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CP-ESP® DISC PROSTHESIS/CEMENTLESS

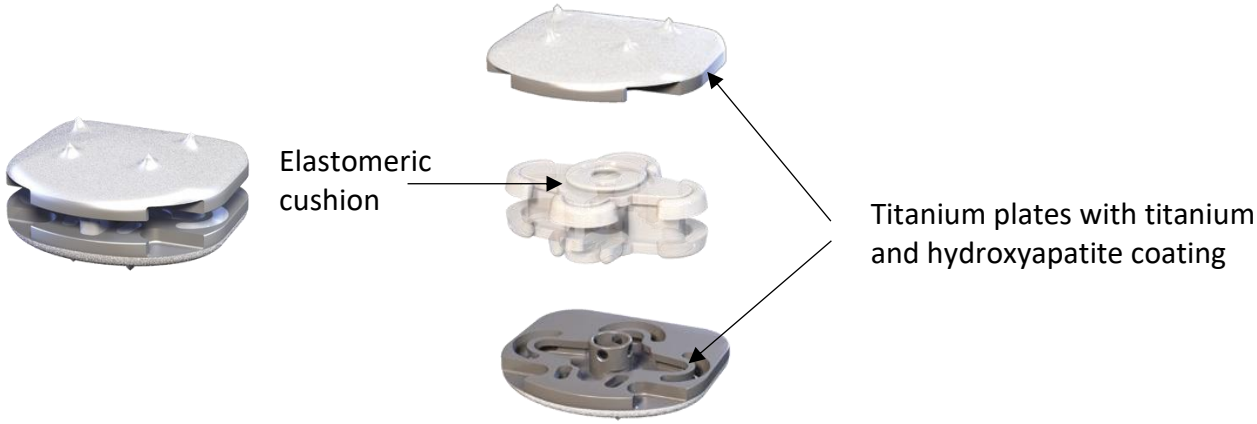
PATIENT INFORMATION

Description

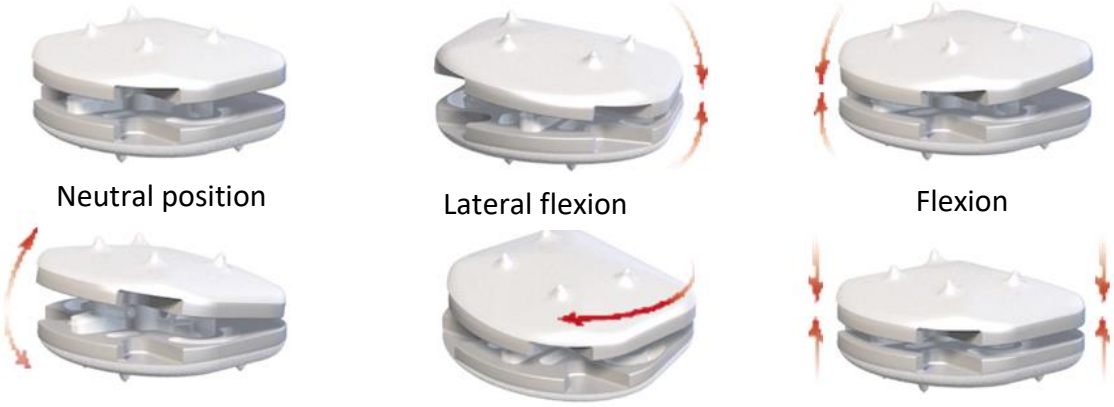
The cervical disc prosthesis CP-ESP® comprises two titanium plates with a thermoplastic elastomer (polycarbonate urethane / PCU) cushion between them. This cushion is designed to enable the prosthesis to reproduce the movements of a natural disc.

The CP-ESP® cervical disc prosthesis is designed to replace a pathological intervertebral disc in the cervical spine. It is intended to treat the disc spaces between the C3 and C7 vertebral bodies.

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



The cervical disc prosthesis CP-ESP® is designed to imitate the structure of the natural intervertebral disc. The prosthesis enables reproduction of the movements of a natural disc (shock absorption, flexion/extension, lateral flexion, axial rotation and translation).



Expected performance and benefits of the device

The CP-ESP® cervical disc prosthesis is designed to reduce pain, re-establish cervical 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 CP-ESP® disc prosthesis: **376036923CP01A2.**

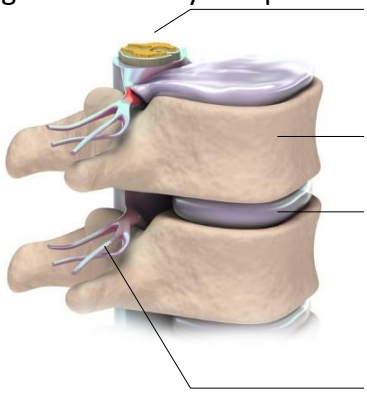
Anatomy of the cervical spine

The cervical spine is made up of 7 cervical vertebrae, often called C1 to C7, stacked on top of one another and connected by disks to enable movement.

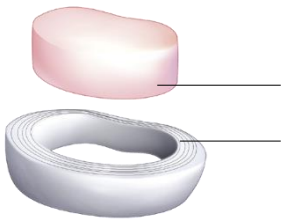
The column enables:

- forward and backward leaning: flexion/extension
- right and left side leaning: lateral flexion
- turning: rotation / translation
- shock-absorption: compression

The column bears the weight of the body and protects the spinal cord and nerve roots.



The discs between the vertebrae are made up of an elastic core, comprising 80% fluid (Nucleus pulposus) and a ring, mostly made of collagen fibres (Annulus fibrosus). They contribute to the movement of the spinal column and also act as shock-absorbers for pressure and impact.



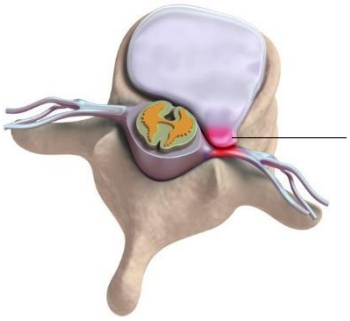
What is disc degeneration?

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 fibrous ring. Disc height is thus reduced, and some of the core content may escape: this is known as disc herniation.

A herniated disc can press against the spinal cord 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 preventive treatments (non-surgical) fail to relieve the symptoms, surgery may be indicated."



Cervical discopathy (disc disease) surgery may be performed by anterior approach to preserve the dorsal muscles and avoid having to push aside the spinal cord.

- The reference intervention consists in removing all or part of the affected disc to relieve pressure on the nerves and therefore 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 CP-ESP® cervical disc prosthesis is intended

The CP-ESP® disc prosthesis is designed for the treatment of degenerative disc disease (DDD) of the cervical spine in skeletally mature patients who have not responded after at least 6 months of conservative treatment.

Contraindications

Specific contraindications

- Fractures, infections, tumours
- Stenosis of the spinal canal resulting from hypertrophic spondylarthritis
- Degeneration of facet joints
- Pathological segmental instability
- Ossification of posterior longitudinal ligament

General contraindications

- Osteoporosis, osteochondrosis or severe osteopenia
- Chronic or acute local, spinal, or systemic infections
- Metabolic and systemic diseases
- Pathologies and surgical situations that preclude any benefit of spinal surgery
- Sensitization to foreign bodies resulting in reaction to implant materials
- Dependence on drugs, drug addiction or alcoholism
- Pregnancy
- Lack of cooperation from the patient

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. Your 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 cervical disc replacement they are mostly related to the approach. Access to the cervical 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:

- Breakage or displacement of the implant, or separation of the implant's components
- Pain
- Neurological disorders (alteration of the voice, uncomfortable swallowing, dizziness, headaches, paralysis)
- Accumulation of liquid or tissue formation in the operation area
- Loss of movement (involuntary fusion) in the affected area
- Instability / hyper mobility
- Loss of movement amplitude
- Development or progression of the illness to other areas of the spinal column
- Lower back, leg, hip or knee problems
- Abnormal non-painful sense of touch (tingling, prickling, numbness)
- Allergy
- Droopy eyelid (Horner's syndrome)
- Adverse effects that may require a second operation and, in some cases, explantation of the implant
- Infection of the surgical wound and/or systemic infection
- Blood circulation problems
- Blood clots and restriction of blood flow, possibly resulting in a pulmonary embolism
- Trauma during the surgical intervention, such as nerve or spinal cord damage, excessive bleeding and/or fractures of vertebral bodies (spinal column bones)
- Surgical error
- Bone resorption
- Death

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 a CP-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 48T²/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 4W/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 1.5T with a WB-SAR measured at 3.50 ± 0.81W/kg and a maximum temperature increase of 3.5 ± 1.0°C at 3T with a WB-SAR measured at 3.94 ± 0.88W/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.

Care after implantation

Your surgeon will monitor your progress and **invite you for regular consultations** until they are 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 four years and continue to gather data to improve our knowledge of the safety and performance of the CP-ESP® cervical disc prosthesis.

Information for safe use of the implant

General

• Turn or tilt the head using normal neck movements.
• Practice the movements according to your own tolerance for pain: listen to your body.
• Walking: as soon as possible after the operation.
• Foam cervical collar for the first 3 weeks: day and night.
• Foam cervical collar after the first 3 weeks: at night.

What is not permitted for the first 3 months

• Forced movement of the spine.
• No spine curls.
• No abdominal exercises.

Driving

• As a passenger for the first 3 weeks after the operation.
• As a driver after authorisation from your surgeon.

Lifting loads

• Not more than 5kg for the first 4 weeks.
• Not more than 10kg for the next 4 weeks.

Treatment

• Pain-killers prescribed by the surgeon.

Sports

• Swimming:
- 3 months after the operation: any technique except butterfly;
- 6 months after the operation: all techniques.
• Cycling:
- After 3-4 months, with the handlebars raised high enough.
• Weight-training:
- After 8 weeks and initially with supervision from a qualified professional,
- Combine weight and cardio training: light weights and multiple repetitions.
• Squash, skiing, tennis, golf:
- After 6 months: if you have not experienced any problems and after suitable preparation and after consulting your doctor.

Sexuality

• Arthroplasty requires certain precautions to be taken during sexual intercourse: ask your surgeon for advice.
• Avoid strain and any painful movements.

Hygiene

• Shower: 1 day after the stitches have been removed.
• When washing, protect all stitches with waterproof covering.
• Bath: 6 weeks after the operation.

Hairdresser
• After 6 weeks.
• At the hairdresser's, be very careful not to over-stretch the neck, particularly during washing (ask your surgeon for advice).

Out-patient monitoring
• Check the incision regularly.
• Decrease pain-killers.
• Stitches to be removed from 10 days after surgery.

Physiotherapy (only with authorisation from the surgeon)
• Rehabilitation:
- Everyday actions, relaxation,
- Isometric contraction exercises,
- Promote healing by working the muscles affected by the surgery,
- Stabilisation exercises.
Limited movement amplitude:
- Flexion, extension and lateral torsion within the limits permitted by the surgeon.

Implant composition
CP-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.
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	Ti6Al4V	PCU	T40	HA
264363	81%<m<90%	5%<m<12%	3%<m<4%	2%<m<3%
264364				
264365				
264366				
264367				
264368				
264369				
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264371				

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
LOT	Lot number/Batch code
UDI	Unique device identification
REF	Catalogue number
UDI-DI	Basic UDI

 Manufactured by	
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