

▲.U.S.T.

MEDACTA UNIVERSAL SCREW TECHNOLOGY

ULTIMATE VERSATILITY IN ONE SYSTEM - FENESTRATED SCREW



Surgical Technique

Joint

Spine

Sports Med

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1. INTRODUCTION

The Medacta Universal Screw Technology [M.U.S.T.] Pedicle Screw System has been designed to give a surgeon ultimate flexibility in their choice of ideal bone anchor position, coupled with unrivalled instrument handling capabilities which 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 with 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, allows the surgeon to achieve independent polyaxial tulip locking which also enables easy parallel compression and distraction. The M.U.S.T. Polyaxial Pedicle screws are available in a solid and a cannulated configuration giving surgeons a choice when using them in standard open- as well as mini-open/MIS surgeries. Furthermore, the broad range in sizes available of the M.U.S.T. screws allows coverage of primary as well as revision surgeries, completing all scenarios of application in posterior spine pathology treatments.

The M.U.S.T. Polyaxial Fenestrated Screw is designed to further complement the innovative design of the existing M.U.S.T. Polyaxial Screw range.

The M.U.S.T. Polyaxial Fenestrated Screw offers improved fixation in the pedicle as well as in the vertebral body. Provided with a constant diameter and with a dual thread design option, this further enhances screw/bone contact whilst simultaneously increasing fixation.

Finally, the option of an augmented cemented screw is optimal for those patients with diminished bone quality and when the screw purchase requires a boost.



1.1 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.

1.2 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/or 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 utilisation would interfere with anatomical structures or expected physiological performance. Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.

1.3 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.

1.4 SURGICAL APPROACH

The M.U.S.T. Pedicle Screw System design focuses on spinal fixation. Surgical approach is at the discretion of the surgeon with posterior approach options including Midline, Wiltse and Mini-Open.

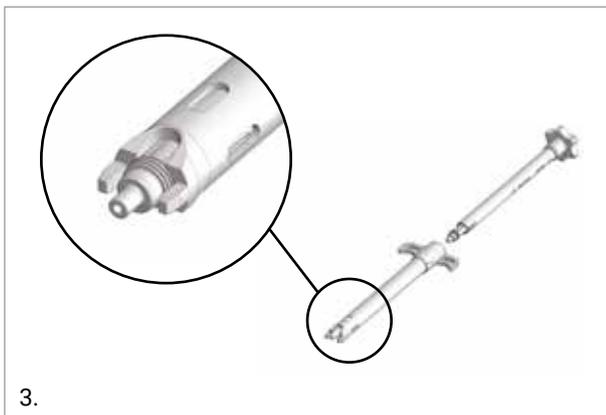
2. STEPS FOR OPEN SURGICAL APPROACH

2.1 PEDICLE PREPARATION AND SCREW FIXATION

Perform pedicle preparation and the following screw fixation according to the M.U.S.T. standard Surgical Technique (ref. 99.46.12).

2.2 ADAPTER PREPARATION

Connect the Adapter Driver with the open Cannula Adapter (See Fig.2) and couple the so-formed assembly with Driver Counter Torque (See Fig.3): confirm all the parts are fully engaged with visual and tactile feedbacks. The Cannula Adapter allows alignment of the tulip with respect to the screw axis.



Match the Adapter Driver - Open Cannula Adapter - Counter Torque Driver Assembly with the Pedicle screw head. Match the Counter-torque pins with the Pedicle screw head and turn the Adapter Driver until the Open Cannula Adapter is fully tightened.



Correct alignment is achieved when the pedicle screw head and the screw are vertically aligned.

Prepare all vertebrae that need to be cement augmented by repeating the above defined process.



WARNING

Before proceeding to the cement injection, a correct pedicle screws placement must be verified. X-rays controls must be taken in order to avoid any possible cement leakage.

2.3 PREPARATION AND CEMENT DELIVERY

Prepare cement according to the supplier's instructions for use. Carefully follow the Time/temperature graph as provided.

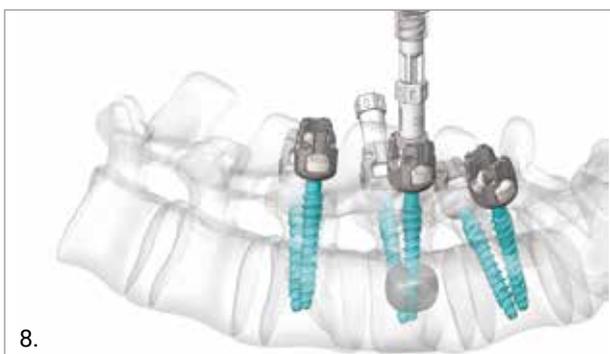
Load cement into the syringe; connect syringe with the open cannula and then insert the cement into the open Cannula adapter to comply with correct delivery of cement to screws in situ.



Gently inject the cement in order to create a cement mantle around the screw shank.

NOTE: Cement delivery should only be started when the Open Cannula Adaptor is sealed. This will prevent any undesirable leakage occurring.

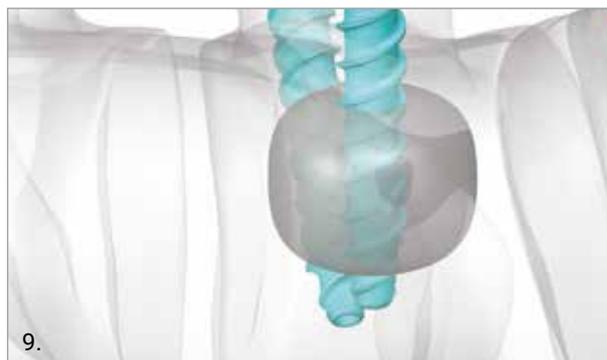
The residual cement volume in the Open Cannula is up to 0.2 ml.



CAUTION

Actively monitor cement flow distribution throughout this process through X-ray imaging in order to prevent excess cement leakage.

NOTE: Surgeons should evaluate the proper volume of cement to inject depending on the bone quality/morphology and patient's need. Some literature data have suggested that a suitable volume of injectable cement should be about 2mL.



Repeat the cement injection procedure for all vertebrae that require augmentation.

2.4 ADAPTER REMOVAL

As cement hardens, proceed with the removal of the adapter.

WARNING

Cannula Adapter removal should only commence once the cement has hardened. This will prevent any undesirable leakages.

Remove the cannula. To remove the Cannula Adapters, couple the Adapter Driver - Adapter Counter Torque assembly to the tulip of the screw and turn the Adapter Driver anticlockwise.



CAUTION

Continue to counter-torque the pedicle screw head during Cannula Adapter removal in order to prevent any undesired screw movements.

3. STEPS FOR MINI - OPEN SURGICAL APPROACH

3.1 PEDICLE PREPARATION AND SCREW FIXATION

Perform the pedicle preparation according to the M.U.S.T. Mini-Open approach (ref. 99.mini46.12).

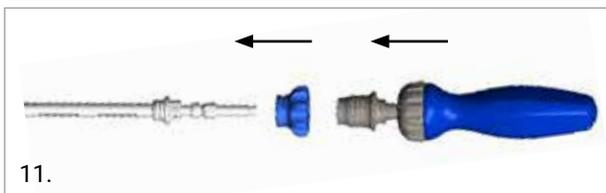
For the screw fixation two different equivalent options are available.

Option 1: standard Mini-Open Approach

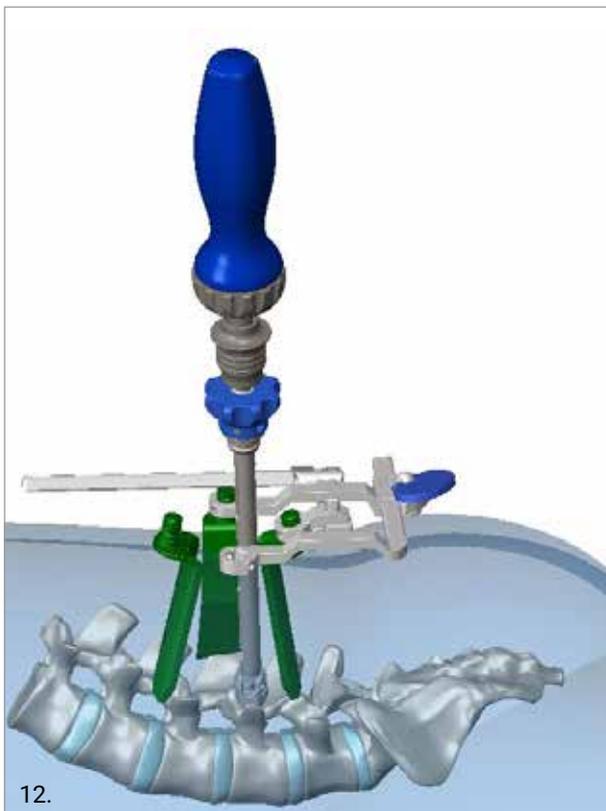
Perform the screw fixation according to the M.U.S.T. Mini-Open approach as described in the dedicated surgical technique (ref. 99.mini46.12).

Option 2: Modular Mini-Open Screwdriver

A dedicated set with a Modular Mini-Open Screwdriver is available. Engage the thumbwheel to the Modular Mini-Open Screwdriver (Fig 11). Engage the pedicle screw by turning the proximal thumbwheel clockwise until the screw is fully tightened.



Insert the screw into the prepared pedicle (Fig 12).



Once the screw is inserted into the pedicle, the Modular Mini-Open Screwdriver- Pedicle screw assembly can be used as an adapter for direct cement injection.

3.2 ADAPTER PREPARATION

Based on the chosen option for the screw fixation, the corresponding cannula preparation should be followed.

Option 1: standard Mini-Open Approach

Connect the Mini-Open Counter-Torque with the Pedicle screw head and introduce the Mini-Open Cannula Adapter into the Pedicle Screw head using a free hand technique (Fig 13).



Match the adapter Driver with the Mini-Open Cannula Adapter and lock it by turning it clockwise until fully tightened within the pedicle screw head.



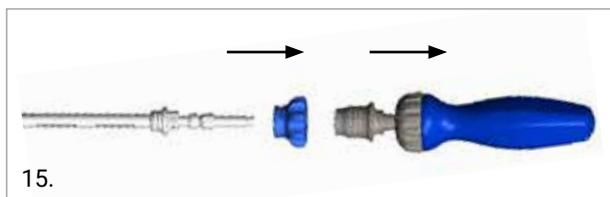
CAUTION

Always apply the Mini-Open Counter-Torque to the pedicle screw head to avoid rotation and to achieve proper screw alignment.

Option 2: Modular Mini-Open Screwdriver

Once the screw is inserted into the pedicle, the Modular Mini-Open Screwdriver- Pedicle screw assembly can be used as an adapter for direct cement injection.

Disengage the thumbwheel from the Modular Mini-Open Screwdriver (Fig.15).



3.3 CANNULA PREPARATION AND CEMENT DELIVERY

Prepare the cement according to supplier's instructions for use. Carefully follow the time/temperature graph as provided.

Load cement into the syringe; connect the syringe with the Mini - Open cannula.

CAUTION

Take special care during this process to avoid damaging the distal shank of the cannula during the manipulation.



Insert the cannula into the adapter following the chosen option.

WARNING

Based on the selected approach the correct cannula should be selected.



Option 1: standard Mini-Open Approach

Insert the Mini-Open cannula in the Mini-Open Cannula Adapter – Counter Torque Assembly. The length of the dedicated cannula is 140mm.

Option 2: Modular Mini-Open Screwdriver

Insert the Mini-Open cannula in the Modular Mini-Open Screwdriver. The length of the dedicated cannula is 210 mm.

NOTE: The Modular Mini-Open Screwdriver - Cannula Assembly can be fixed with a clip to perform the cement injection (fig.18), possibly avoiding the cannula pull-out.



Inject the cement gently, in order to create a cement mantle around the screw shaft.



CAUTION

Actively monitor cement flow distribution throughout this process through X-ray imaging in order to prevent excess leakage.

In the Mini-Open Cannula the residual cement volume is up to 1ml. To fully transfer the cement into the vertebra body disconnect the syringe and introduce the Stylet into the cannula. Push it slowly until fully seated into the Mini-Open Cannula.



When the Stylet is fully seated, all residual cement volume will be transferred into the vertebra body.



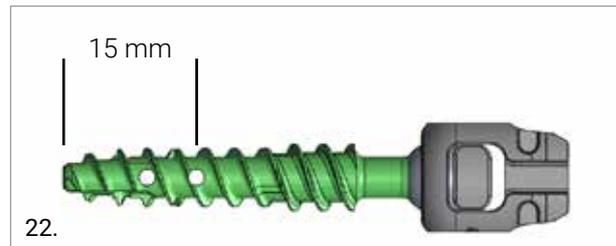
CAUTION

Actively monitor cement flow distribution throughout this process through X-ray imaging in order to prevent excess leakage.

Repeat the injection procedure for all the remaining vertebrae. Repeat the cement injection procedure for all vertebrae that require augmentation.

NOTE: Consider the actual distance between the screw tip and the most proximal fenestration is about 15mm (see fig. 22).

When positioning the screw make sure that the fenestrated portion of the shank is completely covered by unbroken/solid bone to avoid undesired cement leakage.



3.4 ADAPTER REMOVAL

As the cement hardens, proceed with the removal of the Adapter.

WARNING

Cannula Adapter removal should only commence once the cement has hardened. This will prevent any undesirable leakages.

Option 1: standard Mini-Open Approach

Proceed with the removal of the Adapter with the driver. To remove the Cannula Adapter, couple the Adapter Driver - Adapter Counter Torque assembly to the tulip of the screw and turn the Adapter Driver anticlockwise.

CAUTION

Continue to counter-torque the pedicle screw head during Cannula Adapter removal in order to prevent any undesired screw movements.



Option 2: Modular Mini-Open Screwdriver

Disengage the clip and proceed with the removal of the cannula. Engage the thumbwheel to the Modular Mini-Open Screwdriver and, by turning the thumbwheel counter-clockwise, disengage the modular Mini-Open Screwdriver from the pedicle screw.

4. STEPS FOR MIS PERCUTANEOUS APPROACH

4.1 PEDICLE PREPARATION AND SCREW FIXATION

Perform the pedicle preparation according to the M.U.S.T. Percutaneous approach (ref. 99.perc46.12).

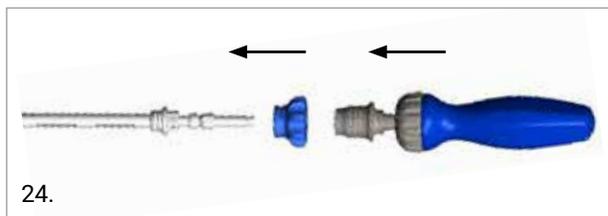
For the screw fixation two different equivalent option are available.

Option 1: Standard Percutaneous Approach

Perform the screw fixation according to the M.U.S.T. Percutaneous approach as described in the dedicated surgical technique (ref 99.perc46.12).

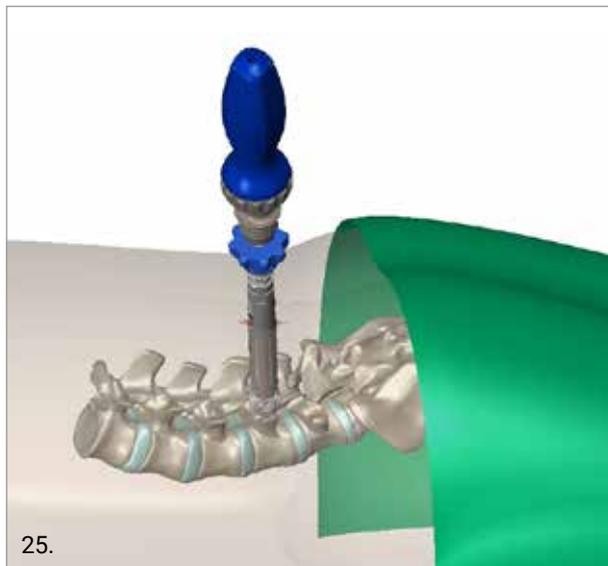
Option 2: Modular Percutaneous Screwdriver

A dedicated set with Modular Percutaneous Screwdriver is available. Engage the thumbwheel to the Modular Percutaneous Screwdriver (Fig 24). Engage the pedicle screw by turning the proximal thumbwheel clockwise until the screw is fully tightened.



24.

Insert the screw percutaneously into the prepared pedicle (Fig 25).



25.

Once the screw is inserted into the pedicle, the Modular Percutaneous Screwdriver- Percutaneous Tower- Pedicle screw assembly can be used as an adapter for direct cement injection.

4.2 ADAPTER PREPARATION

Based on the chosen option for the screw fixation, the corresponding cannula preparation should be follow.

Option 1: Standard Percutaneous Approach

Once the screw is inserted through the Percutaneous Approach, two option are available as adapter for cement injection (see option 1.a and 1.b here below).

Option 1.a: Percutaneous Cannula Adapter

Connect the Percutaneous Cannula Adapter to the Percutaneous Tower and start tightening using a free hand technique.

Match it with the Adapter Driver and tighten it until fully constrained into the pedicle screw head.

Counter-torque the Percutaneous Tower with the MIS Tower fork to avoid rotation and to achieve proper Screw-Adapter alignment (Fig.26).



26.

Option 1.b: MIS Poly-axial Screwdriver

Once the screw is inserted into the pedicle, the MIS Poly - Axial Screwdriver - Percutaneous Tower - Pedicle Screw assembly can be used as an adapter for direct cement injection.

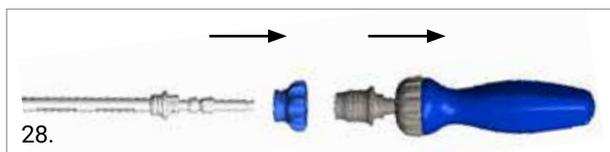


27.

Option 2: Modular Percutaneous Screwdriver

Once the screw is inserted into the pedicle, the Modular Percutaneous Screwdriver- Pedicle screw assembly can be used as an adapter for direct cement injection.

Before coupling it with the Percutaneous Cannula disengage the thumbwheel from the Modular Percutaneous Screwdriver (Fig.28).



4.3 CANNULA PREPARATION AND CEMENT DELIVERY

Prepare cement according to the supplier's instructions for use. Carefully follow the time/temperature graph as provided.

Load cement into the syringe; connect syringe with the Mini - Open cannula.

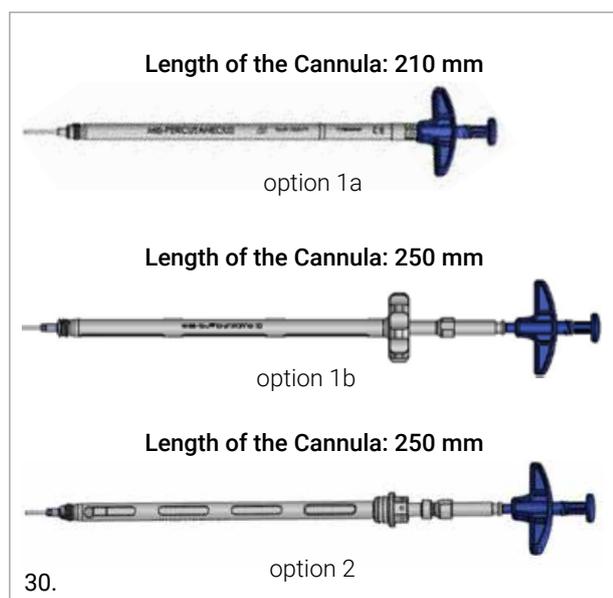
CAUTION

Take special care during this process In order to avoid damaging the distal shank of the cannula during the manipulation.



CAUTION

Based on the selected approach the proper cannula should be selected.



Insert the cannula into the adapter following the chosen option.

Option 1: Standard Percutaneous Approach

Based on the chosen adapter the corresponding cannula must be selected.

Option 1.a: Percutaneous Cannula Adapter

Insert the Percutaneous Cannula into the Percutaneous Cannula Adapter (Fig. 30). For this approach the length of dedicated percutaneous cannula is 210 mm.

Option 1.b: MIS Poly-Axial Screwdriver

Insert the MIS Screwdriver compatible Cannula into the MIS Poly-Axial Screwdriver (Fig. 30). The proper cannula is 250 mm long.

Option 2: Modular Percutaneous Screwdriver

Insert the Percutaneous Cannula into the Modular Percutaneous Screwdriver. The length of the suitable cannula is 250 mm.

NOTE: The Modular Percutaneous Screwdriver - Cannula Assembly can be fixed with a clip to perform the cement injection (Fig. 31)



WARNING

Please note the Percutaneous Cannula is used for Option 1.a and 2, while the MIS Screwdriver compatible Cannula is longer and can be coupled only with the MIS Poly-Axial Screwdriver.

Inject cement gently, in order to create a cement mantle around the screw shaft.

CAUTION

Actively monitor the cement flow distribution throughout this process through X-ray imaging in order to prevent excess leakage.

The residual cement volume in the Percutaneous Cannula is up to 1.6ml, while in the screwdriver compatible Cannula is up to 1.8 ml.

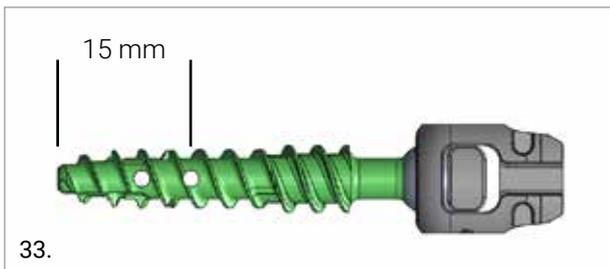
To fully transfer the cement into the vertebra body disconnect the syringe and introduce the Stylet into the cannula. Push it slowly until fully seated into the Cannula. When the Stylet is fully seated, all residual cement volume will be transferred into the vertebra body.



Repeat the injection procedure for all the remaining vertebrae. Repeat the cement injection procedure for all vertebrae that require augmentation.

NOTE: Consider the actual distance between the screw tip and the most proximal fenestration is about 15mm (Fig. 33)

When positioning the screw make sure that the fenestrated portion of the shank is completely covered by unbroken/solid bone to avoid undesired cement leakages.



4.4 ADAPTER REMOVAL

As the cement hardens, proceed with the removal of the Adapter.

WARNING

Adapter removal should only commence once the cement has hardened. This will prevent any undesirable leakages.

Option 1: Standard Percutaneous Approach

Follow the instruction below, based on the previously selected option.

Option 1.a: Percutaneous Cannula Adapter

Remove the Percutaneous Cannula and proceed with the removal of the Adapter with the driver.

CAUTION

Constantly counter-torque the pedicle screw head during Adapter removal. This will help to avoid any undesired screw adjustment



Option 1.b: MIS Poly-Axial Screwdriver

Remove the MIS screwdriver compatible cannula. By turning counter-clockwise the wheel, proceed with the removal of the MIS Poly-Axial Screwdriver – Cannula assembly disengaging it from the pedicle screw.

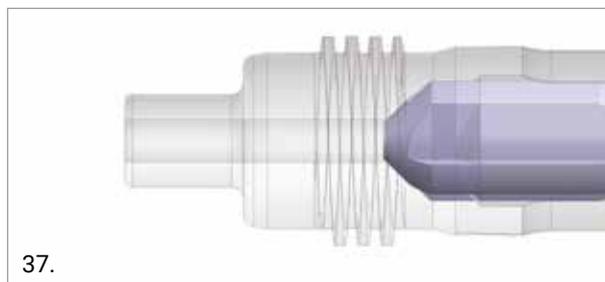
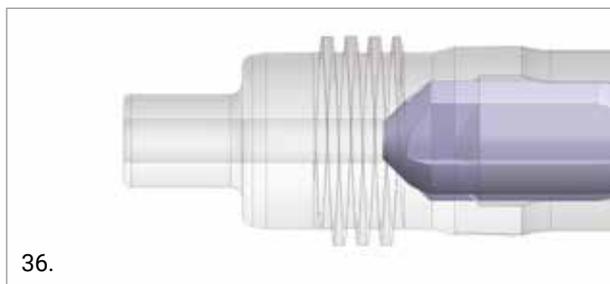
Option 2: Modular Percutaneous Screwdriver

Disengage the clip and proceed with the removal of the cannula. Engage the thumbwheel to the Modular Mini-Open Screwdriver and, by turning the thumbwheel counter-clockwise, disengage the modular Mini-Open Screwdriver from the pedicle screw.

5. ADAPTERS CLEANING

In order to fully remove undesired cement residual volume from the Adapters, introduce the Cleaners (A,C) into the Cannula Adapter and turn it clockwise/ counter-clockwise while advancing through the bore.

Repeat the procedure for both the bore to assure proper clearance (B,D).



WARNING

Cement residue in the Adapters could potentially damage the Cannula tip and/or fail the insertion of the cannulas.

6. CANNULAE OVERVIEW

As previously described in chapter above, for each surgical approach a dedicated cannula is available. The table below summarize the features of each cannula.

APPROACH	LENGTH ¹ (mm)	PRIMING VOLUME (mm/cc)
Open	35	0.2
Mini-open	140	1
Percutaneous and Mini-open	210	1.6
Percutaneous	250	1.8

¹ the Length is measured from the bottom part of the handle to the tip of the cannula.

7. CEMENT OPTIONS

If cement is being used in combination with the M.U.S.T. Fenestrated screws, please make sure the following requirements are met:

- Low or Medium viscosity cement
- Working time not inferior than 8 minutes
- Presence of Radiopaque agent

The M.U.S.T. Fenestrated Pedicle Screw System has been tested with the following cements:

- BonOS Inject - aap Biomaterials
- Opacity+ - Teknimed
- VFix - G21

Medacta International bear no liability when a cement is used outside of those listed above. The cement manufacturer's 'instruction for use' must always be followed.

8. IMPLANTS NOMENCLATURE

FENESTRATED POLYAXIAL PEDICLE SCREW (DUAL-DIAMETER)*

REFERENCE ¹	DIAMETER (mm)	LENGTH (mm)
03.60.312	5	30
03.60.313		35
03.60.314		40
03.60.315		45
03.60.316		50
03.60.317		55
<hr/>		
03.60.321	6	30
03.60.322		35
03.60.323		40
03.60.324		45
03.60.325		50
03.60.326		55
<hr/>		
03.60.335	7	30
03.60.336		35
03.60.337		40
03.60.338		45
03.60.339		50
03.60.340		55
<hr/>		
03.60.353	8	30
03.60.354		35
03.60.355		40
03.60.356		45
03.60.357		50
03.60.358		55
03.60.361		70
03.60.363		80
03.60.365		90
<hr/>		
03.60.371	9	40
03.60.372		45
03.60.373		50
03.60.374		55
03.60.377		70
03.60.379		80
03.60.381		90
<hr/>		
03.60.393	10	70
03.60.395		85
03.60.397		90

¹ includes 1 screw and 1 set screw

FENESTRATED POLYAXIAL CANNULATED PEDICLE SCREW (DUAL-DIAMETER)*

REFERENCE ¹	DIAMETER (mm)	LENGTH (mm)
03.61.312	5	30
03.61.313		35
03.61.314		40
03.61.315		45
03.61.316		50
03.61.317		55
<hr/>		
03.61.321	6	30
03.61.322		35
03.61.323		40
03.61.324		45
03.61.325		50
03.61.326		55
<hr/>		
03.61.335	7	30
03.61.336		35
03.61.337		40
03.61.338		45
03.61.339		50
03.61.340		55
<hr/>		
03.61.353	8	30
03.61.354		35
03.61.355		40
03.61.356		45
03.61.357		50
03.61.358		55
03.61.361		70
03.61.363		80
03.61.365		90
<hr/>		
03.61.371	9	40
03.61.372		45
03.61.373		50
03.61.374		55
03.61.377		70
03.61.379		80
03.61.381		90
<hr/>		
03.61.393	10	70
0361.395		80
03.61.397		90

¹ includes 1 screw and 1 set screw

FENESTRATED POLYAXIAL PEDICLE SCREW

REFERENCE ¹	DIAMETER (mm)	LENGTH (mm)
03.60.015	7	30
03.60.016		35
03.60.017		40
03.60.018		45
03.60.019		50
03.60.020		55

¹ includes 1 screw and 1 set screw

FENESTRATED POLYAXIAL CANNULATED PEDICLE SCREW

REFERENCE ¹	DIAMETER (mm)	LENGTH (mm)
03.61.115	7	30
03.61.116		35
03.61.117		40
03.61.118		45
03.61.119		50
03.61.120		55

¹ includes 1 screw and 1 set screw

MONOAXIAL CANNULATED PEDICLE SCREW (DUAL-DIAMETER)*

Reference ¹	Diameter (mm)	Length (mm)
03.52.206	5	30
03.52.207		35
03.52.201		40
03.52.202		45
03.52.203		50
03.52.204		55
03.52.205	60	
03.52.216	6	30
03.52.217		35
03.52.211		40
03.52.212		45
03.52.213		50
03.52.214		55
03.52.215	60	
03.52.227	7	35
03.52.221		40
03.52.222		45
03.52.223		50
03.52.224		55
03.52.225		60

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 in accordance with 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 orthopaedic devices" available at www.medacta.com.



**REDEFINING BETTER
IN ORTHOPAEDICS
AND SPINE SURGERY**

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

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M.U.S.T. Fenestrated
Surgical Technique

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rev. 03

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