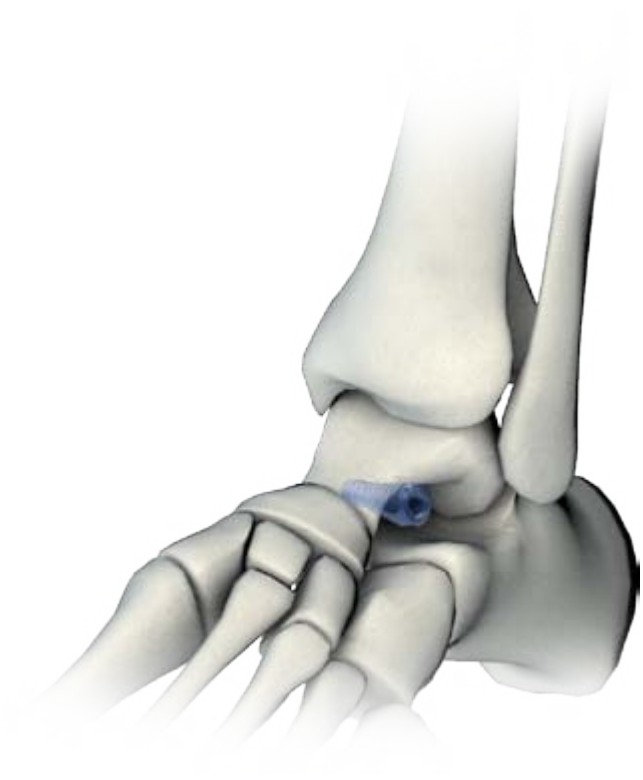
ChM®

Cannulated *(subtalar)* screw

- *IMPLANTS*
- *INSTRUMENT SET 40.6590.000*
- *SURGICAL TECHNIQUE*



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SYMBOLS DESCRIPTIONS	
	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Consult the Instructions For Use.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.

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I. INTRODUCTION

The cannulated *(subtalar)* screw is a one-element device that is used in the treatment of pes plano-valgus *(flat feet)* in children and adolescents.

Indications for use:
- fixed pes plano-valgus,
- flexible pes plano-valgus,
- pes plano-valgus with Achilles tendon contracture.

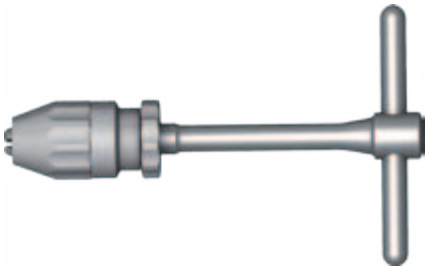
II. IMPLANTS

Cannulated *(subtalar)* **screw**

Catalogue No				
Ø8	**Ø9**	**Ø10**	**Ø11**	**Ø12**
3.1730.000	3.1731.000	3.1732.000	3.1733.000	3.1734.000
Ø8	**Ø9**	**Ø10**	**Ø11**	**Ø12**
colours				

III. INSTRUMENT SET

Instrument set for cannulated *(subtalar)* screws 40.6590.000

No.		Name	Catalogue no.	Pcs.
1		Guide rod 2.0	**40.6597.000**	1
2		Trial 8	**40.6592.000**	1
3		Trial 9	**40.6593.000**	1
4		Trial 10	**40.6594.000**	1
5		Trial 11	**40.6595.000**	1
6		Trial 12	**40.6596.000**	1
7		Screwdriver S4	**40.6591.000**	1
8		Steinmann handle	**40.0987.200**	1
9		Stand	**40.6599.000**	1

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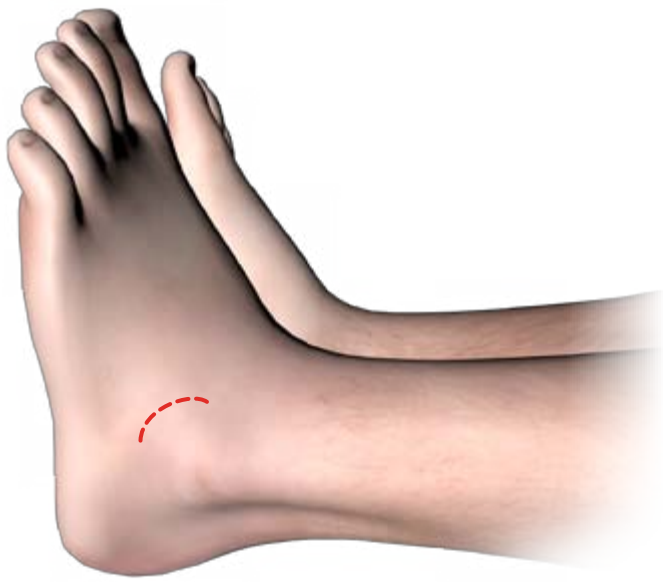
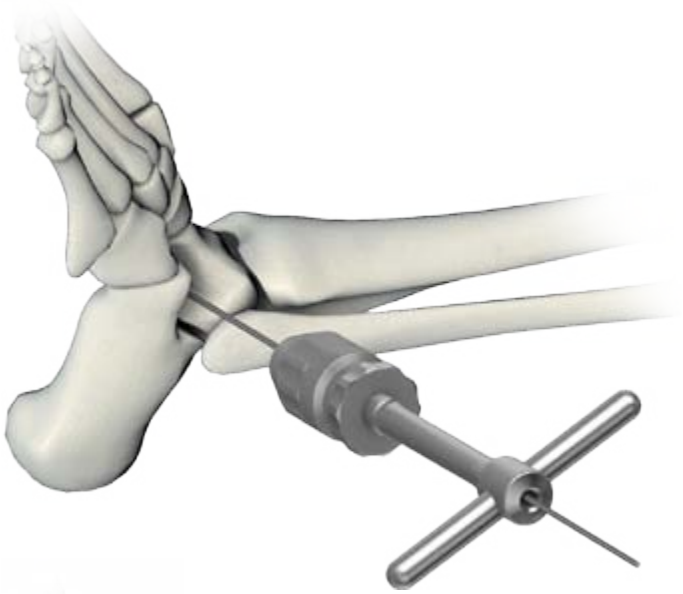
IV. SURGICAL TECHNIQUE

IV.1. SURGICAL APPROACH

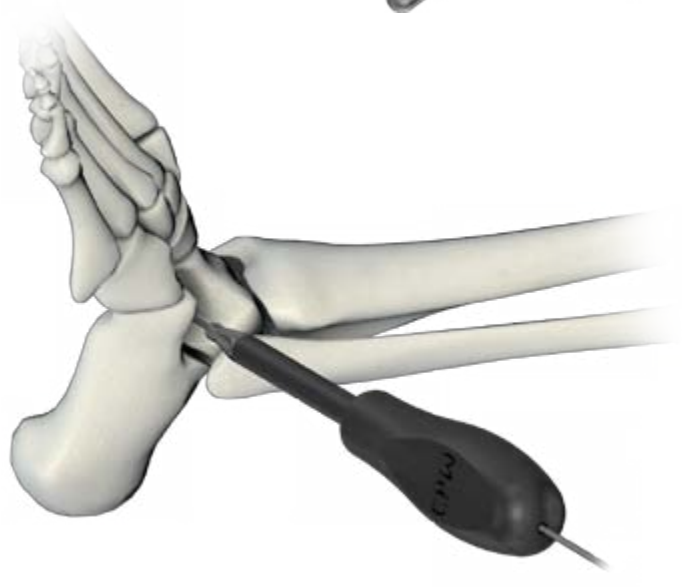


1 Perform an incision for 1-3 cm on the lateral aspect of the foot over the sinus tarsi region.

IV.2. IMPLANT INSERTION



2 Using STEINMANN handle **[40.0987.200]**, insert guide rod **[40.6597]** into the sinus tarsi. The end of the rod should be perceptible on the other side of the food inferior to the medial maleollus - a small bulge of the skin should be visible.

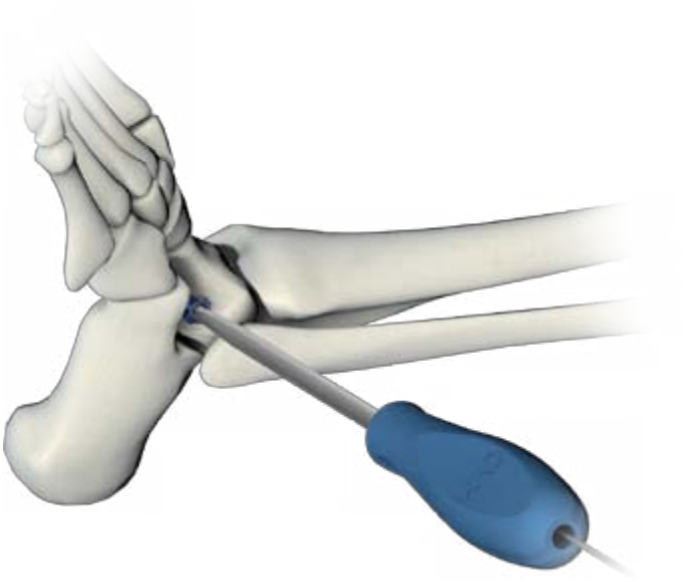


3 Insert in turn trials 8-12 mm until the correct position of the calcaneus is achieved - inclined by 2° ÷4° from the neutral position.

Remove the trial.
Leave guide rod in place.

4 Mount chosen implant to the screwdriver S4 **[40.6591]** tip and via guide rod **[40.6597]** insert it into sinus tarsi.

Remove screwdriver and guide rod.



IV.3. IMPLANT REMOVAL

5 Insert guide rod **[40.6597]** into the sinus tarsi. Using the guide rod, insert screwdriver S4 **[40.6591]** tip in the socket of the subtalar screw. Remove the implant turning the screwdriver counterclockwise.

GB

ISO 9001/ ISO 13485

CE

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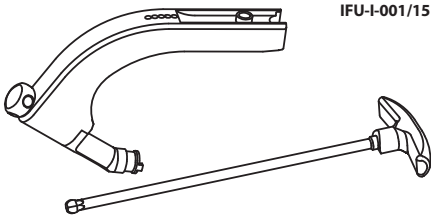
IFU-I-001/15



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INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

Instruments manufactured by **ChM** sp. z o.o. are made of steel, aluminium alloys and plastics according to ISO standards. Each medical instrument is exposed to occurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stay in natural colour *(silvery-grey)*, is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance. The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference on the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: POM-C *(Polyoxymethylene Copolymer)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE)*. 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 pH values from 4 to 9.5.

- *If the material of the device cannot be specified, please contact* **ChM** *sp. z o.o. company representative.*

DISINFECTION AND CLEANING

Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quality of used detergent, the technique of cleaning *(manual/machine)*, the correct rinsing and drying, the proper preparation of the instrument, the time, the temperature. Internal procedures of sterilization rooms, recommendations of cleaning and disinfecting agents, as well as recommendations for cleaning and sterilization in automatic machines shall be observed.

- *Read and follow the instructions and restrictions specified by the manufacturers of the agents used for disinfection and cleaning procedures.*

1. Before the first use, the product has to be thoroughly washed in the warm water with washing-disinfecting detergent. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use water solutions of cleaning-disinfecting agents with a neutral pH.
2. After use, for at least 10 minutes the product has to be immediately soaked in an aqueous disinfectant solution of enzyme detergent with a neutral pH *(with disinfecting properties)* normally used for reusable medical devices *(remember to prevent drying out of any organic remains on the product surface)*. Follow all the instructions specified by the producer of those enzyme detergents.
3. Carefully scrub/clean the surfaces and crevices of the product using a soft cloth without leaving threads, or brushes made of plastic, the nylon brushes are recommended. Do not use brushes made of metal, bristles or another damaging material as they can cause physical or chemical corrosion.
4. Next, thoroughly rinse the instrument under the warm running water, paying particular attention to rinse the slots carefully. Use nylon brushes making multiple moves back and forth on the surface of the product. It is recommended to rinse under demineralized water, in order to avoid water stains and corrosion caused by chlorides, found in the ordinary water, and to avoid forming the stains on the surface *(e.g. anodized one)*. During the rinsing, manually remove the adherent remains.
5. Visually inspect the entire surface of the product to ensure that all contaminants are removed.

- *If there are any residues of human tissue or any other contamination, repeat all stages of the cleaning process.*

6. Then, the instrument has to undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for reusable medical devices and instruments)*.

- *Procedure of washing with 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 agents manufacturer.*

ATTENTION! *The manufacturer does not recommend using any preservatives on surgical and orthopedic devices.*

STERILIZATION

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes, without structure damage *(cracks, fractures, bending, peeling)*. Remember that sterilization is not a substitute for cleaning process!

- *Devices manufactured out of plastics (PEEK, PTFE, POM-C) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards. It is recommended to sterilize in steam sterilizers where sterilizing agent is water vapour. Recommended parameters of the sterilization method:

- temperature: 134°C,
- pressure: 2 atm. of pressure above atmospheric *(overpressure)*,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

Validated sterilization methods are allowed. Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

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

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

IFU-I-001/15; Date of verification: January 2015

SYMBOL TRANSLATION • OBJASNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ
EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY

Do not reuse Nie używać powtórnie Не использовать повторно No reutilizar Nicht wiederverwenden Nepoužívejte opakovaně	Do not resterilize Nie sterylizować ponownie Не стерилизовать повторно No reesterilizar Nicht resterilisieren Nepoužívejte resterilizaci	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
Sterilized using irradiation Sterylizowany przez napromieniowanie Радиационная стерилизация Esterilizado mediante radiación Sterilisiert durch Bestrahlung Sterilizovat zářením STERILE R	Sterilized using hydrogen peroxide Sterylizowany nadtlenkiem wodoru Стерилизован перекисью водорода Esterilizado con peróxido de hidrógeno Sterilisiert mit Wasserstoffperoxid Sterilizováno s peroxidem vodíku STERILE VH202	Non-sterile Niesterylny Не стерильно No estéril Unsteril Nesterilní
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	Caution Ostrzeżenie Осторожно Advertencia Vorsicht Varování	

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