Instructions for Use
ECD – Expandable Corpectomy Device

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

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Dez 11, 2024

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

SE_528360 AF 04/2024

Instructions for Use

ECD – Expandable Corpectomy Device
ECD is a vertebral body replacement device (corpectomy device) designed for use in the cervical and upper thoracic regions of the spine.
The cage component and locking clip are made from PEEK. The cage component contains six TAV radiopaque markers and one TAN pin. The area around the ECD implant can be packed with bone graft material.

The ECD implants are available in different endplate angles and heights.

These instructions for use contain information about the following products:
890.005S
891.300S
891.301S
891.302S
891.303S
891.304S
891.305S
891.306S

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

For accompanying information, such as Surgical Techniques, please visit www.jnjmedtech.com/en-EMEA/product/accompanying-information or contact local customer support.

Materials
PEEK: Polyetheretherketone according to ASTM F 2026
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11
Titanium Alloy: TAV (Titanium – 6% Aluminium – 4% Vanadium) according to ISO 5832-3

Intended Use
The ECD implants are intended for use as vertebral body replacement devices in the cervical and upper thoracic spine (C3-T2) in skeletally mature patients.
Depending on the patient's pathology, ECD can be used in the replacement of one or two adjacent vertebral bodies.
ECD implants must be used with supplemental internal fixation.

Indications
– Replacement of damaged or diseased vertebral bodies

Contraindications
– Poor bone quality in which adequate anterior support cannot be established

Patient Target Group
The ECD implants are intended for use in skeletally mature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Expected Clinical Benefits
When the ECD implants are used as intended and according to the instructions for use and labeling, they are expected to provide maintenance or improvement of patient function and/or relief of pain.

A summary of safety and clinical performance can be found at the following link (upon activation): https://ec.europa.eu/tools/eudamed

Performance Characteristics of the Device
The ECD implants are vertebral body replacement devices, designed to provide anterior and middle spinal column support when used with supplemental fixation.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis; embolism; infection; excessive bleeding; neural and vascular injury; death, stroke; swelling, abnormal wound healing or scar formation; heterotopic ossification; functional impairment of the musculoskeletal system; paralysis (temporary or permanent); complex regional pain syndrome (CRPS); allergy/hypersensitivity reactions; symptoms associated with implant or hardware prominence, implant breakage, loosening or migration; malunion, non-union or delayed union; decrease in bone density due to stress shielding; adjacent segment degeneration; ongoing pain or neurological symptoms; damage to adjacent bones, discs, organs, or other soft tissues; retraction injury; laryngeal swelling; dural tear or spinal fluid leak; spinal cord compression and/or contusion; hoarseness; dysphagia; esophageal perforation, erosion or irritation; device or graft material displacement; dislocation of graft material; vertebral angulation.

Sterile Device

STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

Do not resterilize

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single Use Device

Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical 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, re-use 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.

Warnings and Precautions
- It is strongly advised that the ECD implant is implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.
- Implantation is to take place as per 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.
- Warning: Special considerations should be taken with patients with known allergies or hypersensitivities to implant materials.

Patient positioning
Place the patient in a supine position.
- Always use caution when positioning the patient, as forcing physiological alignment may cause further neurological injury.

Perform corpectomy and prepare endplates
Perform a partial or complete corpectomy as required by the pathology.
- Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the ECD implant, potentially resulting in subsidence.

Prepare for implantation
- When grasping the implant, make sure the arrows on the implant are pointing to the instrument side marked "CRANIAL".

Expand implant
After the appropriate implant size and configuration has been selected and placed in the corpectomy cavity, perform the implant expansion.
- As soon as the implant endplates touch the vertebral endplates, push the instrument slightly caudally in order to ensure the desired function of the expansion mechanism.
- A visual indicator on the implant shows the maximum expansion position. Additional expansion, once this stroke limitation is reached, may destroy the implant.
- Expansion must remain in the physiological range. Once the stroke limitation is reached, do not expand further. If the implant size is too small, remove the implant and replace it with a larger implant.

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices
The ECD implants are applied using associated ECD Instruments.

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 ECD 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 ECD 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 ECD device.

Treatment before Device is Used
Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.
Store sterile devices in their original protective packaging.
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 by visual inspection:
- Inspect the entire area of sterile barrier package including the sealing for completeness and uniformity.
- Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.

Do not use if the package is damaged or expired.

Implant Removal
The ECD implant is intended for permanent implantation and is not intended for removal. Any decision to remove the device must be made by the surgeon and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.
If a ECD implant has to be removed, the following technique is recommended.
- Place the pins of the holder for ECD locking clip (397.129) into the locking clip.
- Remove the clip.
- Attach the holding and distraction instrument (397.127) to the implant.
- Pull back the locking sleeve (UNLOCK).
- Place the holding prongs into the notches of the implant.
- Release the locking sleeve. The force of the spring returns the mechanism to its original position so that the implant is securely attached to the instrument.
- Collapse the implant – push the instrument slightly caudally to facilitate a desired function of the expansion mechanism – turn the rotary handle in the opposite direction (counterclockwise) as indicated on the instrument ("expand") until the implant can be removed.
- To release the implant, pull back the locking sleeve (UNLOCK).

Disposal
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.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions

Position the patient
- Place the patient in a supine position. Proper positioning should be confirmed with a radiograph prior to draping.

Approach
- Expose the vertebral bodies through a corresponding approach to the cervical spine. To have a clear layout of the operative field the cervical retractor set can be used.

Perform corpectomy and prepare endplates
- Perform a partial or complete corpectomy as required by the pathology. Observe the following points:
  - Excise the disc material and the superficial layers of the cartilaginous parts of the adjacent endplates.
  - Adequate cleaning of the endplate, especially in the peripheral parts, is important for the vascular supply.

Assess implant size
- Use the Calliper for corpectomy (324.060) to determine the size of the resulting spinal defect, taking the desired correction into account. Determine the appropriate implant size. The height of the implant in its neutral position should be less than the height of the defect. The implant height when expanded should exceed the height of the defect, including the desired amount of anchorage.
- The range of application for the implant is between its neutral position and 2/3 of its stroke.

Prepare for implantation
- Grasp the implant using the holding and distraction instrument (397.127). Pull back the locking sleeve (UNLOCK). Place the holding prongs into the notches of the implant. Release the locking sleeve. The force of the spring returns the mechanism to its original position so that the implant is securely attached to the instrument.

Implantation
- Insert the ECD implant into the resected part of the spinal column and align it in the sagittal and frontal plane. The recommended position for the ECD implant is in the centre of the vertebral endplate. To allow bony fusion, maintain some space around the implant endplates.
- Verify the position of the ECD implant in relation to the vertebral bodies in the frontal and sagittal planes under fluoroscopy. Three radiographic markers in each implant endplate enables visualization of implant position.

Expand implant
- Expand the ECD implant in situ using the holding and distraction instrument (397.127). Turn the rotary handle in the direction indicated on the instrument ("expand") until the desired height and anchorage is achieved. To release the implant, pull back the locking sleeve ("UNLOCK").
- Verify the final position of ECD implant in relation to the vertebral bodies in the frontal and sagittal plane under fluoroscopy.

Locking ECD implant with clip
– Place the pins of the holding instrument (397.129) into the locking clip. Insert the clip into the caudal notches of the implant. Lift the instrument in a cranial direction to remove it from the clip.
– If necessary, the locking clip can be removed in the same way.

Add bone graft material
– Fill the area around the ECD implant, especially the anterior segment with bone graft material.

Supplemental fixation
– Additional anterior, posterior or combined anterior/ posterior fixation must be used.

Implant Card & Patient Information Leaflet
If supplied with the original packaging, provide the implant card as well as the relevant information according to the patient information leaflet to the patient. The electronic file containing the patient information can be found at the following link: ic.jnjmedicaldevices.com

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedtech.com

Instructions for Use:
www.e-ifu.com