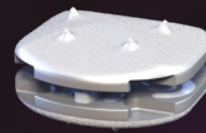


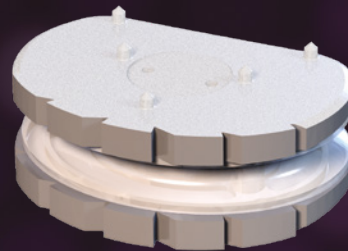


ESP ELASTIC SPINE PAD®

A concept of viscoelastic cervical and lumbar disc prostheses to mimic natural disc and preserve spinal motion



CP·ESP®



LP·ESP®



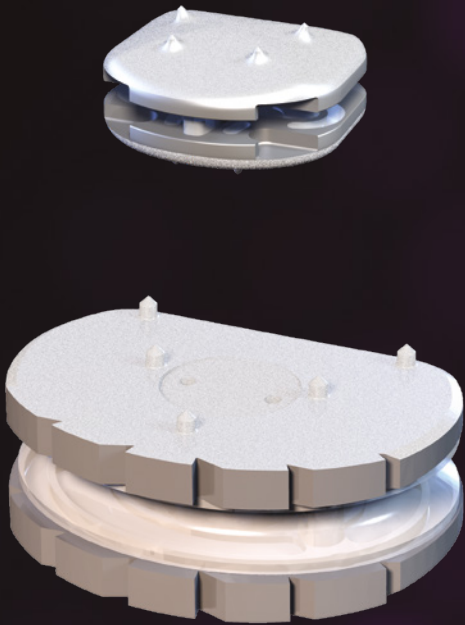
The **ESP® technology** is based on the concept of “**monobloc silent block**” conceived by Professor Raymond Roy-Camille from the Pitié Salpêtrière University Hospital in Paris.

The analysis of the properties of the natural intervertebral disc led him to initiate the development of a specific prosthesis design that could restore them.

After **more than 10 years of research and development**, the first LP-ESP® lumbar disc prosthesis has been implanted in 2004 under a Huriet law clinical evaluation and CE mark has been obtained in 2007.

For the cervical prosthesis CP-ESP®, based on the same technology, CE mark has been obtained in 2012.

The ESP technology® now benefits from over than 15 years of experience.



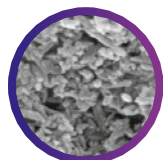
CHARACTERISTICS

The ESP disc prosthesis is made of **2 titanium alloy endplates** and an **elastomeric cushion in polycarbonate urethane (PCU)**. The PCU is a material used in medical devices for its mechanical resistance and its biostability^{(1) (2)}. An **hydroxyapatite (HA)** coating covers a layer of **porous titanium T40**. The rough surface of the prosthetic endplates is combined with the presence of spikes to ease primary fixation.

The elastomeric component is injected in between the titanium endplates in order to enhance **controlled resistance to compression, flexion and rotation**. The design of the intermediate cushion and its connections to the metallic endplates allow to optimize the range and the functional characteristics of the mobilities.

COATING

Superior and inferior endplates are coated with plasma sprayed pure titanium (Ti) and hydroxyapatite (HA)

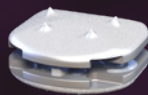


Titanium T40 following ISO 5832-3 includes:
Oxygen, Carbon, Nitrogen, Hydrogen & Titanium.
Titanium is a recognized material in bone surgery to promote osseointegration. ^{(3) (4)}



Hydroxyapatite (HA) includes:
Calcium, Phosphorus, Oxygen & Hydrogen.
Hydroxyapatite has a mineral composition similar to that of bone, it favours the osseointegration of porous titanium with the vertebral endplates. ^{(3) (4)}

CP·ESP®



T40 + HAP

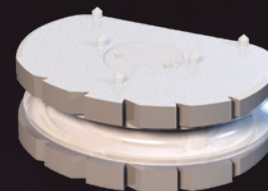


ELASTOMERIC CUSHION MADE OF
POLYCARBONATE URETHANE (PCU)



TITANIUM PLATES

LP·ESP®



T40 + HAP

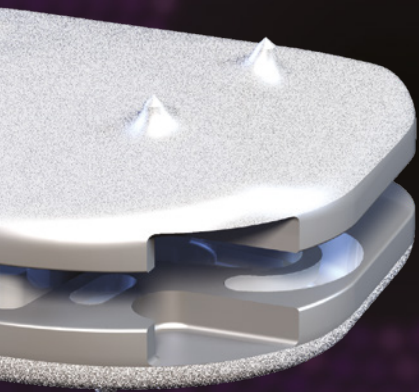
SILICONE INNER CORE
(ELASTIC NUCLEUS)

POLYCARBONATE URETHANE

TITANIUM PLATES



(1) Christenson EM, Dadsetan M, Wiggins M, Anderson JM, Hiltner A. Poly(carbonate urethane) and poly(ether urethane) biodegradation: in vivo studies. J Biomed Mater Res A (2004) 69:407–416
(2) Kurtz SM, Siskey R, Reitman M. Accelerated aging, natural aging, and small punch testing of gamma-air sterilized polycarbonate urethane acetabular components. J Biomed Mater Res B Appl Biomater (2010) 93:442–447
(3) Stanton P, Eck JC. Materials and design characteristics of cervical arthroplasty devices. Techniques in Orthopaedics (2010) 25(2):93–96.
(4) Lazennec J-Y. Lumbar and cervical viscoelastic disc replacement : concepts and current experience. World H Orthop. 2020 Aug 18; 11(8):345-356



CP·ESP®

The ESP® **viscoelastic** disc prostheses are **monobloc**. They show **controlled mobility** to replicate the biomechanical behavior of the natural disc.



NEUTRAL POSITION



EXTENSION



FLEXION



LATERAL FLEXION



AXIAL ROTATION



COMPRESSION

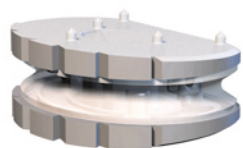
CP-ESP

Flexion / Extension
Lateral flexion
Axial rotation

| | Natural disc ⁽⁵⁾ | | | | ISO 18192 | CP-ESP (in vitro) |
|---------------------|-----------------------------|-------|-------|-------|---------------|----------------------|
| | C3-C4 | C4-C5 | C5-C6 | C6-C7 | | |
| Flexion / Extension | 13° | 12° | 17° | 16° | -7,5° / +7,5° | 14° |
| Lateral flexion | 11° | 11° | 8° | 7° | -6° / +6° | 12° |
| Axial rotation | 11° | 12° | 10° | 9° | -4° / +4° | 8° |

(5) A.A White III and M.M. Panjabi, Clinical Biomechanics of the Spine, Lippincott 1978, pp. 65, 71, 75, 79

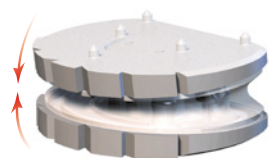
- 6 degrees of freedom
- Shock absorption
- Controlled resistance to rotational and translational movements
- Adaptive center of rotation
- No wear debris linked to friction



NEUTRAL POSITION



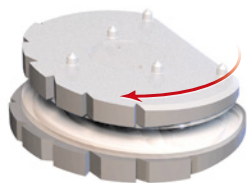
EXTENSION



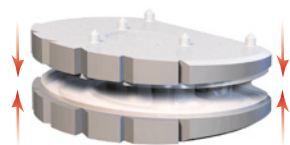
FLEXION



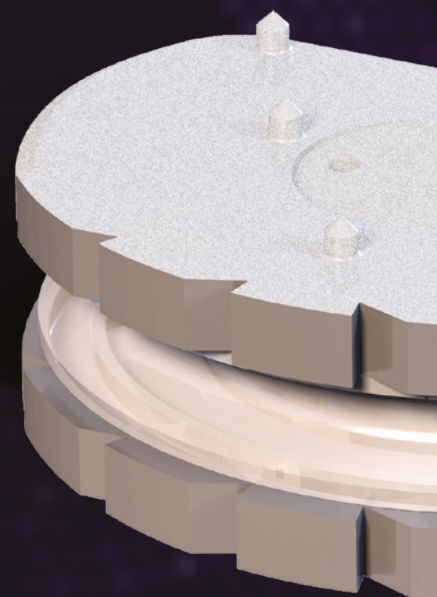
LATERAL FLEXION



AXIAL ROTATION



COMPRESSION



LP·ESP[®]

LP-ESP

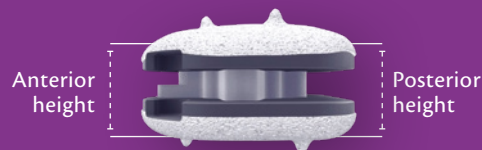
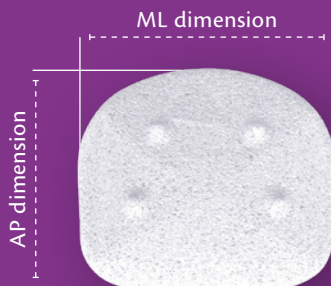
Flexion / Extension
Lateral flexion
Axial rotation

| | Natural disc ⁽⁶⁾ | | ISO 18192 | LP-ESP (in vitro) |
|---------------------|-----------------------------|-------|-----------|----------------------|
| | L4-L5 | L5-S1 | | |
| Flexion / Extension | 6° | 4° | -3° / +6° | 6° |
| Lateral flexion | 4° | 2° | -2° / +2° | 2,5° |
| Axial rotation | 2° | 1° | -2° / +2° | 2° |

(6) Panjabi MM, Oxland TR, Yamamoto I, Crisco JJ (1994). Mechanical behavior of the human lumbar and lumbosacral spine as shown by three-dimensional load-displacement curves. J Bone Joint Surg Am 76:413-424

IMPLANT RANGE AND DIMENSIONS

CP.
ESP
Cervical prosthesis



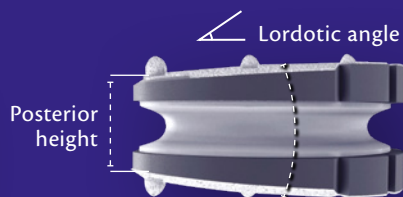
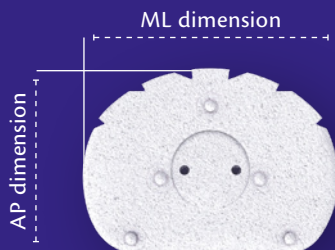
Data in millimeters (mm)

| Ref. | Dimensions |
|---------|-------------------------|
| 264 363 | Size 1 (13X15) height 5 |
| 264 364 | Size 1 (13X15) height 6 |
| 264 365 | Size 1 (13X15) height 7 |

| Ref. | Dimensions |
|---------|-------------------------|
| 264 366 | Size 2 (14X17) height 5 |
| 264 367 | Size 2 (14X17) height 6 |
| 264 368 | Size 2 (14X17) height 7 |

| Ref. | Dimensions |
|---------|-------------------------|
| 264 369 | Size 3 (15X20) height 5 |
| 264 370 | Size 3 (15X20) height 6 |
| 264 371 | Size 3 (15X20) height 7 |

LP.
ESP
Lumbar prosthesis



Data in millimeters (mm)

| Ref. | Dimensions |
|---------|-------------------------------------|
| 255 682 | Size 28x39 inclination 7° height 10 |
| 255 683 | Size 28x39 inclination 7° height 12 |

| Ref. | Dimensions |
|---------|-------------------------------------|
| 255 687 | Size 28x39 inclination 9° height 10 |
| 255 688 | Size 28x39 inclination 9° height 12 |

| Ref. | Dimensions |
|---------|--------------------------------------|
| 255 690 | Size 28x39 inclination 11° height 10 |
| 255 691 | Size 28x39 inclination 11° height 12 |

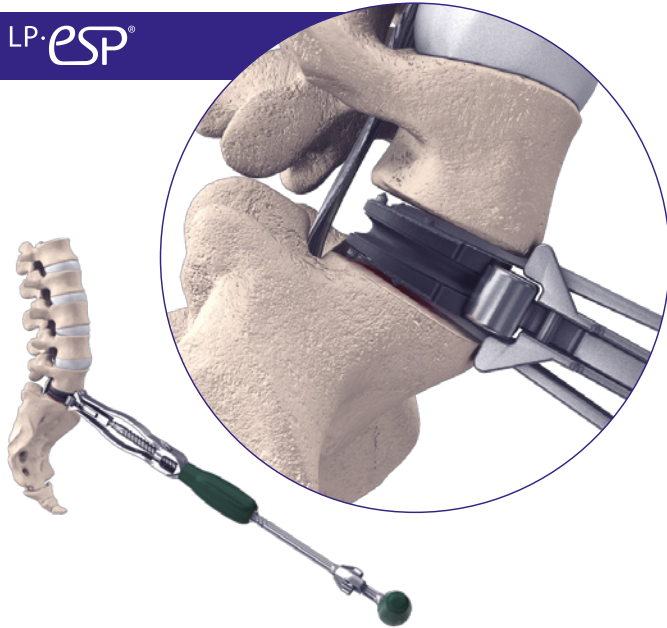


A technical sheet presenting all the dimensions of the prostheses is available upon request.

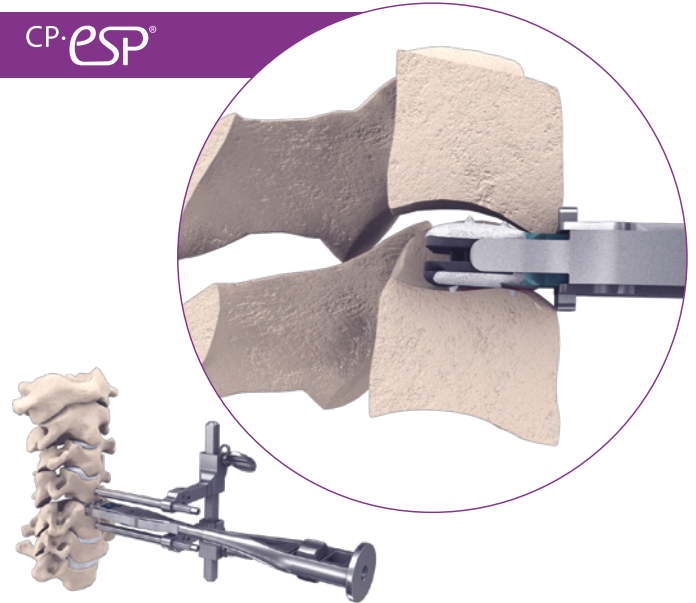
INSTRUMENTATION

- Insertion of the prosthesis in the axis of the disc.
- Easy and reliable implantation thanks to its specific unique implant introducer.
- Final positioning possible until the last step of the surgery thanks to specific repositioning instruments.

LP·ESP®



CP·ESP®



PATIENT LEAFLETS

written by the ESP® expert surgeons to accompany patients in pre- and post-operative care.

Preoperative information



Postoperative recommendations





The ESP disc prostheses are “MR conditional” (MR compatible under conditions)



A technical sheet presenting the MR information of the ESP prostheses is available upon request.

Document intended exclusively for health care professionals. **Device class:** The lumbar disc prosthesis LP-ESP® and the cervical disc prosthesis CP-ESP® are class III medical devices. The LP-ESP® and CP-ESP® instruments are class I medical devices. They have been designed to implant LP-ESP® and CP-ESP® prostheses, respectively. **Indications:** lumbar and cervical degenerative disc disease (detailed indications in the instructions for use). **CE mark:** 0459. **Manufacturer:** FH Industrie. **Distributor:** Spine Innovations. **Recommendations for use:** Carefully read the labelling, the instructions for use and the surgical technique before any intervention.
Last update: August 2022.

Check with Spine Innovations products availability in your country.

Bibliography

- Concept and early results of the ESP six degrees of freedom total disc replacement
Rousseau MA, Lazennec JY, Pascal-Mousselard H, Ricart O, Saillant.
G Spine Arthroplasty Society 2007.
- Pioneering experience with the first bi-composite polymeric disc prosthesis : technical aspects, experimental data and 3 years multicentric clinical evaluation.
Lazennec JY, Pascal-Mousselard H, Ricart O, Rakover JP, Rousseau MA..
Spine Arthroplasty Society 2009.
- 6 years clinical experience with the first bi-elastomeric lumbar disc prosthesis.
Lazennec JY.
EFORT meeting 2011.
- 6 years clinical experience with the first bi elastomeric lumbar disc prosthesis.
Lazennec JY, Rakover JP, Aaron A, Mousselard HP , Rousseau MA.
J. Bone Joint Surg Br 2012 94-B;(SUPP XXXVII) 273.
- The LP-ESP Lumbar Disc Prosthesis: Concept, Development and Clinical Experience.
Lazennec JY, Aaron A, Brusson A, Rakover JP, Rousseau MA.
InTech 2013. (Arthroplasty Update) Plamen Kinov Ed ,ISBN 978-953-51-0995-2
doi:10.5772/53726.
- The Viscoelastic LP-ESP Lumbar Disc Prosthesis With 6 Degrees of Freedom : A Prospective Study of 120 Patients With Two Years Minimum Follow-Up.
Lazennec JY, Brusson A, Rakover JP , Rousseau MA.
Bone Joint J. 2013 95-B;(SUPP 34) 389.
- The LP-ESP(*) lumbar disc prosthesis with 6 degrees of freedom: development and 7 years of clinical experience.
Lazennec JY, Aaron A, Brusson A, Rakover JP, Rousseau MA.
Eur J Orthop Surg Traumatol. 2013 Feb;23(2):131-43. doi: 10.1007/s00590-012-1166-x.
- The Viscoelastic LP ESP Lumbar Disc Prosthesis With 6 Degrees of Freedom: A Prospective Study of 120 Patients With 2 Years Minimum FollowUp.
Lazennec JY.
ISTA meeting 2013.
- Clinical outcomes, radiologic kinematics, and effects on sagittal balance of the 6-degrees-of-freedom LP-ESP® lumbar disc prosthesis.
Lazennec JY, Even J, Skalli W, Rakover JP, Brusson A, Rousseau MA.
Spine J. 2013 Nov 18. doi:pil: S1529-9430(13)01726-9. 10.1016/j.spinee.2013.11.016.
- The viscoelastic LP-ESP lumbar disc prosthesis with 6 degrees of freedom: a prospective study of 120 patients with 2 years minimum follow-up.
Lazennec JY, Aaron A, Brusson A, Rakover JP, Rousseau MA.
The Spine society of Australia 2013 (24th annual meeting).
- The viscoelastic CP-ESP cervical disc prosthesis with 6 degrees of freedom : a prospective study of 49 patients with 1 year follow-up.
Lazennec JY, Brusson A, Ricart O, Rakover JP.
The Spine society of Australia 2014 (25th annual meeting).
- Five-year follow-up of clinical and radiological outcomes of LP-ESP elastomeric lumbar total disc replacement in active patients
Lazennec JY, MD, PhD, Rakover JP, MD, Rousseau MA, MD PhD
The Spine Journal, May 2018.



Manufacturer:

FH INDUSTRIE
6 rue Nobel
Z.I. de Kernevez
29000 Quimper - FRANCE



Distributor:

SPINE INNOVATIONS
11 rue Saint Jean de Dieu - 69007 Lyon - FRANCE
Phone: +33 3 68 32 11 47 • Fax: +33 3 68 34 30 80
www.spine-innovations.com
contact@spine-innovations.com