X-tenz™ Spinal Fusion Carrier

Design Rationale
Surgical Technique

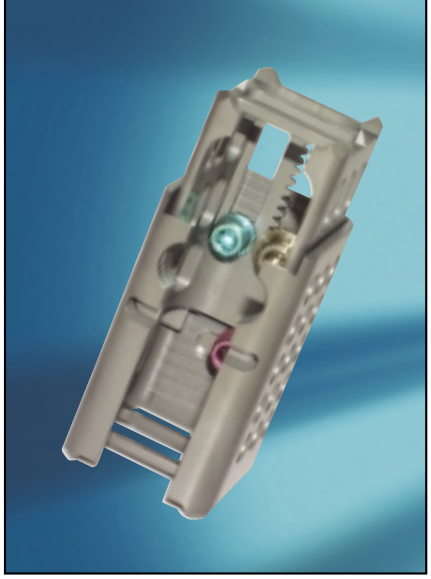
KÖNIGSEE IMPLANTATE UND INSTRUMENTE ZUR OSTEOSYNTHESE GmbH

X-tenz™, developed by Dr Böhm (Germany), is a telescopic Vertebral Body Replacement for the thoracolumbar spine.

Indicated for both Tumour and Trauma pathologies, it is designed to restore the load bearing capabilities of the anterior column and spinal balance.

X-tenz™ - a versatile system for the treatment of vertebral fractures and tumours, for one and two-level corpectomies in the thoracic and lumbar spine.

Designed to be filled in-situ, X-tenz™ offers the surgeon optimum utilisation of the bone graft, whilst restricting subsidence. Its unique rectangular design meets biomechanical requirements and enables it to be implanted endoscopically.



X-tenz™

Telescopic Vertebral Body Replacement

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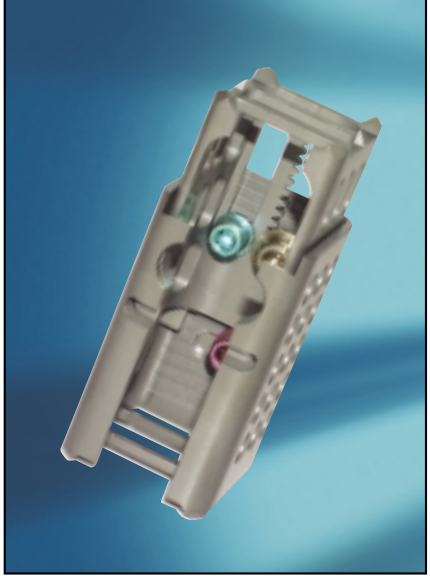
Surgical Technique



X-tenz™

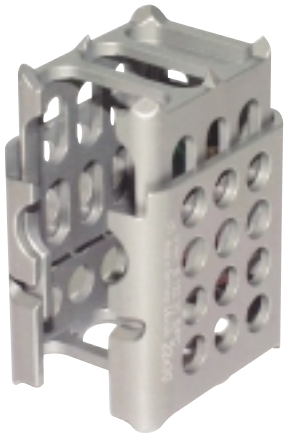
Telescopic Vertebral Body Replacement

Design Rationale

Unstable injuries of the spine may result from fracture of a vertebral body, vertebral tumours or post-traumatic deformities. In such cases, restoration of the load bearing capacity of the anterior column and of the spinal balance are indicated. Techniques that use strut grafts harvested from the patient's iliac crest can be associated with complications such as pain from the donor site or graft dislocation. An alternative for the surgical treatment of these patients is the use of a load bearing implant for complete or partial vertebral replacement.

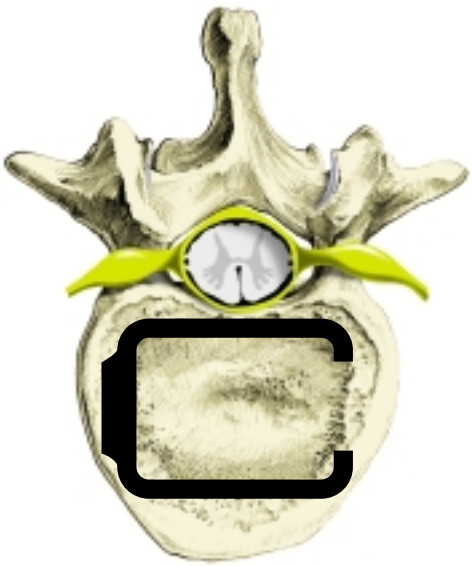
Dr Heinrich Böhm, Head of the Orthopaedic Department at the Klinikum Bad Berka (Thuringia) in Germany, developed X-tenz™ based on his wide clinical experience with spinal pathologies related to trauma and tumour. The main objective for the development of X-tenz™ was to design a versatile system for the treatment of vertebral fractures at a wide range of spinal levels. In Dr Böhm's practice, both open and minimal access approaches are regularly used. Therefore the X-tenz™ implants and instruments have been designed to suit both approaches.

Open Design



X-tenz™ is open on one side and has extensive holes and windows on all other sides. This design has been carefully optimised to achieve a fine balance between open design and mechanical strength. Whenever bone fusion is required, an open implant reduces the risk of vascular obstruction and facilitates contact between the graft and adjacent endplates. Furthermore, the open design allows for complete filling of the already extended cage with graft. If required by the surgeon, the position and height can be adjusted and verified by fluoroscopy. The position is not restricted by bone graft or cured cement, as it is filled after final positioning has taken place.

Rectangular Shape

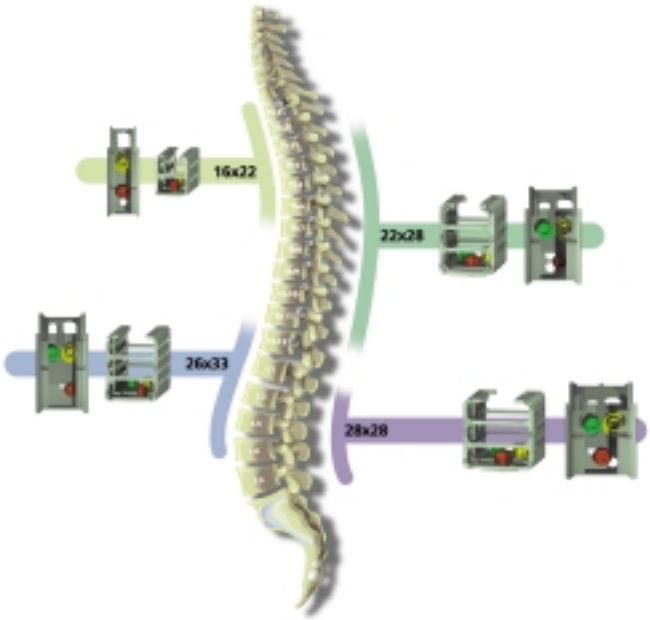


The mechanical strength of X-tenz™ has been extensively tested in static and dynamic tests[1]. One area of particular clinical importance is the interface between the vertebral endplates and the implant. A fine balance is required between mechanical support offered by the endplates, the area of the endplate available for fusion (ie. not covered by the implant) and the need to keep a safe distance from delicate structures. The straight edges of the rectangular shape provide an adequate distance from the implant to the dura posteriorly, as well as from any blood vessels anteriorly.

To withstand any subsidence that may occur, the corners of X-tenz™ use the dense bony ring of the apophysis for support. This does not only increase resistance against subsidence but also provides excellent stability of the construct against bending in both planes, as shown in biomechanical in-vitro testing[2].

Extension / Locking Mechanism

The extension mechanism of X-tenz™ is extremely simple and intuitive. A gear shaft is used to increase height thereby exerting distraction forces onto the anterior column of the spine. Repeated adjustment of height is straightforward and therefore allows for accurate restoration of the spinal curvature. The extension mechanism is securely locked by three separate screws. The screw location and sequence of insertion is defined by colour coding - based on a traffic light sequence (Green, Yellow, Red).



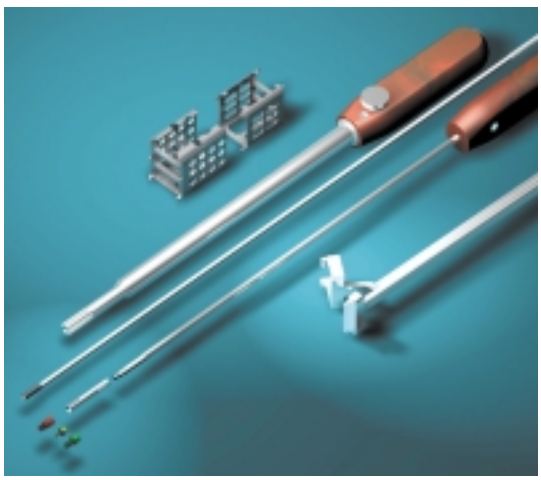
Comprehensive Range of Sizes

The comprehensive range of X-tenz™ provides implant sizes suitable for vertebral body replacement in the high thoracic spine through to L4. The open side faces laterally in accordance with the approach to the thoracic and lumbar spine. The small size, 16x22mm, is not only suitable for the high thoracic spine but also for partial vertebrectomies in the low thoracic and the lumbar spine to L4.

Instruments

The following instruments are required for implanting X-tenz™:

- *Holder: Holding and inserting the implant into the defect.*
- *Guide Rod and Cannulated Extender: Extending and retracting.*
- *Self-retaining screwdriver (with hexagon head): Insertion and tightening of the locking screws.*



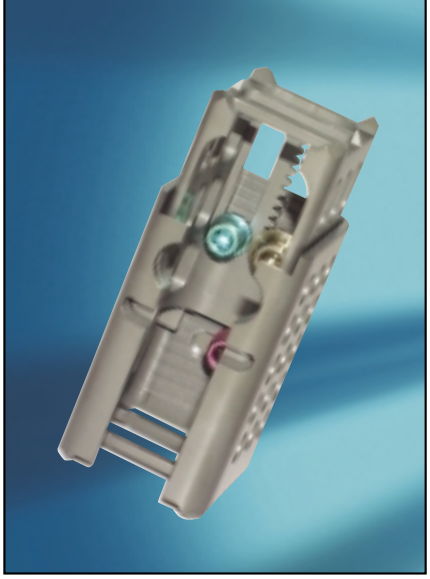
Note: *the implants section on page 16, - details the extension options available with each implant size.*

Indications

X-tenz™ is indicated for use in the thoracic and lumbar spine (ie. T1 to L4) to replace a fully or partly resected, diseased vertebral body for both tumour and trauma pathologies. Following anterior decompression of the spinal cord and neural tissues, X-tenz™ is used to replace a collapsed vertebral body, thus restoring the height and biomechanical integrity of the anterior spinal column. The material of the X-tenz™ System is titanium alloy.

Contraindications

Advanced age and poor general condition must be considered on a case by case basis with the anaesthesiological team. Active infection is a contraindication.



X-tenz™

Telescopic Vertebral Body replacement

Surgical Technique

The X-tenz™ Surgical Technique describes in full the open procedure for corpectomy at level T8. Further procedures cover the variations required for operating at thoracolumbar and lower lumbar levels. The use of X-tenz™ with endoscopic surgical techniques is also described.

Surgical Approach:
Conventional Open Thoracotomy:

Typical region: T3 to T10
Example: Vertebral metastasis T8 with anterior cord compression.

1 *Patient positioning*

The patient is positioned in the left lateral position on an adjustable table (figure 1.)

Figure 1. Left lateral positioning of the patient.

2 Approach to the mid-thoracic spine

Figure 2a. Skin incision from the right in the intercostal space 6/7

The skin is incised from the posterior axillary line along the 6th rib in the direction of the sternum, to give an incision of about 12cm in length.

The muscles of the chest wall are dissected or spread. In the course of the 6th rib the thorax is opened in the intercostal space 6/7, followed by an osteotomy of the 7th rib near the sternum and a rib retractor is introduced (figure 2a).

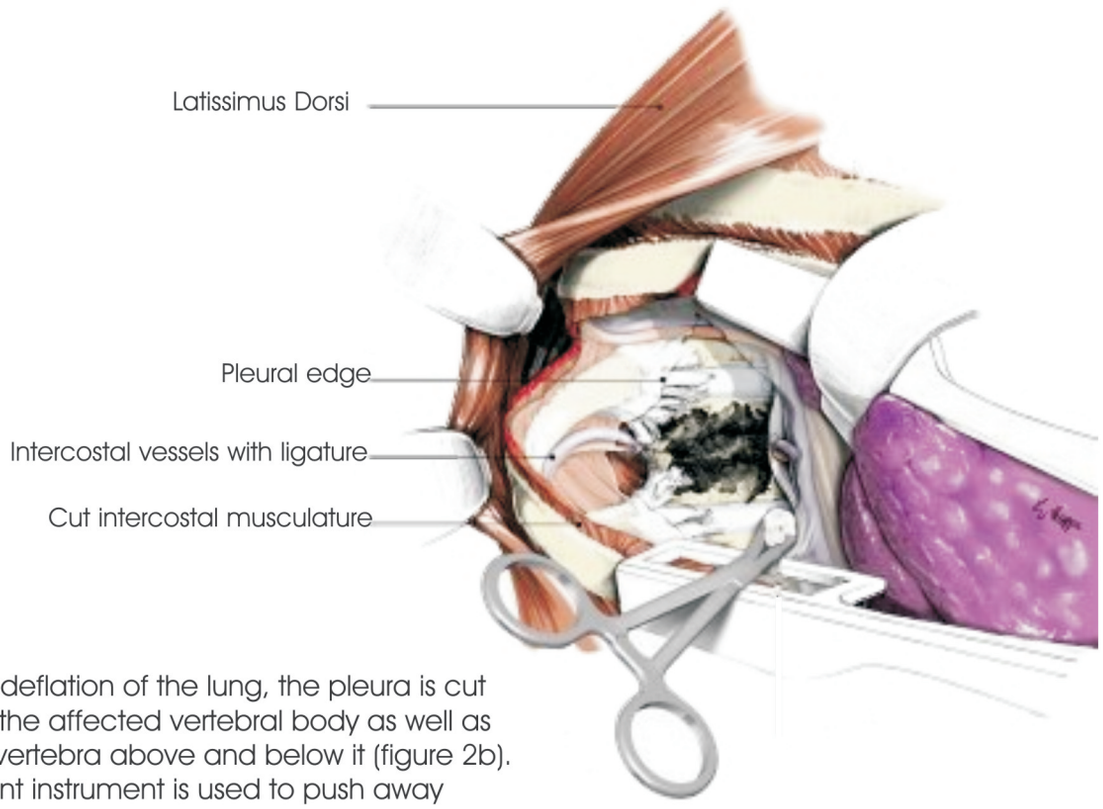
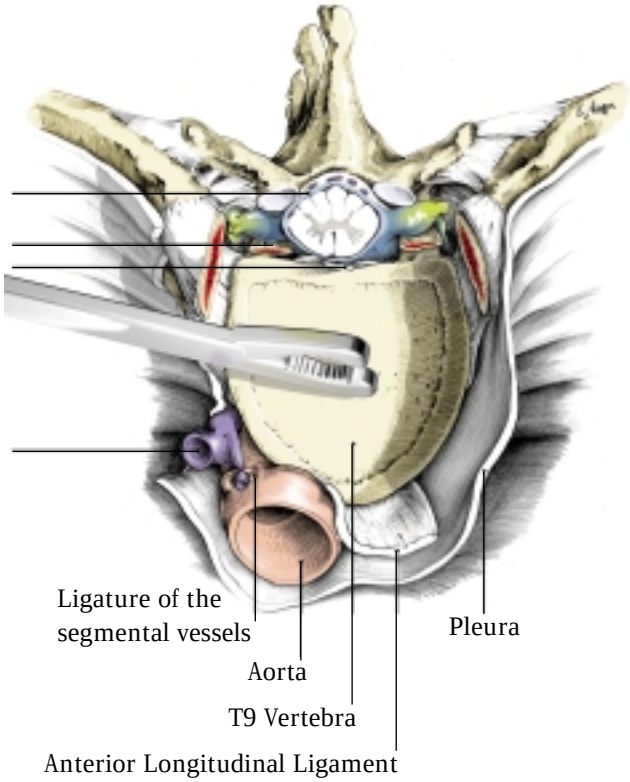


Figure 2b. Surgical approach with vertebra exposed.

After deflation of the lung, the pleura is cut over the affected vertebral body as well as one vertebra above and below it (figure 2b). A blunt instrument is used to push away the pleura. The segmental vessels of the affected vertebra are ligated.

3 *Discectomy and Corpectomy*



The adjoining intervertebral discs are cleared dorsally up to the posterior longitudinal ligament. The discectomy is followed by excision of the head of the rib if required. The intralesional resection of the vertebral body should reach to the opposite side. Any parts of the posterior wall, which may compress the dura, have to be removed. The anatomy after dissection is shown both cranially (figure 3a) and lateraly (figure 3b).

Figure 3a. Cranial view after completed dissection.

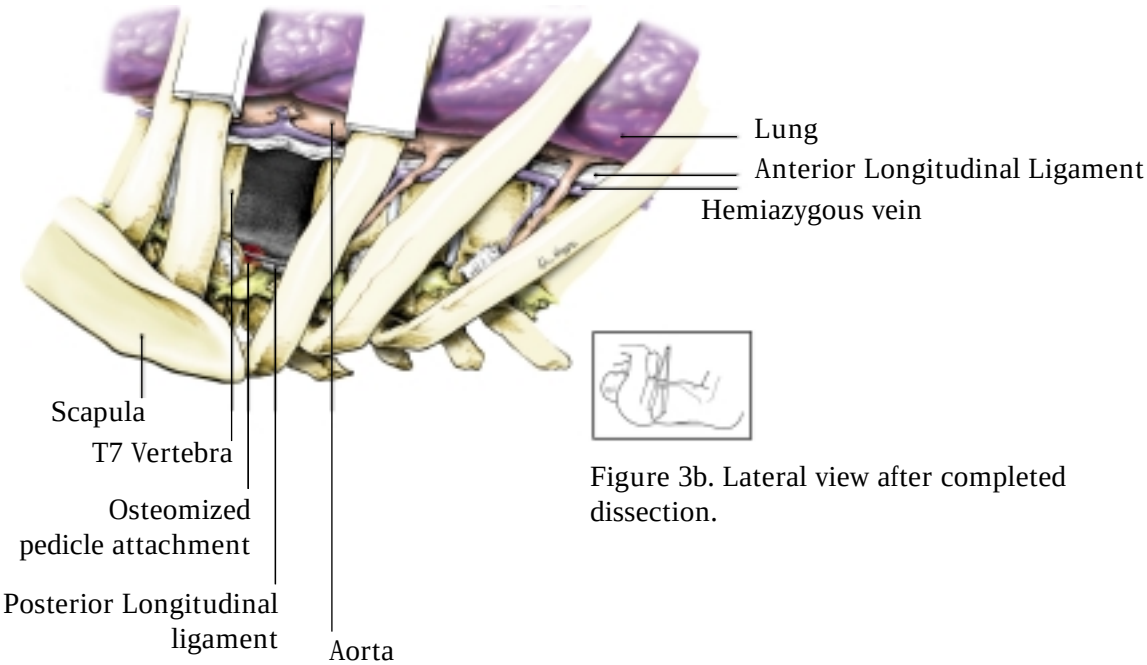


Figure 3b. Lateral view after completed dissection.

4 *Selection of the appropriate implant size*

Ideally the vertebral body endplate should be covered by the rectangular cross-section of the implant, leaving a front and rear protection zone of 4-5mm (figure 4). Initially the Implant Holder, without the implant, may be used to gauge the correct implant size in the anterior-posterior orientation, as the width of the holder equals the A-P length of the implant.

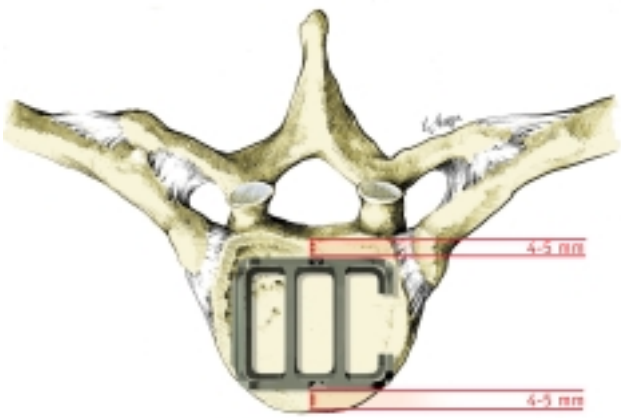


Figure 4. Selection of suitable sizes

Figure 5a. Attachment of implant holder.

5 *Preparation of the implant*

The correct size of Implant Holder is attached so that the arrow on the implant points in the same direction as the arrow on the instrument (figure 5a). The arrow indicates the extension direction and therefore must point cranially. To verify correct assembly, the angled spikes of the inner implant must project cranially.

The Guide Rod is inserted into the smaller threaded hole, which is at the cranial end of the implant.

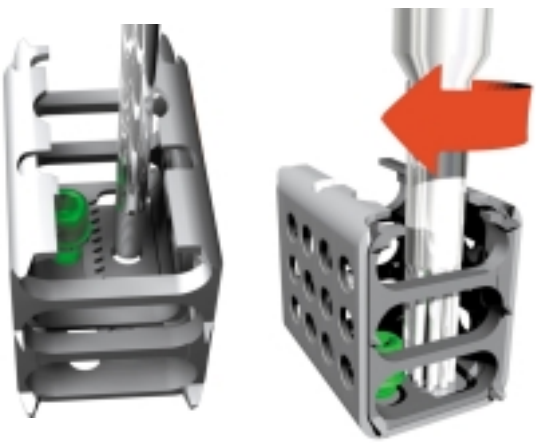


Figure 5b. Implant with green screw, guide rod and cannulated extender.

A green screw is inserted into the larger threaded hole, also at the cranial end of the implant, but is not tightened.

Note: For size 16 x 22mm this step is omitted since no green screw is used.

The Cannulated Extender is placed over the Guide Rod and engaged firmly with the teeth of the inner cage. The extension mechanism is then checked by a trial turn in one direction to extend it and by a turn in the opposite direction to retract it again (figure 5b).

6 Implant placement

The implant is placed into the corpectomy defect with the arrows pointing cranially (figure 6). The correct implant position is parallel to the dura. The holder can be used as an indicator for the correct orientation of the side and front face of the implant. The implant is gently extended to grip the bone and the holder is then detached.

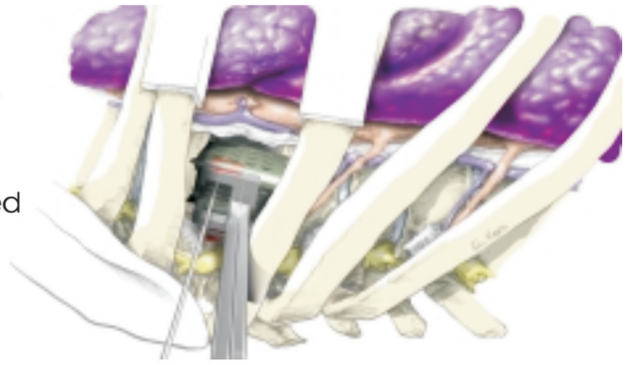


Figure 6. Placement of the implant into the defect.

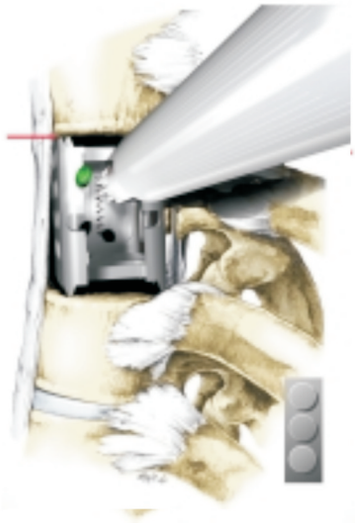


Figure 7a. Implant in-situ prior to the extension manoeuvre.

7 Telescopic extension and locking

Once the implant has been correctly positioned, it can be extended to the desired height by rotating the Cannulated Extender (figure 7a).

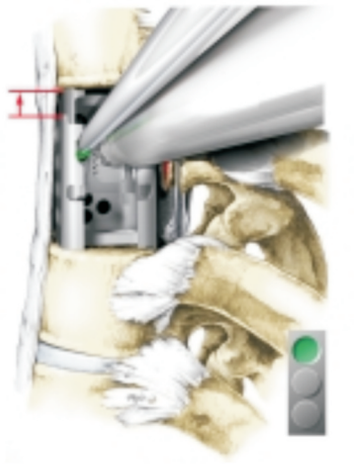


Figure 7a. Locking at desired cage Height with the green screw.

Once the implant is at the desired height, the green screw is tightened securely with the screwdriver while the Cannulated Extender is held firmly (figure 7b).

Note: For the implant size 16 x 22mm the red screw is inserted and tightened securely.

The Cannulated Extender and the Guide Rod can now be removed. If desired, position and height can be verified by fluoroscopy in two planes.

If adjustment is necessary, the Guide Rod and the Cannulated Extender are re-attached, the green locking screw is loosened and the height and/or position corrected and then the green locking screw tightened again.

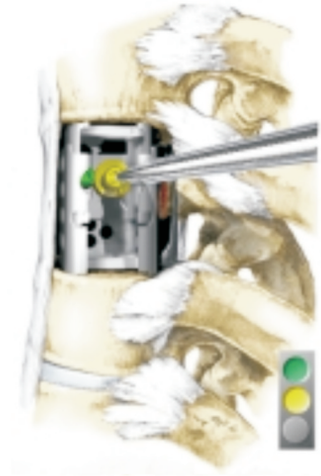


Figure 7c. Supplemented locking with the yellow screw.

Once the position is correct, the Cannulated Extender is removed and the Guide Rod unscrewed. A yellow screw is then inserted into the threaded hole previously occupied by the Guide Rod and is securely tightened (figure 7c).

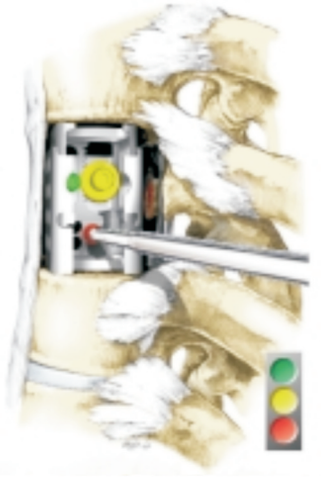


Figure 7d. Final securing with the red screw.

Finally a red screw is inserted into the threaded hole closest to the caudal edge of the inner part of the implant and is securely tightened (figure 7d). If this hole is partially occluded the next hole caudally is selected.

8 Filling the implant

With benign tumours and trauma, the bony can the implant filled with cancellous autograft. In the case of malignant tumours, the implant can be filled with PMMA using a cement gun.

9 Wound closure

The prevertebral pleura is re-attached if desired, any remnant tissue is to be carefully removed before the thorax is lavaged. The thoracotomy is closed and a drain inserted.

Surgical Approach: Open Thoracolumbar Procedure

Typical region: T11 to L3
Example: Burst fracture T12

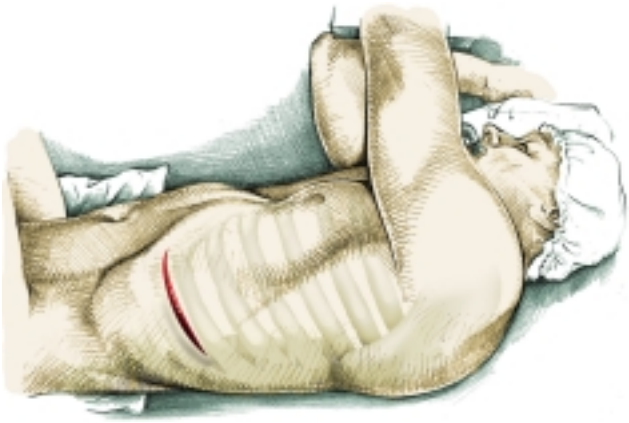


Figure 1. Skin incision from the left in the intercostal space 10/11

1 *Patient positioning*

The preferred access is from the left side, through the intercostal space 10/11 (figure 1).

2 *Preparation of the diaphragm*

In many cases it will be sufficient to cut a notch into the diaphragm close to the spine and then to push away the diaphragm in a caudal direction. In all other cases the diaphragm should be cut, leaving a 1.5cm wide portion near the spine, which can be re-attached at the end of the operation.

FOR ALL REMAINING STEPS OF THE PROCEDURE PLEASE REFER TO THE OPEN THORACOTOMY TECHNIQUE.

Surgical Approach: Endoscopically Assisted Thoracic Procedure

Typical region: T3 to T10
Example: Tumour T8

1 *Patient positioning*

The patient should be positioned in a correct lateral position on the adjustable table. For this procedure single-lung anaesthesia may be chosen. The operation may be carried out under fluoroscopic control, if necessary.

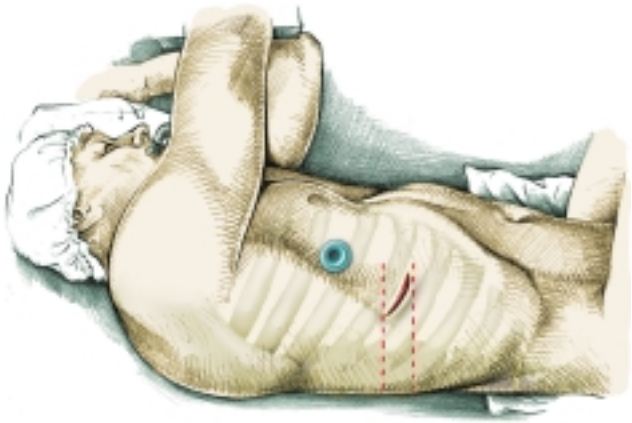


Figure 1. Access to thoracic corporectomy monitored by endoscopy.

2 *Approach to the mid-thoracic spine*

The precise level of the affected vertebra is marked on the skin, at the level of the anterior axillary line. A 3cm long skin incision is made in the intercostal space nearest to this mark (figure 1). The scissors can be used as blunt dissectors, allowing the surgeon to open the chest wall and the intercostal muscles. The pleura is also opened at this stage.

The deflation of the lung is followed by the introduction of the retractor to maintain access. Note that the direction of retraction is performed parallel to the ribs, rather than retracting the ribs. Temporarily, it may be necessary to further spread open the ribs in a perpendicular direction in order to facilitate the cage insertion.

3 *Discectomy and Corpectomy*

Depending on the operated level, a thoracic port is introduced two intercostal spaces further cranially or caudally. Under thoracoscopic control, the lung can be pushed further away for exposure of the desired section of the spine.

The pleura over the affected vertebral body and both adjoining vertebrae is dissected, followed by coagulation of the segmental vessel at T8 or ligation using a Knot Pusher with an outside-in technique.

Note: To facilitate endoscopic implant insertion, the Cannulated Extender locked onto the Guide Rod may be utilised, rather than the Holder. For insertion of the drain, the thoracic port aperture is to be used.

FOR ALL REMAINING STEPS OF THE PROCEDURE PLEASE REFER TO THE OPEN THORACOTOMY TECHNIQUE.

Surgical Approach: Combined Thoracic Approach In Prone Position

Example: Tumour T6
Typical region: T3-T10

1 Patient positioning

This patient position allows a combined approach for thoracoscopic corporectomy and dorsal transpedicular instrumentation without repositioning or redraping.

For the mid and upper thorax, it is better to operate from the right side, whilst for thoracolumbar levels the left side is preferred.

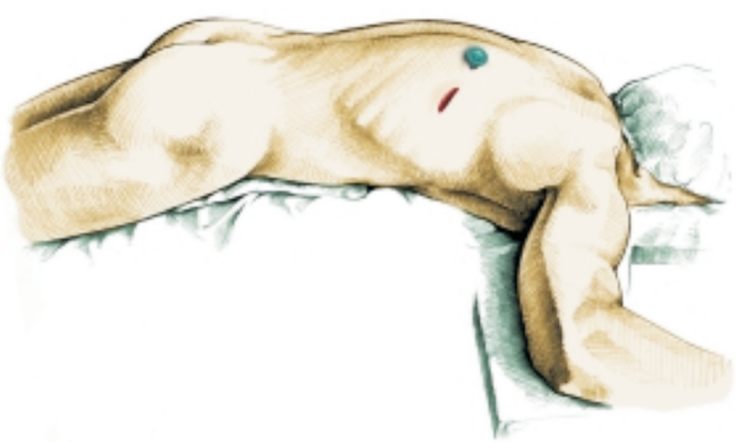


Figure 1. Minimal invasive thoracic approach in prone position

2 Approach to the mid-thoracic spine

The exact level of the affected vertebra is marked near the posterior clavicular line, if necessary under fluoroscopy. The skin incision is made 3cm in length at the appropriate intercostal space (figure 1).

The thoracic wall and the intercostal musculature can be spread open using scissors, which opens the parietal pleura at the same time. The lung is deflated, followed by the introduction of the thoracic wall retractor parallel to the course of the ribs (ie. not pushing the ribs apart). As a temporary measure, it may be necessary to further spread open the ribs in a perpendicular direction in order to facilitate the cage insertion.

After checking the deflation of the lung, a thoracic port for the thoracoscope is inserted in the same intercostal space approximately 4cm further proximally.

Under thoroscopic control, a deployable Lung Retractor is inserted (no single-lung anaesthesia necessary). The pleura is dissected at the level of the head of the rib of the affected vertebra and at both adjoining vertebral bodies. The pleura is then pushed away bluntly and the Lung Retractor is re-positioned between pleura and vertebral body to protect the aorta. The segmental vessel can either be ligated using a Knot Pusher or coagulated.

FOR ALL REMAINING STEPS OF THE PROCEDURE PLEASE REFER TO THE OPEN THORACOTOMY TECHNIQUE.

Surgical Approach: Open Lumbar Procedure

Typical region: L1-L4
Example: L3 fracture

1 Patient positioning

The preferred access is from the left side (figure 1).

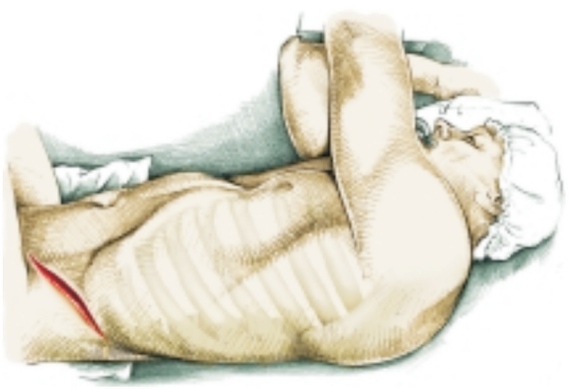


Figure 1. Right lateral positioning and skin incision

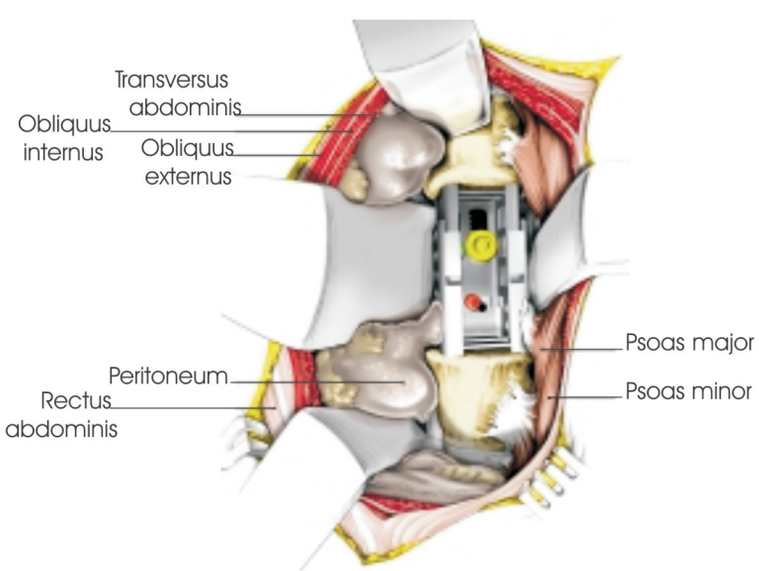


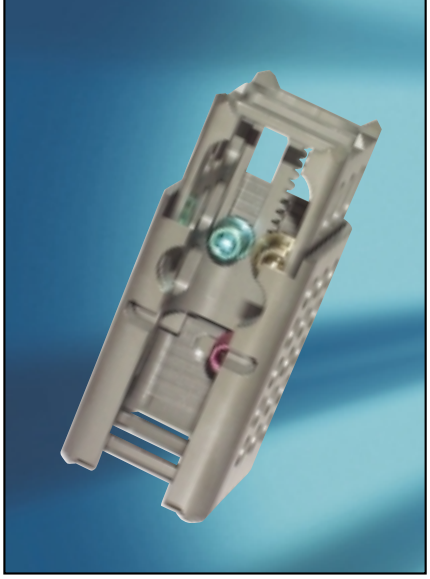
Figure 2. Correctly positioned implant after corporectomy of L3 in lateral view.

2 Approach to the Lumbar Spine

The patient is positioned in an exact right lateral position on an adjustable table. The skin is incised in a oblique direction from the abdomen towards the 10th rib. The musculus externus is spread parallel to the muscle fibres, whereas the musculi internus and transversus are dissected transversally. The peritoneum can be pushed ventro-medially with a blunt instrument. Now, the psoas muscle is exposed and the lumbar spine at its ventral edge.

The segmental vessels of the affected vertebra and one level above and below are ligated. The entire psoas muscle is then pushed off the lateral side of the vertebra in a dorsal direction. This is followed by resection of the vertebral discs adjacent to the affected vertebra and of the vertebral body itself. This is highlighted in figure 2.

FOR ALL REMAINING STEPS OF THE PROCEDURE PLEASE REFER TO THE OPEN THORACOTOMY TECHNIQUE.



X-tenz™

Telescopic Vertebral Body replacement

Implants & Instruments

Implants

Product code	*A/P*	*M/L*	*Height*	*Extension*	*Max Height*	
S.116.25	*16mm*	*20mm*	*25mm*	*8mm*	*33mm*	*16x20x25 (8)*
S.116.30	*16mm*	*20mm*	*30mm*	*10mm*	*40mm*	*16x20x30 (10)*
S.116.35	*16mm*	*20mm*	*35mm*	*10mm*	*45mm*	*16x20x35 (10)*
S.116.40	*16mm*	*20mm*	*40mm*	*15mm*	*55mm*	*16x20x40 (15)*
S.122.22	*22mm*	*28mm*	*22mm*	*5mm*	*27mm*	*22x28x22 (5)*
S.122.25	*22mm*	*28mm*	*25mm*	*8mm*	*33mm*	*22x28x25 (8)*
S.122.30	*22mm*	*28mm*	*30mm*	*10mm*	*40mm*	*22x28x30 (10)*
S.122.40	*22mm*	*28mm*	*40mm*	*15mm*	*55mm*	*22x28x40 (15)*
S.122.50	*22mm*	*28mm*	*50mm*	*15mm*	*65mm*	*22x28x50 (15)*
S.122.60	*22mm*	*28mm*	*60mm*	*15mm*	*75mm*	*22x28x60 (15)*
S.126.25	*26mm*	*33mm*	*25mm*	*8mm*	*33mm*	*26x33x25 (8)*
S.126.30	*26mm*	*33mm*	*30mm*	*10mm*	*40mm*	*26x33x30 (10)*
S.126.35	*26mm*	*33mm*	*35mm*	*10mm*	*45mm*	*26x33x35 (10)*
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S.126.50	*26mm*	*33mm*	*50mm*	*15mm*	*65mm*	*26x33x50 (15)*
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S.128.22	*28mm*	*28mm*	*22mm*	*5mm*	*27mm*	*28x28x22 (5)*
S.128.25	*28mm*	*28mm*	*25mm*	*8mm*	*33mm*	*28x28x25 (8)*
S.128.30	*28mm*	*28mm*	*30mm*	*10mm*	*40mm*	*28x28x30 (10)*
S.128.40	*28mm*	*28mm*	*40mm*	*15mm*	*55mm*	*28x28x40 (15)*
S.128.50	*28mm*	*28mm*	*50mm*	*15mm*	*65mm*	*28x28x50 (15)*
S.128.60	*28mm*	*28mm*	*60mm*	*15mm*	*75mm*	*28x28x60 (15)*
S.220.red	*Red Screw*					
S.210.yellow	*Yellow Screw*					
S.205.green	*Green Screw*					

Instruments

Description	
S.253.16	*X-tenz™ holder Size 1*
S.253.22	*X-tenz™ holder Size 2*
S.253.26	*X-tenz™ holder Size 3*
S.253.28	*X-tenz™ holder Size 4*
S.251.25	*Self retaining screwdriver 2.5mm*
S.252.30	*Guide Rod*
S.250.06	*Cannulated Extender*
19.271.00 Implant Case & 19.270.00 Instrument Case	

KÖNIGSEE IMPLANTATE UND INSTRUMENTE ZUR OSTEOSYNTHESE GmbH

Zertifiziert nach EG Richtlinie 93/42/EWG
DIN ISO 9001 / DIN EN ISO 13485

CE 1275

Patent-Nr.: PCTW099/38460

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Revised:01/2008
Cat No: D.Xtenz0605

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