DIANA® – Sacroiliac Fusion System

Product description:
DIANA® is an implant for use on the sacroiliac joint. The implant serves as a mechanical component for the primary fixation of the sacroiliac intra- and extra-articular distraction arthrodesis until bony fusion occurs. The implant is not explanted again but remains in the patient.
The system is available in various sizes to enable adaptation to different patient anatomies. A tapered, cylindrical implant made of a titanium alloy is at the core of the DIANA® sacroiliac fusion system. It is hollow and radially fenestrated to promote osseointegration. A thread for the primary fixation and stabilisation of the sacroiliac joint is located on the outer surface.
The implantation of DIANA® is performed via posterior access.
Implantation is facilitated by use of the specially developed accessories for insertion and positioning of the implant. Only these accessories ensure safe use.
The corresponding product information provides further system-related information on the surgical method.

Indications:
DIANA® can be used in:
skeletally mature patients with painful sacroiliac joints requiring surgical stabilization through bone grafting and internal fixation.

Contraindications:
- Anomalous bone density, osteoporosis or osteomalacia that prevents stable anchorage of the implant
- Acute or chronic bone or skin infections
- Allergy or intolerance to the implant material
- Metabolic or nutritional disorders that adversely affect the postoperative healing process
- Surgical conditions that rule out any potential benefit from sacroiliac surgery (such as severe damage to bone structures at the implantation site, badly distorted anatomy due to anomalies)
- Medical conditions that could prevent successful implantation (e.g. obesity, mental disorders, pregnancy, paediatric cases, patients in poor general health, systemic or metabolic diseases, lack of patient compliance)
- Cases that are not mentioned under Indications
- Insufficient skin or tissue coverage
- Patients in whom placement of an implant would influence the anatomic structures or the anticipated physiological performance
- Pelvic pain or instability due to primary or metastatic neoplasia
- Developmental or post-traumatic deformities that prevent implantation of the system
- Sacroiliac instability, ligamentous laxity or other ligamental disorders
- Bone surface unsuitable for bone grafting
- Insufficient radiological imaging of the surgical landmarks
- Insufficient surgical experience/training or knowledge of the procedural technique
- Unsuitable bone/bone graft material for performing arthrodesis
- Incomplete or damaged instruments including guidewires, distractors, drilling templates required for the preparation and performance of the implantation steps
- Patient stature too small or too large for the range of instruments and implants
- Insufficient mental or emotional condition to undergo, participate in or recover from major surgery
- Lack of proximity to a medical facility for assessment, reassessment and support/revision of treatment

Material:
The implant is made of the following material:
- Titanium alloy (Ti-6Al-4V) as per ASTM F 136 / ISO 5832-3

Composition:
Titanium alloy (Ti-6Al-4V) as per ASTM F 136 / ISO 5832-3.

For all products made of titanium alloy Ti-6Al-4V:
Nickel-free as per 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, aluminium 5.5–6.5 %, vanadium 3.5–4.5 %, rest titanium.

The implants are coated with oxide layers in different colours for easy identification. Colour changes are caused by factors related to production and reprocessing and do not affect the functionality.

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

Sterility:
Sterile implants and instruments are supplied in double sterile packaging and are gamma sterilised in accordance with DIN EN ISO 11137. They are intended for single use only and are not reusable. Reprocessing and/or reuse can result in infection and/or loss of function and in extreme cases may lead to the death of the patient. Products with opened primary sterile packaging will not be accepted by SIGNUS and must be disposed of properly.
Instruments supplied non-sterile must be processed before use in accordance with hospital guidelines. The instruments are shipped in instrument trays provided by SIGNUS or in a suitable protective packaging for re-orders. Instruments must be stored in their original packaging or in the instrument tray.

Reprocessing:
Non-sterile instruments must be reprocessed before use:
- Completely remove all components of the packaging prior to reprocessing
- All non-sterile instruments must be reprocessed in the SIGNUS trays
- Observe the validated reprocessing procedure in the instructions included with the tray
- Products with cavities as well as gaps, threads, joints and springs must be placed in an ultrasonic bath for 10 minutes at 40°C in a 0.5 % alkaline cleaning solution and then rinsed/flushed for 20 seconds with cold mains water at about 4 bar static pressure (mains pressure)

During sterilisation the following must be noted:
- Procedure: Steam sterilisation method (fractionated pre-vacuum method)
- Temperature: Minimum 132°C, maximum 137°C
- Cycles: At least 4 pre-vacuum pulses
- Sterilisation time: At least 4 minutes (sterilisation time of the one-piece DIANA® tray (SH01AY) with plastic insert (SH01AZ): At least 10 minutes)
- Drying time: Adjust the drying time in accordance with the loading of the steriliser; items to be sterilised must be dry

The instrument tray must undergo a validated cleaning process before being returned to SIGNUS. This must be documented on the delivery note provided, which must be enclosed with the return shipment.

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CE 0483

SIGNUS The Spine Sign®

Labelling:
Explanation of the symbols that may be used on the packaging of SIGNUS products:

CE 0483	CE marking		Manufacturer and date of manufacture
	Do not re-use	STERILE R	Sterilised using irradiation
REF	Item number	NON STERILE	Non-sterile
	Use by	LOT	Batch code
	Do not resterilise	eIFU	Consult the electronic instructions for use (eifu.signus.com)
0°C 35°C	Temperature limit		Do not use if package is damaged

Storage and transport conditions:
Store the products between 0°C and 35°C. During transport, temperatures of up to 40°C for short periods can be tolerated.

Warnings:
- The spinal implants and single-use instruments (Art. No. SH0022 and Art. No. SH0023) are intended for single use only and must not be re-used. Re-use of an implant can cause failure of the implant or instrument, infections and/or death.
- Implants and single-use instruments must be considered as potentially infectious after use. They must therefore be disposed of properly (hazardous medical waste) according to the relevant hygiene and waste disposal guidelines. At the end of their service life, instruments must be similarly disposed of or prepared correctly before disposal.
- SIGNUS implants must be used only with the specified instruments. Correct implantation cannot be guaranteed if implants are placed with other instruments.
- Unless otherwise specified, SIGNUS products must not be combined with the materials/components from other systems.
- The revision implant is never used for primary implantation.

USA: Federal law restricts the sale of this product by or on the order of a physician.

Precautions:
- Store sterile implants and instruments in their original packaging.
- Do not remove instruments from their protective packaging until immediately before use.
- Check expiry date and integrity of the sterile packaging before use.
- Check the implant for scratches and other obvious damage. A damaged implant must not be used.
- Particular attention must be paid to the protection of the nerve structures and blood vessels.

Physiotherapy should not be performed postoperatively before the bone has healed properly.

Application:
- The attending physician, who must be trained and experienced in carrying out spinal interventions, is responsible for determining the indication, selecting the implant and performing the implantation.
- All information about the surgical technique, the range of implants, the instruments and their use is provided in detail in the SIGNUS product information. This information must be available on site and must be known to the surgical team.
- Before performing the surgery, ensure that all necessary implants and instruments are to hand and fit for purpose.
- If there are any preoperative uncertainties relating to the implant system, information must be obtained from SIGNUS.
- Before the surgical intervention, the patient must be informed of all possible risks and complications that can arise in connection with the intervention itself and with use of the implant.
- The surgery must be carried out under fluoroscopic guidance. The correct position of the implant must be verified using radiography.
- Important: The patient must be placed in a stable position to avoid too much lordosis in the lumbar spine as this makes visualisation and exposure of the recess difficult.
- The implant must be firmly connected to the inserter intended for the implant to prevent damage to the implant and potential injury to the patient.
- To optimise the fusion result, it is absolutely necessary to fill bone graft and/or bone graft material into the extra-articular area and in and around the implant.
- The DIANA® implant may only be implanted with the special instruments supplied by SIGNUS; the use of other instruments is not permitted. The instruments developed by SIGNUS are specifically adapted to implants and help to prevent incorrect manipulation to a large extent.
- For correct implantation, the target-oriented instruments specified in the handling instructions must be used. The unguided implantation of the DIANA® implant is not permitted.
- When positioning the patient, care must be taken not to position the pelvis at column height to ensure interference-free fluoroscopy. The image receiver system of the C arm must be located as close as possible to the body area being examined for all fluoroscopic images.
- The dissection of the recess should be performed under microscopic guidance.
- The decorticated recess must be treated like a bone defect which has to make do without the usual compression from the corresponding bone surfaces. For this reason it is absolutely essential to precisely adhere to all the remaining principles of bone healing.
- The position of the guide sleeve must not be altered when replacing the wire.
- In the event that the smallest helix (13 mm) cannot be screwed in forward – the access should be opened carefully up to the front edge of the sacrum with the aid of the pre-milling cutter.
- The implant used must be documented in the patient record, indicating the article number, designation and batch number. All necessary data are indicated on the labels in the original packaging or are printed on the implants and must be pasted into the patient record to ensure lot traceability.
- Aftercare and follow-up examinations must be tailored to the individual patient's requirements and must be determined by the treating physician. After the intervention, the patient should be allowed only very limited physical activity for an appropriate postoperative period. This applies in particular to the lifting of loads, rotating movements and any type of sport. Falls and sudden, jerky movements of the operated region must be avoided.
- In the postoperative phase, special care must be taken to ensure that the patient is given all the necessary information by the treating physician according to the patient's individual requirements.

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Explanation of the symbols that may be used on SIGNUS implants:

	Lordosis angle
	Height of the cage
	Footprint of the cage
SW	Wrench size
CoCr	Material cobalt-chrome

Risks:
These instructions for use do not list the general risks associated with surgery or the complications that can arise from spinal surgery.
The following are potential risks and complications related to the implant and which may necessitate repeat surgery:
- Loss of anchorage/fixation, subsidence or dislocation of the implant
- Sensitivity to foreign bodies, allergic reactions or other local/systemic adverse reactions to the implant materials used
- Incorrect placement
- Infection
- Wear or breakage of implant components
- Pain or recurrent pain
- Absence of fusion

These risks can potentially lead to injuries of all degrees of severity to the surrounding tissue, the nerves and blood vessels, which can in extreme cases even lead to death.

MRI notes:
The safety and compatibility of DIANA® in an MRI environment was not determined. The product has not been tested with regard to heating, migration or artefact formation in an MRI environment.

Product warranty:
SIGNUS Medizintechnik GmbH guarantees that every spinal implant has been manufactured, packaged and tested with the greatest possible care using selected materials and that all processes involved are subject to continuous quality control. Since SIGNUS Medizintechnik GmbH has no influence on the conditions under which a spinal implant is applied and used, nor on the diagnosis of the patient, the method of application or the handling of the spinal implant after leaving the factory, SIGNUS Medizintechnik GmbH gives no warranty either for the success of the procedure or for the non-occurrence of complications. Please inform SIGNUS immediately of any (potential) malfunction of which the user is aware, including the article number(s) and the lot number(s).