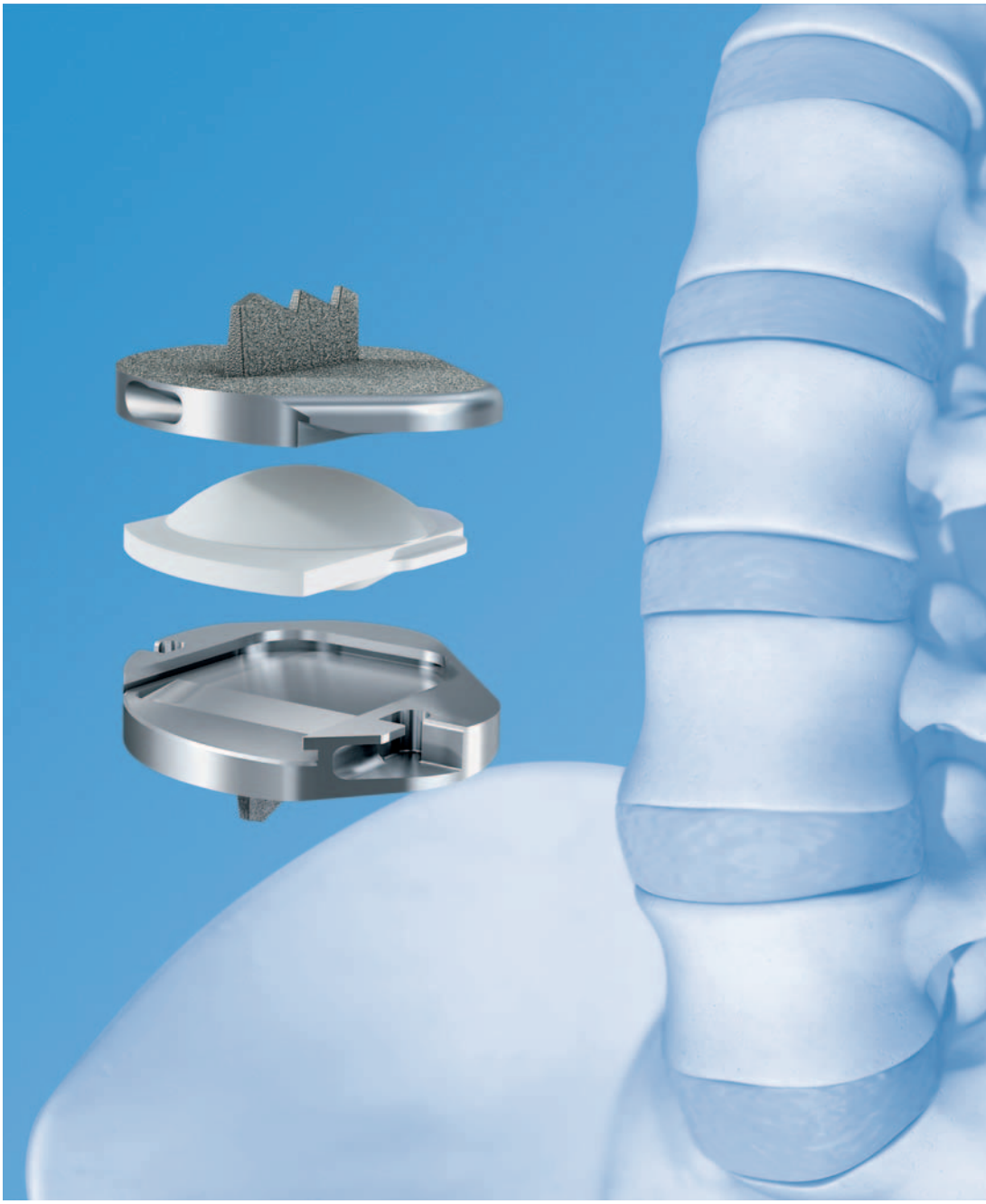
pro**disc O.** Modular disc prosthesis for anterolateral approach.

Technique Guide



CENTINEL SPINE®

Image intensifier control

Warning
This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling these products is mandatory.

Note
Attending training is mandatory. Please contact your local Synthes representative for further information.

Processing, Reprocessing, Care and Maintenance of Centinel Spine Instruments
For general guidelines, function control and dismantling of multi-part instruments, please contact your local sales representative or refer to:
www.centinelspine.com/prodisc_reprocessing.html

For general information about reprocessing, care and maintenance of these devices, instrument trays and cases, please consult included instructions or refer to:
www.centinelspine.com/prodisc_reprocessing.html

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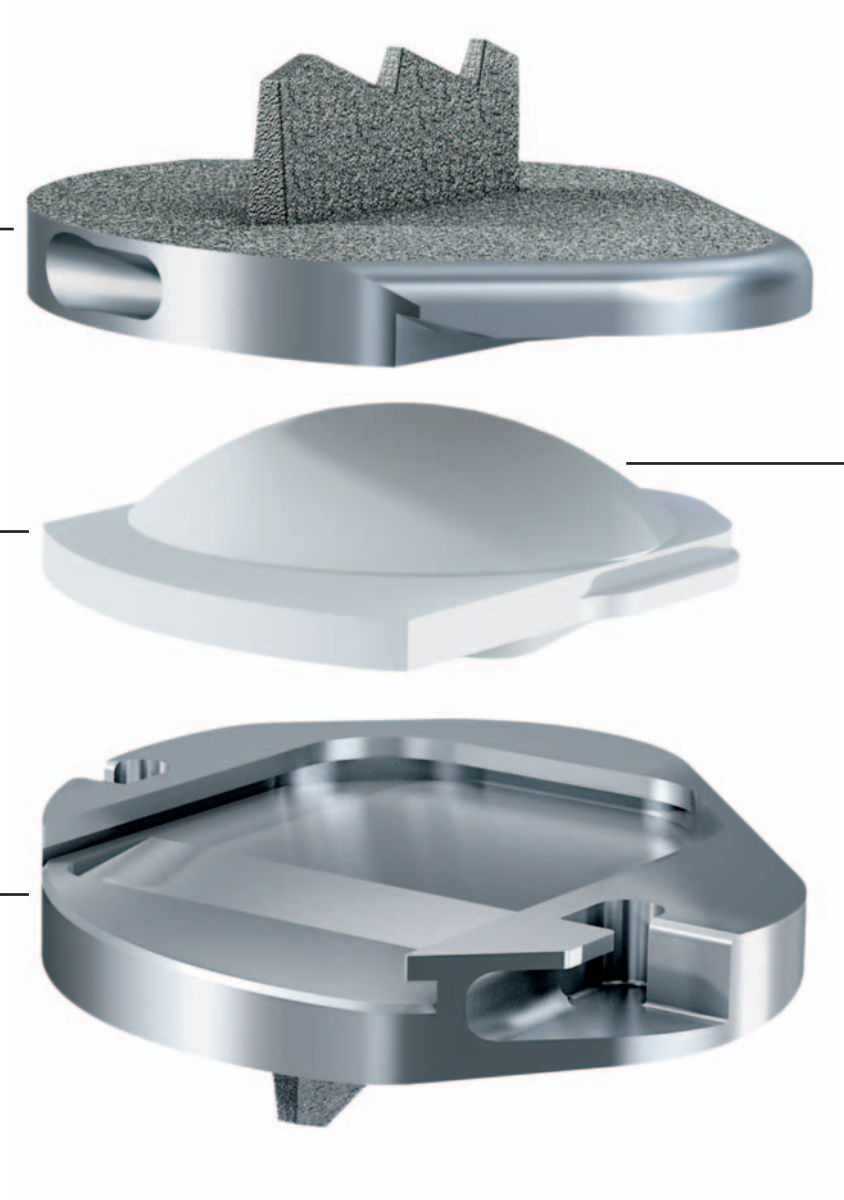
pro**disc O.** Modular disc prosthesis
for anterolateral approach.

Proven design

Modular design for individual implant assembly



Superior plate with obliquely positioned keel
- Keel specially developed for anterolateral approach
- Optimum lordosis adjustment of 3° or 6° angle

PE inlay
- Articulates with the superior plate
- Determines the implant height (10, 12 or 14 mm)

Inferior plate with obliquely positioned keel
- Acts as a foundation for the PE inlay
- Secure locking of the inlay by a snap mechanism
- Optimum lordosis adjustment of 0° or 3° angle

Minimally invasive anterolateral approach

Ball and socket principle
- Preserves mobility of the functional spinal unit
- Preserves the physiological range of motion
- Reduces the segmental shearing forces

Reliable, tested materials
- Cobalt–chromium–molybdenum (CoCrMo) implant plates
- C.P. Titanium plasma spray coating allows for osteointegration and provides high frictional resistance
- Insert consists of ultra-high-molecular weight polyethylene (UHMWPE) and has a tantalum marker for visualization.

Minimal invasive access
- Less mobilization of major vessels and the hypogastric plexus
- Potentially reduced risk of arterial thromboembolism

Surgical technique
- High precision in positioning prosthesis with specially developed instruments
- Modular prosthesis structure for a friction-less positioning

Good primary and secondary stability
- Central keel for implant anchorage in the bone
- Rough Titanium surface coating potentially allows for osteointegration and high resistance to friction

Indications and Contraindications

Intended use
pro**disc O** implants are used to replace lumbar inter-vertebral discs and to restore disc height and segmental motion at vertebral levels L1 to L5. They are inserted by using the antero-lateral approach.

Indications
Lumbar discopathy for levels L1 to L5, for which patient's anatomy allows the antero-lateral approach.[1]

Contraindications
- Vertebral level L5/S1
- Any circumstances preventing antero-lateral access to the spinal column (including extensive abdominal and/or retroperitoneal surgery from the left)
- Compromised vertebral bodies at affected level due to current or past trauma (fractures)
- Substantial loss of disc height, where applied segmental distraction may lead to damage of the great vessels
- Isolated radicular compression syndromes, especially due to disc herniation
- Bony lumbar spinal stenosis
- Spondylolysthesis/Retrolisthesis
- Pars defect
- Complete laminectomy
- Osteoporosis and osteopenia[2]
- Active systemic infection or infection localized to the site of implantation
- Allergy or sensitivity to implant materials (foreign body sensitivity to the implant materials)
- Adipositas
- Pregnancy
- Involved vertebral endplate dimensionally smaller than the minimum implant footprint size in both the medial-lateral and the anteriorposterior directions
- Severe abnormality of the endplate (e.g. large Schmorl nodes)
- Facet joint disease or degeneration

[1] The accessibility of the disc segment L1/L2 depends on the patient's individual anatomy
[2] Bone density T index <-1 SD, according to DXA/DEXA, dual-X-ray apsorptiometry

– Systemic and/or metabolic diseases
– Back or leg pain of unknown etiology
– Active malignancy (e.g. tumors)
– Acute or chronic infections (systemic and/or local)
– Dependency on pharmaceutical drugs or drug abuse, or alcoholism
– Predominant psychosocial factors/illnesses
– Foraminal or lateral spinal canal stenosis
– Lack of patient compliance
– Any cases not listed in the indications

Patient exclusion recommendations

Patient selection is one of the most important factors contributing to the outcome of the total disc replacement procedure. The following may affect clinical outcomes:

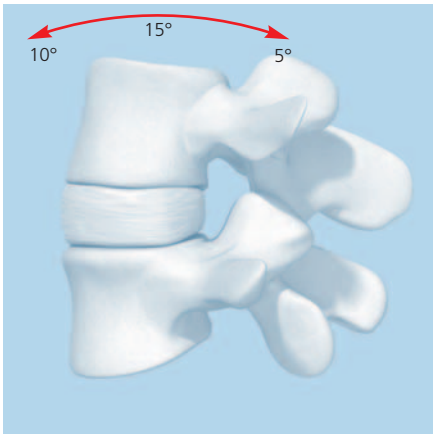
– A condition of senility or mental illness, alcoholism or smoking
– Dependency on pharmaceutical drugs or drug abuse
– The patient's occupation or activity level
– Compromised vertebral bodies at affected level due to current or past trauma (fractures)
– Substantial loss of disc height, where applied segmental distraction may lead to damage of the great vessels
– Involved vertebral endplate dimensionally smaller than the minimum implant footprint size in both the medial-lateral and the anterior-posterior directions
– Severe abnormality of the endplate (e.g. large Schmorl nodes)

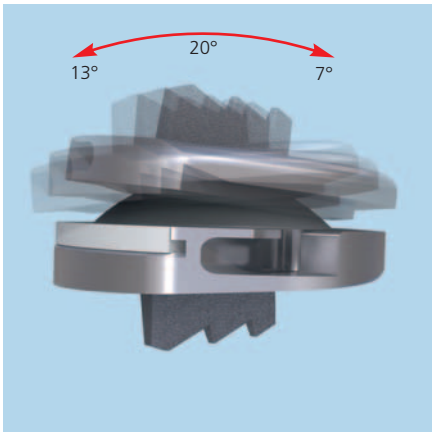
Kinematics

The kinematics of the prodisc O prosthesis correspond to the physiological movement profile within the disc joints:[3]

The rotational center is only just below the superior end-plate of the affected caudal vertebral body. The location of the center of rotation and the flexion radius correspond to the natural joint guidance in the vertebral joints. This allows the physiological range of motion in terms of the flexion/extension and the lateral inclination to be fully restored. The axial rotation is limited only by the anatomical structures and not by the prosthesis. Pure translatory movements in connection with the implant are not possible due to the ball and socket principle.

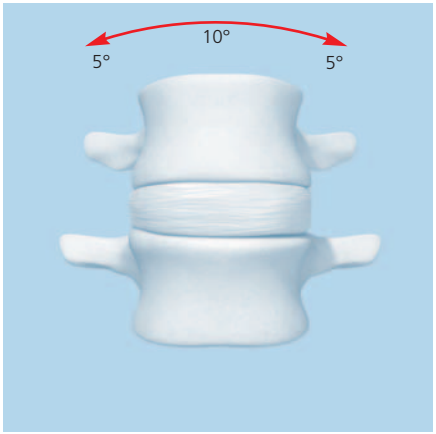
Flexion/extension

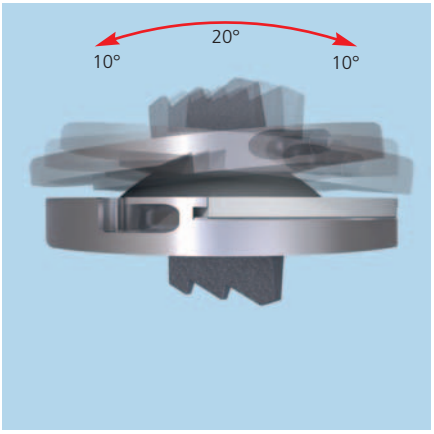




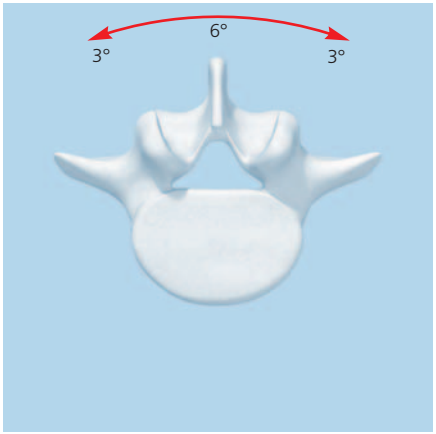
[3] See White, Panjabi 1990; Pearcy, Portek, Shepherd 1984; Pearcy, Tibrewal 1984; Dvorak et al 1991

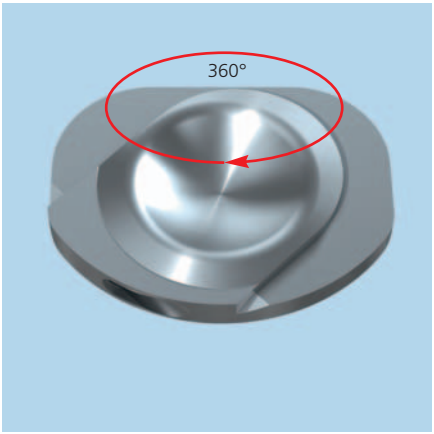
Lateral bending





Axial rotation





Five Rules for Successful Insertion

1a. Do not use if the segmental distraction is insufficient or can damage the anatomical structures due to substantial loss of disc height.

1b. Careful symmetrical mobilization of the affected segment is essential.

2. Never use prodisc O implants where bone density is T<–1.[4]

3. The inferior and superior plate of the implant have to be positioned in parallel and have to line up directly. The distance of the implant to the posterior edge of the disc should be 1–1.5 mm.

4. The central positioning of the implant plates from an anterior to posterior view is crucial to ensure proper function of the prosthesis.

5. After inserting the PE inlay always ensure that it is locked in position.

[4] Bone density T index <-1 SD, according to DXA/DEXA, dual-X-ray apsorptiometry

Preoperative Planning

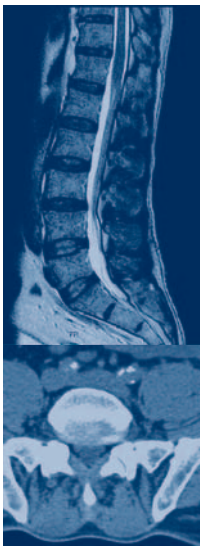
A detailed and correct assessment of the indication is the key for successful results in arthroplasty.

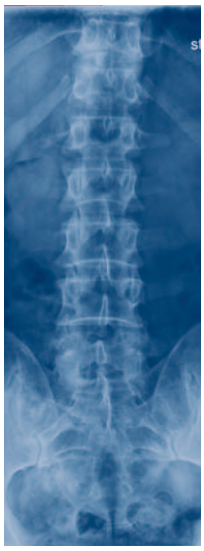
If conservative treatment methods have failed to yield positive results, a diagnosis can be made on the basis of the indication profile as to whether the use of an artificial disc could be a promising option for the patient in question.

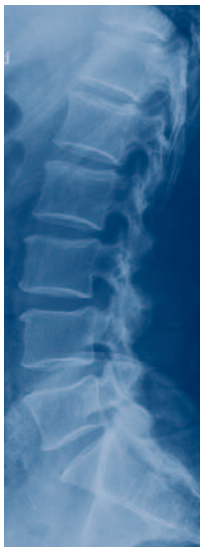
Basic diagnosis
- X-ray, anterior/posterior (AP) and lateral
- X-ray, flexion/extension and lateral inclination (patient standing)
- Magnetic resonance imaging (MRI)

Further diagnostics
Non-invasive:
- Computer tomography (CT)
- Three-dimensional CT angiography
- Bone densitometry (T-score not less than -1)

Invasive:
- Discography
- Facet blocks (radiologically confirmed, intra-articular facet joint infiltration)
- Nerve root blocks (radiologically confirmed radicular infiltration)
- Iliosacral joint block (intra-articular infiltration of the iliosacral joint)


MRI/CT


Preoperative, AP


Preoperative, lateral

X-ray templates

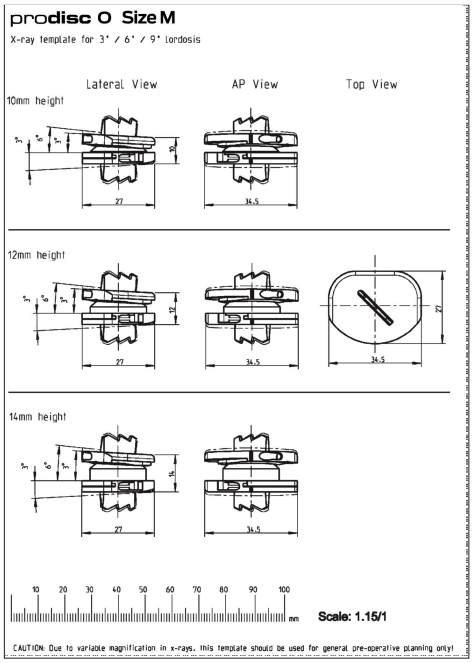
X000053	X-ray Template for prodisc O, size M
X000054	X-ray Template for prodisc O, size L

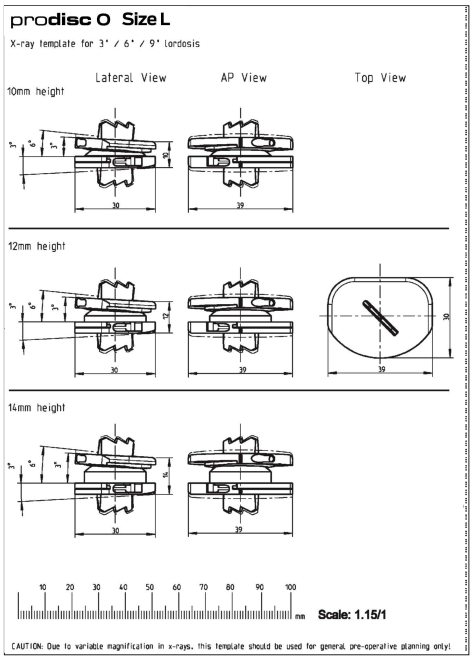
The X-ray templates are used to plan the position, footprint, height and lordosis angle of the prosthesis to be used.

This generally requires X-rays to be taken in two planes, AP and lateral. The height is assessed on the basis of the AP image on the healthy lumbar segment. The depth and the lordosis angle can be determined on the basis of the lateral images.

To make it easier to select the most suitable implant, all heights and possible lordosis angles should be separately listed on the X-ray template.

If CT images are available, the footprint can also be selected by sagittal images. The axes shown on the template show the center of the prosthesis where the center of rotation for the implant is found.





Patient Positioning

The correct patient positioning is essential for carrying out surgery.

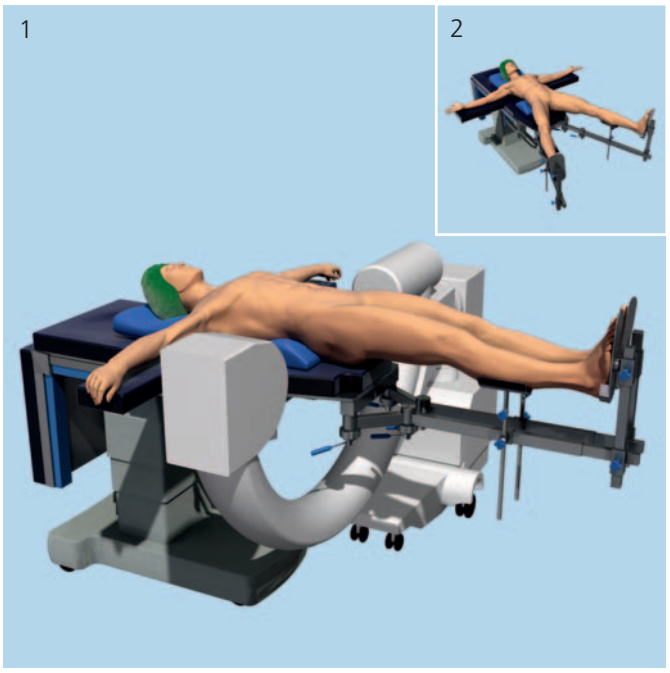
The patient should lay on an adjustable and radiolucent operating table that allows the orthograde use of a C-arm in an anteroposterior and mediolateral plane.

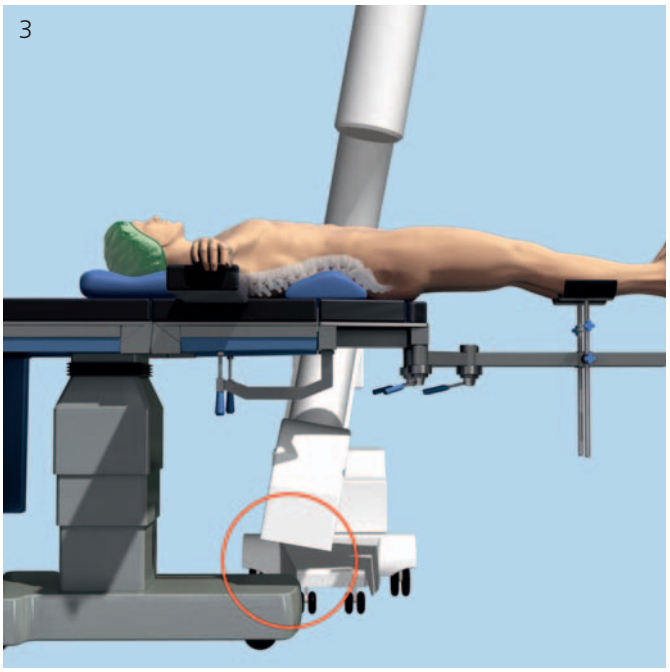
Generally a neutral standard position is recommended in which the legs are parallel and extended and the arms are extended at right angles. (1)

For combined surgery in the L4/L5 segment and L5/S1 segment the "Da Vinci position" is recommended. (2)

It is also important to ensure that the patient is positioned far towards the foot end of the table, to allow an orthograde projection of each segment with the C-arm. (3)

The pulse oximeter should be fitted to the upper extremity because of the risk of compromising the vessels on the left big toe.





Notes:

- In order to minimize the risk of atraumatic periprostheic vertebral fractures, surgeons must consider all co-morbidities, past and present medications, previous treatments, etc. Upon reviewing all relevant information the surgeon must determine whether a bone density scan is prudent. A screening questionnaire, SCORE (Simple Calculated Osteoporosis Risk Estimation) may be used to screen patients if a DEXA is performed, exclusion from receiving the device should be considered if the DEXA bone density measured T-score is <-1.0 as this patient may be osteoporotic.
- The prodisc O implants are not designed to be used with bone cement.

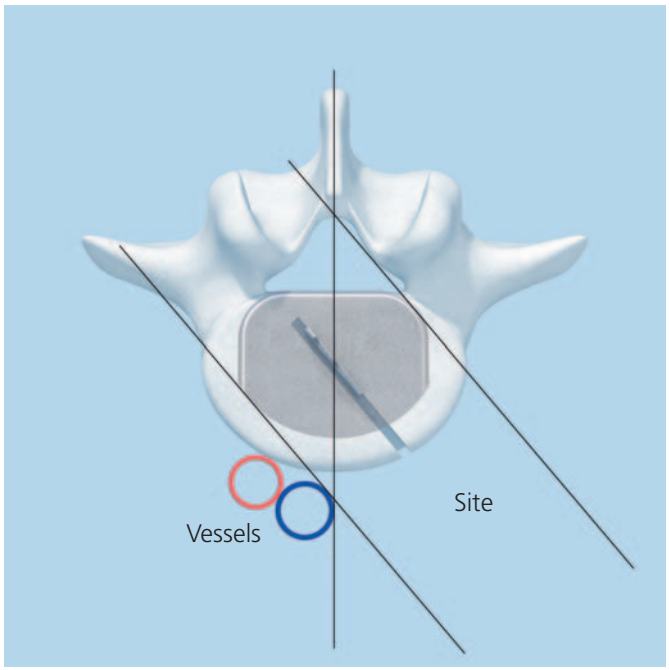
Approach

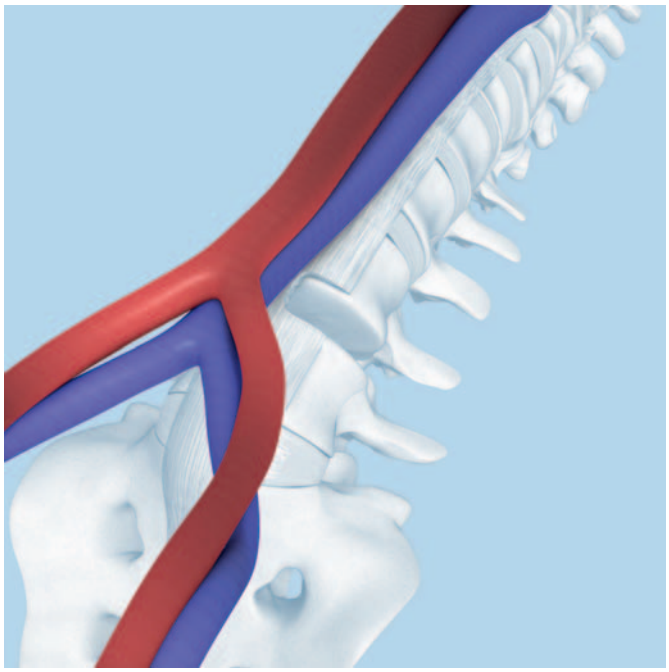
Recommended systems

187.310	SynFrame Basic System in Vario Case
01.609.102	Set SynFrame RL, lumbar

Make an anterolateral incision on the left at the level of the endplate projection of the disc segment to be treated. Use a retroperitoneal approach to the disc segment. If necessary, ligate the V. lumbalis ascendens or the intersegmental vessels.

Mobilize the major vessels to the midline. Secure the site using the appropriate device.





Notes

- The SynFrame retraction system is recommended to ensure the secure preparation of the operative field.
- In view of the minimally invasive surgical technique, suitable illumination of the surgical field by a headlamp or operating microscope is recommended.
- The major vessels should be sufficiently mobilized to avoid the risk of damaging the vessels when the implant is inserted.

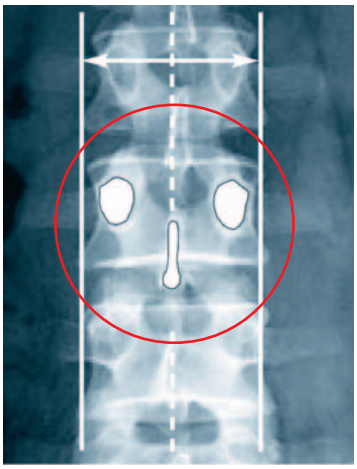
Endplate Preparation and Segment Mobilization

1

Mark the midline

Exact determination of the midline is required to ensure precise positioning of prodisc O in the intervertebral disc space. This must be exactly in the midline between the two pedicle projections ("face of an owl"). Both pedicles should be shown equally large and should be the same distance from the lateral disc outline.

Mark the midline with a permanent marking (e.g. with a chisel).



Note: Marks made by mono/bipolar coagulation are often no longer visible after a discectomy. In addition, monopolar coagulation can lead to permanent damage to the hypogastric plexus.

2
Discectomy and endplate preparation

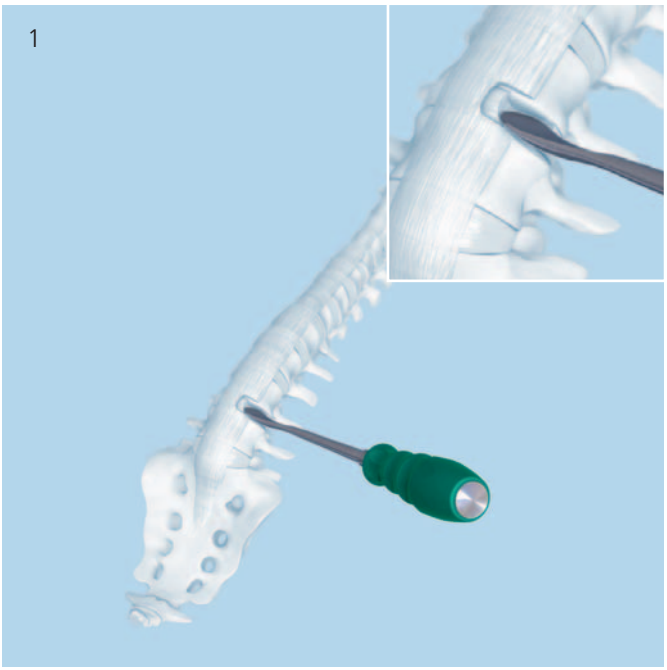
Recommended instruments	
01.600.100	Proprep Set
SFW580R	prodisc L Elevator

Complete removal of the intervertebral disc tissue, particularly the posterolateral area of the disc space, so as to expose the PLL is important for the successful outcome of the operation. (1)

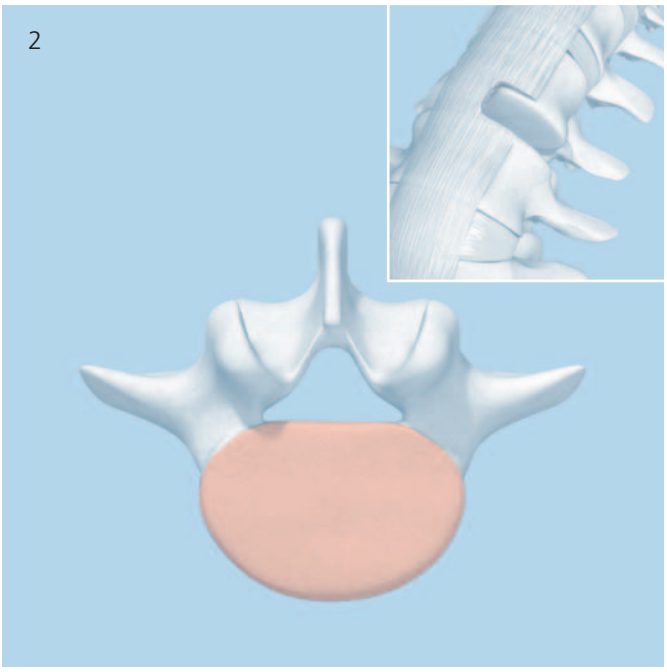
Completely remove the cartilaginous endplates to clearly expose the bony endplates (2). To minimize the risk of implant subsidence, ensure that the bony endplates remain fully intact during this process.

Notes
- Modification of the bony endplates is rarely needed in order to ensure correct seating of the implant. Areas that are not in contact with bone at the time of implantation are usually no longer detectable after 3 to 6 months thanks to bone remodeling.
- Ensure that a complete discectomy is performed and the integrity of the bony end plates is preserved to provide a firm base for mechanical stability and to reduce the potential for device subsidence.

1



2



3
Mobilize segment

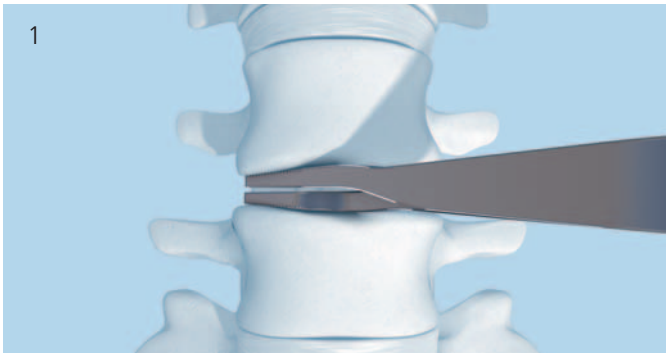
Instruments	
SFW550R	prodisc L Spreader (straight)
SFW650R	prodisc L Spreader Forceps, curved

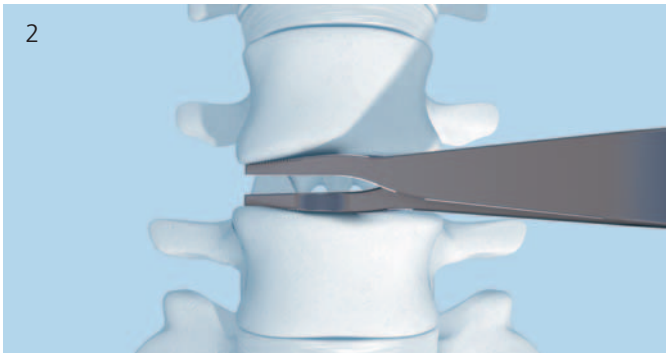
Sufficient mobilization that is equal on all sides is the key to successful implant seating and its later functionality.

Note: Unlike the fusion procedure the process to achieve full segment mobility is considerably more complex.

To check for adequate mobility, completely insert the spreader forceps/spreader down to the posterior part of the disc space (1) under lateral image intensifier control and perform parallel distraction of the segment (2).

Note: A substantial loss in disc height can result in over stretching or injuring adjacent anatomic structures.





Implant Insertion

1
Select and assemble trial implant

Instruments	
03.821.101	Handle for Trial Implants
03.821.021–029	Trial Implants, size M
03.821.041–049	Trial Implants, size L
03.821.139	Centering Device
314.270	Hex Screwdriver, large, ∅ 3.5 mm, with groove, length 240 mm
Optional	
03.821.011–019	Trial Implants, size M, narrow
03.821.021–039	Trial Implants, size L, narrow

The following are determined with the trial implant:
– Lordosis angle
– Height
– Footprint size
– Keel chisels
– Implant position

The correct choice and positioning is essential for the success of the procedure.

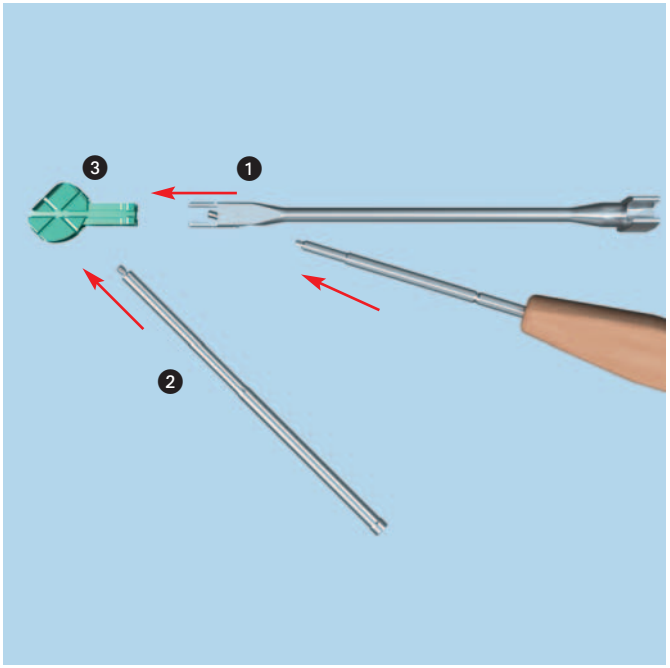
Rules for selecting the appropriate trial implant:
– Largest possible endplate cover
– Smallest possible height
– Restoration of the natural lordosis angle

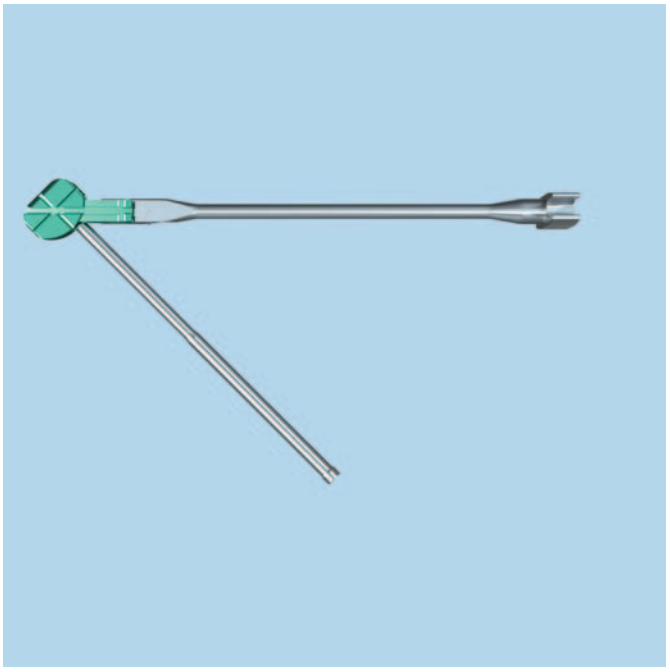
The x-ray images and the x-ray templates can give a guide as to the correct trial implant. 18 trial implants are available.

The trial implants are color-coded and list the height (see item list on page 33):
height 10 mm: green
height 12 mm: blue
height 14 mm: bronze (optional)

Screw the handle ❶ and the centering device ❷ to the appropriate trial implant ❸.

Note: If using the optional narrow trial implants, ensure that despite the smaller dimensions (compared to the final implant) there is sufficient space to use the later implant.





2
Position trial implant

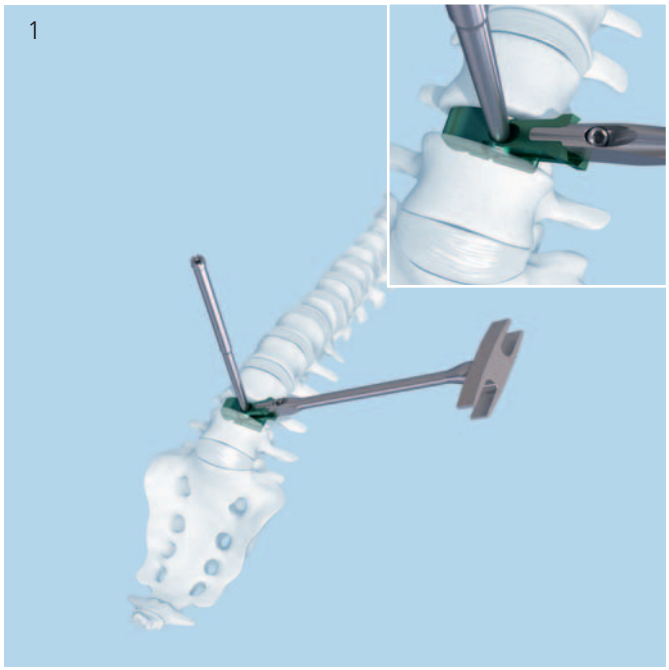
Instruments	
03.821.133/134	Fixation Post, length 200 mm / 250 mm
03.821.138	Socket Wrench ∅ 6 mm with Cardan Joint
Optional	
03.821.132	Tappet

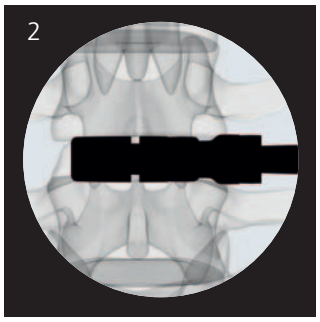
Align the trial implant in the anteroposterior x-ray plane at the midline. (1)

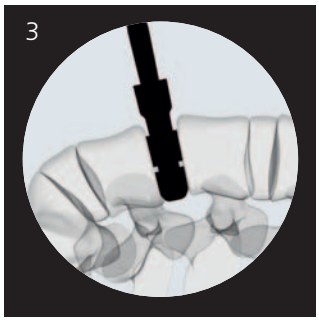
Align the trial implant in an orthograde medial position with the aid of the radiolucent, rectangular cut-outs. The cut-outs must be clearly visible in full size in an x-ray image set in an orthograde position. (2)

Set the trial implant under lateral x-ray control so that the posterior edge of the trial implant is approximately 1–1.5 mm from the posterior edge of the disc space. The lateral, radiolucent, rectangular cut-outs must be clearly visible in full size in an x-ray image set in a lateral position. (3)

Check the final position in both planes. Both radiolucent, rectangular cut-outs in the orthograde AP image and in the lateral x-ray must be clearly visible. If one or more attempts are required to reposition the trial implant until the optimum position is found, an x-ray should be taken in both planes after each correction.

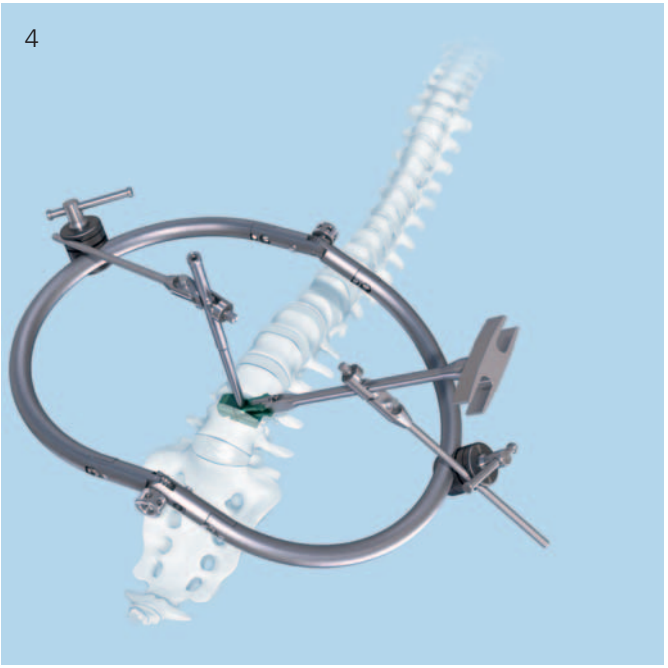






Secure the handle and the centering device to the retraction system with the fixation posts and then tighten (4). When tightening ensure that the position of the trial implant is not in any way changed and that the chisel can later by inserted into the trial implant.

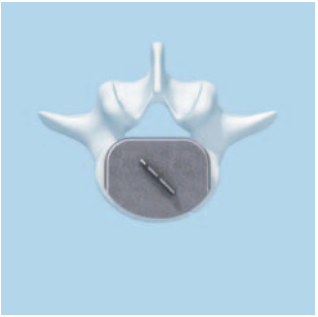
4

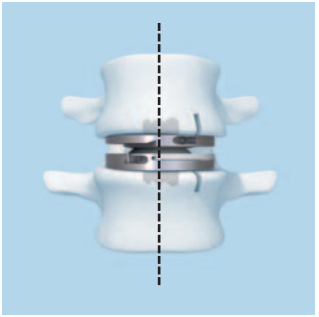


Notes

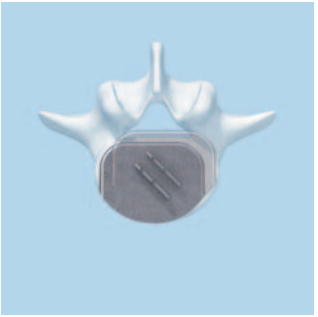
– Do not use the trial implant to mobilize the segment.
– Prepare the keel slots only after the trial implant has been correctly seated in an orthograde position. Positioning in the correct axial alignment and secure fixation of the trial implant to the SynFrame are key factors for the subsequent implant positioning.

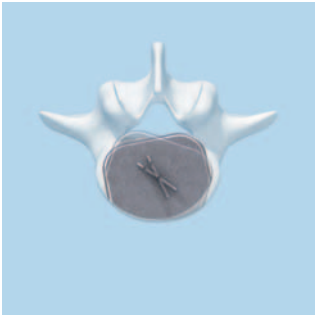
Correct positioning





Possible errors and effects





3
Prepare keel slots

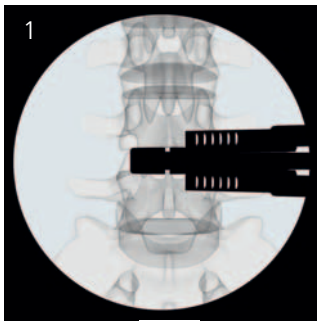
Instruments	
03.821.135	Chisel
03.821.105	Slide Hammer, with Connector, long
SFW691R	Combined Hammer

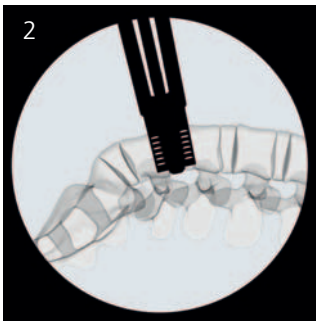
Insert the first chisel caudally over the trial implant handle. Push the chisel blade forwards on the shaft of the trial implant handle, thread into the trial implant guide and use the hammer to tap it in about one third of the way.

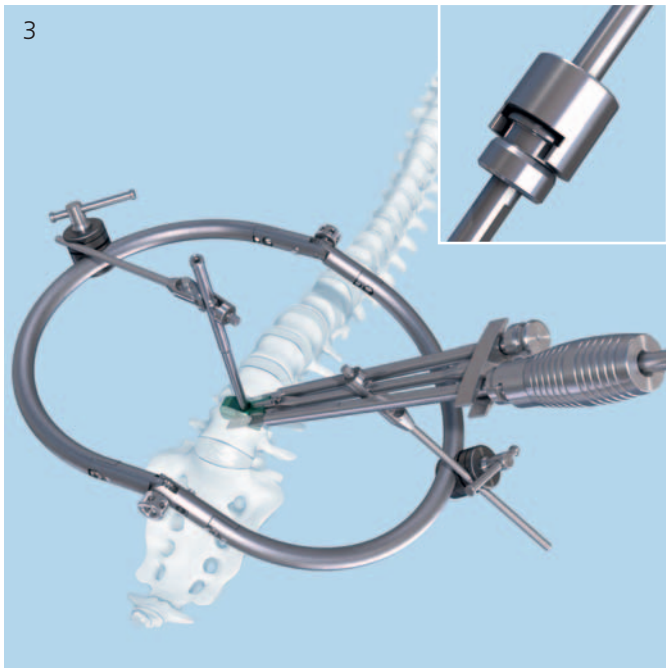
Cranially insert the second chisel in the same way as the first and also hammer in one third of the way (1). Then hammer in each chisel alternately to the stop position under x-ray control (2).

Finally hammer out both chisels with the slap hammer. (3)

Notes
- The chisel may only be used with the inserted trial implant.
- The required keel slots may only be made with the appropriate chisel.
- Always insert the chisel under x-ray control.
- Do not use damaged and/or blunt chisels.







4
Insert strut

Instruments	
03.821.121–129	Struts, angled
03.821.138	Socket Wrench ∅ 6 mm with Cardan Joint
SFW520	pro**disc L** Handle for Strut
Optional	
03.821.111–119	Struts, straight

Struts are used in order to prevent the segment from collapsing when the trial implant is removed.

Unscrew the centering device and fit an angled strut to the medial side of the trial implant. (1)

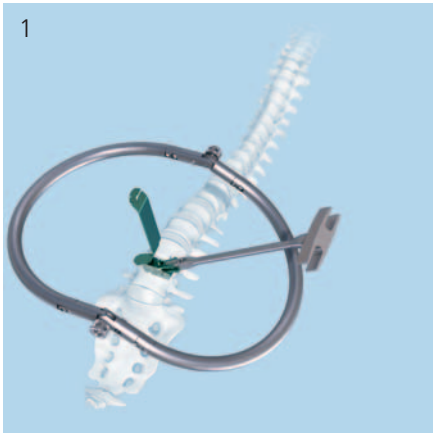
A straight strut can be placed laterally as a further optional aid. Adjust the straight strut according to the height of the disc and the depth of the surgical field. (2)

Secure the strut to the SynFrame using the handle for strut and remove the trial implant. (3)

Caution: Always position the strut first and then remove the trial implant to avoid collapsing of the motion segment.

Caution: Heterotopic ossification (HO) is a possible cause for fusion of the treated segment. Copious saline lavage is recommended to remove osteogenic stimuli (blood/bone marrow). HO might be reduced when bone wax is used to close cavities in the bone (screw holes) and open bone surfaces after removal of anterior osteophytes[1].

1



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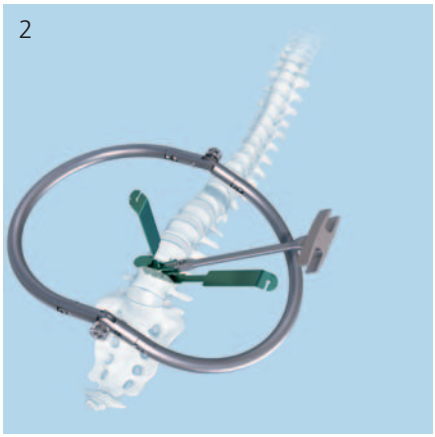

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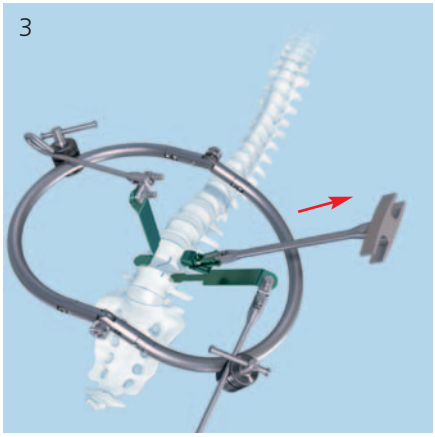


[1] See Barbagallo 2014

5
Assemble the inserter

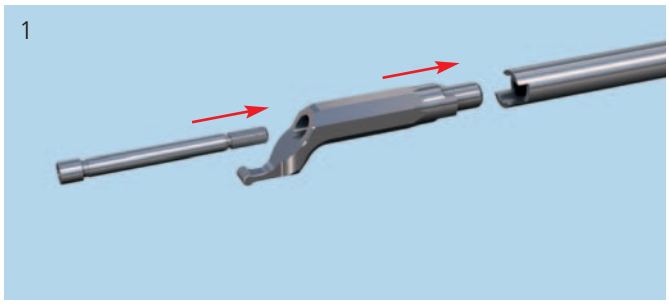
Instruments	
03.821.143	Inserter, size M
03.821.145	Inserter, size L
314.270	Hex screwdriver, large, ∅ 3.5 mm, with groove, length 240 mm

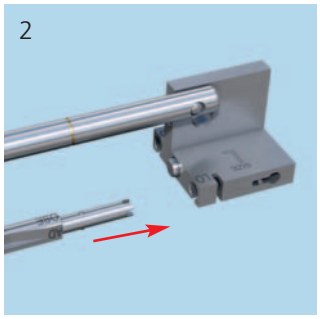
The inserters are available for implant sizes M and L.
The arms can be removed.

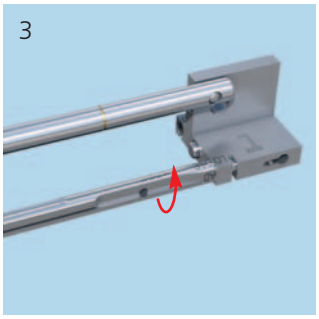
Screw on the superior plate holders
Screw the holder mechanisms of the superior plate to the superior arm of the inserter with the appropriate screw and the hex screwdriver. (1)

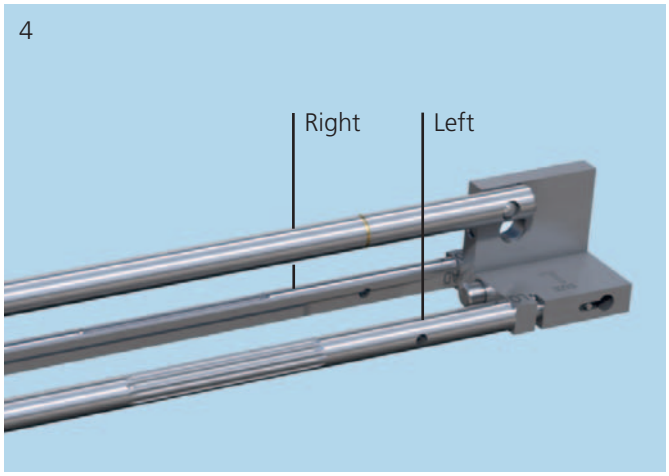
Assemble the inferior arms to the holder block
Secure the arm labelled "LEFT" to the left part of the holder block by pressing the locking mechanism on the holder block (2), inserting the arm in the position "LOOSE" and then turning inwards by 90° to the "LOAD" position (3).

Proceed in the same way with the arm labelled "RIGHT" to fit it to the right half of the holder block. (4)





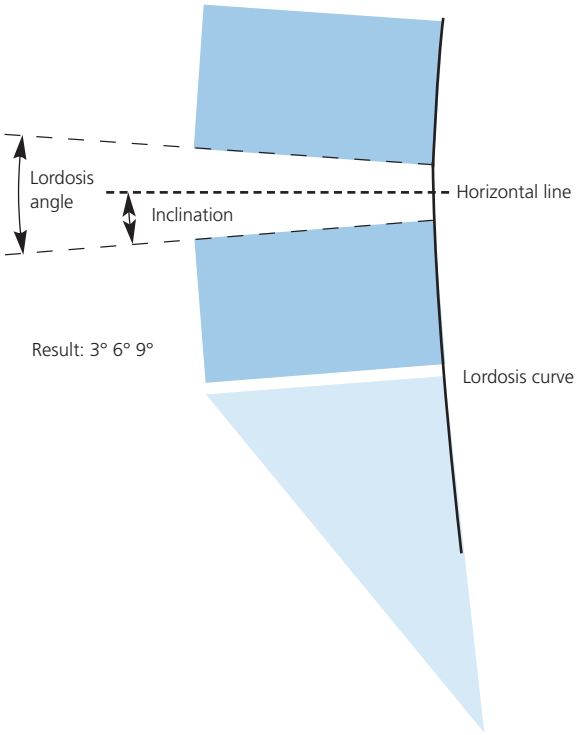




6
Select implant size

Selecting the implant combinations
- Take the size of the footprint from the trial implant.
- Check the height on the trial implant and use a PE-inlay that is the same height and size.
- Check the lordosis angle on the trial implant. The angle can be divided between the superior and inferior plates.
  - Where there is an inclination of over 3°, use an inferior plate with 3° angle and fill the necessary lordosis angle with the superior plate.
  - Where there is an inclination of less than 3°, use an inferior plate with 0° angle and represent the necessary lordosis angle with the superior plate.

Caution: Size M and L for the implant components may never be combined.



Lordosis angle: Angle between caudal endplate of superior segment and cranial endplate of inferior segment
Inclination: Angle between horizontal line and cranial endplate of inferior segment

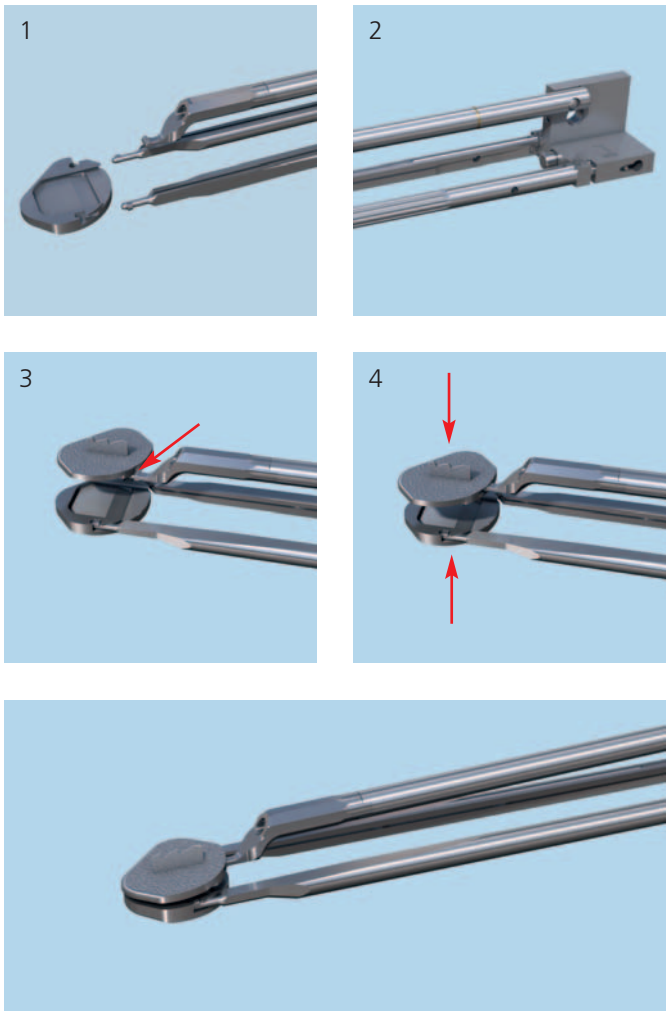
7
Fit the implant plates

Caution: Always check all components to ensure they are not damaged before assembling the implant components.

Fit the inferior implant plate to the inserter (1) and turn both arms inwards by 90°. This secures the plate in the "LOCK" position (2).

Place the superior plate sideways on the cylinder shaped end of the superior arm (3). The keel must always be in the axis of the upper arm, i.e. should form a line. This makes it easier to fit the implant.

Caution: After fitting the implant components to the inserter always hold the inserter so that the inferior and superior plate firmly interlock (4).



8
Secure and insert implant

Instruments	
03.821.142	Guiding Device for Inserter, size M
03.821.144	Guiding Device for Inserter, size L
03.821.143	Inserter, size M
03.821.145	Inserter, size L

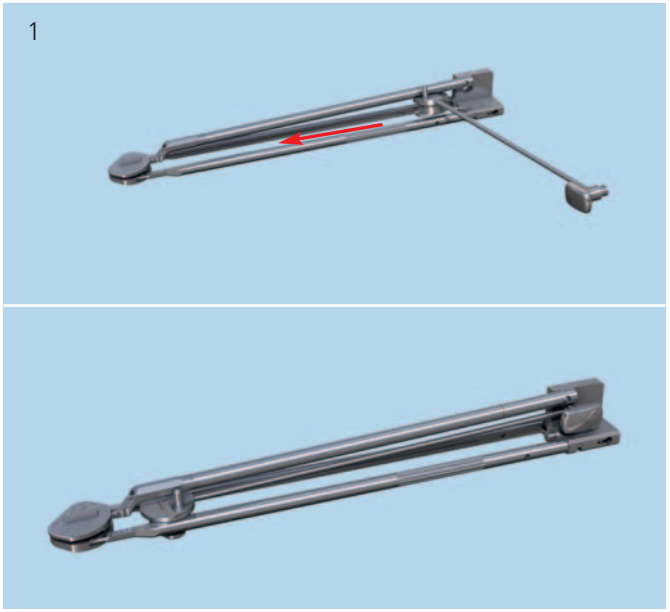
Before inserting the implant secure the superior plate with the guiding device. This prevents the superior arm from loosening as a result of tissue pressure on the upper implant plate.

Position the guide between the arms of the inserter and push towards the implant. Secure the handle of the guiding device in the hole at the back part of the inserter. (1)

Insert the inferior and superior plate in the bone keel slots (2). Use a hammer to insert the implant plates under image intensifier control into their final position within the disc space.

Remove the guiding device from the inserter. Remove the struts.

1



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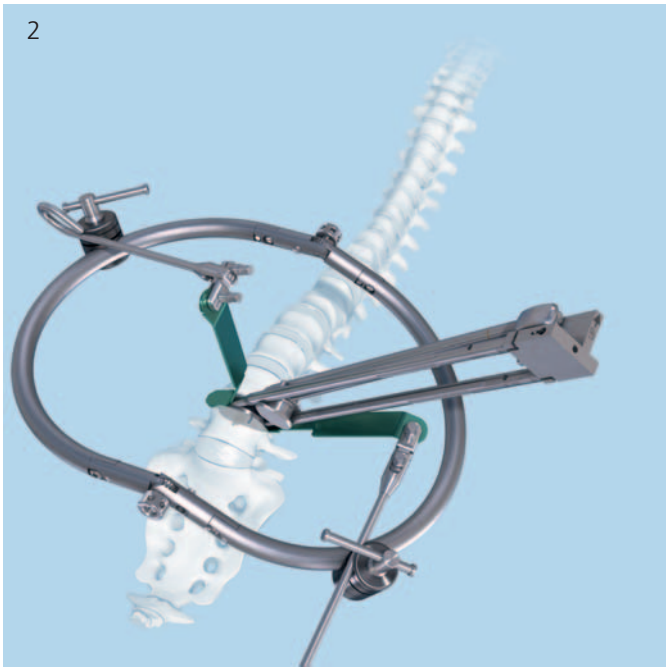


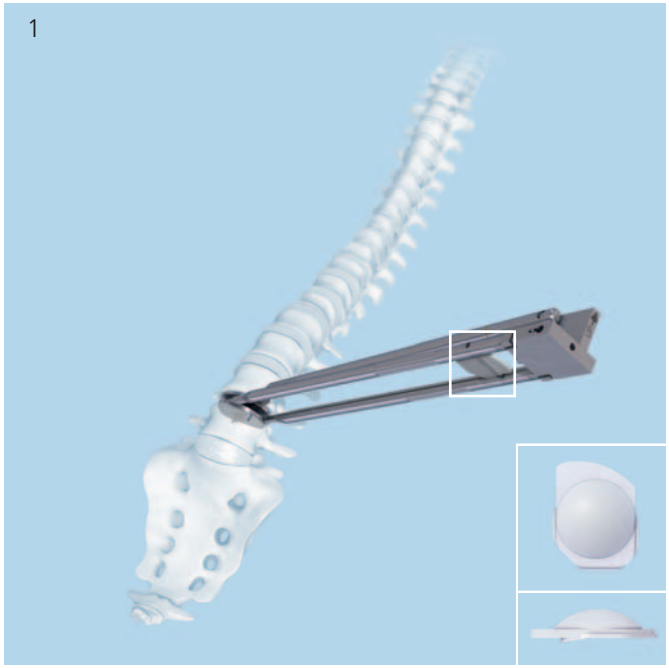
9

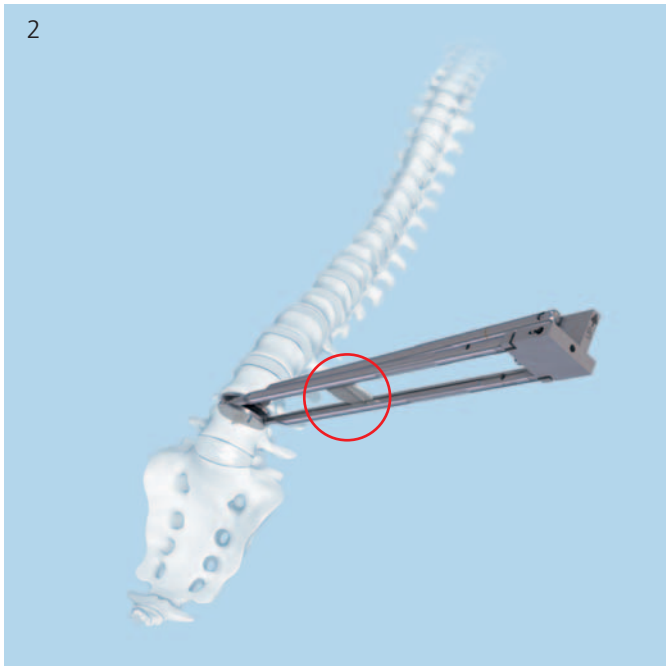
Insert PE inlay into instrument

Lay the PE inlay as shown on the instrument ("dome up") in the slot of the inserter. (1)

Insert the PE inlay to the first stop. (2)

Note: Insert the PE-inlay with the fingers only up to the first stop. Always use the distractor to insert the inlay, otherwise it may become damaged.





10
Distract for inlay insertion

Instruments	
03.821.151	Distractor, size M, height 10 mm
03.821.154	Distractor, size L, height 10 mm
03.821.152	Distractor, size M, height 12 mm
03.821.155	Distractor, size L, height 12 mm
Optional	
03.821.153	Distractor, size M, height 14 mm
03.821.156	Distractor, size L, height 14 mm
SFW582R	Lever for Insertion Instruments

Select the appropriate distractor for the implant height and insert into the appropriate holder block with the hex screw for the wing nut. (1, 2)

Push the distractor over the guide tracks up to the PE inlay.

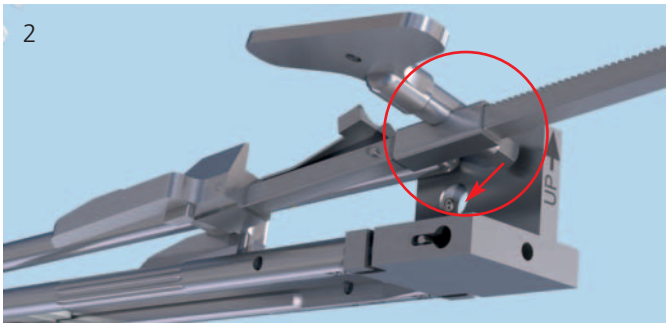
Turn the wing nut on the distractor all the way down to achieve full distraction. The inlay is automatically advanced by the distractor during this operation. (3)

If the forces exerted on the wing nut make it difficult to screw it in, the lever for insertion instruments can be used as an extended lever arm. Place the lever in the appropriate hole in the wing nut.

Note: If there is great resistance, the implant has to be removed again and the release, the mobilization and the height gain have to be improved. If the necessary height is not achieved, the resection of the anterior longitudinal ligament should be considered. The PE inlay used must be replaced by a new inlay.

1

2



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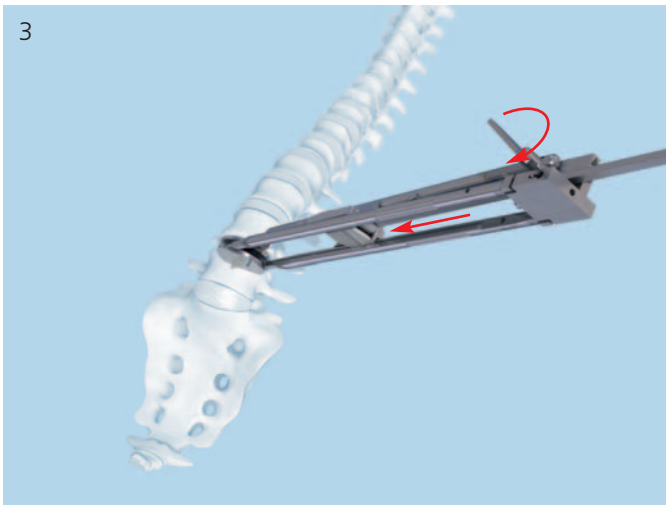


11
Lock PE inlay in position

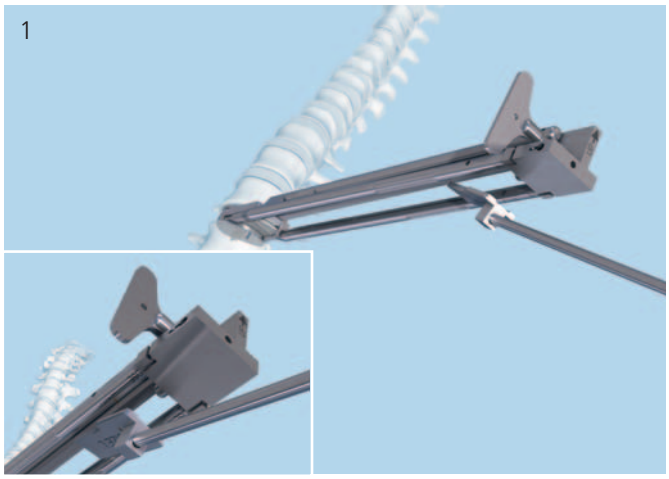
Instruments	
03.821.157	Inserter for PE Inlay, size M
03.821.158	Inserter for PE Inlay, size L

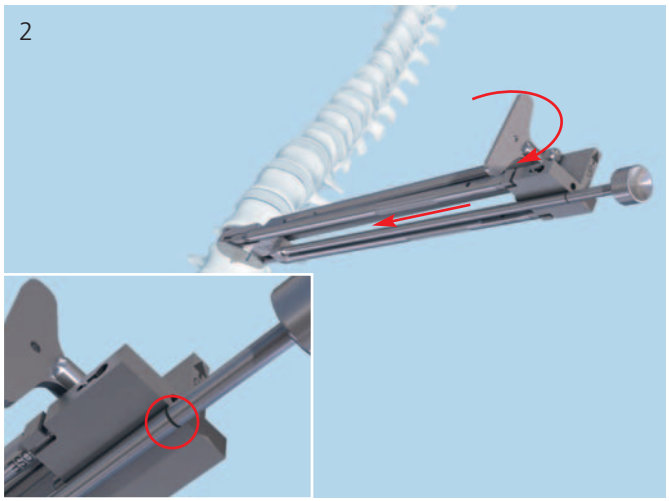
Advance the PE inlay between both implant plates with the inserter (1) until they snap into the inferior plate of the implant. This can be checked by means of a mark on the inserter (2).

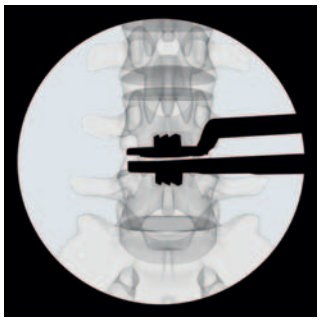
Finally remove the inserter for PE inlay.

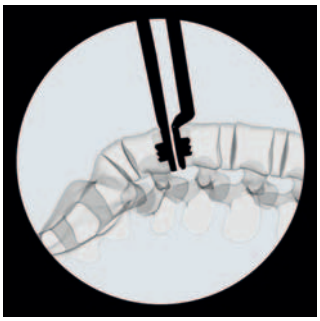
Caution: The inserter for PE inlay must never be advanced with the hammer, but must be slowly and carefully pushed in by hand.

After removing the inserter for PE inlay check that the PE inlay is securely locked. Then discontinue distraction and remove the distractor.



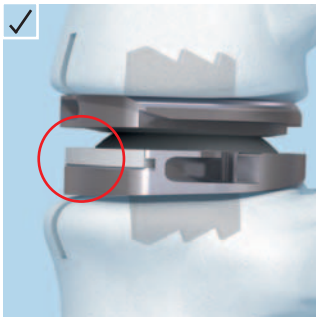


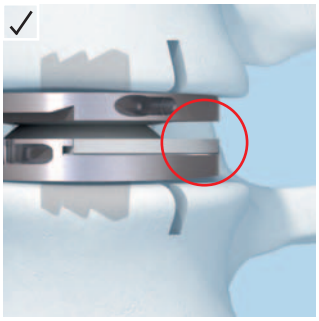




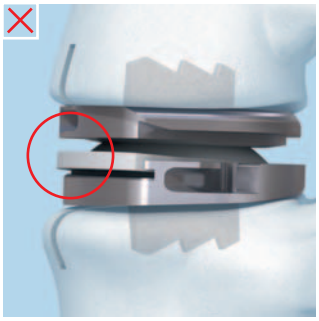
12
Inspection for correct implant positioning

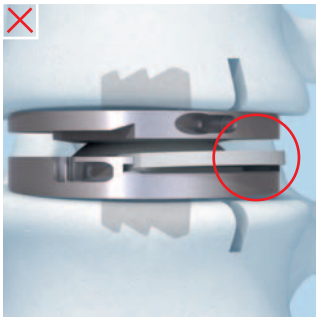
Correct
– PE inlay completely locked in position
– Prosthesis in neutral position





Possible errors in implant positioning
It is crucial to check visually and manually if the PE insert is securely locked into the inferior implant plate (“NO STEP, NO GAP”).





Caution: The actual position of the prosthesis can only be seen once the PE inlay is pushed in. The prosthesis should be in a neutral position after completing this step.

Flexion

Extension

Lateral bending

13
Remove inserter

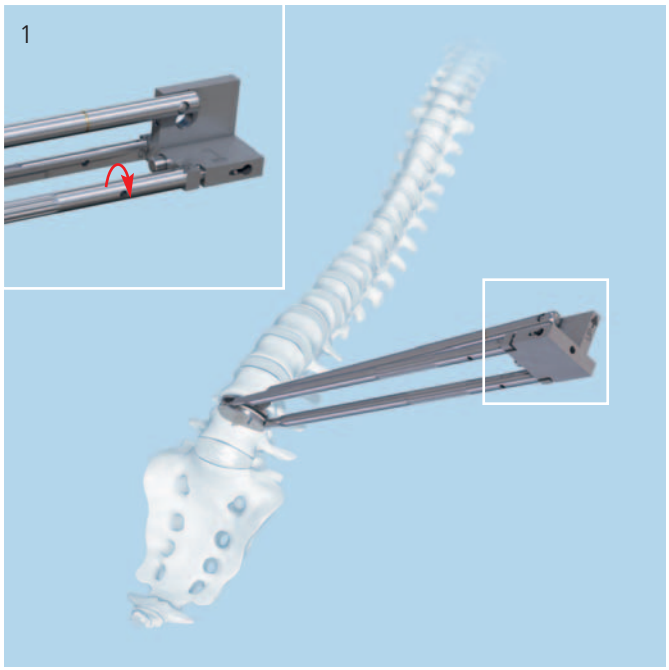
Instruments	
SFW582R	Lever for Insertion Instruments
SFW550R	prodisc L Spreader (straight)
03.821.105	Slide Hammer with Connector, long
03.821.136	Extraction Tool for Inserter

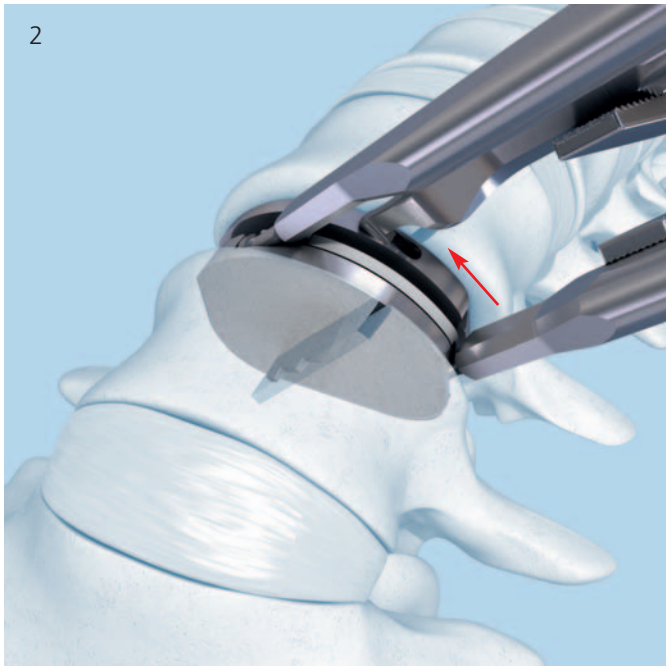
Before the inserter can be removed from the implant plates, check and record the final position of the implant in a lateral and AP plane using the image intensifier.

Unlock the inferior plate by rotating the lower arms outwards ("LOAD" position) (1). The use of a lever for insertion instruments can facilitate the rotation of the inserter arms, if necessary.

Press the upper arm medially and pull the inserter straight back.

The use of the spreader can facilitate loosening of the superior plate from the inserter. To do this, place the spreader between the superior arm and the inferior arms and then distract slightly. The counter-pressure releases the superior plate from the holder mechanism. (2)





Implants

Plates, sterile

09.821.023S	prodisc O Superior Plate, uncemented, size M, 3°
09.821.043S	prodisc O Superior Plate, uncemented, size L, 3°

09.821.026S	prodisc O Superior Plate, uncemented, size M, 6°
09.821.046S	prodisc O Superior Plate, uncemented, size L, 6°

09.821.120S	prodisc O Inferior Plate, uncemented, size M, 0°
09.821.140S	prodisc O Inferior Plate, uncemented, size L, 0°

09.821.123S	prodisc O Inferior Plate, uncemented, size M, 3°
09.821.143S	prodisc O Inferior Plate, uncemented, size L, 3°

Polyethylene inlays, sterile

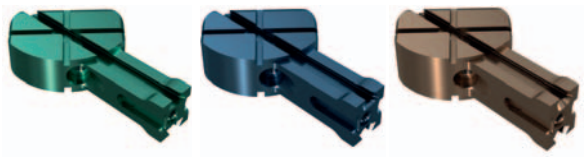
08.821.020S	prodisc O PE-Inlay with X-ray Marker, uncemented, size M, 10 mm
08.821.040S	prodisc O PE-Inlay with X-ray Marker, uncemented, size L, 10 mm

08.821.022S	prodisc O PE-Inlay with X-ray Marker, uncemented, size M, 12 mm
08.821.042S	prodisc O PE-Inlay with X-ray Marker, uncemented, size L, 12 mm

08.821.024S	prodisc O PE-Inlay with X-ray Marker, uncemented, size M, 14 mm
08.821.044S	prodisc O PE-Inlay with X-ray Marker, uncemented, size L, 14 mm

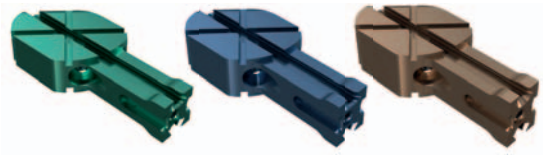
The trial implants and struts are color-coded:

For insertion of 10 mm implants: green
For insertion of 12 mm implants: blue
For insertion of 14 mm implants: bronze (optional)



Trial Implants

03.821.021	Trial Implant, size M, 3°, 10 mm
03.821.024	Trial Implant, size M, 6°, 10 mm
03.821.027	Trial Implant, size M, 9°, 10 mm
03.821.022	Trial Implant, size M, 3°, 12 mm
03.821.025	Trial Implant, size M, 6°, 12 mm
03.821.028	Trial Implant, size M, 9°, 12 mm
03.821.023	Trial Implant, size M, 3°, 14 mm
03.821.026	Trial Implant, size M, 6°, 14 mm
03.821.029	Trial Implant, size M, 9°, 14 mm
03.821.041	Trial Implant, size L, 3°, 10 mm
03.821.044	Trial Implant, size L, 6°, 10 mm
03.821.047	Trial Implant, size L, 9°, 10 mm
03.821.042	Trial Implant, size L, 3°, 12 mm
03.821.045	Trial Implant, size L, 6°, 12 mm
03.821.048	Trial Implant, size L, 9°, 12 mm
03.821.043	Trial Implant, size L, 3°, 14 mm
03.821.046	Trial Implant, size L, 6°, 14 mm
03.821.049	Trial Implant, size L, 9°, 14 mm

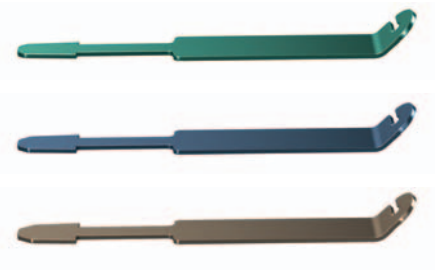


Optional

03.821.011	Trial Implant, size M, 3°, 10 mm, narrow
03.821.014	Trial Implant, size M, 6°, 10 mm, narrow
03.821.017	Trial Implant, size M, 9°, 10 mm, narrow
03.821.012	Trial Implant, size M, 3°, 12 mm, narrow
03.821.015	Trial Implant, size M, 6°, 12 mm, narrow
03.821.018	Trial Implant, size M, 9°, 12 mm, narrow
03.821.013	Trial Implant, size M, 3°, 14 mm, narrow
03.821.016	Trial Implant, size M, 6°, 14 mm, narrow
03.821.019	Trial Implant, size M, 9°, 14 mm, narrow
03.821.031	Trial Implant, size L, 3°, 10 mm, narrow
03.821.034	Trial Implant, size L, 6°, 10 mm, narrow
03.821.037	Trial Implant, size L, 9°, 10 mm, narrow
03.821.032	Trial Implant, size L, 3°, 12 mm, narrow
03.821.035	Trial Implant, size L, 6°, 12 mm, narrow
03.821.038	Trial Implant, size L, 9°, 12 mm, narrow
03.821.033	Trial Implant, size L, 3°, 14 mm, narrow
03.821.036	Trial Implant, size L, 6°, 14 mm, narrow
03.821.039	Trial Implant, size L, 9°, 14 mm, narrow

Struts

03.821.111	Strut, straight, height 10 mm, L1
03.821.114	Strut, straight, height 10 mm, L2
03.821.117	Strut, straight, height 10 mm, L3
03.821.112	Strut, straight, height 12 mm, L1
03.821.115	Strut, straight, height 12 mm, L2
03.821.118	Strut, straight, height 12 mm, L3
03.821.113	Strut, straight, height 14 mm, L1
03.821.116	Strut, straight, height 14 mm, L2
03.821.119	Strut, straight, height 14 mm, L3



03.821.121	Strut, angled, height 10 mm, L1
03.821.124	Strut, angled, height 10 mm, L2
03.821.127	Strut, angled, height 10 mm, L3
03.821.122	Strut, angled, height 12 mm, L1
03.821.125	Strut, angled, height 12 mm, L2
03.821.128	Strut, angled, height 12 mm, L3
03.821.123	Strut, angled, height 14 mm, L1
03.821.126	Strut, angled, height 14 mm, L2
03.821.129	Strut, angled, height 14 mm, L3

03.821.101	Handle for Trial Implants	
03.821.105	Slide Hammer with Connector, long	
03.821.132	Tappet	
03.821.133	Fixation Post, 200 mm	
03.821.134	Fixation Post, 250 mm	
03.821.135	Chisel	
03.821.138	Socket Wrench ∅ 6.0 mm with Cardan Joint	
03.821.139	Centering Device	
SFW520	Handle for Strut	
SFW550R	prodisc L Spreader	
SFW580R	prodisc L Elevator	
SFW582R	prodisc L Lever, for Insertion Instruments	
SFW650R	prodisc L Spreader Forceps, curved	

Insertion instruments and distractors are color-coded. Color coding in the Vario Case indicates the instrument size:

Size M: Violet ring
Size L: Yellow ring

03.821.143	Inserter, size M
03.821.145	Inserter, size L

03.821.151	Distractor, size M, height 10 mm
03.821.152	Distractor, size M, height 12 mm
03.821.153	Distractor, size M, height 14 mm
03.821.154	Distractor, size L, height 10 mm
03.821.155	Distractor, size L, height 12 mm
03.821.156	Distractor, size L, height 14 mm

03.821.157	Inserter for PE Inlay, size M
03.821.158	Inserter for PE Inlay, size L

03.821.136	Extraction Tool for Inserter

03.821.142	Guiding Device for Inserter, size M
03.821.144	Guiding Device for Inserter, size L

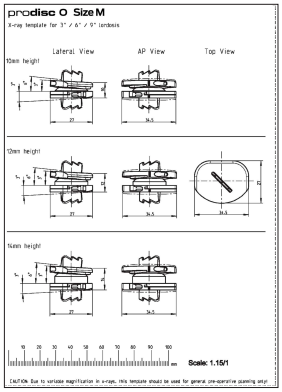
387.347	SynFrame Clamp for Holding Ring No. 387.336

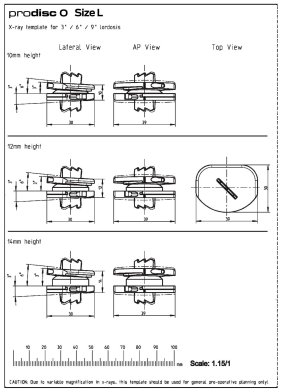
314.270	Screwdriver, hexagonal, large, ∅ 3.5 mm, with Groove, length 240 mm
387.333	SynFrame Extension, with Joint

387.334	SynFrame Extension, with Joint, with Snap-in Locking

X-ray templates

X000053	X-ray Template for pro**disc O**, size M
X000054	X-ray Template for pro**disc O**, size L





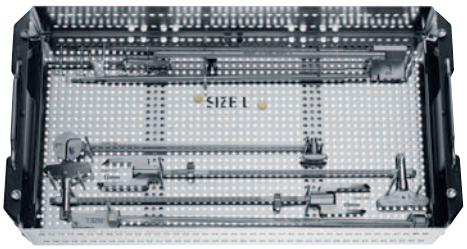
Spare parts

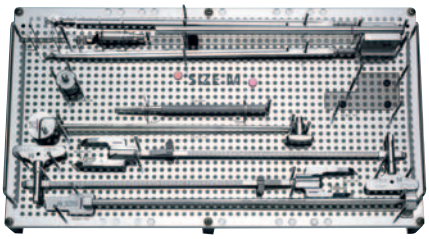
60064875	Superior Arm Tip, complete
60007955	Screw for Superior Arm
60008845	Inferior Arm, right, complete
60008843	Inferior Arm, left, complete
SFW692	pro**disc L** Mallet Impact Surface

Vario Cases and Sets

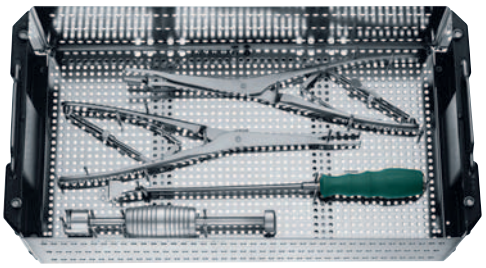
Vario Cases

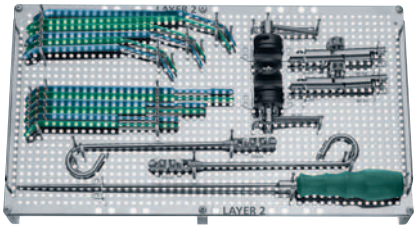
68.821.001 Vario Case for prodisc O Insertion Instruments

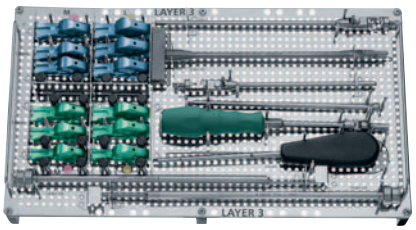




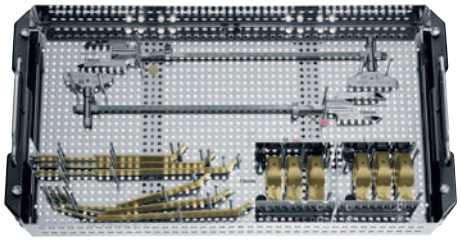
68.821.002 Vario Case for prodisc O Preparation Instruments







68.821.003	Vario Case for prodisc O Additional Instruments



Sets

01.821.001	prodisc O Set Insertion and Preparation Instruments
01.821.002	prodisc O 14 mm Set

The sets contain the Vario Cases and required instruments, along with a full set of implants.

Other Centinel Spine Products for Access, Discectomy and Endplate Preparation

SynFrame

Set

01.609.102	Set SynFrame RL, lumbar
187.310	SynFrame Basic System in Vario Case

Information material

036.000.066	SynFrame, Flyer
036.000.695	SynFrame RL, Flyer

The SynFrame System is a modular approach and retraction system consisting of a basic system (basic construction) and modules specially designed for specific requirements and applications of various indications and/or approach techniques. The structure of the SynFrame basic system is always in the same sequence and according to the same principles. SynFrame RL lumbar is an additional module for the approach and retraction system SynFrame. It includes radiolucent soft tissue and muscle retractors and semi-transparent bone levers for minimally invasive procedures.

Proprep

Set

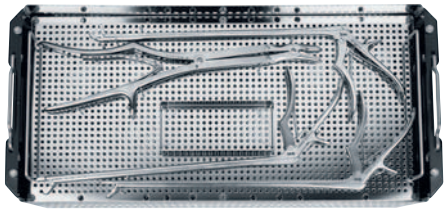
01.600.100	Set Proprep

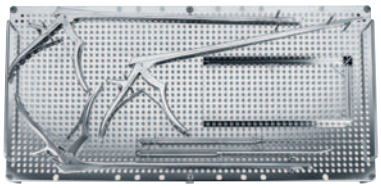
Information material

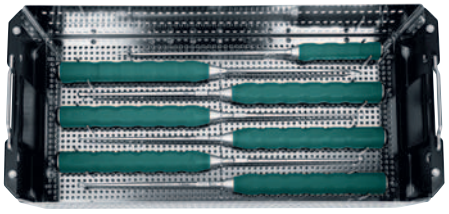
036.000.760	Proprep, Flyer

A practically arranged set for disc preparation and vertebral compression for surgery on the lumbar spine with anterior access.

– Compact yet comprehensive: contains all instruments necessary for disc preparation and vertebral compression.
– Simplified thanks to the angled instruments that allow access even to the posterolateral disc regions, the entire anterior discectomy and corpectomy.
– Thanks to the low-profile instrument it is ideal for use in severely collapsed segments.
– The instrument length has been specifically designed for anterior approaches and patients with a high BMI.
– Maximum instrument control thanks to the silicone handles that can be grasped with both hands.







Electric Pen Drive and Air Pen Drive

Instruments	
05.001.055	Burr Attachment XXL, 20°, for EPD and APD

Information material	
036.000.800	E-Pen Drive, Instruction for Use
036.000.503	Air Pen Drive, Instruction for Use

Compact drive units with specific attachments for a wide range of applications. An optimised attachment to prepare the endplate for prodisc insertion is available.

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