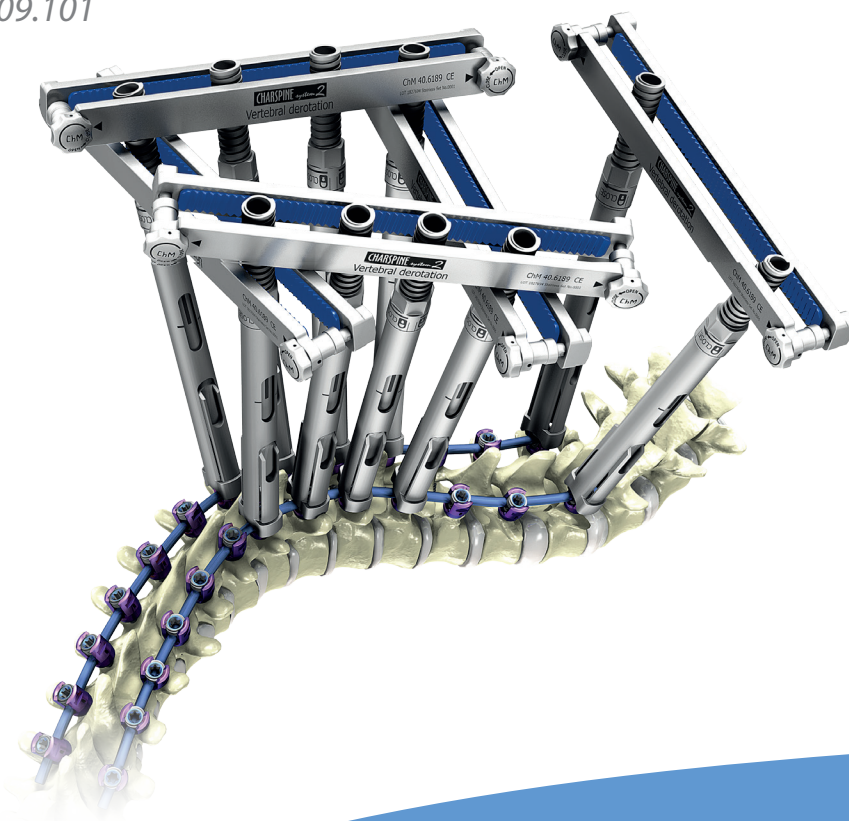


CHM[®]








CHARSPINE *system 2*

CHARSPINE2 VD DIRECT VERTEBRAL BODY DEROTATION

- INSTRUMENT SET 15.0909.101
- SURGICAL TECHNIQUE



SYMBOLS DESCRIPTION

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	Information about the next stages of a procedure.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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*The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu*

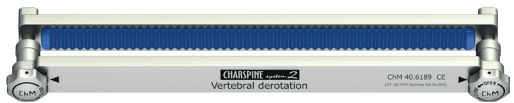


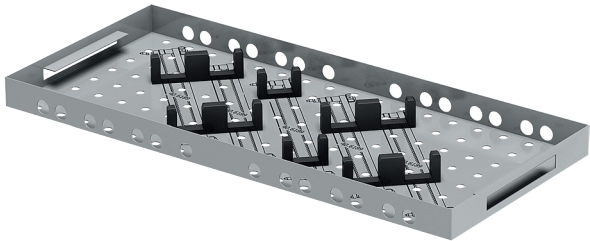
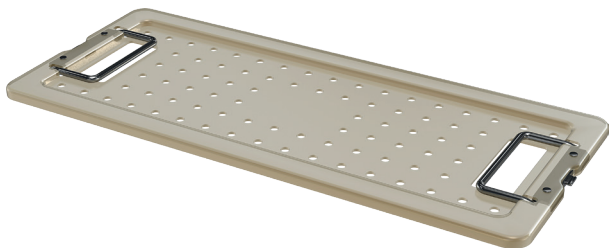
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1. INTRODUCTION

The **CHARSPINE2 VD** set of vertebral body derotation instruments, designed by the team of **ChM** specialists, has been developed to meet the challenges surgeons face when treating complex spine deformities (*scoliosis*) and to broaden the application of recognized and clinically proven **CHARSPINE2** bar stabilization system. **CHARSPINE2 VD** utilizes the direct vertebral derotation technique that enables three-dimensional correction of spinal disorders. The system consists of sleeves and clamps that can be combined into convenient blocks ensuring the most effective correction of deformity. The **CHARSPINE2 VD** instrument set has been especially designed for and is fully compatible with **CHARSPINE2** bar stabilization system.

2. INSTRUMENTS

Instrument set for CHARSPINE2 VD vertebral derotation 15.0909.101

	Name	Catalogue no.	Pcs
	Derotational clamp	40.6189.000	5
	Derotational sleeve	40.6790.000	10
	Wrench S17	40.6793.000	1
	Reamer	40.6794.000	1
	Tray	14.0909.201	1
	Container lid 9x4	14.0909.101	1
	Container lid 9x4	14.0909.102	1



The instruments below are not included in the standard offer.
Please, contact your local representative or ChM Sales Department in order to include them in the ordered CHARSPINE2 VD instruments.

Additional equipment

	Name	Catalogue no.	Pcs
	Container lid	12.0750.200	1
	Container	12.0750.100	1




3. SURGICAL TECHNIQUE

3.1. SCREWS SELECTION

Posterior surgical approach to the thoracolumbar spine and instructions for transpedicular screws insertion have been described in a separate surgical technique No. ST/96 for **CHARSPINE2** thoracolumbar spine stabilization system. The selection of appropriate screws is a key factor to ensure the success of the spine derotation procedure. Monoaxial screws guarantee the highest stability, however, due to possible difficulties with rod fitting, polyaxial or uniplanar screws may be required. For scoliosis correction, the use of reduction screws should be considered since the screws significantly facilitate the bar placement. The transpedicular screws should be inserted at each level of the concave site of the scoliosis, whereas on the convex side - the screws should be inserted at both ends of the scoliosis arch and at its apex.

3.2. ROD CONTOURING

When all the screws are placed in the pedicles, use e.g. rod trial 6/300 [40.5246.300] to measure the length of the rod and define its required curvature. The trial is available as an additional accessory of **CHARSPINE2** system. Contour the rod with adjustable rod bender [40.8074] which is a standard instrument of **CHARSPINE2** system (refer to **CHARSPINE2** surgical technique).

	40.5246.300
	40.8074.000
	40.8069.000



NOTE: To order the rod trial, contact your sales representative or ChM Sales Department.

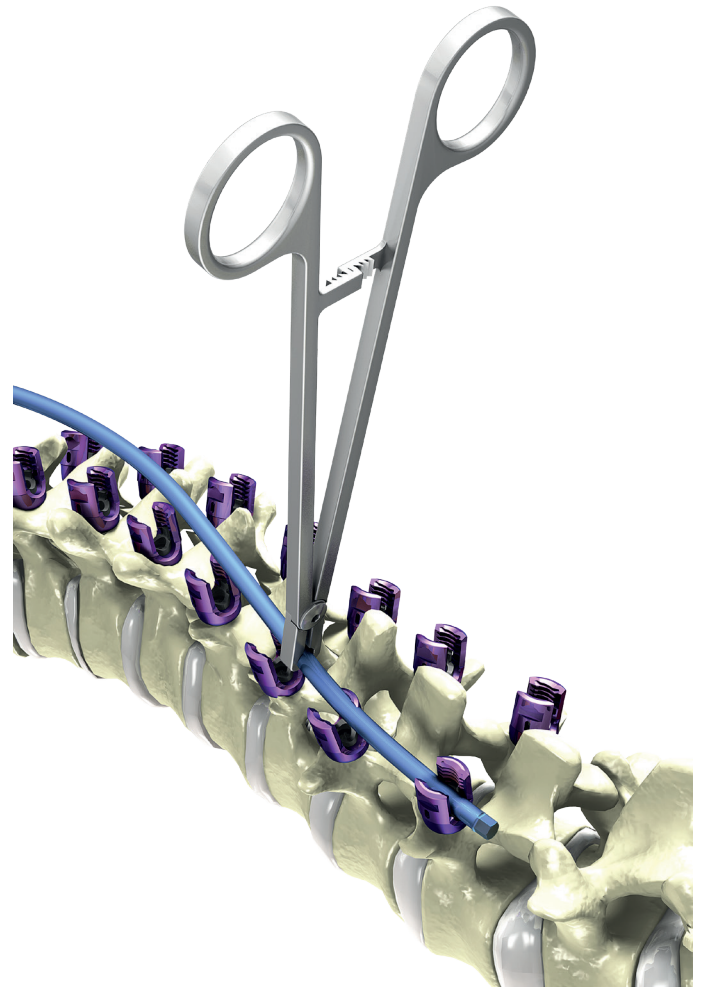


NOTE: Contour the convex rod with less kyphosis to push down on the convex side of the vertebral bodies, thus displacing them anteriorly and decreasing the rib prominence. Contour the concave rod with extra kyphosis to pull the apical vertebrae dorsally out of the chest, correct apical lordosis and decrease the rib prominence.

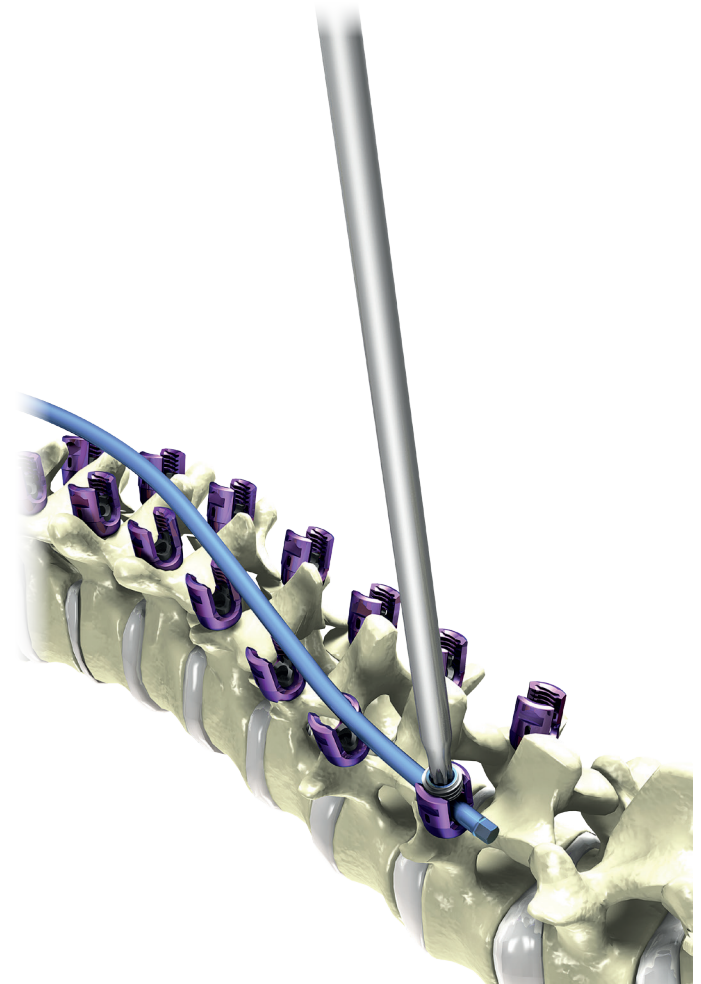


3.3. ROD FIXATION

Use pliers for rod **[40.8109]** to place the contoured rod in the sockets of transpedicular screws.



Initially, lock the rod in the screw inserted in the peripheral, anatomically positioned vertebra. Lock the rod using locking screw **[3.6160]** placed in the head of the transpedicular screw.





NOTE: The locking screw may be mounted on the screwdriver tip only from the upper side of the screw (the locking screw design eliminates any installation errors).



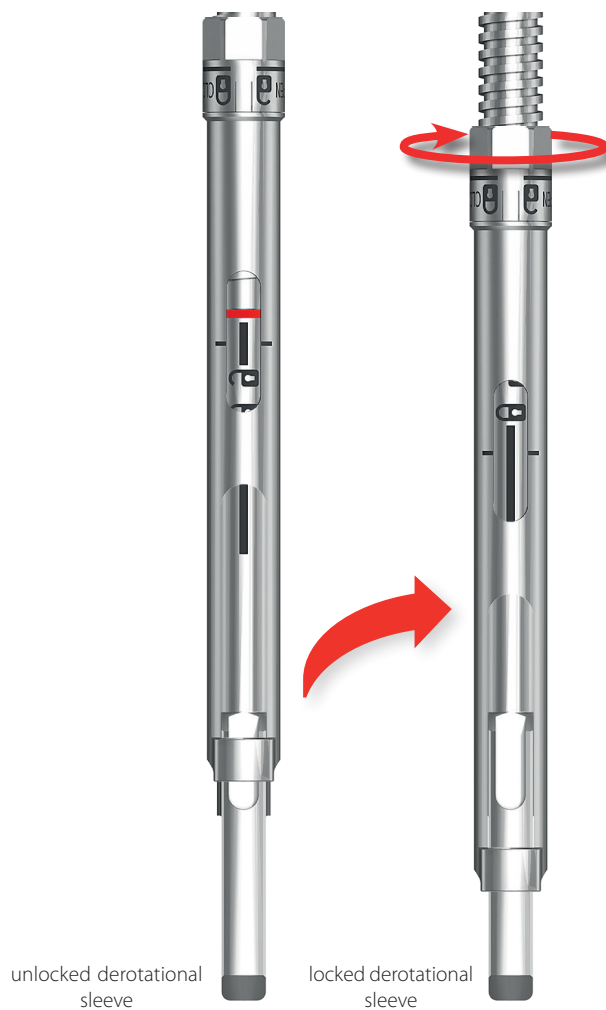
The upper surface of the screw is colour-marked for easier identification.

The locking screw is installed on the tip of the screwdriver T30 [40.8111], then it is inserted into the cut-out on the screw head and slightly tightened in a clockwise direction. The inserted locking screw should allow the rod to move freely in the socket. Pliers for rod and screwdriver T30 are included in **CHARSPINE2** stabilizer set.



3.4. ROD REDUCTION WITH DEROTATIONAL SLEEVE

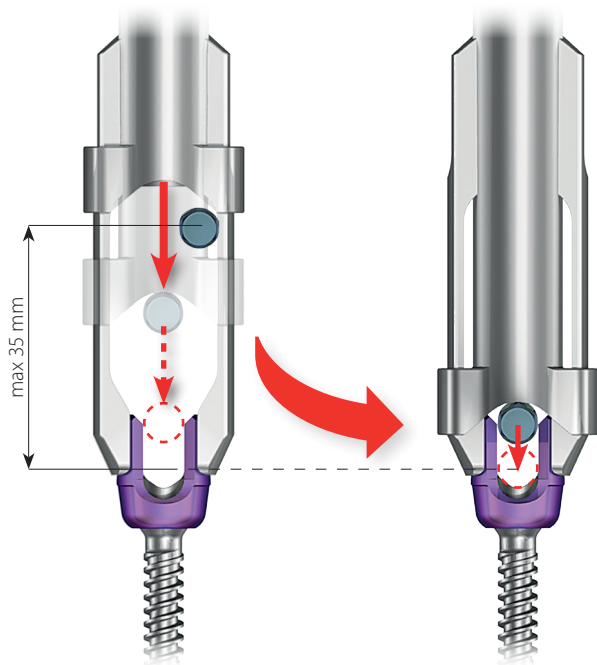
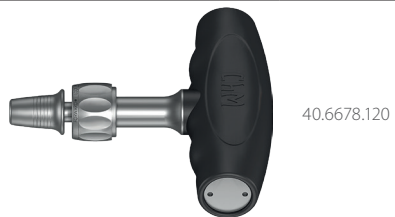
First, place the unlocked derotational sleeve on the screw head (the mark on the outer sleeve matches the field of the open padlock in the slot).



Snap install the unlocked sleeves on the screws heads placed in the adjacent levels of the spine, so that the rod is between the arms of the sleeve.

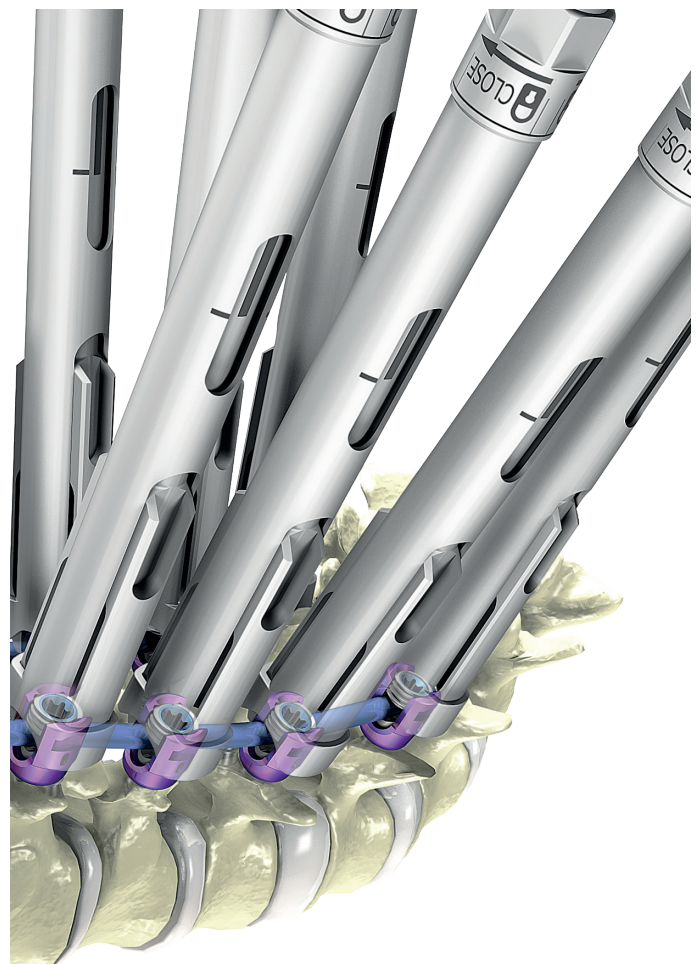
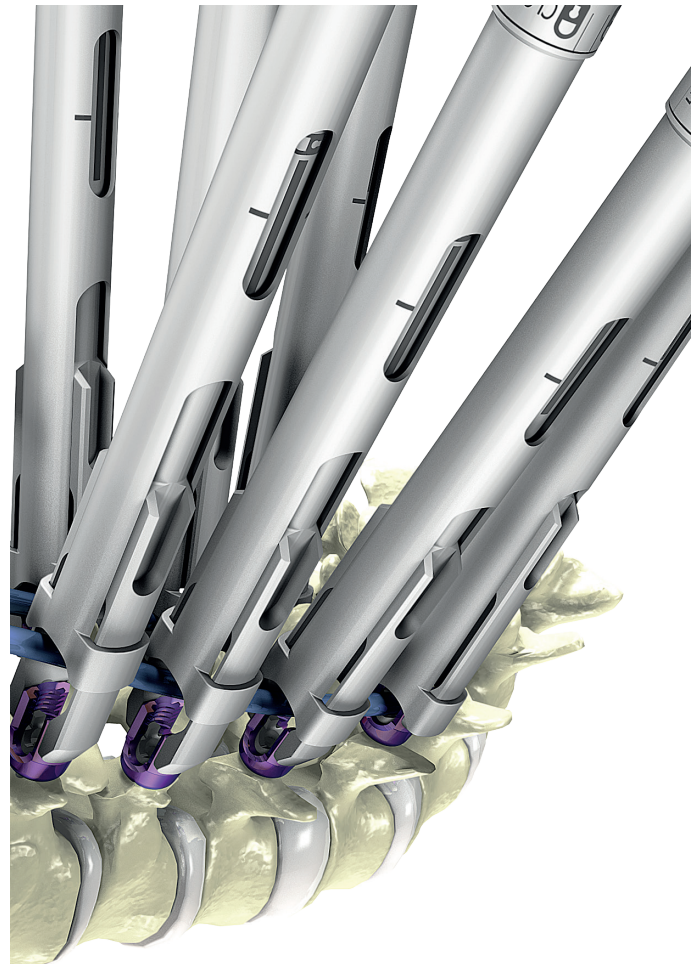


Then, use the wrench S17 [40.6793] combined with the oval head ratchet handle [40.8086] or torque limiting ratchet handle T 12Nm [40.6678.120], and clockwise rotation to gradually lower the outer sleeves. As the sleeve lowers, the rod is being slowly pushed down until seated in the bottom of the socket of the screw head.



The design of the **CHARSPINE2 VD** derotation sleeve allows the rod to be reduced from 35mm down to the correct position.

Secure the seated rod with locking screws.



3.5. ROD DEROTATION



To enlarge the space in the operating field, detach the derotational sleeves (after securing the rod) from the screws, as described in the last chapter of this instruction: Frame detachment.

Having inserted the locking screws, rotate the rods until they are positioned as intended in the sagittal plane. Afterwards, pre-tighten the locking screws. For rotation, use holding forceps ([40.6202] or [40.4516] depending on the instrument set version) that are a part of CHARSPINE2 set. If the rod has original hexagonal ends, an eye wrench [40.8069] can also be used.



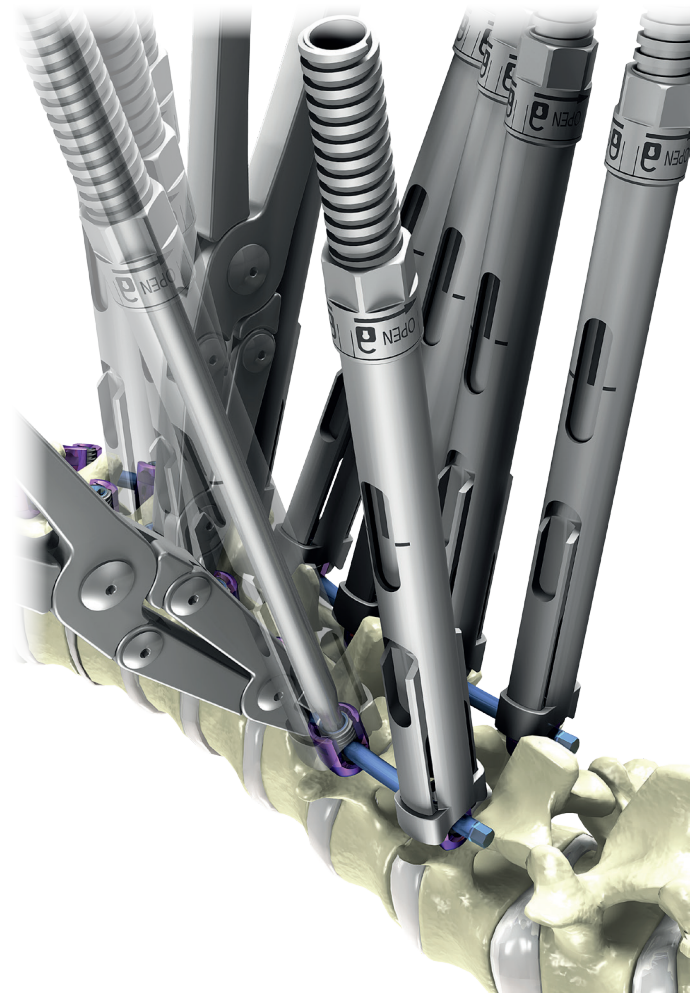
40.6202.000



40.8069.000



NOTE: In the CHARSPINE2 stabilizer sets, there is only 1 piece of holding forceps. For ordering more holding forceps, please contact the sales representative or ChM Sales Department.



3.6. DIRECT DEROTATION

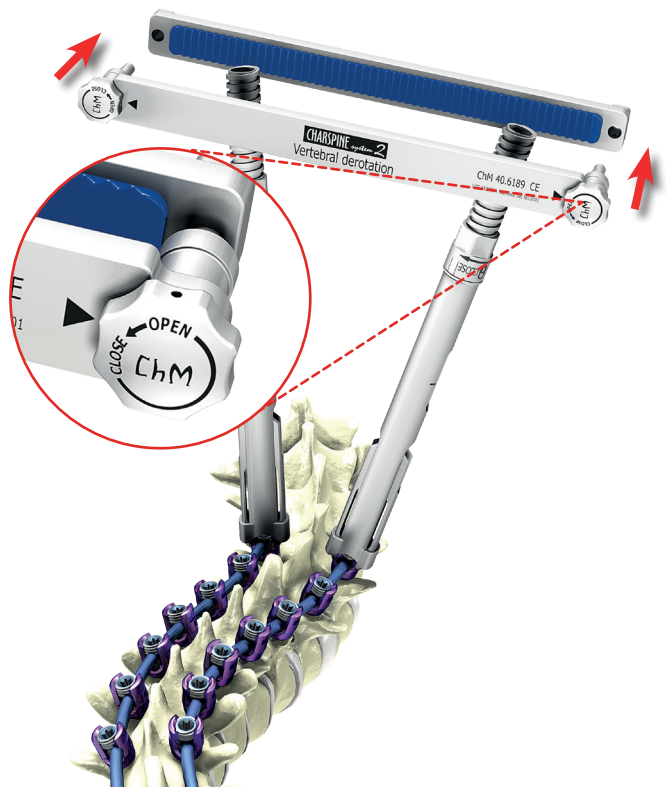
3.6.1. SEGMENTAL TECHNIQUE

Derotation should start from navigating the first neutral (*non-rotated*) vertebral body located below the deformity and the first rotated vertebra.

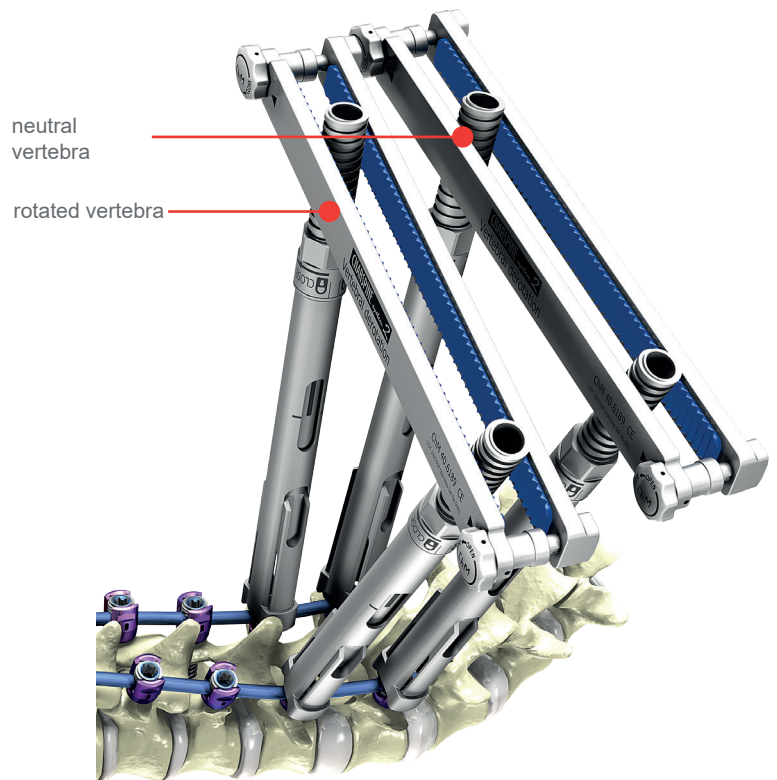
The sleeves located on the same levels should be locked together with derotational clamps, creating two separate frames as presented on the illustration.



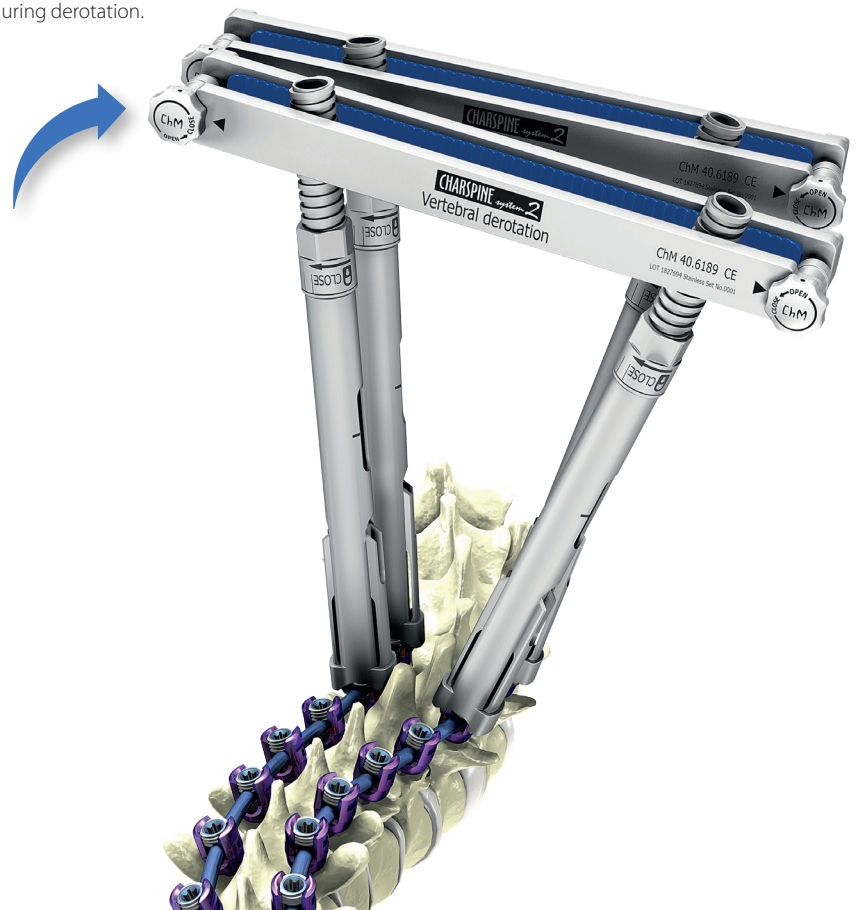
40.6189.000



Locking screws already secured in the transpedicular screws of rotated vertebrae (above the neutral one) should be loosened, yet not completely removed. Locking screws of neutral vertebrae must remain pre-tightened.



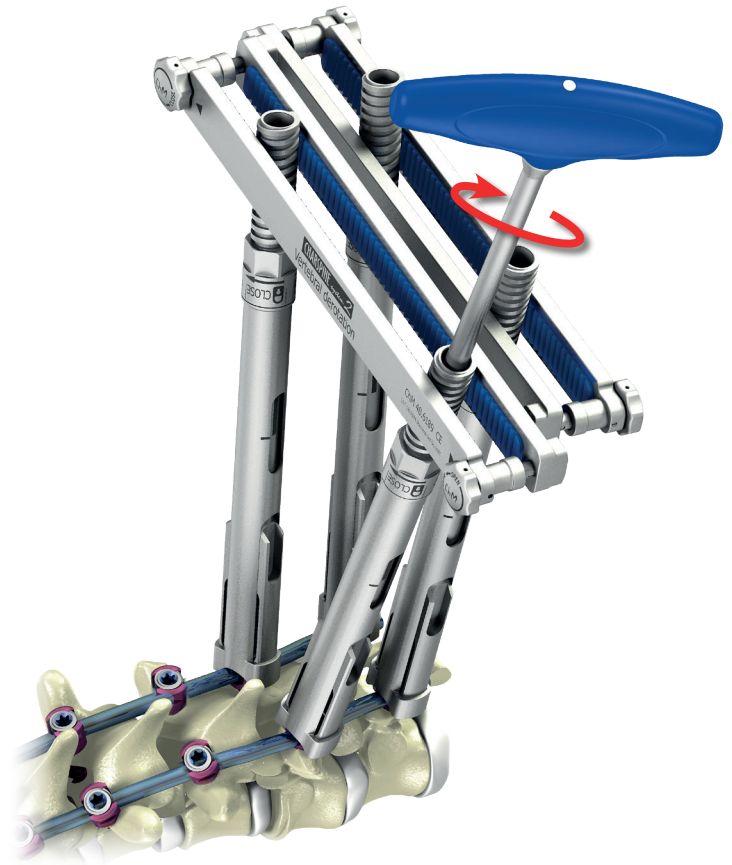
Afterwards, a direct derotation of the first rotated vertebra should be performed. The frame locked on the neutral vertebra will be a reference point for the rotated vertebra and will act as a counter element for forces occurring during derotation.



After derotation, the locking screws located in the rotated vertebra should be pre-tightened with screwdriver T30[40.8111].

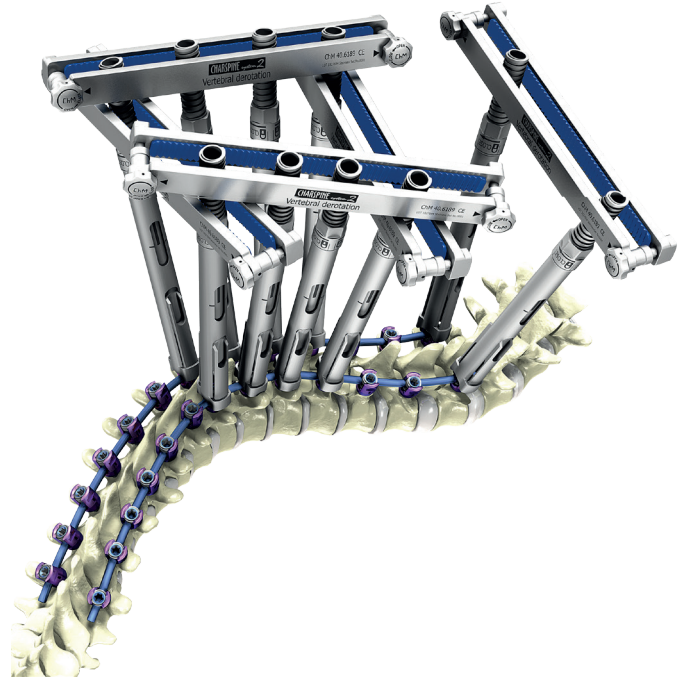


The rotated vertebra will now act as a neutral vertebra and the whole procedure should be repeated moving one segment higher.

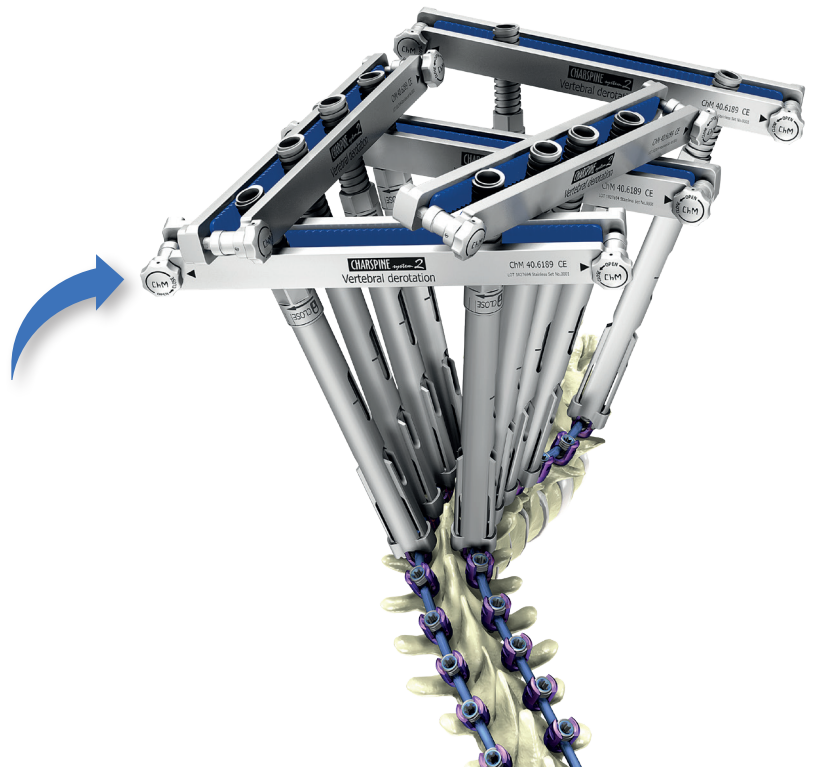


3.6.2. EN BLOCK TECHNIQUE

Derotational sleeves should be placed on deformity apical screws and on the first neutral (*non-rotated*) vertebra located below the deformity. The sleeves on the neutral vertebra should be locked together with the derotational clamp to form a frame. The sleeves located on the rotated vertebrae should also be locked together with the clamp as illustrated, forming a single frame covering several levels. Locking screws should be loosened but not removed. The locking screws in transpedicular screws of the neutral vertebra should be pre-tightened.



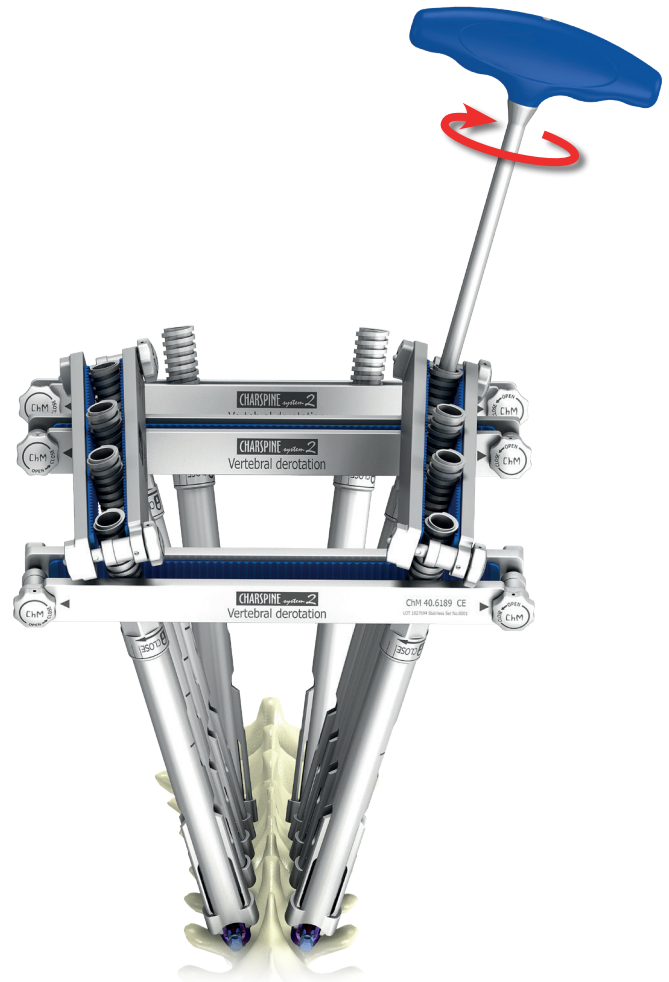
Derotation is performed by manoeuvring the frame locked on the rotated vertebrae until the neutral position is reached. The frame on the neutral vertebra is used as a counter element for the resultant forces.



After performed correction, the locking screws should be pre-tightened with screwdriver T30 [40.8111].

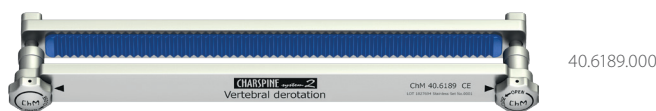


NOTE: To facilitate the derotation procedure, push down the rib prominence.



3.7. FRAME DETACHMENT

The frame disassembly should start with clamps removal - loosen the knob counterclockwise. If clamp removal is not yet possible, unlock the other knob.



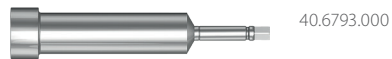
Should it be necessary to reassemble the derotational clamp on the sleeves, both parts of the clamp must first be completely disconnected. This will ensure that the locking mechanism functions correctly when reinstalled.



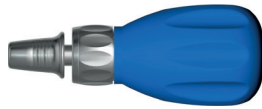
Install the wrench S17 [40.6793] combined with the oval head ratchet handle [40.8086] or torque limiting ratchet handle T 12Nm [40.6678.120] on the sleeve nut and by counterclockwise rotation, keep unlocking the arms of the derotational sleeve until the open padlock symbol appears inside the window, as presented below.



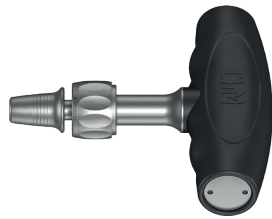
NOTE: Make sure the marker on the sleeve does not pass the thick red line visible inside the window, otherwise the derotational sleeve may disassemble during the procedure.



40.6793.000



40.8086.000

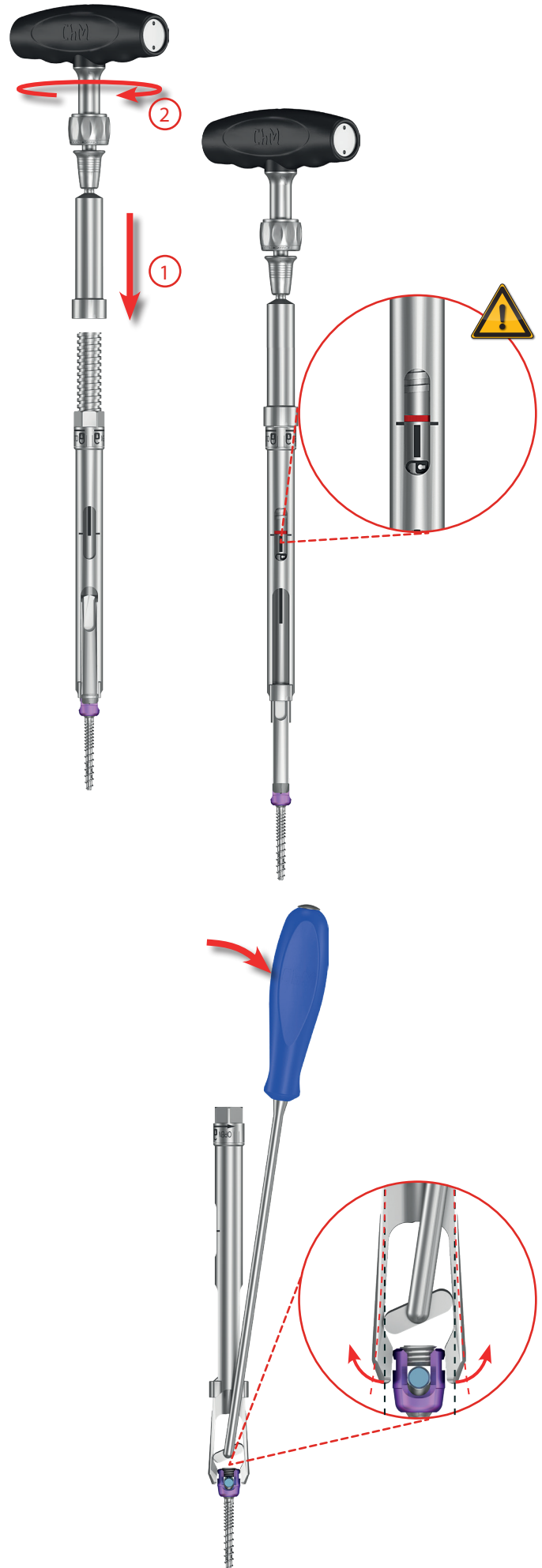


40.6678.120

After unlocking the arms of the outer sleeve, use the reamer [40.6794], the tip of whose is placed between the arms of the derotational sleeve, to open the latch of the arms, and remove the sleeve from the transpedicular screw.

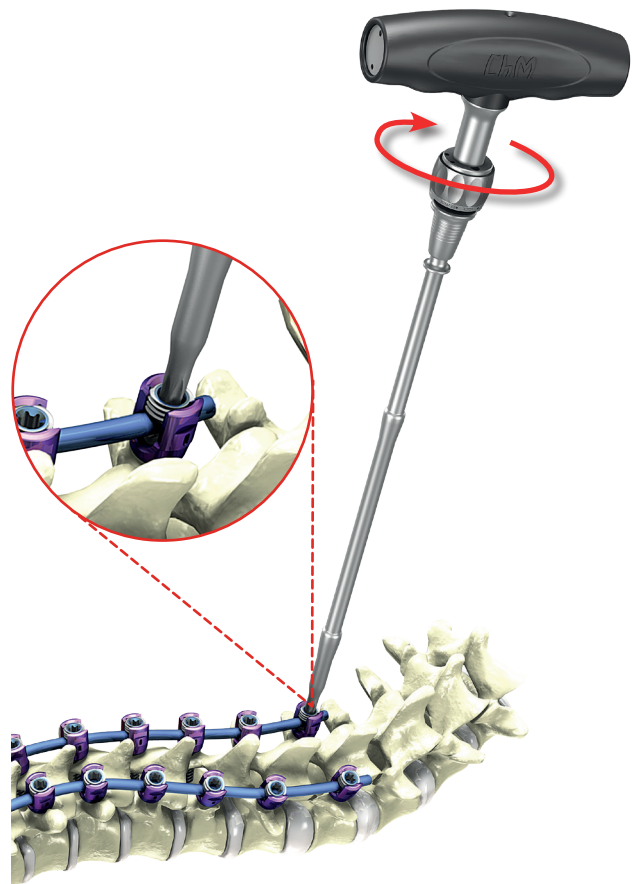
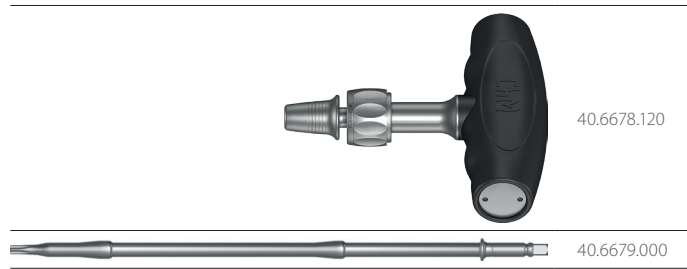


40.6794.000



3.8. FINAL TIGHTENING

Tighten finally up the locking screw with the help of torque limiting ratchet handle T 12Nm [40.6678.120] and screwdriver tip T30 [40.8084].



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