Fact Sheet:
eXtreme Lateral Interbody Fusion (XLIF®)

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About Lateral Access Spine Surgery

Lateral access spine surgery is a safe and reproducible means of addressing certain spine disorders with an approach from the side of the patient, as opposed to an approach from the back or the front. A lateral approach is made safe with the use of nerve monitoring technology.

This approach does not require dissection or retraction of the sensitive back muscles, bones, ligaments, or nerves and allows for more complete disc removal and implant insertion as compared with traditional posterior procedures. Nor does lateral access require the delicate abdominal exposure or present the same risk of vascular injury as traditional anterior approaches. As a result, operating time is often reduced, patient blood loss is minimized, and recovery time is significantly shorter.

By allowing greater access to the disc space, a larger implant can be used, which indirectly decompresses nerves by restoring disc height.

About Lumbar Interbody Fusion

Lumbar interbody fusion is a surgical technique that attempts to eliminate instability in the back.

Instability can be due to degenerated discs and/or facet joints that cause unnatural motion and pain, loss of height of the disc space between the vertebrae that causes pinching of the spinal nerves exiting the spinal canal, slippage of one vertebra over another, and/or change in the normal curvature of the spine.

About eXtreme Lateral Interbody Fusion (XLIF®)

In an XLIF procedure, the spine is approached from the side of the body. The patient is positioned on the surgical table on his or her side. Two small incisions are made: one directly over the side of the waist (through which most of the procedure is performed), and the other slightly behind the first, toward the back muscles (through which the surgeon's finger safely guides the approach).

Until now, widespread acceptance of minimally invasive techniques has evaded spine surgery. The primary reason for this was the inherent difficulty of introducing new technologies while attempting to achieve the same surgical objectives as conventional surgery. The XLIF surgical technique is different, however, because it incorporates two systems developed by NuVasive®: the MaXcess® System and the NVJJB™/M5® System. NuVasive has also developed other products to support the XLIF procedure, such as the XLP® Lateral Plate, the SpheRx® DBR® II System, and the CoRoent® XL device.

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XLIF® Patient Benefits

Reduced operative time – Traditional procedures can take many hours to perform, the while XLIF procedure can be successfully completed in as little as one hour, reducing the amount of anesthesia time.

Reduced blood loss and minimal scarring – The MaXcess® retractor dilates the tissue rather than cutting, resulting in much less trauma to the affected area.

Reduced postoperative pain – The XLIF procedure does not require entry through sensitive back muscles, bones, or ligaments, so patients are usually walking the same day.

Reduced hospital stay – XLIF requires only an overnight stay in the hospital, compared to several days of immobility and hospitalization typical of traditional open approaches.

Rapid return to normal activity – Patients are usually walking the same day after surgery and recovery is typically around 6 weeks, compared to 6 months or more.

Benefits	XLIF Surgery	Traditional Surgery
Hospital Stay	1 – 2 days*	3 – 5 days*
Blood Loss	<100cc*	300 – 600cc
Walking	Same Day*	2 – 4 days*
Return to Normal Activity	4 – 6 weeks	6 months or longer

*Source: Wright N, XLIF - the United States Experience 2003-4, International Meeting on Advanced Spine Techniques, 2005, Banff, Canada

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XLIF® Clinical Applications

The XLIF minimally disruptive procedure can be performed for a number of situations. The list below contains representative examples. The list is not intended to include all possible indications/and or contraindications.

Any thoracolumbar case above L5-S1 requiring access to the disc space and/or vertebral bodies. Examples include:

- DDD with Instability
- Recurrent Disc Herniation
- Degenerative Spondylolisthesis (≤ grade 2)
- Degenerative Scoliosis
- Pseudarthrosis
- Discitis, Vertebral Osteomyelitis (without active infection)
- TDR Revision
- Post-Laminectomy Instability
- Junctional Disease

XLIF May Not Be Right for You if Any of the Following Apply to You:

Any generally accepted contraindication to fusion, such as:

- Systemic infection
- Osteoporosis
- Significant co-morbidities
- L5-S1
- Lumbar deformities with > 30° rotation
- Degenerative spondylolisthesis grade 3
- Bilateral retroperitoneal scarring (e.g., abscess or prior surgery)
- Need for direct posterior decompression through same approach (Second posterior micro-decompression not contraindicated)

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Side Effects:

- Revision or reoperation;
- Change in lordosis;
- Injuries to kidneys or ureters;
- Deterioration in neurological status;
- Facet joint deterioration;
- Spondylolysis;
- Spondylosis;
- Spondylolisthesis;
- Nerve damage due to surgical trauma, neurological difficulties including bowel and/bladder dysfunction, retrograde ejaculation, tethering of nerves in scar tissue, muscle weakness or paresthesia;
- Vascular damage including hematoma, ileus injuries, deep vein thrombosis potentially leading to pulmonary embolism, catastrophic or fatal bleeding;
- Dural tears experienced during surgery resulting in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis;
- Bursitis;
- Paralysis;
- Damage to lymphatic vessels and/or lymphatic fluid exudation;
- Fracture of bony structures;
- Anesthetic reaction;
- Bowel perforation;
- Hernia;
- Infection -- Peritonitis;
- Periotoneal adhesions;
- Failure of the procedure to improve symptoms and/or functions;
- Spinal stenosis;
- Death

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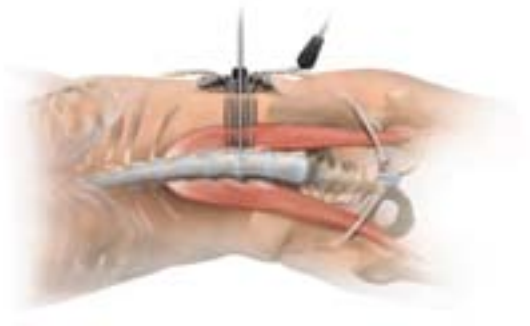
MaXcess® System

The MaXcess System provides customized maximum surgical access while minimizing the soft tissue disruption that often occurs during open surgery. As opposed to minimal access systems, which provide minimal spinal access, minimal visualization, and minimal surgical confidence, the MaXcess System from NuVasive® offers improved visualization, and increased angulation and positioning of instruments and implants.

This provides the surgeon all the benefits of a minimally disruptive surgical approach without compromising conventional surgical techniques.



The MaXcess System allows the fundamentals of conventional surgical techniques to be achieved, while eliminating the unfamiliar requirements of operating coaxially through tubular portals. Additionally, since there are no adjunctive visualization tools (e.g., endoscope, monitor), the MaXcess System enables direct illuminated visualization of the patient's anatomy through conventional methods.

NVM5™

The NVM5 System is a technologically advanced intraoperative nerve monitoring system that assists the surgeon with safe implant placement and surgical technique by monitoring the patient's nerve activity throughout the surgical procedure.

Electromyography (EMG), the study of the electrical activity of muscles, is used during the XLIF® procedure to determine the health and function of nerves, particularly in cervical or lumbar spine surgeries where nerve roots are affected.

The NVM5 System combines intraoperative electrically stimulated EMG and spontaneous EMG activity to assess possible nerve root irritation or injury during surgery. Software algorithms help provide the surgeon with real-time data to assist with patient nerve safety.

Monitoring the muscles requires the placement of adhesive needle electrodes on or under the skin overlying the patient's leg muscles. These electrodes record muscle activity during the procedure, providing information about the health and function of the specific spinal nerves that indicate muscle activity and sensation functions to them.

The NVM5 System's automated features allow it to seamlessly integrate into the surgical technique while providing accurate and reproducible real-time feedback about nerve health and function. The system allows the surgeon to have first-hand knowledge of the monitoring results, confirming the safe progression of the XLIF surgical procedure.

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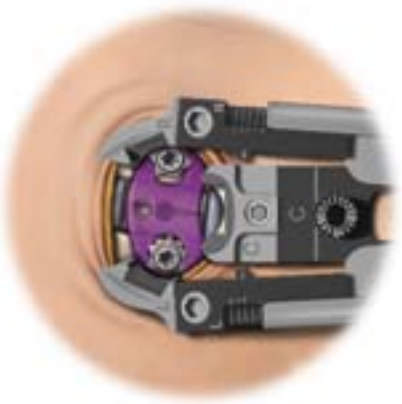
XLP® Lateral Plate



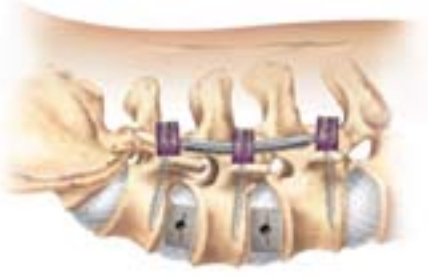
The objective in developing the XLP lateral plate was to provide a simple yet reliable method of internal fixation delivered through a single XLIF approach. XLP lateral plate fixation allows a surgeon to preserve the minimally invasive benefits of a standalone XLIF procedure while providing effective stabilization to the interbody implant. Through clinical evaluation and system refinement, NuVasive has designed each component of the XLP platform to work seamlessly with the MaXcess® retractor and the XLIF approach, resulting in an efficient system.

XLP fixation adds only a few minutes to the XLIF procedure, but saves valuable operating room time by eliminating the need to reposition the patient prior to instrumentation.

The XLP lateral plate is a significant advancement in the evolution of the XLIF approach that provides measurable benefits to the patient, hospital, and surgeon. This single-approach procedure provides a number of benefits, including:

- A safe, reproducible approach
- Decreased operative time
- Shortened hospital stay
- Quicker patient recovery and return to normal activity

SpheRx® DBR® II System



The SpheRx DBR II Minimally Disruptive Fixation System offers a solution for performing effective minimally disruptive spinal fixation in a simple, straightforward manner. Seamless, step-by-step integration of NVJJB™/M5® nerve monitoring provides real-time feedback throughout the surgery and helps to ensure safe hardware placement and neural integrity. Additionally, the spherical end of the SpheRx DBR II rod fits precisely into the screw head, leaving no residual rod overhang at the superior end of the construct. This reduced implant profile may minimize the incidence of hardware-related, adjacent level symptoms.

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CoRoent® XL

CoRoent XL is an anterior column reconstruction device sized for stability, anatomically shaped, and designed for simplicity. Its large, anatomical shape provides maximum surface area and structural stability, and its large apertures allow bony through-growth. CoRoent XL's radiolucent PEEK-OPTIMA® material provides optimal stiffness compatibility with the surrounding bone, and its titanium markers enable easy-to-interpret placement and orientation verification.

CoRoent XL has multiple length options to ensure optimal apophyseal support, reducing the chance of subsidence. Additionally, it's available in lordotic profiles to induce proper sagittal alignment.

It is important that you discuss the potential risks, complications, and benefits of the XLIF procedure with your doctor prior to receiving treatment and that you rely on your physician's judgment. Only your doctor can determine whether you are a suitable candidate for this treatment.

About NuVasive®

NuVasive is a medical device company focused on the design, development, and marketing of products for the surgical treatment of spine disorders. The Company's product portfolio is focused on applications in the over $4.2 billion U.S. spine fusion market. The Company's current principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS®, as well as a growing offering of cervical and motion preservation products.

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