INTERSOMATIC LUMBAR CAGE
SHARK
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 the SHARK intersomatic lumbar cage.

1. Description of the material

- The system is composed of SHARK lumbar interbody cages.
- The SHARK system is made of either PEEK Optima® (with Ti 6-Al 4-V titanium alloy radiological markers) or Ti 6-Al 4-V titanium alloy in accordance with the ISO 5832-3 standard.
- The SHARK system is available in a non-sterile and sterile state (only for PEEK OPTIMA cages).

Origin neither human nor animal - Non absorbable.

2. Proper Usage

The SHARK 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

SHARK 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
- Glass Bone Disease
- Allergy or intolerance to the materials that constitute the suspected or documented implant.
- Any case not described in the instructions.

6. Use

- Consult the surgical technique before each use.
- The surgical approach is the posterior approach and more precisely the transforaminal approach (TLIF).

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 SHARK implants. To obtain 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 SHARK implants, the method of application, the instruments and the surgical technique.
- The components of the SHARK 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 SHARK system 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 SHARK system 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

undesirable effects or potential complications are :

- Severe Pseudarthrosis
- Cranial Cerebrospinal Fluid Leak (CSF)
- Risk of infection of the implantation site
- Neurological and/or vascular damage associated to the surgical procedure
- Pedicle fracture
- Fatigue fracture 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

SHARK 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

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

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

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

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

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

12. Implant Disposal

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

13. Additional information

Date of placing on the market :
PEEK version : Avril 2010 (non-sterile) / Juillet 2015 (sterile)
Titanium version : 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		

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.