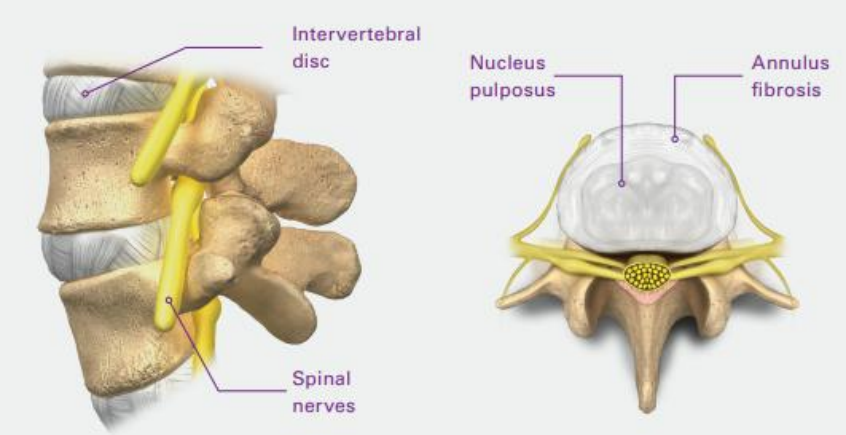
LeVerage Laminoplasty Fixation System (LFS) Patient Information Leaflet

Device Name: Non-sterile Laminar Decompression

Model: NuVasive LeVerage Laminoplasty Fixation System

Anatomy of Spine:
The human spine is made up of 24 bones or vertebrae in the cervical (neck) spine, thoracic (chest) spine and lumbar (lower back) spine plus the sacral bones.

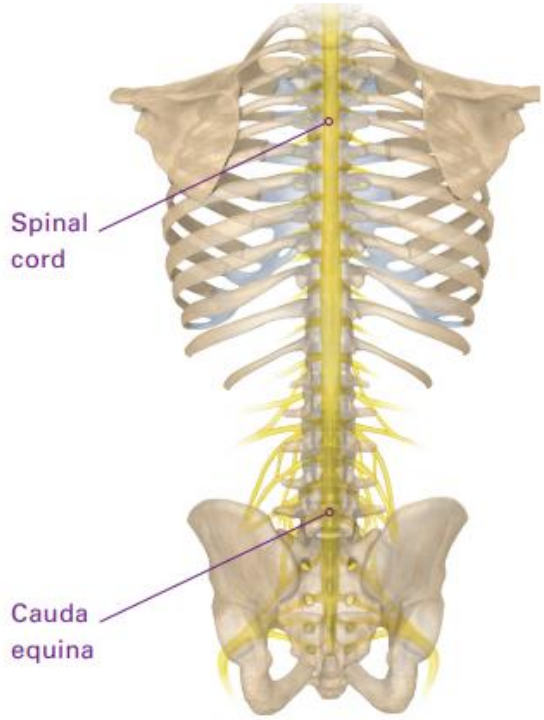
Vertebrae are connected by several joints, which allow you to bend, twist, and carry loads. The main joint between the two vertebrae is called an intervertebral disc. The disc is made of two parts, a tough and fibrous outer layer (annulus fibrosis) and a soft, gelatinous center (nucleus pulposus). These two parts work in conjunction to allow the spine to move, and also provide shock absorption.



Each vertebra has an opening (vertebral foramen) through which a tubular nervous structure travels. Beginning at the base of the brain to the upper lumbar spine, this structure is called the spinal cord.

Below the spinal cord, in the lumbar spine, the nerves that exit the spinal cord continue to travel through the vertebral foramen as a bundle known as the cauda equina.

At each level of the spine, spinal nerves exit the bony spine then extend throughout the body.



What causes pain?
There are several possible causes of spine problems. The most frequent symptoms are caused by either instability or by disc, bone, or ligaments putting pressure on (compressing) the nerve roots, spinal cord, or cauda equina.

What are treatment options?
Many symptoms can be treated without surgery including rest, heat, ice, medication, injections, and physical therapy.

If symptoms do not improve with conservative treatment, physicians may recommend spinal surgery. Surgery is reserved for those who do not gain relief from non-operative forms of treatment, patients whose symptoms are increasing or worsening, and/or patients that present with a spinal condition which indicates the need for surgery. It is important to speak with a physician about the best option.

The surgical option
Interbody decompression is a surgical technique that attempts to create negative pressure on the spinal disc thereby relieving stress on spinal nerves.

LeVerage LFS is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. LeVerage LFS is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

Leverage LFS implants are made from titanium alloy. This material was selected for its stability, corrosion resistance and strong mechanical properties. Long-term clinical experience of the use of this material has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

Warnings, Cautions and Precaution:
As with any surgical procedure, complications may occur following the implantation of this device. These can include but are not limited implant bending, breakage, failure, loosening, movement/migration, bone fracture, and allergic reaction to implant material.

Other general complications associated with any spinal surgical procedure include non-union or delayed union, vertebrae fracture, pain, neurological injury, vascular injury, infection, bursitis, dural leak, paralysis, and death.

Limiting postoperative activity should reduce the risk of bent, broken or loose implant components. To ensure the earliest possible detection of device dysfunction, the devices must be checked by a surgeon periodically postoperatively, using appropriate radiographic techniques.

Contraindications
LeVerage LFS is not to be used:

- For screw attachment or fixation to the posterior elements of the lumbar spine
- For single or two level spondylosis without developmental spinal canal stenosis
- Under any direct load bearing conditions

LeVerage LFS is not to be used when there is:

- Focal anterior compression
- Isolated Radiculopathy
- Loss of anterior column support resulting from tumor, trauma, or infection.

This list above does not include all possible contraindications, complications, warnings, or precautions. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.

MRI Safety Information:
A patient with this device can be scanned in an MR system with the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T)
- Maximum spatial gradient field less than or equal to 1,000 Gauss (G)/cm (10.0T/m).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode).

Consult your surgeon for further information related to magnetic field interference from magnetic resonance imaging devices.

Incident Reporting:
Any serious incident that occurs in relation to the device should be reported to the manufacturer and the Therapeutic Goods Administration.

Name and Address of Manufacturer:

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