Patient information leaflet

Cervical disc prosthesis / Cementless CP-ESP®

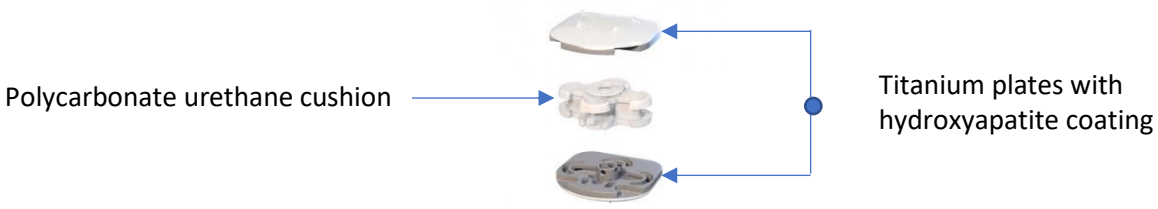
Leaflet content

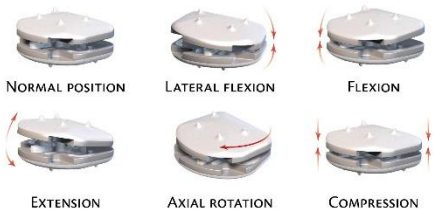
This leaflet answers some common questions about the lumbar disc prosthesis CP-ESP ® (hereinafter referred to as CP-ESP ®). This leaflet does not contain all the available information about this product. It does not take the place of talking to your surgeon. All medical devices and implants have risks 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

CP-ESP® is a cervical disc prosthesis; it is composed of two titanium plates between which is moulded a thermoplastic elastomer cushion (polycarbonate urethane - PCU). The design of the prosthesis allows to reproduce the structure and movements of natural intervertebral disc (compression, flexion/extension, lateral bending, rotation).
The cervical disc prosthesis CP-ESP® is designed to replace a pathological intervertebral disc within the cervical spine. CP-ESP® is offered with different sizes to fit with your anatomy.

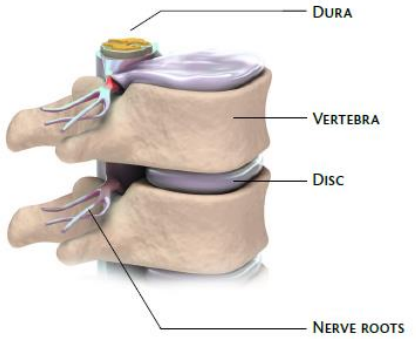
For more details on the materials, please refer to the paragraph "Composition of the implant".



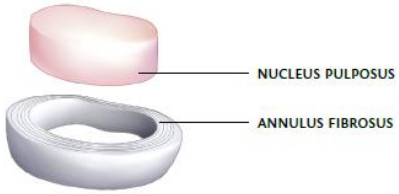


Cervical spine anatomy

It is formed of 7 cervical vertebrae often named C1 to C7; piled on top of each other and bounded by discs allowing movements.
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 plays a protection role of the dura and nerve roots.

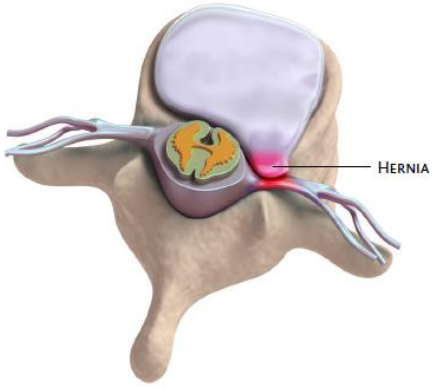


Discs located between the vertebrae are made of an elastic nucleus composed of 80% of fluid (Nucleus pulposus) and of an annulus composed of collagen fibres (Annulus). They are involved in the movements of the spine and play a role in pressure and shock absorption.



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 (pain can irradiate into the shoulder and arm) 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 cervical 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.

Performance

CP-ESP® should alleviate pain and restore disc space and normal disc function. This is a first-intention medical device.

Indications for use

CP-ESP® is designed to address specific indications such as:
Symptomatic cervical discopathy, defined as (radicular) pain and/or functional/neurological deficit in the neck or the arm with at least one of the following pathologies, confirmed by imaging (computerized tomography, MRI, or radiography) and having resisted medical treatment for at least 6 months.
- Herniated nucleus pulposus
- Spondylitis (defined by the presence of osteophytes)
- Radicular compression
- Discal hernia
- Nerve compression

Contraindications

<u>Specifics contraindications</u>
- Fractures, infections, tumours
- Spinal canal stenosis resulting from hypertrophic spondylitis
- Degeneration of the facet joints
- Pathological segmental instability
- Ossification of the posterior longitudinal ligament

General contraindications
- Osteoporosis, osteochondritis, and severe osteopenia
- Acute or chronic, spinal, or localized, systemic infection
- Systemic or metabolic diseases
- Conditions and surgical situations excluding any benefit from spinal surgery
- Sensitivity to foreign bodies leading to a reaction to the implant material

- Drug dependency: drug addiction or alcoholism
- Pregnancy
- No patient cooperation

Conditions of use

CP-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. Implantation must be carried out using the appropriate ancillary equipment, with undamaged instruments, following the recommended surgical technique and the instructions for use, to treat a patient who presents with the indications defined above.

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.

Undesirable Side Effects

It is the surgeon's responsibility to provide the patient with all the information before the operation, and especially to inform the patient of:

- Complications linked to all surgical interventions, including those of the cervical spine
- The risk of rupture of the implant following inappropriate activity, trauma, or other stresses specific to the patient's activity.
- The risk of the implant coming loose following insufficient initial fixation, latent infection, premature of excessive stressing, component malpositionning of trauma.
- The risk of allergy to one of the components of the material mentioned on the product label.
- Side effects that may require further operation, or revision.
- Possible progressive and sometimes asymptomatic bone resorption which may occur around the prosthetic components due to reaction to foreign bodies.
- Rupture of the prosthesis due to an undetected production default
- No biological fixation
- Lesions of the adjoining levels
- Known effects in the case of cervical arthrodesis :
    - Speech disorders, even mental disorders
    - Pain in the neck or the arms
    - Numbness in the extremities
    - Lesion of the dura mater
    - Problems with cicatrization
    - Complications in the event of pregnancy
    - Dysphagia (difficulty in swallowing)
    - Injury to the oesophagus
- Heterotopic ossification
- Degeneration of the facets

- Fracture of the vertebral body
- Damage to the adjoining levels

Precautions

The lifespan of implants is affected by numerous biological and biomechanical factors. Following the advice in this document will help preserve the longevity 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. 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 CP-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.

Safe use of the implant

General information
- Move your neck in normal range motion.
- Your individual pain threshold determines the speed of your mobilization. Please mind your body.
- Walking: As soon as possible after surgery.
- 3 weeks foam cervical collar: Day and night.
- Following 3 weeks foam cervical collar: night.

Not allowed for the first 3 months
- Forced impulsive manipulation of your spine.
- No crunches
- No sit-ups

Driving
- As a passenger for the first 3 weeks.
- As driver after authorization by your surgeon.

Lifting
- No more than 5 kg for the first 4 weeks
- No more than 10 kg for the following 4 weeks

Medication
- Pain medication as prescribed by your surgeon.

Sports
- Swimming:
    - 3 months after the surgery (all styles except butterfly)
    - 6 months after surgery: butterfly
- Cycling:
    - after 3-4 months with high handlebars.
- Weight training:
    - after 8 weeks and initially only with qualified supervision,
    - mixed weight and endurance training: small weights and high number of repetitions.
- Squash, skiing, tennis, golf: after 6 months (if problem-free and after good preparation)

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

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

Hairdresser

- 6 weeks after the surgery
- Specific care needs to be taken at the hair dress, especially at the shampoo sink, avoid hyper extension (ask your surgeon)

Outpatient care

- Regular wound controls.
- Reduction of pain medication.
- Removal of stitches from the 10th day after surgery.

Physiotherapy (only after an authorization of your surgeon)

- Back school:
  - Daily activities, relaxation,
  - Isometric tension exercises,
  - Healing by strengthening partially paretic musculature,
  - Stabilizing exercises,
- Limited range of motion:
  - Flexion, extension and lateral bending until authorized by your surgeon.

Device materials

CP-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. This cushion is moulded between two titanium plates (Ti6AL4V), 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	T40	HA
264363	**81%<m<90%**	**5%<m<12%**	**3%<m<4%**	**2%<m<3%**
264364				
264365				
264366				
264367				
264368				
264369				
264370				
264371				

Expected Device Lifetime
5 years (shelf-life of sterile packaging).

Reporting adverse effects

Any serious incident that occurs in relation to the device CP-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**	
GROUPE FH ORTHO	FH Industrie 6 rue Nobel Z.I. de Kernevez 29000 QUIMPER **www.fhortho.com**	spine innovations	Spine Innovations 3 rue de la Foret 68990 HEIMSBRUNN **www.spine-innovations.com**