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M.U.S.T. Sacral Iliac Screw & Pelvic Trauma System

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

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

M.U.S.T. Sacral Iliac Screw & Pelvic Trauma System - Instruction 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 stress 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. Sacro Iliac / Pelvic Trauma Implant System [M.U.S.T. SI/PT] is designed for the sacroiliac joint fusion in degenerative sacroiliitis and degenerative SIJ disruptions as well as for the fixation of small and long bone fractures in trauma cases.

PRODUCT DESCRIPTION
These instructions for use are intended for all the products belonging to the M.U.S.T. Sacro-Iliac/Trauma Implant System.
The M.U.S.T. SI Joint / PT screws are a hollow–body threaded fusion device.

- Titanium screw with head (Standard M.U.S.T. SI Screw) or without (Headless M.U.S.T. SI Screw) plasma spray coated with rough Hydroxyapatite
- Stainless Steel and Titanium screws (M.U.S.T. PT Screw)
- Stainless Steel (for M.U.S.T. PT screws only) and Titanium Washers (for Standard M.U.S.T. SI and M.U.S.T. PT screws)

Please note that some of the products mentioned in this document could not be available in every country.
The M.U.S.T. SI/PT Joint screws are “non pyrogenic”.

INDICATIONS FOR USE
The M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System is intended for use in skeletally mature patients for fracture fixation of small and long bones of the pelvis, and for sacroiliac joint fusion for patients suffering from sacroiliac joint disruptions and degenerative sacroiliitis.

CONTRAINDICATIONS

1. Deformities or anatomic variations that prevent or interfere with SI implant placement.
2. Bone Tumor involving the site of operation.
3. Active infection at treatment site.
4. Intolerance / Allergy to the materials used in the manufacture of this device.
5. Any active or suspected latent infection or marked local inflammation in or about the affected area.
6. Compromised vascularity that would inhibit adequate blood supply to the operative site.
7. Patients with, fever, tumors, elevated white blood count, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
8. Patients having inadequate tissue coverage over the operative site or inadequate bone stock or quality that cannot provide adequate support and/or fixation of the devices.
9. Implant utilization that would interfere with anatomical structures or physiological performance.
10. Any neuromuscular disorder which could create an unacceptable risk of fixation failure or complications in post-operative care.

11. Other medical or surgical conditions which would preclude the potential benefit of surgery.
12. Reuse or multiple uses.

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.
- 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.
- The M.U.S.T. SI/PT screw system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of M.U.S.T. SI/PT screws system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- The M.U.S.T. SI/PT Stainless Steel implants are not compatible for the MR Imaging.
- The M.U.S.T. SI/PT screw system implants should never be re-implanted. While an implant may appear undamaged, microscopic imperfections may occur and cause implant failure. 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.
- Surgeon should warn patients about these contraindications and limitations when appropriate.

PRECAUTIONS

- The use of the M.U.S.T. SI/PT screw system should only be undertaken after the surgeon has become thoroughly knowledgeable about anatomy and biomechanics, has had experience with procedures and has had hands-on training in the use of this device.
- The M.U.S.T. SI/PT screw system should not be implanted in patients with severe osteoporosis or osteopenia.
- Correct handling of the implants is extremely important.
- Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.
- All the M.U.S.T. SI/PT 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.
- An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
- Pregnancy is not a contraindication for the implants here contemplated, but diagnostic and operative procedures on pregnant women should be undertaken after a comprehensive medical evaluation
- Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician
- Although not absolutely contraindicated, conditions to be considered as potential factors for not using this device include severe bone resorption, osteomalacia, and severe osteoporosis.

ADVERSE EFFECTS

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

1. Early or late loosening of any or all of the components.
2. Foreign body allergic reaction or metal sensitivity to implants.
3. Infection.
4. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
5. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
6. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
7. Neurological injury/deficit which may range from paresthesias to muscle paralysis, loss of rectal or bladder sphincter control, radiculopathies.
8. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.

1. Non-union (pseudarthrosis), delayed union, mal-union.
2. Cessation of any potential growth of the operated portion of the spine.
3. Cardiovascular system compromise.
4. Decrease in bone density due to stress shielding.
5. Device bending, disassembly, fracture, loosening or subsidence.
6. Gastrointestinal complications (i.e. ileus or bowel perforation).
7. Hemorrhage.
8. Incisional complications (i.e. dehiscence, hematoma).
9. Malfunction /Malposition of the fixation device.
10. Organ, connective tissue or nerve damage.
11. Osteoarthritis.
12. Pain, discomfort or abnormal sensation due to device presence.
13. Persistent low back pain.
14. Reproductive system compromise.
15. Screw back-out or breakage possibly leading to local pain, perforation or irritation of adjacent structures.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Death.
19. Potential difficulty in delivering fetus vaginally due to device-related restriction of SI joint stretching.

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 site(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 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.
- The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. 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. The surgeon should be familiar with the various implants before use and should personally verify that all implants are present before the surgery begins.
5. 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.
6. All the components and instruments should be cleaned and sterilized before use. Additional sterile instruments should be available in case of an unexpected need.

INTRAOPERATIVE

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the 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 should not be scratched or notched since such actions may reduce the functional strength of the implant.
5. Utilize an imaging system to facilitate surgery.
6. 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.
7. 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.

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. 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, mechanical vibrations, muscular activity or sudden jolts or shock to the spine.
2. The patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or 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 or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. 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.
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 roentgen 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 ensure cooperation until bony union is confirmed.
5. Any retrieved implants should be treated in such a manner that re-use in another surgical procedure is not possible.
6. Adequately instruct the patient of the appropriated postoperative care. The patient's ability and willingness to follow instructions is one of the most important aspects of successful healing.
7. 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.

PACKAGING

Packages for each of the components must 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. MUST SI/PT screws are available in sterile 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 sterile package is damaged or has been previously opened, do not use the implant.

CLEANING AND DECONTAMINATION:

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 ***Step 2.*** Alkaline 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.

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				
Step2	***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 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 OF IMPLANTS / INSTRUMENTS

Implants are supplied either sterile or non-sterile.
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. Recommendations for cleaning, decontamination and sterilization of Medacta International orthopaedic devices, are provided on www.medacta.com.

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	

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, and 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 device(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.

FURTHER INFORMATION
Recommended directions for the 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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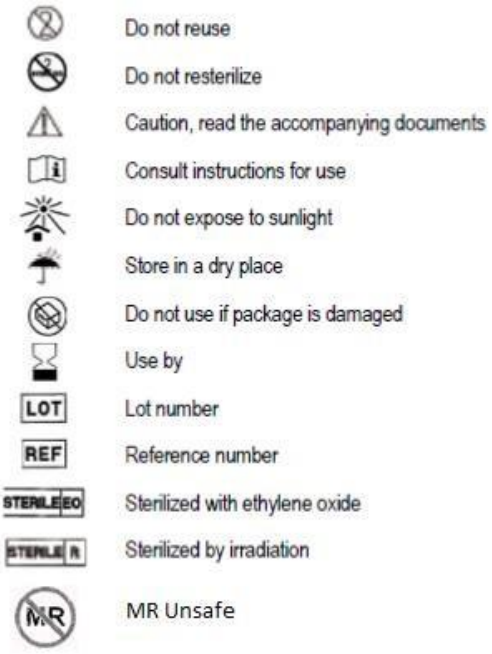

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The reference text is the English text.
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