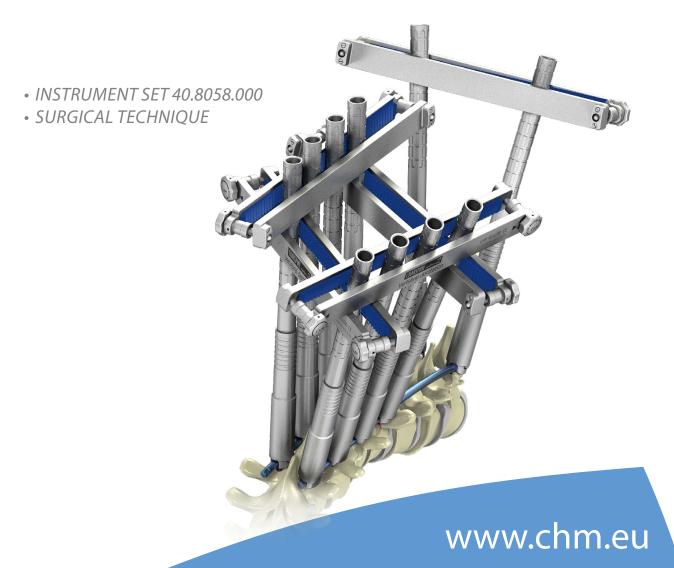




CHARSPINE2 VD DIRECT VERTEBRAL BODY DEROTATION



SYMBOLS DESCRIPTIONS



Caution - pay attention to the particular proceeding.



Perform the activity with X-Ray control.



Information about the next stages of the proceeding.



Proceed to the next stage.



Return to the specified stage and repeat the activity.



Before using the product, carefully read the Instructions for Use supplied with the product. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.



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

www.chm.eu

 Document No
 ST/82

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The manufacturer reserves the right to introduce design changes.

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1. INTRODUCTION

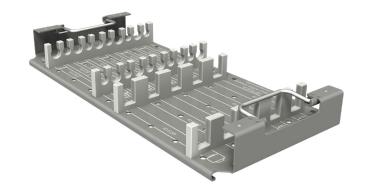
The **CHARSPINE2 VD** set of vertebral body derotation instrumentation, designed by the team of **ChM** specialists, has been developed to meet the challenges surgeons face in the treatment of complex deformations and to broaden the application of known and clinically proven **CHARSPINE2** bar stabilization system. The new system provides solutions to surgeons when treating spinal deformities (*scoliosis*). **CHARSPINE2 VD** utilizes the direct vertebral derotation technique that allows for three-dimensional correction of spinal disorders. The system consists of sleeves and clamps that can be combined into blocks in any way ensuring the most effective correction of deformity. The **CHARSPINE2 VD** instrument set has been especially designed for and is fully compatible with **CHARSPINE2** bar stabilization system.



2. INSTRUMENTS

Instrument set for CHARSPINE2 VD vertebral derotation - 40.8058

	Name	Catalogue no.	Pcs
CHARSPINE	Derotational clamp	40.6189.000	5
	Derotational sleeve	40.6188.000	10



Stand for instrument set for $\textbf{CHARSPINE2}\,\textbf{VD}$

40.8059.000



All the other instruments (except for the ones mentioned above) described in this surgical technique are included in the instrument set for CHARSPINE2 spine stabilizer in the version [40.8060] or [15.0907.001].



3. SURGICAL TECHNIQUE

3.1. SCREWS SELECTION

Surgical posterior approach to the thoracolumbar spine and instructions for transpedicular screws insertion have been described in a separate surgical technique No. ST/63 for **CHARSPINE2** thoracolumbar stabilization system.

The selection of appropriate screws is a key factor to ensure the success of the derotation procedure. Monoaxial screws guarantee the highest stability, however, due to possible difficulties with fitting the rod, polyaxial or uniplanar screws may be required. For scoliosis correction, the use of reduction screws should be considered since the screws significantly facilitate the bar placement.

The transpedicular screws should be inserted at each level of the concave site of the scoliosis, whereas on the convex side - the screws should be inserted at both ends of the scoliosis arch and at its apex.

3.2. ROD CONTOURING

When all the screws are placed in the pedicles, use e.g. rod trial 6/300 **[40.5246.300]** to measure the length of the rod and define its required curvature. The trial is available as an additional accessory of **CHARSPINE2** system. Contour the rod with adjustable rod bender **[40.8074]** which is a standard instrument of **CHARSPINE2** system (refer to **CHARSPINE2** surgical technique).

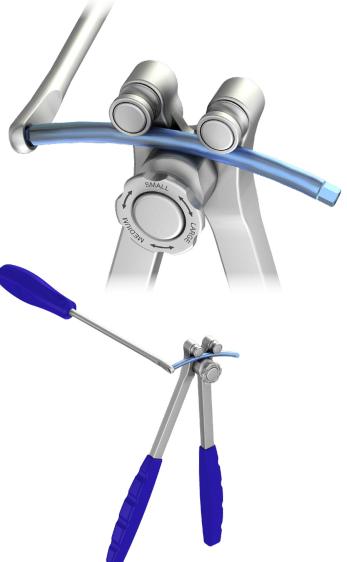




NOTE: To order the rod trial, contact your sales representative or ChM Sales Department.



NOTE: Contour the convex rod with less kyphosis to push down on the convex side of the vertebral bodies, thus displacing them anteriorly and decreasing the rib prominence. Contour the concave rod with extra kyphosis to pull the apical vertebrae dorsally out of the chest, correct apical lordosis and decrease the rib prominence.

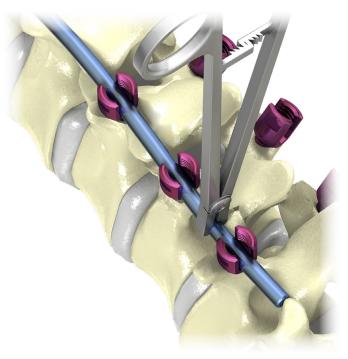




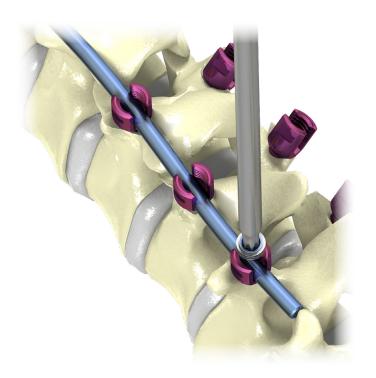
3.3. ROD FIXATION

The rod contoured as desired should be placed in the socket of the transpedicular screw. To do so, use pliers for rod **[40.8109]**.





Lock the rod using locking screw **[3.6160]** that should be placed in the head of the transpedicular screw.





NOTE: The locking screw may be mounted on the screwdriver tip only from the upper side of the screw (the locking screw design eliminates any errors related to the mounting).



The upper surface of the screw is colour-marked for easier identification.

The locking screw is mounted on the tip of the screwdriver T30 [40.8111], then it is inserted into the cut-out on the screw head and slightly tightened up in a clockwise direction. The inserted locking screw should allow the rod to move freely in the socket. Plies for rod and screwdriver T30 are included in **CHARSPINE2** stabilizer set.



Should it be difficult to press the rod to the screw cut-out bottom, use rod impactor [40.8068], fork persuader [40.8100], or screw persuader [40.8096] (please, refer to CHARSPINE2 surgical technique).



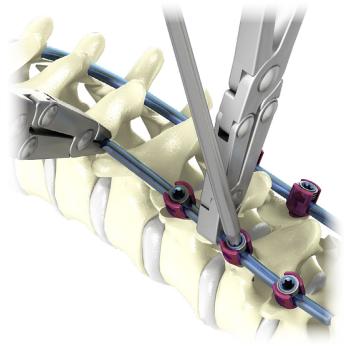




3.4. ROD ROTATION

Having inserted locking screws, rotate the rods until they are positioned as intended in the sagittal plane. For rotation, use holding forceps (**[40.6202]** or **[40.4516]** depending on the instrument set version) that are a part of **CHARSPINE2** set. If the rod has original hexagonal ends, an eye wrench **[40.8069]** can also be used. Afterwards, pre-tighten the locking screws.





3.5. DIRECT DEROTATION



NOTE: If reduction screws are used, firstly, break the arms off using the reduction screw device [40.8108] and then attach the derotation sleeves.



40.8108.000



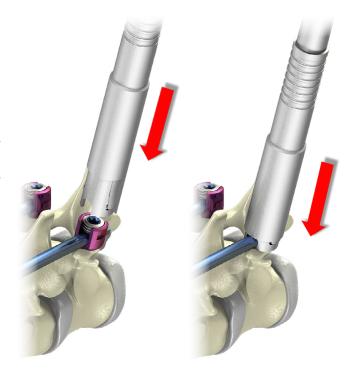


3.6. SEGMENTAL TECHNIQUE

Derotation should start from navigating the first neutral (non-rotated) vertebral body located below the deformity and the first rotated vertebra. Insert the derotation sleeves onto the above-mentioned transpedicular screws as illustrated. Install the derotation sleeve on the screw and then slide the outer sleeve down to lock the lock.



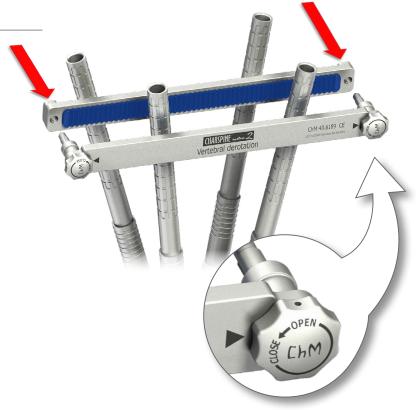
40.6188.000



The sleeves located on the same levels should be linked together with derotation clamps, creating two separate frames. The frames are put together as shown in the illustration.

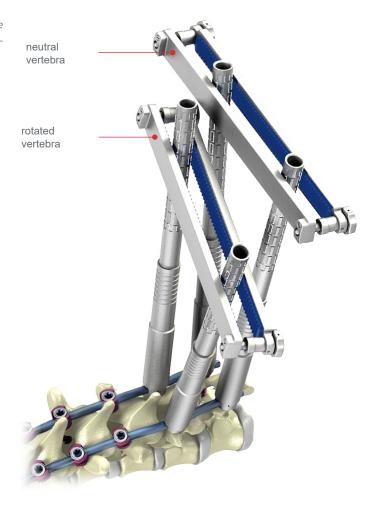


40.6189.000

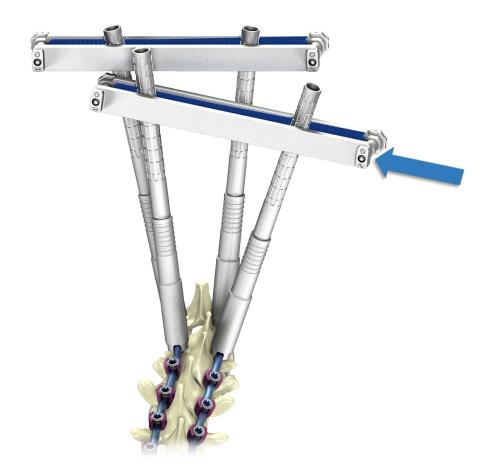




Locking screws already inserted in the transpedicular screws of rotated vertebrae (*above the neutral one*) should be loosened, yet not completely unscrewed. Locking screws of neutral vertebrae must remain pre-tightened.



Afterwards, a direct derotation of the first rotated vertebra should be performed. The frame locked on the neutral vertebra will be the reference point for the rotated vertebra and will act as a counter force for forces occurring during derotation.





After derotation, the locking screws located in the rotated vertebra should be pre-tightened with screwdriver T30[40.8111].



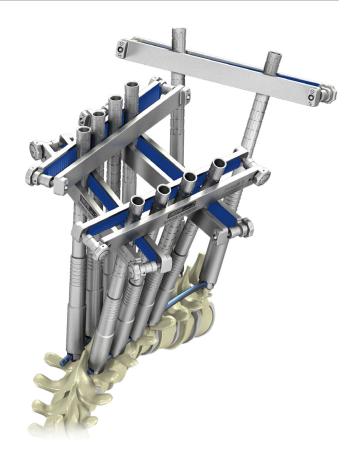
The rotated vertebra will now act as a neutral vertebra and the whole procedure should be repeated moving one segment higher.



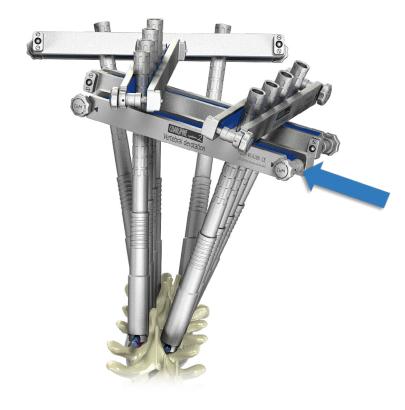


3.7. EN BLOCK TECHNIQUE

Derotation sleeves should be placed on deformity apical screws and on the first neutral (non-rotated) vertebra located below the deformity. The sleeves on the neutral vertebra are to be linked together with the derotation clamp to form a frame. The sleeves located on the rotated vertebrae should also be linked together with the clamp as illustrated, forming a single frame covering several levels. Locking screws should be loosened but not removed. The locking screws in transpedicular screws of the neutral vertebra should be pre-tightened.



Derotation is performed by turning the frame locked on the rotated vertebrae until reaching the neutral position. The frame on the neutral vertebra is used as counter force for the forces that occur.



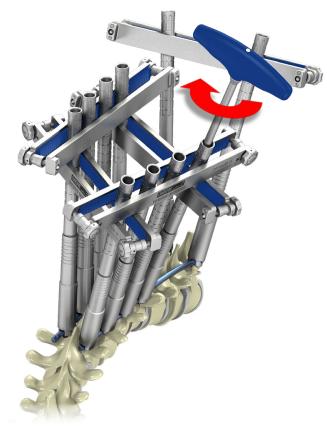


After performed correction, the locking screws should be pre-tightened with screwdriver T30 [40.8111].



NOTE: To facilitate the derotation procedure, push down the rib prominence.





3.8. FRAME DISASSEMBLY

To disassemble the frame, start by removing the clamps, turning one of the knobs counterclockwise. If clamp removal is not yet possible, unlock the other knob.

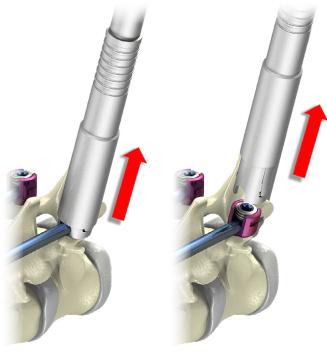


Should it be necessary to reassemble the derotation clamp on the sleeves, both parts of the clamp must first be completely disconnected. This will ensure that the locking mechanism functions correctly when reinstalling.



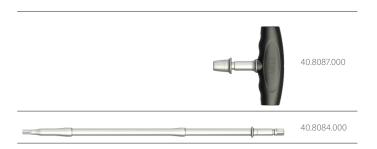
Then remove the derotation sleeves by sliding the outer sleeve upwards.





3.9. FINAL TIGHTENING

Tighten finally the locking screw with the help of T-type torque handle 12Nm **[40.8087]** and screwdriver tip T30 **[40.8084]**.





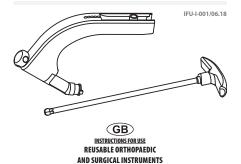
4. INSTRUCTIONS FOR USE







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



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.

- 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 specially designed serillation containers). This instructions for Use is attached both to the unit packs the sets.

 2. The package is equipped with the product label. The label (as a primary label) contains, among others:
 1) logo DMA and the address of the manufacturer.
 2) Catalogue number (REF) e.g. + (MXXXXXXX) and deviree name and size.
 3) Production batch number (GDF), e.g. + (MXXXXXXX) and deviree name and size.
 3) Production batch number (GDF), e.g. + (MXXXXXXX) and the size is not size in the size of the size

- 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

- Ther 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. Justification and produced of corrosion-resistant steel. The protective layer (possive layer) against corrosion is formed on the surface of the device due to high content of chromium.
- tomed on the surface of the elevice due to high ordinent of criomnium. 3 Devices produced of aliminium are mainly stands, paletter, cynettes 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 aliuminium as an effect of electrodemical teatment of fiss surface. 4 Devices made of aluminium with processed layer have good corrision resistance. However, the contact with strong alkaline deaning and disinfecting agents, solutions containing indine or some metal salts, due to chemi-cal interference with the processed aluminium surface, shall be avoided.
- cal intervenee with the processed aluminum surface, shall be avoided.

 Shevices produced of plastics are maily stands, paletes, cuvettes and some parts of instruments such as e.g. handles. Plastics used in the manufacture of instruments are mainly. PSDI Polyphenyslufione), PEEK (Polytechrethechreche, Jellon (PTEF. Polytechrollowoethylore) and silicone. The above-mentioned materials can be processed (worked, deuned, sterilized) at temperatures not higher than 140°C. They are stable in aqueous solu-
- processed (worshed, deemed, sterilized) at temperatures not higher than 140°C. They are stable in aqueous solu-tion of washing-disinfecting agents with a phi 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 barsaion resistance. 7. Jif the material of the device cannot be specified, please contact ChM sp. zo.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.
- use and application. Limproper, 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 pur-pose. Be of instruments on in accordance with their intended purposes may lead to malfunction, accelerated wear and, in consequences, damage to the instrument.

- wear and, in consequences, damage to the instrument.

 Althe surgens 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.

 Seforch et procretor begins, all instruments should be carefully inspected for their condition and proper functioning. They should be undamaged and without any signs of comosion. Bades 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.

 Times into the control of the control

- damaged or comoded instruments is not allowed.

 Glissue structures done to the operative site must be protected.

 T.Gollision of the instrument with metal operating equipment, retractor or other device may cause damage that necessitates introperative replacement of that instrument.

 Bo not apply excessive force when using the instrument it may lead to its permanent damage and, in consequences, to not influction of the device.

 9. Instruments are subject to constant wear processes. While rear, interoperative facture or breakage of the instrument can occur. Instruments with other been subjected to prolongly used or excessive forces are more succeptible to factures, depending on care taken during surgery and the number of procedures performed. Should medical facility procedures.

 In other cases of constructive the instrument parts must be removed and disposed of immediately in accordance with valid medical facility procedures.

 Oli no deer to confirm the memoral of all undesired metal fragments from the surgical field, intrapperative X-Ray examination is recommended.

- examination is recommended.

 If 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.

 12.1 it is cutremely important to follow the calibration deadline which is permanently marked on the torque instruments (see Culd&MRVIO). Use of a foreupe instrument with on oversteped collobration 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 be any usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.
- turer for its re-calination.

 All Instrument with And contact with tissues or body fluids of another patient cannot be re-used prior to its repo-cessing due to a potential risk of cross-infection caused by viruses, bacteria and priors.

 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

- 5 CLEANING, DISINFECTION, STERILIZATION

 1. The device must undeep oclaming, disinfection and sterilization procedures.

 2. Effective desaining is complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of dearing inmanual automated, the proper missing and dying, 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 dearing, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.

 2. Preparation at the place of use.

 3. Ill minufactively after use, remove from instrument blood and other contaminants with disposable doth or paper trowers. Additionally, it is recommended to rise the instrument under running water or to place it in the aqueues disinfectant solution. Do not let blood, tissues, body fluids or other biological impurities dry out on the surface of the device.
- 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

- 3) In order to error contamination reunity sundo-deain ones.
 3. Preparation for washing and disinfection (for all methods).
 1) The used instruments should be exprocessed as soon as possible.
 2) If the instrument can be disassembled, it must be done before cleaning processes.
 3) Rince under moning voter and remove surface debits issuing 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., encodister" Mediciaen force, at temperature of 494-1-27 can dip of 103-410.3 (follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, con-
- mation contained in the instructions prepared by the manufacturer or the agent, in respect of temperature, con-centration, exposure time and water quality).

 4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the product.
- Deaning and disinfection process.

 1) This Instructions for Use describes two ChM-approved deaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated cleaning and disinfection procedures (in a washer-disinfector).
- processures (in a viscures-animetrus).

 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-distincting agents with a plavalue between 10.4 and 10.8. CM used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials that those listed below which may also give a

- cleaming and distinction. It is allowed to use other materias than timose lasted nelow which may also give a comparable effective (producer) needshers "MediClean forte (name of the deepent;) b) disinfectant. Problegert (producer) needshers "Septo Active (name of disinfectant). 3) To prevent product chamage (pitting, rust, discolarotion), do not use aggressive cleaning agents. (MoOH, MoOCI), saline solutions and mustitable cleaning agents. 4) Where possible, it is recommended to use demineralized water to avoid the formation of spots and stains caused by cholories and other compounds present in ordinary water. 5) Manual with ultrazound cleaning.
- Manual with ultrasound deaning.

 Equipment and materiaks: a device for ultrasound deaning, soft, lint-free cloths, plastic brushes, syringes, aquecus solutions of deaning agent.

 Manual deaning initial manual deaning must be performed prior to ultrasound deaning. Rinse under unning water until the product is visually clean. Use plastic brushes to remove heavy or large debris.
- exerts.

 3 Soak the product for at least 10 minutes in an aqueous solution of a detergent at temperature of 40+/-2°C and pli of 10.4-10.8 (follow the information contained in the instruction spepared by the manufacturer of the agent, in respect for impresentation, response time and water quality).

 9 Rinse the product under cold water for at least 2 minutes, paying particular attention to the holes and places

- inflict in the Celaned.

 Prepare lines washing solution. Clean the surfaces and gaps of the product, carefully. Use suitable brushes to dean the holes. Clean the product immersed in the solution.

 Rines the product throughly under warm running water for at least 2 minutes, paying special attention the gaps, blind holes, linges and plints. When cleaning, use brushes and perform multiple reciprocating movements on the surface of the product. When cleaning, use brushes and perform multiple reciprocating movements on the surface of the product for debris and impurity. Repeat the steps described in subsections of huntil the product is visually bean.

 Ultrasound cleaning prepare an aqueues deaning solution at a temperature of 40 +/- 2°C and pil of 10.4-10.8 (follow the information contained in the instructions prepared by the manufacturer of the cleaning agent, in respect of temperature, concentionic, pospour time and vater quality). Immerse fully the product in the aqueous cleaning solution and have it washed in ultrasounds for 1'S minutes.

 Briss the product throughly under demine alized water, paying particular attention to the holes and placed difficult to be cleaned.

- difficult to be cleaned.

 Visually inspect the entire surface of the product for debris and impurity, Repeat the steps described in subsections ck until the product is visually dean.

 Ise deminerables what for final infrasion of the device.

 Dry the device thoroughly using disposable, soft, line-free ofth or compressed air.

 Pepare an aqueous ostulion of disinfricing agent at a temperature of 20+2-72 using 20g of the apent per I liter of water. Immerse the product in the solution, exposure time 15min (foliour the information notation of the intervations proposed by the manufacture of the agent, in respect of temperature, concentration, exposure time intervations produced by the manufacture of the depart, in respect of temperature, concentration to the holes and places difficult to be cleaned.

 Here describes time, rises the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.

 The cannabilated information somewhat the product thoroughly under demineralized under, paying particular attention to the holes and places difficult to be cleaned.
- tion to the interest and interest without to the cannet.

 The cannulated instruments should be treated using a compressed air or air supplied from the syringe.

 Dry the device thoroughly. It is recommended to dry the product in a dryer at a temperature ranging from 90°C to 110°C.
- c. ect the entire surface of the device.

- 1) Misually inspect the entire surface of the device.
 2) Auxiliary like the obstruction in the cannula cannot be removed as indicated in the Instructions for Use, the device should be entouched entire and in the surface of the device should be descarded in accordance with facility procedures and quidelines.
 3) The automated method using a washer disinfector.
 3 Equipment and materials a washer disinfector, auguous solutions of cleaning agent.
 3) Equipment and materials as washer disinfector, auguous solutions of cleaning agent.
 4) Cleaning in the washer-disinfector must be preceded by a manual and ultrasound cleaning, following the procedure device file in subsections 6 or 16 paragraph 5.
 4) CAUTION: The equipment used for washing distinienction should meet the requirements of 150 1583. 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 washinon-disinfection acent manufacturer.
- recommendations of the washer-disinfector manufacturer, and instructions for use prepared by the washing-disinfecting agent manufacturer.
 The device should undergo the process of machine washing in the washer-disinfector using the following
 cycle parameters: [7] per-washing in rold tap water, duration 2 min; [2] woshing in an aqueous solution of cleaning agent at 55+1-27 and pl of 10.4 10.3, duration 10min; [3] rinsing under demineralized water, duration 2 min; [4] thereof addinection in demineral-lead water at your commendation of the processing of the processi

- The 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:
- All parts of the products hould be checked to visible dirt and corrosion. Particular attention should be paid to:
) follows, growers and ages the debits outlink have been pressed into during use.
) Places where dirt can be found, such as joints, latches, etc.
 Generally ummanglink visual inspection under good light conditions is sufficient.
 Each time before re-use and re-sterilization, the functional check of the product should be performed, consist-
- ng or: Verifying the connections in the mating instruments, such as tips, shafts and quick coupling devices.

-) Verifying the connections in the malting instruments, such as tips, shafts and quick coupling devices.)
) Verifying the correct functioning of mechanisms e, as cover which span mechanism, etc.
) Verifying all rotating devices for staippiness of this can be simply achieved by rolling the device on a flat surface.)
) Verifying cutting deeps for shappense.
) Verifying instruments for damage to material structure (racks, dents, peek, etc.).
 Damaged or defective product cannot be approved for further use.
 Prior to storage, the instrument must be checked for dryness.
 CUITION:

 OLIVION:

 The CMIS p.z. oa. obes not define the maximum number of uses appropriate for re-usable medical instruments. The useful lifle 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.

 1) The manufacturer does not recommend using any preservatives on medical devices.
- .Packaging 1) Washed and dried devices shall be stored (if possible) in suitable stands placed in special sterilization cont-ers Separate items should be packed in a packaging intended for the recommended steam sterilization. S revisited and one eurorities share the source physiosoper in standards saming patient in special semination containers. See parate litera should be packed in packaging interioded for the recommended steam sterilization containers, item packaging and packaging process itself have to meet the requirements of 150 11607 standards. The packaging proceedure must be performed in controlled purity conditions. The deview must be packed so that during its removal from the packaging, when used, there is no risk for its re-contamination utilization.
- Jewased, 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 engosue time: 7 min,
 c) minimum drying time: 20 min.
 7 (AIIITON)

- c) minimu
 2) CAUTION:
- n process must be validated and routinely monitored in accordance with the requirements of
- EN ISD 17665-1.

 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° (where SAL stands for Sterility Assurance Level).

 Device must not be sterilized in the packaging in which it was delivered, except specially designed sterilizations.
- tion contains the control of the con

6 STORAGE

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 (*inick or dull)* and/or initiation of corrosion centers. Instruments should be stored in a deam and dry room, at room temperature and of the direct surgificial, if pos-sible, instruments should be stored in suitable palettes placed into specially designed sterilization containers.

7 CALIBRATION

Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments an tory-calibrated, the nominal torque of a calibrated instrument is marked on the device (e.g. 4 Nm). To mai

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 con-struction or factory setting of the torque devices can lead to a potential injury or damage to the product and is prohibited.

1.CMM 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 insurment set that is designed for particular implant systems, 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 ex-

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

IFU-I-001/06.18; Date of verification: June 2018

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



AON \triangle Caution - Ostrzeżenie - Осторожно - Advertencia - Vorsicht - Varování - Avvertenza

Sterilized using irradiation - Sterylizowany przez napromieniowanie - Радиационная стерилизан Esterilizado mediante radiación - Sterilisiert durch Bestrahlung - Sterilizovat zäřením - Sterilizzato mediante irradiazione STERILE R

Sterlized using hydrogen peroxide - Sterylizowany naddlenkiem wodoru - Crepunusosau nepenucao aogopoga - Esterilizado con perioxido de hidrógeno - Sterlisiert mit Wasserstoffperoxid - Sterlizováno s peroxidem vodíku - Sterilizzato mediante perossido di idrogeno STERILE VH202 Catalogue number - Numer katalogowy - Howep no xaran Katalogové číslo - Numero di catalogo REF LOT Batch code • Kod partii • Код партии • Código de lote • Chargennui mer • Číslo šarže • Codice del lotto Mat: Material - Materiał - Material - Material - Material - Material Qty:

Use hy « Użyć do » Mcnonsangars, no » Usar antes de » Verwenden his » Použite do » Da utilizzare entro il

Manufacturer: ChM sp. z o.o.

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