



Talk with your doctor about the iO-Flex® System

For additional information on lumbar spinal stenosis or decompression surgery with the iO-Flex System, visit iO-Flex.com with your doctor.

Are you experiencing lower back pain or shooting pain, weakness, numbness or tingling in your buttocks or legs?

Lumbar Spinal Stenosis affects over 3 million aging Americans each year.¹ Symptoms include lower back pain or shooting pain, weakness, numbness or tingling in your buttocks or legs.

Lumbar stenosis is a degenerative condition, which means if left untreated it will worsen over time. Patients begin to have difficulty with many activities and hobbies they enjoy, like bike riding, gardening, golfing or simply walking their dog. It typically affects men and women starting in their 50s and 60s, and the condition is the number one reason for spine surgery in patients over age 65.^{2,3}

Lumbar stenosis is caused by an overgrowth of bone and tissue in three distinct areas of the vertebra (spinal bone) that press on nerves as they exit the spine and travel to the lower half of the body. There are three distinct areas where lumbar stenosis can occur depending on the location of the overgrown bone and tissue. Research shows most commonly occurs in more than one location.⁷



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There are risks associated with any type of surgery. Your doctor will help explain the risks associated with lumbar decompression surgery using the iO-Flex® System.

The iO-Flex® MicroBlade Shaver® instrument and accessories are designed for accessing, cutting and biting soft tissue and bone during surgery involving the spinal column (K063231). The iO-Flex® Neuro Check® device is designed for use with the Baxano® cutting and biting devices for localization of motor nerves in settings where visualization is compromised (K081742). For complete information regarding precautions and methods of use, please refer to individual device Instructions for Use.

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Ask your doctor about Lumbar Spinal Stenosis and a new minimally invasive decompression treatment with the iO-Flex® System

Decompression Surgery

If conservative treatments such as anti-inflammatory medication, physical therapy and epidural steroid injections fail to relieve symptoms, many patients consider decompression surgery.

About Decompression Surgery

This year alone, an estimated 325,000 surgical procedures that involve decompression to treat lumbar stenosis will be performed in the U.S.⁴ Decompression involves cutting away overgrown bone and tissue to relieve pressure around the impacted nerve. It is well documented as a successful spine surgery.^{5,6,7} The majority of lumbar stenosis patients have good results with decompression, and most leave the hospital in a few days and return to normal activities in only a few weeks.⁷

Current Limitations

Traditional decompression instruments are rigid and knife-like in design, limiting their ability to access all three areas of the spine where lumbar stenosis occurs. Failure to remove all stenosis during a traditional decompression results in poor surgical outcomes almost 60% of the time, such as continued or recurring pain or the need for another operation.^{8,9}

In order to reach the overgrown bone and tissue pressing on the nerve, surgeons sometimes must cut through bone and tissue in a straight line, often requiring the removal of healthy pieces of the patient's spine needed for stability. However, removing as little as 30% of healthy bone and tissue to access the area of the patient's lumbar stenosis during traditional decompression can lead to a complication called instability of the spine and the possible need for a spinal fusion procedure to stabilize the unstable joint.¹⁰

The iO-Flex® System: Precision Decompression from the Inside Out®

Now there is a new alternative to traditional decompression with rigid instruments. The iO-Flex® System is the first minimally invasive set of flexible instruments designed to target lumbar stenosis in all three areas, with minimal disruption to the patient's healthy anatomy. Instead of cutting through healthy pieces of the spine, the iO-Flex® System uses a fine surgical wire to guide the thin iO-Flex® shaver instrument to the location of the overgrown bone and tissue to shave away the stenosis from the inside out (iO).

The iO-Flex® Advantage

Minimally Invasive Surgery

- Designed to be less invasive and less traumatic, may lead to shorter operating times, hospital stays and recovery times compared to traditional decompression
- Only instrument able to reach and relieve pressure surrounding up to two nerves on each side of the spine, through one small incision

Target All Three Areas of Stenosis

- System offers improved access to target all three areas of lumbar stenosis, which occur in the lateral recess, foramen and central canal where the nerves exit the spine and travel to the lower half of the body

Preserving Healthy Bone and Tissue

- MicroBlade Shaver® instrument is guided by a Guidewire into hard to reach areas where stenosis can occur, unlike traditional knife-like tools that must cut in a straight line
- Tissue-sparing instruments preserve healthy bone, ligaments and muscle to help maintain spinal stability



iO-Flex® Patient Stories



“My back pain started over a year ago. It started in my back and then began traveling down into my legs. The pain was so severe that I was taking pain medication every four hours just to cope.

Surgery was the last resort. After surgery, I woke up in the recovery room, and I thought thank you God and thank you doctor! I'm riding the stationary bike and walking a mile per day. I feel like I've been reborn and rejuvenated! I'm totally happy.” **Jane**



“I always kept physically active. I went to the gym four or five times a week, played the drums and enjoyed woodworking. I started to have pain that became gradually worse over time.

It started in my lower back and then crept into my hips and legs. I could no longer do any of my normal activities. I avoided exercise and standing to avoid the severe pain. Having surgery was my last resort. My improvement after surgery was immediate and dramatic. Within a week I felt good & was ready to play the drums again.” **Stuart**