instruction

TLIF PEEK INTERVERTEBRAL CAGES

IMPLANTS ◦
INSTRUMENT SET 40.6125.000 ◦
SURGICAL TECHNIQUE ◦

CHARSPINE system

56A

CE 0197
ISO 9001
ISO 13485

ChM®

Edition 56A dated 02.01.2014, reviewed 05.12.2014

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

I. INTRODUCTION

I.1. Description and indications

The TLIF PEEK Intervertebral Cage system consists of polietheroetheroketone *(PEEK)* cages of various widths, heights and lordotic angles to adapt best to patient's spinal anatomy.
The TLIF PEEK Intervertebral Cage system is designed for implantation via posterolateral *(transforaminal)* approach. These implants are used for treatment of degenerative disc disease *(DDD)*, vertebral instability, Grade 1 spondylolisthesis, and for spinal revision surgery. Implants should be used at one or two contiguous levels from L2 to S1.
Cages should be used with autograft and additional stabilizing devices allowed for surgeries of lumbar spine *(e.g.: a system of posterior pedicle screws and rods)*.
Degenerative disc disease *(DDD)* is defined as a radicular syndrome, and/or myelopathy with disc herniation, and/or osteophyte creation on posterior lamina of vertebral body which trigger symptoms of radicular syndrome, and/or pressure on spinal cord; all of which must be verified by radiographic examination.
Patients qualified for the surgery should have fully mature bones and have undergone at least six months of non-operative treatment.

I.2. Contraindications

CAUTION:
Intervertebral TLIF implants are not intended for use in cervical spine.

The selection of an appropriate device must be preceded by careful and thorough assessment of patient's state of health.
The conditions listed below may preclude or diminish the chances of successful surgery outcome:

- Local infection *(at the operative site)*.
- Symptoms of local inflammation.
- Fever or high leukocytosis.
- Morbid obesity *(specified according to the WHO standards)*.
- Pregnancy.
- Neuromuscular disorders which could pose a high risk of surgery failure or occurence of postoperative complications.
- Any other condition which could preclude any potential benefits resulting from spinal implant usage and could disturb normal bone remodelling, e.g.: the presence of tumors or congential abnormalities, fracture at the operative site, increase in erythrocyte sedimentation rate unjustified by other diseases.
- Suspected or documented allergy to or intolerance of implant materials. When the patient's oversensitivity to the material used is suspected, appropriate tests should be performed prior to implantation.
- Any situation in which there is no need to surgically stabilize the spine.
- Any situation not described in the indications.
- Any patient unwilling to follow postoperative recommendations; mental illness, senility or substance abuse *(these conditions may cause the patients to ignore limitatons and precautions regarding the implant use)*.
- Patients with known hereditary or acquired bone fragility or problems with bone calcification should not be considered for this type of surgery.
- These devices shall not be used for treating children or patients who still undergo skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any situation in which the selected implant components would be too large or too small to achieve a desired result.
- Any situation in which the tissue coverage, bone material or bone quality at the operative site are insufficient.
- Any situation in which the use of implant would interfere with anatomical structures or physiological processes.
- Prior fusion at the level to be treated.

The above-mentioned list of contraindications is not exhaustive.

For further information on:

• adverse effects,
• warnings,
• sterilization,
• pre- and post-operative recommendations,

please refer to the Instructions For Use attached to the implant unit package.

I.3. Implant features

PEEK

- Stiffness of biocompatible PEEK polymer approximates the stiffness of patient's bone, which provides ideal load sharing conditions.
- Radiolucency of PEEK polymer allows for precise visualisation and assessment of the bone fusion.
- Radiopaque tantalum markers facilitate an intraoperative X-Ray visualisation and an assessment of the inserted implant position.

ANATOMICAL SHAPE

TLIF PEEK intervertebral cage has a rounded and bullet-like shape and is available in a variety of sizes to match patients' anatomies.

SERRATIONS

Upper and lower serrated implant surfaces with angled or parallel placement were designed to provide stability via anchoring in laminae of vertebral body.

OPEN DESIGN

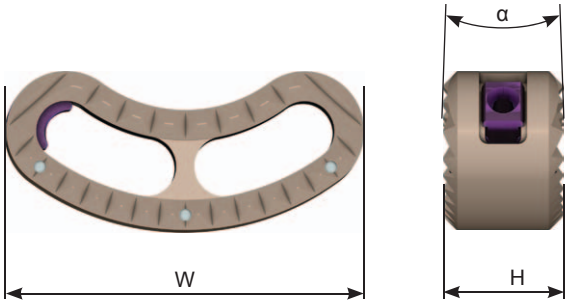
Large openings for bone graft allow for bone tissue ingrowth.

ARTICULATED MECHANISM

TLIF PEEK intervertebral cage has a regulated, articulated mechanism to allow for *in situ* implant rotation.

II. IMPLANTS

Intervertebral cage



		Lordosis angle	
		α = 0°	α = 5°
W [mm]	**H** [mm]	Catalogue no.	
26	7	8.4550.007	8.4551.007
	8	8.4550.008	8.4551.008
	9	8.4550.009	8.4551.009
	10	8.4550.010	8.4551.010
	11	8.4550.011	8.4551.011
	12	8.4550.012	8.4551.012
	13	8.4550.013	8.4551.013
	14	8.4550.014	8.4551.014
	15	8.4550.015	8.4551.015
	16	8.4550.016	8.4551.016
30	7	8.4552.007	8.4553.007
	8	8.4552.008	8.4553.008
	9	8.4552.009	8.4553.009
	10	8.4552.010	8.4553.010
	11	8.4552.011	8.4553.011
	12	8.4552.012	8.4553.012
	13	8.4552.013	8.4553.013
	14	8.4552.014	8.4553.014
	15	8.4552.015	8.4553.015
	16	8.4552.016	8.4553.016

Material: PEEK-OPTIMA®

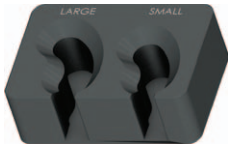
Stand for implants
40.6127.000

Catalogue no.	Name
12.0751.200	Perforated aluminum lid 1/2 306x272x15mm gray
40.6127.100	Palette for implants - TLIF PEEK Cages 1
40.6127.200	Palette for implants - TLIF PEEK Cages 2
12.0751.101	Container with solid bottom 1/2 306x272x114mm

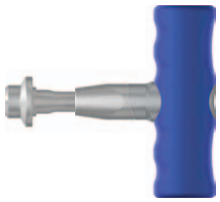
ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

III. INSTRUMENTS

Instrument set for TLIF PEEK cage 40.6125.000

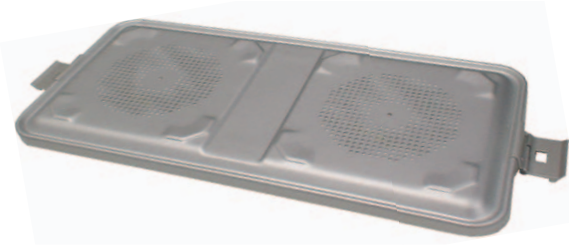
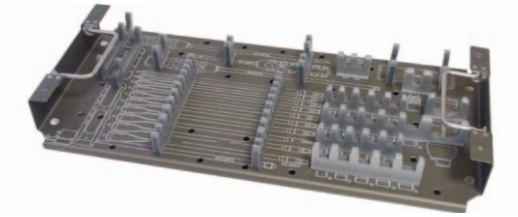
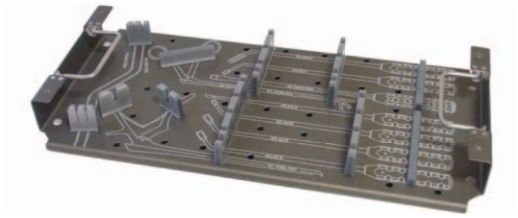
No.		Name	Pcs	Catalogue no.
1		Applicator	1	40.6203.000
2		Persuader	1	40.6204.000
3		Compactor	1	40.6207.000
4		Working stand	1	40.6208.000
5		Impactor-extractor	1	40.6209.000
6		Curved file	1	40.6210.000
7		Curette curved left	1	40.6211.000
8		Curette curved right	1	40.6212.000
9		Bone curette left	1	40.6213.000
10		Bone curette right	1	40.6214.000
11		Impactor	1	40.6215.000
12		SPURLING bone rongeur straight 230mm 4x10mm	1	40.7033.044
13		SPURLING bone rongeur upwards 230mm, 4x10mm	1	40.7034.044
14		KERRISON bone rongeur, upwards ,130°, 230mm, 4mm	1	40.7086.004

Instrument set for TLIF PEEK cage 40.6125.000

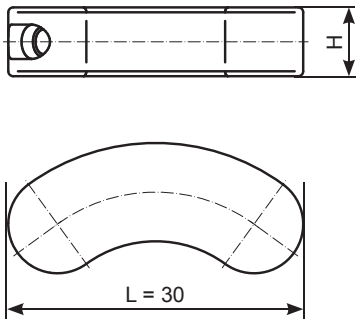
No.		Name	Pcs	Catalogue no.
15		Osteotome	1	40.5803.000
16		Bone curette	1	40.5813.000
17		Elevator 6	1	40.4467.006
18		Elevator 10	1	40.4467.010
19		Reamer 7	1	40.5805.007
20		Reamer 8	1	40.5805.008
21		Reamer 9	1	40.5805.009
22		Reamer 10	1	40.5805.010
23		Reamer 11	1	40.5805.011
24		Reamer 12	1	40.5805.012
25		Reamer 13	1	40.5805.013
26		Reamer 14	1	40.5805.014
27		Reamer 15	1	40.5805.015
28		Reamer 16	1	40.5805.016
29		Big gauge 7	1	40.6205.007
30		Small gauge 7	1	40.6206.007
31		Big gauge 8	1	40.6205.008
32		Small gauge 8	1	40.6206.008
33		Big gauge 9	1	40.6205.009
34		Small gauge 9	1	40.6206.009
35		Big gauge 10	1	40.6205.010
36		Small gauge 10	1	40.6206.010
37		Big gauge 11	1	40.6205.011
38		Small gauge 11	1	40.6206.011
39		Big gauge 12	1	40.6205.012
40		Small gauge 12	1	40.6206.012
41		Big gauge 13	1	40.6205.013
42		Small gauge 13	1	40.6206.013
43		Big gauge 14	1	40.6205.014
44		Small gauge 14	1	40.6206.014
45		Big gauge 15	1	40.6205.015
46		Small gauge 15	1	40.6206.015
47		Big gauge 16	1	40.6205.016
48		Small gauge 16	1	40.6206.016
49		Quick coupling handle T-type	1	40.5638.000
50		Jaws *(complete set)*	1	40.5812.000

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

Instrument set for TLIF PEEK cage 40.6125.000

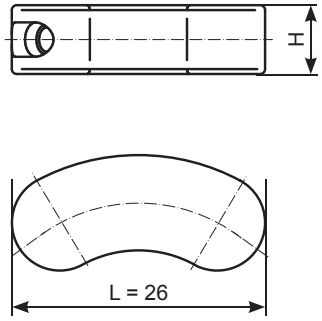
No.		Name	Pcs	Catalogue no.
51		Perforated aluminum lid 1/1 595x275x15mm gray	1	12.0750.200
52		Stand for TLIF PEEK cage instrument set 1	1	40.6126.100
53		Stand for TLIF PEEK cage instrument set 2	1	40.6126.200
54		Container with solid bottom 1/1 595x275x135mm	1	12.0750.102

Gauge *(LARGE)*



L [mm]	**H** [mm]	**Colours**	**Catalogue no.**
30	7		40.6205.007
	8		40.6205.008
	9		40.6205.009
	10		40.6205.010
	11		40.6205.011
	12		40.6205.012
	13		40.6205.013
	14		40.6205.014
	15		40.6205.015
	16		40.6205.016

Gauge *(SMALL)*



L [mm]	**H** [mm]	**Colours**	**Catalogue no.**
26	7		40.6206.007
	8		40.6206.008
	9		40.6206.009
	10		40.6206.010
	11		40.6206.011
	12		40.6206.012
	13		40.6206.013
	14		40.6206.014
	15		40.6206.015
	16		40.6206.016

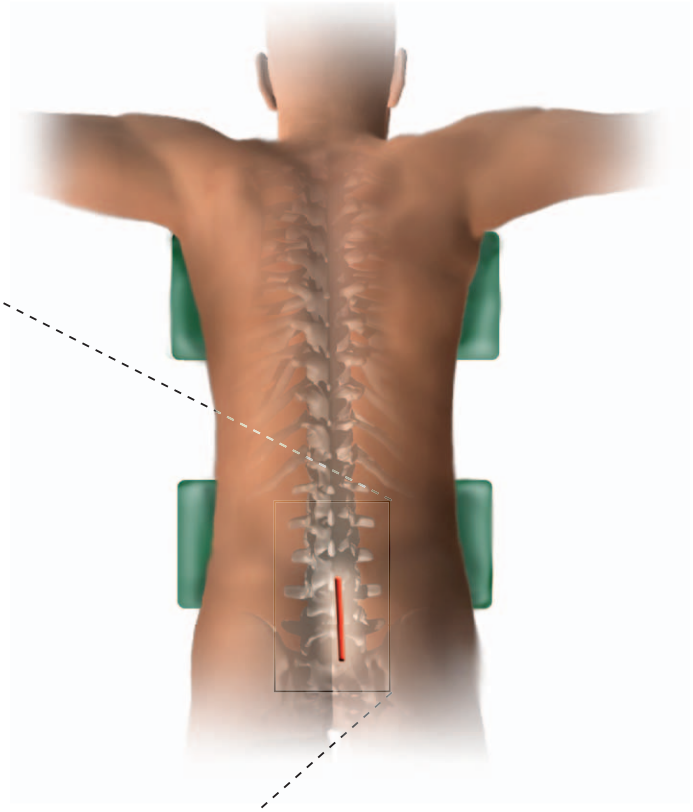
ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

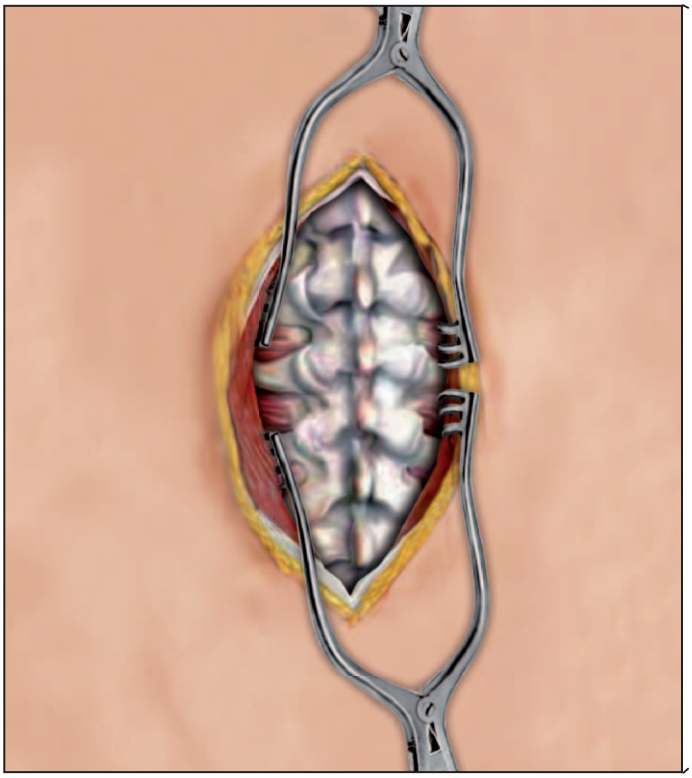
IV. SURGICAL TECHNIQUE

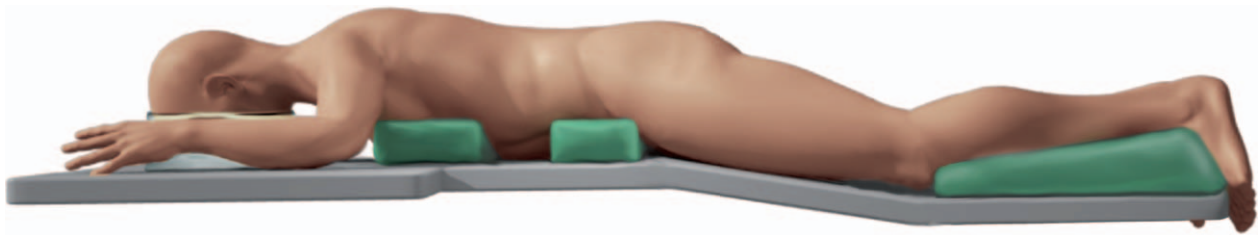
IV.1. Surgical approach and patient positioning

The patient is placed in a prone position on an operating table with adequate clearance available for the fluoroscopic C-arm. Special care should be taken to secure patient's pressure points.

A posterior midline skin incision is made, and the tissues are dissected laterally. The lamina and articular process are exposed laterally until the transverse processes are visible.





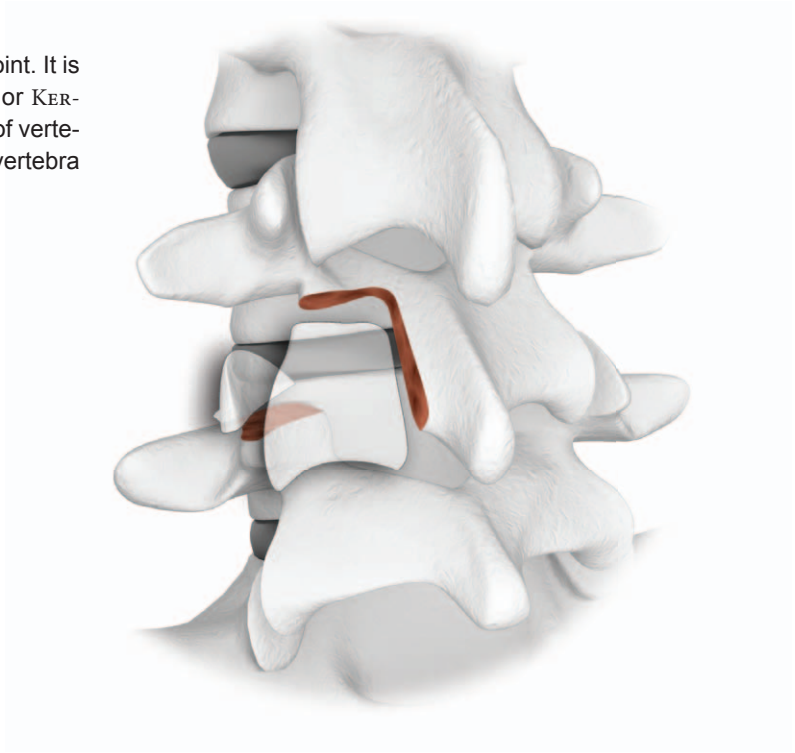


The soft tissue retractors can be used to maintain proper exposure. The C-arm unit can be used to facilitate the precise determination of relevant spinal segments position.

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

IV.2. Removal of articular processes

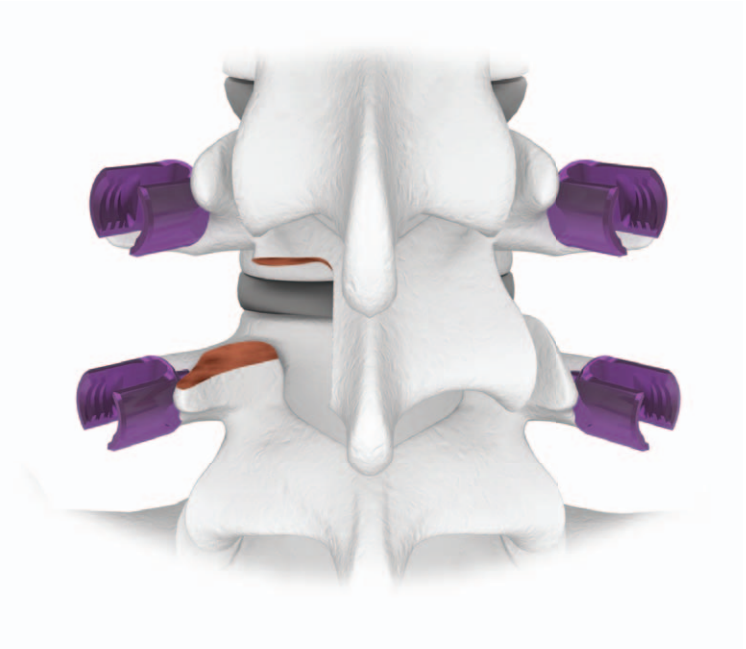
To insert an implant it is necessary to prepare an entry point. It is prepared by lateral removal, with the help of osteotome or KERRISON ronguer, of an inferior articular process with a part of vertebral arch lamina, and of a superior articular process of a vertebra which is below the disc.



IV.3. Insertion of pedicle screws from *CHARSPINE 6.0* system *(optional)*

TIP:
Rod stabilization with the use of pedicle screws *CHARSPINE 6.0* system increases the stability of the operated spine segment. Insertion of screws at this stage allows for intraoperative vertebrae distraction *(IV.4 of the Instructions)* **to facilitate the TLIF procedure. It is also possible to insert the screws after the intervertebral cage insertion** *(IV.10 of the Instructions)*.

The screws are to be inserted into the contiguous vertebrae situated above and below the damaged intervertebral disc on the left and on the right, according to the surgical technique no. 35 SPINE STABILIZATION by **ChM**.



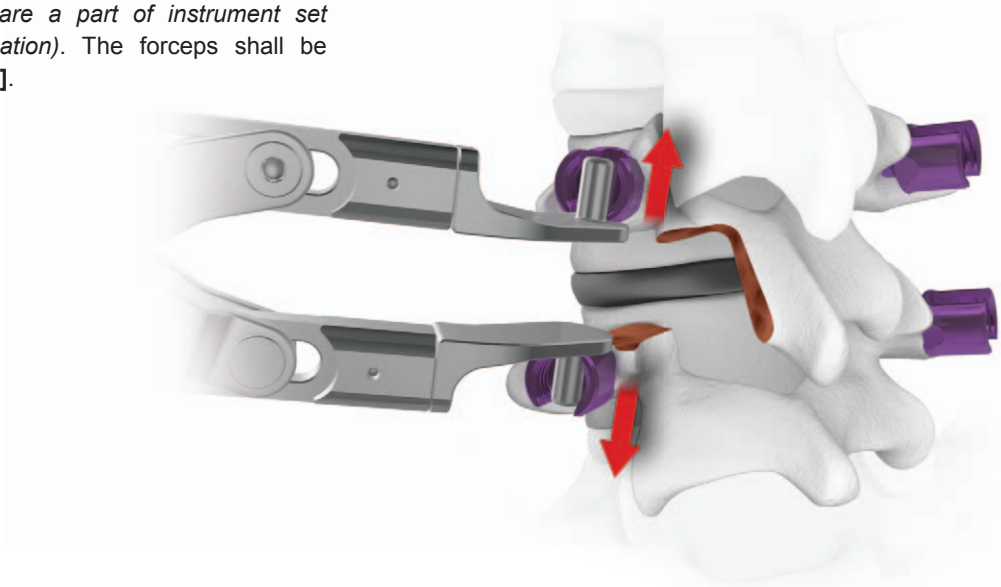
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

IV.4. Distraction *(optional)*

TIP:
Distraction can facilitate the subsequent steps of TLIF PEEK intervertebral cage insertion.

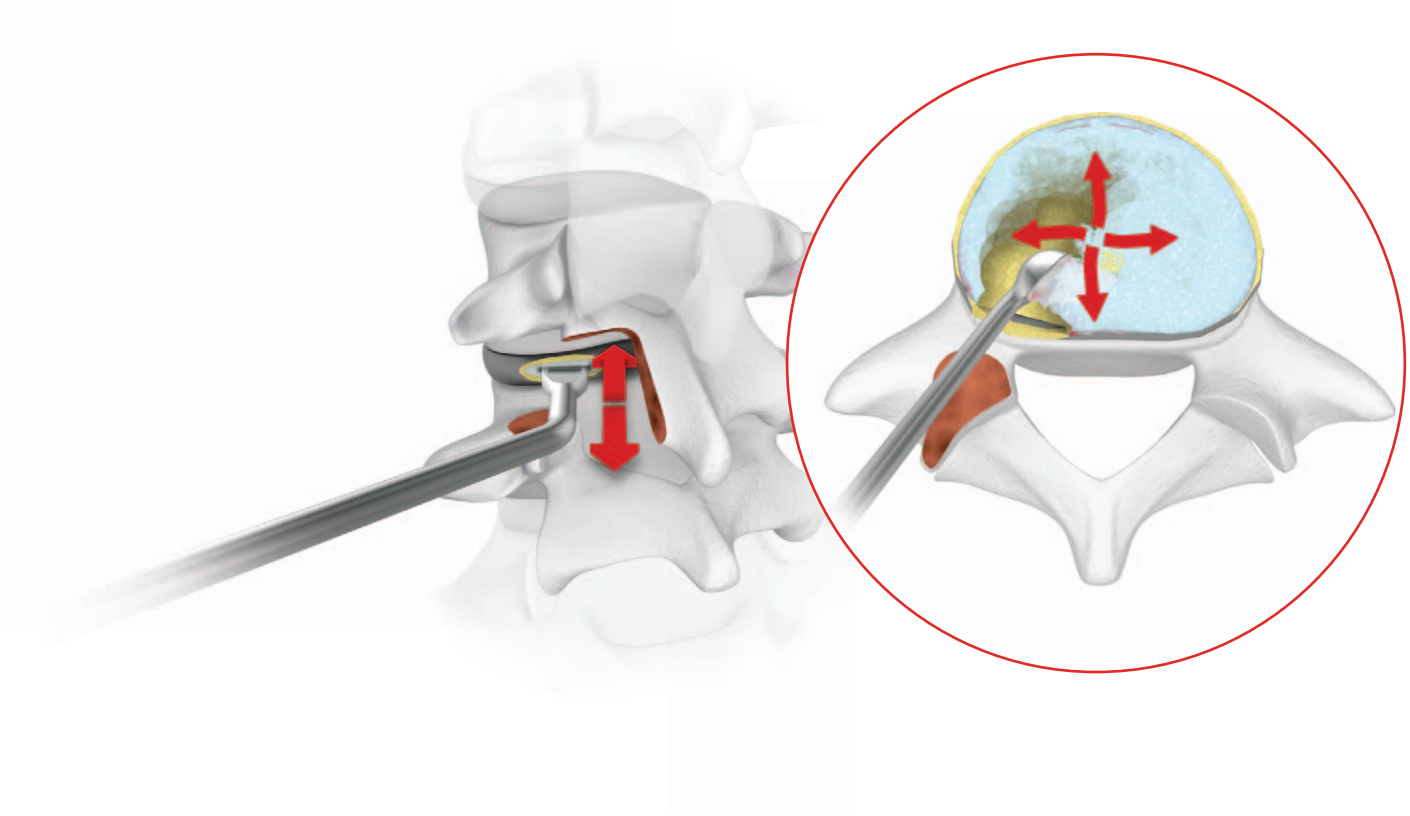
Distraction is performed with the use of previously introduced pedicle screws *(IV.3 of the Instructions)* and parallel distraction forceps **[40.5295]** *(which are a part of instrument set for **CHARSPINE** spine stabilization)*. The forceps shall be equipped with jaws **[40.5812.000]**.



IV.5. Discectomy

The procedure of discetomy begins with preparation of an oval incision *(about 1 cm in length)* in the anulus fibrosus, below the vertebral pedicle *(via previously prepared window)*.

With the help of Kerrison bone rongeur **[40.7086]**, bone curettes **[40.5813]**, **[40.5814]**, **[40.6211]**, **[40.6212]** or reamers **[40.5805]**, through the prepared incision in the anulus vibrosus, remove the fragments of intervertebral disc and leave the outer part of anulus fibrosus. It prevents the bone graft from migrating and facilitates insertion and stabilizes placement of an implant.

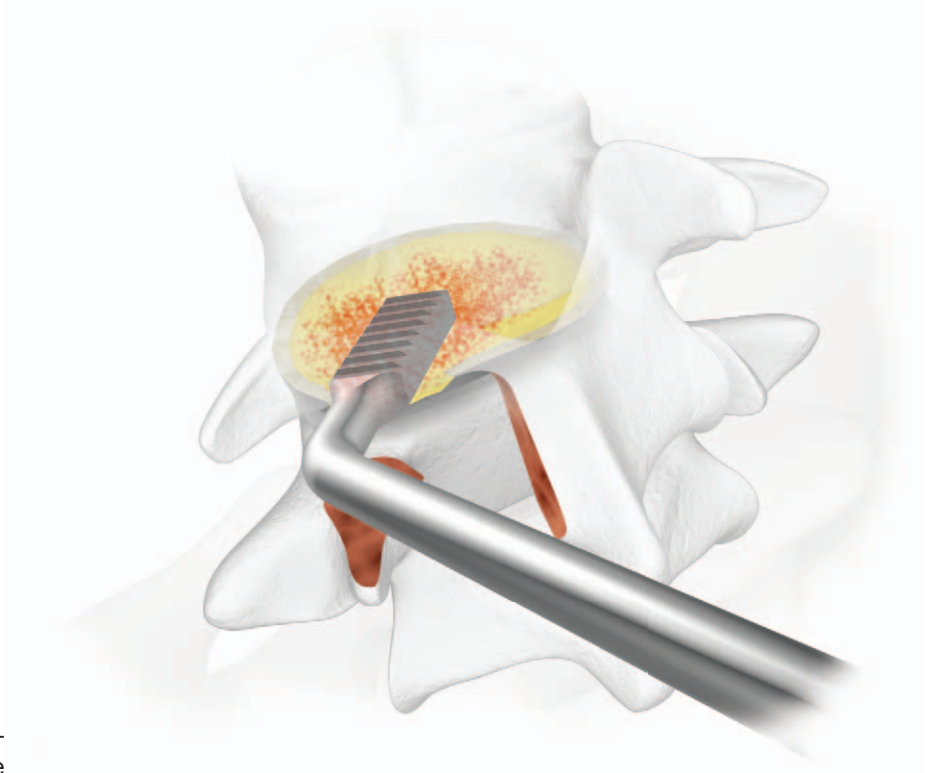


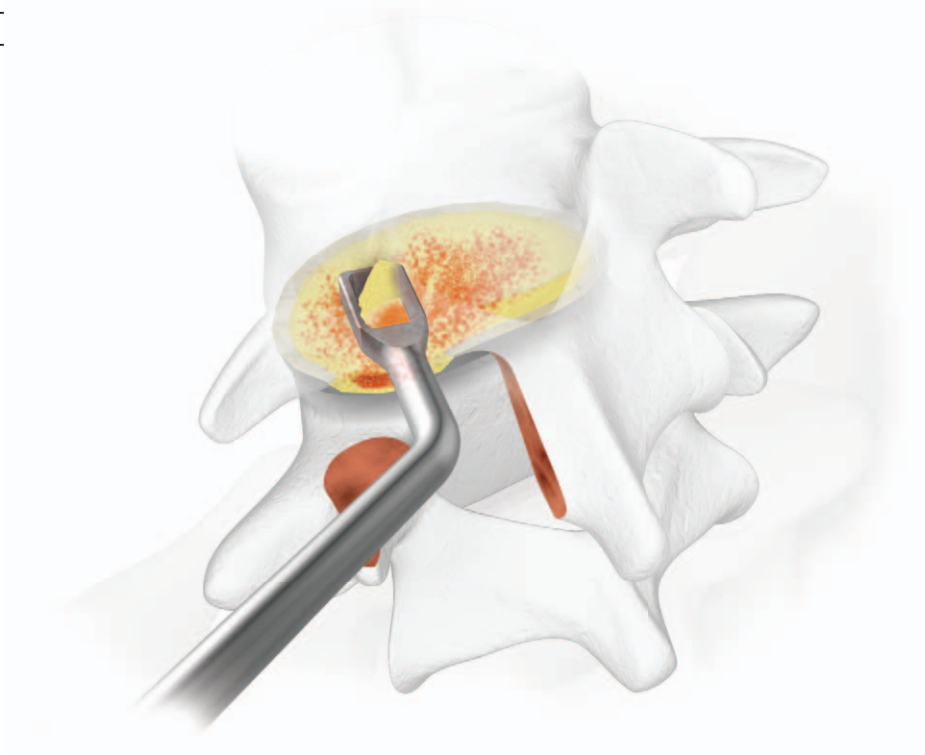
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.6. Preparation of the borderline surfaces of vertebral bodies

TIP:
An appropriate surgical preparation of the surfaces of vertebral bodies adjacent to the removed intervertebral disc is a necessity for the attainment of proper spondylosis.

With the aid of a file **[40.6210]** or bone curettes **[40.6213]** and **[40.6214]** remove the cartilaginous surface *(the remains of removed intervertebral disc)* and the subchondral bone layer until the bleeding bone is exposed.





CAUTION:
Excessive removal of subchondral bone layer weakens the borderline surface of the vertebra; this may result in fracture and, in consequence, in postoperative loss of stability of the operated spine segment.

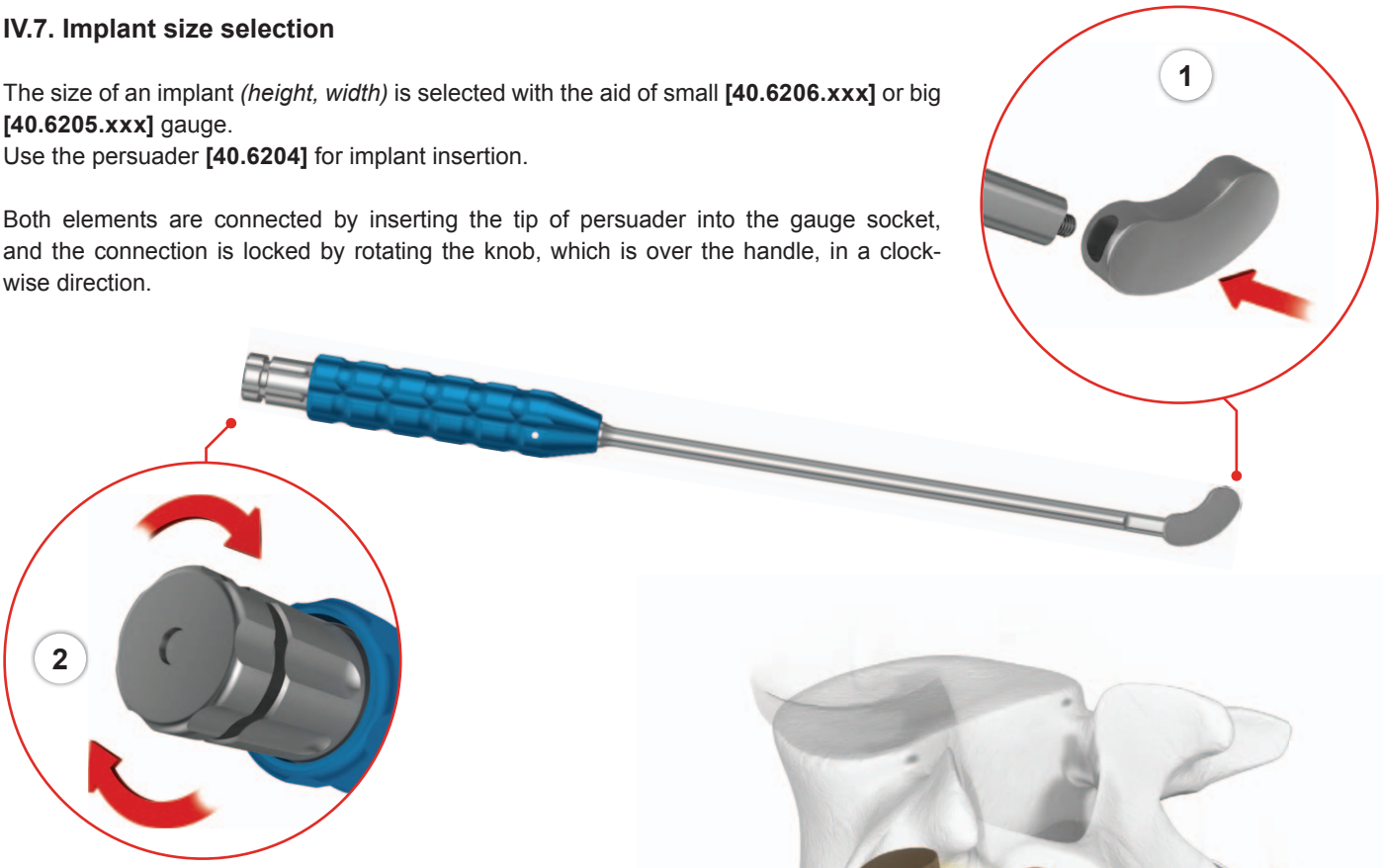
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

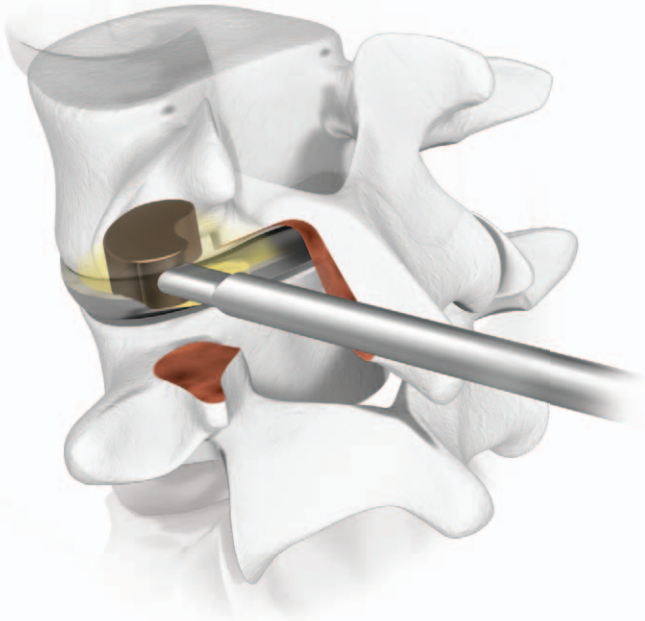
IV.7. Implant size selection

The size of an implant *(height, width)* is selected with the aid of small **[40.6206.xxx]** or big **[40.6205.xxx]** gauge.
Use the persuader **[40.6204]** for implant insertion.

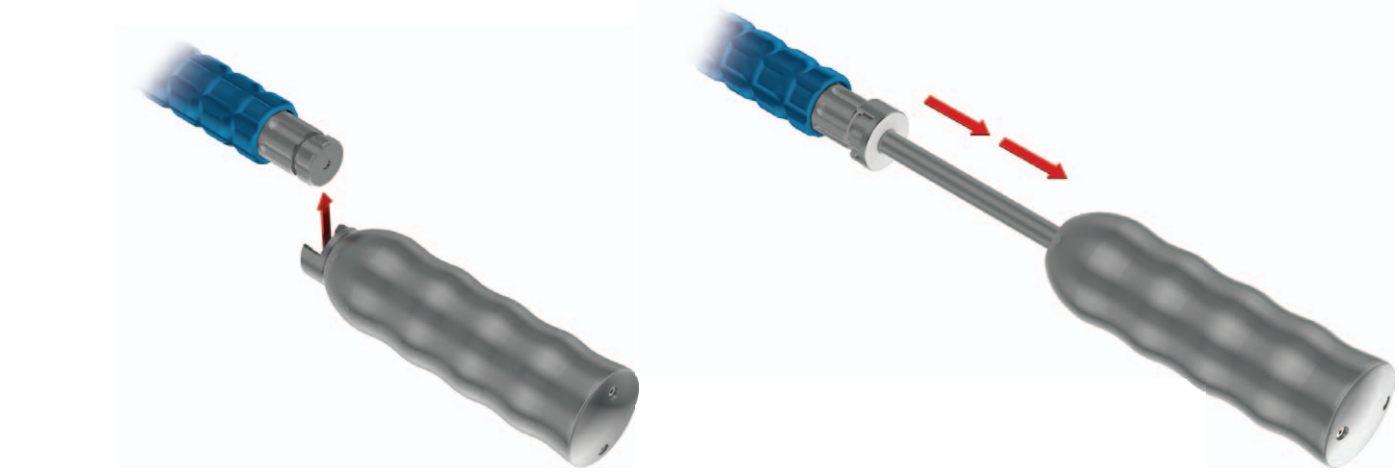
Both elements are connected by inserting the tip of persuader into the gauge socket, and the connection is locked by rotating the knob, which is over the handle, in a clockwise direction.



The gauges are inserted into the intervertebral space starting from the smallest size *(7x26)* up to the size when the gauge fits tightly and precisely. The size of a gauge corresponds to the size of an implant to be used in the further surgery.



One may use the impactor-extractor **[40.6209]** to facilitate the insertion and removal of the gauge.
This device is connected with the persuader by inserting the impactor-extractor handle into the cut on a persuader knob. The gauge is impacted or extracted by a dynamic movement of the butt upwards or downwards.

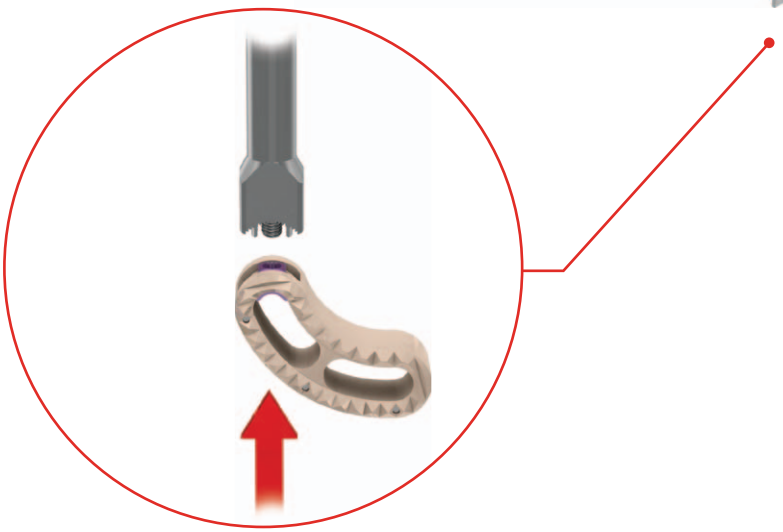


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.8. Filling the implant with autologous bone chips

Connect the selected intervertebral cage *(see section IV.7 of the Instructions)* with the applicator **[40.6203]**. To do so, turn the knob in a counter-clockwise directon to the limit.

Insert the movable implant connector between the two wings located at the tip of applicator.

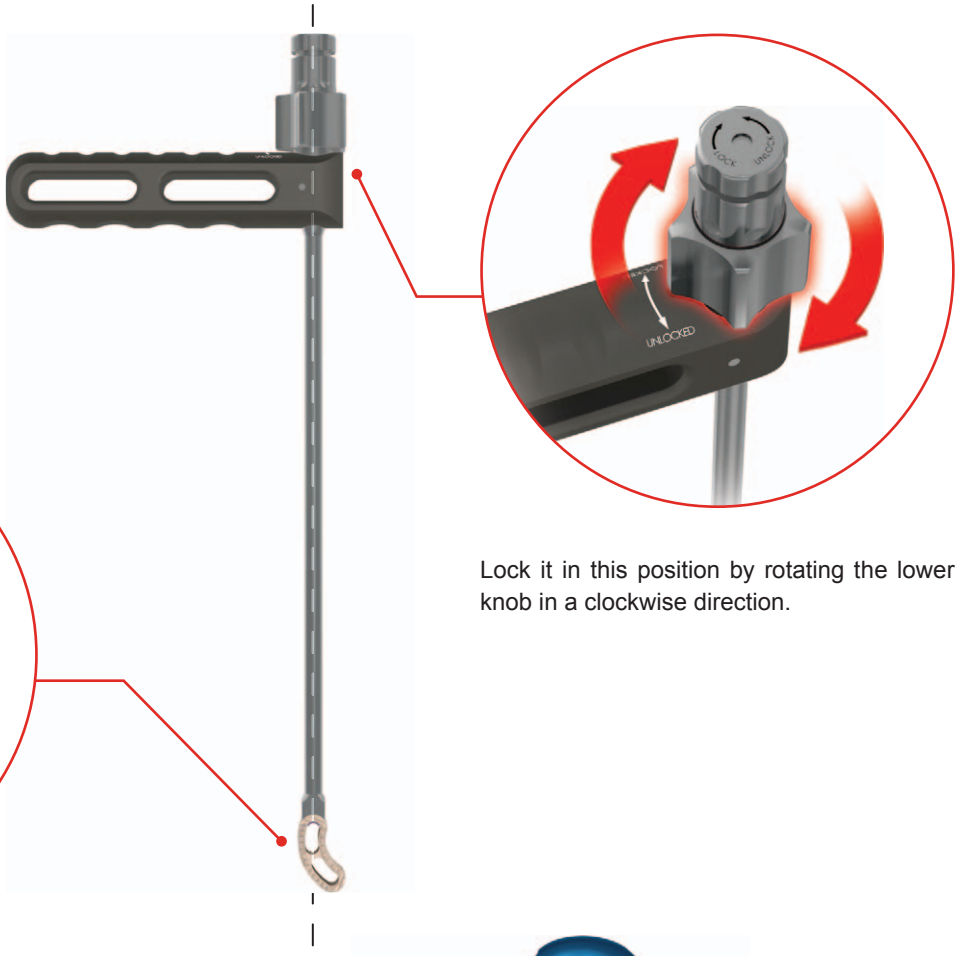


With the help of upper knob screw in the threaded applicator pin end to the limit *(in a clockwise direction)* into the intervertebral cage connector and tighten it.

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

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

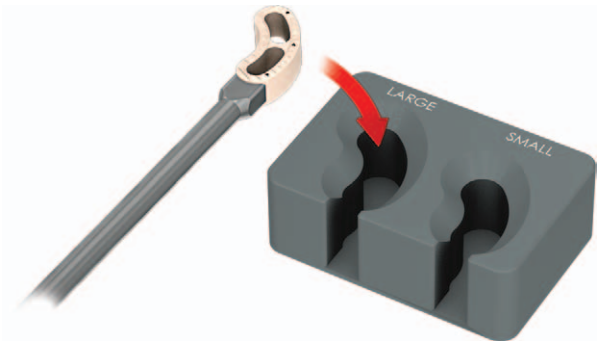
Put the implant maximally upright.

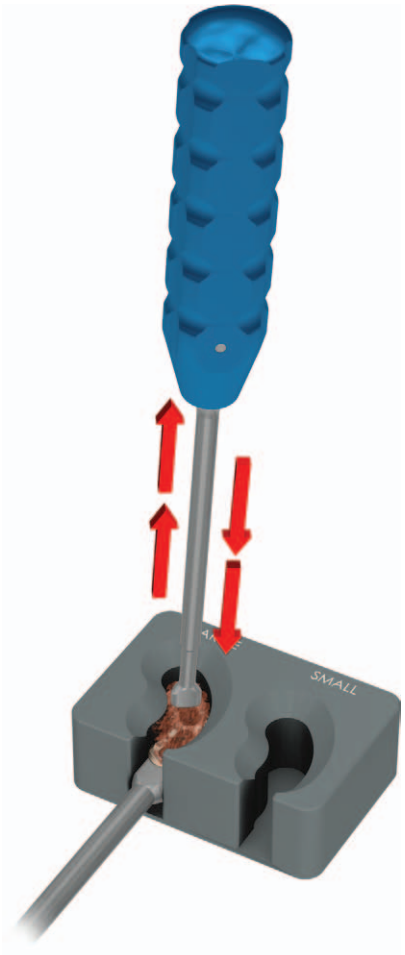


Lock it in this position by rotating the lower knob in a clockwise direction.

Put the intervertebral cage locked with the applicator into one of the sockets of the working stand **[40.6208]** *(corresponding to the implant size)*.

Fill the empty space with bone chips, compressing them with the help of Compactor **[40.6207]** until the compressed material levels with the upper surface of the implant.





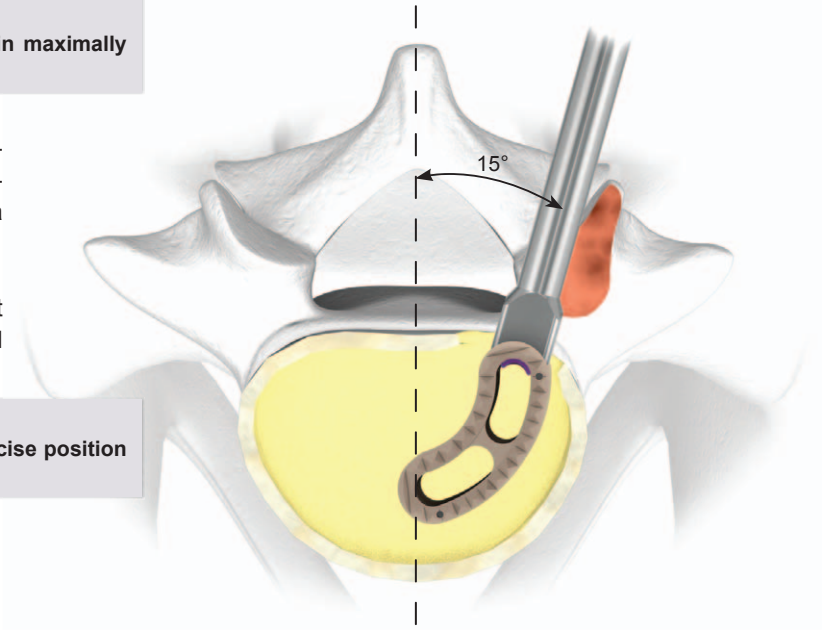
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.9. Insertion of intervertebral cage

TIP:
The intervertebral cage is to be inserted through the incision made in the intervertebral disc during the discetomy. To facilitate the implantation one may retain the previously prepared vertebrae distraction.

CAUTION:
At this stage the implant should be locked in maximally upright position *(as in section IV.8)*.

During the insertion of intervertebral cage it is necessary to retain the angle of about 15° between the persuader tip and the axis of symmetry of the vertebra visible in the transverse plane.



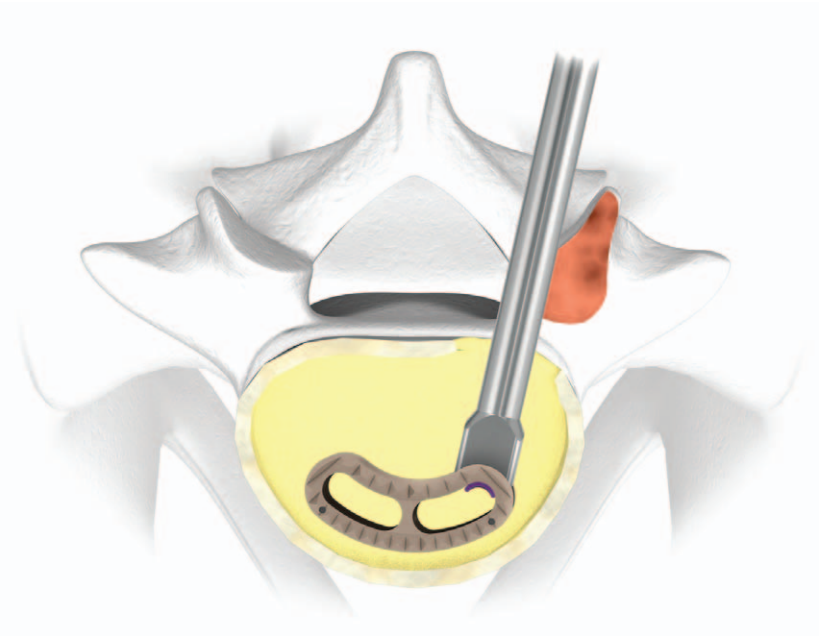
During the first stage, carefully and gradually put the implant into the intervertebral space until its end reaches the internal frontal part of anulus fibrosus.

CAUTION:
Take X-Ray photographs to establish the precise position of the implant.

To release the angular lock of the implant, rotate the larger knob of the applicator in a counter-clockwise direction.

TIP:
Lock release does not detach the implant and the applicator, but it only allows for angular change in its position. Any reposition or complete removal of the implant from the intervertebral space is now possible.

After the lock release the cage automatically positions itself appropriately for TLIF.



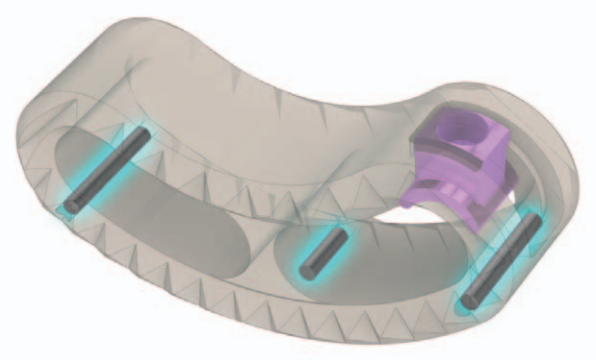
If any correction of the implant position is necessary, the implant should be locked again in appropriate angular position by rotating the lower knob *(rotation in a clockwise direction)*.

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

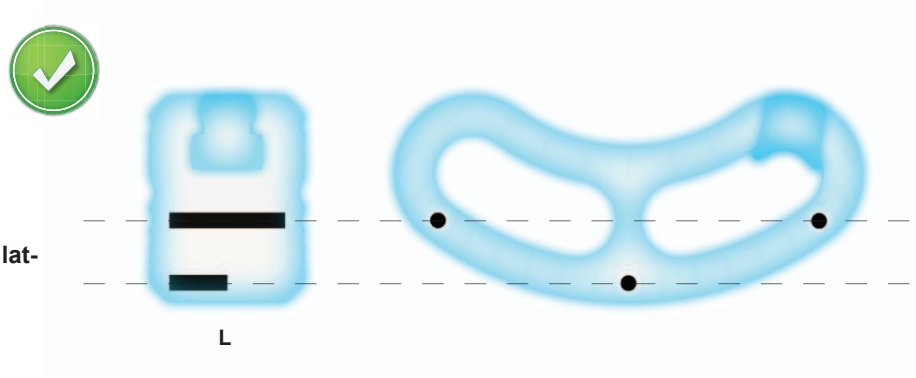
ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

CAUTION:
Take X-Ray photographs to establish the precise position of the implant.

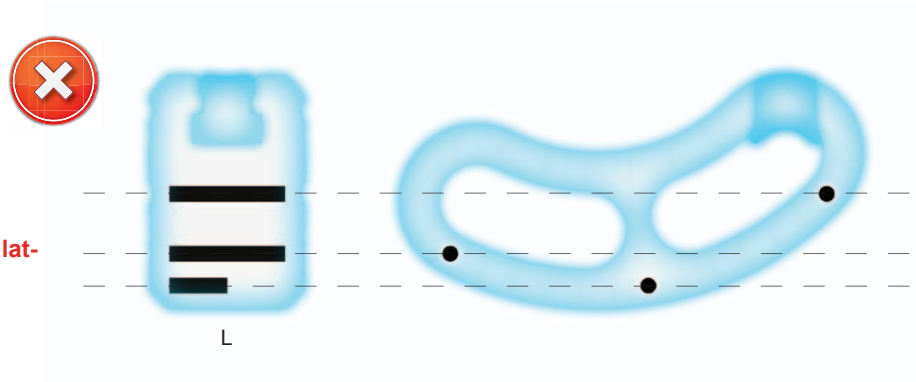
There are 3 radiological markers inside the implant: 2 are located symmetrically at both ends, with their length equal to the height of intervertebral cage, and 1 is located in the axis of symmetry, with its length equal to half of the implant height.



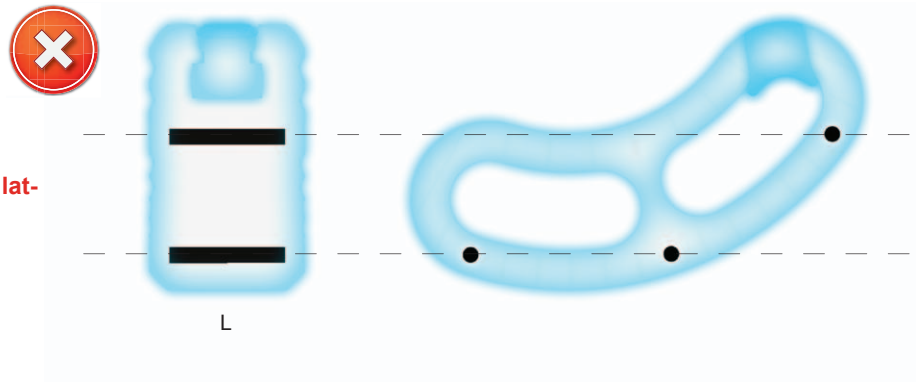
When the position is correct, two markers of different lengths should be visible in the lateral view.



Correct implant positioning.
2 markers of different lengths in the lateral view.



Incorrect implant positioning!
3 markers of different lengths in the lateral view.

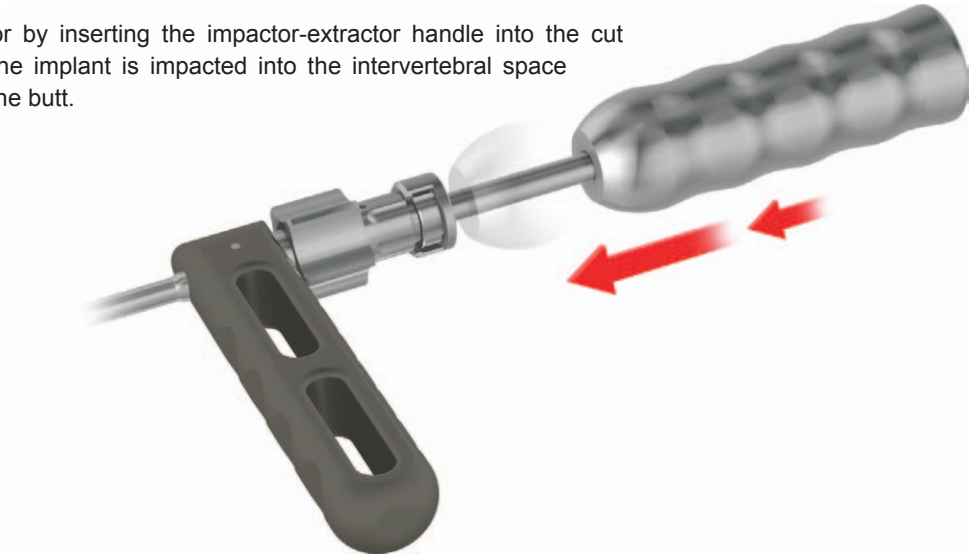


Incorrect implant positioning!
2 markers of the same length in the lateral view.

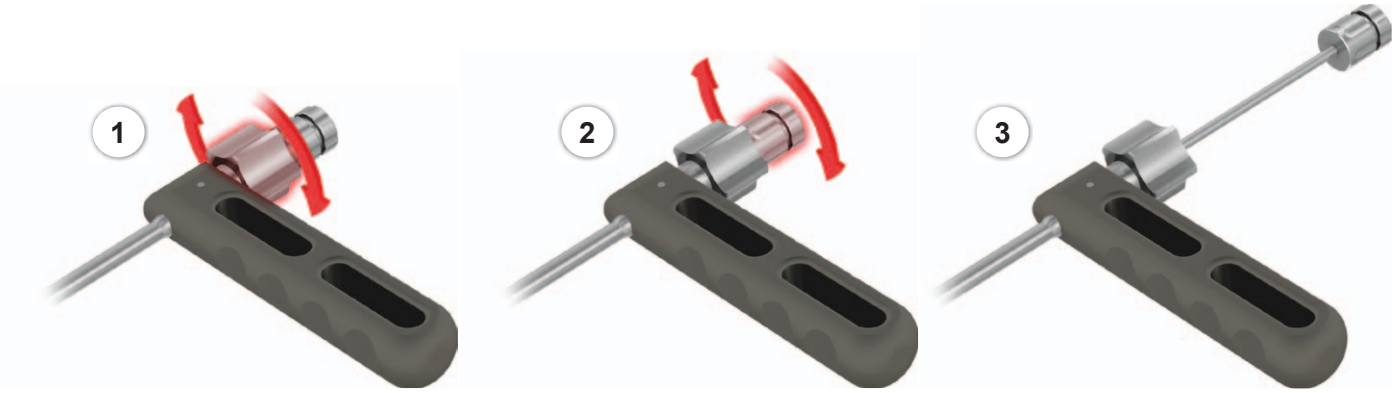
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Use the impactor-extractor **[40.6209]** to facilitate the insertion of intervertebral cage.

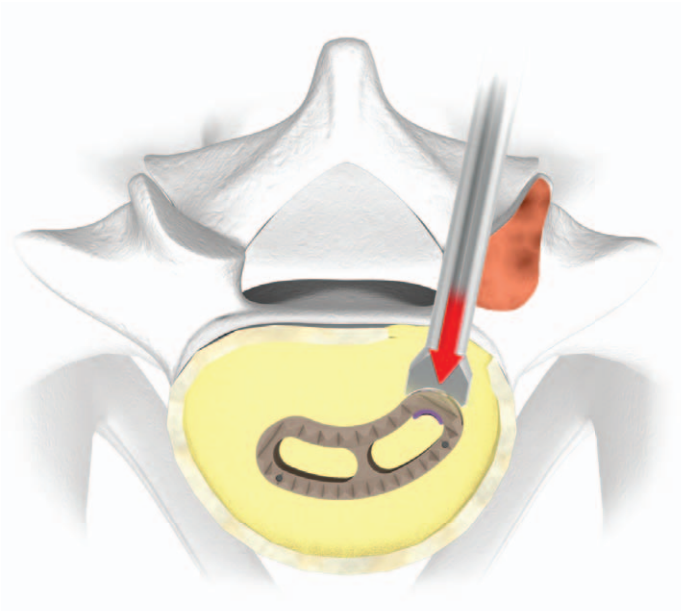
Connect this device with the applicator by inserting the impactor-extractor handle into the cut in the upper knob of the applicator. The implant is impacted into the intervertebral space by a downward dynamic movement of the butt.



A complete detachment of the intervertebral cage from the applicator **[40.6203]** is possible by:
1. unlocking the implant angular position - rotating the lower knob in a counter-clockwise direction,
2. rotating the upper knob in a counter-clockwise direction,
3. removal of the applicator pin.



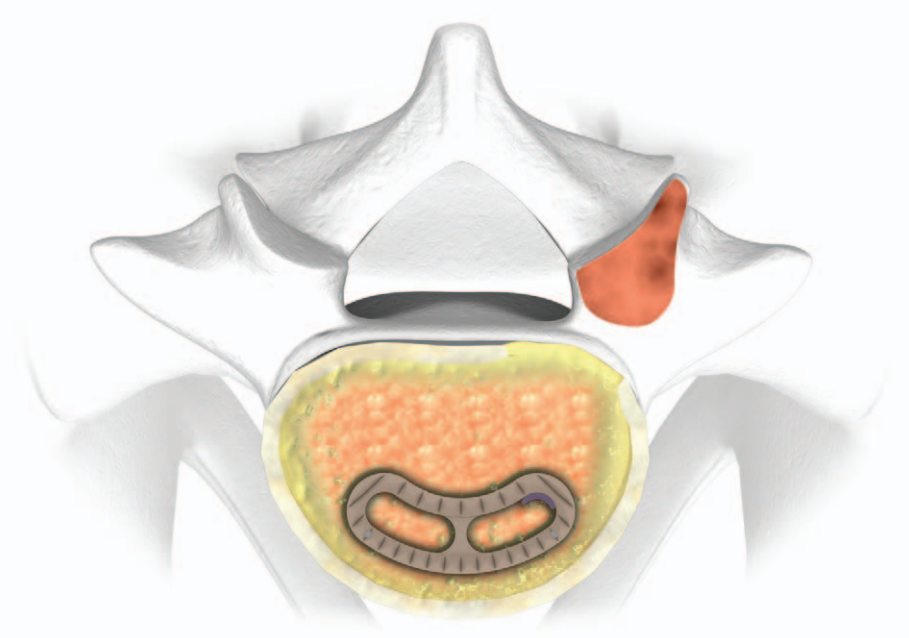
At this stage small corrections of implant positioning may be made by carefully impacting the implant in a desired direction with the use of the impactor **[40.6215]**.



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

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

After correct implant insertion the remaining intervertebral space should be filled with autologous bone graft *(bone chips)*.

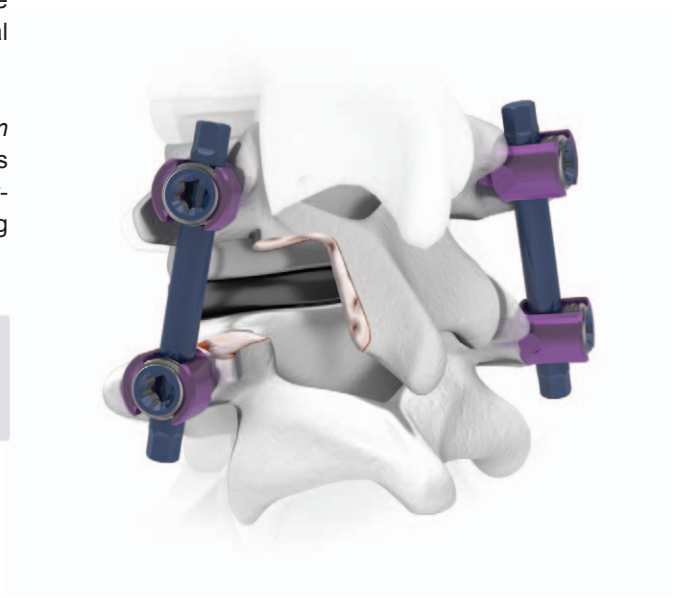


IV.10. Transpedicular stabilization

Transpedicular stabilization shall be performed with the use of pedicle screws made by **ChM** and according to the surgical technique no. 35 SPINE STABILIZATION.

If the pedicle screws were not inserted beforehand *(see section IV.3 of the Instructions)*, they should be introduced on both sides into the vertebral pedicles below and above the damaged intervertebral disc. Further procedures are to be performed according to the surgical technique for pedicle screws by **ChM**.

CAUTION:
According to the surgical technique for transpedicular stabilization with the screws, it is recommended to perform a gentle compression of the vertebrae.

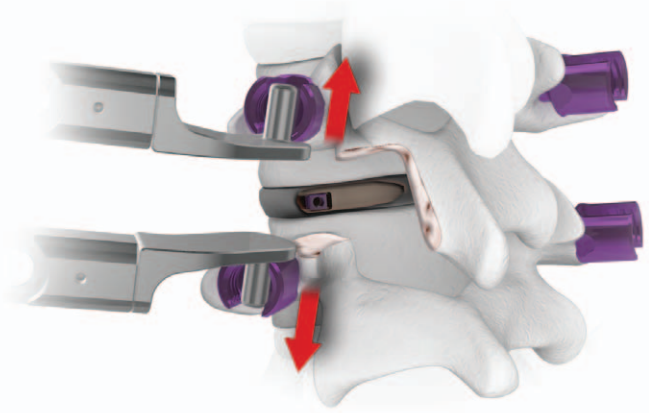


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

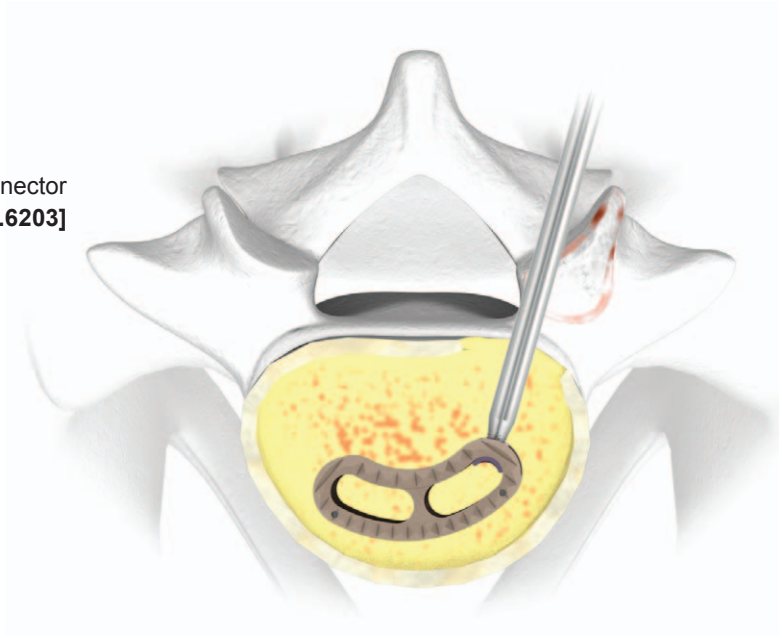
IV.11. Implant removal

In order to remove *(if necessary)* the TLIF PEEK cage, the vertebrae distraction is required.

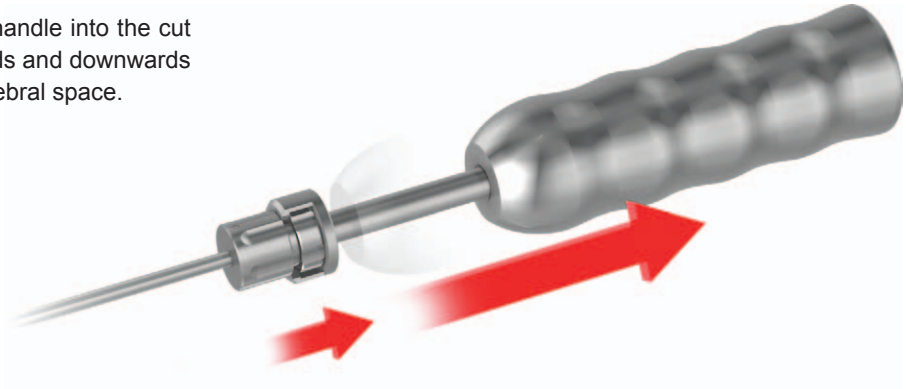
Distraction may be performed directly with the use of reamers **[40.5825.xxx]** or optionally with the use of previously introduced pedicle screws and parallel distraction forceps **[40.5295]** *(available in the instrument set for **CHARSPINE** spine stabilization)*. which are equipped with jaws **[40.5812.000]**.



After the vertebrae distraction, locate the threaded connector of intervertebral cage and screw the applicator pin **[40.6203]** into it.



Next insert the impactor-extractor **[40.6209]** handle into the cut on a pin knob, then by moving the butt upwards and downwards carefully extract the implant from the intervertebral space.



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

ChM Ltd., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND
tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

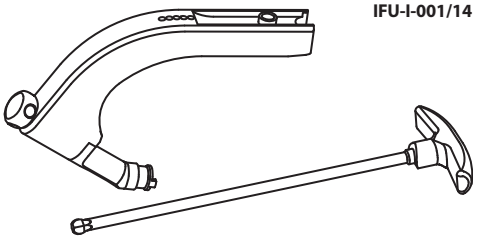
GB

ISO 9001/ ISO 13485

CE

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

IFU-I-001/14



GB

INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

Instruments manufactured by **ChM** sp. z o.o. are made of steel, aluminium alloys and plastics according to ISO standards. Each medical instrument is exposed to occurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stay in natural colour *(silvery-grey)*, is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance. The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference on the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: POM-C *(Polyoxymethylene Copolymer)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE)*. The above mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 9.5.

- *If the material of the device cannot be specified, please contact* **ChM** *sp. z o.o. company representative.*

DISINFECTION AND CLEANING

Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quality of used detergent, the technique of cleaning *(manual/machine)*, the correct rinsing and drying, the proper preparation of the instrument, the time, the temperature. Internal procedures of sterilization rooms, recommendations of cleaning and disinfecting agents, as well as recommendations for cleaning and sterilization in automatic machines shall be observed.

- *Read and follow the instructions and restrictions specified by the manufacturers of the agents used for disinfection and cleaning procedures.*

1. Before the first use, the product has to be thoroughly washed in the warm water with washing-disinfecting detergent. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use water solutions of cleaning-disinfecting agents with a neutral pH.
2. After use, for at least 10 minutes the product has to be immediately soaked in an aqueous disinfectant solution of enzyme detergent with a neutral pH *(with disinfecting properties)* normally used for reusable medical devices *(remember to prevent drying out of any organic remains on the product surface)*. Follow all the instructions specified by the producer of those enzyme detergents.
3. Carefully scrub/clean the surfaces and crevices of the product using a soft cloth without leaving threads, or brushes made of plastic, the nylon brushes are recommended. Do not use brushes made of metal, bristles or another damaging material as they can cause physical or chemical corrosion.
4. Next, thoroughly rinse the instrument under the warm running water, paying particular attention to rinse the slots carefully. Use nylon brushes making multiple moves back and forth on the surface of the product. It is recommended to rinse under demineralized water, in order to avoid water stains and corrosion caused by chlorides, found in the ordinary water, and to avoid forming the stains on the surface *(e.g. anodized one)*. During the rinsing, manually remove the adherent remains.
5. Visually inspect the entire surface of the product to ensure that all contaminants are removed.

- *If there are any residues of human tissue or any other contamination, repeat all stages of the cleaning process.*

6. Then, the instrument has to undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for reusable medical devices and instruments)*.

- *Procedure of washing with the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agents manufacturer.*

ATTENTION! *The manufacturer does not recommend using any preservatives on surgical and orthopedic devices.*

STERILIZATION

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes, without structure damage *(cracks, fractures, bending, peeling)*. Remember that sterilization is not a substitute for cleaning process!

- *Devices manufactured out of plastics (PEEK, PTFE, POM-C) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards. It is recommended to sterilize in steam sterilizers where sterilizing agent is water vapour. Recommended parameters of the sterilization method:

- temperature: 134°C,
- pressure: 2 atm. of pressure above atmospheric *(overpressure)*,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

Validated sterilization methods are allowed. Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

If this instruction appears unclear, please contact the manufacturer, who shall provide all required explanations.

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

IFU-I-001/14; Date of verification: September 2014

SYMBOL TRANSLATION • OBJAŚNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ
EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY

Do not reuse Nie używać powtórnie Не использовать повторно No reutilizar Nicht wiederverwenden Nepoužívejte opakovaně	Do not resterilize Nie sterylizować ponownie Не стерилизовать повторно No reesterilizar Nicht resterilisieren Nepoužívejte resterilizaci	Do not use if package is damaged Nie używać jeśli opakowanie jest uszkodzone Не используйте при поврежденной упаковке No utilizar si el envase está dañado Nicht verwenden falls Verpackung beschädigt ist Nepoužívejte, pokud je obal poškozen
Sterilized using irradiation Sterylizowany przez napromieniowanie Стерилизация облучением Esterilizado mediante radiación Sterilisiert durch Bestrahlung Sterilizovat zářením STERILE R	Sterilized using ethylene oxide Sterylizowany tlenkiem etylenu Стерилизация окисью этилена Esterilizado mediante óxido de etileno Sterilisiert mit Ethylenoxid Sterilizovat ethylenoxidem STERILE EO	Non-sterile Niesterylny Нестерильно No estéril Unsteril Nesterilní
Catalogue number Numer katalogowy Номер по каталогу Número de catálogo Katalognummer Katalogové číslo REF	Batch code Kod partii Код партии Código de lote Chargennummer Číslo šarže LOT	Consult instructions for use Zajrzyj do instrukcji używania Смотри инструкцию по применению Consultar instrucciones de uso Siehe die Gebrauchsanweisung Řiďte se návodem k použití
Material Material Материал Material Material Materiál Mat:	Quantity Ilość Количество Cantidad Menge Množství Qty:	Use by Użyć do Срок годности Fecha de caducidad Verwenden bis Použijte do
	Caution Ostrzeżenie Предупреждение Advertencia Vorsicht Varování	

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

ChM Ltd.

Lewickie 3b
16-061 Juchnowiec K.
Poland

tel. +48 85 713-13-20
fax +48 85 713-13-19
e-mail: chm@chm.eu

SALES OFFICE
tel.: + 48 85 713-13-30 ÷ 38
fax: + 48 85 713-13-39