ChM®

ISO 9001/ ISO 13485

CE 0197

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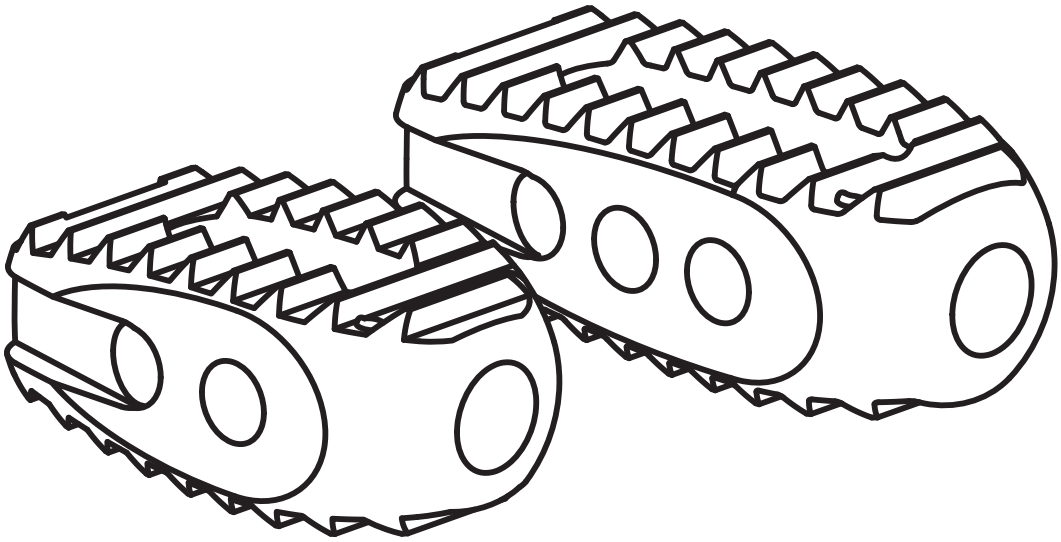

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INSTRUCTIONS FOR USE

Important product information for

THE PEEK CAGE SYSTEM IMPLANTS

CHARSPINE system

1 PURPOSE AND INDICATIONS

1. The PLIF PEEK, TLIF PEEK, ALIF PEEK and cervical intervertebral cages are made of biocompatible PEEK *(polyetheretherketone)*. These implants are offered in various heights and lordotic angles to adapt best to a variety of patient anatomies. The implants have serrated superior and inferior surfaces for fixation and hollow geometry that allows them to be packed with autogenous bone grafts.

1) The cervical intervertebral cages are indicated for vertebral arthrodesis of cervical body procedures in patients with degenerative disc disease *(DDD)*. The implants should be used for adjacent vertebral bodies at levels from C2 to T1.

The cervical intervertebral cages are designed to be used with autogenous bone graft and are intended for use with supplemental fixation systems cleared for use in the cervical spine *(e.g. anterior cervical plates)*.

2) The PLIF PEEK and TLIF PEEK intervertebral cages are indicated for posterior and posterolateral *(transforaminal)* approach, respectively. They are used in the treatment of degenerative disc disease *(DDD)*, vertebral instability, Grade 1 spondylolisthesis as well as in the cases of spine revision surgery. The implants should be used at one or two contiguous levels from L2 to S1. The implants are designed to be used with autogenous bone graft and are intended for use with supplemental fixation systems, cleared for use in the lumbar spine *(e.g. posterior pedicle screw and rod systems)*.
   a) The PLIF PEEK intervertebral cage has atraumatic, ogival anterior portion. This device can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. Radiopaque markers have been embedded within the implant to allow for visualization in radiographic images. CAUTION: The PLIF PEEK intervertebral cages are designed to be implanted bilaterally *(in pairs)*.
   b) The TLIF PEEK intervertebral cage has a curved, kidney-shaped geometry to match the vertebral anatomy and an adjustable articulated mechanism allowing the rotation of the implant in situ. Radiopaque markers have been embedded within the implant to allow for visualization in radiographic images.
3) The ALIF PEEK intervertebral cage is designed for use with an autograft, for anterior vertebral arthrodesis 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.
   a) The ALIF PEEK intervertebral cage is intended for use with supplemental fixation systems, cleared for use in the lumbar spine surgeries *(e.g. pedicle screw and rod systems)*.
   b) The ALIF PEEK locking intervertebral cage is to be used as a stand-alone implant *(without any additional stabilization systems)*. It is equipped with integrated titanium insert which together with four locking bone screws provide secure locking mechanism to stable fixation of vertebral bodies. Radiopaque markers have been embedded within the implant to allow for visualization in radiographic images.
4) Degenerative intervertebral disc disease *(DDD)* is defined as radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Patients qualified for treatment should be skeletally mature and have had six months of non-operative treatment.

2. For the implantation of the aforementioned products, **ChM**'s specialist instrument sets are dedicated. Along with the instrument set, illustrated surgical technique is also provided. Surgical technique is not a detailed instruction of conduct. This is the physician that determines the proper technique and detailed surgical procedure for a particular patient.

2 CONTRAINDICATIONS

1. Contraindications may be relative or absolute. The choice of particular device must be carefully considered in terms of patient's overall condition. Conditions listed below may preclude or reduce the chance of successful outcome:
   1) Infection local to the operative site.
   2) Signs of local inflammation.
   3) Fever or leukocytosis.
   4) Morbid obesity *(defined according to the WHO standards)*.
   5) Pregnancy.
   6) Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care.
   7) Any other condition which would preclude the potential benefit of implant application and may disturb the normal process of bone remodeling, e.g. the presence of tumours or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells *(WBC)* count, or a marked left shift in the WBC differential count.
   8) Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant *(content of the implant material is presented in IMPLANT MATERIAL)*.
   9) Any case not needing a surgical intervention.
   10) Any case not described in the indications.
   11) Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or sub-

stance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage.
12) Any case where the implant components selected for use would be too large or too small to achieve the successful result.
13) Any case that requires the simultaneous use of elements from different systems that are made of different metals.
14) Any case in which there is inadequate tissue coverage of the operative site.
15) Any case in which implant utilization would disturb physiological processes.
16) Inadequate bone quality for stable implant fixation *(bone resorption, osteopenia, and/or osteoporosis)*. This surgical treatment should not be used in patients with a known hereditary or acquired osteogenesis imperfecta or calcification problems.
17) Any case not needing the spine immobilization.
18) Significant anatomical deformity caused by congenital abnormalities.
19) These implants should not be used in children and patients whose spines are still developing.
20) Spondylolisthesis unable to be reduced to Grade 1.
21) Prior fusion at the level to be treated.
22) Blood supply limitation in the operative site.
23) CAUTION: PLIF, TLIF and ALIF intervertebral implants are not intended for use in cervical spine.

2. The above-mentioned list of contraindications is not exhaustive.

3 ADVERSE EFFECTS

1. The adverse effects may necessitate reoperation or revision. The surgeon should warn the patient about the possibility of adverse effects occurrence.
2. The below-mentioned list of adverse events is not exhaustive. There is a risk of occurrence of adverse events with unknown aetiology which may be caused by many unpredictable factors.
3. Potential adverse events include but are not limited to:
   1) Implant damage *(fracture, deformation or detachment)*.
   2) Early or late loosening, or displacement of the implant from the initial place of insertion.
   3) Possibility of corrosion as a result of contact with other materials.
   4) Body reaction to implants as to foreign bodies e.g. possibility of tumour metaplasia, autoimmune disease and/or scarring.
   5) Compression on the surrounding tissues or organs.
   6) Infection.
   7) Bone fractures or *"stress shielding"* phenomenon causing loss of bone above, below or at the operative site.
   8) Haemorrhage and /or hematomas.
   9) Pain.
   10) Inability to perform everyday activities.
   11) Mental condition changes.
   12) Death.
   13) Deep vein thrombosis, thrombophlebitis.
   14) Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary infection, disturbed lung growth, respiratory acidosis, etc.
   15) Scar formation that could cause neurological impairment, or nerves compression and /or pain.
   16) Cessation of any potential growth of the operated portion of the spine.
   17) Fracture, microfracture, resorption, damage, or penetration of any spinal bone *(including the sacrum, pedicles, and/or vertebral body)* and/or bone graft or bone graft harvest site at, above, or below the level of surgery. Retropulsed graft.
   18) Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise, including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injuries. Cerebral spinal fluid leakage.
   19) Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
   20) Urinary retention, urinary incontinence, or other types of urological system compromises.
   21) Reproductive system compromise, including infertility, loss of consortium and sexual dysfunction.
   22) Gastrointestinal system compromise.

23) Late bone fusion or no visible fusion mass and pseudoarthrosis.
24) Loss of proper spinal curvature, necessity to make corrections, change of patient's height, shortening of the spine.
25) Loss of or increase in spinal mobility or function.
26) Bone graft donor site complication.
27) Discitis, arachnoiditis, and/or other types of inflammation.
28) CAUTION: The potential risk of adverse events occurrence as a result of movement or lack of stabilization may increase in the cases where associated supplemental fixation systems are not employed.

4 WARNINGS

1. The important medical information provided in this document should be given to the patient.
2. The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieve the success of the surgery. The surgeon is responsible for this choice.
3. Preoperative and operating procedures, including knowledge of surgical techniques, and correct placement of implants are important and shall be considered by the surgeon in order to achieve success during operation.
4. A successful result is not always achieved in every surgical case. This fact is especially true in the case where other patient's conditions may compromise the results.
5. The proper patient selection, compliance of the patient and observance of post-operative recommendations will greatly affect the results. The bone union is less likely to occur among smoking patients. These patients should be informed about this fact and warned of this consequence.
6. Patients who are overweight, malnourished and/or abuse alcohol or drugs, with weak muscles and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.
7. The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
8. No implant can withstand body loads without the biomechanical continuity of the bone.
9. In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.
10. During normal use all surgical implants are subjected to repeated stresses which can result in material fatigue and failure of the implant.
11. Overweight may cause additional stresses and strains within implant which can lead to fatigue and deformation of the implant.
12. To avoid excessive stress on the implant which could lead to non-union or implant failure and associated clinical problems, the surgeon must inform the patient about the physical activity limitations during the treatment period.
13. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
14. If the patient is involved in an occupation or activity *(e.g.: substantial walking, running, weights lifting, muscles strain)* which may apply excessive stress on the implant, the surgeon must inform the patient that resultant forces can cause implant failure.
15. Use of this product without bone graft or in the cases where the bone union has not been achieved will not be successful.

5 PACKAGING AND STORAGE

1. Implants are single-use devices, provided sterile or non-sterile.
2. Implants not labeled as sterile are non-sterile.
3. Implant packaging must be intact at the time of receipt.
4. The unit package contains:
   1) sterile version - one piece of the product in a sterile condition. A double packaging made of Tyvek-foil or a single blister are typical packaging material.
   2) non-sterile version - one piece of the product. Clear plastic bags are a typical packaging material.
5. A sterility indicator is placed on the sterile package.

6. The package is equipped with the product label. The label *(as a primary label)* contains e.g.:
   1) Sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number *(REF)*, e.g.: 3.XXXX.XXX.
      c) Production batch number *(LOT)*, e.g. XXXXXXX.
      d) Material of the implant *(see IMPLANT MATERIAL)*.
      e) STERILE sign - indicating a sterile device and the sterilization method used, e.g.: R or VH202 *(symbols are described in the footer of this Instructions For Use)*.
      f) Sterilization batch number, e.g.: S-XXXXXXX.
      g) Device pictogram and information symbols *(described in the footer of this Instructions For Use)*.
      h) Expiration date and sterilization method.
   2) Non-sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number *(REF)*, e.g.: 3.XXXX.XXX.
      c) Production batch number *(LOT)*, e.g. XXXXXXX.
      d) Material of the implant *(see IMPLANT MATERIAL)*.
      e) NON-STERILE sign - indicates non-sterile product.
      f) Device pictogram and information symbols *(described in the footer of this Instructions For Use)*.
      g) The expiration date *(for polymeric devices)*.
7. In addition to the device primary label, an auxiliary label with specific market requirements of a given area may be placed on the unit package *(e.g. legal requirements of the country in which the device will be distributed)*.
8. The package may contain: Instructions For Use and labels to be placed in a patient's medical record.
9. 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.
10. Implants should be stored in appropriate protective packagings, in a clean, dry place with a room temperature and under conditions that provide protection from direct sunlight.

6 IMPLANT MATERIAL

1. Identification of the materials
   1) Depending on the type of material used in integrated metallic elements, the following symbols may be marked on the device surface:
      a) Titanium: symbol *(Ti)*.
      b) Tantalum: symbol *(Ta)*.
   2) The **ChM**'s polymeric intervertebral implants are made of biocompatible PEEK-OPTIMA® *(polyetheretheretheketone)*, in accordance with ISO 10993 standards and regulations of USP Class VI. The type of material is marked on the label of the device.
   3) The **ChM**'s polymeric intervertebral implants are equipped with integrated radiopaque markers, made of tantalum in accordance with ISO 13782/ASTM F560.
   4) The TLIF PEEK intervertebral cage and ALIF PEEK locking intervertebral cages contain integrated elements made of titanium alloy.
   5) Percent composition of elements in the implantable materials *(max. values)*:
      a) Titanium alloy according to ISO 5832-3/ASTM F136: | Al:6.75 | V:4.5 | Fe:0.3 | O:0.2 | C:0.08 | N:0.05 | H:0.015 | Ti:balance.
      b) Titanium alloy according to ISO 5832-11/ASTM F1295: | Al:6.5 | Nb:7.5 | Ta:0.5 | Fe:0.25 | O:0.2 | C:0.08 | N:0.05 | H:0.009 | Ti:balance.
   6) ATTENTION: Implantable titanium, titanium alloy and/or implantable cobalt alloy may be used together in the same construct. Never use titanium, titanium alloy and/or cobalt alloy with implantable stainless steel components in the same construct as it may lead to corrosion and reduction of mechanical strength of implants.
2. Magnetic resonance compatibility
   1) The ALIF PEEK locking intervertebral cages and TLIF PEEK intervertebral cages, which contain integrated elements made of titanium or titanium alloy, are conditionally compatible with magnetic resonance imaging.

2) The patient can be scanned safely under the following conditions:
   a) static magnetic field of ≤ 3 Tesla,
   b) maximum magnetic field spatial gradient of ≤ 720 Gauss/cm,
   c) maximum MR system reported whole-body-averaged specific absorption rate *(SAR)* of 3W/kg for 15 minutes of scanning.
3) The PLIF PEEK and ALIF PEEK intervertebral cages and their components *(tantalum radiopaque markers)* are considered to be safe for patients undergoing an MRI procedure.
4) CAUTION: the user should be absolutely familiar with the contraindications and warnings established by the manufacturer of the MRI scanner to be used for imaging procedure.
5) MR imaging may be interfered with if the area of interest is in the exact same area or relatively close to the position of the implant.
6) Do not perform MRI if there are doubts about the tissue integrity and the implant fixation or if the proper location of the implant is impossible to be established.

7 PRE-OPERATIVE RECOMMENDATIONS

1. Only patients that meet the criteria described in the PURPOSE AND INDICATIONS should be selected.
2. Patients' conditions and/or predispositions such as those addressed in the above-mentioned CONTRAINDICATIONS should be avoided.
3. Before deciding about implantation, the surgeon shall inform the patient about indications and contraindications of such procedure and possibility of complications occurrence after the operation. Patient shall be introduced to the purpose and manner of the procedure, and to functional and aesthetic effects of such treatment. Proper clinical diagnosis and accurate operation planning and performance are needed to achieve good final result of treatment.
4. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation *(alloying elements of implant material are presented in IMPLANT MATERIAL)*.
5. The implantation shall be carried out by the surgeon familiar with adequate rules and operating techniques, and who has acquired practical skills of using **ChM** instrument set. The selection of surgical technique adequate for a specific patient remains surgeon's responsibility.
6. The operation procedure shall be carefully planned. The size of implant should be determined prior to the beginning of the surgery. An adequate inventory of implants with required sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. The surgeon should be familiar with all components of the implant system before use and should personally verify if all components and instruments are present before the surgery begins.
8. Do not use the implant if the original, sterile packaging is damaged. Sterility cannot be guaranteed if the package is not intact. The package shall be carefully checked prior to use.
9. Implants are delivered in protective packagings. The package should be intact at the time of receipt.
10. Unless supplied sterile, all implants and instruments should be washed, disinfected and sterilized before use. Additional sterile components should be available in case of any unexpected need.
11. Before procedure begins, all implants should be carefully checked to ensure that there is no damage *(surface scratching, dents, signs of corrosion and shape deformations)*. Damaged implant must not be inserted into the body.

8 RECOMMENDATIONS FOR IMPLANTS PROVIDED STERILE

1. Sterile implant - is delivered in sterile packaging, with the inscription: *"STERILE"*. Such product is sterile and the manufacturer is responsible for the process of sterilization. The sterilization is performed with the use of one of the following methods:
   1) gamma radiation, with a minimum dose of **25 kGy**,
   2) hydrogen peroxide vapour.
2. The symbol designating the sterilization method used is visible on the device label *(symbols are described in the footer of this Instructions For Use)*.
3. Prior to use of a sterile device the following rules apply:
   1) Check out the expiration date of sterilization. Do not use the device with an overstepped sterility date!

2) Check out if the sterile package is not damaged. Do not use the device if the sterile package is damaged!
3) Check out the colour of the sterility indicator on the sterile package which indicates that sterilization of the device was performed. Do not use the device if the sterility indicator colour is different than:
a) red - for devices sterilized with gamma radiation,
b) blue - for devices sterilized with hydrogen peroxide vapour.

4. CAUTION: products should be removed from their packagings in accordance with aseptic rules.

9 RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE

1. The following recommendations apply to unused non-sterile implants. An implant that has been implanted must not be re-processed and re-used.
2. The implant which has not been used but got contaminated by contact with the blood, tissue and/or body fluids/materials, should not be used again. The implant should be handled in accordance with applicable hospital protocol. **ChM** does not recommend re-processing of contaminated implants. Should the contaminated implant be re-processed, **ChM** bears no responsibility.
3. 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.
   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.
4. Preparation for washing and disinfection *(for all methods)*
   1) Prior to cleaning, remove the implant from the original unit packaging. Dispose of the packaging. Protect patient labels, provided with the implant, against accidental loss or damage.
   2) To avoid contamination, the implants should not have contact with the contaminated devices/instruments.
   3) Rinse under running water and remove possible surface dirt *(resulting from e.g.: damage to the unit packaging)* using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*.
   4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the implant.
5. Cleaning and disinfection process
   1) This Instructions for Use describes two validated by **ChM** cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated procedures for cleaning and disinfection *(in the 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) Manual with ultrasound cleaning
      a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, aqueous solutions: of cleaning agent, disinfecting agent or washing – disinfecting agent.
      b) Prepare an aqueous solution of cleaning agent at temperature of 40+/-2 °C and a 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)*.
      c) Immerse the implant in the aqueous solution of the cleaning agent and subject it to ultrasound cleaning for 15 minutes.
      d) Rinse the implant thoroughly under running water, paying particular attention to the holes and places difficult to be cleaned. It is recommended to rinse with demineralized water.
      e) Visually inspect the entire surface of the device for debris and impurity. Damaged implants must be removed.

For dirty implants, the cleaning process should be repeated.

f) Dry the device thoroughly using disposable, soft, lint-free cloth.

g) 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 implant 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)*.

h) After the exposure time, rinse the product thoroughly under running water, paying particular attention to the holes and places difficult to be cleaned. It is recommended to rinse with demineralized water.

i) Dry the device thoroughly. It is recommended to dry the implant in a dryer at a temperature ranging from 90°C to 110°C.

j) Visually inspect the entire surface of the device.

4) The automated method using a washer - disinfector

a) Equipment and materials: a washer - disinfector, aqueous solutions of cleaning agent.

b) 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 washing machine manufacturer, and Instructions for Use prepared by the washing-disinfecting agent manufacturer.

c) The device should undergo a 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 a temperature ranging from 90°C to 110°C, duration - 40min.

6. Packaging

1) Washed and dried devices shall be packed in a packaging intended for the recommended steam sterilization. The packaging and packaging process have to meet the requirements of ISO 11607 standards. The packaging procedure must be performed in controlled purity conditions. The device must be packed in such a way 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 in accordance with the applicable procedures of the customer. 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) Implant must not be sterilized in the packaging in which it was delivered.

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 above-mentioned principles for cleaning and sterilization must be applied to all implants intended for implantation.

f) The surgical instruments used for implants insertion should also be covered by cleaning and sterilization procedure.

10 RE-STERILIZATION

1. It is permitted to re-sterilize a device in case, when its sterile packaging has been damaged or opened. In this case, the product should be washed and sterilized in the manner described in the chapter RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE.

1) ATTENTION: Implant that has been in contact with body tissues or fluids of a patient cannot be re-sterilized or implanted to another patient.

11 PRECAUTIONS

1. Implant is intended for single use only. After removing the implant from the patient's body, it must be secured against re-use, and then finally disposed of in accordance with current hospital procedures.
2. Under no circumstances is it allowed to re-use or re-implant once used device. Even if the removed implant appears to be undamaged, it may have small latent defects or internal stresses, which could lead to early failure, fatigue wear, and as a result to e.g. an implant breakage.
3. Misuse of instruments or implants may cause injury to the patient or operative personnel.
4. Avoid damaging implant surface and deforming its shape during the implantation; the damaged implant cannot be implanted or left in the patient's body.
5. Insertion, removal and adjustment of implants must only be done with instruments specially designated for those implants and manufactured by **ChM** sp. z o.o.
6. Use of **ChM**'s implants and instruments in combination with implants and instruments from other manufacturers may cause damage or failure of those implants or instruments and may lead to improper course of surgery and healing process.
7. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive force are more susceptible to fractures, depending on care taken during surgery, number of procedures performed and attention paid. Instruments should be examined for wear or damage prior to surgery.
8. Extreme caution should be exercised around the spinal cord and nerve roots. Damage to the nerves will cause a loss of neurological functions.
9. To assure proper fusion below and around the implant site, an autogenous bone graft must be used.
10. Bone cement should not be used because this material may cause later removal of these implants difficult or impossible.
11. The heat generated during the curing process of the bone cement may damage or deform the implant made of PEEK polymer.

12 POST-OPERATIVE RECOMMENDATIONS

1. It is essential to follow all of physician's postoperative directions and warnings.
2. It is essential to confirm proper position of the implant by roentgenographic examination.
3. In postoperative treatment period, the correctness of implant positioning and immobilization of union should be confirmed by roentgenographic examination.
4. The surgeon must instruct the patient regarding appropriate and restricted activities during consolidation and maturation of the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and further clinical problems. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
5. If the patient is involved in an occupation or activity which may apply excessive stress on the implant *(e.g. substantial walking, running, lifting, or muscle strain)* the surgeon must advise the patient that resultant forces can cause implant failure.
6. Failure to perform appropriate immobilization of bone when delayed or non-union occurs may lead to excessive fatigue stresses in the implant. Fatigue stresses may be a potential cause of implant becoming bent, loosened or fractured. If non-union of fracture or implant bending, loosening or fracture occurs, the patient should be immediately revised, and the implants should be removed before any serious injuries occur. The patient must be appropriately warned about these risks and closely monitored to ensure compliance during the treatment until the bone union is confirmed.
7. The patient should be warned about the risk should he fail to follow the above-mentioned rules, or should he be unavailable for follow-up clinical examination.
8. The surgeon must instruct the patient to report any unusual changes of the operative site to his/her physician. If any change at the site has been detected, the patient should be closely monitored.
9. The patient should be informed about the type of implant material.
10. The patient should be warned to inform the medical staff about the inserted implants prior to any MRI procedure.

11. The patient should be advised not to smoke or consume alcohol excessively during the period of treatment.

13 CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER TREATMENT

1. When fusion occurs, the device will be deeply integrated into the bone and should not be removed unless the management of a complication or adverse event requires the removal.

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

Updated INSTRUCTIONS FOR USE are available at 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
	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterlilizzare
	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 é 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 instruzioni per l'uso
	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 VH202	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 • Material • 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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