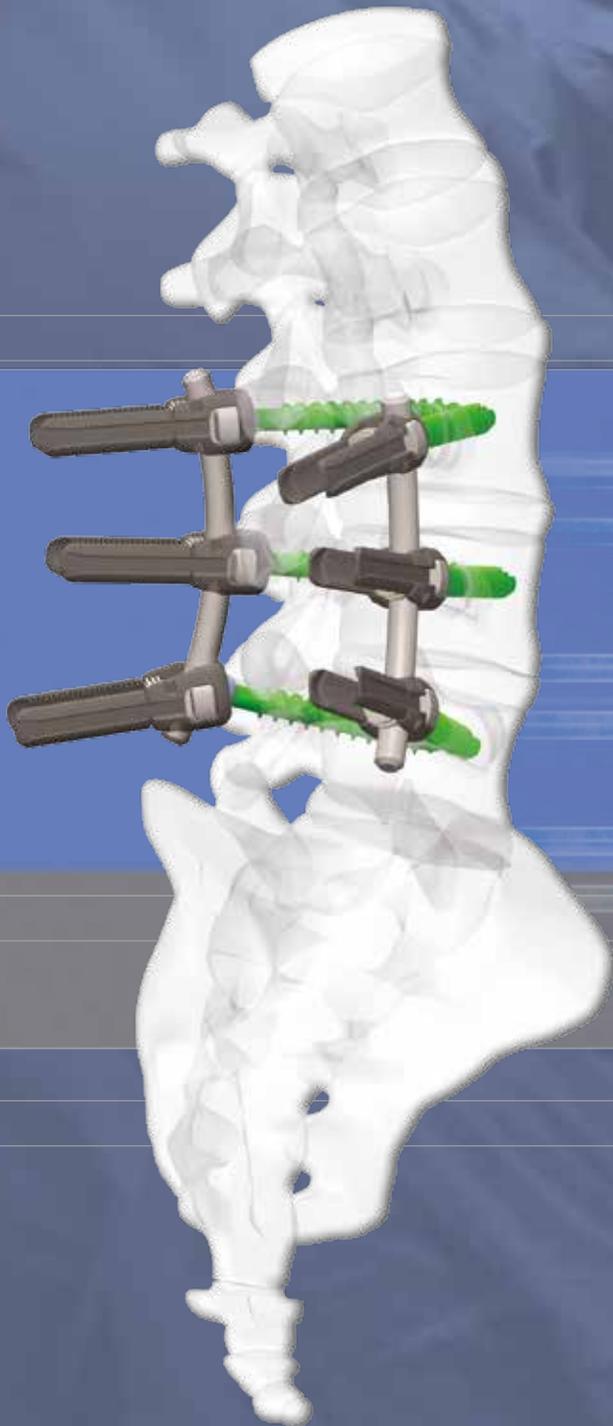


▲▲.U.S.T.

MEDACTA UNCONSTRAINED SCREW TECHNOLOGY - REDUCTION SCREWS



Surgical Technique

Hip

Knee

Spine

Navigation

INTRODUCTION



The Medacta Unconstrained Screw Technology [M.U.S.T.] Pedicle Screw System has been designed to give the surgeon ultimate flexibility in terms of choice of ideal bone anchor position, coupled with its unrivalled instrument handling capabilities that assist in spinal reduction, stabilisation and ultimately fixation.

The M.U.S.T. system consists of a comprehensive range of devices to fully assist surgeons in the posterior spinal fixation.

The M.U.S.T. Polyaxial Pedicle screw features a range of motion of greater than 60°, which coupled with dedicated instruments, allow the surgeon to achieve independent polyaxial tulip locking, allowing for easy parallel compression and distraction. These screws are available in a solid and a cannulated configuration giving the surgeons the chance to use them in standard open- as well as mini-open surgeries. Furthermore, the broad range in size of the M.U.S.T. screws allows to cover primary as well as revision surgeries, completing the scenarios of application in the posterior spine pathology treatment.

The MUST Polyaxial Reduction Screw is designed to further complement the innovative design of the existing MUST Polyaxial Screw range. These screws help to address, correct and also stabilize difficult anatomic variations. The Reduction Screw is designed with removable tabs that allow the surgeon to approximate the spine to the desired sagittal or axial profile.

ACKNOWLEDGEMENTS

Medacta International would like to express its gratitude to

ANGUS GRAY, MD

Sydney Orthopaedic Specialists
Sydney, Australia

CLAUDIO LAMARTINA, MD

Professor at I.R.C.C.S. - Istituto Ortopedico Galeazzi
Milan, Italy

MASOOD SHAFIFY, MD

Nottingham University Hospitals - Queens Medical Centre
Nottingham, UK

for their valuable contributions in the development of the M.U.S.T. implants, instruments and the surgical technique.

CONTENTS

1	INDICATIONS	4
2	CONTRAINDICATIONS	4
3	PRE-OPERATIVE PLANNING	4
4	SURGICAL APPROACH	4
5	PEDICLE PREPARATION	4
6	POLYAXIAL SCREW INSERTION	5
6.1	Polyaxial Screw Fixation	5
6.2	Head Adjusting	6
7	ROD CONTOURING AND INSERTION	7
8	SET SCREW INSERTION AND ROD REDUCTION	8
8.1	Reduction with Reduction Set Screwdriver	8
8.2	Reduction with Power Tool interface Set Screwdriver	9
8.3	Reduction with Modular Temporary Set Screwdriver	9
9	COMPRESSION OR DISTRACTION	10
10	IN SITU BENDING	10
11	TABS REMOVAL	10
12	FINAL TIGHTENING	10
13	M.U.S.T. LINK - CROSS CONNECTOR	11
14	POLYAXIAL REDUCTION SCREWDRIVER CONFIGURATION	11
15	REMOVAL AND REVISION PROCEDURES	11
16	INSTRUMENTS NOMENCLATURE	12
17	IMPLANTS NOMENCLATURE	13
17.1	Sterile Single Package	13

1 INDICATIONS

The M.U.S.T. Pedicle Screw System is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) and nonpedicle fixation, or anterolateral fixation (T8-L5). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis and failed previous fusion in skeletally mature patients.

2 CONTRAINDICATIONS

The use of the M.U.S.T. Pedicle Screw System is contraindicated in the following cases:

- Active infectious process or significant risk of infection (immunocompromised hosts).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance. Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.

3 PRE-OPERATIVE PLANNING

The review of MRI and/or CT based imaging to template and determine the type/size of the implants to be used to match the patient's anatomy is a critical step in the pre-operative planning before each surgery.

4 SURGICAL APPROACH

The M.U.S.T. Pedicle Screw System is designed with the focus on spinal fixation. The choice of the surgical approach is at the discretion of the surgeon.

The different Posterior approaches are Midline, Wiltse, Mini-Open.

5 PEDICLE PREPARATION

Please follow the same procedure described in the dedicated surgical technique of the Medacta M.U.S.T. implant.



WARNING

Before inserting pedicle screws larger than 7mm in diameter, is mandatory to tap the pedicles. In case of sclerotic bone or any other reason that can cause high resistance during screw insertion apply the same procedure for all the other diameters.

6 POLYAXIAL SCREW INSERTION

6.1 Polyaxial Screw Fixation

After the pedicle canal has been prepared and possibly tapped, the surgeon can plan for the M.U.S.T. screw insertion. The size of the screw to implant depends on the diameter and the length of the prepared pedicle canal, in relation to the vertebral anatomy. The M.U.S.T. screws can be inserted and fixed with the Polyaxial Pedicle Reduction Screwdriver specifically designed to easily align the screw in order to avoid toggling.

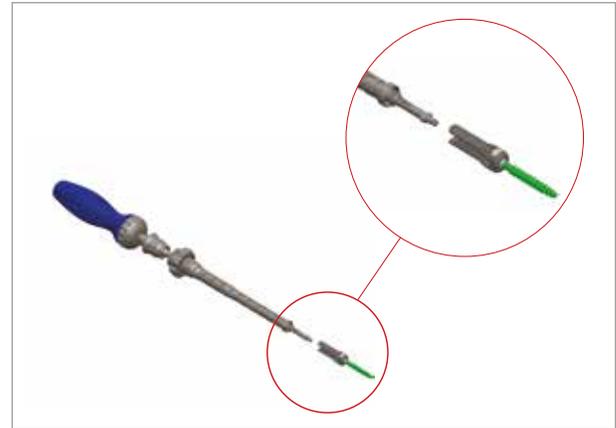


Start with attaching the Polyaxial Pedicle Reduction Screwdriver to the specific handle.

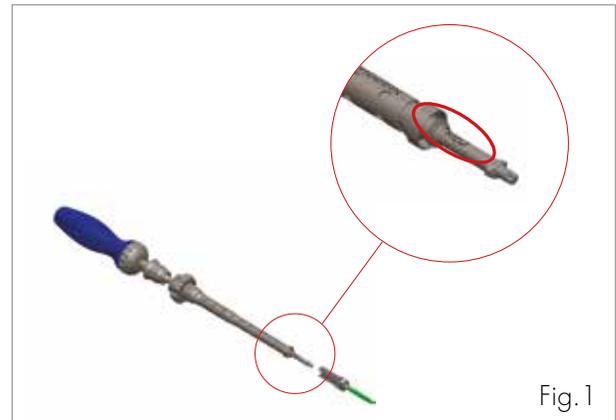


A Spherical, Straight or T-shaped Quick Connecting Ratcheting Handle is available in the standard MUST instrument set to give the surgeon a broad range of choice.

Insert the screwdriver tip into the screw head, locking it in the correct alignment as indicated in the figures here below.



NOTICE: In order to achieve the proper engagement onto the Screwdriver, the instrument has to be set up on the "RED" positioning by pushing the button on to the wheel-thumb (See Fig. 1-2).



As an alternative, it is also possible to proceed with the engagement of the crown sleeve together with the pedicle screw and the screwdriver. The sleeves can be used instead of the Counter torque during the final tightening manoeuvres Reduction Pedicle Screw (See Fig. 3-4).

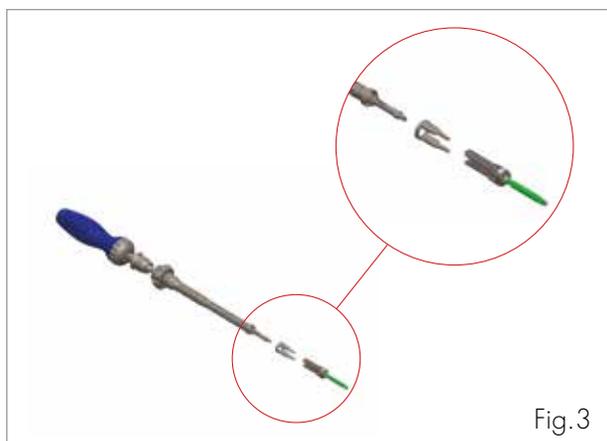


Fig.3

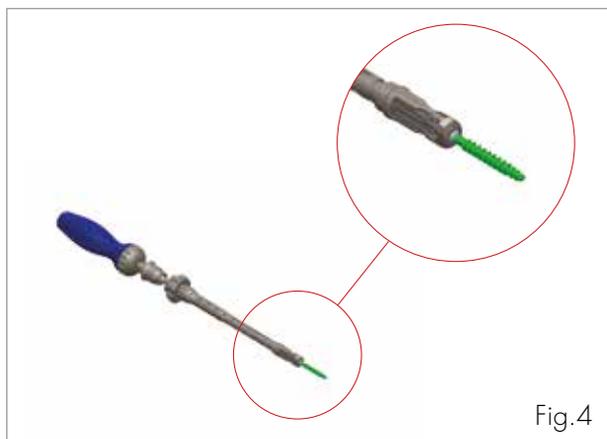


Fig.4

Tighten the head of the pedicle screw to the Polyaxial Screwdriver using the proximal gear, firmly turn it clockwise until the screw is fully tightened. Once secured, it is no longer possible for the screw to move as it is fully engaged with the Polyaxial Pedicle Reduction Screwdriver.

The pedicle screw can now be inserted into the pedicle following the standard MUST Surgical Technique Ref.99.46.12.

Insert the screw into the prepared pedicle canal by turning the Handle clockwise. The screws have a dual lead thread allowing for faster screw insertion (See Fig.5).



Fig.5

After satisfactory fixation of the screw you can easily remove the screwdriver from the pedicle screw head by turning the proximal gear counter-clockwise (See Fig.6).



Fig.6

OPTION

It is possible to use the Bone Screwdriver that does not lock the pedicle screw head (tulip) rotation. The use of the Bone Screwdriver is suggested for further screw advancement, if needed, after the insertion made with the Polyaxial Pedicle Screwdriver.

OPTION

Cannulated screws are available, and can be used following guidewire placement, upon surgeon preference.

6.2 Head Adjusting

Please follow the same procedure described in the dedicated surgical technique of the Medacta M.U.S.T. implant.

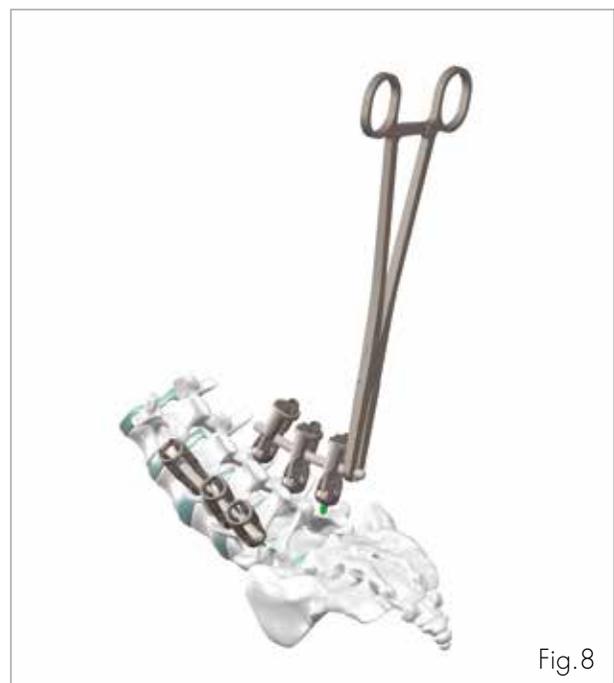
7 ROD CONTOURING AND INSERTION

All rods are available both in Titanium as well as in CoCr alloy with variable lengths, and in both straight and pre-bent forms.

The surgeon can select the rod that most closely approximates the desired sagittal contour. The pre-bent Trial Rods (35-100mm) can be used to facilitate the template process.

If further contouring of the rods is required to achieve the desired alignment, it is also possible to bend the rods with the dedicated bending instruments. For longer constructs, a malleable rod (450mm) is available and can be used to template the desired contouring (See Fig.7).

When using the Reduction Sleeves for Polyaxial Screwdriver, the rod should be inserted from one end of the construct (See Fig.8).



CAUTION

Use only the French Rod Bender available with the standard M.U.S.T. instrumentation to bend the rods. Never bend the rod more than one time. Repeated bending may result in a weakening of the rod and possible rod fracture.

Use the rod insertion forceps to position the rod into the selected pedicle screw heads.



CAUTION

When possible, position the rod with the laser marking facing posteriorly to help the correct alignment within the screw heads.

8 SET SCREW INSERTION AND ROD REDUCTION

Engage the setscrew on to the Reduction setscrew driver by placing the set screw on a flat surface and pushing down the driver as described in picture 9-10 then start the temporary tightening procedure.



Fig.9



Fig.10

NOTICE: All the Temporary Setscrewdrivers require the same procedure in order to properly engage the set screw along with the instrument.

8.1 Reduction with Reduction Set Screwdriver

Once the setscrew is engaged, slide the Enhanced Screwdriver onto the tulip grooves and press down the handle in order to thread the setscrew into the screw head.



When the desired reduction has been obtained, it is possible to temporarily tighten the set screw using the Temporary Reduction Set Screwdriver.



8.2 Reduction with Power Tool interface Set Screwdriver

As an alternative, it is also possible to use a Temporary Setscrewdriver with a specific Power Tool interface to perform the temporary tightening surgical step.



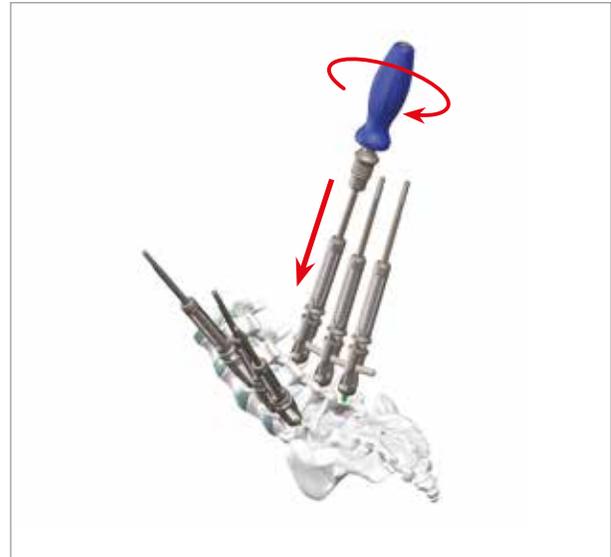
! / WARNING

Before starting the temporary tightening maneuver with the Power Tool, check first the proper engagement of the set screw into the tulip in order to avoid any cross threading.

Avoid also any over tightening by the usage of the Power Tool until the end of the reduction tulip thread.

8.3 Reduction with Modular Temporary Set Screwdriver

If a progressive reduction of the rod is needed, it is possible to tighten the set screw with the Modular Temporary set screwdriver. All the modules can be slid on the implants. The straight handle has to be connected in order to achieve the temporary tightening of the set screw.



Once the temporary tightening is achieved, it is then possible to proceed with the next surgical steps.

9 COMPRESSION OR DISTRACTION

Please follow the same procedure described in the dedicated surgical technique of the Medacta M.U.S.T. implant.

10 IN SITU BENDING

In the standard instrumentation, several bending instruments are available to perform in situ coronal and sagittal rod bending as well as rod rotation.

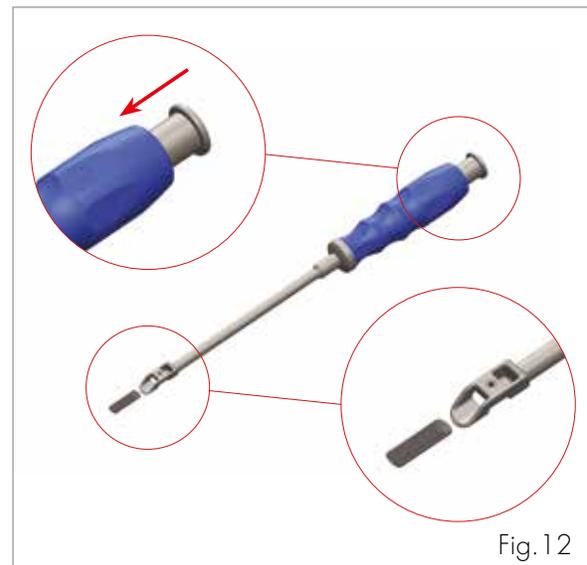
11 TABS REMOVAL

Once the temporary tightening is achieved, it is then possible to start the tabs removal by the aim of the tab removal tool.

To break off the reduction screw tabs, slide the tab removal tool over one side wall of the reduction head. Gently rock the tab removal tool medial then lateral to break the tab wall free from the polyaxial head (See Fig. 11).



The tabs removed can be ejected from the instrument inner shaft by pushing the release button on the top (See Fig. 12).



12 FINAL TIGHTENING

Please follow the same procedure previously described in the dedicated surgical technique of the Medacta M.U.S.T. implant.

NOTICE: The final tightening surgical step using the Counter-torque along with the Torque Limiter is possible only after the complete extended tabs removal.

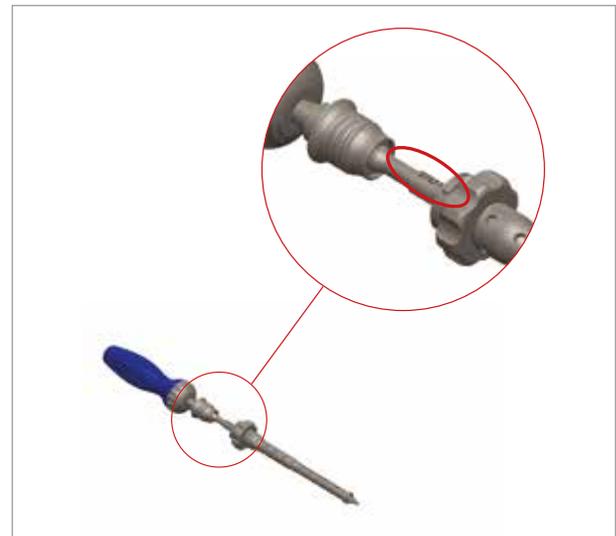
13 M.U.S.T. LINK - CROSS CONNECTOR

Please follow the same procedure previously described in the dedicated surgical technique of the Medacta M.U.S.T. implant.

14 POLYAXIAL REDUCTION SCREWDRIVER CONFIGURATION

In case of necessity, the Polyaxial Reduction Screwdriver can be also be coupled with a MUST standard pedicle screw by pressing the set up button and sliding down the outer shaft of the Screwdriver itself. The instrument has to be set up on the "STD" positioning.

The so configured instrument, can also be used for the reduction pedicle screw unscrewing if necessary.



15 REMOVAL AND REVISION PROCEDURES

The standard M.U.S.T. pedicle screw instruments can be used in case of revision surgery or removal of the implants.



CAUTION

Potential metal fragments have to be removed from the implant to avoid any adverse reaction because of dissimilar metals.

16 INSTRUMENTS NOMENCLATURE

Ref.	Description	Picture
03.51.10.0201	Tabs Remover - Outer Shaft Assy	
03.51.10.0202	Tabs Remover - Inner Shaft Assy	
03.51.10.0203	Temporary Set Screwdriver Reduction	
03.51.10.0221	Polyaxial Screwdriver Reduction Solid	
03.51.10.0222	Polyaxial Screwdriver Reduction Cannulated	
03.51.10.0205	Temporary Set Screwdriver Reduct. Mod. Fast	
03.51.10.0206	Reduction Sleeve	
03.51.10.0207	Temporary Set Screwdriver Reduct. Mod. Short	
03.51.10.0212	Reduction Sleeve MySpine	
03.51.10.0216	Standard Sleeve MySpine	
03.75.10.0071	Small Straight Weber- AO Connection small	
03.75.10.0006	Quick Connection Handle	

17 IMPLANTS NOMENCLATURE

17.1 Sterile Single Package

Polyaxial Reduction Pedicle Screws - Solid

Reference ¹	Diameter (mm)	Length (mm)
03.50.751	4	20
03.50.752		25
03.50.753		30
03.50.754		35
03.50.755		40
03.50.756		45
03.50.757		50
03.50.701	4,5	20
03.50.702		25
03.50.703		30
03.50.704		35
03.50.705		40
03.50.706		45
03.50.707		50
03.50.708	5	25
03.50.709		30
03.50.710		35
03.50.711		40
03.50.712		45
03.50.713		50
03.50.714	6	25
03.50.715		30
03.50.716		35
03.50.717		40
03.50.718		45
03.50.719		50
03.50.720		55
03.50.721		60
03.50.722		65
03.50.728	7	30
03.50.729		35
03.50.730		40
03.50.731		45
03.50.732		50
03.50.733		55
03.50.734		60
03.50.735		65
03.50.736		70
03.50.738		80
03.50.740		90

Polyaxial Reduction Pedicle Screws - Cannulated

Reference ¹	Diameter (mm)	Length (mm)
03.52.701	4,5	20
03.52.702		25
03.52.703		30
03.52.704		35
03.52.705		40
03.52.706		45
03.52.707		50
03.52.708	5	25
03.52.709		30
03.52.710		35
03.52.711		40
03.52.712		45
03.52.713	50	
03.52.714	6	25
03.52.715		30
03.52.716		35
03.52.717		40
03.52.718		45
03.52.719		50
03.52.720		55
03.52.721		60
03.52.722		65
03.52.728	7	30
03.52.729		35
03.52.730		40
03.52.731		45
03.52.732		50
03.52.733		55
03.52.734		60
03.52.735		65
03.52.736		70
03.52.738		80
03.52.740		90

¹ includes 1 screw and 1 set screw

Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilised in an autoclave respecting the regulations of the country, EU 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 sterilisation 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

All trademarks and registered trademarks are the property of their respective owners.

M.U.S.T. Reduction Pedicle Screw System
Surgical Technique

ref: 99.46RS.12US
rev.01

Last update: November 2016