



elastic

medium

stiff

SpineShape System IV

Operative technique

Operative technique for SpineShape System IV

System-IV is an implant system, which relies on the pedicular fixation. The pedicular fixation (introduced by Prof. Raymond Roy-Camille in the 1960ties) belongs nowadays to the standard procedures in the spine surgery. In the System-IV instruments for the clinical application, no instruments for the preparation of the pedicle are foreseen. Surgeons, who will implant System-IV dispose on their own preferred instruments to open a pedicle and to prepare the seat of a screw.

In this operative-technique only those steps are mentioned, which specifically refer to the System-IV. Regarding the approaches, two widely spread standard-techniques are known, namely the medial and the lateral approach. The medial approach is normally used when simultaneously the spinal canal must be opened for treating a disc prolaps for example. The lateral approaches (acc. Wiltse as example) have the advantage, that the pedicles can be accessed along their lateral axis and that the muscular scars are minimized.

System-IV is basically suitable for the entire lumbar spine, i.e. from L1 to S1 (sacrum). For patients with small vertebral bodies it shall priorly be verified whether the upper vertebrae (e.g. L2, L1) allow the accommodation of the existing pedicle screws and connection rods.

The cautionary measures listed in this operational technique originate from the risk analysis of these implants.

Available rods



Std-Rod straight
elastic / medium / stiff



Std-Rod bent
medium / stiff



Varistab straight
medium / stiff



Varistab bent
medium / stiff

Stiffness	Standard		Varistab	
	straight	bent	straight	bent
elastic	21.012.21-200			
medium	21.012.23-200	21.012.23-177	21.015.23-200	21.015.23-177
stiff	21.012.25-200	21.012.25-177	21.015.25-200	21.015.25-177

Selection guide for the correct rod stiffness

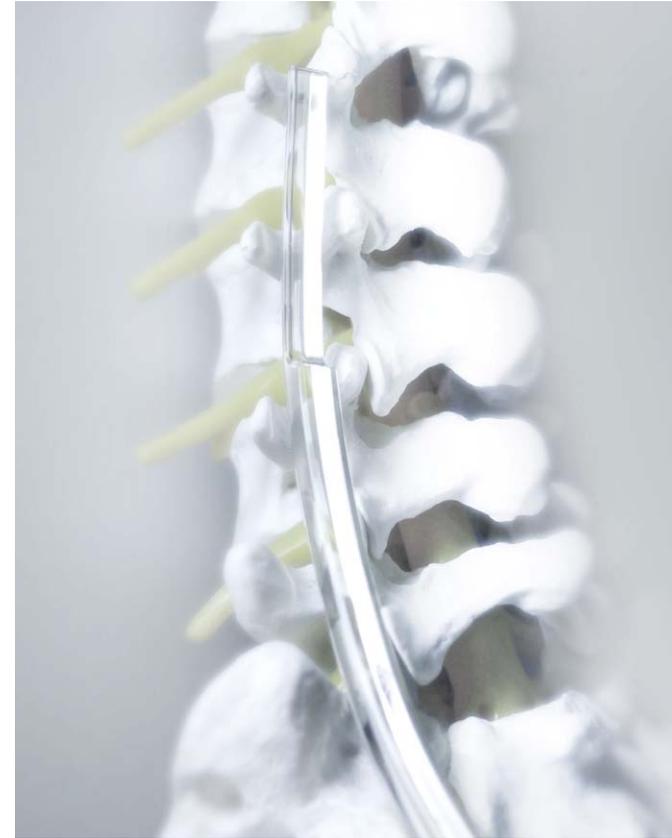
A **stiff** rod shall be used when a patient requires a high degree of stabilization, where a later spontaneous fusion would be desirable.

A **medium** rod shall be used when a patient requires a medium degree of stabilization, e.g. after a decompression surgery with a light iatrogenic destabilization.

An **elastic** rod shall be used when a patient requires a low degree of stabilization, e.g. to protect the nerve roots, to limit motion on the facet joints or to avoid disc bulging. The elastic rod has control tasks rather than load carrying tasks.

Caution: Should the surgeon have doubts upon the selection of the proper rod stiffness, he should then contact the manufacturer for consultation, who will connect him, if necessary, with an experienced colleague.

For the stiff and medium rod, as an option, a version with a stepped cross section (called Varistab) is available, which serves to connect and protect an adjacent segment with half (axial) stiffness. The same pedicle screws and nuts can be used for the stepped region; only the intermediate piece needs to be different. For the standard rod (prismatic) the short intermediate piece (Art.-Nr. 21.016.31-000) is used and for the Varistab (stepped) the long intermediate piece (Art.-Nr. 21.016.31-100) is used.



Caution: If the surgeon by error would install a short intermediate piece instead of a long in the stepped region of a Varistab, the nut would still be rotatable without resistance down to its stop and the rod would still be slideable underneath the intermediate piece. In such case the intermediate piece must be removed and be replaced by a correct one (e.g. long).

Note: A long instead of a short intermediate piece over a standard rod does not represent a danger, because the nut could not be installed.

Caution: Should the surgeon have doubts upon the use and positioning of the Varistab, he should then contact the manufacturer for consultation, who will connect him, if necessary, with an experienced colleague.

Placement of pedicle screws



After determining the diameter and the length, the screw is being screwed on the screw turning shank with holding sleeve (W23-063) and screwed into the pedicle with the attached ratchet (universal handle W32-022 or T-handle W32-230). The pedicle screw shall be only put in to a degree where the rod may be passed unhindered along the facet joints. The pedicle screws shall be oriented towards their neighbour screw according to the direction of rod insertion (from top down or bottom up). For this purpose a Kirschner wire $\varnothing 2.5\text{mm}$ (e.g. W90-029) may be put across the screw turning shank for achieving a proper alignment.

Caution: If a pedicle screw can not be firmly placed (“hand-tight” torque), a longer or thicker screw shall be used.

Measuring and cutting the rod



After a first positioning of the vertebrae in the desired position the length of the rod must be determined in a way that its length exceeds the heads of the end screws by one half to one entire flank height. The compass (W50-034) may be used for this measurement.

Caution: The compass may be advanced only as far as a steady view on its points is given in order to avoid any injury of tissues.



The rod is cut to the desired length using the rod cutting instrument (W01-20)

Placement of the rod

The elastic rod can be directly placed into the open screw heads. The medium and stiff rod must possibly be used in the pre-bent fashion or it must be heated to 60°C in a sterile bath, in order to be easily placed into screw heads which do not lie on one axis. For easy placement right and left rod holding pliers with bent ends (W05-014 and W05-015) are available.

Caution: The rod may only be pushed into a screw head when it is aligned with the rod holding pliers in a way as to slip forward without resistance (without damage).

Note: In order that the intermediate piece and the nut can afterwards correctly be mounted it is important that the rod lies fully forward in the screw head.



Installing the intermediate piece and the nut

Option 1

In simple circumstances (perfect view, screw axis well recognised) the intermediate piece may be pre-mounted into the nut and be put and loosely screwed onto the screw head using the nut tightening set (W24-312).

Caution: A jamming nut will manifest itself by an early sudden stop during rotation. In such case it will be appropriate to rotate the nut tightener by approx. 270° to the left and tighten again under light pressure. Should the nut jam again, Option 2 shall be applied.



Option 2

In a demanding environment the intermediate piece can be placed individually using the intermediate piece mounting instrument positioner (W55-049-1).



For removal of the intermediate piece mounting instrument positioner the intermediate piece mounting instrument removal sleeve (W55-049-2) shall be used and kept in place until the intermediate piece mounting instrument positioner is completely pulled out.

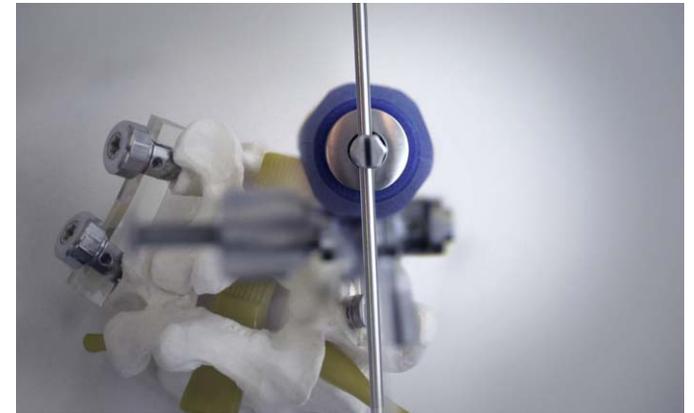


If the intermediate piece can not be properly installed with the intermediate piece mounting instrument positioner (W55-049-1), the intermediate piece may be pointedly guided across the screw retaining blades (W07-167) onto the screw head using the nut placer (W24-311).



For achieving this, the intermediate piece shall be put onto the intermediate piece mounting instrument positioner (W55-049-1) in a way that the top mark points in the direction of the connection rod. The mark may be extended by insertion of the $\text{D}2.5\text{mm}$ Kirschner wire (e.g. W90-029) serving as guide for optimal alignment.

The intermediate piece mounting instrument positioner will then be removed in the same way as mentioned above, i.e. by using the intermediate piece mounting instrument removal sleeve (W55-049-2).



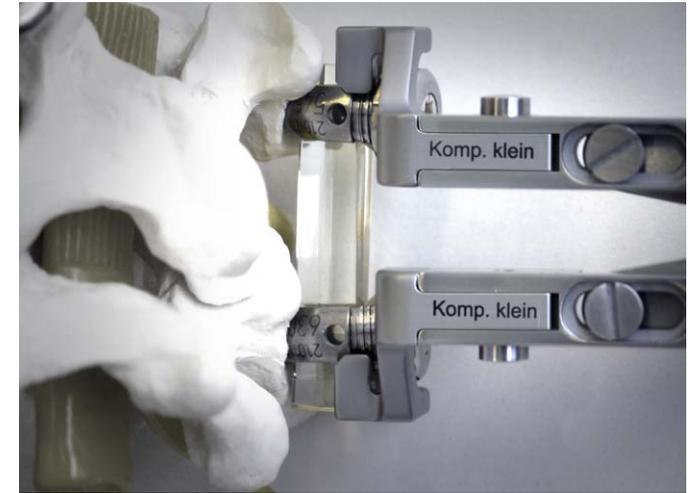
For a safe placement of the nut the screw may be hold with the screw retaining blades (W07-167) snapped into the modular spinal contractor (W06-060). The nut can then be positively driven with the nut placer (W24-311) and loosely screwed onto the screw head.



Control of the relative endplate position

The relative endplate position (lordosing/cyphosing) may be checked with the fluoroscope. Mutually parallel endplates shall preferably be sought for. This may be achieved by a slight lordosing of the endplates prior tightening of the nuts (pedicle screws brought together by approx. 1.0 to 1.5mm). For doing so, the locally cranial and caudal pedicle screw may be hold and repositioned. For the more rarely cyphosing with the small (W07-168) or medium (W07-169) distraction hooks snapped into the modular spinal distractor (W07-071) or for the more frequently lordosing with the small contraction hooks (W07-179) snapped into the modular spinal contractor (W06-060).

Caution: A segmental contraction or distraction with an already inserted rod may only be done as long as the nuts are not yet tightened and the intermediate pieces are not yet in contact with the rod, since otherwise the rod may be damaged.



contraction / lordosing



distraction / cyphosing

Tightening the nut

With the endplates in the desired relative position and with the rod ends still exceeding the screw heads by one half to one entire flank height, the nuts may be tightened. Because the clamping of a polymeric rod is dealt with, no tightening torque can be specified. The clamping of the rod is designed in a way that the nut must simply be tightened until reaching its stop. In addition, the stop is designed to also serve as safeguard against loosening.

Option 1

In simple circumstances and in particular when using the elastic rod, the nut can be tightened using the 2-piece nut tightening set (W24-312). Doing so, the inner rod with the T-handle must firmly hold the intermediate piece in order to assist the bony anchorage of the pedicle screw while reacting the nut's tightening torque and to prevent the pedicle screw from rotating with the connecting rod inserted.



Option 2

In a demanding environment and in particular when using the medium or stiff rod, the screw head can again be held with the screw retaining blades (W07-167) snapped into the modular spinal contractor (W06-060). For withholding high torques the separate handle shall additionally be mounted on the modular spinal contractor. The nut is then tightened until reaching the stop using the torque controlled nut tightening instrument (W22-198).

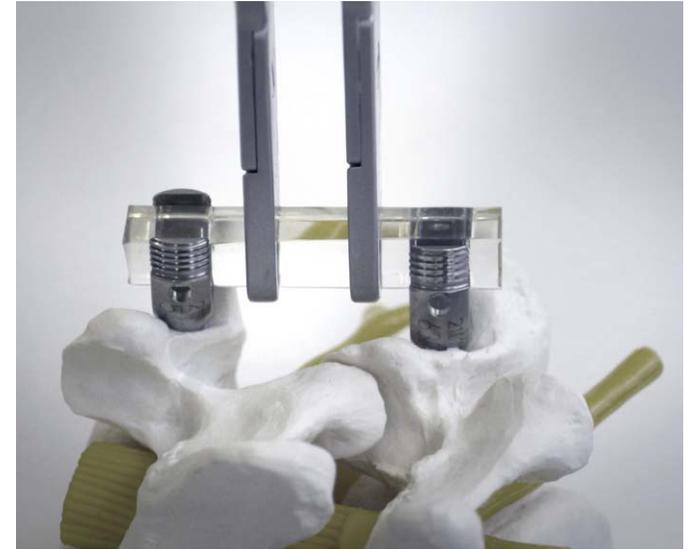
Caution: The nut must absolutely be tightened until the stop is reached, since otherwise the rod may slip underneath the intermediate piece (in flexion) and the safeguard against loosening would not be onset.

Caution: The mark corresponds to approx. 6Nm and serves as guidance. Should higher torques be required, then a short break shall be included in order to let the clamping stress being relieved inside the polymer.



Removal of the rod

Should a rod need to be removed, the nuts and intermediate pieces must priorly be removed. Subsequently the rod is being pulled out of the screw heads using the right and left rod holding pliers with bent ends (W05-014 und W05-015).

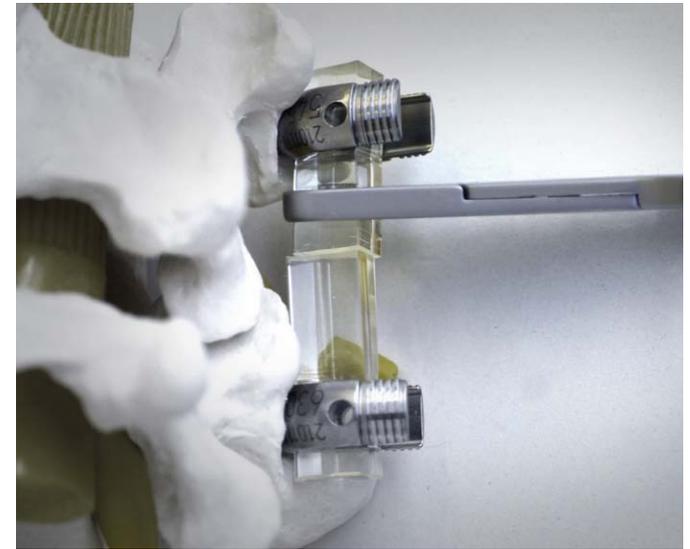


Should this not easily be possible to do, the rod may also be cut in-situ using the rod cutting instrument (W01-020).

Caution: The rod cutting instrument may only be used in-situ, when a steady view on the cutting blade is given and when it is assured that no tissue can be injured.



The stumps can thereafter be individually removed from the screw heads using the right and left rod holding pliers with bent ends (W05-014 und W05-015).



Removal of the screw

For removing the screw, the screw turning shank with holding sleeve (W23-063) is mounted on the screw head and with a snapped on universal or T-handle with ratchet (W32-022 or W32-230) is being screwed out of the pedicle.



Rehabilitation

The patient shall basically save himself in the first six weeks and avoid movements with high loads on the vertebral column, in order not to compromise the proper in-growth of the pedicle screws. Movements with elevated loads shall only be undertaken after six months.

In the first two weeks while regaining mobility the patient shall wear a corset and use crutches. Walking on even ground as well as climbing stairs shall be demonstrated by a physiotherapist. In addition the physiotherapist shall also demonstrate to the patient the movements which he initially shall better avoid due to critical loading. Finally the physiotherapist shall show him also breathing exercises for strengthening the abdominal musculature. The back musculature as well as its proprioception shall initially be trained during staying and walking.

After the first two weeks, when the wound have broadly healed, exercises shall preferably be done in water, if possible for one hour per day during two weeks under the supervision of the physiotherapist. In this period of time smooth flexion, lateral bending and rotation exercises may be begun with.

After four weeks the patient may begin, first temporarily and then increasingly often, omitting the corset. The gradual entry into the activities of daily living shall now be undertaken.

Post-operative examinations and clinical documentation

See separate documentation sheets.

Important

Removed implants shall be returned to the manufacturer for investigation. They shall be packed and sealed air- and water-tight and for the protection of the employees, information about the state of contamination shall be included.



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