

SURGICAL PROCEDURE
RETROGRADE FEMORAL NAIL



Medical Device Description

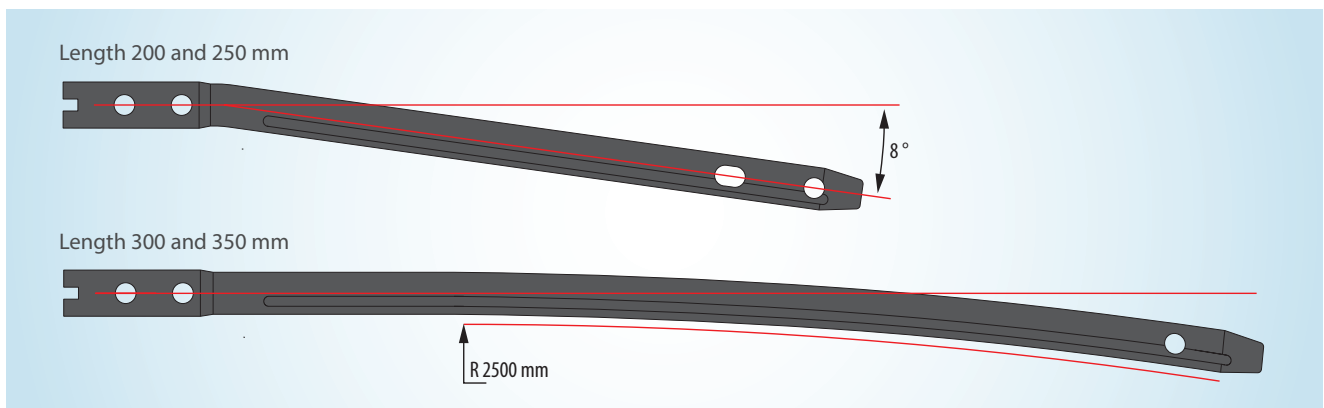
Implant system of retrograde intramedullary femoral nail consists a nail and locking screws. Closing the nail with a stopper is recommended. Firm tightening of the stopper will „lock“ the first distal locking screw.



Retrograde femoral intramedullary nails are hollow, round in cross section. Distal 35 mm in the 10.5 nail size is thickened to 11.5 mm. The 12.5 mm nail has the same diameter along the entire length. The nail is universal, i.e. the same for both the right and left leg. The nail is hollow, allowing the introduction by using a guide wire. They are available in lengths of 200, 250, 300 and 350 mm and in two diameters – 10.5 mm and 12.5 mm.

Locking screws should be used in 5 mm diameter. Commonly used to secure other intramedullary and reconstruction nails.

The implant system is made of titanium alloy (Ti 6Al 4V ISO 5832-3). It is necessary that all of the individual implants are made of this material.



AO ASIF Principles of internal fixation

Generally recognized ground rules for the internal fixation (especially for intramedullary and reconstructive nailing) presented in 1958 by the AO ASIF Association:

- Anatomic reduction
- Stable fixation
- Maintaining the blood supply
- Fast and active mobilization

Indications of the medical device

Indications for retrograde intramedullary femoral nail (the retrograde nail hereinafter) allows for closed and locked osteosynthesis; it can be an advantage when used for distal femur fractures of type A and C according to AO classification. The crucial factor for the indication of osteosynthesis using the antegrade or retrograde intramedullary nail is the fracture line height above the top of intercondylar fossa of the femur. Indications for osteosynthesis using the antegrade locked nail apply to sleeves when the distal fragment fracture line extends at least 5–6 cm above the top of intercondylar fossa of the femur. Indications for osteosynthesis using the retrograde locked nail apply to sleeves when the distal fragment fracture line extends 3–4 cm above the top of intercondylar fossa.

[1] Muller M.E., Allgower M., Schneider R., Willenegger R.: *AO Manual of Internal Fixation*, Third Edition, Springer, Berlin 1991

1. Patient's position

The patient lies on his back on the extension table, or standard operating table. The knee joint should be in 40–60° flexion, in order to allow adequate fracture reduction and determine the entry point for nail insertion. Soft roller inserted under the limb will help achieve the correct reduction and fixed position of the leg.

X-ray equipment should be placed so as to permit the display of femur, including the proximal and distal ends in two projections (lateral and anteroposterior – AP).

Healthy opposite leg should be bent at the hip and knee and should be stored on an elevated support to thereby facilitate the access to the X-ray imaging device (Fig. 1).

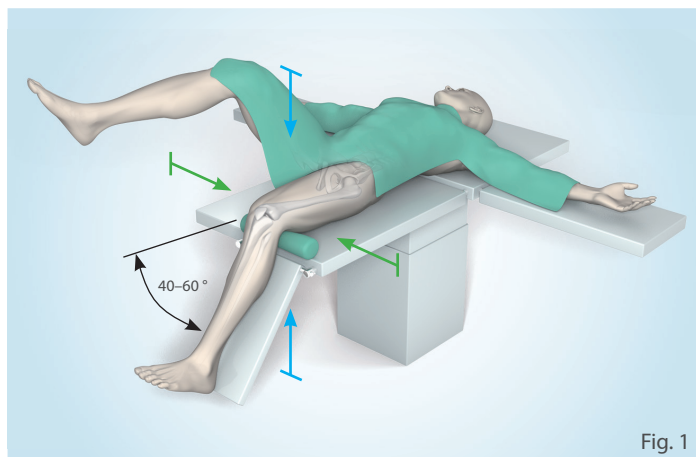


Fig. 1

2. Fracture reduction

Axial traction should be done through manual closed reduction. The whole operation should be controlled by using the X-ray equipment. In certain sleeves the distractor should be used for older fractures.

For fractures of type C (for intra-articular fractures), diacondylar fractured femur should be reduced first and only then stabilized from individual incisions transcutaneously using cannulated or cancellous screws. Those screws will stabilize the fragments. Screws must be placed so as to not interfere with the future path of the nail.

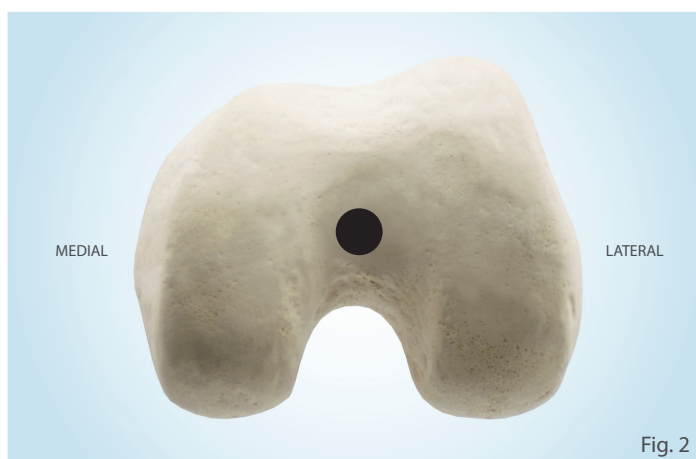


Fig. 2

3. Incision

Longitudinal 5 cm incision extends over the patella ligament.

4. Entry point

Entry Point for the **retrograde nail** introduction is to be in line with the axis of the femoral medullary canal. It is located in the front of intercondylar fossa ceiling, anterior and lateral to cruciate ligaments' insertions (Fig. 2).

The entry point is crucial for the whole operation, especially for the optimal placement of the nail in the medullary cavity. The accurate determination of the entry point is even more important in metaphyseal fractures where the exact location of fracture fragments is vital.

A **guide wire of 3–4 mm in diameter** is introduced into the designated point. It is advisable to introduce the **guide wire** using a **hand chuck device** to a depth of 100–150 mm in the direction of the anatomical axis of the femur, which is inclined by 7° to 9° lateral to the plane perpendicular to the joint surface (Fig. 3).

The introduction of the **guide wire** should be checked in two projections using X-ray equipment (Fig. 4a, 4b).

5. Cavity pre-drilling

Drilling tool is fitted to the checked **guide wire** and pre-drilling a pilot hole for the distal end of the nail is done manually. The tool pre-drills the cavity to the diameter of 13 mm. **Drilling tool** should be drilled into the depth of about 70 mm (Fig. 5).

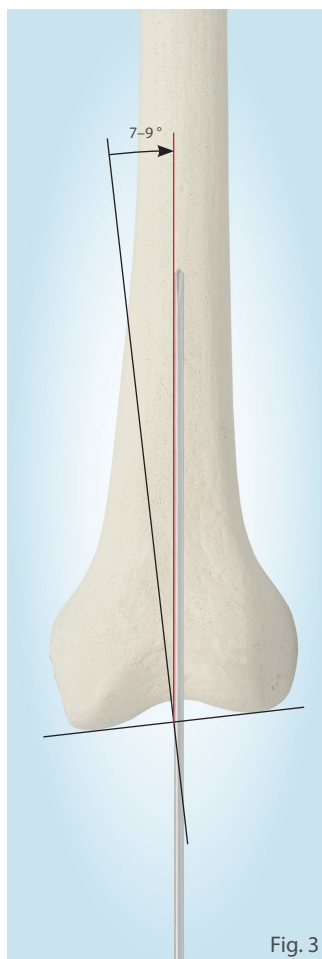


Fig. 3



Fig. 4a



Fig. 4b

It is appropriate to examine the fracture with X-ray equipment before moving to the next step.

The **guide wire** is removed and replaced with the **introducing wire**. Pre-drilling itself is done starting with the smallest diameter of the **flexible cutter**, which is from the diameter of 8 mm, increasing by the $\varnothing 0.5$ mm each cutter. Rotation of the **introducing wire** is removed using a special clamp. **Flexible cutter** gradually shifted in small movements forward and backward with no great power needed.

The cavity for **nails** is pre-drilled 0.5 to 1.5 mm larger than the nail applied (nail diameter 10.5 or 12.5 mm). The diameter of the nail is also determined within pre-drilling so that the pre-drilling for the nail of 12.5 mm in diameter would be finished with pre-drilling cutter diameter of 13–14 mm and for a nail of 10.5 mm in diameter it should be finished with pre-drilling cutter diameter of 11–12 mm (Fig. 6).

More on the use and treatment of flexible cutters see Flexible cutters (medullary cutters).

6. Choosing a nail

It was made in the preoperative phase or is made now.

Diameter of the nail has already been selected by the size of the cavity within the bone pre-drilling; choice of the nail is from diameters of 10.5 mm or 12.5 mm.

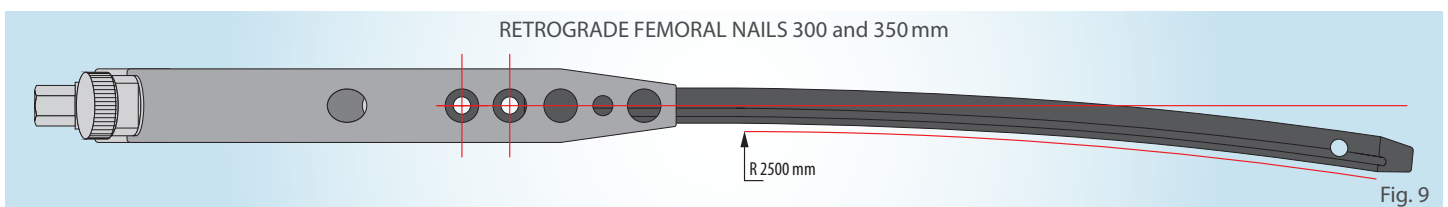
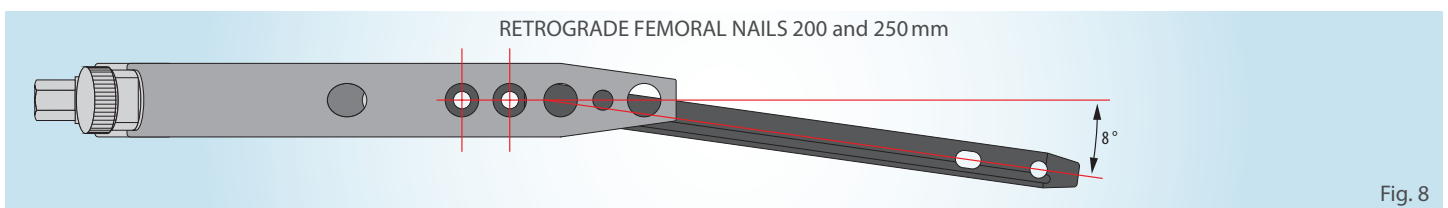
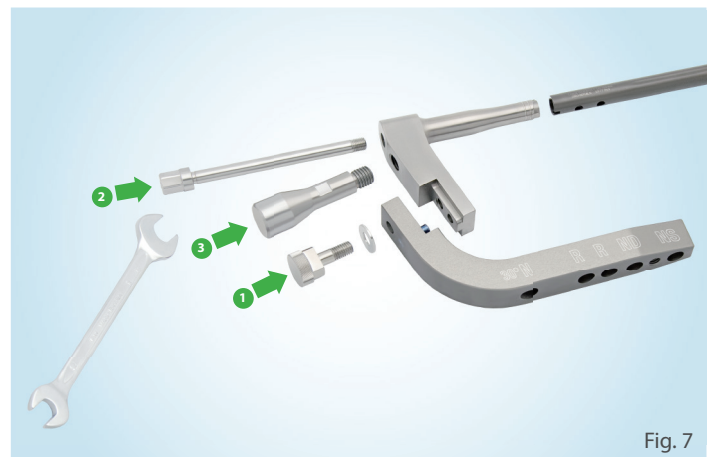
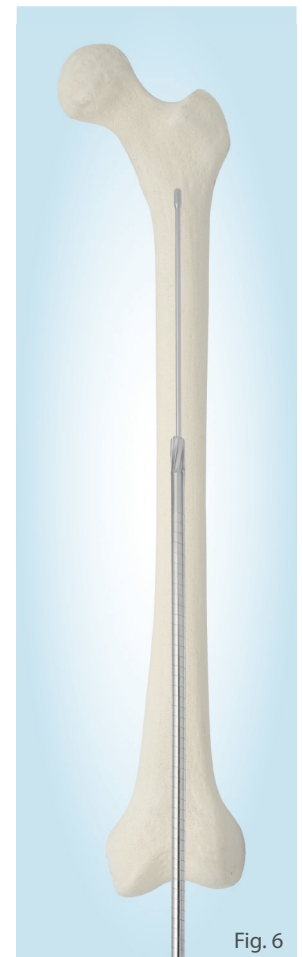
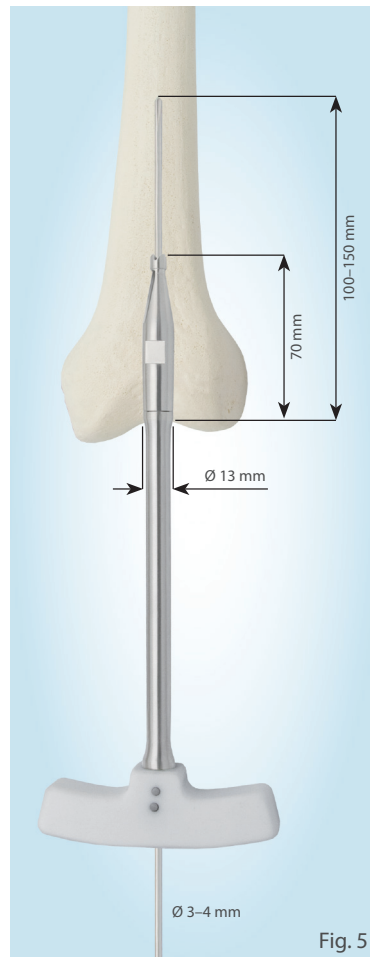
The length of the nail (nail lengths supplied are 200, 250, 300 and 350 mm) should be determined by using **X-ray contrast rule** applied on the femur of a patient. Using X-ray equipment it shall be positioned at the beginning of the entry into the condyle and the required length with subsequent nail selection is read.

The length of the nail can also be determined by measuring the outlet end of the **introducing wire**.

7. Installation of the aiming device and the introduction of the nail

a) Nail and aiming device assembly

Selected **nail** is now assembled with the **aiming device**. Nail is fitted into the grooves of the aiming device and is locked using the **aimer bolt**. The **10/12 wrench** is used to tighten it (Fig. 7). Mounting nails of 200 and 250 mm lengths is to follow Fig. 8, while nails of 300 and 350 mm lengths are to be mounted according to Fig. 9.



b) Completion of the aiming device with a sleeve and review of the nail and aiming device

To secure the retrograde nails in the distal part, openings at the aiming device marked "R" are to be used. Appropriate sleeves are put into the **aiming device**, **sleeve 2** of 8 mm in diameter, **sleeve 3** of 8 / 5 mm in diameter into the previous one, all openings are checked using a **5x250 mm drill** whether the **aimer** matches with **nail**.

Hammer guide rod or **impactor** is also mounted to the **aiming device** depending on the way of nail introduction. **Impactor** is recommended for easier handling during **nail** insertion.

c) Nail introduction

Introducing wire for predrilling is removed and replaced with the **introducing wire** for insertion (3 mm in diameter and 950 mm in length). **Nail** insertion with the **aiming device** into the cavity of the femur is carried out. It is first performed using hand pressure. If difficult, the nail may be inserted into the bone cavity using a **hammer** strikes on the **impactor** or with **weight** on the **rod**. The **nail** must be fully in the bone cavity not to obstruct the movement of the knee. Insertion check should be done using X-ray equipment and notches on the aiming device. The first cut is 3 mm from the end of the nail and the other 6 mm from the end of the nail (Fig. 10).

The correct insertion depth is especially important to be checked in the lateral radiogram (Fig. 11).

The final nail placement must be checked from the AP and lateral view.

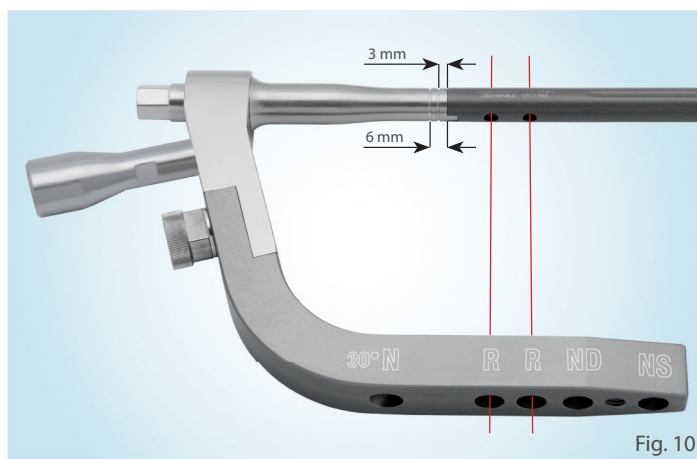


Fig. 10

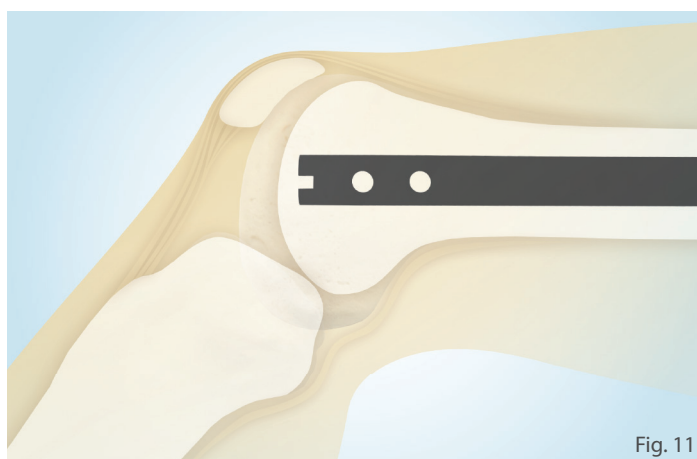


Fig. 11

8. Distal locking

Sleeve 2 (Ø 10/Ø 8) is inserted into appropriate openings of the aimer arm with a **trocar** of 8 mm in diameter. Incision is made in the place of contact with the skin (Fig. 12). **Trocar** Ø 8 mm facilitates the introduction of **sleeve 2** through the soft tissues. At the same time it is possible to use this **trocar** Ø 8 mm to pre-mark the hole to be drilled. **Trocar** Ø 8 mm is removed and sleeves are entered into the aiming device arm matching the type of locking screw.

Our recommendation is to use **locking screws** Ø 5 mm, threaded to the bolt head. Thus avoiding possible difficulties by removing the screw extraction.

The procedure is as follows. First **Sleeve 2** and **Sleeve 4** (Ø 8 / Ø 3.5) are put into the openings in the aiming device arm. Carry out pre-drilling with a **3.5 mm drill** through both cortices (Fig. 13). **Sleeve 4** (Ø 8/Ø 3,5) is removed and the length of the **screw** is determined using the **depth gauge**. It is possible to find the indicative length of the screw by reading it from the scale on the **drill of 3.5 mm in diameter**. Drill must be in the same position as a locking screw should be when in place. Selected locking screw will be introduced through **sleeve 2** using a **hexagonal screwdriver 5 mm**.

The other distal screw can be introduced with the same procedure.

It is of course possible to use other types of locking screws by MEDIN.

Locking screws

For all types of MEDIN intramedullary nails, there are standard **locking screws** prepared with a diameter of 5 mm. These are supplied in lengths of 25 to 90 mm, with 5 mm increments, in three types (Fig. 14).

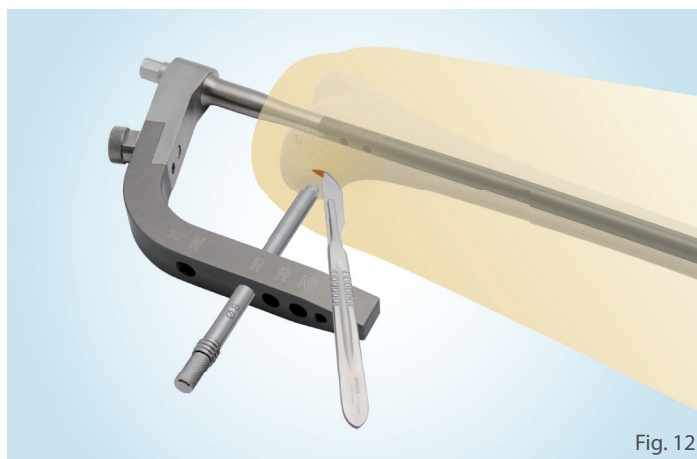


Fig. 12



Fig. 13

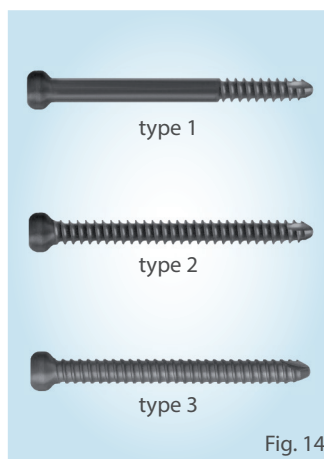
Type 1 has the length of thread 20 mm for all sizes of the screw. For implanting, **sleeve 4** and **3.5-drill** (marked yellow) and **sleeve 3** and **5-drill** (marked white) are used.

Type 2 has a thread reaching to the head. For implanting, **sleeve 4** and **3.5-drill** (marked yellow) are used.

Type 3 has a decreased thread profile; the thread reaches to the head of the screw. For implanting, **sleeve 5** and **4.4-drill** (marked red) are used.

COLOR CODES FOR SLEEVES AND CORRESPONDING DRILLS

Sleeve 3 (129 69 1200) and drill Ø 5 (129 79 4980)	white
Sleeve 4 (129 69 1210) and drill Ø 3,5 (129 79 4990)	yellow
Sleeve 5 (129 79 8460) and drill Ø 4,4 (129 79 8430)	red



9. Condylar screw and nut

Condylar screw with a nut and two washers form a set, which allows compression and subsequent fixation of distal femur articular fractures. This set can be used in combination with a retrograde nail or separately.

a) Place the **aiming device** medially. Insert **sleeve 2** and **trocarr** into the **aimer**. In contact with the skin incision is to be made for the subsequent introduction of **washer** (Fig. 16). Make pre-marking of the hole using a **trocarr**. Remove the **trocarr**.

b) Insert the **sleeve 3** and **drill** through the bone using **5 mm drill** (Fig. 17). Remove the **sleeve 3** and measure the required length of the screw with a **depth gauge**.

c) Introduce the **washer** under the **sleeve 2** and introduce the **condylar screw**, together with **K-wire Ø 1.5 mm** using a **cannulated screwdriver** with 5 mm hexagonal shape through the **sleeve 2**. Then remove the **sleeve 2**.

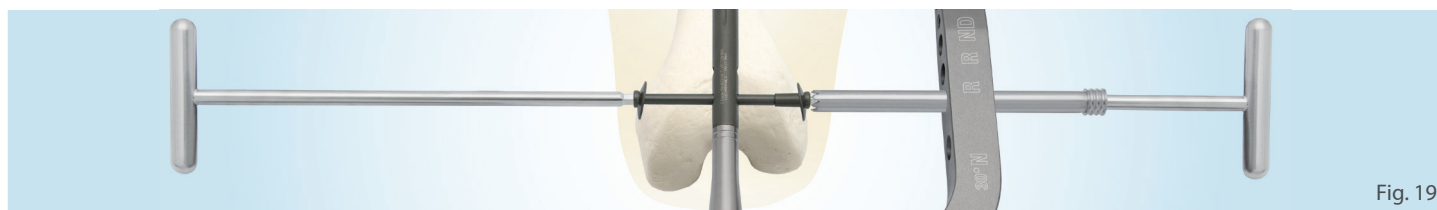
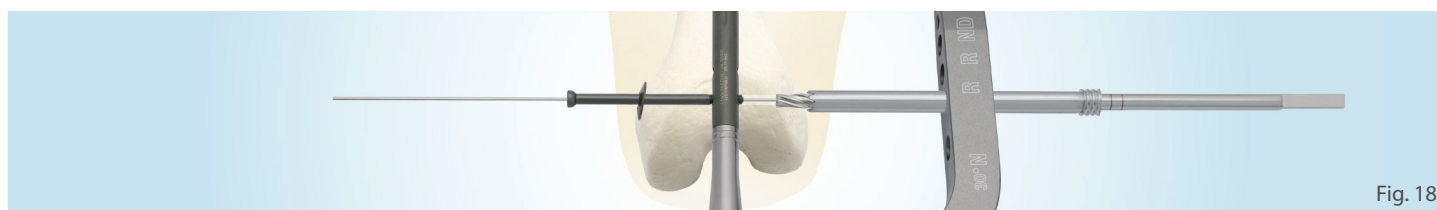
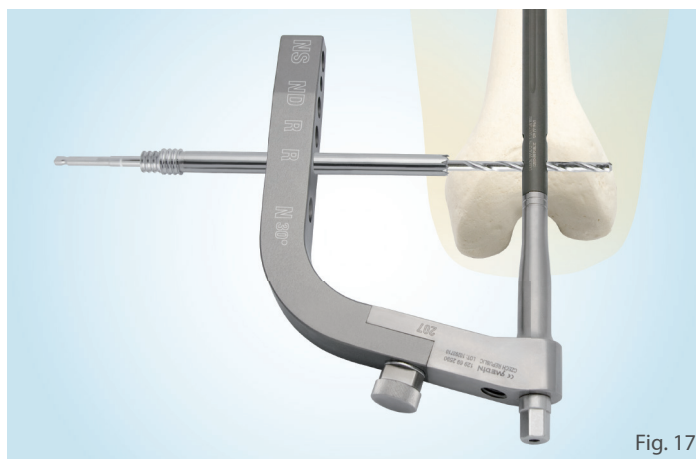
d) Release the **tightening bolt**, turn the **aiming** by 180 ° and tighten the **bolt** again.

e) Again, insert the **sleeve 2** with a **trocarr** to create the incision, as in 9.a.

f) Replace the **trocarr** with a **sleeve 8** and create a recess using a **drill Ø 7.4 mm** depending on **condylar nut** length (Fig. 18). Remove the **drill** and the **sleeve**.

g) Introduce the **washer** under the **sleeve 2** and introduce the **condylar nut** using a **cannulated screwdriver** with 5 mm hexagonal shape using the **K-wire**. Tighten the **screw** to the **nut** with two 5 mm hexagonal **screwdrivers** (Fig. 19). Check tightening with the X-ray equipment.

h) Go on securing other security holes.



10. Closing the nail with a stopper

After proximal and distal locking, the **nail** is closed with a **stopper**. To assemble and disassemble the **stopper** it is appropriate to use a **hexagonal screwdriver 5 mm**. **Stopper** can be introduced through aiming device hub to facilitate mounting (Fig. 20).

Firmly tighten the **stopper** to run the first fixation of the distal locking hole. This fact must be taken into account in the actual removal of the first distal locking screw.

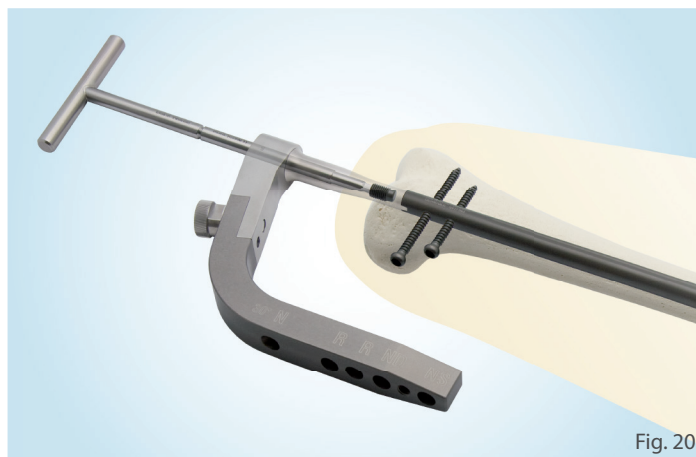


Fig. 20

11. Proximal fixation – ensured by the hand

Proximal fixation shall follow with the same above-mentioned **locking screws**, with a free-hand. For shorter nails in lateral-medial direction, with longer nails it is easier in ventro-dorsal direction.

For shorter **nails with a length of 200 and 250 mm** it is possible to fix in the lateral medial direction, while the proximal opening is intended for static locking and distal for the dynamic locking (Fig. 21).

For shorter **nails with a length of 300 and 350 mm** it is possible to fix in the AP direction, while the proximal opening is intended for static locking and distal for the dynamic locking. The central opening can be used for locking in the medial lateral direction (Fig. 22).

Before you lock the proximal retrograde nail, anatomic reduction should be checked, along with good establishment of fragments and the length of the femur.

a) X-ray equipment settings

Then the X-ray equipment is set above proximal nail openings so as to appear like a circle (Fig. 23a, 23b).

b) Incision

Scalpel tip is placed on the skin over the center opening (Fig. 24) and a **scalpel** is used to make point incision right to the bone.

c) Predrilling

Appropriate **drill** is fit into the power drill; when locking with the **screws of 5 mm in diameter** threaded just up to the head, the drill diameter shall be 3.5 mm. **Drill** is put into the incision made, leans and is adjusted using the X-ray equipment so that its tip is precisely positioned in the center of the opening circle (Fig. 25).

Then the drill bit is rotated so as to be perpendicular to the axis of the nail and the drilling of the holes through both cortices is done.

d) Determining the length of the locking screw

The length of the **locking screw** is determined by measuring with the **depth gauge**.

e) The introduction of the locking screw

Locking screw is fitted to the **screwdriver** and tightened.

It is possible to introduce other proximal locking screws in the same way.

for nails length 200 and 250 mm

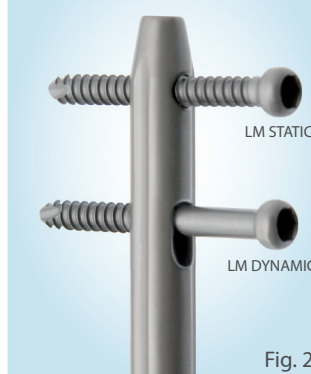


Fig. 21

for nails length 300 and 350 mm

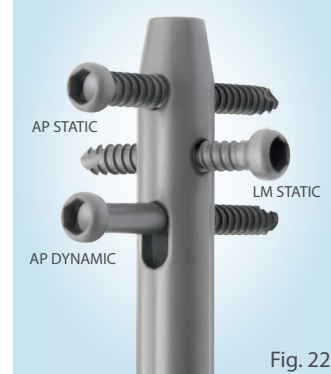


Fig. 22



Fig. 23a

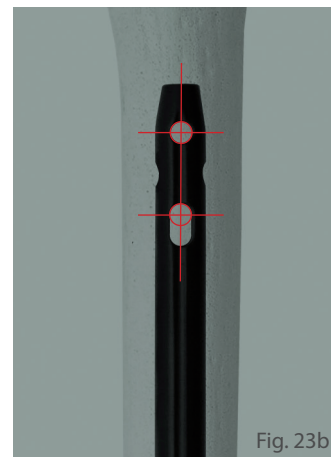


Fig. 23b



Fig. 24

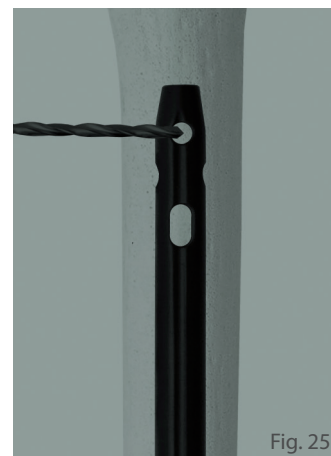


Fig. 25

12. Closure of the operation

After flushing the operation wounds are gradually closing. Suction drain is introduced regularly to the point of nail introducing into the femur bone, but it must not take blood directly from the cavity. The wound is covered with a soft bandage and X-ray documentation is done.

13. Concluding notes

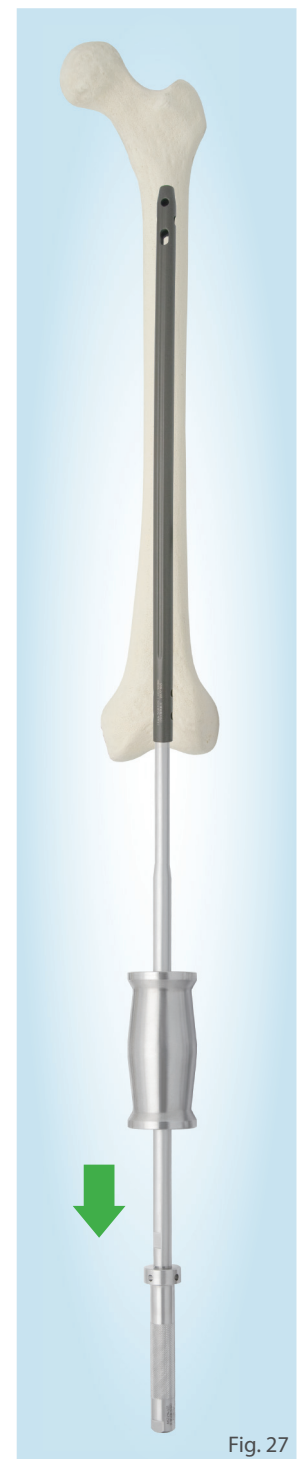
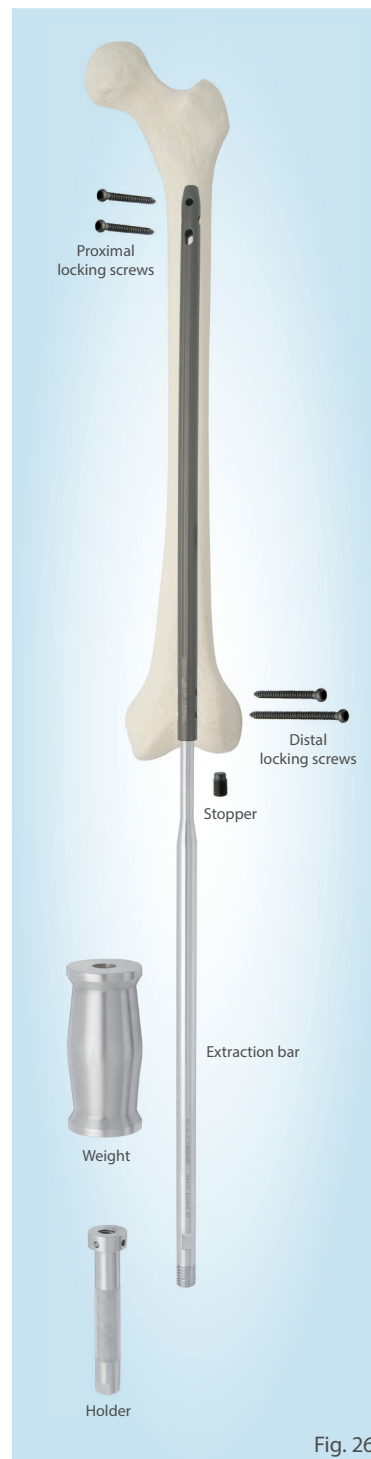
- Prior to the introduction of the nail it is necessary to check following the preparation of the nail and the aiming device whether all the holes into which screws are introduced, correspond to holes in the nail and the aiming device.
- When used for one patient a combination of different materials may never occur.
- To guarantee the safe use of the implant the company MEDIN requires using only company's implants. There must be no combination of implants from other companies.
- The patient must be advised that the implant does not transfer the entire weight of the patient. Patients should use means of support when walking and burden the implant progressively depending on whether the callus creates at the fracture site.
- The implants are designed for single use for one patient and for a single stabilization of damaged bone. Repeated use is prohibited. This fact is mentioned in the leaflet and concerns of all implants.

14. Recommended implant extraction procedure

Implants are in most kept permanently.

In the case of its removal, gradually remove the **screws** from the distal and proximal nail. A hard-tightened **stopper** should be removed before the blocked "locked" **locking screw**. **Nail extractor** should be screwed into the **nail** before removing the last **locking screw** from the **nail** to prevent the possible rotation of the nail in the cavity of the femur. An **extraction bar** is attached into the inner cavity of the proximal end of the nail. The **holder** is mounted and **weight** is put on the **extraction bar** (Fig. 26). The **nail** is hammered out by blows against the **holder** (Fig. 27).

After inserting the **weight** and **handle**, this part of the instrumentation must be constantly held to avoid damaging of the fused bone by bending moment. Attention! IT MAY DAMAGE fused bones!



Instrumentarium

Selected instrumentation tools are stored in two screens (Fig. 28).

Complete lists of instruments, including additional tools are listed in the catalogue of MEDIN.

The instruments are made of austenitic or martensite stainless steel that is used for these purposes for long time. They are supplied non-sterile but clean. The implants from the instrumentation must be sterilised before use. Recommended sterilisation is in steam. The implants and also the instruments are packed separately in PE bags that have self-sticking labels on them. The instruments of the instrumentation can be cleaned repeatedly, disinfected and also sterilised, cared according to PL0088 – instruction of use.

As for the various tools, they are designed for repeated use, until found inadvisable by the doctor (unless specified otherwise). After each washing, the instrumentation is recommended to be checked for the completeness of tools, sharpening of cutting and drilling tools, and whether any of the instruments is damaged. Such an instrument should not be used. The manufacturer recommends the user to have all the instrumentation checked and cutting tools sharpened at the factory at least once a year.

Instruments and implants should be disposed of in hospitals in the same manner as other contaminated material, see PL 0088.

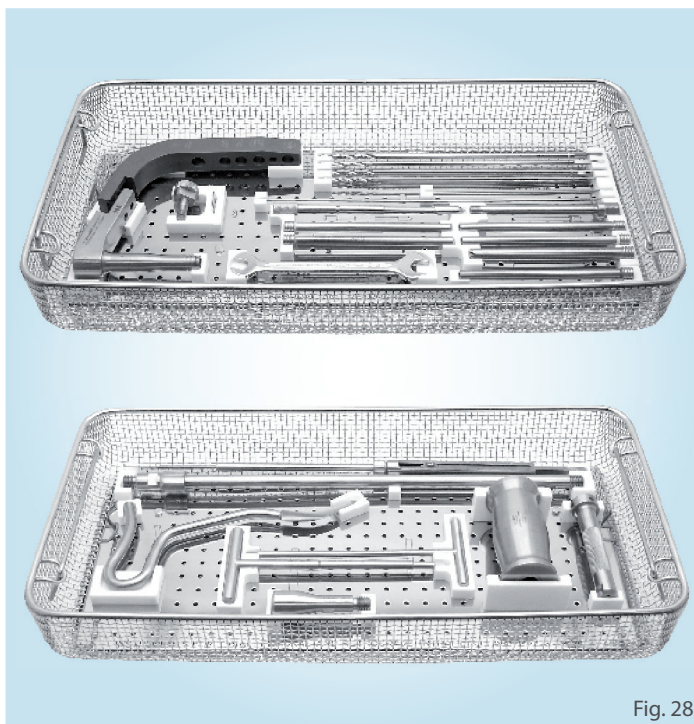


Fig. 28

MEDIN reamers of intramedullary cavity

The line of MEDIN reamers serves for pre-drilling of the tibial medullary cavity. The complete line starts with a reamer of 8 mm in diameter and continues up to 16.5 mm in 0.5 mm steps. Up to 16 mm they belong in the standard set, the 16.5 mm size or, alternatively, a rigid 16.5 mm drill is to be purchased individually. A quick coupler enables connecting of both the reamers and drill to commonly used driving units.

It is not recommended to use the drill in reverse! “Unreeling” of the flexible spindle of the reamers might happen even during slightest weighting.

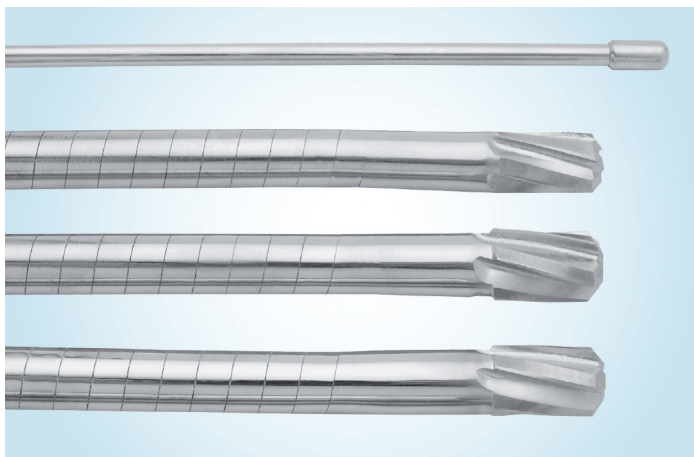
We request using the reamers only with original conductors MEDIN, diameter 3 mm and length 950 and 1150 mm, ended with an olive. It is prohibited to use the reamers without these conductors. Reaming operation has to start with the cutter of 8 mm, this is the only one specially adjusted for frontal cutting. It is not recommended to omit some sizes of cutters; consequently it is necessary to do the reaming after 0.5 mm.

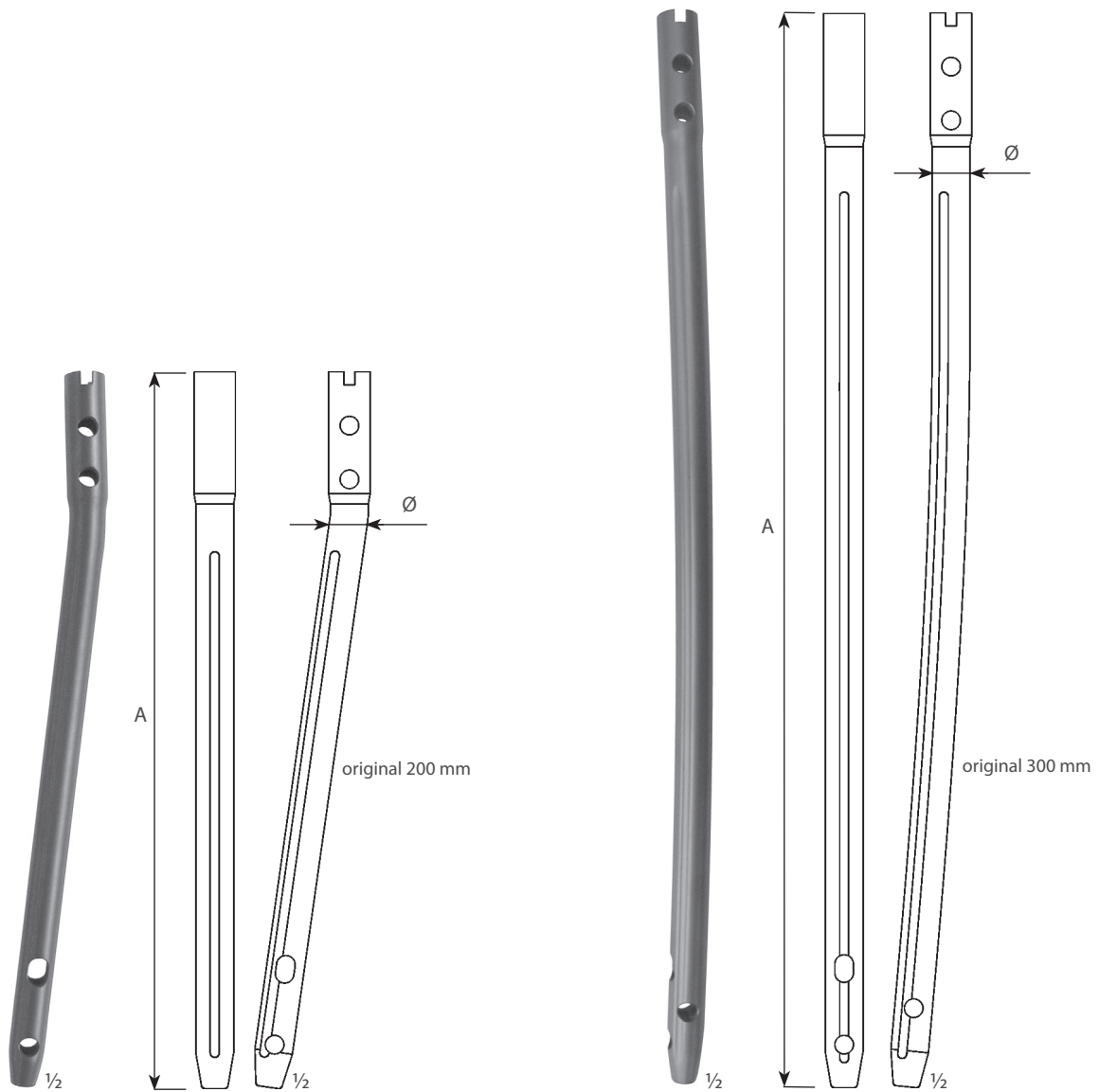
To introduce reconstruction nail it is essential to make wider proximal enter opening and a canal in a medullary cavity to the diameter at least 15.5 mm in the distance of 80 mm (when the cutting of reamer with the whole set is finished). The last size of reamers is used for it. The manufacturer is able to supply the reamers with diameters: 15.5 mm; 16 mm and 16.5 mm.

RECOMMENDED METHOD OF CLEANING

- 1) Mechanical cleaning using water and a brush.
- 2) Rinsing instruments by compressed water, the best is to install a nozzle on a water valve and by means of this pressure to wash the instruments.
- 3) To immerse the instruments into disinfection solution at least for 10 minutes. We recommend 20–30 minutes. A recommended disinfectant is KORSOLEX plus.
- 4) Repeated rinsing by the stream of compressed water until the water is clean. This is possible in conventionally supplied, compressive washing machines when the instruments are connected to the nozzles.
- 5) Cleaning the instruments by pressed air.

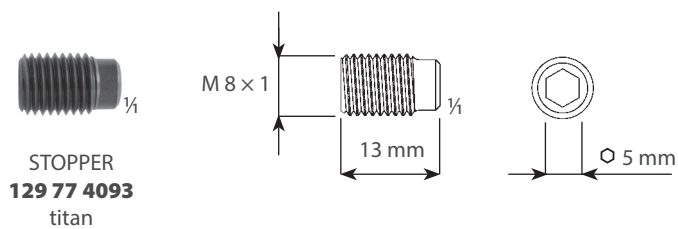
NOTE: While any using and even during cleaning the flexible spindle of the reamer must not be bent too much in particular bending in small diameter. Allowed bending radius is given by bending of reamer which is put on original conductor specified by the producer for the pre-drilling during which excessive weighting is not allowed. When the work is finished all the dirt and soiling should not get dry on the reamers. The cleaning would then need more attention and there would be no guarantee that the instruments would be cleaned to perfection.





Ti	A	Ø
129 77 1883	200 mm	10,5 mm
129 77 1893	250 mm	10,5 mm
129 77 1933	200 mm	12,5 mm
129 77 1943	250 mm	12,5 mm

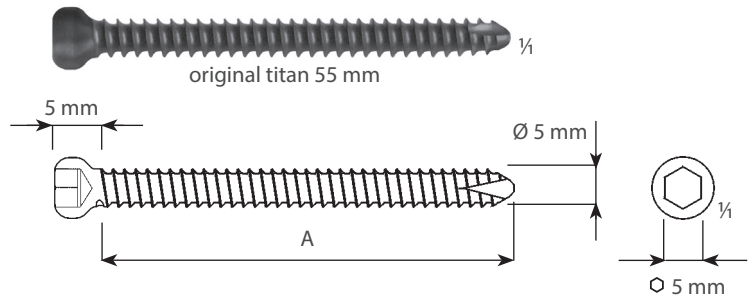
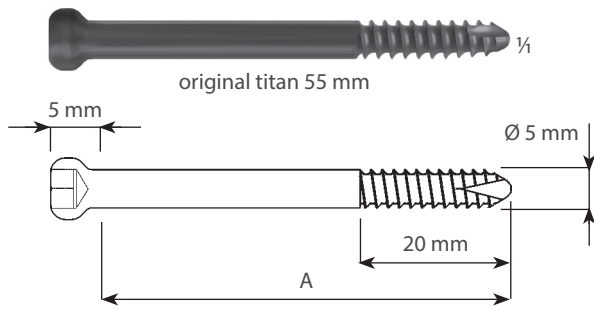
Ti	A	Ø
129 77 1903	300 mm	10,5 mm
129 77 1913	350 mm	10,5 mm
129 77 1953	300 mm	12,5 mm
129 77 1963	350 mm	12,5 mm



NOTES: Ti – titanium version, material: Ti6Al4V ELI in accordance with ISO 5832-3

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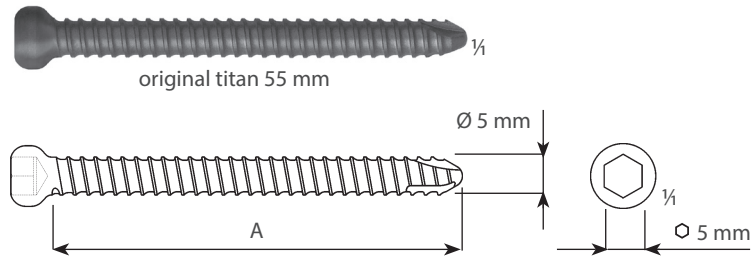
LOCKING SCREWS



Ti	A	Ti	A
129 79 1503	25 mm	129 79 1643	60 mm
129 79 1523	30 mm	129 79 1663	65 mm
129 79 1543	35 mm	129 79 1683	70 mm
129 79 1563	40 mm	129 79 1703	75 mm
129 79 1583	45 mm	129 79 1723	80 mm
129 79 1603	50 mm	129 79 1743	85 mm
129 79 1623	55 mm	129 79 1763	90 mm

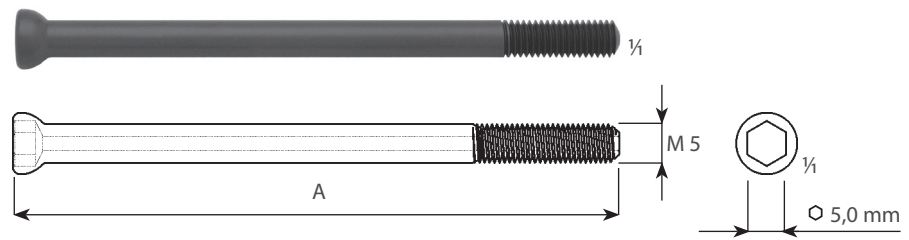
Ti	A	Ti	A
129 79 1513	25 mm	129 79 1693	70 mm
129 79 1533	30 mm	129 79 1713	75 mm
129 79 1553	35 mm	129 79 1733	80 mm
129 79 1573	40 mm	129 79 1753	85 mm
129 79 1593	45 mm	129 79 1773	90 mm
129 79 1613	50 mm	129 79 1293	95 mm
129 79 1633	55 mm	129 79 1303	100 mm
129 79 1653	60 mm	129 79 1313	105 mm
129 79 1673	65 mm		

LOCKING SCREWS WITH LOWER PROFILE OF THE THREAD



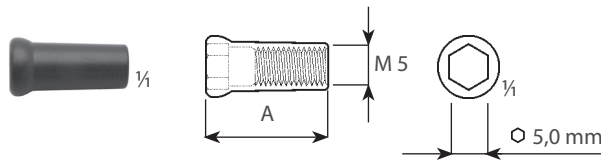
Ti	A	Ti	A
129 79 9634	25 mm	129 79 9704	60 mm
129 79 9644	30 mm	129 79 9714	65 mm
129 79 9654	35 mm	129 79 9724	70 mm
129 79 9664	40 mm	129 79 9734	75 mm
129 79 9674	45 mm	129 79 9744	80 mm
129 79 9684	50 mm	129 79 9754	85 mm
129 79 9694	55 mm	129 79 9764	90 mm

NOTES: Ti – titanium version, material: Ti6Al4V ELI in accordance with ISO 5832-3



CONDYLAR SCREW

Ti	A	Ø	Ti	A	Ø
129 77 9003	50 mm	5 mm	129 77 9063	80 mm	5 mm
129 77 9013	55 mm	5 mm	129 77 9073	85 mm	5 mm
129 77 9023	60 mm	5 mm	129 77 9083	90 mm	5 mm
129 77 9033	65 mm	5 mm	129 77 9093	95 mm	5 mm
129 77 9043	70 mm	5 mm	129 77 9103	100 mm	5 mm
129 77 9053	75 mm	5 mm	129 77 9113	105 mm	5 mm



CONDYLAR NUT

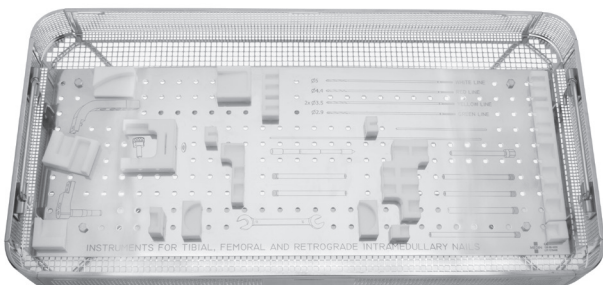
Ti	A	Ø
129 77 8963	16 mm	5 mm
129 77 8973	21 mm	5 mm
129 77 8983	26 mm	5 mm

CONDYLAR WASHER

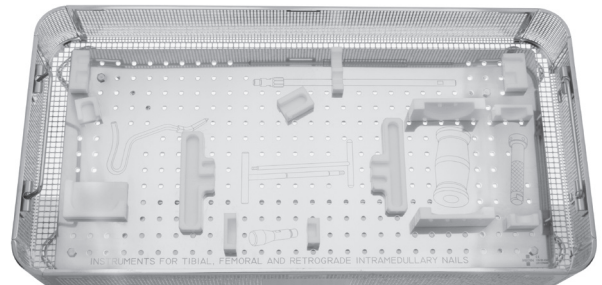
Ti	Ø
129 77 8993	5 mm

NOTES: Ti – titanium version, material: Ti6Al4V ELI in accordance with ISO 5832-3

INSTRUMENTS FOR TIBIAL, FEMORAL AND RETROGRADE INTRAMEDULLARY NAILS



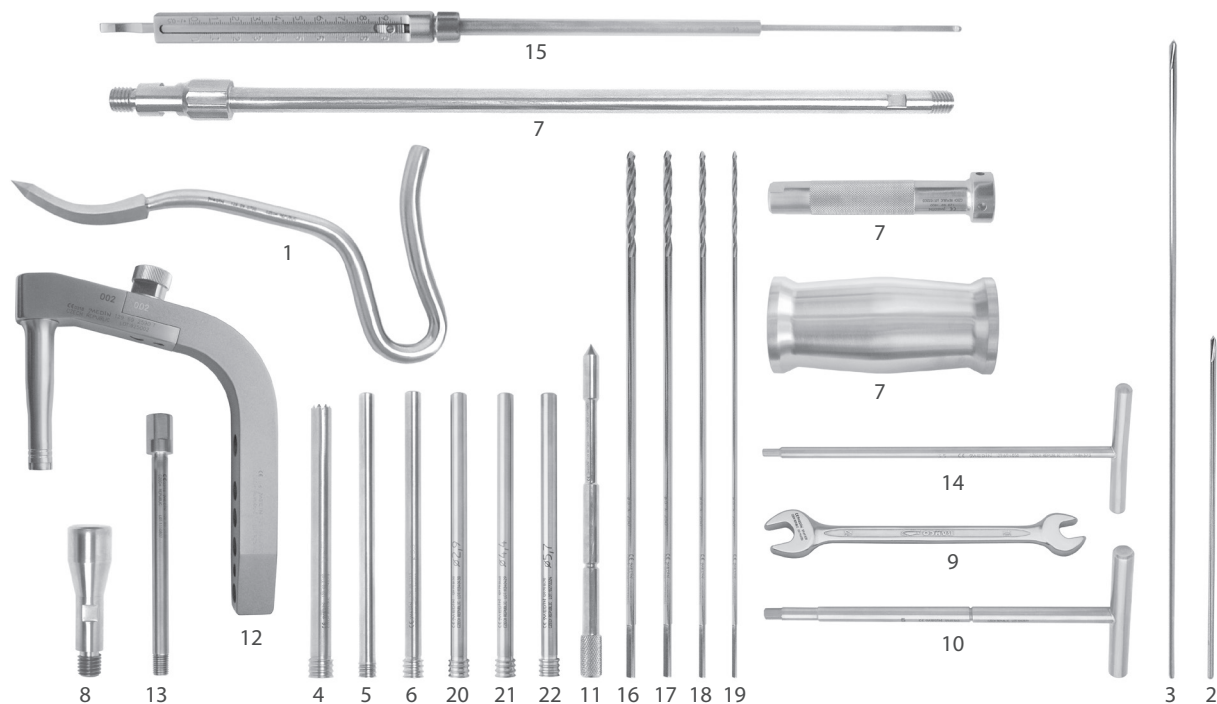
SIEVE FOR INSTRUMENTS FOR INTRAMEDULLARY NAILS
129 69 4530
 480 × 240 × 50 mm
 Fig. 1



SIEVE FOR INSTRUMENTS FOR INTRAMEDULLARY NAILS
129 69 4540
 480 × 240 × 70 mm
 Fig. 2

RETROGRADE FEMORAL NAIL

INSTRUMENTS FOR TIBIAL, FEMORAL AND RETROGRADE INTRAMEDULLARY NAILS



129 79 9240
set

			pcs
1	129 09 0700	Perforator curved 12 mm; 195 mm	1
2	129 09 2510	K-wire 2,5×160 mm	1
3	129 09 2590	K-wire 2,5×300 mm	1
4	129 69 1190	Sleeve 2	1
5	129 69 1200	Sleeve 3	1
6	129 69 1210	Sleeve 4	1
7	129 69 1600	Mallet	1
8	129 69 1620	Impactor	1
9	129 69 1630	Wrench, 10/12	1
10	129 69 1640	Screwdriver T; 5 mm; 175 mm	1
11	129 69 1650	Trocar	1
12	129 69 2590	Aiming device	1
13	129 69 2830	Screw of aiming device	1
14	129 69 4050	Screwdriver T; 3,5 mm; 175 mm	1
15	129 79 2111	Depth gauge	1
16	129 79 4980	Drill; 5,0×250 mm	1
17	129 79 4990	Drill; 3,5×250 mm	2
18	129 79 8430	Drill; 4,4×250 mm	1
19	129 79 8440	Drill; 2,9×250 mm	1
20	129 79 8450	Sleeve 6	1
21	129 79 8460	Sleeve 5	1
22	129 79 8470	Sleeve 7	1

Complete lists of instruments, including additional tools are listed in the catalogue of MEDIN.

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