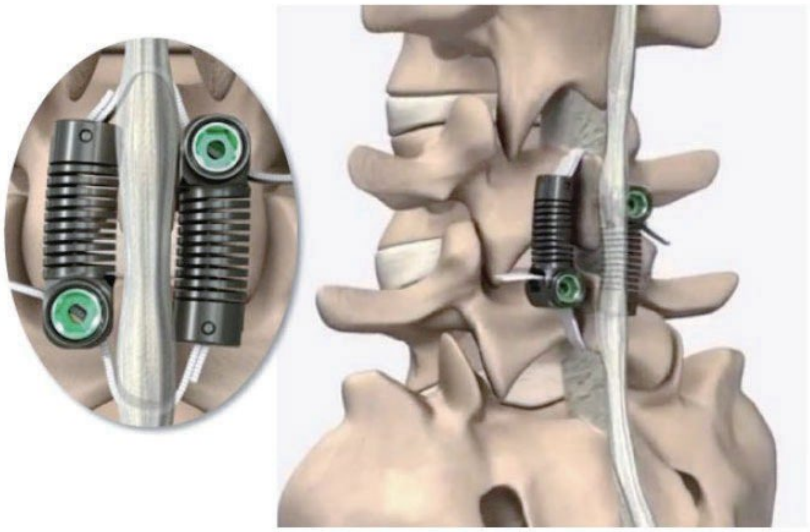
EMPIRICAL SPINE™

LIMIFLEX™
DYNAMIC
SAGITTAL TETHER

Patient Labeling



Prescription device: Federal U.S. law restricts this device to sale by, or on the order of, a physician.

PATIENT LABELING

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I. Glossary of Terms

Anterior – Refers to the front of a structure.

Biomechanical – Relating to the mechanics of the human body. This focuses on the forces from muscles and gravity on the skeleton.

Computed Tomography (CT) – A diagnostic imaging procedure that uses a combination of X-rays and computer technology to produce images of the inside of the body.

Decompression – A procedure to relieve pressure on the spinal cord and nerve roots caused by spinal stenosis or disc degeneration.

Degenerative Spondylolisthesis – A clinical condition characterized by a vertebra slipping over the vertebra below.

Discectomy – The removal of part or all of the spinal intervertebral disc.

Facet Joints – Small, paired joints on the back of the vertebrae that provide stability and motion.

Foramen – An opening in bone.

Incision – A cut in the skin made during surgery to access the surgical site.

Lamina – Bone pieces that stick out from the back of the spine.

Laminectomy – A surgery that creates space or relieves pressure on impinged nerves by removing bone spurs and tissues.

Lumbar spine – The portion of the spine consisting of the five vertebrae of the lower back.

Magnetic Resonance Imaging (MRI) – Magnetic Resonance Imaging is a non-invasive medical imaging procedure that uses magnetic field and pulses of radio waves to generate pictures of structures inside the body.

Nerve – A fiber or bundle of fibers that sends messages to and from the brain. Nerves control movement throughout the body. Nerves also control touch, pain, and numbness.

Nerve Root – The part of the nerve that passes from the spinal cord through an opening between bones of the spine.

Pedicle – Cylinder-shaped projections of hard bone that stick out from the back part of the vertebral body and provide side protection for the spinal cord and nerves.

Posterior – Refers to the back of a structure.

Spinal Fusion – Surgery that permanently connects two or more vertebrae in the spine.

Spinal Stenosis – The narrowing of the spinal canal that can cause pressure on your spinal cord or the nerves that go from your spinal cord to your muscles.

Spinous Process – A bony projection off the back of each vertebra.

Vertebrae – The bones that form the spinal column or backbone. A single spinal bone is called a vertebra.

II. The Lumbar Spine

The lumbar spine consists of five vertebrae in the lower back. It provides support for the weight of your body, surrounds and protects your spinal cord, and facilitates a wide range of body motions. The vertebral bodies of the lumbar spine are large, thick, block-like structures of dense bone. The front (or anterior) part appears rounded, while the back (posterior) parts include lamina, pedicles, and bony processes projecting off the of the vertebral body. These posterior bony structures form the hollow spinal canal that houses lumbar nerves and the cauda equina.

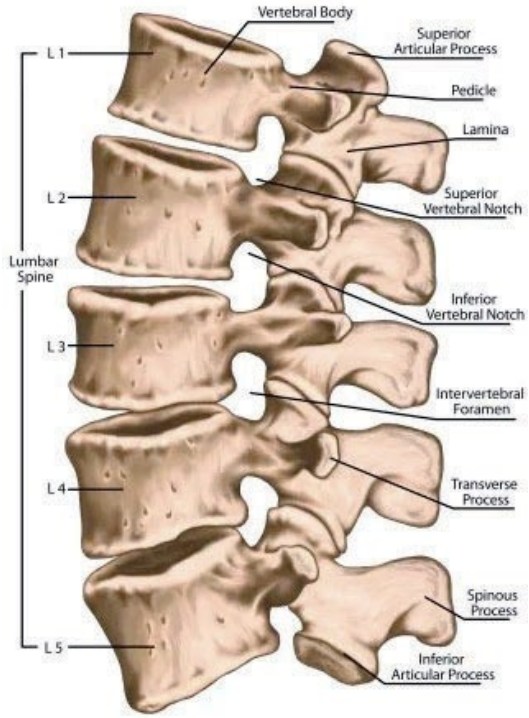

Figure 1: Lumbar Spine Anatomy
(Representative image shown, final illustration pending)

Adjacent vertebral bodies are separated by a single intervertebral disc. The intervertebral discs help bear weight, absorb, and distribute shock and forces during movement, and create the open nerve passageways called foramen or neuroforamen from which nerve rootlets exit the spinal canal to carry signals across the body.

III. What is Degenerative Spondylolisthesis?

As people age, the bones, joints, and ligaments that compose the lumbar spine weaken and lose their ability to maintain spinal column alignment. This can lead to one vertebral body slipping over the one below, a condition clinically referred to as degenerative spondylolisthesis. Lumbar degenerative spondylolisthesis is a major cause of spinal canal stenosis. Stenosis is the pinching of the spinal cord and nerves that travel through the spine. Stenosis can cause low back and leg pain, often called "sciatica."

IV. Symptoms of Degenerative Spondylolisthesis

You may not experience any symptoms related to degenerative spondylolisthesis. Some patients have the condition without knowing. For the patients that do experience symptoms, the most common symptoms include lower back pain that may extend to the buttocks and down the thighs. You may also experience muscle spasms in the hamstrings, back stiffness, difficulty walking or standing for long periods, and pain when bending over.

V. Diagnosis and Treatment Options

Your doctor will take your health history and do a physical examination to understand your symptoms. Your posture, motion, reflexes, muscle strength, and locations of pain are all evaluated during the examination to fully assess all potential sources of your symptoms.

Imaging scans may be required to confirm the diagnosis. Spinal X-rays help your doctor determine if a vertebra is out of place. If your doctor needs more detail regarding the spine or the surrounding soft tissue, such as discs and nerves, you may undergo a CT or MRI scan.

The course of treatment is dependent on the grade of the slippage, symptoms, age, and overall health. For some patients, non-surgical treatment options can relieve their symptoms. This includes rest, medications, steroid injections, physical therapy, and bracing. Discuss further treatment options with your doctor if your symptoms persist after non-surgical treatment.

Surgery to treat spondylolisthesis and lumbar spinal stenosis typically involves spinal decompression. During a decompression surgery, your surgeon may remove a section of bone from one vertebra to relieve pressure on the affected nerve (laminectomy) or remove a section of a damaged disc to relieve pressure on the affected nerve (discectomy). The surgeon may also perform a spinal fusion procedure, which includes spinal decompression followed by the fusing of two or more vertebrae together to create a "block" of bone to stabilize and strengthen the spine while relieving pain.

VI. Decompression with or without Fusion

Degenerative spondylolisthesis with spinal stenosis is treated surgically through decompression. During a decompression surgery, your surgeon may remove parts of bone and/or disc to relieve pressure on the affected nerve. Following decompression surgery, the surgeon may fuse two or more vertebrae together to stabilize and strengthen the spine to compensate for the removal of

tissue and to help prevent recurrent symptoms and increased vertebral slip. Spinal fusion provides clinical benefit but may not be appropriate for all patients due to its complication rate and postoperative morbidity. The LimiFlex Dynamic Sagittal Tether presents a new option for limiting flexion motion of a lumbar spinal motion segment after surgical decompression with limited potential risks, morbidity, and complications of a spinal fusion. The effectiveness of LimiFlex Dynamic Sagittal Tether compared to decompression alone has not been established.

VII. The LimiFlex Dynamic Sagittal Tether

The LimiFlex Dynamic Sagittal Tether provides dynamic flexion-restricting stabilization following decompression for treatment of degenerative spondylolisthesis with spinal stenosis. The device forms a loop around adjacent spinous processes to increase segmental stiffness and reduce flexion range of motion. The LimiFlex Dynamic Sagittal Tether consists of two titanium tension springs, each with a pre-attached ultra-high molecular weight (UHMW) polyethylene textile band.

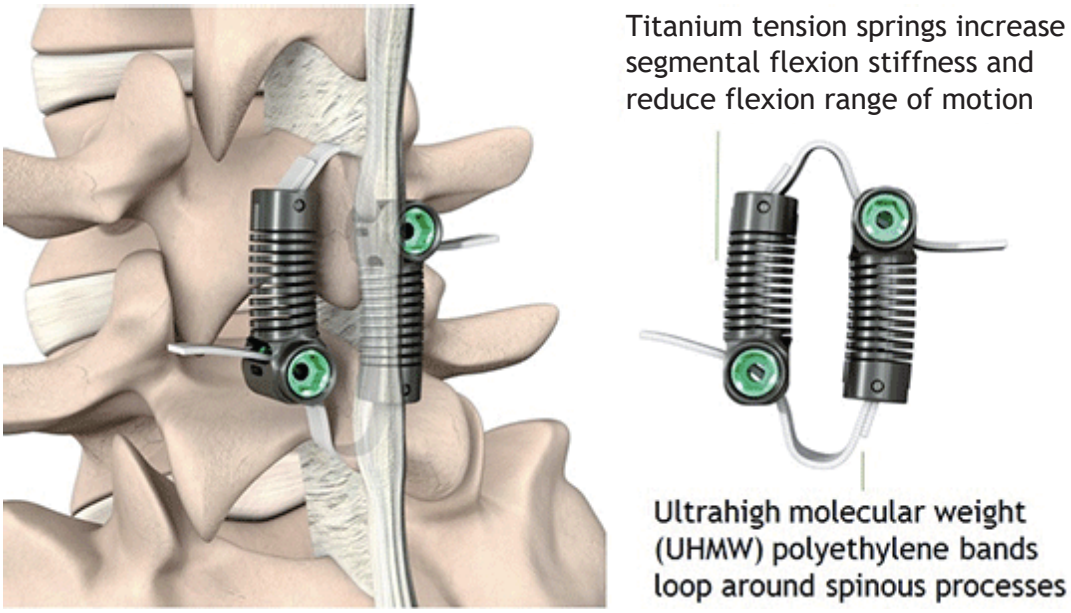

Figure 2: LimiFlex Dynamic Sagittal Tether

The LimiFlex Dynamic Sagittal Tether includes instruments used for device placement.

VIII. Am I a Candidate for surgery with the LimiFlex Dynamic Sagittal Tether?

You will likely be treated non-surgically first. This conservative treatment often includes but is not limited to physical therapy, medications, and/or epidural injections. If those treatments do not provide relief after 3 months, your doctor may suggest surgical treatment.

Please speak to your doctor to understand the benefits and risks of the LimiFlex Dynamic Sagittal Tether. Your doctor will tell you if you are a candidate this procedure.

IX. Who Should Not Receive LimiFlex Dynamic Sagittal Tether (Contraindications)?

The LimiFlex Dynamic Sagittal Tether should not be used in patients with the following conditions:

- Posterior element anatomy inappropriate for interspinous fixation, including:
  - Absence or fracture of spinous processes or posterior elements, or deformity that precludes secure device fixation,
  - Facet joint incompetence,
  - Prediction of resection of greater than 50% of spinous processes or facet joints during decompression of the instrumented segment,
  - Spondylolysis or isthmic spondylolisthesis at the instrumented level,
  - The estimated distance between the LimiFlex Dynamic Sagittal Tether strap attachment points (midpoint of the cranial edge of the cranial spinous process and the midpoint of the caudal edge of the caudal spinous process) is less than 30 mm on pre-operative lateral standing radiographs at the segment to be instrumented,
  - Posterior element tumor,
  - Severe osteoporosis.
- A primary diagnosis of facet-mediated back pain, defined as isolated axial back pain without associated buttock or leg pain, worsened by extension, in the presence of severe facet arthropathy on imaging and absence of radiographic neural compression.
- Symptomatic lumbar stenosis at the instrumented level that is not amenable to a direct surgical decompression
- Documented allergy to implant materials, including titanium or polyethylene
- Active systemic or local infection

X. What are the Warnings and Precautions Associated with the LimiFlex Dynamic Sagittal Tether?

Specific warnings for the LimiFlex Dynamic Sagittal Tether relate to surgeons completing required reading and training, as well as following certain recommendations when using the LimiFlex Dynamic Sagittal Tether, associated instruments and accessories, as well as during the surgical decompression procedure.

The following precautions are associated with the LimiFlex Dynamic Sagittal Tether:

- Note that the LimiFlex Dynamic Sagittal Tether is not intended for pediatric use or correction of scoliosis.
- The effectiveness of the subject device has not been compared to decompression alone.
- The use of the subject device at a spinal segment treated with total disc replacement has not been studied.

The safety and effectiveness of the LimiFlex Dynamic Sagittal Tether has not been established in patients with the following conditions:

- More than one spinal level requiring surgical intervention, other than adjacent

level decompression.
- More than one surgical procedure at any combination of lumbar levels other than adjacent level decompression.
- Prior surgery at any lumbar vertebral level with instrumentation.
- Prior surgery at the index lumbar vertebral level without instrumentation.
- History of Paget's disease, osteomalacia, or other metabolic bone disease.
- History of an autoimmune disease.
- Psychiatric or cognitive impairment.
- Current or recent history of illicit drug or alcohol abuse, or dependence as defined as the continued use of alcohol despite the development of social, legal, or health problems.

XI. What are the Risks of this Type of Surgery?

Complications may occur when you are treated with the LimiFlex Dynamic Sagittal Tether. Potential complications can include, but may not be limited to, the following:

Risks Associated with Any Surgery:
General surgical risks include, but are not limited to:

- Complications from anesthesia such as allergic reaction, anaphylaxis, or other reactions
- Post-surgical pain, bruising, hematoma, swelling, or tenderness at the surgical site
- Complications from medication (e.g., nausea, vomiting, delirium or headache after the surgery)
- Blood loss requiring a blood transfusion
- Blood clots, including pulmonary emboli
- Infection (including urinary tract infection)
- Phlebitis
- Pneumonia
- Poor tissue healing
- Paralysis
- Atelectasis
- Wound complications (such as separation and bruising) and soft tissue damage
- Ileus or intestinal obstruction
- Septicemia
- Myocardial infarction
- Cardiac arrhythmia
- Stroke
- Death

Risks Associated with Decompression Surgery:
Decompression surgery risks include, but are not limited to:

- Dural tear
- Cerebrospinal fluid leak

- Bowel, bladder or sexual dysfunction
- Organ damage
- Disc herniation
- Increased spinal instability requiring additional surgery
- Persistent stenosis requiring additional decompression
- Leg weakness or numbness
- Muscle and tissue injury or damage
- Spinous process fracture
- Cauda Equina damage
- Nerve injury, paralysis or weakness
- Epidural hematoma or bleeding
- Loss of spinal range of motion
- Spontaneous fusion at non-index levels due to heterotopic ossification, development of bridging bone or osteophytes
- Development of new spinal conditions, including but not limited to spinal stenosis and spondylolisthesis

Risks Associated with the LimiFlex Dynamic Sagittal Tether:
Risks specific to posterior lumbar spine surgery (including the LimiFlex Dynamic Sagittal Tether) include, but are not limited to:

- Sensitivity, allergy or chronic inflammation (e.g., foreign body reaction, bursitis)
- Infection related to the device
- Dislocation, malpositioning or lack of fixation of the device after surgery
- Malpositioning of the device
- Malalignment of anatomic structures
- Mechanical failure of the device including device breakage, device separation or disassembly
- Incomplete healing after the procedure
- Unsatisfactory clinical results that may include increased pain at the device level and exacerbation of symptoms
- Fracture and/or erosion of the spinous processes
- Nerve and/or vascular damage
- Spontaneous fusion due to heterotopic ossification, development of bridging bone or osteophytes
- Additional surgery due to any of the above factors (additional surgery includes revision, removal, reoperation or supplemental fixation at the treated level)
- Instability to complete the implantation of the device which may require the use of another treatment modality to complete the therapy
- Pain associated and/or attributed to the device

This is not a full list of risks. There may be other risks with treatment using the LimiFlex Dynamic Sagittal Tether. There is the possibility that this surgery may not be effective in relieving your symptoms. It is possible your symptoms could worsen.

If this happens, you may require additional surgery or treatment. You should discuss these risks and any concerns with your doctor before deciding to have surgery.

XII. The LimiFlex Dynamic Sagittal Tether U.S. FDA Clinical Study

The LimiFlex Dynamic Sagittal Tether was evaluated in a United States clinical trial. It was studied for the safe and effective treatment of degenerative spondylolisthesis with spinal stenosis of the lumbar spine. The clinical trial involved 140 patients who received the LimiFlex Dynamic Sagittal Tether. These patients were compared to 147 patients who underwent transforaminal lumber interbody fusion for the same indications for use. A brief summary of the benefits and adverse effects shown during the clinical trial is presented below. Please ask your doctor for more details about this clinical trial and results.

XIII. What are the Expected Outcomes and Benefits of the LimiFlex Dynamic Sagittal Tether?

The LimiFlex Dynamic Sagittal Tether surgery offers another option of treatment for patients for whom a surgeon would like to limit flexion motion of a lumbar spinal segment with a decompression without adding the potential risks, morbidity, and complications of a fusion. It may help stop the pain and other symptoms caused by degenerative spondylolisthesis and spinal stenosis.

Below are various outcomes and results from the LimiFlex Dynamic Sagittal Tether U.S. clinical study two years after surgery. Please ask your doctor for more details regarding this clinical trial and its associated clinical outcomes and results.

Two years after surgery 76.7% of 140 LimiFlex Dynamic Sagittal Tether patients achieved overall study success, compared to 64.6% of 123 TLIF (control) patients.

Other key results from the study at two years after surgery include:

- Through the 24-month study, a total of 10 patients (7.2%, 10/138) implanted with LimiFlex Dynamic Sagittal Tether experienced a secondary surgical intervention compared to 13 patients (10.9%, 13/119) in the TLIF (control) group.
- A total of 114 patients (91.2%, 114/125) in the LimiFlex Dynamic Sagittal Tether group experienced a meaningful improvement in Oswestry Disability Index (ODI) scores at 24 months compared to 71 (81.6%, 71/87) in the TLIF (control) group.
- A total of 2 patients (1.8%, 2/114) in the LimiFlex Dynamic Sagittal Tether group experienced a device integrity issue through the 24-month study compared to 5 patients (5.7%, 5/95) in the TLIF (control) group.
- Through the 24-month study, 115 patients (95.8%, 115/120) in the LimiFlex Dynamic Sagittal Tether group experienced neurologic success compared to 90 patients (94.7%, 90/95) in the TLIF (control) group.
- Patients in the LimiFlex Dynamic Sagittal Tether group experienced less average blood loss (52.2cc vs. 254.4cc) shorter procedure length (112.0 minutes vs. 190.3 minutes) and a shorter length of hospital stay (0.64 days vs. 2.95 days) compared to patients in the TLIF (control) group.
- Throughout the study, a significantly higher proportion of patients in the LimiFlex Dynamic Sagittal Tether group returned to work than the control group. For example, 90 days after surgery, 90.0% of LimiFlex Dynamic Sagittal Tether

patients and 43.8% of control subjects working preoperatively had returned to work.

- Throughout the study, more than 90% of LimiFlex Dynamic Sagittal Tether patients were satisfied with their surgery.

XIV. What are the Potential Adverse Effects of the LimiFlex Dynamic Sagittal Tether?

During the LimiFlex Dynamic Sagittal Tether FDA clinical study, patients in the study experienced health-related problems that could be related to surgical procedure, the patient's health, or the LimiFlex Dynamic Sagittal Tether. Some of these problems were discussed earlier in the Risk of Surgery section (Section XII). Listed below are adverse rates from the U.S. study for the LimiFlex Dynamic Sagittal Tether investigational and transforaminal lumbar interbody fusion (TLIF) control patient groups.

Adverse Event Category	Investigational Group (N=140)	TLIF Group (N=123)
New/increase back pain	24.3% (34/140)	22.0% (27/123)
New/increased leg pain	21.4% (30/140)	9.8% (12/123)
Other disorder of musculoskeletal system	21.4% (30/140)	14.6% (18/123)
Radiculopathy	19.3% (27/14)	18.7% (23/123)
New/increased musculoskeletal pain	18.6% (26/140)	26.0% (32/123)
Other	15.0% (21/140)	15.4% (19/123)
Numbness/tingling	11.4% (16/140)	13.0% (16/123)
Osteoarthritis, Hip	7.9% (11/140)	4.9% (6/123)
Fracture; specify site	7.1% (10/140)	1.6% (2/123)
Bursitis	5.7% (8/140)	4.1% (5/123)
Osteoarthritis, Knee	5.0% (7/140)	4.9% (6/123)
Worsening gait/ balance	5.0% (7/140)	3.3% (4/123)
Other nervous system disorder	5.0% (7/140)	8.9% (11/123)
Other disorder of digestive system	5.0% (7/140)	7.3% (9/123)
Sensory deficit	5.0% (7/140)	2.4% (3/123)

A complete list of risks is provided in the package insert for the device, which your doctor has received. **Please ask your doctor for more information about any additional risks that could be related to your planned surgery.**

XV. How do I Prepare for Surgery?

Please be sure to follow your doctor's guidance as you prepare for surgery. Here is a list of topics that may be covered prior to surgery:

- Review of your current condition and review of all possible treatment options.
- Evaluation of your overall health to ensure that it is safe for you to have surgery.
- Questions about the medicines you are currently taking. Your doctor will decide if you should stop taking any of them prior to surgery.
- Instructions on not drinking or eating anything the night before surgery.
- Confirmation that you have someone to assist you at home after surgery.
- Confirmation that you can easily access important items you will need on a regular basis.
- The benefits of reading and understanding this entire information guide.
- Any additional questions you have about the risks and benefits of this surgery.

XVI. What Happens during a LimiFlex Dynamic Sagittal Tether Surgery?

The surgeon will begin by creating a midline incision at the affected level to allow for decompression per standard technique. After decompression, your surgeon will verify the competence of your spinous processes and facets to ensure the device can safely be implanted. The device will then be implanted using specialized instrumentation per instruction and training provided to your surgeon.

XVII. What Happens After LimiFlex Dynamic Sagittal Tether Surgery?

Ask your doctor to describe how you will feel after surgery and what will help you to recover. The implantation of the LimiFlex Dynamic Sagittal Tether is a major surgery. It is important to closely follow your doctor's instructions to recover quickly and to increase your chances of a successful result.

As with any major surgery, you should expect some discomfort and to go through a period of recovery. Patients are usually released from the hospital within one day. Listed below are some topics your doctor or other healthcare professionals may discuss with you after the surgery:

- Instructions on surgical wound care to be followed after leaving the hospital.
- Avoid repeated bending, twisting, and lifting.
- Use of oral medications to address pain or nausea.
- Schedule follow-up office visits to monitor your progress.
- Guidance for gradually increasing limited activity at home.
- An exercise program under the direction of a physical therapist.

XVIII. When Should I Call the Doctor After Surgery?

Some pain and discomfort after surgery is normal. The symptoms you had before surgery may not go away immediately. Talk to your doctor about when to call regarding problems after surgery.

If you have any of these problems at any time after surgery, contact your doctor:

- You have a fever.
- The skin around the incision becomes red, swollen, or more painful.

- Excessive drainage or leaking from the incision.
- Trouble walking.
- Difficulty urinating, incontinence
- New or increased back and/or leg pain, weakness, or numbness.

XIX. Frequently Asked Questions

Will I have a large scar?
The average incision is about one to two inches long. When it heals, it is usually not noticeable.

What happens if the surgery is not effective?
If you experience new or increased low back or leg pain after surgery, it could be that the surgery was not effective. You may need additional surgery if your condition does not improve. Contact your doctor immediately if you experience low back or leg pain.

Will pain medication be necessary following surgery?
Pain medicine is not necessary but is recommended. Consult your doctor on whether it is suggested to use pain medication following surgery.

When can I shower after surgery?
You will have to keep your surgical wound dry after surgery. Discuss with your doctor about when and how long you can shower after surgery.

Can I receive an MRI after surgery?
Yes. MRI machines can vary. You should consult your doctor regarding testing conditions. The LimiFlex Dynamic Sagittal Tether is designated as an MRI Conditional device, where a patient with LimiFlex Dynamic Sagittal Tether may be safely scanned anywhere in the body under certain conditions. You will be provided a Medical Device ID card that includes MRI safety information that you may share with radiology providers.

What lifestyle changes will I need to make during recovery?
For a period of time after surgery, your doctor may recommend that you avoid certain activities. This can include driving. Talk to your doctor about activities that you may need to discontinue temporarily while you recover.

XX. For More Information, Talk to Your Doctor

This guide is intended to provide you with useful information that will help you make an informed decision about your treatment options. However, it is not intended to replace medical advice from your doctor.

Your doctor is the only person qualified to diagnose and treat your spinal condition. If you have specific questions regarding the LimiFlex Dynamic Sagittal Tether or its usefulness in your course of treatment, please contact your doctor.