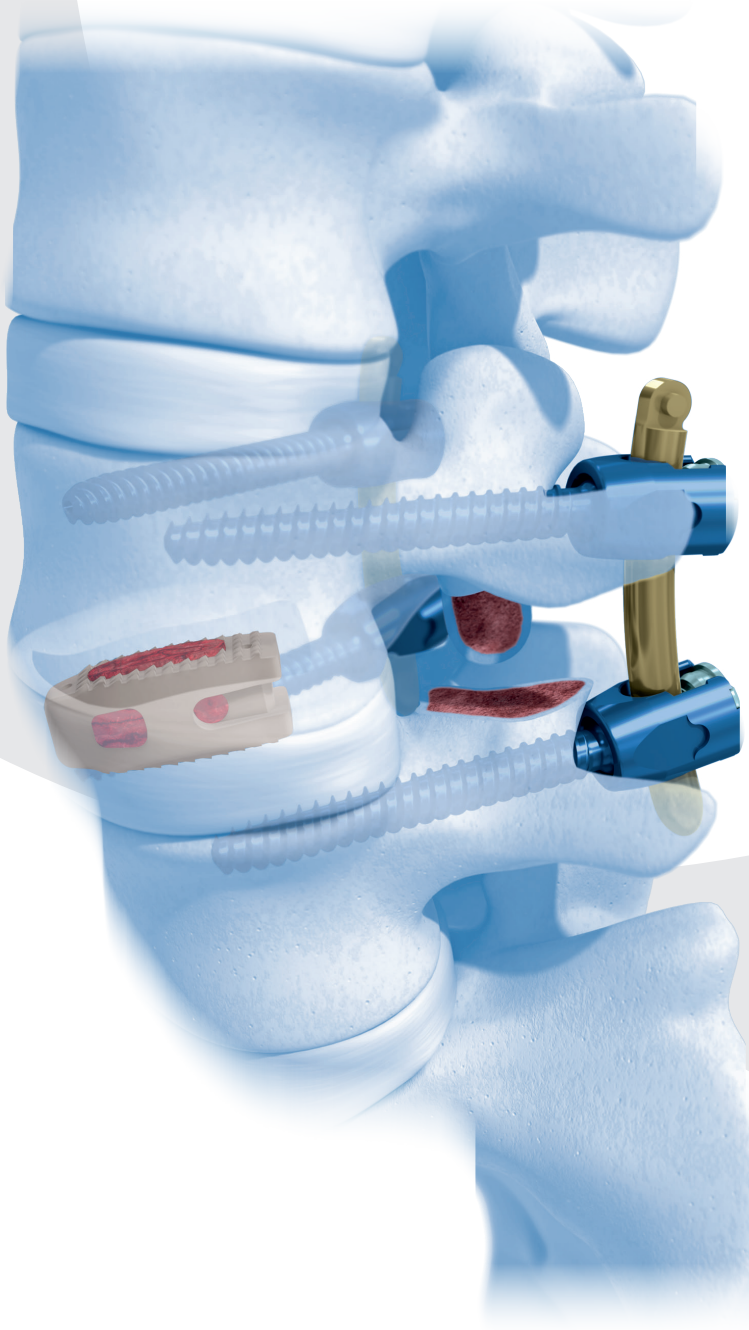
OPAL™ Spacer System

Surgical Technique



DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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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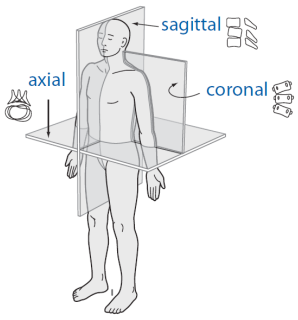
*For Product Catalogue contact your local DePuy Synthes representative.

AO Spine Principles

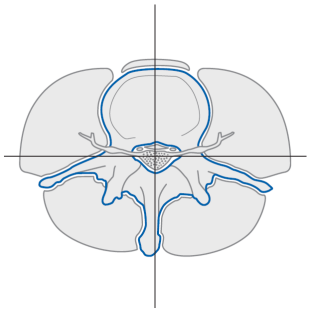
The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.[1,2]

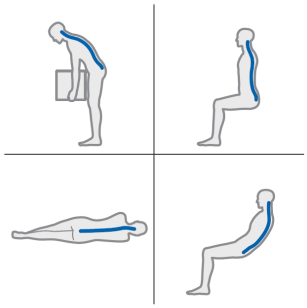
Stability
Stabilization to achieve a specific therapeutic outcome



Alignment
Balancing the spine in three dimensions

Biology
Etiology, pathogenesis, neural protection, and tissue healing





Function
Preservations and restoration of function to prevent disability

Access and Exposure

1. Position the patient

Position the patient in a restored physiological lordosis, avoiding abdominal restriction to reduce venous stasis.

2. Preparation and discectomy

Optional instruments / sets

328.021	Lateral Three-blade Retractor, small
328.025	Medial Three-blade Retractor, large
01.615.002	Insight Retractor Set, Standard Configuration

Resect the posterior anatomy and perform the discectomy. Use a transforaminal approach for insertion of 28mm and 32mm spacers (Figure 1). Use a bilateral posterior approach for insertion of 24mm spacers (Figure 2).

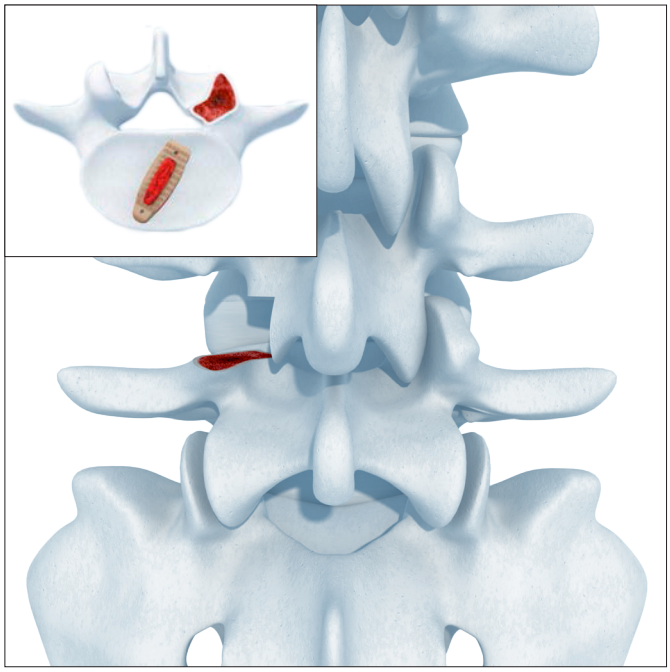


Figure 1

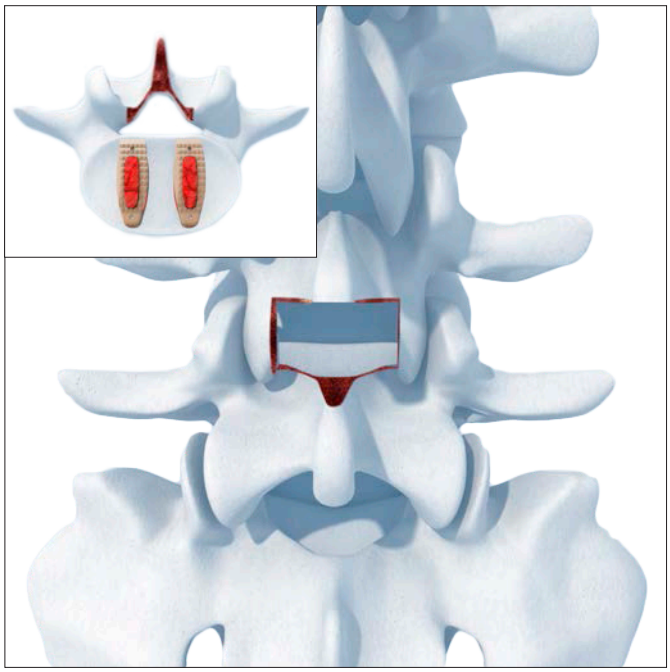


Figure 2

Optional instruments

03.605.504	Bone Curette, 5.5 mm, bayoneted, black
03.605.505	Bone Curette, 45° angled, 5.5 mm, short, bayoneted, black
03.605.507	Rasp, dual-sided, bayoneted, black
03.605.508	Osteotome, straight, black
03.803.054	Curette, rectangular, bayoneted, black
389.767–389.777	Shaver for Intervertebral Discs, size 7–17 mm
394.951	T-Handle with Quick Coupling

Optional system

01.605.903	Set for Minimally Invasive Posterior Instruments

Use the curette to remove the disc through the incision window.

Shavers and excision instruments for intervertebral discs can facilitate removal of the nucleus pulposus and the surface layers of the cartilaginous endplates.

Warning: **Appropriate cleaning of the endplates is important for the vascularisation of the bone transplant. Excessive cleaning however can weaken the endplates by removing bone under the cartilaginous layers. Removal of the entire endplate can cause subsidence and lead to loss of segmental stability.**

Trial for Implant Size

1. Determine implant size

Option A: Insert and rotate technique

Instruments

03.803.011– 03.803.015	Trial Implant OPAL, size 11 mm–15 mm

Precaution: **The insert and rotate technique can only be used for sizes 10 mm–15 mm. For all other sizes, use the impact technique.**

In order to rotate the trial implant in situ, extend the T-handle.

Push the green T-handle out of handle body (1).

Press and hold the button while sliding the T-handle to the end of the instrument (2).

Release the button, allowing the T-handle to lock into position (3).

Insert the trial implant with the etch representing the height of the trial facing the vertebral endplate (4).

Gently impact on the end of the trial implant until the implant is positioned across the midline and 3 mm–4 mm from the anterior longitudinal ligament.

The trial implant shaft should be oriented 30–45° from mid-line. When the trial implant reaches the desired depth, rotate 90° clockwise to distract and assess height adequacy (5).

Repeat using the next larger size trial implant, sequentially distracting until adequate anterior height is obtained.

With the segment fully distracted, the trial implant must fit tightly inside the disc space.

Notes:

- **The trial implants represent implants with a 28 mm length.**
- **Use flouroscopy during the insertion to confirm positioning of the trial implant.**

4

5

Option B: Impact technique

Instruments

03.803.007– 03.803.017	Trial Implant OPAL, size 7 mm–17 mm

Impact an appropriately sized trial implant with the etch representing the axial canal positioned cranial/caudal.

Continue to impact on the end of the trial implant until the cage is positioned across the midline and 3 mm–4 mm from the anterior longitudinal ligament. The trial implant shaft should be oriented 30–45° from midline.

Repeat using the next larger size trial implant, sequentially distracting until adequate anterior height is obtained. With the segment fully distracted, the trial implant must fit tightly inside the disc space.

Note: **The trial implants represent implants with a 28 mm length.**

2. Screw/rod fixation (optional)

For the unilateral oblique posterior approach, a screw/rod construct can be placed on the contralateral side while the trial implant is still in position. Provisionally tighten the construct on the contralateral side to maintain the height in the anterior column.

3. Remove trial implant

Instrument

03.803.055 Slide Hammer with Connector, short

When using the insert and revolve technique, it is recommended that the trial implant be rotated 90° counterclockwise before removal.

If removal of the trial implant requires too much force, the slide hammer can be used.

Slide the slide hammer onto the end of the trial implant. While holding the handle of the trial implant with one hand, apply an upward force to the slide hammer with the other hand.

Repeat this process until the trial implant is removed from the disc space.

The slide hammer can be removed by pushing on the end of shaft.

4. Prepare the implant holder

Option A: Insert and revolve technique

Instruments

03.803.002	OPAL Implant Holder, with Pistol Grip

Option B: Impact technique

Instruments

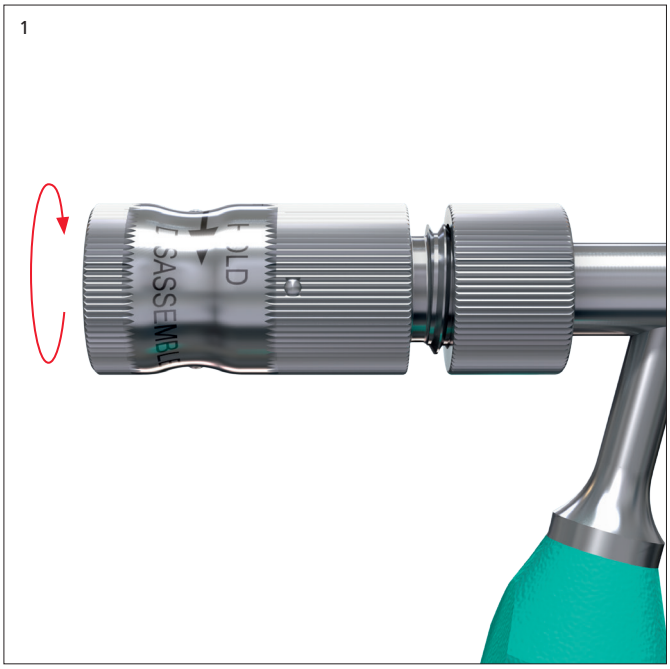
03.803.001	OPAL Implant Holder

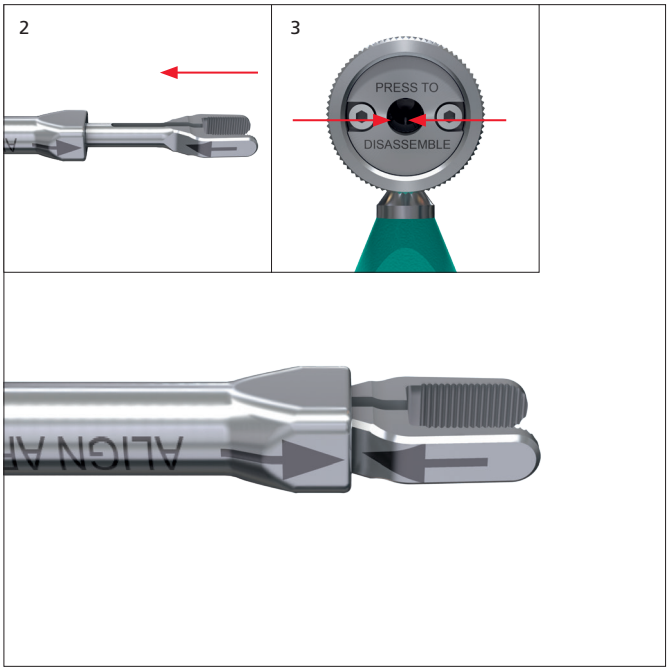
The implant holder must be assembled before insertion of the cage.

Attach the knob to the distal end of the implant holder sleeve by turning the knob counterclockwise (1).

Insert the shaft into the sleeve making sure to align the arrows on the end of the shaft with those on the sleeve (2).

Press the button on the distal end of the implant holder and push the shaft into the holder (3). The shaft should now be held inside the sleeve.





5. Select the OPAL cage

Select a cage that corresponds to the size measured using the trial implant in the previous steps.

Turn the knob at the distal end of the implant holder counterclockwise to open the jaws. Place the jaws over the posterior end of the cage making sure that the jaw's base is firmly seated against the implant. Turn the knob on the end of the implant holder clockwise until the jaws of the implant holder have a tight grip on the cage.

A

B

6. Pack implant with bone graft

Instruments

03.803.057	Cancellous Bone Impactor OPAL
03.803.058	Packing Block OPAL, size 28 × 10 mm
03.803.059	Packing Block OPAL, size 32 × 10 mm

After the cage is fixed to the implant holder, insert it into the appropriate packing block.

It is important to fill the implant until the filling material protrudes from its perforations in order to provide contant with the vertebral endplates

Use the cancellous bone impactor to pack the filling material into the implant cavities.

Warning:

- **The implant holder must be firmly attached to the implant in order to avoid damage to the implant and/or implant holder.**
- **The 24 mm implant must be packed manually.**

7. Insert OPAL cage

Option A: Insert and rotate technique

Instrument

03.803.002	OPAL Implant Holder, with Pistol Grip

Precaution: **The insert and rotate technique can only be used for sizes 10mm-15mm. For all other sizes, use the impact technique.**

Use the pistol grip implant holder and the revolvable cage for this technique. Orient the cage so that the lateral graft window is facing the vertebral endplate.

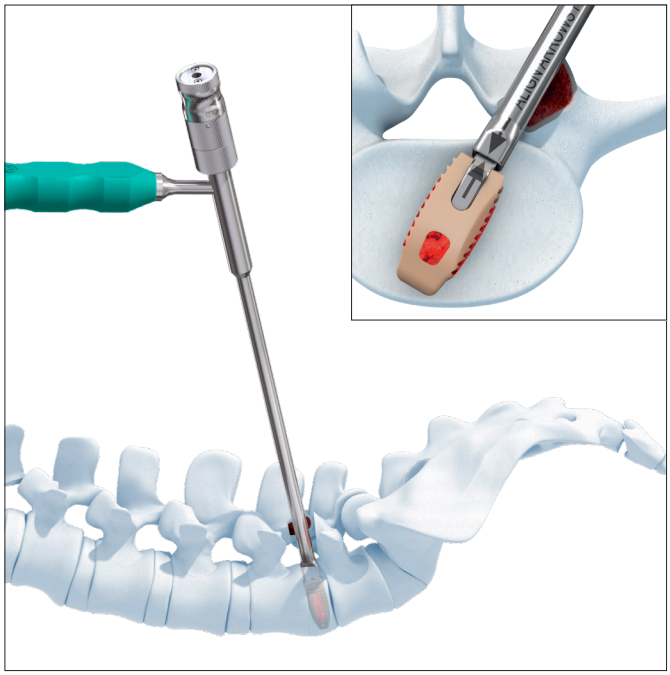
Gently impact on the end of the implant holder, until the cage is positioned across the midline and 3 mm–4 mm from the anterior longitudinal ligament. The implant holder shaft should be oriented 30–45° from midline.

Once the cage is in position, rotate the implant holder 90° clockwise so that the main graft window of the cage is oriented in the cranial/caudal direction.

The implant must fit tightly in order to preserve the segmental height.

- Use fluoroscopy to confirm position and fit of the implant.

When the cage is in the desired location, hold the handle firmly and turn the knob counterclockwise on the end of the implant holder to release it.



Option B: Impact technique

Instrument

03.803.001 OPAL Implant Holder

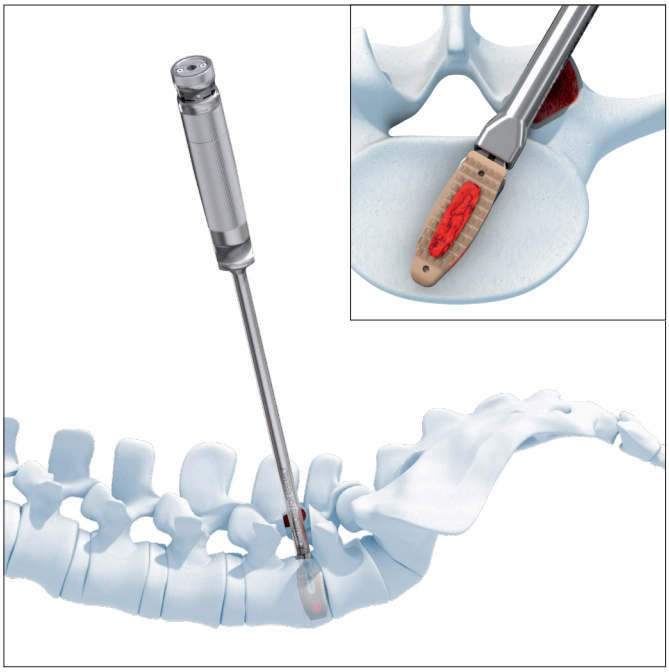
Using the implant holder, orient the cage with the main graft window in the cranial/caudal direction.

Gently impact on the distal end of the implant holder, until the cage is positioned across the midline and 3 mm–4 mm from the anterior longitudinal ligament. The implant holder shaft should be oriented 30–45° from midline.

With the segment fully distracted, the implant must fit tightly in order to preserve the segmental height.

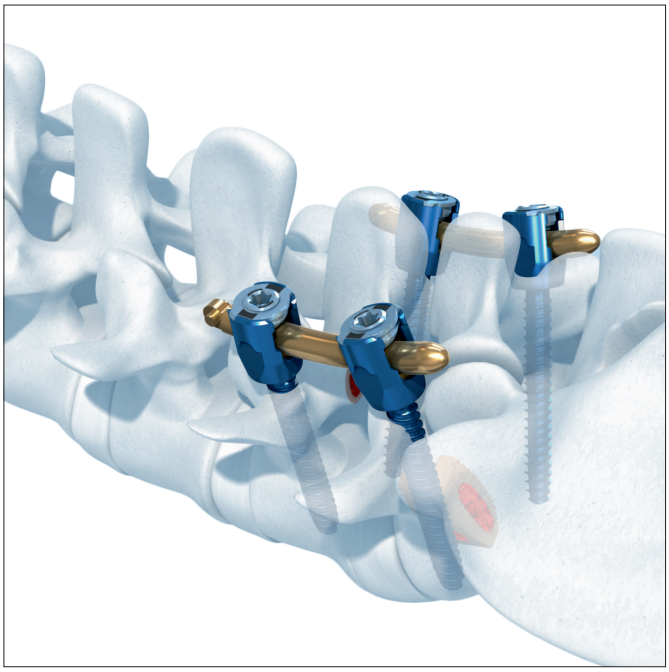
- Use fluoroscopy to confirm position and fit of the implant.

When the cage is in the desired location, hold the handle firmly and turn the knob on the end of the implant holder counterclockwise to release it.



8. Supplemental posterior fixation

The OPAL cage is intended to be used in combination with posterior fixation.



Implant Removal

If an OPAL implant must be removed, the following technique is recommended.

Implant removal with the implant holder

Instruments

03.803.002	OPAL Implant Holder, with Pistol Grip

and/or

03.803.001	OPAL Implant Holder

The implant holder must be assembled before removal of the cage (see page 11 for instructions).

Attach implant to implant holder in the correct cranial/caudal alignment.

Turn the knob at the distal end of the implant holder counterclockwise to open the jaws. Place the jaws over the posterior end of the cage making sure that the jaw's base is firmly seated against the implant. Turn the knob on the end of the implant holder clockwise until the jaws of the implant holder have a tight grip on the cage.

For the Opal Implant Holder, with Pistol Grip: Rotate the implant holder 90° counterclockwise so that the main graft window of the cage is oriented in the cranial/caudal direction.

Carefully remove the implant from the disc space

Note: Distraction of the segment may facilitate implant removal. However, if possible, do not distract before ensuring a firm connection between the implant and the applicator.

Bibliography

1. Aebi M, JS Thalgott, JK Webb. (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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