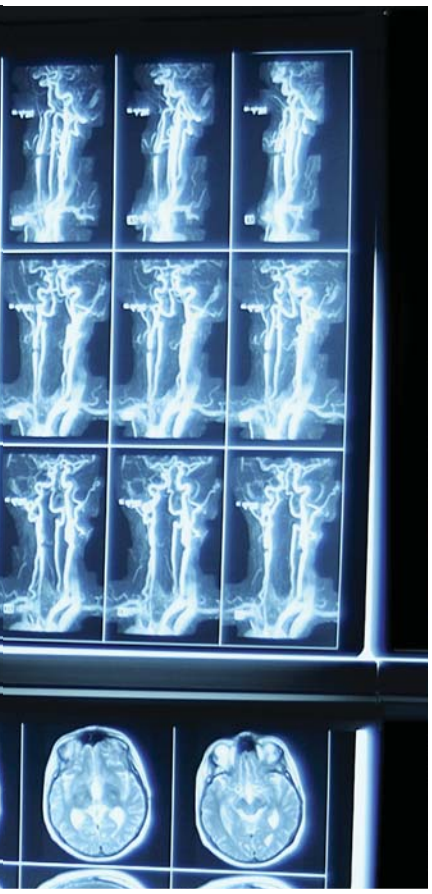
Massachusetts medical devices:

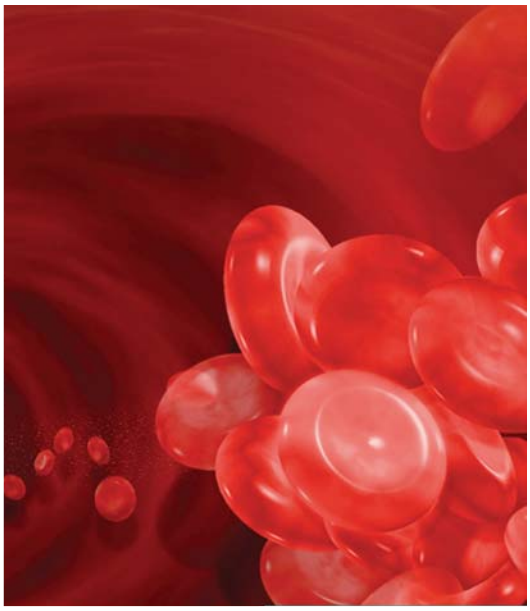
Leveraging the region's capabilities

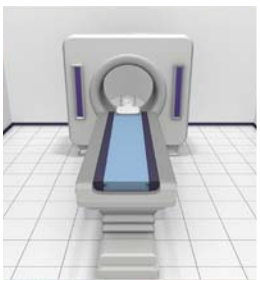
TO EXAMINE THE MEDICAL DEVICES INDUSTRY IN MASSACHUSETTS IS TO SEE THE EMERGENCE OF A ROBUST ECONOMIC CLUSTER RIGHT BEFORE OUR EYES.

Throughout its economic history, Massachusetts has experienced the emergence, growth to national leadership, and decline of regional concentrations of related firms and organizations known as clusters, such as textiles, shipbuilding, footwear and minicomputers. While significant research has been done on the characteristics of fully formed clusters, relatively little work has gone into analyzing the rapid growth process between the emergence and establishment of a successful cluster.

The emergence of a cluster right before our eyes — the medical devices sector — creates that opportunity today in Massachusetts. But as we looked into this dynamic sector, we soon realized that NAICS and SIC codes and other ways by which government classifies and measures a sector were unable to historically track the firms or account for







Michael H. Best

the changing product boundaries of the medical devices cluster. Companies are anonymous and company product mix data is not recorded in government economic data. The anonymity requirement obscures growth dynamics and the neglect of product information obscures cluster boundaries and dynamics. For example, the product of Firm X may primarily be computer components, but it also manufactures imaging systems for computed tomography (CT) medical devices. But because that latter activity is not its major activity, Firm X is classified under a non-medical technology code and is thus not categorized as part of the medical device sector.

To understand how the medical devices cluster (which from here on will be abbreviated as MED) emerged and formed, we needed to better quantify and analyze both the companies and the products that constitute it. To this end, we developed a powerful new database to better measure the scope and substantial growth of the MED sector in Massachusetts. The vTHREAD (Techno-Historical Regional Economic Analysis) database is a longitudinal, historical database of approximately 55,000 public and private, high-tech producers classified by a finely granulated taxonomy. (See box on next page). Because the unit upon which vTHREAD is based is the company itself, it recognizes that product boundaries can run through the middle of a company, that a company may have multiple products in multiple industrial categories. vTHREAD allows us to include firms that make medical products, even though they are classified in non-medical technology codes.

In the case of Massachusetts for 2004, we identified 177 companies classified as medical device firms and another 105 companies that are classified as non-medical device, but

Empirical methodology: vTHREAD

To get inside the faceless and ahistorical companies that are present in official data, we have constructed vTHREAD (Techno-Historical Regional Economic Analysis Database) a database of approximately 55,000 public and private, high-tech producers and a set of research tools designed to analyze regional industrial specialization, growth, decline and reinvention.

The vTHREAD database is populated with a new longitudinal file covering 1989 to the present, based on CorpTech data. The primary purpose of the CorpTech data set is to provide company information on private and public high tech companies in the United States. It is supplied quarterly to subscribers and currently includes approximately 5,000 firms in Massachusetts. Although the dataset is not constructed for scholarly purposes, CorpTech established sophisticated data collection and research methodology, including quality control systems and consistency checks. The data base is longitudinal; that is, firms in the data base are observed and measured over a number of years and their year-to-year records are then linked. The file is organized with a unique, finely granulated taxonomy of companies and products. It can therefore be used quite powerfully for industry studies, because it can identify and measure inter-industry linkages.

The development of the vTHREAD database has been a joint effort. Albert Paquin, the first research assistant, has stayed on from the beginning in various roles. Andrew Frisch did the original programming. Research assistants Hao Xie, MinYu and John Sharko and colleagues Georges Grinstein and Edward March have all made major contributions to either the research methodology or the development of the database. The Chancellor's Office of the University of Massachusetts Lowell and a CVIP Development Fund award from the President's Office of the University of Massachusetts provided financial support.

which make such products. A total of 63 of these firms had more than 200 employees (32 MED, 31 non-MED).

Sector overview

Annual output of American medical devices firms grew from $10 billion in 1979 to more than $90 billion in 2004.[1] By U.S. Department of Commerce data, Massachusetts is ranked within the top five medical device states in value of shipments, employment, payroll and value-added by both per capita and absolute size (Clayton-Mathews 2001: 3)[2]. An index of Massachusetts merchandise exports shows a growth of medical device exports of 78 percent, compared to growth in total exports of 18 percent between 1998 and 2003 (WISER 2004).[3]

Why has Massachusetts been so successful in medical devices? The easy answer lies in the region's plethora of research hospitals, which have attracted a disproportionate share of federal R&D funding, which in turn has fostered technology transfer, business spin-offs and otherwise created opportunities for medical device companies. But what exactly are the links between medical device clusters and research-intensive medical centers, such as Massachusetts General Hospital in Massachusetts and the Mayo Clinic in Minnesota? What makes these regions different from many others that have successful research-intensive hospitals, but lack a substantial medical device industrial counterpart? Part of the answer lies in Massachusetts' long history of precision engineering and instrument making, which collectively has gone through many design iterations with the transitions from defense to minicomputer to information-communication technologies and now to life science-based industries.

With the vTHREAD methodology in place to identify components of the MED sector, we are now better able to understand how these companies and this cluster have grown in Massachusetts. Much of this article examines Boston Scientific, the largest of and paradigm for five MED firms with more than 1,000 employees that have grown rapidly in Massachusetts over the past 15 years. Boston Scientific's sales grew from $2 million in 1965 to $5.6 billion in

Why has Massachusetts been so successful in medical devices? The easy answer lies in the region's plethora of research hospitals, which have attracted a disproportionate share of federal R&D funding, which in turn has fostered technology transfer, business spin-offs and otherwise created opportunities for medical device companies.

2004. We then briefly cite fast-growing, mid-sized MED companies and operating units located in Massachusetts. While most are Massachusetts-headquartered companies, we also find fast-growing operating units of companies headquartered in other states.

As noted, the new database and classification system allow us to identify non-medical device companies that make medical device products and/or provide medical device services. Included here are specialist outsourcing and manufacturing services companies. Such companies straddle industry boundaries and are most important in understanding industrial change and renewal. We have also been able to examine a group of large instruments companies that have transitioned into the medical device industry. The size of these companies suggests they can play a major role in cluster development. Another category of firms is the large group of foreign-headquartered companies that have operating units in Massachusetts. This group offers clues to the distinctive regional capabilities that can not be found elsewhere.

Boston Scientific:
Paradigm of the large, fast growing company

To see the rapid growth of the medical devices industry in the United States and in the Boston area, one need look at only one firm: the growth behemoth called Boston Scientific.

In 1979, the national industry was worth only $10 billion and only one company, Medtronic Inc., was of significant size. By 2004, the industry, narrowly defined, was worth nearly $94 billion. Over the same 25 years, Boston Scientific's revenues grew from $2 million to $5.6 billion. Employing more than 14,000 people worldwide, it has become the largest medical devices company in the world in the category of minimally invasive therapy.[4]

The Boston Scientific story began in the late 1960s, when co-founder John Abele acquired an equity interest in Medi-tech, Inc, an R&D company focused on developing alternatives to traditional surgery. Medi-tech's first products, introduced in 1969, were steerable balloon catheters that

This article was written before the recent $27 billion purchase by Boston Scientific of Indiana-based Guidant Corporation. Also, because company employment numbers used in the tables measure company size and growth, they include global operating units of Massachusetts companies. For example, Boston Scientific has major divisions in Massachusetts and California, as well as one in Galway, Ireland. It also has smaller units elsewhere.

were used in some of the first less invasive procedures. Meditech co-founder Peter Nicholas had run the medical products division of Millipore Corp, a large purification equipment company in the biotech and pharmaceutical sectors.[5] Abele and Nicholas are still leaders at Boston Scientific.

Bring in the docs

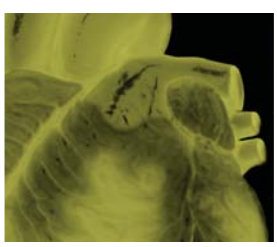
Before 1979, the small size of the medical devices industry reflected the passive character of device production. Medical device companies were primarily small instrument companies that built custom devices to the specifications of physicians. The market development challenge was not only technical, but organizational and even political and academic. Power in the medical community was concentrated with the physicians and in cardiology, where surgeons were both powerful and highly skilled in a well-developed, major surgery methodology. The political and intellectual challenge for Abele and Nicholas was to gain physicians' acceptance of angioplasty, an invasive but non-surgical approach to treating diseased arteries. For many physicians at the time, invasive surgery was immoral and unethical because, as Abele put it, it was "safer to have a big opening so if something went wrong it was easier to fix it."[6]

Abele first had to communicate and win the academic argument within the medical community. Forming a partnership with a leading physician was as crucial to the early development of Boston Scientific as it had been to Medtronic. Medtronic's pacemaker technology was an outcome of a long collaboration between Earl Bakken and Dr. C. Walton Lellehie, a pioneer in open-heart surgery at the University of Minnesota's School of Medicine.[7] A similar partnership between Abele and Dr. Andreas Gruentzig was pivotal to the creation of Boston Scientific's revolutionary angioplasty technology. Bakken and Abele cite the communication role of a clinical doctor/researcher to win over the medical community. In the case of the first battery-powered wearable pacemaker, Bakken noted: "Our friend and collaborator, C. Walton Lillehei of the University of Minnesota, spread the word throughout the worldwide medical community" (Bakken 1999: 63).

But, important as such personal partnerships were to the early development of Medtronics and Boston Scientific, they were not enough to build a company. The new product development process involves the lateral integration of a whole range of specialist activities and skills/occupations. Physicians had to be convinced about the benefits of minimally invasive therapy and educated in the procedures. At the same time, device engineers had to be responsive to the physicians' knowledge and use their feedback in the product design process. The challenge was one of integration and communication across disciplines and specialties. Successful new product development demanded more than inputs from each of these occupational specialties on its own; organizational routines for ongoing dialogue and translation across disciplinary domains had to be institutionalized.

The market development challenge was not only technical, but organizational and even political and academic.

It was also necessary to integrate customers and suppliers into the new product development and production processes. Nicholas led the effort to reorganize business units to interface directly with major customers, rather than through specialist marketing/sales offices. This opened up direct lines of communication between customers and product developers/makers. Suppliers to Boston Scientific were encouraged to re-engineer their own organizations along the same lines, which brought the sales function to the shop floor teams. The organizational design was an application of world-class manufacturing practices to the medical device supply chain. The new organizational design would have met the approval of W. Edwards Deming and his principle of system integration.[8]


Representing the future

Besides organizational process integration, and perhaps fostered by it, Boston Scientific has been a leader in technology integration. Boston Scientific's drug-eluting coronary stent represents the future: drug-device combination

Table 1. Fast-Growing, Big Medical Device Companies: Employment

	Founded	1990	1995	2000	2001	2002	2003
Analogic / Medical Imaging Division	1969	1,275	1,400	1,700	1,850	1,800	1,800
Haemonetics Corporation	1971	666	1,109	1,366	1,366	1,400	1,500
Smith & Nephew Inc. / Endoscopy Division	1986	250	575	750	1,000	1,300	1,500
DePuy Codman (J&J)	1838	850	1,170	1,200	1,200	1,200	1,200
Boston Scientific	1979	1,738*	5,000	13,500	13,500	13,500	14,400

* Boston Scientific employed 1,738 in 1992, the first year for which employment numbers are available from CorpTech.
Source: vTHREAD

products that help the body heal itself. It is a breakthrough technology that is radically changing the cardiovascular field. It reflects Boston Scientific's organizational capabilities in integration, this time with interdisciplinary teams anchored in physics, including fiber-optics, polymeric chemistry, and biologics. Boston Scientific has tapped into the region's leadership in biotech research and is redefining the disciplinary boundaries of medical devices.

Boston Scientific's technology management strategy involves leveraging its technology platform into other specialty markets within the medical field still encumbered by organizational barriers to product development. In the words of Abele:

[W]e were not focused on one marketplace. For example, radiology was big on guide wires, but urology, gastroenterology, and cardiology weren't. But communication between those specialties was, and still is, almost non-existent. Each of these fields presented an opportunity for us to evolve our technology. In essence, every R&D dollar we spent had benefits in multiple fields, giving us a three-to-four-times value for our spending. (Swain 2004: 13-14)

While Boston Scientific invested heavily in organizational capabilities in new product development and technology management, it remained a privately held company until 1992, when an IPO was followed by an aggressive acquisition strategy.

The company's acquisition strategy had two prongs. First, the firm acquired strategically to deepen its core technology. Two of its biggest acquisitions, Minnesota-based SCIMED and Schneider USA, had polymer technologies important to drug-eluting stent development. Second, it acquired to leverage superior capabilities in new product development in growth markets. In the words of Tom Gunderson, a research analyst for Piper Jaffray:

[T]here came the imperative to get newer and better products out as fast as you can. In those days, Boston Scientific was way beyond everyone else from a speed standpoint. (Quoted in Swain 2004:18).

Boston Scientific's drug-eluting coronary stent represents the future: drug-device combination products that help the body heal itself. It is a breakthrough technology that is radically changing the cardiovascular field.

Organizationally, Boston Scientific was the business model from which management in other companies in the region must have learned. It is one of a handful of Massachusetts companies that have grown to Fortune 500 size since the demise of the mini-computer giants in the late 1980s.[9] Life sciences replaced computers as the source of growth over the same period. But the business model of the new leaders has also been transformed. The vertically integrated organizations of the past have been replaced by an open-systems business model in which companies focus on core capabilities and partner for complementary capabilities. It represents, as well, the emergence of a new model of innovation and product development. Design has been diffused across networked groups of companies and decentralized within large companies.

Other fast-growing, big MED firms

While Boston Scientific is in a class of its own, at least four other companies located in Massachusetts and classified in MED by CorpTech boast more than 1,000 employees each (See Table 1). These large, fast-growing Massachusetts-headquartered MED companies fit squarely within one of the three related production capability areas in which Massachusetts has historically had a competitive advantage: instrument making, precision equipment, and complex product systems.[10] Their success can be considered a process of industrial renewal as fast-growing companies reallocate resources in pursuit of new market

These large, fast-growing Massachusetts-headquartered MED companies fit squarely within one of the three related production capability areas in which Massachusetts has historically had a competitive advantage: instrument making, precision equipment, and complex product systems.

opportunities by tapping the region's production and technological capability heritage.

Indeed, Depuy Codman was founded in 1838 by Thomas Codman, a mechanic in Roxbury.[11] Codman successfully designed a cupping instrument for the application of ether. The company boomed during the Civil War with a range of surgery and amputation instruments. While it had many ups and downs, the company's Web site reports that the company maintained a core of skilled instrument makers and apprenticeship program.

In 1964, Codman & Shurtleff, Inc. became a member of the Johnson & Johnson "Family of Companies" while retaining its Codman identity. Codman has a long history of cooperation with surgeons in the development of instruments. In recent years, these have included a hip prosthesis for total hip replacement and a set of instruments that allowed an anterior approach to the cervical spine for treatment of diseased and herniated inter-vertebral discs. In fact, some of the first joint reconstruction implants, marketed under the name Cintor, led to the creation of the Johnson & Johnson Orthopedics division, today named DePuy.

Other big, fast-growing MED companies in Massachusetts include:

- **Smith and Nephew Inc./Endoscopy Division** is an operating unit of its UK parent. This operating unit, originally Dyonics, was founded in 1986 and acquired by Smith and Nephew in 1996. The Endoscopy Division designs, develops and manufactures endoscopic surgical instrumentation used in minimally invasive surgery. This involves miniature cameras, xenon light sources and arthroscopic surgical instruments.

- **Haemonetics Corporation** designs and manufactures automated blood processing systems. The company estimates that 60 million blood collection procedures are performed worldwide every year to obtain blood's three major components: red cells, platelets and plasma. Haemonetics designs and manufactures automated blood processing systems to make this possible.

- **Analogic Corporation's Medical Imaging Division** represents Massachusetts' distinctive regional capability in complex product systems. Analogic is a developmental engineering and manufacturing company that builds medical and security imaging systems for original equipment manufacturers (OEMs). The company claims to supply approximately 75 percent of the data acquisition systems installed in computed tomography (CT) systems worldwide and half of the advanced power systems used in magnetic resonance imaging (MRI). Its product range includes a wide range of imaging systems including digital, laser, phased array, magnetic resonance, and ultrasound. The parent, Analogic Corp., has sales of nearly $500 million.[12]

Mid-sized, fast-growing MED companies

There is a large group of fast-growing, mid-sized, medical device companies, or operating units, located in Massachusetts (see Table 2). Mid-sized is defined as between 200 and 1000 employees. These companies can be divided into two groups: independent companies headquartered in Massachusetts and once-independent companies that have been acquired by medical device companies headquartered elsewhere in the United States but which continue to operate in Massachusetts.

When we analyzed 12 fast-growing, mid-sized MED companies that remain headquartered in Massachusetts, we found the following:

- Employment in these firms increased from under 2,000 in 1989 to between 6,000 and 7,000 in 2003;

- These are long-established companies.[13] Four were founded in the 1970s (Candela, NMC Diagnostics, Lifeline Systems, and Nova Biomedical) and seven in the 1980s. Inverness Medical Innovations is the newest company, founded in 1992;

- These firms reinforce the region's production capabilities in complex product systems, instruments and equipment found in the fast-growing big companies. Companies adopted a technology-focused strategy

Table 2. Fast-Growing, Medium-Sized Medical Device Companies Based on Employee Level

Company	Year Founded	EMPLOYMENT LEVELS					
		1990	1995	2000	2001	2002	2003
Lifeline Systems, Inc	1974	250	325	620	790	850	850
Zoll Medical Corp	1980	150	275	390	430	585	844
Inverness Medical Innovations	1992	-	78	419	704	800	800
Hologic, Inc	1985	130	170	600	839	780	750
Nova Biomedical	2001	475	500	500	664	665	665
Cytyc Corp	1987	25	55	200	495	495	626
Gentex Optics, Inc	1932	120	250	500	500	500	500
Harvard Apparatus	1901	65	95	40	45	257	450
Candela Corp	1970	174	180	285	285	300	325
Clinical Data	1972	9	80	175	285	151	302
Biopure Corp	1984	40	110	180	173	240	240
ABIOMED	1981	55	70	182	265	264	238
Aspect Medical	1987	-	-	100	200	230	205
American Medical Instruments	1975	60	145	145	149	149	195
Organogenesis, Inc*	1985	100	97	200	236	180	180
Hologic Lorad	1989	150	280	350	350	275	-
Summit Technology	1985	60	211	425	*Acquired by Nestle SA 2000*		
MediSense	1981	60	850	*Acquired by Abbott Labs 1996*			
NMC Diagnostics	1971	140	250	*Acquired by Fresenius AG 1998*			

* Listed as a biotechnology company since 2001
Source: vTHREAD

based on product development efforts, rather than mass production;

- They reflect and reinforce the region's technological heritage. At least five are in imaging/scanning, four are in optics, three are in blood processing/diagnostics and two are in cardio equipment. These mirror fairly closely the big medical device companies in Massachusetts. Optics, in particular, is a technology that also goes back to the earliest days of Massachusetts industry.

Five fast-growing companies, founded in Massachusetts, have been acquired by leading MED companies headquartered elsewhere in the nation. Medtronic can be added to this group, as this Minnesota company recently established a major presence in Massachusetts partly by acquisition. The acquirers represent two of the biggest and most successful specialist medical device-making companies in the United States, Medtronic and Stryker, and two global giant healthcare companies, Abbott Laboratories and Johnson & Johnson.

The acquisitions by these leading medical device companies of Massachusetts operating units are a good indicator of the state's distinctive capabilities. These companies, with the exception of Abbotts' acquisition of MediSense, have maintained and expanded the operating units they have acquired. Massachusetts' historic strengths in instruments, including optics and imaging, combined with leadership in biotech, were the key elements in many of the acquisitions. These companies must come to Massachusetts to acquire such capabilities and they are not easily removed to other locations.

In some important cases, medical device companies have moved their headquarters to Massachusetts. The UTI Corporation, a 3,500 employee, integrated outsourcer of manufacturing services for medical device companies, recently moved its headquarters from Pennsylvania to Massachusetts and renamed itself Accellent. Interestingly, the move of Accellent to Massachusetts represents a return of the remains of at least three once independent private companies to Massachusetts: Brimfield Precision, APEX Engineering, and ACT Medical. All three had been acquired earlier by Minneapolis-based MedSources Technologies, before this company itself was acquired by UTI.

Non-MED companies with medical products

Table 3 shows 12 companies that are not classified as medical device companies, but which design and make medical

device products. Six are classified in biotech, two in instruments and one each in pharmaceuticals, advanced materials, photonics, computer hardware, and computer software.

The growth in Massachusetts companies as measured by employment is remarkably similar for this group as it is for big medical device companies. These 12 companies grew from around 2,900 employees in 1990 to nearly 20,000 employees in 2003, compared to the job growth of the six big medical device companies (excluding MediSense), which grew from around 2,200 in 1990 to 22,000 in 2003. The closest to a Boston Scientific in employment is a combination of Genzyme, Parexcel and Charles River Laboratories. None of these three, however, is positioned primarily in medical devices; in that all are life science companies and supply products and services to biotechnology (BIO), pharmaceutical (PHA) firms as well as medical device firms. But they all offer insights into the dynamics of a rapidly reconfiguring cluster.[14]

Perhaps not surprisingly, virtually all of the non-MED companies with MED products are in the life sciences or healthcare technologies. They represent industrial renewal via technology convergence or new technology combinations. In some cases, companies are in life sciences extending into medical devices as a means of drug delivery. In virtually all cases, they imply a regional capability in systems integration: the capacity to redesign or reconfigure the whole in order to take full advantage of design changes in a sub-system.

Genzyme, a leader in biotechnology is a major provider of biodiagnostic products ("in vitro diagnostics") and also supplies bioengineered tissue that help repair damaged cartilage in the implant market. Genzyme's product range straddles biotech and medical devices and represents the convergence of physical and life sciences as the boundaries of the medical device cluster have shifted.

Parexel is one of the world's largest contract research organizations. It specializes in the design and management of clinical research (Phases I-IV), including regulatory, data management and biostatistical services to the pharmaceutical, biotech, and medical device and diagnostic products worldwide. Founded in 1982, Parexel had 5,000 employees worldwide and over $600 million in sales in 2003. Parexel achieves economies of scale in clinical trial management, which enables technology development companies to specialize on their core capabilities and outsource for this critically important function. Its rapid growth and location in Massachusetts are explained by the combined number of companies in all three life science based industries in the state. Partnering can drive down new product development time. Parexel's specialist capability developed in Massachusetts has been leveraged globally; it claims to have participated in the development of 23 of the top 25 drugs introduced in the world in 2000.[15]

Charles River Laboratories, formed in 1946, has repositioned itself in recent years from a company that specialized in animal research and diagnostics to human research models required in R&D for new drugs, devices and therapies. It specializes in clinical trial support and a portfolio

Table 3. Fast-Growing, Non-Medical Device Companies With Medical Device Product Offerings

Company	Year Founded	EMPLOYMENT LEVELS 1990	2003	Primary Industry	Product Applications
Genzyme	1981	450	5,500	Biotechnology	Pharmaceutical, Medical
Charles River Labs	1946	1,200*	5,000	Biotechnology	Medical
PAREXEL International	1982	750**	4,860	Pharmaceutical	Medical, Biotechnology, Computer Hardware
PolyMedica	1988	4	1,679	Advanced Materials	Biotechnology, Chemicals, Medical, Pharmaceuticals
Mercury Computers	1982	180	600	Computer Hardware	Medical, Software, Telecom
Harvard Apparatus	1901	65	450	Biotechnology	Energy, Medical, Components, Test & Measurement
Alkermes	1987	30	425	Biotechnology	Medical, Pharmaceuticals
Perceptive Informatics	2000	-	331	Software	Medical, Telecom
Clinical Data	1972	9	302	Test & Measurement	Medical
M.J. Research	1985	15	220	Biotechnology	Chemicals, Medical, Components, Test & Measurement
Bruker BioSpin	1972	100	180	Test & Measurement	Medical, Components
Organogenesis, Inc	1985	100	180	Biotechnology	Medical, Test & Instruments
Total employees		2,903	19,727		

* Charles River Laboratories employed 1,200 in 1993, the first year for which employment numbers are available from CorpTech.
** PAREXEL employed 750 in 1994.
Source: vTHREAD

Table 4. Foreign-Headquartered Medical Device Companies With Massachusetts Divisions or Facilities

Company	Company Headquarters	Year MA Unit Founded	MA EMPLOYMENT LEVELS			
			1990	1995	2000	2003
HP / Philips	Netherlands	1981	200	100	5,300	6,650
Smith & Nephew	United Kingdom	1986	250	575	750	1,500
Instrumentation Lab Co.	Spain	1959	400	400	500	500
Gentex Optics, Inc.	France	1932	120	250	500	500
Bunzl Extrusion	United Kingdom	1949	-	-	100	149
Straumann Co.	Switzerland	1989	-	35	68	160
Smiths Medical ASD, Inc.	United Kingdom	1986	-	160	240	200
EBTEC/TI and Smiths	United Kingdom	1963	80	60	75	80
Schott AG	Germany	1954	350	265	270	211
Seimens/Draeger Medical	Germany	1988	360	540	320	370
GSI Lumonics	Canada	1968	350	399	1,500	950
Summit Technology, Inc.	Switzerland	1947	60	211	425	-
NMC Diagnostic Services	Germany	1981	140	250	-	-
TUV Product Services, Inc.	Germany	1989	55	-	250	149
Spacelabs Medical	Finland	1987	-	7	120	120
Bionostics, Inc. / Ferraris Group	United Kingdom	1982	40	55	55	55
Pyrosequencing, Inc.	Sweden	2000	-	-	-	30
Light Lab Imaging, LLC	Japan	1998	-	-	-	12
Tecan Boston	Switzerland	1994	-	-	26	12
Symfo, Inc.	Belgium	2000	-	-	-	35
Ophir Optronics, Inc.	Israel	1985	-	-	130	25

Source: vTHREAD

of products and services that enable customers to reduce cost and time and increase productivity and effectiveness of product development in the life sciences.

PolyMedica, established in 1988, was classified in MED from 1992 to 1997, followed by advanced materials, and now in pharmaceuticals. "Poly" in the title is short for polyurethane, a material that can be used in long-term implantable medical devices. The rapid growth of the company, however, has been a consequence of becoming a leading provider of healthcare products and services to patients with chronic diseases. PolyMedica, with nearly 1,700 employees, is the nation's largest provider of blood glucose testing supplies to people with diabetes, most of which are supplied directly to the consumer.

Mercury Computer, a designer and developer of digital signal processing computer systems, grew from 109 employees in 1989 to 600 in 2003. Mercury has leveraged its technology platform, which was originally in defense applications, to medical imaging systems.

Clinical Data was in drug delivery systems and more recently has developed transdermal patch drug delivery products. It primarily develops and manufactures scientific and clinical laboratory instrumentation, including blood coagulation analyzers, chemistry analyzers, spectrophotometric industrial process monitors and diode ray process spectrometers.

Organogenesis manufacturers living organ equivalents, including skin, arterial and knee ligament replacements. It was classified as testing and measurement in 1992, MED from 1993 to 2001 and since as BIO. It designs develops and manufactures medical therapeutics containing living cells and bioengineered surgical products.

Foreign-headquartered companies

Nearly 8 percent of medical device companies in Massachusetts are foreign-headquartered. The behemoth here is **Philips Medical Systems** with 6,650 employees, an estimated 2,000 of whom are in Massachusetts (see Table 4). Philips has a long medical equipment history going back to 1896 when Philips manufactured the first x-ray tubes for medical

If the early emergence and growth of the medical devices industry in Massachusetts was fostered by the plethora of instrument-making companies, the next stages have been marked by the incorporation of photonics and software and, more recently, the integration of devices and drugs, of physics and biologics.

applications. With the acquisition of Agilent Technologies Healthcare Solutions Group (previously Hewlett-Packard Medical Products Group) of Andover in 2001, Philips became the number two medical equipment provider in the world.[16] Philips joins a strong group of local and foreign-headquartered companies in imaging, optic, and laser technologies. In fact, of the 21 foreign-headquartered medical device companies with operating units in Massachusetts, more than half are in imaging and/or optics.

Another example is **Bruker BioSpin Corp**., a Massachusetts-based member of the German-headquartered Bruker family of companies, a worldwide leader in nuclear magnetic resonance (NMR) since its development in the mid-1900s.[17] Bruker has specialized in R&D in high-resolution NMR and its extension into mass spectrometry and into in-vivo NMR or medical research MRI. Today, Bruker BioSpin makes nano-scale precision equipment for drug development and gene and protein research. **GSI Lumonics**, previously **General Scanning, Inc**., was founded in 1968 as a laser components engineering company. It grew from 300 employees in 1990 to 1,500 in 1999, when it merged with Lumonics Inc. of Canada. Today, it supplies a broad line of turn-key systems, subsystems, and components — most of which leverage laser technology — to OEMs that compete in industrial, medical, imaging and laboratory marketplaces.

Conclusion

Our dataset of medical device companies serves as a metaphorical laboratory to study the emergence of a high-tech industrial sector in Massachusetts. It includes rapidly growing companies, transitioning companies, relocating companies and foreign-headquartered subsidiaries. The basis for our analysis is that growing, transitioning and relocating companies drive industrial growth and, as such, they are the carriers, developers, and consolidators of underlying and regionally distinctive technological capabilities.

By applying this research methodology to the medical devices industry of Massachusetts, we find important insight into the processes of regional specialization. New product development (NPD) capability, for example, is at the heart of technology-driven companies. It is also enormously costly, as is technology leadership. From a regional growth perspective, NPD is the immediate source of innovation. The fear was that with the decline of the computer sector and other large industrial operations in Massachusetts, NPD would suffer and the region would go into industrial decline. However, this has not been the case and the MED sector shows one important reason: the region's techno-diversity. This diversity has been a key element in the transition to a new, regional system of innovation. If the early emergence and growth of the medical devices industry in Massachusetts was fostered by the plethora of instrument-making companies, the next stages have been marked by the incorporation of photonics and software and, more recently, the integration of devices and drugs, of physics and biologics. Each shows how the techno-diversity of the region creates enhanced opportunities for NPD. And NPD is the handmaiden of industrial differentiation and growth.

Michael Best is university professor emeritus and a director of the Center for Industrial Competitiveness at the University of Massachusetts Lowell. He is also senior associate in industrial organization, Judge Business School, University of Cambridge.

[1] For these and related statistics and their sources on the size and growth of the U.S. medical devices industry go to www.devicelink.com, the website for the trade publication *Medical Device and Diagnostics Industry*, and www.AdvaMed.org, the website for the medical technology association.

[2] Based on the 1997 Economic Census, U.S. Bureau of the Census. Minnesota is first in all four of the per capita rankings, but between 3rd and 4th in absolute size rankings. (Alan Clayton-Matthews and Rebecca Loveland, *Medical Devices: Supporting the Massachusetts Economy,* University of Massachusetts Donahue Institute, 2004, online at www.massbenchmarks.org).

[3] The source for export growth is the World Institute for Strategic Economic Research (WISER), WISER foreign trade database for 2004. http://www.wisertrade.org/.

[4] Using CorpTech's taxonomy, Boston Scientific's product categories and codes are Minimally invasive cardiovascular diagnostic systems: MED-DG-C (SIC 3845); Ultrasound imaging systems: MED-DG-IU (SIC 3845); Catheters: MED-SU-Q (SIC 3841); and Cardiovascular inflation devices: MED-TH-C (SIC 3841). The value of the CorpTech taxonomy is illustrated by the conversion of over 10,000 catalog product items in over 50 categories into these 4 codes.

[5] Founded in 1954, Millipore (4000 employees and $800 million in sales in 2003) pioneered the use of membrane technology and purification systems widely used today in research laboratories and in pharmaceutical and biopharmaceuticals manufacturing processes. The infiltration equipment is used to purify DNA and RNA proteins. Waters Corporation (4000 employees and $1 billion in sales) and Mykrolis Corporation (900 employees and $200 million in sales) are two large Massachusetts instruments companies that were once divisions of Millipore. Boston Scientific represents 'renewal' of the equipment and instruments industries of Massachusetts in the form of extension into medical devices.

[6] Erik Swain, 'Boston Scientific: *Making the Most of its First 25 Years*,' Medical Device and Diagnostic Industry, August, 2004: 9. Swain is an astute observer and chronicler of the medical devices industry.

[7] In the words of Bakken: "During Medtronic's formative years, I became a more or less regular feature over there…I spent so much time in the offices, surgery suites, and animal labs at the U of M that I was given my own locker" (Earl E. Bakken, *One Man's Full Life*, Medtronic, Inc. 1999: 46).

[8] W. Edwards Deming, *Quality, Productivity and Competitive Position*, Center for Advanced Engineering Study, MIT, 1982.

[9] The others in high tech are EMC, Genzyme Corp. and Biogen Idec Inc. Massachusetts had 11 companies in Fortune's 500 biggest for 2005, the same as Missouri and far below Ohio's 30 and Michigan's 22. Massachusetts still ranks second highest in per capita income behind only Connecticut (see Charles Stein, 'State seeks a few good giants: After Fleet and Gillette, local corporate titans are scarce', The *Boston Globe*, May 17, 2005: F-1,8).

[10] For a description of production capabilities in Massachusetts see Best, *The New Competitive Advantage*, Oxford University Press, 2001.

[11] American Optical Lens, established in 1833, may be the oldest medical device company still operating in Massachusetts.

[12] The employment numbers are for a family of seven divisions, five of which are in medical devices: Life Care Division, B-K Medical Systems, Medical Imaging, and Sky Computers all in Massachusetts and Camtronics Medical Systems, Ltd., in Wisconsin. Its Test and Measurement Division is co-located with Medical Imaging and Life Care Systems at its company headquarters in Peabody, Massachusetts.

[13] Gentex Optics, an even older company founded in 1932 was acquired by Essilor, a French firm and is not included in this section. Cybex, founded in 1953 grew to 700 employees in 1995 before declining to 450 in the early 2000s.

[14] Two other large company candidates for the category of rapidly growing non-MED companies with medical device products are PerkinElmer and Thermo Electron. Instead, they are treated in a separate category below. *The Boston Globe*, for one, classifies both in medical devices but this may be a stretch. Either way, PerkinElmer was not included in the table, although it is a major employer, because it was not a fast growth firm over the period.

[15] See www.parexel.com/about_us/history.asp April 2005.

[16] The acquisition of Agilent Technologies' Healthcare Solutions Group added cardiovascular ultrasound imaging, patient monitoring, electrocardiography, resuscitation products, and e-care business to Philips portfolio. This reflects the region's technological capability in both cardiovascular and imaging technologies. In the same year (2001), Philips acquired Marconi Medical Systems from GEC, a medical imaging innovator in the U.K. since 1915.

[17] The Bruker family of companies specializes in spectrometers for the pharmaceutical, oil, petrochemical, and polymer industries as well as MRI systems. For a discussion of Bruker Instrument's role in the early development of MRI, see Annetine Gelijns and Nathan Rosenberg, "Diagnostic Devices: An Analysis of Comparative Advantages" in *Sources of Industrial Leadership*, ed. David Mowery and Richard R. Nelson (Cambridge U.K., 1999), 328-330.