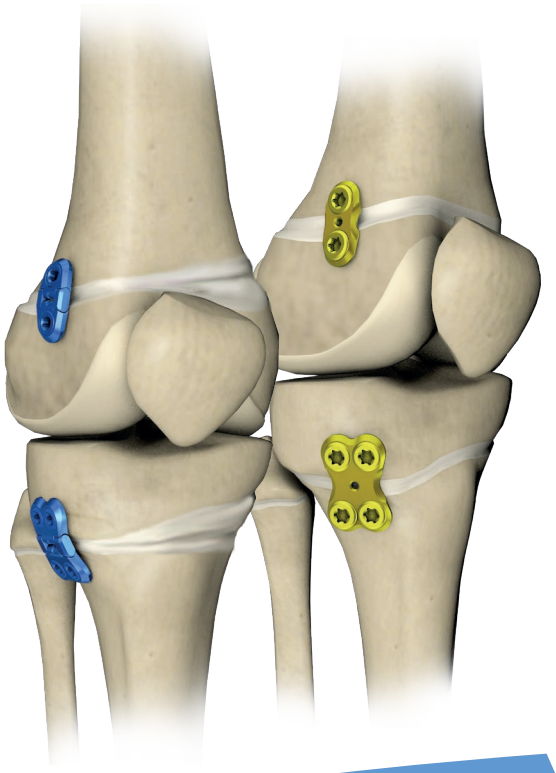
ST/80-702

ChM®

7,0 ChM Locked Plating ChLPsystem

7.0ChLP HEPI plates
3.7098; 3.7099; 3.4159

- *IMPLANTS*
- *INSTRUMENT SET*
- *SURGICAL TECHNIQUE*



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SYMBOLS DESCRIPTIONS

Ti	Titanium or titanium alloy	H	H length [mm]
Co	Cobalt		Angle
L	Left	88 - 340	available lengths
R	Right	4-22	Available number of holes
L R	Available versions: left/right	1.8	Thickness [mm]
Len	Length	1:1	Scale 1:1
	Torx drive		Number of threaded holes in the shaft part of the plate
	Torx drive cannulated		Number of locking holes in the plate
	Hexagonal drive	VA	Variable angle
	Hexagonal drive cannulated	C	Cortical
	Cannulated		Cancellous
	Locking	Ster Non Ster	Available in sterile/ non- sterile condition
	Diameter [mm]		See surgery technique

	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Information about the next stages of the proceeding.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use supplied with the product. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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The manufacturer reserves the right to introduce design changes.

1. INTRODUCTION

This surgical technique applies to plates used for correction of the angle deformity of long bones by inhibiting longitudinal growth of the physis. The plates are a part of the ChLP locked plating system developed by **ChM**. The presented range of implants is made of materials in accordance with ISO 5832 standards. Compliance with the requirements of quality management systems and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

The system includes:
- implants *(plates and screws)*,
- instrument set used in the surgery,
- surgical technique.

Indications

Angular deformity of long bones of upper and lower limbs in patients with active epiphyseal plate.

Plate selection and shaping

The plates are available in different variants of screw holes spacing. This allows for optimal selection of the implant to the deformity type.
Shaping of the plates is not allowed.

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.

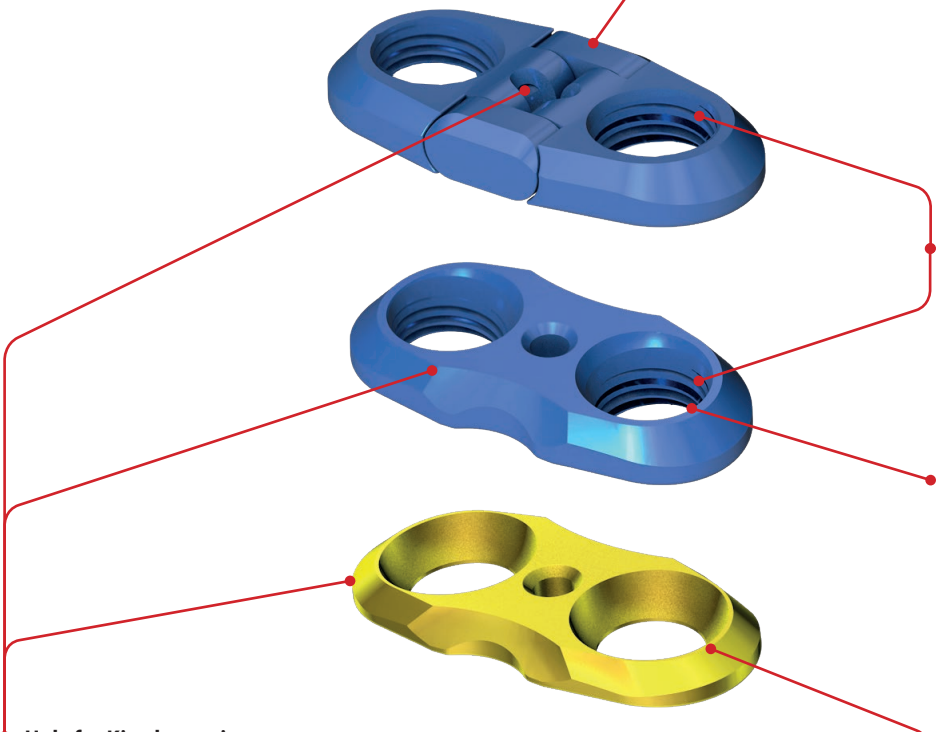
The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

2. IMPLANT FEATURES

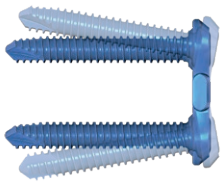
HEPI plates are compatible with screws of 7.0ChLP system. To facilitate the identification, both locking plates and screws are blue anodized, whereas non-locking plates and screws are gold anodized.

Available plates versions

	Two-hole plate	Four-hole plate
hinged locking version **3.7098**		
non-hinged locking version **3.7099**		
non-locking version **3.4159**		

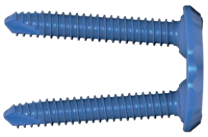


Articulation mechanism:
- the plate fits the bone shape at the implantation site.



Locking hole design:
- the screws heads do not protrude above the surface of the plate what significantly reduces the irritation of periimplant tissues,
- increased strength of the screw-to-plate threaded connection,
- bottom protrusion reduces surface area of the contact with the bone..

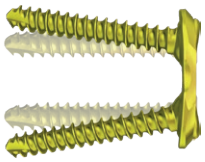
Multi-directional locking screws positioning:
- facilitated screws positioning in relation to the epiphyseal plate.



Hole for Kirschner wire:
- easier plate positioning,
- temporary plate stabilization.

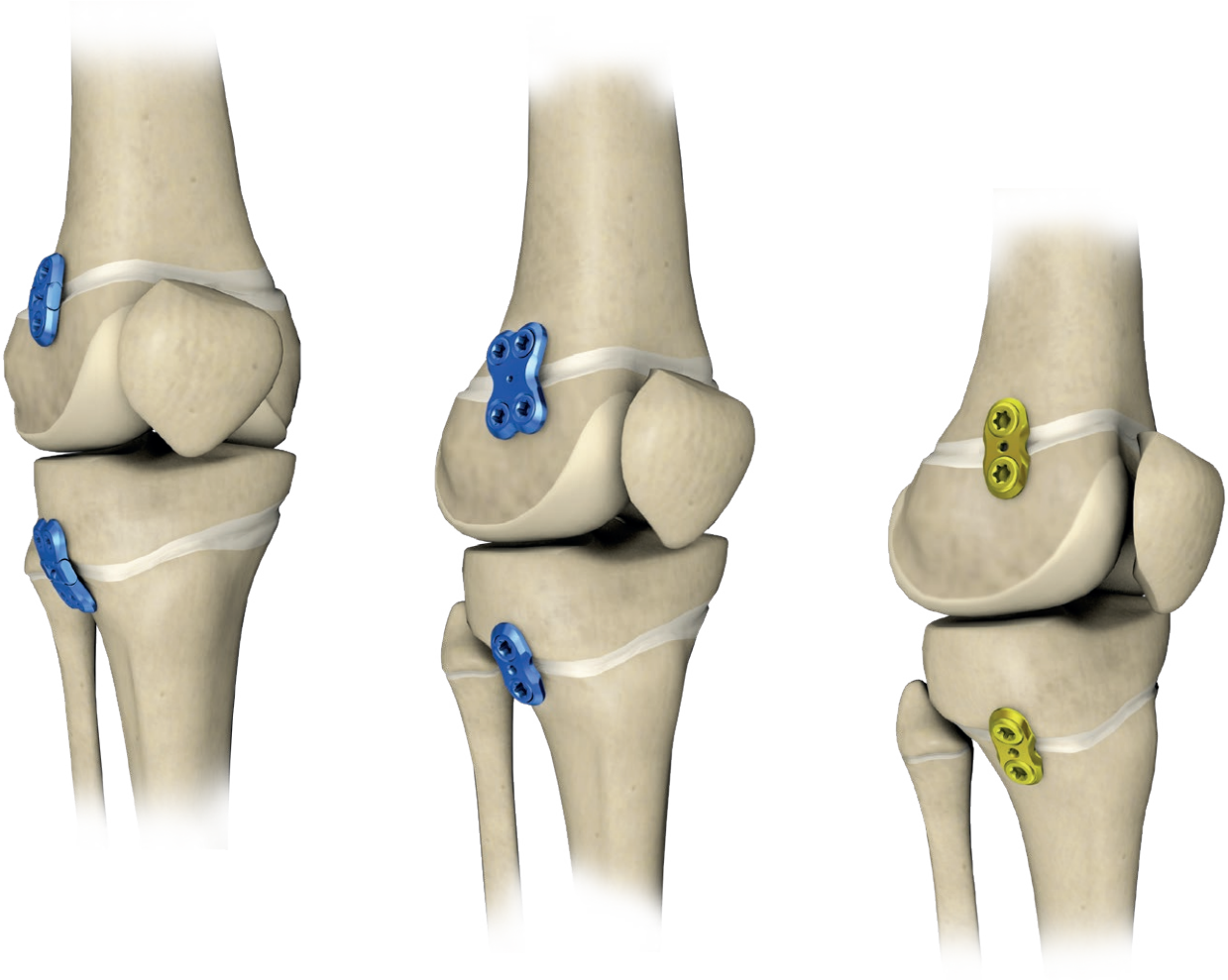
Non-locking hole:
- the screws can be inserted at a chosen angle.

Plate design:
- anatomical profile fits the bone structure.



Beveled profile of the plate's upper edge:
- limited soft tissue irritation.

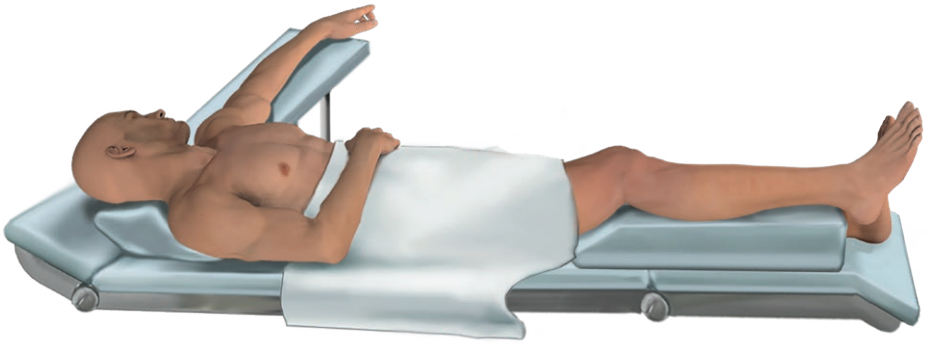
7.0ChLP HEPI plate



3. SURGICAL TECHNIQUE

3.1. PATIENT'S POSITIONING

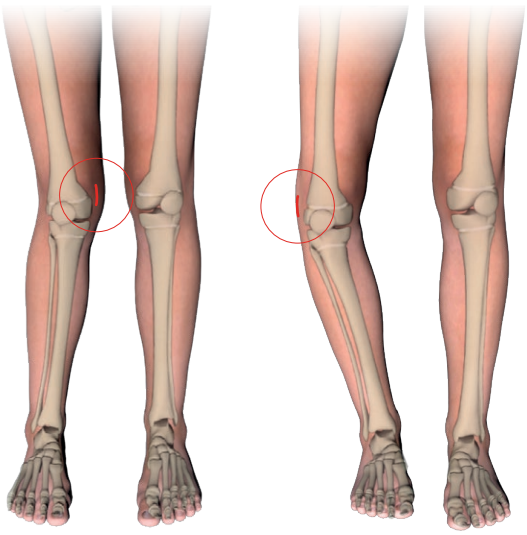
It is recommended to place the patient supine.



3.2. SURGICAL APPROACH

The surgical approach depends on the type and location of the deformity. Perform a longitudinal skin incision of approx. 2-3 cm above the epiphyseal plate. Retract the tissues to expose the implantation site.

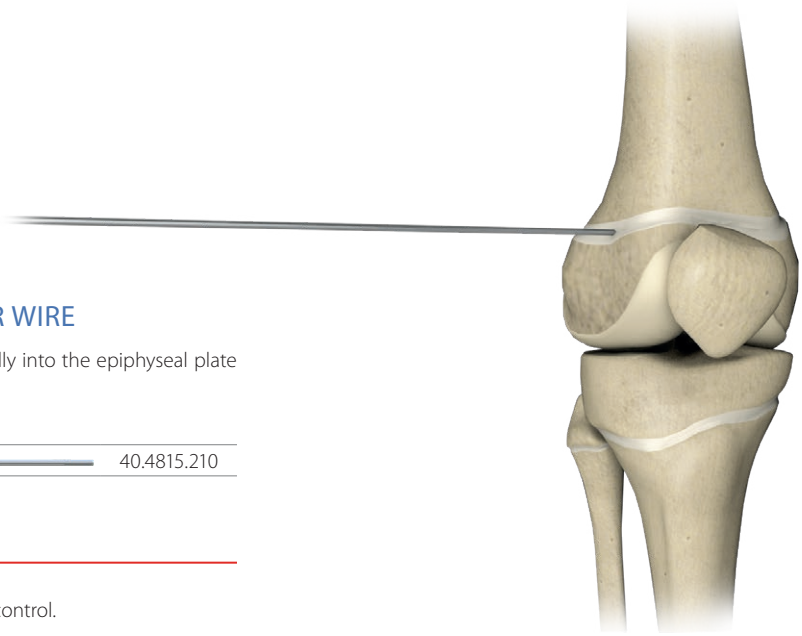
NOTE: confirm the activity and location of the epiphyseal plate using X-Ray imaging.



3.3. IMPLANT SELECTION

Select the right size of an implant to the anatomical bone structure.

The length of the plate should allow insertion of screws above and below the epiphyseal plate.



3.4. INTRODUCTION OF KIRSCHNER WIRE

Insert Kirschner wire 2.0/210 **[40.4815.210]** centrally into the epiphyseal plate to a depth of approx. 1 cm.

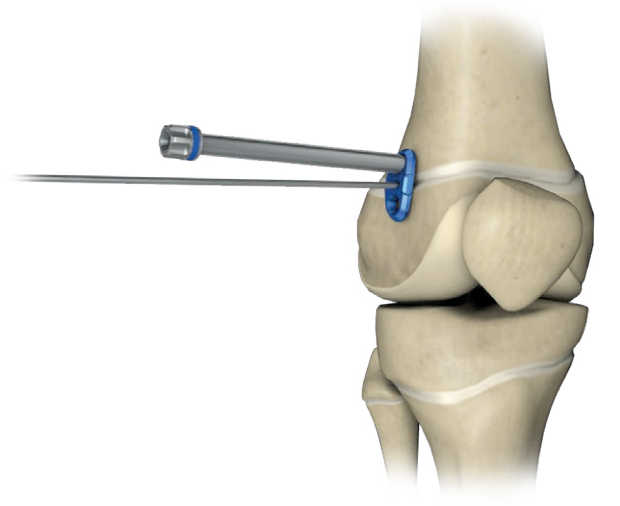
40.4815.210

NOTE: introduce the wire under X-Ray control.

3.5. PLATE INSERTION

Implant the chosen plate using the Kirchner wire.

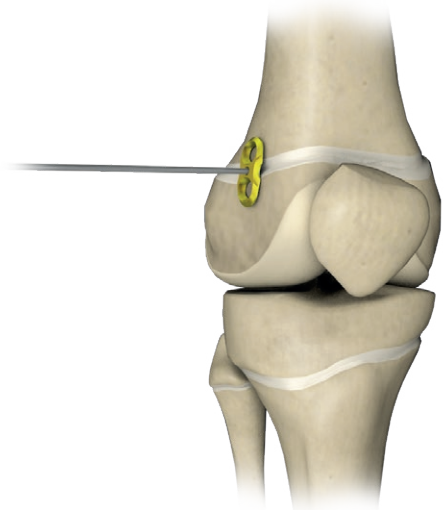
3.5a. LOCKING PLATE INSERTION



40.4815.210

40.5705.740

3.5b. NON-LOCKING PLATE INSERTION



40.4815.210

To facilitate plate insertion, enter the guide sleeve 7.0/4.0 **[40.5705.740]** into the plate locking hole and then both onto the bone using Kirschner wire 2.0/210 **[40.4815.210]**.

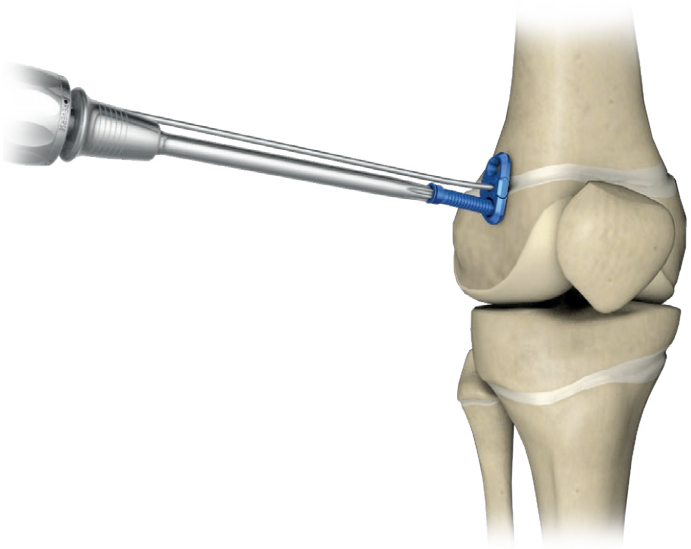
3.6. SCREWS INSERTION

Make sure the screws do not interfere with the epiphyseal plate and the articular surface.

3.6a. INTRODUCTION OF SCREWS TO A LOCKING PLATE

Insert 7.0ChLP self-tapping screws 5.0 **[3.5210]** of appropriate length into the holes of the locking plate *(acc. to procedure 4a)*. Use X-Ray imaging to verify the correct positioning of the plate and screws.

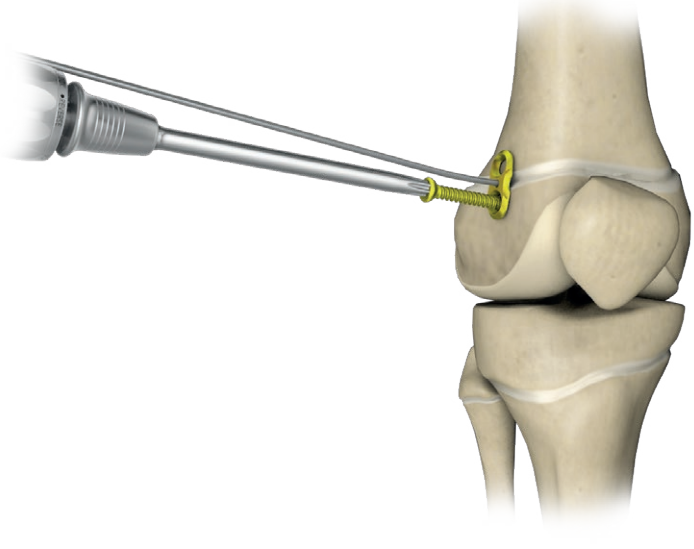
Remove the Kirschner wire.



3.6b. INTRODUCTION OF SCREWS TO A NON-LOCKING PLATE

Insert cortical self-tapping screws 4.5 **[3.1471]** of appropriate length into the holes of the plate *(acc. to procedure 4b)*. Use X-Ray imaging to verify the correct positioning of the plate and screws.

Remove the Kirschner wire.



3.7. WOUND CLOSURE

Before closing the wound, take X-Ray images in at least two projections to confirm implant position. Make sure all the screws are properly tightened.

Use appropriate surgical technique to close the wound.

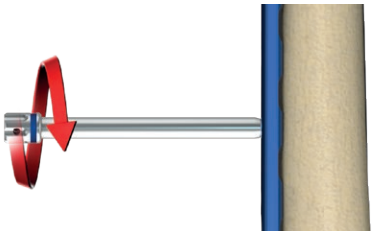
4. SURGICAL PROCEDURES

4a. PROCEDURE OF 7.0ChLP SELF-TAPPING SCREW 5.0 [3.5210] INSERTION

Guide sleeve insertion

- Insert guide sleeve 7.0/4.0 **[40.5705.740]** into a locking hole of the plate.

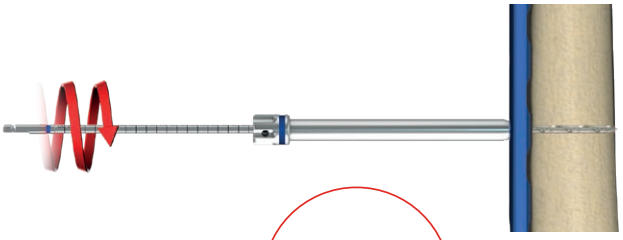

40.5705.740



Hole drilling

Drill using drill with scale 4.0/210 **[40.5651.212]** until desired depth is reached.

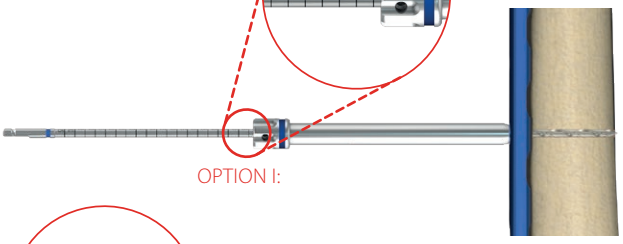
40.5653.212



Measurement of hole depth

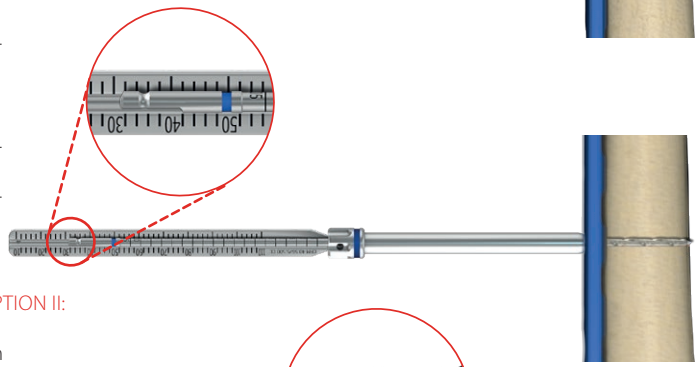
OPTION I: Read the length of the screw from the drill measure **[40.5651.212]**

40.5651.212


OPTION I:

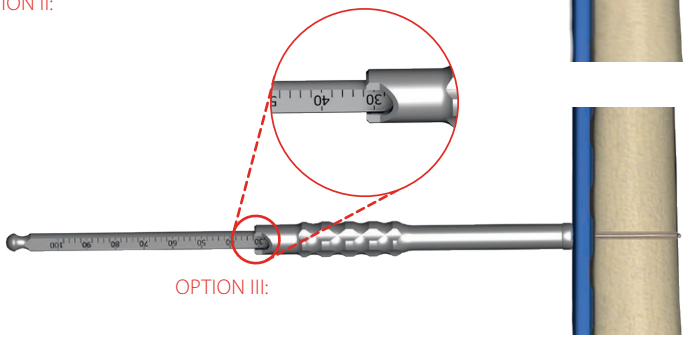
OPTION II: or use screw length measure **[40.5675.500]**.


40.5675.500


OPTION II:

OPTION III: Having removed the guide sleeve 7.0/4.0 **[40.5705.740]**, use depth measure **[40.4639.550]** to determine the length of a screw.


40.4639.550

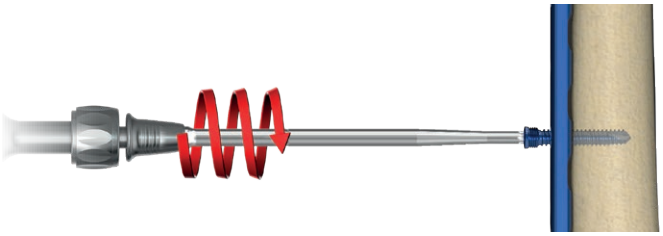

OPTION III:

Screw insertion

Remove the guide sleeve 7.0/4.0 **[40.5705.740]**. Use torque limiting ratchet handle 4Nm **[40.6660.000]** and screwdriver tip T25 **[40.5684.200]** to insert the locking screw.


40.6660.000


40.5684.200

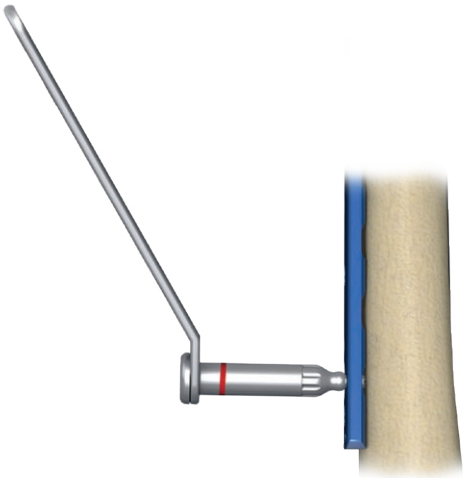


4b. PROCEDURE OF CORTICAL SELF-TAPPING SCREW 4.5 **[3.1471]** INSERTION

Compression guide positioning

Position the compression guide 3.2 **[40.4802.732]** in a desired position:

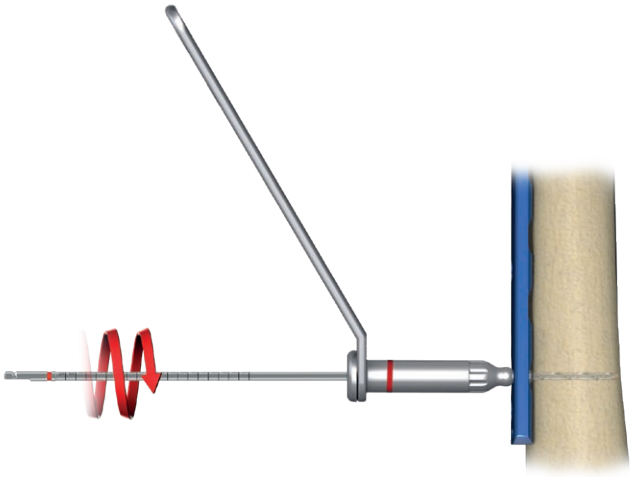
40.4802.732



Hole drilling

Perform a hole through both cortices for a cortical screw 4.5 insertion. For drilling, use drill with scale 3.2/210 **[40.5650.212]** and compression guide in a desired position.

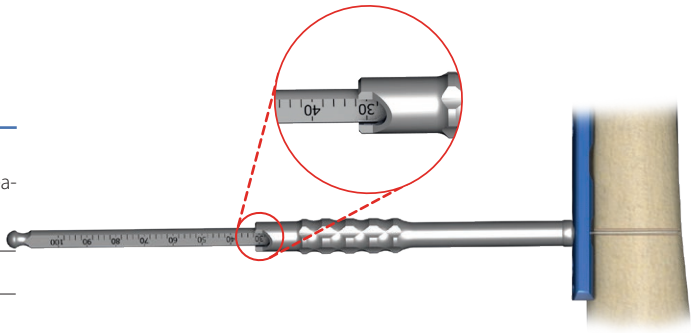
40.5650.212



Measurement of hole depth

Insert depth measure **[40.4639.550]** into drilled hole until the hook of the measure rests against the outer surface of the second cortex.

40.4639.550

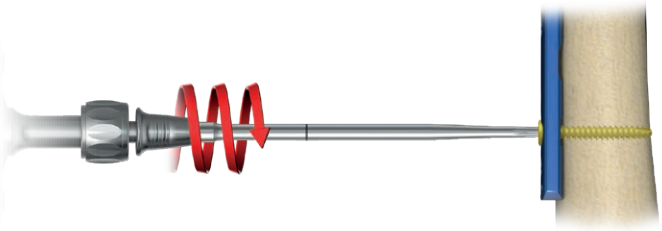


Screw insertion

Insert cortical screw using torque limiting ratchet handle 4Nm **[40.6660.000]** and screwdriver tip T25 **[40.5684.200]**.

40.6660.000

40.5684.200



5. POSTOPERATIVE PROCEDURE

Introduce appropriate post-operative treatment. The physician decides on the post-operative treatment and its conduct.

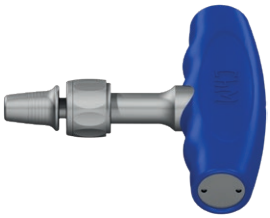
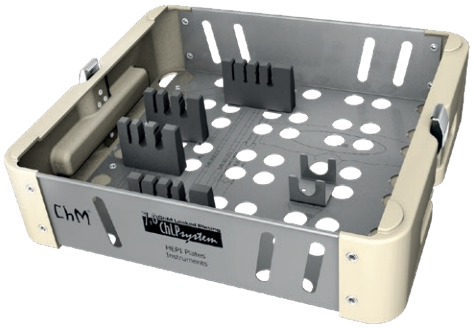
6. IMPLANT REMOVAL

The physician decides about implant removal. In order to remove the locking plate from the body, unlock all the locking screws first and then remove them from the bone. This will prevent any rotation of the plate when removing the last locking screw.

7. CATALOGUE PAGES

7a. INSTRUMENT SET

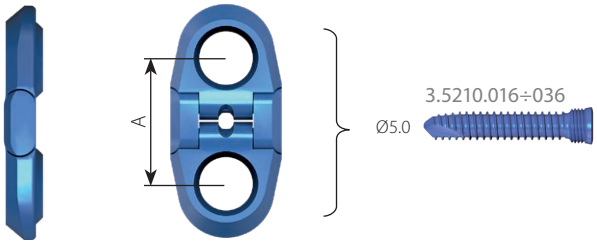
Instrument set for 7.0ChLP 3.7098/7099/4159 4x4H **15.0207.105**

	Name	Catalogue No.	Pcs
	Guide sleeve 7.0/4.0	**40.5705.740**	2
	Compression guide 3.2	**40.4802.732**	1
	Kirschner wire 2.0/210	**40.4815.210**	4
	Drill with scale 4.0/210	**40.5651.212**	2
	Drill with scale 3.2/210	**40.5650.212**	2
	Depth measure	**40.4639.550**	1
	Screwdriver tip T25-1/4	**40.5684.200**	1
	Torque limiting ratchet handle T 4Nm	**40.6660.000**	1
	7.0ChLP container lid 3.7098/7099/4159 4x4 H	**14.0207.106**	1
	7.0ChLP container 3.7098/7099/4159 4x4 H	**14.0207.105**	1

7.0ChLP HEPI plate 2hol.

O	A [mm]	Catalogue No.
2	12	3.7098.112
2	16	3.7098.116
2	20	3.7098.120

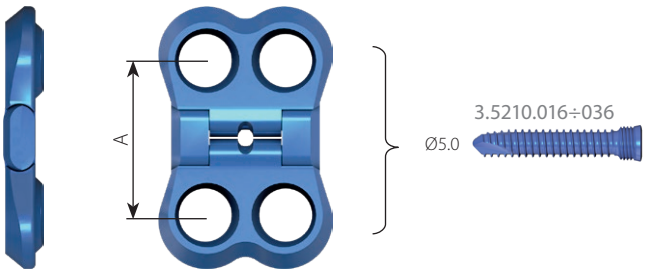
O – threaded holes number

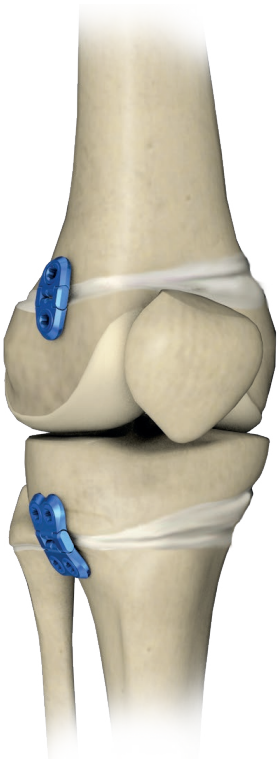


7.0ChLP HEPI plate 4hol.

O	A [mm]	Catalogue No.
4	16	3.7098.216
4	20	3.7098.220

O – threaded holes number

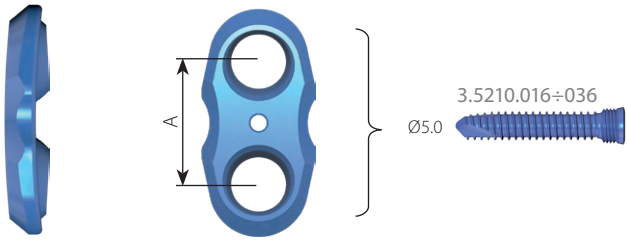




7.0ChLP HEPI plate 2hol.

O	A [mm]	Catalogue No.
2	12	3.7099.112
2	16	3.7099.116
2	20	3.7099.120

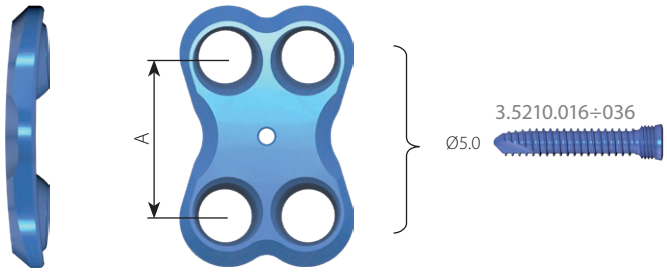
O – threaded holes number

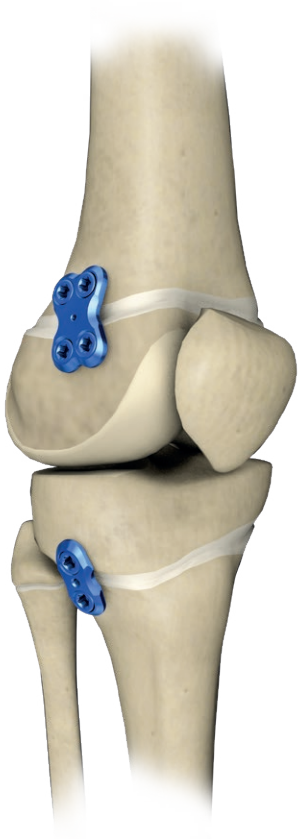


7.0ChLP HEPI plate 4hol.

O	A [mm]	Catalogue No.
4	16	3.7099.216
4	20	3.7099.220

O – threaded holes number

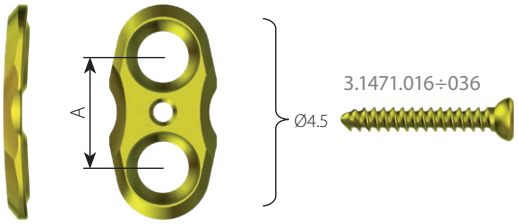




HEPI plate 2hol.

O	A [mm]	Catalogue No.
2	12	3.4159.112
2	16	3.4159.116
2	20	3.4159.120

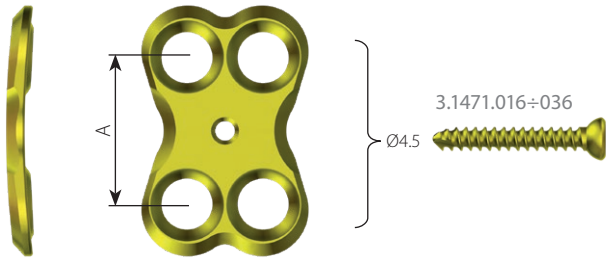
O – screws holes numer

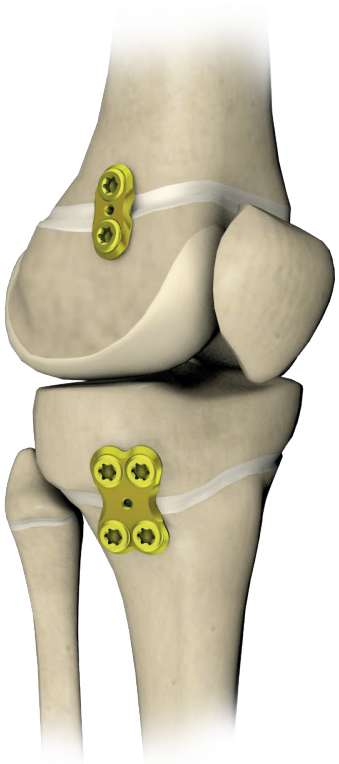


HEPI plate 4hol.

O	A [mm]	Catalogue No.
4	16	3.4159.216
4	20	3.4159.220

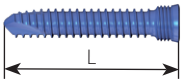
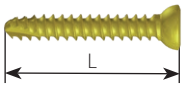
O – screws holes numer





Stand for 7.0ChLP implants 3.7098/7099/4159 4x2H

14.0207.601

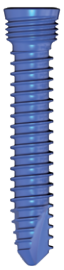
7.0ChLP HEPI plate 2hol.						
7.0ChLP HEPI plate 4hol.						
7.0ChLP self-tapping screw 5.0						
L [mm]	16	20	24	28	32	36
Pcs	4	4	4	4	4	4
HEPI plate						
Cortical self-tapping screw 4.5						
L [mm]	16	20	24	28	32	36
Pcs	4	4	4	4	4	4

* Stand does not include implants

7c. SCREWS

Ti | Ster Non Ster

7.0ChLP self-tapping screw 5.0



Len	Ti
16	3.5210.016
18	3.5210.018
20	3.5210.020
22	3.5210.022
24	3.5210.024
26	3.5210.026
28	3.5210.028
30	3.5210.030
32	3.5210.032
34	3.5210.034
36	3.5210.036

Cortical self-tapping screw 4.5

Len	Ti
16	3.1471.016
18	3.1471.018
20	3.1471.020
22	3.1471.022
24	3.1471.024
26	3.1471.026
28	3.1471.028
30	3.1471.030
32	3.1471.032
34	3.1471.034
36	3.1471.036

8. INSTRUCTIONS FOR USE

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ChM®

CE 0197

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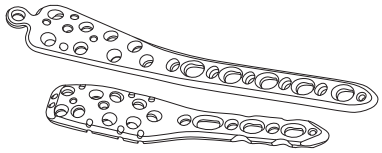
IFU-010/11.18



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INSTRUCTIONS FOR USE

Important product information for

BONE PLATES, SCREWS AND WASHERS

ChM Locked Plating ChLP system | ChM Micro Plates ChMP system | ChM Pelvic System ChARPEL system

1 PURPOSE AND INDICATIONS

1. Bone plates, screws and washers are intended for stabilization and support of bone structure treatment. They are used for treatment of: bone fractures, non-unions, delayed unions, osteotomies, arthrodeses and for the temporary inhibiting of the growth of the epiphyseal plate.
   1) Bone plates are fixed to the bone with the use of bone screws.
   2) Bone screws may be used independently, with bone washers or plates.
   3) Bone washers are used with bone screws.
2. Compatible implants are presented on respective pages in a **ChM** sp. z o.o. catalogue.
3. 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) Pregnancy.
   5) Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care.
   6) 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.
   7) 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*).
   8) Any case not needing a surgical intervention.
   9) Any case not described in the indications.
   10) 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.
   11) Any case where the implant components selected for use would be too large or too small to achieve the successful result.
   12) Any case that requires the simultaneous use of elements from different systems that are made of different metals.
   13) Any case in which implant utilization would disturb physiological processes.
   14) Blood supply limitation in the operative site.
   15) Morbid obesity (*defined according to the WHO standards*).
   16) Any case in which there is inadequate tissue coverage of the operative site.
   17) 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.
   18) Epiphyseal plate closure (*applies for temporary inhibiting of the growth of the epiphyseal plate*).
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) Late bone fusion or no visible fusion mass and pseudoarthrosis.
   17) Loss of proper curvature and/or length of bone.
   18) Bone graft donor site complication.
   19) No correction achieved or overcorrection (*applies for temporary inhibiting of the growth of the epiphyseal plate*).

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. No implant can withstand body loads without the biomechanical continuity of the bone.
5. During normal use all surgical implants are subjected to repeated stresses which can result in material fatigue and failure of the implant.
6. 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.
7. 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.
8. 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.
9. 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.
10. Overweight may cause additional stresses and strains within implant which can lead to fatigue and deformation of the implant.
11. 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.
12. 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.
13. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
14. The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
15. 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.

5 PACKAGING AND STORAGE

1. Implants are single-use devices, provided sterile or non-sterile.
2. Implants not labeled as sterile are non-sterile.
3. Implant packaging must be intact at the time of receipt.
4. The unit package contains:
   1) sterile version - one piece of the product in a sterile condition. A double packaging made of Tyvek-foil or a single blister are typical packaging material.
   2) non-sterile version - one piece of the product. Clear plastic bags are a typical packaging material.
5. A sterility indicator is placed on the sterile package.
6. The package is equipped with the product label. The label (*as a primary label*) contains e.g.:
   1) Sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number (*REF*), e.g.: 3.XXXX.XXX.
      c) Production batch number (*LOT*), e.g. XXXXXXX.
      d) Material of the implant (*see IMPLANT MATERIAL*).
      e) STERILE sign - indicating a sterile device and the sterilization method used, e.g.: R or VH202 (*symbols are described in the footer of this Instructions For Use*).
      f) Sterilization batch number, e.g.: S-XXXXXXX.
      g) Device pictogram and information symbols (*described in the footer of this Instructions For Use*).
      h) Expiration date and sterilization method.
   2) Non-sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number (*REF*), e.g.: 3.XXXX.XXX.
      c) Production batch number (*LOT*), e.g. XXXXXXX.
      d) Material of the implant (*see IMPLANT MATERIAL*).
      e) NON-STERILE sign - indicates non-sterile product.
      f) Device pictogram and information symbols (*described in the footer of this Instructions For Use*).
7. In addition to the device primary label, an auxiliary label with specific market requirements of a given area may be placed on the unit package (*e.g. legal requirements of the country in which the device will be distributed*).
8. The package may contain: Instructions For Use and labels to be placed in a patient's medical record.
9. Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. (*LOT*), catalogue no. (*REF*), type of material and device size.
   1) Additional identification system for the ChLP locking plates has been introduced. On the surfaces of locking plates, an additional feature "*System e.g. 4.0, 4.5, 5.0, 7.0.*" has been placed. It informs that particular screws with head diameters of 4.0, 4.5, 5.0, 7.0. cooperate with particular plates. Additionally, plates and screws included in the system, made of titanium, are coloured: system 4.0 - green, system 4.5 - gold, system 5.0 – brown, system 7.0 - blue.
   2) Additional identification system for the ChMP microplates has been introduced. Plates and basic screws included in the system, made of titanium, are coloured: system 1.2 - blue, system 1.5 - gold, system 2.0 - green, system 2.7 - turquoise.
10. Implants should be stored in appropriate protective packagings, in a clean, dry place with a room temperature and under conditions that provide protection from direct sunlight.

6 IMPLANT MATERIAL

1. Identification of the materials
   1) Depending on the material used, the following symbols may be marked on the device surface:
      a) Steel: symbol (*S*).
      b) Titanium and titanium alloys: symbol (*T*).
      c) Cobalt alloy: symbol (*Co*).
   2) The plates are made of:
      a) Implantable stainless steel.
      b) Implantable titanium or titanium alloy.
      c) Implantable cobalt alloy.
   3) The screws are made of:
      a) Implantable stainless steel.
      b) Implantable titanium alloy.
      c) Implantable cobalt alloy.
   4) The bone washers are made of:
      a) Implantable stainless steel.
      b) Implantable titanium alloy.
   5) Percent composition of elements in the implantable materials (*max. values*):
      a) Steel according to ISO 5832-1/ASTM F138: | C:0.03 | Si:1.0 | Mn:2.0 | P:0.025 | S:0.01 | N:0.1 | Cr:19.0 | Mo:3.0 | Ni: 15.0 | Cu:0.5 | Fe:balance.
      b) Steel according to ISO 5832-9/ASTM F1586: | C:0.08 | Si:0.75 | Mn:4.25 | P:0.025 | S:0.01 | N:0.5 | Cr:22.0 | Mo:3.0 | Nb:0.8 | Ni: 11.0 | Cu:0.25 | Fe:balance.
      c) Titanium according to ISO 5832-2/ASTM F67: | Fe:0.5 | O:0.4 | C:0.1 | N:0.05 | H:0.0125 | Ti:balance.
      d) 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.
      e) 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.
      f) 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) **ChM**'s implants made completely from or containing elements made of implantable steel were not assessed for their safety and compatibility with magnetic resonance imaging procedures. The performance of MRI on these implants (*especially in the magnetic field with a significant induction*) may pose a potential risk of, i.a.:
      a) implant displacement or heating up,
      b) artifacts on MR images.
   2) Implants made of titanium, titanium alloys and cobalt alloys are conditionally compatible with magnetic resonance imaging.
   3) The patient can be scanned safely under the following conditions:
      a) static magnetic field of ≤ 3 Tesla,
      b) maximum magnetic field spatial gradient of ≤ 720 Gauss/cm,
      c) maximum MR system reported whole-body-averaged specific absorption rate (*SAR*) of 3W/kg for 15 minutes of scanning.
   4) CAUTION: the user should be absolutely familiar with the contraindications and warnings established by the manufacturer of the MRI scanner to be used for imaging procedure.
   5) MR imaging may be interfered with if the area of interest is in the exact same area or relatively close to the position of the implant.
   6) Do not perform MRI if there are doubts about the tissue integrity and the implant fixation or if the proper location of the implant is impossible to be established.

7 PRE-OPERATIVE RECOMMENDATIONS

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

8 RECOMMENDATIONS FOR IMPLANTS PROVIDED STERILE

1. Sterile implant - is delivered in sterile packaging, with the inscription: "*STERILE*". Such product is sterile and the manufacturer is responsible for the process of sterilization. The sterilization is performed with the use of one of the following methods:
   1) gamma radiation, with a minimum dose of **25 kGy**,
   2) hydrogen peroxide vapour.
2. The symbol designating the sterilization method used is visible on the device label (*symbols are described in the footer of this Instructions For Use*).
3. Prior to use of a sterile device the following rules apply:
   1) Check out the expiration date of sterilization. Do not use the device with an overstepped sterility date!
   2) Check out if the sterile package is not damaged. Do not use the device if the sterile package is damaged!
   3) Check out the colour of the sterility indicator on the sterile package which indicates that sterilization of the device was performed. Do not use the device if the sterility indicator colour is different than:
      a) red - for devices sterilized with gamma radiation,
      b) blue - for devices sterilized with hydrogen peroxide vapour.
4. CAUTION: products should be removed from their packagings in accordance with aseptic rules.

9 RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE

1. The following recommendations apply to unused non-sterile implants. An implant that has been implanted must not be re-processed and re-used.
2. The implant which has not been used but got contaminated by contact with the blood, tissue and/or body fluids/materials, should not be used again. The implant should be handled in accordance with applicable hospital protocol. **ChM** does not recommend re-processing of contaminated implants. Should the contaminated implant be re-processed, **ChM** bears no responsibility.
3. Prior to use of a non-sterile device, the following rules apply:
   1) The device must undergo cleaning, disinfection and sterilization procedures.
   2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning (*manual, automated*), the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process.
   3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.
4. Preparation for washing and disinfection (*for all methods*)
   1) Prior to cleaning, remove the implant from the original unit packaging. Dispose of the packaging. Protect patient labels, provided with the implant, against accidental loss or damage.
   2) To avoid contamination, the implants should not have contact with the contaminated devices/instruments.
   3) Rinse under running water and remove possible surface dirt (*resulting from e.g.: damage to the unit packaging*) using a disposable cloth, paper towel or plastic brushes (*nylon brushes are recommended*).
   4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the implant.
5. Cleaning and disinfection process
   1) This Instructions for Use describes two validated by **ChM** cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated procedures for cleaning and disinfection (*in the washer-disinfector*).
   2) The chosen washing and disinfecting agents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. **ChM** used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:
      a) detergent - Dr.Weigert (*producer*) neodisher® MediClean forte (*name of the detergent*);
      b) disinfectant - Dr.Weigert (*producer*) neodisher® Septo Active (*name of disinfectant*).
   3) Manual with ultrasound cleaning
      a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, aqueous solutions: of cleaning agent, disinfecting agent or washing – disinfecting agent.
      b) Prepare an aqueous solution of cleaning agent at temperature of 40+/-2 °C and a pH of 10.4 - 10.8 (*follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality*).
      c) Immerse the implant in the aqueous solution of the cleaning agent and subject it to ultrasound cleaning for 15 minutes.
      d) Rinse the implant thoroughly under running water, paying particular attention to the holes and places difficult to be cleaned. It is recommended to rinse with demineralized water.
      e) Visually inspect the entire surface of the device for debris and impurity. Damaged implants must be removed. For dirty implants, the cleaning process should be repeated.
      f) Dry the device thoroughly using disposable, soft, lint-free cloth.
      g) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/-2 °C using 20g of the agent per 1 liter of water. Immerse the implant in the solution, exposure time – 15min (*follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality*).
      h) After the exposure time, rinse the product thoroughly under running water, paying par-

ticular attention to the holes and places difficult to be cleaned. It is recommended to rinse with demineralized water.

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

j) Visually inspect the entire surface of the device.

4) The automated method using a washer - disinfector

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

b) CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883. Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and Instructions for Use prepared by the washing-disinfecting agent manufacturer.

c) The device should undergo a process of machine washing in the washer-disinfector using the following cycle parameters: (*1*) - pre-washing in cold tap water, duration – 2min; (*2*) - washing in an aqueous solution of cleaning agent at 55+/-2 °C and pH of 10.4 - 10.8, duration – 10min; (*3*) - rinsing under demineralized water, duration – 2min; (*4*) - thermal disinfection in demineralised water at 90°C, minimal duration – 5min; (*5*) - drying at a temperature ranging from 90°C to 110°C, duration - 40min.

6. Packaging

1) Washed and dried devices shall be packed in a packaging intended for the recommended steam sterilization. The packaging and packaging process have to meet the requirements of ISO 11607 standards. The packaging procedure must be performed in controlled purity conditions. The device must be packed in such a way that during its removal from the packaging, when used, there is no risk for its re-contamination.

7. Sterilization

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

a) temperature: 134°C,

b) minimum exposure time: 7 min,

c) minimum drying time: 20 min.

2) CAUTION

a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.

b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10^{-6} (*where SAL stands for Sterility Assurance Level*).

c) Implant must not be sterilized in the packaging in which it was delivered.

d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains sterilization recommendations using these methods.

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

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

10 RE-STERILIZATION

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

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

11 PRECAUTIONS

1. Implant is intended for single use only. After removing the implant from the patient's body, it must be secured against re-use, and then finally disposed of in accordance with current hospital procedures.
2. Under no circumstances is it allowed to re-use or re-implant once used device. Even if the removed implant appears to be undamaged, it may have small latent defects or internal stresses, which could lead to early failure, fatigue wear, and as a result to e.g. an implant breakage.
3. Misuse of instruments or implants may cause injury to the patient or operative personnel.
4. Avoid damaging implant surface and deforming its shape during the implantation; the damaged implant cannot be implanted or left in the patient's body.
5. Insertion, removal and adjustment of implants must only be done with instruments specially designated for those implants and manufactured by **ChM** sp. z o.o.
6. Use of **ChM**'s implants and instruments in combination with implants and instruments from other manufacturers may cause damage or failure of those implants or instruments and may lead to improper course of surgery and healing process.
7. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive force are more susceptible to fractures, depending on care taken during surgery, number of procedures performed and attention paid. Instruments should be examined for wear or damage prior to surgery.
8. The plates structure allows for an intraoperative bending, though it should be done carefully. Limitations and instructions issued by the manufacturer should be obeyed due to the fact that implant bending influences its strength parameters, causes surface defects and internal stresses that reduce its fatigue strength. Disobeying the above-mentioned may result in postoperative complications like implant fracture or breakage.
9. If there is a necessity to bend the implant, please, remember that:
   1) it is forbidden to bend an implant which was already bent,
   2) it is forbidden to bend a short fragment of the implant or to bend with a small bending radius,
   3) the bending should occur between plates holes,
   4) before bending the locking plates, it is advisable to insert the locking screws near the bending area, as deformed holes may not provide appropriate plate-screw cooperation,
   5) in shape locking plates only the shaft part may be shaped,
   6) it is forbidden to bend a plate back and forth,
   7) the plate should not be bent more than 20°÷25°,
   8) the bending should be performed only with the use of instruments intended for bending.
10. If the operator decides to cut the bone plate, he must remember that:
    1) cutting the plate may influence the strength characteristics of the implant and of the whole bone fixation,
    2) the plate length and the number of holes for bone screws must be appropriate for the fixation conducted, allow for sufficient support and stable immobilization of the fixation,
    3) it is recommended to cut the plate between the holes for bone screws insertion,
    4) during plate cutting, special attention must be paid to not direct the cut-off fragment in the direction of the user, patient or third parties,
    5) all sharp edges created by cutting on the external surfaces are to be eliminated,
    6) it is important to ensure an unambiguous identification of the implant.
11. While inserting the screw, it is essential to correctly set the screwdriver in relation to the screw. Following the instructions given allows for reduction of the risk of mechanical damage to the screw, screwdriver, or hole in the bone:
    1) screwdriver should be set in the screw axis,
    2) apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible,
    3) the final phase of tightening shall be performed carefully.

12 POST-OPERATIVE RECOMMENDATIONS

1. It is essential to follow all of physician's postoperative directions and warnings.
2. It is essential to confirm proper position of the implant by roentgenographic examination.
3. In postoperative treatment period, the correctness of implant positioning and immobilization of union should be confirmed by roentgenographic examination.
4. The patient should be warned about the risk should he fail to follow the above-mentioned rules, or should he be unavailable for follow-up clinical examination.
5. The surgeon must instruct the patient to report any unusual changes of the operative site to his/her physician. If any change at the site has been detected, the patient should be closely monitored.
6. The patient should be informed about the type of implant material.
7. The patient should be warned to inform the medical staff about the inserted implants prior to any MRI procedure.
8. The patient should be advised not to smoke or consume alcohol excessively during the period of treatment.
9. If the patient is involved in an occupation or activity which may apply excessive stress on the implant (*e.g. substantial walking, running, lifting, or muscle strain*) the surgeon must advise the patient that resultant forces can cause implant failure.
10. The surgeon must instruct the patient regarding appropriate and restricted activities during consolidation and maturation of the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and further clinical problems. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
11. Failure to perform appropriate immobilization of bone when delayed or non-union occurs may lead to excessive fatigue stresses in the implant. Fatigue stresses may be a potential cause of implant becoming bent, loosened or fractured. If non-union of fracture or implant bending, loosening or fracture occurs, the patient should be immediately revised, and the implants should be removed before any serious injuries occur. The patient must be appropriately warned about these risks and closely monitored to ensure compliance during the treatment until the bone union is confirmed.

13 CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER TREATMENT

1. When bone union is achieved, the implants serve no functional purpose and their removal is recommended. The possibility of another surgical procedure and associated risks must be analysed and discussed with the patient. The final decision on implant removal is up to the surgeon. In most patients, removal is indicated because the implants are not intended to transfer forces developed during normal activities.
2. If the device is not removed following completion of its intended use, one or more complications may occur, in particular:
   1) Corrosion and local tissue reaction or pain.
   2) Migration of the implant, possibly resulting in injury.
   3) Risk of additional injury from postoperative trauma.
   4) Bending, loosening, or breakage, which could make implant removal difficult or impossible.
   5) Pain, discomfort, or abnormal sensation due to the presence of the implant.
   6) Increased risk of infection.
   7) Bone loss due to the stress shielding.
   8) Potentially unknown and/or unexpected long term effects.
3. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
4. Implantable stainless steel implant shall be removed after period of not more than two years after its implantation.

If these instructions appear unclear, please contact the manufacturer, who shall provide all required explanations.

Updated INSTRUCTIONS FOR USE are available at the following website: **www.chm.eu**

IFU-010/11.18; Date of verification: November 2018

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	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILE EO	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при повреждённой упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le instruzioni per l'uso
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	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Avvertenza
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH2O2	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • 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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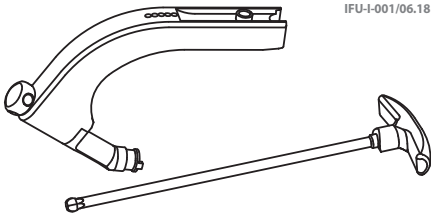

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INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

1 INDICATIONS

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

2 DESCRIPTION

1. The unit package contains one piece of the product in non-sterile condition. Clear plastic bags are a typical packaging material. The products may also be supplied as a complete set *(arranged on palettes and placed into specially designed sterilization containers)*. This Instructions For Use is attached both to the unit packages and the sets.
2. The package is equipped with the product label. The label *(as a primary label)* contains, among others:
   1) Logo ChM and the address of the manufacturer.
   2) Catalogue number *(REF)*, e.g.: 40.XXXX.XXX, and device name and size.
   3) Production batch number *(LOT)*, e.g. XXXXXXX.
   4) NON-STERILE sign - indicates non-sterile product.
   5) Information symbols *(described in the footer of this Instructions For Use)*.
   6) CE conformity mark.
3. Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

3 MATERIALS

1. For the production of instruments, ChM sp. z o.o. uses mainly: steel, aluminum alloys and plastics, approved for use in surgical instruments and in accordance with applicable procedures.
2. Instruments are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the device due to high content of chromium.
3. Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. The protective oxide layer which may be dyed or stays in natural colour *(silvery-grey)* is formed on the aluminium as an effect of electrochemical treatment of its surface.
4. Devices made of aluminium with processed layer have good corrosion resistance. However, the contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminium surface, shall be avoided.
5. Devices produced of plastics are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. Plastics used in the manufacture of instruments are mainly: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)*, teflon *(PTFE - Polytetrafluoroethylene)* and silicone. The above-mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C. They are stable in aqueous solution of washing-disinfecting agents with a pH value from 4 to 10.8.
6. Steel surgical instruments with a hardened insert are more durable than steel products. The advantage of the product is the sintered carbide insert placed in the working part of the instrument. This insert is characterized by great hardness and abrasion resistance.
7. If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

4 WARNINGS AND PRECAUTIONS

1. Instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.
2. Improper, careless and inconsistent with the recommendations provided below handling of the instruments can lead to their chemical, electrochemical or mechanical damage which can adversely affect corrosion resistance and shorten the service life of the devices.
3. Instruments are intended only for specific procedures and must be used strictly according to their intended purpose. Use of instruments not in accordance with their intended purpose may lead to malfunction, accelerated wear and, in consequences, damage to the instrument.
4. The surgeon should be familiar with all components of the device before use and should personally verify if all components and instruments are present before the surgery begins.
5. Before the procedure begins, all instruments should be carefully inspected for their condition and proper functioning. They should be undamaged and without any signs of corrosion. Blades and cutting edges should be sharp and undamaged. Damaged or corroded instruments should be immediately replaced. The use of bent, damaged or corroded instruments is not allowed.
6. Tissue structures close to the operative site must be protected.
7. Collision of the instrument with metal operating equipment, retractor or other device may cause damage that necessitates intraoperative replacement of that instrument.
8. Do not apply excessive force when using the instrument – it may lead to its permanent damage and, in consequences, to mal-function of the device.
9. Instruments are subject to constant wear processes. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive forces are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed. Should breakage occur, the instrument parts must be removed and disposed of immediately in accordance with valid medical facility procedures.
10. In order to confirm the removal of all undesired metal fragments from the surgical field, intraoperative X-Ray examination is recommended.
11. In the case of suspected or documented allergy or intolerance to metallic materials, surgeon shall find out if the patient develops allergic reaction to the instrument material by ordering appropriate tests.
12. It is extremely important to follow the calibration deadline which is permanently marked on the torque instruments *(see CALIBRATION)*. Use of a torque instrument with an overstepped calibration date may lead to potential injury, implant or device damage, or loss of correction. If there appear any irregularities in device operation, e.g. due to heavy usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.
13. Instrument which had contact with tissues or body fluids of another patient cannot be re-used prior to its reprocessing due to a potential risk of cross-infection caused by viruses, bacteria and prions.
14. Middle and working part of the surgical devices with hardened insert shall be used during the surgical procedure. Improper or inconsistent with the intended purpose usage of the product may lead to damage of the working part e.g. damage to the inserts.

5 CLEANING, DISINFECTION, STERILIZATION

1. Prior to use of a non-sterile device, the following rules apply:
   1) The device must undergo cleaning, disinfection and sterilization procedures.
   2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning *(manual, automated)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process, etc.
   3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.
2. Preparation at the place of use.
   1) Immediately after use, remove from instrument blood and other contaminants with disposable cloth or paper towels. Additionally, it is recommended to rinse the instrument under running water or to place it in the aqueous disinfectant solution. Do not let blood, tissues, body fluids or other biological impurities dry out on the surface of the device.
   2) In order to prevent blood and debris from drying out on the instrument surface, transport the product to the processing area in a closed container or covered with a damp cloth.
   3) In order to avoid contamination during transportation, the dirty instruments should be separated from the clean ones.
3. Preparation for washing and disinfection *(for all methods)*.
   1) The used instruments should be reprocessed as soon as possible.
   2) If the instrument can be disassembled, it must be done before cleaning processes.
   3) Rinse under running water and remove surface debris using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*. Particular attention should be paid to openings and places difficult to be cleaned. Very dirty devices should be soaked in an aqueous solution of a detergent or a washing-disinfecting agent, e.g. neodisher® MediClean forte, at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
   4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the product.
4. Cleaning and disinfection process.
   1) This Instructions for Use describes two ChM-approved cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated cleaning and disinfection procedures *(in a washer-disinfector)*.
   2) The chosen washing and disinfecting agents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. ChM used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:
      a) detergent - Dr.Weigert *(producer)* neodisher® MediClean forte *(name of the detergent)*;
      b) disinfectant - Dr.Weigert *(producer)* neodisher® Septo Active *(name of disinfectant)*.
   3) To prevent product damage *(pitting, rust, discoloration)*, do not use aggressive cleaning agents *(NaOH, NaOCl)*, saline solutions and unsuitable cleaning agents.
   4) Where possible, it is recommended to use demineralized water to avoid the formation of spots and stains caused by chlorides and other compounds present in ordinary water.
   5) Manual with ultrasound cleaning.
      a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, syringes, aqueous solutions of cleaning agent.
      b) Manual cleaning: Initial manual cleaning must be performed prior to ultrasound cleaning.
      c) Rinse under running water until the product is visually clean. Use plastic brushes to remove heavy or large debris.
      d) Soak the product for at least 10 minutes in an aqueous solution of a detergent at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
      e) Rinse the product under cold water for at least 2 minutes, paying particular attention to the holes and places difficult to be cleaned.
      f) Prepare fresh washing solution. Clean the surfaces and gaps of the product, carefully. Use suitable brushes to clean the holes. Clean the product immersed in the solution.
      g) Rinse the product thoroughly under warm running water for at least 2 minutes, paying special attention to the gaps, blind holes, hinges and joints. When cleaning, use brushes and perform multiple reciprocating movements on the surface of the product.
      h) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-h until the product is visually clean.
      i) Ultrasound cleaning: prepare an aqueous cleaning solution at a temperature of 40 +/- 2°C and pH of 10.4 - 10.8 *(follow the information contained in the instructions prepared by the manufacturer of the cleaning agent, in respect of temperature, concentration, exposure time and water quality)*. Immerse fully the product in the aqueous cleaning solution and have it washed in ultrasounds for 15 minutes.
      j) Rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
      k) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-k until the product is visually clean.
      l) Use demineralized water for final rinsing of the device.
      m) Dry the device thoroughly using disposable, soft, lint-free cloth or compressed air.
      n) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/-2 °C using 20g of the agent per 1 liter of water. Immerse the product in the solution, exposure time – 15min *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
      o) After the exposure time, rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
      p) The cannulated instruments should be treated using a compressed air or air supplied from the syringe.
      q) Dry the device thoroughly. It is recommended to dry the product in a dryer at a temperature ranging from 90°C to 110°C.
      r) Visually inspect the entire surface of the device.
      s) CAUTION: If the obstruction in the cannula cannot be removed as indicated in the Instructions for Use, the device should be considered at the end of its useful life and should be discarded in accordance with facility procedures and guidelines.
   6) The automated method using a washer - disinfector.
      a) Equipment and materials: a washer - disinfector, aqueous solutions of cleaning agent.
      b) Cleaning in the washer-disinfector must be preceded by a manual and ultrasound cleaning, following the procedure described in subsections c-h of paragraph 5.
      c) CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883. Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washer-disinfector manufacturer, and instructions for use prepared by the washing-disinfecting agent manufacturer.
      d) The device should undergo the process of machine washing in the washer-disinfector using the following cycle parameters: *(1)* - pre-washing in cold tap water, duration – 2min; *(2)* - washing in an aqueous solution of cleaning agent at 55+/-2°C and pH of 10.4 - 10.8, duration – 10min; *(3)* - rinsing under demineralized water, duration – 2min; *(4)* - thermal disinfection in demineralised water at 90°C, minimal duration – 5min; *(5)* - drying at the temperature ranging from 90°C to 110°C, duration - 40min.
5. Inspection
   1) Each time before re-use and re-sterilization, all medical devices should be inspected.
   2) All parts of the product should be checked for visible dirt and corrosion. Particular attention should be paid to:
      b) Holes, grooves and gaps the debris could have been pressed into during use.
      a) Places where dirt can be found, such as joints, latches, etc.
   3) Generally unmagnified visual inspection under good light conditions is sufficient.
   4) Each time before re-use and re-sterilization, the functional check of the product should be performed, consisting of:
      a) Verifying the connections in the mating instruments, such as tips, shafts and quick coupling devices.
      b) Verifying the correct functioning of mechanisms, e.g. screw, ratchet, snap mechanism, etc.
      c) Verifying all rotating devices for straightness *(this can be simply achieved by rolling the device on a flat surface)*.
      d) Verifying cutting edges for sharpness.
      e) Verifying instruments for damage to material structure *(cracks, dents, peels, etc.)*.
   5) Damaged or defective product cannot be approved for further use.
   6) Prior to storage, the instrument must be checked for dryness.
   7) CAUTION:
      a) The ChM sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful and proper use reduces the risk of damage to the product and extends its serviceable life.
      b) The manufacturer does not recommend using any preservatives on medical devices.
6. Packaging
   1) Washed and dried devices shall be stored *(if possible)* in suitable stands placed in special sterilization containers. Separate items should be packed in a packaging intended for the recommended steam sterilization. Sterilization containers, item packaging and packaging process itself have to meet the requirements of ISO 11607 standards. The packaging procedure must be performed in controlled purity conditions. The device must be packed so that during its removal from the packaging, when used, there is no risk for its re-contamination
7. Sterilization
   1) Washed, disinfected, and dried device shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:
      a) temperature: 134°C,
      b) minimum exposure time: 7 min,
      c) minimum drying time: 20 min.
   2) CAUTION:
      a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.
      b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
      c) Device must not be sterilized in the packaging in which it was delivered, except specially designed sterilization containers.
      d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains sterilization recommendations using these methods.
      e) The sterilization temperature for plastic products *(PPSU, PEEK, PTFE, silicone)* cannot be higher than 140°C.

6 STORAGE

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

7 CALIBRATION

1. Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments are factory-calibrated, the nominal torque of a calibrated instrument is marked on the device *(e.g. 4 Nm)*. To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.
2. Instrument calibration is performed by the manufacturer. Any attempt of unauthorized modifications to the construction or factory setting of the torque devices can lead to a potential injury or damage to the product and is prohibited.

8 COMPATIBILITY

1. ChM specialist instrument sets are designed for insertion of ChM implants. A specific, illustrated operating technique that describes the proper use of instruments included in the instrument set that is designed for particular implant system, is provided together with such instrument set. It is not allowed to combine ChM instruments with products from other manufacturers. The physician bears all responsibility for the use of the ChM instruments together with implants and instruments from other manufacturers.

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

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

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