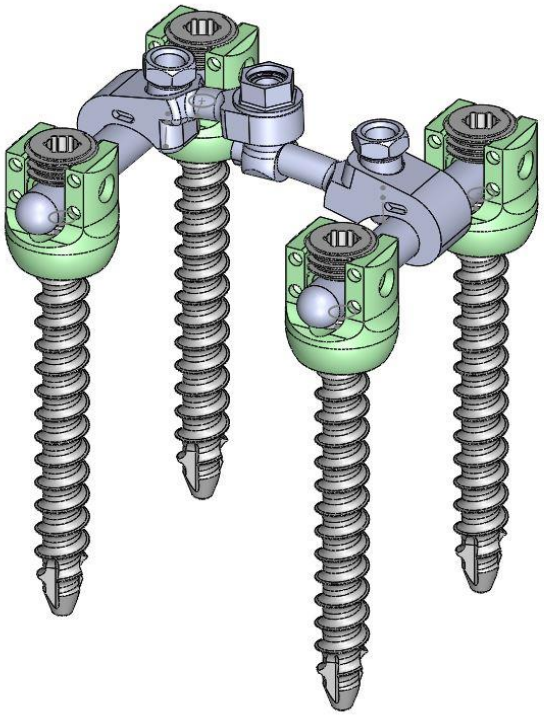
Ackermann©

Instructions for Use

p|spine
Polyaxial Pedicle Screw System



Legal Manufacturer according to MDD 93/42/EEC:

Ackermann Instrumente GmbH
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78604 Rietheim-Weilheim
Germany

CE
1984

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1. Important Information

Before using these products, please read the following information thoroughly! Incorrect handling and care as well as misuse can lead to insufficient sterility or impaired performance.

Warning

Ackermann Polyaxial Pedicle Screw System are for single use only and must not be reused! In case of present or suspected damage to the devices, do not try to repair them. Avoid any further use of damaged products! Ackermann cages are delivered sterile, indicated on the device label by the following symbol:

STERILE R

Do not re-use the devices this may result in exposure infectious matter or impaired functional performance of the devices.

2. Device Description

2.1 Intended Use

The Ackermann Polyaxial Pedicle Screw System p|spine is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion.

2.2 Intended User

The products are only for Professional use for orthopedic/ spinal surgeons.
It is strongly recommended that the products are used only by surgeons who are thoroughly familiar with spinal surgery and the product-specific surgical techniques.

2.3 Indications

The devices are indicated for treatment of:

- Instabilities and malposition of the vertebra
- Degenerative spondylolisthesis
- Fractures and dislocations
- Scoliosis and tumor diseases
- Correction of previous fusions

2.4 Contraindications

The devices are indicated for treatment of:

- Leukocytosis
- Osteoporosis
- Patients with fractures or tumors in the spine area
- Patients with spine associated infections
- Psychiatric disorder
- Pregnancy
- Patients with proven materiel allergy or tendency to react to foreign bodies

2.5 Patient Population

Skeletally mature patients. No limitations in regard to gender or aetiology.

2.6 Mode of Application

Pedicle screws are placed above and below the vertebrae that were fused. A rod is used to connect the screws which prevents movement and allows the bone graft to heal. The aim of this procedure is to add extra support to the spine and to improve stability of the spine while supporting fusion. Pedicle screws can be placed via a free-hand technique, fluoroscopy-guidance (C-arm) and stereotactic navigation.

2.7 Caution

- Implantation of the device must be done by experienced physicians only. The surgeons must have a specific training on the products due to the technically complicated procedure that may cause a risk of serious injuries to the patient.
- Neurological, vascular or visceral injuries, a fracture of a Device component, pseudarthrosis, loss of fixation or a fracture of the vertebrae are potential risk that may be caused during spinal fusion surgery and which may result in additional operations.
- Patients which have been treated in a previous spinal surgery at one or more levels may have other clinical outcomes in comparison to those without a previous spinal application.
- Only use Ackermann p|spine instrumentation intended for the implantation of the Ackermann pedicle screw system. Compatibility between instruments of other manufacturers cannot be ensured.
- The Ackermann p|spine system is designed for spinal fusion surgery and is intended to be used with a placeholder between the vertebral bodies (e.g. Ackermann lumbar t|spine cage).

2.8 Pre-Operative Precautions

The selection of the implant as well as the surgical indication must take certain factors into account:

- Patients involved in a profession or activity where excessive loading upon the cage may occur (e.g. vigorous walking, running, lifting or muscle strain) may have an increased risk of failure of the fusion and/or the device.
- Physicians have to instruct patients in detail about the limitations caused by any implant, which includes as well, but not limited to, the effects of excessive loading due to a patients' activity or weight. A patient should be always told and taught how to manage the activities relating the weight bearing on the spine. The procedure will not restore functions of the spine to the expected level of a usual and healthy one. The patient should not expect unrealistic functionality after the surgery.
- The patient should be carefully advised about potential risks and adverse effects resulting from the interaction of any Titanium implant with the mr-environment such as artifacts and heating at the implant site.

2.9 Information before Initial Use

4.11.1 Delivery Condition

Each implant is delivered sterilized. It is meant for single use only. Devices that pass the expiry date have to be discard and are not allowed to be used!

4.11.2 Packaging

Do not use or re-sterilize the devices if the sterile packaging has been opened or damaged before use, as this could result in impaired device performance or potential transmission of infectious matter.
Discard any Device with damaged or opened sterile packaging.

4.11.3 Storage

For storage conditions, please refer to the information on the product label.

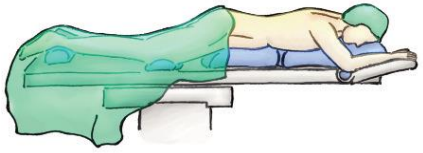
2.10 Colour Coding

3. Surgical Technique

1. Patient Positioning and Access

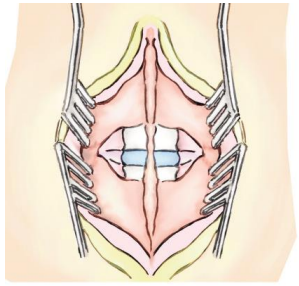
Position the patient in a prone position on an operating table. Use lumbar support to avoid intraoperative bleeding ca used by abdominal compression. Locate the correct level under x-ray radiation (an x-ray c-arm is recommended) and perform a median incision over the concerned segment. The incision should be made carefully to avoid any subcutaneous damage.

Note: After dissection, the musculus erector spinae may be separated laterally to obtain the required exposure of the vertebrae and their facet joints.



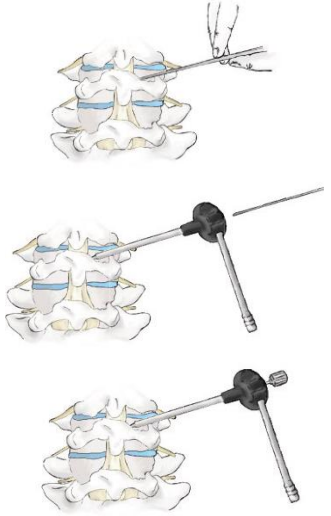
2. Positioning of the Retractor and Annular Window

After incising and retracting the surrounding tissue, insert a retractor. For optima l access to the concerned intervertebral disc, perform a laminectomy or laminotomy, and if needed a facetectomy. Use a nerve root retractor to carefully retract the dura mater and upper nerve roots to the side.



3. Pedicle Opening

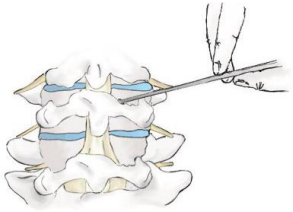
First of all the pedicle walls need to be punctured with a puncture needle or guide wire. Hereby determine the positioning of the screw, which should be inserted in the following step. The cannulated awl is to be passed over the fitting puncture needle, by what the cortex is opened. The deep rash of the awl prevents the surgeon from penetrating the vertebral body too deep.



4. Checking the Pedicle Opening

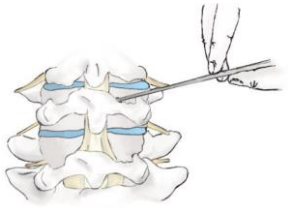
Ensure an optimal screw bearing with the pedicle guide wire.

Afterwards exclude a perforation.



5. Determining Screw Length

Due to the scale on the depth measuring gauge in combination with the k-wire, the optimal screw length can be determined directly and adequately in mm.

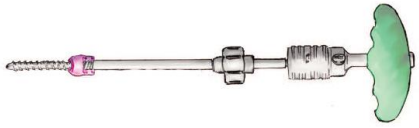


6. Preparing the Pedicle Screw Driver

The pedicle screw driver set is consisting of the following parts:

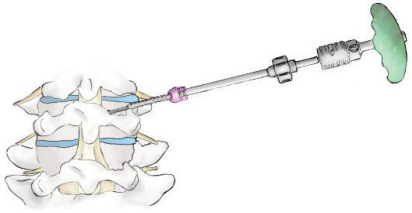
- trocar for pedicle screw driver
- T-handle
- pedicle screw

The final assembly looks like the below scheme:



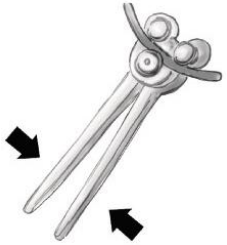
7. Valve and Radiator

Although the Ackermann pedicle screws are self-tapping, thread cutters from 5.0 mm to 7.5 mm are available in the standard product range and also in the operation set. In the case of an extremely hard ended bone wall of the cortex, it might be necessary to return a thread, to guarantee a firm fitting of the pedicle screws.



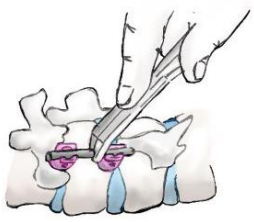
9. Rod Bending

If you are not using our pre-bent connecting rods they can be bent individually with the rod bending forceps.



10. Rod Insertion

Insert the (curved) connecting rod with the rod holding instrument to restore the lordosis.

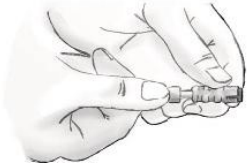


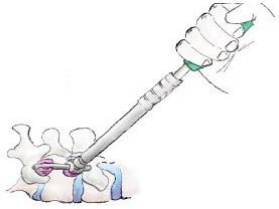
11. Placing the Nut Screw with the Nut Screw Driver

Prepare the positioning instrument for the placement of the nut screw as follows:

Telescope the quick release. Afterwards insert the nut screw. Advance the quick release until it stops. Finally, insert the screw through the guide tube and position it over the rod.

Note: Do not tighten the screw!

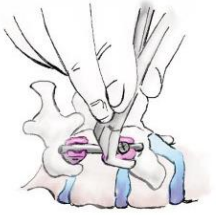




Alternative: Placing the Nut Screw with the Vertebrae Lever Rocker

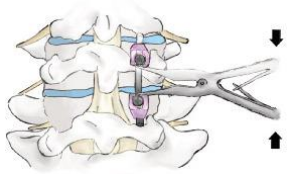
Attach the vertebrae lever rocker to the pedicle screw. Then depress the rod with the buttress nut sleeve [see 11. Placing the Nut Screw with the Nut Screw Driver]. Screw in the nut screw.

Note: Do not tighten the screw!



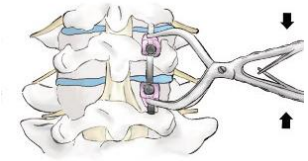
12. Repositioning with the Distraction Forceps

Use the distraction forceps to distract the distance between the two pedicle screws.



13. Repositioning with the Compression Forceps

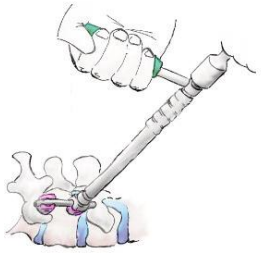
Use the compression forceps to compress the distance between the two pedicle screws.



14. Assembly of Torque Wrench with T-Handle and Anti-Rotation Holder

Insert the torque wrench into the anti-rotation holder. Afterwards insert and set the pressure pad on connecting rod. Tightening the nut screw with max. 8 Nm.

Note: A higher torque can damage the screw! p|spine screws have a self-locking thread, which automatically connects by 8 Nm with the tulip head.



15. Insertion of Lumbar Cages

Now you can start the discectomy as preparation for the insertion of the lumbar cages. For all further steps please see Surgical Technique t|spine or t|spine*curve*.

Side note: For more detailed information (e.g. article number and product description) concerning the instruments mentioned in the surgical technique, please refer to our p|spine catalogue.

4. Appendix

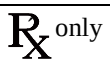
4.1 Pedicle Screws

Pedicle Screws *(sorted by Colour Code)*				
Midnight Blue	***Blue***	***Pink***	***Green***	***Gold***
REF 70-7720-45 70-7721-45 70-7722-45 70-7723-45 70-7724-45 70-7725-45	70-7720 70-7720DT 70-7721 70-7721DT 70-7722 70-7722DT 70-7723 70-7723DT 70-7724 70-7724DT 70-7724L 70-7725 70-7725DT	70-7730 70-7730DT 70-7731 70-7731DT 70-7732 70-7732DT 70-7733 70-7733DT 70-7733L 70-7734 70-7734DT 70-7734L 70-7735 70-7735DT 70-7735L 70-7736 70-7736DT 70-7736L 70-7737 70-7737DT 70-7737L	70-7740 70-7740DT 70-7741 70-7741CM 70-7741DT 70-7742 70-7742CM 70-7742DT 70-7742L 70-7743 70-7743CM 70-7743DT 70-7743L 70-7744 70-7744CM 70-7744DT 70-7744L 70-7745 70-7745DT 70-7746 70-7746DT 70-7747 70-7747DT	70-7750 70-7750DT 70-7751 70-7751DT 70-7752 70-7752DT 70-7753 70-7753DT 70-7754 70-7754DT 70-7755 70-7755DT 70-7756 70-7756DT

4.2 Accessories: Crosslinks & Rods

Crosslinks	**Rods** *(sorted by type)*		
	Standard	***Percutaneous***	***Superflex***
REF 70-7760 70-7761 70-7762 70-7763 70-7764 70-7765 70-7766 70-7767 70-7768	70-7769 70-7769-35 70-7769-45 70-7770 70-7770-55 70-7771 70-7772 70-7773 70-7774 70-7775 70-7775-150 70-7775-300 70-7775-500 70-7776 70-7777 70-7778 70-7778-100 70-7778-150 70-7778-35 70-7778-45 70-7778-50 70-7778-55 70-7778-90 70-7778-90 70-7779	70-7769PCS 70-7770PCS 70-7771PCS 70-7772PCS 70-7773PCS 70-7775PCS 70-7775PCS-120 70-7775PCS-150	70-7776S-F 70-7777S-F 70-7778-100S-F 70-7778-130S-F 70-7778-150S-F 70-7778-35S-F 70-7778-45S-F 70-7778-50S-F 70-7778-55S-F 70-7778-90S-F 70-7778S-F 70-7779S-F

5. Used Symbols

Symbol	Description		
	**Legal manufacturer**	**Ackermann Instrumente GmbH** Eisenbahnstr. 65-67 78604 Rietheim-Weilheim Germany	Tel.: +49 (0) 7461 966 17 0 Fax: +49 (0) 7461 966 17 70 Email: info@ackermanninstrumente.de Website: www.ackermanninstrumente.de
	**Manufacturing date**		
	**Product number**		
	**Batch code**		
	**Prescription use only**		
	**Do not use if package is opened or damaged**		
	**Consult the instructions for use**		
	**Conformity to the essential requirements with notified body number of KIWA**		
	**Sterilized by ionizing radiation**		
	**Do not reuse**		
	**Do not re-sterilize**		
	**Use by date**		
	**Storage temperature range**		
	**Storage humidity range**		
	**Caution, consult accompanying documents**		
	**Protect against moisture**		
	**Keep out of direct sunlight**		