This information is intended for media professionals and investors

Medtronic CD HORIZON® SEXTANT™ Fact Sheet

Fact Sheet
CD HORIZON® SEXTANT™ Spinal System
For Spinal Fusion

The Results

The CD HORIZON® SEXTANT™ Spinal System allows surgeons to deliver and apply screw and rod implants to the posterior aspect of the spine without the major muscle and tissue disruption encountered with traditional spinal fusion surgeries. This minimally invasive technique potentially allows significant patient benefits.

- Shorter hospital stays - one to three days vs. up to a week with open surgery
- Smaller scars - one-inch scars vs. six- to eight-inch scars
- Shorter recovery periods
- Less post-operative pain - no muscle cutting or stripping

Spinal Fusion

Spinal fusion is a process using bone graft to cause two opposing vertebrae to grow, or "weld," together. To ensure position and rigid alignment while fusion takes place, surgeons apply spinal instruments, or implants, such as screws and rods to the spine. These implants are joined together to maintain spinal stability and are rarely removed. Spinal fusion and implants are used to restore stability to the spine, correct deformity and bridge spaces created by the removal of damaged spinal elements such as discs.

The Traditional Spinal Fusion Procedure with Implants

Traditionally, implants are applied directly to the spine through an open approach requiring incisions up and down the middle of the back. Large bands of back muscles are stripped free from the spine and pulled off (retracted) to each side for visualization of the spine and easy access to the bones for instrument implantation. This stripping and retraction can cause considerable back pain, and the muscles, to some degree, are permanently scarred and damaged.

The CD HORIZON SEXTANT Spinal System

The CD HORIZON SEXTANT Spinal System is an implant system composed of rods, screws, specially designed surgical tools and a novel mechanical implant delivery device. This device looks much like the sextant of naval navigation, and is the navigation and insertion tool that allows screws and rods to be applied to the spine in a minimally invasive manner.

Two principal elements comprise this device. The first are screw extenders, which are long metal shafts used to deliver and attach screws to the vertebrae through small skin incisions. These extenders protrude outside of the body, allowing the surgeon to arrange and join their ends so that the second principal part, the rod inserter, may be attached. The rod inserter is an arc-shaped arm that swings on an axis and delivers a pre-cut rod through the skin and muscle and into the heads of the implanted screws.

The Minimally Invasive Approach with CD HORIZON SEXTANT System

Using the METRx™ System's muscle-splitting dilator tubes, surgeons access the lumbar spine through small skin incisions and tunnels created by separating muscle along its natural divisions. The CD HORIZON SEXTANT Spinal System is then used to precisely deliver the screws and rods through the skin incisions.

How It Works

- Using a special "live action" x-ray machine called a fluoroscope to visualize the spine, the surgeon determines screw insertion points.
- A stiff guidewire is inserted through skin and muscle to the screw insertion point on one vertebra.
- METRx System dilating tubes are slowly passed down over the guide wire, creating tunnels through the muscle to the target screw placement area.
- A screw, attached to a screw extender, is delivered through the muscle to the vertebra and secured.
- The process is repeated for the second screw placement.
- The protruding shafts of the extenders are rotated until the screw heads are aligned for rod insertion.
- After rotation, the protruding extenders are joined and secured so the swinging arm rod inserter may be connected.
- A pre-cut rod is attached to the end of the curved arm of the rod inserter.
- The rod inserter swings down and drives the small rod through the skin and muscle, precisely inserting the rod though the heads of the aligned screws.
- The screw extenders and rod inserter are removed.
- The separated muscle flows back together, and the skin incisions are closed, leaving only thumbnail-sized skin incisions.

Procedure Indications*

Common conditions indicated for this procedure include severe disc degeneration, recurrent disc herniation, misaligned vertebrae (spondylolisthesis) or traumatic fracture.

The CD HORIZON SEXTANT Spinal System can only be used for conditions affecting the lumbar spine.

Who can Benefit

- An estimated 190,000 lumbar spinal fusion surgeries will be performed in 2002.
- By the age of 50, 85 percent of the population will show evidence of disc degeneration.
- Disc degeneration affects about 12 million people in the United States.

Clinical Experience

While still a new technology, several preliminary studies have indicated the potential accuracy and reliability of the CD HORIZON SEXTANT Spinal System. A recent study [*Nerurosurgical Focus 10 (4): Article 10, 2001*] followed 12 patients who underwent pedicle screw fixation using the CD HORIZON SEXTANT Spinal System. The system was used in each case to accomplish an instrumented posterior spinal fusion. After completing the surgery, the patients were followed for an average of 6.8 months. Results were classified according to modified McNab criteria, which measure surgical outcomes on a poor to excellent scale. The study results include:

- Six patients were rated with excellent results (no pain; non-restricted mobility; and normal work and activity levels), five patients with good results (occasional non-radicular pain; relief of presenting symptoms; modified work activity), and one with a poor result (continued objective symptoms of root involvement; additional surgery required). A second surgery was performed on the patient with a poor result, and the patient achieved a good clinical result with solid fusion.
- Each of seven patients followed longer than six months achieved solid fusion across the involved levels.
- Six patients were discharged in one to two days after surgery, and the rest by post-operative day three.

Resources

www.back.com
www.medtronicsofamordanek.com

**Notice to healthcare professionals: See package insert for labeling limitations and other important information prior to use.*