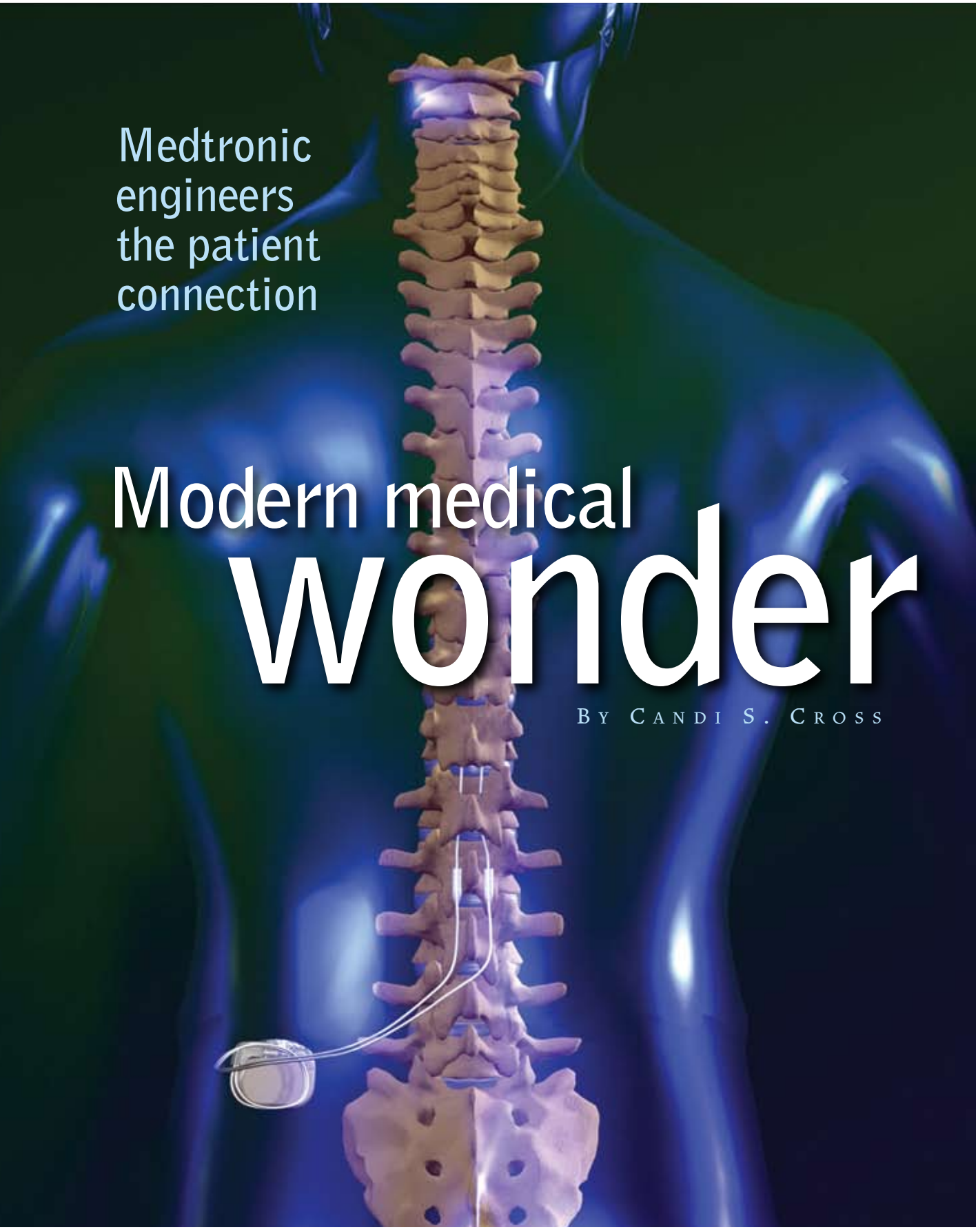


Medtronic engineers the patient connection

Modern medical wonder

By Candi S. Cross

Photos and images courtesy Medtronic, Inc.

To patients, pharmaceutical plants and medical device manufacturers can resemble merely abstracted dots on a map even though their state of health may depend on the products of those companies. In the distance, experts conduct research, develop prototypes, perform various tests on random populations, and voila — three to seven years later, a groundbreaking treatment for a disease or lifesaving device reveals itself everywhere.

For medical device manufacturer Medtronic Inc., this is a realistic description for the release of a product. The company's memorable slogan: "Every five seconds, somewhere in the world, a person's life is saved or improved by a Medtronic product or therapy."

As a matter of fact, at this moment on a computer screen, someone's heart is triggering colorful bursts of activity that may frighten a patient and physician concurrently. However, a Medtronic patient care representative may also be aware of this occurrence and immediately respond. All three parties share a real-time window into the heart's chambers through Medtronic's latest implantable defibrillator, known as the Virtuoso.

In fact, Medtronic is well versed in inventing applications for a wide variety of systems in the human anatomy. The Synchromed, which controls muscle spasticity, is registered to countless patients with cerebral palsy and multiple sclerosis. Intrathecal drug delivery helps thousands of cancer patients manage pain with medication that goes straight to the area surrounding the spinal cord where pain signals travel. And Medtronic's pacemakers have been inserted into at least a million hearts for the purpose of easing rhythm disturbances that could lead to permanent coronary damage or death.

What is rarely known about the company is its direct relationship with patients and how this culture of patient connection crystallizes in departments as varied as research and development, design, manufacturing, marketing, and sales. Approximately 37,000 employees worldwide align with a business mission to alleviate pain and extend lives. The company insists that a mission to manufacture a bottomless inventory of devices that will turn high profits (the average cost for a pacemaker is $20,000) does not align with Medtronic principles that were established in 1949.

First demonstrated by founders Earl Bakken, who tended to electrical problems in operating rooms with his own screwdriver, and Palmer Hermundslie, who piloted his own airplane for emergency deliveries of the company's pacemakers, patient service is an essential component of Medtronic's operations.

No margin for error

Fortune magazine listed Medtronic among the best 100 companies to work for in 2007.

During the winter holidays, employees gather for an event with a reminder that it is the most important meeting of the year.

"We have a 'quality day' where the plant shuts its doors for the day (no small expense) and we hear firsthand from the patients, including children, who we have helped. This is a very emotional and rewarding day for all of us," says Kirk Knock, quality systems manager. "Even though I have come to expect innovative ideas and products here at Medtronic, I continue to witness presentations or see materials that have the 'Wow factor' when improving the lives of the patient or physician. There is no margin for error when dealing with physicians and their patients. When manufacturing a complex device using complex systems we must all have quality, rigor, and the patient in mind. I see that in all levels and roles within the organization."

Witnessing firsthand how a medical device can positively alter someone's existence not only exhilarates product creators. At Medtronic, seeing patients and hearing about their experiences has led to a strong work ethic, motivated continual innovation, and improved manufacturing processes. Bodybuilder Stevie Zee is a quintessential success for the company. Despite cerebral palsy, he made his debut in a national bodybuilding competition thanks to a SynchroMed implant, which helped his muscles contract and extend enough to capitalize on 15 years of prior fitness training. Zee won third place in the Los Angeles Championships last year.

Glowing results such as these reverberate throughout the company's locations from Copenhagen, Denmark to Tolochenaz, Switzerland. Still, the rewards don't come easily for an operation centered on improving and extending human life.

Medical device manufacturing is an industry that includes more than 100,000 products in 1,700 categories. Class III devices, the highest-risk devices that tend to represent new technology and make up Medtronic's product line (usually life-supporting and life-sustaining), bring a host of potentially fatal complications. According to the Department of Health and Human Services, the most common problems that can arise with their use include mechanical failure, faulty design, poor manufacturing quality, adverse effects of materials implanted in the body, improper maintenance or specifications, user error, compromised sterility or shelf life, and electromagnetic interference.

Given the nature of Class III devices, each is subject to stringent controls and requirements within a comprehensive evaluation, including data from clinical studies corroborated in bench and animal tests, clinical trials, the submission of a Premarket Approval Application, and review by an outside advisory panel.

How much work does this amount to for quality assurance teams at Medtronic? To give an idea of the scale, performance

ratings in the medical technology field are often based on strong patent holdings. The U.S. Patent and Trademark Office ranked Medtronic No. 1 in the world due to the number of patents issued for medical devices from 1969 through 1998.

Track records on patient outcome by medical technology companies are also evident in the Manufacturer and User Facility Device Experience Database. The data represent reports of adverse events involving medical devices. Incidents are updated quarterly and consist of voluntary reports, user facility reports, distributor reports, and manufacturer reports. The event location of the failure offers 50 categories, including nursing home, ambulatory surgical facility, maternity ward, playground, and street. Incidents are summarized as life threatening, requiring intervention or hospitalization, a congenital anomaly, occurring with a disability, or resulting in death. Medtronic does have a significant listing in the database.

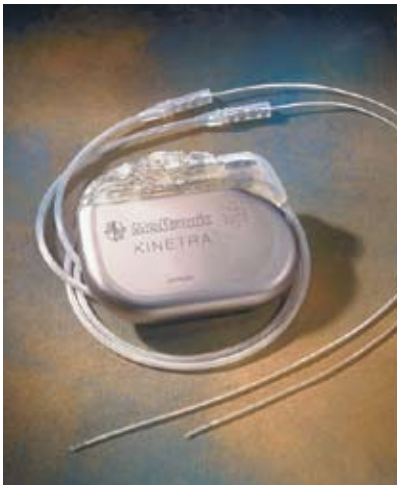
While all the facts regarding a 2005 voluntary recall of Medtronic devices aren't yet known, the retraction of 80,000 life-supporting devices speaks of Medtronic's vulnerabilities amid a relatively polished reputation of positive patient outcome. The acknowledgement of battery depletion and failure in at least seven models of defibrillators and pacemakers (with or without incident) can immediately overshadow the reality of lives being saved.

"Human factors and risk analysis are components of our processes. Medtronic takes a close look at the lives, habits, and hobbies of their patients in order to make the best device possible," says Knock. "The patients' activities must be supported in order for them to lead a normal, enjoyable life. For instance, the device must support and sense a patient that is running as well as one that is at rest. Risk analysis is a procedure that is live to us and we need to constantly be making the product as robust as possible."

Practices in patient care

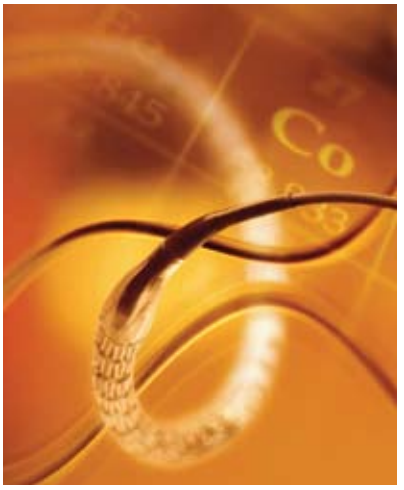
When a product controls the rhythm of someone's heart, Medtronic distinguishes between manufacturing processes and "life-supporting, pain-alleviating manufacturing." In essence, internal procedures on the factory floor and in sophisticated R&D facilities all relate to a culture of patient care. Even the most technical equipment operation manuals may include language around the user's well-being. Metal, wires, and digital programming can ultimately allow someone to live out his or her deepest dreams despite a bleak diagnosis or debilitating condition. Medtronic claims the intersection, reinforcing that employees perform to help people. As improvement programs such as lean Six Sigma are initiated, respective departments not only institute action plans that are practical and modern but also patient-positive.

"The lean sigma program has resulted in quality and business improvements within our manufacturing and supply chain processes. We have had kaizen events, as part of this program that have transformed departments and processes," says Knock. "The incoming materials department was transformed in a matter of days: The facility structure was modified, 'supermarkets' were put in place, takt time between cells decreased dramatically, inventory was reduced, and 5S was instituted. These events take time and resources to plan, but execution is rapid. We are now looking beyond our doors with this program to our supply chain partners."

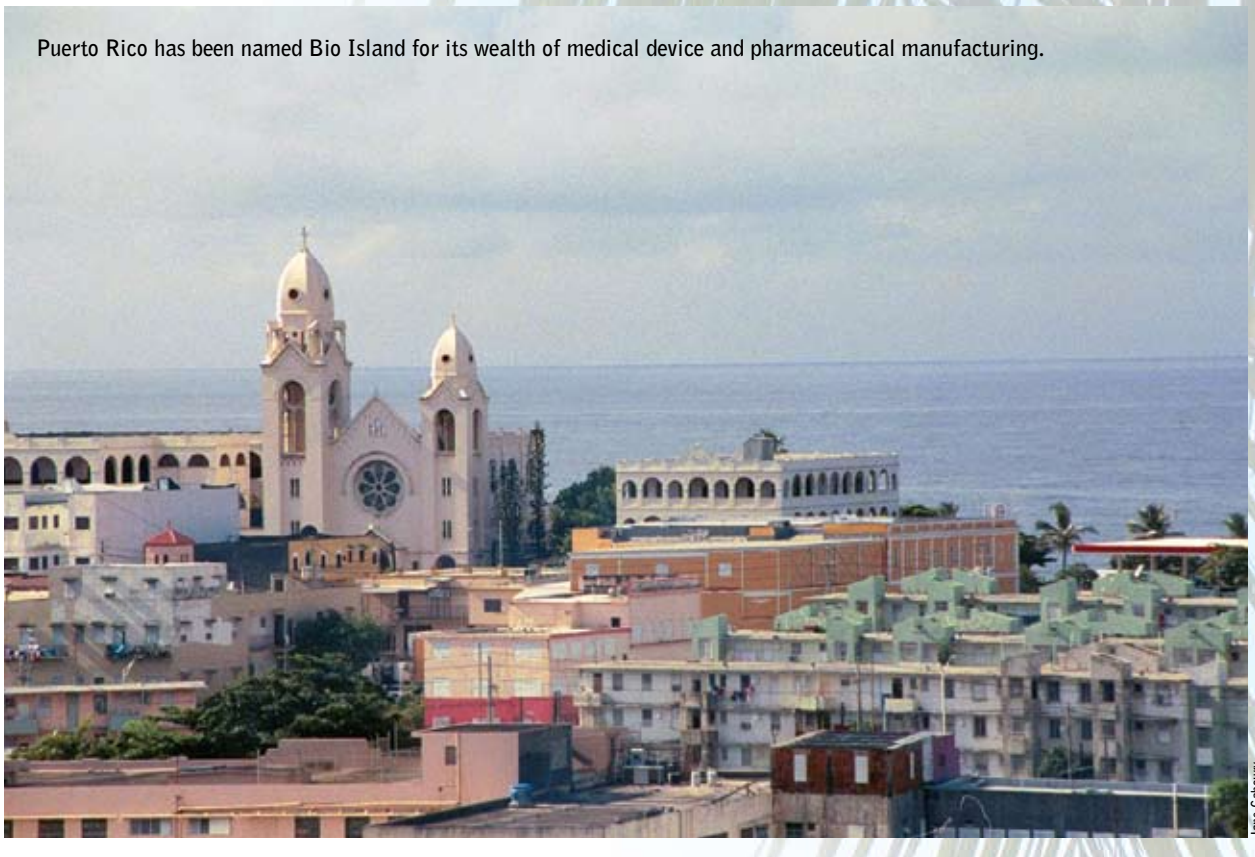


Before Medtronic's Kinetra device, treatment of bilateral symptoms of Parkinson's disease required two separate surgical implants of neurostimulators.

The Real-Time System is the world's only system to integrate an insulin pump with continuous glucose monitoring; it helps prevent harmful lows and highs.



The Endeavor drug-eluting stent opens arteries during angioplasty procedures. It is the first cobalt alloy stent to be launched in 40 countries outside the United States.



Puerto Rico has been named Bio Island for its wealth of medical device and pharmaceutical manufacturing.

Jane Gabourry

ON BIO ISLAND

Underwater treasure hunts, golf on the beach, and ancient Spanish forts have long drawn tourists to Puerto Rico. Surprisingly, tourism accounts for only 7 percent of the Caribbean commonwealth's gross domestic product. One-quarter of the world's biologic output comes from Puerto Rico, according to Fluor-Daniel. Manufacturing accounts for 43 percent of the island's economy.

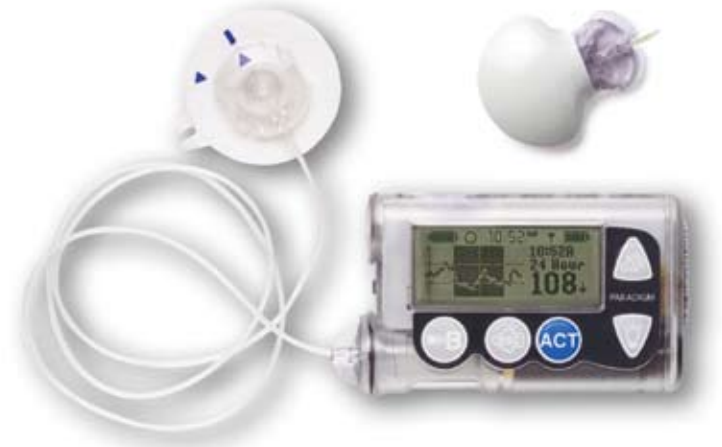
Having attracted the world's most successful medical device companies such as Medtronic, St. Jude Medical, and Novartis, Bio Island, as Puerto Rico has recently been nicknamed, is the eighth largest scientific and medical instrument exporter in the world. It produces 15 of the top 20 blockbuster drugs in the United States.

A forceful political, educational, and industrial backbone has steered medical manufacturing to an ideal incubator — a self-sustaining one that is practically outgrowing its own territory. Consider the facts:

- Puerto Rico is strategically located at the intersection of trade routes from North America and Europe to Latin America and the Caribbean. San Juan Harbor is the seventh largest container port in the Western Hemisphere.
- Served by an extensive network of expressways and superhighways, every company is within two hours of an airport or seaport.
- A telecommunications network links an islandwide optic network under the sea to serve the mainland United States, Europe, and the rest of the world.
- Puerto Rico is a U.S. territory with a foreign tax structure: Companies and residents are not subject to U.S. or foreign taxes on income generated on the island.
- Puerto Rico has the largest non-contiguous Foreign Trade Zone in the United States. Items shipped abroad after processing are exempt from custom duties and from Puerto Rico excise taxes.

Designer "skins" bring personality to insulin pumps and glucose monitors.

The Intrinsic implantable cardioverter-defibrillator is the world's first ICD with a pacing mode that promotes natural heart activity and reduces unnecessary pacing in the lower right chamber.



Medtronic's MiniMed store offers diabetes management supplies such as pumps and meters that can be purchased online.

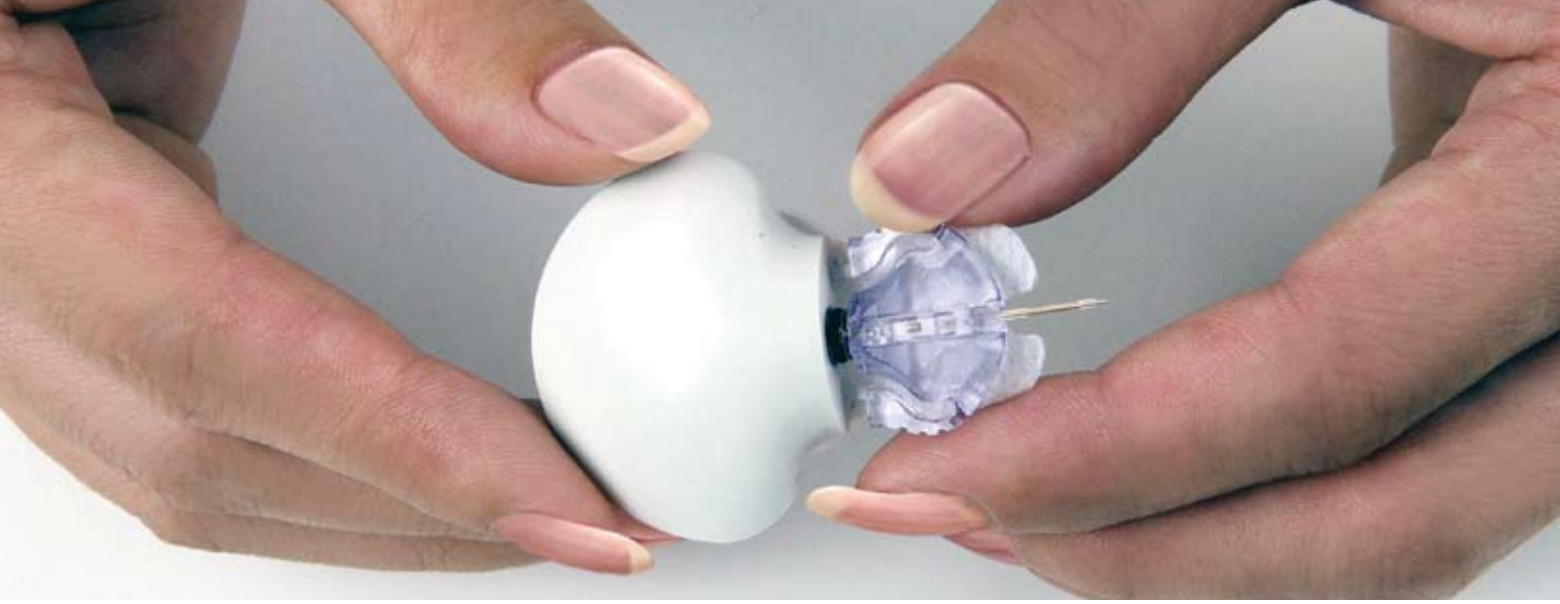
Medtronic's Lifenet products provide a modular solution for emergency data management needs.

The lean Six Sigma program has helped Medtronic recondition its manufacturing process involving implantable cardioverter defibrillators (ICD) since the 2005 recall. The ICD restores normal rhythm when the heart beats too fast by delivering therapies the patient's physician has programmed into the device. Miniscule defects cannot exist in this device because of its comprehensive network. The ICD system consists of three parts: the ICD and lead are implanted in the body while an external computer is set up in the doctor's clinic. The ICD itself is actually a tiny computer plus a battery contained in a small titanium metal case about 2 inches by 3/4 inches and 1/2 inch thick. When it detects an abnormal beat, the ICD delivers an electrical therapy to return the heart to a more normal rhythm. It has a large memory that stores important information that the doctor retrieves during follow-up visits.

Manufacturing takes place in a clean room that prevents foreign particles from entering the inner workings of the ICD. Product assemblers build and test each ICD, which is designed to last five to nine years. Computer-controlled processes play an important role in the assembly and testing as well. All parts of the ICD are tested before assembly, then again after the ICD has been sealed in its metal case. Once the testing is complete, the ICD is sterilized and packaged, ready to be implanted in a person.

After an ICD has been proven effective in the lab, a clinical study may be conducted if needed or required by the U.S. Food and Drug Administration. As with all life-supporting devices, Medtronic sets up a controlled study administered by selected doctors. These doctors choose patients who have volunteered to be treated by the new ICD. Following procedures that are monitored carefully by government agencies, doctors work closely with patients to gather information about how the device is functioning. The ICD is offered as a new product only after clinical trials are proven to be successful and government approval has been received.

"I am fortunate to have a very strong, competent team that is proactive in supporting internal customers and aligning



Compact medical devices continue to fulfill a marketplace that emphasizes micropackaging and functionality.

with external global requirements," says Knock. "Our software, document control and configuration management, calibration, and quality engineering systems must support the entire product lifecycle from design through manufacturing."

Beyond tradition

Medtronic's quality engineering systems touch the most contemporary aspects of health care management, including the Internet. For example, over 50,000 patients were enrolled in the Medtronic CareLink Network during 2005. The network was the first Internet-based system to help physicians and patients manage chronic cardiovascular disease treated by implantable device therapy. Virtually all models of Medtronic implantable cardioverter-defibrillators and combination cardiac resynchronization therapy, along with several Medtronic pacemakers, can be used with the CareLink Network. The system is an important advance in the ongoing medical care of heart rhythm problems, allowing patients to receive expert medical advice while at home or traveling, potentially saving multiple trips each year to their physician's office.

Additionally, the CareLink Network enables patients to transmit data from their implantable device, as instructed by their physician, from anywhere in the 50 states using a portable monitor that is connected to a standard telephone line. Within minutes, the patient's physician and nurses can view the data on a secure Internet site. The information, which is comparable to the information provided during an in-clinic follow-up visit, provides the physician with a view of how a device and patient's heart are operating. The system provides an efficient and convenient way for specialty physicians to monitor the condition of their patients remotely and if needed, make adjustments to medication or prescribe additional therapy. Patients on the Medtronic CareLink Network typically transmit data from their implanted device three times a year.

These strides in medical technology are a far cry from the early days of Medtronic's research and development that carried out on makeshift wooden tables. The company's engineers and scientists relied on notes and sketches drawn on paper bags, and they used spare parts from radios and other appliances.

Customer education, which is considered a key component of patient service in health systems in general, is available at 22 education centers in 16 countries, including the United States, India, Japan, and the Netherlands. These state-of-the-art centers feature classrooms, hands-on training areas, and technical facilities to serve physicians and other health care professionals. Medtronic today devotes approximately 10 percent of its sales to research and development efforts, operating 26 research centers around the globe. To ensure that Medtronic continues to introduce innovative products and therapies, about 20 percent of the research budget is designated for new ventures.

"We have a process here called Global Voices that surveys all Medtronic personnel worldwide. The results demonstrate, on a consistent basis, that Medtronic's mission, and its value to the employee in their role, ranks at the top," says Knock. "Never have I worked at an organization where the mission was so well understood and supported."

ON THE WEB

INDIA POISED TO DOMINATE BIOTECHNOLOGY

Canadian researchers have divulged ground-breaking information that spotlights India's positive impact on world health. Released by Toronto's McLaughlin-Rotman Centre for Global Health, the report is the first known publicly available research revealing product development capabilities and strategies used by India's health biotech firms that develop low cost generic drugs and vaccines.

www.iienet.org/magazine/july07/biotech