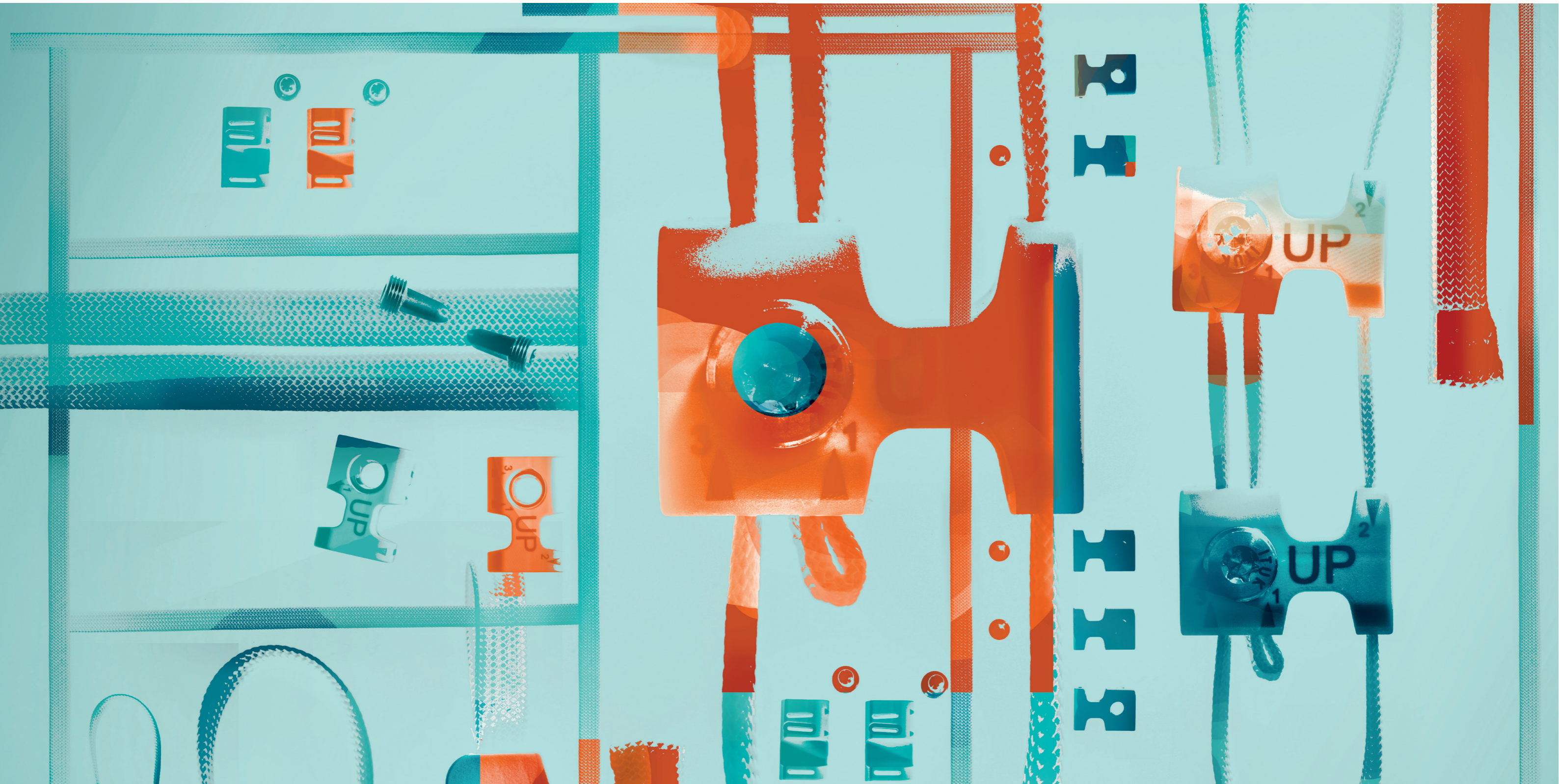


# LISA—

**Lumbar  
Implant for  
Stiffness  
Augmentation**

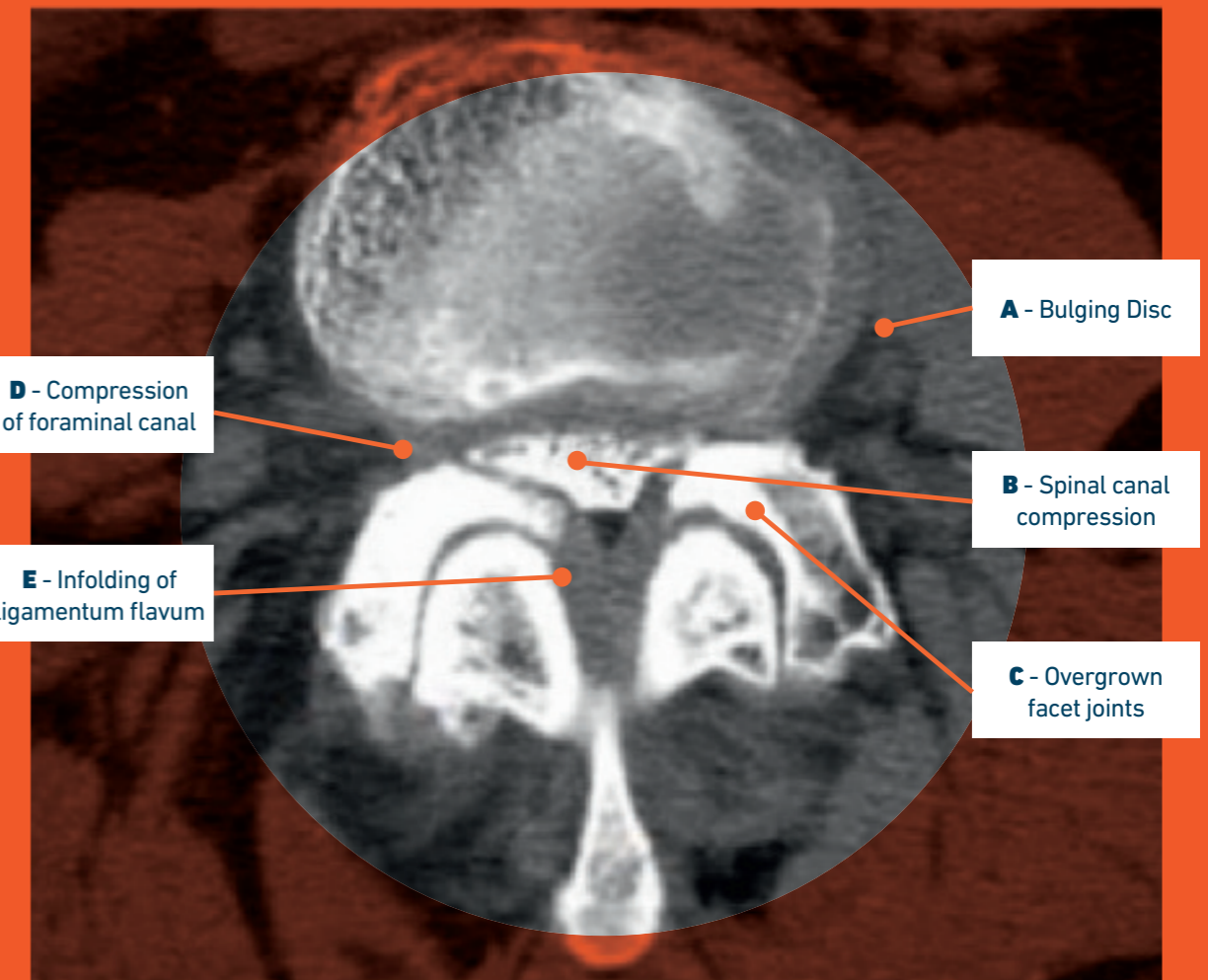


BACKBONE  
81, Boulevard Pierre 1<sup>er</sup>  
33110 LE BOUSCAT - France



# Indications

Lumbar Implant for Stiffness Augmentation, LISA aims to restore healthy functions for lumbar Stenosis patients, and chronic low back pain, unresponsive to non-surgical treatments, by providing an adequate and reversible solution to treat the root cause of the pathology.

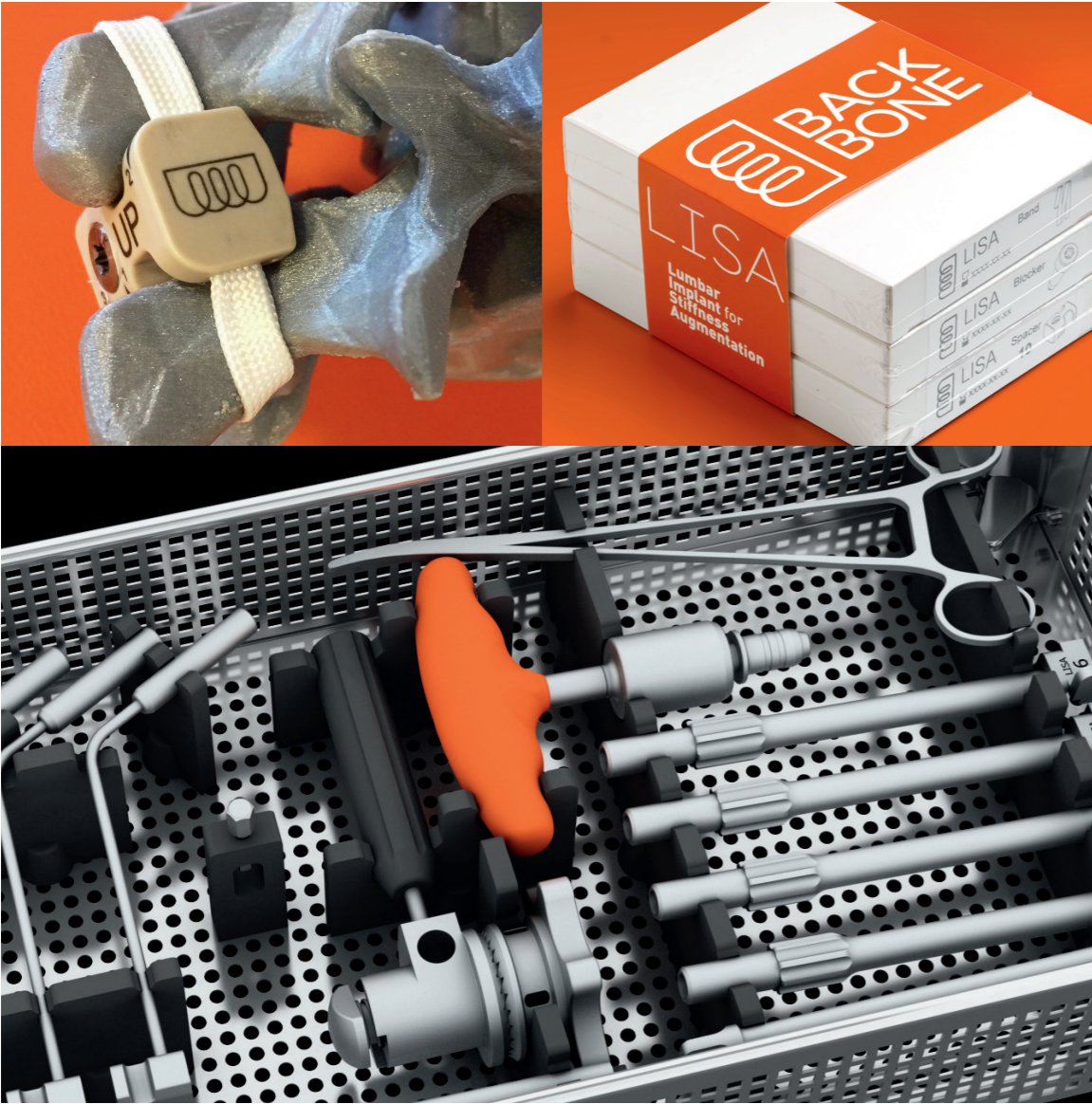


1.Vijay M. Ravindra, MD, MSPH, Steven S. Senglaub, MS, Abbas Rattani, MBe, Michael C. Dewan, MD, MSCI, Roger Härtl, MD, Erica Bisson, MD, MPH, Kee B. Park, MD, and Mark G. Shrime, MD, MPH, PhD, Degenerative Lumbar Spine Disease: Estimating Global Incidence and Worldwide Volume, Global Spine Journal 8(117):219256821877076 · April 2018

Degenerative disease of the lumbar spine is a significant cause of disability in the world; it encompasses conditions such as spondylolisthesis, disc degeneration, and lumbar spinal stenosis. **403** million (5.5%) individuals worldwide with symptomatic disc degeneration, and **103** million (1.41%) individuals worldwide with spinal stenosis annually.<sup>1</sup>

# LISA : Lumbar Implant for Stiffness Augmentation

Surgeon centric and performant device and instrument set.



Top Loading  
Top Tensioning  
Top Tightening

## PET Band

Raw material: **Braided Polytéréphthalate d'éthylène (PET)** - Single Use

- Used in orthopaedic surgery since 1920s
- One unique reference
- Tensile Strength = 170 daN
- Lenght = 700mm - Width = 7mm - Thickness = 1,2m
- Sterile packaging Gamma irradiated

## PEEK Spacer

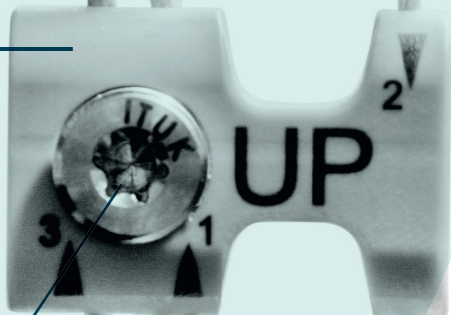
Raw material: **PolyEtherEtherKetone (PEEK Optima LT1 supplied by InVibio)** - Single Use

- Youngs modulus 3675 MPa (close to bone)
- Tensile strength 92 MPa
- Bending strength 170 MPa
- Impact strength 90 J/cm
- Sterile packaging Gamma irradiated.
- Four sizes: 6mm, 8mm, 10mm & 12mm.

## Titanium Blocker

Raw material: **Titanium alloy (TA6V4 ISO 5832/3)** - Single Use

- Widely used for the spinal implants since the 80's
- One unique reference
- Overall dimensions
- A torx imprint



# LISA Benefits

**LISA** is a novel motion preservation surgical device designed to treat painful lumbar spinal stenosis and chronic low back pain.

**LISA** is CE marked

**LISA** is minimally invasive:

- Smaller incisions
- No or little muscle cutting
- Smooth, easy & fast surgery
- Less blood loss
- Reduced infection risk
- Reduced postoperative pain risk
- Less narcotics
- Less rehabilitation
- Faster recovery

**LISA** restores the natural flexion & extension movements at the operated level & preserves adjacent level kinematics without fusion or access to the pedicle.

**LISA** maintains foraminal height

**LISA** is complementary to the anatomy and does not require any bony purchase

**LISA** has a very light foot print in the body

**LISA** off loads the disc and the facet joints

**LISA** protects adjacent segments from extraordinary stress & degeneration.

**LISA** is fully & easily reversible

## Benefits vs. Decompression

Decompression is appropriate for many patients. However, the removal of the bony and stabilizing elements along with hyper mobility caused by the decompression may cause the spine to become unstable. In the largest population study of more than 200,000 patients, Castillo et al<sup>2</sup> found that patients who had previously undergone a lumbar discectomy were roughly three times more likely to undergo a lumbar fusion procedure than a patient with a lumbar diagnosis, but had not undergone a lumbar discectomy.

## Benefits vs. Fusion

Fusion is appropriate for many patients. However, motion is irreversibly lost at the treated segment, and has degenerating consequences for the adjacent levels. Saavedra-Pozo et al<sup>3</sup> advanced that fusion plus the presence of abnormal end-fusion alignment (usually kyphosis) appears to be a major factor in creating end-fusion stresses that result in ASDeg and ASDis.

In a historical cohort study of long-term outcomes of Lumbar fusion among workers' compensation subjects Nguyen et al<sup>4</sup> concludes that Lumbar fusion for the diagnoses of disc degeneration, disc herniation, and/or radiculopathy in a Workers' Compensation setting is associated with significant increase in disability, opiate use, prolonged work loss, and poor Return To Work status.

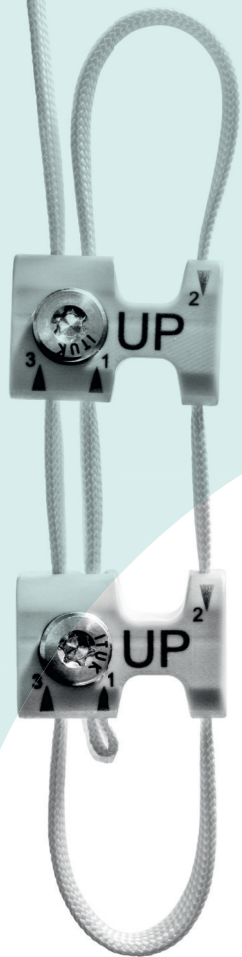


**Adjacent  
Segments  
Relentness  
Degeneration**

2. Shi L. L., MD, Michael J. Lee, MD Lumbar discectomy is associated with higher rates of lumbar fusion. The Spine Journal March 2019 Volume 19, Issue 3, Pages 487-492

3. Saavedra-Pozo F M, MD,1 Deusdara Renato A. M., MD,2 and Benzel E. C., MD3 Adjacent Segment Disease Perspective and Review of the Literature. Ochsner J. 2014 Spring; 14(1): 78-83.

4. Nguyen, Trang H., MD, PhD\*; Randolph, David C., MD, MPH\*; Talmage, James, MD†; Succop, Paul, PhD\*; Travis, Russell, MD†. Long-term Outcomes of Lumbar Fusion Among Workers' Compensation Subjects: A Historical Cohort Study. Spine: February 15, 2011 - Volume 36 - Issue 4 - p 320-331



By restoring normal stiffness in the damaged segment, **LISA** can halt and even reverse the degenerative process through cells machinery reinitialization.

A comprehensive, systematic, and critical evaluation of the pertinent clinical data in relation to the LISA has been carried out and documented. Clinical evidence regarding the safety and performance of the LISA are considered to be validated.

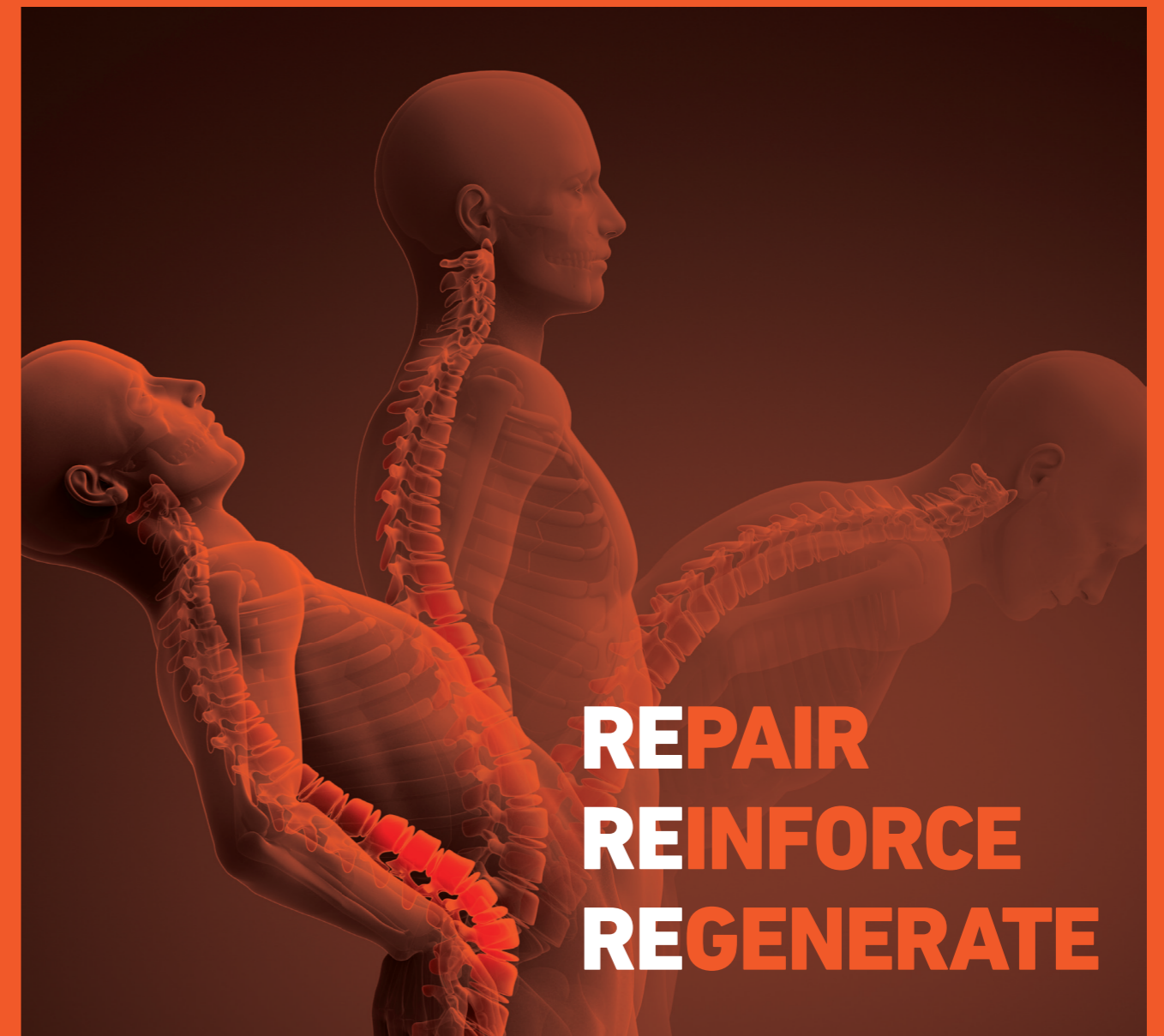
**LISA :**

- **stabilizes** the motion segments by preserving natural mobility,
- **restores** spinal sagittal balance through preservation of lumbar lordosis & **allows** the liberation the neural structures.

**LISA** resolves the undertreatment / overtreatment dilemma for Stenosis patients by granting an adequate choice to :

- **Decompression** alone which may further destabilize the segment
- & **Irreversible** fusion procedure, when the lumbar disc is not entirely collapsed.

# LISA



# Greater Clinical Value

Economic Advantage  
for all stakeholders

Patient + Surgeon + Hospital + Payor

Leg and back pain relief (immediate & long-term)



Less time in the operating room (7" - 15" Vs 45" - 90" for Fusion)



Less blood loss (40cc - 100cc Vs 500cc - 1500cc for Fusion)



Limits paraspinal muscle atrophy



Shorter hospital stay (Ambulatory Vs 3 - 5 days for Fusion)



Faster relief of symptoms & quicker recovery (pain & function)



RoM maintained at both treated & adjacent segments  
Adjacent segment protection

