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-AI 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 recalibration
- 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 ostoporosis
- 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.
- The implants are for single use only and should never be reused. Reuse may lead to the degradation of device performances, contaminations and cross-infections.
- All implants extracted from the patient, damaged or having been incorrectly used should be disposed of once it has been soiled or contaminated with blood, body tissues.
- There are no known risks of mutual interferences between the implant and other medical devices.
- The patient should ask for medical advice before entering potentially dangerous environments (such as electromagnetic or magnetic fields including magnetic resonance environments), which may affect the performances of the implant.
- The implants are made of titanium alloy Ti 6-AI 4-V or PEEK Optima® which are non-magnetic materials. Patients can be exposed to electromagnetic or magnetic fields without any real risks. The patient must notify that he has implant before any exposure to electromagnetic or magnetic fields.
- The patient has to be informed of the risks of the surgical intervention by the medical staff. The patient should follow the advice and recommendations from the surgeon (radiological examinations) during the postoperative phase.
- It is recommended to limit physical activity after the surgery to allow bone fusion. If not, the implant may break or otherwise be damaged necessitating revision surgery. The implant should not be exposed to extreme movements of mechanical vibrations for example.
- All modifications (aspect, pain…) at the implant site must be reported to the medical practitioner. The medical practitioner should also be informed of all type of incidents like a fall for instance, even when there are no visible signs at the implant site.

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:

NON STERILE	Non sterile		Manufacturer
REF	Catalogue number		Manufacturing date
LOT	Batch number		Do not use if package is damaged
	Expiration date		See instructions for use
	Do not re-use	CE 0459	CE mark with notified body identification number
NON STERILE	Non sterile		

Claims:
All claims and/or malfunction reports should be addressed immediately by telephone, fax or letter to NEURO FRANCE Implants.

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