

CAUTION

Federal law (USA) restricts this device to sale distribution and use by or on the order of a physician.



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INTRODUCTION

Medacta Spine continues to support the goal of expanding the spine surgeon's options for the treatment of spinal disorders.

Medacta Spine has developed this surgical technique guide for En Bloc derotation.

The surgical steps of this techniques are described here with the MUST Reduction screw system and the MUST En Bloc instrumentation.

The MUST En Bloc instrumentation set has been developed to address some of the challenges associated with derotation maneuvers.

The MUST family of products includes a wide selection of deformity specific implants and instruments to support the Medacta Spine philosophy of patient driven, pathology specific solutions.

It is accepted that with the use of pedicle screws in scoliosis correction, significant coronal plane correction can be consistently obtained.

True axial plane correction can now be achieved to address the rotational deformity of the spine, ribs and chest wall.

The main goal of derotation maneuvers is to achieve rotational deformity correction, which may decrease the need for thoracoplasty.

1.1 SCREW PLACEMENT

Place the reduction pedicle screws according to the MUST reduction screws technique (99.46RS.12US) and the preoperative surgical plan. On the concave side: if possible, insert the reduction screws at every level.

On the convex side: insert the reduction screw into at least 3-4 convex pedicles at the apex, as well as the proximal and distal foundations.

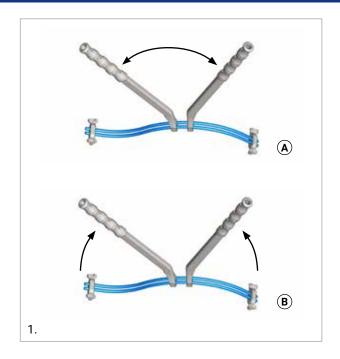
Confirm placement of the screws and check the screw length with fluoroscopy prior to rod insertion.

1.2 ROD CONTOURING

Using the dual rod benders/holders it is possible to simultaneously pre-bend two rods. The following steps address accurate rod contouring to avoid any asymmetrical bending of the rods themselves.

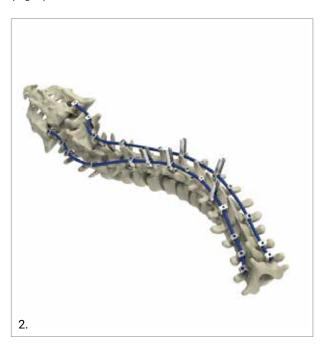
Step 1: Insert the rods through both the left and right dual rod benders and link the rod together with the dual rod holders to both rod extremities.

Step 2: Begin to bend the rod by firmly holding the dual rod benders and applying a distraction (Fig. 1a) or compression (Fig. 1b) force in order to achieve the desired curvature. Proceed through the whole length of the rod until the final desired shape has been achieved.



NOTE: The rod's mechanical properties will be an important factor in kyphosis restoration and derotation. The stiffer rods in the MUST portfolio (i.e. CoCr Alloy rods) will be more effective than Ti rods in axial derotation and sagittal plane restoration, since less flattening of the rod can be expected. The rod stiffness, however, should be matched to the patient's bone density.

Insert the first rod into the pedicle screws on the concave side of the spine leaving the set screws loose. The second rod can be inserted immediately after the first one if needed (Fig. 2).





2. SET SCREW INSERTION AND ROD REDUCTION

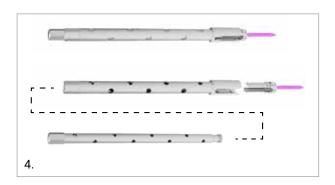
Please follow the same procedure described in the dedicated surgical technique of the Medacta M.U.S.T. reduction screws system (99.46rs.32) until chapter 5.

Insert the screws, the rod and permorm the temporary tightening,



3. DEROTATION

Engage the "Derotation tube" with the reduction pedicle screw previously fixed to the rod, then insert the "Derotation anchors" on the "Derotation tubes" and tighten it until a solid construct is achieved.



Grab the Derotation tube through the Derotation Clamp at the desired level.



Derotation clamps are available in 3 different lengths:

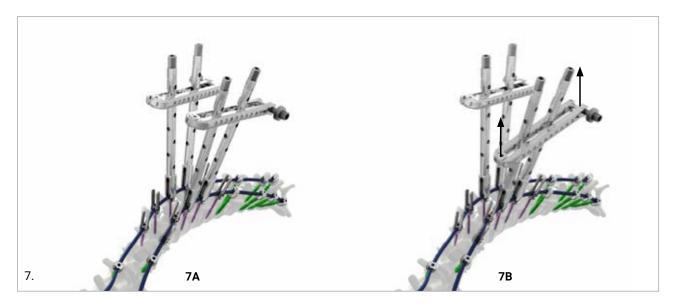
- short
- medium
- long



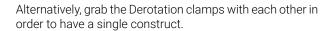
NOTE: Use the Key for the derotation clamp and also the Handle to tighten the Derotation Clamp with the derotation tube.

If desired, it is possible to connect 2 derotation clamps through the Knob and Set Nut. $\begin{tabular}{ll} \hline \end{tabular}$

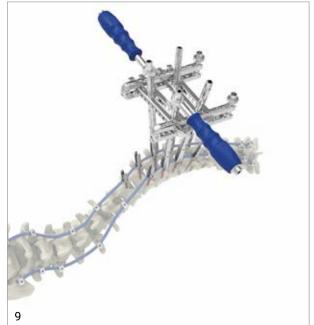
Make sure the clamps are aligned as showed in the picture 7A. If not adjust the clamp position (7B). Conncet the two derotation clamp together with the knob and the set nut. Attach the construct as showed in picture 8.





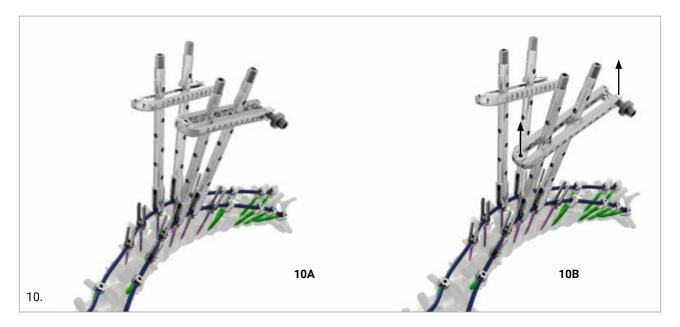


The derotation clamps can be fixed as showed in picture 9





Make sure the clamps are aligned as showed in the picture 10A. If not adjust the clamp position (10B).



OPTION

If desired, it is possible to connect 2 countertorque for a better construct handling

If needed use the temporary setscrews driver to partially release the setscrews



Derotate the connected derotation tubes until anatomical alignment has been achieved.





Remove the Derotation clamps mounted on the derotation tubes and mount the countertorque. Use the driver in combination with the Modular T-handle 9Nm Torque Limiter to complete the final tightening.



OPTION: It is possible to insert the Countertorque pin inside the Countertorque in order to lock the Countertoque with the derotation tube.

4. CLAMP REMOVAL

Unscrew the derotation clamp with the T-handle. Open the clamp and remove from the derotation tube. Repeat the same step for all the clamps. Unscrew the derotation anchor and remove the derotation tube from the tulip. Repeat for all the derotation tubes

WARNING

Do not continue unscrewing the derotation clamp with the T-handle when the mechanical stop is reached. Persist in unscrewing may cause overstress and clamp failure



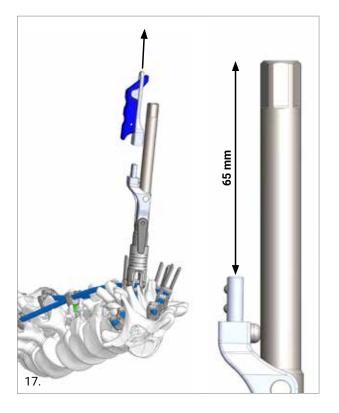
5. DEMOUNTABLE LOCKING TOWER

A second option to perform the EnBloc derotation is the Demountable Locking Tower. Connect the handle to the tower as shown in the following picture, then connect it to the M.U.S.T. Reduction screws following the steps described in the dedicated surgical technique 99.46RS.12.

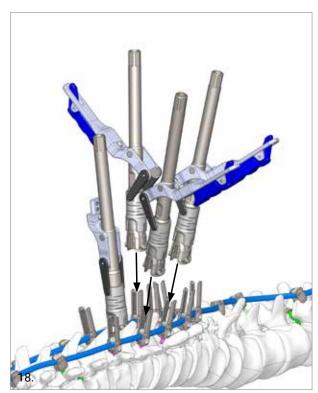




Once the tower is connected, remove the detachable handle.

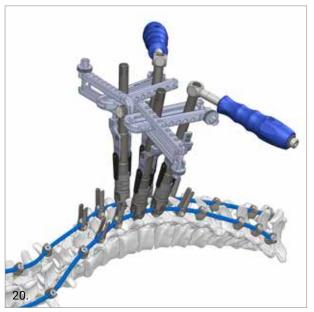


Repeat the described procedure for all the other Demountable Locking Towers needed.

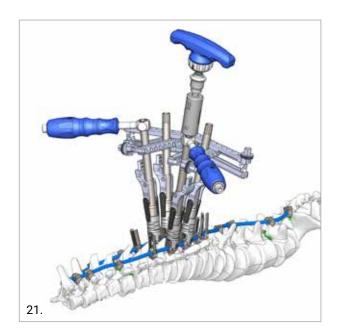




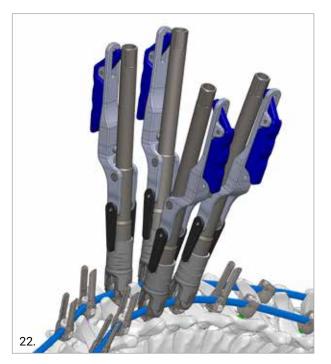
Attach the M.U.S.T. EnBloc Clamp to connect the Demountable Locking Tower. Multiple constructs can be created according to the number of Demontable Locking Towers and Clamps used for the connection.



Connect the Countertorque Handle to facilitate the derotation. If necessary, use the Temporary Set-screwdriver to partially release or lock the setscrew before the derotation. Derotate the spine and perform the final tightening.



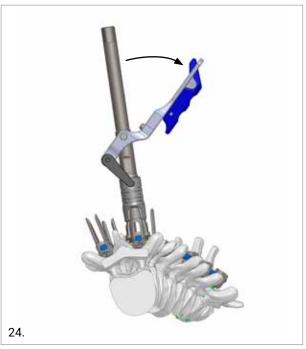
After the derotation manoeuvre is performed, re-attach the modular handles to the Demountable Locking Tower.

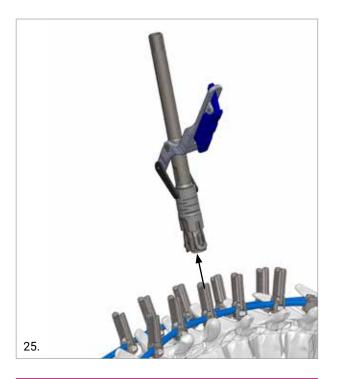




Pull the blue lever to partially open the instrument, then completely open the handle: the instrument is now released from the screw and can be removed.







OPTION

It is possible to insert the Countertorque Pin into the Countertorque Handle in order to lock the Countertorque Handle.



OPTION

The M.U.S.T. EnBloc system allows for the creation of hybrid constructs by simultaneously using the demountable locking tower and the derotation tubes.

M.U.S.T. En Block Derotation System Surgical Technique

6. TABS REMOVAL

Please follow the same procedure described in the dedicated surgical technique of the Medacta M.U.S.T. reduction screw system for screw tabs removal and following surgical steps.



NOTES						

M.U.S.T. En Block Derotation System Surgical Technique



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, US 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.



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M.U.S.T. En Block Derotation System Surgical Technique

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