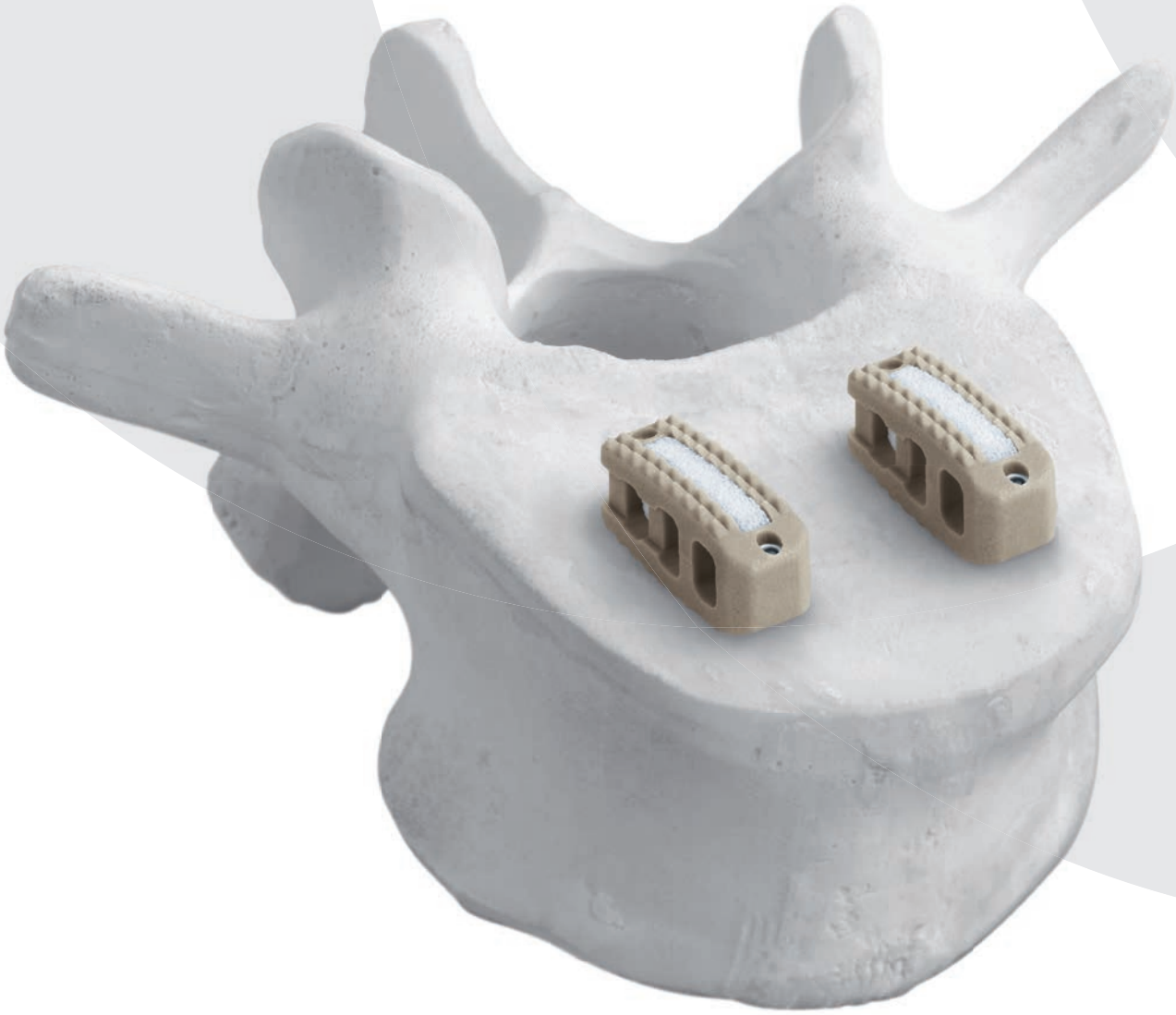
Radiolucent Cage System for Posterior Lumbar Interbody Fusion

Plivios and Plivios chronOS

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

Table of Contents

Plivios and Plivios chronOS. Radiolucent Cage System for Posterior Lumbar Interbody Fusion.

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 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.

Plivios 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%, even two years after iliac crest surgery.[2]

[1] Steffen et al. 2001
[2] Goulet et al. 1997

chronOS – synthetic β-tricalcium phosphate cancellous bone substitute

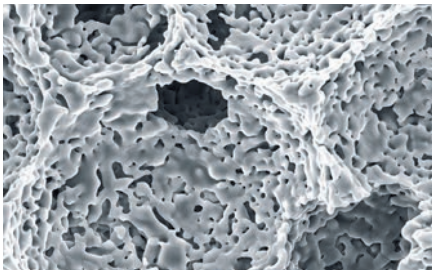
chronOS is a bone graft substitute consisting of pure β-tricalcium phosphate. Its compressive strength is similar to that of cancellous bone once it has been incorporated and remodeled.[1] Based on literature, the use of β-tricalcium phosphate in the spinal column is a valuable alternative to allografts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

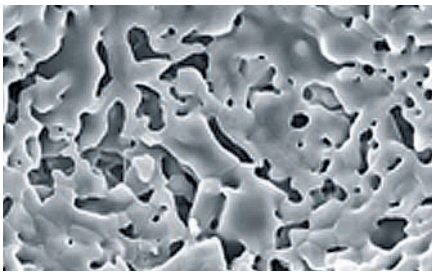
Resorbable
It is being replaced in the human body by host bone in 6 to 18 months; depending on the indication and the patient's conditions.[2,3-5]

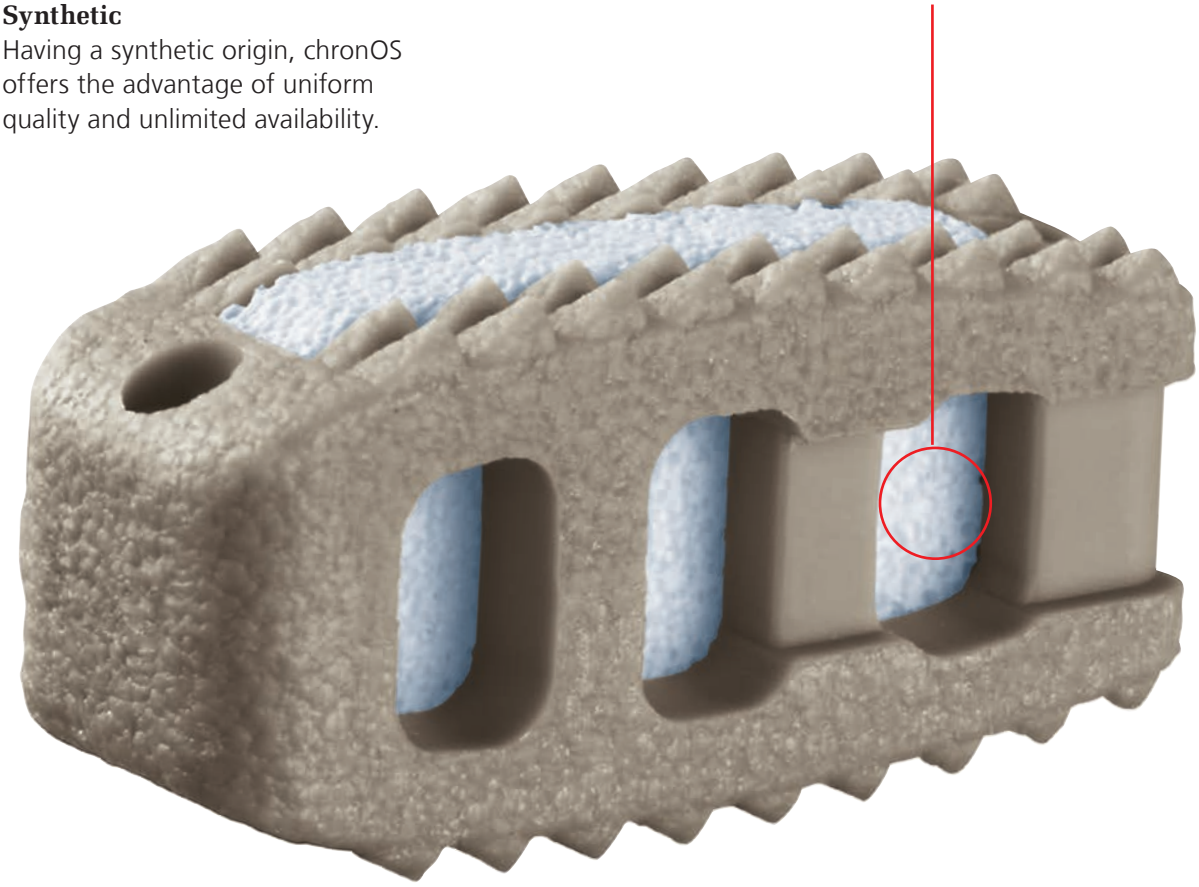
Synthetic
Having a synthetic origin, chronOS offers the advantage of uniform quality and unlimited availability.

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 Plivios 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]





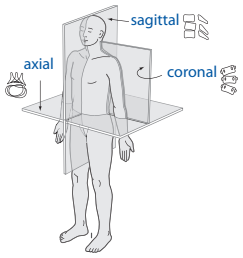


[1] Gazdag et al. 1995
[2] Muschik et al. 2001
[3] Stoll et al. 2004
[4] Becker et al. 2006
[5] Wheeler et al. 2005
[6] Lu et al. 1999

AO Spine Principles

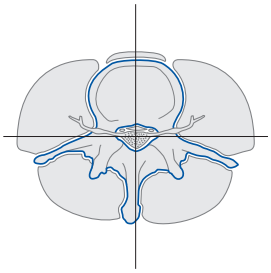
The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.[1,2]

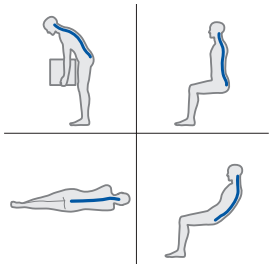
Stability
Stabilization to achieve a specific therapeutic outcome



Alignment
Balancing the spine in three dimensions

Biology
Etiology, pathogenesis, neural protection, and tissue healing





Function
Preservations and restoration of function to prevent disability

[1] Aebi et al (1998)
[2] Aebi et al (2007)

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

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

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.

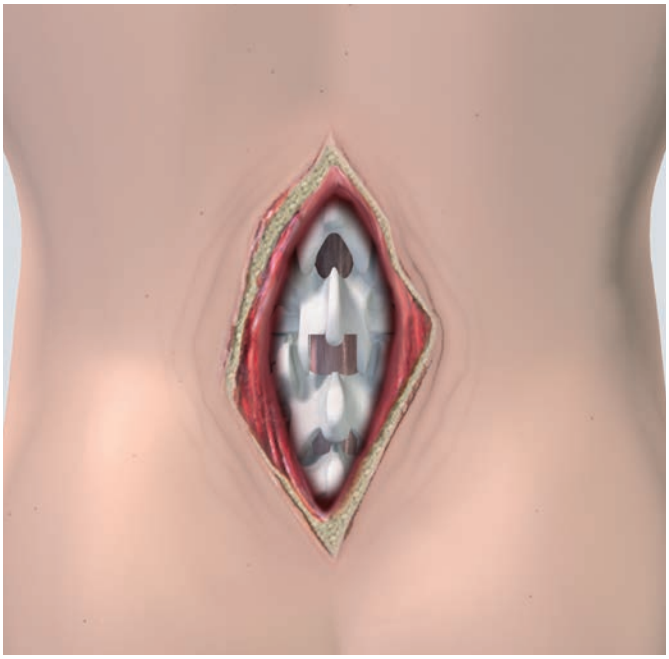
1. Incise and expose disc

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.

Note: **Great care should be taken to protect the nerve root and the dura.**

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

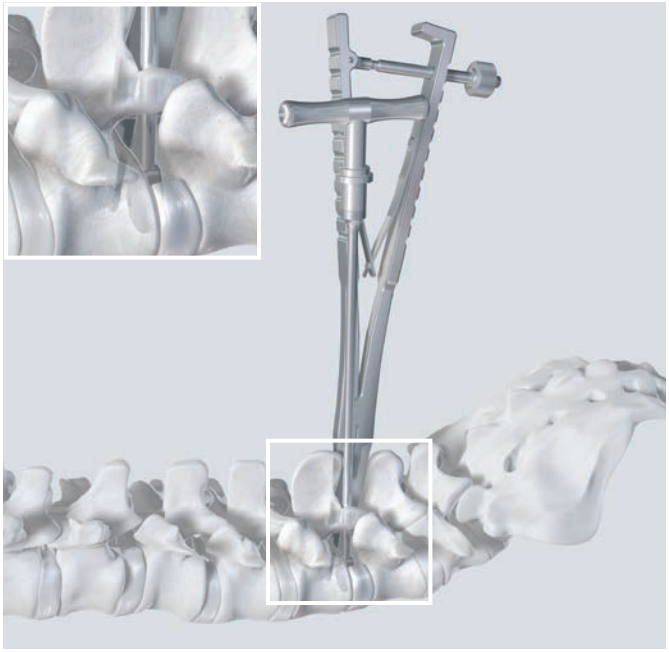
Select the size of the trial implant as estimated during preoperative planning.

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.

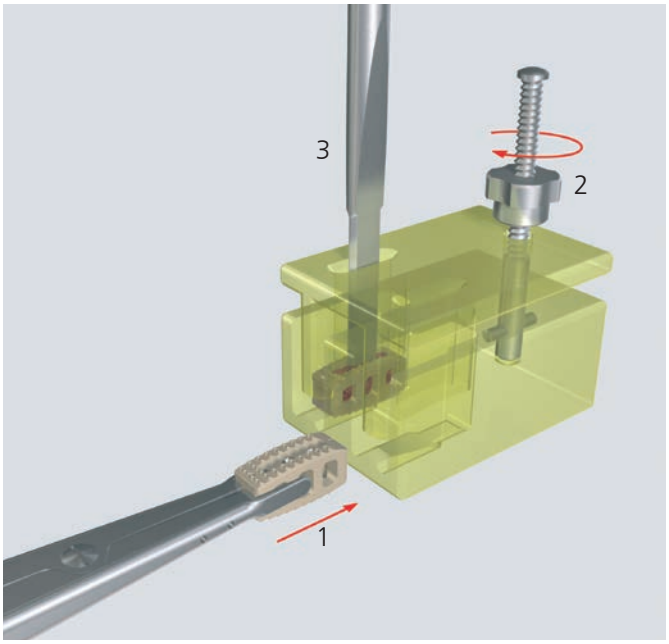
Select the implant corresponding to the correct trial implant.

Remove the trial implant assembly.

5. Determine size and prepare implant

5a. Unfilled Plivios cages

Instruments	
381.102	Packing Block for Plivios Revolution
381.103	Implant Holder for Plivios Revolution
389.288	Cancellous Bone 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.

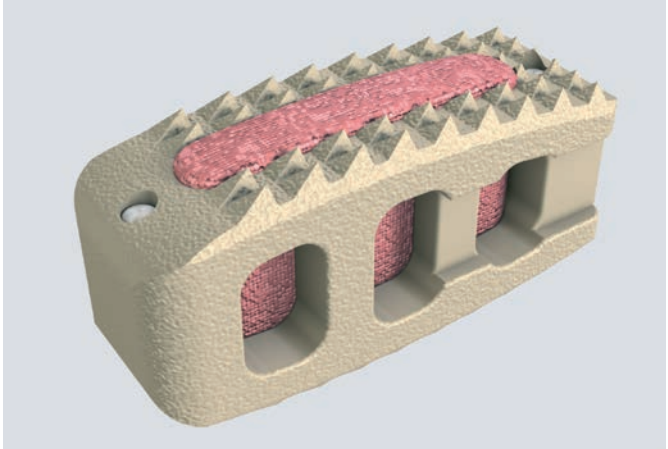
Using the cancellous bone impactor, fill the cages completely with bone graft material pressing it down firmly.

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.

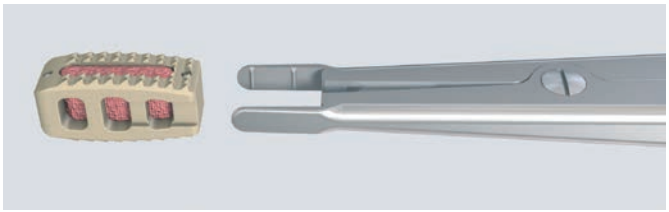
Soak the implant with autologous blood or bone marrow aspirate.



6. Insert implant

Instruments	
381.103	Implant Holder for Plivios Revolution
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.



Note: **The trial implants are not for implantation and must be removed before insertion of the Plivios cage.**

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

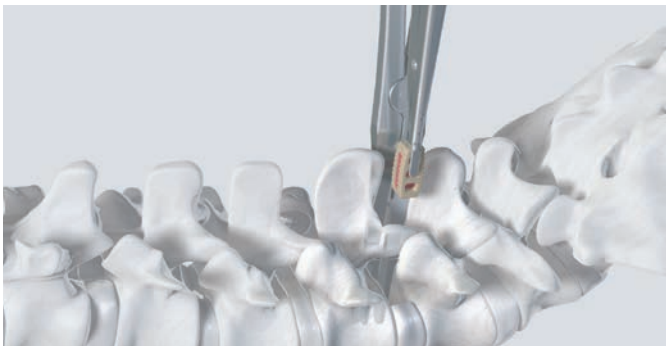
Once the cage is in the desired position, remove the implant holder.

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.

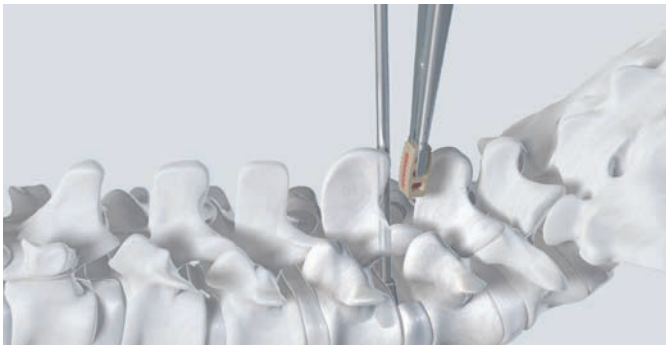
The cancellous bone funnel, cancellous bone pusher, and a cancellous bone impactor can be used for fast and efficient graft placement.

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

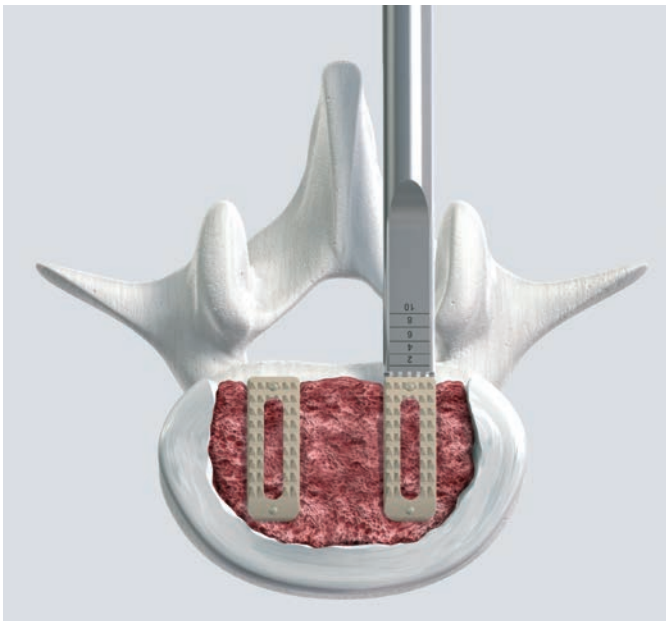
Ensure that the second cage does not displace the first one when inserted. It should be inserted as far laterally as possible. Use gentle impaction as described before.



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 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.

Implants

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

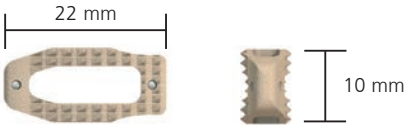
Art. No.	Height	Trial implant
889.844S	7 mm	389.128
889.845S	9 mm	389.129
889.846S	11 mm	389.131
889.847S	13 mm	389.133
889.848S	15 mm	389.135
889.849S	17 mm	389.137

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

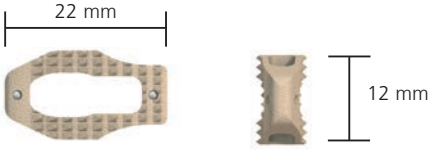


Length 24 mm, width 10 mm, sterile

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

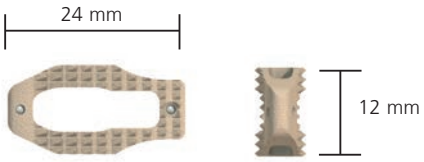
Length 22 mm, width 12 mm, sterile

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.

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 Distracts the vertebrae to ensure maximum implant height and neural foraminal decompression.

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

389.103	Impactor for Plivios 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 Attaches to the Plivios trial implants for secure insertion, manipulation and extraction.	

Bone grafting instruments

381.102	Packing Block for Plivios Revolution 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 Used with the packing block to impact bone graft tightly into the empty Plivios cages.	
394.562	Funnel for Cancellous Bone Graft ∅ 8.0 mm, length 220 mm 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 Used with the cancellous bone funnel (394.562).	
394.579	Cancellous Bone Impactor Used to compact the inserted graft material firmly into the disc space.	

Bibliography

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

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

Allmann M, Florias E, Stoll T, Hoerger F, Bart F (2002): Haematological evaluation of blood samples after vacuumlike impregnation of a Beta-TCP ceramic bone substitute before implantation.

Becker S, Maissen O, Ponomarev I, Stoll T, Rahn B, Wilke I (2006) Osteopromotion by a β-Tricalcium Phosphate/ Bone Marrow Hybrid Implant for Use in Spine Surgery. Spine 31 (1): 11–17

Gazdag AR, Lane JM, Glaser D, Forster RA (1995) Alternatives to autogenous bone graft: efficacy and indications. J Am Acad Orthop Surg 3: 1-8.

Goulet JA, Senunas LE, DeSilva GL, Green.eld ML (1997) Autogenous iliac crest bone graft. Complications and functional assessement. Clin Orthop 339:76–81.

J. X. Lu et al. Role of interconnections in porous bioceramics on bone recolonization in vitro and in vivo. J Mater Sci Mater Med. 1999; 10(2): 111–120.

Müller ME, Allgöwer M, Schneider R, Willenegger H (1995) Manual of Internal Fixation, 3rd expanded and completely revised ed. 1991. Berlin, Heidelberg, New York: Springer

Muschik M, Ludwig R, Halbhubner S, Bursche K, Stoll T (2001) β-tricalcium phosphate as a bone substitute for dorsal spinal fusion in adolescent idiopathic scoliosis – preliminary results of a prospective clinical study. Eur Spine J 10: 178–84.

Muschler GF, Nitto H, Matsukura Y, Boehm C, Valdevit A, Kambic H, Davros W, Powell K, Easley K (2003) Spine fusion using cell matrix composites enriched in bone marrow derived cells. Clinical Orthopaedics and Related Research 407: 120-118

Steffen T, Stoll T, Arvinte T, Schenk RK (2001) Porous tricalcium phosphate and transforming growth factor used for anterior spine surgery. Eur Spine J 10: 132–140.

Stoll T, Maissen O, Meury T, Becker S (2004) New aspects in osteoinduction. Mat.-wiss. u. Werk stofftech 35: 198-202

D. L. Wheeler et al. Grafting of Massive Tibial Subchondral Bone Defects in a Caprine Module Using β-Tricalcium Phosphate versus Autograft. J Orthop Trauma 2005; 19(2): 85–91.

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuysynthes.com

Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

All surgical techniques are available as PDF files at
www.depuysynthes.com/ifu

CE
0123

036.000.153 DSEM/SPN/0814/0158(3) 03/17