LUMBO-SACRAL-SPINAL OSTEOSYNTHESIS SYSTEM POSTERIOR
G2S® GLOBAL SPINE
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 system G2S.

1. Description of the material

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- The G2S® system consists of hooks, monoaxial and polyaxial pedicles, cannulated and not cannulated, screws for the pathology of spondylolisthesis, cement injection screws, and revision screws of diameters and lengths adapted to the vertebral anatomy. The connection system consists of straight or pre-curved titanium bars of 5 mm and 5.5 mm diameters, connectors, articulated cross links, and nuts.
- The entire system is made of titanium alloy Ti 6-Al 4-V in accordance with the ISO 5832-3 standard.
- The G2S® system is available in a sterile and non-sterile state.
- The G2S® system can be used in conjunction with the SpineGuard DSG® system.
- For cement injection screws, Teknimed F20® Surgical Cement is supplied only on request.

Origin neither human nor animal - Non absorbable.

2. Usage revendiqué

The G2S® osteosynthesis system is designed to achieve fixation between two or more vertebrae. The system is made up of pedicle implants and/or hooks, connected to each other by a bar and locked with nuts. The system performs a posterior dorsolumbosacral vertebral arthrodesis.
The 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 G2S® Posterior Dorsal-Lumbar Osteosynthesis System is intended for the treatment of spinal conditions requiring pedicle fixation such as :

- Degenerative spine
- Spine deformity
- Tumor
- Trauma

5. 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)
- 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.
- Abnormalities, elevated sedimentation rate unexplained by other diseases, elevated white blood cell count.
- Suspected or documented allergy or intolerance to implant materials.
- Any case where the implant components selected for use would be too large or too small to achieve a positive result.
- Any patient with insufficient tissue coverage at the surgical site, or inadequate bone stock or bone quality.
- Any patient in whom the use of the implant would interfere with anatomical structures or expected physiological performance.
- Any patient unwilling to follow postoperative instructions.
- Severe bone resorption, osteomalacia
- Any case not described in the indications.

6. Use

- Consult the surgical technique before use.
- The surgical approach is the classical posterior approach, the percutaneous posterior approach and MIS (Minimally Invasive Surgery).
- The choice of using the different sizes of screws of the G2S® system must take into account the patient's build and the level to be osteosynthesised. The surgeon is strongly advised to use pedicle implants of the appropriate diameter and length for the area to be osteosynthesized.
- When the G2S® system is used in combination with the SpineGuard DSG® system, special care should be taken to use the screw holder equipped with the DSG® bipolar sensor:
  - It is strongly recommended to take measurements on the scan pre-operatively to determine the correct screw size to use.
  - The DSG® bipolar sensor must protrude 3±1 mm from the end of the screw;
  - The screw lock should be made opposite the marking indicating the screw length.
  - Carefully remove the DSG® guide wire.

  Refer to the SpineGuard operating technique for further details.

- When using cement-injected screws, Teknimed F20® cement or equivalent is recommended. It is a medium viscosity radiopaque surgical cement with a long working time.
  Please refer to the F20® Operator Information Sheet for further details.

7. General warning

The surgeon is solely responsible for the operation. The surgeon must carefully study the guidelines and recommendations before using G2S® implants. In order to achieve a stable fixation, the surgeon must be familiar with the handling of the ancillary material and the recommendations for use.

8. Warnings / Operating Precautions

- The surgeon must be thoroughly familiar with G2S® implants, the method of application, the instruments and the surgical technique.
- G2S® components must not be combined with devices from other ranges.
- The use of different ancillary components and/or improper use of ancillary devices for the placement of the G2S® System is strongly contraindicated as it may lead to damage to the implants and thus limit the optimization of the desired function.
- Although allergic reactions are very rare, it is recommended that patients with a particularly strong allergy be checked for their level of allergy.
- The G2S® System should be used under completely sterile operating conditions.
- Our implants are for single use only and should never be reused. Re-use may result in reduced performance, contamination and cross-infection.
- Any implant that has been removed from the patient, damaged or misused, should be disposed of as soon as it has come 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 Ti 6-Al 4-V titanium alloy which is a non-magnetic material. They do not pose any real risk to patients when exposed to electromagnetic and magnetic environments.
- The patient must declare that he/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/she should also respect the surgeon's advice and recommendations (radiological controls, limited physical activity, ...) during the post-operative phase.
- For adequate consolidation, it is advisable to limit physical activity after the placement of the medical device and the carrying of heavy loads. Otherwise, the implant may rupture or be damaged, requiring re-operation. The implant should not be exposed to excessive movement, e.g. mechanical vibrations.
- Any changes (appearance, pain, ...) in the implant site should be reported to the practitioner. All types of accidents should be reported to the practitioner even if no external signs at the implant site are visible.

9. Adverse effects / complications

Potential adverse effects or complications include

- Neurological pain
- Durotomy
- Risk of infection of the implantation site
- Neurological and/or vascular damage related to the surgical procedure
- Pedicle and/or laminar fracture
- Fatigue fracture of the material
- Death.

10. Condition of storage of implants

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

11. Sterilisation

- Implants and ancillaries delivered non-sterile

G2S® **implants** and **instrument set** are delivered non-sterile. They must be sterilised under the responsibility of the sterilisation manager of the health care establishment. Sterilisation must be carried out in an autoclave.

Method: Steam sterilisation (moist heat)
Minimum recommended time: 18 minutes
Minimum recommended temperature: 134°C

It is recommended that the sterilisation indicator(s) be checked before opening and that the integrity of the packaging be verified.

- Implants delivered sterile

G2S® implants are delivered sterile in a double vacuum package in a cardboard box, filmed and identified. Sterilisation is carried out by gamma radiation of at least 25 kGy from cobalt 60 sources.

Caution: Do not use these implants in the following case: absence of vacuum which proves a violation of the packaging, which means loss of sterility.

It is recommended to check the integrity of all packaging levels before use and the expiry date.
Product labels are placed inside the package to ensure traceability in health care facilities.

It is recommended that the sterilisation indicator(s) be checked before opening and that the integrity of the packaging be verified.

12. Disposal of implants

Implants must be disposed of following the same procedures as hospital waste in the healthcare facility.

13. Additional information

Date of placing on the market : October 2014

Further information can be obtained from NEURO FRANCE Implants.

Explanation of symbols used on product labeling :

STERILE R	Sterilised using irradiation		Manufacturer
REF	Catalogue number		Date of manufacture
LOT	Batch code		Do not use if package is damaged
	Use by date		Attention! Consult attached documentation
	Do not reuse	CE 0459	CE marking with the identification number of the notified body
NON STERILE	Non-sterile		

Complaints :

All complaints or reports of malfunctions must be made immediately either by telephone, fax, e-mail or post 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.