rigorous evidence-based healthcare resulting in a healthy population. It has also meant that many companies wish to leverage the “approved in Sweden, used by Swedes” brand as it incorporates internationally-renowned medical researchers who strive to improve medical care. The brand also represents a well-educated, socio-economically stable population, with high trust in their healthcare system, and a greater willingness to participate in clinical trials than in many other countries.

- **A network of large, coordinated disease databases that capture input from extensive “patient registers.”** These databases are unique internationally and provide not only a good tool for measuring outcomes of devices being tested but also may indicate an area of unmet need (or room for product development) if there are areas with poor outcomes.

Other reports have cited additional factors benefiting Sweden’s medical device industry. These factors include:

- **Strong industry tradition, with good engineers**
- **Government-initiated institutions focused on early stage commercialization funding**
- **Competent and efficient regulatory authorities, who are known for being efficient in their approval process, leading to shorter lead times than in some other European countries**
- **Teacher’s exemption** that gives researchers and scientists at academic institutions a personal incentive to commercialize findings, since they own 100% of the intellectual property of any findings.

The question is whether Sweden can keep up this strong performance. The industry today still relies, for the bulk of its revenues, on innovations that are 30 to 50 years old (e.g., the gamma knife, dental implants and the dialysis machine). In order to ensure continued success, a continued stream of innovation and global commercialization is required.

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16 Managed by Socialstyrelsen, www.socialstyrelsen.se
17 E.g., Medicin för Sverige! Nyt liv i en framtidbranch, SNS förlag, 2007
18 Teacher’s exemption, see appendix
The bar for success is rising: global trends

Over the past few decades, the global medical technology industry has developed into a much more challenging environment.

Rising bar to achieve product differentiation
There are many more products on the market today compared to 30 years ago. Competition for groundbreaking ideas is fierce and new improvements are fighting for attention. Growth is increasingly driven by improvement in existing products, and as a result, the clinical and economic differentiation between products has lessened. Many companies’ R&D departments are focused on development of integrated systems and solutions, not simply products alone. For example, Kinetics does not just offer a “WoundV.A.C.” product but also provides wound care nurses to train hospitals and home care nurses on its use, as well as reimbursement specialists to assist with billing. In today’s environment, for a company to have a competitive advantage with these more complex offerings it must depend on heavier marketing and sales efforts, thus increasing the cost of doing business.

Longer regulatory approval times
In the European Union, regulatory demands on medical devices have intensified due to the introduction of the CE marking in the 1990s. While the CE marking simplifies the overall regulatory process in Europe by eliminating the need for devices to be certified by every country, it has led to stricter regulations in several countries. The net effect is that a higher investment is required before new products generate revenues.

More complex customer landscape
While physician preference is still an important deciding factor for purchasing medical technology, payors (e.g., insurance companies), providers (e.g., hospitals) and patients are increasingly important customers. Hence, an expanded and improved marketing effort that communicates product/therapy benefits, and makes complex clinical outcome data understandable to this diverse group, is required. For example, Johnson & Johnson directly markets its hip replacement products to patients in television ads in the United States.

Increasing regulatory demands, especially for combination pharma/device products
Today’s advanced products often combine device capabilities with pharmaceutical characteristics (e.g., drug-eluting stents that treat heart disease). These combination products require a more advanced regulatory approval that includes notifying bodies that are able to ensure safety of both the device component (traditional CE mark) and the drug portion (traditional EMEA) with advice from relevant pharmaceutical authorities. Many times, the device companies are not offering a new drug but are offering a new delivery route (drug is delivered by the device as opposed to, for example, orally) and the safety of this new route must be assessed. A combination product typically will have an unpredictable road ahead for regulatory approval in the EU. Compared with pure devices, more sophisticated in-house clinical and regulatory skills are required to tackle the combined pharmaceutical approval process. The result is longer timelines.

Cost pressure
The increased cost pressure on healthcare systems challenges the medical device industry. Hospitals face cost and margin pressure from declining reimbursement levels, while payors are concerned about rising healthcare costs generated from increased utilization of technology and increasingly require evidence of health-economic benefits before paying for newer products. Financially-motivated physicians (via physician ownership and profit sharing) may turn away from premium brands and also demand improved economic evidence before they agree to use certain products. Hence, device companies are forced to deliver compelling economic data as well as clinical data to hospitals, payors, and physicians, especially for new, high-price products and procedures. Hospitals also generate pressure in another way: hospital groups are forming larger and increasingly more skilled purchasing organizations. As a result, device companies will need to build or enhance in-house contracting capabilities to directly negotiate and contract with buying groups and hospitals. Clear pricing strategies, simple but robust contract templates, and commercial capabilities of the sales force will thus become increasingly important for driving pricing/contracting decisions.

Notes:
19 Wound V.A.C. is a low technology device made of sponge, plastic sheet and vacuum device that revolutionized the treatment of large chronic wounds. Kinetic Concepts Inc., www.kcil.com
20 CE marking: see European Commission, Guide to the Implementation of Directives Based on New Approach and Global Approach, chapter 7
21 Johnson & Johnson, www.jnj.com
Is Sweden rising to the challenge?

In many ways, the Swedish medical device industry continues to do very well and most of the leading companies are keeping their position. When trying to assess whether Sweden is on the right track it is, however, important to test the dynamics of the entire industry, from idea generation, through to the establishment of new and exciting companies, as well as the climate for and performance of the established large companies. In all of these areas, the picture is mixed. There are signs that Sweden’s medical device industry is starting to lose some of its distinctiveness in the relevant research communities and that Swedish device companies struggle to turn good ideas into products. The small and medium sized Swedish companies have a relatively limited potential to generate new global leaders. And, while Sweden has strong, leading global companies, it is not able to maximize the value of these companies when it comes to building strong networks and innovation clusters. Indeed, a disproportionate share of the large companies is focused on the slower-growth parts of the industry.

Distinctiveness in innovation and commercialization

The review of Sweden’s strengths in innovation is based on analyses of two indicators: articles published and patents filed. Historically, Sweden has been exceptionally successful in both areas, but other countries are catching up and Sweden has dropped to being “average” relative to European peer countries, such as Switzerland, Denmark, Germany and the Netherlands.

Medical technology publications are difficult to analyze, as there is no obvious way to select publications related to the very diverse field of medical technology. There are few journals dedicated to medical technology, and journals that publish papers on medical device development specialize either in the related therapeutic area, or in the related technology area. For this analysis the choice was made to look at publications that are indexed in Medline under a selection of Medical Subject Headings (commonly known as MeSH terms) that closely relate to our definition of medical devices and diagnostics. This does not, however, separate development of medical devices from applied research using medical devices and technologies.

Using this method, it is clear that although Swedish researchers have maintained a high level of publications over the past 15 years, the pattern is similar to what will be shown for patents. Swedish growth has been slow, other countries are catching up and if the trend continues, Sweden is likely to fall behind European peers in the number of medical technology publications per capita.

Swedish publications represent 1.2% of all the medical technology publications in Medline. Sweden’s areas of strength are closely linked to its largest companies, as shown by reviewing publications in each medical device segment. In comparison to the average, Swedish publications on dental and radiotherapy subjects represent a larger share of the total publications in their respective field, which is likely to be driven by Nobel Biocare and Elekta. Surprisingly, urology and renal medicine do not stand out, despite the presence of Gambro, which produces renal products.

None of the measures chosen are perfect given the diverse nature of the medical device field. Using existing data sources (e.g., patent databases and Medline) does not allow for a completely comprehensive and exclusive analysis of medical device patents and publications as the databases are not categorized well enough. Despite these constraints, the belief is that these indicators together give a good indication on the innovative projects and key opinion leaders in Sweden.

Please also see a) the European Innovation Scoreboard 2006 – Comparative analysis on Innovation Performance accessed via http://trendchart.cordis.europa.eu/ which indicates that Sweden belongs to the “Innovation leaders” but its lead is declining b) Innovation Indicator for Germany 2007, Deutsche Telekom Stiftung which indicates that Sweden is the country which the greatest capacity to innovate

MeSH terms used are reviewed in the appendix

**Medical technology* publications by country and year**

Number of publications/million inhabitants, 1990–2005

<table>
<thead>
<tr>
<th>Year</th>
<th>Sweden</th>
<th>Denmark</th>
<th>Netherlands</th>
<th>Germany</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1995</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Strength of research areas and correlation with local industry**

Number of publications from national scientists/Total number of publications in the country, 2006

Index, country share of all medical technology articles in Medline* = 100

**Therapeutic areas**

- Cardiovascular
- Urology and renal
- Respiratory
- Orthopaedics
- Drug delivery
- Dental
- Radiotherapy
- Diagnostic imaging
- Surgical instruments

- High share of publications (index>105)
- Average share of publications (index 95–105)
- Low share of publications (index<95)

**Countries**

- Sweden
- Denmark
- Netherlands
- Switzerland
- Korea
- Ireland

**Note:**

- Index explanation: E.g., index 105 means that in this segment, the country has 5% higher share of segment specific articles in Medline (as share of total segment specific articles in Medline) than the country’s overall share of medical technology articles in Medline
- Medical articles indexed by selected medical technology MeSH terms (see appendix), include medical technology development as well as applied medical technology

**Source:**

Medline accessed August 2007
**Medical technology patents by country and year**

Number of patents filed to the European Patent Office and to the World Intellectual Property Organization in medical technology* per million inhabitants, 1986–2006

<table>
<thead>
<tr>
<th>Country</th>
<th>1991–2006 CAGR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switzerland</td>
<td>12.6%</td>
</tr>
<tr>
<td>Denmark</td>
<td>14.4%</td>
</tr>
<tr>
<td>Sweden</td>
<td>6.4%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>12.1%</td>
</tr>
<tr>
<td>US</td>
<td>10.9%</td>
</tr>
<tr>
<td>Germany</td>
<td>9.0%</td>
</tr>
<tr>
<td>UK</td>
<td>7.2%</td>
</tr>
</tbody>
</table>


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**On patents**, Sweden ranked second in Europe in the early 90’s, based on the number of medical technology patents per capita, closely behind Switzerland, but clearly ahead of peer countries such as Denmark, Germany and the Netherlands. Throughout the 1990’s several of these countries have increased their number of medical technology patents by more than 10% annually, while Swedish growth has been significantly lower, 6.4%27. Today, Sweden is on the same level as its European peers, and if the current trend continues Sweden will soon see itself falling behind28.

A breakdown of the filed patents by type of assignee shows that in Sweden, private individuals account for a higher proportion of the patents (14%) than they do in peer countries. The breakdown also shows that this number has declined over the past seven years. However, the greatest share of patents comes from companies, many of them active in the medical device industry29 30.

28 This analysis is based on a selection of classes (e.g., A61B, A61C, A61D, A61F, A61G, A61H, A61J, A61L, A61M, H01J, H05G) in the International Patent Classification (IPC) system that matches our definition of medical devices and diagnostics. However, as the IPC classes are not defined to separate medical devices, there are some patents included that are not devices (e.g. absorbent pads) and some that are excluded as they are categorized under various other IPC classes (e.g. hearing aids classified as loudspeakers)
30 In Sweden, roughly 45% of the patents from other industries come from SCA Hygiene Products, as the IPC system unfortunately does not allow separation of wound care products from absorbent hygiene products (diapers, feminine hygiene products). If excluding SCA from the analyses, private individuals’ share of patents would be even higher than 14%
**Private individuals’ share of patents in Sweden compared to peer countries**

**Share of patents filed to World Intellectual Property Organization in medical technology* by assignee type, 2006**

<table>
<thead>
<tr>
<th>Percent</th>
<th>100% =</th>
<th>100% =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Israel</td>
<td>20</td>
<td>416</td>
</tr>
<tr>
<td>Other</td>
<td>43</td>
<td>276</td>
</tr>
<tr>
<td>International company, medtech</td>
<td>44</td>
<td>524</td>
</tr>
<tr>
<td>National company, medtech</td>
<td>6</td>
<td>560</td>
</tr>
<tr>
<td>Technology transfer company</td>
<td>4</td>
<td>211</td>
</tr>
<tr>
<td>University/ research institution</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Private individuals</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

Israel | Sweden | Switzerland | Netherlands | Denmark

<table>
<thead>
<tr>
<th>100%</th>
<th>2000</th>
<th>2003</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other**</td>
<td>34</td>
<td>41</td>
<td>43</td>
</tr>
<tr>
<td>International company, medtech</td>
<td>12</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>National company, medtech</td>
<td>36</td>
<td>37</td>
<td>31</td>
</tr>
<tr>
<td>Technology transfer company</td>
<td>6</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Private individuals</td>
<td>17</td>
<td>16</td>
<td>14</td>
</tr>
</tbody>
</table>

**Share of Swedish medical technology patents* filed to World Intellectual Property Organization by assignee type and year**

<table>
<thead>
<tr>
<th>Percent</th>
<th>CAGR (number of patents)</th>
<th>Driver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Israel</td>
<td>2000</td>
<td>2003</td>
</tr>
<tr>
<td>Other**</td>
<td>34</td>
<td>41</td>
</tr>
<tr>
<td>International company, medtech</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td>National company, medtech</td>
<td>36</td>
<td>37</td>
</tr>
<tr>
<td>Technology transfer company</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Private individuals</td>
<td>17</td>
<td>16</td>
</tr>
</tbody>
</table>

**Action MedTech – Key Measures for Growing the Medical Device Industry in Sweden**

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**Sample includes, for example, SCA Hygiene Products and pharmaceutical companies**

**Companies in other industries include companies like Ericsson, SKF, AGA etc. Companies closely related to medical devices include biotech, safety equipment, dental/orthopedic technicians etc.**

**Source:** Delphion; Corporate web sites; Interviews

---


**Sample includes, for example, SCA Hygiene Products and pharmaceutical companies**

**Companies in other industries include companies like Ericsson, SKF, AGA etc. Companies closely related to medical devices include biotech, safety equipment, dental/orthopedic technicians etc.**

**Source:** Delphion; Corporate web sites; Interviews
Dynamics of small and medium sized companies

There are 310 small and mid-sized medical device and diagnostic companies in Sweden today (revenues <2000 MSEK), but it appears as few, if any, have the potential to grow into large, global players.

To better understand the second tier of the Swedish medical device industry, a review was conducted of the medical technology patents that were filed by private individuals in 2000, and of the performance of a sample of existing small/mid-sized companies.

The review of 17 of the 42 patents registered by Swedish private individuals to the World Intellectual Property Organization in 2000 shows that ten of these patents have become commercialized in some way. Three of them have resulted in companies being started, three are incorporated in existing companies and four have been sold. The rest have not been commercialized in any way.

An analysis of the existing 310 small and mid-sized companies reveals that most (208) are very small (revenues less than SEK 10 million31). Among the companies with revenues between SEK 10 and 2000 million, growth has averaged 15% per year over the past 8 years and the average EBIT in 2006 was 6%.32

### Frequency of commercialization

<table>
<thead>
<tr>
<th>Medical technology* patents in WIPO from private Swedish inventors, 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% = 42 patents</td>
</tr>
<tr>
<td>Not selected for investigation</td>
</tr>
<tr>
<td>43%</td>
</tr>
<tr>
<td>Selected for investigation – patent holders found</td>
</tr>
<tr>
<td>40%</td>
</tr>
<tr>
<td>17% Selected for investigation – patent holders not found**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of patents</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
</tr>
<tr>
<td>7</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medical technology patents 2000 from selected and found patent holders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical technology patents 2000 from selected and found patent holders</td>
</tr>
<tr>
<td>Commer-</td>
</tr>
<tr>
<td>Sold, not used today</td>
</tr>
<tr>
<td>Sold, likely used today</td>
</tr>
<tr>
<td>Incorporated in existing company</td>
</tr>
<tr>
<td>Base for new start-up</td>
</tr>
<tr>
<td>3 companies active today based on patent taken in 2000, all on a small scale</td>
</tr>
</tbody>
</table>

Note: Patents were randomly selected from total group of privately filed patents
** Contact details to patent holders not found
Source: Delphion; Patent holder interviews

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31 Revenue data is missing for 37 of the 208 companies. Assumption made in this effort is that these companies are small with revenues less than SEK 10 million
32 Review of medical device and diagnostic companies in Sweden based on data from Statistics Sweden, Odin, Swedish Companies Registration Office, VINNOVA, Swedish Medtech and interviews. Revenue data from annual reports or Odin
Despite this growth, many companies find expansion difficult, as they are lacking commercialization capabilities (e.g., reimbursement management) and are focused on marginal innovations in small or slow growing segments of the device industry (e.g., making a patient bed that is slightly better). Yet revolutionary innovations are possible in even the slower growing segments (e.g., the “Wound Vacuum-Assisted Closure, V.A.C., system,” by Kinetic Concepts, Inc. improved the lives of many patients with previously large wounds that would not heal). Examples of medical device segments where small and mid-sized Swedish companies are present include the following:

**Patient aids** (25% of aggregated sales of Swedish small and mid-sized companies, 39 Swedish companies) contain a large number of slower growth companies. Modest growth is expected (3.6% CAGR 2004–2010) particularly within the advanced personal mobility sector, where Permobil is the largest company.

**In vitro diagnostics** (17% of aggregated sales of Swedish small and mid-sized companies, 20 Swedish companies) contains the 7th largest Swedish medical device company, Phadia, driving the size of the segment, and a number of very small companies, most of which have been started over the past three years. These companies focus on traditional in vitro testing, point-of-care testing and advanced molecular diagnostics, all of which are strong growth segments.

**Diagnostic imaging** (10% of aggregated sales of Swedish small and mid-sized companies, 30 Swedish companies) is where most of the new advanced technologies are located; however, these companies are still very small and most are focused on the X-ray segment, which has the lowest projected future growth within the imaging segment.

**Dental** (10% of aggregated sales of Swedish small and mid-sized companies, 29 Swedish companies) has the most significant growth opportunities in the implants segment, where there is a strong tradition through Nobel Biocare. However, success in this segment might be challenging as most players are active in very fragmented, slower growth segments.

**Cardiovascular** (8% of aggregated sales of Swedish small and mid-sized companies, 16 Swedish companies), especially the trans-catheter segment, has a high potential for growth but there is a high degree of competition within this segment from device companies headquartered in other countries.

---

33 Companies were called and interviewed regarding e.g., the focus of their product development and perceived major challenges

34 WoundVAC is a low technology device made of a sponge, plastic sheet and vacuum device that revolutionized the treatment of large chronic wounds. Kinetic Concepts Inc., www.kcil.com
Aggregated revenues and number of Swedish small and midsized companies by segment, mapped versus global market size and growth

On a more granular level, management interviews with 33 randomly selected companies\(^{35}\) reveal that only 16% of the companies are competing with unique products in a large or growing market, while the others are either focusing on low growth markets, or working with generic or me-too type products\(^{36}\).

Given these circumstances, it is not surprising that few small companies manage to grow and develop into promising larger international companies.

**Leverage of large companies**

Large\(^{37}\) companies are crucial to the continuing growth and development of the industry. In most successful international cases, these companies act as “engines” for the local innovation clusters (more on this in the next chapter). In Sweden, companies like Gambro and Elekta have played this role to some extent in the past. The question is whether Sweden is fully leveraging these leading companies. There are signs that would suggest this is not the case. Many of the interviews with senior management of these companies revealed that Sweden is often not viewed as a priority for research collaborations and clinical testing. There are weak ties between these companies, academic institutions and hospitals – and such ties are critical to ensuring a well functioning innovation cluster. Anecdotally, Sweden may also be losing some of its historic distinctiveness as a place to base medical device research and development – perhaps illustrated by Siemens’ recent decision to leave the country.

It is also critical for large companies to act as vehicles for commercialization of ideas generated by smaller companies or by individuals. It is very difficult to grow a large company from scratch, and growing a new business area as part of an established global company is often a more feasible route. For example, Medtronic’s success in adding new areas of business has had a huge impact on the local innovation clusters.

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35 46% are founded by engineers or innovators not affiliated to academia and 25% by physicians. Approximately one-fifth of these companies have launched their products internationally, half of them were launched in Sweden and are ready to move beyond the national market, and one quarter were in the process of launch and scale up domestically. The remaining companies were still in the process of clinical testing and product development.

36 Me-too products; products with very similar form and function to existing products, competing with minimal differentiation

37 To learn more about large Swedish companies (revenues > SEK 2 billion) for Gambro visit: www.gambro.com, Getinge visit: www.getinge.com, Nobel Biocare visit: www.nobelbiocare.com, Elekta visit: www.elekta.com, Molndlycke Health Care visit: www.molndlycke.com, AstraTech visit: www.astratech.com
This process is also important to ensure a continuous upgrading of the portfolio of products and business areas, such that the large companies preserve the potential for fast growth and high margins.

A look at Sweden suggests limited success in this area. Some companies have ridden successful s-curves (i.e., been able to grow by the extension of business into non-core areas) and thus have been able to add new, vibrant business areas while others have not. A recent example of success is Getinge, which has a cardiac perfusion business, and which recently acquired Boston Scientific’s cardiac and vascular surgery divisions. The top six Swedish medical device companies are represented in nine different medical device segments (by technology area). Except for Getinge’s participation in the large and high-growth cardiovascular segment and Elekta’s participation in the high-growth energy based technologies segment, none of these segments are representing either the highest growth or largest market segments. Leading Swedish companies are, in the aggregate, not among the highest spenders on research and development.

There is a risk of that control and ownership of companies are becoming less Swedish as a couple of Sweden’s largest companies are currently private equity owned and one has strong links to Switzerland.

38 Boston Scientific acquired the Cardiac Surgery business in April 2006 as part of the Guidant transaction. The Cardiac Surgery business is a leading developer of medical technologies designed for use in surgical cardiac procedures, including beating-heart bypass surgery systems and endoscopic vessel harvesting for coronary bypass surgery. The business employs approximately 450 people. Boston Scientific acquired the Vascular Surgery business in 1993. The Vascular Surgery business develops synthetic grafts and patches used to surgically treat vascular disease, including the repair of abdominal aortic aneurysms and peripheral vascular anatomy. The business has approximately 250 employees. The combined revenues of the two businesses in 2006 were approximately $275 million.
Summary

While Swedish medical device industry has a proud history of strong performance, the bar for success is rising and there are signs that the industry is losing its distinctiveness. Sweden has not been prolific recently in turning ideas into products and companies, few next-generation companies have the potential to grow into global leaders, and the country’s existing leaders are not being fully leveraged.
Building a successful medical device industry requires purposeful collaboration between several stakeholders

In order to understand how a well functioning medical device cluster comes about and functions, a number of international case examples have been studied (in addition to the workshops and interviews described in Chapter 2) where a strong innovation environment and a flourishing medical device industry exist.

Each case is unique and provides valuable insights

- South Korea has developed a strong position in the imaging segment based on technology skills developed in the country’s other industries
- Denmark has a long history in hearing aids based on government intervention and, more recently, joint collaboration
- San Francisco has built a vibrant biotechnology/medical device cluster and leveraged the strengths of the existing semi-conductor industry
- Minneapolis has built a world-leading medical device cluster leveraging the local presence of major medical device companies such as Medtronic, Guidant (Boston Scientific) and St Jude
- Ireland has attracted medical device manufacturing and R&D through a major government led effort including tax breaks and strong focus on network building

Across these examples, there is no single recipe for success, but rather a number of different models that can lead to success. Common to all of them seems to be strong focus, high degree of collaboration and dedication from the stakeholders driving the effort. In addition, given the cross-disciplinary essence of applied medical technology, the stakeholders need to represent different institutions (hospital, universities, and companies) as well as different departments within these institutions. The best practice examples that have been reviewed, and the interviews conducted with industry experts and stakeholders in Sweden, suggest that there are four critical elements or “enablers” contributing to each successful story: strong and well aligned incentives, world class capabilities, active and well connected networks, as well as adequate funding for research and early commercialization.
### Incentives

The international case examples studied reveal that in order to create a strong and vibrant medical device cluster, a number of stakeholders (individual researchers, physicians, academic institutions, hospitals/providers, and commercial companies) need be incentivized to contribute with their knowledge and expertise.

#### Universities

Academics in medicine and technology should be motivated not only to perform high quality, innovative research that aims to solve challenges facing the healthcare environment but also to commercialize ideas so they will be shared and others can benefit from them. This can be achieved in several ways.

**Formal evaluation of publications and patents.** One option is to ensure that innovation and quality are part of the formal evaluation of scientific researchers. In South Korea (box 1), research into medical devices was incentivized by giving more attention to publication in internationally recognized journals as part of the evaluation criteria of researchers. This initiative has led to a dramatic increase in the number of medical technology articles in Medline, as professors strive to achieve better evaluations (and, indirectly, more research funding). In Sweden, where this incentive is deeply rooted in the scientific society, the same incentive may have the opposite effect, driving researchers towards basic rather than applied research, since basic research is more likely to be published in high status journals.
Expert interviews emphasize that it would be beneficial if patent activity was also part of the formal evaluation of researchers, even though this has not been the case in the international case examples studied.

**Intellectual property ownership.** Incentivizing commercialization can be achieved using several different models. In Sweden, the teacher’s exemption\(^{39}\) gives researchers and scientists at academic institutions a personal incentive to commercialize findings, since they own 100% of the intellectual property. This can be contrasted with the US where universities generally have the full ownership of the intellectual property developed by employed researchers, while net income is often shared. For example, Stanford University owns 100% of any patent filed and any potential royalties are shared equally between the inventor, the inventor’s department and the university. The same principle is applied at the University of California. At Northwestern University in Chicago a different model for sharing royalty/licensing fees has been developed: 30% of the net income goes to the inventor, 20% to a university account to support the inventor’s further research (should the inventor leave the university, this amount remains with the university), 10% to the department or departments in which the inventor serves, 5% to the school or center in which the inventor serves and 35% to the central administration.

**Culture of positive recognition for commercial activities.** In many countries, such as the US, there are cultural incentives to commercialize innovation, as successful commercialization gives high status in the surrounding research community and can lead to a significant accumulation of wealth.

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**Box 1: South Korea**

In South Korea, a major government effort known as the G-7 Highly Advanced Nation program was introduced in the early 1990’s aiming to bring the level of Korean science and technology to the level of the G-7 countries. Total investment of USD 160 million (1995–2001) was made. Medical technology was one of the selected investment areas, with a focus on imaging technologies. The result has been a virtual explosion of the medical device industry, particularly in diagnostic imaging, where publications, patents, number of companies and sales have all grown in excess of 15% annually.

**Effect of government programs**

- Large increase in activity in medical technology publications and patents and a 10-fold increase in the production value of the local medical device industry
- Significant foreign investment, several companies choosing Korea as their Asian R&D hubs
- Development of market leading medical imaging solutions in MRI, ultrasound, and x-ray technology
- According to Korea Health Industry Development Institute, the medical technology project had generated about USD 550 million from sales of developed products and another USD 370 million as a substitution effect of imports during 1996–2002
- Out of the top 27 companies in Korea, one third are imaging companies that represent approximately half of these 27 companies’ revenues

\(^{39}\) Teacher’s exemption, see appendix

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* Medline articles indexed by selected medical technology MeSH-terms (see appendix). Hits include medical technology development as well as applied medical technology

**Source:** Interviews; Press clippings; Ministry of Science and Technology; Korea Health Industry Development Institute; Medline accessed August-September 2007; Delphion
University hospitals
Incentives for individual care personnel and hospitals to spend time and effort on clinical research is a prerequisite for a successful innovation environment, through individual (basic) research projects, in organized clinical trials, and in joint product development projects with companies.

Formal evaluation of clinical research and patents. Interviews reveal that evaluating clinical staff and hospitals on the basis of their patent activity, as well as on their contribution to clinical research, could stimulate activities in these fields.

Culture of positive recognition for commercial activities (incl. clinical trials). In the US, there is a culture and tradition of participating in clinical trials and collaborating on/commercializing projects with the industry. These activities are viewed as something a physician “should” do rather than something a physician “could” do.

IP ownership. Many international university-affiliated hospitals follow the university model as described in the previous section.

Companies
The presence and strong integration of large medical device companies is essential for the success of the industry. Attracting foreign companies to a country and sustaining the presence of national companies may require financial incentives and/or unique geographic capabilities.

Tax breaks and cost-efficient labor. Significant tax reductions combined with cost-efficient labor for manufacturing attracted medical device companies to Ireland. In South Korea, the Ministry of Science and Technology works closely with the Ministry of Health and Welfare to coordinate tax benefits for foreign companies in selected industries (manufacturing and healthcare being two). The trend of moving R&D and clinical trials to low-cost countries is not yet occurring as clearly in the medical device industry as it is in the pharmaceutical industry, even though there are a few examples (e.g., Siemens Medical R&D in India).

Strong local research capabilities. South Korea is also able to entice companies by providing unique research capabilities (especially in imaging) and has convinced several large global corporations to select the country as their Asian R&D hub.

Strong local market. Both foreign and national companies can be galvanized by a strong local market. The South Korean success in imaging technology has been driven in part by demand from local hospitals. The hospitals invest heavily in frontline technology since the reimbursement system is set up to make the first years of using a new technology highly profitable for them. Namely, the national health insurance system takes up to two years to specify the reimbursement levels. Since Korean patients are attracted by new technologies, the medical centers price new technologies freely and get reimbursement from the government accordingly.

Another example highlighting the importance of a strong local market is the early development of the hearing aid industry in Denmark (box 2). The industry got its big boost in 1953 when the government created an exceptionally strong home market by promising a free hearing aid for every Dane who needed one.

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41 E.g., Siemens, www.siemens.com
42 Interviews with Korean experts
Box 2: Denmark

Denmark has a strong scientific tradition in audiology. Today three Danish-headquartered global companies together account for 45% of the global hearing aid market. In an effort to strengthen the local academic abilities in applied hearing, the three companies have been involved in establishing the academic Centre for Applied Hearing Aid at the Technical University of Denmark and recruiting world-class researchers in the field. The centre is focused on basic research, and the result has been a research hub attracting top academics from around the world that gives the founding companies unique access to a worldwide academic network. Funding of the centre is provided by the industry (~35%), private and public research funds (~35%) and by the centre itself (~30%).

The strength of today’s industry can be traced back to
- A long heritage of audio technology in Denmark, producing diagnostic tools already a century ago
- A continued strong academic tradition in acoustics
- Support from related industries in Denmark such as:
  - Elite stereo equipment maker Bang & Olufsen
  - Leading manufacturer of sound and vibration solutions Brüel & Kjær
  - Leading hearing diagnostics developers GN Otometrics and Interacoustics
  - Government driven growth of local market: offer free hearing aids

Global hearing instrument market, 2005

100% = USD 3.5 billion

- Siemens 21%
- Widex 8%
- Starkey Lab. 13%
- Phonak 14%
- Oticon 15%

1943: GN Danavox founded to produce loudspeakers, adding hearing aids in 1947
1956: Widex founded by former Oticon employees
1960’s: Technical University of Denmark (DTU) initiates research in psychoacoustics, investigating how humans perceive sound
1904: Oticon (William Demant) founded by Hans Demant to import and later produce hearing aids
1943: First acoustic laboratory established at the Academy of Technical Services
1953: Danish government opens up a local market by promising free hearing aids for every Dane who needs one
2003: Center for applied Hearing founded by Oticon, GN ReSound and Widex in collaboration with DTU


Source: Medicindustrien; Press clippings; Interviews with industry representatives

Governmental support of R&D investments. Attracting foreign companies is an important step but just as important is ensuring that both foreign and local companies want to stay. Ireland (box 3) has been successful in attracting foreign companies and preventing them from fleeing to other countries: after attracting 15 of the world’s top 25 medical device companies’ manufacturing businesses, Ireland is now seeking to increase its share of research activities through financial support of first time R&D and facilitation of collaborations between industry and third level educational institutions in Ireland. First time R&D is supported by the government through IDA Ireland, which provides funding for feasibility studies, training of personnel, and for the first pilot R&D project. When scaling up R&D, support is given to upgrade facilities and further train personnel. Enterprise Ireland, the state development agency for Irish industry, provides financial support for commercially focused, industry led projects in product and process development through the Research Technology & Innovation (RTI) program. The maximum amount is 650,000, of which one-third is given as repayable funds.

43 IDA Ireland, www.idaireland.ie; Enterprise Ireland, www.enterprise-ireland.com
In Ireland, the government initiated International Development Agency (IDA) has led a remarkable effort to attract foreign investment in a number of manufacturing areas, one being medical technology. Today, 15 of the top 25 medical device companies have manufacturing units in Ireland, and the IDA is now broadening its agenda towards the establishment of R&D activities in Ireland. IDA has taken on an important role as the spider in the Irish medical device web, coordinating connections between all involved stakeholders. All of the involved stakeholders contribute to develop a strongly collaborative medical device environment.

**Universities**
- Joining forces to create a strong bioengineering masters program, including industrial and clinical internships
- Clear ownership of intellectual property produced at universities; where researchers get 95% of the net income made in the first 5 years of technology transfer
- Yearly biomedical conference with all Ph.D. students involved in the field: highly social event designed to create connections and inspire collaboration

**Medical device companies**
- Employ 26,000 people in 130 companies with sales in excess of GBP 6 billion annually and annual growth approaching 16%
- Several large companies establishing R&D activities in Ireland (Medtronic, Olympus, Intel Digital Health)

**Trade organization: IMDA**
- Umbrella organization of medical device employers with rotating chairman-ship between large companies (Medtronic, Boston Scientific etc.), well connected with US medical device regions
- Provides natural meeting points between companies through regular networking events
- Facilitates collaboration between companies through working groups focused on regulatory, R&D, supply chain management, marketing and human resources issues

**Government network organization: IDA Ireland**
- Actively sets up and funds university collaborations for new industrial R&D projects
- Closely connected to funding agencies, located in same building. Quick connections and quick decisions attract large companies
- Actively markets and promotes Ireland throughout the world. Also takes Irish stakeholders on tour to successful US companies
- Acts as network hub with contacts to all other stakeholders through a helpful office and an extremely informative web page (case examples, database of support businesses etc.)

**Government funding agencies:**
- **Science Foundation Ireland:** Research funding through Science Foundation Ireland, who recently added biomedical engineering as one of 3 focus areas. Funds projects that are likely to have commercial impact in 10–15 years
- **Enterprise Ireland:** Provides start-up funding for projects that are likely to have commercial impact in ~5 years. In addition to funding, they actively work to assist commercialization
  - Hosts partnering events and meetings at international trade fairs
  - Provides 2 week executive MBA training offered to those starting up companies
  - Produces pamphlets promoting commercialization - “How to get rich”
  - Offers very fast turn around on seed money applications – 24 hour decisions
  - Helps to source management

The diverse stakeholders required to ensure a robust medical device industry require different incentives to compel them to focus on creation and commercialization of products. All stakeholders will ultimately need to set standards/incentives that are supportive of this industry’s growth, with the goal of improved patient care and a healthy, sustainable local economy. Important in deciding on which incentives to offer is ensuring they are crafted to achieve a specific goal in line with the overall focus of the project/mission.

**Capabilities**

Having stakeholders incentivized is meaningless unless they have appropriate capabilities, e.g., academic talent, cross-functional talent with experience in finding technical solutions to medical problems, clinical testing qualifications to support product development and testing, and commercialization skills, including knowledge of regulatory requirements, international sales and distribution specific to the medical device environment.
Universities

Strong academic talent within a focused field. Academic talent can be secured and developed in several different ways: from other industries, from other countries and through cultivation of the skills of one individual scientist/entrepreneur. Successful medical device clusters are often focused on areas closely connected to existing research strengths in the country or region. In South Korea, the imaging industry was selected as a focus based on widely recognized capabilities in electronics, digital displays and semiconductors – areas that generate much of the nation’s export revenues through companies like Samsung and LG. In the San Francisco Bay/Silicon Valley (box 4) cluster, the device industry has taken advantage of the high-tech skills available in Silicon Valley, particularly in semiconductor/surface physics and miniaturization of technologies. For example, Intuitive Surgical has licensed exclusive, worldwide, royalty-free rights to certain IBM patents, related to the application of computers and robotics to surgery in animals and humans, which they employ to develop robotic surgical systems. It is clear from this region, and others, that local expertise (at both universities and companies) can be leveraged to optimize talent. 

In several of the cases studied, a key enabler of a medical device cluster’s success has been a single, strong academician (either national or internationally recruited) who has the ability to set the scientific direction of the center. In South Korea, Siemens has supported the development of the next generation of joint MRI-PET technology at the Neuroscience Research Institute of Gachon Medical School, around the capabilities of one key researcher. In Denmark, the industry actively worked to recruit an internationally renowned young professor to lead the Centre for Applied Hearing. Hence, when mapping capabilities, one researcher might be enough to drive a sub-segment of the industry.

Cross-disciplinary capabilities with experience in finding technical solutions to unmet customer needs. As the medical device products have progressed into more technically advanced solutions applied to medical problems, the importance of cross-disciplinary skills has become more pronounced. Teams of physicians, nurses, engineers and natural scientists (biologists, physicists, chemists) need to work together both to find solutions to issues identified in hospitals and to find valuable applications to newly developed technologies. Cross-functional collaboration has been one of the key enablers of the success of the University of California at San Francisco (box 5). Starting in the 1970’s, UCSF institutionalized interdisciplinary research on a large scale, by grouping researchers into “neighborhoods” of similar interest, rather than by department. As UCSF is now expanding their facilities with their new Mission Bay campus, scientists are clustered according to their research interests.

Educational programs. Securing the future supply of talent also plays an important role and in Ireland academia is joining forces to create a strong bioengineering masters program, where students can combine classes from the participating universities (University College Dublin, University College Cork, Trinity College, National University Galway, and National University Limerick) regardless of location. In addition, the program will include a 6-month industry internship with a medical device company coordinated by the Irish Medical Device Association (IMDA), as well as a clinical internship at a medical clinic. The program is currently under proposal, but will follow the 2nd cycle of the Bologna process to attract students from other European countries.

Commercialization skills. One way to develop the commercial skills of entrepreneurs is of course through formal training in commercialization. UCSF provides an 11-week course, entitled “Idea to IPO - and beyond”, to its scientists and clinicians who are contemplating starting a business, and teaches them how to build commercial value from their research discoveries. This course has contributed to the medical device cluster located in the San Francisco area generating over 60 start-ups, some of which have grown into large global players (including Chiron, a top-four company in the advanced molecular diagnostics area). Enterprise Ireland also supports management of new medical device companies. In cases where inventors want to lead the company themselves, a 2 week MBA-like course is provided to improve skills. When inventors are less interested in leading the company, Enterprise Ireland will help in finding a suitable person to do so.

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44 Interviews with experts in the San Francisco Bay area
45 Neuroscience Research Institute of Gachon Medical School, www.nri.gachon.ac.kr/english/index.asp
46 Centre for Applied Hearing, www.dtu.dk/centre/cahr
47 University of California at San Francisco, www.ucsf.edu
48 The Bologna process is a European educational reform aiming to create uniform academic standards across Europe. The standard consists of three cycles (awarding the equivalent of Bachelor’s, Master’s and doctoral degrees), where students should be able to transfer between academic systems after each cycle
49 Interviews with experts in Ireland
50 Interviews with experts in the Minneapolis region
Box 4: San Francisco Bay Area/Silicon Valley

In the San Francisco Bay Area, a medical device cluster has developed alongside the biotech industry. Today, the region is one of the strongest in the US, both in biotech and medical devices, with a growing number of medical device companies. Of the 84 companies with reported revenues above USD 8 million, the number of companies decreases by a third for each time revenues double, indicating a healthy funnel of growing companies. Local academic institutions, in particular the University of California at San Francisco (UCSF), have been heavily involved in the success (see box 5).

Medical device companies, San Francisco Bay Area/Silicon Valley*  
Number of companies by revenue segment, USD million

<table>
<thead>
<tr>
<th>Revenue segment</th>
<th>Company examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>8–16</td>
<td>Ophthalmic Imaging Systems, Radiant Medical</td>
</tr>
<tr>
<td>16–32</td>
<td>Endoscopy Medical Systems, Fox Hollow Surgical Corp.</td>
</tr>
<tr>
<td>32–64</td>
<td>American Medical Systems, VNUS Medical Techn.</td>
</tr>
<tr>
<td>64–128</td>
<td>Stryker Endoscopy, Volcano, Medtronic vascular, Philips/Totol techn.</td>
</tr>
<tr>
<td>128–256</td>
<td>Kyphon, Intuitive surgical</td>
</tr>
<tr>
<td>256–512</td>
<td>J&amp;J ALZA, Varian Medical Systems</td>
</tr>
<tr>
<td>512–1048</td>
<td>J&amp;J ALZA</td>
</tr>
<tr>
<td>&gt;1048</td>
<td>J&amp;J ALZA</td>
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</tbody>
</table>

* Based on companies from the San Francisco Bay Area/Silicon Valley with revenues above USD 8 million registered in OneSource

Source: OneSource

University hospitals

Clinical testing and trials. Attractive clinical testing environments are especially important as medical devices (compared to pharmaceuticals) require close collaboration between the physicians involved in the trials and the scientists and engineers who design them. This has the effect of making the medical device industry less prone to relocation to low-cost countries and more attracted by the ability to work with top-tier medical facilities. At UCSF, a deliberate strategy to encourage industry collaboration has resulted in scientists engaging with external partners in nearly 200 clinical trials and 100 research collaborations annually, attracting contracts worth USD 26 million in 2004. This strategy is facilitated through the Office for Sponsored Research, which acts as the primary point of contact for companies, assists in matching clinical trials with clinicians, and negotiates and executes contracts. UCSF has master agreements in place with over 30 companies, resulting in quicker trial set-up, and a dedicated committee handles potential conflicts of interest and confidentiality issues to make sure the scientists are able to serve several companies without legal problems.

Commercialization skills. As for university employees, it is important for clinical staff to have the skills or support needed to commercialize products invented in-house, either through partnerships or alone. None of the international case examples studied have established specific programs/structures to achieve this, but interviews point out that success in this area would be a competitive advantage.

Process for identification and articulation of unmet clinical needs. An aspiration that medical device company representatives interviewed wished for is a way for hospitals to effectively capture and describe unmet medical needs and then articulate this information to academic and company research departments. This process occurs somewhat organically at medical society meetings (and of course, is what spurs some clinician-researchers in their own work) but could be improved.

Health economics. Interviews with company representatives conducted during this effort stressed the importance of health economical evaluations. In the U.S., just because a product is approved by the FDA does not mean a caregiver will use it or a payor (private or governmental health insurance) will pay for it. Providers (hospitals/physicians) and payors often review the long term health economics of a new device before allowing it "on formulary" (that is, allowed in the hospital for use by the staff and/or automatically covered by the insurance policy). Hence, in the US, medical device companies present cost-benefit analysis of their products versus the cost-effectiveness of competing or current medical treatments (and products) to hospital and insurance approval boards. If this data holds up to analysis, the device is likely to be approved and therefore used in the hospital setting.
Box 5: University of California at San Francisco

At UCSF, targeted efforts to improve cross-disciplinary collaboration, industry collaboration, clinical research and commercialization have created an environment for successful technology-transfer and corporate collaboration. The entrepreneurial climate also attracts scientists with an interest in taking innovation to the next level, contributing to the positive trend.

Cross-disciplinary collaboration
- Collaborative research across department borders since the 1960’s
- Neighborhoods of chemists, mathematicians and biologists working together on a common interest
- Non-hierarchical atmosphere where young faculty collaborate with significant professors across borders

Industry collaboration
- Single point of contact for industry relations through the Office of Industry Partnerships
- Office of Sponsored Research dedicated to coordinating clinical trials
- Collaboration facilitated by divisions for Industry Contracts, Conflict of Interest Committee and framework agreement with several companies

Commercialization skills
- First biomedical university to train students and faculty in commercialization
- Office of Technology Management handling IP and technology transfer
- BioFellow program, where entrepreneurial students get experience from a medical device company over a 1 year internship
- Center for BioEntrepreneurship coordinating training and mentorship programs

Clinical research skills
- Experience from over 1,600 trials over the past 10 years
- Partnering with non-profit research organization SRI International to improve skills in clinical trial set-up

Source: University of California at San Francisco; Press clippings; Interviews

Companies

Commercialization, business development, innovation sourcing skills. Strong commercialization and sales skills from the medical device industry are just as, or even more, important to the industry’s success as the possession of attractive products. The Minneapolis-based company ev3 (box 6) has taken this to the extreme, starting their vascular business in 2002 without a single product in their hands. Through strongly focused, strategic acquisitions of emerging therapies at the fringe of the vascular market, the company has grown by more than 50% annually and now sells more than 100 different products in the peripheral vascular, cardiovascular, and neurovascular segments, in more than 60 countries. This has been made possible by recruiting very strong management, marketing, sales, and regulatory personnel, ensuring R&D has a constant customer focus (vs. technology for technology’s sake), and defining market strategies even prior to product creation. In addition, the company has built a direct distribution network throughout Europe, Japan, and North America31.

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31 Ev3, www.ev3.net; interviews with industry experts
Box 6: Story of ev3

Founded in 2000

ev3 is a US based medical device company focusing on endovascular technologies for minimally invasive treatment of vascular disease and disorders. The company was started in 2000 by former SciMed Life Systems executives wanting to create a mid-sized alternative in this polarized industry, with few players in the segment between the large giants and small startups.

Strong focus from the beginning

ev3 executives wanted to build a successful and sustainable enterprise for everyone – employees, customers, and shareholders. By creating a multi-product company with a critical mass for growth but strong focus on the endovascular area, they aimed to be the “first mover” in the chosen areas.

Backed by two venture groups, both aligned with the aim to create a different kind of cardiovascular company, the company grew through strategic acquisitions of emerging technologies at the fringe of the vascular market where large global companies are not focused.

With strong management and marketing executives in place, the company’s first priority was a strong customer focus, avoiding developing technology for technology’s sake.

Building a strong base of clinical evidence

ev3 focused on market development from the beginning, building clinical proof to convince physicians to use their products. Were able to attract very experienced sales representatives as well as skilled in-house product development capabilities. Strong relationships with clinical thought leaders with a will to change the practice of medicine have also been important.

Annual revenues
USD millions

- Publicly listed on NASDAQ since 2005
- Portfolio of >100 products in the peripheral vascular, cardiovascular, and neurovascular segments
- Sales in more than 60 countries through a direct sales force in Europe, Japan, and North America and distributors in selected other markets
- Focus on Europe first, where 1st and 2nd generation products are launched. 3rd generation products are also launched in the US

Just as with academic talent, commercialization and sales skills may be found in one person who can drive a sub-segment. In Minneapolis (box 7), part of the success in creating a strong funnel of company development has been a group of individual, highly skilled entrepreneurs who founded a number of companies, grew them, and eventually sold them to larger device players. Once the company is sold, they focus on a new company and so contribute to the success of the region.

Internal R&D skills. Although some companies like ev3 heavily rely on an ability to recognize and purchase the latest research projects (sales and marketing based companies) that can be commercialized, other companies rely on internal R&D skills as they develop most products themselves, which they then either market themselves or license for a royalty.

52 Interviews with experts in the Minneapolis region
Box 7: Minneapolis

The Minneapolis area in the US state of Minnesota is today the most significant medical device hub in the world, grown out of companies like Medtronic, St. Jude Medical and Guidant (now part of Boston Scientific), all in the cardiovascular business. 3M Healthcare (wound care, infection control, dental appliances etc.) and Patterson Companies (dental, rehabilitation equipment etc.) are other large companies in the area. The area also has a large number of medium sized companies, but unlike San Francisco, the Minneapolis area has a smaller share of fast-growing, small companies. This may be an effect of the larger companies acquiring promising smaller businesses.

Medical device companies, Minneapolis*

Number of companies by revenue, USD millions, segment

<table>
<thead>
<tr>
<th>Revenue segment</th>
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<td>Urologix, Myocor, Wheelchairs Plus, Rochester Medical</td>
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<td>16–32</td>
<td>Accelent, CompaX Techn, Vascular Solutions</td>
</tr>
<tr>
<td>32–64</td>
<td>Starkey Lab, ev3, Empi, Smiths Medical</td>
</tr>
<tr>
<td>64–128</td>
<td>St. Jude Medical, Patterson Companies</td>
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* Based on companies from the Twin Cities (Minneapolis/St. Paul) area with revenues above USD 8 million registered in OneSource

Source: OneSource, Interviews

Direct funding

In all medical device clusters studied, funding has been central in enabling the development. However, the source of the funding has varied widely.

Government

The Korean imaging effort was backed by significant government investment, totaling 25% of the annual industry revenues over 5 years. Some of this has been in the form of matching funds, which has increased the total amount going into the industry by attracting investment by foreign companies. Specifically, the Ministry of Science and Technology has been central in facilitating foreign companies’ investment in local research institutes, as well as in distributing financing.

In Ireland, the government has invested by reducing the capital expenditure connected to setting up new operations. Providing infrastructure and lowering taxes on intellectual property are examples of such initiatives. In addition, Enterprise Ireland offers financial support to companies engaged in collaborative research projects with Irish universities and Institutes of Technology, through the Innovation Partnership Initiative, where grants of 50% to 70% of the research project costs are given. Application and project administration is handled by the academic institutions, and the collaborating partners jointly define the research project, with the objective of bringing the research close to market readiness.

Investors

In San Francisco (and Minneapolis) venture capital has played a major role in supporting the industry. In the area around San Francisco and Silicon Valley alone, over 100 different enterprises invest around USD 1.5 billion in medical device companies each year. In Minnesota, investment is lower, but there are over 60 members of Minnesota Venture Capital Association, many of whom are active investors in medical devices.

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53 Ministry of Science and Technology, www.most.go.kr/en
54 Enterprise Ireland, www.enterprise-ireland.com
55 Interview with venture Expert, Minnesota Venture Capital Association, www.mnvca.org
Successful clusters also proactively respond to the funding environment. As venture capitalists shifted to invest in later stage products, UCSF partnered with universities such as Stanford and UC San Diego, and nonprofit clinical research institute SRI International, to form PharmaStart, a consortium aimed at moving the discoveries made at the schools into clinical trials. The universities still need to provide funding for the trials, but they are supported by the consortium in designing and conducting preliminary trials that may be required to attract further investment.

Universities
Funding may also come directly from universities. An example of where a university has contributed to the funding of a specific medical technology segment is DTU\textsuperscript{56} in Denmark. DTU provided 30% of the approximately DKK 30 million needed to fund the Centre for Applied Hearing Aid the first 5 years.

University hospitals
Interviews reveal that in order for hospitals to focus on medical technology innovation, rather than basic medical research, targeted funding is needed, either through existing budgets or through industry collaborations.

Companies
Sufficient funding for R\&D. Many of the companies that are engines in existing medical device clusters are spending more than industry average (approximately 6-8\%) on R&D. For example, Medtronic and Boston Scientific, which are both present in the Minneapolis cluster, spend 9.9\% and 12.9\% of revenues respectively on R&D and Siemens Medical, which has established itself in the Korean imaging cluster, is spending 11.1\% of revenues on R&D\textsuperscript{57}.

Contribution to funding of joint collaboration projects. The Centre for Applied Hearing in Denmark mentioned above started with full funding for the first 5 years, as a combination of industry, government and university funds. The local hearing aid industry provided the centre with approximately 35\% of the funding needed. The funding has enabled the centre to focus on setting a strong academic agenda, and to establish itself as a major force in their field of science\textsuperscript{58}.

No matter what the source of funding, all stakeholders in the examples ensured that it was targeted for a select area of medical technology. Universities and hospitals applied for both internal and external funding. And companies not only provided sufficient funding for in-house R&D but also contributed to joint collaboration projects.
Collaboration and networks

To enable different stakeholders to find each other and collaborate with low friction, both formal and informal networks are important to successful medical device development. Companies need to be connected both to academic institutions and to medical clinics. Academic researchers need access to the healthcare system (both clinicians and patients). Start-up teams need to be able to tap those with industry expertise, and larger companies must have in place a network of support businesses. Collaboration among all stakeholders is required and can be led by an appointed network organization and/or by individual stakeholders.

Both Ireland and South Korea have used central facilitation to enable a close connection between the industry and academic/medical institutions. In Ireland, the government has taken a role in assisting connections, dialogue and collaboration between all stakeholders through the International Development Agency (IDA) and Enterprise Ireland. South Korea similarly uses government institutions to encourage dialogue. Enterprise Ireland hosts partnering events and meetings at international trade fairs and IDA acts as a network hub with contacts to all stakeholders through a dedicated office and an informative web page. In addition, IDA actively sets up university collaborations for new industry R&D projects.

Universities

Technology transfer offices and incubators. Start-up companies have specific networking needs in that they must find financiers, and connect with industry experts both to learn from (e.g., to gain understanding on regulations, reimbursement systems and distribution challenges specific to the medical device industry) and to hire. This can be facilitated by technology transfer offices or incubators. At UCSF, the Center for BioEntrepreneurship (CBE) is the hub for technology transfer, coordinating commercialization courses, mentoring UCSF entrepreneurs, and facilitating informal discussions with entrepreneurs and other trade professionals.

Approximately 700 people participate in CBE programs each year\(^59\).

Portal with capabilities as interface to the industry and hospitals. Interviews with company representatives emphasize the necessity for universities to map and market their capabilities (e.g., through a user-friendly web page) extensively to enable fruitful collaboration projects with other stakeholders.

University hospitals

Primary point of contact. Many voices raised in this effort have emphasized the need for access to hospitals to enable collaboration projects and clinical trials through the creation of a dedicated one-point-of-contact entry. At UCSF, this has been achieved by the creation of an “office of sponsored research” and an “office of industry partnerships”. The latter is responsible for coordinating and facilitating research collaborations, technical licensing deals, clinical trials and entrepreneurial education.

Companies

Active contribution to innovation clusters. Communication does not necessarily need to be driven by the government. Through the Centre for Applied Hearing, the Danish hearing industry has gained access to a world-wide network of excellent academic research, attracted to Denmark via the Centre. Conferences and industry meetings held at the center provide as much value to the industry as does the research performed at the Centre\(^60\).

Participation in job rotation and fellowship programs. Interviews with Swedish stakeholders have revealed that leveraging and developing cross-disciplinary skills (which is a key capability in this industry), is linked to the participation of representatives from both small and large medical device companies and universities in job rotational and fellowship programs and would be beneficial for all stakeholders in the industry.

Summary

International cases show that building a successful medical device industry requires focus, and a high degree of collaboration and dedication from stakeholders, to create conditions that help four enablers to co-exist: incentives, capabilities, direct funding and collaboration and networks. Different combinations of these enablers have been key ingredients in the recipe for success for many international clusters.

\(^{59}\) University of California at San Francisco, www.ucsf.edu

\(^{60}\) Interview with representative from Danish hearing aid company
Measured against international best practice, the Swedish environment for medical devices has important shortcomings.

The Swedish environment for medical technology innovation today does not give confidence that Sweden can continue to be a leading and dynamic player in the global medical technology arena. There is a lack of focus, and there are important opportunities for improvements across all the enablers identified (incentives, capabilities, funding, and collaboration and networks).
### Incentives

#### Universities and university hospitals

The international examples and interviews showed the need for a variety of incentives for universities and hospital staff – to promote applied medical technology research, to commercialize products, and to participate in clinical trials and collaboration projects. Some of these incentives (e.g., intellectual property ownership) are partly in place in Sweden, while others are lacking (e.g., positive recognition of participation in medical device research, clinical trials and commercialization activities).

#### Formal evaluation of publications/patents and clinical research

In most of Sweden’s universities and hospitals some form of recognition of staff who are published in scholarly publications is carried out (e.g., when evaluating candidates for job positions and applications for ALF-funding, publication in scholarly journals is looked upon favorably). However, the director of a division or clinic within a hospital has few incentives to focus on innovation. Instead the focus is on meeting the budget set for the year. The director of a clinic at Karolinska University hospital, for example, is not formally evaluated on the level of innovation or commercia-
I...ation in his or her clinic but largely on the department’s financial status, clinical productivity (often expressed as number of patients, number of surgeries etc.) and length of queues. In addition, some interviewees have pointed out that department directors today are less likely to be combined MD/PhD’s than in the past, and some feel this “deacade-mication” may make clinical research and innovation less prioritized. Patent activity is rarely evaluated, either formally or informally.

**Intellectual Property ownership** is different between hospitals and universities. Although this is something of a gray zone today, for hospital staff the intellectual property right is formally owned by the hospital. Some hospitals have started to address this and are working to provide individual incentives (e.g., the second largest county council in Sweden, Västra Götaland, has started to develop a policy for how the intellectual property rights might be divided between hospitals and employees). In the universities, on the other hand, Sweden has chosen to have a teacher’s exemption, which gives researchers and scientists at academic institutions 100% ownership of the intellectual property of any findings. This is in contrast to the US model where universities own the entire property right or large parts of it. Convincing arguments can be given for both models as shown in recent investigations. There is a need for continued discussion on possible ways to improve this important incentive.

**Culture of positive recognition for commercial activities.** The prevailing culture in Swedish universities and hospitals is not geared toward commercializing research. Nor is it geared toward working closely together with the industry. This has resulted in a system where commercialization and collaboration is not perceived as valuable. In addition, companies’ efforts to engage hospital staff are often viewed with suspicion. Some hospitals (e.g., Sahlgrenska University Hospital) have a vision of becoming an engine for the development of regional businesses, though in reality there is limited focus and action on this vision.

**Companies**

Swedish companies are potentially also short on incentives but this has not been the focus of investigation for this report. More importantly they are suffering from the lack of incentives in university hospitals and universities.

- **Strong local research capabilities.** Based on input from workshops it is clear that one top priority of Swedish medical device companies is to source innovation from US universities. As a consequence or perhaps as a result, the interaction of the device companies with Swedish universities is limited. This does not, however, mean these capabilities do not exist in Sweden. Workshop participants claim that Sweden has strong research skills, but the reasons to locate R&D to other countries include a) the difficulty of accessing these skills in Sweden and b) Sweden’s small market (as companies generally claim advantages of having R&D in the major markets).

- **Financial incentives for companies.** Analysis of the possible effects of a) tax breaks, b) increased labor cost efficiency, c) direct funding to private companies, and d) direct creation of local markets in Sweden has not been carried out as part of the work to support this report.

In summary, there are relatively few incentives for hospital staff, directors of hospital clinics and academic researchers to focus on medical device innovation. Companies might also be more interested in locating or staying in Sweden if additional economic drivers were in place.

### Capabilities

Workshops, interviews and the international case examples noted the importance for universities and hospitals to have academic talent, commercialization skills, and cross disciplinary capabilities, with experience in focused innovation, clinical trial skills and high quality educational programs. It is also critical for companies (especially smaller ones) to have commercialization skills and management talent. Specific attention to leveraging skills from other industries in developing medical device innovation was also seen in the Korea and San Francisco cases.

**Universities and university hospitals**

- **Strong academic talent within focused field.** Sweden has a strong set of technical and medical universities, with high-quality research qualifications in a number of basic research fields. But although Sweden has strong academic talent it is

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The application of technical research tends to be technology-driven \cite{62}, rather than driven by needs of potential customers. This can be problematic in two ways: the technology may not serve a large enough customer base to be worth commercializing or the technology may not meet customer needs. Applied researchers would benefit from adapting more of their work toward needs-driven innovations – namely, starting from a user/customer problem and subsequently developing a solution to that specific problem.

Finally there is, with few exceptions, a general lack of cross-disciplinary educational programs combining medical and technological competence. This lack creates both a scarcity of technological competence in newly examined physicians/nurses as well as a scarcity in medically competent engineers to be recruited by the medical technology industry.

**Commercialization skills.** Workshops and interviews with venture capitalists and researchers highlighted that within universities and hospitals commercialization skills are lacking across three categories: 1) commercialization encouragement, 2) general commercialization training, and 3) medical device-specific commercialization skills (e.g., regulatory). Issues in the first and second group are addressed here and there, e.g., KI and Karolinska University Hospital currently run some courses such as "From clinic to medical innovation". Another interesting example, geared at introducing commercialization competence in the early stages of the research process, is the

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**Clinical testing and trials.** Karolinska University hospital has recently created the Karolinska Trial Alliance (KTA) as a first step to support clinical trials in a fully FDA and CE/EMEA compliant fashion. KTA provides infrastructural support needed to conduct trials (e.g., planning, contractual and economic issues). Similar platforms have been set up in other hospitals. However, this journey is only at its beginning and further effort is needed to match international best-practice examples.

**Cross-disciplinary capabilities with experience in finding technical solutions to unmet customer needs.** Expertise found at universities – whether specific to medical technology or indirectly linked to it (e.g., industrial processes and product development) – can be harnessed to contribute to the advancement of medical device products. To develop its talent and cross-specialty utilization of skills, Sweden needs to further develop its cross-disciplinary platform beyond the steps that have already been taken, such as joint professorships (e.g., in Stockholm where KTH and KI jointly fund two professors in medical technology, initiated by Centre for Technology in Medicine and Health, (CTMH)).

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62 Interviews with Venture Capitalists
“Innovation Driven Research Education” at PIEp, Product Innovation Engineering program, a new national program for research and education. Many of the incubators also provide skills in the second group. There is, however, a lack of courses and programs for graduate as well as Ph.D. students dealing with, and creating incentives for, commercialization. Interviews and workshops with venture capitalists as well as researcher-entrepreneurs in the field of medical technology clearly state the importance and potential in creating the possibility of commercial thinking in the early stages of the applied research process. Capabilities within the third category are also scarce, with the exception of some new and interesting initiatives.

Educational programs. Some company representatives claim that a key reason for staying in Sweden is the talented R&D workforce. Sweden is considered to have good educational programs, but could strengthen its position by creating tailored programs to specific medical technology segments and by launching cross-disciplinary programs in collaboration with the industry. The development of such educational programs is not only of great importance for dealing with the future professional roles in healthcare and the medical technology industry, but would also provide a long-term financing and critical mass of networks for the segment. Experience from KTH and Chalmers also shows that the field of medical technology is perceived as one of the most motivating ones among engineering students. Also at the level of Ph.D. students educational programs geared towards cross-disciplinary collaborations between medical and technical faculty is a way of creating competence for the industry as well as highly needed cross-institutional networks.

Process for identification and articulation of unmet clinical needs. As discussed in the previous chapter, company representatives and academics believe that Swedish hospitals could largely improve the identification and articulation of unmet clinical needs as this would allow companies and academics to focus on key customer problems.

Health economics. In Sweden, as well as in other European countries, medical device company representatives interviewed report a feeling that health economics are not prioritized as a rationale for trying or allowing a new medical device in the
Direct funding is a critical component in many of the international cases. As will be shown, most funding is provided by one set of stakeholders – government and industry, and is given to another set – the universities and hospitals. Hence, this section is subdivided by the purpose (research versus commercialization) of the funding rather than the stakeholder providing or receiving it. The purpose of funding in the successful international cases was targeted funding to specific medical technology segments or efforts. This, for the most part, is not the case in Sweden.

**Funding of research**

Sweden invests more in R&D than most other countries (as a share of GDP); but a disproportionate share of this comes from private funding (vs. government funding).

Several indicators show that funding levels and funding growth for pure basic medical and technical research is not the major problem. It is increasing (at best) or stable (at worst). Another example is Karolinska’s R&D funding, which grows by approximately 2% per year.

**R&D spend by country and source**

<table>
<thead>
<tr>
<th>Country</th>
<th>Government</th>
<th>Industry</th>
<th>Other (private foundations etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
<td>0.9</td>
<td>2.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Korea</td>
<td>0.9</td>
<td>1.9</td>
<td>0.2</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1.0</td>
<td>1.5</td>
<td>0.4</td>
</tr>
<tr>
<td>US</td>
<td>0.6</td>
<td>2.0</td>
<td>0.1</td>
</tr>
<tr>
<td>Germany</td>
<td>0.6</td>
<td>1.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Denmark</td>
<td>0.7</td>
<td>1.5</td>
<td>0.3</td>
</tr>
<tr>
<td>Netherlands</td>
<td>0.5</td>
<td>1.3</td>
<td>0.1</td>
</tr>
<tr>
<td>UK</td>
<td>0.6</td>
<td>0.8</td>
<td>0.4</td>
</tr>
<tr>
<td>Ireland</td>
<td>0.4</td>
<td>0.8</td>
<td>0.1</td>
</tr>
</tbody>
</table>

**Source:** OECD

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63 Interviews with company representatives, e.g., Ulf Rosén (CEO of ProstaLund). The cost for ProstaLund’s PLFT® system for the treatment of BPH (benign prostatic hyperplasia) is about 68% of the cost for TURP (the dominant surgical procedure) after the first three years. (Kobelt G et al. The cost of feedback microwave thermotherapy compared with transurethral resection of the prostate for treating benign prostatic hyperplasia, BJU, 2004). Despite these positive health benefits, ProstaLund has experienced that it is not a valid argument in discussions with clinics

64 Representatives from 33 small and mid-sized companies with revenues of less than SEK 2 billion were interviewed
### Growth in research funding by research area

Research council funding* used by Swedish universities, SEK millions

<table>
<thead>
<tr>
<th>Research Council Funding</th>
<th>1995</th>
<th>1997</th>
<th>1999</th>
<th>2001</th>
<th>2003</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>1,521</td>
<td>1,335</td>
<td>1,364</td>
<td>1,204</td>
<td>1,467</td>
<td>2,051</td>
</tr>
<tr>
<td>Medical technology</td>
<td>150</td>
<td>141</td>
<td>105</td>
<td>59</td>
<td>108</td>
<td>169</td>
</tr>
<tr>
<td>Technical sciences</td>
<td>329</td>
<td>252</td>
<td>245</td>
<td>112</td>
<td>233</td>
<td>248</td>
</tr>
<tr>
<td>Medicine</td>
<td>368</td>
<td>325</td>
<td>344</td>
<td>336</td>
<td>370</td>
<td>377</td>
</tr>
<tr>
<td>Natural sciences</td>
<td>464</td>
<td>441</td>
<td>487</td>
<td>377</td>
<td>481</td>
<td>631</td>
</tr>
</tbody>
</table>

#### Note:
Medical technology is defined as part of both medicine and technical sciences.
*Research council funding from the Swedish Research Council (Vetenskapsrådet), Swedish Council for Working Life and Social Research (FAS), and the Swedish Research Council FORMAS, as reported by Swedish universities in 1995 prices. Vetenskapsrådet accounts for ~9% of the total in 2005.

### Karolinska’s R&D and educational funds development by source and usage

SEK millions

#### Financing sources for R&D and education for Karolinska

<table>
<thead>
<tr>
<th>Source</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALF funds</td>
<td>339</td>
<td>361</td>
<td>371</td>
</tr>
<tr>
<td>SLL funds</td>
<td>338</td>
<td>327</td>
<td>353</td>
</tr>
<tr>
<td>Government grants/faculty funds</td>
<td>468</td>
<td>477</td>
<td>485</td>
</tr>
<tr>
<td>External funds</td>
<td>964</td>
<td>953</td>
<td>974</td>
</tr>
</tbody>
</table>

#### Distribution of ALF and SLL funds*

- **Core facilities**: 5%
- **ALF projects**: 38%
- **Activity-base compensation**: 16%
- **FoU premises**: 13%
- **Premises**: 12%
- **Base compensation**: 17%
- **Education**: 17%

*~50% of the ALF and SLL funds are distributed according to the percentages below.

### Source:
Statistics Sweden, 2007; Karolinska
However, medical technology-specific research grants are rare. Interviews and workshops reveal that there is a lack of funding for research projects concerning applied medical technology research problems—whether technologically or needs-driven. Researchers in this cross-disciplinary area find themselves competing for grants directed towards either medical or technical research, thus often falling in-between. A great deal of the funding described above does not concern research on medical devices, neither basic nor applied. For example, there is no funding within Karolinska’s R&D funds that is specific to medical devices. Similarly, the evaluation criteria for receiving funds (from the approximate SEK 300 million of ALF-funds and SLL-funds, which are divided among the clinical departments) are not specifically focused on applied research.

### Criteria for ALF and SLL funding distribution

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Weight in evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degrees awarded</td>
<td></td>
</tr>
<tr>
<td>Number of Ph.D. degrees over past 3 years</td>
<td>21.75</td>
</tr>
<tr>
<td>Number of Licenciat* degrees over past 3 years</td>
<td>1.85</td>
</tr>
<tr>
<td>Number of new Docent* over past 3 years</td>
<td>7.4</td>
</tr>
<tr>
<td>External research funding</td>
<td></td>
</tr>
<tr>
<td>Research council funding</td>
<td>31.9</td>
</tr>
<tr>
<td>Other external funding</td>
<td>4.1</td>
</tr>
<tr>
<td>Publications</td>
<td></td>
</tr>
<tr>
<td>Number of peer-reviewed articles</td>
<td>13.6</td>
</tr>
<tr>
<td>Number of other publications</td>
<td>1.4</td>
</tr>
<tr>
<td>Courses</td>
<td></td>
</tr>
<tr>
<td>Number of specialist courses</td>
<td>3.4</td>
</tr>
<tr>
<td>Weeks of undergraduate courses</td>
<td>5.8</td>
</tr>
<tr>
<td>Number of postgraduate courses</td>
<td>3.8</td>
</tr>
<tr>
<td>Implementation factor</td>
<td></td>
</tr>
<tr>
<td>Number of staff who have been trained in Good Clinical Practise (GCP) over the past 3 years</td>
<td>0.14</td>
</tr>
<tr>
<td>Number of trials where staff have acted as principal investigators</td>
<td>1.55</td>
</tr>
<tr>
<td>Income from clinical trials</td>
<td>3.0</td>
</tr>
<tr>
<td>Other reports published</td>
<td>0.31</td>
</tr>
</tbody>
</table>

100

* Swedish postgraduate degrees/positions, where a licenciate degree is awarded before a doctoral degree, and a docent equals an American associate professor

Source: Karolinska

There are signs that this situation is improving. The Swedish research council launched a specific fund for basic research in medical technology in 2002 and by 2005 SEK 45-50 million had been provided through this initiative. However, a clear message from the interviews and workshops is that there is still a gap in funding regarding applied and needs-driven medical technology research.

Although medical funding may not broadly be an issue, additional large grants specifically targeted at applied and needs-driven research on medical devices is of great importance for encouraging additional innovation in this area. The research funding today (both basic and applied) is also fragmented: some of the capital comes from the government-sponsored research councils, some from the hospitals in the form of ALF funds, and a significant amount comes from private sources (e.g., the Wallenberg Foundation). As shown below, the Department of Biomedical Engineering at LiU (an institution focused on medical technology innovation) has a total of 79 grants, which in total amounts to SEK 31 million or SEK 390,000 on average per grant. This fragmentation means that researchers may have to spend a disproportionate amount of time applying (and waiting) for multiple grants rather than being able to deliver on the research itself.

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65 Interview with Karolinska’s R&D director
66 Represents approximately 50% of Karolinska’s total ALF and SLL funds
67 Swedish Research Council’s annual report
Funding and average grant size at Department of Biomedical Engineering, LiU

<table>
<thead>
<tr>
<th>Year</th>
<th>Total funding, Department of Biomedical Engineering, LiU</th>
<th>Average grant size, Department of Biomedical Engineering, LiU</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1997</td>
<td>22.7</td>
<td>0.27</td>
</tr>
<tr>
<td>1998</td>
<td>27.2</td>
<td>0.16</td>
</tr>
<tr>
<td>1999</td>
<td>28.4</td>
<td>0.42</td>
</tr>
<tr>
<td>2000</td>
<td>29.3</td>
<td>0.52</td>
</tr>
<tr>
<td>2001</td>
<td>33.9</td>
<td>0.36</td>
</tr>
<tr>
<td>2002</td>
<td>33.1</td>
<td>0.55</td>
</tr>
<tr>
<td>2003</td>
<td>30.8</td>
<td>0.44</td>
</tr>
<tr>
<td>2004</td>
<td>28.4</td>
<td>0.56</td>
</tr>
<tr>
<td>2005</td>
<td>33.9</td>
<td>0.57</td>
</tr>
<tr>
<td>2006</td>
<td>36.7</td>
<td>0.39</td>
</tr>
</tbody>
</table>

* EU, other universities/counties, county councils, company funding etc.

Source: Department of Biomedical Engineering, Linköping University

Funding of commercialization
With regard to financing the commercialization of products, there are government-initiated institutions (e.g., Innovationsbron and Almi) that provide early stage funding. Venture capital firms have also been interested in the medical device sector, resulting in medical technology receiving the second-highest level of venture capital investments in 2006 of all industries68. Yet workshops and interviews revealed that many stakeholders believe there is a not enough commercialization funding in early stages.

Collaboration and networks

International case examples show the importance of collaboration and formal/informal networks and that there are many different ways in which they can be organized (e.g., company/university led as in Denmark or government/network organization led as in Ireland). In addition, each stakeholder needs to proactively contribute to the collaboration by actively seeking contact and marketing their own skills and needs.

Universities and university hospitals
Both universities and university hospital have room for improvement in creation of a portal towards industry and others that 1) outlines the primary point of contact as well as 2) maps the research areas, clinical capabilities and/or areas of unmet patient need.

Interaction with companies. Hospitals and academic institutions acknowledged during the workshops that they could do more to market themselves and their skills to companies. Today, few of the universities and hospitals have a primary point of entry that is clearly marketed on the first page of their home page.

Interactions between universities and hospitals. There are signs that the network between different universities is improving, at least on a regional level. The joint KI/KTH and SLL initiative, Centre for Technology in Medicine and Health (CTMH), is one example of this. Another example is that Sahlgrenska Academy and University Hospital, Chalmers University of Technology, and the University college of Borås have initiated work towards a common medical technology platform. The platform has been located in a new constel--

68 Svenska riskkapitalföreningen
lation within the hospital so as to facilitate greater interaction between industry, academy and the healthcare sector. The proposed platform, which is an expressed strategic ambition of the partners, strives towards cross disciplinary collaboration on research, education and positions.

**Interactions with others.** Through Innovationsbron, the government has established many incubators to support/collaborate with researchers/clinicians commercializing their ideas. The issue is that these incubators do not have a sufficient supply of the extensive specific knowledge required for medical device development (e.g., clinical trials design, regulatory approval pathways, and medical sales and marketing expertise).

**Companies**

There is very little collaboration (active contribution to innovation clusters) among stakeholders in Sweden – particularly for large companies interacting with universities/hospitals. Elekta, for example, has not had a single project with a Swedish hospital or academic institution in ten years. Gambro recently initiated a research collaboration initiative with Sahlgrenska’s 69, which is the first the company has had in Sweden in many years. During interviews and workshops many company representatives stated that they had no idea what type of skills existed in the Swedish hospitals and academic institutions. More importantly they had no idea on how to contact the institutions and “find their way to the right person”.

In addition, there are few existing job rotational/fellowship programs that offer stakeholders the opportunity to develop their skills across different types of organizations and leverage them.

**Network organizations**

Sweden is home to two industry organizations, Swedish Medtech and SwedenBIO. Swedish Medtech is solely focused on medical technology and has traditionally focused on sales & marketing as well as tendering questions for the community of Swedish and foreign medical device companies. However, for the last few years the organization has increased its focus on innovation and R&D questions, through the creation of their R&D group, which consists of R&D heads of a number of companies (e.g., Elekta, Getinge, Gambro, and St Jude).

SwedenBio, which is a private non-profit organization, has a wider life science focus. One of its six industry working groups is “Medtech,” which is comprised of representatives from Capman, Elekta, Orivus, Carmel Pharma, ProstaLund, Aerocrine and CellaVision. The group's goals are to 1) strengthen marketing competence and experience in international marketing and sales, 2) improve competence in international reimbursement processes, 3) create platforms for collaboration between healthcare, research and industry to support innovation and commercialization.

Although many steps have been taken to increase collaboration among the key stakeholders in Sweden, it is currently far from where it needs to be in order to create substantial and long-term impact. However, the workshops held in conjunction with the writing of this report indicate that there is great interest in increased collaboration.

**Summary**

Although funding is not the primary issue for medical research in Sweden, there is an important gap in the funding of the applied research stages of the innovative process for new medical technology. Other important, more complex, issues are a) incentivizing doctors and researchers to focus on applied medtech research with a clear focus on healthcare needs as well as on commercialization of research, b) strengthening commercialization skills, ability to identify unmet needs and developing cross-disciplinary platforms e.g. educational programs for medical and engineering students, c) creating platforms and networks where all stakeholders can leverage the expertise of others. Sweden has far to go on many of these areas. The final chapter explores the ways all parties might work to remedy the current situation.

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69 For more information please visit www.sahlgrenska.gu.se/aktuellt/nyheter/Nyheter+Detalj/?contentId=627181
Each stakeholder needs to take action to ensure a strong future for the industry

Strengthening Sweden’s medical device industry is going to require Swedish stakeholders to set goals that are ambitious but achievable.

They should work toward developing a medical technology industry bearing the following characteristics:

• A thriving academic environment that conducts applied research and encourages industry collaboration in a selection of prioritized medical device segments, as well as conducts basic research in a number of segments.
• An environment for product development and clinical testing that is recognized around the world for its rigor and high standards.
• A flourishing industry of small/mid-sized high potential companies that have a track record of commercializing their products, domestically and internationally, or selling them to larger companies.
• A number of globally leading medical device companies that share knowledge and act as engines for innovation.
• An attractive climate for foreign investment.

Many of the issues discussed in the previous chapters are complex, and despite having been raised several times before 70, relatively little action has been taken. However, much of what needs to be done does not require grand reforms. Stakeholders should not focus solely on the big policy issues that only the government controls, but rather look to take pragmatic action in critical areas, which are fully within their control. This does not mean that the policy agenda is not important, but it should not become an excuse for not acting now. Below are a series of recommendations for each stakeholder. In addition, it is suggested that the selection of a few focus clusters can serve as a real catalyst for change – across stakeholders.

70 Medicin för Sverige! Nytt liv i en framtidsbransch, SNS förlag, 2007; Focus Medtech Agenda: How to create a successful medtech industry in Sweden, 2005; International Evaluation of Swedish Research in Biomedical Engineering, Vetenskapsrådets rapportserie, 2006
Key recommendations by stakeholder

While greater collaboration is one of the enablers to address, this can only happen if each stakeholder takes action.

**Technical and medical universities**

Based on the concerns raised in chapter 6, and with the goal of focusing on innovative projects and subsequent commercialization in medical technology, universities should take the following six actions

1. Emphasize medical technology innovation and make it a high priority on their strategic agendas, develop concrete strategic plans with priority research areas, appoint medical device taskforces to deliver on the strategic plan and secure funding for research and collaboration
2. Map and market their research capabilities towards the industry and other academic institutions and develop IP sharing models to simplify collaboration between stakeholders
3. Develop medical technology knowledge platforms, e.g., joint professorships, seminars on healthcare needs, awards for medical technology innovation based on cross-disciplinary collaboration
4. Develop and launch medical technology educational programs of relevance to the industry
5. Encourage and support research staff to focus on medical technology research and product development through a medical technology-targeted research fund
6. Encourage and support commercialization of research output through high-quality business programs and incubators

**University hospitals and county councils**

1. Work together to ensure that medical technology innovation is a high priority on their strategic agendas, develop concrete strategic plans with priority research areas, appoint medical technology taskforces to deliver on the strategic plan and secure funding for research and collaboration
2. Increase collaboration (product development, clinical research and testing, advisory boards) with, and outreach to, academia and industry and be transparent about clinical problems in need of medical technology solutions
3. Encourage hospital staff to focus on medical technology research, commercialization and clinical testing by including collaboration experience as criteria for appointing positions within the hospital, making funding available, creating prestigious innovation awards and making universities business programs available for hospital staff
4. Ensure that health economic priorities are set within county councils and communicated throughout the organization

**Companies**

1. Identify areas for innovations that can be sourced – and need to be sourced – from outside the company
2. Proactively reach out to academia and university hospitals in Sweden to explore what they have to offer in relation to these areas
3. Build business oriented connections with small and midsized companies to share knowledge in sales and marketing, regulatory and reimbursement issues
4. Engage in a Swedish “focus cluster” (described below)

**Government**

1. Make available a significant medical technology-focused cluster fund and make investments subject to clear commercially viable investment criteria
2. Allocate funds for applied medical technology research with a needs-driven focus for which individual researchers can apply
3. Incentivize academic institutions to motivate and support researchers in commercialization by for example providing additional funding for commercialization and reviewing an option to include an additional regulated task for universities (i.e., commercialization of research output)
4. Engage in a Swedish “focus cluster” (described below)

**Catalyzing joint actions**

- Focus clusters
- Customer focused innovation competitions
- Partnering events

Source: Interviews and workshops with university and hospital staff as well as medical device industry representatives
These actions require substantial changes to the way many universities think about medical technology today. Our recommendations for how to do this are described below.

1. **Emphasize medical technology innovation and make it a high priority on their strategic agendas, develop concrete strategic plans with priority research areas, appoint medical technology taskforces to deliver on the strategic plan and secure funding for research and collaboration**

First, the representatives of the leadership team of each university must agree that medical technology should be a focus area and include it on the strategic agenda.

Second, the leadership should develop a concrete strategic plan that contains specific medical technology priority areas (e.g., elderly care, patient aids, diagnostic imaging) as this type of focus has been shown to be critical in international case examples. These priority areas could be selected based on a) existing in-house capabilities and b) clearly defined healthcare needs. The strategic plan should also contain clear activities, milestones and expected output in terms of number of product ideas, the number of products launched, the number of industry collaborations, and the number of researchers devoted to medical technology.

Third, the leadership should set up a medical technology taskforce consisting of dedicated people, ideally both from medical and technical universities, and led by a representative from the leadership team. This representative should be responsible for delivering on the strategic plan and continuously reporting progress back to the leadership.

Finally, the leadership should create a fund, ideally together with selected companies, specifically focused towards medical technology.

2. **Map and market their research capabilities towards the industry and other academic institutions and develop IP sharing models to simplify collaboration between stakeholders**

The medical technology taskforce appointed by the leadership should be responsible for mapping the university’s in-house capabilities, i.e., search for research groups that either are already conducting medical technology research or whose capabilities could be applied in medical technology. Ideally this should be done together with heads of research of companies from a wide range of medical technology segments. The focus of the work should be highlighting areas where the university is world-class as well as where the university could improve. In addition to identifying areas where the university’s research is world-class, the medical taskforce could also identify additional areas where medical device research is conducted by announcing to researchers the possibility to apply to the university for funding that is specific to medical technology (from the fund introduced in point 1 and outlined in point 4). An easy-to-complete application template should be developed (including questions about the specific medical problem being studied, clinicians interviewed, hospitals visited, possible product outcomes and expected time to market).

The medical technology taskforce should also be responsible for marketing the university’s capabilities to the industry primarily by leveraging existing tools such as easily accessible databases, as well as through more proactive marketing campaigns to the medical device industry. In addition, the taskforce could develop proposals for IP sharing models to simplify collaboration between researchers and companies.

3. **Develop medical technology knowledge platforms, e.g., joint professorships, seminars on healthcare needs, awards for medical technology innovation based on cross-disciplinary collaboration**

Universities should launch joint professorships and Ph.D. positions across medical and technical universities and across disciplines within medical and technical universities.

Platforms should be established in the technical universities to foster greater interest in medical technology among research groups conducting research in other areas with high relevance for the medical device industry (e.g., industrial processes).

Moreover, the universities need to develop a comprehensive understanding of the needs of the healthcare environment. This can be done in many ways, through fellowships and Ph.D. courses, but also through structured seminars with clinicians (both physicians and nurses from different therapeutic areas) arranged by the medical technology task force. In addition, among the criteria for applying for the funding specific to medical technology should be a requirement to have met with clinicians to discuss the medical needs and to have visited clinics to see the problems appearing in practice.

The medical technology taskforce should arrange short seminars with inspirational speakers who have solved a medical need through an innovation coming from academia. Some of these seminars should be devoted to award entrepreneurial/commercially successful researchers. Among the goals of these seminars should be to inspire researchers to focus on medical technology problems while also challenging the sometimes commercially-adverse culture in the universities.
4. **Develop and launch medical technology educational programs of relevance to the industry**

Technical and medical universities should jointly launch educational programs (undergraduate, graduate and post-graduate programs) with high industry relevance. Representatives from the universities (e.g., the medical technology task force) should proactively reach out to the industry to get them involved in the creation of these programs.

5. **Encourage and support research staff to focus on medical technology research and product development through a medical technology-targeted research fund**

The fund specifically focused on medical technology (introduced above) should propose a clear incentive for researchers to start/continue to focus on medical technology problems. There are many ways such a fund could be set up, but ideally it should be a joint effort between technical and medical universities and potentially also a selection of companies. It would be for the different stakeholders contributing to the fund to decide its focus, but it would be important for it to support cross-disciplinary applied research. In addition, to fund pure applied research activities this fund should also cover close-to-market activities, such as researchers’ participation in medical conferences and meetings with venture capital firms/hospital staff.

6. **Encourage and support commercialization of research output through high-quality business programs and incubators**

Universities should introduce high-quality business programs (or leverage existing ones), consisting of intellectual property, marketing & sales and financing (in undergraduate, graduate and post-graduate educational programs) and offer this also to researchers applying for funding specific to medical technology and to clinical staff.

In addition, the medical technology taskforce should work together with existing incubators to involve them proactively in supporting research groups with early business coaching and contacts with industry, and in later stages help arrange meetings with venture capital firms.

University hospitals and county councils

Sweden is home to six university hospitals, spread across six counties, each with a deep understanding of the real challenges facing the healthcare sector. To be able to leverage this knowledge, and contribute to the development of the medical device industry, and thereby benefit from it, each county council and the affiliated university hospital should take the following four actions:

1. **Work together to ensure that medical technology innovation is a high priority on their strategic agendas, develop concrete strategic plans with priority research areas, appoint medical technology taskforces to deliver on the strategic plan and secure funding for research and collaboration**

2. **Increase collaboration (product development, clinical research and testing, advisory boards) with, and outreach to, academia and industry and be transparent about clinical problems in need of medical technology solutions**

3. **Encourage hospital staff to focus on medical technology research, commercialization and clinical testing by including collaboration experience as criteria for appointing positions within the hospital, making funding available, creating prestigious innovation awards and making universities business programs available for hospital staff**

4. **Ensure that health economic priorities are set within county councils and communicated throughout the organization**

Some of these actions are necessary for county councils and university hospitals to take joint action, whereas some of the areas are changes that the university hospitals should act on independent of county councils. To be implemented, the proposed changes will require a vigorous effort, since they are very different from how medical technology innovation, commercialization and collaboration is prioritized and encouraged today.

There are alternative ways to achieve these proposed changes, and different county councils and university hospitals might have different prerequisites that make one solution more suitable than another. Outlined below are recommendations for one way to achieve the changes required.

1. **Work together to ensure that medical technology innovation is a high priority on their strategic agendas, develop concrete strategic plans with priority research areas, appoint medical technology taskforces to deliver on the strategic plan and secure funding for research and collaboration**

Similar to universities, the leadership of the county council and of the university hospital need to agree that medical technology should be a focus area. Once an agreement has been reached, a decision needs to be made concerning how ambitious the goals should be for focusing on medical tech-

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71 For related recommendations please read Technology Transfer and Commercialization Partnerships, Innovation Associates, 2007
ology. To make the substantial changes needed, and to create the conditions needed for the healthcare system to benefit from a strengthened medical technology industry, the goals should be very ambitious, yet also achievable.

Subsequently, the leadership of the county council and the university hospital should, based on the agreed ambition level, task to a medical technology taskforce (e.g., the R&D director of the county council and the R&D director of the university hospital) with jointly mapping in-house capabilities and needs (e.g., in the same way as universities are proposed to do it) and to develop a concrete strategic plan, with clear activities, milestones, output in terms of e.g., number of industry collaborations (including clinical testing), number of product development collaborations with academia, number of product ideas, number of products launched, number of medical technology devoted researchers. Specific medical technology priority areas should be selected based on a) mapped in-house capabilities and b) clearly defined healthcare needs.

In addition, the leadership of the county council and the university hospital should act as a steering group to which the medical technology task force reports progress on the strategic plan.

Finally, a fund specifically focused on medical technology should be created, by devoting part of the existing ALF fund to medical technology innovation and commercialization.

2. Increase collaboration (product development, clinical research and testing, advisory boards) with, and outreach to, academia and industry and be transparent about clinical problems in need of medical technology solutions

The university hospital should create a one-point-of-contact entry for companies and academics, with the goal of facilitating access to the healthcare system. This could be accomplished by leveraging and extending an existing organization, or by creating a new one. This organization should be easily found on the internet and committed to handling requests from industry and academia, and knowledgeable on which capabilities/resources the university hospital possesses and what needs it has. The organization should be responsible for guiding companies to the right clinicians and facilitate discussions between the two parties. This could be achieved by the development of a policy document regulating interaction between industry and the healthcare system, to support collaboration and remove skepticism among clinicians. This policy document could also outline guidelines on IP rights concerning innovations arising from collaboration projects.

In addition, the organization should also be responsible for communicating externally the hospital’s capabilities and needs through web sites and proactive marketing materials. The “one-point-of-contact” organization should be responsible for tailoring and organizing meetings with advisory boards (consisting of clinicians) to which innovators (e.g., small companies and academics) can turn for advice or to test product ideas. There are different models on how to make this work. For example, the first meeting could be for free and subsequent meetings could be charged (and the advisory board participants get a share of the payment).

3. Encourage hospital staff to focus on medical technology research, commercialization and clinical testing by including collaboration experience as criteria for appointing positions within the hospital, making funding available, creating prestigious innovation awards and making universities business programs available for hospital staff

Medical technology related research and innovation is by its nature applied research. This type of applied research is today often considered less attractive among researchers than basic medical research. In addition, entrepreneurial activities are sometimes viewed with skepticism among clinicians. Therefore, there is a need to encourage clinical staff to focus on medical technology innovation and commercialization, both when it is conducted together with companies and academia (i.e., joint product development and clinical testing projects) and when it is conducted independent of external collaborations. There are four potential ways to encourage these activities.

First, establish medical technology specific industry and academic collaboration selection criteria when appointing new positions. Second, let researchers/clinicians apply for funding from the specific fund described in point 1. Key criteria for being awarded the funding should be that the research is applied research and that it is clearly aimed at solving a specific medical need. Third, award special prizes to clinicians focused on medical technology innovation, commercialization and collaboration to acknowledge them as role models. Fourth, leverage the business programs developed by universities (see university section) and invite and encourage clinicians to participate.

4. Ensure that health economic priorities are set within county councils and communicated throughout the organization

The political leadership of the county councils should require that health economics should be a priority, for example in large investment decisions, and clearly communicate this to the organization. This means that the capabilities in this area in the county councils and in the hospitals need to be enhanced.
Companies

The existing companies in Sweden have an important role to play in helping to develop the country’s medical device industry. As mentioned in previous chapters, over 90% of the revenues of the Swedish medical device industry originate from eight companies. In addition, there are many foreign companies with operations in Sweden. These companies have an important role to play as strong engines for future growth and expansion and should consider the following four recommendations:

1. **Identify areas for innovations that can be sourced — and need to be sourced — from outside the company**
   
   The head of R&D could, in collaboration with each research division, review current development portfolios to identify unsolved issues where capabilities are not clearly available in-house and prioritize these issues by a) potential for external development and b) level of strategic priority. After this, the team should ideally identify what capabilities are needed to solve each problem.

2. **Proactively reach out to academia and university hospitals in Sweden to explore what they have to offer in relation to these areas**
   
   The head of R&D could speak at medical technology seminars arranged by universities (described under universities above), and describe the type of work performed and the capabilities and collaborations needed. In addition, the head of R&D could proactively reach out to technical and medical universities where a medical technology taskforce is in place, and to university hospitals, where a one-point-of-contact organization is in place. The goal would be to meet in person to discuss what capabilities the company is looking to find, and how this matches with university and hospital capabilities. Moreover the head of R&D could make sure company researchers attend seminars in fields of science where external collaboration is needed.

   Where matches are found, the head of R&D could set up personal meetings between company researchers and academic researchers/clinical staff to outline possible strategic collaboration projects (e.g., master thesis projects or longer-term research projects).

3. **Build business oriented connections with small and mid-sized companies to share knowledge in sales and marketing, regulatory and reimbursement issues**

   Representatives from large companies could increase interactions with small and mid-sized companies to support these in fields identified as problem areas, i.e., regulatory affairs, international reimbursement processes and sales and marketing.

   This could be done in a number of ways (e.g., by the creation of mentorship or fellowship programs or on a more informal basis).

4. **Engage in a Swedish “focus cluster”**

   Working with academia and the healthcare system, there should be a focus on identifying a medical technology segment around which a Swedish “focus cluster” could be set up and then engage in setting it up and driving it (further described under catalyzing joint actions).
Government
While most actions to strengthen the medical device industry in Sweden need to be taken by individual stakeholders, regardless of the support of the government, there are some interventions that the government should consider pursuing, to support the long-term sustainability of select initiatives.

1. Make available a significant medical technology-focused cluster fund and make investments subject to clear commercially viable investment criteria
2. Allocate funds for applied medical technology research with a needs-driven focus for which individual researchers can apply
3. Incentivize academic institutions to motivate and support researchers in commercialization by for example providing additional funding for commercialization and reviewing an option to include an additional regulated task for universities (i.e., commercialization of research output)

This report will not outline in detail how the government could proceed in considering these actions. However, some suggestions are proposed below

1. Make available a significant medical technology-focused cluster fund and make investments subject to clear commercially viable investment criteria

Consider providing significant targeted resources specifically for medical technology clusters through creation of a specific fund managed by an institution such as Innovationsbron or Vinnova. The fund should be open for applications from joint project teams (i.e., with representatives from companies, medical and technical universities) and investments should be subject to clear follow up and to commercially viable investment criteria that a) address a significant unmet customer need, b) fit with the capabilities of the academic institutions, and c) have a commitment from an existing and motivated large company willing to dedicate resources.

Catalyzing joint actions

While each stakeholder has a significant agenda of actions to tackle, the greatest value will come from focused collaboration. There are several ways to achieve this. One option is to create focus clusters in specific subsegments with joint involvement from key stakeholders. Another option is to organize customer-focused innovation competitions. Yet another option is to bring new energy into the existing partnering events.

Focus clusters
A strong focus on a specific medical device field has been a key driver of success in several of the international cases studied in previous chapters, such as the cardiovascular theme around Minneapolis, the imaging focus in Korea and the specialization on hearing aids in Denmark. One of the main challenges in the Swedish industry is its diversity and lack

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72 For further examples please also read Technology Transfer and Commercialization Partnerships, Innovation Associates, 2010
of focus. Therefore, the development of a small number of world leading focus clusters could ignite change in the medical device community.

The industry, academia and county councils/hospitals could together find a number of focus areas where there is natural energy and then build a world leading focus cluster around such areas. Areas selected should a) have a good starting point based on core academic capabilities, b) address significant unmet customer needs and c) be attractive for the existing industry to exploit. Ideally, areas should also be within attractive market segments where innovation plays a major role. For each of these areas, an immediate, directed effort to form a world-leading R&D cluster should be initiated, with the goal of becoming recognized as world class in 5-10 years. Given the ambitious goals, it is unlikely that Sweden will be able to support more than 2-3 such clusters. There are many alternatives for defining a focus cluster. A cluster could either be a specific medical device segment (e.g., patient aids) or could have more of a system focus where many different technologies could be used for a common purpose (e.g., elderly care).

One potential cluster is e-health. Sweden has a strong starting point given its industrial strengths in telecommunications and information technology (e.g., Ericsson), its many successful medical technology companies with focus on telecommunications and information technology (Sectra’s wireless communications, Orivus’ information and decision making support systems, Cambio Healthcare administration systems), as well as several information technology companies (TietoEnator, WM Data) that are active in the health sector. In addition, the increasing amounts of information involved in patient care makes e-health both an urgent question for our Swedish hospitals, as well as an attractive segment for a broader market, where innovation could increase quality and lower cost of operations for economically pressured care providers around the world.

Another potential area could be a sub-segment of cancer treatment, such as brain tumors, leveraging the combined competencies of world leading radiotherapy company Elekta, fast-growing radiation therapy software developer RaySearch Laboratories, and the Karolinska Institute cancer facilities (Cancer Center Karolinska and Radiumhemmet). These institutions have the potential to join together in a focus cluster to address the growing need for better cancer therapies and solutions.

Other potential focus clusters in Sweden could be patient aids (Permobil and many small and midsized companies) and elderly care (Aleris, Attendo). Focus clusters could be jointly funded by the industry, a technical institution, a medical institution, the government, a university hospital and a county council and could be run as a joint venture between the stakeholders. A board of directors, with representatives from all financiers, should set the research agenda and raise and evaluate commercialization opportunities. World-leading researchers in the area would need to be recruited to the cluster, and in addition to performing research the cluster should design educational programs to be given to both medical and technical graduate and post-graduate students.

The aspirations for such a focus cluster would be to

1. Become a world leading research organization in the selected focus area, thereby making Sweden internationally recognized in this specific niche
2. Launch a number of products both on the national and the international market
3. Generate successful spin-off companies
4. Contribute to improved and more cost-efficient care amongst Swedish hospitals and help them become early adopters of the developed new technology

The creation of such clusters would require a strong local network that would orchestrate the planning, set-up and development of the clusters. Examples of activities that the network should orchestrate are development of strategic agenda and implementation plan and decisions on resources. In some cases, existing local organizations could play this role (e.g., Centre for Technology in Medicine and Health (CTMH) in the Stockholm region) while in other cases this type of network would need to be created.

Customer focused innovation competitions
As mentioned in previous chapters, one of the key findings from workshops has been that Sweden’s medical device development sometimes struggles with putting healthcare needs in focus. One concrete way of focusing attention on needs could be to arrange customer-focused innovation competitions where inventors are offered substantial financial rewards if they find medical device solutions to a set of pre-defined healthcare problems. This approach has been successful in extracting great innovation from a large talent pool in other scientific areas, such as the challenge Canadian gold miner Goldcorp gave the academic community in 2000.

In the mid-1990’s executives thought the company’s 50-year-old mine in Red Lake Mine, Ontario, was nearing the end of its life. Conventional tests indicated there were unknown deposits of gold, but the company’s geologists couldn’t estimate or agree on the precise locations. In 1999 the CEO of
Goldcorp, Rob McEwen, attended an MIT conference on open source software and he realized that this was how he wanted to identify where the likely gold veins where Therefore Goldcorp launched a challenge with USD 500,000 in prize money for the best suggestions as to the locations of the gold veins. They published every last detail of geological data they had on the site stretching back to 1948. The challenge was highly successful. Many of the entrants used unconventional computer visualization techniques. Goldcorp was so impressed with 10 contestants that it hired them, and has subsequently discovered an additional 8 million ounces of gold.

Another example of public involvement is Danish Lego, who has embraced "lead user mass innovation" for their most successful product line, Lego Mindstorms. For the creation of the next generation of Mindstorms, Lego sought to use their existing Mindstorms community. Four lead users were selected from the community to provide direct input on product development and shape Mindstorms NXT from prototype to final product. The users were paid solely in Lego 'bricks' – and in the fame they received within the community. Adjusted to the medical device field, a business competition could be launched in which individual companies or a national (e.g., Swedish Medtech and SwedenBio) or regional (e.g., Centre for Technology in Medicine and Health) medical device network organization would aim to solve a number of predefined healthcare needs, in return for a significant prize for the best solution developed. One such example could be within e-health, where a large company developing e-health solutions (e.g., Ericsson), together with a hospital, can develop a list of predefined healthcare challenges for the public to solve. The best solutions could be rewarded with a sum of money provided by the company, which would have the rights to develop the solution commercially.

A simple example to illustrate could be home care monitoring (a sub segment within e-health). It is today possible to monitor whether or not a person has opened a box of medication each day, through the use of a triggering signal. The signal can be processed into a text message to the care giver or to a relative. But how can one be sure the medication is actually taken? The company solving this conundrum would have a competitive advantage over other providers, and would also be able to provide better care for home patients.

Partnering events

New energy could be injected into the existing Scandinavian Biotech and Medtech partnering event organized by Biotech Forum. The event is held yearly and its focus is both on medical device companies and biotech companies. The purpose of the partnering event is to increase connectivity between companies/venture capital firms and researchers. Today, there are relatively few (foreign and national) medical device companies participating; instead, most participating companies are biotech companies. An extensive marketing campaign is needed to attract a critical mass of medical device companies. This campaign could be orchestrated by a network organization, but should be enforced by the large companies.

The opportunity to improve the environment for medical technology innovation and commercialization in Sweden is significant and very real. And the time to act is now. Current shortcomings in the Swedish environment have been formed over several years and the lead times to create a positive trajectory should not be underestimated. It is critical to continue the process of enthusiastic dialogue that has been initiated during this effort. This dialogue has already led to concrete collaboration projects, but much more is needed to enhance the long-term viability of Sweden's medical device industry. Stakeholders now need to sit down and commit to each other that they will act on their respective agendas. They should jointly identify the 2-3 areas they are enthusiastic about. For these areas, they need to make ambitious plans and agree on governance and resourcing models that have a real chance of creating world leading focus clusters. The next six months will show whether the will and the energy exist to create true focused collaboration.

Next step is to start the implementation process among the stakeholders through the development of a more detailed action plan for 2008-2010, which would reflect the action points listed in our final recommendation chapter. Although not yet decided on at the time of printing, the steering group of this project are willing to support the continued process and finds it realistic with a completed and transparent plan for KTH-KI-Karolinska University Hospital by the end of the first quarter 2008. This should be coordinated with other ongoing Swedish initiatives.
The report’s definition of medical technology

Definition of medical technology* used in this report

**Biotechnology**
- Biotechnical tools
- Bioproduction
- Agro biotechnology
- Biotechnical food
- Environmental biotechnology
- Biotechnical medical technology

**Pharmaceuticals**
- Drug formulation
- Drug development and CRO
- Drug production

**Medical devices**
- Medical devices

**Diagnostics**
- Diagnostics

Definition of medical devices and diagnostics

- High-technology devices (equipment and supplies) and/or solutions/systems used to:
  - Diagnose, prevent, supervise, treat or alleviate a disease/injury/handicap
  - Examine, modify or replace the anatomy or a physiological process

- "Lower"-technology devices mainly used to assist health care professionals in their care of patients, e.g.,
  - Infection control, patient hygiene etc.
  - Hospital beds, patient lifts etc.

Not included
- Lab equipment/analytical tools mainly used for research purposes in companies/academia
- Pure administrative IT
- Services such as dental and orthopedic technicians, equipment servicing, consultant services, etc.
- Contract manufacturing

* Please note that “Medical devices”, “Medical devices and diagnostics” and “Medical Technology” are used interchangeably throughout this report
Analysis performed on Medline data using software from Visione, www.visione.info

MeSH-terms selected from the Analytical, Diagnostic and Therapeutic Techniques and Equipment branch of the Medline MeSH-tree


Source: Medline

Additional analyses on Sweden’s distinctiveness on research and innovation

Through the use of network analysis it is possible to determine how connected the Swedish researchers are in the network of European medical technology researchers, by looking at the extent of co-publication between frequently published authors in a group of countries. An author’s status is measured by the frequency of publication and co-authorship within the network, and an author’s connectedness is defined as how important an author is in linking different clusters of authors in the network. A comparison of the status of Swedish authors of medical technology publications in the network consisting of Sweden, Denmark, the Netherlands, Germany, Switzerland, the UK and Israel in 1991 and 2006 shows that Sweden is falling behind. While 27 of the Swedish authors fell within the top 100 authors in the network in 1991, only one Swedish author is among the top 100 in the 2006 network. The pattern is the same for connectedness. In 1991, Swedish authors acted as key nodes in the European network and were central to the connectivity within Europe. In 2006, Swedish authors were significantly less vital to the network.

There are potential flaws in these types of measures, the most significant being the importance of researchers applying rather than developing medical technology. Medline, which is the source of the analysis, does not allow for separation of publications describing new technology developed and publications using technology to verify other research results.
**Status of the Swedish authors 1991 versus 2006**

Network of European authors ranked by status of medical technology* publications, 1991 and 2006

* Network analysis of Medline articles indexed by selected medical technology MeSH terms for Sweden, Denmark, Germany, the Netherlands, Switzerland, the UK and Israel. Hits include medical technology development as well as applied medical technology. Restriction to authors with a minimum of 4 (1991) and 7 (2006) publications

Source: Medline October 2007; Visione

In 1991, 12% of the top 10% authors came from Sweden....

...but in 2006, only 2% of the authors appearing among the top 10% are Swedish

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**Top Swedish authors connectedness with European scientists 1991 versus 2006**

Connectedness in network of European authors of medical technology* publications

* Network analysis of Medline articles indexed by selected medical technology MeSH terms for Sweden, Denmark, Germany, the Netherlands, Switzerland, the UK and Israel. Hits include medical technology development as well as applied medical technology. Restriction to authors with a minimum of 4 publications during the year 1991 (1296 authors) and 7 publications during the year 2006 (1988 authors)

Source: Medline October 2007; Visione

1991 Connectedness

2006 Connectedness

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**Action MedTech – Key Measures for Growing the Medical Device Industry in Sweden**
**Terminology**

Artificial bone: Composite material, which replaces metal in bone implants. (Rensselaer Polytechnic Institute)

Benign prostatic hyperplasia: A condition causing non-cancerous enlargement of the prostate. (Prostatehealth)

Biodegradable drug eluting stents: A stent is a small, flexible, spring-like device used to support artery walls. Drug eluting stents (also known as drug coated stents or medicated stents), are coated with a drug that interferes with arterial re-blocking. In place of the stainless steel currently used in stents, various biodegradable frameworks are under early phases of investigation. Since metal, as a foreign substance, provokes inflammation, scarring, and thrombosis (clotting), it is hoped that biodegradable or bioabsorbable stents may prevent some of these effects. (FDA)

Bone stimulation: The technique of promoting bone growth in difficult to heal fractures by applying a low electrical current or ultrasound to the fracture. Stimulators may be implanted or worn externally. (Health A to Z)

Brachytherapy: A form of radiotherapy where a radioactive source is placed inside or next to the area requiring treatment (also known as sealed source radiotherapy or endocurietherapy). Brachytherapy is commonly used to treat localized prostate cancer and cancers of the head and neck. (West Virginia Medical Journal)

CAGR: compounded annual growth rate = \[(\text{ending value}) / (\text{beginning value})^\frac{1}{\text{# of years}}-1\]

CE: The CE mark, a stylized "CE" (for Conformité Européenne), placed on products to signify conformance with European Union regulations

Cell therapy: The administration of genetically engineered cells, healthy donor cells, or a patient’s own stem cells as a part of medical treatment. (University of Pittsburgh Medical Center)

Charnley intramedular hip: Many people credit Sir John Charnley, a British orthopedist, with performing the first modern total hip replacement. His innovations included combining a metal stem and ball with a plastic shell and using a methylacrylate cement to hold the devices in place. (American Academy of Orthopedic Surgeons)

Coronary artery bypass graft: Surgery for coronary artery disease, a condition in which arteries that supply blood and oxygen to the heart muscle become narrowed and hardened. In coronary artery bypass surgery, the surgeon attaches a piece of vein from another part of the body to the coronary artery above and below the narrowed area or blockage. This allows blood to bypass the blockage. (MedlinePlus)

Coronary stenting: A stent is a metal tiny tube placed into a coronary artery to hold the structure open. (MedlinePlus)

CT scanners: CT imaging uses special X-ray equipment to produce multiple images or pictures of the inside of the body and a computer to join them together in cross-sectional views of the area being studied. The images can then be examined on a computer monitor or printed. (Radiological Society of North America)

Diagnostic electrophysiology: Electrophysiology is the science of measuring the electrical potentials generated within the body. For example, intracardiac electrophysiology involves placing wire electrodes within the heart to determine the characteristics of heart arrhythmias. (MedlinePlus)

Digital subtraction angiography: An imaging technique used in interventional radiology to examine the heart or brain. After a contrast medium is injected into a vein in the arm, an X-ray machine quickly takes a series of pictures. (American Heart Association)

Drug eluting stents: A stent (see above) with medication on it intended to slow the re-closing of coronary arteries. (American Heart Association)

EBIT: Earnings before interest and taxes

Endometrial ablation: Treatment to destroy (ablate) part of the womb lining (endometrium). It is used to treat women who have heavy periods, known as menorrhagia. (BUPA)

Endoscopic surgery: A procedure in which an endoscope, a long, thin tube holding a camera, is used to perform surgery on a joint or organ. (MedlinePlus)

Epilepsy pacers: Vagus nerve stimulation is a type of treatment in which short bursts of electrical energy are directed into the brain via the vagus nerve, a large nerve in the neck. This treatment may reduce or eliminate seizures. (Epilepsy Foundation)
External defibrillator: A machine that is used to deliver an electric shock to the heart to restore a normal heart rhythm. (American Heart Association)

External pacing: Pacemakers detect a slow heart beat and send electrical impulses to the heart to stimulate the heart muscle to beat faster. The first pacemakers were not totally implanted in the body. One end of a small wire, called a “lead,” was implanted into the heart. The other end of the lead was connected to an external pacemaker that was AC powered by means of an extension cord. (Medtronic)

GDP: gross domestic product = consumption + investment + government spending + (exports – imports), or, GDP = C + I + G + (X-M)

Growth factor: A substance (as a vitamin B12 or an interleukin) that promotes growth and especially cellular growth. (Merriam-Webster)

G7: the seven leading industrial countries (US, Germany, Japan, France, UK, Canada and Italy)

Heart-lung bypass: A heart-lung machine is also called a cardiopulmonary bypass machine. It takes over for the heart during heart surgery by replacing the heart’s pumping action and by adding oxygen to the blood. (Texas Heart Institute)

Hemodialysis: The most common method used to treat advanced and permanent kidney failure. In hemodialysis, blood is allowed to flow through a special filter that removes wastes and extra fluids. (US National Institute of Diabetes and Digestive and Kidney Diseases)

Hollow fiber dialysis: Hemodialysis using dialyzers made with capillary-sized hollow membranes, making for more efficient cleansing of the blood. (Fresenius)

Implanted defibrillator: A small device, which is placed in the chest or abdomen. The device uses electrical pulses or shocks to control life-threatening, irregular heartbeats. (National Heart, Lung and Blood Institute)

Intra-aortic balloon pump: Implanted device that provides circulatory assistance to patients with heart failure. (MedlinePlus)

Intra-ocular lens: A tiny artificial lens for the eye (often called IOL). An IOL permanently replaces the eye’s natural lens when it is removed during cataract surgery. (American Academy of Ophthalmology)

Intravenous oxygen therapy: Intravenous infusions of oxygen have been used as a complementary therapy for arthritis and other inflammatory conditions. (MedlinePlus)

In vitro diagnostics (IVD): Medical tests conducted in a test tube, or more generally in a controlled environment outside a living organism. (British In Vitro Diagnostics Association)

IPPV ventilator: A machine, which provides short term or intermittent mechanical ventilation to help the lungs expand and assist breathing. (Guidelines.gov)

Magnetic Resonance Imaging (MRI): MRI uses a large magnet and radio waves to look at organs and structures inside the body. MRI does not use ionizing radiation. (MedlinePlus)

Mechanical heart valve: Artificial (mechanical) valves, made of metal, replace diseased heart valves. Valves control the direction of blood flow through the heart. (MedlinePlus)

Nasal ventilation for sleep ventilation: Sleep apnea is a serious sleep disorder in which people stop breathing for short periods while asleep. A common treatment for sleep apnea is called “continuous positive airway pressure,” or CPAP. The patient wears a special mask over the nose and mouth while sleeping. The mask keeps the airway open by adding pressure to the air the patient breathes. (Familydoctor.org)

Neurostimulation: Pain relief through stimulation of neurons. There are two types of neurostimulation systems: one that is completely internal (surgically implanted) and one with both internal and external components. For a totally implantable neurostimulation system, the power source (battery) and lead(s) are surgically implanted. In the other type of system, a radio-frequency receiver and leads are implanted, and the power source is worn externally with an antenna over the receiver. (Medtronic)

Obstetrics: A branch of medical science that deals with birth and with its antecedents and sequelae. (Merriam-Webster)

Percutaneous aortic valve replacement: In percutaneous aortic valve replacement (PAVR), a synthetic valve is transported to the heart through a small hole made in a blood vessel in the groin. This procedure can be compared to that performed when placing a stent, or performing balloon angioplasty. (Circulation)

PTCA: Percutaneous transluminal coronary angioplasty. A thin, flexible plastic tube, called a catheter, with a balloon is inserted into an artery and advanced to the blockage in the
coronary artery. The balloon is inflated, squeezing open the fatty plaque deposit. Then the balloon is deflated, and the catheter is withdrawn. Often a stent is also placed to hold the artery open. (American Heart Association)

PTFE vascular graft: A vascular graft is a man-made tube which replaces or bypasses part of a blood vessel, most commonly an artery. It provides a tubular bypass for arteries, which have become narrow or blocked. PTFE refers to the material from which the grafts are made, PolyteTetraFluoroEthylene. (Terumo; MedlinePlus)

Pulse oximetry: Using a small monitor usually taped to the finger, pulse oximetry measures the amount of oxygen in the blood. (MedlinePlus)

Radial keratotomy: A surgical procedure popular in the recent past to correct myopia, or nearsightedness. It has been almost completely replaced by LASIK. (MedlinePlus)

Radiofrequency ablation (RFA): Catheter ablation is a technique in which a thin tube is inserted into the site of diseased tissue in order to destroy it. RFA generates heat to destroy the tissue. (MedlinePlus)

R&D: Research and development

Skin staplers: A mechanical alternative to sutures (stitches) or adhesives to close wounds. Stapling can result in less scarring and fewer infections. (Dannemiller Memorial Educational Foundation)

Solid state X-ray: In this imaging technology, X-ray film is replaced by solid-state detectors that convert X-rays into electrical signals. These detectors are similar to those found in digital cameras. (Radiological Society of North America)

Teacher’s exemption: In Sweden, a person who is employed and compensated for work, and whose employment includes making inventions, normally has to accept that the immaterial rights (such as patents, copyrights) are owned by the employer (the law of the employer’s right to inventions (1949:345)). This law is not applied at the university. Instead, a practice called “the teacher’s exemption” has been developed. According to the teacher’s exemption, teachers at the university own the right to commercially exploit the inventions they make in the context of their employment. Inventions may for example be results from research

Tissue engineering: Methods that promote the regrowth of cells lost to trauma or disease (University of Pittsburgh Medical Center)

Tissue growth factors: Biotechnology-based therapies, which have the potential to fix or replace damaged tissue in various parts of the body. Applications might include improved wound healing and growing new nerve pathways in patients with Alzheimer's disease. (Scrip Reports)

Transcutaneous electrical nerve stimulation (TENS): The passage of low-voltage electrical current to electrodes pasted on the skin. The current is delivered through wires from a small battery-powered unit. TENS is usually used to alleviate pain. (InteliHealth)

UCSF: The University of California, San Francisco

Ultrasound: Ultrasound uses high-frequency sound waves to look at organs and structures inside the body. No ionizing (X-ray) radiation is used. Images are captured in real time, so they can show movement and blood flow within the body. (Radiological Society of North America)

Vulnerable plaque: An atheromatous plaque which is particularly prone to produce sudden major problems, such as a heart attack or stroke. (The New England Journal of Medicine)

WIPO: World Intellectual Property Organization. A specialized agency of the United Nations. It is dedicated to developing a balanced and accessible international intellectual property (IP) system, which rewards creativity, stimulates innovation and contributes to economic development while safeguarding the public interest. WIPO was established by the WIPO Convention in 1967 with a mandate from its Member States to promote the protection of IP throughout the world through cooperation among states and in collaboration with other international organizations. (WIPO)

Xenotransplantation: Any procedure, which involves the transplantation, implantation or infusion into a human recipient of live cells, tissues or organs from a nonhuman animal source. Potentially, this technology could alleviate the shortage of human organs for transplant. (FDA)

X-ray angiography: Angiography is a minimally invasive medical test. A thin plastic tube, called a catheter, is inserted into an artery through a small incision in the skin. Once the catheter is guided into the area being examined, a contrast material is injected through the tube and images are captured using a small dose of ionizing radiation (X-rays.) (Radiological Society of North America)
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