

# **Prodisc-L.** Modular Intervertebral Disc Prosthesis for Stabilizing the Lumbar Spine and Restoring the Physiological Range of Motion.

Technique Guide





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● Image intensifier control

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### **Warning**

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

**Note:** Attending training is essential. Please contact your local Synthes representative for further information.

# Prodisc-L. Modular Intervertebral Disc Prosthesis for Stabilizing the Lumbar Spine and Restoring the Physiological Range of Motion.

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## Proven concept from the field of joint endoprosthesis

### Extensive experience

- Developed as a result of decades of experience in knee and hip prosthetics
- Over 15,000 implanted Prodisc-L prostheses since 1990
- A retrospective study with 11 years of follow-up reveals a patient satisfaction level of 93%
- Polyethylene inlays in conjunction with cobalt-chromium-molybdenum plates have demonstrated outstanding abrasion behavior in knee, hip and spinal prosthetics for several decades

### Motion preservation

- Retention of the physiological range of motion for flexion/extension, rotation and lateral inclination
- Restoration of the height of the relevant segment, anatomical balance, and the stability of the spinal column
- Guided, controlled motion limits the load on facet joints
- Discharges neighboring segments from overload

### Good anatomical fit

- The size of the implant, the lordosis angle and the height of the prosthesis can be interchanged to suit patient anatomy
- Anatomical design of the implant plates

### Superior fixation

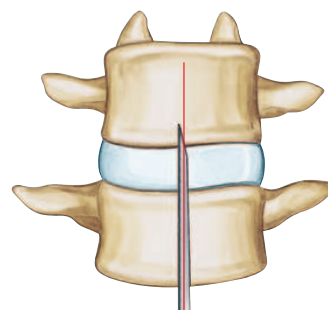
- Central keels and spikes provide primary fixation
- Porous titanium-coated implant plates promote bony on-growth



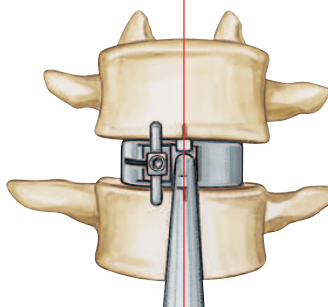
## Minimally invasive access, simple and safe surgical technique

The instruments are simple and safe to handle:

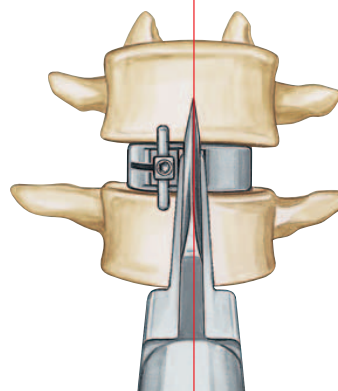
- Narrow, indicated instruments allow short, minimally invasive surgery and therefore earlier patient mobilization
- Trial implants with adjustable stop to prevent excessive posterior positioning
- The keel bed is prepared while the chisel is safely guided over the trial implant
- The implant is guided into proper position via the chisel cut
- Orientation at the midline for precise implanting



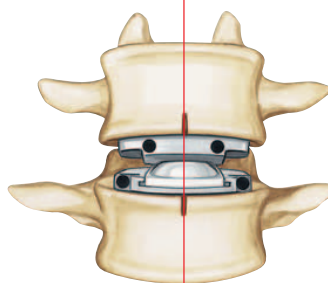
Mark the midline



Insert the trial implant



Chisel the keel bed guided over the trial implant



Final position of the implant



# Indications and Contraindications

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Prodisc-L implants are used to replace a lumbar intervertebral disc and to restore disc height and segmental motion.

## Indications

Lumbar discopathy

## Contraindications

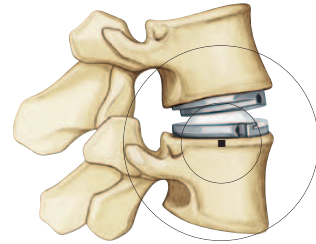
- Spinal stenosis, radiculopathy
- Increased segmental instability
- Spinal deformities, spondylolisthesis above 25%
- Radiological confirmation of severe facet joint disease or degeneration
- Osteoporosis, osteochondrosis, and severe osteopenia
- Acute or chronic systemic, spinal, or localized infections
- Systemic and metabolic diseases
- Any medical and surgical conditions precluding the potential benefit of spinal surgery
- Foreign body sensitivity to the implant materials
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism
- Pregnancy
- Obesity
- Lack of patient cooperation



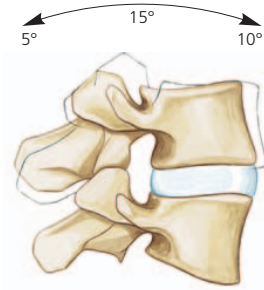
# Kinematics

The kinematics correspond to the physiological conditions in the vertebral joints<sup>1</sup>:

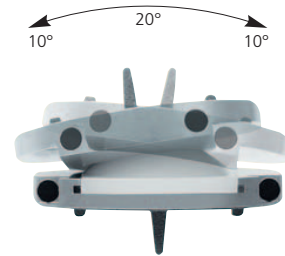
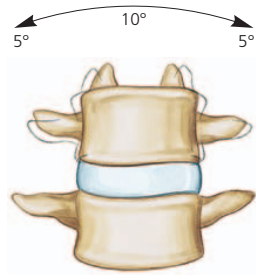
The rotational center is just below the superior endplate of the affected caudal vertebral body. The location of the center of rotation and the flexion radius correspond to the natural joint guidance in the vertebral joints. The physiological range of motion in regard to flexion/extension and lateral bending is restored. The axial rotation is limited only by the anatomical structures and not by the prosthesis. Pure translatory movements are not possible due to the ball and socket principle.



## Flexion/extension



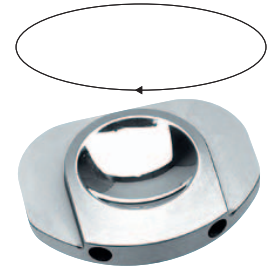
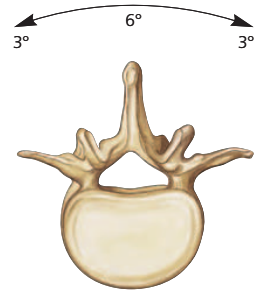
## Lateral bending



<sup>1</sup> See White, Panjabi 1990; Pearcy, Portek, Shepard 1984; Pearcy, Tibrewal 1984; Dvorak et al 1991

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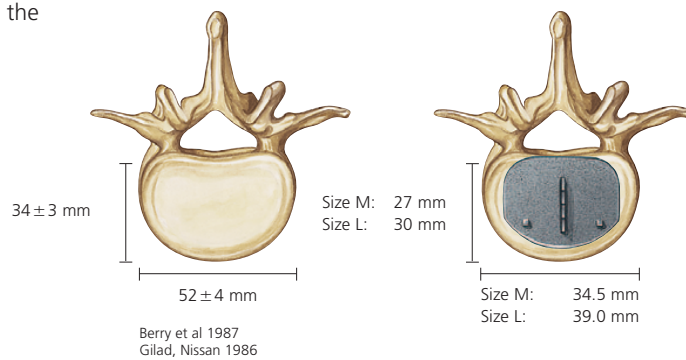
**Axial rotation**



# Implants

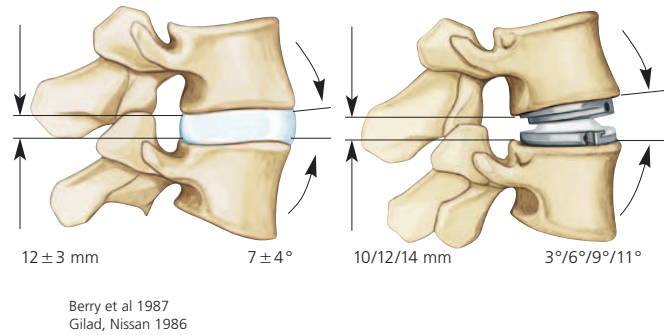
Two different sizes are available for optimal coverage of the vertebral endplates:

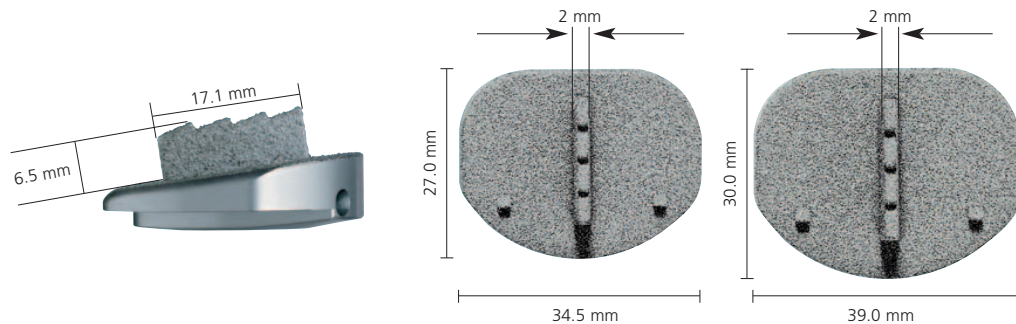
- M and L



The patient-specific intervertebral disc height and sagittal alignment of the affected segment can be restored thanks to:

- three different heights (10, 12 and 14 mm)
- four lordosis angles (3°, 6°, 9° and 11°)





		M	L
Superior plates	3°	SSX660K	SSX670K
	6°	SSX520K	SSX540K
	11°	SSX522K	SSX542K
Inferior plates	0°	SSX524K	SSX544K
	3°	SSX662K	SSX672K
	8°	SSX664K	SSX674K
PE-inlays	10 mm	SSX626	SSX646
	12 mm	SSX627	SSX647
	14 mm	SSX628	SSX648

**Note:** Please observe the recommendations for the application of the different lordosis angles (page 22).

# Instruments

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The Prodisc-L instrument set has been developed for minimally invasive, endoscopic or microscopic procedures.

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## Discectomy and mobilization

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SFW580R Elevator



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SFW650R Prodisc-L Spreader Forceps, curved



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### Trial implant system

24 trial implants correspond to the possible implant combinations.



#### Trial implant M, 3°

Art. no.	Height
SFW751R	10 mm
SFW752R	12 mm
SFW753R	14 mm

#### Trial implant M, 6°

Art. no.	Height
SFW651R	10 mm
SFW652R	12 mm
SFW653R	14 mm

#### Trial implant M, 9°

Art. no.	Height
SFW754R	10 mm
SFW755R	12 mm
SFW756R	14 mm

#### Trial implant M, 11°

Art. no.	Height
SFW654R	10 mm
SFW655R	12 mm
SFW656R	14 mm

---

**Trial implant L, 3°**

Art. no.	Height
SFW757R	10 mm
SFW758R	12 mm
SFW759R	14 mm

**Trial implant L, 6°**

Art. no.	Height
SFW657R	10 mm
SFW658R	12 mm
SFW659R	14 mm

**Trial implant L, 9°**

Art. no.	Height
SFW760R	10 mm
SFW761R	12 mm
SFW762R	14 mm

**Trial implant L, 11°**

Art. no.	Height
SFW660R	10 mm
SFW661R	12 mm
SFW662R	14 mm

SFW601R Adjustable Stop  
 The adjustable stop is attached to the trial implant to prevent excessive posterior positioning.



SFW565R Handle for Trial Implants



SFW602R Screwdriver for Adjustable Stop



**Chisel instruments**

Chisel, slotted

Art. no.	Height
SFW867R	10 mm
SFW868R	12 mm
SFW869R	14 mm



SFW691R Combined Hammer



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**Instruments for implant insertion**

Inserter

Art. no.	Size
SFW672R	M
SFW673R	L



This multifunctional instrument is used for inserting the two implant plates, distracting the intervertebral space and inserting the PE-Inlay into the inferior plate.

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SFW582R	Lever, for Insertion Instruments
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Distractor

Art. no.	Height
SFW874R	10 mm
SFW875R	12 mm
SFW876R	14 mm



Used to distract the inserter arms

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Inserters for PE-Inlay

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Art. no.	Size
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SFW577R	M
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SFW578R	L
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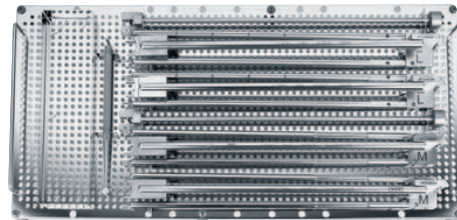
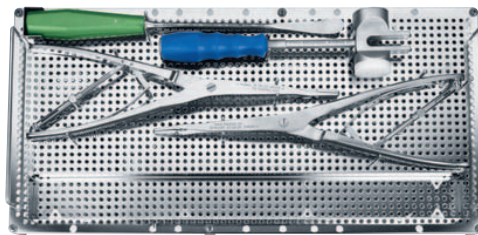
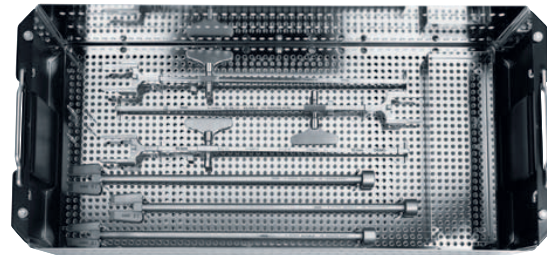
Used to push PE-Inlay into inferior plate

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**Sets**

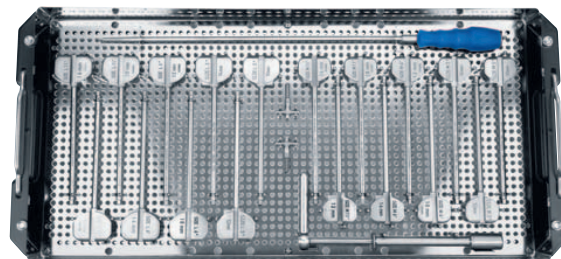
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SFW784R      Vario Case for  
                    Prodisc-L Instruments



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SFW785R      Vario Case for  
                    Prodisc-L Trial Implants



## Optional Instruments

### Struts

straight

Art. no.	Dimensions
SFW521	Height 10 mm, 6°, length 150 mm
SFW522	Height 12 mm, 6°, length 150 mm
SFW531	Height 10 mm, 6°, length 170 mm
SFW532	Height 12 mm, 6°, length 170 mm
SFW541	Height 10 mm, 6°, length 190 mm
SFW542	Height 12 mm, 6°, length 190 mm

angled

Art. no.	Dimensions
SFW621	Height 10 mm, 6°, length 150 mm
SFW622	Height 12 mm, 6°, length 150 mm
SFW631	Height 10 mm, 6°, length 170 mm
SFW632	Height 12 mm, 6°, length 170 mm
SFW641	Height 10 mm, 6°, length 190 mm
SFW642	Height 12 mm, 6°, length 190 mm

388.140 Socket Wrench  $\varnothing$  6.0 mm,  
with straight handle

SFW520 Handle for Strut



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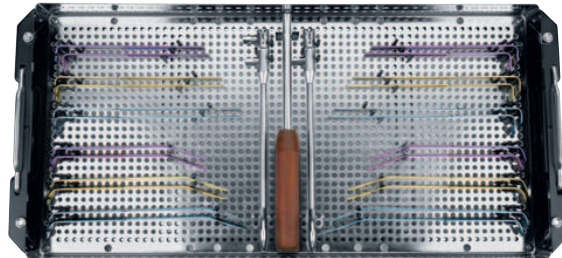
SFW788R Vario Case for Prodisc-L Struts

The Prodisc-L struts hold the disc segment open and facilitate the discectomy procedure and the insertion of the prosthesis. The struts can be secured to the SynFrame.

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**Note:** The struts should never be used to spread the segment, only to hold open a segment that has already been mobilized. The struts are positioned upright into the intervertebral disc space without applying any force while the intervertebral disc space is held open by the spreader forceps (SFW650R).

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Chisels with non-slotted blades

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Art. no.            Height

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SFW567R            10 mm

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SFW568R            12 mm

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SFW569R            14 mm

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Spreader Forceps, straight

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Art. no.

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SFW550R

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Wing Nut for Distractors

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Art. no.

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SFW893R

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The wing nuts allow the distractors to be used with both hands.

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Revision Set

An indicated instrument set is available for any revisions to the Prodisc-L. Please contact your Synthes representative.

## Other Synthes Products for Access, Discectomy and Endplate Preparation

**SynFrame.** Modular approach and retraction system for minimally invasive surgery.



**SynFrame-RL.** Radiolucent retractors

The radiolucent components (retractors and bone levels) allow the relevant parts to be constantly visible during Prodisc surgery.

Information material

Art. no.	Title
036.000.066	SynFrame, Flyer
036.000.695	SynFrame-RL, Flyer



**Proprep.** Intervertebral disc preparation set for anterior lumbar surgery.

Information material

Art. no.	Title
036.000.760	Proprep, Flyer



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**Electric Pen Drive and Air Pen Drive.** Compact drive units with specific attachments for a wide range of applications. A specific attachment is available for endplate preparation (05.001.055).



Information material

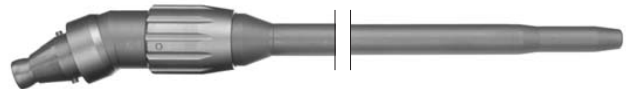
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Art. no.	Title
036.000.097	E-Pen Drive, Flyer
036.000.502	Air Pen Drive, Flyer

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Optimized attachment to prepare the endplate for Prodisc insertion.



For further information please contact your local Synthes representative.

# Preoperative Planning

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## Recommendation on the application of the various lordosis angles

If the patient is in an upright position, the PE-inlay should always be placed in as horizontal a position as possible. It is essential to ensure that the PE-inlay is not inclined in a posterior direction.

The following recommendations apply to most cases:

### L5/S1

Inferior plates with lordosis angles should be selected for L5/S1 if the angle between the horizontal (for upright patients) and the S1 endplates is at least 15°.

Examples: A combination of 3° superior plate and 3° inferior plate for a segmental lordosis of 6°, or a combination of 3° superior plate and 8° inferior plate for a segmental lordosis of 11°.

### L4/L5 and higher

Inferior plates without a lordosis angle (0°) should generally be used for L4/L5 segments and higher.

A prosthesis with a 3° lordosis angle (combination of 3° superior plate and 0° inferior plate) should only be used in segments with a segmental lordosis of close to 0°.

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**Note:** Only implants with a total lordosis angle (3°, 6°, 9° and 11°) represented by a trial implant may be implanted.

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# Surgical Technique

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## 1

### Approach

Expose the intervertebral disc and the adjacent vertebral bodies through the anterior approach to the lumbar spine.

- The approach can either be transperitoneal or retroperitoneal. Identify and mark the midline with the image intensifier.

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## 2

### Discectomy

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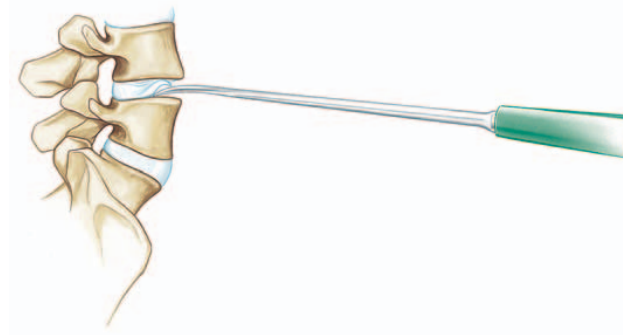
#### Required instruments

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SFW580R	Elevator
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Carefully clean out the intervertebral space with the elevator and remove the intervertebral disc tissue and cartilage fragments from the endplates.



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### 3

#### Mobilize segment

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#### Required instruments

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SFW550R	Spreader Forceps, straight
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SFW650R	Spreader Forceps, curved
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Prior to distraction ensure that the position of the spreader forceps posterior is adequately deep. Check the lateral position using the image intensifier.

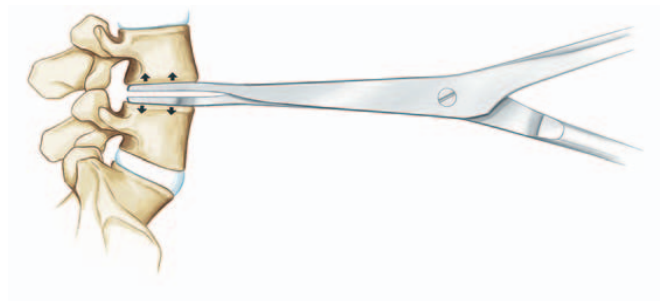


Distraction the intervertebral space with the spreader forceps in a parallel manner to restore the height and to enable access to the posterior part.

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**Note:** An essential prerequisite for a satisfactory clinical result is good mobilization. Insufficient mobilization can also result in an overload of the insertion instruments.

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## 4

### Insert the trial implant

#### Required instruments

Trial implant

SFW565R Handle for Trial Implants

SFW601R Adjustable Stop

SFW602R Screwdriver for Adjustable Stop

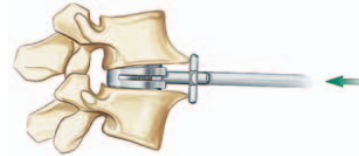
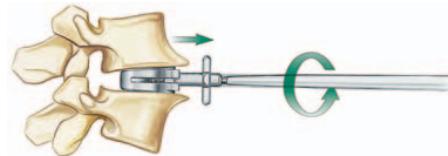
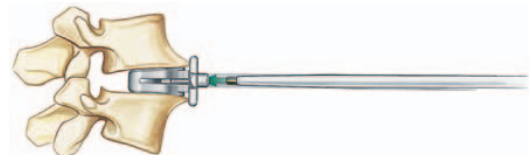
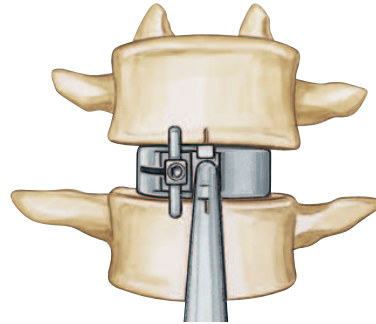
SFW691R Combined Hammer

Determine the final size, height and lordosis angle and the position of the prosthesis. The aim is to select the largest possible footprint with the smallest necessary height.

- Align the trial implant with the midline; while monitoring the process on the image intensifier, carefully use the hammer to insert the trial implant into the intervertebral space to the rear edge of the endplate.

- The trial implant should be lightly secured by the endplates of the adjacent vertebral bodies. If the implant is seated too loosely in the intervertebral space, select the next highest size. Check the position of the trial implant using the image intensifier, both from an AP perspective as well as laterally.

**Note:** The trial implant can be optimally positioned with the aid of the adjustable stop to prevent the implant from being inserted too far into the intervertebral space. If the trial implant must be positioned more deeply, the stop can be adjusted using the screwdriver. One 360° rotation equals 1 mm.



## 5 Chiseling

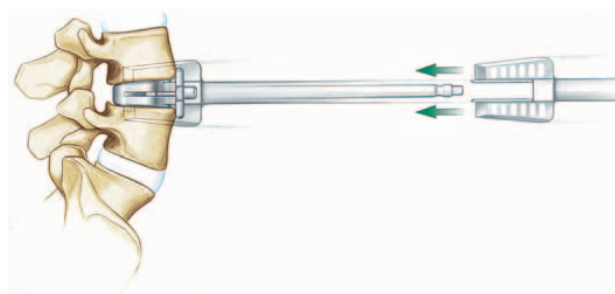
### Required instruments

SFW867R	Chisel, 10 mm
SFW868R	Chisel, 12 mm
SFW869R	Chisel, 14 mm
SFW691R	Combined Hammer

Guide the chisel over the shaft of the trial implant and create the keel bed for the prosthesis.

The selected trial implant serves as a guide for the chisel and sets the direction and chisel depth.

- ❶ The chisel cut determines the final implant position and must therefore be checked with the image intensifier.



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## 6

### Insert the implant plates

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#### Required instruments

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SFW672R      Inserter  
SFW673R

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SFW691R      Combined Hammer

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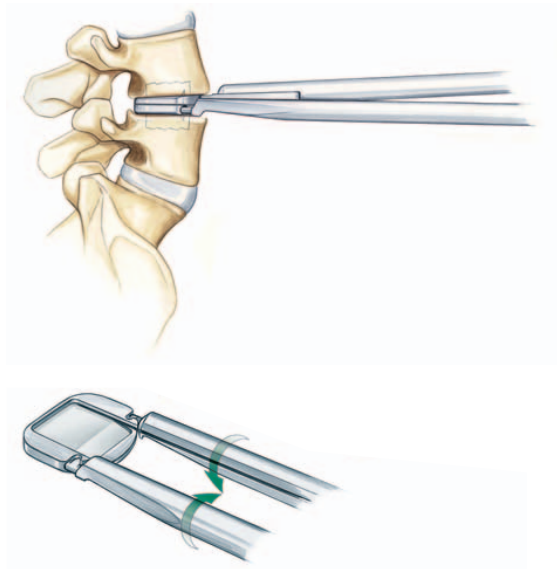
Place the top and bottom implant plates on the inserter. Lock the bottom plate by turning the inserter arms. Using the chisel cuts as a guide, insert the implant plates into the intervertebral space.

- Check the final position of the implant using the image intensifier, both from an AP perspective as well as laterally.

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**Note:** This step is done without distraction so as not to damage tissues, longitudinal ligaments and nerve roots.

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**7****Insert the PE-inlay****Required instruments**

SFW874R	Distractor 10 mm
SFW875R	Distractor 12 mm
SFW876R	Distractor 14 mm
SFW577R	Inserters for PE-Inlay, M
SFW578R	Inserters for PE-Inlay, L

Lay the PE-Inlay as shown on the instrument (“dome up”) in the slot of the inserter. Use the distractor corresponding to the selected implant height and attach it to the inserter.

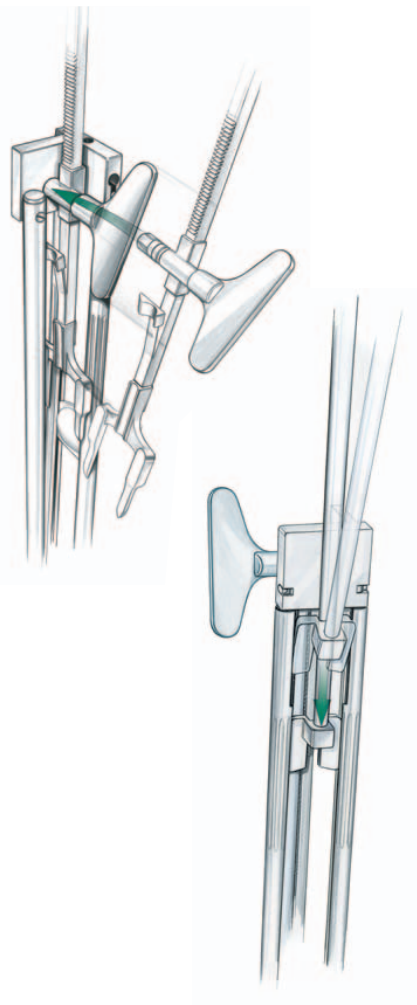
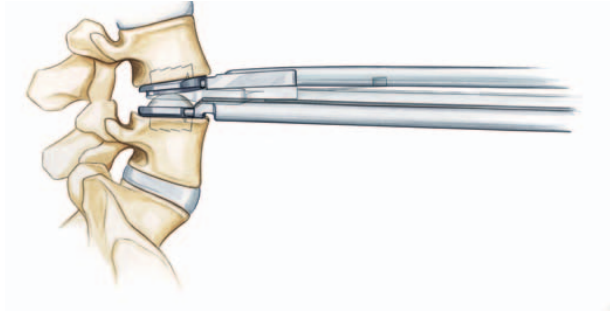
Use the wing nut to screw the distractor down to the mechanical stop. While distracting the segment the PE-Inlay is automatically brought into position along the slot.

- Check the distance between the implant plates using the image intensifier. There should be a visible radiolucent space between the metal plates.

Using the inserter, insert the PE-Inlay into the bottom plate of the implant until it snaps into place.

**Note:** It is crucial to check visually and manually if the PE-inlay is securely locked into the inferior implant plate (“no step, no gap”).

- Check the final position of the prosthesis using the image intensifier.



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## 8

### Remove instruments

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#### Required instruments

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SFW691R	Combined Hammer
SFW582R	Lever for Insertion Instruments

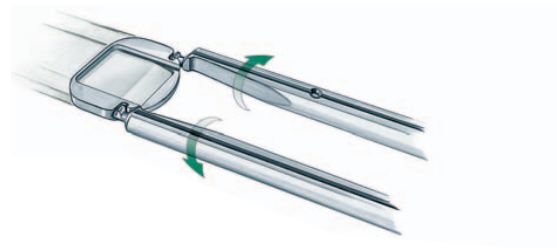
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Unlock the inferior plate by turning the arms outwards. Using a slide hammer, pull the inserter straight back and remove from the operative field.

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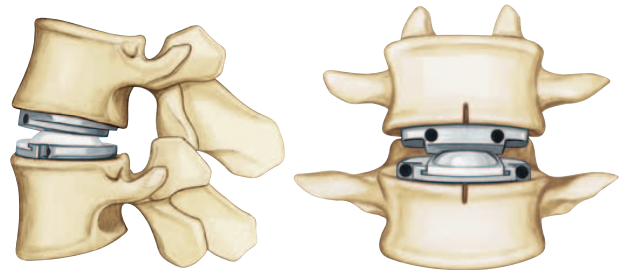
**Note:** The use of a lever for insertion instruments can facilitate the rotation of the distractor arms.

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The implant is now – oriented on the midline – securely seated on the cortical ring of the vertebral body.

- Check the final position of the implant using the image intensifier, both from an AP perspective as well as laterally.



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### **Multisegmental procedures**

Perform multisegmental operations one segment at a time.

All instruments must be removed from the treated segment before the next affected segment can be exposed and cleaned out.

Follow steps 2-8 as described above.

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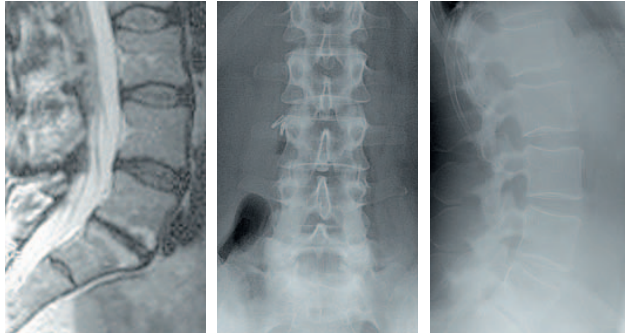
**Note:** In the case of multisegmental surgery, always start with the segment that is most severely collapsed.

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# Cases

## Case 1: Degenerative disc disease L5/S1

Preoperative

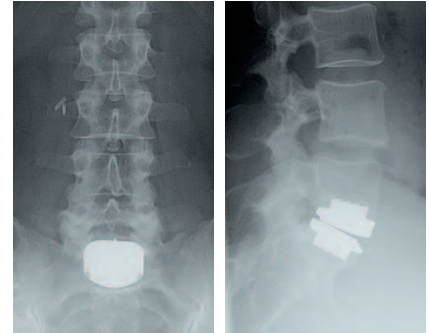


MRI lateral

Anteroposterior

Lateral

Postoperative



Anteroposterior

Lateral

**Patient:**

Female, 56 years of age

**Symptoms:**

Continuous, severe pain in the lower back

**Diagnosis:**

Back pain arising from an intervertebral disc in the lumbar region L5/S1

Segmental instability

Herniated nucleus pulposus L5/S1

Signs of Modic change

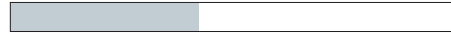
**Prior therapy:**

Unsuccessful conservative treatment (for more than 6 months)

**Visual analogue scale:**



Preoperative: 8.5

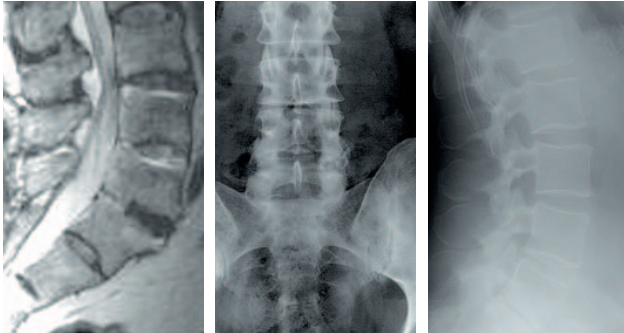


Postoperative: 3.0 (24 months after operation)

Satisfaction: Episodic back pain, completely satisfied with the treatment

**Case 2: Degenerative disc disease L3/L4 and L4/L5**

Preoperative



MRI lateral

Anteroposterior

Lateral

**Patient:**

Male, 47 years of age

**Symptoms:**

Continuous, severe pain in the lower back

**Diagnosis:**

Back pain arising from an intervertebral disc in the lumbar region L3–L5  
Segmental instability of L3–L5  
modic signs

**Prior therapy:**

Unsuccessful spinal surgery (for more than 6 months)

**Visual analogue scale:**



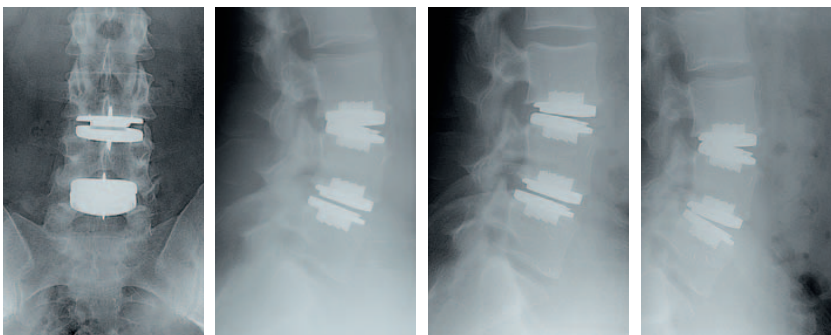
Preoperative: 8.0



Postoperative: 0.0 (24 months after operation)

Satisfaction: No back pain, completely satisfied with the treatment

Postoperative



Anteroposterior

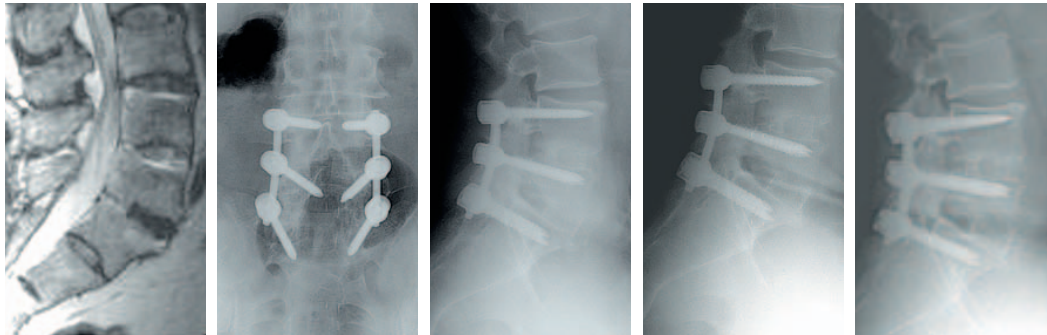
Lateral

Lateral flexion

Lateral extension

**Case 3: Degenerative disc disease L3/L4 – fused segments L4–S1**

Preoperative



MRI lateral

Anteroposterior

Lateral

Lateral flexion

Lateral extension

**Patient:**

Male, 57 years of age

**Symptoms:**

Continuous, severe pain in the lower back

**Diagnosis:**

Back pain arising from an intervertebral disc in the lumbar region L3/L4  
 Segmental instability at L3/L4 neighbouring fusion of L4–S1  
 Secondary spinal stenosis L3/L4

**Prior therapy:**

Unsuccessful conservative treatment (for more than 6 months)

**Visual analogue scale:**



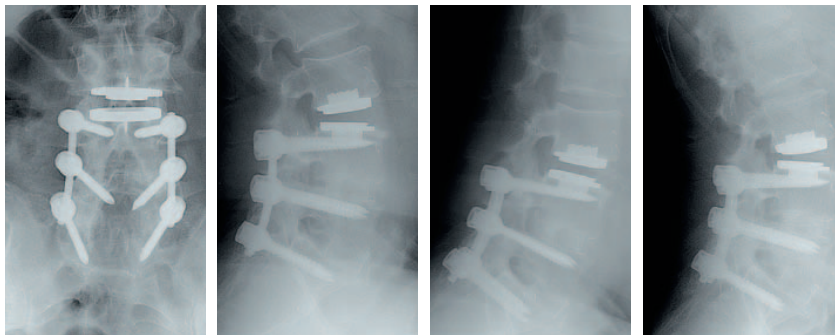
Preoperative: 6.2



Postoperative: 1.0 (24 months after operation)

Satisfaction: No back pain, completely satisfied with the treatment

Postoperative



Anteroposterior

Lateral

Lateral flexion

Lateral extension

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