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.

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Apr 13, 2022

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PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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 SE_528365 AE 11/2021

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:

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

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.

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
- Traumatic fractures with destruction of the vertebral body
- Replacement of vertebral bodies due to tumor resection

Contraindications
- Poor bone quality in which adequate anterior support cannot be established
- Multilevel metastatic destruction of the spine
- Absence of intact neighboring segments
- Active systemic infection

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; swelling, abnormal wound healing or scar formation; functional impairment of the musculoskeletal system; 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, organs, discs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; device or graft material displacement; vertebral angulation.

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 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.

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 Instrumentation.

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
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
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.

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.

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Instructions for Use:
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