

OLIF25[™] and OLIF51[™] Procedures

Medtronic



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OVERVIEW

Your spine is a complex but essential part of the skeletal system. It provides upright support, protects the spinal cord, and aids in movement. It is made up of 33 vertebral bones. Each vertebra is cushioned by discs above and below elastic rings of cartilage that allow the individual bones of the spine to bend and twist. Each disc has an outer wall called the annulus and an inner cavity filled with liquid called the nucleus. Facet joints in the back of the spine aid the spine's movement. They serve to stabilize the spine and keep it from moving out of place too far.

The spine is shaped like the letter "S." It is made up of three segments — cervical (neck), thoracic (middle), and lumbar (lower). A majority of back and leg pain originates from the lumbar spine which also bears the most stress. The OLIF25 and OLIF51 Procedures allow spine surgeons to treat lumbar spine conditions from an oblique lateral position.



WHAT IS CAUSING MY PAIN?

Changes to our spine are a natural part of the aging process. Pain is often the result of transformations in the composition of our bone or tissue. Most everyone undergoes these changes. Sometimes these changes put pressure on the nerves and lead to back and/or leg pain, possibly leading to the following pathologies:

- Degenerative Disc Disease (DDD)
- Adult Degenerative Scoliosis
- Degenerative Spondylolisthesis
- Spinal Stenosis







SPINAL STENOSIS



AN INTRODUCTION TO THE OLIF25 AND OLIF 51 PROCEDURES

This brochure was created to answer some of your questions about the Oblique Lateral Interbody Fusion (OLIF25 and OLIF51) Procedures. Not all of the information provided will follow your individual treatment plan. This brochure is not meant to replace a physician's consultation or conversation with your health care professional.

The interbody options used in OLIF25 Procedures are indicated to treat the following pathologies:

- Degenerative Disc Disease (DDD)
- Adult Degenerative Scoliosis
- Degenerative Spondylolisthesis
- Spinal Stenosis



Pivox™ Oblique Lateral Spinal System



Clydesdale™ Spinal System

The interbody options used in OLIF51 Procedures are indicated to treat the following pathologies:

- Degenerative Disc Disease (DDD)
- Degenerative Spondylolisthesis
- Spinal Stenosis
- Adult Degenerative Scoliosis*



Sovereign[™] Spinal System



Divergence-L™ Anterier/Oblique Lumbar Fusion System

^{*}Divergence-L Anterior/Oblique Lumbar Fusion System only

What are my treatment options?

Options such as rest, steroid injections, heat, and physical therapy may relieve pain. If your symptoms do not improve, your doctor may recommend spinal fusion surgery to alleviate pain.

Spinal Fusion Surgery

The goal of spinal fusion is to restore stability to the spine. During the procedure, the surgeon removes the disc between the vertebrae in order to stabilize the spine. The surgeon will insert material between the vertebrae which will promote the two vertebral bodies to "fuse" into one bone structure.

An evolving trend in spinal surgery is minimally invasive surgery. This technique makes the use of smaller incisions to do traditional surgeries through new approaches.

The OLIF25 and OLIF51 Procedures are a type of "minimally invasive" spinal fusion surgery.

How does minimally invasive spine surgery differ from open spine surgery?

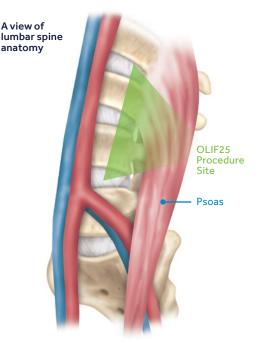
In a traditional open spine surgery, the doctor makes a large incision and retracts the muscles to the side to get a clear view of the spine. With minimally invasive spine surgery, surgeons can achieve the same operative goals as an open procedure, but in a less invasive way.¹

¹ Fessler R, Khoo L. Minimally Invasive Cervical Microendoscopic Foraminotomy: An Initial Clinical Experience. Neurosurgery. 51: 37-45, 2002.

What are the benefits of the OLIF25 Procedure?

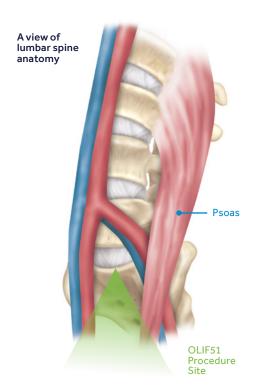
One of the biggest adaptations OLIF25 makes to Lateral Lumbar Interbody Fusion (LLIF) is avoiding the Psoas muscle that surrounds the spine on both sides in the lower levels. The muscle is filled with nerves that aid in leg movement. Sparing the muscle means limiting the chance to damaging those nerves and thus reducing the risk of leg pain, thigh weakness, and numbness.

- Avoids harming major blood vessels by going behind intestines (peritoneum)
- Reduces the potential risk to the nerves located in Psoas muscle surrounding the spine by going around the muscle
- Interbody footprint allows for more degree correction options and larger surface area to promote spinal fusion



What are the benefits of the OLIF51 Procedure?

The OLIF51 Procedure is essentially a traditional ALIF (anterior lumbar interbody fusion) retroperitoneal procedure with the patient positioned on their side instead of being positioned lying on their back. The change in positioning allows the abdominal contents to fall away from the spine which then provides visibility to the L5 disc space for the operating surgeon.



What should I expect the day of my procedure?

STEP 1

Before Surgery

- Your physician will review x-ray images of your spine to plan the procedure. He or she will review expectations and answer questions about medications, physical therapy, and the recovery process.
- You will likely be asked to arrive at the hospital early in the morning, prepped for surgery, and have your surgical site cleaned.
- After you are sedated, placed on your side and draped, the operating team will begin the procedure.



STEP 2

Accessing the Spine

- Your physician will make an incision on your side between your belly button and hip.
 Intraoperative fluoroscopy will ensure an accurate pathway.
- A long tube will dilate your skin to hold the incision. The surgeon will position your muscles to provide clear access and visualization to the affected part of the spine.

STEP 3

Disc Removal

- When the surgeon reaches the spine, the process of removing the degenerated disc begins. Using a variety of instruments, the disc is removed from the spine.
- To provide stabilization and keep the vertebrae in place after the disc is removed, an interbody device (usually made of a polymer or titanium) is inserted between the vertebral bodies.
- In order to facilitate bone growth, soft bone may be harvested from another bone in the body and placed into the interbody between the vertebrae.
- The interbody acts as a "cage" to support the spine and hold the soft bone during the fusion process.

STEP 4

Fixation

- After inserting the interbody, the surgeon will create an internal brace that will secure the spine during the bone healing and fusion process.
- The surgeon may do this by implanting rods in your back, screws into your facet joints, spinal clamps, and anterior plates and screws. Your surgeon will contour these low profile devices to your spine.
- The end result creates a stable construct. If the recovery process goes as planned, within a few months the two vertebrae should fuse into one vertebra, creating stability.



CD Horizon™ Solera™ Voyager™ Spinal System

FREQUENTLY ASKED QUESTIONS

What risks are involved in surgery?

All treatment plans and outcomes are specific to the individual patient. Results may vary. Consult your physician for a complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information. A potential risk of spinal fusion is failure of the vertebral bone and graft to fuse properly, a condition that may require additional surgery. Potential risks associated with interbody implants include: implant migration, device breakage, and reaction of the body to a foreign material. Potential risks associated with minimally invasive procedures include:

- Neurological damage
- Damage to the surrounding soft tissue
- Instrument malfunction
- Longer operation times
- Having to transition to an open procedure

What will the recovery process look like?

Your surgeon will have a specific recovery plan to help you increase your activity level as soon as possible. Your surgeon may ask the hospital staff to help you get up and walk by the end of the first day. After an OLIF25 or OLIF51 Procedure, you may notice an immediate improvement of some or all of your symptoms, or improvement may happen gradually.

Other symptoms may improve more gradually. The amount of time that you have to stay in the hospital will depend on your individual treatment plan. Your return to work will be determined by your doctor and will depend on how well your body is healing and the type of work/activity level to which you plan to return. Your surgeon will work closely with you to determine your specific recovery plan. Follow his or her instructions to optimize the healing process.

When can I drive?

After surgery, activities which require some degree of mobility may be limited. Ask your surgeon for more details.

When can I return to work?

As part of your recovery process, you may have to take time off work to limit your exertion. Your return will depend on your occupation and level of mobility. Consult with your physician to craft a plan that will fit your needs.

Will I have a scar?

The procedure will leave a small scar on the left side of your abdomen of a couple of inches. The size will depend on how many spinal levels on which the surgeon will be operating.

Can I travel?

Many spinal implants are made from metal. Due to the nature of security measures, before traveling consult your local airport authority to obtain more information that might help you pass through security more comfortably. Your physician may be able to assist by providing a patient identification card.

The information here is for educational purposes only and cannot replace the relationship that you have with your health care professional. It is important that you discuss the potential risks, complications and benefits of surgery with your doctor prior to receiving treatment, and that you rely on your doctor's judgment. Medtronic does not practice medicine or provide medical services or advice. Only your doctor can determine whether you are a suitable candidate for this treatment.

GLOSSARY OF TERMS

Adult Degenerative Scoliosis – Develops when a curve forms in the spine resulting from changes in the structure of the spine such as Degenerative Disc Disease or gradual deterioration of the spine's facet joints, which serve to stabilize the spine.

Bone Graft – During spinal fusion surgery, the disc between the vertebrae is removed, creating an open space. In order to fill the space and provide stability, a bone graft is placed between the vertebrae. Bone is harvested from another part of the body (such as the hip) and placed inside a cage that fits between the vertebrae. The goal is to use the patient's own bone to regenerate new bone, to fill the space, and create one bone.

Degenerative Disc Disease (DDD) – Occurs when we lose water in the nucleus and the disc flattens due to age. As the space between the vertebrae shrinks, the spaces the nerve roots move through become more constricted. Pressure on nerves leads to lower back and/or leg pain.

Degenerative Spondylolisthesis – Occurs when the joints, through arthritis, lose their ability to keep the alignment of the spine in its normal position. This can cause the vertebra to slip forward.

Disc- Intervertebral discs are elastic rings of cartilage that allow the individual bones of the spine to bend and twist. Each disc has an outer wall called the annulus, and an inner cavity filled with liquid called the nucleus.

Facet Joints - The facet joints connect the

OLIF25 AND OLIF51 PROCEDURES GLOSSARY OF TERMS

vertebral bodies to one another, and can also become arthritic and painful, and can be a source of back pain. The facet joints are located at the back of the spine and counterbalance the intervertebral discs. They help keep the normal alignment of the spinal vertebrae and limit motion.

Interbody – An interbody is a small cage made of either titanium or a plastic compound that is inserted between the vertebrae during spinal fusion in order to provide stability and structure. It is filled with a bone graft that will promote the new bone growth necessary for fusion of two vertebrae.

Neurological Structure – may refer to any of the nerves that make up the nervous system such as the spinal cord or branching nerve roots. During spinal fusion surgery it is important for the surgeon to be aware of neurological structures as damaging them may result in complications after surgery.

Posterior Fixation – is an important part of the fusion process, which includes the placement of rods and screws that provide stability to the spinal column during the bone healing process.

Spinal Fusion Surgery – A surgical procedure designed to stop motion at a painful vertebral segment. This is done by taking out the spongy disc between the vertebral bodies and inserting bone graft material. Over time the bone graft will help the two vertebral bodies "fuse" together, creating one bone, and stopping the painful movement. Often, to keep the bones in place while new bone is growing, rods, screws, a small clamp, or plate will be fastened to the bone.

Spinal Stenosis – is a disorder that is caused by

OLIF25 AND OLIF51 PROCEDURES GLOSSARY OF TERMS

a narrowing of the spinal canal. This narrowing happens as a result of the degeneration of both the facet joints and the intervertebral discs. In this condition, bone spurs (also calledosteophytes) can grow into the spinal canal.

Vertebral Body – The spine consists of thirty-three unique bony structures. Together they work to allow the body to move forward and back, flex to the side, and twist. They also provide support and stability to the skeletal structure and protect internal organs.

WHO IS MEDTRONIC?

As a global leader in medical technology, services and solutions, Medtronic improves the health and lives of millions of people each year. We believe our deep clinical, therapeutic and economic expertise can help address the complex challenges — such as rising costs, aging populations and the burden of chronic disease — faced by families and healthcare systems today. But we can't do it alone. That's why we're committed to partnering in new ways and developing powerful solutions that deliver better patient outcomes.

Founded in 1949 as a medical repair company, we're now among the world's largest medical technology, services and solutions companies, employing more than 85,000 people worldwide, serving physicians, hospitals and patients in more than 160 countries. Join us in our commitment to take healthcare Further, Together. Learn more at Medtronic.com.

OLIF25 AND OLIF51 PROCEDURES **NOTES**

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Medtronic

Spinal and Biologics Business Worldwide Headquarters

2600 Sofamor Danek Drive Memphis, TN 38132



Medtronic Sofamor Danek USA, Inc.

1800 Pyramid Place Memphis, TN 38132

(901) 396-3133 (800) 876-3133

Customer Service: (800) 933-2635

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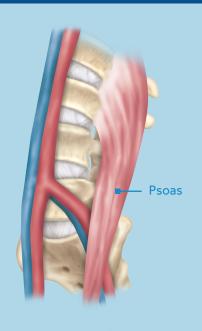
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OLIF

Oblique Lateral Interbody Fusion

A minimally invasive alternative to traditional Anterior Lumbar Interbody Fusion (ALIF)





The oblique lateral approach of the OLIF procedure avoids the psoas muscle which is filled with nerves that aid in leg movement. Learn more about the OLIF Procedure and the associated surgical benefits.