ISO 9001/ ISO 13485

CE 0197

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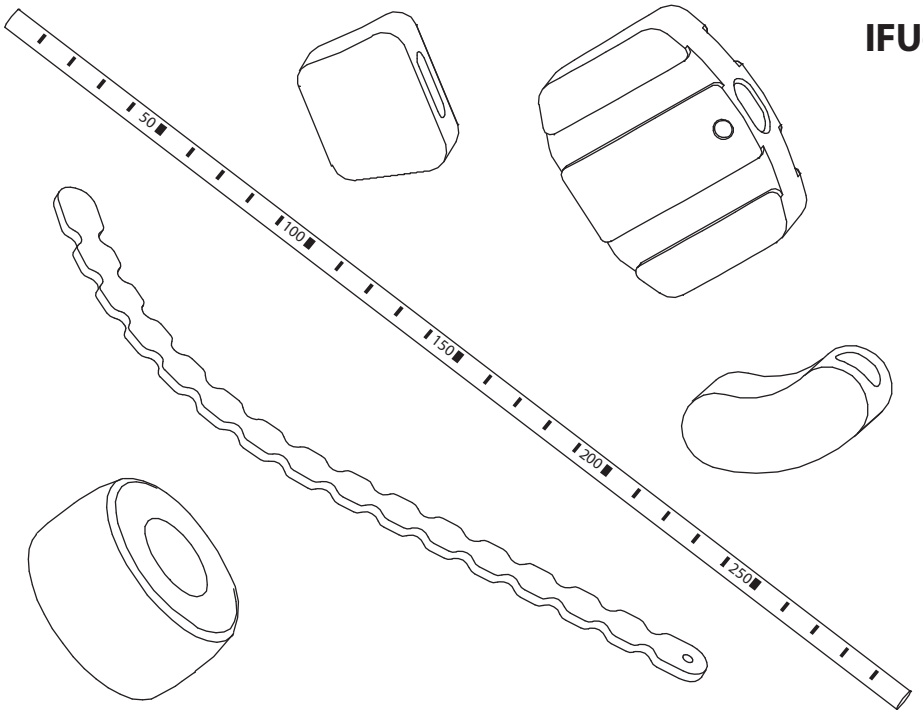

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INSTRUCTIONS FOR USE

Important product information for

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

TRIALS

1 INDICATIONS

1. Trials function differently depending on the operated segment of the human skeleton. **ChM** sp. z o.o. produces the following types of trials:
   1) Trials for spine intervertebral cages
   a) Cages trials are used for the initial assessment of the size of the intervertebral space in order to facilitate the selection of the proper implant size *(the intervertebral cage)* in spine intervertebral stabilization procedures.
   2) Trials for sterno-costal plate

a) Plate trials are used for initial rough assessment of the size and shape of the patient's chest in order to facilitate the selection of the proper implant size *(sterno-costal plate)*, and for the initial determination of the shape of the implant to match the shape of the chest, in the treatment procedures for the chest deformity.

3) Trials for plates

a) Plate trials are used for determination of length and/or shape of the implant *(plate)* to match the implantation site and the type of fracture/correction.

4) Trials for rod

a) Rod trials are used for initial rough assessment of the size and shape of the rod and to facilitate the selection of the proper size of the spinal rod, in the spinal stabilization procedures using transpedicular screws.

5) Trials for nails

a) Nails trials are used for the proper implant selection. They are used to reflect the initial curvature of the bone or initial assessment of the nail length.

6) Trials for head of radial head prosthesis

a) Head trials are used as *"duplicates"* of head prosthesis in the initial phase of the surgery. Test fitting of the diameter and height of the head allows for intraoperative selection of proper implant size.

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

2 DESCRIPTION

1. The unit package contains one piece of the product in non-sterile condition. Clear plastic bags are a typical packaging material. The products may also be supplied as a complete set *(arranged on palettes and placed into specially designed sterilization containers)*. This Instructions For Use is attached both to the unit packages and the sets.
2. The package is equipped with the product label. The label *(as a primary label)* contains, among others:
   1) Logo **ChM** and the address of the manufacturer.
   2) Catalogue number *(REF)*, e.g.: 40.XXXX.XXX, and device name and size.
   3) Production batch number *(LOT)*, e.g. XXXXXXX.
   4) NON-STERILE sign - indicates non-sterile product.
   5) CE conformity mark and the Notified Body number *(0197)*.
   7) Information symbols *(described in the footer of this Instructions For Use)*.
3. Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. *(LOT)*, catalogue no. *(REF)*, trial material, trial size and word *"Trial"*, additionally, the information *"Do not implant"*, which is permanently placed on the surface of the product.

3 MATERIALS

1. Trials are made of: titanium, titanium alloys, stainless steel, aluminum alloys and plastics - mainly PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)* and silicone. These materials are approved for production of surgical instruments in accordance with applicable procedures.
2. Instruments manufactured from titanium and its alloys are characterized by: high strength, small weight and high resistance to corrosion. Their surfaces are anodized.
3. Devices made of aluminum form protective oxide layer on their surface as a result of electrochemical treatment. The surface may be dyed or stays in natural colour *(dark grey)*.
4. Devices made of aluminium with processed layer have good corrosion resistance. However, the contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminium surface, shall be avoided.
5. If the material of the device cannot be specified, please contact **ChM** sp. z o.o. representative.

4 WARNINGS AND PRECAUTIONS

1. Instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.
2. Improper, careless and inconsistent with the recommendations provided below handling of the instruments can lead

to their chemical, electrochemical or mechanical damage which can adversely affect corrosion resistance and shorten the service life of the devices.

3. The surgeon should be familiar with all components of the device before use and should personally verify if all components and instruments are present before the surgery begins.
4. Tissue structures close to the operative site must be protected.
5. Collision of the instrument with metal operating equipment, retractor or other device may cause damage that necessitates intraoperative replacement of that instrument.
6. Do not apply excessive force when using the instrument – it may lead to its permanent damage and, in consequences, to mal-function of the device.
7. Deformable trials *(e.g. plate, rod trials)* have limited lifetime which depends on, e.g. the degree of deformation applied, the number of bendings performed, etc. The breakage of the instrument should be considered the end of the product lifetime.
8. Instruments are subject to constant wear processes. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive forces are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed. Should breakage occur, the instrument parts must be removed and disposed of immediately in accordance with valid medical facility procedures.
9. In order to confirm the removal of all undesired metal fragments from the surgical field, intraoperative X-Ray examination is recommended.
10. Instruments are intended only for specific procedures and must be used strictly according to their intended purpose. Use of instruments not in accordance with their intended purpose may lead to malfunction, accelerated wear and, in consequences, damage to the instrument.
11. Use of trials manufactured by **ChM** together with implants and instruments manufactured by other companies may lead to incorrect readings, damage or destruction of trials or implants/instruments and improper course of surgery and healing process.
12. Instrument which had contact with tissues or body fluids of another patient cannot be re-used prior to its reprocessing due to a potential risk of cross-infection caused by viruses, bacteria and prions.
13. 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.

5 CLEANING, DISINFECTION, STERILIZATION

1. Prior to use of a non-sterile device, the following rules apply:
   1) The device must undergo cleaning, disinfection and sterilization procedures.
   2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning *(manual, automated)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process, etc.
   3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.
2. Preparation at the place of use.
   1) Immediately after use, remove from instrument blood and other contaminants with disposable cloth or paper towels. Additionally, it is recommended to rinse the instrument under running water or to place it in the aqueous disinfectant solution. Do not let blood, tissues, body fluids or other biological impurities dry out on the surface of the device.
   2) In order to prevent blood and debris from drying out on the instrument surface, transport the product to the processing area in a closed container or covered with a damp cloth.
   3) In order to avoid contamination during transportation, the dirty instruments should be separated from the clean ones.
3. Preparation for washing and disinfection *(for all methods)*.
   1) The used instruments should be reprocessed as soon as possible.

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

4. Cleaning and disinfection process.

1) This Instructions for Use describes two **ChM**-approved cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated cleaning and disinfection procedures *(in a washer-disinfector)*.
2) The chosen washing and disinfecting agents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. **ChM** used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:
a) detergent - Dr.Weigert *(producer)* neodisher® MediClean forte *(name of the detergent)*;
b) disinfectant - Dr.Weigert *(producer)* neodisher® Septo Active *(name of disinfectant)*.
3) To prevent product damage *(pitting, rust, discoloration)*, do not use aggressive cleaning agents *(NaOH, NaOCl)*, saline solutions and unsuitable cleaning agents.
4) Where possible, it is recommended to use demineralized water to avoid the formation of spots and stains caused by chlorides and other compounds present in ordinary water.
5) Manual with ultrasound cleaning.
a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, syringes, aqueous solutions of cleaning agent.
b) Manual cleaning: Initial manual cleaning must be performed prior to ultrasound cleaning.
c) Rinse under running water until the product is visually clean. Use plastic brushes to remove heavy or large debris.
d) Soak the product for at least 10 minutes in an aqueous solution of a detergent at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
e) Rinse the product under cold water for at least 2 minutes, paying particular attention to the holes and places difficult to be cleaned.
f) Prepare fresh washing solution. Clean the surfaces and gaps of the product, carefully. Use suitable brushes to clean the holes. Clean the product immersed in the solution.
g) Rinse the product thoroughly under warm running water for at least 2 minutes, paying special attention to the gaps, blind holes, hinges and joints. When cleaning, use brushes and perform multiple reciprocating movements on the surface of the product.
h) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-h until the product is visually clean.
i) Ultrasound cleaning: prepare an aqueous cleaning solution at a temperature of 40 +/- 2°C and pH of 10.4 - 10.8 *(follow the information contained in the instructions prepared by the manufacturer of the cleaning agent, in respect of temperature, concentration, exposure time and water quality)*. Immerse fully the product in the aqueous cleaning solution and have it washed in ultrasounds for 15 minutes.
j) Rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
k) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-k until the product is visually clean.
l) Use demineralized water for final rinsing of the device.
m) Dry the device thoroughly using disposable, soft, lint-free cloth or compressed air.
n) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/-2 °C using 20g of the agent per 1 liter of water. Immerse the product in the solution, exposure time – 15min *(follow the information contained*

in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality).

o) After the exposure time, rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
p) The cannulated instruments should be treated using a compressed air or air supplied from the syringe.
q) Dry the device thoroughly. It is recommended to dry the product in a dryer at a temperature ranging from 90°C to 110°C.
r) Visually inspect the entire surface of the device.
s) CAUTION: If the obstruction in the cannula cannot be removed as indicated in the Instructions for Use, the device should be considered at the end of its useful life and should be discarded in accordance with facility procedures and guidelines.

6) The automated method using a washer - disinfector.
a) Equipment and materials: a washer - disinfector, aqueous solutions of cleaning agent.
b) Cleaning in the washer-disinfector must be preceded by a manual and ultrasound cleaning, following the procedure described in subsections c-h of paragraph 5.
c) CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883. Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washer-disinfector manufacturer, and instructions for use prepared by the washing-disinfecting agent manufacturer.
d) The device should undergo the process of machine washing in the washer-disinfector using the following cycle parameters: *(1)* - pre-washing in cold tap water, duration – 2min; *(2)* - washing in an aqueous solution of cleaning agent at 55+/-2°C and pH of 10.4 - 10.8, duration – 10min; *(3)* - rinsing under demineralized water, duration – 2min; *(4)* - thermal disinfection in demineralised water at 90°C, minimal duration – 5min; *(5)* - drying at the temperature ranging from 90°C to 110°C, duration - 40min.

9. Inspection

1) Each time before re-use and re-sterilization, all medical devices should be inspected.
2) All parts of the product should be checked for visible dirt and corrosion. Particular attention should be paid to:
a) Places where dirt can be found, such as joints, latches, etc.
b) Holes, grooves and gaps the debris could have been pressed into during use.
3) Generally unmagnifed visual inspection under good light conditions is sufficient.
4) Each time before re-use and re-sterilization, the functional check of the product should be performed, consisting of:
a) Verifying the connections in the mating instruments, such as tips, shafts and quick coupling devices.
b) Verifying the correct functioning of mechanisms, e.g. screw, ratchet, snap mechanism, etc.
c) Verifying instruments for damage to material structure *(cracks, dents, peels, etc.)*.
5) CAUTION:
a) The **ChM** sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful and proper use reduces the risk of damage to the product and extends its serviceable life.
b) The manufacturer does not recommend using any preservatives on medical devices.
6) Damaged or defective product cannot be approved for further use.
7) When verifying the condition of the rod trials, care must be taken to ensure that the continuity of the silicone coating is maintained. In the case of damage *(e.g. cuts or defects expose the metal core)*, the device should be considered at the end of its useful life and should be discarded in accordance with facility procedures and guidelines.
8) Prior to storage, the instrument must be checked for dryness.

10. Packaging

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

11. Sterilization

1) Washed, disinfected, and dried device shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:

a) temperature: 134°C,
b) minimum exposure time: 7 min,
c) minimum drying time: 20 min.

2) CAUTION:

a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.
b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
c) Device must not be sterilized in the packaging in which it was delivered, except specially designed sterilization containers.
d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains sterilization recommendations using these methods.
e) The sterilization temperature for plastic products *(PPSU, PEEK, PTFE, silicone)* cannot be higher than 140°C.

6 STORAGE

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

7 COMPATIBILITY

1. Trials are compatible with adequate implant systems of **ChM** sp. z o.o. production. It is not allowed to use products manufactured by **ChM** sp. z o.o. with products from other manufacturers. This is the physician who takes responsibility for the use of instruments from other manufacturers.

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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