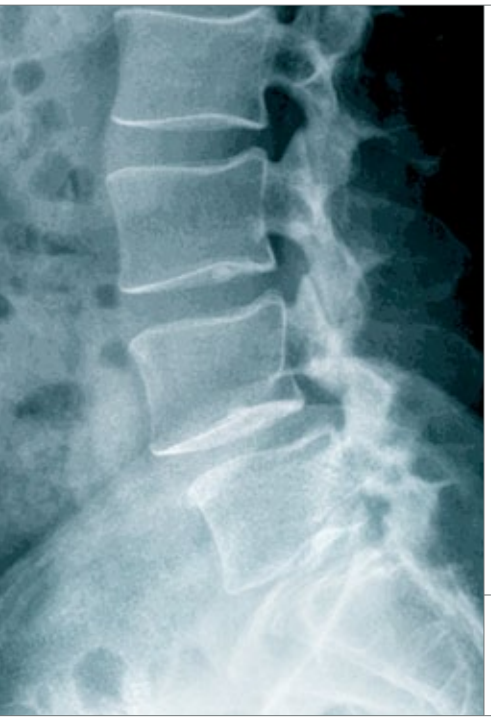
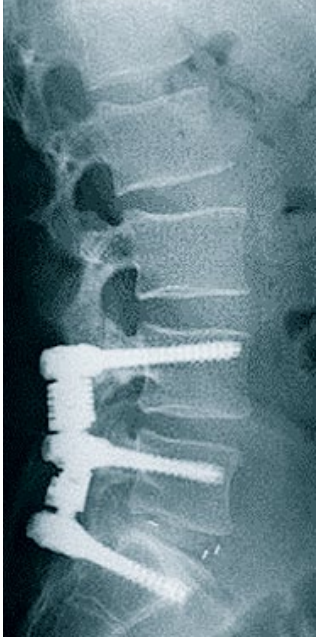
PARADIGM SPINE

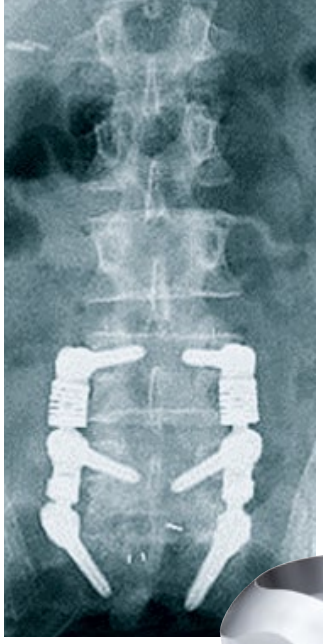
the movement in spine care

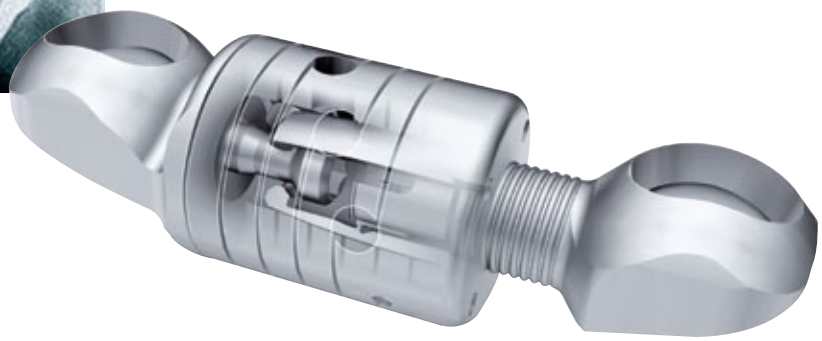


Dynamic Stabilization System DSS™

Lumbar Dynamic Stabilization







Dynamic St

DSS™

The basic concept of the DSS system was developed in cooperation with the Institute of Orthopedic Research and Biomechanics of the University of Ulm.

The goal was the development of a dynamic connector that reduces the natural range of motion (ROM) by approximately 50% whilst maintaining the physiological center of rotation.

To maintain physiological kinematics length adaptation under flexion / extension movements is mandatory. Based on a validated Finite Element model of a lumbar spinal segment , the mechanics of the dynamic coupler was developed and confirmed in a biomechanical experiment. The results were published in SPINE by Prof. Wilke.*

The DSS system was launched in 2008 after 2 years of development.

The product obtained FDA approval in 2009.
In contrast to the 1st generation dynamic systems, the DSS system has following features:

- Controlled movement of the dynamic coupler
- Combination of fusion and dynamic stabilization
- Controlled dynamic stabilization of hypermobile segments while effectively protecting adjacent levels above and below fusion
- Restoration of physiological center of rotation
- Shock absorption; axial compression
- Control of rotation and stress reduction on facet joints
- Significant reduction of shear forces

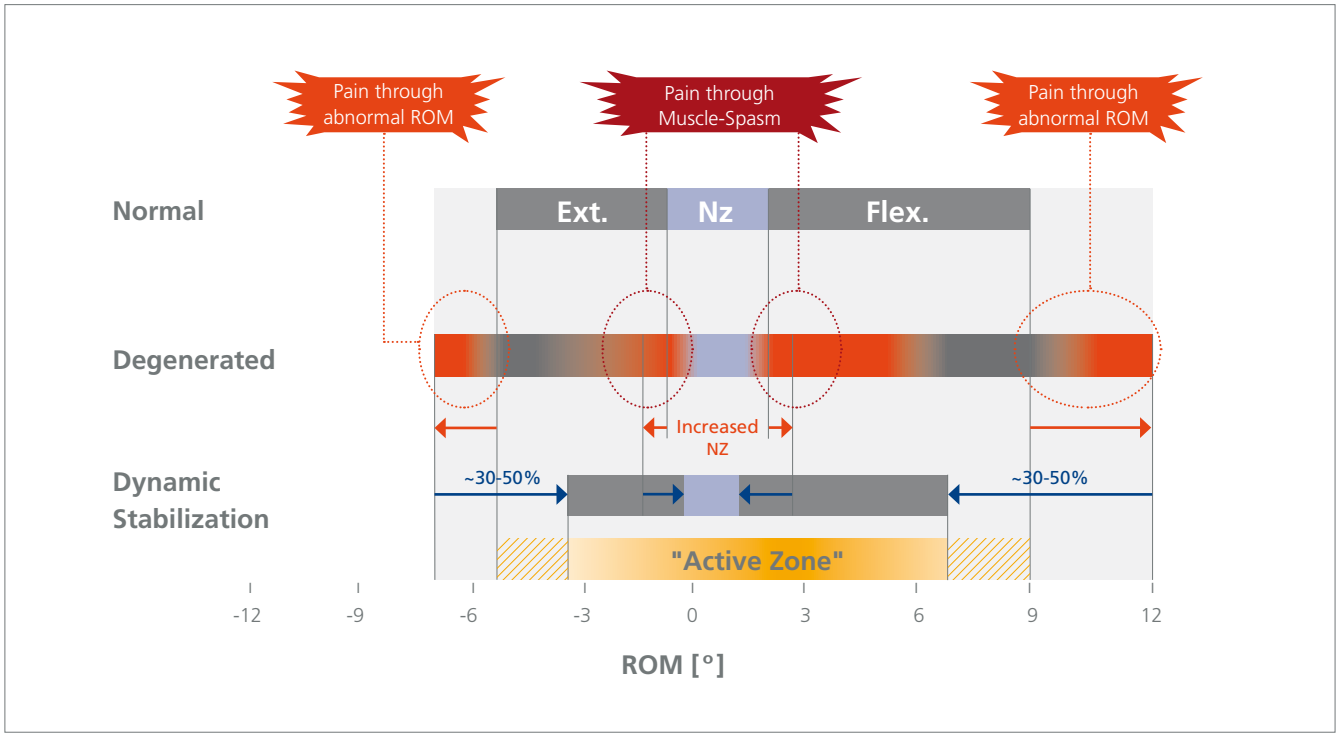
* *Prof.H-J. Wilke, Frank Heuer, PhD, Hendrik Schmidt, PhD*
2009, Prospective Design Delineation and Subsequent In Vitro Evaluation of a New Posterior Dynamic Stabilization System, SPINE Volume 34, Number 3, pp 255–261, Institut für Orthopädische Forschung und Biomechanik, Ulm, Deutschland

Next generation dynamic stabilization

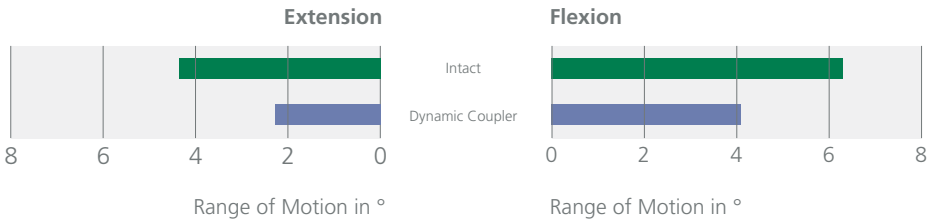
Progressive degeneration of a spinal motion segment leads to an increase of the range of motion in flexion / extension, lateral bending and rotation. The neutral zone is increased as well. Hypermobility causes back pain and muscle spasms.
The DSS system achieves effective stabilization by reducing the segmental mobility (by the stiffness of the coupler), as well as significant reduction of rotational and translational movements (protection of the facet joints).
Extreme segmental movements are eliminated. The range of motion is limited to an "active zone".

In cooperation with different anatomical institutes Paradigm Spines offers DSS training courses focusing on the paraspinal approach. Clinical visits in various reference centers are also possible.
For scientific documentation an internet-based registry is available, that allows for easy documentation of patient data and allows easy evaluation and exportation of charts and graphics for PowerPoint presentations, patient conversations or publications.

abilization

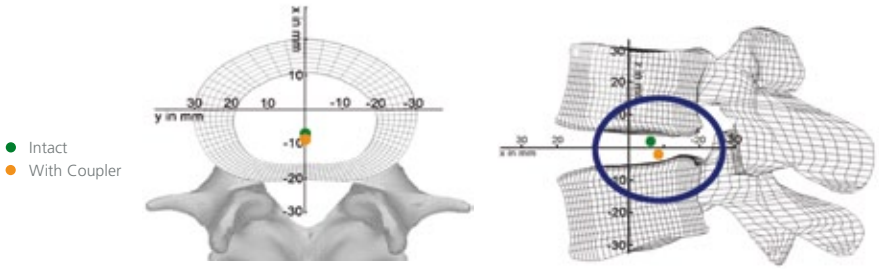


Reduction of Range of Motion [1]



The coupler stiffness reduces the range of motion in the lumbar spine.

Maintenance of Center of Rotation [2]

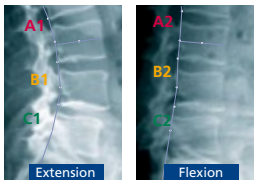


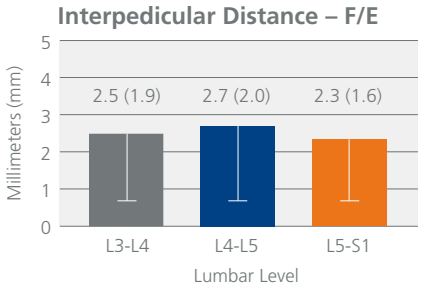
- The inner pin/sleeve mechanism allows 2mm displacement.
- In combination with the coupler design the natural center of rotation is maintained.

Pedicle Displacement [2]

Methods

Radiographic Measurement Technique
for Interpedicular Distance:
DF – DE = Δ (mm, MEC)



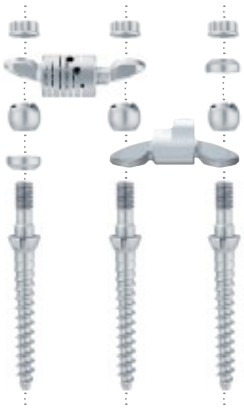


- Inner coupler mechanism allows 2mm pedicle displacement to maintain natural center of rotation.
- Non-physiological motion is limited.
- Hypermobility at the end range of motion (flexion and extension) is avoided.
- Coupler mechanism is overload protected.

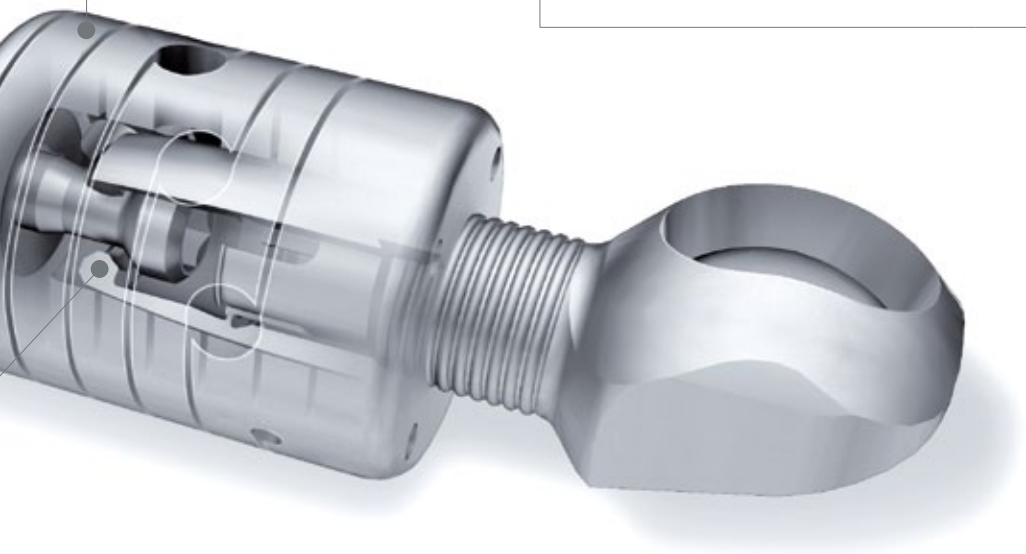
1. *Prof.H-J. Wilke, Frank Heuer, PhD, Hendrik Schmidt, PhD*
2009, Prospective Design Delineation and Subsequent In Vitro Evaluation of a New Posterior Dynamic Stabilization System, SPINE Volume 34, Number 3, pp 255–261, Institut für Orthopädische Forschung und Biomechanik, Ulm, Deutschland

2. *Bryan W. Cunningham, MSc, Dennis Colleran, BS, Gwen E. Holsapple, BS, Karen A. Adams, BS, Paul McAfee, MD (2006): Lumbar Spine Kinematics – a Radiographic Assessment of the Change in Interpedicular Distance throughout the Range of Motion. SAS 6 Global Symposium on Motion Preservation Technology, Montreal. Orthopaedic Spinal Research Laboratory, St. Joseph Medical Center, Towson, Maryland, USA.*

Modular Design



Modularity of the system allows combination of fusion and dynamic (hybrid) solutions. Polyaxial positioning of +/- 14° possible through the coupler-spacer interface.



Biomechanic

Stabilization

Pain Relief
- Controlled dynamic stabilization of hypermobile segments
- Restoration of physiological center of rotation
- Shock absorption; axial compression
- Control of rotation and stress reduction on facet joints

Hybrid Solutions
- Modularity of system allows combination of fusion and dynamic stabilization
- Adjacent levels are effectively protected

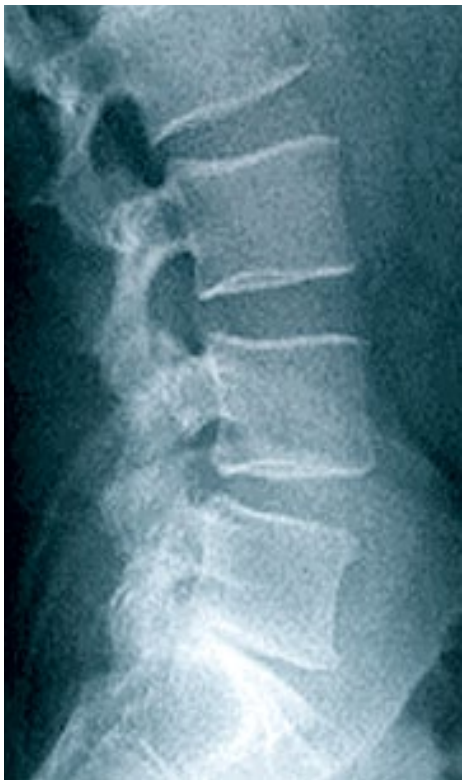
Ease of Use
- Cannulated screws support minimally invasive application
- Paraspinal muscle splitting technique minimizes iatrogenic trauma
- Easy to use instrumentation

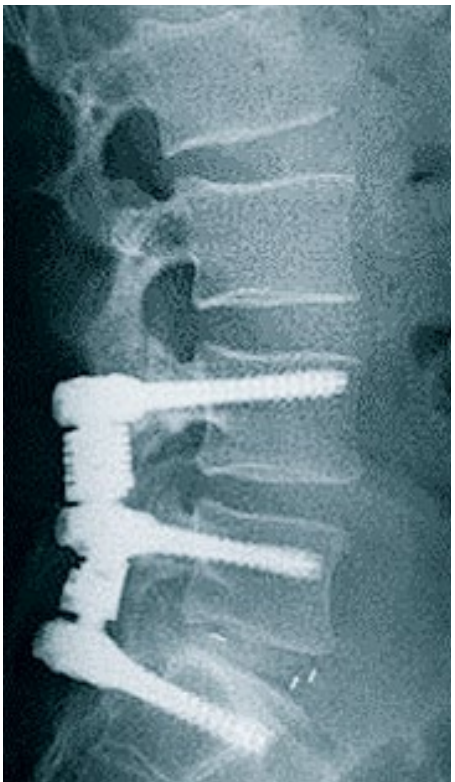
DSS™ Implant – Indications

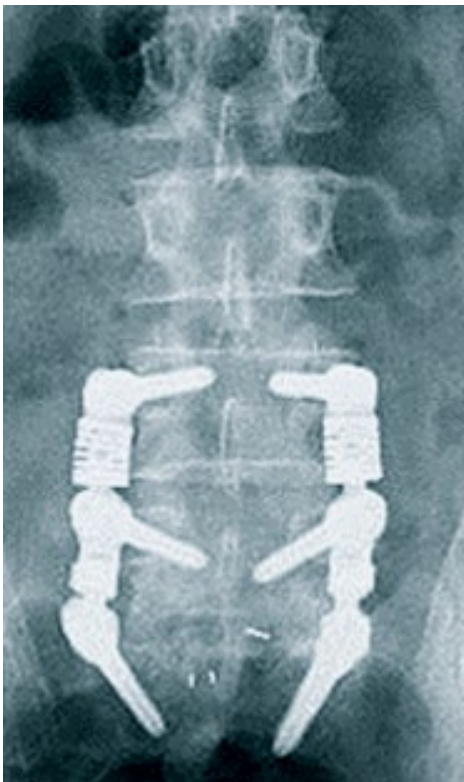
- The DSS system is indicated for skeletally mature patients with degenerative disc disease (DDD) at one to three levels from L1 to S1, including conditions up to grade 1 spondylolisthesis.

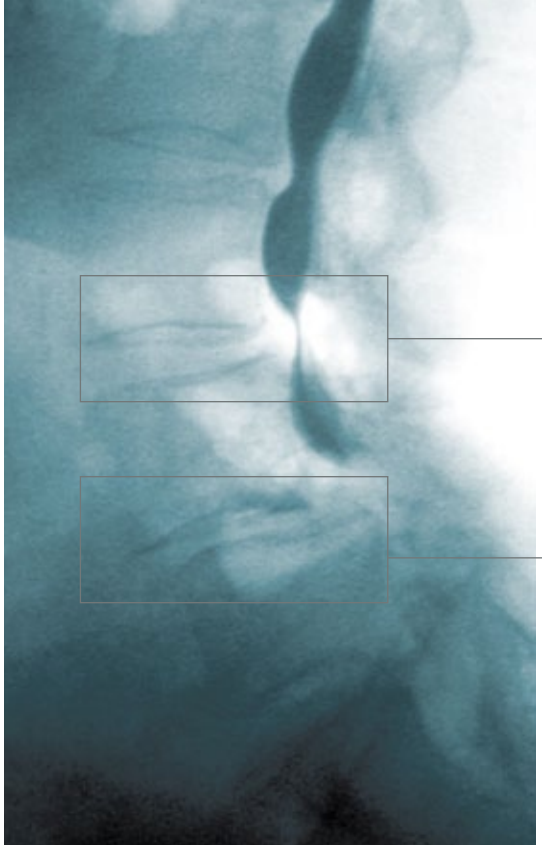
- DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies, e.g.:
  · Segmental sagittal hypermobility
  · Position of segment in X-Ray (Standing Position)
  · Disc height (Black Disc)
  · Modic signs (MRT)
  · Painful degeneration of facet (positive infiltration)
  · Painfree response from segmental epidural injection

Modular









Semi-rigid stabilization + Fusion

Fusion

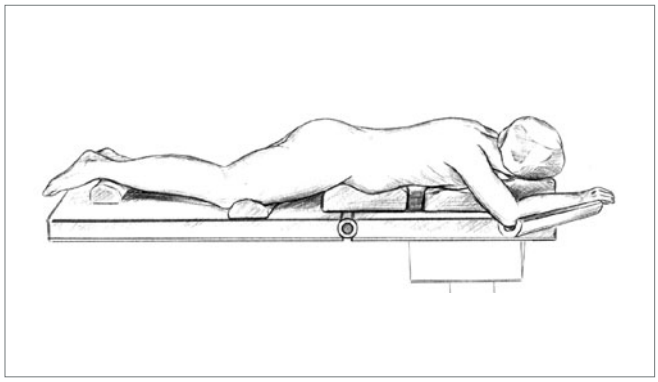
System DSS™

Modular System

- Modularity of system allows combination of fusion and dynamic stabilization.
- Pathologies can be addressed individually by motion segment.
- Adjacent segments are protected.

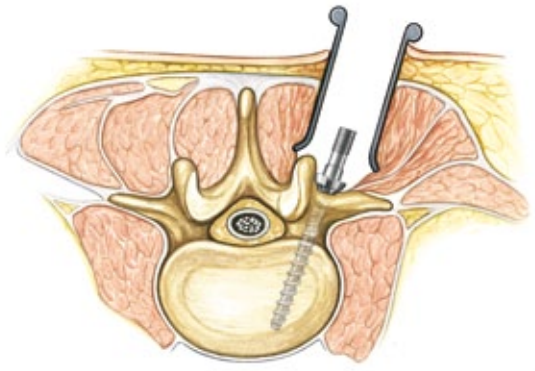
1. Patient Positioning

- The patient is placed in neutral position.



2. Paraspinal Intermuscular Approach

- Intermuscular approach between multifidus and longissimus muscle (along the fascia).
- Cannulated screws in combination with K-wires support minimally invasive, tissue-sparing application.



3. Pedicle Preparation

- After standard skin incision via a midline or bilateral paramedial approach the pedicles are exposed and the pedicle entry point is marked under X-ray control using the pedicle awl.
- This awl opens the cortical bone and creates an initial hole in the pedicle as a starting point for further pedicle exploration and drilling.

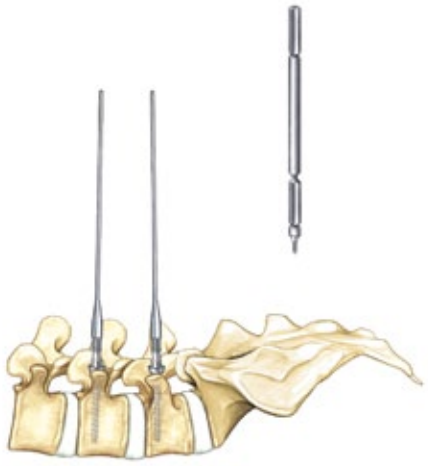
DSS™

4. Screw Insertion

- Cannulated, ratcheting T-Handle connects to self-capturing Pedicle Screw Inserter.
- Facilitates rapid and safe screw insertion.
- Screw held securely - control during insertion.
- Cannulated screws in combination with K-wires support minimally invasive, tissue-sparing application.

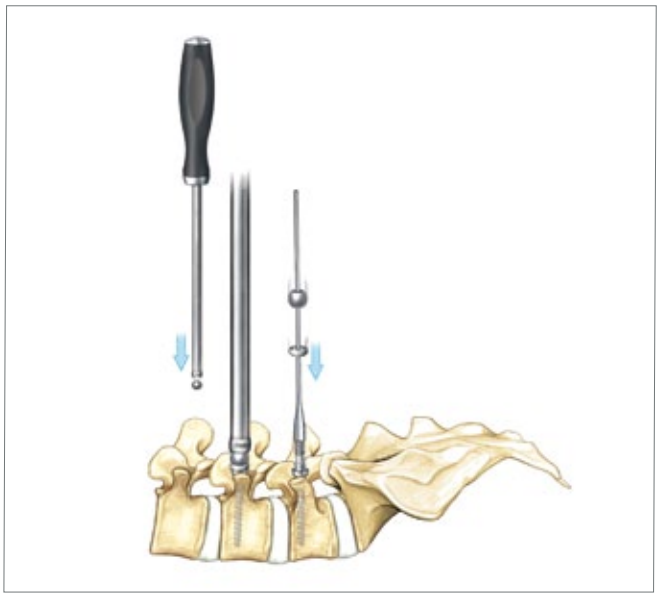
5. Pedicle Screw Implant Guide

- Securely fixed to screws facilitate implant delivery for true MIS benefits.
- The Extension Rod (DAT40410) has a predetermined breaking point.



6. Delivery of Spacers and Washers over the Implant Guides

- The spacers and washers are delivered over the implant guides.
- The pusher slides over the implant guides.

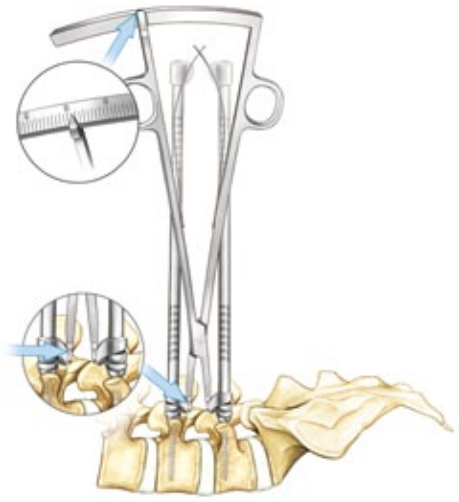


7. Caliper Adapters

- Depending on the desired coupler position (high or low assembly) the caliper adapters are attached over the extension rods.

8. Measuring

- The caliper measures the distance between the caliper adapters to determine the exact coupler length.
- Caliper adapters face one another.
- Caliper is positioned between adapters and allowed to expand.
- Exact coupler length is read on graduated scale.



9. Coupler Selection

- Choose appropriate coupler according to caliper measurements.
- Adjust coupler length using the Coupler Length Adjuster.
- Note: one full turn represents 0.5mm length change.

10. Coupler Positioning

- The coupler pusher seats the coupler onto the construct.
- In the low assembly the spacer is used to maintain the coupler in place.
- Compression and distraction Instruments may be utilized to bring the slotted Coupler down.

DSS™

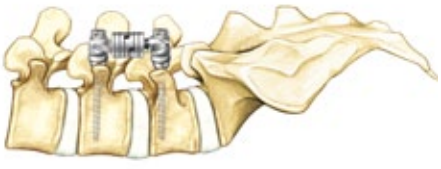
11. Nut Placement

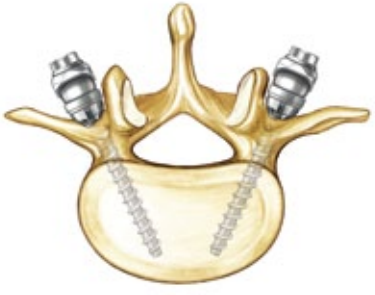
- Slide breaking nut over the extension rod (shorter side down) and pre-tighten nuts using the nut driver.
- During nut tightening the retaining forceps slotted coupler or the retaining forceps rigid coupler should be utilized.
- Pre-tighten nuts using the nut driver.

12. Breaking Nuts and Final Tightening

- Ratchet goes on top of the nut driver.
- The upper part of the nut breaks off at a safety torque of 12 Nm.
- Final nut tightening using the nut driver and the counter torque instrument.
- Care has to be taken to keep the dynamic coupler aligned during tightening.

13. Final Position

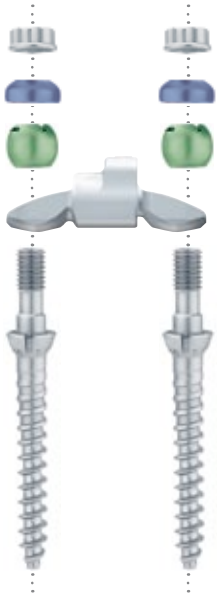




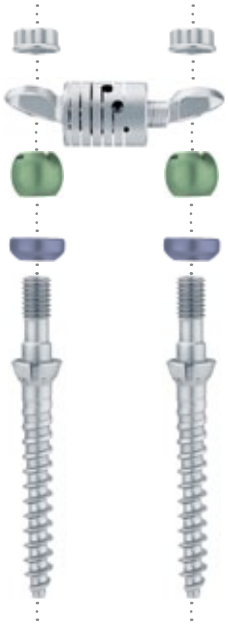
Assembly

DSS™

Monosegmental

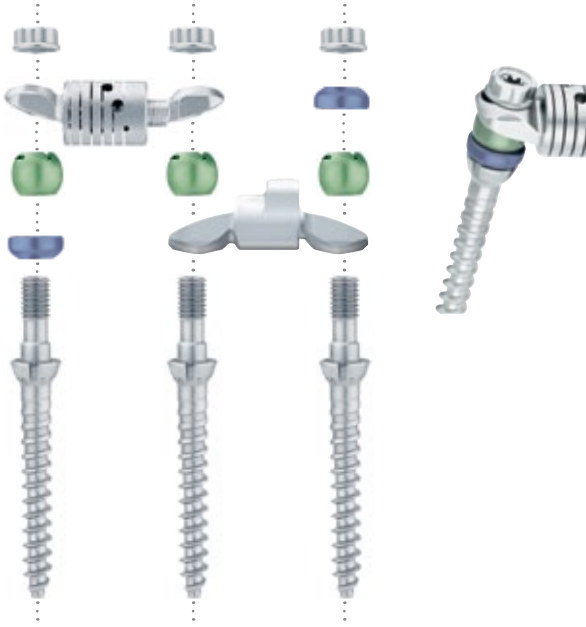


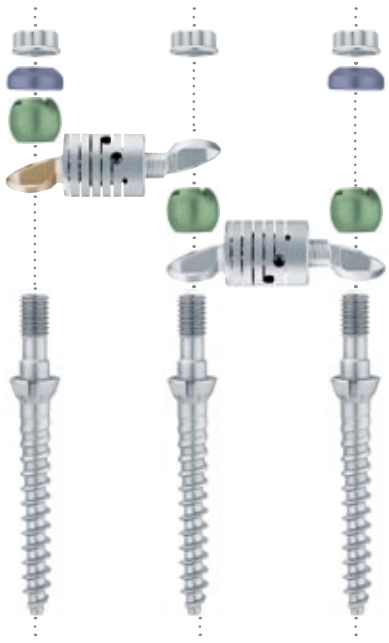
Breaking Nut
Washer
Spacer
Fusion Coupler
Pedicle Screw



Breaking Nut
Dynamic Coupler
Washer
Spacer
Pedicle Screw

Bisegmental

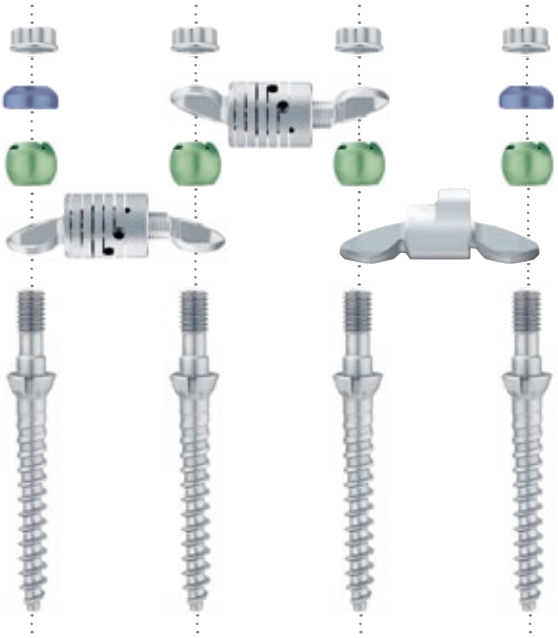




Instructions

Three Level

Washers („blue“) are placed at the end points of assembly. Note: If a hybrid construct is assembled, the fusion coupler has to be placed first.



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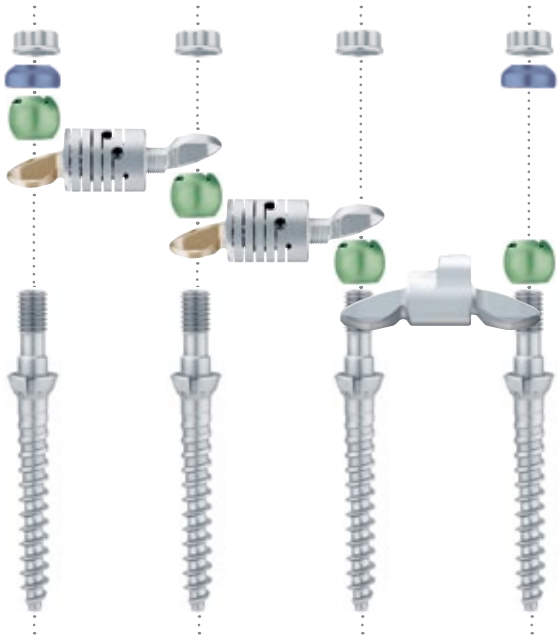
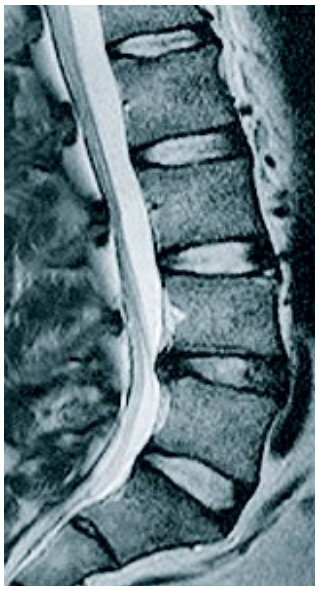
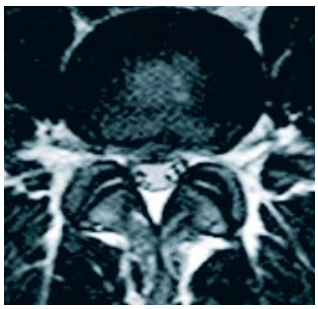


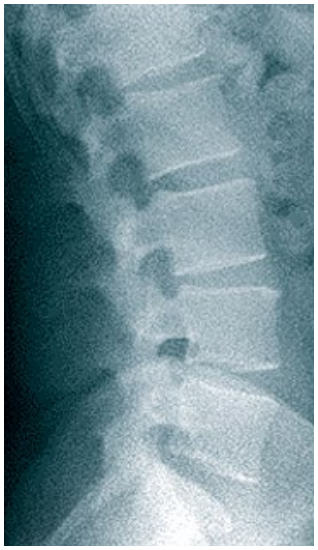
Patient Cases

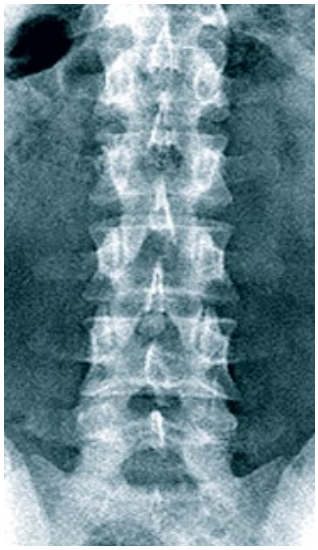
DSS™



Preoperative



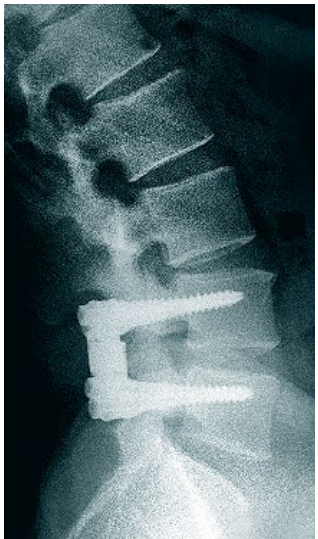


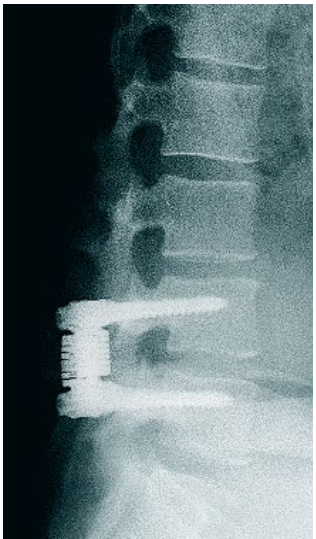


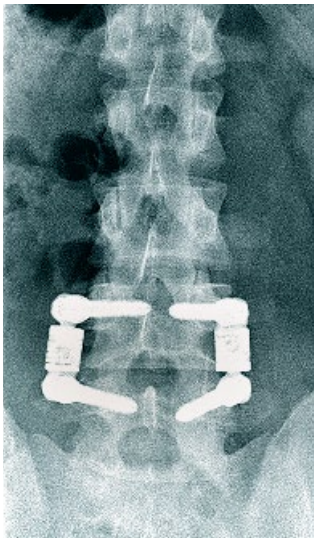
Case 1:
Male, 38 years

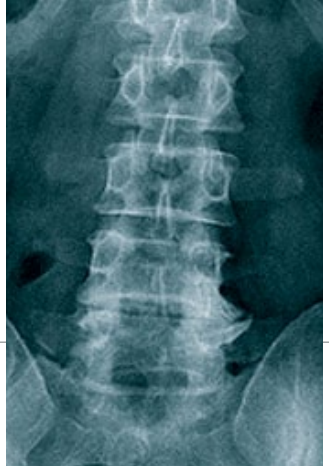
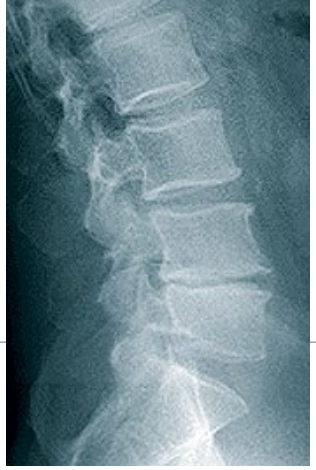
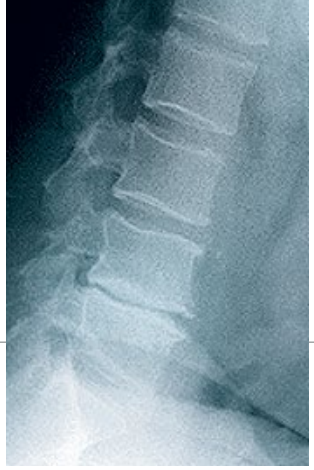
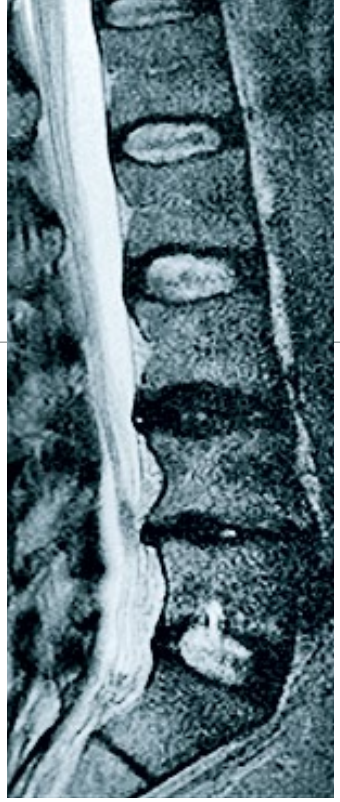
- Low back pain for 8 years with occasional leg pain while walking. ODI 64%, VAS back pain 7 and leg pain 3.
- Diagnosis: Chronic lumbago with DDD and medial protrusion.
- Previous therapy: Failed conservative treatment including facet infiltration.
- Surgery: Dynamic stabilization with DSS™ at level L4/5.
- Follow-up after 6 months: Reduction of ODI to 25% and improvement of VAS back pain 3 and leg pain 1.

Postoperative

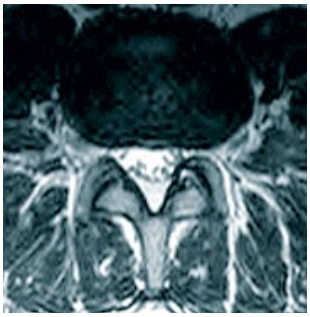
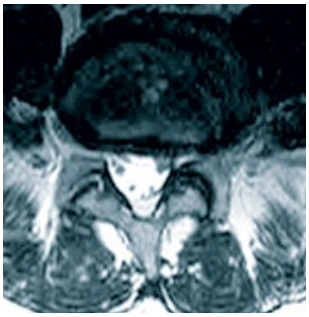






Preoperative

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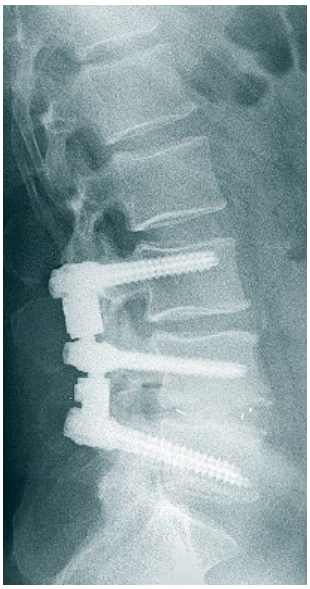
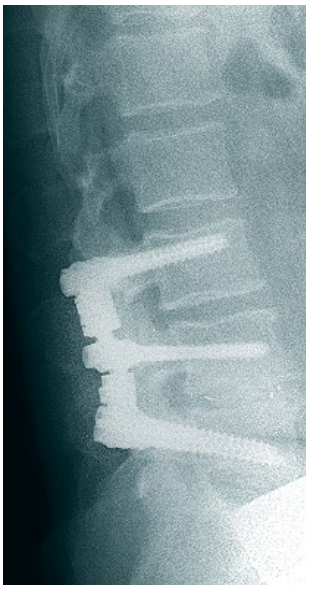
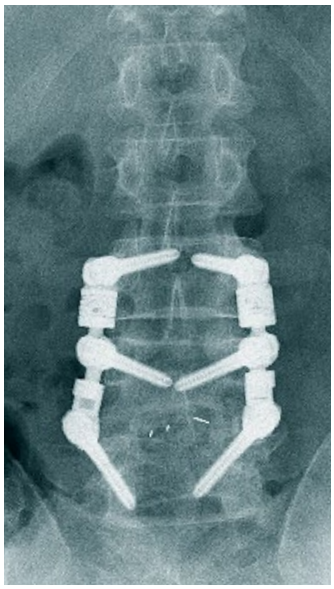




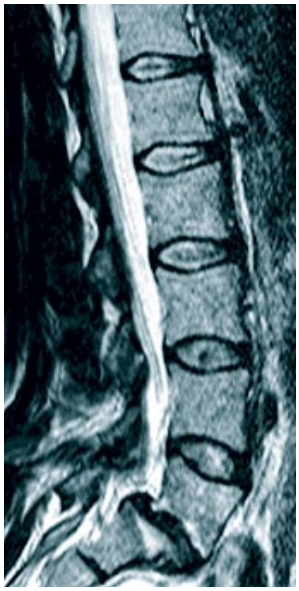
Case 2:
Male, 52 years

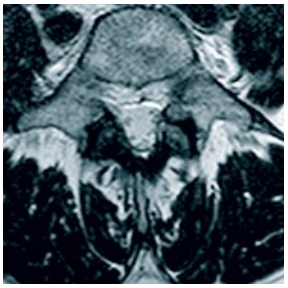
- Low back pain for 6 years. ODI 63%, VAS back pain 7 and leg pain 3.
- Diagnosis: Severe DDD with rotational instability at level of L4/5, osteophytes left as signs for rotational instability and initial degeneration in L3/4 with hypermobility.
- Previous therapy: Failed conservative therapy for 5 years with constant pain medication. Since two years physiotherapy without improvement of symptoms.
- Surgery: Dynamic stabilization with DSS™ at level L3/4 and fusion at level L4/5 with additional implantation of TLIF at L4/5.
- Follow-up after 6 weeks out: Reduction of ODI to 34% and improvement of VAS back pain 4 and leg pain 1.

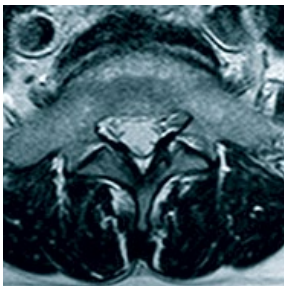
Patient Cases

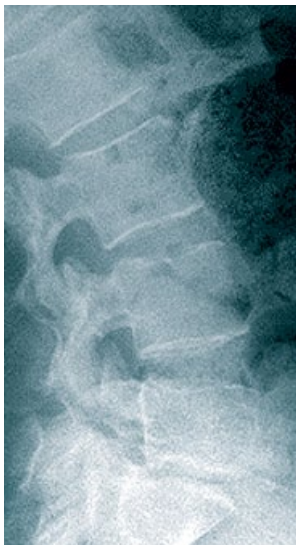
DSS™

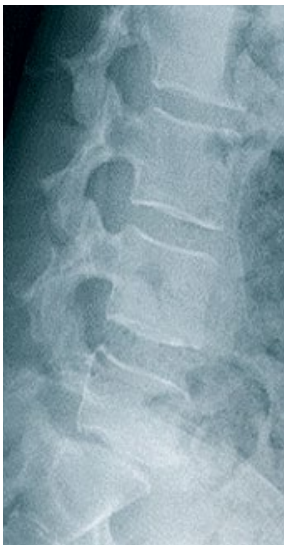
Preoperative







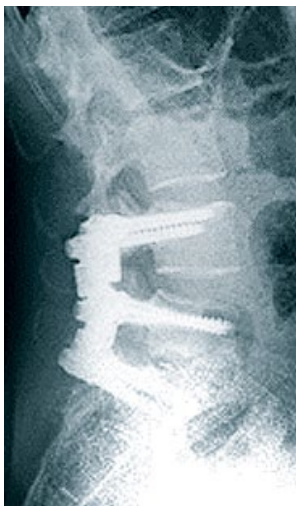


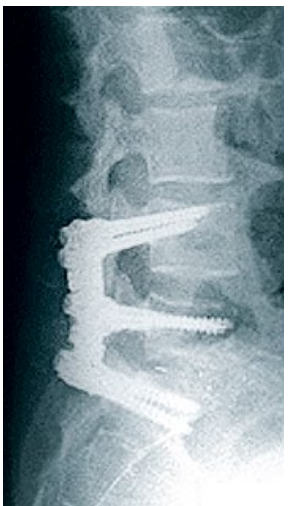


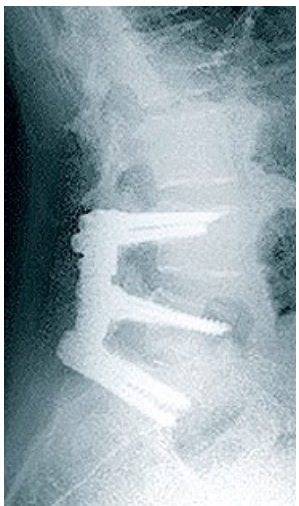
Case 3:
Female, 52 years

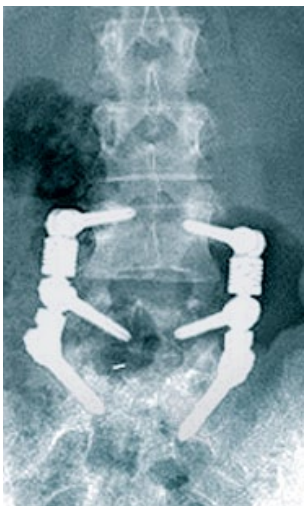
- Low back pain for many years during standing and walking, virtually no physical activity possible through back pain. ODI 66%, VAS back pain 7 and leg pain 4.
- Diagnosis: Isthmic spondylolisthesis L5/S1, facet arthrosis L4/5 grade 3 (Fujiwara) and functional retrolisthesis L4/5.
- Previous therapy: Failed conservative treatment including continuous physiotherapy for 5 years. Constant pain medication according to WHO1 classification for 3 years.
- Surgery: Dynamic stabilization with DSS™ at level L4/5 and fusion at level L5/S1 with additional implantation of TLIF at L5/S1.
- Follow up: Full reduction and normalization on L4/5, L5/S1. Direct postop drop of back pain to VAS 5. After 6 months VAS back pain 3 and no leg pain.

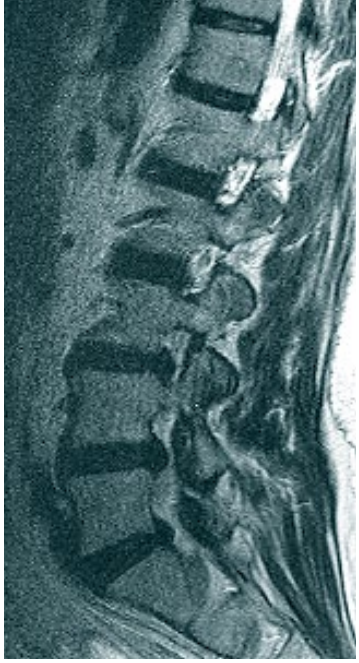
Postoperative

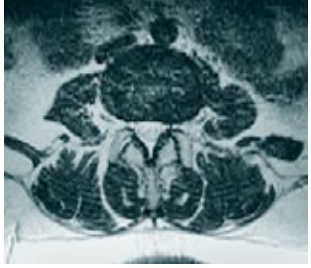


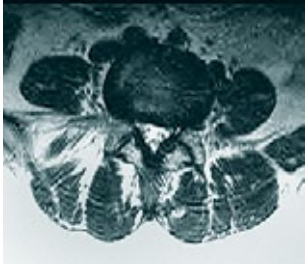


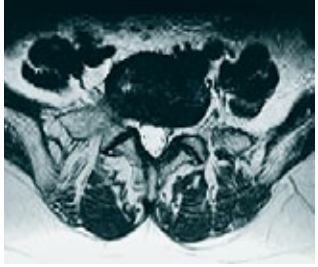




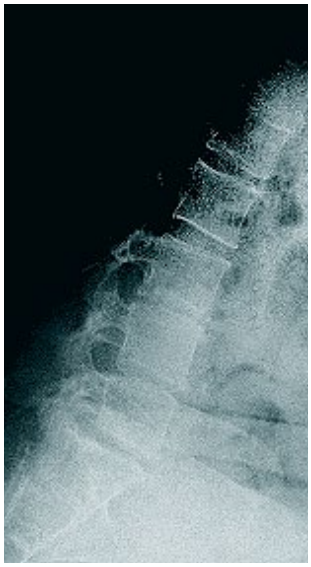


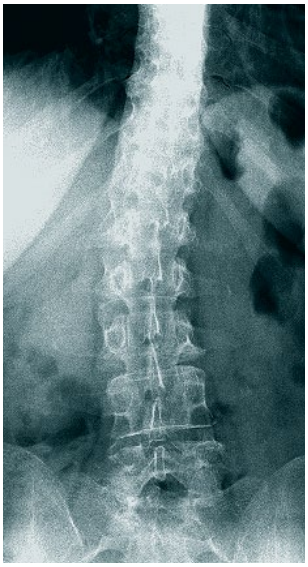


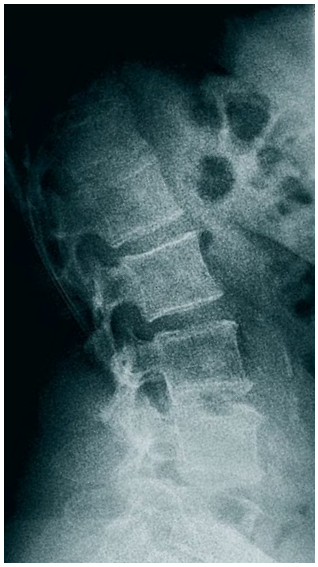




Preoperative



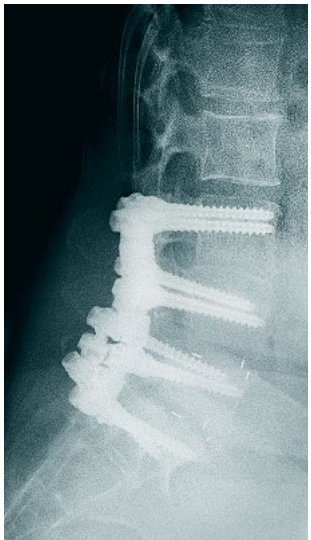


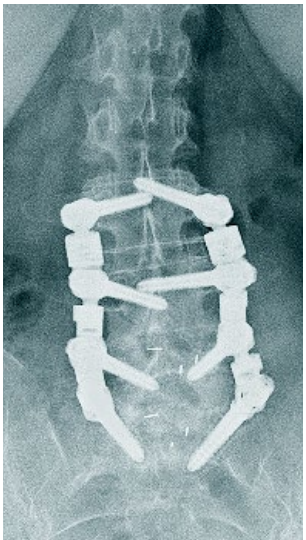


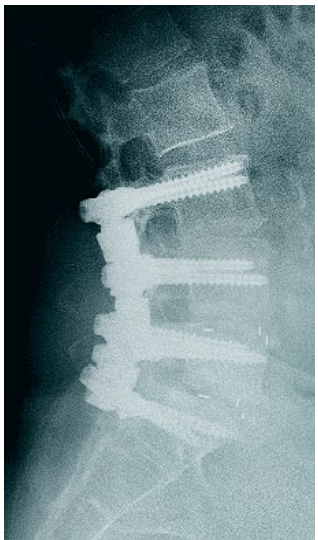
Case 4:
Female, 64 years

- Low back pain for 10 years with occasional pseudoradicular leg pain. Walking distance 50m, ODI 68%, VAS back pain 8 and leg pain 5.
- Previous therapy: Failed conservative treatment, disc protrusion L3/4 to L5/S1 with decompression. Spondylarthrosis grade 3 as well as scoliosis
- Surgery: Dynamic stabilization with DSS™ at level L3/4 and fusion at level L4-S1 with additional implantation of TLIF at L4/L5 and L5/S1.
- Follow-up after 6 months: Improvement of back pain from VAS 8 to 4. Walking distance increased to 250m. ODI 38%.
- Follow-up after 18 months: ODI 6%, VAS back pain 2 and leg pain 2.

Postoperative



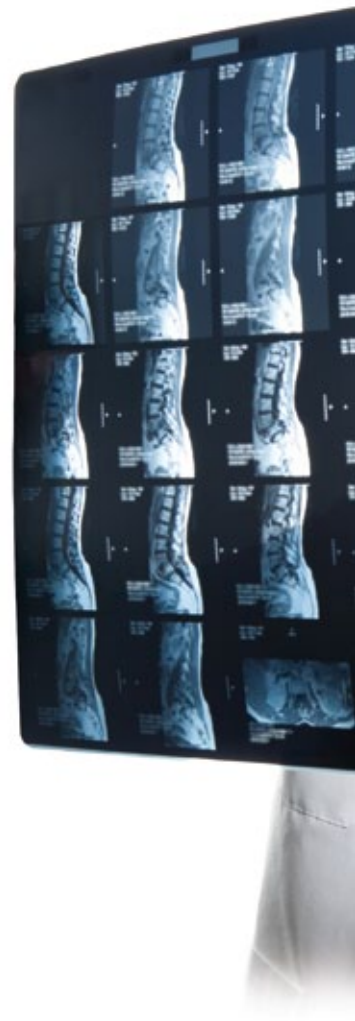




Objective

During the last several years, dynamic stabilization systems in spine surgery have become important clinical options for surgeons and patients. However, there are few long-term studies which present the safety and effectiveness of these new methods in comparison to the gold standard. Randomized clinical studies are often long, very complex and costly.

As an alternative to these studies, Paradigm Spine established a worldwide Registry to support prospective data collection on safety and efficacy of our DSS™ technology.. The data will be documented in the Registry which is available exclusively through Paradigm Spine.



Description

The Paradigm Spine Registry is an internet-based system for patient documentation. Relevant clinical data will be collected and standard reports are possible.

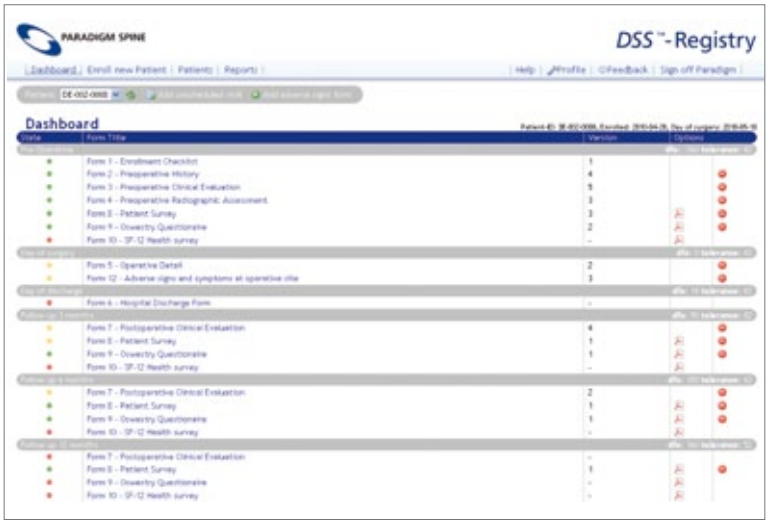
The data entry is conducted online:

- Preoperative forms (clinical and radiographic evaluation)
- Surgery details (diagnosis and treatment)
- Postoperative forms (clinical evaluation, different follow-up intervals are possible)
- Patient forms (VAS and ODI resp. NDI scores, pre- and postoperative)
- Hospital Discharge details (postoperative treatment)

The Registry is available for documenting the DSS™ system and the DCI™ implant.

Paradig

www.para



Reports

The Registry provides several clinical reports. The reports are up to date at any time and can be easily generated via mouse click. Among others, the following reports are available:

- VAS score
- ODI resp. NDI index
- SF-12v2® score

Reports may be generated for a single patient, as well as for all patients of one site. In addition to that a comparison against the entire data of the Registry is possible. The graphs can be easily transferred into various IT programs (e.g. PowerPoint) and used for presentations.

m Spine Registry

digmspine.com/registry

Advantages

The Paradigm Spine Registry offers several benefits to its users:

- Patient documentation online
- Control of clinical results
- Internet-based database, less paperwork
- Platform for studies and user groups
- Fast clinical reports and statistics
- Eases preparation of lectures and podium presentations
- Basis for publications
- Worldwide access

Data Privacy

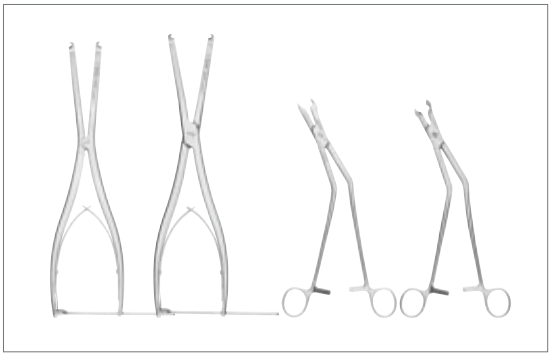
The data privacy regulations have been followed, and all data collection is anonymous. The identification of a patient is only traceable by the surgeon.

Access to the Registry is only available with a separate personal password.

Instruments

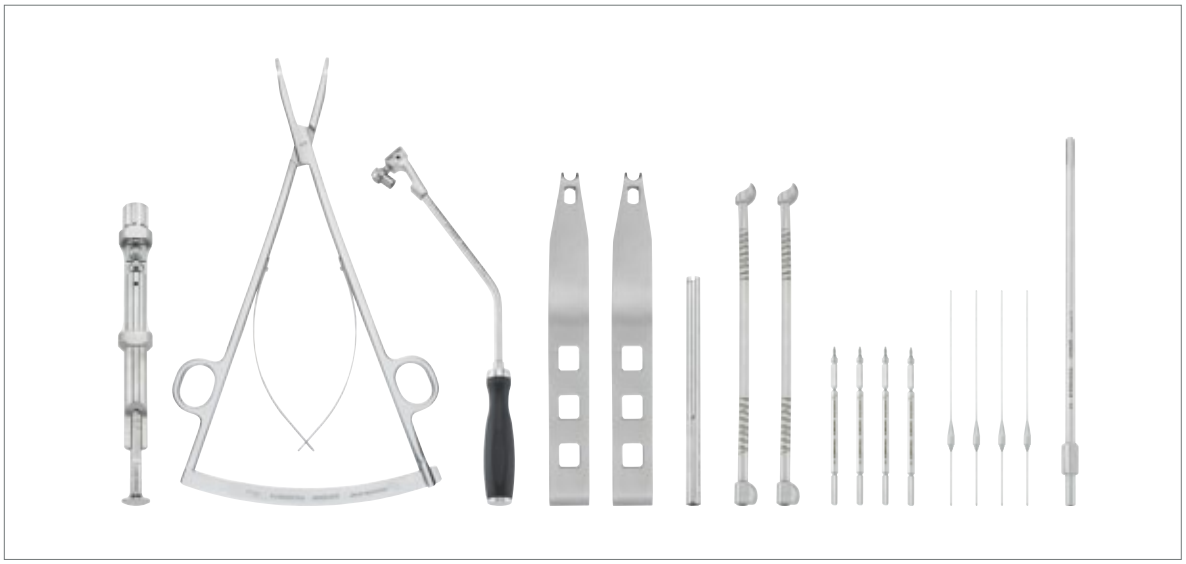
DSS™

Additional instruments



① Pedicle preparation and screw insertion

② Measuring



③ Implant positioning / tightening

Pedicle Screw Sets
(includes 2 cannulated Pedicle Screws per package)

Length	ø 6	ø 7	ø 8
35 mm		DAI47035	DAI48035
40 mm	DAI46040	DAI47040	
45 mm	DAI46045	DAI47045	DAI48045
50 mm	DAI46050	DAI47050	
55 mm	DAI46055	DAI47055	DAI48055

Closure Sets
(includes 2 Nuts, 2 Spacers, 2 Washers per package)

Standard (Breakoff)	Optional (Non-Breakoff) 
DAI06041	DAI06042

Coupler
(1 coupler per package)

Dynamic	
Sizes	**Ref. / Order No.**
24-26 mm	DAI35024
26-28 mm	DAI35026
28-31 mm	DAI35028
31-35 mm	DAI35031
35-40 mm	DAI35035

Fusion	
Sizes	**Ref. / Order No.**
20 mm	DAI70020
22-25 mm	DAI70022
25-31 mm	DAI70025
31-43 mm	DAI70031

Optional

Spacer with Thread
DAI06020

Implant Guides, Sterile Packed
DAT40611

Biocompatibility

All DSS™ 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.

Retraceability

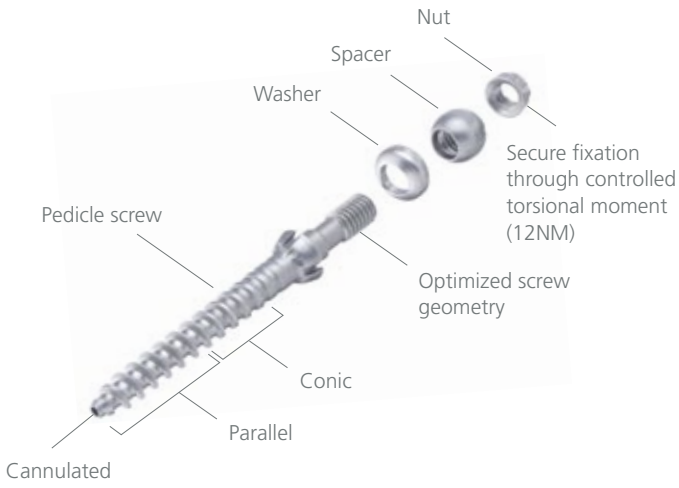
All DSS™ Implants are delivered sterile packed.

Patent

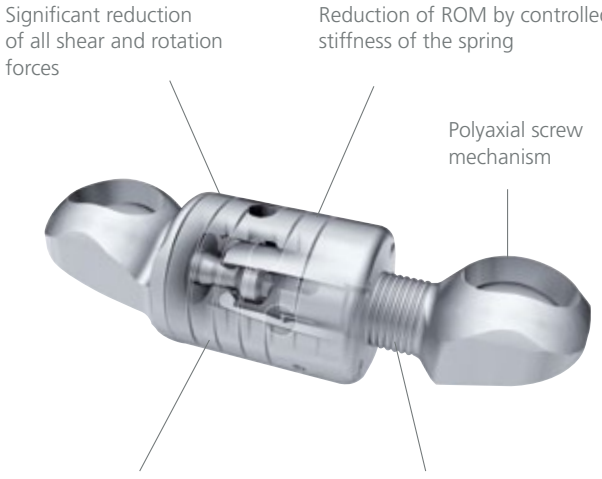
Patent applied for DSS™ system.

DSS™

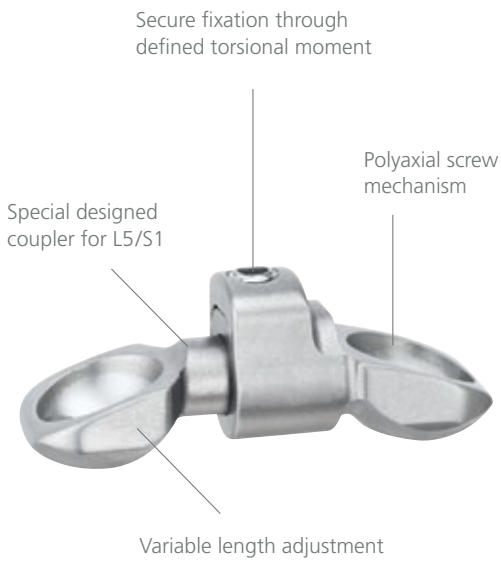
Pedicle Screw Set



Dynamic Coupler



Fusion Coupler



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the movement in spine care

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Product not available in the USA