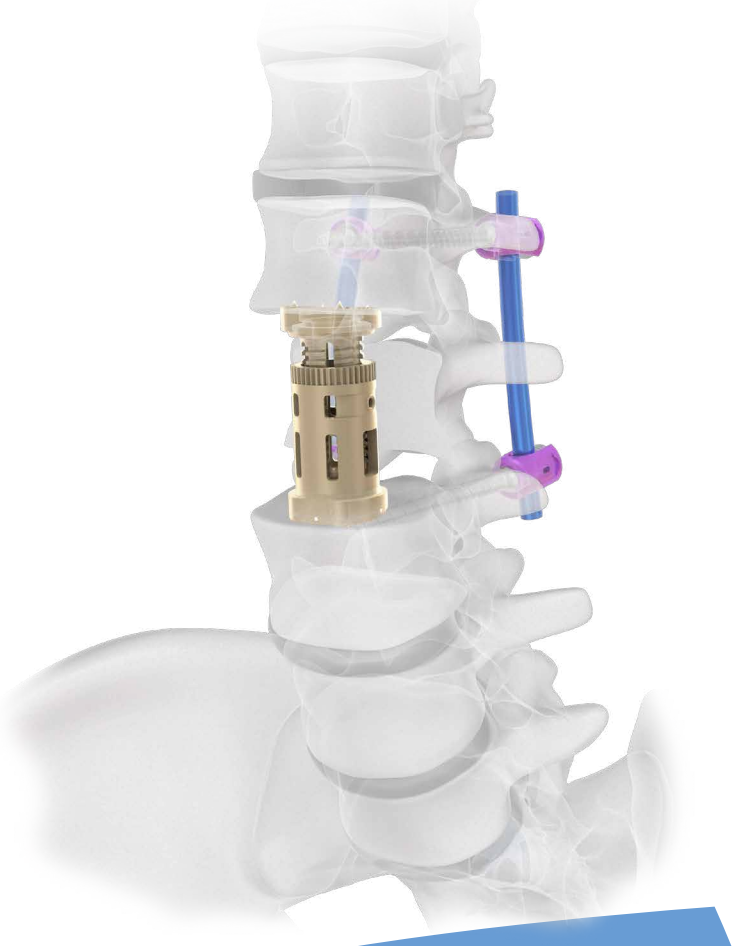
ST/88A

CHARSPINE system VBR
Vertebral Body Replacement System

CHARSPINE VBR expandable implants system

- *IMPLANTS*
- *INSTRUMENT SET 15.0914.101*
- *SURGICAL TECHNIQUE*



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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

1. INTENDED USE

The **CHARSPINE VBR** system is intended for reconstruction and stabilization of the thoracolumbar spine for partially or completely removed single-, or multilevel vertebral bodies. The implants of the **CHARSPINE VBR** system are designed to replace the removed vertebral bodies by taking over the loads acting on them and to stabilize and maintain the correct curvature of the spine until spondylodesis occurs.

CONTRAINDICATIONS

Intervertebral VBR implants are not intended for cervical spine.

The choice of a particular implant must be carefully considered in terms of patient's medical condition.
Circumstances listed below may preclude or reduce the chance of successful outcome:

- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity (*defined according to the W.H.O. standards*).
- Pregnancy.
- Neuromuscular disorder which would create unacceptable risk of fixation failure or complications in postoperative care.
- Any other condition which would preclude the potential benefit of spinal implant surgery and disturb the normal process of bone remodeling, e.g. the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases.
- Suspected or documented allergy or intolerance to implant materials. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions; mental illness, senility or substance abuse (*these conditions may cause the patient to ignore certain necessary limitations and precautions in the use of the implant*).
- Patients with a known hereditary or acquired bone fragility or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in whom inserted implant would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

The above list is not exhaustive.

For further information on:

- adverse effects,
- warnings,
- sterilization,
- pre- and post-operative recommendations,

please, refer to the Instructions For Use for the product.

2. IMPLANT FEATURES

The **CHARSPINE VBR** device developed by the **ChM**, depending on the level of spine segment treated and surgeon's preferences, can be implanted using anterior, anterolateral, lateral or posterior-lateral approaches. The design of the device allows for a smooth in vivo change of its height, making the implantation simple and ensuring perfect match of the implant with the patient's anatomy.

The **CHARSPINE VBR** system includes a set of implants, instruments and stands. All these elements allow for friendly, simple and intuitive us, facilitating: preparation for the procedure, implantation surgery, washing and disinfection. The implants are made of the highest quality biocompatible materials - PEEK OPTIMA INVIBIO - a plastic with high biocompatibility and stiffness similar to human bones, and metals - tantalum and titanium alloy.

For the production of instruments, high-quality materials used in the medical industry, such as stainless steels, silicones and plastics, were used. Resultantly, modern, easy-to-use, ergonomic and easy-to-clean specialized surgical instruments have been achieved.

2.1. IMPLANTS

Endplate

Expandable body

Extension (*optional*)

Endplate

CHARSPINE VBR implant includes:

a) Expandable body - 1 pcs.
b) Endplate - 2pcs.
c) Extension (*optional, for the total height of the* **CHARSPINE VBR** *prosthesis exceeding 64mm*) - max. 2pcs.

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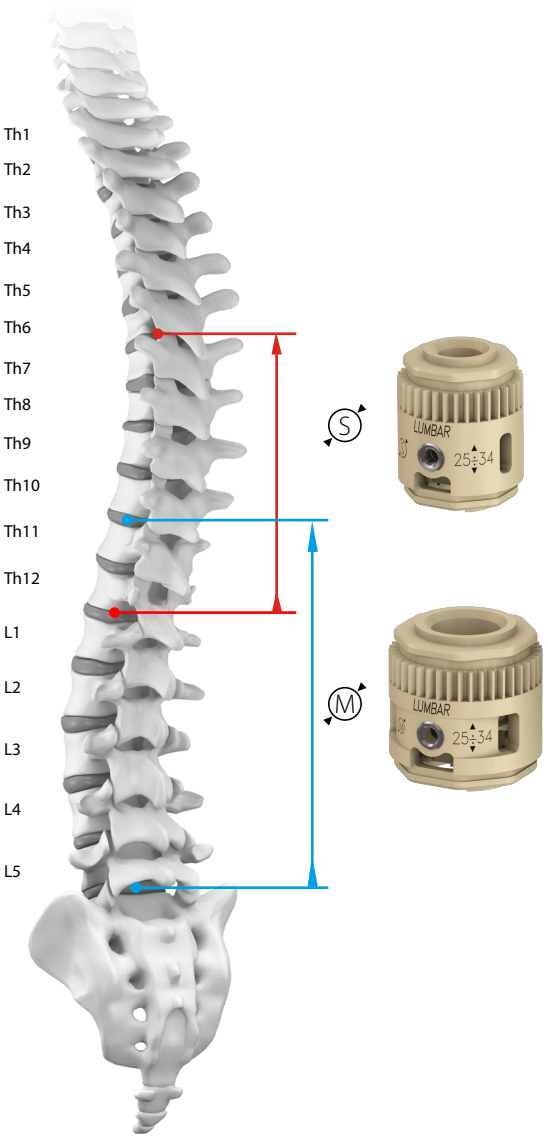
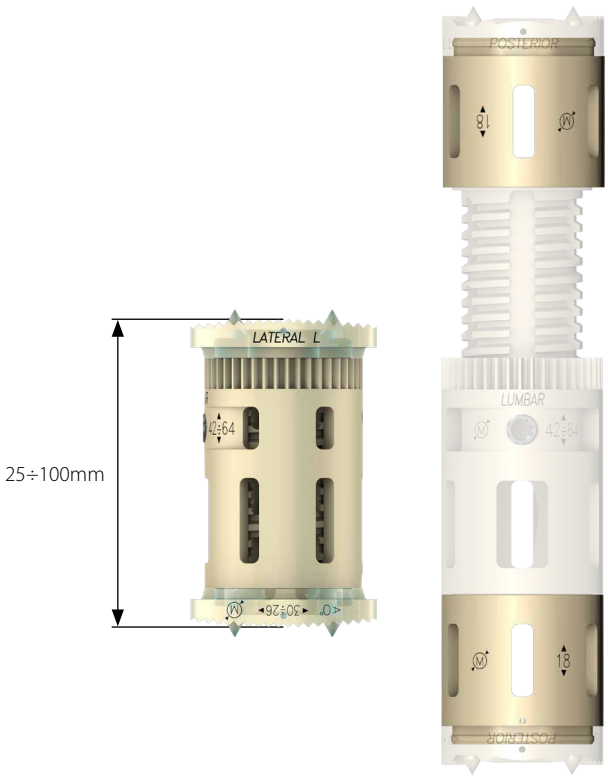
AVAILABLE IMPLANTS:

S	SMALL	for Th6 to Th12 levels
M	MEDIUM	for Th10 to S1 levels



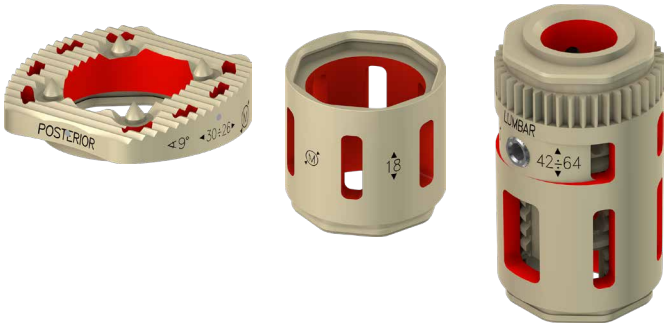
Height range from 25 to 100mm
(*use extensions for heights over 64mm*).

The height ranges given are for expandable bodies with two 0° endplates installed.



Smooth change of the prosthesis height based on a reliable screw mechanism that does not require locking.

Large openings for maximum osseointegration of the prosthesis.



Special construction of the socket connecting the prosthesis with the persuader ensures high stability and strength of the connection.

The stability of the connection is increased by the use of a threaded sleeve made of high-strength titanium alloy.

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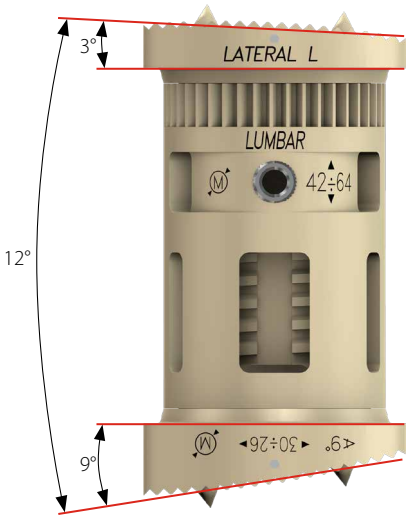
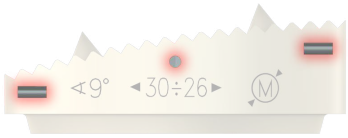
Using two endplates with different angles, as many as 10 different angles of inclination of the VBR prosthesis endplate surfaces matching the anatomical curvatures of the spine can be obtained.

0°	3°	5°	6°	8°	9°	10°	12°	14°	18°
(0°+0°)	(0°+3°)	(0°+5°)	(3°+3°)	(3°+5°)	(0°+9°)	(5°+5°)	(3°+9°)	(5°+9°)	(9°+9°)

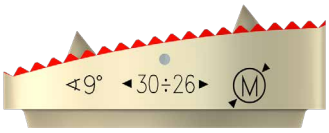


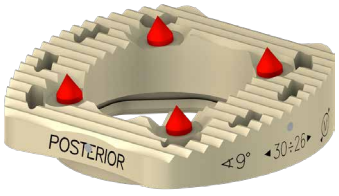
For proper in vivo VBR prosthesis positioning, 4 tantalum markers have been embedded in each endplate. They determine the line of the endplate surface and the angle at which the surface is tilted; along with the expandable body, the full height of the VBR prosthesis is indicated.



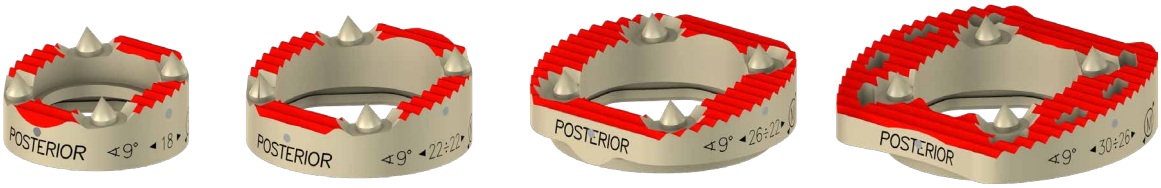
Anatomical line of the upper surface of the endplates

For better stability, the endplate surfaces are serrated to increase the friction forces at the implant-to-bone contact point, and four sharp spikes that anchor the implant in bone.

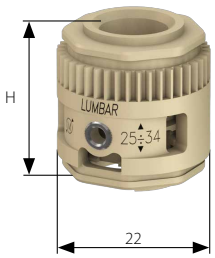




Four different endplate sizes are available.

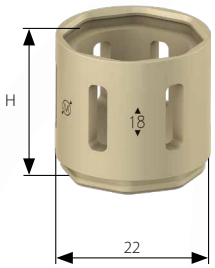


MEDIUM



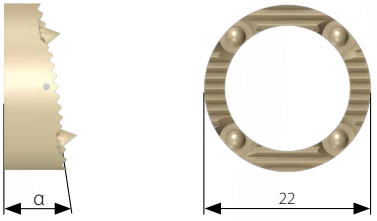
Expandable body M Ø22

Size	Cat. No.
25÷34	8.6050.025
31÷46	8.6050.031
42÷64	8.6050.042



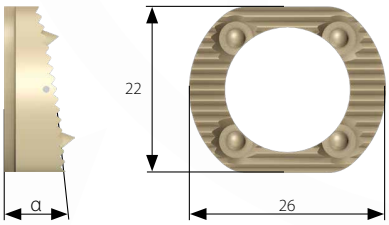
Extension M Ø22

H	Cat. No.
9	8.6051.009
18	8.6051.018



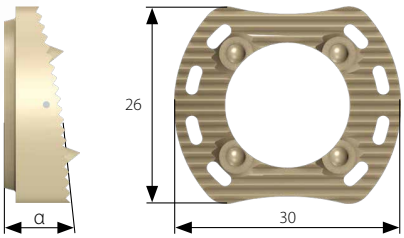
Endplate M Ø22

α	Cat. No.
0°	8.6052.000
3°	8.6052.003
5°	8.6052.005
9°	8.6052.009



Endplate M 26x22

α	Cat. No.
0°	8.6053.000
3°	8.6053.003
5°	8.6053.005
9°	8.6053.009



Endplate M 30x26

α	Cat. No.
0°	8.6054.000
3°	8.6054.003
5°	8.6054.005
9°	8.6054.009

CAUTION:
The MEDIUM endplates and extensions should only be used with MEDIUM expandable bodies.

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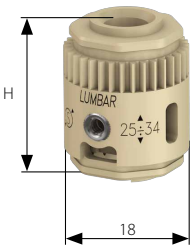
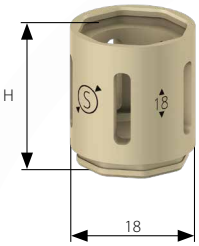
SMALL



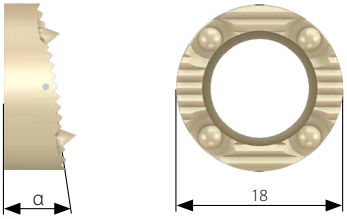
Expandable body S Ø18

Size	Cat. No.
25÷34	8.6040.025
31÷46	8.6040.031
42÷64	8.6040.042



Extension S Ø18

H	Cat. No.
9	8.6041.009
18	8.6041.018

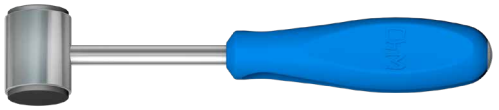


Endplate S Ø18

α	Cat. No.
0°	8.6042.000
3°	8.6042.003
5°	8.6042.005
9°	8.6042.009

CAUTION:
The SMALL endplates and extensions should only be used with SMALL expandable bodies.

2.2. INSTRUMENT SET

Instrument set for expandable VBR implants 15.0914.101	Name	Catalogue no.	Pcs
	Container lid 9x4	14.0914.102	1
	Container 9x4H	14.0914.101	1
	Persuader	40.6780.000	1
	Trial S 18	40.6788.000	1
	Trial M 22	40.6781.022	1
	Trial M 26x22	40.6781.026	1
	Trial M 30x26	40.6781.030	1
	Hammer 300g	40.6782.000	1
	Working stand	40.6783.000	1
	Elevator	40.6784.000	1
	Mallet	40.6785.022	1
	Guide sleeve M	40.6786.022	1
	Mallet	40.6785.018	1
	Guide sleeve S	40.6787.000	1
	Trial	40.8640.000	1

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3. SURGICAL TECHNIQUE

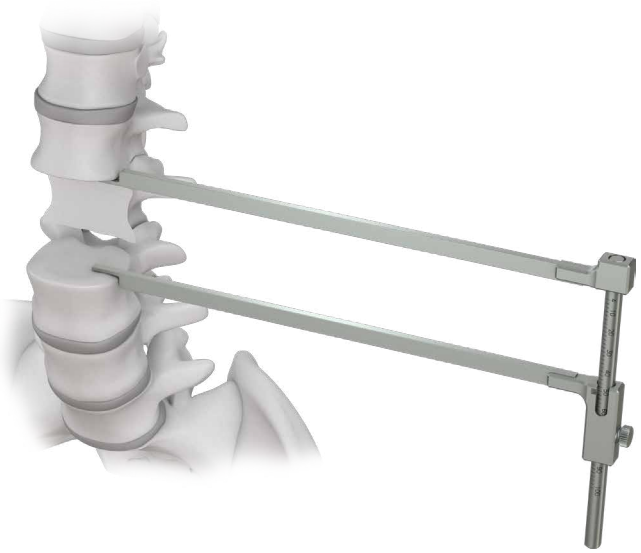
3.1. PATIENT POSITIONING AND SURGICAL APPROACH

The patient position and surgical approach depend on the section of spine to be treated and the surgeon's preferences. The VBR prosthesis can be inserted through the anterior, anterolateral, lateral and posterior-lateral approaches. Having performed the corpectomy or vertebrectomy and prepared the endplate surfaces of the adjacent vertebral bodies (*removal of the surface layers of cartilaginous plates until the bleeding bone is exposed*), the implant may be inserted. This manual describes the L1 surgical technique using the lateral approach from the left side.

3.2. IMPLANT SELECTION

Pre-operatively, based on X-Rays, determine:
- implant version (*SMALL or MEDIUM*),
- the height of the prosthesis (*the distance between the endplate surfaces of the vertebral bodies adjacent to the body that will be removed*),
- the inclination angle of the endplates (*the total value of the inclination of the two endplates should be as close as possible to the angle between the endplate surfaces of the vertebral bodies adjacent to the body that will be removed*),
- the size of the endplates (*for MEDIUM version*).

The operator is able to insert the VBR implant from each of four surgical approaches: anterior, anterolateral, lateral and posterolateral, regardless of the selected elements of the VBR prosthesis.

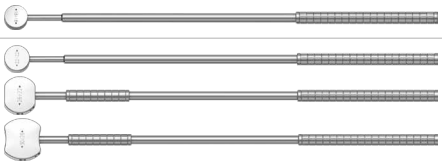


The size of the expandable body is determined on the basis of X-Rays images (*prior to surgery*), or intraoperatively using the trial **[40.8640.000]** and measuring the distance between the vertebral bodies adjacent to the removed one. The measure should be taken in their middle parts.

For values above 64mm (*the highest available expandable body*), an extension should be used and attached to the expandable body (*described later in this manual*). Depending on the extension used and its number (*maximum two*), the height of the expandable body increases by 9, 18 or 36mm.

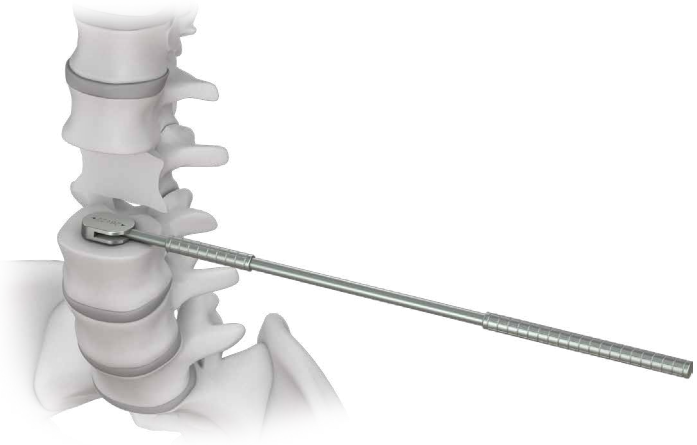
40.8640.000

Use trials for endplates **[40.6781.0xx]**, to determine the size of the endplates to be used. There are three sizes of endplates and corresponding trials: 22; 26x22; 30x26.



40.6788.000

40.6781.0xx



Depending on the surgical approach, the position of the trial head can be adjusted in relation to the grip.

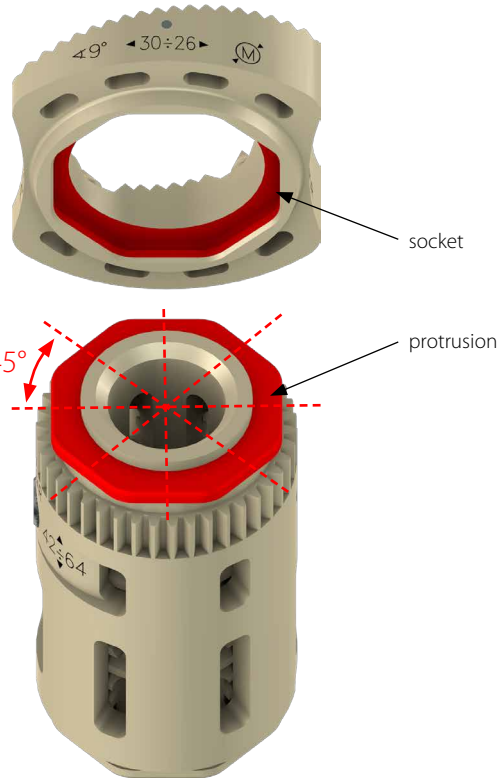
Trials 40.6788.000 and 40.6781.022 have a fixed head due to their shape (*cylinder*).

The angle of inclination of the endplates should be selected on the basis of X-Ray images and be in total (*adding the angle of inclination of two endplates to each other*) close to the angle of inclination of the endplate surfaces of the vertebral bodies adjacent to the removed one.

Endplates with different angles of inclination may be used together.

3.3. VBR PROSTHESIS ASSEMBLY

Selected elements of the VBR prosthesis should be joined together. To connect the elements, insert octagonal protrusion of an implant into an octagonal socket of the other implant. The manner the elements are joined allows angular positioning of the elements in eight positions at 45° intervals, matching the VBR prosthesis to the selected surgical approach and treated spine segment.



The connection can only be made between the socket and protrusion.

To determine the approach and level the VBR prosthesis can be implanted, appropriate inscriptions are provided on the implants:

- Posterior, Anterior, Lateral L - endplates
- Lumbar, Thoracic - expandable bodies

During assembly of the VBR prosthesis components, the inscriptions visible in line on the expandable body and the upper endplate (*located closer to the socket mounting the body with persuader*) indicate the surgical approach and the level at which the prosthesis is to be implanted.

LATERAL L – LUMBAR
LATERAL R – THORACIC
lateral lumbar access from the left side
(*or from the right side for the thoracic level*)

ANTERIOR – LUMBAR
POSTERIOR – THORACIC
anterior lumbar access
(*or posterior for the thoracic level*)

POSTERIOR – LUMBAR
ANTERIOR – THORACIC
posterior lumbar access
(*or anterior for the thoracic level*)

The other endplate should be attached in such a way that the POSTERIOR / ANTERIOR inscriptions, that are placed on the side walls, lie on the same side and parallel to the corresponding inscriptions of the first endplate.

For MEDIUM implants, the VBR prosthesis components are connected on a working stand **[40.6783.000]** coupled with guide sleeve **[40.6786.022]**, and for SMALL - the guide sleeve S **[40.6786.018]**.


40.6783.000

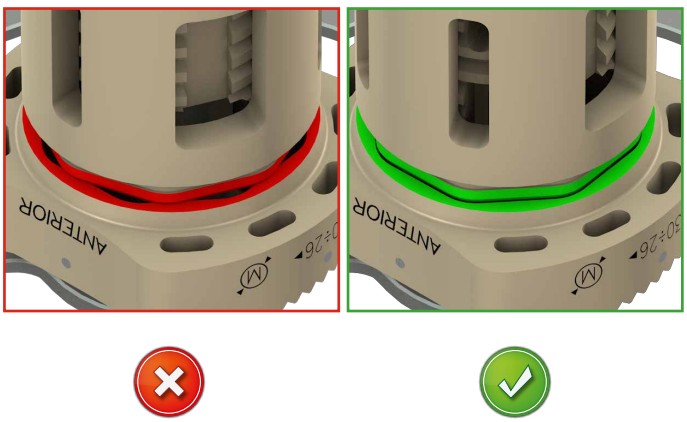

40.6786.022


40.6787.000

Install the implants to be joined onto the compatible guide sleeve. The socket of one implant must face the protrusion of the other. The assembly order is optional. It is not recommended to connect more than two components of the VBR prosthesis at the same time.

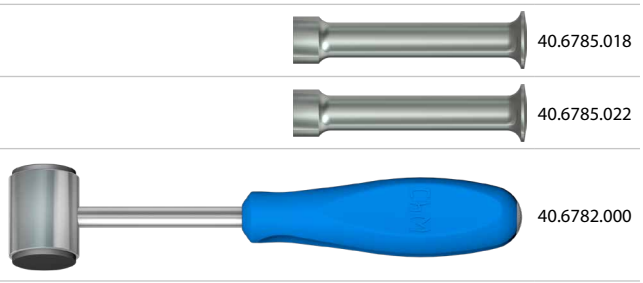
Pay attention to the position of the endplates in relation to each other and expandable body. Their position determines the level of implantation and surgical approach.

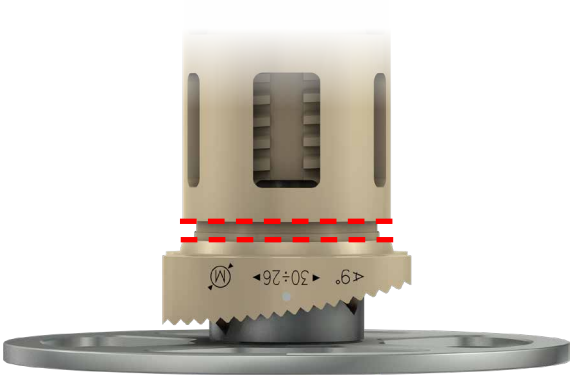
Before connecting, verify the correct positioning of the sockets and protrusions. The surfaces forming the octagonal sockets and protrusions should be parallel to each other.



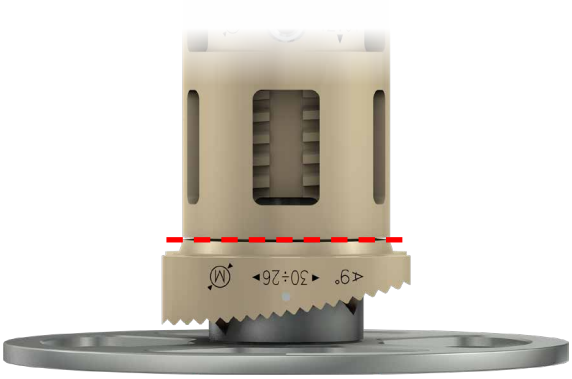
Install mallet M **[40.6785.022]** (*for MEDIUM implants*) or mallet S **[40.6785.018]** (*for SMALL implants*) onto the compatible guide sleeve.

Use hammer 300g **[40.6782.000]** to hit the mallet and insert the protrusion of one implant into the socket of the other.





BEFORE ASSEMBLY



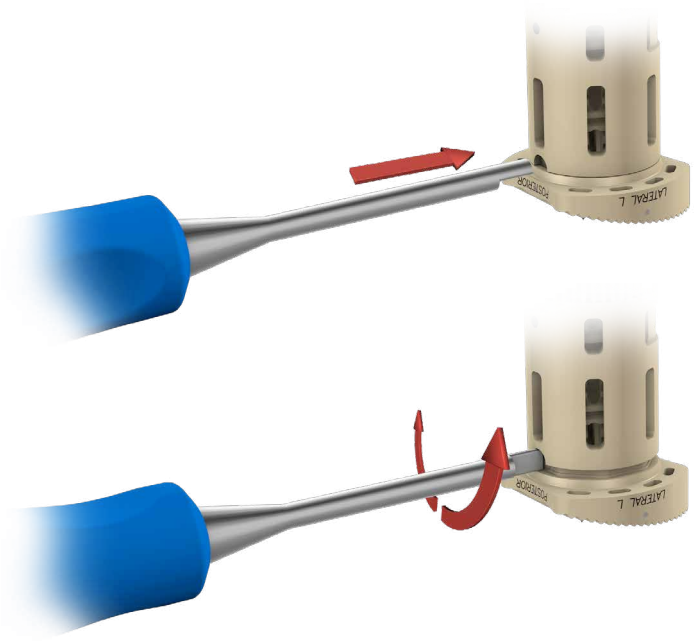
AFTER ASSEMBLY

Repeat for the other elements.

3.4. DISASSEMBLY OF IMPLANT COMPONENTS

Use elevator **[40.6784.000]** to disassemble the connected elements of the VBR prosthesis. Insert the elevator into the semi-circular socket between the connected implants and turn by 90° in any direction.

40.6784.000



With the expandable body not activated, the semi-circular socket is not visible - is behind the gear (*Fig. 1*).

Rotate the gear clockwise to expand the body until the semi-circular socket is visible (*Fig. 2*).

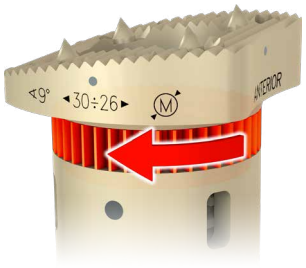


Fig. 1

Disassembly of the VBR prosthesis components is only allowed in exceptional situations when it is absolutely necessary (*e.g. in case of a mistakable assembly*). Repeated assembly /disassembly significantly reduces the strength of the connection and can result in vivo implant instability.

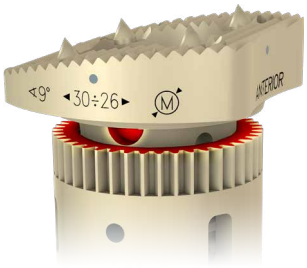
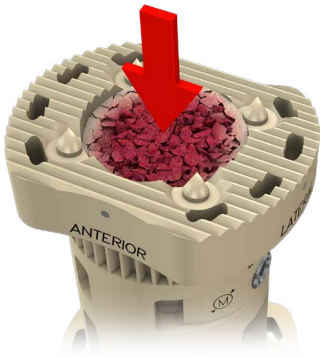


Fig. 2

3.5. FILLING WITH AUTOLOGOUS MATERIAL

Fill the implant with autologous material (*bone chips*) through the central hole in the endplate and compress gently with elevator **[40.6784.000]**.

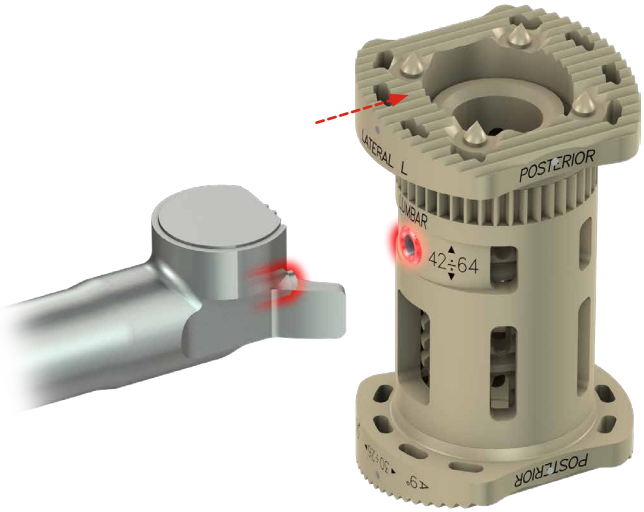
Do not compress the autologous material, excessively. Do not fill the side holes as it may hinder the implant distraction.

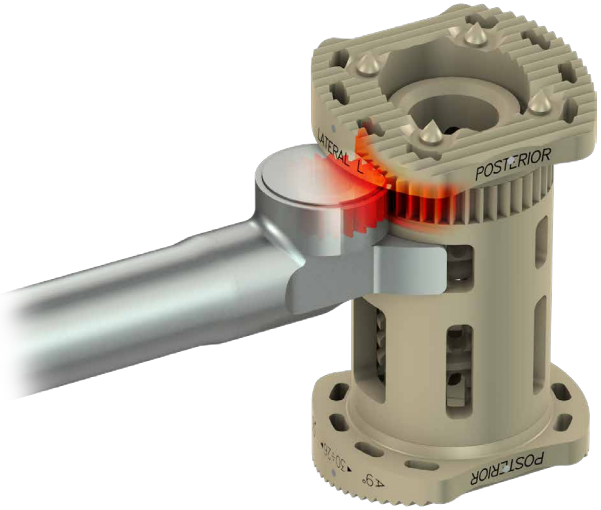


3.6. PERSUADER USE

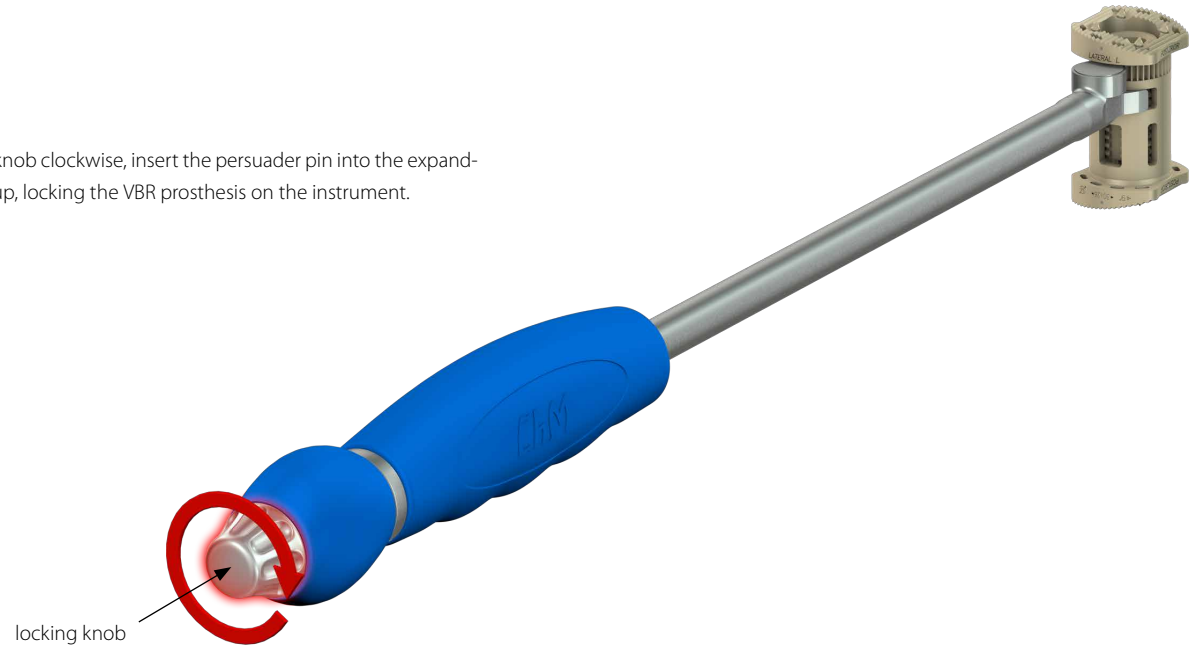
Persuader **[40.6780.000]** is used for both, the insertion and distraction of VBR prosthesis.

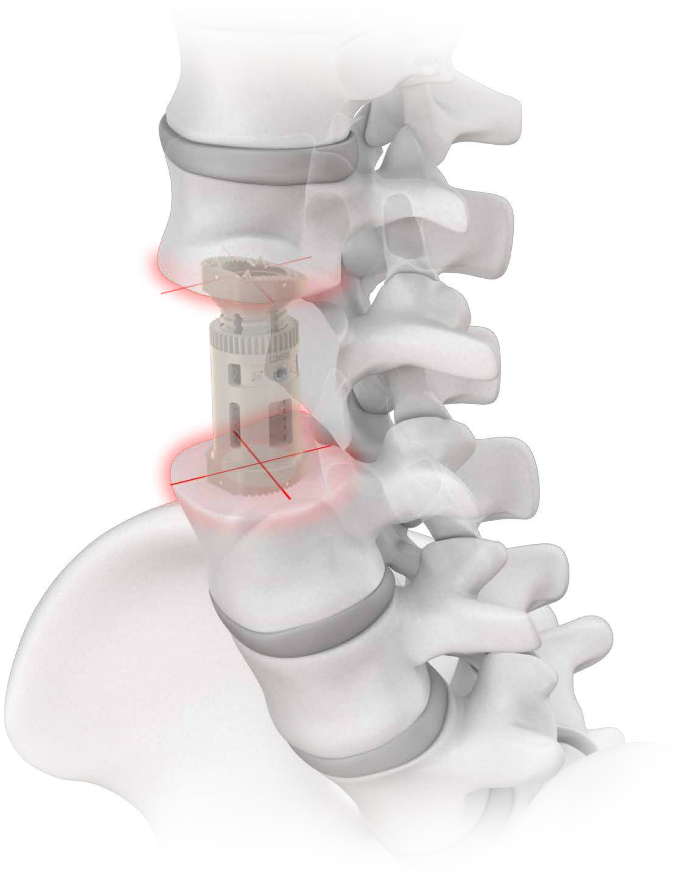
Insert the persuader head into the socket located under the gear of the expandable body so that the persuader gear matches with the gear of the implant, and the threaded pin of the persuader locks with the threaded sleeve located in the center of the socket of the expandable body.





By rotating the locking knob clockwise, insert the persuader pin into the expandable body and tighten up, locking the VBR prosthesis on the instrument.





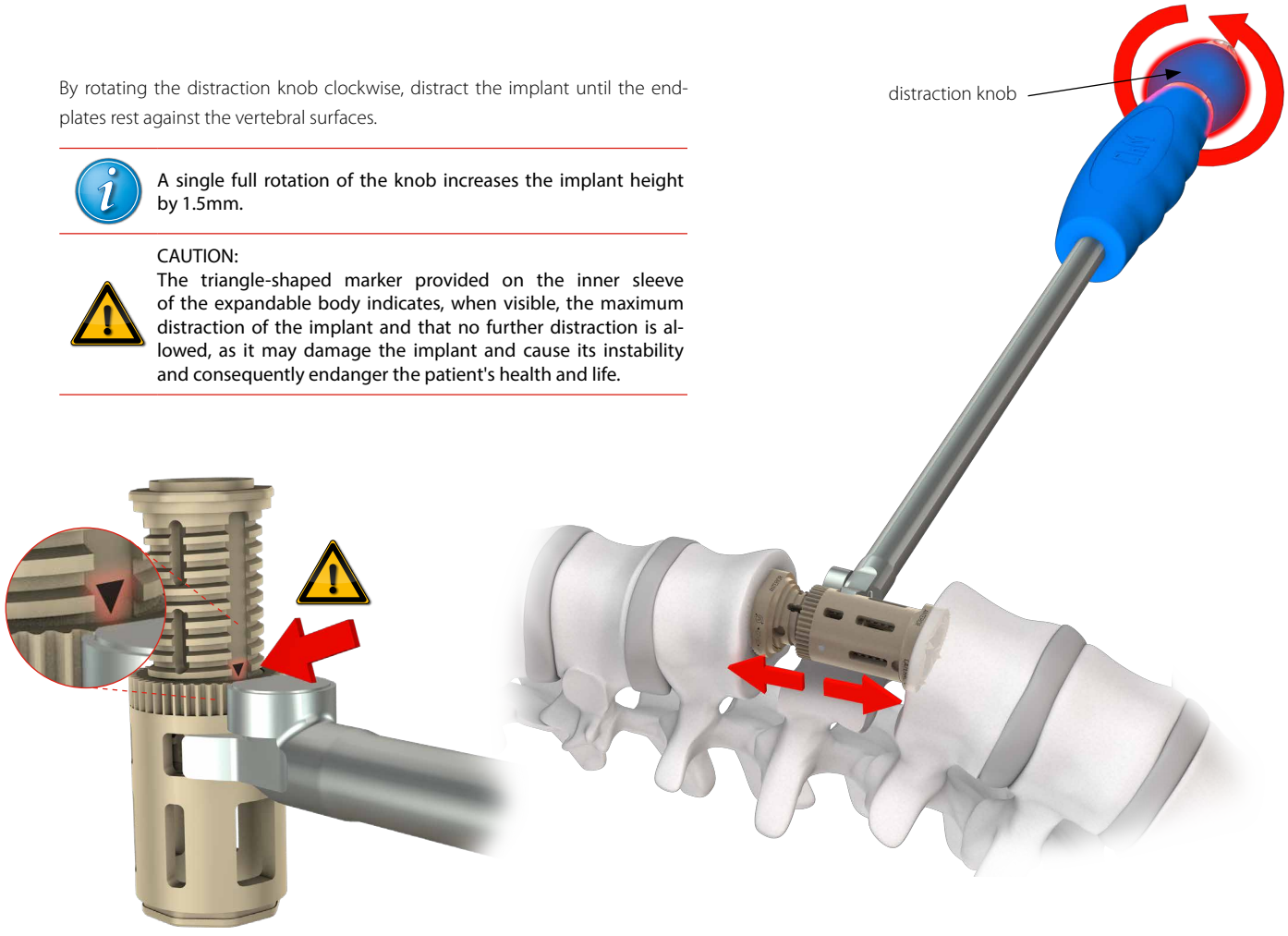
3.7. IMPLANT INSERTION

Use the persuader **[40.6780.000]** to insert the prosthesis in the place of the removed vertebral body. The optimal location for VBR prosthesis is the central part of the surfaces of the vertebral bodies.

By rotating the distraction knob clockwise, distract the implant until the endplates rest against the vertebral surfaces.

A single full rotation of the knob increases the implant height by 1.5mm.

CAUTION:
The triangle-shaped marker provided on the inner sleeve of the expandable body indicates, when visible, the maximum distraction of the implant and that no further distraction is allowed, as it may damage the implant and cause its instability and consequently endanger the patient's health and life.

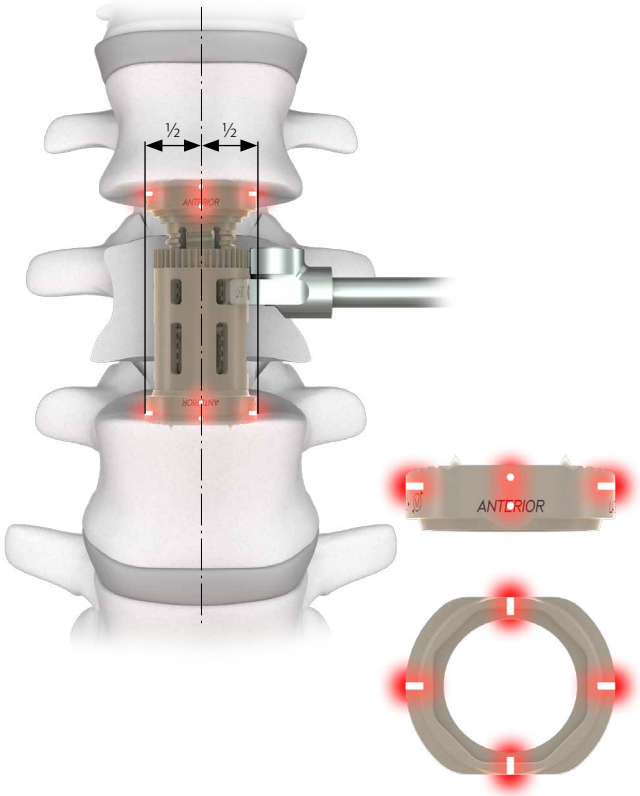


Verify the implant position by taking an X-Ray image in the AP projection. The tantalum markers visible in the pictures should be symmetrically spaced from the central axis of the spine.

If there is a need to change the position, reduce the height of the VBR prosthesis by rotating the distraction knob counterclockwise, loosening the implant. Reposition the prosthesis and perform distraction. Verify the position again by taking an X-Ray image.

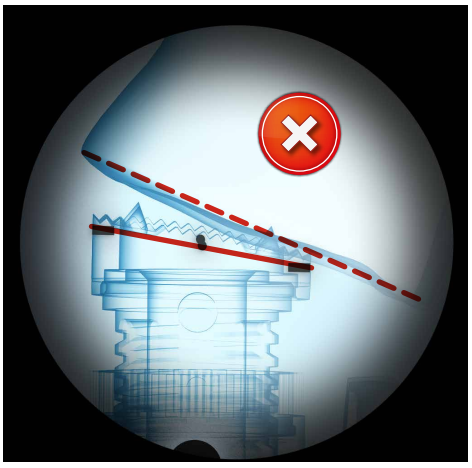
The markers are placed about 1mm below the upper (*serrated*) surface of the endplates.

Perform final distraction to obtain the correct implant height that will correspond to the height of the excised structures.



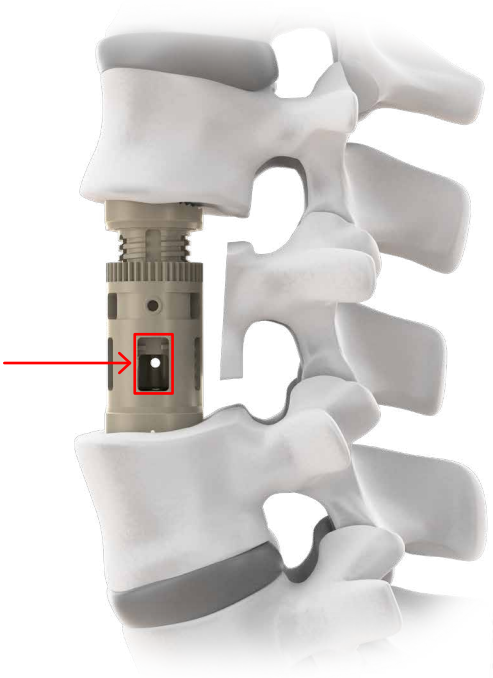
Disconnect the persuader from the VBR implant by rotating counter-clockwise the locking knob (*until the fixation pin is completely removed*).

Verify the implant position by taking X-Ray images in AP and lateral projection. Radiological markers should be equidistant from the surfaces of vertebral body endplates.



The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

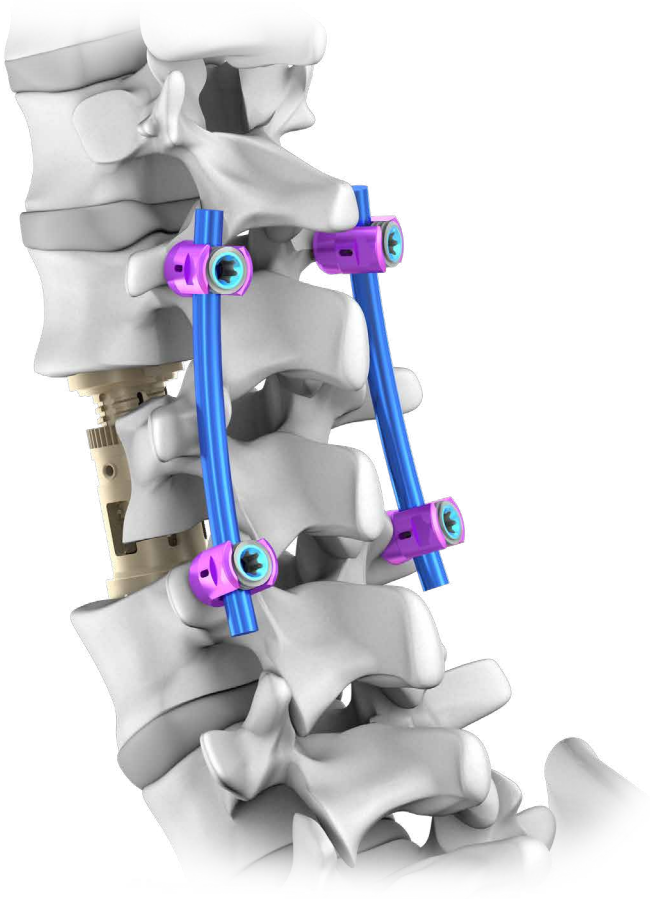
Use autologous material to fill in the space around and inside the prosthesis (*the resultant space after implant distraction*). To pack in the prosthesis in vivo, use a window located in the expandable body under the socket for mounting the persuader.



When filling in the prosthesis, do not use excessive force that may result in implant displacement.

4. SUPPLEMENTARY STABILIZATION

To ensure the stability of the spine, it is necessary to perform additional fixation that will increase the immobility of the treated spine segment and introduce additional compression to stabilize the VBR prosthesis. Therefore, it is recommended to perform bar stabilization with e.g. **ChM CHARSPINE 2** system.



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