

## Return to health: The aging population and technological advances will bolster industry growth

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# IBISWorld Industry Report 33451b Medical Device Manufacturing in the US

December 2018

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# About this Industry

## Industry Definition

This industry includes manufacturers of electromedical and electrotherapeutic apparatuses, such as magnetic resonance imaging equipment, medical ultrasound equipment, pacemakers, hearing aids, electrocardiographs and electromedical endoscopic equipment. The industry also manufactures irradiation apparatuses and tubes for medical diagnostic, medical therapeutic, industrial, research, scientific evaluation and other applications.

## Main Activities

### The primary activities of this industry are

Fabricating medical diagnostic and therapeutic apparatus  
 Research and development  
 Marketing and distribution

### The major products and services in this industry are

Cardiovascular devices  
 Diabetes devices  
 Irradiation devices  
 Neuromodulation and spinal devices  
 Patient recovery and noninvasive devices  
 Other devices

## Similar Industries

### 33331 Copier & Optical Machinery Manufacturing in the US

This industry manufactures optical instruments, which may be used in some medical applications.

### 33531 Electrical Equipment Manufacturing in the US

This industry manufactures motor control switches and relays, including timing relays.

### 33911a Medical Instrument & Supply Manufacturing in the US

This industry manufactures nonelectrical medical and therapeutic apparatuses.

### 33911b Glasses & Contact Lens Manufacturing in the US

Some Medical Device Manufacturing industry operators, such as Johnson & Johnson, also manufacture vision products, such as contact lenses.

## Additional Resources

### For additional information on this industry

[www.advamed.org](http://www.advamed.org)  
 Advanced Medical Technology Association  
[www.cdc.gov](http://www.cdc.gov)  
 Centers for Disease Control and Prevention

**Additional Resources  
continued**

[www.mddionline.com](http://www.mddionline.com)  
Medical Device and Diagnostic Industry

.....  
[www.medicaldevices.org](http://www.medicaldevices.org)  
Medical Device Manufacturers Association

IBISWorld writes over 1 000 US industry reports, which are updated up to four times a year. To see all reports, go to [www.ibisworld.com](http://www.ibisworld.com)

# Industry at a Glance

Medical Device Manufacturing in 2018

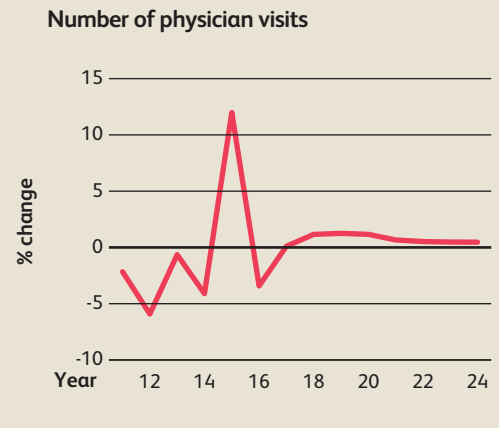
## Key Statistics Snapshot

Revenue	Annual Growth 13–18	Annual Growth 18–23
<b>\$39.2bn</b>	<b>-1.5%</b>	<b>2.4%</b>
Profit	Exports	Businesses
<b>\$783.2m</b>	<b>\$11.8bn</b>	<b>839</b>

### Market Share

Medtronic PLC	41.2%
General Electric Company	19.4%
Abbott Laboratories	10.1%
Danaher Corporation	7.3%
Johnson & Johnson	5.8%

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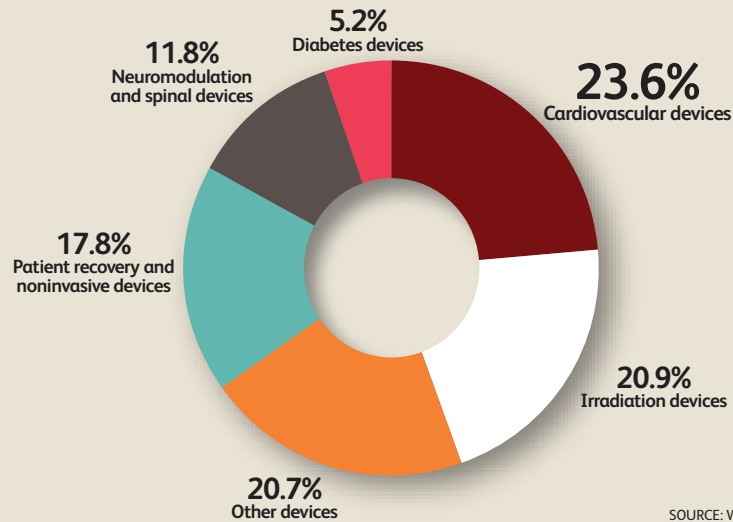
SOURCE: WWW.IBISWORLD.COM

### Key External Drivers

- Number of physician visits
- Number of adults aged 65 and older
- Total health expenditure
- Federal funding for Medicare and Medicaid
- Trade-weighted index

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### Products and services segmentation (2018)



SOURCE: WWW.IBISWORLD.COM

## Industry Structure

Life Cycle Stage	Mature	Regulation Level	Heavy
Revenue Volatility	Medium	Technology Change	High
Capital Intensity	Low	Barriers to Entry	Medium
Industry Assistance	Medium	Industry Globalization	High
Concentration Level	High	Competition Level	High

FOR ADDITIONAL STATISTICS AND TIME SERIES SEE THE APPENDIX ON PAGE 39

# Industry Performance

Executive Summary | Key External Drivers | Current Performance  
Industry Outlook | Life Cycle Stage

## Executive Summary

Medical devices are essential healthcare products. Therefore, their producers are generally protected from significant revenue volatility. However, these products also relatively expensive, which makes the Medical Device Manufacturing industry slightly more vulnerable to fluctuations in economic conditions. Technological advances, increased healthcare spending and the improving economy have stimulated demand for medical devices over the past five years. The aging US population has further contributed to industry revenue, given

expected to slow over the next five years. Growth in medical device manufacturing in other countries has led to decreased exports and increased imports. Continued globalization will influence the composition of the industry over the next five years, as companies increasingly outsource manufacturing, research and development (R&D) and other operations, pressuring the total number of domestic industry operators. Meanwhile, profit-squeezed operators looking to gain market share will seek to procure new technologies by acquiring small, innovative companies instead of investing in their own in-house R&D. However, due to a growing number of small niche manufacturers, the total number of operators is expected to grow at an annualized rate of 1.7% to 839 enterprises over the five years to 2018.

**Despite strong domestic growth, the total value of industry exports is expected to fall**

the high incidence of health issues requiring medical devices among elderly people. However, declines in the manufacturing sector as a whole have affected the industry, resulting in an overall decline in revenue. IBISWorld expects industry revenue to decline an annualized 1.5% over the five years to 2018, including 2.2% growth in 2018 alone, to total \$39.2 billion.

Despite strong domestic growth, the total value of industry exports is expected to fall an annualized 2.1% over the five years to 2018, although this trend is

Over the five years to 2023, the industry is expected to return to growth at an annualized rate of 2.4% to \$44.1 billion. The aging baby boomer population and technological developments will continue to bolster industry growth, while the changing regulatory environment will likely support profitability. Additionally, input prices are expected to rise only slightly, resulting in a marginal increase in profit from 2.0% of revenue in 2018 to 2.1% in 2023.

## Key External Drivers

### Number of physician visits

Hospitals are one of the major purchasers and users of medical devices. The need to purchase or replace equipment directly correlates with the total number of physician visits in a year; therefore, an increase in physician visits bolsters demand for medical devices. The number of physician visits is expected to increase in 2018, representing a potential opportunity for the industry.

### Number of adults aged 65 and older

Recent medical advancements and longer life expectancy have boosted the number of adults aged 65 and older. Incidences of disease and disorder rise with age, increasing demand for medical treatment. Therefore, growth in the number of adults aged 65 and older leads to greater industry demand. The number of adults aged 65 and older is expected to increase in 2018.

# Industry Performance

## Key External Drivers continued

### Total health expenditure

Total health expenditure includes private and public spending on activities that promote health and prevent diseases. Increased healthcare funding programs (such as the Patient Protection and Affordable Care Act) result in more available funding for the replacement of medical equipment and supplies, increasing industry demand. Total health expenditure is expected to increase in 2018.

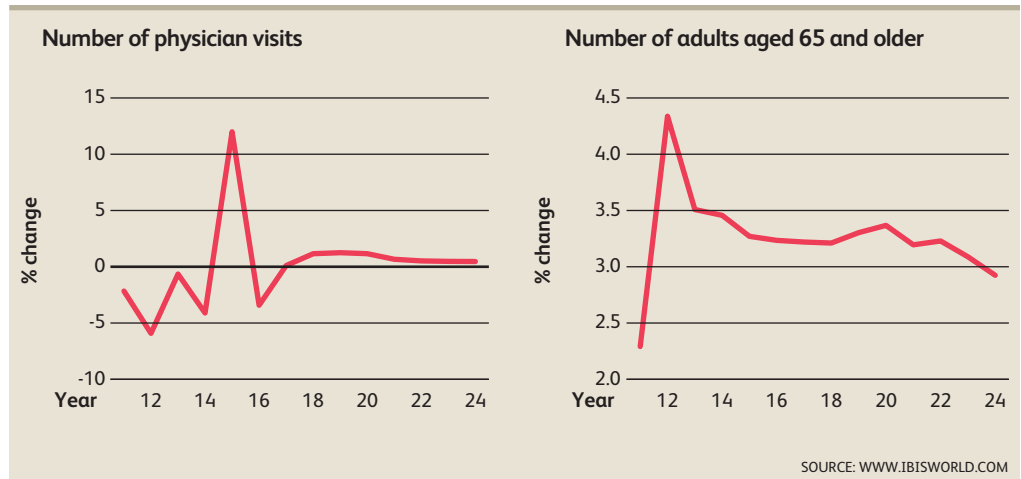
### Federal funding for Medicare and Medicaid

Health coverage is an important factor for patients and doctors choosing treatment options. Medicare coverage is particularly significant, as it directly

affects the number of patients who have to pay for industry products and the amount that manufacturers receive in Medicare payments. Federal funding for Medicare and Medicaid is expected to increase in 2018.

### Trade-weighted index

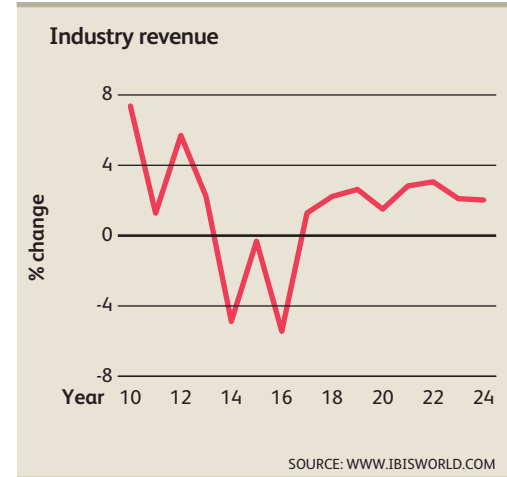
The trade-weighted index (TWI) measures the relative strength of the US dollar. A higher TWI discourages Americans from purchasing domestically manufactured devices and makes it more expensive for foreign customers to purchase US products. The TWI is expected to decrease in 2018. However, its overall upward trend poses a threat to the industry.



# Industry Performance

## Current Performance

As a highly competitive, high-margin industry that produces largely nondiscretionary products, the Medical Device Manufacturing industry has performed well over the past five years. Revenue fell early in the period, as slim profit margins constrained hospitals' ability to raise capital for large purchases. However, in 2018, revenue is expected to grow 2.2% to \$39.2 billion, as an aging population, expanded healthcare coverage and technological advances bolster market growth. The improving economy has encouraged more consumers to seek medical care, and spending on healthcare has consequently increased at an annualized rate of 3.5% over the five years to 2018. As more individuals increase spending on healthcare and are diagnosed with conditions requiring medical devices, demand for industry products has increased. However, the declines early in the period have resulted in an overall drop in revenue. Over the five years to 2018, industry revenue is expected to fall at an annualized rate of 1.5%.



Additionally, rising costs are placing downward pressure on industry profit. To offset costs, companies are increasingly outsourcing manufacturing functions, implementing automated processes over pricey human labor and looking to acquire smaller companies with disruptive and innovative technologies.

## Aging population

Incidences of disease and disorder increase with age. According to data from the Centers for Disease Control and Prevention, people aged 65 and older account for about 40.0% of those diagnosed with some form of heart disease or arthritis. Recent medical advancements, coupled with improved nutrition and safety standards, have boosted the size of this age group at an annualized rate of 3.3% to 52.5 million people over the five years to 2018. The industry's cardiovascular, neurological and orthopedic device segments are most likely to benefit from this expansion.

Moreover, the healthcare system is adjusting to meet the needs of this growing population. Compared with previous generations, baby boomers have a greater interest in managing their own care, as they are more affluent, better educated and more engaged in their wellness. These consumers are particularly interested in patient-centered, in-home care for individuals with diabetes, heart disease and other chronic conditions. Current technology is advancing to meet demand with home medical devices that quickly and easily link to a healthcare provider's electronic records.

# Industry Performance

## Regulation and profit

Industry operators often have the weak hand in price negotiations, with large purchasing groups acting as distributors for about half of the nation's hospitals. Most large manufacturers rely heavily on purchasing groups to distribute their products. Smaller medical device and supply companies are often shut out of sales to hospitals, as larger competitors

usually secure exclusive contracts with purchasing groups. Since these purchasing group customers comprise a considerable percentage of industry revenue, manufacturers sometimes have to concede in pricing negotiations. Over the five years to 2018, profit margins are expected to decline from 7.4% of revenue in 2013 to 2.0% in 2018.

## Consolidation and globalization

Consolidation has driven mergers and acquisitions within the industry, as manufacturers are more likely to secure contracts with large purchasing organizations if they can offer a wide product assortment. Shorter product life cycles and higher costs of developing new technology have further driven industry consolidation, as both of these trends encourage large players to acquire new technologies from small companies. However, while the largest companies are expanding their product lines, small companies are emerging in niche markets. Though there is a significant amount of consolidation among larger companies, the industry is growing as a result of this increased niche participation. The total number of industry operators is expected to increase at an annualized rate of 1.7% to 839 operators over the five years to 2018.

Historically, the industry has maintained a low level of outsourcing activity. In the past, medical device manufacturers avoided outsourcing because cost and time to market had not yet become major factors driving product development and manufacturing. Companies experienced stronger profit margins and ample cash flow, providing them with the resources to invest in facility infrastructure and the equipment necessary to manufacture their own products.

Today, tightening global regulations, increased global competition and new

**The industry has become more globalized over the past five years**

market opportunities have prompted manufacturers to outsource a range of critical operations. Despite some reasons for keeping production domestic, such as perceived concerns about quality control, regulatory compliance and competitive pressures, higher competition makes outsourcing an increasingly attractive option for industry players. Furthermore, many of the traditional barriers to outsourcing have lessened or disappeared. The industry has become more globalized over the past five years, with medical device manufacturers growing stronger in other countries. This growth has resulted in the value of exports decreasing at an annualized rate of 2.1% to \$11.8 billion and the value of imports increasing at an annualized rate of 3.6% to \$17.0 billion over the five years to 2018.

Despite outsourcing, industry employment has continued to grow over the past five years at an annualized rate of 1.1% to 83,821 employees. However, the most skilled work, such as product design and engineering, is still largely done in the United States, as indicated by an annualized growth rate of 2.0% in wage spending to reach \$8.1 billion over the past five years.



# Industry Performance

## Industry Outlook

Factors that influenced the Medical Device Manufacturing industry over the past five years, such as healthcare reform, technological advancements, outsourcing, regulation and an aging population, will continue to drive industry development over the next five years. The combined effect of these factors is forecast to boost revenue growth at an annualized rate of 2.4% to \$44.1 billion in 2023.

The changing demographics of the United States favor the industry.

Although the majority of baby boomers are still under the age of 65, a significant portion of the group will cross this age threshold over the five years to 2023, resulting in annualized growth of 3.2% in the 65-and-over demographic. Medical innovations will continue to expand the average lifespan, with high-tech fields such as biotechnology and 3D printing likely enabling the development of new therapeutic and diagnostic product lines.

## Effects of legislation

Recent changes to healthcare legislation have created a degree of uncertainty for medical device companies. However, IBISWorld expects the average industry profit margin to rise slightly from 2.0% of revenue in 2018 to 2.1% in 2023. The Physician Payment Sunshine Act is expected to increase industry costs and possibly reduce revenue, since it requires covered manufacturers to annually report any transfers of value to physicians. Some small payments and other payment types are exempt from the disclosure obligations, but the industry may have cause for concern nonetheless, due to the increased costs of monitoring and accurately reporting such activity.

However, other recent legislation will likely continue to benefit the industry, as

**Recent changes to healthcare legislation have created uncertainty for industry operators**

US healthcare reform is aimed at expanding coverage to a broader range of patients. The PPACA accomplishes this by significantly loosening the eligibility criteria for enrollment in Medicaid, as well as making private insurance more accessible to consumers. As a result, more people will have access to healthcare, which will likely boost the average number of physician visits. This, in turn, will raise demand for some medical services and devices.

## Regulation and consolidation

In addition to increased costs under healthcare reform, rising regulatory scrutiny and the FDA's impending 510(k) reform are contributing to industry anxiety. Medical device companies must have 510(k) approval from the Food and Drug Administration (FDA) to market products in the United States, and changes to the 510(k) process are expected to increase regulatory costs and restrain innovation.

Changes in the economic and regulatory environments will make it

increasingly attractive to do business abroad, as illustrated by some operators already moving various functions overseas. Domestic consumers are continuing to accept products from abroad, as indicated by the anticipated annualized 2.1% increase in the value of industry imports over the next five years, totaling \$18.8 billion in 2023. Many domestic industry players will also likely consider conducting research and development, initial product filings and

# Industry Performance

## Regulation and consolidation continued

product launches in other countries. However, small companies are expected to continue entering into niche domestic markets, focusing on one or two medical devices. Consequently, the number of industry operators is expected to increase

at an annualized rate of 1.7% to 912 operators over the five years to 2023. Similarly, industry employment is projected to grow at an annualized rate of 2.0% to 92,323 individuals during the outlook period.

## Downstream pressures

Despite expected increases in medical procedure volumes, the prices that medical device manufacturers are able to charge will likely remain a concern for industry operators over the next five years. Although access to insurance will increase, standards for device reimbursements will become more stringent due to governmental cost-containment efforts for healthcare and continued pressure from local hospitals and health systems. The net effects of these pressures will likely drive customers to demand lower pricing. Moreover, stricter reimbursement requirements could directly hurt the total revenue of key customer groups, such as hospitals and clinics. Hospitals that receive small reimbursements per procedure will need to perform more procedures to justify new equipment purchases. In turn, manufacturers may be pressured to reduce per-unit costs to keep sales up.

## Medical device companies will likely expand into lucrative developing markets

Due to growth constraints in established markets, medical device companies will likely aim to expand into lucrative developing markets. Emerging markets such as China, India and countries in Central and Eastern Europe represent potential avenues for future industry growth. Demand for medical devices and services is expected to continue growing in these emerging markets due to their improving economies, rapidly increasing and aging populations and the prevalence of chronic disease. As a result, the value of exports is forecast to rise at a slow annualized rate of 0.5% to \$12.1 billion over the five years to 2023.

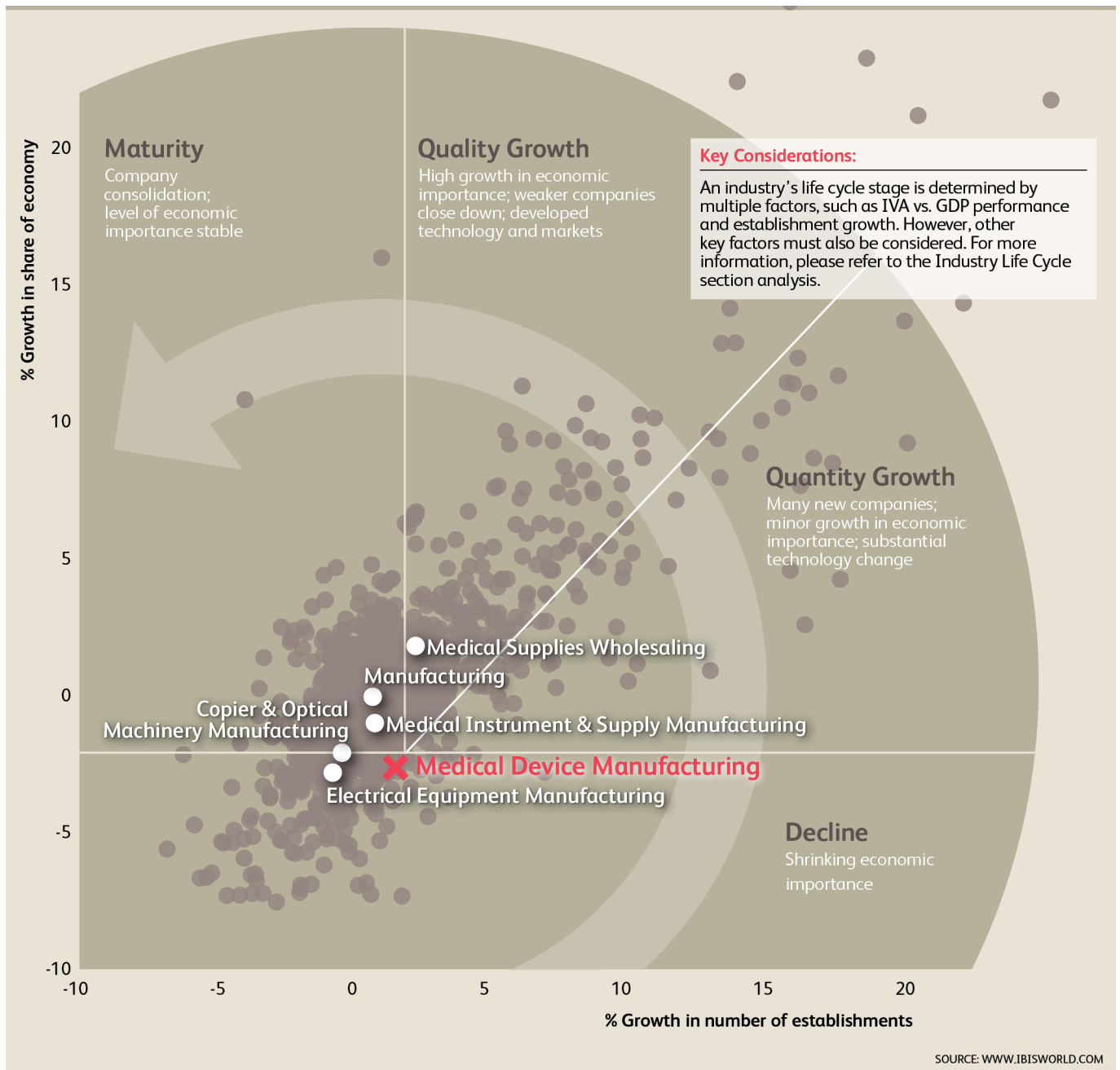
# Industry Performance

## Life Cycle Stage

The industry is projected to decline as a share of the US economy over the 10 years to 2023

Technology is changing rapidly, spurring the introduction of new product lines

Demographic trends are expected to support rising demand for medical devices over the next five years



SOURCE: WWW.IBISWORLD.COM

# Industry Performance

## Industry Life Cycle

This industry is **Mature**

Over the 10 years to 2023, IBISWorld expects the Medical Device Manufacturing industry to decline as a share of the US economy. Industry value added (IVA), which measures an industry's contribution to the economy, is forecast to fall at an annualized rate of 0.6% during the period, while GDP is expected to grow 2.2% over the same period. While declining IVA is typically a sign of a declining industry, the Medical Device Manufacturing industry is in the mature stage of its life cycle.

Industry growth is largely supported by demographic trends. Aging populations in the United States, improvements in technologies and other advanced economies drive demand for medical devices. Demand for medical devices is expected to continue to rise over the 10 years to 2023, as the aging population prompts greater public and

private spending on health. This spending will be further encouraged by increased access to healthcare under the Patient Protection and Affordable Care Act. Industry sales of cardiovascular and neurological devices, as well as equipment used to treat age and obesity-related health problems, will likely rise accordingly.

This increased demand is driving new product development and rapid technological change, such as the development of 3D bioprinted devices. Moreover, IBISWorld expects greater access to healthcare for an expanding elderly population to contribute to an at-home healthcare trend. As seniors who can afford medical devices opt to undergo medical care in their own homes, medical device manufacturers will need to develop new product lines for this burgeoning market, further driving overall industry growth.

# Products & Markets

Supply Chain | Products & Services | Demand Determinants  
 Major Markets | International Trade | Business Locations

## Supply Chain

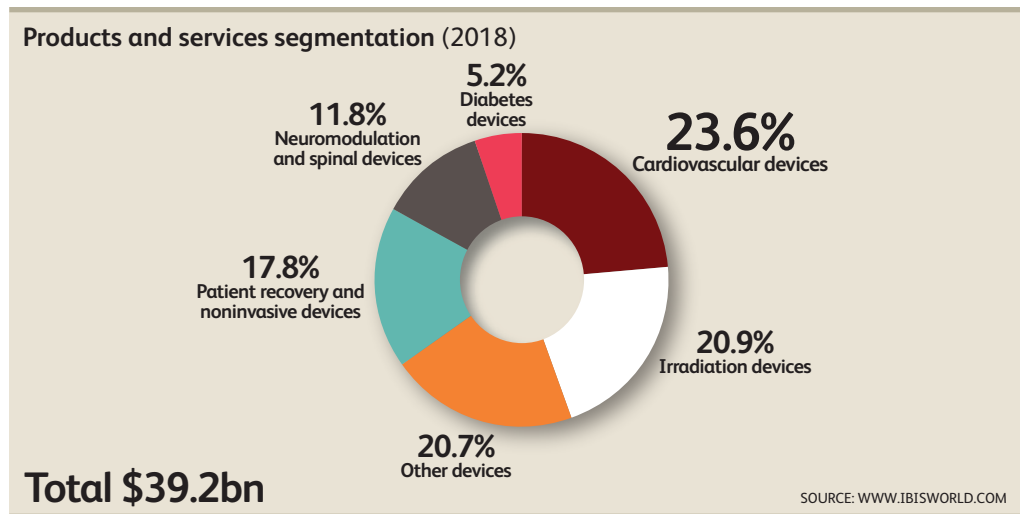
### KEY BUYING INDUSTRIES

31-33	<b>Manufacturing in the US</b> Manufacturers purchase components for use within their own products.
42345	<b>Medical Supplies Wholesaling in the US</b> Medical supplies wholesalers demand medical devices for resale.
62111b	<b>Specialist Doctors in the US</b> Specialist doctors demand industry products to treat patients.
62211	<b>Hospitals in the US</b> Hospitals demand medical devices in order to treat patients.

### KEY SELLING INDUSTRIES

31-33	<b>Manufacturing in the US</b> This industry uses various specialized manufactured products as part of its production. These products include metal, plastic and glass products.
33531	<b>Electrical Equipment Manufacturing in the US</b> Electrical equipment and components are used in the manufacture of industry products.

## Products & Services



The cardiovascular (CV) device segment is highly competitive and has reached market saturation, as many companies produce similar products that limit room for innovation. Over the five years to 2018, this has resulted in low growth rates of therapeutic devices such as pacemakers, defibrillators and drug eluting stents, as well as diagnostic devices such as electrocardiograph machines. Innovations in niche sectors, such as atrial fibrillation and ventricular

assist devices, are poised for stronger growth in the near future. Over the past five years, top companies operating in the CV segment acquired smaller companies to expand their product portfolios and gain market share in new regions. Recent years have thereby experienced a considerable rise in consolidation activities among major companies. Some major players have also established manufacturing facilities outside of the United States to enhance cost

# Products & Markets

## Products & Services continued

containment and product distribution. The CV device market accounts for 23.6% of industry revenue.

### Irradiation devices

Irradiation devices use X-rays, beta-rays, gamma-rays and other ionizing radiation for medical diagnoses, therapeutic applications and research purposes. Irradiation apparatus include generators, tubes, lamps, CT/CAT scanners and nuclear irradiation equipment and represents about one-quarter of industry revenue. Irradiation equipment generally represents a significant capital investment for a hospital or clinic. As a result, demand for this segment's products was low during the recession, as cash-strapped medical care facilities opted to get old machinery repaired instead of buying new products. As the economy has slowly recovered over the past five years, demand for new irradiation devices has increased. The sale of irradiation devices accounts for 20.9% of industry revenue.

### Neuromodulation and spinal devices

Neuromodulation devices are designed for the treatment of pain, urological and gastroenterological disorders, movement disorders and psychological disorders. This segment has performed notably well over the past five years, driven by neurostimulation's potential to alleviate many debilitating conditions in which neural pathways play a role; these include chronic pain, Parkinson's disease, essential tremor and dystonia, epilepsy, gastroparesis, hearing loss, major treatment-resistant depression, obsessive-compulsive disorder and urinary incontinence.

Spinal devices are designed for treatment of the spine and musculoskeletal system. The industry develops a range of products and therapies to treat a variety of spinal conditions, such as herniated discs,

degenerative disc disease, spinal deformity, spinal tumors and fractures and stenosis. Demand for spinal devices has increased due to demographic and social trends, including the aging population and the obesity epidemic. In many cases, neuromodulation involves spinal treatment and stimulation. Together, these segments account for 11.8% of industry revenue.

### Other devices

The growing diabetes market is increasingly gaining attention from the Medical Device Manufacturing industry. Continuous glucose monitoring (CGM) is moving closer to becoming a staple in effective diabetes treatment. Three large companies that produce CGM devices (Medtronic, DexCom and Abbott Laboratories) are active in demonstrating the value this technology offers; however, other market entities are also playing a major role in the process, as independent studies and testing by various clinicians move the use of CGM devices forward. Meanwhile, the focus on CGM continues to affect demand for other products, including insulin pumps. When these pumps are combined with CGM, the basic diagram for the long-sought-after artificial pancreas, or closed-loop system, is created. Diabetes devices are expected to generate 5.2% of industry revenue in 2018.

Respiratory devices, such as continuous positive airway pressure (CPAP) machines and ventilators, have generated relatively stable revenue over the past five years. These devices are intended for both home use (e.g. patients with sleep apnea may need at-home CPAP therapy) as well as in-hospital use (such as ventilators and anesthesia apparatus used during surgery). In addition to traditional industry markets, respiratory devices for home use are often sold to consumers through specialized clinics, such as sleep disorder clinics.

# Products & Markets

## Products & Services continued

Other significant sources of revenue for this industry include dialysis machines, urology devices, specialty

surgical devices, hearing aids and devices designed specifically to clean medical equipment.

## Demand Determinants

Demand for medical devices is influenced by demographic factors, government funding, regulatory framework and currency fluctuations. The age and health of the population drives demand for industry products and insulates the industry during periods of weak economic growth. An aging population and rising community expectations will drive demand for medical devices over the coming years. With the rise of conditions such as heart disease, cancer, AIDS and hepatitis, demand for specialized instrumentation and equipment such as ultrasonics, lasers, cardiographics and other electromedical and electrotherapeutic apparatuses will also rise.

Another important demand factor is the level of capital expenditure (both public and private) on equipment in the healthcare sector. Spending by hospitals and other markets is strongly affected by capital expenditure on health services. The age of capital equipment will determine demand for products, as the life span of equipment averages three to five years and can also be as little as 18 months.

Technological changes also drive demand for products. Demand increases

with the development of new products, which can replace the functions of earlier equipment much more efficiently. The ability to patent new product innovations and other intellectual property rights encourages new product development and, consequently, demand for products. Without sufficient protection for intellectual property, manufacturers do not have adequate incentive to invest the large sums needed in research and development to develop new products. As demand is driven by new product introductions, intellectual property protection is an important factor supporting demand for electromedical and electrotherapeutic devices.

Medical specialists and surgeons influence decision making on the purchase of medical devices. Key considerations made when purchasing equipment include product performance, reliability of delivery, company research and development and customer service and support. The decision to use particular medical technologies is driven by medical practitioners in consultation with patients and the incentive structures of the healthcare system.

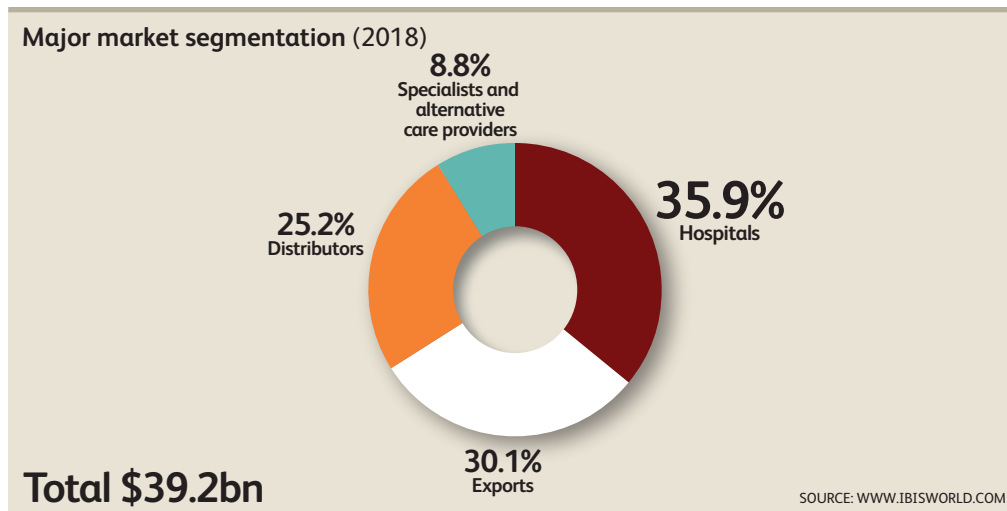
## Major Markets

The main markets for medical device manufacturers are hospitals and clinics, specialists and alternate-care providers, third-party healthcare providers, distributors and other institutions, including governmental healthcare programs and group purchasing organizations. In keeping with the increased emphasis on cost-effectiveness in healthcare delivery, customers of

medical device manufacturers are consolidating into larger purchasing groups to enhance purchasing power. As a result, over the five years to 2018, transactions with customers have become increasingly significant, more complex and tend to involve long-term contracts. This enhanced customer purchasing power has placed pressure on pricing and increased the use of preferred vendors.

# Products & Markets

## Major Markets continued



### Hospitals and clinics

Hospitals are the largest market for this industry, accounting for an estimated 35.9% share. Due to their size, hospitals have the resources to purchase larger, advanced medical devices produced by the industry. General medical and surgical hospitals require machinery and equipment so they can provide inpatient, outpatient and nonadmitted patient (e.g. emergency department) care, as well as teaching and research abilities. Smaller, community-based hospitals are more numerous and tend to be located closer to the population. These hospitals have different needs and will therefore require various types of electromedical and electrotherapeutic products and irradiation apparatus.

The number of physician visits, which affects demand for medical devices from hospitals, grew consistently over the five years to 2018. The number of visits per person has recently increased slightly, to about three visits annually, largely due to the mounting prevalence of chronic disease and the aging population. The number of physician visits is expected to grow throughout 2018, due to health insurance exchanges and the subsidization of insurance premiums for individuals with income less than

400.0% of the poverty line. These initiatives, which are part of the Patient Protection and Affordable Care Act (PPACA) of 2010, have already begun to increase the number of individuals with healthcare coverage. Since insurance coverage reduces the out-of-pocket expense for physician visits, patients will be better able to afford doctor visits. Additionally, as Americans grow older and live longer, there will be greater public and private spending on healthcare, which is expected to help hospitals afford equipment upgrades. As a result, this segment's share of total industry revenue has grown over the past five years and is expected to continue to grow over the five years to 2023.

### Distributors

Medical supplies wholesalers that account for an estimated 25.2% of the total industry market serve as a valuable link between medical device manufacturers and healthcare providers. They purchase large volumes of medical and surgical equipment, instruments and supplies from manufacturing companies, store these items at distribution centers and provide delivery of these products and related services to medical and dental practitioners, clinics and hospitals.



# Products & Markets

## Major Markets continued

Over the past five years, medical supplies wholesalers have tried to offer value-added services to customers to offset wholesale bypass, in which healthcare providers purchase medical devices directly from manufacturers, reducing the need for distributors. Nonetheless, wholesale bypass has caused this market's share of total industry revenue to shrink slightly over the five years to 2018.

### Specialists and alternative care providers

The alternative care market consists of more than 500,000 healthcare facilities and providers, including outpatient medical centers and surgery centers, medical and diagnostic laboratories, imaging and diagnostic centers, home healthcare service providers, long-term care providers and physician practices. The segment also includes specialists in disciplines such as ophthalmology, pediatrics and radiology, as well as dentists and optometrists. This group represents an estimated 8.8% of the market for medical devices.

The market for alternative care has grown over the five years to 2018. The PPACA has improved access to various types of treatment and therapies. Changes under the reform package brought new rights and benefits to

patients, extending opportunities for alternative care. In the past, critics have held that health insurance often steers patients toward medical doctors and away from systems and practices that are not considered part of the mainstream. In addition to expanding access to care, the PPACA is expected to give patients more treatment options and change the way that insurance companies compensate caregivers. While the PPACA has been changed recently, these rules have remained in place. This will cause increased demand for medical devices from specialists and alternative care providers.

### Exports

The industry is global, and local manufacturers design and manufacture devices and apparatus not just for the domestic market, but for international markets as well. Exports represent 30.1% of revenue, and key markets include Japan, China, the Netherlands and Germany. The total share of industry revenue made from exports has decreased from 31.2% in 2013, as slow global economic recovery has kept demand sluggish in many downstream markets, while domestic demand has increased, widening the gap between exports and total revenue.

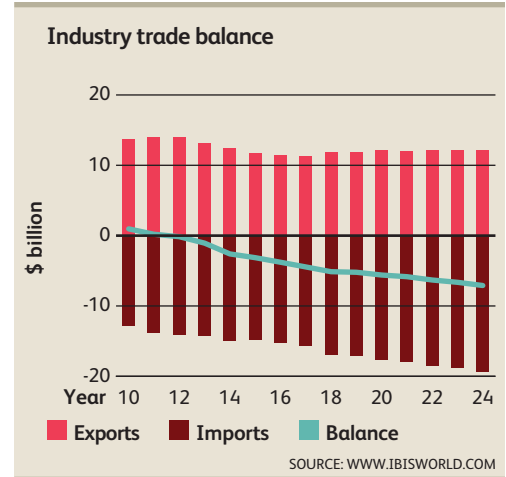
# Products & Markets

## International Trade

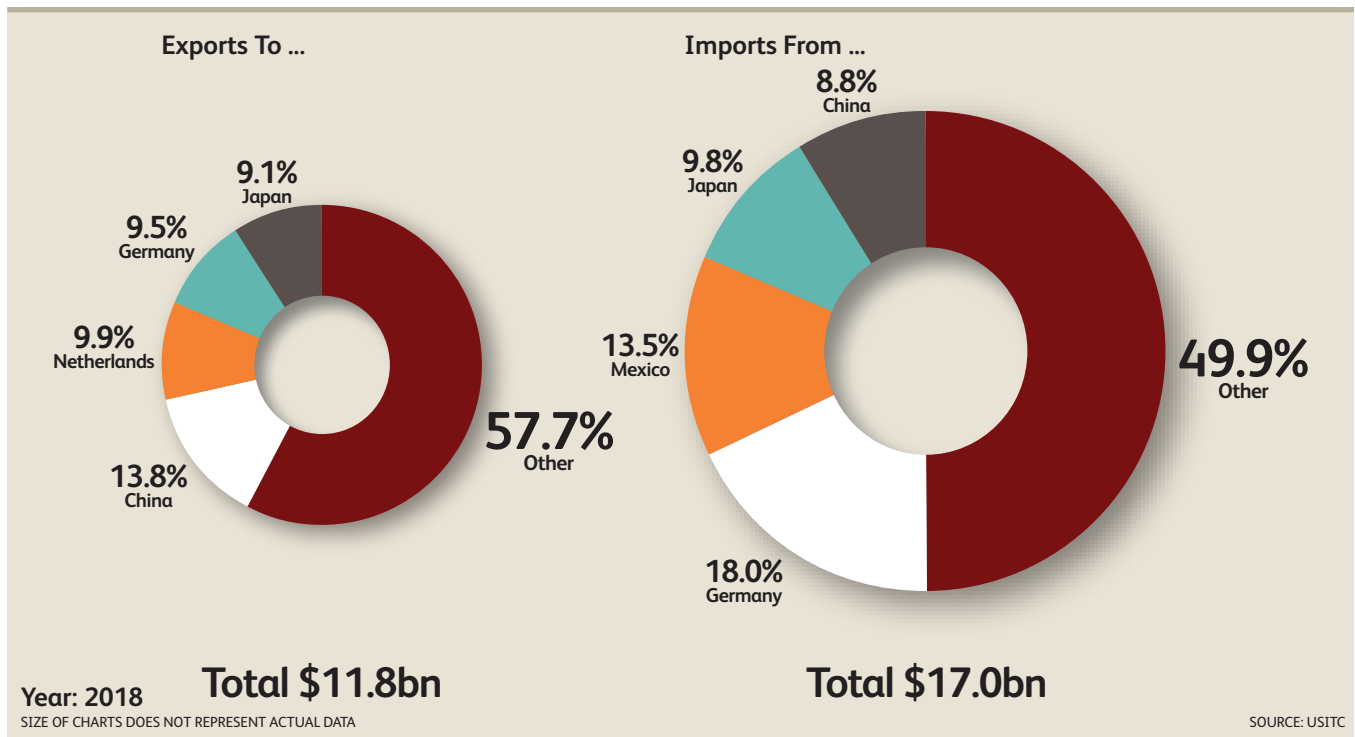
Level & Trend  
Exports in the industry are **High and Decreasing**  
Imports in the industry are **High and Increasing**

IBISWorld estimates that imports of industry products have increased at an annualized rate of 3.6% to \$17.0 billion over the five years to 2018. In 2018, imports are expected to rise 8.1% despite the depreciation of the US dollar. Much of the growth in the value of imports has come as a result of growing medical device manufacturing industries in low wage countries like Mexico and China, as well as technologically advanced countries like Japan. This growth has outpaced domestic demand, resulting in imports accounting for 38.3% of domestic demand in 2018, up from 32.8% in 2013.

Meanwhile, exports are anticipated to decrease at an annualized rate of 2.1% over the five years to 2018. In 2018, the total value of exports is expected to rise 5.2%, to total \$11.8 billion. Exports' total share of industry revenue is also expected to decline over the five years to 2018; comprising 30.2% of revenue in 2018, down from 31.2% in 2013. More manufacturers are establishing operations abroad, thereby



reducing the need for other countries to import devices from the United States. Countries such as Singapore and China have made significant national investments in domestic biotechnology efforts (such as 3D bioprinting), which may keep them near the forefront of new product development, decreasing their dependence on the United States for such scientific research.



# Products & Markets

## Business Locations 2018



SOURCE: WWW.IBISWORLD.COM

# Products & Markets

## Business Locations

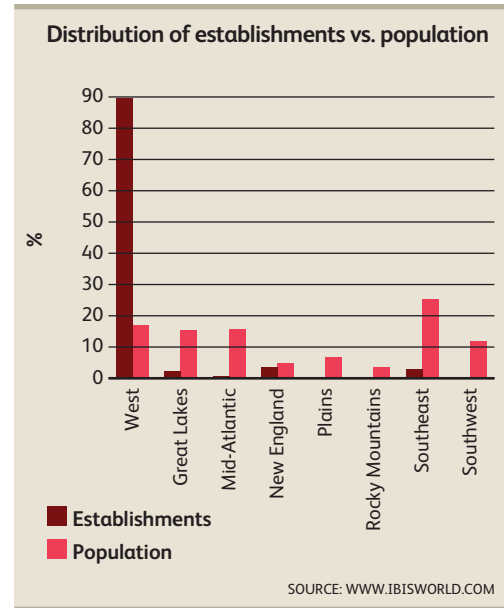
Medical device manufacturers are located throughout the country but are mainly concentrated in certain states known for other high-technology industries, including microelectronics and biotechnology. Other factors affecting geographic distribution include proximity to complementary industries, location of customers, location of suppliers, the traditional development of various industry segments and the location and accessibility of high-skilled labor.

### West

The Medical Device Manufacturing industry is concentrated in the West. This region accounts for 89.6% of industry establishments and more than one quarter of total revenue. Within this region, much industry activity is located in California; the state is home to 89.4% of the industry's total establishments. Numerous biomedical companies are grouped in the San Francisco Bay Area (home of Silicon Valley), Los Angeles, Orange County and San Diego. For this reason, the health of California's medical device and diagnostic companies are often considered an indicator of the entire industry's performance. Medical device manufacturers in the West are close to Silicon Valley and have strong links to export markets.

### Southeast

The Southeast is home to the second-largest number of medical device manufacturers with 15.2% of industry operators. This is mainly due to the region's high portion of the population (25.7%). Florida, in particular, accounts for 2.8% of industry establishments due to its large healthcare sector. In addition,



many states in the Southeast are knowledge centers and homes to respected universities and associated research institutes and organizations that support the development of advanced technology, such as electromedical devices.

### Other

Minnesota also has a high concentration of medical device manufacturers, with 0.2%, which outpaces the state's portion of the country's population (1.7%). Like Massachusetts and New York, Minnesota is home to research institutes and universities that support the development of medical devices, such as the Medical Devices Center at the University of Minnesota. Ohio is also quickly gaining steam as a global player in the industry. The University of Ohio ranks second in the nation (next to Duke University) in biotech industry-sponsored research.

# Competitive Landscape

Market Share Concentration | Key Success Factors | Cost Structure Benchmarks  
Basis of Competition | Barriers to Entry | Industry Globalization

## Market Share Concentration

Level  
Concentration in this industry is **High**

IBISWorld estimates that the top four industry participants hold a combined share of 78.0% of total industry revenue in 2018, indicating a high level of industry concentration. Small operators (i.e. companies employing fewer than 20 people) are common in this industry; these operators typically specialize in developing technology and products for a niche area. Larger players frequently look to acquire these companies to expand their product offerings or gain access to a particular technology. Though there has

been a pattern of the largest companies acquiring medium-sized operators, the number of participants in the industry has increased over the past five years. However, the concentration of the market has risen as the largest companies continue to grow and account for a higher portion of industry revenue. As this trend continues over the next few years, the industry will become more competitive for small operators, leading to an eventual decrease in the number of industry operators and higher concentration.

## Key Success Factors

IBISWorld identifies 250 Key Success Factors for a business. The most important for this industry are:

### Access to the latest technology

Companies must have access to the latest technology, either by investing in research and development or obtaining it by acquiring other enterprises with patented technology.

### Economies of scale

Companies with large manufacturing facilities can cut variable costs and selling prices while maintaining profit margins.

### Having contacts within key markets

Having access to distributors and end users is key to successful sales of industry products.

### Establishment of export markets

The industry operates internationally, so successful players must develop export markets to increase capacity usage and reduce reliance on the domestic market.

### Access to highly skilled workforce

The design and production of medical devices is highly technical, so operators with access to skilled staff will experience a competitive advantage. The importance of a skilled workforce is reflected in the industry's high average wage.

## Cost Structure Benchmarks

### Profit

Profit in the industry varies according to company size, product mix and market focus. IBISWorld estimates that in 2018, profit (measured as earnings before interest and taxes) will represent 2.0% of revenue for an average industry operator. The larger players in the industry generate profit margins higher than 20.0%; however, the majority of the 225 members in the Medical Device Manufacturers Association have much lower profit margins, with some small or new companies operating at a loss before their devices gain market approval. The

average industry profit margin has increased over the past five years, albeit only slowly, due to industry constraints associated with the Patient Protection and Affordable Care Act (PPACA).

### Wages

Wages account for 20.6% of revenue in 2018. Labor is required in the design and manufacturing of products, and since the most competitive (and highest-margin) medical devices are typically technologically advanced, employees are highly skilled and can command high wages. As a result, the average industry

# Competitive Landscape

## Cost Structure Benchmarks continued

wage is high. The increasing use of automated equipment has enabled some reduction in labor costs. However, because this industry requires skilled labor to design and manufacture products, wages will likely remain a significant cost for industry operators.

### Purchases

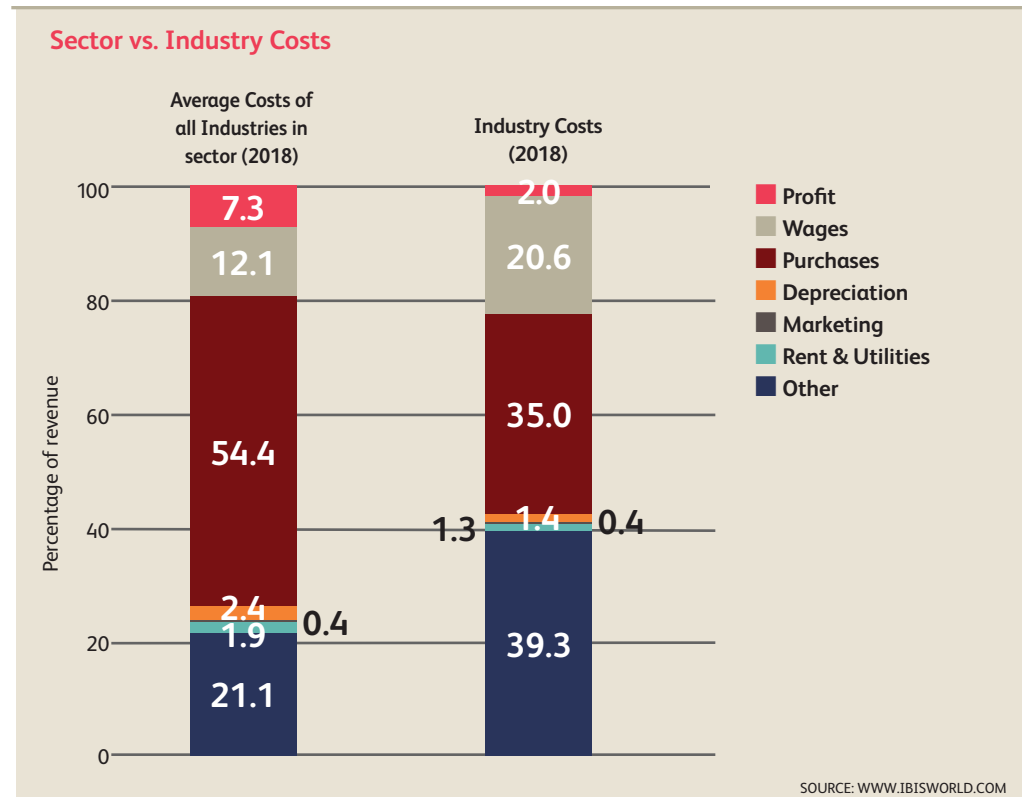
As is the case for most manufacturing industries, input purchases are the largest expense for medical device manufacturers. IBISWorld estimates that purchases will account for 35.0% of industry revenue in 2018. Purchased materials include fabricated metal products, printed circuit boards, semiconductors, electronic circuitry products, fabricated plastic products, current-carrying wiring devices, electronic computing equipment and many other materials, components and supplies. The industry's purchase cost

has increased slightly in recent years, as the cost of some raw materials to inputs (e.g. plastic and steel) have risen.

### Other

Research and development (R&D) expenses make up 12.0% of industry revenue. Given the competitive nature and strong dependence on product innovation of this industry, R&D is vital to keep up with technological advances in the healthcare field. R&D departments of large industry players (such as GE) may benefit from economies of scale, as their medical device researchers may be able to share proprietary information with R&D professionals in other in-house industries. As a share of total industry revenue, R&D costs have not significantly changed over the past five years.

Other industry expenses include insurance, electricity, rent, marketing



# Competitive Landscape

## Cost Structure Benchmarks continued

and miscellaneous costs, such as those associated with contracted legal or accounting services.

## Basis of Competition

Level & Trend  
Competition in this industry is **High** and the trend is **Increasing**

Many traditional manufacturing industries primarily compete on the basis of price and convenience; for low-margin production industries, quality and innovation often take a backseat to affordability and distribution. However, the Medical Device Manufacturing industry produces high-tech, highly specialized devices, which have a significant effect on the quality of life for the end user. Therefore, device quality and performance are particularly important bases of competition.

Moreover, the high-tech, cutting-edge nature of these products encourages manufacturers to tightly guard their intellectual property by requiring customers to sign confidentiality agreements. These agreements generally obscure pricing information, thereby limiting price competition across the industry, while driving the perceived value of technological innovation. However, recession-induced cost cutting across all downstream customer industries has kept price from becoming altogether irrelevant; the relative importance of price is likely to grow in coming years, as the Patient Protection and Affordable Care Act shines new light on healthcare costs and in-home medical care (toward which consumers are generally more cost-sensitive) grows in popularity.

Sales are driven by the introduction of new products, which are created with the support of significant research and development investment. Companies that are first in the market with a new product can benefit from patents and intellectual property protection, giving them a competitive advantage. Products with strong brands can also gain an advantage compared with other lesser-known brands.

## Quality and innovation

To be competitive, a medical device must be superior to other medical devices used for the same purposes in product reliability, clinical outcomes and doctors' perceptions of a product's quality. A device's ability to produce consistent results is of the utmost importance, as healthcare providers look to devices to improve patient health and minimize the need for human labor in the medical treatment process.

In addition to reliability, the specific functionality of a device can also give an industry company a competitive advantage. Companies in this industry spend a significant amount on research and development, in an effort to beat competitors to market with new and innovative devices. Companies that cannot stay up-to-date with the latest technological advance may incur significant revenue losses. For instance, industry operator St. Jude's experienced losses when its once-dominant pacemaker market share dropped significantly in recent years, as the company neglected to manufacture MRI-compatible pacemakers, which have recently experienced a demand surge in US and Japanese markets.

## Meeting customer needs

The price of an operator's product is a significant competitive factor. As many of the industry's products are intermediate inputs for downstream companies, price can be an important consideration for buyers. Government cost containment policies have increasingly forced medical device manufacturers to compete on the basis of price, but companies can avoid this to some degree by supplying

# Competitive Landscape

## Basis of Competition continued

products to niche markets. The specialized nature of many industry products captures demand from downstream niche markets.

In the years ahead, price competition will become more important to success, as government and healthcare providers push for price concessions. Operators within the industry will increasingly exploit sources of cost leadership: economies of scale, proprietary technology and lower-cost materials. IBISWorld expects industry competition to continue to place pressure on pricing and terms, including a trend toward vendor-owned (i.e. consignment) inventory at hospitals. Healthcare reform will also likely result in more hospital consolidations over time and this consolidation will spur related pressure on the pricing and terms of device contracts. Manufacturers that can deliver a quality home device, at a price point that consumers can afford, will do well in this growing market. Device companies that can reliably aggregate helpful patient information and then

verify, secure, analyze and present that data will do even better.

### Industry loyalty, not brand loyalty

Most users of medical devices cannot recall the brand of the device, so it is likely that buying decisions are not primarily brand driven. However, consumers do express a preference for products made by medical device companies such as Medtronic, compared with those made by consumer electronics manufacturers such as Sony. Medical device companies are perceived to have more expertise in understanding healthcare needs. Consumers also value the recommendations of healthcare professionals and watchdog organizations but do not see employers or health insurance providers as knowledgeable or useful sources of information. This implies that device manufacturers would benefit from working with healthcare professionals to design, promote and distribute their devices.

## Barriers to Entry

Level & Trend  
Barriers to Entry  
in this industry are  
**Medium and Steady**

The Medical Device Manufacturing industry's high average profit margins may appeal to potential industry entrants; however, several barriers may discourage industry entry, including heavy regulation, high investment costs, a high level of competition and a fast rate of technological change. In this industry, most goods are manufactured under patent; moreover, industry operators highly guard their technological know-how and intellectual property. Companies looking to enter some industry markets will accordingly encounter incredibly high technical demands with little publicly available technical information.

Therefore, industry operators (particularly those looking to compete in the more highly specialized industry

### Barriers to Entry checklist

Competition	High
Concentration	High
Life Cycle Stage	Mature
Capital Intensity	Low
Technology Change	High
Regulation and Policy	Heavy
Industry Assistance	Medium

SOURCE: WWW.IBISWORLD.COM

product markets) will need to invest significantly in research and development (R&D). Moreover, the average industry player will experience diminishing returns on these R&D dollars; as the markets for several products become saturated, the importance of further innovation (and, therefore, the cost of



# Competitive Landscape

## Barriers to Entry continued

R&D) will increase and further deter new entrants.

Some government policies also act as a barrier for new entrants. Medical devices are subject to the general controls of the Federal Food Drug & Cosmetic Act, which are contained in the final procedural regulations in Title 21 Code of Federal Regulations Part 800-1200 (21 CFR Parts 800-1299). These controls are baseline requirements that apply to all medical devices necessary for marketing,

proper labeling and monitoring its performance, and new entrants must adhere to these regulations.

The cost of insurance against product liability claims may also deter entry to the industry. In the health field, claims can be devastatingly high, and costs are trending upward. Additionally, access to a highly skilled labor force to perform high-level research and development is essential and constitutes another barrier to entry, as highly specialized labor is a finite resource.

## Industry Globalization

Level & Trend  
Globalization in  
this industry is  
**High** and the trend  
is **Increasing**

While US companies tend to dominate the industry, the proliferation of international giants shows that the industry is generating more profit from global outreach efforts, particularly in China, Japan and Europe. In addition, demand for medical equipment and other devices is growing in emerging markets, such as Brazil, Russia, India and China, where the middle classes are expanding and seeking better healthcare. Many US medical device manufacturers are starting to locally design and manufacture products tailored to the emerging markets because price points tend to be much lower in these markets. Furthermore, US manufacturers cannot ignore globalization by simply importing their products or transferring the manufacture of traditional models without local features.

The industry has a medium level of globalization, with many industry operators participating in or owning international operations and subsidiaries in foreign countries. Although Medtronic and St. Jude Medical still generate the majority of their revenue from the US market, international sales account for a significant portion of their total revenue. There is also a significant number of foreign players that have establishments and facilities in the United States. The level of globalization is expected to increase over the coming years, as the industry consolidates and many operators look to emerging markets for sales. Moreover, Medtronic's 2015 acquisition of Covidien will likely shift the company's headquarters to Dublin, Ireland, further increasing the effect of global operations on this industry.

# Competitive Landscape

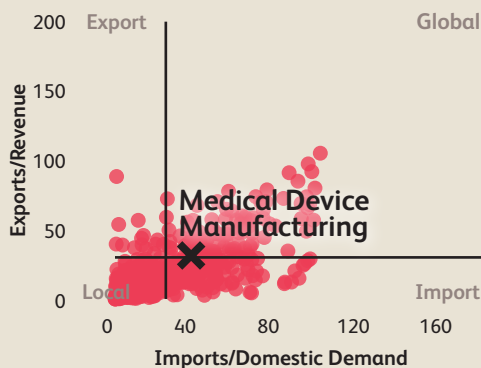
## Industry Globalization continued

International trade is a major determinant of an industry's level of globalization.

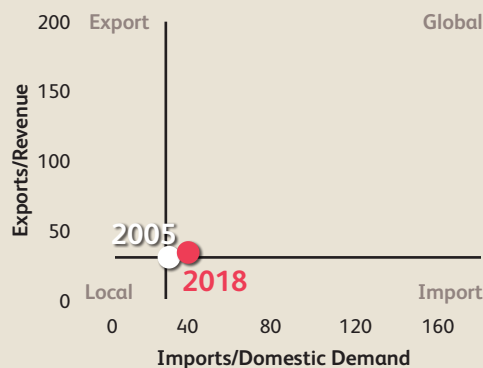
Exports offer growth opportunities for firms. However there are legal, economic and political risks associated with dealing in foreign countries.

Import competition can bring a greater risk for companies as foreign producers satisfy domestic demand that local firms would otherwise supply.

Trade Globalization



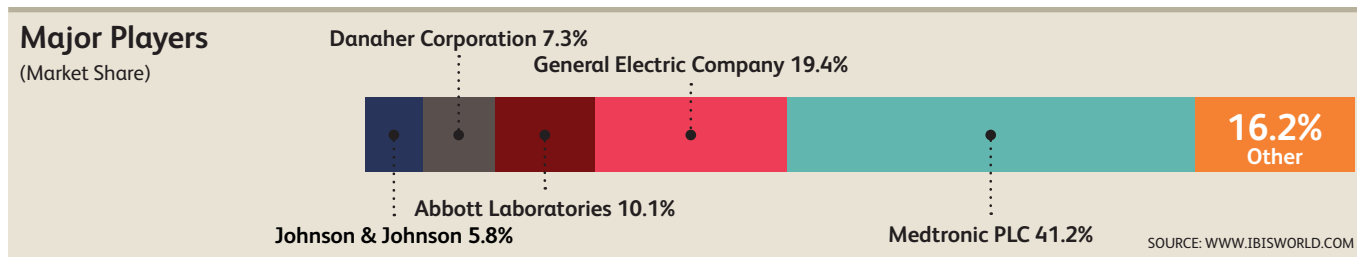
Going Global: Medical Device Manufacturing 2005–2018



SOURCE: WWW.IBISWORLD.COM

# Major Companies

Medtronic PLC | General Electric Company | Abbott Laboratories  
Danaher Corporation | Johnson & Johnson | Other Companies



## Player Performance

**Medtronic PLC**  
Market Share: 41.2%

Founded in 1949 and headquartered in Minneapolis, Medtronic PLC (Medtronic) develops and manufactures therapeutic medical devices for chronic diseases. The company markets its products to healthcare institutions and physicians in more than 140 countries worldwide. Foreign sales account for more than 40.0% of the company's total revenue, and this percentage has increased in recent years due to sales growth in emerging markets. Medtronic manufactures its products at 37 manufacturing facilities worldwide and employs about 45,000 people.

Medtronic has a diversified business portfolio, operating through four major segments: cardiac and vascular (cardiac rhythm disease management, coronary, structural heart and endovascular) products, which account for 46.2% of total sales; restorative

therapies (spinal, neuromodulation and surgical technologies), which account for 33.3%; minimally invasive technologies, which account for 11.8%; and diabetes-management products, which account for the remaining 8.7%. This cross-market diversity enables the company to withstand demand fluctuations in specific segments. While growth has slowed in several of the company's key markets, such as implantable cardioverter defibrillators and spinal procedures, Medtronic has remained focused on its fundamental strategy of innovation. The company is often first to market, with regular product releases and a dominant position in the emerging neuromodulation market; the company's revenue from neuromodulation products has consistently grown during the period.

Medtronic has sought to broaden its product portfolio and expand its

## Medtronic PLC (US industry-specific segment) - financial performance\*

Year**	Revenue		Operating Income	
	(\$ million)	(% change)	(\$ million)	(% change)
2013-14	9,247.0	2.1	2,073.4	-13.7
2014-15	11,305.0	22.3	2,101.3	1.3
2015-16	16,422	45.3	3,013.5	43.4
2016-17	16,663	1.5	2,989.4	-0.8
2017-18	15,875	-4.7	3,525.0	17.9
2018-19	16,146.5	1.7	2,955.5	-16.2

\*Estimates; \*\*Year-end April

SOURCE: ANNUAL REPORT AND IBISWORLD

# Major Companies

## Player Performance continued

international operations through many strategic acquisitions in recent years. Most significantly, in June 2014, the company announced plans to buy medical supplies giant Covidien for \$42.9 billion. In addition to acquiring Covidien's sizable assets and market share, the deal also opened the door for Medtronic to move its headquarters to Covidien's hometown of Dublin, which could enable the new company to save millions annually on US taxes. The purchase was completed in January 2015, and the companies estimate that the merger has resulted in annual cost savings as high as \$850.0 million.

## Financial performance

Medtronic manages to maintain low revenue volatility as a result of its diversified product mix. Over the past five years, the company's US revenue has grown at an annualized rate of 11.8% to \$16.1 billion. This includes an estimated increase of 1.7% in fiscal 2018. The rapid 2016 growth is a result of the now completed Covidien merger, which greatly increased the companies' output levels. Also, profit has largely recovered due to internal cost-cutting efforts based on lean manufacturing, developing a comprehensive manufacturing strategy and working closely with suppliers. Profit is expected to account for 18.3% of industry-specific revenue this year.

## Player Performance

**General Electric Company**  
Market Share: 19.4 %

Headquartered in Fairfield, CT, General Electric Company (GE) is a multinational conglomerate with operations that span the healthcare, financial services, energy, industrial manufacturing and media industries. The company employs more than 300,000 people across the globe. The company's medical device manufacturing division is referred to as its healthcare business, which comprises 16.0% of the company's total revenue. GE Healthcare provides a range of services

that improve productivity for health-service providers, helping them to better diagnose, treat and manage patients with conditions such as cancer, Alzheimer's disease and cardiovascular disease. GE's healthcare division operates technology, service and manufacturing centers in North America, Europe and Asia.

GE has noted that the global demand for cancer-profiling products and services has grown from \$15.0 billion in 2005 to about \$47.0 billion in 2015. The company

## General Electric Company (US industry-specific segment) - financial performance\*

Year	Revenue		Operating Income	
	(\$ million)	(% change)	(\$ million)	(% change)
2013	7,939.2	-0.5	1,330.1	0.1
2014	7,986.9	0.6	1,328.5	-0.1
2015	7,999.8	0.2	1,307.1	-1.7
2016	7,929.6	-0.9	1,370.4	4.8
2017	7,251.1	-8.6	1,307.9	-4.6
2018	7,613.0	5.0	1,412.6	8.0

\*Estimates

SOURCE: ANNUAL REPORT AND IBISWORLD

# Major Companies

## Player Performance continued

also acquired several healthcare services businesses in early 2014, including API Healthcare, a healthcare workforce management software and analytics solutions provider, and some of the life sciences operations of Thermo Fisher Scientific, a biotechnology research product manufacturer.

### Financial performance

Over the five years to 2018, GE Healthcare's US revenue is expected to decline slightly at an annualized rate of 0.8% to \$7.6 billion. Although healthcare reform has strengthened demand for and access to healthcare, new regulations placed on healthcare device manufacturers have limited operator

growth. Stubbornly low prices due to a strengthening US dollar have kept a damper on revenue over the past five years and are expected to do the same over the next five years.

GE does the majority of its business outside of the United States, and the company has been expanding its presence worldwide, particularly in emerging markets. Although this revenue (and profit) will remain external to the Medical Device Manufacturing industry, GE Healthcare will benefit as a whole from this expanded presence, and some of these benefits will trickle down to the industry-relevant bottom line, particularly in the form of research and development findings.

## Player Performance

**Abbott Laboratories**  
Market Share: 10.1 %

Abbott Laboratories (Abbott) is global manufacturer of pharmaceuticals and medical devices. The company was founded in 1888 and employs more than 94,000 in more than 150 countries. About 31.0% of Abbott's products are manufactured in the United States. Prior to this year, Abbott accounted for only a small portion of industry revenue; however, in January 2017, Abbott acquired St. Jude Medical

Inc., formerly a major industry player. Since then, the company has rapidly expanded its product offerings and industry-relevant revenue.

Abbott specializes in vascular products, diagnostic products and pharmaceutical delivery devices. The company sells these products to both consumers and healthcare providers. Since the acquisition, Abbott now has the assets of St. Jude Medical, as well, which

### Abbott Laboratories (US industry-specific segment) - financial performance\*

Year	Revenue (\$ million)	(% change)	Operating Income (\$ million)	(% change)
2013	1,999	-5.5	216.9	43.5
2014	1,852	-7.4	237.7	9.6
2015	1,927	4.0	270.7	13.9
2016	2,017	4.7	308.1	13.8
2017	3,416	69.3	215.3	-30.1
2018	3,958	15.9	413.3	92.0

\*Estimates

SOURCE: ANNUAL REPORT

# Major Companies

## Player Performance continued

specialized in defibrillators, pacemakers, cardiovascular devices and neurostimulation products. With these new resources, Abbott accounts for a significant portion of industry revenue.

### Financial performance

As a result of the St. Jude acquisition, over the five years to 2018, Abbott's industry-specific revenue is expected to grow at an annualized rate of 14.6% to

\$4.0 billion. This includes growth of 49.1% in 2017 as the effects of the acquisition occur. In addition, the company's profit is expected to rise to \$413.3 million as the St. Jude acquisition takes effect and the company moves past the initial cost of the acquisition. Though this growth is only temporary, industry-relevant revenue and profit are expected to remain high over the next five years.

## Player Performance

**Danaher Corporation**  
Market Share: 7.3 %

The Danaher Corporation (Danaher) is an international producer of medical devices and equipment. Danaher employs about 66,000 people worldwide, more than half of which are based outside of the United States. The company, which was founded as a real estate trust in 1969 and is currently headquartered in Washington, DC, designs, manufactures and markets professional, medical, industrial, commercial and consumer products. The company manufactures industry-relevant digital imaging and magnification systems, as well as diagnostic and analytical tools for medical and dental use under many of its operating segments. Industry-relevant sales account for about one-fifth of the

company's total revenue, and 37.3% of these sales occur in the United States.

Over the past five years, Danaher has strengthened its market share through significant M&A activity. Most recently, Danaher has acquired Cepheid, Integrated DNA Technologies, AVT and Pall. While not all of these acquisitions have been industry-relevant, some have contributed to increased innovation throughout the company.

### Financial performance

Over the five years to 2018, Danaher's industry-relevant revenue is expected to rise at an annualized rate of 6.2% to \$2.8 billion. This growth has largely been driven by the company's aggressive

## Danaher Corporation (US industry-specific segment) - financial performance\*

Year	Revenue		Operating Income	
	(\$ million)	(% change)	(\$ million)	(% change)
2013	2,109.1	N/C	329.3	N/C
2014	2,195.4	4.1	344.6	4.6
2015	2,496.5	13.7	385.5	11.9
2016	2,565.0	2.7	400.3	3.8
2017	2,679.4	4.5	399.9	-0.1
2018	2,843.3	6.1	492.8	23.2

\*Estimates

SOURCE: ANNUAL REPORT AND IBISWORLD

# Major Companies

## Player Performance continued

acquisition strategy. As the company has purchased more operations, it has expanded its scope and profile, thus growing the company's market.

Additionally, expanded operations have contributed to strong profit growth. In 2018, profit is expected to account for 17.3% of industry-relevant revenue.

## Player Performance

**Johnson & Johnson**  
Market Share: 5.8 %

Johnson & Johnson (J&J) is a leading healthcare company that develops, manufactures and markets a diverse portfolio of pharmaceutical, medical-device and consumer-health products. Incorporated in 1887, J&J currently operates globally, employing more than 128,000 people worldwide. The company is headquartered in New Brunswick, NJ and has 51 domestic manufacturing facilities. While the United States and Europe represent the company's largest markets, J&J has recently begun expanding its geographic foothold in Asia, especially in China, as well as other emerging markets.

Through its medical devices segment, the company offers diabetes-management devices, cardiovascular equipment (such as electrocardiographs) and surgical precision and imaging systems, among other devices. Only 9.7% of the company's revenue is industry-relevant; the rest of the medical devices

segment's revenue is generated by sales of vision products and medical supplies (IBISWorld reports 33911a and 33911b).

### Financial performance

IBISWorld estimates that J&J's industry-specific revenue will total \$2.3 billion in 2018. Although the improving economy and strong demand for cardiovascular products has boosted company sales in recent years, competitive price pressure in the diabetes-care-device market has resulted in revenue declining at an annualized rate of 2.6% over the past five years. According to a company statement, J&J's industry-specific sales were down in the second quarter of 2014 due to price decreases for diabetes devices, thanks to recently implemented competitive bidding via Medicare.

The company's industry-relevant profit has fluctuated over the past five years. Although the highly specialized, technical nature of the company's industry-

## Johnson & Johnson (US industry-specific segment) - financial performance\*

Year	Revenue (\$ million)	(% change)	Operating Income (\$ million)	(% change)
2013	2,499.3	-3.6	461.5	-32.1
2014	2,488.7	-0.4	719.1	55.8
2015	2,440.8	-1.9	618.0	-14.1
2016	2,274.8	-6.8	465.5	-24.7
2017	2,273.0	-0.1	430.1	-7.6
2018	2,284.8	0.5	422.9	-1.7

\*Estimates

SOURCE: ANNUAL REPORT AND IBISWORLD

# Major Companies

## Player Performance continued

relevant products has historically translated into high margins, litigation, acquisitions and regulation have had a

negative effect on profit, which rose to \$719.1 million in 2014 and declined to \$422.9 million in 2018.

## Other Company Performance

**Boston Scientific Corporation**  
Market Share: 4.7 %

Boston Scientific Corporation (Boston Scientific) is a developer, manufacturer and marketer of medical devices that are used in interventional medical specialties, including cardiac rhythm management, electrophysiology, interventional cardiology, peripheral interventions, neurovascular, endoscopy, urology, women's health and neuromodulation. In early 2014,

Boston Scientific announced that the FDA had approved its next-generation Dynagen and Inogenlines of implantable defibrillators and cardiac resynchronization therapy devices, which are expected to drive company growth in 2018 and beyond. In 2018, IBISWorld expects Boston Scientific's industry-relevant revenue to reach \$1.8 billion.

## Other Company Performance

**Varian Medical Systems Inc.**  
Market Share: 2.0 %

Varian Medical Systems Inc. (Varian) designs, manufactures, sells and services equipment and software products used for treating cancer with radiotherapy, stereotactic radiosurgery and brachytherapy. The company also designs, manufactures, sells and services X-ray tubes for original equipment manufacturers, replacement X-ray tubes

and flat-panel digital image detectors for filmless X-rays in medical, dental, veterinary, scientific and industrial applications. In 2018, IBISWorld forecasts that Varian's global revenue will total \$3.0 billion; 30.8% of this revenue, or \$772.8 million, will be generated by the sale of products within the United States.



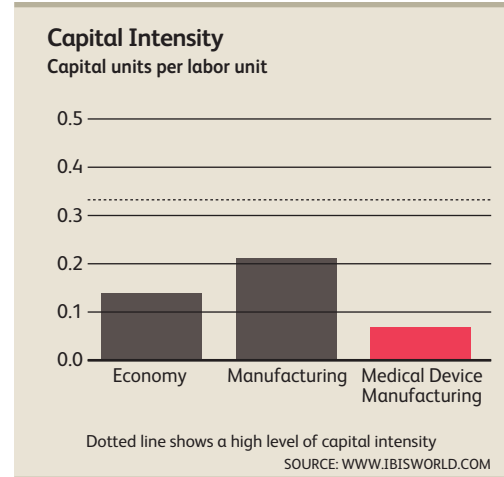
# Operating Conditions

Capital Intensity | Technology & Systems | Revenue Volatility  
 Regulation & Policy | Industry Assistance

## Capital Intensity

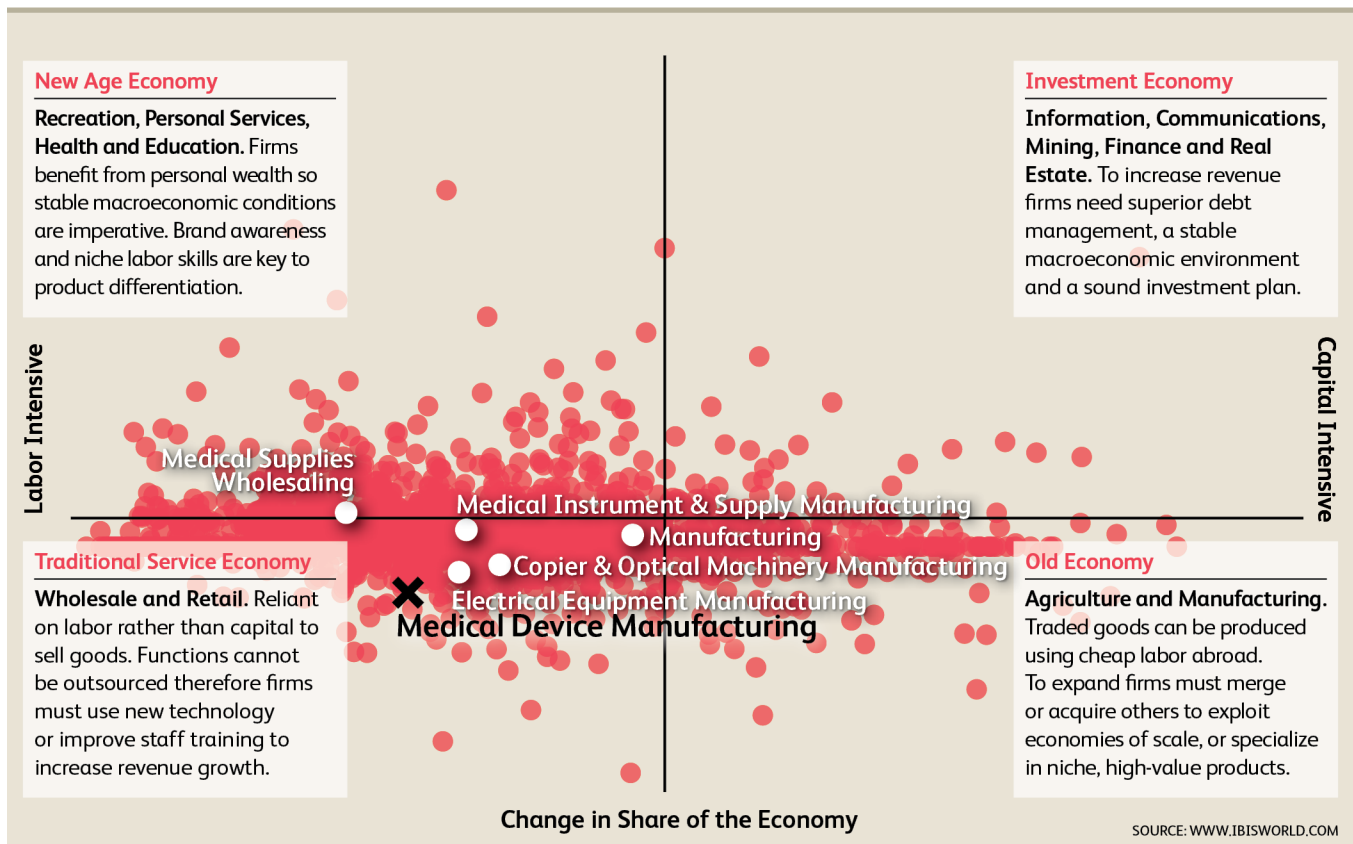
**Level**  
 The level of capital intensity is **Low**

The industry has a moderately low level of capital intensity; for every \$1.00 an average industry company spends on labor, they invest \$0.08 into capital improvements. Although the cost of assets can be high for industry operators, not all products can be manufactured on an automated production line. Medical device manufacturers produce a range of products for highly specialized applications, and the development and production of many of these devices requires hands-on work, which keeps industry labor costs high. Skilled specialists are needed to research and develop medical devices, and these employees command salaries well above the manufacturing sector's average wage. Consequently, wages are estimated to account for 20.6% of revenue in 2018,



while depreciation (which can be used as a proxy for capital expenditure) is only expected to account for 1.6%.

## Tools of the Trade: Growth Strategies for Success



# Operating Conditions

## Technology & Systems

### Level

The level of technology change is **High**

The Medical Device Manufacturing industry is highly competitive and is characterized by rapid product development and technological change. The importance of technology to the industry is reflected in the high percentage (12.0%) of revenue that the average industry operator devotes to research and development (R&D). Sales are driven by the introduction of new products to the market, and thus technological advances drive product development. As a result, it is vital for companies to gain access to the latest technology, either through their own research and development efforts or by acquiring the technology from another company (in the case of the large players, this often means buying small enterprises). Industry players vigorously enforce intellectual property regulations and patents, as proprietary technologies provide a source of critical advantage over the competition.

Nonindustry-specific advances in science and engineering have further driven the development of new products and reduced the costs of manufacturing through improved efficiency. For instance, the creation of high-performance

synthetic materials has driven new industry R&D efforts. Industry players may also increasingly look to incorporate technological advances made outside the industry into their own production processes. For example, potential advances in 3D printing may enable the creation of devices made from biological material. Although most companies investing in and advancing 3D bioprinting currently operate outside the industry (e.g. industrial design companies, biotechnology operators and prosthetics manufacturers), their discoveries may have a significant effect on the Medical Device Manufacturing industry. New and enhanced products such as bioprinted stents may be less expensive to produce and easier for the body to accept than traditionally produced stents. In addition to potentially creating new product lines and affecting demand for traditional industry products, such technological advances may encourage industry operators to invest in these new and disruptive technologies, although these investments would require significant upfront capital and take years to pay off, due to significant federal regulation of biological products and processes.

## Revenue Volatility

### Level

The level of volatility is **Medium**

The Medical Device Manufacturing industry is relatively resilient and well insulated from the short-term effect of many economic changes. The economic environment does not pose a direct threat to industry performance; regardless of the state of the broader economy, doctors are unlikely to cease adoption of the more effective treatment of spines, coronary and peripheral arteries, diabetes or neonatal illnesses. Nonetheless, hospitals may curtail purchases or opt for less-expensive alternatives in times of budgetary constraint. Over the five years to 2018, revenue is expected to fluctuate an average of 5.0% each year.

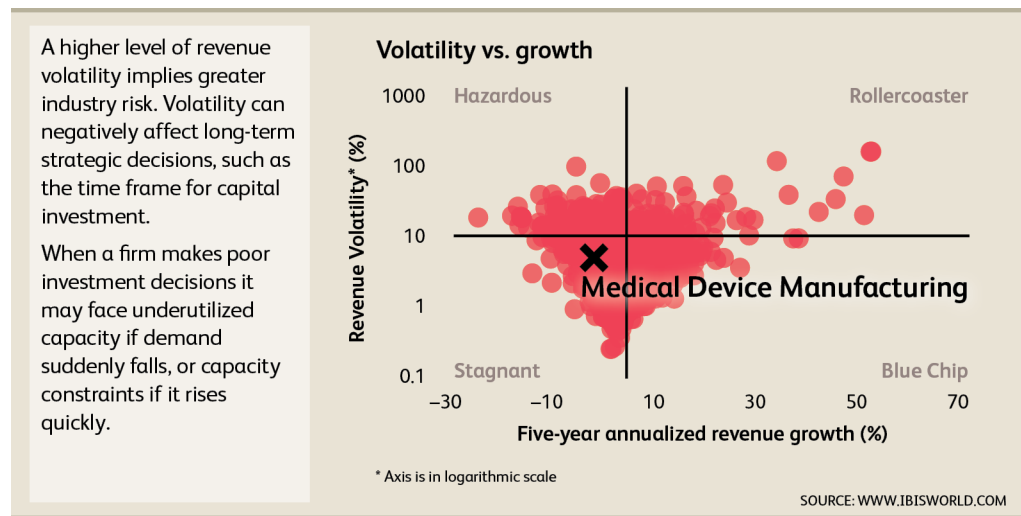
Additionally, companies use patents, trademarks, copyrights, trade secrets and confidentiality agreements to create and protect proprietary technology. Product innovation helps drive demand and revenue. Although the necessity of industry goods and intellectual property helps stabilize revenue, medical device manufacturers operate in a global market, which exposes them to greater volatility due to exchange rate fluctuations and changes in global economic conditions. The industry has a significant level of trade, with exports accounting for 30.1% of total industry revenue.

# Operating Conditions

## Revenue Volatility continued

Volatility also increases by the rate of new product adoption. In 2018, most products have become widely accepted and used. However, revenue volatility may increase in coming years due to new biotechnology advances such as 3D bioprinting. Substitute product lines based on high-tech scientific advances

may have a disruptive effect on industry revenue. Industry revenue may spike if an industry company gains FDA approval for a widespread interest in a new product; similarly, revenue may dip if consumers are wary of new products or if such devices are developed by companies outside the industry.



## Regulation & Policy

**Level & Trend**  
The level of Regulation is **Heavy** and the trend is **Increasing**

The Medical Device Manufacturing industry is subject to regulation by numerous government agencies and international groups. The major regulating bodies affecting the industry include the Food and Drug Administration (FDA) and the Global Harmonization Task Force (GHTF).

### FDA regulations

The FDA governs the laws and regulations relating to the development, testing, manufacturing, labeling, marketing and distribution of medical devices. The basic regulatory requirements that manufacturers of medical devices distributed in the United States must comply with are discussed below.

The 510(k) process requires industry participants to demonstrate that a new medical device they intend to market is

substantially equivalent to a medical device first marketed before May 1976. In this process, participants must submit data that supports what the medical device claims. Once an order from the FDA is obtained, the new device can be commercially distributed. Products that require Premarket Approvals (PMAs), conversely, are generally devices that pose a significant risk of illness or injury. The PMA process is lengthier than the 510(k) process, because PMA requires companies to independently demonstrate that a new medical device is safe and effective by submitting clinical data to support claims made for the device.

The FDA also enforces Good Manufacturing Practices, which require that domestic or foreign manufacturers have a quality system for the design, manufacture, packaging, labeling, storage,

# Operating Conditions

## Regulation & Policy continued

installation and servicing of finished medical devices intended for commercial distribution in the United States. Quality System regulations help ensure that medical devices are safe and effective for the intended use.

Medical device reporting regulation helps the FDA and manufacturers identify and monitor adverse events involving medical devices. Manufacturers must report deaths, serious injuries and malfunctions within 30 calendar days of becoming aware of the event; events that may pose unreasonable risk of substantial harm to the public health within five working days from becoming aware of the event; and interim and annual updates if any baseline information changes occur after initial submission.

Manufacturers are required to track certain devices throughout the production and distribution chain. Tracking is carried out on devices that may pose a serious risk to health. Medical device tracking information is used to locate goods in commercial distribution in the event that the FDA orders product recalls for the goods.

### Trade regulations

Imports are subject to the same regulations as domestically produced goods. Exceptions are made for approved or unapproved import device parts, components or subassemblies that may be imported for further processing or incorporation into unapproved devices that are to be subsequently exported. Companies are not permitted to import finished unapproved devices without prior marketing clearance, even if the device is to be imported solely for subsequent export.

Any medical device legally on the US market may be exported anywhere in the world without prior FDA notification or approval. Unapproved devices, or medical devices considered to be

adulterated or misbranded, may be exported provided the device is intended solely for export, is in accord with the specifications of the foreign purchaser, is not in conflict with the laws of the country to which it is being exported, is labeled as an export on the outside of the shipping package and is not sold or offered for sale in domestic commerce.

Every country has specific medical device regulations. Companies generally obtain regulatory approval for medical devices in foreign countries before they are approved in the United States because foreign systems are often faster and simpler than that of the United States. In the European Union, a single regulatory approval process has been created, and approval is represented by the Certificate of Exportation (CE) Mark.

### GHTF

The Global Harmonization Task Force (GHTF) encourages convergence in regulatory practices across Europe, Asia-Pacific and North America. The group endeavors to ensure the safety, effectiveness, performance and quality of medical devices, promote technological innovation and facilitate international trade. The GHTF bases its harmonized guidance documents on regulatory practices from the above geographic areas.

### Healthcare reform

The Patient Protection and Affordable Care Act (PPACA) has substantially affected the Medical Device Manufacturing industry. Most notably, medical device manufacturers have been subject to a new tax. The tax is 2.3% of the sale price and applies to all devices sold since January 1, 2013. Currently, taxable medical devices are vaguely defined as any devices intended for humans; proposed regulations will likely clarify which medical devices are taxable. The medical device fee applies to all manufacturers, regardless of size and

# Operating Conditions

## Regulation & Policy continued

revenue levels. The excise tax is estimated to cost the industry \$20.0 billion over the next 10 years; this profit squeeze could strain the US innovation system for medical technology even further.

Another of the PPACA's major provisions that affects medical device manufacturers is comparative effectiveness research (CER). CER involves the generation and synthesis of evidence to evaluate the benefits and harms of alternative methods to prevent, diagnose, treat and monitor clinical conditions or improve the delivery of care. In the beginning of fiscal 2010, the American Recovery and Reinvestment Act (ARRA) provided funding for the PPACA's newly mandated and immediately effective CER entity, the Patient-Centered Outcomes Research Institute (PCORI). By sponsoring scientifically rigorous CER studies, PCORI is responsible for assisting patients, clinicians, payers and policy makers in making informed healthcare decisions by advancing the quality and relevance of evidence. This funding has expanded substantially; it totaled \$10.0 million in 2010 and rose to \$150.0 million by 2012. Between 2013 and 2019, the trust is funded through an annual appropriation of \$150.0 million, to be supplemented by fees imposed on Medicare and private health insurance companies.

CER has significant implications for pharmaceutical, biotechnology and medical device manufacturers. In particular, uncertainty among companies

may be stifling investment in research and development (R&D). For medical device and pharmaceutical manufacturers, CER conducted by a quasi-independent agency could create uncertainty about the fate of their products. Safety and efficacy demonstrated under ideal conditions will no longer be sufficient to gain or maintain market access; instead, incremental value over other treatment options will become the decision point. Some fear that innovation may suffer due to CER, as return on R&D investments will be less certain. International experience, however, indicates that a consistent CER process and decision-making algorithm may actually encourage innovation. By instituting this form of research, manufacturers can learn what product features are valued and rewarded. In this new environment, a departure from the tried and true will be necessary for success.

The implementation of CER should also be closely monitored by medical product manufacturers because of the interest among certain groups and government entities in using CER to assist with respect to healthcare cost containment efforts. For example, the Healthcare Reform Law helps the Secretary of the Department of Health and Human Services use CER results to make a determination concerning Medicare coverage, particularly if a determination to deny coverage is not based solely on CER.

# Operating Conditions

## Industry Assistance

**Level & Trend**  
The level of Industry Assistance is **Medium** and the trend is **Steady**

The industry receives assistance in the form of tariffs on certain devices. Tariffs vary depending on the product and the material used to make the product. Some examples include a 0.4% tariff on computed tomography apparatus for dental, medical, surgical or veterinary uses; a 0.8% tariff on electrocardiographs, ultrasonic scanning apparatus, magnetic resonance imaging apparatus, patient monitoring systems, basal metabolism, blood pressure apparatus and pacemakers; and a 1.6% tariff on electro-surgical instruments and appliances (except for extracorporeal shock wave lithotripters).

### Industry associations

Several bodies represent the industry, including the Association of Medical Diagnostics Manufacturers (AMDM), the Medical Device Manufacturers Association (MDMA) and the Advanced Medical Technology Association (AdvaMed).

The AMDM acts as a liaison between industry members and Regulatory Agencies. The MDMA was created in 1992 and acts as a watchdog against unreasonable regulation in the Medical Device Manufacturing industry and represents the interests of medical device manufacturers. The MDMA is a national trade association that provides

educational and advocacy assistance to medical technology companies. Since 1992, MDMA has been the voice for smaller companies, playing a proactive role in helping to shape policies that affect the medical device innovator. This is accomplished by maintaining relationships with key members of Congress and through the grassroots support of members. In October 2013, the MDMA made headlines as it lobbied hard for the repeal of the medical device excise tax as a bargaining chip in the Congressional efforts to end the government shutdown. Although these efforts were ultimately thwarted, the MDMA successfully took advantage of the opportunity to portray the industry as innovative and job-creating.

AdvaMed is the largest medical technology association in the world and represents medical device manufacturers and makers of medical equipment, medical software and medical supplies. AdvaMed promotes fast product approvals by industry regulators worldwide; more timely coverage and payment determinations globally; fair access to international markets; and effective communications about the value of medical technology to key audiences including legislators, regulators, medical societies and patient organizations.

# Key Statistics

## Industry Data

	Revenue (\$m)	Industry Value Added (\$m)	Establishments	Enterprises	Employment	Exports (\$m)	Imports (\$m)	Wages (\$m)	Domestic Demand	Number of physician visits (Mil)
2010	38,548.9	10,316.0	805	717	80,098	13,721.2	12,760.2	7,193.6	37,587.9	1,008.8
2011	39,040.6	10,889.1	838	753	81,274	13,949.9	13,755.4	7,297.4	38,846.1	987.0
2012	41,265.3	10,882.6	916	825	79,689	13,935.6	14,088.7	7,540.1	41,418.4	928.6
2013	42,181.4	11,078.2	860	770	79,222	13,139.9	14,206.6	7,324.1	43,248.1	922.6
2014	40,123.1	10,411.7	898	805	82,149	12,432.6	15,033.9	7,603.2	42,724.4	884.7
2015	39,997.0	10,834.6	927	817	80,950	11,700.9	14,834.5	7,674.8	43,130.6	990.8
2016	37,820.7	10,177.7	917	813	81,326	11,499.0	15,282.0	7,795.0	41,603.7	956.9
2017	38,307.9	9,187.1	919	813	82,104	11,234.3	15,684.6	7,884.7	42,758.2	957.9
2018	39,160.9	9,405.4	947	839	83,821	11,823.5	16,952.0	8,069.3	44,289.4	969.0
2019	40,190.2	9,606.9	954	844	85,360	11,907.5	17,115.2	8,251.4	45,397.9	981.1
2020	40,795.7	9,761.9	984	872	86,931	12,129.0	17,731.8	8,410.2	46,398.5	992.5
2021	41,948.4	9,985.3	992	877	88,635	12,057.9	17,894.9	8,613.4	47,785.4	999.1
2022	43,232.7	10,286.7	1,021	903	90,844	12,189.8	18,500.0	8,864.2	49,542.9	1,004.3
2023	44,141.6	10,443.1	1,032	912	92,323	12,138.4	18,776.6	9,035.6	50,779.8	1,009.1
2024	45,036.1	10,683.3	1,063	940	94,262	12,214.6	19,306.4	9,242.3	52,127.9	1,013.8
Sector Rank	43/193	30/193	85/193	81/193	42/193	25/184	34/184	20/193	41/184	N/A
Economy Rank	243/694	230/694	543/694	519/694	338/694	28/216	36/216	189/694	44/216	N/A

## Annual Change

	Revenue (%)	Industry Value Added (%)	Establishments (%)	Enterprises (%)	Employment (%)	Exports (%)	Imports (%)	Wages (%)	Domestic Demand (%)	Number of physician visits (%)
2011	1.3	5.6	4.1	5.0	1.5	1.7	7.8	1.4	3.3	-2.2
2012	5.7	-0.1	9.3	9.6	-2.0	-0.1	2.4	3.3	6.6	-5.9
2013	2.2	1.8	-6.1	-6.7	-0.6	-5.7	0.8	-2.9	4.4	-0.6
2014	-4.9	-6.0	4.4	4.5	3.7	-5.4	5.8	3.8	-1.2	-4.1
2015	-0.3	4.1	3.2	1.5	-1.5	-5.9	-1.3	0.9	1.0	12.0
2016	-5.4	-6.1	-1.1	-0.5	0.5	-1.7	3.0	1.6	-3.5	-3.4
2017	1.3	-9.7	0.2	0.0	1.0	-2.3	2.6	1.2	2.8	0.1
2018	2.2	2.4	3.0	3.2	2.1	5.2	8.1	2.3	3.6	1.2
2019	2.6	2.1	0.7	0.6	1.8	0.7	1.0	2.3	2.5	1.2
2020	1.5	1.6	3.1	3.3	1.8	1.9	3.6	1.9	2.2	1.2
2021	2.8	2.3	0.8	0.6	2.0	-0.6	0.9	2.4	3.0	0.7
2022	3.1	3.0	2.9	3.0	2.5	1.1	3.4	2.9	3.7	0.5
2023	2.1	1.5	1.1	1.0	1.6	-0.4	1.5	1.9	2.5	0.5
2024	2.0	2.3	3.0	3.1	2.1	0.6	2.8	2.3	2.7	0.5
Sector Rank	31/193	44/193	65/193	64/193	32/193	129/184	82/184	29/193	29/184	N/A
Economy Rank	138/694	179/694	330/694	343/694	184/694	145/216	94/216	161/694	33/216	N/A

## Key Ratios

	IVA/Revenue (%)	Imports/Demand (%)	Exports/Revenue (%)	Revenue per Employee (\$'000)	Wages/Revenue (%)	Employees per Est.	Average Wage (\$)	Share of the Economy (%)
2010	26.76	33.95	35.59	481.27	18.66	99.50	89,809.98	0.07
2011	27.89	35.41	35.73	480.36	18.69	96.99	89,787.63	0.07
2012	26.37	34.02	33.77	517.83	18.27	87.00	94,619.08	0.07
2013	26.26	32.85	31.15	532.45	17.36	92.12	92,450.33	0.07
2014	25.95	35.19	30.99	488.42	18.95	91.48	92,553.77	0.06
2015	27.09	34.39	29.25	494.10	19.19	87.32	94,809.14	0.06
2016	26.91	36.73	30.40	465.05	20.61	88.69	95,848.81	0.06
2017	23.98	36.68	29.33	466.58	20.58	89.34	96,033.08	0.05
2018	24.02	38.28	30.19	467.20	20.61	88.51	96,268.24	0.05
2019	23.90	37.70	29.63	470.83	20.53	89.48	96,665.89	0.05
2020	23.93	38.22	29.73	469.29	20.62	88.34	96,745.69	0.05
2021	23.80	37.45	28.74	473.27	20.53	89.35	97,178.32	0.05
2022	23.79	37.34	28.20	475.90	20.50	88.98	97,576.06	0.05
2023	23.66	36.98	27.50	478.12	20.47	89.46	97,869.44	0.05
2024	23.72	37.04	27.12	477.78	20.52	88.68	98,049.05	0.05
Sector Rank	58/193	59/184	43/184	76/193	35/193	39/193	9/193	30/193
Economy Rank	392/694	65/216	52/216	210/694	284/694	62/694	56/694	230/694

Figures are in inflation-adjusted 2018 dollars. Rank refers to 2018 data.

SOURCE: WWW.IBISWORLD.COM

## Industry Financial Ratios

	Apr 2013 - Mar 2014	Apr 2014 - Mar 2015	Apr 2015 - Mar 2016	Apr 2016 - Mar 2017	Apr 2016 - Mar 2017 by company revenue		
					Small (<\$10m)	Medium (\$10-50m)	Large (>\$50m)
<b>Liquidity Ratios</b>							
Current Ratio	2.2	2.2	2.1	2.2	2.0	2.3	2.3
Quick Ratio	1.2	1.2	1.1	1.2	1.0	1.3	1.2
Sales / Receivables (Trade Receivables Turnover)	7.6	7.5	7.8	7.3	8.3	7.2	7.0
Days' Receivables	48.0	48.7	46.8	50.0	44.0	50.7	52.1
Cost of Sales / Inventory (Inventory Turnover)	4.0	4.0	3.9	3.8	4.0	3.4	4.0
Days' Inventory	91.3	91.3	93.6	96.1	91.3	107.4	91.3
Cost of Sales / Payables (Payables Turnover)	11.3	12.6	12.4	12.9	14.0	12.9	11.3
Days' Payables	32.3	29.0	29.4	28.3	26.1	28.3	32.3
Sales / Working Capital	5.3	4.9	5.3	5.1	6.3	4.6	4.6
<b>Coverage Ratios</b>							
Earnings Before Interest & Taxes (EBIT) / Interest	9.9	9.9	8.2	6.3	3.3	9.0	7.2
Net Profit + Dep., Depletion, Amort. / Current Maturities LT Debt	3.9	3.3	2.7	3.3	2.0	3.4	5.0
<b>Leverage Ratios</b>							
Fixed Assets / Net Worth	0.3	0.3	0.3	0.3	0.3	0.3	0.7
Debt / Net Worth	1.0	1.0	1.1	1.0	1.0	0.9	1.2
Tangible Net Worth	40.4	41.4	36.8	38.4	31.9	45.4	33.3
<b>Operating Ratios</b>							
Profit before Taxes / Net Worth, %	21.8	22.0	20.1	13.7	14.3	15.7	8.9
Profit before Taxes / Total Assets, %	8.1	9.0	7.8	5.9	4.8	6.4	4.9
Sales / Net Fixed Assets	16.9	17.1	17.1	14.3	26.2	14.0	7.9
Sales / Total Assets (Asset Turnover)	1.8	1.7	1.8	1.6	2.0	1.6	1.3
<b>Cash Flow &amp; Debt Service Ratios (% of sales)</b>							
Cash from Trading	42.1	40.7	41.7	42.2	43.3	43.3	37.5
Cash after Operations	7.2	7.1	7.0	6.1	4.8	7.1	8.2
Net Cash after Operations	6.7	6.7	5.9	5.6	4.1	6.7	7.6
Cash after Debt Amortization	2.4	2.3	2.0	1.4	1.3	1.1	3.6
Debt Service P&I Coverage	4.0	3.1	3.2	2.3	1.9	2.2	4.9
Interest Coverage (Operating Cash)	10.6	7.3	10.3	6.2	3.7	7.2	8.6
<b>Assets, %</b>							
Cash & Equivalents	14.5	15.0	14.3	14.1	13.7	14.7	12.9
Trade Receivables (net)	25.6	26.1	25.8	24.7	27.8	24.3	19.6
Inventory	25.7	25.3	26.0	25.5	26.6	26.7	20.2
All Other Current Assets	4.3	4.1	4.0	4.1	3.6	4.4	4.2
Total Current Assets	70.1	70.5	70.1	68.4	71.6	70.2	56.9
Fixed Assets (net)	14.6	15.1	15.2	15.3	13.3	15.8	18.2
Intangibles (net)	9.1	8.3	8.2	9.7	7.7	8.0	18.4
All Other Non-Current Assets	6.2	6.1	6.4	6.6	7.4	6.0	6.5
Total Assets	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Total Assets (\$m)	13,682.8	15,087.2	15,737.8	12,621.8	543.3	3,421.3	8,657.2
<b>Liabilities, %</b>							
Notes Payable-Short Term	6.9	8.1	7.4	6.7	9.6	6.0	2.6
Current Maturities L/T/D	2.0	2.1	2.2	2.3	2.8	1.8	2.5
Trade Payables	11.5	10.5	11.0	10.1	11.4	9.9	8.0
Income Taxes Payable	0.4	0.4	0.4	0.3	0.4	0.3	0.3
All Other Current Liabilities	14.5	14.3	15.0	14.0	15.7	13.1	12.9
Total Current Liabilities	35.2	35.4	36.0	33.4	39.9	31.1	26.3
Long Term Debt	8.4	9.4	10.2	10.5	9.5	9.5	15.3
Deferred Taxes	0.5	0.5	0.6	0.6	0.4	0.6	1.2
All Other Non-Current Liabilities	6.3	5.1	8.2	7.4	10.7	5.4	5.6
Net Worth	49.5	49.7	45.0	48.1	39.6	53.4	51.7
Total Liabilities & Net Worth (\$m)	13,682.8	15,087.2	15,737.8	12,621.8	543.3	3,421.3	8,657.2
Maximum Number of Statements Used	536	544	541	452	164	209	79

Source: RMA Annual Statement Studies, rmahq.org. RMA data for all industries is derived directly from more than 260,000 statements of member financial institutions' borrowers and prospects.

Note: For a full description of the ratios refer to the Key Statistics chapter online.





# Jargon & Glossary

## Industry Jargon

**3D BIOPRINTING** A process of generating items from biological material, wherein cell function and viability are preserved within the printed item.

**510(K)** A premarket notification for most devices, named for the section of the law that requires these submissions.

**ELECTROMEDICAL** Electrically operated diagnostic and other medical equipment.

**MEDICAL DEVICE REPORTING** Submissions to the Food and Drug Administration when death or serious injury occurs while using a medical device.

**NEUROMODULATION** The alteration of nerve activity through the delivery of electrical stimulation or chemical agents to targeted sites of the body.

## IBISWorld Glossary

**BARRIERS TO ENTRY** High barriers to entry mean that new companies struggle to enter an industry, while low barriers mean it is easy for new companies to enter an industry.

**CAPITAL INTENSITY** Compares the amount of money spent on capital (plant, machinery and equipment) with that spent on labor. IBISWorld uses the ratio of depreciation to wages as a proxy for capital intensity. High capital intensity is more than \$0.333 of capital to \$1 of labor; medium is \$0.125 to \$0.333 of capital to \$1 of labor; low is less than \$0.125 of capital for every \$1 of labor.

**CONSTANT PRICES** The dollar figures in the Key Statistics table, including forecasts, are adjusted for inflation using the current year (i.e. year published) as the base year. This removes the impact of changes in the purchasing power of the dollar, leaving only the "real" growth or decline in industry metrics. The inflation adjustments in IBISWorld's reports are made using the US Bureau of Economic Analysis' implicit GDP price deflator.

**DOMESTIC DEMAND** Spending on industry goods and services within the United States, regardless of their country of origin. It is derived by adding imports to industry revenue, and then subtracting exports.

**EMPLOYMENT** The number of permanent, part-time, temporary and seasonal employees, working proprietors, partners, managers and executives within the industry.

**ENTERPRISE** A division that is separately managed and keeps management accounts. Each enterprise consists of one or more establishments that are under common ownership or control.

**ESTABLISHMENT** The smallest type of accounting unit within an enterprise, an establishment is a single physical location where business is conducted or where services or industrial operations are performed. Multiple establishments under common control make up an enterprise.

**EXPORTS** Total value of industry goods and services sold by US companies to customers abroad.

**IMPORTS** Total value of industry goods and services brought in from foreign countries to be sold in the United States.

**INDUSTRY CONCENTRATION** An indicator of the dominance of the top four players in an industry. Concentration is considered high if the top players account for more than 70 % of industry revenue. Medium is 40 % to 70 % of industry revenue. Low is less than 40 %.

**INDUSTRY REVENUE** The total sales of industry goods and services (exclusive of excise and sales tax); subsidies on production; all other operating income from outside the firm (such as commission income, repair and service income, and rent, leasing and hiring income); and capital work done by rental or lease. Receipts from interest royalties, dividends and the sale of fixed tangible assets are excluded.

**INDUSTRY VALUE ADDED (IVA)** The market value of goods and services produced by the industry minus the cost of goods and services used in production. IVA is also described as the industry's contribution to GDP, or profit plus wages and depreciation.

**INTERNATIONAL TRADE** The level of international trade is determined by ratios of exports to revenue and imports to domestic demand. For exports/revenue: low is less than 5 %, medium is 5 % to 20 %, and high is more than 20 %. Imports/domestic demand: low is less than 5 %, medium is 5 % to 35 %, and high is more than 35 %.

**LIFE CYCLE** All industries go through periods of growth, maturity and decline. IBISWorld determines an industry's life cycle by considering its growth rate (measured by IVA) compared with GDP; the growth rate of the number of establishments; the amount of change the industry's products are undergoing; the rate of technological change; and the level of customer acceptance of industry products and services.

**NONEMPLOYING ESTABLISHMENT** Businesses with no paid employment or payroll, also known as nonemployers. These are mostly set up by self-employed individuals.

**PROFIT** IBISWorld uses earnings before interest and tax (EBIT) as an indicator of a company's profitability. It is calculated as revenue minus expenses, excluding interest and tax.

# Jargon & Glossary

## IBISWorld Glossary continued

**VOLATILITY** The level of volatility is determined by averaging the absolute change in revenue in each of the past five years. Volatility levels: very high is more than  $\pm 20\%$ ; high volatility is  $\pm 10\%$  to  $\pm 20\%$ ; moderate volatility is  $\pm 3\%$  to  $\pm 10\%$ ; and low volatility is less than  $\pm 3\%$ .

**WAGES** The gross total wages and salaries of all employees in the industry. The cost of benefits is also included in this figure.

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