Temposonics®

Magnetostrictive, Absolute, Non-contact
Linear-Position Sensors

MTS SENSORS

Precision Injection Control for Disc Arthroplasty

Document No.: 551113
Revision A

Case Study

Temposonics C-Series linear-position sensor

Disc Arthroplasty

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.

Sensor Aids New Approach

Many people suffer from mild to severely debilitating back or back-radiated leg pain. Physicians estimate that four out of five Americans will complain of back pain at some time in their lives. Though people do experience temporary pain from no clear cause or after muscle strain, injury to the spine or damage from arthritis and aging are essentially permanent and are more difficult to treat with noninvasive therapy and medication.

The spine is composed of 22 or more bony vertebrae separated by shock absorbers called intervertebral discs that are formed of two types of cartilage. The discs cushion shock loads on the spine and allow movement for twisting and bending the body (articulation). Each disc is comprised of a gel-like inner material, called the nucleus, surrounded by a strong, fibrous outer rim called the annulus. The annulus contains the nucleus and allows it to withstand static loads up to 130 lb/in.2 and dynamic loads that are much higher. A herniation (hole) in the annulus can allow the nucleus to extrude from the disc space between the vertebrae and press on trunk nerves, causing severe pain or loss of sensation.

Injury, aging, or other conditions can cause the nucleus to dehydrate and shrink, creating a condition known as degenerative disc disease (DDD). When the disc shrinks, space between the two adjacent vertebrae closes and can apply pressure on the spinal nerves radiating from the spinal cord at that junction to cause the pain associated with DDD. In severe disease, the vertebrae may even come in contact during certain motions.

Herniation and mild cases of DDD may be treated initially with bed rest and medication for pain and inflammation. Nucleus material may also be removed surgically (a micronuclectomy) to relieve pressure on a nerve. In advanced cases, traditional therapy has offered only surgical 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. Then bone grafts made using bone from the pelvis or some other location, or from cages that encourage bone growth, are inserted. 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.

Devices for total disc replacement with an artificial disc have been approved recently in the US and Europe. But this approach is at least as invasive as fusion and involves significant recovery time.

Newer approaches, particularly spine arthroplasty, provide non-fusion therapy that reduces invasion, and restores motion to the disc. Such therapies include nucleus replacement, dynamic stabilization, and facet joint replacement, as well as annulus and nucleus repair and regeneration. One type of spine arthroplasty, called disc arthroplasty, has been developed to where the patient can experience only a small incision to gain access to the affected area and replace the disc nucleus. Called the Dascor Disc Arthroplasty.

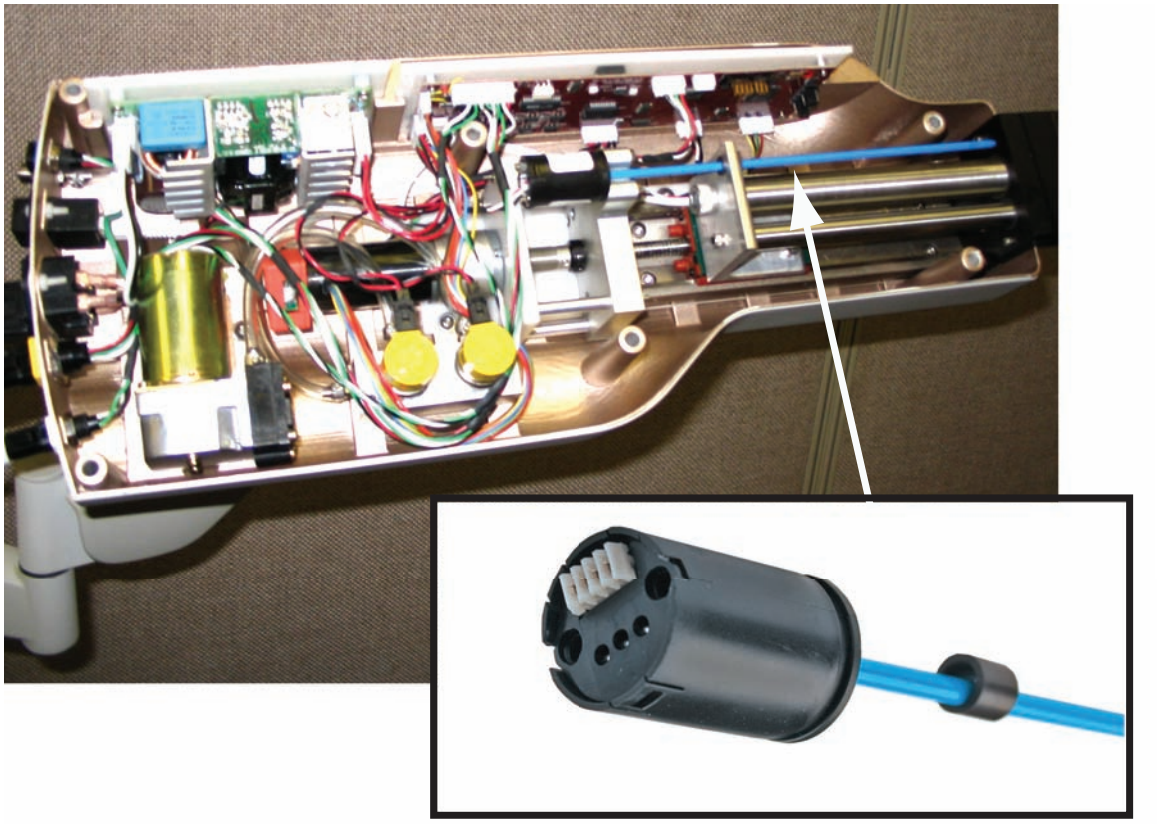
In less than two years, Devicix℠ integrated software, electrical, and mechanical subsystems into a product that allows fine, closed-loop control of polymer injection via feedback from linear position and pressure sensors. Instead of the pneumatic system, a brushless motor drives a ball screw monitored by the Temposonics C-Series linear-position sensor to deliver a measured quantity of the polymer at several pressure stages.

Forward and rearward travel limits are calibrated from the C-Series sensor signal, eliminating the need for redundant limit switches. Though the linear transducer was installed originally to provide power-up position information and calibrate a rotary incremental encoder on the drive motor, the absolute output of the C-Series sensor proved so resolute and reliable that the encoder was eliminated. Resolution of the implant volume is ¼ cc out of 50 ccs, or approximately ½ percent. Devicix chose the C-Series sensor because it does not experience wear or drift over time, requires no calibration, and was easily connected to the mechanical system.

The C-Series sensor, identified in the picture below by its blue tube, is used to measure position of the injector mechanism for control of injector rate and detection of anomalous motions.

The required implant volume is calculated from a CT scan and compared by a formula in the injector with the delivered volume measured from the sensor signal. This assures the physician that the correct final size was obtained and the proper nucleus space was distracted.

By basing the injection system on micro-processor operation, DDI and Devicix were able to add more functionality. For example, the system can monitor the progress of the procedure and provide real-time feedback to the surgical team. The latest generation injector leads the user through each step of the procedure via a pendant control, tablet PC display, or voice prompts to ensure a consistent procedure and reliable filling of the implant.



The Temposonics C-Series Sensor

The C-Series is the smallest magnetostrictive sensor available. It is designed for higher-volume OEM applications, such as medical devices. The low cost of the C series sensor make them attractive to high-volume OEMs with constrained space and budgets.

The head of the C-Series sensor is 36 mm, 45 percent smaller than other models. The sensor shaft diameter is 4 mm, with the dead zone at 18 mm and null zone at 21 mm along the shaft. The useable shaft length (active zone to overall length ratio) is at least 17.5 percent greater, so devices can be smaller and lighter. The C-Series sensor offers enhanced sensitivity and automatic adjustment features, along with new small, compact electronics that contribute to the size reduction.

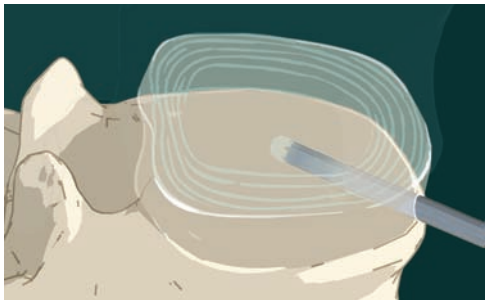
When sensor housing is required by OEMs, such as for medical-level measurement, modular options for the C-Series core sensor include a standardized IP67 housing and float, or customized housings, that can be added to the core sensor to protect it from routine, harsh, or unusual environmental factors,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

HOW IT WORKS

The inspiration behind the Dascor Disc Arthroplasty System is its curable, two-part polyurethane material and an expandable polyurethane balloon. The proprietary polymer has a compressibility and restorability very similar to healthy disc nucleus. The balloon and polymer are inserted into the disc in seven steps.

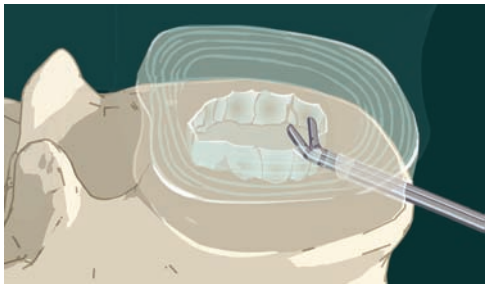
STEP 1

A small entry or access hole is made through the annulus of the diseased intervertebral disc (in the gap between two vertebrae). This low degree of invasion minimizes the amount of wound to heal later and speeds recovery.



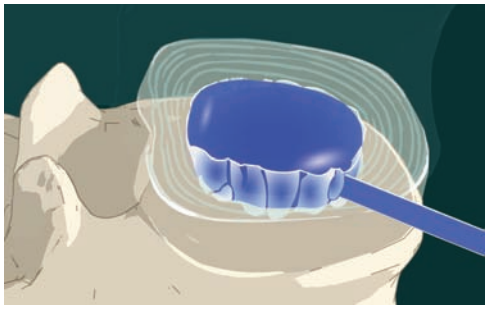
STEP 2

Bit by bit, the nucleus is removed from the disc through the access hole. Then a catheter tipped with a balloon is inserted through the hole.



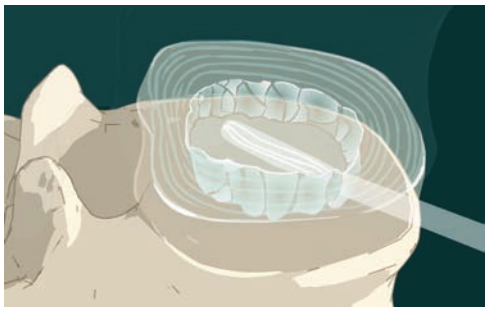
STEP 3

The balloon is inflated with a contrast solution to the same pressure as will be used to deploy the implant. The surgeon checks the balloon via x-ray and measures to determine if the implant will be positioned correctly and to determine the final size . This catheter is then removed.



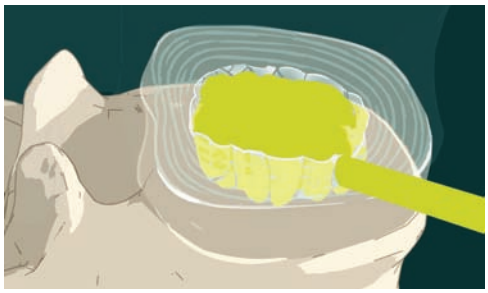
STEP 4

A second catheter equipped with the implant balloon is inserted into the disc space. Then liquid implant, composed of the two-part polymer mixed at an exact ratio, is pumped into the balloon. Once the balloon fills the disc nucleus space completely the injector automatically moves to a dwell, or curing mode



STEP 5

The two polymer components begin to cure immediately after they are mixed



STEP 6

The polymer and the balloon bond together to form a monolithic implant that is highly elastic and quickly restores the original disc function.

STEP 7

In the final step, the catheter is cut off at the edge of the implant and removed.

Published date: 2005

Part Number: 551113 Revision A 12-07, 02-09

MTS®
SENSORS

MTS Systems Corporation
Sensors Division

3001 Sheldon Drive
Cary, North Carolina,
27513, USA
Tel.: +1-800-633-7609
Fax: +1-919-677-2343
+1-800-498-4442
e-mail: sensorsinfo@mts.com
http://www.mtssensors.com

MTS Sensor Technologie
GmbH & Co. KG

Auf dem Schüffel 9
D - 58513 Lüdenscheid, Germany
Tel.: +49-2351-9587-0
Fax: +49-2351-56491
e-mail: info@mtssensor.de
http://www.mtssensor.de

MTS Sensors Technology
Corporation

737 Aihara-cho, Machida-shi
Tokyo 194-0211, Japan
Tel.: +81-42-775-3838
Fax: +81-42-775-5516
e-mail: info@mtssensor.co.jp
http://www.mtssensor.co.jp