# Plivios and Plivios chronOS.

Radiolucent cage system for posterior lumbar interbody fusion.

Technique Guide

SYNTHES®

Original Instruments and Implants of the Association for the Study of Internal Fixation – AO ASIF

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Image intensifier control

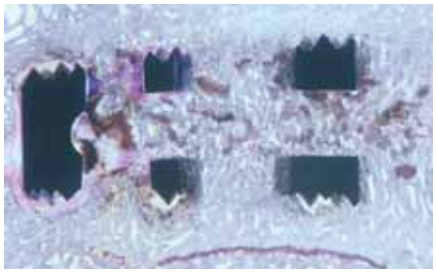
**Warning**
This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

**Plivios chronOS.** Plivios cages prefilled with the synthetic cancellous bone substitute chronOS.

## Plivios cage design

**Radiolucent**
- PEEK Optima allows the growth of the bone in 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 within even a short space of time.



The histology of a cage filled with chronOS in sheep shows complete fusion after 24 weeks and only a small residue of chronOS (Prof. Dr. med. Robert Schenk – department of oral surgery, Bern, Switzerland).[1]

## Plivios pre-filled with chronOS

**Patient friendly, reduces surgery time**
- Low patient morbidity as there is no need for secondary surgery to remove autologous bone.* The operation time is also shortened.
- Easy handling as the cage is only saturated with blood or bone marrow.

* Studies have demonstrated that the chronic pain rate can still be 18.7%, even two years after iliac crest surgery.[2, 3]

1 Steffen et al. 2000
2 Goulet et al. 1997
3 Silber et al. 2003

# chronOS – synthetic β-tricalcium phosphate cancellous bone substitute

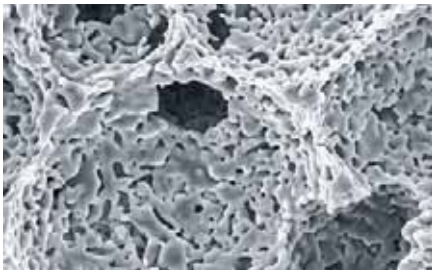
The use of β-tricalcium phosphate in the spinal column is a valuable alternative to allografts and autografts, even when larger amounts are required.[4]

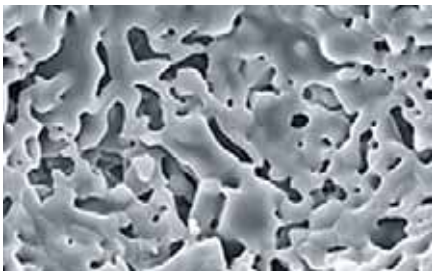
**Resorbable**
– It is converted to vital bone within 6–18 months

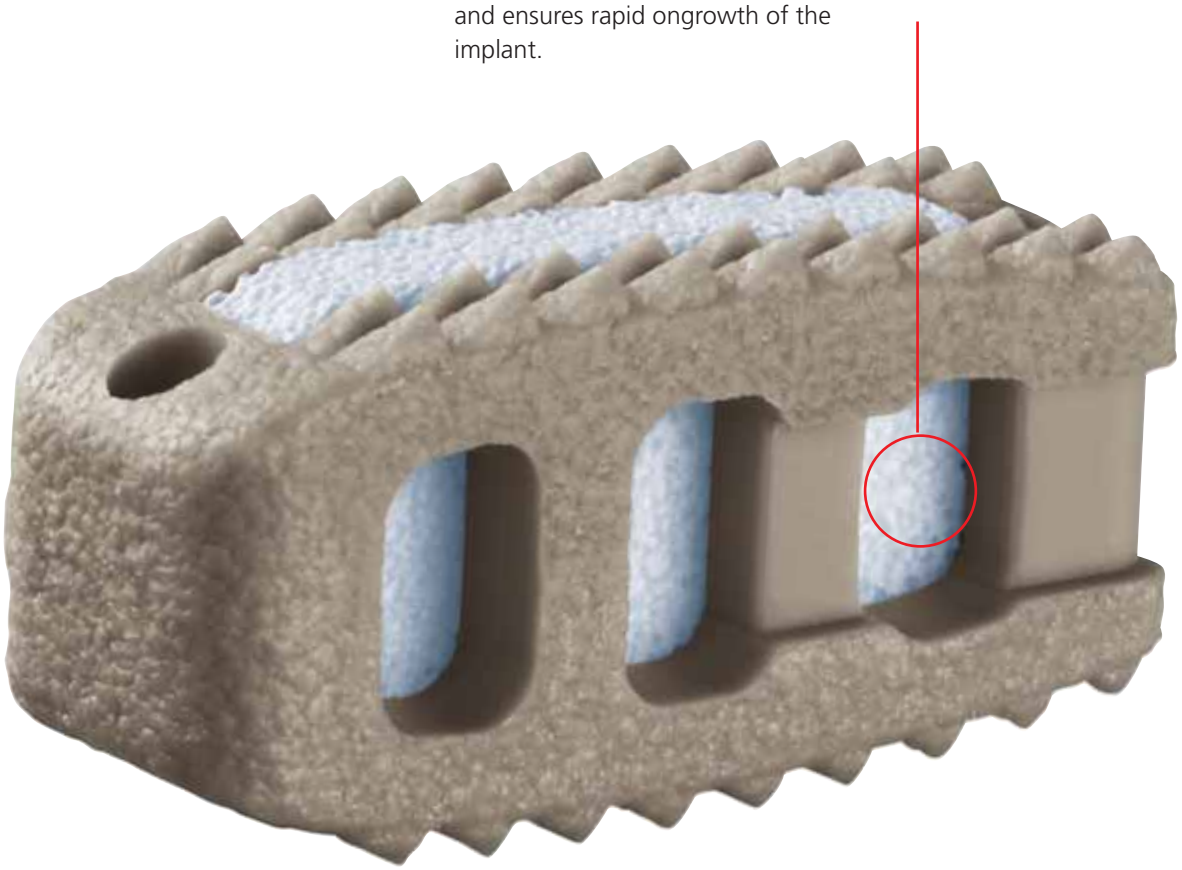
**Safe**
– 100% synthetic – no risk of cross infection

**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 enhance the properties of chronOS required for fusion.[5]

**Osteopromotive**
The Plivios 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 of the implant.







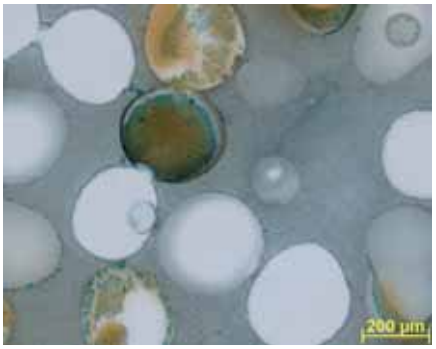
[4] Muschik et al. 2001
[5] Allman et al. 2002; Stoll et al. 2004

## Synthes Perfusion System.

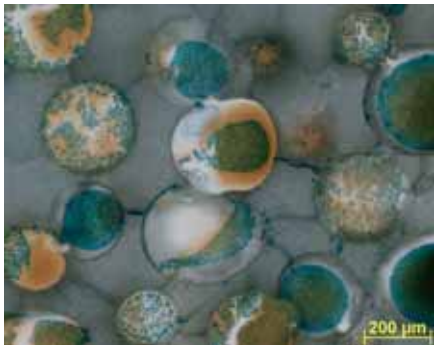
To impregnate an implant under vacuum with osteoinductive factors.

### 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.

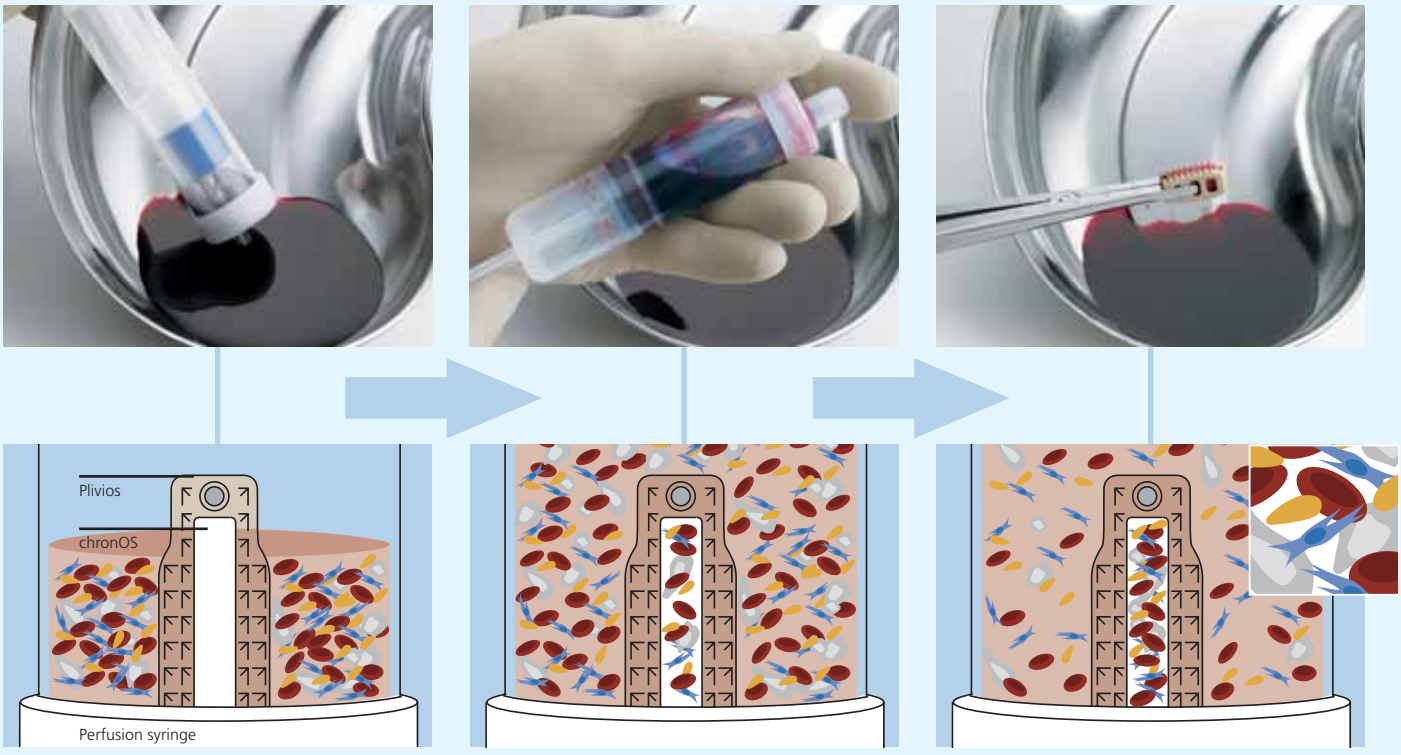



Conventional dip method: The cage is soaked in blood for 1 hour. Only relatively few blood components penetrate the center of the cage.




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.

## Simple handling

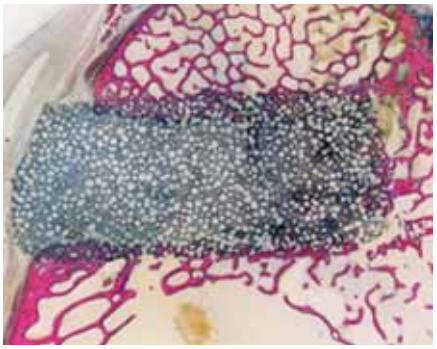


# Bone Marrow Aspiration System (BMAS).
Perfusion with bone marrow.

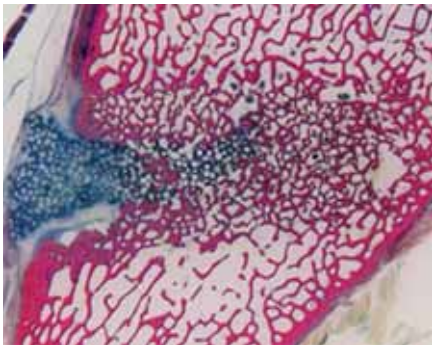
**Gold standard: autologous bone**
Autologous bone is the preferred choice for reconstructing bone. However, the patient's own bone is not always available in the necessary quality or quantity. The operation time required to obtain the autologous bone also increases patient morbidity.

**Effective substitute: Perfusion with bone marrow**
Studies have shown that the combination of chronOS and autologous bone marrow supports and accelerates osteointegration.[6]

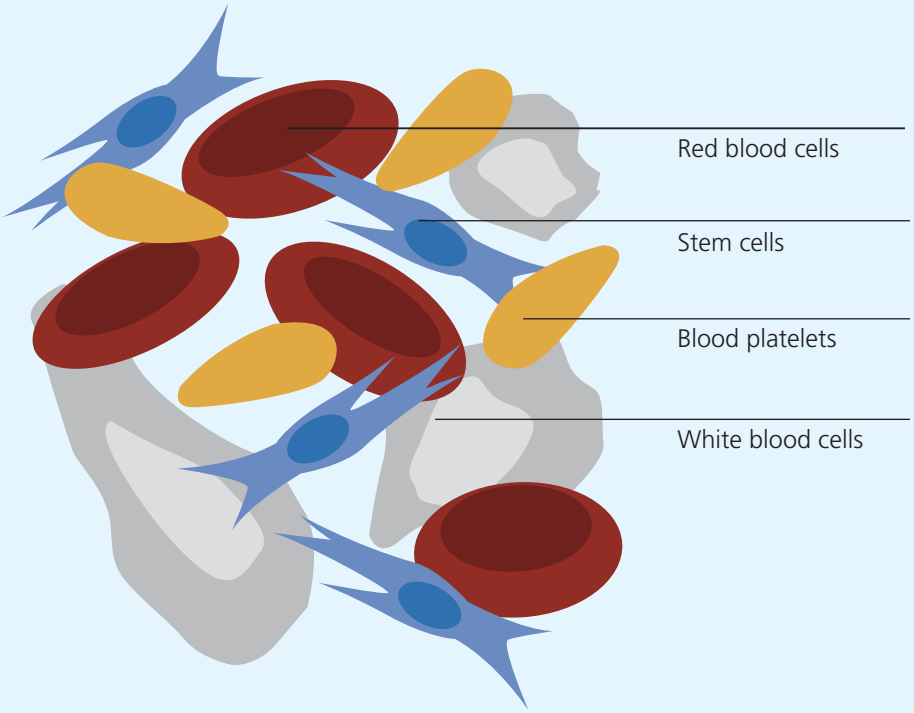
[6] Becker et al. 2006

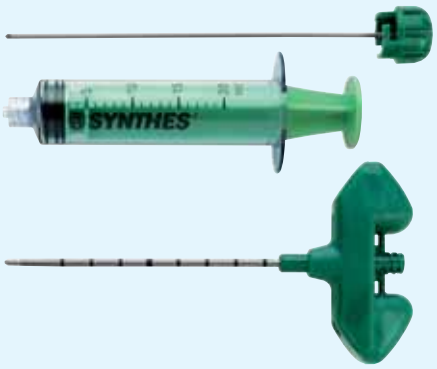


Comparison of bone formation in sheep 12 weeks after surgery, with blood [6]



Comparison of bone formation in sheep 12 weeks after surgery, with bone marrow [6]




Bone graft 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.

# AO ASIF Principles

In 1958 the Association for the Study of Internal Fixation (AO ASIF) formulated four basic principles which have become the guidelines for internal fixation. 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.[1]

**AO ASIF Principles as applied to the spine[2]**

**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

Plivios is designed for Posterior Lumbar Interbody Fusion (PLIF). It is designed to match vertebral anatomy and restore lordosis to reliably restore normal spinal alignment, stability and provide optimal conditions for fusion.

**Indications**
Lumbar and lumbosacral degenerative pathologies for which segmental spondylodesis is indicated:

– Degenerative disc diseases and instabilities
– Degenerative spondylolisthesis grade I or II
– Isthmic spondylolisthesis grade I or II
– Pseudarthrosis or failed spondylodesis

Additional posterior fixation with a pedicle screw system is required.

**Contraindications**
– Severe osteoporosis
– Unstable burst fractures and compression fractures
– Destructive tumours
– Involvement of 3 or more levels
– Spondylolisthesis grade III and IV
– Acute infections
– Extensive peridural scarring

# Preoperative Planning and Patient Positioning

## Preoperative planning

| Instruments | |
|---|---|
| XXX0005 | Plivios X-ray template |

The appropriate cage size must be estimated prior to surgery.

The initial estimate of the correct cage height can be made by comparing the X-ray template for Plivios with the adjacent intervertebral discs on a lateral radiograph. With the segment fully distracted, the implants must fit tightly and accurately between the endplates.

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

## Patient positioning

Place the patient in a prone position on a lumbar frame.

Radiographic equipment can assist in confirming the precise intraoperative position of the patient.

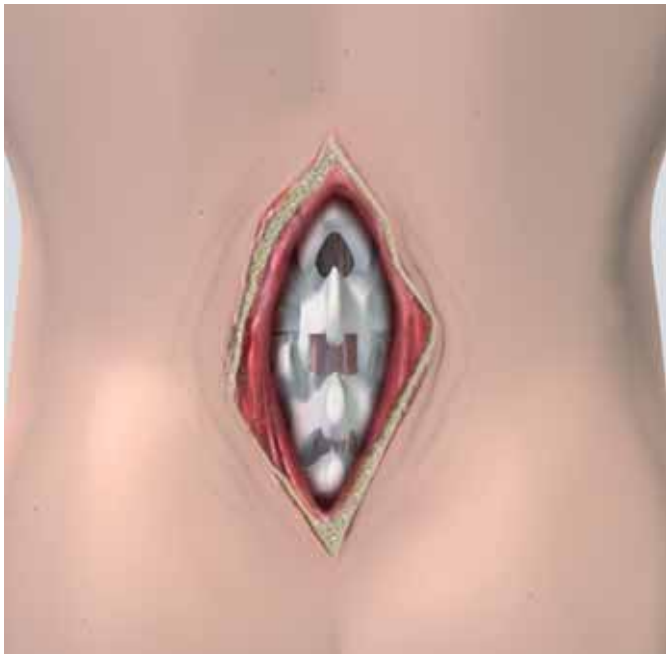
## 1
**Incise and expose disc**

| Instruments | |
|---|---|
| 389.125 | Osteotome, 5 mm |

Incise and dissect the skin from the midline laterally and locate the spinous process and the lamina of the appropriate level(s).

Preserve as much of the facets as possible as they provide stability to the intervertebral segment.

With the osteotome perform a laminotomy to the medial aspect of the facet. Retract the dura to expose an approximately 13 mm window to the disc space.



## 2
**Prepare disc and endplates**

| **Instruments** | |
|---|---|
| 389.124 | Bone Curette, rectangular, straight, 8 mm |
| 389.125 | Osteotome, 5 mm |
| 389.714 | Bone Rasp, straight, 8 mm |
| **Optional instruments** | |
| 389.767–777 | Shavers for Intervertebral Discs |
| 389.780–785 | Excisors for Intervertebral Discs |

Using the bone curette, remove the disc through the window until only the anterior and lateral annuli remain.

Using the bone rasp, remove the superficial layers of the entire cartilaginous endplates to expose bleeding bone

**Option**
The shavers and excisors for intervertebral discs may assist in the removal of the nucleus pulposus and of the superficial layers of the cartilaginous endplates.

**Note:** Adequate cleaning of the endplates is important for vascular supply of the bone graft. Excessive cleaning, however, may weaken the endplates due to removal of bone underlying the cartilaginous layers. Removing the entire endplate may result in subsidence and loss of segmental stability.

## 3
**Distract segment**

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

Plivios is designed to fit tightly into the natural concavity between two adjacent vertebral bodies. The tension of the longitudinal ligaments and annulus fibrosus contribute to the stability of the inserted implant, hence care must be taken not to overdistract the segment(s).

There are 3 options for distraction.

## 3a
**Distraction across pedicle screws**

This method temporarily opens the posterior disc space and promotes increased exposure for both decompression and insertion of the implant. In case of a collapsed or extremely thin disc it can already be applied to facilitate disc removal and endplate preparation (prior to step 2).

Insert pedicle screws. Distract the segment over the heads of the inserted screws.

**Note:** To avoid inducing a kyphotic curve, care should be taken to ensure proper longitudinal distraction.

## 3b

**Distraction with Plivios distractor**

| Instruments | |
|---|---|
| 389.101 | Distractor for Plivios |

Place the distractor blades into the disc space lateral to the dural sac. The curved recess on the distractor should be oriented towards the midline.

Completely insert the distractor blades into the disc space so that the ridges at the end of the blades rest on the vertebral body.

- Under fluoroscopy confirm that the distractor blades are parallel to the endplates.

- Gently distract the segment, taking care not to overdistract. Preoperative planning, fluoroscopy and tactile judgment can assist in determining the correct amount of distraction.

## 3c

**Distraction with trial implant**

| Instruments | |
|---|---|
| 389.128 | Plivios Trial Implant, size 7 mm |
| 389.129 | Plivios Trial Implant, size 9 mm |
| 381.100 | Plivios Trial Implant, size 10 mm |
| 389.131 | Plivios Trial Implant, size 11 mm |
| 381.101 | Plivios Trial Implant, size 12 mm |
| 389.133 | Plivios Trial Implant, size 13 mm |
| 389.135 | Plivios Trial Implant, size 15 mm |
| 389.137 | Plivios Trial Implant, size 17 mm |
| 394.951 | T-Handle with Quick Coupling |

Select the size of the trial implant as estimated during preoperative planning.

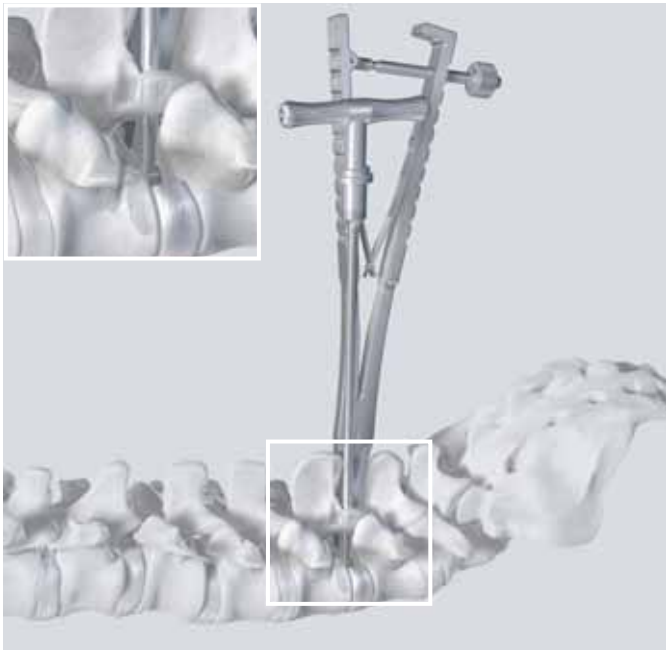
Attach the trial implant to the T-handle. Insert the trial implant assembly horizontally into the disc space and turn vertically to distract the segment.

Use fluoroscopy and tactile feedback to confirm the fit of the trial implant. If the trial implant appears too loose or too tight, try the next larger or smaller size until a secure fit is achieved.

## 4

**Determine trial implant size (required after using distraction methods 3a and 3b)**

| Instruments | |
|---|---|
| 389.101 | Distractor for Plivios |
| 389.128 | Plivios Trial Implant, size 7 mm |
| 389.129 | Plivios Trial Implant, size 9 mm |
| 381.100 | Plivios Trial Implant, size 10 mm |
| 389.131 | Plivios Trial Implant, size 11 mm |
| 381.101 | Plivios Trial Implant, size 12 mm |
| 389.133 | Plivios Trial Implant, size 13 mm |
| 389.135 | Plivios Trial Implant, size 15 mm |
| 389.137 | Plivios Trial Implant, size 17 mm |
| 394.951 | T-Handle with Quick Coupling |



Select the size of the trial implant as estimated during preoperative planning.

Attach the trial implant to the T-handle. Insert the trial implant assembly into the contralateral disc space applying gentle impaction.

Use fluoroscopy and tactile feedback to confirm the fit of the trial implant. If the trial implant appears too loose or too tight, try the next larger or smaller size until a secure fit is achieved.

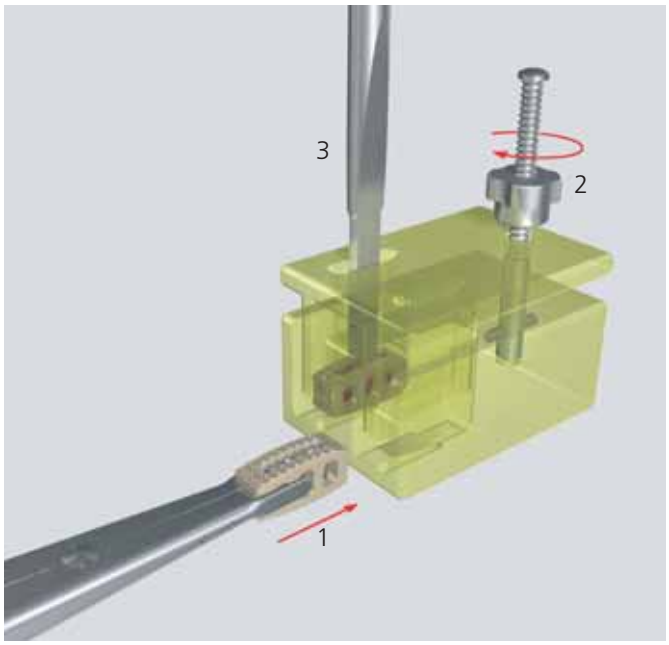
Select the implant corresponding to the correct trial implant.

Remove the trial implant assembly.

# 5
**Determine size and prepare implant**

## 5a
**Unfilled Plivios cages**

| Instruments | |
|---|---|
| 381.102 | Packing Block |
| 381.103 | Implant Holder |
| 389.288 | Impactor for Travios and Plivios, 8 × 2.5 mm |
| 394.579 | Cancellous Bone Impactor |




Select the appropriate Plivios cage size according to the trial implant size determined in step 3c or 4.

Attach the cage to the holder and insert it into the open packing block.

Remove the holder, insert the second cage, close the packing lid and tighten the knurled nut.

Using the cancellous bone impactor, fill the cages completely with bone graft material pressing it down firmly.

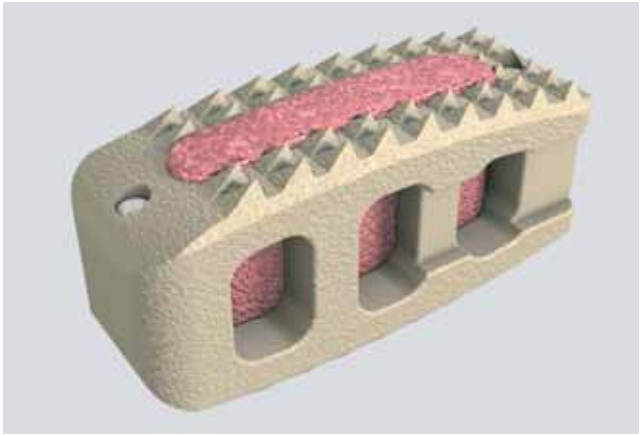
After the cages are filled, lift the packing lid and remove the cages with the implant holder. They are now ready for insertion.

## 5b

**Pre-filled Plivios chronOS cages**

Select the appropriate Plivios chronOS cage size according to the trial implant size determined in step 4.

Perfuse the implant with autologous blood or bone marrow aspirate (see page 4).



## 6
**Insert implant**

| **Instruments** | |
|---|---|
| 381.103 | Implant Holder |
| 389.288 | Cancellous Bone Impactor for Travios and Plivios, 8 × 2.5 mm |
| 394.579 | Cancellous Bone Impactor |
| **Optional instruments** | |
| 389.103 | Impactor for Plivios |
| 394.562 | Funnel for Cancellous Bone Graft ∅ 8.0 mm, length 220 mm |
| 394.572 | Cancellous Bone Impactor ∅ 8.0 mm, for No. 394.562 |

Grasp the selected cage using the implant holder. The cage has holding slots to be gripped with the jaws of the implant holder. The cage must be held flush against the holder neck. Tighten the speed nut on the handle to ensure that the cage is held securely in the jaws of the holder.

Introduce the correctly oriented cage into the contralateral disc space. Slight impaction will be necessary using the implant holder and, if necessary, the impactor.

Once the cage is in the desired position, remove the implant holder.

Prior to placement of the second cage, autogenous cancellous bone or a bone graft substitute should be placed in the anterior and medial aspect of the vertebral disc space.

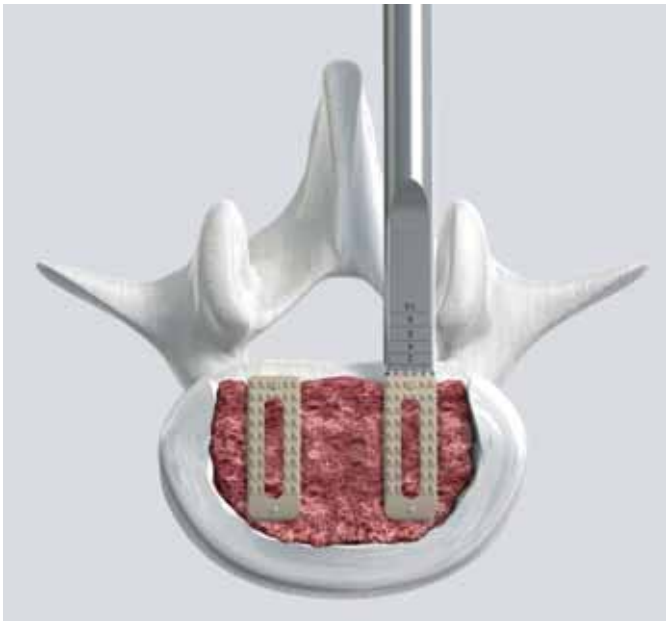
The cancellous bone funnel, cancellous bone pusher, and a cancellous bone impactor can be used for fast and efficient graft placement.

Remove the distractor or trial implant and insert a second cage of the same height into the available disc space.

Ensure that the second cage does not displace the first one when inserted. It should be inserted as far laterally as possible. Use gentle impaction as described before.

Distraction with Plivios distractor (3b)

Distraction with Plivios trial implant (3c)



## 7

### Verify cage position

Check the position of the cages under fluoroscopy. Both cages should be positioned 2–4 mm beyond the posterior rim of the vertebral body and laterally close to the hard bone of the vertebral body rim. If necessary recess the cages using the impactor.

Remove the implant holder.

# Posterior Stabilization and Postoperative Care

**Posterior stabilization**
Additional posterior fixation with transpedicular screws (e.g. Pangea) is recommended.

**Postoperative care**
Bed rest must be observed for a three-day period and a corset should be worn for three months to restrict excessive movement.

Take anteroposterior and lateral X-rays to ensure correct positioning of the cages and pedicle screws before mobilization of the patient.

# Notes and Warnings

– Plivios cages are supplied pre-sterilized by gamma irradiation; it is not recommended that they be resterilized.
– In exceptional cases, the non-filled Plivios cages 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 dioxide or formaldehyde) or gas plasma (e.g. hydrogen peroxide).
– The trial implants are not for implantation and must be removed before insertion of the Plivios cage.
– Protect the nerve root and dura with a root retractor wherever possible.

**Please consult the package insert for further information.**

## Plivios

All cage footprints are available in 6 heights, increasing in 2 mm increments, and are supplied sterile pre-packed.

Length 22 mm, width 8 mm, sterile


| Art. No. | Height | Trial implant |
|---|---|---|
| 889.844S | 7 mm | 389.128 |
| 889.845S | 9 mm | 389.129 |
| 889.846S | 11 mm | 389.131 |
| 889.847S | 13 mm | 389.133 |
| 889.848S | 15 mm | 389.135 |
| 889.849S | 17 mm | 389.137 |

Length 24 mm, width 8 mm, sterile


| Art. No. | Height | Trial implant |
|---|---|---|
| 08.803.002S | 7 mm | 389.128 |
| 08.803.003S | 9 mm | 389.129 |
| 08.803.004S | 11 mm | 389.131 |
| 08.803.005S | 13 mm | 389.133 |
| 08.803.006S | 15 mm | 389.135 |
| 08.803.007S | 17 mm | 389.137 |

Length 22 mm, width 10 mm, sterile

| Art. No. | Height | Trial implant |
|---|---|---|
| 08.803.012S | 7 mm | 389.128 |
| 08.803.013S | 9 mm | 389.129 |
| 08.803.014S | 11 mm | 389.131 |
| 08.803.015S | 13 mm | 389.133 |
| 08.803.016S | 15 mm | 389.135 |
| 08.803.017S | 17 mm | 389.137 |


Length 24 mm, width 10 mm, sterile

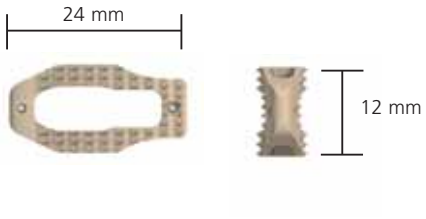
| Art. No. | Height | Trial implant |
|---|---|---|
| 08.803.022S | 7 mm | 389.128 |
| 08.803.023S | 9 mm | 389.129 |
| 08.803.024S | 11 mm | 389.131 |
| 08.803.025S | 13 mm | 389.133 |
| 08.803.026S | 15 mm | 389.135 |
| 08.803.027S | 17 mm | 389.137 |


Length 22 mm, width 12 mm, sterile

| Art. No. | Height | Trial implant |
|---|---|---|
| 08.803.032S | 7 mm | 389.128 |
| 08.803.033S | 9 mm | 389.129 |
| 08.803.034S | 11 mm | 389.131 |
| 08.803.035S | 13 mm | 389.133 |
| 08.803.036S | 15 mm | 389.135 |
| 08.803.037S | 17 mm | 389.137 |

Length 24 mm, width 12 mm, sterile

| Art. No. | Height | Trial implant |
|---|---|---|
| 08.803.042S | 7 mm | 389.128 |
| 08.803.043S | 9 mm | 389.129 |
| 08.803.044S | 11 mm | 389.131 |
| 08.803.045S | 13 mm | 389.133 |
| 08.803.046S | 15 mm | 389.135 |
| 08.803.047S | 17 mm | 389.137 |




**Plivios chronOS**

Plivios chronOS cages prefilled with synthetic cancellous bone graft substitute chronOS are available in 6 heights, increasing in 2 mm increments, and are supplied sterile prepacked in a perfusion syringe.

Length 22 mm, width 8 mm, sterile

| Art. No. | Height | Trial implant |
|---|---|---|
| 870.984S | 7 mm | 389.128 |
| 870.985S | 9 mm | 389.129 |
| 870.986S | 11 mm | 389.131 |
| 870.987S | 13 mm | 389.133 |
| 870.988S | 15 mm | 389.135 |
| 870.989S | 17 mm | 389.137 |

# Instruments

The Plivios instrument set is uncomplicated and efficient. It contains a comprehensive set of user-friendly instruments for trouble-free PLIF surgery.

**Instruments for disc and endplate preparation**

389.124 Bone Curette, rectangular, straight, 8 mm
Facilitates efficient removal of the intervertebral disc and of the cartilaginous endplates to expose bleeding bone.

389.125 Osteotome, 5 mm
Removes osteophytes and bony structures.

389.714 Bone Rasp, straight, 8 mm
Optimizes cleaning and preparation of the endplates without damaging the subchondral bone. Permits removal of cartilaginous tissue from the endplate to expose bleeding bone.

## Shavers for intervertebral discs

Available in 6 heights, increasing in 2 mm increments corresponding to endplate geometry.

| Art. No. | Height |
|---|---|
| 389.767 | 7 mm |
| 389.769 | 9 mm |
| 389.771 | 11 mm |
| 389.773 | 13 mm |
| 389.775 | 15 mm |
| 389.777 | 17 mm |

Permit the removal of cartilaginous tissue from the endplate to expose bleeding bone. Help to prepare the endplate without damaging the subchondral bone.

## Excisors for intervertebral discs

Available in 6 heights, increasing in 2 mm increments corresponding to endplate geometry.

| Art. No. | Height |
|---|---|
| 389.780 | 7 mm |
| 389.781 | 9 mm |
| 389.782 | 11 mm |
| 389.783 | 13 mm |
| 389.784 | 15 mm |
| 389.785 | 17 mm |

Facilitate the removal of the nucleus pulposus. Permit removal of cartilaginous tissue from the endplate to expose bleeding bone while preserving the natural anatomy. Help to prepare endplate without damaging the subchondral bone.

## Instruments for implant and trial implant manipulation

| | |
|---|---|
| 389.101 | Distractor for Plivios<br>Distracts the vertebrae to ensure maximum implant height and neural foraminal decompression. |

| | |
|---|---|
| 381.103 | Implant Holder for Plivios Revolution<br>Securely grips the Plivios cage, enables impaction during insertion and allows maximum control upon implant insertion. |

| | |
|---|---|
| 389.103 | Impactor for Plivios<br>Seats the Plivios cage into the disc space at measured depths and aids radiographic visualization of final implant position. The textured end minimizes slipping during impaction. |

## Plivios trial implants

| Art. No. | Height |
|---|---|
| 389.128 | 7 mm |
| 389.129 | 9 mm |
| 381.100 | 10 mm |
| 389.131 | 11 mm |
| 381.101 | 12 mm |
| 389.133 | 13 mm |
| 389.135 | 15 mm |
| 389.137 | 17 mm |

| | | |
|---|---|---|
| 394.951 | T-Handle with Quick Coupling<br>Attaches to the Plivios trial implants for secure insertion, manipulation and extraction. |  |

**Bone grafting instruments**

| | | |
|---|---|---|
| 381.102 | Packing Block for Plivios Revolution<br>Used with 389.288 (below) to fill the empty Plivios cages with bone graft: Provides a quick and easy way to completely fill the cages with graft material to ensure a good fusion result. |  |
| 389.288 | Cancellous Bone Impactor for Travios and Plivios, 8 × 2.5 mm<br>Used with the packing block to impact bone graft tightly into the empty Plivios cages. |  |
| 394.562 | Funnel for Cancellous Bone Graft<br>∅ 8.0 mm, length 220 mm<br>Used with the Cancellous Bone Impactor (394.572) for efficient insertion of autologous bone graft or bone graft substitute in the anterior and medial aspects of the disc space. |  |
| 394.572 | Cancellous Bone Impactor ∅ 8.0 mm<br>Used with the cancellous bone funnel (394.562). |  |
| 394.579 | Cancellous Bone Impactor<br>Used to compact the inserted graft material firmly into the disc space. |  |

# Recommended Supplementary Material

### Bone graft harvesting set

| | |
|---|---|
| 177.300 | Set for Bone Graft Harvesting in SynCase<br>An efficient tool for the harvesting of autologous bone from the iliac crest when using unfilled Plivios cages. |

### chronOS granules

Synthetic cancellous bone graft substitute β-TCP (beta-tricalcium phosphate) for supplementing autologous bone graft material. Can be used for placement around the implant in the intervertebral space.

| Art. No. | Granule size | Quantity |
|---|---|---|
| 710.014S | 1.4–2.8 mm | 5 cc |
| 710.019S | 1.4–2.8 mm | 10 cc |
| 710.021S | 1.4–2.8 mm | 20 cc |

### Posterior stabilization

**Pangea**
The Pangea Degenerative Spine System is a posterior pedicle screw fixation system (T1–S2) intended to provide precise and segmental stabilization of the spine in skeletally mature patients.

| | |
|---|---|
| 68.620.000 | Vario Case for Basic Instruments Pangea Polyaxial, with Lid, without Contents |
| 01.620.015 | Pangea Polyaxial Basic Instruments in Vario Case |
| 68.620.004 | Vario Case for Implants Pangea Polyaxial, with Lid, without Contents |
| 01.620.018 | Pangea Polyaxial Implants in Vario Case |

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