icotec Pedicle Systems – Instructions for Use

Product Description

The icotec Pedicle Systems consist of polyaxial pedicle screws and rods made of BlackArmor®, carbon-fiber-reinforced polyetheretherketone (Carbon/PEEK), and/or titanium alloy. They are complemented with pedicle screws, cross-links and nut screws made of titanium alloy. Tantalum (Ta) markers in the BlackArmor® Carbon/PEEK screws and rods ensure sufficient radiological visibility of the implant.
The icotec Pedicle Systems include various types of BlackArmor® Carbon/PEEK polyaxial screw designs. In particular, the fenestrated VADER® pedicle screw is designed to be used in combination with bone cement for screw augmentation. In the area of the pedicle, all BlackArmor® Carbon/PEEK pedicle screws are coated with cp-titanium to improve direct bone ongrowth. In addition, the icotec Titanium pedicle screws are made completely of titanium alloy. The implant's various sizes allow surgeons to take account of individual anatomical features, and the cannulated screws can be used in both an open and a posterior percutaneous approach with the respective icotec instruments. The implant material exhibits optimal biocompatibility. BlackArmor® generates minimal artifacts in all diagnostic imaging modes (MRI, CT and X-ray). Embedded tantalum markers ensure the required radiologic visibility of the implant during surgery and follow-up.
Prior to using the icotec Pedicle Systems, please carefully read the complete "Surgical Technique" manual, where you can find a detailed product description.
Request the "Surgical Technique" manual from your local distributor or from icotec.

Clinical Benefits

- On average, patients experience significant relief of symptoms (i.e., pain, neurological symptoms)
- On average, patients experience a significant improvement in function (i.e., ADL).

Material

- BlackArmor® Carbon/PEEK rods: carbon-fiber-reinforced polyetheretherketone with tantalum markers according to ASTM F560
- BlackArmor® Carbon/PEEK pedicle screws: carbon-fiber-reinforced polyetheretherketone with tantalum markers according to ASTM F560 and titanium tulip/nut screw (Ti6Al4V ELI) according to ASTM F136. In the area of the pedicle, the BlackArmor® Carbon/PEEK pedicle screw is coated with cp-titanium according to ASTM F1580
- Titanium pedicle screws, rods and cross-links: Ti6Al4V ELI according to ASTM F136

Intended Purpose

The icotec Pedicle System is intended to be used for immobilization and stabilization of the thoracolumbar and sacral spine as an adjunct to fusion following treatment of spinal disorders. Surgery can be performed with either a minimally invasive or open approach.

Indications

The icotec Pedicle System is a posterior fixation device indicated for use in the thoracolumbar and sacral spine (T1 to S2) in skeletally mature patients in the treatment of degenerative spine disease, tumor, trauma, deformities.

The fenestrated screws were evaluated for the use with the following commercially available bone cements:

- BonOs® Inject, OSARTIS GmbH
- CONFIDENCE SPINAL CEMENT SYSTEM®, DePuy Synthes Inc.
- VERTECEM™ V+ Bone Cement, DePuy Synthes Inc.
- V-STEADY, G21 srl
- V-FAST, G21 srl
- VertaPlex HV Bone Cement, Stryker
- MEDTRONIC HV-R™ FENESTRATED SCREW CEMENT, Medtronic Sofamor Danek USA, Inc.
- F20®, Teknimed S.A.S.
- Mendec® Spine HV System, Tecres S.p.A.

Contraindications

- Any patient not having adequate nonoperative care prior to being treated with a lumbar fusion device
- Discitis, spondylodiscitis
- Insufficient form fit between the implant and the vertebral body owing to deformation or destruction of the pedicles
- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies
- Open wounds
- Bone tumors in the region of the implant anchoring
- Prior fusion at the level(s) to be treated
- Any medical or surgical condition that could preclude the potential success of the implantation
- Allergy or intolerance to PEEK, carbon, titanium, tantalum, aluminum, or vanadium
- Foreign body sensitivity
- Systemic or metabolic illnesses
- Generally poor condition of the patient
- Psychosocial issues; lack of cooperation by the patient
- Drug abuse or alcoholism
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Patients with severe cardiac and/or pulmonary insufficiency
- Any condition not described in the indications for use

Relative Contraindications

- Presence of vertebral bone with high bone mineral density (e.g., osteoblastic or sclerotic bone) in the area of the planned spinal fixation
- Osteoporosis or similar bone density loss, when used without augmentation
- Adiposity
- Pregnancy
- Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices

Intended Patient Population

The implants of the icotec Pedicle System are intended for use in skeletally mature patients.

Intended User

The implantation of the icotec Pedicle System should be performed only by experienced spine surgeons with specific training in the use of these systems, and they must follow the instructions in the "Surgical Technique" manual, because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Warnings

- Potential risks identified with the use of these device systems, which may require additional surgery, include device component fracture, loss of fixation, pseudarthrosis (i.e., nonunion), fracture of the vertebra, neurological injury, and vascular or visceral injury.
- All sterile delivered implants (irradiation sterilized) are intended for single use only. Do not use if the sterile package is damaged or unintentionally opened, or if expiration date has passed.
- Cleaning and resterilization is not permitted and may have negative effects on the sterility or biocompatibility of the implant.
- The instruments (unless marked sterile and clearly labeled as such in an unopened sterile package) are provided nonsterile and must be cleaned and sterilized by the hospital prior to use. All packaging materials must be removed prior to sterilization. See instructions for processing (IFP) for the recommended steam sterilization parameters.
- The icotec Pedicle Systems must be implanted only with the specific icotec instruments. When used in a posterior percutaneous approach, the VADER® Pedicle System MIS instruments must be used. When used in an open approach, the VADER® Pedicle System instruments must be used. Moreover, only products listed in the "Surgical Technique" manual can be combined.
- The correct selection of the implant is extremely important. The potential for satisfactory fixation is increased by the selection of the proper size of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to indefinitely withstand the stress created due to unlimited activity.
- Implants can break when subjected to the extended loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches, or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
- The safety and effectiveness of pedicle fixation systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5 to 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 is unknown.

Precautionary Measures

- Make sure to measure the relevant spinal structures before (e.g., by CT) and during surgery to confirm the suitability of the selected device size.
- Surgical implants must never be reused. An explanted implant should never be reimplanted.
- Bending of the implant: BlackArmor® Carbon/PEEK components must never be bent, as component fracture could result. Unlike metallic devices, which can be slightly bent or contoured to match the anatomic condition, BlackArmor® Carbon/PEEK implants cannot be bent.
- Damaging the surface of BlackArmor® Carbon/PEEK implants: improper use of instruments may damage the BlackArmor® Carbon/PEEK material. Therefore, care should be taken not to damage the surface of the BlackArmor® Carbon/PEEK implants by applying excessive forces through rod grippers and other manipulation instruments.
- Before screw insertion into the pedicle is performed, pretapping of the screw trajectory is mandatory. This helps to reduce the stress placed on the screw. During the pretapping step, only the tap instrument of the corresponding diameter of the screw must be used. The tapping depth must be slightly deeper than the actual length of the screw to be placed.
- Removal of the implants after healing: implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shielding of bone, even after healing, particularly in young, active patients. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative treatment to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant, thus eliminating the risk involved with a second surgery.
- If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) migration of implant position resulting in injury; (2) risk of additional injury from postoperative trauma; (3) loosening and/or breakage, which could make removal difficult or impractical; (4) pain, discomfort, or abnormal sensations due to the presence of the device; (5) possible increased risk of infection; and (6) bone loss due to stress shielding.
- Based on the dynamic testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the device.
- Loss of anterior column support after surgery may lead to excessive forces on the posterior stabilization system and therefore may increase risk of failure.
- Postoperative care: the patient must be instructed in the limitations of the implant and be advised regarding activity level, weight bearing, and body stresses on the implant prior to firm bone healing. The patient should be informed that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

MRI Safety Information

Non-clinical testing has demonstrated the VADER® Pedicle System is MR Conditional.

MR Conditional

A patient with the VADER® Pedicle System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Condition of Use/Information
Static Magnetic Field Strength (B_0)	1.5 T, 3 T
Static Magnetic Field (B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Polarization	Circular Polarized (CP)
RF Transmit Coil	Integrated Whole Body Transmit RF Coil
RF Receive Coil	Any Receive RF Coil may be used
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Maximum Whole-Body Averaged SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
$B1^+_{rms}$	1.5 T: 7 µT 3 T: 3.5 µT **NOTE:** $B1^+_{rms}$ shall be used on all MR systems with this limitation parameter. Use SAR only on MR systems not providing $B1^+_{rms}$ limitation.
Scan Duration	Scan up to 9 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series)
MR Image Artifact	The presence of this implant may produce an image artifact of 38.7 mm.

Risks and Possible Adverse Outcomes

- Component damage may occur if the system is used in contraindicated cases or when not observing the "Warnings" and "Precautionary Measures"
- Early or late loosening, bending, disassembly, and/or breakage of any or all implants
- Screw backout, possibly leading to implant loosening, and/or reoperation for device removal
- Foreign body sensitivity (implant material allergic reaction), including metallosis, staining, and/or scarring
- Infection, early or late
- Nonunion, delayed union
- Bone loss due to resorption or stress shielding, decrease in bone density, or bone fracture at, above, or below the level of surgery
- Pain, discomfort, or abnormal sensations due to mechanical irritation of adjacent tissues
- Nerve damage due to surgical trauma or presence of the device; neurological difficulties including radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia
- Vascular damage could result in catastrophic or total bleeding; malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period
- Fat embolism due to injected bone cement forcing the bone marrow into the blood circulation
- Screw revision: in the area of the pedicle fixation, the BlackArmor® Carbon/PEEK pedicle screw is coated with cp-titanium to provide an osseoconductive surface; in a revision case, as a result of the bony fixation, this could hamper the removal of the pedicle screw; in such cases, damage/fracture of a well fixed pedicle screw shank may occur
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation, and/or wound complications
- Tissue damage resulting from improper placement of implants or instruments
- Misalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction, and/or height
- Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
- Paralysis
- Damage to lymphatic vessels with lymphatic fluid exudation
- Spinal cord impingement or damage with subsequent palsy
- Fracture of bony structures
- Degenerative changes or instability in segments adjacent to fused vertebral levels
- Death

Patient Selection

In selecting patients for internal fixation devices, the following factors can play an important role to the eventual success of the procedure:

- The patient's occupation or activity: if the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the device.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- The patient's weight: an overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
- A condition of senility, mental illness, alcoholism, or drug abuse: these conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- Certain spinal diseases: in some cases, the progression of the disease (degenerative, tumor) may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
- Foreign body sensitivity: where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Smoking: patients who smoke have been observed to experience higher rates of pseudarthrosis following spinal fusion procedure. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

Informed Consent Regarding Possible Complications and Treatment Results

Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among 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. The patient should understand that an implant is not as strong as normal healthy bone and could loosen, bend, and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly adhere to the postoperative treatment plan is at risk.
The surgeon is responsible for obtaining the patient's informed consent. The informed consent discussion and documentation must contain the following items:

- A realistic assessment of the expected treatment outcome
- Mention of all general complications that could occur in the context of the surgical procedure
- Complications associated with patient positioning
- Paraplegia
- The patient should be instructed that, in spinal segments adjacent to the treated levels, degenerative changes can occur within a short period of time; degeneration of adjacent segments can cause pain or remain nonsymptomatic
- Local complications, including:
  - Hematoma
  - Infection
  - Pseudarthrosis
  - Injury to nerves or blood vessels, radicular pain, or radicular paresis
  - Pain at the donor site of bone graft
  - Loosening or breakage of the implant

Complaints/Serious Incidents

Any health care professional who has complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance should notify the distributor or icotec ag. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, and the nature of the malfunction. Further, any suspected serious incident that has occurred in relation to an icotec medical device should be reported to icotec and the national competent authority.

Processing of Instruments

Instruments for implantation are provided nonsterile and must be thoroughly cleaned and sterilized prior to each use. For details, please see instructions for processing (IFP) of the specific instrument set. Request the IFP from your local distributor or from icotec.

Disposal

Removed implants must be disposed of as medical waste in accordance with hospital standards, applicable local and national regulations.
If explanted implant devices are returned to icotec for investigation, place them in a safe container or bag marked with a biohazard label and coordinate the return with icotec or your icotec representative. Sharps must be carefully placed in puncture-resistant containers and treated in an appropriate manner.
The surgical instruments are mostly made of metal. Surgical instruments should be properly disposed if damage or defects are identified on the devices. If known, assumed, or suspected to be infectious, they must be treated as medical waste in accordance with hospital standards, applicable local and national regulations.
If instruments are returned to icotec they must pass through the entire reprocessing procedure before returning them to icotec. The reprocessing must be certified in writing.

Product Warranty

icotec ag guarantees that all of its implants and instruments have been manufactured, tested, and packaged with the highest possible care and in accordance with continuously verified quality assurance procedures. Given the fact that icotec ag is not in a position to control the handling and application of its implants and instruments after they have been delivered, the company cannot guarantee treatment success and the absence of complications. icotec ag accepts no liability for the improper use of any of its implants and instruments.

Additional Copies and Symbols Glossary

Information needed to use the device and a glossary of symbols that may appear on the product labeling and the meaning of the symbols are made available in electronic form; current and previous versions can be downloaded in electronic form at ifu.icotec-medical.com (code = REF) or can be requested by email or phone from icotec. On request, icotec will provide a paper version within seven calendar days at no charge.
The electronic versions can be viewed with a freely available PDF reader (e.g., Adobe Acrobat Reader, which can be downloaded at www.adobe.com).

(EU Only:) Summary of Safety and Clinical Performance (SSCP)

The SSCP for the icotec Pedicle Systems is available from icotec upon request. After the launch of the European Database on Medical Devices (EUDAMED) https://ec.europa.eu/tools/eudamed, the SSCP will be available there.
It will be linked there to the Basic UDI-DI (764017255PSISCRBA00185).

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