SACRONAIL® – Transsacral Stabilization

Product Description:
The present implant system offers sustainable, stable treatment of dorsal pelvic ring fractures and sacral insufficiency fractures due to its intraosseous location as well as its direct, biiliac symmetrical anchorage. Anatomical structures are restored by implant design and surgical method, and the blood supply to the pelvis is preserved. It is possible to accommodate the patient's anatomical features through a variety of implant component size increments and a precisely defineable compression distance intraoperatively. The angular stability gives the implant system a high degree of stability; movements of the pelvis do not lead to loosening of the individual components in relation to each other.

Indications for Use Statement:
The SIGNUS SACRONAIL Transsacral Stabilization System is intended for fixation of fractures of the posterior pelvis, in areas of superior posterior iliac spine and posterior inferior iliac spine, for sacral fractures and fracture-dislocations of the sacro-iliac joint.

Intended Use:
The insertion is performed in a minimally invasive surgical technique after lateral access at the os ilium at the level of S1 and / or S2 corridor in the case of:
- Bilateral unstable lesions of the posterior pelvic ring (SI dislocations ±sacral fractures)(AO / OTA classification: 61B3, 61C2 + 61C3 with the exception of 61C3.1.1 + 61C3.1.2).
- Transiliosacral fractures with type III according to Gay's classification (Gay et al. 2007).
- Type II (when conservative treatment did not produce a positive outcome) to Type IV fractures according to Rommens classification (Rommens et al. 2013).
- Tumor-related trauma with fracture risk in the posterior pelvic ring region.
- Pseudarthrosis/s in fracture/s of the posterior pelvic ring.

Contraindications:
- Fractures according to AO / OTA classification: 61C3.1.1 + 61C3.1.2
- Type I unstable fractures of the pelvis (Rommens Klassifikation, Rommens et al. 2013).
- Allergic reaction to the implant material
- Morel-Lavallée lesion
- Insufficient skin coverage (patient- and/or trauma-related) in the area of the surgical field.
- Insufficient bone stability
- Probable or present infections of the pelvic ring.
- Young patients with unstable, unilateral lesions of the posterior pelvic ring.
- Obesity
- Traumas which are not listed under indications.

Material:
The implant is made of the following material:
- Titanium alloy (TiAl6V4) according to ASTM F 136 / ISO 5832-3

Composition:
For all titanium alloy TiAl6V4 products:
- Nickel free according to ASTM F 136 / ISO 5832-3 Nitrogen 0.05 % max, Carbon 0.08 % max,
- Hydrogen 0.012 % max, iron 0.25 % max, oxygen 0.13 % max, aluminum 5.5 – 6.5 %, vanadium 3.5 – 4.5 %, balance titanium.

The materials are established for use as implants. They are biocompatible, corrosion resistant and non-toxic in the biological environment.

Sterility:
Implants and instruments supplied non-sterile must be reprocessed according to hospital guidelines before use. The implants and instruments are delivered in the implant/instrument trays provided by SIGNUS or, in the case of repeat orders, in suitable protective packaging. Implants and instruments must be stored in their original packaging or in the implant/instrument trays.

Preparation:
Non-sterile implants and instruments must be prepared before use.
- Before reprocessing, all packaging parts must be removed completely.
- All non-sterile implants and instruments must be reprocessed in the SIGNUS sieves.
- Observe the validated reprocessing procedure in the instructions enclosed with the sieve!
- Products with cavities as well as joints, threads, joints and springs are to be rinsed off / through in an ultrasonic bath for 10 minutes at 40° C in a 0.5 % alkaline cleaner and then for 20 seconds at approx. 4 bar static pressure (line pressure) with cold tap water.

In the case of sterilization, the following must be observed:
- Process: Steam sterilization process (fractionated prevacuum process)
- Temperature: minimum 132°C, maximum 137°C
- Cycles: At least 4-fold pre-vacuum
- Sterilization time: At least 4 minutes
- Drying time: Adjust according to the load of the sterilizer, sterile items must be dry The implant and instrument sieve used must undergo a validated cleaning procedure before being returned. This must be documented on the accompanying certificate provided and enclosed with the return shipment.

Storage and transport conditions:
The products are to be stored between 0° and 35° C. For transport, temperatures up to 40° C can be accepted for a short time.

Warnings:
- The implants as well as guide wires/guide pins and obturator wires are intended for single use only and cannot be reused. Reuse may result in failure of the implant or instrument, infection and/or death.
- Implants as well as guide wires/guide mandrels and obturator wires must be considered potentially infectious after use and disposed of properly (medical hazardous waste) in accordance with the applicable hygiene and waste disposal regulations. Instruments must be disposed of in the same way at the end of their life or properly reprocessed before disposal.
- SIGNUS implants may only be inserted with the instruments intended for this purpose. Correct implantation cannot be guaranteed if the implants are inserted using other instruments.
- Unless otherwise specified, SIGNUS products must not be combined with the materials/components of other systems.
- An additional fixation of the anterior pelvic ring cannot be generally omitted by the use of SACRONAIL® and is the decision of the treating physician.

USA: Restricted by federal law, the implant may only be sold to, used by, or on the order of physicians.

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SIGNUS The Spine Sign®

Precautions:
- Check the implant for scratches and other obvious damage. A damaged implant must not be used.
- The applied size indication must be compared with the one determined with the length indicator.
- Do not knock in the implant.
- Special attention should be paid to the protection of nervous structures and blood vessels.

Application:
- Excessive compression may result in neurological lesions or iatrogenic fractures. The application and amount of compression force is the responsibility of the user. The bone quality is decisive here.
- The indication, selection and implantation are the responsibility of the practitioner, who must be experienced and trained in performing osteosynthesis of the pelvic ring.
- All information on the surgical technique, the implant assortment, the instruments and their use are described in detail in the SIGNUS product information. This information must be available on site and known to the surgical team.
- Before performing the operation, ensure that all necessary implants and instruments are available and functional on site.
- Only the instruments provided by SIGNUS and described in the product information must be used to implant the system.
- If the preoperative situation is unclear and related to the implant system, information must be obtained from SIGNUS.
- Prior to surgery, the patient must be informed of all potential risks and complications associated with the procedure itself and the use of the implant.
- When inserting the implant, refrain from using excessive force to protect the adjacent structures.
- During and after the implantation procedure, the correct position of the implant components of the system must be checked radiographically.
- It is mandatory that the final fixation of the locking screws and screw caps is carried out with the SIGNUS torque limiter.
- The implant used must be documented in the patient file with the article number, designation and lot number.
- Aftercare must be individually tailored to the patient and defined by the attending physician. After the operation, physical activities should only be permitted by the patient to a very limited extent. This applies in particular to lifting weights, twisting movements and any kind of sporting activity. Falls or sudden jerky movements should be avoided.

Risks:
General risks of a surgical procedure and complications that may occur during a spinal procedure are not listed in these instructions for use.
Potential risks and complications associated with the implant that may require revision surgery include:
- Wear, bending or breakage of implant components
- Loss of fixation, dislocation, sintering
- Foreign body susceptibility, allergic or other local/systemic side effects with regard to the implant materials used.
- Misplacement
- Neural lesions with reversible or permanent neurological deficits or paralysis.
- Infection
- Nerve root/spinal canal injury and/or perforation
- Visceral injury/deep infection.
- Temporary paraparesis
- Pseudoarthrosis/failure to fuse
- Screw loosening
- Pain or recurring pain
- Pressure exerted by component parts on surrounding tissue in patients with insufficient tissue cover

These risks can result in injury to surrounding tissues, nerves and blood vessels in all degrees of severity, including death.
SIGNUS Medizintechnik GmbH has not approved the use of bone cement (e.g. PMMA) in the treatment with this system.

MRI Notes:
The SACRONAIL® has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of SACRONAIL® in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Product warranty:
SIGNUS Medizintechnik GmbH guarantees that each implant has been manufactured, packaged and tested with the greatest possible care from selected materials and under constant control of the manufacturing processes. Since SIGNUS Medizintechnik GmbH has no influence on the conditions under which an implant is inserted and used, on the patient's diagnosis, on the method of application and on the handling of the implant after it has left the factory, SIGNUS Medizintechnik GmbH guarantees neither the success nor the absence of complications. Please inform SIGNUS immediately of any (possible) malfunction that becomes known, stating the article number(s) and the lot number(s).

Labeling:
The symbols that may be applied to the packaging of SIGNUS products are explained below:

	CE marking		Manufacturer and date of manufacture
	Do not reuse	STERILE R	Radiation sterilized
REF	Item number	NON STERILE	Non-sterile
	Usable until	LOT	Batch code
	Do not sterilize again	eIFU	Electronic instruction manual Note (eifu.signus.com)
0°C 35°C	Temperature limit		Do not use if packaging is damaged

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