
Instructions for Use

SYNEX™

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



Authorised Representative

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Instructions for Use

SYNEX™

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-6Al-7Nb) ISO 5832-11

Intended use

SYNEX is a vertebral body replacement and is implanted using an anterior approach in the thoracic spine from T5 to T12, and in the lumbar spine from L1 to L4. It is used to support the anterior column of the spine.

Depending on anatomical and pathological requirements, SYNEX can be used for mono-, bi- and trisegmental fusions.

Indications

- Primary or secondary tumours of the thoracic or lumbar spine
 - Fracture of a thoracic or lumbar vertebral body
 - Post-traumatic kyphosis
 - Infectious diseases, where the resection of parts of vertebral bodies is indicated
- Note: Always combine SYNEX with an additional, intrinsic stable internal fixator such as DePuy Synthes Spine supplemental fixation to bear tensile forces as well as torsion, flexion and extension moments.

Contraindications

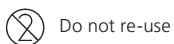
- Severe osteoporosis
- Reconstruction of more than two adjacent vertebral bodies
- Multilevel metastatic destruction of the spine

Potential risks

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 loosening, malunion, non-union, ongoing pain; damage to adjacent bones (e.g. subsidence), discs (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.

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 re-sterilization) 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 SYNEX 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.

Magnetic Resonance environment

MR Conditional:

Non-clinical testing of the worst-case scenario has demonstrated that the implants of the SYNEX system 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 3 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the SYNEX implant will produce a temperature rise not greater than 5.2°C at a maximum whole body averaged specific absorption rate (SAR) of 3 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 SYNEX device.

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.depuyssynthes.com/hcp/reprocessing-care-maintenance>

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