

# Medical Devices in the USA

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Vlaams Agentschap voor Internationaal Ondernemen



# Medical Devices: An Introduction to the U.S. Market

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## 1. INTRODUCTION

### 1.1 MEDICAL DEVICES... OR IS IT MEDTECH?

Depending on the sources one takes into consideration, the names of the industry we want to focus on in this overview can be different or refer to a slightly different content, and with that, the numbers that go with it can vary quite a bit depending on the source.

MedTech (Medical Technologies), Advanced Medical Technology (AMT), Medical Devices... one industry with different names and a cluster with many different sectors and subsectors. And the MedTech galaxy belongs to an even bigger entity: Biosciences.

While Biosciences are a major industry sector in the U.S. economy, generating more than \$270 billion annually, our focus here will be on **Medical Devices**. From a ball park range perspective, we can say that, in the U.S., medical devices accounts for one third of the complete biosciences industry, both in terms of market value (\$) and of employment.

#### A bird's eye view of the US market

Biosciences: \$ 270 billion 1.5 million jobs	<b>Medical devices: \$ 100 billion 500,000 jobs</b>	AMT*: \$ 150 billion 520,000 jobs
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\* Advanced Medical Technology

### MEDICAL DEVICES

In 2011, Medical Devices roughly generated \$ 100 billion in sales, 500,000 direct employment, with 15,000 establishments. That is approximately one third of the U.S. Bioscience industry with 1.5 million direct employment (and a total employment impact [direct + indirect] of 8 million jobs).

2011	Sales	Employment	Establishments
Biosciences	\$ 270 billion	1.42 million (total impact: 8 million jobs)	47,593
<b>Medical devices</b>	<b>\$ 105.8 billion</b>	<b>435,509</b>	<b>15,227</b>

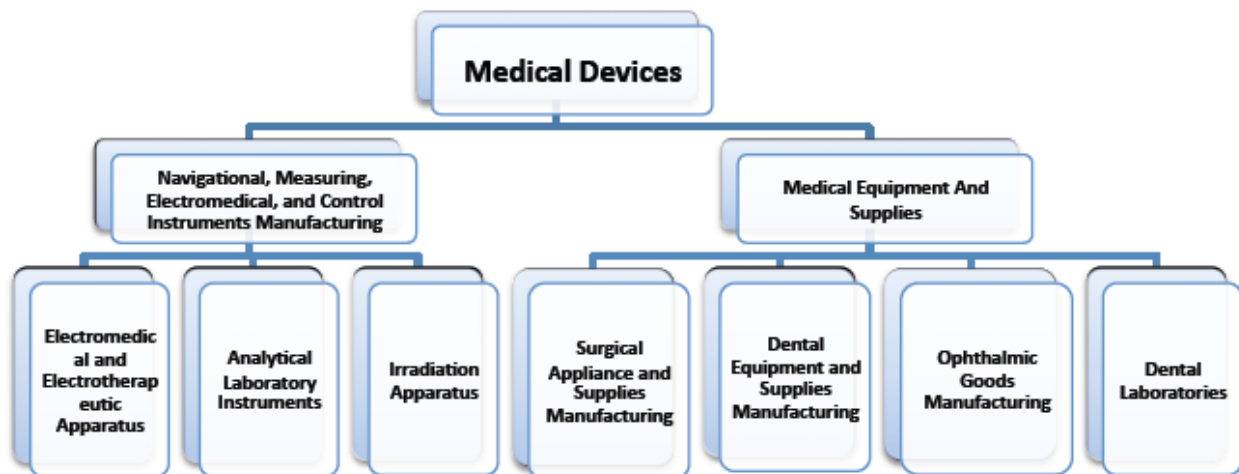
Source: mainly Battelle Report 2010

As defined in the North American Industry Classification System (NAICS - <http://www.naics.com> + [http://www.naics.com/naicsfiles/2012\\_NAICS\\_Changes.pdf](http://www.naics.com/naicsfiles/2012_NAICS_Changes.pdf) see code 3391), there are 27 industry groups in biosciences, clustered into four encompassing subsections:

- Agricultural Feedstock and Chemicals;
- Drugs and Pharmaceuticals;
- Medical Devices and Equipment;
- Research, Testing, and Medical Labs.

The subsector of Medical Devices and Equipment that we are focusing on offers a wide variety of biomedical instruments and other health care products and supplies, for surgery, patient care, laboratories and diagnostics.

When we zoom in on Medical Devices (and Equipment), we discover a whole range of subsectors:



8 NAICS subsectors are at the core of medtech:

	NAICS code
1. In-vitro diagnostic substance manufacturing	325413
2. Electro-medical and electrotherapeutic apparatus manufacturing	334510
3. Irradiation apparatus manufacturing	334517
4. Surgical and medical instrument manufacturing	339112
5. Surgical appliance and supplies manufacturing	339113
6. Dental equipment and supplies manufacturing	339114
7. Ophthalmic goods manufacturing	339115
8. Dental laboratories manufacturing	339116
9. A portion of a ninth subsector, the scientific R&D sector, is also included in the industry definition.	5417

New expanding and converging fields keep popping up, permanently adding to the definition: nanotechnology, bioMEMS (microelectromechanical systems), bioelectronics, tissue-engineering, genomics, materials science, imaging, etc.

Defining Medical Devices becomes easier once we get into the specifics. Here is a description of five broad product groups as suggested by E&Y:

- **Imaging:** products used to diagnose or monitor conditions via imaging technologies, including products such as MRI machines, computed tomography (CT) and X-ray imaging and optical biopsy systems
- **Non-imaging diagnostics:** products used to diagnose or monitor conditions via non-imaging technologies, which can include patient monitoring and in-vitro testing equipment
- **Research and other equipment:** equipment used for research or other purposes, including analytical and life science tools, specialized laboratory equipment and furniture
- **Therapeutic devices:** products used to treat patients, including therapeutic medical devices, tools or drug delivery/infusion technologies
- **Other:** products that do not fit in any of these categories

**Examples of products**

- Bioimaging equipment
- Surgical supplies and instruments
- Orthopedic/prosthetic implants and devices
- Laser eye surgery instruments
- Automated external defibrillators (AEDs)
- Vascular stents and other implantable devices
- Dental instruments and orthodontics
- Walkers, wheelchairs, and beds

**Major US medical device companies:**

- Abbott Diagnostics & Vascular
- Alcon
- Baxter (Medical Products)
- Becton, Dickinson and Co.
- Boston Scientific Corp.
- GE Healthcare
- Johnson & Johnson (Medical Devices and Diagnostics)
- Medtronic
- STERIS
- Stryker
- Zimmer
- 3M Health Care

Company	Revenue			Operating Income	
	(\$ million)	% change from previous year	Market share (%)	(\$ million)	% change from previous year
Medtronic Inc.	9,560.7	+2.1	15.8	2,626.7	+1.8
General Electric Company	7,958.9	+5.3	13.2	1,273.0	+13.3
St. Jude Medical Inc.	2,949.7	+11.1	4.9	750.5	+4.4

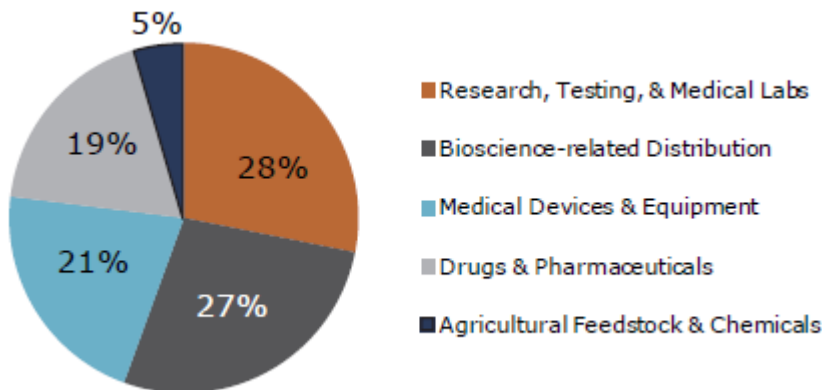
Source: 2012 Battelle Report

In 2010, sales of three of the major U.S. medical devices companies aggregate to a third of the total. Medtronic 15.8% + GE 13.2% + St Jude Medical 4.9% = 33.9 %.

Medtronic and St Jude focus on cardiac rhythm management devices (defibrillators, pacemakers, etc.), GE Health mainly in diagnostic imaging technologies (CT & MRI).

In 2010, R&D amounted to \$1.46 billion, at Medtronic only, and \$ 631 million at St Jude.

**Employment Composition of the U.S. Bioscience Industry, 2010**



Source: 2012 Battelle Report

The **medical devices and equipment subsector** employs about one in five workers (21%) in the bioscience industry, totaling more than 343,000 jobs in 2010 that span nearly 7,000 advanced manufacturing establishments. The subsector entered the recession with momentum—from 2005 through even the first year

of the recession in 2008, the subsector steadily added jobs before decreasing by a modest 9,000 jobs or 2.6 percent over the 2008–2010 period.

Looking out over the decade, medical devices has weathered relatively minor ups and downs in employment and ended 2010 essentially flat compared with 2001, down just 0.3 percent over the decade.

When we look at employment numbers by state, the top 10 ranking clearly points at the **major clusters** in the US.

## ECONOMIC IMPACTS OF THE TEN LARGEST STATES IN ADVANCED MEDICAL TECHNOLOGY INDUSTRY (2009):

### Total Employment

Total Employment	
California	366,615
Minnesota	158,075
Florida	105,933
Massachusetts	98,174
Pennsylvania	92,444
New York	81,178
New Jersey	79,440
Indiana	71,757
Illinois	67,119
Texas	66,304

Source: Battelle analysis; IMPLAN 2009 Model for each state.

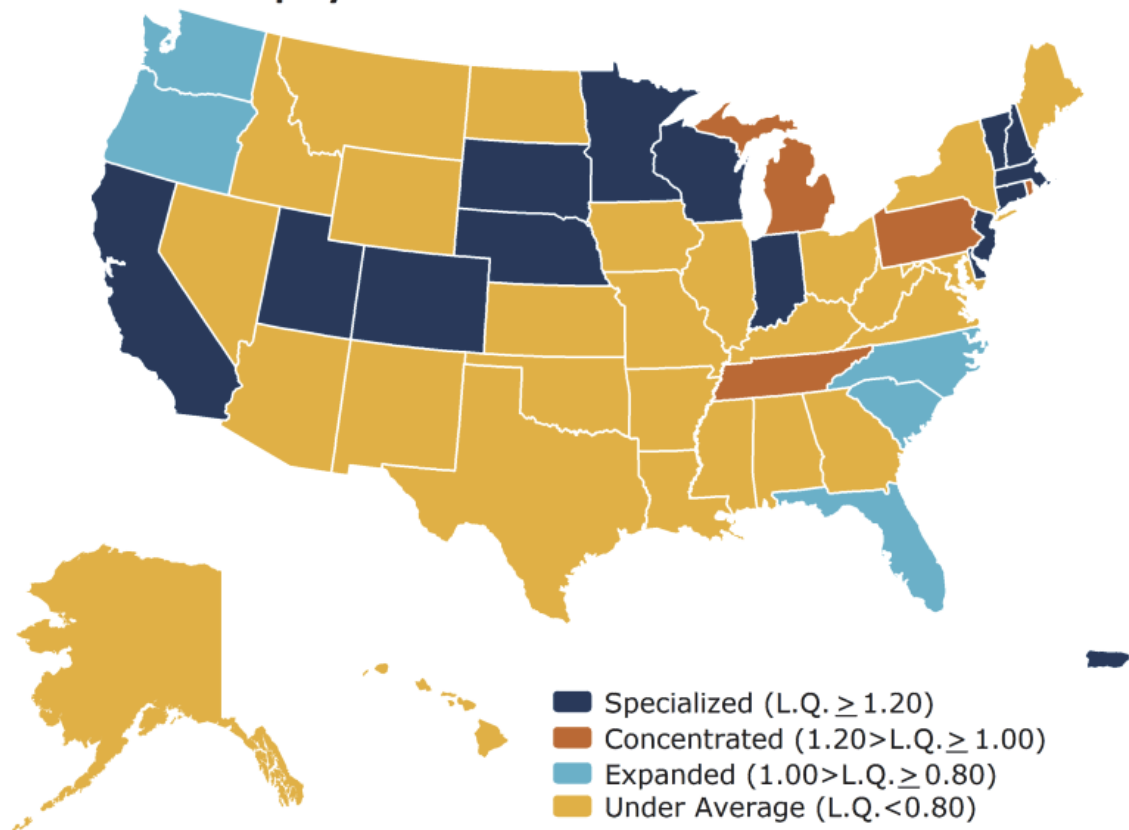
### Total Output (\$ in millions)

Total Output	
California	\$80,610.2
Minnesota	\$34,006.5
Massachusetts	\$22,592.9
Florida	\$19,517.6
New Jersey	\$19,478.1
Pennsylvania	\$17,418.0
New York	\$17,216.9
Illinois	\$14,671.2
Indiana	\$13,969.3
Wisconsin	\$12,602.4

Source: Battelle analysis; IMPLAN 2009 Model for each state.

These numbers also indicate that the MedTech industry in the US is geographically dispersed.

### Employment Concentration Relative to the U.S.



Source: Battelle Report 2012



STATES WITH LARGE AND SPECIALIZED EMPLOYMENT IN MEDICAL DEVICES AND EQUIPMENT (2010 FIGURES).

State	Establishments, 2010	Employment, 2010	Location Quotient, 2010	Share of U.S. Employment
California	995	59,450	1.54	17.3%
Minnesota	332	26,774	3.81	7.8%
Massachusetts	281	20,182	2.30	5.9%
Indiana	143	18,936	2.56	5.5%

Source: Battelle analysis of BLS, QCEW data; enhanced file from IMPLAN.

**California, Massachusetts, Minnesota and Indiana** have both a large employment base (employment concentration 20 % higher than US concentration) and a specialized concentration of jobs in medical devices and equipment.

To put those data in perspective, it seems relevant to point at the differences in total population in those top 4 states, especially between California and the other three: California has a population of 37.6 million (estimate 2011), Minnesota = 5.3 million, Massachusetts 6.5 and Indiana 6.5 too.

Zooming in on the major states, we can further identify the metropolitan areas with the largest employment levels in medical devices and equipment (data from 2008):

Metropolitan Statistical Area	2008 Employment
Los Angeles-Long Beach-Santa Ana, CA	31,488
Minneapolis-St. Paul-Bloomington, MN-WI	27,686
New York-Northern New Jersey-Long Island, NY-NJ-PA	19,592
Boston-Cambridge-Quincy, MA-NH	16,596
Chicago-Naperville-Joliet, IL-IN-WI	13,499
San Jose-Sunnyvale-Santa Clara, CA	10,413
San Francisco-Oakland-Fremont, CA	9,908
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	8,920
Miami-Fort Lauderdale-Miami Beach, FL	8,632
Salt Lake City, UT	7,264
Dallas-Fort Worth-Arlington, TX	7,143
San Diego-Carlsbad-San Marcos, CA	6,483
Tampa-St. Petersburg-Clearwater, FL	6,221
Milwaukee-Waukesha-West Allis, WI	6,037
Indianapolis, IN	5,890
Riverside-San Bernardino-Ontario, CA	5,826
Seattle-Tacoma-Bellevue, WA	5,502
Denver-Aurora, CO	5,154
Pittsburgh, PA	4,971
Cleveland-Elyria-Mentor, OH	4,651
New Haven-Milford, CT	4,621
Portland-Vancouver-Beaverton, OR-WA	4,350
Rochester, NY	4,245
Providence-New Bedford-Fall River, RI-MA	4,147
Memphis, TN-MS-AR	4,002

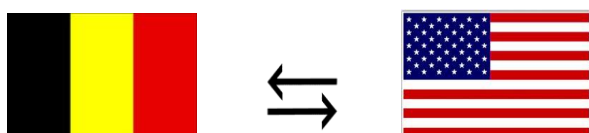
Source: Battelle Report, 2010.

Export revenues from the US medtech industry represent over \$40 billion, with a positive industry **trade balance** of \$3 billion.

Year	Exports (Thousands)	Imports (Thousands)	Net Balance of Trade (Thousands)
2006	29,032,869	28,131,117	901,752
2007	32,001,287	31,006,617	994,670
2008	36,734,516	34,359,974	2,374,542
2009	36,789,839	32,541,687	4,248,152
2010	40,064,329	37,043,134	3,021,195
	<b>174,622,840</b>	<b>163,082,529</b>	<b>11,540,311</b>

Source: U.S. International Trade Commission

## 1.2.US-BELGIAN TRADE IN MEDICAL DEVICES



The U.S. is the largest consumer of medical devices and is the world leader in their production.

U.S. imports of medical devices from Belgium in the key product categories identified by NAICS were valued at approximately \$76.61 million in 2011 and exports to Belgium were valued \$3,118.25 million, which increased by 44.83% and 28.18% respectively.

U.S. Medical Devices Imports from Belgium (U.S. Dollar Millions)					
Description	2009	2010	2011	Change 2009- 2010	Change 2010- 2011
Medical Equipment And Supplies	\$ 20.91	\$ 19.76	\$ 30.69	-5.53%	55.37%
Electromedical and Electrotherapeutic Apparatus	\$ 3.24	\$ 4.72	\$ 2.47	45.70%	-47.71%
Analytical Laboratory Instruments	\$ 10.22	\$ 14.59	\$ 9.53	42.80%	-34.67%
Irradiation Apparatus	\$ 44.14	\$ 13.83	\$ 33.92	-68.67%	145.23%
<b>Total</b>	<b>\$ 78.51</b>	<b>\$ 52.90</b>	<b>\$ 76.61</b>	<b>-32.62%</b>	<b>44.83%</b>

U.S. Medical Devices Exports to Belgium (U.S. Dollar Millions)					
Description	2009	2010	2011	Change 2009- 2010	Change 2010- 2011
Medical Equipment And Supplies	\$ 1,720.38	\$ 1,619.09	\$ 2,204.97	-5.89%	36.19%
Electromedical and Electrotherapeutic Apparatus	\$ 476.66	\$ 453.33	\$ 578.38	-4.90%	27.59%
Analytical Laboratory Instruments	\$ 234.29	\$ 262.77	\$ 228.56	12.16%	-13.02%
Irradiation Apparatus	\$ 82.40	\$ 97.58	\$ 106.34	18.42%	8.97%
<b>Total</b>	<b>\$ 2,513.73</b>	<b>\$ 2,432.77</b>	<b>\$ 3,118.25</b>	<b>-3.22%</b>	<b>28.18%</b>

Source: Medical Devices in Wisconsin.

### 1.3. AMT: ADVANCED MEDICAL TECHNOLOGY

When we slightly expand the contours of the Medical Device industry to also include the technology and manufacturing aspects, the numbers will fluctuate accordingly.

The 2012 Battelle report for Advamed states that the advanced medical technology (AMT) industry is responsible for generating almost 1.9 million U.S. jobs: the AMT industry directly accounts for 518,684 jobs in the U.S. economy, to which adds another 512,000 jobs among its suppliers, and the spending of all those workers throughout the economy generates a further 857,000 jobs.

Along the same lines, the AMT industry in the U.S. generates nearly \$150 billion in direct output (the U.S. roughly accounts for 50 % of the world market, Europe: 25 %), over \$113 billion in personal income for U.S. workers and \$191 billion in value-added activity. This all adds up to \$381 billion in national economic output altogether.

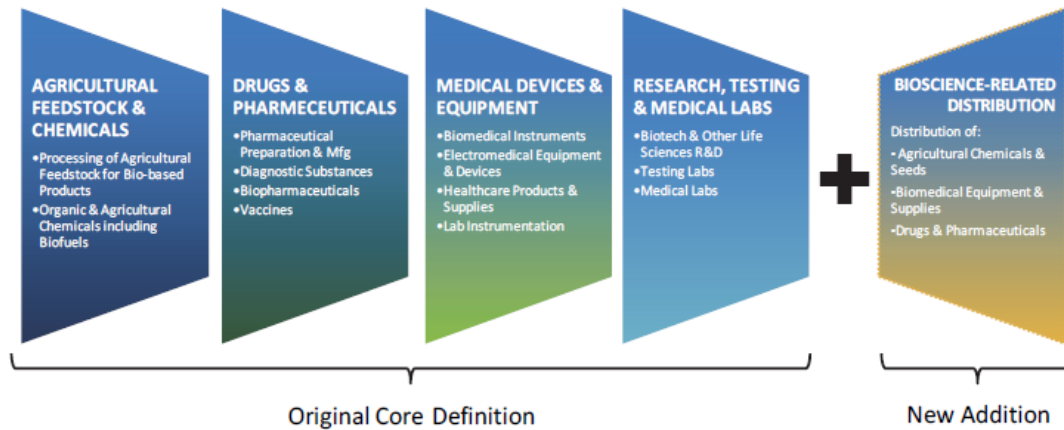
To fully appreciate the importance and the economic impact of the advanced medical technology industry in the U.S. we should consider that every \$ 1 billion in AMT Industry revenues in the U.S. generates an additional \$ 1.69 billion in national economic output, almost 13,000 jobs and \$ 778 million in personal income.

That also means that a scenario of a \$ 3 billion decline in the industry would result in the loss of nearly 39,000 jobs and \$ 8 billion in output in the economy.

### 1.4. MEDICAL DEVICES DISTRIBUTION INDUSTRY

The changing nature of bioscience technology and applications prompted another recent new focus in the professional literature: the inclusion of a new fifth subsector for the bioscience industry. This new subsector is categorized as bioscience-related distribution.

Increasingly bioscience-related distribution involves specialized approaches such as cold storage and highly regulated product monitoring, and new technologies for distribution such as automated pharmaceutical distribution systems. These include three detailed distribution industries: one associated with medical equipment and device distribution; another with drug distribution; and a third with agricultural-related chemicals and seed distribution. Each of these bioscience-related industries is becoming integral in the primary production of bioscience goods in an age of advanced logistics and the increasingly specialized nature of biosciences product development.



Employment in the bioscience-distribution subsector is widely distributed with 12 states having a specialized concentration and eight others with a location quotient that is well concentrated. The top ten states in the subsector combine to employ just 54 percent.

- Large States: California, Florida, Texas, Illinois
- Sizable States: Ohio, New Jersey, Pennsylvania, New York, Tennessee, North Carolina

**States that are Both Large and Specialized: Florida and Illinois**

State	Establishments, 2010	Employment, 2010	Location Quotient, 2010	Share of U.S. Employment
Florida	2,982	34,514	1.39	7.8%
Illinois	2,006	26,869	1.39	6.1%

Source: Battelle analysis of BLS, QCEW data; enhanced file from IMPLAN.

Examples of Distribution Companies (different subsectors)

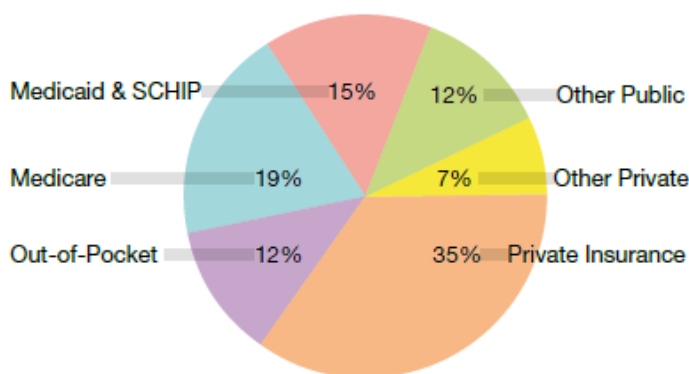
- McKesson [www.mckesson.com/en\\_us/McKesson.com](http://www.mckesson.com/en_us/McKesson.com)
- Cardinal Health [www.cardinal.com](http://www.cardinal.com)
- AmerisourceBergen [www.amerisourcebergen.com/abc](http://www.amerisourcebergen.com/abc)
- Monsanto [www.monsanto.com](http://www.monsanto.com)
- Express Scripts [www.express-scripts.com](http://www.express-scripts.com)
- Medco Health [www.medcohealth.com/medco/corporate/home.jsp](http://www.medcohealth.com/medco/corporate/home.jsp)
- Omnicare [www.omnicare.com](http://www.omnicare.com)
- Wilbur-Ellis [www.wilburellis.com/pages/Home.aspx](http://www.wilburellis.com/pages/Home.aspx)
- Owens & Minor [www.owens-minor.com/Pages/default.aspx](http://www.owens-minor.com/Pages/default.aspx)
- Henry Schein [www.henryschein.com/Default.aspx](http://www.henryschein.com/Default.aspx)
- Patterson Companies [www.pattersoncompanies.com](http://www.pattersoncompanies.com)

## 1.5. THE US MARKET FOR MEDICAL DEVICES: THE LARGEST IN THE WORLD!

Year	Million
1990	35.1
2000	35.1
2010	40.2
2020	54.6
2030	71.5
2040	80.8
2050	86.7

**US Population aged 65 and above:**  
 40 million in 2010 and growing strong (Baby boomers).  
 Source: US economic Census.

At an estimated US\$105.8 billion in 2011, the US medical device market is the world's largest. Per capita expenditure, at US\$339, is the third highest in the world.



Much of the market is in private hands; there is no single health system as we know it in Belgium. Since 1960, the Medicare system has provided hospital care for the elderly (65+); this has also provided prescription drug coverage since 2006.

More on Medicare @ [http://en.wikipedia.org/wiki/Medicare\\_%28United\\_States%29](http://en.wikipedia.org/wiki/Medicare_%28United_States%29)  
 Other public healthcare systems, known as Medicaid, for those on low incomes, are operated by each State.  
<http://en.wikipedia.org/wiki/Medicaid>

### HOW IS US HEALTH SPENDING SPREAD?

#### HALF PRIVATE, HALF PUBLIC?

16.2 % of US GDP goes to healthcare (Belgium: around 10 % [\*]).  
 Noteworthy is that adding up Medicare and Medicaid (+ State Children's Healthcare Insurance Program) also amounts to 34 %, which is basically paid for by a single payer (the Government) through taxes; when we add to that the 12 % of Other Public (military, veterans, general health activities), the public sector accounts for 46 %.  
 A perception not shared –or unknown- by most of the American public.

[\*] Also see <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5813a5.htm> (2009 data).

On the Private side, 35 % of those expenses are covered by the American private insurance system. Adding Out-of-Pocket expenses (12 %) and Other Private (7 %), Private Payers take care of more than half of national health expenditures.

Source <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html?redirect=/NationalHealthExpendData/>  
+ National Center for Health Statistics <http://www.cdc.gov/nchs/>  
<http://www.cms.gov/Research-Statistics-Data-and-Systems/Research-Statistics-Data-and-Systems.html>  
note yellow tabs on top.

President Obama succeeded in signing his healthcare reform bill into law on March 23, 2010. The bill, formally called the Patient Protection and Affordable Care Act HR 3590, will eventually extend health insurance cover to an estimated 32 million Americans who don't have any form of health insurance.  
[http://en.wikipedia.org/wiki/Patient\\_Protection\\_and\\_Affordable\\_Care\\_Act](http://en.wikipedia.org/wiki/Patient_Protection_and_Affordable_Care_Act)

In January 2012, the Obama administration said the bill is on track to being implemented, despite opposition from some States. In June 2012, the U.S. Supreme Court upheld the contested constitutionality of the Bill. The law requires all States to create new health insurance markets called exchanges, so that people who do not have insurance can buy tax-payer subsidized private cover. The law also expands eligibility for Medicaid so low-income adults who have no dependent children can get government insurance. Putting the two approaches together, more than 30 million Americans are expected to gain coverage by January 2014. Over 20 States are planning to overturn requirements of the law, and have made little progress in planning or creating these exchanges. If State plans are not approved by January 2013, one year before the exchanges are to be up and running, the Federal government can intervene and manage the process.

The USA is home to many of the world's leading medical device manufacturers, such as Johnson & Johnson, General Electric, Baxter, Covidien and Medtronic. Seven out of the world's top ten medical device manufacturers are US companies.

Imports are forming an increasingly significant part of the US market, and now account for around 32% of the total. This growth is partly explained by US manufacturers using cheap locations abroad, such as Ireland or Mexico, in order to re-export to the US market.

The market is highly regulated, and can be an expensive one in which to operate. It is, however, transparent and 'rules-based'. The US is a major site for R&D and clinical trials.

## 2. TRENDS AND CHALLENGES OF THE U.S. MARKET

### 2.1. THE BIG PICTURE

Although the recent economic recession and turbulences did not spare any sector of activity, the medtech sector kept showing a pretty **steady performance** thanks mainly to its specific conjuncture: aging Western populations and longer life expectancies, further expansion into emerging and underserved markets and a gradual improvement in the global economy. Those factors, amongst many others, are expected to positively impact medtech **long-term growth**. Projected growth for the medical devices industry between 2011 and 2016 is forecast at 6.4 % annually.

#### U.S. MEDTECH AT A GLANCE, 2010

(US\$b, data for non-conglomerates except where indicated)

Public company data	2010	2009	% change
Revenues	\$204.9	\$196.7	4%
Conglomerates	\$73.3	\$68.8	7%
Non-conglomerates	\$131.6	\$127.8	3%
R&D expense	\$9.8	\$9.1	8%
SG&A expense	\$41.4	\$40.6	2%
Net income	\$12.4	\$7.9	57%
Cash and cash equivalents and short-term investments	\$33.0	\$27.9	18%
Number of employees	462,730	456,150	1%
Number of public companies	279	285	-2%

Source: Ernst & Young and Capital IQ

#### EUROPEAN MEDTECH AT A GLANCE, 2010

(US\$b, data for non-conglomerates except where indicated)

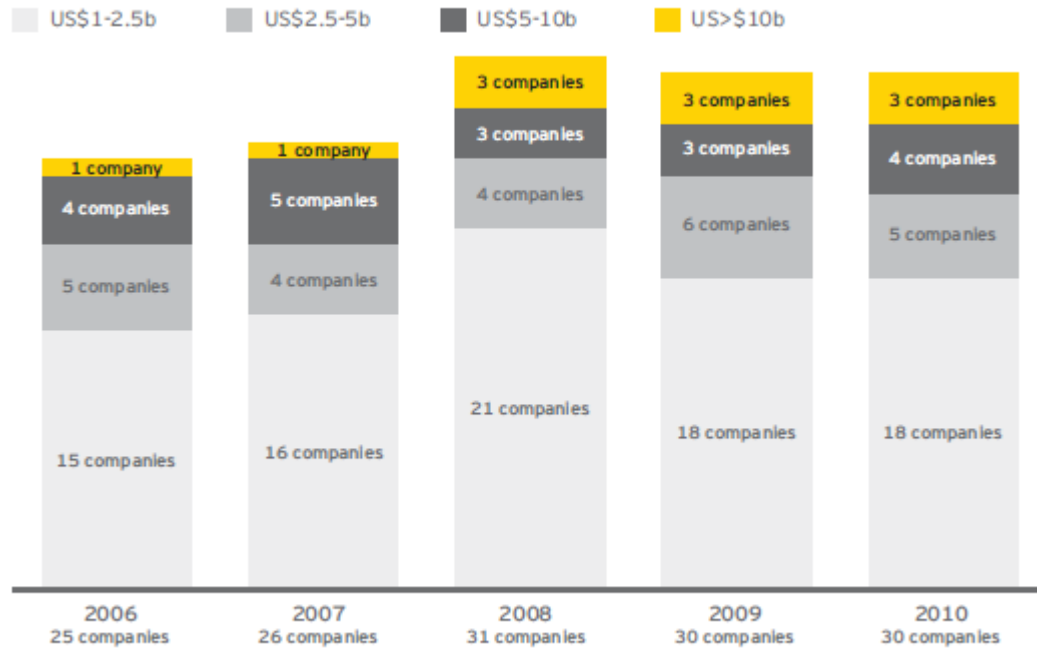
Public company data	2010	2009	% change
Revenues	\$111.1	\$106.9	4%
Conglomerates	\$49.0	\$47.6	3%
Non-conglomerates	\$62.1	\$59.3	5%
R&D expense	\$2.6	\$2.5	3%
Net income	\$5.1	\$4.3	17%
Cash and cash equivalents and short-term investments	\$9.0	\$7.9	13%
Number of employees	299,174	283,073	6%
Number of public companies	157	158	-1%

Source: Ernst & Young and Capital IQ

## 2.2. INDUSTRY PROSPECTS

The future of the industry however will be anything but business as usual. Many **changes** already developed over the last few years and still happen as we write these words: increased industry concentration, new funding environment (funding capital more concentrated, higher debt financing), new tax policies perceived as discouraging innovation, shift to overseas production, increasing regulatory uncertainty...

### "The billion dollar club," 2006-10



Source: Ernst & Young  
Chart shows non-conglomerates segmented by total revenues in each year.

## 2.3. A NEW FUNDING ENVIRONMENT

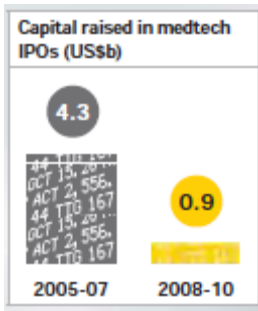
Capital raised in the US and Europe, 2005-H1 2011 (US\$m)

Type	2005	2006	2007	2008	2009	2010	H1 2011
Venture	\$3,214	\$4,423	\$5,108	\$5,043	\$4,809	\$4,204	\$2,211
IPO	\$988	\$1,445	\$1,816	\$125	\$103	\$568	\$329
Follow-on public offering	\$733	\$1,060	\$1,828	\$1,435	\$1,537	\$961	\$1,301
Debt	\$1,306	\$10,341	\$6,061	\$4,506	\$7,073	\$17,030	\$6,020
PIPE	\$702	\$2,309	\$1,095	\$389	\$655	\$824	\$201
<b>Total</b>	<b>\$6,943</b>	<b>\$19,578</b>	<b>\$15,908</b>	<b>\$11,498</b>	<b>\$14,177</b>	<b>\$23,587</b>	<b>\$10,062</b>

Source: Ernst & Young, Capital IQ, BMO Capital Markets, Dow Jones VentureSource and Windhover

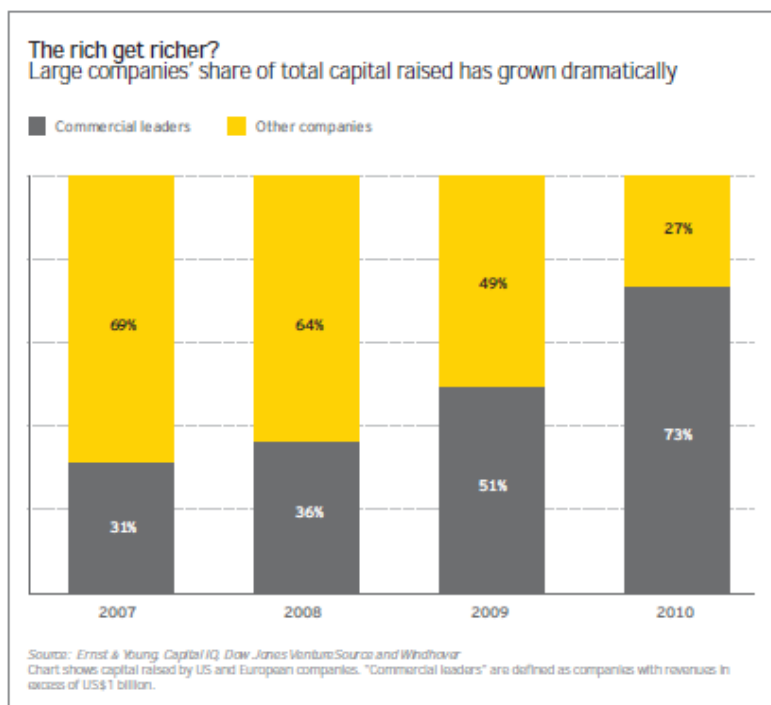
Medical technology companies in the US and Europe raised nearly US\$23.6 billion in 2010 — an astounding 66% increase over 2009's total and the highest annual total in the six years shown here. The trend continued in the first six months of 2011, with financing totals generally keeping pace with those seen in 2010.



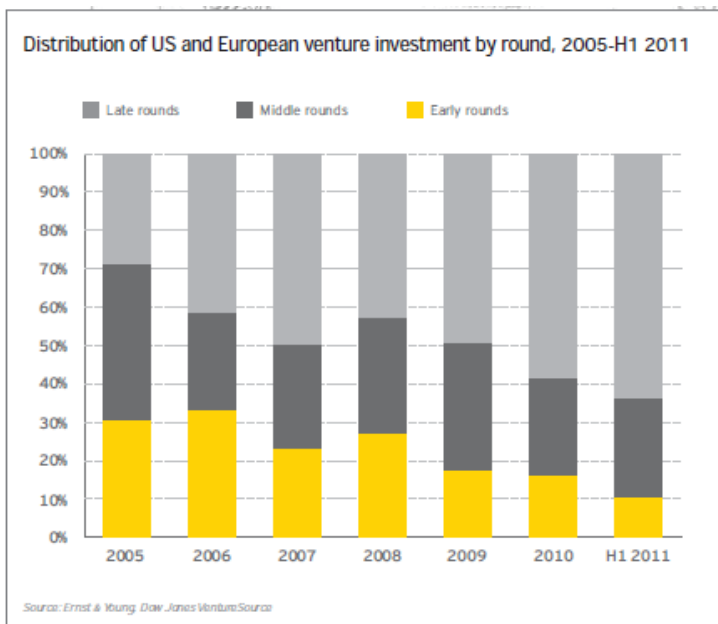


However, the remarkable increase in capital raised was not driven by a fundamental shift in investor sentiment toward medtech and it has not made the financing environment any easier for the vast majority of emerging companies. Instead, the increase in funding was mostly concentrated in a handful of mature companies that took advantage of historically low interest rates to raise debt — funds that were typically used to restructure balance sheets, finance acquisitions or fund general operations.

While the explosion in debt financing is a 2010 and 2011 phenomenon, it is just the latest manifestation of a longer-term trend. Since the advent of the financial crisis, there is a growing disparity in funds raised by established and emerging companies.



The share of funds raised by companies with more than US\$1 billion in revenues has increased steadily over this period, to reach a high of **73%** in 2010. Meanwhile, emerging, pre-commercial companies faced a very different funding environment. Venture financing dropped for the third consecutive year in 2010 — falling by 13% relative to 2009 — though the amount raised is still consistent with levels seen in 2005 and 2006, before the cresting of the “easy money” era. The challenging market conditions faced by medtech companies — including growing regulatory and pricing pressures and the preference of strategic buyers for later-stage assets — continue to delay exits and squeeze returns for VCs.



This graph clearly shows that venture investment for **early stage** development is on a down trend, from around 30 % of venture capital in 2006 to merely 10 % in 2011.

Medtech companies have historically focused on developing innovative products. In the new outcomes-focused ecosystem, however, companies will also need to demonstrate how a particular intervention improves patient outcomes and enhances the efficiency of the healthcare system.

The increasingly urgent need to rein in escalating health care costs — already manifested in the growing pressure on prices, the movement toward

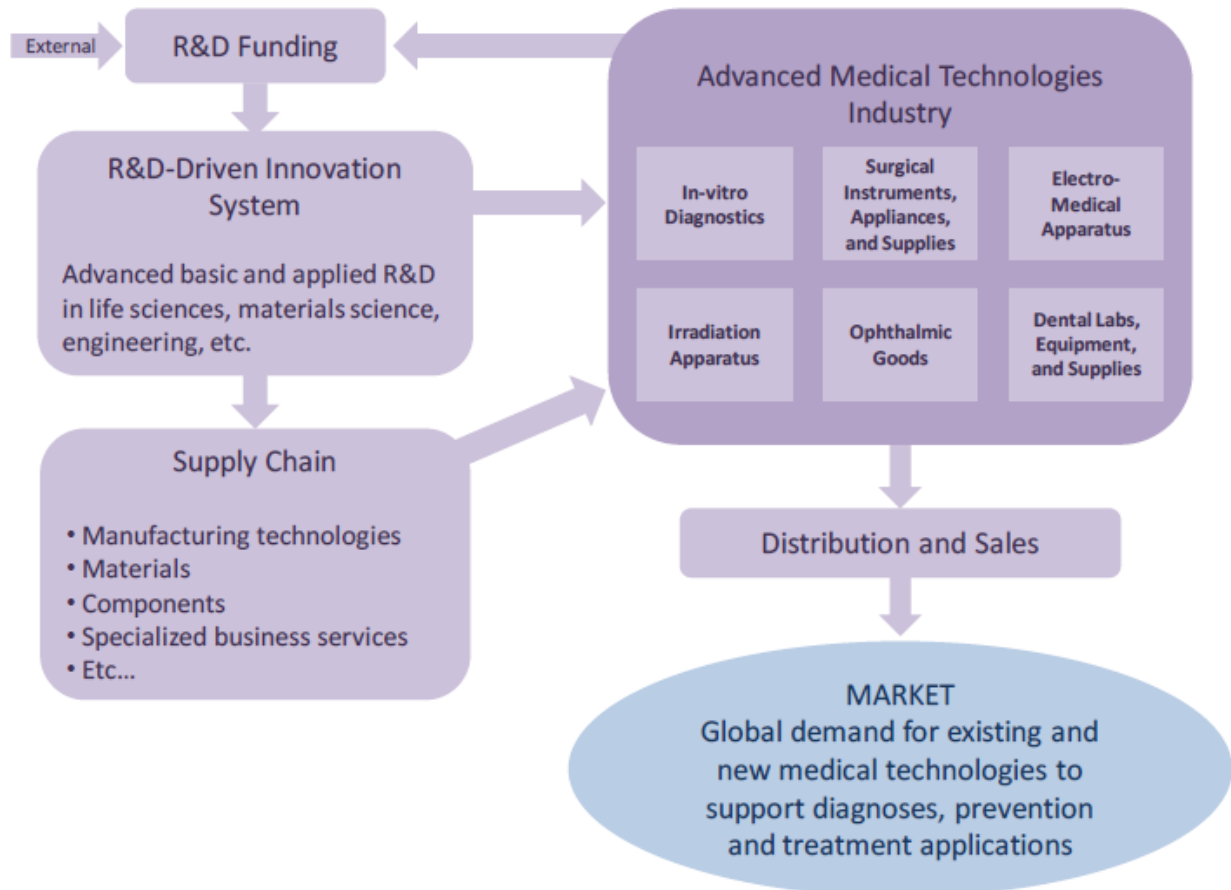
comparative effectiveness research, and more — is also inexorably pushing us to a future where companies' success or failure will hinge on their ability to demonstrate how they are improving health outcomes for patients and for the broader health system.

Making health care **sustainable** will require vast improvements in **efficiency** across the system, and will require patients to take more responsibility for managing their health. Technology can provide a big part of the answer. New technologies and platforms are creating an explosion in the quantity and types of data — everything from electronic health records to social media discussion threads to real-time data generated by increasingly mobile devices and diagnostics.

Information technology is also starting to enable another fundamental shift: the empowerment of the patient. Just as new technologies have empowered consumers in other industries, similar developments in health care promise to dramatically empower individuals, transforming them from the passive patients of yesterday to the educated, engaged “superconsumers” of tomorrow.

## 2.4. R&D DRIVEN SECTOR

Firms in the medical device and equipment subsector produce a variety of biomedical instruments and other health care products and supplies for diagnostics, surgery, patient care, and laboratories. The subsector is continually advancing the application of electronics and information technologies to improve and automate testing and patient care capabilities.



## 2.5. CROWDSOURCING

The new health ecosystem, with its rapidly emerging technologies and more widely distributed information, could also provide opportunities to cast a wider net. Medtronic, for instance, has begun crowdsourcing some of its innovation with the November 2010 launch of Medtronic Eureka, a European web-based portal that allows physicians and medical technology innovators to submit product ideas.

<http://www.medtronicureka.com/>

**Medtronic**

Medtronic EUreka **Medical Device Innovation for Improved Lives Together**

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- About Medtronic & MD Start
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- Submit your idea
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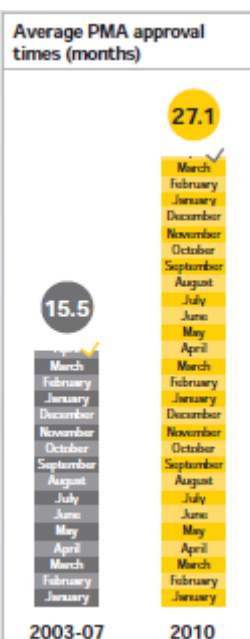
### Medical device innovation & ideas

Welcome to Medtronic Eureka, the European Idea Submission Portal from Medtronic. **Medical device ideas** from European inventors have already improved the lives of millions of patients worldwide through collaboration with Medtronic.

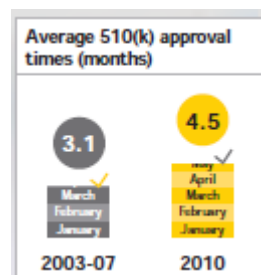
Submit yours.

[Click here to learn more about Medtronic Eureka](#)

## 2.6. REGULATORY AND PRICING PRESSURES

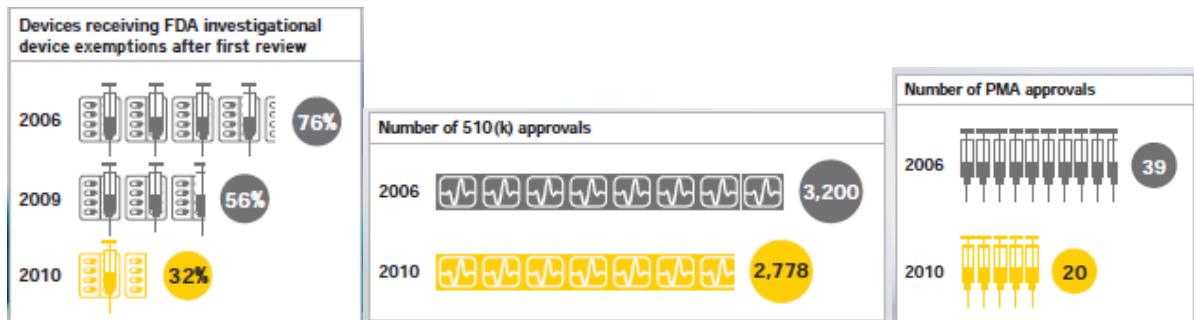


In recent years, the FDA's 510(k) process for clearing certain classes of medtech products has come under considerable scrutiny. Critics have charged that the 510(k) process — which, unlike the premarket approval (PMA) process used for life-sustaining products, does not require clinical trials — needs to be changed. The FDA responded by initiating a review of the 510(k) process and also asking the Institute of Medicine (IOM) to conduct a separate review.



In July 2011, the IOM released its report, “Medical Devices and the Public’s Health: The FDA 510(k) clearance Process at 35 Years.” The IOM report’s recommendations were certainly bold — rather than proposing reforms to the existing system, the institute recommended scrapping the 510(k) process altogether and replacing it with “an integrated premarket and postmarket regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle.” The FDA soon announced that it does not intend to implement this proposal, while some policymakers continue to decry the agency for not considering it.

## 2.7. OUS: OUT OF U.S. STRATEGY



Uncertain regulatory and reimbursement environment (less and longer FDA approvals) combined with questions about healthcare reform, the future of Medicare, the market’s financial background, tougher funding, etc. have prompted (mainly emerging) U.S. companies to first obtain marketing approval of new products in non-US markets (Europe for example, but not only). That practice has become increasingly common in recent years. The trend though is more prominent when clinical trials are involved.

### OUS

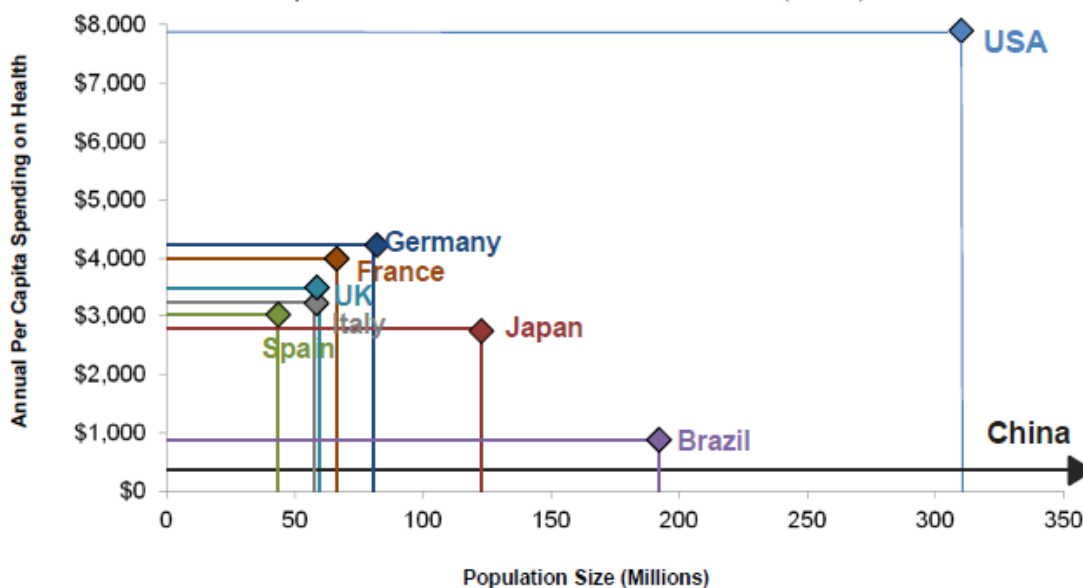
*‘So why the OUS strategy? Simply put, gaining U.S. approvals take too long and cost too much, said Jeffrey Jump, CEO of Biosensors International. “In Europe, the process takes 6 months to 2 years; in Japan, the process takes 3 to 5 years and costs about \$3 million; and in China, it takes 3 to 5 years and costs less than Japan.”*

*What about the U.S.? “We’re looking at 2 to 7 years and costs of \$50 to \$150 million.”*

*From <http://medicaldesign.com/engineering-prototyping/regulatory/o-u-s-strategy-disturbs-20101018/>*

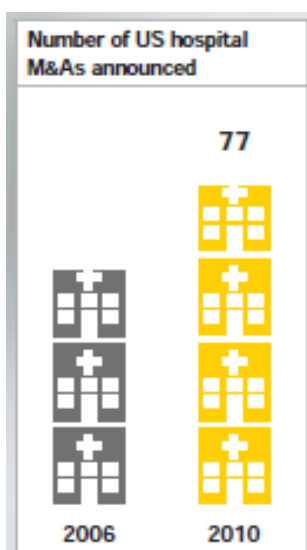
Europe occupies a critical space for medical devices launches, in terms of R&D, and higher-range spending on healthcare.

### Snapshot of Global Healthcare Markets (2010)

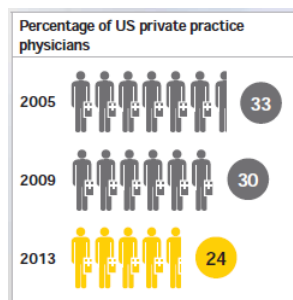


Source: OECD, 2011  
[http://www.oecd.org/document/16/0,3343,en\\_2649\\_34631\\_2085200\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/16/0,3343,en_2649_34631_2085200_1_1_1_1,00.html)

## 2.8. U.S. HOSPITALS MERGERS



All those market pressures also have prompted more U.S. hospitals to merge over the last years, primarily in an effort to cut costs. They also increasingly rely on technology assessment committees and group purchasing organizations to consolidate and standardize purchasing decisions. As a result, surgeons no longer can pick just what they prefer but have to choose between a limited number of options.



Moreover, this tendency is reinforced by the fact that more and more doctors in the U.S. tend to abandon small private practices to become employees of large hospital systems.

Source of graphs: E&Y, Pulse of the Industry

### **Medtech: same problem as pharma 10 years ago?**

*In the words of Alex Gorsky, J&J (source: E&Y report), medtech is running into the same issues as the pharmaceutical industry 10 years ago (even though medtech has a much faster pace of innovation than pharma: roughly 15 years of R&D and an investment of \$1billion to get a new drug to market).*

*Similarities though are such that medtech could learn from pharma's experience.*

*Alex Gorsky points at 3 major lessons learned by pharma:*

- *Lean forward: changes brought by the crisis (tighter regulation, lower prices, stricter utilization standards) are here to stay. The way forward will be lean.*
- *Reinvent our business model (and do it soon): not just a smaller version of the old model, but a really novel approaches, in R&D, commercial and service.*
- *Pay attention to how we are perceived: do we care for people over profits? Did we 'get it'? We must be part of the solution (rather than part of the problem).*

## 2.9. THE EXCISE TAX

Obama's healthcare reform, also known as the Patient Protection and Affordable Care Act (PPACA - [http://en.wikipedia.org/wiki/Patient\\_Protection\\_and\\_Affordable\\_Care\\_Act](http://en.wikipedia.org/wiki/Patient_Protection_and_Affordable_Care_Act) ) will extend healthcare coverage to a great number of Americans; this will generate a greater demand for medical devices.

But PPACA also contains a provision for a new 2.3% excise tax (to be paid by the companies) on the sale of certain medical devices, scheduled to take effect January 1, 2013. This tax is projected to generate \$20 billion of revenue for the Federal Government over the next decade. The medical technology industry has asked Congress to repeal the excise tax.

The 2.3% Medical device excise tax applies to sales after December 31, 2012. The excise tax could have an adverse impact on R&D investment and job creation. The tax comes at a time when the US capacity for medical technology innovation is declining and start-up companies find it difficult to raise capital to bring new technologies to market.

More: <http://www.pwc.com/us/en/health-industries/publications/medtech-focus-on-excise-tax.jhtml>

Some critics of the excise tax claim it will cost more than 43,000 jobs nationwide and will roughly double the total tax bill of the U.S. medical devices companies. The most outspoken of the detractors of the tax say U.S. manufacturers will be more likely to close plants and go abroad. The 2.3% tax could cause a 10% shift in production offshore, which would translate in 2.124 jobs lost in Indiana alone, says David Floyd from OrthoWorx (<http://orthoworxindiana.com> ) in Warsaw, Indiana, world capital of orthopedics.

### 3. ZOOMING IN ON SPECIALTIES

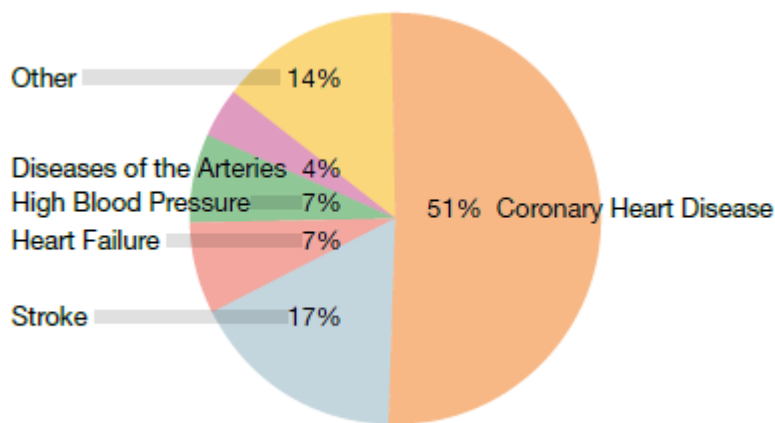
Medical devices come in many different subsectors and specialties. This section zooms in on the most prevalent.

More information than presented here is available on most of the specialties. Please contact FIT Chicago ([chicago@fiagency.com](mailto:chicago@fiagency.com)) if you are interested in more detailed data regarding your specific industry niche.

#### 3.1. CARDIOVASCULAR

The U.S. cardiovascular devices market was valued at \$14.1 billion in 2008 and is forecast to grow to a value of just under \$20 billion (19.6) in 2012, according to Global Markets Direct.

##### Deaths from cardiovascular diseases



The market for **ICD** (Implantable Cardiac Defibrillators) is highly concentrated, with only 3 companies accounting for 99%:

- Medtronic 47%
- Boston Scientific 28%
- St. Jude Medical 24%
- Others 1%

Source: Osec report, 2009.

	2007 Share (%) (US Only)	2008 Share (%) (Worldwide)	2011 Share (%) (Worldwide)
Xience (Abbott Laboratories)		16	32
Promus (Boston Scientific)		11	21
Taxus (Boston Scientific)	55	31	17
Cypher (Johnson & Johnson)	45	27	15
Endeavor (Medtronic)		14	15

Likewise, the market for **DES** (Drug Eluting Stents) is in the hands a limited number of companies, with only two companies dominating the U.S. scene. The worldwide picture includes a few more players.

Source: Osec report, 2009.



## Major players in the cardiovascular sector

- Abbott Laboratories, Inc. [www.abbott.com](http://www.abbott.com)
- Abiomed, Inc. [www.abiomed.com/index.cfm](http://www.abiomed.com/index.cfm)
- Boston Scientific [www.bostonscientific.com](http://www.bostonscientific.com)
- Cordis Corporation [www.cordis.com](http://www.cordis.com)
- Edwards Lifesciences [www.edwards.com](http://www.edwards.com)
- Ethicon, Inc [www.ethiconinc.com](http://www.ethiconinc.com)
- Medtronic [www.medtronic.com](http://www.medtronic.com)
- St. Jude Medical, Inc. [www.sjm.com](http://www.sjm.com)
- Teleflex Medical [www.teleflexmedical.com](http://www.teleflexmedical.com)
- Thoratec Corporation [www.thermocardio.com](http://www.thermocardio.com)
- WorldHeart Corporation [www.worldheart.com](http://www.worldheart.com)

## 3.2. ORTHOPEDICS

Orthopedics is the second largest segment behind Cardiovascular in the U.S. medical device market. The segment accounts for about 29 % of the U.S. medical device industry sales. In 2008, the U.S. orthopedic device market was estimated at \$21.4 billion. U.S. sales of orthopedic devices represent about 60 percent of worldwide sales.

- Main Subsectors in orthopedics
  - Joint reconstruction
  - Spinal implants
  - Arthroscopy, Sports Medicine, Softgoods and Bracing

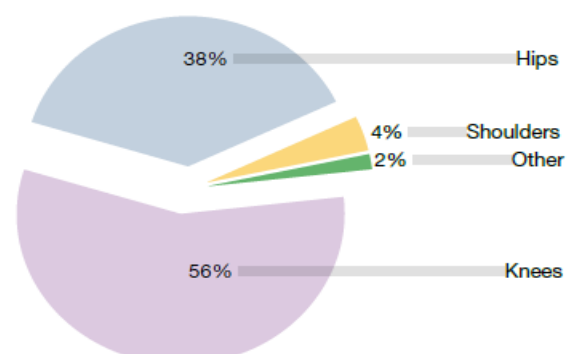
- Major Competitors

There is a strong orthopedic cluster in Indiana, in the Warsaw area: Biomet (Warsaw, IN), DePuy Orthopedics / Johnson & Johnson (Warsaw, IN), Zimmer Holdings (Warsaw, IN)  
+ Stryker Orthopedics (Kalamazoo, MI)

### Leading competitors worldwide.

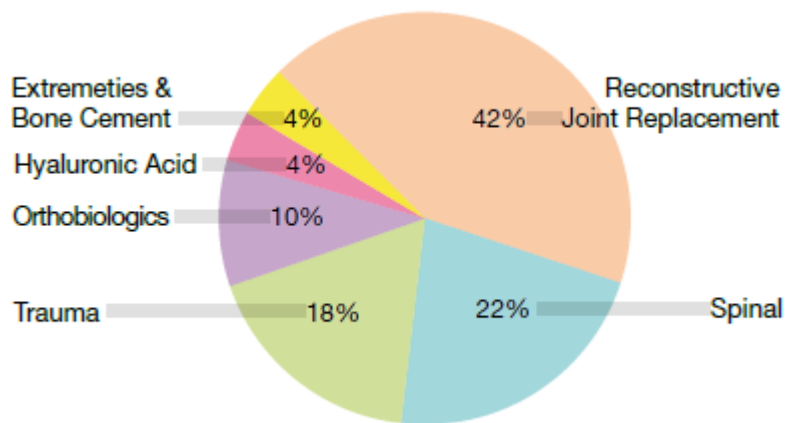
1 Stryker	15%
2 JOHNSON & JOHNSON DePuy	13%
3 Zimmer	11%
4 Medtronic	10%
5 Synthes	9%
6 Smith & Nephew	8%
7 Biomet	6%
all other	28%

### Orthopedics (Reconstructive Joint Replacement) share of Medical Devices market in the US



Source: Osec report, 2009.

## Worldwide orthopedics market share segmentation



Source: Osec report, 2009.

### Other market segments

More details available by request ([chicago@fitagency.com](mailto:chicago@fitagency.com)).

## 3.3 MINIMALLY INVASIVE SURGICAL TECHNIQUES

→ all laparoscopic surgeries + hearing aids etc. + robotic surgery

- Major Competitors
- ArthroCare Corporation [www.arthrocare.com](http://www.arthrocare.com)
- Boston Scientific [www.bsci.com](http://www.bsci.com)
- Clarus Medical [www.clarus-medical.com](http://www.clarus-medical.com)
- ConMed Corp. [www.conmed.com](http://www.conmed.com)
- Covidien [www.ussurg.com](http://www.ussurg.com)
- Ethicon Endo-Surgery, Inc. [www.ethiconendo.com](http://www.ethiconendo.com)
- Gyrus ACMI was acquired by Olympus (Japan) in February 2008.
- [www.gyrusgroup.com](http://www.gyrusgroup.com)
- Intuitive Surgical Inc. (ISI) is the global leader in pioneering and developing robotic systems (da Vinci) for minimally invasive surgery.
- [www.intuitivesurgical.com](http://www.intuitivesurgical.com)
- Karl Storz [www.karlstorz.com](http://www.karlstorz.com)
- Linvatec Corp. [www.conmed.com/newdesign.php](http://www.conmed.com/newdesign.php)
- Medtronic ENT [www.xomed.com](http://www.xomed.com)
- Medtronic Kyphon [www.kyphon.com/us/home.aspx?siteid=1](http://www.kyphon.com/us/home.aspx?siteid=1)
- Mentice Medical [www.mentice.com](http://www.mentice.com)
- ROBODOC [www.robodoc.com](http://www.robodoc.com)
- Smith & Nephew [www.smith-nephew.com](http://www.smith-nephew.com)
- Stryker Corporation [www.stryker.com](http://www.stryker.com)
- Teleflex, Inc. [www.teleflexmedical.com](http://www.teleflexmedical.com)

### 3.4 IN VITRO DIAGNOSTICS

- Includes Laboratory equipment, Point-of-care devices, medical diagnostic kits
- Major competitors, worldwide:

Company	% Share
1 Roche Diagnostics	19
2 Siemens Healthcare Diagnostics	18
3 Johnson & Johnson	13
4 Abbott Diagnostics	12
5 Beckman Coulter	6
6 bioMérieux	6
all others	26

### 3.5 REHABILITATION EQUIPMENT

- Primary product areas
  - Orthopedic products: braces, splints, continuous passive motion machines
  - Aids to daily living: dressing, bathing, dining services
  - Rehabilitation equipment: treatment tables, mat platforms, stationary bicycles
  - Clinical products: exercise bands, weights, ball, mats
  - Mobility products: walkers, canes, crutches, scooters, wheelchairs + accessories
- The Market leader is Patterson Medical ([www.pattersonmedical.com](http://www.pattersonmedical.com)) established in the Chicago area. The U.S. rehabilitation equipment and supplies market is a highly fragmented market with many competitors of various sizes. Some of the larger companies such as Invacare, Medline, and Patterson Medical manufacture and distribute their own products, and they also distribute products from other manufacturers. Only a few companies have national coverage while most of the companies are either regionally or locally focused.
  - GNR Health Systems: physical therapy, rehabilitation, fitness products  
<http://www.gnr-inc.com>
  - Invacare Corp.: home medical equipment  
[www.invacare.com](http://www.invacare.com)
  - MedCom Direct: online store en direct supply of home rehab equipment  
[www.medcomgroup.com](http://www.medcomgroup.com)
  - Medical Supplies and Equipment Company (MSEC): internet sales  
[www.medical-supplies-equipment-company.com](http://www.medical-supplies-equipment-company.com)
  - Medline, Inc.  
[www.medline.com](http://www.medline.com)
  - Patterson Medical (Sammons Preston Rolyan in the U.S.)  
[www.pattersonmedical.com](http://www.pattersonmedical.com)
  - Pro-Med Products  
[www.pro-medusa.com](http://www.pro-medusa.com)
  - WidsomKing: online store  
[www.wisdomking.com](http://www.wisdomking.com)

### 3.6 DENTAL

The Centers for Medicare & Medicaid Services (CMS) estimates that national expenditures for Dental Services was valued at \$95.2 billion or about 4.2% of total national health expenditures in 2007. CMS forecasts the total amount of national expenditures for dental services will grow to \$106.3 billion in 2010 and \$136.3 billion in 2015, an increase of about 4.6% per year.

Major consolidation is taking place in the U.S. dental industry. Presently there is a handful of major players manufacturing and supplying the dental market. Wholesalers play a major role in the industry, so much so that the major manufacturers are also taking on the role of wholesalers within the market, becoming the desired one-stop-shop for the dentist.

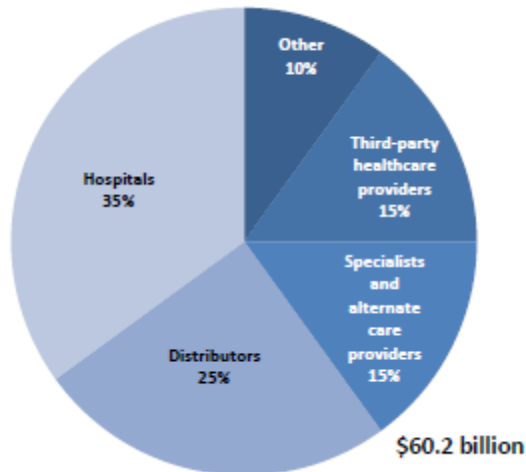
- Major competitors
  - Biomet 3i [www.biomet3i.com](http://www.biomet3i.com)
  - Dentsply [www.dentsply.com](http://www.dentsply.com)
  - Henry Schein Dental Group [www.henryschein.com](http://www.henryschein.com)
  - KaVo [www.kavo.com](http://www.kavo.com)
  - Patterson Companies [www.pattersondental.com](http://www.pattersondental.com)
  - Sybron Dental Specialties [www.sybrondental.com](http://www.sybrondental.com)
  - Young Innovations, Inc. [www.yiinc.com](http://www.yiinc.com)

### 3.7 DRUG-DEVICE COMBINATION PRODUCTS

- Combination products: e.g. drug-delivery systems (patches, transdermal /intra-dermal injections, inhalation devices, spays, drug-eluting disks), gene therapy systems, personalized medicine drugs, nanotechnology, drug-enhanced devices (drug-eluting stents, coated catheters, anti-infective sutures, bone cements with antimicrobial agents), etc.
- Major Players:
  - Cordis (J&J) [www.cordis.com](http://www.cordis.com)
  - Boston Scientific [www.bostonscientific.com](http://www.bostonscientific.com)
  - Abbott Laboratories [www.abbott.com](http://www.abbott.com)
  - Medtronic [www.medtronic.com](http://www.medtronic.com)
  - Cook Medical, etc. [www.cookmedical.com](http://www.cookmedical.com)

## 4. APPROACHING THE AMERICAN MARKET

### 4.1 CLASSIC CHANNELS



This pie chart shows the major market segmentation as it influences demand.

Although the end-users of certain medical devices like pacemakers and insulin pumps are patients, devices are primarily marketed to healthcare providers. Only hospitals and other large healthcare provider groups have the purchasing power to buy expensive equipment such as a magnetic resonance imaging (MRI) machine or a CT scanner.

Like the pharmaceutical industry, the demand of medical devices is largely based on insurance coverage, age demographics, and the health of the public—the sicker the insured population, the greater the demand for

medical devices. Medical specialists also place a high demand on new technologies to better serve their patients. The demand for better devices necessitates the industry to develop new and innovative products.

Source: American Action Forum.

Depending on your business plan and your export strategy, many options are available to you in your efforts to approach the American market.

Visiting a couple of **trade shows** in your field remains a strongly recommended first step. Maybe you can even consider exhibiting at one of them in order to achieve optimal exposure. You could also plan a targeted **prospection trip** to potential U.S. partners: **importers, agents, distributors**, etc. Only those direct contacts will tell you where you stand and how to move forward.

Our FIT office can help you in your quest for the right business partner. In your search for that partner, you probably have a pretty specific idea of the profile of the contacts you would like us to search for. We can discuss it with you, maybe fine tune it a bit, and deliver a select list of contacts.

You may be interested in **OEM** (Original Equipment Manufacturers); they are the big names in the industry (Baxter, Boston Scientific, G.E. Healthcare, Johnson & Johnson, Medtronic, St. Jude Medical, etc.). Or you might prefer to directly approach the final users yourself (hospitals for example) or you think distribution of your product(s) through a **wholesaler** is the best option. All of those approaches and many others are possible. Each case is different and each strategy has advantages... and inconvenients. There is no 'one size fits all'.

Once you have found the right partner and you want to get down to business, it is time then to give your partnership an adequate legal frame (distribution contract for example). In the U.S. it is a crucial step in entering the market. Please make sure to contact your FIT office again at that stage; we can refer you to a number of lawyers in our network, who are familiar with that kind of international ventures.

Besides the most common strategies broached here above (OEM, users, etc.) a number of other options are available, as for example:

- Group Purchasing Organizations
- Subcontractors
- Contract manufacturers

## 4.2 GROUP PURCHASING ORGANIZATIONS (GPO)

Nearly all US hospitals buy through GPO's –also called Direct Purchasing Organizations-, which are cooperatives that increase the buying power of their healthcare provider members. GPO's save their members an average of 10% on supply costs.

Hospitals and nursing homes purchase about 80% of their supplies through GPO and integrated delivery network contacts: Amerinet (St Louis, MO), Consorta (Schaumburg, IL), etc.

Here is a select sample of such GPO's:

- Amerinet (*St Louis, MO*) [www.amerinet-gpo.com](http://www.amerinet-gpo.com)
- Broadlane [www.broadlane.com](http://www.broadlane.com)
- Consorta, Inc. (*Schaumburg, IL*) [www.consorta.com](http://www.consorta.com)
- HealthTrust Purchasing Group [www.healthtrustpg.com](http://www.healthtrustpg.com)
- Innovatix, LLC [www.innovatix.com](http://www.innovatix.com)
- MedAssets [www.medassets.com](http://www.medassets.com)
- Novation/VHA/UHC [www.novationco.com](http://www.novationco.com)
- Premier [www.premierinc.com](http://www.premierinc.com)

### **Margins**

Medical device companies have an average margin of **14%** (more than the 8% for the overall healthcare industry)

For therapeutic and diagnostic products, market leaders (like Medtronic, St Jude, Boston Scientific, Zimmer, Stryker) reach a 25-30% range.

Mature market products like hospital supplies (considered a commodity) go by high volumes and low margins.

## 4.3 CONTRACT MANUFACTURERS

More and more OEMs are focusing their efforts on R&D, design, regulatory issues, and marketing of new medical devices, and they are outsourcing a larger share of their manufacturing and assembly operations to contract manufacturers.

Approximately 50% of the contract manufacturing market for medical devices is controlled by no more than 12 firms, with leader Accellent Inc. (Wilmington, MA - [www.accelent.com](http://www.accelent.com) ) controlling an estimated 12% of the market. Beyond the 12 leading firms, the other 50% of the contract manufacturing market is highly fragmented, comprised of firms that hold less than 1% market share each.

Other major contract manufacturers in the U.S. are:

- Analogic Corporation [www.analogic.com](http://www.analogic.com)
- C&J [www.cjmedical.com](http://www.cjmedical.com)
- Creganna TractX Medical [www.cregannatactx.com](http://www.cregannatactx.com)
- CSI Medical [www.csimed.com](http://www.csimed.com)
- Group BIT [www.group-bit.com](http://www.group-bit.com)
- Heraeus Medical Components [www.heraeus-medicalcomponents.com](http://www.heraeus-medicalcomponents.com)
- Nortech Systems [www.nortechsys.com](http://www.nortechsys.com)
- Plexus Corp. [www.plexus.com](http://www.plexus.com)
- Ventrex Inc. [www.ventrexinc.com](http://www.ventrexinc.com)

To get a sense of the complexity of the industry, it is interesting to compare that overview with a list of the top contract manufacturers in the specific subsector of orthopedic devices:

- Accellent Inc. [www.accelent.com](http://www.accelent.com)
- AeroMed Inc. [www.aerom.com](http://www.aerom.com)
- ASTRO Medical Devices Inc. [www.astromedical.com](http://www.astromedical.com)
- B&G Medical Manufacturing [www.bgmedmfg.com](http://www.bgmedmfg.com)
- IncisionTech [www.incisiontech.com](http://www.incisiontech.com)
- Metal [www.metal-craft.com/index.html](http://www.metal-craft.com/index.html)
- Microcision [www.microcision.com](http://www.microcision.com)
- New Jersey Precision Technologies Inc. [www.njpt.com](http://www.njpt.com)
- Symmetry Medical Inc. [www.symmetrymedical.com](http://www.symmetrymedical.com)

#### 4.4 SME MANUFACTURERS

In some subsectors, there are a number of additional Small and Medium size manufacturers, on top of the major OEM. In orthopedics for example, two thirds of the U.S. market is taken by seven leading OEM's (DePuy (J&J), Zimmer, Stryker, Synthes, Biomet, Smith & Nephew and Wright Medical). Sometimes though, it may prove difficult to approach them. Therefore it can be a smart move to get in touch with smaller OEM's and start ups, which usually are easier to access.

Top 10 list of SME Manufacturers in orthopedics:

- Ascension Orthopedics [www.ascensionortho.com](http://www.ascensionortho.com)
- Accumed designs [www.acumed.net](http://www.acumed.net)
- Amedica Corporation [www.amediacorp.com](http://www.amediacorp.com)
- Consensus Orthopedics [www.consensusortho.com](http://www.consensusortho.com)
- DJO Surgical [www.djosurgical.com](http://www.djosurgical.com)
- Endotec Inc. [www.endotec.com](http://www.endotec.com)
- Exactech Inc. [www.exac.com](http://www.exac.com)
- Interventional Spine, Inc. [www.i-spineinc.com](http://www.i-spineinc.com)
- Small Bone Innovations [www.totalsmallbone.com](http://www.totalsmallbone.com)
- Stelkast Company [www.stelkast.com](http://www.stelkast.com)

Several other subsectors call upon a number of **subcontractors** too for their manufacturing activities. As a rule of thumb, they are easier to access than the major OEM corporations.

#### 4.5 IMPORTING INTO THE U.S.

On the commercial side of exporting, establishing the first contacts and implementing your strategy to penetrate the American market clearly will require a lot of attention.

But you also need to prepare for all the logistics and the customs related procedures and formalities. Because you have a lot of experience with exporting, you probably are familiar with all the nitty-gritty of the matter. It might be a good idea though to skim through our e-manual on Customs, available online on FIT's website. We hope it will provide you with additional useful information on the subject.



[http://www.flanderstrade.be/appl/marktkennis.nsf/0/BAFAC087A95BD1D1C12578EF00518C41/\\$file/E-handleiding%20Douane%20customs%20in%20de%20VS.pdf](http://www.flanderstrade.be/appl/marktkennis.nsf/0/BAFAC087A95BD1D1C12578EF00518C41/$file/E-handleiding%20Douane%20customs%20in%20de%20VS.pdf)

#### 4.6 SETTING UP A COMPANY IN THE U.S.



Along the same lines, even if it may seem premature, you might be interested in browsing through the FIT-brochure on setting up a company in the U.S. (available on FIT's website). The version illustrated here focuses on specific contacts located in Chicago and the Midwest but most of the information is generic and applies to the whole of the United States. Each of the 5 FIT offices in the US (contact information at the end of this document) can provide all the required local contacts to help you further.

<http://www.flanderstrade.be/appl/marktkennis.nsf/documentatie/592111005180225?opendocument>

### 5. FDA AND OTHER REGULATORY INSIGHTS

#### 5.1 FDA - CDRH

The medical device industry is a highly regulated sector, which has significant implications for the industry's performance both in the U.S. and abroad. Accordingly, the medical device industry devotes considerable resources toward the product approval processes, clinical trials, user fees, and plant audits/inspections. The U.S. Food and Drug Administration's Center for Devices and Radiological Health (USFDA/CDRH - <http://www.fda.gov/MedicalDevices/default.htm>) governs the regulatory oversight of medical devices. The FDA maintains three risk categories that determine the type and depth of review necessary for the marketing of medical devices.

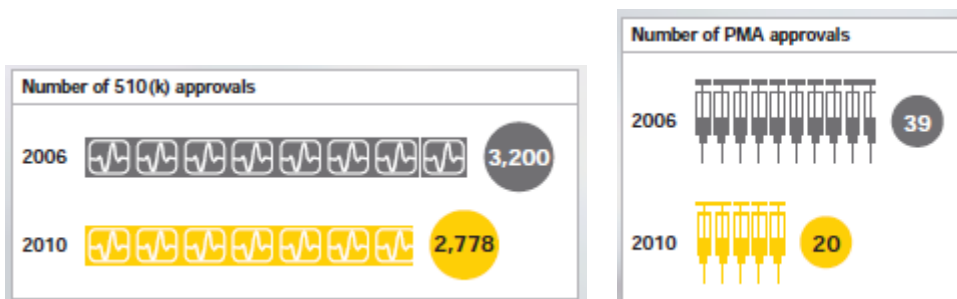


## 5.2 FDA DEVICE CLASSIFICATION

Device Classification	Examples	Required Submission
<b>Class I (low-risk)</b>	Elastic bandages, examination gloves, hand-held surgical instruments	Registration only unless 510(k) specifically required
<b>Class II (moderate-risk)</b>	Powered wheelchairs, infusion pumps, surgical drapes	510(k) clearance unless exempt; IDE <sup>1</sup> possible
<b>Class III (high-risk)</b>	Heart valves, silicone gel-filled breast implants, implanted cerebella stimulators	PMA approval unless 510(k) exempt; IDE probable

Source: American Action Forum.

Although an elementary notion, it is important to point out that not all medical devices require FDA 'Approval'. 510(k) procedures (Class I devices), by far the most common (compare the numbers underneath), actually are a premarket notification which will translate into FDA registration and listing. Only Class III, high-risk devices, are subject to premarket approval.



Source: E&Y, Pulse of the industry, 2011.

One third of all medical devices entering the market go through the 510(k) clearance process, used by the FDA to clear for marketing purposes those devices that are similar to existing products on the market. In Indiana, specialized in orthopedics, more than 80% of manufactured devices go through this process.

## 5.3 COMPARING 510(K) REGISTRATION AND PMA APPROVAL

	510(k)	PMA
<b>Devices Subject to Requirements</b>	Few Class I, most Class II, and some Class III pre-amendment devices.	All Class III post-amendment devices and some Class III pre-amendment devices.
<b>Clinical Data Requirements</b>	Most are not supported by clinical data.	Clinical studies usually required to support submission.
<b>Evidence of Safety and Efficacy Required</b>	Information and data to support "sub-stantial equivalence" to a predicate device.	Clinical data and/or scientific evidence supporting "safety and efficacy" claims.
<b>Marketing Barriers</b>	Low barrier to competitors.	High barrier to competitors.
<b>Average FDA Review Time</b>	Approx. 75 days [traditional 510(k)].	411 Days.
<b>Regulations on Device Changes</b>	Must file new 510(k) if change could "significantly affect" the safety or efficacy of the device.	Must file a new PMA or other filing depending on the nature of the change.
<b>Advisory Panel Review</b>	No APR for almost all 510(k) devices.	APR for some, but not all PMAs.

Source: OSEC report, 2009.

The USFDA is working toward increasing the number of electronic applications for approval and has published proposed rules that would require electronic reporting of adverse events that might occur with post-market medical devices. Known as the Sentinel Initiative, the premise calls for a national electronic system that would allow the firm to search existing databases for safety information on medical products approved by the USFDA.

<http://www.fda.gov/safety/FDASentinelInitiative/ucm2007250.htm>

The FDA has also proposed streamlining current good manufacturing practice standards for combination products. This would help prevent the application from becoming inconsistent or different from the latest standards, and avoid negatively affecting product safety and public health.

The USFDA is re-examining the “510(k)” process, an approval process for medical devices that are substantially equivalent to other products already authorized for sale on the marketplace. The USFDA is attempting to remove vague or nontransparent requirements and determine whether it should restrict the types of products that can pursue a 510 (k) clearance track.

Another key regulatory development is an announcement by the FDA in August 2009. Beginning February 2011 medical device manufacturers, importers, and facilities are required to submit Adverse Event Reports (AERs) to CDRH electronically.

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>

Previously, CDRH received most incident reports on paper, which then had to be inputted into the Manufacturer and User Facility Device Experience (**MAUDE**) database. The FDA says the old process was not only costly, but hindered CDRH’s ability to review safety data quickly to uncover potential public health problems. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

## 5.4 FDA: IT’S ALL ON THE WEB

**FDA Medical Devices:** <http://www.fda.gov/medicaldevices/default.htm>

- o **Products and Procedures:**  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/default.htm>
- o **Approvals and Clearances:** New Device Approval + Market Notification 510 (k) & PMA  
<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/default.htm>
- o **Searchable databases:** e.g. previously approved or pending e.g. 510(k)  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

If you need more guidance or specific advice, please contact FIT Chicago ([chicago@fitagency.com](mailto:chicago@fitagency.com)). If necessary, we can also put you in touch with **professional FDA/ regulatory advisers** within our network who are specialized in helping foreign companies importing (or planning to) in the United States.

## 5.5 FDA FEES

### FDA Government User Fee

- In September 2007, the U.S. Congress authorized FDA to collect a user fee (a.k.a. registration fee) for the registration of certain establishments
- Certain establishments are required to pay the fee at:
  - initial registration and
  - annual re-registration (between Oct 1 & Dec 31)
- The fee is paid to FDA by electronic funds transfer through the Device Facility User Fee (DFUF) portal
- The user fee is subject to increase on a yearly basis
- The Registration User Fee for 2012: \$2,364

For 2012, the **Registration User Fee is \$2,364**. In most cases, registration has to be renewed each year. However, for companies under \$30 million a year, those fees can be waived under specific conditions. *Source: Registrar Corp.*



If the classification of the product is unknown, the 513(g) process applies.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209841.htm>

## 5.6 U.S. AGENT

For the purpose of FDA registration and listing, any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device imported into the United States must identify a United States agent (U.S. agent) for that establishment. The U.S. Agent must be residing in the U.S. It can also be a regulatory consultant for example. FIT Chicago can provide useful contacts for this purpose. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053196.htm>

FDA also requires registration as a foreign Subcontractor (form FDA 2891): <http://www.nadl.org/lib//FDARegulations/FDARegistrationForm2891.pdf>

## 5.7 UDI: UNIQUE DEVICE IDENTIFIER



The Food and Drug Administration (FDA) has released a proposed rule that most medical devices distributed in the United States carry a unique device identifier, or UDI. Congress passed legislation in 2007 directing the FDA to develop regulations establishing a unique device identification system for medical devices.

It is still unknown when the UDI will be implemented but our sources indicated that the application of the new rule will be phased in over 3 years for Class III devices and over 5 years for Class I.

*Example of UDI. From:*

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>

## 5.8 MEDICAL DEVICES LABELING



**FDA U.S. Food and Drug Administration**  
Protecting and Promoting *Your Health*

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics

**CFR - Code of Federal Regulations Title 21**  
FDA Home | Medical Devices | Databases

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification  
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports

NEW Search

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H--MEDICAL DEVICES  
PART 801 LABELING

**Subpart A--General Labeling Provisions**  
 § 801.16 - Medical devices; Spanish-language version of certain required statements.  
 § 801.17 - Medical devices; name and place of business of manufacturer, packer or distributor.  
 § 801.18 - Meaning of intended uses.  
 § 801.19 - Medical devices; adequate directions for use.  
 § 801.20 - Medical devices; misleading statements.  
 § 801.21 - Medical devices; prominence of required label statements.

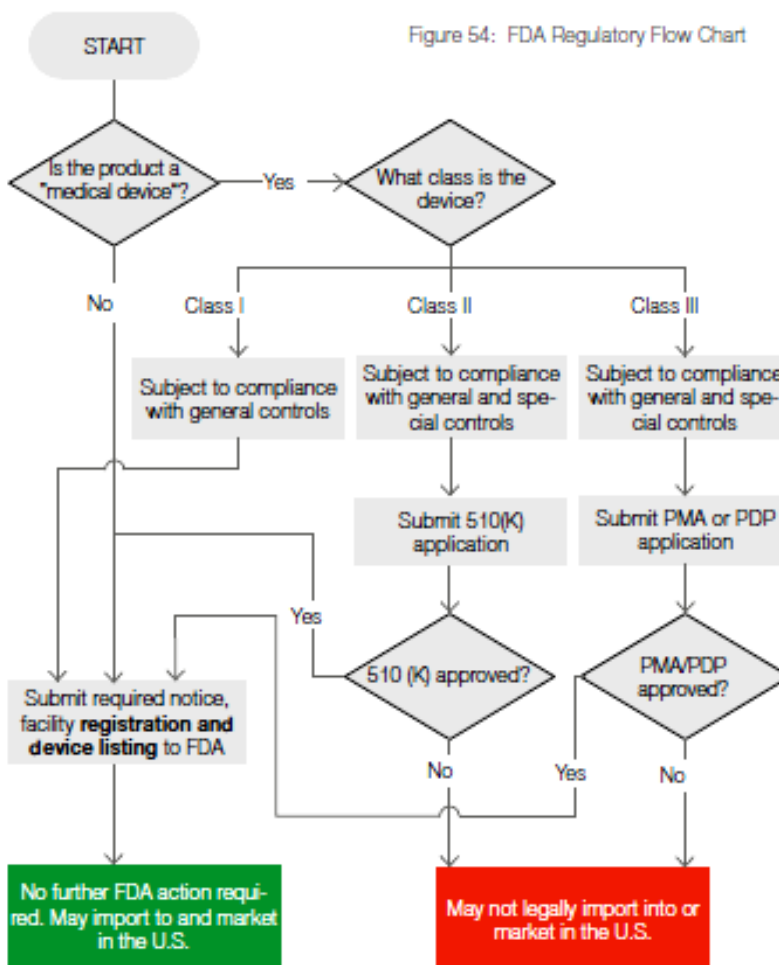
**Subpart B [Reserved]**

**Subpart C--Labeling Requirements for Over-the-Counter Devices**  
 § 801.60 - Principal display panel.  
 § 801.61 - Statement of identity.  
 § 801.62 - Declaration of net quantity of contents.

The U.S. Code of Federal Regulations (**CFR**), under its Title 21, mainly Parts 801, 809, 812 and 820, provides all stipulations relative to the **labeling** of medical devices.

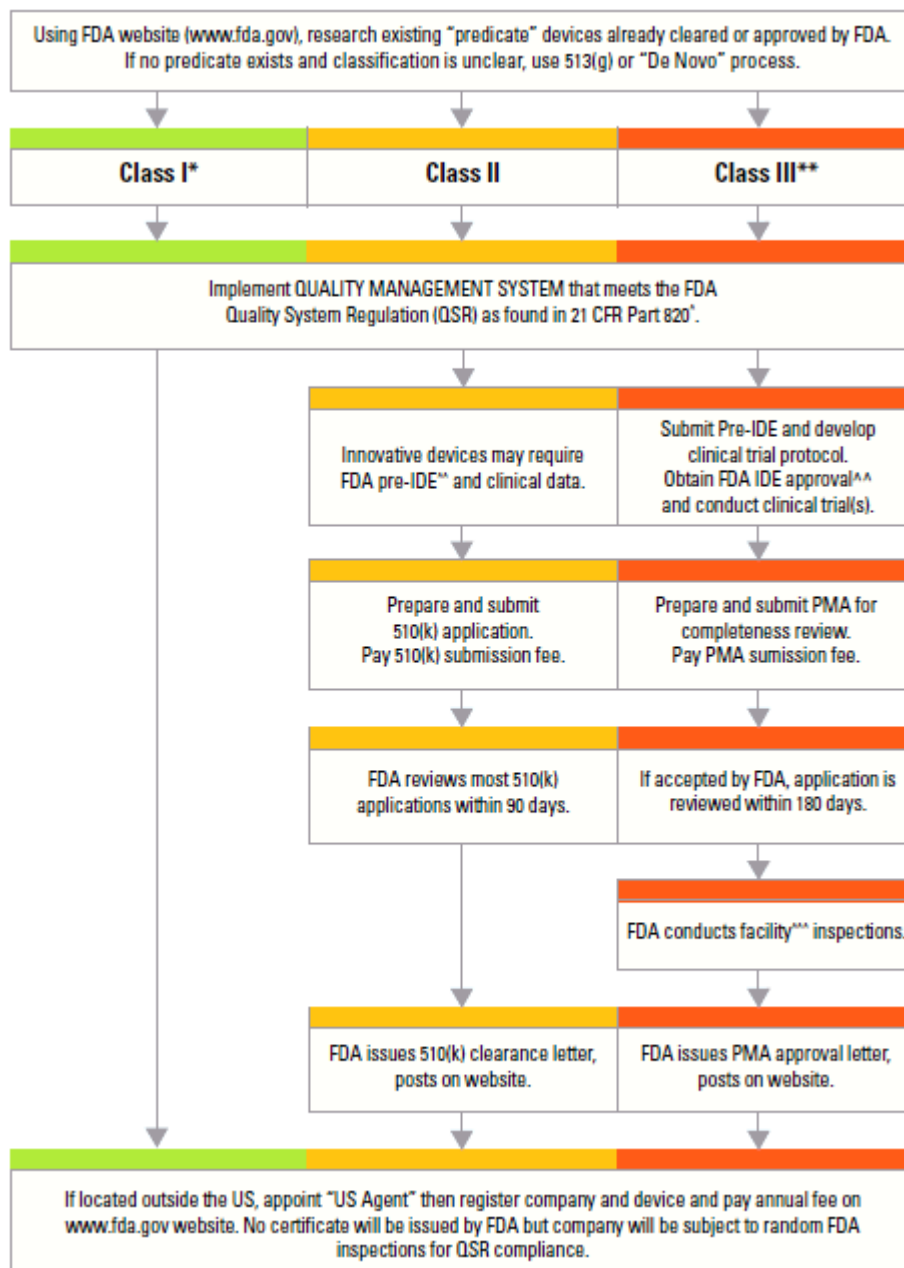
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=801>

## 5.9 USA REGULATORY PROCESS FOR MEDICAL DEVICES



Source: OSEC report, 2009.

Another interesting overview of the Regulatory Process for Medical Devices in the US can be found at: [www.emergogroup.com/literature](http://www.emergogroup.com/literature)



A similar flow process chart is available for other countries or regions, Europe being one of them. [www.emergogroup.com/literature](http://www.emergogroup.com/literature)

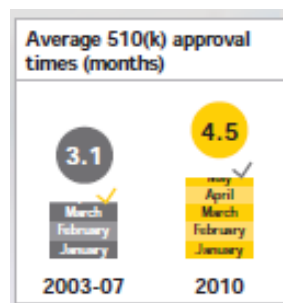
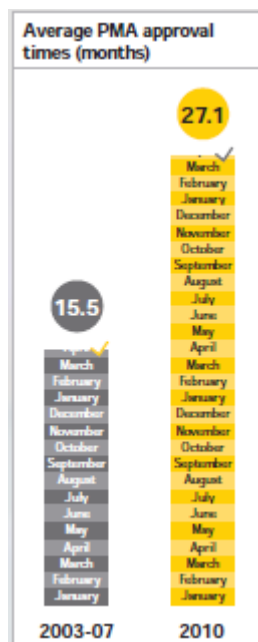
## 5.10 REGULATORY CHALLENGES AND ISSUES

### Reform of the 510(k)

As mentioned before, the FDA's 510(k) process for clearing certain classes of medical devices has come under considerable scrutiny in recent years. Critics have charged that the **510(k) process** — which, unlike the premarket approval (PMA) process used for life-sustaining products, does not require clinical trials — needs to be changed. The FDA responded by initiating a review of the 510(k) process and also asking the Institute of Medicine (IOM) to conduct a separate review.

In July 2011, the IOM released its report, “Medical Devices and the Public’s Health: The FDA 501(k) clearance Process at 35 Years.” The IOM report’s recommendations were certainly bold — rather than proposing reforms to the existing system, the institute recommended scrapping the 510(k) process altogether and replacing it with “an integrated premarket and post market regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle.” The FDA soon announced that it does not intend to implement this proposal, while some policymakers continue to decry the agency for not considering it.

### Long and uncertain



The major criticism from the medtech industry in the U.S. is that (especially for Class III devices), the approval process has become much longer than it used to be. According to the American Action Forum data, the average time for FDA decision (510(k) track) went from **90 days** in 2005 to **140 days** in 2010 (= + 55%). These numbers are pretty much consistent with the E&Y report (2011) that we already mentioned previously in this document.

This evolution has created a sort of global regulatory competition, especially with Europe where many devices are approved in roughly half the time it takes FDA to do so.

More global pressures constrain the U.S. medical devices industry, as for example the rise of the East, competing mainly on a price/cost base, and the development of specialty hospitals in Asia.

Source: E&Y, *Pulse of the industry*, 2011.

Those factors, - long and complicated regulatory process, not to forget the high cost of clinical trials for Class III - combined with a slower pace of growth in the mature economies have incited many U.S. companies in the medtech industry to pursue a OUS (Out of the U.S.) strategy. It also made it more difficult for startups to attract venture capital when needed (in the early stages).

## 5.11 REIMBURSEMENT: CODING, COVERAGE AND PAYMENT



Most patients cannot afford to pay for medical devices and procedures on their own: they rely on insurance to pay about 88 percent of all healthcare expenses. Reason enough for public (Medicare and Medicaid) and many private insurance companies to have their say in which medical procedures and devices they will reimburse.

The public and private sectors operate independently from each other. On the public side, The Centers for Medicare and Medicaid Services (CMS; [www.cms.gov/](http://www.cms.gov/)) takes the leading role in making decisions while on the private side the individual companies conduct their own reviews and make their own decisions (they tend to follow the lead of CMS though). CMS is also increasingly

positioning itself as an active purchaser rather than a mere passive payer of healthcare.

THE ASSESSMENT OF MEDICAL DEVICES THAT IS THE BASE OF THE REIMBURSEMENT DECISION IS DONE MAINLY BY:

- CMS (Centers for Medicare and Medicaid Services)  
[www.cms.gov/](http://www.cms.gov/)
- the National Blue Cross/Blue Shield Technology Evaluation Center  
<http://www.bcbs.com/blueresources/tec/what-is-tec.html>
- the American Association of Health Care Plans  
<http://www.ahip.org/>
- ECRI (initially Emergency Care Research Institute): an independent, nonprofit health services research agency that performs many technology assessments for the insurance industry.  
<https://www.ecri.org/Pages/default.aspx>



If you are not familiar with the concepts of Coding, Coverage and Payment in the U.S. you will find more information on the topic of reimbursement here:

- o Advanced Medical Technology Association  
[www.advamed.org](http://www.advamed.org)
- o American College of Cardiology (Payer Advocacy/HIPAA)  
[www.acc.org/advocacy/pmr/payer\\_issues/payer\\_issues.htm](http://www.acc.org/advocacy/pmr/payer_issues/payer_issues.htm)
- o CMS: Medicare Learning Network  
[www.cms.hhs.gov/MLNGenInfo](http://www.cms.hhs.gov/MLNGenInfo)
- o D&MD Publications - *Guide to US Reimbursement for Drugs, Medical Devices, and Diagnostic*  
[www.bioportfolio.com/reports/DMD\\_Guide\\_to\\_Medical.htm](http://www.bioportfolio.com/reports/DMD_Guide_to_Medical.htm)
- o E-Expert Reimbursement Partners  
[www.eexpertpartners.com/home.html](http://www.eexpertpartners.com/home.html)
- o FDC Reports  
[www.fdcreports.com](http://www.fdcreports.com)
- o Medical Device Manufacturers Association  
[www.medicaldevices.org/public/issues/reimbursement.asp](http://www.medicaldevices.org/public/issues/reimbursement.asp)
- o The Gray Sheet  
[www.thegraysheet.com/FDC/Weekly/gray/TOC.htm](http://www.thegraysheet.com/FDC/Weekly/gray/TOC.htm)

Full access to some information on those sites may require a subscription or registration.

A number of specialized companies can also provide information and advice, for a fee, about payer trends and industry requirements, and can help develop reimbursement strategies: Strategic Reimbursement Consulting ([www.strategic-reimbursement.com](http://www.strategic-reimbursement.com)), Reimbursement Principles ([www.reimbursementprinciples.com](http://www.reimbursementprinciples.com)), Regulatory & Clinical Research Institute (RCRI - [www.rcri-inc.com](http://www.rcri-inc.com)), Princeton Reimbursement Group (PRG - [www.prgweb.com](http://www.prgweb.com)), etc.

Please contact us for a more extensive list.

## 5.12 PATENTS



Three types of patents are defined by the U.S. Patent and Trademark Office (USPTO):

- **Utility** patents, which may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof.
- **Design** patents, which may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture.
- **Plant** patents, which may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.

Read more about patents on the USPTO's website: <http://www.uspto.gov/>  
Also: [http://medicaldesign.com/engineering-prototyping/patents\\_medical\\_devices/](http://medicaldesign.com/engineering-prototyping/patents_medical_devices/)



## 6. A CLOSER LOOK AT KEY STATES

### 6.1 CALIFORNIA (CA)



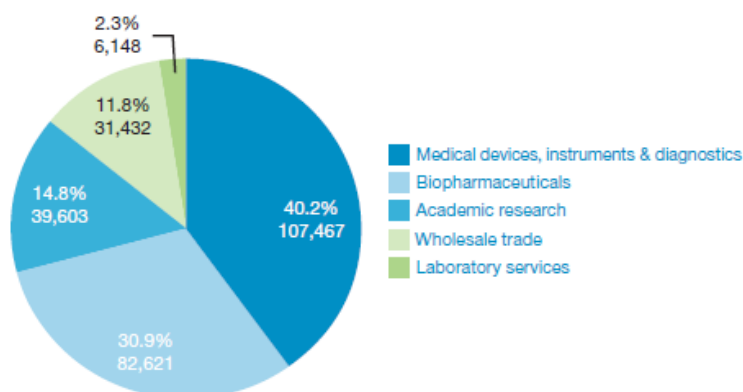
With 2,323 companies in the biomedical industry as a whole, **California** is a major player in the life science industries, totaling 267,271 jobs (data 2010).

Of course 'Biomedical' covers a wide range of subsectors and activities (detailed hereunder). Medical devices/ medtech is one of them, with **107,467 jobs**, or **40.2%** of total biomedical employment. Following a slightly different boundary definition, the 2010 data for California in the

Battelle Report 2012 mention a direct employment level of **59,450** in Medical Devices & Equipment.

In a very general way, one could say that the life science/biotech companies tend to locate in the Bay Area (San Francisco Bay, Northern California) while there is a higher concentration of medtech companies in Southern California (Los Angeles Orange County and San Diego).

### BIOMEDICAL INDUSTRY SECTORS



Source: Bureau of Labor Statistics Quarterly Census of Employment and Wages and Company Specific SEC filings.

The biomedical industry encompasses all life sciences based research and commercial organizations that are pursuing innovative research and technological development to benefit human health.

**Basic research** in California's universities and public and private research centers adds to the body of scientific knowledge. In addition to training young technical specialists and providing space, equipment and resources for ongoing research, these institutions fuel innovation via technology transfer and the formation of spin-off companies.

**Biopharmaceuticals** is the product category that includes human therapeutics – drugs – whether small-molecule chemical compounds, biologics (genetically engineered proteins) or cell therapies.

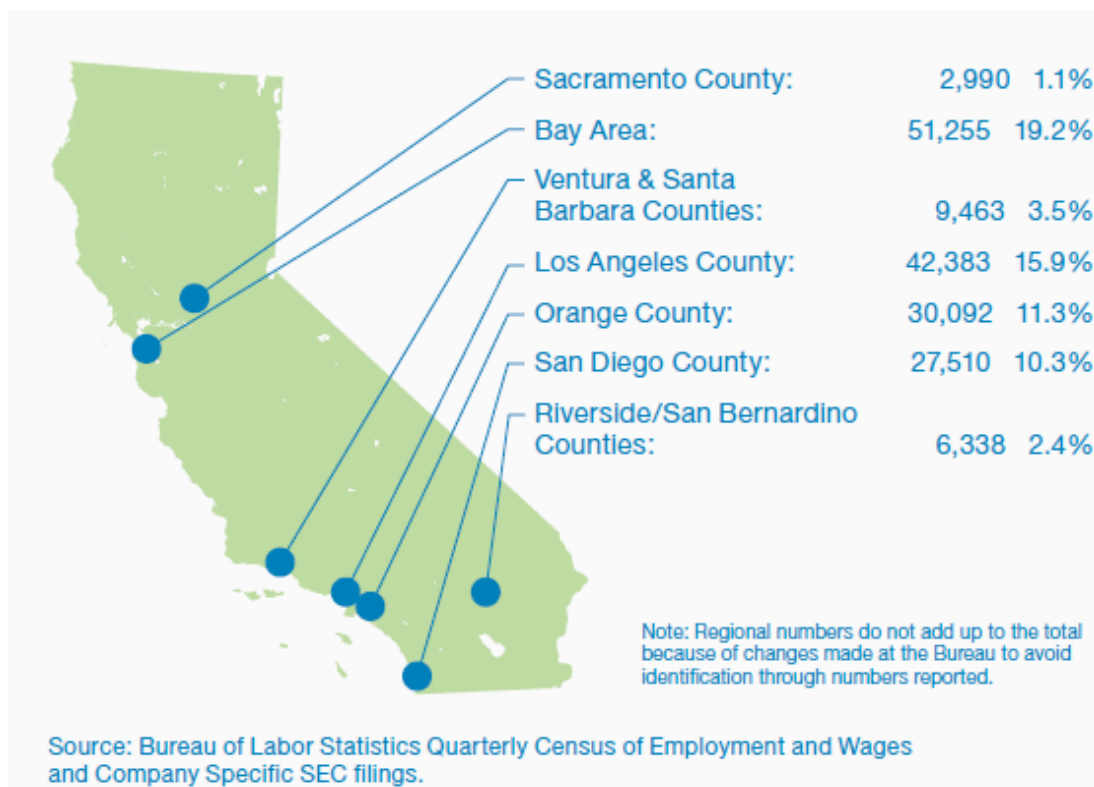
**Diagnostics** are technologies – from simple home test kits to genomic sequencing equipment – that characterize patients' conditions. These products are essential in providing correct diagnoses and informing treatments for the best possible outcomes.

**Medical technology** or "medtech" includes a broad range of devices and tools that improve human health and mobility. The sector produces everything from clinicians' instruments to patients' monitoring devices to orthopedic implants.

**Research tools** companies are a subset of the medical technology segment. These firms design, develop and produce the equipment and supplies essential to others' research and development programs. **Laboratory services** include the testing of patients' or research samples with precisely calibrated and strictly regulated equipment and procedures to ensure accurate results.

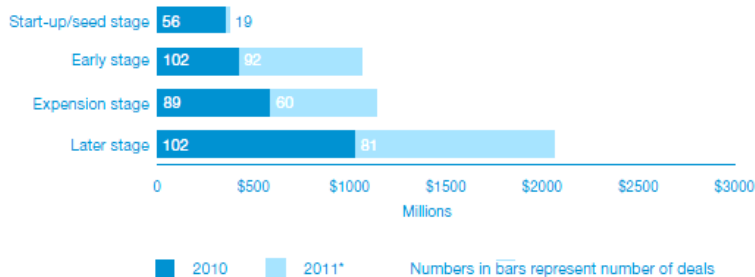
**Wholesale trade companies** manage the import, export and exchange of pharmaceuticals, medical devices, diagnostics and research reagents and other supplies in the global market.

## CA LIFE SCIENCES CLUSTERS, BY EMPLOYMENT



## VENTURE CAPITAL

### U.S. medical devices venture capital by stage



\*Data for 2011 only represents the first 3 quarters.  
Source: PricewaterhouseCoopers/National Venture Capital Association MoneyTree™ Report based on data from Thomson Reuters.

Source: *California Biomedical Industry Report, 2012.*

Overall, VCs are weighting their U.S. biotechnology support – both in total dollars and numbers of transactions – toward later development stages. The medical device sector saw a steep decline in start-up/seed stage financing in the first three quarters of 2011 as compared to 2010. This slowdown may foreshadow lean capital years ahead. With investors unable to find exits from their portfolios and forced to support companies longer, they are, in turn, unable to invest in early stage companies. If so, 2012 and 2013 could mark a critical turning point for the U.S. biomedical industry.

At the end of 2010, VCs' U.S. investments were not rewarding all project stages equally. On the biotechnology side, there was a decisive shift toward later stage projects: in the first nine months of 2011, the category had received more money than it had garnered in all of 2010. Medical technology companies across the country, in contrast, recorded the biggest increases in early stage projects.

## CA Resources

- **CHI-California Healthcare Institute** [www.chi.org](http://www.chi.org)  
The California Healthcare Institute (CHI) is a non-profit public policy research organization for California's biomedical R&D industry. CHI represents leading medical device, biotechnology, diagnostics and pharmaceutical companies and public and private academic biomedical research organizations. CHI's mission is to advance responsible public policies that foster medical innovation and promote scientific discovery.
- **BayBio** [www.baybio.org](http://www.baybio.org)  
BayBio is Northern California's life science association. It supports the regional bioscience community through advocacy, enterprise support, and enhancement of research collaboration. BayBio maintains Northern California's leadership in life science innovation by supporting entrepreneurship, science education and life science career development through the BayBio Institute. Its members include organizations engaged in, or supportive of, research, development and commercialization of life science technologies.

## MEDICAL DEVICES IN SOUTHERN CALIFORNIA



Stretching south from Orange County's bustling medical device hub through San Diego County's research institutes and pockets of innovation in Carlsbad, Torrey Pines and Sorrento Valley, Southern California attracts investors, partners and imitators from around the globe.

What began more than 35 years ago with a single biotechnology startup has evolved into one of the world's largest life sciences hubs. Several major forces put the region on the map: science breakthroughs out of the research institutes on the Torrey Pines Mesa and in and around Irvine, as well as the success of the region's first true biotechnology company, Hybritech, and the growth of the medical device industry in both San Diego and Orange counties.

Scientists out of UC San Diego founded San Diego-based Hybritech. The company's signature product,

a diagnostic test for prostate cancer – the PSA test – and the company's acquisition by pharmaceutical giant Eli Lilly for \$400 million cash in 1986, created the first generation of Southern California biotechnology entrepreneurs with the finances and connections to start new companies.

In Orange County, the medical device industry's story of growth began much as it did in San Diego County. Scientists and engineers originally attracted to the region for military research and manufacturing jobs began to translate basic bioscience research from the surrounding labs and universities into potential products. Edwards Lifesciences, founded in Santa Ana in the late 1950s, anchored the device cluster to the north. It, too, graduated a new generation of entrepreneurs who started their own companies in Orange County. Meanwhile, Allergan, an Irvine eye drug company also founded in the 1950s, began to move into the new field of biotechnology in the late 1980s, with the acquisition of Botox.

**BIOCOM** [www.biocom.org](http://www.biocom.org)

BIOCOM is the nonprofit trade association that represents Southern California's life sciences industry.

Its 560 members encompass all sectors of the life sciences, as well as academia and research institutes, service providers and patient advocacy agencies.

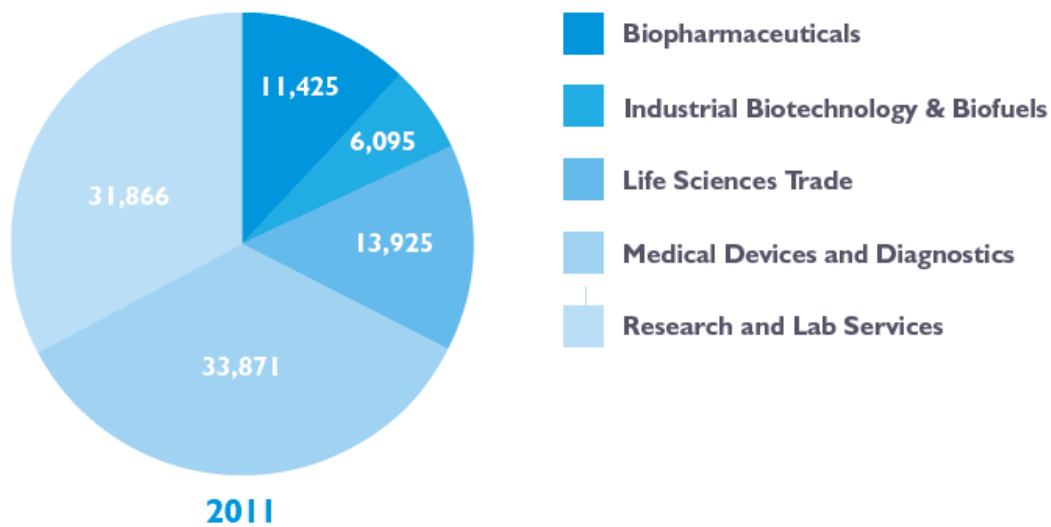
BIOCOM was launched in 1992 when San Diego's biotechnology start-ups realized that they needed a strong and united voice to deal with city and state officials who had recently proposed measures that could decimate the industry, including water restrictions. Twenty years later, BIOCOM continues to provide public policy support in city halls, in Sacramento (State capital) and on Capitol Hill (Washington D.C.), where it partners with peer industry groups from across the nation.

Most of the data presented here focus on the 4 most Southern counties in Southern California: San Diego, Orange, Riverside and Imperial.

When we look at employment in **Southern California**, we observe that **Medical Devices and Diagnostics** offers **33,871 jobs**, out of a total of 97,000 jobs, spread over 5 sectors. This is about a third of all medtech jobs in California.

#### LIFE SCIENCE EMPLOYMENT BY INDUSTRY

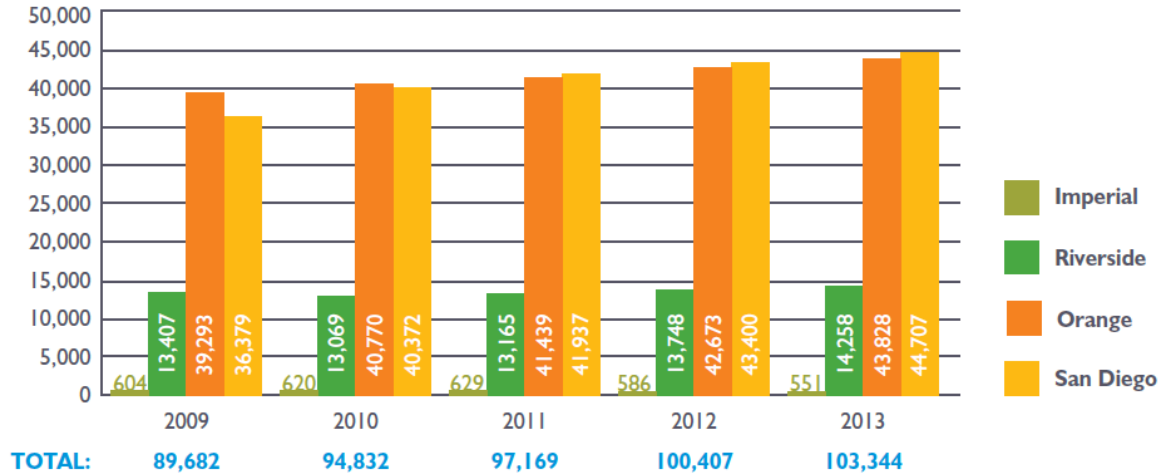
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Source: EMSI Complete Employment, Hendershot Economics

The bar chart detailing life science employment (by County) in Southern California clearly shows the predominance of **Orange County and San Diego**.

#### LIFE SCIENCE EMPLOYMENT BY COUNTY



Source: EMSI Complete Employment, Hendershot Economics

The picture is further enhanced by examining the breakdown of the number of establishments by industry and by County. Out of a total of **715 medical device establishments** in the 4 counties, 388 are located in Orange County and 240 in San Diego (together: 628; which is 88% of the total 715).

#### NUMBER OF ESTABLISHMENTS BY INDUSTRY & COUNTY

SECTOR	IMPERIAL	ORANGE	RIVERSIDE	SAN DIEGO	REGION
Biopharmaceuticals	0	87	19	108	214
Industrial Biotechnology and Biofuels	105	84	189	308	686
Life Sciences Trade	1	377	105	228	711
Medical Devices & Diagnostics	1	388	86	240	715
Research and Lab Services	6	281	101	821	1,209
<b>TOTAL</b>	<b>113</b>	<b>1,217</b>	<b>500</b>	<b>1,705</b>	<b>3,535</b>

Source: BIOCOM Southern California Economic Impact Report, 2012.

Then again, the average employment by establishment shines a different light: most (60) for Riverside but only 4 for San Diego.

#### AVERAGE EMPLOYMENT BY ESTABLISHMENT

SECTOR	IMPERIAL	ORANGE	RIVERSIDE	SAN DIEGO
Biopharmaceuticals	N/A	54	73	50
Industrial Biotechnology and Biofuels	5	12	9	9
Life Sciences Trade	10	20	24	17
Medical Devices & Diagnostics	36	50	60	4
Research and Lab Services	5	32	25	25
<b>AVERAGE</b>	<b>6</b>	<b>34</b>	<b>26</b>	<b>25</b>

#### MEDICAL DEVICES & DIAGNOSTIC IMPACT: EMPLOYMENT

COUNTY	DIRECT	INDIRECT	INDUCED	TOTAL
Imperial	36	7	6	49
Orange	19,212	12,066	14,783	46,061
Riverside	5,125	2,205	3,148	10,478
San Diego	9,498	5,160	7,182	21,840
<b>TOTAL</b>	<b>33,871</b>	<b>19,438</b>	<b>25,118</b>	<b>78,428</b>

Sources: EMSI Complete Employment, IMPLAN, Hendershot Economics

#### MAJOR EMPLOYERS (MEDICAL DEVICES & DIAGNOSTICS)

BUSINESS NAME	LOCAL EMPLOYEES
Edwards Lifesciences Corp	1,800
Gen-Probe Inc	650
Applied Medical Resources Corp	650
Signet Armorlite Inc	550
Masimo Corp	500
Sybron Dental Specialties Inc	500
Newport Corp	500
DJO Global	450
Volcano Corp	430
CareFusion Corp	400

Source: BIOCUM Southern California Economic Impact Report, 2012.

## WHOLESALE DISTRIBUTION

The Life Sciences TRADE sector is engaged in the WHOLESALE DISTRIBUTION of professional medical equipment, pharmaceuticals, and instruments used by hospitals, research labs, other life science companies, ophthalmologists and other health professionals.

BUSINESS NAME	LOCAL EMPLOYEES
B Braun Medical Inc	1,400
Professional Hospital Supply	1,000
V Q Ortho Care	200
3D Instruments Llc	150
Cameron Health Inc	150
Halozyme Therapeutics Inc	102
Care Credit	100
Victor Medical Co	100
Dental Alloy Products Inc	100
Physician Sales & Svc	90

Source: EMSI, Claritas, Hoover's

In 2011, the Medical Devices industry in Southern California accounted for **\$3.5 billion exports** (of which Orange County \$2.1 billion, out of a total of \$6 billion export for Life Sciences overall).

NAICS codes for LIFE SCIENCES TRADE (=wholesalers)

- 423450 Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers
- 423460 Ophthalmic Goods Merchant Wholesalers

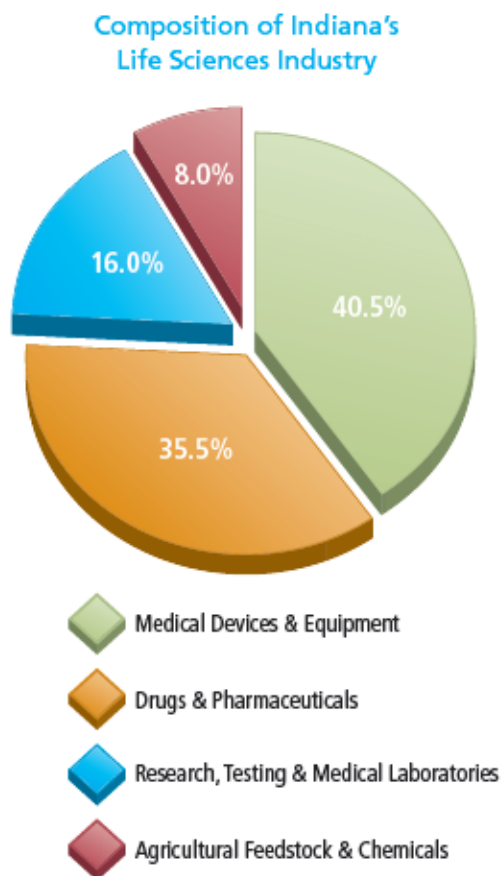
## 6.2 INDIANA (IN)



**Indiana's** medical device industry is one of the state's most valuable economic assets and has made Indiana a nationally recognized leader in the health care sector. The sector employs over **20,000** people, accounting for more than 40 percent of the jobs in the state's life sciences industry, and has propelled Indiana to the fifth largest state in percentage of medical technology industry employment. The industry generates more than **\$10 billion** of annual economic output, and its reach extends far

beyond direct employment (20,000) because of its extensive supply chain and heavy concentration of manufacturing operations. Another 28,000 indirect jobs bring the total close to 50,000.

Indiana medical device companies produce orthopedic, cardiovascular, diagnostic and urological products utilized by patients and clinicians throughout the world. The global pharmaceutical company **Eli Lilly** also is headquartered in Indianapolis, IN. With products like Prozac, Cialis, Cymbalta, Eli Lilly generates over \$20 billion turnover and employs over 30,000 people worldwide.



The medical device industry produces a diverse set of products in the state ranging from commodity products like bandages to highly-advanced implantable and precision-engineered devices. Furthermore, the industry is geographically diverse, extending its reach and positive benefits to all corners of Indiana.

**Warsaw, IN**, is the **Orthopedics Capital of the World**. Home to three of the world's top five manufacturers of orthopedic devices (**Zimmer, DePuy and Biomet**) and one-third of the world's orthopedics industry, the Warsaw region enjoys 6,800 medical device industry jobs. These companies manufacture a range of orthopedic devices including artificial knees, hips, and spine products. The city of 14,000 is a strong example of a well-established industry cluster with DePuy's history dating to the 1890s and Zimmer to the late 1920s. Only three (and each, far larger) U.S. regions (Orange County, CA; Los Angeles, CA; and Minneapolis, MN) have more medical device jobs.

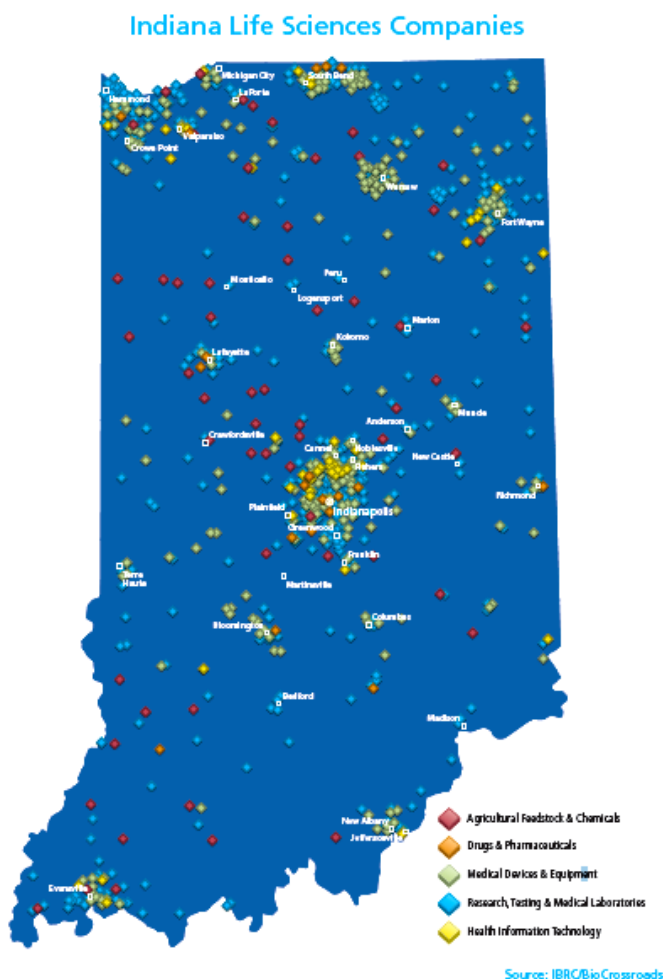
Source: *Indiana's Life Sciences Industry: 2002-2010 – BioCrossroads*



Several other major companies are based in Indiana:

- Roche Diagnostics (Indianapolis): laboratory diagnostic tools to diagnose and monitor diseases e.g. monitor blood glucose levels (diabetes).
- Cook Group (Bloomington, Spencer and West Lafayette): catheters for surgical and diagnostic procedures, stents, guidewires and a tissue-based scaffold to heal wounds.
- Boston Scientific (Spencer): development of innovative products, particularly in the field of urology conditions.

The State of Indiana has developed novel public-private partnerships to establish privately managed **venture capital funds** that balance fiduciary responsibility to their investors with a need to address insufficient private investment available for in-state life sciences firms. While the funding needed to commercialize a medical device is relatively less than other life sciences products such as pharmaceuticals, the cost can still exceed \$50 million dollars for a single product. Access to risk-based capital is a key component of successfully bringing a medical device to the market.



Indiana's 25 Largest Medical Device Companies (Employment)

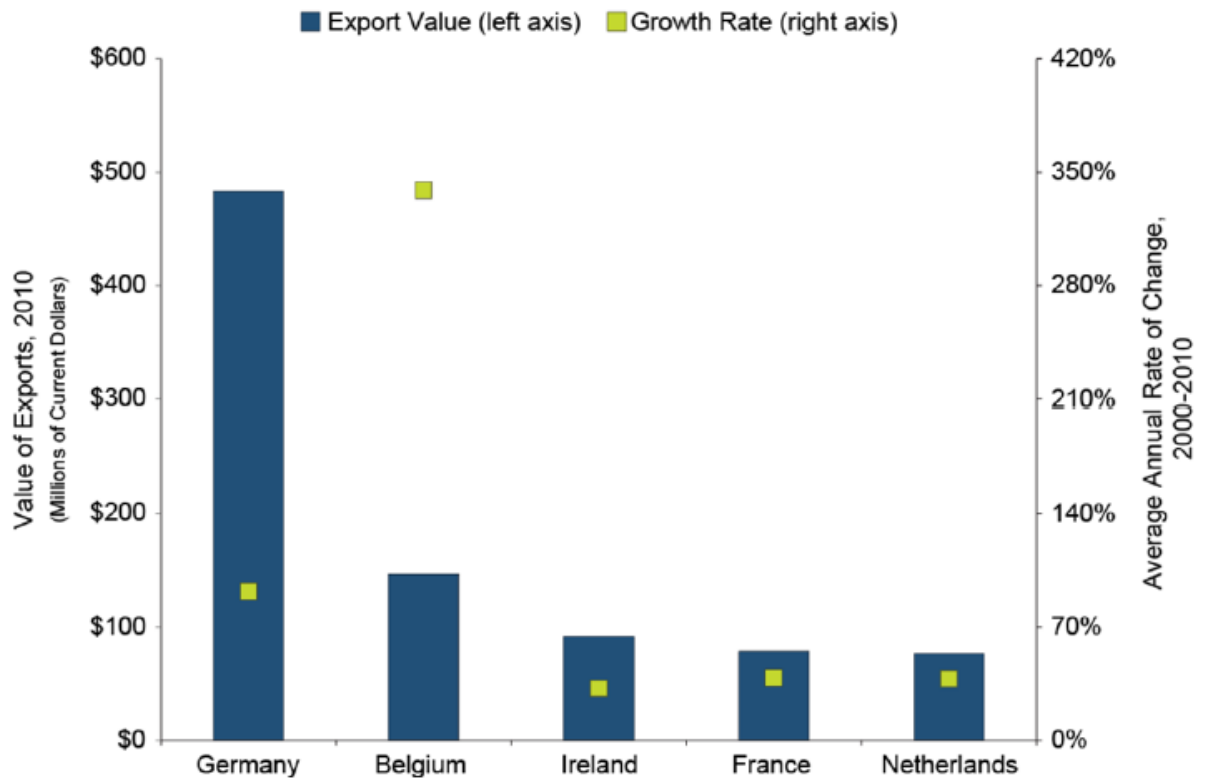
Company	City
Advantis	Medical Greenwood
American Renolit	La Porte
AO Safety	Plymouth
Beckman Coulter	Indianapolis
Biomet	Warsaw
Boston Scientific	Spencer
C&A Tool Engineering	Churubusco
Cook Group	Bloomington
DePuy	Warsaw
EHOB	Indianapolis
Fort Wayne Metals	Fort Wayne
Helmer	Noblesville
Heraeus Kulzer	South Bend
Hologic	Indianapolis
King Systems	Noblesville
Medtronic	Warsaw
Micropulse	Columbia City
Paragon Medical	Pierceton
Point Medical	Crown Point
Quadrant	Fort Wayne
Roche Diagnostics	Indianapolis
Smiths Medical	Gary
Symmetry Medical	Warsaw
TP Orthodontics	Westville
Zimmer	Warsaw

Source: BioCrossroads. [http://www.biocrossroads.com/Documents/BIOX\\_LifeSciMap\\_r5.aspx](http://www.biocrossroads.com/Documents/BIOX_LifeSciMap_r5.aspx)

## PHARMACEUTICAL DISTRIBUTION & LOGISTICS

Indiana has also identified and pursued another distinctive industry niche – pharmaceutical distribution and logistics – which builds on the state’s central location and cluster strengths in both logistics and life sciences. Major companies in that field are Medco Health (<http://www.medcohealth.com/medco/corporate/home.jsp>) and Express Scripts ([www.express-scripts.com/](http://www.express-scripts.com/)). In addition, Indianapolis is home to FedEx’s second largest cargo hub and several cold chain storage facilities.

### Top 5 export destinations for Indiana optical and medical instruments, 2000-2010



Source: WISER Trade

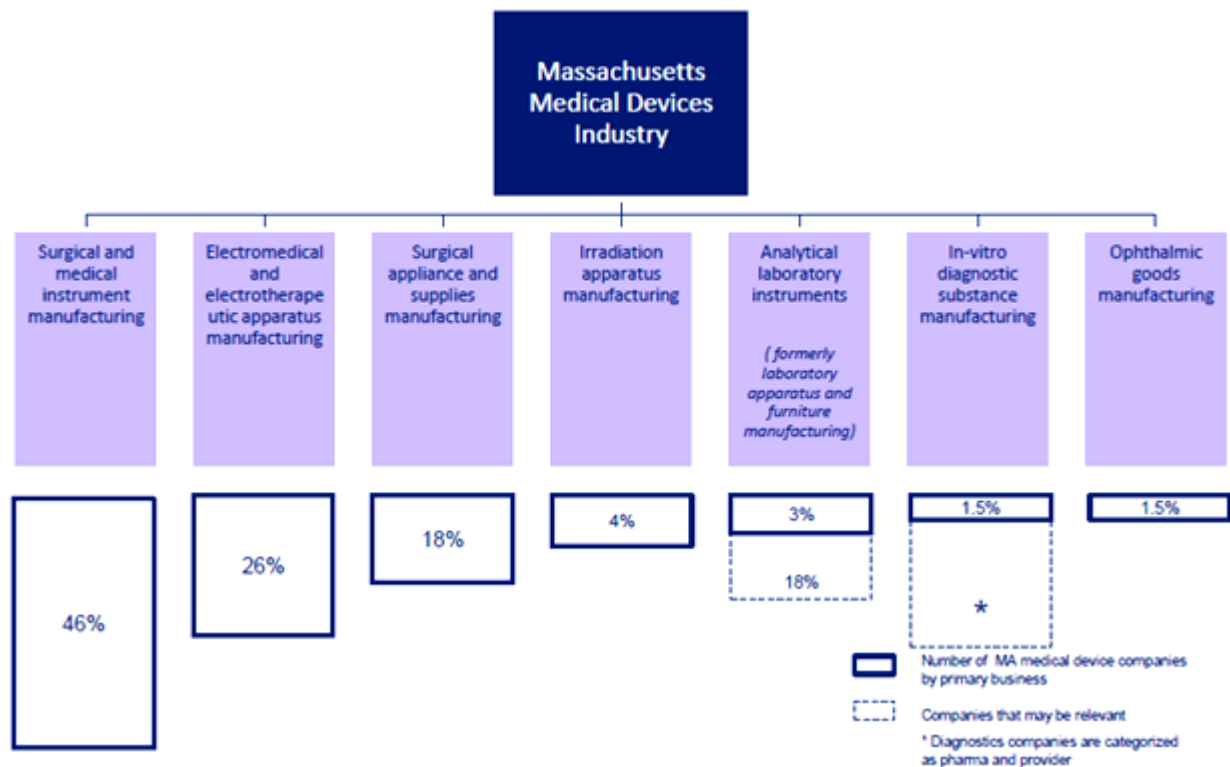
## 6.3 MASSACHUSETTS (MA)



**Massachusetts** (population 6.6 million – of which 4.5 million in Boston) ranks 2<sup>nd</sup> with **6%** of total U.S. employment in the medical device industry, preceded only by the State of California (population 37.6 million) that accounts for a solid 16% (data 2008).

**400** Massachusetts companies focus on medical devices, with surgical and medical instrument manufacturers leading the pack. The state's medical device industry employs close to **25,000** people (**direct employment**), with another 80,000 jobs created in related industries.

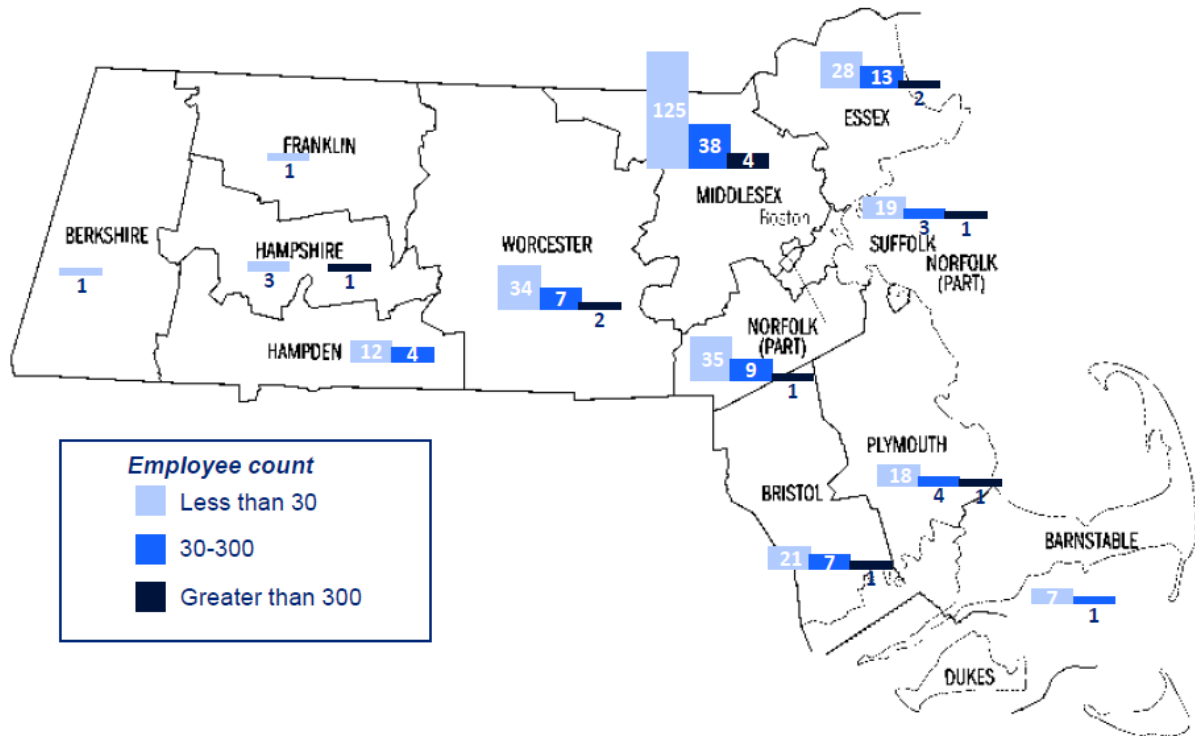
Manufacturers of surgical and medical instruments account for no less than 46% of the total (number of companies). Adding electromedical and electrotherapeutic apparatus (26%) and surgical appliances and supplies (18%), those three categories account for 90% of Massachusetts' medtech companies.



Source: Deloitte presentation at MassMEDIC, 2011

MA medical devices are more than 10% (13% in 2010) of total state exports and they also represent 10% of U.S. medical device exports. The European market is the biggest consumer of Massachusetts' medical devices export, with 49% (Asia = 37%).

As shown by the map, there is a heavy concentration of medical device firms in Eastern Massachusetts (Boston area), although medtech companies are present in almost all regions of the state.



Source: Deloitte presentation at MassMEDIC, 2011

### Explore MA's medtech

Boston Scientific and Covidien may be the most familiar names of Massachusetts based medtech companies but, as mentioned before, there are 400 hundred more, not to mention the subcontractors and suppliers.

Two interesting web based tools will allow you to explore and search the industry:

- <http://www.massmedic.com/directory/> Suppliers Directory of the Massachusetts Medical Device Industry Council
- <http://www.massdevice.com/directory> going even beyond Massachusetts only: the New England Medical Device Directory

## 6.4 MICHIGAN (MI)



While Michigan obviously and deservedly is first and foremost associated with the automotive industry, centered in and around the Detroit area, the state also is considered 'sizable' when it comes to the industrial footprint of the medical devices and equipment subsector.

Total **direct employment** in medical devices and equipment in Michigan was **10,328** in 2010 (Source: Battelle Report 2012).

To put these 10,000 in perspective, let us compare that number with the top 4 states in medical devices: 59,450 in California, 26,774 in Minnesota, 20,182 in Massachusetts and 18,936 in Indiana.

Two main regions of Michigan particularly deserve our attention with regard to medical devices:

- Southwest Michigan and the Kalamazoo area
- Southeast Michigan centered on Detroit.

### SOUTHWEST MICHIGAN / KALAMAZOO

Research and Development Companies	Location
Abbott Laboratories	Sturgis, MI
Advanced Cooling Therapy	Kalamazoo, MI
Azenic Dental	Kalamazoo, MI
Borgess Research Institute	Kalamazoo, MI
Bronson Medical Center	Kalamazoo, MI
Covance	Battle Creek, MI
Keystone Solutions Group	Kalamazoo, MI
Medtronic	Grand Rapids, MI
Monteris Medical	Kalamazoo, MI
Stryker Corporation - Headquarters	Kalamazoo, MI
• Stryker Instruments	Kalamazoo, MI
• Stryker Medical	Portage, MI
• Stryker EMS	Kalamazoo, MI
• Stryker Surgical	Kalamazoo, MI
• Stryker Craniofacial	Kalamazoo, MI
• Stryker Neuro Spine and ENT	Kalamazoo, MI
Tekna	Kalamazoo, MI
Thermo Fisher Scientific	Kalamazoo, MI
OEM Product Design	Location
Keystone Solutions Group	Kalamazoo, MI
Tekna	Kalamazoo, MI
Development Contract Research Organizations	Location
BioMedPharmIS	Kalamazoo, MI
BioSTAT Consultants	Portage, MI

Only a couple of hours (driving) away from Chicago, the region of Kalamazoo is home to **Stryker** Corporation ([www.stryker.com](http://www.stryker.com)), one of the major U.S. players in medical devices - and, on a different note, to Kellogg's (cereals) headquarters in Battle Creek -.

Besides the Stryker HQ, Southwest Michigan also is home to over 200 regional life science companies, including major players like Abbott Laboratories, Medtronic, Thermo Fisher Scientific... Important subcontractors involved in OEM product design, like Keystone Solutions Group and Tekna also are based in the area, not to mention other manufacturing suppliers, OEM manufacturers, R&D and product design companies (see [www.southwestmichiganfirst.com/industry/medical\\_devices.cfm](http://www.southwestmichiganfirst.com/industry/medical_devices.cfm))

In a very effective partnership with **Southwest Michigan First** ([www.southwestmichiganfirst.com/](http://www.southwestmichiganfirst.com/)) the local business development agency, the **Michigan Medical Device Accelerator** ([www.mmdaccelerator.com](http://www.mmdaccelerator.com)) provides a favorable environment for a sustainable development of the medical device industry in the region and the state.

Focusing more on biotechnology, **Michigan Bio** ([www.michbio.org](http://www.michbio.org)) can be another useful resource to search for potential partners in Michigan (searchable directory: <https://m360.michbio.org/frontend/search.aspx?cs=2576>).

## SOUTHEAST MICHIGAN/ DETROIT

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Oakland County, in the vicinity of Detroit, developed an interesting initiative called **Medical Main Street**. It brings together a unique alliance of world-class hospitals, universities, medical device and bio-pharma companies as well as some of the country's top medical professionals.

<http://www.advantageoakland.com/expand/emergingsectors/medicalmainstreet/Pages/default.aspx>

To find out all the details about Medical Main Street (brochure [Medical Devices & Instrumentation](#)), go to [http://www.advantageoakland.com/ResearchPortal/Documents/emg\\_medicaldevices.pdf](http://www.advantageoakland.com/ResearchPortal/Documents/emg_medicaldevices.pdf)

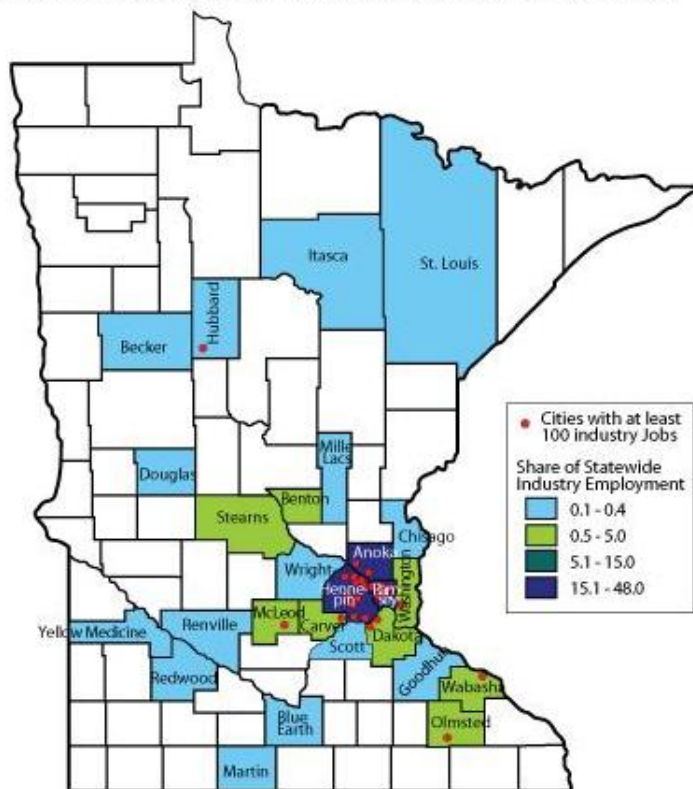
A Directory of [Michigan Medical Device Manufacturers](#) is available under [http://www.advantageoakland.com/ResearchPortal/Documents/mms\\_medical\\_mfg\\_dir.pdf](http://www.advantageoakland.com/ResearchPortal/Documents/mms_medical_mfg_dir.pdf)

## 6.5 MINNESOTA (MN)



With a direct employment level reaching **26,774** (2010 – Source: *Battelle Report, 2012*), **Minnesota** is one of the top states in medical devices. **455 firms** are active in electromedical apparatus manufacturing and medical equipment and supplies, covering a wide range of products, from catheters, pacemakers, dental instruments, eyeglass lenses to hearing aids. Additionally, 280 medical equipment merchant wholesalers, employ 4,750 people. Statewide concentration in medical devices jobs is four times the national average.

### Medical Devices Industry Employment Distribution



There is a high concentration of medtech companies in the **Twin Cities** area (Minneapolis / St Paul). **85%** of statewide medtech employment is concentrated in **Minneapolis/St Paul**.

An important factor in the development of the medtech industry in Minnesota is the presence of prestigious research institutions like the University of Minnesota or the famous Mayo Clinic in Rochester, 180 km south of Minneapolis/St Paul. Minnesota companies and research institutions were the first to develop a wide variety of life-saving and life-improving innovations, including implantable cardiac pacemakers, artificial heart valves, implantable drug transfusion pumps, anesthesia monitors, blood pumps, hearing aids and wireless cardiac monitoring systems.

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

Between 2005 and 2009, Minnesota registered 2,220 **patents** in medical devices, representing **10.5%** of medical device patents in the US (only California had more). More than 900 of these patents were in light, thermal and electrical surgical applications, surpassing all foreign countries combined (519 patents) in this patent class.

In 2007, Minnesota exported \$2.1 billion in the 'miscellaneous manufacturing' industrial category (which includes medical devices), ranking 7<sup>th</sup> nationwide. The top 5 countries that received 67% of Minnesota exports are Ireland, Belgium, The Netherlands, Canada and Japan.

MINNESOTA MEDICAL DEVICE INDUSTRY, PAYROLL EMPLOYMENT (2007)

Industry	Average Number of Establishments	Average Number of Employees
Electromedical Apparatus Manufacturing	80	12,874
Medical Equipment and Supplies Manufacturing	375	16,477
Surgical and Medical Instrument Mfg	101	9,118
Surgical Appliance and Supplies Manufacturing	99	3,997
Ophthalmic Goods Manufacturing	24	1,701
Dental Laboratories	139	1,368

Source: Positively Minnesota, online.

**Top Medical Device Companies in Minnesota**

- Medtronic [www.medtronic.com](http://www.medtronic.com)
- St. Jude Medical [www.sjm.com](http://www.sjm.com)
- Smiths Medical [www.smiths-medical.com](http://www.smiths-medical.com)
- 3M Health Care  
[http://solutions.3m.com/wps/portal/3M/en\\_US/Products/ProdServ/Dir/HealthCare/?WT.mc\\_id=ww.w.3m.com/us/healthcare/index.jhtml](http://solutions.3m.com/wps/portal/3M/en_US/Products/ProdServ/Dir/HealthCare/?WT.mc_id=ww.w.3m.com/us/healthcare/index.jhtml)
- American Medical Systems Holdings [www.americanmedicalsistemas.com/home.html](http://www.americanmedicalsistemas.com/home.html)
- Gn Hearing Care Corporation [www.gnresound-group.com](http://www.gnresound-group.com)
- Tornier, Inc. [www.tornier-us.com](http://www.tornier-us.com)
- Boston Scientific [www.bostonscientific.com/home.bsci](http://www.bostonscientific.com/home.bsci)

All those companies are headquartered in Minnesota (except of course Boston Scientific, based in Massachusetts).

Source: Hoovers Database

**Employment** projections suggest that the medical equipment and supplies manufacturing industry will **grow 14 percent** from 2006 to 2016, adding more than 2,100 new jobs to the state economy. Electronic instrument manufacturing, which includes electromedical and electrotherapeutic apparatus manufacturing, is projected to grow 12 percent, adding nearly 2,900 new jobs. Employment growth will be greatest in the Twin Cities, which has a larger share of medical device industry employment.



## 6.6 OHIO (OH)



**Ohio** is the 7th largest state in the nation and home to 11.5 million people. Just under half of all Ohioans live in the three largest metro areas: Columbus, Cleveland, and Cincinnati.

Ohio's pillar bioscience companies include Battelle, Abbott Nutrition, Cardinal Health, Procter & Gamble Health Care, Meridian Bioscience, Ethicon Endo-Surgery, STERIS, Boehringer Ingelheim's Ben Venue Laboratories and Roxane Laboratories, Philips Healthcare, and Eurand, among many others. Several of these businesses have expanded their Ohio operations in recent years.

At least 1,345 bioscience-related firms (1,800 total locations) were operating in Ohio through 2009. These organizations range from Fortune 500 to incubating startups and cover a wide range of activities, including Medical Devices & Equipment manufacturers (604 locations in 2009)

### LOCATIONS BY SUBSECTOR

Subsector	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Agricultural Biotechnology	117	121	121	123	124	126	128	134	140	163
Medical & Testing Laboratories	339	350	430	453	478	508	564	590	622	647
Medical Device & Equipment Manufacturers	589	609	609	615	616	626	627	624	607	604
Pharmaceuticals & Therapeutics	68	67	66	71	74	78	82	85	91	94
Research & Development	177	197	203	195	206	222	244	270	278	292
<b>All Bioscience in Ohio</b>	<b>1,290</b>	<b>1,344</b>	<b>1,429</b>	<b>1,457</b>	<b>1,498</b>	<b>1,560</b>	<b>1,645</b>	<b>1,703</b>	<b>1,738</b>	<b>1,800</b>

Source: BioOhio, Bioscience Growth Report 2010.

In addition to Ohio's 1,345 bioscience-related firms, more than 1,200 other organizations provide supplies and services to the state's growing bioscience industry ([www.bioohio.com/directory](http://www.bioohio.com/directory)). There also are at least 46 ISO 13485 ([http://en.wikipedia.org/wiki/ISO\\_13485](http://en.wikipedia.org/wiki/ISO_13485)) certified companies in Ohio.

**BioOhio** Accelerating Bioscience in Ohio

bio science in ohio business growth working & learning mer

Ohio Bioscience Resource Directory

The Ohio Bioscience Resource Directory is the most comprehensive collection of Ohio companies, organizations, and res biosciences. From large to small, from well-known to newborn, from biotech to pharma to devices to bioinformatics to cli name it.

**SEARCH**

Search by Name, City, County, Keywords, Zip, etc.

**BROWSEABLE CATEGORY INDEX**

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q  
Y | Z | #

- ▷ Medical Devices / Equipment (1332)
- ▷ Pharmaceuticals / Therapeutics (395)
- ▷ Research / Development (435)
- ▷ Professional Services / Business Assistance (801)
- ▷ Education / Workforce Development (148)
- ▷ Healthcare IT / Bioinformatics / Software (256)
- ▷ Testing / Medical Laboratories (876)
- ▷ Distribution / Logistics / Wholesale (486)
- ▷ AgBio (195)

**Ohio suppliers and service providers:**

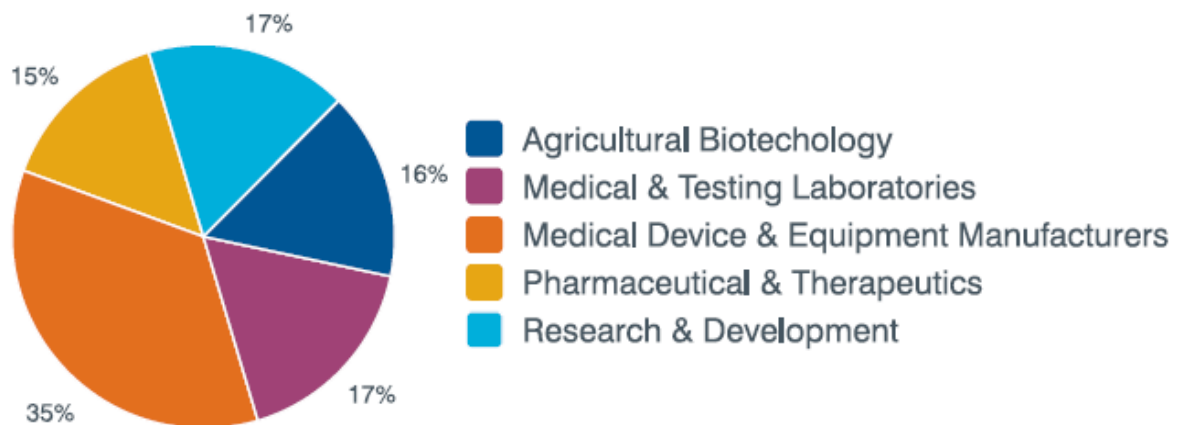
[www.bioohio.com/directory](http://www.bioohio.com/directory)

(You can search by category, subcategory, region...)

The economic impact of the bioscience sector and its five subsectors, measured for Ohio and each of the six geographical regions in terms of employment, is considerable: it amounts to a total of 195,835 jobs, 62,000 direct and 87,000 indirect.

**Medical devices** accounts for 35% or **22,047 jobs** (from the 62,000 direct employment in bioscience). It is the largest subsector of bioscience in Ohio, in terms of employment.

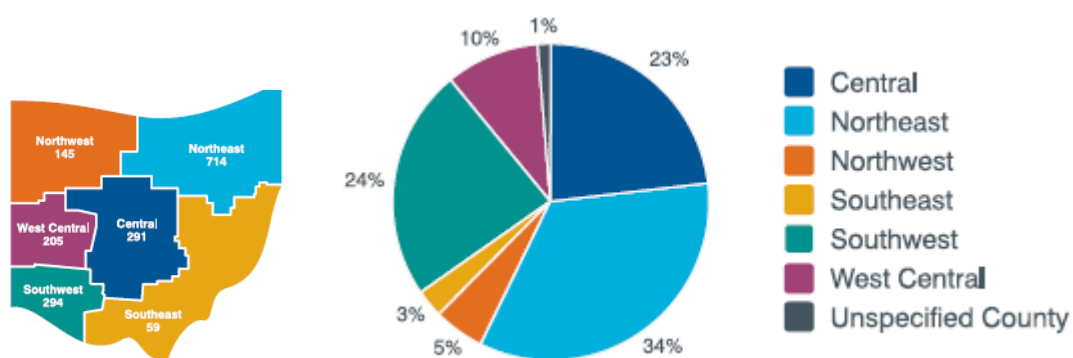
### BIOSCIENCE EMPLOYMENT IN OHIO BY SUBSECTOR, 2009



Subsector	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Agricultural Biotechnology	9,837	9,857	9,820	9,881	9,788	9,189	9,372	9,520	10,029	9,933
Medical & Testing Laboratories	6,788	7,236	7,758	7,997	9,357	9,476	9,979	10,475	10,484	10,619
Medical Device & Equipment Manufacturers	21,282	21,893	22,082	21,338	21,414	21,732	21,685	21,712	22,011	22,047
Pharmaceuticals & Therapeutics	6,704	7,003	7,135	7,848	8,301	8,853	9,409	9,531	10,292	9,265
Research & Development	7,699	7,762	8,140	8,317	8,351	8,742	9,278	9,578	10,105	10,668
<b>Total</b>	<b>52,311</b>	<b>53,750</b>	<b>54,935</b>	<b>55,381</b>	<b>57,211</b>	<b>57,992</b>	<b>59,723</b>	<b>60,816</b>	<b>62,921</b>	<b>62,533</b>

Source: BioOhio, Bioscience Growth Report 2010.

2



Bioscience employment in Ohio by Region, 2009

NE: Cleveland/Akron

Central: Columbus

SW : Cincinnati

Ohio's robust clinical network and prominent medical reputation make it an ideal testing environment for biomedical innovations. Ohio hosts nearly 17% of all **clinical trials** conducted in the nation. As of February 2011, a total of 3,850 clinical trials were in progress or actively recruiting patients in Ohio, which ranks seventh among all states and first in the Midwest in this important indicator. A majority of these trials are in either phase II (36.3%) or phase III (38.1%), indicating that Ohio is a prime location for validating bioscience research as it approaches commercialization.

Ohio Hospitals in 2010 "America's Best Hospitals" Rankings <i>U.S. News &amp; World Report</i>
Cincinnati Children's Hospital Medical Center
Rainbow Babies and Children's Hospital (Cleveland)
Nationwide Children's Hospital (Columbus)
Children's Hospital Cleveland Clinic
Cleveland Clinic
Ohio State University Hospital (Columbus)
University Hospitals Case Medical Center (Cleveland)
University Hospital, Cincinnati (Cincinnati)
Ohio State University James Cancer Hospital (Columbus)
Good Samaritan Hospital (Cincinnati)
Lutheran Hospital (Cleveland)
Christ Hospital (Cincinnati)

This is obviously related to a solid network of **hospitals**: of the 12 Ohio hospitals included in the 2010 *U.S. News & World Report* rankings, the Cleveland Clinic maintained the highest ranking as fourth overall in the nation. In addition, Cleveland Clinic's Heart Center again was named the nation's best for cardiac care—a distinction it has earned for 16 consecutive years. The magazine's survey also ranked 15 Cleveland Clinic specialty care areas among the nation's best.

See US News 'America's Best Hospitals' rankings: <http://health.usnews.com/best-hospitals/rankings>

### **Third Frontier Project**

Created in 2002, the Ohio Third Frontier is an unprecedented commitment to create new technology-based products, companies, industries and jobs. In May 2010, the Ohio Third Frontier was extended through 2015 indicating a widely held understanding by the populace that technology and innovation will lead to economic prosperity both today and for future generations.

Today, the Ohio Third Frontier is **innovation** creating opportunity. The \$2.3 billion initiative provides funding for open innovation, entrepreneurial support, value chain development, and expansion of a skilled talent pool that can support technology-based economic growth. The Ohio Third Frontier's strategic intent is to create an "innovation ecosystem" that supports the efficient and seamless transition of great ideas from the laboratory to the marketplace.

Find out more: [www.thirdfrontier.com](http://www.thirdfrontier.com)

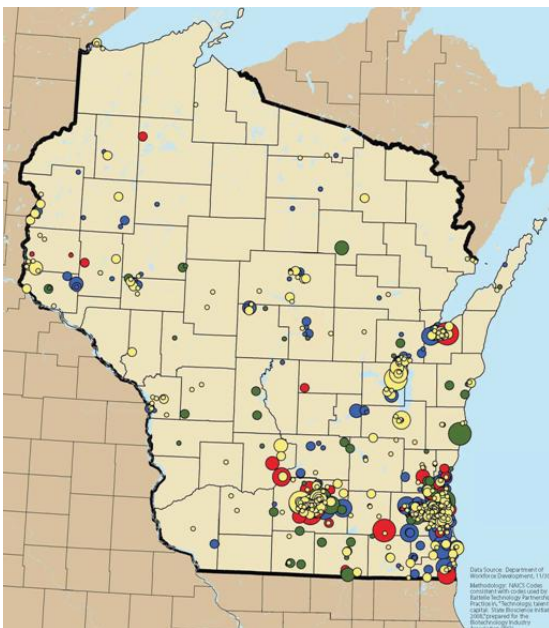
- **NE OH** = Cleveland + Akron + Canton + Youngstown
  - home to 60 hospitals – including the Cleveland Clinic
  - More than 400 international businesses , and more than 25 Biomedical-related, European-owned businesses
  - Home to several global medical leaders: GE Healthcare, Steris, Invacare, Member Health, Siemens Medical, Philips, Boehringer Ingelheim, Hitachi, Toshiba
  - 600+ biomedical businesses with over 230,000 health care and bioscience workers.
    - More than 1800 companies in biomedical related manufacturing
    - More than 1200 companies in biomedical related wholesale
  - Biomedical businesses have attracted \$975 million in new investment since 2003, and the region’s biomedical industry has grown by 34% in the same period.
  
- Find out more about NorthEast Ohio and Cleveland’s biomedical initiatives and companies: <http://www.clevelandplusbiomedical.com/Plus-Overview.aspx>
  - Medical IMAGING: <http://www.clevelandplusbiomedical.com/Imaging.aspx>
    - Global players such as [GE Healthcare](#); [Siemens Medical](#); [Philips Healthcare](#); [Toshiba Medical Systems](#); and [Hitachi Medical Systems](#) – these companies have a combined 90% worldwide market share in CT and MRI;
    - 55+ mid-market and early-stage companies covering multiple modalities of components and devices, e-radiology, information technology and service, and distribution;
  - ORTHOPAEDICS: <http://www.clevelandplusbiomedical.com/Orthopaedics.aspx>
    - There are now more than 50+ companies directly related to the orthopedic device industry in the Cleveland region. These include emerging technology companies, contract manufacturers, component makers, machining facilities and final demand manufacturers, such as makers of limb, spine, implant, disc and bone substitute products.
    - New collaborations such as the \$80 million+ Austen **BiInnovation Institute in Akron** have expanded the tremendous commercial, academic and healthcare opportunities residing at the interface of musculoskeletal biology, polymer/material sciences, and clinical orthopedic needs.
  - NEURODEVICES: <http://www.clevelandplusbiomedical.com/Neurodevice.aspx>
    - *neurostimulation* and *neuromodulation* technologies and in the discipline of *neural engineering*. NeuroInsights Report considers Cleveland+ “among the neurotechnology regions to watch worldwide” as Northeast Ohio is rated as #5 in the world for *neurotech healthcare* and #6 for *neurodevice companies*.
  - CARDIOVASCULAR: <http://www.clevelandplusbiomedical.com/Cardiovascular.aspx>
    - Cleveland Clinic has been ranked No.1 in the nation for cardiac care by U.S. News and World Report every year since 1995. Clinic doctors and cardiologists have shaped the modern era of heart care with the invention of coronary angiography and coronary artery bypass operation.

## 6.7 WISCONSIN (WI)



**Wisconsin's** bioscience industry is sizeable and growing, with nearly 31,000 jobs in 2010 that span 1,366 business establishments. The state has a specialized employment concentration in **medical devices**, a sector that has added jobs overall since 2007. Medical Devices and Equipment account for **10,675 jobs** (direct employment) over **196 establishments** (Source: Battelle Report, 2012). Bioscience's second largest subsector is bioscience related distribution, employs more than 10,000 and is well concentrated in Wisconsin.

As the leading medical device manufacturer in Wisconsin, **GE Healthcare** (Milwaukee) is ranked 3rd in annual revenue among top medical manufacturers in the U.S.



### Milwaukee and Madison, WI

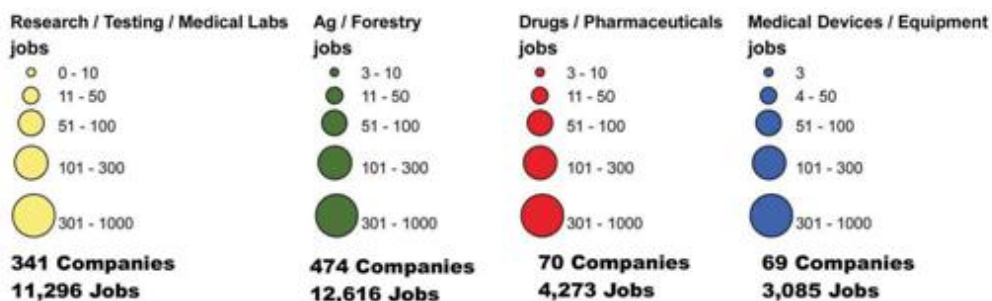
Bioscience employment in Wisconsin is highly concentrated.

The combination of the **"Milwaukee 7"** (seven counties in the Greater Milwaukee Area - [www.choosemilwaukee.com/milwaukee7/default.aspx](http://www.choosemilwaukee.com/milwaukee7/default.aspx)) and **"Thrive"** ([www.thrivehere.org](http://www.thrivehere.org)), located respectively in the Milwaukee and Madison regions, accounts for about 80% of all bioscience employment and the majority of activity in the state. This is also apparent in the employment distribution and company location distribution maps.

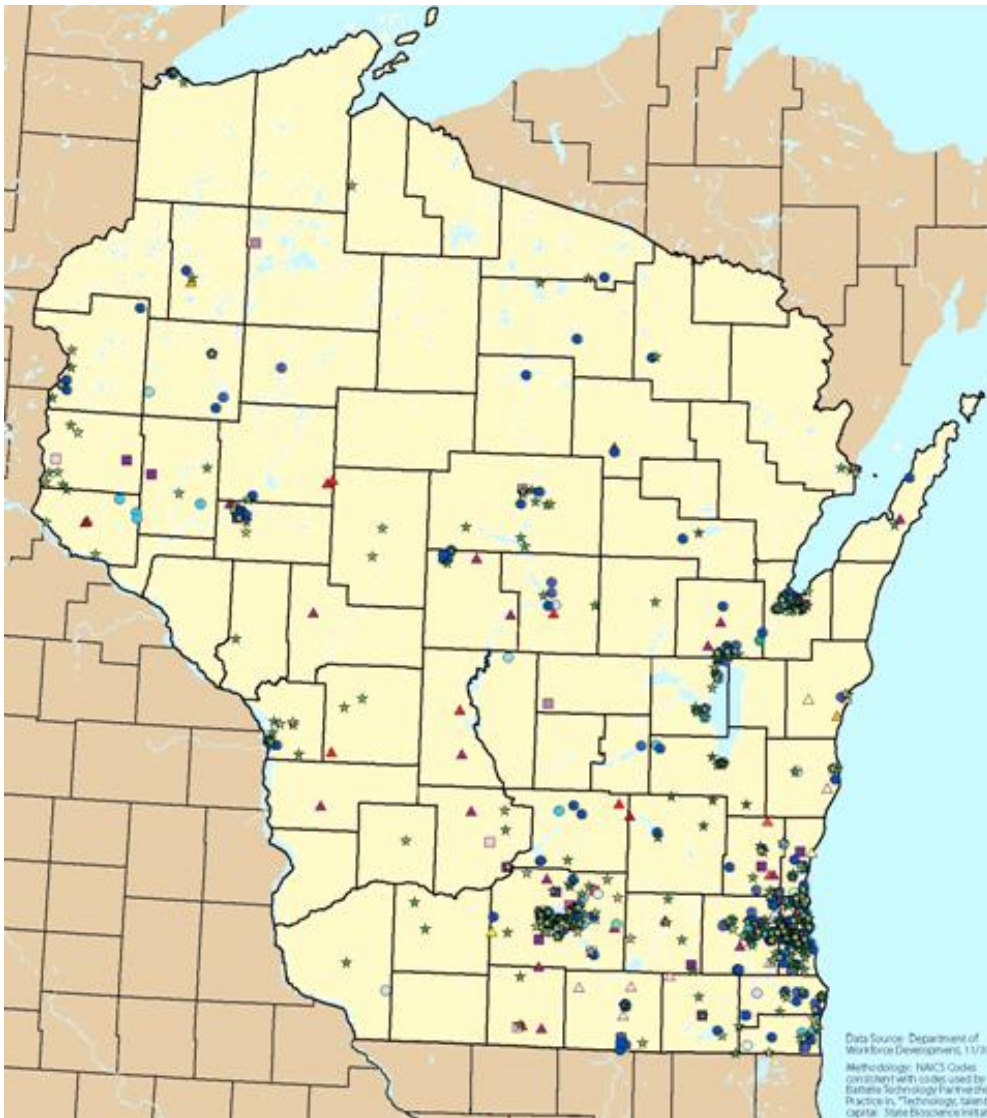
As defined by NAICS Codes, over 3,000 jobs are spread over about 70 medical devices and equipment companies.

### Biotechnology Companies –Jobs by Industry Sub-Sector Sectors Defined by NAICS Codes

April 2010  
MADISON VALLEY ASSOCIATES



Source: Wisconsin Medical Devices Report, 2012.



Source: Wisconsin Medical Devices Report, 2012.



University bioscience research is an important contributor to the state's bioscience field, both in terms of intellectual property and economic impact. As was briefly noted above, one institution, **UW-Madison**, contributes markedly to the Thrive and Dane County economy. Three other institutions, the Medical College of Wisconsin, UW-Milwaukee, and Marquette University, contribute substantially to the bioscience employment of the Milwaukee 7 region and of Milwaukee County. The cooperation between medical device companies and academic institutions has been increasing significantly.

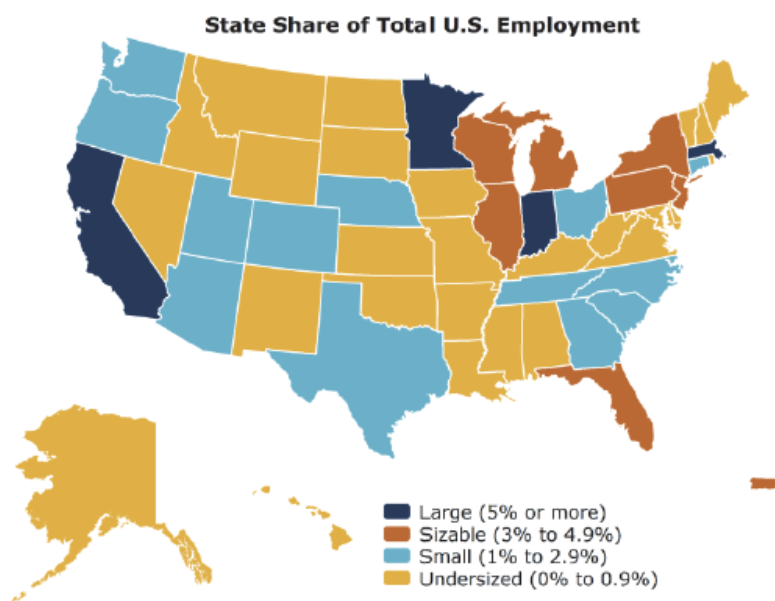
In 2011, the **imports** of medical equipment and supplies in Wisconsin from **Belgium** (excluding the Navigational, Measuring, Electromedical and Control Instruments sectors) rose to \$1.124 million from \$0.211 million. Meanwhile the **exports** increased by 4.27%, from \$6.691 million to \$6.997 million.

**WISCONSIN ASSOCIATIONS:**

- Biomedical Associations of Wisconsin [www.baw.org](http://www.baw.org)
- Wisconsin Biotechnology and Medical Device Association (WBMA), in Madison <http://www.wisconsinbiotech.org>
- Wisconsin Association of Medical Equipment Service <http://www.wames.org>

**6.8 OTHER STATES**

U.S. medical device and equipment companies employed 343,468 in 2010 or 21 percent of the national bioscience sector. These advanced manufacturing jobs produce an array of medical devices, supplies, and equipment at nearly 7,000 individual establishments.



The top 10 employer states account for 61 percent of national subsector jobs.

- Large States: California, Minnesota, Massachusetts, Indiana
- Sizable States: Florida, Pennsylvania, New Jersey, New York, Puerto Rico, Illinois, Wisconsin, Michigan

Source: Battelle Report, 2012.

Four states have both a large employment base and a specialized concentration of jobs in medical devices and equipment.

**STATES WITH LARGE AND SPECIALIZED EMPLOYMENT IN MEDICAL DEVICES AND EQUIPMENT, 2010**

State	Establishments, 2010	Employment, 2010	Location Quotient, 2010	Share of U.S. Employment
California	995	59,450	1.54	17.3%
Minnesota	332	26,774	3.81	7.8%
Massachusetts	281	20,182	2.30	5.9%
Indiana	143	18,936	2.56	5.5%

Source: Battelle Report, 2012.

We have zoomed in on those four states (and a few additional ones) in this overview. If you need more information on other U.S. States please contact us directly with your specific request.

## 7. ADDITIONAL RESOURCES: ASSOCIATIONS, PUBLICATIONS, WEBSITES, TRADE SHOWS

### 7.1 ASSOCIATIONS

#### Main industry organizations

- *American Association for Clinical Chemistry (AACC)* [www.aacc.org](http://www.aacc.org)
- *Advanced Medical Technology Association (Advamed)* [www.advamed.org](http://www.advamed.org)
- *Association of Medical Diagnostics Manufacturers (AMDMD)* [www.amdm.org](http://www.amdm.org)
- *Medical Device Manufacturers Association (MDMA)* [www.medicaldevices.org](http://www.medicaldevices.org)
- *Massachusetts Medical Device Industry Council (MassMEDIC)* [www.massmedic.com](http://www.massmedic.com)
- *Life Science Alley (Minnesota)* [www.lifesciencealley.org](http://www.lifesciencealley.org)
- *Regulatory Affairs Professionals Society (RAPS)* [www.raps.org](http://www.raps.org)
- *Medical Imaging Technology Alliance (MITA)* [www.medicalimaging.org](http://www.medicalimaging.org)
- *Dental Trade Alliance (DTA)* [www.dentaltradealliance.org](http://www.dentaltradealliance.org)
- *International Association of Medical Equipment Remarketers & Servicers (IAMERS)* [www.iamers.org](http://www.iamers.org)



**Advamed** is the Advanced Medical Technology Association.

[www.advamed.org](http://www.advamed.org)

AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. Advamed promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets. <http://advamed.org/MemberPortal/>

Advamed also holds an annual Conference. In 2011 it was in Washington, D.C., in 2012 in Boston:

<http://advamed2012.com>



The Massachusetts Medical Device Industry Council (MassMEDIC) is an organization of medical device manufacturers, suppliers and associated non-profit groups in Massachusetts and the surrounding region. Founded in 1996, MassMEDIC now has over 350 members.

[www.massmedic.com](http://www.massmedic.com)

Their **Suppliers Directory** (open access) can be an interesting resource:

[www.massmedic.com/directory/](http://www.massmedic.com/directory/)





**MedTech IGNITE**, an initiative of the Massachusetts Medical Device Industry Council (MassMEDIC- mentioned hereabove), provides free mentoring to medical device entrepreneurs at the early stages of their company's conceptualization, formation and development. The program focuses solely on medtech startups; their goal is to increase the number and sustainability of quality early stage medical device companies in New England by providing industry-specific, one-on-one coaching to medtech entrepreneurs.

<http://medtechignite.com/>

Very interesting background information on Regulatory and Reimbursement matters :

[http://medtechignite.com/resources.php#regulatory\\_and\\_reimbursement](http://medtechignite.com/resources.php#regulatory_and_reimbursement)



**LifeScience Alley**<sup>®</sup>, a Minnesota-based trade association serving over 680 member organizations, provides access to industry leaders, education and networking opportunities, insights into current trends, regulations, research and emerging technologies, and the power of a legislative voice. Their member list includes Medtronic, St. Jude Medical, Mayo Clinic, Boston Scientific, Upsher-Smith Laboratories, Cargill, the University of Minnesota, etc. <https://www.lifesciencealley.org/>

## 7.2 PUBLICATIONS



**Medical Product Outsourcing (MPO):** magazine

Interesting website too: <http://www.mpo-mag.com/>

See for example:

- Outsourcing Directory <http://www.mpo-mag.com/od>
- Industry Organizations [http://www.mpo-mag.com/industry\\_organizations](http://www.mpo-mag.com/industry_organizations)
- Top Companies Report <http://www.mpo-mag.com/articles/2012/07/the-top-30>

When you scroll down to the bottom of the screen, you will discover a whole array of Sister Sites (and magazines):



**Orthopedic Design & Technology (ODT)**

<http://www.odtmag.com/>

**MEDICALDEVICENOW**

Home

**Medical Device Now**

<http://www.medicaldevicenow.com/>

AND A FEW MORE:



[BeautyPackaging.com](http://BeautyPackaging.com)

[Happi.com](http://Happi.com)

[medicaldevicenow.com](http://medicaldevicenow.com)

[NutraceuticalsWorld.com](http://NutraceuticalsWorld.com)

[CoatingsWorld.com](http://CoatingsWorld.com)

[InkWorldMagazine.com](http://InkWorldMagazine.com)

[MPO-mag.com](http://MPO-mag.com)

[ODTmag.com](http://ODTmag.com)

[ContractPharma.com](http://ContractPharma.com)

[LabelAndNarrowWeb.com](http://LabelAndNarrowWeb.com)

[Nonwovens-Industry.com](http://Nonwovens-Industry.com)

[PrintedElectronicsNow.com](http://PrintedElectronicsNow.com)

<http://www.mpo-mag.com/>

## 7.3 SEARCH TOOLS AND OTHER RESOURCES ONLINE



**Qmed:** [www.qmed.com/](http://www.qmed.com/)

Qualified Suppliers to the Medical Device Industry (search by categories).

### Medical Device Supplier Directory

Adhesives and Adhesive Products

Components

Consultants

Electronic Components

IVD

Materials

Motors and Motion Control

Printing, Labeling, and Bar Coding

R&D and Design Services

Testing, Metrology, and Inspection

Cleanrooms and Environmental Control

Computing and Software

Contract Manufacturing Services

Filters and IV Products

Manufacturing Equipment

Molding Services and Equipment

Packaging and Sterilization

Pumps and Valves

Surface Treatment

Tubing and Extrusion



The **MassDevice Network** is a **directory** of medical device companies and service providers in the northeastern United States (New England). The filters allow you to refine the list by business type (manufacturer or service provider) and business sector. You can also search by keyword or company name. The results are grouped alphabetically to show you the number of entries per letter.

<http://www.massdevice.com/directory>



Their **Suppliers Directory** (open access) can be an interesting resource: [www.massmedic.com/directory/](http://www.massmedic.com/directory/)

## Software Advice

**Software Advice** : overview of medical (office) software

<http://www.softwareadvice.com/medical/>

By industry – Medical (Billing, Scheduling, Archiving...)



**ESPICOM** Market Intelligence: list of publications

<http://espicom.com/ProdCat2.nsf/web/webnav?OpenDocument&BCID=00000018>



**ATiA:** Assistive Technology Industry Association <http://www.atia.org/i4a/pages/index.cfm?pageid=1>

See Member Directory : [http://www.atia.org/i4a/member\\_directory/feSearchForm.cfm?directory\\_id=3](http://www.atia.org/i4a/member_directory/feSearchForm.cfm?directory_id=3)



**Barnett Educational Services:**

Publications on Medical Devices

<http://www.barnettinternational.com/EducationalServices/Publications.aspx?t=Medical%20Device>

See their 'Adverse Events: Managing and Reporting for Medical Devices' → introduction to FDA regulations for newcomers in the field of medical device safety.



**MedTrade:** connecting the HME Industry (HME: Home Medical Equipment)

<http://www.medtrade.com/medtrade-spring/>

Check exhibitor list: <http://www.medtrade.com/medtrade-spring/show/exhibitor-list>



**Statistics:** <http://statlistics.com/>

B2B lead search (for a fee).

You can request specific Categories e.g.

- Medical Device and Diagnostic Industry
- Medical Design Technology
- Surgical Products



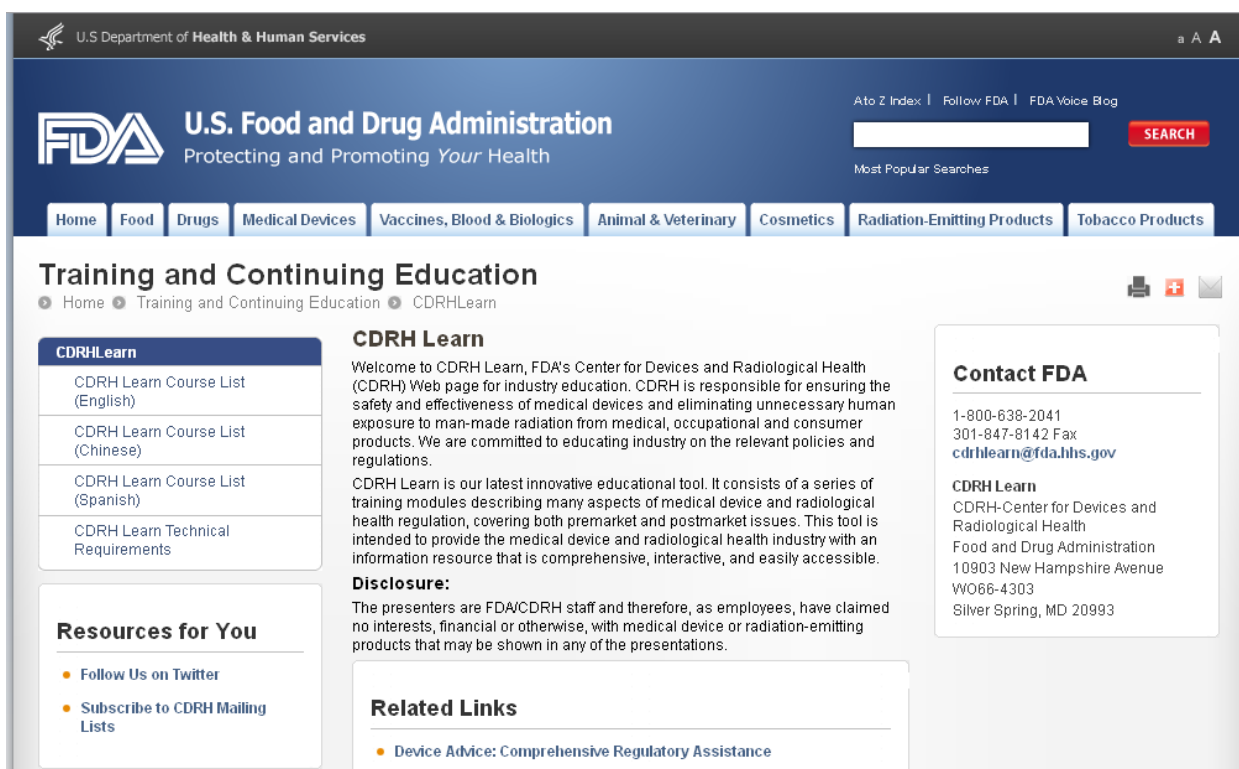
**FDA Medical Devices:**

<http://www.fda.gov/medicaldevices/default.htm>



- **Products and Procedures:**  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/default.htm>
- **Approvals and Clearances:** New Device Approval + Market Notification 510 (k) & PMA  
<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/default.htm>
- **Searchable databases:** e.g. previously approved or pending e.g. 510(k)  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

**FDA 'CDRH LEARN' - TRAINING AND CONTINUING EDUCATION**



<http://www.fda.gov/training/CDRHLearn/>

## 7.4 MAJOR TRADE SHOWS, EXHIBITIONS AND CONFERENCES

Advamed, FIME and RSNA are major international events.



**AdvaMed**  
**2012** THE MEDTECH CONFERENCE  
ACCESS. INSIGHT. OPPORTUNITY.

**OCTOBER 1-3, 2012**  
BOSTON CONVENTION & EXHIBITION CENTER  
BOSTON, MA

**EXHIBIT**

<http://advamed2012.com/>



UBM Canon

**OrthoTec**

Conference and Exhibition:  
**June 5-6, 2013**  
Orthopaedic Capital Center at Grace College  
Winona Lake (Warsaw), IN

<http://www.canontradeshows.com/expo/ortho12/>



UBM Canon

**MEDevice**  
forum • San Diego

Conference and Supplier Showcase  
**SEPTEMBER 19-20, 2012**  
San Diego Convention Center, Hall F | San Diego, CA

**REGISTER**

HOME CONFERENCE SUPPLIER SHOWCASE EXHIBITING TRAVEL EVENT INFO CONTACT US MEDIA

<http://www.canontradeshows.com/expo/medevice12>



UBM Canon

**BIOMEDevice**  
An **M&M** Event

Exposition and Conference  
**April 10-11, 2013**  
Boston Convention and Exhibition Center | Boston, MA  
**BIOMEDeviceBoston.com**

**BIOMEDevice** is an exposition and conference ; one is held on the East Coast (Boston):

<http://www.canontradeshows.com/expo/bioboston12/#>

Another similar event is held in **California**:



UBM Canon

**BIOMEDevice**  
An **M&M** Event

Featuring **MEMS**  
IN MEDICAL DEVICES

BIOMEDevice Exposition: **December 4-5, 2012**  
BIOMEDevice Conference: **December 4-5, 2012**  
MEMS in Medical Devices Conference: **December 3, 2012**  
San Jose Convention Center | San Jose, CA  
**BIOMEDeviceSanJose.com**

<http://www.canontradeshows.com/expo/biomed12>

+ Other similar events, in different locations throughout the United States:

### North America

[BIOMEDevice Boston](#)

[BIOMEDevice San Jose](#)

[MD&M Chicago](#)

[MD&M East](#)

[MD&M Florida](#)

[MD&M Online](#)

[MD&M Minneapolis](#)

[MD&M Texas](#)

[MD&M West](#)

[MEDevice San Diego](#)

[OrthoTec](#)

[Pharmapack North America](#)

Most of those shows are organized by **UBM Canon**.

More on <http://www.ubmcanon.com/industry-groups/medical-design-and-manufacturing>

Or: [http://www.canontradeshows.com/expo/industry\\_medical.html](http://www.canontradeshows.com/expo/industry_medical.html)



<http://www.fimeshow.com/>

**FIME** is particularly indicated if your strategy is consistent with using the U.S. as a platform for distribution in Latin America. More information and a report on the 2012 FIME conference are available on FIT's website (Marktinformatie).

<http://www.flanderstrade.be/appl/marktkennis.nsf/documentatie/592120810001545?opendocument>



RSNA (Radiological Society of North America) – Major trade show, in Chicago.

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



**AACC** (American Association for Clinical Chemistry)

[http://www.aacc.org/EVENTS/ANNUAL\\_MEETING/Pages/default.aspx#](http://www.aacc.org/EVENTS/ANNUAL_MEETING/Pages/default.aspx#)



**ATIA** (Assistive Technology Industry Association), based in Chicago, with trade shows in Florida and Chicago.

<http://www.atia.org/i4a/pages/index.cfm?pageid=4299>



**MedTrade:** connecting the HME Industry (HME: **Home Medical Equipment**)

<http://www.medtrade.com/medtrade-spring/>



## 8. SOURCES – BIBLIOGRAPHY

### 8.1 GENERAL/NATIONAL U.S. MARKET

#### BATTELLE/BIO

State Bioscience Industry Development  
2012

<http://www.bio.org/node/9542>

#### BATTELLE/BIO

State Bioscience Initiatives  
2010

[http://www3.bio.org/local/battelle2010/Battelle\\_Report\\_2010.pdf](http://www3.bio.org/local/battelle2010/Battelle_Report_2010.pdf)

#### THE ECONOMIC IMPACT OF THE U.S. ADVANCED MEDICAL TECHNOLOGY INDUSTRY

Prepared by Battelle for AdvaMed (the Advanced Medical Technology Association)  
March 2012

[http://www.chi.org/uploadedFiles/Industry\\_at\\_a\\_glance/BattelleFinalAdvaMedEconomicImpactReportMarch2012.pdf](http://www.chi.org/uploadedFiles/Industry_at_a_glance/BattelleFinalAdvaMedEconomicImpactReportMarch2012.pdf)

#### MEDICAL DEVICE MANUFACTURING IN THE US

IBISWorld Industry Report 33451b  
December 2011

<http://www.ibisworld.com/industry/default.aspx?indid=764>

#### MEDICAL DEVICE MARKET

Intelligence Report  
Belgium

Espicom Business Intelligence, 2011

[http://www.espicom.com/prodcat2.nsf/Product\\_ID\\_Lookup/00000534?OpenDocument](http://www.espicom.com/prodcat2.nsf/Product_ID_Lookup/00000534?OpenDocument)  
USA

[http://www.espicom.com/Prodcat2.nsf/Product\\_ID\\_Lookup/00000110?OpenDocument](http://www.espicom.com/Prodcat2.nsf/Product_ID_Lookup/00000110?OpenDocument)

#### PULSE OF THE INDUSTRY

Medical technology report 2011  
Ernst & Young

[http://www.ey.com/Publication/vwLUAssets/Pulse\\_of\\_the\\_industry/\\$FILE/Pulse-of-the-industry.pdf](http://www.ey.com/Publication/vwLUAssets/Pulse_of_the_industry/$FILE/Pulse-of-the-industry.pdf)

#### THE U.S. MARKET FOR MEDICAL TECHNOLOGY

Opportunities and Challenges for Swiss Companies  
6<sup>th</sup> Edition, November 2009, Osec

[http://www.osec.ch/sites/default/files/bbf\\_usa\\_medtech\\_report\\_2009.pdf](http://www.osec.ch/sites/default/files/bbf_usa_medtech_report_2009.pdf)

## EYEFORTRANSPORT

Healthcare & Life Sciences Supply Chain Industry Report Series

Medical Devices Focus

<http://events.eyefortransport.com/meddex/pdf/Healthcare-Report-Medical-Devices.pdf>

The Medical Device Industry

American Action Forum, September 2011

[http://americanactionforum.org/sites/default/files/OHC\\_MedDevIndPrimer.pdf](http://americanactionforum.org/sites/default/files/OHC_MedDevIndPrimer.pdf)

## STATE ECONOMIC IMPACT OF THE MEDICAL TECHNOLOGY INDUSTRY

Prepared for AdvaMed

Submitted by The Lewin Group

June 2010

<http://www.advamed.org/NR/rdoonlyres/F9FF4E5B-BD99-4245-A9F4-A6CA85A8896B/0/StateEconomicImpactoftheMedicalTechnologyIndustry61510.pdf>

## 8.2 STATE LEVEL

### CALIFORNIA BIOMEDICAL INDUSTRY

2012 Report

CHI – PWC – BayBio

<http://www.chi.org/uploadedfiles/report2012/MW-12-0125%20CHI%20report%20interactive%20v2.pdf>

or <http://www.pwc.com/us/en/health-industries/publications/california-biomedical-industry-2012-report.jhtml>

### 2012 SOUTHERN CALIFORNIA ECONOMIC IMPACT REPORT

The Life Sciences Industry of Southern California

Biocom

[http://www.biocom.org/?m=sp\\_view\\_doc&file=Shared%20Documents/Images/Home%20page/BIOCOM\\_EconomicImpactReport.pdf](http://www.biocom.org/?m=sp_view_doc&file=Shared%20Documents/Images/Home%20page/BIOCOM_EconomicImpactReport.pdf)

### INDIANA'S LEADERSHIP IN MEDICAL DEVICES

From Hearts to Hips

BioCrossroads, January 2012

<http://www.biocrossroads.com/Documents/Reports/2012-Indiana-Medical-Devices-Report.aspx>

### INDIANA'S LIFE SCIENCES INDUSTRY 2002-2010

<http://www.biocrossroads.com/Documents/Indiana-Life-Sciences-Industry-Report-2002-2010.aspx>

### INDIANA'S EXPORTS AND FOREIGN DIRECT INVESTMENT

Global Positioning

September 2011

Kelley School of Business, Indiana University, Indiana Business Research Center

<http://www.ibrc.indiana.edu/international/pdf/globalpositioning2011.pdf>

## ILLINOIS CENTERS OF EXCELLENCE IN BIOTECHNOLOGY

Illinois Global Partnership

<http://www.prnewswire.com/news-releases/illinois-global-partnership-showcases-leading-biotech-capabilities-in-illinois-56405522.html>

## THE MEDICAL DEVICE INDUSTRY IN MASSACHUSETTS

Deloitte, 2011 (PowerPoint presentation)

## SOUTHWEST MICHIGAN FIRST - MEDICAL DEVICES

[http://www.southwestmichiganfirst.com/industry/medical\\_devices.cfm](http://www.southwestmichiganfirst.com/industry/medical_devices.cfm)

Michigan Medical Device Accelerator (MMDA)

<http://mmdaccelerator.com/>

## MEDICAL MAIN STREET

Oakland County, Michigan

<http://www.oakgov.com/globaloakland/sectors/mms/index.html>

## POSITIVELY MINNESOTA

Medical Devices Manufacturing: Prescription for Success

Minnesota Economic Trends, October 2008

[http://www.positivelyminnesota.com/Data\\_Publications/Publications/LMI/PDFs/MN\\_Economic\\_Trends/October\\_2008/medical.pdf](http://www.positivelyminnesota.com/Data_Publications/Publications/LMI/PDFs/MN_Economic_Trends/October_2008/medical.pdf)

## POSITIVELY MINNESOTA

Biosciences / Medical Devices

[http://www.positivelyminnesota.com/Business/Locating\\_in\\_Minnesota/Major\\_Industries\\_Sectors/Biosciences\\_2.aspx](http://www.positivelyminnesota.com/Business/Locating_in_Minnesota/Major_Industries_Sectors/Biosciences_2.aspx)

## OHIO BIOSCIENCE GROWTH REPORT 2010

Bio Ohio

<http://www.bioohio.com/pdfs/growthreport10.aspx>

## MEDICAL DEVICES IN WISCONSIN 2012

World Trade Center Wisconsin, Milwaukee, WI

## WISCONSIN BIOTECHNOLOGY AND MEDICAL DEVICE BUSINESS DIRECTORY

<http://www.biotechprofiles.com/articles/daddd9a54557456db1ffcb6ed6bcaef3.pdf>

## THE CONTRIBUTION OF THE BIOSCIENCE INDUSTRY TO THE WISCONSIN ECONOMY

September 2010

[http://www.bioforward.org/resource/resmgr/industry\\_analysis\\_docs\\_and\\_images/bioforward\\_economic\\_impact\\_s.pdf](http://www.bioforward.org/resource/resmgr/industry_analysis_docs_and_images/bioforward_economic_impact_s.pdf)

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