LSZ3®

Product description:
The hook and rod system is a fixation system that provides a strong interlocking connection between a rod and two or more hooks. Other fixation elements such as cross bars can also be used. The hook and rod system is used to provide temporary internal posterior stabilisation for one or more segments in the thoracic and lumbar spine until fusion of the bones has occurred. The hooks are positioned directly along the inside of the lamina. Once the hook has been positioned, it is secured using the lamina screw. The different implant heights enable the selection of an implant that best matches the individual patient's requirements. The surgeon makes the final decision as to how long the implant remains in the patient's body and when the implant is to be explanted. Implantation is facilitated by using the specially developed accessories for insertion and positioning of the implants. Only these accessories ensure safe use. The use of instruments from other manufacturers for insertion and positioning of the implant is not permitted. Our product information provides further system-related information on the surgical method.

Indications:
The system is indicated for stabilisation of the thoracic/lumbar spine (T2–L5) in patients until stable fusion of the spine has been achieved after surgery:
- Instability or malposition of the spine
- Fractures
- Postoperative or degenerative instability
- Tumours and spondylodiscitis
- Correction of spondylolisthesis
- Disc prolapse
- Stenosis of the lumbar spine
- Disc resection
- Pathological lordosis/kyphosis/scoliosis
- Degenerative segmental disease

Contraindications:
- Infectious processes in, on or in regions adjacent to the spine
- Surgery precluded due to the physical condition of the patient, e.g. fever or leucocytosis
- Rapidly progressive arthropathy, bone absorption, osteopenia, osteomalacia or osteoporosis. Osteoporosis or osteopenia is a relative contraindication as these conditions may limit the amount of time available for recovery or immobilisation.
- Patients whose tissue cover above the surgical site or whose bone mass or bone quality at the surgical site is inadequate
- Patients in whom placement of an implant would influence the anatomic structures or the anticipated physiological performance
- Systemic or metabolic diseases Allergy or intolerance to implant material
- Surgical conditions which rule out any potential benefit from spinal surgery (such as severe damage to bone structures at the implantation site)
- Medical conditions that could prevent successful implantation (e.g. obesity, mental illness, pregnancy, patients in poor general health, lack of patient compliance)
- Cases that are not mentioned under Indications

Material:
Titanium alloy (Ti6Al4V) Nickel-free as per ASTM F 136 / ISO 5832-3.
Composition:
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.

Implants are available in different colours for easy identification. Colour changes have no effect on functionality. The material is an established material for use as an implant. It is biocompatible, corrosion-resistant and non-toxic in the biological environment and allows for interference-free X-ray and CT imaging. This product was not tested with regard to safety and compatibility in an MR environment. This product was not tested with regard to heating or migration in an MR environment.

Sterility:
- Non-sterile implants are supplied in suitable protective packaging or in the implant tray.
- Store implants in the original packaging or in the implant tray.
- Sterile implants are supplied in double sterile packaging and are gamma sterilised in accordance with DIN EN ISO 11137.

Warnings for sterile implants:
- Store implants in the original packaging
- Check expiry date and integrity of the sterile packaging before use
- Do not remove implants from their protective packaging until directly before use
- Sterile implants are intended for single use. They are not reusable – re-use can lead to infection, implant failure and/or death
- Implants with opened sterile packaging will not be accepted by SIGNUS

Reprocessing:
Non-sterile implants and instruments must be reprocessed before use.
- Completely remove all components of the packaging prior to reprocessing
- Products with cavities as well as gaps, threads, joints and springs must be placed in an ultrasonic cleaning 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).
- Sterilisation must be carried out under the conditions described
  - 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; the items to be sterilised must be dry
- Follow the validated reprocessing procedure in the instructions included with the tray.

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CE 0483

SIGNUS The Spine Sign®

Implants:
If not precluded on the commercial packaging or the primary packaging, a non-sterile implant may be reprocessed, provided this is compatible with the hospital guidelines and provided appropriate validated cleaning and sterilisation processes have been established.
- Completely remove all components of the packaging prior to reprocessing
- Where applicable, implants must be stored in the SIGNUS implant trays only

The implant and 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.

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	Sterilised using irradiation
REF Item number	Non-sterile
Use by	LOT Batch code
Do not resterilise	Consult instructions for use
0°C 35°C Temperature limit	Do not use if package is damaged

Warnings:
- The spinal implants are intended for single use and must not be re-used. Re-use of an implant can cause implant failure, infections and / or death.
- Implants 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.

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

Precautions:
- Store implants and sterile instruments in their original packaging.
- Do not remove implants from their protective packaging until directly before use.
- Check expiry date and integrity of the sterile packaging before use.
- Before opening the packaging, check that the packaging is intact.
- The implant must likewise be checked for integrity before being implanted. The size indicated on the implant must be compared with the size determined using the trial implant.
- Do not forcibly hammer the implant into place.
- Particular attention must be paid to the protection of nerve roots.

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 surgical intervention, it must be ensured that all required 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.
- When inserting the implant, refrain from using excessive force in order to protect the adjacent vertebral bodies.
- During and after the implantation process, the correct position of the pedicle screws and the rods must be verified radiographically
- The implant used must be documented in the patient record, indicating the article number, designation and batch number.
- Aftercare 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. This applies in particular to the lifting of loads, rotating movements and sporting activities of any kind. Falls and sudden, jerky movements of the spine 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.

Risks:
General risks associated with a surgical intervention and complications that can arise in connection with a surgical intervention on the spine are not listed in detail in these instructions for use.
Possible, but not typical, consequences of a surgical intervention on the spine are:
- Neurological loss of function, including paralysis, occurrence of nerve root disorders
- Pain with possible follow-up surgery
- Pressure on the skin by component parts in patients with inadequate tissue cover above the implant
- Death

Potential risks and complications that are related to pedicle screw systems may necessitate repeat surgery. These include but are not limited to:
- Wear, bending out of shape or breakage of implant components
- Loss of fixation, dislocation, subsidence
- Sensitivity to foreign bodies, allergic reactions to the implant materials used
- Incorrect placement
- Infection
- Pedicle fracture
- Pedicle/nerve root perforation
- Nerve root/spinal canal injury
- Injury and vascular damage due to bone cement leakage (e.g. PMMA)
- Visceral injury/deep infection
- Temporary paraparesis
- Pseudoarthrosis
- Screw loosening

These risks can potentially lead to injuries of all degrees of severity to the surrounding tissue, nerve structures and blood vessels. Adverse events related to the use of bone cement must be taken into account.

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).