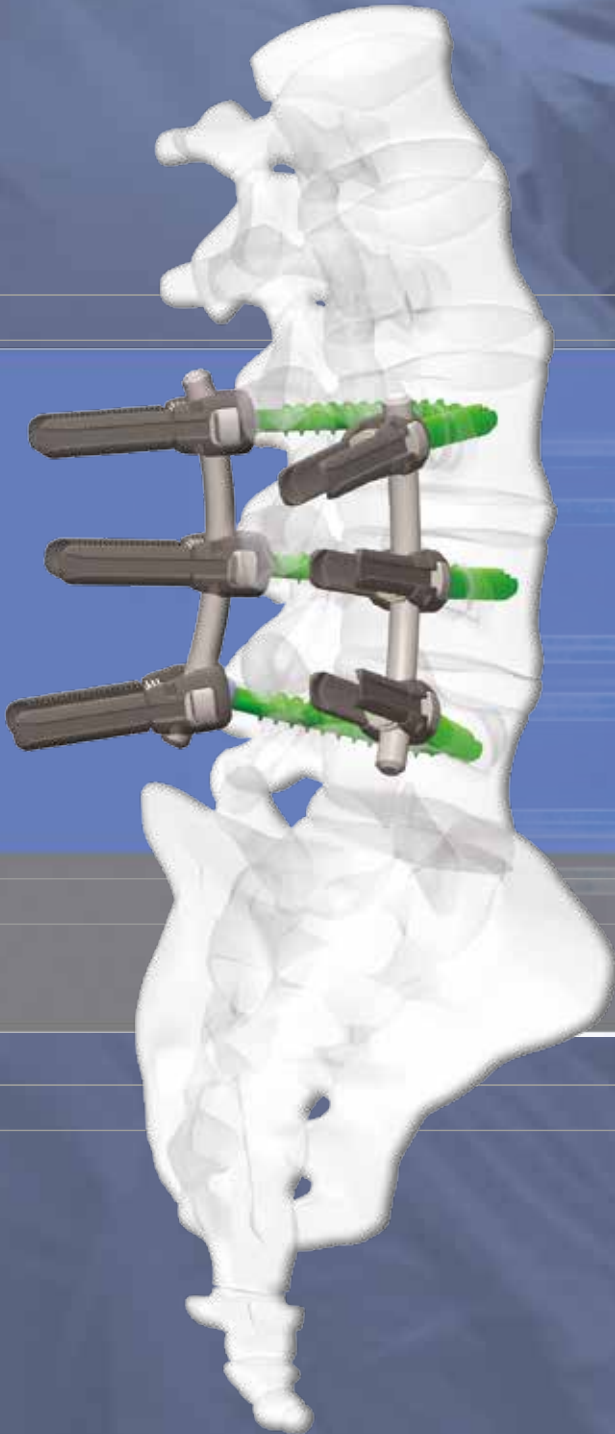


# ▲▲.U.S.T.

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

|             |   |    |
|-------------|---|----|
| <b>1</b>    | INDICATIONS   | 4  |
| <b>2</b>    | CONTRAINDICATIONS                                   | 4  |
| <b>3</b>    | PRE-OPERATIVE PLANNING                              | 4  |
| <b>4</b>    | SURGICAL APPROACH                                   | 4  |
| <b>5</b>    | PEDICLE PREPARATION                                 | 4  |
| <b>6</b>    | POLYAXIAL SCREW INSERTION                           | 5  |
| <b>6.1</b>  | Polyaxial Screw Fixation                            | 5  |
| <b>6.2</b>  | Head Adjusting                                      | 6  |
| <b>7</b>    | ROD CONTOURING AND INSERTION                        | 7  |
| <b>8</b>    | SET SCREW INSERTION AND ROD REDUCTION               | 8  |
| <b>8.1</b>  | Reduction with Reduction Set Screwdriver            | 8  |
| <b>8.2</b>  | Reduction with Power Tool interface Set Screwdriver | 9  |
| <b>8.3</b>  | Reduction with Modular Temporary Set Screwdriver    | 9  |
| <b>9</b>    | COMPRESSION OR DISTRACTION                          | 10 |
| <b>10</b>   | IN SITU BENDING                                     | 10 |
| <b>11</b>   | TABS REMOVAL  | 10 |
| <b>12</b>   | FINAL TIGHTENING                                    | 10 |
| <b>13</b>   | M.U.S.T. LINK - CROSS CONNECTOR                     | 11 |
| <b>14</b>   | POLYAXIAL REDUCTION SCREWDRIVER CONFIGURATION       | 11 |
| <b>15</b>   | INSTRUMENTS NOMENCLATURE                            | 11 |
| <b>16</b>   | IMPLANTS NOMENCLATURE                               | 12 |
| <b>16.1</b> | Sterile Single Package                              | 12 |

## 1 INDICATIONS

The M.U.S.T. Pedicle Screw System is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) 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.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the M.U.S.T. implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The system is intended to be used with autograft and/or allograft. Pediatric applications are limited to a posterior approach.

## 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.

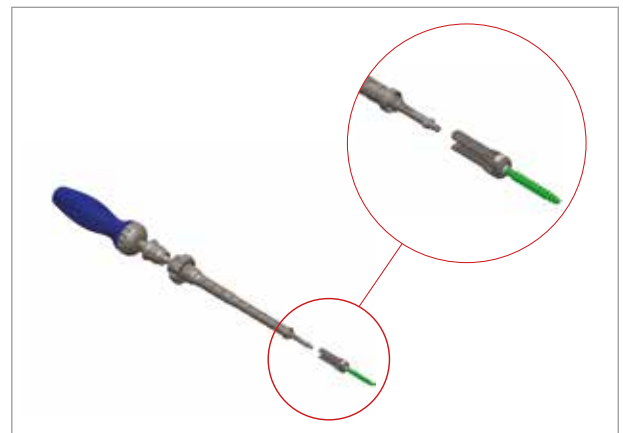


Start with attaching the Polyaxial Pedicle Reduction Screwdriver to the specific handle.



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).

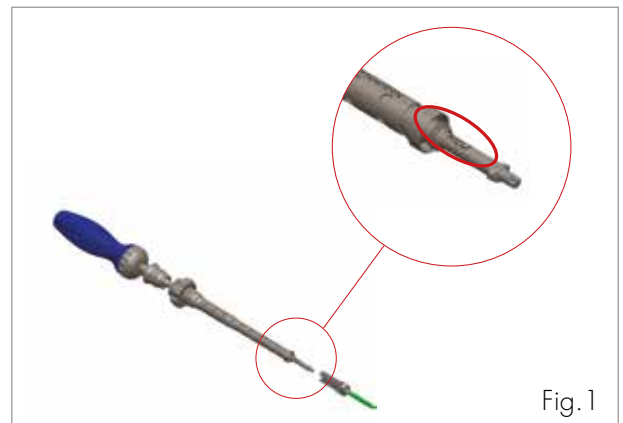


Fig. 1



Fig. 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).

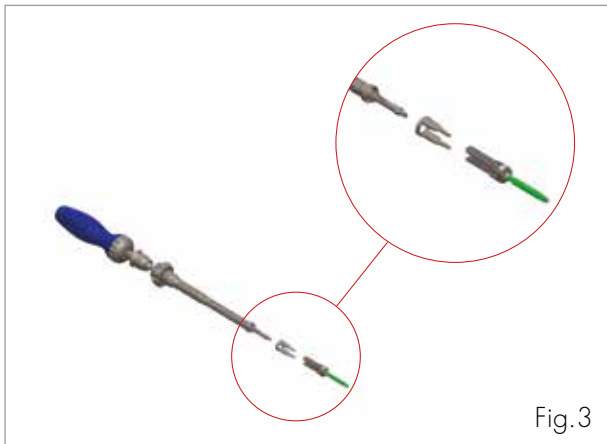


Fig.3

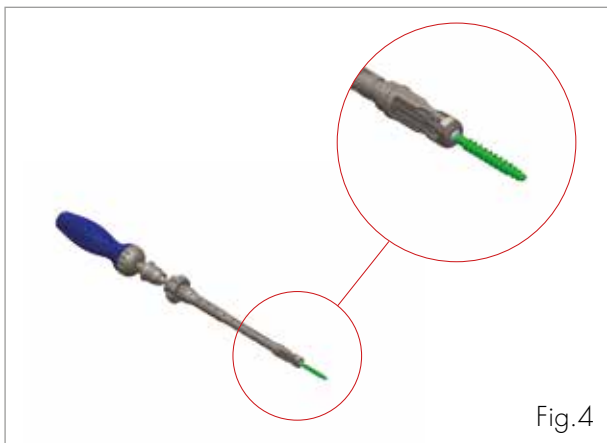


Fig.4

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).



Fig.7



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 slided 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).



Fig. 11

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

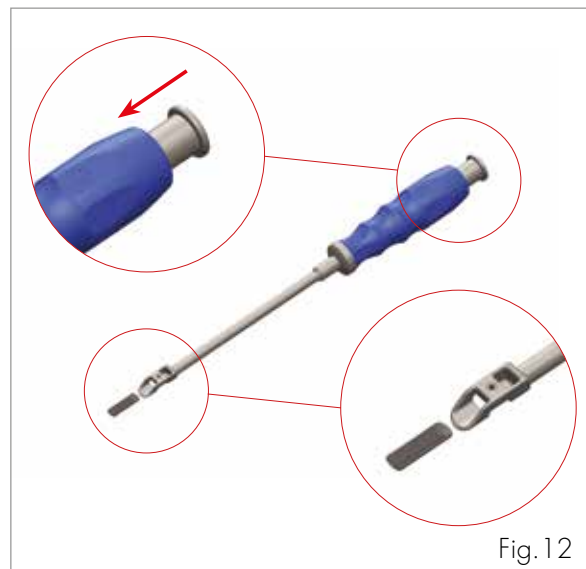


Fig. 12

## 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.

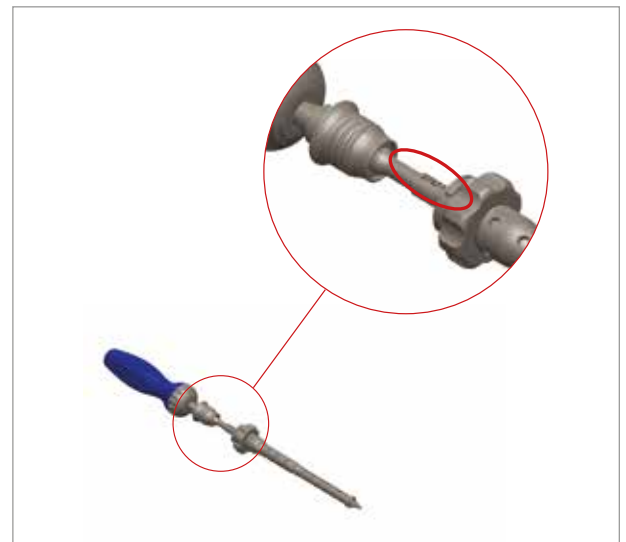
## 13 M.U.S.T. LINK - CROSS CONNECTOR

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 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          |  |
| 03.51.10.0204 | Polyaxial Screwdriver Reduction Solid        |  |
| 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                      |  |

## 16 IMPLANTS NOMENCLATURE

### 16.1 Sterile Single Package

#### Polyaxial Reduction Pedicle Screws - Solid

| Reference <sup>1</sup> | Diameter (mm) | Length (mm) |
|------------------------|---------------|-------------|
| 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          |
| <hr/>                  |               |             |
| 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          |
| <hr/>                  |               |             |
| 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          |
| <hr/>                  |               |             |
| 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 <sup>1</sup> | Diameter (mm) | Length (mm) |
|------------------------|---------------|-------------|
| 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          |
| <hr/>                  |               |             |
| 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          |
| <hr/>                  |               |             |
| 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          |

<sup>1</sup> includes 1 screw and 1 set screw





Part numbers subject to change.

## NOTE FOR STERILISATION

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

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





International



## HEADQUARTERS

**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

## REPRESENTATIVE

**Switzerland - Frauenfeld**  
Gewerbestrasse 3 - 8500 Frauenfeld  
Phone +41 (0) 848 423 423  
Fax +41 (0) 848 423 424  
info@medacta-swiss.ch

## SUBSIDIARIES

**Australia** Medacta Australia PTY.LTD - Unit F37, 16 Mars Road - Lane Cove Business Park - NSW  
Phone +61 (2) 94202944 - Fax +61 (2) 94202578 - info@medacta.com.au

**Belgium** Medacta Belgium B.V.B.A./S.P.R.L. - 5a Rue de la Maîtrise - 1400 Nivelles  
Phone +32 (0) 67 555 482 - Fax +32 (0) 67 555 483 - info@medacta.be

**Canada** Medacta Canada Inc. - 31 McBrine Drive, Unit 11- N2R 1J1 - Kitchener, Ontario  
Phone +1 519 279 1934 - Fax +1 519 279 1938 - info@medacta.ca

**China** Medacta China - Room B, 32/F, New SH Intl Tower - No. 360 Pudong South Road - Shanghai 200120, China  
Phone +86 21 5835 1149 - info@medacta.cn

**France** Medacta France SAS - 6 Rue du Commandant d'Estienne d'Orves - Parc des Chanteraines - 92390 Villeneuve - La Garenne  
Phone +33 147 39 07 22 - Fax +33 147 39 73 17 - info@medacta.fr

**Germany** Medacta Ortho GmbH - Jahnstrasse 86 - D - 73037 Göppingen  
Phone +49 (0) 7161 50 44 312 - Fax +49 (0) 7161 50 44 320 - info@medacta.com

**Italy** Medacta Italia Srl - Via G. Stephenson, 94 - 20157 Milano  
Phone +39 02 390 181 - Fax +39 02 390 00 704 - mail@medacta.it

**Japan** Medacta Japan CO. LTD - 100-0014 Chiyoda House 201 - 2 - 17-8, Nagatacho, Chiyoda-ku, Tokyo  
Phone +81 (0) 3 5510 8883 - Fax +81 (0) 3 5510 8884 - info@medacta.co.jp

**Spain** Medacta España SLU - Avda de las Jacarandas - 2 - Edificio CREA Oficina 631- 46100 - Burjassot  
Phone +34 (0) 963 484 688 - Fax +34 (0) 963 484 688 - info@medacta.es

**UK** Medacta UK Limited - 16 Greenfields Business Park - Wheatfield Way - Hinckley - Leicestershire - LE10 1BB  
Phone +44 (0) 1455 613026 - Fax +44 (0) 1455 611446 - info@medacta.co.uk

**USA** Medacta USA, Inc. - 1556 West Carroll Avenue - Chicago - IL 60607  
Phone +1 312 878 2381 - Fax +1 312 546 6881 - info@medacta.us.com

## DISTRIBUTORS

|           |         |          |        |             |              |         |
|-----------|---------|----------|--------|-------------|--------------|---------|
| Argentina | Austria | Belarus  | Brazil | Bulgaria    | Colombia     | Greece  |
| Indonesia | Kuwait  | Malaysia | Mexico | New Zealand | South Africa | Vietnam |

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

ref: 99.46RS.12  
rev.00

Last update: March 2015  
CE 0476