MEDTRONIC INC
Form 10-K
June 24, 2008

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

- x Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934.
  For the fiscal year ended April 25, 2008.
- o Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
  For the transition period from _____ to _____

Commission File No. 1-7707

Medtronic, Inc.

(Exact name of registrant as specified in charter)

Minnesota	**41-0793183**
(State of incorporation)	**(I.R.S. Employer Identification No.)**

710 Medtronic Parkway
Minneapolis, Minnesota 55432
(Address of principal executive offices) (Zip Code)

Telephone Number, including area code: (763) 514-4000

Securities registered pursuant to section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common stock, par value $0.10 per share	**New York Stock Exchange, Inc.**
Preferred stock purchase rights	**New York Stock Exchange, Inc.**

Securities registered pursuant to section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.
Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

Aggregate market value of voting stock of Medtronic, Inc. held by nonaffiliates of the registrant as of October 26, 2007, based on the closing price of $47.82, as reported on the New York Stock Exchange: approximately $54.2 billion. Shares of Common Stock outstanding on June 19, 2008: 1,125,244,102

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s 2008 Annual Report filed as Exhibit 13 hereto are incorporated by reference into Parts I and II hereto and portions of Registrant s Proxy Statement for its 2008 Annual Meeting are incorporated by reference into Part III hereto.

TABLE OF CONTENTS

Table of Contents

Annual Meeting and Record Dates

Medtronic, Inc. s (Medtronic or the Company) Annual Meeting of Shareholders will be held on Thursday, August 21, 2008 at 10:30 a.m., Central Daylight Time at the Company s World Headquarters, 710 Medtronic Parkway, Minneapolis (Fridley), Minnesota. The record date for the Annual Meeting is June 23, 2008 and all shareholders of record at the close of business on that day will be entitled to vote at the Annual Meeting.

Medtronic Website

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available through our website (www.medtronic.com under the Investor Relations caption) free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

Information relating to corporate governance at Medtronic, including our Principles of Corporate Governance, Code of Conduct (including our Code of Ethics for Senior Financial Officers), Code of Business Conduct and Ethics for Board Members and information concerning our executive officers, directors and Board committees (including

committee charters), and transactions in Medtronic securities by directors and officers, is available on or through our website at www.medtronic.com under the Corporate Governance and Investor Relations captions.

We are not including the information on our website as a part of, or incorporating it by reference into, our Form 10-K.

Available Information

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public can obtain any documents that the Company files with the SEC at http://www.sec.gov. The Company files annual reports, quarterly reports, proxy statements and other documents with SEC under the Securities Exchange Act of 1934 (Exchange Act). The public may read and copy any materials that the Company files with the SEC at the SEC s Public Reference Room at 100 F Street, N.E., Room 1580 Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

Table of Contents

PART I

Item 1. Business

Overview

Medtronic is the global leader in medical technology alleviating pain, restoring health, and extending life for millions of people around the world. We are committed to offering market-leading therapies to restore patients to fuller, healthier lives. With beginnings in the treatment of heart disease, we have expanded well beyond our historical core business and today provide a wide range of products and therapies that help solve many challenging, life-limiting medical conditions. We hold market-leading positions in almost all of the major markets in which we operate.

Medtronic was founded in 1949, incorporated as a Minnesota corporation in 1957, and today serves physicians, clinicians and patients in more than 120 countries worldwide. Beginning with the development of the heart pacemaker in the 1950s, we have assembled a broad and diverse portfolio of progressive technology expertise both through internal development of core technologies as well as acquisitions. We remain committed to a mission written by our founder more than 40 years ago that directs us to contribute to human welfare by application of biomedical engineering in the research, design, manufacture and sale of products that alleviate pain, restore health and extend life.

With approximately 40,000 dedicated employees worldwide personally invested in supporting our mission, our success in leading global advances in medical technology is the result of several key strengths:

- Broad and deep technological knowledge of microelectronics, implantable devices and techniques, power sources, coatings, materials, programmable devices and related areas, as well as a tradition of technological pioneering and breakthrough products that not only yield better medical outcomes, but more

cost-effective therapies.

Strong intellectual property portfolio that underlies our key products.

High product quality standards, backed with stringent systems to help ensure consistent performance that meet or surpass customers expectations.

Strong professional collaboration with customers, extensive medical educational programs, and thorough clinical research.

Full commitment to superior patient and customer service.

Extensive experience with the regulatory process and sound working relationships with regulators and reimbursement agencies, including leadership roles in helping shape regulatory policy in the major markets in which we operate.

A proven financial record of sustained revenue and earnings growth and continual introduction of new products.

Table of Contents

We currently function in seven operating segments that manufacture and sell device-based medical therapies. During the first quarter of fiscal year 2008, we revised our operating segment reporting to combine our former Vascular and Cardiac Surgery businesses into the new CardioVascular operating segment. Additionally, the Navigation business was separated from Spinal for most of fiscal year 2008 and was reported as part of a stand alone segment named Corporate Technologies and New Ventures. In the fourth quarter of fiscal year 2008, the decision was made to include the Navigation business as a component of the Ear, Nose and Throat segment, which was renamed Surgical Technologies to reflect the expanding scope and focus of this business. Our operating segments are:

Cardiac Rhythm Disease Management

Spinal

CardioVascular

Neuromodulation

Diabetes

Surgical Technologies

Physio-Control

The chart above shows the net sales and percentage of total net sales contributed by each of our operating segments for the fiscal year ended April 25, 2008 (fiscal year 2008).

With innovation and market leadership, we have pioneered advances in medical technology in all of our businesses and enjoyed steady growth. Over the last five years, our net sales on a compound annual growth basis have increased more than 12 percent, from $7.665 billion in fiscal year 2003 to $13.515 billion in fiscal year 2008. We attribute this growth to our commitment to develop or acquire new products to treat an expanding array of medical conditions. In

the coming decade, we anticipate that technology advancements, the Internet, and increasing patient participation in treatment decisions will transform the nature of healthcare services. Medtronic is positioned to deliver on this promise of integration across device technology, biotechnology, and information technology by building on trusted partnerships with caregivers; leveraging our scale, scope, and expertise; and benefiting patients worldwide.

We will accomplish this goal by operating as ONE Medtronic, reaching within and across our operating segments to make the whole of Medtronic greater than the sum of its parts. The main tenets of this approach are:

- Driving sustainable long-term growth through innovation
- Strong focus on improving operating margins
- Delivering EPS growth and disciplined capital allocation
- Aligning the organization for relentless and consistent execution

Our primary customers include hospitals, clinics, third party healthcare providers, distributors, and other institutions, including governmental healthcare programs and group purchasing organizations.

Cardiac Rhythm Disease Management (CRDM)

CRDM is the world s leading supplier of medical devices for cardiac rhythm disease management. We pioneered the modern medical device industry by developing the first wearable external cardiac pacemaker in 1957, and manufactured the first reliable long-term implantable pacing system in 1960. Since then, we have been the world s leading producer of cardiac rhythm technology, and from these beginnings, a $10 billion industry has emerged. Today, our products and technologies treat and monitor a wide variety of heart rhythm diseases and conditions.

Table of Contents

Conditions Treated

Natural electrical impulses stimulate the atria and ventricles, the heart s chambers, to rhythmically contract and relax with each heartbeat. Irregularities in the heart s normal electrical signals can result in debilitating and life-threatening conditions, including sudden cardiac arrest, one of the leading causes of death. Physicians rely on our CRDM products to monitor and correct these irregularities and restore the heart to its normal rhythm. Our CRDM products are designed to treat and monitor a broad range of heart conditions, including those described below.

- Bradycardia abnormally slow or unsteady heart rhythms, usually less than 60 beats per minute, or unsteady heart rhythms that cause symptoms such as dizziness, fainting, fatigue, and shortness of breath.
- Tachyarrhythmia heart rates that are dangerously fast or irregular. In the lower chambers of the heart, called ventricles, this is called ventricular tachycardia or fibrillation and can lead to sudden cardiac arrest. In the upper chambers, called the atria, this is called atrial arrhythmia which can affect blood flow to the body and increase the risk of stroke.

Heart Failure impaired heart function resulting in the inability to pump enough blood to meet the body s needs, characterized by difficulty breathing, chronic fatigue and fluid retention.

Sudden Cardiac Arrest condition when the heart s ventricles suddenly develop a rapid, irregular rhythm (ventricular fibrillation) and the quivering ventricles cannot pump blood to the body, which, without immediate treatment, will almost always lead to death.

Syncope a sudden loss of consciousness, which occurs when the blood pressure drops and not enough oxygen reaches the brain. Causes vary and include heart-related conditions, exhaustion, stress, overheating, illness and certain medications.

Atrial Fibrillation condition when the atria quiver instead of pumping blood effectively. Blood in the atria may pool and clot. If a clot breaks loose and advances to the brain, a stroke can result.

The charts below set forth net sales of our CRDM products as a percentage of our total net sales for each of the last three fiscal years:

We offer the broadest array of products in the industry for the diagnosis and treatment of heart rhythm disorders and heart failure. Because many patients exhibit multiple heart rhythm problems, we have developed implantable devices that specifically address complex combinations of arrhythmias. In addition to implantable devices, we also provide leads, ablation products, electrophysiology catheters, and information systems for the management of patients with our devices. Our CRDM devices are currently implanted in more than 3 million patients worldwide.

Implantable Cardiac Pacemakers. Bradycardia is a common condition, with hundreds of thousands of patients diagnosed each year, and millions of people worldwide suffering from its effects. The only known treatment for this condition is a cardiac pacemaker, a battery-powered device implanted in the chest that delivers electrical impulses to stimulate the heart to beat at an appropriate rate.

Table of Contents

Pacemaker technology has extended the lives of millions of patients with heart rhythm conditions, and each year nearly 1 million pacemakers are implanted in patients worldwide. Medtronic s Adapta family of fully automatic pacemakers, which includes the Adapta, Versa, and Sensia models, incorporates an array of automatic features to help physicians improve pacing therapy and streamline the patient follow-up process, potentially minimizing the amount of time spent in a physician s office. An example is Atrial Capture Management, which is intended to automatically adjust impulses for optimal stimulation of the heart s upper right chamber. Adapta offers a pacing mode called Managed Ventricular Pacing (MVP), which enables the device to be programmed to minimize unnecessary pacing pulses to the right ventricle. Clinical studies have shown that unnecessary pacing in the right ventricle can increase the risk for heart failure and atrial fibrillation. In September 2007, the results of the Search AV Extension and Managed Ventricular Pacing for Promoting Atrioventricular Conduction (SAVE PACe) trial, funded by Medtronic, were published in the *New England Journal of Medicine.* This trial of more than 1,000 patients showed that reducing right ventricular pacing to less than 10 percent in patients with dual chamber pacemakers reduced the relative risk of developing persistent atrial fibrillation by 40 percent compared with conventional dual chamber pacing. MVP has been shown to reduce the amount of right ventricular pacing to less than 5 percent, compared to 50 percent or more

from devices with typical dual-chamber pacing. The Adapta family leads our portfolio of pacemakers, which also includes the EnRhythm and EnPulse families.

Following the launch of our international trial in February 2007 of 350 patients, in January 2008 we announced the start of a United States (U.S.) clinical trial of 470 patients to confirm the safety and efficacy of the Medtronic EnRhythm MRI SureScan pacing system, the first-ever pacemaker system to be developed and tested specifically for safe use in Magnetic Resonance Imaging (MRI) machines under specified scanning conditions. The EnRhythm MRI SureScan pacing system consists of the dual-chamber EnRhythm MRI SureScan pacemaker and CapSureFix MRI SureScan pacing leads. Currently, individuals with implanted cardiac devices such as pacemakers, implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices are prohibited from receiving MRI scans, since MRI machines may interact with traditional systems, potentially compromising therapy and patient safety. While improvements to pacing technology have continued since its development nearly 50 years ago, this advance marks a concerted effort to pursue compatibility with MRI scans, an important healthcare diagnostic procedure.

Implantable Cardioverter-Defibrillators. Approximately 7 million people worldwide have tachyarrhythmia. Tachyarrhythmia is a potentially fatal condition that can lead to sudden cardiac arrest, the sudden and complete cessation of heart activity. Sudden cardiac arrest is one of the leading causes of death in the U.S. responsible for more than 310,000 deaths annually, with most due to ventricular fibrillation. ICDs are stopwatch-sized devices that continually monitor the heart and deliver appropriate therapy when an abnormal heart rhythm is detected. Several large clinical trials have shown implantable defibrillators significantly improve survival as compared to commonly prescribed antiarrhythmic drugs. In 2005, the results of Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), sponsored by the National Institutes of Health, with funding provided by Medtronic, were published in the *New England Journal of Medicine.* This 2,521 patient trial, the largest ICD trial ever conducted, showed ICDs reduced death by 23 percent in people with moderate heart failure compared to those who did not receive ICDs. Also in 2005, the Centers for Medicare and Medicaid Services expanded coverage of ICDs for Medicare beneficiaries who meet SCD-HeFT indications. Despite the mounting evidence demonstrated in clinical trials such as SCD-HeFT, only about 35 percent of all patients in the U.S., and significantly less outside the U.S., who are indicated for an ICD actually receive one, leaving hundreds of thousands of people at an increased risk for sudden cardiac death. Our Virtuoso family of dual and single chamber ICDs offer unique features including Anti-tachyarrhythmia Pacing (ATP) During Charging, OptiVol Fluid Status Monitoring, our pacing mode MVP , and Conexus Wireless Telemetry with SmartRadio. ATP During Charging is a feature that automatically uses pacing pulses to stop fast, dangerous heartbeats, while concurrently preparing to deliver a shock, if needed, with no delay. OptiVol automatically monitors fluid status in the thoracic cavity, the chest area encompassing the lungs and heart. The accumulation of thoracic fluid is a primary indicator of worsening heart failure and will often result in patient hospitalization. The OptiVol Fluid Status Monitoring diagnostic feature allows physicians earlier access to warning signs of deteriorating heart failure, which can then be used for early treatment of the patient s

Table of Contents

heart failure. In July 2007, we announced the launch of the Virtuoso family of ICDs in Japan, following launches in the U.S. and Europe in May and June 2006, respectively.

Implantable Cardiac Resynchronization Therapy. Heart failure is a large and growing health problem. It is typically a late manifestation of one or more other cardiovascular diseases, including coronary artery disease, hypertension, cardiomyopathy, and valvular disease. Chronic heart failure occurs when the heart is unable to pump enough blood to sustain adequate circulation in the body s tissues. Approximately 22 million patients suffer from heart failure globally and an estimated $80 billion is spent each year to manage heart failure patients. Approximately 5.2 million Americans suffer from heart failure and more than 550,000 new cases are estimated to develop each year. Heart failure is the most costly cardiovascular disease in the U.S., with an estimated $40 billion spent on managing heart failure patients each year. Further, there are more than one million hospitalizations in the U.S. annually with a primary diagnosis of heart failure.

Since 1997, Medtronic has supported more than 20 randomized, controlled clinical studies evaluating device therapy in more than 8,000 heart failure and post-myocardial infarction patients. This research has resulted in several medical firsts, among them the first U.S. Food and Drug Administration (FDA) approved resynchronization device for the treatment of heart failure, which was based on results from the groundbreaking MIRACLE trial; the first study of the risk of sudden cardiac death in a heart failure patient population with SCD-HeFT; and the landmark CARE-HF trial, which demonstrated that patients with moderate and severe heart failure who received a Medtronic CRT device experienced a significant reduction in risk in mortality and morbidity, and that long-term treatment with a CRT-pacing (CRT-P) device or CRT-defibrillator (CRT-D) device is a cost-effective way to improve survival in patients with heart failure. In the fall of 2007, data from IMPROVE HF was presented at the scientific sessions of the Heart Failure Society of America Annual Scientific Meeting and the American Heart Association. This is the largest study of U.S.-based heart failure patients in the outpatient setting and is being sponsored by Medtronic. Data demonstrated significant underutilization of many guideline-indicated life-saving medical and device therapies provided to heart failure patients, particularly for women and the elderly. Based on current medical guidelines, only 39 percent of eligible patients received CRT or CRT-D therapy, and only 51 percent of eligible patients received ICD therapy. This data underscores the challenge and opportunity of the ICD market.

Medtronic continues to offer the industry s broadest selection of devices and features for the growing number of patients with heart failure who are also considered at high risk of sudden cardiac arrest. The Concerto CRT-D, together with the Virtuoso ICD, are Medtronic s first cardiac rhythm disease management devices to utilize our proprietary Conexus wireless telemetry, enabling communication remotely between the implanted device and programmers at the time of implant, during follow-up in a clinician s office, or remotely using a patient home monitor. The Concerto CRT-D/Virtuoso ICD family represents our next step in the delivery of premium implantable devices, which, in addition to MVP and ATP During Charging, include OptiVol Fluid Status Monitoring. Concerto CRT-D also offers Left Ventricular Capture Management (LVCM). LVCM is intended to automatically sense and adjust impulses for stimulation of the heart s left ventricle. Concerto, along with previously released CRT-D devices (InSync Maximo and InSync Sentry), offer sequential biventricular pacing or V-to-V (ventricle to ventricle) timing, a feature that allows physicians to separately adjust the timing of electrical therapy delivered to the heart failure patient s two ventricles, which can optimize the beating of the heart and enhance the flow of blood throughout the body. These CRT-D devices represent important clinical advances since sudden cardiac arrest occurs in heart failure patients at six to nine times the rate observed in the general population. In July 2007, we announced the commercial launch of the Concerto CRT-D in Japan, following launches in the U.S. and Europe in May and June 2006, respectively.

Diagnostics and Monitoring Approximately 1.5 million people worldwide suffer from unexplained syncope. In almost 10 percent of patients, syncope has a cardiac cause; in 50 percent of patients, a non-cardiac cause; and in 40 percent of patients the cause of syncope is unknown. It is a leading cause of emergency room visits. Syncope is difficult to diagnose as syncopal episodes are often too infrequent and unpredictable for detection with conventional monitoring techniques. Our Reveal DX, which launched in Europe in July 2007 and the U.S. in December 2007, is a device that is placed under the skin and continuously monitors the heart s electrical activity before, during, and after a syncopal event. With

Table of Contents

the information obtained from the Reveal DX, the physician can understand if the cause of syncope is cardiac related, which may help to appropriately manage the patient s arrhythmia.

Atrial Fibrillation (AF) is the most common cardiac arrhythmia, experienced by approximately 4 to 5 million people worldwide. Treatment of AF can be difficult as episodes may show no symptoms and therefore go unnoticed by patients. AF can lead to a two to seven times higher risk of stroke and an increased risk of heart failure with its attendant risk of sudden cardiac arrest. Our Reveal XT Insertable Cardiac Monitor, launched in Europe in July 2007, monitors AF patients 24 hours a day, every day for up to three years. There are a variety of ways to treat AF, but prior to the launch of Reveal XT physicians had no means of gathering detailed data over an extended period on the progression of AF and the effect of treatment. Reveal XT gives new insight into patients heart rhythms, which may help physicians to evaluate stroke risk and determine appropriate treatment options for their patients.

Patient Management Tools. We have three different patient management tools, CareLink, Paceart, and CardioSight Service. The Medtronic CareLink Network, monitor, and software help physicians and patients better manage chronic cardiovascular disease treated by implantable device therapy. CareLink enables patients to transmit data from their pacemaker, ICD, or CRT-D using a portable monitor that is connected to a standard telephone line. Within minutes, the patient s physician and nurses can view the data on a secure Internet website. The information, which is comparable to that provided during an in-clinic device follow-up visit, provides the physician with a view of how the device and patient s heart are operating. The system provides an efficient, safe and convenient way for specialty physicians to remotely monitor the condition of their patients and, if needed, make adjustments to medication or prescribe additional therapy. It also saves patients time by potentially eliminating some in-office visits. For patients implanted with devices featuring Conexus Wireless Telemetry, clinicians can schedule routine follow-ups to occur automatically while the patient sleeps, alleviating compliance issues, and program the device to send a CareAlert notification to physicians wirelessly and automatically, providing the potential for treatment decisions before the condition worsens. The information in the Medtronic CareLink Network, which can be forwarded automatically to Paceart, provides access to detailed patient and device data for clinicians from a myriad of sources including in-clinic device interrogations, for inclusion in the patient s Paceart record; from Paceart, via HL7 industry standard protocols, the data can move seamlessly to the hospital or clinic s electronic health record system. Today, the Medtronic CareLink Network is being utilized in more than 2,400 clinics and hospitals, and more than 250,000 patients are being monitored. In June 2007, CareLink was launched in Europe, and is now currently available in the U.S., Canada, and Western Europe, and is being piloted in other parts of the world including Japan and Australia.

For more than 20 years, the Paceart System has led in the development of information solutions for device clinic management, including activities such as automating patient scheduling, correspondence and reporting. Paceart supports a common workflow by organizing and archiving data for cardiac devices from all major device manufacturers, serving as the central hub for patients device data. In addition to automatically downloading data from the Medtronic CareLink Network, Paceart can automatically receive data from the Medtronic 2090 Programmer, using SessionSync technology. Paceart acts as the gateway for managing clinics device data, receiving registration and scheduling data from, and sending patient and device data to more than 15 of the leading electronic health record and practice management systems. Paceart can interface with any HL7-compatible system and is actively sharing data with such industry leaders as athenahealth, EPIC, GEMMS, and NextGen Healthcare, among others. Today, more

than 1,100 clinics are using the Paceart System to streamline clinicians daily activities and better serve 1.5 million patients.

The third patient management tool we offer is called CardioSight Service, which is an in-clinic data access tool available to physicians treating heart failure patients who have one of several Medtronic CRT-D or ICD devices. CardioSight provides clinically valuable, device-derived information to help specialty physicians discern the status of the heart failure patient s symptoms. The CardioSight Reader gives insight into a patient s condition without using a device programmer. Within minutes of downloading device information using the reader, a Heart Failure Management Report or Cardiac Compass Trends Report is available to the clinic and can be added to the patient chart before the physician consults with the patient.

Table of Contents

Customers and Competitors

The primary medical specialists who use our implanted cardiac rhythm devices include electrophysiologists, implanting cardiologists, heart failure specialists, and cardiovascular surgeons. We hold the leading market position among implantable cardiac rhythm device manufacturers. Our primary competitors in the CRDM business are Boston Scientific Corporation and St. Jude Medical, Inc.

Spinal

Our Spinal business is a leading supplier for innovative medical devices and implants used in the treatment of the spine. Today we offer a wide range of products and therapies to treat a variety of conditions of the spine.

Conditions Treated

Our Spinal business offers products for treatment and diagnosis of many spinal conditions, including those listed below.

Herniated Disc A disc herniation occurs when the inner core of the intervertebral disc bulges out through the outer layer of ligaments that surround the disc. This tear in the outer layer of ligaments causes pain in the back at the point of herniation. If the protruding disc presses on a spinal nerve, the pain may spread to the area of the body that is served by that nerve. The terms ruptured, slipped, and bulging are also commonly used to describe this condition.

Degenerative Disc Disease As part of the natural aging process, intervertebral discs lose their flexibility and shock absorbing characteristics. The ligaments that surround the discs become brittle and easier to tear. At the same time, the inner core of the disc starts to dry out and shrink. Over time, these changes can cause the discs to lose their normal structure and/or function.

Spinal Deformity When viewed from behind, the human spine appears straight and symmetrical. When viewed from the side, however, the spine is curved. Some curvature in the neck, upper trunk, and lower

trunk is normal. These curves help the upper body maintain proper balance and alignment over the pelvis. The term deformity is used to describe any variation in this natural shape. One form of spinal deformity, scoliosis, involves a lateral, or side-to-side, curvature of the spine. The vertebrae rotate along with the spine as a consequence of a scoliotic curve. Depending on the severity of the curve, a scoliotic spine may create asymmetries in the shoulders, thoracic spine, and pelvis, leading to an imbalance of the trunk and significant disfigurement.

Spinal Tumors Tumors or cancers of the spine and spinal cord are relatively rare. Three types of tumors affect the spine and spinal cord: primary benign tumors, primary malignant tumors, and metastatic tumors. The term primary is used to designate a tumor originating from actual spine cells. Secondary spinal tumors, or cancers, which are more commonly called metastases, spread from other organs in the body.

Trauma/Fracture Trauma to the spine refers to injury that has occurred to bony elements, soft tissues, and/or neurological structures. Stability to the spinal column can be compromised when bony elements are injured or there is disruption to soft tissues such as ligaments. Instability causes the back to become unable to successfully carry normal loads, which can lead to permanent deformity, severe pain, and, in some cases, catastrophic neurological injuries. Most often the instability comes from a fracture in one of the bony parts of the vertebra. Osteoporosis, a condition characterized by loss of bone mass and structural deterioration of bone tissue, can lead to bone fragility and an increased susceptibility to fracture.

Stenosis A condition caused by a gradual narrowing of the spinal canal, stenosis results from degeneration of both the facet joints and the intervertebral discs. Bone spurs, called osteophytes, which develop because of the excessive load on the intervertebral disc, grow into the spinal canal. The facet joints also enlarge as they become arthritic, which contributes to a decrease in the space available for the nerve roots.

Table of Contents

The charts below set forth net sales of our Spinal products as a percentage of our total net sales for each of the last three fiscal years:

Our Spinal products, include thoracolumbar, cervical and interbody devices that are employed utilizing the most modern surgical techniques, including the latest Minimal Access Spinal Technologies (MAST) along with bone growth substitutes, and devices for vertebral compression fractures and spinal stenosis.

Spinal Instrumentation. Each year approximately 25 million Americans experience back pain that is severe enough to visit a healthcare professional. Of the approximately 25 million Americans, 13 million endure a significant impairment of activity. We are committed to providing spinal surgeons with the most advanced options for treating low back pain and other spinal conditions.

Today we offer one of the industry s broadest lines of devices, including a wide range of sophisticated internal spinal stabilization devices, instruments, and biomaterials used in the treatment of spinal conditions. Spinal fusions, which are currently one of the most common types of spine surgery, join two or more vertebrae to eliminate pain caused by movement of the unstable vertebrae. Our Spinal products are used in spinal fusion of both the thoracolumbar region, referring to the mid to lower vertebrae, as well as of the cervical region, or upper spine and neck vertebrae. Products

used to treat spinal conditions include rods, pedicle screws, hooks, plates, and interbody devices, such as cages, as well as biologic products, which include bone growth substitutes, dowels and wedges.

In October 2007, we launched the CD HORIZON LEGACY Anterior Spinal System. The newest member of the CD HORIZON family offers an anterior (frontal) fixation solution for complex spinal surgery. The fixation system is designed to assist with stability of the thoracic and lumbar spine when performing modern spinal fusion surgery and may also help patients suffering from degenerative disc disease, trauma, tumors, severe curvatures and other degenerative diseases of the spine. The system features titanium construction, low profile screw design, top loading, top tightening screws, and color coding to make the procedure easier.

Dynamic Stabilization. In July 2007, we launched the PRESTIGE Cervical Disc, the first artificial disc commercially available in the U.S. for use in the neck. The PRESTIGE Cervical Disc gives some patients who are suffering from degenerative disc disease that can cause intolerable neck and/or arm pain the potential for motion at the treated level of the spine as well as another option for pain relief and restored function. With its patented ball-and-trough design, the PRESTIGE Cervical Disc is designed to maintain motion and flexibility while replacing a diseased disc that is removed during surgery. In July 2007, the Company also announced that the BRYAN Cervical Disc received a recommendation for approval from the U.S. FDA s Orthopedic and Rehabilitation Devices advisory panel. The BRYAN Cervical Disc, composed of a polyurethane nucleus surrounded by titanium endplates, is designed to replicate normal, physiologic motion of the cervical spine.

In addition to the PRESTIGE and BRYAN Cervical Discs we have two additional disc replacement programs currently under investigation in the U.S.: the MAVERICK Artificial Disc for the lumbar spine; and the PRESTIGE LP, our next generation lower profile cervical disc, made of unique ceramic titanium composite.

Table of Contents

Minimal Access Spinal Technologies. We have developed a series of MAST that facilitate safe, reproducible access to the spine with minimal disruption of vital muscles and complementary structures. These techniques involve the use of advanced navigation and instrumentation to allow surgeons to operate with smaller incisions and less tissue damage than traditional surgeries, thus reducing pain and blood loss and improving recovery periods.

Our expanding portfolio of minimally invasive spinal technologies includes the CD HORIZON SEXTANT II System, a next-generation METRx System, to treat herniated discs and allow minimally invasive access for fusion and the MAST QUADRANT Retractor System a retractor that allows access to complex degenerative pathology.

Biologics. Our INFUSE Bone Graft, used in spinal fusion, contains a recombinant human bone morphogenetic protein, or rhBMP-2, that induces the body to grow its own bone, eliminating the need for a painful second surgery to harvest bone from elsewhere in the body. In Europe, INFUSE Bone Graft is marketed as InductOs Bone Graft for spinal fusion. We also offer INFUSE Bone Graft for the treatment of certain types of acute, open fractures of the tibial shaft, a long bone in the lower leg, as well as certain oral maxillofacial indications.

In September 2006, we co-launched the MASTERGRAFT MATRIX and MASTERGRAFT PUTTY synthetic bone graft products, which were developed to provide surgeons with a comprehensive solution. Embedded with

MASTERGRAFT GRANULES, both grafts are osteoconductive, malleable, and designed to fill gaps in the skeletal system. These new grafts give surgeons more handling options, while providing an osteoconductive implant that localizes biologic components. These grafts are designed to aid cellular proliferation and osteointegration during the bone healing process. MASTERGRAFT MATRIX is a compressive-resistant collagen scaffold block that is designed to facilitate uninterrupted bone growth. MASTERGRAFT PUTTY is a malleable collagen scaffold that may be used with bone marrow aspirate or sterile water. When the hydrated graft is combined with local bone, it may provide more suitable handling characteristics for the surgical procedure. In May 2007, we announced the immediate, nationwide availability of PROGENIX DBM, a bone graft substitute and bone void filler used in voids or gaps of the pelvis, ilium, and extremities.

Late in April 2007, we began to market INFUSE Bone Graft for certain oral maxillofacial and dental regenerative bone grafting procedures. It is estimated that more than 350,000 bone grafting procedures of this type are performed in the U.S. each year. Medtronic has also submitted a pre-market approval (PMA) with the FDA for a posterolateral spinal indication for INFUSE Bone Graft.

Kyphon. During the third quarter of fiscal year 2008, we consummated the acquisition of Kyphon Inc. (Kyphon), a public company, and it became our wholly owned subsidiary. Kyphon develops and markets medical devices designed to restore and preserve spinal function using minimally invasive technology. Kyphon s primary products are used in balloon kyphoplasty for the treatment of spinal compression fractures caused by osteoporosis, trauma or cancer, and in the interspinous process decompression (IPD) procedure for treating the symptoms of lumbar spinal stenosis (LSS). In the U.S., Kyphon s X-STOP IPD Device provides us with the first FDA-approved minimally invasive device for the treatment of mild to moderate LSS patients. In Europe, both the X-STOP and the next generation Aperius PercLID device are available for the treatment of LSS.

It is expected that the acquisition of Kyphon will add to the growth of our existing Spinal business by extending its product offerings into some of the fastest growing product segments of the spine market, enabling us to provide physicians with a broader range of therapies for use at all stages of the care continuum.

Customers and Competitors

The primary medical specialists who use our Spinal products are spinal surgeons, orthopedic surgeons, neurosurgeons, and interventional radiologists. Our competitors in the Spinal business include Zimmer, Inc., Johnson & Johnson, Stryker Corporation, Synthes-Stratec, Inc., and over 200 small physician owned companies.