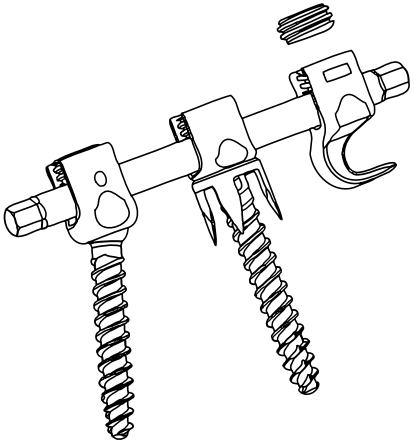
ChM®



CHARSPINE system | CHARSPINE system 2 | CHARSPINE system OCT Occipito-Cervico-Thoracic Stabilization System | CHARSPINE system 2 MIS Minimally Invasive Surgery

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Date: 2021.04.12 17:45:16 EEST
Reason: MoldSign Signature
Location: Moldova

IFU-013/2020-12-16

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

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare • Не використовувати повторно
	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterlilizzare • Не стерилізувати повторно
	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 • Не використовувати, якщо пошкоджено упаковку
	Consult instructions for use • Zapoznać się z instrukcją stosowania • Смотрите инструкцию по применению • Consultar las instrucciones de uso • Gebrauchsanweisung beachten • Viz návod k použití • Consultare le istruzioni per l'uso • Зверніться до інструкції з використання
	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile • Нестерильний виріб
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Avvertenza • Увага
	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione • Стерилізовано опроміненням
	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 • Стерилізовано перекисом водню
	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo • Каталожний номер
	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto • Код партії
	Medical device • Wyrób medyczny • Медицинское изделие • Dispositivo médico • Medizinprodukt • Zdravotnický prostředek • Dispositivo medico • Медичний виріб
	Serial number • Numer seryjny • Серийный номер • Número de serie • Seriennummer • Sériové číslo • Numero di serie • Серійний номер
Mat:	Material • Materiał • Материал • Material • Material • Materiál • Materiale • Матеріал
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita' • Кількість
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il • Термін придатності (використати до)
	Date of manufacture • Data produkcji • Дата изготовления • Fecha de fabricación • Herstellungsdatum • Datum výroby • Data di fabbricazione • Дата виготовлення
	Manufacturer • Producent • Производитель • Fabricante • Hersteller • Výrobce • Fabbricante • Виробник
	Keep away from sunlight • Trzymać z dala od promieniowania słonecznego • Не допускать воздействия солнечного света • Manténgase alejado de la luz solar • Vor Sonnenlicht schützen • Chraňte před slunečním světlem • Proteggere dalla luce solare • Не піддавати дії прямих сонячних променів
	Keep dry • Przechowywać w suchym miejscu • Беречь от влаги • Mantener seco • Trocken lagern • Udržujte v suchu • Tenere all'asciutto • Берегти від вологи
	Temperature limit • Ograniczenie dopuszczalnych temperatur • Нижняя граница температурного диапазона • Límites de temperatura. • Temperaturgrenzen • Teplotní omezení • Limites de température • Нижня межа температурного діпазону
	Humidity limitation • Ograniczenie dopuszczalnej wilgotności • Диапазон влажности • Límites de humedad. • Luftfeuchtigkeitsgrenzen • Mezní hodnoty vlhkost • Limites d'humidité • Діапазон вологості

GB

INSTRUCTIONS FOR USE

Important product information for

SPINE STABILIZER

CHARSPINE system · CHARSPINE system 2 · CHARSPINE system OCT Occipito-Cervico-Thoracic Stabilization System · CHARSPINE system 2 MIS Minimally Invasive Surgery

1 PURPOSE AND INDICATIONS

1. The CHARSPINE, CHARSPINE2 and BIALSTAB spinal stabilizer systems are intended to provide immobilization and stabilization of spinal segments to achieve fusion, in skeletally mature patients.
   1) The CHARSPINE system (*6.0mm rod system*) is intended for pedicle screw stabilization of thoracolumbar and sacral spine, using posterior approach and thoracolumbar spine using antero-lateral approach.
   2) The staples of the CHARSPINE, CHARSPINE2 pedicle screw stabilizer system are intended for use by means of anterior approach only.
   3) The CHARSPINE2 system (*6.0mm rod system*) is intended for pedicle screw stabilization of thoracolumbosacral spine and ilium using posterior approach and thoracolumbar spine using antero-lateral approach.
   4) The CHARSPINE, CHARSPINE2 pedicle screw stabilizer system consists of the following elements: monoaxial and polyaxial pedicular screws, spinal hooks, locking screws, rods, rod connectors, cross-connectors, and clamps.
   5) The BIALSTAB pedicle screw stabilizer (*5.0mm rod system*) is intended for treatment of thoracolumbar spine in small stature patients (*small and thin*), using posterior approach solely.
   6) The BIALSTAB spine stabilizer system consists of the following elements: monoaxial and polyaxial pedicular screws, spinal hooks, counter-hooks, locking screws, locking caps, rods, and cross-connectors.
   7) The hooks of CHARSPINE, CHARSPINE2 and BIALSTAB systems are intended for posterior use only.
   8) Indications for use:
      a) Degenerative 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.
      b) Spondylolistheses.
      c) Fractures and dislocations.
      d) Deformities (*e.g.: scolioses, kyphoses*).
      e) Tumours.
      f) Stenoses.
      g) Pseudoarthroses.
      h) Failed previous fusion.
   9) The CHARSPINE2 MIS pedicle screw stabilizer is intended for minimally invasive, percutaneous treatment of thoracolumbar and sacral spine, using posterior approach. The CHARSPINE2 MIS screws have fenestrations, allowing for delivery of bone cement.
   10) The CHARSPINE2 MIS pedicle screw stabilizer system consists of cannulated, fenestrated polyaxial screws and rods intended for percutaneous method.
2. The cervical locking plate system is intended for the treatment of the cervical spine using an anterior surgical approach. The system includes locking cervical plates and screws and a set of instruments necessary for implants insertion. Using the system, the following may be performed: for plates with four or more holes - stabilization and immobilization of the cervical spine or additional stabilization in combination with another cervical stabilization system; plates with two holes are used only as a protection against backing out of the implanted intervertebral cervical cages from the intervertebral space.
   1) Indications for plates with four or more holes:
      a) Instabilities caused by trauma or associated with correction of cervical lordosis and kyphosis deformity.
      b) Pseudoarthoses as a result of previously failed surgery.
      c) Instabilities caused by major reconstructive surgery due to tumour.
      d) Instabilities associated with single or multiple level corpectomy.
      e) Spinal canal stenoses and cervical myelopathy.
   2) Indications for plates with two holes:
      a) The two-hole plates are indicated for use with cervical intervertebral cages to protect them against backing out from the intervertebral space. Two-hole plates cannot be used to stabilize the cervical segment as a stand-alone implant!
3. The CHARSPINE OCT stabilization system is intended to provide immobilization and stabilization of spinal segments from posterior approach in skeletally mature patients, as an adjunct to fusion in treatment of instabilities of the craniocervical junction, the cervical spine (*C1 to C7*) and the thoracic spine (*T1-T3*). The system consists of polyaxial screws, hooks, locking screws, rods, connctors, occipital plates and screws.
   1) Indications for use:
      a) Fractures and instabilities.
      b) Deformities.
      c) Spinal stenosis.

d) Failed previous fusions (*e.g. pseudoarthrosis*).
e) Tumors involving the cervical/thoracic spine.
f) Degenerative disease, including radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic examination.

4. The CHARSPINE titanium intervertebral cage system implants are designed to be implanted bilaterally (*in pairs*) and are indicated for a posterior approach. The CHARSPINE intervertebral fixation system consists of titanium intervertebral cages.
   1) Indications for use:
      a) Treatment of degenerative disc disease (*DDD*).
      b) Vertebral instabilities.
      c) Grade 1 spondylolistheses.
      d) Spine revision surgery.
   2) The implants should be used at one or two contiguous levels from L2 to S1. Patients qualified for treatment should be skeletally mature and have had six months of non-operative treatment. The cage system 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*).
5. 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 substance 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) Blood supply limitation in the operative site.
   21) Additional contraindications related to bone cement augmentation include:
      a) Suspected or documented allergy or intolerance to any of the components of the bone cement,
      b) Burst fracture of the vertebra with ≥20% narrowing of the spinal canal,
      c) Vertebral body collapse to less than 1/3 original height,
      d) Vertebral fracture with neurological deficits or radiculopathy,
      e) Breach of the pedicle wall when inserting pedicle screws. Injection of bone cement in this situation will carry a high risk of leakage into the spinal canal or neural foramen.

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) Additional potential adverse events related to bone cement augmentation include:
      a) Leakage of the bone cement outside the intended application site or into the vascular system resulting in the lung and/or heart embolism or other clinical sequelae,
      b) Leakage of the bone cement into the intervertebral discs and/or adjacent tissues,
      c) Leakage of the bone cement into the spinal canal or neural foramen possibly resulting in paralysis or sensory disorders,
      d) For other possible adverse events related directly to the used bone cement, consult the instructions for use delivered with this product.
   29) Cervical spine procedures may be associated with vascular and neurological complications such as: arterial injury, cord contusion and damage, peripheral nerve damage, including but not limited to peripheral paralysis, sensory disorders, vascular disorders, loss or disturbance of bladder and bowel functions.

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. The implants are intended as an aid to the healing process and are **NOT** intended to replace body structures or bear the body weight when the treatment process has not yet finished.
9. No implant can withstand body loads without the biomechanical continuity of the bone.
10. 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.
11. During normal use all surgical implants are subjected to repeated stresses which can result in material fatigue and failure of the implant.
13. 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. Overweight may cause additional stresses and strains within implant which can lead to fatigue and deformation of the implant.
14. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
15. 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.
16. Use of this product without bone graft or in the cases where the bone union has not been achieved will not be successful.
17. Additional warnings related to bone cement augmentation include:
    1) Consult the instructions for use delivered with the bone cement, cannulas and cement mixing/delivery system for warnings associated with the use this equipment.
    2) Only use cement intended for percutaneous cementoplasty of the spine and offered or recommended by **ChM**.
    3) Only use cannulas for cement delivery provided by **ChM** and intended for use with the CHARSPINE2 MIS screws. The use of cannulas from other manufacturers can result in cement leakage and associated complications.
    4) Only use cement mixing/delivery devices that are offered or recommended by **ChM**. Assure that the components of the mixing/delivery device are compatible with cannula for bone cement and are firmly connected prior to cement injection. Improperly secured connections could result in the unintended disconnection of components and cement leakage.
    5) The CHARSPINE2 MIS fenestrated screws cannot be placed bicortically. It is very important not to breach the pedicle wall or the anterior cortex of the vertebral body to avoid cement extrusion into the retroperitoneal space. This may result in serious complications, including cement extravasation, embolism or even death, especially if the cement is inadvertently extruded through the tip of the screw.
    6) Accurate pedicle preparation, screw sizing and placement must be practiced, as well as a careful cement delivery technique. There may be an increased risk of cement egress into pedicle if the screw length is too short, or if excessive cement volume is pumped into the vertebral body. Too aggressive cement injection may result in cement leakage.
    7) When using cement to augment multiple screws and levels, attention must be paid not to exceed the working time of the cement prior to completion of cement delivery through the screws. When the cement working time is close to completion, a new cement package should be used.
    8) The mixing/delivery device is designed for single use with one package of bone cement. If a second package of cement is needed, use a second mixing/delivery device.
    9) Do not attempt to force the injection of cement if excessive resistance is felt. Always determine the cause of the resistance and take appropriate action. If the cement is seen outside of the vertebral body or in the circulatory system during the procedure, immediately stop injecting the cement.
    10) It is critical that no torsion movement should be applied to the screw after injecting the cement in order to avoid breaking the cement bridges between screw and bone.
    11) After cement introduction is complete, the cannula for bone cement must be removed immediately from the screw. The cement setting while the cannula is still connected to the screw may lead to difficulty in removal, and a new cannula may be required for additional levels.

12) During the application of the cement, radiological control (*fluoroscopy or CT*) is essential so that the operator can follow the progress of the filling and stop the procedure if the slightest leakage of cement is detected. Appropriate imaging technique will enable to confirm correct screw placement, absence of damage to surrounding structures and appropriate location of injected cement.

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. Implants can be delivered in a unit package. The unit package of the product 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. Plastic bags are a typical packaging material.
5. Implants can be delivered on stands, palettes (*non-sterile version only*).
6. A sterility indicator is placed on the sterile package.
7. Products are delivered with a 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*).
8. 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*).
9. The package contains patient tracking labels to be placed in a patient's medical record.
10. 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.
11. 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 material used, the following symbols may be marked on the device surface:
      a) Titanium and titanium alloys: symbol (*Ti*).
      b) Cobalt alloy: symbol (*Co*).
   2) Rods belonging to the CHARSPINE, CHARSPINE2, CHARSPINE2 MIS and BIALSTAB pedicular stabilization systems are made of implantable titanium alloy or cobalt alloy.
   3) All remaining components of CHARSPINE, CHARSPINE2, CHARSPINE2 MIS and BIALSTAB systems are made of implantable titanium alloy.
   4) 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.

c) Cobalt alloy according to ISO 5832-12/ASTM F1537:|Cr:30 | Mo:7 | Fe:0.75 | Mn:1 | Si:1|C:0.14 | Ni:1 | N:0.25|Co: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) Implants made of titanium, titanium alloys and cobalt alloys are conditionally compatible with magnetic resonance imaging.
2) The patient can be scanned safely under the following conditions:
   a) static magnetic field of 1.5-Tesla and 3-Tesla, only,
   b) maximum spatial gradient magnetic field of ≤ 720 Gauss/cm,
   c) maximum MR system reported whole-body-averaged specific absorption rate (*SAR*) of 2W/kg for 15 minutes of scanning (*per pulse sequence*).
3) 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.
4) 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.
5) 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 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 – 15 min (*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,