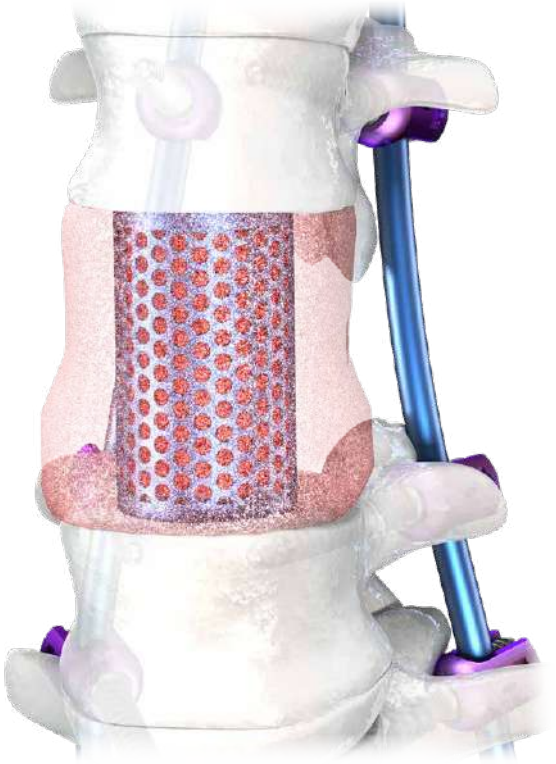
CHARSPINE system VBR
Vertebral Body Replacement System

# CHARSPINE VBR mesh implant system

- *IMPLANTS*
- *INSTRUMENT SET 15.0016.001*
- *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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| | |
|---|---|
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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 5

I.1. CONTRAINDICATIONS 5

II. IMPLANT FEATURES 6

II.1. IMPLANTS 6

II.2. INSTRUMENT SET 8

III. SURGICAL TECHNIQUE 10

III.1. PATIENT POSITIONING AND SURGICAL APPROACH 10

III.2. IMPLANT SELECTION 10

III.3. IMPLANT ASSEMBLY 12

III.4. DISASSEMBLY OF THE IMPLANT 17

III.5. USE OF APPLICATOR 18

III.6. IMPLANTATION 19

IV. SUPPLEMENTARY STABILIZATION 22

V. IMPLANT REMOVAL 23

# 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 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,

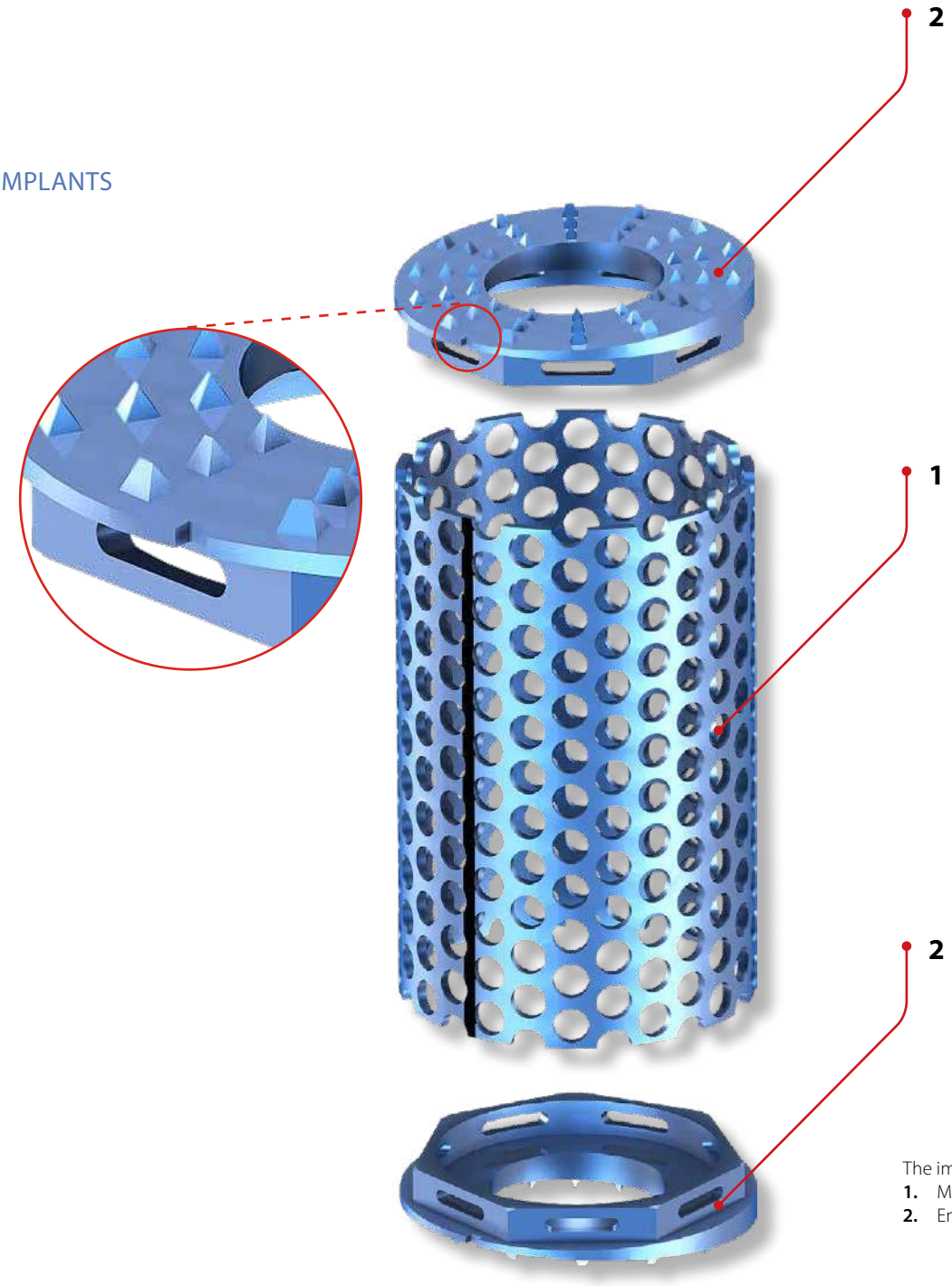
please, refer to the Instructions For Use enclosed to the implant packaging unit.

# II. IMPLANT FEATURES

The **CHARSPINE VBR** mesh implants system developed by the **ChM**, depending on the level of the 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 cutting 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 tbiocompatible 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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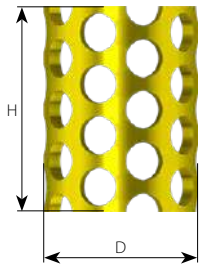
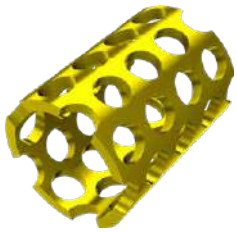
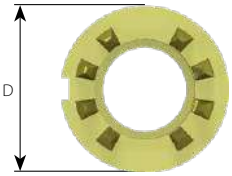
CHARSPINE system VBR
Vertebral Body Replacement System




## 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 |

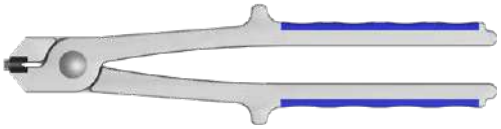
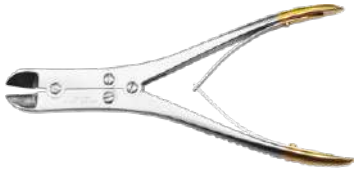
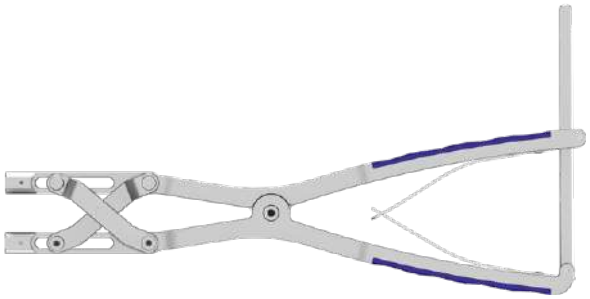
## Endplate

| α | D | H | Colour | Cat. No. |
|---|---|---|---|---|
| 0 | 10 | 0.5 | | 3.6910.000 |
| 2.5 | | 1 | | 3.6910.250 |
| 5 | | 1 | | 3.6910.500 |
| 0 | 12 | 0.5 | | 3.6911.000 |
| 2.5 | | 1 | | 3.6911.250 |
| 5 | | 1.5 | | 3.6911.500 |
| 0 | 15 | 0.5 | | 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 | 40.8646.000 | 1 |
|   | Position retainer | 40.8647.000 | 1 |
|   | Position retainer | 40.8647.025 | 1 |
|   | Position retainer | 40.8647.050 | 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 | 40.8648.000 | 1 |
|  | Trial | 40.8640.000 | 1 |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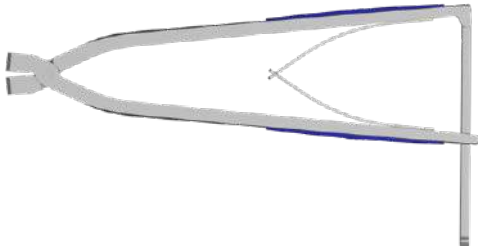
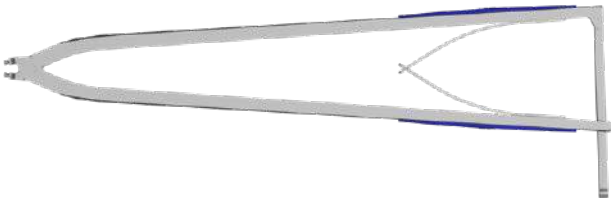
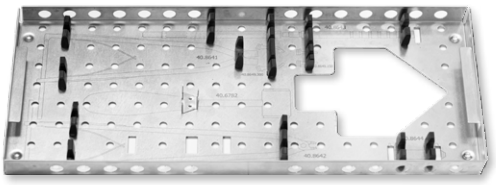
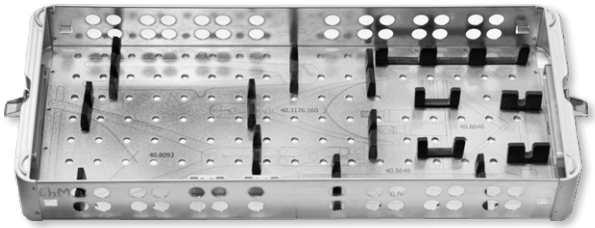
| Instrument set for VBR mesh implants | | | 15.0916.001 |
|---|---|---|---|
| | **Name** | **Catalogue no.** | **Pcs** |
|  | Impactor | 40.8643.000 | 1 |
|  | Applicator | 40.8641.000 | 1 |
|   | Holder | 40.8649.150 | 2 |
|   | Holder | 40.8649.300 | 2 |
|  | Hammer 300g | 40.6782.000 | 1 |
|  | Applicator | 40.8642.000 | 1 |
|  | Mallet | 40.8644.000 | 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:

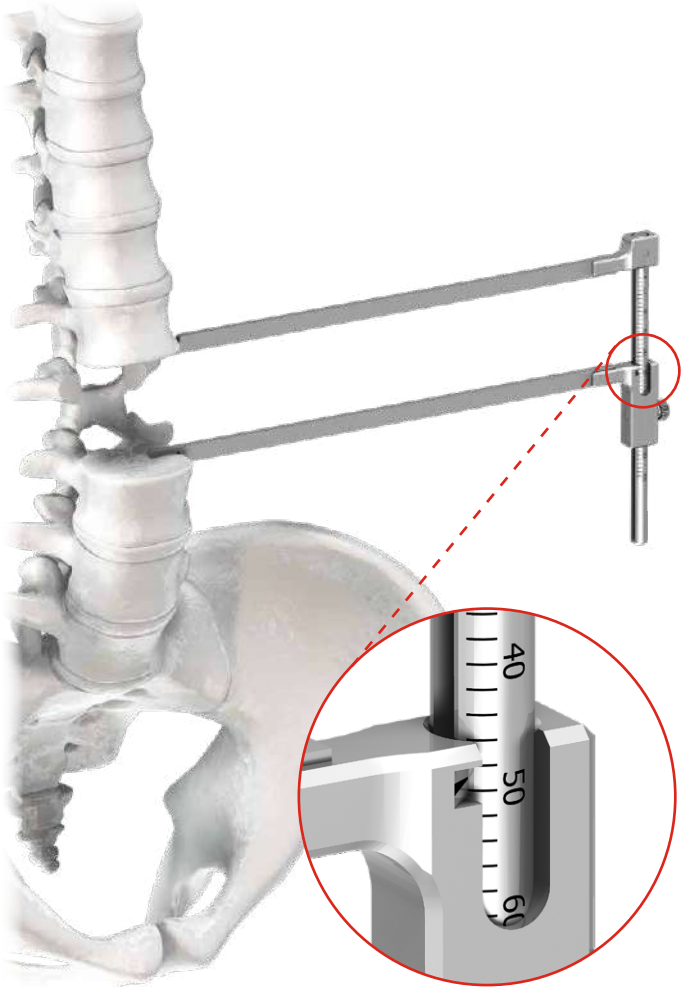
- the height of the prosthesis *(the distance between the endplate surfaces of the vertebral bodies adjacent to the body that will be removed)*,
- the inclination angle of the endplate surfaces of the vertebral bodies adjacent to the body that will be removed).

**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

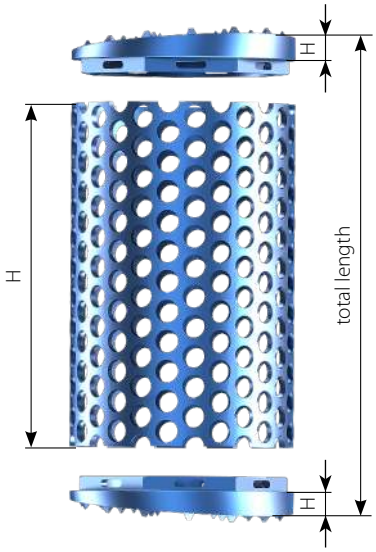




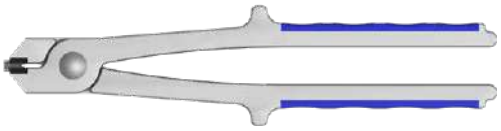

*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

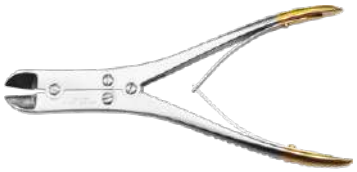
It should be remembered that, after assembly of the implant *(mesh body + endplates)*, the total height of the implant will be the result of the sum of the heights of the mesh body and both endplates.

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.

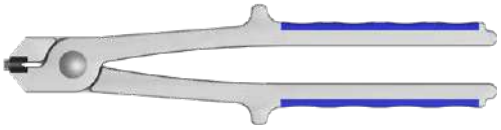


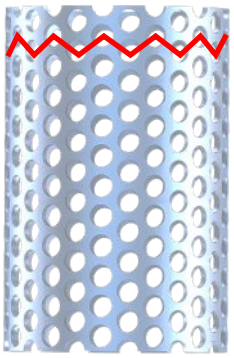

The cut off part of the mesh body, not used in the surgical procedure, cannot be re-used *(used in another procedure)*. It should be handled in accordance with the disposal procedure for implants that came in contact with blood, tissue and/or body fluids.

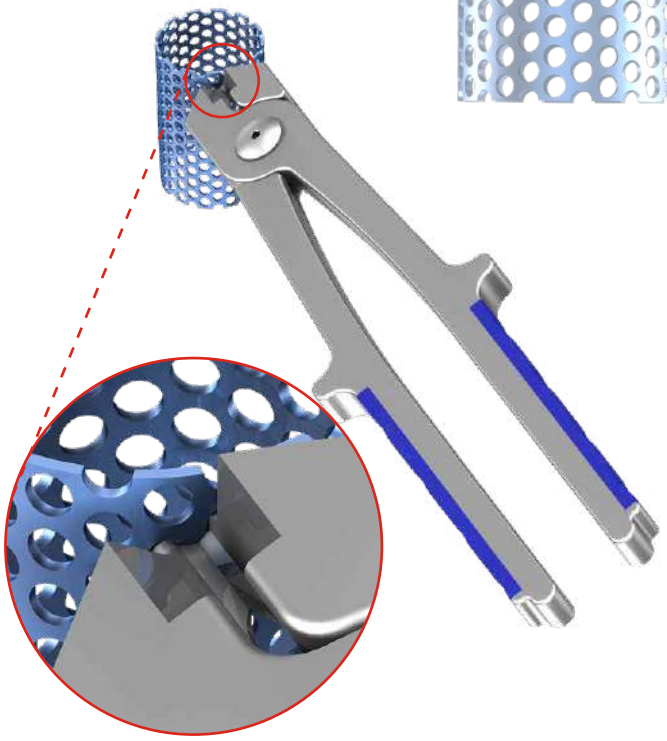

40.8645.000


40.3176.160

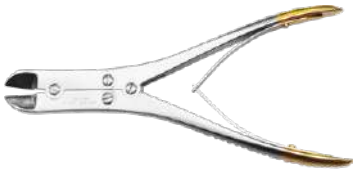
### III.2.1. Use of cutting pliers [40.8645]


40.8645.000

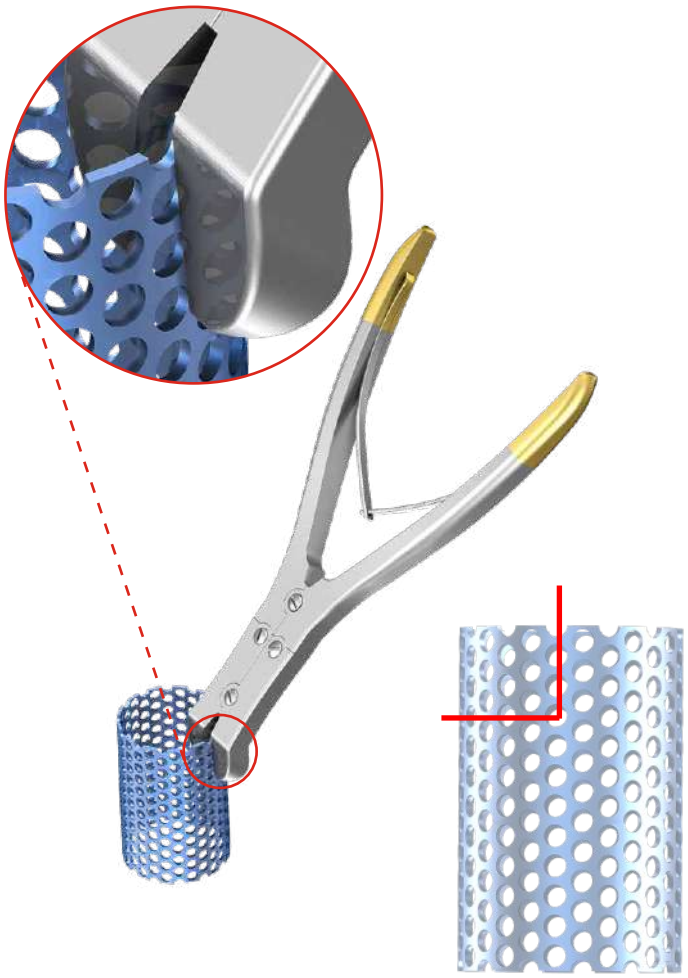




### III.2.2. Use of wire cutting pliers [40.3176.160]



40.3176.160



## III.3. IMPLANT ASSEMBLY

Use working stand **[40.8646]** to assemble the mesh body and endplates. For this purpose use the position retainer **[40.8647.000]**, **[40.8647.025]**, **[40.8647.050]** with angular version corresponding to the chosen endplates.

40.8646.000


40.8647.000


40.8647.025


40.8647.050

**Position retainer 0° [40.8647.000]**

**Position retainer 2.5° [40.8647.025]**

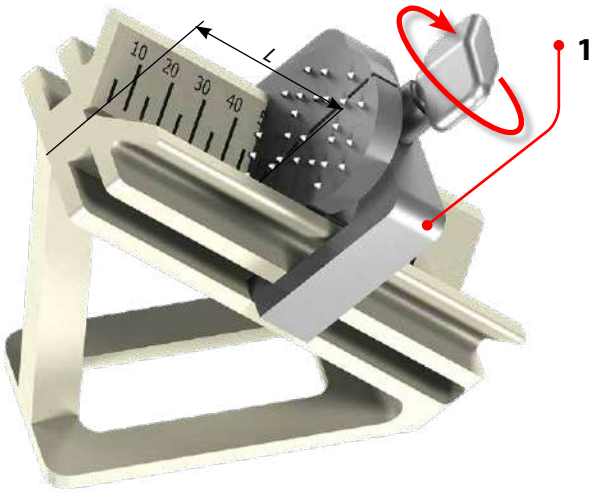
**Position retainer 5° [40.8647.050]**

Insert the chosen position retainer to the working stand **[40.8646]** as presented in the picture [1].

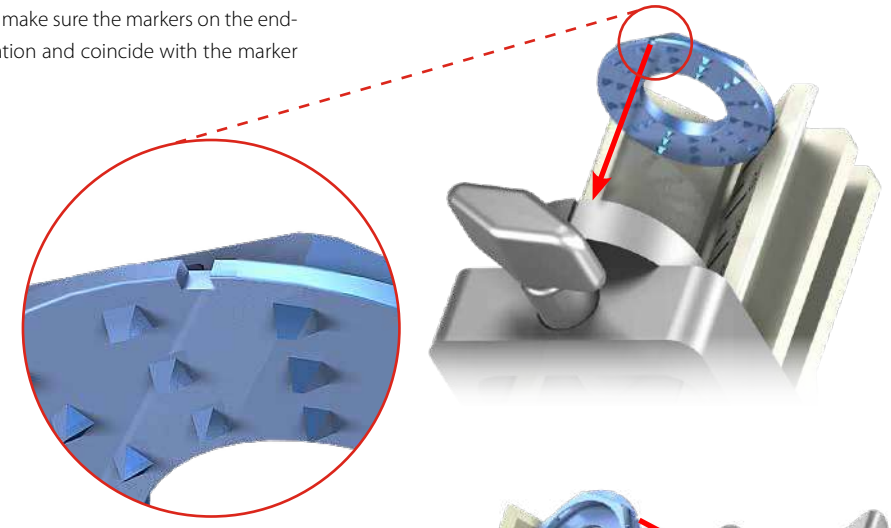
Re-position the position retainer so that the mesh body extends approx. 5mm beyond the edge of the stand *(L value)*.

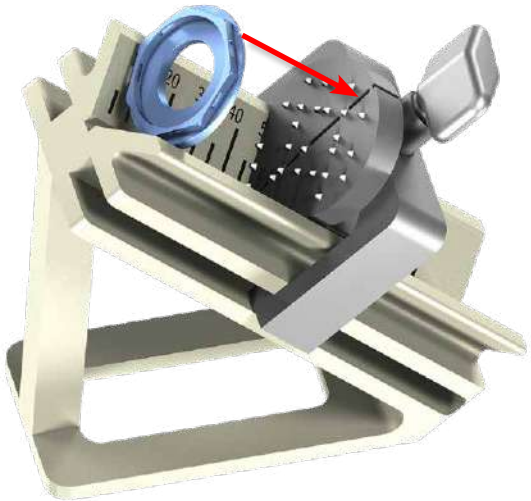
The scale marked on the stand will facilitate proper installation of the position retainer.

40.8646.000

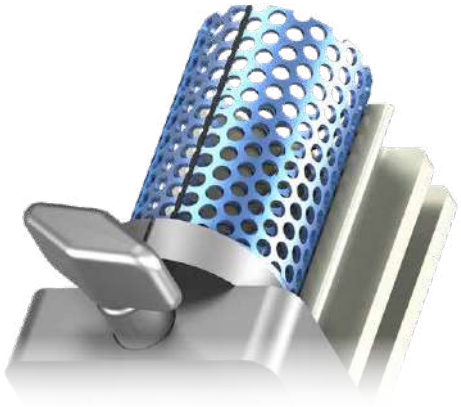



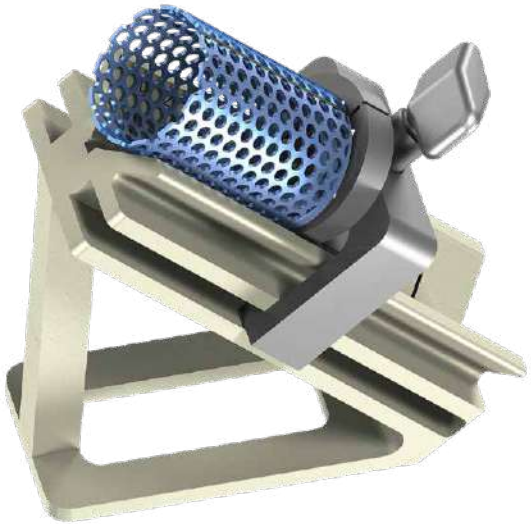

Should angular version of endplates be used, make sure the markers on the endplates are positioned as shown in the illustration and coincide with the marker on the position retainer.





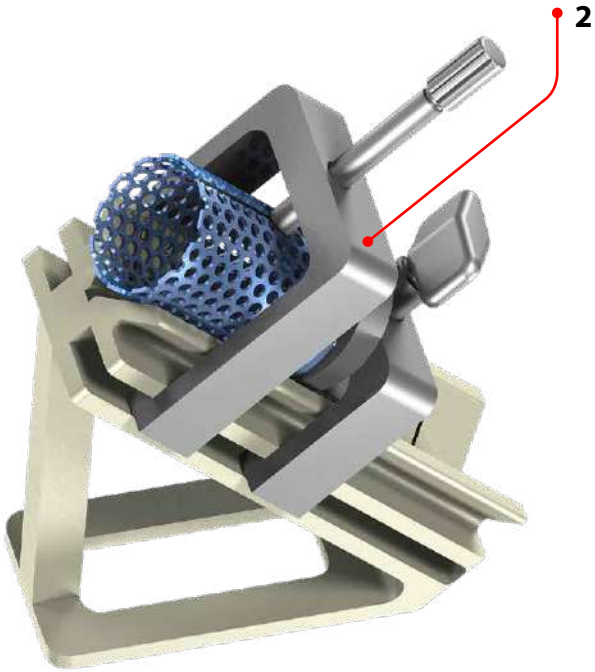
Then, place the mesh body in the working stand so that the markers on the body, endplates and position retainer are in line.
Re-position the position retainer so that the mesh body extends approx. 5mm beyond the edge of the stand.





To immobilize the mesh body in the working stand, attach the clamp [2], position it approximately halfway through the length of the implant, and then slightly tighten the fixing screw.

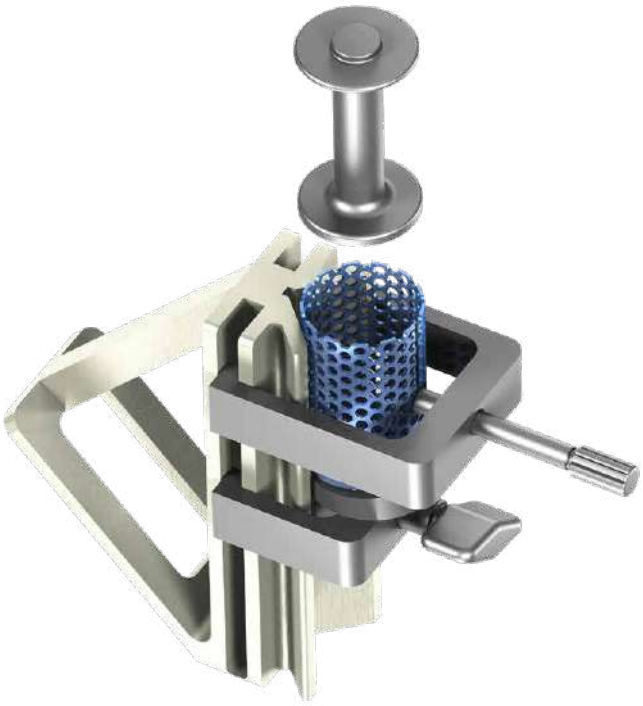
CAUTION:
Do not deform the implant by over-tightening the fixing screw.



Use mallet **[40.8644]** to connect the mesh body with the endplate.
The mallet is equipped with a conical tip and concentrically located channels. The diameters of the channels correspond to the diameters of the offered mesh bodies.

CAUTION:
Position the mallet properly on the implant so that the edge of the mesh body slides concentrically into the corresponding channel on the mallet.


40.8644.000



Having positioned the mallet **[40.8644]**, use the hammer **[40.6782]** and lightly tap the mesh body into the endplate.

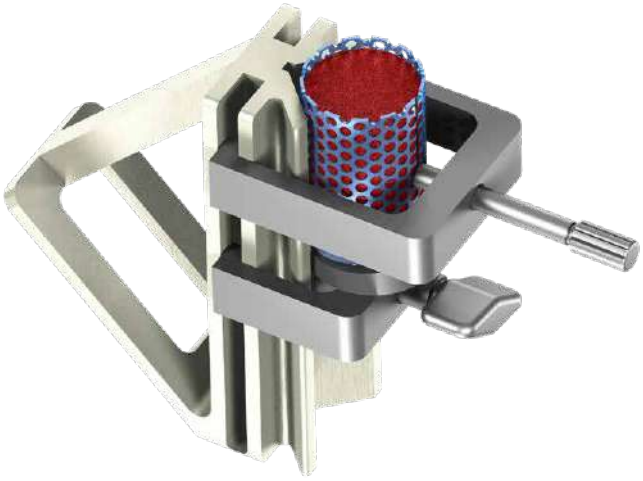
For easier implants assembly, the working stand **[40.8646]** can be positioned so that the mesh body is perpendicular to the ground.


40.8644.000


40.6782.000


40.8646.000

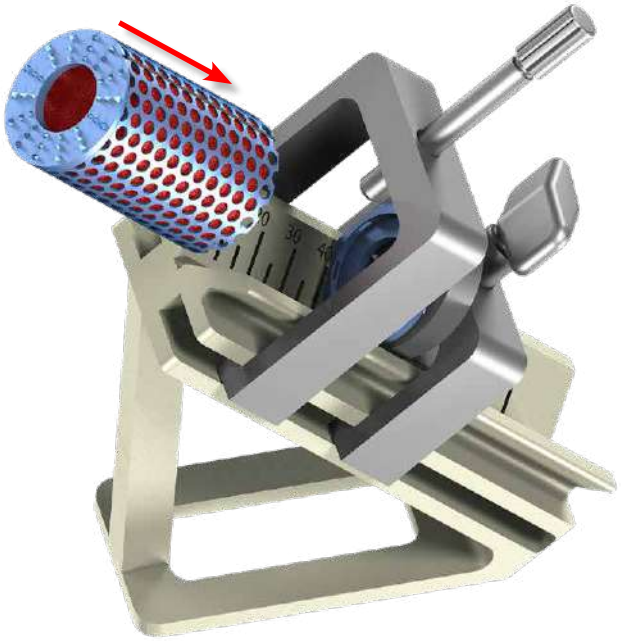
After mounting the first endplate, fill the mesh body with an autogenous graft and compress it gently. The bone graft should reach a height of about 2-3mm lower than the height of the mesh body.



Having packed the graft, release the implant, install the other endplate on the stand, rotate the body by 180°, set the clamp [2] and lock the body with the fixing screw.

CAUTION:
Should the other endplate have a different angle of inclination than the first one, the position retainer should be replaced with a corresponding one.

CAUTION:
When mounting the other endplate, make sure the implants are positioned correctly on the working stand.

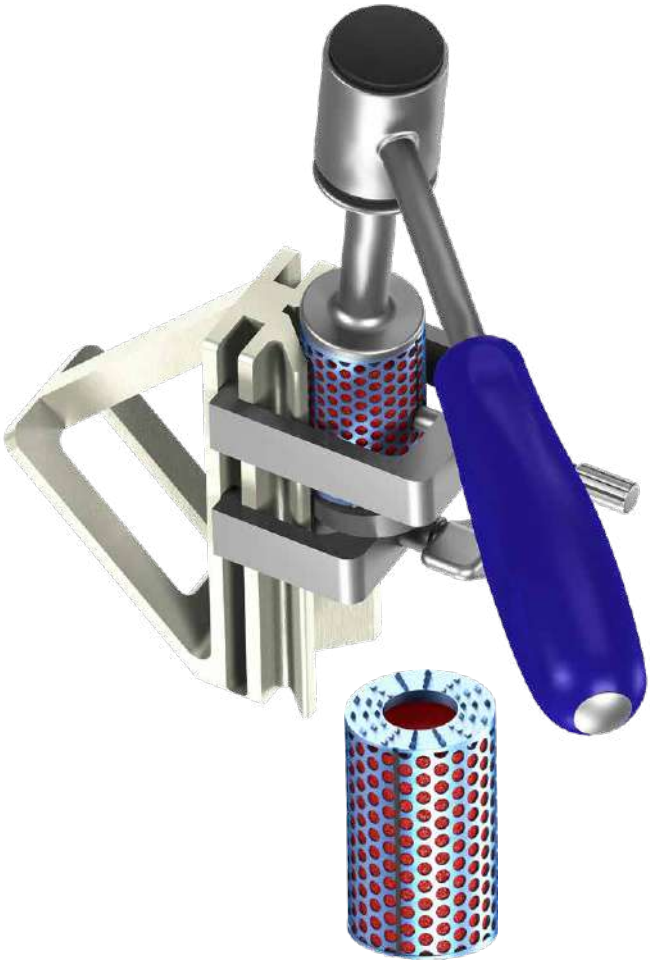


Use mallet **[40.8644]** and hammer **[40.6782]** to insert the other endplate.

If necessary, fill the implant with an additional autogenous graft after installing the other endplate using the central holes in the endplates.


40.8644.000


40.6782.000



## III.4. DISASSEMBLY OF THE IMPLANT

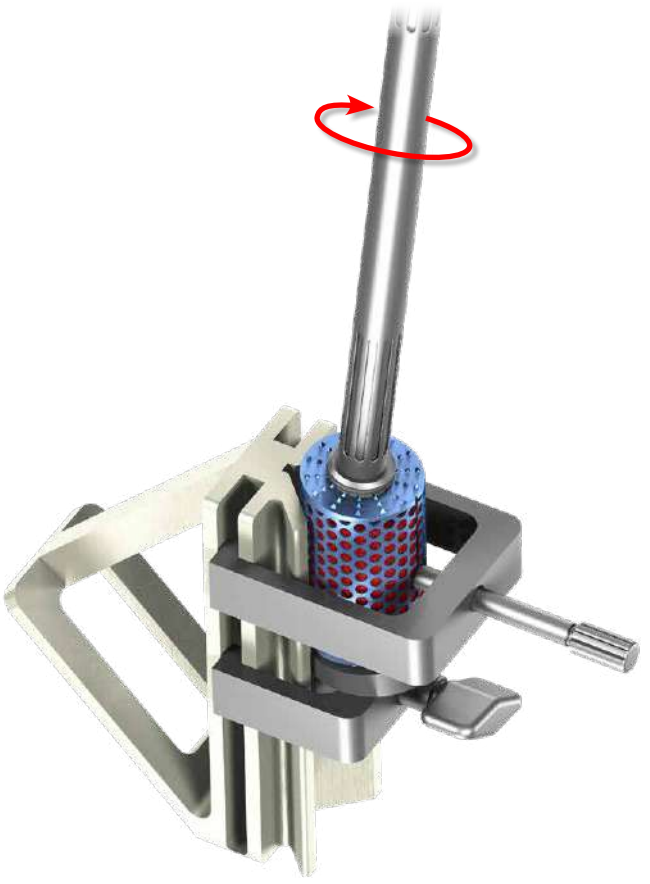
The system ensures intraoperative disassembly of endplates from the mesh body, if, e.g. the need to use a different angular version of endplates occurs.

For this purpose, place the already assembled implant back on the working stand, insert the persuader **[40.8648]** into the central hole of the endplate, and, with swinging movements, remove the endplate from the mesh body.

The persuader **[40.8648]** is equipped with two different cones. The smaller one is used for endplates with diameters of 10, 12, 13 and 15mm. The larger one is used for 20, 25, 30mm diameter implants.

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.

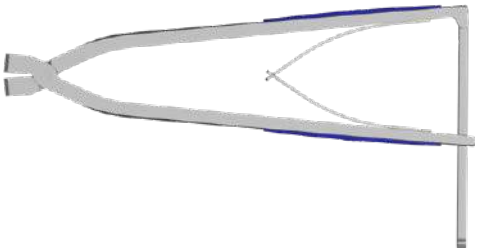

40.8648.000



## III.5. USE OF APPLICATOR

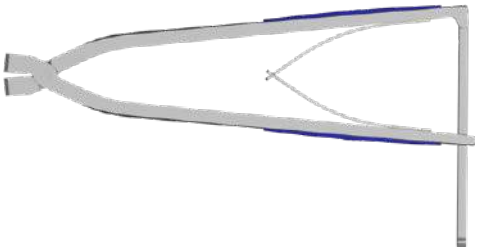
The instrument set includes two types of applicators, designed for insertion of implants into the intervertebral space.

The applicator **[40.8641.000]** is designed for use on the outer diameter of mesh bodies and with two sizes of interchangeable holders.



40.8641.000

Prior to use, install the appropriate holders to the applicator **[40.8641.000]** and then grasp the implant.



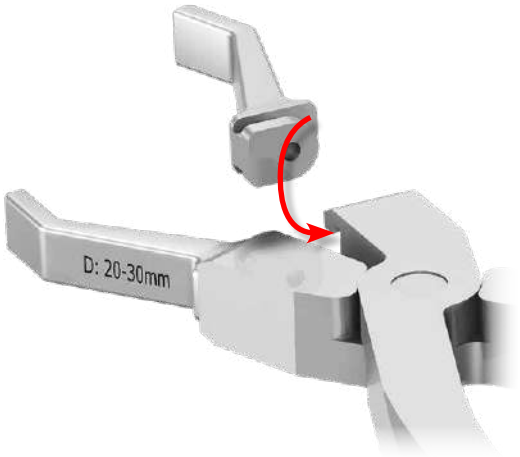
40.8641.000

**Holder 40.8649.150**

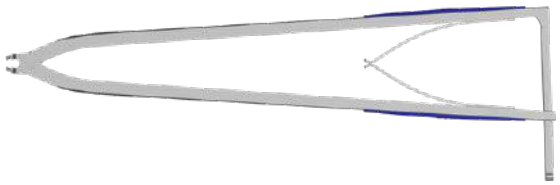

For implants with a diameter of 7-15mm

**Holder 40.8649.300**


For implants with a diameter of 20-30mm

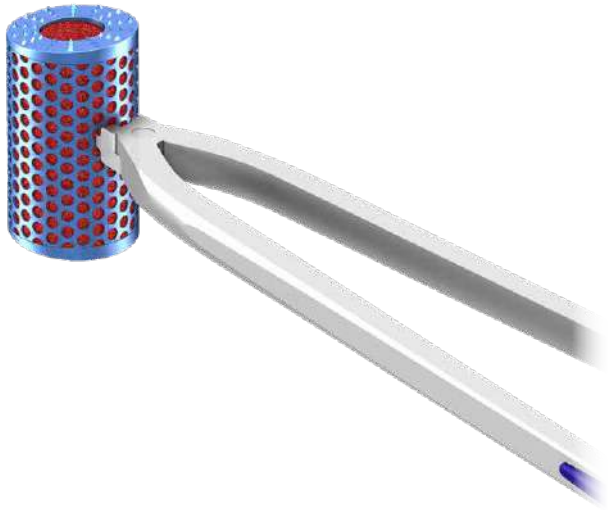



The applicator **[40.8642.000]**, on the other hand, has tips intended to be placed in the holes of the mesh body. To install the implant on the applicator, insert the tips into the body holes and tighten the levers.



40.8642.000

CAUTION:
The applicator **[40.8642.000]** should be used with mesh bodies greater than 7mm.

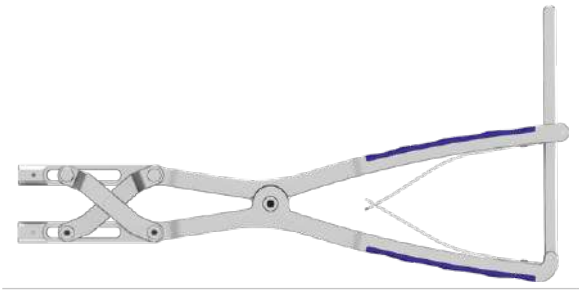


## III.6. IMPLANTATION

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 120mm high.

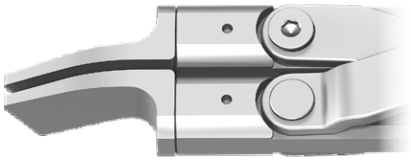


40.8093.000

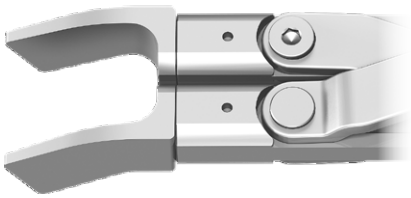
40.8650.650

40.8650.920

**Distraction forceps-jaws 40.8650.650**

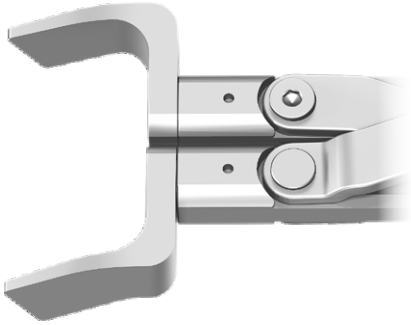


1st installation method - range from 4mm to 45mm



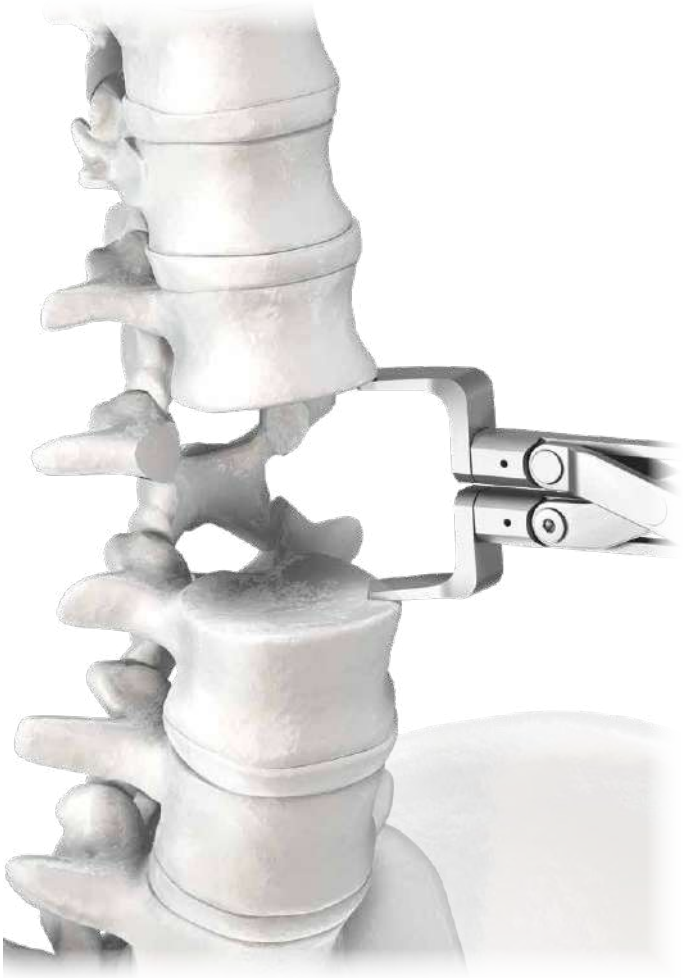
2nd installation method - range from 24mm to 65mm

**Distraction forceps-jaws 40.8650.920**

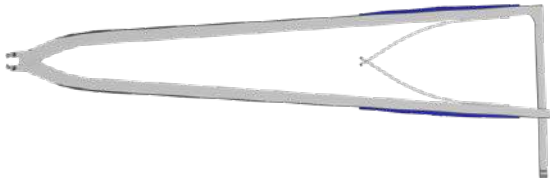


The range from 61 to 102mm

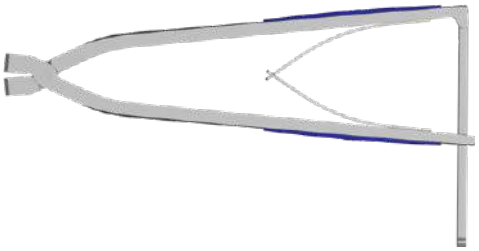
Perform distraction of the vertebral bodies adjacent to the resected one. Distraction facilitates proper implant positioning in the intervertebral space.



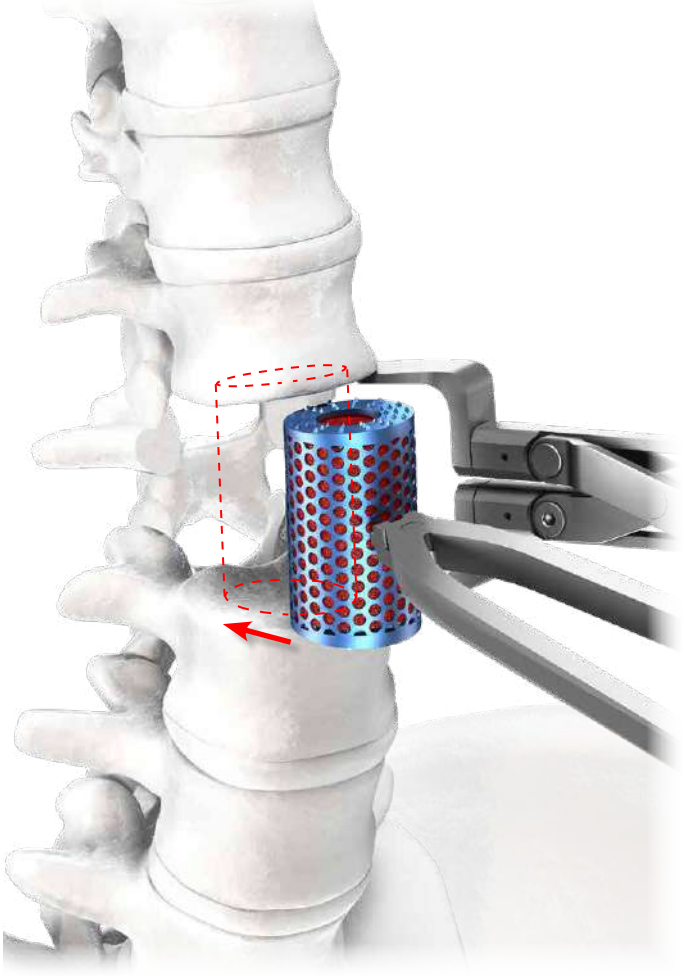
Use applicator **[40.8642]** or **[40.8641]** to insert the implant in place of the resected vertebral body. The optimal place for implant placement is the central part of the endplates of the vertebral bodies.



40.8642.000

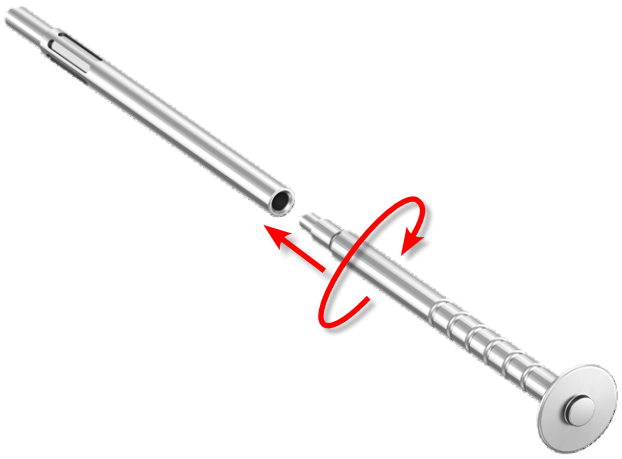


40.8641.000



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.

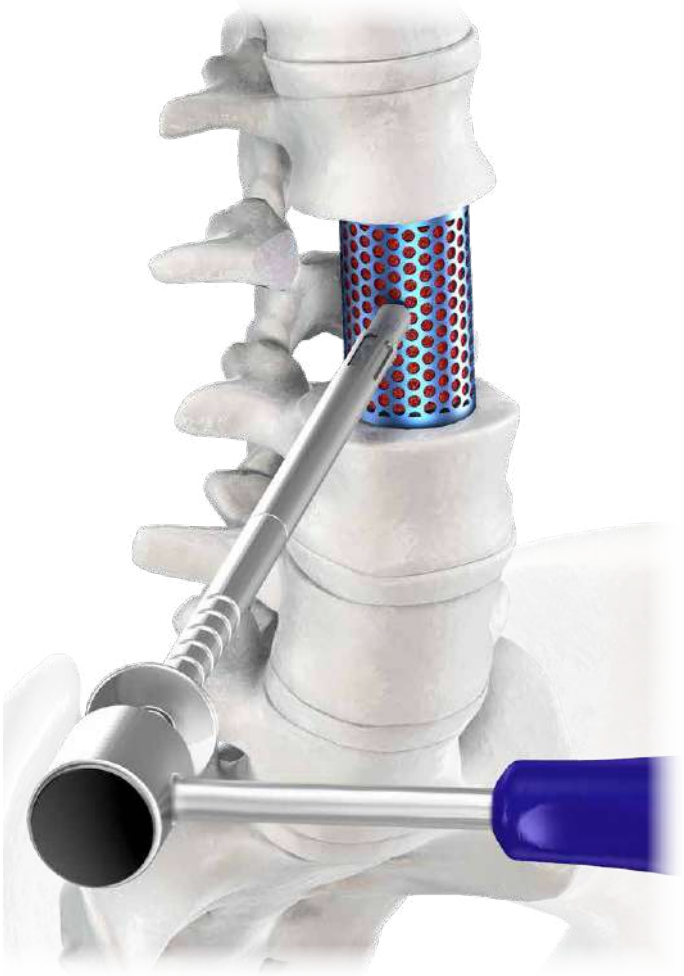

40.8643.000



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

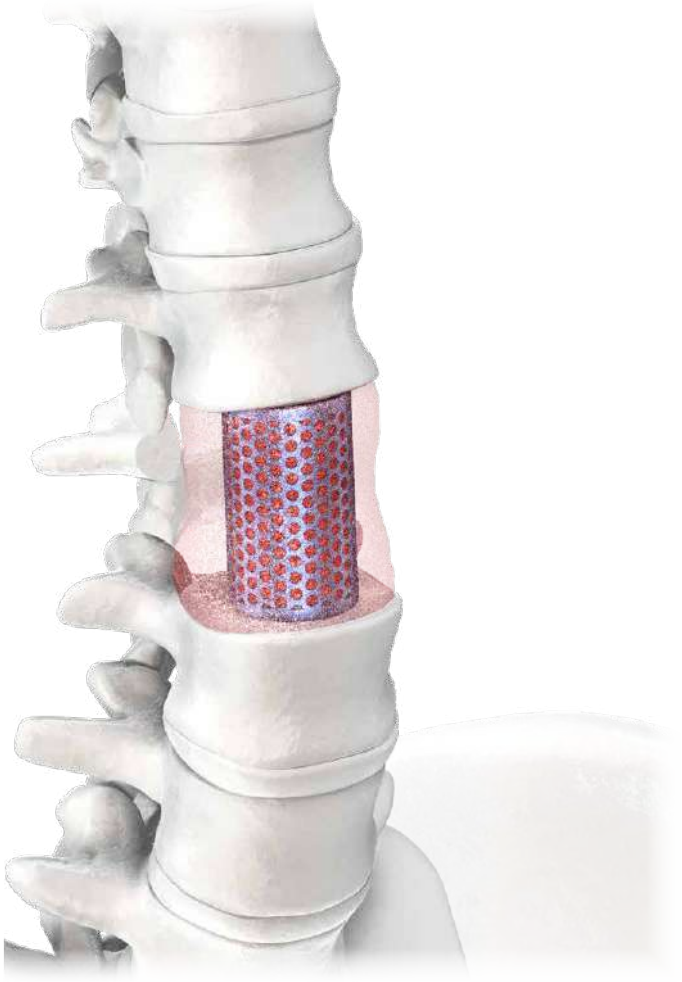

40.8643.000


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***).*

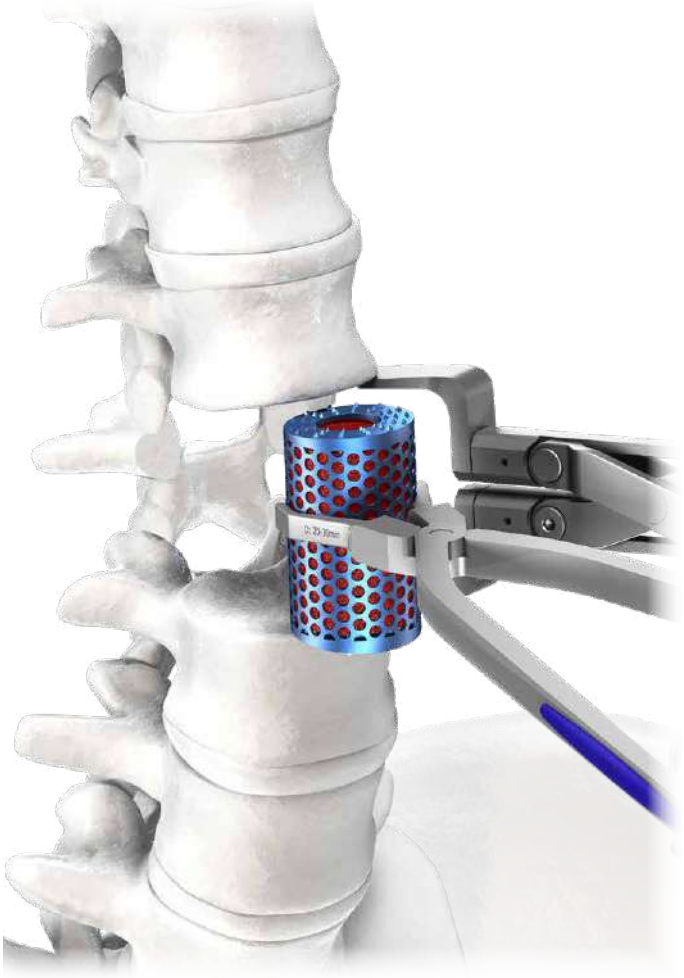
The additional stabilization of spine is introduced to immobilize and stiffen the treated spine and to provide additional compression to stabilize the mesh implant.

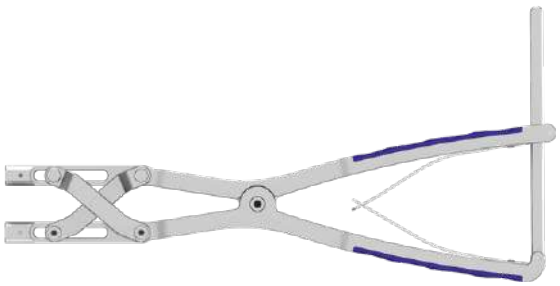


*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

## 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 **[40.8641.000]** assembled with the holder **[40.8649.150]** or **[40.8649.300]**, depending on the diameter of the implant.

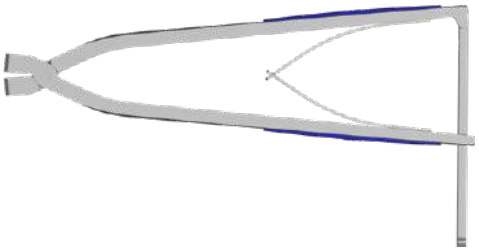




40.8093.000

40.8650.650

40.8650.920



40.8641.000


40.8649.150

40.8649.300

**ChM sp. z o.o.**
Lewickie 3b
16-061 Juchnowiec Kościelny
Polska
tel. +48 85 86 86 100
fax +48 85 86 86 101
chm@chm.eu
www.chm.eu

CE 0197