Instructions for Use
PANGEA™ Spine System

This instruction for use is not intended for distribution in the USA.

EC REP

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Instructions for Use

PANGEA™ Spine System
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material

Material:	Standard:
TAN (Ti-6AI-7Nb)	ISO 5832-11
Comercially Pure Titanium (CPTi)	ISO 5832-2

Intended use
The PANGEA Spine System is a posterior pedicle screw and hook fixation system (T1–S2) designed to provide precise and segmental stabilization of the spine in skeletally mature patients.

The PANGEA Perforated screws are an addition to the PANGEA Spine System, a posterior pedicle screw and hook fixation system (T1-S2) designed to provide precise and segmental stabilization of the spine in skeletally mature patients. PANGEA Perforated pedicle screws may be inserted traditionally as solid PANGEA screws and with K-wire guidance as PANGEA Cannulated screws including a minimally invasive approach with SpiRIT. PANGEA Perforated screws direct Vertecem or V+ through lateral perforations to augment the pedicle screw in the vertebral body. Augmentation of pedicle screw with cement increases pedicle screw anchoring in vertebral bone, especially in cases of diminished bone quality.

Indications
PANGEA Spine System:
– Degenerative disc disease
– Spondylolisthesis
– Trauma (i.e., fracture or dislocation)
– Tumor
– Stenosis
– Pseudoarthrosis
– Failed previous fusion
– Deformities (i. e. scoliosos, khyphosis and/or lordosis)
Note: For deformity corrections, polyaxial screws can only be used in conjunction with monoaxial screws.

PANGEA perforated:
– Degenerative disc disease
– Spondylolisthesis
– Trauma (i.e., fracture or dislocation)
– Tumor
– Stenosis
– Pseudoarthrosis
– Failed previous fusion
– Deformities (i.e. scoliosis, kyphosis and/or lordosis)
– Osteoporosis when used concurrent with Vertecem or Vertecem V+
Note: For deformity corrections, polyaxial screws can only be used in conjunction with monoaxial screws.

Contraindications
– In fractures and tumors with severe anterior body disruption, an additional anterior support or column reconstruction is required
– Osteoporosis when used without augmentation
– Severe Osteoporosis

Contraindications related to Vertecem and Vertecem V+:
Please refer to the corresponding technique guide

Potential adverse events
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common may include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Complex regional pain syndrome (CRPS), allergy/hypersensitivity reactions, side effects associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones (e.g. subsidence), disc (e.g. adjacent level degeneration), or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, partial displacement of the graft, vertebral angulation.

Sterile device

Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.


Do not resterilize

Single-use device


Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions
The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information".

Warnings
It is strongly advised that the PANGEA Spine System is implanted only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical techniques. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
The PANGEA perforated screws, however, are combined with Vertecem and Vertecem V+. Please refer to the associated product information for details on their use, precautions, warnings and side effects.

Magnetic Resonance environment
MR Conditional:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the PANGEA Spine and PANGEA perforated systems are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 15 minutes of scanning.
Based on non-clinical testing, PANGEA Spine and PANGEA perforated implants will produce a temperature rise not greater than 5.3°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.
MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the PANGEA Spine or the PANGEA perforated devices.

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling Multipart Instruments" can be downloaded from:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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