INTERSOMATIC LUMBAR CAGE
PDP / AVENIR
INSTRUCTIONS FOR USE

Manufacturer : NEURO FRANCE Implants
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Important information for the practitioner :
The practitioner should carefully study the guidelines and advice and recommendations before using of the lumbar interbody fusion cage.

1. Description of the material

- The PDP system consists of interbody lumbar cages. The AVENIR cage is the titanium version of the PDP cage.
- The cage is made of PEEK Optima® (with Ti 6 -Al 4-V Titanium alloy radiological markers in accordance with the ISO 5832-3 standard). The AVENIR cage is made of Titanium Ti 6-Al 4-V in accordance with the ISO 5832-3 standard).
- The PDP unit is available in a non-sterile and sterile (only in PEEK OPTIMA®) state.

Origin neither human nor animal - Non absorbable.

2. Proper Usage

The PDP & AVENIR cages are intended for performing an interbody fusion. These implants restore the height of the intervertebral space.
Since interbody implants have not been designed as "independent" implants, they require the use of posterior instrumentation (pedicle screw type).

3. Expected Clinical Performance

- At least 15% improvement in current clinical scores for VAS and ODI pain over a period of one year
- Fusion rate greater than 85% at one year postoperatively.

4. Indications

PDP& AVENIR lumbar interbody cages are intended for the treatment of spinal conditions such as :

- Degenerative spine
- Spine deformities
- Trauma

5. Contraindications

The choice of treatment belongs to the practitioner who has the training and experience necessary for it.
Factors compromising implantation (non-exhaustive list):

- Severe osteoporosis
- Active infectious process or significant risk of infection (immuno compromised)
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Hyperactivity
- Mental illness
- Any other medical or surgical condition that would exclude the potential benefit of spinal implant surgery.
- Anomalies, elevation of the rate of sedimentation unexplained by other diseases, increase in the number of white blood cells.
- Allergy or intolerance to the materials constituting the suspected or documented implant.
- All cases where implant components chosen for use would be too large or too small to achieve a positive result.
- Any patient with insufficient tissue coverage at the operative site, or inadequate bone stock or bone quality.
- Any patient in whom the use of the implant would interfere with the expected anatomical structures or physiological performance.
- Any patient not wishing to follow postoperative instructions.
- Severe bone resorption, osteomalacia
- Any case not described in the indications.

6. Use

- Consult the surgical technique before each use.
- The surgical approach is the posterior pathway and more precisely the unilateral pathway (UNILIF).

7. General warning

The surgeon is solely responsible for the operation. He should carefully study the guidelines and advice as well as recommendations before using PDP & AVENIR implants. To have a stable fixation, he must know perfectly the handling of ancillary equipment and recommendations for use.

8. Warnings / Operating Precautions

- The surgeon must be fully familiar with PDP & AVENIR implants, the method of application, the instruments and the surgical technique.
- The components of the PDP range must not be associated with devices of other ranges.
- The use of different ancillary components and / or incorrect use of the ancillaries necessary for the installation of the PDP & AVENIR unit is strongly contraindicated since this can lead to damage to the implants and thus limit the optimization of the desired function.
- Although allergic reactions are very rare, it is recommended to check the allergic level of the patients with particularly strong ground.
- The PDP unit must be used under perfectly sterile operating conditions.
- Our implants are for single use and should never be reused. Reuse can result in decreased device performance, contamination, and cross-infection.
- Any implant removed from the patient, damaged or misused, should be removed as soon as it has been in contact with blood or body tissue.
- There is no known risk of reciprocal interference between the implant and other medical devices.
- The implants are made of titanium alloy Ti 6-Al 4-V or PEEK Optima® which are non-magnetic materials. They pose no real risks to patients when exposed to electromagnetic and magnetic environments.
- The patient must declare that he is an implant holder before exposure to electromagnetic and magnetic environments.
- The patient will be informed by the medical staff of the risks generated by the surgical procedure (contraindications, adverse effects / complications, precautions to take, limited life of the device). He must also respect the surgeon's advice and recommendations (radiological checks, limited physical activity, etc.) during the postoperative phase.
- For proper consolidation, it is advisable to limit physical activity after placing the medical device and carrying heavy loads. Otherwise, the implant could rupture or damage which would require re-operation. The implant should not be exposed to excessive movements of mechanical vibrations for example.
- Any changes (appearance, pain,...) at the implanted site should be reported to the practitioner. All types of accidents such as a fall, for example, should be reported to the practitioner even if no external sign at the implanted site is visible.

9. Undesirable effects / complications

The undesirable effects or potential complications are :

- Severe pseudarthrosis
- Risk of infection of the implantation site
- Neurological and / or vascular damage related to the surgical procedure
- Displacement or expulsion of the implant requiring a new intervention
- Fracture of fatigue of the material
- Death.

10. Implant storage condition

The implants should be stored in a dry place at room temperature.
Sterile implants must also be stored away from sunlight and UV light.

11. Sterilization

- Implants and ancillaries delivered non-sterile

PDP & AVENIR **implants** and **ancillaries** are delivered non-sterile. They must be sterilized under the responsibility of the sterilization manager of the health facility. Sterilization must be performed by autoclaving.

Method : Sterilization with water vapor (moist heat)
Minimum recommended time: 18 minutes
Minimum recommended temperature: 134° C

It is recommended to check the sterilization indicator (s) before opening and the integrity of the sterilization packaging

- Implants delivered sterile

PDP implants are delivered sterile under double vacuum packaging in a cardboard box, filmed and identified. Sterilization is performed by gamma irradiation of at least 25 kGy from a cobalt 60 source.

Caution: Do not use these implants in the following case: absence of air gap that proves a violation of the packaging, which means loss of sterility.

It is recommended to check before use the integrity of all levels of packaging and the expiry date.

Product labels are placed inside the packaging to ensure traceability in health facilities.

It is recommended to check the sterilization indicator (s) before opening and the integrity of the packaging.

12. Implant Disposal

The disposal and rebut of the implant follows the same procedures in the facility as hospital waste.

13. Additional information

Date of placing on the market
PEEK version (PDP CAGE) : June 2012 (non-sterile) / February 2015 (sterile)
Titanium version (AVENIR CAGE) : February 2019 (non-sterile)

Further information can be obtained from NEURO FRANCE Implants.

Explanation of symbols used on product labeling :

STERILE R	Radiation sterilized		Manufacturer
REF	Catalog Number		Date of manufacture
LOT	Lot Number		Do not use if the packaging is damaged
	Use before		Attention! Consult attached documentation
	Do not reuse	CE 0459	CE marking with the Notified Body's identification number
NON STERILE	Non sterile material		

Complaints :
Any complaint or report of malfunction must be made immediately by telephone, fax, email or mail to NEURO FRANCE Implants.

Please read the instructions carefully.
These implants are class IIb medical devices and are marked :

CE 0459
Our notified body is the GMED.