

U.S.T. MINI

POSTERIOR CERVICAL SCREW SYSTEM

ONE SYSTEM, MULTIPLE OPTIONS



Surgical Technique

Hip

Knee

Spine

Navigation

INTRODUCTION



The M.U.S.T. Mini posterior cervical screw system is a modular solution to fix and stabilize the posterior cervical and the upper thoracic spine.

The system design is simple and flexible; a comprehensive set of components allows the surgeon to assemble the desired construct according to the anatomy of the patient and the pathology that requires treatment.

The M.U.S.T. Mini posterior cervical screw system consists of polyaxial screws, rods, hooks and multiple connectors

The M.U.S.T. Mini polyaxial screws are available in solid and cannulated options. The self-stabilising system of the tulip simplifies the rod insertion and the freedom of orientation is greater than 90° ($\pm 45^\circ$) at all angular position (360°). The set of implants includes fully threaded and partially threaded screws.

Three designs of laminar hooks are available to stabilize the posterior elements of the spine in different pathologies such as tumors, degenerative or deformity cases.

Head to head or standard (STD) cross connectors increase the torsional stiffness and the overall stability of the assembly. The connectors are available in several lengths to accommodate different patients' anatomy.

Finally, rod to rod connectors enable the system to be connected from cervical to the upper thoracic spine as well as the connection of rods of different diameters.

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1 INDICATIONS

The M.U.S.T. Mini posterior cervical screw system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures, and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The M.U.S.T. Mini posterior cervical screw system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the M.U.S.T. Mini posterior cervical screw system may be connected to the M.U.S.T. system rods with the M.U.S.T. Mini rod connectors. Transition rods with differing diameters may also be used to connect the M.U.S.T. Mini posterior cervical screw system to the M.U.S.T. system. Refer to the M.U.S.T. system package insert for a list of the M.U.S.T. indications of use.

2 CONTRAINDICATIONS

The M.U.S.T. Mini posterior cervical screw system is contraindicated in the following cases:

- Active infectious process or significant risk of infection (immunocompromise).
- Morbid obesity.
- Open wounds.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Severe osteoporosis may preclude implant stability.
- Suspected or documented metal allergy or intolerance.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- 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.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any case not needing a bone graft and fusion.
- Any patient unwilling to follow post-operative instructions.
- Any case not described in the indications.

3 PRE-OPERATIVE PLANNING

The pre-operative material, MRI or CT images, is used to inspect the anatomy of the patient and the pathology that requires treatment, providing the surgeon with information to plan the surgery in advance.

4 SURGICAL APPROACH

The patient is placed in the prone position on the operating table, the head and the neck are securely fixed. Caution should be taken to place the cervical spine in the physiological alignment to avoid undesired pressure points. The correct positioning should be checked by image intensifier or radiograph.

A posterior midline incision is made along the level to be treated and the soft tissues are gently moved laterally. Decortication is then carefully performed to expose the spinous process, the lamina, the facet joints and, if needed, the lateral masses of the vertebrae.

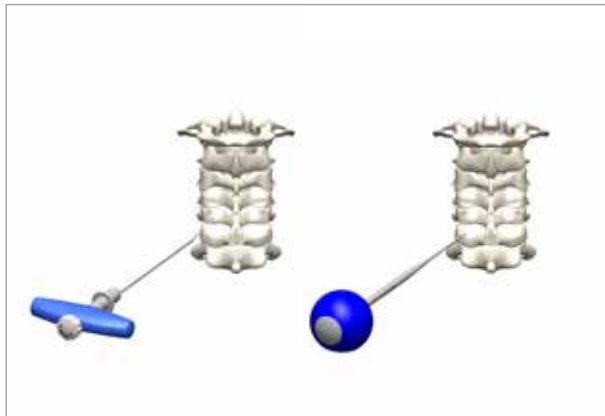
Care must be taken when performing dissection in order to avoid damage to the spinal cord, the interspinous ligament, the C2 nerve root or the vertebral arteries.

5 PEDICLE OR LATERAL MASS PREPARATION

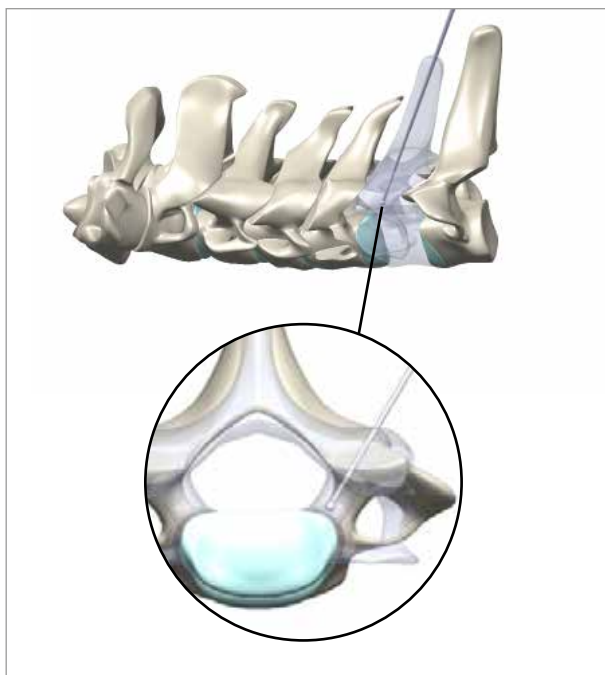
The M.U.S.T. Mini polyaxial screw can be inserted inside the pedicle or inside the lateral mass of the vertebra according to the surgeon's preference.

The following surgical steps refer to polyaxial screw insertion inside the pedicle. The same steps can be followed to insert the screw inside the lateral masses. A combined approach is also possible according to the surgeon's needs.

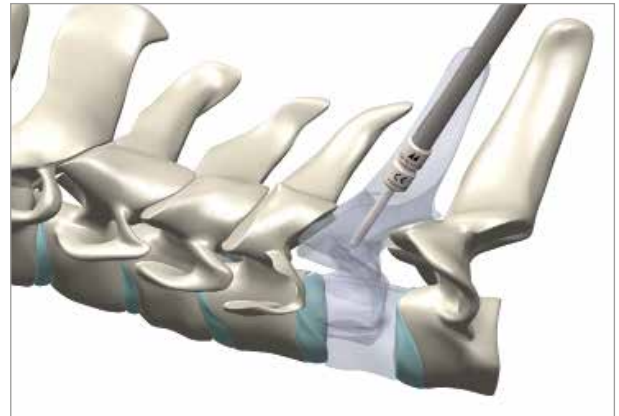
Locate the desired entry point of the screw and perforate the outer cortex with the Pedicle Awl. Use the Pedicle Probe and gently open the pedicle canal. The Pedicle Probe is graduated, in 10mm incremental markings, to give an initial visual indication of the pedicle canal depth reached.



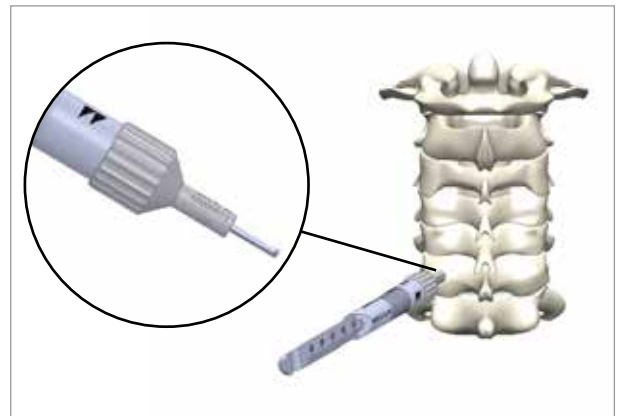
Check, with the Ball Tip Feeler, the pedicle walls in order to verify if a violation of the pedicle has occurred.



Correct positioning can also be checked using the Pedicle Marker under radiographic control.

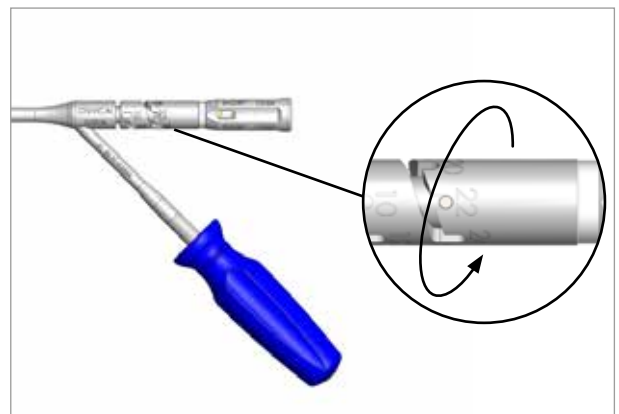


The Depth Gauge is available to measure the canal depth and to help determine the length of the polyaxial screw.

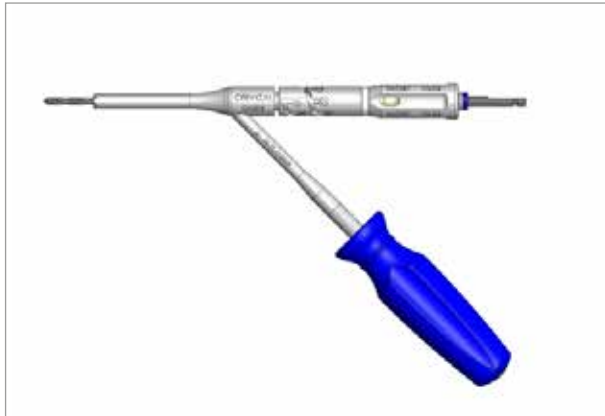


NOTICE: In case of sclerotic bone or any other reason that can cause high resistance avoid to strongly hammer the awl. A burr can be used to flatten the bone surface and facilitate insertion of the awl.

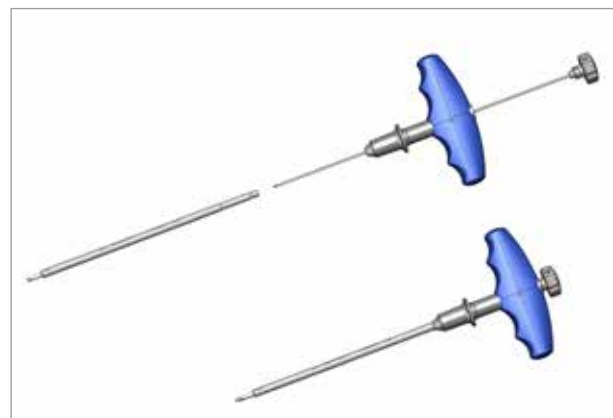
Open the pedicle canal using the Drill Guide. Set the rotating outer wheel of the Drille Guide to the desired depth of the hole to be drilled (2mm increments).



Insert the Drill Bit into the Drill Guide and drill the pedicle until the mechanical stop is reached.

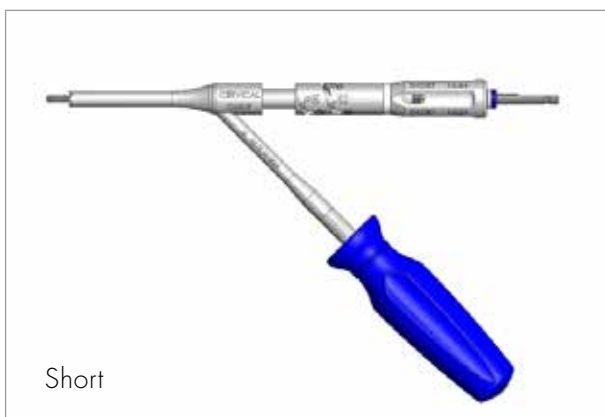


Another option to prepare the pedicle or the lateral mass of the vertebra to the screw insertion is to use a K-wire guided technique. Assemble the cannulated awl with the inner pin hand wheel.

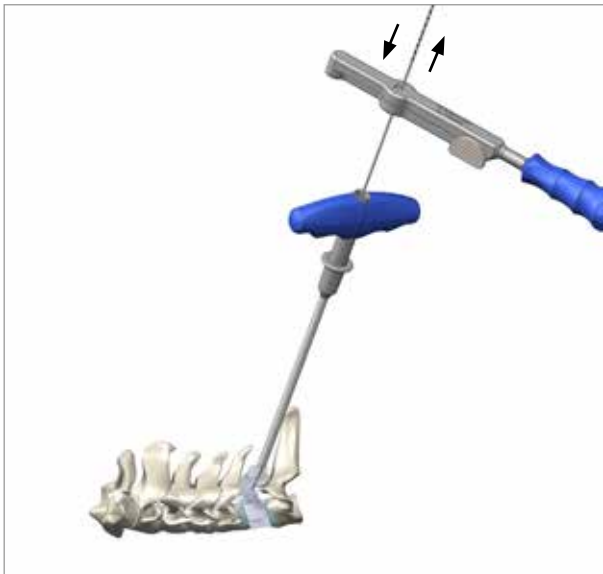


Drill Guides are available, in a short version and in a long version. Each guide is compatible only with the associated Drill Bit (same color).

Target the pedicle and perforate the outer cortex with the Cannulated Awl.



Remove the pin hand wheel and insert the graduated (5mm increments) Kirschner wire. Check the K-Wire position under radiographic imaging. A K-wire holder, available in the M.U.S.T. percutaneous set (99.51S.031), can be used for insertion or removal of the wire itself. The K-wire holder is used to either advance or remove Kirschner wires during the procedure.



To use the K-wire holder, push the lock button and slide the tool over the Kirschner wire few centimeters above the end of the cannulated awl, then release the locking button. Lightly mallet the impactation surface of the holder to advance the Kirschner wire. Stop impacting before the tool reaches the top of the cannulated awl. If further K-wire insertion is needed, after checking fluoroscopy, slide the wire holder back and repeat the manoeuvre. Once the K-wire has been inserted remove the K-wire holder and the cannulated awl.

! WARNING

Make sure the K-wire does not slip off during the procedure. A variety of solid and cannulated Drills and Taps are available and may be used at the discretion of the surgeon. To drill/tap the pedicle, select the desired Drill bit/Tap and connect it with an AO connection handle.

! CAUTION

In order to facilitate the insertion of the cervical polyaxial screw it is recommended to tap the pedicle.

5.1 Polyaxial Screw Fixation

Once the canal has been prepared and eventually tapped the M.U.S.T. Mini posterior cervical screws can be inserted.

The size of the screw depends on the diameter and the length of the prepared pedicle canal, in relation to the vertebral anatomy.

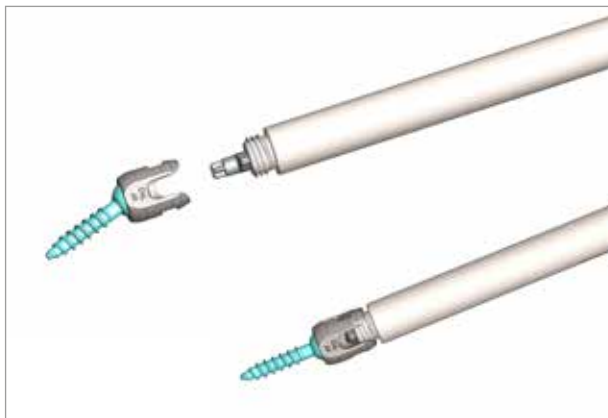
The M.U.S.T. Mini posterior cervical screws can be inserted and fixed using the Polyaxial Screwdriver which has been specifically designed to easily align the screw to avoid wobbling.



The protection sleeve must be coupled with the shaft of the screwdriver.



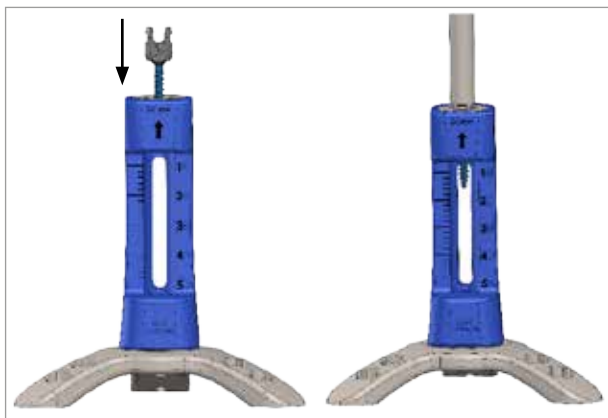
Insert the tip of the screwdriver into the screw head and lock the screw in the correct alignment as shown below.



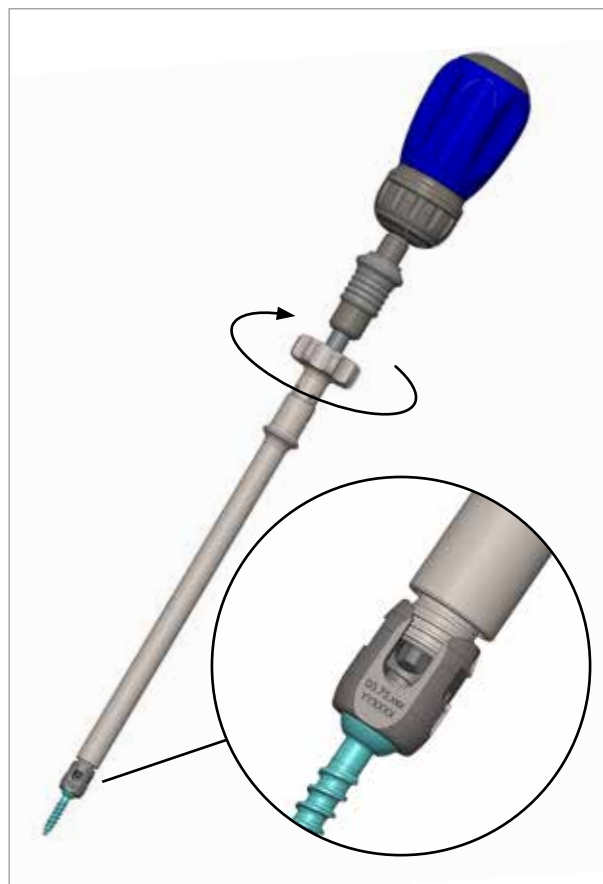
NOTICE: The correct polyaxial screw/polyaxial screwdriver coupling may be reached after a slight rotation and re-alignment of the screw body.

OPTION

Place the screw in the dedicated loading station and insert the tip of the screwdriver in the screw head.

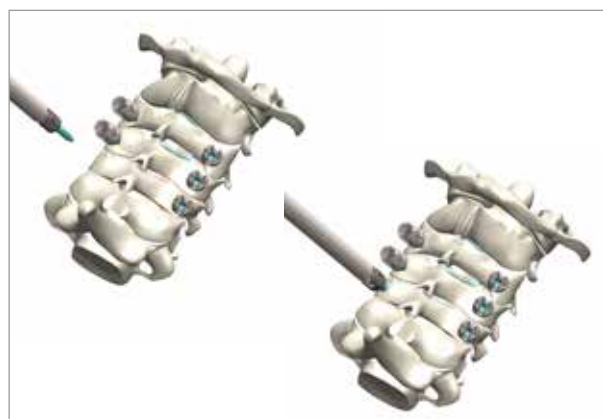


Tighten the head of the polyaxial screw to the Polyaxial Screwdriver using the proximal gear, firmly turn it clockwise until the screw is fully tightened. Once secured, it is no longer possible for the screw to move as it is fully engaged with the Polyaxial Screwdriver.

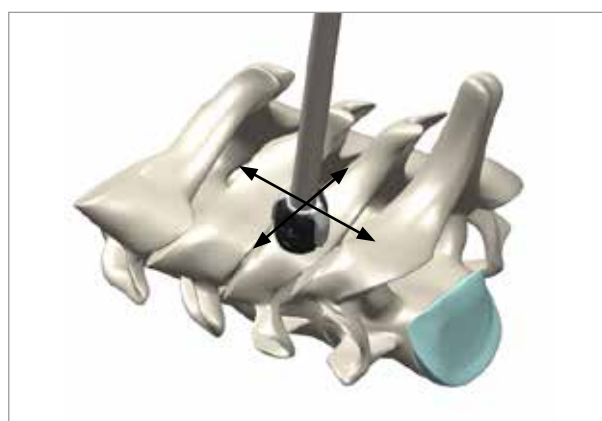
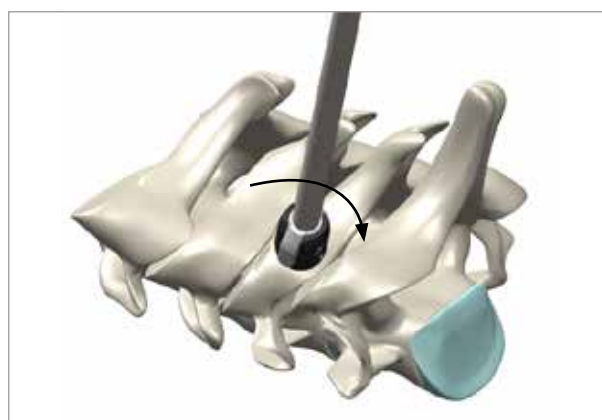
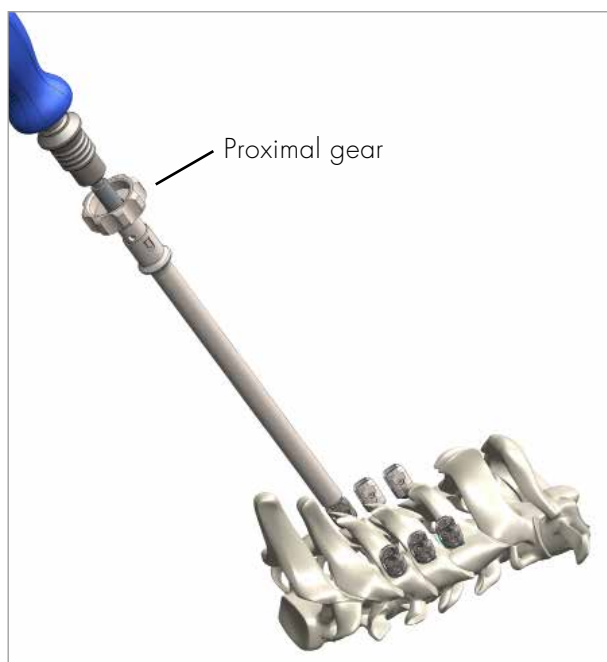


Insert the screw into the prepared pedicle canal by turning the Handle clockwise.

NOTICE: Do not hold the proximal gear during the screw insertion to avoid screw disengagement from the screwdriver tip.



Once the pedicle screw has been inserted disengage the Polyaxial Screwdriver by turning the proximal gear counter-clockwise.

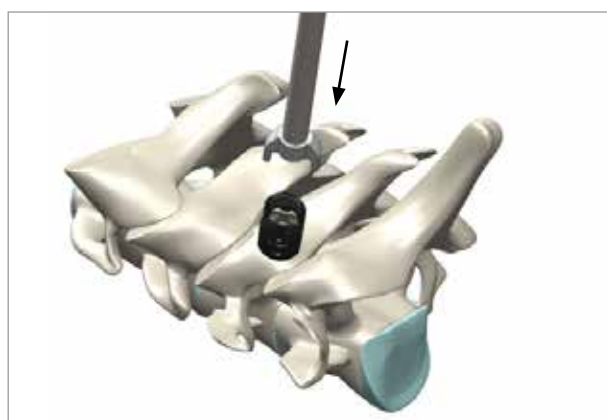


OPTION

Cannulated screws are available and can be inserted following the K-wire trajectory. The screw insertion may be preceded by drilling and tapping depending on the surgeon's preferences.

5.2 Head Adjusting

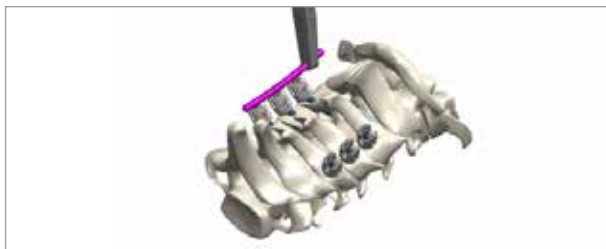
Before placing the rod, check the orientation of the polyaxial screw head. Use the Head Adjuster instrumentation to align the polyaxial screw head in the desired position.



If the head of the polyaxial screw resists alignment, use the Bone Screwdriver to slightly unscrew it.

6 ROD CONTOURING AND INSERTION

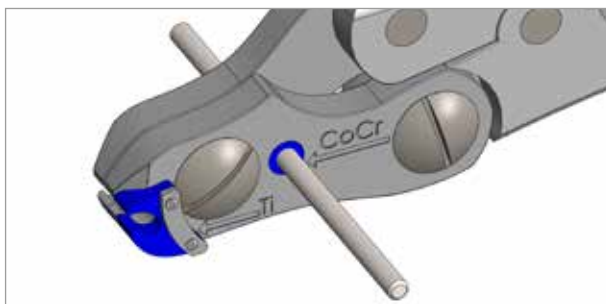
All rods are available in both Titanium and CoCr alloy and in multiple lengths. The surgeon can select the most appropriate rod length using the rod template.



The rod can be contoured with the Rod Bender to reach the desired shape and, eventually cut with the in situ Rod Cutter to reach the desired rod length.

! WARNING

Rod in CoCr must be cut only with the lateral hole of the Rod Cutter as indicated by the laser marking.



Use the Rod Insertion Forceps to position the rod into the selected heads.



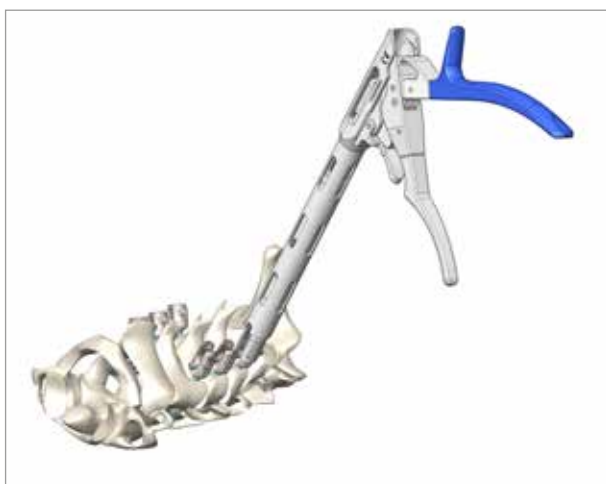
! CAUTION

Rods should only be bent using the Rod Bender that is included with the standard M.U.S.T. Mini instrumentation. Never bend the rods more than once as repeated bending may result in weakening or fracture of the rod.

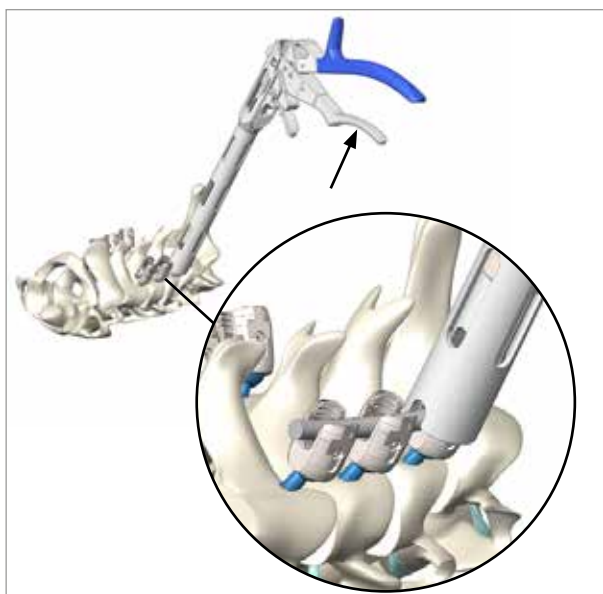
7 ROD REDUCTION TECHNIQUES

The rod must be completely seated within the screw heads to allow final rod manipulation and construct positioning. Rod reduction can be performed with the Rod Reduction Device.

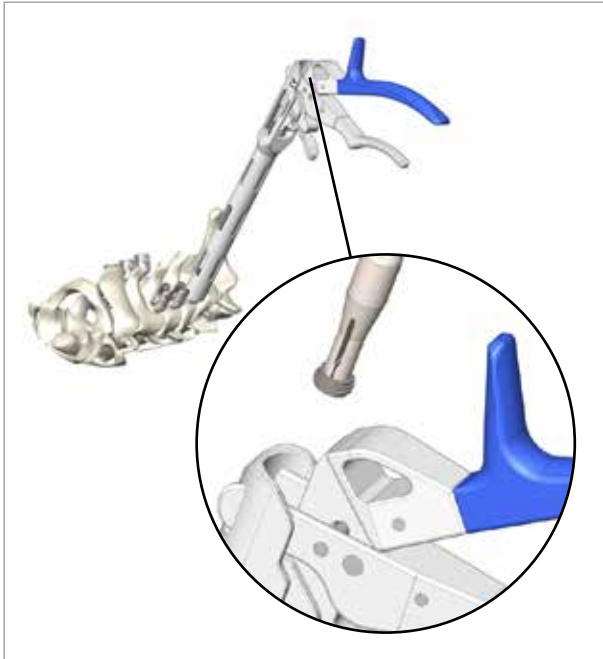
Place the rod reduction device on the polyaxia screw head until mechanical stop.



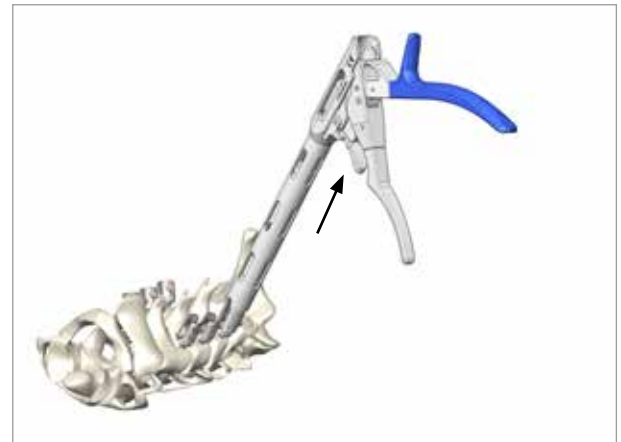
Tighten the handle until the rod is fully seated in the screw head.



Engage the set screw with the dedicated Temporary Set Screwdriver. Insert the screwdriver through the rod reduction shaft and tighten the set screw on the polyaxial screw head.



Once the set screw has been inserted squeeze the trigger of the Rod Reduction device for the release and disengage the instrument from the polyaxial screw head.



OPTION

A Rod Pusher is also available to perform the Rod Reduction. Couple the rod pusher with the polyaxial screw head and the rod. Perform the reduction. The Rod Pusher can also be used as a counter torque during the temporary set screw tightening.

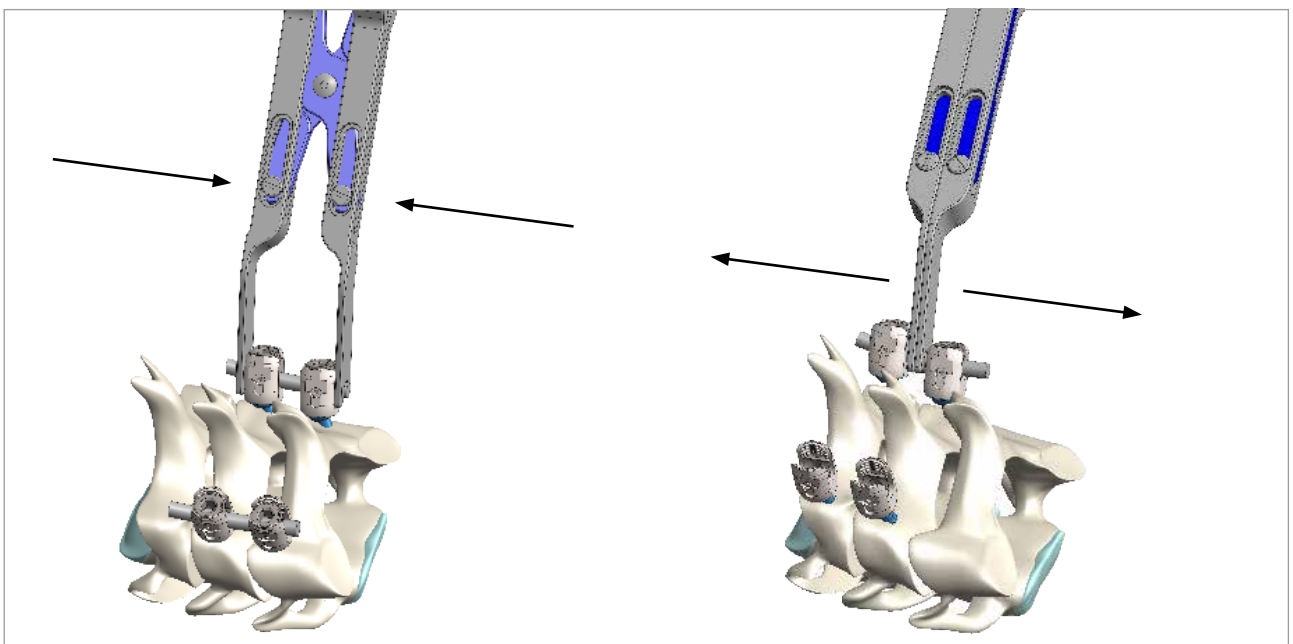
CAUTION

Do not use the Temporary Set Screwdriver for the final locking as this instrument should only be used for temporary locking of the set screw.

8 COMPRESSION OR DISTRACTION

Before the set screw is finally tightened, compression or distraction may be performed.

Use the compression forceps to achieve compression or the distraction forceps to achieve distraction. Once the desired position has been reached tighten the set screw as described in the section 10, 'Final Tightening'.

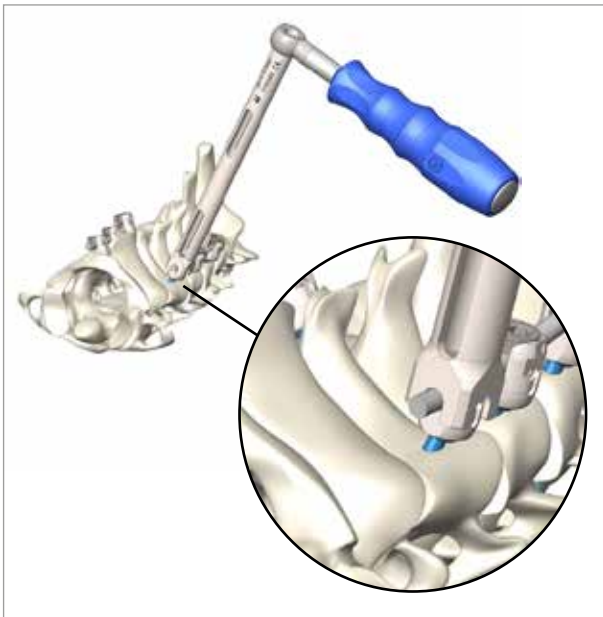


9 IN SITU ROD BENDING AND ROTATION

If further contouring of the rods is required to achieve the desired alignment, it is also possible to bend the rods using the dedicated bending instruments. These bending instruments are available to perform in situ coronal and sagittal rod bending as well as rod rotation.

10 FINAL TIGHTENING

To perform the final tightening engage the Counter Torque to the pedicle screw head.



Insert the Torque Limiter into the Counter Torque. Firmly grip the Counter Torque and perform final fixation until the audible noise indicates that the required torque has been reached.



OPTION
Final tightening can be performed with the Rod Reducer Device. In this case only the Long Torque Limiter can be used.

CAUTION
If, after final tightening has been performed, repositioning of the set screw is necessary, it is advisable to untighten the set screw and replace it with a new one.

11 CROSS CONNECTOR

The construct can be reinforced by adding cross connectors according to the specific anatomy of the patient and the amount of available space between the polyaxial screw heads.

Two designs of M.U.S.T. Mini cross connectors are available. The STD cross connector is attached to the rod through the connector clamp while the screw-to-screw connector is coupled on the polyaxial screw heads. The cross connectors are available in multiple lengths.

Measure the appropriate length of the connector by placing the cross connector size indicator on the desired position.



Hold the selected cross connectors and place it onto the construct. The STD cross connector can be engaged using the dedicated STD cross connector inserter. A loading station is also available if needed.

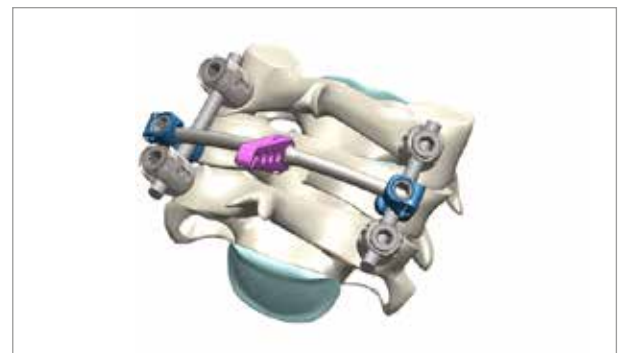


Once the connector has been positioned, engage the Counter torque with the connector's head and tighten the set screw with the 3.0N-m Torque Limiter. The counter torque is available only for STD connectors.

The screw to screw connector plate is placed over the polyaxial screw head with the Rod Insertion Forceps. Use the temporary set screwdriver to engage the set screw with washer and screw it into the polyaxial screw head. Perform the final tightening with the 3.0N-m torque limiter instrument.



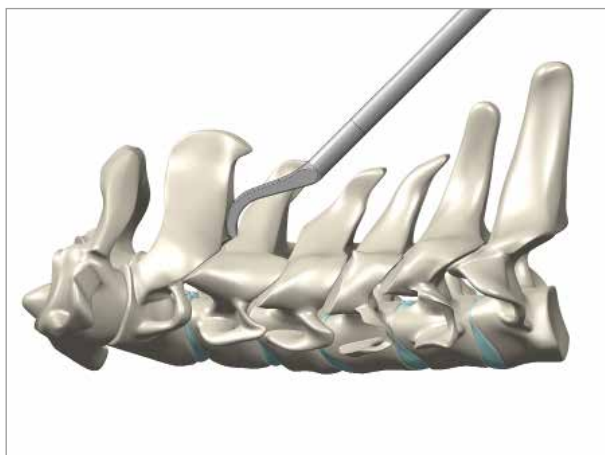
A further option is the cross connector with the spinous process integrated. This connector is locked to the rods through the cross connectors clamp as per the STD connectors.



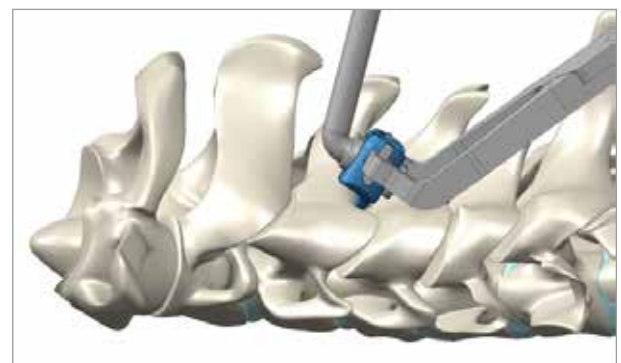
12 HOOKS

A comprehensive set of laminar hooks is available for the surgeon to choose the most suitable implant that matches the thickness of the vertebral lamina.

Before inserting the laminar hook care must be taken to dissect the ligament flavum and to expose the vertebral lamina ensuring a good contact between the hook and the bone. Use the Lamina Elevator to separate the ligamentum flavum from the lamina.



Select the appropriate hook to implant using the trial sample. Attach the hook to the hook Forceps and place it on the lamina, using the hook Pusher if needed.



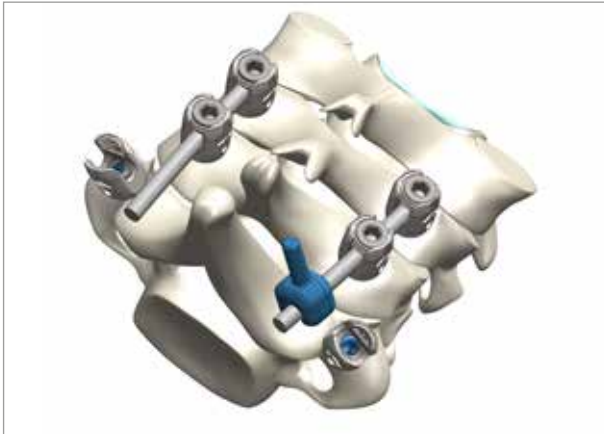
Repeat the process for each lamina, then perform as described above the following surgical steps:

- Rod Contouring and Insertion
- Rod Reduction
- Compression and Distraction
- Final Tightening

13 LATERAL CONNECTORS

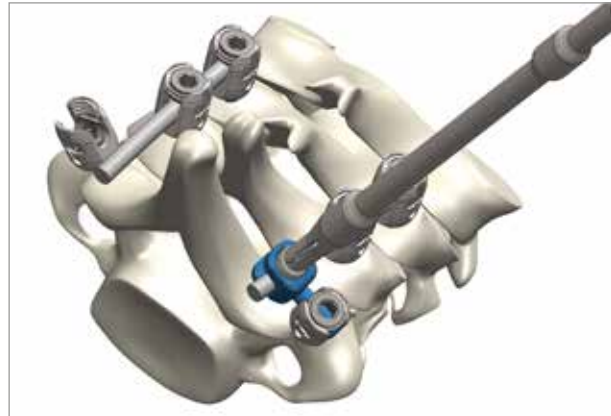
The lateral connectors are used to compensate the Medio/Lateral offset between the screw head and the rod. The lateral connectors are available in short and long versions.

Once the desired lateral connector has been chosen, engage the connector on the rod as shown in the following picture.



Rotate the connectors to engage it with the head of the polyaxial screw.

Use the Temporary Set Screwdriver and temporary lock the lateral connector and the pedicle screw.



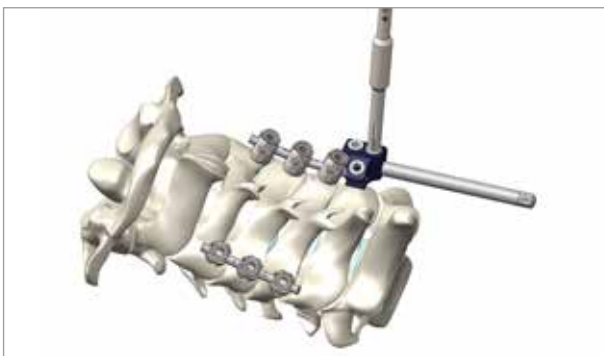
Perform the final tightening of both set screws with the 3.0 N·m Torque Limiter as described in section 10 'Final Tightening'.

14 ROD TO ROD CONNECTORS

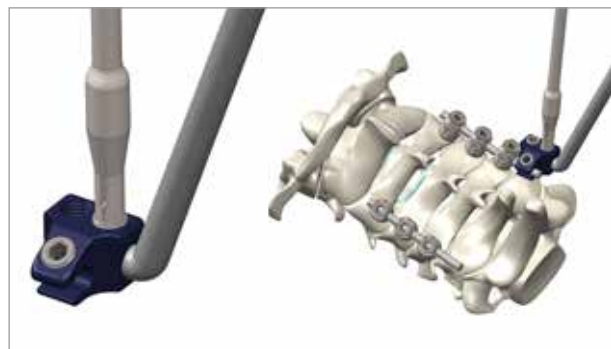
Rod to rod connectors are used to allow rod connection between the cervical and upper thoracic spine. The connectors allow rod transition from a smaller to a larger diameter. Four designs of rod to rod connectors are available, STD, Angled, Open and Adjustable.

14.1 Rod-to-Rod Connectors Positioning

Hold the connector and place it in the already positioned rod. Temporarily lock the set screws with the Temporary Set Screwdriver. Insert the second rod and proceed with the final tightening of the set screws using the 3.0 N·m Torque Limiter.



As option use the Connector Inserter of the M.U.S.T. Thoracolumbar set. Attach the connector inserter to the implant by tightening the set screw using the Temporary Set Screwdriver.



Insert the rod to rod connectors into the rod that is already in position and lock the set screws temporarily with the Temporary Set Screwdriver. Slide out the connector inserter, insert the rod to be connected and proceed with the final tightening of the set screws using the 3.0 N·m Torque Limiter.

15 REMOVAL AND REVISION PROCEDURES

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



CAUTION

Check carefully that no metal fragments from the removed implants remain in situ.

16 IMPLANTS NOMENCLATURE

16.1 Sterile Single Package

Polyaxial Screw Solid - Full thread



Reference ¹	Diameter (mm)	Length (mm)
03.75.000*	ø 3.5	10
03.75.001		12
03.75.002		14
03.75.003		16
03.75.004		18
03.75.005		20
03.75.006		22
03.75.007		24
03.75.008		26
03.75.009		28
03.75.010		30
03.75.011		32
03.75.012*		34
03.75.013*		36
03.75.014*		38
03.75.015*		40
03.75.100*		ø 4.0
03.75.101*	12	
03.75.102*	14	
03.75.103*	16	
03.75.104*	18	
03.75.105*	20	
03.75.106*	22	
03.75.107*	24	
03.75.108*	26	
03.75.109*	28	
03.75.110*	30	
03.75.111*	32	
03.75.112*	34	
03.75.113*	36	
03.75.114*	38	
03.75.115*	40	

Reference ¹	Diameter (mm)	Length (mm)
03.75.308*	ø 4.5	26
03.75.309*		28
03.75.310*		30
03.75.311*		32
03.75.312*		34
03.75.313*		36
03.75.314*		38
03.75.315*		40
03.75.316*		42
03.75.317*		44
03.75.318*		46
03.75.319*		48
03.75.320*	50	

¹ includes 1 screw and 1 set screw

* Special order

Polyaxial Screw Cannulated - Full thread



Reference ¹	Diameter (mm)	Length (mm)	
03.75.200*	ø 4.0	10	
03.75.201		12	
03.75.202		14	
03.75.203		16	
03.75.204		18	
03.75.205		20	
03.75.206		22	
03.75.207		24	
03.75.208		26	
03.75.209		28	
03.75.210		30	
03.75.211		32	
03.75.212*		34	
03.75.213*		36	
03.75.214*		38	
03.75.215*		40	
03.75.408*		ø 4.5	26
03.75.409			28
03.75.410	30		
03.75.411	32		
03.75.412	34		
03.75.413	36		
03.75.414	38		
03.75.415	40		
03.75.416*	42		
03.75.417*	44		
03.75.418*	46		
03.75.419*	48		
03.75.420*	50		

Polyaxial Screw Solid - Partial thread



Reference ¹	Diameter (mm)	Length (mm)
03.75.500*	ø 4.0	26
03.75.501*		28
03.75.502*		30
03.75.503*		32
03.75.504*		34
03.75.505*		36
03.75.506*		38
03.75.507*		40
03.75.508*		42
03.75.548*		ø 4.5
03.75.549*	28	
03.75.550*	30	
03.75.551*	32	
03.75.552*	34	
03.75.553*	36	
03.75.554*	38	
03.75.555*	40	
03.75.556*	42	

¹ includes 1 screw and 1 set screw

* Special order

Polyaxial Screw Cannulated - Partial thread



Reference ¹	Diameter (mm)	Length (mm)
03.75.524	ø 4.0	26
03.75.525		28
03.75.526		30
03.75.527		32
03.75.528		34
03.75.529		36
03.75.530*		38
03.75.531*		40
03.75.532*		42
<hr/>		
03.75.572	ø 4.5	26
03.75.573		28
03.75.574		30
03.75.575		32
03.75.576		34
03.75.577*		36
03.75.578*		38
03.75.579*		40
03.75.580*		42

¹ includes 1 Screw and 1 set screw

Hook



Reference ²	Type	L/R	Size
03.75.905	STD	N.A.	4.5
03.75.906	STD	N.A.	6
03.75.915	ANGLED	L	4.5
03.75.916	ANGLED	L	6
03.75.926	ANGLED	R	4.5
03.75.927	ANGLED	R	6
03.75.935	OFFSET	L	4.5
03.75.936	OFFSET	L	6
03.75.945	OFFSET	R	4.5
03.75.946	OFFSET	R	6

² includes 1 Hook and 1 set screw

Set Screw



Reference	Type
03.75.900	Set screw

Straight Rods



Reference	Material	Diameter x Length (mm)
03.75.600	Titanium	3.5 x 80
03.75.601	Titanium	3.5 x 120
03.75.602	Titanium	3.5 x 240
03.75.603*	Titanium	3.5 x 350
03.75.604*	Cobalt-Chrome	3.5 x 80
03.75.605*	Cobalt-Chrome	3.5 x 120
03.75.606	Cobalt-Chrome	3.5 x 240
03.75.607*	Cobalt-Chrome	3.5 x 350

* Special order

Transition Rods



Reference	Material	Diameter x Length (mm)
03.75.610	Titanium	3.5/ 5.5 x 420
03.75.612	Cobalt-Chrome	3.5/5.5 x 420

STD cross connectors



Reference ³	Type	Length (mm)
03.75.713*	WITH MEC.STOP	23
03.75.714*	WITH MEC.STOP	30
03.75.715*	WITH MEC.STOP	37
03.75.716*	WITH MEC.STOP	44
03.75.717*	WITH MEC.STOP	51
03.75.718*	WITH MEC.STOP	58
03.75.719	WITH MEC.STOP	65

³ includes 1 STD cross connectors and 2 cross connector clamp and 2 screw M5

STD cross connectors



Reference ³	Type	Length (mm)
03.75.710*	STD	35
03.75.711*	STD	60

³ includes 1 STD cross connectors and 2 cross connector clamp and 2 screw M5

Cross link



Reference ⁴	Type	Length (mm)
03.75.740*	Spinous Reconstruction	SMALL
03.75.741*	Spinous Reconstruction	MEDIUM
03.75.742*	Spinous Reconstruction	LARGE

⁴ includes 1 Spinous Recon. cross link 2 cross connector clamps and 2 screws M5

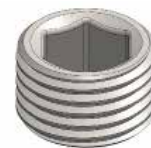
Clamp for cross connector



Reference ⁵	Description
03.75.712	Cross connectors Clamp

⁵ includes 1 Screw M5

Locking screw



Reference	Type
03.75.732	Screw M5 HEX3

Cross connector



Reference	Type	Length (mm)
03.75.743*	CLAMP	SMALL
03.75.744	CLAMP	MEDIUM
03.75.745*	CLAMP	LARGE

* Special order

Screw with Washer



Reference	Description
03.75.720*	Screw with Washer

Lateral connectors



Reference ⁶	Size
03.75.730	10 mm
03.75.731	15 mm

⁶ includes lateral connector and 1 screw M6

Locking screw



Reference	Type
03.75.700	M6 HEX3

* Special order

Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It M.U.S.T. 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.

Screw-to-screw cross connectors



Reference ⁷	Type	Length (mm)
03.75.721*	Screw-to-screw	22-30
03.75.722*	Screw-to-screw	29-37
03.75.723*	Screw-to-screw	36-44
03.75.724*	Screw-to-screw	43-51
03.75.725*	Screw-to-screw	50-58

⁷ includes 1 screw-to-screw cross connectors and 2 Screw with Washer

Rod to Rod connectors



Reference ⁸	Type	Rod Diameter (mm)
03.75.703	STD	3.5 to 5.5
03.75.705*	ANGLED	3.5 to 5.5
03.75.707	OPEN	3.5 to 5.5
03.75.709*	ADJ	3.5 to 5.5

⁸ includes 1 Rod to Rod connector, 4 screw M6 for STD version or 3 screw M6 for ANGLED OPEN, ADJUSTABLE, version



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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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