# SYNEX™

## VERTEBRAL BODY REPLACEMENT SYSTEM

## Surgical Technique

DePuy Synthes

THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image intensifier control

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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For Product Catalogue contact your local DePuy Synthes representative.

Image Intensifier Control

▲ Warnings/Precations

# 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]

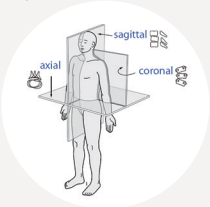
## AO Principles[1,2]

**1.**

**Stability**

Stabilization to achieve a specific therapeutic outcome.

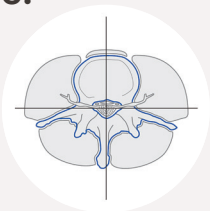
**2.**




**Alignment**

Balancing the spine in three dimensions.

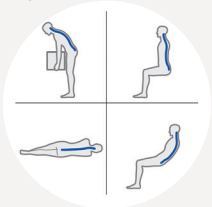
**3.**



**Biology**

Etiology, pathogenesis, neural protection, and tissue healing.

**4.**



**Function**

Preservations and restoration of function to prevent disability.

# Surgical Technique

## 1. Approach

Different approaches are suitable depending on the affected spinal segment and the position of the defect.

## 2. Preparation of endplates/ corpectomy

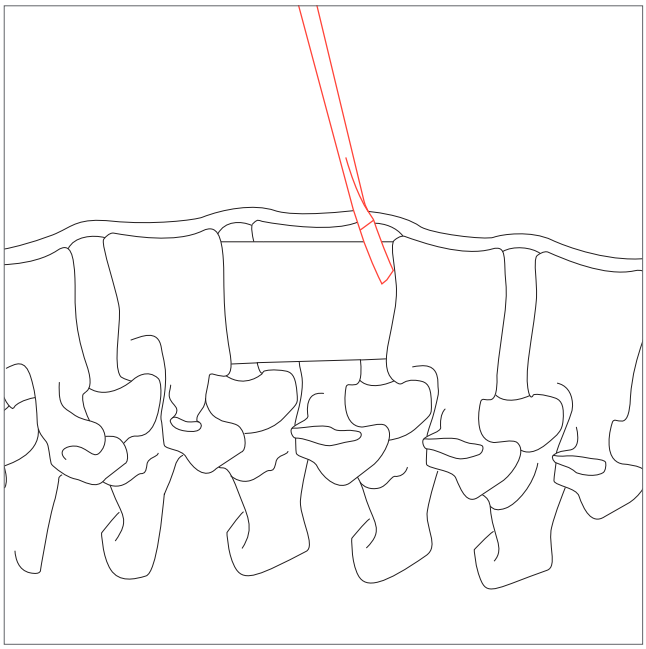
Perform a partial or complete corpectomy depending on the pathology. Remove the surface layers of the cartilaginous endplates to the bleeding bone.

**▲ Warning**

- **Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the SYNEX implant, potentially resulting in subsidence.**

If possible:

- Leave the anterior and posterior longitudinal ligaments intact.
- Leave a shell of the most anterior, contralateral and/ or posterior parts of the vertebral body intact if possible.

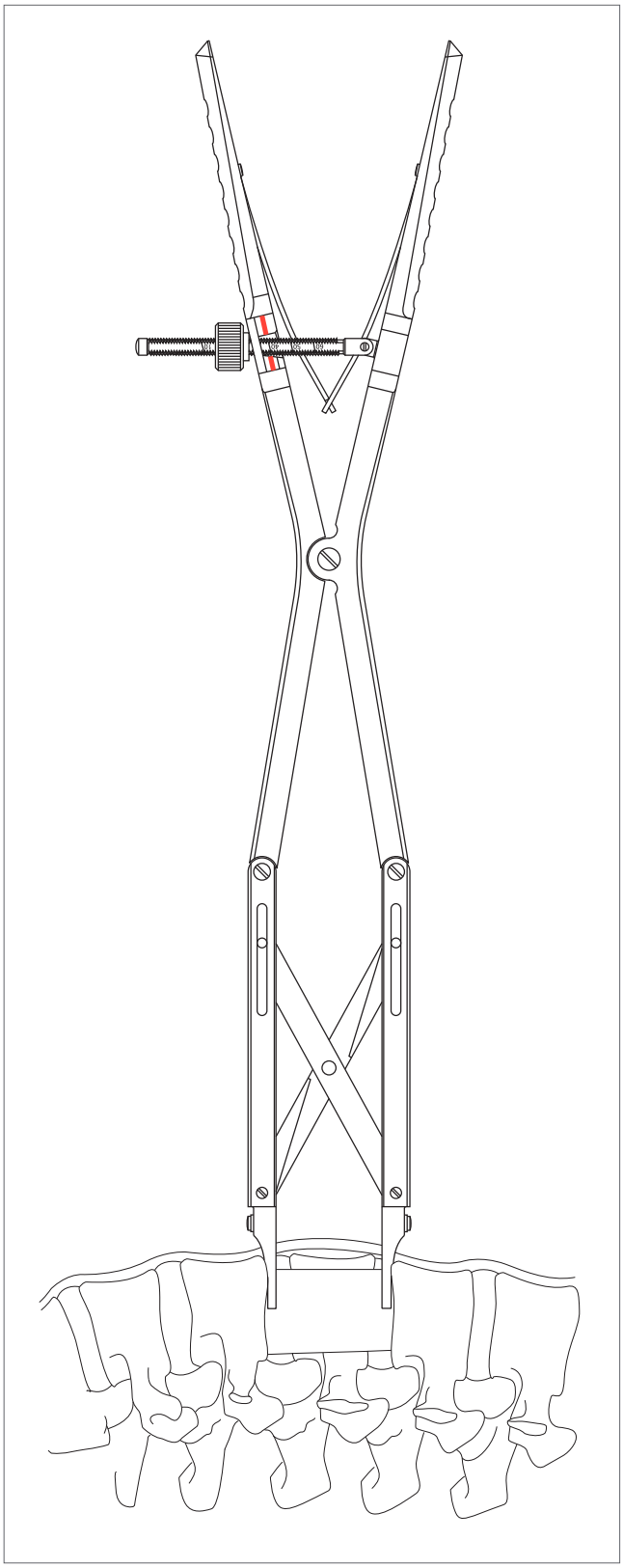


## 3. Determine implant size

Determine the height of the created defect and the desired correction using the Spreader Forceps (389.193). The scale on the handle of the spreader forceps indicates the height of the required implant. The minimum and maximum height of each implant is indicated on the
implant tray.

The height of the implant in its neutral position should be less than the height of the defect, the height when expanded should exceed the previously determined height of the defect, including the desired amount of anchorage.

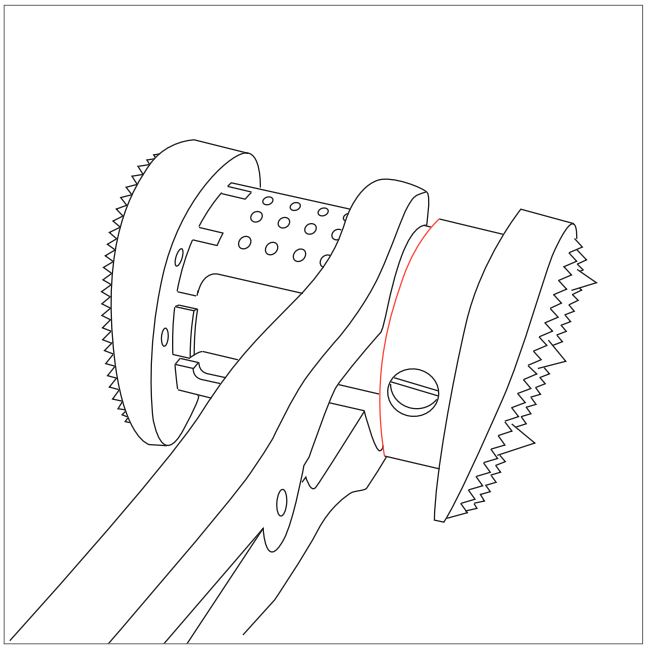
Make sure the endplates of the implant will be completely in contact with the endplates of the adjacent vertebral bodies. However, it is important to keep the endplates of the vertebral bodies intact.



## 4. Pick up the SYNEX Implant

Pick up the SYNEX Implant using the Implant Holder (389.204), holding it at the thin part of the cylinder close to the securing ring (1). Filling and release openings should face the surgeon.

For the smallest implants (495.315 and 495.316), place the implant holder close to the lower implant endplate.



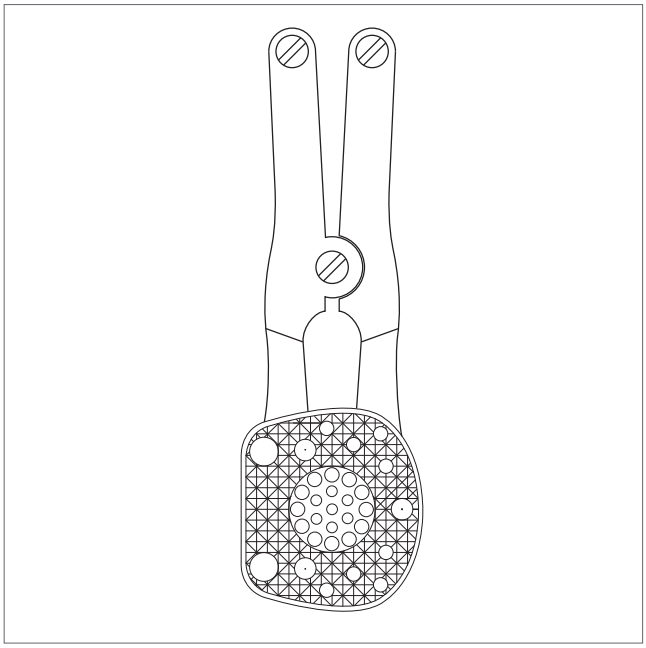
## 5. Fill the implant cups and the contralateral side of the spinal column with bone chips

The bone cups at the endplates of the implant can be filled with bone chips before implantation. If the necessary amount of bone chips is not available, the cups can be left empty. To provide the opportunity for fusion to occur, it is important to fill the area around the implant (as described in step 10 on page 11).

To facilitate contact and on-growth to the adjacent vertebral bodies, the bone chips should fill the hollow body of the implant and protrude from the implant endplates.

The hollow body of the implant is filled only after expansion as described in step 10 on page 11.

Use bone chips to fill the area of the defect that cannot be reached once the implant has been implanted (ie the contralateral side of the spinal column).

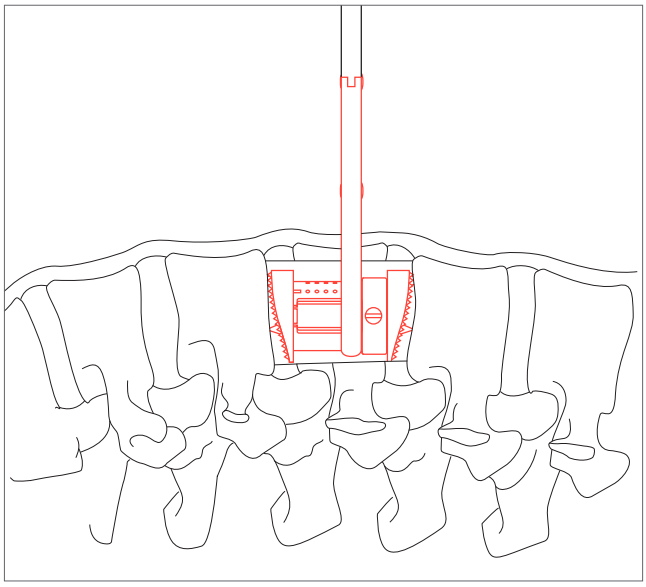


## 6. Implantation

Guide and position SYNEX with the implant holder. Ensure the release opening is facing towards the implant holder in case SYNEX needs to be reduced to its neutral position.

The desired position for SYNEX is the centre of the vertebral endplate. Reserve some space around the endplate of the implant to allow bone fusion to take place.

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

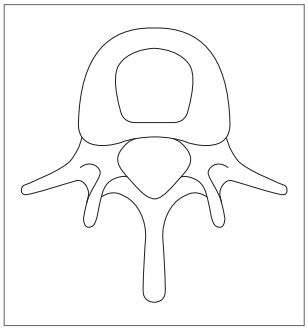


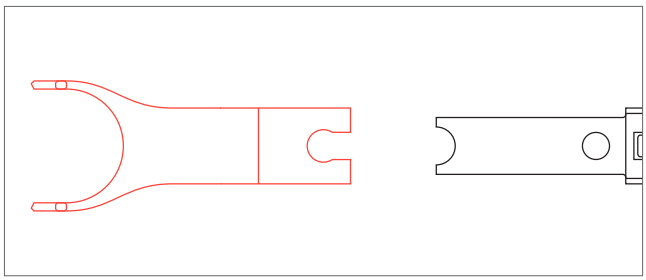
## 7. Mount headpieces onto spreader forceps

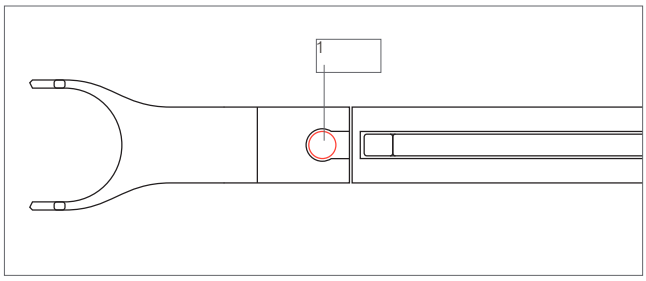
Click the required pair of headpieces onto the fork of the spreader forceps in order to expand the implant.

There are two different sizes of headpieces which correspond to the diameter of the implant. Use the headpieces with a large diameter labelled “B” (389.206) for blue SYNEX implants, and headpieces with a small diameter labelled “G” (389.205) for green SYNEX implants.

To disassemble the headpieces after use, press the button (1) on the tip of the spreader and pull.







## 8. Expansion

Expand SYNEX in situ using the spreader forceps, which can be used in combination with the implant holder.
Expand until satisfied with the height and amount of anchorage reached. Each step of the ratchet mechanism corresponds to a distraction of 2.5 mm.

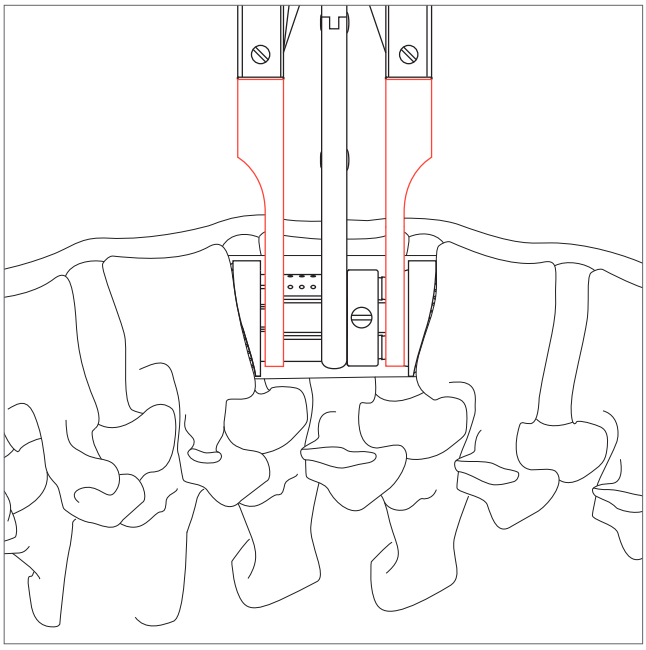
The stop at the end of the ratchet mechanism of the implant prevents the two parts from falling apart.

**▲ Precaution**

- **Do not increase the force acting on the spreader forceps once this position is reached. If the height of the chosen implant size is not correct, remove the implant as described below and replace it with a longer implant.**

When using small SYNEX implants (495.320, 495.315, 495.316), remove the implant holder prior to expansion.

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



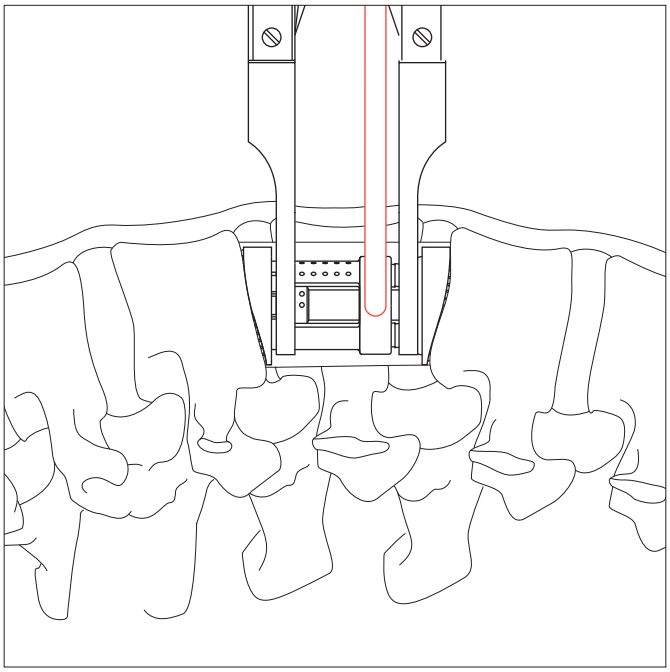
## Option

### Reduce SYNEX to its neutral position

If not satisfied with the result after expansion, use the Disconnecting Instrument (389.201) to reduce the expanded implant to its neutral position.

Since the securing ring is locked when the implant is under compression, release the mechanism using the spreader forceps with headpieces. Introduce the disconnecting instrument into the slot between the two ends of the securing ring and turn it by quarter of a revolution. Remove SYNEX using the implant holder.

If the two parts do not slide inside each other, slight shaking of the disconnecting instrument helps the parts to slide.

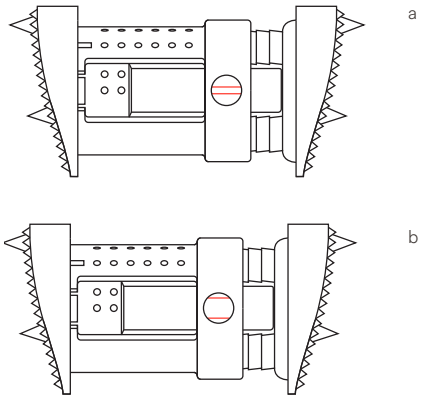


**▲ Precaution**

- Do not re-use SYNEX implants once they have been implanted or expanded.

## 9. Check if securing ring is closed

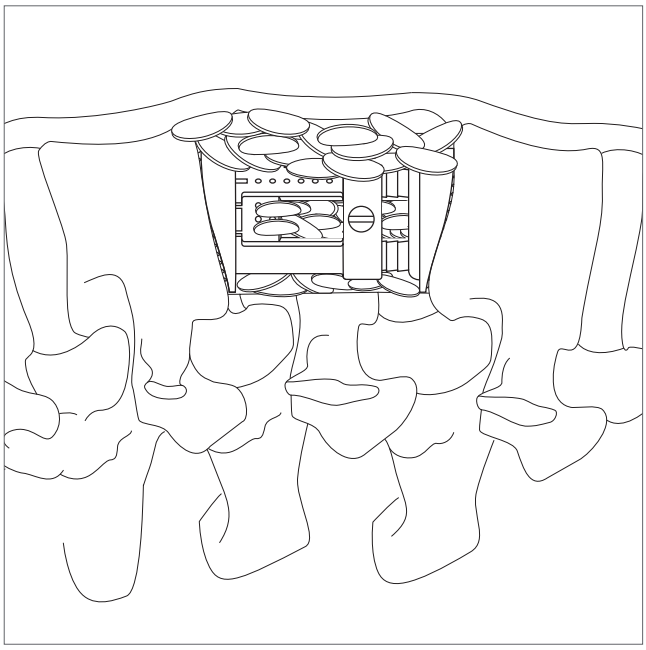
After expansion check the closure of the securing ring. If there is a gap of approximately 1 mm, SYNEX is locked and in secure position (a). If the slot is larger (b), expand the implant slightly in order to engage the securing ring.




## 10. Fill SYNEX with bone chips

Check the position of the implant before filling. The area around SYNEX close to the vascularised tissue is the area most likely to fuse and provide stability later on. Therefore fill the area around SYNEX with the largest possible amount of bone chips, especially the anterior part of the instrumented zone.
The formation of a bony bridge in the anterior part is important for longterm stability.

If you consider filling the hollow body inside the implant, it must be filled in situ and after expansion. Fill SYNEX with bone graft or a bone substitute material.



## 11. Additional fixation

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

## 12. Implant Removal

If a SYNEX implant has to be removed the following technique is recommended:

### Reduce Implant

- Reduce SYNEX to its neutral position (See page 10 for the appropriate technique)

### Remove Implant

- Remove the SYNEX Implant using the Implant Holder (389.204), holding it at the thin part of the cylinder close to the securing ring. For the smallest implants (495.315 and 495.316), place the implant holder close to the lower implant endplate.

# Bibliography

1. Aebi M, Thalgott JS, Webb JK. (1998). AO ASIF Principles in Spine Surgery. Berlin: Springer-Verlag.

2. Aebi M, Arlet V, Webb JK (2007). AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.

# 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.

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