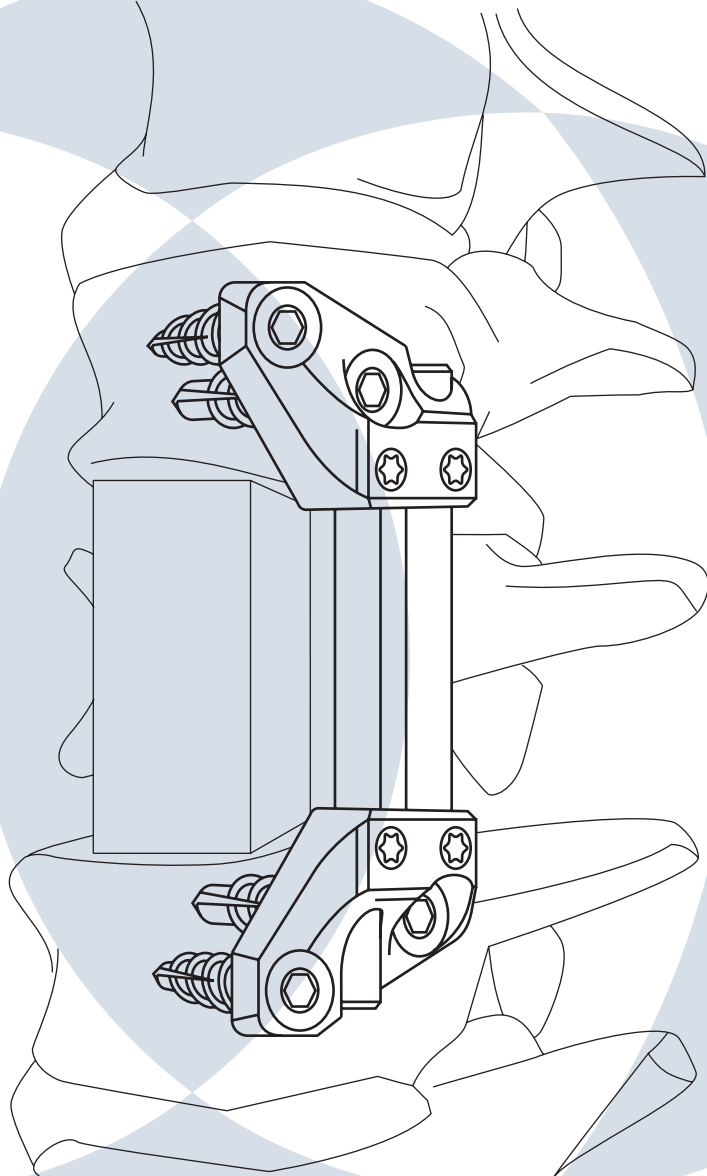


VENTROFIX



PRODUCT OBSOLETE – 30th June 2017
DSEM/SPN/0616/0527(1)

Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.

 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuyshes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuyshes.com/hcp/reprocessing-care-maintenance>

TABLE OF CONTENTS

INTRODUCTION	Indications and Contraindications	2
	AO Spine Principles	3
	System description	4
	Preparation	6

SURGICAL TECHNIQUE	Double rod technique	8
	Single rod technique	18
	X-rays	27

PRODUCT INFORMATION	Implants	28
	Instruments	30

REFERENCES		31
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INDICATIONS AND CONTRAINDICATIONS

VentroFix is a modular, stable rod system developed for the fixation of the anterior thoracic and lumbar spine.

Four different clamp types made of a titanium alloy (TAN) can be combined in various ways. This enables the surgeon to choose implant configurations suited to the individual pathology and anatomical conditions.

Locking screws are used to secure the clamps to the vertebral bodies.

These locking screws have a self-tapping cancellous thread and a short machine thread which keeps them firmly locked to the clamp.

The implant may be compressed or distracted when instrumentation has been completed.

Indications

VentroFix is implanted using an anterior approach and is used to stabilize the spine in

- Fractures
- Tumours and infections
- Degenerative diseases
- Posttraumatic kyphoses

Contraindications

- Severe osteoporosis
- Scolioses

AO SPINE PRINCIPLES

The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.^{1,2}

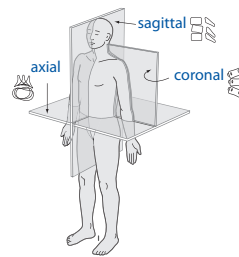
Stability

Stabilization to achieve a specific therapeutic outcome



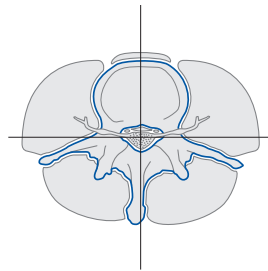
Alignment

Balancing the spine in three dimensions



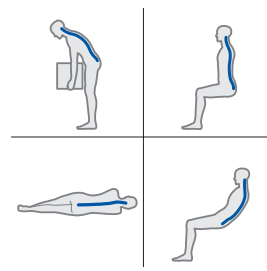
Biology

Etiology, pathogenesis, neural protection, and tissue healing



Function

Preservations and restoration of function to prevent disability



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¹ Aebi et al (1998)

² Aebi et al (2007)

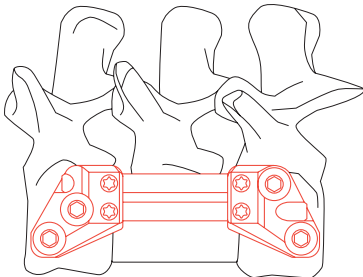
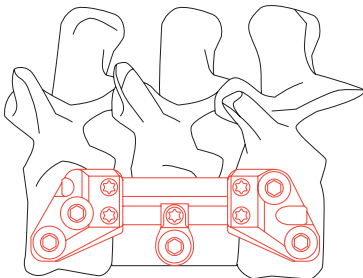
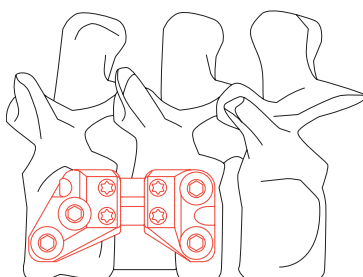
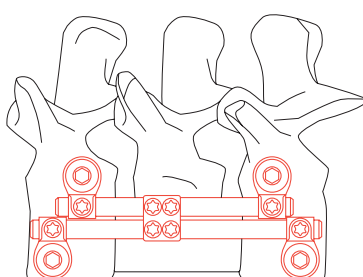
SYSTEM DESCRIPTION

Anatomical areas of application

VentroFix is indicated for the thoracic, thoracolumbar and lumbar spine:

- Double rod technique: T8–L5
- Single rod technique: T4–T10

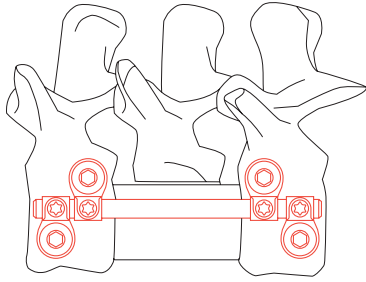
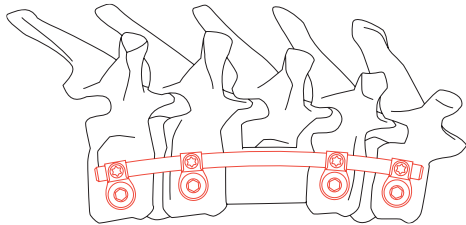
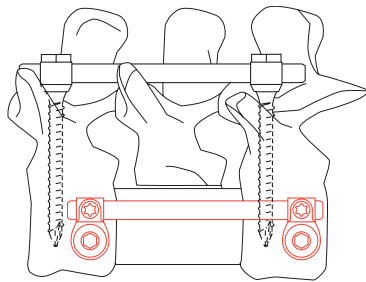
Double rod technique

System configuration	Region	Page
<p>Fixation using double rod clamps</p> 	T8–L5	8–17
<p>Fixation using double rod clamps and a single clamp</p> 	T8–L5	8–17
<p>Monosegmental fracture fixation using caudal fracture clamp (only approach from the left possible).</p> <p>Monosegmental fracture fixation is possible when approx. two-thirds of the fractured vertebral body is undamaged and the pedicles are not separated.</p> 	T8–L5	8–17
<p>Double rod technique using single clamp and parallel connector</p> 	T10–L5	8–17

Single rod technique

The single rod technique is contra-indicated in the lumbar and thoracolumbar spine due to the great forces exerted there and due to the limited stability against rotation of this construction.

Exception: VentroFix single rod fixation combined with posterior fixation.

System configuration	Region	Page
<p>Thoracic single rod fixation using two single clamps per vertebral body</p> 	T6–T10	18–26
<p>Thoracic fixation using one single clamp per vertebral body</p> 	T4–T10	18–26
<p>Anterior single rod fixation combined with posterior fixation</p> 	T4–L5	18–26

PREPARATION

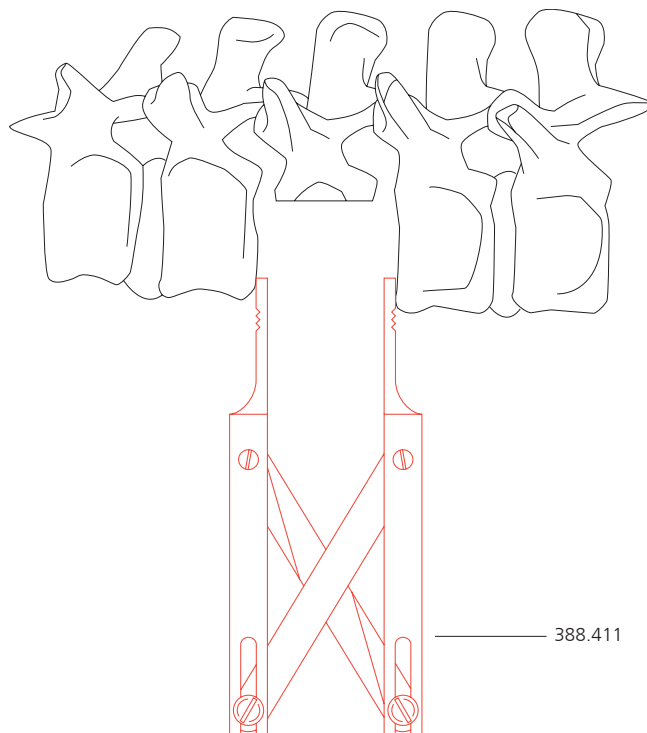
Approach

VentroFix is inserted anterolaterally using standard approaches. The localization of the pathology on the spine is crucial for the choice of approach. The various anterior approaches are described in detail in standard textbooks.^{1,2}

Spreading

After exposure and decompression of the spinal cord, correct kyphosis using the Spreader Forceps (388.411) and insert bone graft.

If a **VentroFix single rod configuration** is used for stabilization, distraction may be performed directly over the implant previously inserted in order to perform a bone graft.



1. Aebi (1996)
2. Bauer et al (1998)

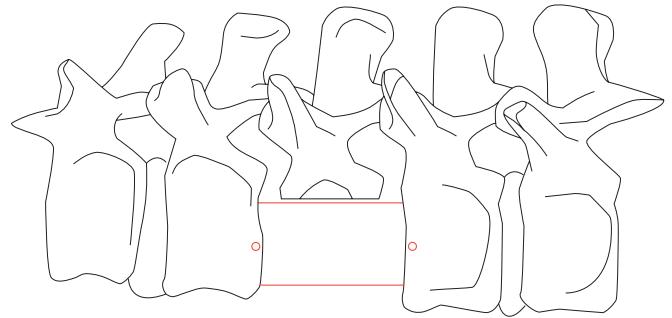
Alternative spreading technique

If the spreader forceps prevents insertion of a bone graft, the spine may be corrected by an internal fixator inserted temporarily: Insert a Schanz screw (5 mm dia.) into the vertebral body above and below the lesion. The Schanz screws which are connected to an internal fixator may be used to distract with the Spreader Forceps (388.411) and correct the position of the spine.

After inserting the bone graft, remove the internal fixator and the Schanz screws.

Reduction check

Mark the outer endplates of the vertebral body to be instrumented using small fragment screws. Check their position and the anatomical position of the vertebrae with the image intensifier.



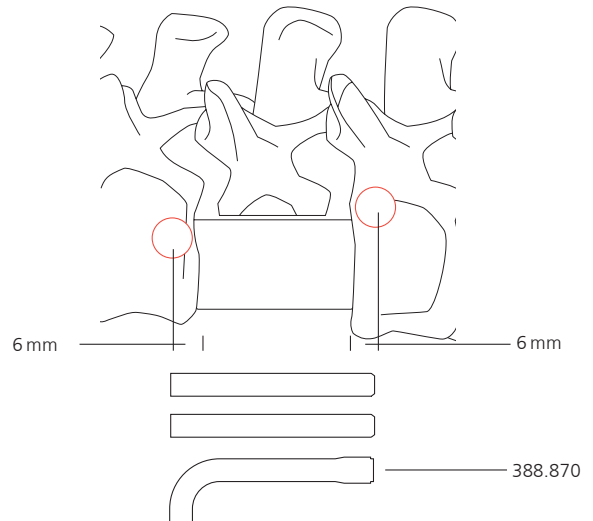
DOUBLE ROD TECHNIQUE

1

Determine length of rod required

After correcting the spine, determine the length of rod required using the Trial Rod (388.870). To do this, measure the distance to the points where the posterior screws shall be inserted later (min. distance from inner endplate = 6 mm).

The rods may not be bent when the double rod technique is used.



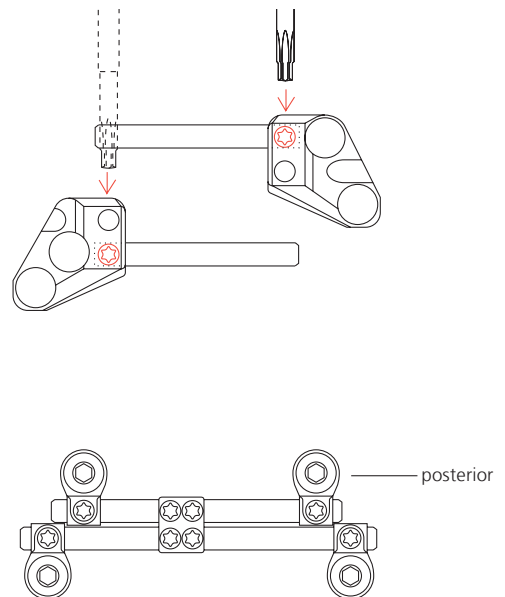
2

Insert rods in clamps

Insert the two cut rods into the Double Rod Clamps (498.261–498.262) and firmly tighten the set screws in the blind holes.

Note on double rod technique using single clamps: When using the double rod technique with parallel connector, push the parallel connector into the middle of both rods and firmly tighten the set screws. A Single Clamp (498.260) is then mounted at each end of the rod according to the diagram, the two posterior clamps being nearer the lesion. Firmly tighten the set screws of the posterior clamps and slightly tighten those of the anterior clamps.

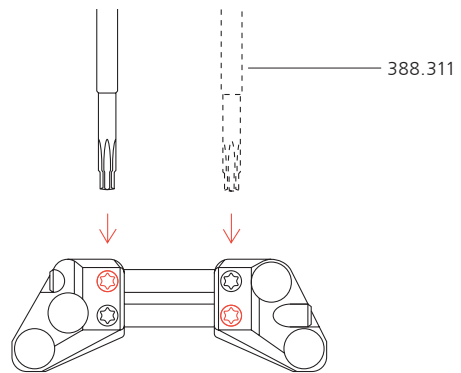
Then proceed to step 4.



3

Slightly fix the set screws of the through holes

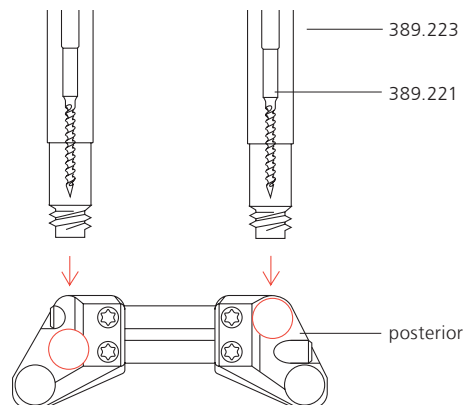
Slide the rods into the clamps and adjust the implants to the required position by moving the clamps. Slightly tighten the set screws of the through holes so that the length of the implant can be optimized when placed on the spine (step 5).



4

Mount drill sleeves with integrated fixation pins

Insert one Drill Sleeve (389.223) with integrated Fixation Pin (389.221) into each of the two posterior inner holes of the double rod clamps.



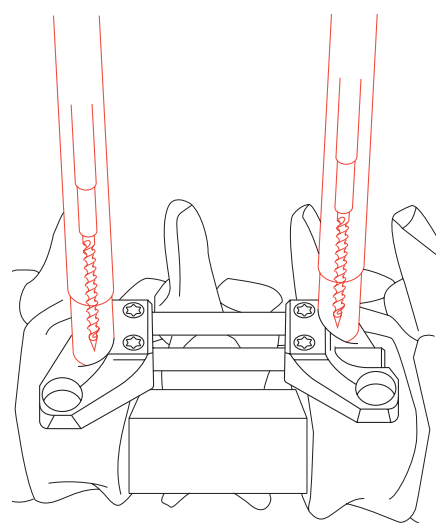
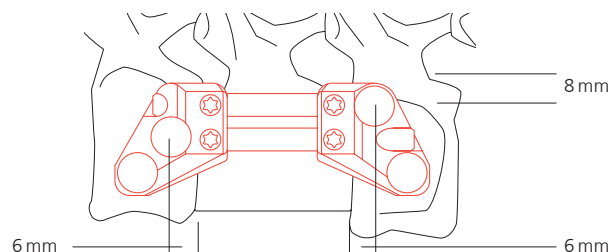
5

Position VentroFix on the spine

When positioning the implants on the spine, please observe the following minimum distances:

- Screw holes with mounted drill sleeves: 8 mm from the spinal canal and 6 mm from the lower or upper endplate of the vertebral body.
- Anterior screw holes: at least 6 mm from the upper or lower endplate of the vertebral body.

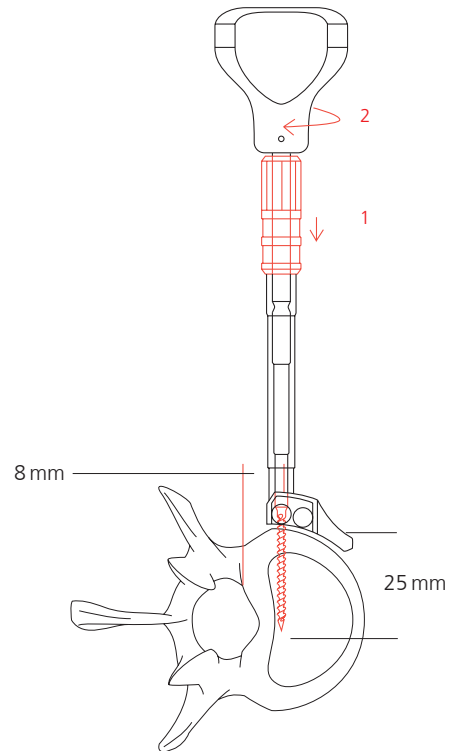
Align the rods parallel to the spine.



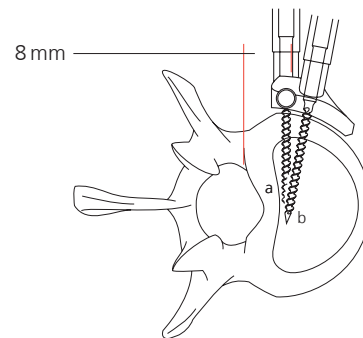
6

Insert fixation pins

Temporary fixation of the implants on the spine: unlock the two self-tapping fixation pins by advancing the locking sleeve at the upper end of the drill sleeve and insert them into the vertebral body (insertion depth limited to 25 mm). Please ensure that the drill sleeves with the fixation pins are not aligned against neural structures.



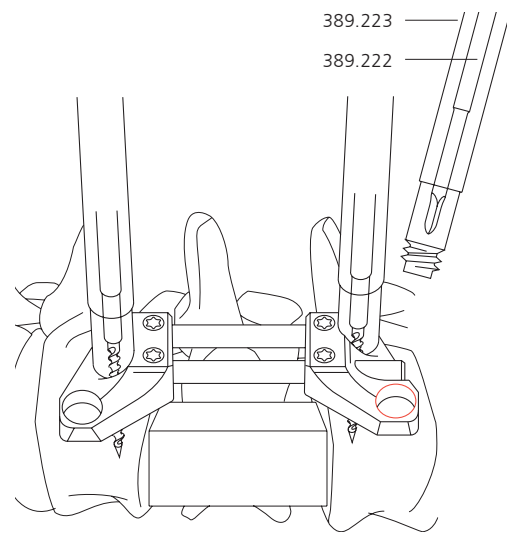
- Check position of fixation pins and implants (image intensifier)



7

Mount drill sleeve with integrated awl

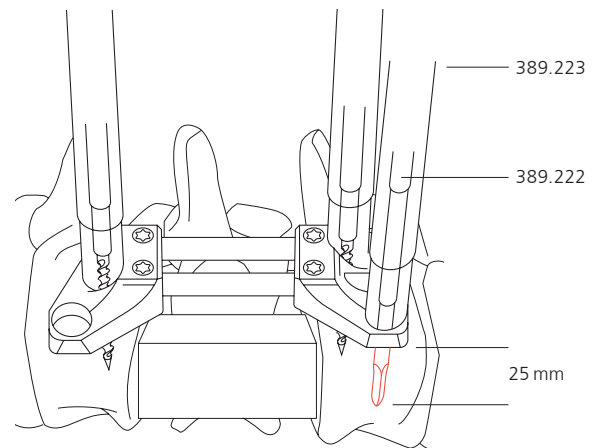
Mount the Drill Sleeve (389.223) with integrated Awl (389.222) in the anterior clamp hole.



8

Open screw hole with awl

Unlock the 4.9 mm awl and open the screw hole (insertion depth limited to 25 mm).

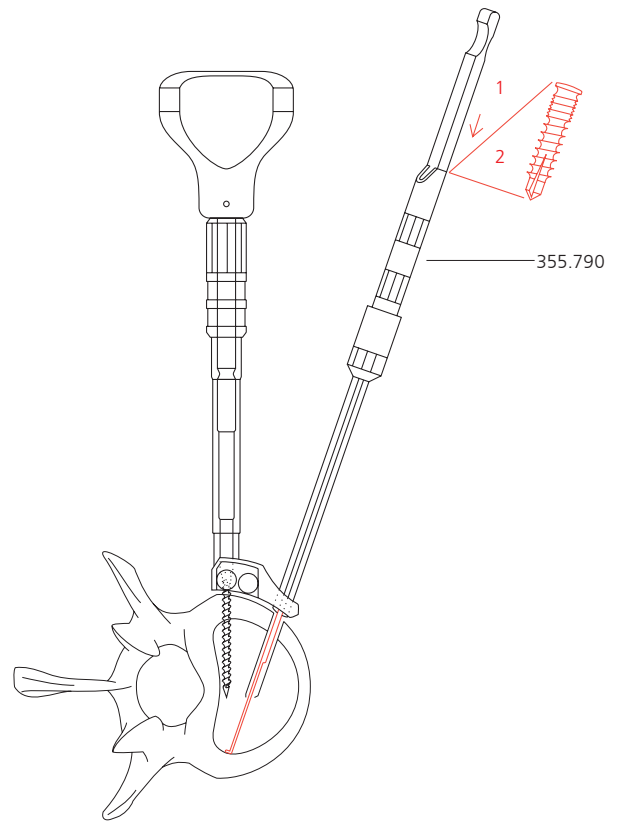


9

Determine length of screw required

After removing the drill sleeve with integrated awl, determine the length of screw required using the depth gauge (355.790) which is inserted through the clamp hole up to the far cortex.

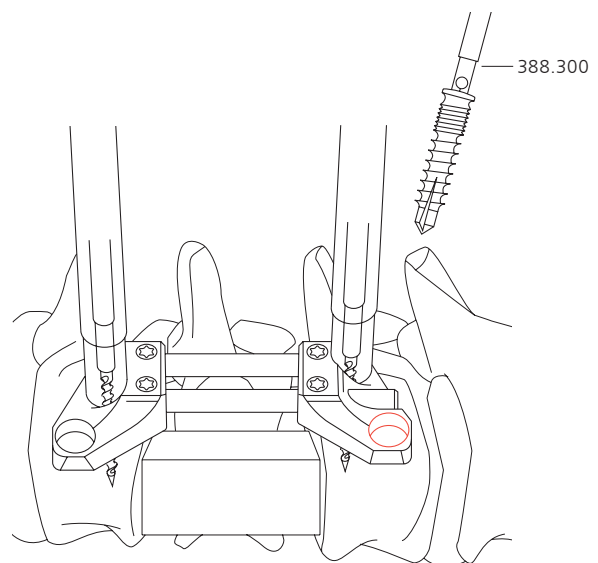
(Due to the locking mechanism and the triangulation of the bone screws, perforation of the far cortex is not required. If the bone is weak, you should use a screw which is 5 mm longer so that the far cortex can be grasped.)



10

Insert screw into clamp

Insert the locking screw of desired length into the clamp hole using the self-holding Positioner (388.300).

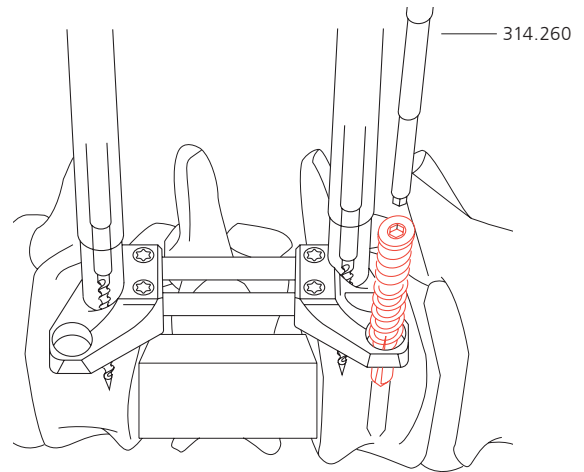


11

Insert screw into bone

Using the Hexagonal Screwdriver (314.260), insert the locking screw into the bone up to the limit stop under pressure.

Repeat steps 7 to 11 for the second anterior screw.

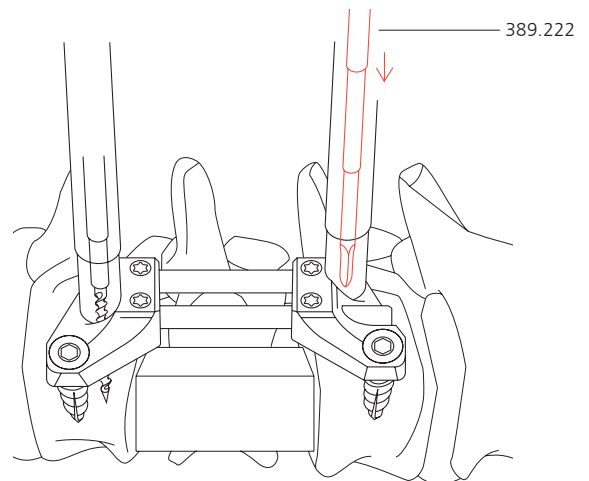


12

Remove fixation pin and insert awl

Remove a fixation pin by holding the drill sleeve in one hand and extracting the fixation pin in an anticlockwise direction with the other hand. Insert the awl into the mounted drill sleeve and repeat steps 8 to 11.

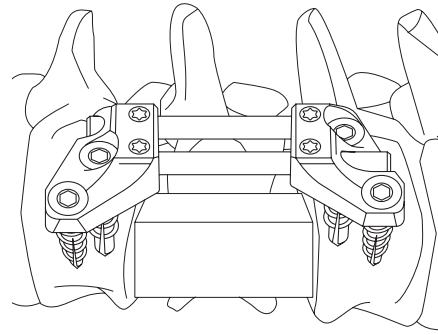
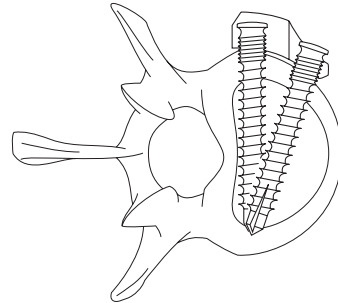
Repeat step 12 for the second posterior hole.



13

All four screws inserted

The correct position of the screws in a cross-section of the vertebral body.

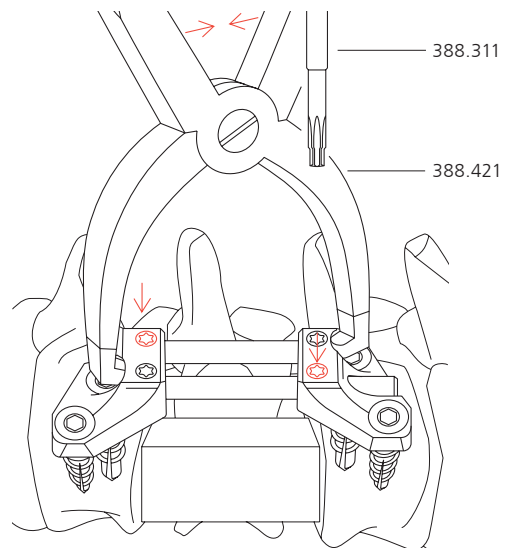


14

Compression with short-distance fixation

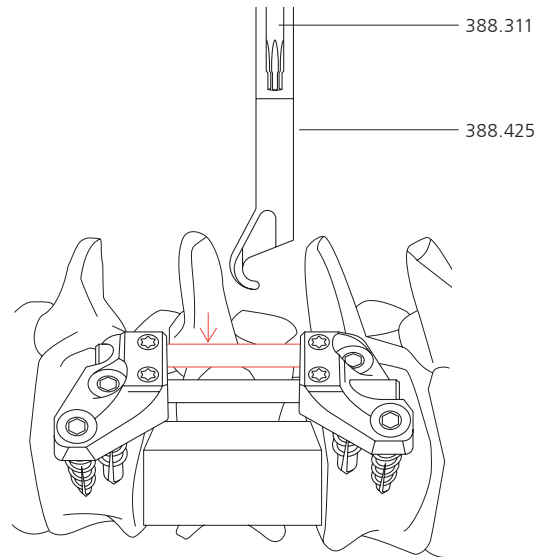
Loosen the set screws of both through holes. Leave the set screws of the blind holes firmly tightened.

Mount the Compression Forceps (388.421) diagonally onto both double rod clamps, compress and tighten the set screws of the through holes.



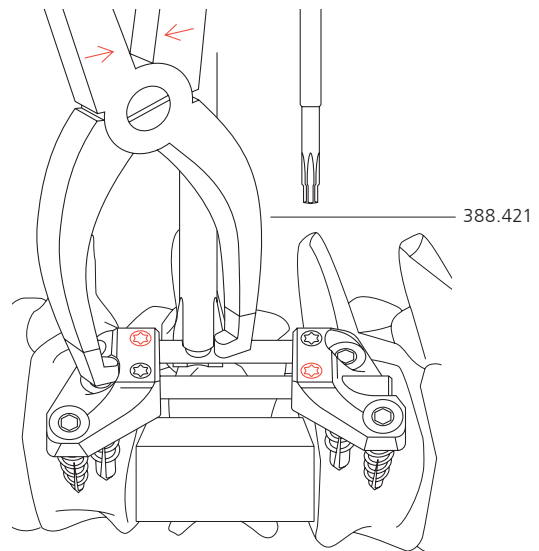
Compression with long-distance fixation

- a If the distance between the clamps is greater than the maximum width of the compression forceps, fasten the Compression Support (388.425) onto the posterior rod using the Torxscrewdriver (388.311).



- b Loosen the set screws of the two through holes. Leave the set screws of the blind holes firmly tightened.

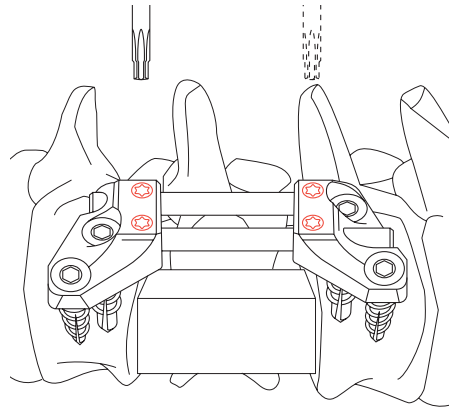
Mount the Compression Forceps (388.421) behind the blind hole of the left-cranial Clamp (498.262) and at the compression support, compress and tighten the set screws of the through holes.



15

Firmly tighten set screws

Firmly tighten the set screws and remove the compression support if mounted.

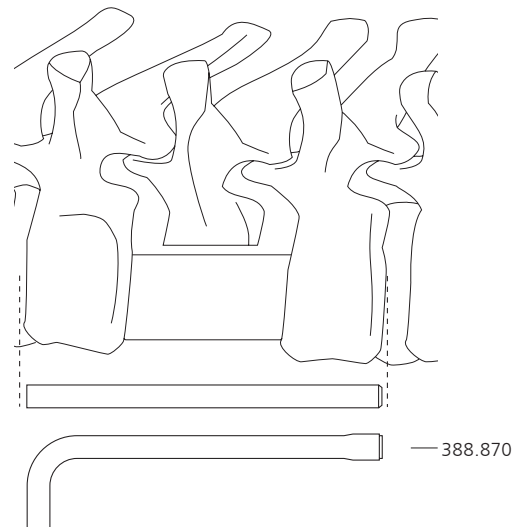


SINGLE ROD TECHNIQUE

1

Determine length of rod required

After correcting the spine, determine the length of rod required using the Bending Template (388.870). To do this, measure the distance to the outer endplates of the furthest vertebral bodies to be instrumented. If required, bend the rod to correspond to the curvature of the spine. Please remember that the rod must not be bent back (titanium).

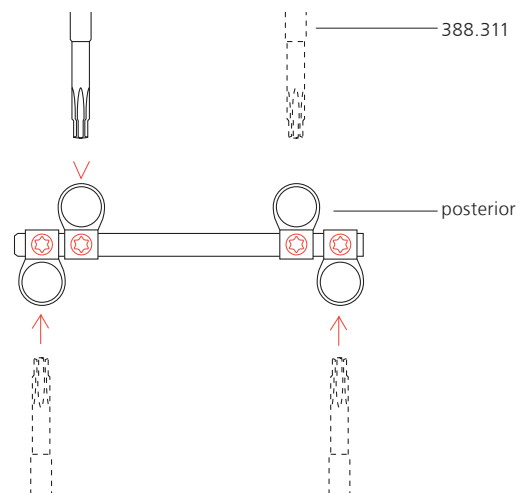


2

Mount clamps onto rod

Mount the single clamps onto the cut rod in such a way that the posterior clamps are nearer the lesion.

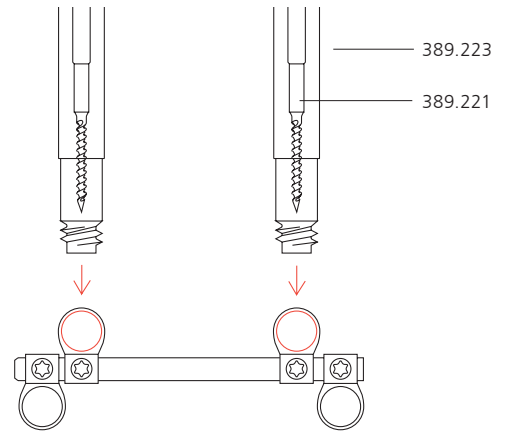
Using the Torx Screwdriver (388.311), tighten the set screws of the inner clamps firmly and those of the outer clamps slightly.



3

Mount drill sleeves with integrated fixation pins

Insert the Drill Sleeves (389.223) with the integrated Fixation Pins (389.221) into the two inner single clamps.



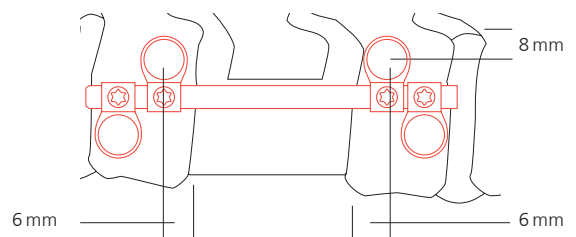
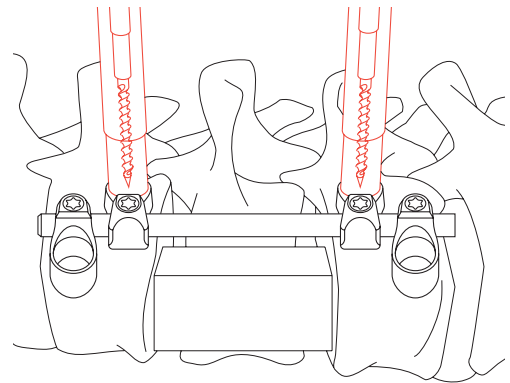
4

Position VentroFix onto spine

Please observe the following minimum distances when positioning the implants:

- Screw holes with mounted drill sleeves: 8 mm from the spinal canal and 6 mm from the lower or upper endplate of the vertebral body.
- Anterior screw holes: at least 6 mm from the upper or lower endplate of the vertebral body.

Align the rod parallel to the spine.

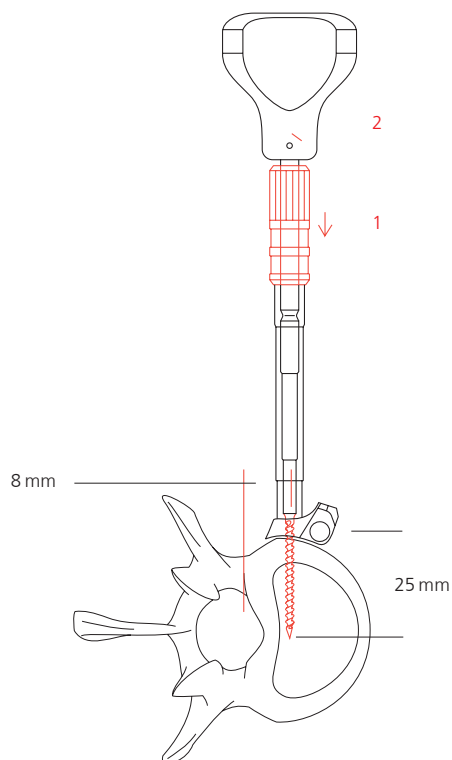


5

Insert fixation pins

Temporary fixation of the implants on the spine: unlock the two self-tapping fixation pins by advancing the locking sleeve at the upper end of the drill sleeve and insert them into the vertebral body (insertion depth limited to 25 mm). Please ensure that the drill sleeves with the fixation pins are not aligned against neural structures.

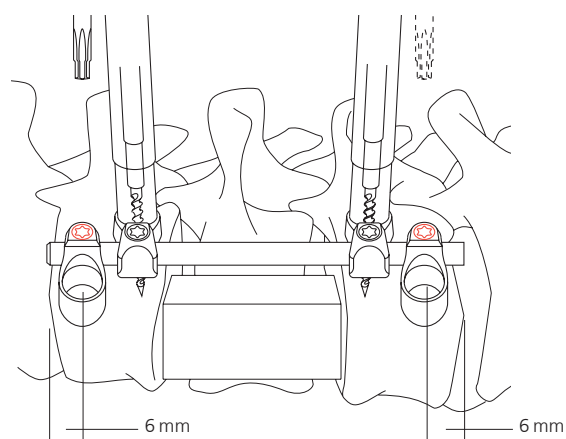
- Ⓒ Check position of fixation pins and implants (image intensifier)



6

Tighten set screws on outer clamps

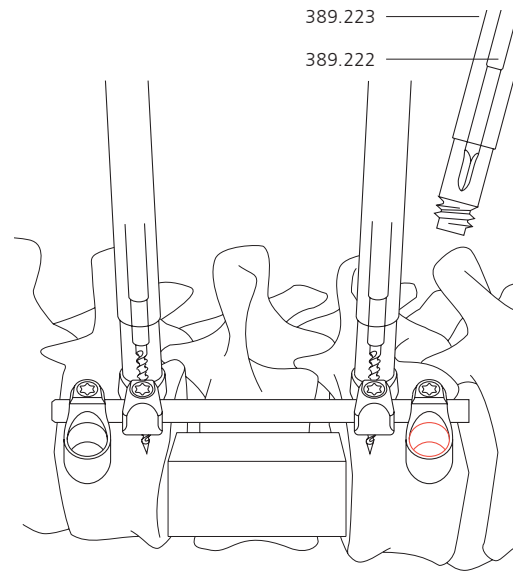
Position the outer clamps at least 6 mm away from the outer endplate and position the clamp (by rotating around the rod) so that it lies on the vertebral body. Please consider the position of neural structures when doing this. Firmly tighten the set screws on the outer clamps.



7

Mount drill sleeve with integrated awl

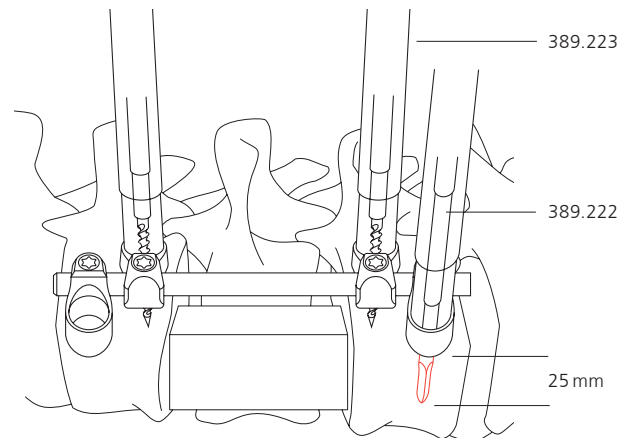
Insert the Drill Sleeve (389.223) with integrated Awl (389.222) into one of the two outer single clamps.



8

Open screw hole with awl

Unlock the 4.9 mm awl and open the screw hole (insertion depth limited to 25 mm).

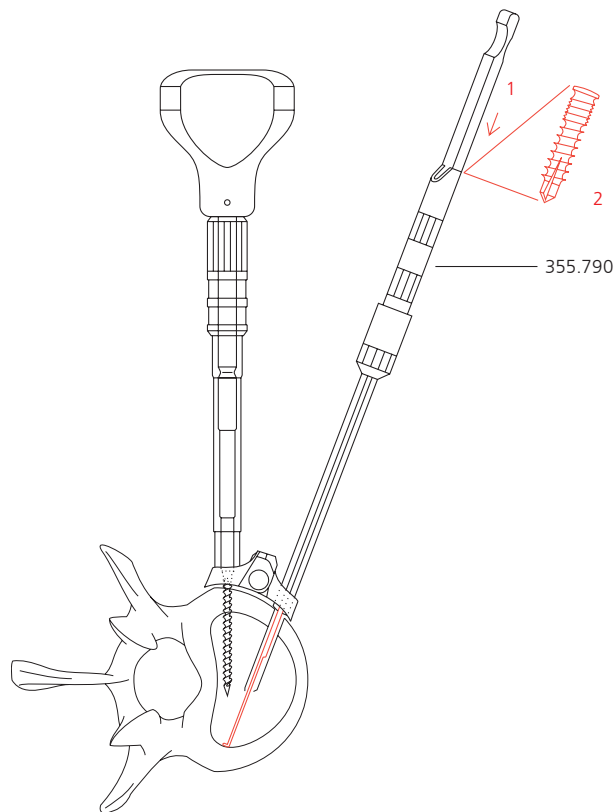


9

Determine length of required screw

After removing the drill sleeve with integrated awl, determine the length of the required screw using the depth gauge (355.790) which is inserted through the clamp hole up to the far cortex.

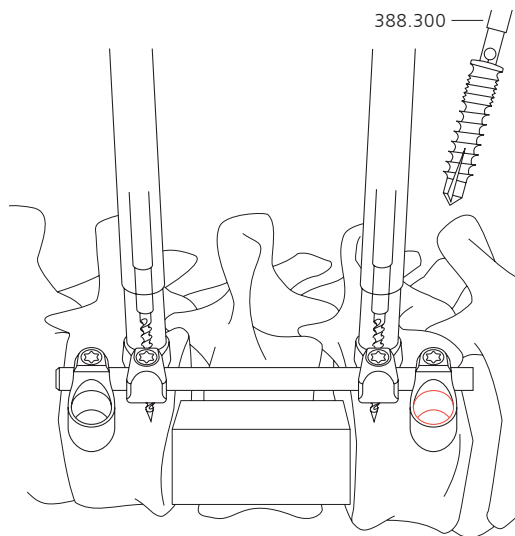
(Due to the locking mechanism and the triangulation of the bone screws, perforation of the far cortex is not required. If the bone is weak, you should use a screw which is 5 mm longer so that the far cortex can be grasped.)



10

Insert screw into clamp

Insert the locking screw of desired length into the clamp hole using the self-holding Positioner (388.300).

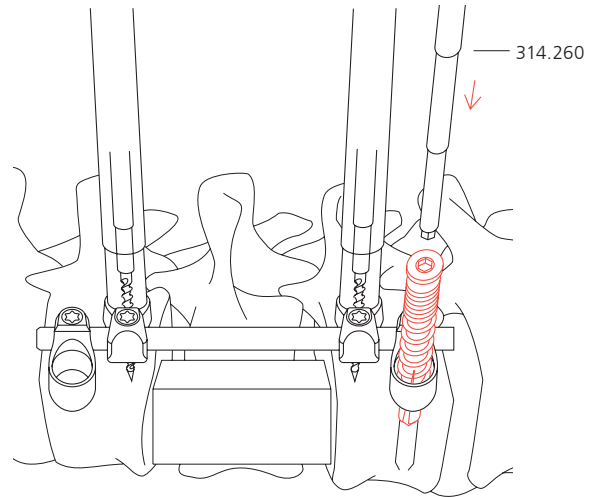


11

Insert screw into bone

Using the Hexagonal Screwdriver (314.260), insert the locking screw into the bone under pressure up to the limit stop.

Repeat steps 7 to 11 for the second anterior clamp.

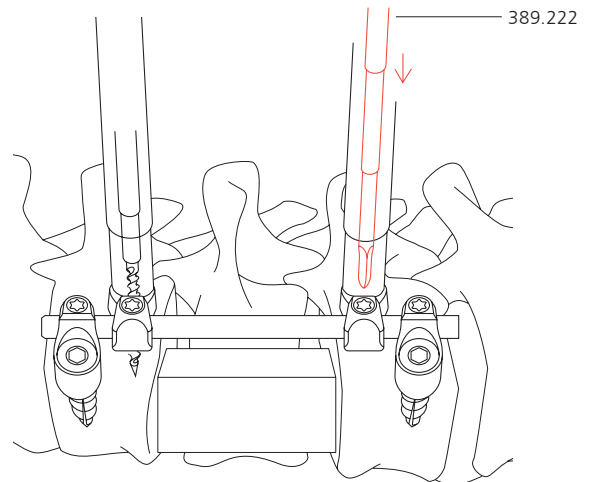


12

Remove fixation pin and insert awl

Remove a fixation pin by holding the drill sleeve in one hand and extracting the fixation pin in an anticlockwise direction with the other hand. Insert the Awl (389.222) into the mounted drill sleeve and repeat steps 8 to 11.

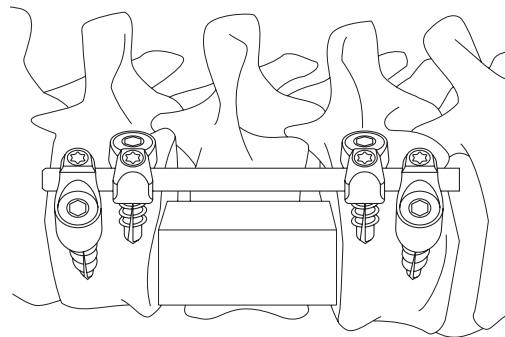
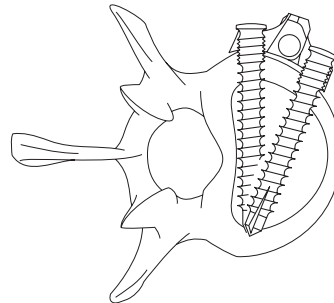
Repeat step 12 for the second posterior clamp.



13

All four screws inserted

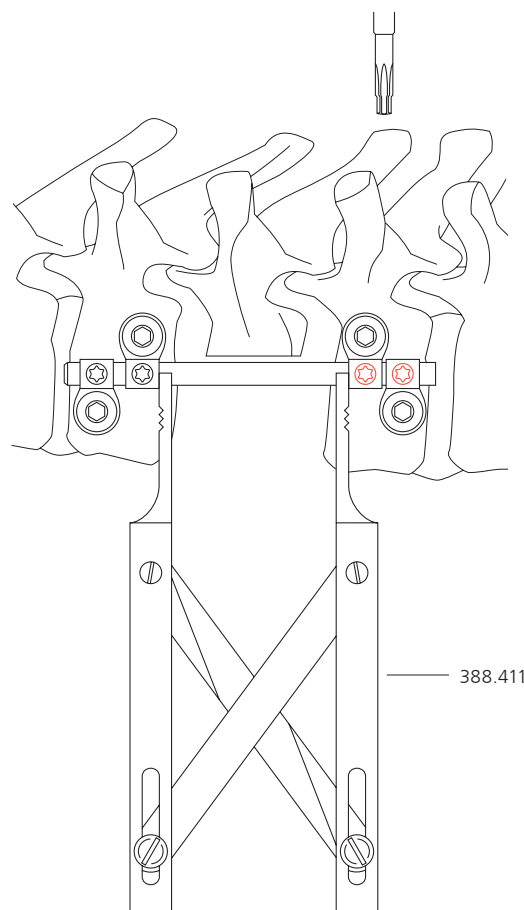
The correct position of the screws in a cross-section of the vertebral body.



If a bone graft has not yet been inserted: distraction and insertion of bone graft

In order to correct kyphosis and insert a bone graft, the Spreader Forceps (388.411) may be used to distract directly over the inserted implant:

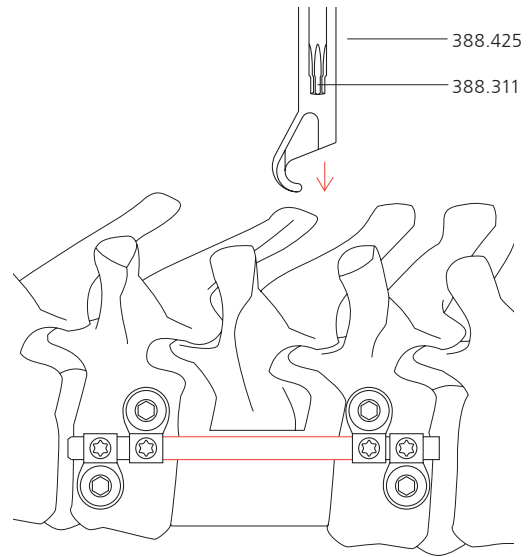
1. Loosen the set screws of the caudal single clamps.
2. Distract over the implant using the Spreader Forceps (388.411) and insert bone graft.
3. Tighten the set screws of the caudal single clamps.



14

Secure compression support

Use the Torx Screwdriver (388.311) to secure the Compression Support (388.425) to the rod between the caudal and the cranial clamps.

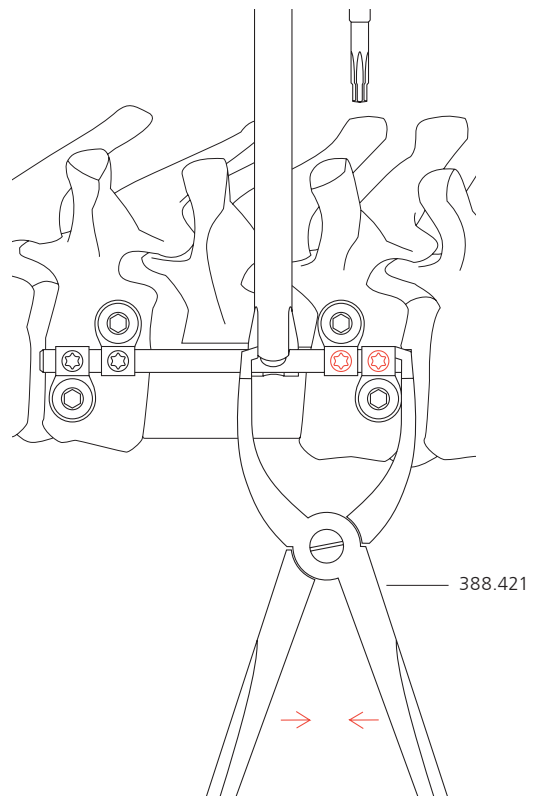


15

Compression

Loosen the set screws of both caudal single clamps. Leave the set screws of the cranial clamps tightened firmly.

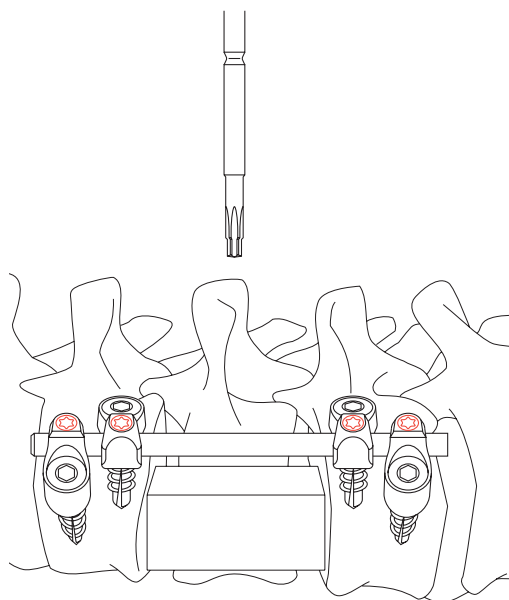
Mount the Compression Forceps (388.421) onto the caudal single clamp and on the compression support, compress and retighten the set screws on the caudal clamps.



16

Firmly tighten set screws

Firmly tighten all set screws and remove compression support if mounted.



X-RAYS

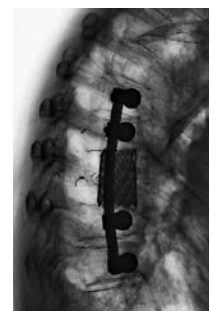
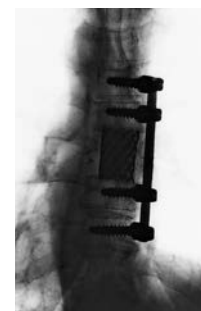
Fracture treatment

Burst fractures T12; partial ventral corporectomy of T12, interposition and alignment of bone graft, VentroFix double rod technique T11–L1.












Tumour treatment

Tumour metastasis T7; ventral corporectomy of T7, vertebral body replaced by titanium cage, VentroFix single rod technique T5/T6–T8/T9.



IMPLANTS

498.102	Rod Ø 6.0 mm, hard, length 50 mm, Pure Titanium	
498.103	Rod Ø 6.0 mm, hard, length 75 mm, Pure Titanium	
498.104	Rod Ø 6.0 mm, hard, length 100 mm, Pure Titanium	
498.105	Rod Ø 6.0 mm, hard, length 125 mm, Pure Titanium	
498.106	Rod Ø 6.0 mm, hard, length 150 mm, Pure Titanium	
498.160	Parallel Connector for USS Rods Ø 6.0/6.0 mm, Titanium Alloy (TAN)	
498.164	VentroFix Parallel Connector Ø 6.0/6.0 mm, Titanium Alloy (TAN)	
498.202	Set Screw T15, Titanium Alloy (TAN), dark blue	
498.260	VentroFix Single Clamp, Titanium Alloy (TAN)	
498.261	VentroFix Double Rod Clamp, right-cranial, Titanium Alloy (TAN)	
498.262	VentroFix Double Rod Clamp, left-cranial, Titanium Alloy (TAN)	
498.263	VentroFix Fracture Clamp, Titanium Alloy (TAN)	
498.780	Locking Screw Ø 7.5 mm, self-tapping, length 25 mm, Titanium Alloy (TAN), dark blue	
498.781	Locking Screw Ø 7.5 mm, self-tapping, length 30 mm, Titanium Alloy (TAN), dark blue	
498.782	Locking Screw Ø 7.5 mm, self-tapping, length 35 mm, Titanium Alloy (TAN), dark blue	

498.783	Locking Screw Ø 7.5 mm, self-tapping, length 40 mm, Titanium Alloy (TAN), dark blue
498.784	Locking Screw Ø 7.5 mm, self-tapping, length 45 mm, Titanium Alloy (TAN), dark blue
498.785	Locking Screw Ø 7.5 mm, self-tapping, length 50 mm, Titanium Alloy (TAN), dark blue
498.786	Locking Screw Ø 7.5 mm, self-tapping, length 55 mm, Titanium Alloy (TAN), dark blue

INSTRUMENTS

314.260	Screwdriver, hexagonal, large, Ø 3.5 mm, with Groove, length 300 mm	
324.078	Compression Forceps	
355.790	Depth Gauge for Locking Bolts, measuring range up to 90 mm	
388.300	Positioner, self-holding, for hexagonal socket Ø 3.5 mm	
388.311	Screwdriver T15, length 300 mm	
388.411	Spreader Forceps, parallel, length 450 mm	
388.421	Compression Forceps for VentroFix, length 335 mm	
388.425	Compression Support for USS Rods Ø 6.0 mm	
388.656	Pedicle Awl Ø 4.0 mm with Silicone Handle, length 255 mm, for Pedicle Screws Ø 5.0 to 7.0 mm	
388.870	Trial Rod Ø 6.0 mm, length 150 mm	
388.960	Bending Pliers with Rolls for USS Rods Ø 6.0 mm, length 300 mm	
389.221	Fixation Pin, for No. 389.223	
389.222	Awl Ø 4.9 mm, for Locking Screw Ø 7.5 mm	
389.223	Drill Sleeve for Awl Ø 4.9 mm	
389.224	Screwdriver, hexagonal, Ø 3.5 mm, length 375 mm, for USS	
394.075	Distractor for External Fixator for Distal Radius	
397.084	Distractor for Lateral Approach, for SynCage	

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