SES (SES Evolution®, SES AXIS, SES PLUS) VERTEBRAL OSTEOSYNTHESIS SYSTEM
INSTRUCTIONS FOR USE

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Important information for the medical practitioner:
The medical practitioner should carefully read the instructions and advice as well as the recommendations before using the SES (SES Evolution®, SES AXIS, SES PLUS) vertebral osteosynthesis system.

1. Description of the system
- The SES system is composed of the SES Evolution®, the SES AXIS and the SES PLUS.
  The SES system has monoaxial screws (SES Evolution®, SES PLUS) and polyaxial screws (SES AXIS). It is a system with interpedicular connections by plates or rods; these require the use of hooks, connectors or articulated or simple transverse links.
- The entire system is made of titanium alloy Ti 6-AI 4-V in compliance with the ISO 5832-3 standard,
- The SES system is available in the non sterile condition.

Of neither human nor animal origin- Non absorbable.

2. Intended clinical performance
- Correction of the deformation (improvement of the Cobb angle)
- Stabilization of the level(s) treated by the spinal surgery
- Decreased actual clinical pain scores (ODI, EVA) by at least 15% at 12 months postoperatively.

The implants are not intended to withstand anatomic mechanical stresses longer than one year without bone grafting and / or prior fusion.

3. Indications
Le posterior vertebral osteosynthesis SES (SES Evolution®, SES AXIS, SES PLUS) system is intended for the treatment of adult spine diseases such as:
- Degenerative spine
- Spinal deformities
- Spine trauma

4. 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):
- Severe osteoporosis,
- Active infectious process or significant risk of infection (immuno compromised)
- Local signs of inflammation
- Fever or leukocytosis
- Severe obesity
- Pregnancy.
- Hyperactivity
- Mental disorders
- Any other medical or surgical condition that excludes the potential benefits of spinal implant surgery.
- Anomalies, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells level.
- Allergy, intolerance to metals, suspected or documented.
- All cases where the selected implant components would be too large or too small to achieve a positive result.
- Any patient with insufficient tissue coverage at the operative site or an inadequate stock or quality of bone.
- Any patient in whom the use of the implant would interfere with the anatomical structures or the expected physiological performance.
- Any patient not wishing to follow the postoperative instructions.
- Severe bone resorption, osteomalacia
- All disorders non mentioned as indications.

5. Use
- Please consult the surgical technique before use.
- The surgical approach is the posterior surgery.
- Choosing the right size of the SES system 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 suited to the area to be osteosynthesized.

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

7. Caution / Operative precautions
- The surgeon must be fully experienced in the use of the SES implants (SES Evolution®, SES AXIS, SES PLUS), the application method, the instruments and the surgical technique.
- The components of the SES range (SES Evolution®, SES AXIS, SES PLUS) must not be associated with devices of other ranges.
- The use of different instruments and/or the incorrect use of the instruments necessary for the implantation of the SES (SES Evolution®, SES AXIS, SES PLUS) system is proscribed and 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 SES (SES Evolution®, SES AXIS, SES PLUS) 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 implants are made of titanium alloy Ti 6-AI 4-V which is a non-magnetic material. 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 exposed to extreme 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.

8. Adverse effects
The potential adverse effects are:
- Neurological pain
- Breach of the dura mater
- Surgical site infection
- Neurological or vascular damage caused by the surgical procedure,
- Pedicle and/or laminar fracture
- Material fatigue fracture
- Death.

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

10. Sterilization
The SES (SES Evolution®, SES AXIS, SES PLUS) 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.

11. Disposal of the implants
Implants must be disposed of according to the relevant hygiene and waste disposal guidelines of the healthcare facility for medical/biohazard waste.

12. Additional information
Additional information may be obtained from NEURO FRANCE Implants.
Put on the market: January

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 the 10/01/2019