IMPALA® – Interspinous Implant

Product description:
IMPALA® is an interspinous implant for use in the lumbar spine. It is used to relieve the posterior structures. The aim is not to induce bony fusion. The implant is a permanent implant that is not explanted but remains in the patient.
IMPALA® consists of two U-shaped components that are connected via a hinge and a closure component that fixes the final position. The three-part implant is inserted unilaterally between two spinous processes using a dorsal approach with no resection of the supraspinous ligament.
The implant does not require any additional fixation. It is held in position by its shape and the anatomical structures such as ligaments and bony processes.
The implant is made of polyether ether ketone. The radiolucent PEEK implants have X-ray markers to enable intraoperative and postoperative visualisation. Implantation is facilitated by use of the specially developed accessories for insertion and positioning of the implant. Only these accessories ensure safe use. Our product information provides further system-related information on the surgical method.

Indications:
IMPALA® can be used with the following lumbar diseases between the spinous processes in the L1–S1 region:
- Radiographically confirmed, moderate stenosis of the spinal canal of varying aetiology with neurological impairment, resulting in claudication and/or radicular symptoms
- The implant is furthermore applied in cases of moderate impairment in which, according to experience, freedom from symptoms is achieved through flexion, such as radicular symptoms with or without concomitant back pain
- The procedure is limited to one or two levels
- For patients > 30 years

Contraindications:
- Infections
- Anomalous bone density, osteoporosis or osteomalacia that prevents stable anchorage of the implant
- Allergy or intolerance to the implant material (marker made of tantalum)
- Surgical conditions that rule out any potential benefit from spinal 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
- Anatomical conditions that prevent secure anchorage of the implant and render it unstable such as:
  - Significant instability of the segment being treated, for example, due to fractures or severe spondylolisthesis (grade > I)
  - Use is contraindicated in patients with significant scoliosis; the indication in this regard must be specifically checked by the physician
  - Insufficient height of the spinous process, particularly of S1, or insufficient height of the intervertebral foramen

Material:
The implant is made of the following materials:
- Polyether ether ketone (PEEK-OPTIMA®) as per ASTM F2026
- Tantalum as per ASTM F 560

Composition:
PEEK as per ASTM F 2026: 100 %
Tantalum as per ASTM F560:
Nitrogen 0.01 % max, carbon 0.01 % max, iron 0.01 % max, hydrogen 0.015 % max, oxygen 0.03 % max, tungsten 0.05 % max, niobium 0.1 % max, molybdenum 0.02 % max, silicon 0.005 % max, nickel 0.01 % max, titanium 0.01 % max, remainder tantalum.

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 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
- Follow 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 duration: At least 4 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:
- Sterile implants are intended for single use only and must not be re-used. Reprocessing or reuse of an implant can result in infection and/or loss of function and in extreme cases may lead to the death of the patient.
- Sterile implants must be considered potentially infectious after use. They must therefore be disposed of properly (hazardous medical waste) according to the relevant hygiene and waste disposal guidelines. Instruments must be disposed of in the same way or prepared correctly before disposal at the end of their service life.
- 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 materials or components from other systems.

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

Precautions:
- Store sterile implants 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.
- The size indicated on the implant must be compared with the size determined using the trial implant.

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.
- The implant must not be used on its own for the purpose of spreading. The distractor as well as appropriate positioning of the patient are required for spreading. The force applied when distracting the stenotic segment must be minimised because excessive force may lead to fracture of the process.
- When inserting the implant, refrain from using excessive force in order to protect the spinal cord, the nerve roots and the adjacent vertebrae.
- The click mechanism must snap into place to establish a secure connection between the implant components because the components can otherwise become detached from each other.
- Spreading or rotating the implant against resistance must be avoided. This may damage the implant.
- With a view to secure positioning of the implant and the clinical outcome, over-distraction must be avoided.
- 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.
- To ensure secure interlocking of the implant components, confirm during closure that no tissue is present between the components of the implant.
- 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 post-operative 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.

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

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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
- Intraoperative fracture of the spinous process
- Pressure on the skin due to implant components in patients with inadequate subcutaneous fatty tissue

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:
An expert report recommends labelling IMPALA® as 'MRI conditional'. A patient with this implant can be safely scanned in an MRI system in accordance with the justification and the test methods in ASTM F2502.
Testing of the effects due to forces (ASTM F2052) or torque (ASTM F2213), heating (ASTM F2182) or artefact formation (ASTM F2119) was not carried out for the following reasons:
1. Long metallic objects less than 20 mm
2. Non-metallic PEEK as base material
3. Metal content less than 16 % proportional weight
4. Medical devices made of titanium and tantalum are labelled as 'MRI conditional' with < 25 T/m
5. The counterforces of the body hold the implant in position.

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).

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