ST/55A-2

ChM®

INTRAMEDULLARY OSTEOSYNTHESIS
Elastic intramedullary nail for children

- *IMPLANTS*
- *INSTRUMENT SET 15.0504.100*
- *SURGICAL TECHNIQUE*

www.chm.eu

SYMBOLS DESCRIPTION УМОВНІ ПОЗНАЧЕННЯ

Ti	Titanium or titanium alloy Титан або сплав титану
St	Steel Сталь
L	Left Лівий
R	Right Правий
L R	Available versions: left/right Доступні варіанти: лівий/правий
Len	Length Довжина
	Torx drive Шліц *„torx" (зірка)*
	Torx drive cannulated Шліц *„torx" (зірка)* канюльований
	Hexagonal drive Шліц шестигранний
	Hexagonal drive cannulated Шліц шестигранний канюльований

	Cannulated Канюльований
	Locking Блокуючий
	Diameter Діаметр
	Inner diameter Внутрішній діаметр
	Recommended length range for a particular nail Діапазон довжин, рекомендований для використання з конкретним стержнем
	Angle Кут
16 ÷ 90	Available lengths Доступні довжини
Ster Non Ster	Available in sterile/ non- sterile condition Доступні варіанти: стерильний / нестерильний

	Caution - pay attention to a special procedure. Попередження - звернути увагу на особливу процедуру.
	Perform the activity under X-Ray control. Виконувати під контролем рентгенівського апарату.
	Information about the next stages of a procedure. Ознайомитись з інструкцією з використання.
	Proceed to the next stage. Перехід до наступного етапу процедури.
	Return to the specified stage and repeat the activity. Повернення до попереднього етапу та повтор дії.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product. Перед застосуванням виробу слід уважно прочитати інструкцію, яка постачається разом з виробом, а також додається в кінці цього документу. Серед іншого, вона містить показання, протипоказання, небажані наслідки, а також рекомендації та застереження, пов'язані з використанням виробу.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure. Наведений опис не є детальною інструкцією. Рішення про вибір операційної техніки приймає лікар.

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The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

I. INTRODUCTION

I.1. INDICATIONS

Elastic intramedullary nails for children are intended for fractures of lower limbs in children *(also in older small-statured patients)* and fractures of upper limbs in all patients. These nails can also be used in bones with a narrow medullary canal. Elastic nails do not disturb bone growth in children.

Intramedullary osteosynthesis with elastic nails comprises:
- implants *(intramedullary nail, end cap)*,
- instrument set for the device implantation and removal when the treatment process has been finished,
- surgical technique.

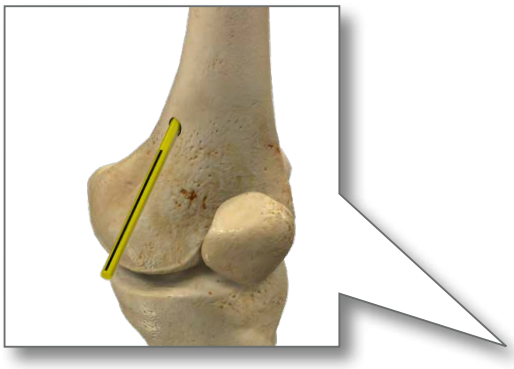
The presented range of implants is made of titanium and its alloys and implantable steel in accordance with ISO 5832 standards.

Advantages:
- no need for cast immobilization,
- faster fracture stabilization,
- immediate patient mobility after surgery,
- protection of periosteum and soft tissue in the area of fracture,
- fast anatomic bone union.

Contraindications:
- use of the nails in overweight or very muscular patients,
- fractures of the femoral neck and trochanteric region,
- intra-articular fractures,
- long oblique spiral fractures,
- in children with neuromuscular disorders or congenital bone fragility - immobilization period should be minimized.

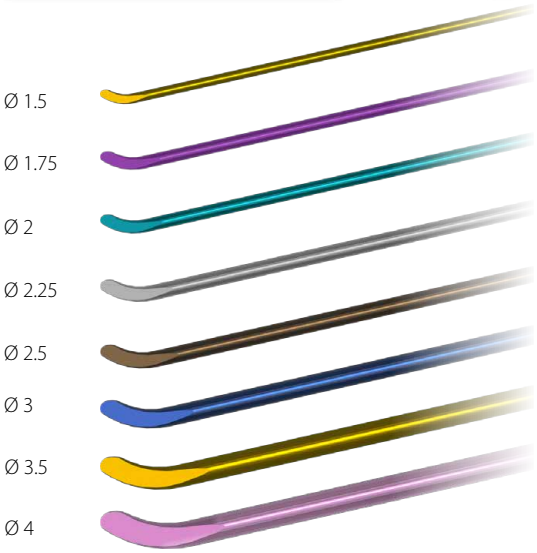
II. IMPLANTS

II.1. ELASTIC INTRAMEDULLARY NAIL FOR CHILDREN



Ø	Len	Ti
1.5	300	3.5089.300
1.75		3.2418.300
2		3.5090.300
2.25		3.2419.300
2.5		3.5091.300
1.5	350	3.5089.350
1.75		3.2418.350
2.25		3.2419.350
1.5	440	3.5089.440
1.75		3.2418.440
2		3.5090.440
2.25		3.2419.440
2.5		3.5091.440
3		3.5092.440
3.5		3.5093.440
4		3.5094.440

available	Ø	1.5 mm ÷4 mm
	L	300 mm ÷ 440 mm



II.2. LOCKING ELEMENTS

END CAP 5.5

15	3.5088.055

The maximum diameter of the nail - 2.5 mm

END CAP 7.5

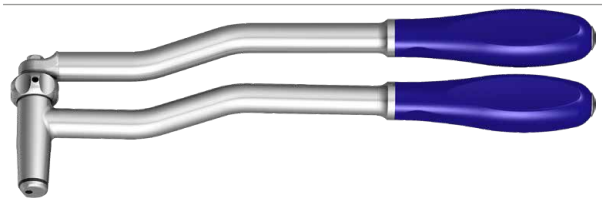
28	3.5088.075

The maximum diameter of the nail - 4 mm

III. INSTRUMENT SET

For bone fragments osteosynthesis using elastic nails and their removal after the treatment process has been completed, the instrument set [15.0504.100] is used. The instruments included in the set are placed on a stand and covered with a cover - to facilitate their storage and transportation to the operating room. The set includes the following instruments:

15.0504.100

	Name	Catalogue no.	Pcs
	Handle	**40.6381.100**	1
	Awl 5.0	**40.6382.100**	1
	Awl 9.0	**40.6382.200**	1
	Drill 5.0	**40.6384.000**	1
	Drill 3.2	**40.6385.000**	1
	Handle	**40.6386.000**	1
	Impactor-extractor	**40.6387.100**	1
	Nails cutting device	**40.6388.300**	1
	Mallet	**40.6389.100**	1
	Mallet	**40.6390.100**	1
	Mallet	**40.6394.000**	1
	Curved awl 9.0	**40.6393.100**	1
	Curved awl 5.0	**40.6393.000**	1
	Wrench 4.5	**40.6395.000**	1
	F clasp	**40.6396.100**	1

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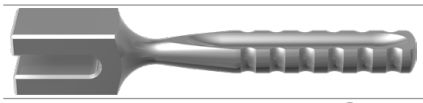
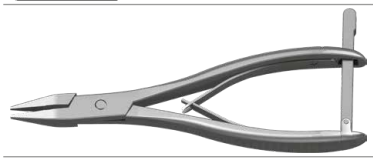
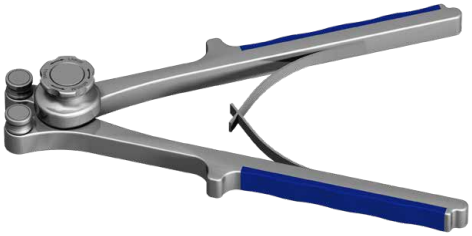
15.0504.100

	Name	Catalogue no.	Pcs
	Protective guide 5.0	**40.2539.050**	1
	Mallet	**40.4595.100**	1
	Forceps	**40.8531.000**	1
	Extractor	**40.6397.000**	1
	Bender	**40.6398.000**	1
	Cutting pliers	**40.7253.000**	1
	Star screwdriver T15	**40.0670.200**	1
	Star screwdriver T25	**40.0671.100**	1
	Perforated aluminum lid 1/1 595x275x15mm Gray	**12.0750.200**	1
	Stand	**14.0504.100**	1
	Container with solid bottom 1/1 595x275x185mm	**12.0750.103**	1

IV. SURGICAL TECHNIQUE

NOTE! The following description covers the most important stages of the implantation of the elastic 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.

IV.1. SURGERY PLANNING

Prior to the procedure, an x-ray image of the broken bone should be taken in AP and lateral position, to determine the type of fracture and size selection of an intramedullary nail *(diameter, length)* to be used.

IV.2. NAIL SELECTION

To choose the nail properly:

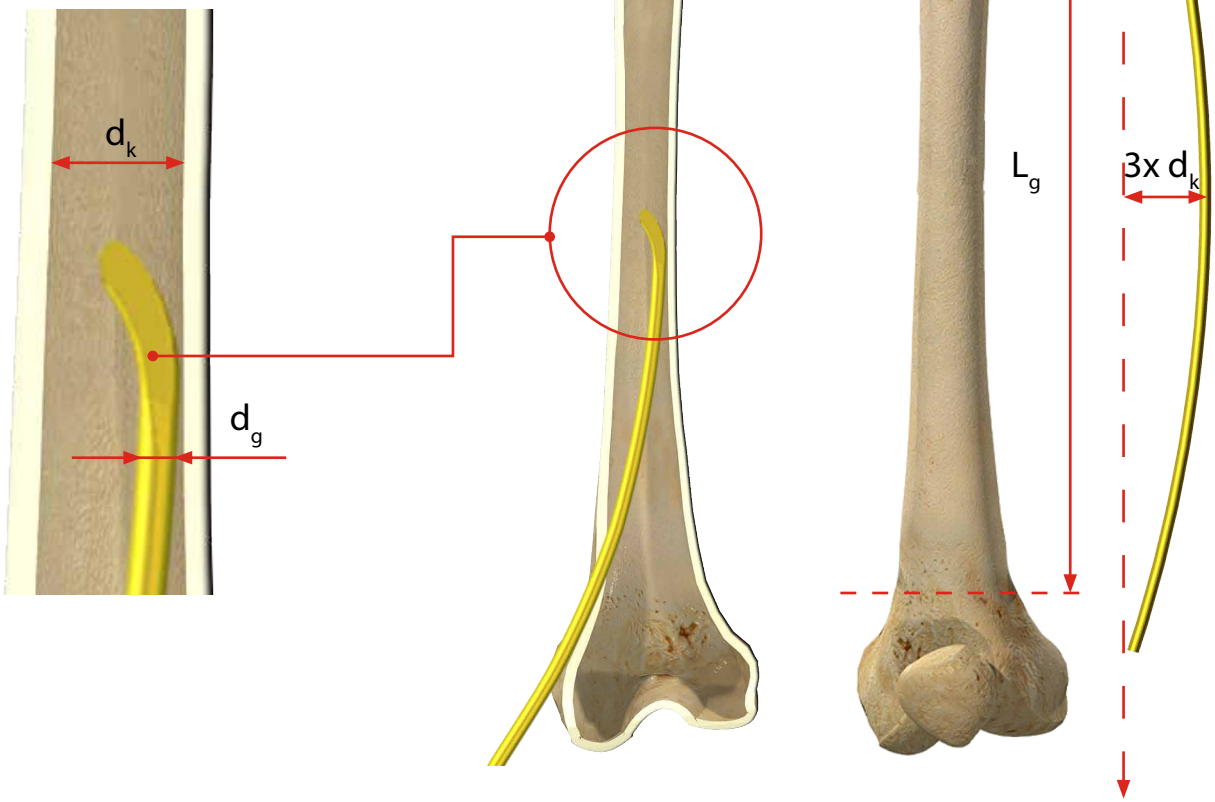
- choose d_g *(nail diameter)* so that the dependence:

d_g *(nail diameter)* = d_k *(medullary canal diameter)* x 0.4 is satisfied

- choose L_g *(nail length)* by dependence:

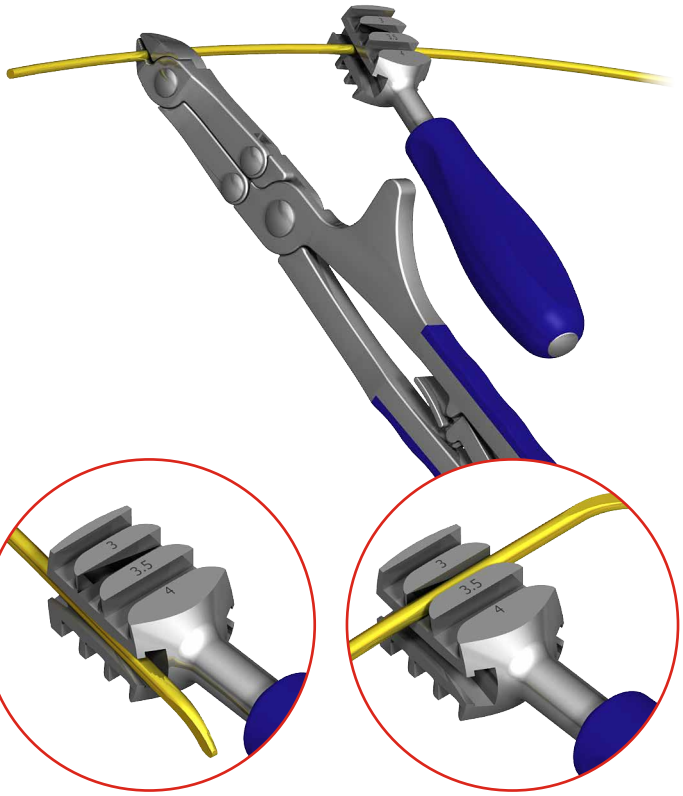
3 x d_k *(medullary canal diameter)*

Choose the length so that the nail end to be cut off is as small as possible.



IV.3. NAIL CUTTING

Using the handle **[40.6381.100]** and extractor **[40.6397]**, adjust the shape of the nails to the medullary canal. The bent part of the nail should be located at the fracture level. A number of nail profiling slots is provided in the handle to fit best nail diameter.

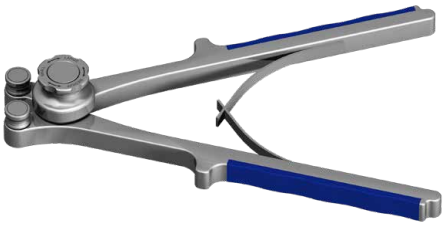


NOTE! Do not bend the nail repeatedly in the same place. This may result in the loss of its mechanical properties or, in extreme cases, the implant fracture.
- It is important to obtain the desired shape of the nail with as few bends as possible. Excessive bending can lead to postoperative implant fracture.
- Implants that have been bent repeatedly cannot be used.

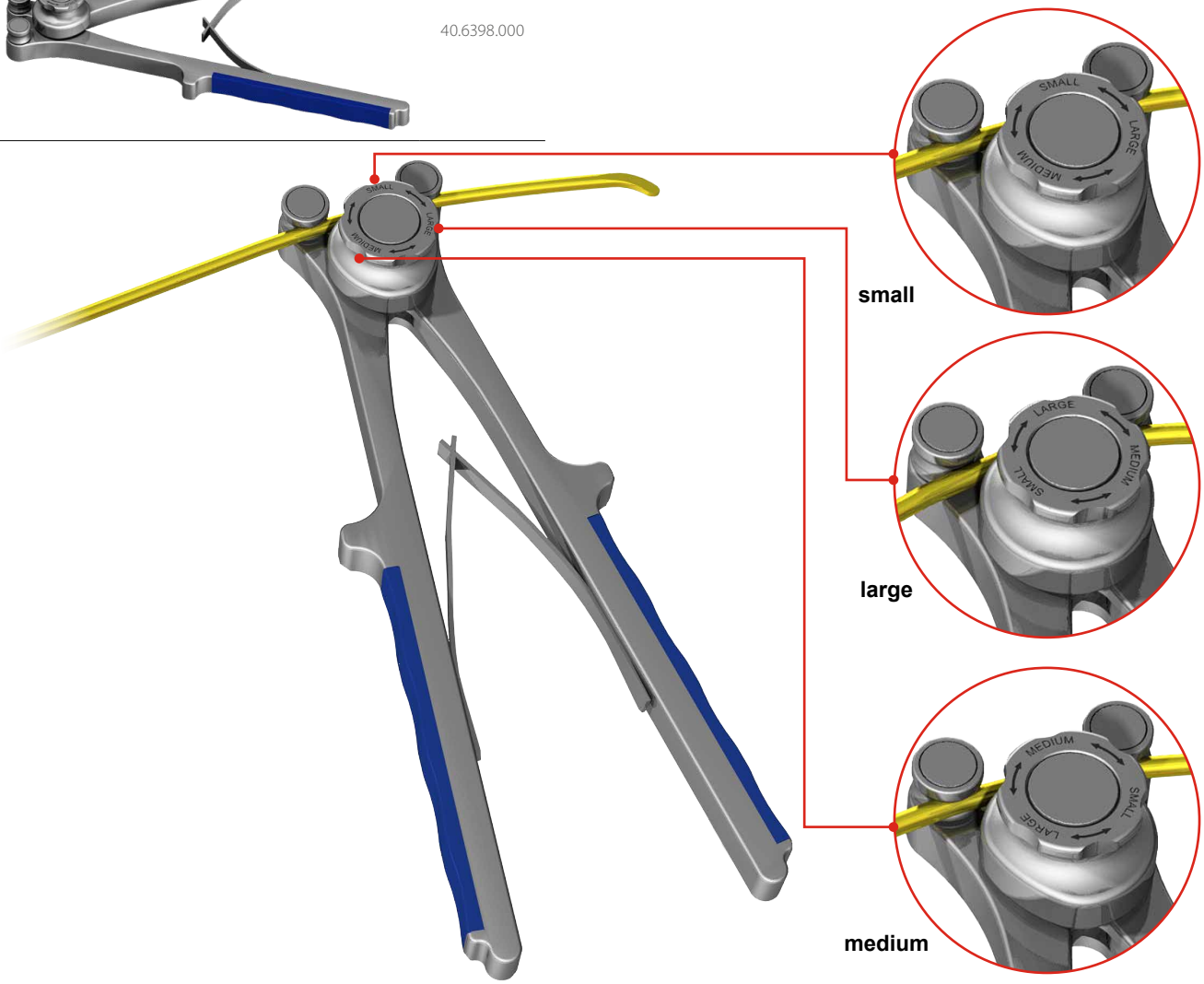
40.6381.100

40.6397.000

The nails of any diameter can also be profiled using bender **[40.6398]**.
The instrument is equipped with an implant adjustable bending radius mechanism *(3 positions)*.

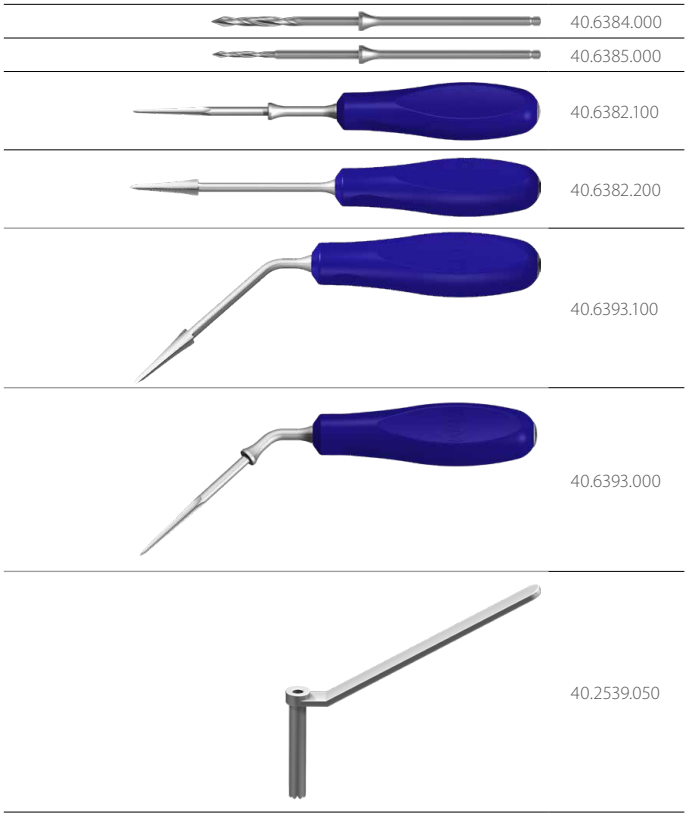


40.6398.000



IV.4. MEDULLARY CANAL OPENING

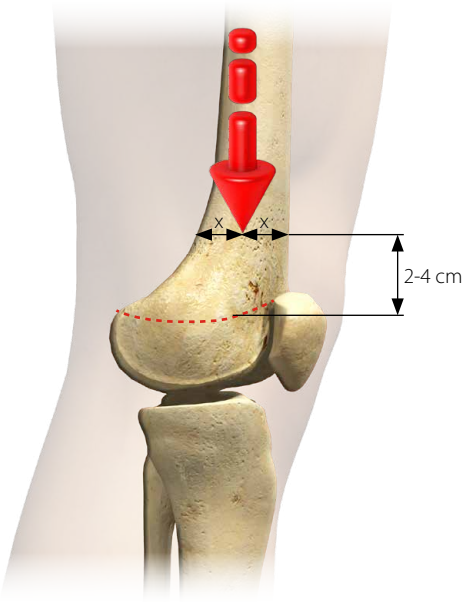
The first layer of cortical bone can be punctured using drills 5.0 **[40.6384]** and 3.2 **[40.6385]** and awls 5.0 **[40.6382.100]** and 9.0 **[40.6382.200]** *(if need be, curved awls 5.0 [40.6393] and 9.0 [40.6393.100] may be used)*. It is recommended to use the protective guide 5.0 **[40.2539.050]**, when using drills 5.0 and 3.2 and awl 5.0, since the guide secures soft tissues and prevents excessive bone puncturing.

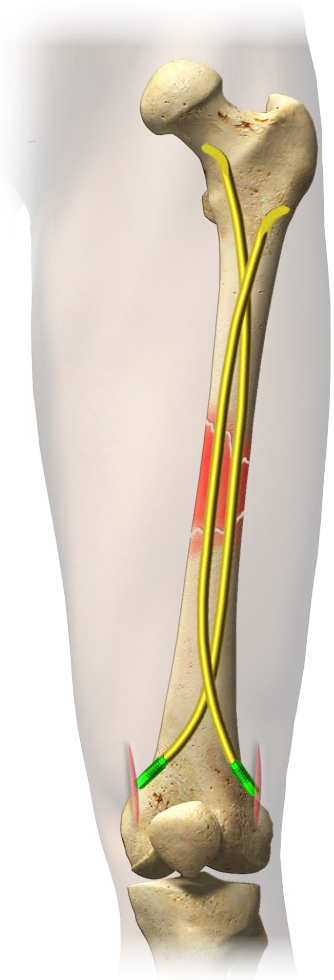


To take full advantage of the possibilities of intramedullary osteosynthesis with elastic nails, the following guidelines must be observed:
1) The bent part of the nail is located at the fracture level
2) Nails are facing each other in the canal
3) Nails cross above and below the fracture site.

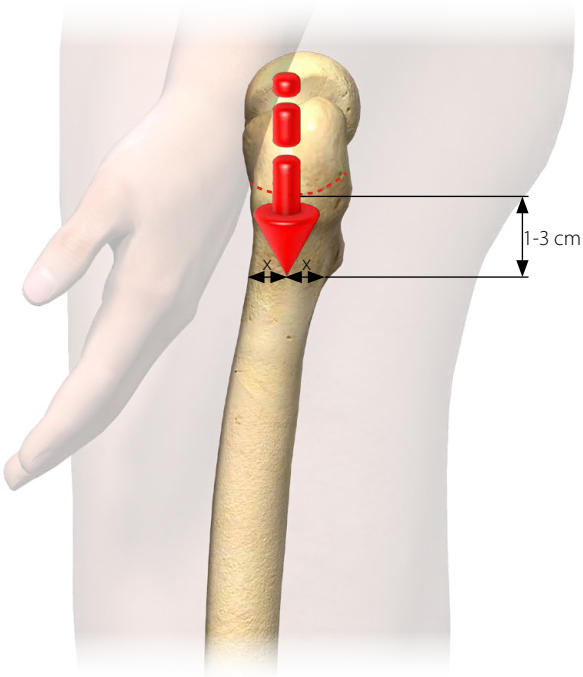
IV.4.1. Femur

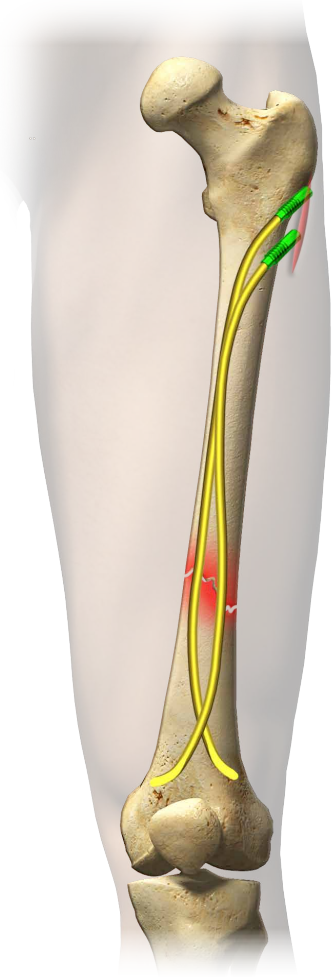
The nail entry point for retrograde nailing.





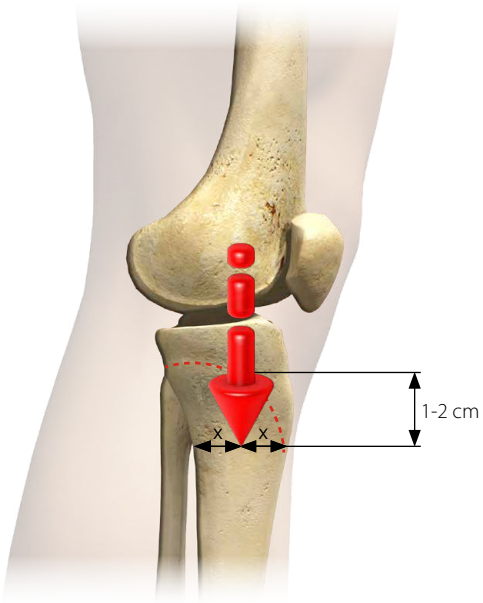
The nail entry point from the proximal part.

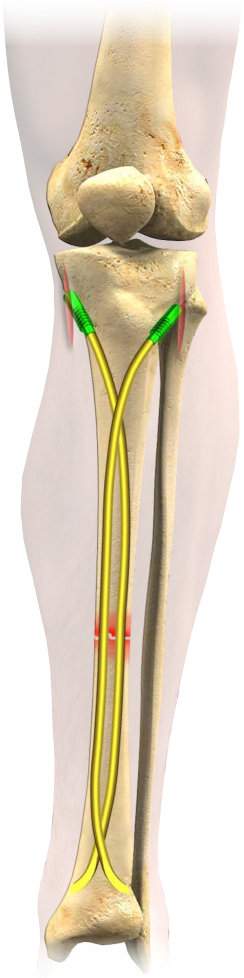




IV.4.2. Tibia

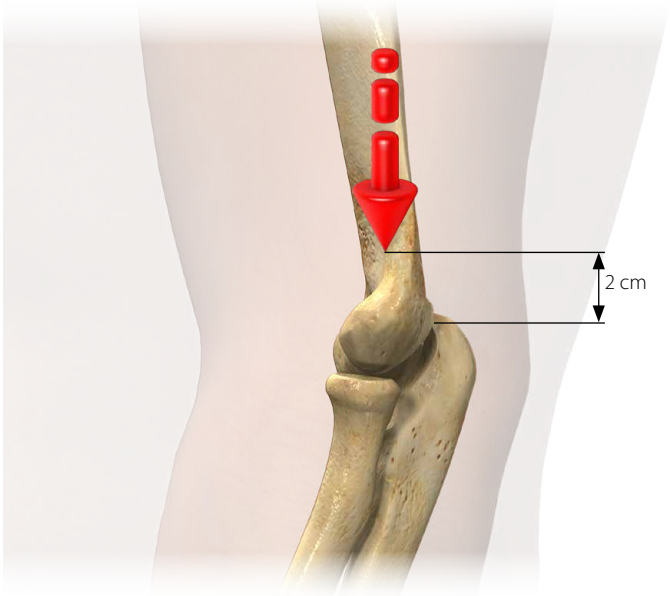
The nail entry point from the proximal part.

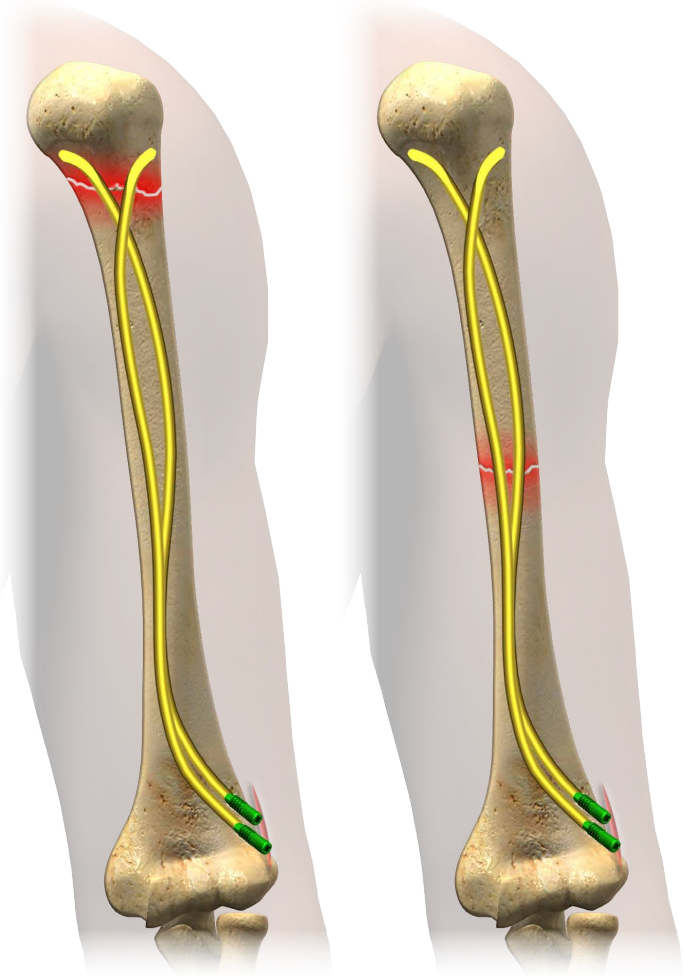




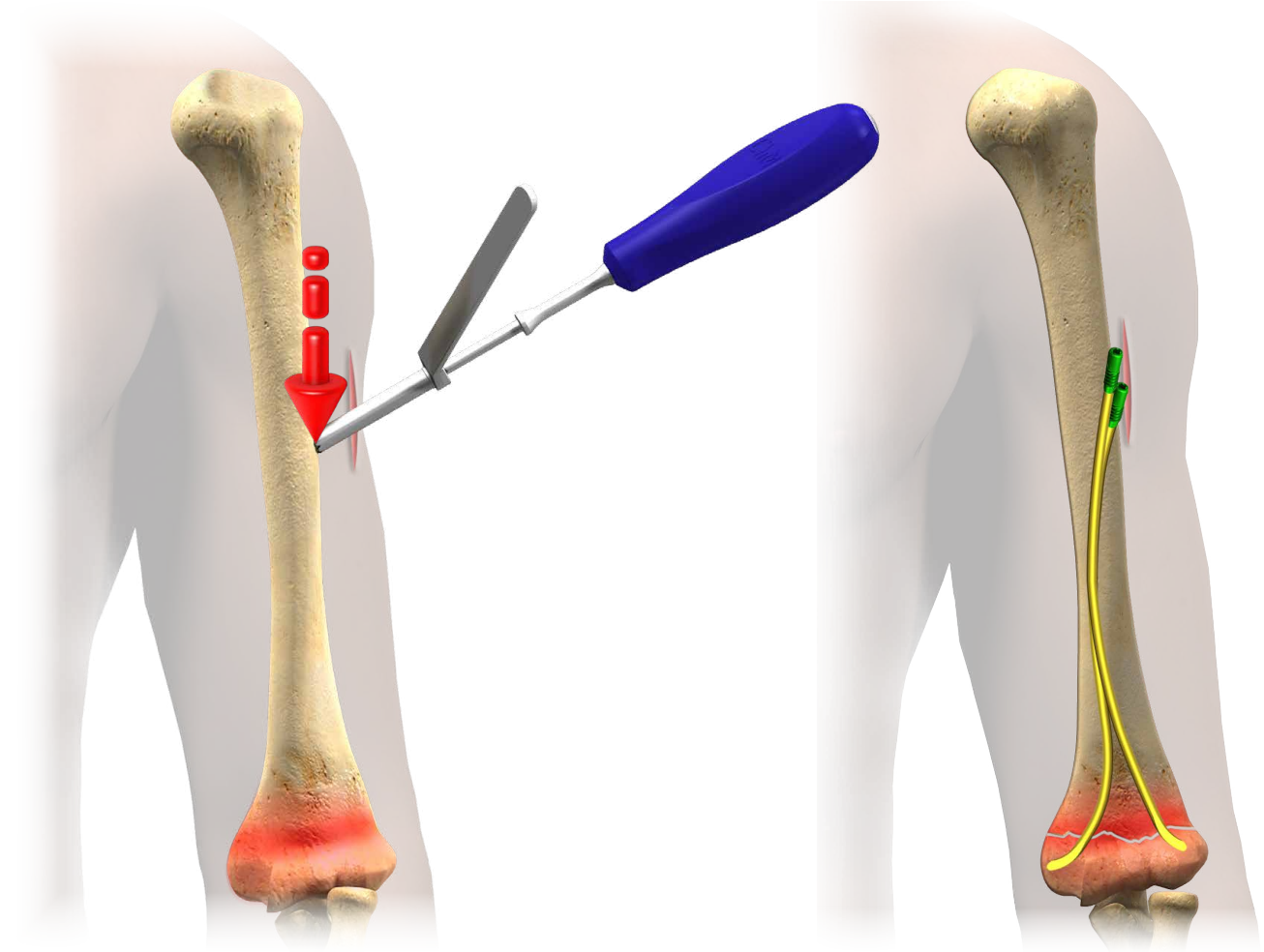
IV.4.3. Humerus

The nail entry point for retrograde nailing.



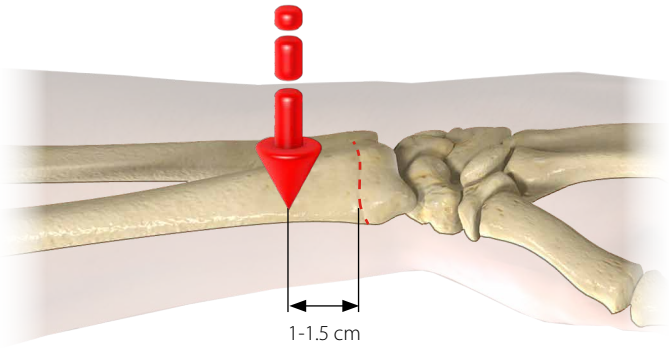


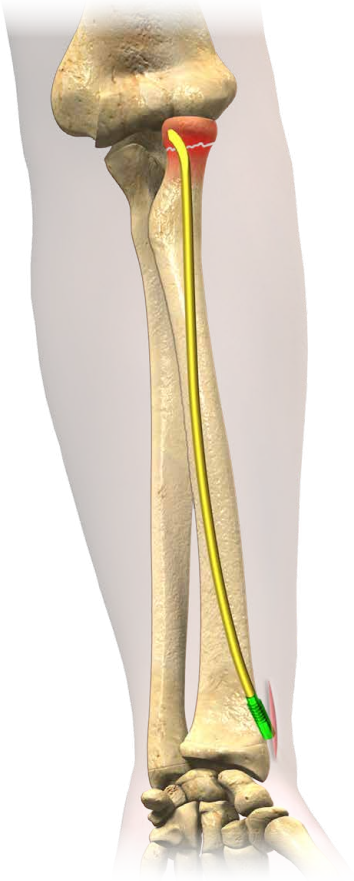
The nail entry point for supracondylar fracture of the humerus.



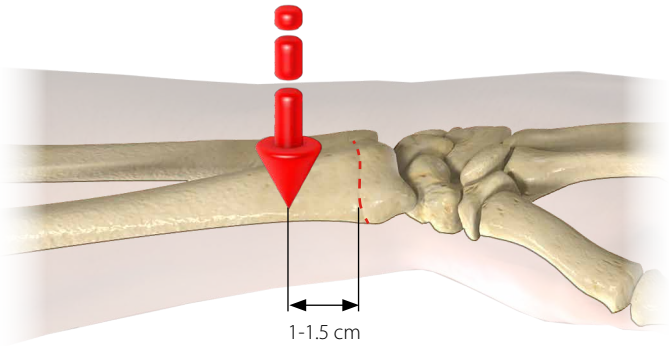
IV.4.4. Forearm bones

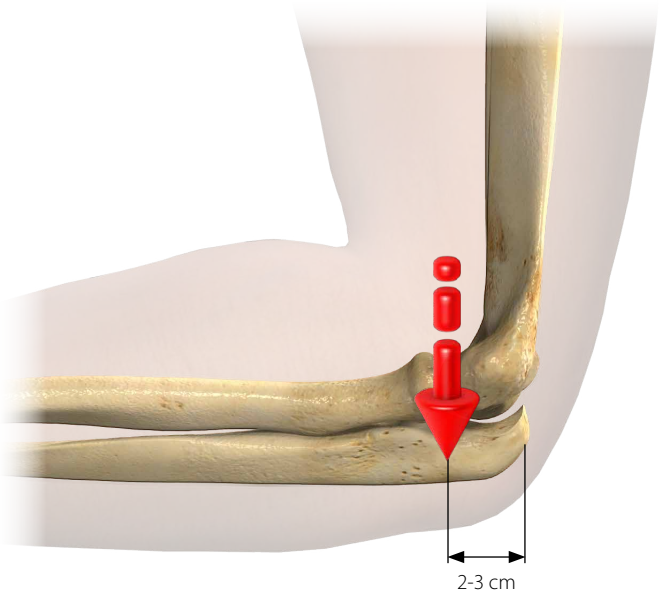
The nail entry point for radius fracture.

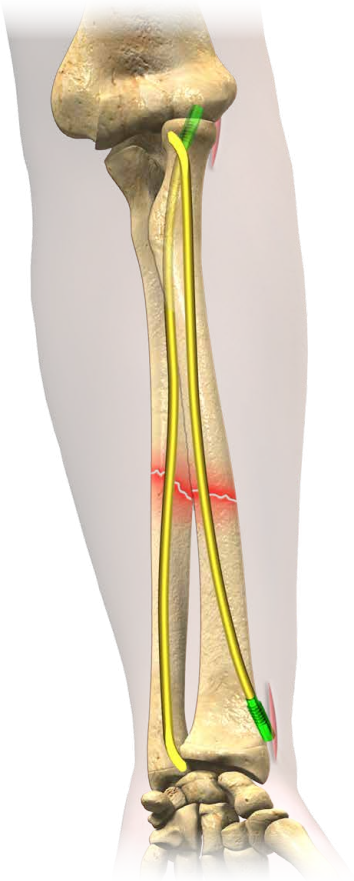




The nail entry points for radius and ulna fractures.

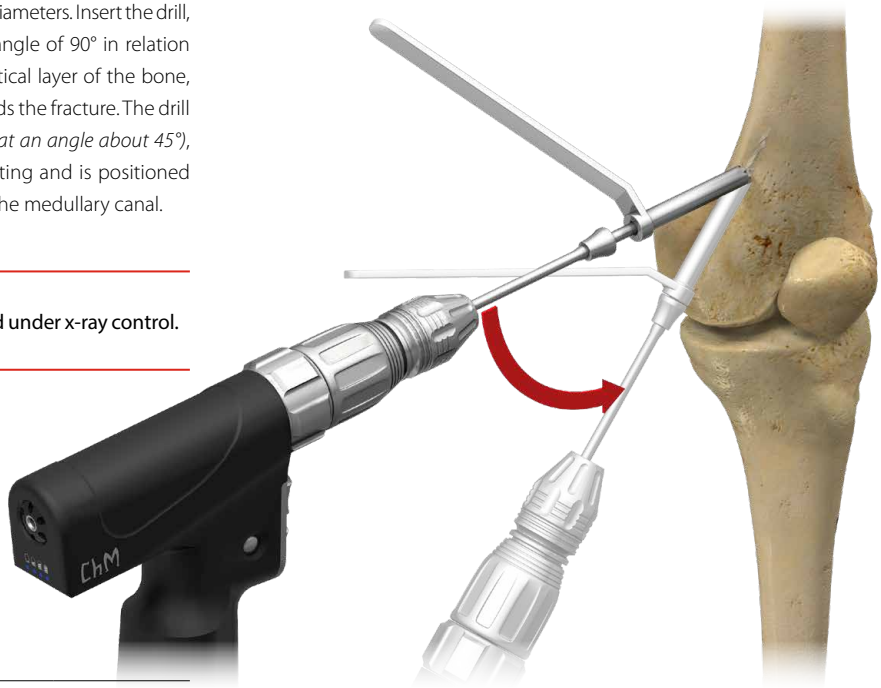






IV.4.5. Opening medullary canal with a drill

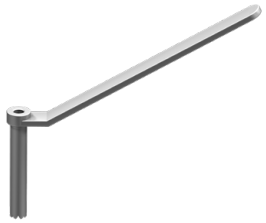
To open the medullary canal, use the drill 5.0 **[40.6384]** for the nail diameters from 3mm up, and drill 3.2 **[40.6385]** for other nails with smaller diameters. Insert the drill, through the protective guide 5.0 **[40.2539.050]**, at an angle of 90° in relation to the cortical bone. Having passed through the first cortical layer of the bone, carefully position the drill with the guide at an angle towards the fracture. The drill should rotate, but should not move when positioning *(at an angle about 45°)*, otherwise, the drill may break. Then, the drill that is rotating and is positioned at the correct angle, can be insert further until it reaches the medullary canal.



NOTE! This procedure should be performed under x-ray control.

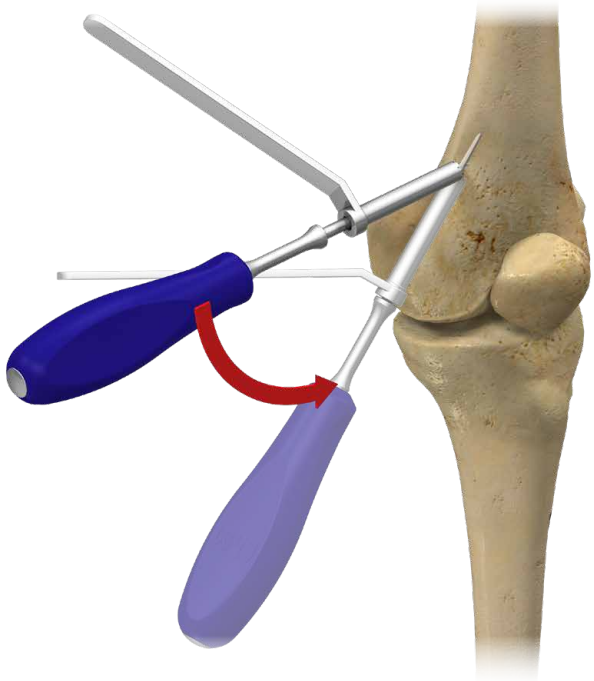

40.6384.000


40.6385.000


40.2539.050

IV.4.6. Opening medullary canal with an awl

To open the medullary canal, use the awl 9.0 **[40.6382.200]** for the nail diameters from 3mm up, and awl 5.0 **[40.6382.100]** for other nails with smaller diameters. Insert the awl, through the protective guide 5.0 **[40.2539.050]**, at an angle of 90° in relation to the cortical bone. Having passed through the first cortical layer of the bone, carefully position the awl with the guide at an angle towards the fracture. Rotate the awl and position it at an angle about 45° and then insert it further until it reaches the medullary canal. Proceed similarly when using the awl 9.0 *(but without the protective guide)*.




40.6382.200


40.6382.100


40.2539.050

NOTE! This procedure should be performed under x-ray control.

IV.5. NAIL INSERTION

Attach a selected implant to the handle **[40.6386]** and insert into already opened medullary canal. If necessary, attach the impactor-extractor **[40.6387.100]** to the handle **[40.6386]** and continue the insertion using mallet **[40.4595.100]**. Insert the implants until fracture site of the bone is reached. Use F clasp **[40.6396.100]** to align fracture elements. Afterwards, continue implants insertion. The nails inserted should cross above and below the line of fracture. The bent part of the nail should be at the level of fracture.

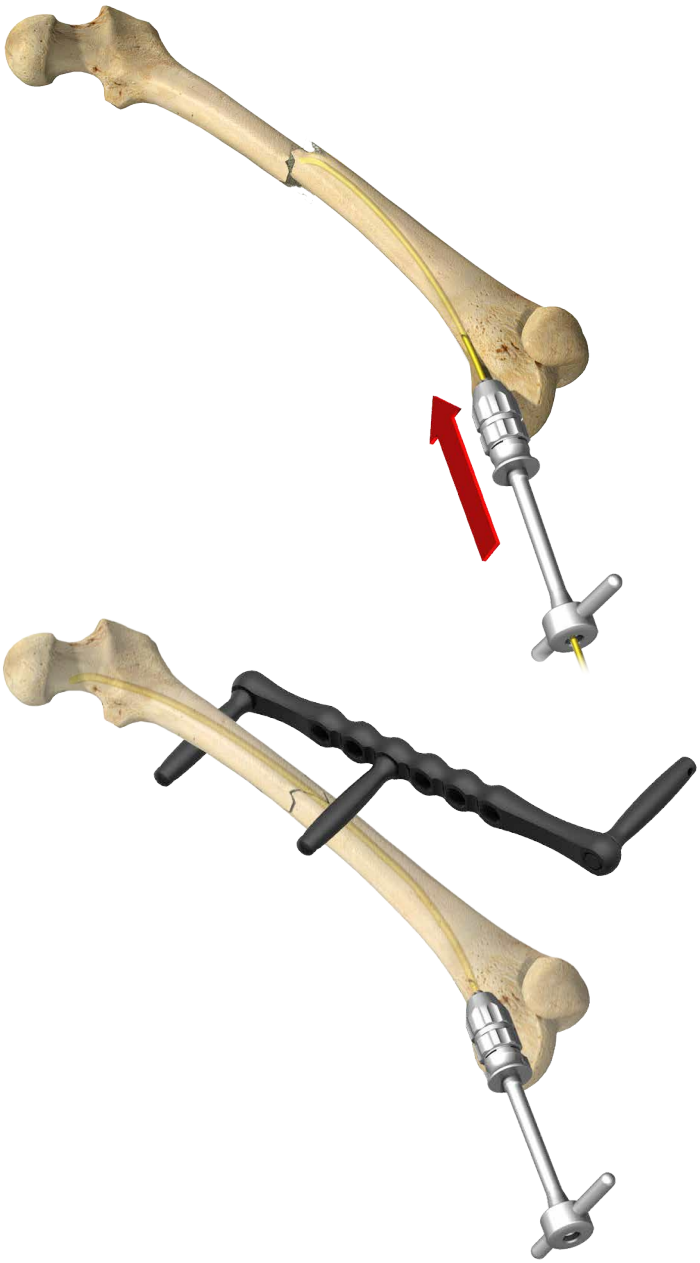
NOTE! This procedure should be performed under x-ray control.


40.6386.000


40.6387.100


40.4595.100


40.6396.100

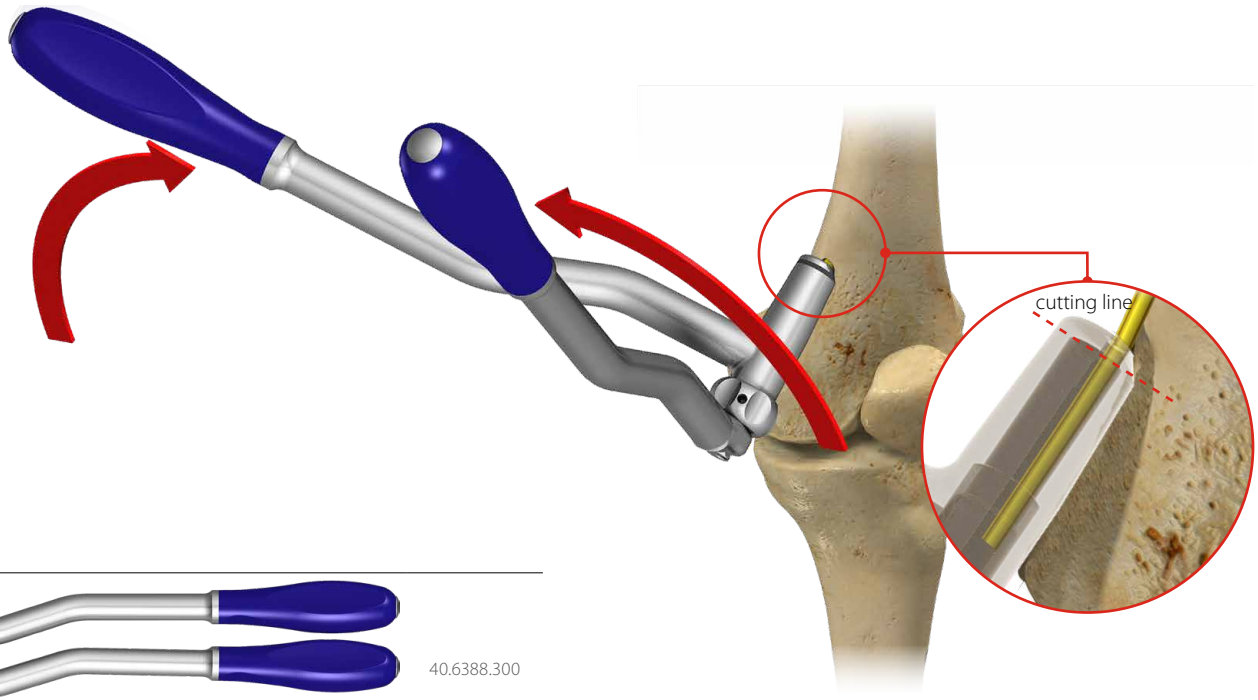


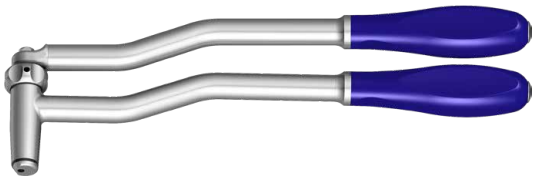
NOTE: Visible marker indicates the location of the bent end fragment of the nail.

IV.6. CUTTING THE NAIL ENDS OFF

Use nail cutting device **[40.6388.300]** to cut off the protruding ends of the nails. The device has 3 holes of different diameters corresponding to available nail diameters.

The black ring on the cutting sleeve indicates the line at which the implant will be cut off.
Having placed the cutting sleeve on the nail, move the handles firmly and smoothly to cut the end of the nail off. The cut-off part is kept inside the device.
To cut off the end of a nail with a diameter of up to 2.5 mm, cutting pliers **[40.7253]** can also use used.





40.6388.300

40.7253.000

IV.7. FINAL NAIL POSITIONING

Using the mallet **[40.4595.100]** and other suitable mallet, determine the final position of the protruding end of the implant:
- mallet **[40.6389.100]**, with an oblique ending, for nail diameters of 3-4 mm,
- mallet **[40.6390.100]**, with an oblique ending, for other diameters of the nail,
- mallet **[40.6394]**, with a standard ending, for all diameters of the nail.


40.4595.100


40.6389.100


40.6390.100


40.6394.000

IV.8. END CAP INSERTION

Use star screwdriver T25 **[40.0671.100]** or star screwdriver T15 **[40.0670.200]** *(depending on the nail diameter)* to place
- end cap **[3.5088.055]** - maximum diameter of the nail - 2.5 mm
- end cap **[3.5088.075]** - maximum diameter of the nail - 4 mm

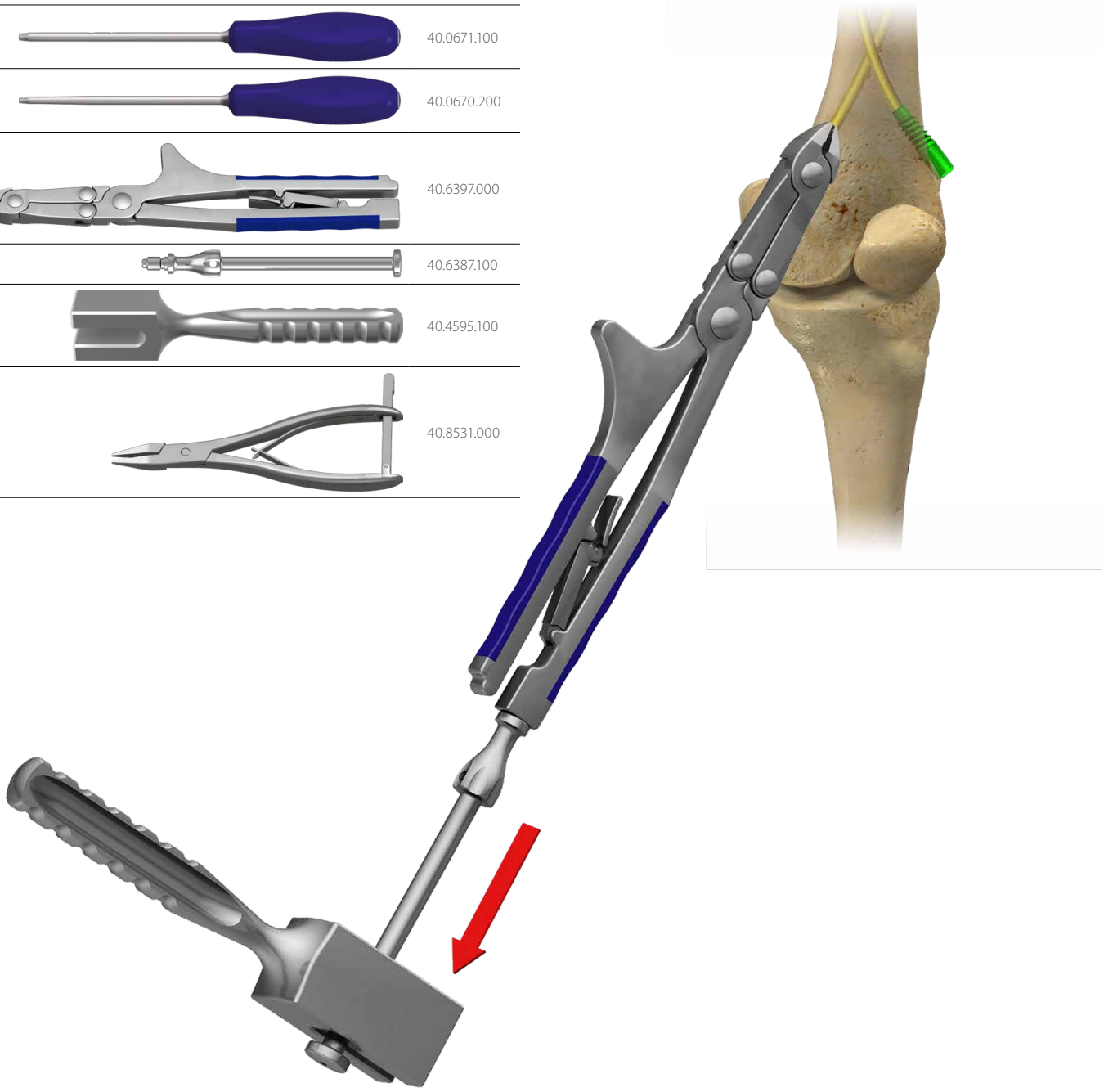
on the protruding ends of the nails and tighten them up,
The end cap prevents migration of the implant and reduces soft tissue irritation.


40.0671.100


40.0670.200

IV.9. NAIL REMOVAL

Use star screwdriver T25 **[40.0671.100]** or star screwdriver T15 **[40.0670.200]** to remove the end cap. Place the extractor **[40.6397]** on the protruding end of the implant, attach the impactor-extractor to the extractor's arm and with the help of the mallet **[40.4595.100]**, remove the nail from the medullary canal. Should the access to the protruding tip of the nail be difficult, use forceps **[40.8531]**.



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