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

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.

INDICATION FOR 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.

CONTRAINDICATIONS

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 an exacerbation of discogenic origin confirmed by patient history and radiographic studies). The cervical device is to be used in patients who have had no weeks of non-operative treatment prior to treatment with the device.

PRECAUTIONS

The Mecta-C implants should only be used when the surgeon has become thoroughly knowledgeable about spinal anatomy and biomaterials, has had experience with intervertebral fusion procedures and surgical implantation techniques and has had experience in the use of the device.

Safety and effectiveness have not been established for the use of the Mecta-C implants in all surgical procedures, including surgical procedures where the dissection is close to the dura. Adverse events may necessitate re-operation or revision. A revision procedure is defined as an operation on an implanted device which may result in further injury or the need to remove the implant prematurely.

Inability to resume activities of normal daily living

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Surgical results depend upon the ability of the surgeon to appropriately determine the role and use of an implant and their strength is limited by the need to adapt this design to the human anatomy. Knowledge of implant selection is an important contribution to the outcome of the procedure.

NOTES

Care should be taken in the handling and storage of the implant(s). They should not be scratched or damaged.

Further information about this system will be provided upon request.
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important. Nepacta-C™ implants are interbody implants intended to stabilize the operative area during the fusion process.

1. The patient should be advised not to smoke or consume excess alcohol during the bone fusion process.
2. 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.
3. 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.
4. 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.
5. The patient should be advised not to smoke or consume excess alcohol during the bone fusion process.
6. 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 breaks of the implant(s) are complications which may occur as a result of early or excessive weight-bearing, mechanical failure, and/or infection.
7. Additional sterile implants should be available in case of any unexpected need.

PRODUCT COMPLAINTS

Any healthcare professional (eg customer or user of this system of products) who has any complaints or who has experienced any complications should notify Medacta®. 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

TRADEMARKS

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REFERENCES

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