SES PLUS DORSO-LUMBAR-SACRAL POSTERIOR AND ANTEROLATERAL OSTEOSYNTHESIS SYSTEM
INSTRUCTIONS FOR USE

Manufacturer: NEURO FRANCE Implants
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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 PLUS posterior and anterolateral dorso-lumbar osteosynthesis system.

1. Description of the system
- The SES PLUS system is composed of monoaxial screws and a system of connections by rods; these require the use of hooks, connectors, articulated or simple transverse links, nuts and 3D washers.
- The entire system is made of titanium alloy Ti 6-Al 4-V in compliance with the ISO 5832-3 standard,
- The SES PLUS system is available in the non sterile condition.

Of neither human nor animal origin. Non absorbable.

2. Intended use
The SES PLUS osteosynthesis system is intended to achieve fixation between two or more vertebrae. The system is achieved by means of screws implanted in the pedicles or vertebral bodies, supplanted by hooks, and linked together by a bar and immobilized by means of nuts. The system performs posterior dorso-lumbo-sacral or anterolateral vertebral arthrodesis.
The implants are not intended to withstand anatomic mechanical stresses for longer than one year without successful bone grafting and/or without prior bone fusion.

3. Intended clinical performance
- Stabilisation of the vertebral column level(s) which have undergone surgery in over 90% of cases.
- Reduction in current clinical pain and invalidity scores (VAS, ODI) by at least 40%, 12 months post-operatively.
- In the case of scoliosis: improvement in the Cobb angle by at least 40%.

4. Indications
The SES PLUS posterior or anterolateral dorso-lumbo-sacral osteosynthesis system is intended for the treatments of vertebral column disorders from T1 to S2 in adults, such as:
- Degenerative disc disease
- Spondylolisthesis
- Spinal deformity (i.e. scoliosis)
- Trauma (i.e. fracture)

5. 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.

6. Use
- Please consult the surgical technique before use.
- The surgical approach is the posterior or anterolateral surgery.
- Choosing the size of the SES PLUS system screws must take into account certain important criteria such as the patient's corpulence and the level of the spine to be treated. It is highly recommended to use the appropriate diameters and lengths suited to the area to be osteosynthesized.

7. 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 PLUS implants. To achieve a stable fixation, he must know perfectly the handling of ancillary equipment and the recommendations for use.

8. Caution / Operative precautions
- The surgeon must be fully experienced in the use of the SES PLUS implants, the application method, the instruments and the surgical technique.
- The components of the SES PLUS range 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 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-Al 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 (contraindications, adverse effects / complications, precautions to be taken, limited lifespan of the device).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.

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- 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.

9. Adverse effects
The potential adverse effects are:
- Neurological pain
- Durotomy
- Haematoma
- Adjacent disc disorder
- Superficial or deep infection of the implantation site
- Neurological and/or vascular damage due to the surgical procedure
- Pedicular and/or laminar fracture
- Stress fracture and/or migration of materials
- Death.

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

11. Sterilization
The 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.

12. 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.

13. Additional information
Additional information may be obtained from NEURO FRANCE Implants.
Put on the market: March 2019

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.

Please read the instructions carefully.
These implants are class IIb medical devices and are marked :

CE 0459

Our notified body is the GMED. *Revised the 17-02-2021*