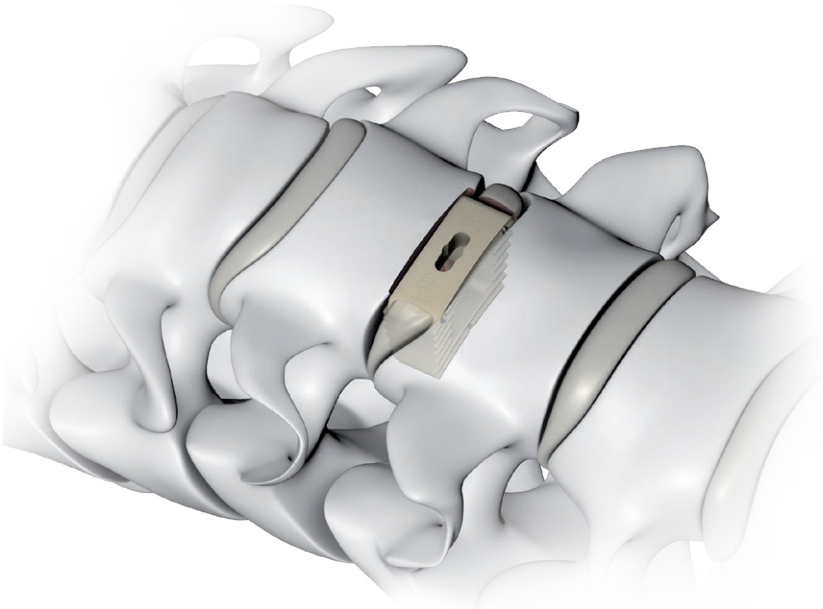
ST/66B

CHM®

CHARSPINE system 2

INTERVERTEBRAL CERVICAL CAGE

- *IMPLANTS*
- *INSTRUMENT SET 15.0902.002*
- *SURGICAL TECHNIQUE*



www.chm.eu

SYMBOLS DESCRIPTIONS

	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Information about the next stages of the proceeding.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use supplied with the product. 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/66B

Date of issue 26.10.2017

Review date P-006-24.08.2020

The manufacturer reserves the right to introduce design changes.

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

I. SYSTEM DESCRIPTION 5

I.1. INDICATION 5

II. IMPLANTS 6

II.1. AVAILABLE SIZES AND VARIANTS 7

III. INSTRUMENT SET 10

IV. SURGICAL TECHNIQUE *(USING CASPAR CERVICAL DISTRACTOR)* 14

IV.1. PATIENT POSITIONING AND SURGICAL APPROACH 14

IV.2. INSERTION OF CASPAR CERVICAL DISTRACTOR 14

IV.3. DISCECTOMY 16

IV.4. IMPLANT SELECTION 17

IV.5. PREPARATION OF THE VERTEBRAL BODIES ENDPLATES 20

IV.6. IMPLANT PREPARATION 21

IV.7. IMPLANT INSERTION 22

V. SURGICAL TECHNIQUE *(WITHOUT USING CASPAR CERVICAL DISTRACTOR)* 25

V.1. PATIENT POSITIONING AND SURGICAL APPROACH 25

V.2. DISCECTOMY 25

V.3. IMPLANT SELECTION 26

V.4. PREPARATION OF THE VERTEBRAL BODIES ENDPLATES 29

V.5. IMPLANT PREPARATION 30

V.6. IMPLANT INSERTION 31

VI. IMPLANT REMOVAL 33

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 level of 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)* or tantalum,
- spine infections,
- vertebral fractures.

(The above list is not exhaustive).

II. IMPLANTS

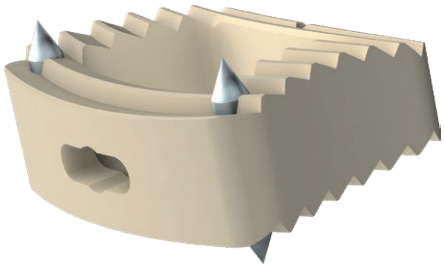
ChM implants have been designed for the best fit to the anatomical shapes of the cervical bodies, to maximize their safety.
The arc-shaped anterior wall of the implant imitates the curvature of the anterior part of the vertebral body maximizing the contact surface of the implant with the endplates and 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:

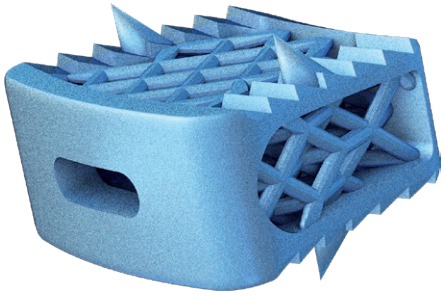
PEEK

- 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.

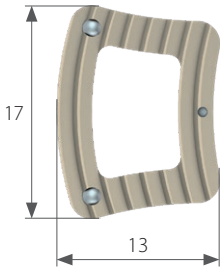


For quick identification, each implant is marked with the size and shape.

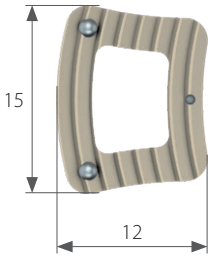
ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 86 86 100, fax + 48 85 86 86 101, chm@chm.eu, www.chm.eu

II.1. AVAILABLE SIZES AND VARIANTS

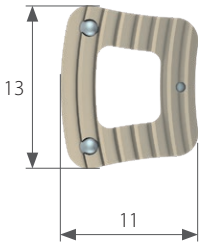
Overall dimensions [mm]



17x13

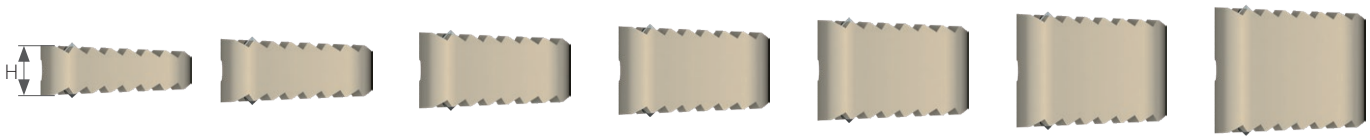


15x12



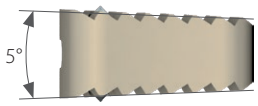
13x11

Height sizes H [mm]

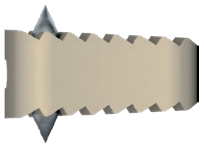


4 5 6 7 8 9 10

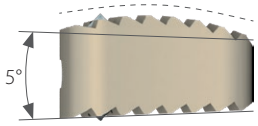
Variants



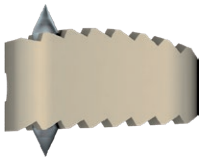
Angular



Angular with spikes



Convex



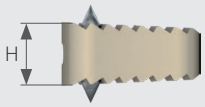
Convex with spikes

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

Angular cervical intervertebral cage

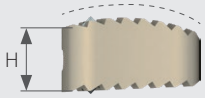
Size 17x13 [mm]		Size 15x12 [mm]		Size 13x11 [mm]	
Catalogue no.	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**
8.4558.004	4	8.4554.004	4	8.4556.004	4
8.4558.005	5	8.4554.005	5	8.4556.005	5
8.4558.006	6	8.4554.006	6	8.4556.006	6
8.4558.007	7	8.4554.007	7	8.4556.007	7
8.4558.008	8	8.4554.008	8	8.4556.008	8
8.4558.009	9	8.4554.009	9	8.4556.009	9
8.4558.010	10	8.4554.010	10	8.4556.010	10

Angular cervical intervertebral cage *(with spikes)*



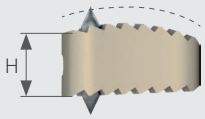
Size 17x13 [mm]		Size 15x12 [mm]		Size 13x11 [mm]	
Catalogue no.	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**
8.4584.004	4	8.4582.004	4	8.4580.004	4
8.4584.005	5	8.4582.005	5	8.4580.005	5
8.4584.006	6	8.4582.006	6	8.4580.006	6
8.4584.007	7	8.4582.007	7	8.4580.007	7
8.4584.008	8	8.4582.008	8	8.4580.008	8
8.4584.009	9	8.4582.009	9	8.4580.009	9
8.4584.010	10	8.4582.010	10	8.4580.010	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]**
8.4559.004	4	8.4555.004	4	8.4557.004	4
8.4559.005	5	8.4555.005	5	8.4557.005	5
8.4559.006	6	8.4555.006	6	8.4557.006	6
8.4559.007	7	8.4555.007	7	8.4557.007	7
8.4559.008	8	8.4555.008	8	8.4557.008	8
8.4559.009	9	8.4555.009	9	8.4557.009	9
8.4559.010	10	8.4555.010	10	8.4557.010	10

Convex cervical intervertebral cage *(with spikes)*

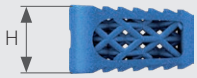


Size 17x13 [mm]		Size 15x12 [mm]		Size 13x11 [mm]	
Catalogue no.	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**
8.4585.004	4	8.4583.004	4	8.4581.004	4
8.4585.005	5	8.4583.005	5	8.4581.005	5
8.4585.006	6	8.4583.006	6	8.4581.006	6
8.4585.007	7	8.4583.007	7	8.4581.007	7
8.4585.008	8	8.4583.008	8	8.4581.008	8
8.4585.009	9	8.4583.009	9	8.4581.009	9
8.4585.010	10	8.4583.010	10	8.4581.010	10

Material: PEEK-OPTIMA®

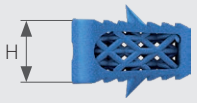
ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 86 86 100, fax + 48 85 86 86 101, chm@chm.eu, www.chm.eu

3D-Ti Angular cervical intervertebral cage



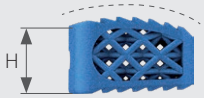
Size 17x13 [mm]		Size 15x12 [mm]		Size 13x11 [mm]	
Catalogue no.	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**
3.6937.004	4	3.6936.004	4	3.6935.004	4
3.6937.005	5	3.6936.005	5	3.6935.005	5
3.6937.006	6	3.6936.006	6	3.6935.006	6
3.6937.007	7	3.6936.007	7	3.6935.007	7
3.6937.008	8	3.6936.008	8	3.6935.008	8
3.6937.009	9	3.6936.009	9	3.6935.009	9
3.6937.010	10	3.6936.010	10	3.6935.010	10

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



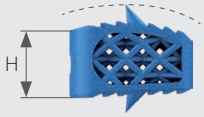
Size 17x13 [mm]		Size 15x12 [mm]		Size 13x11 [mm]	
Catalogue no.	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**	**Catalogue no.**	**Height H [mm]**
3.6940.004	4	3.6939.004	4	3.6938.004	4
3.6940.005	5	3.6939.005	5	3.6938.005	5
3.6940.006	6	3.6939.006	6	3.6938.006	6
3.6940.007	7	3.6939.007	7	3.6938.007	7
3.6940.008	8	3.6939.008	8	3.6938.008	8
3.6940.009	9	3.6939.009	9	3.6938.009	9
3.6940.010	10	3.6939.010	10	3.6938.010	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]**
3.6943.004	4	3.6942.004	4	3.6941.004	4
3.6943.005	5	3.6942.005	5	3.6941.005	5
3.6943.006	6	3.6942.006	6	3.6941.006	6
3.6943.007	7	3.6942.007	7	3.6941.007	7
3.6943.008	8	3.6942.008	8	3.6941.008	8
3.6943.009	9	3.6942.009	9	3.6941.009	9
3.6943.010	10	3.6942.010	10	3.6941.010	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]**
3.6946.004	4	3.6945.004	4	3.6944.004	4
3.6946.005	5	3.6945.005	5	3.6944.005	5
3.6946.006	6	3.6945.006	6	3.6944.006	6
3.6946.007	7	3.6945.007	7	3.6944.007	7
3.6946.008	8	3.6945.008	8	3.6944.008	8
3.6946.009	9	3.6945.009	9	3.6944.009	9
3.6946.010	10	3.6945.010	10	3.6944.010	10

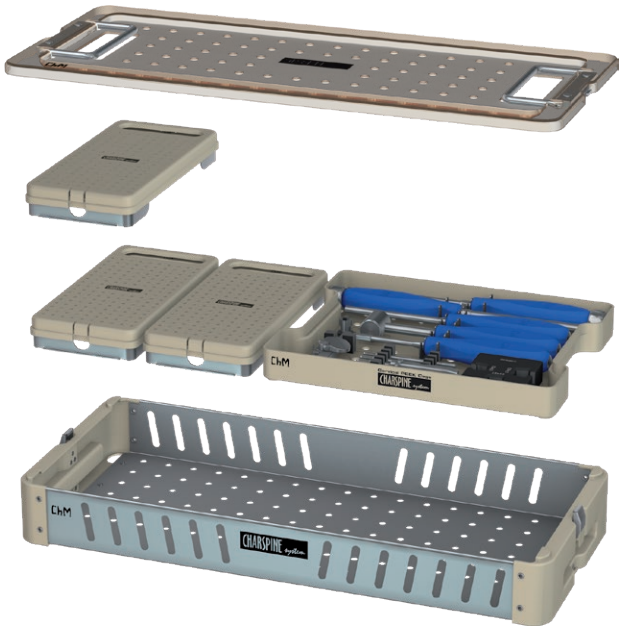
Material: Ti

III. INSTRUMENT SET

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.

Set – Cervical intervertebral cages	15.0902.002



14.0902.102
Lid
- Cervical intervertebral cages 9x4

15.0902.202
Instrument set
- Cervical intervertebral cages

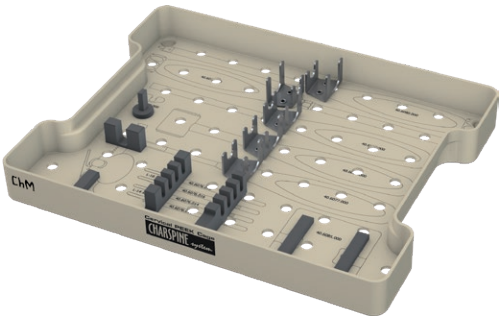
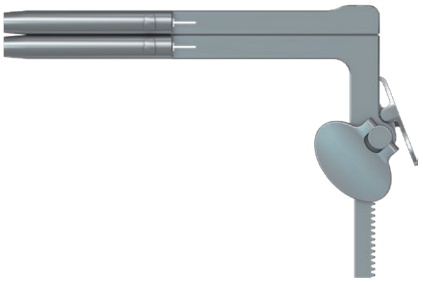
15.0902.203
Instrument set
- Cervical intervertebral cages

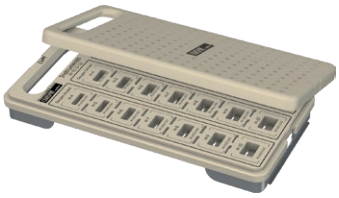
15.0902.204
Instrument set
- Cervical intervertebral cages

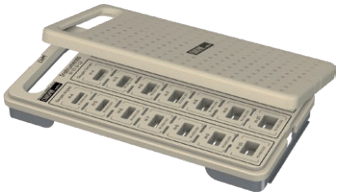
15.0902.201
Instrument set
- Cervical intervertebral cages

14.0902.101
Container
- Cervical intervertebral cages 9x4 1/2H

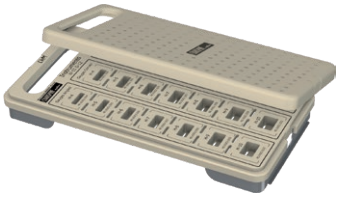
ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 86 86 100, fax + 48 85 86 86 101, chm@chm.eu, www.chm.eu

Instrument set - Cervical intervertebral cages 15.0902.201	**Name**	**Catalogue No.**	**Pcs**
	Tray for instrument set -Cervical intervertebral cages 5x4 1/2H	14.0902.201	1
	Applicator	40.6078.000	1
	Persuader	40.6080.000	1
	Screwdriver for Caspar pins	40.6086.000	1
	Compactor	40.6077.000	1
	Hammer 200g	40.6087.000	1
	Working stand	40.6085.000	1
	Position retainer	40.6079.000	1
	Caspar cervical distractor	40.6075.000	1
	Caspar pin 3.0x14	40.6076.014	2
	Caspar pin 3.0x16	40.6076.016	2

Instrument set - Cervical intervertebral cages 15.0902.202	Name	Catalogue No.	Pcs
	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

Instrument set - Cervical intervertebral cages 15.0902.203	Name	Catalogue No.	Pcs
	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

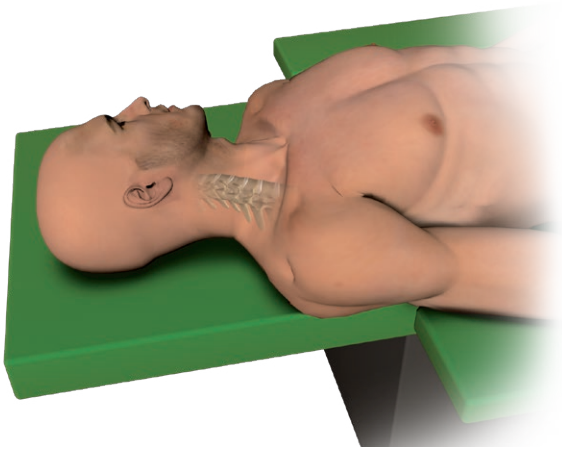
ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 86 86 100, fax + 48 85 86 86 101, chm@chm.eu, www.chm.eu

Instrument set - Cervical intervertebral cages 15.0902.204	Name	Catalogue No.	Pcs
	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

IV. SURGICAL TECHNIQUE *(USING 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.

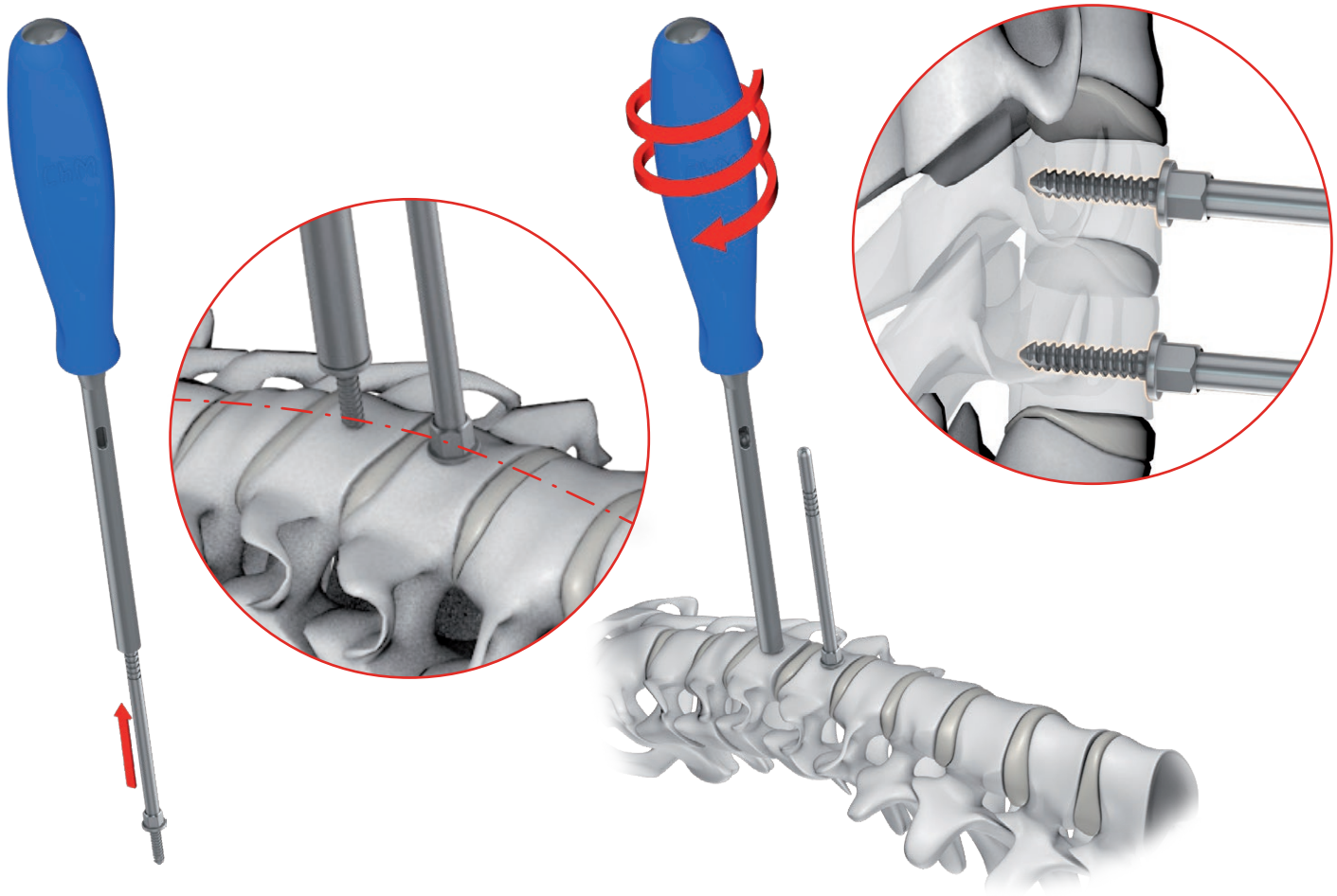


IV.2. INSERTION OF CASPAR CERVICAL DISTRACTOR

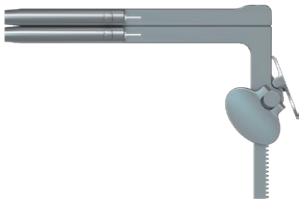
Caspar cervical distractor prevents closing of the intervertebral space during the discectomy and the remaining operating procedure.

	40.6076.0xx
	40.6086.000

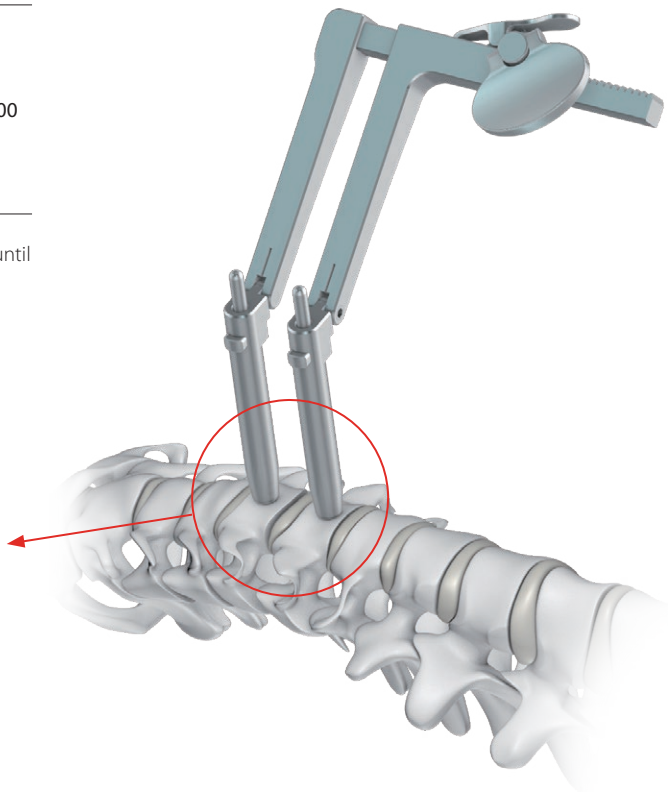
Choose intraoperatively, on the basis of X-Ray image, the length of the Caspar pin **[40.6076.0xx]** *(14mm or 16mm)*. Insert the selected pins using screwdriver **[40.6086.000]** in a vertebra located above and below the operated intervertebral disc, in the central part of the front surface of the vertebral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



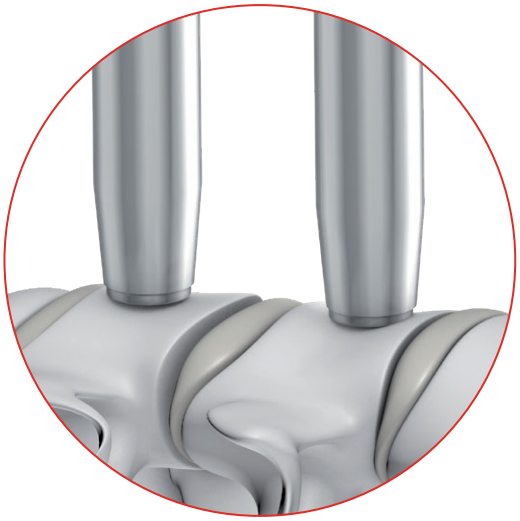
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



40.6075.000

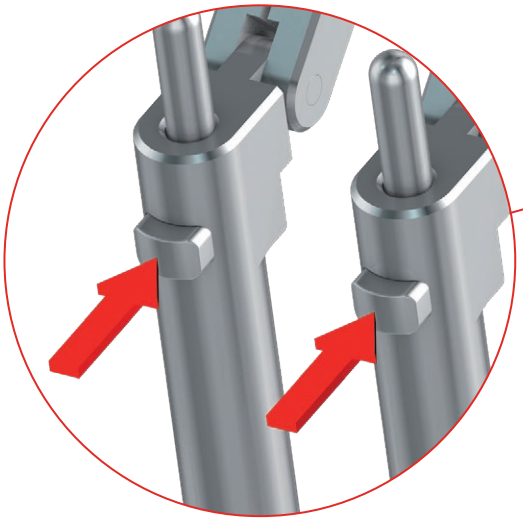


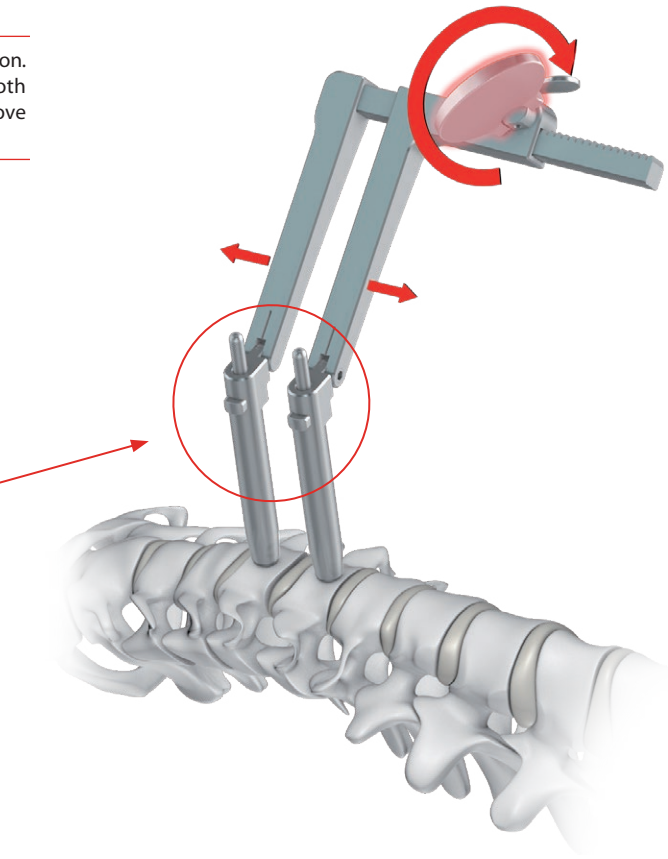
Insert Caspar cervical distractor **[40.6075.000]** sleeves onto the Caspar pins until the sleeves meet the collars of the pins.



Perform gentle distraction by turning 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.

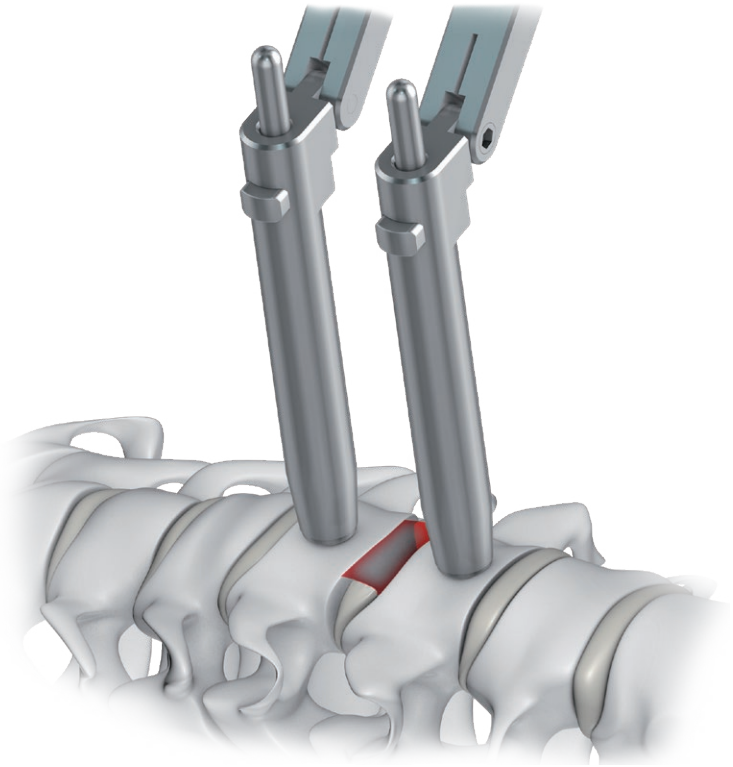




IV.3. DISCECTOMY

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.



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

IV.4. IMPLANT SELECTION

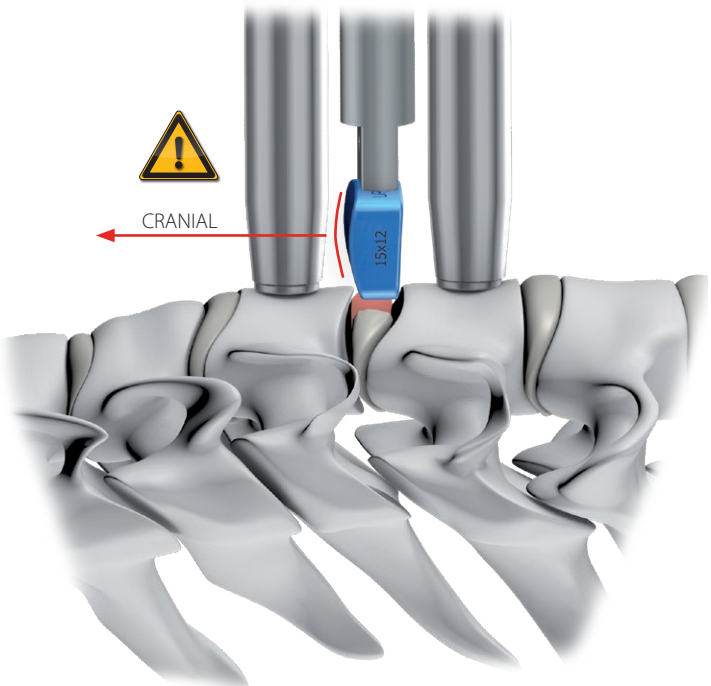
Implant size is selected on the basis of trials **[40.6082.0xx]**, **[40.6083.0xx]**, **[40.6089.0xx]**, **[40.6090.0xx]**, **[40.6092.0xx]**, **[40.6093.0xx]** whose shapes and dimensions correspond to the available implants.

	40.6082.0xx, 40.6083.0xx 40.6089.0xx 40.6090.0xx 40.6092.0xx 40.6093.0xx
	40.6080.000

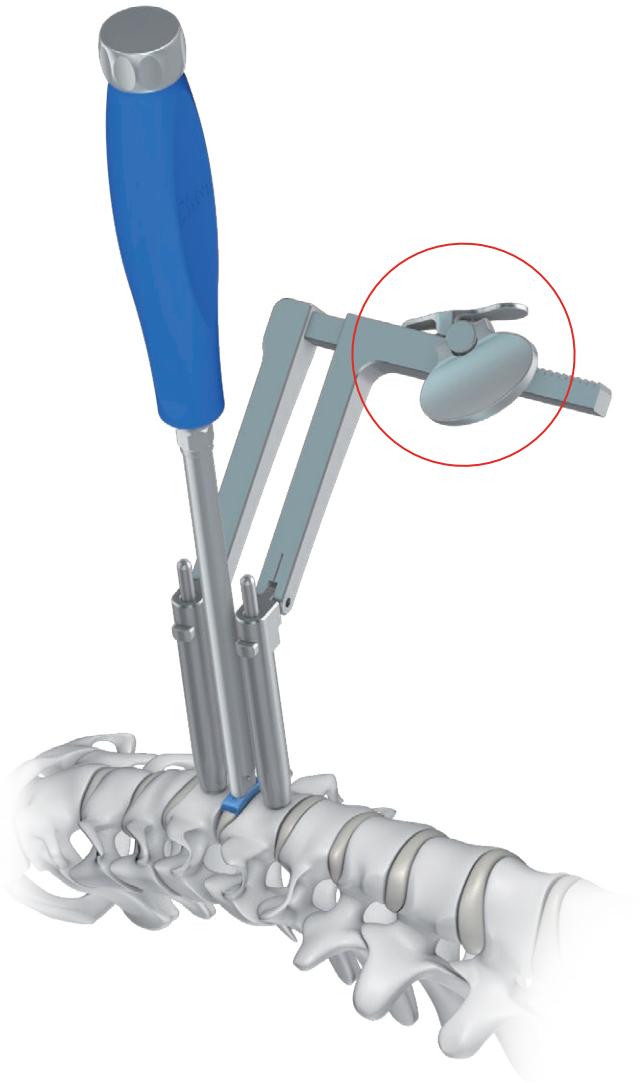
Choose intraoperatively, on the basis of X-Ray image, one of the trials **[40.6082.0xx]**, **[40.6083.0xx]**, **[40.6089.0xx]**, **[40.6090.0xx]**, **[40.6092.0xx]**, **[40.6093.0xx]** whose shape and height corresponds best to the intervertebral space.

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

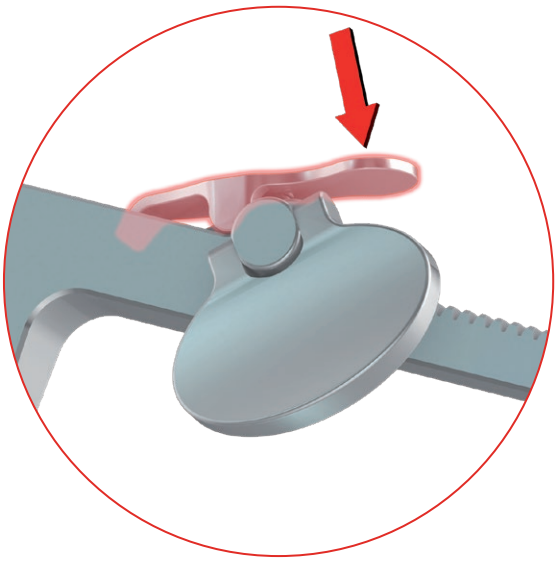
The convex trials **[40.6082.0xx]**, **[40.6088.0xx]**, **[40.6092.0xx]** should be introduced with the convex surface facing the head *(cranial direction)*.



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.

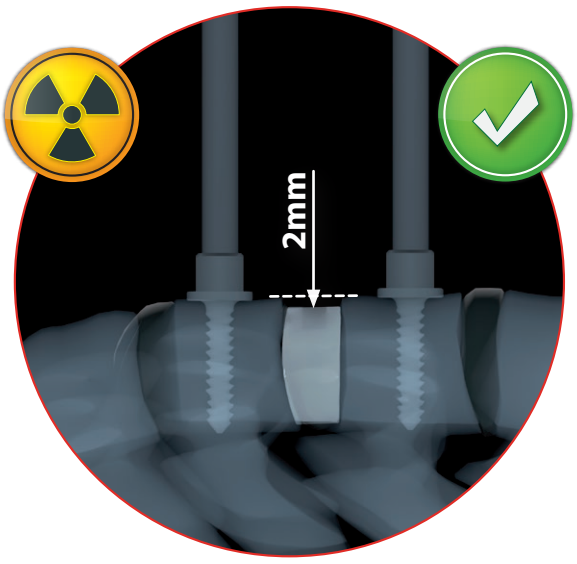


Release the distraction pushing the Caspar cervical distractor's locking lever.

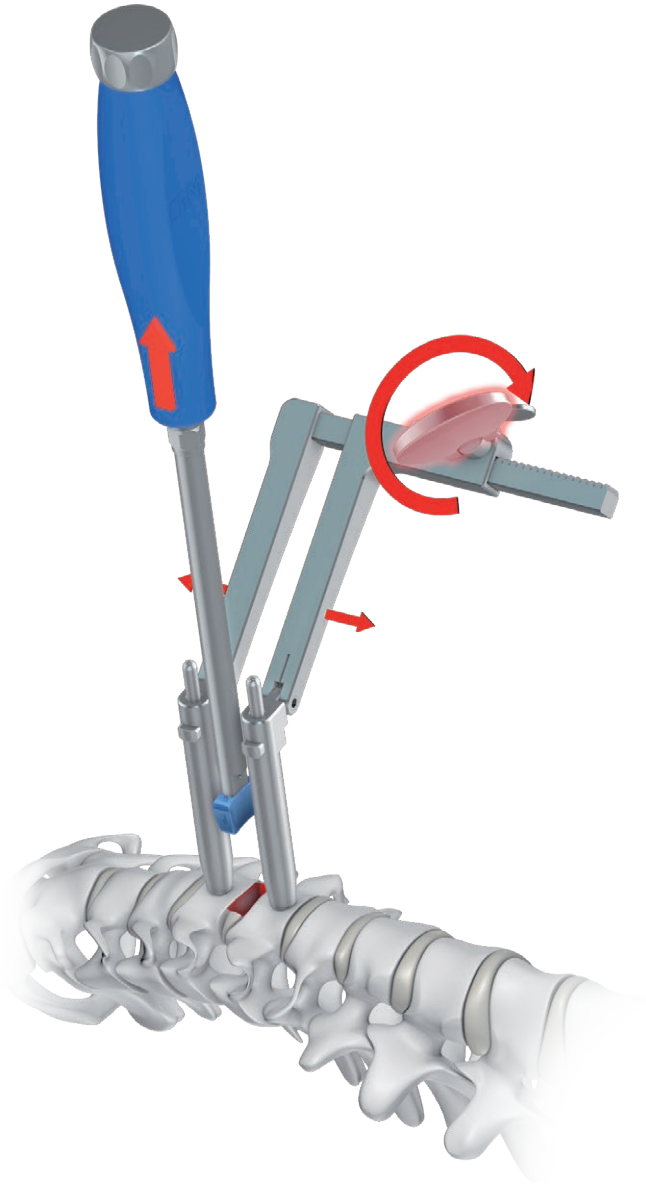


Verify the position of the trial using X-Ray imaging.

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 from 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 to the intervertebral space.

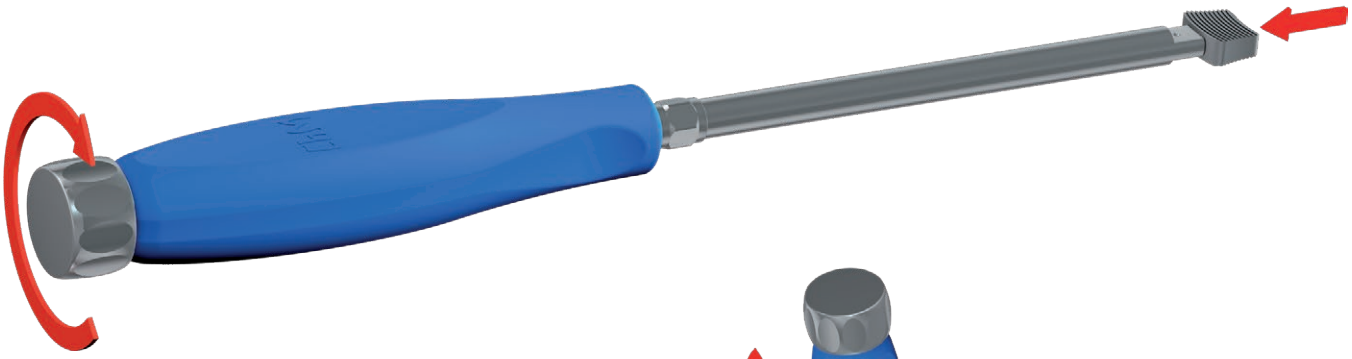
Based on the selected trial, choose an implant of the same size and shape. The implant will be used later in the procedure.

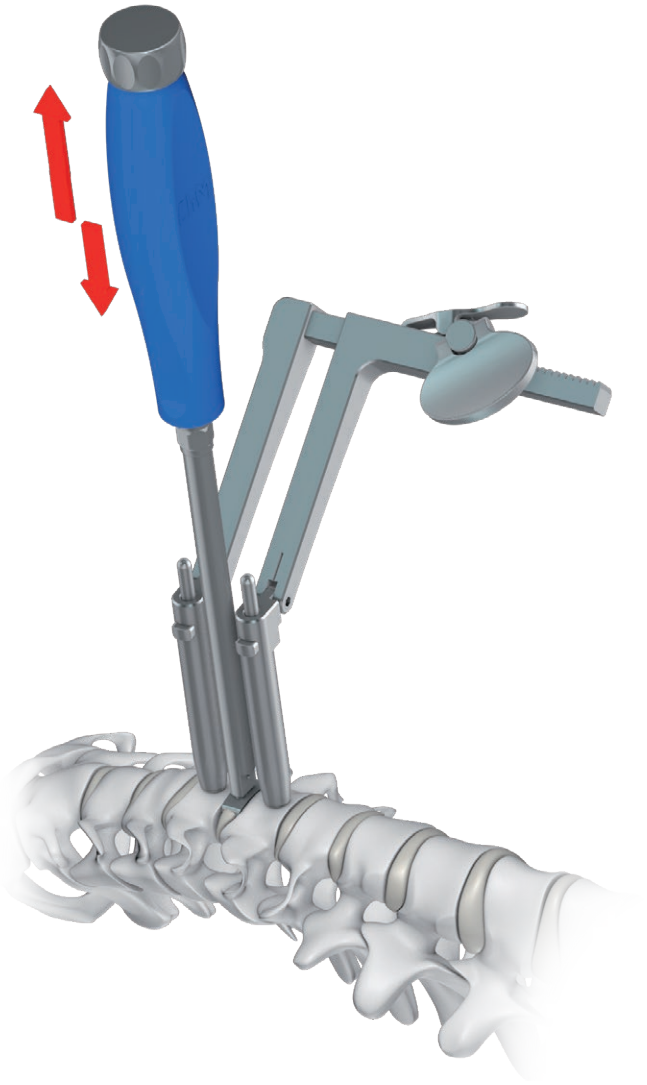
IV.5. PREPARATION OF THE VERTEBRAL BODIES ENDPLATES

Preparation of the vertebral bodies endplates 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
	40.6080.000

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 **[40.6080.000]** – insert the bone rasp on the persuader tip and by turning the persuader's knob clockwise, tighten the locking pin in the socket of the bone rasp.





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.

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

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

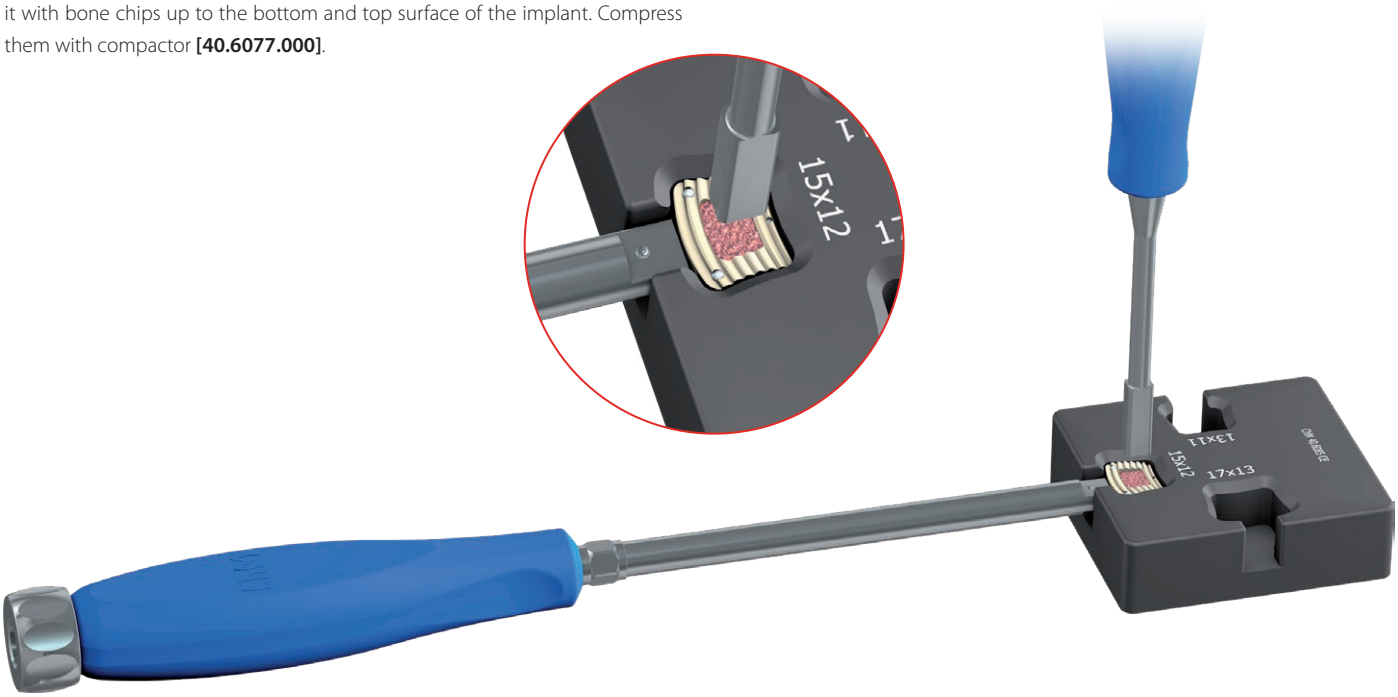
40.6078.000

Mount the selected cage to the applicator **[40.6078.000]** – insert the implant on the applicator tip and by turning the applicator's knob clockwise, lock the implant on the applicator.

40.6085.000

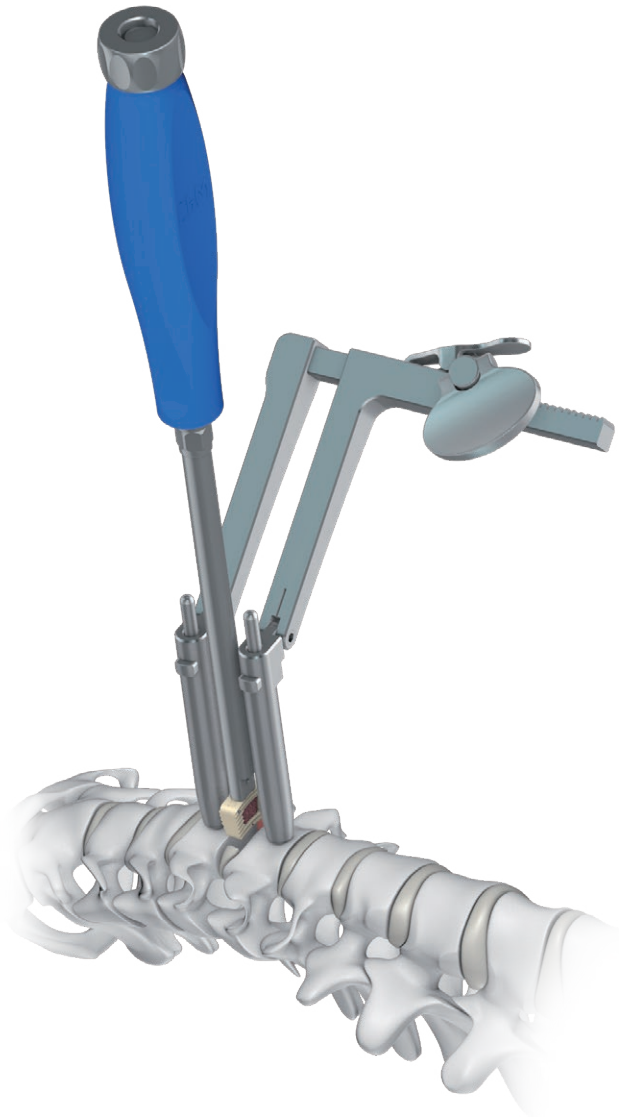
40.6077.000

Place the implant in the working stand's appropriate socket **[40.6085.000]** and fill it with bone chips up to the bottom and top surface of the implant. Compress them with compactor **[40.6077.000]**.

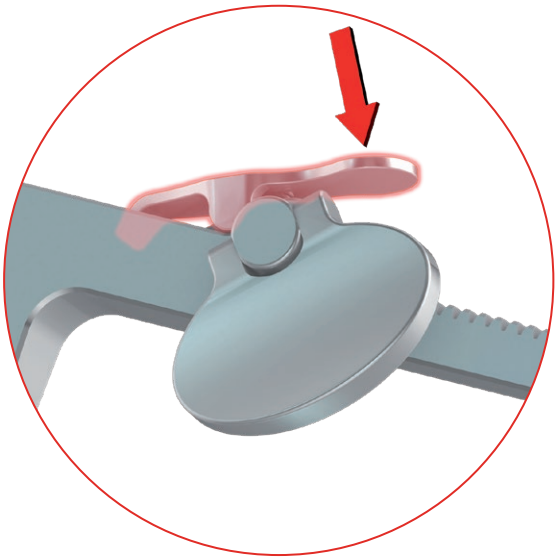


IV.7. IMPLANT INSERTION

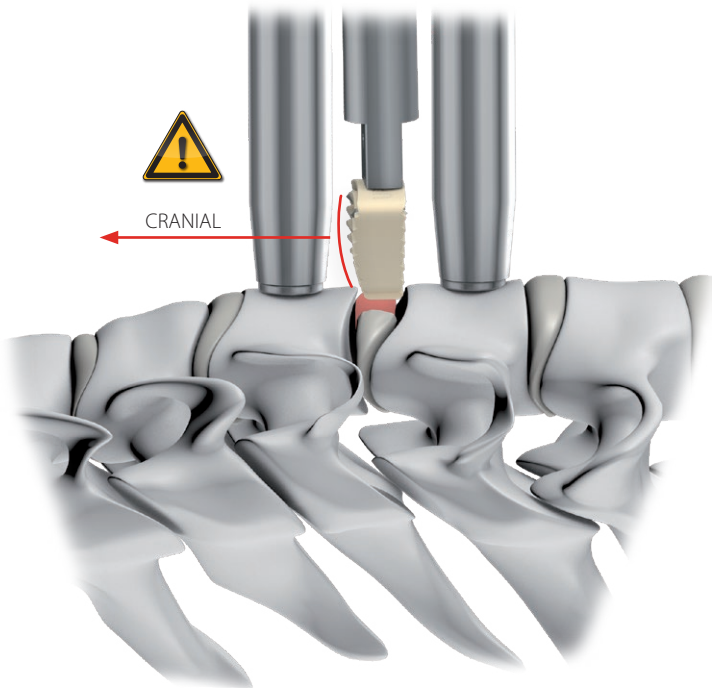
Insert implant, filled with bone graft, into the intervertebral space, so that the top surface of the implant is placed about 2 mm below the top surface of the vertebral body.



Release the distraction pushing the Caspar cervical distractor's locking lever.

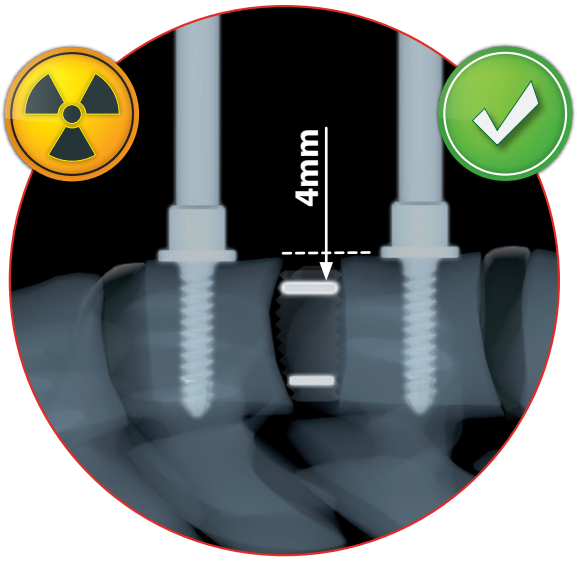


Convex cervical intervertebral cages **[8.4555.xxx]**, **[8.4557.xxx]**, **[8.4559.xxx]**, **[8.4581.xxx]**, **[8.4583.xxx]**, **[8.4585.xxx]** should be inserted with the convex surface facing the head *(cranial direction)*.



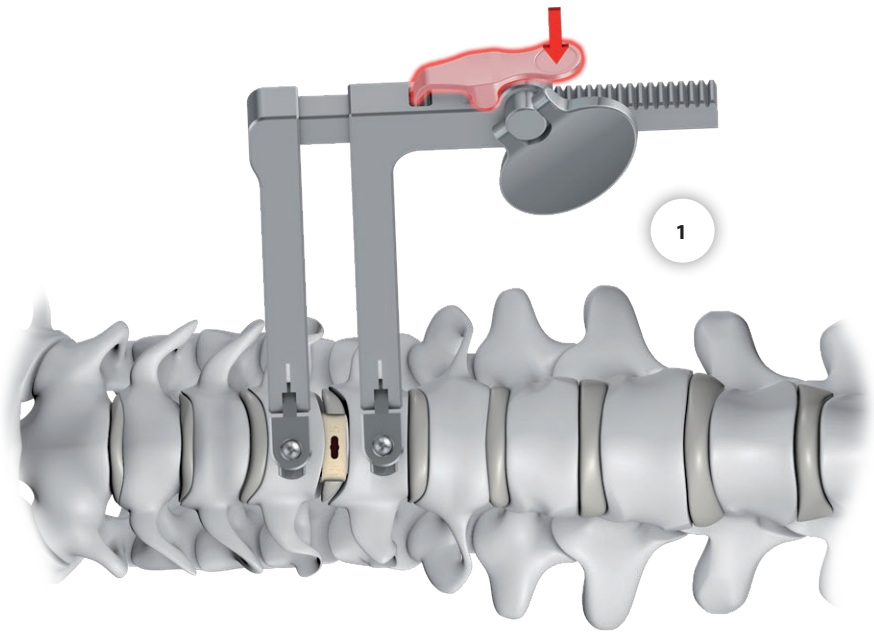
Check the position of the implant using X-Ray imaging. The position of PEEK implants is determined on the basis of three embedded radioopaque markers.

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

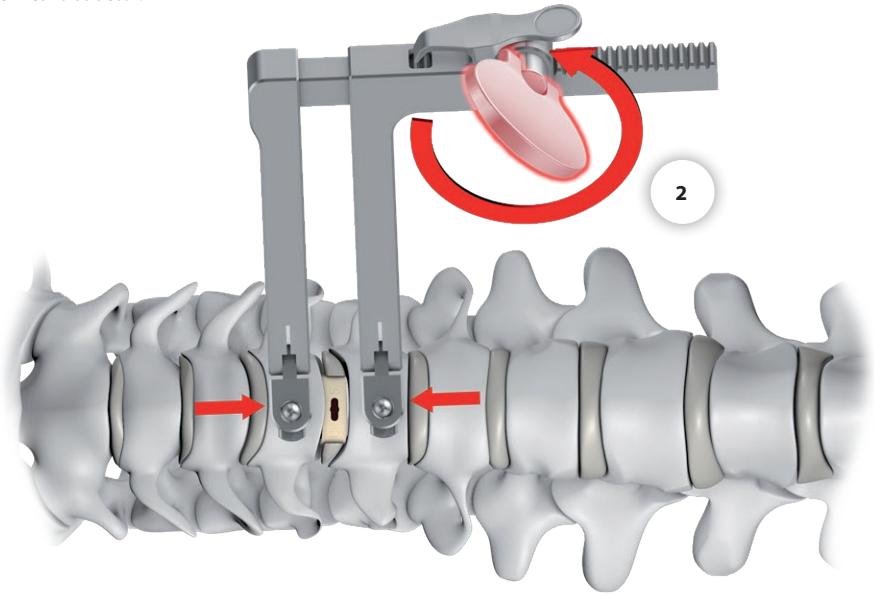


In the lateral projection, a proximal marker should be placed about 4mm below the outer surface of the vertebral body.

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



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



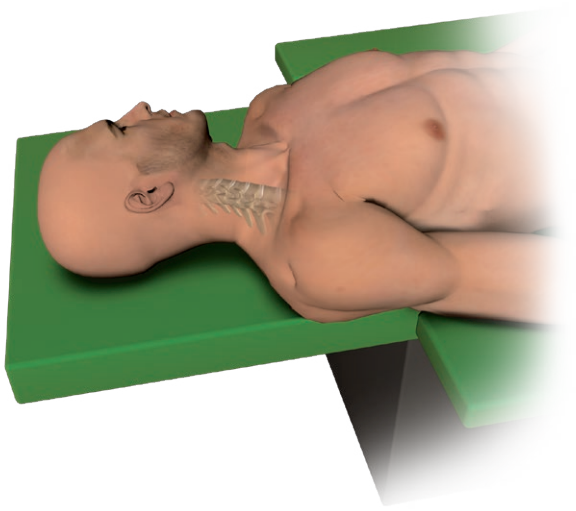
Remove Caspar cervical distractor and pins.

V. SURGICAL TECHNIQUE *(WITHOUT USING CASPAR CERVICAL DISTRACTOR)*

The following procedure is not recommended when using implants with spikes.

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. 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.3. 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.

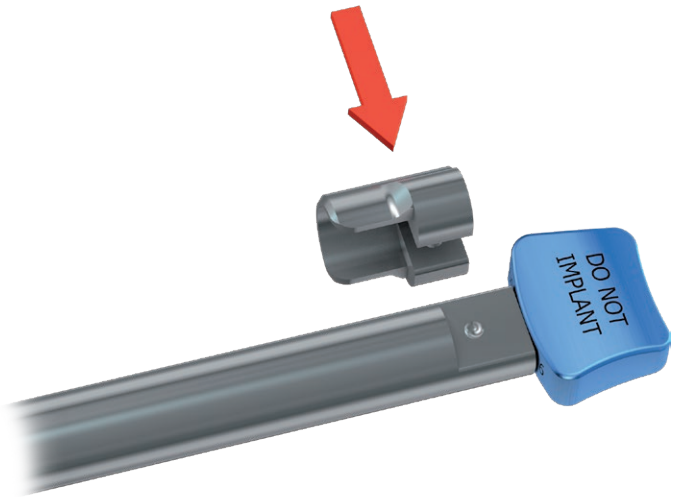
	40.6082.0xx, 40.6083.0xx 40.6089.0xx 40.6090.0xx 40.6092.0xx 40.6093.0xx
	40.6080.000
	40.6079.000

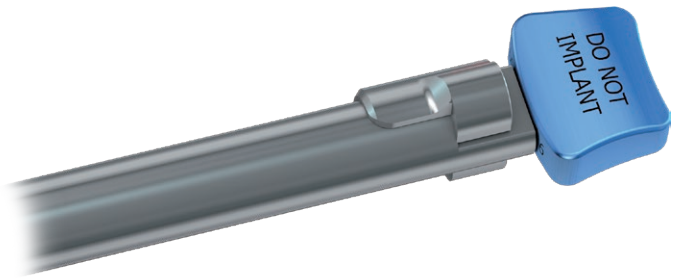
Choose intraoperatively, on the basis of X-Ray image, one of the trials **[40.6082.0xx]**, **[40.6083.0xx]**, **[40.6089.0xx]**, **[40.6090.0xx]**, **[40.6092.0xx]**, **[40.6093.0xx]** whose shape and height corresponds best to the intervertebral space.

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

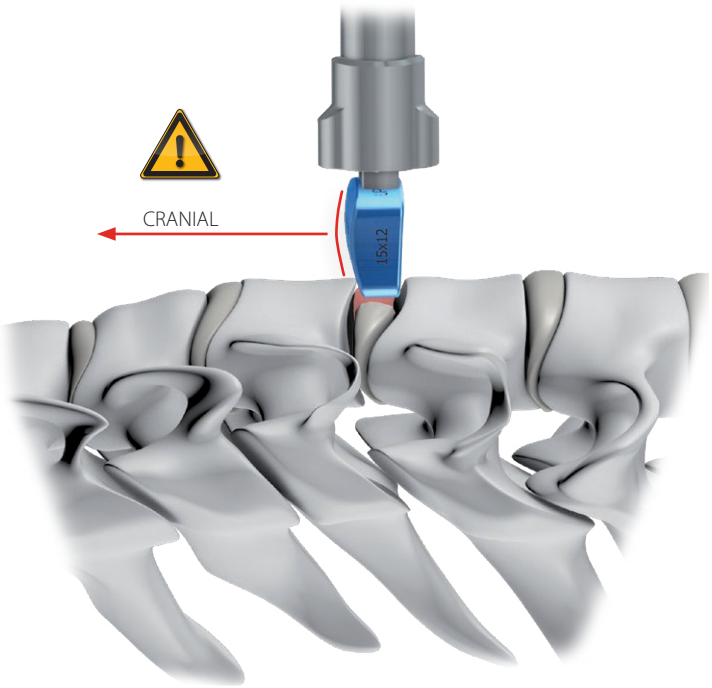
Attach the position retainer **[40.6079.000]** on the persuader's **[40.6080.000]** shaft end.

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





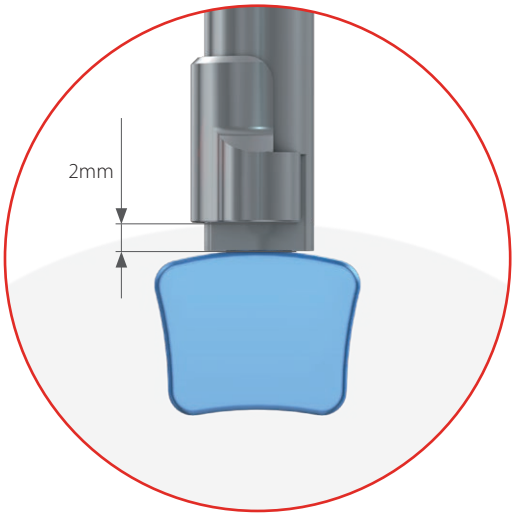
Convex trials **[40.6082.0xx]**, **[40.6088.0xx]**, **[40.6092.0xx]** should be inserted with the convex surface facing the head *(cranial direction)*.



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 what corresponds to a depth of about 2mm below its top surface..



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

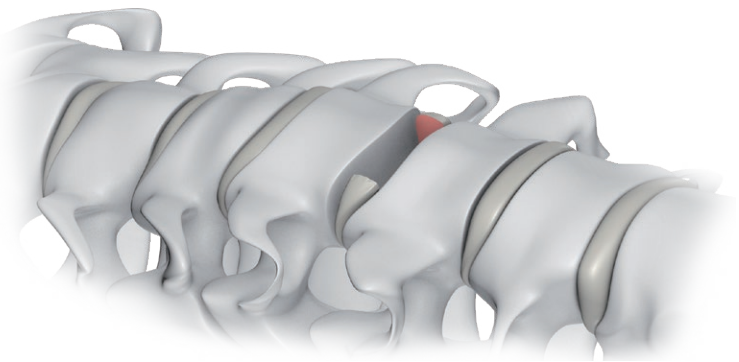
In the anterior projection, the lateral edges of the trial should be symmetrical to the vertical axis of the vertebrae.

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

Remove the trial.

Should the trial be incorrectly placed, repeat the procedure using a trial better fitting to 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.4. PREPARATION OF THE VERTEBRAL BODIES ENDPLATES

Preparation of the vertebral bodies endplates 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
	40.6080.000

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 **[40.6080.000]** – insert the bone rasp on the persuader tip and by turning the persuader's knob clockwise, tighten the locking pin in the socket of the bone rasp.

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.

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.

V.5. IMPLANT PREPARATION

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

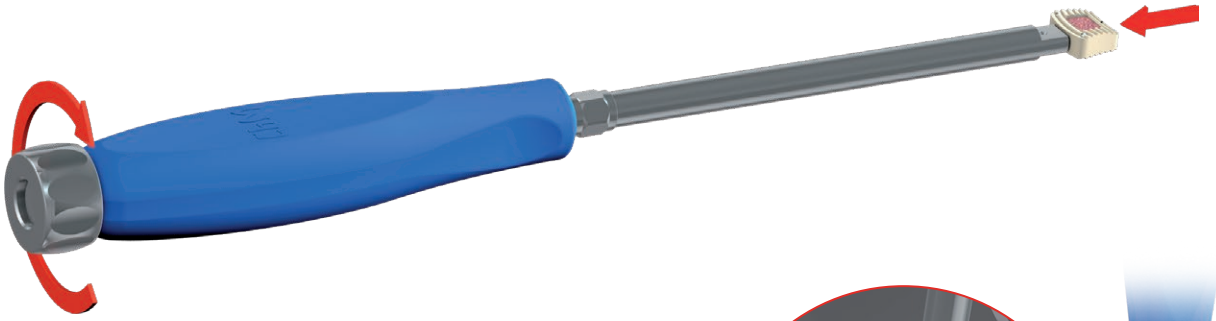

40.6078.000


40.6079.000

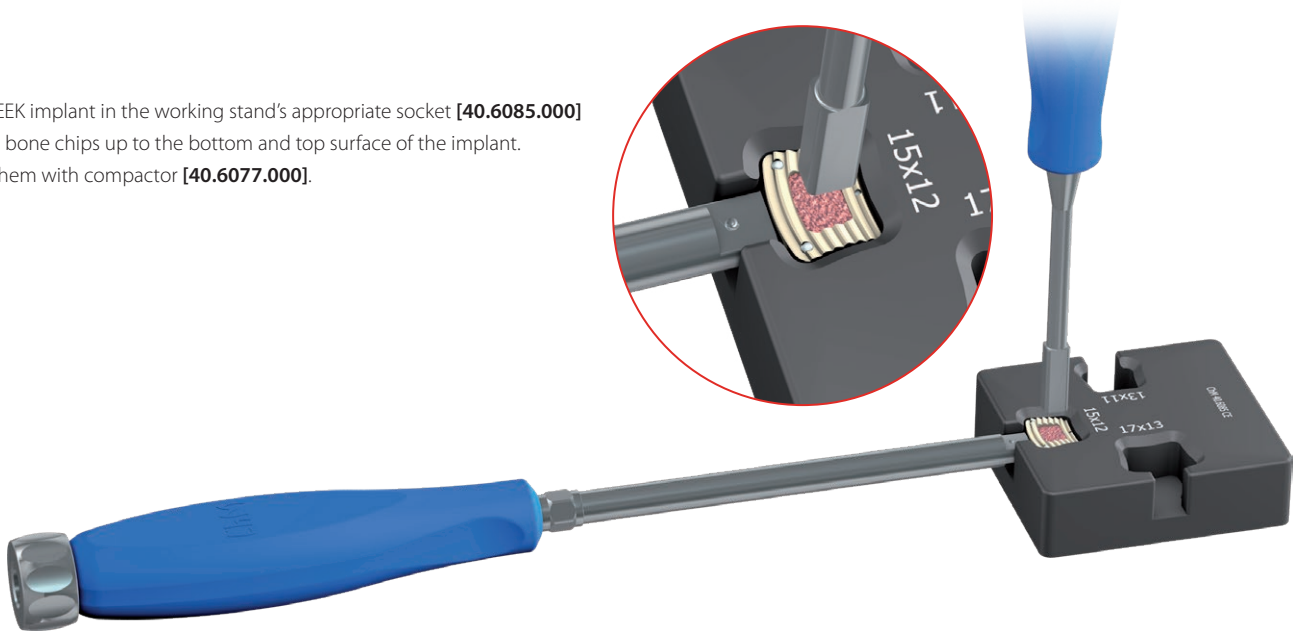
40.6085.000


40.6077.000

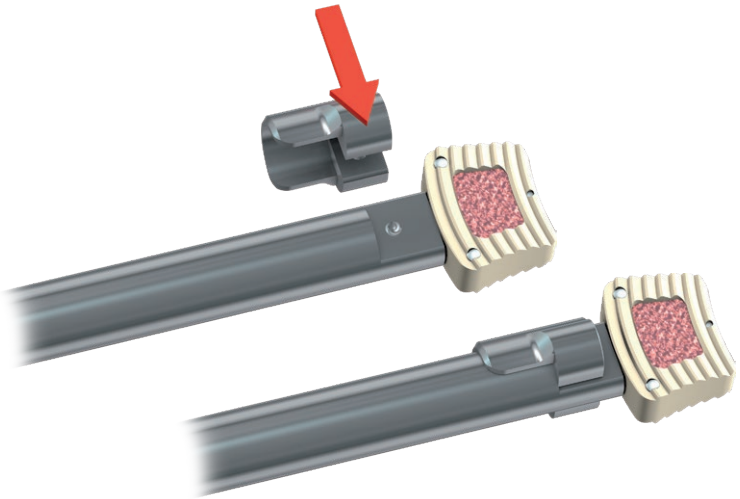
Mount the selected cage to the applicator **[40.6078.000]** – insert the implant on the applicator tip and by turning the applicator's knob clockwise, lock the implant on the applicator.



Place the PEEK implant in the working stand's appropriate socket **[40.6085.000]** and fill with bone chips up to the bottom and top surface of the implant. Compress them with compactor **[40.6077.000]**.



Attach the position retainer **[40.6079.000]** on the applicator.



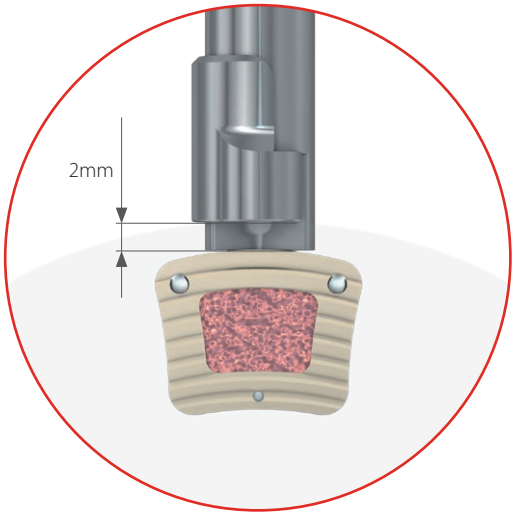
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

V.6. IMPLANT INSERTION

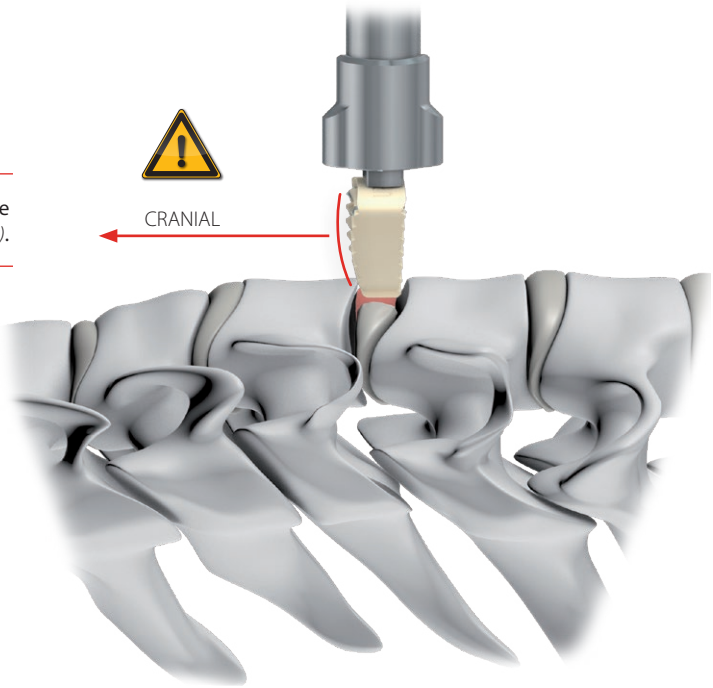
Insert implant, filled with bone graft, into the intervertebral space.

40.6087.000

Use hammer **[40.6087.000]** when necessary, gently tapping on the applicator's knob. Insert the implant until the position retainer leans against the vertebral surface.

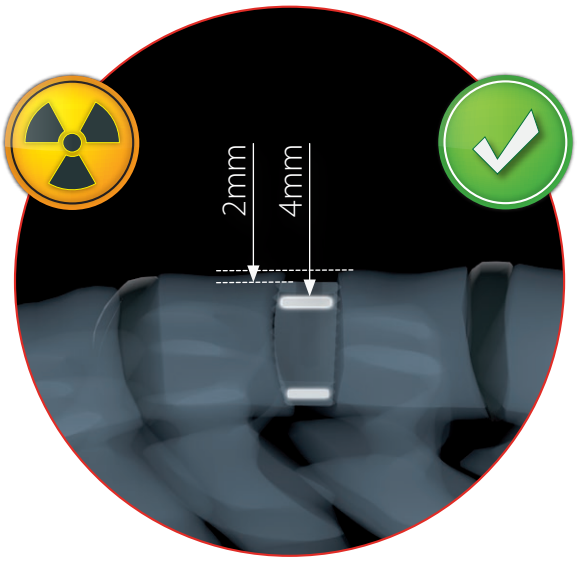


Convex cervical intervertebral cages **[8.4555.xxx]** should be inserted with the convex surface facing the head *(cranial direction)*.



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.

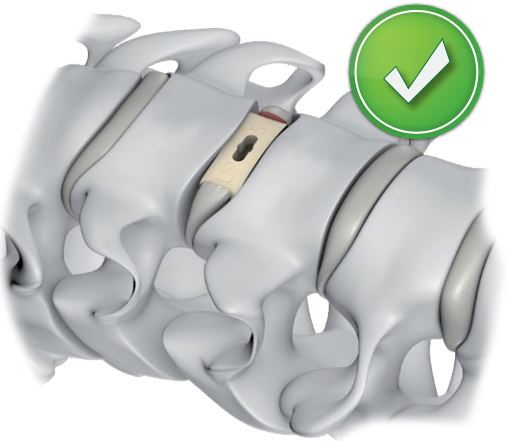
In the front projection, tantalum markers of the implant should be symmetrical to the vertical axis of vertebrae.



In the lateral projection, a proximal marker should be placed about 4mm from the outer surface of the vertebral body.

Remove the applicator from the cervical cage by rotating the applicator's knob counter-clockwise until resistance is felt.

Remove the applicator's tip from the implant's socket.

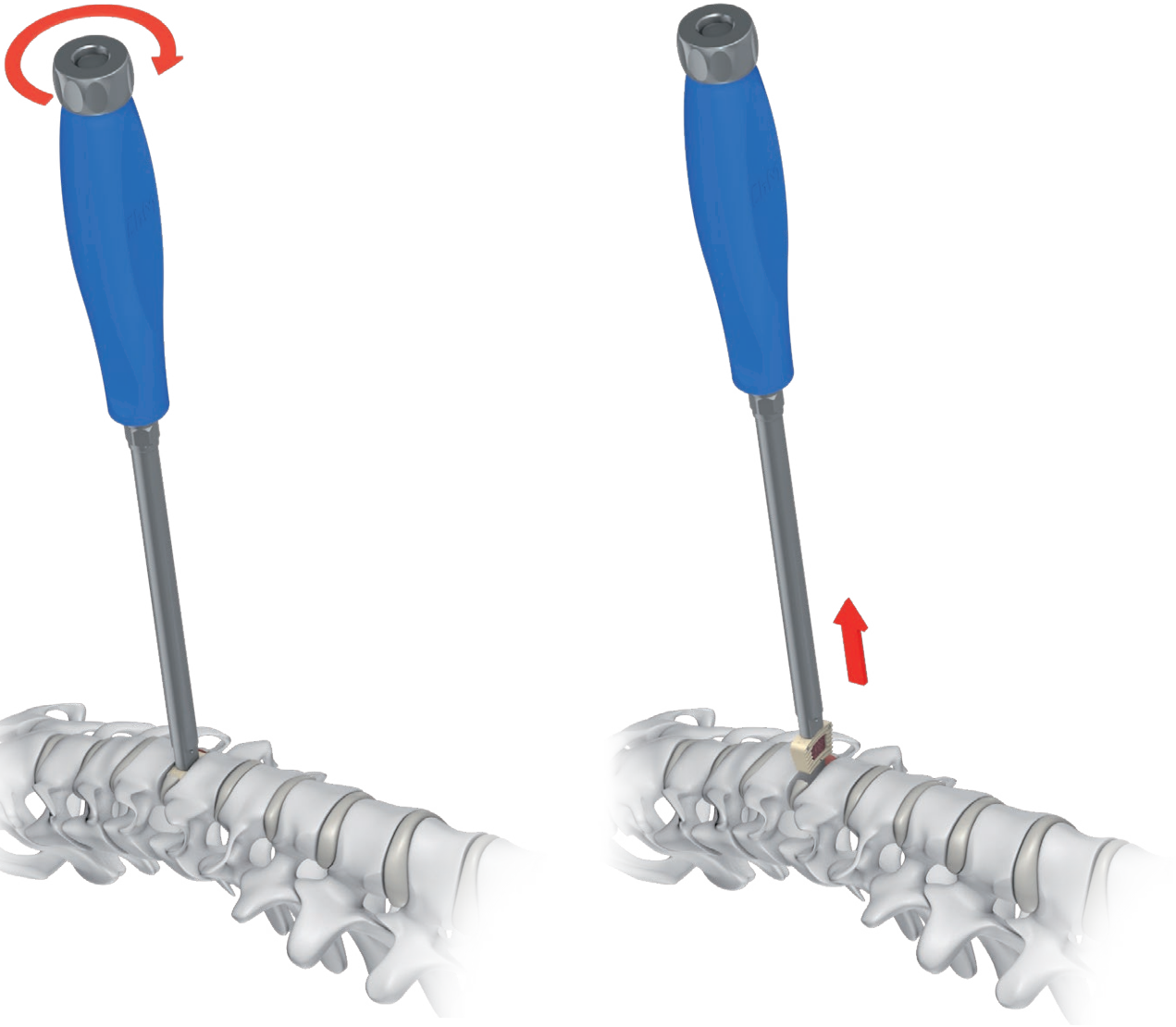


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

VI. IMPLANT REMOVAL

Should there be no spinal fusion between the vertebrae after 2.5 years since implantation, the treatment shall be deemed as a failure and it is necessary to remove the implant. To do so, attach the applicator **[40.6078.000]** to the implant and remove the intervertebral cage from the intervertebral space.

40.6078.000



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

please, refer to the Instructions for Use provided with the unit packaging of the implant.

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