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

• Rapid joint disease, bone resorption, osteopenia.
• Reuse or multiple uses
• Care should be taken in the handling and storage of the implant(s). They should not be scratched or damaged
• Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided
• Only patients that meet the criteria described in the indications should be selected
• Qualified personnel and in an environment where conditions of hygiene are controlled. The correct usage of instruments is described in the surgical technique. Medacta®. In the interests of patient safety it is therefore recommended that Medacta® implants are not used with implants from any other source.
• Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by
• The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Periodic follow-up
• Excessive loads, such as excessive torque, tensile or compression load applied to long handle insertion tools attached to the implant or direct

INDICATIONS FOR USE

The M.U.S.T. SI/PT Joint screws are "non pyrogenic". These instructions for use are intended for all the products belonging to the M.U.S.T. Sacro-Iliac/Trauma Implant System. The warnings must be heeded and the instructions for use must be strictly followed.

CONTRAINDICATIONS

• 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.
• Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those who have not experienced
• Preoperative and operating procedures, including knowledge of the surgical techniques and correct selection and placement of the implants are important for achieving a successful outcome. The surgeon must have proper training and selection and the completion of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of fusion. These patients should be used
• Proper selection and proper placement of the implant may result in failure or the need to remove the implant prematurely due to insufficient bone support.
• The following circumstances may reduce the chance of a successful outcome: age of the patient, heavy smoking, obesity or nutritional status, or implant design and shape of human bone present limitations on the size, shape and strength of implants.

WARNING

• Potential difficulty in delivering fetus vaginally due to device-related restriction of SI joint stretching
• Intolerance / Allergy to the materials used in the manufacture of this device
• Active infection at treatment site
• Deformities or anatomic variations that prevent or interfere with SI implant placement

PRECAUTIONS

• All the products belonging to the M.U.S.T. Sacro-Iliac/Trauma Implant System have been tested for safety and compatibility in the MRI environment. It has not been tested for heating, migration, or image drift in the MRI environment. The safety of M.U.S.T. SI/PT system screws in the MR environment is unknown. Scanning a patient with such devices may result in heating of the implant(s) and is not recommended.
• Correct handling of the implants is extremely important. Alterations will produce defects in surface finish or internal stresses which may become the cause of the implant failure. The surgeon may reduce the risk of failure if he adheres the instructions for use. If the implants are not implanted properly, the screw may not engage or the bone may not be adequately secured.
• The M.U.S.T. SI/PT screw system has not been evaluated for safety and compatibility in the MRI environment. Therefore, the use of Medacta® implants in an environment where conditions of hygiene are controlled. The correct usage of instruments is described in the surgical technique. Medacta®. In the interests of patient safety it is therefore recommended that Medacta® implants are not used with implants from any other source.

Correct handling of the implants is extremely important. Alterations will produce defects in surface finish and internal stresses which may become the cause of the implant failure. The surgeon may reduce the risk of failure if he adheres the instructions for use. If the implants are not implanted properly, the screw may not engage or the bone may not be adequately secured.
• The M.U.S.T. SI/PT screw system has not been evaluated for safety and compatibility in the MRI environment. Therefore, the use of Medacta® implants in an environment where conditions of hygiene are controlled. The correct usage of instruments is described in the surgical technique. Medacta®. In the interests of patient safety it is therefore recommended that Medacta® implants are not used with implants from any other source.
The surgeon should be familiar with the various implants before and should promptly verify that all implants present are before the surgery begins.

The end of the implant for the surgeon is then determined by the clinical situation. All adhesions of metal implants should be available immediately.

All the components and instruments must be cleaned and sterilized before use. Additional sterile instruments should be available in case of unexpected complications.

The dorso-lateral approach should be carefully followed!

The damage to the nerve may cause loss of neurological functions.

Bleeding, drainage or release of blood or accumulation in the surgical site should be avoided. The device is secured with the appropriate surgical suture. The suture is cut a few centimeters from the margin of the implant.

To ensure proper fusion between and around the location of the future, autogenous bone graft or subcutaneous graft bone graft should be used.

Use an imaging planer to minimize bleeding.

A guide wire should be first placed, followed by a sharp tap. Carefully: the guide-wire is used, if not retractable, to bend, form, break and/or be broken. Ensure that the guide wire does not get obstructed during drilling.