# SURGICAL TECHNIQUE RETROGRADE FEMORAL NAIL



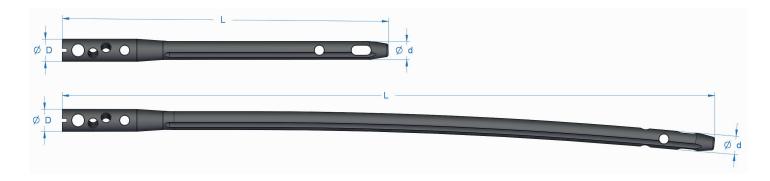
### **Medical device description**

The implant system of the femoral retrograde nail consists of the nail and securing screws.

The length of the nails are 175, 200, 250, 300 and 350 mm and they are in two diameters - diameter of 10 mm and diameter of 12 mm. Nails of the lengths of 175 and 200 mm are straight and nails of the lengths 250, 300 and 350 mm are anatomically curved.

The nails are provided with two types of holes for the screws. The most distal nail hole of the diameter of 6.5 mm is intended exclusively for the securing screw of the diameter of 6.5 mm. The other holes have a diameter of 5 mm and are intended for the securing screws of the diameter of 5 mm. The most proximal hole of the nail (the area of the proximal femur end) has an oval shape for the possibility of dynamization. The nail is universal and can be used for the left and right leg. The nail is hollow, which allows its introduction along the guide wire. The nail end is closed with a plug.

A list of all implants can be found at the end of this surgical procedure manual.



### The medical device indication

The indication of the femoral retrograde nail enables the closed secured osteosynthesis and it can be useful for fractures of the distal femur of the type A and C according to the AO classification. The decisive factor for the indication of osteosynthesis with the retrograde nail is the height of the fracture line above the roof of intercondylar fossa. The osteosynthesis by the retrograde nail is indicated in case, when the fracture line of the distal fragment is 3-4 cm above the roof of intercondylar fossa.

### **Surgical procedure**

### 1. The patient's position

The patient is lying on his/her back on the extension operating table, where appropriate on the classic operating table. The knee joint is in a flexion of 40-60° in order to perform the appropriate surgical reposition of the fracture and determine the entry point for the introduction of the nail. The soft cylinder inserted under the limb facilitates the achievement of a correct reposition and a steady limb position. The X-ray equipment must be positioned so as to allow the femur imaging included proximal and distal end in two projections (lateral and anteroposterior - AP). A healthy limb should be bent in the hip and knee and should be positioned on an elevated rest to facilitate the access of the X-ray equipment when imaging.

### 2. Reposition of the fracture

It is suitable to perform a manual closed reposition using an axial traction. The whole act is necessary to control under the X-ray amplifier. It will be necessary in some cases of the older fractures to apply distractor. First perform a reposition from a single transcutaneous incision and stabilise by cancellous or cannulated screws the intercondylar fracture of the distal femur at the fractures of the type C (intraarticular fractures). Stabilise the individual fragments using the screws after the correct anatomical reposition (with the control of the anatomical repositioning of the articular area). The screws have to be positioned so that they do not interfere with the future path of the nail.

### 3. Incision

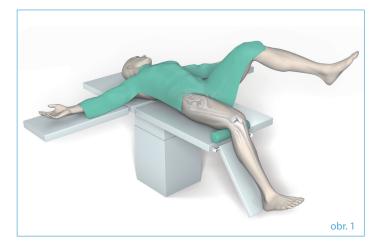
Perform the longitudinal incision of the length of about 5 cm through the ligament patellae or just next to it, move the ligament so it's possible to properly aim the location for the introduction of the nail, perform arthrotomy and revise the articular surfaces.

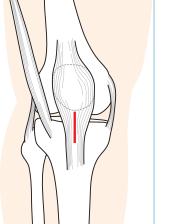
# 4. The Entry Point

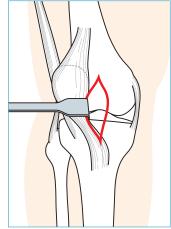
The entry point for the introduction of the retrograde nail is aligned with the plane of the femoral medullary canal. It is located in the roof of an intercondylar fossa in front, anteriorly and laterally relative to the insertions of the cruciate ligaments. The entry point is crucial for the whole procedure, especially in terms of the optimal positioning of the nail in the medullary canal. The exact determination of the entry point and of the direction of the nail introduction is even more important at the fractures of metaphysis to avoid angulation of the distal fragment against the femur diaphysis.

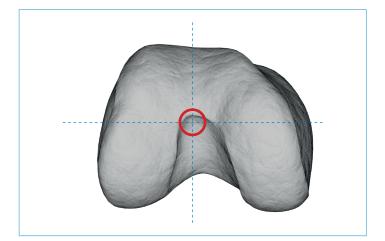


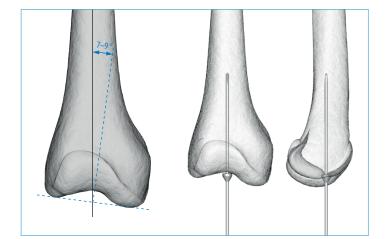
Insert a guide wire with olive of the diameter of 3 mm into the determined point. Use the protective sleeves to protect the soft tissues. Introduce the wire to the bone up to the olive. Introduce the wire in the direction of the anatomical axis of femur which goes in the angles of 7 to 9° laterally towards the plane, which is perpendicular to the surface of the joint. Check the introduction of the wire using two X-ray projections. Remove the wire sleeve and leave only an outer cutter sleeve there.











Put the cutter onto the guide wire and pre-drill the hole for the distal end of the nail. Push the safety guiding sleeve to bone to provide protection of the soft tissues and at the same time you can watch the drilling depth, which can be read from the scale directly on the cutter.

The cutter creates a hole with a diameter of 13 mm and it should be drilled in the depth of approximately 50 mm. The correct direction of drilling is very important for the correct introduction of the nail. Then remove the cutter and the guide wire. Bone material that remains after cutting inside of the cutter can be removed by pushing it out with the olive, or you can use the side grooves on the cutter to remove it.

It is possible to use a perforator to create the entry point for the nail that is guided along the wire of the diameter of 3 mm.

# It is appropriate to carry out a check of the fracture repositioning using the X-ray device before the next steps.

If necessary you can pre-drill the medullary cavity for easier introduction of the nail. Perform the pre-drilling starting with the smallest diameter of the flexible cutter, which is the diameter of 8mm, increase the diameter gradually by 0.5 mm. To avoid the rotation of the guide for pre-drilling hold it using the special clips. Introduce the flexible cutter without much force gradually by small movements forward and back. Pre-drill the cavity for the nail 0.5 to 1.5 mm larger than the size of the nail which will be used (diameter of the nail of 10 or 12 mm). Finish the pre-drilling with the pre-drilling with the pre-drilling with the pre-drilling with the pre-drilling cutter of the diameter of 13 to 14 mm for the nail diameter of 12 mm should be terminated when using the nail of the diameter of 10 mm. For more information on the use of the flexible cutters, See the chapter **Flexible cutters** at the end of this manual.

# 6. The choice of the nail

The choice of the nail has been carried out during the preoperative preparation or is to be carried out now. The diameter of the nail was already selected according to the size of the cavity during the bone pre-drilling. It is also possible to determine the length of the nail by measuring of the protruding end of the guide for pre-drilling.

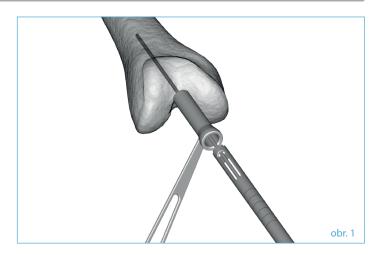
# 7. How to assemble the aiming device and fasten the nail

### 7.1 Assemble the aiming device

When assembling start with the clamping bolt. The parts belonging together are marked by the same number of the dots.

The arm with one dot belongs to the groove on the clamping bolt with one dot and the crossbeam with one dot belongs to the arm with one dot.

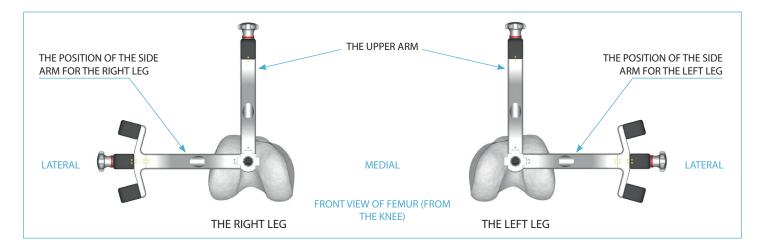
Put the arms onto the clamping bolt. The lower section of the aiming device (i.e. clamping bolt and the arms) is marked in green (1 or 2 dots) and clamping bolt has a description of how to assemble the aiming device for the right or left leg.











The upper arm marked by one dot is universal (i.e. for both the right and left side). The side arm marked by two dots, is intended for use on the lateral side.

Fix the arms to the clamping bolt using the screws. The screws reasonably fasten by screwdriver with the hexagonal tip of the size of 5 mm. Place the crossbeams on the upper part of the arm. The upper part (i.e. arms and crossbeams) is marked in yellow (1 or 2 dots). Attach the crossbeams to the arms using the special screws. The crossbeams have to be possible to be put on freely without any prying. The crossbeam with the arm have to fit on each other before the fastening by the screw. It is possible to use the appropriate tightening rod for tightening.



It is enough to install only the side (lateral) arm when using the short nails (length 175 or 200 mm). If you use long nail (250, 300 or 350 mm), it is necessary to deploy both – the side (lateral) arm and the upper arm.

It is possible to assemble the aiming device without these auxiliary arms in the case where there is no need to use oblique holes in the distal part of the nail. Use the shorter from the pair of the screws here.



Use the longer screw marked as "LONG" (on the screw head) for attaching the crossbeam, if the aiming device is assembled completely, including the arm for the diagonal holes in the distal part of the nail.



### 7.2 Fit the nail to the assembled aiming device

Put the nail onto the clamping bolt into the grooves. The grooves at the end of the nail ensure the correct orientation of the nail (the nail cannot be fitted the wrong way round). The nail must be freely installed onto the grooves to ensure that the end of the nail rests on the face of the clamping bolt. Then secure the nail by the appropriate tightening of the clamping screw. The tightening rod inserted into the opening under the screw head can be used to tighten the clamping screw.

# 8. The check of the function of the aiming device

# It is necessary to check the correct functioning of the aiming device before the introduction of the nail.

Use sleeves and drills to verify a correct functioning of the aiming device. All openings on the aiming device must correspond to the holes in the nail. This performance of this check will prevent possible complications that can occur during the procedure.

350

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< 250 X

You can plug the holes in the aiming device which you intend to use to facilitate orientation during the operation. During surgery just remove the plug and replace it by the outer sleeve.

In the case that the holes in the aiming device are not identical with the holes in the nail, it is not possible to use the aiming device.



Warning: Avoid strikes of a hammer on the parts of the aiming device (especially on the plastic arms) when introducing the nail, or other powerful handling (prying, bending, ...). There is a risk of the irreversible damage or destruction of the aiming device.

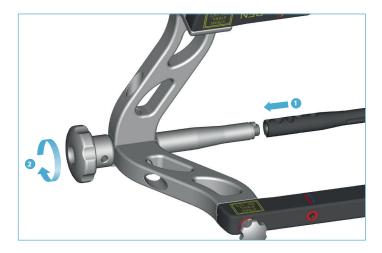
Remove the guide for the pre-drilling and replace it by the introducer (of the diameter of 3 mm and the length of 950 mm). Introduce the nail with the aiming device into the bone cavity. The nail must be inserted in the bone cavity (under the niveau of the articular area), in order not to prevent the movements of the knee. The exact location of the distal end of the nail can be determined by using a wire (of the diameter of maximally 2 mm), which is put into the red marked hole "END OF NAIL". The clamping bolt has a groove, which also determines the position of the distal end of the nail. It is appropriate to use the X-ray equipment to check the introduction. A correct introduction depth has to be be checked in particular from the lateral view. The final positioning of the nail is necessary to check from AP and from the lateral view.

# 10. Distal locking

There are 4 holes to ensure the nail in the distal part. The first (most distal) hole is intended for the securing screw of the diameter of 6.5 mm, the remaining holes are intended for the securing screws of the diameter of 5mm.

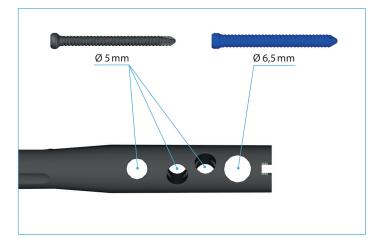
#### The table of the recommended dimensions of the drill for each screw

	The securing screw Ø 5 mm (gray colour)	The securing screw Ø 6.5mm (blue colour)	
a healthy bone	drill Ø 4.4mm (red colour)	drill Ø 5.5mm (black colour)	
a porotic bone	drill of 3.5mm (yellow colour)	drill Ø 4.4mm (red colour)	









Insert the outer sleeve with trocar to the holes of the aiming device (marked with the blue bars). Perform the incision at the place of contact with the skin. Push the sleeve with trocar gradually up to the bone. This procedure will minimize the possibility of damage to the soft tissues. It is also possible to pre-mark the drilling hole using trocar.



Remove the trocar from the outer sleeve and replace it with the internal sleeve for the drill. Select the size of the drill and the appropriate sleeve according to the screw which you want to use, and in accordance with the bone condition (see table above). The sleeves are specially adapted to avoid falling out when handling with the aiming device. Then pre-drill the hole for the screw using a drill (drill through both cortices). The drilling depth can be read directly on the scale of the drill. Remove the drill and inner sleeve after pre-drilling of the hole.



To measure the depth of the hole you can also use the depth gauge. Insert the depth gauge into the remaining outer sleeve. Pull the hook through the drilled hole, hook it into the second cortex and read the depth of the hole from the scale on the handle of the depth gauge. Read the value on the top end of the outer sleeve. It is necessary to push the outer sleeve up to the bone for the correct function of the measuring of the depth by using the drill or the depth gauge, otherwise the measured values are not correct. Choose the appropriate length of the screw according to the measured dimension.



Put the desired length of the screw onto the screwdriver with the hexagonal end of the size of 5 mm directly in the stand. The end of the screwdriver keeps the screw attached to facilitate its introduction. Introduce the screw through the outer sleeve in the aiming device. The scale on the screwdriver indicates the remaining distance to the bone. The screw head is screwed into the bone completely at a time when the upper end of the outer sleeve aligns with a mark 0 on the screwdriver. Same as before, the outer sleeve has to be pushed up to the bone for the correct functioning of the scale on the screwdriver.

A bit with the hexagonal end of the size of 5 mm with the AO tip can also be used for introduction of the screw. Use only the manual screwdriver to tighten the screw!



Introduce the other securing screws in the distal part the same way. A thread in the bone must not be damaged when introducing the screw.



# The hole marking which can be used to introduce the nail of the given length (250, 300, 350 mm) **〈** 250 **〉** < 350 > < 300 > Dynamic hole

The proximal holes are oriented lateromedially in the case of the short nails (175 and 200 mm). There are two holes ventrodorsally and one lateromedially in the case of the long nails (250, 300 and 350 mm). All openings are aimed from the aiming device, it is necessary only in the case of the long nails (250, 300 and 350 mm) to aim lateromedial hole freely from the hand under the control of the X-

The aiming device has markings which determine the position of the holes for a better orientation. An oval hole for dynamic locking is marked on the aiming

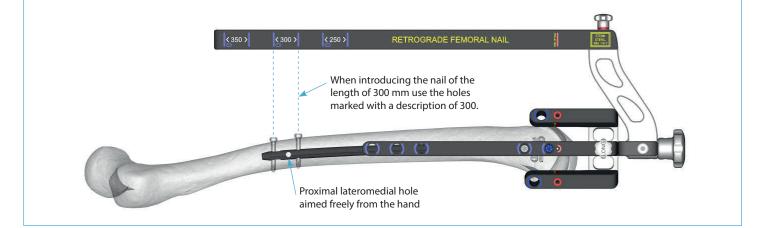
11. Proximal locking

device - see figure.

the static locking.

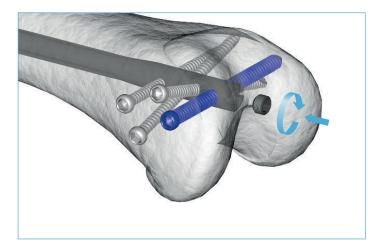
Perform the proximal locking same way as in the case of the distal locking (see paragraph 10 of the surgical technique).





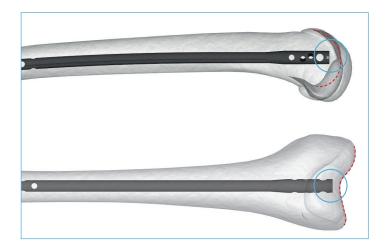
### 12. Final check

Check using the X-ray amplifiers if all the screws are in the correct position eventually check the tightening of all screws after completion of the distal and proximal locking of the nail. If everything is correct, you can continue further.



# 13. Closure of the nail with the plug

Remove the clamping screw of the aiming device. If it is not possible to loosen the screw by hand, a helping rod which is included in instruments can be used. Leave the aiming device placed on the nail (it is necessary to hold the aiming device when loosening and removing the clamping screw of the nail) for easier plug introduction. Put the plug onto the screwdriver with the hexagonal end of the size of 5 mm and introduce through the hole of the aiming device into the nail. A locking of the most distal screw against the axial movement will happen by the tightening of the plug. The distal nail end and plug have to be inserted under the niveau of the articular area! Finally, remove the screwdriver and remove the entire aiming device.



# 14. Closure of the operation

Perform sutures of all wounds after irrigation. Introduce the suction drain to the place of the nail introduction into the femoral bone but it must not suck blood directly from the cavity. Cover the wound with a soft bandage and perform X-ray documentation.

### 15. Recommended procedure of implant removal

The implants are left in their place in most cases. Remove the screws from the distal and proximal part of the nail step by step when necessary to extract the implant. It is necessary to remove the plug earlier than the locked securing screw when the plug is tighten firmly. It is possible to put the aiming device onto the nail to facilitate finding and extraction of the screws and to remove the single screws using the sleeves.

Then screw into the distal end of the nail a pulling rod. It is advisable to keep in the nail at least one screw to prevent a rotation of the nail and a possible damage to the bone. Slide the weights onto the pulling rod and screw a handle to its end. Extract the nail with strikes of the weight against the handle. These instruments are included in the set for the nail extraction. See catalogue of MEDIN company.

### **Final notes**

The implants (nail, screw, plug) from various materials can never be combined at one patient. It is always necessary to use all implants only from the stainless steel or from the titanium alloy!

The patient must be warned that the implant does not bear the entire weight of the patient. The patient must use support when walking and burden implant progressively depending on how callus is being created at the fracture site.

The implants are intended for single use, single patient and single bone stabilization only. Repeated use is forbidden.



### **Additional information**

# How to assemble the aiming device for the old type of the nails and the nail fastening

It is possible to introduce or pull out also the older type of the femoral retrograde nails using these instruments.

Specifically, the following products:

ordering number	length	Ø
129 77 1883	200 mm	10,5 mm
129 77 1893	250 mm	10,5 mm
129 77 1903	300 mm	10,5 mm
129 77 1913	350 mm	10,5 mm
129 77 1933	200 mm	12,5 mm
129 77 1943	250 mm	12,5 mm
129 77 1953	300 mm	12,5 mm
129 77 1963	350 mm	12,5 mm

#### Assemble the aiming device

Parts for the assembly of this aiming device are stored in the sieve separately from the parts of a standard aiming device and marked (AIMING DEVICE FOR OLD RETROGRADE FEMORAL NAILS).

Use the parts of the standard aiming device to assemble the aiming device. Only the clamping bolt and the aiming crossbeam are different.

The clamping bolt (397 129 69 9090) and the aiming crossbeam (397 129 69 9080) are the accessories to the standard aiming device (397 129 69 5890). They enable the introduction and removal of the old femoral retrograde nail. Use the clamping screw, crossbeam screw and the arm from the aiming device (397 129 69 5890).

Attention - keep the colour codes of the assembly clamping bolt - arm - aiming crossbeam. It will not be able to assemble the aiming device or it won't aim properly if you don't keep the previous sequence!

Put the arm of the standard aiming device onto the clamping bolt (marked by the sign OLD NAILS). The arm is colour-marked. Fix the arm to the clamping bolt using the screw. Fasten the screw by the T-screwdriver with hexagonal end of the size of 5 mm. Put the crossbeam onto the upper part of the arm (marked by the sign OLD NAILS). The crossbeam is again colour-marked. Attach the crossbeam to the arm using the standard screws. It is possible to use the appropriate tightening rod for tightening.

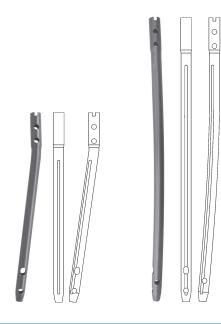
### Fit the nail to the assembled aiming device

Put the nail onto the clamping bolt into the grooves and subsequently secure the nail by tightening of the clamping screw.

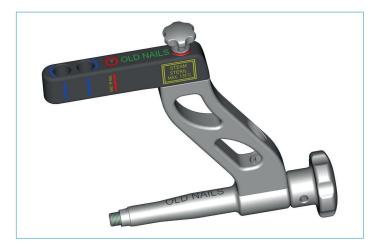
Further continue the same way as in the case of using the new nail (from the article 8 of this technique).

### **Flexible cutters**

A set of flexible MEDIN cutters is intended for the pre-drilling of the medullary cavity. The complete set starts with a cutter of the diameter of 8 mm and continues with 0,5 mm increments. A quick coupler enables to connect the cutters and drill onto the commonly used power units. It is not allowed to use a reverse mode of the drill! A flexible shaft can "unroll" even at the slightest load of the cutter. The cutters has to be used only with the original MEDIN guides of the diameter of 3 mm, length of 950 and 1150 mm which are ended by the olive. It is forbidden to use these cutters without the guide wires. The cutting has to start with the cutter of the diameter of 8 mm. This is the only one which is adapted to the frontal cut. It is not recommended to skip some cutter sizes, it is necessary to cut with 0.5 mm cutter increments..

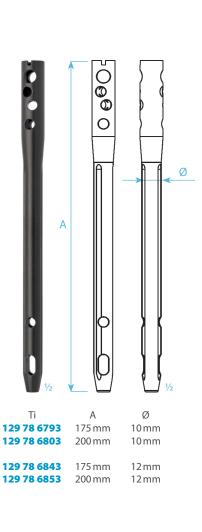


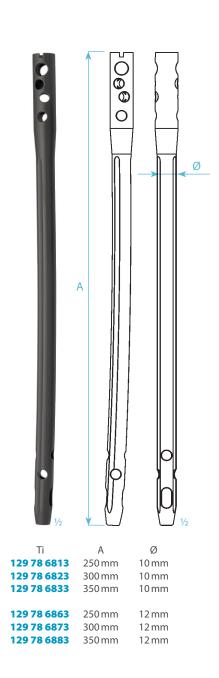






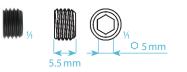
# IMPLANTS FOR THE FEMORAL RETROGRADE NAIL



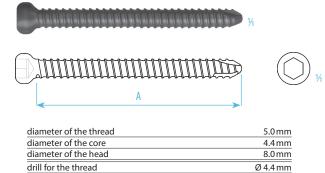


Femoral retrograde nail

# IMPLANTÁTY PRO HŘEB FEMORÁLNÍ RETROGRÁDNÍ







O 5 mm

Ø 4.4 mm

05mm

	/ (
129 79 9634	25 mm
129 79 9644	30 mm
129 79 9654	35 mm
129 79 9664	40 mm
129 79 9674	45 mm
129 79 9684	50 mm
129 79 9694	55 mm
129 79 9704	60 mm
129 79 9714	65 mm
129 79 9724	70 mm

Ti

129 79 9684	50 mm
129 79 9694	55 mm
129 79 9704	60 mm
129 79 9714	65 mm
129 79 9724	70 mm
129 79 9734	75 mm
129 79 9744	80 mm
129 79 9754	85 mm
129 79 9764	90 mm

Securing reinforced screw 5 mm

А

	И
	(
A	
diameter of the thread	6.5 mm
diameter of the core	5.9 mm
diameter of the head	8.0 mm

screwdriver

drill for the thread

screwdriver

The securin	ig screw	6.5 mm
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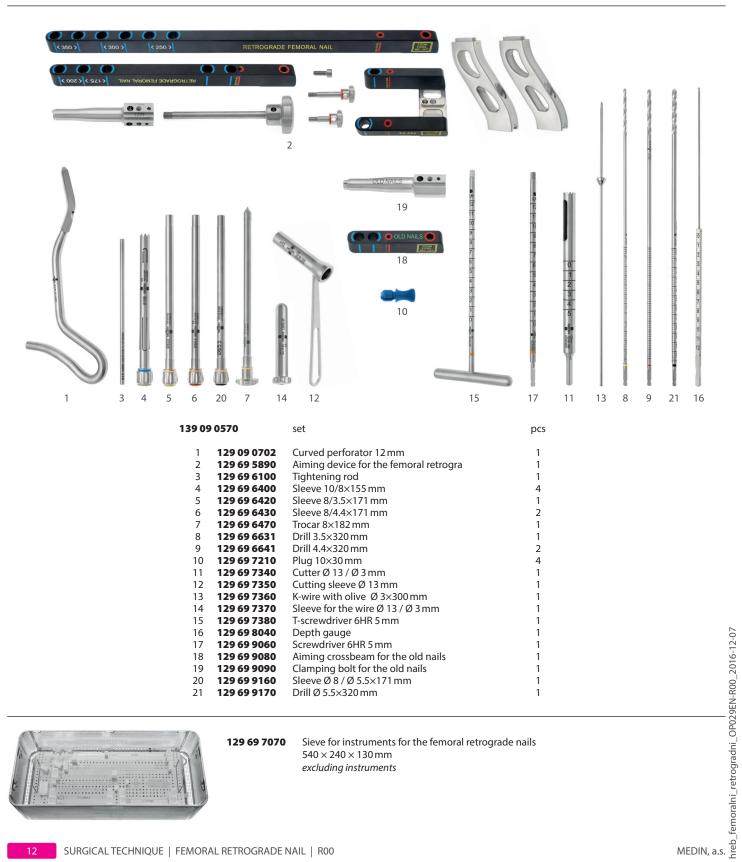
Ti	А
129 70 9274	40 mm
129 70 9284	45 mm
129 70 9294	50 mm
129 70 9304	55 mm
129 78 9154	60 mm
129 78 9164	65 mm
129 78 9174	70 mm
129 78 9184	75 mm
129 78 9194	80 mm
129 78 9204	85 mm
129 78 9214	90 mm
129 78 9224	95 mm
129 78 9234	100 mm
129 78 9244	105 mm
129 78 9254	110 mm
129 78 9264	115 mm
129 78 9274	120 mm

NOTES: Ti - version titanium, material Ti6Al4V ELI according to ISO 5832-3

# INSTRUMENT SET FOR THE FEMORAL RETROGRADE NAIL



<sup>139 09 0575</sup> Set of instruments instruments for the femoral retrograde nails  $540 \times 240 \times 130 \,\text{mm}$ instruments included





129 69 7070 Sieve for instruments for the femoral retrograde nails  $540 \times 240 \times 130 \,\text{mm}$ excluding instruments

SURGICAL TECHNIQUE | FEMORAL RETROGRADE NAIL | R00

# INSTRUMENT SET FOR THE FEMORAL RETROGRADE NAIL



**129 69 7090** Sieve for the femoral retrograde nails 540 × 240 × 50 mm without implants



**129 69 7900** Stand for the securing screws for the femoral retrograde nail 180 × 146 × 136 mm without implants

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