

spineshape S-IV

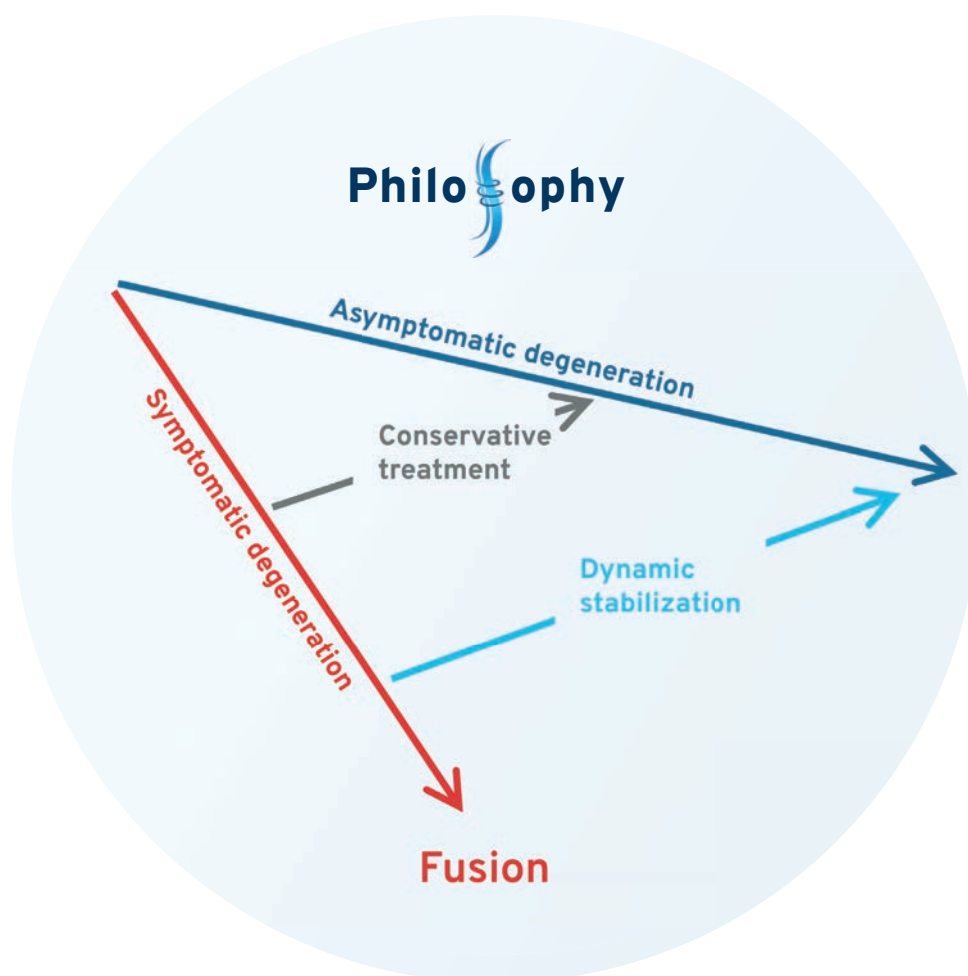


The dynamic solution
for the spine



The revolutionary implant system **spineshape S-IV**

The spineshape S-IV is a dynamic stabilization system that has been specially developed to maintain the physiological mobility of the lumbar spine. This is made possible by flexible connecting rods, which anatomically align directly with the supporting structures of the spine. Different rod elasticities allow patient- and indicationspecific treatment. The inserted implants relieve the spinal column structures across all operated motion segments and guide their movement.



Philosophy of spineshape

The spineshape S-IV is a treatment option for users after conservative forms of treatment have been exhausted. It is designed to ensure that existing structures - especially the discs - can be preserved and do not have to be removed or irreversibly altered by ossification. The structures retain their basic functionality. The reversibility of the system means that further treatment options remain available in the event of persistent degeneration.

- ✔ Unique system for multi-segmental dynamic treatment of the lumbar spine L1-S1
- ✔ Preservation of the anatomical structures
- ✔ Indication-specific relief via three selectable degrees of elasticity of the connecting rods



spineshape S-IV Connecting rods



The connecting rods are the centerpiece of the spineshape S-IV. Depending on the degree of elasticity, they take on part of the loads acting on the lumbar spine. By relieving the peak loads, pain-inducing movements are reduced.

The biomechanical principles of dynamic stabilization consist of controlling and limiting the uncoordinated and painful relative movements between two vertebral bodies. Optimum stabilization is achieved within the specified biomechanical movement sequences.

As is particularly important with dynamic stabilization systems, the connecting rods are located near the facet joints. This ensures that the momentary center of rotation during flexion and extension is only slightly affected, additional relief of the facet joints is achieved, and the natural load stimulus of the intervertebral disc is maintained.

The spineshape S-IV provides three different degrees of elasticity for individual, indication-dependent relief.

► The soft variant is ideal when only a low degree of stabilization is required, for example to protect the nerve roots, to limit the movement of the facet joints or to prevent disc protrusions. The elastic rod primarily fulfils a control function and less of a support function.

► With the medium variant, a medium degree of stabilization is achieved, for example after decompression surgery as part of iatrogenic destabilization.

► The hard variant provides a high degree of stabilization, when a high degree of relief of the structures is necessary and subsequent spontaneous fusion is desirable.

A special form of the connecting rod, Varistab™, is available. It has a stepped cross-section that supports the adjacent segment due to its increased elasticity in the stepped part. The Varistab™ can be used for pre-degenerative but not yet pathological adjacent segments.

The connecting rods made of polycarbonate urethane (PCU) mimic the function of natural ligaments (collagenous structures) and have comparable viscoelastic properties. With regard to tensile and bending loads, their behaviour is similar, although they can also absorb compressive loads.

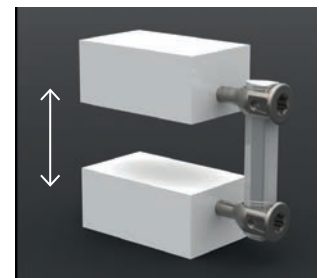


Front view of connecting rods

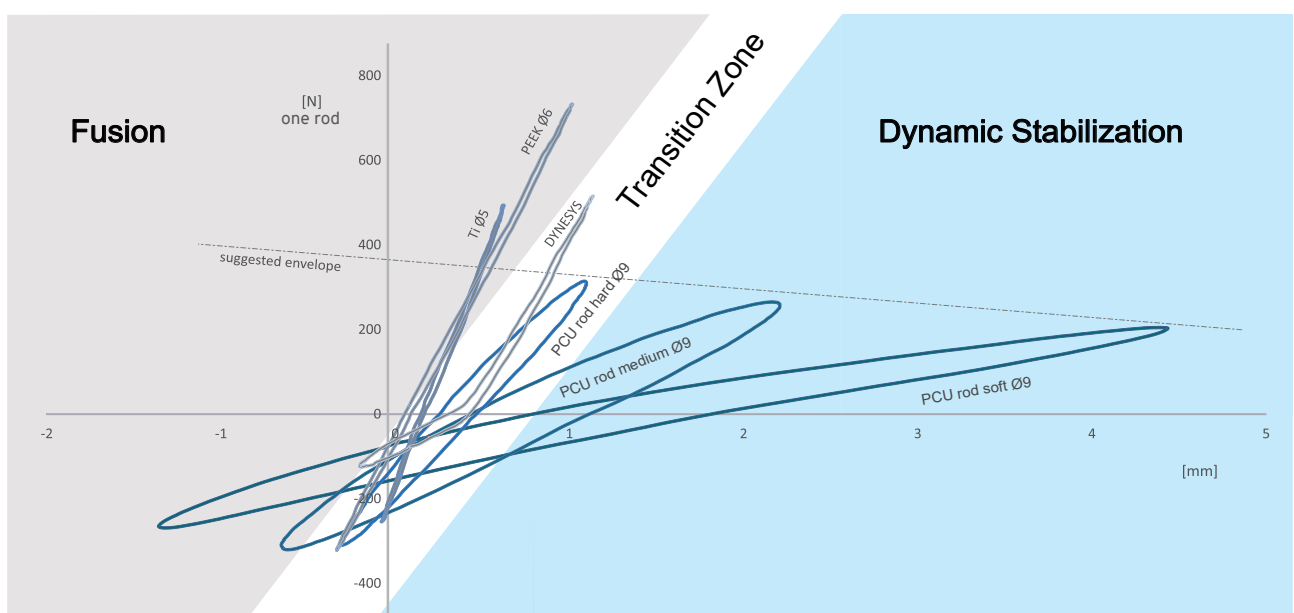
SpineSave tests the connecting rods via the corpectomy model in regular quality tests of 1 million cycles with maximum load (see the graph below). This is done in both a longitudinal and a transversal test arrangement. Depending on the approach taken, 1 million cycles with maximum load reflect between 30 and 124 years of implantation time in the body.

and the hard PCU rods belong. The curves shown correspond to 1 million cycles of longitudinal maximum load.

Based on in-vitro tests, literature data and clinical experience, different stabilization systems can be assigned to the following groups: Titanium and PEEK rods belong to the fusion zone, and the soft and medium PCU rods to the dynamic zone. In between is the transition zone, to which DYNESYS® (ZIMMER Inc.)



Corpectomy model



Force-displacement diagram for spineshape PCU connecting rods and comparison products

spineshape S-IV Pedicle screws



The spineshape S-IV pedicle screws provide reliable anchoring of the rod system to the pedicle. They are designed with a monoaxial screw head. The patented support of the rod in the screw head is provided via a special cross-section with plane-parallel sides and a set screw with an external thread.

The monoaxial screw head ensures vertical and therefore optimum force transmission.

- The pedicle screws are available in thread length increments between 35 and 55mm and 4 different shaft thread diameters from 5.4 to 7.8mm.
- The pedicle screws are also available with a hydroxyapatite coating

spineshape S-IV

Areas of application

The main areas of application for the spineshape S-IV are dynamic stenosis, discopathy and facet joint syndrome/spondyloarthrosis.

INDICATION	ROD ELASTICITY**		
	SOFT	MEDIUM	HARD
(Dynamic) stenosis	X	X	
Facet joint syndrome/Spondyloarthrosis	X	X	
Osteochondrosis Modic Type I oder III	X	X	
Discopathy (recurrent disc prolapse/herniation)		X	
Late adjacent segment syndrome		X	
Complement to disc prosthesis		X	
Osteochondrosis Modic Type II		X	X
Degenerative spondylolisthesis (Meyerding < 1)		X	X
(Degenerative) Scoliosis (early stage - non rigid)		X	X
Instability*		X	X



*Hypermobility with anterolisthesis/hypomobility with retrolisthesis when decompressed

**The functional length of the rod must also be taken into account for the optimum choice of rod stiffness.


Implant product list

spineshape S-IV



	Length (mm)	Diameter (mm)			
		5.4	6.2	7.0	7.8
Cannulated pedicle screw 	35	-	-	21.018.11-735-S	21.018.11-835-S
	40	21.018.11-540-S	21.018.11-640-S	21.018.11-740-S	21.018.11-840-S
	45	21.018.11-545-S	21.018.11-645-S	21.018.11-745-S	21.018.11-845-S
	50	21.018.11-550-S	21.018.11-650-S	21.018.11-750-S	21.018.11-850-S
	55	-	21.018.11-655-S	21.018.11-755-S	21.018.11-855-S
Cannulated pedicle screw with HA coating 	35	-	-	21.024.11-735-S	21.024.11-835-S
	40	21.024.11-540-S	21.024.11-640-S	21.024.11-740-S	21.024.11-840-S
	45	21.024.11-545-S	21.024.11-645-S	21.024.11-745-S	21.024.11-845-S
	50	21.024.11-550-S	21.024.11-650-S	21.024.11-750-S	21.024.11-850-S
	55	-	21.024.11-655-S	21.024.11-755-S	21.024.11-855-S

The pedicle screws are sterile-packed in packs of 2 including 2 set screws.


		ROD ELASTICITY		
		SOFT	MEDIUM	HARD
Connecting rod prismatic <i>Total length 200 mm</i>		21.012.21-200	21.012.23-200	21.012.25-200

The prismatic connecting rod is sterile-packed in packs of 1.

Connecting rod stepped (Varistab™) <i>Total length 200 mm (150 mm + 50 mm shoulder)</i>		—	21.015.23-200	21.015.25-200
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The stepped connecting rod (Varistab™) is sterile-packed in packs of 2.

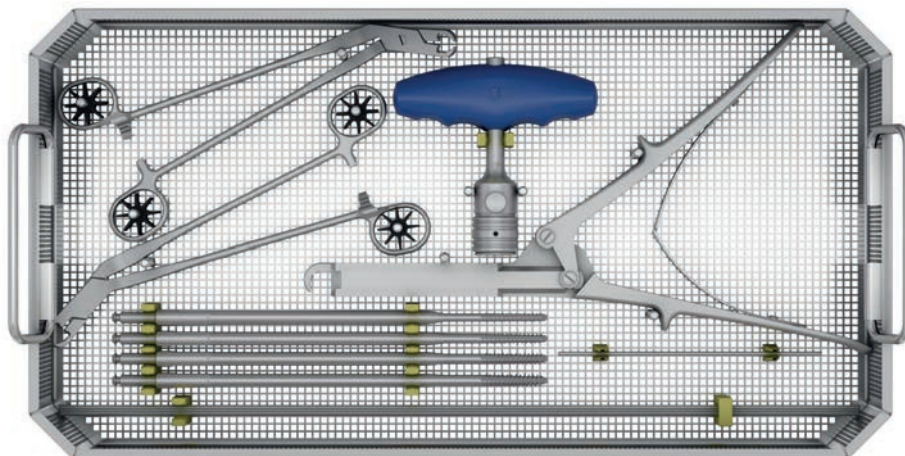
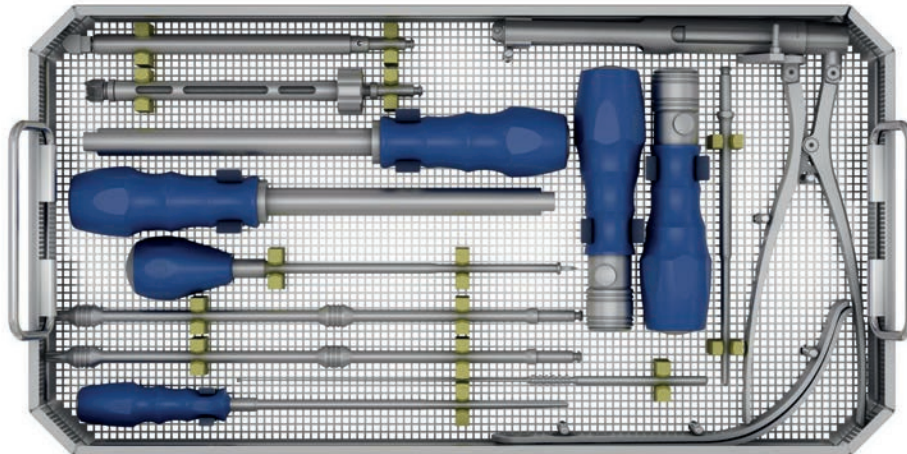
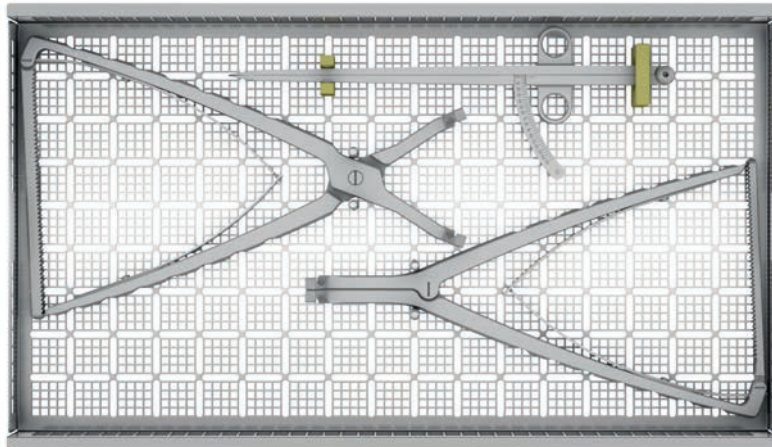
Additional set screws

	for connecting rod prismatic	21.019.11-000-S
	for connecting rod stepped (Varistab™)	21.019.11-100-V

The set screws are sterile-packed in packs of 2.

Instruments for spineshape S-IV

Our clear design philosophy is also reflected in the deliberate simplicity of our instruments, which enable intuitive handling. Whether the lateral or medial approach is chosen, the spineshape instrument set provides the necessary tools for smooth implantation.



SpineSave

The company behind spineshape

Founded in Switzerland in 2009, SpineSave AG has focused on the development of motion-preserving implant systems and provides users with solutions that combine proven procedures with innovations.

In 2021, another company, SpineSave GmbH was founded in Germany in order to deepen SpineSave's roots in the European Union.

SpineSave combines 35 years of development experience in biomechanics with 25 years of experience in the production of medical technology.

Its founders, Stefan Freudiger and Rolf Diener, combine precision, Swiss quality and a fascination with the pioneering spirit required for advancement of the dynamic stabilization of the spine.





- Rolf Diener was one of the first to produce high-strength conical pedicle screws.
- Stefan Freudiger is a pioneer in the development of dynamic stabilization systems.
- spineshape S-IV is the fourth system for which Stefan Freudiger is listed as a (co-)inventor.



Stefan Freudiger *Rolf Diener*



+ Swissness.
Precision.
Fascination.



 spineshape instruments
 spineshape implants

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