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MECTALIF® INTERVERTEBRAL BODY FUSION DEVICES

MectaLIF® Posterior, MectaLIF® Oblique, MectaLIF® Transforaminal, MectaLIF® – TiPEEK Posterior
MectaLIF® – TiPEEK Oblique, MectaLIF® – TiPEEK Transforaminal

CAUTION

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

All Medacta® implants are supplied in a sterile form in single-use packages. The sterilization method is indicated on the label.

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

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 package is damaged
	Use by
LOT	Lot number
REF	Reference number
STERILE R	Sterilized by irradiation
	Manufacturer

ENGLISH

ENG – MECTALIF® INTERVERTEBRAL BODY FUSION DEVICES - INSTRUCTIONS FOR USE

1. GENERAL

Before any surgery, the surgeon must be familiar with the sales literature and operative technique and must read carefully these instructions for use. Patient selection is as important as implant placement or 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. The MectaLIF implants must be used in combination with supplemental fixation.

2. PRODUCT DESCRIPTION

These instructions for use are intended for all the products described here below. The MectaLIF intervertebral body fusion devices consist of the following materials:

- MectaLIF Oblique/Posterior consist of a PEEK body and tantalum markers
- MectaLIF-TiPEEK Oblique/Posterior consist of a PEEK body and tantalum markers, the implant surface is coated with titanium
- MectaLIF Transforaminal consists of a PEEK body, tantalum markers and a titanium gear that acts as an instrument interface
- MectaLIF-TiPEEK Transforaminal consists of a PEEK body, tantalum markers and a titanium gear that acts as an instrument interface. The implant surface is coated with plasma-sprayed titanium.

The cages are offered in various widths, heights and angulations, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar 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.

3. INTENDED USE

The MectaLIF Intervertebral Body Fusion Devices are fusion devices intended for stabilization use and to promote bony fusion during the normal healing process following surgical correction of disorders of the spine.

4. INDICATIONS

The MectaLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

5. CONTRAINDICATIONS

The MectaLIF implants in combination with a pedicle screw system should not be implanted in patients with active systemic infection or infection localized to the site of implantation.

The MectaLIF Interbody Fusion Devices have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the MectaLIF Interbody Fusion Devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

6. ADVERSE EFFECTS AND COMPLICATIONS

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:

- Implant migration
- Breakage of the implant(s)
- Foreign body reaction to the implants including possible tumor formation, auto immune disease and / or scarring
- Pressure on the surrounding tissues or organs
- Loss of proper spinal curvature, correction, height and / or reduction
- Infection
- Bone fracture or stress shielding at, above or below the level of surgery
- Non-union (or pseudarthrosis)
- Loss of neurological function, appearance of radiculopathy, dural tears and / or development of pain. Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males or other types of serious injury. Cerebral spinal fluid leakage
- Haemorrhage of blood vessels and / or haematomas
- Discitis, arachnoiditis and / or other types of inflammation
- Deep venous thrombosis, thrombophlebitis and / or pulmonary embolus
- Bone graft donor site complication
- Inability to resume activities of normal daily living
- Early or late loosening or movement of the implant (s)
- Urinary retention or loss of bladder control or other types of urological system compromise
- Scar formation possibly causing neurological compromise or compression around nerves and / or pain
- Fracture, micro fracture, resorption, damage or penetration of any spinal bone (including the sacrum, pedicles and / or vertebral body) 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
- Loss of or decrease in spinal mobility or function
- Reproductive system compromise, including sterility, loss of consortium and sexual dysfunction
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia etc
- Change in mental status
- Cessation of any potential growth of the operation portion of the spine
- Death

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.

7. WARNINGS

- When more than two involved spinal levels are treated, longer operative times and higher blood loss are likely to occur. (Related to the supplemental posterior fixation)
- As the number of previous surgeries at the involved spinal level(s) increases, the potential for intra-operative dural tears increases
- 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, good reduction 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 MectaLIF implants have not been evaluated for safety and compatibility in the MR environment. The MectaLIF implants have not been tested for heating or migration in the MR environment.
- The MectaLIF implants should never be reimplanted. While an implant may appear undamaged, microscopic imperfections may occur and cause implant failure.

8. PRECAUTIONS

- The use of the MectaLIF 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 pedicle screw system fixation and has had hands-on training in the use of this device.
- Two posterior or one Transforaminal / Oblique implant should be implanted at each surgical level. Safety and effectiveness have not been established for the use of a single MectaLIF posterior implant in conjunction with a posterior pedicle screw fixation system.
- Safety and effectiveness have not been established for the use of MectaLIF implants without the use of a posterior spinal pedicle screw system.
- The MectaLIF implants should not be implanted in patients with severe osteoporosis or osteopenia.
- Safety and effectiveness have not been established in patients who did not receive an interbody fusion in conjunction with a posterolateral fusion (360° fusion).
- Safety and effectiveness have not been established in patients with the following conditions: three or more levels to be fused, morbid obesity or pregnancy.
- All the MectaLIF implants are supplied sterile and should be handled with appropriate precautions to maintain sterility.

9. 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 applied to long handle insertion tools attached to the implant (threaded insertion holes) or direct application of loads to the threads on a small area of the MectaLIF implant, 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.

10. 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.

11. PREOPERATIVE PHASE

- 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 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 surgeon should be familiar with the various implants before use and should personally verify that all implants are present before the surgery begins.
- 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
- Additional sterile implants should be available in case of any unexpected need.

12. HANDLING

The packages must be stored in a cool, dry place, not exposed to sunlight. All Medacta® implants are supplied in a sterile form in single-use packages. If a package is damaged or has been previously opened, do not use the implant. Do not re-sterilize. Damaged packages or products should not be used and should be returned to Medacta®.

13. SURGICAL TECHNIQUE

- The instructions in the MectaLIF implants surgical technique manual should be carefully followed.
- 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.
- Breakage, slippage or misuse of instruments or implants may cause injury to the patient or operative personnel.
- To assure proper fusion below and around the location of the fusion, bone graft must be used. 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.

14. POSTOPERATIVE CARE AND FOLLOW-UP

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 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, muscular activity or sudden jolts or shock to the spine.
- The patient should be advised not to smoke or consume excess alcohol during the bone fusion process.
- 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.
- 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.
- MectaLIF implants are interbody implants intended to stabilize the operative area during the fusion process.
- Any retrieved implants should be treated in such a manner that re-use in another surgical procedure is not possible.

15. 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®.

16. 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.

17. STORAGE

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

18. PRODUCT COMPLAINTS

Any healthcare professional (e.g. 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 malfunctions (i.e. 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.

19. 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®.

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