In May 1994, Kari Krumwiede sat at a picnic table with her family enjoying coffee at a state park in South Dakota, where she lives. It was Memorial Day weekend. The group had commented on a peculiar tree near them that had a branch growing almost parallel to the ground.

That day, as she sat near the tree, Kari remembers her brother shouting...
Kari Krumwiede, a paraplegic, used self-catherization and medication before she had the Vocare Bladder System implanted as part of a clinical trial.

as she looked up to see the enormous branch falling toward her. The limb struck Kari on the side, puncturing her lung and injuring her spinal cord, leaving her paralyzed from the waist down (a complete T10-level injury).

Following the accident, Kari spent two weeks recovering in her local hospital in Sioux Falls. Spinal rods were inserted from T7 to L1 to help stabilize her spine. She was then transferred to Denver’s Craig Hospital for six weeks of additional rehabilitation.

Today, Kari uses the device morning, noon, evening and night. What used to take nearly three hours a day now takes less than 30 minutes.
The Vocare Bladder System has internal and external components. Internally, a pacemaker-type stimulator (C) is surgically implanted under the skin of the chest or abdomen. The device sends electrical signals through electrodes (D) to the spinal nerves (E) that lead to the bladder (G) and bowel (F). These signals cause the muscles of the bladder and urethral sphincter to contract. After the bladder has contracted in response to the electrical stimulus, the sphincter muscles relax, allowing the bladder to empty.

The implant is controlled with an external transmitter (A), which is about the size of a handheld cassette player. This unit consists of a microprocessor and a small transmitter antenna (B), used when bladder or bowel stimulation is needed. The transmitter, powered by rechargeable batteries, can be stored and brought out as needed.

Once a month, Kari began taking Ditropan, an anticholinergic, to help control her spastic bladder, although she experienced its uncomfortable side effects, such as “dry mouth.”

In addition, she managed her bladder with intermittent self-catheterization. Her bowel program took one hour every morning.

In January 1996, Kari, who has an identical twin, traveled to New York to participate in a study on the effects of paraplegia or quadriplegia on one twin when the other is nondisabled. It was here that she learned of the Vocare Bladder System of bladder management from another twin who had had the implant and no longer had UTIs.

Kari contacted the team conducting the clinical trials of the system at the Cleveland Veterans Affairs Medical Center. The neuroprosthesis that Kari was interested in is under clinical investigation.
in the United States by Cleveland-based NeuroControl Corp.

The system uses electrical stimulation technology that restores some bladder and bowel function. The stimulation causes contraction of the bladder, facilitating the emptying of the bladder. The stimulation also causes contraction of the rectum to produce evacuation.

The client carries an external transmitter and antenna to send electrical impulses through the skin to the implanted receiver. The receiver conveys impulses to the electrodes, which stimulate contraction.

The system can be used in people who are at least 16 years old or skeletally mature, have a clinically complete spinal cord injury, have been injured for at least one year, and have suitable bladder contractions.

Kari decided to have the system implanted. Most of her preoperative testing, which included urodynamics, urine cultures and urinary tract imaging, was completed in one afternoon by her physician in South Dakota. The data were then sent to the Cleveland team, which includes a neurosurgeon, a physical medicine and rehab physician, a research nurse and a biomedical engineer affiliated with the Cleveland VA Medical Center and MetroHealth Medical Center.

On September 10, 1996, Kari underwent surgery to implant the system. Removal of part of the rods placed in her back from previous surgery was required to allow the implantation of the electrodes.

The surgery lasted 10 hours, due to the additional time needed to remove the spinal rods (the implantation usually takes between five and seven hours). The surgery was done under general anesthesia and included two incisions in her back, one at the T12-L1 area and one at the S1-S3 area of the pelvis. Smaller incisions on her side and abdomen were needed to implant the receiver and electrode leads.

Howard Mattoy, a 66-year-old with a T8-level spinal cord injury, received his Vocare Bladder System implant in January 1997. Before the surgery, he managed his bladder by self-catheterization and was taking anticholinergic medication for spasticity. Although Howard had infrequent urinary tract infections, he had a problem with incontinence, and imaging evaluations of his upper urinary tract revealed the presence of reflux damage to the right ureter and kidney. He also reported a great deal of problems with his bowel program.

Howard’s surgery began with removal of the lower section of the spinal rods that ran from T7 to T12. After the rod removal, the bladder stimulator implant went according to protocol. Y. Takaoka, MD, began with a laminectomy of T12-L1 to complete the posterior rhizotomy. The electrodes were then implanted on the sacral nerve leading to the bladder and bowel through a second laminectomy at the S1-S3 level. The receiver was implanted under the skin in the lower abdomen.

Howard began using the stimulator on the third day after surgery, after some adjustments. He was discharged on the seventh day. During his hospital stay, the device emptied the bladder with very low residual volumes (less than 20 ml).
About the Vocare Bladder System

The Vocare Bladder System is part of an ongoing FDA-supervised clinical evaluation. This type of device has been used in Europe for more than 15 years, but its safety and effectiveness have not yet been established in the United States. NeuroControl Corp., Cleveland, has worldwide distribution rights for the system.

The system is based on the Finetech-Brindley Bladder Controller originally developed in England with the support of the Medical Research Council of Great Britain. The initial testing of the device in the United States was conducted by researchers at Case Western Reserve University, Cleveland; the Cleveland Veterans Affairs Medical Center; and the MetroHealth Medical Center in conjunction with the Cleveland FES Center.

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Today, Kari uses the device morning, noon, evening and night. What used to take nearly three hours a day now takes less than 30 minutes. Instead of using a catheter, Kari uses the device by placing the external transmitter (a small handheld device) over the implanted receiver under the skin of the abdomen. Stimulation of the bladder for two minutes or less results in voiding, with measured post-void residuals of less than 50 ml. Her bowel program has been reduced from one hour each day to 20 minutes every two days. She has also been able to discontinue the use of the Ditropan.

Kari, a wife and mother of four boys less than 10 years old, reports that the bladder stimulator has had many beneficial effects. Those range from the time saved each day, which she can devote to her family, to improvement in her independence and self-esteem.