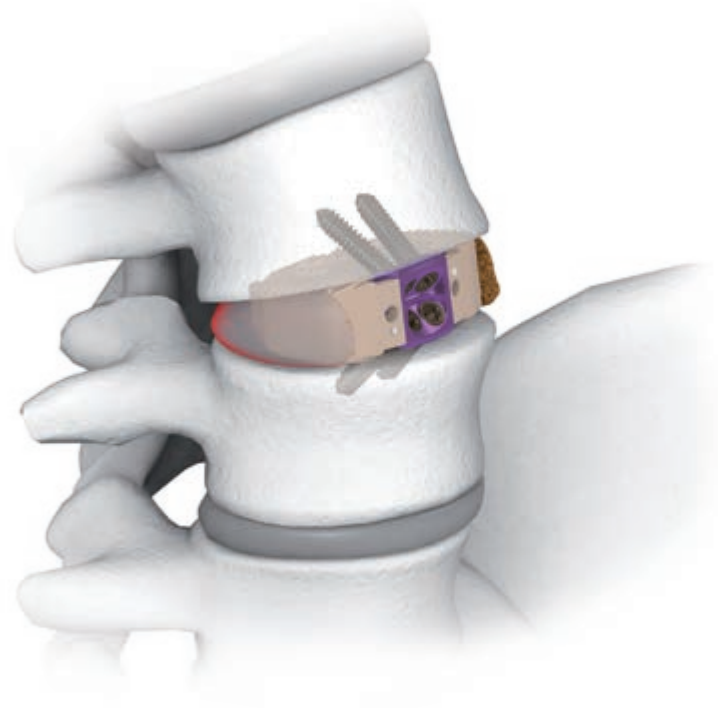
ST/54B

CHARSPINE system 2

ALIF PEEK INTERVERTEBRAL LOCKING CAGES

- *IMPLANTS*
- *INSTRUMENT SET 15.0905.001*
- *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/54B
Date of issue	09.08.2013
Review date	P-006-22.01.2019

I. INTRODUCTION

I.1. DESCRIPTION AND INDICATIONS

The ALIF PEEK Intervertebral Locking Cage system consists of polietheroetheroketon (*PEEK*) cages of various widths, heights and angles to adapt best to variety of patients' anatomies.

The ALIF PEEK Intervertebral Locking Cage is designed for use with autograft, as stand-alone device (*without supplemental fixation systems*) for anterior intervertebral body fusion at one level or two contiguous levels of lumbar spine.
The implants are indicated for the treatment of degenerative disc disease (*DDD*) and grade 1 spondylolisthesis in lumbar spine from L2 to S1.
Degenerative disc disease (*DDD*) is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients qualified for treatment should be skeletally mature and have had at least six months of non-operative treatment.

I.2. CONTRAINDICATIONS

Intervertebral ALIF implants are not intended for cervical spine use.

The choice of a particular implant must be carefully considered in terms of patient's overall evaluation.
Circumstances listed below may preclude or reduce the chance of successful outcome:

- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity (*defined according to the W.H.O. standards*).
- Pregnancy.
- Neuromuscular disorder which would create unacceptable risk of fixation failure or complications in postoperative care.
- Any other condition which would preclude the potential benefit of spinal implant surgery and disturb the normal process of bone remodeling, e.g. the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases.
- Suspected or documented allergy or intolerance to implant materials. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions; mental illness, senility or substance abuse (*these conditions may cause the patient to ignore certain necessary limitations and precautions in the use of the implant*).
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in whom inserted implant would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

The above list is not exhaustive.

For further information on:

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

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

I.3. IMPLANT FEATURES

PEEK

- Stiffness of biocompatible PEEK polymer 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.

ANATOMICAL DESIGN

The serrated surface of the implant is convex shaped to fit the anatomy of the disc space.

SERRATIONS

Serrated superior and inferior surfaces designed to provide stability by engaging vertebral endplates.

OPEN DESIGN

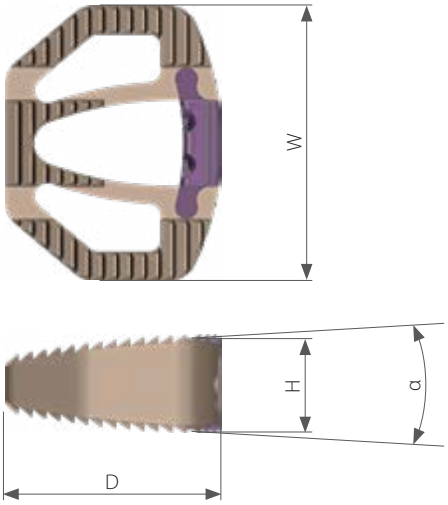
Big holes for bone graft which provide ingrowth of bone tissue.

STAND-ALONE

The ALIF PEEK Intervertebral Locking Cage is stand-alone device, not requiring supplemental fixation systems. The ALIF locking cage is equipped with integrated titanium insert, which together with four locking bone screws provide secure locking mechanism to stable fixation of vertebral bodies.

II. IMPLANTS

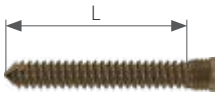
Intervertebral cage



Size	W [mm]	D [mm]	H [mm]	Lordosis angle α = 8° Catalogue no.	Lordosis angle α = 12° Catalogue no.
MEDIUM	32	26	12,0	8.3992.082	8.3992.122
			13,5	8.3992.083	8.3992.123
			15,0	8.3992.085	8.3992.125
			17,0	8.3992.087	8.3992.127
			19,0	8.3992.089	8.3992.129
LARGE	38	30	12,0	8.3993.082	8.3993.122
			13,5	8.3993.083	8.3993.123
			15,0	8.3993.085	8.3993.125
			17,0	8.3993.087	8.3993.127
			19,0	8.3993.089	8.3993.129

Material PEEK-OPTIMA®

Locking screw 4.5



L [mm]	Catalogue no.
10	3.3920.015
15	3.3920.020
20	3.3920.025
25	3.3920.030


self-tapping

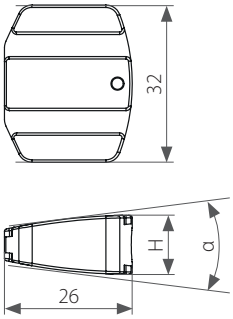
III. INSTRUMENTS

Instrument set for ALIF PEEK Intervertebral Locking Cages 15.0905.001	Name	Catalogue no.	Pcs
	Persuader	40.6224.000	1
	Trocar	40.6246.000	1
	Screwdriver T15	40.5822.000	1
	Distraction forceps	40.5826.000	1
	Dissecting forceps Standard 30cm	30.3317.000	1
	Mallet	40.6247.000	1
	Compactor	40.6190.000	1
	T-type torque handle 2.8Nm	40.6666.000	1
	Container lid 9x4	14.0905.103	1
	Container 9x4H	14.0905.101	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

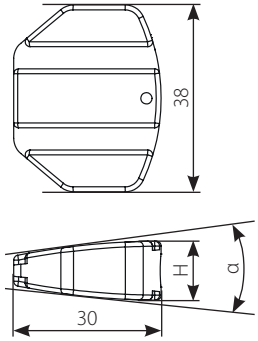
Instrument set for ALIF PEEK Intervertebral Locking Cages 15.0905.001	Name	Catalogue no.	Pcs
	Holder	40.5820.000	1
	Aiming block H12	40.5821.002	1
	Aiming block H13.5	40.5821.003	1
	Aiming block H15	40.5821.005	1
	Aiming block H17	40.5821.007	1
	Aiming block H19	40.5821.009	1
	Bone rasp medium 12	40.5816.002	1
	Bone rasp medium 13.5	40.5816.003	1
	Bone rasp medium 15	40.5816.005	1
	Bone rasp medium 17	40.5816.007	1
	Bone rasp medium 19	40.5816.009	1
	Medium trial 12/8	40.5818.082	1
	Medium trial 12/12	40.5818.122	1
	Large trial 12/8	40.5819.082	1
	Large trial 12/12	40.5819.122	1
	Medium trial 13.5/8	40.5818.083	1
	Medium trial 13.5/12	40.5818.123	1
	Large gau trial ge 13.5/8	40.5819.083	1
	Large trial 13.5/12	40.5819.123	1
	Medium trial 15/8	40.5818.085	1
	Medium trial 15/12	40.5818.125	1
	Large trial 15/8	40.5819.085	1
	Large trial 15/12	40.5819.125	1
	Medium trial 17/8	40.5818.087	1
	Medium trial 17/12	40.5818.127	1
	Large trial 17/8	40.5819.087	1
	Large trial 17/12	40.5819.127	1
	Medium trial 19/8	40.5818.089	1
	Medium trial 19/12	40.5818.129	1
	Large trial 19/8	40.5819.089	1
	Large gauge 19/12	40.5819.129	1
	Working stand	40.5825.000	1
	Container 9x4H	14.0905.102	1

Medium trial



Size	Colors	H [mm]	Lordosis angle α = 8° Catalogue no.	Lordosis angle α = 12° Catalogue no.
MEDIUM		12,0	40.5818.082	40.5818.122
		13,5	40.5818.083	40.5818.123
		15,0	40.5818.085	40.5818.125
		17,0	40.5818.087	40.5818.127
		19,0	40.5818.089	40.5818.129

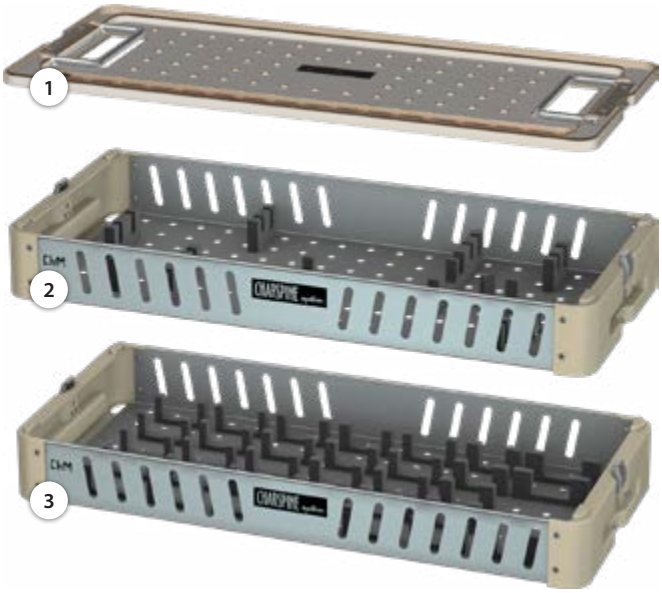
Large trial



Size	Colors	H [mm]	Lordosis angle α = 8° Catalogue no.	Lordosis angle α = 12° Catalogue no.
LARGE		12,0	40.5819.082	40.5819.122
		13,5	40.5819.083	40.5819.123
		15,0	40.5819.085	40.5819.125
		17,0	40.5819.087	40.5819127
		19,0	40.5819.089	40.5819.129

III.1. CONTAINERS ARRANGEMENT

No.	Name	Catalogue No.	Pcs
1	Container lid 9x4	14.0905.103	1
2	Container 9x4H	14.0905.101	1
3	Container 9x4H	14.0905.102	1



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

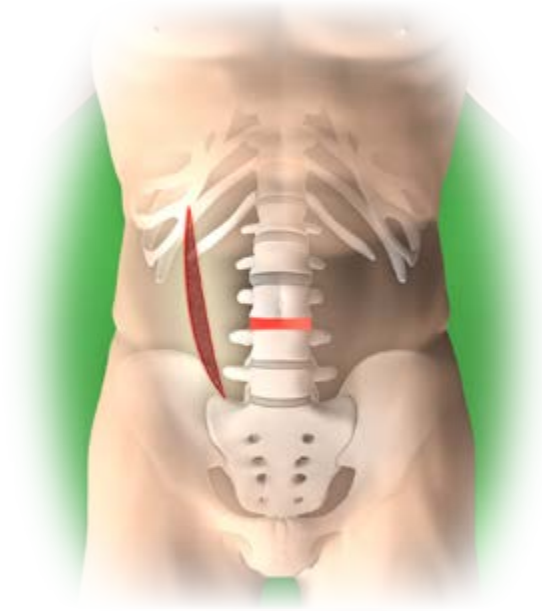
IV. SURGICAL TECHNIQUE

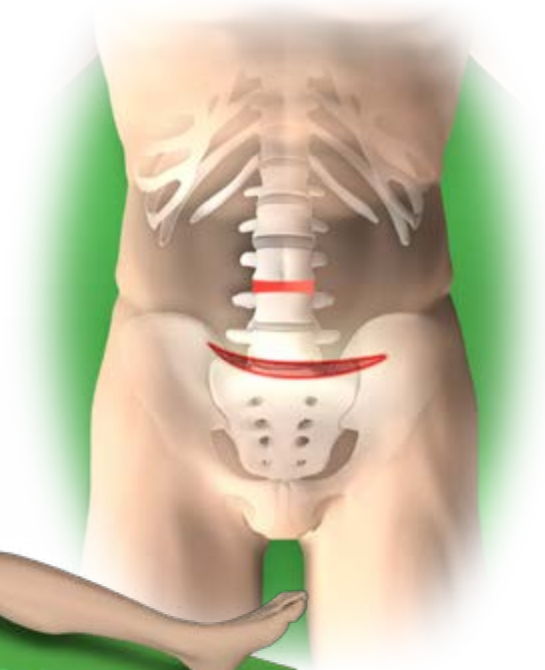
IV.1. SURGICAL APPROACH AND PATIENT POSITION

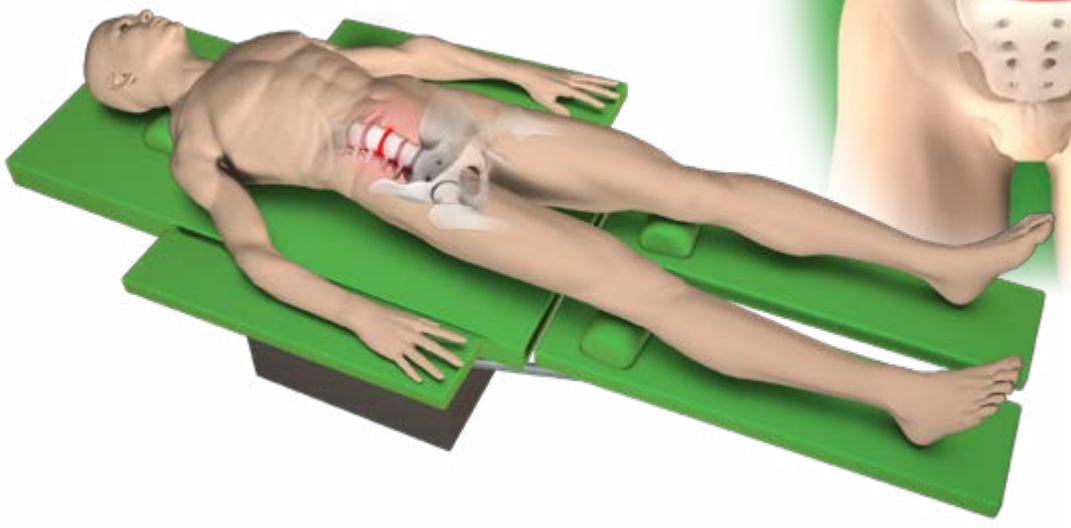
The surgical approach depends on the level to be treated, however, direct anterior access to lumbar spine is required for the insertion of the locking screws.

The desired level may be approached through a transperitoneal or retroperitoneal exposure (*depending on surgeon's preference*).

The surgery should be preceded by thorough preoperative plan and carried out with the participation of a vascular surgeon or general surgeon trained as a spinal access surgeon.
The operating table should be radiolucent and should allow for intraoperative C-arm movement.
The patient is placed in the supine position to allow anterior access to the lumbar vertebral bodies.
During implant placement an intraoperative adjustability of lordosis using a hinged table or inflatable pillow is often useful.





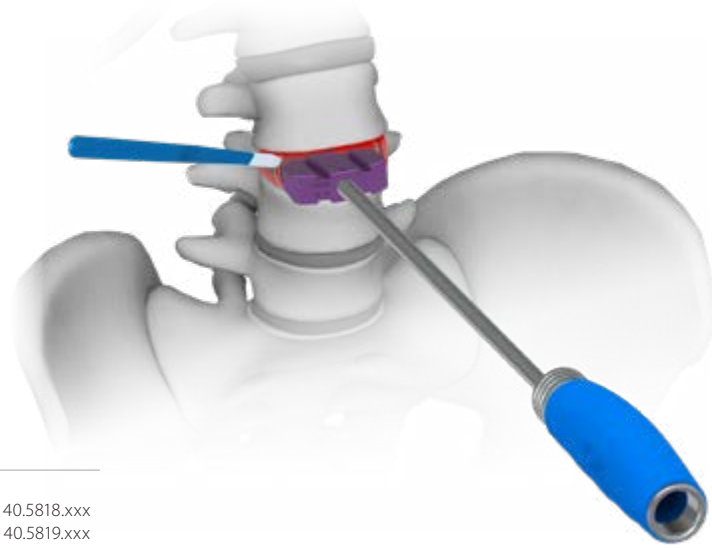


Locate correct operative disc level and expose segment to produce sufficient space on either side of the vertebral midline, equal to the width of the implant (*two implant widths are available, 32mm and 38mm*).
Mark the midline of vertebrae above and below the discectomy site.

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

IV.2. DISCECTOMY

Perform a discectomy wide enough to accommodate the chosen size of the implant, ensuring the posterolateral corners of the vertebral space are freed of disc material. On this stage a trial (*medium or large*) may be used to determine the appropriate implant width.



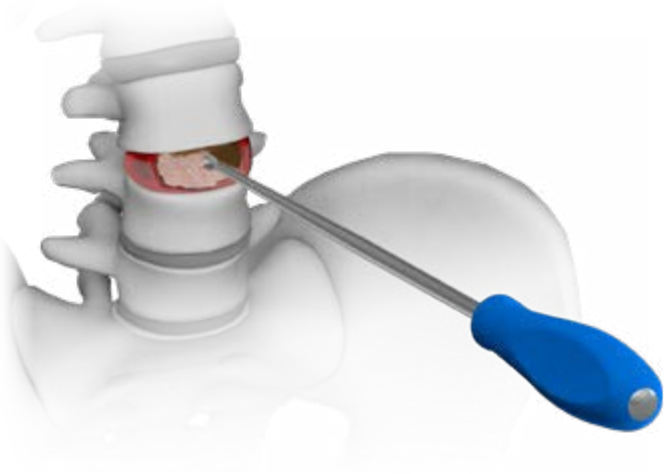
40.5818.xxx
40.5819.xxx

40.6224.000

Remove the superficial layers of the cartilaginous endplates.
This can be done with instruments such as curettes and rasps.
Adequate preparation of the endplates is important to enhance vascular supply to the implantation site.

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

Curettes are not included in the instrument set.

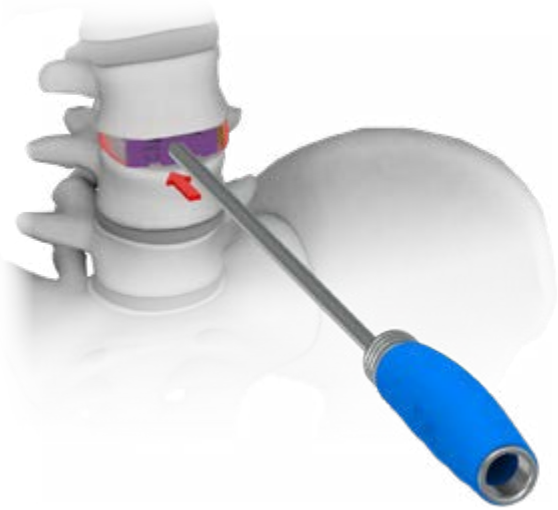


IV.3. TRIALING

The optimal implant width and height can be determined by using the trials **[40.5818.xxx]** and **[40.5819.xxx]** which are available in two sizes (*Medium - width 32mm and Large - width 38mm*), two angular versions (*8° and 12°*) and five heights 12mm, 13.5mm, 15mm, 17mm and 19mm.

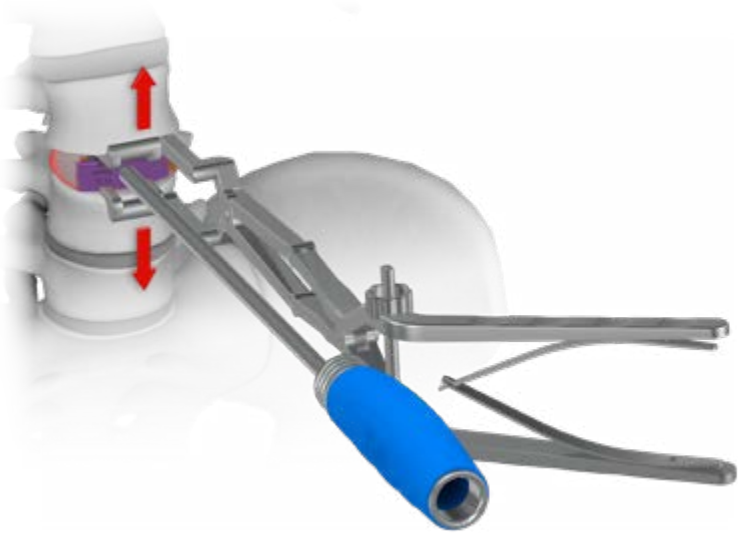
40.5818.xxx
40.5819.xxx

40.6224.000



To facilitate proper selection of the implant, trial implants are laser etched with the size (*Medium or Large*), height and lordotic angle. Trials and fixation plates (*integrated with the implant*) are color coded.
Select the medium trial 32mm **[40.5818.082]** with angle of 8° and 12mm in height, attach to the persuader **[40.6224.000]** and insert into the discectomy site. If the medium trial is too narrow, switch it to large trial 38mm **[40.5819.082]**. Once the width is determined, use incrementally higher trials until a tight fit is achieved. There should be no gaps between the prepared site and the trial. Use the largest size possible to ensure maximum stability.

A distraction forceps **[40.5826.000]** may be used to assist guiding the trial into the intervertebral space.
An intraoperative lateral X-Ray image can be taken to illustrate posterior endplate contact with the trial. If necessary, use the 12° trial instead of 8° to fit better to lumbar lordosis.



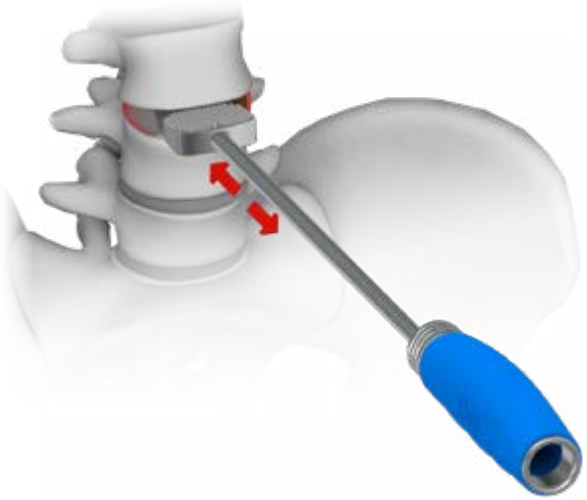
40.5826.000

Prior to attaching the trial, remove screwdriver T15 from the persuadre 40.6224.000.

IV.4. ENDPLATE PREPARATION

Once final sizing has been determined, use the appropriate size of the rasp to complete endplate preparation. Insert rasp **[40.5821.xxx]** attached to the persuader into intervertebral space and remove the cartilage and bone material until bleeding bone is exposed.

40.5821.xxx



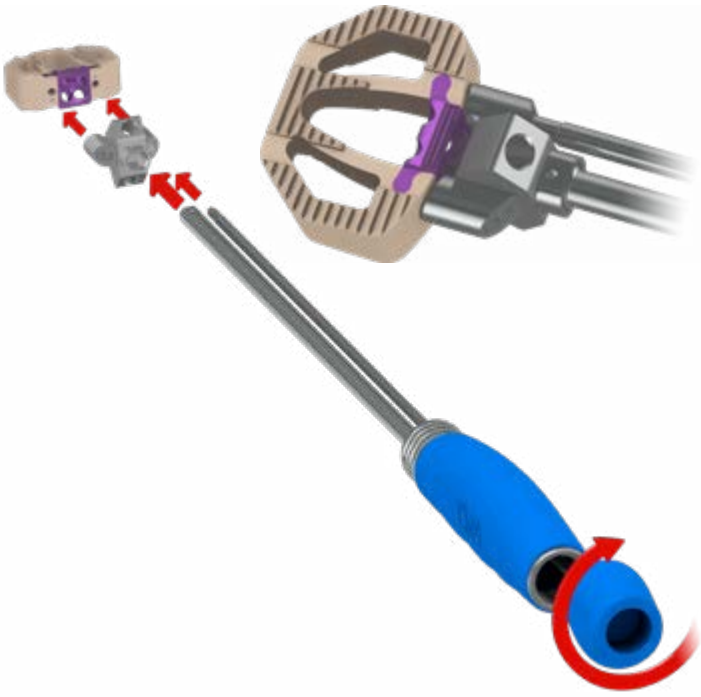
Excessive removal of subchondral bone may weaken the vertebral bodies and, consequently, may result in implant subsidence and loss of stability of the segment.

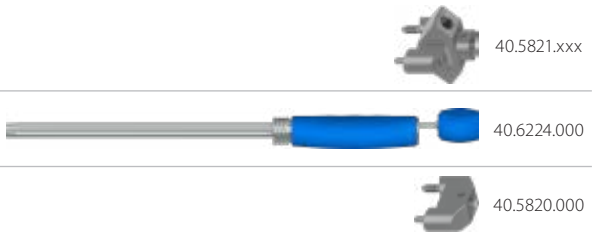
Prior to attaching the rasp, remove screwdriver T15 from the persuadre 40.6224.000.

IV.5. IMPLANT PREPARATION

When implant insertion without use of the distraction forceps is planned (*by punching the implant in the intervertebral space*), attach the adequate aiming block **[40.5821.xxx]** on the quick coupling tip of the persuader **[40.6224.000]**.

Then, position the assembled instrument so that both, positioning pin and threaded tip of cooperating screwdriver (*located symmetrically on both sides of the aiming block*) align with the corresponding holes in the implant. Then, turning the knob clockwise, fasten the instrument to the implant.

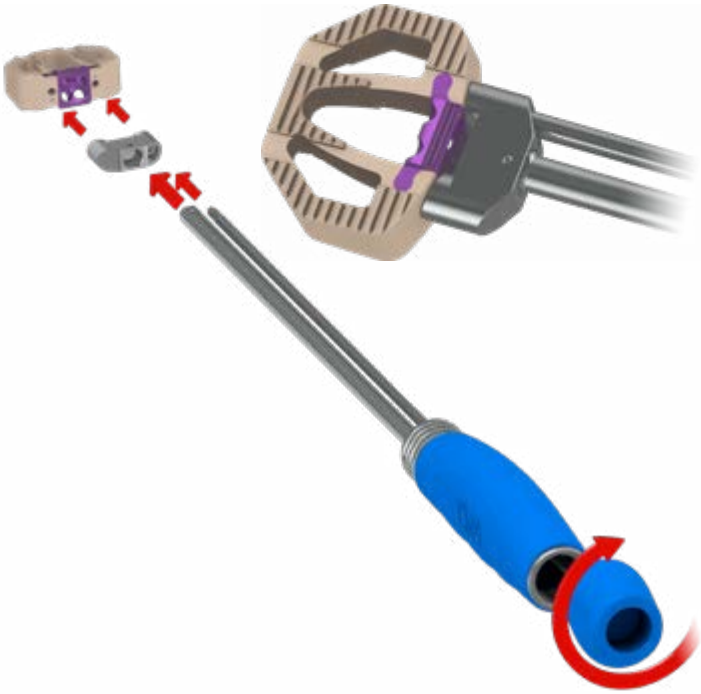




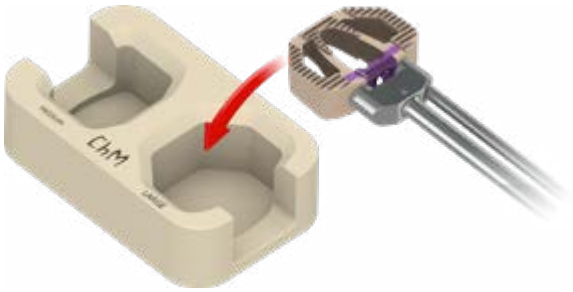
When implant insertion with the use of distraction forceps **[40.5826.000]** is planned, the use of the holder **[40.5820.000]** is needed. Attachment of the aiming block should take place at the later stage.

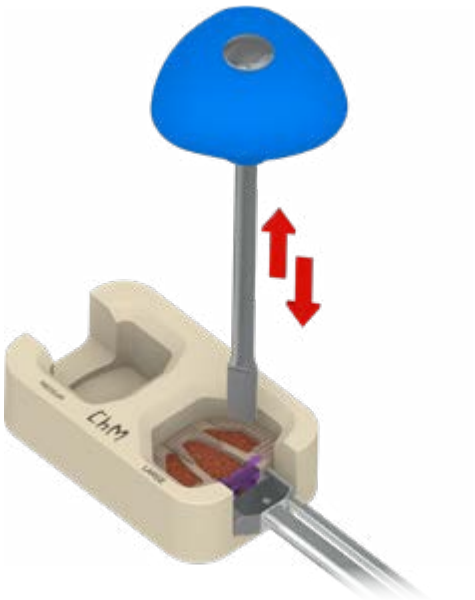
Insertion of the implant using aiming block [40.5821.xxx] will cause distraction forceps removal impossible.

Attach the holder **[40.5820.000]** on the quick coupling tip of the persuader **[40.6224.000]**, and then rotating knob of cooperating screwdriver clockwise, fasten the implant to the instrument.



Place the implant in the working stand **[40.5825.000]** and fill it with autograft material.
Use compactor **[40.6190.000]** to firmly pack the filling material into the implant cavities.





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

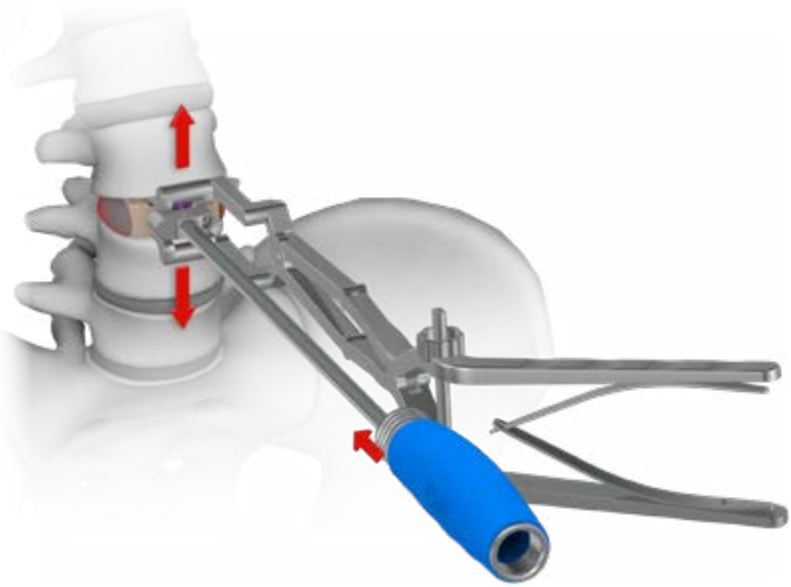
IV.6. IMPLANT INSERTION

The distraction forceps **[40.5826.000]** can be used to facilitate implant insertion. In such case, once the cage is inserted, release the distractor to make sure the implant is fully engaged with vertebral endplates.
After distractor removal, make sure the implant is properly fitted by delicate tapping the persuader handle **[40.6224.000]** with the mallet **[40.6847.000]**.
Remove the holder by rotating the knob counterclockwise.

40.5826.000

40.6224.000

While implant insertion, remove screwdriver T15 from the persuadre.



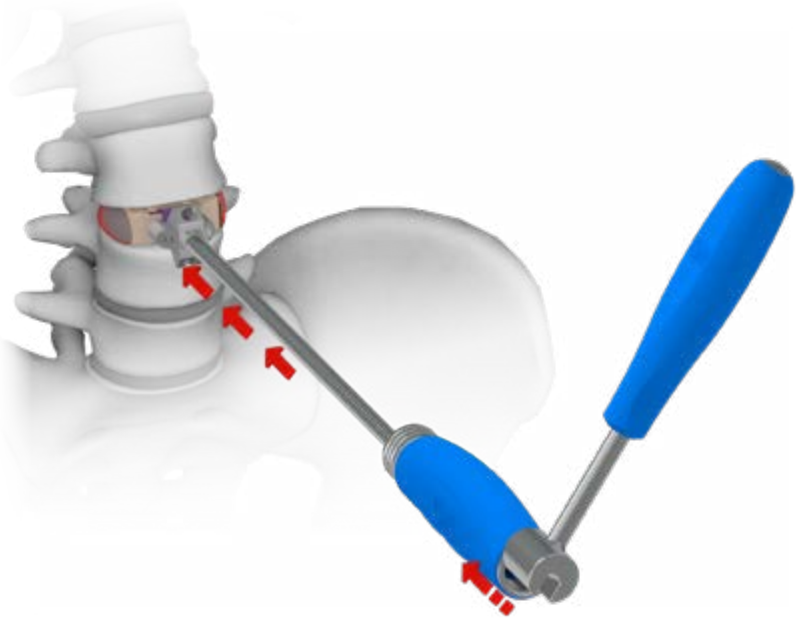
IV.7. IMPLANT INSERTION - ALTERNATIVE METHOD

Insert the implant into intervertebral space, taking care to align the sagittal plane of the implant with the previously marked vertebrae midline.
Make sure the implant is fully engaged with vertebral endplates by tapping the persuader handle **[40.6224.000]** with the mallet **[40.6247.000]**.

40.6247.000

40.6224.000

While implant insertion, remove screwdriver T15 from the persuadre.



Remove the persuader by releasing the lock (*as shown on picture*), leaving the aiming block attached to the implant.

Verify proper implant position with the use of an intraoperative lateral X-Ray.

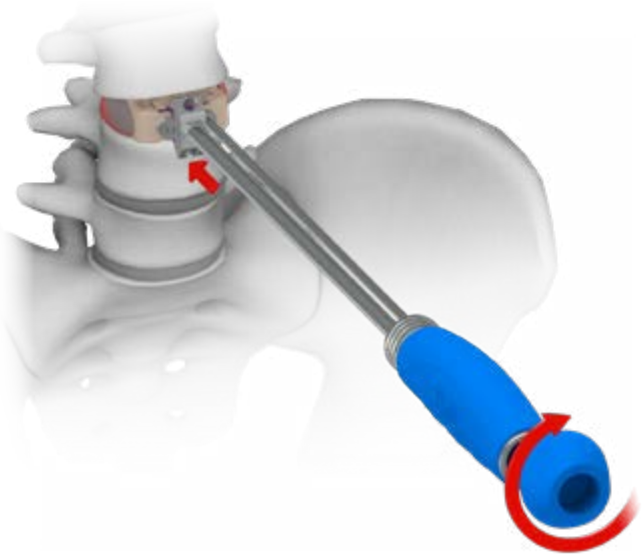
IV.8. SCREW INSERTION

Has it not been done before, select the aiming block **[40.5821.xxx]** with size corresponding to the size of the implant and attach to the quick coupling tip of persuader **[40.6224.000]**.

Then, turning the knob clockwise, fasten the instrument to the implant.


40.5821.xxx


40.6224.000



Insert the trocar **[40.6246.000]** into a chosen hole of the aiming block. Applying pressure on the handle of the trocar, perform a series of oscillating movements to prepare the hole for a locking screw insertion. The forceps **[30.3317.000]** should be used during insertion of the trocar to avoid injury of surrounding soft tissue and to provide directional control of hinged tip of the trocar.

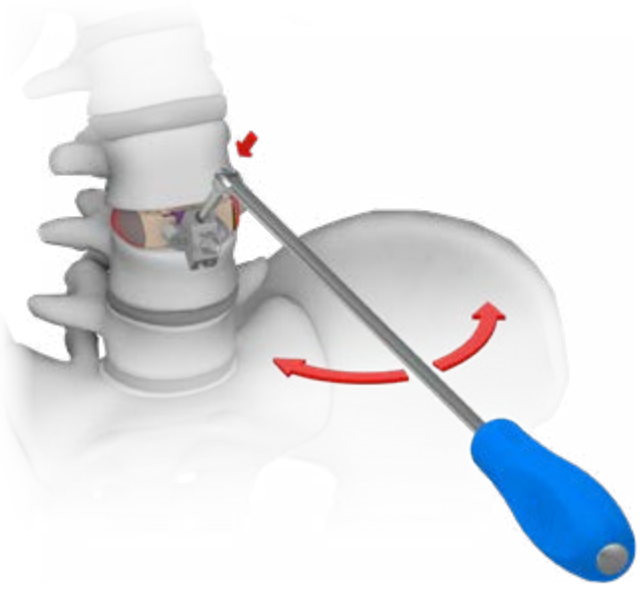
A lateral X-Ray image should be taken now in order to determine the proper screw length.

Repeat the procedure for the other hole in the aiming block.

Length of selected screws should allow the penetration through the entire cortex. For a two-level procedure, the length of the screws should be selected carefully to prevent their possible interference.


40.6246.000


30.3317.000



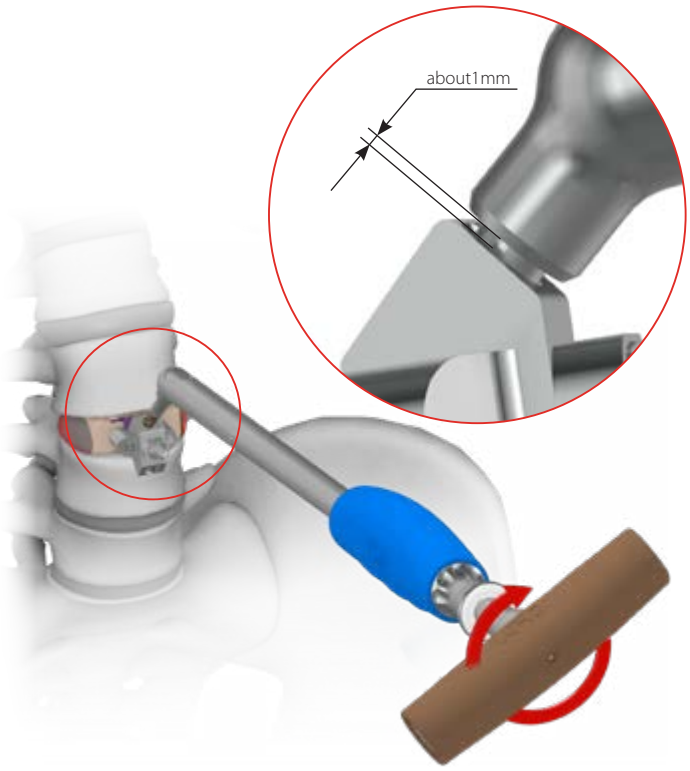
Choose the proper size of a locking screw, attach it to the tip of the screwdriver T15 **[40.5822.000]** (*that is mounted to the torque handle 2.8Nm [40.6666.000]*) and insert it through the hole of the aiming block **[40.5821.xxx]**.
When the laser etched marking on the screwdriver meets the entry point of the aiming block guiding hole, the screw's head is locked in implant's titanium insert. Tighten the screw up.

Repeat the procedure for the other hole of the aiming block.


40.5822.000

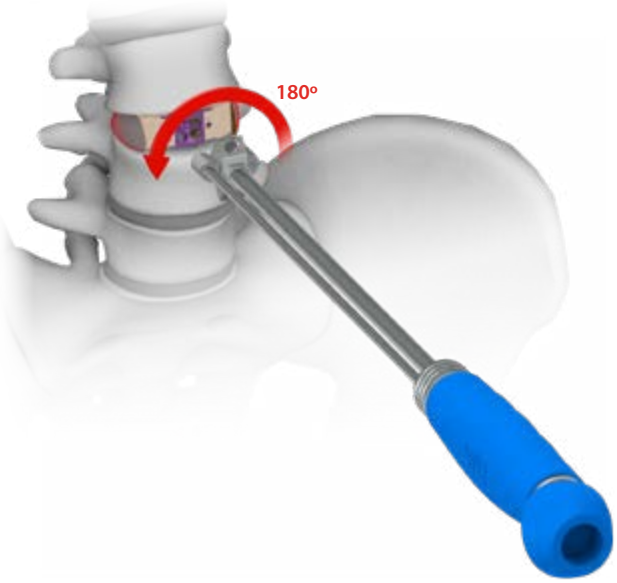

40.6666.000


40.5821.xxx



To insert the two remaining locking screws, the aiming block must be rotated by 180°.

For this purpose, re-attach the persuader to the aiming block, release the threaded locking pin by turning the knob counterclockwise. Then rotate the aiming block by 180° and fix again. Prepare the holes and insert locking screws as described in section IV.8.



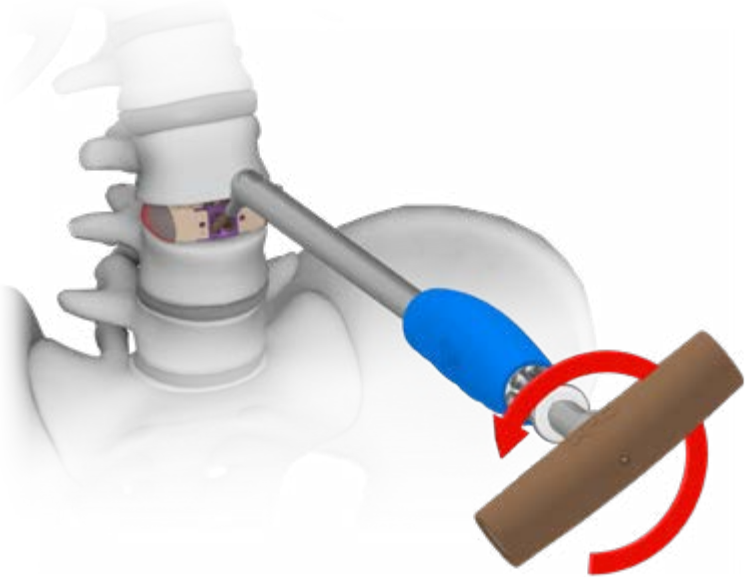
V. IMPLANT REMOVAL

Should it become necessary to remove the ALIF PEEK locking cage, the following steps should be taken:

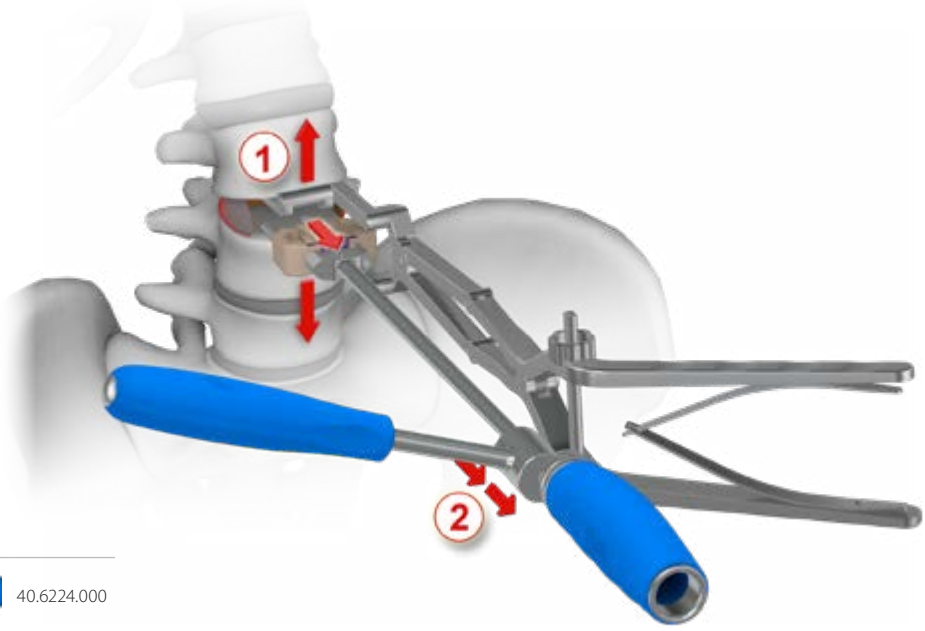
- remove soft tissue from the anterior surface of the implant;
- remove the screws with use of T15 screwdriver **[40.5822.000]** (*that is mounted to torque handle [40.6666.000]*);


40.5822.000


40.6666.000



- once all screws are removed, assembly the persuader **[40.6224.000]** with the holder **[40.5820.000]** and then attach to the implant;
- distract the vertebrae with the use of distraction forceps **[40.5826.000]**;
- if need be, use mallet **[40.6247.000]** to punch the implant out from the intervertebral space.




40.6224.000


40.5820.000


40.5826.000


40.6247.000

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

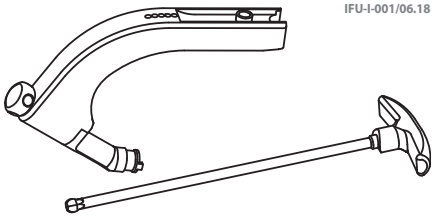
GB

ChM®

CE

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu

IFU-I-001/06.18



GB

INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

1 INDICATIONS

1.Surgical and orthopaedic instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.

2 DESCRIPTION

1.The unit package contains one piece of the product in non-sterile condition. Clear plastic bags are a typical packaging material. The products may also be supplied as a complete set *(arranged on palettes and placed into specially designed sterilization containers)*. This Instructions For Use is attached both to the unit packages and the sets.

2.The package is equipped with the product label. The label *(as a primary label)* contains, among others:
1) Logo ChM and the address of the manufacturer.
2) Catalogue number *(REF)*, e.g.: 40.XXXX.XXX, and device name and size.
3) Production batch number *(LOT)*, e.g. XXXXXXX.
4) NON-STERILE sign - indicates non-sterile product.
5) Information symbols *(described in the footer of this Instructions For Use)*.
6) CE conformity mark.

3.Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

3 MATERIALS

1.For the production of instruments, ChM sp. z o.o. uses mainly: steel, aluminum alloys and plastics, approved for use in surgical instruments and in accordance with applicable procedures.

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

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

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

5.Devices produced of plastics are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. Plastics used in the manufacture of instruments are mainly: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)*, teflon *(PTFE - Polytetrafluoroethylene)* and silicone. 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 a pH value from 4 to 10.8.

6.Steel surgical instruments with a hardened insert are more durable than steel products. The advantage of the product is the sintered carbide insert placed in the working part of the instrument. This insert is characterized by great hardness and abrasion resistance.

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

4 WARNINGS AND PRECAUTIONS

1.Instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.

2.Improper, careless and inconsistent with the recommendations provided below handling of the instruments can lead to their chemical, electrochemical or mechanical damage which can adversely affect corrosion resistance and shorten the service life of the devices.

3.Instruments are intended only for specific procedures and must be used strictly according to their intended purpose. Use of instruments not in accordance with their intended purpose may lead to malfunction, accelerated wear and, in consequences, damage to the instrument.

4.The surgeon should be familiar with all components of the device before use and should personally verify if all components and instruments are present before the surgery begins.

5.Before the procedure begins, all instruments should be carefully inspected for their condition and proper functioning. They should be undamaged and without any signs of corrosion. Blades and cutting edges should be sharp and undamaged. Damaged or corroded instruments should be immediately replaced. The use of bent, damaged or corroded instruments is not allowed.

6.Tissue structures close to the operative site must be protected.

7.Collision of the instrument with metal operating equipment, retractor or other device may cause damage that necessitates intraoperative replacement of that instrument.

8.Do not apply excessive force when using the instrument – it may lead to its permanent damage and, in consequences, to mal-function of the device.

9.Instruments are subject to constant wear processes. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive forces are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed. Should breakage occur, the instrument parts must be removed and disposed of immediately in accordance with valid medical facility procedures.

10.In order to confirm the removal of all undesired metal fragments from the surgical field, intraoperative X-Ray examination is recommended.

11.In the case of suspected or documented allergy or intolerance to metallic materials, surgeon shall find out if the patient develops allergic reaction to the instrument material by ordering appropriate tests.

12.It is extremely important to follow the calibration deadline which is permanently marked on the torque instruments *(see CALIBRATION)*. Use of a torque instrument with an overstepped calibration date may lead to potential injury, implant or device damage, or loss of correction. If there appear any irregularities in device operation, e.g. due to heavy usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.

13.Instrument which had contact with tissues or body fluids of another patient cannot be re-used prior to its reprocessing due to a potential risk of cross-infection caused by viruses, bacteria and prions.

14.Middle and working part of the surgical devices with hardened insert shall be used during the surgical procedure. Improper or inconsistent with the intended purpose usage of the product may lead to damage of the working part e.g. damage to the inserts.

5 CLEANING, DISINFECTION, STERILIZATION

1.Prior to use of a non-sterile device, the following rules apply:
1) The device must undergo cleaning, disinfection and sterilization procedures.
2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning *(manual, automated)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process, etc.
3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.

2.Preparation at the place of use.
1) Immediately after use, remove from instrument blood and other contaminants with disposable cloth or paper towels. Additionally, it is recommended to rinse the instrument under running water or to place it in the aqueous disinfectant solution. Do not let blood, tissues, body fluids or other biological impurities dry out on the surface of the device.
2) In order to prevent blood and debris from drying out on the instrument surface, transport the product to the processing area in a closed container or covered with a damp cloth.
3) In order to avoid contamination during transportation, the dirty instruments should be separated from the clean ones.

3.Preparation for washing and disinfection *(for all methods)*.
1) The used instruments should be reprocessed as soon as possible.
2) If the instrument can be disassembled, it must be done before cleaning processes.
3) Rinse under running water and remove surface debris using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*. Particular attention should be paid to openings and places difficult to be cleaned. Very dirty devices should be soaked in an aqueous solution of a detergent or a washing-disinfecting agent, e.g. neodisher® MediClean forte, at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the product.

4.Cleaning and disinfection process.
1) This Instructions for Use describes two ChM-approved cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated cleaning and disinfection procedures *(in a washer-disinfector)*.
2) The chosen washing and disinfecting agents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. ChM used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:
a) detergent - Dr.Weigert *(producer)* neodisher® MediClean forte *(name of the detergent)*;
b) disinfectant - Dr.Weigert *(producer)* neodisher® Septo Active *(name of disinfectant)*.
3) To prevent product damage *(pitting, rust, discoloration)*, do not use aggressive cleaning agents *(NaOH, NaOCl)*, saline solutions and unsuitable cleaning agents.
4) Where possible, it is recommended to use demineralized water to avoid the formation of spots and stains caused by chlorides and other compounds present in ordinary water.
5) Manual with ultrasound cleaning.
a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, syringes, aqueous solutions of cleaning agent.
b) Manual cleaning: Initial manual cleaning must be performed prior to ultrasound cleaning.
c) Rinse under running water until the product is visually clean. Use plastic brushes to remove heavy or large debris.
d) Soak the product for at least 10 minutes in an aqueous solution of a detergent at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
e) Rinse the product under cold water for at least 2 minutes, paying particular attention to the holes and places difficult to be cleaned.
f) Prepare fresh washing solution. Clean the surfaces and gaps of the product, carefully. Use suitable brushes to clean the holes. Clean the product immersed in the solution.
g) Rinse the product thoroughly under warm running water for at least 2 minutes, paying special attention to the gaps, blind holes, hinges and joints. When cleaning, use brushes and perform multiple reciprocating movements on the surface of the product.
h) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-h until the product is visually clean.
i) Ultrasound cleaning: prepare an aqueous cleaning solution at a temperature of 40 +/- 2°C and pH of 10.4 - 10.8 *(follow the information contained in the instructions prepared by the manufacturer of the cleaning agent, in respect of temperature, concentration, exposure time and water quality)*. Immerse fully the product in the aqueous cleaning solution and have it washed in ultrasounds for 15 minutes.
j) Rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
k) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-k until the product is visually clean.
l) Use demineralized water for final rinsing of the device.
m) Dry the device thoroughly using disposable, soft, lint-free cloth or compressed air.
n) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/-2 °C using 20g of the agent per 1 liter of water. Immerse the product in the solution, exposure time – 15min *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
o) After the exposure time, rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
p) The cannulated instruments should be treated using a compressed air or air supplied from the syringe.
q) Dry the device thoroughly. It is recommended to dry the product in a dryer at a temperature ranging from 90°C to 110°C.
r) Visually inspect the entire surface of the device.
s) CAUTION: If the obstruction in the cannula cannot be removed as indicated in the Instructions for Use, the device should be considered at the end of its useful life and should be discarded in accordance with facility procedures and guidelines.
6) The automated method using a washer - disinfector.
a) Equipment and materials: a washer - disinfector, aqueous solutions of cleaning agent.
b) Cleaning in the washer-disinfector must be preceded by a manual and ultrasound cleaning, following the procedure described in subsections c-h of paragraph 5.
c) CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883. Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washer-disinfector manufacturer, and instructions for use prepared by the washing-disinfecting agent manufacturer.
d) The device should undergo the process of machine washing in the washer-disinfector using the following cycle parameters: *(1)* - pre-washing in cold tap water, duration – 2min; *(2)* - washing in an aqueous solution of cleaning agent at 55+/-2°C and pH of 10.4 - 10.8, duration – 10min; *(3)* - rinsing under demineralized water, duration – 2min; *(4)* - thermal disinfection in demineralised water at 90°C, minimal duration – 5min; *(5)* - drying at the temperature ranging from 90°C to 110°C, duration - 40min.

5.Inspection
1) Each time before re-use and re-sterilization, all medical devices should be inspected.
2) All parts of the product should be checked for visible dirt and corrosion. Particular attention should be paid to:
b) Holes, grooves and gaps the debris could have been pressed into during use.
a) Places where dirt can be found, such as joints, latches, etc.
3) Generally unmagnified visual inspection under good light conditions is sufficient.
4) Each time before re-use and re-sterilization, the functional check of the product should be performed, consisting of:
a) Verifying the connections in the mating instruments, such as tips, shafts and quick coupling devices.
b) Verifying the correct functioning of mechanisms, e.g. screw, ratchet, snap mechanism, etc.
c) Verifying all rotating devices for straightness *(this can be simply achieved by rolling the device on a flat surface)*.
d) Verifying cutting edges for sharpness.
e) Verifying instruments for damage to material structure *(cracks, dents, peels, etc.)*.
5) Damaged or defective product cannot be approved for further use.
6) Prior to storage, the instrument must be checked for dryness.
7) CAUTION:
a) The ChM sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful and proper use reduces the risk of damage to the product and extends its serviceable life.
b) The manufacturer does not recommend using any preservatives on medical devices.

6.Packaging
1) Washed and dried devices shall be stored *(if possible)* in suitable stands placed in special sterilization containers. Separate items should be packed in a packaging intended for the recommended steam sterilization. Sterilization containers, item packaging and packaging process itself have to meet the requirements of ISO 11607 standards. The packaging procedure must be performed in controlled purity conditions. The device must be packed so that during its removal from the packaging, when used, there is no risk for its re-contamination

7.Sterilization
1) Washed, disinfected, and dried device shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:
a) temperature: 134°C,
b) minimum exposure time: 7 min,
c) minimum drying time: 20 min.
2) CAUTION:
a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.
b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
c) Device must not be sterilized in the packaging in which it was delivered, except specially designed sterilization containers.
d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains sterilization recommendations using these methods.
e) The sterilization temperature for plastic products *(PPSU, PEEK, PTFE, silicone)* cannot be higher than 140°C.

6 STORAGE

1.The devices should be properly stored. When storing surgical instruments, it is recommended that they never be stacked together. It may lead to damage of cutting edges *(nick or dull)* and/or initiation of corrosion centers. Instruments should be stored in a clean and dry room, at room temperature and off the direct sunlight. If possible, instruments should be stored in suitable palettes placed into specially designed sterilization containers.

7 CALIBRATION

1.Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments are factory-calibrated, the nominal torque of a calibrated instrument is marked on the device *(e.g. 4 Nm)*. To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.

2.Instrument calibration is performed by the manufacturer. Any attempt of unauthorized modifications to the construction or factory setting of the torque devices can lead to a potential injury or damage to the product and is prohibited.

8 COMPATIBILITY

1.ChM specialist instrument sets are designed for insertion of ChM implants. A specific, illustrated operating technique that describes the proper use of instruments included in the instrument set that is designed for particular implant system, is provided together with such instrument set. It is not allowed to combine ChM instruments with products from other manufacturers. The physician bears all responsibility for the use of the ChM instruments together with implants and instruments from other manufacturers.

If this instructions 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-001/06.18; Date of verification: June 2018

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

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILE	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при повреждённой упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le istruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Avvertenza
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH2O2	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu

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