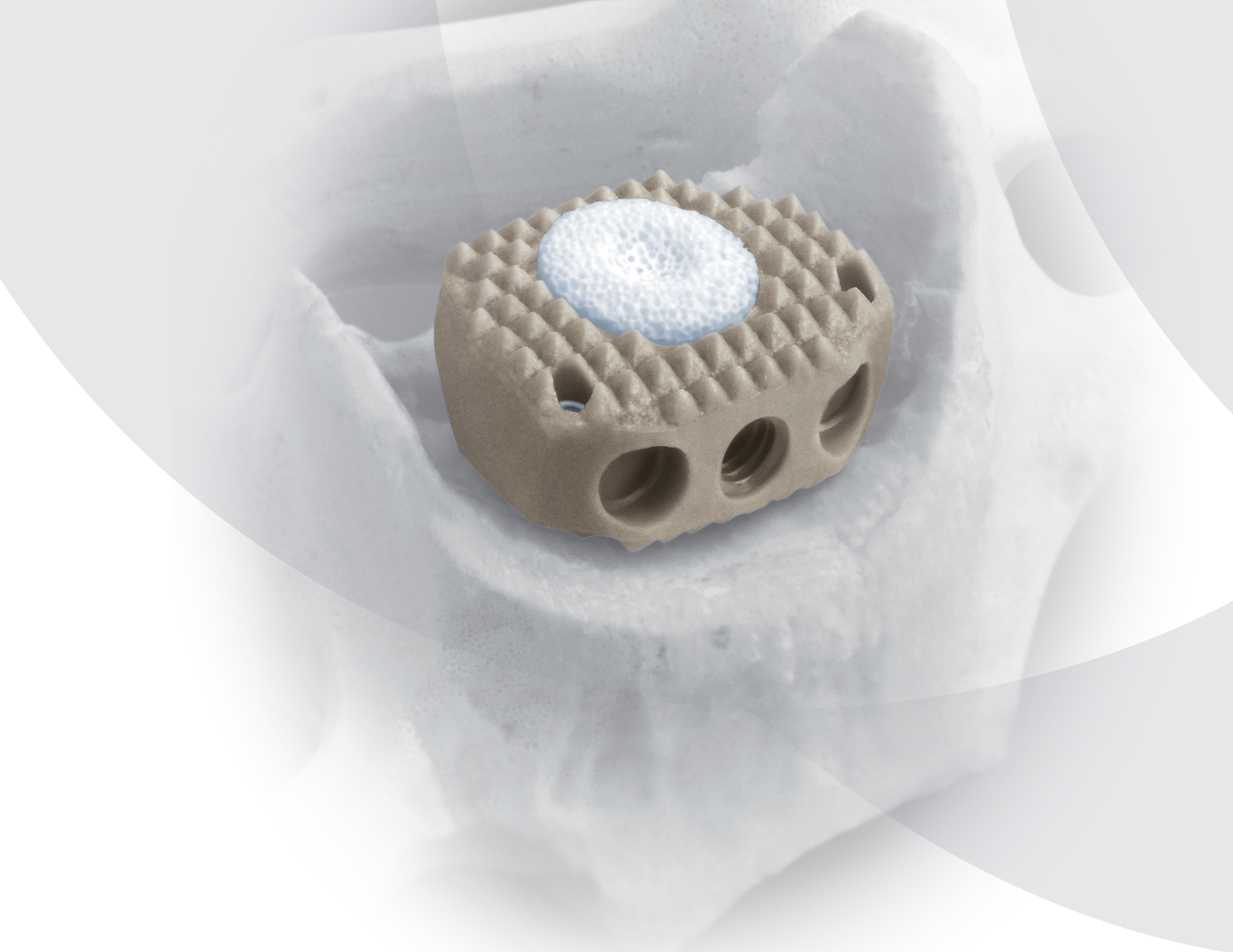
PEEK Cage for Anterior Cervical Interbody Fusion

CERVIOS™ and CERVIOS chronOS™ Cage 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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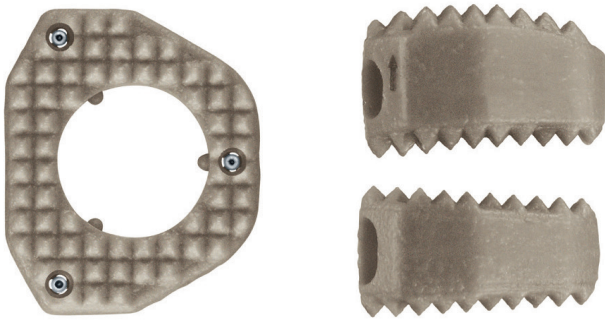
* For Product Catalog contact your local DePuy Synthes representative.

CERVIOS™ and CERVIOS chronOS™ Cage System

CERVIOS cage design

- PEEK-Optima® cage with Titanium radiopaque markers
- Pyramidal teeth on superior and inferior surface of cage
- Curved and wedge-shaped sagittal profiles available



CERVIOS pre-filled with chronOS

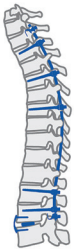
- chronOS is a bone graft substitute consisting of pure β-tricalcium phosphate.
- chronOS can be saturated with blood or bone marrow.

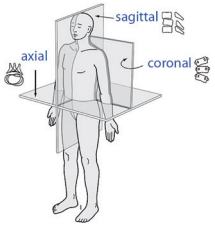
*PEEK-Optima® is a registered trademark of Invibio Ltd.

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]

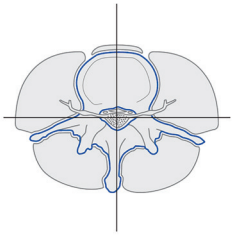
Stability
Stabilization to achieve a specific therapeutic outcome

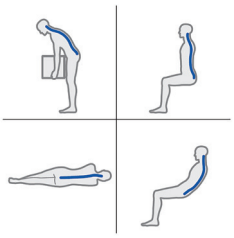




Alignment
Balancing the spine in three dimensions

Biology
Etiology, pathogenesis, neural protection, and tissue healing





Function
Preservations and restoration of function to prevent disability

Patient Positioning

Position the patient in a supine position on a radiolucent operating table. Ensure that the neck of the patient is in a sagittally neutral position and supported by a cushion. When treating C6–C7 make sure that the shoulders do not limit the x-ray monitoring.

- For all cases, both vertebrae should be completely visible on radiographic imaging.

Exposure and Discectomy

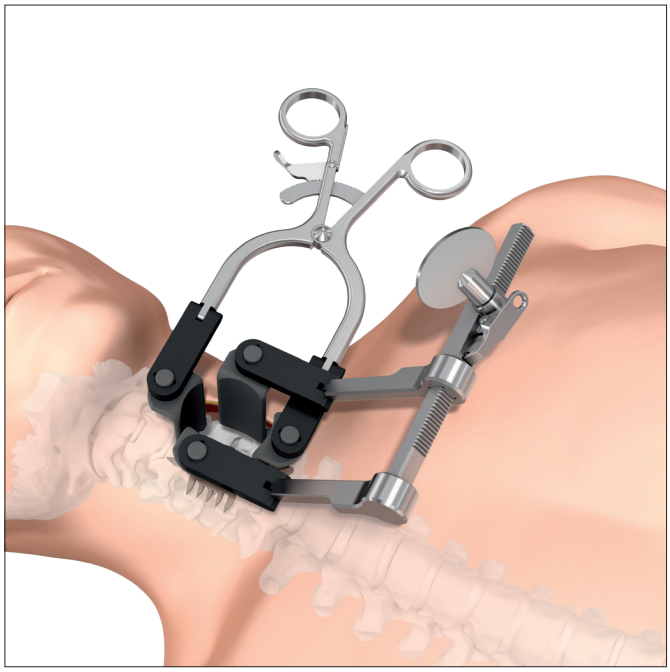
1. Access

Instrument	
Optional set	187.797 Cervical Retractors and Distractors

Locate the correct operative level using radiographic imaging.

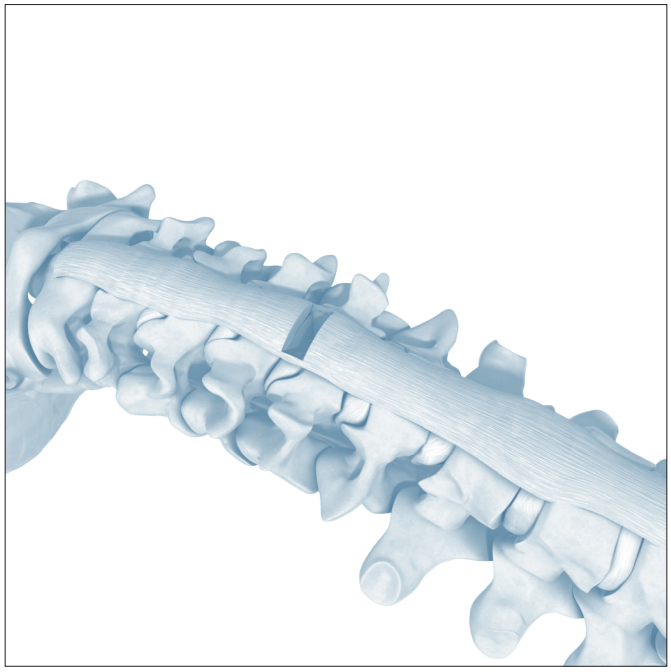
Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine.

Precaution: **Careful positioning of the retractor is required to protect against soft tissue damage.**



2. Discectomy

Prepare the fusion site following the appropriate technique for the given indication.



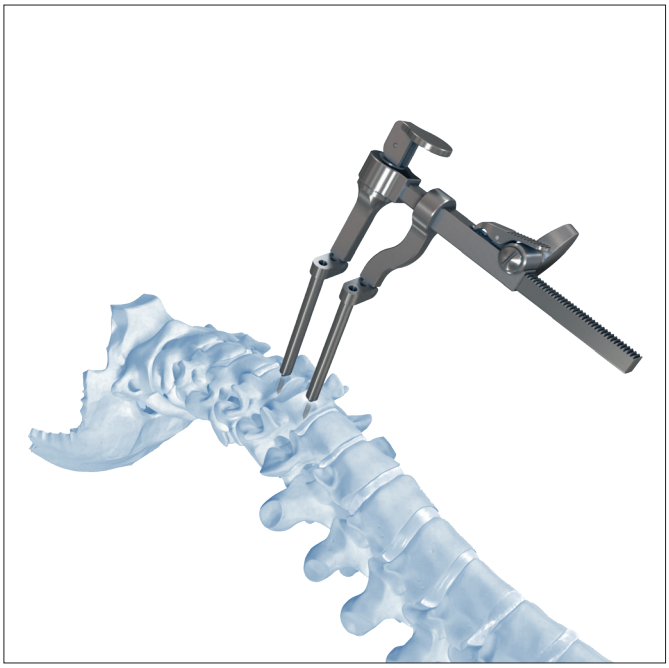
Segment Distraction and Endplate Preparation

3. Segment Distraction

Instrument	
396.395/396	Cervical Distractor left/right, with adjustable angle

Perform segmental distraction.

Note: **Distraction of the segment is essential for restoring disc height and for providing access to the intervertebral space.**



4. Endplate Preparation

When the discectomy is complete, remove the superficial cartilaginous layers of the endplates to expose bleeding bone.

Warnings:

- **Adequate cleaning of the endplates is important for vascular supply of the autologous bone graft or bone graft substitute. Excessive cleaning, however, may result in removal of bone underlying the cartilaginous layers and weaken the endplates.**
- **The removal of any osteophytes is crucial for achieving complete decompression of the neural structures and for reducing the risk of partial compression after implant insertion.**

5. Determine implant size and shape with trial implant

Choose the trial implant based on the height of the disc space and the patient's anatomy. Select the shape of trial implant (curved or wedge-shaped) that best matches the prepared end plates.

Note: **To distinguish the curved and wedge-shaped design the trial implants are colour-coded. Curved trial implants are golden, wedge-shaped trial implants are dark blue.**

Trial implants

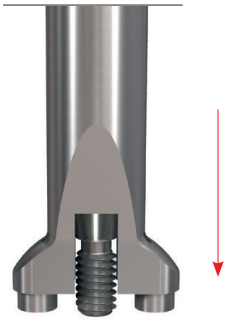
Height	Curved (golden)	Wedge-shaped (dark blue)
5 mm	396.931	396.921
6 mm	396.932	396.922
7 mm	396.933	396.923
8 mm	396.934	396.924
9 mm	396.935	396.925
10 mm	396.936	396.926

Curved

Wedge-shaped

6. Connect trial implant to holder

Instrument	
396.891	Holder, short, for CERVIOS and SynCage-C short
or	
396.989	Holder for Cervical Cages



Holders are etched “CRANIAL” and “CAUDAL” to properly engage the trial implants with the holders.

Connecting curved trial implant
The curved surface of the trial implants and implants must always face cranially. They are marked with 2 arrows pointing cranially. Connect the trial implant to the holder so that the cranial implant surface matches with the side etched “CRANIAL” of the holder.

Connecting wedge-shaped trial implant
The wedge-shaped trial implants and implants do not have a dedicated cranial or caudal side. They can be attached to the holder with any surface pointing cranially.

7. Option: Attach depth limitator to holder

Instrument	
396.993	Depth Limitator for Holder for SynCage-C and CERVIOS

The depth limitator can be attached to the side of the holder. It has a stop that will contact the anterior edge of the vertebral body when the CERVIOS implant is inserted 2 mm beyond the anterior edge of the vertebral body.

8. Insert trial implant and check size

Warning: **Before inserting the trial ensure that all disc material has been removed from the insertion path to avoid displacing it into the spinal canal.**

Orient the holder in the correct cranial/caudal alignment and carefully insert the trial implant into the disc space.

If necessary, controlled and light hammering with the mallet can be used to help advance the trial implant into the intervertebral disc space.

Precautions:

- **Excessive impaction force during trial implant insertion must be avoided.**
- **An image intensifier should be used to check the position during insertion.**

If the trial implant appears too loose or too tight, try the next larger or smaller size height until the most secure fit is achieved.

Warnings:

- **With the segment fully distracted, the trial implant must fit tightly between the endplates. To reduce potential increased risk to the patient, it is recommended to first trial with smaller height trial implants before trialing with taller trial implants.**
- **Trial implants are not for implantation and must be removed before insertion of the implant.**

Note: **The height of the trial implants is the same as the height of the implants.**

9. Determine size

Select the curved or wedge-shaped cage corresponding to the trial implant.

Cages

Height	Shape	CERVIOS	CERVIOS chronOS
5 mm	curved	889.931S	870.931S
6 mm	curved	889.932S	870.932S
7 mm	curved	889.933S	870.933S
8 mm	curved	889.934S	870.934S
9 mm	curved	889.935S	870.935S
10 mm	curved	889.936S	870.936S
5 mm	wedge-shaped	889.921S	870.921S
6 mm	wedge-shaped	889.922S	870.922S
7 mm	wedge-shaped	889.923S	870.923S
8 mm	wedge-shaped	889.924S	870.924S
9 mm	wedge-shaped	889.925S	870.925S
10 mm	wedge-shaped	889.926S	870.926S

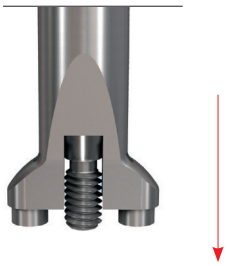
Curved

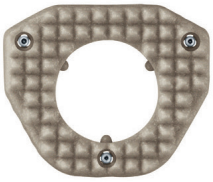
Wedge-shaped

Prepare the Implant

10a. CERVIOS

Instruments	
396.891	Holder, short, for CERVIOS and SynCage-C short
or	
396.989	Holder for Cervical Cages
396.996	Packing Block for CERVIOS
396.999	Cancellous Bone Impactor for CERVIOS





Remove the depth limitator from the holder. Connect the selected implant to the holder.

Connecting curved implant
The curved surface of implants must always face cranially. They are marked with 2 arrows pointing cranially. Connect the implant to the holder so that the cranial implant surface matches with the side etched "CRANIAL" of the holder.

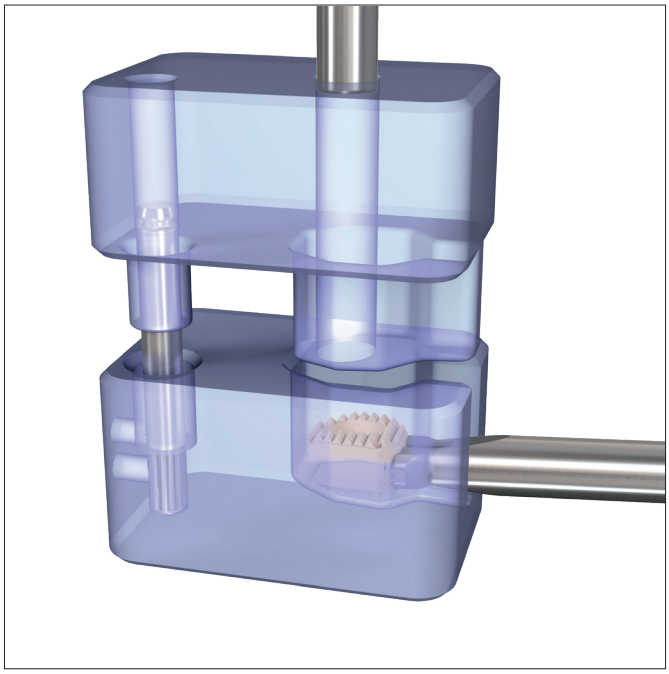
Connecting wedge-shaped implant
The wedge-shaped trial implants and implants do not have a specified cranial or caudal side. They can be attached to the holder with either surface pointing cranially.

Place CERVIOS implant with the cranial side facing upwards into the open packing block.

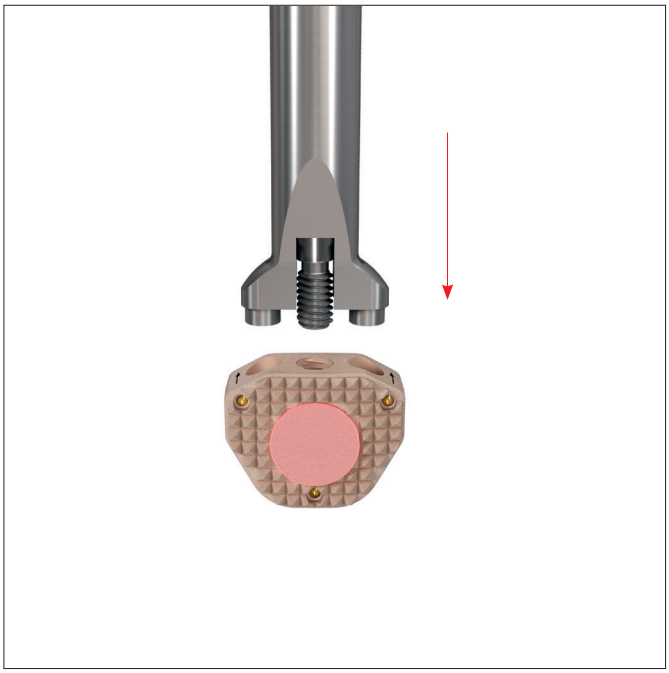
Close the lid of the packing block.

Fill the packing block through the lid opening with cancellous bone or bone substitute using the cancellous bone impactor. The implant must be completely filled.

Precaution: **Excessive impaction of the implant with the cancellous bone impactor should be avoided to prevent possible implant damage.**



10b. CERVIOS chronOS



Filling of the CERVIOS implant is not required if CERVIOS chronOS is used:

The implant can be soaked with autologous blood or bone marrow aspirate.

Connect cage to holder
Remove the depth limitator from the holder. Connect the selected implant to the holder.

Connecting curved implant
The curved surface of implants must always face cranially. They are marked with 2 arrows pointing cranially. Connect the implant to the holder so that the cranial implant surface matches with the side etched "CRANIAL" of the holder.

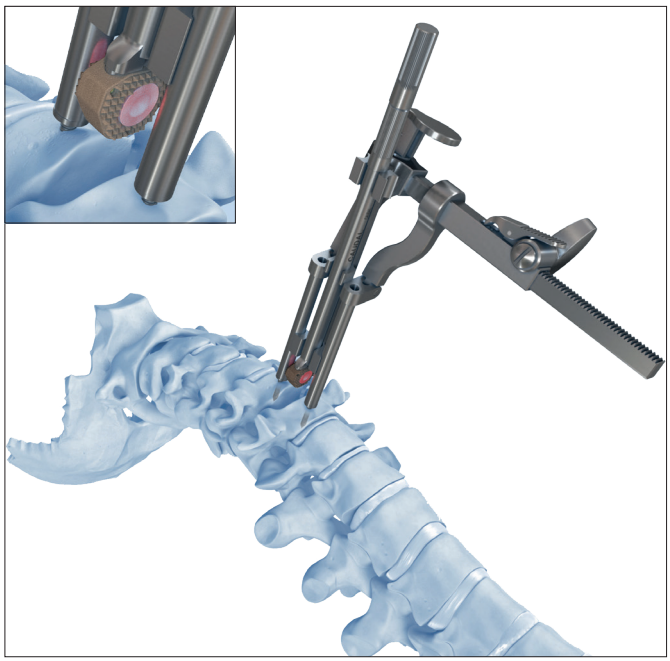
Connecting wedge-shaped implant
The wedge-shaped trial implants and implants do not have a specified cranial or caudal side. They can be attached to the holder with either surface pointing cranially.

Implant Insertion

11. Implant cage

Instrument	
396.891	Holder, short, for CERVIOS and SynCage-C short
or	
396.989	Holder for Cervical Cages

Optional instrument	
396.993	Depth Limitator for Holder for SynCage-C and CERVIOS



If desired, attach the depth limitator to the side of the holder.

Orient implant and holder in the correct cranial/caudal alignment and carefully insert the implant into the distracted segment. Positioning may be accomplished by gentle impaction with a hammer on the holder.

Release the distractor and remove all instruments.

Precaution: **Image intensifier control should be used to check the position during insertion.**

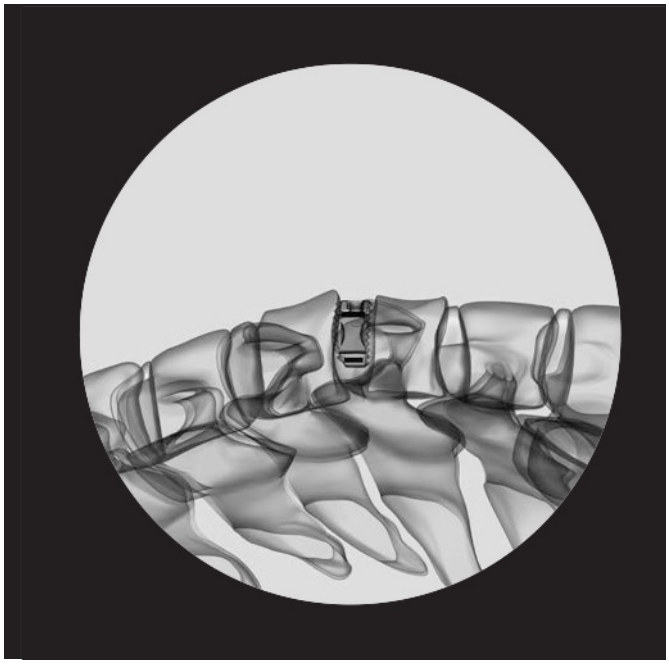
Warning: **Excessive impaction must be avoided to prevent implant damage or inserting the cage too deep.**

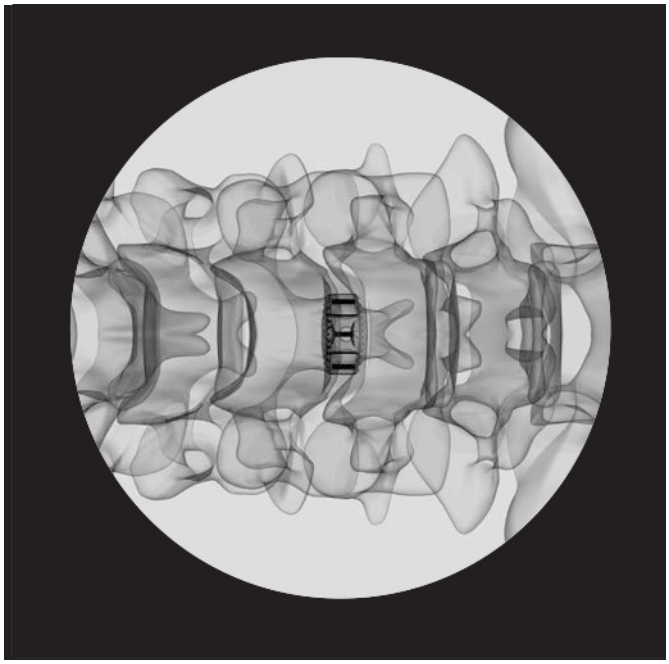
12. Verify cage position

The optimal position of the cage is centred within the periphery of the vertebral end plates.

Warning: **Verify final implant position relative to the vertebral bodies in the anteroposterior (AP) and lateral views using intraoperative imaging. The CERVIOS implant has three x-ray markers incorporated in the implant to enable intraoperative radiographic assessment of the implant position.**

Note: **The x-ray markers are 2 mm from the anterior edge of the implant and 1mm from the posterior edge.**





Implant Removal

Instrument	
396.891	Holder, short, for CERVIOS and SynCage-C short
or	
396.989	Holder for Cervical Cages

If a CERVIOS implant must be removed, the following technique is recommended.

Attach implant to implant holder in the correct cranial/caudal alignment. Carefully remove the implant from the disc space.

Warning: **Take care not to push the implant towards the posterior elements.**

Precautions:
- **Excessive tilting of the insertion device must be avoided to prevent implant separation or damage.**
- **Implants are single-use and should not be reused.**

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, Thalgott JS, Webb JK (1998) AO/ASIF Principles in Spine Surgery. Springer-Verlag, Germany.

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

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