

MEDTRONIC INC  
Form 10-K  
June 30, 2004

[QuickLinks](#) -- Click here to rapidly navigate through this document

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-K**

ý  
Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934.  
For the fiscal year ended April 30, 2004.

o  
Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 1-7707

---

**Medtronic, Inc.**

(Exact name of registrant as specified in charter)

**Minnesota**  
(State of incorporation)

710 Medtronic Parkway  
Minneapolis, Minnesota 55432  
(Address of principal executive offices)  
Telephone Number: (763) 514-4000

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

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

Edgar Filing: MEDTRONIC INC - Form 10-K

Title of each class	Name of each exchange on which registered
Common stock, par value \$0.10 per share	New York Stock Exchange, Inc.
Preferred stock purchase rights	New York Stock Exchange, Inc.
Securities registered pursuant to section 12(g) of the Act:	
None	

Indicate by check mark 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. (  )

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  No

Aggregate market value of voting stock of Medtronic, Inc. held by nonaffiliates of the Registrant as of October 24, 2003, based on the closing price of \$46.33, as reported on the New York Stock Exchange: approximately \$56.1 billion.

Shares of Common Stock outstanding on June 23, 2004: 1,209,418,824

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Parts I and II are incorporated herein by reference to Exhibit 13 hereto and such portions will also be included in the Registrant's 2004 Annual Report; portions of Registrant's Proxy Statement for its 2004 Annual Meeting are incorporated by reference into Part III.

---

---

---

## TABLE OF CONTENTS

Item	Description	Page
<b>PART I</b>		
1.	Business	1
2.	Properties	27
3.	Legal Proceedings	27
4.	Submission of Matters to a Vote of Security Holders	30
<b>PART II</b>		
5.	Market for Medtronic's Common Equity, Related Shareholder Matters, and Issuer Purchases of Equity Securities	31
6.	Selected Financial Data	31
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	31
7A.	Quantitative and Qualitative Disclosures About Market Risk	31
8.	Financial Statements and Supplementary Data	31
9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	31
9A.	Controls and Procedures	32
<b>PART III</b>		
10.	Directors and Executive Officers of Medtronic	32
11.	Executive Compensation	32
12.	Security Ownership of Certain Beneficial Owners and Management	32
13.	Certain Relationships and Related Transactions	32
14.	Principal Accountant Fees and Services	33
<b>PART IV</b>		
15.	Exhibits, Financial Statement Schedules, and Reports on Form 8-K	33

**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®, AT®, AT500®, Attain®, Attain Deflectable , Attain Prevail , Aurora , Bolus Wizard®, Bravo , BRYAN®, Cardiac Compass , Cardioblate®, CD HORIZON®, CG Future , CGMS®, Contegra®, Crosslink®, CrossPoint® TransAccess®, Driver , ECLIPSE®, Endeavor , EnPulse®, EnRhythm , Enterra®, EnTrust , FluoroNav®, Freestyle®, Gatekeeper , GEM III®, GFX®, Guardian®, GuardWire Plus®, Hancock®, INFUSE®, InSync®, InSync Sentry , Intercept , INTER FIX , InterStim®, iON , Jewel®, Kappa®, Kintera®, KOBRA , LEGACY , LIFEPAK®, LT-CAGE®, Magellan , Marquis®, Maverick , Maximo , Medtronic Carelink®, Medtronic Hall®, METRx , Micro-Driver , Mosaic®, Multi-Exchange , MVP , Octopus®, Paradigm®, Paradigm Link®, Polestar , Prestige®, Racer , SEXTANT , Sprinter , SST , Starfish®, Stormer®, Strata®, SynchroMed®, Synergy®, Synergy Versitrel®, Talent , TUNA®, Urchin®, Vertex®

## Edgar Filing: MEDTRONIC INC - Form 10-K

INTER FIX implants and instruments, INTER FIX RP implants and instruments, INTER FIX device + INFUSE® bone graft, INTER FIX RP device + INFUSE® bone graft, LT-CAGE® implants and instruments, LT CAGE® device + INFUSE® bone graft, and BRYAN® TCD Instruments incorporate technology developed by Gary K. Michelson, M.D.

### **Annual Meeting and Record Dates**

Medtronic's Annual Meeting of Shareholders will be held on Thursday, August 26, 2004 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 2, 2004 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.

---

**PART I**

**Item 1. Business**

**Overview**

Medtronic is a world leading medical technology company, providing lifelong solutions for people with chronic disease. 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  
Surgical Navigation Technologies (SNT)

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 ending April 30, 2004 (fiscal year 2004).

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 \$4.233 billion in fiscal year 1999 to \$9.087 billion in fiscal year 2004. 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 31,000 dedicated employees worldwide personally invested in supporting our mission, our success in leading global advances in medical technology is rooted in 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.

## Edgar Filing: MEDTRONIC INC - Form 10-K

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

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

Full commitment to superior patient and customer service.

Long experience with the regulatory process and sound working relationships with regulators and reimbursement agencies, including leadership roles in helping shape 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 geographical presence in developed and developing markets.

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

Selectively merge with market leaders who complement or expand our broad base of market leadership in our core areas of interest and expertise, and 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 health care services and will result in better care at lower cost to the health care 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 nearly \$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, one of the leading causes of death in the United States (U.S.). Physicians rely on our cardiac rhythm management products to correct these irregularities and restore the heart to its normal rhythm. Our cardiac rhythm management products are designed to treat a broad range of heart conditions, including those described below.

**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.

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 sudden cardiac arrest, 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.

## Edgar Filing: MEDTRONIC INC - Form 10-K

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.

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, electrophysiology catheters, navigation systems and information systems for the management of patients with our devices. Our CRM devices are currently implanted in nearly 1.8 million patients worldwide.

***Implantable Cardiac Rhythm Devices.*** Bradycardia is a very 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. We are the world's leading provider of pacing systems, offering the broadest and most complete line of pacemakers, leads and related accessories. Our EnPulse® pacemaker, the world's first completely automatic pacemaker, was introduced in Europe in October 2003 and was approved by the United States Food and Drug Administration (FDA) in March 2004. 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. The Enpulse joins our industry-leading pacing product family, which includes the Kappa® 900 pacemaker, the world's most popular pacemaker, and the Medtronic AT500® pacing system, the first multiple-therapy pacing system to treat various atrial heart rhythm problems.

Tachyarrhythmia is a potentially fatal condition that can lead to sudden cardiac arrest (SCA), the sudden and complete cessation of heart activity. SCA is responsible for approximately 450,000 deaths annually in the U.S., 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 March 2004, 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 presented at

the American College of Cardiology meeting. 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. Despite this mounting evidence, less than 20 percent of all patients who are indicated for an ICD actually receive one, leaving hundreds of thousands of people at risk for sudden cardiac death. SCA is the second-leading cause of death in the U.S. and kills more people than AIDS, lung cancer, breast cancer, and stroke combined, yet ICDs account for less than 0.2 percent of the \$1.6 trillion health care budget.

We offer the most comprehensive product choices to treat various kinds of tachyarrhythmias. In October 2003, we announced the FDA approval of the Maximo ICD, a high-output ICD with the most advanced combination of delivered energy and features in the industry. The Maximo is built on the platform of the Medtronic Marquis® ICD, the most widely prescribed ICD in the world, and adds the clinical benefit of 35 joules of delivered energy. Devices based on the Marquis platform offer short charge times for increased patient safety and improved longevity for less frequent replacement. Marquis devices also offer our exclusive Cardiac Compass system, which helps physicians monitor cardiac disease progression for more effective treatment. For patients who suffer from both ventricular and atrial tachyarrhythmias, we offer the GEM III® AT® defibrillator.

The ICD market continues to experience a significant expansion, driven in part by new guidelines issued last year by a joint committee of the American Heart Association, the American College of Cardiology and the Heart Rhythm Society recommending the use of antiarrhythmic devices in certain heart attack survivors to reduce mortality. In addition, the ICD market benefited from the results of Multicenter Automatic Defibrillator Implantation Trial (MADIT) II, a large medical study that indicated the number of people proven to be at high risk of sudden cardiac arrest has significantly increased. In June 2003, the Centers for Medicare and Medicaid Services (CMS) expanded coverage of ICDs for Medicare beneficiaries who meet certain MADIT II indicators. Additionally, in October 2003, CMS implemented a new reimbursement structure for these newly covered patients.

Heart failure is a large and growing health problem, afflicting nearly 5 million Americans. Up to 550,000 new cases are diagnosed each year, making it the most costly cardiovascular illness in the U.S., with an estimated \$40 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 Europe and the U.S. Continuing our leadership in research of device-based therapies to help the millions of people afflicted with heart failure, we initiated a major new clinical study in January 2004 called BLOCK HF. This study is designed to determine if biventricular pacing can slow the perilous progression of heart failure in patients with mild to moderate heart failure symptoms and the need for a pacemaker.

In fiscal year 2004 we introduced two new devices for the growing number of patients with heart failure who are also considered at high risk of SCA. In June 2003, we launched our fifth and most advanced CRT device, the InSync III Marquis ICD system, in Europe. The InSync III Marquis device offers the improved cardiac resynchronization function of the InSync III including biventricular pacing for more precise pacing of the two lower chambers of the heart and the advanced therapies of the Marquis ICD. The InSync III Marquis device is currently under clinical evaluation in the U.S. In August 2003, we announced FDA approval of the InSync II Marquis CRT with defibrillator back-up (CRT-D), our third CRT system approved by the FDA in 2003. The InSync II Marquis system offers independent, programmable ventricular outputs and unique heart failure management reports, both designed to help physicians better manage each patient's specific heart failure condition. The InSync II Marquis system also offers 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 the heart failure market. In January 2004, we announced the market release of two new left heart delivery systems, Attain® Prevail and Attain Deflectable. These devices represent the first steerable delivery systems designed specifically for left heart lead placement. The Attain Prevail steerable catheter system and the Attain Deflectable catheter delivery system are specifically designed to help physicians navigate challenging heart anatomies during the CRT implant procedure.

We continue to drive rapid technological advancement in therapies for heart failure and have fifth-generation devices in development. In April 2004, we announced the first clinical implants of our new family of pacemakers and ICDs the EnRhythm pacemaker and the EnTrust ICD. This family represents our next step in the delivery of premium implantable devices that include features such as MVP (Managed Ventricular Pacing), a new pacing mode that is designed to promote natural heart activity by automatically minimizing unnecessary right ventricular pacing. In addition to MVP, the EnTrust ICD will, for the first time, offer 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.

Most recently, in June 2004, we announced the European market release of the InSync Sentry CRT-D. The Insync Sentry is the world's first CRT-D with automatic fluid status monitoring, which can be programmed to alert patients and clinicians to changes in fluid accumulation in the lungs and thoracic cavity. When used with other standard clinical assessments, this indicator offers the potential for early warning of fluid accumulation and appropriate clinical response to prevent hospitalization. Heart failure is the number one cause of hospital admissions, and most of these admissions are due to fluid accumulation in the lungs, which is extremely challenging to manage and often goes undetected until the patient is critically ill.

**Patient Management.** To achieve optimal results from our cardiac rhythm management devices, physicians obtain diagnostic and therapeutic information 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 health care costs and can inconvenience patients. The Medtronic CareLink® Patient Management Network 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 Network is the first, and only, internet-based service that connects cardiac device 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 Network 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 monitor automatically downloads the data and sends it through a standard telephone connection directly to the secure Medtronic CareLink Network. 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 Network is currently available to nearly 400,000 pacemaker patients and approximately 130,000 patients with any of our mainline ICDs or CRT-Ds. Pacing devices compatible with the Medtronic Carelink Network include the Kappa family and EnPulse pacemakers. ICD and CRT-D devices compatible with the Medtronic Carelink Network include the Medtronic GEM family, Marquis family, InSync family, and Maximo ICDs as well as our InSync Marquis and InSync II Marquis CRT-Ds. Today, the Medtronic Carelink system is being utilized in more than 150 electrophysiology clinics/practices and nearly 9,000 patients are being monitored with the Medtronic CareLink system. 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 approximately 1,200 people die in the U.S. due to SCA; however, most could be saved if they had quicker access to automated external defibrillators. Nationally, the survival rate for victims of SCA is less than 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 November 2003, results from the largest-ever clinical trial studying the outcomes of public access to defibrillation (PAD) were presented at the American Heart Association's Annual Scientific Sessions conference. The data indicated that the use of portable automatic external defibrillators (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 350,000 LIFEPAK devices distributed worldwide. In February 2004, we announced partnerships with Walgreens Co. and Costco Wholesale Corporation to offer AEDs by prescription on their respective electronic commerce web sites, [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.

#### **Customers and Competitors**

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

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

Our Spinal, ENT and SNT business is well known for its innovative spinal products, commitment to customers and unsurpassed technical support. Strong partnerships with leading spine surgeons help us pioneer new and effective ways to treat spinal conditions, and have propelled us to global leadership 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., the world's leading ENT surgical product manufacturing company. Today we offer a wide range of products and therapies to treat a variety of disorders of the cranium and spine that often dramatically impair the quality of life, as well as treat diseases and conditions affecting the ear, nose and throat.

#### **Conditions Treated**

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

Spinal disorders    herniated disc, congenital spine disorders, degenerative disc disease, tumor, trauma/fracture and stenosis

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

## Edgar Filing: MEDTRONIC INC - Form 10-K

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

### *Principal Products*

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

**Spinal.** Back pain is the third most cited reason for visits to a health care professional, after the common cold and routine check-ups. Each year nearly 20 million Americans experience back pain that is severe enough to visit a health care professional. Of the nearly 20 million Americans, 11 million endure a significant impairment of activity. We are committed to providing spine surgeons with the most advanced options for treating low back pain and other spinal problems.

Today we offer the industry's broadest line of devices, instruments, computerized image guidance products and biomaterials used in the treatment of spine disorders, including a wide range of sophisticated internal bone fixation 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, essentially "weld" two or more vertebrae together to eliminate pain caused by movement of the unstable vertebrae. Products used to treat spinal disorders and deformities include rods and pedical screws, plating systems, and interbody devices like spinal cages, bone dowels and bone wedges.

Our Spinal business leads the industry 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 surrounding 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 now includes the CD HORIZON® SEXTANT system, to facilitate multi-level spinal fusion, the METRx MicroDiscectomy System, to treat herniated discs, and the CD HORIZON ECLIPSE® Spinal System, to correct curvature of the spine in scoliosis patients. In November 2003, we acquired the Vertelink Corporation (Vertelink), described under "Acquisitions and Investments" on page 17, further expanding our minimally invasive spine surgery options. Vertelink has pioneered innovative 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. The KOBRA Fixation System obtained FDA approval in the third quarter of fiscal year 2004. The SST Spinal Fixation System is under review in Europe.

Introduced in July 2002, INFUSE® Bone Graft is rapidly becoming the standard of care in spinal fusion therapy. INFUSE Bone Graft contains a recombinant 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 Genetics Institute (now Wyeth) and demonstrates our commitment to the advancement of science in the spine field. This past year our INFUSE Bone Graft technology achieved a number of significant milestones. In May 2003, an analysis of several high-quality studies published in the Journal of Spinal Disorder & Techniques, found that INFUSE Bone Graft, used in conjunction with the LT-CAGE® Lumbar Tapered Fusion Device, delivered statistically better spinal fusion results with less pain and blood loss, shorter recovery times, and fewer complications than transplanted bone. In July 2003, CMS approved a special add-on payment for patients who undergo spinal fusion surgery using INFUSE Bone Graft. This was the first time CMS has approved such a payment for a new medical device. In August 2003, we reached agreements with Wyeth and Yamanouchi Pharmaceutical Co., Ltd. to acquire the remaining worldwide exclusive rights to promote rhBMP-2 for spine, orthopaedic and trauma indications. In December 2003, we received FDA approval for the expanded use of INFUSE Bone Graft with certain sizes of our INTER FIX and INTER FIX RP Threaded Fusion Devices. In May 2004, we announced that the FDA approved the use of INFUSE Bone Graft in the treatment 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.

We are pursuing a broad array of solutions for patients suffering from degenerative disc disease. We have three disc replacement programs currently under investigation in the U.S.: the BRYAN® cervical disc, obtained through the acquisition of Spinal Dynamics (SDC) in October 2002 described under "Acquisitions and Investments" on page 17; the Maverick Artificial Disc for the lumbar spine; and the Prestige®, an internally developed cervical disc. In May 2004, we announced the completion of patient enrollment in our U.S. pivotal clinical trial for the Prestige artificial disc and we are nearing the completion of enrollment in both the Maverick and BRYAN trials. The BRYAN and Maverick artificial discs are commercially available in Europe and we have sold approximately 8,000 devices thus far.

**ENT.** We are the leading provider of products for ENT surgical specialists, offering the broadest product line for the surgical treatment of ENT disorders, including powered systems for tissue removal and sinus micro-endoscopy, image-guided surgery systems, nerve monitoring systems, implantable devices and biomaterials. Certain of these products are dramatically changing the way ENT medical procedures are performed by replacing highly invasive procedures with new minimally invasive instruments and techniques.

**SNT.** Our image-guided surgery systems use sophisticated multi-dimensional imaging and navigation technologies that enable surgeons to optimize their surgical plans and use this advanced surgical information during the procedure and delivery of therapies. Our FluoroNav® and iON fluoroscopic navigation systems enable intra-operative visualization and navigation for spinal and orthopedic procedures, while significantly reducing radiation exposure for patients, physicians and operating room staff. In October 2003, the Polestar N-20 interoperative MRI system, a product that we market on behalf of a third-party manufacturer, received FDA clearance. The Polestar N-20 system is a compact, mobile MRI unit designed to seamlessly integrate into the operating room. These advanced imaging and navigation technologies enable physicians to perform safer and less invasive surgical procedures.

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

The primary medical specialists who use our spinal and SNT products are spine surgeons, orthopedic surgeons and neurosurgeons. The primary medical specialists who use our ENT products are ENT

surgeons (otorhinolaryngologists). Our primary competitors in the Spinal business are Zimmer Inc., Johnson & Johnson, Inc., Stryker Corporation, and Synthes-Stratec, Inc.; the most significant competitors in the ENT business are Gyrus Group PLC and Stryker Corporation; and the primary competitors in the SNT business are BrainLAB, Inc. and Stryker Corporation.

### **Neurological and Diabetes**

Neurological and Diabetes 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 of our time. We are applying our proprietary stimulation technologies to develop effective therapies for intractable chronic diseases throughout the body, including gastroenterology and urology, two underserved market segments with large, unmet medical needs. We are also the 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.

#### ***Conditions Treated***

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

Neurological disorders including Parkinson's disease, 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:

#### ***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 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. Our movement disorder therapies achieved several significant milestones during the year, including the publication of a landmark article in the New England Journal of Medicine that reported patients with advanced Parkinson's disease experienced "marked improvement" in motor function and mobility when treated with our bilateral deep brain stimulation technology, called Activa® Therapy. Compared to baseline measures the article reports that, at five years, patients with Activa Therapy showed significant improvement in motor function (off medication) and activities of daily living. Additionally, in January 2004, we announced the FDA approval of the Kinetra® Neurostimulator, along with its Access® Therapy Controller, that simplify Activa Therapy for physicians and patients by using one device to deliver deep brain stimulation therapy to both sides of the brain.

In April 2004, we announced the start of the U.S. pivotal clinical trial 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.

We have the medical device industry's broadest offering of implantable neurostimulators designed to treat chronic debilitating pain, including our Synergy® and Synergy Versitrel® systems, which deliver neurostimulation through one or two leads surgically placed near the spinal cord. Stimulation patterns are adjustable along multiple parameters, with the stimulation levels delivered by each lead controlled separately.

We offer a complete line of implantable drug delivery systems, including both programmable and fixed-rate devices that are used to treat chronic malignant and non-malignant pain, spasticity and colorectal cancer that has spread to the liver. In April 2004, we launched the SynchroMed® II, our newest drug delivery system, in Europe and began limited release in the U.S. Full U.S. release of the SynchroMed II began in June 2004. The SynchroMed II is 30% smaller than the SynchroMed EL, but has a larger reservoir and increased functionality. The SynchroMed II drug delivery system is a small, programmable, implantable drug pump that is placed in the abdomen together with a catheter that delivers medication directly to the fluid-filled area that bathes the spinal cord. By delivering precise doses of medication directly to the central nervous system, the SynchroMed II drug delivery system reduces the amount of medication necessary to control pain and spasticity, thereby minimizing undesirable side effects.

Our pain therapies also achieved significant milestones during fiscal year 2004. In March 2004, Pain Medicine (the official journal of the American Academy of Pain Medicine) published an editorial "Intrathecal Drug Delivery for Chronic Back Pain: Better Science for Clinical Innovation," providing valuable prospective multi-center data on 136 patients receiving the SynchroMed II for low back pain management. The twelve-month multi-center data included positive results in the areas of back pain relief, functional disability reduction, and patient satisfaction.

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 160,000 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, biometals, 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 more than 170 million people worldwide. Approximately 20 million people have diabetes in the U.S., where it is now the fifth 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. health care system, with more than \$130 billion spent annually on diabetes and its complications, including \$90 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 (currently approved for distribution in Europe but not yet cleared for marketing in the U.S.) and an implantable glucose sensor, which is currently in U.S. clinical trials. 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 the 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 July 2003, we announced the FDA clearance of the first "intelligent" insulin pump and glucose monitoring system. The wireless system is comprised of a Paradigm 512 Insulin Pump and a Paradigm Link® Blood Glucose Monitor, co-developed with Becton, Dickinson and Company. Using wireless technology, the Paradigm Link monitor automatically transmits a blood sugar reading to the Paradigm 512 insulin pump. The pump's Bolus Wizard® calculator determines the recommended insulin dosage. In October 2003, we launched the Paradigm 712 insulin pump in the U.S. The Paradigm 712 incorporates a larger reservoir for patients requiring more insulin to keep their blood sugar levels in the normal range. Similar to the Paradigm 512 pump system, the Paradigm 712 system wirelessly integrates blood sugar information using the Paradigm Link Blood Glucose Monitor. In June 2003, we launched the CGMS® System Gold enhanced continuous glucose monitoring system used by physicians to identify unhealthy blood sugar patterns in people with diabetes. The monitoring system can take up to 288 glucose measurements over a 24 hour period, providing physicians with up to 72 times more information than typical glucose measurements using finger sticks. In February 2004, we announced FDA approval of the Guardian® Continuous Glucose Monitoring System, a patient-used device designed to protect diabetes patients by alerting them to potentially dangerous fluctuations in blood sugar levels. The Guardian system is an external device that utilizes a glucose sensor to continuously record blood sugar readings and transmit the information to a monitor, which is designed to sound an alarm when blood sugar levels reach high or low limits preset by the patient or health care professional. Information from the system's monitor can be downloaded to a computer for additional trend analysis to further improve diabetes care.

**Gastroenterology and Urology.** Our diagnostic and therapeutic products for gastroenterology and urology include the Enterra® Therapy for gastroparesis, and 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.

In May 2003, the American Journal of Gastroenterology published the results of a study that confirmed our Bravo pH Monitoring System, the first catheter-free diagnostic system for measuring acid levels in the esophagus, is a "well-tolerated and reliable" method for accurate diagnosis of GERD and yields better data on esophageal pH levels than traditional techniques. GERD is a common and frequently misdiagnosed disorder that is caused when the lower esophageal sphincter, which separates the stomach from the esophagus, becomes weak and ineffective, allowing stomach contents to flow back, or reflux, into

the esophagus. In May 2003, we received European regulatory approval of the Gatekeeper Reflux Repair System, an innovative non-invasive treatment for GERD that uses biocompatible prostheses to mimic a normal functioning barrier between the stomach and the esophagus. In November 2003, we announced the start of the U.S. pivotal trial for the Gatekeeper Reflux Repair System. Our InterStim Therapy device for urinary control treats urinary retention and symptoms of an overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency, by delivering mild electrical impulses to the sacral nerves with an implantable medical device similar to a cardiac pacemaker. The sacral nerves, located in the lower back, influence bladder function. In September 2003, we marked the 10,000<sup>th</sup> implant of the InterStim therapy for urinary control. TUNA Therapy is designed to treat benign prostatic hyperplasia (BPH), an aggressive and naturally occurring condition that enlarges the prostate gland and afflicts more than 29 million men worldwide. TUNA Therapy is a non-surgical procedure that uses low-level, precisely controlled radio frequency energy to diminish prostate tissue while protecting adjacent structures from harm. TUNA procedures reduce the risk of side effects, such as incontinence and impotence, often associated with transurethral resection of the prostate, the standard surgical treatment for BPH.

### *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.

### *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. We offer a variety of balloon angioplasty catheters, including our NC Stormer® and Sprinter Semi-Compliant dilatation catheters. Our NC Stormer dilatation catheter is available on both our Multi-Exchange and Over-the-Wire Balloon Dilatation Catheter systems, and received FDA clearance for U.S. commercial sales in July 2003. The Sprinter Semi-Compliant dilatation catheter is presently available in Europe and Japan and currently in U.S. clinical trials.

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, 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 was launched in the U.S. during October 2003. The Micro-Driver coronary stent, specifically designed for use in small vessels, was launched in Europe during June 2003 and is currently in U.S. clinical trials.

***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 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 three-phase Endeavor Drug-Eluting Coronary Stent clinical trial program achieved a number of significant milestones during fiscal year 2004. In September 2003, the principal investigator for the ENDEAVOR I, a 100-patient feasibility clinical trial, reported positive four-month results at the Transcatheter Cardiovascular Therapeutics annual symposium. In May 2004, 12-month data for ENDEAVOR I was presented at the Paris Course on Revascularization demonstrating continued favorable results. In July 2003, we started our Pivotal Clinical Trial, ENDEAVOR II, and completed enrollment of the 1,200-patient trial in January 2004. ENDEAVOR II is currently in the follow-up phase and results are expected to be presented in March 2005 at the American College of Cardiology annual scientific meeting. In February 2004, we started the third and final phase of our drug-eluting stent program, ENDEAVOR III, a 436-patient equivalency study comparing our Endeavor Drug-Eluting Coronary Stent to the Johnson & Johnson Cypher® Sirolimus-eluting stent. We anticipate completing enrollment in ENDEAVOR III during the middle of calendar year 2004. 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.

***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® 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® and Talent 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 2003, we announced the start of the VALOR (Evaluation of the Safety and Efficacy of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms) study. This study is an important step in establishing treatment options for patients with life-threatening thoracic aneurysms. 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 Self-Expandable Stent System and in November 2003, our Racer Biliary Stent became the first cobalt-alloy biliary stent commercially available for use in the U.S.

#### ***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 the 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 in patients who cannot be effectively treated with angioplasty or stents

Heart valve disorders diseased or damaged heart valves can restrict blood flow or leak. This limits the heart's ability to pump blood, and makes the heart 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 and surgical accessories.

**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. Approximately 820,000 bypass procedures are performed each year worldwide. 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 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. The Magellan Autologous Platelet Separator, which continues to experience a small but growing acceptance, is part of our circulatory support systems and benefits patients in a variety of ways, including a reduction in the risk of infection. As beating heart surgery has become more popular, the market for arrested heart surgery products has been declining. For patients undergoing cardiac surgery, who also suffer from atrial arrhythmias, our Cardioblade® Ablation System is designed to allow surgeons to efficiently restore a normal heart rhythm by neutralizing the cells causing troublesome electrical activity. In August 2003, we announced the first use of our Cardioblade BP (Bipolar) system, the latest addition to our Cardioblade

Surgical Ablation Systems. The Cardioblade BP system is the world's first bipolar surgical radio frequency (RF) ablation instrument that delivers an electrolytic irrigation solution along with its RF energy.

**Beating Heart Surgery.** Increasingly, 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® 4.3 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 25% 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 product 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. Other tissue product offerings include the Freestyle® and Hancock® II. Our mechanical heart valve offerings include the Medtronic Hall®, currently available in the U.S., and the ADVANTAGE Supra® bileaflet, which was released in Europe during November 2003; the bileaflet valve is designed to allow the implantation of a larger valve thereby optimizing blood flow. Currently, the bileaflet valve is in U.S. clinical evaluation. Our repair products include the Duran Flexible and CG Future Band annuloplasty systems. In November 2003, we announced that a Humanitarian Device Exception had been approved by the FDA, making our Contegra® Pulmonary Valved Conduit available to correct congenital defects of the right side of the heart in children.

#### **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 2004, 2003, and 2002, we spent \$851.5 million (9.4% of net sales), \$749.4 million (9.8% of net sales), and \$646.3 million (10.1% 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 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.

In January 2004, we acquired certain assets of Radius Medical Inc. (Radius) for a total consideration of \$5.1 million. Radius specializes in the research, development and manufacture of interventional guide wires and related products for the cardiovascular marketplace. The assets acquired from Radius will broaden and enhance our existing guide wire product and technology portfolio.

In January 2004, we also acquired substantially all of the assets of Premier Tool, Inc. (Premier Tool) for approximately \$4.0 million. Premier is engaged in the engineering and manufacturing of metal instruments used to implant spinal devices. These assets will enhance our current line of spinal instrumentation devices.

In November 2003, we acquired all of the outstanding stock of Vertelink for approximately \$22.1 million in cash, subject to purchase price increases, which would be triggered by the achievement of certain milestones. Vertelink is a privately held development stage company that develops material and techniques for "over-the-wire" spinal fixation devices that can achieve multi-level stabilization of the cervical, thoracic, and lumbar spine. Vertelink's products will further enhance the strategic initiative of our Spinal business that focuses on MAST.

In September 2003, we acquired substantially all of the assets of TransVascular, Inc. (TVI) for total consideration of \$58.7 million, subject to purchase price increases, which would be triggered by the achievement of certain milestones. TVI develops and markets the CrossPoint® TransAccess® Catheter System, a proprietary delivery technology for several current and potential vascular procedures. This strategic acquisition is expected to complement our current commitment to advance therapies and treatments by combining biologic and device therapies.

In October 2002, we acquired all of the outstanding common shares of Spinal Dynamics Corporation (SDC) for total consideration of \$254.3 million. SDC is a developer of an artificial cervical disc that is designed to maintain mobility of the cervical spine after surgery. This acquisition is expected to complement our full suite of spinal surgery products.

## 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 health care delivery, the current trend among hospitals and other customers of medical device manufacturers is to consolidate into larger 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.

### **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 we believe that the patent litigation incident to our business will generally not have a material adverse impact on our consolidated financial position, it may be material to the consolidated results of operations or cash flows of any one period. See "Item 3 Legal Proceedings" for additional information.

### **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 health care 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 health care 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 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 will be included in our fiscal year 2004 Annual Report to Shareholders (the "2004 Annual Report").

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

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 will be included in our 2004 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 money management issues requiring sophisticated analysis to meet our financial objectives.

#### **Production and Availability of Raw Materials**

We manufacture most of our products at 21 manufacturing facilities located in various countries throughout the world. The largest of these manufacturing facilities are located in Arizona, California, Indiana, Ireland, 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 30, 2004, we employed approximately 31,000 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 510K 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 regulations. We must receive an order from the FDA finding substantial equivalence before we can commercially distribute the new medical device. Modifications to cleared medical devices can be made without using the 510K 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 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 510K 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 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. 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.

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 health care providers that submit electronic claims, health plans and health care clearinghouses. Other than our MiniMed subsidiary and our health 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. We do not expect the costs and impacts of the HIPAA privacy rule to be material to our business.

Government and private sector initiatives to limit the growth of health care 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 health care insurance and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments. 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 health care providers who use the medical devices or therapies. Even though a new 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 health care 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 health care. Foreign governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services.

The U.S. federal health care laws apply when we submit a claim on behalf of a federal health care program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally-funded health care 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 health care programs (the "Anti-Kickback Law") and those that prohibit health care 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 we believe that the patent litigation incident to our business will generally not have a material adverse impact on our consolidated financial position, it may be material to the consolidated results of operations or cash flows of any one period. See "Item 3 Legal Proceedings" 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, coupled with an 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 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.

#### **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, 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. Any statement that 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 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

our ability to successfully complete planned clinical trials to develop and obtain approval for products on a timely basis

## Edgar Filing: MEDTRONIC INC - Form 10-K

timing, size, and nature of strategic initiatives, market opportunities, and research and technology platforms available to us

price and volume fluctuations in the stock markets and their effect on the market prices of technology and health care 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 manufacture quality products

our ability to maintain or increase research and development expenditures

our ability to maintain 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

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

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 health care cost-containment efforts

new laws and judicial decisions related to health care availability and payment for health care 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

## Edgar Filing: MEDTRONIC INC - Form 10-K

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

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.**

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.

## Edgar Filing: MEDTRONIC INC - Form 10-K

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 56, 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 Adva Med (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 43, has been Senior Vice President and Chief Information Officer of the Company 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 47, 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, 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.

**Michael F. DeMane**, age 48, has been Senior Vice President and President, Spinal, ENT and SNT, 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 Ellis**, age 47, has been Vice President, Corporate Controller and Treasurer since October 1999. Prior to that, he was Vice President and Corporate Controller since August 1994. Mr. Ellis joined Medtronic in 1989 as Assistant Corporate Controller and served as Vice President, Finance, Medtronic Europe, from 1992 until being named Corporate Controller in 1994. Before coming to Medtronic, Mr. Ellis was a Senior Audit Manager for PricewaterhouseCoopers, LLP, which he joined in 1978.

**Janet S. Fiola**, age 62, 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 55, has been Senior Vice President and President, Cardiac Surgery, since August 1999, and 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 50, has been President and Chief Operating Officer since May 2004. He served as Senior Vice President and President, Vascular, from January 2002 to May 2004. He served as President and Chief Executive Officer of Novoste Corp. 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.

**Ronald E. Lund**, age 69, has been Senior Vice President, General Counsel and Secretary since January 2004, and he served in this capacity from July 1992 to January 2000, prior to his retirement from Medtronic. He was Senior Vice President and General Counsel from January 1989 to July 1992. After his retirement, he practiced law independently, served one year as General Counsel of the American Red Cross and then became a member of Briggs and Morgan, a Minneapolis/St. Paul law firm. Prior to joining Medtronic, Mr. Lund spent 28 years with Pillsbury Company, where he held a number of executive positions in both the legal and business areas.

**Stephen H. Mahle**, age 58, 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 31 years and served in various general management positions prior to 1990.

**Stephen N. Oesterle, M.D.**, age 53, 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 Associate Professor of Medicine at Stanford University and Director of Cardiac Catheterization and Coronary Intervention Laboratories at the Stanford University Medical Center from 1992 to 1998. Prior to that he held other academic positions and directed interventional cardiology programs at Georgetown University and in Los Angeles.

**Robert L. Ryan**, age 61, has been Senior Vice President and Chief Financial Officer since April 1993. Prior to joining the Company, Mr. Ryan was Vice President, Finance, and Chief Financial Officer of Union Texas Petroleum Corp. from May 1984 to April 1993, Controller from 1983 to 1984, and Treasurer from 1982 to 1983.

**Scott R. Ward**, age 44, has been Senior Vice President and President, 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.

## Edgar Filing: MEDTRONIC INC - Form 10-K

**Keith E. Williams**, age 51, has been Senior Vice President since September 2003. Prior to that, he was Senior Vice President and President, Asia Pacific, from May 2003 to September, Senior Vice President and Chief Quality Officer from February 2002 to May 2003, and Senior Vice President and President, Neurological, Spinal and ENT, from August 2000 to February 2002. Prior to that, he served as Senior Vice President and President, Asia Pacific, from May 1999 to August 2000. Mr. Williams joined the Company in April 1997 as President, Asia Pacific. Prior to that he held various sales, marketing and general management positions with GE's Medical Systems division for 23 years, including President, GE Medical Systems China, from 1993 to 1996.

**Barry W. Wilson**, age 60, 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, Denmark, 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 102 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

On October 6, 1997, Cordis Corporation (Cordis), a subsidiary of Johnson & Johnson, Inc. (J&J), filed suit in federal court in the District Court of Delaware against Arterial Vascular Engineering, Inc. (AVE), which we acquired in January 1999. The suit alleged that AVE's modular stents infringe certain patents now owned by Cordis. Boston Scientific Corporation is also a defendant in this suit. On December 22, 2000, a Delaware jury rendered a verdict that the previously marketed MicroStent and GFX® stents infringe valid claims of two patents and awarded damages to Cordis totaling approximately \$270.0 million. On March 28, 2002, the District Court entered an order in favor of AVE, deciding as a matter of law that AVE's MicroStent and GFX stents do 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 has now issued a new

claim construction and directed the parties to file new expert reports and brief certain issues. Neither the Circuit Court nor the District Court has affirmed the jury's verdict as to liability or damages. Consequently, Medtronic has not recorded an expense related to this matter.

On December 24, 1997, Advanced Cardiovascular Systems, Inc. (ACS), a subsidiary of Guidant Corporation (Guidant), sued AVE in federal court in the Northern District of California alleging that AVE's modular stents infringe certain patents held by ACS, and is seeking injunctive relief and monetary damages. AVE denied infringement and in February 1998, AVE sued ACS in federal court in the District Court of Delaware alleging infringement of certain of its stent patents, for which AVE is seeking injunctive relief and monetary damages. The cases have been consolidated in Delaware and are in the discovery stage. Trial has been scheduled to commence in January 2005.

On June 15, 2000, we filed suit in U.S. District Court in Minnesota against Guidant seeking a declaration that the Jewel® AF device does not infringe certain patents held by Guidant and/or that such patents were invalid. Thereafter, Guidant filed a counterclaim alleging that the Jewel AF and the Gem III AT devices infringe certain patents relating to atrial fibrillation. The Court held a hearing to determine construction of claims and on May 25, 2004, issued its order interpreting certain of the claims in the patents. The case will now proceed through expert discovery, further motions and pretrial preparations.

On September 12, 2000, Cordis filed an additional suit against AVE in the District Court of Delaware alleging that AVE's S670, S660 and S540 stents infringe the patents asserted in the October 1997 Cordis case above. The Court has stayed proceedings in this suit until the appeals are decided in the 1997 case discussed previously. No case schedule has been set for this matter.

On January 26, 2001, DePuy/AcroMed, Inc. (DePuy/AcroMed), a subsidiary of J&J, filed suit in U.S. District Court in Massachusetts alleging that Medtronic Sofamor Danek, Inc. (MSD) was infringing a patent relating to a design for a thoracolumbar multiaxial screw (MAS). In March 2002, DePuy/AcroMed 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 the M10 and M8 multiaxial screws and the Vertex screws, respectively, do not infringe. There will be further proceedings with respect to the previously sold MAS. Trial is scheduled to commence in August 2004.

On May 9, 2001, MSD filed a lawsuit against Dr. Gary Karlin Michelson and Karlin Technology, Inc. (together, KTI) in the U.S. District Court for the Western District of Tennessee. The suit seeks damages and injunctive relief against KTI for breach of purchase and license agreements relating to intellectual property in the field of threaded and non-threaded spinal interbody implants and cervical plates, fraud, breach of non-competition obligations and other claims. In October 2001, KTI filed several counterclaims against MSD as well as a third-party complaint against Sofamor Danek Holdings, Inc., a related entity, seeking damages and injunctive relief based on several claims, including breach of contract, infringement of several patents, fraud and unfair competition. The parties have disputed the scope of the rights in the above agreements with respect to future improvements. In November 2003, the court issued a ruling limiting the Company's rights under such purchase and license agreements to inventions disclosed in a patent and patent applications identified in the agreements and excluding rights to later inventions. The case will now proceed in the District Court on the patent infringement claims made by KTI against MSD with respect to certain of its threaded and non-threaded spinal interbody implants and the parties' respective breach of contract and other claims. Trial commenced on June 2, 2004.

On June 6, 2001, MiniMed and its directors were named in a putative class action lawsuit filed in the Superior Court of the State of California for the County of Los Angeles. The plaintiffs purport to represent a class of stockholders of MiniMed asserting claims in connection with our acquisition of MiniMed, alleging violation of fiduciary duties owed by MiniMed and its directors to the MiniMed stockholders. Among other things, the complaint sought preliminary and permanent injunctive relief to prevent completion of the acquisition. In August 2001, the Court denied the plaintiffs' request for injunctive relief to prevent completion of the acquisition. Plaintiffs have amended their complaint and the

court has granted plaintiffs' motion seeking certification of a class action. The class is defined as holders of record of MiniMed common stock on July 16, 2001, excluding any such shareholders who were also shareholders of a related company, MRG, on that date. The parties have agreed upon settlement in principle, subject to the Court's approval. A motion for preliminary approval was granted on June 4, 2004. Class members have until July 15, 2004 to object. A final settlement hearing is scheduled for August 10, 2004. The settlement is funded by insurance.

On October 31, 2002, the 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 private attorneys (Relators), 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 has accepted an interlocutory appeal to review that decision. Appellate briefs have been filed and the parties are awaiting a date for oral argument. A previously set trial date has been taken off the court's calendar.

On May 2, 2003, Cross Medical Products, Inc. (Cross) sued MSD in the United States District Court for the Central District of California. The suit alleges that our CD HORIZON, Vertex and Crosslink® products infringe certain patents owned by Cross. We have counterclaimed that Cross' 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 LEGACY screw products infringe one of the patents. A hearing on the validity of that patent will be held on July 12, 2004. Trial is scheduled for December 2004.

On August 19, 2003, Edwards Lifesciences LLC and Endogad Research PTY Limited sued Medtronic, Medtronic Vascular, Inc. (formerly Medtronic AVE), Cook Incorporated and W.L. Gore & Associates, Inc. in the United States District Court for the Northern District of California. The suit alleges that a patent owned by Endogad and licensed to Edwards is infringed by our 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 is seeking to have Medtronic named as the rightful owner of the patent. The litigation has been stayed pending the Court's determination as to ownership of the patent.

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. The case remains under seal in the United States District Court for the Western District of Tennessee. The Company is cooperating fully with the investigation and is independently evaluating the matter, the internal processes associated therewith, and certain employment matters related thereto under the supervision of a special committee of the Board.

On October 2, 2003, Etex Corporation served MSD, Medtronic and Medtronic International Ltd. with a Notice and Demand for Arbitration, under the terms of a Purchase and Option Agreement between Medtronic and Etex Corporation entered into on March 27, 2002. The arbitration demand alleges breach of the agreements, fraud, deceptive trade practices and antitrust violations and asks for specific performance and/or monetary damages. The arbitration is governed by Minnesota law and the federal

Arbitration Act. An arbitrator has been selected and the parties are in the process of setting the case schedule.

On October 2, 2003, Cordis sued Medtronic Vascular, Inc. in the U.S. District Court, Northern District of California, alleging that the 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.

On November 11, 2003, Endoscopic Technologies, Inc., d/b/a Estech, Inc., filed suit in U.S. District Court for the Northern District of California asserting claims under the Sherman Antitrust Act, the California State Antitrust Act and unfair trade practices under the California Business and Professions Code. The case was designated a related case to a suit for patent infringement that Medtronic had filed against Estech relating to Estech's stabilization device for cardiac surgery. The antitrust case is on hold pending a decision by the court on Medtronic's motion to dismiss. In the patent case, Estech has also asserted certain infringement claims against Medtronic related to heart positioners and other devices used in cardiac surgery. The patent case is in the discovery stage with a trial scheduled for September 2005.

We believe that we have meritorious defenses against the above claims and intend to vigorously contest them. Negative outcomes of the litigation matters discussed above are not considered probable or cannot be reasonably estimated. Accordingly, we have not recorded reserves regarding these matters in our financial statements as of April 30, 2004. We record a liability when a loss is known or considered probable and the amount can be reasonably estimated. If a loss is not probable or a probable loss cannot be reasonably estimated, a liability is not recorded. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate, the minimum amount of the range is accrued. While it is not possible to predict the outcome of the actions discussed above, we believe that costs associated with them will not have a material adverse impact on our consolidated financial position, but may be material to the consolidated results of operations or cash flows of any one period.

**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 2004 Annual Report.

The following table provides information about the shares repurchased by Medtronic during fiscal year 2004:

Fiscal Period	Total Number of Share Purchased(1)	Average Price per Share	Total Number of Shares Purchased as a Part of Publicly Announced Programs	Maximum Number of Shares that May Yet Be Purchased Under the Programs
4/26/03 - 7/25/03	3,292,300	\$ 48.08	3,292,300	11,211,562
7/26/03 - 10/24/03	7,396,222	48.21	7,396,222	33,815,340
10/25/03 - 1/23/04	3,262,854	47.15	3,262,854	30,552,486
1/24/04 - 4/30/04	4,466,800	47.45	4,466,800	26,085,686
<b>Total Fiscal Year 2004</b>	<b>18,418,176</b>	<b>\$ 47.81</b>	<b>18,418,176</b>	<b>26,085,686</b>

(1)

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 purchased these shares pursuant to these repurchase programs publicly announced on June 28, 2001 and November 12, 2003, respectively. Each program will expire when its total number of authorized shares have been repurchased.

**Item 6. Selected Financial Data**

The information for the fiscal years 2000 through 2004 in the section entitled "Selected Financial Data" is incorporated herein by reference to Exhibit 13 and will be included in our 2004 Annual Report.

**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 2004 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 2004 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 2004 Annual Report.

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

Not applicable.

**Item 9A. Controls and Procedures**

(a)

Evaluation of disclosure controls and procedures.

As of the end of fiscal year 2004, 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. Based on that evaluation, the CEO and CFO have concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

(b)

Changes in internal controls.

The CEO and CFO have concluded there were no significant changes in the Company's internal controls or in the other factors that could significantly affect those controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

**PART III**

**Item 10. Directors and Executive Officers of Medtronic**

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 2004 Annual Shareholders' Meeting are incorporated herein by reference. See also "Executive Officers of Medtronic" on pages 26 through 28 hereof.

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 2004 Executive Compensation", "Shareholder Return Performance Graph", and "Executive Compensation" in our Proxy Statement for our 2004 Annual Shareholders' Meeting are incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management**

The sections entitled "Share Ownership Information" and "Equity Compensation Plan Information" in our Proxy Statement for our 2004 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 2004 Annual Shareholders' Meeting is incorporated herein by reference.



**Item 14. Principal Accountant Fees and Services**

The information contained on pages 25 and 26 of our Proxy Statement for our 2004 Annual Shareholders' Meeting, with respect to principal accountant fees and services, is incorporated herein by reference.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K**

(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 "Statements of Consolidated Earnings" years ended April 30, 2004, April 25, 2003 and April 26, 2002 are set forth in Exhibit 13 hereto and will be included in our 2004 Annual Report.

The section entitled "Consolidated Balance Sheets" April 30, 2004 and April 25, 2003 is set forth in Exhibit 13 hereto and will be included in our 2004 Annual Report.

The section entitled "Statements of Consolidated Shareholders' Equity" years ended April 30, 2004, April 25, 2003 and April 26, 2002 is set forth in Exhibit 13 hereto and will be included in our 2004 Annual Report.

The section entitled "Statements of Consolidated Cash Flows" years ended April 30, 2004, April 25, 2003, and April 26, 2002 is set forth in Exhibit 13 hereto and will be included in our 2004 Annual Report.

The section entitled "Notes to Consolidated Financial Statements" is set forth in Exhibit 13 hereto and will be included in our 2004 Annual Report.

**2. Financial Statement Schedules**

Schedule II. Valuation and Qualifying Accounts years ended April 30, 2004, April 25, 2003 and April 26, 2002 (set forth on page 43 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.
- 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)

## Edgar Filing: MEDTRONIC INC - Form 10-K

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 4.10).(h)
* 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	Form of Employment Agreement for Medtronic executive officers (Exhibit 10.5).(a)
* 10.6	Capital Accumulation Plan Deferral Program (Exhibit 10.6).(a)
* 10.7	Executive Nonqualified Supplemental Benefit Plan (Exhibit 10.7).(i)
* 10.8	Stock Option Replacement Program (Exhibit 10.8).(a)
* 10.9	1998 Outside Director Stock Compensation Plan, as amended. (Exhibit 10.8).(b)
* 10.10	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)
10.11	Director and Officer Indemnity Trust Agreement.
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, set forth on page 31 of this report.
21	List of Subsidiaries.
23	Consent of Independent Registered Public Accounting Firm (set forth on page 42 of this report).
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 the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (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.
- (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 January 23, 2004, filed with the Commission on March 5, 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.

\*

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.

(b) ***Reports On Form 8-K***

The Company filed a Report on Form 8-K on February 11, 2004 reporting the third quarter 2004 financial results under Items 5 and 7.

Subsequent to the quarter ended April 30, 2004, we filed one Report on Form 8-K, on May 24, 2004 reporting under Items 7 and 12 fourth quarter and fiscal year 2004 financial results.

**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, 2004

**By:** /s/ ARTHUR D. COLLINS, JR.

---

**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, 2004

**By:** /s/ ARTHUR D. COLLINS, JR.

---

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

Dated: June 29, 2004

**By:** /s/ ROBERT L. RYAN

---

**Robert L. Ryan  
Senior Vice President and  
Chief Financial Officer  
(Principal Financial and Accounting Officer)**

**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  
JEAN-PIERRE ROSSO  
JACK W. SCHULER  
GORDON M. SPRENGER**

**DIRECTORS**

Ronald E. Lund, 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, 2004

**By:** /s/ RONALD E. LUND

---

**Ronald E. Lund  
Attorney-In-Fact  
Senior Vice President,  
General Counsel and Secretary**

MEDTRONIC, INC. AND SUBSIDIARIES

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS  
(dollars in millions)

	Balance at Beginning of Fiscal Year	Charges/ (Credits) to Earnings	Other Changes (Debit) Credit	Balance at End of Fiscal Year
Allowance for doubtful accounts:				
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
Year ended 4/26/02	\$ 34.9	\$ 22.6	\$ (13.6)(a) \$ 0.3 (b) \$ 33.3 (c)	\$ 77.5

- (a) Uncollectible accounts written off, less recoveries.
- (b) Reflects primarily the effects of foreign currency fluctuations.
- (c) Allowance related to current year acquisitions.

Commission File Number 1-7707



QuickLinks

TABLE OF CONTENTS

PART I

Item 1. Business

Item 2. Properties

Item 3. Legal Proceedings

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

PART II

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

Item 6. Selected Financial Data

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Item 8. Financial Statements and Supplementary Data

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

Item 9A. Controls and Procedures

PART III

Item 10. Directors and Executive Officers of Medtronic

Item 11. Executive Compensation

Item 12. Security Ownership of Certain Beneficial Owners and Management

Item 13. Certain Relationships and Related Transactions

Item 14. Principal Accountant Fees and Services

PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

SIGNATURES

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS (dollars in millions)