ST/92A

CHARSPINE system VBR
Vertebral Body Replacement System

CHARSPINE VBR mesh implant system

- *IMPLANTS*
- *INSTRUMENT SET 15.0916.001*
- *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

I. INTENDED USE

The **CHARSPINE VBR** mesh system is intended for reconstruction and stabilization of the thoracolumbar and cervical 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.

I.1. CONTRAINDICATIONS

The choice of a particular implant must be carefully considered in terms of a 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 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,

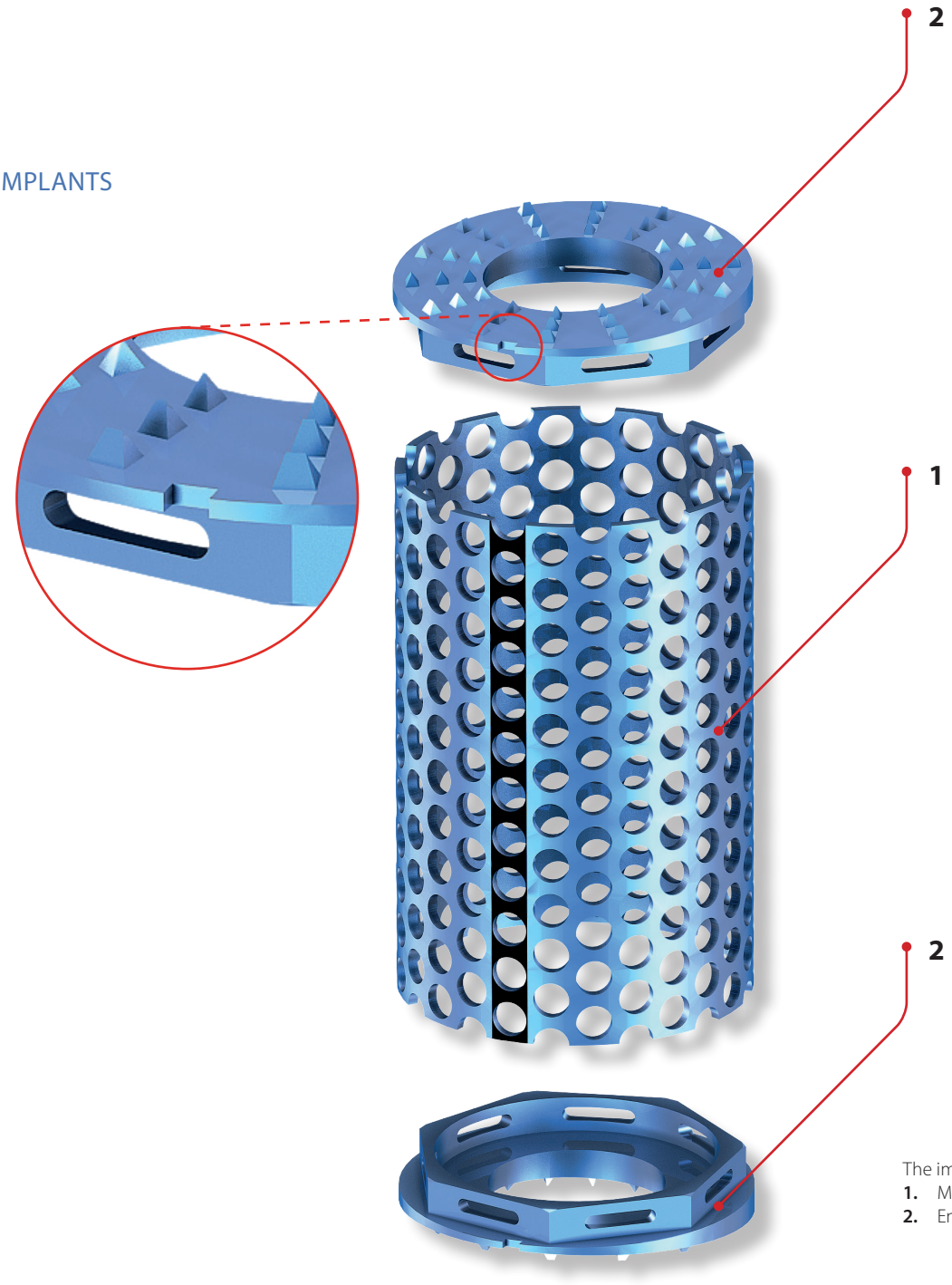
please, refer to the Instructions For Use for the product.

II. IMPLANT FEATURES

The **CHARSPINE** VBR mesh implants system developed by **ChM**, depending on the level of treated spine segment and the surgeon's preferences, can be introduced using anterior, anterolateral, lateral or posterior-lateral approaches. The system offers a wide range of sizes, and the instrument set ensures trimming of implants to the desired length.
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 a biocompatible titanium alloy in accordance with the requirements of ISO 5832 standards.

For the production of instruments, high-quality materials used in the medical industry, such as stainless steels, silicones and plastics, were used.

II.1. IMPLANTS



The implant system includes:
1. Mesh bodies,
2. Endplates.

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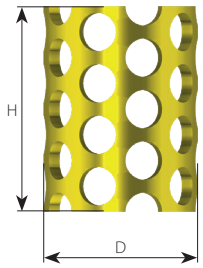
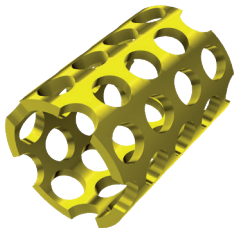
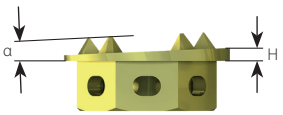
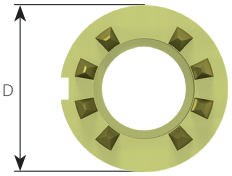
CHARSPINE system VBR
Vertebral Body Replacement System









Mesh body

	D	H	Colour	Cat. No.
cervical spine	10	7		3.6917.070
		8		3.6917.080
		12		3.6917.120
		16		3.6917.160
		20		3.6917.200
		88		3.6917.880
	12	7		3.6918.070
		8		3.6918.080
		12		3.6918.120
		16		3.6918.160
		20		3.6918.200
		32		3.6918.320
		88		3.6918.880
cervical and thoracic spine	15	7		3.6920.070
		8		3.6920.080
		12		3.6920.120
		16		3.6920.160
		20		3.6920.200
		32		3.6920.320
		88		3.6920.880
thoracic spine	20	8		3.6921.080
		16		3.6921.160
		20		3.6921.200
		24		3.6921.240
		28		3.6921.280
		52		3.6921.520
		64		3.6921.640
		88		3.6921.880
thoracolumbar spine	25	8		3.6922.080
		16		3.6922.160
		20		3.6922.200
		28		3.6922.280
		32		3.6922.320
		36		3.6922.360
		40		3.6922.400
		52		3.6922.520
		64		3.6922.640
		88		3.6922.880
	30	8		3.6923.080
		16		3.6923.160
		20		3.6923.200
		28		3.6923.280
		32		3.6923.320
		36		3.6923.360
		40		3.6923.400
		52		3.6923.520
		64		3.6923.640
		88		3.6923.880

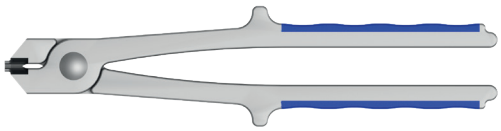
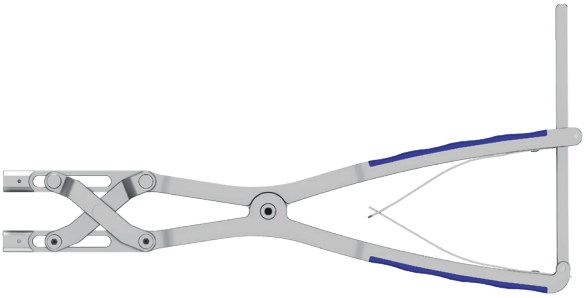
Endplate

α	D	H	Colour	Cat. No.
0	10	0.7		3.6910.000
2.5		1		3.6910.250
5		1		3.6910.500
0	12	0.7		3.6911.000
2.5		1		3.6911.250
5		1.5		3.6911.500
0	15	0.7		3.6913.000
2.5		1		3.6913.250
5		1.5		3.6913.500
0	20	0.7		3.6914.000
2.5		1		3.6914.250
5		2		3.6914.500
0	25	0.7		3.6915.000
2.5		1.5		3.6915.250
5		3		3.6915.500
0	30	0.7		3.6916.000
2.5		1.5		3.6916.250
5		3		3.6916.500

40.8651.000
Stand for implants - VBR mesh implants system

II.2. INSTRUMENT SET

CHARSPINE system VBR
Vertebral Body Replacement System

Instrument set for VBR mesh implants			15.0916.001
	Name	Catalogue no.	Pcs
	Cutting pliers	40.8645.000	1
	Working stand	40.8646.100	1
	Wire cutting pliers 16cm hardened	40.3176.160	1
	Parallel distraction forceps	40.8093.000	1
	Distraction forceps-jaws	40.8650.650	2
	Distraction forceps-jaws	40.8650.920	2
	Persuader	40.8648.100	1
	Trial	40.8640.000	1
	Impactor	40.8643.000	1
	Applicator	40.8652.000	1
	Hammer 300g	40.6782.000	1

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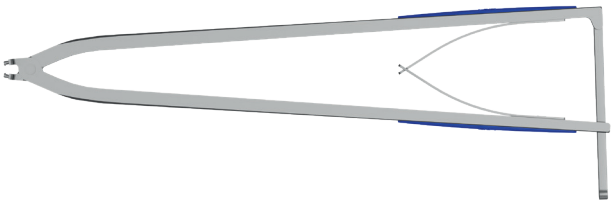
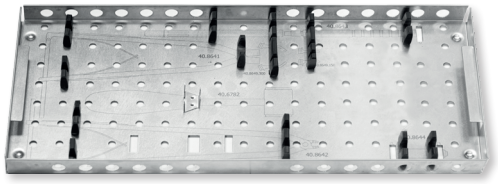
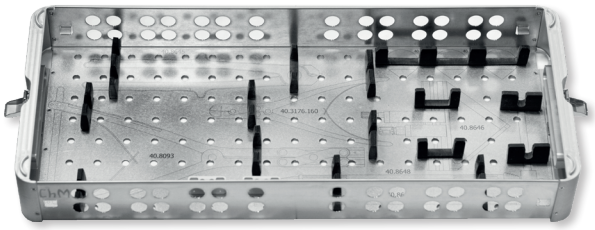
Instrument set for VBR mesh implants			15.0916.001
	Name	Catalogue no.	Pcs
	Applicator	40.8642.000	1
	Mallet	40.8644.100	1
	Container lid 9x4	14.0916.102	1
	Tray 9x4 1/2H	14.0916.201	1
	Container 9x4H	14.0916.101	1

III. SURGICAL TECHNIQUE

III.1. PATIENT POSITIONING AND SURGICAL APPROACH

The patient position and surgical approach depend on the section of the spine to be treated and the surgeon's preferences. The implants 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.

III.2. IMPLANT SELECTION

Pre-operatively, based on X-Rays, it is possible to pre-determine:

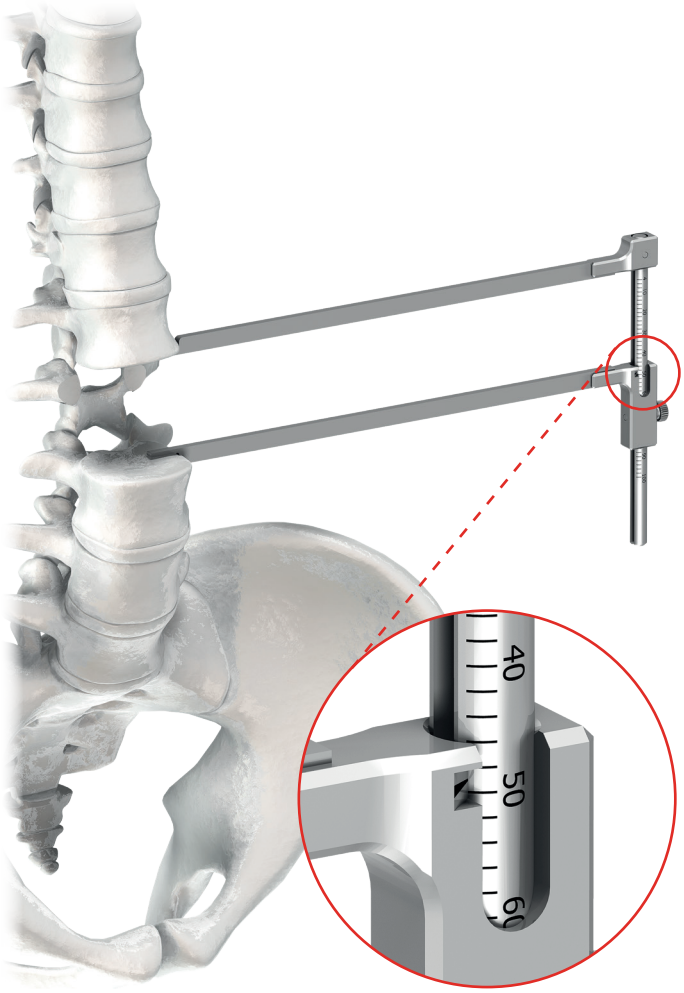
- the distance between the endplate surfaces of vertebral bodies adjacent to the body that will be removed),
- the inclination angle of the endplate surfaces of the vertebral bodies adjacent to the body that will be removed.

The size of the mesh 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.

Then, determine the diameter of the mesh body and select the appropriate endplate *(inclination of the endplate is determined on the basis of the X-Ray image)*.

Endplates with different inclination may be used together.

40.8640.000

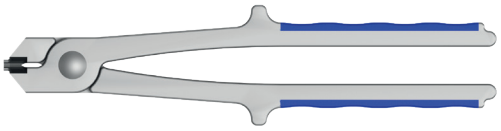


The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

It should be remembered that, after assembly of the implant *(mesh body + endplates)*, the total height of the implant will be the result of the sum of the heights of the mesh body and both endplates.

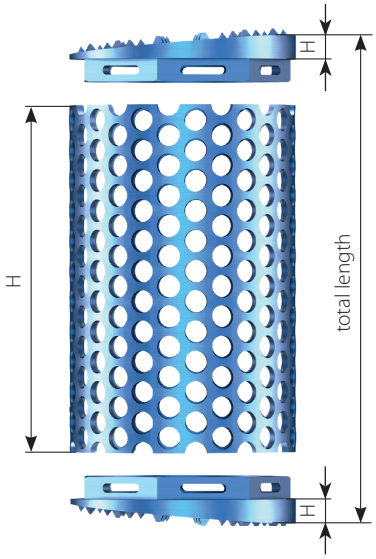
The mesh bodies can also be trimmed to the desired size using cutting pliers **[40.8645]** or wire cutting pliers 16cm hardened **[40.3176.160]** available in the instrument set.

The cut off part of the mesh body, not used in the surgical procedure, cannot be re-used *(used in another procedure)*. It should be handled in accordance with the disposal procedure for implants that came in contact with blood, tissue and/or body fluids.

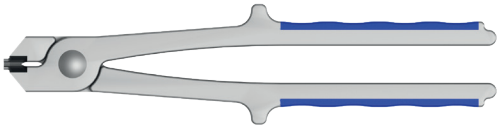


40.8645.000

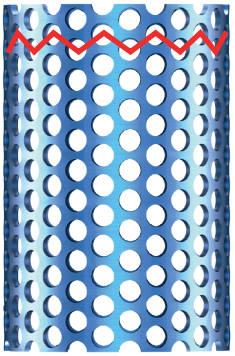
40.3176.160

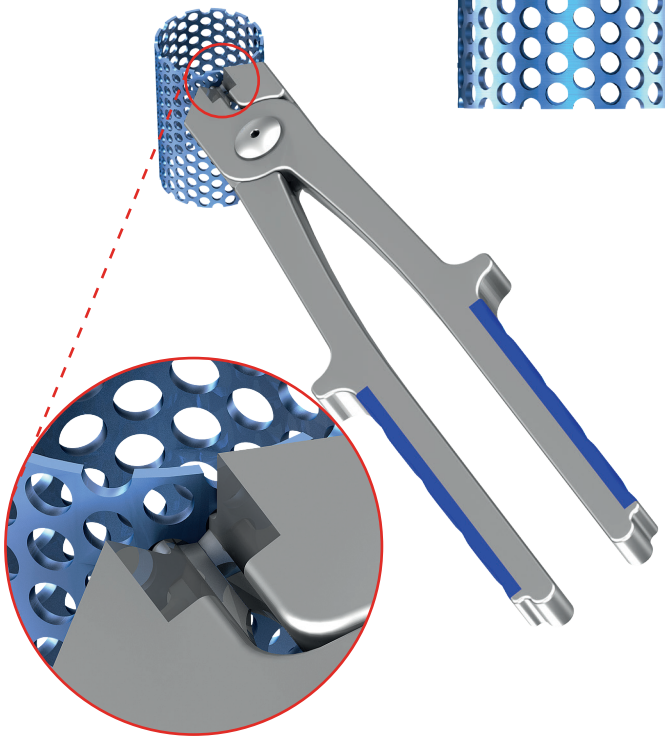


III.2.1. Use of cutting pliers [40.8645]



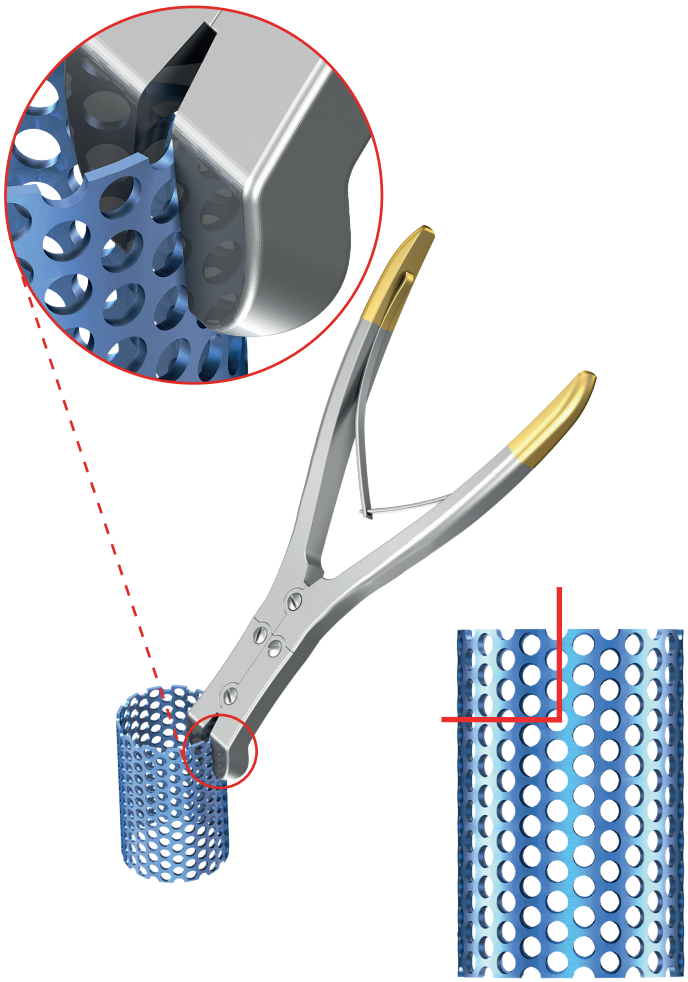
40.8645.000





III.2.2. Use of wire cutting pliers [40.3176.160]

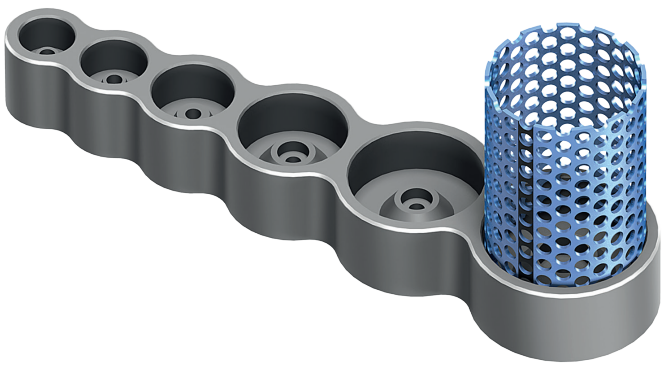
40.3176.160



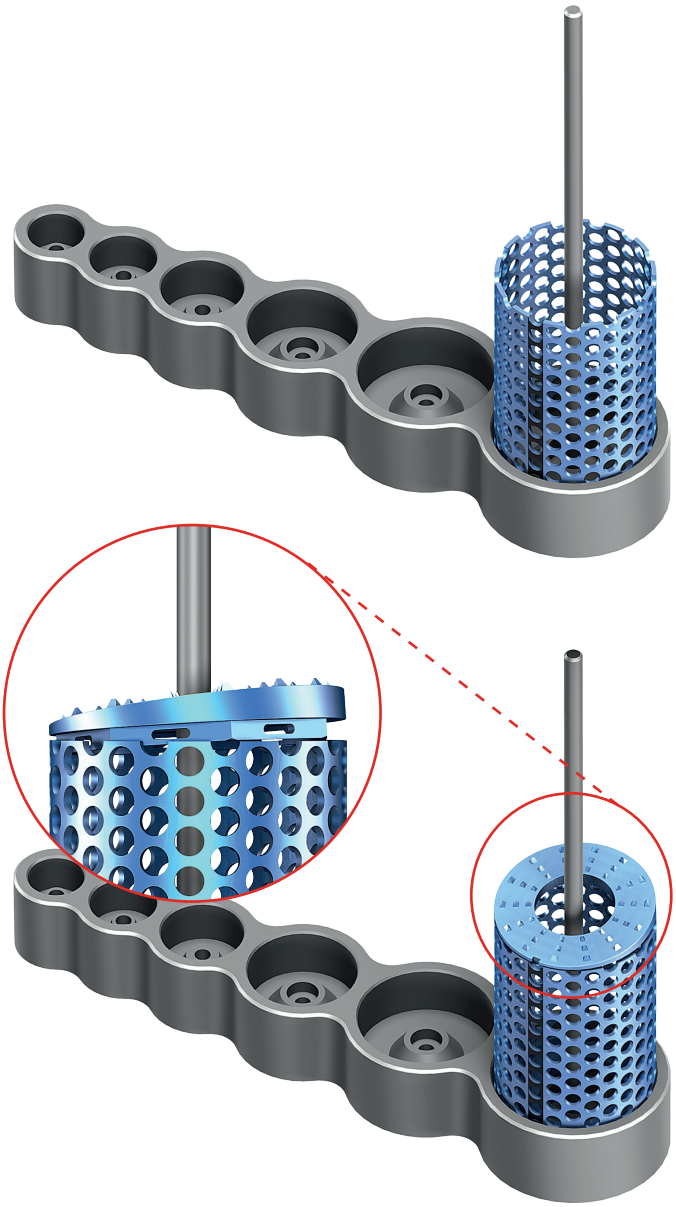
III.3. IMPLANT ASSEMBLY

Use working stand **[40.8646.100]** to assemble the mesh body and endplates. Place the mesh body in the socket of the working stand **[40.8646.100]** that corresponds to the diameter of the implant.

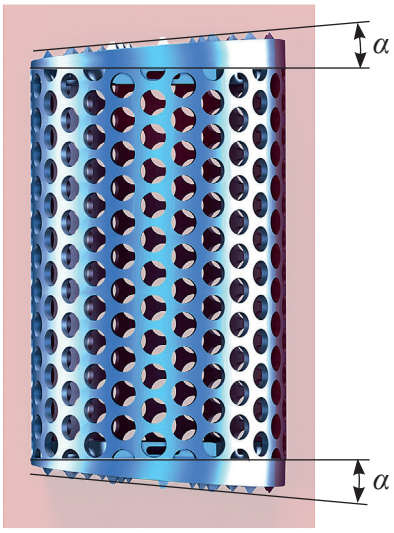
40.8646.100

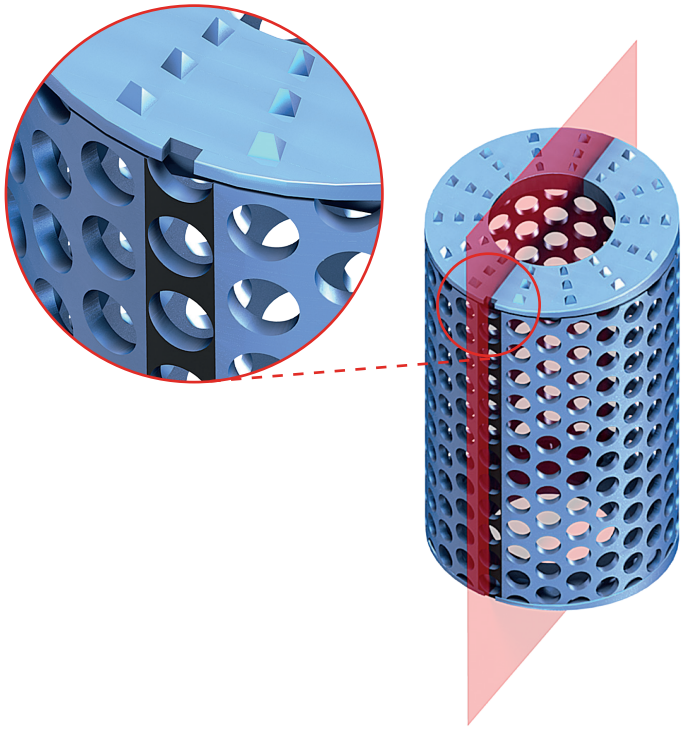


Insert the guide into the socket slot in which the mesh body has been placed. Then install the first endplate.



For angular endplates, make sure the markers on the endplate and mesh body are positioned as shown in the illustration.





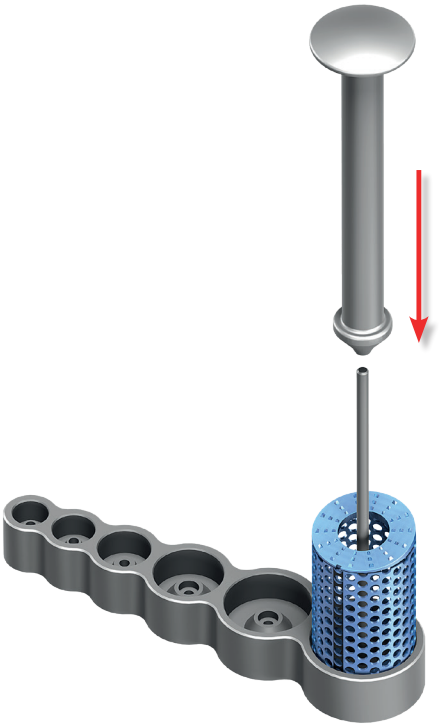
The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Position the mallet **[40.8644.100]** on the guide and with the use of the hammer **[40.6782]**, engage the endplate with the mesh body.

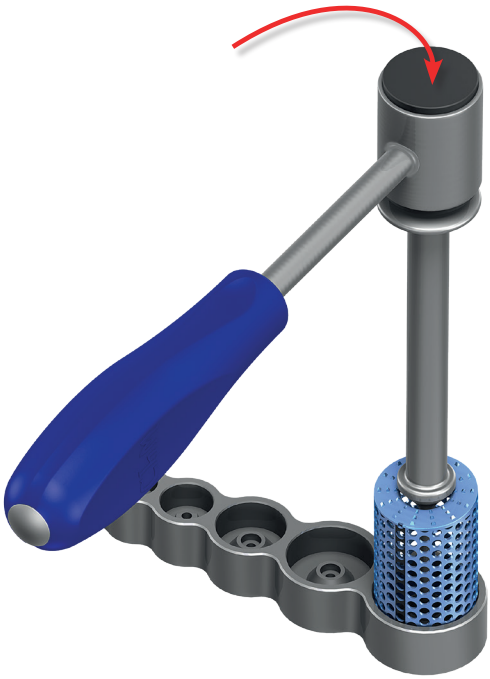

40.8644.100

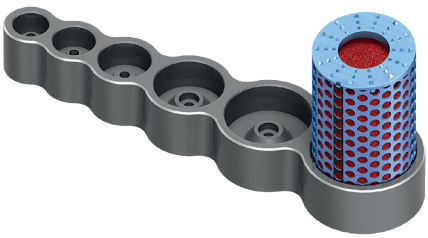

40.6782.000

Having installed the first endplate, rotate the implant by 180° and insert the other one.



Fill the assembled implant up with autologous graft or bone substitute, using the holes in the endplates.





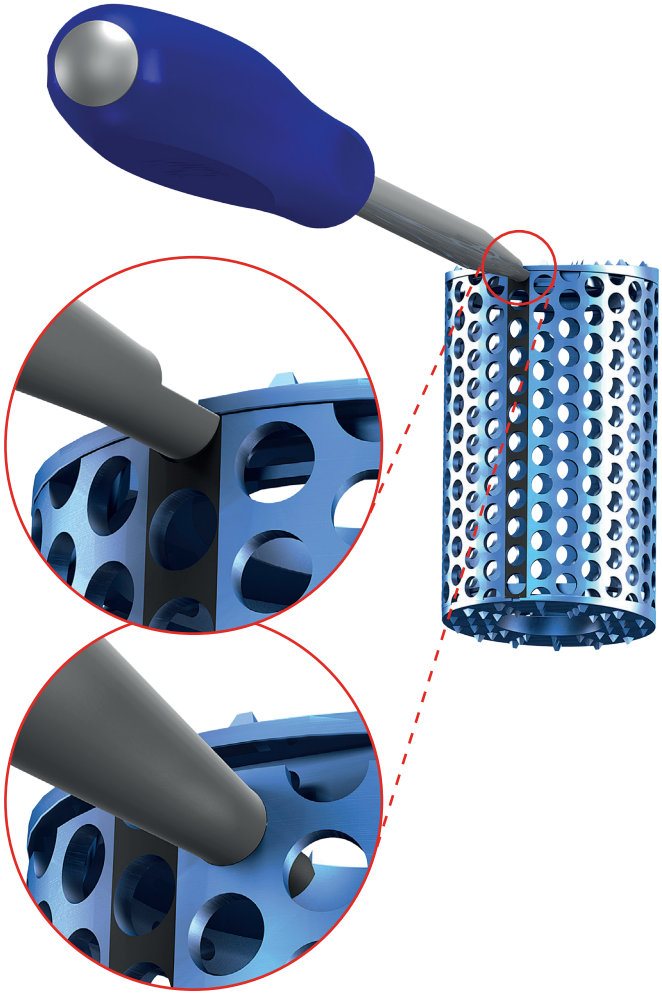
III.4. DISASSEMBLY OF THE IMPLANT

The system ensures intraoperative disassembly of endplates from the mesh body, if, e.g. the need to use a different angular version of endplates occurs.

In order to disassemble the implant, place the persuader **[40.8648.100]** tip in the mesh hole just below the endplate *(see illustration)* or in any other hole where a part of the endplate is visible and can accommodate the tip, and rotate the instrument by 90°. The procedure will cause the plate to partially slide out of the mesh body. Repeat the step in next holes until the endplate is completely disengaged.

CAUTION:
The disassembly of implant components is only permitted in exceptional cases when it is absolutely necessary *(e.g. if improper components were used)***. Repeated assembly/disassembly can significantly reduce the strength of the connection and, consequently, can lead to in vivo instability of the implant.**

40.8648.100

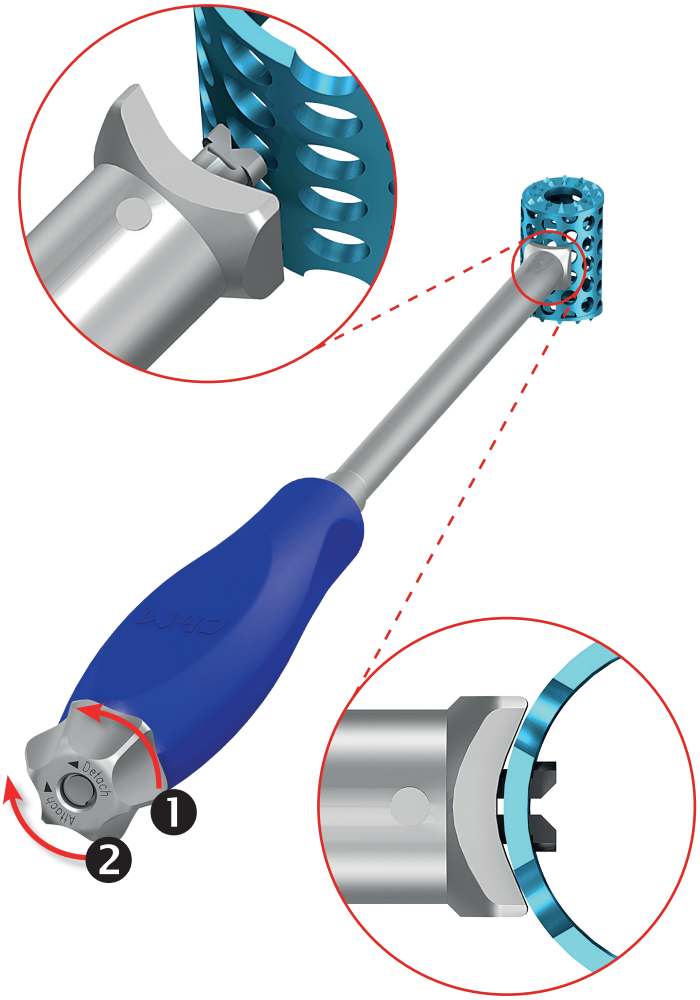


III.5. USE OF APPLICATOR

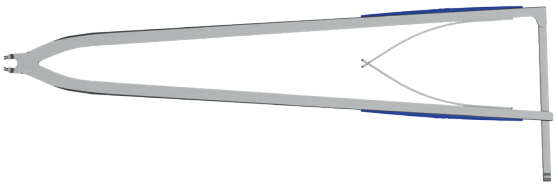
The instrument set includes two types of applicators, designed for insertion of implants into the intervertebral space.

The applicator **[40.8652.000]** is compatible with implants used for cervical and cervical-thoracic spine treatment. To install the implant on the instrument, make sure the knob is maximally at *«Detach»* position *(1)*, then insert the tip of the applicator into the hole of the mesh body and rotate the knob clockwise to *«Attach»* and lock the implant *(2)*.

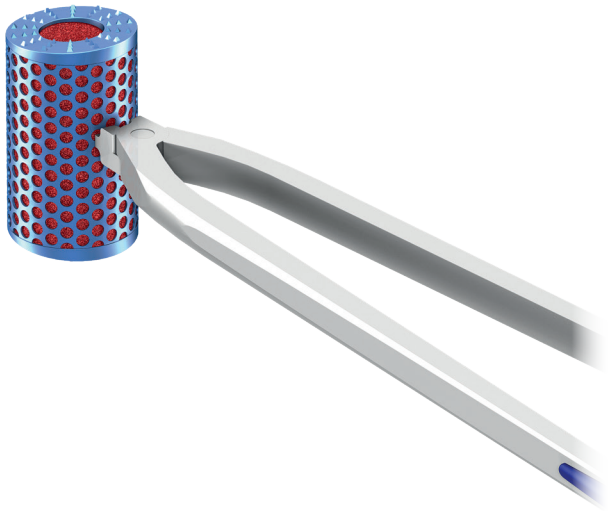
40.8652.000



The applicator **[40.8642.000]** is compatible with implants used for thoracic and lumbar spine treatment. To install the implant on the instrument, insert the tips into the mesh body holes and tighten the levers.



40.8642.000

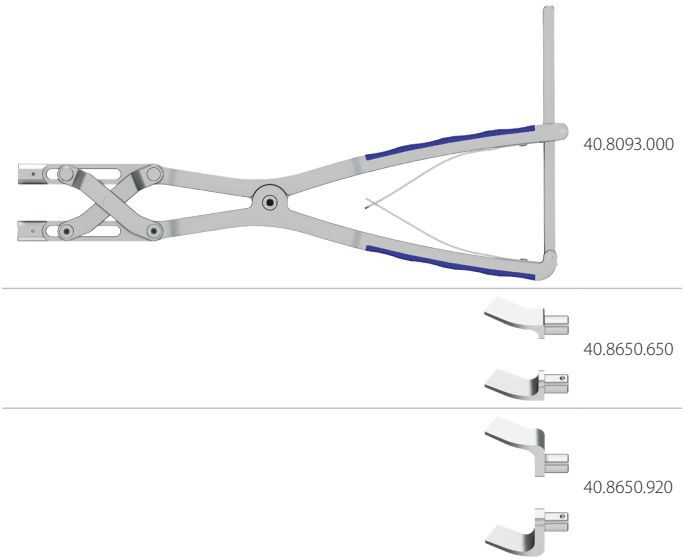


III.6. IMPLANTATION

Prior to insertion of the implant, perform distraction of the vertebral bodies using distraction forceps **[40.8093]**. The forceps are used with two sets of replaceable jaws, which are selected depending on the total height H of the implant.

Using two sets of jaws, 3 possible distraction ranges are obtained.

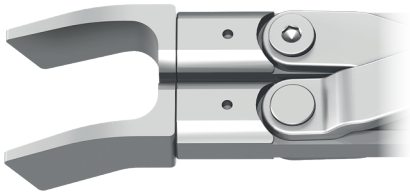
Distraction forceps-jaws **[40.8650.650]** are used for implants from 4mm up to 65mm high.
Distraction forceps-jaws **[40.8650.920]** are used for implants from 61mm up to 102mm high.



Perform distraction of the vertebral bodies adjacent to the resected one. Distraction facilitates proper implant positioning in the intervertebral space.

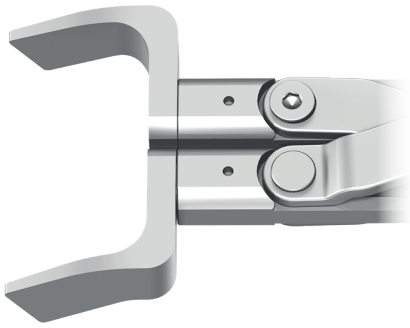
Distraction forceps-jaws 40.8650.650

1st installation method - range from 4mm to 45mm



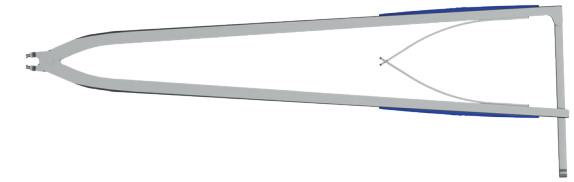
2nd installation method - range from 24mm to 65mm

Distraction forceps-jaws 40.8650.920

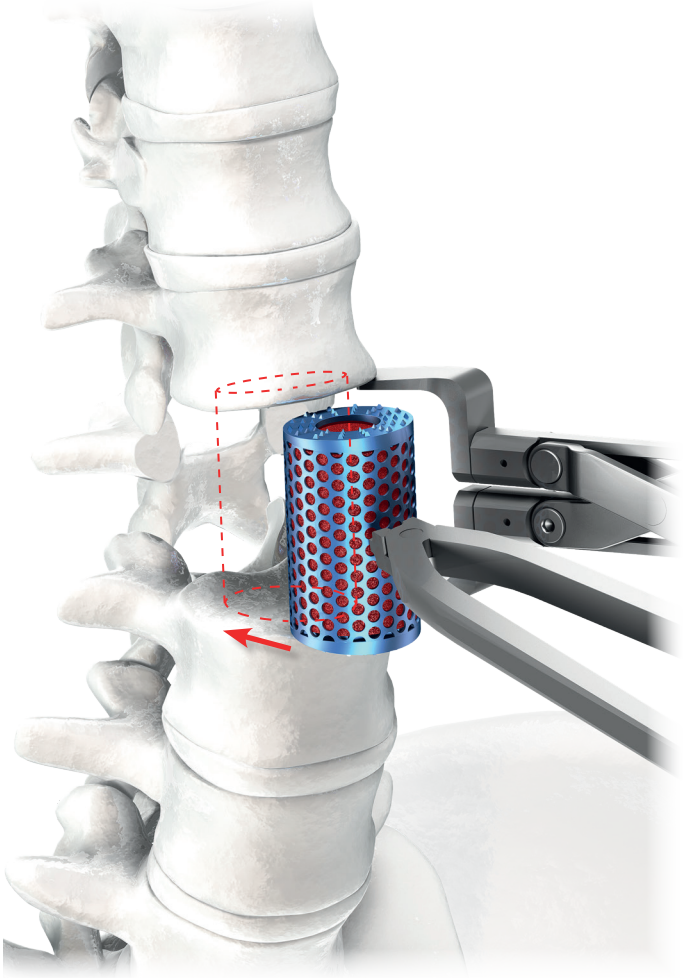


The range from 61 to 102mm

Use applicator **[40.8642]** or **[40.8652]** to insert the implant in place of the resected vertebral body. The optimal place for implant positioning is the central part of the endplates of the vertebral bodies.


40.8642.000


40.8652.000

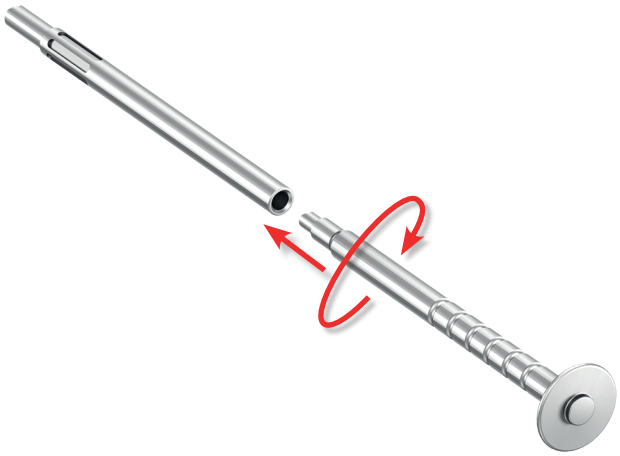


CAUTION:
If the applicator **[40.8652.000]** was used, to disengage, rotate the knob in the direction of ‚Detach' and remove the tip of the instrument from the hole.

CAUTION:
If the applicator **[40.8642.000]** was used, to disengage, loosen the levers and remove the tips from the holes.

If the implant needs to be re-positioned, the impactor **[40.8643.000]** can be used. The impactor consists of two combinable elements enabling adjustment of the instrument length to the operator's needs.

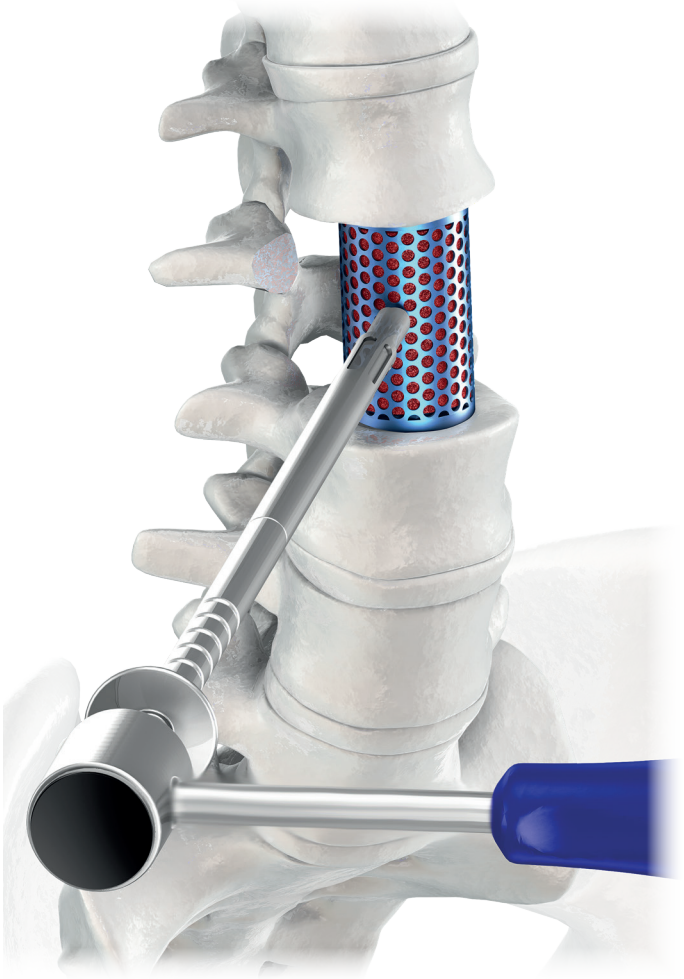

40.8643.000



Use hammer **[40.6782]** to tap the impactor **[40.8643.000]** and position the implant as desired.

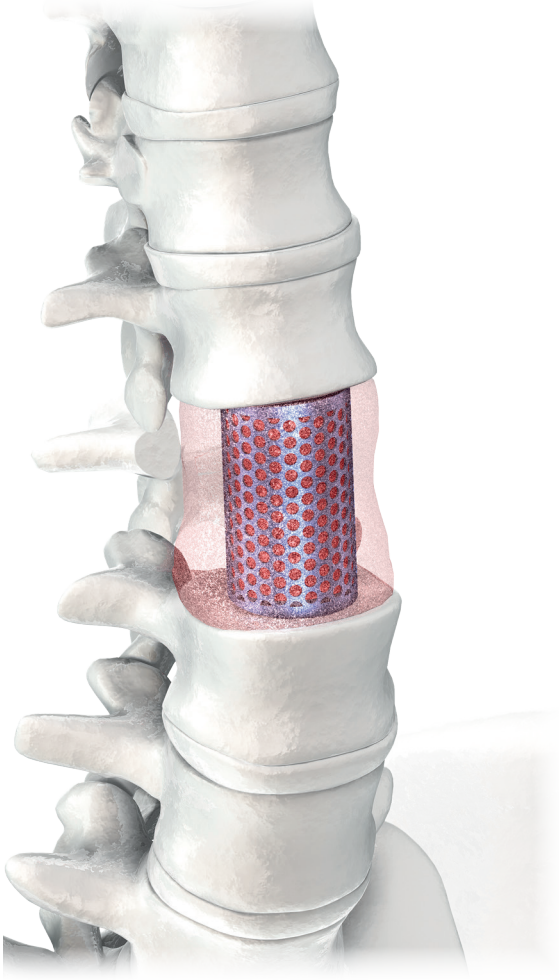

40.8643.000


40.6782.000



Supplement the space around the implant with autologous material.

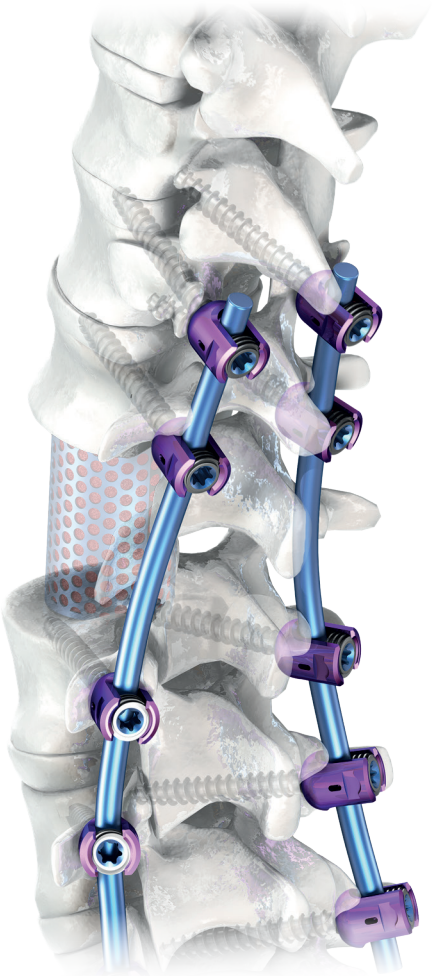
CAUTION:
When supplementing the space with autologous material, be careful not to move the implant.



IV. SUPPLEMENTARY STABILIZATION

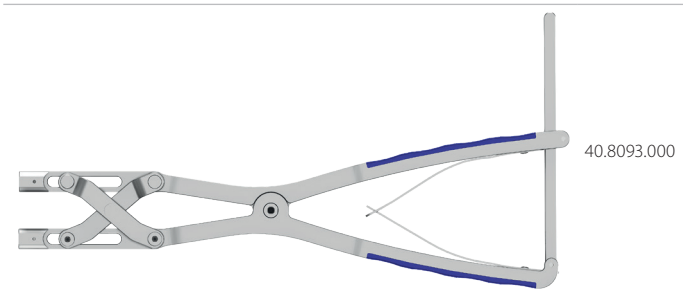
To ensure proper stability of the spine, VBR mesh implants must be used together with additional stabilization devices approved for use in spine surgeries on a given spine segment *(e.g. the* **ChM** *system of spinal screws and rods* **CHARSPINE OCT** *or* **CHARSPINE2***)*.

The additional stabilization of spine is introduced to immobilize and stiffen the treated spine and to provide additional compression to stabilize the mesh implant.

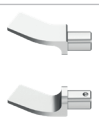


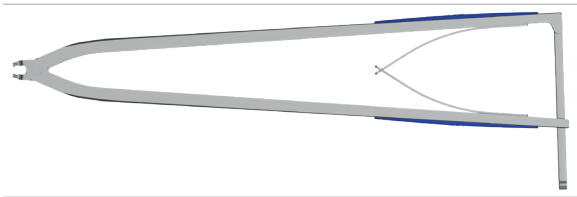
V. IMPLANT REMOVAL

Should the revision removal of the VBR mesh implant be necessary, vertebral distraction is to be performed. For distraction, use distraction forceps **[40.8093]** together with *(depending on the height of the intervertebral space)* jaws **[40.8650.650]** or **[40.8650.920]**. After distraction, remove the implant using applicator **[40.8642.000]** or **[40.8652.000]**.


40.8093.000


40.8650.650


40.8650.920


40.8642.000


40.8652.000

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

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