

SYNEX

The vertebral body replacement
with ratchet mechanism



Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

 Image intensifier control

Warning

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.depuyshes.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.depuyshes.com/hcp/reprocessing-care-maintenance>

TABLE OF CONTENTS

INDICATIONS AND CONTRAINDICATIONS	2
<hr/>	
IMPLANTS	3
<hr/>	
SURGICAL TECHNIQUE	4
<hr/>	
CLEANING OF INSTRUMENTS	12
<hr/>	
OPTIONAL SPREADING INSTRUMENTS	13

INDICATIONS AND CONTRAINDICATIONS

Synex is a vertebral body replacement and is implanted using an anterior approach in the thoracic spine from T5 to T12, and in the lumbar spine from L1 to L4. It is used to support the anterior column of the spine.

Depending on anatomical and pathological requirements, Synex can be used for mono-, bi- and trisegmental fusions.

Indications include

- Primary or secondary tumours of the thoracic or lumbar spine
- Fracture of a thoracic or lumbar vertebral body
- Post-traumatic kyphosis
- Degenerative or infectious diseases, where the resection of parts of vertebral bodies is indicated

Note: Always combine Synex with an additional, intrinsic stable internal fixator such as a DePuy Synthes Spine supplemental fixation to bear tensile forces as well as torsion, flexion and extension moments.

Contraindications

- Severe osteoporosis
- Reconstruction of more than two adjacent vertebral bodies
- Multilevel metastatic destruction of the spine

IMPLANTS

Synex is a pre-assembled vertebral body replacement with ratchet mechanism.

Different implant types of varying diameters, heights and endplate inclinations are available. This enables the surgeon to choose the configuration appropriate to the individual pathology and anatomical condition.

The ratchet mechanism of Synex allows an in situ expansion with a self-locking mechanism.

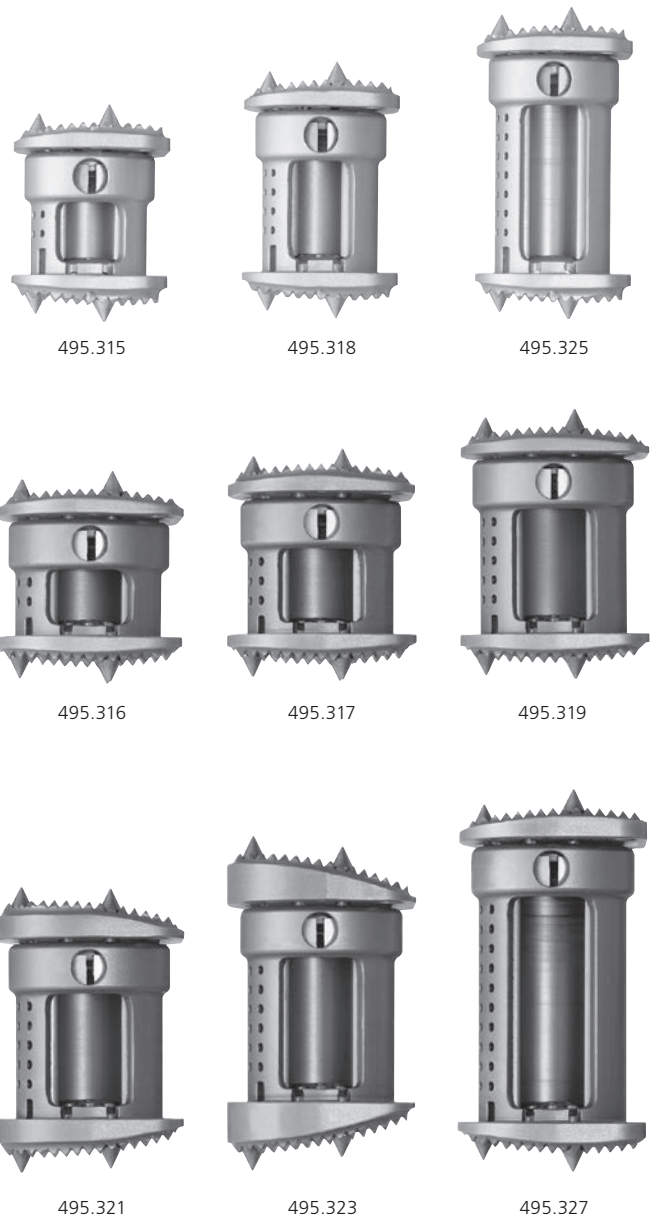
Thoracic implants, footprint 22 × 21 mm

Art. no.	Range	Angle
495.315	23–31 mm	-5°
495.318	28–40 mm	-5°
495.320	20–25 mm	-5°
495.325	36–56 mm	-5°

Lumbar implants, footprint 25 × 28 mm

Art. no.	Range	Angle
495.316	23–31 mm	0°
495.317	26–36 mm	0°
495.319	31–46 mm	0°
495.321	33–48 mm	10°
495.323	37–55 mm	20°
495.327	45–73 mm	-6°

Note: Positive angles of endplates indicate lordotic implant endplates, negative angles indicate kyphotic implant endplates.



SURGICAL TECHNIQUE

1

Approach

Synex is inserted using one of the following approaches, according to the spinal level involved. The localisation of the pathology of the spine is crucial for the choice of the approach.

The following approaches are recommended:

- Th5–Th9 Thoracotomy from the left side
- Th10–L2 Thoracotomy between the 9th and 10th rib, with minimal splitting of the diaphragm
- L3–L4 Lumbotomy

2

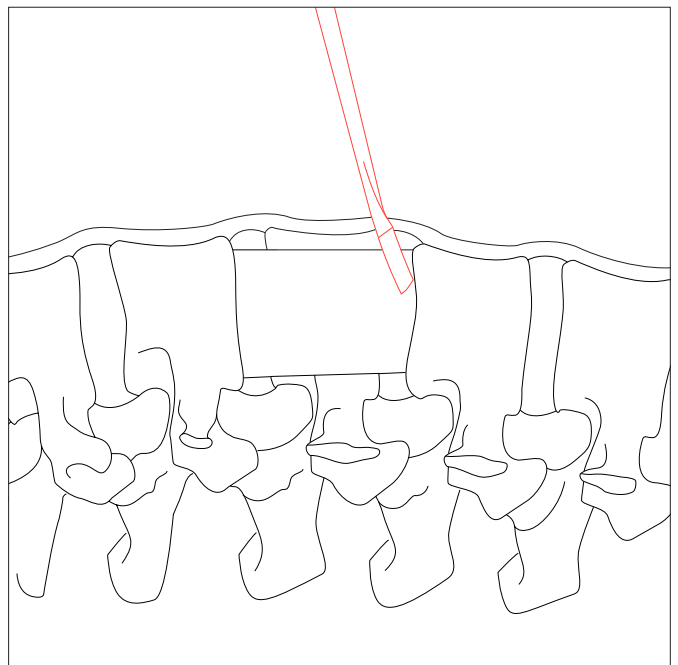
Preparation of endplates/corpectomy

Perform a partial or complete corpectomy as required by the pathology observing the following points:

Excise the disc material and the superficial layers of the cartilaginous parts of the endplates. Adequate cleaning of the endplate – especially in the peripheral parts – is important for vascular supply. Excessive tissue debridement and the removal of dense bone, however, may weaken the endplate and therefore impair the seating of Synex and potentially result in subsidence. In order to maintain the mechanical strength of the adjacent vertebral body endplates, avoid using chisels and resecting bony parts.

If possible, leave the anterior and posterior longitudinal ligaments intact.

To enhance the integration of the transplanted material, leave a shell of the most anterior, contralateral and/or posterior parts of the vertebral body intact if possible.



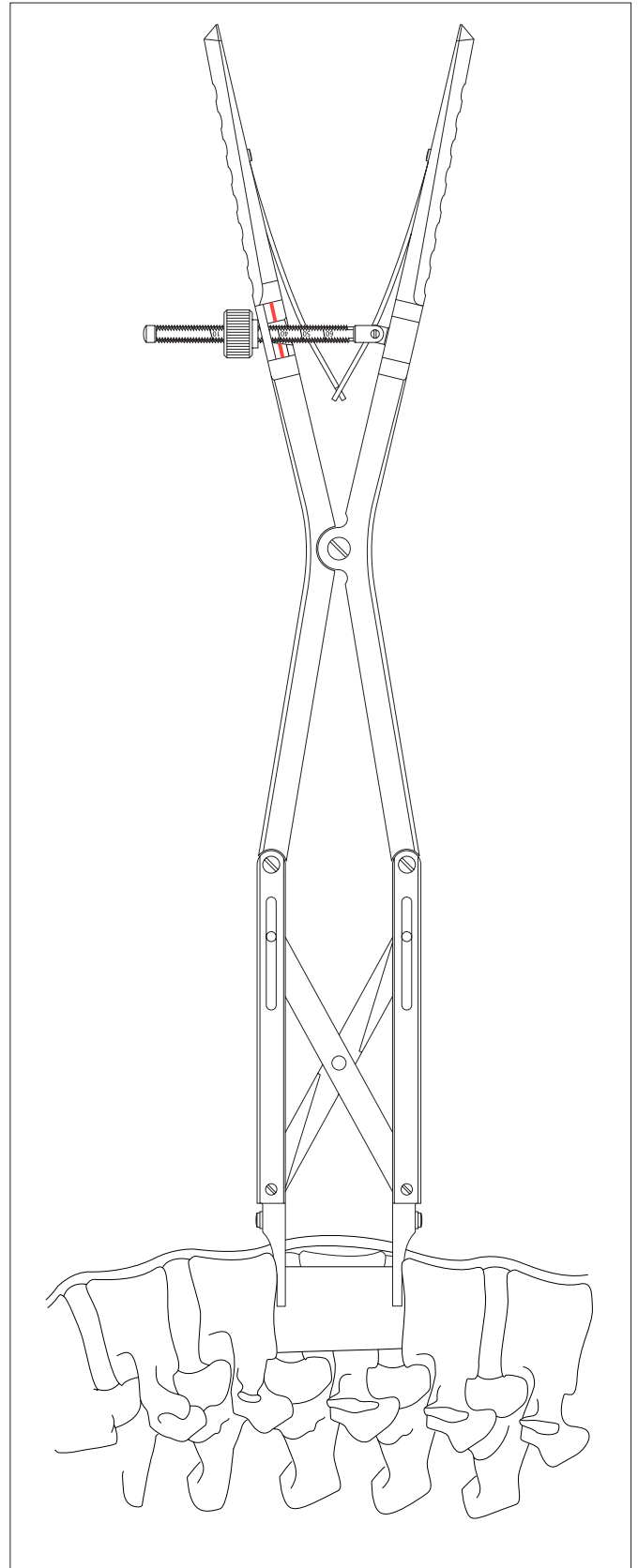
3

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.

An evaluation of the preoperative X-ray with the X-ray Template (X000011) gives additional information about the required height and endplate inclination. Determine the appropriate type of Synex: 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.

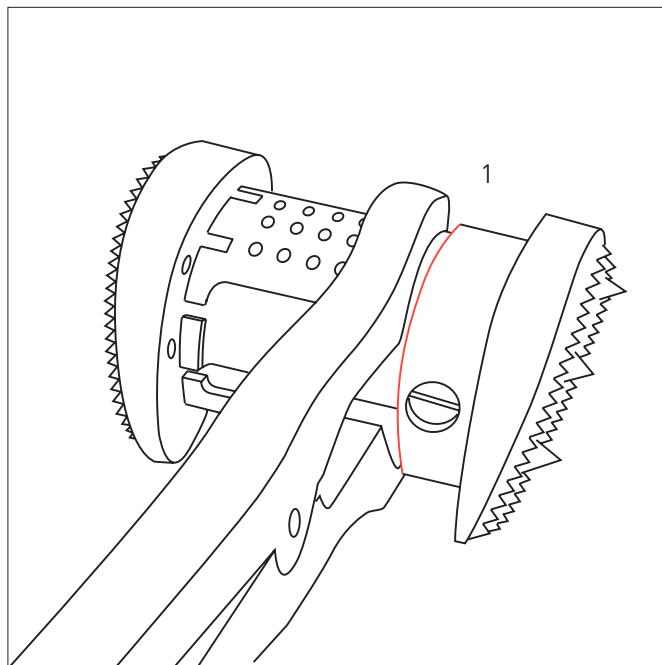


4

Pick up Synex

Pick up Synex with 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.

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



5

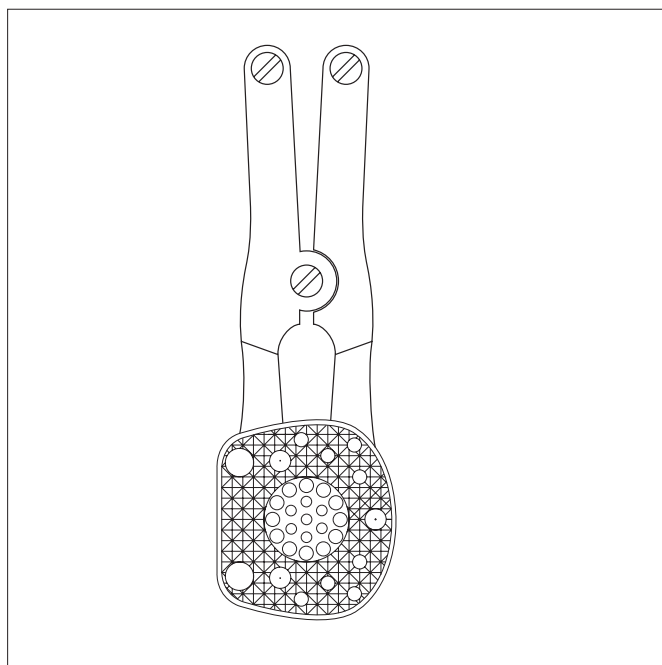
Fill the implant cups and the contralateral side of the spinal column with bone chips

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. In order to achieve a fusion, it is more important to fill the area around the implant (as described in step 10 on page 9).

To ensure a good contact/on-growth to the adjacent vertebral bodies, the bone chips should exceed the implant endplates.

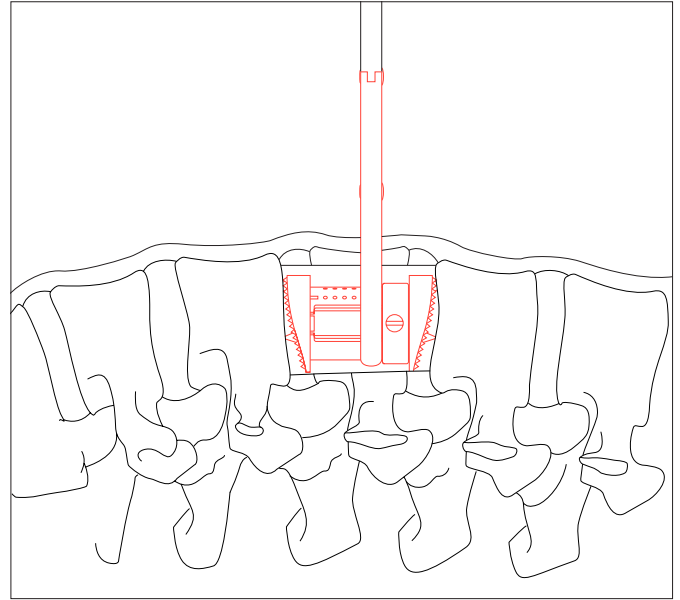
Note: The hollow body of the implant is filled only after expansion as described in step 10 on page 9.

Fill the zone which cannot be reached after insertion of Synex with bone chips (i.e. the contralateral part of the spinal column).



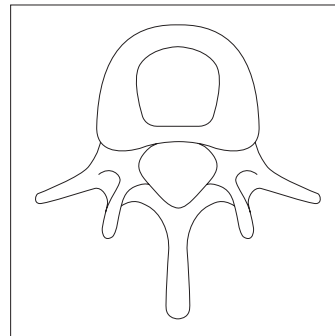
6 Implantation

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 optimal 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.

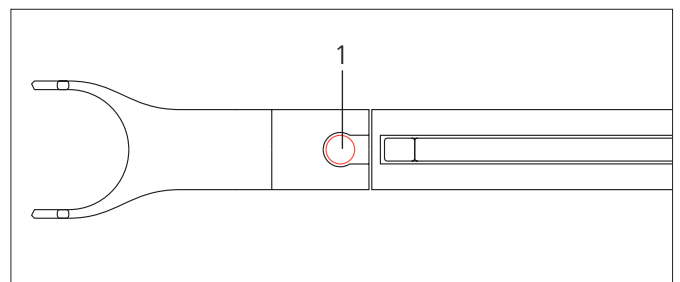
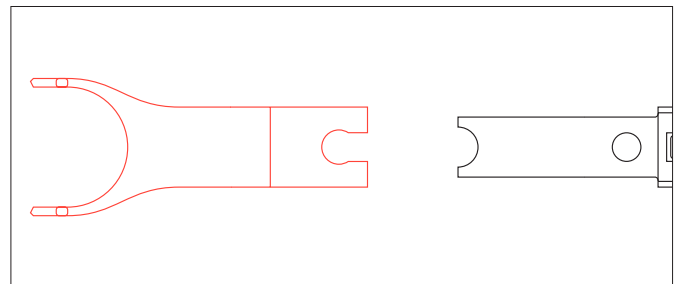


7 Mount headpieces onto spreader forceps

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

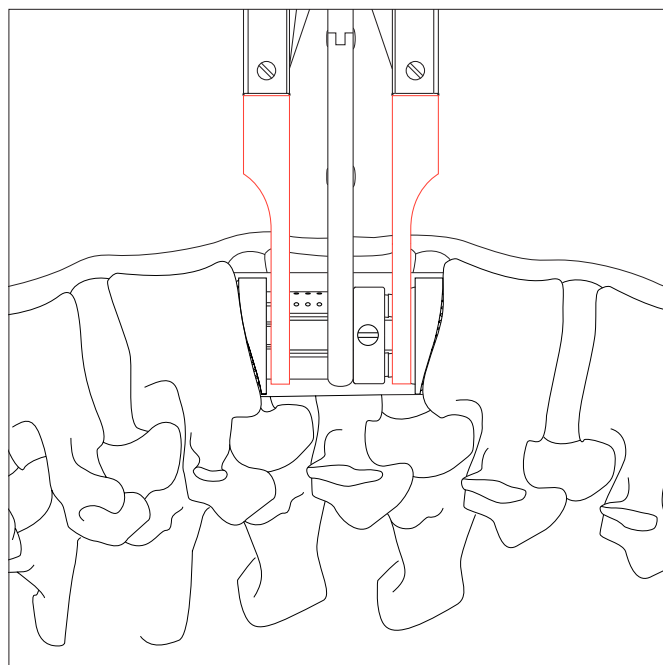
Expand Synex in situ using the spreader forceps, which can be used in combination with the implant holder. Expand until satisfied with the height and amount of anchorage reached. Each step of the ratchet mechanism corresponds to a distraction of 2.5 mm.

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

Note: 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 (Option) and replace it by 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

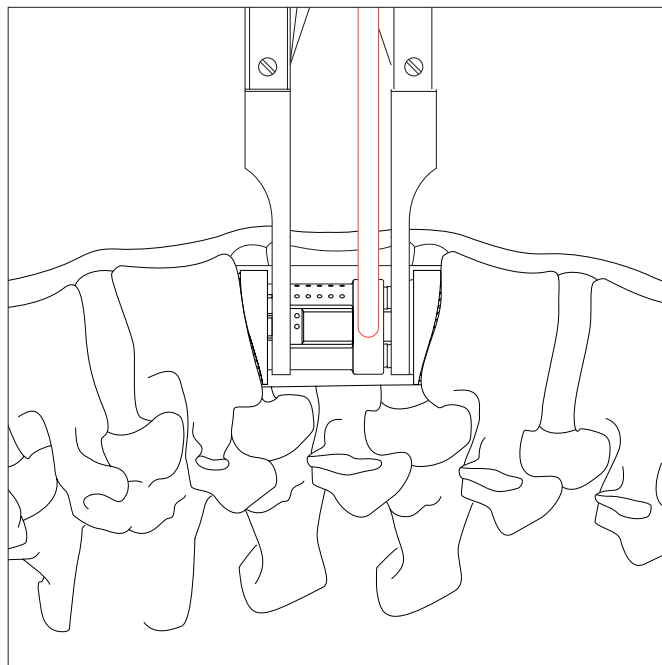
Reduce Synex to its neutral position

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.

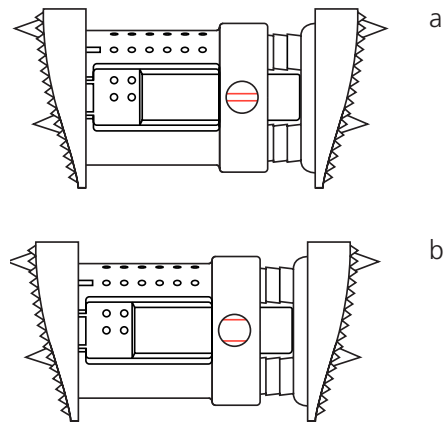
Note: Do not re-use Synex implants once they have been implanted or expanded.



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.



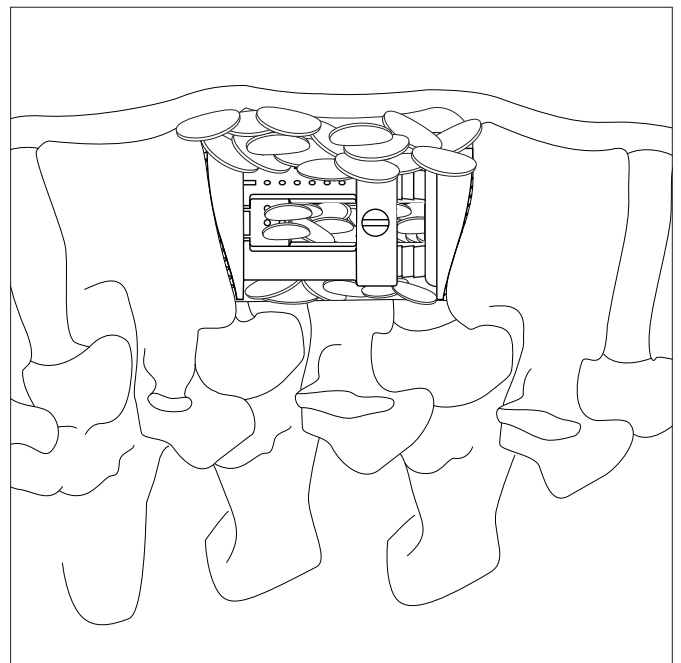
10

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. It can be filled with bone chips or adequate material such as bone cement. If the implant is filled before expansion, the filling material might obstruct the self-locking mechanism.



11

Additional fixation

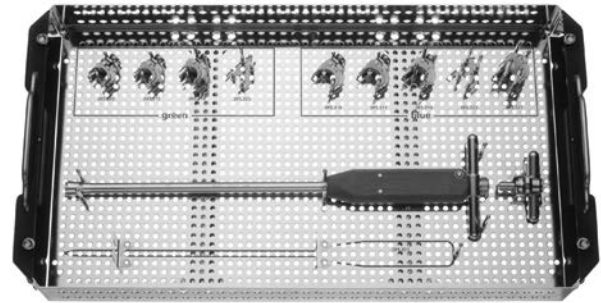
As with all vertebral body systems, Synex must be used in combination with a stable internal fixation system, e.g. a DePuy Synthes Spine supplemental fixation, which is capable of absorbing tensile forces as well as torsional, flexion and extension moments.

CLEANING OF INSTRUMENTS

Open the Spreader Forceps (389.193) approximately 20–30 mm before cleaning and tighten the set screw on its handle.

OPTIONAL SPREADING INSTRUMENTS

187.370 Endoscopic Spreader for Synex in Vario Case Polyaxial instrument for minimal invasive or endoscopic-assisted approaches



389.202 Synex Spreader for MIS Allows a more controlled distraction through a smaller incision



