LUMBAR INTERSOMATIC CAGE
PDP
INSTRUCTIONS FOR USE

Manufacturer: NEURO FRANCE Implants
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Important information for the medical practitioner:
The practicing physician should carefully read the instructions and advice as well as the recommendations before using the lumbar intersomatic cage PDP.

1. Description of the system
- The system is composed of lumbar intersomatic cage PDP.
- The cage is made of PEEK Optima® and the radiological markers are made of titanium alloy Ti 6-Al 4-V according to the ISO 5832-3 standard.

2. Indications
The lumbar intersomatic cage PDP is for the treatment of spine diseases such as:
- Intersomatic vertebral fusion
- Degenerative spine diseases
- Trauma
- Recurrent spinal disc herniation
- Posterior vertebral instability
- Intersomatic recalcification
- Degenerative spondylolisthesis
- Every surgical procedure intended for performing a fusion.

3. Contraindications
The choice of the treatment is determined by the practitioner who has the required skills, knowledge and experience.
Factors which may compromise the implantation include (but are not limited to):
- Infection
- Allergy, intolerance to alloying elements of the titanium alloy and to PEEK Optima®
- Obesity
- Hyperactivity, mental illness
- Severe vertebral osteoporosis
- Congenital deformation
- Tumor.

4. Use
- Please consult the surgical technique before use.
- The surgical approach is posterior associated with a circumferential surgery.

5. Warning / Operating precautions
- The surgeon must be fully experienced in the use of the PDP implants, the application method, the instruments and the surgical technique.
- The use of similar implants in conjunction with the PDP system is proscribed.
- The use of other instruments and/or the incorrect use of the instruments required to fit the PDP implants may lead to a deterioration of the implants that will limit the optimization of the desired function. It is therefore proscribed.
- Although allergic reactions are extremely rare, we recommend to make an allergy check-up on patients with a particularly strong predisposition to allergies.
- The PDP system must be used under perfectly sterile conditions.

6. Adverse effects and complications
The potential adverse effects and complications are:
- Pseudarthrosis,
- Surgical site infection,
- Displacement or expulsion of the implant which may require revision surgery
- Neurological complications, breach of the dura mater, nerve root injury
- Vascular damage caused by the surgical procedure
- Stress fracture of the implant.

7. Storage conditions
Implants must be stored in their original packaging in a dry environment and at room temperature.

8. Sterilization
The PM cage® implants and the instrument set are supplied non-sterile. They must be sterilized under the responsibility of the person responsible for sterilization in the healthcare facility. Sterilization must be carried out in an autoclave.
Method: Sterilization by steam (moist heat)
- Minimum duration: 18 minutes
- Minimum temperature: 134°C

It is recommended to check the sterilization indicators and the integrity of the packaging before opening.

9. Disposal of implants
Implants must be disposed of according to the relevant hygiene and waste disposal guidelines of the healthcare facility for medical waste.

10. Additional information
Put on the market: June 2012
Additional information can be obtained from NEURO FRANCE Implants.

Examples of symbols used on the labels:

<table>
<thead>
<tr>
<th>NON STERILE</th>
<th>Manufacturer number</th>
<th>Manufacturing date</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Catalogue number</td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch number</td>
<td>See instructions for use</td>
</tr>
<tr>
<td></td>
<td>Expiration date</td>
<td>Do not re-use</td>
</tr>
<tr>
<td></td>
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<td>CE mark with notified body identification number</td>
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</tbody>
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Claims:
All claims and/or malfunction reports should be addressed immediately by telephone, fax or letter to NEURO FRANCE Implants.

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