

Medical device description

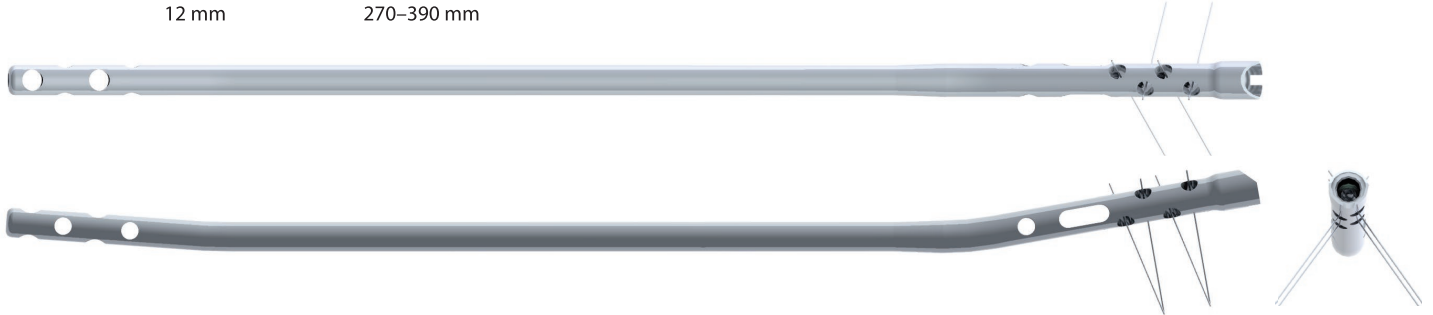
The implant system consists of the nail, locking screws, end cap and alternatively compression screw.

Proximal tibial nails

Nails are either full with 8–10 mm diameter or cannulated with 9–12 mm diameter. Nails are anatomically bent in proximal 80 mm at 10° and in distal 60 mm at 4° angles.

Nail sizes:	nail Ø	nail length in 15 mm increments:
	8 mm	240–360 mm
	9 mm	270–420 mm
	10 mm	270–420 mm
	11 mm	270–390 mm
	12 mm	270–390 mm

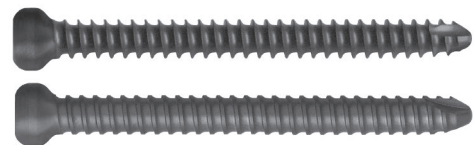
Proximal two pairs of holes for the screws head at 35° angle posteromedially and posterolaterally into the condyles of tibial plateau. The second pair of screws heading to the right has slight 10° proximal direction to ensure that the first two proximal screws will “prominate” the second corticalis in the same horizontal level considering the size of tibial plateau. It is about 35 mm from the axis of diaphyseal part of the nail in a mediolateral view. There is a dynamic and static hole mainly for diaphyseal fractures distally from those four screws. There are also two pairs of holes for screws in a distal nail part. The first pair heads in lateromedial and the second in AP directions.



Locking screws for nails of 9–12 mm Ø:

Locking screw of 5 mm Ø with cortical thread in lengths of 25–105 mm in increments of 5 mm.

Locking reinforced screw of 5 mm Ø with a reinforced core and a lowered cortical thread in lengths of 25–90 mm in increments of 5 mm.



Locking screws for nails of 8 mm Ø:

Locking reinforced screw of 3.5 mm Ø with a reinforced core and a lowered cortical thread in lengths of 20–50 mm in increments of 2 mm and 55–70 mm in increments of 5 mm.



End caps

There are three sizes of the caps 0; 5 and 10. The size 0 is fully hidden in the nail. The sizes 5 and 10 project above the nail 5 and 10 mm respectively.



Compression screws

There are two diameters of the compression screws: Ø 3.2 mm for nails of 8 mm Ø and Ø 4.4 mm for nails of 9–12 mm Ø.



Indications

Proximal tibial nail is intended for osteosynthesis of metaphyseal and diaphyseal fractures and simple intercondylar proximal and distal tibial fractures. Mainly for fracture treatment of types 41 – A2, A3; 42; 43 – A1, A2, A3 according to Müller.

This brochure should be only considered as an illustrative guideline of tibial proximal nail and the instrumentation. The main purpose of this brochure is to provide a quick orientation for surgeons and suture nurses. To show the correct composition and usage of the instrumentation and implants so that the best surgery result would be achieved. If you have any queries do not hesitate to contact sales people of MEDIN, a.s.

Surgical technique

1. Procedure planning

We recommend to go through the surgical process before the osteosynthesis. Pre-select suitable implants. Compare X-ray images of both extremities and then specify the repositioning of the fragments back to its anatomical position. We recommend to plan location of the supporting implants (K-wires, cancellous screws) used for transfixation of the fragments and major implants as well as with respect to the soft tissues.

2. Patient position

The patient is placed on the extension table and the operated extremity is positioned into the body axis and into the flexion of about 90° (Fig. 1). Possibility to check whole tibia in AP and ML projections is a must. Traction can be performed using skeletal calcaneal drilling, soft traction by figure-of-eight bandage or one-time traction during surgery.

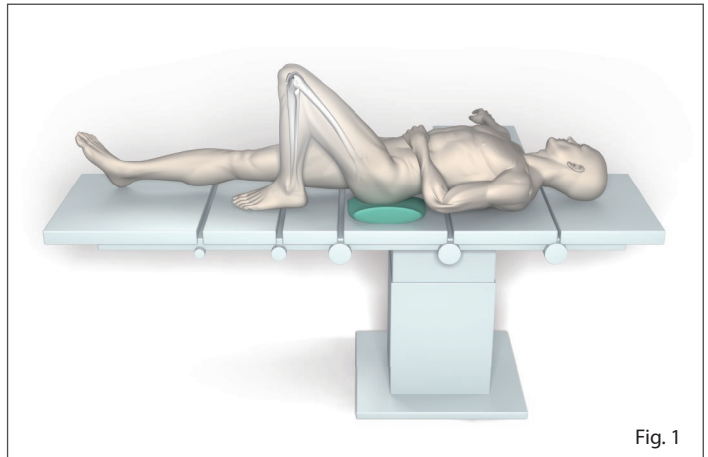


Fig. 1

3. Reposition

Reposition fragments into the original anatomical position. Fix the repositioned fragments at least by two K-wires. Reposition fragments of the tibial plateau and fix by K-wires. Then perform the compression using cancellous screws. Check reposition using X-rays. Keep in mind that poor reposition may adversely affect the correct function and the correct grow of the fragments.

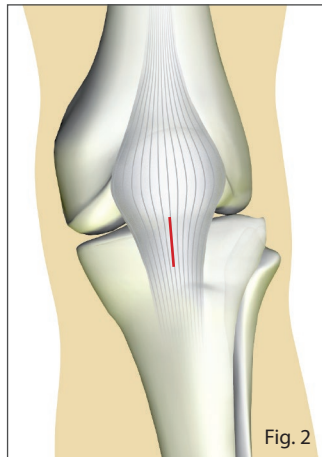


Fig. 2

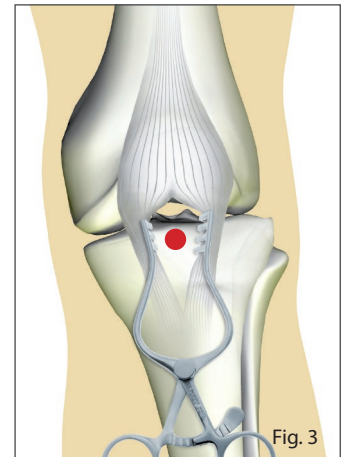


Fig. 3

4. Entry point

Entry point can differ from the fracture location and with regard to tibial axis. Approximately five centimetre incision perform over the centre of *lig. proprium patellae*. Cut in half the ligamentum and both halves pull apart and hold by retractor (Fig. 2, 3). Introduce K-wire of 2 mm \varnothing 3–4 mm proximally from the entry point (because of perforator construction) approximately 60 mm deep. Create the entry point using cannulated perforator (Fig. 4–6).



Fig. 4



Fig. 5

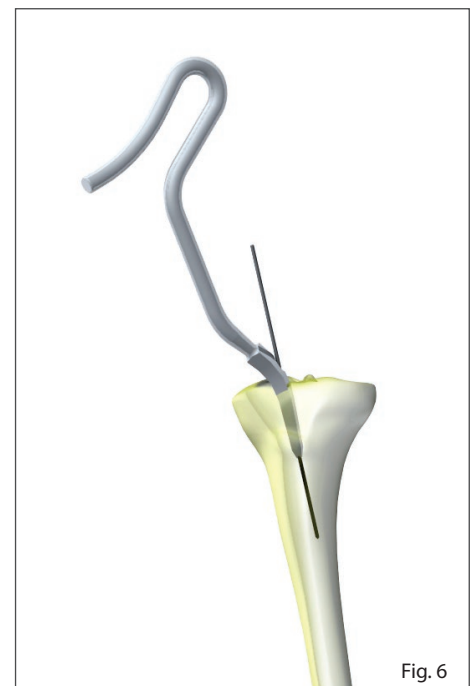


Fig. 6

5. Preparation of an intramedullary cavity

You can pre-drill the cavity by a flexible cutter. Introduce the introducer with an olive into the cavity. Always cut the cavity with cutters step by step from 8 ø up to diameter 1 mm bigger than is the diameter of the chosen nail. Drain the cavity when finished cutting and remove the introducer with an olive. You can use introducer without an olive if you will introduce cannulated nail.

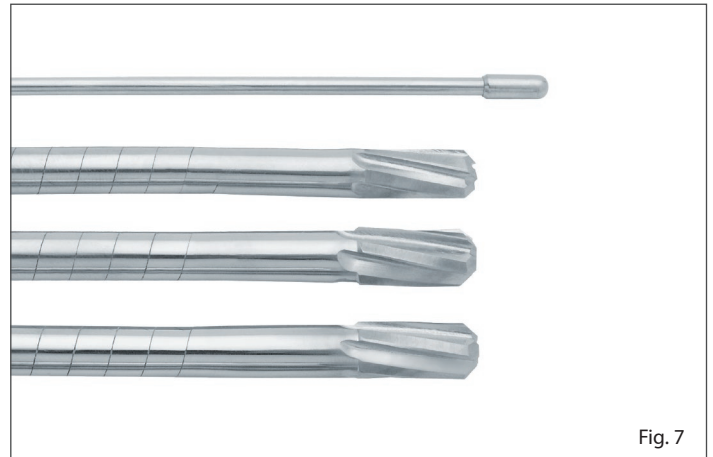


Fig. 7

6. Completing of aiming device with mallet

The aiming device is supplied with a clap for Tibial nail and with second clap for Tibial nail proximal. Connect the clap with the chosen nail using a screw and tighten it. After you can connect the clap with the aiming device arm. Alternatively you can connect them after the nail introduction. Slide the weight onto the hammer rod and screw the handle. After screw the mallet into the aiming device clap (Fig. 9–11).



Fig. 8



Fig. 9



Fig. 10



Fig. 11

7. Nail introduction

Introduce the nail as carefully as possible with respect to the fragments. Slightly knock with the mallet weight in the introduction direction in case of a hard introduction. Pull the nail by reverse knocking of mallet into the handle in case of excessive nail introduction to the tibia as during extraction. In case that fragments are dislocated during nail introduction perform fragment reposition back to the anatomical position and verify under X-rays.

Alternatively you can use a driver instead of a mallet (Fig.12). In this case when hard introduction knock onto a driver with a surgical mallet.

Remove the mallet or the driver after the nail introduction.

You can use K-wire introduced into the red colour marked holes in the arm to check the correct depth of the nail introduction in respect to the tibia (Fig. 13).



Fig. 12



Fig. 13

You can check the correct depth of nail introduction in respect to the locking screw position and nail rotation using K-wire with maximal of 2 mm \varnothing introduced together with sleeves of 10/8 mm \varnothing and 8/2 mm \varnothing into two proximal holes in the nail (Fig. 14).



Fig. 14

8. Pre-drilling of the proximal screws

Introduce a sleeve of 10/8 mm \varnothing together with trocar into the hole in the nail (Fig. 15) and perform incision at the site of contact with skin. Always introduce a sleeve of 10/8 mm \varnothing together with trocar, it will prevent soft tissues intrusion into the sleeve. Push trocar into the bone and remove it. Push sleeve into the bone, too. Insert a sleeve of 8/3.5 mm \varnothing and drill both fragments through using a drill of 3.5 mm \varnothing (Fig. 16).

ATTENTION! INSERT THE SCREWS IN THE AREA OF PROXIMAL TIBIA MONO-CORTICALLY ONLY!

Remove the sleeve of 8/3.5 \varnothing and drill of 3.5 mm \varnothing .

Insert a sleeve of 8/5 mm \varnothing and drill through the first fragment only using a drill of 5 mm \varnothing if you need to perform compression and/or pull fragment in (Fig. 17). Remove the sleeve of 8/5 \varnothing and drill of 5 mm \varnothing . Note: These tools are available only on special order.



Fig. 15



Fig. 16



Fig. 17

Locking screw of 3.5 mm \varnothing pre-drill with a drill of 2,9 \varnothing introduced through a sleeve of 8/2.9 mm \varnothing (Fig. 18).



Fig. 18

9. Introduction of the proximal bone screws

Measure depth of a pre-drilled hole for a screw by depth gauge (Fig. 19). You can measure a drilled hole depth with a drill, too, but this value is only approximate (Fig. 18). Assemble a screwdriver and insert a locking screw (Fig. 20). Measure the depth of screwing on the shaft of the screwdriver. Repeat this process for the required number of locking screws. Use a hexagon screwdriver 5 mm for locking screws of 5 mm diameter.

Use a hexagon screwdriver 3.5 mm and a guide sleeve of 6.8 mm \varnothing for locking screws of 3.5 mm \varnothing .

It may not be necessary to ensure the nail in the proximal four holes at osteosynthesis of diaphyseal fractures, but it's sufficient to lock the nail in the dynamic or static hole. A dynamic compression can be performed at a maximum range of 10 mm with compression screw during the introduction of the locking screw into the hole. This screw is introduced into the nail from top as well as an end cap after removal of the aiming device. The nail has to be already locked in a distal part for such performed compression.

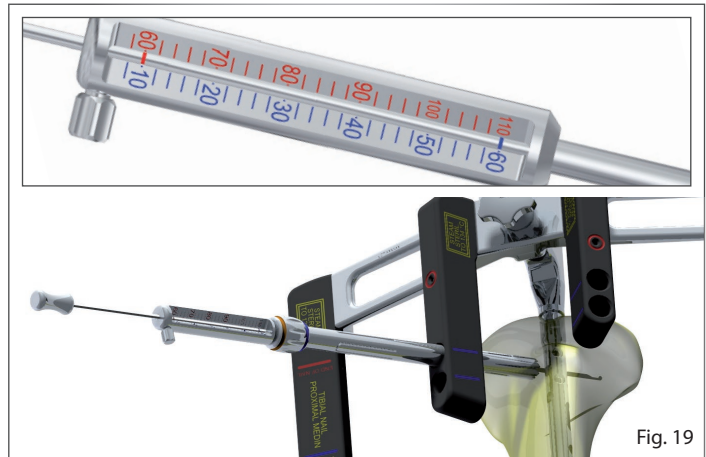


Fig. 19

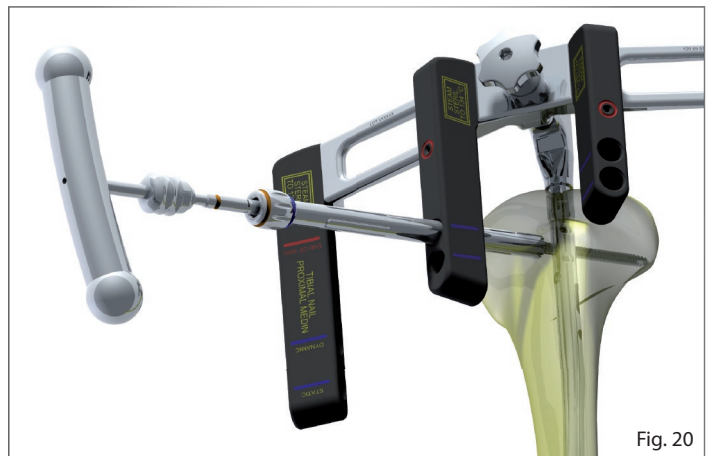


Fig. 20

10. Distal locking

Distal locking perform using the same locking screws of 3.5 \varnothing for nail of 8 mm \varnothing and 5 mm for nail diameters of 9–12 mm with a free hand. Screws can be introduced lateromedially and ventrodorsally as needed.

Before distal locking is performed, check anatomic reposition, correct fragment position and the length of the tibial bone. Set X-ray device over the distal holes in the nail in a way that those will be displayed as circles (Figs. 21, 22). Place the tip of the scalpel on the skin over the hole centre (Fig. 23), and perform a stab incision with a scalpel down to the bone. Attach the appropriate drill into the drilling machine and introduce into the performed incision along with a protective sleeve, tilt and adjust under X-ray device so that the drill tip will be positioned exactly in the centre of the circle hole (Fig. 24). Then rotate drilling machine with a drill so that it is perpendicular to the axis of the nail and drill a hole through both cortices. Measure depth of a screw by depth gauge. Attach the locking screw onto the screwdriver and screw it. Introduce the other distal locking screws as needed.



Fig. 21

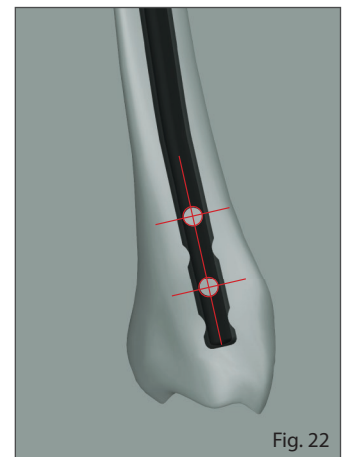


Fig. 22



Fig. 23



Fig. 24



11. Closure of the operation

After irrigation gradually close the incision. Introduce the suction drain to the place of the nail introduction into the bone but it must not suck blood directly from the cavity. Cover the wound with a soft bandage and perform X-ray documentation.

12. Final notes

- Prior to the nail introduction it is required after assembly of the nail and aiming device to check whether all the holes into which the screws should be introduced match with the holes in the aiming device and nail.
- Never combine different materials in one patient.
- The MEDIN company requires to use their own implants only to guarantee safe use of the implant. Implants from different companies must never be combined.
- 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. This fact is stated in the product leaflet and is valid for all implants.

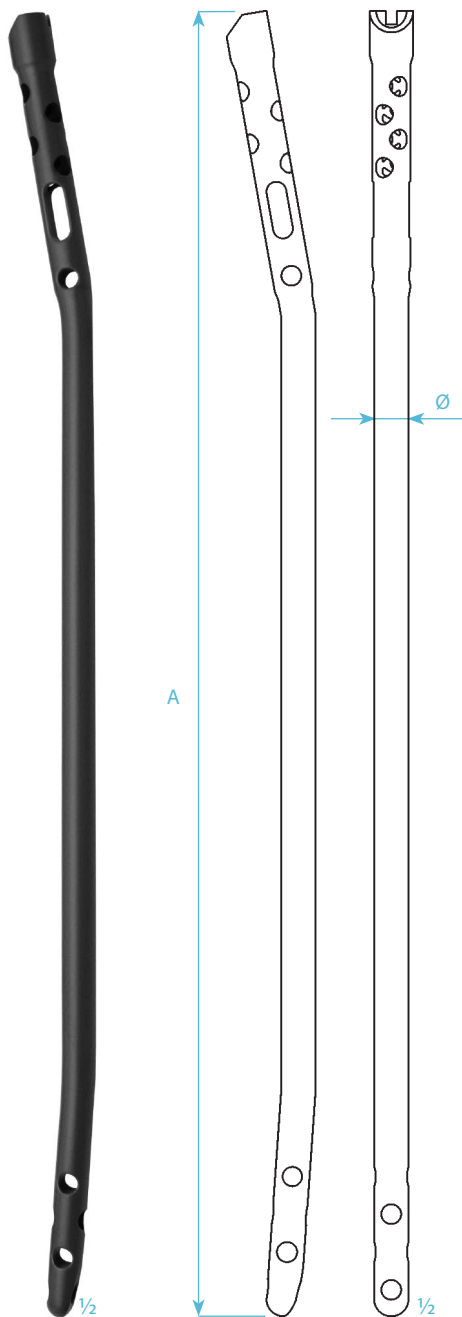


13. Recommended procedure of implant removal

Implants are mostly retained permanently.

When removing the implant, gradually remove the cap and after the screws from the distal and proximal parts of the nail. Nail extractor should be screwed into the nail before removing the last locking screw from the nail to prevent possible rotation of the nail in the tibial cavity. Introduce an extraction bar into the inner cavity of the proximal nail end and attach a weight and screw a handle to it. Knock out the nail using the weight punches against the handle. This part of the instrumentation has to be hold constantly to avoid burden of the fused bone by a bending moment. Attention! FUSED BONE COULD BE DAMAGED!





Proximal tibial nail full

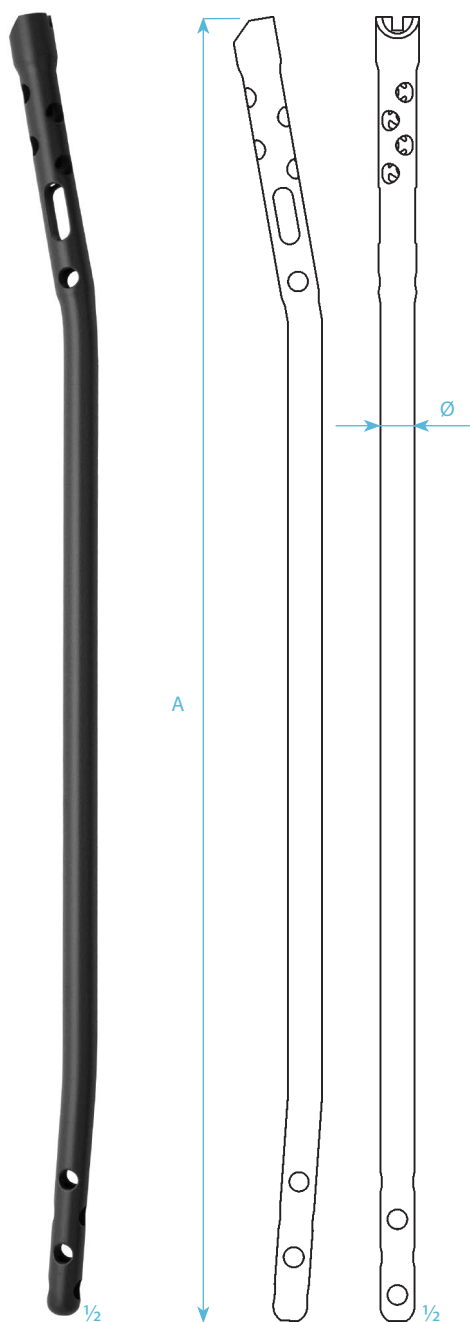
SSt	Ti	A	Ø
129 78 1500	129 78 1503	240 mm	8 mm
129 78 1510	129 78 1513	255 mm	8 mm
129 78 1520	129 78 1523	270 mm	8 mm
129 78 1530	129 78 1533	285 mm	8 mm
129 78 1540	129 78 1543	300 mm	8 mm
129 78 1550	129 78 1553	315 mm	8 mm
129 78 1560	129 78 1563	330 mm	8 mm
129 78 1570	129 78 1573	345 mm	8 mm
129 78 1580	129 78 1583	360 mm	8 mm
129 78 1610	129 78 1613	270 mm	9 mm
129 78 1620	129 78 1623	285 mm	9 mm
129 78 1630	129 78 1633	300 mm	9 mm
129 78 1640	129 78 1643	315 mm	9 mm
129 78 1650	129 78 1653	330 mm	9 mm
129 78 1660	129 78 1663	345 mm	9 mm
129 78 1670	129 78 1673	360 mm	9 mm
129 78 1680	129 78 1683	375 mm	9 mm
129 78 1690	129 78 1693	390 mm	9 mm
129 78 1700	129 78 1703	405 mm	9 mm
129 78 1710	129 78 1713	420 mm	9 mm
129 78 1740	129 78 1743	270 mm	10 mm
129 78 1750	129 78 1753	285 mm	10 mm
129 78 1760	129 78 1763	300 mm	10 mm
129 78 1770	129 78 1773	315 mm	10 mm
129 78 1780	129 78 1783	330 mm	10 mm
129 78 1790	129 78 1793	345 mm	10 mm
129 78 1800	129 78 1803	360 mm	10 mm
129 78 1810	129 78 1813	375 mm	10 mm
129 78 1820	129 78 1823	390 mm	10 mm
129 78 1830	129 78 1833	405 mm	10 mm
129 78 1840	129 78 1843	420 mm	10 mm

NOTES: SSt – stainless steel in accordance with ISO 5832-1

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

PROXIMAL TIBIAL NAIL

PROXIMAL TIBIAL NAILS CANNULATED

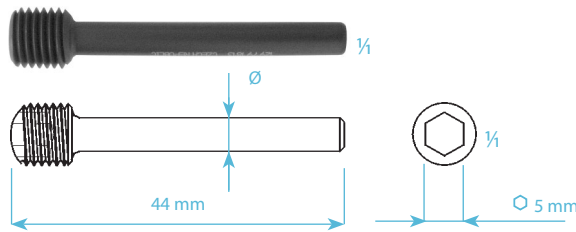


Proximal tibial nail cannulated

SSt	Ti	A	Ø
129 78 2090	129 78 2093	270 mm	9 mm
129 78 2100	129 78 2103	285 mm	9 mm
129 78 2110	129 78 2113	300 mm	9 mm
129 78 2120	129 78 2123	315 mm	9 mm
129 78 2130	129 78 2133	330 mm	9 mm
129 78 2140	129 78 2143	345 mm	9 mm
129 78 2150	129 78 2153	360 mm	9 mm
129 78 2160	129 78 2163	375 mm	9 mm
129 78 2170	129 78 2173	390 mm	9 mm
129 78 2180	129 78 2183	405 mm	9 mm
129 78 2190	129 78 2193	420 mm	9 mm
129 78 2220	129 78 2223	270 mm	10 mm
129 78 2230	129 78 2233	285 mm	10 mm
129 78 2240	129 78 2243	300 mm	10 mm
129 78 2250	129 78 2253	315 mm	10 mm
129 78 2260	129 78 2263	330 mm	10 mm
129 78 2270	129 78 2273	345 mm	10 mm
129 78 2280	129 78 2283	360 mm	10 mm
129 78 2290	129 78 2293	375 mm	10 mm
129 78 2300	129 78 2303	390 mm	10 mm
129 78 2310	129 78 2313	405 mm	10 mm
129 78 2320	129 78 2323	420 mm	10 mm
129 78 1870	129 78 1873	270 mm	11 mm
129 78 1880	129 78 1883	285 mm	11 mm
129 78 1890	129 78 1893	300 mm	11 mm
129 78 1900	129 78 1903	315 mm	11 mm
129 78 1910	129 78 1913	330 mm	11 mm
129 78 1920	129 78 1923	345 mm	11 mm
129 78 1930	129 78 1933	360 mm	11 mm
129 78 1940	129 78 1943	375 mm	11 mm
129 78 1950	129 78 1953	390 mm	11 mm
129 78 1980	129 78 1983	270 mm	12 mm
129 78 1990	129 78 1993	285 mm	12 mm
129 78 2000	129 78 2003	300 mm	12 mm
129 78 2010	129 78 2013	315 mm	12 mm
129 78 2020	129 78 2023	330 mm	12 mm
129 78 2030	129 78 2033	345 mm	12 mm
129 78 2040	129 78 2043	360 mm	12 mm
129 78 2050	129 78 2053	375 mm	12 mm
129 78 2060	129 78 2063	390 mm	12 mm

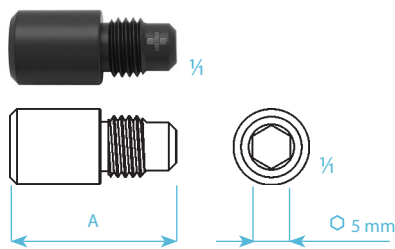
NOTES: SSt – stainless steel in accordance with ISO 5832-1

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



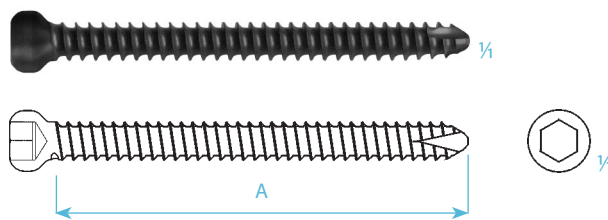
Compression screw

SSt	Ti	Ø	for nail
129 79 1800	129 79 1803	3.2 mm	Ø 8 mm
129 79 1810	129 79 1813	4.4 mm	Ø 9–12 mm



End cap

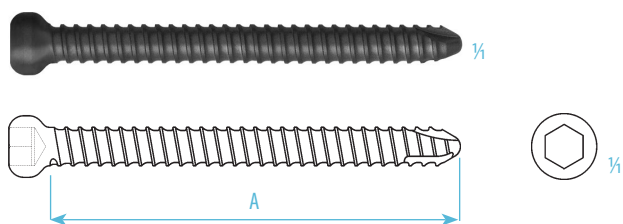
SSt	Ti	A
129 78 1420	129 78 1423	12 mm
129 78 1430	129 78 1433	22 mm
129 78 1440	129 78 1443	27 mm



Locking screw 5 mm, fully threaded

thread diameter	5.0 mm
core diameter	3.5 mm
head diameter	8.0 mm
drill bit for threaded hole	Ø 3.5 mm
drill bit for gliding hole	Ø 5.0 mm
screwdriver	Ø 5.0 mm

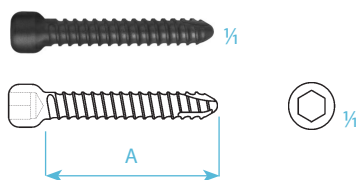
SSt	Ti	A
129 79 1510	129 79 1513	25 mm
129 79 1530	129 79 1533	30 mm
129 79 1550	129 79 1553	35 mm
129 79 1570	129 79 1573	40 mm
129 79 1590	129 79 1593	45 mm
129 79 1610	129 79 1613	50 mm
129 79 1630	129 79 1633	55 mm
129 79 1650	129 79 1653	60 mm
129 79 1670	129 79 1673	65 mm
129 79 1690	129 79 1693	70 mm
129 79 1710	129 79 1713	75 mm
129 79 1730	129 79 1733	80 mm
129 79 1750	129 79 1753	85 mm
129 79 1770	129 79 1773	90 mm
129 79 1290	129 79 1293	95 mm
129 79 1300	129 79 1303	100 mm
129 79 1310	129 79 1313	105 mm



thread diameter	5.0 mm
core diameter	4.4 mm
head diameter	8.0 mm
drill bit for threaded hole	Ø 4.4 mm
drill bit for gliding hole	Ø 5.0 mm
screwdriver	Ø 5.0 mm

Locking screw strengthened 5 mm

SSt	Ti	A
129 79 9631	129 79 9634	25 mm
129 79 9641	129 79 9644	30 mm
129 79 9651	129 79 9654	35 mm
129 79 9661	129 79 9664	40 mm
129 79 9671	129 79 9674	45 mm
129 79 9681	129 79 9684	50 mm
129 79 9691	129 79 9694	55 mm
129 79 9701	129 79 9704	60 mm
129 79 9711	129 79 9714	65 mm
129 79 9721	129 79 9724	70 mm
129 79 9731	129 79 9734	75 mm
129 79 9741	129 79 9744	80 mm
129 79 9751	129 79 9754	85 mm
129 79 9761	129 79 9764	90 mm



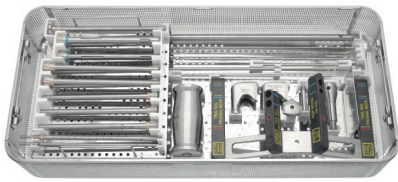
thread diameter	3.5 mm
core diameter	2.9 mm
head diameter	5.6 mm
drill bit for threaded hole	Ø 2.9 mm
drill bit for gliding hole	Ø 3.5 mm
screwdriver	Ø 3.5 mm

Locking screw strengthened 3.5 mm

SSt	Ti	A
129 77 6551	129 77 6554	20 mm
129 77 6561	129 77 6564	22 mm
129 77 6571	129 77 6574	24 mm
129 77 6581	129 77 6584	26 mm
129 77 6591	129 77 6594	28 mm
129 77 6601	129 77 6604	30 mm
129 77 6611	129 77 6614	32 mm
129 77 6621	129 77 6624	34 mm
129 77 6631	129 77 6634	36 mm
129 77 6641	129 77 6644	38 mm
129 77 6651	129 77 6654	40 mm
129 77 6661	129 77 6664	42 mm
129 77 6671	129 77 6674	44 mm
129 77 6681	129 77 6684	46 mm
129 77 6691	129 77 6694	48 mm
129 77 6701	129 77 6704	50 mm
129 77 6711	129 77 6714	55 mm
129 77 6721	129 77 6724	60 mm
129 77 6731	129 77 6734	65 mm
129 77 6741	129 77 6744	70 mm

NOTES: SSt – stainless steel in accordance with ISO 5832-1

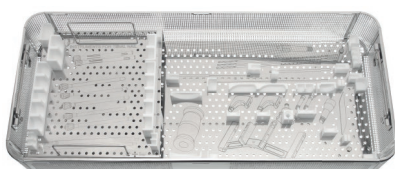
Ti – titanium version, material: Ti6Al4V ELI in accordance with ISO 5832-3



139 09 0375 Set of instruments for tibial nails
540 × 240 × 130 mm
including instruments



139 09 0370		set	pcs
1	129 09 0702	Perforator curved; 12 mm	1
2	129 09 2570	K-wire MEDIN Ø 2.0×300 mm	3
3	129 69 4785	Depth gauge	1
4	129 69 5130	Screwdriver handle	1
5	129 69 5252	Screwdriver; hexagon 3.5 mm	1
6	129 69 5272	Screwdriver; hexagon 5 mm	1
7	129 69 5660	Impactor	1
8	129 69 5670	Mallet	1
9	129 69 5780	Aiming device for tibial proximal nails	1
10	129 69 6100	Wrench rod	1
11	129 69 6400	Sleeve Ø 10/8×155 mm	3
12	129 69 6420	Sleeve Ø 8/3.5×171 mm	2
13	129 69 6430	Sleeve Ø 8/4.4×171 mm	2
14	129 69 6440	Sleeve Ø 8/2.9×171 mm	1
15	129 69 6450	Sleeve Ø 8/6×171 mm	1
16	129 69 6460	Sleeve Ø 8/2.5×171 mm	1
17	129 69 6470	Trocar Ø 8×182 mm	1
18	129 69 6621	Drill Ø 2.9×320 mm	1
19	129 69 6631	Drill Ø 3.5×320 mm	1
20	129 69 6641	Drill Ø 4.4×320 mm	1
21	129 69 7190	Color table of compatibility	1
22	129 69 7210	Plug 10×30 mm	4
23	129 69 7320	Thread adapter M12/M8×1	1



129 69 6610 Sieve for instruments for tibial nails
540 × 240 × 130 mm
excluding instruments



129 69 6570 Stand for locking screws 5 and 3,5 mm
212 × 154 × 98 mm
excluding implants

REFID