KONG® VBR Systems – Instructions for Use

Product Description

The KONG®-C VBR System and the KONG®-TL VBR System components are made of BlackArmor®, a carbon-fiber-reinforced polyetheretherketone (Carbon/PEEK). The KONG®-C VBR M consists of two end plates, which are connected to a body designed as monobloc, whereas the KONG®-TL VBR E features a continuously expandable main body, which is connected to two end plates. Tantalum (Ta) markers in the BlackArmor® Carbon/PEEK end plates as well as markers in the body ensure sufficient radiological visibility of the implant.

In the area of possible bone contact, BlackArmor® Carbon/PEEK components are coated with rough cp-titanium.

The implant's various sizes allow surgeons to take account of individual anatomical features of the patient. The instruments for the KONG®-C VBR M are designed for an anterior approach, whereas the design of the KONG®-TL VBR E instruments allows all surgical approaches.

Prior to using the icotec KONG®-C VBR System or the KONG®-TL VBR System, please carefully read the complete "Surgical Technique" manual, where you can find a detailed product description.

Material for the KONG®-C VBR System

- BlackArmor® Carbon/PEEK VBR: carbon-fiber-reinforced polyetheretherketone with tantalum markers
- In the bone contact area, the BlackArmor® Carbon/PEEK VBR is coated with rough cp-titanium

Material for the KONG®-TL VBR System

- BlackArmor® Carbon/PEEK VBR: carbon-fiber-reinforced polyether-etherketone with tantalum markers and titanium pins/screw/spikes (Ti6Al4V ELI)
- In the bone contact area, the BlackArmor® Carbon/PEEK VBR is coated with rough cp-titanium

Indications

KONG®-C VBR System devices are intended for use in the cervical spine (from C2 to T1) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The KONG®-C VBR System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. These implants may be used with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft. These implants are 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 in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

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

KONG®-TL VBR System devices are intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor and or trauma (i.e., fracture). When used in the thoracolumbar spine, the KONG®-TL VBR System is intended to be used with FDA-cleared supplemental fixation appropriate for the implanted level, including icotec Pedicle Screw Systems.

These implants may be used with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft. These implants are 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 thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

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Contraindications

- Insufficient form fit between the implant and the vertebral body
- Open wounds
- Bone tumors in the region of the implant anchoring
- Risk that the implant can subside into the vertebral bodies (i.e., in the case of osteoporosis)
- Active infection, local or systemic
- Allergy or intolerance to PEEK, carbon, titanium, aluminum, vanadium, or tantalum
- Foreign body sensitivity
- 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

- Osteoporosis or similar bone density loss
- Partial horizontal corpectomy
- Adiposity
- Pregnancy
- 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 these vertebral body replacement devices, which may require additional surgery, include implant component fracture, loss of fixation, pseudarthrosis (i.e., nonunion), fracture of the vertebra, neurological injury, and vascular or visceral injury.
- Due to potential risk of neural injury in the cervical spine, use of fluoroscopy and/or neuromonitoring during cervical procedures is recommended
- Incorrect preparation of the endplates may increase the risk factor for subsidence or vertebral body fracture, careful attention should be given to endplate preparation prior to insertion of the device
- 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 the expiration date has passed.
- The KONG®-C VBR System and KONG®-TL VBR System must be implanted only with the specific icotec instruments.
- Cleaning and resterilization of the implant is not permitted.
- The correct selection of the implant size 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. The KONG® VBR 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. VBRs are load-sharing devices that are used to obtain alignment until normal healing occurs. If fusion is the surgical goal and 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.
- The safety and effectiveness of the KONG® VBR Systems have been established only for spinal conditions with a significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are a significant mechanical instability or deformity of the thoracolumbar or cervical vertebrae due to trauma or spinal tumors. The safety and effectiveness of these devices for any other condition 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 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.
- 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 manipulation of instruments.

- 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 device.
- The implantation of either KONG® VBR Systems should be performed only by experienced spinal surgeons with specific training in the use of these 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.
- 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 for additional surgery to remove the device thereafter.
- Acute or chronic systemic infections that make the patients a poor surgical candidate may increase surgical risk.

MRI Safety

The implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration. The safety of 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, disassembly, and/or breakage of the implant
- Foreign body sensitivity (allergic reaction to implant material), including metallosis, staining, and/or scarring
- Infection, early or late
- Nonunion, delayed union
- Loss of fixation, dislocation, subsidence
- 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 fatal 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
- 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) or trauma 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 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
    - Subsidence into the vertebral body

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 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 www.adobe.com).

icotec ag

Contact in the USA:

222 Pitkin Street, Suite 126
East Hartford CT 06108, United States
Phone: (860) 404-6999
info@icotec-medical.com
www.icotec-medical.com

icotec ag, 9450 Altstätten, Switzerland

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