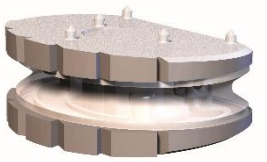
# Patient information leaflet

Lumbar disc prosthesis / Cementless LP-ESP®



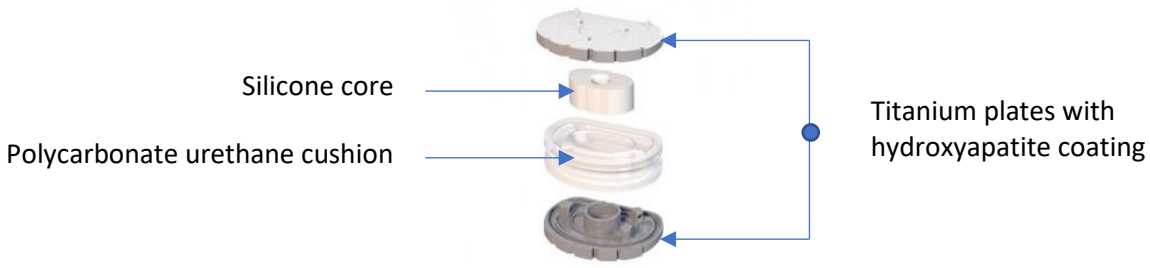
**Leaflet content**

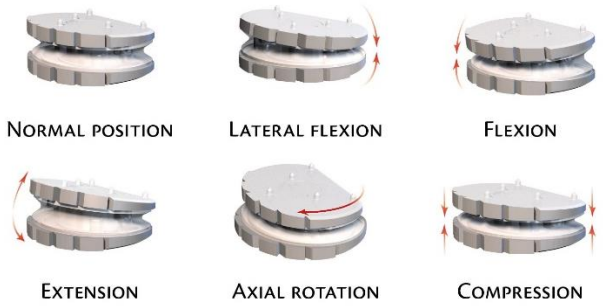
This leaflet answers some common questions about the lumbar disc prosthesis LP-ESP ® (hereinafter referred to as LP-ESP ®). This leaflet does not contain all the available information about this product. It does not take the place of talking to your surgeon. All medical devices and implants have risks and benefits. Your surgeon has weighed the risks of using this product against the benefits that are expected. Follow your surgeon's advice even if it differs from what is in this leaflet.
***Please read this leaflet carefully and keep it in a safe place, so you may refer to it in the future if needed.***

**Device description**

LP-ESP® is a lumbar disc prosthesis; it is composed of two metal plates (titanium) between which is moulded a thermoplastic elastomer cushion (polycarbonate urethane - PCU). In the centre of the PCU cushion there is a core made of silicone. The titanium plates are coated with hydroxyapatite. The design of the prosthesis reproduces the structure and movements of natural intervertebral disc.
LP-ESP® is designed to replace a pathological intervertebral disc within the lumbar spine. It is intended to treat the disc spaces between the L2 and S1 vertebral bodies. LP-ESP® is offered with different sizes to fit with your anatomy.

For more details on the materials, please refer to the paragraph "Composition of the implant".

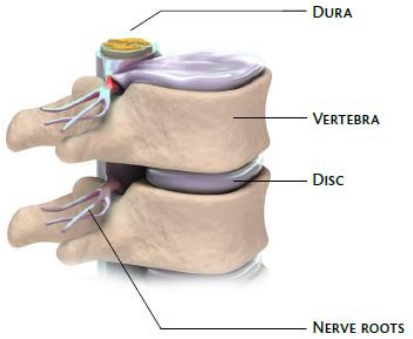


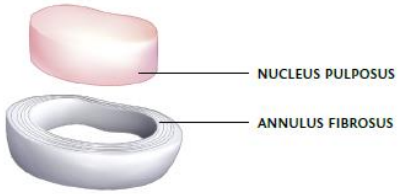
**Lumbar spine anatomy**

It is formed of 5 lumbar vertebrae often named L1 to L5; piled on top of each other and bounded by discs allowing movements. The L5 vertebra is also articulated with the sacrum S1.
The spine allows:
- to bent back and forth: flexion/extension
- to bent right and left: lateral bending
- to turn: rotation / translation
- to absorb shocks

The spine supports all the body weight and play a protection role of the dura and nerve roots.

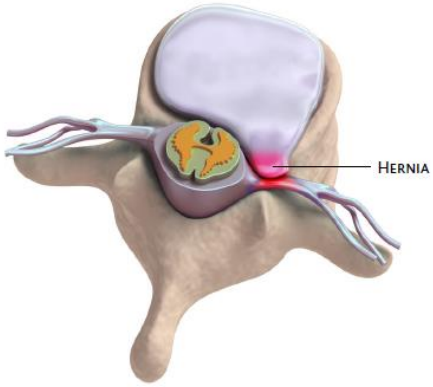



Discs located between the vertebrae are made of an elastic nucleus composed of 80% of fluid (Nucleus pulposus) and of an annulus composed of collagen fibres (Annulus). They are involved in the movements of the spine and play a role in pressure and shock absorption.




**Disc degeneration**

Disc degeneration is a natural phenomenon that occurs with aging. It can be accelerated by different factors such as genetics or lifestyle (smoking, bad posture, etc.). When the wear happens too fast it can cause a rupture of the fibrous annulus. The disc height is then decreased, and a part of the nucleus content can go out; this is called a disc hernia. The hernia can push on dura and on nerve roots. This pressure on the nerves causes the pain and can sometimes lead to sensory disturbances or functional deficits.
If medication and/or other conservative treatments fail to relieve the symptoms, surgery may be indicated.




The surgery of lumbar discopathy can be realized through an anterior approach to preserve dorsal muscles and to avoid mobilization of the dura.
• The reference procedure consists in removing the herniated disc to relieve pressure on nerves and so the pain.
• Disc space is then filled with an implant. Depending on the pathology your surgeon will choose to implant either prosthesis or a cage.

**Performance**

LP-ESP® must enable pain reduction, re-establish the lumbar curvature, and reproduce the functions of the disc. This medical device is used for primary treatment.

**Indications for use**

LP-ESP® is designed to address specific indications such as:
• lower back pain caused by lumbar disc disease that is resistant to medical treatment
• lower back pain caused by disc disease after treating a herniated disc
• lumbar radiculopathy caused by a herniated disc recurrence (apart from sequestered disc)

**Contraindications**

1. Spinal stenosis, radiculopathy,
2. Significant segmental instability,
3. Spinal deformation, spondylolisthesis greater than 25%,
4. X-ray confirmation of severe lesions or degeneration of the facet joints,
5. Osteoporosis, osteochondrosis, and severe osteopenia,
6. Chronic or severe, local, spinal, or systemic infections,
7. Metabolic and systemic diseases,
8. Pathologies and surgical situations that preclude any benefit or spinal surgery,
9. Sensitivity to the implant's materials,
10. Dependency with regards to medications: drug addiction or alcoholism,
11. Pregnancy,
12. Obesity,
13. Lack of cooperation from the patient.

**Conditions of use**

LP-ESP® must be implanted in an operating facility, under aseptic conditions, and in compliance with hygienic practice, by an orthopaedic surgeon who regularly practices this type of implantation. The implantation must be performed with suitable non-damaged instrumentation by applying the recommendations in the surgical technique and instructions for use, to treat a patient with the indications defined above, either as a primary or revision arthroplasty procedure.

**Warnings**

This leaflet reminds important recommendations after a total disc arthroplasty (implantation of a disc prosthesis). To recover safely, it is important not to rush the resumption of movements and to respect authorized activities after the surgery.
These recommendations are provided as a guideline, the times indicated may vary depending on the patient and the specific indications. Your surgeon will indicate the protocol adapted to your case. Please respect his instructions in priority.

**Residual risks and adverse events**

Any surgical procedure involves risks. Access to the lumbar spine through an anterior approach requires the mobilization of blood vessels and internal organs. Your surgeon is the best person to answer all your questions.
Possible complications that may occur individually or in combination include:

- Trauma during surgery, such as nerve or spinal cord injury, excessive bleeding and/or fractures of the vertebral body (bones of the spine)
- Pain
- Accumulation of blood under the skin (hematoma)
- Fluid accumulation or hernia formation in the operated area
- Infection of your wound at the surgical site and/or systemic infection
- Implant breakage or displacement
- Destruction of bone tissue that may occur around the implant
- Loss of motion (involuntary fusion) at the treated site
- Development or progression of disease at other levels of your spine
- Sexual disorders
- Circulatory disorders
- Urinary leakage
- Neurological disorders
- Nerve or spinal cord injury which can lead to impairment
- Blood clots and restricted blood flow that can lead to pulmonary embolism
- Cardiovascular problems that can lead to heart attack or stroke
- Allergic reaction to implant materials
- Side effects that may require a new operation and in some cases removal
- Surgical error

**Precautions**

The lifespan of implants is affected by numerous biological, biomechanical, and other factors. As a result, carefully following the indications, contraindications, precautions, and warnings for this product plays an essential role in its use.
The outcome of intervertebral disc prosthesis depends on the patient's medical history. It is indispensable that you are psychologically prepared.

You must be informed of the limitations of the device, including among others, the impact of overbunding caused by weight or excessive activities. You must be advised as how to modify your activities accordingly. In any case, the prosthesis will completely restore functions formerly performed by a normal, healthy joint. You should consult your surgeon in the event of abnormal problems experienced at the device location.

**MR compatibility**


If an MRI examination needs to be performed, the radiologist must be informed of the presence of a LP-ESP®. Information to be provided:
Non-clinical testing has shown that the ESP discs are "MR conditional" as defined by the standard ASTM F2503-20. A patient with a device of this range can be safely scanned in an MRI system meeting the following conditions:

- Patient implanted with one ESP disc only,
- Patients with uncompromised thermoregulation (all persons without impaired systemic or reduced local thermoregulation),
- Patients under controlled conditions (a medical doctor or a dedicated person can respond instantly to heat induced).
- Horizontal bore MRI system with a static magnetic field of 1.5 Tesla or 3 Tesla.
- Gradient magnetic fields lower or equal to 19T/m.
- B 0 *|dB 0 /dr|s product lower or equal to 48T2/m.
- RF whole body transmit/receive coil use only.
- Whole body averaged SAR (Specific Absorption Rate) limited to First Level Controlled operating mode (WB-SAR ≤4W/kg).
- During non-clinical testing, the ESP disc produced a maximal temperature rise of 5.0•}1.0°C at 1.5T for a measured WB-SAR of 3.50±0.81W/kg and a maximal temperature rise of 3.5±1.0°C at 3T for a measured WB-SAR of 3.94 ± 0.88 W/kg both after 15 minutes of continuous scanning.
- The ESP disc is expected to produce a maximum in-vivo temperature rise of 5.7±1.8°C at 1.5T and of 3.6±1.3°C at 3T for a WB-SAR of 4W/kg.
- MR image quality may be compromised if the imaging area of interest is in the same area of
- the implant.
- Some manipulation of scan parameters may be required to compensate for the artifact.

**Postoperative monitoring**

Your surgeon must monitor your postoperative care and will call you for regular consultations until he is sure that everything is going as planned, then an annual monitoring will be offered. Recovery time may vary depending on the patient and the specific indications.
Today we are accumulating 5 years of clinical data and we continue to accumulate data to continue to improve our knowledge of the safety and performance of the LP-ESP® lumbar disc prosthesis.

**Safe use of the implant**

General information

- An adaptable lumbar brace may be recommended as soon as standing up.
- Your individual pain threshold determines the speed of your mobilization. Please mind your body.

- Walking: as soon as possible after surgery.

Not allowed for the first 3 months
- Forced impulsive manipulation of your spine.
- No crunches
- No sit-ups
- No sitting on the floor
- No squat position

Sitting
- 1 week after surgery: not sitting.
- 6 weeks after surgery: sitting upright (back and legs perpendicular).
- Only sit if problems do not arise. Start by sitting for only a short time (for 15 minutes 3-4 times daily). You should take frequent breaks in sitting, even later, and change position several times daily).

Medication
- Pain medication as prescribed by your surgeon.

Movement
- For 6 weeks holding the back unnaturally stiff when standing.
- From the 6th week after surgery the spine can be gradually moved when standing.
- Stiffness is detrimental to the eventual resilience of your spine.

Washing
- Shower: the day after having the stitches removed.
- Use a waterproof plaster for stitches for showering.
- Bathing: from 6th week after surgery.

Lifting
- 6-8 weeks after surgery: weights up to 2kg.
- 4-6 months after surgery: weights up to 5kg.
- Remember to always keep your lumbar spine extended when lifting, to tense your abdominal muscles and breathe out.

Driving
- As passenger from 14 days after surgery.
- As driver after authorization by your surgeon.
- At the beginning, have frequent stops for exercise breaks.
- Use lumbar support (cushions, lumbar bulge).

Physiotherapy (only after an authorization of your surgeon)
- For the first 6 months after surgery:
  - developing the core muscles with tension exercises (isometric).
  - relaxation (massage, heat treatment).
- From 6 months after surgery:
  - increasing mobilisation of the spine
  - do stretching exercises: the hamstrings, quadriceps and trapezius muscles (i.e. the muscle of the thighs) tend to be shortened. This would bring your spine in suboptimal position.

Mattress
- It is not necessary to have a special mattress.

Return to work
- Different for each activity, your surgeon will give you advices.

Workplace
- Ergonomic transformation may be needed:
  - making it possible to sit upright (back and thigh perpendicular)
  - raising the table if necessary standing desk.
- Take frequent exercise breaks for example occasional standing exercises.

Sexuality
- Disc replacement or disc fusion require taking precautions during sexual relations: ask your surgeon.
- Avoid every forced or painful movement

Outpatient aftercare
- Regular wound checks.
- Reduction/phasing out of pain medication.
- Removal of stitches from the 10th day after surgery.

Toilets
- Wear your brace or hold both hands on your belly while sitting on the toilets.

Sports
- Cycling: after 3 months with high handlebars.
- Swimming: 6 months after surgery (all styles except butterfly).
- Jogging: after 6 months.
- Strength training: after 6 months, initially with qualified supervision. Mixed strength/endurance training (small weights, high
- number of repetitions).
- Squash, skiing, tennis, golf: after 6 months (if problem-free, after good preparation, after consultation with a doctor).

**Device materials**

LP-ESP® lumbar disc prosthesis is made of polycarbonate-urethane (PCU) cushion called BIONATE 80A. BIONATE 80A belongs to a family of highly biocompatible medical grade polymers with approved physical and mechanical properties. At the heart of this cushion is a silicone core with the aim of reconstructing the anatomy of the natural disc. This cushion is molded between two Ti6AL4V titanium plates, this material is standardized and commonly used in the field of orthopaedic implants.
The titanium plates receive a layer of titanium (T40) and a layer of bone substitute called hydroxyapatite (HA) to increase the roughness of the plates and to promote bone reconstruction, allowing the plates to be bonded to the vertebrae.

Quantitative composition of implanted materials in mass percentage:

| Part numbers | Titanium | PCU | Silicone | T40 | HA |
|---|---|---|---|---|---|
| **255682** | **63%<m<65%** | **25%<m<27%** | **7%<m<8%** | **1%** | **1%** |
| **255683** | | | | | |
| **255687** | | | | | |
| **255688** | | | | | |
| **255690** | | | | | |
| **255691** | | | | | |

**Expected Device Lifetime**
5 years (shelf-life of sterile packaging), no limitations of lifetime in implanted state.

**Reporting adverse effects**

Any serious incident that occurs in relation to the device LP-ESP® should be reported. Please talk to your surgeon and report the incident to the manufacturer or main distributor. Reporting should also be made directly to the Therapeutic Goods Administration via their website: http://www.tga.gov.au/reporting-problems

| **Manufacturer** | **Distributor** |
|---|---|
| FH Industrie<br>6 rue Nobel<br>Z.I. de Kernevez<br>29000 QUIMPER<br>**www.fhortho.com** | Spine Innovations<br>3 rue de la Foret 68990<br>HEIMSBRUNN<br>**www.spine-innovations.com** |