MOBIS®, WOMBAT®, NOVAL®, SEMIAL®, TETRIS™

Product description:
The above-named products are disc replacement implants for use in the lumbar spine. They serve as temporary placeholders to restore disc height until firm bony fusion has taken place. They are not explanted again but remain in the patient. The implants are available in various designs, footprints and heights to enable adaptation to different patient anatomies. The MOBIS and NOVAL product families comprise slightly curved, angled and hollow implants with or without lordosis.
The WOMBAT product family comprises biconvex implants with or without lordosis. The SEMIAL product family comprises hemispherical, wedge-shaped and hollow implants with lordosis. The implants in the MOBIS, NOVAL, WOMBAT and SEMIAL product families are used singly. The TETRIS product family is made up of cuboid, hollow implants with fenestrated surfaces and with or without lordosis. Implants in the TETRIS product family are used in pairs. The upper and lower sides have small teeth for secure primary stabilisation. The implant cavities can be filled with autologous bone and / or bone graft material to encourage bone ingrowth. The implants are made either of the titanium alloy or a titanium lattice structure (TI-6AL-4V) or the high-performance medical polymer PEEK-OPTIMA®. The radiolucent PEEK-OPTIMA implants have X-ray markers to enable intraoperative and postoperative verification. Implantation is facilitated by use of 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:
A spinal implant is used in the following lumbar diseases (L1–S1):
- Degenerative disc diseases
- Mechanical instability
- Osteochondrosis

Contraindications:
- Infections
- Massive osteoporosis
- Specific metal allergy (titanium implants, titanium or tantalum markers)
- Myelopathic focus in the fused segment (only for titanium alloy implants)
- Medical conditions that could prevent successful implantation (e.g. obesity, mental disorders, pregnancy, paediatric cases, patients in poor general health, lack of patient compliance)
- Cases that are not mentioned under Indications

Material:
The implants and X-ray markers described are made from the following materials:
- PEEK-OPTIMA as per ASTM F2026
- Titanium alloy (Ti-6Al-4V) as per ASTM F 136 / ISO 5832-3
- Titanium as per ASTM F67 / ISO 5832-2
- Tantalum as per ASTM F560

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.

PEEK as per ASTM F2026: 100%

Tantalum as per ASTM F560:
Nitrogen 0.01 % max., carbon 0.01 % max., iron 0.01 % max., hydrogen 0.0015% 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.

Titanium as per ASTM F67 Gr4:
Nitrogen 0.05% max., carbon 0.08 % max., iron 0.5 % max., hydrogen 0.015% max., oxygen 0.4% max., remainder titanium.

The material is an established material for use as an implant. It is biocompatible, corrosion-resistant and non-toxic in the biological environment and enables interference-free X-ray imaging. It is MRI-compatible with reservations. Safety information must be obtained from SIGNUS before an MRI examination is carried out.

Sterility:
Sterile implants are supplied in double sterile packaging and are gamma sterilised in accordance with DIN EN ISO 11137.
Implants with opened primary sterile packaging will not be accepted by SIGNUS.

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.

REPROCESSING:

Instruments:
Instruments must be reprocessed before use.
- Completely remove all components of the packaging prior to reprocessing
- Observe the validated reprocessing procedure in the instructions included with the tray (valid version: eifu.signus.com)

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.

Implants:
Implants that are supplied sterile must not be resterilised. Reprocessing can result in infection and / or loss of function, which in extreme cases can lead to the death of the patient.

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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		Consult instructions for use
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 are intended for single use only 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.
- The cages of the ST line (MOBIS II, WOMBAT ST) consist of a very rough titanium lattice structure. The implant should therefore be handled with great caution to prevent tearing of the glove.
- 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.
- After preparation, carefully inspect the intervertebral disc cavity for bone fragments.
- Do not forcibly hammer the implant into place.
- Avoid combining flat and angled implants.
- 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 spinal cord, the nerve roots and the adjacent vertebrae
- The surgery must be carried out under fluoroscopic guidance. The correct position of the spinal implant must be verified using radiography.
- Excessive ablation or even complete removal of the cortical base plates and cover plates of adjacent vertebral bodies must be avoided.
- The spinal implant must be checked for integrity and the correct size before being implanted.
- Ensure that the implant makes the greatest possible contact with the adjacent vertebrae in order to avoid point stresses and to encourage fusion of the segment.
- The implants must not be used as stand-alone devices but rather must be combined with a spinal fixator.
- The MOBIS II implant is introduced using a special inserter. Intraoperative reduction/revision must be performed using increased distraction and a firm connection between the implant and the inserter.
- To ensure secure implantation of MOBIS II, intraoperative levering must be avoided under all circumstances.
- 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 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. 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.

U.K. Distributor

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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 implants listed above and which may necessitate repeat surgery:

- Wear or breakage of implant components
- Loss of fixation, dislocation, subsidence
- Sensitivity to foreign bodies, allergic reactions or other local/systemic adverse reactions to the implant materials used
- Incorrect placement
- Infection
- Vascular lesion
- Neural lesions with reversible or permanent neurological deficits or paralysis

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

Product family	PEEK product variants	Ti-6Al-4V product variants
MOBIS	MOBIS; MOBIS XL; MOBIS II	MOBIS II
NOVAL	NOVAL	
SEMIAL	SEMIAL	
TETRIS	TETRIS; TETRIS TBS; TETRIS II; TASMIN R	TETRIS; TETRIS II
WOMBAT	WOMBAT	WOMBAT

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).