icotec Anterior Cervical Plate System – Instructions for Use

Product Description

The icotec Anterior Cervical Plate System is made of BlackArmor®, a carbon-fiber-reinforced polyetheretherketone (Carbon/PEEK), and contains tantalum (Ta) markers to ensure sufficient radiological visibility of the implant.

The implant's various sizes allow surgeons to take account of individual anatomical features. The implant material exhibits optimal biocompatibility.

Prior to using the icotec Anterior Cervical Plate, please carefully read the complete "Surgical Technique" manual, where you can find a detailed product description.

Material

- BlackArmor® Carbon/PEEK screw: carbon-fiber-reinforced polyetheretherketone with tantalum markers (ASTM F560)
- BlackArmor® Carbon/PEEK plate: carbon-fiber-reinforced polyetheretherketone

Indications

The icotec Anterior Cervical Plate System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine (C2 to T1) in whom life expectancy is of insufficient duration to permit achievement of fusion.

Caution: federal law restricts this device to sale by or on the order of a physician.

Contraindications

- Insufficient form fit between the implant and the vertebral body
- Open wounds
- Bone tumors in the region of the implant anchoring
- Allergy or intolerance to PEEK, carbon, or tantalum
- 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
- 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
- Pregnancy
- Osteoporosis
- Adiposity
- Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices

Warnings

- Potential risks identified with the use of this device system, 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 opened or damaged, or if expiration date has passed.
- Cleaning and resterilization is not permitted.
- 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. Cervical plate systems 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 usage, 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.
- This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- The instruments 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 reprocessing (IFR) for the recommended steam sterilization parameters.
- The icotec Anterior Cervical Plate System must be implanted only with the specific icotec instruments. Moreover, only products listed in the "Surgical Technique" manual can be combined.

Precautionary Measures

- 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 other manipulation instruments.
- 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.
- Make sure that the size of the selected implant is consistent with the size of the decisive probe.
- Surgical implants must never be reused. An explanted implant must never be reimplanted. Even if the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
- The implantation of the icotec Anterior Cervical Plate Systems should be performed only by experienced surgeons with specific training in the use of these internal fixation systems, and they must comply with the instructions contained in the "Surgical Technique" manual, because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Removal of the implant after healing: it has to be borne in mind that if the anatomic structures in the vicinity of the original approach are scarred over, removal of an implant from the anterior aspect of the cervical spine may be very difficult and hazardous. If such a cicatrization is suspected, removal of the implant from the opposite side is to be taken into consideration.
- 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. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved in a second surgery.
- Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- The correct handling of the implant is extremely important. Excessive torque applied to the screws when seating the plate may cause failure of the bone resulting in stripped threads and/or compromised screw purchase.

- Acute or chronic systemic infections that make the patients a poor surgical candidate may increase surgical risk
- The implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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
- Fracture or loosening of the implant, screw backout: this may lead to irritation or erosion of the esophagus and may require surgical repair of the esophagus and/or implant removal
- Infection, early or late
- 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
- 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
- Dysfunction in swallowing; this problem is normally harmless and disappears spontaneously within some days or weeks
- Damage to the recurrent laryngeal nerve, resulting in hoarseness; this also may spontaneously resolve in a short time period, but in rare instances remains
- Esophageal perforation, erosion or irritation
- 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.
- In some cases of tumor disease, the progression of the disease 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.

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
    - Dysfunction in swallowing
    - Hoarseness

Reprocessing of Instruments

Instruments for implantation are reusable and provided nonsterile and must be thoroughly cleaned and sterilized prior to each use.

For details, please see instructions for reprocessing (IFR) of the specific instrument set. Request the IFR from your local distributor or from icotec.

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.

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.

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).

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