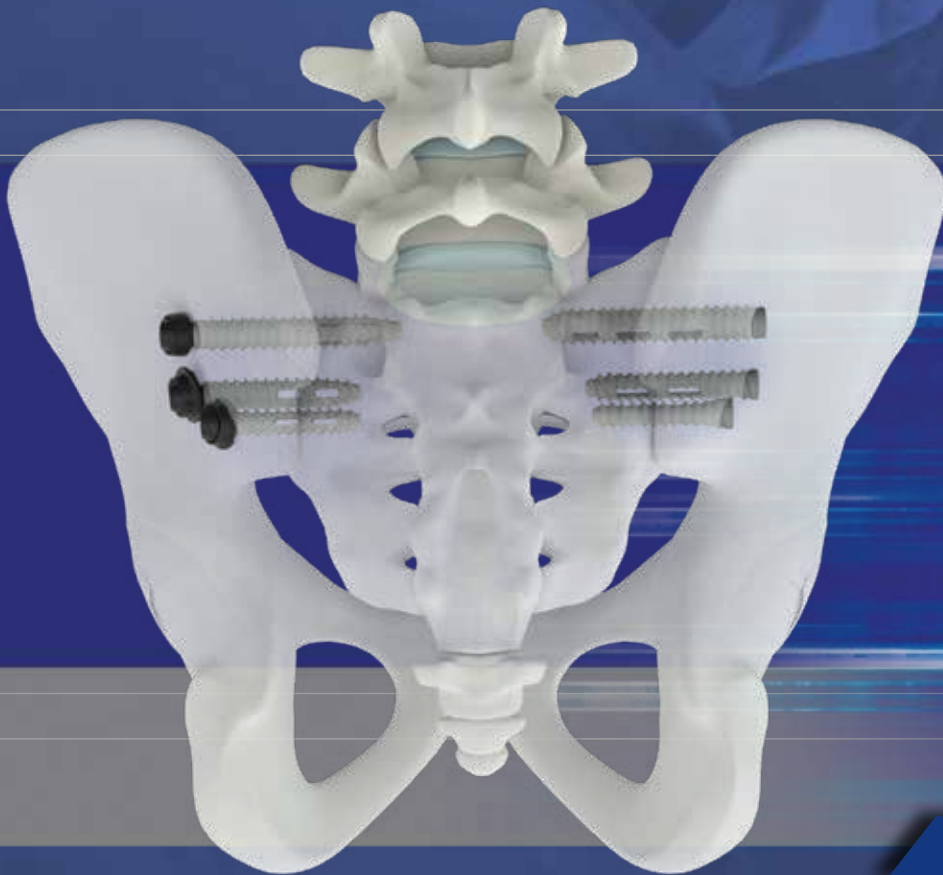


**U.S.T.® SI**

SACRO-ILIAC JOINT SCREW SYSTEM

A COMPLETE SYSTEM WITH DIFFERENT OPTIONS



**Surgical Technique**

Joint

**Spine**

Sports Med

**edacta**  
International 

## **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. INTRODUCTION

The M.U.S.T. Sacro Iliac Screws System [M.U.S.T. SI] is designed for the sacroiliac joint fusion in degenerative SIJ disruptions and degenerative sacroiliitis.



The M.U.S.T. SI screws are hollow-body, threaded fusion devices. The screws are designed with multiple fenestrations on the shaft to promote arthrodesis, with:

- Tapered screw tip to aid in guidance through a pilot hole
- Long pitch along with dual lead thread for accelerated screw insertion and removal
- Cannulated shaft accepts Ø3.2mm guide wire for better bone purchase
- A comprehensive range of lengths to accommodate patient anatomy

M.U.S.T. SI: Titanium plasma spray-coated screws with rough hydroxyapatite are designed to be used in cases of SI joint degeneration. The hydroxyapatite rough plasma spray-coating allows for biological fluid fixation and potentially leads to arthrodesis. Radial fenestration slots along the screws's body intended to allow surrounding bone access.

Two different versions of the M.U.S.T. SI Screw are available:

- Standard SI-Joint Screw: the head of the screw works as a mechanical stop during the insertion and is compatible with the modular washer.
- Headless SI-Joint Screw: the "anatomical headless design" allows the surgeon to fully insert the screw inside the bone.

Standard M.U.S.T. SI Screw only: "One-size-fits-all" Washers with favored angles capable to accommodate higher angulation. Self-tapping screws to facilitate screw insertion.

### 1.1 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.

### 1.2 CONTRAINDICATIONS

- Deformities or anatomic variations that prevent or interfere with SI implant placement
- Bone tumor involving the site of operation
- Active infection at the treatment site
- Intolerance / allergy to the materials used in the manufacturing of the device
- Any active or suspected latent infection or marked local inflammation in or surrounding the affected area
- Compromised vascularity that would inhibit adequate blood supply to the operated site
- Patients with fever, tumor, elevated white blood cell count, mental illness and other medical conditions which would prevent a 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 lead to an unacceptable risk of fixation failure or complications in postoperative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery
- Reuse or multiple uses
- Rapid joint disease, bone absorption, osteopenia

### 1.3 PREOPERATIVE PLANNING

The review of MRI and/or CT-based imaging to model 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.

## 2. ACCESS POINT PREPARATION

Depending on the selected screw design (M.U.S.T. SI Standard or Headless screw) some surgical steps may be different. Subsections 2.1 and 2.2 describe the common steps, while Sections 3 and 4 describe the steps to be followed for the M.U.S.T. SI Standard screw and the M.U.S.T. SI Headless screw respectively.

### 2.1 GUIDE WIRE INSERTION & SCREW LENGTH MEASUREMENT

Insert the wire positioner through the incision until it comes in contact with the bone surface to be treated (Fig. 2, 3). Once in place, insert the selected guide wire (305 mm or 450 mm length) through the guided sleeve into the bone.

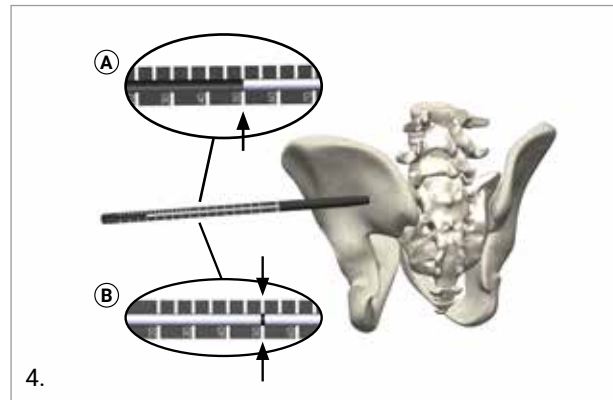
Check the proper insertion and depth with the image intensifier.



Slide the screw depth gauge through the guide wire down to the bone.

**NOTE:** When using the 305mm guide wire, the screw length measurement is taken from the end of the guide wire (Fig. 4A). When using the 450mm guide wire, the proper screw length measurement is taken from the corresponding black laser marking on the wire (Fig. 4B).

**NOTE:** Ensure that the depth gauge is placed against the cortex for accurate screw length measurement.



### 2.2 DRILLING AND TAPPING

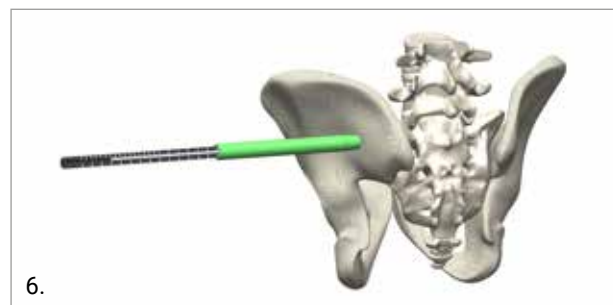
If a hard bone is encountered, it may be useful to drill and/or tap before inserting the screw.

**NOTE:** The set includes a green sleeve to be used as a tissue protector for drilling and tapping.

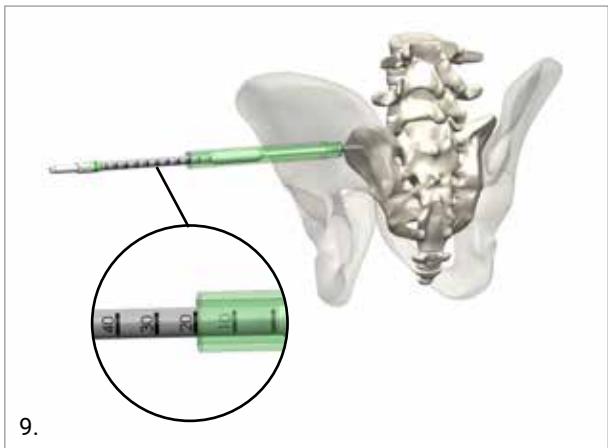
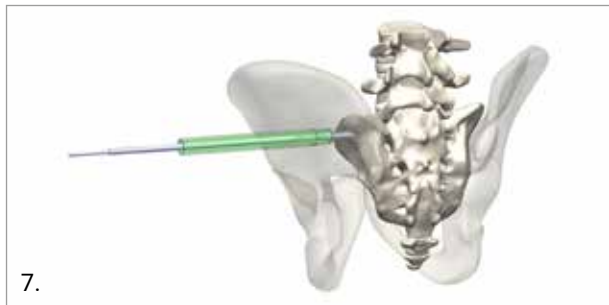
#### **WARNING**

With an internal diameter of 11mm, the green sleeve also acts as a tissue retractor for the insertion of the M.U.S.T. SI Headless screw and the M.U.S.T. SI Standard screws without washer. See Sections 3 and 4 for further details.

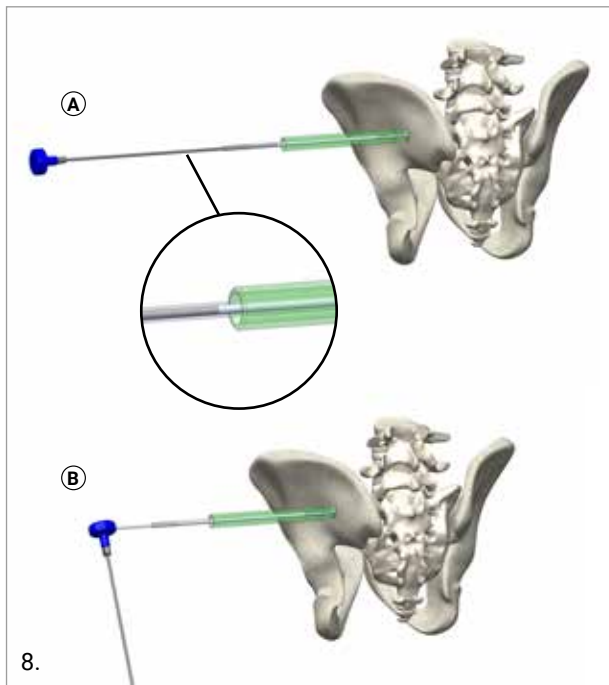
Slide the green sleeve over the depth gauge (Fig. 6). Remove the depth gauge.



Connect the drill bit with a surgical power tool. Slide the drill bit over the guide wire and begin drilling (Fig. 7). Check the drilling with the CT scan.



To easily remove the drill bit, a pin pusher is available in the set. The following figure (Fig. 8 A and B) shows two equivalent methods to use pin pusher. Remove the drill bit.

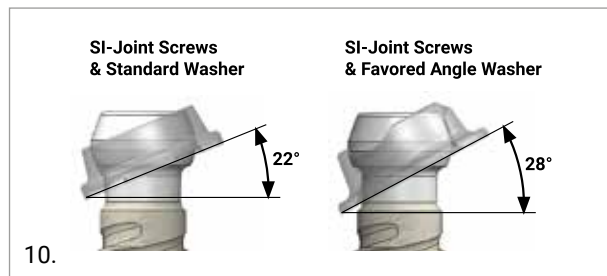


**NOTE:** The taps are 0.5mm undersized.

Insert the taps over the guide wire. The length of the tapping can be controlled through the scale marked over the shaft of the instrument (Fig. 9). When the tap and the green sleeve are in contact with the bone surface, the green sleeve is aligned with the 0mm marking on the tap.

### 3. M.U.S.T. SI STANDARD SCREW

If desired, Washers may be preassembled along with the M.U.S.T. SI Standard screws, before inserting the screw into the bone. Standard Washers are appropriate for typical angles, while the favored angle Washer may accommodate extreme angulation (see figure 10 for details).



If not needed, the M.U.S.T. SI Standard screw can be inserted alone, without the Washer (see Subsection 3.1). If the M.U.S.T. SI Standard screw is inserted with the Washer, please refer to Subsection 3.2.

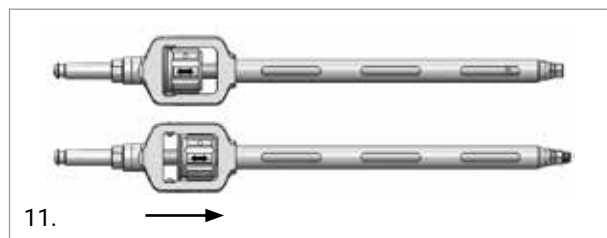
#### 3.1 M.U.S.T. SI STANDARD SCREW WITHOUT WASHER

##### Soft tissue retraction

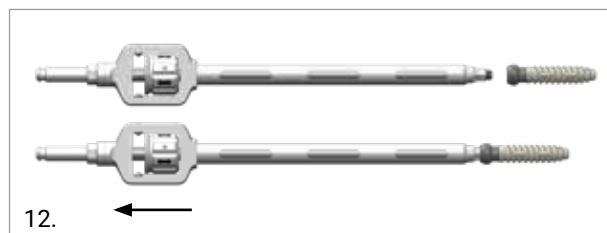
After performing the drilling and tapping, the green sleeve can also be used as a tissue retractor for the insertion of the M.U.S.T. SI Standard Screw without Washer. There is no need to perform further soft tissue retraction.

##### Screw insertion

Prepare the screwdriver for the screw insertion by pulling down the proximal wheel to extract the distal threaded tip (Fig. 11).



Insert the screwdriver threaded tip into the screw head and lock it by tightening the proximal wheel clockwise until a mechanical stop is achieved (Fig. 12).



Slide the M.U.S.T. SI Standard Screw-screwdriver assembly inside the green sleeve over the guide wire (Fig. 13). Screw until the mechanical stop is reached and the optimal fixation is achieved.



To release the screwdriver, turn the proximal wheel counterclockwise to release the screw head and pull it to complete the disengagement. Obtain final radiographic images to confirm screw placement/fracture reduction.

To insert additional screws, repeat the above procedure, starting from Subsection 2.1.

#### CAUTION

When placing multiple screws, the size of the screws must be evaluated to avoid their overlapping in situ.

Perform the wound closure according to standard techniques.

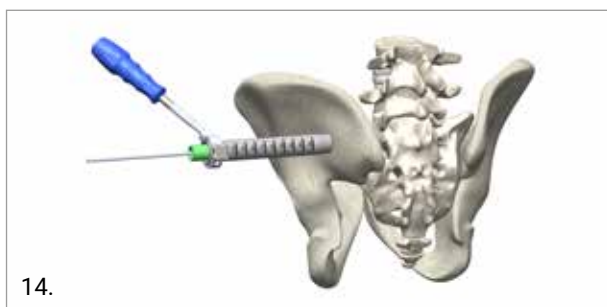
### 3.2 M.U.S.T. SI STANDARD SCREW WITH WASHER

#### Soft tissue retraction

In addition to the green sleeve, the set includes two dilators (Ø 15mm and Ø20 mm) to be coupled with the Ø16mm and Ø21mm retractors, respectively. With a larger diameter of the Washer, a larger dilation of the soft tissue is required.

#### M.U.S.T. SI Standard Screw coupled with Ø13mm and/or Ø15mm washer

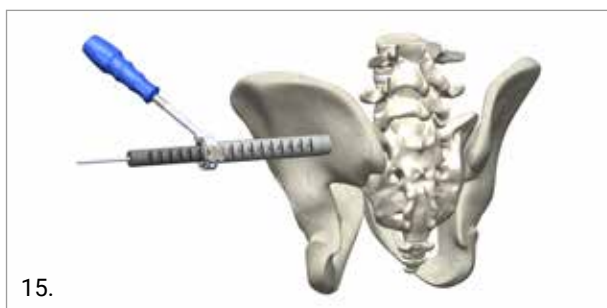
After the insertion of the green sleeve, the proper tissue dilation is reached by using the Ø16mm retractor. Insert the Ø16mm retractor over the green sleeve. A dedicated offset handle can be specifically coupled with the retractor for better handling (Fig. 14).



14.

#### OPTION

If the green sleeve is not in place, an alternative dilator with an external diameter of 15 mm is available in the set. Slide the dilator over the depth gauge and then proceed to insert the Ø16mm retractor (Fig. 15)

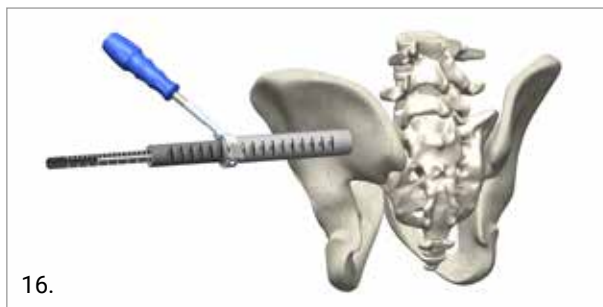


15.

Remove all the dilators, leaving in place only the Ø16mm retractor tube.

#### M.U.S.T. SI standard screw coupled with the Ø17mm and/or Ø20mm washer

Insert again the depth gauge inside the green sleeve and over the guide wire. Remove the green sleeve, then slide first the Ø20mm dilator and then the Ø21mm retractor tube over the depth gauge. A dedicated Offset Handle can be specifically coupled with the retractor for better handling (Fig. 16)



16.

Remove all the dilators, leaving in place only the Ø21mm retractor tube.

#### Selection of the Washer

After the soft tissue retraction, the next step is the selection of the proper size of the Washer with the help of the washer trial. Slide the washer trial over the guide wire inside the proper retractor tube:

- Ø13 and Ø15 washer trials inside Ø16 retractor tube
- Ø17 and Ø20 washer trials inside Ø21 retractor tube

All the steps are described in details in the paragraph above “soft tissue retraction”.



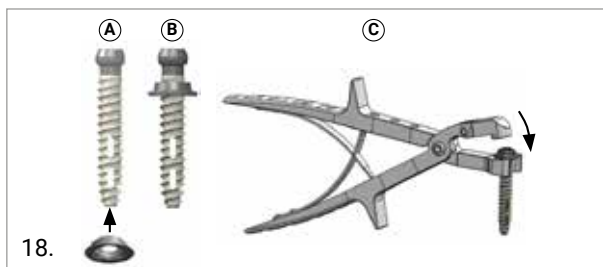
17.

Once the proper size of the Washer has been selected, proceed with the Washer assembly and with the Screw-Washer insertion, as described in the following sections.

#### Screw-Washer assembly

Before inserting the screw, assemble the Washer with the screw. Load the Washer from the distal tip of the screw (Fig. 18A) into a preliminary position (Fig. 18B). Place the Screw-Washer assembly onto the Washer clamp and compress it (Fig. 18C) until an audible sound confirms the proper assembly of the Washer into the head of the Screw.

**NOTE:** Once assembled according to the steps mentioned above, the Washer is securely connected with the screw.



18.



**WARNING**

The Washer must be correctly assembled to the Screw. WRONG assembly is shown in Fig. 19.



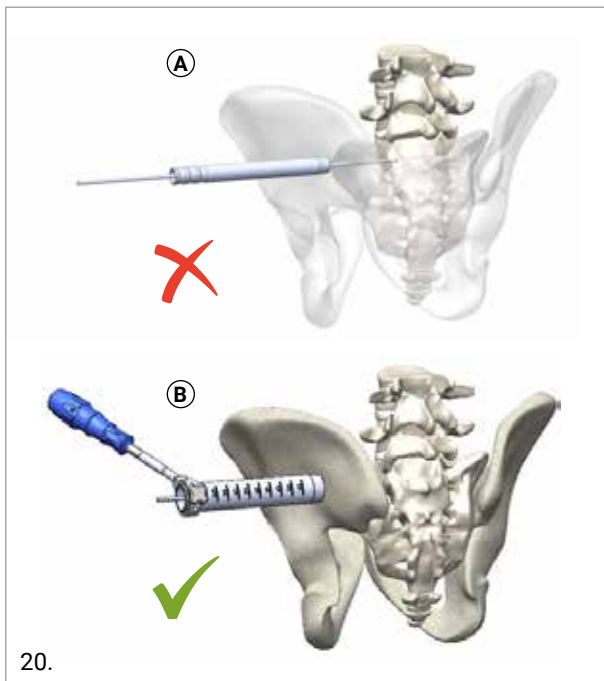
**NOTE:** The washer clamp has self-aligning plates to properly mount the Washer. Subsequent steps to adjust the Washer profile may be needed to provide a final appropriate assembly.

Once the screw is assembled with the washer, the surgeon can proceed with the insertion of the implant following the procedure described below.

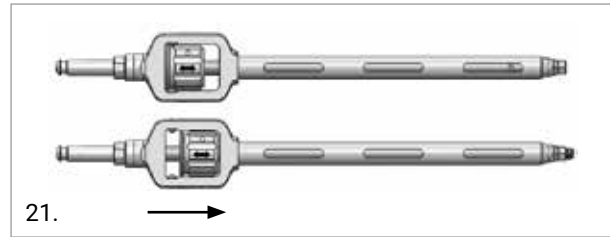
**Screw insertion**

**CAUTION**

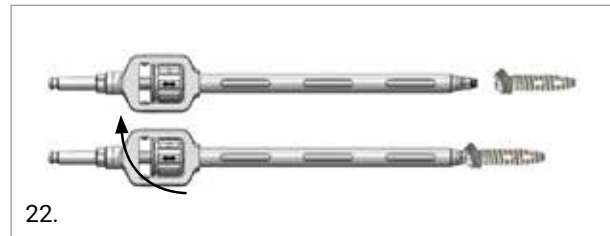
The screw insertion cannot be performed with the green sleeve in place. All the steps for an adequate retraction of the soft tissue have been explained in the paragraph "Soft tissue retraction". Please refer to this paragraph for any further detail.



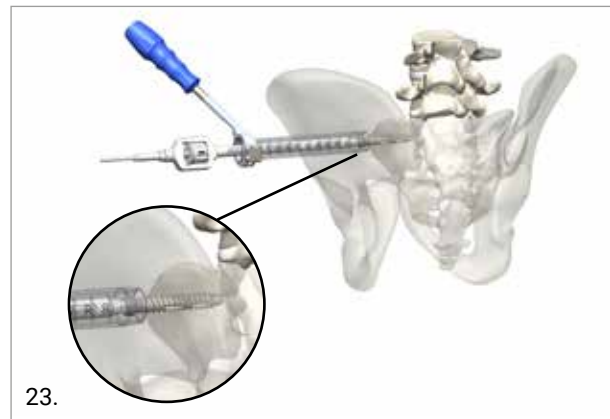
Prepare the screwdriver for the screw insertion by pulling down the proximal wheel to extract the distal threaded tip (Fig. 21).



Insert the screwdriver threaded tip into the screw head and lock it by tightening the proximal wheel clockwise until a mechanical stop is achieved (Fig. 22).



Insert the M.U.S.T. SI Standard Screw-Washer-screwdriver assembly through the retractor over the guide wire (Fig. 23). Screw until the the mechanical stop is reached and the optimal fixation is achieved (Fig. 23).



To release the screwdriver, turn the proximal wheel counterclockwise to release the screw head and pull it to complete disengagement. Obtain final radiographic images to confirm screw placement/fracture reduction.

To insert additional screws, repeat the above procedure, starting from Subsection 2.1.

**CAUTION**

When placing multiple screws, the sizes of the Washer and screws must be evaluated with the washer trial to avoid their overlap in situ.

Perform the wound closure according to standard techniques.

## 4. M.U.S.T. SI HEADLESS SCREW

### Soft Tissue Retraction

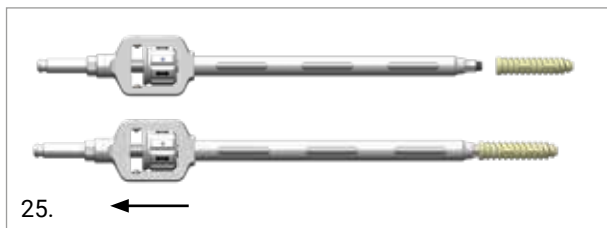
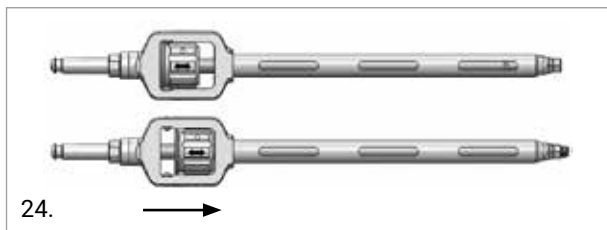
After performing the steps described in Subsections 2.1 and 2.2, the green sleeve is already in place and there is no need to perform further soft tissue retraction.

### CAUTION

The M.U.S.T. SI Headless Screw does not have a mechanical stop (like the washer or the screw head itself) with the bone when the insertion is completed. To avoid an undesired and excessive penetration, the M.U.S.T. SI Headless Screw must be inserted through the green sleeve, which acts as a mechanical stop when the screw insertion is completed. The mechanical stop cannot be achieved with any other dilators or retractor tubes in place. Make sure to have in place over the guide wire only the green sleeve before proceeding. If the green sleeve is not already in place, it must be inserted.

### Screw insertion

Prepare the screwdriver for the screw insertion by pulling down the proximal wheel to extract the distal threaded tip (Fig. 24). Insert the screwdriver threaded tip into the screw head and lock it by tightening the proximal wheel clockwise until a mechanical stop is achieved (Fig. 25).



Insert the M.U.S.T. SI Headless Screw-screwdriver assembly through the green sleeve over the guide wire. Screw until the mechanical stop between the driver and the

green sleeve is reached (Fig. 26). Once the stop is reached the screw is properly inserted into the bone.



To release the screwdriver, turn the proximal wheel counterclockwise to release the screw head and pull it to complete disengagement.

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

To insert additional screws, repeat the above procedure, starting from Subsection 2.1.

### CAUTION

When placing multiple screws, the sizes of the screws must be evaluated to avoid their overlapping in situ.

Perform the wound closure according to standard techniques.

## 5. IMPLANT REMOVAL

To remove the M.U.S.T. SI screw, the patient is positioned on the table in the same position as for the screw insertion and, utilizing standard surgical techniques, the wound is reopened. Implant removal can be performed by simply coupling the screwdriver Hex tip to the screw head and applying counterclockwise rotation.

Enhanced implant removal could be provided by sliding the threaded tip of the screwdriver.

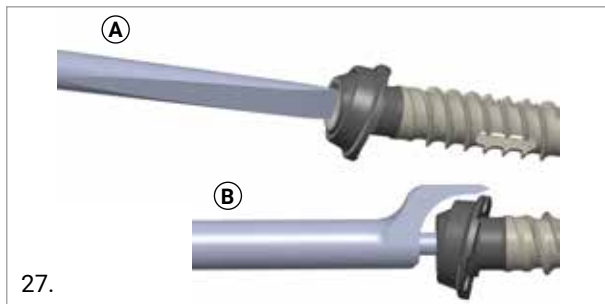
A set of a Hex Osteotomes (Fig. 27A) and an Offset Osteotome (Fig. 27B) can be used to clean the screw head as well as the head surrounding bony bridges before extracting the screw. The osteotomes can be used with all the screw designs described above.

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### WARNING

If bone has grown into the screw, removal may not be feasible.

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If necessary, as in the case of long screw rupture or screw bone stripping, a Screw Extractor can be used to retract the placed screw (Fig. 28).




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### WARNING

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

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## 6. IMPLANTS NOMENCLATURE

### M.U.S.T. SI STANDARD SCREW - 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

\* On demand

### M.U.S.T. SI HEADLESS SCREW - 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
7.5x30	03.65.551	9x30	03.65.651	11x30	03.65.751
7.5x35	03.65.552	9x35	03.65.652	11x35	03.65.752
7.5x40	03.65.553	9x40	03.65.653	11x40	03.65.753
7.5x45	03.65.554	9x45	03.65.654	11x45	03.65.754
7.5x50	03.65.555	9x50	03.65.655	11x50	03.65.755
7.5x55	03.65.556	9x55	03.65.656	11x55	03.65.756
7.5x60	03.65.557	9x60	03.65.657	11x60	03.65.757
7.5x65	03.65.558	9x65	03.65.658	11x65	03.65.758
7.5x70	03.65.559	9x70	03.65.659	11x70	03.65.759
7.5x75	03.65.660	9x75	03.65.660	11x75	03.65.760

### TITANIUM WASHER - STANDARD

---



SIZE [mm]	REFERENCE
Ø13	03.65.901
Ø15	03.65.902
Ø17	03.65.903
Ø20*	03.65.904

\* On demand

### TITANIUM WASHER - FAVORED ANGLE

---



SIZE [mm]	REFERENCE
Ø15	03.65.912
Ø17	03.65.913
Ø20*	03.65.914

\* On demand



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](http://www.medacta.com).



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