ST/68C

CHM®

CHARSPINE system 2

ALIF PEEK INTERVERTEBRAL CAGES

- *IMPLANTS*
- *INSTRUMENT SET 15.0906.101*
- *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.

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Document No ST/68C

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The manufacturer reserves the right to introduce design changes.

I. INTRODUCTION

I.1. DESCRIPTION AND INDICATIONS

The ALIF PEEK Intervertebral Cage system consists of polietheroetheroketone *(PEEK)* cages of various widths, heights and angles to adapt best to variety of patients' anatomies.
The ALIF PEEK Intervertebral Cages are designed for use with bone grafting for spondylodesis of one level or two contiguous levels of lumbar spine. Anterior, antero-lateral or lateral approaches may be used.
The implants are indicated for treatment of degenerative disc disease *(DDD)* and grade 1 spondylolisthesis in lumbar spine from L2 to S1. The ALIF PEEK Intervertebral Cages should be used with 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 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

ALIF intervertebral implants are not intended for cervical spine use.

Contraindications may be relative and absolute.
The selection of an appropriate implant must be preceded by careful and thorough assessment of patient's state of health.

Certain disease and physiological states such as:

- spine infection,
- morbid obesity,
- mental illness,
- addiction to alcohol or drugs,
- pregnancy,
- intolerance to metals, foreign bodies,
- inadequate tissue coverage or open wounds in the surgical site,

may preclude or reduce the chance of successful outcome.

A detailed list of contraindications is included in the Instructions for Use *(IFU)* intended for the product.

WARNINGS
It is not always possible in every patient to achieve a positive result of treatment. This fact is especially true in surgery where other factors related to patients' condition may compromise the results. The proper selection and the compliance of the patient with post-operative recommendations will greatly affect the results. Patients who smoke have been shown to have a higher incidence of bone non-, mal-union. These patients should be informed of this fact and warned of this consequence.

A detailed list of warnings, precautions and post-operative recommendations is included in the Instructions for Use *(IFU)* intended for the product.

Implants of CHARSPINE spine stabilization system manufactured by ChM have been designed and tested exclusively for use with applicable instruments of ChM. This surgical technique is intended only as a guide. Similarly to other surgical procedures, the surgeon should be thoroughly trained before surgery and must take into account the specific needs of each patient.

I.3. IMPLANT FEATURES

PEEK

- Stiffness of biocompatible PEEK polymer approximates the patient's bone which provides ideal load sharing attributes.
- Radiolucency of PEEK polymer offers an accurate visualization and assessment of the fusion.
- Radioopaque tantalum markers facilitate intraoperative X-Ray visualization of inserted implant.

ANATOMICAL DESIGN

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

SERRATIONS

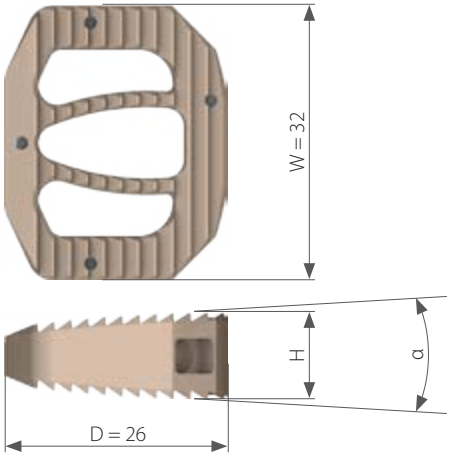
Serrated superior and inferior surfaces designed to provide stability by engaging to vertebral endplates.

OPEN DESIGN

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

II. IMPLANTS

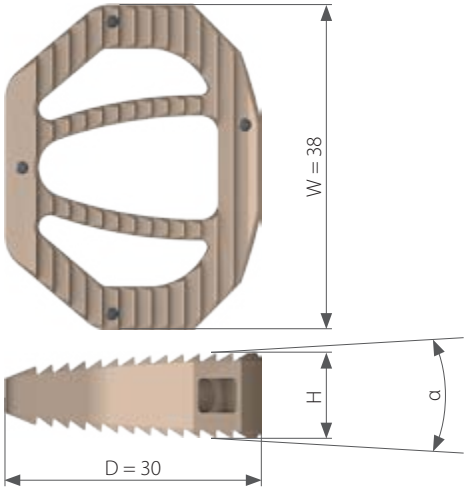
Intervertebral cage, medium



				Lordosis angle	
				α = 8°	α = 12°
Size	**W** [mm]	**D** [mm]	**H** [mm]	**Catalogue no.**	
MEDIUM	32	26	10	8.4560.010	8.4561.010
			11	8.4560.011	8.4561.011
			13	8.4560.013	8.4561.013
			15	8.4560.015	8.4561.015
			17	8.4560.017	8.4561.017
			19	8.4560.019	8.4561.019

Material: PEEK-OPTIMA®

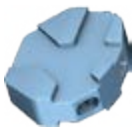
Intervertebral cage, large



				Lordosis angle	
				α = 8°	α = 12°
Size	**W** [mm]	**D** [mm]	**H** [mm]	**Catalogue no.**	
LARGE	38	30	10	8.4562.010	8.4563.010
			11	8.4562.011	8.4563.011
			13	8.4562.013	8.4563.013
			15	8.4562.015	8.4563.015
			17	8.4562.017	8.4563.017
			19	8.4562.019	8.4563.019

Material: PEEK-OPTIMA®

III. INSTRUMENTS

Instrument set for ALIF PEEK Intervertebral Cages 15.0906.101	Name	Pcs	Catalogue no.
	Persuader	2	40.6182.000
	Distraction forceps	1	40.6233.000
	Mallet	1	40.6247.000
	Compactor	1	40.6190.000
	Bone rasp medium H-10	1	40.6183.010
	Bone rasp medium H-11	1	40.6183.011
	Bone rasp medium H-13	1	40.6183.013
	Bone rasp medium H-15	1	40.6183.015
	Bone rasp medium H-17	1	40.6183.017
	Bone rasp medium H-19	1	40.6183.019
	Medium trial H-10/8°	1	40.6184.010
	Medium trial H-10/12°	1	40.6185.010
	Large trial H-10/8°	1	40.6186.010
	Large trial H-10/12°	1	40.6187.010
	Medium trial H-11/8°	1	40.6184.011
	Medium trial H-11/12°	1	40.6185.011
	Large trial H-11/8°	1	40.6186.011
	Large trial H-11/12°	1	40.6187.011
	Medium trial H-13/8°	1	40.6184.013
	Medium trial H-13/12°	1	40.6185.013
	Large trial H-13/8°	1	40.6186.013
	Large trial H-13/12°	1	40.6187.013
	Medium trial H-15/8°	1	40.6184.015
	Medium trial H-15/12°	1	40.6185.015
	Large trial H-15/8°	1	40.6186.015
	Large trial H-15/12°	1	40.6187.015
	Medium trial H-17/8°	1	40.6184.017
	Medium trial H-17/12°	1	40.6185.017
	Large trial H-17/8°	1	40.6186.017
	Large trial H-17/12°	1	40.6187.017
	Medium trial H-19/8°	1	40.6184.019
	Medium trial H-19/12°	1	40.6185.019
	Large trial H-19/8°	1	40.6186.019
	Large trial H-19/12°	1	40.6187.019
	Working stand	1	40.6232.000

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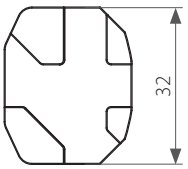
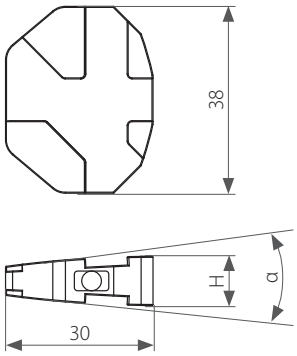
Instrument set for ALIF PEEK Intervertebral Cages 15.0906.101	Name	Pcs	Catalogue no.
	Container lid 9x4	1	14.0906.102
	Container 9x4H	1	14.0906.101

Medium trial



			Lordosis angle	
			α = 8°	α = 12°
Size	Colors	H [mm]	Catalogue no.	
MEDIUM		10	40.6184.010	40.6185.010
		11	40.6184.011	40.6185.011
		13	40.6184.013	40.6185.013
		15	40.6184.015	40.6185.015
		17	40.6184.017	40.6185.017
		19	40.6184.019	40.6185.019

Large trial



			Lordosis angle	
			α = 8°	α = 12°
Size	Colors	H [mm]	Catalogue no.	
LARGE		10	40.6186.010	40.6187.010
		11	40.6186.011	40.6187.011
		13	40.6186.013	40.6187.013
		15	40.6186.015	40.6187.015
		17	40.6186.017	40.6187.017
		19	40.6186.019	40.6187.019

IV. SURGICAL TECHNIQUE

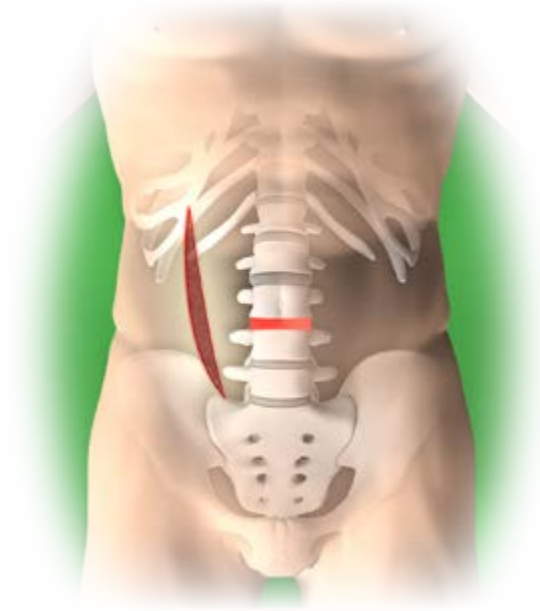
IV.1. SURGICAL APPROACH AND PATIENT POSITIONING

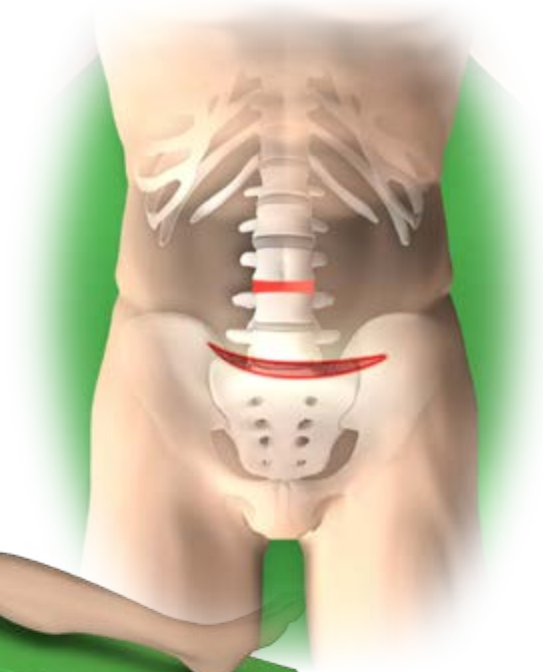
The surgical approach depends on the level to be treated. Surgery is performed utilizing anterior transperitoneal, or anterior retroperitoneal approach *(depending on the surgeon's preference)*.

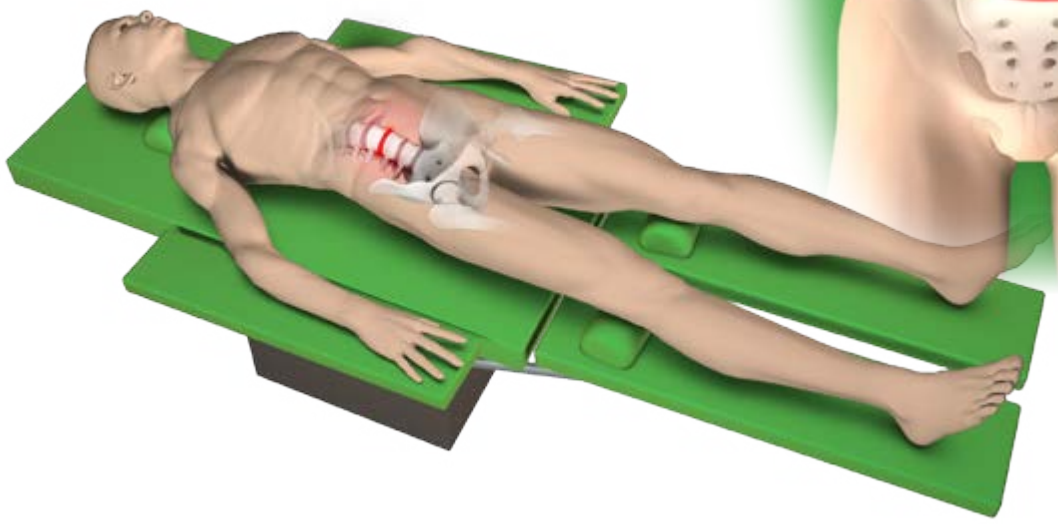
The surgery should be preceded by thorough preoperative plan and carried out with the participation of a vascular surgeon or general surgeon trained to perform spinal surgical approaches.

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.







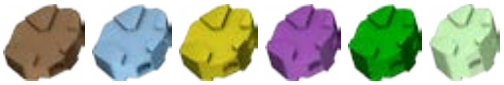
Locate correct operative disc level and expose segment to produce sufficient space on either side of the vertebral midline, equal to the width of the implant *(two implant widths are available, 32mm and 38mm)*.

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.

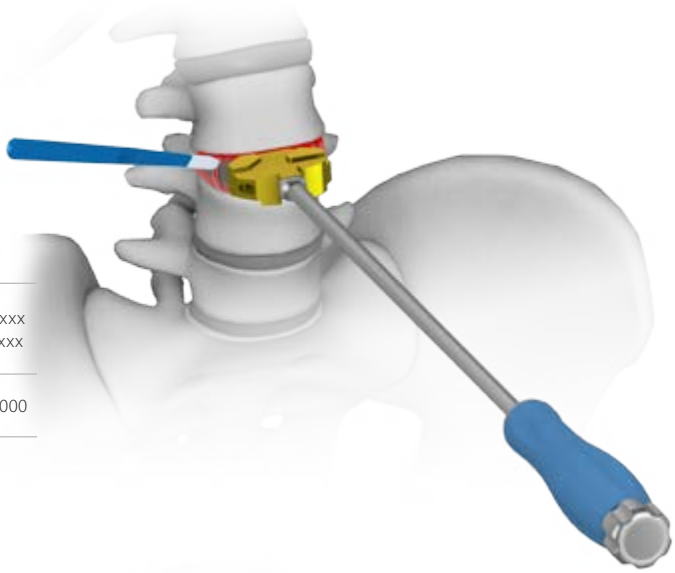
IV.2. DISCECTOMY

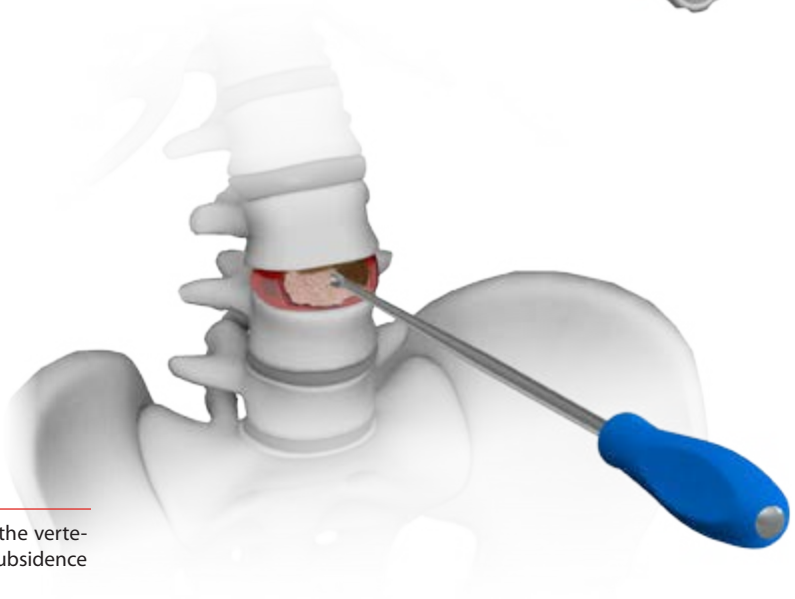
Perform a discectomy wide enough to accommodate the chosen size of the implant, ensuring that the posterolateral corners of the vertebral space are freed of disc material.
A trial *(medium or large)* may be used now to determine the appropriate implant width.



40.6183.xxx
40.6187.xxx

40.6182.000





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.

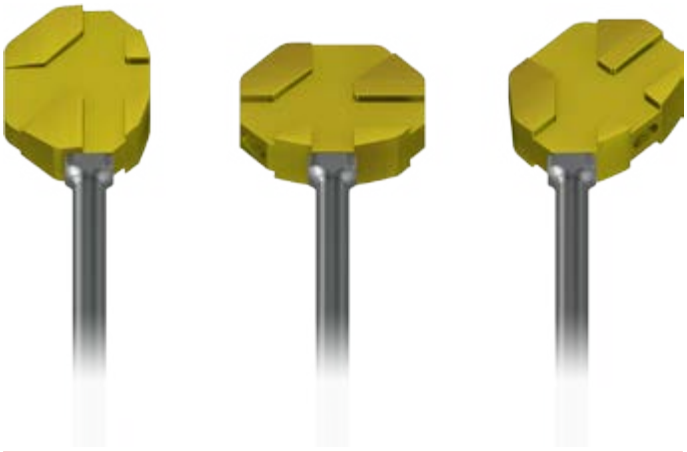
Excessive removal of subchondral bone may weaken the vertebral bodies and, consequently, may result in implant subsidence and loss of stability of the segment.

The curettes are not included in the instrument set.

IV.3. TRIALING

The optimal implant width and height can be determined by using trials **[40.6184.xxx]**, **[40.6185.xxx]**, **[40.6186.xxx]** and **[40.6187.xxx]** which are available in two sizes - medium *(width 32mm)* and large *(width 38mm)*; two angular versions *(8° and 12°)* and six heights 10mm, 11mm, 13mm, 15mm, 17mm and 19mm.

To facilitate proper selection of the implant, trial implants are laser etched with the size *(medium or large)*, height and lordotic angle. Trials are color-coded.

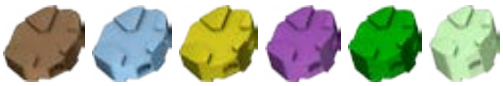


Trials have three slots, which allow the persuader to be mounted with the trial in different positions, to facilitate the insertion depending on the surgical approach.

Select the medium trial 32mm, **[40.6184.010]** with angle of 8° and 10mm height, attach to the persuader **[40.6182.000]** and insert it into the discectomy site.

If the medium trial is too narrow, switch it to large trial 38mm, **[40.6186.010]**.

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.

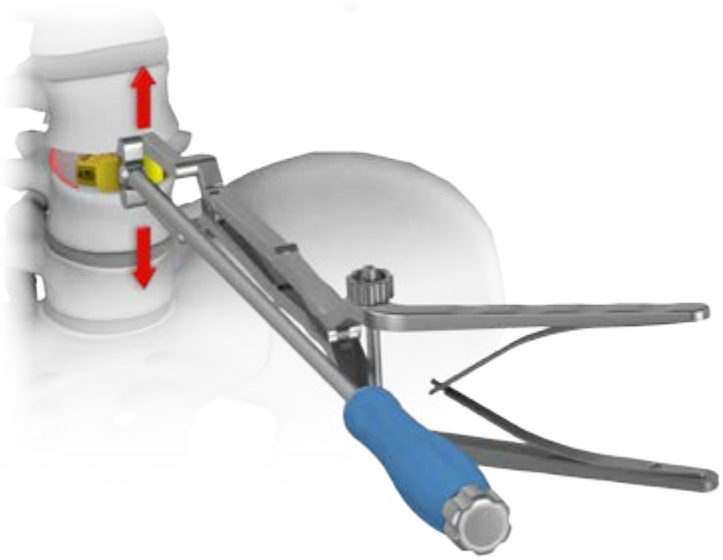


40.6183.xxx
40.6187.xxx

40.6182.000

Distraction forceps **[40.6233.000]** may be used to assist with guiding the trial into the intervertebral space.

An intraoperative lateral X-Ray image can be utilized to illustrate posterior endplate contact with the trial. If necessary, use the 12° trial instead of 8° to fit better to lumbar lordosis.



40.6233.000

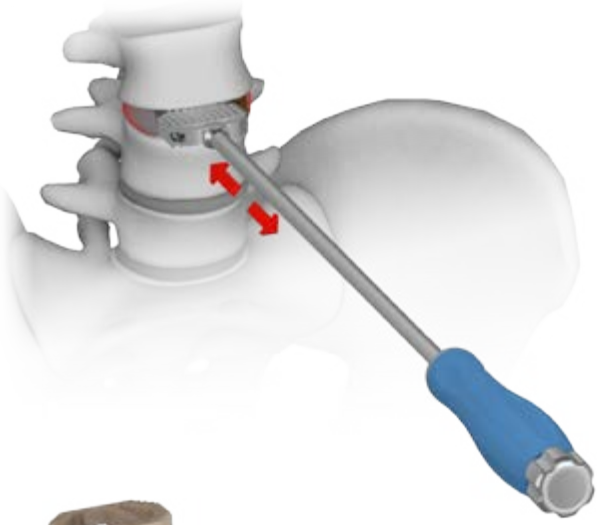
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.4. ENDPLATES PREPARATION

Once final sizing has been determined, use the appropriate size of bone rasp **[40.6183.xxx]** to complete endplate preparation. Insert rasp attached to the persuader into intervertebral space and remove the cartilage and bone material until bleeding bone is exposed.

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

40.6183.xxx

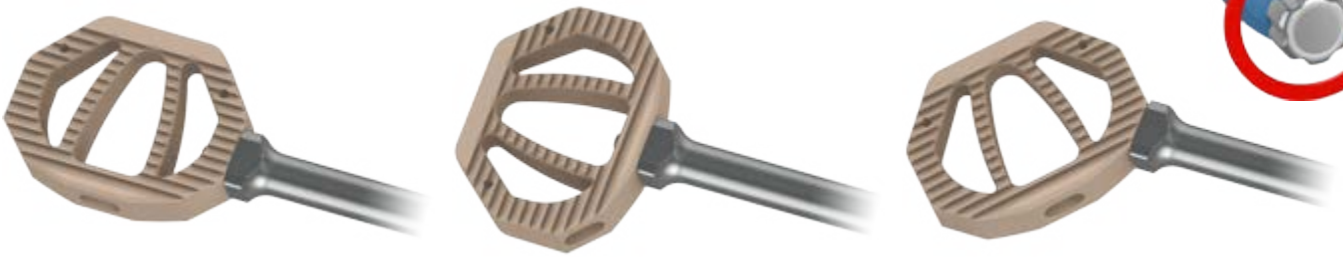


IV.5. IMPLANT PREPARATION

Attach the implant to the persuader **[40.6182.000]** by inserting the tip of the instrument in one of the implant's socket.

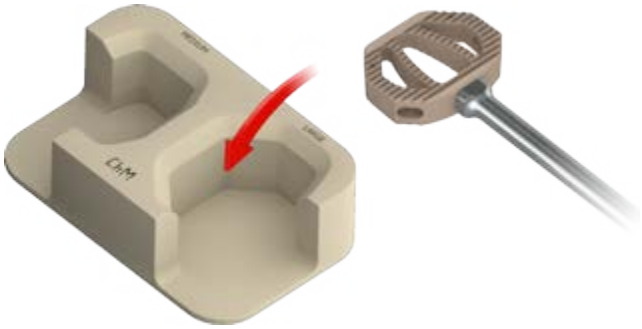
Implants have three slots, which allow the persuader to be mounted with the implant in different positions, to facilitate the insertion depending on the surgical approach.

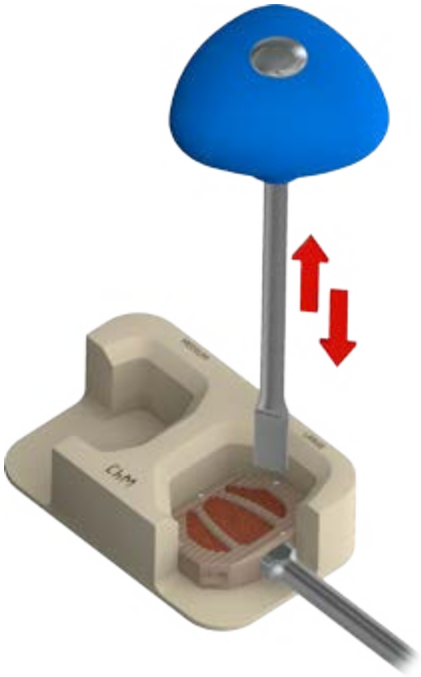
Tighten the locking pin of the persuader by turning its knob clockwise.



Place the implant on the working table **[40.6232.000]** and fill with autograft material.

The compactor **[40.6190.000]** may be used to firmly compress the filling material into the implant cavities.





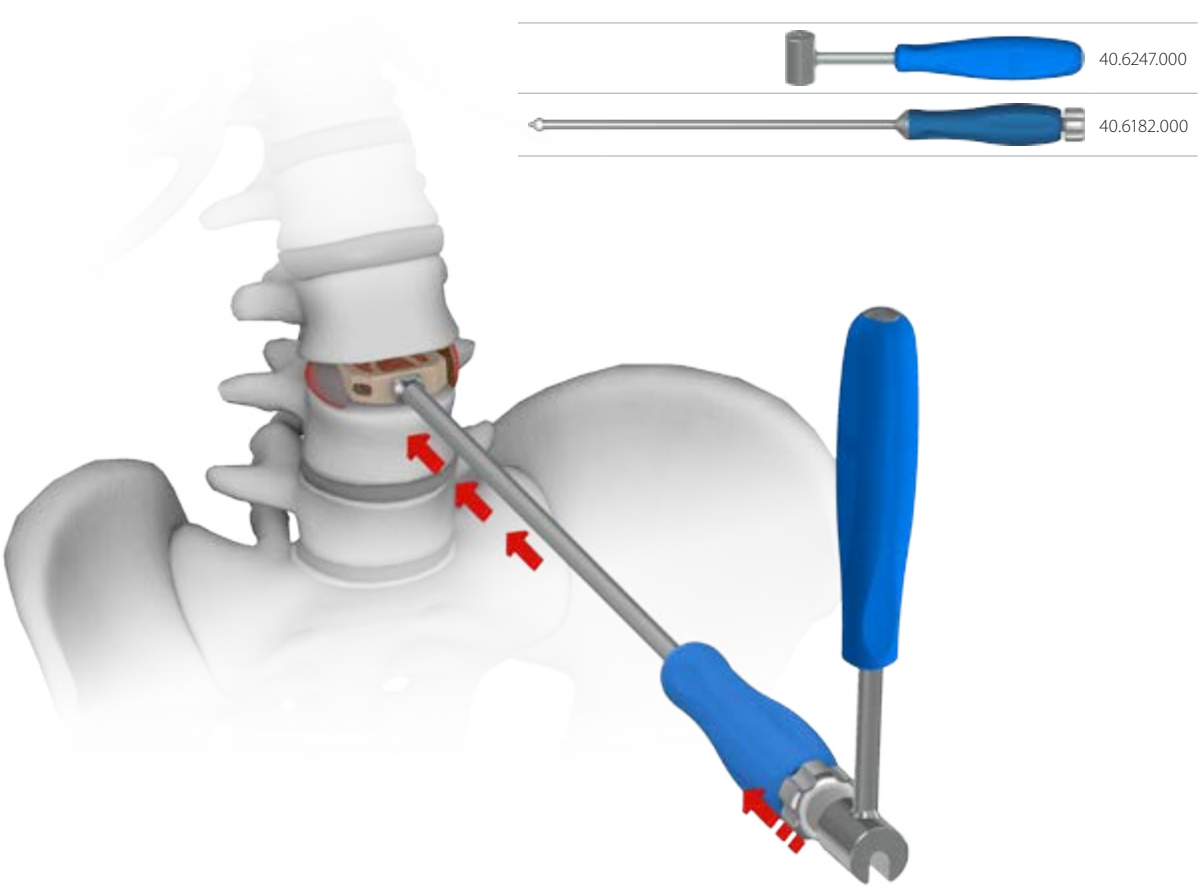
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.6. IMPLANT INSERTION

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 knob **[40.6182.000]** with the mallet **[40.6247.000]**.
Remove the persuader by releasing the lock *(turn the knob counter-clockwise)*.

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



IV.7. ADDITIONAL STABILIZATION

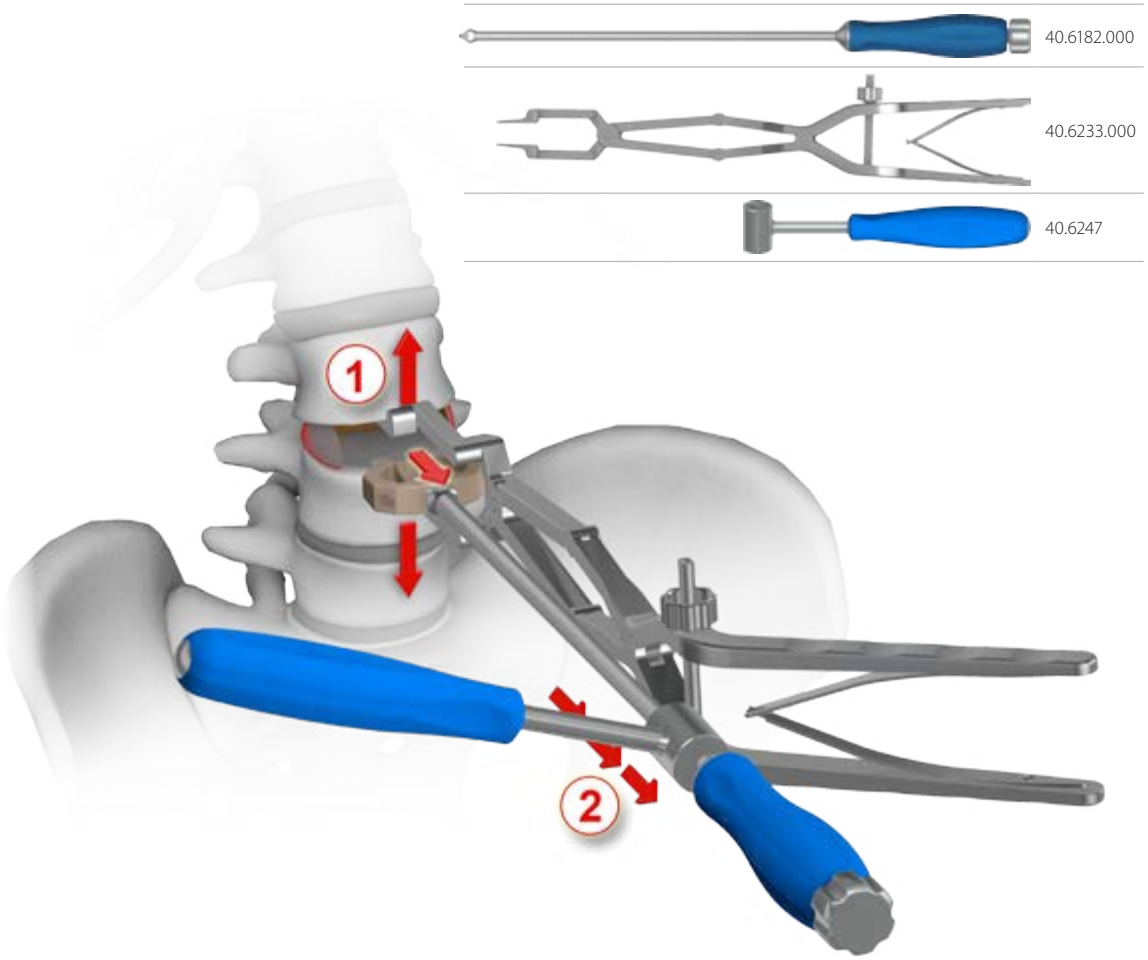
Having implanted the intervertebral cage, an additional stabilization using the system to stabilize the thoraco-lumbar spine *(***CHARSPINE**, **CHARSPINE 2** *systems are recommended)* performed through anterolateral or posterior approach is required.

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

V. IMPLANT REMOVAL

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

- remove soft tissue from the anterior surface of the implant;
- assembly the persuader **[40.6182.000]** to the implant;
- distract the vertebrae with use of distraction forceps **[40.6233.000]**;
- if need be, use the mallet **[40.6247.000]** to punch out the implant from the intervertebral space.



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ChM®

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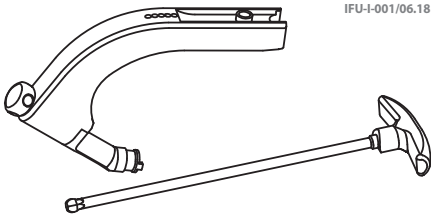

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INSTRUCTIONS FOR USE

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**

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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

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