ST/66C

ChM®

CERVICAL INTERVERTEBRAL CAGE

- *IMPLANTS*
- *INSTRUMENTS 15.0902.001*
- *SURGICAL TECHNIQUE*

www.chm.eu

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.

www.chm.eu

Document No ST/66C

Date of issue 21.10.2024

Review date P-001-18.04.2025

The manufacturer reserves the right to introduce design changes.

Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

I. SYSTEM DESCRIPTION

I.1. INDICATION

Cervical intervertebral cage, and dedicated instruments, are designed for the surgical treatment of the cervical spine diseases at the levels from C3 to C7, where spinal arthrodesis is advisable. Cervical spine diseases include:

- hernias,
- Degenerative Disc Diseases *(DDD)*,
- vertebrae instabilities,
- re-operations,
- degenerative scoliosis.

(The above list is not exhaustive).

It is not recommended to use the system in case of:

- spine tumors,
- bad physical and mental state of the patient,
- osteoporosis,
- allergy or intolerance to polyetheretherketone *(PEEK Optima)* or tantalum,
- spine infections,
- vertebral fractures.

(The above list is not exhaustive).

II. IMPLANTS

ChM implants have been designed for the best fit to the anatomical shapes of the cervical spine, to maximize their safety.
The arc-shaped anterior wall of the implant imitates the curvature of the anterior part of the vertebral body maximizing the contact surface of the implant with the endplates and eliminating the risk of protruding beyond the line of the bodies.
The posterior concavity also ensures the maximum contact surface of the implant with the endplates, minimizing the danger of the pressure being exerted by the cage on the spinal cord.
The concave arches of the side walls prevent the vertebral bodies from resting only on the side edges of the cage. Moreover, the cages are offered in a variant with spikes, effectively protecting the cage against migration.

All types and sizes of cervical intervertebral cages differing in size, height and shape of contact surfaces are presented below.
All sizes and varieties of cervical intervertebral cages are made of highly biocompatible materials, PEEK and titanium alloy. For the manufacture of the latter, the additive manufacturing technique with use of Selective Laser Melting *(SLM)* technology *(3D)* is used.

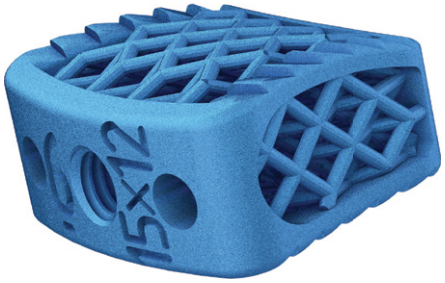
Depending on the material used, specific properties of implants are obtained:

PEEK

- Stiffness approximates the host bone, which provides ideal load sharing attributes.
- Radiolucentcy of PEEK polymer offers an accurate visualization and assessment of the fusion.
- Radioopaque tantalum markers facilitate intraoperative X-Ray visualization of inserted implant.
- Open design for bone tissue ingrowth.

Titanium alloy

- A spatial structure for bone tissue ingrowth.
- High osseointegration with bone structures.

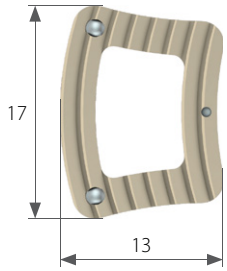


For quick identification, each implant is marked with the size and shape.

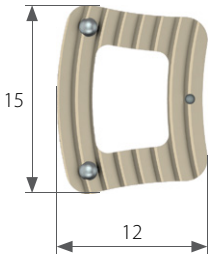
ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 86 86 100, fax + 48 85 86 86 101, chm@chm.eu, www.chm.eu

II.1. AVAILABLE SIZES AND VARIANTS

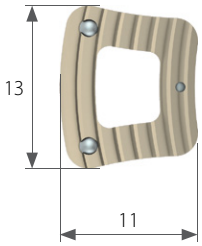
Overall dimensions [mm]



17x13

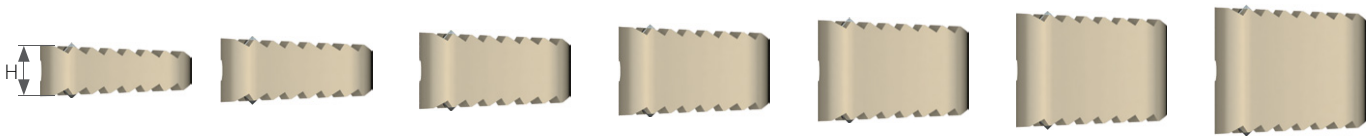


15x12



13x11

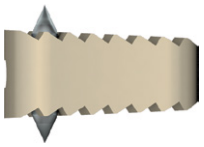
Height sizes H [mm]



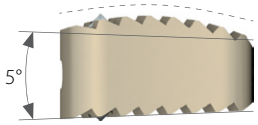
4 5 6 7 8 9 10

Variants

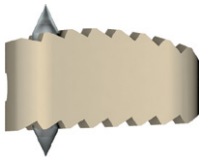
Angular



Angular with spikes



Convex



Convex with spikes

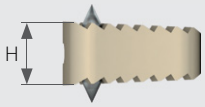
CAUTION: the above sizes and variants apply to both cages made of PEEK and titanium alloy.

PEEK cervical intervertebral cages are available non-sterile and sterile.
For sterile implants, add suffix „*S*" to the catalog number (*e.g. 8.4556.007S*)

Angular cervical intervertebral cage

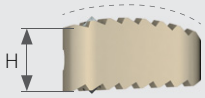
Size 17x13 [mm]		Size 15x12 [mm]		Size 13x11 [mm]	
Catalogue no.	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]
8.8202.004	4	8.8201.004	4	8.8200.004	4
8.8202.005	5	8.8201.005	5	8.8200.005	5
8.8202.006	6	8.8201.006	6	8.8200.006	6
8.8202.007	7	8.8201.007	7	8.8200.007	7
8.8202.008	8	8.8201.008	8	8.8200.008	8
8.8202.009	9	8.8201.009	9	8.8200.009	9
8.8202.010	10	8.8201.010	10	8.8200.010	10

Angular cervical intervertebral cage *(with spikes)*



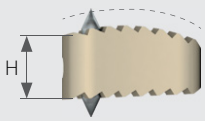
Size 17x13 [mm]		Size 15x12 [mm]		Size 13x11 [mm]	
Catalogue no.	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]
8.8205.004	4	8.8204.004	4	8.8203.004	4
8.8205.005	5	8.8204.005	5	8.8203.005	5
8.8205.006	6	8.8204.006	6	8.8203.006	6
8.8205.007	7	8.8204.007	7	8.8203.007	7
8.8205.008	8	8.8204.008	8	8.8203.008	8
8.8205.009	9	8.8204.009	9	8.8203.009	9
8.8205.010	10	8.8204.010	10	8.8203.010	10

Convex cervical intervertebral cage



Size 17x13 [mm]		Size 15x12 [mm]		Size 13x11 [mm]	
Catalogue no.	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]
8.8208.004	4	8.8207.004	4	8.8206.004	4
8.8208.005	5	8.8207.005	5	8.8206.005	5
8.8208.006	6	8.8207.006	6	8.8206.006	6
8.8208.007	7	8.8207.007	7	8.8206.007	7
8.8208.008	8	8.8207.008	8	8.8206.008	8
8.8208.009	9	8.8207.009	9	8.8206.009	9
8.8208.010	10	8.8207.010	10	8.8206.010	10

Convex cervical intervertebral cage *(with spikes)*



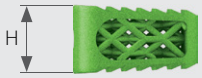
Size 17x13 [mm]		Size 15x12 [mm]		Size 13x11 [mm]	
Catalogue no.	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]
8.8211.004	4	8.8210.004	4	8.8209.004	4
8.8211.005	5	8.8210.005	5	8.8209.005	5
8.8211.006	6	8.8210.006	6	8.8209.006	6
8.8211.007	7	8.8210.007	7	8.8209.007	7
8.8211.008	8	8.8210.008	8	8.8209.008	8
8.8211.009	9	8.8210.009	9	8.8209.009	9
8.8211.010	10	8.8210.010	10	8.8209.010	10

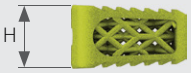
Material: PEEK-OPTIMA®

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

3D-Ti cervical intervertebral cages are available sterile only.

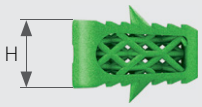
3D-Ti Angular cervical intervertebral cage

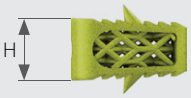


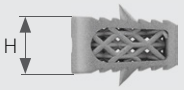


Size 17x13 [mm]		**Size 15x12** [mm]		**Size 13x11** [mm]	
Catalogue no.	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]
3.8117.004S	4	3.8116.004S	4	3.8115.004S	4
3.8117.005S	5	3.8116.005S	5	3.8115.005S	5
3.8117.006S	6	3.8116.006S	6	3.8115.006S	6
3.8117.007S	7	3.8116.007S	7	3.8115.007S	7
3.8117.008S	8	3.8116.008S	8	3.8115.008S	8
3.8117.009S	9	3.8116.009S	9	3.8115.009S	9
3.8117.010S	10	3.8116.010S	10	3.8115.010S	10

3D-Ti Angular cervical intervertebral cage *(with spikes)*

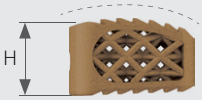


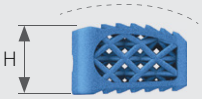


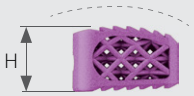


Size 17x13 [mm]		**Size 15x12** [mm]		**Size 13x11** [mm]	
Catalogue no.	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]
3.8120.004S	4	3.8119.004S	4	3.8118.004S	4
3.8120.005S	5	3.8119.005S	5	3.8118.005S	5
3.8120.006S	6	3.8119.006S	6	3.8118.006S	6
3.8120.007S	7	3.8119.007S	7	3.8118.007S	7
3.8120.008S	8	3.8119.008S	8	3.8118.008S	8
3.8120.009S	9	3.8119.009S	9	3.8118.009S	9
3.8120.010S	10	3.8119.010S	10	3.8118.010S	10

3D-Ti Convex cervical intervertebral cage

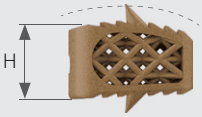


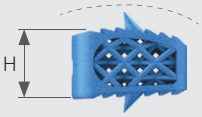


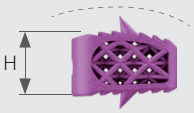


Size 17x13 [mm]		**Size 15x12** [mm]		**Size 13x11** [mm]	
Catalogue no.	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]
3.8123.004S	4	3.8122.004S	4	3.8121.004S	4
3.8123.005S	5	3.8122.005S	5	3.8121.005S	5
3.8123.006S	6	3.8122.006S	6	3.8121.006S	6
3.8123.007S	7	3.8122.007S	7	3.8121.007S	7
3.8123.008S	8	3.8122.008S	8	3.8121.008S	8
3.8123.009S	9	3.8122.009S	9	3.8121.009S	9
3.8123.010S	10	3.8122.010S	10	3.8121.010S	10

3D-Ti Convex cervical intervertebral cage *(with spikes)*







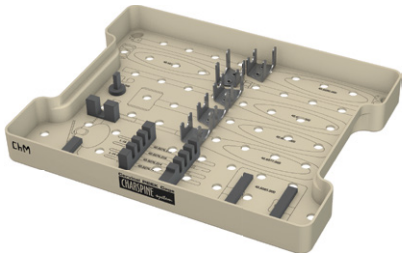
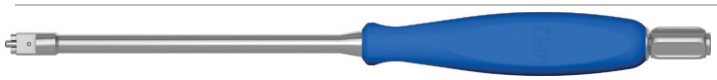
Size 17x13 [mm]		**Size 15x12** [mm]		**Size 13x11** [mm]	
Catalogue no.	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]	**Catalogue no.**	**Height H** [mm]
3.8126.004S	4	3.8125.004S	4	3.8124.004S	4
3.8126.005S	5	3.8125.005S	5	3.8124.005S	5
3.8126.006S	6	3.8125.006S	6	3.8124.006S	6
3.8126.007S	7	3.8125.007S	7	3.8124.007S	7
3.8126.008S	8	3.8125.008S	8	3.8124.008S	8
3.8126.009S	9	3.8125.009S	9	3.8124.009S	9
3.8126.010S	10	3.8125.010S	10	3.8124.010S	10

Material: Ti

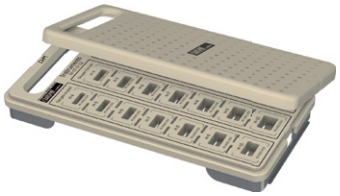
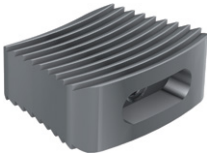
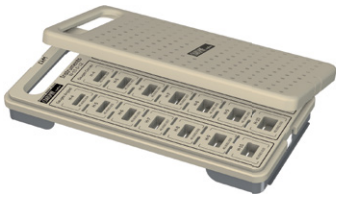
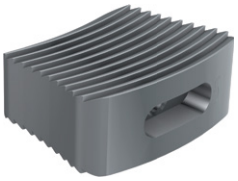
III. INSTRUMENTS

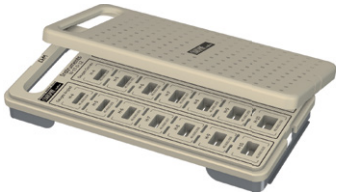
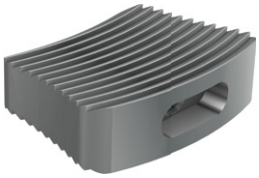
Features:

- high ergonomics,
- instruments provided with slender silicone handles,
- color-coded implant trials,
- instruments made of high quality steel *(stainless steel)*,
- easy to clean,
- modern, small pallets system for storage, usage and sterilization of instruments and implants,
- a fully equipped set of instruments with Caspar pins and cervical distractor.

Instruments - Cervical intervertebral cages 15.0902.001			
Instruments - Cervical intervertebral cages	**Name**	**Catalogue No.**	**Pcs**
	Container 9x4 H	14.0902.103	1
	Container lid 9x4	14.0913.106	1
	Tray for instrument set -Cervical intervertebral cages 5x4 1/2H	14.0902.205	1
	Applicator	40.6096.000	1
	Persuader	40.6080.100	1
	Screwdriver for Caspar pins	40.6086.000	1
	Compactor	40.6077.000	1
	Hammer 200g	40.6087.000	1
	Working stand	40.6085.001	1
	Position retainer	40.6079.000	1

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

	Caspar cervical distractor	40.6075.000	1
	Caspar pin 3.0x14	40.6076.014	2
	Caspar pin 3.0x16	40.6076.016	2
	Stand for instrument set -Cervical intervertebral cages 4x2 1/2H	14.0902.203	1
	Bone rasp 4x13x11	40.6088.004	1
	Bone rasp 5x13x11	40.6088.005	1
	Bone rasp 6x13x11	40.6088.006	1
	Bone rasp 7x13x11	40.6088.007	1
	Bone rasp 8x13x11	40.6088.008	1
	Bone rasp 9x13x11	40.6088.009	1
	Bone rasp 10x13x11	40.6088.010	1
	Angular trial 4x13x11	40.6090.004	1
	Angular trial 5x13x11	40.6090.005	1
	Angular trial 6x13x11	40.6090.006	1
	Angular trial 7x13x11	40.6090.007	1
	Angular trial 8x13x11	40.6090.008	1
	Angular trial 9x13x11	40.6090.009	1
	Angular trial 10x13x11	40.6090.010	1
	Convex trial 4x13x11	40.6089.004	1
	Convex trial 5x13x11	40.6089.005	1
	Convex trial 6x13x11	40.6089.006	1
	Convex trial 7x13x11	40.6089.007	1
	Convex trial 8x13x11	40.6089.008	1
	Convex trial 9x13x11	40.6089.009	1
	Convex trial 10x13x11	40.6089.010	1
	Stand for instrument set -Cervical intervertebral cages 4x2 1/2H	14.0902.202	1
	Bone rasp 4x15x12	40.6081.004	1
	Bone rasp 5x15x12	40.6081.005	1
	Bone rasp 6x15x12	40.6081.006	1
	Bone rasp 7x15x12	40.6081.007	1
	Bone rasp 8x15x12	40.6081.008	1
	Bone rasp 9x15x12	40.6081.009	1
	Bone rasp 10x15x12	40.6081.010	1
	Angular trial 4x15x12	40.6083.004	1
	Angular trial 5x15x12	40.6083.005	1
	Angular trial 6x15x12	40.6083.006	1
	Angular trial 7x15x12	40.6083.007	1
	Angular trial 8x15x12	40.6083.008	1
	Angular trial 9x15x12	40.6083.009	1
	Angular trial 10x15x12	40.6083.010	1

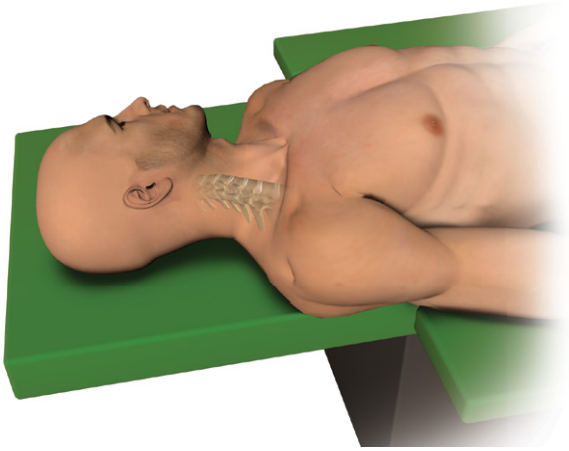
	Convex trial 4x15x12	40.6082.004	1
	Convex trial 5x15x12	40.6082.005	1
	Convex trial 6x15x12	40.6082.006	1
	Convex trial 7x15x12	40.6082.007	1
	Convex trial 8x15x12	40.6082.008	1
	Convex trial 9x15x12	40.6082.009	1
	Convex trial 10x15x12	40.6082.010	1
	Stand for instrument set -Cervical intervertebral cages 4x2 1/2H	14.0902.204	1
	Bone rasp 4x17x13	40.6091.004	1
	Bone rasp 5x17x13	40.6091.005	1
	Bone rasp 6x17x13	40.6091.006	1
	Bone rasp 7x17x13	40.6091.007	1
	Bone rasp 8x17x13	40.6091.008	1
	Bone rasp 9x17x13	40.6091.009	1
	Bone rasp 10x17x13	40.6091.010	1
	Angular trial 4x17x13	40.6093.004	1
	Angular trial 5x17x13	40.6093.005	1
	Angular trial 6x17x13	40.6093.006	1
	Angular trial 7x17x13	40.6093.007	1
	Angular trial 8x17x13	40.6093.008	1
	Angular trial 9x17x13	40.6093.009	1
	Angular trial 10x17x13	40.6093.010	1
	Convex trial 4x17x13	40.6092.004	1
	Convex trial 5x17x13	40.6092.005	1
	Convex trial 6x17x13	40.6092.006	1
	Convex trial 7x17x13	40.6092.007	1
	Convex trial 8x17x13	40.6092.008	1
	Convex trial 9x17x13	40.6092.009	1
	Convex trial 10x17x13	40.6092.010	1

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

IV. SURGICAL TECHNIQUE

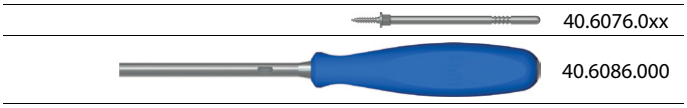
IV.1. PATIENT POSITIONING AND SURGICAL APPROACH

The patient shall be in supine position with his head in a neutral position or rotated about 30° from the neutral position to the left or right, opposite to the surgical approach.

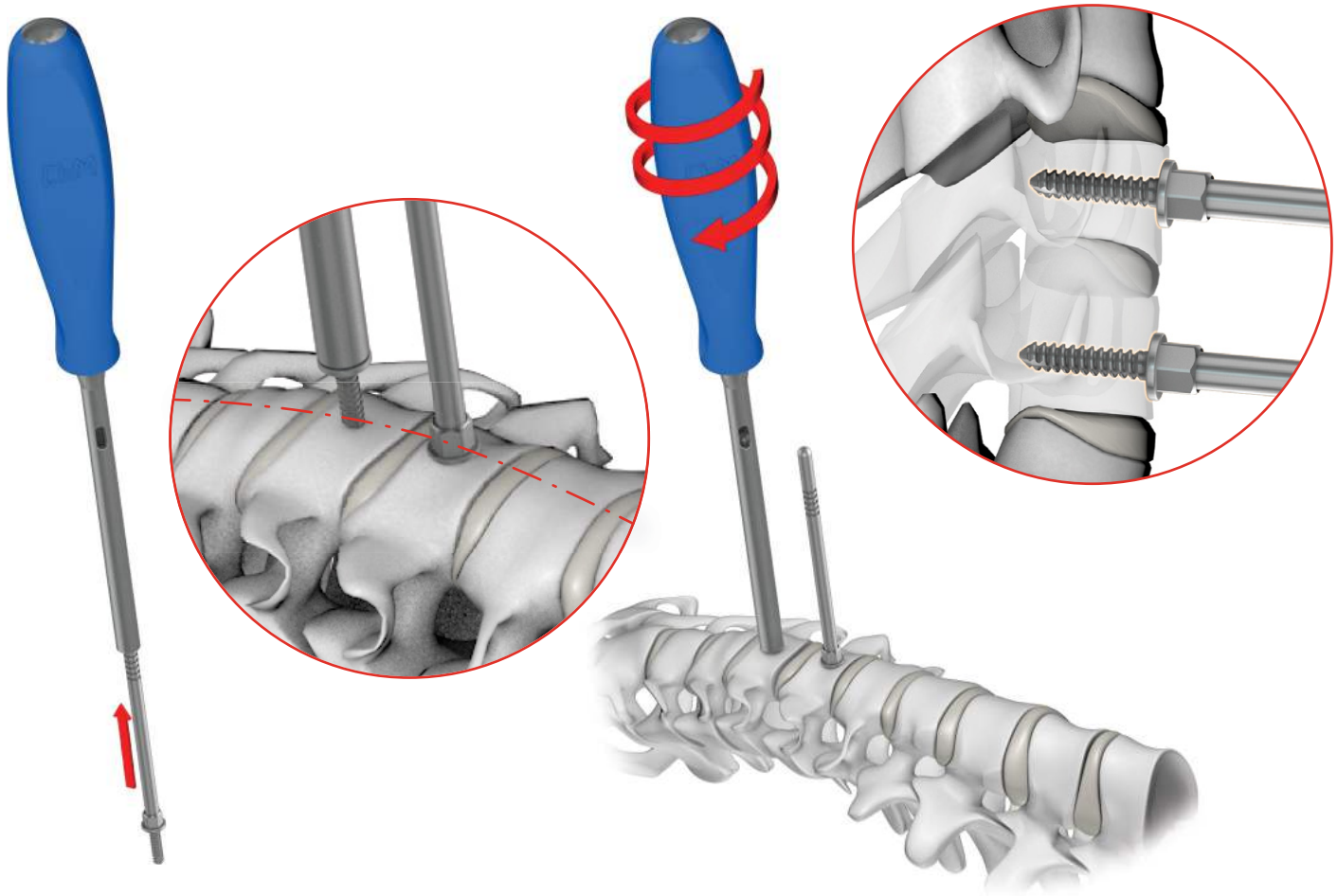


IV.2. INSERTION OF CASPAR CERVICAL DISTRACTOR

Caspar cervical distractor prevents closing of the intervertebral space during the discectomy and the remaining operating procedure.

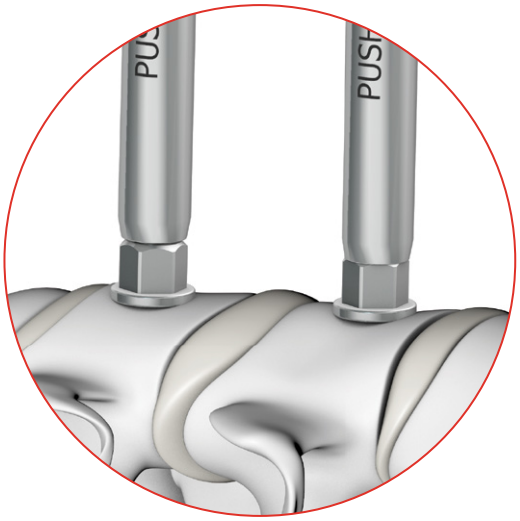


Choose intraoperatively, on the basis of X-Ray image, the length of the Caspar pin **[40.6076.0xx]** *(14mm or 16mm)*. Insert the selected pins using screwdriver **[40.6086.000]** in a vertebra located above and below the operated intervertebral disc, in the central part of the anterior surface of the vertebral bodies. The inserted pins should be parallel to each other and perpendicular to the anterior surface of the vertebral bodies.



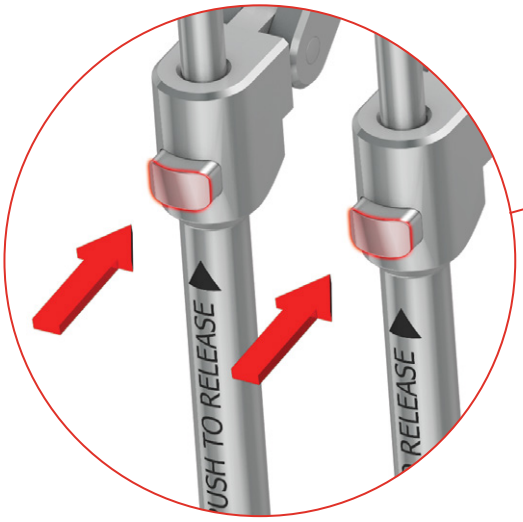
40.6075.000

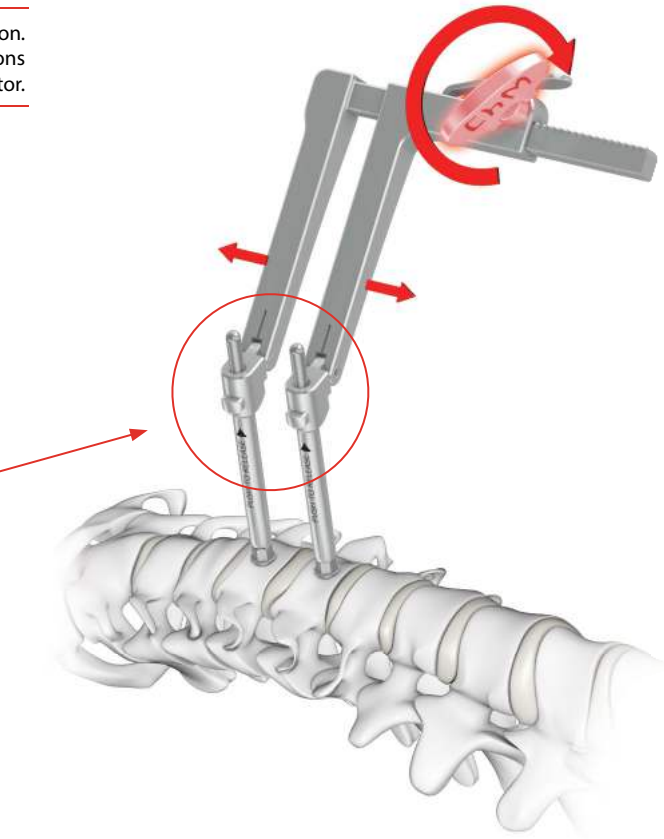
Insert sleeves of Caspar cervical distractor **[40.6075.000]** down the Caspar pins.



Perform gentle distraction by turning the knob clockwise.

Pins are secured in the distractor from unintentional disconnection. To remove the distractor, press and hold pressed both buttons located at the upper part of the sleeves and remove the distractor.

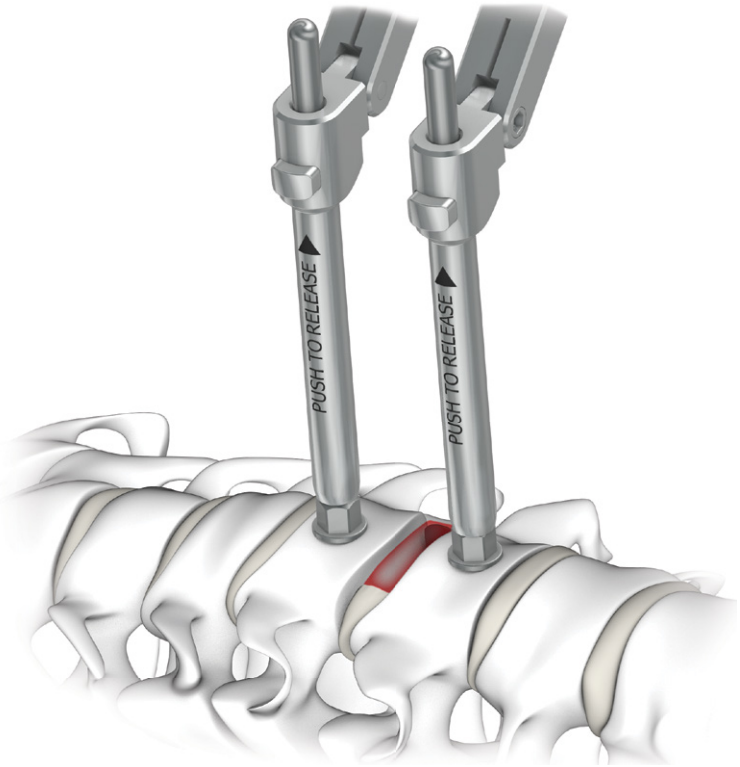




IV.3. DISCECTOMY

Remove the intervertebral disc using standard procedure and dedicated instruments.

The instruments used for discectomy are not included in the instrument set for Cervical Intervertebral Cage.



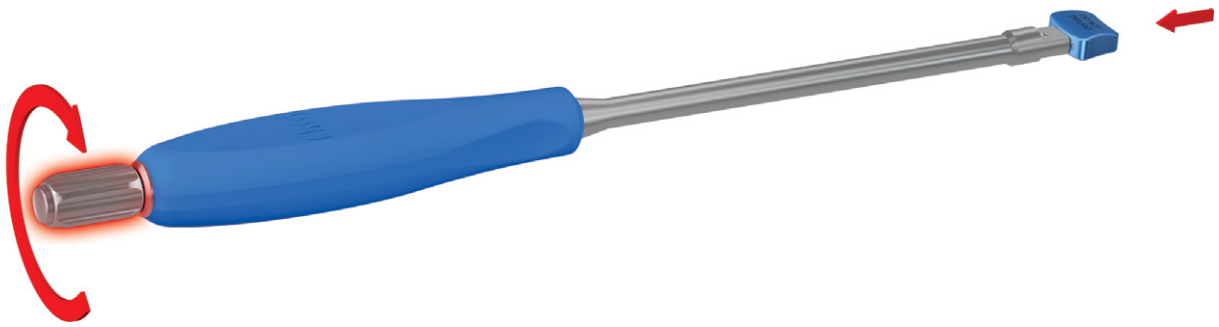
IV.4. IMPLANT SELECTION

Implant size is selected on the basis of trials [40.6082.0xx], [40.6083.0xx], [40.6089.0xx], [40.6090.0xx], [40.6092.0xx], [40.6093.0xx] whose shapes and dimensions correspond to the available implants.

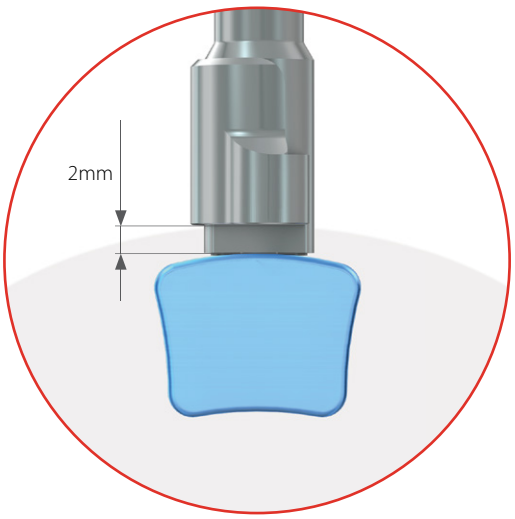
	40.6082.0xx, 40.6083.0xx 40.6089.0xx 40.6090.0xx 40.6092.0xx 40.6093.0xx
	40.6080.100
	40.6079.000

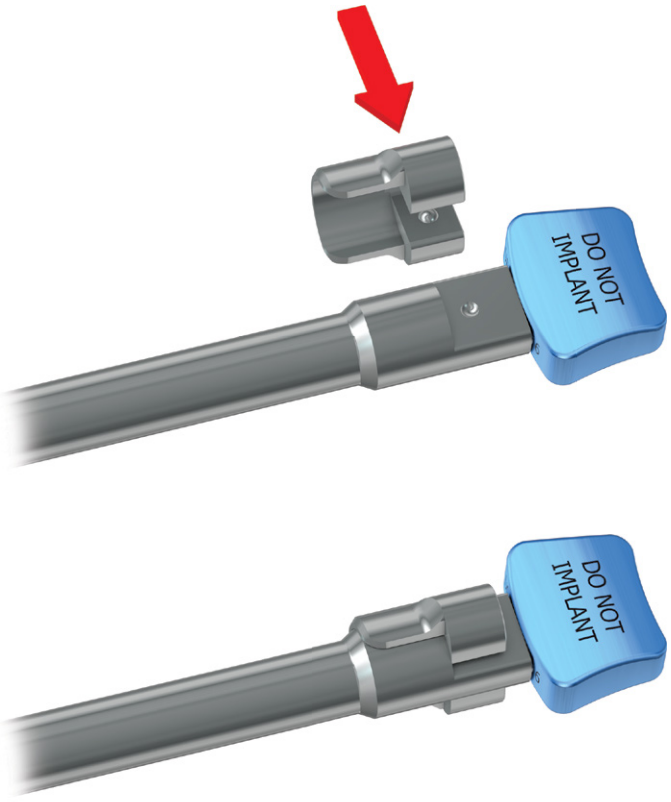
Choose intraoperatively, on the basis of X-Ray image, one of the trials **[40.6082.0xx]**, **[40.6083.0xx]**, **[40.6089.0xx]**, **[40.6090.0xx]**, **[40.6092.0xx]**, **[40.6093.0xx]** whose shape and height corresponds best to the intervertebral space.

Mount the selected trial to the persuader **[40.6080.100]** – insert the trial on the persuader tip and by turning the persuader's knob clockwise, tighten up the locking pin in the socket of the trial.

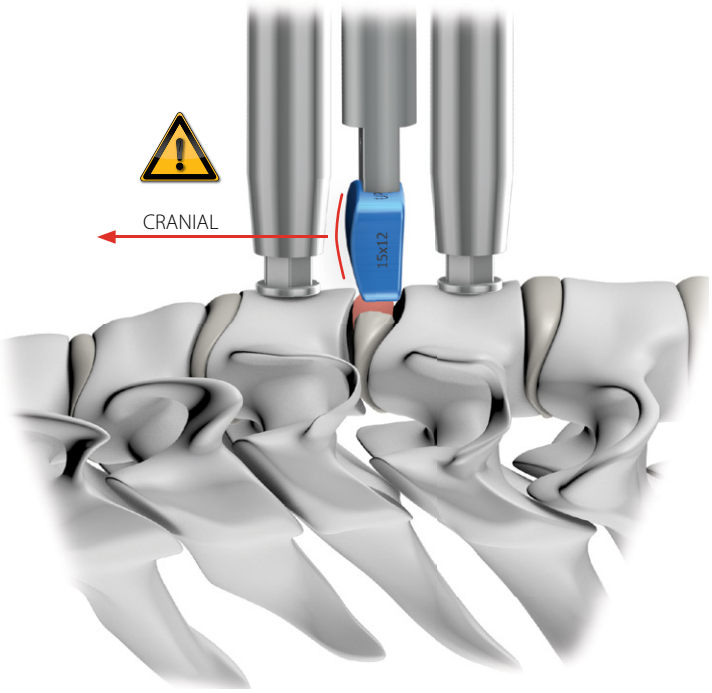


Optionally, a position retainer **[40.6079.000]** can be installed at the tip of the persuader which prevents the trials and rasps from excessive penetration of the intervertebral space.





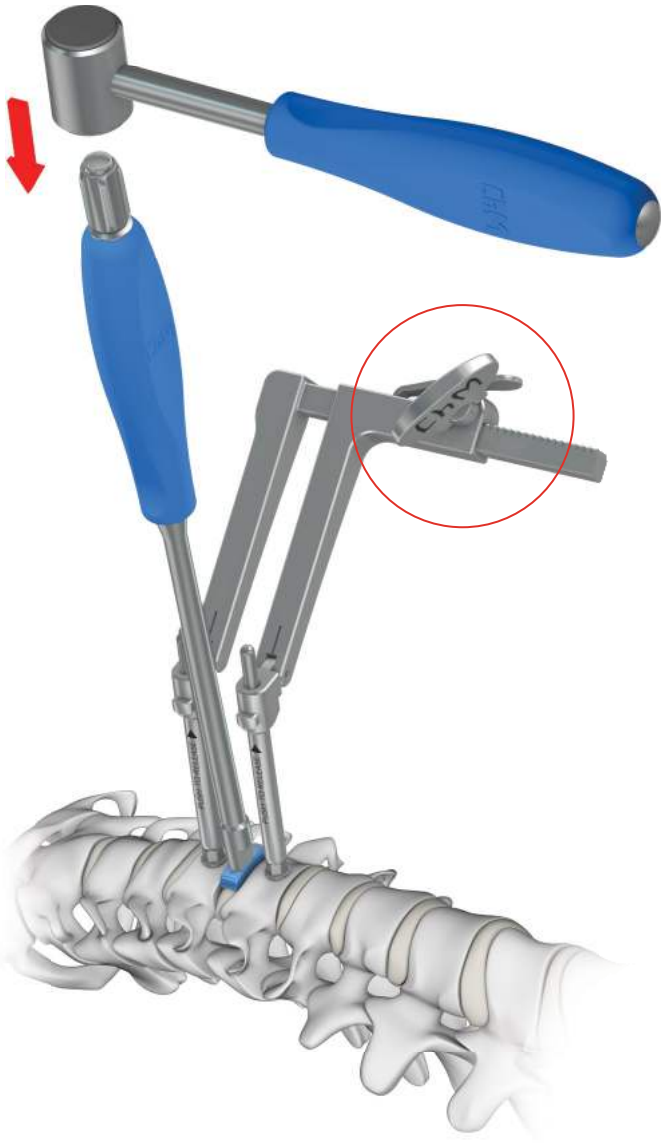
The convex trials [40.6082.0xx], [40.6088.0xx], [40.6092.0xx] should be introduced with the convex surface facing the head*(cranial direction)*.



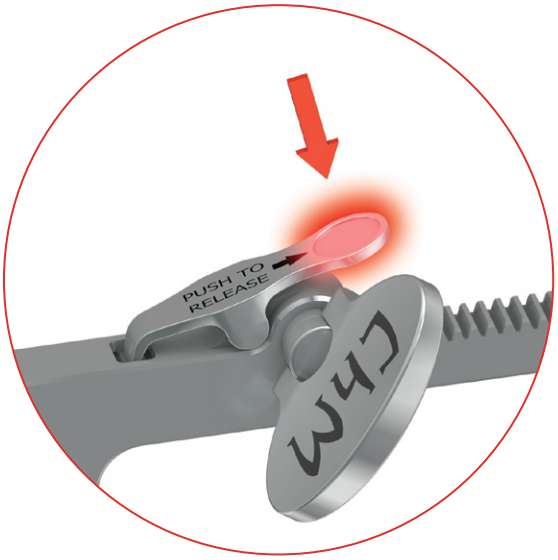
Insert the selected trial into the intervertebral space, so that the top surface of the trial is placed about 2 mm below the top surface of the vertebral body.

When inserting the trial, gentle tapping with a hammer **[40.6087.000]** can be applied.

40.6087.000

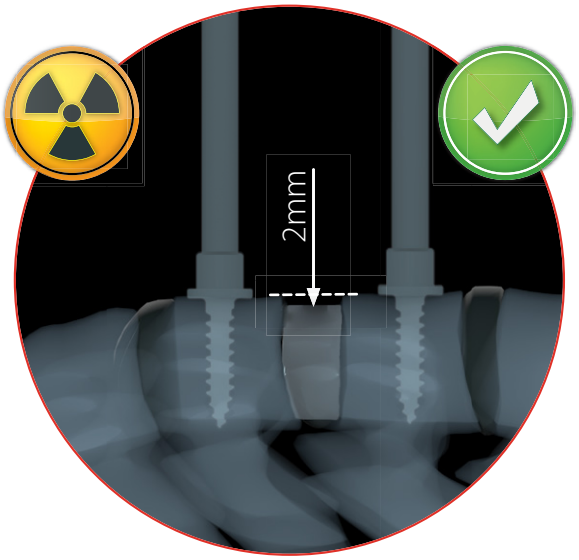


Release the distraction by pushing the locking lever of the Caspar cervical distractor.



Verify the position of the trial using X-Ray imaging.

In the anterior projection, the lateral edges of the trial should be symmetrical to the vertical axis of the vertebrae.

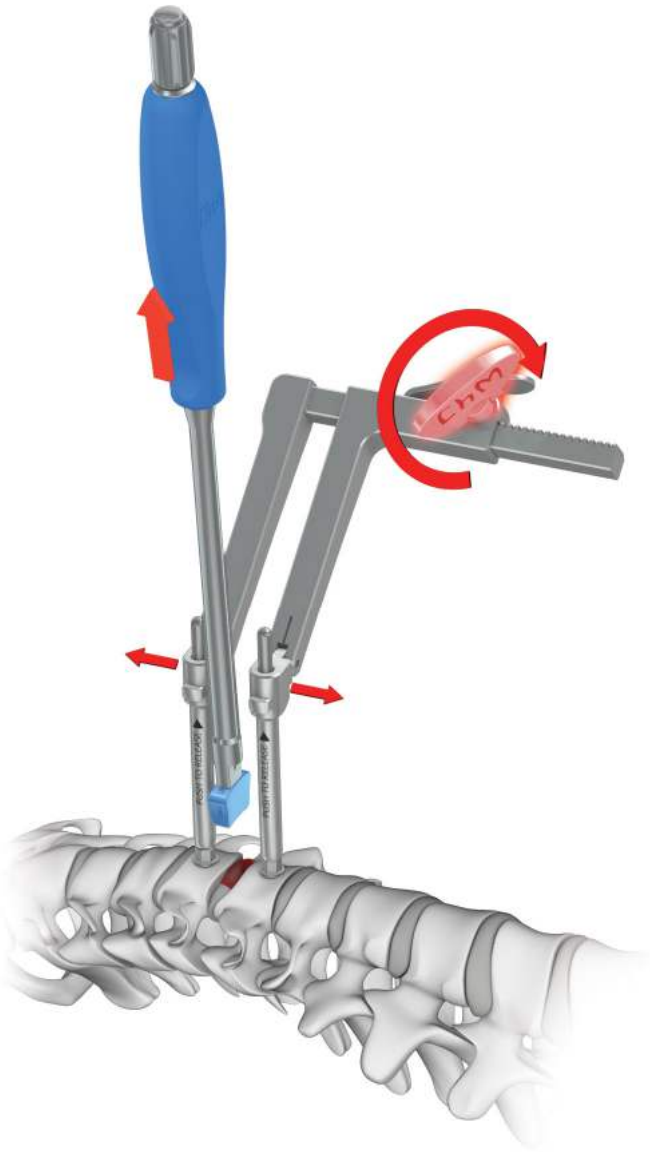


In the lateral projection, the top surface of the trial should be placed about 2 mm below the outer edge of the vertebral body.

Distract the vertebrae again and remove the trial.

Should the trial be incorrectly placed, repeat the procedure using a trial better fitting the intervertebral space.

Based on the final trial, choose an implant of the same size and shape. The implant will be used later in the procedure.



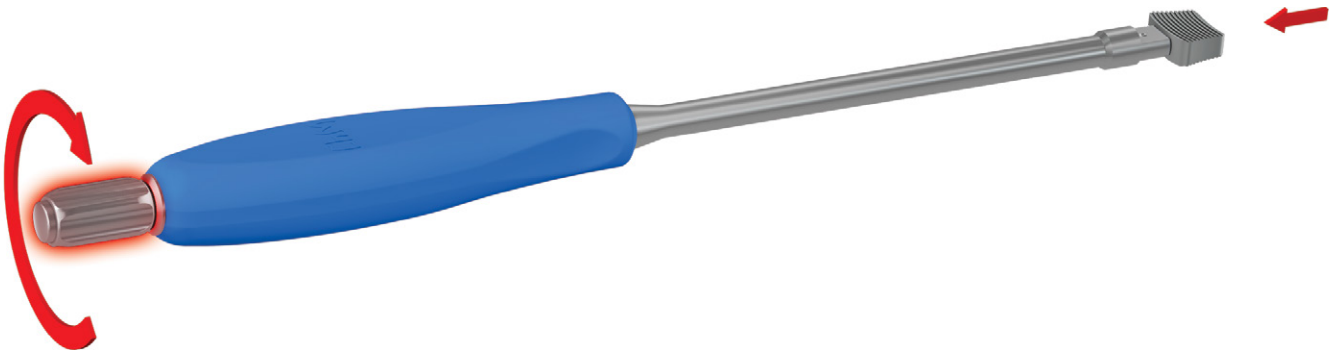
IV.5. PREPARATION OF THE ENDPLATES

Preparation of the endplates of vertebral bodies involves removal of the surface layers of the cartilage and improves vascularization of the implantation site and bony union between the vertebrae.

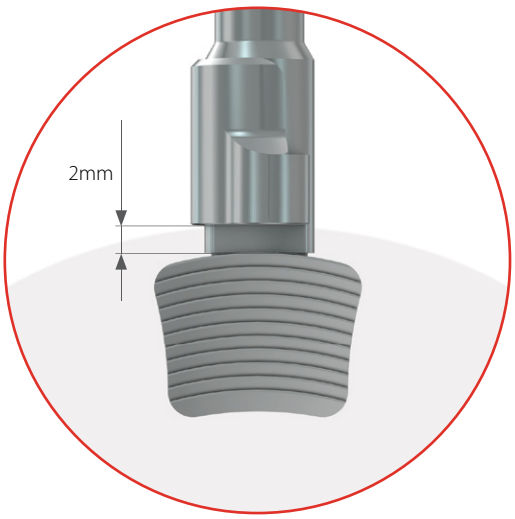
	40.6081.0xx 40.6088.0xx 40.6091.0xx
	40.6080.100
	40.6079.000

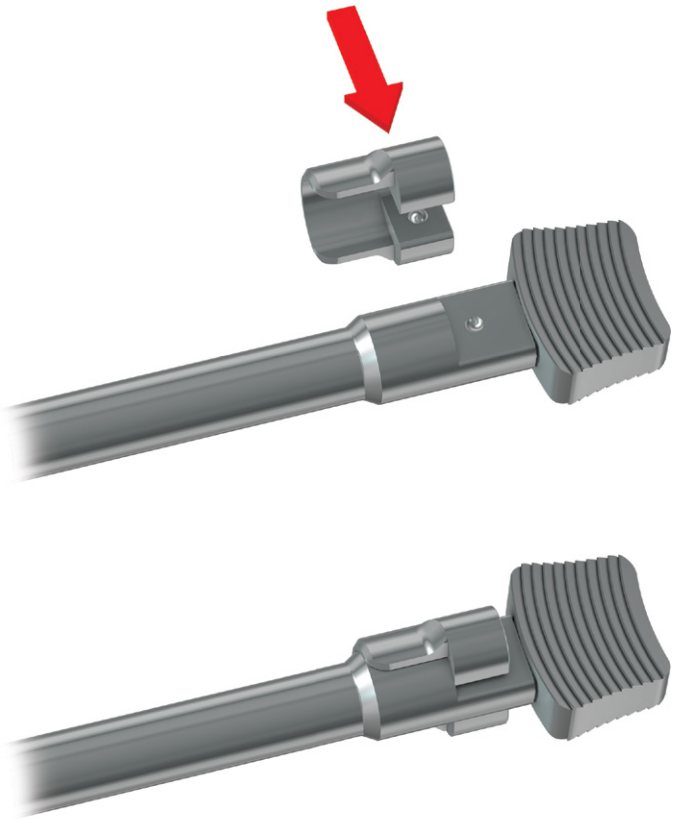
For the preparation of the endplates choose, on the basis of the trial used, adequate size of bone rasp.

Mount the selected bone rasp to the persuader **[40.6080.100]** – insert the bone rasp on the persuader's tip and by turning the persuader's knob clockwise, tighten up the locking pin in the socket of the bone rasp.



Optionally, a position retainer **[40.6079.000]** can be installed at the tip of the persuader which prevents the trials and rasps from excessive penetration of the intervertebral space.





Insert the bone rasp in the intervertebral space, push it to the endplates and, by pulling, remove the surface layers of the cartilage outside the vertebra.

When inserting the bone rasp, gentle tapping with a hammer **[40.6087.000]** can be applied.

40.6087.000

Excessive removal of the subchondral bone may weaken the vertebral bodies and, consequently, lead to subsidence of the implant which may result in a loss of the segment stability.

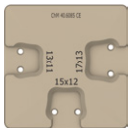
IV.6. IMPLANT PREPARATION

Mount the selected cage to the applicator **[40.6096.000]** – install the implant on the applicator's tip and by rotating the applicator's knob clockwise, lock the implant on the device.

40.6096.000

CAUTION:
Do not over-tighten the implant!

CAUTION:
If the PEEK cervical intervertebral cage is used, fill the cage with autologous material *(bone chips)* prior to implantation.
Do not use autologous material with 3D-Ti intervertebral cages since they have a spatial 3D structure that ensures overgrowth with newly created bone tissue.

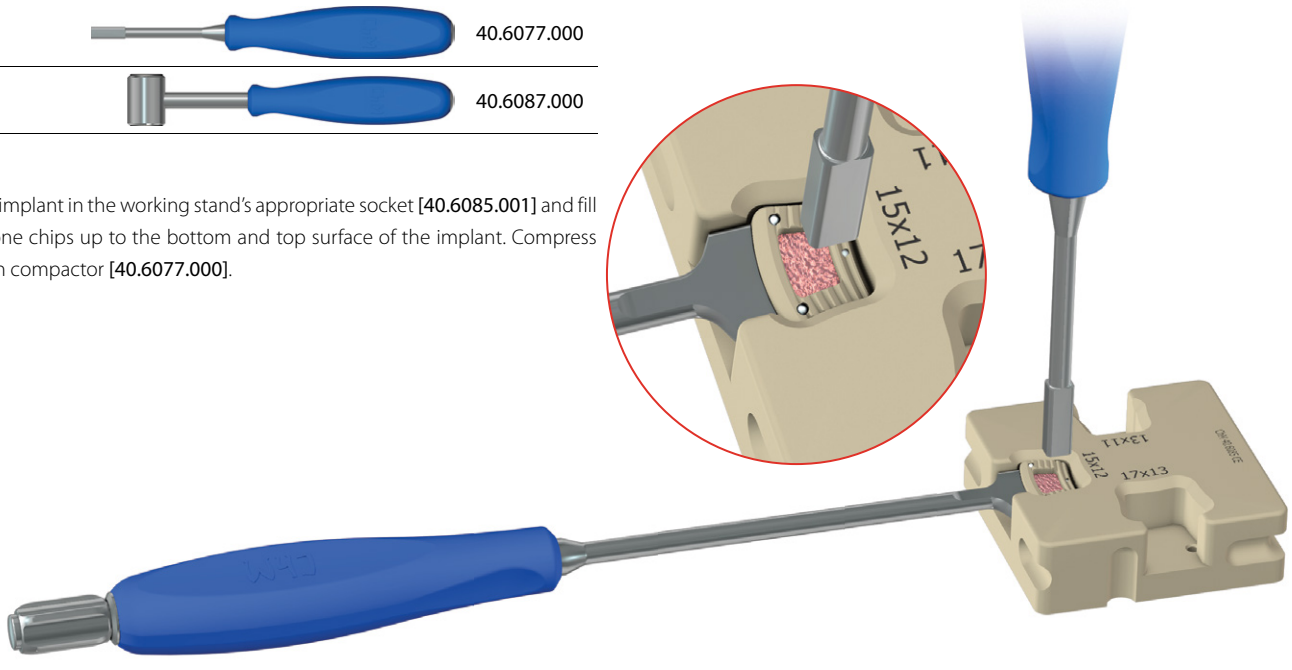


40.6085.001

40.6077.000

40.6087.000

Place the implant in the working stand's appropriate socket **[40.6085.001]** and fill it with bone chips up to the bottom and top surface of the implant. Compress them with compactor **[40.6077.000]**.

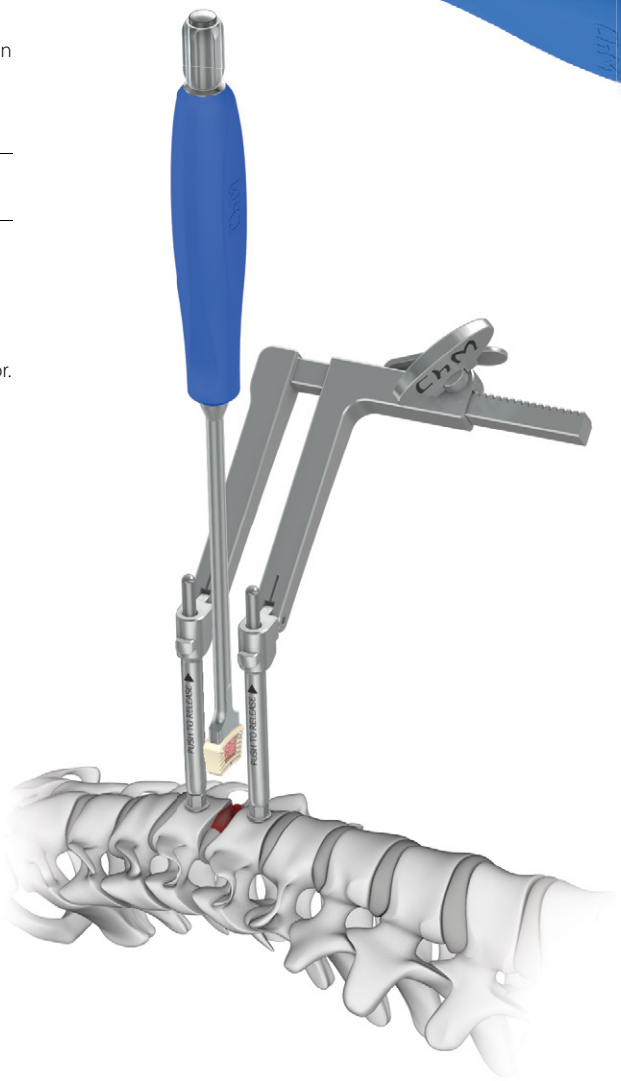


IV.7. IMPLANT INSERTION

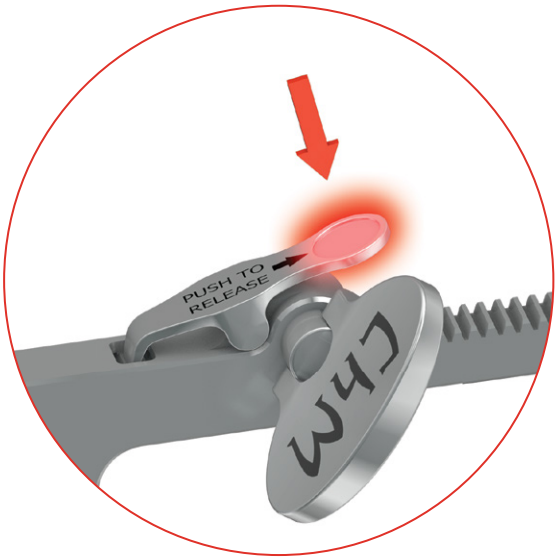
Insert implant into the intervertebral space, so that the top surface of the implant is placed about 2 mm below the top surface of the vertebral body.

When inserting the implant, gentle tapping with a hammer **[40.6087.000]** can be applied.

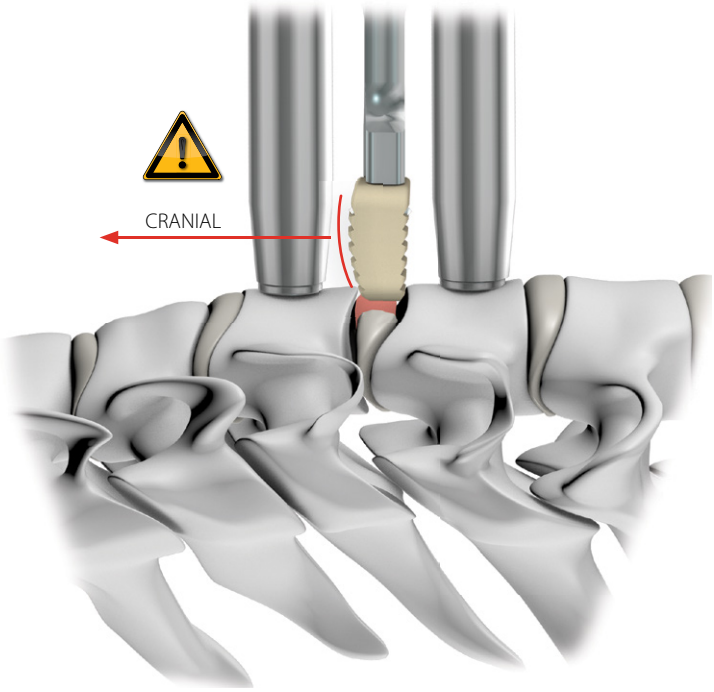
40.6087.000



Release the distraction by pushing the locking lever of Caspar cervical distractor.

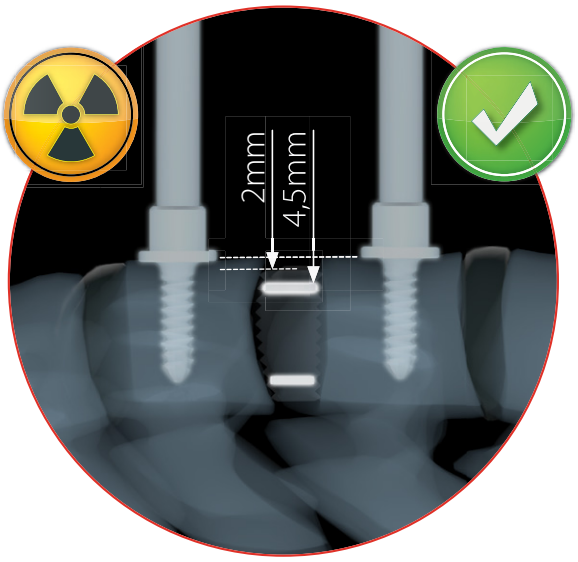


Convex cervical intervertebral cages should be inserted with the convex surface facing the head *(cranial direction)*.



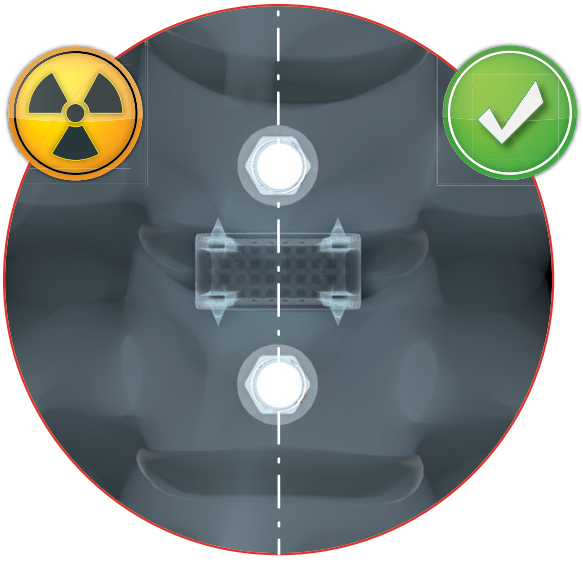
Check the position of the implant using X-Ray imaging. The position of PEEK implants is determined on the basis of three embedded radioopaque markers.

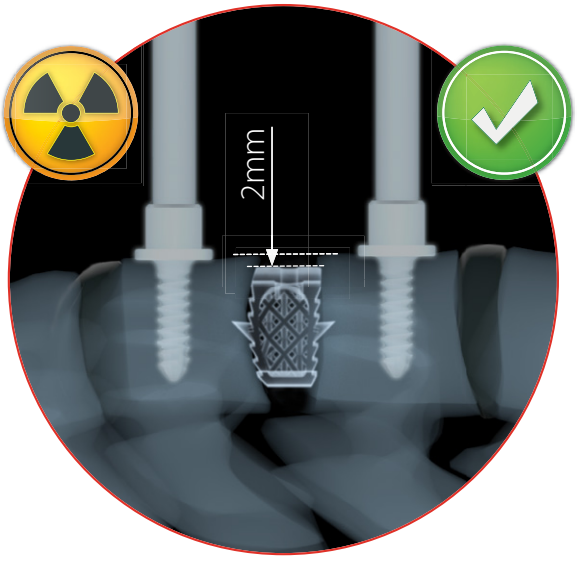
In the front projection, tantalum markers of the implant should be symmetrical to the vertical axis of vertebrae.



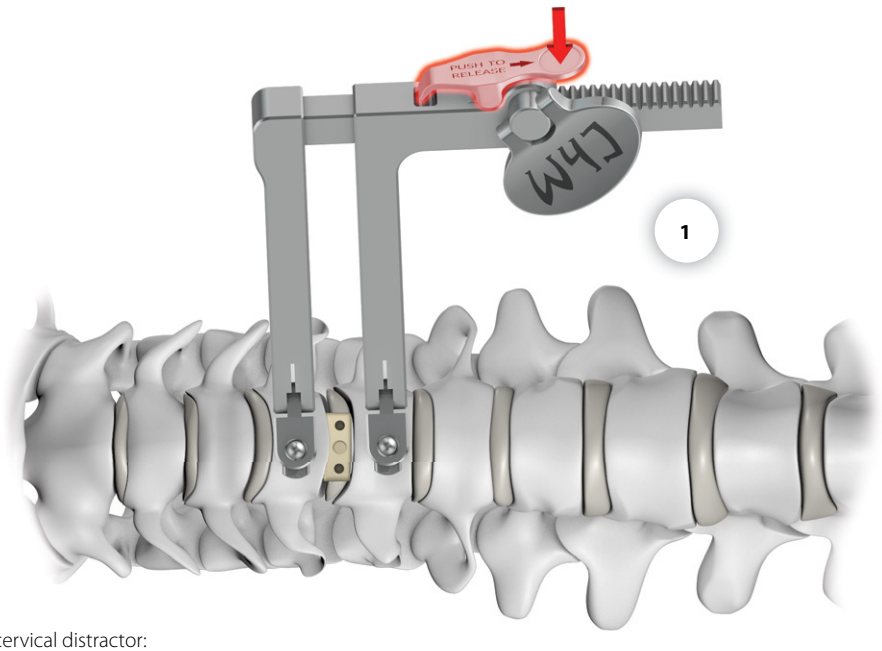
In the lateral projection, a proximal marker should be placed about 4.5mm below the outer surface of the vertebral body.

3D-Ti intervertebral cages

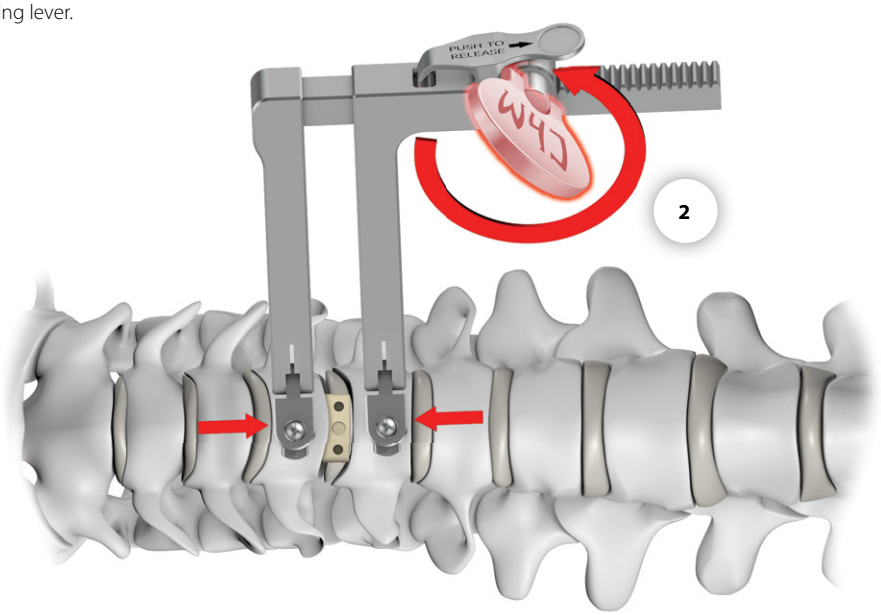


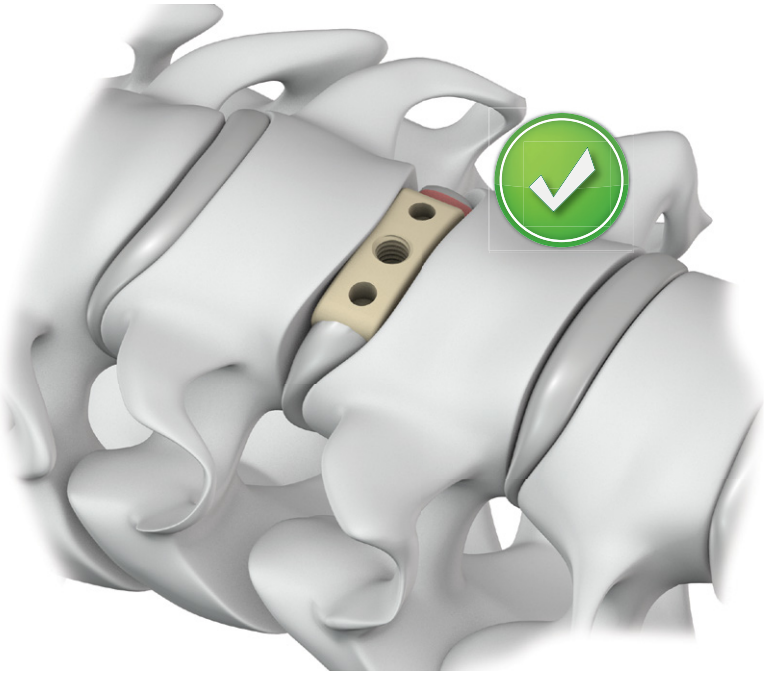


Remove the applicator from the cervical cage by rotating the applicator's knob counter-clockwise.
Remove the applicator's tip from the implant's socket.



Perform the compression of the vertebrae using Caspar cervical distractor:
1. Press and hold pressed Caspar cervical distractor's locking lever.
2. Turn the knob counter-clockwise.



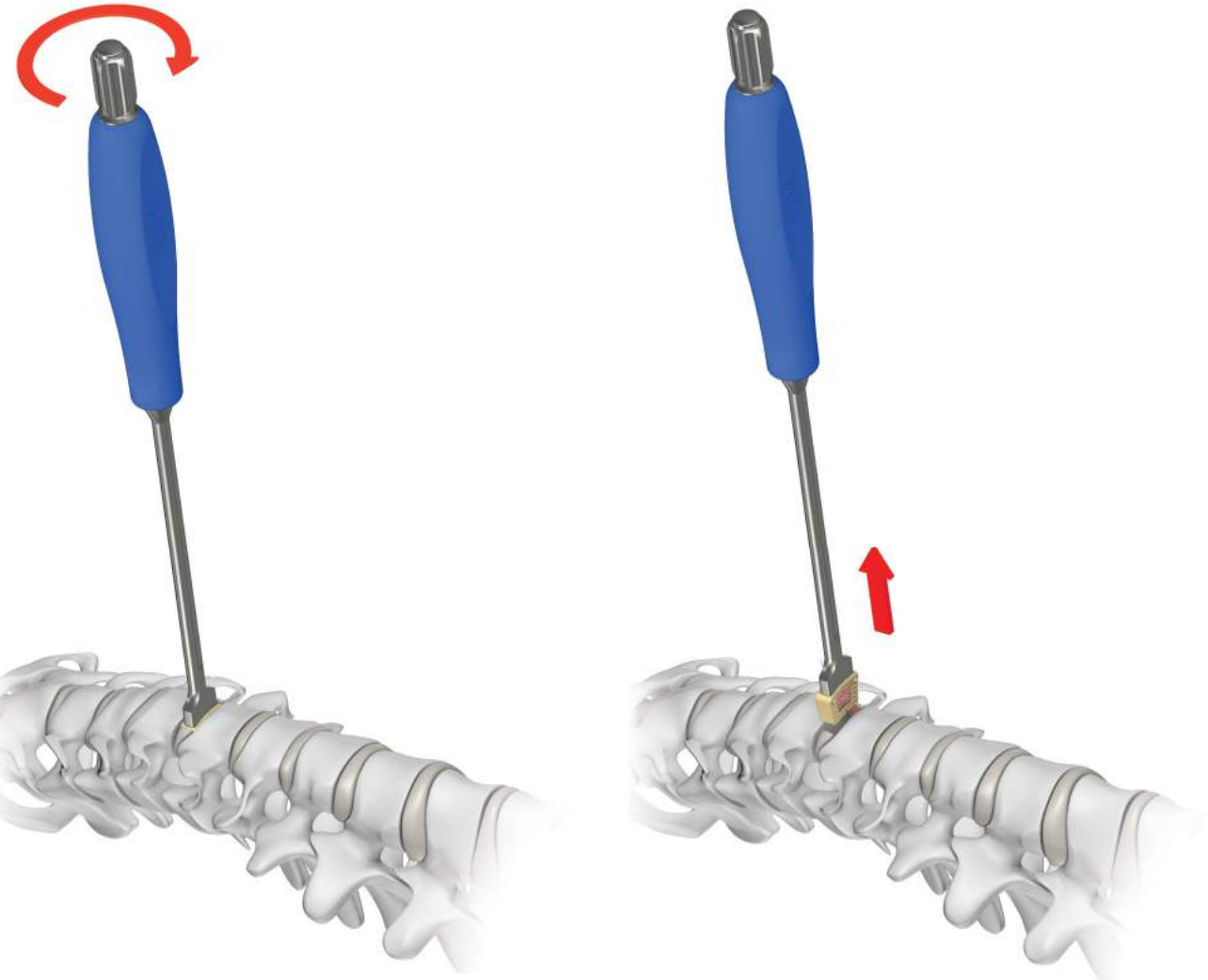


Remove Caspar cervical distractor and pins.

V. IMPLANT REMOVAL

Should there be no spinal fusion after 2.5 years since implantation, the treatment shall be deemed failure and it is necessary to remove the implant. To do so, install the applicator **[40.6096.000]** to the implant and remove the intervertebral cage from the intervertebral space.

40.6096.000



For further information on:
- adverse effects,
- warnings,
- sterilization,
- pre- and post-operative recommendations,

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

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

CE 0197