SynCage
Surgical Technique
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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Product Overview

Intended Use

The SynCage system is an implant and instrument system for anterior lumbar interbody fusion (ALIF). It was designed to:

• allow for interbody fusion in an optimum anatomical position
• allow distraction of the disc space and permit restoration of disc height, lordosis, and consequent widening of the neural foramina
• maintain the integrity of the endplates
• provide optimal implant-endplate interface, potentially limiting the risk of sinkage into the adjacent vertebrae
• allow for bone ingrowth through the cage
**Implant Description**

The SynCage implant features convex superior and inferior surfaces which are designed to mimic the natural endplate curvature. Its wedge-shaped design helps to restore the natural lordotic curvature of the spine and to restore the disc height. The superior and inferior surfaces also feature holes for bony ingrowth. The pattern of the holes together with the large contact surface of the implant with the endplate serve to potentially reduce the risk of sinkage into the endplate and to transfer stresses to the strong peripheral bone of the vertebral body.

The SynCage is available in five sizes, each of which is anodised in a different colour to allow easy differentiation.

The SynCages are manufactured of high-strength titanium alloy (TAN) which provides MRI/CT compatibility.
While the contents of the SynCage set are minimal, the instrumentation is designed to provide the surgeon with the flexibility in choosing the surgical approach and insertion technique.

**SynCage Trial Implants**

*(397.030, 397.029, 397.031, 397.032, 397.033)*

Allow precise selection of the SynCage size and can also serve to help open the disc space.
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.\textsuperscript{1,2}

<table>
<thead>
<tr>
<th>Stability</th>
<th>Alignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stabilization to achieve a specific therapeutic outcome</td>
<td>Balancing the spine in three dimensions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Biology</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etiology, pathogenesis, neural protection, and tissue healing</td>
<td>Preservations and restoration of function to prevent disability</td>
</tr>
</tbody>
</table>

Product Overview

Handle for SynCage Trial Implants, straight (397.034), and Handle for SynCage Trial Implants, angled (397.035)

The Trial Implant is screwed onto the Trial Implant Handle at a position corresponding to 0°, 45° or 90° to the vertebral midline. The choice of position depends upon the surgical approach.

An alternative to the straight version, the angled handle is specifically designed for use at L5–S1.
Distractor Handle for anterior approach (397.081) and Distractor Blades (397.082, 397.083)

For use when the implant is inserted from anterior. The Distractor (blades mounted on handle) allows simultaneous distraction and implant insertion without compromising the space available within the intervertebral disc region for placement of the implant.

Distractor for Lateral Approach (397.084) and Seldrill Schanz Screw Ø 6.0 mm (294.796)
(screws not pictured here)

For use when the implant is inserted from anterolateral.

This instrument is designed to be useful when performing a “mini-ALIF” procedure or if the vessels cannot be mobilised. It is best used with Seldrill screws, which are inserted without drilling or tapping.
**Implant Holder, straight (397.087)**

Allows secure control of the SynCage during implantation. The instrument can grasp the implant on the anterior or lateral faces. Ensure that the instrument is fitted firmly in the slot of the SynCage before closing the handles of the instrument, otherwise damage to the SynCage and/or instrument can result.

The SynCage is secured on the Implant Holder by closing the handles of the instrument and tightening the locking nut.

**Implant Holder for Lateral Approach, angled (397.088)**

Allows secure control of the SynCage during implantation. This instrument is useful for insertion of the implant from anterolateral.

The SynCage is mounted on the instrument by aligning the “A” (anterior) marking on the implant with the “A” marking on the instrument.
Packing Block for SynCage (397.092) and Cancellous Bone Impactor, straight (394.570)

Allows ease of insertion and compacting of bone graft in the SynCage.

The lid of the packing block is pivoted up and away to allow ease of insertion of the cage. The lid is then pivoted back over the implant to secure the implant for packing.

**Note:** The Implant Holder must be assembled to the implant prior to packing.

Lateral view radiograph: SynCage at L5–S1 with translaminar screw fixation.
Indications and Contraindications

Indications
Lumbar and lumbosacral pathologies which may require segmental arthrodesis, including:

• degenerative disc disease and instability
• primary surgery for certain advanced disc disease
• revision surgery for post-discectomy syndrome
• pseudoarthrosis or failed arthrodesis
• degenerative spondylolisthesis
• isthmic spondylolisthesis

Contraindications
• spinal fractures
• spinal tumor
• major spinal instability
• primary spinal deformity
Surgical Technique

Preoperative Planning

Prior to surgery, the desired surgical approach and an estimation of the appropriate SynCage size is determined. The desired surgical approach is dependent on the level to be treated and the surgeon’s preference. As the SynCage can be inserted from either the anterior or anterolateral direction, the surgeon is free to use the approach of choice. The technique for insertion of the SynCage varies slightly depending on the direction chosen.

An initial estimate of the SynCage size can be determined by comparing the SynCage Radiograph Template (0330.060) with the adjacent intervertebral discs on a lateral radiograph. The height of the template is 1 mm (half the height of the two sets of teeth) shorter than that of the respective SynCage to account for penetration of the teeth into the vertebral bone.

The SynCage must fit firmly with a tight press-fit between the endplates with the segment fully distracted. It is essential that the tallest possible SynCage be used so as to enhance the stability of the segment resulting from tension in the ligament and annulus fibrosus.

Surgical Approach

The patient is positioned as required for the chosen approach. For treatment of the lower lumbar levels from anterior the patient is placed in the Trendelenburg position. If the SynCage is to be introduced anterolaterally, for example at higher levels of the lumbar spine, the patient is placed in either a supine or lateral decubitus position.
Surgical Technique
for Anterior Approach

1. Attain exposure

For anterior insertion, the intervertebral disc is exposed such that there is a clear space on either side of the vertebral midline equal to half the width of the SynCage. If the vessels and/or tissues cannot be retracted sufficiently, insertion from anterolateral direction may be indicated.

2. Cut anterior window

A rectangular window the width of the SynCage is cut in the anterior longitudinal ligament and annulus fibrosus. A Trial Implant (397.030, 397.029, 397.031, 397.032, 397.033) may be used to measure the width of the window.

Care is taken to retain as much of these structures as possible as they are important for the stability of the instrumented segment.
3. Prepare the disc space

Through the window in the anterior longitudinal ligament and annulus fibrosus, the disc material is excised and the superficial layers of the cartilaginous endplates removed such that bleeding bone is attained. Adequate cleaning of the endplate is important for vascular supply to the bone graft, however, excessive cleaning may weaken the endplate due to removal of the denser bone of the endplate. If possible, the endplate is prepared such that its curvature matches that of the superior and inferior surfaces of the implant.

Once the endplates have been prepared and any additional surgical procedures completed, the SynCage is introduced into the intervertebral space as follows.

Notes:
• It is essential that enough material is removed from the intervertebral disc to accommodate the SynCage, otherwise disc material may be displaced posteriorly during insertion of the implant.
• Excessive removal of the subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and loss of segmental stability may result.
4. Distract the segment

Distraction of the segment is essential for restoration of disc height, opening of the neural foramina and stability of the SynCage.

**Distraction is achieved prior to insertion of the SynCage using the Distractor Handle for anterior approach (397.081) with attached Distractor Blades (397.082, 397.083).**

To ensure that the SynCage is inserted symmetrically in the disc space, the line on the blades indicating the vertebral midline is aligned with the anterior midline of the vertebral bodies.

Compressing the Distractor Handle opens the disc space.

**Notes:**
- Distraction may also be performed using the SynCage Trial Implants (397.029–397.033) and/or with a vertebral spreader.
- In patients with existing posterior instrumentation, care must be taken to avoid excessive distraction of the disc space(s) as this may result in difficulty removing the blades of the Distractor Handle.
5. Trial for implant size

The Trial Implant that corresponds with the SynCage size determined during the preoperative planning is selected and attached to the straight Handle for SynCage Trial Implants (397.034).

The SynCage is colour-coded by height:

<table>
<thead>
<tr>
<th>Size</th>
<th>Item No.</th>
<th>Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>XXS</td>
<td>495.508</td>
<td>light blue</td>
</tr>
<tr>
<td>Extra-small</td>
<td>495.307</td>
<td>gold</td>
</tr>
<tr>
<td>Small</td>
<td>495.309</td>
<td>dark blue</td>
</tr>
<tr>
<td>Medium</td>
<td>495.311</td>
<td>violet</td>
</tr>
<tr>
<td>Large</td>
<td>495.313</td>
<td>green</td>
</tr>
</tbody>
</table>

With the SynCage of the correct height chosen, it is secured on the straight Implant Holder (397.087).

6. Select the implant

The SynCage corresponding to the Trial Implant is then selected.

The SynCages are colour-coded by height:

Precaution: The SynCage Trial Implants are not for implantation and must be removed before insertion of the SynCage.
7. Pack implant with bone graft

To assist packing the graft, the SynCage with the Implant Holder attached is set into the Packing Block for SynCage (397.092). The Cancellous Bone Impactor (394.570) is used to firmly pack the graft material into the implant.

It is important that the SynCage is completely filled so that the graft protrudes from the holes in the SynCage, improving the blood supply to the graft.

8. Insert implant

With the SynCage ready for insertion, the segment is again distracted. The distraction is fixed by tightening the locking screw on the handle.

The SynCage is then introduced into the disc space by sliding it between the Distractor Blades.

The SynCage may require light hammering to fully introduce it into the disc space.

**Note:** The Distractor should be withdrawn prior to hammering.

**Precaution:** Use caution in handling the SynCage. Damage to the surface finish and/or teeth can lead to fatigue failure or displacement of the SynCage.
9. Remove instruments

Once the SynCage is in the correct position, the locking screw on the Distractor Handle is loosened and the distraction released. The Distractor is gently removed while the SynCage is maintained in position by the Implant Holder.

The Implant Holder is then released from the SynCage by loosening the locking nut, leaving the SynCage in its final position.

10. Verify placement

The desired position for the SynCage is centred within the periphery of the vertebral endplate.

Depending on the size of the vertebrae, the anterior edge of the SynCage will be approximately three to four millimetres posterior from the anterior edge of the adjacent vertebrae.

The location of the SynCage relative to the vertebral bodies in the AP direction should be verified using an image intensifier.
1. Insert Seldrill screws

Once exposure of the intervertebral disc is attained, the surrounding tissues and vessels retracted and the disc space prepared, a Seldrill Schanz Screw Ø 6.0 mm, Stainless Steel (294.796) is inserted into each of the vertebral bodies adjacent to the disc to be treated. These screws are self-drilling and self-tapping and should be inserted under low power, high torque. These screws should be introduced parallel to each other. Care must be taken to ensure that they are not inserted too deeply.

Note: This is an abbreviated text. Surgical technique steps common to the anterior approach are not repeated in detail here.

2. Apply Lateral Distractor

The tubular extensions of the Distractor for Lateral Approach (397.084) are slid over the screws.

Precaution: Use of the Distractor for Lateral Approach (397.084) is contraindicated for patients with osteoporosis.
3. Distract the segment

The vertebral segment is distracted by turning the knob of the Distractor.

If necessary, additional distraction may be achieved using a vertebral spreader to open the space, using then the Lateral Distractor to hold the distraction. Trial Implants may also be used to help open the segment.

4. Trial for implant size

To determine the correct size of SynCage, the Trial Implant is slid into the distracted disc space.

If a tight fit is not achieved, try the next larger Trial Implant size; or if the Trial Implant cannot be inserted, try the next smaller size. With the segment fully distracted, the SynCage must fit firmly with a tight press-fit between the endplates such that disc height is not lost once the Distractor is removed.

Once the size of SynCage has been selected, the distraction is temporarily relaxed.

Precaution: The SynCage Trial Implants are not for implantation and must be removed before insertion of the SynCage.
5. Select implant

The SynCage corresponding to the Trial Implant is then selected. The SynCages are colour-coded by height:

<table>
<thead>
<tr>
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</tr>
<tr>
<td>Large</td>
<td>495.313</td>
<td>green</td>
</tr>
</tbody>
</table>

With the SynCage of the correct height chosen, it is secured on the desired Implant Holder. Depending on the angle of the approach the SynCage is introduced with either the Implant Holder for Lateral Approach (397.088), or the straight Implant Holder (397.087).

For SynCage XXS (495.508) use the Implant Holder for SynCage XXS, straight (397.111).

6. Pack implant with bone graft

The SynCage is then packed with bone graft as previously described (page 16).
7. Insert implant

With the SynCage ready for insertion, the segment is again distracted.

The SynCage is then introduced into the distracted disc space.

The SynCage may require light hammering to fully introduce it into the disc space.

**Precaution:** Use caution in handling the SynCage. Damage to the surface finish and/or teeth can lead to fatigue failure or displacement of the SynCage.

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8. Remove instruments

Once the SynCage is in the correct position and the Implant Holder removed, the distraction is released and the Lateral Distractor is removed. The two Seldrill screws are then removed.
9. Verify placement

The desired position for the SynCage is centred within the periphery of the vertebral endplate.

Depending on the size of the vertebrae, the anterior edge of the SynCage will be approximately three to four millimetres posterior from the anterior edge of the adjacent vertebrae. The location of the SynCage relative to the vertebral bodies in the AP direction should be verified using an image intensifier.
Supplemental Posterior Stabilization

For treatment of spondylolisthesis, the use of a supplemental pedicle screw construct is indicated. In such cases, the posterior procedure is performed first. Care must then be taken to ensure that the disc space is not excessively distracted as this may cause difficulty in removing the blades of the distraction instrument.

Note: In patients with existing posterior instrumentation, care must be taken to avoid excessive distraction of the disc space(s) as this may result in difficulty removing the blades of the Distractor Handle.

Postoperative Care

The patients can be mobilised one day after surgery. A brace (T.L.S.O. or L.S.O.) is recommended to be worn for the first three months postoperatively. The patients should be cautioned against activities that place unreasonable stress on the region. Excessive physical activity and trauma affecting the involved vertebrae may cause premature failure through loosening and/or fracture of the endplate.
Supplemental Instruments

Other instruments which may be useful during the SynCage procedure include:

- **Universal Chuck with T-Handle (393.100)**
  if standard Schanz Screw Ø 6.0 mm (294.680) are used with the Lateral Distractor and are inserted manually.

- **Cancellous Bone Impactor B 8.0 mm (397.730) and Handle with Quick Coupling (397.700)**
  a larger version of the Cancellous Bone Impactor (394.570).

- **Bone Spreader (399.100, 399.130)**
  spreaders that can be used to distract the vertebral segment.

- **Hammer 500 g/700 g (399.420, 399.430)**
  for final seating of the implant and for packing bone graft into the implant.

- **Spinal Instruments for Anterior Surgery**
  a range of instruments specifically designed for the requirements of anterior spinal surgery. Included are Punches, Rongeurs and Curettes.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>495.508</td>
<td>SynCage XXS, 12 × 24 × 30 mm</td>
</tr>
<tr>
<td>495.307</td>
<td>SynCage, Extra-small, anterior/posterior height 13.5/8.5 mm, Titanium Alloy (TAN), gold</td>
</tr>
<tr>
<td>495.309</td>
<td>SynCage, small, anterior/posterior height 15.0/10.0 mm, Titanium Alloy (TAN), dark blue</td>
</tr>
<tr>
<td>495.311</td>
<td>SynCage, medium, anterior/posterior height 17.0/12.0 mm, Titanium Alloy (TAN), violet</td>
</tr>
<tr>
<td>495.313</td>
<td>SynCage, large, anterior/posterior height 19.0/14.0 mm, Titanium Alloy (TAN), green</td>
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## SynCage Trial Implants

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>397.030</td>
<td>SynCage Trial Implant, XXS, 12 × 24 × 30 mm</td>
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<tr>
<td>397.029</td>
<td>SynCage Trial Implant, extra-small, for No. 495.307</td>
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<tr>
<td>397.031</td>
<td>SynCage Trial Implant, small, for No. 495.309</td>
</tr>
<tr>
<td>397.032</td>
<td>SynCage Trial Implant, medium, for No. 495.311</td>
</tr>
<tr>
<td>397.033</td>
<td>SynCage Trial Implant, large, for No. 495.313</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>--------</td>
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<tr>
<td>294.680</td>
<td>Schanz Screw Ø 6.0 mm, length 190/50 mm, Stainless Steel</td>
</tr>
<tr>
<td>294.796</td>
<td>Seldrill Schanz Screw Ø 6.0 mm, length 200/80 mm, Stainless Steel</td>
</tr>
<tr>
<td>393.100</td>
<td>Universal Chuck with T-Handle</td>
</tr>
<tr>
<td>394.570</td>
<td>Cancellous Bone Impactor, straight</td>
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<td>397.034</td>
<td>Handle for SynCage Trial Implants, straight</td>
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<tr>
<td>397.035</td>
<td>Handle for SynCage Trial Implants, angled</td>
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<tr>
<td>397.081</td>
<td>Distractor Handle for anterior approach</td>
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<tr>
<td>397.082</td>
<td>Distractor Blade, left, for Distractor Handle No. 397.081</td>
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<tr>
<td>397.083</td>
<td>Distractor Blade, right, for Distractor Handle No. 397.081</td>
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<td>Code</td>
<td>Description</td>
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<tr>
<td>397.084</td>
<td>Distractor for Lateral Approach, for SynCage</td>
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<tr>
<td>397.087</td>
<td>Implant Holder, straight, for SynCage</td>
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<tr>
<td>397.088</td>
<td>Implant Holder for Lateral Approach, angled, for SynCage</td>
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<tr>
<td>397.092</td>
<td>Packing Block for SynCage</td>
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<tr>
<td>397.111</td>
<td>Implant Holder for SynCage XXS, straight</td>
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<tr>
<td>397.700</td>
<td>Handle with Quick Coupling</td>
</tr>
<tr>
<td>397.730</td>
<td>Cancellous Bone Impactor Ø 8.0 mm, round</td>
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<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>399.100</td>
<td>Bone Spreader, speed lock, width 8 mm, length 210 mm</td>
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<tr>
<td>399.130</td>
<td>Bone Spreader, speed lock, width 12 mm, length 270 mm</td>
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<tr>
<td>399.420</td>
<td>Hammer 500 g</td>
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<tr>
<td>399.430</td>
<td>Hammer 700 g</td>
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