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M.U.S.T. Mini posterior cervical screw system

CAUTION: For a US specific package insert, please go to www.medacta.com or call toll free 800-901-7836

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 M.U.S.T. Mini posterior cervical screw system devices are fixation devices intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine.

PRODUCT DESCRIPTION
These instructions for use are intended for all the products described here below.

The M.U.S.T. Mini posterior cervical screw system devices consist of the following materials:
- M.U.S.T. Mini polyaxial fully and partially threaded screws, made of Ti6Al4V alloys, available in different lengths and diameters.
- M.U.S.T. Mini polyaxial cannulated screws fully and partially threaded, made of Ti6Al4V alloys, available in different lengths and diameters.
- M.U.S.T. Mini occipital plates made of Ti6Al4V.
- M.U.S.T. Mini occipital screws made of Ti6Al4V available in different length and diameters
- M.U.S.T. Mini set screws made of Ti6Al4V alloy.
- M.U.S.T. Mini rods, made of Ti6Al4V or CoCrMo alloys and available in different lengths and diameters.
- M.U.S.T. Mini Link (cross connectors) of different sizes and designs made of Ti6Al4V
- M.U.S.T. Mini Hooks of different sizes made of Ti6Al4V
- M.U.S.T. Mini Lateral Connectors of different sizes made of Ti6Al4V
- M.U.S.T. Mini Rod to Rod connectors of different designs made of Ti6Al4V

Screws, set screws and bars are available in sterile packaging, see the packaging paragraph.

INDICATION FOR USE
The MUST Mini posterior cervical screw system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1 to T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The MUST Mini posterior cervical screw system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the M.U.S.T. Mini posterior cervical screw system may be connected to the M.U.S.T. system rods with the M.U.S.T. Mini rod connectors. Transition rods with differing diameters may also be used to connect the

M.U.S.T. Mini posterior cervical screw system to the M.U.S.T. system. Refer to the M.U.S.T. system package insert for a list of the M.U.S.T. indications of use.

When used with the Occipital Plate the M.U.S.T Mini posterior cervical screw system is also intended to provide immobilization and stabilization for the occipito-cervico-thoracic junction (occiput – T3) in treatment of the instabilities mentioned above, including occipitocervical dislocation.

CONTRAINDICATIONS

The M.U.S.T. Mini posterior cervical screw system is contraindicated in the following cases:

- Active infectious process or significant risk of infection (immunocompromised).
- Morbid obesity.
- Open wounds.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Severe osteoporosis may preclude implant stability.
- Suspected or documented allergy or intolerance to the materials to be implanted.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any case not needing a bone graft and fusion.
- Any patient unwilling to follow post-operative instructions.

Any case not described in the indications

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.
- 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 fixation.
- 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 leucocytosis; metal/polymer sensitivity/allergies to the implant material; grossly distorted anatomy due to congenital abnormalities; osteopenia and/or osteoporosis; unsuitable or insufficient bone support, bone immaturity a mental disease that is likely to cause a behavior that may subject the implants to excessive loads.
- The M.U.S.T. Mini posterior cervical screw system implants should never be re-implanted. While an implant may appear undamaged, microscopic imperfections may occur and cause implant failure.
- The safety and effectiveness of cervical screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses.

- In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend or fracture as a result of exposure to every day mechanical stresses.
- CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants.
- Never use Stainless Steel components in combination with the Titanium/Cobalt Chrome M.U.S.T. Mini posterior cervical implants.

PRECAUTIONS

- The use of the M.U.S.T. Mini posterior cervical screw system must 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 to avoid serious injury to the patient.
- The M.U.S.T. Mini posterior cervical screw system must not be implanted in patients with severe osteoporosis or osteopenia.
- Correct handling of the implants is extremely important. Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screw will significantly decrease the fatigue life and may cause failure.
- All the M.U.S.T. Mini posterior cervical screw system devices supplied sterile should be handled with appropriate precautions to maintain sterility.
- The important medical information given in this document should be conveyed to the patient.
- The M.U.S.T. Mini explanted metal implant must never be re-implanted. Even if the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

  Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.

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. Disassembling, bending or breakage of the implant
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease and / or scarring
4. Pressure on the surrounding tissues or organs
5. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant, possibly causing skin penetration, irritation, fibrosis, neurosis and/or pain, bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
6. Loss of proper spinal curvature, correction, height and / or reduction.
7. Infection.
8. Bone fracture or bone loss or decrease in bone density, possibly caused by stress shielding at, above or below the level of surgery.
9. Non-union (or pseudarthrosis), delayed union or mal-union.
10. Loss of neurological function, appearance of radiculopathy, development of pain, dysesthesias, hyperesthesia, anesthesia, paresthesia, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
11. Neurovascular compromise including paralysis, cerebral spinal fluid leakage
12. Hemorrhage of blood vessels and/or hematomas occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
13. Discitis, arachnoiditis and / or other types of inflammation.
14. Deep venous thrombosis, thrombophlebitis and / or pulmonary embolus.
15. 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.
16. Inability to resume activities of normal daily living.
17. Early or late loosening or movement of the implant.
18. Scar formation possibly causing neurological compromise or compression around nerves and / or pain.
19. Fracture, microfracture, resorption, damage or penetration of any spinal bone (including pedicles, lateral masses and / or vertebral body) and / or bone graft or bone graft harvest site at, above and / or below the level of surgery. Retropulsed graft.
20. Herniated nucleus pulposus, disc disruption or degeneration at, above or below the level of surgery.
21. Loss of or decrease in spinal mobility or function.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
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, e.g. 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 re-operation 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 devices can damage the implant/instrument interface.
- Once the fusion has healed, the surgeon and patient should carefully weigh the risks and benefits if considering the removal of the posterior 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.
- 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). 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. Implants and instruments should be protected during storage, especially from corrosive environments.
7. 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.
8. Additional sterile implants should be available in case of any unexpected need.
9. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. The instructions in the M.U.S.T. Mini posterior cervical screw system surgical technique 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 must 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 index level(s), autogenous bone graft or autologous bone graft should be used.
6. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
7. Utilize an imaging system to facilitate surgery.
8. In case of cannulated screws, to insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-wire does not advance during tapping or screw insertion. Remove the guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.

9. Do not overtap or use a screw that is either too long or too large. Overtapping, using an incorrectly sized screw, or accidentally advancing the guidewire during tap or screw insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws are being inserted into spinal pedicles, use as large a screw diameter as will fit into each pedicle.
10. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws. Once this is completed go back and firmly tighten all of the screws and nuts. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

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 implant should be given to the patient by the surgeon and they have to be informed about the implant's load restrictions and the recommended postoperative behavior, including progressive increasing of physical loads. Failure to do this can generate malalignment, delayed bone healing, implant failure, infections, thrombophlebitis, and/or wound hematomas. The patient must also be warned that loosening and / or breakage of the implant(s) are complications which may occur as a result, mechanical vibrations, muscular activity or sudden jolts or shock to the spine. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is excessively active, debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone graft healing 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. By the mechanism of fatigue, these stresses can cause the 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 radiographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. M.U.S.T. Mini posterior cervical implants are fixation devices intended to stabilize the operative area during the healing/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 appropriate postoperative care. The patient's ability and willingness to follow instructions is one of the most important aspects of successful healing.
8. Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.
9. While the final decision on implant removal is, of course, up to the surgeon and patient, 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 postoperative trauma; (4) Bending, loosening and 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; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
10. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.

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 must not be used, and should be returned to Medacta International or to the local distributor.

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 sterile package is damaged or has been previously opened, do not use the implant.

WARNING

Carefully verify that packaging parts like protections cups foam or similar are properly removed from the implant.

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.

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

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 malfunction (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.

MRI COMPATIBILITY
Non clinical testing has demonstrated the MUST MINI is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3 T.
- Maximum spatial field gradient of 6,400 gauss/cm.
- Maximum Force Product 180,000,000 G2/cm (108 T2/m)
- The theoretically estimated maximum whole body averaged specific absorption rate (SAR) of <2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the MUST MINI is expected to produce a maximum temperature rise of less than:

- 2.4°C (2W/kg, 1.5Tesla) RF-related temperature increase with a background temperature increase of 0.8°C(2W/kg, 1.5Tesla)
- 2.1°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of 0.2°C (2 W/kg, 3 Tesla) after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 69.3 mm from the MUST MINI when imaged with a gradient echo pulse sequence and a 3 T MRI system.
CAUTION
Patient safety is ensured up to a static magnetic field of 3T. No further analysis has been performed for higher values.

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


MR Conditional

TRADEMARKS
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