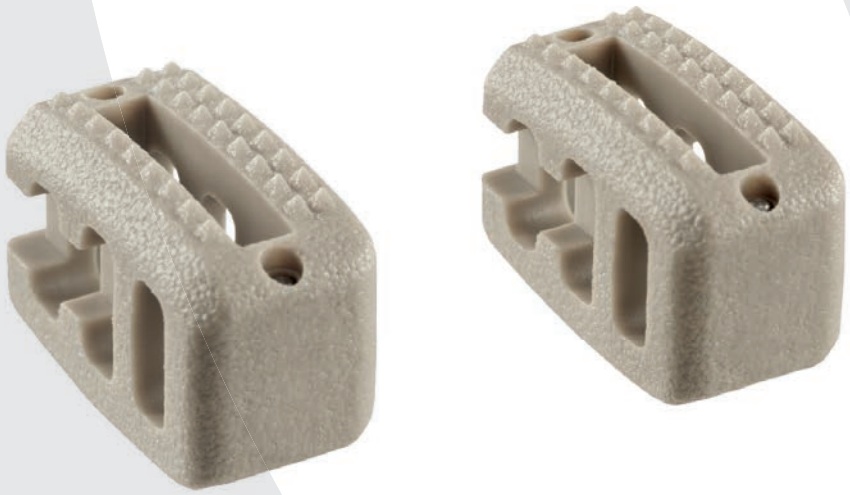
PEEK Cage for Posterior Lumbar Interbody Fusion (PLIF)

Plivios Revolution

Surgical Technique



DePuy Synthes

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Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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Features and Benefits

The Plivios System
Plivios is the Synthes Cage System for Posterior Lumbar Interbody Fusion (PLIF). It consists of radiolucent PEEK implants and the corresponding instruments.

Toothed upper and lower surfaces
Anchorage in the adjacent vertebral body endplates designed to provide primary stability.

Anatomical design
Convex surfaces:
- Tight fit to the concave endplates designed to provide contact over a large surface area between implant and endplate.

Rounded leading end:
- Designed to facilitate insertion and spares the end-plates; no drilling or cutting required.

Plivios Revolution
The Plivios Revolution implants represent a further development of the Plivios System. The cages are aligned in situ by rotation and allow an atraumatic restoration of the body's natural lordosis.

The rotation in situ is facilitated by
- specially aligned teeth
- bevelled edges

Only small insertion window is required which might allow the posterior rim of the endplates to stay intact, thus potentially reducing the risk of cage migration.

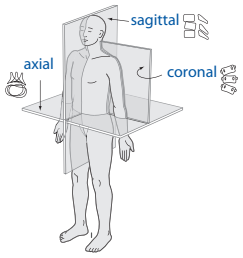
Fusion
The interplay of design and material creates desired conditions for fusion:
- Perforated structure for bone ingrowth and throughgrowth
- Roughened surface designed to allow bone ongrowth.

- Two x-ray markers facilitate radiologic identification
- PEEK OPTIMA™ is biocompatible.

AO Spine Principles

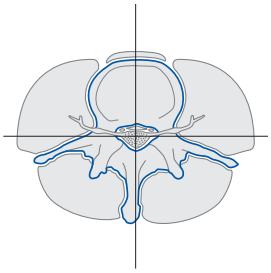
The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.[1,2]

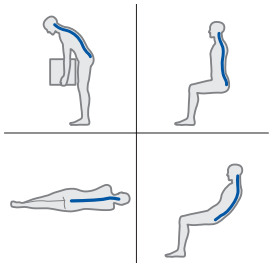
Stability
Stabilization to achieve a specific therapeutic outcome



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

Intended use
PLIVIOS is the Synthes Cage System for Posterior Lumbar Interbody Fusion (PLIF). It consists of radiolucent PEEK implants and the corresponding instruments.
The PLIVIOS REVOLUTION implants represent a further development of the PLIVIOS System. The cages are aligned in situ by rotation and allow an atraumatic restoration of the body's natural lordosis.

Indications
Degenerative lumbar and lumbosacral conditions requiring segmental fusion:
- Degenerative disc disease and instability
- Degenerative spondylolisthesis, grade I or II
- Spondylolisthesis with stenosis, grade I or II
- Pseudarthrosis or failed arthrodesis

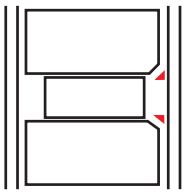
Notes:
- **Since the Plivios Revolution Cages were not developed as "stand-alone" implants, the use of additional posterior instrumentation (for example with pedicle screws) is strongly advised.**
- **The management of spondylolisthesis in grades III and IV, or higher levels of scarring deserves special attention. The same applies to destructive tumours. (Note that the Plivios Revolution System was not primarily developed for the restoration of the natural anatomy if three or more motion segments are involved.)**

Contraindications
- Severe osteoporosis
- Unstable burst and compression fractures
- Acute infections

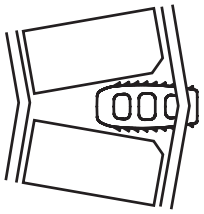
The Rotation Principle

The rotation principle
The Plivios Cage is inserted horizontally and then rotated into the vertical position.

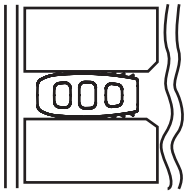
Without rotation:
For cage impaction without rotation, the posterior vertebral rim must be removed. This may lead to cage migration.



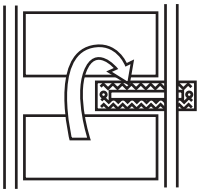
The dorsal structures must be overstretched in order to insert the taller anterior part of the cage into the intervertebral disc space.

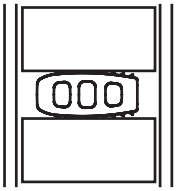


This involves the risk of limiting the stability of the segment which can lead to cage migration.



With rotation:
The Plivios Revolution Cage is inserted horizontally and then rotated into the vertical position clockwise. Overstretching is thus avoided. The slight distraction produced by the width of the cage will potentially result in tensioning of the anterior and posterior longitudinal ligaments without damaging them. This rotation step may protect the neural structures throughout the implantation process.





Implants

Plivios Revolution Cages

- The Plivios Revolution Cages are available in 6 heights and 2 angles (4° and 8°)
- The implants become wider with increasing height
- The Plivios trial implants precisely match the cage heights (including teeth)

Plivios Revolution, 4°, sterile, PEEK

Height × width	Implant	Trial implant
9 mm × 8 mm	889.500S	389.129
10 mm × 8 mm	889.501S	381.100
11 mm × 9 mm	889.502S	389.131
12 mm × 10 mm	889.503S	381.101
13 mm × 10 mm	889.504S	389.133
15 mm × 11 mm	889.505S	389.135

also available (non-rotatable)

7 mm × 8 mm	889.844S	389.128

Plivios Revolution, 8°, sterile, PEEK

Height × width	Implant	Trial implant
9 mm × 8 mm	889.510S	389.129
10 mm × 8 mm	889.511S	389.100
11 mm × 9 mm	889.512S	389.131
12 mm × 10 mm	889.513S	389.101
13 mm × 10 mm	889.514S	389.133
15 mm × 11 mm	889.515S	389.135

Instruments

Instruments for disc and endplate preparation

389.124 Plivios Bone Curette, rectangular, straight, 8 mm
Rectangular curette designed for the efficient removal of the intervertebral disc and cartilaginous endplates down to bleeding bone.

389.125 Osteotome, 5 mm
Removes osteophytes and bony structures.

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

Instruments for the manipulation of the implants and trial implants

389.006/
389.007 Disc Space Opener
Designed to provide ease of distraction of severely degenerated segments without excessively stressing the endplates.

Height × width	Instrument
8 mm × 4 mm	389.006
9 mm × 5.5 mm	389.007

389.101 Distractor for Plivios
For segmental distraction. Designed to enable the largest possible implant to be inserted and decompresses the nerve roots.

381.103 Implant Holder for Plivios Revolution, Stainless Steel
For holding the Plivios Revolution Cages and impacting during insertion. Offers control during implant insertion.

389.103 Impactor for Plivios
For impacting the cage into the desired position. The roughened end is designed to prevent implant slippage during the impaction process.
The scale on the instrument indicates the distance between the implant and the posterior rim of the vertebral body.

Trial Implants

- Used in connection with x-ray templates to determine the desired implant size
- 6 sizes, matching the cage sizes
  (see page 7 for article numbers)

394.951 T-Handle with Quick Coupling
The T-handle is attached to the Plivios trial implants. It allows insertion, manipulation and extraction of the trial implants.

Bone chip instruments

381.102 Packing Block for Plivios Revolution
For use with the Impactor (389.288). Allows quick, complete and ease in packing of the cage with bone chip material.

389.288 Cancellous Bone Impactor for Travios and Plivios, 8 × 2.5 mm
Used with the Packing Block (381.102) to pack the empty Plivios Revolution Cages with bone chips.

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
Used with the Cancellous Bone Funnel (394.562).

394.579 Cancellous Bone Impactor
Designed to firmly compress the inserted bone chip material in the intervertebral disc space.

Additional Instruments

chronOS Granules Bone Void Filler

chronOS Bone Void Filler Granules are a bone replacement material of synthetic, porous and resorbable β-tricalcium phosphate (β-TCP). In its function as temporary bone substitute, it serves to fill and bridge bone defects in children, adolescents and adults.

Art. No.	∅ (mm)	Content (mL)
710.014S	1.4–2.8	5
710.019S	1.4–2.8	10
710.021S	1.4–2.8	20

1. Preoperative planning

Prior to surgery, determine the appropriate cage height with the x-ray template.

An initial estimate of the cage size can be made by comparing the x-ray template with the adjacent intervertebral discs on a lateral radiograph.

The implant must be seated firmly with a tight fit between the endplates when the segment is fully distracted. It is essential to use the tallest possible implant to enhance segmental stability.

The final size is determined during surgery with the aid of the trial implants.

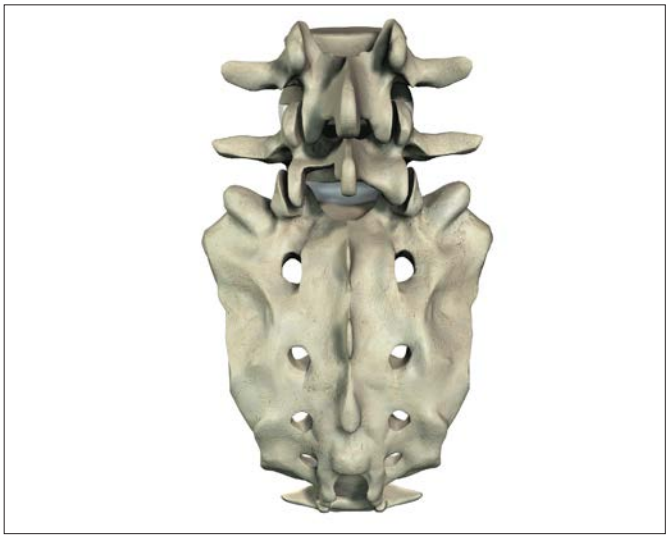
2. Position patient

Place the patient in the prone position on a lumbar support. The x-ray unit can be used to help determine the precise intraoperative position of the relevant segment.

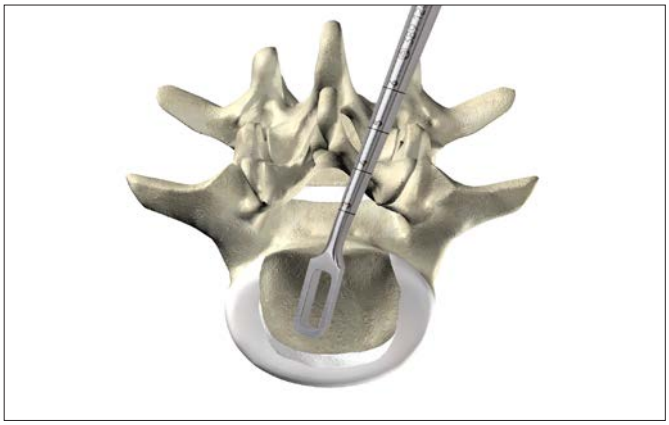
3. Expose intervertebral disc and perform incision

Incise the skin and dissect laterally from the midline. Locate the spinous process and the lamina of the corresponding layer(s).

Perform a laminotomy sufficiently large for the PLIF preparation. Ensure that the neurogenic structures are spared as much as possible.



4. Remove intervertebral disc and prepare endplates



Required instruments

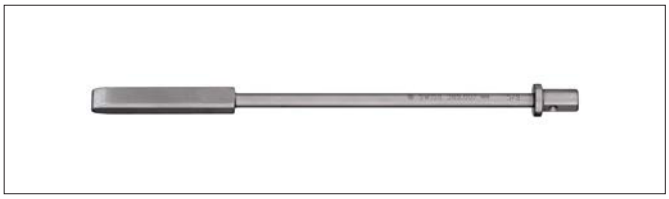
389.124	Bone Curette, rectangular, straight, 8 mm

Use the curette to remove the disc through the incision window leaving only the anterior and lateral annulus intact.

Remove the superficial layers of the cartilaginous endplates down to bleeding bone.

Note: **Appropriate cleaning of the endplates is important for the vascularization of the bone chip material. Excessive cleaning, on the other hand, can weaken the endplates. Removal of the whole endplate can cause subsidence and the loss of segmental stability.**

5. Open intervertebral disc space



Required instruments

389.006	Disc Space Opener, width 4 mm, height 8 mm
389.007	Disc Space Opener, width 5.5/5 mm, height 9 mm

Insert a small disc space opener horizontally into the intervertebral space on one side. Rotate the instrument vertically and clockwise by approx. 100° and then, for better anchorage of the teeth, counterclockwise by approx. 10°. This method can be employed to distract the posterior aspects of severly collapsed segments that are found in certain circumstances.

6. Distract segment

Distraction is crucial for the restoration of the intervertebral disc height and facilitates access to the disc space for subsequent preparation of the endplates.

The Plivios Revolution implants were designed to fit snugly into the natural concavity between two adjacent vertebral bodies. Additional stability for the inserted implants is provided by the longitudinal ligaments and the annulus fibrosus. These should not be overdistracted.

Three distraction methods can be used depending on the pathology and the surgeon's preference:
- across pedicle screws
- using the Plivios distractor
- using a Plivios trial implant

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

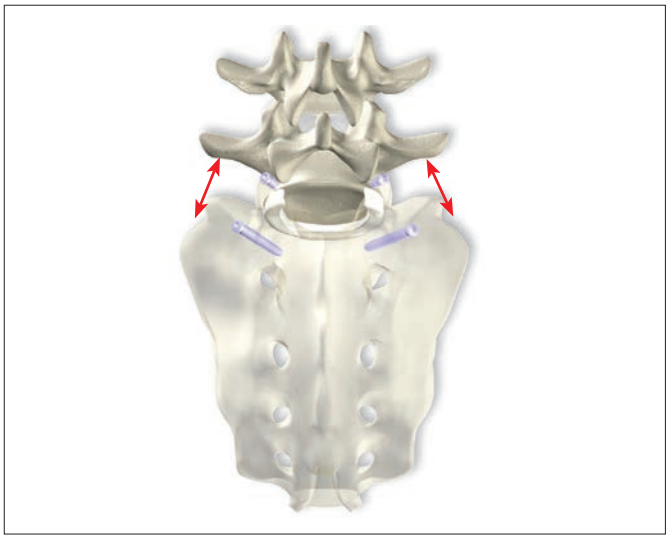
6a. Distraction across pedicle screws

Distraction is applied between the heads of the pedicle screws following their insertion.

This method temporarily opens up the posterior disc space, providing better access for decompression and the insertion of the implant.

If dealing with a collapsed or extremely thin disc, this distraction method can even be used for disc removal and preparation of the endplates.

Note: **Appropriate longitudinal distraction must be applied to avoid kyphosis; a trial implant can be used to achieve this (see step 6c).**

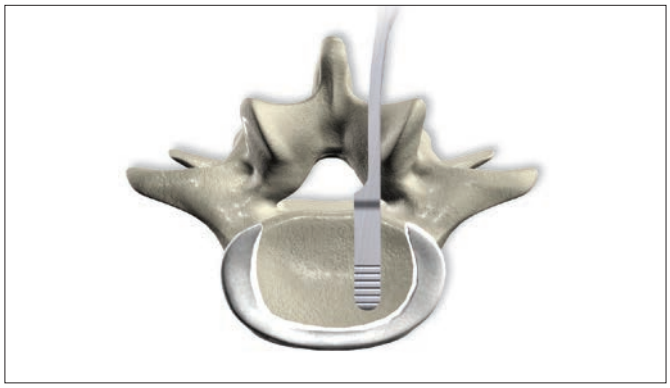


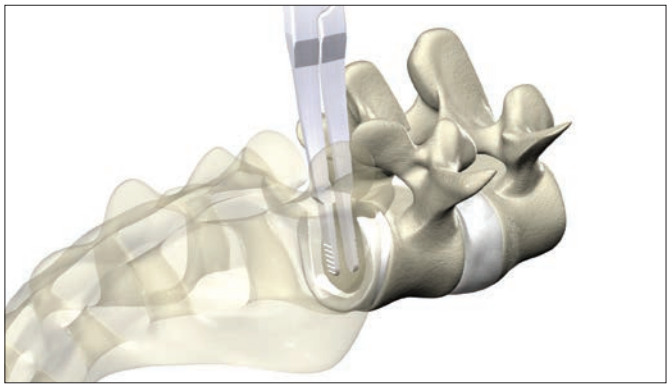
6b. Distraction using a distractor

Required instruments

389.101	Distractor for Plivios

Place the distractor blades in the intervertebral disc space laterally to the epidural space. Align the curve of the distractor with the midline. Insert the distractor blades fully into the disc space so that the grooves at the end of the blades are located in the intervertebral space. Use the image intensifier to check whether the blades are parallel to the endplates. When correctly placed, the distractor blades will be angled cranially, particularly at L5–S1. Carefully distract the segment, avoiding excessive distraction. Image intensifier control, preoperative planning and tactile judgement can assist in determining the correct degree of distraction.





6c. Distraction using a trial implant

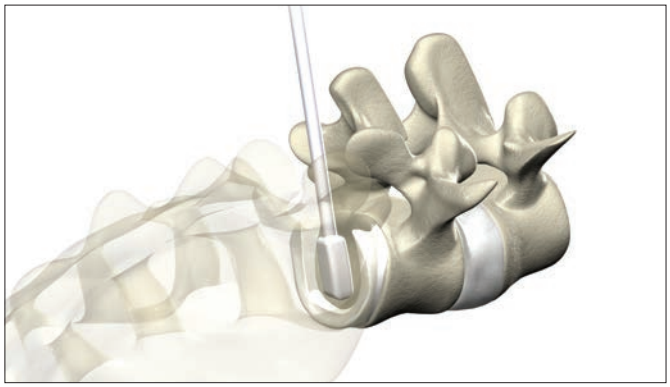
Required instruments

394.951	T-Handle with Quick Coupling

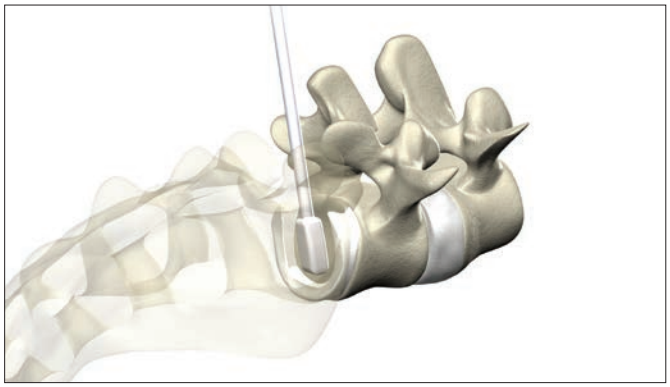
Attach a trial implant (see page 7) of the respective preoperatively determined size to the T-handle.

Insert the trial implant horizontally into the disc space and rotate vertically to distract the segment. Check the secure fit of the trial implant with the aid of the image intensifier and palpation. If the trial implant is too loose or too tight, try the next larger/smaller size until a secure fit is achieved.

Select the implant that matches the trial implant.
Proceed to step 8.



7. Determine cage size using trial implants (required for distraction methods 6a and 6b)



Required instruments

394.951	T-Handle with Quick Coupling

After distraction across pedicle screws or with a distractor, attach a suitably sized trial implant to the T-handle with quick-acting closure. Carefully impact the T-handle-trial implant assembly into the contralateral disc space. Check the correct fit of the trial implant with the aid of the image intensifier and palpation.
If the trial implant is too loose or too tight, try the next larger/smaller size until a secure fit is achieved. Select the implant that matches the trial implant.

Remove the T-handle and the attached trial implant.

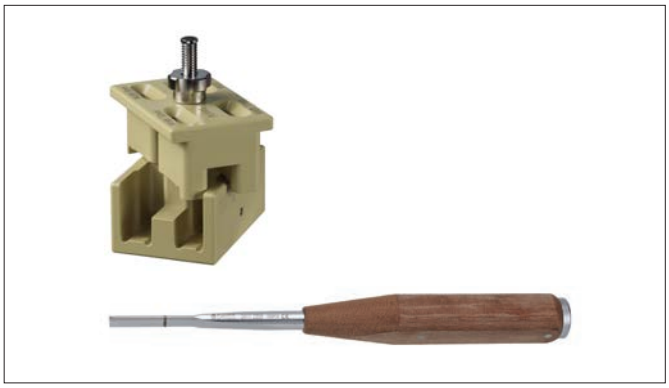
8. Attach cage to the implant holder

Required instruments

381.103	Implant Holder for Plivios Revolution, Stainless Steel

Attach the selected implant to the Plivios Revolution implant holder. Ensure that the cage is fully inserted into the holder with no gap between the neck of the holder and the posterior part of the cage. Tighten the speed nut on the holder.

9. Pack implant with bone chip material

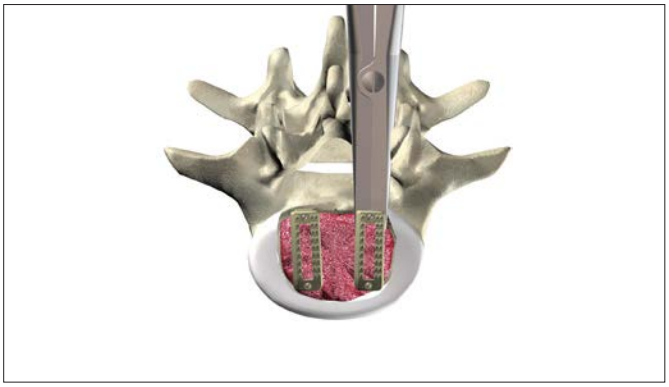


Required instruments	
381.102	Packing Block for Plivios Revolution
389.288	Cancellous Bone Impactor for Travios and Plivios, 8 × 2.5 mm

Insert the cage, attached to the implant holder, into the packing block and fill completely with bone chip material using the impactor. Compact the material firmly.

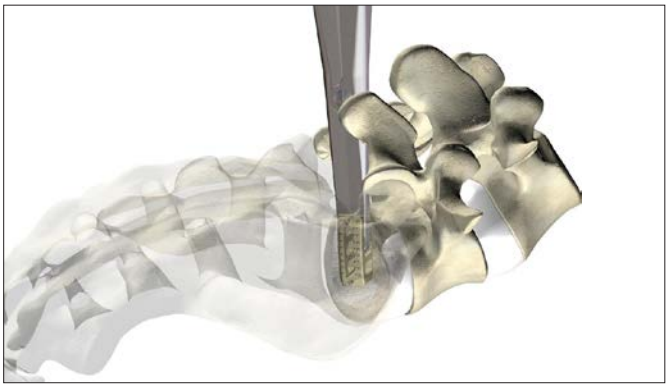
The cage can now be implanted.

10. Insert implant



Insert the cage horizontally into the intervertebral disc space by gentle impaction. Protect the nerve roots and dura with a suitable instrument.

To prevent the shaft of the knurled nut on the implant holder obscuring the midline, comply with the following procedure:
Insert the left cage with the knurled nut oriented caudally and advance the cage to the correct depth (approx. 3 to 4 mm beyond the posterior rim of the vertebral body). Check the depth against the scale on the implant holder. Now rotate the cage clockwise, the knurled nut and shaft now lie lateral to the midline.



Insert the right cage with the knurled nut oriented cranially. Advance the cage to the correct depth. Now rotate the cage clockwise; the knurled nut and shaft now lie lateral to the midline.

Notes:

- **Although the anterior annulus fibrosus and the anterior longitudinal ligament are resistant in most patients, this resistance may be lacking in the case of degenerated discs. Be aware of the risk of perforation.**
- **The trial implants are not intended for implantation and must be removed before insertion of the Plivios Revolution Cages.**

11. Rotate cage to the upright position

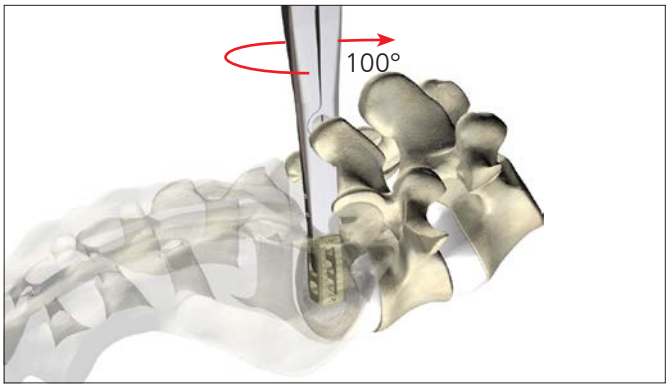
Optional instruments

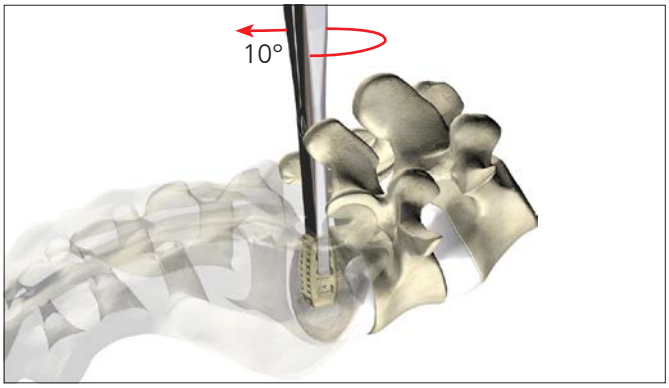
389.103	Impactor for Plivios

Rotate the cage clockwise by approx. 100° to an upright position and then, counterclockwise by approx. 10° so that the specially aligned teeth on the surface of the implant anchor themselves into the vertebral body endplates.

Note: **Should it prove necessary to turn the cage back to the horizontal position, the rotation should be clockwise and may require further gentle impacts.**

Remove the implant holder once the implant is in the desired position.





12. Pack disc space and insert second cage

Required instruments	
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
394.579	Cancellous Bone Impactor
381.103	Implant Holder for Plivios Revolution, Stainless Steel

Prior to placement of the second cage, autologous bone or bone substitute should be inserted in the intervertebral disc space. The cancellous bone funnel and cancellous bone pusher can be used for fast and efficient graft placement.

Remove the distractor/trial implant.

Insert a second cage of the same height as laterally as possible, leaving a clear gap between the first cage. Ensure that the first cage is not displaced during the insertion of the second cage.

Remove the implant holder.

Check cage position

Remove all instruments. Check the position of the cages with the image intensifier. Their desired position is anterior to the posterior rim in the concavity of the vertebral body and, laterally, close to the cortical bone of the vertebral body edge.

Removal of the Cages
Posterior Stabilization

Removal of an incorrectly placed cage
Attach the implant holder to the cage and release the implant from the concavity of the endplates by clockwise rotation.

Additional distraction on the contralateral side with the Plivios distractor or a taller trial implant may prove helpful.

Posterior stabilization
Additional posterior stabilization by internal fixation is strongly recommended. Perform an additional postero-lateral fusion if necessary.

Bibliography

Aebi M, Thalgott JS, Webb JK (1998) AO ASIF Principles in Spine Surgery. Berlin Heidelberg New York: Springer

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

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES
People inspired™

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

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