POSTERIOR LUMBO-SACRAL- SPINAL OSTEOSYNTHESIS
KM SYSTEM
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 posterior dorso-lumbar osteosynthesis KM system.

1. Description of the material

- The KM system consists of hooks, articulated transverse links, connectors, monoaxial and polyaxial pedicle screws of diameters and lengths adapted to vertebral anatomy, and nuts. The connection system consists of titanium straight bars with a diameter of 5 mm or 6 mm.
- The entire system is made of titanium alloy Ti 6-Al 4-V in accordance with the ISO 5832-3 standard.
- The KM system is available in a non-sterile state.

Origin neither human nor animal - Non absorbable.

2. Proper Usage

The KM osteosynthesis system is intended to provide fixation between two or more vertebrae. The system is achieved by means of pedicular implants and / or hooks, connected together by a bar and locked with nuts. The system performs posterior dorso-lumbo-sacral vertebral arthrodesis.
Implants are not designed to withstand anatomical mechanical stresses beyond one year without bone grafting and / or anterior fusion.

3. Expected Clinical Performance

- Decreased clinical ODI and VAS pain scores by 15% at 12 months post operatively
- Stabilization of the operated spine level(s).

4. Indications

The KM posterior lumbar osteosynthesis system is intended for the reduction, fixation of spinal disorders in the dorso-lumbo-sacral spine in adults such as :

- Degenerative spine
- Spine deformities
- Tumor
- 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 approach.
- The choice of use of the different screw sizes of the KM system must take into account the patient's corpulence and the level to be osteosynthesized. The practitioner is strongly advised to use pedicular implants with diameters and lengths adapted to the area to be osteosynthesized.

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 KM 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 KM implants, the method of application, the instruments and the surgical technique.
- The components of the KM 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 KM 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 KM 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 which is a non-magnetic material. 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 :

- Neurological pain
- Durotomy
- Risk of infection of the implantation site
- Neurological and / or vascular damage related to the surgical procedure
- Pedicular and / or lamic fracture
- Fracture of fatigue of the material
- Death.

10. Implant storage condition

The implants should be stored in a dry place at room temperature.

11. Sterilization

KM **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.

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 : March 2005
Further information can be obtained from NEURO FRANCE Implants.

Explanation of symbols used on product labeling :

LOT	Lot Number :	NON STERILE	Non-sterile
REF	Catalog Number :		Do not reuse
	Manufacturer	CE 0459	CE marking with the Notified Body's identification number
	Attention! Consult attached documentation		

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.