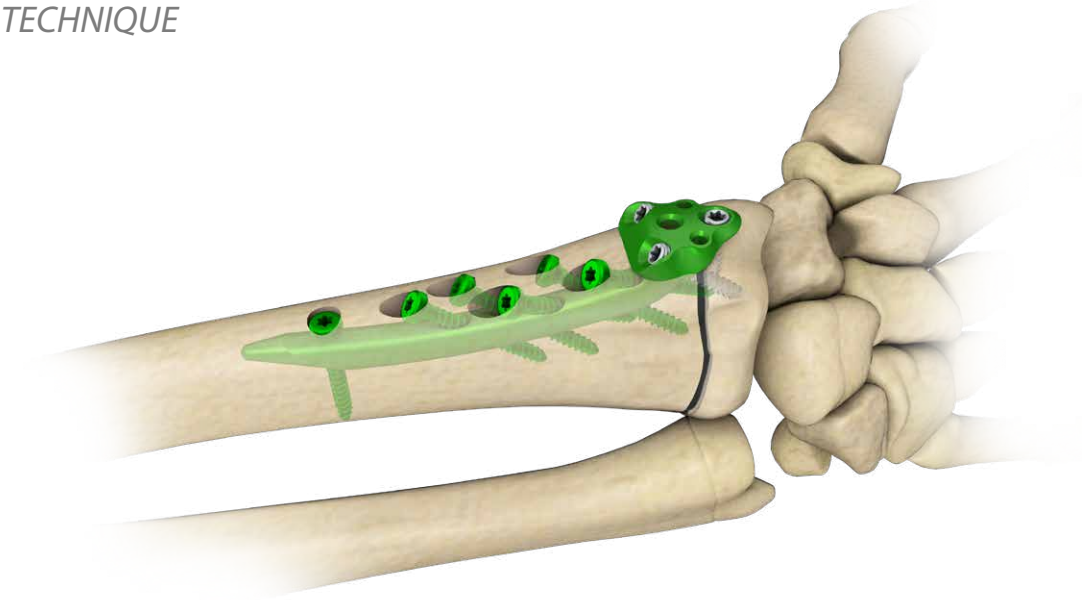
ST/85A

ChM®

INTRAMEDULLARY OSTEOSYNTHESIS OF DISTAL RADIUS FRACTURES WITH RADIAL NAIL

- *IMPLANTS*
- *INSTRUMENT SET 15.0429.100*
- *SURGICAL TECHNIQUE*



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SYMBOLS DESCRIPTIONS

Ti	Titanium or titanium alloy
St	Steel
L	Left
R	Right
L R	Available versions: left/right
Len	Length
	Torx drive
	Torx drive cannulated
	Hexagonal drive
	Hexagonal drive cannulated
	Cannulated
	Locking
	Diameter
	Inner diameter
	Recommended length range for a particular nail
	Angle
16 ÷ 90	Available lengths
Ster Non Ster	Available in sterile/ non- sterile condition

	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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Document No ST/85A
Date of issue 29.01.2019
Review date P-002-12.11.2019

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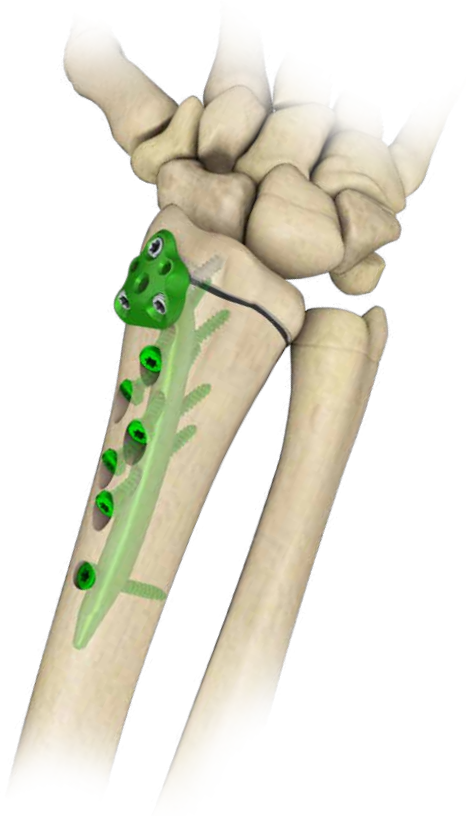


1. INTRODUCTION

Intramedullary osteosynthesis of radius with radial nail consists of:

- implants (*intramedullary nail, locking screws*),
- instrument set for implants insertion and removal,
- surgical technique.

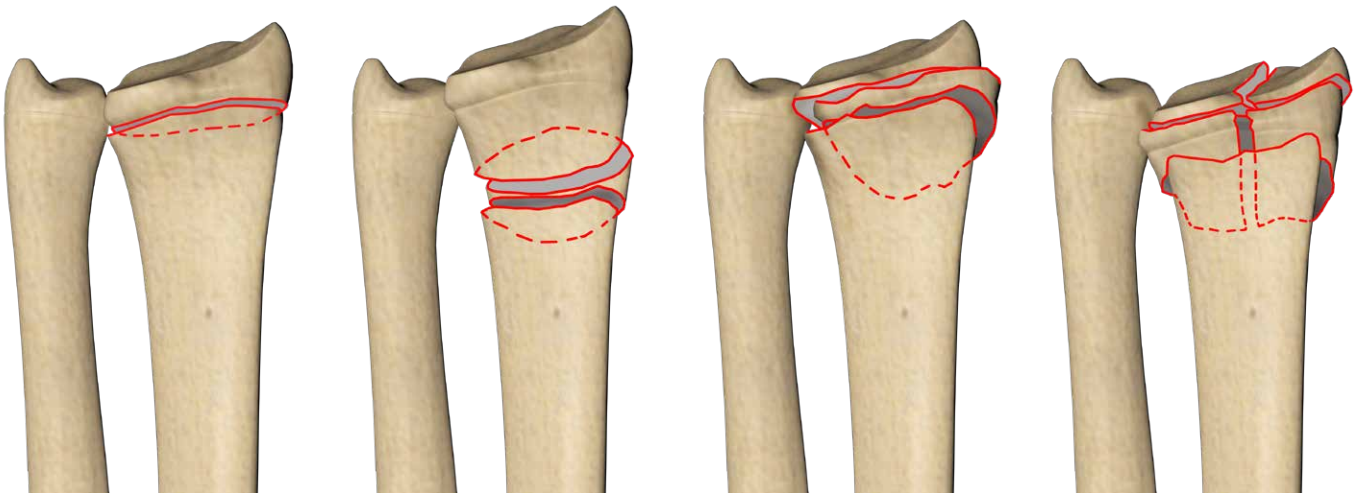
Intramedullary osteosynthesis of radius with radial nail allows for stable reduction of fracture fragments in distal radius.

The presented range of implants is made of materials in accordance with ISO 5832 standard. Compliance with the requirements of quality management systems and the directive concerning medical devices guarantee high quality of the offered implants.

Indicated use:

- distal radius fractures, 'loco typico' included.

AO Classification of fractures

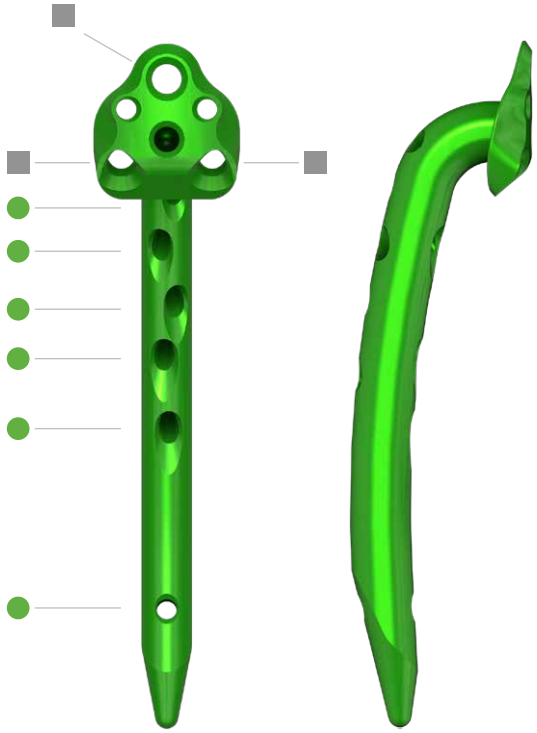


A2 A3 C1 C3

2. IMPLANTS

CHARFIX2 RADIAL NAIL L-68

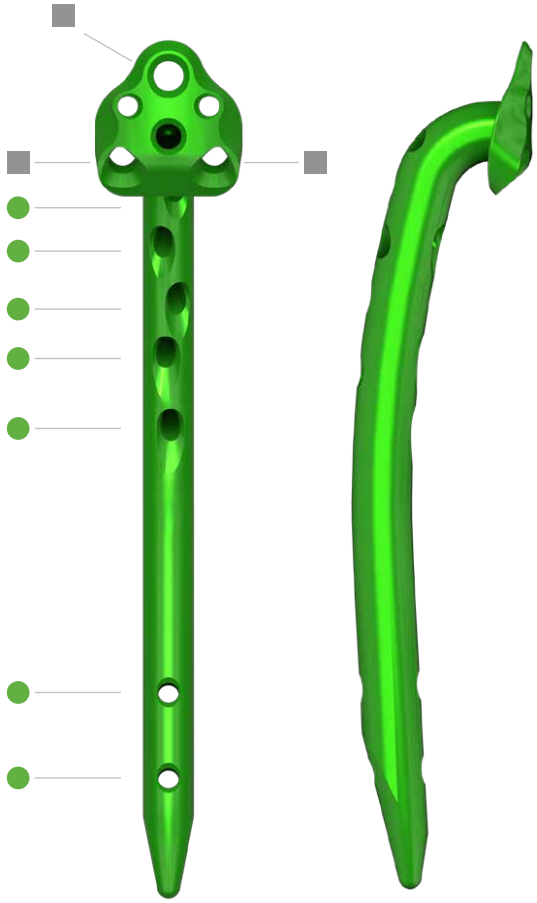
Len	Ti
68	3.5322.000



	Ti			
	3.5332.xxx	✓	2.4	10÷50
	4.5235.xxx	✓	2.4	6÷40

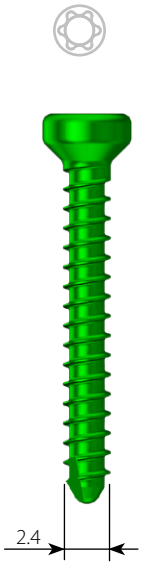
CHARFIX2 RADIAL NAIL L-85

Len	Ti
85	3.5324.000



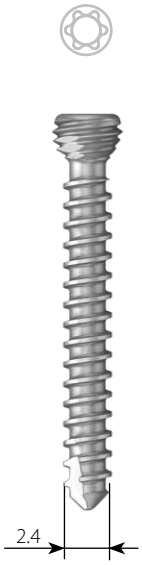
	Ti			
	3.5332.xxx	✓	2.4	10÷50
	4.5235.xxx	✓	2.4	6÷40

CHARFIX2 Locking screw 2.4

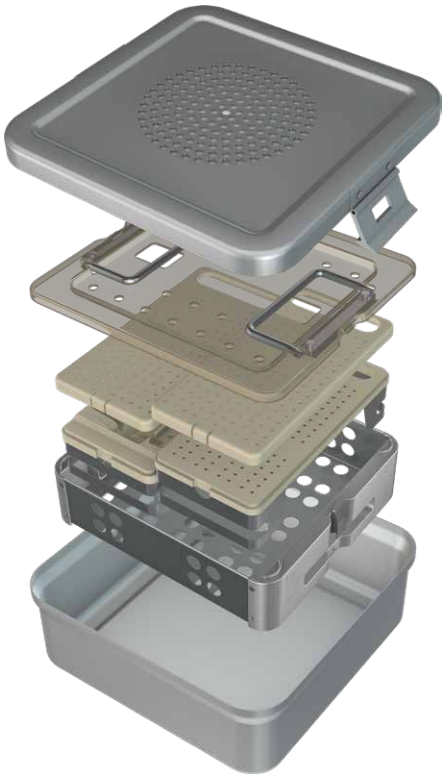


Len	Ti
10	3.5332.010
12	3.5332.012
14	3.5332.014
16	3.5332.016
18	3.5332.018
20	3.5332.020
22	3.5332.022
24	3.5332.024
26	3.5332.026
28	3.5332.028
30	3.5332.030
32	3.5332.032
34	3.5332.034
36	3.5332.036
38	3.5332.038
40	3.5332.040
42	3.5332.042
44	3.5332.044
46	3.5332.046
48	3.5332.048
50	3.5332.050

4.0ChLP screw VA 2.4



Len	Co
6	4.5235.006
8	4.5235.008
10	4.5235.010
12	4.5235.012
14	4.5235.014
16	4.5235.016
18	4.5235.018
20	4.5235.020
22	4.5235.022
24	4.5235.024
26	4.5235.026
28	4.5235.028
30	4.5235.030
32	4.5235.032
34	4.5235.034
36	4.5235.036
38	4.5235.038
40	4.5235.040



Stand for implants and radial nails **15.0429.600**

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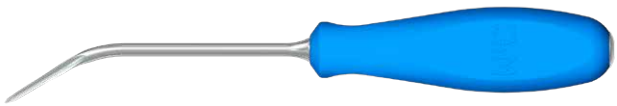
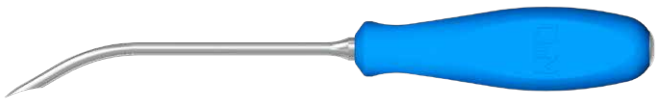
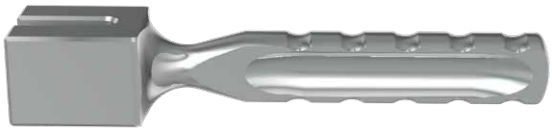
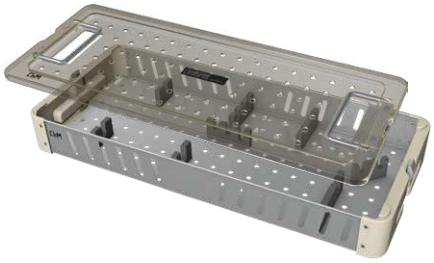
3. INSTRUMENT SET

Instrument set for radial nails **15.0429.100**

	Name	Catalogue No.	Pcs
	Targeter arm	**40.6751.000**	1
	Targeter B	**40.6752.000**	1
	Connecting screw M3	**40.6753.000**	1
	Protective guide 5.5/3.5	**40.6754.000**	2
	Drill guide 3.5/1.8	**40.6755.000**	2
	Protective guide 6.5/4.5	**40.6757.000**	2
	Drill guide 4.5/1.8	**40.6758.000**	2
	Trocar 4.5	**40.6759.000**	1
	Drill 1.8/245	**40.6760.000**	3
	Screw length measure	**40.6761.000**	1
	Screw length measure	**40.6762.000**	1
	Drill	**40.6763.000**	1
	Drill	**40.6764.000**	1
	Screwdriver T8	**40.6765.000**	1
	Awl	**40.6766.000**	1
	Curved awl 5.0	**40.6767.000**	1
	Impactor-extractor	**40.6768.000**	1
	Mallet	**40.6769.000**	1

	Guide VA 1.8	**40.5928.018**	1
	Perforated aluminum lid 1/1 595x275x15mm Gray	**12.0750.200**	1
	Stand	**14.0429.100**	1
	Container with solid bottom 1/1 595x275x86mm	**12.0750.100**	1

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4. SURGICAL TECHNIQUE

The following description covers the most important stages of the implantation of the radial nails; however, it is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure and its application in each individual case.

4.1. INTRODUCTION

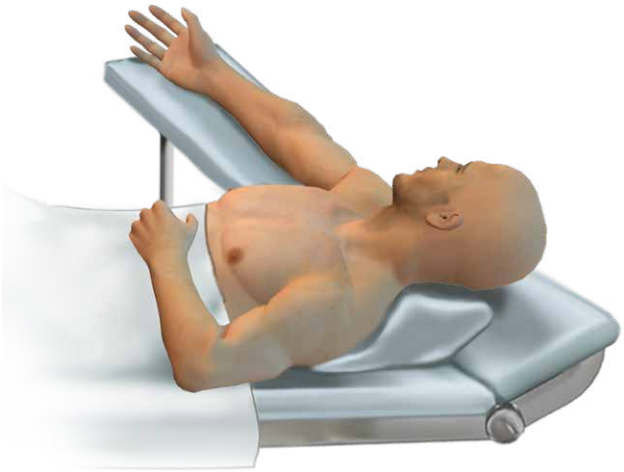
Patient positioning on the operating table is an integral part of the surgery.
Intramedullary osteosynthesis presented in this method requires intraoperative radiological control.

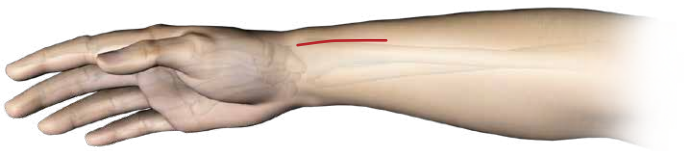
Each surgical treatment must be planned carefully. Prior to surgery, take appropriate X-Ray images of the entire radius with the adjacent joints (*in ap and lateral position*) so as not to miss any damage to its proximal and medial parts. Should there appear any doubt, take a comparative X-Ray image of the opposite limb and/or computed tomography (*CT*).

4.1.1. PATIENT POSITIONING

Position the patient on the back with their hand supported on the table transparent to X-Rays.
Posterolateral approach should be used with the hand positioned in the intermediate position (*between pronation and supination*). In this position, the radial bone is directed upwards. Perform the skin incision along the radial bone, above the fracture gap. The incision must allow the nail and locking screws to be inserted into the fracture gap. Approach to the bone through the first dorsal compartment.

When preparing the approach, carefully retract: the terminal branches of the radial nerve superficial branch, the tendon of extensor pollicis longus muscle (*EPL*), the tendon of extensor pollicis brevis muscle (*EPB*), and the tendon of abductor pollicis longus muscle (*APL*).



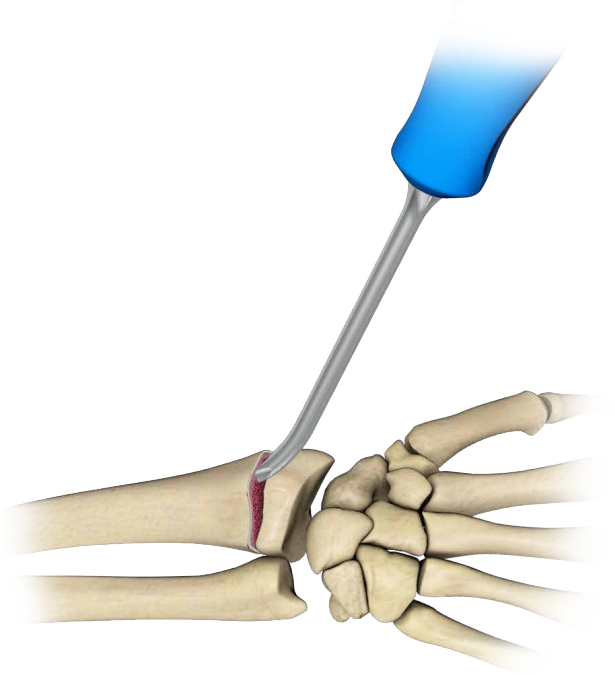


4.2. OPENING THE FRACTURE GAP AND PREPARATION OF THE MEDULLARY CANAL FOR RADIAL NAIL INSERTION

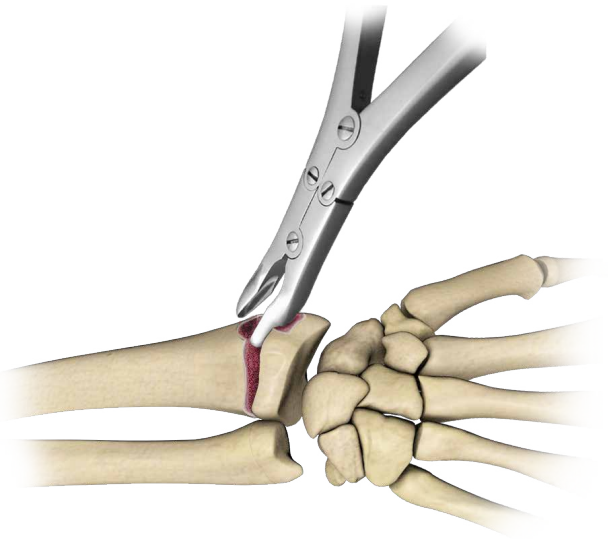
1. Having located the fracture gap, use the awl **[40.6766]** or curved awl 5.0 **[40.6767]** to create a hole for nail insertion between the fragments of the bone.


40.6766.000


40.6767.000



2. Use a bone rongeur (*available as a standard instrument of operating theater equipment*) to enlarge the hole in the bone for the nail to better fit the bone and to obtain the smallest fracture gap possible after nail implantation.

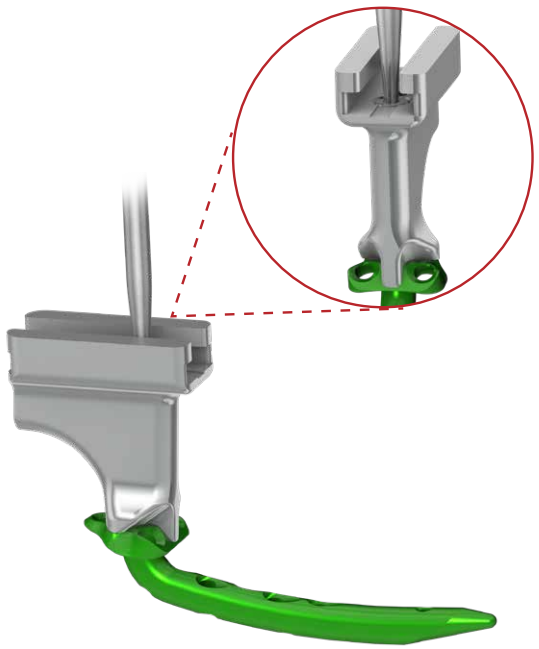


4.3. NAIL-TO-TARGETER ASSEMBLY, NAIL IMPLANTATION

1. Attach targeter arm **[40.6751]** to the plate part of the nail using connecting screw M3 **[40.6753]**.


40.6751.000


40.6753.000



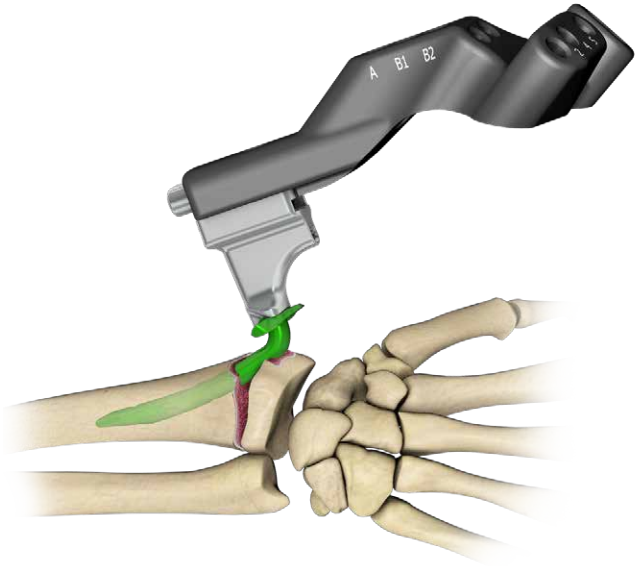
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

Attach targeter B **[40.6752]** to the targeter arm **[40.6751]** and insert the nail through the prepared fracture gap into the medullary canal. Adjust the position of the nail to the bone, so that the plate part adheres as close as possible to the bone. Re-align bone fragments.

Remove the targeter B **[40.6752]**.

40.6751.000

40.6752.000



When inserting the nail, make sure that the plate part of the nail do not press on the tendons and superficial branch of the radial nerve.

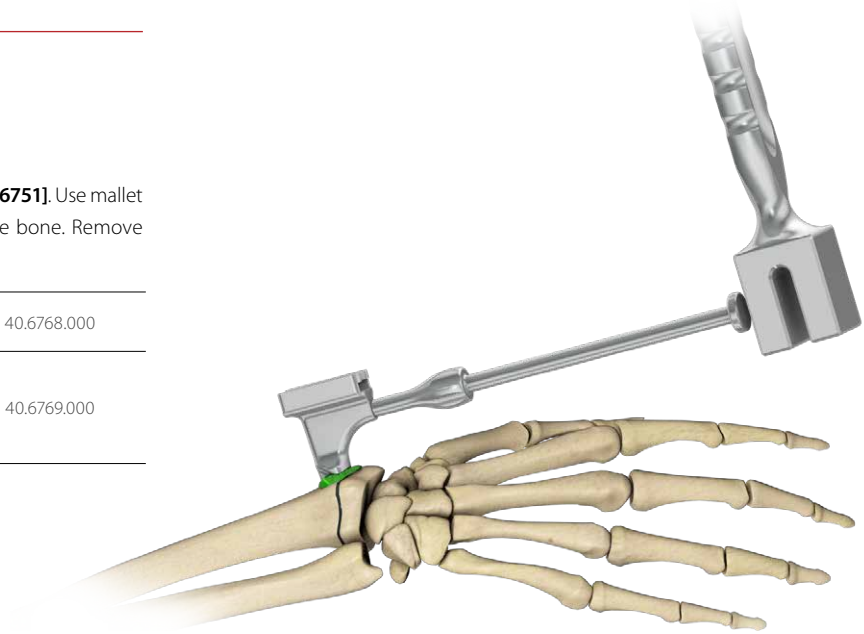
Use X-Ray control to verify the position of the nail in the medullary canal.

Should the nail be properly positioned at this stage, skip the step 3.

2. Attach impactor - extractor **[40.6768]** to the targeter arm **[40.6751]**. Use mallet **[40.6769]** to achieve the desired position of the nail in the bone. Remove the impactor - extractor.

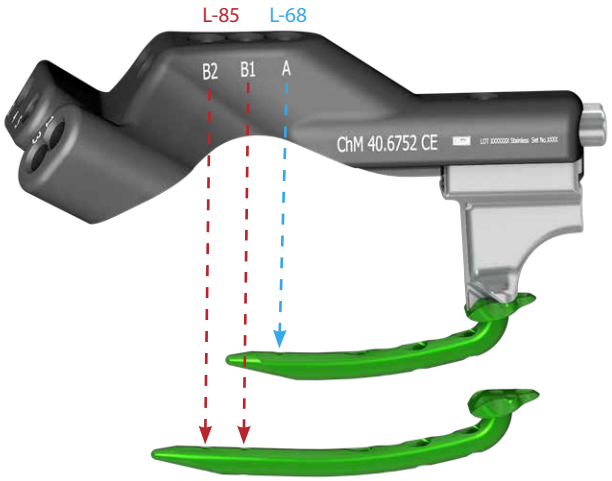
40.6768.000

40.6769.000



4.4. LOCKING THE NAIL IN THE PROXIMAL PART

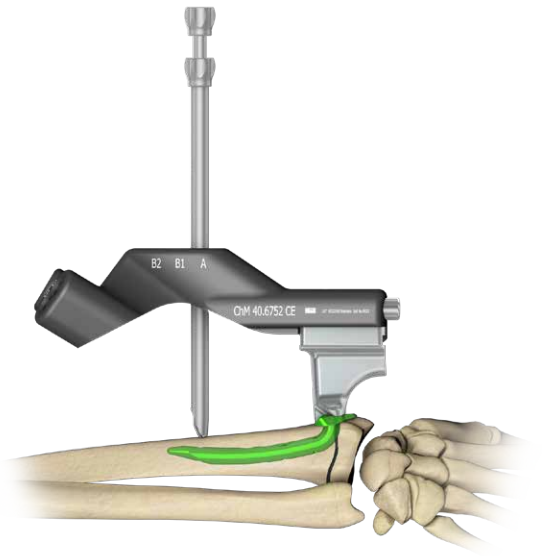
Holes in the proximal part are located perpendicular to the shaft part of the nail. There are two holes in the radial nail L-85, and a single one in the L-68 version in the proximal part, for locking screws 2.4 insertion. Use targeter B and three parallel locking holes provided therein for locking the proximal part. The hole closest to the plate part of the nail, marked „*A*", shall be used for locking the nail L-68. The other two holes, marked „*B1*" and „*B2*" are intended for nail L-85.



1. Attach targeter B **[40.6752]** to the targeter arm **[40.6751]**. Insert protective guide 6.5/4.5 **[40.6757]** with trocar 4.5 **[40.6759]** to the appropriate hole in the targeter B. Use the trocar to mark on the cortex an entry point for a drill and simultaneously push the protective guide as close to the bone as possible.

Remove the trocar.

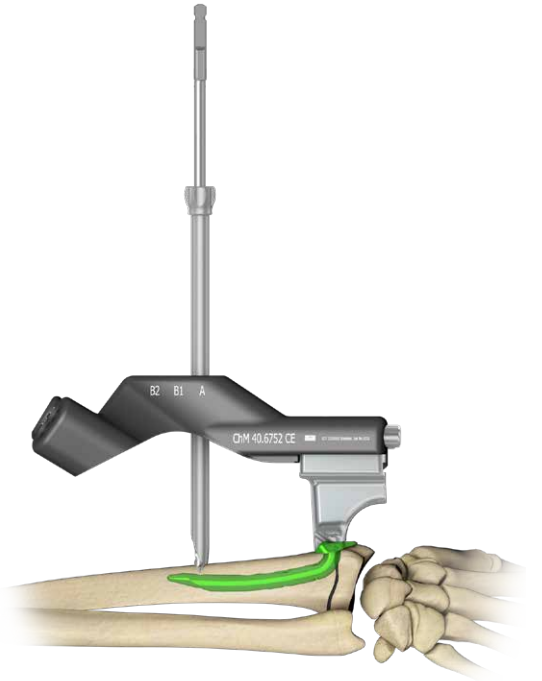
	40.6757.000
	40.6759.000



2. Use protective guide 6.5/4.5 **[40.6757]** and drill **[40.6763]** mounted in a drive to initially drill a hole for the drill 1.8, to a depth of up to 2mm.

Remove the drill.

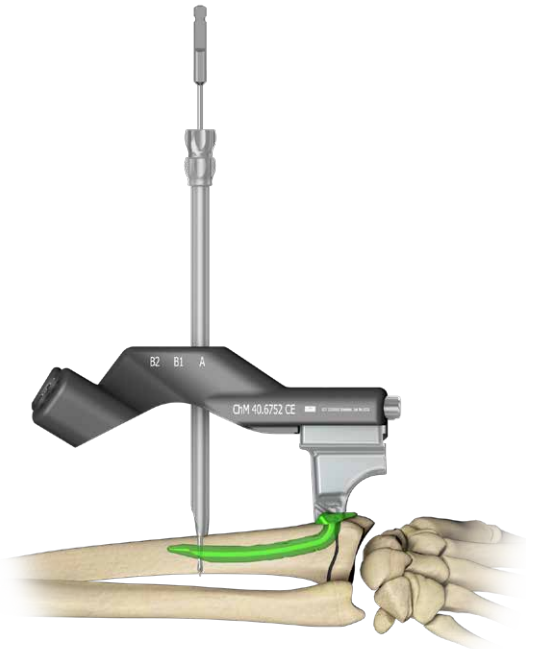
	40.6763.000



3. Insert a drill guide 4.5/1.8 **[40.6758]** into the protective guide 6.5/4.5 **[40.6757]**. Use the drive and the drill 1.8/245 **[40.6760]** to drill a hole in the radius through both cortex layers and the hole in the nail.

	40.6758.000
	40.6760.000

Perform hole drilling under X-Ray control.

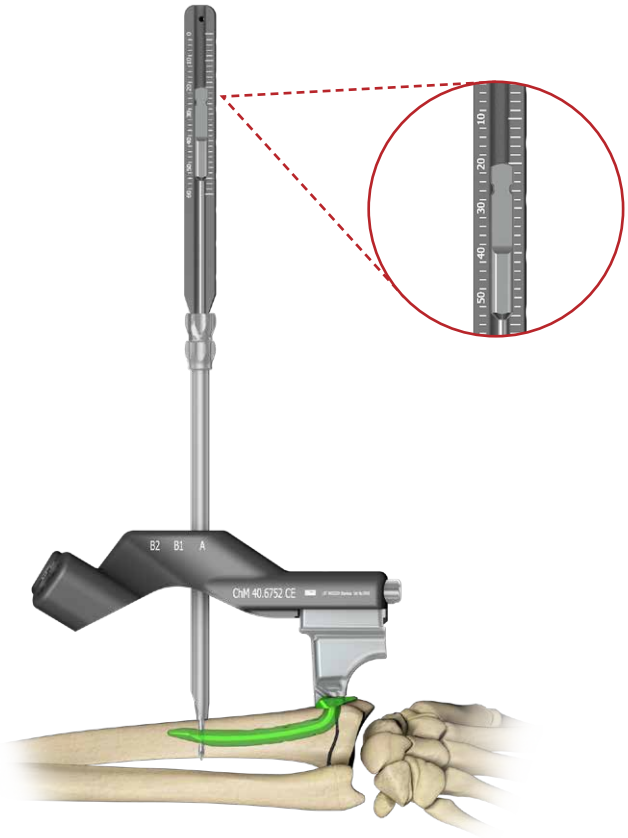


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

4. Use screw length measure **[40.6761]**, to determine the length of a locking screws 2.4

Remove the screw length measure, drill 1.8/245 and drill guide 4.5/1.8.

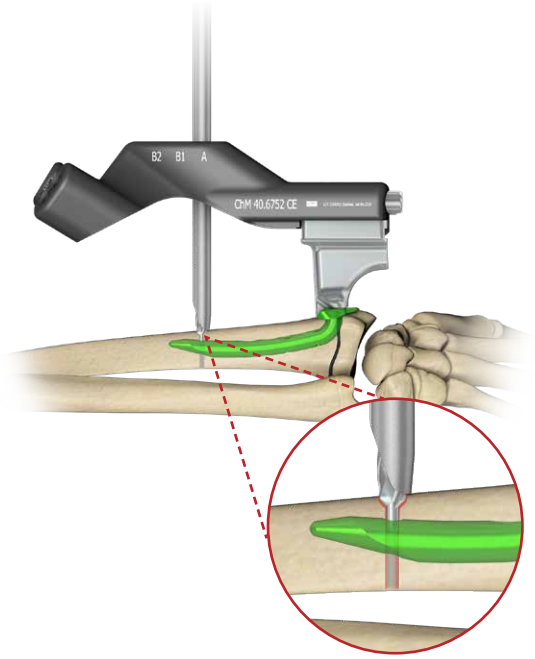
	40.6761.000



5. Use protective guide 6.5/4.5 **[40.6757]** and drill **[40.6764]** mounted in the drive to drill a deepening for the head of locking screw 2.4. The surgeon decides about the size of the deepening, however it should be not greater than 2.5mm.

Remove the drill.

	40.6757.000
	40.6764.000

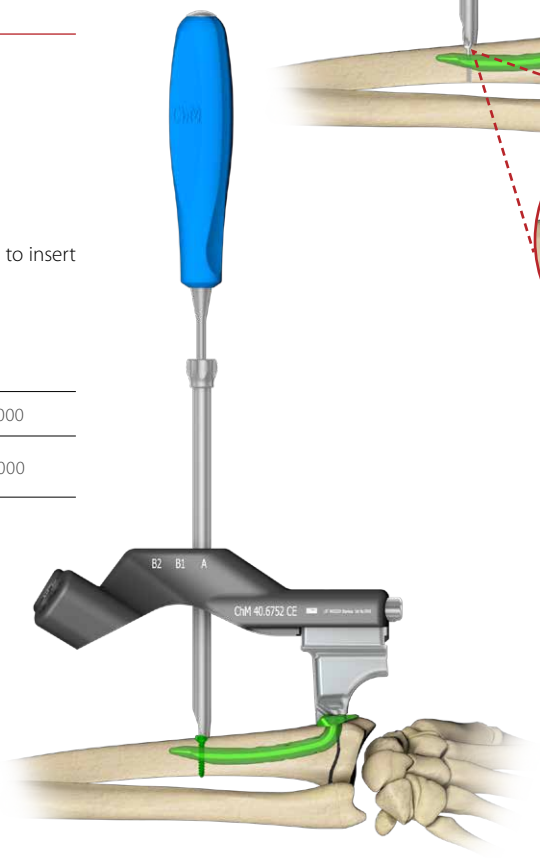


Deepening performed for the screw head should not be excessively large - the drill should not pass through the cortex layer.

6. Use screwdriver T8 **[40.6765]** and protective guide 6.5/4.5 **[40.6757]** to insert the locking screw 2.4 of a suitable length.

Remove the screwdriver and protective guide.

	40.6757.000
	40.6765.000



4.5. LOCKING THE NAIL IN ITS PLATE PART

Three holes located in the bone-based plate part are provided for VA-type screws 2.4 insertion; one hole in the axis of the nail is positioned perpendicular to the outer surface of the plate part, and two angular holes are located on the sides. The holes located on the sides can be locked with targeter B using the holes marked „*Screws VA*". All three holes can be locked using drill guide 3.5/1.8 and the „*free hand*" technique. The advantage of the „*free hand*" technique is the possibility of inserting the screw in any direction with up to 15° deviation from the hole axis.

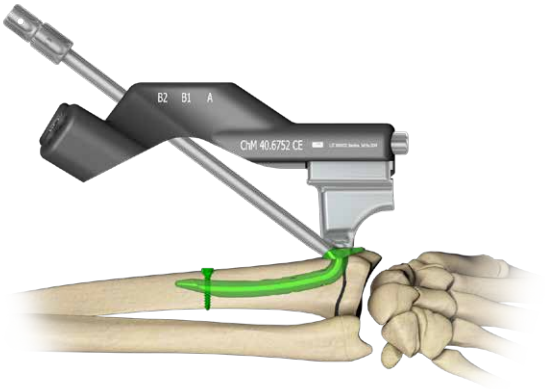
4.5.1. LOCKING THE NAIL IN ITS PLATE PART WITH TARGETER B

1. Insert the drill guide 3.5/1.8 **[40.6755]** into protective guide 5.5/3.5 **[40.6754]** and then into the corresponding hole in the targeter B **[40.6752]**. The drill guide should be screwed into the locking hole.

40.6752.000

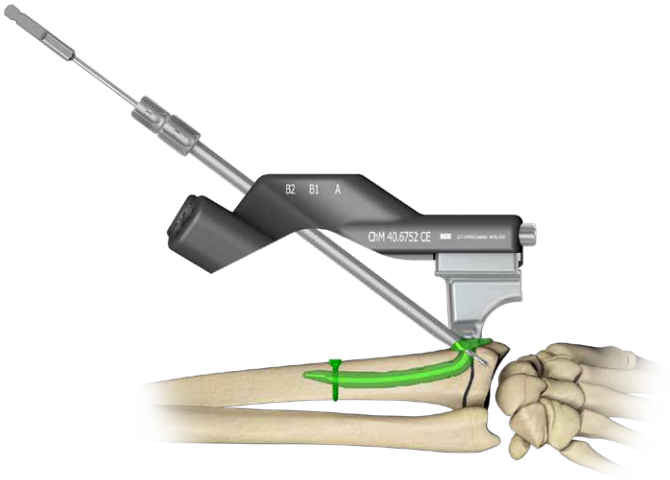
40.6754.000

40.6755.000



2. Use the drill guide 3.5/1.8 **[40.6755]** and drill 1.8/245 **[40.6760]** to drill a hole in the radial bone passing through the nail hole and the first cortex layer.

40.6760.000



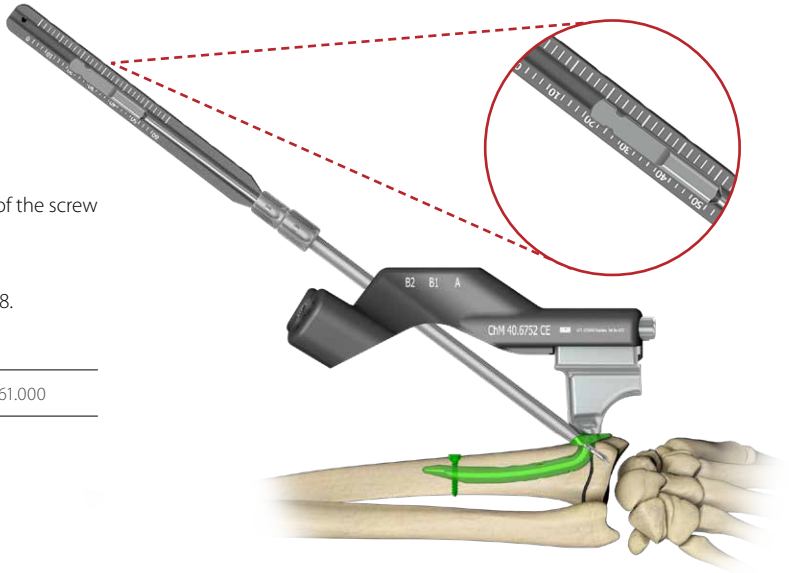
Drill under X-Ray control.

Do not penetrate the other cortex layer!

3. Use the screw length measure **[40.6761]** to determine the length of the screw VA 2.4.

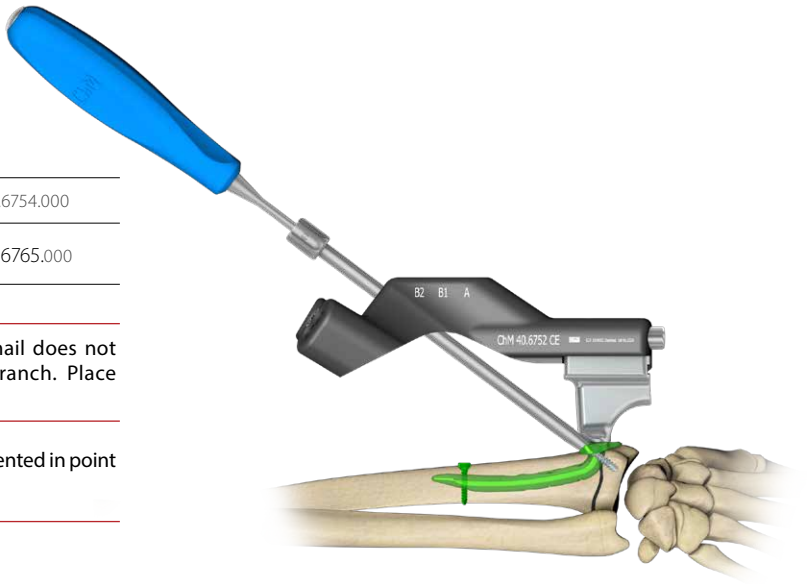
Remove the screw length measure, drill 1.8/245 and drill guide 3.5/1.8.

40.6761.000



4. Use screwdriver T8 **[40.6765]** and protective guide 5.5/4.5 **[40.6754]** to insert the **4.0ChLP** screw VA 2.4 of a suitable length.

Remove the screwdriver and protective guide.




40.6754.000


40.6765.000

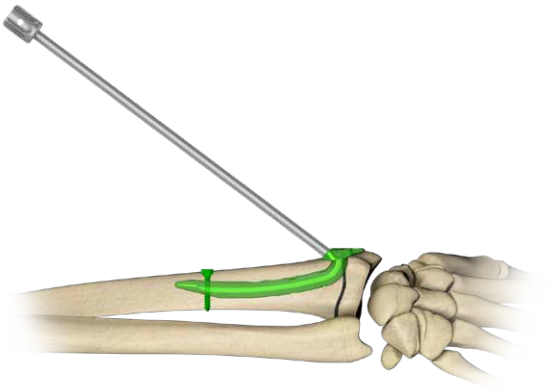
Having implanted the nail, make sure that the nail does not compress the tendons and the radial nerve branch. Place the tendons on the plate part of the nail.

When implanting the next VA screw, proceed as presented in point 4.5.1. from stage 1 to 4.

4.5.2. LOCKING THE NAIL IN ITS PLATE PART WITH DRILL GUIDE 3.5/1.8

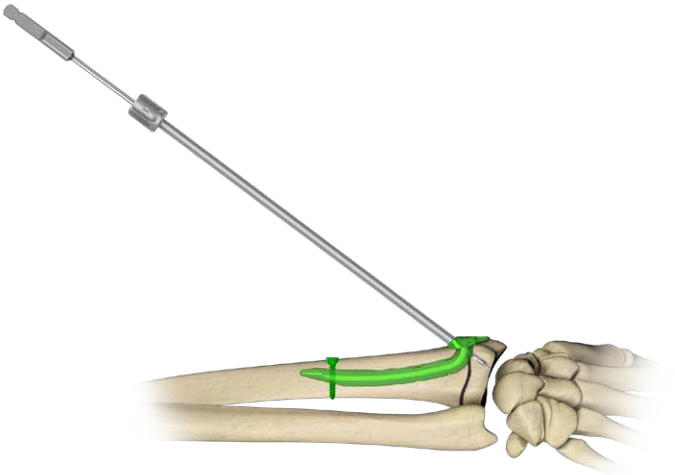
At this stage, when locking the nail, remove the targeter arm **[40.6751]** and targeter B **[40.6752]** from the nail.

1. Insert the drill guide 3.5/1.8 **[40.6755]** into the hole of the plate part of the nail.




40.6755.000

2. Use the drill guide 3.5/1.8 **[40.6755]** and drill 1.8/245 **[40.6760]** to drill a hole in the radial bone passing through the nail hole and the first cortex layer.



40.6760.000

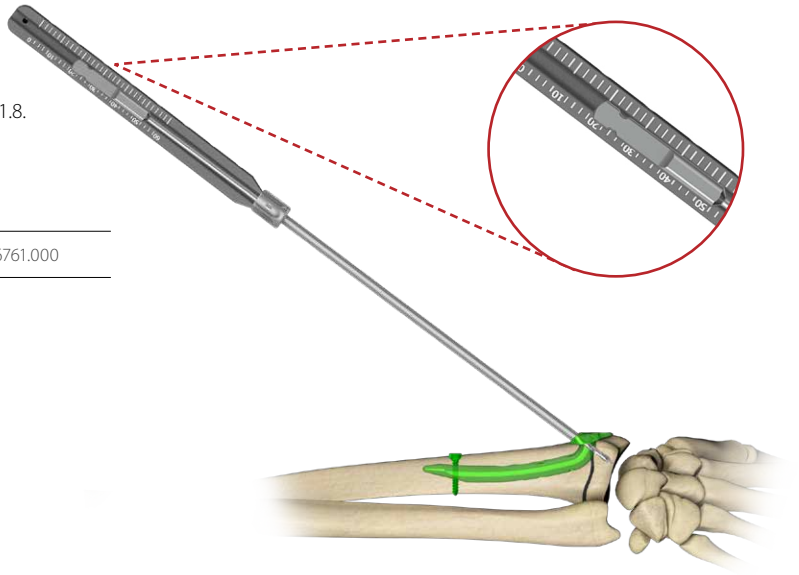
Drill under X-Ray control.

Do not penetrate the other cortex layer!

3. Use the screw length measure **[40.6761]** to determine the length of the screw VA 2.4.

Remove the screw length measure, drill 1.8/245 and drill guide 3.5/1.8.

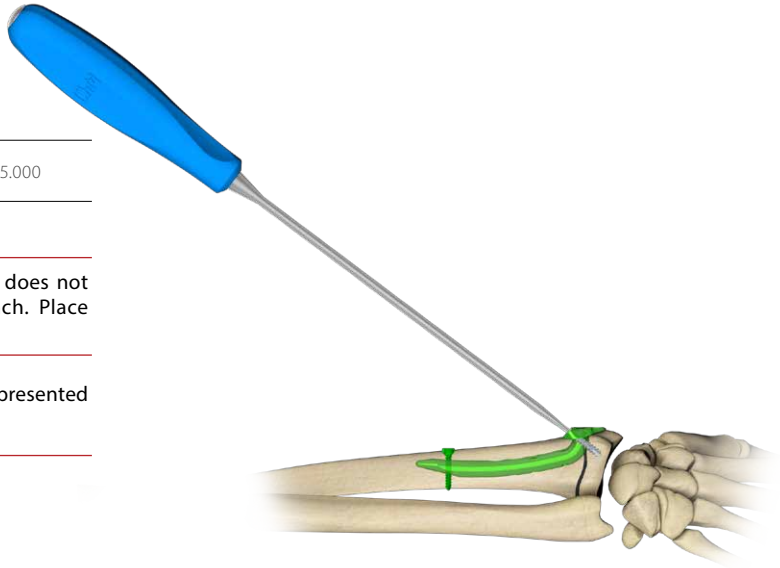
40.6761.000



4. Use screwdriver T8 **[40.6765]** to insert the **4.0ChLP** screw VA 2.4 of a suitable length.

Remove the screwdriver.

40.6765.000



Having implanted the nail, make sure that the nail does not compress the tendons and the radial nerve branch. Place the tendons on the plate part of the nail.

When implanting the rest of VA screws, proceed as presented in point 4.5.2. from stage 1 to 4.

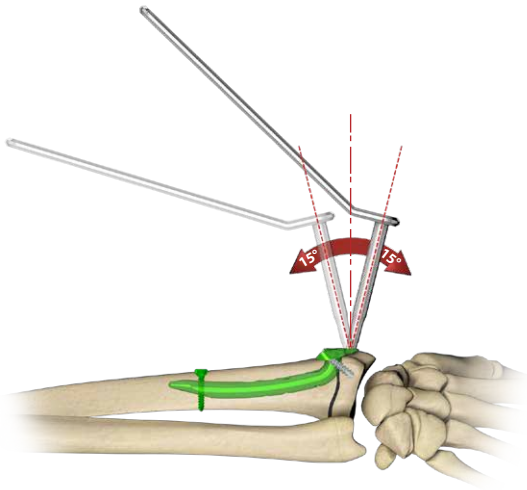
4.5.3. LOCKING THE NAIL IN ITS PLATE PART WITH 'FREE HAND' TECHNIQUE

At this stage, when locking the nail, remove the targeter arm **[40.6751]** and targeter B **[40.6752]** from the nail.

1. Insert the guide VA 1.8 **[40.5928.018]** fully into the axis of locking hole.

Position the guide as required. The guide can be positioned at 15° in each direction in relation to the axis of the locking hole.

40.5928.018



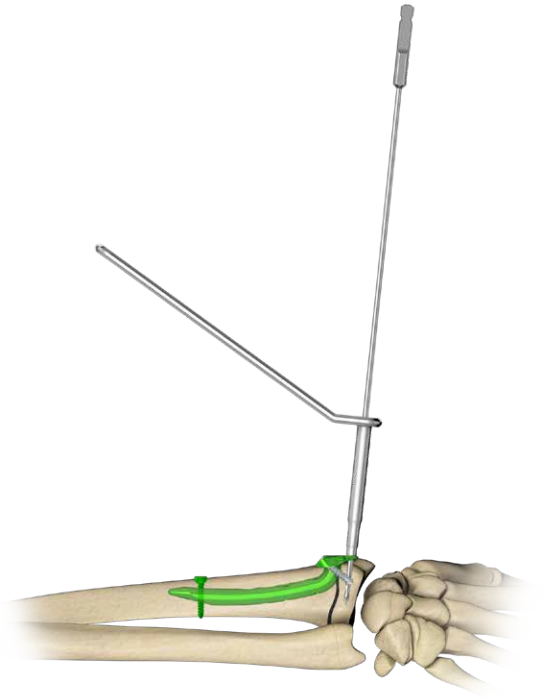
Exceeding a deviation angle of more than 15° may prevent the VA screw from being locked properly in the hole!

2. Use the guide VA 1.8 **[40.5928.108]** and drill 1.8/245 **[40.6760]** to drill a hole in the radial bone passing through the nail hole and the first cortex layer.


40.6760.000


Drill under X-Ray control to avoid the collision of the drill with already implanted screws.

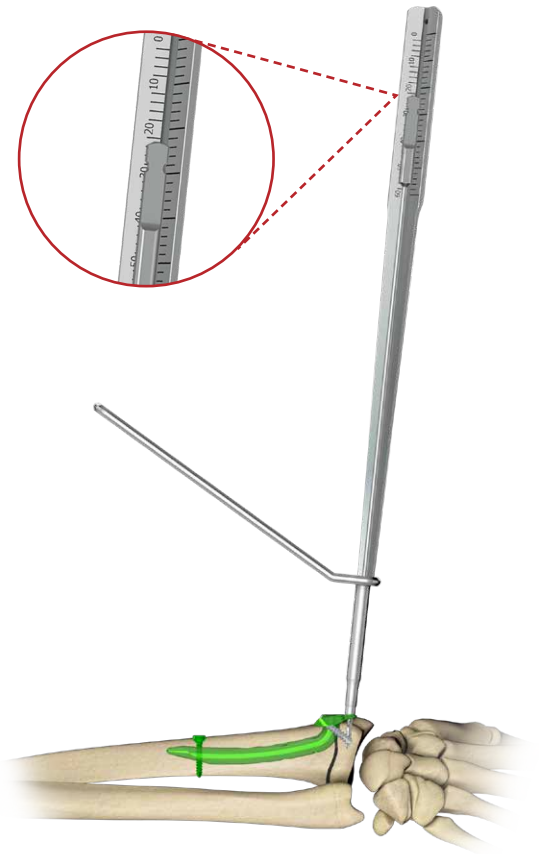

Make sure the drill does not penetrate the joint!



3. Use the screw length measure **[40.6762]** to determine the length of the screw VA 2.4.

Remove the screw length measure, drill 1.8/245 and guide VA 1.8.

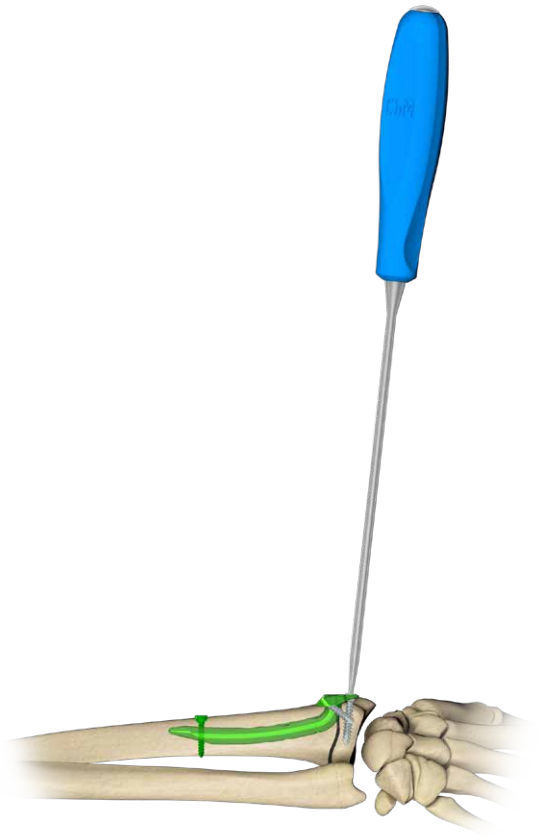

40.6761.000



4. Use screwdriver T8 **[40.6765]** to insert the **4.0ChLP** screw VA 2.4 of a suitable length.

Remove the screwdriver.

40.6765.000

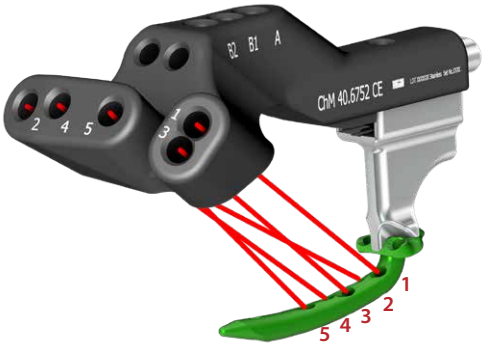


Having implanted the nail, make sure that the nail does not compress the tendons and the radial nerve branch. Place the tendons on the plate part of the nail.

When implanting the rest of VA screws using this method, proceed as presented in point 4.5.3. from stage 1 to 4.

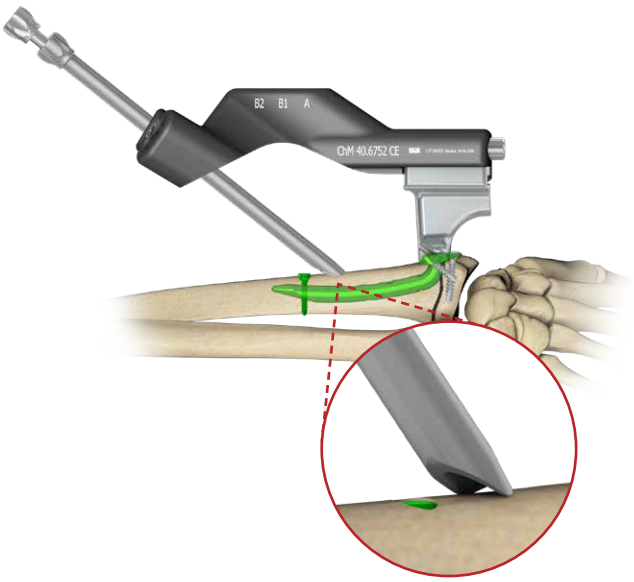
4.6. LOCKING THE NAIL IN ITS CENTRAL PART

Five holes in the central part pf the plate are located multiplanar and are intended for locking screws 2.4 insertion. Use holes marked with numbers from „*1*" to „*5*" on targeter B to implant the screws in the middle part of the plate.



1. Insert trocar 4.5 **[40.6759]** into the protective guide 6.5/4.5 **[40.6757]** and then into the appropriate hole in the targeter B. Use trocar to mark on the cortex an entry point for the drill and simultaneously push the protective guide as close to the bone as possible.

Remove the trocar.



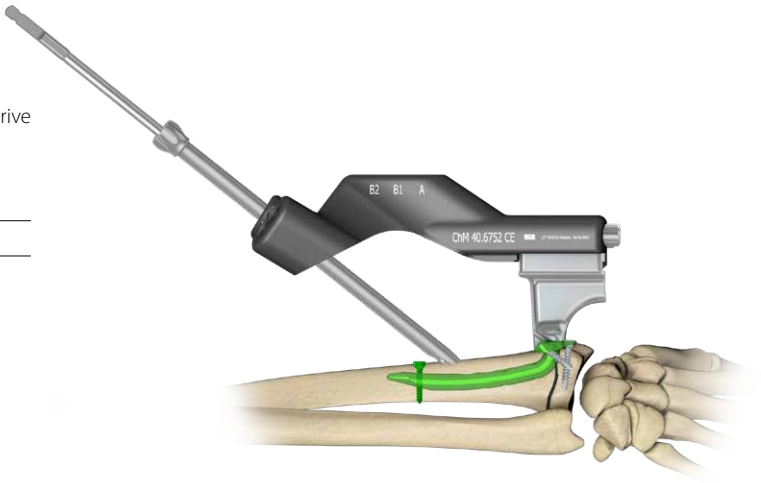
Position the protective guide tip 6.5/4.5 **[40.6757]** so that it fits the bone curvature.

40.6757.000

40.6759.000

2. Use protective guide 6.5/4.5 **[40.6757]** and drill **[40.6763]** mounted in the drive to initially drill a hole for the drill 1.8, to a depth of up to 2mm.
Remove the drill.

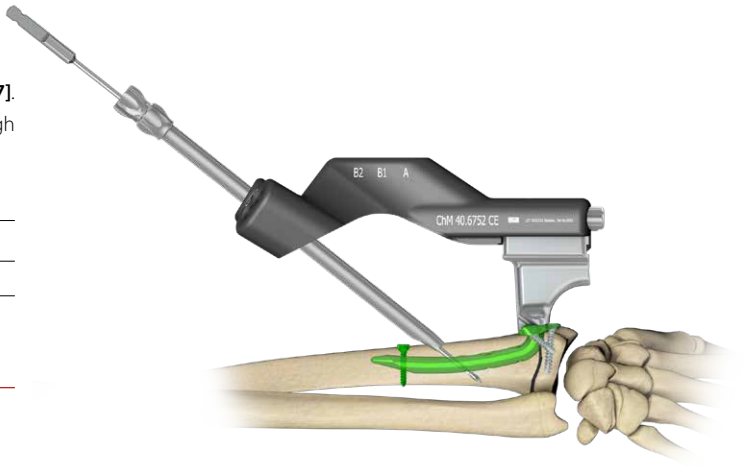
40.6763.000



3. Insert the drill guide 4.5/1.8 **[40.6758]** into the protective guide 6.5/4.5 **[40.6757]**. Use the drive and the drill 1.8/245 **[40.6760]** to drill a hole in the radius through first cortex layer and the hole in the nail.

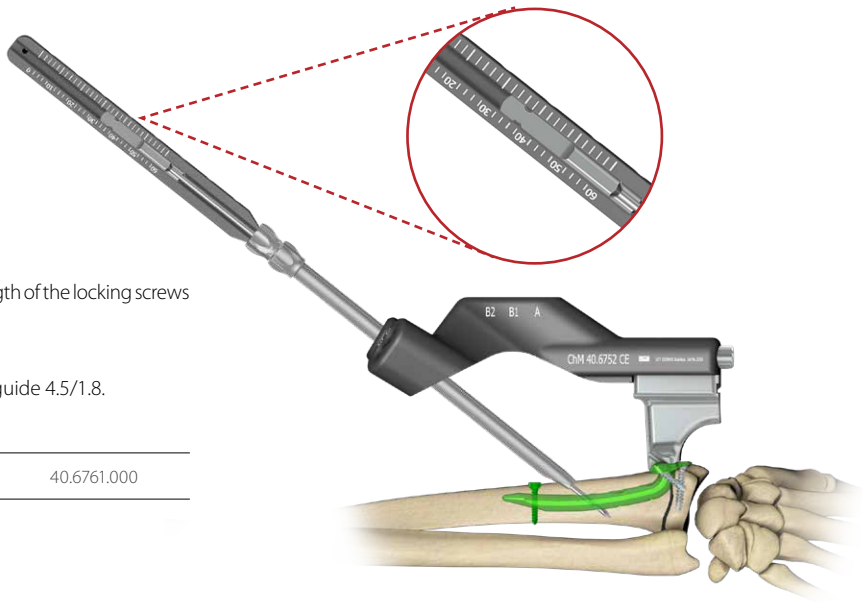

40.6758.000


40.6760.000




Drill under X-Ray control.

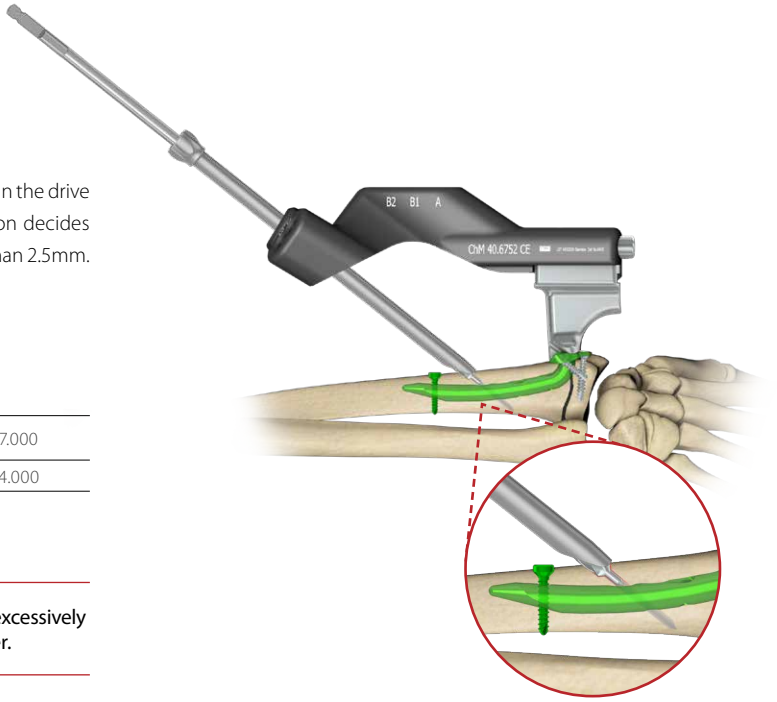

Do not penetrate the other cortex layer.



4. Use screw length measure **[40.6761]**, to determine the length of the locking screws 2.4

Remove the screw length measure, drill 1.8/245 and drill guide 4.5/1.8.


40.6761.000

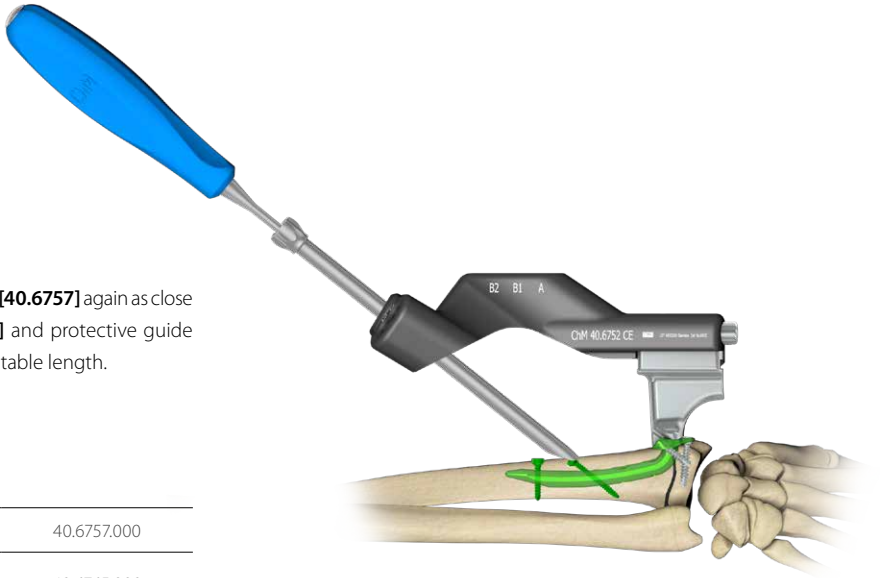


5. Use protective guide 6.5/4.5 **[40.6757]** and drill **[40.6764]** mounted in the drive to drill a deepening for the head of locking screw 2.4. The surgeon decides about the size of the deepening, however it should be not greater than 2.5mm.

Remove the drill.

	40.6757.000
	40.6764.000

Deepening performed for the screw head should not be excessively large - the drill should not pass through the cortex layer.



6. Position adequately and press the protective guide 6.5/4.5 **[40.6757]** again as close to the bone as possible. Use screwdriver T8 **[40.6765]** and protective guide 6.5/4.5 **[40.6757]** to insert the locking screw 2.4 of a suitable length.

Remove the screwdriver and protective guide.

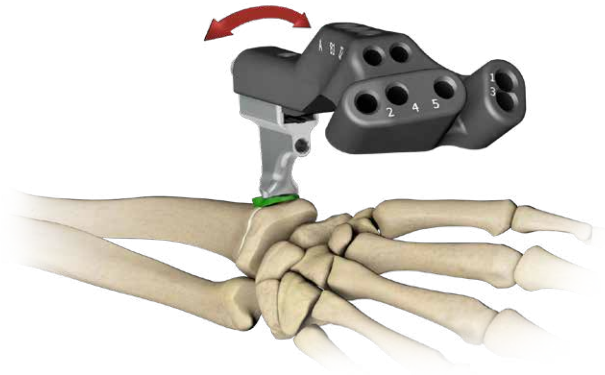
	40.6757.000
	40.6765.000

When implanting the rest of screws in central part of the nail, proceed as presented in point 4.6. from stage 1 to 6.

4.7. RADIAL NAIL REMOVAL

1. Use screwdriver T8 **[40.6765]** to remove all locking screws 2.4 and screws VA 2.4.

40.6765.000



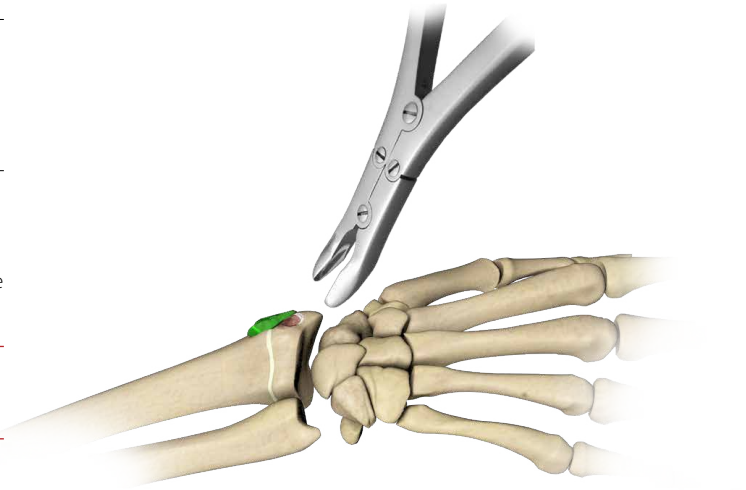
2. Position the targater arm **[40.6751]** on the plate part of the nail and join them using connecting screw M3 **[40.6753]**. Attach the targeter B **[40.6752]** to the targeter arm **[40.6751]**. Moving in all directions, loosen and then remove the nail.

Remove the targeters.

40.6751.000

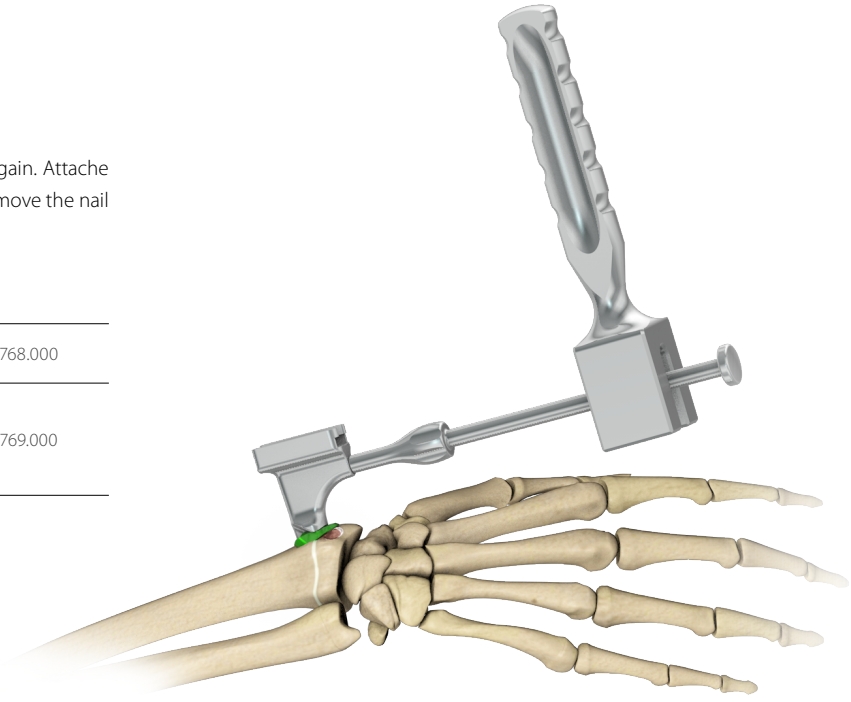
40.6753.000

40.6752.000



3. Using a bone rongeur, available at the operating theater, make a hole for the nail removal.

Repeat steps 2 and 3 several times if necessary.



4. Attach the targater arm **[40.6751]** to the plate part of the nail again. Attache impactor-extractor **[40.6768]** and using the mallet **[40.6769]**, remove the nail from the medullary cannal.

40.6768.000

40.6769.000

5. INSTRUCTIONS OF USE

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ChM®

CE

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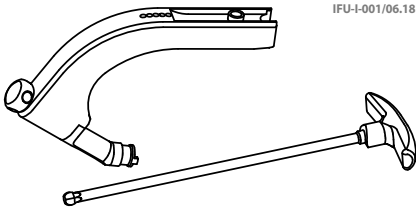
IFU-I-001/06.18



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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 deaning 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 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 all rotating devices for straightness *(this can be simply achieved by rolling the device an 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.

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

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

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

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILIZE	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
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Niesterilní • 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 • Sterilizován 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 • 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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