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Regional Specialization and Cluster Drivers: Medical Devices in Massachusetts

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The American medical devices industry has grown at an approximate annual rate of approximately 8 percent for twenty-five years. Massachusetts is near or at the top in many regional specialization indicators such as enterprise location quotient and exports. To examine the rapid growth and development of a Massachusetts medical devices cluster we apply vTHREAD (Techno-Historical Regional Economic Analysis Database), a longitudinal database of approximately 60,000 public and private high-tech producers classified by a finely granulated taxonomy. We focus on technology-based companies that have contributed to the rapid growth of medical devices. We look at fast-growing big and medium-size medical device companies, including out-of-state companies with operating units in Massachusetts. We then turn to fast-growing and large multi-industry companies that have migrated into producing medical devices. Finally, we examine the nearly 8 percent of industry companies with foreign headquarters. We conclude that rapidly growing and market-repositioning firms have been the drivers of growth in the medical devices cluster in Massachusetts. They have contributed to an ongoing renewal process in the production and technological capabilities long central to the region's industrial success, albeit in different sectors.

Annual output of American medical devices firms grew from $10 billion in 1979 to over $90 billion in 2004.[1] Massachusetts is a success story within

[1] vTHREAD database development has been a joint effort. Albert Paquin, the first research assistant, has stayed on in various roles. Andrew Frisch did the original programming. Research assistants Hao Xie, Min Yu, and John Sharko and colleagues Georges Grinstein and Edward March have all made major contributions to either research methodology or database development. The University of Massachusetts Lowell Chancellor's Office and a President's Office CVIP Development Fund award have both provided financial support. For these and related statistics and their sources on the size and growth of the U.S. medical devices industry, go to **http://www.devicelink.com/**, the website for the trade

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URL: http://www.thebhc.org/publications/BEHonline/2005/best.pdf.

this rapidly growing industry. According to 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.[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.[3]

Why has Massachusetts been so successful in medical devices? The easy answer is that the region has a plethora of research hospitals that have attracted a disproportionate share of federal research and development (R&D) funding, which in turn has fostered technology transfer, business spin-offs, and otherwise created opportunities for medical-device companies. No doubt, world-renowned medical research centers like the Massachusetts General Hospital, founded in 1811, and the Mayo Clinic in Minnesota have played roles in the success of the medical device industries in these two states. But what makes these regions different from many others that have successful research-intensive hospitals, but lack a substantial medical device industrial counterpart?

Characterizing Technological Capabilities

The phenomenon of geographical concentration of industries into "industrial districts" or "clusters" has long been noted. The explanation has been less satisfactory. Lacking an account in terms "internal" to conventional economic theory, economists rely on the concept of "externalities" of various types. Often cited externalities include "common technologies, skills, knowledge, and purchased inputs."[4] While few would disagree that such "externalities" can be found in successful clusters, the externality postulation does not offer insight into their emergence or development.

Why do accounts of regional specialization rely so heavily on externalities? An important part of the explanation is that the firm as an organizational entity is missing from both theoretical and empirical accounts of regional specialization and industry growth.

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publication *Medical Device and Diagnostics Industry*, and **http://www.AdvaMed.org/**, the website for the Medical Technology Association.

[2] Alan Clayton-Mathews, "The Medical Device Industry in Massachusetts" (University of Massachusetts, Donahue Institute, 2001: 3), viewed 1 Nov. 2005; URL: **http://www.donahue.umassp.edu**. Rankings 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 third and fourth in absolute size rankings.

[3] The source for export growth is the Massachusetts Institute of Social and Economic Research, MISER foreign trade database 2004, viewed 1 Nov. 2005.; URL: **http://www.misertrade.org/**.

[4] Michael Porter, "The Economic Performance of Regions," *Regional Studies*, 37.6 and 37.7 (Aug.-Oct. 2003): 562.

In this paper, I contribute to an account of regional specialization in which the growing firm is central to the story. The firm is important (in its own right), not only as a driver of technological change, but as a carrier and developer of a region's distinctive skill base and technological capabilities.[5] A central claim is that a region's distinctive technological capabilities are a source of competitive advantage to the firms that populate it. Technological capabilities, like externalities, are not visible. Nevertheless, can they be inferred from an examination of the companies and the products they make?

A research methodology is proposed for characterizing, or creating "images" of a region's technology "DNA."[6] The technique involves the application of a finely granulated taxonomy to the product categories of a selected population of firms and their historical evolution. The taxonomy acts as a "technoscope" to penetrate below the product-level surface of firms to read the underlying technological capabilities. A set of criteria is presented to select the firms that are likely to offer the most information on a region's distinctive technological capabilities.

The medical devices industry of Massachusetts and the firms that constitute it offer a "laboratory" in which to study the emergence of a regionally specialized high-tech industry or cluster. This presents an empirical challenge.

Although the medical devices industry is not a category in government classification systems, researchers have defined the industry in terms of a group of SIC (Standard Industrial Classification) or NAICS (North America Industrial Classification System) sub-sectors and measure it in employment, output, and number of establishments for any given year. As

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[5] Technological capabilities are about engineering knowledge embedded in production, including labor skills; they are critically important to opportunities for new product development. Regional technology capabilities constitute a form of intra- and extra-firm knowledge community that combines formal engineering knowledge with specialized technical knowledge.

[6] Two earlier on-line publications are Michael Best, "Lowell's Industrial Regeneration: Dynamic Technological Capabilities," viewed 1 Nov. 2005; URL: **http://www.thebhc.org/publications/BEHonline/2003/beh2003.html** and Best, "Discovering Regional Competitive Advantage: Massachusetts High Tech" (with Albert Paquin and Hao Xie); URL: **http://www.thebhc.org/publications/BEHonline/2004/beh2004.html**. The dynamic capabilities perspective is developed in Best, *The New Competition* (Cambridge, Mass., 1990) and *The New Competitive Advantage: The Renewal of American Industry* (New York, 2001). The growth of firms is about the development of capabilities: organizational, production, and technological. Organizational and production capabilities tend to be generic, while technological capabilities are firm-specific and account for much of the variation within "clusters." Regional growth demands that skills grow at the pace of, and be in accord with, the technological capabilities of the region's enterprises.

useful as this information can be, for regional specialization research purposes it has several limitations.

First, government data are not company-specific because of the confidentiality requirement. This precludes longitudinal and organizational analysis of business capabilities. Second, industrial sectors are defined with a static taxonomy that is hard to maintain where technological change is rapid and product differentiation is common. Third, the taxonomy lacks the granularity required to characterize specialization at the regional level. Fourth, the taxonomy is applied to establishments, but not to the products they make.

These data limitations are historical. The classification architecture and associated industrial categories were developed in the heyday of mass production of generic products, when new product development (NPD) capabilities were not integrated with production. High-tech industries were not yet prominent and product-led competition had not become widespread. Since the 1930s, industrial "speciation" or differentiation has engendered the emergence of new industries not easily captured by the classification system.[7] Characterization of regional specialization demands higher resolution.

Empirical Methodology: vTHREAD

To get inside the faceless and ahistorical companies that feature 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.[8] 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 dataset is to provide company information on private and public high-tech companies in the United States. It is supplied quarterly to subscribers and presently includes approximately 55,000 high-tech companies in the United States and 5,000 in Massachusetts. Although the CorpTech dataset is not constructed for scholarly purposes, there is an incentive for accuracy and comprehensiveness because its business success depends upon both. CorpTech established a sophisticated data collection and research methodology, including quality control systems and consistency checks.[9]

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[7] The very success of business enterprises in developing new organizational forms has undermined the usefulness of official enterprise data. It was once reasonable, for example, to classify companies and ignore products. This is problematic in the case of multi-product companies and product-led strategies.

[8] See "Lowell's Industrial Regeneration" and "Discovering Regional Competitive Advantage" for earlier applications of vTHREAD.

[9] CorpTech's data collection methodology has eight phases: company identification using a variety of sources: telephone interview, after which the

The CorpTech dataset has several virtues for purposes of studying regional specialization. First, it is a company dataset, whereas census data and other datasets exclude company information for confidentiality reasons. Second, it is longitudinal dataset of named companies covering the period from 1989 to the current quarter. Most other datasets used to study change rely upon aggregate snapshots of different times. Third, companies are classified by a finely granulated technology taxonomy that enables the researcher to drill down to characterize companies technologically. Fourth, the products a company makes are subject to the same taxonomy, which makes it possible to account for companies that may be classified in one category, but make products that fit in another.

The taxonomy starts with eighteen high-tech industry codes that explode to 300 major product codes and to 3,000 minor product codes. Figure 1 and Tables 1-3 illustrate the taxonomy with medical technologies (MED). Companies classified in one industry code may have products in other industry codes, and companies classified in one industry may migrate to another in later years.

An enterprise location quotient (ELQ) query provides a starting point for regional analysis. ELQs are defined as the ratio of high-tech firms in a specific industrial category within a region to those in the country divided by the ratio of population in the region to population in the country. As shown in Table 4, Massachusetts and Minnesota have high ELQs in MED. Table 5 shows that Massachusetts is more specialized than Minnesota in diagnostic equipment (MED-DG) and medical services (MED-SV), and that Minnesota is more specialized in rehabilitation devices (MED-HA).

Table 6 shows a further difference between Massachusetts and Minnesota in product/technology concentration. Massachusetts has particularly high location quotients in test and measurement (TAM), photonics (PHO), and in biotechnology (BIO) and pharmaceuticals (PHA). The high location quotients are a clue that Massachusetts has greater engineering knowledge in those technologies; these skills and specialist knowledge could offer comparatively abundant resources for new product development in medical devices. New product development is often about developing new technology combinations and new engineering skills and knowledge.

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companies' products are coded; editing by a senior researcher; data entry; internal proofing; machine check that applies various tests to each record; external proofing; and written verification of the record from the listed company.

FIGURE 1
CorpTech Technology Classification System

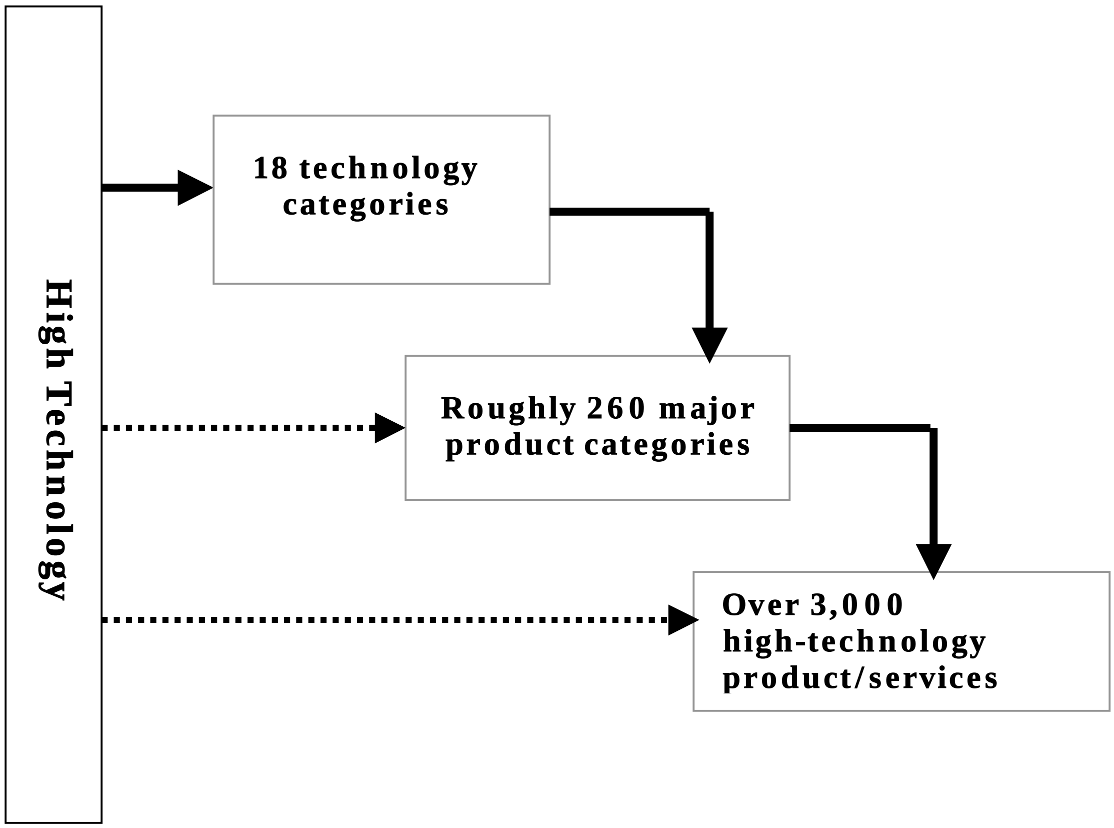


TABLE 1

CorpTech Technology Classification System

18 High Technology Categories	
AUT-Factory Automation	MED-Medical Equipment
BIO-Biotechnology	PHA-Pharmaceuticals
CHE-Chemicals	PHO-Photonics and Optics
COM-Computer Hardware	SOF-Computer Software
DEF-Defense	SUB-Subassemblies & Components
ENR-Energy	TAM-Test and Measurement
ENV-Environmental	TEL-Telecommunications & Internet
MAN-Manufacturing Equipment	TRN-Transportation
MAT-Advanced Materials	ZZZ-Holding Companies

TABLE 2

CorpTech Major Product Code System

13 Medical Equipment Major Product Codes	
MED-DE	Dental equipment
MED-DG	Medical diagnostic
MED-HA	Handicap aids
MED-HH	Home healthcare products
MED-IM	Implants/prostheses
MED-MO	Medical monitoring
MED-RE	Rehabilitation devices
MED-RP	Medical-related reproduction
MED-SU	Surgical/medical
MED-SV	Medical services
MED-TH	Medical therapeutic
MED-VT	Veterinary
MED-ZZ	Other medical

TABLE 3
CorpTech Minor Product Code System
MED-DG (diagnostic equipment) Product/Service Codes

MED-DG-A Medical analyzers	MED-DG-LE Electrolyte analysis
MED-DG-B Blood processing equipment	MED-DG-LM Microtomes
MED-DG-C Cardiovascular equipment	MED-DG-LP Pathology processors
MED-DG-D MED diagnostics instruments	MED-DG-LS Staining machines
MED-DG-I Medical imaging systems	MED-DG-LT Serological testing equipment
MED-DG-IA Array imaging systems	MED-DG-LZ Other medical laboratory equipment
MED-DG-IC Computer equipment for images of isolated body structures	MED-DG-M Electronic diagnostic equipment
MED-DG-ID Digital imaging equipment	MED-DG-MR Respiratory diagnostic equipment
MED-DG-IF Film imaging equipment	MED-DG-MP Physiological testing equipment
MED-DG-II Imaging processing equipment	MED-DG-MT Thermographic equipment
MED-DG-IL Laser imaging equipment	MED-DG-MZ Other electronic med diagnosis equipment
MED-DG-IM Mammography equipment	MED-DG-P Medical cameras
MED-DG-IN Nuclear medicine equipment	MED-DG-T Medical test kits
MED-DG-IR Magnetic Resonance equipment	MED-DG-TB Blood test kits
MED-DG-IS Spectral tomography equipment	MED-DG-TC Cancer test kits
MED-DG-IT Transillumination equipment	MED-DG-TD Drug test kits
MED-DG-IU Ultrasound imaging systems	MED-DG-TI Infectious disease test
MED-DG-IX X-ray imaging systems	MED-DG-TF Fecal test kits
MED-DG-IZ Other med. Imaging systems	MED-DG-TM Immunology test kits
MED-DG-L Medical lab equipment	MED-DG-TU Urine test kits
MED-DG-LB Microbiological test equipment	MED-DG-TZ Other medical test kits
MED-DG-LC Cell counters	MED-DG-Z Other medical diagnostic equipment

TABLE 4
Enterprise Location Quotients: MED

Year	California	Minnesota	Massachusetts	New Jersey
1990	1.2	3.4	3.5	2.6
1995	1.3	2.9	3.5	2.2
2000	1.6	3	4.2	2.1
2003	1.6	3	4.2	2

TABLE 5
Enterprise Location Quotients (MED major product codes)

		Massachusetts ELQs	# of Companies	Minnesota ELQs	# of Companies
MED-DE	Dental	2.6	8	2.1	5
MED-DG	Diagnostic	4.4	79	1.9	26
MED-HA	Handicap aids	3.7	12	6.3	16
MED-HH	Home healthcare products	3.8	4	4.9	4
MED-IM	Implants/Prostheses	6.9	24	6.6	18
MED-MO	Monitoring equipment	4	26	5.5	28
MED-RE	Rehab devices	1.4	2	4.5	5
MED-RP	Reproductive-related equipment	0	0	2.7	1
MED-SU	Surgical/Medical equipment	4.4	83	3.6	53
MED-SV	Medical services	5.3	68	2.5	25
MED-TH	Therapeutic equipment	3.7	43	4.5	41
MED-VT	Veterinary equipment	3.4	4	1.5	1

TABLE 6
Enterprise Location Quotients: MED-Related Technologies

Category	Massachusetts		Minnesota	
	1990	2003	1990	2003
Tests and Measurements	3.3	3.3	1.9	1.7
Photonics	5	4.2	1.5	1.1
Medical	3.5	4.2	3.4	3
Biotechnology	3.6	4.7	1.6	1.2
Pharmaceuticals	2.9	3.9	1.5	1.1

Enterprise location quotients are interesting first indicators of distinctive regional technological capabilities. The technology taxonomy provides more information about specialization patterns than SIC- or NAICS-based research. Nevertheless, the information provided by ELQs is limited. We have not taken account, for example, of company size. In addition, ELQs do not offer an explanation of development processes. For that information, we need to go inside the firm.[10]

As noted, the technology taxonomy is applied to both the firm and its products. This allows us to include firms that are classified in non-medical technology codes, but that make medical products. In the case of Massachusetts for 2004, of the 282 operating units, we identified 177 companies classified as MED in Massachusetts and another 105 companies that are classified as non-MED, but that make MED products (see Table 7 for the years the MED companies were founded). A total of sixty-three of these had more than two hundred employees (32 MED, 31 non-MED).[11]

TABLE 7
Founding Years for 2004 (4th quarter)
Massachusetts MED Companies

Years	**#**
Pre-1950s	18
1950s	5
1960s-1970s	28
1980s	64
1990s	50
2000s	12
Total	**177**

[10] Recently we have become aware of an ambitious effort to build a longitudinal dataset of all companies in the United States using Dun and Bradstreet and D&B's extended SIC classification system. Referred to as NETS for National Establishment Time Series, this has considerable merit. Viewed online 1 Nov. 2005. URLs: **http://www.iza.org/conference_files/TAM2005/neumark_d1769.pdf** and **http://www.ppic.org/content/pubs/R_405JZR.pdf**.

[11] In this paper we focus most of our attention on companies with more than 200 employees. We have employment numbers over the period 1989 to 2004 period for 63 companies with 200 or more employees (32 of which are not classified as in MED, but which make MED products) and 199 with fewer than 200 employees for which employment data are available. There are another group of companies that either had over 200 employees sometime between 1989 and 2003, but which have been declining in size or which are no longer operating in Massachusetts. Subtracting these, we are left with roughly one hundred companies of over 200 employees that have produced MED products in Massachusetts over the 1990 to 2004 period.

We begin by looking at a group of seven fast-growing medical device firms with over 1,000 employees that grew rapidly in Massachusetts over the past fifteen years. This group is lead by Boston Scientific, whose sales grew from $2 million in 1965 to over $3.5 billion in 2003. Second, we look at fast-growing, mid-size medical device companies and operating units located in Massachusetts. While most are Massachusetts-headquartered companies, we also identified fast-growing operating units of companies headquartered in other states.

Third, we turn to fast-growing, non–medical device companies that make medical device products. As noted, the database and classification system allow us to identify non–medical device companies that make medical device products or provide medical device services. Included here are specialist outsourcing and manufacturing services companies. These companies straddle industry boundaries and are most important in understanding industrial change and renewal.

Fourth, we examine a group of large-instruments companies that have transitioned into medical devices. The size of these companies suggests they can play a major role in cluster development.

Finally, we identify a large group of foreign-headquartered companies that have operating units in Massachusetts. This group offers clues to the distinctive regional capabilities that cannot be found elsewhere.

Growing a Cluster: Entrepreneurial Firms and Regional Technology Development

Firms drive cluster growth but not all firms do so. Our attention is on entrepreneurial firms defined as enterprises that compete on the basis of new products, processes, technologies, and/or organizational capabilities.[12] Growth is an indicator of success.

Fast-Growing, Big Companies. Fast-growing medical device companies with over 1000 employees located in Massachusetts are shown in Figure 2 and Table 8. However, the story begins with Boston Scientific, a leader in organizational innovation.

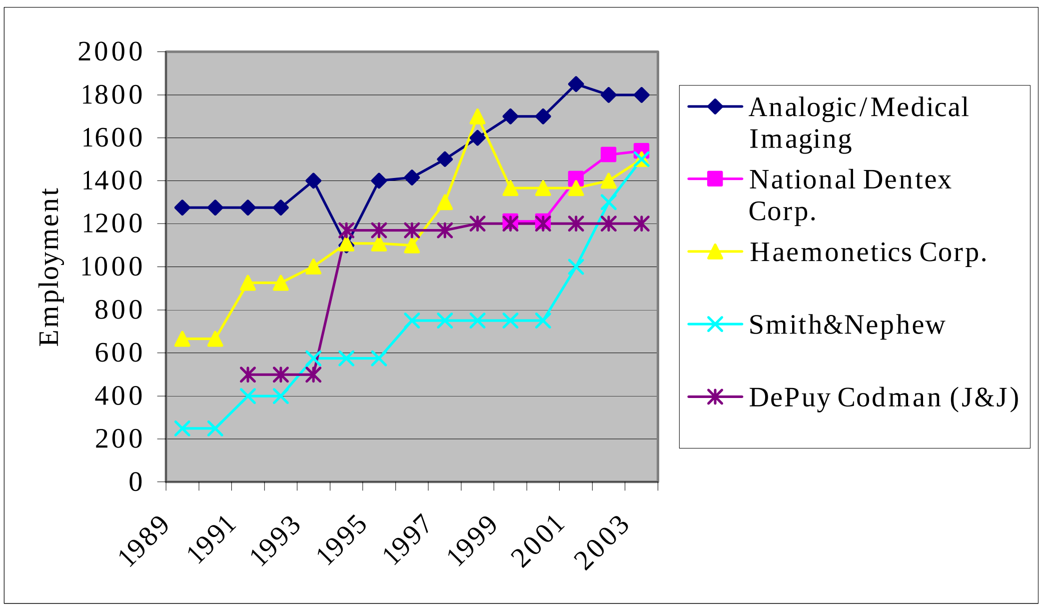
Boston Scientific: The Paradigm Case. Boston Scientific is a growth behemoth. If one had to explain the rapid growth of the medical devices industry in the United States and in the Boston area in terms of one firm, that firm would be Boston Scientific. In 1979, the national industry was worth only $10 billion and only one company, Medtronic, Inc., had significant size; in 2004, the industry, narrowly defined, was worth nearly $94 billion. Over the same twenty-five years, Boston Scientific's revenues grew from $2 million to $5.6 billion. Employing over 17,000 worldwide, it

[12] The debt to Joseph Schumpeter is obvious: *Capitalism, Socialism and Democracy* (New York, 1942), 84.

has become the largest medical devices company in the world in the category of minimally invasive therapy.[13]

The Boston Scientific story began in 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, which were used in some of the first less invasive procedures. Peter Nicholas, co-founder, had run the medical products division of Millipore Corp, a large purification equipment company in the biotech and pharmaceutical sectors.[14] Both men are still leaders at Boston Scientific.

FIGURE 2
Fast-Growing, Big MED Massachusetts Companies
(excluding Boston Scientific)



[13] 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 conversion of over 10,000 catalog product items in over fifty categories into these four codes illustrates the value of the CorpTech taxonomy.

[14] Founded in 1954, Millipore (4,000 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 company uses infiltration equipment to purify DNA and RNA proteins. Waters Corporation (4,000 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. In a sense, Boston Scientific represents "renewal" of the equipment and instruments industries of Massachusetts in the form of extension into medical devices.

The small size of the medical devices industry pre-1979 reflected the bespoke and passive character of device production. Medical device companies were primarily small-instrument companies that built custom devices to physicians' specifications.

The market development challenge was organizational (even political and academic), as well as technical. Power in the medical community was concentrated in the physicians and in cardiology; 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 physician acceptance of angioplasty, a less-invasive, non-surgical approach to treating diseased arteries. In the words of Abele, for many physicians at the time, non-invasive surgery was immoral and unethical because it was "safer to have a big opening so if something went wrong it was easier to fix it."[15]

Abele first had to win the academic argument and communicate it within the medical community. Forming a partnership with a leading physician was crucial to the early development of Boston Scientific as it was to Medtronic. Medtronic's pacemaker technology was an outcome of a long collaboration between Earl Bakken and Dr. C. Walton Lillehei, a pioneer in open-heart surgery at the University of Minnesota's School of Medicine.[16] A similar partnership between John Abele and Andreas Gruentzig, M.D., was pivotal to the creation of Boston Scientific's revolutionary angioplasty technology. Both Bakken and Abele emphasize 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 writes the following: "Our friend and collaborator, C. Walton Lillehei of the University of Minnesota, spread the word throughout the worldwide medical community."[17]

Both companies built such partnerships into their product development and technology management processes. In the words of Abele: "Our strategy was to find the Gruentzigs of the world, who would look at a new technique and then do the appropriate research, teaching and communicating."[18] Boston Scientific engaged the medical community directly, as well, by sponsoring seminars in the medical research com-

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[15] Erik Swain, "Boston Scientific: Making the Most of its First 25 Years," *Medical Device and Diagnostic Industry* (Aug. 2004), 9.

[16] 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* (Minneapolis, Minn., 1999), 46.

[17] Bakken, *One Man's Full Life*, 63.

[18] Swain, "Boston Scientific," 8.

TABLE 8
Fast-Growing, Big MED Companies
(employees)

Company	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Analogic/Medical Imaging	1,275	1,275	1,275	1,275	1,400	1,100	1,400	1,414	1,500	1,600	1,700	1,700	1,850	1,800	1,800
National Dentex Corp.											1,211	1,211	1,408	1,521	1,540
Haemonetics Corp.	666	666	925	925	1,002	1,109	1,109	1,100	1,300	1,700	1,366	1,366	1,366	1,400	1,500
Smith&Nephew	250	250	400	400	575	575	575	750	750	750	750	750	1,000	1,300	1,500
DePuy Codman (J&J)			500	500	500	1,170	1,170	1,170	1,170	1,200	1,200	1,200	1,200	1,200	1,200
MediSense/Abbott Labs (1999)	60	60	701	800	650	650	850	2,000	2,000	500	1,500	1,500	700	800	800
Boston Scientific				1,738	2,050	4,200	5,000	5,430	9,580	11,000	14000	13,500	13,500	13,500	14,400

munity including in the hospitals. This was new: "The idea of somebody from business giving a presentation at a medical school, even if it were technical, was heretical." No doubt the large number of research hospitals in the Boston area was a source of competitive advantage in establishing collaborative relationships.

However, 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 not only had to be convinced of the arguments for the new technology and methodology of minimally invasive therapy (MIT); they also had to be educated in the procedures and earn Food and Drug Administration (FDA) acceptance.[19] At the same time, device engineers had to be responsive to the physicians' knowledge and able to channel feedback into the product design process. The challenge was one of integration, of communication across disciplines and specialties. Successful new product development demanded more than inputs from each of these occupational specialties on their own; it was necessary to develop organized procedures for ongoing dialogue and translation across disciplinary domains.

It was necessary to integrate customers and suppliers into the new product development and production processes as well. Nicholas led the effort to reorganize business units to interface directly with major customers, rather than through specialist marketing or sales offices. This tactic opened up direct lines of communication between customers and product developers and makers. Suppliers to Boston Scientific were encouraged to reengineer their own organizations along the same lines; this 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.[20]

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 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. Here Boston Scientific has both

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[19] While medical devices were brought under FDA regulatory authority in 1976, the control of product design and operating procedures was in the hands of physicians and the medical profession.

[20] W. Edwards Deming, *Quality Productivity and Competitive Position* (Cambridge, Mass., 1982).

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 specialty markets within the medical field that are still encumbered by organizational barriers to product development. In the words of Abele:

> . . . we were not focused on one marketplace. For example, radiology was big on guidewires, but urology, gastroenterology, and cardiology weren't. But communication between those specialties was, and still is, almost nonexistent. 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.[21]

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 initial public offering (IPO) was followed by an aggressive acquisition strategy. These moves were triggered by the withdrawal of Abbott Laboratories, a substantial investor in Boston Scientific, due to the uncertainty associated with the Clinton healthcare plan. In the words of Abele: "Neither Peter nor I wanted to go public, because we were concerned about managing to short-term expectations as opposed to strategic building but realized it was the least-worst option."[22]

Ironically, Boston Scientific was a major beneficiary of the threat to the industry created by the Clinton healthcare plan. Minimally invasive surgery was consistent with the new focus on driving costs down. Moreover, the concerns about profit margins reduced share prices at exactly the time that Boston Scientific undertook its acquisition strategy. By the end of 1995, Boston Scientific had made five acquisitions, entered two alliances, and gone from under 2,000 employees in 1992 to 5,000. Employment would double again in the next three years.

Boston Scientific's acquisition strategy had two prongs. First, Boston Scientific 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: "...there 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."[23]

Organizationally, Boston Scientific must have provided the business model for management in other companies in the region. It is one of a

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[21] Swain, "Boston Scientific," 13-14.
[22] Ibid., 7.
[23] Ibid., 18.

handful of Massachusetts companies that have grown to Fortune 500 size since the demise of the minicomputer giants in the late 1980s.[24] The life sciences replaced computers as the source of growth over the same period. However, the business model of the new leaders has also been transformed. An open-systems business model, in which companies focus on core capabilities and partner for complementary capabilities, has replaced the vertically integrated organizations of the past. It also represents 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 Companies. While Boston Scientific, with over 14,000 employees worldwide is in a class of its own, at least five other companies located in Massachusetts and classified in MED by CorpTech can boast over 1,000 employees (see Table 8). If Boston Scientific is the largest medical devices company in Massachusetts, DePuy Codman, founded in 1838 by Thomas Codman, a mechanic in Roxbury, Massachusetts, is likely the oldest.[25] 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. The company had many "ups and downs," but, according to its website, maintained a core of skilled instrument makers and an apprenticeship program.[26]

In 1964, Codman & Shurtleff, Inc., became a member of the Johnson & Johnson "Family of Companies" while retaining its Codman company 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, later, a set of instruments that allowed an anterior approach to the cervical spine for treatment of diseased and herniated intervertebral discs. In fact, some of the first joint reconstruction implants, marketed under the name Cintor, led to the creation of the Johnson & Johnson Orthopaedics division, today named DePuy.

The Endoscopy Division of Smith and Nephew, Inc., is an operating unit of its U.K. parent. Originally Dyonics (founded in 1986), Smith and Nephew acquired this operating unit in 1996. The Endoscopy Division designs, develops, and manufactures endoscopic surgical instrumentation

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[24] 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," *Boston Globe*, 17 May 2005, F-1, 8.

[25] Another candidate is American Optical Lens, established in 1833.

[26] Viewed 4 Nov. 2005; URL: **http://www.jnjcodman.com/about.asp**.

used in minimally invasive surgery, including miniature cameras, xenon light sources, and arthroscopic surgical instruments.

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

Analogic Corporation's Medical Imaging Division represents Massachusetts's 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 variety of imaging systems including digital, laser, phased array, magnetic resonance, and ultrasound. The parent, Analogic Corp., has sales of nearly $.5 billion.[27]

MediSense, founded in 1981 as an R&D unit in bio-diagnostics, moved into biosensor technology for blood glucose monitoring in the personal healthcare market. It grew to 850 employees in 1995.[28] Acquired by Abbott Laboratories in 1999, it merged with Abbott Diabetes Care in California in 2004.

National Dentex Corporation, headquartered in Massachusetts, is the nation's largest operator of dental laboratories. Its chain of forty-one laboratories manufactures bridges, crowns, and dentures for 20,000 dentists throughout the United States.

Six of the seven big, fast-growing Massachusetts-headquartered MED companies (including Boston Scientific, but not including National Dentex or MediSense) fit squarely within one of the three related production capability areas in which Massachusetts has historically had competitive advantage: instrument-making, precision equipment, and complex product systems.[29] In this sense, their success can be considered a process

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[27] 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.

[28] Employment reported to CorpTech was erratic in the post-1995 period, sometimes as high as 2,000, but 850 appears more reliable.

[29] For a description of production capabilities in Massachusetts, see Best, *The New Competitive Advantage.*

of industrial renewal, as fast-growing companies reallocate resources in pursuit of new market opportunities, but also tap the region's production and technological capability heritage.

Fast-Growing, Mid-size Medical Device Companies

A large group of fast-growing, mid-size medical device companies, or operating units, is located in Massachusetts (see Table 9). Mid-size is defined as having between 200 and 1,000 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.

TABLE 9
Fast-Growing, Medium-Sized MED Companies
(employees)

Companies	Founded	1990	1995	2000	2001	2002	2003
Lifeline Systems, Inc	1974	250	325	620	790	850	850
Inverness Med Innovations	1992		78	419	704	800	800
Hologic, Inc.	1985	130	170	600	839	780	750
Nova Biomedical	1976	475	500	500	664	665	665
Cytyc Corp.	1987	25	55	200	495	495	626
Zoll Medical	1980	150	275	390	430	585	585
Candela Corp.	1970	174	180	285	285	300	325
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 Instru.	1975	60	145	145	149	149	195
Hologic/Lorad	1989	150	280	350	350	275	
Summit Technology	1985	60	211	425	Acquired by Nestle SA		
NMC Diagnostics	1971	140	250	Acquired by Fresenius AG in 1998			

Massachusetts Headquartered. An analysis of twelve fast-growing, mid-sized MED companies that remain headquartered in Massachusetts reveals the following:

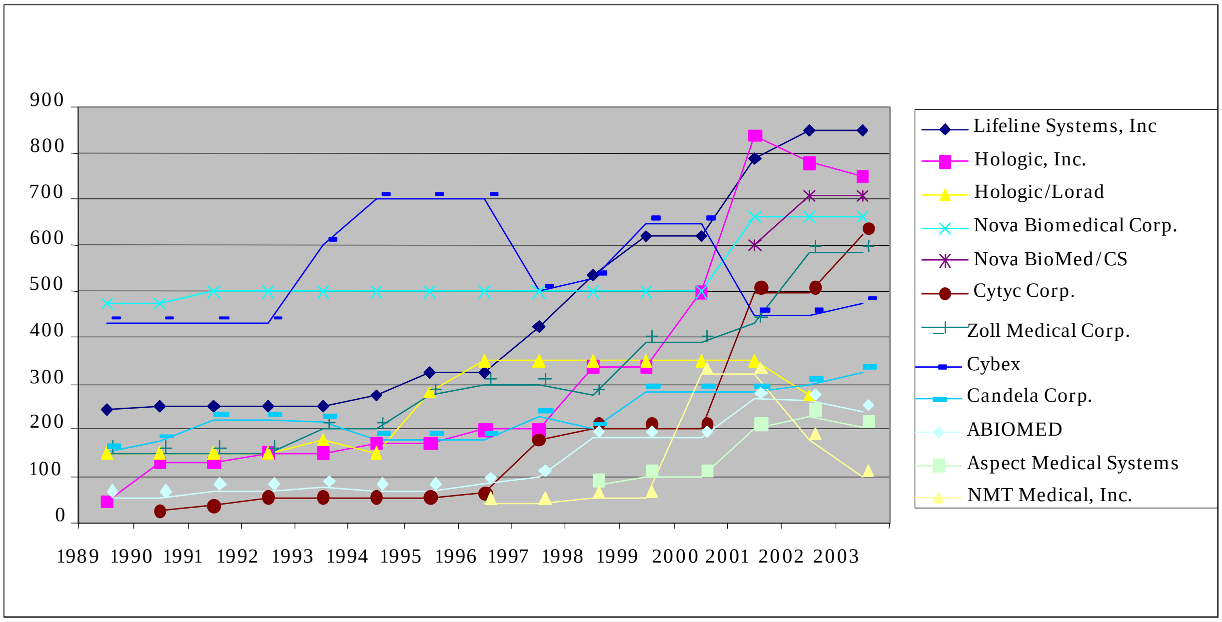
a) Employment increased from under two thousand in 1989 to between six and seven thousand in 2003. A scatter plot of employment growth is shown in Figure 3.
b) They are long established companies. Cybex was founded in 1953.[30] Four were founded in the 1970s (Candela, NMC Diagnostics, Lifeline Systems, and Nova Biomedical) and eight in the 1980s.

[30] Gentex Optics, founded in 1932, was acquired by Essilor, a French firm, in 1995 and is included in the foreign-headquartered section below.

c) They 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 that centers on product development efforts and not mass production.

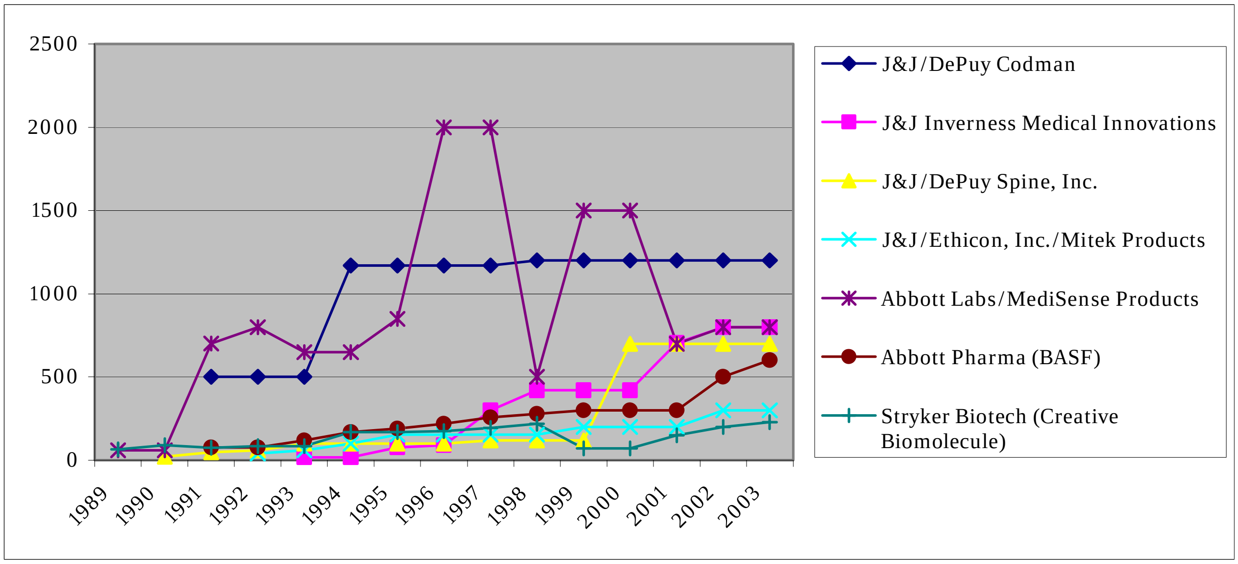
d) They reflect and reinforce the region's technological heritage. At least five are in imaging/scanning, four in optics, three are in blood processing/diagnostics, and two are in cardio equipment. These mirror fairly closely the big medical device companies in Massachusetts. Optics, in particular, is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

FIGURE 3
Massachusetts-Headquartered, Fast-Growing, Mid-Size MED Companies (employment)



Massachusetts Units Acquired by Out-of-State Companies. A group of five fast-growing, Massachusetts-founded companies acquired by leading MED companies headquartered elsewhere in the United States is shown in Figure 4. Medtronic can be added to this group, as this Minnesota company recently established a major presence in Massachusetts, in part 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.

FIGURE 4
Fast-Growing Massachusetts Units Acquired by Out-of-State Companies (employees)



Stryker Biotech (230 employees and $25 million in sales in 2002) is an operating unit of Stryker Corporation, a Michigan-headquartered Fortune 500 company that specializes in bone and joint repair and replacement.[31] As part of its move into biotechnology implants, Stryker acquired the aptly named Creative Biomolecules of Massachusetts in 1998 and moved to Hopkinton, Massachusetts. The use of human protein to initiate bone and joint tissue regeneration may revolutionize traditional bone graft procedures. The move to Massachusetts was likely a consequence of the region's biotech resources; the move into human protein implants is extending the boundaries of medical devices into life sciences.

Medtronic (31,000 employees, $9 billion in sales in 2004), founded in 1949, is the largest and most successful medical devices company in the United States. Mary Shelley's *Frankenstein* inspired Earl Bakken, its founder, to better understand the life-giving powers of electricity. Founded in the early days of electronics, Medtronic successfully anticipated the opportunities offered by technological advances in

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[31] Stryker Corporation, founded in 1946, had 14,000 employees and $4 billion in sales in 2004. Stryker generated a compound annual earnings growth of 25% over a 25-year period and was recently ranked #1 in *Fortune*'s America's Most Admired Companies in Medical Products and Equipment; see *Fortune* (3 May 2004), 162.

electricity and electronics to continuously redesign medical devices, starting with the heart pacemaker.[32]

In the last three years, Medtronic has made two strategic investments in Massachusetts technology development companies. First, Medtronic commissioned and completed a fast-track, multi-phased renovation project of a 137,000 square-foot building that includes a 26,000 square-foot, Class 100,000 clean room. This is part of a relocation of Medtronic's Medtronic Avenue unit, which manufactures angioplasty balloons and guiding catheters, from Santa Rosa California. Employing 600, the new Medtronic vascular unit designs and manufactures stents, stent grafts, balloon angioplasty catheters, guide catheters, guidewires, and diagnostic catheters and accessories. Boston Scientific presently is the market leader in this product range. Historically, Medtronic specialized in cardiac devices such as pacemakers and defibrillators, but has likely decided that the best place to operate a plant in minimally invasive cardio-therapy is in Boston Scientific's back yard.

Second, Medtronic has entered into a joint venture with the other largest company in the Massachusetts medical devices industry, Genzyme. Given Boston Scientific's success in combining devices with drugs and the vibrant biotechnology cluster in Massachusetts, it is likely that here, too, Medtronic came to Massachusetts for technology resources not available in its headquarters state of Minnesota. If technological convergence between medical devices and electricity was a platform for product development in Medtronics' early days, it is increasingly the present convergence of medical devices and biologics.

Abbott Laboratories (70,000 employees, $18 billion in sales, founded in 1888, headquartered in Illinois) has made several major investments in Massachusetts companies. It had been a substantial investor in Boston Scientific since 1983, but withdrew in 1992 because of uncertainty surrounding the Clinton healthcare proposals.[33] In 2002, Abbott created Abbott Pharmaceuticals with the purchase of BASF's Bioresearch Corp in Worcester, Massachusetts. Renamed Abbott BioResearch Center, the 600-employee unit is an R&D organization specializing in cancer and diseases of the immune system, but it also supplies contract-manufacturing services for biologics companies. In 1999, Abbott Laboratories acquired MediSense, a rapidly growing Massachusetts company specializing in the development and manufacture of blood glucose monitors. While growing from 60 employees in 1989 to 1,500 at

[32] Medtronic has not only been the leading U.S. medical devices company for much of its existence; it also spearheaded the growth of Minnesota's Medical Alley. Medtronic's family tree includes thirty-five companies that have been founded by ex-Medtronic employees; see Bakken, *One Man's Full Life*, 97. Not surprisingly, many are in the cardiac pacemaker arena.

[33] Swain, "Boston Scientific," 14.

the time of the acquisition, the unit was merged into Abbott Diabetes Care in California in 2004.

Johnson & Johnson (J&J) has had a low-key, almost unknown, presence in the Massachusetts medical device industry. They acquired Codman in 1964 with the acquisition of Ethicon, Inc., and Mitek in 1994. Codman (a name in medical devices that goes back a quarter-century before the Civil War) obtained "affiliate status as a free standing Johnson & Johnson subsidiary in 1966 and moved to Massachusetts headquarters in 1994."[34] Mitek's history is shorter, but it has applied minimally invasive surgery to implants, which facilitates the reattachment of damaged tendons and ligaments to bone. It was the first to apply Nitinol, an intelligent nickel-titanium alloy to implants and instruments. Today it is a leader in surgical sports medicine particularly in knee and shoulder reconstruction. In 2001, J&J acquired Inverness Medical Innovations, Inc., a manufacturer of in-vitro diagnostics products, and a specialist in non-invasive glucose sensors and fertility indicators. At the same time, J&J entered into a marketing partnership with Alkermes, a fast-growing Massachusetts biotech company.

J&J did not follow the pattern of pharmaceutical companies to sell off medical device companies in the mid-1990s.[35] J&J's corporate strategy of minimal interference in the operation of operating units may explain its success. The low price of medical device companies in the mid-1990s made them attractive for J&J as well as to specialist medical device companies, like Boston Scientific, seeking to leverage R&D and specialist technology platforms.

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 Abbott's 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. The companies must come to Massachusetts to acquire such capabilities, which are not easily removed to other locations.

Fast-Growing, Non–Medical Device Companies with Medical Device Products

Table 10 shows twelve companies that are not classified as medical device companies, but which design and make medical device products. Seven are classified in biotech, two in instruments, and one each in pharma-

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[34] Viewed 1 Nov. 2005; URL: **http://www.codman.com/**.

[35] Zimmer Holdings (1927) is another beneficiary of being cut loose by a pharmaceutical, in this case Bristol-Myers Squibb; see *Fortune* (3 May 2004), 164.

ceuticals, advanced materials, photonics, computer hardware, and computer software or pharmaceuticals, and three in physical science.

The growth in Massachusetts companies as measured by employment is remarkably equivalent in this group to that of big medical device companies. The twelve companies shown in Table 10 grew from around 1,000 employees in 1990 to nearly 20,000 employees in 2003, compared to the growth of the six big medical device–classified companies shown in Table 8, excluding MediSense, from around 2,200 in 1990 to 22,000 in 2003. The closest to Boston Scientific in employment is a combination of Genzyme, Parexcel, and Charles River Laboratories. None of the three, however, is located primarily in medical devices; all are life science companies and supply products and services to BIO, PHA, and MED. However, they all offer insights into the dynamics of a rapidly reconfiguring cluster.[36]

TABLE 10
Fast-Growing, Non-MED Companies with Medical Products

Company	Year Established	1990	2003		Product Codes
Genzyme	1981	450	5,500	BIO	MED, PHA
Charles River Labs	1946		5,000	BIO	MED
Parexcel International	1982		4,860	PHA	MED, BIO, COM
PolyMedica	1988	4	1,679	MAT	BIO, CHE, MED, PHA
Mercury Com	1982	180	600	COM	MED, SOF, TEL
Harvard Apparatus	1904	65	450	BIO	ENR, MED, SUB, TAM
Alkermes	1987	30	425	BIO	MED, PHA
Perceptive Informatics	2000		331	SOF	MED, TEL
Clinical Data	1972	9	302	TAM	
MJ Research	1985	15	220	BIO	CHE, MED, SUB, TAM
Bruker BioSpin	1972	100	180	TAM	MED, SUB
Organogenesis Inc.	1985	100	180	BIO	MED, TAM
Total Employees		953	19,727		

Genzyme, a leader in biotechnology, is categorized as pharmaceutical in both SIC and NAICS, but it is in "in vitro diagnostics," a rapidly expanding medical device category. It is considered squarely within the Medical Devices by the major trade publication *Medical Devices and Diagnostic Industry* and by most definitions of the medical devices

[36] Two other large company candidates for the category of rapidly growing non-MED companies with medical device products are PerkinElmer and Thermo Electron; they are treated in a separate category. The *Boston Globe*, for one, classifies both in medical devices, but this may be a stretch. Either way, PerkinElmer was not included in Table 10, although it is a major employer, because it was not a fast-growth firm over the period.

"cluster." 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. Genzyme is a major provider of bio-diagnostic products. It also supplies bioengineered tissue that helps repair damaged cartilage in the implant market.

Medtronic and Genzyme's recent joint venture, MG Biotherapeutics, was created to develop cellular therapies for cardiovascular disease. Cell therapy is the transplantation of human or animal cells to replace or repair damaged tissue. For example, cells involved in muscle formation are obtained from a patient prior to coronary bypass procedures and grafted into the heart to stimulate self-repair of, in this case, a muscle that does not have regenerative capacity.[37] Genzyme will provide biologic technology and Medtronic will provide biomaterials and deliver tools, imaging, and navigational technologies to deliver the cell therapies.

Parexel is one of the largest contract research organizations in the world. 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 industries 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 in their core capabilities and outsource 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. Collaborating 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 twenty-three of the top twenty-five drugs introduced in the world in 2000.[38]

Perceptive Informatics is an operating unit of Parexel that links information technology to clinical trial management in the form of web-based hosting services, interactive voice response systems, and medical trial software, thus combining TEL, SOF, and MED.

The rapid growth of Parexel in clinical trial services is one example of the rapid development of outsourcing in medical devices. Another is the UTI Corporation, a leading "integrated" outsourcer of manufacturing services. UTI acquired Minneapolis-based MedSource Technologies, Inc., making the 3,500-employee combined entity one of the world's largest

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[37] The joint venture will be managed initially by a six-member board of directors consisting of three representatives from each company, and the fifty-strong staff will continue to be employees of their respective parent companies: "This is a compelling advantage, in that we can benefit from the talent, expertise and resources of the parent companies immediately—rather than building a new work force." URL: **http://www.medtronic.com/Newsroom** (4/28/2005).

[38] Viewed 1 Nov. 2005; URL: **http://www.parexel.com/about_us/history.asp** .

medical device outsource manufacturing, design, and engineering companies. The renamed entity, Accellent, has moved its headquarters from Pennsylvania to Massachusetts. Interestingly, Accellent's relocation represents a return of the remains of at least three once-independent private companies to Massachusetts: Brimfield Precision, APEX Engineering, and ACT Medical. MedSource Technologies earlier acquired all three.

Charles River Laboratories, formed in 1946, has repositioned itself in recent years from a company specializing in animal research and diagnostics to human research models required in R&D for new drugs, devices, and therapies. It now specializes in clinical trial support and a portfolio 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, is another very fast-growing company in the medical device and diagnostic industry, although classified in Advanced Materials. "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 its becoming a leading provider of healthcare products and services to patients with chronic diseases. Polymedica is the nation's largest provider of blood glucose testing supplies to people with diabetes, most of which are supplied directly to the consumer.

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 turnkey systems, subsystems, and components (most of which leverage laser technology) to OEMs that compete in industrial, medical, imaging, and laboratory marketplaces. Besides developing and making laser imaging equipment for medical applications, GSI Lumonics designs, develops, and manufactures laser-based systems for precision-manufacturing applications such as silicon wafer marking and high-focus drilling and cutting.

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

Clinical Data was in drug delivery systems and, more recently, has developed transdermal patch products for drug delivery. 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. Thus, Clinical Data is classified as an instruments testing and measurement (TAM) company with chemistry expertise and medical applications.

MJ Research manufactures molecular bioelectronic equipment and instrumentation, including DNA analysis equipment, and sells to biochemical, biomedical, and molecular biology markets.

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

Market Transition Companies

Big Instrument Makers. PerkinElmer and Thermo Electron, two large and long-established Massachusetts instrument makers, are classified as medical device companies in the *Boston Globe*'s annual Globe 100 for 2005.

PerkinElmer is the present name of EG&G, a company founded in 1931 in a garage on Boston's Brookline Avenue by Massachusetts Institute of Technology professors Harold Edgerton and Kenneth Germeshausen, later joined by Herbert Grier. Along with Raytheon, EG&G became the state's leading federal government prime contractor in the postwar period.[39]

In 1999, EG&G sold its extensive portfolio of government services to URS, a large California-based prime contractor. As part of a dramatic transformation from government prime contractor into "life and analytical sciences," the company gave the rights to the EG&G name to URS and acquired the long-established corporate name of PerkinElmer with the acquisition of Applera, also in 1999. The PerkinElmer brand name fit the company's new direction.[40]

PerkinElmer, founded in 1937 in New York City, grew from humble beginnings in optics to a market-leading position in analytical instrumentation. PerkinElmer was often the first American instrument maker into new technologies, including gas chromatography in the 1950s, atomic absorption in the 1960s, liquid chromatography in the 1970s, and mass spectrometry (inductively coupled plasma) in the 1980s. In 1999, the Analytical Instruments Division of PerkinElmer was acquired by EG&G along with the "premium global brand" name in analytical instrumentation.

The new PerkinElmer acquired NEN Life Sciences and Parkard BioScience in 2000 and 2001. PerkinElmer has successfully made the transition to a supplier of a comprehensive set of instruments and instrument services to health science customers. It has moved into

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[39] Susan Rosegrant and David Lampe, *Route 128: Lessons from Boston's High-Tech Community* (New York, 1992), 25.

[40] Mass High Tech, viewed 1 Nov. 2005; URL: **http://www.masshightech.com/**, lists PEI as "Medical-other medical," and its product offering as life sciences instruments and consumables, test and analytical instrumentation, and telecommunications/communications equipment. Its CorpTech code is BIO.

instrumentation for genetic disease screening as well as drug discovery. The new PerkinElmer offers outsourcing services to pharmaceutical, biotech, and medical device companies for the maintenance, calibration, and validation of their instruments across the whole spectrum of techniques in their labs.

Although a smaller company today than during its EG&G heyday, the new PerkinElmer is large and, in recent years, successful. It has 12,500 employees and operations in over 125 countries, and it is a component of the S&P 500 Index. Sales grew by 10 percent in 2004 to nearly $1.7 billion. The growth is attributed to its medical imaging and its laboratory instruments services unit.[41] PerkinElmer also has divisions in optoelectronics and fluid sciences.

Thermo Electron, with $2.2 billion in sales in 2004, a 16 percent gain, is a second giant Massachusetts-founded and -based instruments company that has transitioned into the medical devices industry. Both the Boston Globe 100 and Mass High Tech directories classify Thermo Electron as a medical devices company.[42]

Long a world-leading manufacturer of measurement instruments that monitor, collect, and analyze information for a broad range of industries, Thermo Electron has recently established a leading position in markets for biomedical products (such as heart-assist devices, respiratory care equipment, and mammography systems).[43]

The next frontier after mapping genomes is the identification of all the proteins that genes express. It is a daunting task. Both PerkinElmer and Thermo Electron have leveraged mass spectrometry instrument technologies into, and anticipated, the emerging field of proteomics. Both make a range of mass spectrometers and similar instruments that tackle various challenges in protein characterization. While instrumentation to measure the mass of molecules was developed early in the twentieth century, technological innovations and advances in computational power have been integral to opening the worlds of genomics and proteomics to scientific investigation.[44] Thermo Electron takes the concept of full service supplier all the way to the provision of the services required to establish a fully operational laboratory, including coordination, procurement, delivery, and installation.

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[41] Ross Kerber, "Medical Devices: Years of Toil Pay Off in 2004," *Boston Globe*, 17 May 2005, F21.

[42] Mass High Tech classifies Thermo Electron as "Medical-medical device" contract manufacturers and its product offering as medical device contract manufacturer, industrial, and manufacturing controls/systems, engineering service, and medical equipment.

[43] Mass High Tech website viewed online 1 Nov. 2005; URL: **http://www.masshightech.com/**.

[44] Thermo Electron recently opened a new biomarker research facility in conjunction with Massachusetts General Hospital.

Foreign Companies

In medical devices, two complementary technologies stand out as candidates for achieving technology consolidation in the region: imaging and optics, both in instruments and in complex product systems. Operating units of leading foreign-headquartered companies benefit from and advance the region's specialized technology genealogy.

The behemoth here is Philips with 6650 employees, an estimated 2,000 within Massachusetts (see Table 11). Philips has a long medical equipment history going back to its founding in 1896, when Philips manufactured the first x-ray tubes for medical applications. With the acquisition of Agilent Technologies Healthcare Solutions Group (previously Hewlett-Packard Medical Products Group) of Andover, Massachusetts, in 2001, Philips became the number two medical equipment provider in the world.[45]

Philips also brings to the region a long history as a leading supplier of diagnostic imaging systems including x-ray, computerized tomography, and magnetic resonance imaging. In this, it joins a strong group of local and foreign-headquartered companies in imaging, optic, and laser technologies. In fact, of the twenty-one foreign-headquartered medical device companies with operating units in Massachusetts shown in Table 10, more than half are in imaging and/or optics.

Bruker BioSpin Corporation is 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.[46] Bruker has specialized since its founding on R&D in high-resolution NMR and its extension into mass spectrometry and in-vivo NMR or medical research MRI. Today, Bruker BioSpin makes nano-scale precision equipment for drug development and gene and protein research. The characterization of protein structures on a genome-wide basis is being pursued by a range of technologically related instruments combining x-ray crystallography, NMR spectroscopy, mass spectrometry, and cryo-electron microscopy, together with the help of bioinformatics, information management, and laboratory robotics.

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[45] 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 United Kingdom since 1915.

[46] 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 (New York, 1999), 328-30.

General Scanning, Inc., founded as a laser components engineering company in Massachusetts in 1968, grew to 1,500 employees when it merged with Lumonics, Inc., of Canada. Among other laser-based systems, GSI Lumonics develops and makes laser-imaging equipment for medical applications.

TABLE 11
Foreign-Headquartered MED Companies Located in Massachusetts (employment)

Company	Founded	1990	1995	2000	2003
HP/Philips (Holland)	1981	200	100	5,300	6,650
Smith&Nephew (UK)	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 MA, LLC (UK)	1949			100	149
The Straumann Co. (Switz.)	1989		35	68	160
Smiths Medical ASD, Inc. UK	1986		160	240	200
EBTEC/TI and Smiths UK	1963	80	60	75	80
Schott AG (Ger.)	1954	350	265	270	211
Seimens/Draeger Medical Systems, Inc.	1988	360	540	320	370
GSI Lumonics (Canada)	1968	350	399	1,500	950
Summit Technology Inc. (Switz)	1947	60	211	425	
NMC Diagnostics Services, Inc. (Ger.)	1981	140	250		
TUV Product Services Inc. (Ger.)	1989			250	149
Spacelabs Medical (Fin.)	1987		7	120	120
Bionostics, Inc./Ferraris Group (UK)	1982	40	55	55	55
Pyrosequencing, Inc. Sweden	2000				30
LightLab Imaging, LLC Japan	1998				12
Tecan Boston, Switz.	1994			26	12
Symfo (USA) Inc. Belgium	2000				35
Ophir Optronics, Inc. (Israel)	1985			130	25

Locally headquartered companies in the technology mini-cluster surrounding MRI include Analogic's Medical Imaging Division with over 1,000 employees and Mercury Computer with 600 employees in 2003. The state also has a number of small locally headquartered MRI companies such as ONI Medical Systems with 60 employees. However, ONI's small size is misleading, because its products are marketed and sold by Medtronic Surgical Navigation Technologies. Medtronic's alliance with this Massachusetts company is another indicator of the region's distinctive capability in imaging technologies.

Endoscopy is a second fast-growing medical device product domain in which foreign-headquartered companies have acquired and developed operating units in Massachusetts to gain the benefits of the region's distinctive technology genealogy. Optics in Massachusetts goes back nearly two centuries to the combined development of interchangeability and precision machining. American Optical Lens Company, still operating in 2005, was founded in 1833. Gentex Optics, acquired by Essilor of France in 1995, was founded in 1932.

Endoscopy, which allows the illumination and visualization of organs, tissues, bones, and joints, is the cornerstone of minimally invasive surgery. It is a rapidly growing field in which Massachusetts has a number of large, innovating companies. The U.K.-headquartered Smith and Nephew, which acquired Dyonics in 1996 to create an endoscopy division in Worcester, Massachusetts, to specialize in joints, now has 1,500 employees.

The region has a long record of innovation in endoscopy-related technologies and companies. ACMI (American Cystoscope Makers, Inc.), founded in 1908 and recently headquartered in Southborough, Massachusetts, has been a leader in the development and production of the world's finest endoscopy instrumentation. More recently, ACMI is credited with developing the first endoscopic instruments using flexible glass fiber technology to conduct images through thousands of flexible glass fibers rather than rigid rod lenses. In 1986, ACMI joined with CIRCON Corporation to launch the first successful medical video system. In 2005, its R&D group claims to have developed the world's smallest digital camera and video color sensor. While located in Stamford, Connecticut for several decades, today ACMI has approximately 1,000 employees worldwide.

Findings

We have used a historical dataset of medical device companies as a metaphorical laboratory to study the emergence of a high-tech industrial district in Massachusetts. We screened the dataset for rapidly growing companies, transitioning companies, and foreign-headquartered subsidiaries. The analytical preconception is that growing, transitioning, and relocating companies are the drivers of industrial growth and, as such, the carriers, developers, and consolidators of underlying and regionally distinctive technological capabilities. The theoretical motivation is to contribute to a perspective on regional specialization and economic growth in which the development of capabilities and the advance of associated skills and expertise are center stage. The research challenge is to characterize the distinctive capabilities that impart regional competitive advantage and are not immediately obvious even to the entrepreneurs who build the successful enterprises. While not meeting the full challenge, our findings from the application of this research methodology to the medical devices industry of Massachusetts do offer insight into the processes of regional specialization and the construction of regional competitive advantage. These include:

Technology development, specialist companies with long time horizons. Most of the rapidly growing firms, mid-size and large, have been established for at least a decade. Many were established for a decade or more before a high-growth period. Further, most are specialist technology development companies as distinct from component suppliers linked by supply chains. Surprisingly few are competing in the same market niche; most are in pursuit of an innovative product or technology. The most successful, such as Boston Scientific, first developed a technology platform and then pursued an acquisition strategy to develop and leverage the platform in new markets.

Although not examined in this paper, small firms also play a major role. Perhaps the most obvious effect (and difference in business model from the heyday of the vertically integrated multidivisional) is the spread of an "open systems" business model. It creates opportunities for small firms to specialize in technology development and to outsource many of the requisite complementary capabilities.

Technology as a never-completed project. Perhaps surprisingly, the product domain in which medical device companies operate does not change much over time. What does change is the technology incorporated into and engineering knowledge that are applied to the product. In this sense, technology is an incomplete project; new product development, in important part, is about advancing the technological properties of the product and involves tapping new sources and types of technological expertise. The prize is the development of a technology platform that gives the company a stream of products and the ability to leverage the technology platform in new markets.

Production capability heritage. Over nearly two hundred years of industrial history, Massachusetts has developed knowledge communities, in the form of specific engineering expertise or "deep craft skills," in instruments, precision equipment, and complex product systems. The firms that have been most successful in these product domains have not been large by Fortune 500 standards. The region has never been home to mass production, high-throughput production capabilities, or the large vertically integrated and multi-divisional enterprises that developed them. Big industrial enterprises operating in high-volume consumer products are virtually non-existent and have been so for much of the region's modern industrial history.

Nevertheless, the region has maintained a sizable and vigorous industrial base that has been obscured by the conventional classification systems and measures of industrial activity. The region's technology and product base has been renewed many times over with the design and development of new product generations and the establishment of new industrial sectors. The medical devices field, with its plethora of mid-size firms, is but the latest in a long history of a product/technology sector that has both tapped into, and further advanced, the region's unique production capability and skill heritage.

Regional technology "DNA." A region's technological heritage is harder to characterize, but, in all likelihood, is closely linked to its production heritage in industrial products. Turbine technology, for example, which first optimized the energy from water to power textile mills, can be applied to jet engines and to traditional power generation as well as to renewable energy. Firms across market sectors and, over time, within a region, are able to draw from this technical knowledge community and, in the process of ongoing activities, contribute back to it.

Medical device companies have benefited from the region's historic and distinctive capability in working with small size dimensions. This began in the early days of applying the production principle of interchangeability at the Springfield Armory and the resultant emergence of a precision machine-tool industry and precision engineering skills. It is true today in the development of nano-dimension devices to deliver biotech products to specific cells. In addition, today's medical device companies leverage a regional technology heritage in optics and imaging. In recent decades, the region has attracted out of state and foreign-headquartered companies in optics and imaging-related technologies including opto-electronics and photonics.

Perhaps not surprisingly, many 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 in life sciences are 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. Massachusetts' long history of precision engineering and instrument-making capabilities has gone through many design iterations with transitions from defense to minicomputer to information-communication technologies, and now to life science–based industries.

Regional technology consolidation. Over half of the roughly twenty foreign-headquartered operating units in Massachusetts are in the optics, imaging, and laser technology domain. This concentration reflects the historic strengths of Massachusetts and implies the co-location of enough enterprises and expertise to suggest a regional technology consolidation. Foreign-headquartered Bruker BioSpin, Philips, and GSI Lumonics all attest to a technology consolidation in MRI, spectroscopy instruments, and related imaging equipment in the region. Similarly, the location of Smith and Nephew's endoscopy division and the relocation of ACMI's headquarters to Massachusetts is an indication that the region is gaining a critical mass of companies in this rapidly growing technology.

More recently, Massachusetts has established a regional advantage in the overlapping medical devices and biotech technology domain. Medtronics' joint venture with Genzyme to develop cellular therapies for cardiovascular disease unites medical devices and biotech at the organizational level, devices and drugs at the product level, and physics and biologics at the scientific level. Similarly, Stryker Corporation, a 14,000-employee, Michigan-headquartered medical devices company, established its biotech implant unit in Massachusetts with deep technical expertise at the boundaries of medical devices and biotech. Consolidation of a technology capability in a region will act as a magnet attracting companies working in the same technology domain, reinforcing the region's distinctive technology capabilities.

Techno-convergence, industrial differentiation, and growth. Jane Jacobs focused attention on growth as a process of industrial differentiation, including the creation of new industrial sub-sectors.[47] Boston Scientific opened up a new product domain with the development of angioplasty as a minimally invasive technology substitute for open-heart surgery. This may not qualify as a new industry, but it has many of the characteristics of one, including the integration of devices and drugs. Similarly, Genzyme's development of biological diagnostics led to the rapid growth of what has become a major sub-sector of medical devices. The rapid growth of these two companies in the ranks of Fortune 500 companies has pulled along a whole "industry" of imitators in minimally invasive surgery and in vitro diagnostics. Thus, Medtronic moved its cardiac stent operating unit to Massachusetts, where Boston Scientific has long established market leadership. Minnesota's Medical Alley does not have the same degree or scale of specialized technological expertise.

Why did Boston Scientific and Genzyme grow so rapidly in Massachusetts? Part of the reason is that the region had deep craft skills in both devices/instruments and biotech/tools. Such rapid growth necessitated the attraction and mobilization of technically skilled resources on a large scale. There is no doubt that the region's academic research hospitals were also critical, but they were not sufficient. The early success of the two firms has contributed to processes of cumulative causation in which an initial early advantage was converted into distinctive regional capabilities.

The emergence of a regional innovation system. New product development capability is at the heart of technology-driven companies. It is also enormously costly. With the decline in the big enterprises that dominated the computer industry in Massachusetts, the region lost a host of sizable enterprises with large R&D budgets. Technology and NPD are highly costly. From a regional growth perspective, NPD is the immediate source

[47] Jane Jacobs, *The Economy of Cities* (New York, 1969).

of innovation. The fear that technology and NPD would suffer and that the region would go into industrial decline has not been realized.

The major reason is that the organizational model of innovation and NPD has undergone structural change, a transition from an organizational structure of vertical integration to one of “open-systems.” With it, the design and experimentation activities central to NPD have been decentralized and diffused.

It remains true that larger, successful companies can afford to establish NPD departments and/or project groups in which the product-to-market process is integrated via cross-functional teams. However, the product development function has been altered in two ways. First, the “open-systems” focus and network business model have fostered a proliferation in the number of firms with NPD capabilities. Second, product development increasingly involves leveraging the capabilities of partners.

We have noted that a common feature of most of the rapidly growing mid-size firms is the drive to develop new products and a unique technology platform from which to leverage their product capability into new markets. At the same time, the rapid pace of new product development has put pressure on firms to form alliances based on open standards so that each firm can concentrate its R&D on its distinctive expertise—for example, the rise of outsourcing expertise in manufacturing with specialist companies like Accellent or in clinical trials with Parexel. Both companies not only provide products or services; they also participate directly in their partners’ product development processes.

Here, again, the region’s techno-diversity has been an advantage. It has been a key element in the transition to a new, regional system of innovation. The NPD process is the vehicle by which new industrial sub-sectors are created, and NPD often involves technology integration. 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. The high enterprise location quotient in each of these domains reflects the techno-diversity of the region and the enhanced opportunities for NPD, the handmaiden of industrial differentiation.

In this, the region can be said to have NPD and technology management capabilities even though many of the firms, especially the smaller firms, do not individually have such capabilities. Collectively, the technology-driven enterprises comprise elements of a regional innovation system constituted by networked groups of self-organizing entities. The number of new product and next-generation technology experiments expands in proportion to the widely diffused design capabilities. The system extends beyond medical device companies to companies that work in technologies that cut across industry boundaries and in complementary technologies.