NUBIC™, NUBIC™ XL and RABEA™ – Spinal Implants

Device description:
The basic shape of the RABEA™, NUBIC™ device is a rectangular frame. The upper and lower aspects of the implant are open with surface spikes which assist in the positive anchorage and seating of the implant between the superior and inferior 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. A connecting screw is available which permits attachment of the NUBIC™ (without strut) to the SIGNUS TOSCA™ II anterior cervical plate if the surgeon so chooses.

The RABEA™ device components are manufactured from either titanium alloy (Ti-6Al-4V) as described in ASTM F136 or poly-etheretherketone (PEEK-OPTIMA™ LT1, InvibioTM) as described by ASTM F2026. The NUBIC™/NUBIC™ XL device components are manufactured form polyetheretherketone (PEEK-OPTIMA® LT1, Invibio) as described by ASTM F2026. Integral marker pins in the PEEK implants and the connecting screw are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Indications for use:
When used as a vertebral body replacement, the NUBIC™/NUBIC™ XL devices are indicated for use in skeletally mature patients to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use in thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The NUBIC™/NUBIC™ XL device may be implanted singularly or in pairs and may be used with allograft or autograft.

When used as an intervertebral fusion device, the NUBIC™/NUBIC™ XL devices are intended for use in skeletally mature patients at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The devices are designed for use with autograft to facilitate fusion and intended for use with supplemental internal fixation. One NUBIC device is used per intervertebral space. A connecting screw is available which allows the NUBIC™/NUBIC™ XL device (without strut) to be physically attached to the SIGNUS TOSCA® or TOSCA® II anterior cervical plate system if desired.

When used as a vertebral body replacement, the RABEA™ devices are indicated for use in skeletally mature patients to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use in thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The RABEA™ device is intended to be implanted in pairs and may be used with allograft or autograft.

When used as an intervertebral fusion device, the RABEA™ devices are intended for use in skeletally mature patients at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The devices are designed for use with autograft to facilitate fusion and intended for use with supplemental internal fixation. One RABEA™ device is used per intervertebral space.

Caution:
- These Spinal Implant Devices are intended for single use only and should not be re-implanted
- 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

Precautions:
- 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.
- 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.
- Throughout the entire procedure particular care must be exercised to protect nerve roots.
- Carefully check and remove any bone splinters following resection.
- Prior to implantation, check the required implant size.
- Do not use excessive force to introduce the implants.
- The selection of size and implantation of the implant remain the exclusive responsibility of the user surgeon who must be experienced in spinal surgery.
- 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.
- The devices NUBIC™ and RABEA™ have not been evaluated for safety and compatibility in the MR environment. NUBIC™ and RABEA™ devices have not been tested for heating or migration in the MR environment.

How supplied:
The NUBIC™/NUBIC™ XL and RABEA™ 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.

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SIGNUS The Spine Sign®

Pre-Cleaning:
Manual pre-cleaning is performed to remove gross contaminants. Immerse the Instrument without any bubbles at minimum of 5 min, in cold regular tap 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 jointings, threads, hinges and springs have to be soaked in an ultrasonic bath for 10 min. at 40°C with 0.5% solution of alkanine cleaner (neodisher FA) and then rinsed from the inside and outside with a water spray gun at 58 psi (4 bar) static power for minim 20 s with cold regular tap water.

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):
1. Minimum 2 min pre-washing with cold regular tap water.
2. Drain
3. Dosing of e.g. neodisher FA (Dr. Weigert, Hamburg) at 40°C
4. At 55°C, for 5 min cleaning with Neodisher FA forte, 0.5% (Miele, Princeton NJ) or alternative cleaning with a adequate purifier
5. Drain
6. 3 min neutralization with warm water (>40°C)
7. Drain
8. 2 min rinsing with warm water (>40°C)
9. Drain with demineralised 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).

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 reused 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 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 sterilisation
Cycle:	4 times pre-vacuum
Temperature:	minimum 270°F (132°C) maximum 280°F (137°C)
Exposure Time:	4 minutes
Drying Time:	20 minutes

Storage:
Store the sterilised instruments in a dry, clean and non-fuzzing environment at room ambient temperature.

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.