PARADIGM SPINE
the movement in spine care

Hybrid Performance System HPS™

Thoracolumbar Stabilization

SHORTENING THE LENGTH OF FUSION THROUGH DYNAMIC STABILIZATION

The answer to adjacent segment degeneration?

Spondylodesis is the gold standard in the treatment of symptoms and degenerative changes in the spine. However, fusion of mobile segments always constitutes a compromise between rapid pain relief and potential future problems through higher loads on adjacent segments.

The loss of mobility in the segments that have been treated results in changes in movement patterns that are accompanied by abnormal load transfers and thus increased loads on the intervertebral discs and facet joints. The result of this is accelerated adjacent segment degeneration (ASD).

Sears et al. report on an annual incidence of 2.5 % for clinically relevant ASD in a retrospective follow-up study on 1,000 fused segments in 912 patients. While genetic and environmental factors play a significant role, it is primarily the length of fusion that is a decisive factor in this process. The longer the fusion, the greater the load compensated in the adjacent segments.

The annual incidence in the study increases from 1.7 % to 3.6 % and 5 % for level 1, 2 and 3 fusions, respectively.[1]

From a biomechanical perspective, a reduction in loading in the adjacent segments can be achieved through the preservation of the natural range of motion and the physiological centre of rotation. Dynamic implants enable segmental stabilization, while simultaneously preserving motion, and thus facilitate a smoother transition in the adjacent segments.

The rise in the incidence of ASD with increasing length of fusion makes clear that a solution that preserves motion is meaningful, especially in cases of multi-segment disease. The ***HPS™*** – Hybrid Performance System – closes the gap in the treatment spectrum and contributes towards shortening the length of fusion.

[1] *William R. Sears, Ioannis G. Sergides, Noojan Kazemi, Mari Smith, Gavin J. White, Barbara Osburg; Incidence and prevalence of surgery at segments adjacent to a previous posterior lumbar arthrodesis. The Spine Journal 11 (2011) 11–20*

HPS™
HYBRID PERFORMANCE SYSTEM

HPS™ is a universal system for stabilization of the spine. It allows for multisegmental fusion with the option of dynamic stabilization of the cranial segment. The aim is to shorten the length of fusion and to thus reduce the risk of degeneration in the adjacent segments.

The dynamic coupler controls movement of the spine in all directions. Mobility is ensured for flexion, extension and lateral bending, while translation and axial rotation are reduced to a minimum.

The capacity for controlled axial adjustments in length permit changes in the distance between the pedicles of just under 2 mm. This allows the system to cushion axial forces, to reduce the load on facet joints and intervertebral discs and to preserve the physiological centre of rotation in the index and adjacent segments.

The dynamic *HPS*™ coupler – controlled range of motion and physiological quality of movement.

HPS™ =	Fusion	+	Option: Dynamic Stabilization
	HPS™ is a pedicle screw/rod system for multisegmental stabilization of the thoraco-lumbar spine. It allows simple and rapid multisegmental fusion in a variety of indications.		It simultaneously provides the option of dynamically stabilizing the cranial segment. This shortens the length of fusion and reduces the risk of adjacent segment degeneration through the creation of a soft transition.

HPS™ – STABILIZATION AND MOTION PRESERVATION

The degeneration of a segment leads to an increase in mobility in relation to flexion, extension, lateral bending and rotation. The neutral zone is also increased. Hypermobility and non-physiological movement patterns cause back pain and muscle spasms. The range of motion and the neutral zone (NZ) must be reduced through stabilization in order to alleviate pain. Preservation of mobility in the segment that has been treated simultaneously protects the adjacent segments.

The dynamic coupler was developed in cooperation with the Institute for Orthopaedic Research and Biomechanics at the University of Ulm based on a validated FEA model and was verified using biomechanical experiments.[2] The initial aim was to develop a dynamic coupler that reduces the range of motion in relation to flexion/extension, lateral bending and rotation by about 50–70 % based on its spring stiffness.

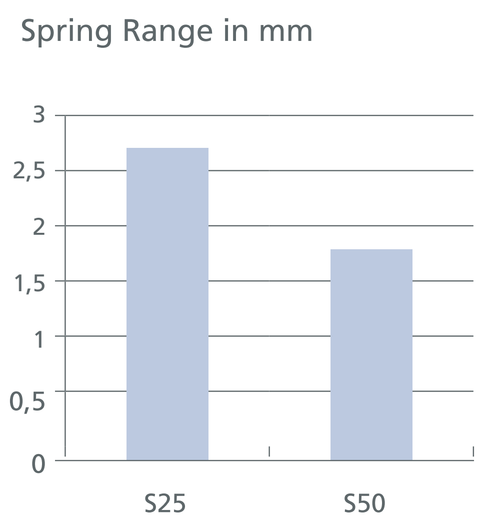
In addition, the change in the distance between the pedicles during movements involving flexion and extension requires a controlled adjustment to the length of the implant by about 2 mm.[3] This process preserves the natural centre of rotation.

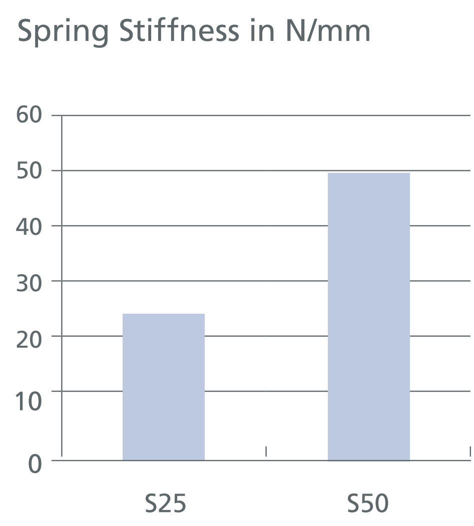
The overall range of motion in the spring must simultaneously be limited mechanically to protect the implant from mechanical overloading and to thus achieve fatigue strength.

Two variants are made available as the two parameters – stiffness and range – are mutually dependent.

S25 (low stiffness and higher range of spring)
S50 (high stiffness and lower range of spring)

Use of the element S25, that permits a greater range, is recommended, in particular, for multisegmental constructs.

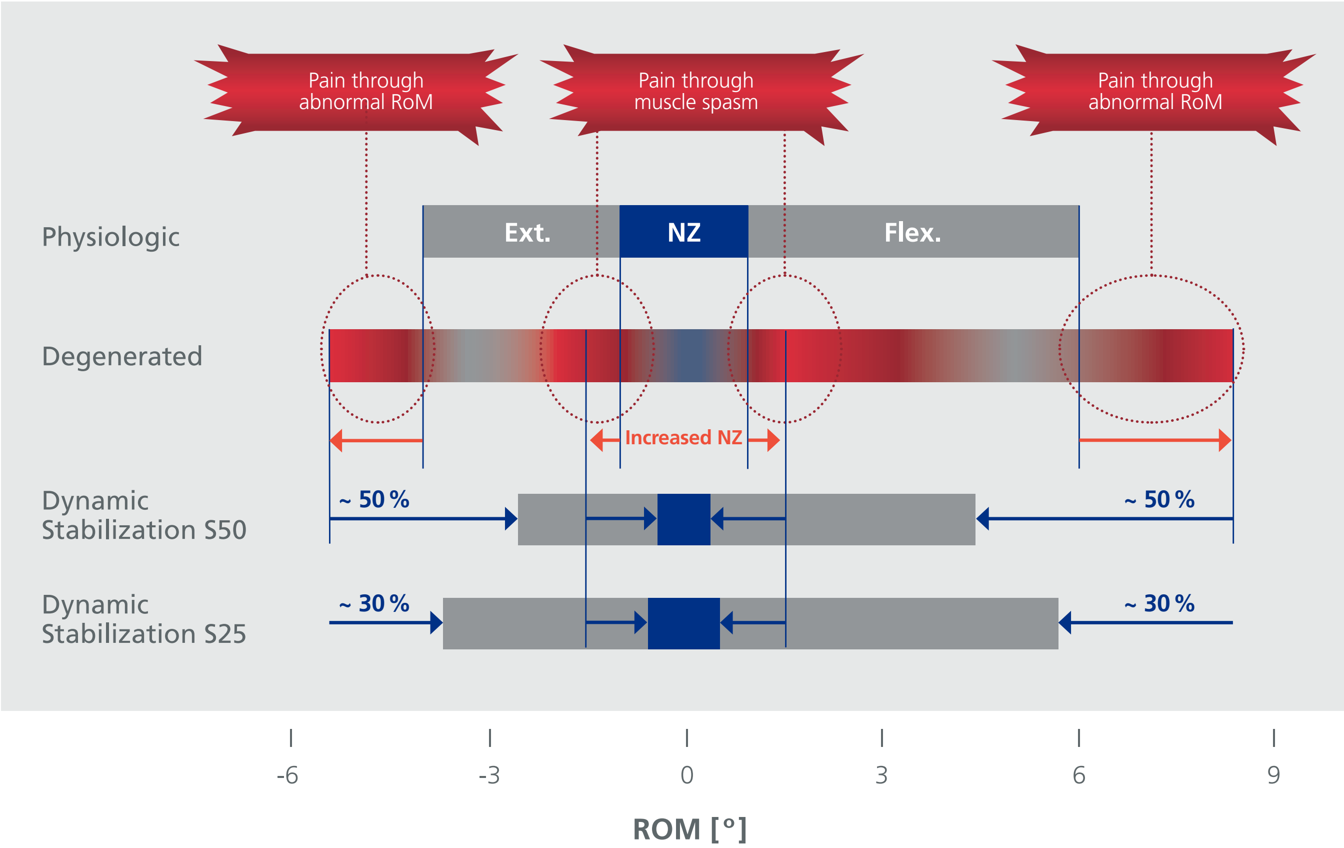




[2] *Prof. Hans-Joachim Wilke, Frank Heuer, PhD, Hendrik Schmidt, PhD; Prospective Design Delineation and Subsequent In Vitro Evaluation of a New Posterior Dynamic Stabilization System. SPINE Volume 34, Number 3 pp 255-261, 2009, Institut für Orthopädische Forschung und Biomechanik, Ulm, Deutschland*

[3] *That value is based on a study by Cunningham et al. which annalyzed the changes of the interpedicular distances of the different segments when going from flexion to extension.*
Bryan W. Cunningham, MSc, Dennis Colleran, BS, Gwen E. Holsapple, BS, Paul McAfee, MD; Lumbar Spine Kinematics – a Radiographic Assessment of the Change in Interpedicular Distance throughout the Range of Motion. SAS 6

Pain Relief through Stabilization



Dynamic Couplers

The dynamic couplers S25 and S50 differ in their stiffness and maximum range. This permits the implants to have both intermediate and extensive ranges, as well as providing efficient stabilization and relief from pain.

S25 Coupler

S50 Coupler

THE KINEMATIC SIGNATURE OF THE DYNAMIC COUPLER

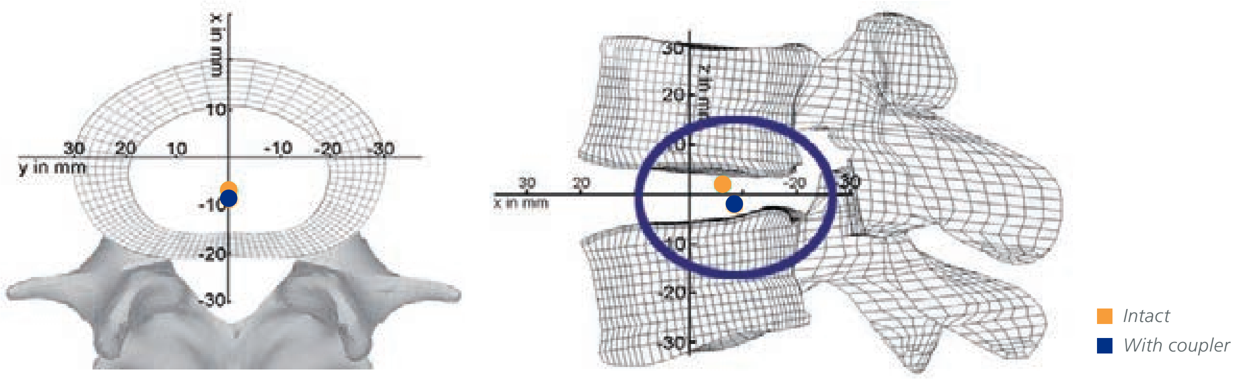
Biomechanical test and FE analysis by Prof. Wilke et al., University of Ulm[4]

This in-vitro study compares the kinematic signature of the dynamic ***DSS®-/HPS™*** coupler (S50) with fusion using a pedicle-screw system.
It reveals that the dynamic coupler provides adequate stabilization and simultaneously preserves motion.

Motion was maintained in the presence of clear stabilization after implantation of the dynamic coupler. In comparison to the intact status, the range of motion was reduced by 54 % in flexion, 39 % in extension, 45 % in lateral bending and by 7 % in axial rotation. Fusion of the segment severely restricted movement in all directions of loading (Figure "Range of Motion and Neutral Zone" on page 9).

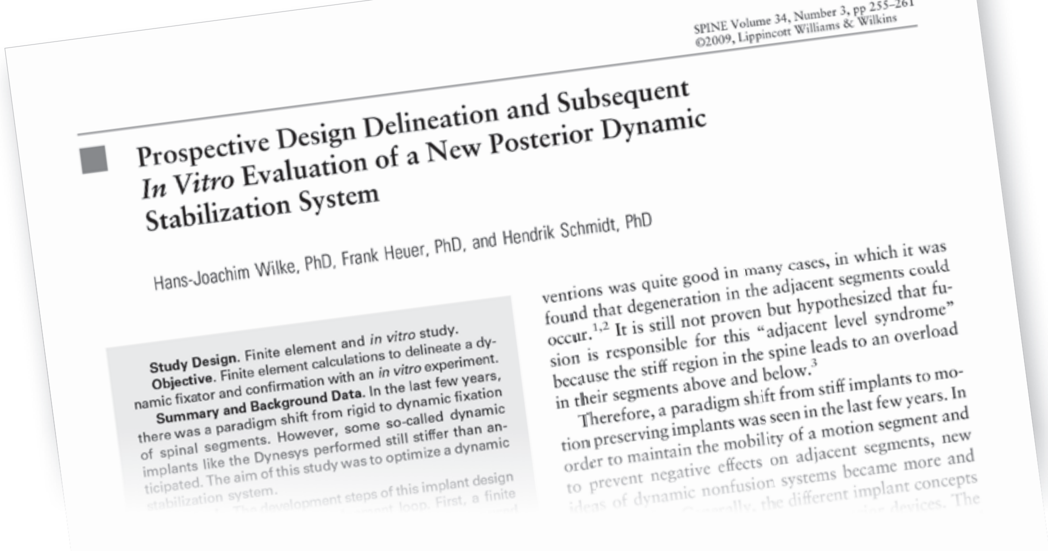
The centre of rotation in the mobile segments remained in the physiological condition after implantation of the ***DSS®-/HPS™*** coupler (Figure "Analysis of Center of Rotation"). This points to good quality of motion.

Analysis of Center of Rotation



- The mechanism inside the dynamic coupler permits a range of spring of up to 2 mm.
- Implantation of the dynamic coupler preserves the centre of rotation close to the physiological centre of rotation.

[4] *Prof. Hans-Joachim Wilke, Frank Heuer, PhD, Hendrik Schmidt, PhD; Prospective Design Delineation and Subsequent In Vitro Evaluation of a New Posterior Dynamic Stabilization System. SPINE Volume 34, Number 3 pp 255-261, 2009, Institut für Orthopädische Forschung und Biomechanik, Ulm, Deutschland*


SPINE Volume 34, Number 3, pp 255–261
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Prospective Design Delineation and Subsequent *In Vitro* Evaluation of a New Posterior Dynamic Stabilization System

Hans-Joachim Wilke, PhD, Frank Heuer, PhD, and Hendrik Schmidt, PhD

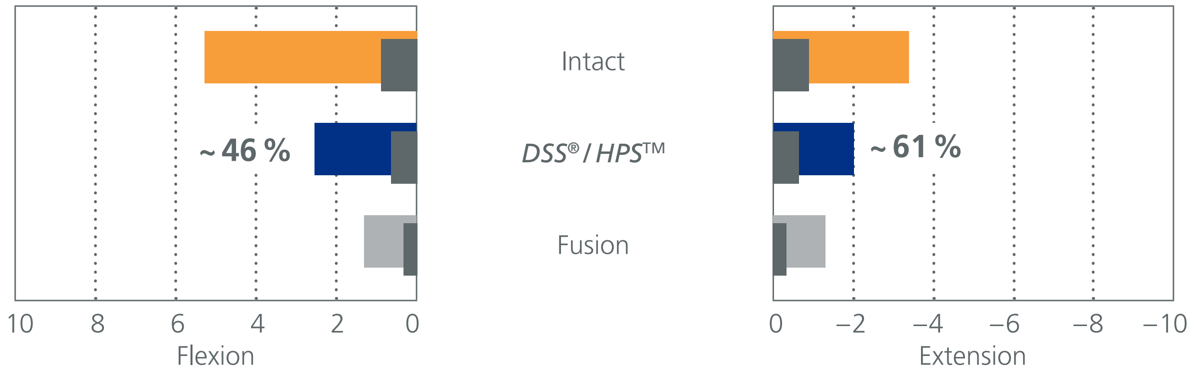
Study Design. Finite element and *in vitro* study.
Objective. Finite element calculations to delineate a dynamic fixator and confirmation with an *in vitro* experiment.
Summary and Background Data. In the last few years, there was a paradigm shift from rigid to dynamic fixation of spinal segments. However, some so-called dynamic implants like the Dynesys performed still stiffer than anticipated. The aim of this study was to optimize a dynamic stabilization system.

ventions was quite good in many cases, in which it was found that degeneration in the adjacent segments could occur.[1,2] It is still not proven but hypothesized that fusion is responsible for this "adjacent level syndrome" because the stiff region in the spine leads to an overload in their segments above and below.[3]
Therefore, a paradigm shift from stiff implants to motion preserving implants was seen in the last few years. In order to maintain the mobility of a motion segment and to prevent negative effects on adjacent segments, new ideas of dynamic nonfusion systems became more and

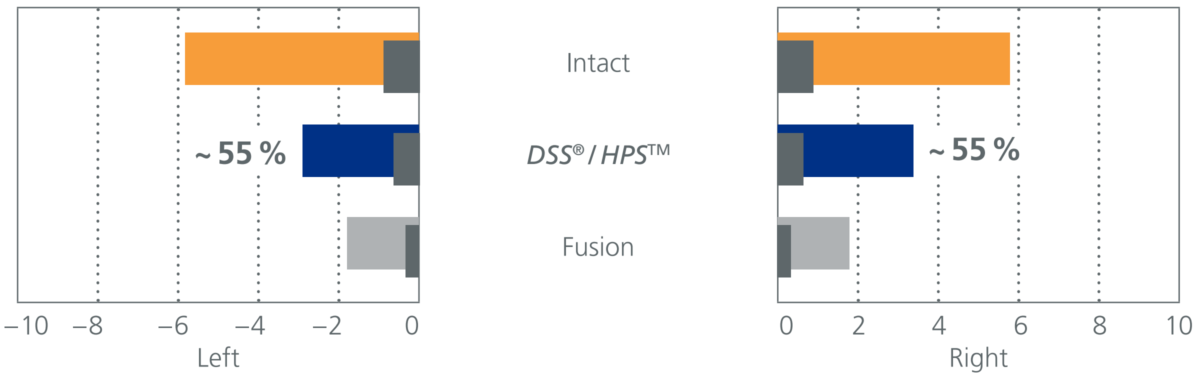
Range of Motion and Neutral Zone (in °)

Range of motion
NZ (neutral zone)

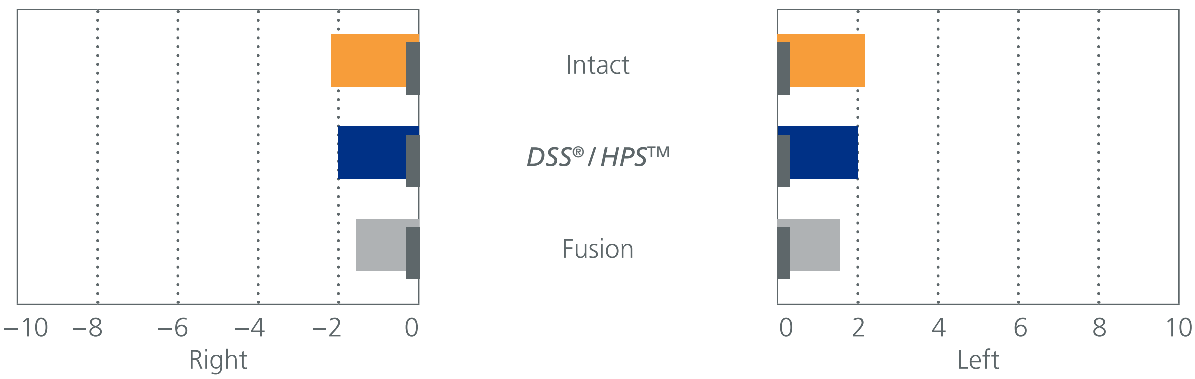
Flexion – Extension



Lateral Bending



Axial Rotation



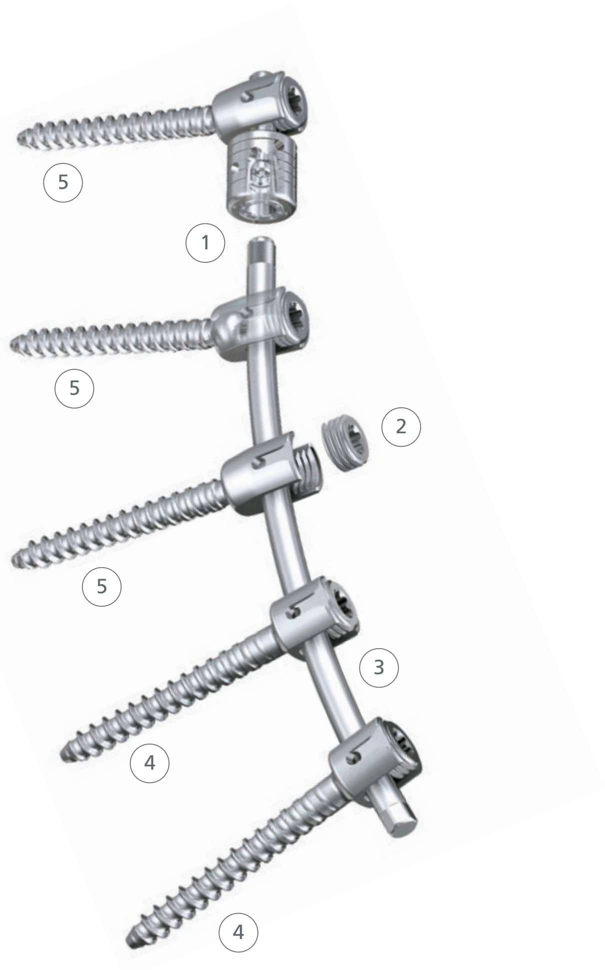
The implantation of the dynamic coupler increased stability while preserving motion.

INTELLIGENT IMPLANT DESIGN

(1) **Thread** allows intraoperative connection between coupler and rod

(2) **Locking screw**
- Optimised thread design prevents cross-threading of the screw and locking screw
- Torx fixing allows easy positioning of the screw driver and optimum force transmission
- Secure fastening with torque wrench

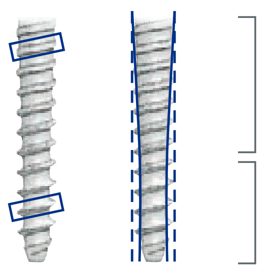
(3) **Rod**
- Straight or pre-bent
- Marking (line) simplifies bending
- 5.5 mm diameter
- Lengths of 40 to 300 mm
- Hexagonal end of rod for easy positioning and orientation of rod



(4) **Monoaxial Screws** facilitate repositioning

(5) **Polyaxial Screws**
- Screw head angle of > 40° allows easy positioning of rod
- Friction-fit feature of the screw head facilitates rapid insertion of rod

Screw Design
- Canulation of screws supports insertion via K-wire that is minimally invasive to tissue
- Cylindrical and conical shaft, as well as thread design with enlarged flanks towards screw head end, ensures secure press-fit anchoring in the pedicle



Stabilization

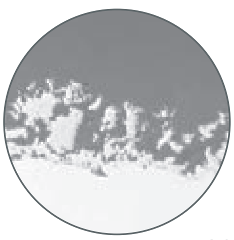
- Reduction in range of motion for effective alleviation of pain
- Protection of facet joints through high AP and rotation stiffness
- Reduction of instabilities through shear stiffness
- Reduction of the neutral zone and reduction of the load on the intervertebral disc and facet joints through axial stiffness

Motion Preservation

- Preservation of motion to protect the adjacent segments
- Preservation of the centre of rotation through adjustment to changing distances between the pedicles during flexion and extension
- Restriction of range of motion through spring openings and internal mechanism

Polyaxial Screw with Plasma-Sprayed Titanium Coating

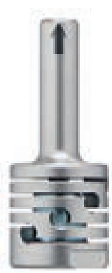
- Surface porosity creates optimum contact between screw and bone
- The larger surface comes into contact with the bone, resulting in optimal growth of bone into the screw
- The coating is biocompatible and results in a normal tissue reaction



200 µm

Dynamic couplers

Different ranges of motion in the dynamic couplers allow implants across intermediate to extensive ranges, with efficient stabilization and alleviation of pain



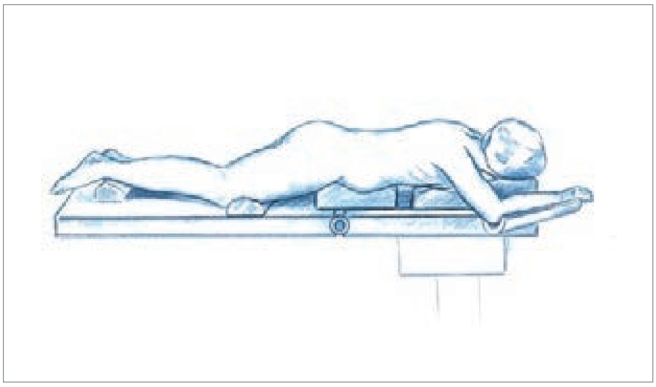
S25 Coupler

S50 Coupler

HPS™ SURGICAL TECHNIQUE

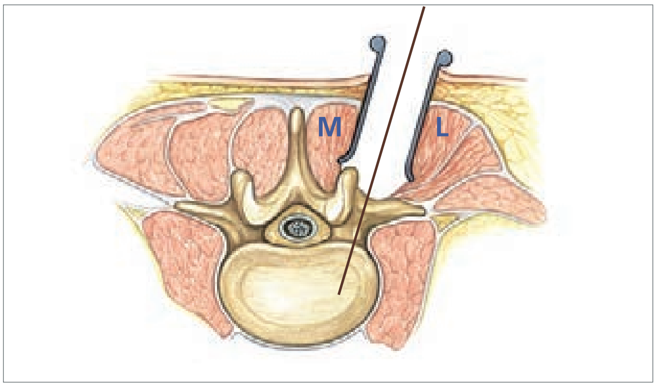
Patient Positioning

- The patient is placed in neutral position
- Abdominal compression should be prevented for lowering venous pressure and decreasing the risk of bleeding



Paraspinal Intermuscular Approach

- Intermuscular approach between multifidus and longissimus is recommended
- Cannulated screws in combination with K-wires support minimally invasive, tissue-sparing application



Pedicle Preparation

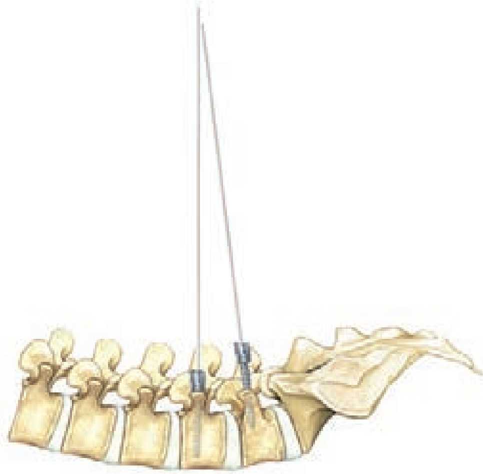
- After standard skin incision via a midline or bilateral paramedial approach the pedicles are exposed
- Use the trocar to open the cortical bone and create an initial entry into the pedicle
- The pedicle entry point is marked under X-ray

Determination of Screw Length and Diameter

- A suitable screw length can be determined by the depth marks of the awl which commences at 30 mm with 5 mm increments

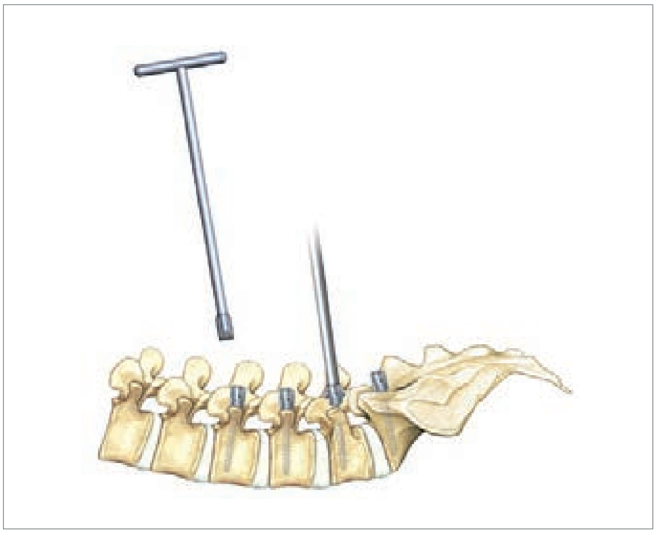
Screw Placement

- K-wires can be placed within the cannulated pedicle to guide screw placement
- The pedicle is prepared with a tap prior to screw placement
- **Important:** Taps are already undersized (tap size and screw size must be identical). Taps are non-cannulated
- **Note:** Use of smaller taps may impede screw insertion and cause bone fragmentation



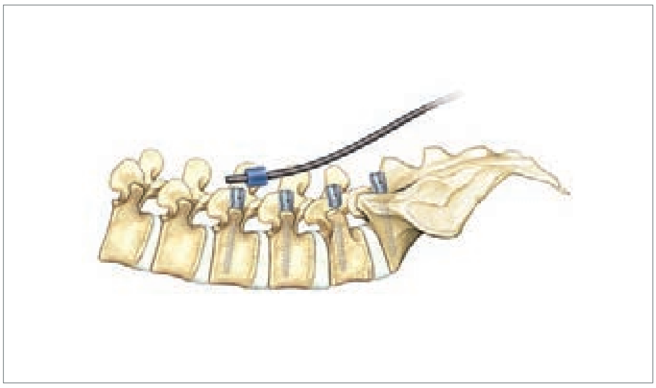
- Poly- or monoaxial screws may be used according to surgeon`s preference
- **Important:** Polyaxial screws are obligatory for the two screws next to the dynamic *HPS™* coupler
- Larger screw diameters are encouraged
- **Attention: Turning back of screws should be avoided to minimize the loss of bone purchase and screw loosening**
- It is important to leave some room between the pedicle screw head and bony anatomy to ensure that its polyaxial characteristics are maintained

Screw Head Alignment



- Use the head aligner to position the screw heads for ideal rod placement
- The friction fit feature of the polyaxial screw heads allows for optimal screw head positioning intraoperatively

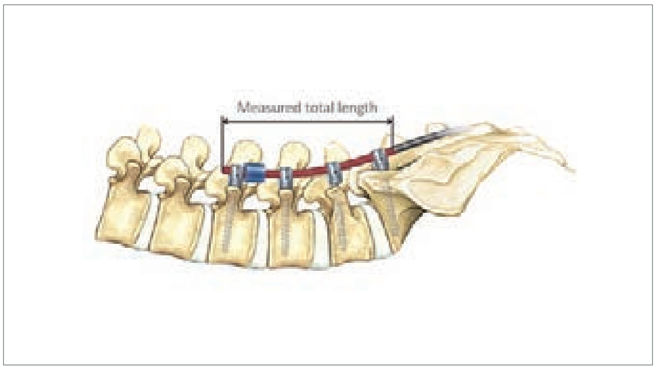
Determination of Rod Contour and Coupler Fit



- The coupler template is placed on the template rod
- Bend the template rod as necessary to achieve a proper alignment to the screw heads and to use it for the contouring of the rod
- The template rod is inserted into the screw heads to measure the required rod length and to determine the needed rod contour
- **Important:** The coupler template ensures that the coupler will fit between screw heads
- The Template rod overhang should be a minimum of 5 mm on both sides

Determination of Rod Length

- **Required rod length = Measured total length minus coupler length (35 mm)**
- The total rod length should project a minimum overhang of 5 mm on both sides



Rod Contouring

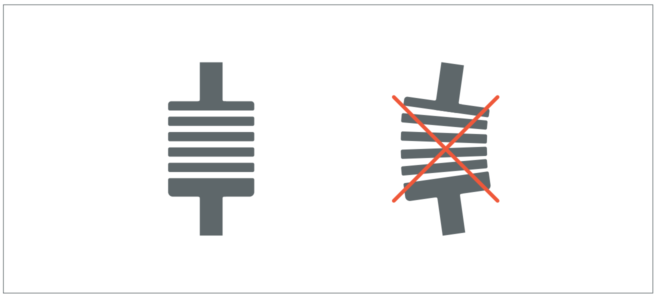
- The rods are bent as required utilizing bending pliers and bending tools
- **Care has to be taken that the thread is not damaged during the bending process!**
- The contoured rod template can be utilized for proper bending of the rod
- **Important to note: Titanium rods must never be bent back and forth! This may weaken the rod**

Coupler Assembly

- The coupler is screwed onto the rod
- Wind the rod on the rod coupler until all blue-colored thread grooves are hidden then wind back half a turn to keep threads exposed
- **Important: Do not turn in the thread completely**
- **Note:** Leaving the coupler loose avoids torsion forces during insertion and stabilization of the segment

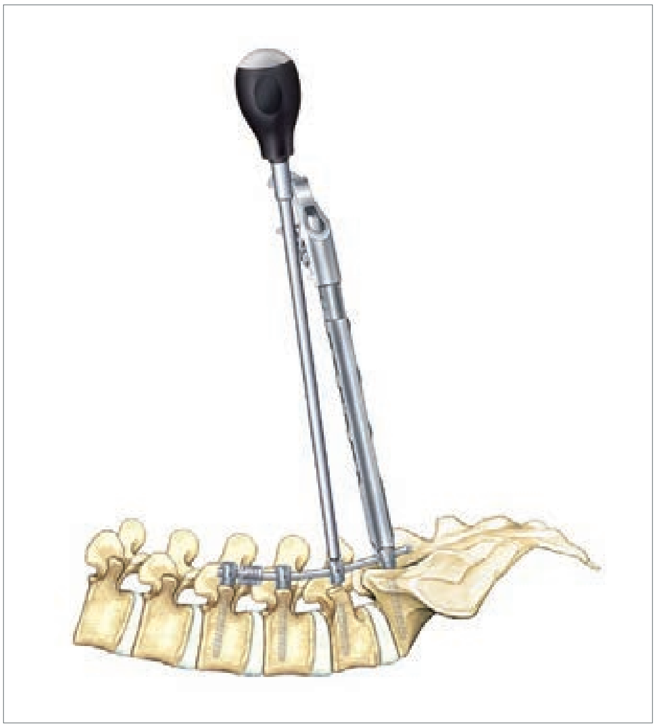
Rod Assembly and Positioning

- Use the rod holder and the vice grips to insert the rod into the aligned screw heads
- The arrows on the cranial end of the coupler should be oriented to be facing posteriorly



- **When placing the rod and coupler into the screw heads, the coupler has to be in neutral position. Compression and distraction forces have to be avoided**
- **Important:** Care has to be taken that the coupler slots are parallel

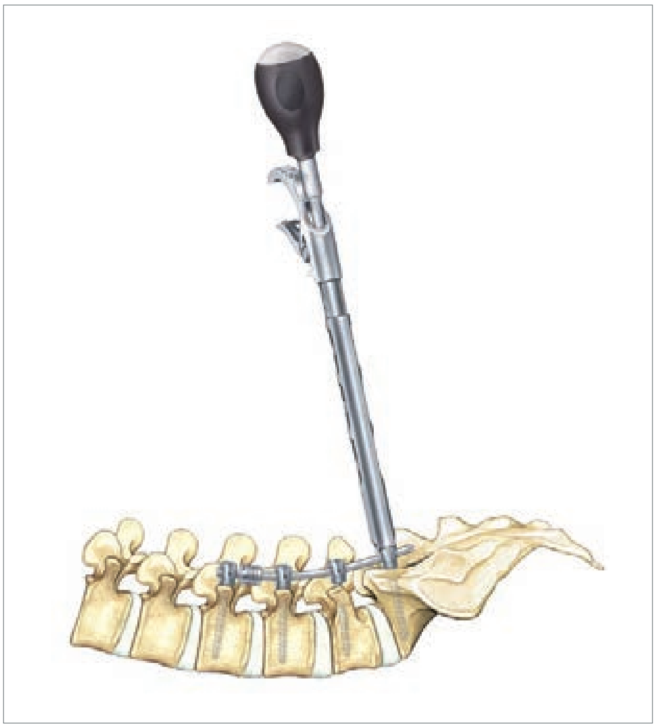
Set Screw Insertion



- Pre-tighten the set screws using the set screw inserter
- To ease the insertion of the set screws and for additional reduction maneuvers various instruments such as rod pusher, rocker and persuader are available

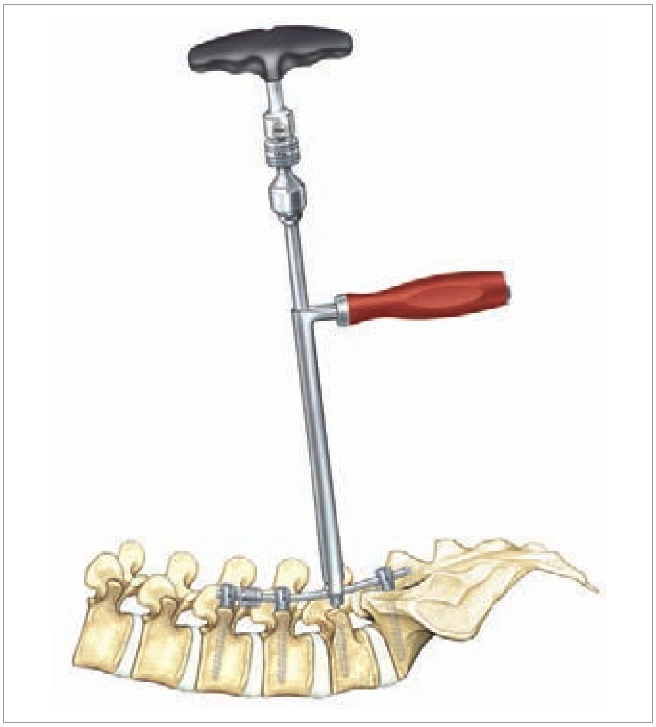
Set Screw Insertion and Tightening

- Apply the persuader onto the screw head and compress the handle to reduce the rod into place
- Carefully use the set screw inserter to place the set screw into the screw head through the persuader
- **Important:** Do not tighten the set screw completely. Final tightening must be performed by a torque wrench to ensure a torque of 11 Nm



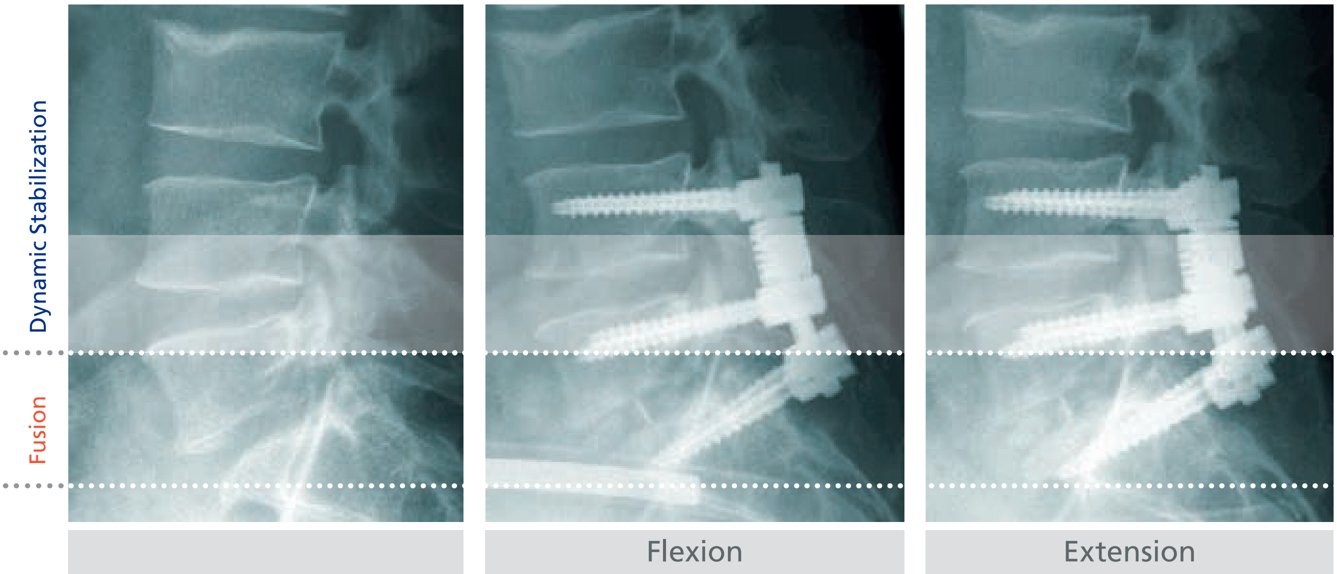
Final Tightening of the Set Screws

- **Important:** The torque wrench must be applied in order to finally tighten the screws with a torque of 11 Nm
- Utilize the torque wrench together with the counter torque handle for final tightening of set screws



INDICATION

The *HPS*™ Hybrid Performance System is indicated for skeletally mature patients with degenerative disc disease (DDD) or for painful segmental degeneration of the disc and/or facet joints. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.



Fusion

Use of the fusion components are indicated for monosegmental or multisegemental stabilization of the thoracic and lumbar spine for supporting fusion. Fusion may be necessary due to:

- Degenerative instability
- Pseudarthrosis / delayed union
- Post-discectomy syndrome
- Spondylolisthesis
- Degenerative lumbar scoliosis
- Lumbar spinal canal stenosis
- Fracture
- Tumor
- Long idiopathic or congenital deformities

Dynamic Stabilization

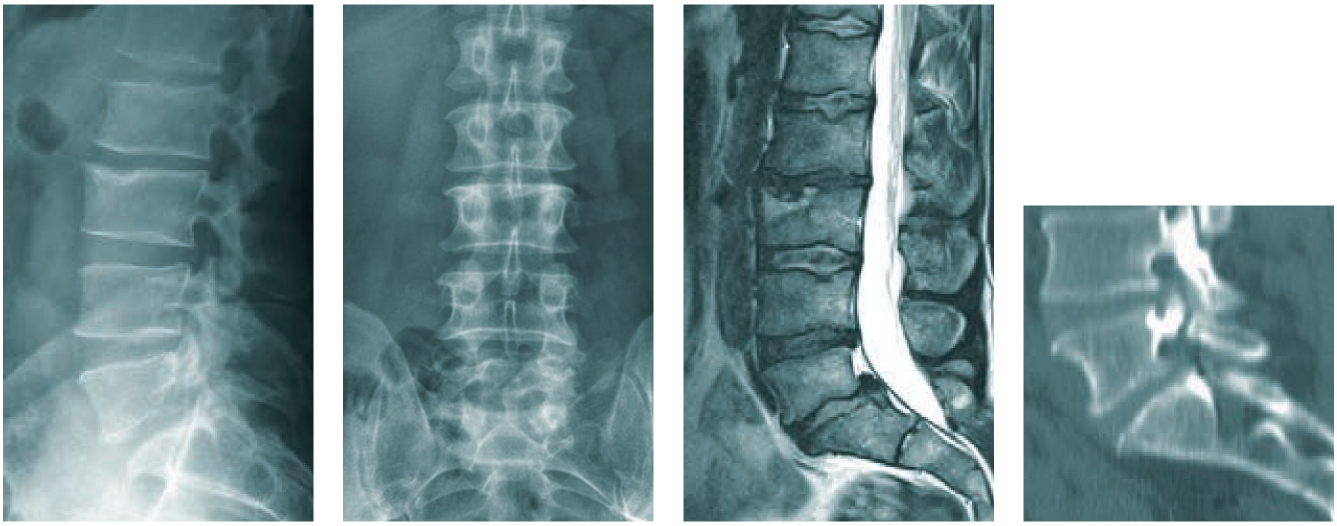
The use of the dynamic coupler is indicated for segmental degeneration or minor segmental instability (disc and/or facet joints) including grade 1 spondylolisthesis.

PATIENT CASES

Case 1:

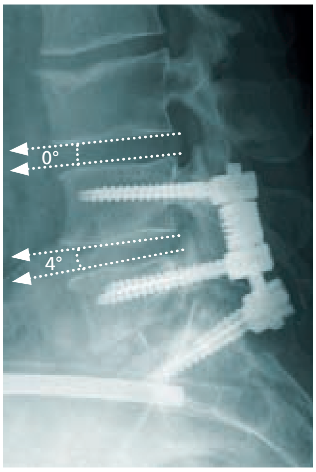
Male, 39 Years

- **Symptoms:** Back pain for several years with occasional leg pain in both legs. No improvement of symptoms after conservative therapy.
  Preoperative: VAS back pain 7, VAS leg pain 5.6.
- **Diagnosis:** Isthmic Spondylolisthesis L5/S1 with spondylolysis L5, black disc L4/5, Spondylosis L2/3.
- **Surgery:** Dynamic stabilization with the ***HPS*™** coupler L4/5 and fusion in L5/S1 with additional implantation of an interbody cage in L5/S1.
- **Follow up examination 1 year post op:** Patient is very happy with the result. Totally regressed leg pain. VAS back pain 2. Radiologically no signs of a progredient degeneration of the adjacent segment L3/4 with a segmental RoM of 8°. The dynamically treated segment L4/5 still has a RoM of about 50% (4°).

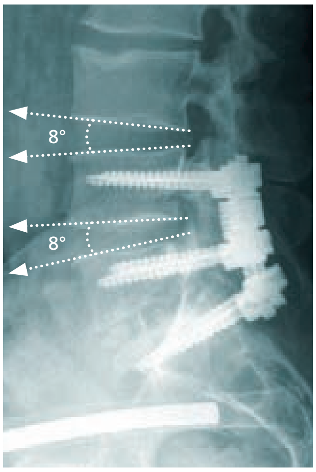


Pre-OP

Post-OP



Flexion



Extension

Case 2:

Female, 48 Years

- **History:** L4/5 decompression and PLIF for spinal canal stenosis and Grade 1 degenerative spondylolisthesis

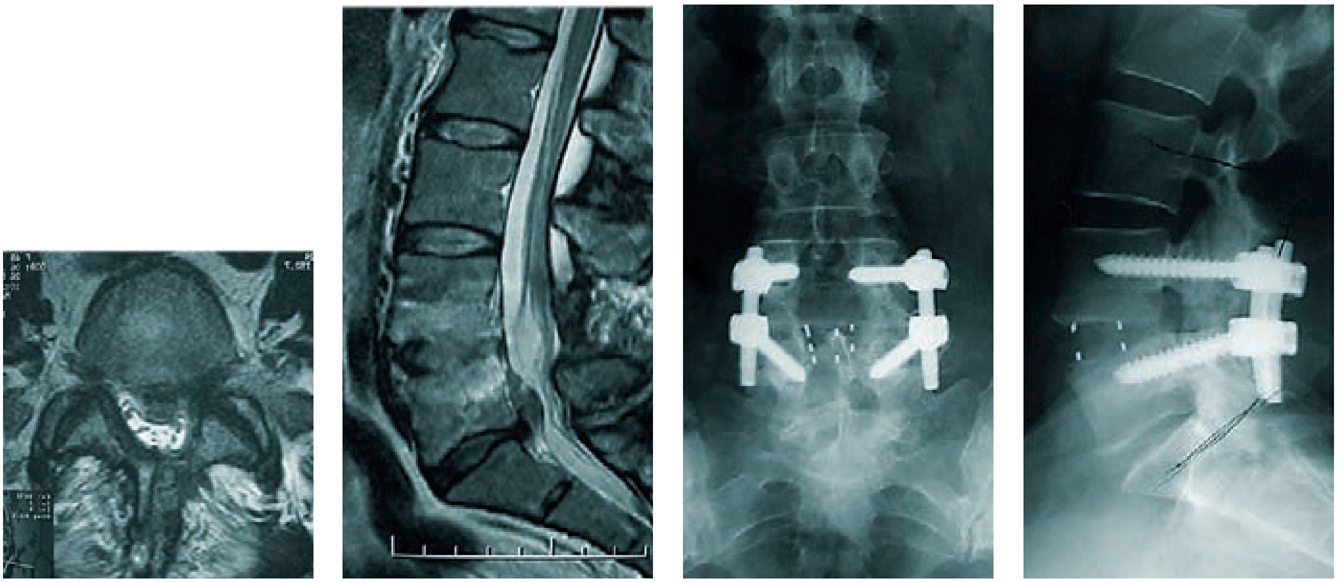
  L5/S1 microdiscectomy for new L5/S1 disc herniation with low back pain and right sciatica

  Recurrent L5/S1 disc herniation with recurrent pain

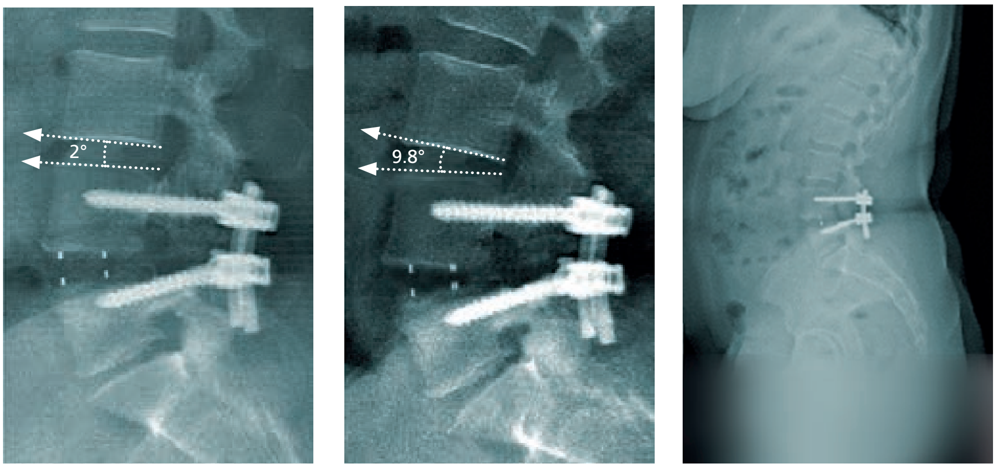
- **Surgery:** L5/S1 discectomy, PLIF and insertion of HPS™ dynamic coupler at the level of L3/4

- **Pain scores Pre-OP:**
  VAS (back pain): 51/100
  VAS (leg pain): 53/100
  Oswestry Disability Index score (ODI): 44
  SF-36 PCS: 45

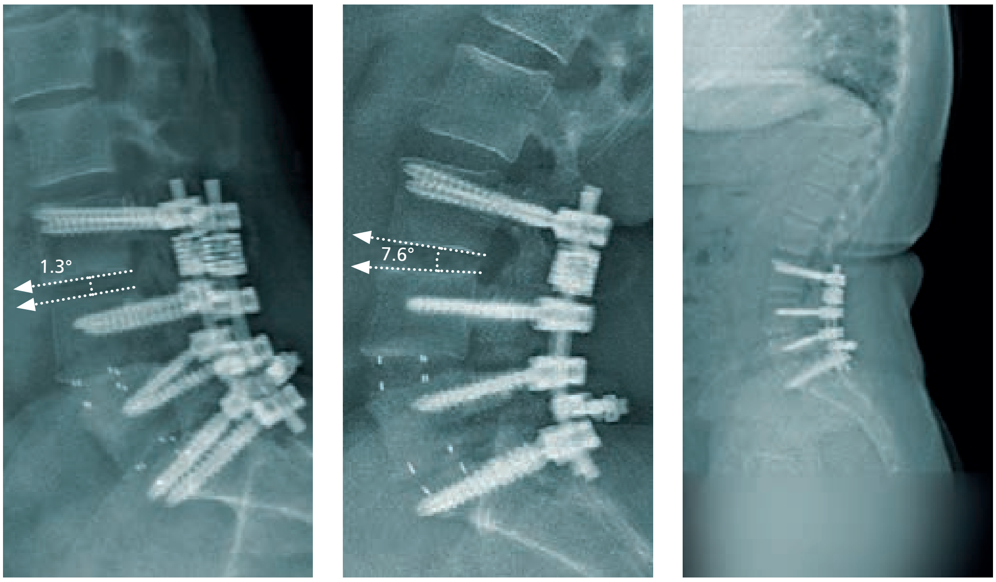
- **At 13 months follow-up, patient remains well. X-rays show satisfactory coupler function.**
  VAS back and leg pain scores: 5/100
  ODI: 0
  SF-36 PCS: 59



X-ray and MRI, Pre-OP



Pre-OP



13 months Post-OP

HPS™ – IMPLANTS

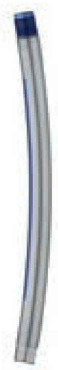
HPS™ – Polyaxial Pedicle Screw
includes 2 Polyaxial pedicle screws and 2 Set screws

Length	Ø 5 mm	Ø 6 mm	Ø 7 mm	Ø 8 mm	Ø 9 mm
35 mm	HAI85035	HAI86035	HAI87035	–	–
40 mm	HAI85040	HAI86040	HAI87040	HAI88040	HAI89040
45 mm	HAI85045	HAI86045	HAI87045	HAI88045	HAI89045
50 mm	HAI85050	HAI86050	HAI87050	HAI88050	HAI89050
55 mm	–	HAI86055	HAI87055	HAI88055	HAI89055
60 mm	–	–	HAI87060	HAI88060	–

HPS™ – Monoaxial Pedicle Screw
includes 2 Monoaxial pedicle screws and 2 Sets screws

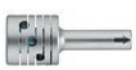
Length	Ø 6 mm	Ø 7 mm	Ø 8 mm
35 mm	-	HAI67035	-
40 mm	HAI66040	HAI67040	HAI68040
45 mm	HAI66045	HAI67045	HAI68045
50 mm	HAI66050	HAI67050	HAI68050
55 mm	HAI66055	HAI67055	HAI68055

HPS™ – Rod
includes 2 ø 5.5mm Rods



Pre-bent Rods	
40 mm	HAI93004
50 mm	HAI93005
60 mm	HAI93006
70 mm	HAI93007
80 mm	HAI93008
110 mm	HAI93011
Straight Rods	
150 mm	HAI91015
300 mm	HAI91030

HPS™ – Dynamic Coupler
includes 1 dynamic coupler

	Dynamic Coupler, S=25N/mm, L=25mm	HAI92525
	Dynamic Coupler, S=50N/mm, L=50mm	HAI95525

HPS™ – Polyaxial Pedicle Screw with Porous Titanium Coating
includes 2 Polyaxial pedicle screws and 2 Set screws

Length	Ø 6 mm	Ø 7 mm
45 mm	HFI86045	HFI87045
50 mm	HFI86050	HFI87050
55 mm	–	HFI87055

Biocompatibility

All *DSS-HPS™*-Implants consist of Titanium 6-Aluminium 4-Vanadium (ISO 5832-3).

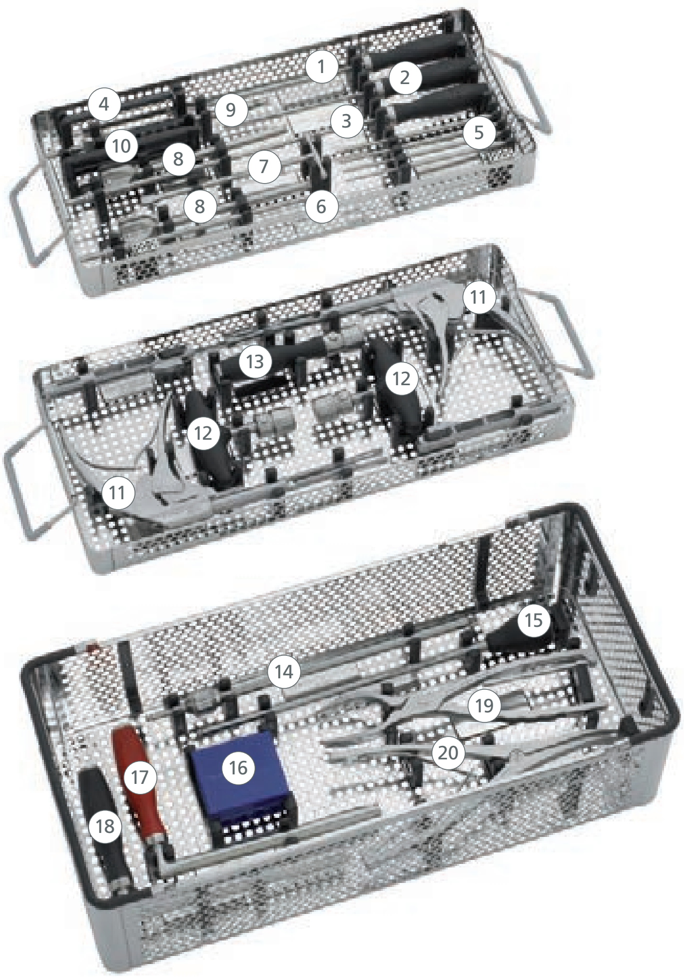
MRT

Titanium is a non-ferromagnetic material, therefore magnetic resonance imaging can be done.

Traceability

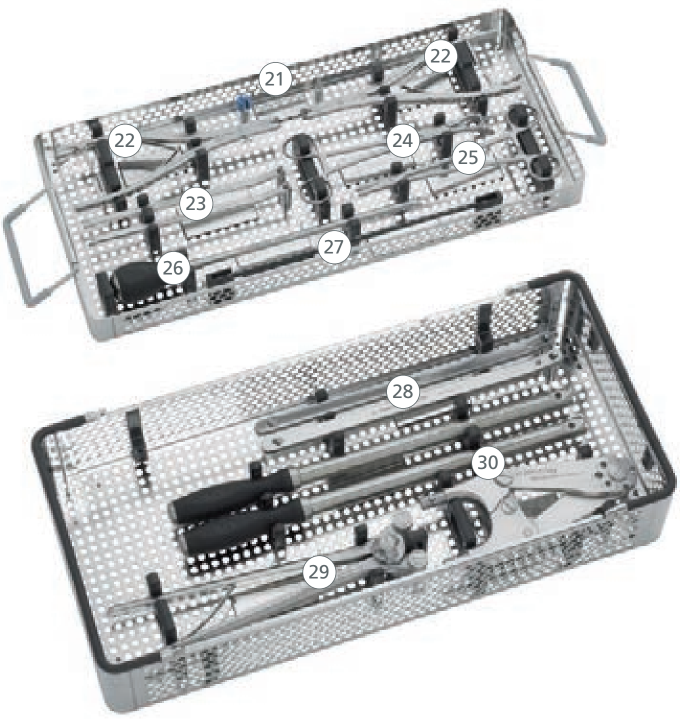
All *HPS™*-Implants are delivered sterile packed.

HPS™ – INSTRUMENTS



Container 1

1. Trocar
2. Awl
3. Dissector
4. Pedicle probe
5. Tap, 5 mm – 9 mm
6. K-wire
7. Aligner
8. Screwdriver, polyaxial
9. Screwdriver, monoaxial (optional)
10. Rotation sleeve
11. Persuader
12. T-handle
13. Handle, straight
14. Torque wrench
15. Nut inserter
16. Screw template
17. Counter torque
18. Counter torque rod-rod
19. Compressor
20. Distractor



Container 2

21. Coupler template
22. Vice grip
23. Ring wrench
24. Rocker
25. Rod holder
26. Rod pusher
27. Rod template
28. Bending tool
29. Bending pliers
30. Rod cutter

HAM00001 Rev. E

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Product not available in the USA