LISA – Lumbar Implant for Stiffness Augmentation

DYNAMIC STABILIZATION OF THE LUMBAR SPINE

This booklet was made for informational purposes and is intended for patients only. You have recently had a spinal procedure with the LISA device. This booklet gives you the information you need. The implant card provided after the surgery should be kept as long as the LISA device remained in your body and shown during medical examinations.

BACKBONE designs, develops, manufactures and markets Implantable medical devices for spine surgery. Its vocation is to create innovative and effective surgeon-centered motion preservation solutions to treat the root cause of spinal pathologies, systematically considering the needs of all stakeholders (Patients, Surgeons, Hospital staff & Payors) for mini-invasive surgery.

Patient Leaflet - EN

BACK BONE

GLOSSARY

Terms	Definition
Allergic reaction	Hypersensitivity of the organism to substances, generally harmless and causing an inappropriate response of the organism.
Bony spurs	Bone spurs, or osteophytes, are bony growths that form in your joints or in the spine.
Bulging Disc	A disc bulge is an extension of disc tissues beyond vertebrae edges.
Decompression	Spinal decompression relieves pressure on spinal cord or nerve roots.
Degenerated disc	When one of the discs loses its strength.
Degenerative	Progressive conditions for which, over time, there is an increase in the impairments and disabilities of those affected.
Disc Degeneration with Osteophyte Formation	Osteophytes (bone spurs) development affecting more than one intervertebral disk.
Dynamic Stabilization System (DSS)	Unique surgical technique for immobilizing and stabilizing adult spinal segments using single-level fixation system from T4 to S1.
Fusion procedure	It is essentially a welding process. The basic idea is to fuse together two or more vertebrae so that they heal into a single, solid bone.
Herniated Disc	A herniated disc means that one of the discs between your vertebrae or spinal bones pushes out.
MRI	MRI stands for Magnetic Resonance Imaging, a medical imaging exam.
Nucleus pulposus	Soft central portion of the intervertebral disk that moves within the disk with changes in posture.
Pfirmann classification	Classification that enables to grade the discal degeneration stage, from 1 to 5 according to MRI results, « 1 » corresponding to a stage where the disc is intact, 5 corresponding to a stage where the disc is collapsed. (*Figure 1 - Pfirrmann CW, Metzdorf A, Zanetti M, Hodler J, Boos N. Magnetic resonance classification of lumbar intervertebral disc degeneration. Spine (Phila Pa 1976). 2001 Sep 1;26(17):1873-8. doi: 10.1097/00007632-200109010-00011. PMID: 11568697.*)
Prolapsed disc	When the outer fibres of the intervertebral disc are injured, and the soft material known as the nucleus pulposus, ruptures out of its enclosed space.
Spinal stenosis	Lumbar spinal stenosis is a global narrowing of the spinal canal.
Thinning Disc	The disc that separates the bones of the spine becomes thinner.

01 SPINAL ANATOMY AND ITS DISEASE

The Spine or Vertebral Column is formed by an assembly of vertebrae divided into five zones:

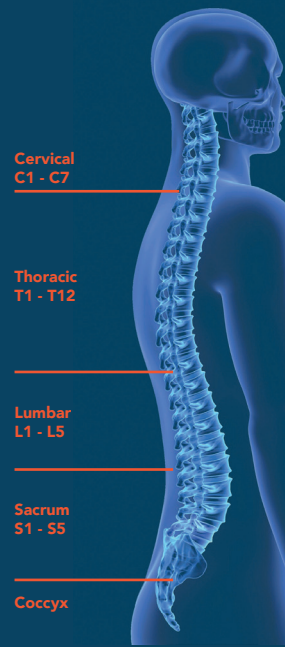
Cervical spine: 7 vertebrae

Thoracic spine: 12 vertebrae on which the ribs articulate

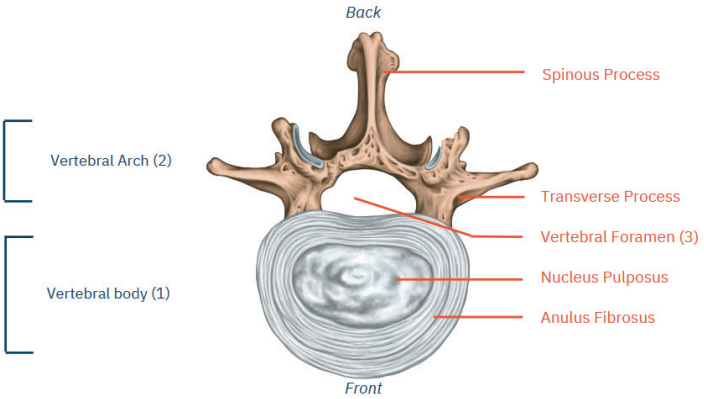
Lumbar spine: 5 vertebrae

Sacrum: 5 sacral vertebrae, welded together and connected to the pelvis

Coccyx: 3 to 5 coccygeal vertebrae (atrophied)



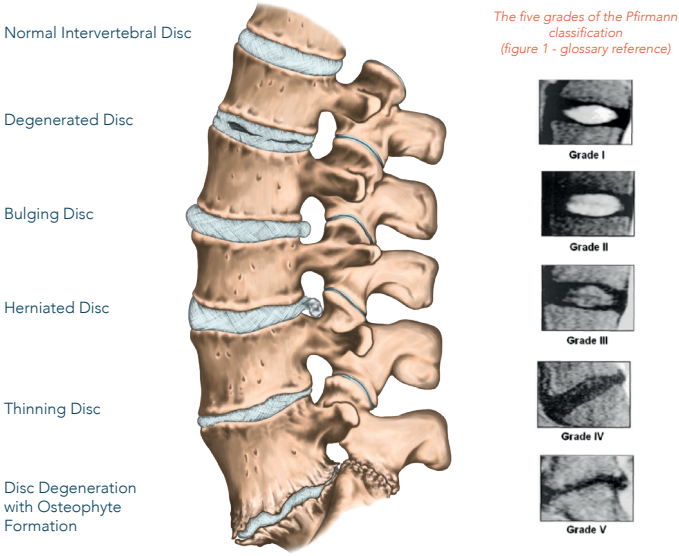
All vertebrae except the sacrum and coccyx are broadly similar in shape. Each vertebra is made up of a massive anterior part, the vertebral body (1), behind which is a bony arch (the vertebral arch (2)) which defines a circular orifice: the vertebral foramen (3).



Lumbar spine plays a predominant role in lower spine mobility. Between each vertebra is an intervertebral disc which resembles a small cushion and acts as a shock absorber during movements (walking, jumping, etc.).

... AND THE ORIGIN OF YOUR BACK PAIN

With aging, the disc can degenerate and we use the Pfirmann classification to grade the discal degeneration stage.



Among the **degenerative disc diseases**, the lumbar spinal stenosis is the most frequent.

KEY ELEMENTS ABOUT DEGENERATIVE DISC DISEASES AND LUMBAR SPINAL STENOSIS

The space enclosed by the vertebral arch is often considerably reduced resulting in pressure on the spinal nerves and emerging roots, leading to gradual lumbar stenosis, which can cause sudden pain due to inflammation or acute disc herniation.

The Lumbar Stenosis diagnosis is mainly defined by the following symptoms:

- **Low back pain**
- **Radicular pain and leg pain:** pain radiates to the buttocks and the legs forcing the patient to stand still.

If the herniated disc can sometimes resolve itself over time via physiotherapy or drug treatment, lumbar stenosis cannot be resolved without surgery. Surgery is rarely urgent but is often mandatory because permanent nerve damage can occur due to the constant pressure exerted by the narrowed spinal canal.

In such a case, the use of a LISA implant is particularly indicated.

02 SURGICAL SOLUTIONS - LISA (Lumbar Implant for Stiffness Augmentation)

The principals of spinal surgery include decompression of neural elements, stabilization of motion segments, and balancing the vertebral alignment.

Decompression

A decompression surgery removes pressure on irritated nerve fibers. The vertebral arch, bony spurs, thickened ligaments and joints, and herniated or prolapsed disc tissue can be removed in one or more spinal segments. It prevents recurrence of spinal canal stenosis and maintains flexibility.

Use of a Dynamic Stabilization System such as the LISA (Lumbar Implant for Stiffness Augmentation)

The use of the LISA implant after decompression surgery is intended to restore the functional dynamic stabilization (in flexion and extension) and the sagittal balance of the spinal column. The procedure is performed in a minimally invasive setting. It is an alternative to a fusion procedure that consists of welding the concerned vertebrae irreversibly.

The aim is to remove the pain caused by the lumbar stenosis and restore or replicate as close as possible the original spinal biomechanics through a less invasive surgical operation. The LISA Posterior Dynamic Stabilization System treats low-back pain that accompanies degenerative lesions of grades II, III, and IV (Pfirrmann MRI classification).

LISA
Dynamic Stabilization of the lumbar spine

SIZE AND MATERIAL

The LISA is composed of:

The spacer is made of PEEK (poly-ether-ether-ketone) polymer. It is in contact with spinous process, blood and soft tissue. The volume of substance-exposed to the patient is:

- o Spacer size 6: V = 3153,9 mm^3
- o Spacer size 8: V = 3715,38 mm^3
- o Spacer size 10: V = 4337,71 mm^3
- o Spacer size 12: V = 4917,97 mm^3

The blocker is made of Ti6Al4V titanium alloy (ISO 5832/3). It is in contact with blood and soft tissue. The volume of substance-exposed to the patient is V= 312.24 mm^3.

The band is made of Woven PET (polyethylene terephthalate). The device is a flat band (700 mm long and 7,2 mm wide). The surface of substance exposed to the patient during the surgery is S=10253 mm^2.

Materials that have been recognized in the orthopedic field for several decades and that comply with current international standards, known as «ISO» and/or American «ASTM» standards.

03 THE PROCEDURE

The procedure is performed under a local or general anesthesia.

The procedure involves determining the exact location of the origin of your low back pain, incising the skin, pushing back muscles, decompressing irritated nerve fibers, widening the spinal canal, and selecting the appropriate LISA implant. The spacer is inserted in the interspinous space, maintained with a polyester braid and blocker.

The LISA implant will stabilize the treated segment of the spinal column while preserving spinal mobility and anatomy.

04 REHABILITATION AND FOLLOW-UP

Although the wound site after surgery can be uncomfortable, the implant is immediately ready to bear weight and to stabilize the spinal column.

After the implantation of LISA, you should receive the implant card completed by healthcare professional with the identification labels of the LISA implants used.

- A rigid external lumbar support usually is not required. However, this decision is up to the surgeon, depending on each patient (bone quality, treated and related diseases, patient-level of activity and weight, etc…).
- Patient physical activity: intense physical activity increases the risk of mobility, deformation and rupture of the implants.
- A physical handicap will require special attention or adaptation to the post-operative rehabilitation method.

RECOMMANDATIONS

During the first week after surgery, you should generally avoid severe stress on the spine. The patient must avoid heavy lifting, twisting and/or leaning backwards.

The expected lifetime of the device is evaluated to be 5 years, depending on wear and tear, age and activity. The surgeon should set you the necessary post-operative visits. Please, follow-up with your surgeon about visits. Annual clinical and medical imaging monitoring are highly recommended.

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or if you are concerned about risks. To prevent infections, tell your doctors that you have a spinal implant.

05 WARNINGS AND PRECAUTIONS

A patient with LISA implant can undergo an MRI (Magnetic Resonance Imaging) scan under certain conditions. Contact your healthcare professional for the conditions for safe MRI procedures.

06 COMPLICATIONS

From literature review and adverse event database review, all clinical risks were identified and reduced as far as possible. The known undesirable side-effects of the implants of the LISA dynamic stabilization system are the following:

- All potential side effects of spinal surgery independent of the medical device are possible.
- With the use of LISA implants, the list of potential side effects includes, among others: neurological complications, paralysis, soft tissue injuries, pain, device migration, erosion, implant breakage, inflammatory phenomena or allergic reactions.

In the event of a serious incident related to the implant, contact the manufacturer.
Information contained in this leaflet are available on the website https://backbone.pro.

The Summary of safety and clinical performance is available in the European database on medical devices (Eudamed), using the corresponding Basic UDI-DI, at the URL:
https://ec.europa.eu/tools/eudamed:

- LISA Band: 376024863LISA101FT
- LISA Blocker: 376024863LISA104FZ
- LISA Spacer: 376024863LISA106G5

BACKBONE
81, Boulevard Pierre 1er
33110 LE BOUSCAT - France

contact@backbone.pro
www.backbone.pro

CE 2797

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