

North America Medical Equipment Sectors

A Company and Industry Analysis

September 2012

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Current Environment – Key Points

- The US medical device industry showed signs of improvement over the last six months, although European debt concerns still weighed on revenue growth as the industry faced challenges with consumers postponing elective surgery.
- However, the recession did little to deter hospitals and other customers from purchasing medical devices, and the predictable economic upturn helped the industry to rebound somewhat.
- In the seven months to July 31, 2012, the share prices of Medtronic (NYSE: MDT), Baxter International (NYSE: BAX), Stryker (NYSE: SYK), Becton Dickinson & Co (NYSE: BDX) and Boston Scientific (NYSE: BSX) advanced by an average of 3.54%, from an increase of 0.78% in the same period in 2011.
- The level of product recalls rose, with Stericycle ExpertRECALL, an industry leader in managing consumer products, pharmaceutical, medical device, juvenile product and food and beverage recalls, reporting that more than 123 million medical devices were recalled in the second quarter of 2012.
- There was a pick-up in medical device merger and acquisition (M&A) activity, as cash-rich, big medical device manufacturers stepped up acquisitions of young companies with promising technology pipelines.

Industry Profile – Key Points

- The US medical device market has seen good growth since the global financial crisis hit in 2008, thanks to a rise in national healthcare expenditure, new regulatory requirements to ensure product safety and effectiveness, and changes in insurance coverage.
- Imports of medical devices account for about one quarter of the US market and the value of imported devices grew by 4.08% to US\$15.71 billion in the first half of 2012.
- Bureau of Economic Analysis (BEA) data shows the US imported US\$2.55 billion worth of medical devices in June 2012.
- On July 10, 2012, the US Food and Drug Administration (FDA) proposed that most medical devices distributed in the US carry a unique device identifier.
- Medical/health products, which includes monitoring equipment and handicap aids, saw a 111% increase in funding to US\$137 million, from US\$64.93 million in the second quarter of 2011.

Market Trends and Outlook – Key Points

- The patient monitoring device sector in the US is growing rapidly, driven by the ageing of the US population, mounting healthcare costs, and an acute shortage of healthcare practitioners in most hospitals.
- Economic uncertainty and a government focus on trimming healthcare costs will continue to boost reprocessing growth, as will the ageing population and mounting incidence of diseases that can be treated with medical devices.
- The growth prospects for Canada's medical device industry remain bright and are still highest among developed countries, despite the global financial crisis.
- Further healthcare reforms, high levels of government funding for healthcare, a high penetration level of medical insurance products and rebounding disposable income are expected to raise demand for quality healthcare services, boosting demand for medical devices.



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Current Environment

United States



Sector Overview

The US medical device industry showed signs of improvement over the last six months, although European debt concerns still weighed on revenue growth as the industry faced challenges with consumers postponing elective surgery. However, the recession did little to deter hospitals and other customers from purchasing medical devices, and the predictable economic upturn helped the industry to rebound somewhat.

During the seven months to July 31, 2012, the share prices of Medtronic (NYSE: MDT), Baxter International (NYSE: BAX), Stryker (NYSE: SYK), Becton Dickinson & Co (NYSE: BDX) and Boston Scientific (NYSE: BSX) improved by an average of 3.54%, compared with an increase of 0.78% in the corresponding period in 2011. The share prices of four out of the five companies examined rose. The industry continued to be one of the most vital and dynamic sectors in the US and a leading force in the revolution that is changing the healthcare system. Medical device makers continued to focus on the ageing population, while the influx of newly insured people due to healthcare reform drove demand for devices.

There were some hitches over the period, including widespread product recalls. During the second quarter of 2012, more than 123 million medical devices, including knee replacement devices, syringes, gels used in ultrasound procedures, dental implants and products used in heart surgery, were recalled, according to Stericycle ExpertRECALL, an industry leader in managing consumer products, pharmaceutical, medical device, juvenile product and food and beverage recalls. The number of products affected reached an eight-quarter high, above 100 million for the first time since the third quarter of 2010.

Among the companies affected by the recalls was Californian-based global medical technology corporation CareFusion Corp (NYSE: CFN). In June 2012, it recalled its EnVe ventilators, after it was found they could potentially compromise patient ventilation. This followed a voluntary recall of its AirLife infant breathing circuit in May.

Sector Performance

The medical device industry performed well in the first seven months of 2012. The iShares Dow Jones US Medical Devices Index Fund gained 4.64%, or 2.77 points, from 59.74 to 62.51. The fund measures the performance of the medical equipment sector of the US equity market, and includes medical equipment companies, such as manufacturers and distributors of medical devices, including magnetic resonance imaging (MRI) scanners, prosthetics, pacemakers, x-ray machines, and other non-disposable medical devices. From January 1, 2012 to July 31, 2012, the Dow Jones Industrial Average rose by 4.93%, or 611.3 points, to 13,008.68. In the same period of 2011, the index increased by 4.05%, from 11,670.75 to 12,143.24. The broader S&P 500 Index gained 8%, or 102.26 points, from 1,277.06 to 1,379.32, while in the comparable 2011 period it increased by 1.6% to 1,292.28.

Baxter International's shares were the biggest gainers in the first seven months of 2012, with its price up 15.77%, compared with an increase of 15.07% a year earlier. This was attributed mainly to the company's solid end-market demand, which posted robust growth in conjunction with flattering pricing patterns. Baxter International generated US\$1.2 billion profit, or US\$2.24 per share, in the first six months of 2012, or 9% EPS growth. Baxter International

Table 1: Performances of Key Medical Device Indices, 2011-2012

Index	2012			2011		
	January 3, 2012	July 31, 2012	Percentage Change (%)	January 3, 2011	July 29, 2011	Percentage Change (%)
Dow Jones Industrial Average	12,397.38	13,008.68	4.93%	11,670.75	12,143.24	4.05%
Standard & Poor's 500	1,277.06	1,379.32	8%	1,271.89	1,292.28	1.6%
Dow Jones US Medical Device Index	59.74	62.51	4.64%	59.73	64.76	8.42%

Source: Mergent analysis

Current Environment - United States

Table 2: Closing Price for Leading Medical Device Companies, January 1 to July 31, 2012

Company	January 3, 2012	July 31, 2012	Percentage Change (%)	Highest Closing Price	Lowest Closing Price
Medtronic	US\$38.69	US\$39.42	1.89%	US\$40.65	US\$36.18
Baxter International	US\$50.54	US\$58.51	15.77%	US\$60.27	US\$49.03
Stryker	US\$51.07	US\$52.03	1.88%	US\$55.67	US\$49.84
Becton Dickinson & Co	US\$74.45	US\$75.71	1.69%	US\$80.53	US\$72.18
Boston Scientific	US\$5.36	US\$5.17	-3.54%	US\$6.36	US\$4.97

Source: Mergent analysis

is one of the few companies that has potential to buck the industry trend in view of its attractive end-market exposure. In the seven months under review, shares traded between a low of US\$49.03 and a high of US\$60.27, and closed at US\$58.51, 19.34% above the low.

The share price of Medtronic also improved, by 1.89%, compared with a drop of 3.64% in the corresponding period the previous year, thanks to its steady sales growth and cost reduction, which improved margin and profitability. Medtronic is a growth medical technology company with diversified products and has grown in the 7-9% range for the past five years. Poor sales in 2011 turned around in the first half of 2012, bringing revenue growth of 6.57%, mainly due to international sales, which grew 6.79%. Continuous investment in R&D enabled the company to introduce several new products. In the period under review, Medtronic's shares traded between a low of US\$36.18 and a high of US\$40.65, and closed at US\$39.42, 8.96%.

The share prices of Stryker and Becton Dickinson & Co also increased, by 1.88% and 1.69%, respectively, compared with 0.44% and 1.32%, in the same period of 2011. Boston Scientific, however, saw its share price dropped 3.54% from US\$5.36 to US\$5.17, as a sluggish global market for implantable heart devices sent its shares to their lowest price since the mid-1990s. Its shares traded between a low of US\$4.97 and a high of US\$6.36, and closed at US\$5.17, 4.02% above the low.

Leading Companies

Medtronic Inc (NYSE: MDT)

Minneapolis-based Medtronic Inc is a global leader in medical technology, alleviating pain, restoring health and extending life for people with chronic diseases. In the

fourth quarter of fiscal 2012, net earnings grew by 27.71% to US\$991 million, or US\$0.85 per diluted share, compared with US\$776 million, or US\$0.71 per diluted share a year earlier, while net sales rose by 3.12% to US\$4.3 billion, from US\$4.17 billion. The company's growth was broad-based across businesses and geographies, including strong US launches of the Resolute Integrity drug-eluting stent and RestoreSensor spinal cord stimulator, and strong growth in emerging markets.

Cardiac and vascular segment revenue grew by 2.69% to US\$2.25 billion, from US\$2.19 billion a year earlier, thanks to sales growth of coronary, transcatheter valves, endovascular, atrial fibrillation (AF) solutions, renal denervation and peripheral equipment, partially offset by small declines in pacing and implantable cardioverter defibrillators (ICDs). Cardiac rhythm disease management (CRDM) revenue fell by 1.52% to US\$1.26 billion in the quarter ended April 27, 2012, compared with US\$1.32 billion in the same quarter of 2011. Restorative therapies revenues were up by 3.6% to US\$2.04 billion, from US\$1.97 billion a year earlier, driven by solid performances in surgical technologies, neuromodulation and diabetes equipment, partially offset by declines in spinal devices.

Baxter International Inc (NYSE: BAX)

Baxter International Inc, headquartered in Deerfield, Illinois, is a diversified medical products and services company. In the first quarter of 2012, its net income rose by 7.48% to US\$661 million, or US\$1.19 per diluted share, from US\$615 million, or US\$1.07 per diluted share, in the corresponding quarter of 2011. Net sales rose by 1.02% to US\$3.57 billion, from US\$3.54 billion, primarily driven by improved volumes. Sales within the US grew by 5.99% to US\$1.5 billion, from US\$1.42, while international sales dropped by 2.36% to US\$2.07 billion, from US\$2.12 billion.

Current Environment - United States

BioScience revenues totaled US\$1.57 billion, an increase of 0.84% from US\$1.55 billion in the second quarter ended June 30, 2011. Driving this performance was the improved demand, particularly in the US, for Advate, an anti-hemophilic drug, for the treatment of hemophilia, and strong growth in select specialty plasma-based therapeutics and the company's portfolio of surgical sealants. Also contributing was the benefit of the Minnesota-based Synovis Life Technologies Inc (NASDAQ: SYNO) acquisition, completed during the first quarter of 2012. Synovis is a worldwide leader in developing, manufacturing and marketing innovative surgical tools and implantable biomaterials.

Medical product sales totaled US\$2.01 billion, an increase of 1.16% from US\$1.98 billion in the same quarter of 2011, driven primarily by solid gains in the number of peritoneal dialysis patients, growth of certain injectable and nutritional therapies, and the impact from the company's acquisition of Baxa Corp. Baxter International completed its acquisition of Baxa on November 2011, a privately held global company based in Englewood, Colorado, for a cash consideration of US\$380 million.

Stryker Corp (NYSE: SYK)

Michigan-based Stryker Corp manufactures orthopedic implants used in joint replacement, trauma, spinal and craniomaxillofacial surgeries. Its net earnings improved by 4.84% to US\$325 million, or US\$0.85 per diluted share, in the second quarter of 2012, compared with US\$310 million, or US\$0.79 per diluted share, in the corresponding quarter of 2011. Net sales increased by 2.93% to US\$2.11 billion, from US\$2.05 billion a year earlier. Sales grew by 4.4% due to increased unit volume and changes in product mix and by 2.2% because of acquisitions, but were partially offset by unfavorable impacts of 1.6% due to changes in price and 2% from foreign currency exchange rates.

Sales from its reconstructive segment increased by 1.2% to US\$927 million, from US\$916 million in the same quarter of 2011, with a 4% rise due to increased unit volume and changes in product mix and 1.9% because of acquisitions, partially offset by unfavorable impacts of 2.4% from price changes and a 2.3% from foreign currency exchange. MedSurg segment sales were up 1.68% to US\$786 million, from US\$773 million, with a 3% rise due to increased unit volume and changes in product mix and 0.3% because of acquisitions. These were partially offset by unfavorable impacts of 0.1% from price

changes and 1.6% from foreign currency exchange rates. Neurotechnology and spine segment sales rose by 10.08% to US\$393 million, from US\$357 million, with an 8.2% rise due to increased unit volume and changes in product mix and 7.2% because of acquisitions, partially offset by an unfavorable impact of 3% from price changes and 2.2% from foreign currency exchange rates.

Becton Dickinson & Co (NYSE: BDX)

Becton Dickinson and Co, based in Franklin Lakes, New Jersey, is a global medical technology company that develops, manufactures and sells medical devices, instrument systems and reagents used by healthcare institutions, life science researchers, clinical laboratories, the pharmaceutical industry and the general public. Its net income dropped 6.73% to US\$291.03 million, or US\$1.38 per diluted share, in the second quarter of fiscal 2012, compared with US\$312.02 million, or US\$1.68 per diluted share, a year earlier. With all three segments — medical, diagnostics and biosciences — contributing to growth, revenues were up 3.58% to US\$1.99 billion, from US\$1.92 billion in the corresponding quarter of fiscal 2011.

Medical segment revenues grew by 4.06% to US\$1.02 billion, from US\$981.33 million in the same quarter of fiscal 2011, reflecting strong pharmaceutical systems and diabetes care unit sales, and solid sales by the medical surgical systems unit. Diagnostics segment sales rose by 4.08% to US\$630.02 million, from US\$605.35 million a year earlier, primarily driven by strong sales by the pre-analytical systems unit and solid growth in women's health and cancer segments. Biosciences segment revenue increased by 1.27% to US\$339.61 million, from US\$335.34 million, primarily due to clinical reagent sales by the cell analysis unit and strong emerging market sales as overall segment growth continued to be negatively affected by weakness in the US research market.

Boston Scientific Corp (NYSE: BSX)

Boston Scientific Corp, headquartered in Natick, Massachusetts, develops, manufactures and markets medical devices used in a range of interventional medical specialties, including cardiac rhythm management, electrophysiology, interventional cardiology, peripheral interventions, neurovascular, endoscopy, urology, women's health and neuromodulation. In the second quarter of 2012, its net loss totaled US\$3.4 billion, or US\$2.39 per diluted

Current Environment - United States

share, compared with a net income of US\$146 million, or US\$0.10 per diluted share, in the same period of 2011, due to impairment charges tied to weaker European growth outlook, although margins improved on lower costs. Net sales fell by 7.44% to US\$1.83 billion, from US\$1.98 billion a year earlier, amid pressure on top heart-device markets.

The company saw double-digit sales declines in both its interventional-cardiology business, which includes stents, and its heart-rhythm unit. Interventional cardiology sales accounted for 30.03% of net sales and totaled US\$549 million in the second quarter of 2012, a decrease of 15.8%, from US\$652 million in the corresponding quarter of 2011. The business for drug-coated stents — tiny tubes that prop open-heart arteries and use medication to ward off scar-tissue growth — faced challenges from sliding prices and tough competition. Cardiac rhythm management (CRM) sales accounted for 26.7% of net sales and totaled US\$488 million, down 10.29% from US\$544 million in the equivalent quarter of 2011.

St Jude Medical Inc (NYSE: STJ)

St June Medical Inc, headquartered in Little Canada, Minnesota, focused on the development, manufacture and distribution of cardiovascular medical devices for the global cardiac rhythm management, cardiology, cardiac surgery and atrial fibrillation therapy areas and implantable neurostimulation medical devices for the management of chronic pain. The company's net profit increased by 1.66% to US\$244 million, compared with US\$241 million in the same quarter of 2011. Net earnings in the second quarter of 2012 were negatively impacted by after-tax special charges of US\$27 million, primarily related to ongoing restructuring charges to realign certain activities in our CRM business and our sales and selling support organizations. Its net sales went by 2.49% to US\$1.41 billion in the second quarter of 2012, compared with the US\$1.45 billion in the equivalent quarter of 2011. Foreign currency translation had an unfavorable impact of US\$47 million of the second quarter net sales, primarily due to the strengthening of the greenback against the euro.

Net sales in CRM dropped 5.8% to US\$746 million, compared with US\$792 million in the same period a year ago. Net sales ICD dropped 3.8% to US\$459 million, compared with US\$477 million in 2011, primarily driven by a decline in the US market, which the company estimate contracted at a mid single-digit percentage rate from the

first quarter of 2011. The US ICD market continues to be negatively impacted by a decline in implant volumes and pricing resulting from the publication of an ICD utilization article in January 2011 in the Journal of the American Medical Association, subsequent hospital investigation by the US Department of Justice and a significant increase in hospital ownership of physician practices.

Net sales in cardiovascular fell by 0.6% to US\$340 million in the second quarter of 2012, from US\$342 million in the same periods one year ago. Net sales in vascular products went down by 4.8% to US\$180 million, compared with US\$189 million in the same periods in 2011, primarily due to the termination of a distribution contract in Japan.

Merger, Acquisition and Alliance Activity

The pick-up in the level of medical device merger and acquisition (M&A) activity continued in 2012. Most leading medical device players came through the financial crisis and recession with strong balance sheets and large cash reserves available for acquisitions. Cash-rich, big medical device manufacturers on the lookout for growth stepped up acquisitions of young companies with promising technology pipelines but lacking capital, while stock prices were depressed, making valuations attractive to device makers seeking to supplement their growth.

Boston Scientific Corp made two deals in the first eight months of 2012, acquiring California-based Cameron Health Inc, on June 8, hoping that Cameron Health's alternative to traditional defibrillators can boost sales. Cameron Health developed the world's first and only commercially available completely subcutaneous ICD (S-ICD System), an investigational device and limited under US law to investigational use only, which is not available for sale in the US. However, Boston Scientific expects The US Food and Drug Administration (FDA) approval in the first half of 2013. Approval will provide physicians and their patients with an option to choose either the industry's thinnest, longest-lasting transvenous ICD or the world's first and only commercially available completely S-ICD System.

Boston Scientific paid US\$150 million at closing, with an additional potential payment of US\$150 million upon FDA approval of the S-ICD System and up to an additional US\$1.05 billion of probable payments on the accomplishment of specified revenue-based criterion over a six-year period following FDA approval.

Current Environment - United States

The combination of Boston Scientific's already strong arrhythmia management product portfolio and commercial capabilities and Cameron Health's breakthrough technology are likely to help to unlock the massive potential of the S-ICD System. Equally exciting is the promise of next-generation subcutaneous technology that is likely to continue to expand the reach of ICD therapy to more patients.

Following the approval of the transaction by World Heart stockholders, HeartWare International Inc (NASDAQ: HTWR), a leading innovator of less invasive, miniaturized circulatory support technologies that are revolutionizing the treatment of advanced heart failure, acquired Utah-based World Heart Corp (NASDAQ: WHRT) on August 6, 2012. World Heart Corp designs mechanical circulatory support devices that assist failing hearts to pump blood.

HeartWare acquired all of the outstanding voting securities of World Heart for approximately US\$8 million in HeartWare common stock, with each World Heart share converted into the right to receive 0.003 shares of HeartWare common stock.

Current Environment

Canada



Sector Overview

Along with a broader recovery of the global economy, Canada's medical device industry remained buoyant over the last six months, with most leading companies seeing improvements in device sales in the first half of 2012. The level of alliance and M&A activity also continued to pick up as the year progressed, with many medical device firms combating slow domestic growth via penetration into foreign markets.

The sector was also buoyed by government initiatives. Seeking to create jobs, economic growth and long-term prosperity the Canadian Government invested in medical device R&D to support medical technologies that create new economic opportunities and employment while improving patient care for countless individuals. On August 17, the Government invested C\$900,000 to help Southmedic Inc, a vertically integrated custom manufacturing facility, which specializes in cleanroom injection molding of medical components, automate a major phase of its medical device production, such as the OxyMask line.

This was part of government plans to help Southern Ontario businesses become more innovative, productive and competitive in the global market, and is likely to produce 18 new jobs in Barrie, Southern Ontario. The investment is through the Federal Economic Development Agency for Southern Ontario's Prosperity Initiative, which support businesses, non-profit organizations and post-secondary institutions in developing projects that will result in a more productive, diversified and competitive economy.

Despite these efforts, the sector saw fewer new product license applications. Most medical devices sold in Canada require a license, and these devices are regulated by Health Canada's Therapeutic Products Directorate and are subject to the Medical Devices Regulations under the FDA. These medical devices are categorized as Class I, II, III, or IV, by Health Canada, based on the risks associated with their use, including the degree of invasiveness, duration of contact with the patient, energy transmission hazard, and consequences of device malfunction or failure. A medical device license (MDL) is required for manufacturers of Class II, III, and IV medical devices in Canada.

The MEDEC, the national association created by and for the Canadian medical technology industry, estimates the number of MDL and amendment applications to Health Canada's Medical Devices Bureau (MDB) dropped over the first three months of 2012. In the first quarter of 2012, Health Canada received 1,180 applications, 12% fewer than in the fourth quarter of 2011, and 15% lower than in the previous four quarters. In addition, market authorization timeframes also rose on the Medical Devices Bureau (MDB)'s side. Although Health Canada has made some development in terms of reviewing high-risk device applications, manufacturers of Class II and III devices still faced significant market approval delays when it comes to medical device registration in Canada.

Sector Performance

Despite broader market challenges, the global share market continued to stabilize, leading to a rise in the stock prices of key listed medical devices companies. Leading medical device companies reported favorable financial results over the seven months to July 31, 2012. The top four companies — Imris (TSX: IM), Prism Medical (TVX: PM), Novadaq Technologies (TSX: NDQ) and Unilens Vision (TVX: UVI) — saw their share prices improve by an average of 29.2%, compared with an average drop of 0.48% in the same period a year earlier. Three out of four companies had double-digit share price increases.

Novadaq Technologies' shares were the biggest gainers, growing by 61.8%, compared with an increase of 23.64% in the corresponding period in 2011, thanks to a good performance in the first two quarters of 2012. Novadaq Technologies saw increased adoption of breast reconstruction and partial nephrectomy, giving it an 18% sequential increase in recurring revenues in the second quarter of 2012. Breast reconstruction is a surgery to rebuild a breast's shape after a mastectomy, while partial nephrectomy is a surgery to remove only the diseased part of your kidney while sparing the healthy, functioning kidney tissue. Concurrently, there was a greater focus on its Pinpoint endoscopic fluorescence imaging system. In the seven months under review, its shares traded between a low of C\$4.80 (US\$4.87) and a high of US\$8.13 (US\$8.24), and closed at C\$8.09 (US\$8.2), 68.54% above the low.

Current Environment - Canada

Table 3: Closing Price for Leading Medical Device Companies, January 1 to July 31, 2012

Company	January 3, 2012	July 31, 2012	Percentage Change (%)	Highest Closing Price	Lowest Closing Price
Prism Medical	C\$4.90 (US\$4.97)	C\$6.15 (US\$6.23)	25.51%	C\$6.50 (US\$6.59)	C\$4.90 (US\$4.97)
Imris	C\$2.80 (US\$2.84)	C\$3.56 (US\$3.61)	27.14%	C\$3.80 (US\$3.85)	C\$2.30 (US\$2.33)
Novadaq Technologies	C\$5 (US\$5.07)	C\$8.09 (US\$8.20)	61.8%	C\$8.13 (US\$8.25)	C\$4.80 (US\$4.87)
Unilens Vision	C\$3 (US\$3.04)	C\$3.07 (US\$3.11)	2.33%	C\$3.08 (US\$3.12)	C\$2.66 (US\$2.70)

Source: Mergent analysis

Imris' share price grew 27.14%, compared with a drop of 5% a year earlier, thanks to its optimistic outlook. Imris received orders for three Visius Surgical Theatres in the second quarter of 2012, continuing the first quarter trend, bringing total first half system orders to six. Imris believes that the year-over-year trend of increasing bookings is likely to continue, driven by the underlying clinical demand for Visius Surgical Theatres. Its priorities remain a focused drive to maximize bookings, targeted marketing programs and increased investment to bring the company's image guided surgical robot to market. In the seven months, Imris' shares traded between a low of C\$2.30 and a high of US\$3.80, and closed at US\$3.56, 54.78% above the low.

The share price of Prism Medical rose by 25.51%, and of Unilens Vision by 2.33%, in the first seven months of 2012. In the same period in 2011, the share price of Prism Medical increased by 23.64%, while that of Unilens Vision dropped by 27.54%.

Leading Companies

Prism Medical Ltd (TVX: PM)

Toronto-based Prism Medical Ltd provides durable medical equipment and related services to the mobility disadvantaged in Canada, the US and the UK. In the second quarter of 2012, its net income rose by 24.56% to C\$1.54 million (US\$1.56 million), or C\$0.18 (US\$0.18) per diluted share, from C\$1.14 million (US\$1.16 million), or C\$0.16 (US\$0.16) per diluted share in the corresponding quarter of 2011, thanks to strong Canadian sales and recent bundled contract wins in the UK. Its revenues grew by

16.49% to C\$21.91 million (US\$22.22 million), from C\$18.81 million (US\$19.07 million) a year earlier.

Its UK revenues were up 12.79% to C\$11.18 million (US\$11.33 million), from C\$9.91 million (US\$10.05 million) in the same period of 2011. Its revenues were boosted by the Leonard Cheshire contract and the acquisition of Movement 2 Ltd, a provider of home care patient moving and handling equipment, servicing and repair in the East Midlands region of the UK. Its Canadian revenues picked up 71.14% to C\$6.24 million (US\$6.32 million), from C\$3.65 million (US\$3.7 million), due to the continuation of strong institutional demand for the company's products to replace end-of-life products. In addition, new institutional facilities were built in several provinces and the company continued to penetrate the Quebec market. Its US revenue fell by 14.47% to C\$4.49 million (US\$4.55 million), from C\$5.25 million (US\$5.32 million) a year earlier, due to timing delays in several institutional projects.

Imris Inc (TSX: IM)

Imris Inc, based in Winnipeg, Manitoba, is a global leader in fully integrated, intraoperative imaging systems, and neuroscience centers. In the second quarter of 2012, its net loss widened to US\$4.28 million, or US\$0.09 per diluted share, compared with a net loss of US\$2.87 million, or US\$0.06 per diluted share, in the equivalent quarter of 2011. This reflected year-over-year increases in operating losses, driven primarily by lower revenue, lower gross profit and higher operating expenses. Sales dropped by 8.72% to US\$17.24 million in the third quarter of 2012, from US\$18.88 million a year earlier. Delivery activities

Current Environment - Canada

were consistent with prior periods but a change in product mix resulted in a US\$2 million decrease in Visius Surgical Theatre revenue compared with the previous quarter.

Its revenues in North America surged 106.63% to US\$12.31 million, from US\$5.96 million in the equivalent quarter of 2011, due to increased Visius system and installation activity in the US, offset by a drop in installations and revenues from the Asia-Pacific, where its revenue dropped 50.27% to US\$4.85 million, from US\$9.76 million a year earlier.

Its gross profit was up 5.33% to US\$6.66 million, from US\$6.32 million in the second quarter of 2011, thanks to the delivery of certain equipment as part of a collaborative arrangement in the previous year. Operating expenses rose by 14% to US\$10.73 million, from US\$9.41 million, due primarily to the planned increase in R&D costs for robotics, MR-guided radiation therapy and other ancillary research projects, and increased recruiting costs. These were partially offset by lower costs for marketing and promotion because of overall efforts to manage costs.

Novadaq Technologies Inc (TSX: NDQ)

Ontario-based Novadaq Technologies Inc develops clinically relevant fluorescence imaging solutions for use in surgical procedures. Its net loss narrowed to US\$1.4 million, or US\$0.04 per share, in the second quarter of 2012, from a net loss of US\$4.39 million, or US\$0.13 per share, in the corresponding quarter of 2011. The loss was reduced by a lower non-cash shareholder warrant revaluation expense to US\$2.3 million, a US\$1.11 million increase in gross profit, and a US\$10,000 rise in finance income, offset by a US\$422,000 rise in operating costs. Its revenue rose by 47.93% to US\$5.39 million, from US\$3.65 million a year earlier, driven by continued adoption of Spy Elite and Firefly procedures and higher Spy Elite and Firefly system sales.

Its gross profit increased by 50.46% to US\$3.3 million, from US\$2.2 million, mainly due to increased sales from alliances with LifeCell Corp and Intuitive Surgical Inc, while increasing Spy product sales continued to produce higher margins. R&D expenses increased by 8.5% to US\$1.38 million, from US\$1.27 a year earlier, due to a US\$239,000 rise in salaries and fringe benefits to support expanded operations. The higher expenses also included a US\$50,000 no-cash stock option cost, US\$33,000 higher office expenses, US\$128,000 higher patent and trademark

costs, and US\$44,000 higher clinical trial costs, offset by US\$381,000 lower product design costs, due to completion of the Spy Elite design and US\$5,000 lower miscellaneous costs.

Unilens Vision Inc (TVX: UVI)

Unilens Vision, based in Vancouver, British Columbia, licenses, manufactures, distributes and markets specialty optical lens products using its proprietary design and manufacturing technology. For the third quarter of fiscal 2012, its net income increased by 1.1% to US\$30,055, from US\$296,792 in the corresponding quarter of fiscal 2011. Its revenue improved by 2.35% to US\$2.22 million, from US\$2.17 million in the same period a year earlier, helped by increases in custom soft lens sales.

Disposable lens sales were down by 4.26% to US\$885,110, from US\$924,457 a year earlier, as sales of its C-Vue disposable multifocal lenses continued to be affected by economic conditions in the US and competition from competitor product offerings and promotional programs. Custom soft lens sales increased by 26.2% to US\$442,078, from US\$350,287 in the same period in 2011, primarily due to increased demand for its new C-Vue Advanced HydraVUE line of silicone hydrogel custom contact lenses for monthly replacement, launched in January 2011.

Sales of gas permeable lenses fell by 4.55% to US\$100,177, from US\$104,955, primarily due to the continued overall decline in gas permeable fits in the contact lens industry. Replacement and other lens sales decreased by 0.18% to US\$159,576, from US\$159,856, due to the expected decline in product lines that are nearing the end of their life cycle.

Imaging Dynamics Co Ltd (TVX: IDL)

Imaging Dynamics Co Ltd, based in Calgary, Alberta, is a medical technology company that has been an innovative force in the fast-growing field of digital radiography (DR) equipment. In the second quarter of fiscal 2012, the company reported a net profit of C\$ 239,813 (US\$242,258), compared with a net loss of C\$437,512 (US\$443,637) in the corresponding quarter of fiscal 2011. Its revenue, however, fell 66.64% to US\$677,834, from US\$2 million in the same period a year earlier, mainly driven by lower than expected sales from Asia-Pacific and Latin American regions. Its revenues from the US remained stagnant and

Current Environment - Canada

most of the capital equipment purchases are still being put on hold or deferred.

In the second quarter of 2012, revenue from Asia-Pacific fell by 73.39% to C\$254,957, compared with C\$957,951 in the corresponding quarter in 2011. Its revenue from Latin America dropped by 72.22% to C\$108,854 (US\$110,378), compared with C\$391,791 (US\$397,276) in the second quarter of 2011.

Its gross profit totaled C\$209,619 (US\$212,554) in the second quarter of 2012, down 59.46% from C\$517,070 (US\$524,309) in the same quarter last year. The decline was driven by decrease in revenues from emerging markets due to working capital constraints. Its gross margins were 31% for the quarter, compared with 26% for the same quarter last year, largely due to lower margin sales into the Asia-Pacific region.

Merger, Acquisition and Alliance Activity

Despite continued macro-economic uncertainty, Canadian medical device companies were quite active in the first half of 2012, fighting slow domestic growth by making acquisitions or alliances abroad.

On March 21, ZoomMed Inc (TVX: ZMD) announced that its wholly owned subsidiary ZoomMed USA had formed a strategic alliance with New York-based Smart eCharts, a healthcare service provider, which develops and offers web-based electronic medical records (EMR) to US healthcare professionals. Under the agreement, ZoomMed's web-based e-prescribing platform ZRx Prescriber will be interfaced with its new partner's solutions, allowing them to converse and swap information between their respective platforms, to generate, aggregate and convey electronic prescriptions to pharmacies via Surescripts Nation's E-Prescription Network. By interfacing their individual solutions, Smart eCharts will complement its offering and ZoomMed will obtain privileged access to another important network of healthcare providers and institutions.

During the same month, ZoomMed USA formed a similar strategic alliance agreement with US-based Insurance Data Services Inc (IDS), which provides medical billing solutions to US healthcare professionals, which are used to bill more than 100,000 patients a month in 15 states.

Industry Profile

United States



Industry Size and Value

The US is the world's largest market, valued at an estimated US\$120.4 billion in 2012, equal to 39.1% of the global total, compared with US\$105.8 billion in 2011. Driven by national healthcare expenditure, which includes costs of new regulatory requirements to ensure product safety and effectiveness, and changes in insurance coverage, the US medical equipment market has seen good growth. The US spends a larger percentage of its GDP and more per capita on healthcare than any other country, with US\$339 per capita expenditure in 2011. Standard and Poor's (S&P) Industry Surveys showed that medical equipment is the second largest sub-industry within the healthcare sector, accounting for 15.3% of the S&P Healthcare Sector index in 2011.

The US medical equipment and supplies industry comprises 11,000 companies, including major firms such as Baxter International, Boston Scientific, Johnson & Johnson and Medtronic, the International Trade Administration (ITA), an agency of the US Department of Commerce, estimates. Of the world's 46 medical technology companies with more than US\$1 billion in annual revenue, 32 are based in the US. The segment is concentrated, with the 50 of largest companies accounting for about 60% of revenue.

The size of the domestic market provides significant mass for access and adoption of innovative products. The industry develops products in an estimated 90 distinct areas, including specific products such as pacemakers, heart defibrillators, MRI devices, ultrasonic scanning devices, computerized axial tomography (CAT) scanners and cardiographs. The industry is segmented into electro-medical devices, electrotherapeutic devices and irradiation equipment.

Imports and Exports

Imports account for about 25% of the US market and, in the first half of 2012, the value of imported devices grew by 4.08%, or US\$616 million to US\$15.71 billion, from US\$15.09 billion in first half of 2011, the Bureau of Economic Analysis (BEA) estimates. In June, the US imported US\$2.55 billion worth of medical devices, down by 3.22% from US\$2.64 billion in May, with leading sources including Mexico, Ireland, and China.

In the same period, the US exported US\$16.68 billion worth of medical devices, up 5.27% from US\$15.85 billion a year earlier, according to BEA data. June exports totaled US\$2.85 billion, up 2.29% from US\$2.79 billion in May. Exports represent about 20% of US production and their largest markets are Japan, the Netherlands and Canada.

US device manufacturers gain 40% to 50% of their revenues in foreign markets, with emerging markets, mainly China, experiencing faster growth as an increase in wealth is spurring demand for higher quality medical products. Greater demand by physicians for better and more accurate diagnostics and imaging to guide them on patient disease status and apposite disease management, whether surgical or pharmaceutical (or both), are driving the growth of the US medical device industry.

Sector Employment

More than 50% of global medical device companies are based in the US and employ more than 300,000 Americans directly and two million indirectly. The Bureau of Labor Statistics (BLS) estimates that the industry employed 305,640 people in May 2011, and forecast an increase to 359,500 by 2018. Of the May 2011 workforce, 165,280 worked in production, 42,150 in office and administrative support, and 20,370 in architecture and engineering, while the average annual salary for all occupations was US\$48,320, or US\$23.23 an hour.

Medical equipment repairers, also known as biomedical equipment technicians (BMET), repair a wide variety of electronic, electromechanical, and hydraulic equipment used in hospitals and health practitioners' offices. BLS data shows that in May 2011 there were 34,710 medical equipment repairers in the US, an increase of 5.25% from 32,980 in May 2010. Of these, 30.94%, or 10,470, held jobs in professional and commercial equipment and supplies wholesalers, with annual earnings of US\$47,120, or US\$22.66 an hour.

The remainder held jobs in electronic and precision equipment repair and maintenance, general medical and surgical hospitals, health and personal care stores, and consumer goods rental. The states with the highest

Industry Profile - United States

employment were California, 3,050, Florida, 2,950, Texas, 2,710, and Pennsylvania, 2,050. Medical equipment repairers earn an average US\$47,010 a year, or about US\$22.60 an hour, with the highest pay in Utah, US\$59,830, Arizona, US\$57,800, and Alaska, US\$55,390.

Greater demand for healthcare services and the use of increasingly complex medical equipment is likely to boost employment of medical equipment repairers by 31% from 2010 to 2020, exceeding the average for all occupations. Those with an associate's degree in biomedical equipment technology or engineering should have the best job opportunities.

Sector Investment

The National Venture Capital Association (NVCA) estimates investment in the medical devices and equipment sector slipped by 9.33% in dollar terms and 14.44% in the number of deals in the first six months of 2012, with US\$1.4 billion going into 160 deals, compared with US\$1.54 billion in 187 deals in the same period in 2011. Venture capitalists are being extra careful over the type of investments they are making in the device and diagnostic field due to the uncertainty over FDA approval processes. In the second quarter of 2012, medical device and equipment investment totaled US\$699.53 million in 84 deals, a monetary drop of 17.37%, and a drop in volume terms of 10.64%, from US\$846.59 million in 94 deals in the equivalent quarter of 2010. In the quarter, the sector ranked third overall in attracting investment in the US.

Only one medical device subsector showed an investment increase in the second quarter of 2012. Medical/health products, which includes monitoring equipment and handicap aids, saw a 111% increase in funding to US\$137 million, from US\$64.93 million in the second quarter of 2011. However, investment in diagnostics shrank by 44% to US\$54 million, from US\$96.43 million; and investment in therapeutic devices, comprising implants and surgical techs, fell by 26% to US\$508 million, from US\$686.49 million.

In the second quarter of 2012, early-stage funding fell by 10% to US\$274 million, from US\$304.44 million in a year earlier, while late-stage funding decreased by 22% to US\$426 million, from US\$546.15 million.

In the industry overall, venture capitalists injected US\$7.04 billion in 898 deals in the second quarter of 2012, down

12% in monetary terms and 15.04% numerically from US\$8 billion in 1,057 deals in the equivalent period in 2011.

Table 4: Total Medical Devices and Equipment Investment, Second Quarters 2011 and 2012

	Q2 2012	Q2 2011
Investment (in millions)	US\$699.53 million	US\$846.59 million
Number of Deals	84	94

Source: National Venture Capital Association

Policy and Regulatory Environment

In response to requirements in legislation passed by Congress with broad bipartisan support, the US Food and Drug Administration (FDA), on July 10, 2012, proposed that most medical devices distributed in the US carry a unique device identifier (UDI). UDIs carry two types of information — a unique numeric or alphanumeric code, or device identifier, which is specific to a device model, and a production identifier, which includes the current production information for the device, such as the lot or batch number, the serial number and/or expiration date.

The proposed rule would require that device packaging and labeling include a UDI in plain-text and in a form that uses automatic identification and data capture (AIDC) technology. Certain categories of devices, such as implantables and those intended for reprocess, would need UDIs imprinted upon them directly.

A UDI system can provide several benefits including:

- Allowing more precise reporting, reviewing and analyzing of adverse event reports, leading to faster corrective actions;
- Reducing medical errors by enabling healthcare practitioners and others to more quickly and accurately identify a device and obtain important information concerning the characteristics of the device;
- Providing consistent input of information about devices to electronic health records and clinical information systems;
- Providing more effective management of recalls through standardized identifiers;
- Providing a foundation for a secure global distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.

Industry Profile - United States

The FDA outlined and publicized the proposed regulation following four pilot programs and input from industry, healthcare professionals, hospitals, payers and patients. To curtail industry costs and expedite implementation, the regulation builds upon current standards and systems in use by some companies. The FDA is seeking comment on the proposal for 120 days from the date of publication, July 10.

Industry Profile

Canada



Industry Size and Value

Canada's medical devices industry offers significant economic opportunities through sustained market growth, economic diversification, employment expansion and global export markets. With more than 1,000 firms, the industry produces a wide range of diagnostic and therapeutic products. The best Canadian technology markets include disposable equipment and supplies, in-vitro diagnostics (IVD), electro-medical devices, and diagnostics imaging and homecare. The prime therapeutic applications markets are for cardiovascular and dental devices, both predominantly import-dependent.

Canadian medical device makers develop and produce high-demand products that use the latest innovations from other industries, such as biotechnology, advanced materials, microelectronics, telecommunications, software and informatics. The industry is concentrated in Ontario, Quebec and British Columbia, with more than 80% in Ontario and Quebec. Statistics Canada reports that about 90% of medical device facilities are Canadian-owned, unchanged since 2000. Foreign-owned facilities are usually larger, with 21% having 50 or more employees, compared with just 4% of locally owned facilities.

Despite the global financial slowdown since 2008, the medical devices industry continues to expand and Canada is in a good position to develop its medical device business. It profits from a sturdy economic environment, rooted in a robust banking system, and very favorable tax incentives for manufacturing and R&D, making it a competitive contender for companies interested in entering the North American market. Annual costs to establish and operate a medical device manufacturing facility are the lowest in the G7, with Canada having a 4.8% cost advantage over the US. With the adoption of innovative medical technologies, the industry is likely to maintain annual growth rates of between 5% and 6%, reaching C\$8.6 billion (US\$8.72 billion) by 2015. The Canada Trade Association estimates the medical market was worth US\$6.2 billion in 2011, making it one of the biggest in the world.

Imports and Exports

Much of it is supplied by imports, with more than half derived from the US. In 2011, imports totaled C\$4.74 billion

(US\$ billion), up 6.71% from C\$4.44 billion (US\$4.5 billion) in 2010, Statistics Canada estimates. The US is the top exporter, supplying 50.13% of all imports — C\$2.36 billion (US\$2.39 billion) worth in 2011, up 5.03% from C\$2.26 billion (US\$2.29 billion) a year earlier. China, the second largest exporter of medical equipment and supplies to Canada, accounted for 9.98%, or C\$472.95 million (US\$479.57 million), of total imports — 8.42% more than the C\$436.2 million (US\$442.31 million) in 2010. Mexico was the third largest exporter, with 5.55%, worth C\$262.97 million (US\$271.72 million), up by 19.95% from C\$219.23 million (US\$222.3 million) in 2010.

Statistics Canada estimates that exports of medical equipment and supplies in Canada totaled C\$940.89 million (US\$954.06 million) in 2011, up 5.15% from C\$894.8 million (US\$907.33 million) in 2010. The US remains by far the main market for Canadian exports, taking 68.46% of all devices exported in 2011, with their value increasing by 8.88% to C\$644.12 million (US\$653.14 million), from C\$591.6 million (US\$599.88 million) the previous year. The Netherlands took 4.34%, or C\$40.79 million (US\$41.36 million), of exports in 2011, down 12.88% from C\$46.82 million (US\$47.46 million) in 2010; followed by Germany 3.44%, or C\$32.38 million (US\$32.83 million), Italy, including Vatican City State, 3.01% or C\$28.34 million (US\$28.74 million), and the UK, 2.92%, or C\$27.47 million (US\$27.85 million).

Sector Employment

Statistics Canada estimates the medical device industry employed 19,603 people in 2011, up 6.24% from 18,452 in 2010. The number of production employees rose by 5.97%, from 13,207 in 2010 to 13,995, accounting for 71.4% of the total, while the number of administrative employees grew from 5,245 in 2010 to 5,608 in 2011, an increase of 6.92%, comprising 28.6% of the total.

The bulk of the industry is made up of small and mid-sized companies, although large companies provide 43% of industry employment, according to data published by MEDEC, the national association created by and for the Canadian medical technology industry. Of all the medical device firms in Canada, 57% have fewer than 25 employees,

Industry Profile - Canada

37% have 25-49, and about 4% are medium sized (50 to 150), while less than 1% have more than 150 employees.

Statistics Canada estimates that wages and salaries in 2011 totaled C\$867.9 million (US\$880.05 million), with 62.04%, or C\$538.5 million (US\$546.04 million), paid to production workers, and the remaining 37.96%, or C\$329.4 million (US\$ million), going to administrative staff, with an average annual salary of C\$44,273 (US\$334.01).

Policy and Regulatory Environment

Effective June 1, 2012, medical device industry companies in British Columbia, including manufacturers, importers, distributors and retailers, were subject to electronic equipment recycling regulations, which were promulgated in 2004. The regulations are enforced by the Electronic Products Recycling Association (EPRA), a non-profit entity tasked with improving the efficiency and the effectiveness of Canada's industry-led and regulated electronics stewardship programs. Health Canada-approved medical devices are subject to environmental handling fees (EHF) in British Columbia, and include radiological image processing systems, echocardiograph equipment, electronic sleep therapy products, incubators and defibrillators.

In order to comply, companies must either inform their customers of EHF or add the fees to the cost of their devices. Companies must specify EHF on their invoices or provide some other notification. EHF are determined by weight, and range from C\$0.40 (US\$0.41) for products weighing below two kilograms to C\$31.75 (US\$32.19) for products weighing between 50 and 200 kilograms. Devices sold to remitters should be labeled "EHF exempt".

Market Trends & Outlook

United States



Patient Monitoring Device Sector Expands

With many hospitals busier than ever, the demand for patient monitoring is growing, as it helps healthcare practitioners to administer clinical information and helps capture and interpret key clinical measurements, improving patient outcomes and improving efficiency. The ongoing evolution of patient monitoring systems reduces the need for manual measurements and enables caregivers to devote more time to patient care. As more hospital departments move to central stations and data-access through local area networks, the resulting integration and interconnectivity will enable the simultaneous monitoring of more patients.

The monitoring devices sector comprises multi-parameter vital sign monitors, wireless ambulatory telemetry monitoring, telehealth, intra-cranial pressure monitors and consumables, electromyogram devices and consumables, electroencephalogram monitors, cerebral oximetry monitors and consumables, fetal and neonatal monitors, pulse oximetry monitors, consumables and circuit boards, cardiac output devices and consumables, and blood pressure monitors.

Solid growth is projected as monitoring expands to previously unmonitored hospital departments, and is increasingly adopted as a consumer healthcare product. Kalorama Information, a leading provider of market research reports for pharmaceuticals, diagnostics, life science and healthcare markets, estimates the advanced patient monitoring systems market in the US surged to US\$8.9 billion in 2011, or by 128.21% from US\$3.9 billion in 2007, and is likely to total US\$20.9 billion by 2016. The ageing of the US population, mounting healthcare costs, and the acute shortage of healthcare practitioners in most hospitals is boosting the need for reliable, easy-to-use patient monitoring devices.

Reprocessed Medical Device Market Remains Solid

Reprocessing, long a part of the medical devices life cycle, has become an imperative, cost-cutting, refined process in developed economies, due to the poor economic environment. In the US, it is regulated by the FDA, and is one that promises to diminish healthcare spending in the long-term, provide annual cost-savings and a respite to the dwindling bottom lines of hospitals.

Efforts to trim costs and waste have pushed hospitals to reuse devices, and an industry watcher estimated that healthcare facilities will save US\$290 million in supply costs in 2012, thanks to reprocessing cardiovascular, laparoscopic, orthopedic/arthroscopic and gastrointestinal devices. About one quarter of hospitals recycle at least one category of these devices, with larger hospitals more likely to reprocess, as reprocessing in bulk brings large savings.

Reprocessed medical devices in the US are expected to witness a healthy growth rate, averaging almost 9% per annum through 2017, as aspects of the 2010 healthcare reform start to benefit the industry starting in 2014, when growth is expected to pick up. Current economic conditions and increasing government focus on cutting costs will continue to fuel reprocessing growth, as will the ageing population and mounting incidence of diseases that can be treated with medical devices.

Market Outlook

The medical device industry continues to be one of the most vital and dynamic sectors in the US economy and a leading force in the revolution that is transforming the healthcare system. It is central both to economic growth and to the delivery of new, much-needed medical technology to patients. Demand for medical devices will increase as the population grows, and as the growing share of elderly patients uses a bigger share of resources. Innovative products are the fuel for market growth, and new technologies could yield considerable first partaker advantage and help facilitate significant margins as they come to market.

Market Trends & Outlook

Canada



Canada Poised to Raise the Bar in Medical Devices Manufacturing

With more than 1,000 medical device manufacturing facilities, a workforce of 25,000 and exports worth more than C\$2.3 billion in 2011, Canada remains a strong and thriving market that produce a broad spectrum of specialties, including diagnostic and therapeutic products. The country is also an attractive market for overseas companies seeking to export medical devices. Canada's ageing baby boomers have spurred demand for devices such as prosthetics, orthotics, implants and highly specialized surgical stimulation systems and tools. This has provided opportunities to develop and manufacture high-demand products that integrate the latest discoveries from other industries such as microelectronics, telecommunications, advanced materials, software and biotechnology.

However, Canada's medical development and export activities still lag behind those of other industrialized nations due to lack of investment, medical device experts and a national strategy. The Medical Devices Innovation Institute (MDI²) at the University of Ottawa is trying to push for the establishment of a high strategic priority on developing medical devices. It is asking hospitals, universities, the Government, medical researchers and industry to concentrate jointly on discovering, developing, manufacturing and the utilization of medical devices in patient care.

In a two-day Medical Devices Summit conference in Ottawa in October 2011, MDI² said that Canada was poised to capitalize on a worldwide medical devices market estimated to expand by 20% annually, heading to a trillion dollars in the next several years. The institute is working on 24 innovative technologies in projects such as the electronic nose device (Enose) that can diagnose diseases such as heart failure in a non-invasive way through breath and saliva tests using custom algorithms. Another example is a portable DNA detector that can identify DNA from a single fingerprint in less than 15 seconds.

Wound Management a Greater Priority

In Canada, the number of wound care patients and the amount spent on wound management products is expected to rise in coming years due to an aging population and the escalating number of obese people and people with diabetes. With the number of seniors growing, physical

activity falling and rates of obesity getting higher, the diabetes prevalence is likely to remain high or even increase for some time. According to the Canadian Diabetes Association, more than two million Canadians have diabetes and the number is expected to rise. It is estimated that another five million are pre-diabetic.

A driving force behind the growth in the number of wound care management products and devices includes notably the growth in number of diabetic ulcers on top of the other chronic wounds. Often chronic wounds that are slow to heal can affect the patient's quality of life and can raise costs to healthcare providers, while exposed acute wounds can be life threatening.

The Canadian Association of Wound Care estimates that 15%, or 345,000 out of 2.3 million Canadians, are likely to develop a diabetic foot ulcer in their lifetime, with the cost of treating them totaling more than C\$150 million annually. In Quebec alone, more than 165,000 people suffer from a preventable pressure ulcer yearly. A new advocacy group, the Wound Care Alliance Canada has been formed to make wound care a major health issue. It will work with health professionals and bring together individuals with clinical, academic and government expertise to help reduce patient suffering and lower wound management costs.

Growth in advanced wound management, wound closure devices, negative pressure wound therapy, compression therapy and ultrasonic wound debridement systems will be propelled by the development of new technologies and products. In 2011, Health Canada issued a medical device license to Spiracur Inc, the developer of disposable, non-powered negative pressure wound therapy solutions, allowing the company to sell its Smart Negative Pressure Wound Care System throughout the country. The Canadian market offers great opportunities to medical device companies to expand the presence of these innovative treatment devices, providing patients with faster healing and reducing time in hospital.

A Greater Focus on the Need for Innovation

Innovation is the aptitude to turn knowledge into new and improved goods and services. Ageing Canadians are increasingly relying on medical innovations such as

Market Trends & Outlook - Canada

joint replacements and dental implants to maintain a high quality of life. Hence, there is plenty of room for growth and innovation in the booming medical device industry in Canada.

The Canadian medical and dental manufacturing industry is a promising sector represented by a highly diversified group of companies ranging from small start-ups to large, mature firms. The industry hires 35,000 people across 1,500 companies, generating an estimated C\$6 billion in sales annually. In addition, Canada is well supplied with good universities, engineering schools, teaching hospitals and technical institutes, which produce science that is highly respected around the world.

New innovations are crucial for businesses looking to expand their presence in the sector. Driven by the need to support ageing populations, the resulting chronic disease incidence and a greater demand for quality of life solutions, this sector is likely exceed C\$7 billion by 2014, according to the non-profit Society of Manufacturing Engineers (SME), which support lifelong manufacturing education. The vast majority of activity takes place in Ontario and Quebec and is concentrated on cardiovascular devices, medical imaging, in-vitro diagnostics, dental and assistive devices and home healthcare products.

Market Outlook

Despite the worldwide recession, the growth prospects for Canada's medical device industry remain solid and are still highest among developed countries. The combination of stronger economic growth than in other regions, reforms, government funding, higher penetration of medical insurance products and higher disposable income, is expected to raise demand for quality healthcare services, boosting demand for medical equipment. The Canadian industry continues to grow at a lively pace, thanks to ageing baby boomers, soaring unmet medical needs and rising numbers of lifestyle ailments such as diabetes, hypertension, obesity and cardiovascular diseases.

The performance of medical device makers is likely to be lifted by a continued and orderly demand for improved manufacturing efficiencies, greater geographical coverage and revenues and profits from product innovations such as robotic surgery technologies. In the medium-term, the Canadian Government plans to boost investment funding in medical technologies, the majority of which is likely to be directed towards medical imaging and diagnostic equipment.

Currency Conversion Table

Currency exchange rates as of August 31, 2012

Currency Unit	Units Per US\$	US\$ Per Unit
US Dollar (US\$)	1	1
Canadian Dollar (C\$)	0.9862	1.014

Source: Federal Reserve Bank of New York

The Scope Of This Report

This report looks at the medical equipment industry in the US and Canada. The report aims to give general picture of the current environment, profile the industry and discuss market trends using available data and an examination of key public companies. Key financial results for leading companies in each country are presented in the comparative data tables on the proceeding pages.

Research analysts draw on a range of credible industry and company data sources as well as news and information services to research and analyze the current trading environment, industry landscape and market trends and outlook for a particular sector. Primary sources are used, unless otherwise indicated, and include company data, e.g. annual reports and company financial results; macroeconomic and trade data; data and information from global country regulatory, industry and trade bodies; government data; and reports from industry organizations and private research organizations.

Industries covered by the industry reports are defined by standard industry classification systems and leading companies are identified on this basis. The following SIC codes are relevant to the industry: 3841 (Surgical and Medical Instrument Manufacturing); 3842 (Surgical Appliances and Supplies Manufacturing); 3843 (Dental Equipment and Supplies Manufacturing); 3844 (Irradiation Apparatus Manufacturing); 3845 (Electromedical and Electrotherapeutic Apparatus Manufacturing); and 3851 (Ophthalmic Goods Manufacturing).

Key References

Global

Organisation for Economic Cooperation and Development (OECD)

The OECD group's 30 member countries share a commitment to democratic government and the market economy. The OECD plays a prominent role in fostering good governance in the public service and in corporate activity.

<http://www.oecd.org>

World Health Organization (WHO)

WHO is the United Nations' specialized agency for health.

<http://www.who.int>

World Trade Organization (WTO)

The global international organization dealing with the rules of trade between nations that aims to liberalize trade, negotiate trade agreements and settle trade disputes.

<http://www.wto.org>

United States

Advanced Medical Technology Association (AdvaMed)

AdvaMed is a medical technology association representing manufacturers of medical devices, diagnostic products and medical information systems.

<http://www.himanet.com>

Centers for Disease Control and Prevention (CDC)

CDC is the principal agency in the US government for protecting the health and safety of all Americans and for providing essential human services, especially for those people who are least able to help themselves.

<http://www.cdc.gov>

Government Accountability Office (GAO)

GAO is a federal agency that examines the use of public funds, evaluates federal programs and activities, and provides analyses, options, recommendations, and other assistance to help the Congress make effective oversight, policy, and funding decisions.

<http://www.gao.gov>

International Trade Administration (ITA)

ITA is the US government agency for international trade.

<http://ita.doc.gov>

International Trade Commission (ITC)

ITC is an independent, quasi-judicial federal agency with broad investigative responsibilities on matters of trade.

<http://www.usitc.gov>

Medical Device Manufacturers Association (MDMA)

MDMA is national trade association based in Washington DC that represents independent manufacturers of medical devices, diagnostic products and healthcare information systems.

<http://www.medicaldevices.org>

National Venture Capital Association (NVCA)

NVCA is a trade association that represents the US venture capital industry.

<http://www.nvca.org>

National Center for Health Statistics (NCHS)

NCHS is the nation's principal health statistics agency that compiles statistical information.

<http://www.cdc.gov/nchs/>

US Census Bureau

The bureau is a government agency that produces US demographics data.

<http://www.census.gov>

US Department of Commerce (DoC)

The department is the government agency that provides key information and statistical analysis of the US economy and industries.

<http://www.commerce.gov>

US Food and Drug Administration (FDA)

The FDA is a branch of the US Department of Health and Human Services and promotes and protects public health by helping safe and effective products reach the market.

<http://www.fda.gov>

US Department of Health and Human Services (HHS)

The department is the US Government's principal agency for protecting the health of Americans and providing essential human services, especially for those who are least able to help themselves.

<http://www.os.dhhs.gov>

Canada**Canadian Institutes of Health Research (CIHR)**

CIHR is a major federal agency responsible for funding health research in Canada.

<http://www.cihr-irsc.gc.ca>

Government of Canada

An official Canadian government website that links to government services and departments, tourism, immigration, maps, business information and general facts.

<http://www.canada.gc.ca>

Health Canada

A federal department that provides national leadership to develop health policy, enforce health regulations, promote disease prevention and enhance healthy living for all Canadians.

<http://www.hc-sc.gc.ca>

Industry Canada

A department that aims to help build a dynamic and innovative economy by promoting industry and business growth and promoting a fair, efficient and competitive marketplace.

<http://www.ic.gc.ca>

Medical Devices Canada (MEDEC)

MEDEC, a principal trade association, helps improve healthcare for Canadians through the advocacy and advancement of medical technologies and devices.

<http://www.medec.org>

Statistics Canada

The national agency that provides official Canadian social and economic statistics and products.

<http://www.statcan.ca>

Company	Country	Ticker	Exchange	Primary SIC	Other SICs			
Medtronic Inc	United States	MDT	NYSE	3845	5047			
Baxter International Inc	United States	BAX	NYSE	3841	2834	3842		
Stryker Corp	United States	SYK	NYSE	3841	3842	3845		
Becton Dickinson & Co	United States	BDX	NYSE	3841	3842	3829	3826	
Boston Scientific Corp	United States	BSX	NYSE	3841	5047			
St Jude Medical Inc	United States	STJ	NYSE	3845	3842	5047		
Zimmer Holdings Inc	United States	ZMH	NYSE	3842				
CR Bard Inc	United States	BCR	NYSE	3841	3842	3845		
Dentsply International Inc	United States	XRAY	NMS	3843	3821	3826	8072	3842
Teleflex Inc	United States	TFX	NYSE	3841	3845	3728	3999	

Company	Total Revenue - FYE - 1	Total Revenue - FYE - 2	Total Revenue - FYE - 3	EBITDA - FYE - 1	EBITDA - FYE - 2	EBITDA - FYE - 3
Medtronic Inc	\$15,933,000,000	\$15,817,000,000	\$14,599,000,000	\$4,976,000,000	\$5,154,000,000	\$3,476,000,000
Baxter International Inc	\$13,893,000,000	\$12,843,000,000	\$12,562,000,000	\$3,533,000,000	\$2,662,000,000	\$3,470,000,000
Stryker Corp	\$8,307,000,000	\$7,320,000,000	\$6,723,000,000	\$2,167,000,000	\$2,139,000,000	\$2,009,000,000
Becton Dickinson & Co	\$7,828,904,000	\$7,372,333,000	\$6,986,722,000	\$2,261,162,000	\$2,179,407,000	\$2,050,436,000
Boston Scientific Corp	\$7,622,000,000	\$7,806,000,000	\$8,188,000,000	\$1,640,000,000	\$146,000,000	-\$67,000,000
St Jude Medical Inc	\$5,611,696,000	\$5,164,771,000	\$4,681,273,000	\$1,404,287,000	\$1,528,173,000	\$1,314,774,000
Zimmer Holdings Inc	\$4,451,800,000	\$4,220,200,000	\$4,095,400,000	\$1,384,000,000	\$1,256,900,000	\$1,356,200,000
CR Bard Inc	\$2,896,400,000	\$2,720,200,000	\$2,534,900,000	\$622,400,000	\$818,900,000	\$761,400,000
Dentsply International Inc	\$2,537,718,000	\$2,221,014,000	\$2,159,378,000	\$383,527,000	\$444,831,000	\$445,395,000
Teleflex Inc	\$1,528,911,000	\$1,433,282,000	\$1,434,885,000	\$316,903,000	\$279,343,000	\$345,603,000

Company	Net Income - FYE - 1	Net Income - FYE - 2	Net Income - FYE - 3	EPS - FYE - 1	EPS - FYE - 2	EPS - FYE - 3
Medtronic Inc	\$3,096,000,000	\$3,099,000,000	\$2,070,000,000	\$2.87	\$2.80	\$1.85
Baxter International Inc	\$2,224,000,000	\$1,420,000,000	\$2,205,000,000	\$3.91	\$2.41	\$3.63
Stryker Corp	\$1,345,000,000	\$1,273,000,000	\$1,107,000,000	\$3.48	\$3.21	\$2.79
Becton Dickinson & Co	\$1,270,994,000	\$1,317,610,000	\$1,231,603,000	\$5.75	\$5.62	\$5.12
Boston Scientific Corp	\$441,000,000	-\$1,065,000,000	-\$1,025,000,000	\$0.29	-\$0.70	-\$0.68
St Jude Medical Inc	\$825,793,000	\$907,436,000	\$777,226,000	\$2.55	\$2.76	\$2.28
Zimmer Holdings Inc	\$760,800,000	\$596,900,000	\$717,400,000	\$4.05	\$2.98	\$3.34
CR Bard Inc	\$328,000,000	\$509,200,000	\$460,100,000	\$3.75	\$5.39	\$4.66
Dentsply International Inc	\$244,520,000	\$265,708,000	\$274,258,000	\$1.73	\$1.85	\$1.85
Teleflex Inc	\$323,329,000	\$201,094,000	\$302,994,000	\$7.98	\$5.04	\$7.63

Company	Total Current Assets - FYE - 1	Total Current Assets - FYE - 2	Total Current Assets - FYE - 3	Long-Term Debt - FYE - 1	Long-Term Debt - FYE - 2	Long-Term Debt - FYE - 3
Medtronic Inc	\$9,117,000,000	\$9,839,000,000	\$7,452,000,000	\$8,112,000,000	\$6,944,000,000	\$6,253,000,000
Baxter International Inc	\$8,650,000,000	\$7,989,000,000	\$8,271,000,000	\$4,749,000,000	\$4,363,000,000	\$3,440,000,000
Stryker Corp	\$7,211,000,000	\$7,632,000,000	\$5,851,200,000	\$1,751,000,000	\$996,000,000	N/A
Becton Dickinson & Co	\$4,668,331,000	\$4,505,250,000	\$4,646,954,000	\$2,484,665,000	\$1,495,357,000	\$1,488,460,000
Boston Scientific Corp	\$3,105,000,000	\$3,615,000,000	\$4,599,000,000	\$4,257,000,000	\$4,934,000,000	\$5,915,000,000
St Jude Medical Inc	\$3,390,566,000	\$2,912,148,000	\$2,560,206,000	\$2,713,275,000	\$2,431,966,000	\$1,587,615,000
Zimmer Holdings Inc	\$3,276,600,000	\$3,009,700,000	\$2,738,000,000	\$1,576,000,000	\$1,142,100,000	\$1,127,600,000
CR Bard Inc	\$1,685,900,000	\$1,529,300,000	\$1,491,800,000	\$908,700,000	\$896,900,000	\$149,800,000
Dentsply International Inc	\$1,012,903,000	\$1,315,045,000	\$1,217,796,000	\$1,490,010,000	\$604,015,000	\$387,151,000
Teleflex Inc	\$1,280,256,000	\$921,233,000	N/A	\$954,809,000	\$813,409,000	\$1,192,491,000

Company	Return on Equity (Most Recent Yr)	Profit Margin (Most Recent Yr)	Date FYE - 1	Date FYE - 2	Date FYE - 3
Medtronic Inc	19.39	19.43	29-Apr-2011	30-Apr-2010	24-Apr-2009
Baxter International Inc	33.77	16.01	31-Dec-2011	31-Dec-2010	31-Dec-2009
Stryker Corp	17.51	16.19	31-Dec-2011	31-Dec-2010	31-Dec-2009
Becton Dickinson & Co	26.32	16.23	30-Sep-2011	30-Sep-2010	30-Sep-2009
Boston Scientific Corp	3.88	5.79	31-Dec-2011	31-Dec-2010	31-Dec-2009
St Jude Medical Inc	18.46	14.72	31-Dec-2011	1-Jan-2011	2-Jan-2010
Zimmer Holdings Inc	13.81	17.09	31-Dec-2011	31-Dec-2010	31-Dec-2009
CR Bard Inc	18.40	11.32	31-Dec-2011	31-Dec-2010	31-Dec-2009
Dentsply International Inc	13.23	9.64	31-Dec-2011	31-Dec-2010	31-Dec-2009
Teleflex Inc	16.32	21.15	31-Dec-2011	31-Dec-2010	31-Dec-2009

Notes to Comparative Data

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- All figures are as reported by the company.

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- N/L = Not Listed.
- Companies ranked by total revenue for the full year most recently reported.

Definitions

- Total Revenue = All revenues, including net sales, operating revenues, interest income, royalties, excise taxes etc.
- EBITDA = Earnings before interest, taxes, depreciation and amortization.
- EPS Cont Operations = Earnings Per Share as reported by company excluding extraordinary items.
- Total Current Assets = All assets expected to be realized within the next year, includes cash, accounts receivable and inventories.
- Long Term Debt = Debt due to be paid at a date more than one year in the future.
- Return on Equity = The company's earnings divided by its equity (book value).
- Profit Margin = The company's net income as a percent of revenues.

Company	Country	Ticker	Exchange	Primary SIC	Other SICs				
Prism Medical Ltd	Canada	PM	TVX	5047					
IMRIS Inc	Canada	IM	TSX	3841	3842				
Novadaq Technologies Inc	Canada	NDQ	TSX	3845	3851				
Unilens Vision Inc	Canada	UVI	TVX	3851	3827				
Ergoresearch Ltd	Canada	ERG	TVX	5047					
Imaging Dynamics Co Ltd	Canada	IDL	TVX	3844					
TSO3 Inc	Canada	TOS	TSX	3841					
ZoomMed Inc	Canada	ZMD	TVX	3845	5047				
Theralase Technologies Inc	Canada	TLT	TVX	3841	5047				
Titan Medical Inc	Canada	TMD	TVX	3841	3842				
Company	Total Revenue - FYE - 1	Total Revenue - FYE - 2	Total Revenue - FYE - 3	EBITDA - FYE - 1	EBITDA - FYE - 2	EBITDA - FYE - 3			
Prism Medical Ltd	\$65,375,451	\$62,132,866	\$41,995,389	\$6,775,187	\$8,066,833	\$6,766,193			
IMRIS Inc	\$51,797,000	\$71,907,929	\$42,367,437	-\$17,075,000	\$2,001,256	-\$6,653,952			
Novadaq Technologies Inc	\$15,292,441	\$13,871,321	\$8,224,655	-\$7,320,140	-\$11,791,551	-\$12,169,802			
Unilens Vision Inc	\$8,779,356	\$9,194,190	\$9,598,209	\$2,655,439	\$2,801,767	\$3,174,482			
Ergoresearch Ltd	\$7,481,359	\$6,312,406	\$4,608,058	\$1,095,804	\$1,141,047	\$654,204			
Imaging Dynamics Co Ltd	\$5,419,711	\$9,293,540	\$13,751,344	-\$3,855,917	-\$5,426,265	-\$11,970,047			
TSO3 Inc	\$3,289,315	\$1,143,220	\$1,263,392	-\$6,823,763	-\$7,030,850	-\$8,253,782			
ZoomMed Inc	\$2,964,536	\$1,495,046	\$567,378	-\$2,968,062	-\$3,035,672	-\$3,879,468			
Theralase Technologies Inc	\$1,987,113	\$2,044,886	\$2,250,912	-\$1,376,890	-\$1,071,319	-\$63,195			
Titan Medical Inc	N/A	N/A	N/A	-\$15,807,151	-\$3,761,446	-\$717,822			
Company	Net Income - FYE - 1	Net Income - FYE - 2	Net Income - FYE - 3	EPS - FYE - 1	EPS - FYE - 2	EPS - FYE - 3			
Prism Medical Ltd	\$3,503,325	\$4,334,587	\$3,663,066	\$0.63	\$0.82	\$0.74			
IMRIS Inc	-\$20,925,000	-\$1,449,082	-\$8,741,897	-\$0.47	-\$0.04	-\$0.31			
Novadaq Technologies Inc	-\$10,153,328	-\$14,187,319	-\$14,989,331	-\$0.32	-\$0.52	-\$0.61			
Unilens Vision Inc	\$1,491,774	\$1,548,397	\$1,870,127	\$0.63	\$0.43	\$0.41			
Ergoresearch Ltd	\$402,661	\$432,895	\$640,573	\$0.01	\$0.01	\$0.01			
Imaging Dynamics Co Ltd	-\$4,195,273	-\$5,694,873	-\$12,791,779	-\$0.04	-\$0.07	-\$0.17			
TSO3 Inc	-\$7,504,564	-\$7,780,768	-\$8,792,099	-\$0.13	-\$0.14	-\$0.18			
ZoomMed Inc	-\$3,804,433	-\$4,129,939	-\$5,077,305	-\$0.03	-\$0.04	-\$0.05			
Theralase Technologies Inc	-\$1,425,322	-\$1,170,840	-\$230,426	-\$0.04	-\$0.03	-\$0.01			
Titan Medical Inc	-\$15,809,722	-\$3,769,074	-\$712,780	-\$0.29	-\$0.09	-\$0.02			
Company	Total Current Assets - FYE - 1	Total Current Assets - FYE - 2	Total Current Assets - FYE - 3	Long-Term Debt - FYE - 1	Long-Term Debt - FYE - 2	Long-Term Debt - FYE - 3			
Prism Medical Ltd	\$31,011,092	\$28,912,378	\$21,017,114	\$3,570,998	\$15,095,408	\$11,307,198			
IMRIS Inc	\$69,308,000	\$90,800,108	\$48,132,415	N/A	N/A	N/A			
Novadaq Technologies Inc	\$14,237,744	\$9,004,778	\$6,944,500	\$4,223,454	\$3,891,753	\$3,527,700			
Unilens Vision Inc	\$3,410,201	\$3,819,430	\$4,979,059	\$3,894,136	\$4,300,000	N/A			
Ergoresearch Ltd	\$2,626,220	\$2,795,512	\$2,034,448	\$48,722	\$250,575	\$465,420			
Imaging Dynamics Co Ltd	\$4,204,779	\$6,463,069	\$10,399,816	N/A	N/A	N/A			
TSO3 Inc	\$14,190,091	\$21,121,559	\$12,972,499	N/A	N/A	N/A			
ZoomMed Inc	\$1,996,222	\$2,932,263	\$3,161,763	N/A	N/A	\$47,569			
Theralase Technologies Inc	\$1,058,065	\$1,062,405	\$1,909,486	\$1,407	\$5,776	\$10,715			
Titan Medical Inc	\$10,576,075	\$9,772,378	\$3,131,357	N/A	N/A	N/A			
Company	Return on Equity (Most Recent Yr)		Profit Margin (Most Recent Yr)		Date FYE - 1		Date FYE - 3		
Prism Medical Ltd	16.95		5.36		30-Nov-2010		30-Nov-2008		
IMRIS Inc	-28.07		-40.40		31-Dec-2011		31-Dec-2009		
Novadaq Technologies Inc	-1620.83		-66.39		31-Dec-2011		31-Dec-2009		
Unilens Vision Inc	-91.19		16.99		30-Jun-2011		30-Jun-2009		
Ergoresearch Ltd	10.42		5.38		30-Jun-2011		30-Jun-2009		
Imaging Dynamics Co Ltd	N/A		N/A		31-Dec-2010		31-Dec-2008		
TSO3 Inc	-48.78		-228.15		31-Dec-2011		31-Dec-2009		
ZoomMed Inc	-87.43		-128.33		31-May-2011		31-May-2009		
Theralase Technologies Inc	-319.44		-71.73		31-Dec-2011		31-Dec-2009		
Titan Medical Inc	-172.61		N/A		31-Dec-2011		31-Dec-2009		

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- Profit Margin = The company's net income as a percent of revenues.



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