The KIMBA®, KIMBA® mini, MOBIS®, MOBIS® II PEEK, MOBIS® II ST, NOVAL™, SEMIAL®, PEEK TETRIS™ and Titanium TETRIS™, TETRIS™ II PEEK, TETRIS™ II Titanium, TASMIN R® – Spinal Implants

Device description:
MOBIS®, NOVAL™, SEMIAL®, KIMBA®, KIMBA® mini, TETRIS™
The basic shape of the KIMBA®, KIMBA® mini, MOBIS®, NOVAL™, SEMIAL®, PEEK TETRIS™ and Titanium TETRIS™devices is a hollow structural frame. The upper and lower aspects of the implant are open. Surface spikes assist in the positive anchorage and seating of the implant between the vertebral bodies. The device is available in a variety of sizes enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition.

TETRIS™ II
The basic shape of the TETRIS™ II devices is a hollow structural frame having a rounded, tapered leading face. The upper and lower aspects of the implant are open. Surface spikes assist in the positive anchorage and seating of the implant between the vertebral bodies. The device is available in a variety of sizes and angulations thereby enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition.

TASMIN® R
The basic shape of the TASMN® R devices is a hollow strucutral frame having a rounded, tapered leading face. The upper and lower aspects of the implant are open with peaked teeth that assist in anchoring and seating the implant between the vertebral bodies. There are lateral fenestrations for bony in-growth. The device is available in a variety of sizes and angulations thereby enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition.

MOBIS® II PEEK
The basic shape of the MOBIS® II devices is a hollow structural frame having a rounded, tapered leading face. The upper and lower aspects of the implant are open. Surface spikes assist in the positive anchorage and seating of the implant between the vertebral bodies. The device is available in a variety of sizes and two angulations thereby enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition.

MOBIS® II ST
The MOBIS® II ST Spinal implants have a hollow, slightly curved frame with areas of an open-pore titanium grid structure. Restoration of the intervertebral space can be achieved by the large selection of implants that, at the same time, offers a high degree of intraoperative flexibility. In addition to straight implants, the MOBIS® II ST cage is also available with a 5° lordotic angle. Due to its design, the implant can be aligned with the anterior curvature of the intervertebral body and so is suited for unilateral, dorsal access (TLIF) in the L2 to S1 region of the spine.

Indications for use:
When used as a vertebral body replacement, the MOBIS®, SEMIAL®, TASMIN® R and PEEK and Titanium TETRIS™ and TETRIS™ II devices are indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation.
When used as a vertebral body replacement, the KIMBA® and KIMBA® mini devices are indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The devices are intended for use as a vertebral body replacement in the lumbar spine (from L1 to L5) and are intended for use with supplemental internal fixation.
When used as an intervertebral fusion device in skeletally mature patients, the KIMBA®, KIMBA® mini, MOBIS®, MOBIS® II, NOVAL™, SEMIAL®, TASMIN® R and TETRIS™, TETRIS™ II devices are intended for use at one level in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device. The devices are intended for use with a supplemental internal fixation system and with autograft to facilitate fusion.

Caution:
- These implants are intended for single use only and should not be re-implanted.
- The implants manufactured from titanium grid structure (MOBIS® II ST) must not be resterilized.
- Federal law restricts this device to sale by or on the order of a physician.

Contraindications:
- Advanced osteoporosis
- Specific metal allergy (Titanium only)
- Infection

Complications:
The patient should be informed of the following possible complications:
- Haematoma
- Pain
- Implant impaction
- Local or systemic infection
- Paraplegia
- Damage to local structures

SIGNUS Medizintechnik GmbH I Industriestr. 2 I 63755 Alzenau/Germany
t. +49 (0) 6023 9166 0 I f. +49 (0) 6023 9166 161 I info@signus.com I www.signus.com

SIGNUS The Spine Sign®

Precautions:

1. These implants are supplied sterile. Do not use if sterile packaging is opened or damaged. These devices are intended for single use only. Do not re-implant, re-sterilize, reprocess or reuse.
2. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level and other patient conditions which may impact the performance of the system
3. Throughout the entire procedure particular care must be exercised to protect nerve roots.
4. Carefully check and remove any bone splinters following resection.
5. Prior to implantation, check the required implant size.
6. The cages of the ST-Line consist of a very coarse titanium grid structure. The implant should therefore be handled with great caution to prevent tearing of the glove.
7. Do not use excessive force to introduce the implants.
8. 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.
9. The selection of size and implantation of the implant remain the exclusive responsibility of the user surgeon who must be experienced in spinal surgery.
10. Intraoperative levering must be prevented in all circumstances!
11. To ensure safe use with no levering motion, use the product specific instrumentation.
12. It is imperative that dissimilar metals do not come into contact in vivo. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.

Warnings:

- The spinal implants are intended for single use only and may not be re-used. Re-use can cause implant failure, infections and/or death.
- The attending physician is responsible for establishing the indication, selecting the implant and carrying out the implantation procedure, and must be experienced as well as trained in the requisite surgical technique.
- Implant components and instruments not belonging to the system must not be used.
- Instruments specially developed by SIGNUS are available for application of the implants. These ensure safe application.
- Prior to surgery, ensure that the instruments belonging to the system are sterile and fit for purpose.
- Prior to implantation, examine the implant for integrity and check the given size with the instruments for comparison.
- 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, as well as of post-operative behavior.
- The operation must be carried out under fluoroscopy. The correct position of the implant system used must be verified radiographically.
- The implant must not be scratched or notched, as this can lead to a reduction in mechanical stability.
- All implant components used, must be documented in the patient file with item numbers, name and lot 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 all kinds of sporting activities. Falls and sudden jerking 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 his individual requirements.

How supplied:

The KIMBA®, KIMBA® mini, MOBIS®, MOBIS® II, NOVAL™, SEMIAL®, and PEEK and Titanium TETRIS™ devices are provided sterile. All sterile products are labelled "STERILE." Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave sterile implants.
The associated instruments are provided clean but not sterile. Instruments are provided in an autoclavable tray. All instruments must be disassembled (if applicable) and cleaned before sterilization and introduction into a sterile surgical field.

Cleaning:

During use, keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. Thoroughly clean all instruments as soon as possible after use. Implant inserters must be disassembled prior to cleaning. This is accomplished by pulling on the knob end of the threaded inserter to withdraw the component from the cannulated outer shaft.
For MOBIS® II Inserter a separate cleaning instruction for assembly and disassembly needs to be on site.

Pre-Cleaning:

Manual pre-cleaning is performed to remove gross contaminants. Presoak the surgical devices for a minimum of 3 minutes in cold water. All movable components must be repeatedly mobilized under running water, until no visible contamination remains. Brush all exposed surfaces with a nylon bristle brush.
Instruments with cavities as well as joints, threads, hinges and springs have to be rinsed inside and outside by water spray gun at a pressure of 58 psi (4 bar) for a minimum of 20 seconds using cold water. Surfaces have to be brushed with a soft brush until visible contaminations are removed completely.

Automated cleaning:

Automated cleaning is the preferred cleaning method. Manual cleaning (above) should be performed prior to using automated cleaning equipment. Instruments have to be placed in the instrument tray of the purifier/disinfector (e.g. Miele G7735). Instruments with cannula must be placed in the tray for micro-invasive surgery (MIS) instruments and must be connected to the spray nozzle system.
Clean the instruments by using a program with analogue parameters (e.g. Vario TD):

- Minimum 2 min pre washing with cold tap water
- intermediate rinsing
- Under 55°C, for 5 min cleaning with Neodisher FA forte, 0.5% (Miele, Princeton NJ) or alternative cleaning with a adequate purifier
- 3 min neutralization with tap water
- intermediate rinsing
- 2 min rinsing with demineralized water

Disinfection:

Manual disinfection:
Disinfect the instruments by using an FDA cleared disinfectant (VAH-list of the Association of applied Hygiene). Cavities as well as joints, threads, hinges and springs must be water-rinsed inside and outside.

Automated operation:
Automated thermal disinfection, at a maximum temperature of 93°C in the purifier / disinfector (part of the above mentioned Vario TD program) is performed under consideration of national requirements regarding the thermal disinfection performance of the equipment in use (e.g. A0-Value according standard EN ISO 15883-1).

SIGNUS Medizintechnik GmbH I Industriestr. 2 I 63755 Alzenau/Germany
t. +49 (0) 6023 9166 0 I f. +49 (0) 6023 9166 161 I info@signus.com I www.signus.com

SIGNUS The Spine Sign®

Drying:
Manual drying:
Dry the instrument with a fluff-free fabric. Cavities as well as joints, threads, hinges and springs have to be dried by compressed air. Also, the application of a vapor-permeable lubricant, suitable for steam sterilization based on paraffin/white-oil basis, should be used on moving parts.

Automated operation:
Drying of the Instrument in the purifier/disinfector (one drying cycle, part of the Vario TD program) if applicable, the instrument can be dried by a fluff-free fabric. Cavities as well as joints, threads, hinges and springs have to be dried by compressed air. The application of a vapor-permeable lubricant, suitable for steam sterilization based on paraffin/white-oil basis, should be considered at these parts, too.
After cleaning/disinfecting, the disassembled instruments should be re-examined for visible soil. If visible soil is found, repeat the cleaning process. Following re-examination, the instruments should be dried using a soft cloth and placed in their proper locations in the instrument cases. The disassembled inserter components are reassembled by introducing the threaded inserter shaft into the cannulated outer shaft until the two pieces are engaged.

Inspection:
Unless marked otherwise, instruments may be re-used after reprocessing and sterilization. Before each reuse, inspect instruments including inaccessible areas, joints and moving parts for possible damage, wear or non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all movable parts. Damaged or defective instruments should not be used or processed. Contact your local sales representative for repair or replacement.

Sterilization:
Sterilization validation studies have shown that the following recommendations for instrument sterilization are effective to an SAL of 10-6.
The use of an FDA approved sterilization wrap is recommended.

Method:	Steam
Cycle:	pre-vacuum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Drying Time:	30 minutes

Product Guarantee:
SIGNUS Medizintechnik GmbH guarantees that each individual spinal implant is manufactured with the greatest of care and from selected material. The entire process, from manufacture to final packaging, is under constant quality control. However, given that SIGNUS Medizintechnik GmbH has no influence over the selection or use of the implant, the diagnosis of the patient or the surgical technique used, or the handling of the implant following dispatch from our company, no guarantees can be given regarding a successful surgical result or the lack of complications.