G2S® GLOBAL SPINE 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 G2S® Global Spine System.

1. Description of the system
- The G2S® system is composed of hooks, pedicle screws (monoaxial and polyaxial, cannulated and non-cannulated, spondylolisthesis or not), cement-injectable cannulated screws, revision screws which diameters and lengths are compatible with the vertebral anatomy. The linking system is composed of 5mm and 5.5mm diameter rods, connectors and cross links.
- The entire system is made of titanium alloy Ti 6-Al 4-V in compliance with the ISO 5832-3 standard.
- The G2S® system can be used in association with the DSG™ (Dynamic Surgical Guidance) technology of SpineGuard.
- For the cement-injectable cannulated screws, the radiopaque bone cement F20® of Teknimed can be supplied on demand.

2. Indications
The G2S® posterior fixation system is intended for the treatment of spine diseases with pedicular fixation such as:
- Degenerative Spine
- Osteoporotic Spine
- Spine trauma
- Tumor
- Scoliosis (single or double curvature)
- Hyperlordosis, hyperkyphosis
- Spondylolisthesis
- Revision surgery for pseudarthrosis
- 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.

4. Use
- Please consult the surgical technique before use.
- The surgical approach is the conventional posterior surgery, the percutaneous posterior surgery, and also the MIS (Minimally Invasive Surgery).
- Choosing the right size of the G2S® 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.
- When the G2S® system is used in combination with the DSG™ technology of Spineguard, please take a particular care to the use of the screw holder equipped with the DSG™ bipolar sensor:
  - It is highly recommended to take the measures on the scan during the preoperative phase in order to determine the right screw size to use.
  - The DSG™ bipolar sensor should protrude approximately 3±1mm beyond the tip of the screw.
  - The screw should be locked respecting the marking which indicates the screw length.
  - Remove the DSG™ pin carefully.

  For more information, please consult the SpineGuard's surgical technique.
- When using the cement-injectable cannulated screws, the radiopaque bone cement F20® of Teknimed or equivalent is recommended.
  F20® is a surgical cement of medium viscosity with a high radio-opacity and a long working time.
  For more information, please consult the operator information document for F20®.

5. Warning / Operating precautions
- The surgeon must be fully experienced in the use of the G2S® implants, the treatment method, the instruments and the surgical technique.
- The G2S® system screws must be used only with 5mm and 5.5mm diameter rods.
- The use of similar implants in association with the G2S® system is proscribed.
- The surgical procedure using the G2S® system should only be performed with the instruments provided and according to 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 G2S® 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 which is a non-magnetic material. Patients may be exposed to electromagnetic or magnetic fields without any real risks. Patient 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:
- 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.

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

8. Sterilization
The G2S® 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: October 2014
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.

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