Cervios and Cervios chronOS.
Radiolucent cage system for anterior cervical interbody fusion.
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### Warning

This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is highly recommended.
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 ensure primary stability and prevent migration of the cage
– Roughened surface promotes integration and 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

Patient friendly, reduces surgery time
– Low patient morbidity as there is no need for secondary surgery to remove autologous bone*
– Shortened operating time

* 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

The use of β-tricalcium phosphate in the spinal column is a valuable alternative to allografts and autografts, even when larger amounts are required.\(^3\)

**Resorbable**
– It is converted to vital bone within 6–18 months

**Safe**
– 100% synthetic – no risk of cross infection

**Osteoconductive**
Interconnecting macropores of a defined size (100–500 μm) facilitate bone ingrowth. Interconnected micropores (10–40 μm) allow an optimum supply of nutrients. The patient’s blood, blood platelet concentrate or bone marrow aspirate enhances the properties of chronOS required for fusion.\(^4\)

**Osteopromotive**
The Cervios chronOS cage can be simply and quickly saturated with the patient’s own blood or bone marrow during surgery using the perfusion system. This supports bone integration and ensures rapid ongrowth to the implant.

\(^3\) Muschik et al. 2001
\(^4\) Allman et al. 2002; Stoll et al. 2004
**Synthes Perfusion System.**
To impregnate an implant under vacuum with osteoinductive factors.

---

**Better than the conventional dip method**
The vacuum method uses the patient’s own bone marrow or blood, forcing or suctioning it through the pores of the cage filled with chronOS, thus expelling any air in the cage. The cage is thereby saturated three times better than using the conventional dip method. It has also been shown that the vacuum method does not destroy the blood cells.

Conventional dip method: The cage is soaked in blood for 1 hour. Only relatively few blood components penetrate the center of the cage.

Vacuum method: The cage is impregnated with blood 4 to 5 times using a perfusion syringe. There are considerably more blood components in the center of the cage.

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**Simple handling**
Bone Marrow Aspiration System (BMAS).
Perfusion with bone marrow.

Gold standard: autologous bone
Autologous bone is the preferred choice for reconstructing bone. However, the patient’s own bone is not always available in the necessary quality or quantity. The process of obtaining the autologous bone also increases patient morbidity.

Effective substitute: Perfusion with bone marrow
Studies have shown that the combination of chronOS and autologous bone marrow supports and accelerates osteointegration.5

5 Becker et al. 2006

Red blood cells
Stem cells
Blood platelets
White blood cells

Bone marrow harvesting with the Bone Marrow Aspiration Set.
Perfusion with blood or bone marrow: The cage is supplied sterile in the perfusion syringe to facilitate the perfusion of the implant.
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.¹ They are:

– Anatomical reduction
– Stable internal fixation
– Preservation of blood supply
– Early, active pain-free mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.

**AO Principles as applied to the spine²**

**Anatomical reduction**
Restoration of normal spinal alignment to improve the biomechanics of the spine.

**Stable internal fixation**
Stabilization of the spinal segment to promote bony fusion.

**Preservation of blood supply**
Creation of an optimal environment for fusion.

**Early, active pain-free mobilization**
Minimization of damage to the spinal vasculature, dura, and neural elements, which may contribute to pain reduction and improved function for the patient.

¹ Müller et al. 1995
² Aebi et al. 1998
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
– Instabilities
– Spinal fractures
– Spinal tumors
– Spinal infections
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

Optional Instrument

– – –  Bone Spreader

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 avoiding 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

<table>
<thead>
<tr>
<th>Height</th>
<th>Curved (golden)</th>
<th>Wedge-shaped (dark blue)</th>
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<tbody>
<tr>
<td>5 mm</td>
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</tr>
<tr>
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<td>396.922</td>
</tr>
<tr>
<td>7 mm</td>
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<td>396.923</td>
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<tr>
<td>8 mm</td>
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<td>396.924</td>
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<tr>
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<td>396.935</td>
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</tr>
<tr>
<td>10 mm</td>
<td>396.936</td>
<td>396.926</td>
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</table>
6

Connect trial implant to holder

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>396.891 Holder, short, for Cervios</td>
<td></td>
</tr>
<tr>
<td>or</td>
<td>396.989 Holder for Cervical Cages</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Instrument</th>
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<tbody>
<tr>
<td>396.993</td>
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</tbody>
</table>

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**

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

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.
Determine size

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

### Cages

<table>
<thead>
<tr>
<th>Height</th>
<th>Shape</th>
<th>Cervios</th>
<th>Cervios chronOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 mm</td>
<td>curved</td>
<td>889.931S</td>
<td>870.931S</td>
</tr>
<tr>
<td>6 mm</td>
<td>curved</td>
<td>889.932S</td>
<td>870.932S</td>
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<td>7 mm</td>
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<td>870.936S</td>
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<td>wedge-shaped</td>
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<td>wedge-shaped</td>
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<td>wedge-shaped</td>
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Prepare implant

a. Unfilled Cervios cages

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>396.891 or 396.989</td>
<td>Holder, short, for Cervios or Holder for Cervical Cages</td>
</tr>
<tr>
<td>396.996</td>
<td>Packing Block for Cervios</td>
</tr>
<tr>
<td>396.999</td>
<td>Cancellous Bone Impactor for Cervios</td>
</tr>
</tbody>
</table>

Optional set

| 177.300              | Set for Bone Graft Harvesting in SynCase       |

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. 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 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.
b. Pre-filled Cervios chronOS cages

To ensure rapid onset of fusion and subsequent remodelling of the chronOS insert, the pre-filled Cervios chronOS may be used with the Perfusion System. The Perfusion System is a steril packed system which includes a perfusion syringe including the prefilled implant.

**Perfuse with blood**
Open the sterile pack and remove the perfusion syringe containing the Cervios chronOS cage.

1. Transfer blood from incision into perfusion device
   Remove the small cap at the tip of the syringe. Transfer the blood from the incision by gently pulling the syringe plunger.

2. Perfuse chronOS implant (fig. 1)
   Re-attach the small cap firmly in order to close the syringe airtight. Perfuse the chronOS implant uniformly by gently pumping the plunger 10 to 15 times.

3. Remove chronOS implant (fig. 2)
   Remove the small cap and the surplus blood. Unscrew the syringe lid. Place the implant onto a sterile cloth or into a sterile dish using the plunger of the syringe.
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.
11

Implant cage

Instrument

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<tr>
<td>396.891</td>
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</tr>
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<td>or</td>
<td></td>
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<td>396.989</td>
<td>Holder for Cervical Cages</td>
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Optional instrument

<table>
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<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>396.993</td>
<td>Depth Limitator for holders 396.891 and 396.989</td>
</tr>
</tbody>
</table>

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.
- 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
  Cervios chronOS is pre-packed in a perfusion syringe

Shapes

1. Curved

<table>
<thead>
<tr>
<th>Height</th>
<th>Trial implant</th>
<th>Cervios</th>
<th>Cervios chronOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 mm</td>
<td>396.931</td>
<td>889.931S</td>
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<tr>
<td>6 mm</td>
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<td>889.932S</td>
<td>870.932S</td>
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<td>7 mm</td>
<td>396.933</td>
<td>889.933S</td>
<td>870.933S</td>
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<tr>
<td>8 mm</td>
<td>396.934</td>
<td>889.934S</td>
<td>870.934S</td>
</tr>
<tr>
<td>9 mm</td>
<td>396.935</td>
<td>889.935S</td>
<td>870.935S</td>
</tr>
<tr>
<td>10 mm</td>
<td>396.936</td>
<td>889.936S</td>
<td>870.936S</td>
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</table>

2. Wedge-shaped

<table>
<thead>
<tr>
<th>Height</th>
<th>Trial implant</th>
<th>Cervios</th>
<th>Cervios chronOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 mm</td>
<td>396.921</td>
<td>889.921S</td>
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<td>6 mm</td>
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<td>10 mm</td>
<td>396.936</td>
<td>889.926S</td>
<td>870.926S</td>
</tr>
</tbody>
</table>
Instruments

Required Instruments for Cervios and Cervios chronOS cages

396.891  Holder, 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 easy 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.
Instruments

Additionally required instruments for unfilled Cervios implants

396.996  Packing Block for Cervios
Provides a quick and easy 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
An efficient tool for the 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 to further simplify the anterior cervical approach.

187.796  Cervical Retractors
Provide a clear layout of the operative field through the use of retractors for length-wise and transverse retraction. For more information see brochure 036.000.068.

Cervical Disc Shavers (187.772)
The cervical disc shavers facilitate removal of nucleous pulposus.

<table>
<thead>
<tr>
<th>Art. no</th>
<th>Height</th>
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<tbody>
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</tbody>
</table>
Notes on Sterilization

- Cervios and Cervios chronOS cages are supplied pre-sterilized by gamma irradiation; **it is not recommended that they be resterilized.**

- **Non-filled** Cervios cages – in exceptional cases – may be carefully resterilized in a steam autoclave. In such an event, the steam sterilization temperature must not exceed 134°C. They may not be resterilized using gas (e.g. ethylene oxide or formaldehyde) or gas plasma (e.g. hydrogen peroxide).

- **Pre-filled Cervios chronOS cages must not be resterilized.**

- Never sterilize the packing block by gamma irradiation.

Consult the package insert for further information.


