MTS SENSORS

Precise Injection Control for Disc Arthroplasty

TECHNICAL ARTICLE

Debilitating back pain is a serious condition that affects millions of Americans. While traditional treatments are quite invasive, resulting in long recovery times, recently developed therapies are leading to better alternatives. This article illustrates how a sensor is contributing to the success of one such therapy.

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LOOKING AHEAD

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- Treatment Options
- Arthroplasty System
- The Sensor's Role

Temposonics®

Many people suffer from mild to severely debilitating back or back-radiated leg pain. In fact, it has been reported by physicians that 4 out of 5 people will complain about back pain at some point in their lives. Many cases have no clear cause and some are related to muscle strain problems, but damage to the spine, arthritis and results of aging are more permanent and less likely to be treatable with non-invasive therapy or medications.

The spine is composed of bony vertebrae separated by shock absorbers called discs. These discs cushion shock loads in the spine and allow movement for twisting and bending the body. Each disc is comprised of a soft inner volume called the nucleus surrounded by a fibrous outer rim called the annulus. The annulus provides a containment boundary for the nucleus that prevents it from extruding out when the body is bending or experiencing loads. A herniated annulus can allow the nucleus to extrude from the disc space between the vertebrae.

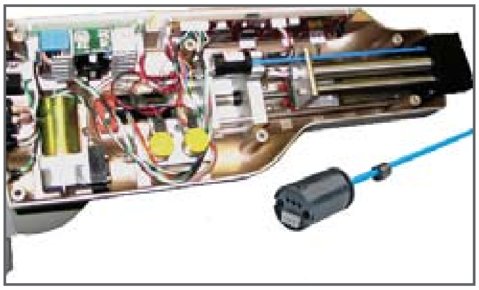
When injury, aging or some other condition causes the nucleus to dehydrate and shrink, it's known as Degenerative Disc Disease (DDD), sometimes diagnosable with X-rays, CT and MRI scans. Shrinking of the disc can allow the two adjacent vertebrae to close up the space between them, putting pressure on the spinal nerves radiating from the spinal cord at that junction, frequently causing the pain associated with DDD.

Traditionally, the surgical route requires fusion (arthrodesis) of the two adjacent vertebrae into one solid bone. The technique involves major surgery, either from the back or the front of the patient, or sometimes both. First the joint is fixed, so it can't move, by some mechanical means and then bone grafts are made using bone from the pelvis or some other part of the skeleton. Once the bone has grown to solidify the joint, movement is limited and, hopefully, the lack of motion relieves pain. This technique is very invasive, can take up to a year for recovery, and can have mixed results. Adjacent non-treated discs may see increased stress of up to 30%, possibly accelerating degeneration of those joints.

Newer, minimally invasive Spine Arthroplasty techniques involve non-fusion techniques that reduce the invasive effects and include total disc replacement, nucleus replacement, dynamic stabilization, motion preservation technologies, facet joint replacement as well as annulus and nucleus repair and regeneration. Total disc replacement with an artificial disc has been done with some success. But it's still considerably invasive and involves significant recovery time.

One type of Spine Arthroplasty, called Disc Arthroplasty, has been envisioned where the patient should only experience a small incision to gain access to the affected area and treat the condition. The bone of the spine and the muscles surrounding the spine should be undisturbed, accelerating recovery time. In this type of Disc Arthroplasty, the nucleus material could be removed and replaced with an artificial nucleus that could restore the proper gap height between the vertebrae with a patient-specific implant.

Researchers' initial versions of a surgical tool that could be used to install an artificial nucleus proved to have control problems. Delivery of the material that forms the artificial nucleus was done pneumatically. Compressibility of the air and seal stiction problems caused inconsistent and difficult fill control of the balloon used to contain the artificial nucleus material while it is being injected and during curing.



The **Temposonics C-Series Sensor***, seen here identified by its blue tube, is used to measure position of the injector mechanism for control of injector rate and detection of anomalous motions.*

Devicix, in Eden Prairie, Minnesota integrated the surgery procedural requirements into a viable surgical tool that addressed these problems and provided more controllable, measureable results.

Devicix integrated software, electrical and mechanical disciplines into a micro-processor based tool that allows closed loop control of the artificial nucleus material injection via feedback from position and pressure sensors. Now instead of the pneumatic system, a motor driving a ball screw monitored by a C-Series Temposonics linear-position sensor delivers a measured quantity of the artificial nucleus.

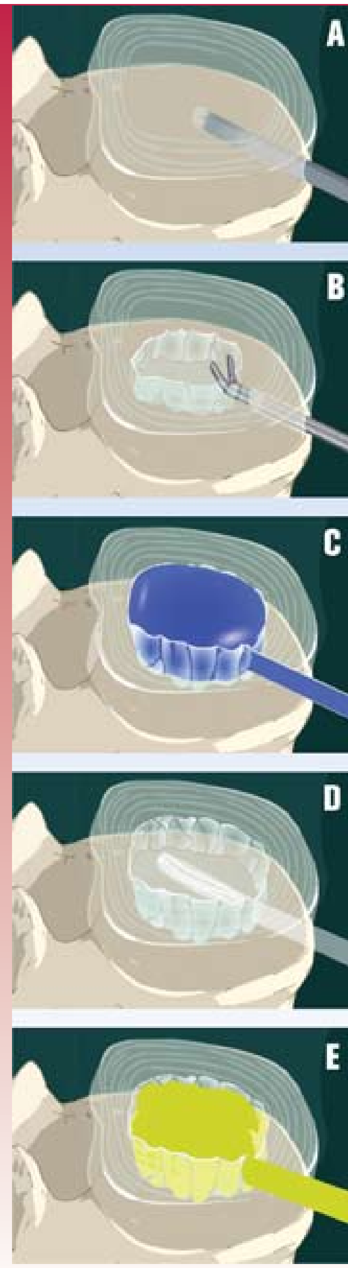
Forward and rearward travel limits are calibrated from the Temposonics C-Series sensor position feedback, eliminating the need for redundant limit switches. Originally installed to provide power up position information to calibrate the position of rotary incremental encoders, the absolute output of the Temposonics C-Series sensor proved so resolute and reliable that the encoders were eliminated. Resolution of the volume is 0.25 cc out of 50 cc's, or 0.5%. The Temposonics C-Series sensor was chosen because of its no wear nature, zero drift over time, lack of calibration requirement, and ease of connection to the mechanical system.

During filling, volume in the balloon, as determined from the Temposonics C-Series sensor feedback, can be compared with the required calculated volume determined from CT scan images until a final target size is achieved, while at the same time helping to prevent the balloon from becoming too large.

How It Works

To be viable, the system requires a curable-in-place artificial nucleus material and an expandable polyurethane balloon. The material should have a compressibility similar to the nucleus material. Generally, the balloon and artificial nucleus material can be inserted into the disc in these steps with the Devicix machine.

A) A small entry or access hole can be made through gaps in the vertebrae and other soft structures, minimizing the amount of wound to heal later, into the annulus or fibrous outer cover of the disc.
B) Bit by bit, the nucleus can then be removed through that access hole. Next a catheter tipped with a balloon can be inserted through that access hole.
C) The balloon can be inflated with a contrast solution, allowing the surgeon to see it on X-rays and determine if the balloon is positioned ensure the final size is correct. The catheter can then be removed.
D) A second catheter equipped with the implant balloon can inserted into the disc space. Then the artificial nucleus material can now be pushed into the balloon, filling the balloon and the disc space. The artificial nucleus material can now begin to cure into a pliable analog of the disc nucleus. The artificial nucleus material and the balloon should form a monolithic implant that is intended to restore a portion or all of the original disc function.
E) Last, the catheter can be cut off at the edge of the implant and removed.

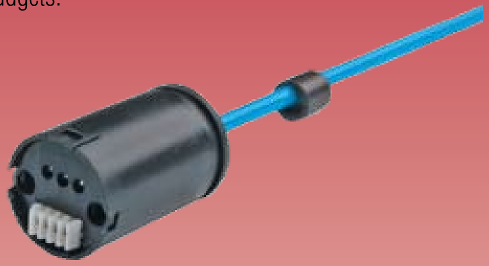


The complete Devicix model shown here.

In addition, micro-processor data management allowed more functionality to be added. For example, the system monitor can detect holes or tears in the balloon via disposable pressure sensors. If a balloon breaks during filling, it should be detected by a sudden drop in monitored pressure. Automatic calibration of the pressure system was also included to allow the disposable feature. The Devicix design leads the user through the procedure via a pendant control or tablet PC ensuring a more consistent procedure and more repeatable filling. The tablet PC also has video training files, minimizing the need for multiple language support. A multi-source power supply allows system to be used anywhere in the world.

The Temposonics C-Series Sensors

Designed for use in higher-volume OEM products such as medical devices, small cutting/fastening/forming tools, and various consumer products, the C-Series sensor is the smallest magnetostrictive sensor available and the lowest cost, making it useful to high volume OEMs with constrained space and budgets.



At 36 mm, the C-Series sensor head is much smaller than its industrial forefathers, and the sensor shaft diameter at 4 mm, dead zone at 18 mm and null zone at 21 mm are the smallest of any magnetostrictive sensor. These shorter zones improve the overall length to active zone ratio so important in smaller device implementations common in medical deck-top size machines. The C-Series sensor offers enhanced sensitivity and automatic adjustment features, along with small, compact electronics that contribute to the size reduction.

When housings are required by OEMs, such as for medical level measurement, modular options for the C-Series sensors include a standardized IP67 housing and float, and other semi or fully customized housings. These can be added to the Core sensor to protect it from routine, harsh or unusual environmental factors, as well as accommodate special needs.

The C-Series modular magnetostrictive product line is designed for embedding into applications such as infusion devices, x-y positioners, medical beds, injection systems, immunoassay machines, surgical robots, therapy tools and machines, surgical fluid collection systems, dental chairs, specialized wheel chairs and many other medically related mobility applications.

About the companies:

MTS Systems Corporation, headquartered in Eden Prairie, Minnesota and with sensors divisions in Cary, North Carolina, Ludenscheid, Germany and Tokyo, Japan, is a global supplier of testing products and industrial sensors. MTS testing products help customers accelerate and improve their design, development, and manufacturing processes and are used for determining the mechanical behavior of materials, products, and structures. They include computer-based mechanical testing and simulation systems, modeling and testing software, and consulting services. MTS Temposonics position sensors are used to improve the productivity, performance and safety of a wide variety of industrial and light industrial equipment, including medical systems.

Devicix is an Eden Prairie, Minnesota, medical design firm with capabilities in electronics, mechanics and software. Devicix designs and develops innovative solutions for medical devices and specialized biomedical equipment for clients. Devicix project interest is broad, from developing large integrated systems to small disposables to cost reduction of existing products for early-stage companies, individual inventors and large manufacturers.

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