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Mecta-C Intervertebral Body Fusion Devices

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

ENGLISH **Instructions for use - Mecta-C Intervertebral Body Fusion Devices**

Important notice: the implant(s) can be prescribed and implanted only by a doctor legally authorized to perform this type of surgery.

GENERAL
Before any surgery, the surgeon must be familiar with the sales literature and operative technique and must carefully read these instructions for use. Patient selection is as important as implant placement and positioning. Obesity or unsuitable functional requirements may generate exceptional stresses and reduce the implant life. The warnings must be heeded, and the instructions for use must be strictly followed.

INTENDED USE
The Mecta-C Intervertebral Body Fusion Devices are fusion devices intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the cervical spine.

PRODUCT DESCRIPTION
The Mecta-C Intervertebral Body Fusion Devices are fusion devices intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the cervical spine.

The Mecta-C intervertebral body fusion devices consist of the following materials.
- Mecta-C implants consist of a PEEK body and radiopaque markers.
- Mecta-C TiPEEK consist of a PEEK body and radiopaque markers, the implant surface is coated with titanium.

The markers are placed in the implant on each end of the PEEK cages to allow easier radiological assessment of the position and orientation of the radiolucent PEEK cages. The cages are offered in various widths, heights, footprint geometries and lordosis which can be inserted between two cervical vertebra bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with bone graft. All the implants are supplied in a sterile form in single-use packages.

INDICATION FOR USE
The Mecta-C intervertebral body fusion device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with supplemental spinal fixation.

The Mecta-C device is intended for use at one level in the cervical spine, from C2-T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment prior to treatment with the device.

CONTRAINDICATIONS
The Mecta-C implants in combination with supplemental spinal fixation should not be implanted in patients with active systemic infection or infection localized to the site of implantation.

WARNINGS
- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful.
- Preoperative and operating procedures, including knowledge of the surgical techniques and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Furthermore, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished and / or alcohol / drug abuse patients and those with poor muscle and bone quality and / or nerve paralysis are also poor candidates for spinal fusion.
- Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those who have not experienced previous surgery.
- The following circumstances may reduce the chance of a successful outcome: Signs of local inflammation; fever or leukocytosis; Metal/ polymer sensivity/allergies to the implant material; Grossly distorted anatomy due to congenital abnormalities; osteopenia and/or osteoporosis; unsuitable or insufficient bone support, bone immaturity.
- The Mecta-C 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 Mecta-C in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- The Mecta-C implants should never be reimplanted. While an implant may appear undamaged, microscopic imperfections may occur and cause implant failure.

PRECAUTIONS
- The use of the Mecta-C implants should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics, has had experience with intervertebral fusion procedures and spinal supplemental fixation and has had hands-on training in the use of this device.
- Safety and effectiveness have not been established for the use of Mecta-C implants without the use of supplemental fixation.
- The Mecta-C implants should not be implanted in patients with severe osteoporosis or osteopenia.
- Safety and effectiveness have not been established in patients with the following conditions: two or more levels to be fused, morbid obesity or pregnancy.
- All the Mecta-C implants are supplied sterile and should be handled with appropriate precautions to maintain sterility.

ADVERSE EFFECTS
Adverse effects may occur when the implant is used either with or without associated instrumentation.
The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:
1. Implant migration.
2. Breakage of the implant.
3. Foreign body reaction to the implants including possible tumour formation, auto immune disease and / or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height and / or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above or below the level of surgery.
8. Non-union (or pseudarthrosis).
9. Loss of neurological function, appearance of radiculopathy, development of pain. Neurovascular compromise including paralysis, Cerebral spinal fluid leakage.
10. Haemorrhage of blood vessels and / or haematomas.
11. Discitis, arachnoiditis and / or other types of inflammation.
12. Deep venous thrombosis, thrombophlebitis and / or pulmonary embolus.
13. Bone graft donor site complication.
14. Dural tear requiring surgical repair. This risk is related to the surgical procedure. The intended use of the device does not require it to be close to the dura.
15. Inability to resume activities of normal daily living
16. Early or late loosening or movement of the implant.
17. Scar formation possibly causing neurological compromise or compression around nerves and / or pain.
18. Fracture, microfracture, resorption, damage or penetration of any spinal bone (including pedicles and / or vertebral body) and / or bone graft or bone graft harvest site at, above and / or below the level of surgery.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above or below the level of surgery.
20. Loss of or decrease in spinal mobility or function.
21. Development of respiratory problems, eg pulmonary embolism, atelectasis, bronchitis, pneumonia etc.
22. Change in mental status.
23. Death.

Adverse events may necessitate re-operation or revision. A revision is a procedure which adjusts or in any way modifies the original implant configuration, eg adjusting the position of the original configuration or removal of implants with their subsequent replacement. A removal is a procedure which removes one or more implants of the original device configuration without any replacement. A reoperation is a procedure which involves any surgical procedure at the involved spinal level(s) which does not remove, modify or add any implants.

INSTRUCTIONS FOR USE
IMPLANT SELECTION:
- The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use and their strength is limited by the need to adapt the design to the human anatomy. Unless great care is taken in patient selection, placement of the implant and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage of the implant before the fusion process is complete, which may result in further injury or the need to remove the implant prematurely.
- Excessive loads, such as excessive torque, tensile or compression load applied to long handle insertion tools attached to the implant or direct application of loads to a small area of the Mecta-C, can split or fracture the cage as well as damage the implant/instrument interface. Split or fractured cages should be removed and replaced.
- Once the fusion has healed, the surgeon and patient should carefully weigh the risks and benefits if considering the removal of the posterior pedicle screw fixation system.
- Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant.
- The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

IMPLANT FIXATION
Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by Medacta®. In the interests of patient safety it is therefore recommended that Medacta® implants are not used with implants from any other source.

PREOPERATIVE
The surgeon and operating theatre personnel should wear sterile surgical gloves. Under no circumstances should the components come into contact with hard objects (unless otherwise specified in the surgical technique). Under no circumstances should the porous surfaces come into contact with any cloth or material which can release fibres. Before use, each component must be visually inspected for imperfections. Special surgical instruments are required for the surgery. To avoid damaging the implants and the instruments, these should be handled with the utmost care by qualified personnel and in an environment where conditions of hygiene are controlled. The correct usage of instruments is described in the surgical technique. Instruments must be inspected visually before the operation. Distorted or damaged instruments may result in malposition of the implant or implant failure.
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and / or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be taken in the handling and storage of the implant(s). They should not be scratched or damaged.
4. Further information about this system will be provided upon request.

5. The surgeon should be familiar with the various implants before use and should personally verify that all implants are present before the surgery begins.
6. The size of the implant(s) 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.
7. Additional sterile implants should be available in case of any unexpected need.

INTRAOPERATIVE
1. The instructions in the Mecta C implants surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage or misuse of instruments or implants may cause injury to the patient or operative personnel.
4. The implant surface should not be scratched or notched since such actions may reduce the functional strength of the implant.
5. To ensure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
6. Bone cement (PMMA) should not be used, because this material may make removal of these implants difficult or impossible. The heat generated from the curing process may damage or deform the PEEK implants.

PREOPERATIVE
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
1. Detailed instructions on the use and limitations of the implant should be given to the patient. The patient must be warned that loosening and / or breakage of the implant(s) are complications which may occur as a result of early or excessive weight-bearing, mechanical vibrations, muscular activity or sudden jolts or shock to the spine.
2. The patient should be advised not to smoke or consume excess alcohol during the bone fusion process.
3. The patient should be advised of the inability to bend at the point of spinal fusion and be taught to compensate for this permanent physical restriction in body motion.
4. It is important that the immobilization of the union is established and confirmed by radiographic examination. If a non-union develops or if the implants loosen, migrate and / or break, the implant should be revised and / or removed immediately before serious injury occurs.
5. Mecta-C implants are interbody implants intended to stabilize the operative area during the fusion process.
6. Any retrieved implants should be treated in such a manner that re-use in another surgical procedure is not possible.
7. Adequately instruct the patient in the appropriated postoperative care. The patient's ability and willingness to follow instructions is one of the most important aspects of successful healing.

INSTRUMENTS
Instruments are supplied non-sterile and must be cleaned and sterilized prior to use. Recommended cleaning, decontamination and sterilization instructions are provided on www.medacta.com.

PACKAGING
All Medacta® implants are supplied in a sterile form in single-use packages. The sterilization method is indicated on the label. The expiration date must be checked on the label as well as the package integrity to ensure that sterility of the contents has not been compromised. If a package is damaged or has been previously opened, do not use the implant. Do not re-sterilize. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all implants and instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used and should be returned to Medacta® .

STORAGE
The packages must be stored in a cool, dry place, not exposed to sunlight.

PRODUCT COMPLAINTS
Any healthcare professional (eg customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and / or performance should notify Medacta® or the distributor. Furthermore, if any of the implanted spinal system implant(s) ever malfunction (ie does not meet any of its performance specifications or otherwise does not perform as intended) or is suspected of doing so, the distributor should be notified immediately. If any Medacta® product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the implant(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact Medacta® . Distributed by Medacta® USA, 3973 Delp St., Memphis, TN 38118 Phone +961-203-3970 - Fax +1 312 546 6881

SYMBOLS


Do not reuse


Do not resterilize


Caution, read the accompanying documents


Consult instructions for use


Do not expose to sunlight


Store in a dry place


Do not use if packaging is damaged


Use by

Lot number

Reference number

Sterilized with ethylene oxide

Sterilized by irradiation

MR Unsafe

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