

.U.S.T. SI

SACRO-ILIAC JOINT SCREW SYSTEM

A COMPLETE SYSTEM WITH DIFFERENT OPTIONS



Surgical Technique

Joint

Spine

Sports Med

INTRODUCTION

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

The M.U.S.T. SI/PT screws are a hollow-body threaded fusion device.

- Titanium screw plasma spray coated with rough Hydroxyapatite are thought to accommodate SI joint degeneration
- Stainless Steel as well as Titanium screws are available in both full thread and partial threaded fashion to guarantee fixation in the trauma cases

Features

- Hydroxyapatite rough plasma spray coating allows for biological fixation and potentially lead to arthrodesis
- Choices of thread lengths in combination with Washer application offer fit into bone fragments to allow for compression
- "One-fits-all" Washers with Favored angles capable to accommodate higher angulation
- Radial windowed slots along the screw's body intended to allow surrounding bone access to the bone substitute
- Self-Tapping screws to facilitate screw insertion
- Long Pitch along with Dual Lead Thread for accelerated screw insertion and removal
- Reverse Cutting Flute to facilitate removal
- Cannulated shaft accepts Ø3.2mm Guide Wire for better bone purchase
- Tapered screw tip to aid in guidance through pilot hole
- Comprehensive range of lengths to accommodate patient anatomy



CAUTION

Federal law (USA) restricts this device to sale distribution and use by or on the order of a physician.

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1. INDICATIONS

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.

2. CONTRAINDICATIONS

- Deformities or anatomic variations that prevent or interfere with SI implant placement
- Bone Tumor involving the site of operation
- Active infection at treatment site
- Intolerance / Allergy to the materials used in the manufacture of this device
- Any active or suspected latent infection or marked local inflammation in or about the affected area
- Compromised vascularity that would inhibit adequate blood supply to the operative site
- Patients with, fever, tumors, elevated white blood count, mental illness and other medical conditions which would prohibit beneficial surgical outcome
- 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
- Implant utilization that would interfere with anatomical structures or physiological performance
- Any neuromuscular disorder which could create an unacceptable risk of fixation failure or complications in post-operative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery
- Reuse or multiple uses
- Rapid joint disease, bone absorption, osteopenia

3. PREOPERATIVE PLANNING

The review of MRI and/or CT based imaging to template and determine the type/size of the implants to be used in

order to correctly match the patient's anatomy is a critical step in pre-operative planning.

4. SURGICAL STEPS

4.1 GUIDE WIRE INSERTION

Insert the Wire Positioner through the incision until it gets in contact with the bone surface to treat (Fig. 1, 2) and insert the Guide Wire through the guided sleeve into the bone.

Check the proper insertion and depth at the image intensifier.



OPTION

Parallel Guide Wire Insertion. Slide the Parallel Guide onto the Guide Wire previously placed (and eventually couple it with the Retractor).

Set the distance between the next screw by moving the inner Sliding Block that will also guide the direction of the second Guide Wire.

CAUTION

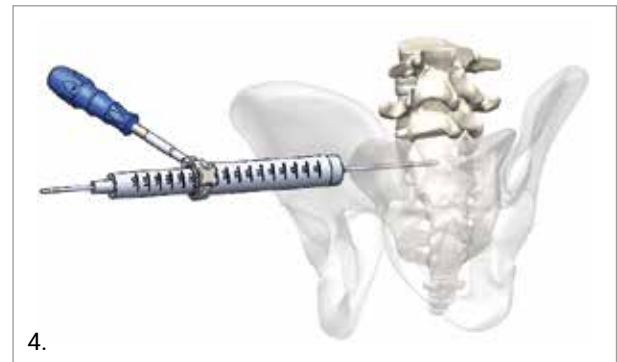
When placing multiple screws, the size of concomitant Washers must be evaluated in order to avoid their overlap in situ.

4.2 TISSUE SHIELD PLACEMENT

Remove the Wire Positioner and place the Dilator Tube(s) over the previously inserted Guide Wire (Fig. 3, 4).

Place the Retractor Tube over the Dilator Tube-Guide Wire previously placed and then remove the Dilator Tube(s) (Fig. 5).

A dedicated Offset Handle can be specifically coupled with the Retractor for better handling.

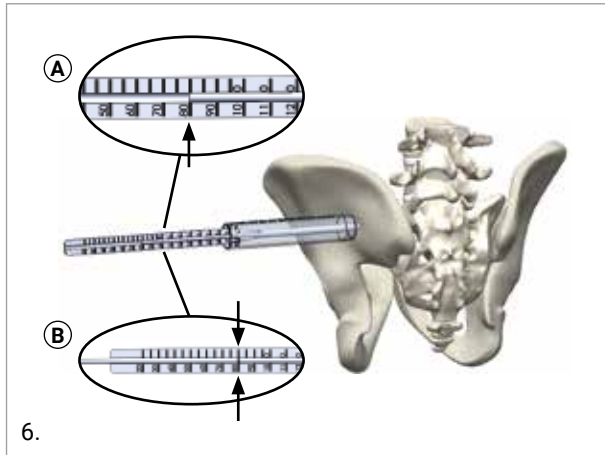


4.3 SCREW LENGTH MEASUREMENT

Slide the Screw Depth Gauge through the Guide Wire down to the bone.

NOTICE: When using the 305mm Guide Wire the screw length measurement is taken from the end of the Guide Wire (Fig. 6A); for the 450mm Guide Wire the proper screw length measurement is taken from the corresponding black laser marking on the wire (Fig. 6B).

NOTICE: Ensure that the measuring Gauge is placed against the cortex for accurate screw length measurement.



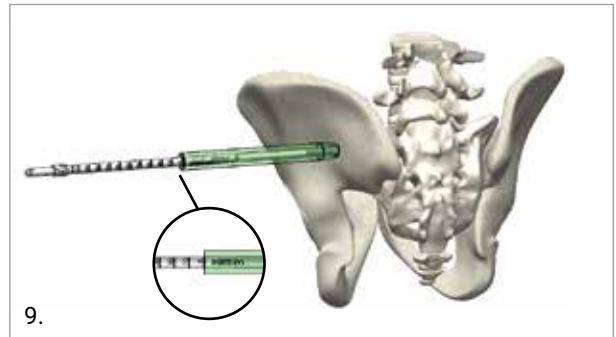
4.4 DRILLING & TAPPING

If hard bone is encountered, it may be useful to drill and/or tap prior to screw insertion.

Slide the Drill Bit over the Guide Wire and through the previously set Retractor (Fig. 8).

Slide the Tap over the Guide Wire (and through the Tap Sleeve) down to the bone. Tap to the desired depth noting the calibrations on the Tap against the back of the Tap Sleeve (Fig. 9).

NOTICE: When both the Tap and Tap Sleeve are flush to the bone cortex the scale reading on the Tap is initially set to "0".



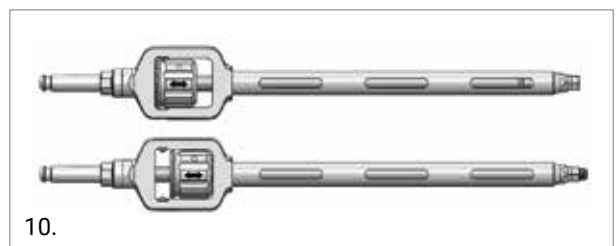
CAUTION

The Tap Sleeve does not slide within the Ø10mm Retractor tube; use it only with the bigger footprint Retractors of Ø15 & Ø20mm.

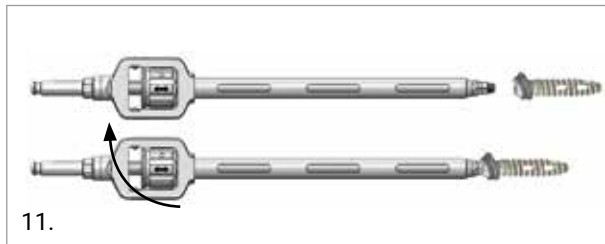
NOTICE: Please note that the Taps are 0.5mm undersized.

4.5 SCREW PREPARATION

Select the M.U.S.T. SI screw with the appropriate length; prepare the Screwdriver for the screw insertion by pulling down the proximal wheel in order to extract the distal threaded tip (Fig. 10).



Insert the Screwdriver threaded tip into the screw head and lock it by clock-wise tightening the proximal wheel until a mechanical stop is achieved (Fig. 11).



4.6 SCREW INSERTION

Insert the M.U.S.T. SI screw through the Retractor and insert it over the Guide Wire (Fig. 12); screw until mechanical stop is reached and the optimal compression is achieved (Fig. 13).

NOTICE: Washer may be pre-assembled as per the steps described in chapter 4.7.

To release the Screwdriver, turn the proximal wheel counter-clockwise to release the screw head and pull it to complete disengagement.

Obtain final radiographic images to confirm screw placement / fracture reduction.

Multiple screws insertion can be achieved by repeating all the above reported steps.

Wound closure follows standard technique.



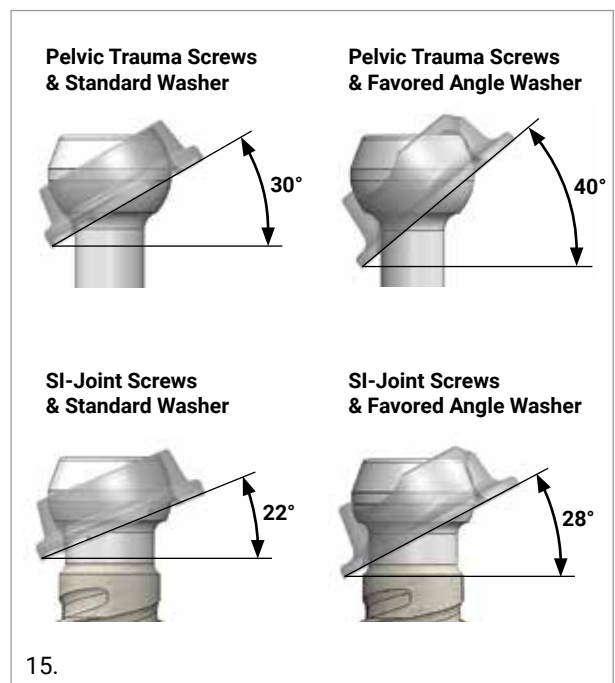
CAUTION

When using the standard length Screwdriver the use of the Retractor Long sleeve [180mm] must be avoided because of interference. Only the Screwdriver Long is compatible with the Retractor Long sleeve.

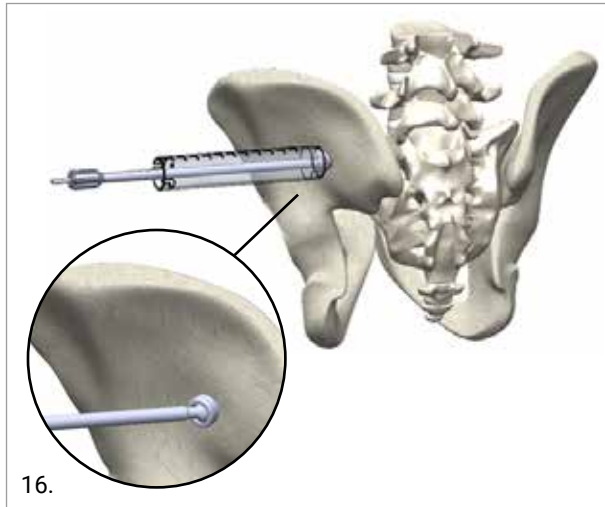
4.7 WASHER INSERTION

If desired, Washers may be preassembled along with the screws prior to screw insertion into the bone.

Standard Washer can help reaching up to typical angles while Favored angle Washer may accommodate extreme angulation (see following figure for details).

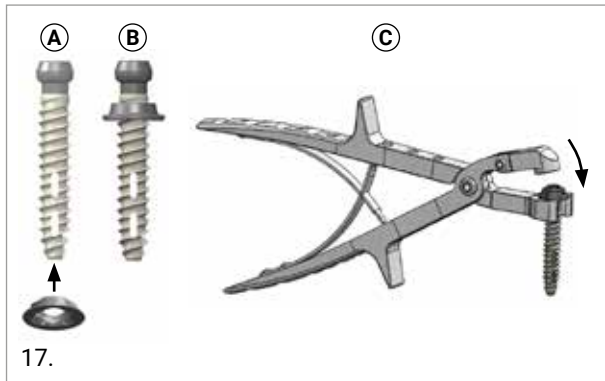


Insert the Washer Trial through the Dilator Tube and insert it over the Guide Wire in order to load the Washer of the proper size (Fig. 16).



Load the Washer from the distal tip of the screw (Fig. 17A) into a preliminary positioning (Fig. 17B); place the screw-Washer assembly onto the Washer clamp and compress it (Fig. 17C) until an audible sound confirms the proper assembly of the Washer into the screw head.

NOTICE: Once assembled with the steps above mentioned, the Washer is inseparably connected with the screw.

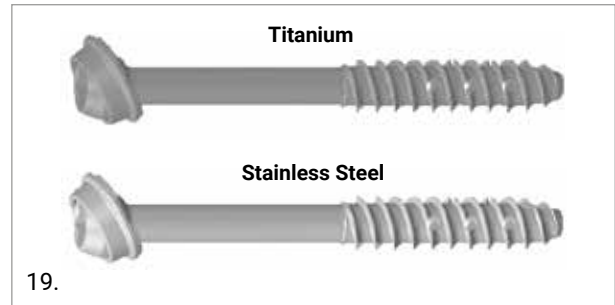


WARNING

The Washer must be correctly assembled to the screw. WRONG assembly is shown in the following picture.



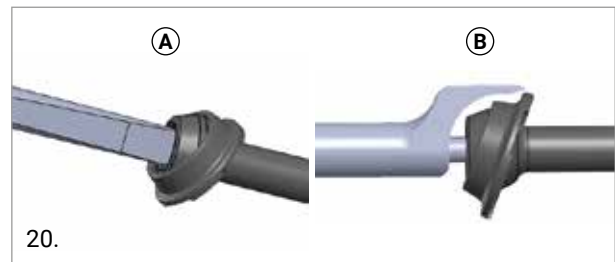
NOTICE: Titanium vs Stainless Steel Implants can be recognized as per the color, as shown in the following figure.



NOTICE: The Clamp Washer provides self-aligning plates to hold and mount the Washer in a proper way; subsequent steps to adjust the Washer profile may be needed to provide a final appropriate assembly.

4.8 IMPLANT REMOVAL

Implant removal can be performed by simply coupling the Screwdriver Hex tip to the Screw Head and applying counter-clock wise rotation. Enhanced implant removal could be provided by sliding the threaded tip of the Screwdriver (previously shown in Fig. 10). A set of an Hex Osteotome (Fig. 20A) and an Offset Osteotome (Fig. 20B) can be used to clean the screw head as well as the head surrounding bony bridges before extracting the screw.



If necessary, as in the case of long screw rupture or screw bone strip, a Screw Extractor can be used to retract the placed screw (Fig. 21).



WARNING

As the Screw Extractor generates irreversible screw damage, a new screw must be used afterwards.

5. IMPLANTS NOMENCLATURE

TRAUMA SCREWS



Partial Thread

Full Thread

Size - Ø x L [mm x mm]	Titanium Screws	Stainless Steel Screws	Titanium Screws	Stainless Steel Screws
7.3x70	03.65.001	03.67.001	03.65.021	03.67.021
7.3x75	03.65.002	03.67.002	03.65.022	03.67.022
7.3x80	03.65.003	03.67.003	03.65.023	03.67.023
7.3x85	03.65.004	03.67.004	03.65.024	03.67.024
7.3x90	03.65.005	03.67.005	03.65.025	03.67.025
7.3x95	03.65.006	03.67.006	03.65.026	03.67.026
7.3x100	03.65.007	03.67.007	03.65.027	03.67.027
7.3x110	03.65.008	03.67.008	03.65.028	03.67.028
7.3x120	03.65.009	03.67.009	03.65.029	03.67.029
7.3x130	03.65.010	03.67.010	03.65.030	03.67.030
7.3x140	03.65.011	03.67.011	03.65.031	03.67.031
7.3x150	03.65.012	03.67.012	03.65.032	03.67.032
7.3x160	03.65.013	03.67.013	03.65.033	03.67.033
7.3x170	03.65.014	03.67.014	03.65.034	03.67.034
7.3x180	03.65.015	03.67.015	03.65.035	03.67.035
7.3x200	03.65.016	03.67.016	03.65.036	03.67.036
8x70	03.65.101	03.67.101	03.65.121	03.67.121
8x75	03.65.102	03.67.102	03.65.122	03.67.122
8x80	03.65.103	03.67.103	03.65.123	03.67.123
8x85	03.65.104	03.67.104	03.65.124	03.67.124
8x90	03.65.105	03.67.105	03.65.125	03.67.125
8x95	03.65.106	03.67.106	03.65.126	03.67.126
8x100	03.65.107	03.67.107	03.65.127	03.67.127
8x110	03.65.108	03.67.108	03.65.128	03.67.128
8x120	03.65.109	03.67.109	03.65.129	03.67.129
8x130	03.65.110	03.67.110	03.65.130	03.67.130
8x140	03.65.111	03.67.111	03.65.131	03.67.131
8x150	03.65.112	03.67.112	03.65.132	03.67.132
8x160	03.65.113	03.67.113	03.65.133	03.67.133
8x170	03.65.114	03.67.114	03.65.134	03.67.134
8x180	03.65.115	03.67.115	03.65.135	03.67.135
8x200	03.65.116	03.67.116	03.65.136	03.67.136

TRAUMA SCREWS



Partial Thread

Full Thread

Size - Ø x L [mm x mm]	Titanium Screws	Stainless Steel Screws	Titanium Screws	Stainless Steel Screws
9x70	03.65.201	03.67.201	03.65.221	03.67.221
9x75	03.65.202	03.67.202	03.65.222	03.67.222
9x80	03.65.203	03.67.203	03.65.223	03.67.223
9x85	03.65.204	03.67.204	03.65.224	03.67.224
9x90	03.65.205	03.67.205	03.65.225	03.67.225
9x95	03.65.206	03.67.206	03.65.226	03.67.226
9x100	03.65.207	03.67.207	03.65.227	03.67.227
9x110	03.65.208	03.67.208	03.65.228	03.67.228
9x120	03.65.209	03.67.209	03.65.229	03.67.229
9x130	03.65.210	03.67.210	03.65.230	03.67.230
9x140	03.65.211	03.67.211	03.65.231	03.67.231
9x150	03.65.212	03.67.212	03.65.232	03.67.232
9x160	03.65.213	03.67.213	03.65.233	03.67.233
9x170	03.65.214	03.67.214	03.65.234	03.67.234
9x180	03.65.215	03.67.215	03.65.235	03.67.235
9x200	03.65.216	03.67.216	03.65.236	03.67.236
10x70	03.65.301	03.67.301	03.65.321	03.67.321
10x75	03.65.302	03.67.302	03.65.322	03.67.322
10x80	03.65.303	03.67.303	03.65.323	03.67.323
10x85	03.65.304	03.67.304	03.65.324	03.67.324
10x90	03.65.305	03.67.305	03.65.325	03.67.325
10x95	03.65.306	03.67.306	03.65.326	03.67.326
10x100	03.65.307	03.67.307	03.65.327	03.67.327
10x110	03.65.308	03.67.308	03.65.328	03.67.328
10x120	03.65.309	03.67.309	03.65.329	03.67.329
10x130	03.65.310	03.67.310	03.65.330	03.67.330
10x140	03.65.311	03.67.311	03.65.331	03.67.331
10x150	03.65.312	03.67.312	03.65.332	03.67.332
10x160	03.65.313	03.67.313	03.65.333	03.67.333
10x170	03.65.314	03.67.314	03.65.334	03.67.334
10x180	03.65.315	03.67.315	03.65.335	03.67.335
10x200	03.65.316	03.67.316	03.65.336	03.67.336

SI-JOINT SCREWS - TITANIUM HYDROXYAPATITE COATED



Size - Ø x L [mm x mm]	Reference Number	Size [Ø x L] [mm x mm]	Reference Number	Size [Ø x L] [mm x mm]	Reference Number
8x25	03.65.501	9x25	03.65.601	10x25	03.65.701
8x30	03.65.502	9x30	03.65.602	10x30	03.65.702
8x35	03.65.503	9x35	03.65.603	10x35	03.65.703
8x40	03.65.504	9x40	03.65.604	10x40	03.65.704
8x45	03.65.505	9x45	03.65.605	10x45	03.65.705
8x50	03.65.506	9x50	03.65.606	10x50	03.65.706
8x55	03.65.507	9x55	03.65.607	10x55	03.65.707
8x60	03.65.508	9x60	03.65.608	10x60	03.65.708
8x65	03.65.509	9x65	03.65.609	10x65	03.65.709
8x70	03.65.510	9x70	03.65.610	10x70	03.65.710
8x75	03.65.511	9x75	03.65.611	10x75	03.65.711
8x80	03.65.512	9x80	03.65.612	10x80	03.65.712

WASHER



Standard Washer



Favored Angle Washer

Size [Ø-mm]	Titanium	Stainless Steel	Titanium	Stainless Steel
Ø13	03.65.901	03.67.901		
Ø15	03.65.902	03.67.902	03.65.912	03.67.912
Ø17	03.65.903	03.67.903	03.65.913	03.67.913
Ø20	03.65.904	03.67.904	03.65.914	03.67.914

Part numbers subject to change.

NOTE FOR STERILIZATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable and following the instructions for use of the autoclave manufacturer.

For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilization of Medacta International reusable orthopedic devices" available at www.medacta.com.



**REDEFINING BETTER
IN ORTHOPAEDICS
AND NEUROSURGERY**

MEDACTA.COM



Medacta International SA
Strada Regina - 6874 Castel San Pietro - Switzerland
Phone +41 91 696 60 60 - Fax +41 91 696 60 66
info@medacta.ch

Find your local dealer at: medacta.com/locations

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