# THORACO LUMBAR FIXATION SYSTEM
# KM
# INSTRUCTIONS FOR USE

**Manufacturer:** NEURO FRANCE Implants
ZA LE BOURG – 25 RUE DES ECOLES
41160 LA VILLE AUX CLERCS – FRANCE
Phone: (33) 02 54 80 90 90
Fax: (33) 02 54 80 83 33

**Important information for the medical practitioner:**
The medical practitioner should carefully read the instructions and advice as well as the recommendations before using the thoraco-lumbar fixation system KM.

## 1. Description of the system

- The KM system is composed of hooks, rods, connectors, monoaxial and polyaxial pedicle screws with diameters and lengths compatible with the vertebral anatomy. The linking system is composed of straight titanium alloy rods, diameter 5 or 6mm and pre-curved PEEK rods, diameter 6mm.
- The entire system is made of titanium alloy Ti 6-Al 4-V in compliance with the ISO 5832-3 standard, except for the pre curved PEEK rods, which are made of PEEK Optima®.

## 2. Indications

The KM posterior fixation system is intended for the treatment of spine diseases with pedicular fixation such as:

- Degenerative spine
- Spine trauma
- Scoliosis (single or double curvature)
- Hyperlordosis,
- Hyperkyphosis
- Tumor
- Invalidating posterior vertebral instability.

## 3. Contra-indications

The type of treatment is determined by the practitioner who has the required medical qualification and experience.
Factors which may compromise the implantation (non exhaustive list):

- Infection
- Allergy, intolerance to components of the titanium alloy Ti 6-Al 4-V.
- Obesity
- Hyperactivity/mental disorders
- Severe vertebral osteoporosis
- Pregnancy.

## 4. Use

- Please consult the surgical technique before use.
- The surgical approach is the conventional posterior surgery.
- Choosing the right size of the KM screws must take into account certain important criteria such as the patient's corpulence and the region of the spine to be treated. It is highly recommended to use the appropriate diameters and lengths for the pedicular implants.

## 5. Warning / Operating precautions

- The surgeon must be fully experienced in the use of the KM implants, the treatment method, the instruments and the surgical technique.
- The use of similar implants in association with the KM system is proscribed.
- The surgical procedure using the KM system should only be performed with the instruments provided and in accordance with the surgical technique. If not, it may lead to a degradation of the implants that will limit the optimization of the desired function.
- Although allergic reactions are extremely rare, we recommend to make an allergy check-up on patients with a particularly strong predisposition to allergies.
- The KM system must be used under perfect sterile conditions.
- The implants are for single use only and should never be reused. Reusing the device may reduce its performances, cause contaminations and cross-infections.
- All implants explanted, damaged or having been incorrectly used should be disposed of once it has come into contact with blood or body tissues.
- There are no known risk of mutual interferences between the implants and other medical devices.
- The patient should ask for medical advice before entering potentially adverse environments (for example 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-Al 4-V or PEEK Optima®, which are non-magnetic materials. Patients may be exposed to electromagnetic or magnetic fields without any real risks. The patients with implants must notify this information before any exposure to electromagnetic or magnetic fields.
- The patient should be informed of the risks of the surgical intervention by the medical staff. The patient should follow the advice and recommendations from the surgeon (X-ray controls, …) during the postoperative phase.
- To ensure an adequate consolidation, it is recommended to limit physical activity after the implant placement and also not to carry heavy loads. If not, the implant may break or be damaged requiring a revision surgery. The implant should not be subjected to extreme movements of mechanical vibrations.
- All modifications (aspect, pain…) at the implant site and also all types of accidents (even if there are no visible signs at the implant site) should be reported to the medical practitioner.

## 6. Adverse effects

The potential adverse effects are:

- Severe pseudarthrosis
- Surgical site infection
- Neurological damage, breach of the dura mater, nerve root injury caused by the surgical procedure
- Pedicular fracture
- Laminar fracture
- Vascular damage caused by the surgical procedure
- Material fatigue fracture
- Death.

## 7. Storage conditions

Store the implants in their original packaging in a dry environment and at room temperature.

## 8. Sterilization

The KM 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/biohazard waste.

## 10. Additional information

Put on the market: March 2005
Additional information may be obtained from NEURO FRANCE Implants.

Examples of symbols used on the labels:

| | | | |
|---|---|---|---|
| LOT | Batch number | NON STERILE | Non sterile |
| REF | Catalogue number | | Single use |
| | Manufacturer | CE 0459 | CE mark with Notified Body identification number |

**Claims:**
All claims or incident reports should immediately be addressed by phone, fax or letter to NEURO FRANCE Implants.

*Revised: 23/05/2017*