

MEDTRONIC INC  
Form 10-K  
July 14, 2003

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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 25, 2003

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

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**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:

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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 25, 2002, based on the closing price of \$45.45, as reported on the New York Stock Exchange: approximately \$55.4 billion.

Shares of Common Stock outstanding on July 3, 2003: 1,217,868,613

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of Registrant's 2003 Annual Report are incorporated by reference into Parts I, II and IV; portions of Registrant's Proxy Statement for its 2003 Annual Meeting are incorporated by reference into Part III.

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### Trademarks and Other Rights

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

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

Activa®, ADVANTAGE®, AneuRx®, Assurant®, AT , AT 500 , Attain®, Aurora , Bravo , Bridge , Bryan®, Cardiac Compass , Cardioblade®, CD HORIZON®, CG Future , Crosslink®, Driver , Eclipse®, EnPulse , Entera®, EnteraFluoroNav®, Freestyle®, Gatekeeper Reflux Repair System , GEM®, GFX®, GuardWire Plus®, Hancock®, INFUSE®, InSync®, InterStim®, iON , Jewel®, Kappa®, LIFEPAK®, LT-CAGE®, Magellan , Marquis®, Maverick , Medtronic CareLink , Medtronic Hall®, METRx , Micro-Driver , Mosaic®, Multi-Exchange , Octopus®, Paradigm®, Prestige , SEXTANT , Starfish®, Stormer®, Strata®, SynchroMed®, Synergy®, Synergy Versitrel , TUNA®, Vertex®, Xpedient , and Zipper

### Annual Meeting and Record Dates

Medtronic's Annual Meeting of Shareholders will be held on Thursday, August 28, 2003 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 3, 2003 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) 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

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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. Today, every seven seconds, someone, somewhere in the world is either alive or living a more full life because of our products or therapies. We hold market-leading positions in almost all of the major markets in which we compete.

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

Cardiac Rhythm Management (CRM)

Neurological and Diabetes

Spinal, Ear, Nose and Throat (ENT) and Surgical Navigation Technologies (SNT)

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 25, 2003 (fiscal year 2003).

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 \$3.423 billion in fiscal year 1998 to \$7.665 billion in fiscal year 2003. 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 30,000 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, and a tradition of technological pioneering and breakthrough products that not only yield better medical outcomes, but more cost-effective therapies.

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

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

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Full commitment to superior patient and customer service.

Long experience with the regulatory process and sound working relationships with regulators, 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 that 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 manufacturing 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 \$6 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.

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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 cardiac rhythm management 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 cardiac rhythm management devices are currently implanted in more than 2 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 suffer 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 Kappa® 900 pacemaker is the world's most popular pacemaker, due in part to its advanced diagnostic capabilities that gather information about heart activity and allow physicians to make better patient management decisions. In March 2003, we launched the AT500 Pacing System, the first multiple-therapy pacing system to treat various atrial heart rhythm problems. In addition, clinical evaluation of our EnPulse pacing system, the world's first fully automatic pacemaker designed to optimize therapy and simplify care, began in May 2003.

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 improve survival between 30 percent and 60 percent compared to commonly prescribed antiarrhythmic drugs. Despite this mounting evidence, less than one-third of all patients who are indicated for an ICD actually receive them, 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 and breast cancer combined, yet ICDs account for only 0.17 percent of the \$1.3 trillion health care budget. Tachyarrhythmias

that occur in the upper chambers (the atria), such as atrial fibrillation, can negatively affect quality of life and, if left untreated, can lead to strokes.

We offer the most comprehensive product choices to treat various kinds of tachyarrhythmias. The Marquis® DR ICD defibrillator is our most advanced defibrillator, and is the most widely prescribed ICD in the world. In December 2002, our Marquis family of ICDs expanded with

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United States Food and Drug Administration (FDA) approval of the Marquis VR ICD defibrillator, featuring more than 20 new or updated technological advances. 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. We also offer the GEM® III AT defibrillator for patients who suffer from both ventricular and atrial tachyarrhythmias.

The ICD market is currently experiencing a significant expansion, driven in part by new guidelines issued by a joint committee of the American Heart Association (AHA), the American College of Cardiology (ACC) and the North American Society of Pacing and Electrophysiology (NASPE) recommending the use of antiarrhythmic devices in certain heart attack survivors to reduce mortality. In addition, we expect the ICD market to benefit from the results of MADIT II, a large medical study that significantly increases the number of people proven to be at high risk of sudden cardiac arrest, and SCD-HeFT, the largest ICD trial to-date of its kind to assess the benefit of ICD's in a broad group of patients at risk for sudden cardiac arrest. MADIT II was approved by the FDA and endorsed by the ACC and other international medical organizations. In June 2003, the Centers for Medicare and Medicaid Services (CMS) expanded coverage of ICDs for Medicare beneficiaries who meet certain MADIT II indicators. SCD-HeFT results are expected to be available near the end of fiscal year 2004.

Heart failure is a large and growing health problem, afflicting nearly 5 million Americans currently. 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 was the world's first tri-chamber heart device and is available commercially in Europe and the U.S. Medtronic's InSync III, our third generation cardiac resynchronization device, has advanced programming functions to help physicians better manage heart failure patients and is now available in Europe and the U.S. Adoption of CRT is supported by a mounting body of clinical evidence. In June 2002, the New England Journal of Medicine published results of the MIRACLE (Multi-Center InSync Randomized Clinical Evaluation) study, demonstrating, among other things, that patients receiving CRT from our InSync device had 50% fewer hospitalizations and 77% fewer hospital days related to heart failure than those in the control group. In February 2003, an article in the Journal of the American Medical Association showed that "cardiac resynchronization reduced death from progressive heart failure by 51% relative to controls." In April 2003, an article published in CIRCULATION, the official journal of the American Heart Association, showed that patients in a large clinical study who received CRT developed smaller, stronger hearts, a concept known as reverse remodeling.

In fiscal year 2003, two of our devices were approved by the FDA for the growing number of patients with heart failure who are also considered at high risk of SCA. This was an important clinical advance since SCA occurs in heart failure patients at six to nine times the rate observed in the general population. The InSync ICD device, approved by the FDA in June 2002, provides CRT for heart failure plus advanced defibrillation capabilities. Our InSync Marquis system, approved by the FDA in March 2003, combines the cardiac resynchronization of InSync devices with the state-of-the-art defibrillation therapies of the Marquis ICD platform. Both devices protect patients from the potentially lethal tachyarrhythmias that may lead to SCA. In May 2002, the FDA approved the Attain® Over-the-Wire lead which is designed to increase

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steerability and stability, facilitating faster, easier placement in the small and medium-sized cardiac veins of the left-heart.

We continue to drive rapid technological advancement in therapies for heart failure and have fifth-generation devices in development. The InSync III Marquis device combines the best of the InSync III device and the InSync Marquis systems, with important new functions that are designed to improve the effectiveness of CRT. The InSync III Marquis system includes new features designed to help maintain cardiac resynchronization during episodes of atrial fibrillation, the most common arrhythmia, and provides monitoring capabilities for managing patients' heart failure status. It is currently under clinical evaluation in the U.S. and Europe.

**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 currently 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 home and even while traveling in the U.S. 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

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available to approximately 100,000 patients with various Medtronic GEM model ICDs and the Medtronic Marquis DR ICD defibrillator. 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. Our LIFEPAK® series of external defibrillators offers a broad range of life-saving tools for multiple user needs and 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.

### **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.

### **Neurological and Diabetes**

Neurological and Diabetes is composed of sectors that develop, manufacture, and market 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

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and restore the normal 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. The acquisitions of Endonetics, Inc., (Endonetics) in December 2001 and VidaMed, Inc. (VidaMed) in April 2002 described under "Acquisitions and Investments" on page 15 strategically positioned us to become a worldwide leader providing total solutions to our gastroenterology and urology customers. 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 and healthier lives. We entered the diabetes market through the acquisitions of MiniMed, Inc. (MiniMed) and Medical Research Group (MRG) in August 2001, described under "Acquisitions and Investments" on page 15.

### **Conditions Treated**

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

Neurological disorders including chronic pain, Parkinson's disease, tremor, 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, 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. The increase in fiscal year 2002 net sales was mainly due to the acquisition of our Diabetes business in August 2001, as described below under "Diabetes."



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***Principal Products***

Our neurological and diabetes products consist of therapeutic and diagnostic devices, including implantable neurostimulation systems, external and implantable drug administration devices, continuous glucose monitoring systems, hydrocephalic shunts and drainage devices, surgical instruments and functional diagnostic equipment.

***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 a national coverage decision for our unique Aactiva® Parkinson's Control Therapy from the Centers for Medicare and Medicaid Services. This decision extends access to Aactiva Parkinson's Control Therapy to hundreds of thousands of people seeking relief from the debilitating slowness, stiffness, shaking and abnormal, involuntary movements that are common symptoms of advanced Parkinson's disease. In addition, in April 2003, the FDA approved a Humanitarian Device Exemption making Aactiva Therapy available to people with dystonia, the hard-to-treat condition that causes involuntary muscle contractions forcing certain parts of the body into uncontrolled, sometimes painful, movements or postures.

We have the broadest offering of any medical device company 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. Pain-relieving stimulation is felt as a slight tingling sensation. 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. The SynchroMed® EL 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 EL drug delivery system reduces the amount of medication necessary to control pain and spasticity, thereby minimizing undesirable side effects. The handheld N'Vision Programmer, commercially released in Europe in May 2002, and in the U.S. in January 2003, is a common programmer platform intended for use with all of our implantable neurostimulators and drug pumps.

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 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, and is the fifth leading cause of death in the U.S. Diabetes has been described as an epidemic, and afflicts more than 170 million people worldwide, with approximately 20 million in the U.S., approximately 2,200 new cases are diagnosed each day in the U.S. Currently, our products serve the insulin dependent population, which includes approximately five 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 adults who are twenty to seventy-four years old, treated 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.'s health care system, with more than \$130 billion spent annually on diabetes and its complications, including \$90 billion in direct medical costs.

Our products are used for intensive insulin management and include external pumps and related disposables, a continuous glucose monitoring system, 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 in clinical trials. Currently, 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 properly produce or use insulin. Our Paradigm® insulin infusion pump is currently the leading choice in insulin pump therapy. Pump wearers can deliver insulin without accessing the pump by using a hand-held remote programmer. The Paradigm pump is the smallest full-featured pump available on the market and the easiest to use. 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 longer-acting insulin, it helps diabetes patients to better control their glucose levels within a near-normal range, offering both short-term and long-term health benefits. In January 2003, we announced a strategic alliance with Becton, Dickinson & Co. (BD) to accelerate awareness of pump therapy among the insulin using population, and to jointly develop products integrating BD's glucose meter and strip technology with our insulin pumps and continuous glucose sensors. We believe this integration will simplify diabetes management, fostering patient adherence, and leading to tighter blood glucose control and overall health.

**Gastroenterology and Urology.** Our diagnostic and therapeutic products for gastroenterology and urology include the Enterra<sup>SM</sup> Therapy for gastroparesis, Bravo pH monitoring system and Gatekeeper Reflux Repair System for the evaluation and treatment of gastroesophageal reflux disease (GERD), or acid reflux. Our gastroenterology and urology products also include our InterStim® Therapy device for urinary and bowel control and our TUNA® (transurethral needle ablation) therapy for enlarged prostate and functional diagnostic equipment.

In May 2002, we began U.S. commercial sales of the Bravo pH monitoring system, the first catheter-free diagnostic system for measuring acid levels in the esophagus, to evaluate GERD. A common disorder that is frequently misdiagnosed, GERD is caused when the lower esophageal sphincter that separates the stomach from the esophagus becomes weak and ineffective, allowing stomach contents to flow back, or reflux, into the esophagus. The Gatekeeper Reflux Repair System for the non-invasive treatment of GERD is undergoing clinical trials in the U.S. and Europe.

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. TUNA is designed to treat benign prostatic hyperplasia (BPH), an aggressive and naturally occurring condition that enlarges the prostate gland and afflicts up to 23 million men worldwide. TUNA 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, and Stryker Corporation. Our primary competitors for gastroenterology and urology products are Boston Scientific

Corporation, and Urologix, Inc. Our primary competitors for diabetes products are Animas Corporation, Disetronic Medical Systems, Inc., and Smiths Group plc.

#### **Spinal, Ear, Nose, and Throat (ENT) and Surgical Navigation Technologies (SNT)**

Our Spine division is well known for its innovative spinal products, commitment to customers and unsurpassed technical support. Strong partnerships with leading spine surgeons help us to 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 1999. Also in 1999, we acquired Xomed Surgical Products, Inc., the world's leading ENT surgical product manufacturing company. Today we offer a range of products and therapies to treat a variety of disorders of the cranium and spine that often dramatically affect 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

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, surgical navigation tools and surgical products used by ENT physicians.

***Spinal.*** Back pain is the third most cited reason for visits to a health 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 professional. Of those, 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, both in 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. The allograft bone products we distribute come primarily from Regeneration Technologies, Inc. (RTI). In June 2002, we entered into a new license and distribution agreement with RTI that replaced two existing agreements. As under the prior agreements, we remain RTI's exclusive distributor in the spinal market for the allograft tissue that is screened, tested and processed by RTI. The new agreement is for an initial term expiring June 2014, subject to earlier termination under certain limited circumstances.

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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, the METRx MicroDiscectomy System, used to treat herniated discs, and the CD Horizon® Eclipse® Spinal System, used to correct curvature of the spine in scoliosis patients.

In July 2002, we received FDA approval of our INFUSE® Bone Graft for use with the LT-CAGE® Lumbar Tapered Fusion Device for treatment of certain types of spinal degenerative disc disease, a common cause of low back pain. Due to convincing clinical results and compelling patient benefits, INFUSE Bone Graft is generating significant patient demand and high rates of surgeon adoption. While still early, uptake among key opinion leaders has been particularly strong, and INFUSE Bone Graft is rapidly becoming the standard of care at our nation's premier spine centers. 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 BioPharma) and demonstrates our commitment to the advancement of science in the spine field.

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 15; the Maverick Artificial Disc for the lumbar spine; and the Prestige, an internally developed cervical disc. The Bryan cervical disc is commercially available and selling well in Europe, and the Maverick lumbar disc has been well received by surgeons since its European launch in February 2003. The Prestige has not been market released as it is in development.

**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 neurosurgeons to optimize their surgical plans and use this advanced surgical information during the procedure and delivery of therapies. Our FluoroNav® and iON fluoroscopic

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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. These advanced imaging and navigation technologies enable physicians to perform safer, less invasive surgical procedures that improve outcomes.

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

The primary medical specialists who use our spinal 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 Centrepulse, Johnson & Johnson, and Synthes-Stratec, Inc., in the ENT business are Gyrus Group PLC and Stryker Corporation and in the SNT business are BrainLAB, Inc. and Stryker Corporation.

### **Vascular**

Our Vascular division 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 1999.

### ***Conditions Treated***

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

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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 (AAA) and weakening or dissection of the thoracic aorta (TAA)

The charts below set forth net sales of our vascular products as a percentage of our total net sales for each of the last three fiscal years. The decrease in Vascular net sales in fiscal year 2002 of 3% and again in fiscal year 2003 of 14% was primarily due to a September 2001 court order that required us to stop selling our line of rapid exchange perfusion delivery systems in the U.S. after a finding that our systems infringed a competitor's patent. We continue to offer all of our coronary stents with other delivery systems in the U.S. and with rapid exchange delivery systems outside the U.S. Late in fiscal year 2003, we introduced our Multi-Exchange delivery system, Zipper Delivery Platform, in the U.S. and as a result have now re-entered the short wire segment of this market.

### ***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 Stormer® Over-The-Wire Balloon Dilatation Catheter system, which received FDA clearance for U.S. commercial sales in May 2002.

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. We offer a variety of coronary stents, including our unique S70 modular stent which offers sophisticated design characteristics, including a low crossing profile and excellent scaffolding. Our next 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 making possible very strong, ultra-thin struts that offer excellent flexibility and excellent vessel support. The Driver stent was launched in Europe in January 2003, and the Micro-Driver coronary stent, specifically designed for use in small vessels, was launched in June 2003. The Driver and Micro Driver stents are currently in clinical trials in the U.S.

During fiscal year 2003, we introduced a new delivery system for use in either balloon angioplasty or stent delivery, our innovative Zipper Delivery Platform, which represents a fundamental shift from existing technologies. The proprietary Zipper technology facilitates quick, easy exchange of wires and catheters during a coronary angioplasty or stenting procedure.

**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. A drug-eluting stent was commercially released by Johnson and Johnson, Inc. in the U.S. market in April 2003, and is expected to become a significant competitive factor in the worldwide market for stents. We are pursuing an integrated strategy that combines an innovative delivery system, an advanced stent, an effective drug, and a polymer coating that controls the release of the drug into the vessel wall. Our drug-eluting stent program achieved several important milestones in fiscal year 2003. 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 (a rapamycin analogue), as well as the phosphoryl choline coating Abbott has licensed from Biocompatibles International PLC for use

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in conjunction with ABT-578. This proprietary biocompatible polymer has been shown in clinical studies to be a safe polymeric drug-eluting platform. In January 2003, we started a 100- patient feasibility study of a coated version of our Driver stent, and in April 2003, less than a year after our agreement with Abbott, enrollment was successfully completed. We expect to begin a pivotal trial in Europe by the fall of 2003.

**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, where it may 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 had 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 January 2003, we launched the new and easy-to-use Xpedient Delivery System for AneuRx grafts, which makes deployment easier for physicians, while facilitating delivery through tortuous vasculature. 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. Our Bridge Assurant® Balloon-Expandable Stent Delivery System for biliary treatment was commercially released in the U.S. in May 2002 and our next generation Aurora Self-Expandable Stent System received FDA approval in May 2003.

#### **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 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, Cardiac Rhythm Management 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.

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The charts below set forth net sales of our cardiac surgery products 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 stents, 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 850,000 bypass procedures are performed each year worldwide. There are two primary techniques, arrested heart surgery and beating heart surgery described below.

***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 has experienced 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. The Magellan Autologous Platelet Separator was market released in the U.S. in December 2002. 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 Cardioblate® Ablation System is designed to allow surgeons to efficiently restore a normal heart rhythm by neutralizing the cells causing troublesome electrical activity.

***Beating Heart Surgery.*** Increasingly, physicians are performing coronary artery bypass surgery on the beating heart to avoid the complexity and potential risks of stopping the heart. To assist physicians performing beating heart surgery, we offer positioning and stabilization technologies. Our Starfish® 2 Heart Positioner, commercially released in the U.S. in May 2002, uses suction technology to gently lift and position the beating heart to expose arteries on any of its surfaces. The Starfish heart positioner is designed to work in concert with our Octopus® 4 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 350,000 coronary artery bypass surgeries that take place in the U.S. each year.

***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 because of 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

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implant the valve. Other tissue product offerings include the Freestyle® and Hancock® II. In February 2003, we significantly strengthened our mechanical valve line in Europe with the launch of the ADVANTAGE® bileaflet mechanical heart valve. It remains in clinical evaluation in the U.S., Canada, Japan and Australia. Currently, the Medtronic Hall® mechanical valve, is available in the U.S. Our repair products include the Duran Flexible and CG Future Band annuloplasty systems.

### *Customers and Competitors*

The principal medical specialists who use our cardiac surgery products are cardiac surgeons. Our primary competitors in the Cardiac Surgery business are Edwards LifeSciences Corporation, Guidant Corporation, Johnson & Johnson 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 2003, 2002, and 2001, we spent \$749.4 million (9.8% of net sales), \$646.3 million (10.1% of net sales), and \$577.6 million (10.4% 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 results of operations, financial condition, or cash flows.

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.

In April 2002, we also acquired the remaining equity in a joint venture we formed to distribute spinal products in Japan for \$128 million in cash, of which \$58 million will be paid in installments through fiscal year 2009.

In April 2002, we acquired VidaMed, Inc. (VidaMed) for approximately \$329 million in cash. With VidaMed's TUNA system for the non-surgical treatment of enlarged prostate glands, we added a significant product to our urology business.

In December 2001, we acquired Endonetics, Inc. (Endonetics), a privately held company, for approximately \$67 million in cash. Endonetics develops diagnostic and therapeutic devices to manage gastrointestinal conditions, including the Bravo pH monitoring system for patients experiencing or suspected of having gastroesophageal reflux disease. We acquired Endonetics to accelerate our entry into the gastrointestinal market.



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In August 2001, we acquired MiniMed and a related company, MRG, for a total of approximately \$3.8 billion in cash. With these acquisitions, we became a leading provider of external programmable insulin pumps and continuous glucose monitoring systems and a leader in the development of implantable insulin pumps and glucose sensors.

### 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 to 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 and 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.

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### 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. Although our intellectual property rights are important to our success, our business as a whole is not materially dependent on any particular patent or license.

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 financial position or cash flows, it may be material to the results of operations 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

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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 addressing areas of significant demand in the marketplace, obtain regulatory approvals and manufacture and successfully market these products.

### **Worldwide Operations**

We sell products in more than 120 countries. 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, which are included in our fiscal year 2003 Annual Report to Shareholders (the "2003 Annual Report"), incorporated herein by reference.

### **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, potential 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, which are included in our 2003 Annual Report and incorporated herein by reference. Certain countries also limit or regulate the repatriation of earnings to the U.S. Operations outside of the U.S., in general, 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 25, 2003, we employed approximately 30,000 full-time equivalent 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.

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### Government Regulation and Other Considerations

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

Authorization to commercially distribute a new medical device in the U.S. is generally received in one of two ways. The first, known as the 510(k) process, requires us to demonstrate that our new medical device is substantially equivalent to a legally marketed medical device. In this process, we must submit data that supports our equivalence claim. If human clinical data is required, it must be gathered in compliance with FDA investigational device 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 510(k) process if the changes do not significantly affect safety or effectiveness.

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

Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experience and other information to identify potential problems with marketed medical devices. We may be subject to periodic inspection by the FDA for compliance with the FDA's good manufacturing practice regulations. These regulations, also known as the Quality System Regulations, govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, and require us to notify health professionals and others that the 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 us, our officers or employees. The FDA can also recommend prosecution to the Department of Justice.

The FDA also 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 whom 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.

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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

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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 payers 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 payers. 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 governments' 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 from providing certain services to a patient if that patient was referred by a physician who 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, the Company, 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 financial position, or cash flows, it may be material to the results of operations of any one period. See "Item 3 Legal Proceedings" for additional information.

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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 in manufacturing and sterilization processes. We do

not expect that compliance with environmental protection laws will have a material impact on our 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. 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 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 for future results. Our forward-looking statements generally relate to growth strategies, financial results, product development, regulatory approvals, competitive strengths, the scope of our intellectual property rights, and sales efforts. Words such as "anticipates," "believes," "could," "estimates," "expects," "forecast," "intend," "may," "plan," "possible," "project," "should," "will" and similar expressions generally identify our forward-looking statements. 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

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

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our ability to effectively manage our inventory mix and inventory levels

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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 payer 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

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

the impact of more vigorous compliance and enforcement activities

changes in the tax and environmental laws affecting our business

### **Legal disputes, including:**

disputes over intellectual property rights

product liability claims

claims asserting securities law violations

claims asserting violations of federal law in connection with Medicare and/or Medicaid reimbursement

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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.

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) could affect, our ability to implement our business strategy and may 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.

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**Arthur D. Collins, Jr.**, age 55, 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.

**Jeffrey A. Balagna**, age 42, has been Senior Vice President, Chief Information and Quality Officer of the Company since October 2002. Previously, Mr. Balagna was Senior Vice President and Chief Information Officer of the Company from March 2001 to October 2002. 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.

**Michael F. DeMane**, age 47, has been Senior Vice President and President, Spinal, ENT, and SNT, since February 2002 and President, Spinal Systems, since November 1999. From June 1998 to November 1999, he was President, Interbody Technologies, a division of Sofamor Danek. 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.

**Janet S. Fiola**, age 61, 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 54, 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



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various management positions within General Electric Corporation, including GE's Medical Systems division.

**William A. Hawkins**, age 49, joined the Company as Senior Vice President and President, Vascular, in January 2002. 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.

**Stephen H. Mahle**, age 57, has been Senior Vice President and President, Cardiac Rhythm Management, since January 1998. Prior to that, he was President, Brady Pacing, from May 1995 to December 1997 and Vice President and General Manager, Brady Pacing, from January 1990 to May 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 52, has been Senior Vice President, Medicine and Technology, since January 2002. 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. He has also held other academic positions and directed interventional cardiology programs at Georgetown University and in Los Angeles.

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**Robert L. Ryan**, age 60, 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 May 1983 to May 1984, and Treasurer from March 1982 to May 1983.

**David J. Scott**, age 50, has been Senior Vice President and General Counsel since joining the Company in May 1999 and Secretary since January 2000. Prior to that, Mr. Scott was General Counsel of London-based United Distillers & Vintners from December 1997 to April 1999, General Counsel of London-based International Distillers & Vintners (IDV) from April 1996 to November 1997, and Senior Vice President and General Counsel of IDV's operating companies in North and South America from January 1993 to March 1996.

**Scott R. Ward**, age 43, has been Senior Vice President and President, Neurological and Diabetes, since February 2002, 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.

**Keith E. Williams**, age 50, became Senior Vice President and President, Asia Pacific, in October 2002. Mr. Williams was previously Senior Vice President and Chief Quality Officer from February 2002 to October 2002, and was Senior Vice President and President, Neurological, Spinal and ENT, from August 2000 to February 2002. 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. He also 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 59, has been Senior Vice President since September 1997 and President, International, since April 2001. He was President, Europe, Middle East and Africa, from April 1995 to March 2001. Mr. Wilson was also President 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.

### 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, India, 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 95 locations in 33 states or jurisdictions and outside the U.S. at approximately 104 locations in 32 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

In October 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. In December 2000, a Delaware jury rendered a verdict that the previously marketed MicroStent and GFX® stents infringe valid

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claims of two patents and awarded damages to Cordis totaling approximately \$270.0 million. In March 2002, the 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 the Court of Appeals for the Federal Circuit heard oral argument on May 6, 2003. The timing of the appellate court's ruling is unknown.

In December 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.

In June 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 case is in the discovery stage.

In September 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 have been decided in the 1997 case above.

In January 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, and now claims that MSD's M10, M8 and Vertex screws infringe the patent. On April 17, 2003, the District Court ruled that the M10 and M8 multiaxial screws do not infringe. There will be further proceedings with respect to the Vertex screws and the previously sold MAS.

In May 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 case is in discovery, the court has under consideration certain motions for partial summary judgment, and trial is scheduled for January 2004.

In June 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 court has under consideration defendants' motion for summary judgment.

In October 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

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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. In June 2003, Medtronic's motion to dismiss the action on several grounds was denied by the U.S. District Court, Southern District of Ohio. A petition for permission to appeal is pending, a trial date of January 2004 is set pending the appellate court decision.

In May 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. No case schedule has been set for this matter.

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 25, 2003. 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 or cash flows, but may be material to the consolidated results of operations of any one period.

Note 14 to the consolidated financial statements in our 2003 Annual Report is incorporated herein by reference.

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

Not applicable.

**PART II**

**Item 5. Market for Medtronic's Common Equity and Related Shareholder Matters**

The information in the section entitled "Price Range of Medtronic Stock" in our 2003 Annual Report is incorporated herein by reference.

**Item 6. Selected Financial Data**

The information for the fiscal years 1999 through 2003 in the section entitled "Selected Financial Data" in our 2003 Annual Report is incorporated herein by reference.

**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" in our 2003 Annual Report is incorporated herein by reference.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

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The information in the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Market Risk" and in Note 4 to the consolidated financial statements in our 2003 Annual Report is incorporated herein by reference.

### **Item 8. Financial Statements and Supplementary Data**

The consolidated financial statements and notes thereto, together with the report thereon of independent auditors contained in our 2003 Annual Report, are incorporated herein by reference.

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

Not applicable.

## **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 2003 Annual Shareholders' Meeting is incorporated herein by reference. See also "Executive Officers of Medtronic" on pages 23 through 25 hereof.

We have adopted a written Code of Ethics that applies to our chief executive officer, chief financial officer, corporate controller and treasurer, and to other senior financial officers performing similar functions who are identified from time to time by the chief executive officer. This Code of Ethics, which is part of our broader Code of Conduct applicable to all employees, is posted on our website, [www.medtronic.com](http://www.medtronic.com), under the "Corporate Governance" caption. Any amendments to, or waivers of, this Code of Ethics 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 2003 Executive Compensation", "Shareholder Return Performance Graph", and "Executive Compensation" in our Proxy Statement for our 2003 Annual Shareholders' Meeting are incorporated herein by reference.

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

The sections entitled "Share Ownership Information" and "Equity Compensation Plan Information" in our Proxy Statement for our 2003 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 2003 Annual Shareholders' Meeting is incorporated herein by reference.

### **Item 14. Controls and Procedures**

- (a) Evaluation of disclosure controls and procedures.

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Within the 90-day period prior to the filing of this report, 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 IV

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

(a)

##### 1. Financial Statements

**The sections entitled "Report of Independent Auditors" and "Statements of Consolidated Earnings" years ended April 25, 2003, April 26, 2002 and April 27, 2001 in our 2003 Annual Report are incorporated herein by reference.**

The section entitled "Consolidated Balance Sheets" April 25, 2003 and April 26, 2002 in our 2003 Annual Report is incorporated herein by reference.

The section entitled "Statements of Consolidated Shareholders' Equity" years ended April 25, 2003, April 26, 2002 and April 27, 2001 in our 2003 Annual Report is incorporated herein by reference.

The section entitled "Statements of Consolidated Cash Flows" years ended April 25, 2003, April 26, 2002, and April 27, 2001 in our 2003 Annual Report is incorporated herein by reference.

The section entitled "Notes to Consolidated Financial Statements" in our 2003 Annual Report is incorporated herein by reference.

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##### 2. Financial Statement Schedules

Schedule II. Valuation and Qualifying Accounts years ended April 25, 2003, April 26, 2002 and April 27, 2001 (set forth on page 36 of this report)

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

##### 3. Exhibits

- 3.1 Medtronic Restated Articles of Incorporation, as amended (Exhibit 3.1).(a)
- 3.2 Medtronic Bylaws, as amended to date (Exhibit 3.2).(b)
- 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

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Indenture, dated as of September 11, 2001, between Medtronic, Inc. and Wells Fargo Bank Minnesota, N.A. (Exhibit 4.2).(d)

4.3	Registration Rights Agreement, dated as of September 11, 2001, among Medtronic, Inc., Banc of America Securities LLC, Goldman, Sachs & Co., and Morgan Stanley & Co. Incorporated (Exhibit 4.3).(d)
4.4	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)
4.5	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)
4.6	First Amendment to 364-Day Revolving Credit Facility, dated as of August 21, 2002 (Exhibit 4.6).(f)
4.7	First Amendment to Five Year Revolving Credit Facility, dated as of August 21, 2002 (Exhibit 4.7).(f)
4.8	Second Amendment to 364-Day Revolving Credit Facility, dated as of January 23, 2003 (Exhibit 4.8).(g)
4.9	Second Amendment to Five Year Revolving Credit Facility, dated as of January 23, 2003 (Exhibit 4.9).(g)
*	10.1 1994 Stock Award Plan, as amended. (Exhibit 10.1).(b)
*	10.2 Medtronic Incentive Plan.
*	10.3 Management Incentive Plan (Exhibit 10.2).(h)
*	10.4 1979 Nonqualified Stock Option Plan, as amended. (Exhibit 10.3).(b)
*	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.
*	10.8 Stock Option Replacement Program (Exhibit 10.8).(a)
*	10.9 1998 Outside Director Stock Compensation Plan, as amended. (Exhibit 10.8).(b)

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*	10.10 Amendment effective March 5, 1998 to the 1979 Nonqualified Stock Option Plan (Exhibit 10.14).(i)
*	10.11 Amendments effective October 25, 2001, regarding change in control provisions in the following plans: Management Incentive Plan, 1998 Outside Director Stock Compensation Plan, Capital Accumulation Plan Deferred Program and Executive Nonqualified Supplemental Benefit Plan. (Exhibit 10.10)(b)
	12.1 Computation of ratio of earnings to fixed charges.
	13 Those portions of Medtronic's 2003 Annual Report expressly incorporated by reference herein, which shall be deemed filed with the Commission.
	21 List of Subsidiaries.
	23 Consent and Report of Independent Auditors (set forth on page 35 of this report).
	24 Powers of Attorney.
	99.1 Certifications pursuant to 8 U.S.C. section 1350, as adopted 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.







- c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. Medtronic's other certifying officer and I have disclosed, based on our most recent evaluation, to Medtronic's auditors and the audit committee of Medtronic's board of directors:
- a. all significant deficiencies in the design or operation of internal controls which could adversely affect Medtronic's ability to record, process, summarize and report financial data and have identified for Medtronic's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in Medtronic's internal controls; and
6. Medtronic's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: July 14, 2003

/s/ ARTHUR D. COLLINS, JR.

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

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**Certification of Chief Financial Officer  
Pursuant to Section 302 of the  
Sarbanes-Oxley Act of 2002**

I, Robert L. Ryan, certify that:

1. I have reviewed this annual report on Form 10-K of Medtronic, Inc. (Medtronic);
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report; and
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of Medtronic as of, and for, the periods presented in this annual report.
4. Medtronic's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for Medtronic and we have:
  - a.

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designed such disclosure controls and procedures to ensure that material information relating to Medtronic, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

- b. evaluated the effectiveness of Medtronic's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
- c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. Medtronic's other certifying officer and I have disclosed, based on our most recent evaluation, to Medtronic's auditors and the audit committee of Medtronic's board of directors:

- a. all significant deficiencies in the design or operation of internal controls which could adversely affect Medtronic's ability to record, process, summarize and report financial data and have identified for Medtronic's auditors any material weaknesses in internal controls; and
- b. any fraud, whether or not material, that involves management or other employees who have a significant role in Medtronic's internal controls; and

6. Medtronic's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: July 14, 2003

/s/ ROBERT L. RYAN

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Robert L. Ryan  
Senior Vice President and  
Chief Financial Officer

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### **REPORT OF INDEPENDENT AUDITORS ON FINANCIAL STATEMENT SCHEDULE**

To the Board of Directors of Medtronic, Inc.:

Our audits of the consolidated financial statements referred to in our report dated May 19, 2003 appearing in the 2003 Annual Report to Shareholders of Medtronic, Inc. (which report and consolidated financial statements are incorporated by reference in this Annual Report on Form 10-K) also included an audit of the financial statement schedule listed in Item 15(a)2 of this Form 10-K. In our opinion, this financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

/s/ PricewaterhouseCoopers LLP

Minneapolis, Minnesota  
May 19, 2003

**CONSENT OF INDEPENDENT AUDITORS**

We hereby consent to the incorporation by reference in each Registration Statement on Form S-8 (Registration Nos. 33-169, 33-24212, 33-37529, 33-44230, 33-55329, 33-63805, 333-04099, 333-07385, 333-65227, 333-71259, 333-71355, 333-74229, 333-75819, 333-90381, 333-52840, 333-44766, 333-66978, 333-68594, 333-100624 and 333-106566) and the Registration Statement on Form S-3 (Registration No. 333-74994) of Medtronic, Inc. of our report dated May 19, 2003 relating to the consolidated financial statements, which appears in the 2003 Annual Report to Shareholders of Medtronic, Inc., which report is incorporated by reference in this Annual Report on Form 10-K. We also consent to the incorporation by reference of our report dated May 19, 2003 relating to the financial statement schedule, which appears in this Annual Report on Form 10-K.

/s/ PricewaterhouseCoopers LLP

Minneapolis, Minnesota  
July 10, 2003

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**MEDTRONIC, INC. AND SUBSIDIARIES**

**SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**  
(in millions)

	<b>Balance at Beginning of Fiscal Year</b>	<b>Charges/ (Credits) to Earnings</b>	<b>Other Changes (Debit) Credit</b>	<b>Balance at End of Fiscal Year</b>
<b>Allowance for doubtful accounts:</b>				
Year ended 4/25/03	\$ 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
Year ended 4/27/01	\$ 30.2	\$ 9.0	\$ (4.5)(a) \$ 0.2 (b)	\$ 34.9

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

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SIGNATURES

Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

REPORT OF INDEPENDENT AUDITORS ON FINANCIAL STATEMENT SCHEDULE

CONSENT OF INDEPENDENT AUDITORS

MEDTRONIC, INC. AND SUBSIDIARIES

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS (in millions)