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
US toll free phone number: 800-901-7836

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

STERILE M.U.S.T. SI GUIDEWIRE & DRILL

CAUTION

Federal law (USA) restricts this device to sale, by or on the order of a physician.
All Medacta M.U.S.T. SI Instruments are supplied in single-use packages. The sterilization method is indicated on the label.

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 package is damaged
	Use by
	Lot number
	Reference number
	Sterilized by irradiation
	Manufacturer

STERILE M.U.S.T: SI GUIDEWIRE AND DRILL - INSTRUCTIONS FOR USE

1. GENERAL

Use of the instrumentation requires knowledge of the anatomy and pathology, biomechanics and surgical corrections of the spine. The instrumentation can be used only by a qualified surgeon who practices with an awareness of current advances in science and surgical techniques. The user should ensure that the instruments are intact and in good working order before use. The user should also take all necessary precautions to avoid any accidents (gloves, protective glasses...). No undesirable side effects are known if these Instructions for use are respected.

Before any surgery, the surgeon must be familiar with the sales product literature and operative technique and must carefully read these Instructions for use. The instrumentation should be used only for its intended purpose as indicated in the surgical techniques. The use of some motor-driven instruments (drill bits, taps, etc.) may cause a temperature rise between these instruments and the bone. It is advisable to spray these instruments with physiological saline solution during use. Under no circumstances should an item of instrumentation be implanted.

2. PRODUCT DESCRIPTION

The instrumentation is made from materials appropriate for the manufacture of surgical instruments. These materials are not intended to stay in permanent contact with the patient. The instrumentation is supplied sterile and it is intended to be for single use. The instrumentation manufactured by Medacta International meets the mechanical and functional characteristics of the operative technique and these instructions. Before surgery, the user should refer to the surgical technique and other labeling or contact the representative of the company for more details on how to use the instrumentation.

3. INTENDED USE

The guide wires and the drills are part of the M.U.S.T. SI system, which is intended for sacroiliac joint fusion for skeletally mature patients suffering from sacroiliac joint disruptions, degenerative sacroiliitis and degenerative sacro-iliac arthritis, secondary to pelvic disruption.

4. INDICATIONS

The guide wires and the drills are intended for use with the M.U.S.T. SI system and according to its approved indications for use.

5. CONTRAINDICATIONS

The contraindications for the drills and the guide wires are the same as contraindications for sacroiliac joint fusion. Please refer to the M.U.S.T. SI technique for a comprehensive list of contraindications.

6. WARNINGS

Check the expiration date prior to use. Care should be taken to ensure that the correct size (diameter and length) is being used. At any time during the surgical procedure, the surgeon can verify and confirm that the guidewires and the drills are positioned correctly on the sacrum by fluoroscopy. Visually inspect the instruments after use in order to verify they did not experience any mechanical damage which may cause release of particles in the human body. Any malfunctioning instruments should be immediately returned to Medacta. The type of malfunction should also be reported.

7. HANDLING

The instrumentation should be handled with care. The surgical instruments can be damaged by inappropriate handling: visually inspect the instrument and check for damage prior to use.

8. PACKAGING

The drills and the guide wires are supplied sterile, in single-use individual packages. The sterilization method is indicated on the label. The expiration date and package integrity must be checked in order to ensure that the sterility of the contents has not been compromised. If the package is damaged, do no use the component. Do not resterilize.

9. STORAGE

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

10. 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.

Distributed by Medacta USA, 3973 Delp St., Memphis, TN 38118 Phone +961-203-3970 - Fax +1 312 546 6881
Last update June 2020

This document is intended for the US market