

SYNMESH™

Vertebral Body Replacement System

Surgical Technique Guide

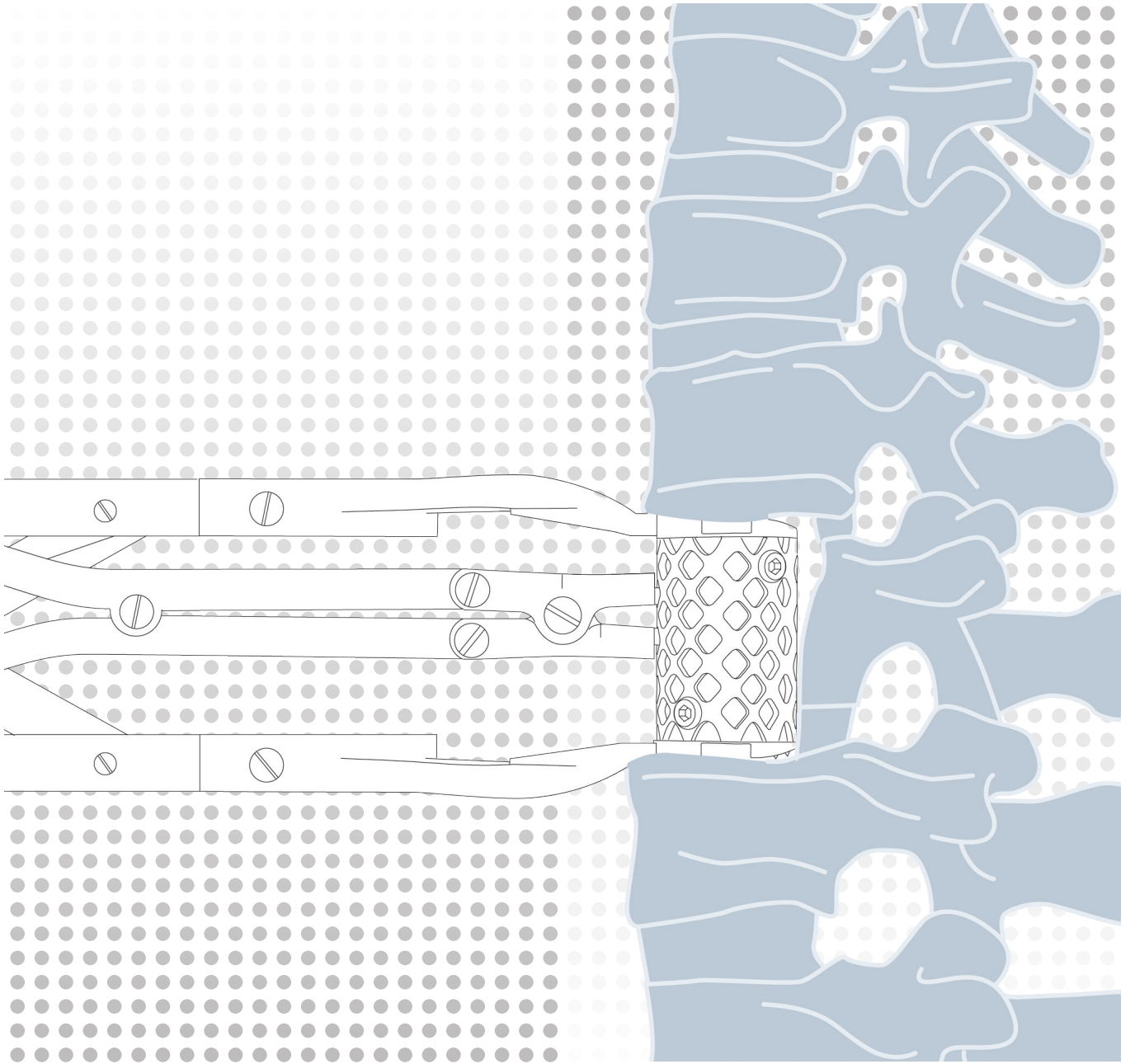



 Image intensifier control

 Warnings and Precautions

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance>

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AO Spine Principles

The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability, Alignment, Biology, Function.^{1,2}

AO Principles

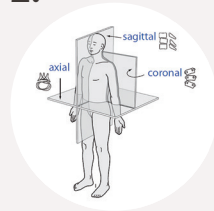
1.



Stability

Stabilization to achieve a specific therapeutic outcome.

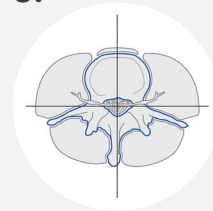
2.



Alignment

Balancing the spine in three dimensions.

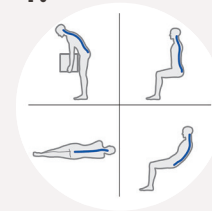
3.



Biology

Etiology, pathogenesis, neural protection, and tissue healing.

4.



Function

Preservations and restoration of function to prevent disability.

Surgical Technique

1. Select approach

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

2. 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.

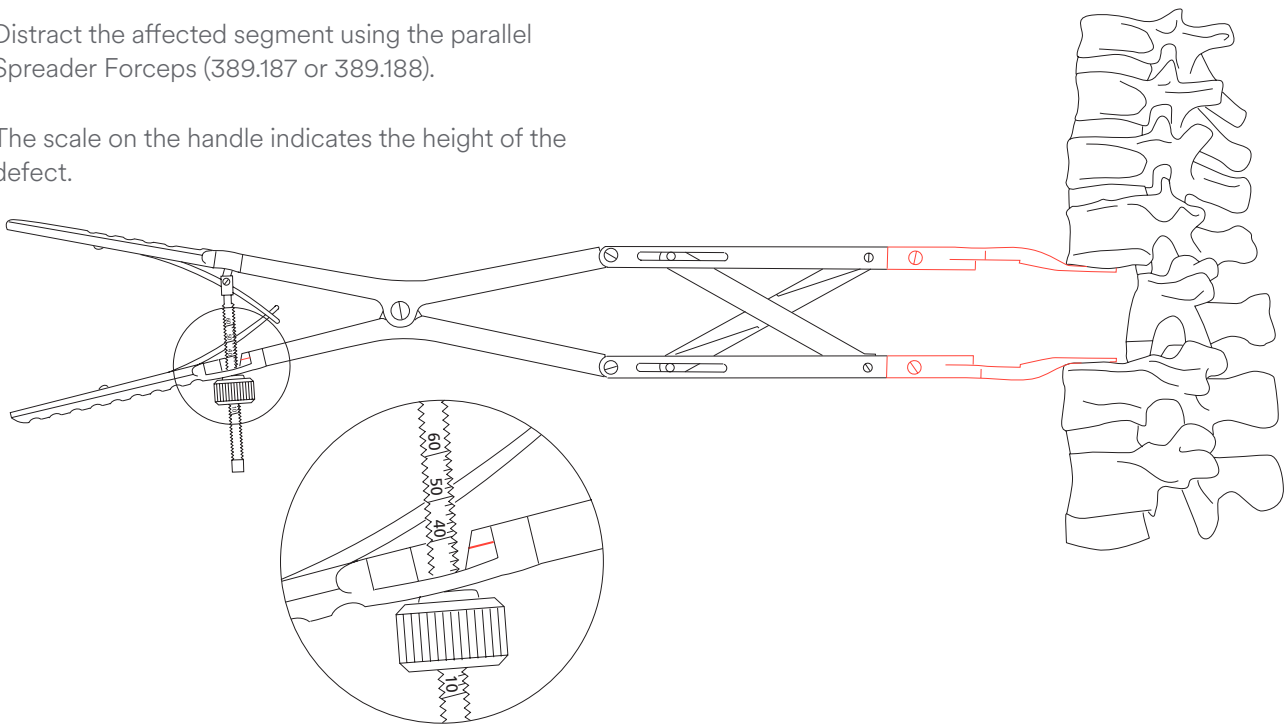
▲ **Warning:**

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.

3. Determine implant size

Distract the affected segment using the parallel Spreader Forceps (389.187 or 389.188).

The scale on the handle indicates the height of the defect.

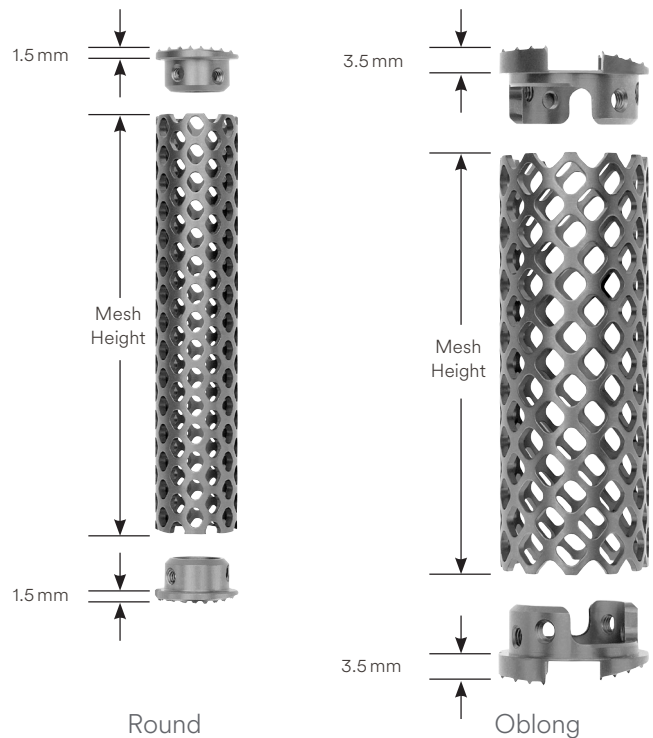


Alternatively, the Calliper for Corpectomy (389.186) can be used to determine the height of the defect.

When determining the implant size:

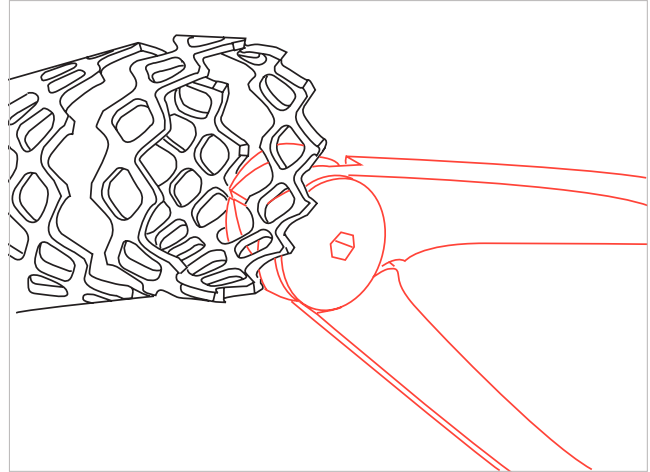
- Add a total of 3 mm to the mesh height if using round end rings
- Add a total of 7 mm to the mesh height if using oblong end rings

Construct height



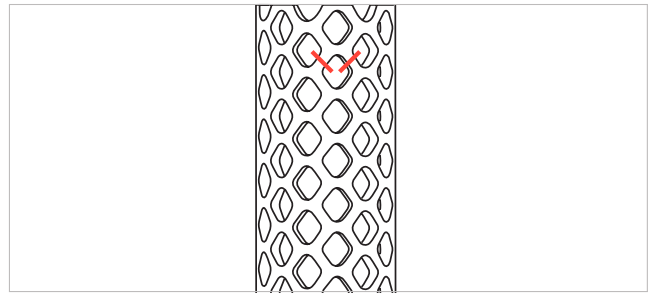
4. Cut mesh (optional)

If necessary, use the SYN MESH Cutter (397.091) to trim the mesh to the appropriate height.



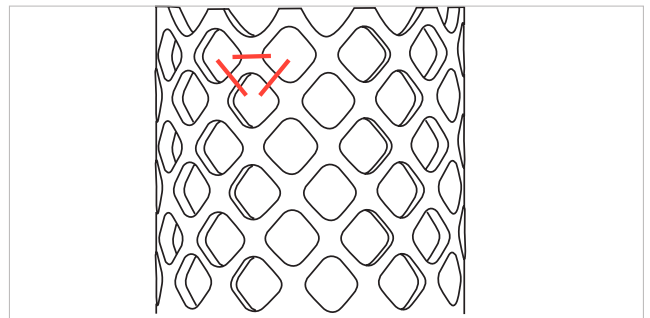
a. Mesh, round, \varnothing 10 mm and 12 mm

Make diagonal cuts.



b. Mesh, round, \varnothing 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 (391.963) line up the desired end rings with the mesh and adjust tabs as necessary.

▲ **Precaution:**

If an end ring with locking screw is used, the mesh has to be cut on the horizontal.

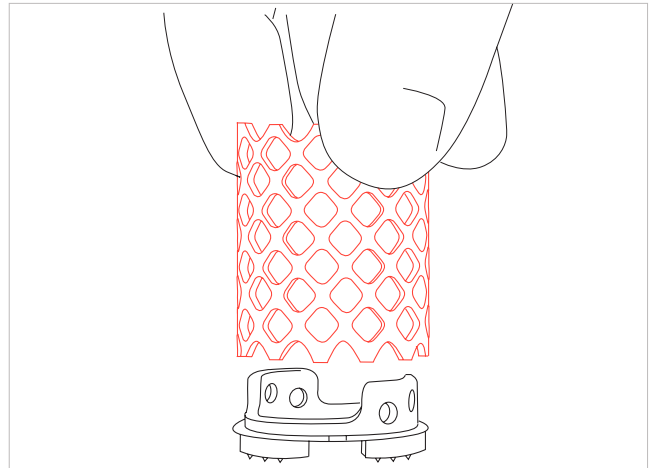
The following section describes the securing technique for end rings with locking screw. Alternatively, press fit end rings may be used.

5. Attach first end ring

Attach desired end ring to mesh.

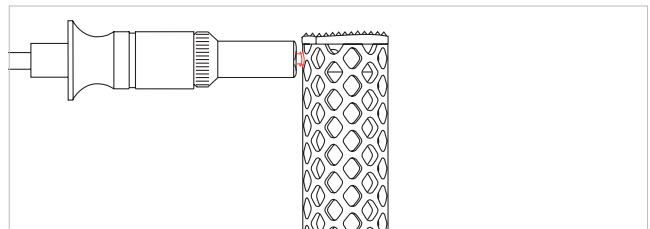
a. SYNMESH, round, Ø 10 mm and 12 mm

Secure end ring with a locking screw M2 (495.410) using the Screwdriver Shaft 2.0, cruciform with Holding Sleeve and Mini Quick Coupling (314.672) and Handle, small, with Mini Quick Coupling (311.011).



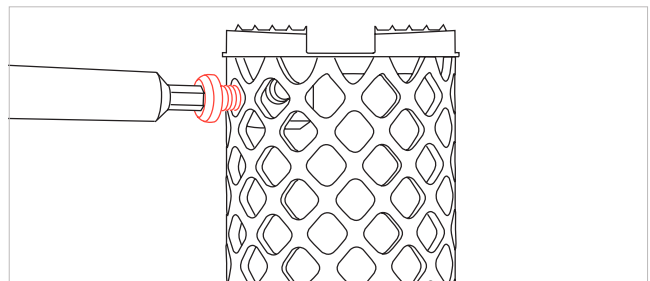
b. SYNMESH, round, Ø 15 mm and all oblong SYNMESH implants

Secure end ring with a locking screw M3 (495.491) using the Screwdriver, hexagonal, small, B 2.5mm, with Groove (314.250).



▲ Precaution:

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.



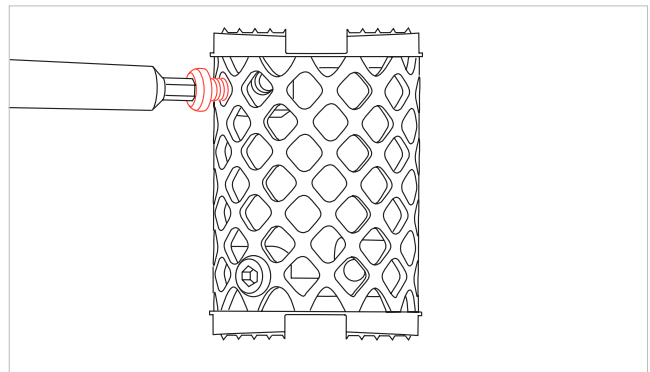
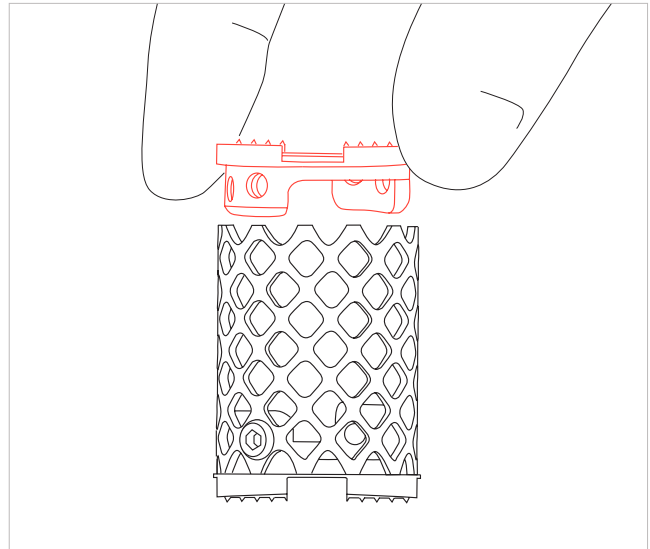
Option:

Fill SYNMESH with bone graft material.

6. 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.



7. Distract segment and insert implant

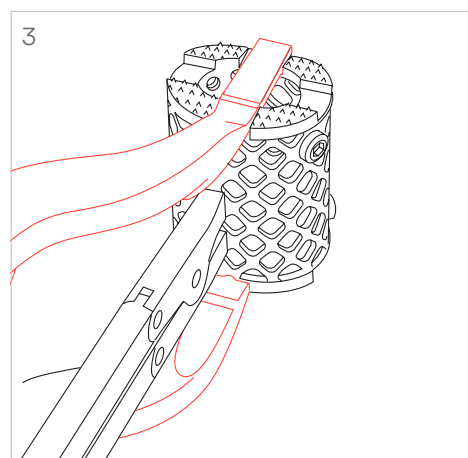
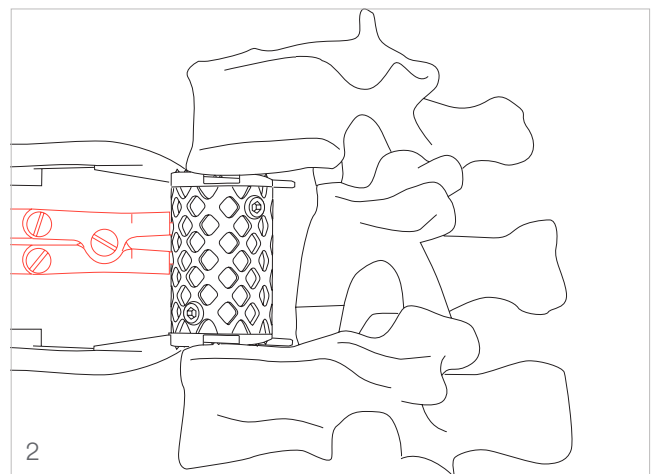
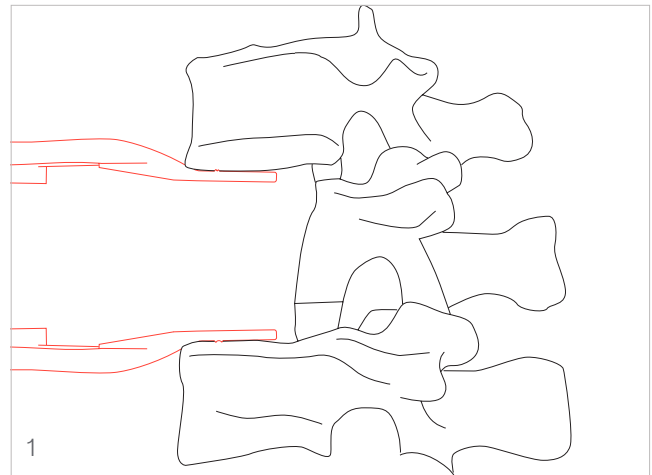
Using the parallel spreader forceps, distract the affected segment until the desired spinal alignment is achieved (1). While under distraction, insert the SYNMESH implant using the appropriate implant holder (396.388, 396.389) (2).

▲ Precaution:

When using oblong end rings, ensure that the blades of the spreader forceps align with the slots in the end rings (3). When using round meshes the spreader forceps must be removed before implantation.

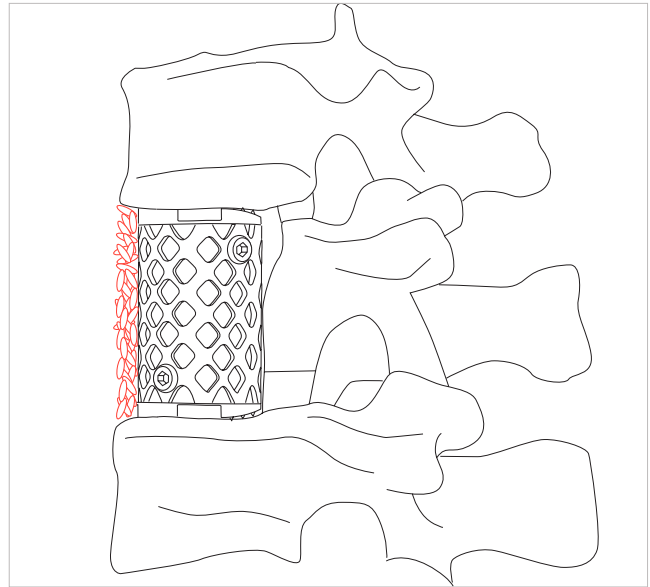
Final seating of the implant may be accomplished by gently tapping the implant holder. Once the implant is in place, carefully remove the implant holder and spreader forceps. Appropriate impactors may be used if necessary to achieve final seating of the implant.

- Verify the position of SYNMESH in relation to the vertebral bodies in the frontal and sagittal planes intraoperatively using an image intensifier.



8. 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.



9. Additional fixation

As with all vertebral body replacement devices, SYN_MESH must be combined with a supplemental internal fixation system which is designed for absorbing tensile forces as well as torsional, flexion and extension moments.

Implant Removal

SYN_MESH implants are not intended to be removed. If removal is required, spreader forceps and implant holder may be used to remove SYN_MESH implant.

Indications and Contraindications

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu.

Bibliography

1. Aebi M, Arlet V, Webb JK (2007). AOSPINE Manual(2 vols), Stuttgart, New York: Thieme.
2. Aebi M, JS Thalgott, JK Webb. (1998). AO ASIF Principles in Spine Surgery. Berlin: Springer-Verlag.

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