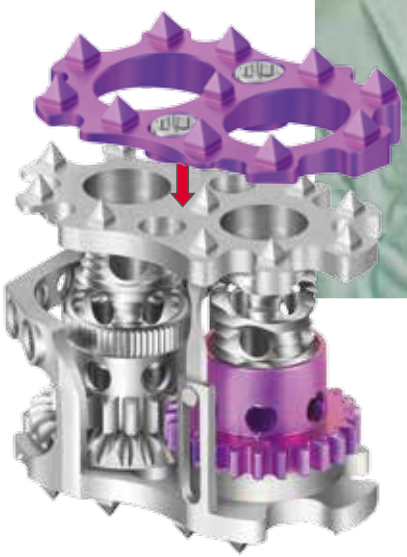
Surgical Technique and Instrumentation



Surgical Technique and Instrumentation

mediExpand® TL

THORACIC / LUMBAR

Vertebral body replacement in case of tumours on the thoracic and lumbar spine

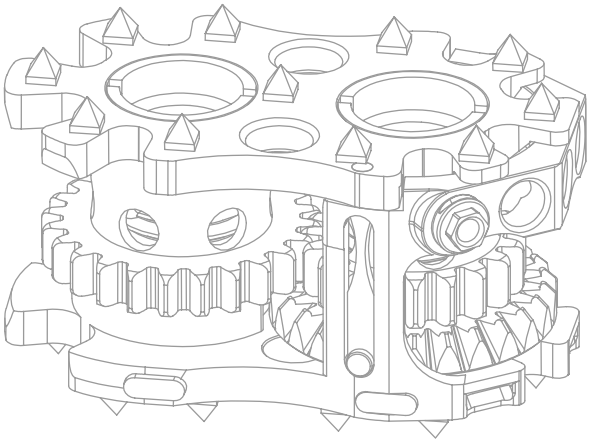
medicon®

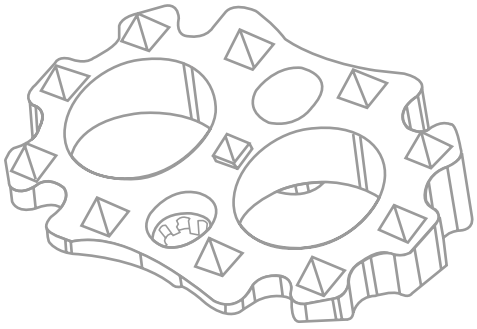
Index

Only the latest revision of the Surgical technique and instrument preparation for use applies.
Due to constant technical development the contents of these MEDICON surgical technique and instrument preparation for use are updated regularly.

These instructions for the surgical technique do not suffice for the instant application of the vertebral replacement and its instruments.
The “mediExpand®” -TL may be used only by surgeons with sufficient experience in spinal operations who have received an appropriate introduction to the system by Medicon.

Comprehensive information on application, preparation, maintenance and care can be found in the operating instructions GA588250.





Not all products illustrated in this documentation are available for sale in all countries.
Please contact your local distributor for more information.

References

General notes

The implants are delivered in non-sterile state and must therefore be cleaned, disinfected and sterilised before the unique application and before each sterile provision in the surgical area. Please observe the following instructions. These will ensure accurate and reliable functioning of the product.

Intended Use / Indication

The expandable vertebral replacement "mediExpand®" -TL is used for stable, load-bearing reconstruction of the natural height of the removed lumbar and thoracic vertebra(e). For dorsal stabilisation, the vertebral replacement must be inserted using a "pedicle screw system".
The vertebral replacement may be implanted only in hospitals and clinical practices by surgeons with sufficient experience in spinal operations (neurosurgery, orthopaedics, accident surgery, etc.) who have received an induction into the system.
The implants are single-use products and may be used only together with the standard components.

Contraindications

The expandable vertebral replacement "mediExpand®" -TL may not be used in cases of:

– Severe osteoporosis
– Regions of vertebrae with highly tumorous lesions
– Anatomically unsuitable parts of the spine
– Other skeletal sections for which it is not intended
– Patients who are unable to comply with the instructions for postoperative care. Reasons are e.g. patients with psychological, mental or neurological problems
– Patients in unstable physical and / or mental condition
– Patients with inadequate or low-quality bone tissue, with perfusion problems or latent infections
– Proven allergy to titanium
– Material hypersensitivity, i.e. reaction of the patient to foreign bodies. Here appropriate tests are mandatory before implantation (even in case of mere suspicion!)
– Acute infections

Possible adverse events and complications

Possible undesired effects and complications related to the "mediExpand®" -TL expandable vertebral replacement include:

– Failure of the implant due to loosening in the bone
– Failure of the implant due to insufficient bone fusion or insufficient reinforcement of the area operated on and thus absence of mechanically stable conditions
– In the event of a lack of cooperation on the part of the patient or where cooperation cannot possibly be obtained, pseudarthrosis formation and/or implant failure and dislocation may occur
– Loosened implants can lead to secondary irritations or injury to adjacent anatomical structures such as the spinal cord, nerve roots, vertebral arteries or oesophagus
– Incorrect implantation of the expandable vertebral body replacement may lead to vertebral fractures, damage or injury to the spinal cord, nerve root damage, or even to paraplegia
– Selection of the wrong size of the expandable vertebral replacement can lead to secondary disorders
– Material hypersensitivity of the patient in the form of allergic reactions
– Discomfort, pain, abnormal sensations due to the implant
– Breaking, bending, migration, loosening of the implant and/or further surgical intervention to remove the system
– Early or late infections
– Neurological damage resulting from the surgical trauma or the presence of the implant. Neurological symptoms, including bowel and/or bladder dysfunctions, impotence, retrograde ejaculation and paraesthesia, paraplegia, quadriplegia.
– Injuries to the dura mater occurring during the operation may require further surgical intervention to restore the dura, and may lead to continued leakage of cerebrospinal fluid or a fistula, and under certain circumstances even to meningitis
– Vascular damage, above all in the region of the operative access, as a result of surgical trauma. Vascular damage may lead to life-threatening or fatal haemorrhaging. Incorrectly positioned implants in the vicinity of large blood vessels may erode these vessels and lead to life-threatening haemorrhaging in the late postoperative period
– Degenerative changes or instability in segments that are adjacent to a stiffened spine

References

When the “mediExpand®” -TL expandable vertebral replacement remains in the body after full recovery, the following complications may occur either individually or collectively:

– Corrosion with localized tissue reaction or pain

– Changes in the position of the implant with resulting injuries

– Risk of additional injuries due to postoperative trauma

– Bending, loosening and/or fracture, making follow-up operations more difficult

– Pain, discomfort or non-physiological sensations due to the presence of the product

– A possibly increased risk of infection

– Bone loss caused by stress shielding

When selecting patients, the following factors should be observed that promote possible adverse events and complications:

Patient weight:
Excess weight or obesity of a patient can increase the load on the implant in such a way that failure is more likely.

Occupation or activity of the patient:
Heavy lifting, muscle strain, body rotation, repeated bending, stooping, running or manual labour should be avoided in private or occupational activities until to the bones have healed completely. Even after complete healing, the patient may not be able to successfully perform the activities listed above any longer.

Senility, mental illness, alcoholism or drug abuse:
These circumstances may contribute to the patient ignoring certain restrictions or precautions that the implant calls for. This can lead to failure of the implant or to other complications.

Sensitivity to foreign bodies:
Preoperative testing may not entirely exclude hypersensitivity or allergy. Such complications can occur even if the implant has already been in the body for some time.

Smoking:
In smokers, a higher rate of pseudarthroses was found after surgical procedures where bone implants were used. Smoking-induced progressive degeneration of adjacent segments can lead to later clinical failure (intermittent pain), even if initially successful stiffening of the bone has occurred and clinical improvement has been demonstrated.

In addition to the undesirable effects and complications already mentioned, the surgical procedure can lead to other problems such as nerve damage, infections, pain etc. that cannot be attributed to the implant.

Introduction

mediExpand® TL
THORACIC / LUMBAR

Vertebral body replacement in case of tumours on the thoracic and lumbar spine

Operating instructions

The expandable vertebral replacement “mediExpand®”-TL is used for stable, load-bearing reconstruction of the natural height of the removed lumbar spine and thoracic spine vertebrae.

The implantation of the vertebral replacement “mediExpand®” -TL must always be secured with an additional dorsal stabilisation (reinforcement of the spinal area with an additional stabilisation system).

The vertebral replacement may be implanted only in hospitals and clinical practices by surgeons with sufficient experience in spinal operations (neurosurgery, orthopaedics, traumatology) who have received an induction into the system.

The implants are single-use products and may be used only together with the standard components.

Product Information

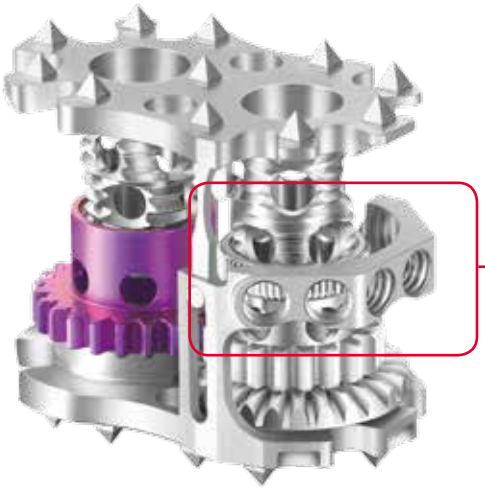
2.1 Structure of the Vertebral Body Replacement

The special design of the vertebral replacement is based on a two-column architecture. The two columns threaded in opposite directions allow (depending on the selected implant size) a variable expansion that can be adjusted finely and continuously from 55 to 66% of the original size. The very large contact surfaces of the “mediExpand®” -TL prevent sinking in into the base and top plate of the neighbouring vertebral bodies and ensure tight anchoring with optimal dislocation protection.

To compensate for the anatomical circumstances and the individual medical condition, the surgeon can select from various sizes.

The sizes differ regarding the dimensions of the serrated end plates of the “mediExpand®” -TL, and also regarding the minimum and maximum heights.

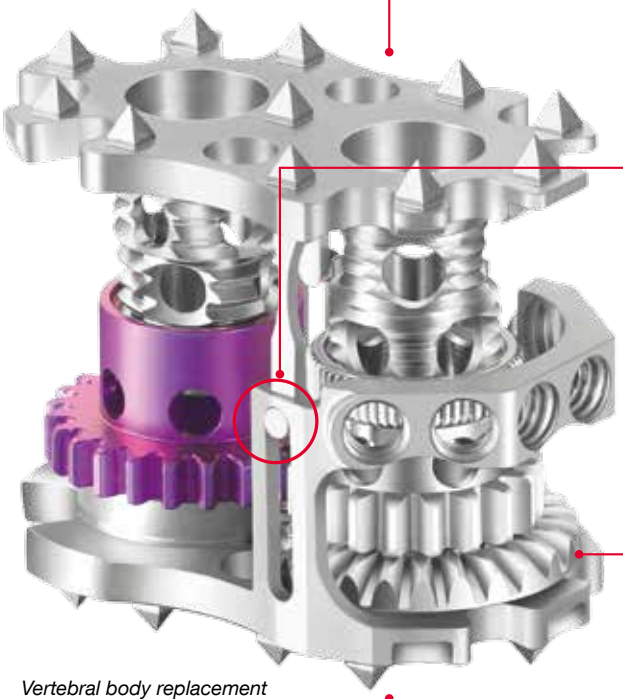
The special construction of the vertebral body replacement allows special angular connections with the insertion instrument that allow implantation using the dorsolateral and lateral approaches.



- For dorsolateral approach / TLIF technique
- For lateral approach
- For dorsolateral approach / TLIF technique

Connector component and its connection possibilities

2.1 Structure of the Vertebral Body Replacement



Vertebral body replacement "mediExpand®" -TL and its key components

Serrated end plate

- cranial

Expansion limiter

- limits the maximum expansion height

Angled connector component

- for special angular connection with the insertion instrument
- with threaded hole for locking screw

Bevel wheel

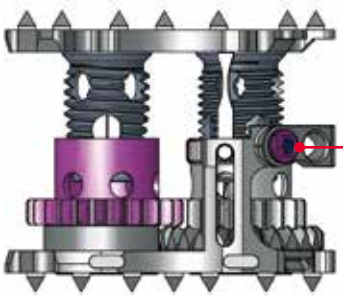
- for expansion
- the bevel pinion is located on the insertion instrument

Serrated end plate

- caudal
- with chuck for retention lug

2.2 Locking screw

The locking screw 58.82.61/ 62/ 63/ 64 + 58.82.69/ 70 is used to secure the expansion height.



Hexagon head

- with internal thread for screwdriver

Product Information

2.3 Spreader

Spreader for holding, expanding and securing the vertebral body replacement.
The two retention rods can be pulled out.

Spreader and its key components

View 58.82.67 from front and side

Expansion rod

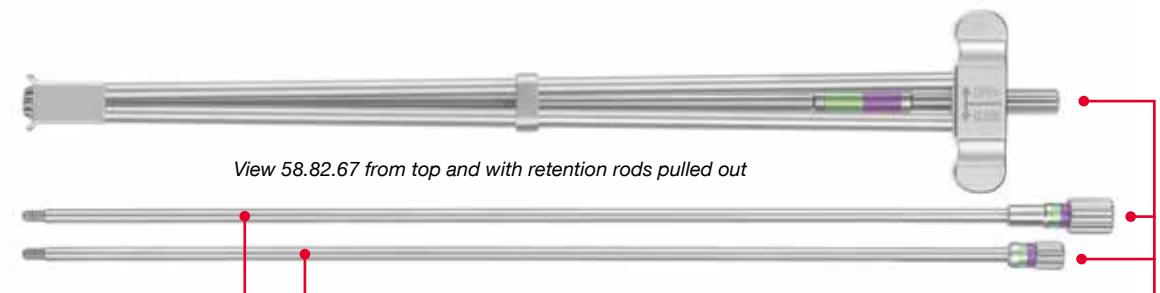
- with bevel pinion for expansion

Retention lug

- for stable anchoring on the caudal end plate

Handle plate

- for secure hold



View 58.82.67 from top and with retention rods pulled out

Retention rods

- for secure connection with the implant

Knurled heads

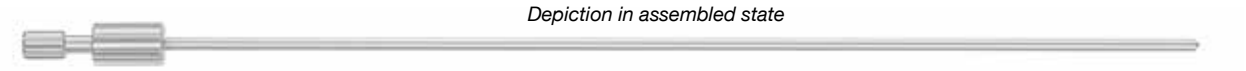
- for manual rotation
- with hexagon socket for rotating using the Torx wrench 58.82.68

The depictions of the instruments are not to scale and serve for illustration only.

2.4 Screwdriver for Locking screw

The screwdriver is used for holding and screwing in the locking screw into the corresponding threaded hole of the connector component on the vertebral body replacement.

Depiction in assembled state



Screwdriver sleeve

- with hexagon socket
- for screwing in the locking screw

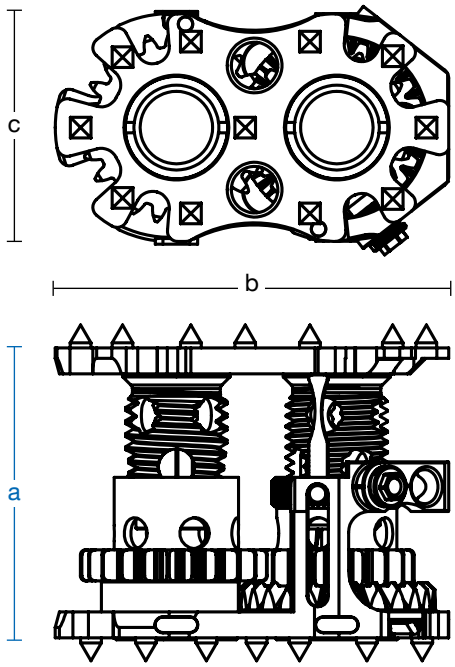
Threaded rod

- for secure holding of the locking screw

The depictions of the instruments are not to scale and serve for illustration only.

Implants

Vertebral body replacement
“mediExpand®” -TL



		a	b	c
58.82.54		15 – 24 mm	24 mm	16 mm
58.82.55		15 – 24 mm	30 mm	18 mm
58.82.50		18 – 28 mm	24 mm	16 mm
58.82.51		18 – 28 mm	28 mm	18 mm
58.82.52		18 – 28 mm	35 mm	22 mm
58.82.53		18 – 28 mm	38 mm	22 mm
58.82.58		22 – 34 mm	35 mm	22 mm
58.82.59		22 – 34 mm	38 mm	22 mm
58.82.56		30 – 50 mm	35 mm	22 mm
58.82.57		30 – 50 mm	38 mm	22 mm

The depictions of the instruments are not to scale and serve for illustration only.

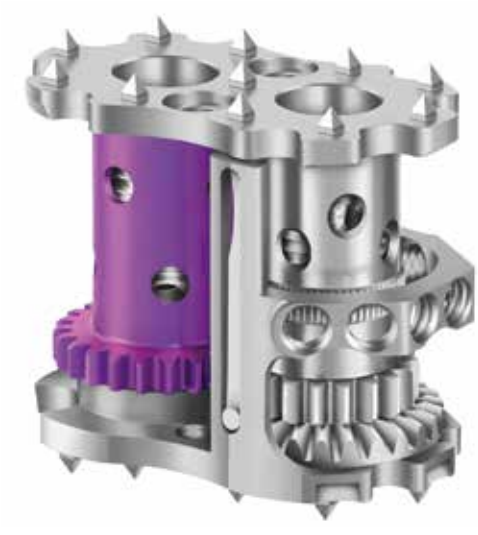
Implants

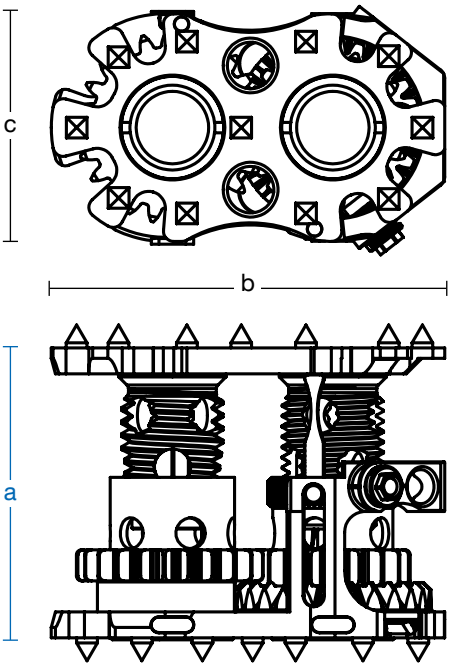
Locking screw
for the vertebral body replacement
“mediExpand®” -TL

58.82.61	Ø = 4.0 mm	for 58.82.53/ 57/ 59
58.82.62	Ø = 4.0 mm	for 58.82.52/ 56/ 58
58.82.63	Ø = 3.5 mm	for 58.82.51
58.82.64	Ø = 3.5 mm	for 58.82.50
58.82.69	Ø = 3.5 mm	for 58.82.54
58.82.70	Ø = 3.5 mm	for 58.82.55

Implants

The following implant sizes can be used with angled end plates.



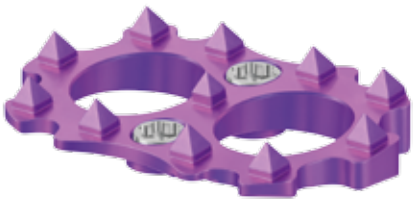


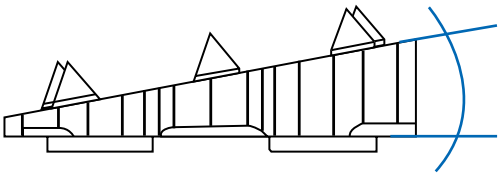
		a	b	c
for use with angled end plates	**58.82.52**	18 – 28 mm	35 mm	22 mm
	58.82.53	18 – 28 mm	38 mm	22 mm
	58.82.58	22 – 34 mm	35 mm	22 mm
	58.82.59	22 – 34 mm	38 mm	22 mm
	58.82.56	30 – 50 mm	35 mm	22 mm
	58.82.57	30 – 50 mm	38 mm	22 mm

The depictions of the instruments are not to scale and serve for illustration only.

Implants

Angled end plates
for “mediExpand®” -TL
including fastening screws

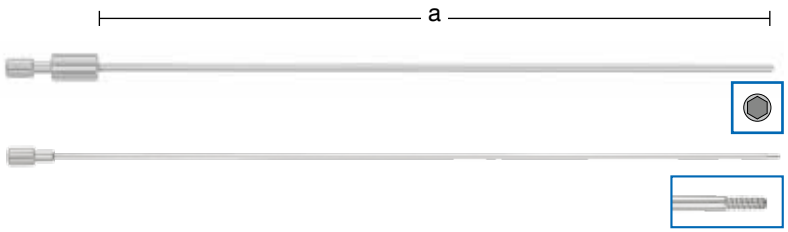




58.82.80	∠ = 2°	for 58.82.52/58/56
58.82.81	∠ = 2°	for 58.82.53/59/57
58.82.90	∠ = 5°	for 58.82.52/58/56
58.82.91	∠ = 5°	for 58.82.53/59/57
58.82.92	∠ = 10°	for 58.82.52/58/56
58.82.93	∠ = 10°	for 58.82.53/59/57
58.82.94	∠ = 15°	for 58.82.52/58/56
58.82.95	∠ = 15°	for 58.82.53/59/57

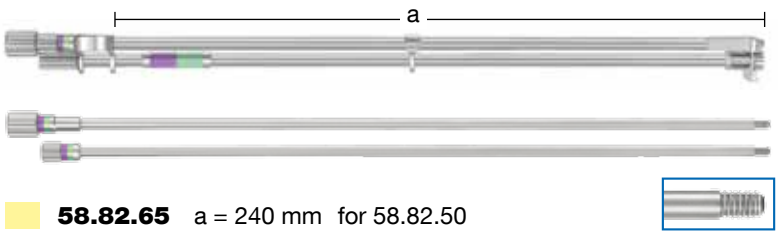
Instrumentation

Screwdriver
for all locking screw



58.82.75 a = 295 mm for 58.82.61/ 62/ 63/ 64/ 69/ 70

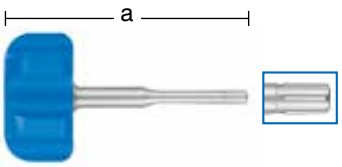
Spreader for insertion of the
vertebral body replacement
“mediExpand®” -TL



58.82.65 a = 240 mm for 58.82.50
58.82.66 a = 240 mm for 58.82.51
58.82.77 a = 240 mm for 58.82.54
58.82.78 a = 240 mm for 58.82.55

58.82.67 a = 240 mm for 58.82.52/ 53/ 56/ 57/ 58/ 59

Torx wrench
for the spreader



The Torx wrench improves the transmission of force in the use of all rotatable parts of the spreader.

58.82.68 a = 70 mm for 58.82.65/ 66/ 67/ 77/ 78

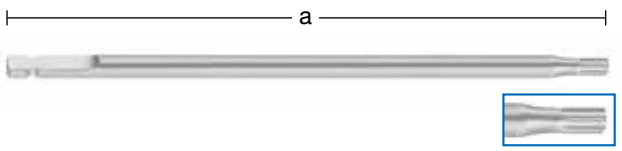
Torque handle
with quick coupling
for 58.82.72

58.81.96

The depictions of the instruments are not to scale and serve for illustration only.

Instrumentation

Torx key with quick coupling
for the angled end plate



58.82.72 a = 118 mm for 58.82.80/ 81/ 90/ 91/ 92/ 93/ 94/ 95

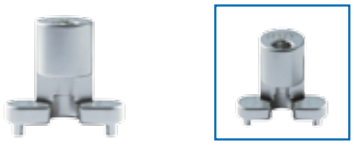
Fastening screw
for the angled end plates

58.82.88

Counterholder
for the angled end plate

58.82.79

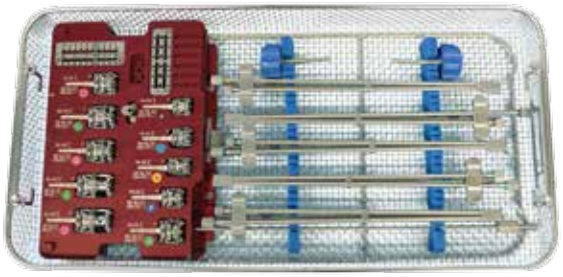
Applicator
for locking screws



58.82.71 for 58.82.61/ 62/ 63/ 64/ 69/ 70

Tray complete
(without implants and tools)

Depiction of a loaded tray.



906.93.38

The depictions of the instruments are not to scale and serve for illustration only.

Surgical technique and instrumentation

4.0 Surgical technique and instrumentation

The special construction of the vertebral body replacement allows special angular connections with the spreader that allow implantation with the TLIF technique using the dorsolateral and lateral approaches.

The instruments intended for application of the expandable vertebral body replacement are subject to wear and mechanical stress even when used normally. In order to prevent failure of the implants and instruments during surgery, these parts should be checked before use to ensure that they are mechanically intact, that there are no deformations, and that the parts are fully functioning. Damaged instruments must not be used, and are to be replaced.

4.1 Preparation

A partial or complete corpectomy using one of the approaches mentioned above and the freshening of the base and top plates of the neighbouring vertebral bodies was performed. During the preoperative preparation, the appropriate size of the vertebral body replacement that is suitable for the height of the defective vertebra(e) is determined using the x-ray image.

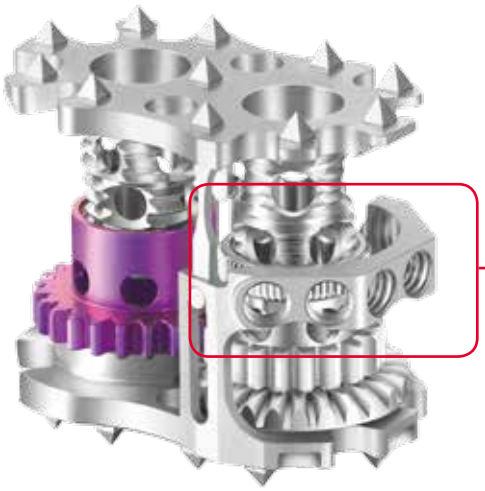
In the non-expanded state, the height of the vertebral body replacement should be smaller than the defect. In the expanded state, the maximum height should be larger than the defect.

4.2 Preparing the Vertebral Body Replacement

Remove the vertebral body replacement that is suitable for reconstruction from the tray compartment and perform a functional test. (Carefully move the coloured gearwheel back and forth with a finger.)

Depending on the approach applied, one of the three positions on the connector component of the vertebral body is determined (marked red). Place the required instruments and the locking screw in suitable colour coding ready.

The assembly of the vertebral body replacement with the spreader is performed ex situ.



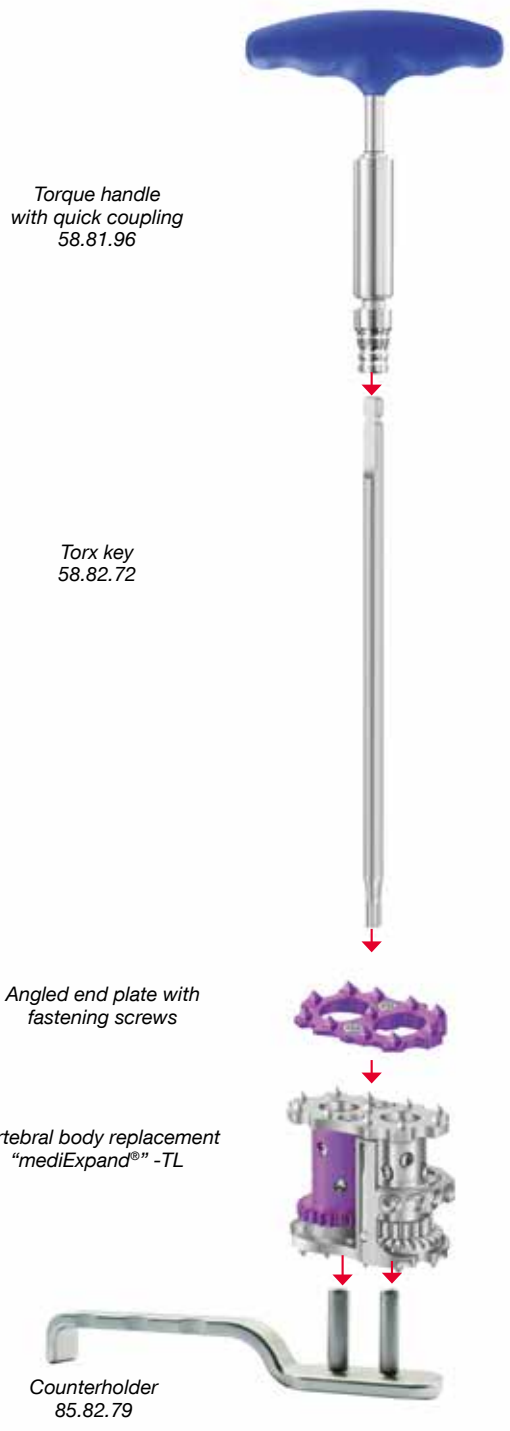
- For dorsolateral approach / TLIF technique
- For lateral approach
- For dorsolateral approach / TLIF technique

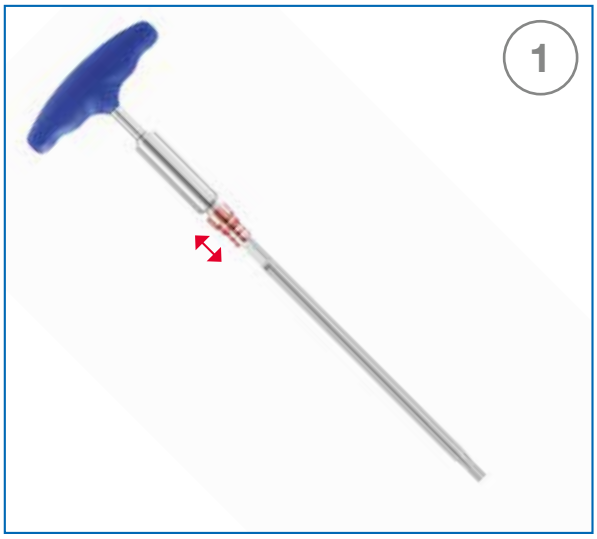
Connector component and its access possibilities

NOTE:
For better illustration, the following description of the technical application is based on a lateral approach!

Surgical technique and instrumentation

4.3 Surgical technique and instrumentation



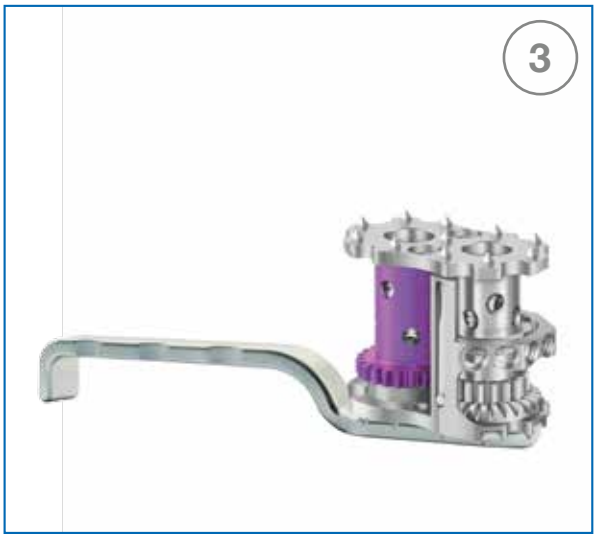


During preparation, the two parts (torx key and torque handle) must be combined.

NOTE:
The fastening screws may fall out if they are turned counter-clockwise!

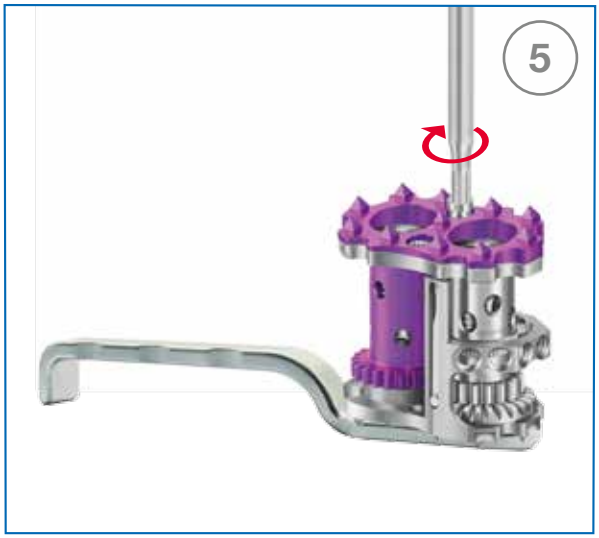
Angled end plates for “mediExpand®” -TL including the fastening screws.

Surgical technique and instrumentation



For reliable hold, the vertebral body replacement “mediExpand®” -TL is inserted into the counterholder. The counterholder facilitates positioning and fixation of the angled end plate and protects the user from injuries caused by the teeth of the end plates.

Now place the angled end plate on the vertebral body replacement “mediExpand®” -TL.

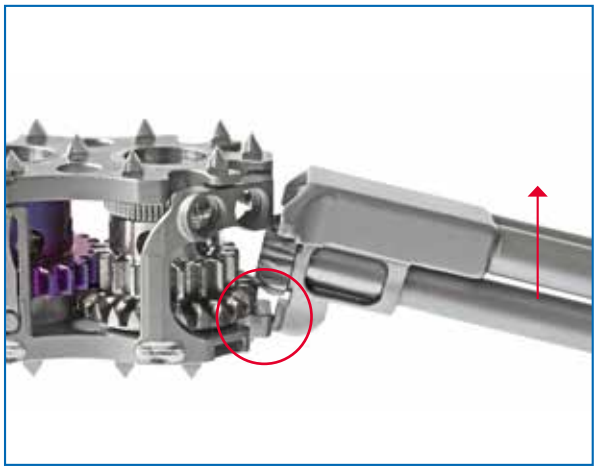


Tighten the two fastening screws using the torque handle in clockwise direction.

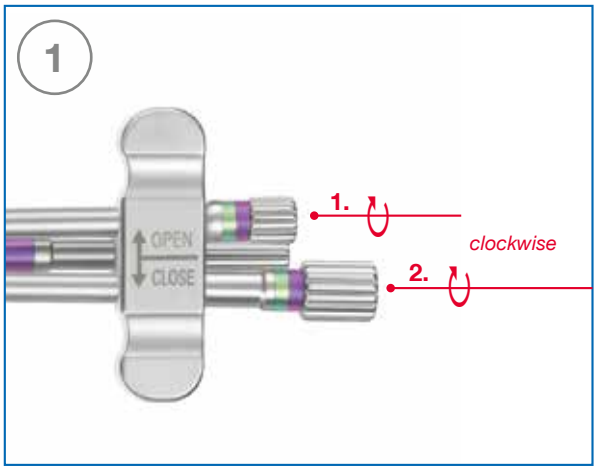
Once the torque limit is reached, the torque handle slips, and a click can be heard.

Surgical technique and instrumentation

4.3 Connecting the Vertebral Body Replacement with the Spreader

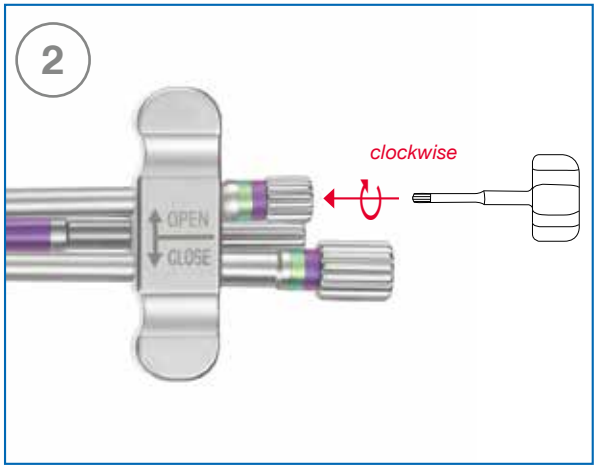


Insert the retention lug of the spreader into the corresponding chuck of the end plate of the "mediExpand®" -TL by means of a small tilting movement from bottom to top.



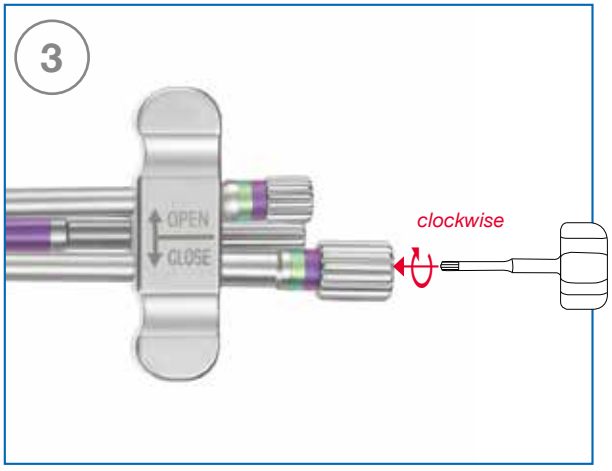
First screw the shorter retention rod into the threaded hole of the connector component, thereby securing the connection manually. Then insert the longer retention rod and also screw in manually.

Check the expansion mechanism over the bevel wheel gear for proper and smooth function!



Successively insert the Torx wrench into the knurled heads of the two retention rods and tighten the rods by rotating them in clockwise direction.

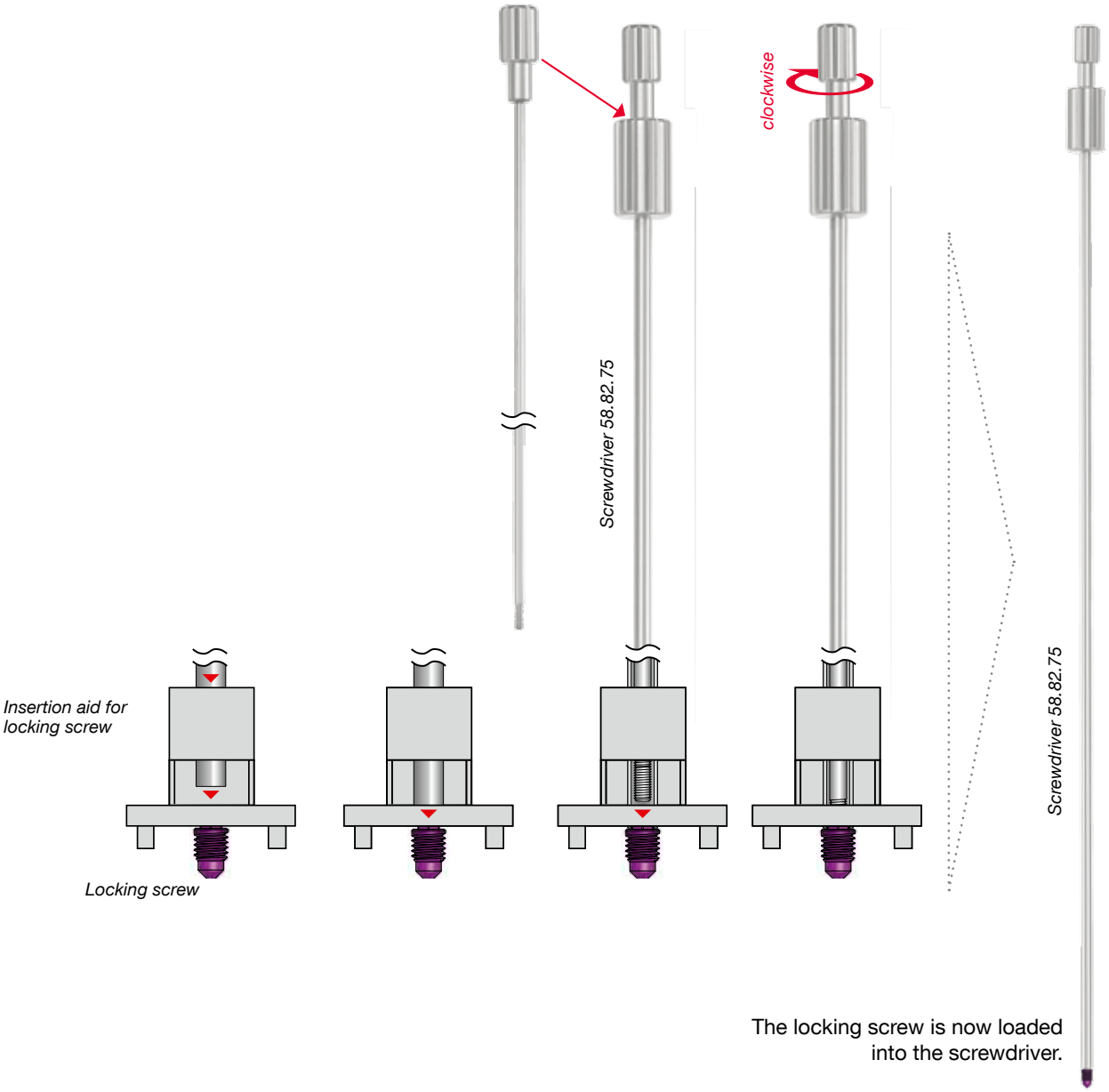
The good transmission of force by the Torx wrench helps to establish a stable connection!



4.4 Preparing the Screwdriver and Loading the Screws

Insert the threaded rod into the screwdriver sleeve. Place the complete screwdriver with the front hexagon socket onto the locking screw in the magazine and tightly screw in the threaded rod into the internal thread of the locking screw.

> The colour of the locking screw must be identical with the colour code of the vertebral body replacement of the spreader! Also see the numbering of the implants and screws in the tray.



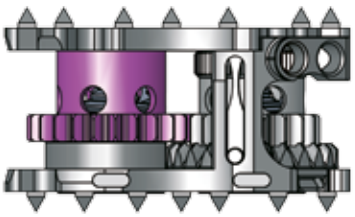
The locking screw is now loaded into the screwdriver.

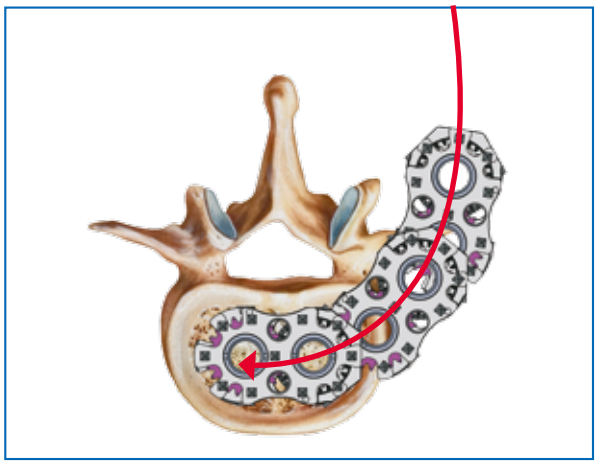
The depictions of the instruments are not to scale and serve for illustration only.

Surgical technique and instrumentation

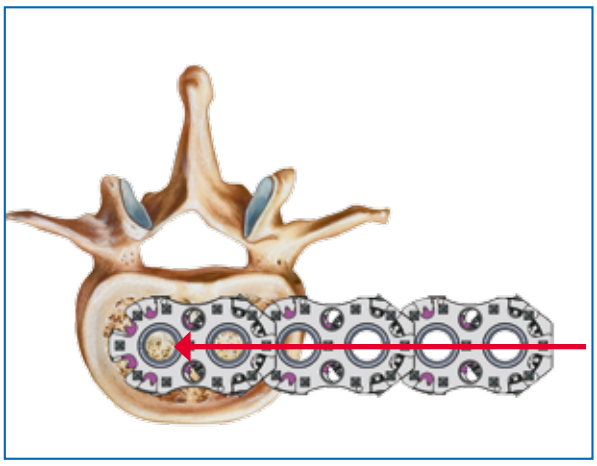
4.5 Inserting the Vertebral Body Replacement

Implant the vertebral body replacement with the spreader into the resected area of the spine and then check the proper in situ position using x-ray.





Dorsolateral approach / TLIF technique



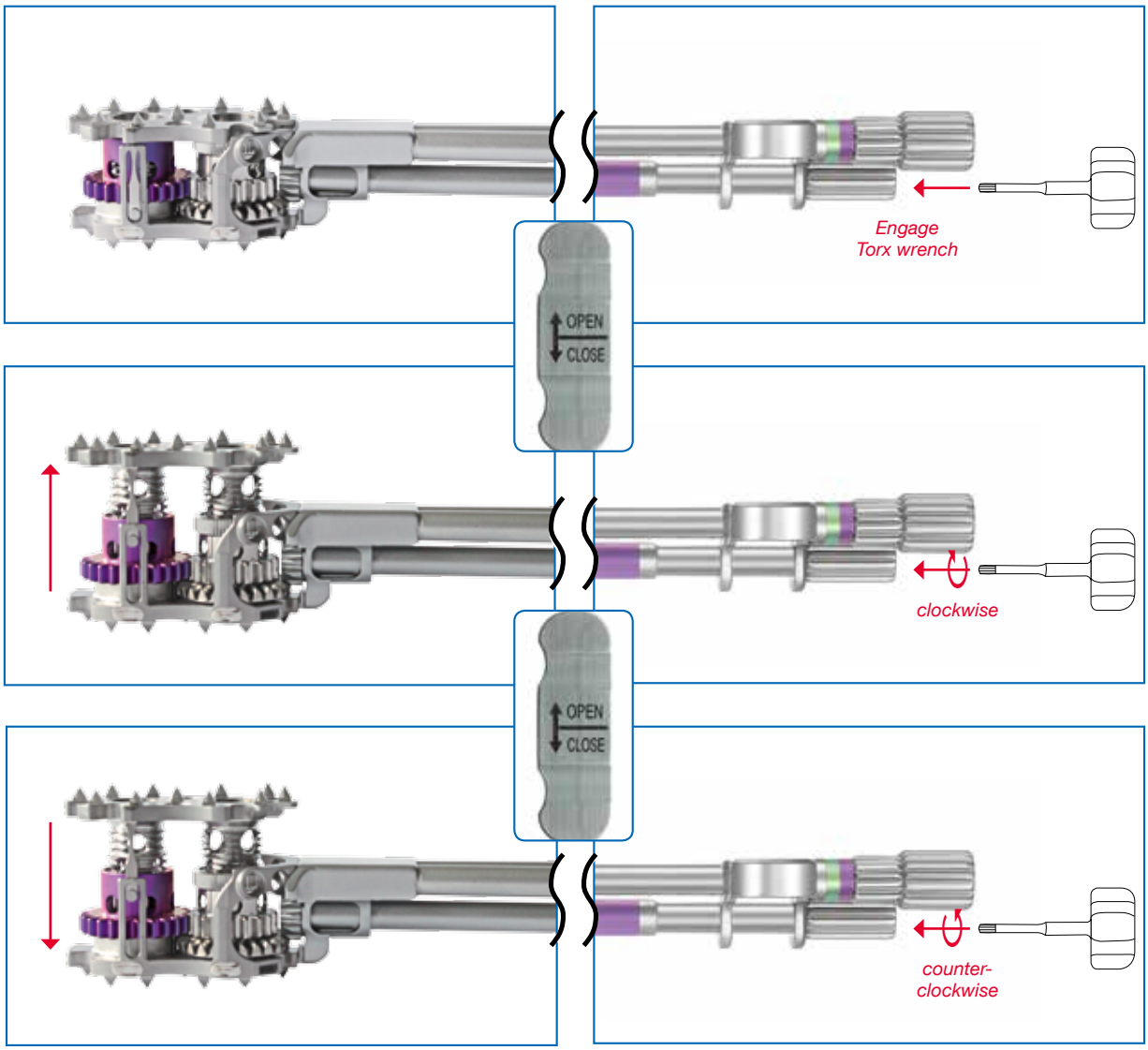
Lateral approach

4.6 Expanding the Vertebral Body Replacement

Insert the Torx wrench into the knurled head of the expansion rod and expand the vertebral body replacement in situ under x-ray control by carefully rotating it in clockwise direction (see directional arrow and inscription “OPEN” on the handle plate of the spreader) until the desired height is reached.

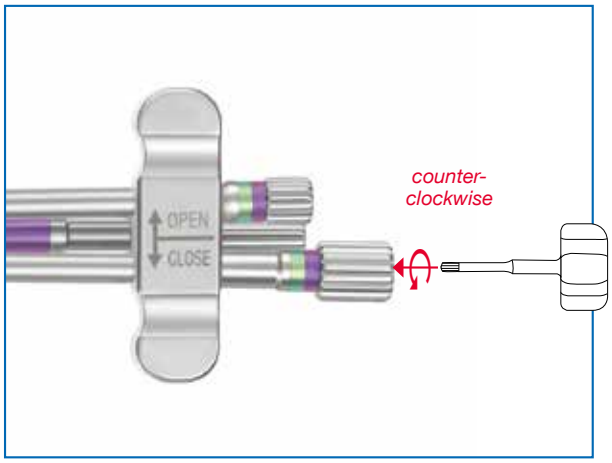
The maximum expansion height is limited by two limiters.

By rotating in opposite direction (see directional arrow and inscription “CLOSE” on the handle plate of the spreader), the expansion height of the “mediExpand®” -TL can be reduced until the minimum height is reached.

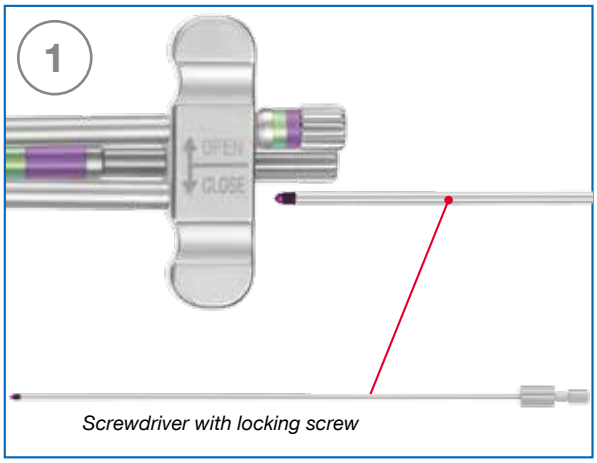


Surgical technique and instrumentation

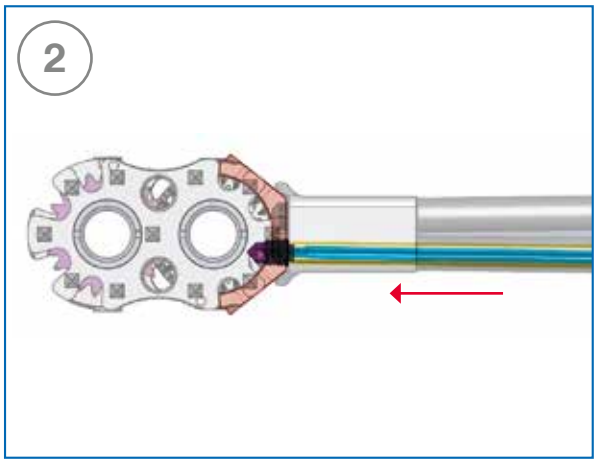
4.7 Securing the Vertebral Body Replacement

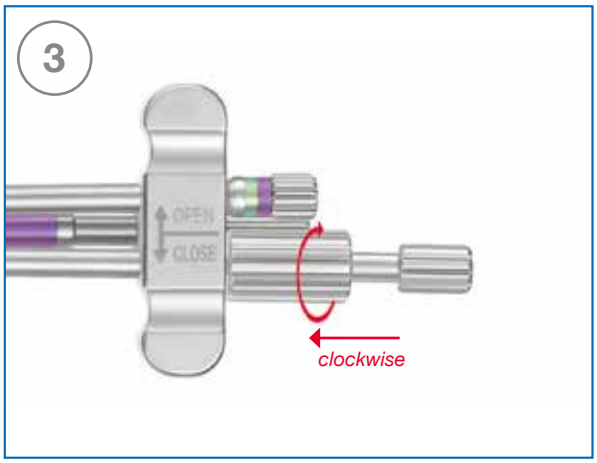


Insert the Torx wrench into the knurled head of the long retention rod.
Loosen the rod from the vertebral body replacement by rotating it in counter-clockwise direction, and then pull it out.

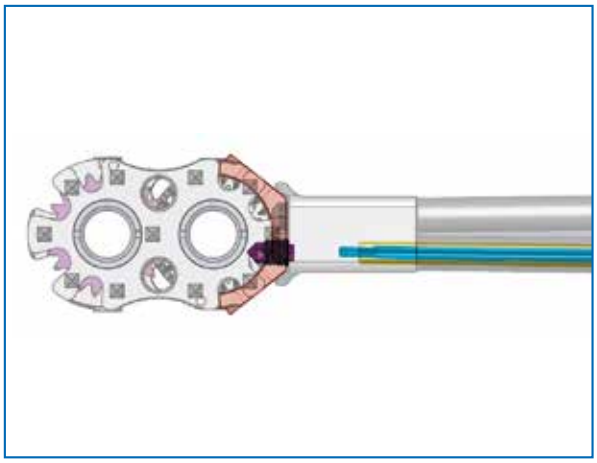


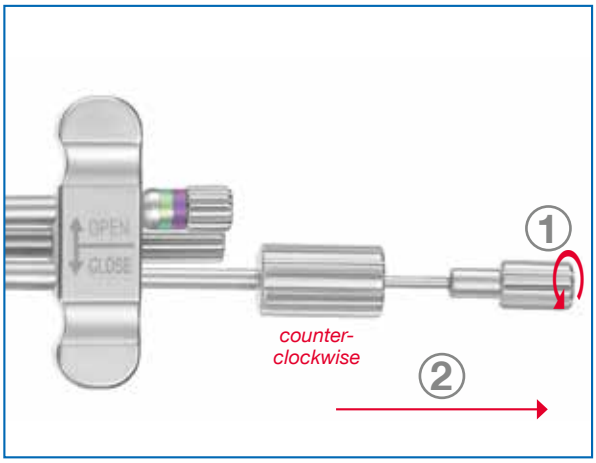
Insert the loaded screwdriver (see section 4.4) into the free sleeve ① until a resistance can be felt ②, and tightly screw the locking screw into the threaded hole of the large knurled head ③ by turning it to the right.



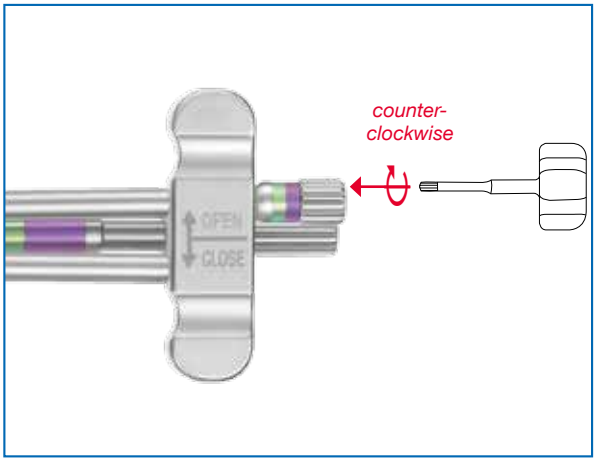


4.8 Extracting the Spreader





First loosen the inner threaded rod by turning the locking screw to the left, and then pull the complete screwdriver out of the sleeve of the spreader.



Insert the Torx wrench into the knurled head of the retention rod that has remained in the spreader and loosen the rod from the vertebral body replacement by turning it to the left (counter-clockwise).

The connection with the vertebral body replacement has been removed. Remove the emptied spreader from the operating area.

Liability

5.0 Liability

In the event of discrepancies between the english and the german version of these instructions for use only the german version shall be applicable.

Only the latest revision of the instructions for use applies. Due to constant technical development the contents of these MEDICON instructions for use are updated regularly. Please use the MEDICON extranet *www.medicon.de/extranet* to ensure that you are using the current version. The current version date is printed on each edition of the instructions for use.

MEDICON eG assumes no liability for damages caused by improper use, care or maintenance or non-compliance with the restrictions for use, non-observance of post-operative instructions and other guidelines in the instructions for use.

The liability for defects by MEDICON eG is also not applicable in case of changes or repairs to the product without prior written consent from MEDICON eG as well as in case of repairs which were not carried out by workshops authorised by MEDICON eG or the Medicon Repair Service (MRS).

Federal law and regulations in the United States restrict the sale of this device to a physician or hospital or on prescription.

Product documents

▶ Visual product presentation on CD-ROM

▶ Prospect

For general information on the complete MEDICON product range please refer to the Internet.

www.medicon.de

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