Instructions for Use
SYNMESH™ Vertebral Body Replacement System

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

Not all products are currently available in all markets.

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

EC REP

Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

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the most current version of each manual is always available online.
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DePuy Synthes
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Instructions for Use

SYNMESH™ Vertebral Body Replacement System
The SYNMESH implants are vertebral body replacement devices designed for use in the cervical, thoracic, and lumbar region of the spine. These implants can be filled with bone graft material.

The SYNMESH implants can be inserted through anterior, lateral or anterolateral approaches, depending on the spinal level involved. The round shaped implants comprised of corpectomy devices (mesh cages), end rings (press fit and with locking screw option) and the oblong shaped implants comprised of corpectomy devices (mesh cages), end rings (press fit and with locking screw option) and standard rings. Locking screws are used to fix the end rings (with locking screw option) and standard rings.

The SYNMESH implants are available in different footprints and heights, allowing the implant to be assembled as a spinal construct.

These instructions for use contain information about the following products:

495.341S	495.392S	495.455S	495.352	495.402	495.466
495.342S	495.393S	495.461S	495.353	495.403	495.467
495.343S	495.394S	495.462S	495.354	495.405	495.468
495.344S	495.395S	495.463S	495.355	495.406	495.469
495.346S	495.396S	495.464S	495.356	495.407	495.471
495.347S	495.397S	495.465S	495.357	495.410	495.472
495.348S	495.398S	495.466S	495.361	495.411	495.473
495.349S	495.399S	495.467S	495.362	495.412	495.474
495.351S	495.401S	495.468S	495.363	495.413	495.475
495.352S	495.402S	495.469S	495.364	495.414	495.476
495.353S	495.403S	495.473S	495.365	495.415	495.477
495.354S	495.405S	495.474S	495.366	495.416	495.478
495.355S	495.406S	495.475S	495.371	495.421	495.479
495.356S	495.407S	495.476S	495.372	495.422	495.481
495.357S	495.410S	495.477S	495.373	495.423	495.482
495.361S	495.411S	495.478S	495.374	495.424	495.483
495.362S	495.412S	495.479S	495.376	495.427	495.484
495.363S	495.413S	495.481S	495.377	495.428	495.485
495.364S	495.414S	495.482S	495.378	495.429	495.486
495.365S	495.415S	495.483S	495.379	495.430	495.487
495.366S	495.416S	495.484S	495.381	495.433	495.488
495.371S	495.421S	495.485S	495.382	495.434	495.489
495.372S	495.422S	495.486S	495.384	495.435	495.490
495.373S	495.423S	495.487S	495.385	495.436	495.491
495.374S	495.424S	495.488S	495.386	495.441	495.601
495.376S	495.427S	495.489S	495.387	495.442	495.602
495.377S	495.428S	495.490S	495.388	495.443	495.603
495.378S	495.429S	495.491S	495.389	495.444	495.604
495.379S	495.430S	04.817.448	495.391	495.445	495.605
495.381S	495.433S	495.341	495.392	495.446	495.611
495.382S	495.434S	495.342	495.393	495.447	495.612
495.384S	495.435S	495.343	495.394	495.451	495.613
495.385S	495.436S	495.344	495.395	495.455	495.614
495.386S	495.443S	495.346	495.396	495.461	495.615
495.387S	495.444S	495.347	495.397	495.462	495.621
495.388S	495.445S	495.348	495.398	495.463	495.622
495.389S	495.446S	495.349	495.399	495.464	495.623
495.391S	495.451S	495.351	495.401	495.465	495.624

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
Titanium: TiCP (Commercially pure Titanium) according to ISO 5832-2

Intended Use
The SYNMESH implants are intended for use as vertebral body replacement devices in the cervical, thoracic, and lumbar spine (C3-L5) in skeletally mature patients. Depending on the patient's pathology, SYNMESH implants can be used for one, two, or three adjacent vertebral level fusions.
SYNMESH 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 SYNMESH 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 SYNMESH 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 SYNMESH 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; lymphatic injury; 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

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 SYNMESH 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.

Preparation of endplates/corpectomy
Perform a partial or complete corpectomy depending on the pathology.
- Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the SYNMESH implant, potentially resulting in subsidence.

Cut mesh
If necessary, use the cutter to trim the mesh to the appropriate height.
- If an end ring with locking screw is used, the mesh has to be cut on the horizontal.

Attach first end ring
Attach desired end ring to mesh
- Check to ensure that end rings are correctly secured. The locking screw can only be inserted correctly through one hole. If the screw is inserted in the wrong hole, a gap will remain between the end ring and the mesh. In this case, remove the screw and secure it in the correct hole.

Distract segment and insert implant
- When using oblong end rings, ensure that the blades of the spreader forceps align with the slots in the end rings. When using round meshes the spreader forceps must be removed before implantation.

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

Combination of Medical Devices
The SYNMESH implants are applied using associated SYNMESH 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 SYNMESH 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 SYNMESH implant will produce a temperature rise not greater than 5.1 °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 SYNMESH 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.

Non-Sterile Device:
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”.

Implant Removal
The SYNMESH 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 SYNMESH implant has to be removed, the following technique is recommended.
- Distract the affected segment using spreader forceps
- Attach the appropriate implant holder to the implant
- Remove the implant
- Remove spreader forceps

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure “Important Information”. Assembly and disassembly instructions of instruments “Dismantling multipart instruments” are available on the website.

Special Operating Instructions

Select approach
- SYNMESH can be inserted anteriorly, laterally or anterolaterally, depending on the spinal level involved.

Preparation of endplates/ corpectomy
- Perform a partial or complete corpectomy depending on the pathology. Remove the surface layers of the cartilaginous endplates to the bleeding bone.

Determine implant size
- Distract the affected segment using the parallel spreader forceps.
- The scale on the handle indicates the height of the defect.
- Alternatively, the calliper for corpectomy can be used to determine the height of the defect.
- When determining the implant size:
  - Add a total of 3 mm to the mesh height if using round end rings.
  - Add a total of 7 mm to the mesh height if using oblong end rings.

Cut mesh (optional)
- If necessary, use the SYNMESH cutter to trim the mesh to the appropriate height.
  - Mesh, round, ∅ 10 mm and 12 mm: make diagonal cuts.
  - Mesh, round, ∅ 15 mm and all oblong meshes: make diagonal or horizontal cuts.
- To determine if the tabs of the mesh need to be adjusted with the universal bending pliers line up the desired end rings with the mesh and adjust tabs as necessary.
- The following steps describe the securing technique for end rings with locking screw. Alternatively, press fit end rings may be used.

Attach first end ring
- Attach desired end ring to mesh.
  - SYNMESH, round, ∅ 10 mm and 12 mm: secure end ring with a locking screw M2 using the screwdriver shaft 2.0, cruciform with holding sleeve and mini quick coupling and handle, small, with mini quick coupling.
  - SYNMESH, round, ∅ 15 mm and all oblong SYNMESH implants: secure end ring with a locking screw M3 using the screwdriver, hexagonal, small, ∅ 2.5 mm, with groove.
- Option: fill SYNMESH with bone graft material.

Attach second end ring
– Attach second end ring as described in the previous step.
  – If using a longer construct, a standard ring may be inserted for added stability. Place the standard ring inside the mesh at the desired location. Using the hexagonal screwdriver, insert two locking screws M3 through the mesh and into the standard ring to secure it in place.
  – Pack additional bone graft material inside the end rings as needed.

Distract segment and insert implant
– Using the parallel spreader forceps, distract the affected segment until the desired spinal alignment is achieved. While under distraction, insert the SYNMESH implant using the appropriate implant holder.
– Final seating of the implant may be accomplished by gently tapping the implant holder. Once the implant is in place, carefully remove the implant holder and spreader forceps. Appropriate impactors may be used if necessary to achieve final seating of the implant.
– Verify the position of SYNMESH in relation to the vertebral bodies in the frontal and sagittal planes intraoperatively using an image intensifier.

Apply bone graft material
– The area around SYNMESH close to the vascularised tissue is the area most likely to fuse and provide stability later on. Therefore, fill this area with the largest possible amount of bone graft, especially the anterior part of the instrumented zone.

Additional fixation
– SYNMESH must be combined with a supplemental internal fixation system which is designed for absorbing tensile forces as well as torsional, flexion and extension moments.

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.

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

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

Instructions for Use:
www.e-ifu.com