Plivios Revolution. PEEK Cage for Posterior Lumbar Interbody Fusion (PLIF).

Technique Guide

SYNTHEs®

This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation.
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**Warning**

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is mandatory.

**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: www.synthes.com/reprocessing

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: www.synthes.com/reprocessing
**Plivios Revolution.** PEEK Cage for Posterior Lumbar Interbody Fusion (PLIF).

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**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.

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**Toothed upper and lower surfaces**

Anchorage in the adjacent vertebral body endplates ensures good primary stability.

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**Anatomical design**

Convex surfaces:
- Optimal fit to the concave endplates ensures contact over a large surface area between implant and endplate

Rounded leading end:
- Facilitates insertion and spares the endplates; 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. The posterior rim of the endplates is left intact, thus considerably reducing the risk of cage migration.

Stronger fusion

The interplay of design and material creates ideal conditions for fusion:
– Perforated structure for bone ingrowth and throughgrowth
– Roughened surface promotes integration and bone ongrowth
– Two x-ray markers facilitate radiologic identification
– PEEK OPTIMA™ is biocompatible. The absence of carbon fibres minimises the risk of systemic uptake and local inflammatory reactions.
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 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

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 results in effective tensioning of the anterior and posterior longitudinal ligaments without damaging them. This rotation step ensures that the neural structures remain protected throughout the implantation process.

Primary distraction takes place in the intervertebral space. The longitudinal ligaments are in ideal tension without being overstretched.

The posterior ligament remains intact and can therefore provide the cage with extra stability and effective tensioning.
**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**

<table>
<thead>
<tr>
<th>Height × width</th>
<th>Implant</th>
<th>Trial implant</th>
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<tbody>
<tr>
<td>9 mm × 8 mm</td>
<td>889.5005</td>
<td>389.129</td>
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<td>10 mm × 8 mm</td>
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<td>11 mm × 9 mm</td>
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<td>389.135</td>
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also available (non-rotatable)

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<td>7 mm × 8 mm</td>
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**Plivios Revolution, 8°, sterile, PEEK**

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<tr>
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## Instruments

### Instruments for disc and endplate preparation

<table>
<thead>
<tr>
<th>Code</th>
<th>Instrument</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>389.124</td>
<td>Plivios Bone Curette</td>
<td>Rectangular curette for the efficient removal of the intervertebral disc and cartilaginous endplates down to bleeding bone.</td>
</tr>
<tr>
<td>389.125</td>
<td>Plivios Osteotome</td>
<td>Removes osteophytes and bony structures.</td>
</tr>
<tr>
<td>389.714</td>
<td>Bone Rasp</td>
<td>For optimal cleaning and preparation of the endplates without damaging the subchondral bone. Removes the cartilaginous tissue from the endplate to expose bleeding bone.</td>
</tr>
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</table>

### Instruments for the manipulation of the implants and trial implants

<table>
<thead>
<tr>
<th>Code</th>
<th>Instrument</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>389.006</td>
<td>Disc Space Opener</td>
<td>Simplifies the distraction of severely degenerated segments without excessively stressing the endplates.</td>
</tr>
<tr>
<td>389.007</td>
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<tr>
<td>8 mm x 4 mm</td>
<td></td>
<td>Instrument</td>
</tr>
<tr>
<td>9 mm x 5,5 mm</td>
<td></td>
<td></td>
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<tr>
<td>389.101</td>
<td>Plivios Distractor</td>
<td>For segmental distraction. Ensures that the largest possible implant can be inserted and decompresses the nerve roots.</td>
</tr>
<tr>
<td>381.103</td>
<td>Plivios Revolution Implant Holder</td>
<td>For holding the Plivios Revolution Cages and impacting during insertion. Offers maximum control during implant insertion.</td>
</tr>
<tr>
<td>389.103</td>
<td>Plivios Impactor</td>
<td>For impacting the cage into the desired position. The roughened end prevents implant slippage during the impaction process. The scale on the instrument allows exact measurement of the distance between the implant and the posterior rim of the vertebral body.</td>
</tr>
</tbody>
</table>
Trial Implants

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

394.951 T-Handle with Quick-acting Closure
The T-handle is attached to the Plivios trial implants. It guarantees reliable insertion, manipulation and extraction of the trial implants.

Bone chip instruments

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

389.288 Impactor for Plivios Revolution Packing Block
Used with the Packing Block (381.102) to pack the empty Plivios Revolution Cages with bone chips.

394.562 Cancellous Bone Funnel

394.572 Cancellous Bone Pusher
Used with the Cancellous Bone Funnel (394.562).

394.579 Cancellous Bone Impactor
For firmly compressing the inserted bone chip material in the intervertebral disc space.
Bone Graft Harvesting Set

177.300 Bone Graft Harvesting Set
An efficient system for removing autologous bone from the iliac crest when using unfilled Plivios and Plivios Revolution Cages.

chronOS granules

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

<table>
<thead>
<tr>
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<th>Granule size</th>
<th>Quantity</th>
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<tr>
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<td>1.4–2.8 mm</td>
<td>5 cc</td>
</tr>
<tr>
<td>710.0195</td>
<td>1.4–2.8 mm</td>
<td>10 cc</td>
</tr>
<tr>
<td>710.0215</td>
<td>1.4–2.8 mm</td>
<td>20 cc</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>68.620.000</td>
<td>Vario Case for Basic Instruments Pangea Polyaxial, with Lid, without Contents</td>
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<tr>
<td>01.620.015</td>
<td>Pangea Polyaxial Basic Instruments in Vario Case</td>
</tr>
<tr>
<td>68.620.004</td>
<td>Vario Case for Implants Pangea Polyaxial, with Lid, without Contents</td>
</tr>
<tr>
<td>01.620.018</td>
<td>Pangea Polyaxial Implants in Vario Case</td>
</tr>
</tbody>
</table>
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 maximise 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

Bone Curette, rectangular, straight, 8 mm 389.124

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

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

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 severely collapsed segments that are found in certain circumstances.
Distract segment

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

The Plivios 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 over-distracted.

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

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**

| Plivios Distractor | 389.101 |

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.

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6c

**Distraction using a trial implant**

**Required instruments**

| T-Handle with Quick-acting Closure | 394.951 |

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

Required instruments
T-Handle with Quick-acting Closure 394.951

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-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.

Attach cage to the implant holder

Required instruments
Plivios Revolution Implant Holder 381.103

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.

Pack implant with bone chip material

Required instruments
Packing Block 381.102
Impactor 389.288

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.
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.

**Note:** 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.

Rotate cage to the upright position

Optional instruments

| Plivios Impactor | 389.103 |

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.
Pack disc space and insert second cage

Required instruments

- Cancellous Bone Funnel, Ø 8.0 mm, length 220 mm – 394.562
- Cancellous Bone Pusher Ø 8.0 mm, for no. 394.562 – 394.572
- Cancellous Bone Impactor – 394.579
- Plivos Revolution Implant Holder – 381.103

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 optimal 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 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 posterolateral fusion if necessary.

Notes and warnings

The trial implants are not intended for implantation and must be removed before insertion of the Plivios Revolution Cages.

Protect the nerve roots and dura with a nerve root retractor whenever possible.


