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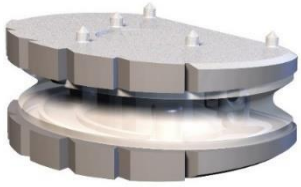
LP-ESP® LUMBAR DISC PROSTHESIS / CEMENTLESS
PATIENT INFORMATION

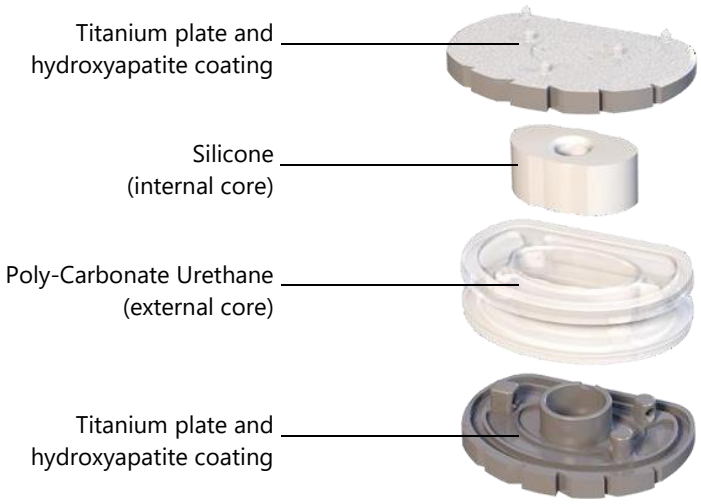
Description

The LP-ESP® lumbar disc prosthesis is an implant composed of two metal (titanium) plates, with a moulded central polymer plastic (polycarbonate urethane) cushion between them. There is a silicone core in the centre of the cushion. The prosthesis is designed to imitate the structure of the natural intervertebral disc.

The LP-ESP® lumbar disc prosthesis is intended to replace a pathological intervertebral disc in the lumbar spine. It is intended to treat the disc spaces between the vertebral bodies L3 to S1.

For more information on the materials, please refer to the section “Implant composition”.





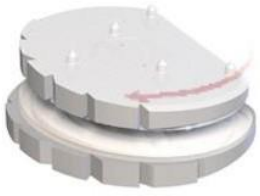
The LP-ESP® lumbar disc prosthesis enables reproduction of the movements of a natural disc (compression, flexion / extension, lateral flexion, rotation, and translation).

Neutral position

Lateral flexion

Flexion

Extension



Axial rotation

Compression

Expected performance and benefits of the device

The LP-ESP® lumbar disc prosthesis is designed to reduce pain, re-establish lumbar curvature, and reproduce the functions of the disc.

The summary of safety and clinical performance (SSCP) for the prosthesis can be found in the European database of medical devices (Eudamed): https://ec.europa.eu/tools/eudamed

This summary can be found on the Eudamed website by entering the UDI-DI for the LP-ESP® disc prosthesis: **376036923LP01BZ**.

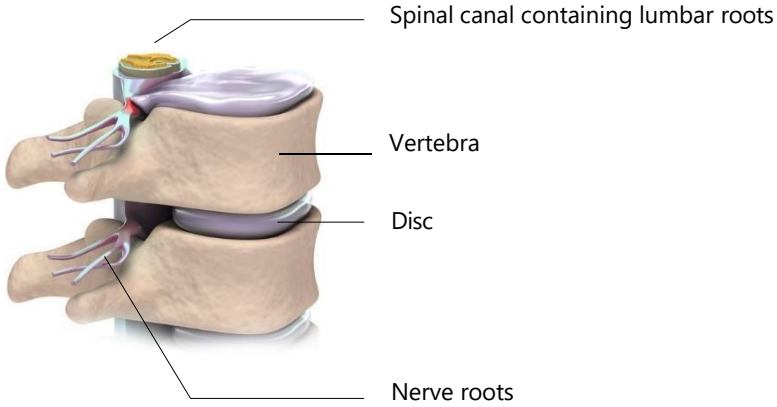
Anatomy of the lumbar spine

The lumbar spine is made up of 5 lumbar vertebrae, often called 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.

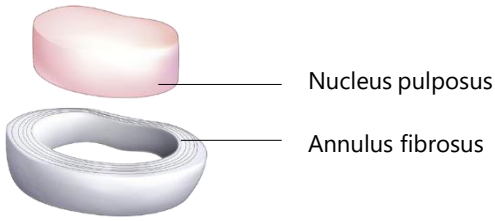
The spine allows:

- To bent back and forth: flexion/extension
- To bent right and left: lateral flexion
- To turning: rotation / translation
- To absorb shocks: compression

The spine bears the weight of the body and protects the spinal canal and the nerve roots.



Discs located in between the vertebrae are made up of an elastic nucleus, comprising 80% fluid (Nucleus pulposus) and of an annulus mostly made of collagen fibres (Annulus fibrosus). They contribute to the movement of the spine and act as shock-absorbers for pressure and impact.

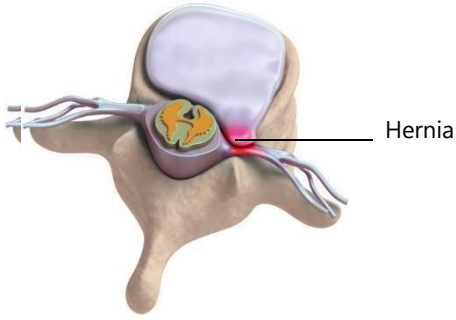


What is disc degeneration?

Disc degeneration occurs naturally with ageing. The phenomenon can be accelerated by various factors, such as genetics and certain lifestyle habits (smoking, bad posture, etc.). If wear occurs too quickly, it can result in rupture of the annulus fibrosus. Disc height is thus reduced, and some of the nucleus content may escape this is known as disc herniation.

A herniated disc can press against the spinal canal and nerve roots. This pressure on the nerves can

cause pain and, in some cases, result in sensory or muscular disorders.
If pharmaceutical treatments and/or other conservative treatments (non-surgical) fail to relieve the symptoms, surgery may be indicated.



Lumbar discopathy surgery (disc disease) can be performed through an anterior approach to preserve dorsal muscles and avoid the need to spread the spinal canal.
- The standard procedure is to remove all or part of the affected disc to relieve pressure on the nerves and thus the pain.
- The disc space can then be filled with an implant.
In the case of total disc replacement with a prosthesis, the entire affected disc is removed.

Patients for whom the LP-ESP® lumbar disc prosthesis is intended
The LP-ESP® disc prosthesis is designed for surgical treatment of degenerative disc disease (DDD) of the lumbar spine in skeletally mature patients under 65 years old who have not responded after at least 6 months of conservative treatment.

Contra-indications
- Fractures
- Tumours
- Spinal stenosis, radiculopathy
- Significant segmental instability
- Spinal deformation, spondylolisthesis greater than 25%
- X-ray confirmation of severe lesions or degeneration of the facet joints
- Osteoporosis, osteochondrosis, and severe osteopenia
- Chronic or acute local, spinal, or systemic infections
- Metabolic and systemic diseases
- Sensitivity to the implant's materials
- Medication dependency, drug addiction or alcoholism
- Pregnancy
- Obesity
- Lack of cooperation from the patient
- Pathologies and surgical situations that preclude any benefit of spinal surgery, such as arteritis of the lower limbs, genitourinary disorders of neurological origin, damage to more than 2 lumbar discs.

Warning
This document recalls the important recommendations after a total disc arthroplasty (prosthesis implantation).
After the intervention, it is important not to rush back into all movements and to respect the everyday activities that are permitted to ensure totally safe recovery.
The recommendations contained herein are provided for information only. The time periods given may vary depending on the patient and the specific indication. The surgeon will indicate the protocol specific to your situation. Priority is to be given to respect of the surgeon's instructions.

Any serious incident occurring in relation to the device must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is located.
Australian residents should report to the Therapeutic Goods Administration (Australian authority) website: https://www.tga.gov.au

Residual risks and adverse effects
All surgical interventions imply risks, in the case of lumbar disc replacement they are mostly related to the approach. Access to the lumbar spine requires the mobilisation of blood vessels and internal organs. Your surgeon is the best person to answer your questions.
Possible complications that may occur individually or in combination include the following:

- Trauma during the surgical intervention, such as nerve or spinal cord damage, excessive bleeding and/or fractures of vertebral bodies (spinal column bones)
- Pain
- Accumulation of blood under the skin (haematoma)
- Accumulation of liquid or formation of a hernia in the operation area
- Infection of the surgical wound and/or systemic infection
- Implant that breaks or moves
- Destruction of bone tissue possibly occurring around the implant
- Loss of movement (involuntary fusion) in the affected area
- Development or progression of the illness to other areas of the spinal column
- Sexual disorders
- Circulatory disorders
- Neurological disorders
- Lesion of the nerves or spinal cord, possibly resulting in deficiency
- Blood clots and restriction of blood flow, possibly resulting in a pulmonary embolism
- Cardiovascular problems, possibly resulting in heart attack or stroke
- Allergic reaction to the implanted materials
- Adverse effects that may require a second operation and, in some cases, explantation of the implant
- Surgical error

Precautions
The lifespan of implants is affected by numerous biological and biomechanical factors. Respect of the advice herein will help preserve the lifespan of your implant. 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. You have been informed of the limitations of the device, including, among others, the impact of overburdening caused by weight or excessive activities. You should be advised how to modify your activities accordingly. Joint replacement can never reproduce the exact functions formerly performed by a normal, healthy joint. You should consult your surgeon if you experience any problems in the area of the device

MRI exams

If you are to undergo an MRI exam, you must inform the radiologist that you have an LP-ESP® implant. This is the information you must provide:

Non-clinical tests have demonstrated that the ESP range of discs is "MR conditional" in accordance with the definitions of the ASTM F2503-20 standard. A patient with a device in this range can be scanned safely in an MRI system when the following conditions are met:

- Patient with a single ESP® disc prosthesis implanted

- Patients has no thermoregulation disorder (i.e. no alteration of systemic thermoregulation or decreased local thermoregulation) and
- Patients are under controlled conditions (a doctor and a dedicated trained person who can respond immediately to the physiological stress triggered by heat).
- MRI system with a horizontal tunnel and static magnetic field of 1.5 Tesla or 3 Tesla.
- Spatial gradient of magnetic field below or equal to 19T/m.
- System with B0 * |dB 0 / dr| below or equal to $48T^2/m$.
- Only the whole-body transmission/receipt RF coil is used.
- First level controlled operating mode is used i.e. the specific absorption rate averaged over the whole body (WB-SAR) does not exceed 4 W/kg.
- During non-clinical tests, after 15 minutes of continuous acquisition, the ESP disc produced a maximum temperature increase of 5.0 ± 1.0 ° C at 1.5 T with a WB-SAR measured at 3.50 ± 0.81 W/kg and a maximum temperature increase of 3.5 ± 1.0 ° C at 3T with a WB-SAR measured at 3.94 ± 0.88 W/kg.
- With a WB-SAR of 4W/kg, the ESP disc should produce a maximum temperature increase of 5.7 ± 1.8°C at 1.5T and 3.6 ± 1.3°C at 3T.

MRI image quality may be compromised if the area of interest is in the same region as the implant. It may be necessary to manipulate the acquisition parameters to compensate for this artefact.

Postoperative care

Your surgeon will monitor your progress and **invite you for regular consultations** until he is sure that everything is as expected, then annual monitoring will be proposed. The recovery period may vary from one patient to another and depending on the specific indication.

We currently have clinical data covering a period of five years and continue to gather data to improve our knowledge of the safety and performance of the LP-ESP® lumbar disc prosthesis.

Information for safe use of the implant

General

- You may be recommended to wear an adjustable lumbar belt for standing up.
- Practice the movements according to your own tolerance for pain: listen to your body.
- Walking: as soon as possible after the operation.

Not permitted the first 3 months

- Forced movement of the spinal column.
- No spine curls.
- No abdominal exercises.
- No sitting on the floor.
- No crouching.

Sitting

- 1st week after the operation: no sitting.
- 6 weeks after the operation: straight-backed sitting position (back perpendicular to the legs).
- Then, sitting position only if no problems are experienced. Start by sitting for short periods of time (15 minutes, 3-4 times a day). Even well after the operation, avoid sitting for too long and change your position regularly.

Treatment

- Painkillers prescribed by the surgeon.

Movements

- For the first 6 weeks, make sure your back is straight when standing.

- From 6 weeks after the operation, gradually start to move the spinal column when standing.
- In the long term, if you are too stiff, your spine will be less resistant.

Hygiene

- Shower: one a day after the stitches have been removed.
- When washing, protect all stitches with waterproof covering.
- Bath: 6 weeks after the operation.

Lifting loads

- 6-8 weeks after the operation: 2kg max.
- 4-6 months after the operation: 5kg max.
- To lift loads, remember to extend your lower back (lumbar region), contract your abdominal muscles and breathe out.

Driving

- As a passenger, 14 days after the operation.
- As a driver, after authorization from your surgeon.
- Stop frequently at first to move around.
- Use lumbar supports (lower back cushion).

Physiotherapy (only with the authorization from the surgeon)

- First 6 months after the operation:
    - Core strength contraction exercises (isometric),
    - Relaxation (massage, heat).
- 6 months after the operation:
    - Start to mobilise the spine more,
    - Stretching: hamstrings, quadriceps (thigh muscles) and the trapezoids tend to become shorter, bringing the spinal column into a non-optimal position.

Mattress

- No specific mattress is required.

Return to work

- This depends on your activity; ask your doctor for advice.

Workstation

- Ergonomic modifications may be necessary:
    - To be able to remain straight in the sitting position (back perpendicular to the legs),
    - Place the desk higher, work standing up if necessary.
- Take frequent breaks to move around, or simply stand up, for example.

Sexuality

- Lumbar arthroplasty requires certain precautions to be taken during sexual intercourse; ask your surgeon for advice.
- Avoid strain and any painful movements.

Out patient monitoring

- Check the incision regularly.
- Gradually reduce and stop taking the painkillers.
- Stitches to be removed from 10 days after surgery.

Toilets use

- While sitting on the toilet, wear your lumbar belt or put both hands on the stomach.

Sport

- Cycling: 3 months after the operation, with the handlebars raised high enough.
- Swimming: 6 months after the operation (any technique except butterfly).
- Running: 6 months after the operation.
- Weight-training: 6 months after the operation, initially with supervision from a qualified professional. Combine weight and cardio training (light weights and multiple repetitions).
- Squash, skiing, tennis, golf: 6 months after the operation (provided you do not experience any problems, after suitable preparation and having consulted your doctor beforehand).

Implant composition

LP-ESP® discs are composed of a cushion made of polycarbonate urethane (PCU), called BIONATE 80A. BIONATE 80A belongs to a family of highly biocompatible medical grade polymers, whose physical and mechanical properties have been approved.
In the centre of the cushion, there is a silicone core, to mimic the anatomy of the natural disc.
This cushion is assembled between 2 titanium Ti6AL4V plates. This material is normalised and regularly used in orthopaedic implants.
The titanium plates are coated with titanium (T40) and a bone substitute called hydroxyapatite (HA) to increase plate roughness and encourage bone reconstruction to weld the plates to the vertebrae.

Quantitative composition of the implanted materials in mass percentage:

Sales reference	Titanium	PCU	Silicone	T40	HA
255682	63%<m<65%	25%<m<27%	7%<m<8%	1%	1%
255683					
255687					
255688					
255690					
255691					

Symbols meaning	
	Patient name or Patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and address of manufacturer
	Information website for patients
MD	Device name
SN	Serial number
LOT	Lot number/Batch code
UDI	Unique device identification

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Manufactured by

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