LUMBAR INTERBODY CAGE
BANANA
INSTRUCTION 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 interbody BANANA cage.

1. Description of the system

- The system consists of BANANA interbody lumbar cages.
- The cage is made either of PEEK Optima® (with radiological markers in Titanium Ti 6-Al 4-V alloy) or of Titanium Ti 6-Al 4-V alloy complying with the ISO 5832-3 standard.
- The BANANA system is available in a non-sterile state.

Neither human nor animal origin - Non-absorbable.

1. Claimed use

BANANA cages are designed to achieve interbody fusion. These implants restore the height of the intervertebral space.
Interbody implants have not been designed as "independent" implants and therefore require the use of posterior instrumentation (pedicle screws).

2. Expected clinical performance

- Improvement of at least 15% at 1 year in current clinical scores for VAS and ODI pain assessment
- Merger rate of more than 85% at one year post-operatively.

3. Indications

The BANANA interbody lumbar cages are intended for the treatment of spinal column disorders such as :

- Degenerative spine
- Spine deformities
- Trauma

4. Contraindications

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

- Severe osteoporosis
- Active infectious process or significant risk of infection (immuno-compromised)
- Comminuted fractures (burst-fractures) and compression fractures
- Tumours
- Spondylolisthesis grade IV
- Extensive epidural fibrosis
- Morbid obesity
- Pregnancy
- Hyperactivity
- Mental illness
- Glass Bone Disease
- Suspected or documented allergy or intolerance to the implant materials.
- All cases not described in the indications.
- Translated with www.DeepL.com/Translator (free version)

5. Use

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

6. Mise en garde générale

The surgeon is solely responsible for the operation. He or she must carefully study the instructions and advice and the recommendations before using BANANA implants. In order to have a stable fixation, he must be perfectly familiar with the handling of the ancillary equipment and the recommendations for use.

7. Warnings / Operating precautions

- The surgeon must be fully familiar with BANANA implants, the application method, instruments and surgical technique.
- The components of the BANANA range must never be combined with devices from other ranges.
- The use of different ancillary components and/or improper use of the ancillary devices required for the placement of BANANA implants is strongly contraindicated as this may lead to deterioration of the implants and therefore limits the optimisation of the desired function.
- Although allergic reactions are very rare, it is recommended to check the allergic level of patients with particularly strong terrain.
- The BANANA system must be used under perfectly sterile operating conditions.
- Our implants are single-use and must never be reused. Re-use can lead to reduced device performance, contamination and cross-infection.
- Any implant removed from the patient, damaged or misused, must be disposed of as soon as it comes into contact with blood or body tissue.
- There is no known risk of mutual interference between the implant and other medical devices.
- The implants are made of Titanium Ti 6-Al 4-V alloy or PEEK Optima® which are non-magnetic materials. They do not present any real risk to patients when exposed to electromagnetic and magnetic environments.
- The patient must declare that he or she is an implant wearer before any exposure to electromagnetic and magnetic environments.
- The patient will be informed by the medical staff of the risks involved in the surgical procedure (contraindications, adverse effects/complications, precautions to be taken, limited lifetime of the device). He will also have to respect the advice and recommendations of the surgeon (radiological controls, limited physical activity, ...) during the post-operative phase.
- For adequate consolidation, it is advisable to limit physical activity after the medical device has been fitted and to carry heavy loads. Otherwise, the implant could break or be damaged, which would require a reoperation. The implant must not be exposed to excessive movements such as mechanical vibrations.
- Any changes (appearance, pain...) at the implant site must be reported to the practitioner. All types of accidents such as a fall, for example, must be reported to the practitioner even if no external signs are visible at the implant site.

8. Adverse effects / complications

Side effects or potential complications are :

- Severe pseudoarthrosis
- Risk of site infection
- Neurological and/or vascular damage related to the surgical procedure
- Displacement or expulsion of the implant requiring a new operation
- Fatigue fracture of the material
- Death.

9. Storage condition of the implants

Implants must be stored in a dry place at room temperature.

10. Sterilization

BANANA implants and instruments set are delivered non-sterile. They must be sterilised under the responsibility of the health establishment. Sterilisation must be carried out in an autoclave.

Method : Steam sterilization (moist heat)
Minimum recommended duration : 18 minutes
Minimum recommended temperature : 134°C

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

11. Additional information

Disposal and disposal of the implant follows the same procedures in place in the health care facility as hospital waste.

12. Additional information

Date of placing on the market : June 2017 (PEEK version)
February 2019 (titanium version).

Further information can be obtained from NEURO FRANCE Implants.

Explanation of symbols used on product labelling :

LOT	Batch number	NON STERILE	Non sterile
REF	Catalogue number		Single use
	Manufacturer	CE 0459	CE mark with Notified Body identification number
	Watch out! See attached documentation		

Complaints :
Any complaint or malfunction report must be made immediately either by telephone, fax, e-mail 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.