

MEDICAL INNOVATION: IMPLANTABLE PACEMAKER (MEDICAL DEVICE: THERAPEUTIC)

Physician: Drs. C. Walton Lillehei, William Chardack and Andrew Gage and electrical engineer Wilson Greatbatch
Industry: Medtronic

Situation

A leading cause of death

Heart rhythm disorders, or arrhythmias, occur when the heart beats too quickly, too slowly, or in a chaotic manner. These disorders, which affect two million Americans each year, are caused by electrical problems in the heart, and result in fatigue, fainting, dizziness and even sudden death.

In addition, five million Americans suffer from congestive heart failure, which causes the main chambers of the heart to pump inefficiently and can cause the heart to beat in an unsynchronized manner, also referred to as ventricular fibrillation. The vast majority of the 335,000 sudden deaths that occur in the United States every year are believed to be caused by ventricular fibrillation. Heart failure is the main cause of hospital stays in the U.S., and its total cost to the economy is over \$30 billion annually.

Physician-Industry Collaboration

Building on a pioneering design

In the 1950's, external heart pacemakers existed to help regulate heart rhythm, however they were bulky, relied on external electrodes, and had to be plugged into a wall outlet, and could fail during a power blackout. One of the co-founders of medical device manufacturer Medtronic, engineer Earl Bakken, collaborated with a pioneer in open heart surgery at the University of Minnesota Medical School, Dr. C. Walton Lillehei, to develop a wearable, external, battery-powered pacemaker not much larger than a paperback book. This signaled the beginning of a new era in the therapeutic application of electrical stimulation for patients around the world.

Yet long-term application of wearable pacemakers to treat heart rhythm disorders presented several problems: an external pacemaker worn 24 hours a day was inconvenient for the patient; the wires could become dislodged from the heart; and, most importantly, the passage of wires through the skin to the heart introduced the possibility of infection.

In the United States, the first successful attempts at designing a totally implantable pacemaker were reported by Drs. William Chardack and Andrew Gage at the Veterans Administration Hospital in Buffalo, New York, and Wilson Greatbatch, an electrical engineer. The three men carried out more than two years of experimental work and testing, then published a paper about their work in 1960. Medtronic's founders read the article with interest and soon contacted the New York researchers. Palmer Hermundslie of Medtronic flew his own plane to Buffalo to meet Dr. Chardack and Greatbatch, and signed a contract giving the company exclusive rights to produce and market the Chardack-Greatbatch implantable pulse generator, or pacemaker. Within two months of beginning production in late 1960, Medtronic had received orders for 50 of the \$375 implantable units.

Innovation Benefits

A new era in heart pacing

Fifty years of improvement in this original device have brought us to a new era of heart pacing with implanted units not much larger than a silver dollar and battery lives of close to a decade. The latest generation of implantable pacemakers is 99 percent effective in stopping life-threatening arrhythmias and restoring normal heart rhythm.

Today's pacemakers weigh little more than an ounce, and can be checked remotely via telephone every few months to verify a patient's heart rate and rhythm and evaluate the device's function and remaining battery life.

Patient Benefits

“My pacemaker gave me a new lease on life”

Milton M., who is in his eighties, has an incredibly positive attitude. As he [related](#) to Medtronic, Milton is quick to tell people that this wasn't always the case. When he was 62, Milton began to have episodes of a slow heart rate (bradycardia). “Whenever it would happen, I would feel weak and tired, as though I were in a daze.”

A high school history teacher for 26 years, Milton was teaching a lesson one day when he felt an episode coming on. He found another teacher to take over his class and had his wife, Rhoda, take him to the hospital immediately. At the hospital, doctors were able to record Milton's abnormally slow heartbeat and diagnose him with bradycardia.

After an external pacemaker was able to return Milton's heart rate to normal, his cardiologist recommended an implantable pacemaker as soon as possible, and he was fitted with one the next day. While the device helped his heart return to a normal rhythm, Milton had been a runner most of his life, and grew frustrated at the prospect of an inactive lifestyle. Deciding he couldn't “just sit around” any longer, he asked his cardiologist if there was any way he could resume vigorous exercise. Milton was given the green light.

Milton started slowly and built up his exercise regimen over the next year to include weight training and running. At the end of the year, Milton was in better shape and able to reduce his medications dramatically. Empowered by his renewed health, at age 71 Milton signed up for his first Senior Olympics running event. He has been competing ever since and has a collection of medals to show for his efforts, including several gold medals won at various Senior World Olympics events over the years.

“My pacemaker gave me a new lease on life,” he said. “Not only did it save my life, it allowed me to resume my full range of activities, and compete with the best in my age group!”

