

MEDTRONIC INC  
Form 10-K  
June 29, 2005

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-K

Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934.

For the fiscal year ended April 29, 2005.

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

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**Medtronic, Inc.**

(Exact name of registrant as specified in charter)

Minnesota(State of incorporation)

41-0793183(I.R.S. Employer Identification No.)

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

Telephone Number: (763) 514-4000

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

Title of each class

Common stock, par value \$0.10 per share

Preferred stock purchase rights

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

None

Name of each exchange on which registered

New York Stock Exchange, Inc.

New York Stock Exchange, Inc.

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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  No

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 an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934).

Yes   x   No     o

Aggregate market value of voting stock of Medtronic, Inc. held by nonaffiliates of the Registrant as of October 29, 2004, based on the closing price of \$51.11, as reported on the New York Stock Exchange: approximately \$61.8 billion.

Shares of Common Stock outstanding on June 24, 2005: 1,213,729,424

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's 2005 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 2005 Annual Meeting are incorporated by reference into Part III.

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## Trademarks and Other Rights

This Report contains trademarks, service marks, and registered marks of Medtronic, Inc. and its subsidiaries, ( Medtronic or the Company ) and other companies, as indicated.

The following are registered and unregistered trademarks of Medtronic, Inc. and its affiliated companies:

Access®, Activa®, ADVANTAGE Supra®, AneuRx®, Attain®, Attain Select , Aurora , Bolus Wizard®, Bravo®, BRYAN®, CAPSTONE , Cardioblate®, Catalyst , CD HORIZON®, CD HORIZON LEGACY , CD HORIZON SEXTANT , CG Future®, CGMS®, Chronicle®, Clo-Sur P.A.D. , Crosslink®, CrossPoint®, Cypher®, Driver®, ECLIPSE®, Endeavor , EnPulse®, EnRhythm , Enterra®, EnTrust , EVS , Equestra , Freestyle®, Gatekeeper , GEM III®, GFX®, Guardian®, GuardWire Plus®, Hancock®, HOURGLASS , INFUSE®, InSync®, InSync Marquis , InSync Maximo , InSync Sentry , InSync II Marquis , Intercept , INTER FIX , InterStim®, Intrinsic , Kappa®, Kinetra®, KOBRA , Legend®, LIFENET®, LIFEPAK®, LIFEPAK CR , LT-CAGE®, Magellan®, Marquis®, MAVERICK , Maximo®, MAST , Medtronic CareLink®, Medtronic CareLink , Medtronic Hall®, Medtronic StimPilot , METRx , Micro-Driver , Mosaic®, Mosaic Ultra , MVP , Multi-Exchange , NIM-Response®, NIM-Spine , Octopus®, OptiVol , Paradigm®, Paradigm Link®, Pioneer , PoleStar , PRESTIGE®, Racer®, Restore , SEXTANT , Sprint Fidelis , Sprint Quattro®, Sprinter®, SPYDER , SST , Starfish®, StealthStation®, StimPilot , Stormer®, Strata®, SynchroMed®, Synergy®, Synergy Compact+ , Synergy Plus+ , Talent , TransAccess®, TUNA®, U-Clip , Urchin®, Vertex®, VERTE-STACK®, Vitatron®, Xcelerant and XPS®.

InductOs is a trademark of Wyeth.

## Annual Meeting and Record Dates

Medtronic's Annual Meeting of Shareholders will be held on Thursday, August 25, 2005 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 July 1, 2005 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](http://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](http://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.

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## 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 worldwide 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 compete.

We currently function in five operating segments that manufacture and sell device-based medical therapies. Our operating segments are:

Cardiac Rhythm Management (CRM)

Spinal, Ear, Nose and Throat (ENT) and  
Navigation

Neurological and Diabetes

Vascular

Cardiac Surgery

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 29, 2005 (fiscal year 2005).

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 have more than doubled, from \$5.016 billion in fiscal year 2000 to \$10.055 billion in fiscal year 2005. We attribute this growth to our continuing commitment to develop or acquire new products to treat an expanding array of medical conditions.

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 33,000 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 ensure consistent performance, that meet or surpass customers' expectations.

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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.

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

Our strategic objective is to provide patients and the medical community with comprehensive, life-long solutions for the management of chronic disease. Our key strengths parallel the following basic, but well-implemented, strategies that guide our growth and success:

Increase market share in core product lines.

Meet unmet medical needs by leveraging our technologies.

Broaden our global presence in developed and developing markets.

Ensure that people who could benefit from our device therapies increasingly have access to them.

Acquire or invest in breakthrough technologies to treat an increasing number of chronic diseases.

In this decade, we anticipate that technology advancements, the Internet and increasing patient participation in treatment decisions will transform the nature of healthcare services and will result in better care at lower cost to the healthcare system and greater quality of life and convenience to the patient.

#### Cardiac Rhythm Management

We are the world's leading supplier of medical devices for cardiac rhythm 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 greater than \$8 billion industry has emerged. Today, our products and technologies treat a wide variety of heart rhythm disorders.

### ***Conditions Treated***

Natural electrical impulses stimulate the heart's chambers (atria and ventricles) 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 heart failure and sudden cardiac arrest (SCA), one of the leading causes of death in the United States (U.S.). Physicians rely on our CRM products to correct these irregularities and restore the heart to its normal rhythm. Our CRM products are designed to treat a broad range of heart conditions, including those described below.

**Tachyarrhythmia** – heart rates that are dangerously fast or irregular, including ventricular tachycardia and fibrillation, which occur in the ventricles (the lower chambers of the heart) and can lead to SCA, as well as atrial arrhythmias, or rapid and inconsistent beating of the atria (the upper chambers of the heart), 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

**Bradycardia** – abnormally slow or unsteady heart rhythms (usually less than 60 beats per minute) that cause symptoms such as dizziness, fainting, fatigue, and shortness of breath

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

### ***Principal Products***

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 external defibrillators, leads, ablation products, electrophysiology catheters, navigation systems and information systems for the management of patients with our devices. Our CRM devices are currently implanted in nearly 2.0 million patients worldwide.

***Implantable Cardiac Rhythm Devices.*** 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. Medtronic is the world's leading provider of pacing systems, offering the broadest and most complete line of pacemakers, leads and related accessories. In May 2005, we announced U.S. Food and Drug Administration (FDA) approval of EnRhythm™, our newest dual-chamber pacemaker, which promotes natural heart activity by significantly reducing unnecessary pacing in the right ventricle. The EnRhythm device is the first-ever pacemaker to offer an exclusive pacing mode called MVP™ or Managed Ventricular Pacing, which enables the device to be programmed to minimize 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. EnRhythm joins our industry leading pacing product family which includes the EnPulse® pacemaker, the world's first completely automatic pacemaker. The EnPulse system incorporates an array of unique features to help

physicians optimize pacing therapy and simplify patient care including a pioneering feature called Atrial Capture Management (ACM), which enables the pacemaker to automatically adjust the electrical impulses delivered to the heart's upper right chamber.

Approximately 3 million people worldwide have tachyarrhythmia. Tachyarrhythmia is a potentially fatal condition that can lead to SCA, the sudden and complete cessation of heart activity. SCA is one of the leading causes of death in the U.S., responsible for more than 300,000 deaths annually, with most due to ventricular fibrillation. Defibrillators are the only therapy proven to stop these life-threatening episodes once they begin. Implantable cardioverter defibrillators (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 January 2005, the results of the landmark Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), sponsored by the National Institutes of Health (NIH), with funding provided by Medtronic and Wyeth, 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 January 2005, the Centers for Medicare and Medicaid Services (CMS) expanded coverage of ICDs for Medicare beneficiaries who meet SCD-HeFT indications. Despite the mounting evidence

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demonstrated in clinical trials such as SCD-HeFT, less than 20 percent of all patients who are indicated for an ICD actually receive one, leaving hundreds of thousands of people at an increased risk for sudden cardiac death. We offer the most comprehensive product choices to treat various kinds of tachyarrhythmias. In August 2004, we announced the FDA approval of our Intrinsic dual-chamber ICD, the world's first ICD with our new pacing mode MVP, which has been shown to reduce the amount of right ventricular pacing to less than 5 percent, compared to 50 percent or more from ICDs with typical dual-chamber pacing. In a clinical study of this new mode, 78 percent of patients experienced ventricular pacing less than 1 percent of the time. For patients with little or no pacing needs, this clinical difference can be dramatic over a lifetime.

Heart failure is a large and growing health problem, afflicting nearly 5 million Americans and 22 million people worldwide. Up to 550,000 new cases are diagnosed each year, making it the most costly cardiovascular illness in the U.S., with an estimated \$38 billion spent on managing heart failure each year. We have pioneered innovative device-based treatments for this progressive, debilitating disease. For patients suffering from heart failure, we offer devices that provide cardiac resynchronization therapy (CRT), which improves the efficiency of the heart by synchronizing the contractions of multiple heart chambers. Our InSync® CRT system is the world's first tri-chamber heart device. The InSync III, our third generation cardiac resynchronization device, has advanced programming functions to help physicians better manage heart failure patients and is available in both Europe and the U.S. In March 2005, the results of the Cardiac Resynchronization in Heart Failure (CARE-HF) trial were reported at the American College of Cardiology conference and concurrently published in the *New England Journal of Medicine*. This 813 patient study was the first of its kind to show that patients who received Medtronic's CRT showed a 37 percent reduction in combined all-cause mortality (death) or unplanned cardiovascular hospitalization. CRT patients in the study also showed a reduction in heart failure hospitalizations and improved heart failure symptoms.

The ICD market continues to experience significant expansion, driven by an increasing body of clinical data that clearly demonstrates the lifesaving benefits of ICD therapy. In addition to the results of the SCD-HeFT trial referenced above, in May 2004, the results of the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial were published in the *New England Journal of Medicine*. The results of this trial showed a 20 percent risk reduction in combined all-cause mortality or first all-cause hospitalization for heart failure patients

who received a cardiac resynchronization device with defibrillator back-up (CRT-D) and a 36 percent risk reduction in all-cause mortality for heart failure patients who received a CRT-D. Also building on SCD-HeFT's strong clinical data referenced above, in November 2004, compelling cost-effectiveness data was presented at the American Heart Association Scientific Sessions. The data showed that the cost to add one year of life for these heart failure patients with an implantable defibrillator is \$33,192. Medical therapies that add a patient year of life for \$50,000 or less, such as primary coronary stenting, are commonly considered to be cost-effective treatments, demonstrating that ICDs represent an economically attractive way to save lives.

In fiscal year 2005, we introduced several new devices and features for the growing number of patients with heart failure who are also considered at high risk of SCA. In June 2004, we launched our highest energy CRT-D device, the InSync Maximo, which incorporates proven CRT to treat heart failure and the capacity to deliver high-output defibrillation energy to stop a lethally fast heart rhythm. With 35 joules of delivered energy and the industry's fastest charge times, the InSync Maximo provides the highest margin of safety in treating SCA. In November 2004, we announced FDA approval of the InSync Sentry CRT-D, with our exclusive new OptiVol feature. InSync Sentry is the world's first implantable medical therapy offering automatic fluid status monitoring in the thoracic cavity, the chest area encompassing the lungs and heart. We believe that this feature will provide an advantage in managing heart failure, since thoracic fluid accumulation is a primary indicator of worsening heart failure and often results in patient hospitalizations. In April 2005, we announced FDA approval to add a new feature to both the InSync Maximo and the InSync Sentry. Sequential biventricular pacing or V-to-V (ventricle to ventricle) timing is the new 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. Both InSync Maximo and

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InSync Sentry, along with previously approved InSync II Marquis system, offer independent, programmable ventricular outputs and unique heart failure management reports, which are both designed to help physicians better manage each patient's specific heart failure condition. All of these systems also offer unique ICD therapies including anti-tachycardia pacing (ATP) options for the pain-free termination of life-threatening tachyarrhythmias. The continued introduction of these new CRT-D devices are an important clinical advance since SCA occurs in heart failure patients at six to nine times the rate observed in the general population.

Leads and associated delivery systems remain a significant contributor to our leadership in both the ICD and the heart failure markets. In August 2004, we announced the FDA approval of the Attain® 4194 Bipolar over-the-wire left-heart lead for use in cardiac resynchronization systems. The Attain 4194 is the fourth generation of left-heart leads designed for use with the Medtronic InSync family of CRT devices and is the first true bipolar lead that offers the unique advantage of pacing options. In September 2004, we announced the FDA approval of the Sprint Fidelis family of leads, the world's smallest defibrillation leads. The small size of the Sprint Fidelis lead helps improve passage into a patient's venous system for an easier implant and minimizes venous obstruction. In March 2005, we also announced the introduction of the Attain Select 6238 TEL Guide Catheter, which aids in the safe implantation of device leads in the veins that serve the left side of the heart for the treatment of heart failure. This catheter is part of a family of catheters that are highly specialized and innovatively designed to give physicians a broad range of choices as they work from outside the body to safely and effectively maneuver in tortuous veins between the lower chambers of the heart.

We continue to drive rapid technological advancement in therapies for heart failure and have next-generation devices in development. In March 2005, the results of the Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure (COMPASS-HF) clinical trial were presented at the American College of



Cardiology. COMPASS-HF evaluated the use of a new investigational device, the Chronicle implantable hemodynamic monitor that is designed to continuously track intracardiac pressure, body temperature, physical activity and heart rate in patients with heart failure. Study results showed a 22 percent reduction in combined heart failure-related hospitalizations, emergency department and urgent care visits among Class III and IV heart failure patients whose physicians had regular access to data transmitted from the Chronicle monitor. Amongst Class III heart failure patients, the reduction was 41 percent, which was statistically significant. Additionally, patient outcomes were improved as demonstrated by a 33 percent reduction in the proportion of patients that experienced worsening heart failure.

Most recently, in February 2005, we announced the European market release of the EnTrust ICD. The EnTrust family represents our next step in the delivery of premium implantable devices, which, in addition to MVP, will include for the first time, anti-tachycardia pacing during charging of the capacitor. As a result, the device is ready to deliver full power therapy when needed, but not before it attempts to painlessly pace the patient out of the potentially life-threatening rhythm. We expect to launch EnTrust in the U.S. later this calendar year.

In May 2005, we announced FDA approval to distribute a wireless-enabled, in-clinic programmer, the Medtronic CareLink® programmer (Model 2090). The new programmer version will enable wireless communication with implanted devices using high-speed data connectivity. This approval sets the foundation for efficient and flexible clinician access to important information retrieved from Medtronic devices that can help guide the care of chronic disease. Later this fiscal year, we also plan to launch a family of wireless implantable devices, including ICDs and CRT-Ds in the U.S. These new wireless devices will be compatible with the Medtronic CareLink Service.

**Patient Management.** To achieve optimal results from our CRM devices, physicians obtain diagnostic and therapeutic data collected by the device and then tailor various device parameters to meet the individual needs of each patient. This has historically required periodic office visits, which increase healthcare costs and can inconvenience patients. The Medtronic CareLink Service, currently available in the U.S., was developed to allow physicians to evaluate patient information remotely via the Internet, offering the potential for more efficient chronic disease management and better patient outcomes. The Medtronic CareLink Service is the first, and only, Internet-based service that connects cardiac device

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patients and physicians for virtual office visits allowing patients with our heart devices to receive medical care from the comfort of their home or even while traveling. Patients using the Medtronic CareLink Service can send data about their heart and ICD activity to their physician from anywhere in the 50 states by holding a small antenna over their implanted device. The system monitor automatically downloads the data from the antenna and sends it through a standard telephone connection directly to the secure Medtronic CareLink Service. Clinicians access their patients' data by logging onto the clinician website from any Internet-connected computer in their office, home or while traveling. Patients also can view information about their device and condition on their own personalized website, and family members or other caregivers can view this information if granted access by the patient. The Medtronic CareLink Service is currently available to pacemaker patients with the Kappa® family and EnPulse pacemakers and with any of our mainline ICDs or CRT-Ds. ICD and CRT-D devices compatible with the Medtronic CareLink Service include the Medtronic GEM III® family, Marquis® family, InSync family, and Maximo ICDs as well as our InSync Marquis , InSync II Marquis, InSync Maximo and InSync Sentry CRT-Ds. Today, the Medtronic CareLink Service is being utilized in more than 540 electrophysiology clinics/practices and more than 35,000 patients are being monitored with the Medtronic CareLink Service. In the future, thousands of people with our other implantable cardiac devices potentially could benefit from this innovative system, as it is designed to support all of our implanted cardiac rhythm devices.

**External Defibrillators.** Each day nearly 1,000 people die in the U.S. due to SCA; however, many could be saved if they had quicker access to automated external defibrillators (AEDs). Nationally, the survival rate for victims of SCA is only about 5% because the average response time to an emergency call for help is six to twelve minutes. Chances of survival are reduced significantly if the victim is not treated within five minutes. In August 2004, results from the largest-ever clinical trial studying the outcomes of public access to defibrillation were published in the *New England Journal of Medicine*. The data indicated that the use of portable AEDs by trained volunteers can significantly improve the probability of saving lives that otherwise might have been lost to SCA. Our LIFEPAK® series of external defibrillators offers a broad range of life-saving tools for multiple user needs and have been incorporated in environments ranging from hospitals to emergency medical units to public places such as airports, sports arenas, schools and workplaces. Today there are more than 500,000 LIFEPAK devices distributed worldwide. In February 2004, we announced collaborations with Walgreens Co. and Costco Wholesale Corporation to offer AEDs by prescription on their respective electronic commerce websites, [www.walgreens.com](http://www.walgreens.com) and [www.costco.com](http://www.costco.com). These partnerships are designed to help small businesses and consumers more easily access the life saving therapy of AEDs to protect their customers and their families. In April 2005, we announced the Keep the Beat cause campaign, a nationwide outreach and education program designed to raise awareness of SCA and the benefits of early defibrillation. The initial phase of the Keep the Beat cause campaign will raise funds to support Neighborhood Heart Watch, a non-profit organization that will help implement AED programs in schools across the country. AED placement in schools is important since up to 20 percent of the combined child and adult U.S. population can be found in schools on any given school day. AED programs in schools could mean the difference between life and death for students and educators and may make a tremendous impact on a community.

### ***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. The primary customers for our AED products are schools, governments, businesses, and any other public facility. Our primary competitors in the CRM business are Guidant Corporation and St. Jude Medical, Inc. Our primary competitors in the AED business are Cardiac Science, Inc., Zoll Medical Corporation and Royal Philips Electronics.

### **Spinal, Ear, Nose, and Throat and Navigation**

Our Spinal, ENT and Navigation business is well known for its innovative spinal products, commitment to customers and unsurpassed technical support. Strong partnerships with leading spinal

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surgeons help us pioneer new and effective ways to treat spinal conditions, and have propelled us to a solid position in the worldwide spine market. We entered the spine market with the acquisition of Sofamor Danek in fiscal year 1999. Also in fiscal year 2000, we acquired Xomed Surgical Products, Inc., a well established ENT surgical product manufacturing company. Today we offer a wide range of products and therapies to treat a variety of conditions of the cranium and spine that often dramatically impair the quality of life, as well as to treat diseases and conditions affecting the ear, nose and throat.

### ***Conditions Treated***

Our Spinal, ENT, and Navigation business offers products for treatment of the conditions described below.

Spinal conditions herniated discs, degenerated discs, spinal deformity, spinal tumors, trauma/fracture and stenosis

*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.

*Degenerated Disc* 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 (forward bend), and lower trunk (backward bend) 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 side-to-side (lateral) 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. The causes of scoliosis are numerous, yet for the majority of people who have it, the cause is not known.

*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.

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ENT conditions diseases and disorders affecting the ear, nose and throat such as chronic sinusitis and middle-ear infections

Navigation products for use in precision cranial, spinal, ENT, and orthopedic surgeries

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

### ***Principal Products***

Our Spinal, ENT, and Navigation products, used in surgical procedures of the cranium and spine, include thoracolumbar cervical and interbody, and spinal devices, bone growth substitutes, surgical navigation tools and surgical products used by ENT physicians.

***Spinal.*** Back pain is the second most cited reason for visits to a healthcare professional, after the common cold. 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, instruments, computerized image guidance products and biomaterials used in the treatment of spinal conditions, including a wide range of sophisticated internal spinal stabilization devices. Our spinal products are used in spinal fusion of both the thoracolumbar (mid to lower vertebrae) and cervical (upper spine and neck) regions of the spine. Spinal fusions, which are currently one of the most common types of spine surgery, join the vertebrae to eliminate pain caused by movement of the unstable vertebrae. Products used to treat spinal conditions include rods, pedicle screws, hooks, plates, and interbody devices, such as cages, as well as biologics, which include bone growth substitutes, dowels and wedges.

Our Spinal business is one of the industry leaders in the quest to find new surgical techniques that offer the potential to dramatically improve patient recovery by changing how surgeons access the spine. We have developed a series of Minimal Access Spinal Technologies (MAST™) that allow 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, blood loss and improving recovery periods. MAST techniques have been described as having the same impact on spinal fusion surgery that arthroscopy had on knee surgery. Our expanding portfolio of minimally invasive spinal technologies includes the CD HORIZON® SEXTANT System, to provide percutaneous spinal fixation, the METRx System, to treat herniated discs and allow minimally invasive access for fusion, the MAST QUADRANT Retractor System, a retractor that allows access to complex degenerative pathology, and the CD HORIZON ECLIPSE® Spinal System, to correct curvature of the spine in scoliosis patients.

Introduced in July 2002, INFUSE® Bone Graft with an interbody device has become what we believe to be the standard of care in spinal fusion therapy. INFUSE Bone Graft contains a recombinant

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human bone morphogenetic protein, or rhBMP-2, which induces the body to grow its own bone, eliminating the need for a painful second surgery to harvest bone from elsewhere in the body. This product resulted from a strategic alliance with Wyeth and demonstrates our commitment to the advancement of science in the spine field. In May 2004, we announced that the FDA approved the use of INFUSE Bone Graft in the treatment of certain types of acute, open fractures of the tibial shaft, a long bone in the lower leg. The approval broadens the indications for the use of our revolutionary INFUSE Bone Graft technology. Since April 2005, we have the right to market InductOs Bone Graft (known as INFUSE Bone Graft in the U.S.) for use with certain sizes of the LT-CAGE® Lumbar Tapered Fusion Device for single-level lumbar spinal fusion in adults.

The CD HORIZON® LEGACY Spinal System, one of the most comprehensive spinal systems on the market today, has been instrumental in driving growth throughout the fiscal year. The system provides tools for the treatment

of certain types of deformity in patients and specific posterior solutions for smaller patients. The CD HORIZON LEGACY Spinal System offers multiple rod diameters (6.35, 5.5, 4.5, 3.5 mm), incorporates iliac fixation and provides implants in both titanium and stainless steel. Our CD HORIZON LEGACY Spinal System has become widely accepted in the U.S., with one in four thoracolumbar fusion surgeries utilizing this technology.

We are pursuing a broad array of stabilization and dynamic stabilization solutions for patients suffering from degenerative disc disease. In April 2005, we announced the beginning of enrollment in the PRESTIGE® LP Cervical Disc clinical trial, our fourth major artificial disc trial. In addition to the PRESTIGE LP Disc trial, we have three other disc replacement programs currently under investigation in the U.S.: the BRYAN® Cervical Disc, obtained through the acquisition of Spinal Dynamics Corporation (SDC) in October 2002; the MAVERICK Artificial Disc for the lumbar spine; and the PRESTIGE ST Cervical Disc, an internally developed cervical disc. In the second half of calendar 2004, we announced the completion of patient enrollment in our U.S. pivotal clinical trials for the BRYAN, MAVERICK and PRESTIGE ST Discs. The BRYAN, MAVERICK, PRESTIGE ST, and PRESTIGE LP Discs are commercially available outside the U.S.

Through the settlement with Gary Michelson, M.D. and Karlin Technology, Inc. (Michelson) (see Acquisitions and Investments for further discussion) we acquired approximately 100 issued U.S. patents, more than 110 pending U.S. patent applications and numerous foreign counterparts to these patents. The patents pertain to novel spinal technology and techniques that have both current application and the potential for future patentable commercial products.

**ENT.** We are a developer of products to treat people with diseases of the ear, nose, and throat. Our main products include powered tissue-removal systems and other microendoscopy instruments, implantable devices, nerve monitoring systems, disposable fluid-control products, image-guided surgery systems, and a Ménière's treatment device. We also offer a line of ophthalmic products. These products are dramatically changing the way ENT medical procedures are performed by replacing highly invasive procedures with new minimally invasive instruments and techniques.

**Navigation.** Our image guided surgery systems are sophisticated multi-dimensional imaging and navigation technologies that enable surgeons to optimize their surgical plans and use this advanced surgical information during precision cranial, spinal, ENT, and orthopedic surgeries. We are one of the leaders in the field of computer-assisted surgery (CAS) and have installed approximately 2,000 StealthStation® Treatment Guidance Systems in hospitals worldwide. In recent years, the pace of innovation in CAS has quickened considerably. In response, we have developed and delivered new and updated hardware and software solutions to assist with varied surgeries including total joint replacements, minimally invasive spinal surgery, cranial tumor resection, biopsies, functional neurosurgery and functional endoscopic sinus surgery.

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### ***Customers and Competitors***

The primary medical specialists who use our Spinal and Navigation products are spinal surgeons, orthopedic surgeons and neurosurgeons. The primary medical specialists who use our ENT products are ENT surgeons (otolaryngologists). Our primary competitors in the Spinal business are Zimmer Inc., Johnson & Johnson, Inc., Stryker Corporation, and Synthes-Stratec, Inc. The primary competitors in our Navigation business are BrainLAB, Inc. and Stryker Corporation, and the most significant competitors in the ENT business are Gyrus Group PLC and Stryker Corporation.

## Neurological and Diabetes

Our Neurological and Diabetes business develops, manufactures, and markets devices for neurological disorders, diabetes, gastroenterological disorders and urological disorders. We are a pioneer in the field of restorative neuroscience, using site-specific neurostimulation and drug delivery to modulate and restore function of the central nervous system. Through close partnerships with our customers we have developed a unique portfolio of diagnostic and therapeutic products for the treatment of some of the most debilitating neurological disorders. We are applying our proprietary stimulation technologies to develop effective therapies for intractable chronic diseases throughout the body, including chronic pain, gastroenterology and urology, three underserved market segments with large, unmet medical needs. We are also a world leader in advanced, device-based medical systems for the treatment of diabetes, and we are committed to providing improved tools and technologies to help people with diabetes live longer, healthier lives.

In the fourth quarter of fiscal year 2005 we created a new Obesity Solutions business. The Obesity Solutions business was formed to focus on developing and marketing device technologies to address the epidemic of obesity. Approximately 65 million Americans are defined as obese and it is estimated that obesity costs the U.S. healthcare system more than \$100 billion per year. Obesity has also been shown to increase the risk of developing other serious conditions such as diabetes, heart disease, high blood pressure, stroke and cancer.

***Conditions Treated***

Our Neurological and Diabetes business offers products for the treatment of the conditions described below.

Neurological disorders including Parkinson's disease, essential tremor, chronic pain, spasticity, dystonia, hydrocephalus and traumatic brain injury

Diabetes inability to control blood glucose levels resulting from a failure of the pancreas to produce sufficient insulin or the body's inability to properly use insulin

Gastroenterology and urology disorders including gastroparesis, gastroesophageal reflux disease (GERD), incontinence and enlarged prostate (benign prostatic hyperplasia)

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

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***Principal Products***

Our Neurological and Diabetes products consist of therapeutic and diagnostic devices, including implantable neurostimulation systems, external and implantable drug administration devices, neurosurgery products, urology products, gastroenterology products, hydrocephalic shunts and drainage devices, surgical instruments, functional diagnostic and sensing equipment and medical systems for the treatment of diabetes.

***Neurological.*** We produce implantable systems that deliver drugs or electrical stimulation to the spinal cord and brain to treat pain and movement disorders. During fiscal year 2005, we advanced our portfolio of such systems, with the full launch of the SynchroMed® II programmable pump system. This technology is implanted by physicians for the treatment of chronic pain and the management of severe spasticity associated with cerebral palsy, multiple sclerosis, stroke, brain injury and spinal cord injury. The SynchroMed II pump's smaller size and contoured shape is

designed to enhance patient comfort, and the system also enables customized programming and reduced physician management burden. In December 2004, the FDA approved Prialt, a new biologic manufactured by Elan Corporation, which is used with both the SynchroMed EL and the SynchroMed II for the treatment of chronic pain. Prialt joins morphine and baclofen as drugs approved for intrathecal delivery by our implantable neurological pumps. Going forward, we anticipate pursuing development of drug delivery-based therapies utilizing additional biologics and drug compounds. In February 2005, we entered into an agreement with Alnylam Pharmaceuticals, Inc. (Alnylam) to collaboratively research such opportunities, specifically in the area of neurodegenerative disorders such as Huntington's, Alzheimer's and Parkinson's disease. Alnylam is a Cambridge, Massachusetts-based leader in ribonucleic acid (RNA) interference technologies.

As in implantable programmable pumps, we are also a world leader in neurostimulation technology and took steps to improve our range of solutions during fiscal year 2005. In September 2004, we introduced the Medtronic StimPilot System for use during implant procedures involving our deep brain stimulation (DBS) technologies, including the Kinetra® Neurostimulator and DBS Leads used with the Access® Therapy Controller. The system is designed to make DBS surgery less difficult and more efficient for medical providers, specifically through reducing capital costs associated with traditional equipment and integrating imaging and microelectrode recording capabilities to facilitate optimal therapy targeting within the brain. The StimPilot represents one step of many that we have taken or will pursue in order to improve patient access to the dramatic benefits of DBS therapy.

Additionally, in fiscal year 2005 we continued to make progress in clinical trials designed to extend the application of our neurostimulation technologies to new neurological disorders from which patients suffer. In September 2004, we announced the first implant in ONSTIM (Occipital Nerve Stimulation for the Treatment of Intractable Migraine), a preliminary study to evaluate neurostimulation for treatment of chronic migraine headache. We estimate that approximately 40,000 people in the U.S. do not respond to existing treatments for this condition, and many may be candidates for an alternative therapy such as that under testing in the ONSTIM trial.

Other trials we have underway in neurostimulation include the SANTE (Stimulation of the Anterior Nucleus of the Thalamus for Epilepsy) study for the Intercept Epilepsy Control System, our deep brain stimulation therapy for patients with epilepsy. Epilepsy is a condition that affects more than 2.5 million Americans, and about one-third of these people do not respond to current treatment options and continue to experience seizures. With the goal of achieving leadership in the area of deep brain stimulation for psychiatric disorders, we are also evaluating our technologies in patients suffering from treatment-resistant depression and in fiscal year 2006 are targeting the receipt of a Humanitarian Device Exemption (HDE) from the FDA in order to offer Activa® Deep Brain Stimulation Therapy for the treatment of chronic, treatment-resistant obsessive-compulsive disorder (OCD).

We have the medical device industry's broadest offering of implantable neurostimulators designed to treat chronic debilitating pain, including our Restore Rechargeable Neurostimulation System, approved in late fiscal year 2005 to deliver therapy through one or two leads surgically placed near the spinal cord. The Restore system is indicated to manage chronic, difficult-to-treat pain in the trunk and/or multiple limbs that is associated with failed back syndrome, post laminectomy pain, unsuccessful disc

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surgery or degenerative disc disease, among others. Unlike a conventional neurostimulation technology, physicians and patients may use the Restore system to treat such pain using high levels of stimulation without the compromise of premature, permanent battery depletion. The Restore system is characterized by the most powerful rechargeable battery on the market, lengthy recharge intervals for patient convenience and advanced, easy-to-use programming capabilities. We expect the Restore system to represent an increasingly significant portion of our product mix in fiscal

year 2006, and to add to our leading portfolio of neurostimulation technologies for the treatment of chronic pain with the introduction of the Synergy Plus and Synergy Compact+ systems.

Our Strata® valve is a shunt used in the treatment of hydrocephalus, an abnormal accumulation of cerebrospinal fluid in the ventricles of the brain. The Strata valve diverts excess cerebrospinal fluid from the brain cavity to the abdomen where it becomes reabsorbed by the body. Each year, about 180,000 people worldwide receive a hydrocephalic shunt. Our neurological product group also includes powered surgical tools, including pneumatic and electrical instrumentation devices for surgical dissection of bones, biomaterials, bioceramics and bioplastics, as well as instruments for use in orthopedic, otolaryngological, maxillofacial and craniofacial procedures.

**Diabetes.** Diabetes is a condition in which the body cannot properly use energy from food, resulting in uncontrolled blood sugar levels. Diabetes has been described as an epidemic, afflicting nearly 200 million people worldwide. Approximately 18 million people have diabetes in the U.S., where it is now the sixth leading cause of death. Currently, our products serve the insulin dependent population, which includes over four million people in the U.S. The key to managing diabetes is to maintain tight control of blood glucose levels. If not well-managed, diabetes can lead to blindness, kidney failure and amputation. In fact, diabetes is the leading cause of new cases of blindness (among twenty to seventy-four year olds), end-stage renal disease, and non-traumatic lower-limb amputations in the U.S. Diabetes is also a major factor in both heart disease and impotence. As a result, diabetes is the most costly, chronic condition facing the U.S. healthcare system, with more than \$130 billion spent annually on diabetes and its complications, including \$92 billion in direct medical costs.

Our diabetes products are used for intensive insulin management and include external pumps and related disposables, continuous glucose monitoring systems, an implantable insulin pump (which has received CE Mark, but not yet cleared for marketing in the U.S.) and an implantable glucose sensor, which is currently in testing and not yet approved for commercialization. Our pumps are primarily used by patients with Type 1 diabetes, which occurs when the pancreas is unable to produce insulin. In order to survive, people with Type 1 diabetes must administer insulin using injections or an insulin pump. Our therapies are also helpful in managing Type 2 diabetes, which results from the body's inability to produce enough insulin or properly use the insulin.

Our family of Paradigm® insulin infusion pumps are currently a leading choice in insulin pump therapy. Worn on a belt like a pager, the Paradigm insulin infusion pump offers a simplified and intuitive menu system to program insulin delivery, making it easier for people with diabetes to manage their disease without injections. Because pump therapy is more predictable than injections of insulin, it helps diabetes patients better control their glucose levels within a near-normal range, offering both short-term and long-term health benefits. In support of this, in July 2004, *Diabetes Care* published results from a study demonstrating improved HbA1c levels (a measure of glycemic control) in pediatric patients using a Medtronic insulin pump, relative to patients who continued to use multiple daily injection therapy.

In November 2004, we announced the FDA clearance of our next generation intelligent insulin pump and glucose monitoring system. The wireless system is comprised of a Paradigm 515 or larger reservoir sized Paradigm 715 Insulin Pump with an enhanced Bolus Wizard® calculator, a Paradigm Link® Blood Glucose Monitor (co-developed with Becton, Dickinson and Company) and access to Medtronic CareLink Service for Diabetes, an online portal through which uploaded glucose values and other information is made available to patients in order to better enable self-management. In the future, Medtronic CareLink Service for Diabetes is expected to incorporate a healthcare professional portal to facilitate the exchange of information between patients and their healthcare professionals, as well as to provide healthcare professionals with online access to consolidated reports and simple tools to assess and refine therapy. We expect these tools to greatly simplify pump therapy initiation and ongoing fine tuning adjustments associated with improving disease management.



Looking forward, we intend to further integrate advanced diabetes management technologies into our portfolio and with one another. In August 2004, we received FDA approval of our Guardian® RT technology, a leading continuous glucose monitoring device that provides users with frequent, automated and accurate blood glucose readings. The Guardian RT and subsequent generation technologies will form the basis of our planned sensor-augmented and external closed-loop pump technologies. We intend to introduce the world's first sensor-augmented pump therapy system (consisting of a Guardian RT and a Paradigm 522 or 722 pump, among ancillary technologies) later this fiscal year. A feasibility study presented at the annual meeting of the American Diabetes Association in June 2004 highlighted trends toward improved glucose levels among patients using our sensor-augmented pump technology. We expect to test this technology more extensively in the upcoming STAR (Sensor Augmented Therapy for A1c Reduction) trials, which evaluate sensor-augmented therapy versus traditional pump therapy and multiple daily injection therapy. It is our aim to drive acceptance and improved reimbursement for pump therapy using the results anticipated from the STAR series of trials.

***Gastroenterology and Urology.*** Our diagnostic and therapeutic products for gastroenterology and urology include the Enterra® Therapy for gastroparesis, the Bravo® pH Monitoring System and Gatekeeper® Reflux Repair System for the evaluation and treatment of GERD. Our gastroenterology and urology products also include our InterStim® Therapy device for urinary and bowel control, our TUNA® (transurethral needle ablation) Therapy for enlarged prostate, and our functional diagnostic equipment.

During fiscal year 2005, we succeeded in achieving increased penetration of our minimally invasive and stimulation-based diagnostics and therapies. InterStim therapy for the treatment of incontinence remains our largest product line in the area of gastroenterology and urology. Thanks to market development efforts, InterStim therapy is increasingly accepted by physicians as an effective treatment option for bladder control problems. Likewise, our Bravo pH diagnostic, a minimally invasive technology that encapsulates a small radiotransmitter for use in assessing pH levels and monitoring gastric reflux, is becoming more widely recognized by physicians and patients for allowing subjects to enjoy their regular diet and activities without the embarrassment and discomfort associated with traditional pH testing.

Our Gastroenterology and Urology unit also offers the minimally invasive TUNA Therapy for treatment of enlarged prostate. TUNA Therapy realized strong growth during fiscal year 2005, and was recognized in the June issue of the *Journal of Urology* for enabling targeted patient outcomes in a trial comparing it with an established treatment option (tissue removal surgery).

### ***Customers and Competitors***

The primary medical specialists who use our neurological products are neurosurgeons, neurologists, pain management specialists, and orthopedic spine surgeons. The primary medical specialists who use our diabetes products are endocrinologists and internists, and those who use our gastroenterology and urology products are urologists, urogynecologists and gastroenterologists. Our primary competitors for neurological products are Advanced Neuromodulation Systems, Inc., Johnson & Johnson, Inc., Boston Scientific Corporation and Stryker Corporation. Our most significant competitors for diabetes products are Animas Corporation, Roche Ltd. and Smiths Group PLC. Our primary competitors for gastroenterology and urology products are Boston Scientific Corporation and Urologix, Inc.

### **Vascular**

Our Vascular business offers a full line of innovative, minimally invasive products and therapies to treat coronary artery disease, peripheral vascular disease, and aortic aneurysms. The interventional vascular market is large, dynamic and driven by technological innovation. We are committed to building upon our competitive position in the vascular

marketplace by developing and acquiring market-leading products and technologies to treat vascular disease. We strengthened our Coronary Vascular business and intellectual property position with the acquisition of Arterial Vascular Engineering (AVE) in fiscal year 1999.

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### ***Conditions Treated***

Our Vascular business offers minimally invasive products for the treatment of the conditions described below.

Coronary artery disease deposits of cholesterol and other fatty materials (plaque) on the walls of the heart's arteries, causing narrowing or blockage of the vessel and reducing the blood supply to the heart

Peripheral vascular disease narrowing or blockage of arteries or veins outside the heart, impeding blood supply to vital organs

Abdominal/Thoracic aortic aneurysm (AAA/TAA) weakening, and ballooning of the abdominal aorta and weakening or dissection of the thoracic aorta

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

### ***Principal Products***

Our Vascular products include coronary, endovascular, and peripheral stents and related delivery systems, stent graft systems, distal embolic protection systems and a broad line of balloon angioplasty catheters, guide catheters, guidewires, diagnostic catheters and accessories.

***Coronary Stents.*** If a blockage in a coronary artery prevents the heart from receiving sufficient oxygen, the heart cannot function properly and a heart attack or stroke may result. Coronary artery disease is commonly treated with balloon angioplasty, a procedure in which a special balloon is threaded through the coronary artery system to the site of the arterial blockage, where it is inflated, pressing the obstructive plaque against the wall of the vessel to improve blood flow. In July 2004, we announced the FDA approval of the Sprinter<sup>®</sup> Semi-Compliant Over-the-Wire Balloon dilatation catheters designed to treat the most challenging coronary lesions. The Sprinter joins the NC Stormer<sup>®</sup> family of balloons which have been designed to address the needs of cardiologists in the era of drug-eluting stents.

Following balloon angioplasty, physicians often place coronary stents at the blockage site to prop open diseased arteries to maintain blood flow to the heart. Stents are cylindrical, wire-mesh devices small enough to insert into coronary arteries. Our new-generation coronary stent system, the Driver<sup>®</sup>, is the first modular stent to be composed of an advanced cobalt-based alloy, which surpasses the limitations of stainless steel by creating very strong, ultra-thin struts that offer excellent flexibility and vessel support. The Driver stent launched in Japan in August 2004 and is now available in all major markets worldwide.

***Coating Technologies.*** Like other companies in the stent market, we are developing stents with drug coatings, known as drug-eluting stents, to inhibit the re-narrowing or re-clogging of arteries, known as restenosis, after placement of a stent. Our Endeavor Drug-Eluting Coronary Stent combines an innovative delivery system leveraging our discrete technology, our advanced Driver cobalt-alloy stent, an effective drug ABT-578 (a rapamycin analogue), and a proprietary polymer coating that controls the release of the drug into the vessel wall. In May 2002, we entered

into a ten year agreement with Abbott

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Laboratories (Abbott) granting us co-exclusive use of Abbott's proprietary immunosuppressant drug ABT-578, as well as the phosphoryl choline coating Abbott has licensed from Biocompatibles International PLC for use in conjunction with ABT-578. Clinical studies have shown that this proprietary biocompatible polymer is a safe, polymeric drug-eluting platform.

Our Endeavor Drug-Eluting Coronary Stent clinical trial program achieved a number of significant milestones during fiscal year 2005. In May 2004, 12-month data for ENDEAVOR I was presented at the Paris Course on Revascularization demonstrating favorable results. In March 2005, the positive results of the ENDEAVOR II Pivotal Clinical Trial were presented at the American College of Cardiology annual scientific session. The ENDEAVOR II trial included 1,197 patients comparing the Endeavor Drug-Eluting Coronary Stent to Medtronic's Driver cobalt-alloy stent. In September 2004, we completed patient enrollment in the third clinical trial in our drug-eluting stent program, ENDEAVOR III, a 436-patient equivalency study comparing our Endeavor Drug-Eluting Coronary Stent to the Johnson & Johnson, Inc. Cypher<sup>®</sup> Sirolimus-eluting stent. We expect to present the results of this trial in October of this year at the Transcatheter Cardiovascular Therapeutics (TCT) annual symposium. In the fourth quarter of fiscal year 2005, we began patient enrollment in, ENDEAVOR IV, the fourth and final phase of our U.S. clinical program for the Endeavor Drug-Eluting Stent. ENDEAVOR IV will include more than 1,500 patients randomized one-to-one against the Taxus Paclitaxel-Eluting Coronary Stent System from Boston Scientific Corporation. We continue to progress toward the European and U.S. launches of our Endeavor Drug-Eluting Stent, which will be the first drug-eluting stent utilizing the advanced technology of a cobalt-alloy stent. We expect to release the Endeavor Drug-Eluting Coronary Stent in Europe and many emerging markets in the first half of fiscal year 2006 and in the U.S. during calendar 2007.

***Embolic Protection System.*** Embolic protection systems are designed to capture debris dislodged from the wall of the vessel, during balloon angioplasty or placement of a stent, that might otherwise flow downstream toward the heart and result in complications such as a heart attack or stroke. Our GuardWire Plus<sup>®</sup> System is the first embolic protection system commercially available in the U.S. and is indicated for use in vein graft interventions for certain individuals who have previously undergone coronary artery bypass graft surgery.

***Endovascular Stent Grafts and Peripheral Stents.*** Our Vascular product line includes a range of endovascular stent grafts and other peripheral vascular products. These include the market-leading AneuRx<sup>®</sup> and Talent<sup>®</sup> Stent Grafts for minimally invasive AAA and TAA repair. Our AneuRx Stent Graft system is available in the U.S. and Europe, while the Talent Stent Graft system is available only in Europe. In November 2004, we announced the FDA approval of the Xcelerant<sup>®</sup> Delivery system for use with the AneuRx Stent Graft. The Xcelerant Delivery system is designed to provide physicians with a smooth, controlled and more trackable delivery platform. The Xcelerant Delivery system is also available for use with the Talent Stent Graft in markets outside the U.S. We also offer balloon expandable and self-expanding biliary stents that are designed to maintain bile flow in liver ducts restricted or blocked by malignant tumors. In August 2003, we announced FDA clearance of our next generation Aurora<sup>®</sup> Self-Expandable Stent System and in November 2003, our Racer<sup>®</sup> Biliary Stent became the first cobalt-alloy biliary stent commercially available for use in the U.S.

***Vascular Closure.*** In November 2004, we announced the acquisition of Angiolink Corporation (Angiolink) (see Acquisitions and Investments), a privately held medical device company focused on developing innovative wound closure solutions for vascular procedures. Angiolink's EVS (Expanding Vascular Stapling) Vascular Closure System, which received FDA approval in November 2004, is engineered to close the femoral artery access site after

vascular procedures, such as diagnostic angiography, balloon angioplasty and stenting. Vascular closure is an emerging market and complementary to Medtronic's coronary and peripheral vascular businesses. Physicians use vascular closure systems to close arteries used as entry or access sites into the body for vascular procedures, such as coronary stenting and angioplasty. The EVS system provides safe and effective mechanical closure of arterial puncture sites without disturbing the lumen, or interior, of the targeted vessel. The system can be used by a single operator and is designed to apply a titanium staple that stabilizes and closes the artery. The system is designed to quickly stop access site bleeding and contribute to reducing patient recovery time.

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### ***Customers and Competitors***

The primary medical specialists who use our products for treating coronary artery disease are interventional cardiologists, while products treating peripheral vascular disease may be used by interventional radiologists, vascular surgeons and interventional cardiologists. Our primary competitors in the Vascular business are Boston Scientific Corporation, Guidant Corporation and Johnson & Johnson, Inc.

### **Cardiac Surgery**

We have competed in the Cardiac Surgery marketplace for over two decades, and are a worldwide market leader with solid platforms in revascularization, heart valve repair and replacement, and blood management. We offer cardiac surgeons the industry's broadest range of products for use in the operating room. Together our Cardiac Surgery, CRM and Vascular businesses offer an extensive array of products and services for cardiac care.

### ***Conditions Treated***

Our cardiac surgery products are used in the treatment of the conditions described below.

Coronary artery disease    blockage in a coronary artery can prevent the heart from receiving sufficient oxygen, which prevents the heart from functioning properly and a heart attack or stroke may result

Heart valve disorders    diseased or damaged heart valves can restrict blood flow or leak, which limits the heart's ability to pump blood, causing the heart to work harder to meet the needs of the circulatory system

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

### ***Principal Products***

Our Cardiac Surgery products consist of positioning and stabilization systems for beating heart surgery, perfusion systems which warm, oxygenate, and circulate a patient's blood during arrested heart surgery, products for the repair and replacement of heart valves, surgical accessories and epicardial ablation products.

***Coronary Artery Bypass Surgery.***    When physicians determine that they cannot effectively treat a blockage in a coronary artery using balloon angioplasty or a stent, they typically turn to cardiac surgery to address the problem. The most common surgical procedure used to treat blockage in a coronary artery is a coronary artery bypass graft (CABG). In a CABG procedure, surgeons re-route the blood flow around the blockage by attaching a graft, usually from an artery or vein from another part of the patient's body, as an alternative pathway to the heart. There are two

primary techniques, arrested heart surgery and beating heart surgery described as follows.

**Arrested Heart Surgery.** In a conventional coronary artery bypass procedure, the patient's heart is temporarily stopped, or arrested. The patient is placed on a circulatory support system that temporarily

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replaces the patient's heart and lungs and provides blood flow to the body. We offer a complete line of blood-handling products that form this circulatory support system and maintain and monitor blood circulation and coagulation status, oxygen supply and body temperature during open heart surgery. As beating heart surgery has become more popular (see below), the market for arrested heart surgery products has been declining. For patients undergoing cardiac surgery, who also suffer from atrial arrhythmias, our Cardioblate® Ablation System is designed to allow surgeons to efficiently restore a normal heart rhythm by neutralizing the cells causing troublesome electrical activity. In December 2004, the first patient was enrolled in the CAFÉ (Cardioblate Atrial Fibrillation) Study, the world's first prospective, randomized, blinded trial to study surgical ablation for the treatment of atrial fibrillation. In May 2005, we announced the U.S. commercial introduction of Cardioblate® BP2 (Bipolar) System, the latest addition to our Cardioblate surgical ablation systems, which offers cardiac surgeons new ease and flexibility in creating ablation lines during open heart procedures.

**Beating Heart Surgery.** As an alternative to conventional bypass surgery, physicians are performing coronary artery bypass surgery on the beating heart to avoid the complexity and potential risks of arresting the heart. To assist physicians performing beating heart surgery, we offer positioning and stabilization technologies. These technologies include our Starfish® 2 and Urchin® heart positioners, which use suction technology to gently lift and position the beating heart to expose arteries on any of its surfaces. These heart positioners are designed to work in concert with our Octopus® tissue stabilizer, which holds a small area of the cardiac surface tissue nearly stationary while the surgeon is suturing the bypass grafts to the arteries. It is currently estimated that beating heart surgeries make up about 20% of the more than 300,000 coronary artery bypass surgeries that take place in the U.S. each year. In April 2004, the results of a study published in the *Journal of the American Medical Association* provided compelling evidence of the benefits of performing CABG surgery while the patient's heart is still beating.

**Heart Valves.** We offer a complete line of valve replacement and repair products for damaged or diseased heart valves. Our replacement products include both tissue and mechanical valves. The valve market continues to shift from mechanical to tissue valves, which is beneficial to us due to our broad selection of tissue valve products. Our Mosaic® bioprosthetic heart valve is a reduced-profile valve engineered from porcine tissue incorporating a proven flexible stent. The low profile and flexibility of the stent make it easier for the surgeon to implant the valve. Earlier this calendar year we released our newest tissue valve, the Mosaic Ultra . The Mosaic Ultra valve includes a reduced sewing ring profile that facilitates the use of a larger valve. Other tissue product offerings include the Freestyle® stentless and Hancock® II stented valves. Our mechanical heart valve offerings include the Medtronic Hall®, the ADVANTAGE and the ADVANTAGE Supra® bileaflet valves. The ADVANTAGE Supra valve was released in Europe in November 2003 and is designed to allow the implantation of a larger valve thereby optimizing blood flow. Currently, the standard ADVANTAGE bileaflet valve is in U.S. clinical evaluation. Our valve repair products include the Duran Flexible and CG Future® Band Annuloplasty Systems.

### **Customers and Competitors**

The principal medical specialists who use our cardiac surgery products are cardiac surgeons. Our primary competitors in the Cardiac Surgery business are Edwards LifeSciences Corporation, Guidant Corporation, Johnson & Johnson, Inc., and St. Jude Medical, Inc.

## Research and Development

Our research and development staff regularly works with clinicians at medical and academic institutions in the development of new technologies and the evaluation and testing of our products. These relationships are valuable in generating data necessary for regulatory compliance. During fiscal years 2005, 2004 and 2003, we spent \$951.3 million (9.5% of net sales), \$851.5 million (9.4% of net sales) and \$749.4 million (9.8% of net sales), on research and development, respectively. Our research and development activities include improving existing products and therapies, expanding their applications for use, and developing new products.

The markets in which we participate are subject to rapid technological advances. Constant improvement of products and introduction of new products is necessary to maintain market leadership. Our

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research and development efforts are directed toward maintaining or achieving technological leadership in each of the markets we serve in order to assure that patients using our devices and therapies receive the most advanced and effective treatment possible. We are committed to developing technological enhancements and new indications for existing products, as well as less invasive and new technologies to address unmet patient needs and to help reduce patient care costs and length of hospital stays. We have not engaged in significant customer or government sponsored research.

## Acquisitions and Investments

Our strategy to provide a broad range of therapies to restore patients to fuller, healthier lives requires a wide variety of technologies, products and capabilities. The rapid pace of technological development in the medical industry and the specialized expertise required in different areas of medicine make it difficult for one company alone to develop a broad portfolio of technological solutions. In addition to internally generated growth through our research and development efforts, historically we have relied, and expect to continue to rely, upon acquisitions, investments, and alliances to provide access to new technologies both in areas served by our existing businesses as well as in new areas.

We expect to make future investments or acquisitions where we believe that we can stimulate the development of, or acquire, new technologies and products to further our strategic objectives and strengthen our existing businesses. Mergers and acquisitions of medical technology companies are inherently risky and no assurance can be given that any of our previous or future acquisitions will be successful or will not materially adversely affect our consolidated results of operations, financial condition, or cash flows.

On June 24, 2005, we announced we had entered into an agreement to acquire all of the outstanding stock of Transneuronix, Inc. (TNI) for approximately \$260.0 million in cash, subject to purchase price increases, which would be triggered by the achievement of certain milestones. We had an existing \$28.8 million equity investment in TNI, which is accounted for under the cost method. TNI is a privately-held company that develops implantable gastric stimulation systems for use in obesity therapy. The acquisition is expected to be completed in the first quarter of fiscal year 2006.

On May 18, 2005, we completed the acquisition of substantially all of the spine-related intellectual property and related contracts, rights, and tangible materials owned by Michelson. The agreement reached requires a total cash payment of \$1,350.0 million for the settlement of all ongoing litigation and the purchase of a portfolio of more than 100 issued U.S. patents, over 110 pending U.S. patent applications and numerous foreign counterparts to these

patents. A value of \$550.0 million was assigned to past damages in the case and recorded in the fourth quarter of fiscal year 2005, and the remaining \$800.0 million will be recorded to the value of the intellectual property purchased and recorded in the first quarter of fiscal year 2006. Upon reaching a definitive agreement in the fourth quarter of fiscal year 2005, we made a \$10.0 million down payment on the intellectual property and upon closing in May of 2005, paid an additional \$1,310.0 million in cash and committed to three future installments of \$10.0 million to be paid in May of 2006, 2007 and 2008. The \$1,310.0 million payment was funded with approximately \$715.0 million in cash and approximately \$595.0 million with the proceeds from the issuance of commercial paper. The patents pertain to novel spinal technology and techniques that have both current application and the potential for future patentable commercial products.

On November 1, 2004, we acquired all of the outstanding stock of Angiolink, a privately held company that developed wound closure devices for vascular procedures. Angiolink's EVS Vascular Closure System, which has received U.S. FDA approval, is engineered to close the femoral artery access site after vascular procedures, such as diagnostic angiography, balloon angioplasty and stenting. The EVS System provides safe and effective mechanical closure of arterial puncture sites without disturbing the lumen, or interior, of the targeted vessel. This acquisition provides us an additional vascular closure offering to our current closure product—the non-invasive Clo-Sur P.A.D.M. The net consideration paid for Angiolink was approximately \$42.3 million in cash, subject to purchase price increases, which would be triggered by the achievement of certain milestones. The net cash purchase price of \$42.3 million is a product of the \$45.2 million purchase price, including direct acquisition costs, less \$2.9 million of acquired cash.

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On August 25, 2004 we acquired substantially all of the assets of Coalescent Surgical, Inc. (Coalescent). Coalescent developed the U-Clip Anastomotic Device and the SPYDER Proximal Anastomotic Device. The U-Clip device creates high-quality anastomoses (a seamless connection) without sutures and is primarily used in coronary artery bypass surgery. The SPYDER device automatically deploys a series of U-Clip devices when attaching the bypass graft to the aorta. This acquisition is expected to complement our surgical product line and strategy to develop technologies to promote surgical procedures that produce better patient outcomes, and reduce trauma and hospitalization. The consideration paid for Coalescent was approximately \$59.1 million in cash, including a \$5.0 million milestone payment made in March 2005 for the successful transition of product and technology to us following the acquisition. The purchase price remains subject to purchase price increases, which would be triggered by the achievement of certain milestones.

In May 2004, we formed a joint venture with Genzyme Corporation (Genzyme) to accelerate the development of new treatments for some of the most intractable forms of cardiovascular disease. The new venture, named MG Biotherapeutics, is working to develop therapies that leverage the complementary strengths of two industry leaders - Medtronic's experience developing delivery devices for targeted therapy and leadership in treating heart disease, as well as imaging and navigational technologies; and Genzyme's experience developing biological approaches for cardiac repair and the treatment of heart disease.

On January 8, 2004, we acquired certain assets of Radius Medical Inc. (Radius), which was accounted for as a purchase of assets. Radius was a privately held corporation that specialized in the research, development and manufacture of interventional guidewires and related products for the cardiovascular marketplace. The assets acquired from Radius broadened and enhanced our existing guidewire product and technology portfolio. The consideration paid was \$5.6 million in cash, including a \$0.5 million milestone payment made in fiscal year 2005 for the successful transfer of assets. The purchase price remains subject to purchase price increases, which would be triggered by the achievement of certain milestones.

On January 5, 2004, we acquired substantially all of the assets of Premier Tool, Inc. (Premier Tool). Premier Tool was a privately held corporation engaged in the engineering and manufacturing of metal instruments used to implant spinal devices. The assets acquired enhanced our current line of spinal instrumentation. The consideration paid was approximately \$4.0 million in cash.

On November 19, 2003, we acquired all of the outstanding stock of Vertelink Corporation (Vertelink). Vertelink was a privately held development stage company that developed materials and techniques for over-the-wire spinal fixation devices that can achieve multi-level stabilization of the cervical, thoracic and lumbar spine. Key Vertelink products include the KOBRA Fixation System and the SST Spinal Fixation System. Both systems permit surgeons to place spinal instrumentation utilizing tissue-sparing, minimally invasive methods. At the time of the acquisition, the KOBRA Fixation System was being reviewed by the FDA for 510(k) approval, which was subsequently obtained during the third quarter of fiscal year 2004. Vertelink's products enhanced the strategic initiative of our Spinal business that focuses on MAST.

The consideration paid for Vertelink was approximately \$28.1 million in cash, including two \$3.0 million milestone payments made in fiscal year 2005. The purchase price remains subject to purchase price increases, which would be triggered by the achievement of certain milestones. In connection with the acquisition we have allocated \$22.0 million of the costs to IPR&D, which was expensed on the date of the acquisition, and the remaining amount to fixed assets and other intangible assets. In the third and fourth quarters of fiscal year 2005, Vertelink obtained FDA approval for the KOBRA II System and CE Mark approval for the SST Fixation System, respectively. As a result of attaining these approvals, we triggered two existing milestone payments in the purchase agreement.

On September 10, 2003, we acquired substantially all of the assets of TransVascular, Inc. (TVI). Prior to the acquisition, we had an equity investment in TVI, which was accounted for under the cost method of accounting. TVI developed and marketed the Pioneer Catheter (formerly the CrossPoint® TransAccess® Catheter System), a proprietary delivery technology for several current and potential intravascular

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procedures, such as the potential ability to deliver therapeutic agents, including cells, genes and drugs to precise locations within the vascular system. The Pioneer Catheter received FDA 510(k) clearance in 2002 and is indicated to facilitate the positioning and placement of catheters within the peripheral vasculature. This strategic acquisition complemented our commitment to advance therapies and treatments by combining biologic and device therapies.

The consideration paid was approximately \$58.7 million subject to purchase price increases, which would be triggered by the achievement of certain milestones. The initial consideration included approximately 1.2 million shares of Medtronic common stock valued at \$57.5 million, our prior investment in TVI and acquisition-related costs. The Medtronic common shares were valued based on the average of our trading share prices several days before and after the date when the trading share prices to be issued became known.

#### Patents and Licenses

We rely on a combination of patents, trademarks, copyrights, trade secrets, and confidentiality agreements to establish and protect our proprietary technology. We have filed and obtained numerous patents in the U.S. and abroad, and regularly file patent applications worldwide in our continuing effort to establish and protect our proprietary technology. In addition, we have entered into exclusive and non-exclusive licenses relating to a wide array of third-party technologies. We have also obtained certain trademarks and trade names for our products to distinguish our genuine products from our competitors' products, and we maintain certain details about our processes, products and



strategies as trade secrets. Our efforts to protect our intellectual property and avoid disputes over proprietary rights have included ongoing review of third-party patents and patent applications.

There can be no assurance that pending patent applications will result in issued patents, that patents, trademarks or trade names issued to us or patents licensed by us will not be challenged or circumvented by competitors, or that such patents, trademarks or trade names will be found to be valid or sufficiently broad to protect our proprietary technology or to provide us with a competitive advantage.

We operate in an industry characterized by extensive patent litigation. Patent litigation can result in significant damage awards and injunctions that could prevent the manufacture and sale of affected products or result in significant royalty payments in order to continue selling the products. At any given time, we are generally involved as both a plaintiff and a defendant in a number of patent infringement actions. While it is not possible to predict the outcome of patent litigation incident to our business, we believe the costs associated with this litigation could generally have a material adverse impact on our consolidated results of operations, financial position, or cash flows for any one interim or annual period. See Item 3 Legal Proceedings for additional information.

### Markets and Distribution Methods

We sell most of our medical devices through direct sales representatives in the U.S. and a combination of direct sales representatives and independent distributors in international markets. The main target markets for our medical devices are the U.S., Western Europe, and Japan. Our primary customers include physicians, hospitals, other medical institutions and group purchasing organizations.

Our marketing and sales strategy is focused on rapid, cost-effective delivery of high-quality products to a diverse group of customers worldwide. To achieve this objective, we organize our marketing and sales teams around physician specialties. This focus enables us to develop highly knowledgeable and dedicated sales representatives who are able to foster close professional relationships with physicians and other customers, and enhance our ability to cross-sell complementary products. We believe that we maintain excellent working relationships with physicians and others in the medical industry that enable us to gain a detailed understanding of therapeutic and diagnostic developments, trends and emerging opportunities, and respond quickly to the changing needs of physicians and patients. We attempt to enhance our presence in the medical community through active participation in medical meetings and by conducting comprehensive training and educational activities. We believe that these activities contribute to physician expertise and loyalty to our products.

In keeping with the increased emphasis on cost-effectiveness in healthcare delivery, the current trend among hospitals and other customers of medical device manufacturers is to consolidate into larger

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purchasing groups to enhance purchasing power. As a result, transactions with customers have become increasingly significant, more complex and tend to involve more long-term contracts than in the past. This enhanced purchasing power may also lead to pressure on pricing and increased use of preferred vendors. We are not dependent on any single customer for more than 10% of our total net sales.

### Competition and Industry

We compete in both the therapeutic and diagnostic medical markets in more than 120 countries throughout the world. These markets are characterized by rapid change resulting from technological advances and scientific

discoveries. In the product lines in which we compete, we face a mixture of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. In addition, we face competition from providers of alternative medical therapies such as pharmaceutical companies. Competitive factors include:

- product reliability
- product performance
- product technology
- product quality
- breadth of product lines
- product services
- customer support
- price
- reimbursement approval from healthcare insurance providers

Major shifts in industry market share have occurred in connection with product problems, physician advisories and safety alerts, reflecting the importance of product quality in the medical device industry. In the current environment of managed care, economically motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price. In order to continue to compete effectively, we must continue to create or acquire advanced technology, incorporate this technology into proprietary products, obtain regulatory approvals in a timely matter and manufacture and successfully market these products.

#### Worldwide Operations

For financial reporting purposes, net sales and long-lived assets attributable to significant geographic areas are presented in Note 16 to the consolidated financial statements and is set forth in Exhibit 13 hereto and which will be included in our fiscal year 2005 Annual Report to Shareholders (the 2005 Annual Report ).

#### Impact of Business Outside of the U.S.

Our operations in countries outside the U.S. are accompanied by certain financial and other risks. Relationships with customers and effective terms of sale frequently vary by country, often with longer-term receivables than are typical in the U.S. Inventory management is an important business concern due to the potential for obsolescence, long lead times from sole source providers and currency exposure. Currency exchange rate fluctuations can affect net sales from, and profitability of, operations outside the U.S. We attempt to hedge these exposures to reduce the effects of foreign currency fluctuations on net earnings. See the Market Risk section of Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 4 to the consolidated financial statements, set forth in Exhibit 13 hereto and which will be included in our 2005 Annual Report. Certain countries also limit or regulate the repatriation of earnings to the U.S. In general, operations outside the U.S. present complex tax and cash management issues requiring sophisticated planning and analysis to meet our financial objectives.

We manufacture most of our products at 22 manufacturing facilities located in various countries throughout the world. The largest of these manufacturing facilities are located in Arizona, California, Indiana, Ireland, Massachusetts, Mexico, Minnesota, Puerto Rico and Switzerland. We purchase many of the components and raw materials used in manufacturing these products from numerous suppliers in various countries. For reasons of quality assurance, sole source availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. We work closely with our suppliers to assure continuity of supply while maintaining high quality and reliability. Due to the FDA's requirements regarding manufacture of our products, we may not be able to quickly establish additional or replacement sources for certain components or materials. Generally, we have been able to obtain adequate supplies of such raw materials and components. However, the reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our operations.

#### Employees

On April 29, 2005, we employed approximately 33,000 employees. Our employees are vital to our success. We believe we have been successful in attracting and retaining qualified personnel in a highly competitive labor market due to our competitive compensation and benefits, and our rewarding work environment. We believe our employee relations are excellent.

#### Seasonality

Worldwide sales do not reflect any significant degree of seasonality.

#### Government Regulation and Other Considerations

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our medical devices.

Authorization to commercially distribute a new medical device in the U.S. is generally received in one of two ways. The first, known as the 510(k) process, requires us to demonstrate that our new medical device is substantially equivalent to a legally marketed medical device. In this process, we must submit data that supports our equivalence claim. If human clinical data is required, it must be gathered in compliance with FDA investigational device exemption regulations. We must receive an order from the FDA finding substantial equivalence to another legally marketed medical device before we can commercially distribute the new medical device. Modifications to cleared medical devices can be made without using the 510(k) process if the changes do not significantly affect safety or effectiveness.

The second, more rigorous process, known as pre-market approval (PMA), requires us to independently demonstrate that the new medical device is safe and effective. We do this by collecting data, including human clinical data for the medical device. The FDA will authorize commercial release if it determines there is reasonable assurance that the medical device is safe and effective. This process is generally much more time-consuming and expensive than the 510(k) process.

Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers required reports of adverse experience and other information to identify potential problems with marketed medical devices. We may be subject to periodic inspection by the FDA for compliance with the FDA's good manufacturing practice regulations. These regulations, also known as the Quality System Regulations, govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. If the FDA were to conclude that we are not in compliance with applicable laws or

regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, and require us to notify health professionals and others that the

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devices present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the Department of Justice.

The FDA administers certain controls over the export of medical devices from the U.S. International sales of our medical devices that have not received FDA approval are subject to FDA export requirements. The FDA, in cooperation with U.S. Customs and Border Protection, also administers controls over the import of medical devices into the U. S. Each foreign country to which we export medical devices also subjects such medical devices to their own regulatory requirements. Frequently, we obtain regulatory approval for medical devices in foreign countries first because their regulatory approval is faster or simpler than that of the FDA. However, as a general matter, foreign regulatory requirements are becoming increasingly stringent. In the European Union, a single regulatory approval process has been created, and approval is represented by the CE Mark. To obtain a CE Mark in the European Union, defined products must meet minimum standards of safety and quality (*i.e.*, the essential requirements) and then comply with one or more of a selection of conformity routes. A Notified Body assesses the quality management systems of the manufacturer and the product conformity to the essential and other requirements within the Medical Device Directive.

To be sold in Japan, medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they are granted approval, or *shonin*. The Japanese government, through the Ministry of Health, Labour, and Welfare (MHLW), regulates medical devices under recently enacted revisions to the Pharmaceutical Affairs Law (PAL). Implementation of PAL and enforcement practices thereunder are evolving, and compliance guidance from MHLW is still in development. Consequently, companies continue to work on establishing improved systems for compliance with PAL. Penalties for a company's noncompliance with PAL could be severe, including revocation or suspension of a company's business license and criminal sanctions.

The process of obtaining approval to distribute medical products is costly and time-consuming in virtually all of the major markets where we sell medical devices. We cannot assure that any new medical devices we develop will be approved in a timely or cost-effective manner.

Federal and state laws protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of that protected information. In particular, in December 2000, the U.S. Department of Health and Human Services (HHS) published patient privacy rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA privacy rule). This regulation was finalized in October 2002. The HIPAA privacy rule governs the use and disclosure of protected health information by Covered Entities, which are healthcare providers that submit electronic claims, health plans and healthcare clearinghouses. Other than our MiniMed subsidiary and our health insurance plans, each of which is a Covered Entity, the HIPAA privacy rule affects us only indirectly. The patient data that we access, collect and analyze may include protected health information. We are committed to maintaining patients' privacy and working with our customers and business partners in their HIPAA compliance efforts. The ongoing costs and impacts of assuring compliance with the HIPAA privacy rules are not material to our business.

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, and managed-care arrangements, are continuing in many countries where we do business, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical devices. Government programs, including Medicare and Medicaid, private healthcare insurance and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments, and other mechanisms designed to constrain utilization and contain cost, including, for example, gain sharing, where a supplier of medical goods or services is required to share any realized cost savings with either the medical provider or payor as a condition of doing business with an entity. This has created an increasing level of price sensitivity among customers for our products. Some third-party payors must also approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the medical devices or therapies. Even though a new

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medical device may have been cleared for commercial distribution, we may find limited demand for the device until reimbursement approval has been obtained from governmental and private third-party payors. As a result of our manufacturing efficiencies and cost controls, we believe we are well-positioned to respond to changes resulting from the worldwide trend toward cost-containment; however, uncertainty remains as to the nature of any future legislation, making it difficult for us to predict the potential impact of cost-containment trends on future operating results.

The delivery of our devices is subject to regulation by HHS and comparable state and foreign agencies responsible for reimbursement and regulation of healthcare items and services. U.S. laws and regulations are imposed primarily in connection with the Medicare and Medicaid programs, as well as the government's interest in regulating the quality and cost of healthcare. Foreign governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services.

The U.S. federal healthcare laws apply when we submit a claim on behalf of a federal healthcare program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or other federally-funded healthcare programs. The principal federal laws include those that prohibit the filing of false or improper claims for federal payment, those that prohibit unlawful inducements for the referral of business reimbursable under federally-funded healthcare programs (the Anti-Kickback Law) and those that prohibit healthcare service providers seeking reimbursement for providing certain services to a patient who was referred by a physician that has certain types of direct or indirect financial relationships with the service provider (the Stark Law).

The laws applicable to us are subject to evolving interpretations. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, Medtronic, its officers and employees, could be subject to severe criminal and civil penalties including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

We operate in an industry characterized by extensive patent litigation. Patent litigation can result in significant damage awards and injunctions that could prevent the manufacture and sale of affected products or result in significant royalty payments in order to continue selling the products. At any given time, we are generally involved as both a plaintiff and a defendant in a number of patent infringement actions. While it is not possible to predict the outcome of patent litigation incident to our business, we believe the costs associated with this litigation could generally have a material adverse impact on our consolidated results of operations, financial position, or cash flows for any one interim or annual period. See Note 14 to the consolidated financial statements for additional information.

We operate in an industry susceptible to significant product liability claims. These claims may be brought by individuals seeking relief or by groups seeking to represent a class. In addition, product liability claims may be asserted against us in the future based on events we are not aware of at the present time.

We are also subject to various environmental laws and regulations both within and outside the U.S. Like other medical device companies, our operations involve the use of substances regulated under environmental laws, primarily manufacturing and sterilization processes. We do not expect that compliance with environmental protection laws will have a material impact on our consolidated results of operations, financial position, or cash flows.

At the beginning of fiscal year 2003, we elected to transition most of our insurable risks to a program of self-insurance, with the exception of director and officer liability insurance, which was transitioned in fiscal year 2004. This decision was made based on current conditions in the insurance marketplace that have led to increasingly higher levels of self-insurance retentions, increasing number of coverage limitations and dramatically higher insurance premium rates. We will continue to monitor the insurance marketplace to evaluate the value to us of obtaining insurance coverage in the future. Based on historical loss trends, we believe that our self-insurance program accruals will be adequate to cover future losses. Historical trends, however, may not be indicative of future losses. These losses could have a material adverse impact on our consolidated results of operations, financial position or cash flows.

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**Cautionary Factors That May Affect Future Results** This Annual Report on Form 10-K, including the information incorporated by reference herein and the exhibits hereto, may include forward-looking statements. Forward-looking statements broadly involve our current expectations or forecasts of future results. Our forward-looking statements generally relate to our growth strategies, financial results, product development, regulatory approvals, competitive strengths, the scope of our intellectual property rights, mergers and acquisitions, and sales efforts. Such statements can be identified by the use of terminology such as anticipate, believe, could, estimate, expect, forecast, intend, may, plan, possible, project, should, will and similar words or expressions. is not a historical fact, including estimates, projections, future trends and the outcome of events that have not yet occurred, are forward-looking statements. Our ability to actually achieve results consistent with our current expectations depends significantly on certain factors that may cause actual future results to differ materially from our current expectations. Some of these factors include:

Effective management of and reaction to risks involved in our business, including:

- our ability to successfully complete planned clinical trials to develop and obtain approval for products on a timely basis;
- our ability to manufacture quality products;
- timing, size, and nature of strategic initiatives, market opportunities, and research and technology platforms available to us;
- our ability to achieve manufacturing efficiencies, including gross margin benefits from our manufacturing process and supply chain programs;
- our ability to manage financial assets, including effective cash management;
- price and volume fluctuations in the stock markets and their effect on the market prices of technology and healthcare companies;

the efficient integration of acquired businesses;

the trend of consolidation in the medical device industry as well as among our customers, resulting in more significant, complex, and long-term contracts than in the past, and potentially greater pricing pressures;

our ability to anticipate and react effectively to the changing managed-care environment;

our ability to effectively manage our inventory mix and inventory levels;

our ability to maintain or increase research and development expenditures;

our ability to maintain or improve our effective tax rate.

Competitive factors, including:

pricing pressures, both in the U.S. and abroad;

development of new products by competitors having superior performance compared to our current products;

technological advances, patents, and registrations obtained by competitors;

issues with licensors, suppliers, and distributors.

Difficulties and delays inherent in the development, manufacturing, marketing and sale of medical products, including:

lengthy and costly regulatory clearance processes, which may result in lost market opportunities or harm product commercialization;

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our ability to obtain favorable third-party payor reimbursement authorizations for our products;

the suspension or revocation of authority to manufacture, market or distribute existing products;

the imposition of additional or different regulatory requirements, such as those affecting manufacturing and labeling;

ongoing efficacy or safety concerns for existing products;

field actions or seizure or recall of products;

the failure to obtain, limitations on the use of, or the loss of patent and other intellectual property rights.

Governmental action, including:

impact of continued healthcare cost-containment efforts;

new laws and judicial decisions related to healthcare availability and payment for healthcare products and services or the marketing and distribution of products;

changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

the impact of more vigorous compliance and enforcement activities;

changes in the tax and environmental laws affecting our business.

Legal disputes, including:

- disputes over intellectual property rights, including the risk of court ordered injunctions prohibiting our manufacture or sale of a product following a finding of patent infringement;
- product liability claims;
- claims asserting securities law violations;
- claims asserting violations of federal law in connection with Medicare and/or Medicaid reimbursement;
- derivative shareholder actions;
- claims asserting antitrust violations;
- environmental matters.

General economic conditions, including:

- international and domestic business conditions;
- political instability in foreign countries;
- interest rates;
- foreign currency exchange rates;
- changes in the rate of inflation;
- the market value of our investments in other companies;
- our ability to reduce the impact of these conditions on our results.

**Other factors beyond our control, including earthquakes (particularly in light of the fact that we have significant facilities located near major earthquake fault lines), floods, fires, explosions, or acts of terrorism or war.**

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You must carefully consider forward-looking statements and understand that such statements involve a variety of risks and uncertainties, known and unknown, and may be affected by inaccurate assumptions. It is not possible to foresee or identify all factors that may affect our forward-looking statements, and you should not consider any list of such factors to be an exhaustive list of all risks, uncertainties or potentially inaccurate assumptions affecting such forward-looking statements.

We caution you to consider carefully these factors as well as the specific factors discussed with each specific forward-looking statement in this annual report, including, among others, those discussed in the above section entitled Government Regulation and Other Considerations and in our other filings with the Securities and Exchange Commission. In some cases, these factors have affected, and in the future (together with other unknown factors) may affect, our ability to implement our business strategy and could cause actual results to differ materially from those contemplated by such forward-looking statements. No assurance can be made that any expectation, estimate or projection contained in a forward-looking statement can be achieved.

We also caution you that forward-looking statements speak only as of the date made. We undertake no obligation to update any forward-looking statement, but investors are advised to consult any further disclosures by us on this



subject in our filings with the Securities and Exchange Commission, especially on Forms 10-K, 10-Q, and 8-K (if any), in which we discuss in more detail various important factors that could cause actual results to differ from expected or historical results. We intend to take advantage of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 regarding our forward-looking statements, and are including this sentence for the express purpose of enabling us to use the protections of the safe harbor with respect to all forward-looking statements.

#### Executive Officers of Medtronic

Set forth below are the names and ages of current executive officers of Medtronic, Inc., as well as information regarding their positions with Medtronic, Inc., their periods of service in these capacities, and their business experience for the past five or more years. Executive officers generally serve terms in office of approximately one year. There are no family relationships among any of the officers named, nor is there any arrangement or understanding pursuant to which any person was selected as an officer.

**Arthur D. Collins, Jr.**, age 57, has been Chairman of the Board and Chief Executive Officer of the Company since April 2002, was President and Chief Executive Officer from May 2001 to April 2002, President and Chief Operating Officer from August 1996 to April 2001, Chief Operating Officer from January 1994 to August 1996 and from June 1992 to January 1994 was Executive Vice President and President of Medtronic International. He has been a director since August 1994. Prior to joining the Company, Mr. Collins was Corporate Vice President, Diagnostic Products, at Abbott Laboratories from October 1989 to May 1992 and Divisional Vice President, Diagnostic Products, from May 1984 to October 1989. He is also a director of U.S. Bancorp and Cargill, Inc., a member of the Board of Overseers of The Wharton School at the University of Pennsylvania, and Chairman of AdvaMed (Advanced Medical Technology Industry Association).

**Susan Alpert, M.D., Ph.D.**, age 58, has been Vice President, Chief Quality and Regulatory Officer since May 2004, and was Vice President, Regulatory Affairs and Compliance, from July 2003 to May 2004. Prior to that, she was Vice President of Regulatory Sciences at C.R. Bard, Inc. from October 2000 to July 2003. She held a variety of positions at the Food & Drug Administration from June 1987 to August 2000.

**Jeffrey A. Balagna**, age 44, has been Senior Vice President and Chief Information Officer since March 2001. Prior to joining the Company, Mr. Balagna held several management positions within General Electric Company from June 1997 to March 2001, including General Manager, Operations for GE Medical Systems Americas and Chief Information Officer, GE Consumer Motors and Controls. Prior to his tenure at General Electric, Mr. Balagna was Manager, Information Management at Ford Motor Company from October 1995 to June 1997.

**Jean-Luc Butel**, age 48, has been Senior Vice President and President, Asia Pacific, since September 2003. Prior to that, he was President of Independence Technology, a Johnson & Johnson Company,

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from 1999 to 2003. From 1991 to 1999, he worked for Becton Dickinson, initially as General Manager of its Microbiology business in Japan and then as President of Nippon Becton Dickinson. His last assignment at Becton Dickinson was President, Worldwide Consumer Healthcare. From 1984 to 1991, Mr. Butel was with Johnson & Johnson and served multiple roles including General Manager of Fiji, China Project Manager and Marketing Director of the Johnson & Johnson ophthalmic business in Southeast Asia.

**Terrance L. Carlson**, age 52, has been Senior Vice President, General Counsel and Secretary since October 2004. Prior to that, he was Senior Vice President, Business Development, General Counsel and Secretary at

PerkinElmer, Inc. from June 1999 to September 2004; Deputy General Counsel of AlliedSignal (Honeywell International) and General Counsel of AlliedSignal Aerospace from April 1994 to June 1999; and an associate and partner of Gibson Dunn & Crutcher from November 1978 to April 1994.

**Michael F. DeMane**, age 49, has been Senior Vice President and President, Spinal, ENT and Navigation, since February 2002 and President, Spinal, since January 2000. Prior to that, he was President, Interbody Technologies, a division of Sofamor Danek, from June 1998 to December 1999. Prior to joining the Company in 1998, Mr. DeMane served as Managing Director, Australia and New Zealand, for Smith & Nephew, Pty. Ltd from April 1996 to June 1998, after a series of research and development and general management positions with Smith & Nephew Inc.

**Gary L. Ellis**, age 48, has been Senior Vice President and Chief Financial Officer since May 2005. Prior to that, he was Vice President, Corporate Controller and Treasurer since October 1999 and Vice President Corporate Controller from August 1994. Mr. Ellis joined Medtronic in 1989 as Assistant Corporate Controller and was promoted to Vice President of Finance for Medtronic Europe in 1992, until being named as Corporate Controller in 1994.

**Janet S. Fiola**, age 63, has been Senior Vice President, Human Resources, since March 1994. She was Vice President, Human Resources, from February 1993 to March 1994, and was Vice President, Corporate Human Resources, from February 1988 to February 1993.

**Robert M. Guezuraga**, age 56, has been Senior Vice President and President, Medtronic MiniMed since November 2004. He was Senior Vice President and President Cardiac Surgery, from August 1999 to November 2004. He served as Vice President and General Manager of Medtronic Physio-Control International, Inc., from September 1998 to August 1999. Mr. Guezuraga joined the Company after its acquisition of Physio-Control International, Inc. in September 1998, where he had served as President and Chief Operating Officer since August 1994. Prior to that, Mr. Guezuraga served as President and CEO of Positron Corporation from 1987 to 1994 and held various management positions within General Electric Corporation, including GE's Medical Systems division.

**William A. Hawkins**, age 51, has been President and Chief Operating Officer since May 2004. He served as Senior Vice President and President, Medtronic Vascular, from January 2002 to May 2004. He served as President and Chief Executive Officer of Novoste Corporation from 1998 to 2002, and was Corporate Vice President of American Home Products Corporation and President of its Sherwood Davis & Geck Division from April 1997 to May 1998. He held executive positions with American Home Products, Johnson & Johnson, Guidant Corporation, Eli Lilly & Co. and Carolina Medical Electronics, having begun his medical technology career in 1977.

**Stephen H. Mahle**, age 59, has been Executive Vice President and President, Cardiac Rhythm Management, since May 2004, and prior to that was Senior Vice President and President, Cardiac Rhythm Management, since January 1998. Prior to that, he was President, Brady Pacing, from 1995 to 1997 and Vice President and General Manager, Brady Pacing, from 1990 to 1995. Mr. Mahle has been with the Company for 32 years and served in various general management positions prior to 1990.

**Stephen N. Oesterle, M.D.**, age 54, has been Senior Vice President, Medicine and Technology, since January 2002. Prior to that, he was Associate Professor of Medicine at Harvard Medical School and Director of Invasive Cardiology Services at Massachusetts General Hospital from 1998 to 2002, and was

academic positions and directed interventional cardiology programs at Georgetown University and in Los Angeles.

**Oern R. Stuge, M.D.**, age 51, has been Senior Vice President and President of Medtronic Cardiac Surgery since March 1, 2005 and Vice President of Cardiac Rhythm Management, Western Europe since May, 2002. Prior to that he was Vice President of Neurological, Spinal and Diabetes for Western Europe from May 2000 to May 2002 and Vice President of Neurological for Europe, Middle East & Africa from May 1998 to May 2000. Prior to joining the Company in 1998, Mr. Stuge worked at Abbott Laboratories where he held regional director and general manager positions for the various Nordic countries and the Netherlands.

**Scott R. Ward**, age 45, has been Senior Vice President and President, Medtronic Vascular since May 2004. He served as Senior Vice President and President, Neurological and Diabetes Business, from February 2002 to May 2004, and was President, Neurological, from January 2000 to January 2002. He was Vice President and General Manager of Medtronic's Drug Delivery Business from 1995 to 2000. Prior to that, Mr. Ward led the Company's Neurological Ventures in the successful development of new therapies. Mr. Ward also held various research, regulatory and business development positions since joining Medtronic in 1981.

**Barry W. Wilson**, age 61, has been Senior Vice President and President, Europe, Middle East, Canada and Emerging Markets since May 2004. Prior to that, Mr. Wilson was Senior Vice President and President, International, from April 2001 to April 2004, and Senior Vice President, International, since September 1997. He was President, Europe, Middle East and Africa, from April 1995 to March 2001. Prior to that, Mr. Wilson was President, International, of the Lederle Division of American Cyanamid/American Home Products from 1993 to 1995 and President, Europe, of Bristol-Myers Squibb from 1991 to 1993, where he also served internationally in various general management positions from 1980 to 1991.

#### Website Access

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](http://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. Also, copies of the reports will be made available, free of charge, upon written request to our Investor Relations Department.

#### Item 2. Properties

Our principal offices are owned by us and located in the Minneapolis, Minnesota metropolitan area. Manufacturing or research facilities are located in Arizona, California, Colorado, Connecticut, Florida, Indiana, Massachusetts, Michigan, Minnesota, Tennessee, Texas, Utah, Washington, Puerto Rico, Canada, China, France, Ireland, Mexico, the Netherlands and Switzerland. Our total manufacturing and research space is approximately 3.3 million square feet, of which approximately 75% is owned by us and the balance is leased.

We also maintain sales and administrative offices in the U.S. at approximately 90 locations in 40 states or jurisdictions and outside the U.S. at approximately 110 locations in 35 countries. Most of these locations are leased. We are using substantially all of our currently available productive space to develop, manufacture and market our products. Our facilities are in good operating condition, suitable for their respective uses and adequate for current needs.

#### Item 3. Legal Proceedings

A discussion of the Company's policies with respect to legal proceedings is discussed in the management's discussion and analysis of financial condition and results of operations set forth in

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Exhibit 13 incorporated herein by reference, and other loss contingencies are described in Note 14 of the consolidated financial statements.

On October 6, 1997, Cordis Corporation (Cordis), a subsidiary of Johnson & Johnson, Inc. (J&J), filed suit in U.S. District Court for the District of Delaware against Arterial Vascular Engineering, Inc., which Medtronic acquired in January 1999 and which is now known as Medtronic Vascular, Inc. (Medtronic Vascular). The suit alleged that Medtronic Vascular's modular stents infringe certain patents owned by Cordis. Boston Scientific Corporation is also a defendant in this suit. On December 22, 2000, a jury rendered a verdict that Medtronic Vascular's previously marketed MicroStent and GFX® stents infringed valid claims of two Cordis patents and awarded damages to Cordis totaling approximately \$270.0 million. On March 28, 2002, the District Court entered an order in favor of Medtronic Vascular, deciding as a matter of law that Medtronic Vascular's MicroStent and GFX stents did not infringe the patents. Cordis appealed, and on August 12, 2003, the Court of Appeals for the Federal Circuit reversed the District Court's decision and remanded the case to the District Court for further proceedings. The District Court thereafter issued a new patent claim construction and a new trial was held in March 2005. On March 14, 2005, the jury found that the previously marketed MicroStent and GFX stent products infringed valid claims of Cordis' patents. Medtronic Vascular has made post-trial motions challenging the jury's findings of infringement and validity, and the District Court has not yet ruled on those motions. Cordis has made a motion to reinstate the previous jury's verdict as to damages in the amount of approximately \$270.0 million and has asked the District Court to determine pre- and post-judgment interest on that amount. Medtronic Vascular has opposed entry of judgment on damages on the grounds that it is premature until the Appellate Court has reviewed the liability findings of the jury. Alternatively, Medtronic Vascular also opposes the interest rate and method of compounding that Cordis has requested. The District Court has not yet decided the motion and the timing of a decision is unknown. Since the District Court has not affirmed the jury's verdict as to liability or damages, Medtronic has not recorded an expense related to damages in this matter.

On December 24, 1997, Advanced Cardiovascular Systems, Inc. (ACS), a subsidiary of Guidant Corporation (Guidant), sued Medtronic Vascular in U.S. District Court for the Northern District of California alleging that Medtronic Vascular's modular stents infringe the Lau stent patents held by ACS, and seeking injunctive relief and monetary damages. Medtronic Vascular denied infringement and in February 1998, Medtronic Vascular sued ACS in U.S. District Court for the District of Delaware alleging infringement of Medtronic Vascular's Boneau stent patents. On January 5, 2005, the District Court found as a matter of law that the ACS products in question did not infringe any of Medtronic Vascular's Boneau stent patents. Medtronic Vascular has appealed this finding by the District Court. In February 2005, following trial, a jury determined that the ACS Lau stent patents were valid and that Medtronic's Driver, GFX, MicroStent and S7 stents infringe those patents. Medtronic Vascular has made numerous post-trial motions challenging the jury's verdict of infringement and validity and the District Court has not yet ruled on those motions. On June 7 and 8, 2005, the District Court held an evidentiary hearing on Medtronic's claim that the ACS Lau stent patents are unenforceable due to inequitable conduct of ACS in obtaining the Lau patents. The District Court has not yet issued a decision on Medtronic's defense of inequitable conduct. Issues of damages have been bifurcated and will not be addressed by a jury or the Court until some undetermined future date.

On September 12, 2000, Cordis filed an additional suit against Medtronic Vascular in U.S. District Court for the District of Delaware alleging that Medtronic Vascular's S670, S660 and S540 stents infringe the patents asserted in the October 1997 Cordis case above. The Court temporarily stayed proceedings in this suit until the appeals were decided in the 1997 case. The District Court thereafter lifted that stay, and Cordis has now added claims that Medtronic Vascular's S7 and Driver stents infringe the asserted patents. Medtronic Vascular made a motion to stay the trial proceedings pending arbitration of Medtronic Vascular's defense that its products are licensed under a 1997 Agreement between Medtronic Vascular and Cordis. The Court has granted that motion and the District Court proceedings have

been stayed pending an arbitration of the license issues. A panel of three arbitrators has been selected, and the arbitration proceedings are scheduled to be held in November 2005.

On January 26, 2001, DePuy/AcroMed, Inc., a subsidiary of J&J, filed suit in U.S. District Court for the District of Massachusetts alleging that Medtronic Sofamor Danek, Inc. (MSD) was infringing a

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patent relating to a design for a thoracolumbar multiaxial screw (MAS). In March 2002, DePuy/AcroMed, Inc. supplemented its allegations to claim that MSD's M10, M8 and Vertex® screws infringe the patent. On April 17, 2003 and February 26, 2004, the District Court ruled that those screws do not infringe. On October 1, 2004, a jury found that the MAS screw, which MSD no longer sells in the U.S., infringes under the doctrine of equivalents. The jury awarded damages of \$21.0 million and on February 9, 2005, the Court entered judgment against MSD, including prejudgment interest, in the aggregate amount of \$24.3 million. The Company has recorded an expense equal to the \$24.3 million judgment in the matter. DePuy/AcroMed, Inc. has appealed the Court's decisions that the M10, M8 and Vertex screws do not infringe, and MSD has appealed the jury's verdict that the MAS screw infringes valid claims of the patent.

On October 31, 2002, the U.S. Department of Justice filed a notice that the U.S. was declining to intervene in an action against Medtronic filed under seal in 1998 by two relators, private attorneys who file suit, under the qui tam provisions of the federal False Claims Act. Relators alleged that Medtronic defrauded the FDA in obtaining pre-market approval to manufacture and sell Models 4004, 4004M, 4504 and 4504M pacemaker leads in the late 1980s and early 1990s. Relators further alleged that Medtronic did not provide information about testing of the pacemaker leads to the FDA in the years after the agency's approval of the leads. Pursuant to the requirements of the False Claims Act, the case remained under seal while the U.S. Department of Justice determined whether to intervene in the action and directly pursue the claims on behalf of the U.S. On June 6, 2003, Medtronic's motion to dismiss the action on several grounds was denied by the U.S. District Court, Southern District of Ohio. The Sixth Circuit Court of Appeals accepted an interlocutory appeal to review that decision, and on April 6, 2005, a panel of the Sixth Circuit reversed the District Court and remanded the case for dismissal. Relators petitioned the Sixth Circuit for a rehearing on May 23, 2005.

On May 2, 2003, Cross Medical Products, Inc. (Cross) sued MSD in the U.S. District Court for the Central District of California. The suit alleges that MSD's CD HORIZON, Vertex® and Crosslink® products infringe certain patents owned by Cross. MSD has counterclaimed that Cross's cervical plate products infringe certain patents of MSD, and Cross has filed a reply alleging that MSD infringes certain cervical plate patents of Cross. On May 19, 2004, the Court issued a ruling that held that the MAS, Vertex, M8, M10, CD HORIZON SEXTANT and CD HORIZON LEGACY screw products infringe one Cross patent. A hearing on the validity of that patent was held on July 12, 2004, after which the District Court ruled that the patents were valid. Cross made a motion for permanent injunction on the multiaxial screw products, which the District Court granted on September 20, 2004, but stayed the effect of the injunction until January 3, 2005. MSD requested an expedited appeal of the ruling and the U.S. Court of Appeals for the Federal Circuit granted the request. In April 2005, the District Court ruled invalid certain claims in the patents Cross asserted against MSD's Crosslink and cervical plate products. The Court also ruled that Cross cervical plate products infringe MSD's valid patents and that MSD's redesigned pedicle screw products infringe one claim of one of the patents owned by Cross. Cross thereafter moved for an injunction against the redesigned screw products, which the District Court granted on May 24, 2005. The District Court then stayed the effectiveness of the injunction for 90 days or August 22, 2005. MSD has requested a further stay from the Court of Appeals for the Federal Circuit and is also awaiting the Federal Circuit's decision on an appeal of the District Court's September injunction. Appeals of the various liability rulings are likely to be heard before trial of any remaining damages claims.

On August 19, 2003, Edwards Lifesciences LLC (Edwards) and Endogad Research PTY Limited (Endogad) sued Medtronic Vascular, Cook Incorporated (Cook) and W.L. Gore & Associates, Inc. (Gore) in the U.S. District Court for the Northern District of California. The suit alleges that a patent owned by Endogad and licensed to Edwards is infringed by Medtronic Vascular's AneuRx Stent Graft and/or Talent Endoluminal Stent Graft System, and by products of Cook and Gore. On June 4, 2004, Medtronic filed suit alleging that the inventor of the patent had breached a contract with Medtronic and seeking to have Medtronic named as the rightful owner of the patent. The patent suit brought by Edwards and Endogad has been stayed pending the Court's determination as to ownership of the patent in the suit brought by Medtronic against the inventor. The issues as to ownership of the patent will be tried in early calendar year 2006.

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On September 4, 2003, Medtronic was informed by the Department of Justice that the government is investigating allegations that certain payments and other services provided to physicians by MSD constituted improper inducements under the federal Anti-Kickback Statute. The allegations were made as part of a civil qui tam complaint brought pursuant to the federal False Claims Act. On November 21, 2003, Medtronic was served with a government subpoena seeking documents in connection with these allegations. On September 2, 2004, Medtronic received a copy of a second civil qui tam complaint brought by a second relator asserting similar allegations under the False Claims Act. The Company views the second complaint as having arisen out of essentially similar facts and circumstances as the first qui tam complaint, and believes that the second complaint does not materially expand the nature of the existing inquiry in which the Company is cooperating. The cases remain under seal in the U.S. District Court for the Western District of Tennessee. The Company is cooperating fully with the investigations and is independently evaluating these matters, the internal processes associated therewith, and certain employment matters related thereto, in each case under the supervision of a special committee of the Board.

On October 2, 2003, ETEX Corporation (ETEX) served MSD, Medtronic and Medtronic International Ltd. with a Notice and Demand for Arbitration, under the terms of an agreement between Medtronic and ETEX entered into on March 27, 2002. The arbitration demand alleged breach of the agreement, fraud, deceptive trade practices and antitrust violations and asked for specific performance and monetary damages. On March 24, 2005 an arbitrator found in favor of Medtronic on all antitrust, fraud and tort claims alleged by ETEX. The arbitrator, however, upheld termination of the agreement and awarded ETEX breach of contract damages. After an adjustment for a calculation error in the original arbitration award, the arbitrator's final award was \$63.6 million, inclusive of interest and a partial award of attorneys' fees and costs. In reaching the final award, the arbitrator deemed as paid \$16.5 million previously owed by ETEX to Medtronic. The final award was paid subsequent to the end of fiscal year 2005. Medtronic's equity interest in ETEX remains unaffected by the arbitrator's decision.

On October 2, 2003, Cordis sued Medtronic Vascular in the U.S. District Court for the Northern District of California, alleging that Medtronic Vascular's S7 stent delivery system infringes certain catheter patents owned by Cordis. Pursuant to stipulation of the parties, the Court has stayed the suit and referred the matter to arbitration. The arbitrators have not yet been selected.

#### Item 4. Submission of Matters to a Vote of Security Holders

Not applicable.

## PART II

Item 5. Market for Medtronic's Common Equity, Related Shareholder Matters, and Issuer Purchases of Equity Securities

The information in the section entitled "Price Range of Medtronic Stock" is incorporated by reference herein to Exhibit 13 hereto and will be included in our 2005 Annual Report.

In June 2001, our Board of Directors authorized the repurchase of up to 25 million shares. An additional 30 million shares were authorized for repurchase in October 2003. We purchase shares pursuant to these programs publicly announced on June 28, 2001 and November 12, 2003, respectively. As authorized by the Board of Directors each program expires when its total number of authorized shares have been repurchased. There were no shares repurchased by Medtronic during the fourth quarter of fiscal year 2005.

Item 6. Selected Financial Data

The information for the fiscal years 2001 through 2005 in the section entitled "Selected Financial Data" is incorporated herein by reference to Exhibit 13 and will be included in our 2005 Annual Report.

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The information in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" is incorporated herein by reference to Exhibit 13 and will be included in our 2005 Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The information in the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Market Risk" as well as Note 4 to the consolidated financial statements is incorporated herein by reference to Exhibit 13 and will be included in our 2005 Annual Report.

Item 8. Financial Statements and Supplementary Data

The Consolidated Financial Statements and Notes thereto, together with the report of independent registered public accounting firm, are incorporated herein by reference to Exhibit 13 and will be included in our 2005 Annual Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

As of April 29, 2005, an evaluation was carried out under the supervision and with the participation of the Company's management, including the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO), of the effectiveness of our disclosure controls and procedures (as defined in the Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by the report. Based on that evaluation, the CEO and CFO have concluded

that the Company's disclosure controls and procedures were effective as of April 29, 2005.

#### Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of April 29, 2005. Management's assessment of the effectiveness of the Company's internal control over financial reporting as of April 29, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

#### Changes in Internal Control over Financial Reporting

There were no significant changes in the Company's internal control over financial reporting that occurred during the Company's most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

#### Item 9B. Other Information

None.

### PART III

#### Item 10. Directors and Executive Officers of the Registrant

The sections entitled "Proposal 1 Election of Directors Directors and Nominees", "Governance of the Company Audit Committee Financial Experts", and "Section 16(a) Beneficial Ownership Reporting Compliance" of our Proxy Statement for our 2005 Annual Shareholders Meeting are incorporated herein by reference. See also "Executive Officers of Medtronic" on page 27 herein.

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We have adopted a written Code of Ethics that applies to our Chief Executive Officer, Chief Financial Officer, Corporate Controller and Treasurer, and other senior financial officers performing similar functions who are identified from time to time by the Chief Executive Officer. We have also adopted a written Code of Business Conduct and Ethics for Board members. The Code of Ethics for senior financial officers, which is part of our broader Code of Conduct applicable to all employees, and the Code of Business Conduct and Ethics for Board members are posted on our website, [www.medtronic.com](http://www.medtronic.com) under the "Corporate Governance" caption. Any amendments to, or waivers for executive officers or directors of, these ethic codes will be disclosed on our website promptly following the date of such amendment or waiver.

#### Item 11. Executive Compensation

The sections entitled "Proposal 1 Election of Directors Director Compensation", "Report of the Compensation Committee on Fiscal 2005 Executive Compensation", "Shareholder Return Performance Graph", and "Executive Compensation" in our Proxy Statement for our 2005 Annual Shareholders Meeting are incorporated herein by



reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters

The sections entitled *Share Ownership Information* and *Equity Compensation Plan Information* in our Proxy Statement for our 2005 Annual Shareholders Meeting are incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions

The section entitled *Proposal 1 Election of Directors Certain Relationships and Related Transactions* in our Proxy Statement for our 2005 Annual Shareholders Meeting is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The section entitled *Audit and Non-Audit Fees* in our Proxy Statement for our 2005 Annual Shareholders Meeting is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

***(a) 1. Financial Statements***

The following report and consolidated financial statements are incorporated herein by reference in Item 8.

The sections entitled *Report of Independent Registered Public Accounting Firm* and *Consolidated Statements of Earnings* years ended April 29, 2005, April 30, 2004 and April 25, 2003 are set forth in Exhibit 13 hereto and will be included in our 2005 Annual Report.

The section entitled *Consolidated Balance Sheets* April 29, 2005 and April 30, 2004 is set forth in Exhibit 13 hereto and will be included in our 2005 Annual Report.

The section entitled *Consolidated Statements of Shareholders Equity* years ended April 29, 2005, April 30, 2004 and April 25, 2003 is set forth in Exhibit 13 hereto and will be included in our 2005 Annual Report.

The section entitled *Consolidated Statements of Cash Flows* years ended April 29, 2005, April 30, 2004 and April 25, 2003 is set forth in Exhibit 13 hereto and will be included in our 2005 Annual Report.

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The section entitled *Notes to Consolidated Financial Statements* is set forth in Exhibit 13 hereto and will be included in our 2005 Annual Report.

***2. Financial Statement Schedules***

Schedule II. *Valuation and Qualifying Accounts* years ended April 29, 2005, April 30, 2004 and April 25, 2003 (set forth on page 39 of this report)

All other schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

### 3. Exhibits

- 3.1 Medtronic Restated Articles of Incorporation, as amended (Exhibit 3.1).(a)
- 3.2 Medtronic Bylaws, as amended to date. (Exhibit 3.2).(k)
- 4.1 Rights Agreement, dated as of October 26, 2000, between Medtronic, Inc. and Wells Fargo Bank Minnesota, National Association, including as: Exhibit A thereto the form of Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Shares of Medtronic, Inc.; and Exhibit B the form of Preferred Stock Purchase Right Certificate. (Exhibit 4.1).(c)
- 4.2 Indenture, dated as of September 11, 2001, between Medtronic, Inc. and Wells Fargo Bank Minnesota, N.A. (Exhibit 4.2).(d)
- 4.3 364-Day Revolving Credit Facility, dated as of January 24, 2002, among Medtronic, Inc. as Borrower, certain of its subsidiaries as guarantors, Bank of America, N.A., as Administrative Agent and Banc of America Securities LLC as Sole Lead Arranger and Sole Book Manager (Exhibit 4.4).(e)
- 4.4 Five Year Revolving Credit Facility dated as of January 24, 2002, among Medtronic, Inc. as Borrower, certain of its subsidiaries as guarantors, Bank of America, N.A., as Administrative Agent and Banc of America Securities LLC as Sole Lead Arranger and Sole Book Manager (Exhibit 4.5).(e)
- 4.5 First Amendment to 364-Day Revolving Credit Facility, dated as of August 21, 2002 (Exhibit 4.6).(f)
- 4.6 First Amendment to Five Year Revolving Credit Facility, dated as of August 21, 2002 (Exhibit 4.7).(f)
- 4.7 Second Amendment to 364-Day Revolving Credit Facility, dated as of January 23, 2003 (Exhibit 4.8).(g)
- 4.8 Second Amendment to Five Year Revolving Credit Facility, dated as of January 23, 2003 (Exhibit 4.9).(g)
- 4.9 Third Amendment to 364-Day Credit Agreement dated January 22, 2004 (Exhibit 4.1).(h)
- 4.10 Credit Agreement (\$1,000,000,000 Five Year Revolving Credit Facility) dated as of January 20, 2005, among Medtronic, Inc. as Borrower, certain of its subsidiaries as guarantors, Citicorp USA, Inc., as Administrative Agent and Bank of America, N.A. as Syndication Agent, and Citigroup Global Markets Inc. and Banc of America Securities LLC as Joint Lead Arrangers and Joint Book Managers (Exhibit 4.1).(m)
- 4.11 Form of Indenture between Medtronic, Inc. and Wells Fargo Bank, National Association (Exhibit 4.1).(l)
- \*10.1 1994 Stock Award Plan, as amended. (Exhibit 10.1).(b)
- \*10.2 Medtronic Incentive Plan (Exhibit 10.2).(i)
- \*10.3 Executive Incentive Plan (Appendix C).(j)
- 10.4 2003 Long-Term Incentive Plan (Appendix B).(j)
- 10.5 Amendment to 2003 Long-Term Incentive Plan (Exhibit 10.1).(h)

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- \*10.6 Form of Employment Agreement for Medtronic executive officers (Exhibit 10.5).(a)
  - \*10.7 Capital Accumulation Plan Deferral Program (Exhibit 10.6).(a)
  - \*10.8 Executive Nonqualified Supplemental Benefit Plan (Exhibit 10.7).(i)
  - \*10.9 Stock Option Replacement Program (Exhibit 10.8).(a)
  - \*10.10 1998 Outside Director Stock Compensation Plan, as amended. (Exhibit 10.8).(b)
  - \*10.11 Amendments effective October 25, 2001, regarding change in control provisions in the following plans: Management Incentive Plan, 1998 Outside Director Stock Compensation Plan, Capital Accumulation Plan Deferred Program and Executive Nonqualified Supplemental Benefit Plan. (Exhibit 10.10)(b)

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- 10.12 Director and Officer Indemnity Trust Agreement. (Exhibit 10.11).(k)
- 10.13 Asset Purchase Agreement and Settlement Agreement among Medtronic, Inc., Medtronic Sofamor Danek, Inc., SDGI Holdings, Inc., Gary K. Michelson, M.D. and Karlin Technology, Inc.
- \*10.14 Form of Restricted Stock Award Agreement. (Exhibit 10.3).(m)
- \*10.15 Form of Non-Qualified Stock Option Agreement 2003 Long-Term Incentive Plan (four year vesting). (Exhibit 10.1).(m)
- \*10.16 Form of Non-Qualified Stock Option Agreement 2003 Long-Term Incentive Plan (immediate vesting). (Exhibit 10.2).(m)
- \*10.17 Form of Initial Option Agreement under the Medtronic, Inc. 1998 Outside Director Stock Compensation Plan
- \*10.18 Form of Annual Option Agreement under the Medtronic, Inc. 1998 Outside Director Stock Compensation Plan
- \*10.19 Form of Replacement Option Agreement under the Medtronic, Inc. 1998 Outside Director Stock Compensation Plan
- \*10.20 Form of Restricted Stock Units Award Agreement 2003 Long-Term Incentive Plan
- \*10.21 Form of Performance Share Award Agreement 2003 Long-Term Incentive Plan
- 12.1 Computation of ratio of earnings to fixed charges.
- 13 This exhibit contains the information referenced under Part II, Items 5, 6, 7, 7A and 8.
- 21 List of Subsidiaries.
- 23 Consent of Independent Registered Public Accounting Firm.
- 24 Powers of Attorney.
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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- (a) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 27, 2001, filed with the Commission on July 26, 2001.
  - (b) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 26, 2002, filed with the Commission on July 19, 2002.

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- (c) Incorporated herein by reference to the cited exhibit in our Report on Form 8-A, including the exhibits thereto, filed with the Commission on November 3, 2000.
  - (d) Incorporated herein by reference to the cited exhibit in our Report on Form 8-K/A, filed with the Commission on November 13, 2001.
  - (e) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended January 25, 2002, filed with the Commission on March 8, 2002.
  - (f) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended October 25, 2002, filed with the Commission on December 6, 2002.
  - (g) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended January 24, 2003, filed with the Commission on March 7, 2003.

- (h) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended July 30, 2004, filed with the Commission on September 2, 2004.
- (i) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 25, 2003, filed with the Commission on July 14, 2003.
- (j) Incorporated herein by reference to the cited appendix to our 2003 Proxy Statement, filed with the Commission on July 28, 2003.
- (k) Incorporated herein by reference to the cited Exhibit in our Annual Report on Form 10-K for the year ended April 30, 2004, filed with the Commission on June 30, 2004.
- (l) Incorporated herein by reference to the cited Exhibit in our registration statement on Amendment No. 2 to Form S-4, filed with the Commission on January 20, 2005.
- (m) Incorporated herein by reference to the cited Exhibit in our Quarterly Report on Form 10-Q for the quarter ended January 20, 2005, filed with the Commission on March 7, 2005.

\*Items that are management contracts or compensatory plans or arrangements required to be filed as an exhibit pursuant to Item 15(c) of Form 10-K.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**MEDTRONIC, INC.**

Dated: June 29, 2005

**By: /s/ Arthur D. Collins, Jr.**

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**Arthur D. Collins, Jr.  
Chairman of the Board and  
Chief Executive Officer**

Pursuant to the requirements of the Securities Exchange Act of 1934, the report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Dated: June 29, 2005

**By: /s/ Arthur D. Collins, Jr.**

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**Arthur D. Collins, Jr.  
Chairman of the Board and  
Chief Executive Officer**

Dated: June 29, 2005

**By: /s/ Gary L. Ellis**

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**Gary L. Ellis  
Senior Vice President and  
Chief Financial Officer  
(Principal Financial and Accounting Officer)**

**Directors**

**Richard H. Anderson**  
**Michael R. Bonsignore**  
**William R. Brody, M.D., Ph.D.**  
**Arthur D. Collins, Jr.**  
**Antonio M. Gotto, Jr., M.D., D.Phil.**  
**Shirley Ann Jackson, Ph.D**  
**Denise M. O Leary**  
**Robert C. Pozen**  
**Jean-Pierre Rosso**  
**Jack W. Schuler**  
**Gordon M. Sprenger**

Terrance L. Carlson, by signing his name hereto, does hereby sign this document on behalf of each of the above named directors of the registrant pursuant to powers of attorney duly executed by such persons.

Dated: June 29, 2005

By: /s/ Terrance L. Carlson

**Terrance L. Carlson**  
**Attorney-In-Fact**  
**Senior Vice President,**  
**General Counsel and Secretary**

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**MEDTRONIC, INC. AND SUBSIDIARIES**  
**SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**

*(dollars in millions)*

	<b>Balance at Beginning of Fiscal Year</b>	<b>Charges/ (Credits) to Earnings</b>	<b>Other Changes (Debit) Credit</b>	<b>Balance at End of Fiscal Year</b>
<b>Allowance for doubtful accounts:</b>				
Year ended 4/29/05	\$ 145.3	\$ 43.2	\$ (21.0)(a) \$ 7.4(b)	\$ 174.9
Year ended 4/30/04	\$ 99.5	\$ 70.2	\$ (28.2)(a) \$ 3.8(b)	\$ 145.3
Year ended 4/25/03	\$ 77.5	\$ 42.6	\$ (25.2)(a) \$ 4.6(b)	\$ 99.5

(a) Uncollectible accounts written off, less recoveries.

- (b) Reflects primarily the effects of foreign currency fluctuations.  
Commission File No. 1-7707