INTESS® Cervical Cage

Product Instructions for Use

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Non-Sterile Product ***SINGLE USE***

BEFORE USING THIS PRODUCT, READ THE FOLLOWING THOROUGHLY.

Important Information on the INTESS® Cervical Cage

Description:

The INTESS Cervical Cage intervertebral body fusion device is used to maintain disc space distraction in skeletally mature adults requiring an intervertebral body fusion. It is designed to be used in conjunction with supplemental spinal fixation instrumentation. The implant is available in a range of footprints and heights to suit each individual's pathology and anatomical conditions. The implant has a hollow center to allow placement of autogenous bone graft to promote intervertebral body fusion. Ridges on the superior and inferior surfaces of the implant help prevent implant migration and/or expulsion.

The INTESS Cervical Cage intervertebral body fusion device is made from the Zeniva® ZA500 PEEK polymer radiolucent material with embedded tantalum radiographic markers as specified in ASTM F2026 and ASTM F560, respectively.

Caution:

Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

All implants are intended for single use only. The INTESS Cervical Cage must not be reused under any circumstances. The INTESS Cervical Cage is not a stand-alone device and must be utilized in conjunction with supplemental anterior cervical plate fixation. These instructions for use are designed to assist in use of the INTESS Cervical Cage and are not a reference for surgical techniques.

Indications:

The INTESS Cervical Cage is intended for anterior interbody spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is intended for use with supplemental internal fixation systems and autogenous bone graft implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with intervertebral cage.

Contraindications:

- Acute or chronic infectious diseases of any etiology and localization
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Metal/polymer sensitivity/allergies to the implant materials
- Mental illness, alcoholism, drug abuse
- Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery.
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis.
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance, or if the patient has grossly distorted anatomy caused by congenital abnormalities.
- Symptomatic cardiac disease.
- Systemic or terminal illness.
- Prior fusion at the level to be treated.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

Possible Adverse Events:

A listing of possible adverse events includes, but is not limited to:

- Bending or fracture of implant.
- Loosening of the implant.
- Implant material sensitivity, or allergic reaction to a foreign body.
- Infection, early or late.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Dural tears.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status.
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function.
- Inability to perform the activities of daily living.
- Paralysis.
- Death.

Note: Re-operation or revision may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions:

The INTESS Cervical Cage is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the INTESS Cervical Cage is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, loosening, disassembly and/or breakage of the device will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the INTESS Cervical Cage by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery.

The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of cervical cage systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

If a reusable device is/was used in a patient with, or suspected of having, Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize and eliminate the risk of cross-contamination.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

CAUTION: The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. The physician should always consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the intervertebral body fusion device.

The INTESS Cervical Cage has not been evaluated for safety and compatibility within the MR environment. The INTESS™ Cervical Cage has not been tested for heating or migration in the MR environment.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Implant Selection:

The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. Overweight patients may be responsible for additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon must be thoroughly trained with the surgical procedure, instrumentation and implant characteristics prior to performing surgery. The use of dissimilar materials (e.g., titanium and stainless steel) should not be used together because of the risk of galvanic corrosion. INTESS Cervical Cage components should not be used with components from other manufacturers.

Preoperative:

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The INTESS Cervical Cage components are not to be combined with the components from another manufacturer.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
- All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.
- A surgical technique manual may be obtained from Kalitec Medical or any of its representatives.

Intraoperative:

- Any instruction manual should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.
- Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.
- Before closing the soft tissues, all of the devices should be securely seated.
- Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of initial implant removal.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved INTESS Cervical Cage components should ever be reused under any circumstances.

Packaging:

Packages for each of the components should be intact upon receipt. All sets and components should be carefully checked for completeness and lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to Kalitec Medical.

Cleaning and Decontamination:

Implants and instruments of the INTESS Cervical Cage are supplied clean and NOT STERILE, and must be sterilized prior to use.

All instruments must first be cleaned before sterilization and introduction into a sterile surgical field.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

Some device materials may develop changes in mechanical, physical or chemical characteristics under conditions of repeated use, cleaning and re-sterilization that may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications.

The instruments should be inspected and checked following a thorough cleaning to make certain they are functioning properly. Visually inspect all devices for any evidence of deterioration, corrosion, and/or discoloration and if found, the instrument should be replaced.

Manual Cleaning:

Prepare an enzymatic cleaning solution per manufacturer's specifications. Separate dissimilar metal instruments and disassemble all instruments. Fully immerse and soak all instruments in enzymatic cleaner for 15 minutes. Use a small soft-bristle brush to remove visible soil from all surfaces of the instrument while fully immersed in the solution paying special attention to remove soil from hinges, jaws, tips, box locks, and ratchets. Agitate the instruments in the solution while scrubbing. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Actuate any movable parts to loosen any trapped soil. Rinse instruments under warm (38-49°C) running water until all evidence of detergent is removed. Place the instrument into a bath containing warm (38-49°C) water. Agitate the instruments by hand for at least three minutes. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Prepare an enzymatic cleaning solution to the manufacturer's specifications using distilled water. Ultrasonicate devices for 10 minutes, ensuring the devices are completely submerged. Rinse instruments under warm running water for at least one minute or until all evidence of detergent is removed. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Dry with clean lint-free cloth and/or allow to air dry.

Automated Cleaning:

Automated cleaning should be performed after manual removal of debris using the manual cleaning process identified above.

The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with the approved efficacy (e.g., FDA approval, complying with and validated according to the ISO 15883 series) should be used.

Place the instruments in a suitable washer/disinfector basket and process following the minimum recommended wash cycle parameters in the following table:

Cycle	Description
1	Prewash- Cold tap water- 2 minutes
2	Enzymatic wash – Hot tap water - 43C min, 5 minutes using enzymatic detergent
3	Detergent wash - Hot tap water – 55C min- 5 minutes using neutral detergent
4	Rinse 1 - Hot tap water - 2 minutes
5	Rinse 2 - Pure water - 90C- 1 minute
6	Dry – Hot air – 90C- 15 minutes

Sterilization:

The INTESS Cervical Cage System instruments and implants are provided non-sterile. All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the process parameters below:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Gravity Displacement	270°F(132°C)	30 minutes	60 minutes
Steam	Prevacuum	270°F(132°C)	4 minutes	60 minutes

Wrap tray with a towel placed between tray and FDA cleared wrap.

The Sterility Assurance Level (SAL) is 1×10^{-6}, via the indicated methods. No claims of pyrogenicity are made.

Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to Kalitec Medical.

This gravity displacement sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.

Product Complaints:

Any Health Care Professional, who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify Kalitec Medical or its representative. Further, if any of the implanted INTESS® Cervical Cage component(s) ever malfunctions, Kalitec Medical or its representative must be notified immediately.

If any Kalitec Medical product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or Kalitec Medical must be notified immediately by telephone, fax or in writing.

For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help Kalitec Medical understand the cause of the complaint.

If further information is needed or required, please contact:

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