Instructions for Use
VEPTR™ II

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

DePuy Synthes
SPINE
COMPANIES OF Johnson&Johnson

CE
0123

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Instructions for Use

VEPTR™ II
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	ISO 5832-11
CPTI	ISO 5832-2

Intended use
VEPTR is based on a three-dimensional thoracic approach to treat patients with complex chest wall and/or spinal deformities where the thorax is unable to support normal respiration or lung growth (Thoracic Insufficiency Syndrome). Additionally VEPTR devices control and may correct scoliosis.
VEPTR is designed to mechanically stabilize and distract the thorax to improve respiration and lung growth in infantile and juvenile patients.
Devices are attached perpendicularly to the patient's natural ribs (superior attachment point) and more caudal ribs, a lumbar vertebra or to the ilium (inferior attachment point). Once the VEPTR device is in place, its design allows expansion, anatomic distraction, and replacement of components through less-invasive surgery.
All components of the VEPTR II system are manufactured from a titanium alloy (Ti-6Al-7Nb) with the exception of the Ala-hook and S-rod, which are manufactured from commercially pure titanium.

Goals of treatment
1. Increase thoracic volume
2. Scoliosis correction
3. Improve thoracic function
4. Establish thoracic symmetry by lengthening the concave, restricted hemithorax
5. Avoid growth-inhibiting procedures
6. Maintain these improvements throughout the patient's growth

Indications
The device is indicated for:
Primary Thoracic Insufficiency Syndrome (TIS) due to a threedimensional deformity of the thorax
- Progressive thoracic congenital scoliosis with concave fused ribs
- Progressive thoracic congenital scoliosis with flail chest due to absent ribs
- Progressive thoracic congenital, neurogenic or idiopathic scoliosis without rib abnormality
- Hypoplastic thorax syndrome, including
  - Jeune's syndrome,
  - Jarcho-Levin syndrome,
  - Cerebro costal mandibular syndrome,
  - others.
- Congenital chest wall defect, posterolateral
- Aquired chest wall defect, posterolateral
  - Chest wall tumor resection
  - Traumatic flail chest
  - Surgical separation of conjoined twins

Secondary Thoracic Insufficiency due to lumbar kyphosis (non gibbus)

Contraindications
The VEPTR device should not be used under the following conditions:
- Inadequate strength of bone (ribs/spine) for attachment of the VEPTR
- Absence of proximal and distal ribs for attachment of the VEPTR
- Absent diaphragmatic function
- Inadequate soft tissue for coverage of the VEPTR
- Age beyond skeletal maturity for uses of the VEPTR
- Age below 6 months
- Known allergy to any of the device materials
- Infection at the operative site

Side effects
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, Sudeck's disease, allergy/hypersensitivity reactions, side effects associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones, discs, 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 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
Patients implanted with the VEPTR should not be braced. The VEPTR device is designed to allow for thoracic cavity growth and the restrictive nature of a brace would not help the condition, but defeat its purpose.
Patients may require additional wound protection to prevent inadvertent rubbing or bumping of the wound.
Patients with a diagnosis of spina bifida should have an occlusive dressing over the wound site to keep the site dry.
It is strongly advised that VEPTR 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 VEPTR II 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 2 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the VEPTR II implant will produce a temperature rise not greater than 4.2°C at a maximum whole body averaged specific absorption rate (SAR) of 2 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3 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 VEPTR II 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://www.synthes.com/reprocessing

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