Medacta International

ref: 75.09.034US rev.01

CE 0476
2013

Strada Regina
CH - 6874 Castel San Pietro - Switzerland
Phone : + 41 91 696 60 60 Fax +41 91 696 60 66
Info@medacta.ch – www.medacta.com

Manufactured by:
Medacta International SA
CH-6874 Castel San Pietro - Switzerland

CAUTION
Federal law (USA) restricts this device to sale distribution and use by or on the order of a physician.
For a US specific package insert, please go to www.medacta.com or call toll free 800-901-7836.

ENGLISH **Mecta-C - Anterior Cervical Plates System - Instructions for use**

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 Anterior Cervical Plate System components are intended for anterior interbody screw/plate fixation of the cervical spine during the development of a cervical spinal fusion.

PRODUCT DESCRIPTION
The Mecta-C Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates, screws, and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The Mecta-C Anterior Cervical Plate System implant components are made from Titanium alloy (Ti-6Al-4V) described by ISO 5832-3. Do not use any of the Mecta-C Anterior Cervical Plate System components with the components from any other system or manufacturer. All the implants are intended to be single use only.

INDICATION FOR USE
The Mecta-C plate system is intended for anterior Interbody screw/plate fixation from C2 to T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis,or scoliosis), 5) psuedarthrosis, and/or 6) failed previous fusion.

This device system is intended for anterior cervical intervertebral body fusions only.

CONTRAINDICATIONS
This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
Contraindications include, but are not limited to:
1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. 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.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any case not described in the Indications.
14. Any patient unwilling to cooperate with the post-operative instructions.
15. Any time implant utilization would interfere with anatomical structures or expected physiological performance.

WARNINGS
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The Mecta-C Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the Mecta-C Anterior Cervical Plate System 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, bending, loosening, disassembly and/or breakage of the device(s) 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 Mecta-C Anterior Cervical Plate 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. The Mecta-C Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The Mecta-C Cervical Plate System has not been tested for heating or migration in the MR environment

POSSIBLE ADVERSE EFFECTS
Adverse effects may occur when the implant is used either with or without associated instrumentation. Potential adverse events include, but are not limited to:
1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears.
8. 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.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. 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.
13. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. 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.
16. Bone loss or decrease in bone density, possibly caused by stress shielding.
17. Graft donor site complications including pain, fracture, or wound healing problems.
18. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
19. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
20. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
21. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
22. Change in mental status.
23. Death.

Additional surgery may be necessary to correct some of these anticipated adverse events.

INSTRUCTION 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. Metallic 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 metal fatigue and consequent breakage, bending 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.

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
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 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.
4. 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.
5. 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 Mecta-C Anterior Cervical Plate System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Caution: Based on fatigue testing results, when using the Mecta-C Cervical Plate System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

INTRAOPERATIVE
1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
7. Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Also secure the locking screw into place to cover the portion of the screw heads which are located at the ends of the plate. Failure to do so may result in screw loosening.

Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

POSTOPERATIVE
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 device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, 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.
2. 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.
3. 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.
4. If a non-union develops or if the components loosen, bend, 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 bending, 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 insure cooperation until bony union is confirmed.
5. The MECTA-C Anterior Cervical Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain, (2) Migration

of implant position possibly resulting in injury, (3) Risk of additional injury from post-operative trauma, (4) Bending, loosening and/or breakage, which could make removal impractical or difficult, (5) Pain, discomfort, or abnormal sensations due to the presence of the device, (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. 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 removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.

6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the Mecta-C Anterior Cervical Plate System components should ever be reused under any circumstances.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including 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 International or to the local distributor. Mecta-C Plate and screws are available both in sterile and unsterile packaging. For the implants provided sterile, 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. 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.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened Medacta International package, all instruments must be disassembled, if applicable, and cleaned using dedicated cleaners before sterilization and introduction into a sterile surgical field.

Visually inspect each device under normal lighting paying close attention to hard-to-reach areas. For difficult to view design features, apply 3% hydrogen peroxide (bubbling is indicative of the presence of blood).

Note: Rinse the instruments thoroughly with warm water following hydrogen peroxide testing. If visible soil remains, repeat cleaning procedure again.

The following recommendations should be followed for cleaning and decontamination of unsterile instruments and implants:

Manual Cleaning				
Step1. Enzymatic detergent	Immersion for >=5 mins in the prepared detergent	Actuation of moveable mechanisms, retraction / bending / opening of the parts to free trapped blood and debris	Use of a soft-bristled brush to scrub and flush with a syringe to reach difficult areas.	Rinse with deionized water at ambient temperature. Inspect and repeat cleaning if soil is visible.
Step 2. Alkaline detergent				

Or

Automatic Cleaning				
Step1. Enzymatic detergent	Immersion for >=5 mins in the prepared detergent	Actuation of moveable mechanisms, retraction / bending / opening of the parts to free trapped blood and debris	Use of a soft-bristled brush to scrub and flush with a syringe to reach difficult areas.	Rinse with deionized water at ambient temperature. Inspect and repeat cleaning if soil is visible.

Automatic Cleaning				
Step 2. Alkaline detergent	Phase	Recirculation Time (min: sec)	Water Temperature	Detergent type and concentration
	Pre-wash	02:00	1 Cold tap water	N/A
	Enzyme wash	02:00	Hot tap water	Neutral pH Enzymatic detergent
	Wash 1	02:00	65.0°C [150°F] (Set point)	Neutral pH Enzymatic detergent
	Rinse 1	02:00	Hot tap water	N/A
	Thermal Rinse	01:00	82.2°C [180°F]	N/A
	Purified water	00:10	Treated water	N/A
	Dry time	07:00	115°C [240°F]	N/A

Do not exceed 140°C [284°F] during processing steps.
Detergents with a pH range between 6.0 and 8.0 should be used. The use of detergents with a pH outside this range, but not higher than 11, must be evaluated by means of technical sheets and material resistancy verification by the final user. Enzymatic detergents aid in the removal of organic soil such as blood. Detergents should be used at the concentration level recommended by the detergent manufacturer.

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants 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 one of the sets of process parameters as documented in 75.09.050US - Recommendations for Cleaning Decontamination and Sterilization of Medacta International Orthopedic Devices.

Effective steam sterilization (10-6 Sterility Assurance Level) of unsterile implants / instruments can be achieved using the following minimum cycles that have been validated by Medacta International SA under laboratory conditions:

Sterilizer Type	Pre-Vacuum	Gravity
Minimum Temperature	132°C [270°F]	Gravity Not Recommended
Full Cycle Time	4 minutes	
Minimum Dry Time	50 minutes	
Configuration	Double wrapped with FDA cleared 1-ply polypropylene wrap and towel placed between tray and wrap	

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.

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 Lot number

REF Reference number

STERILE EO Sterilized with ethylene oxide

STERILE R Sterilized by irradiation

The reference text is the English text.
Last update: August 2014

Distributed by Medacta USA, 1556 West Carroll Avenue - Chicago - Illinois 60607