Instructions for Use (USA)
joimax® Percusys® *Plus* rods

These instructions for use apply to the following Percusys® Plus rods:

Rods lordotic	Rods straight
JMPP0020RL – JMPP0120RL	JMPP0130RS – JMPP0300RS
JMPP6020RL – JMPP6120RL	JMPP6030RS – JMPP6300RS

INTENDED USE

joimax® Percusys® Plus rods in combination with joimax® Percusys® Plus pedicle screws are designated, preferably during percutaneous surgeries, for fixation, reconstruction and fusion of vertebrae in the area of the non-cervical spinal column

INDICATIONS

The Percusys® Plus pedicle screw system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD – defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture, dislocation)
- Spinal stenosis
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

CONTRAINDICATIONS

- Infection
- Known allergic reaction to materials the implant is manufactured of
- Physiologically or psychologically inadequate patient
- Insufficient skin, bone or neurovascular condition
- Possibility of a conservative treatment
- Blood supply limitations and previous infections, which may retard healing
- All non-listed indications

INSTRUCTIONS FOR USE

joimax® Percusys® and Percusys® Plus instruments have scales and markings for indication of the required rod length. Please consider the Percusys® Plus product usage guide. Additionally, use imaging techniques to control surgical steps and sizing. joimax® Percusys® Plus pedicle screws are to be inserted according to their instructions for use.
A second incision might be necessary depending on the rod length. The appropriate rod length can be determined by the rod caliper. Its two extensions have to be inserted into the tulip of the pedicle screws. All rods have a tip at one side and a ball connector for the rod inserter on the other side. The fixing nut of the rod inserter has to be released to connect the rod manually to the inserter with little effort. Please ensure that the two lateral surfaces of the ball connector are aligned with the inserter and pay attention to the orientation of lordotically pre-bent rods. The rod is fixed in the coupling of the rod inserter by turning the fixing nut. Depending on the desired stability of the rod in the inserter, the lever of the fixing nut can be swiveled out and used for stronger fixation. The screw's lengthening shaft features grooves to guide the rod during implantation. During insertion, the rod reaches the lateral opening of the lengthening shaft. Then, it is deflected into the tulips of the screws to be connected by lateral force onto the inserter. Repeated locking and unlocking of the coupling between rod and inserter may be necessary at this point to adjust the angulation between the two parts. For the final positioning of the rod, the inserter should be close to the lengthening shaft of the pedicle screw. The rod is introduced into the tulip by lowering the set screw into the screw head. The set screw must be tightened by applying a preset torque with the torque limiting handle. Correct positioning of the rod inside the tulip can be verified by a laser marking on the screwdriver that aligns with the screw shaft. Only then, the rod is released from the rod inserter.
Before manual tightening of the set screw, compression or distraction forceps can be used to compress, distract or straighten the affected segments. After fixation of all set screws with the preset torque, the shaft break-off instrument is inserted into each lengthening shaft. By clockwise rotation, the shaft is sheared off at a predetermined breaking point and separated from the screw head. The detached shafts can now be removed from the surgical site and the incision is closed.

COMBINATION POSSIBILITIES

Percusys® Plus implants can be used with both Percusys® and Percusys® Plus instruments. Percusys® and Percusys® Plus implants are interchangeable, and can be used in combination. However, Percusys® Plus rods with 6mm diameter can only be used in combination with Percusys® Plus pedicle screws.

⚠ ADVERSE EFFECTS

All adverse effects that may result from spinal fusion without instrumentation are possible. The following list shows a non-exhaustive overview of possible adverse effects that may be associated with spinal fusion with instrumentation.

- Deep and superficial infections
- Allergies or other reactions to the implanted material
- Loosening, bending or breaking of the implants
- No or delayed healing
- Reduced bone density due to lack of physical strain
- Pain, discomfort or abnormal sensations
- Nerve damage
- Vascular or visceral injury
- Skin penetration, irritation, fibrosis, necrosis, and/or pain in case of insufficient soft tissue coverage
- Postoperative change of spinal curvature (e.g. loss of correction, height, and/or reposition of the spine)
- Fracture
- Injury or impact on the spinal cord
- Adjacent segment disease
- Death

Note: Additional surgical interventions may be necessary in order to correct some of the aforementioned adverse effects.

⚠ PRECAUTIONS

- The implantation of Percusys® Plus products is a technically demanding procedure and should be performed only by experienced spinal surgeons with specific training in the use of this spinal system.
- It is mandatory that the user, surgeon and surgery personnel are familiar with the respective surgical technique for the instruments and implants used.
- Surgical instruments and implants may only be used for surgeries, for which the designated application of the instrument and implant is explicitly necessary and defined.
- Qualified personnel are obligated to examine the surgical implant and its sterile packaging for damages prior to each application, i.e. use. If the implant or its packaging are damaged or deformed, it must not be used.
- Correct handling of the implant is extremely important. Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the device when contouring. Modifications will produce surface defects and internal stress, which may become the weak point for eventual breaking of the implant. Bending of rods will significantly reduce the fatigue life and may cause failure.
- Only and exclusively joimax® instruments (contained in the respective set) are to be used! If using other instruments, function, warranty and liability of joimax® expire.
- After the shaft is broken off, it must be removed and properly disposed.

⚠ WARNINGS

- Surgical instruments and implants by joimax® might possibly have tips and sharp cutting edges, which can perforate skin.
- This product may only be used with accessories from the respective joimax® Percusys®/Percusys® Plus sets. Application and use of instruments or implants from other manufacturers are not permitted.
- Cutting edges, blades, tips etc. can be very sensitive to false handling. Thus, these instruments must be handled with care.
- joimax® Percusys® Plus implants have not been tested for heating or migration in the MR environment.
- After having fixed the set screw with torque, releasing of the set screw and repositioning of the rod is not allowed. As a deformation of the rod and, therefore, a weakening cannot be ruled out.
- Additional stabilization may be required if the anterior part of the vertebral body is damaged.
- Do not use the implants if the sterile packaging is damaged or defect.
- Safety and effectiveness of spinal pedicle screw systems have only been proven to be effective for spinal conditions with significant mechanical instability or de-

formity requiring fusion with instrumentation. This comprises significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

- Contouring and bending of a system component may reduce its fatigue strength and cause failure under load. If spinal screws are bent or otherwise damaged during insertion or adjustment, they must not be implanted and must be replaced. Rods should only be contoured with proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted.
- Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are amongst the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as healthy bone and could loosen, bend and/or break if excessive force is placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage nerves or blood vessels. An active, feebleminded, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

MATERIAL PROPERTIES

This product was manufactured from a Titanium alloy according to ASTM F136 and/or ISO 5832-3.

MR SAFETY INFORMATION

joimax® Percusys® Plus implants are MR safe in magnetic fields up to 3 Tesla.

DELIVERY FORM

Implants are sterile packaged individually.

STORAGE

Keep in a cool and dry place. Keep away from direct sunlight. Follow storage conditions for sterile products. Do not use after expiration date.

CLEANING AND STERILIZATION

joimax® pedicle rods are delivered sterile. They are single use products. Cleaning, resterilization and reuse are not allowed.

INFORMATION

For further information or product demonstration, please contact the authorized joimax® product specialist.

LIMITED WARRANTY

joimax® guarantees to manufacture the products with utmost care.
joimax® GmbH issues the legally specified warranty period with regard to the function of instruments. The validity period of this warranty is limited to claims made within the specified warranty period after the instrument's purchase date, with reference to repairs if required and with specification of the invoice number.
This warranty only encompasses defects not caused by normal wear and tear, misuse, wrong handling, no or incorrect preparation or force majeure. This warranty excludes wearing parts. This is the only valid warranty and replaces all other issued warranty declarations.
joimax® component sets as well as individual products are compatible with each other. Before using individual joimax® products/sets with other products, the user must ensure the user-specific compatibility of individual products. We recommend introductory training and regular attendance at training events. We are available for any further required information.
joimax® has no influence on the application of the product, on the diagnosis of the patient and handling of the product outside of joimax®. joimax® cannot guarantee good results nor the complication free application of the products.
joimax® employees are not entitled to change the previously mentioned conditions, extend liability or enter additional product related obligations.
joimax® reserves the right to make product changes.

joimax® GmbH is grateful for any information regarding possible errors and obscurities in these instructions for use.

CE MARKING

The CE marking confirms product compliance with the Medical Device Directive 93/42/EEC and the German Medical Devices Act (MPG).

EMERGENCY NUMBER

Please notify us of any events according to MPG § 29 or § 2 of the Medical Devices Safety Plan Ordinance under the following telephone number: **+49 (0) 721 255 14 - 999 (24-hour availability)**.

SYMBOLS

	Caution!
	Consult instructions for use
	Manufacturer
	Use by date
LOT	Batch code
REF	Catalogue number
CE 0123	Manufacturer's CE marking according to Directive 93/42/EEC
℞ only	Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician
	Do not use if packaging is damaged
	Do not reuse
	Do not resterilize
STERILE R	Sterilized using irradiation
Ø	Diameter
Ti-alloy	Titanium alloy
QTY	Packaging unit
	Keep dry
	Keep away from sunlight

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℞ only

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joimax® GmbH
Amalienbadstraße 41
RaumFabrik 61
76227 Karlsruhe, Germany

Phone: +49 (0) 721 255 14-0
Fax: +49 (0) 721 255 14-920
E-Mail: info@joimax.com
Net: www.joimax.com

In USA distributed by
joimax®, Inc.
140 Technology Drive, Suite 150
Irvine, CA 92618, USA

Phone: +1 949-859-3472
Fax: +1 949-859-3473
E-Mail: info@joimaxusa.com
Net: www.joimax.com