DIANA® – Sacroiliac Fusion System

Product description:
The DIANA sacroiliac fusion device is a tapered hollow cylindrical implant made of titanium alloy. It is hollow and has radial fenestrations to encourage bony in-growth. The outer surface of the device is threaded to provide fixation and to stabilise the sacroiliac joint. Several sizes are available to match the patient's individual anatomy.

The implant serves as the mechanical component to temporarily stabilise the sacroiliacal intra- and extraarticular distraction arthrodesis until fusion occurs. It will not be explanted, but remains in the patient. To improve the fusion results it is mandatory to place bone graft and / or bone substitute, for example KAINOS®+, into the extra-articular space and into and around the implant.

Instruments specially developed by SIGNUS for use with the implant system are available to ensure safe application.

Area of application:
DIANA is a sacroiliac fusion implant for stabilisation of the sacroiliac joint. This implantation is performed through a posterior approach.

Indications:
Painful sacroiliac joints in skeletally mature patients, requiring surgical stabilisation by bone grafting and internal fixation.

Contraindications:
Acute or chronic infection of bone or skin. Hypersensitivity or allergy to implant material. Deformity, post traumatic or developmental, that will not accept the device. Inadequate bone density, osteoporosis or osteomalacia to hold the device. Compromised metabolic or nutritional status that will impair postoperative healing. Inadequate skin or soft tissue coverage. Sacroiliac instability, or ligamentous laxity or inadequacy. Inadequate bone surface area to accept a bone grafting procedure. Inadequate ability to visualize with proper imaging equipment/bone landmarks. Inadequate surgical training and experience with the technique. Inadequate or inappropriate bone graft bone substitute or bone-like material to accomplish the grafting/arthrodesis procedure successfully. Incomplete set of the necessary instruments, including proper guide pins and tools for the distracting, alignment drilling, preparation and implantation steps. Very small or very large stature outside the range of available surgical tools and implants. Surgical conditions that preclude the possible benefits of sacroiliac surgery (e.g. severe damage to bony structures at the implant site, severely deformed anatomy due to anomalies). Medical conditions that could be an obstacle to successful implantation (e.g. obesity, mental illness, pregnancy, paediatric cases, poor general health, lack of cooperation on the part of the patient). Inadequate psychosocial or psycho-emotional resources to undergo or recover from complex surgery. Inadequate physical proximity to medical care, to undergo evaluation, re-evaluation and support/revision of the procedure. Pelvic pain or instability due to neoplasia, primary or metastatic. Cases not included in the indications

Material:
This implant is made of a titanium alloy (Ti6Al4V) according to ASTM F 136 / ISO 5832-3

Composition:
Titanium alloy (Ti6Al4V) as per ASTM F 136 / ISO 5832-3.
For all products made of titanium alloy Ti6Al4V:
Nickel-free as per ASTM F 136 / DIN 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%, remainder titanium.

The material is an established material for use as an implant. It is biocompatible, corrosion-resistant, non-toxic in the biological environment and allows for interference-free X-ray imaging.
The effects of an MR environment have not been ascertained for this implant. This implant has not been tested with regard to heating or migration in an MR environment.

Sterility:
All implants are supplied in double sterile packaging, and are gamma-sterilised in accordance with DIN EN ISO 11137.

Warning notices:
- Store the implants under suitable conditions in the original packaging.
- Before use check the expiry date and the integrity of the sterile packaging. Do not use if sterile package is, or appears to be, damaged.
- Only remove from the protective packaging immediately before use.
- Implants and single-use instruments are not intended to be reused once they have been used.
- Re-use after reprocessing can result in failure of the implant or instrument, infection and / or death of the patient.
- 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.
- The combination of implants made of different metallic materials is not permissible, unless this is expressly intended by SIGNUS.
- Check the implant for scratches or other evident damage. A damaged implant must not be used.
- Store the implants at temperatures between 0°C and 35°C. During transport, temperatures of up to 40°C for short periods can be tolerated.

Reprocessing of the instruments:
- Instruments must be reprocessed before use.
- Completely remove all components of the packaging prior to reprocessing.
- Observe the validated reprocessing procedure, cleaning and steam sterilisation, in the instructions included with the tray.
- Before returning an instrument tray, the used instrument tray must undergo a validated cleaning procedure. This reprocessing 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	STERILE R	Sterilised using irradiation
	Do not re-use	NON STERILE	Non-sterile
REF	Item number	LOT	Batch code
	Use by		Consult instructions for use
0°C 35°C	Temperature limit		Do not use if package is damaged
	Manufacturer and date of manufacture		

Application:
- Establishing the indication, selecting the implant, and the implantation remain the responsibility of the surgeon, who must be experienced and trained in performing spinal procedures and who is therefore familiar with the surgical procedure and aware of the intended use, indications and contraindications.
- All information on 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 the surgical team must be familiar with it.
- Before performing the operation, ensure that all necessary implants and instruments are ready and fit for purpose.
- If there are any pre-operative uncertainties relating to the implant system, information must be obtained from SIGNUS.
- Before surgery, the patient must be informed of all possible risks and complications that can arise in connection with the intervention itself, and from use of the implant.
- The DIANA implant must only be used with the appropriate instruments supplied by SIGNUS. Other instruments may not be used. SIGNUS instruments are specially adapted to implants to avoid incorrect use.
- The implantation must be performed with the guiding instruments provided. Unguided, 'free hand' implantation is not allowed and will lead to implant misplacement.
- During the implantation procedure, verify the correct position of the implant by radiography.
- The article number, description and batch number of the implant used must be documented in the patient's records. All necessary data are shown on the original packaging labels and must be pasted into the patient's records to ensure batch traceability.
- Aftercare must be tailored to the individual patient and defined by the surgeon responsible. After the procedure, the patient should be permitted only very limited physical activity, in particular avoiding heavy lifting, turning movements and all kinds of sporting activity. Falls and sudden jerky movements must be avoided. Failure to comply may lead to the failure of the implant.
- In the postoperative phase, the treating physician should ensure that the individual patient is given all necessary information.

Risks:
These 'Instructions for Use' do not list the risks associated with surgical operations in general or the complications that can arise from spinal surgery.

The potential risks and complications relating to DIANA and which may necessitate a repeat operation are:
- Fracture of the implant
- Loss of the anchorage, subsidence or dislocation of the implant
- Foreign body reaction, allergic reaction to the implant materials used
- Incorrect placement
- Infection
- Non-fusion

These risks can lead to injury of all degrees of severity to the surrounding tissue, the nerves and blood vessels.

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

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 it has left 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).