

Radiolucent Cage System for Anterior Cervical Interbody Fusion

Cervios and Cervios chronOS

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.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>

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Cervios and Cervios chronOS. Radiolucent Cage System for Anterior Cervical Interbody Fusion.

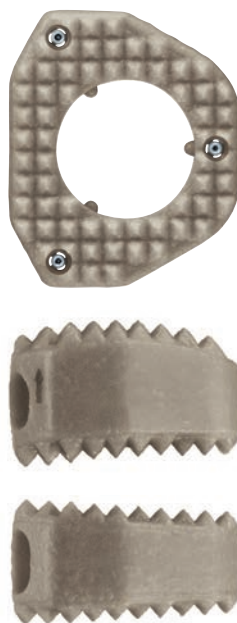
Cervios cage design

Radiolucent

- PEEK Optima allows the growth of the bone through the center hole of the cage to be visualized.
- X-ray markers to visualize the cage.

Good primary and secondary stability

- Sharp teeth on the surface of the implant are designed to provide primary stability and potentially prevent the migration of the cage.
- Roughened surface designed to allow bone ongrowth – even onto the teeth of the cage – for good secondary stability.
- Curved and wedge-shaped designs to accommodate endplate shape variance.



Cervios pre-filled with chronOS

- There is no need for secondary surgery to remove autologous bone*. Therefore patient morbidity is lowered and operation time is shortened.
- chronOS is saturated with blood or bone marrow.

* Studies have demonstrated that the chronic pain rate can still be 18.7%, two years after iliac crest surgery.^{1,2}

¹ Goulet et al. 1997

² Silber et al. 2003

chronOS – synthetic β -tricalcium phosphate cancellous bone substitute

chronOS is a bone graft substitute consisting of pure β -tricalcium phosphate. Its compressive strength is similar to that of cancellous bone once it has been incorporated and remodeled.¹ Based on literature, the use of β -tricalcium phosphate in the spinal column is a valuable alternative to allografts and autografts, even when larger amounts are required.²

Resorbable

It is being replaced in the human body by host bone in 6 to 18 months; depending on the indication and the patient's conditions.^{2,3-5}

Synthetic

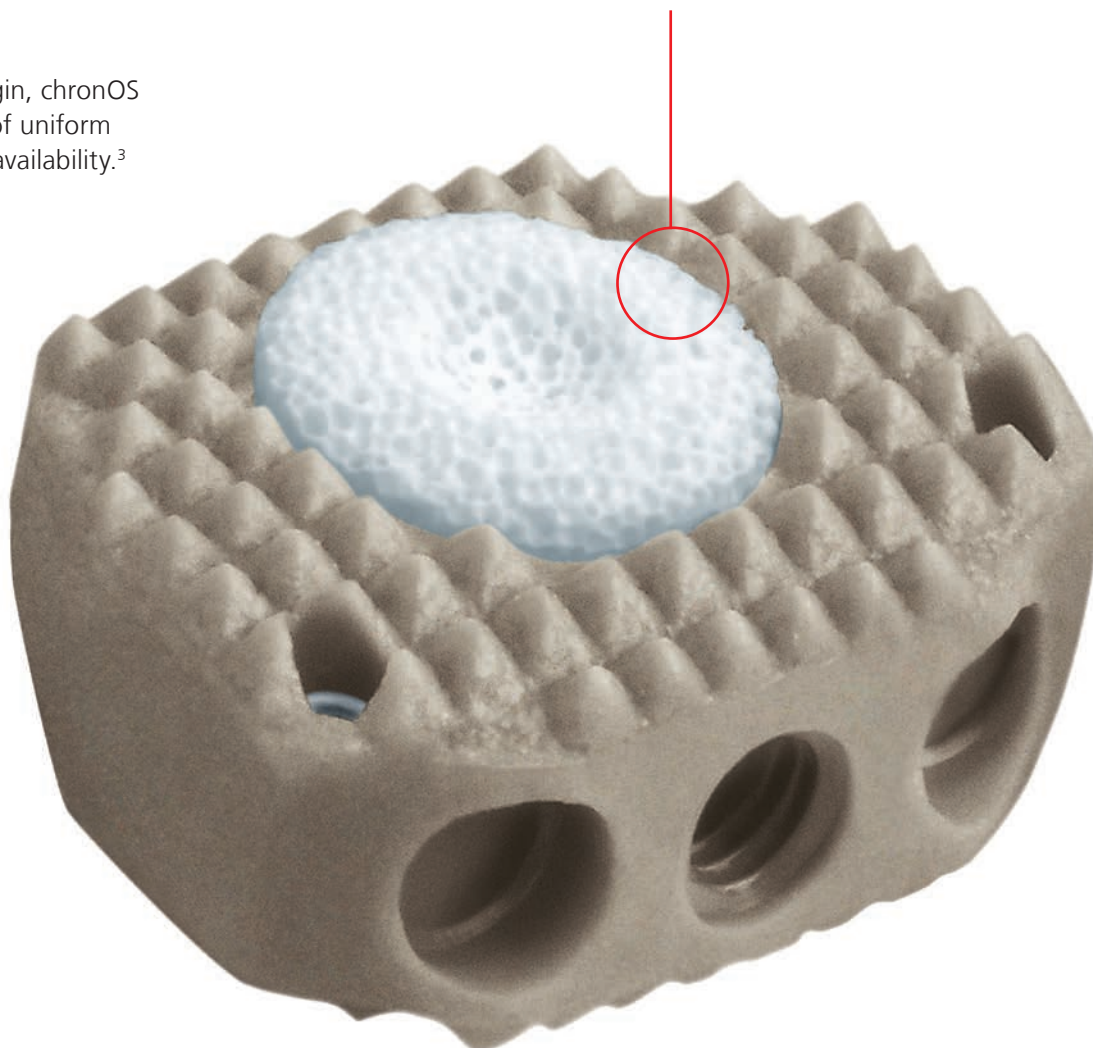
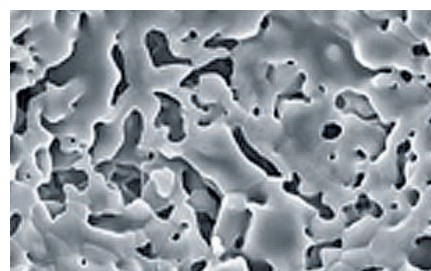
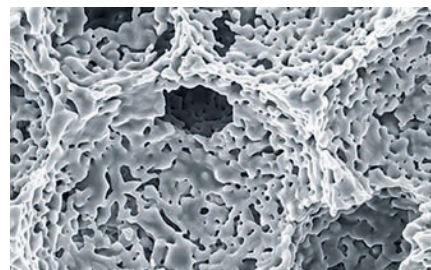
Having a synthetic origin, chronOS offers the advantage of uniform quality and unlimited availability.³

Osteoconductive

Interconnected macropores of defined size (100–500 μm) facilitate bone formation throughout the entire implant. Interconnected micropores (<10 μm) allow supply of nutrients.^{1,6}

Osteoinductive with bone marrow

The Cervios chronOS cage can be saturated with the patient's own blood or bone marrow during surgery. The combination of chronOS with bone marrow accelerates and enhances osteointegration.^{4,5}



¹ Gazdag et al. 1995
² Muschik et al. 2001
³ Stoll et al. 2004
⁴ Becker et al. 2006
⁵ Wheeler et al. 2005
⁶ Lu et al. 1999

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}

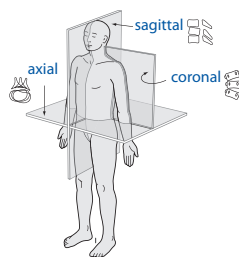
Stability

Stabilization to achieve a specific therapeutic outcome



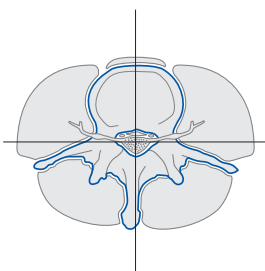
Alignment

Balancing the spine in three dimensions



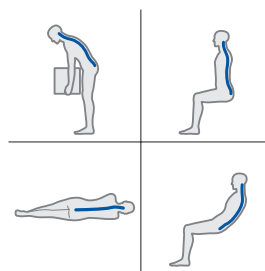
Biology

Etiology, pathogenesis, neural protection, and tissue healing



Function

Preservations and restoration of function to prevent disability



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¹ Aebi et al (1998)

² Aebi et al (2007)

Indications and Contraindications

Cervios is designed for Anterior Cervical Interbody Fusion (ACIF).

Indications

Cervical pathologies for which segmental arthrodesis is indicated:

- Ruptured and herniated discs
- Degenerative disc diseases and instabilities
- Pseudarthrosis or failed spondylodesis

For multisegmental fusions additional stabilization with a plate is recommended.

Contraindications

- Osteoporosis
- Severe Instabilities
- Spinal fractures
- Spinal tumors
- Spinal infections

For Indications, Contraindications, Precautions, Warnings and Side Effects for Cervios chronOS, please refer to the corresponding Instructions for Use chronOS Prefilled Cages.

Surgical Technique

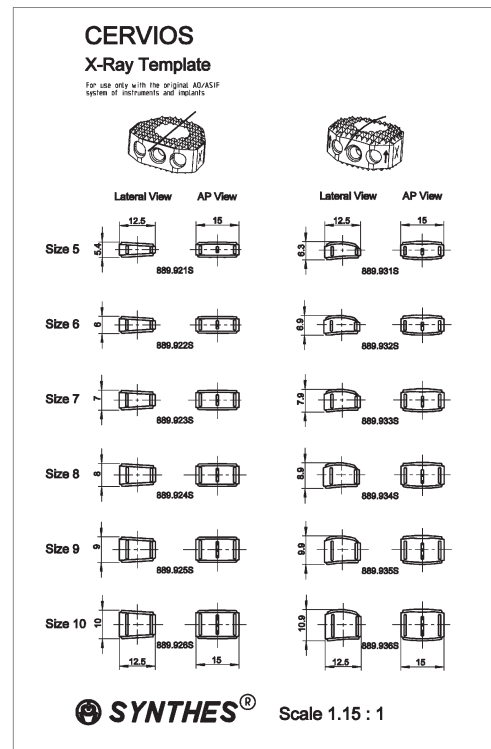
1. Preoperative planning

Instrument

X000007 X-Ray Template for Cervios

The appropriate cage height and shape must be estimated prior to surgery. Compare the X-ray template for Cervios with the adjacent intervertebral discs on a lateral radiograph. With the segment fully distracted, the implant must fit tightly and accurately between the end plates.

The final choice of height and shape will be made with the help of a trial implant during surgery. To achieve maximum segment stability, it is essential to implant the largest possible cage.



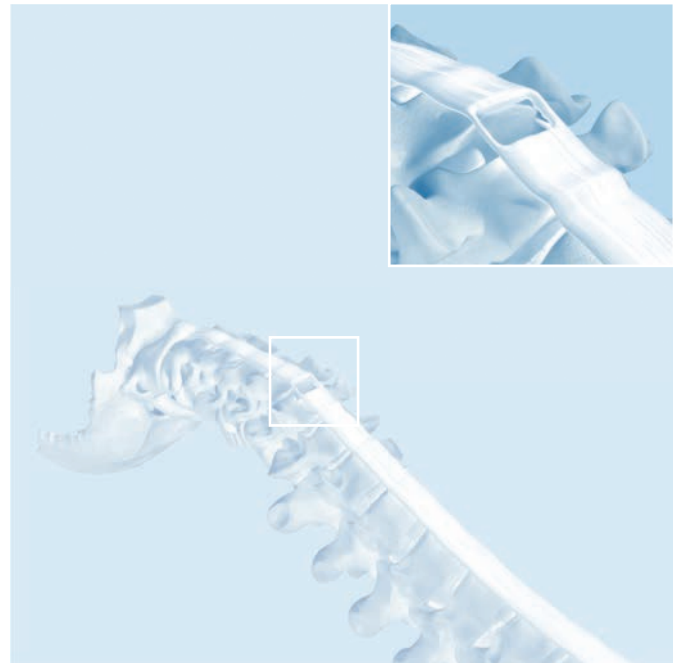
2. Expose and prepare disc

Expose the affected disc and adjacent vertebral bodies through an anterolateral incision in the cervical spine.

Cut a rectangular window matching the width of the Cervios cage (15 mm) in the anterior longitudinal ligament and annulus fibrosus.

Note: Preserve as much of these structures as possible since they are important for the stability of the operated segment.

Using a rongeur remove the disc material through the window.



3. Distract segment

Instrument

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

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

Distract the segment with the cervical distractor.

Option in case of insufficient distraction:

Bone spreader

In severely degenerated, collapsed discs with posterior osteophytes, it may be difficult to achieve sufficient distraction using the cervical distractor only. In such cases a bone spreader may be used to achieve better distraction and provide better access to the posterior part of the vertebral body.

Note: The use of a bone spreader generates a powerful distraction force, which could result in over-distraction if not used cautiously. Refer to measurements taken in preoperative planning to avoid over-distraction.



4. Prepare vertebral end plates

Remove the cartilaginous layers from the surface of the adjacent vertebral end plates with a ring curette to expose bleeding bone.

This preparation technique preserves the natural shape of the bone and the cortical bone beneath the cartilaginous layers so that resistance to implant subsidence is increased.

Notes:

- **Adequate cleaning of the end plates is important for vascular supply of the bone graft or chronOS material. Excessive cleaning, however, may result in removal of bone underlying the cartilaginous layers and weaken the end plates.**
- **The removal of any osteophytes is crucial for achieving complete decompression of the neural structures and 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 preoperatively estimated implant height 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

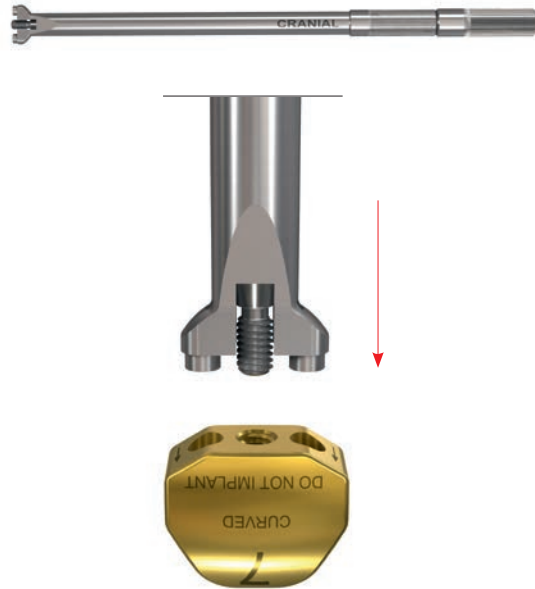
Holders are etched "CRANIAL" and "CAUDAL" to properly engage the trial implants with the holders.

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 limiter to holder

Instrument

396.993	Depth Liminator for Holder for SynCage-C and Cervios
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The depth limiter 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

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

- ① Using the image intensifier check the position of the trial implant. With the segment fully distracted, it should fit tightly and accurately between the end plates so as to preserve disc height after removal of the distractor.

Use the largest possible trial implant to maximize segment stability through the tension in the longitudinal ligament and the annulus fibrosus.

Important: If the largest insertable trial implant does not fit really tight between the two vertebrae, for a better fit, choose the next larger implant height for final implantation.

Note: The trial implants are not for implantation and must be removed before inserting the Cervios cage.



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

10a. Prepare implant

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

Optional set

177.300	Set for Bone Graft Harvesting in SynCase
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Remove the depth limiter from the holder. Connect the selected implant to the holder.

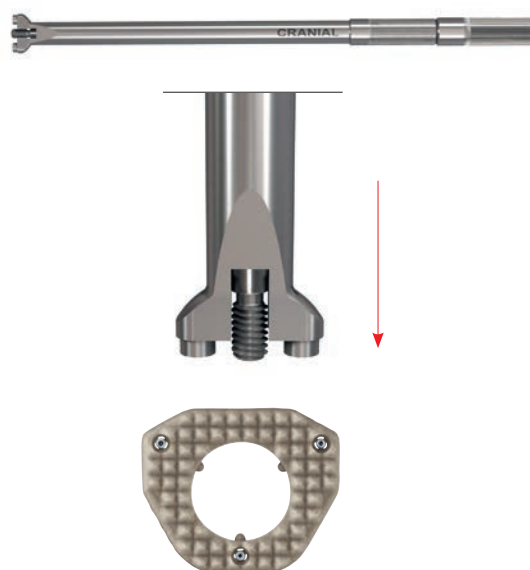
Connecting curved implant

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.

Insert the cage with the cranial side facing upwards into the open packing block.

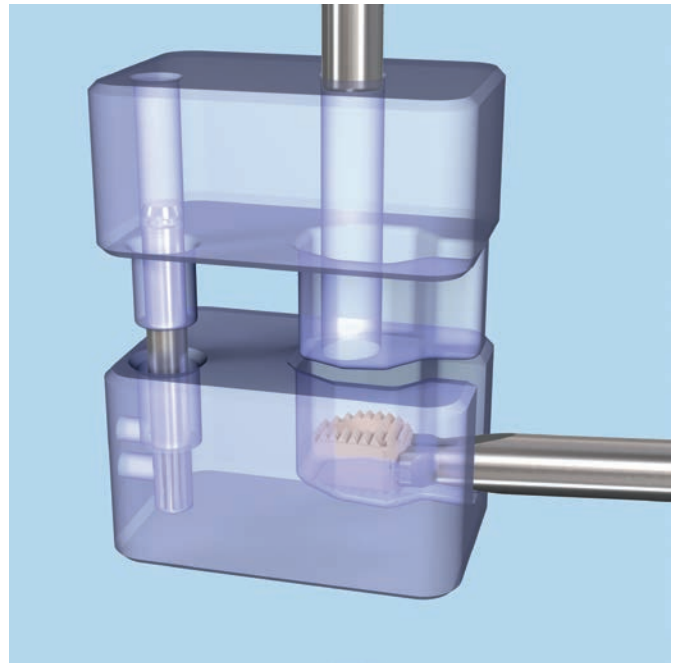


Close the lid of the packing block.

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.

Option: Bone graft harvesting set

For obtaining bone graft from the iliac crest, the use of the bone graft harvesting set is recommended. It permits one-step removal of autologous bone in the exact diameter of the cage opening. This eliminates the need for further shaping or preparation of the graft material and reduces donor site morbidity.



10b. Cervios chronOS

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

To ensure rapid onset of fusion of the prefilled Cervios and subsequent remodeling of the chronOS insert, soak the implant with autologous blood or bone marrow aspirate.

Connect cage to holder

Remove the depth limiter 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.



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.

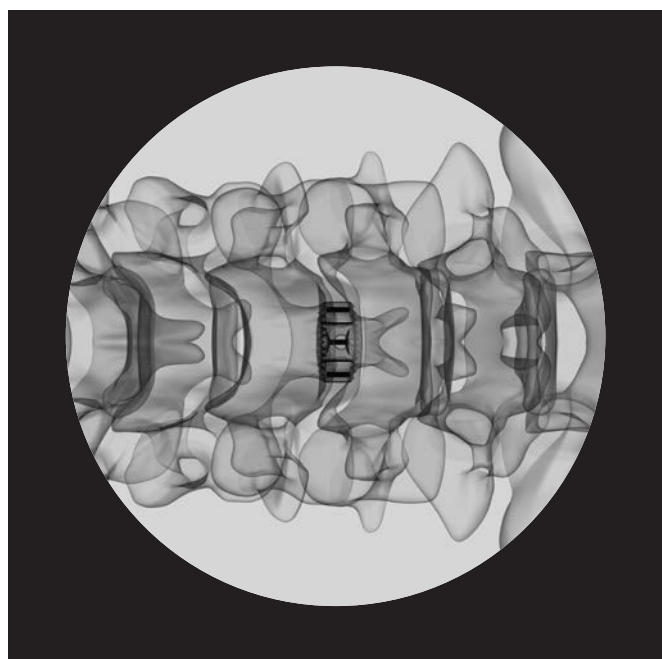
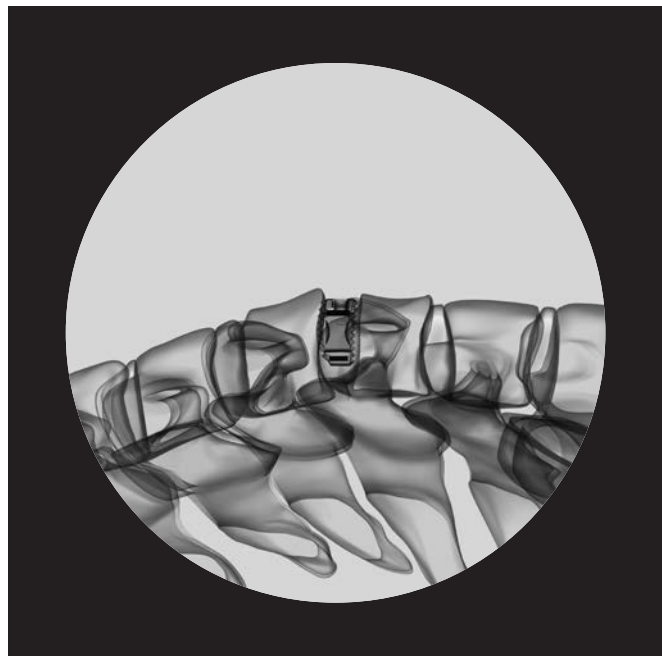
Release the distractor and remove all instruments.



12. Verify cage position

The optimal position of the cage is centred within the periphery of the vertebral end plates. Depending on the size of the vertebrae, the anterior edge of the cage will be approximately 2 mm behind the anterior edge of the adjacent vertebrae.

- Under image intensifier verify the optimal position of the cage.



Implants

- Dimensions: 15 mm wide, 12.5 mm deep
- Curved and wedge-shaped cages are available in 6 heights from 5 to 10 mm.
- **All cages are supplied sterile pre-packed**

Shapes

1. Curved



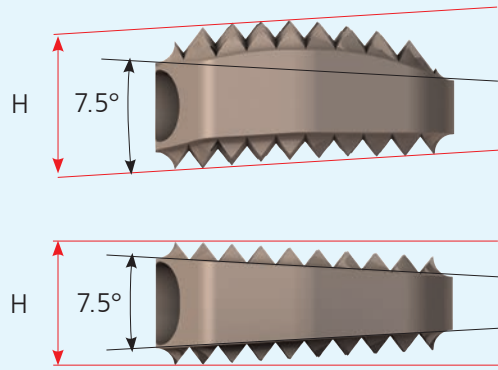
Height	Trial implant	Cervios	Cervios chronOS
5 mm	396.931	889.931S	870.931S
6 mm	396.932	889.932S	870.932S
7 mm	396.933	889.933S	870.933S
8 mm	396.934	889.934S	870.934S
9 mm	396.935	889.935S	870.935S
10 mm	396.936	889.936S	870.936S

2. Wedge-shaped

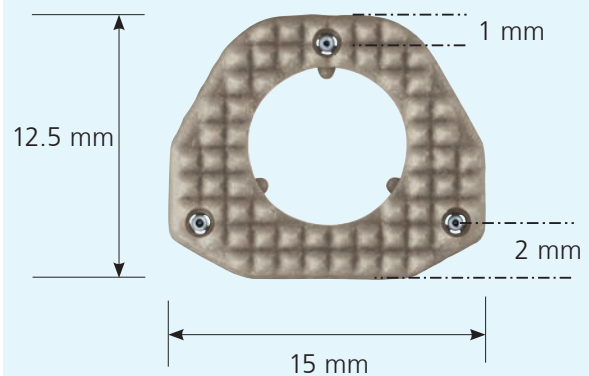


Height	Trial implant	Cervios	Cervios chronOS
5 mm	396.921	889.921S	870.921S
6 mm	396.922	889.922S	870.922S
7 mm	396.923	889.923S	870.923S
8 mm	396.924	889.924S	870.924S
9 mm	396.925	889.925S	870.925S
10 mm	396.926	889.926S	870.926S

Lordotic angulation and height H



Footprint



Instruments

396.891 Holder, short, for Cervios and SynCage-C short

Fully compatible with the following systems: Cervios, Cervios chronOS



396.989 Holder for Cervical Cages

Staggered mounting pins with clearly etched labels indicating cranial and caudal sides prevent incorrect mounting of curved trial implants and cages



396.931–936 Cervios Trial Implants, curved, gold



396.921–926 Cervios Trial Implants, wedge-shaped, dark-blue



Color coded for ease of identification.

Optional:

396.993 Depth Limitator for Holder for SynCage and Cervios

Can be attached to trial implant/implant holder. It has a stop that will contact the anterior edge of the vertebral body when the implant is inserted 2 mm beyond the anterior edge of the vertebral body.



Additionally Required Instruments for Unfilled Cervios Implants

396.996 Packing Block for Cervios

Designed to provide a quick way to completely fill the implant with graft material.



396.999 Cancellous Bone Impactor for Cervios

Used with the packing block to impact bone graft tightly into the empty Cervios cages.



Recommended Supplementary Instruments

177.300 Set for Bone Graft Harvesting in SynCase

A tool designed for efficient harvesting of autologous bone from the iliac crest when using unfilled Cervios cages.



187.780 Instrument Set for Cervical Distractors in Vario Case

Distractor system designed to simplify the anterior cervical approach.



187.796 Cervical Retractors

Designed to provide a clear layout of the operative field through the use of retractors for lengthwise and transverse retraction. For more information see brochure 036.000.068.



Cervical Disc Shavers (187.772)

The cervical disc shavers are designed to facilitate removal of nucleus pulposus.



Art. no	Height
389.741	5 mm
389.742	6 mm
389.743	7 mm
389.744	8 mm
389.745	9 mm
389.746	10 mm
389.747	11 mm
389.748	12 mm

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