Mecta-C - Anterior Cervical Plate 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 an important aspect of implant placement and positioning. Osseous or unfavorable functional requirements may generate excessive 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 achieved 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 spinal cervical 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) pseudarthrosis, and/or 6) failed previous fusion.

This device 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.

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of implant position possibly resulting in injury. (3) Risk of additional injury from post-operative trauma, (4) Bender, 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 Orthopaedic 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 and the risk to 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 provided. Complete sets should be checked before sterilization and introduction into a sterile surgical field.

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.

Note: Rinse the instruments thoroughly with 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:

<table>
<thead>
<tr>
<th>Manual Cleaning</th>
<th>Immersion for &gt;=5 mins in the prepared detergent</th>
<th>Actuation of moveable mechanism, retraction / bending / opening of the parts to free trapped blood and debris</th>
<th>Use of a soft-bristled brush to scrub and flush with a syringe to reach difficult areas.</th>
<th>Rinse with deionized water at ambient temperature. Inspect and repeat cleaning if soil is visible.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1. Enzymatic detergent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 2. Alkaline detergent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

Or

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</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 2 Alkaline detergent</th>
<th>Phase</th>
<th>Recondition Time</th>
<th>Water Temperature</th>
<th>Detergent type and concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash</td>
<td>02:00</td>
<td>1 Cold tap water</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Enzyme wash</td>
<td>02:00</td>
<td>Hot tap-water</td>
<td>Neutral pH Enzymatic detergent</td>
<td></td>
</tr>
<tr>
<td>Wash 1</td>
<td>02:00</td>
<td>65.0°C [150°F]</td>
<td>Neutral pH Enzymatic detergent</td>
<td></td>
</tr>
<tr>
<td>Rinse 1</td>
<td>02:00</td>
<td>Hot tap water</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Thermal Rinse</td>
<td>01:00</td>
<td>82.2°C [180°F]</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Purified water</td>
<td>02:10</td>
<td>Treated water</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Dry time</td>
<td>07:00</td>
<td>115°C [240°F]</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

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 resistance 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 sterile and clearly labeled as such, 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 Orthopaedic 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:

<table>
<thead>
<tr>
<th>Sterilizer Type</th>
<th>Minimum Temperature</th>
<th>Full Cycle Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum</td>
<td>132°C [270°F]</td>
<td>4 minutes</td>
<td>50 minutes</td>
</tr>
<tr>
<td>Gravity</td>
<td></td>
<td></td>
<td>Gravity Not Recommended</td>
</tr>
</tbody>
</table>

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 number
- Reference number
- Sterilized with ethylene oxide
- Sterilized by irradiation

The reference text is the English text.

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