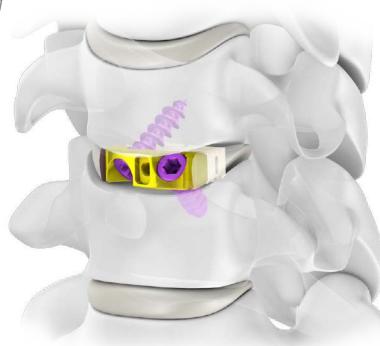
ST/103A





INTERVERTEBRAL CERVICAL LOCKING CAGE

- IMPLANTS
- INSTRUMENT SET 15.0917.101
- SURGICAL TECHNIQUE



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SYMBOLS DESCRIPTION

\wedge	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
i	Information about the next stages of a procedure.
	Proceed to the next stage.
\bigcirc	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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The manufacturer reserves the right to introduce design changes.		

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

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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).

CHM CHARSPINE system 2

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 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.

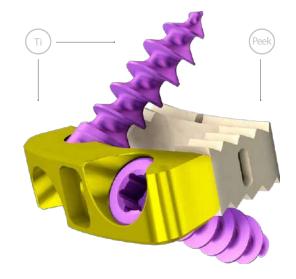
Cervical intervertebral cages are made of highly biocompatible materials: PEEK, titanium and tantalum alloys. Locking screws are made of titanium alloy.

PEEK

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

Titanium alloy

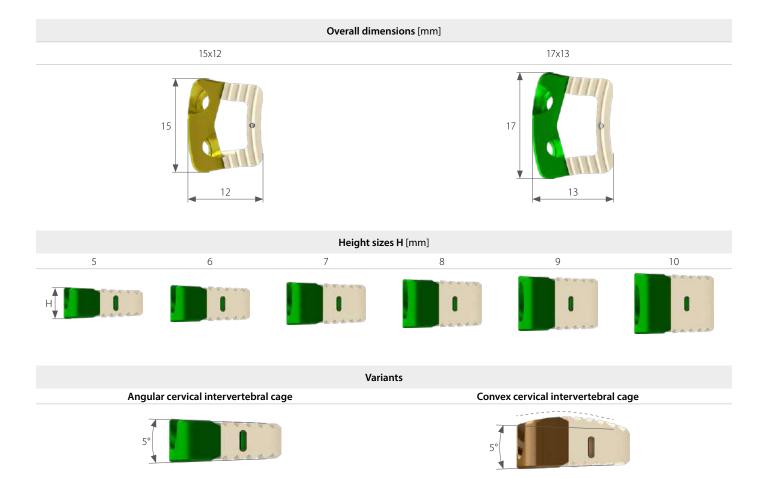
- Facilitated X-Ray imaging for precise determination of the implant position.
- High osseointegration with bone structures.
- High strength enables the use of bone locking screws compatible with the cage.





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

II.1. AVAILABLE SIZES AND VARIANTS



Angular cervical intervertebral cage				
H 1000 Size 15x12 [mm]		H Size 17×		
Catalogue no.	Height H [mm]	Catalogue no.	Height H [mm]	
8.6970.505	5	8.6971.505	5	
8.6970.506	6	8.6971.506	6	
8.6970.507	7	8.6971.507	7	
8.6970.508	8	8.6971.508	8	

Convex cervical intervertebral cage



8.6970.509

8.6970.510

Н



8.6971.509

8.6971.510

Size 17x13 [mm]

Catalogue no.	Height H [mm]	Catalogue no.	Height H [mm]
8.6972.005	5	8.6973.005	5
8.6972.006	6	8.6973.006	6
8.6972.007	7	8.6973.007	7
8.6972.008	8	8.6973.008	8
8.6972.009	9	8.6973.009	9
8.6972.010	10	8.6973.010	10

Material: PEEK- OPTIMA

9

10

9

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ChM (HARSPINE system 2





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

Cervical locking screw 3.5 (self-tapping)



Diameter Length [mm]		Colour	Catalogue no.
3.5	10		3.6976.010
3.5	12		3.6976.012
3.5	14		3.6976.014
3.5	16		3.6976.016

Cervical locking screw 4.0 (self-tapping)



Diameter	Length [mm]	Colour	Catalogue no.
4	10		3.6977.010
4	12		3.6977.012
4	14		3.6977.014
4	16		3.6977.016



Stand for implants - set	Name	Catalogue No.	Pcs
Cim ()	Container lid 4x4	14.0917.103	1
J. Hitting and the second sec	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

(HARSPINE system 2

IMPLANTS

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.

ument set for cervical intervertebral locking cages 15.0917.101	Name	Catalogue No.	P
	Container lid 9x4	14.0917.102	1
	Applicator	40.8784.000	1
	Persuader	40.6080.000	1
	Compactor	40.6077.000	
	Hammer 200g	40.6087.000	
ince isso	Working stand	40.8786.000	
	Position retainer	40.6079.000	
	Aiming block H-5	40.8785.050	
	Aiming block H-6	40.8785.060	
() () () () () () () () () () () () () (Aiming block H-7	40.8785.070	
	Aiming block H-8	40.8785.080	
	Aiming block H-9	40.8785.090	
	Aiming block H-10	40.8785.100	
	Trocar	40.8780.000	
	Trocar	40.8781.000	
	Drill with limiter 1.7/8	40.8788.080	
	Drill with limiter 1.7/12	40.8788.120	
	Drill with limiter 1.7/16	40.8788.160	
	Drill with joint and limiter 1.7/8	40.8787.080	
	Drill with joint and limiter 1.7/12	40.8787.120	
	Drill with joint and limiter 1.7/16	40.8787.160	
	Screwdriver tip T10	40.8783.000	
	Screwdriver tip T10 with joint	40.8782.000	
	Handle ratchet device	40.6654.001	
	Extractor	40.8789.000	

INSTRUMENTS

	Name	Catalogue No.	Pcs
A CONTRACTION OF THE OWNER OWNER OF THE OWNER OWNER OF THE OWNER OW	Stand 9x4	14.0917.201	1
	Angular trial5x15x12	40.6083.005	1
100	Angular trial6x15x12	40.6083.006	1
D'ANGUR	Angular trial7x15x12	40.6083.007	1
15x13 0	Angular trial8x15x12	40.6083.008	1
350	Angular trial9x15x12	40.6083.009	1
	Angular trial10x15x12	40.6083.010	1
	Convex trial5x15x12	40.6082.005	1
8- 3 ANT	Convex trial6x15x12	40.6082.006	1
- Sur	Convex trial7x15x12	40.6082.007	1
15	Convex trial8x15x12	40.6082.008	1
UP	Convex trial9x15x12	40.6082.009	1
	Convex trial10x15x12	40.6082.010	1
	Angular trial5x17x13	40.6093.005	1
25 5	Angular trial6x17x13	40.6093.006	1
SOLARS	Angular trial7x17x13	40.6093.007	1
17 _{X12}	Angular trial8x17x13	40.6093.008	1
	Angular trial9x17x13	40.6093.009	1
	Angular trial10x17x13	40.6093.010	1
	Convex trial5x17x13	40.6092.005	1
Subhi	Convex trial6x17x13	40.6092.006	1
- Fair	Convex trial7x17x13	40.6092.007	1
b. Starting of the starting of	Convex trial8x17x13	40.6092.008	1
UP CONTRACTOR	Convex trial9x17x13	40.6092.009	1
	Convex trial10x17x13	40.6092.010	1
		14.0917.101	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

INSTRUMENTS

Distraction set	Name	Catalogue no
	Container lid 4x4	14.0000.102
ADDRESSION AND ADDRESSION AND ADDRESSION ADD	Caspar cervical distractor	40.6075.000
	Screwdriver for Caspar pins	40.6086.000
	Caspar pin 3.0x14	40.6076.014
	Caspar pin 3.0x16	40.6076.016
44 0	Tray 4x4 ½H	14.0918.220
	Container 4x4 ½H	14.0000.004
erilization container (for the distraction set)	Name	Catalogue No.
	Perforated aluminum lid ½ 306x272x15mm Gray	12.0751.200
	Container with solid bottom ½ 306x272x85mm	12.0751.100

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

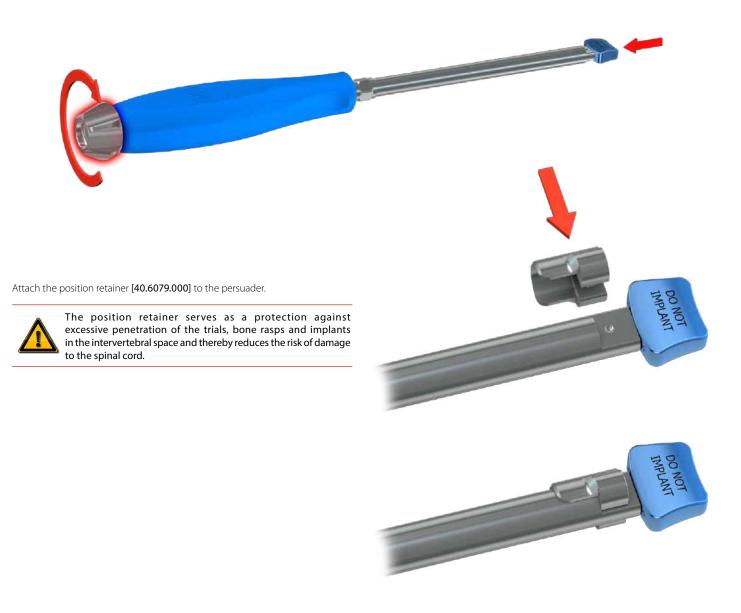


Implant size is selected on the basis of trials [40.6082.0xx], [40.6083.0xx], [40.6092.0xx], [40.6093.0xx] whose shapes and dimensions correspond to the available implants.

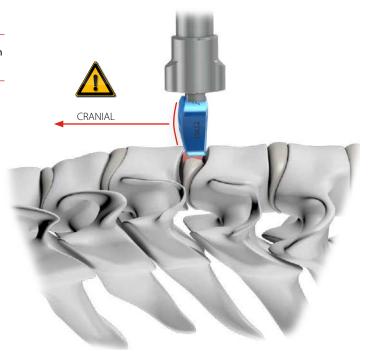


Choose intraoperatively, on the basis of X-Ray image, one of the trials [40.6082.0xx], [40.6083.0xx], [40.6092.0xx], [40.6093.0xx] whose shape and height corresponds best to the intervertebral space.

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.



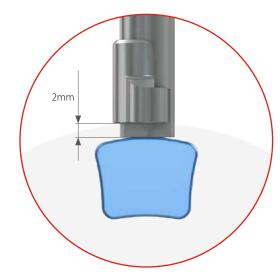
Convex trials [40.6082.0xx], [40.6092.0xx] should be inserted with the convex surface facing the head (*cranial direction*).

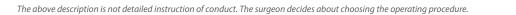




Insert the selected trial into the intervertebral space. Use hammer **[40.6087.000]** when necessary, gently tapping on the persuader's knob.

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.



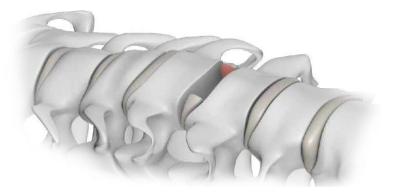


In the anterior projection, the lateral edges of the trial should be symmetrical to the vertical axis of the vertebrae.

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

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



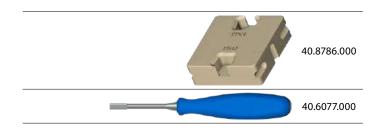
Before implantation, the space in the PEEK intervertebral cervical cage should be filled with autologous bone graft (*bone chips*) which allow for spinal fusion.



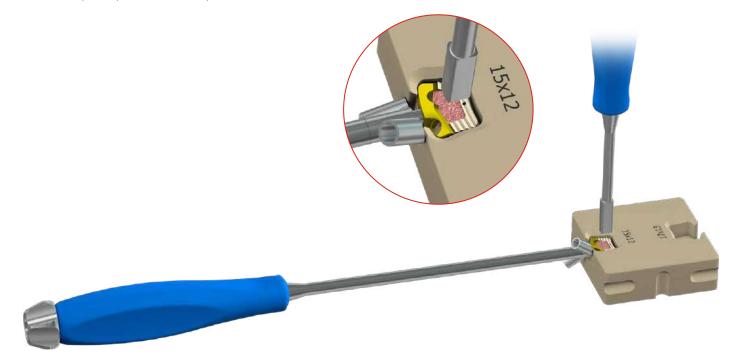


Then connect the intervertebral cage with the applicator and the aiming block installed therein (the height H of the implant must be the same as the size of the aiming block installed).

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



Place the implant in the working stand's appropriate socket **[40.8786.000]** 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.



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

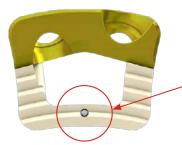
Continue inserting the implant until the aiming block leans against the vertebral surface.





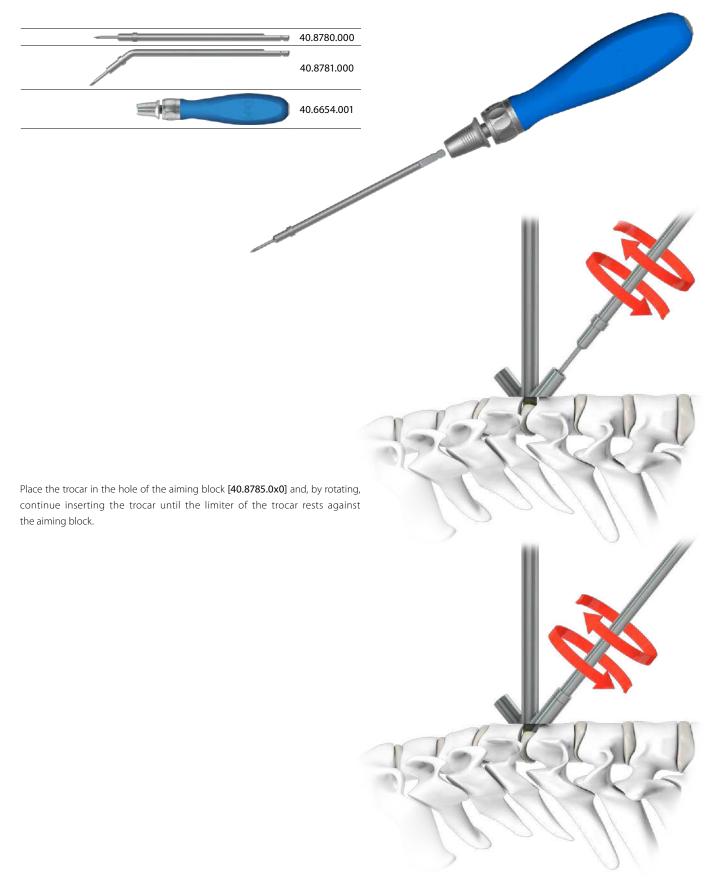
Convex cervical intervertebral cages [8.6972.xxx] should be inserted with the convex surface facing the head (*cranial direction*).

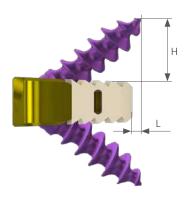
The embedded tantalum marker is used to navigate the position of the posterior wall of the intervertebral cage (*the marker is located 1mm from the edge of the cage*). The marker is also used to determine whether the endplates of the vertebral bodies adhere properly to the cage.



IV.6. HOLES DRILLING AND SCREWS INSERTION

Connect the trocar (*straight*) **[40.8780.000]** or (*angled*) **[40.8781.000]** to the handle ratchet device **[40.6654.001]**.





Cage 15x12			
Drill length	Screw length	L	н
8	10	Does not protrude	3.6
12	12	Does not protrude	4.8
12	14	0.7	6
16	16	2.2	7.3

Cage 17x13			
Drill length	Screw length	L	Н
8	10	Does not protrude	3.7
12	12	Does not protrude	4.9
	14	Does not protrude	6.1
16	16	1.2	7.3

Tab.1. Selection of drills and screws (recommended screw length is indicated)

Based on the X-Ray image and table 1, select the appropriate length of the drill. The drill should be used with handle ratchet device **[40.6654.001]**.

The instrument set includes drills with limiter **[40.8788.xxx]** and drills with joint and limiter **[40.8787.xxx]** of the following lengths: 8, 12, 16mm. The drill lengths and dedicated corresponding screws are presented in table1.

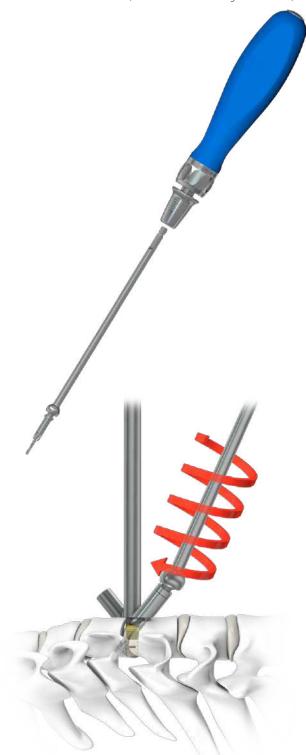




It is recommended to select the screws that do not protrude outside the contour of the intervertebral cage in the lateral view. The use of such screws minimizes the risk of spinal cord injury.

The length of the drill must not exceed the length of the screw that will be used to lock the cage.

Place the drill in the appropriate hole in the aiming block and, by rotating, continue drilling the hole for the screw, until the drill limiter rests on the block.



IV.7. SCREWS INSERTION

Connect the handle ratchet device **[40.6654.001]** with screwdriver tip T10 with joint **[40.8782.000]** or screwdriver tip T10 **[40.8783.000]**.







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.



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

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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 turning 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.

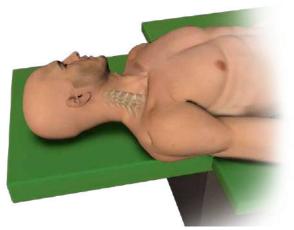
V.2. INSERTION OF CASPAR CERVICAL DISTRACTOR



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.

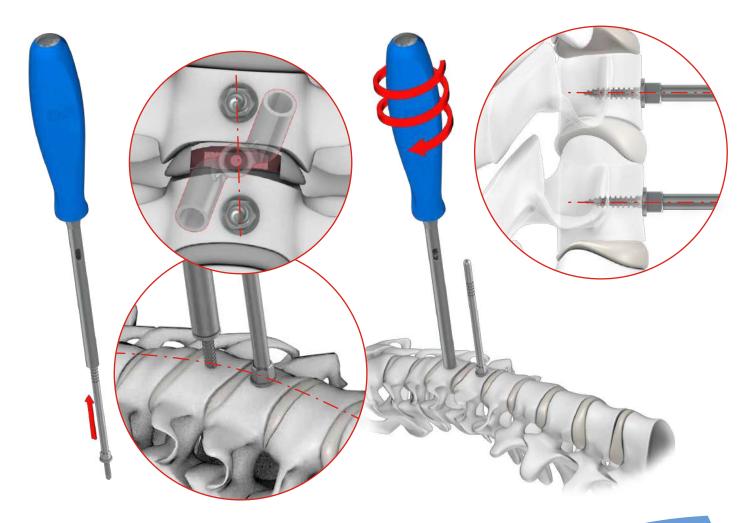
The Caspar cervical distractor is used to prevent the closure of the intervertebral space during discectomy and further surgical procedure.





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.

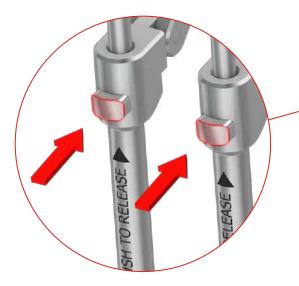




Perform gentle distraction by rotating the knob clockwise.



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.



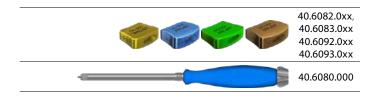
The instruments used in the discectomy are not included in the instrument set for Cervical Intervertebral Cage.



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.



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.

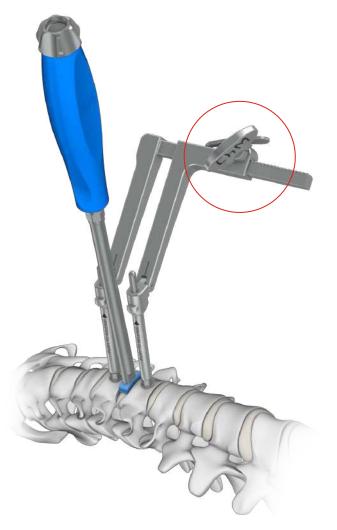
Mount the selected trial to the persuader [40.6080.000] - insert the trial on the persuader tip and by rotating the persuader knob clockwise, tighten the locking pin in the socket of the trial.



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.

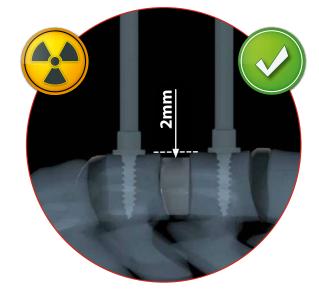
Release the distraction by pushing the Caspar cervical distractor's locking lever.





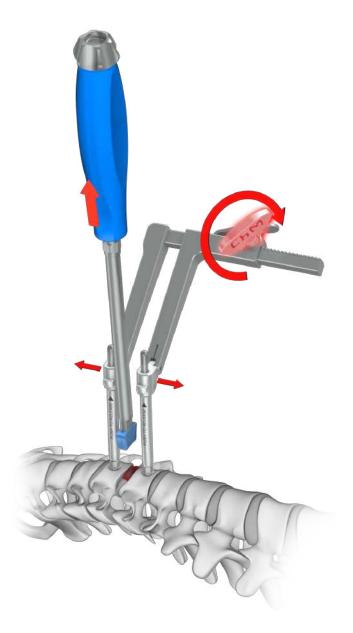
Verify the position of the trial using X-Ray imaging.





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

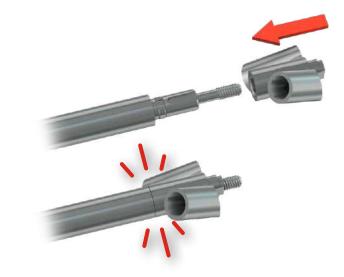
Based on the selected trial, choose an implant of the same size and shape. The implant will be used later in the procedure.

V.5. IMPLANT PREPARATION



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

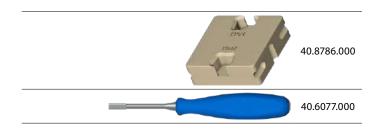




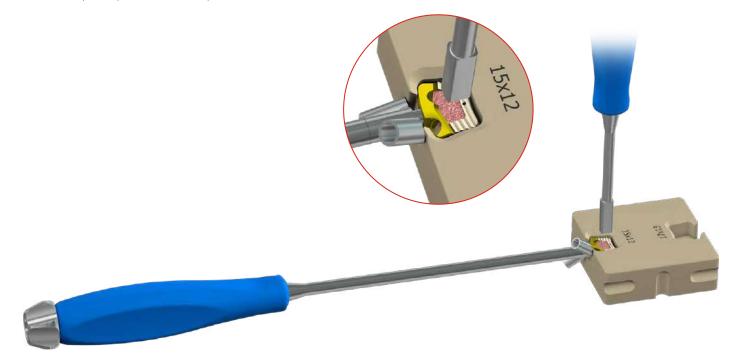
Install the selected aiming block **[40.8785.0x0]** (the height H of which must be the same as for the height of the final trial used) to the applicator **[40.8784.000]** - the click sound must be heard.

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.





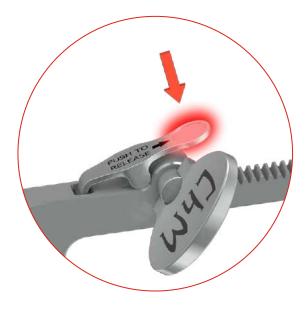
Place the implant in the working stand's appropriate socket **[40.8786.000]** and fill with bone chips. Compress them with compactor **[40.6077.000]**.



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 Caspar cervical distractor's locking lever.

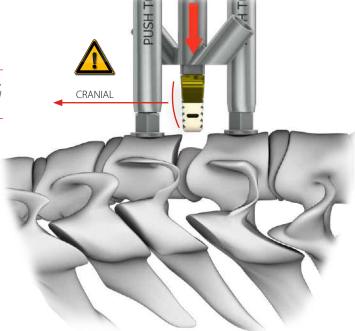




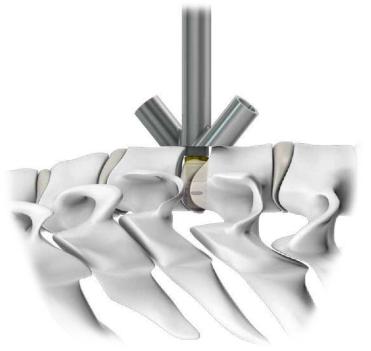
SURGICAL TECHNIQUE



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

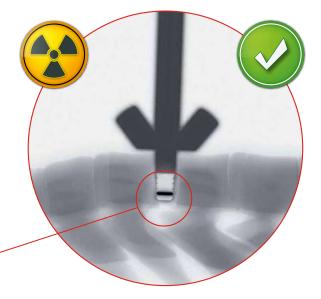


Having inserted the cage into the intervertebral space, remove the Caspar distractor and pins and leave the applicator in place.



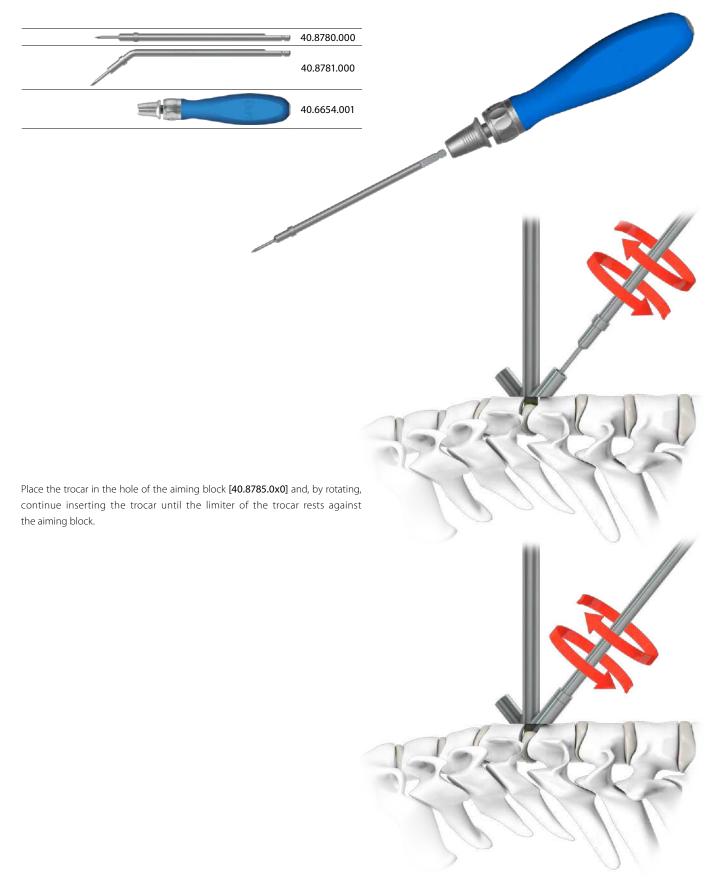
The embedded tantalum marker is used to navigate the position of the posterior wall of the intervertebral cage (*the marker is located 1mm from the edge of the cage*). The marker is also used to determine whether the endplates of the vertebral bodies adhere properly to the cage.

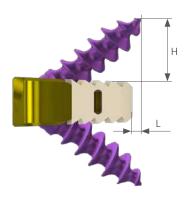




V.7. HOLES DRILLING AND SCREWS INSERTION

Connect the trocar (*straight*) **[40.8780.000]** or (*angled*) **[40.8781.000]** to the handle ratchet device **[40.6654.001]**.





Cage 15x12			
Screw length	L	н	
10	Does not protrude	3.6	
12	Does not protrude	4.8	
14	0.7	6	
16	2.2	7.3	
	Screw length 10 12 14	Screw lengthL10Does not protrude12Does not protrude140.7	

Cage 17x13			
Drill length	Screw length	L	н
8	10	Does not protrude	3.7
12	12	Does not protrude	4.9
	14	Does not protrude	6.1
16	16	1.2	7.3

Tab.1. Selection of drills and screws (recommended screw length is indicated)

Based on the X-Ray image and table 1, select the appropriate length of the drill. The drill should be used with handle ratchet device **[40.6654.001]**.

The instrument set includes drills with limiter **[40.8788.xxx]** and drills with joint and limiter **[40.8787.xxx]** of the following lengths: 8, 12, 16mm. The drill lengths and dedicated corresponding screws are presented in table1.

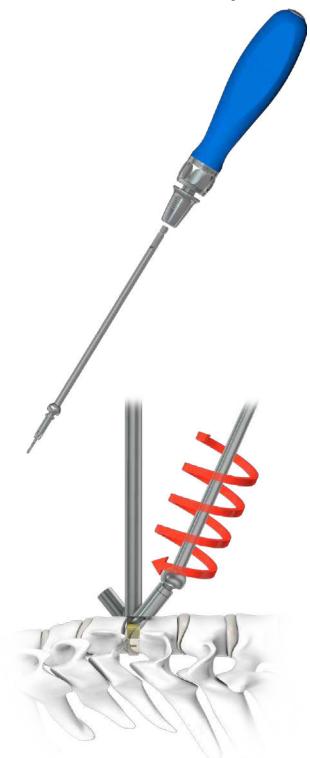




It is recommended to select the longest screws that do not protrude outside the contour of the intervertebral cage in the lateral view. The use of such screws minimizes the risk of spinal cord injury.

The length of the drill must not exceed the length of the screw that will be used to lock the cage.

Place the drill in the appropriate hole in the aiming block and, by rotating, continue drilling the hole for the screw, until the drill limiter rests on the block.



V.8. SCREWS INSERTION

Connect the handle ratchet device **[40.6654.001]** with screwdriver tip T10 with joint **[40.8782.000]** or screwdriver tip T10 **[40.8783.000]**.







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.



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

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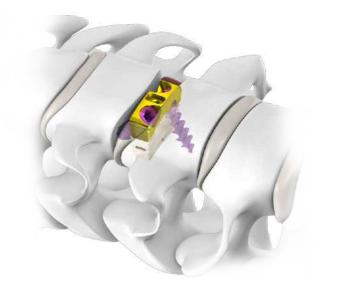
When the marker on the screwdriver shaft lines with the aiming block, the screw has been properly inserted and the securing ring of the screw got locked in the groove in the intervertebral cage.



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 turning 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

In order to remove the implant, connect the extractor with the intervertebral cage, by inserting the threaded tip of the instrument in the socket of the locking screw.

Rotate the knob clockwise to tighten the connection.





Then, rotate the lower knob counter-clockwise to lower the sleeve until it rest against the cage.

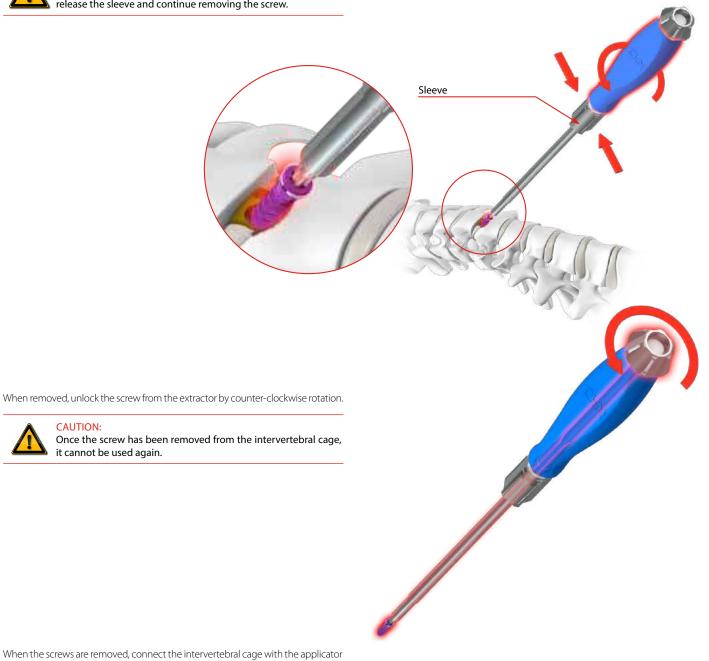




Hold the sleeve and remove the sleeve and remove the screw using the silicone handle and counter-clockwise rotation.



CAUTION: when the screw "pops out" of the socket in the intervertebral cage, release the sleeve and continue removing the screw.



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,

CAUTION:

it cannot be used again.

 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



