ChM®

INTERVERTEBRAL CERVICAL LOCKING CAGE

- *IMPLANTS*
- *INSTRUMENT SET 15.0917.102*
- *SURGICAL TECHNIQUE*

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/107A

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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. SYSTEM DESCRIPTION

I.1. INDICATION

Cervical intervertebral cage, together with instrument set, is 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 instability,
- 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)*, titanium alloy 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 bodies, to maximize their safe use.

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 the cage 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.

Dedicated locking screws are used with the intervertebral cage to immobilize the implant and eliminate the need for additional stabilization.

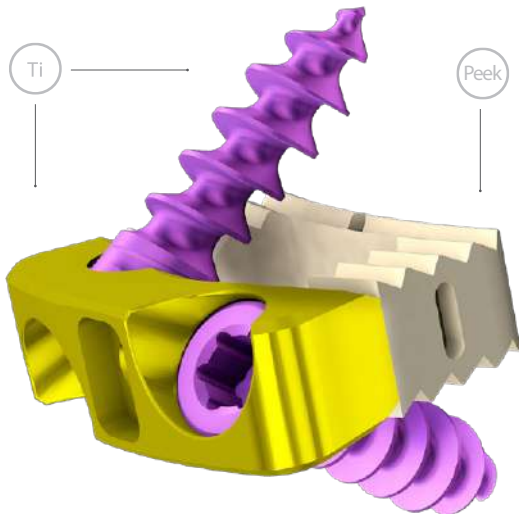
Cervical intervertebral cages are made of highly biocompatible materials: PEEK, titanium and tantalum alloys.
Locking screws are made of titanium alloy.

PEEK

- Stiffness approximates the host bone, which provides ideal load sharing attributes.
- Radiolucency 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 to maximize the volume of bone tissue.

Titanium alloy

- Facilitated X-Ray imaging for precise determination of the implant position.
- High osseointegration with bone structures.
- High strength enables the use of bone locking screws compatible with the cage.



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

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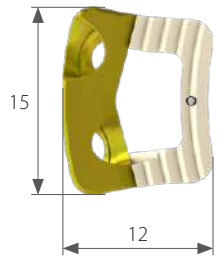
II.1. AVAILABLE SIZES AND VARIANTS

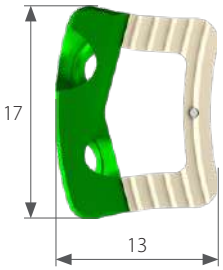
PEEK-OPTIMA®

Overall dimensions [mm]

15x12



17x13



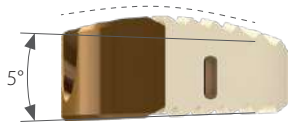
Height sizes H [mm]

5 6 7 8 9 10

Variants

Angular cervical intervertebral cage

Convex cervical intervertebral cage



Angular cervical intervertebral cage

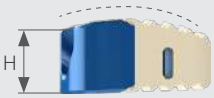
Size 15x12 [mm]

Catalogue no.	Height H [mm]
8.6970.505	5
8.6970.506	6
8.6970.507	7
8.6970.508	8
8.6970.509	9
8.6970.510	10

Size 17x13 [mm]

Catalogue no.	Height H [mm]
8.6971.505	5
8.6971.506	6
8.6971.507	7
8.6971.508	8
8.6971.509	9
8.6971.510	10

Convex cervical intervertebral cage



Size 15x12 [mm]

Catalogue no.	Height H [mm]
8.6972.005	5
8.6972.006	6
8.6972.007	7
8.6972.008	8
8.6972.009	9
8.6972.010	10

Size 17x13 [mm]

Catalogue no.	Height H [mm]
8.6973.005	5
8.6973.006	6
8.6973.007	7
8.6973.008	8
8.6973.009	9
8.6973.010	10

Cervical locking screw 3.5 *(self-drilling)*

Diameter	Length [mm]	Colour	Catalogue no.
3.5	10		3.6974.010
3.5	12		3.6974.012
3.5	14		3.6974.014
3.5	16		3.6974.016

Cervical locking screw 4.0 *(self-drilling)*

Diameter	Length [mm]	Colour	Catalogue no.
4	10		3.6975.010
4	12		3.6975.012
4	14		3.6975.014
4	16		3.6975.016

Material: Ti

Stand for implants - set		Name	Catalogue No.	Pcs
		Container lid 4x4	14.0917.103	1
		Stand for implants - Cervical intervertebral cages 4x2 ½H	14.0917.401	1
		Stand for implants - Cervical intervertebral cages 4x2 ½H	14.0917.501	1
		Container 4x4H	14.0000.003	1

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Sterilization container *(for the stand for implants - set)*	**Name**	**Catalogue No.**	**Pcs**
	Perforated aluminum lid ½ 306x272x15mm Gray	**12.0751.200**	1
	Container with solid bottom ½ 306x272x85mm	**12.0751.100**	1

III. INSTRUMENT SET

Features:

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

Instrument set for cervical intervertebral locking cages 15.0917.102	Name	Catalogue No.	Pcs
	Container lid 9x4	14.0917.105	1
	Applicator	40.8784.000	1
	Persuader	40.6080.000	1
	Compactor	40.6077.000	1
	Hammer 200g	40.6087.000	1
	Working stand	40.8786.100	1
	Position retainer	40.6079.100	1
	Aiming block H-5	40.8785.105	1
	Aiming block H-6	40.8785.106	1
	Aiming block H-7	40.8785.107	1
	Aiming block H-8	40.8785.108	1
	Aiming block H-9	40.8785.109	1
	Aiming block H-10	40.8785.110	1
	Trocar	40.8780.100	1
	Trocar	40.8781.100	1
	Screwdriver tip T10	40.8783.100	1
	Screwdriver tip T10 with joint	40.8782.100	1
	Handle ratchet device	40.6654.001	1
	Extractor	40.8789.000	1

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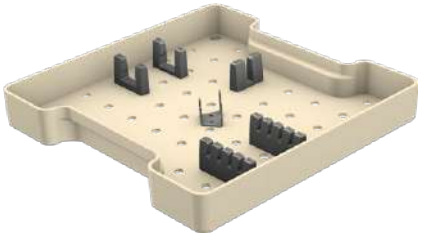
	Name	Catalogue No.	Pcs
	Stand 9x4	14.0917.201	1
	Angular trial5x15x12	40.6083.005	1
	Angular trial6x15x12	40.6083.006	1
	Angular trial7x15x12	40.6083.007	1
	Angular trial8x15x12	40.6083.008	1
	Angular trial9x15x12	40.6083.009	1
	Angular trial10x15x12	40.6083.010	1
	Convex trial5x15x12	40.6082.005	1
	Convex trial6x15x12	40.6082.006	1
	Convex trial7x15x12	40.6082.007	1
	Convex trial8x15x12	40.6082.008	1
	Convex trial9x15x12	40.6082.009	1
	Convex trial10x15x12	40.6082.010	1
	Angular trial5x17x13	40.6093.005	1
	Angular trial6x17x13	40.6093.006	1
	Angular trial7x17x13	40.6093.007	1
	Angular trial8x17x13	40.6093.008	1
	Angular trial9x17x13	40.6093.009	1
	Angular trial10x17x13	40.6093.010	1
	Convex trial5x17x13	40.6092.005	1
	Convex trial6x17x13	40.6092.006	1
	Convex trial7x17x13	40.6092.007	1
	Convex trial8x17x13	40.6092.008	1
	Convex trial9x17x13	40.6092.009	1
	Convex trial10x17x13	40.6092.010	1
		14.0917.104	1

Sterilization container *(for the Instrument set for cervical intervertebral locking cages)*	Name	Catalogue No.	Pcs
	Perforated aluminum lid ½ 595x275x15mm Gray	12.0750.200	1
	Container with solid bottom ½ 595x275x86mm	12.0750.100	1

15.0918.220	Name	Catalogue no.	Pcs
	Caspar cervical distractor	40.6075.000	1
	Screwdriver for Caspar pins	40.6086.000	1
	Caspar pin 3.0x14	40.6076.014	2
	Caspar pin 3.0x16	40.6076.016	2
	Tray 4x4 ½H	14.0918.220	1

	Name	Catalogue no.	Pcs
	Container lid 4x4	14.0000.102	1
	Container 4x4 ½H	14.0000.004	1

Sterilization container *(for the distraction set)*	Name	Catalogue No.	Pcs
	Perforated aluminum lid ½ 306x272x15mm Gray	12.0751.200	1
	Container with solid bottom ½ 306x272x85mm	12.0751.100	1

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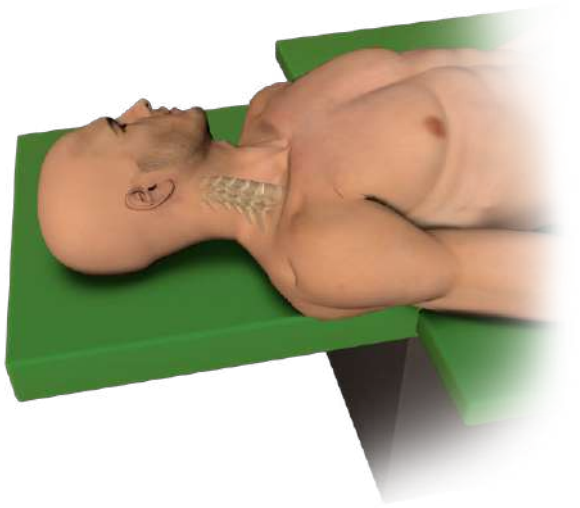
IV. SURGICAL TECHNIQUE *(WITHOUT USE OF CASPAR CERVICAL DISTRACTOR)*

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.



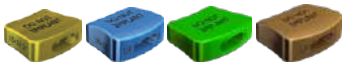
IV.2. DISCECTOMY

Remove the intervertebral disc using standard procedure and instruments to perform such an operation.

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

IV.3. IMPLANT SELECTION

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

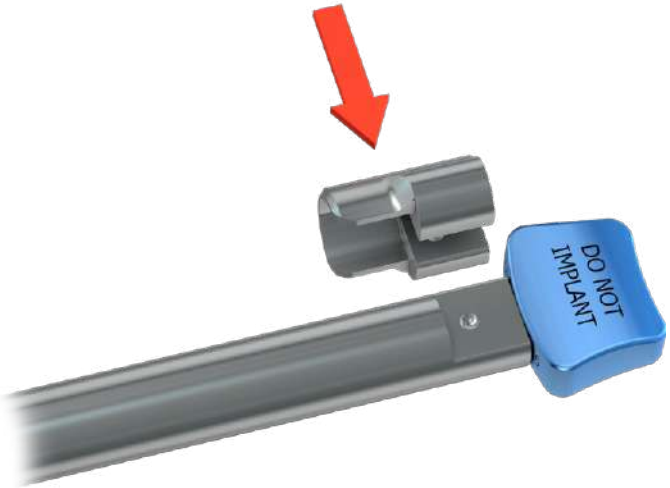
	40.6082.0xx, 40.6083.0xx 40.6092.0xx 40.6093.0xx
	40.6080.000
	40.6079.100

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

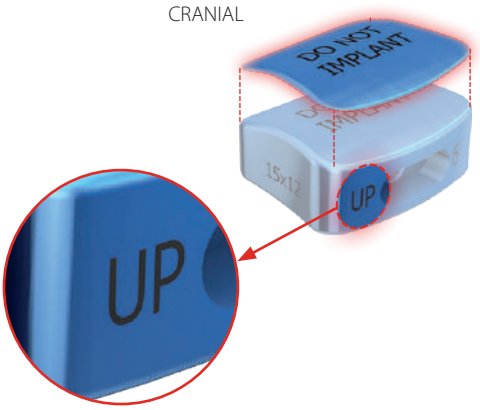
Mount the selected trial to the persuader **[40.6080.000]** - insert the trial on the persuader tip and by rotating the persuader knob clockwise, tighten the locking pin in the socket of the trial.

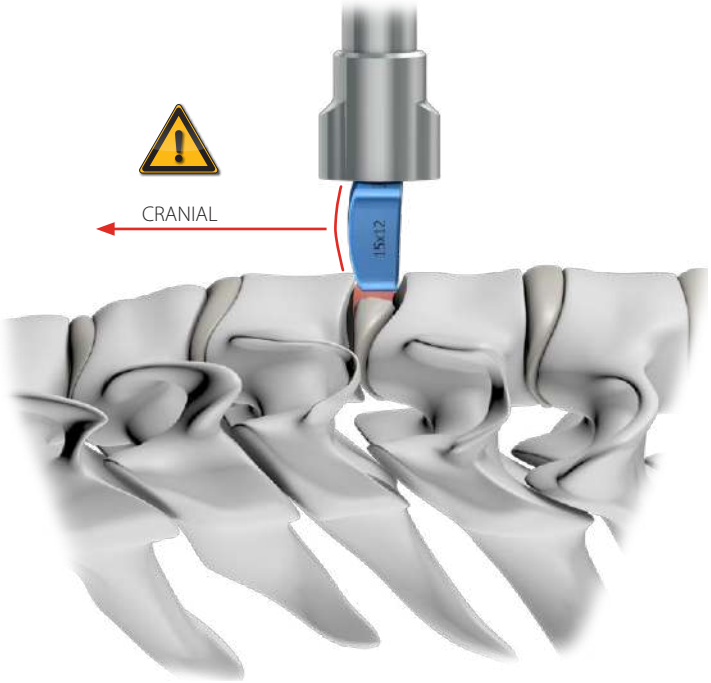
Attach the position retainer **[40.6079.100]** to the persuader.

The position retainer serves as a protection against excessive penetration of the trials, bone rasps and implants in the intervertebral space and thereby reduces the risk of damage to the spinal cord.



Convex trials [40.6082.0xx], [40.6092.0xx] should be inserted with the convex surface facing the head *(cranial direction)*.
The convex part of the trial is above the word *"UP"*.

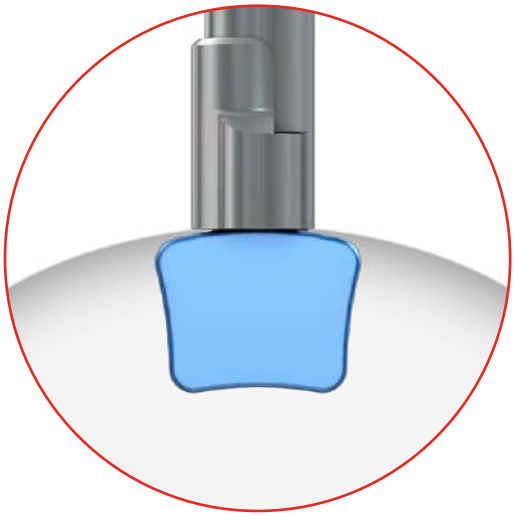




40.6087.000

Insert the selected trial into the intervertebral space.
Use hammer **[40.6087.000]** when necessary, gently tapping on the persuader's knob.

Insert the trial until the position retainer leans on the vertebra's surface.



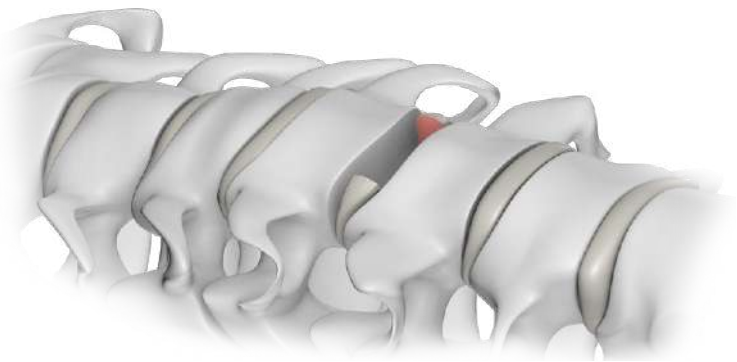
Verify the position of the trial using X-Ray imaging.

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

Remove the trial.

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

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

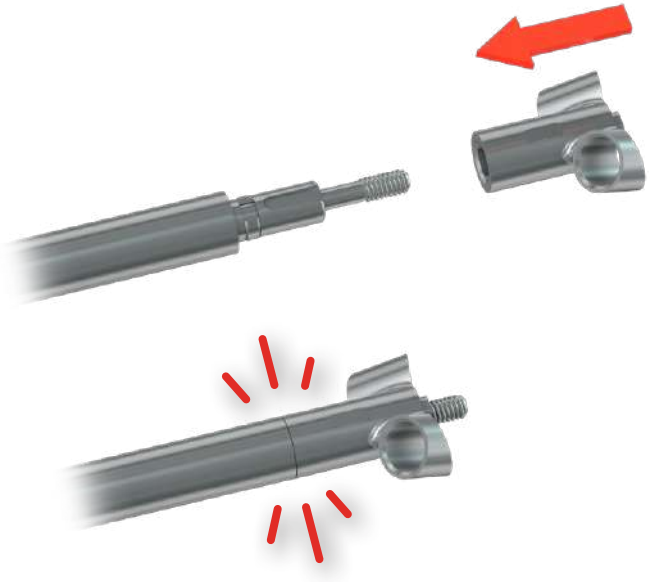


IV.4. IMPLANT PREPARATION

Before implantation, the space in the PEEK intervertebral cervical cage should be filled with autologous bone graft *(bone chips)* which allows for spinal fusion.

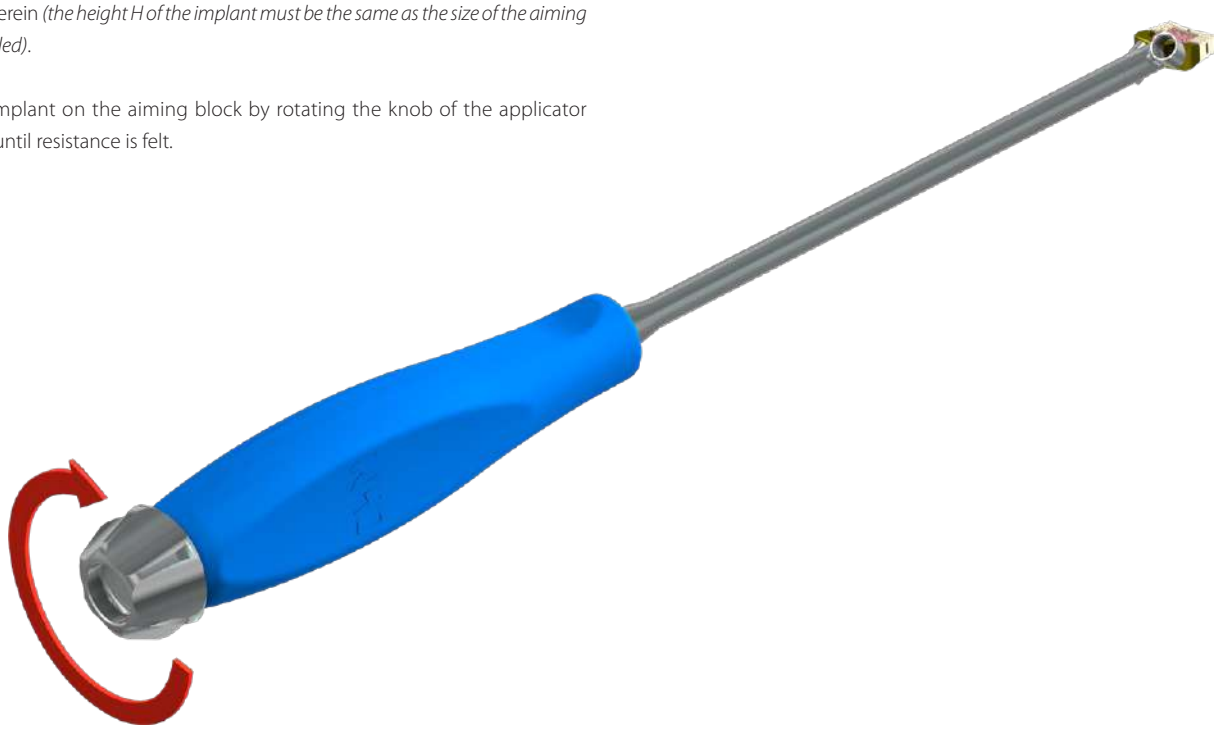
	40.8784.000
	40.8785.105 40.8785.106 40.8785.107 40.8785.108 40.8785.109 40.8785.110

Install the selected aiming block **[40.8785.1xx]** *(the height H of which must be the same as for the height of the final trial used)* to the applicator **[40.8784.000]** - the click sound must be heard.



Then connect the intervertebral cage with the applicator and the aiming block installed therein *(the height H of the implant must be the same as the size of the aiming block installed)*.

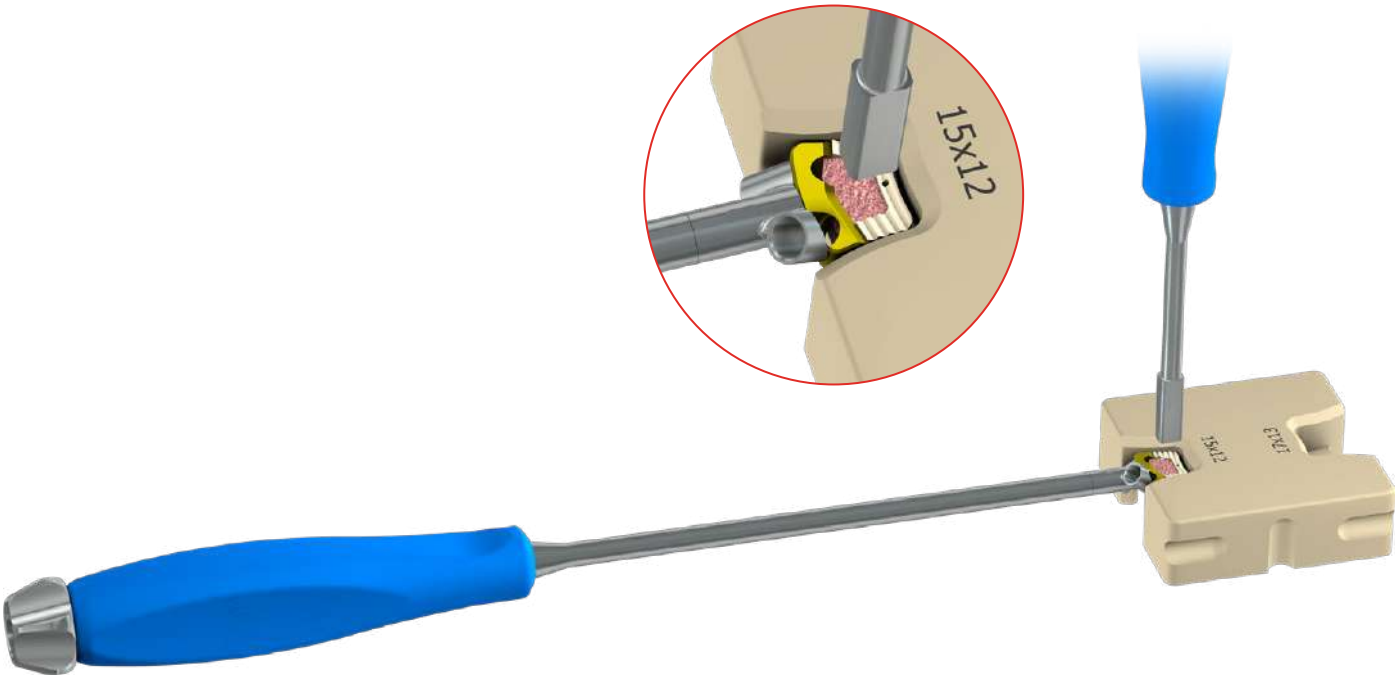
Lock the implant on the aiming block by rotating the knob of the applicator clockwise until resistance is felt.



40.8786.100

40.6077.000

Place the implant in an appropriate socket of the working stand **[40.8786.100]** and fill with bone chips. Compress them with compactor **[40.6077.000]**.



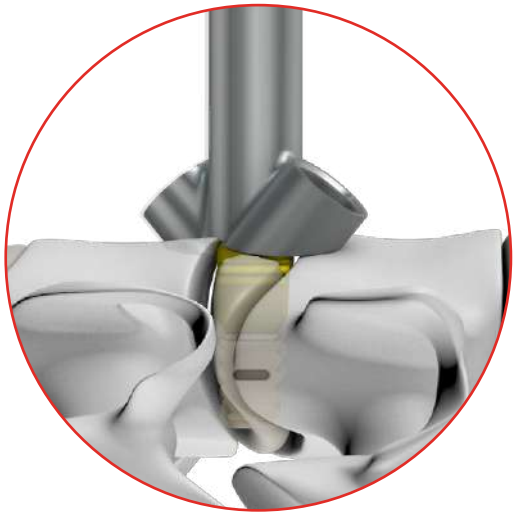
IV.5. IMPLANT INSERTION

Insert implant, filled with bone graft, into the intervertebral space.

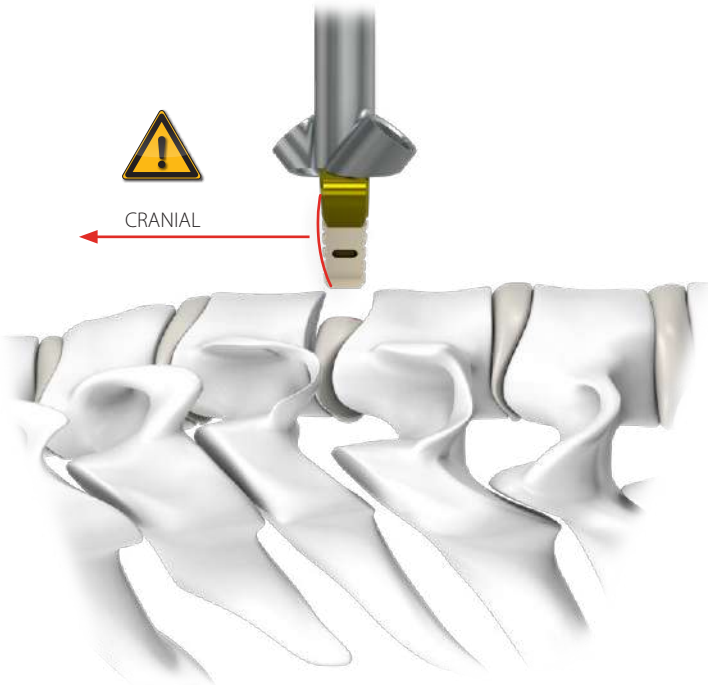
40.6087.000

Use hammer **[40.6087.000]** when necessary, gently tapping on the applicator's knob.

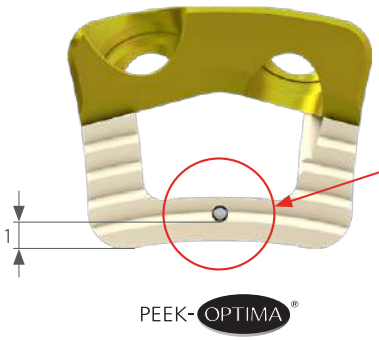
Continue inserting the implant until the aiming block leans against the vertebral surface.

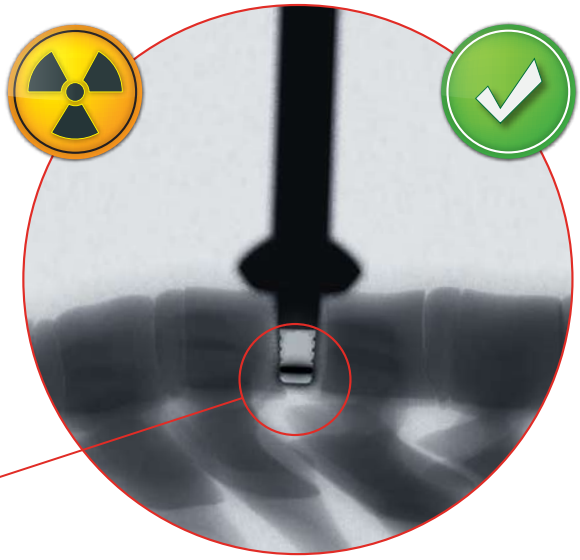


Convex cervical intervertebral cages [8.6972.xxx], [8.6973.000] should be inserted with the convex surface facing the head *(cranial direction)*.



The embedded tantalum marker is used to navigate the position of the posterior wall of the intervertebral cage *(the marker is located 1mm from the edge of the cage)*. The marker is also used to determine whether the endplates of the vertebral bodies adhere properly to the cage.

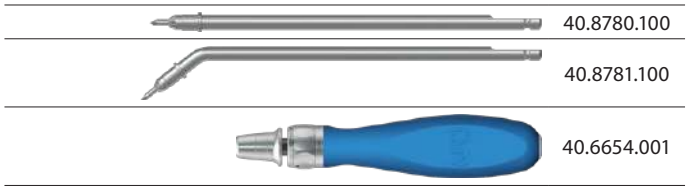


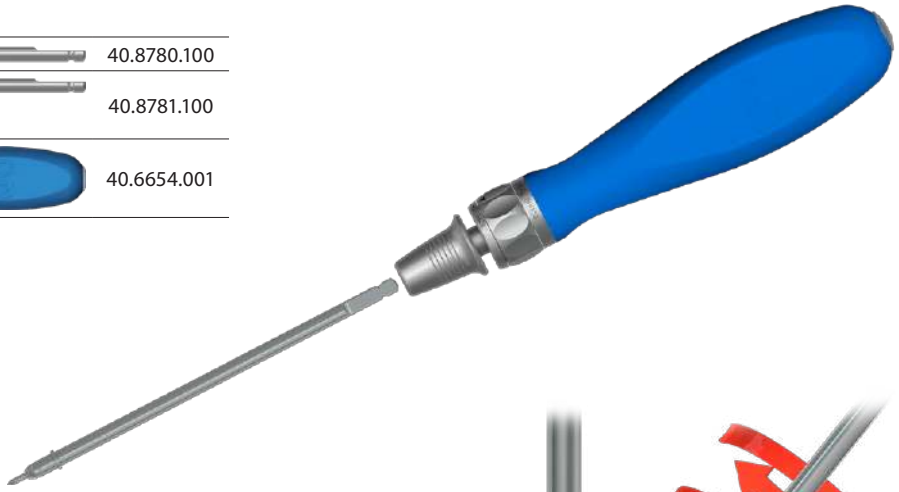


PEEK-Ti implant in X-Ray imaging

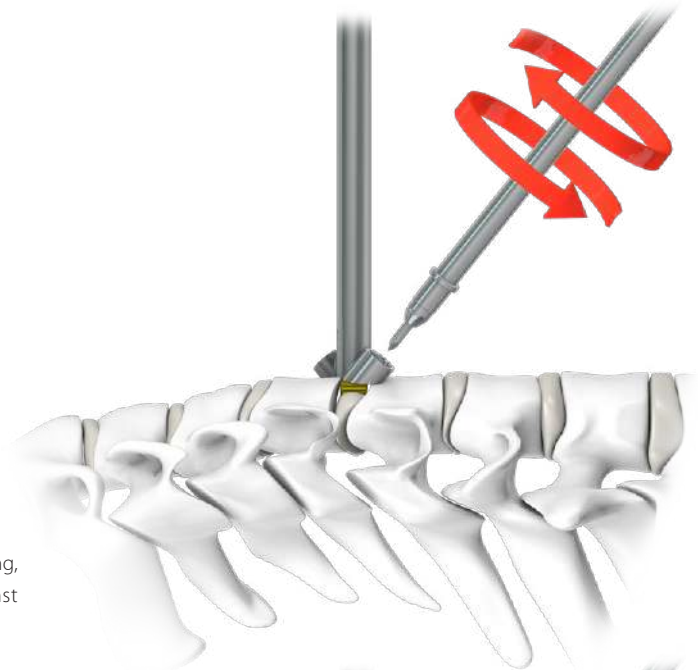
IV.6. HOLES DRILLING AND SCREWS INSERTION

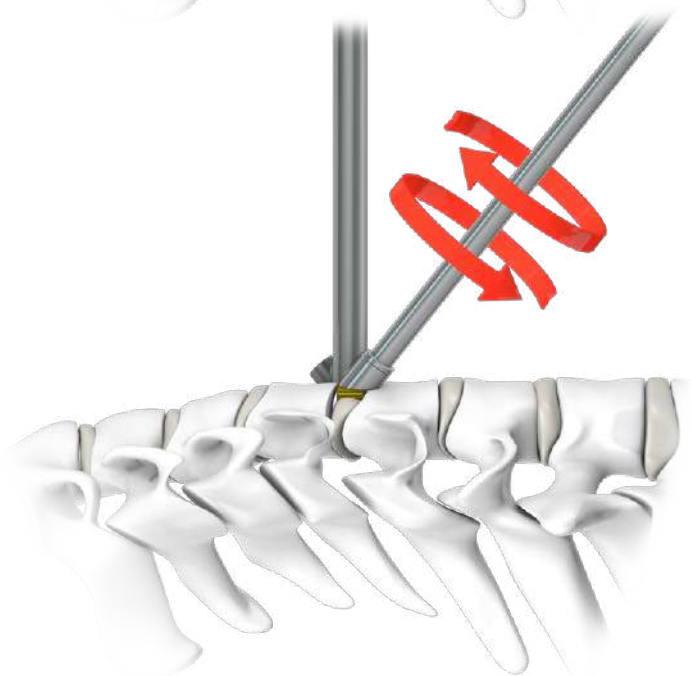
Connect the trocar *(straight)* **[40.8780.100]** or *(angled)* **[40.8781.100]** to the handle ratchet device **[40.6654.001]**.





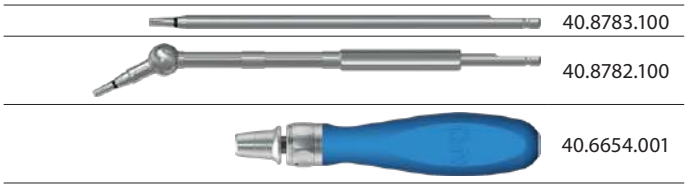
Place the trocar in the hole of the aiming block **[40.8785.100]** and, by rotating, continue inserting the trocar until the limiter of the trocar rests against the aiming block.

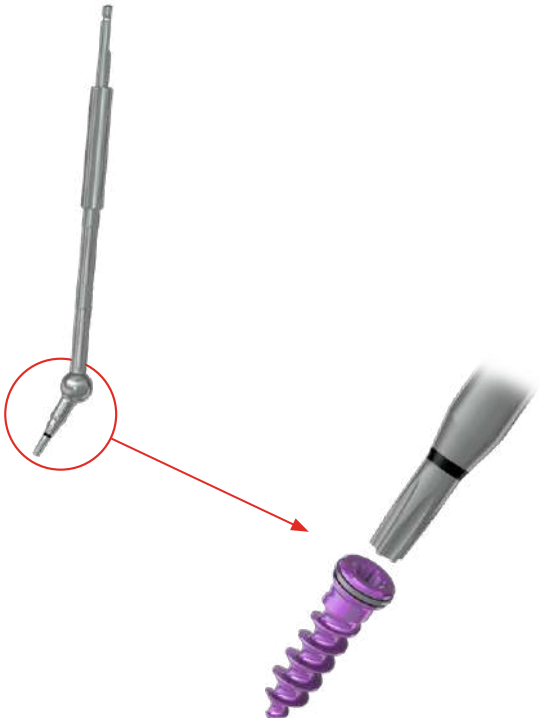




IV.7. SCREWS INSERTION

Connect the handle ratchet device **[40.6654.001]** with screwdriver tip T10 with joint **[40.8782.100]** or screwdriver tip T10 **[40.8783.100]**.



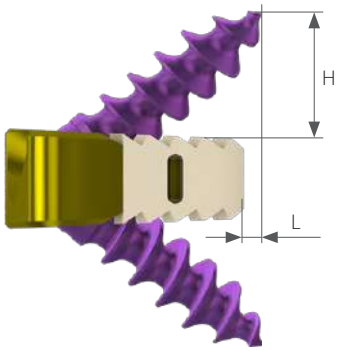


Install the determined screw.

3.5mm diameter screws should be used first.

4.0mm screws should only be used in emergency situations when the use of 3.5mm screw does not ensure secure anchoring of the intervertebral cage.

CAUTION:
For optimal stabilization, it is recommended to use the longest screws.
When selecting the screws, consider the information on the protrusion of screws outside the intervertebral cage of the table *(Tab.1)*.

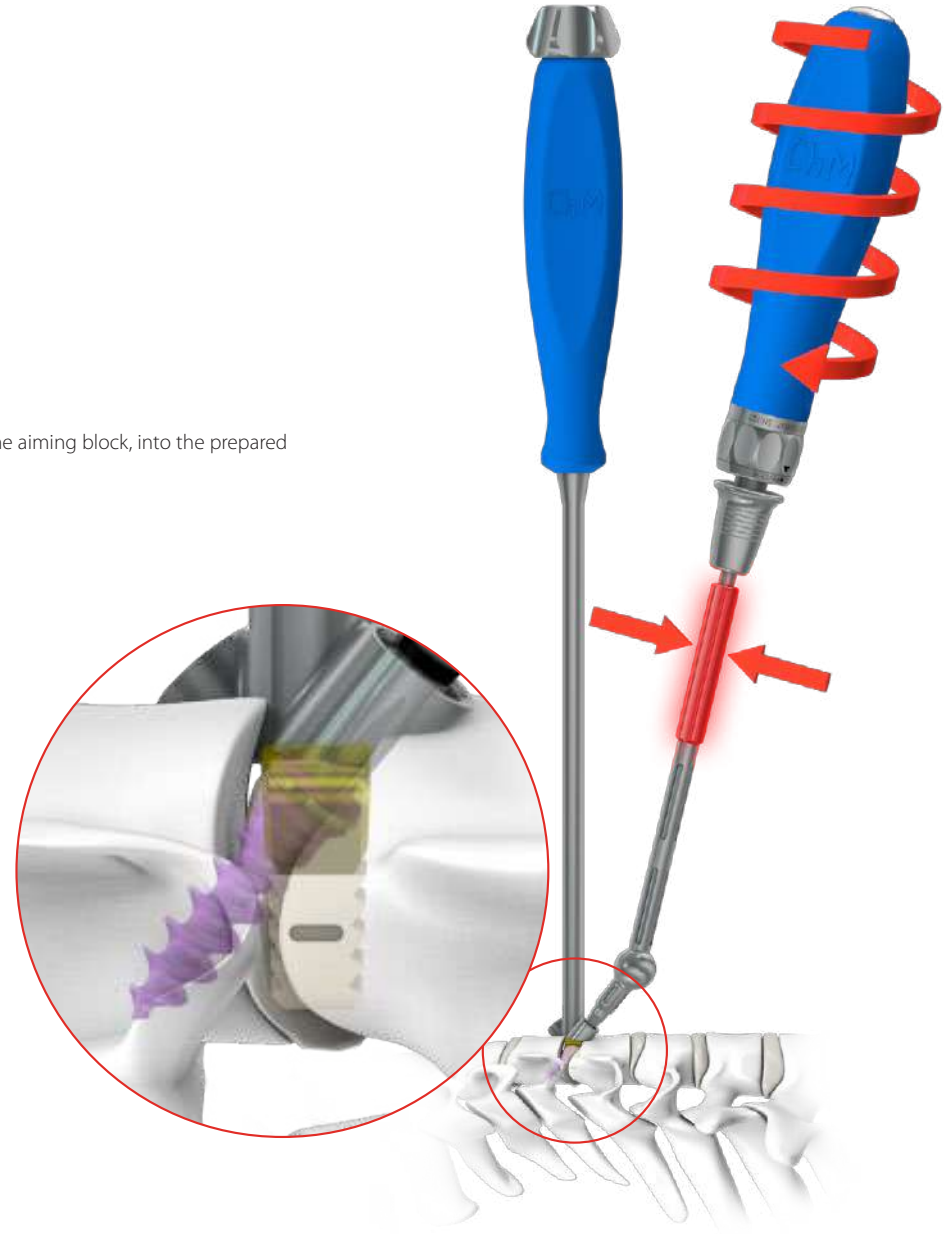


Cage 15x12		
Screw length	**L**	**H**
10	Does not protrude	3.6
12	Does not protrude	4.8
14	0.7	6
16	2.2	7.3

Cage 17x13		
Screw length	**L**	**H**
10	Does not protrude	3.7
12	Does not protrude	4.9
14	Does not protrude	6.1
16	1.2	7.3

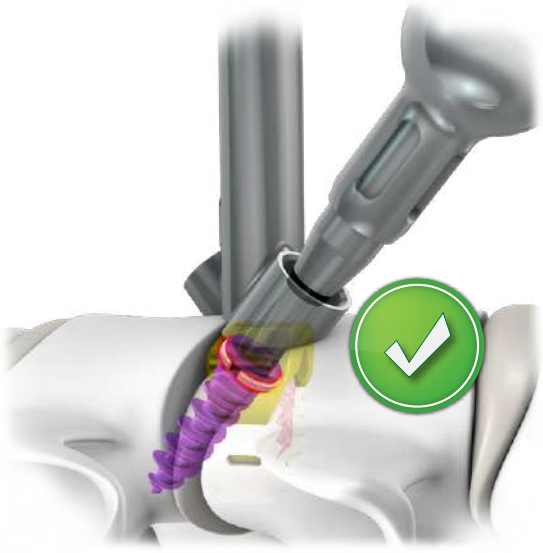
Tab.1. Selection of screws

Carefully insert the attached screw, through the aiming block, into the prepared hole using clockwise rotation.



When the marker on the screwdriver shaft lines with the aiming block, the screw has been properly inserted and the securing ring of the screw got locked in the groove in the intervertebral cage.

Not locked screw



Locked screw

For the intervertebral cage to be properly locked, repeat the procedure for the other hole.

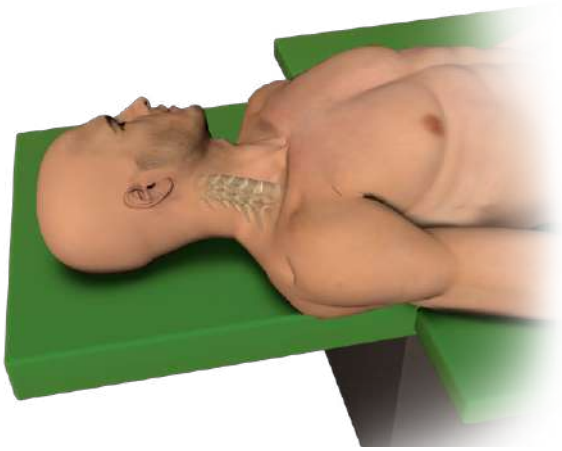
After locking the cage, remove the applicator **[40.8784.000]** by rotating the knob counter-clockwise.

To make sure that the screws have been properly locked, ensure, after removing the applicator, that the rings on the screws are hidden in the cage.

V. SURGICAL TECHNIQUE *(WITH USE OF CASPAR CERVICAL DISTRACTOR)*

V.1. PATIENT POSITIONING AND SURGICAL APPROACH

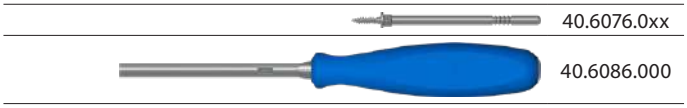
The patient shall be in supine position with his head in a neutral position or rotated about 30° from the neutral position to the left or right, opposite to the surgical approach.



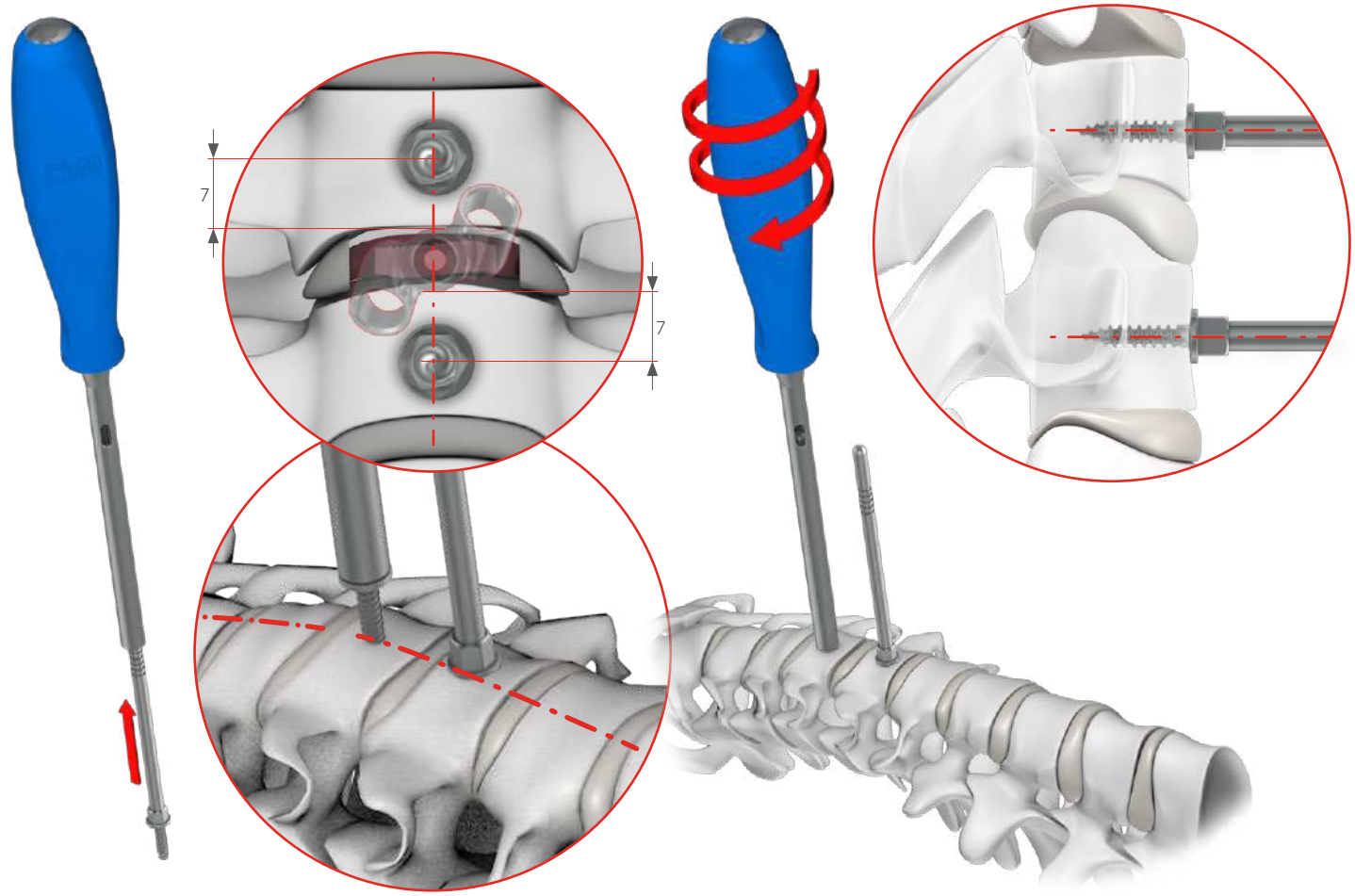
V.2. INSERTION OF CASPAR CERVICAL DISTRACTOR

Caspar cervical distractor [40.6075.000], Caspar pins [40.6076.0xx], and screwdriver for Caspar pins [40.6086.000] are not included in the standard set.
In order to include them to the ordered instrument set for cervical locking cages, please contact your local representative or **ChM** Sales Department.

The Caspar cervical distractor is used to prevent the closure of the intervertebral space during discectomy and further surgical procedure.



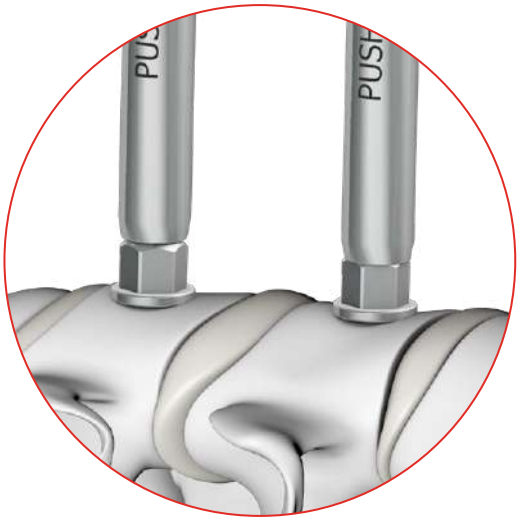
Choose intraoperatively, on the basis of X-Ray image, the length of the Caspar pin **[40.6076.0xx]** *(14mm or 16mm)*.
Insert the selected pins using screwdriver **[40.6086.000]** in a vertebra located above and below the operated intervertebral disc. The inserted pins should be parallel to each other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



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

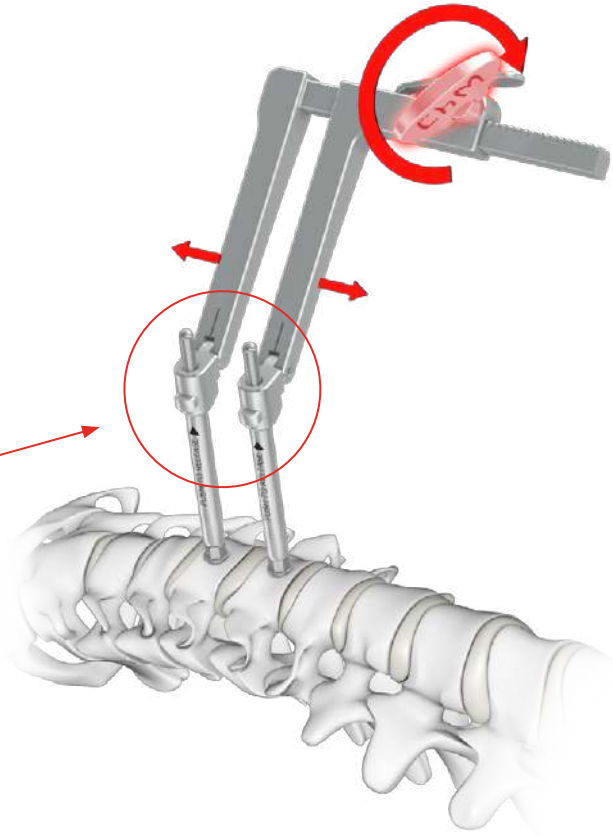
40.6075.000

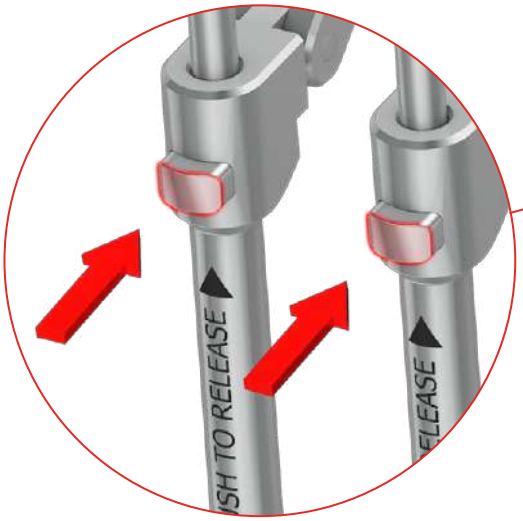
Insert Caspar cervical distractor **[40.6075.000]** sleeves onto the Caspar pins until the sleeves meet the collars of the pins.



Perform gentle distraction by rotating the knob clockwise.

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

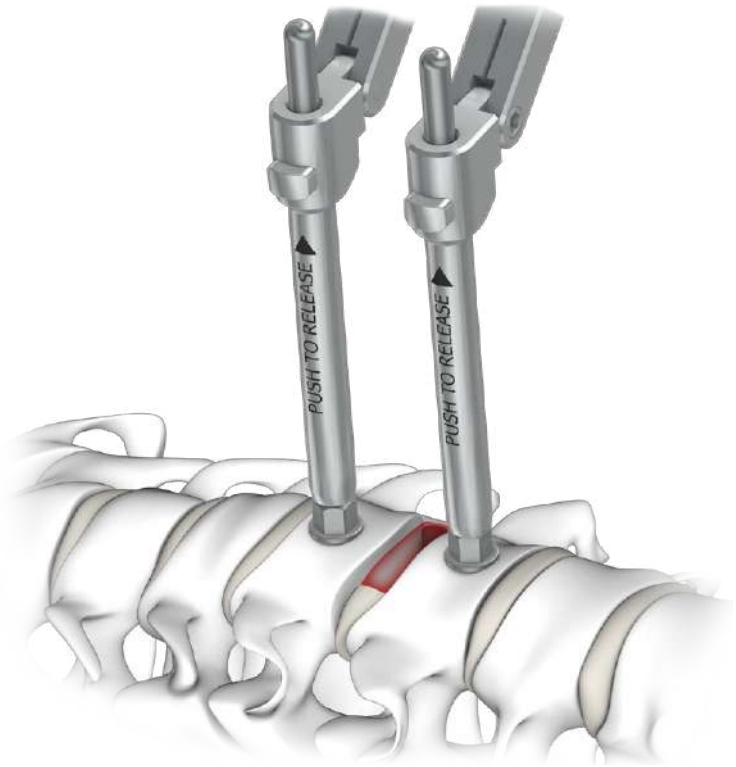




V.3. DISCECTOMY

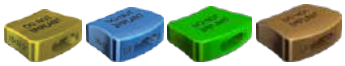
Remove the intervertebral disc using standard procedure and instruments to perform such an operation.

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



V.4. IMPLANT SELECTION

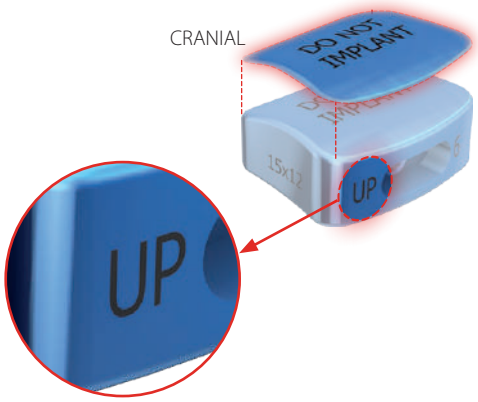
Implant size is selected on the basis of trials [40.6082.0xx], [40.6083.0xx], [40.6092.0xx], [40.6093.0xx] whose shapes and dimensions correspond to the available implants.

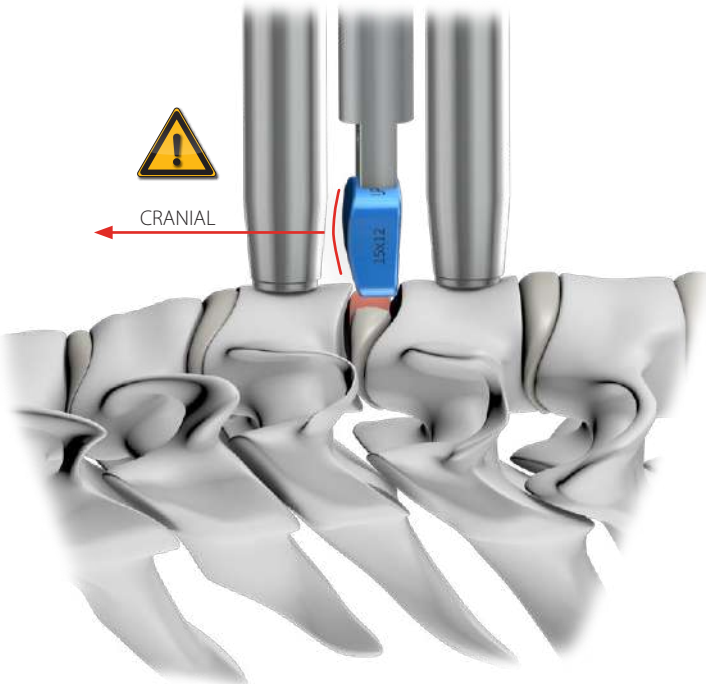
	40.6082.0xx, 40.6083.0xx 40.6092.0xx 40.6093.0xx
	40.6080.000

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

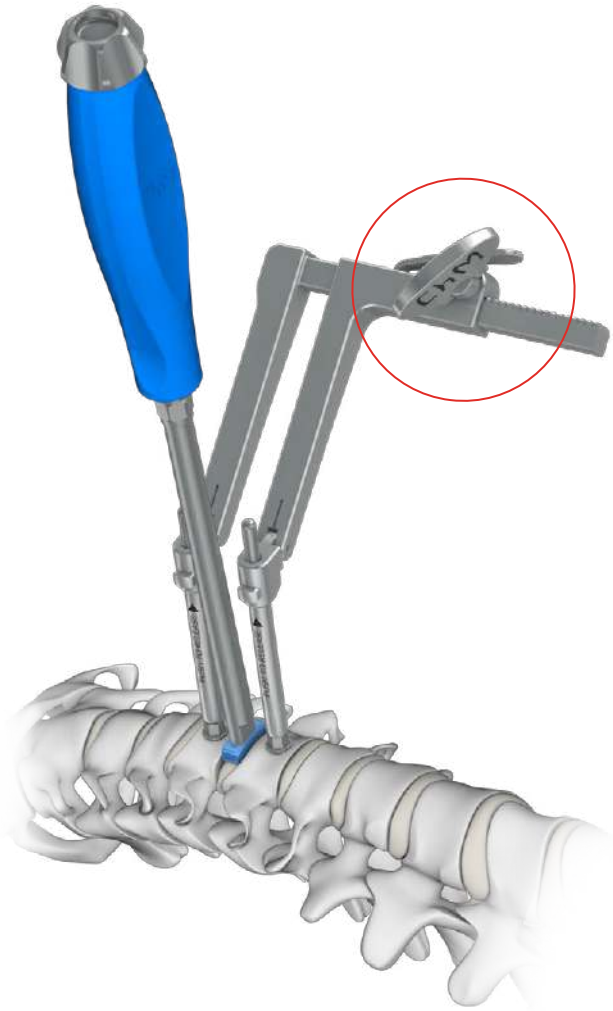
Mount the selected trial to the persuader **[40.6080.000]** - insert the trial on the persuader tip and by rotating the persuader knob clockwise, tighten the locking pin in the socket of the trial.

Convex trials [40.6082.0xx], [40.6092.0xx] should be inserted with the convex surface facing the head *(cranial direction)*.
The convex part of the trial is above the word *"UP"*.





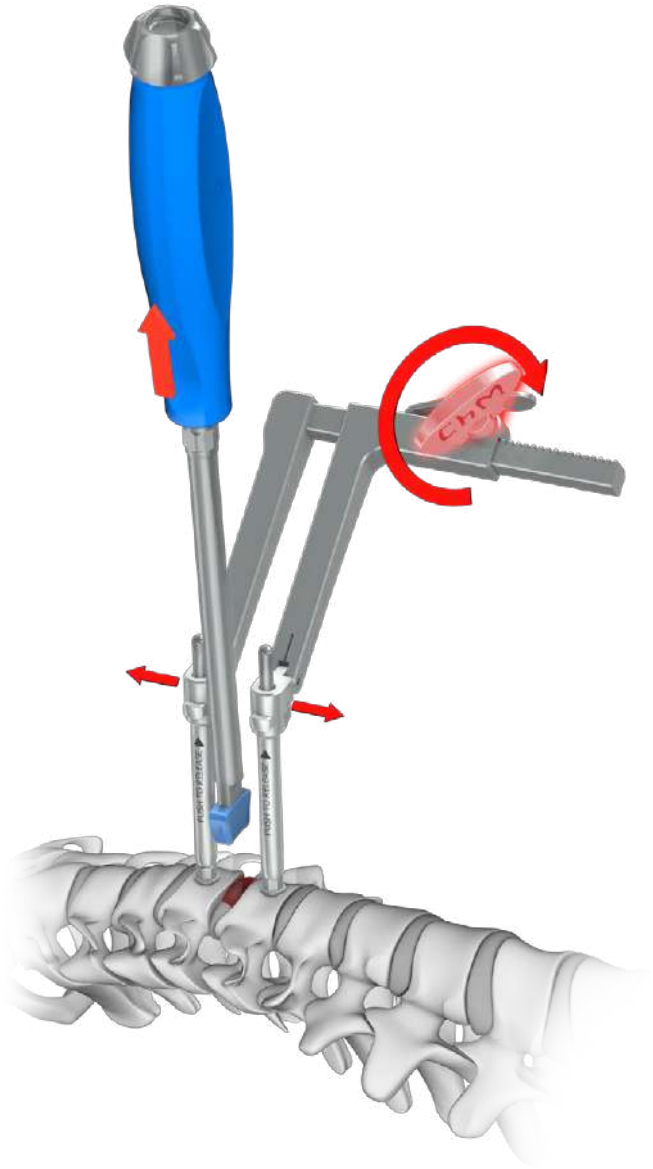
Insert the selected trial into the intervertebral space so that the top surface of the trial is located approximately 2mm below the top surface of the vertebral body.



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.



Distract the vertebrae again and remove the trial.

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

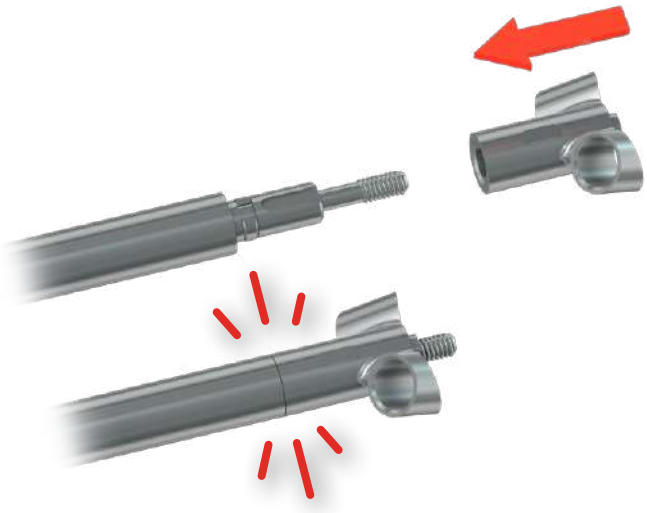
Based on the selected trial, choose an implant of the same size and shape. The implant will be used later in the procedure.

V.5. IMPLANT PREPARATION

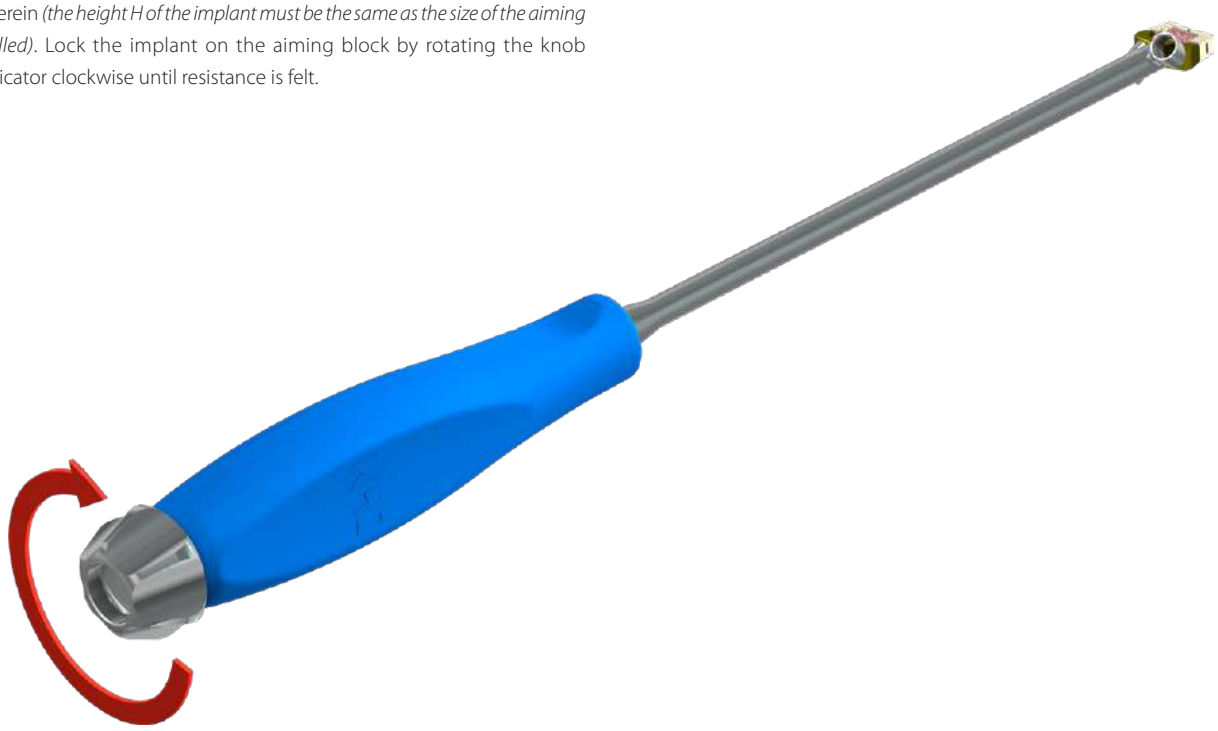
Before implantation, the space in the PEEK intervertebral cervical cage should be filled with autologous bone graft *(bone chips)* which allows for spinal fusion.

	40.8784.000
	40.8785.105 40.8785.106 40.8785.107 40.8785.108 40.8785.109 40.8785.110

Install the selected aiming block **[40.8785.1xx]** *(the height H of which must be the same as for the height of the final trial used)* to the applicator **[40.8784.000]** - the click sound must be heard.

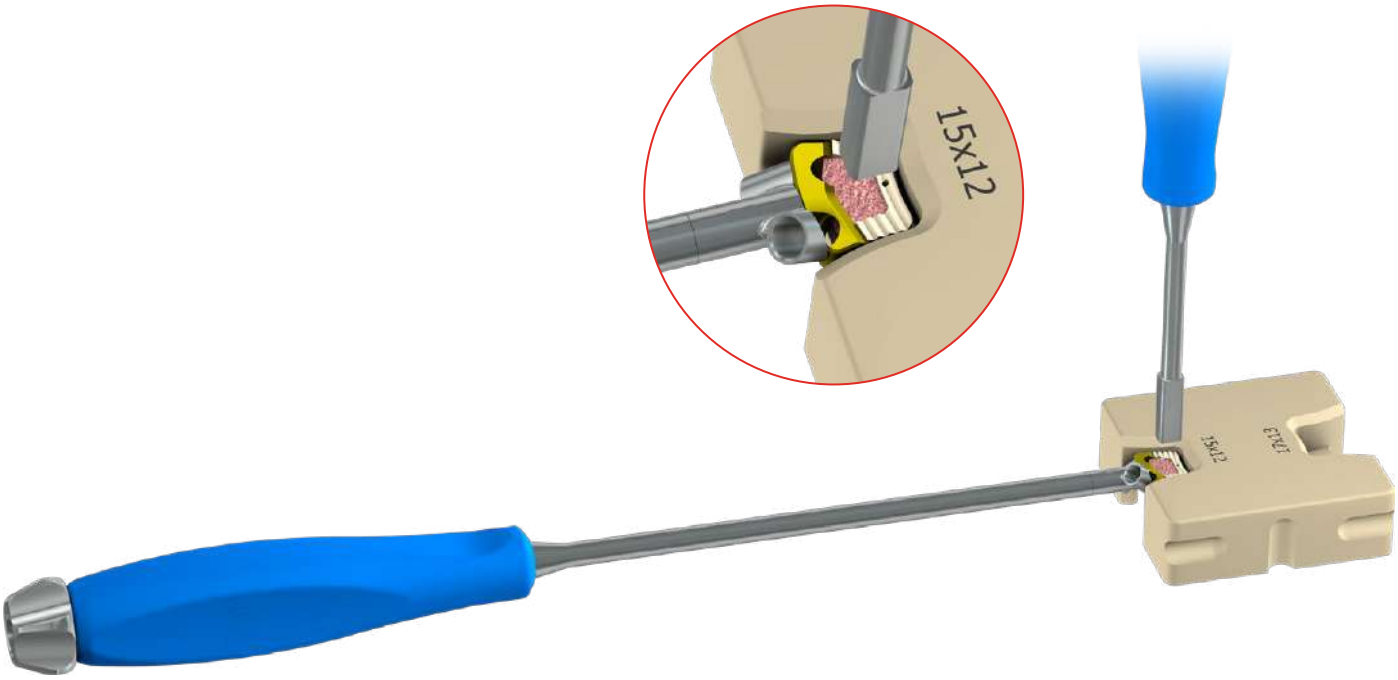


Then connect the intervertebral cage with the applicator and the aiming block installed therein *(the height H of the implant must be the same as the size of the aiming block installed)*. Lock the implant on the aiming block by rotating the knob of the applicator clockwise until resistance is felt.



	40.8786.100
	40.6077.000

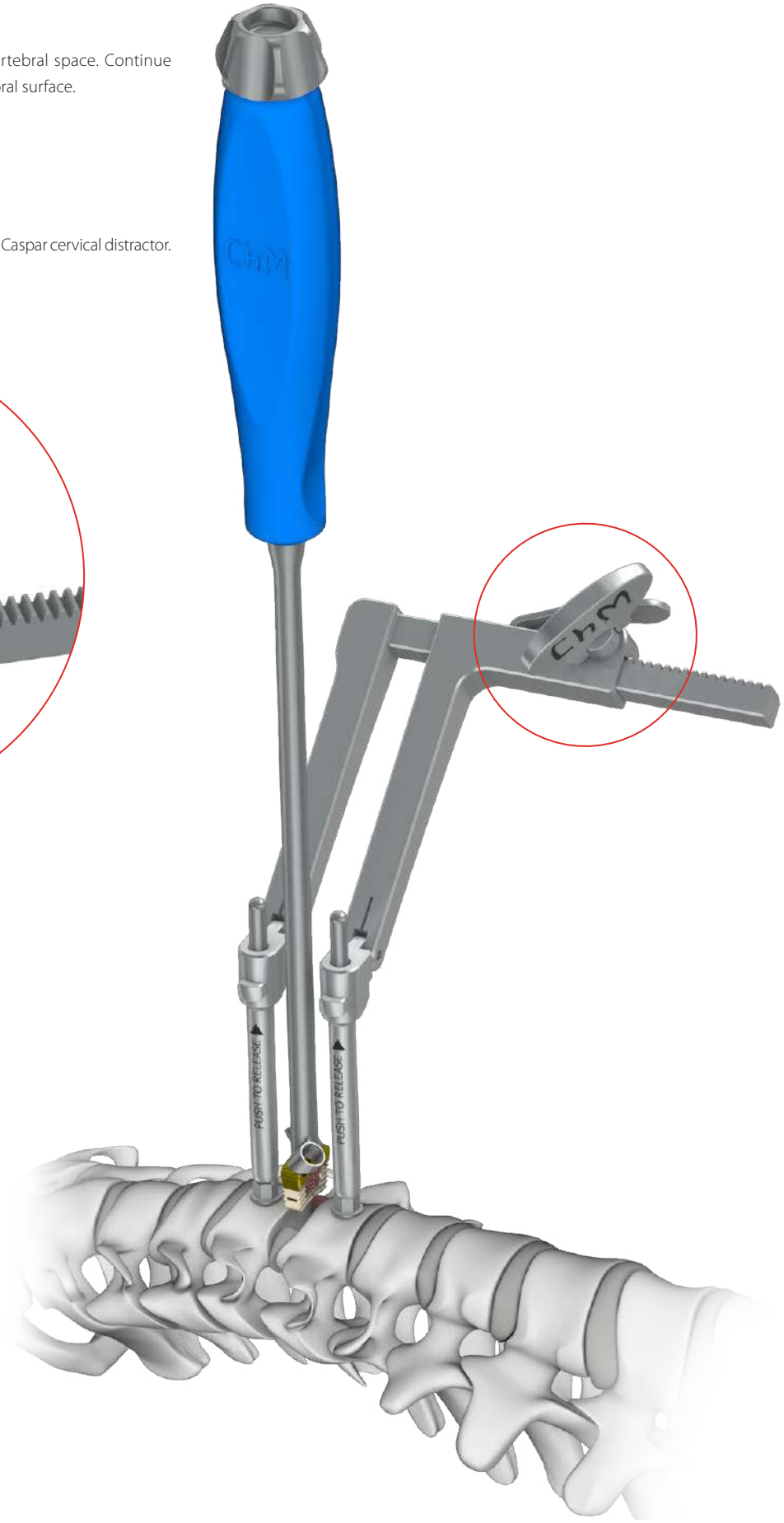
Place the implant in an appropriate socket of the working stand **[40.8786.100]** and fill with bone chips. Compress them with compactor **[40.6077.000]**.



V.6. IMPLANT INSERTION

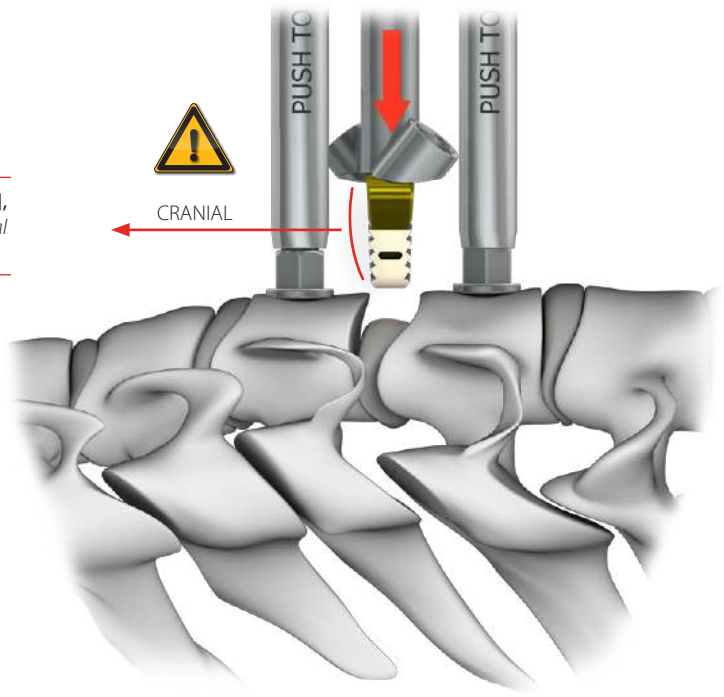
Insert implant, filled with bone graft, into the intervertebral space. Continue inserting until the aiming block leans against the vertebral surface.

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

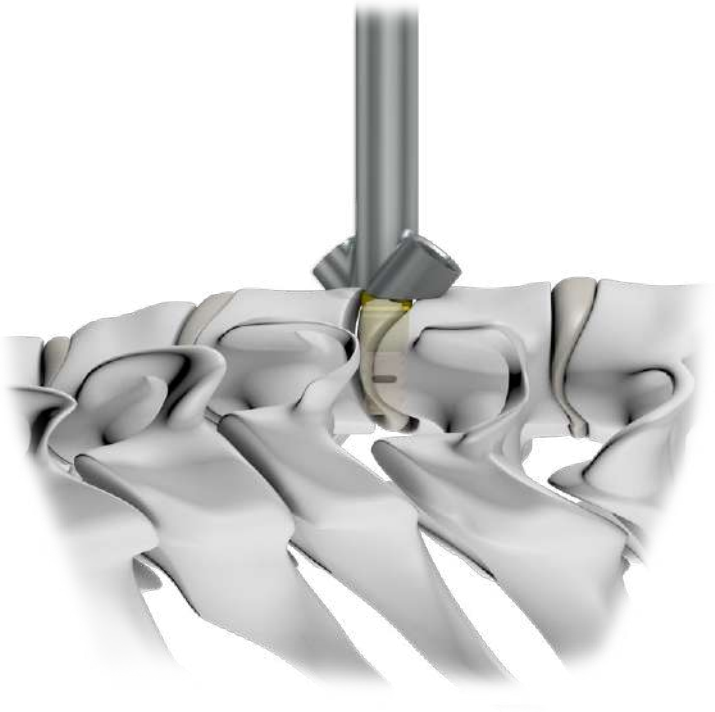


The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

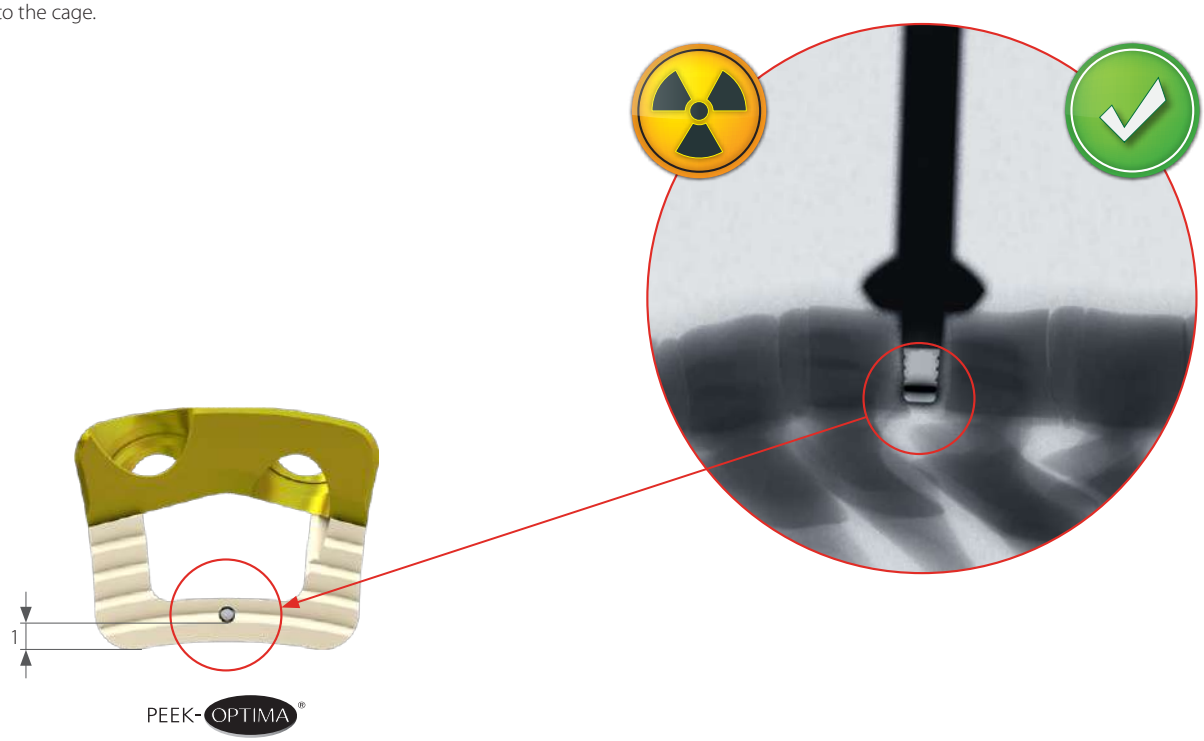
Convex cervical intervertebral cages [8.6973.xxx], [8.6972.xxx], should be inserted with the convex surface facing the head *(cranial direction)*.



Having inserted the cage into the intervertebral space, remove the Caspar distractor and pins and leave the applicator in place.

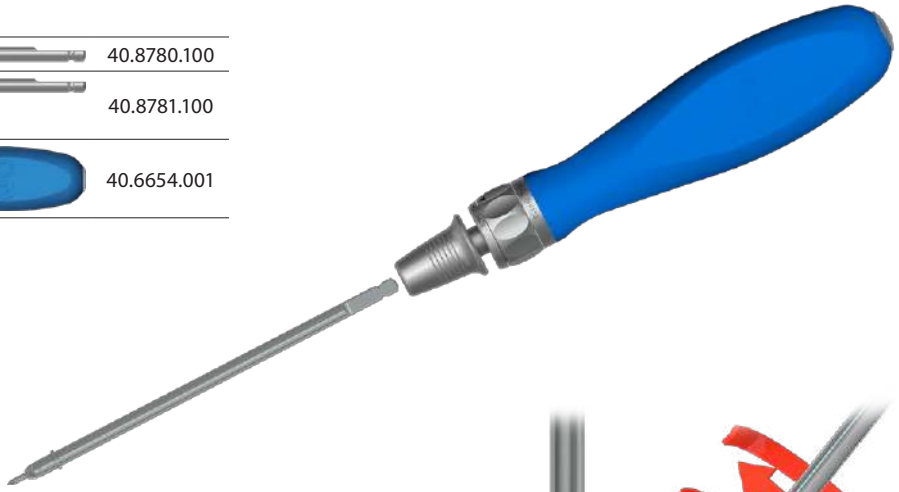


The embedded tantalum marker is used to navigate the position of the posterior wall of the intervertebral cage *(the marker is located 1mm from the edge of the cage)*. The marker is also used to determine whether the endplates of the vertebral bodies adhere properly to the cage.

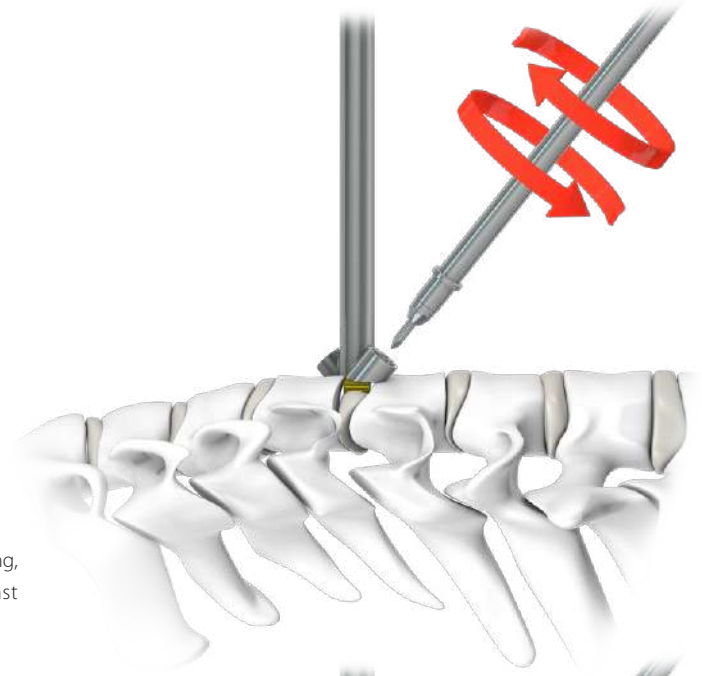


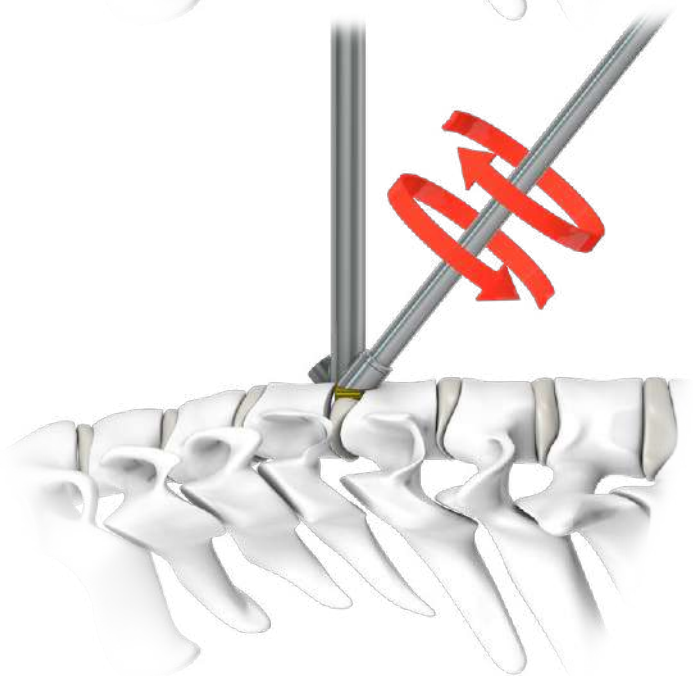
V.7. HOLES DRILLING AND SCREWS INSERTION

Connect the trocar *(straight)* **[40.8780.100]** or *(angled)* **[40.8781.100]** to the handle ratchet device **[40.6654.001]**.



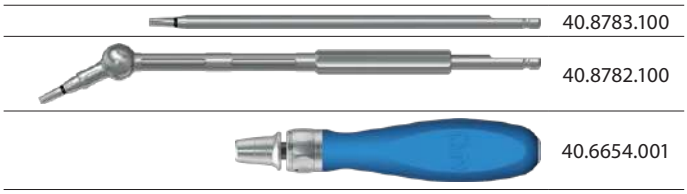
Place the trocar in the hole of the aiming block **[40.8785.1xx]** and, by rotating, continue inserting the trocar until the limiter of the trocar rests against the aiming block.





V.8. SCREWS INSERTION

Connect the handle ratchet device **[40.6654.001]** with screwdriver tip T10 with joint **[40.8782.100]** or screwdriver tip T10 **[40.8783.100]**.

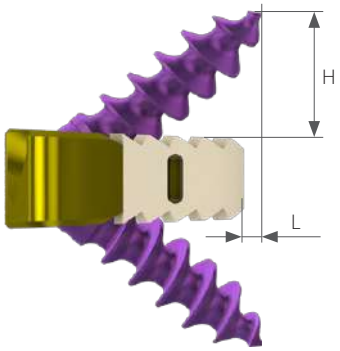


Install the determined screw.

3.5mm diameter screws should be used first.

4.0mm screws should only be used in emergency situations when the use of 3.5mm screw does not ensure secure anchoring of the intervertebral cage.

CAUTION:
For optimal stabilization, it is recommended to use the longest screws.
When selecting the screws, consider the information on the protrusion of screws outside the intervertebral cage of the table *(Tab.1)*.

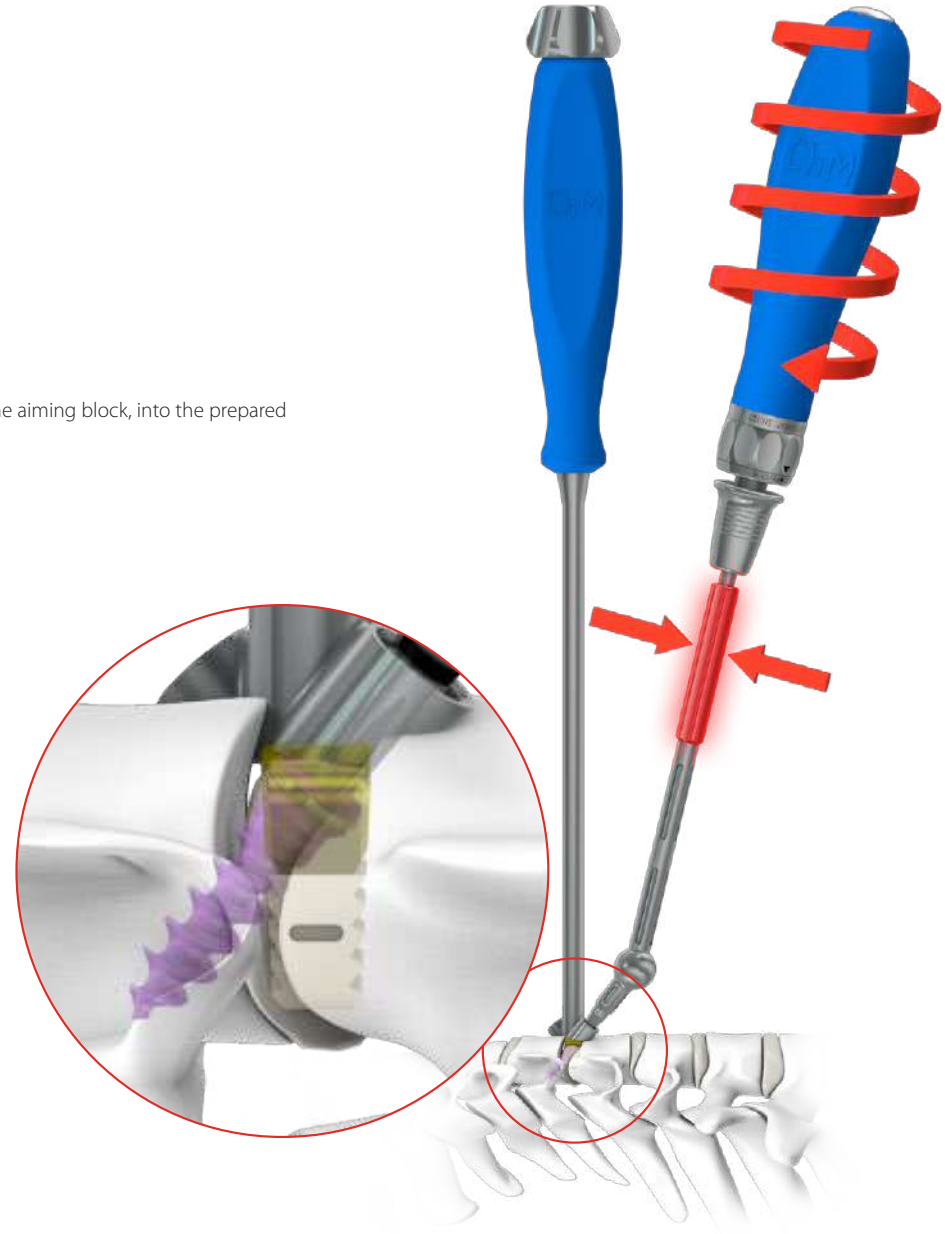


Cage 15x12		
Screw length	**L**	**H**
10	Does not protrude	3.6
12	Does not protrude	4.8
14	0.7	6
16	2.2	7.3

Cage 17x13		
Screw length	**L**	**H**
10	Does not protrude	3.7
12	Does not protrude	4.9
14	Does not protrude	6.1
16	1.2	7.3

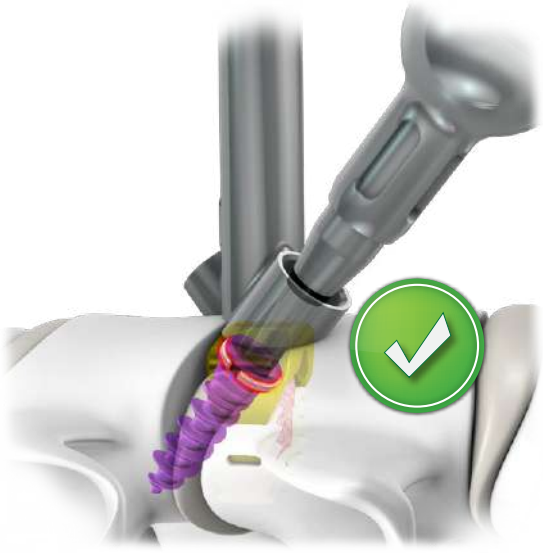
Tab.1. Selection of screws

Carefully insert the attached screw, through the aiming block, into the prepared hole using clockwise rotation.



When the marker on the screwdriver shaft lines with the aiming block, the screw has been properly inserted and the securing ring of the screw got locked in the groove in the intervertebral cage.

Not locked screw



Locked screw

For the intervertebral cage to be properly locked, repeat the procedure for the other hole.

After locking the cage, remove the applicator **[40.8784.000]** by rotating the knob counter-clockwise.

To make sure that the screws have been properly locked, ensure, after removing the applicator, that the rings on the screws are hidden in the cage.

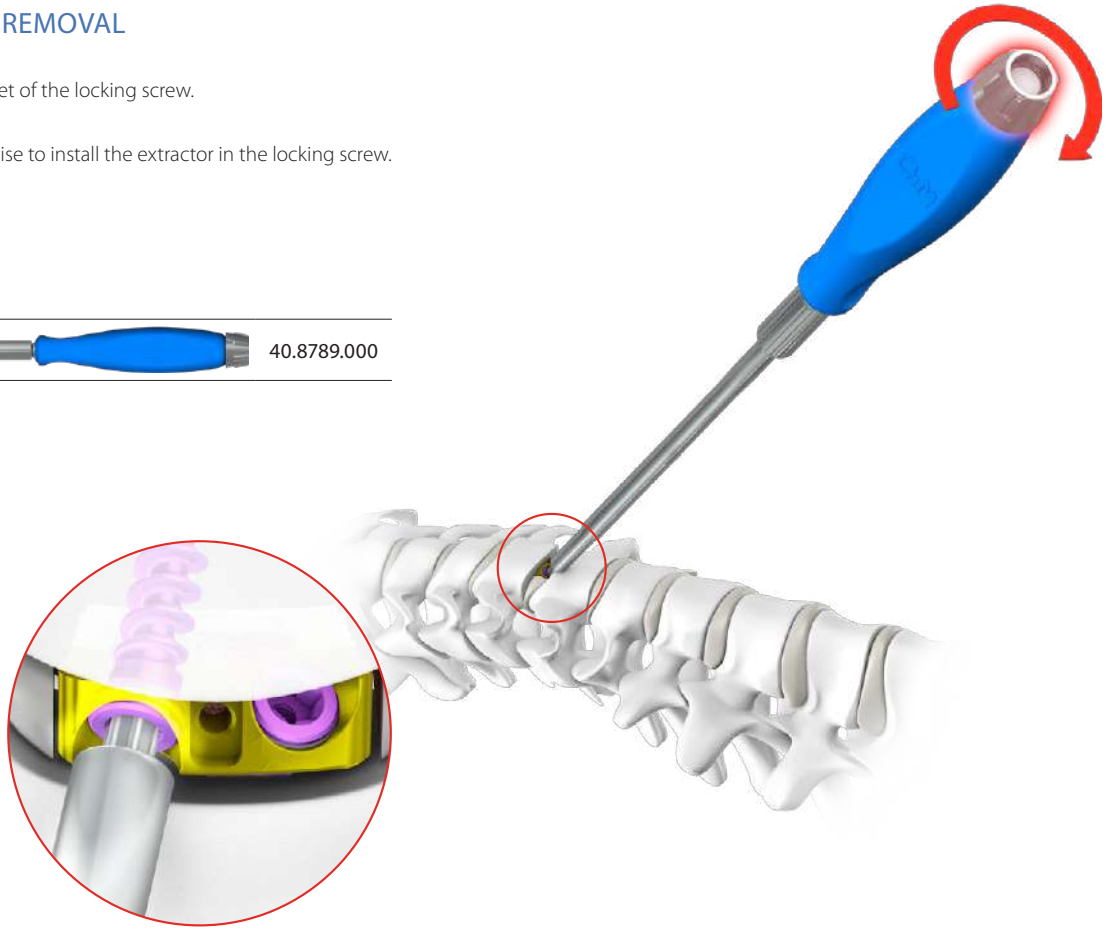
VI. IMPLANT REMOVAL

VI.1. LOCKING SCREWS REMOVAL

Insert the extractor tip in the socket of the locking screw.

Rotate the knob of the pin clockwise to install the extractor in the locking screw.

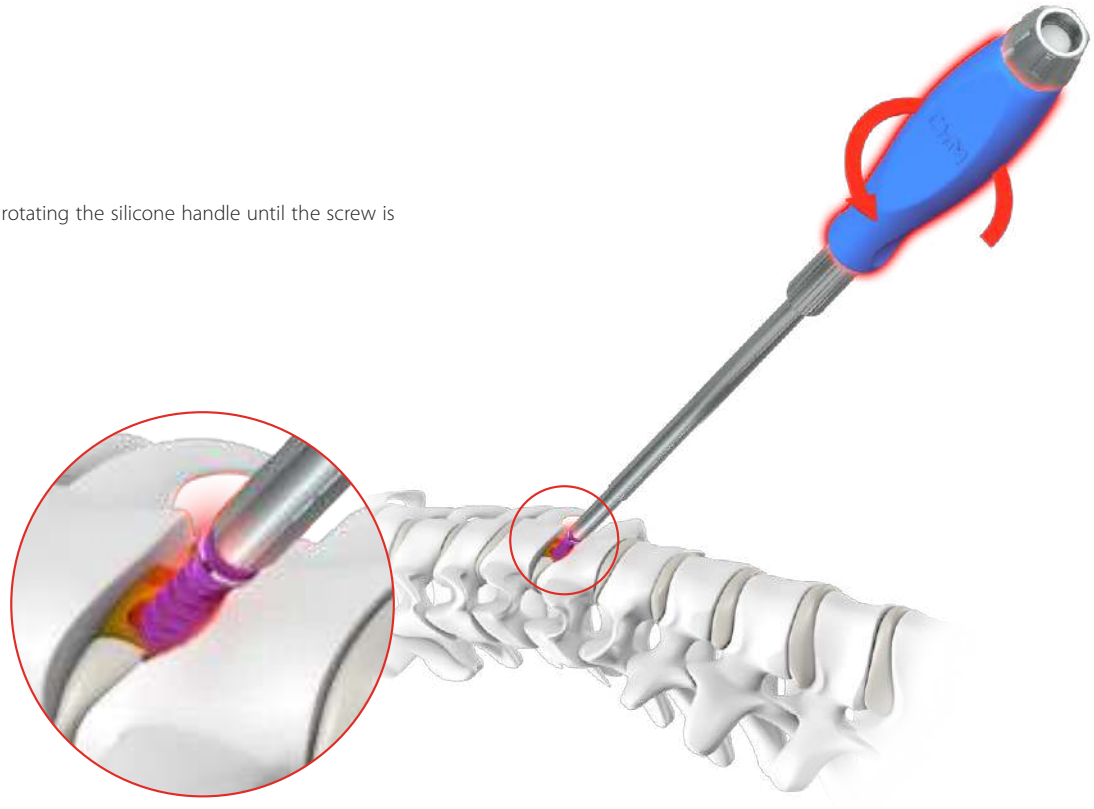
40.8789.000



Lower the extractor sleeve until it stops by rotating the sleeve knob clockwise.

While holding the extractor sleeve *(against its rotation)*, continue rotating the silicone handle counterclockwise *(about 1 full rotation)* until strong resistance on the sleeve is felt *(the screw is unlocked)*.

Release the sleeve and continue rotating the silicone handle until the screw is completely removed.



When removed, unlock the screw from the extractor by counter-clockwise rotation.

CAUTION:
Once the screw has been removed from the intervertebral cage, it cannot be used again.

VI.2. INTERVERTEBRAL CAGE REMOVAL

When the screws are removed, connect the intervertebral cage with the applicator and the aiming block installed therein and gently pull out the implant.

If necessary, Caspar distractor should be used to distract the vertebral bodies.

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

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

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