

Proximal Tibial Plate

Description of medical device

The Proximal Tibial Plate is used in epiphyseal and metaphyseal fractures of the proximal end of the tibia. The implantable system consists of a plate and angularly stable or cortical screws. Plates are anatomically shaped and laterally different for the left and right limb. The distal end is rounded to facilitate easier implementation of mini-invasive insertion. The distal portion is lighter at the bottom of the plate in order to minimize contact and possible compression of the periosteum. In the proximal part, the plate is extended to enable potential insertion of three angularly stable screws under the tibial plateau. In the proximal and distal shaft portion, the plate has holes for angular screws with a diameter of 5 mm. Below the proximal part is positioned an oval opening for attaching using a cortical screw with a diameter of 4.5 mm.

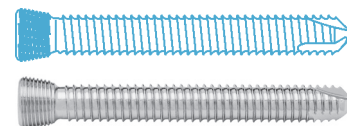
Indication

This surgical technique is intended for both simple dislocated and more complicated, fragmented intra-articular fractures of the proximal end of the tibia, primarily for the treatment of fractures types 41 – A2, A3, B1, B3, C1, C2, C3; based on the Muller classification, and of some storey fractures.

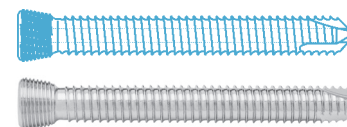


Proximal tibial plates
right

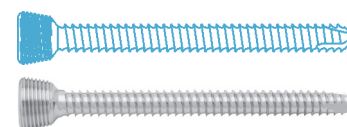
Proximal tibial plates
left



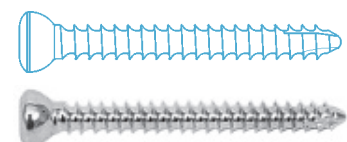
Locking Bone Screws
Ø 5 mm



Cannulated Locking Bone
Screws Ø 5 mm



Locking Bone Screws
Ø 5/3.5 mm



Cortical Screws
self-tapping Ø 4.5 mm

This brochure only serves as an illustrative guide for proximal tibial plates and the instrumentarium. The aim of the brochure is to give physicians and suture nurses a quick guide in the use of the instruments and implant and their composition in order to achieve the best operational outcome. If you have any questions, please contact the MEDIN, a.s. sales representative.

1. Preoperative planning and principle of surgery technique

The principle of the surgery is the fixation of anatomically repositioned fragments using angular stable screws that are secured in the plate. This system functions as an internal fixator and its task is to hold the fragments in place while the fracture is healing.

Before surgery, plan the following on preoperative X-rays:

- If it is suitable to use this surgical technique.
- Reposition of fragments or implementation of trans-fixation or additional implants and placement of soft tissue (arteries, nerves...) which must be not be injured during surgery.
- Access, placement and size of the incision.
- The size of the plate or length and screws.

NOTE: It is advisable to take X-ray images of both limbs and compare them in order to achieve the correct reposition.

2. Preparation

2.1. Preparation of implant

2.1.1. Choosing a plate

The implant (plate) is designed specifically for left and right tibia. Plates are supplied in non-sterile versions. Before use, they must be disinfected, washed and sterilized.

The length of the plate should be chosen so that the distal half of the plate is outside of fracture area and can be attached to the tibial shaft using screws.

2.2. Preparation of instruments

Before the surgery, it is necessary to check the completeness and functionality of all of the instruments. The instruments are supplied in non-sterile versions. Before use, they must be disinfected, washed and sterilized.

3. Surgical technique

3.1. Preoperative preparation

3.2. Positioning of the patient

Place the patient on a surgical table in the supine position, and the limb that the surgery is to be performed on in such a way that X-rays can be projected in two perpendicular planes.

3.3. Drawing positions of the bones and tendons

It is a good idea to draw on the skin of the patient the place where the incision is to be made, and localization of soft tissue, for better visualization and preoperative planning.

3.4. Incision

Based on the nature of the fracture, the surgeon can choose the anterolateral (Fig. 1), or the mini-invasive (Fig. 2) approach if the surgeon wants to insert the plate using the minimally invasive technique.

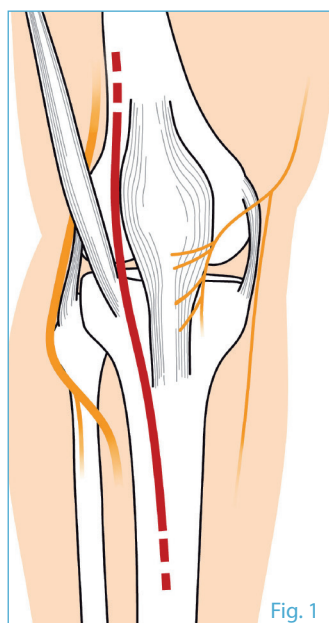


Fig. 1

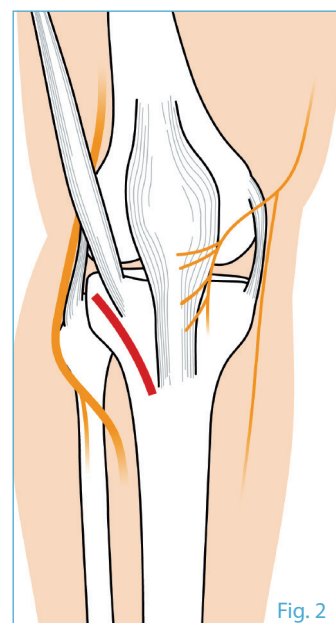


Fig. 2

3.5. Repositioning of the articular surface and the anatomical position and fixation of the repositioned fragments

3.5.1. Repositioning

Correct repositioning is one of the key components of osteosynthesis. Pay attention to this: it is very important to place the fragments into the original anatomical position, particularly the fragments of the articular surfaces. Otherwise, it is likely that the patient will feel pain during movement, or limited mobility.

3.5.2. Fixation using lag screws and K-wires

Attach the repositioned articular surface with two “lag screws” (Fig. 3), or K-wires; this will eliminate the dislocation of fragments when inserting the plate or screws.

Attach the other dislocated fragments in a similar manner.



Fig. 3

3.6. Inserting the plate

3.6.1. Preparation of the location for inserting the plate

If the plate is to be inserted via a large incision, we will check the soft tissues and attach the plate to the tibia from the lateral side.

If the plate is to be inserted using the mini-invasive method, it will be necessary to create space via a raspatorium on the lateral side between soft and bone tissues.



Fig. 4

3.6.2. Inserting the plate

Tightening the lockable sleeves into the plate will improve manipulability with the plate in the surgical wound (Fig. 4). Check the position of the plate using X-ray. Insert the plate and attach it. The attaching can be done in several ways:

- By using the HA 4.5 cortical screw in the oval opening (Fig. 5). This fixation allows for the movement and shifting of the plate around the cortex screw.
- By tightening the plate with K-wires in the proximal part of the plate where there are openings created for them.
- It is also possible to use K-wires to stabilize the plates in the surgical wound through the lock and guide sleeves, especially in the distal part.

Check the correct length and position of the plate. In the distal part, check that it was placed in the centre of the shaft, under the front edge of the tibia.

If you are using the minimally invasive method, insert the sleeve into the second most distal opening after inserting the plate.



Fig. 5

3.6.3. Inserting angularly stable screws

Insert the locking targeted sleeves into the proximal openings in the stabilized plate, and insert the guide sleeves for K-wires, diameter 1.5 mm (Fig. 6) into the proximal opening. Use these K-wires to check the correct positioning of the screws. The screws may not perforate the articular surface of the tibia and must not collide with the screws and K-wires.



Fig. 6

After you have checked the position of the screws, drill an opening with a diameter of 3.9 mm (Fig. 7).

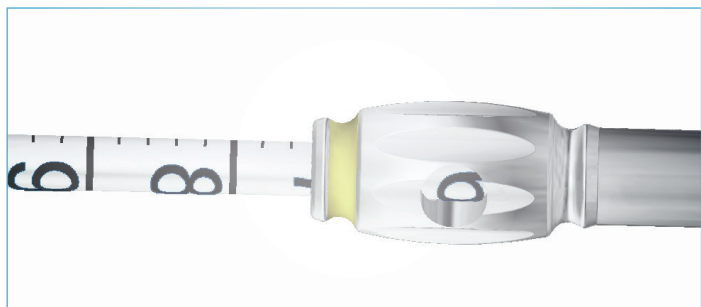


Fig. 7

On the drill, you can read the length of the screws, or measure it with a depth gauge (Fig. 8).

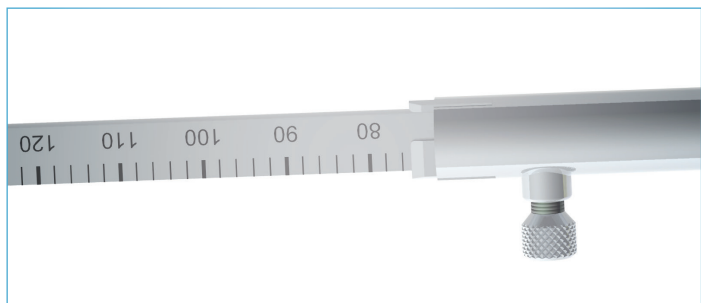


Fig. 8

Only insert the screws in the proximal part monocortically. Complete the handle with the torque coupling and 3.5 mm hexagonal screwdriver and insert the screw (Fig. 9).

Apply this procedure for all the screws that are necessary for stable fixation. In the distal part, below the area of the fracture, insert at least three screws bicortically and insert the final screw monocortically. The force will thus be spread over the last two screws.

The three holes above the oval opening support the three proximal screws under the tibial plateau. Thus, if the tibial plateau width is greater than 65 mm, the maximum length of the fourth and fifth proximal screws is 55 mm and the sixth proximal screw at most 70 mm. If you insert longer screws, the screws will collide with each other (Fig. 10 and 11).

3.6.4. Inserting other fixation screws

The instrumentation allows for angularly stable screws with a diameter of 3.5 mm bone thread to be inserted. Pre-drill these screws using a 2.9 mm diameter drill through lockable guide sleeve, diameter of 3.9/3 mm. In certain cases it will be necessary to insert cannulated angularly stable 5 mm diameter screw. This screw is pre-drilled using a cannulated 3.9 mm diameter drill. The cannulated screw and drill is guided using 1.5 mm diameter wire.

If necessary, it is possible to insert into the plate 4.5 mm diameter cortex screws. To insert these screws, use the instrumentation intended for this purpose.

3.7. Final check and end of surgery

Check the reposition, placement and length of the plate and screws. Take a final X-ray and close the wound with sutures.

3.8. Final comments

- The various materials can under no circumstances ever be combined for one patient.
- In order to guarantee the safe use of implants, MEDIN requires that only the recommended implants are used - they may not be combined with implants from other companies.
- Patients must be informed that the implant will not bear their full weight. Patients must use a means of support while walking, and gradually place more weight on the implant based on how the callus forms at the location of the fracture.
- The implants are intended for one use; repeated use is prohibited.



Fig. 9

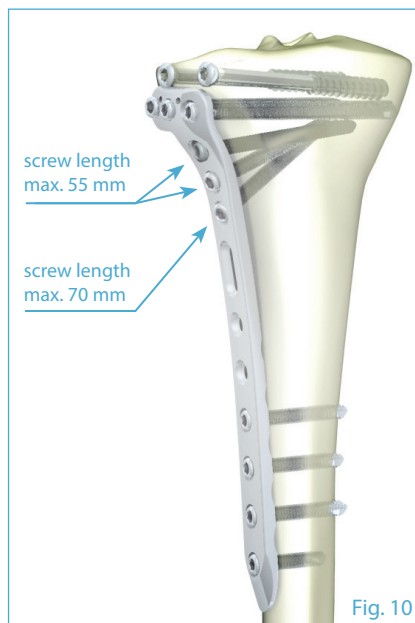


Fig. 10

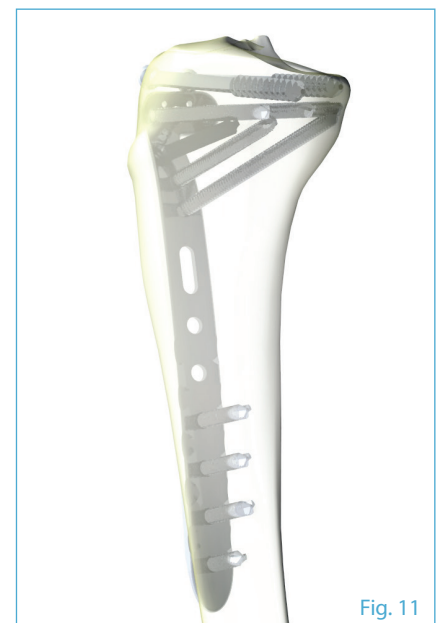


Fig. 11



3.9. Recommended procedure for extracting the implant

The implants may be left in permanently if the risks associated with extracting them are more serious than the reasons to extract them. We recommend the potential extracting of the implants after a minimum of 12 months from when they were implanted, after a callus has formed and the fracture has healed – unless there are reasons to extract them earlier.

Extraction procedure:

- Loosening of screws (Fig. 12)
- Removal of screws (Fig. 13)
- Extraction of plate (Fig. 14)

4. Follow up

After the surgery, it is necessary to examine motion. We recommend a CT scan to check the correct fixation to the joint. On the first postoperative day the patient will begin to practice mobility in the knee joint. Gradual load on the limb is possible only after 6–8 weeks after the operation, depending on the forming of the callus. Full load placed on the joint is only possible 10 weeks after surgery.

An X-ray is recommended after surgery: at 2, 4 and 8 weeks.



Fig. 12



Fig. 13



Fig. 14

5. Set of instruments

Set of instruments for 5 mm angularly stable screws	139 09 0260
Sieve for instruments	129 69 5180
Sieve for tibial proximal plates	129 69 5920

Instruments:

pcs	Name	order number
2	Guide sleeve Ø 3.9/1.8 mm	129 69 4410
2	Guide sleeve Ø 3.9/2.9 mm	129 69 4430
4	Aiming sleeve lockable Ø 6.8/3.9×80 mm	129 69 4300
1	Screwdriver handle	129 69 5130
2	Screwdriver; hexagon 3.5 mm	129 69 5261
2	Screwdriver; hexagon 3.5 mm	129 69 5251
1	Depth gauge	129 79 8910
1	Drill Ø 3.9×220; cannulated	129 69 4401
1	Drill Ø 2.9×220	129 69 5201
1	Drill Ø 3.9×220	129 69 5141
3	K-wire MEDIN 1.5×300 mm	129 09 2550
1	Torque limiter 4 Nm	129 69 5121



Recommended equipment in addition to the basic surgery set:

1. Retractor
2. Hook
3. Elevator
4. Pliers for K-wires
5. Scalpel
6. Sutures
7. Suction pump
8. Coagulation
9. Raspatorium

Recommended cleaning method

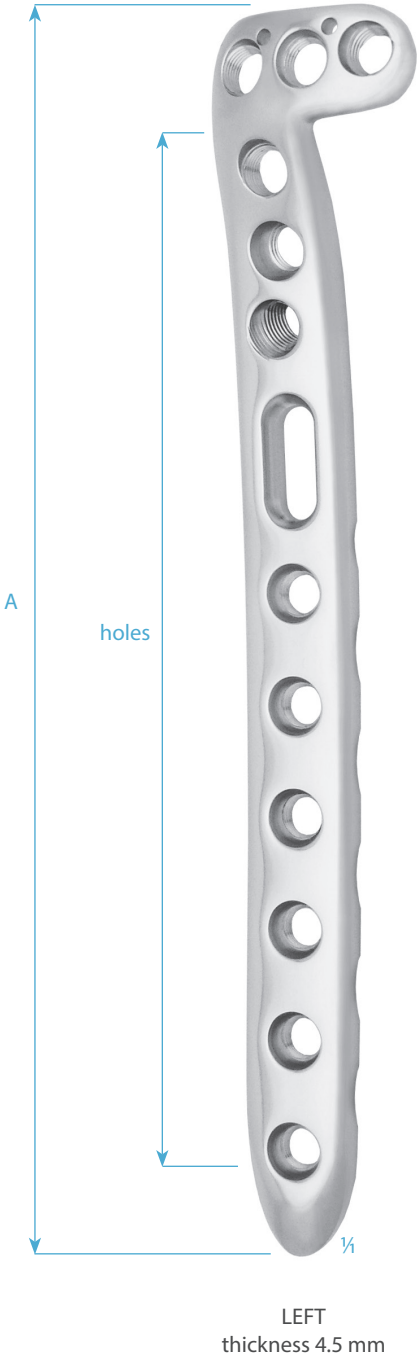
1. Mechanically cleaned with water using a brush.
2. Rinse instruments with pressurized water
3. Place the instruments into disinfectant solution for 20 to 30 minutes. Our recommended disinfectant is KORSOLEX plus. If you are using another solution, there is risk of damage to the instruments.
4. Re-flush using pressured water until clean water begins flowing. Flushing is possible in conventional pressure washers when connecting the instruments to jets.
5. Blow the instruments with compressed air.

Recommended sterilization procedure

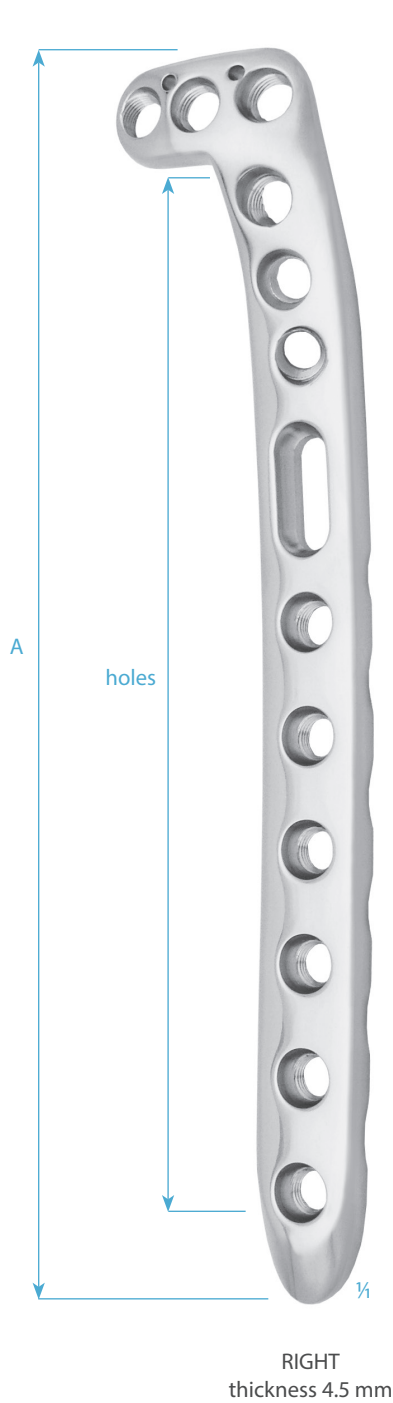
Before use, the instruments should be thoroughly washed and disinfected. We recommend steam sterilization. The sterilization temperature must not exceed 135 °C. If the temperature exceeds 135 °C, the plastic parts and colour coding of the instruments will be degraded. Instruments damaged in such a way must not be put into use.

PROXIMAL TIBIAL PLATE

PROXIMAL TIBIAL PLATES ANGULARLY STABLE, LEFT



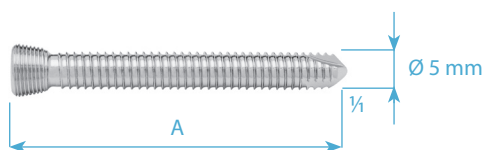
SSt	Ti	A	holes
129 78 2490	129 78 2493	135 mm	8
129 78 2510	129 78 2513	165 mm	10
129 78 2530	129 78 2533	195 mm	12
129 78 2550	129 78 2553	225 mm	14
129 78 2590	129 78 2593	285 mm	18
for special order			
129 78 2480	129 78 2483	120 mm	7
129 78 2500	129 78 2503	150 mm	9
129 78 2520	129 78 2523	180 mm	11
129 78 2540	129 78 2543	210 mm	13
129 78 2560	129 78 2563	240 mm	15
129 78 2570	129 78 2573	255 mm	16
129 78 2580	129 78 2583	270 mm	17
129 78 2600	129 78 2603	300 mm	19



SSt	Ti	A	holes
129 78 2350	129 78 2353	135 mm	8
129 78 2370	129 78 2373	165 mm	10
129 78 2390	129 78 2393	195 mm	12
129 78 2410	129 78 2413	225 mm	14
129 78 2450	129 78 2453	285 mm	18
for special order			
129 78 2340	129 78 2343	120 mm	7
129 78 2360	129 78 2363	150 mm	9
129 78 2380	129 78 2383	180 mm	11
129 78 2400	129 78 2403	210 mm	13
129 78 2420	129 78 2423	240 mm	15
129 78 2430	129 78 2433	255 mm	16
129 78 2440	129 78 2443	270 mm	17
129 78 2460	129 78 2463	300 mm	19

PROXIMAL TIBIAL PLATE

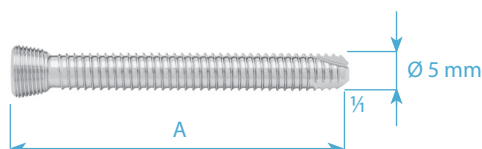
LOCKING BONE SCREWS 5 mm



NOTES:
drilled with Ø 3.9 mm drill
introduction by a screwdriver with 3.5 mm socket

SSt	Ti	A
129 77 7981	129 77 7984	16 mm
129 77 7991	129 77 7994	18 mm
129 77 8001	129 77 8004	20 mm
129 77 8011	129 77 8014	22 mm
129 77 8021	129 77 8024	24 mm
129 77 8031	129 77 8034	26 mm
129 77 8041	129 77 8044	28 mm
129 77 8051	129 77 8054	30 mm
129 77 8061	129 77 8064	32 mm
129 77 8071	129 77 8074	34 mm
129 77 8081	129 77 8084	36 mm
129 77 8091	129 77 8094	38 mm
129 77 8101	129 77 8104	40 mm
129 77 8111	129 77 8114	42 mm
129 77 8121	129 77 8124	44 mm
129 77 8131	129 77 8134	46 mm
129 77 8141	129 77 8144	48 mm
129 77 8151	129 77 8154	50 mm
129 77 8161	129 77 8164	55 mm
129 77 8171	129 77 8174	60 mm
129 77 8181	129 77 8184	65 mm
129 77 8191	129 77 8194	70 mm
129 77 8201	129 77 8204	75 mm
129 78 7401	129 78 7404	80 mm
129 78 7411	129 78 7414	85 mm
129 78 7421	129 78 7424	90 mm
129 78 7431	129 78 7434	95 mm
129 78 7441	129 78 7444	100 mm
129 78 7451	129 78 7454	105 mm

CANNULATED LOCKING BONE SCREWS 5 mm



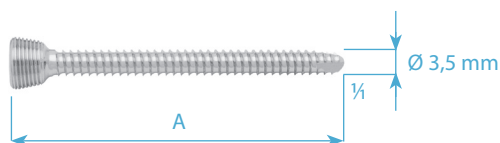
NOTES:
drilled with Ø 3.9 mm cannulated drill
introduction by a screwdriver with 3.5 mm socket
guide wire Ø 1.5 mm

CANNULATED		
SSt	Ti	A
129 77 8681	129 77 8684	16 mm
129 77 8691	129 77 8694	18 mm
129 77 8701	129 77 8704	20 mm
129 77 8711	129 77 8714	22 mm
129 77 8721	129 77 8724	24 mm
129 77 8731	129 77 8734	26 mm
129 77 8741	129 77 8744	28 mm
129 77 8751	129 77 8754	30 mm
129 77 8761	129 77 8764	23 mm
129 77 8771	129 77 8774	34 mm
129 77 8781	129 77 8784	36 mm
129 77 8791	129 77 8794	38 mm
129 77 8801	129 77 8804	40 mm
129 77 8811	129 77 8814	42 mm
129 77 8821	129 77 8824	44 mm
129 77 8831	129 77 8834	46 mm
129 77 8841	129 77 8844	48 mm
129 77 8851	129 77 8854	50 mm
129 77 8861	129 77 8864	55 mm
129 77 8871	129 77 8874	60 mm
129 77 8881	129 77 8884	65 mm
129 77 8891	129 77 8894	70 mm
129 77 8901	129 77 8904	75 mm
129 78 7541	129 78 7544	80 mm
129 78 7551	129 78 7554	85 mm
129 78 7561	129 78 7564	90 mm
129 78 7571	129 78 7574	95 mm
129 78 7581	129 78 7584	100 mm
129 78 7591	129 78 7594	105 mm

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

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

LOCKING BONE SCREWS 5/3.5 mm



NOTES:
drilled with Ø 2.9 mm drill
introduction by a screwdriver with 3.5 mm socket

SSt	Ti	A
129 77 8231	129 77 8234	16 mm
129 77 8241	129 77 8244	18 mm
129 77 8251	129 77 8254	20 mm
129 77 8261	129 77 8264	22 mm
129 77 8271	129 77 8274	24 mm
129 77 8281	129 77 8284	26 mm
129 77 8291	129 77 8294	28 mm
129 77 8301	129 77 8304	30 mm
129 77 8311	129 77 8314	32 mm
129 77 8321	129 77 8324	34 mm
129 77 8331	129 77 8334	36 mm
129 77 8341	129 77 8344	38 mm
129 77 8351	129 77 8354	40 mm
129 77 8361	129 77 8364	42 mm
129 77 8371	129 77 8374	44 mm
129 77 8381	129 77 8384	46 mm
129 77 8391	129 77 8394	48 mm
129 77 8401	129 77 8404	50 mm
129 77 8411	129 77 8414	55 mm
129 77 8421	129 77 8424	60 mm
129 77 8431	129 77 8434	65 mm
129 77 8441	129 77 8444	70 mm
129 77 8451	129 77 8454	75 mm
129 78 7471	129 78 7474	80 mm
129 78 7481	129 78 7484	85 mm
129 78 7491	129 78 7494	90 mm
129 78 7501	129 78 7504	95 mm
129 78 7511	129 78 7514	100 mm
129 78 7521	129 78 7524	105 mm

SELF-TAPPING CORTICAL BONE SCREWS – HA 4.5 mm



NOTES:
drilled with Ø 3.2 mm drill
introduction by a screwdriver with 3.5 mm socket

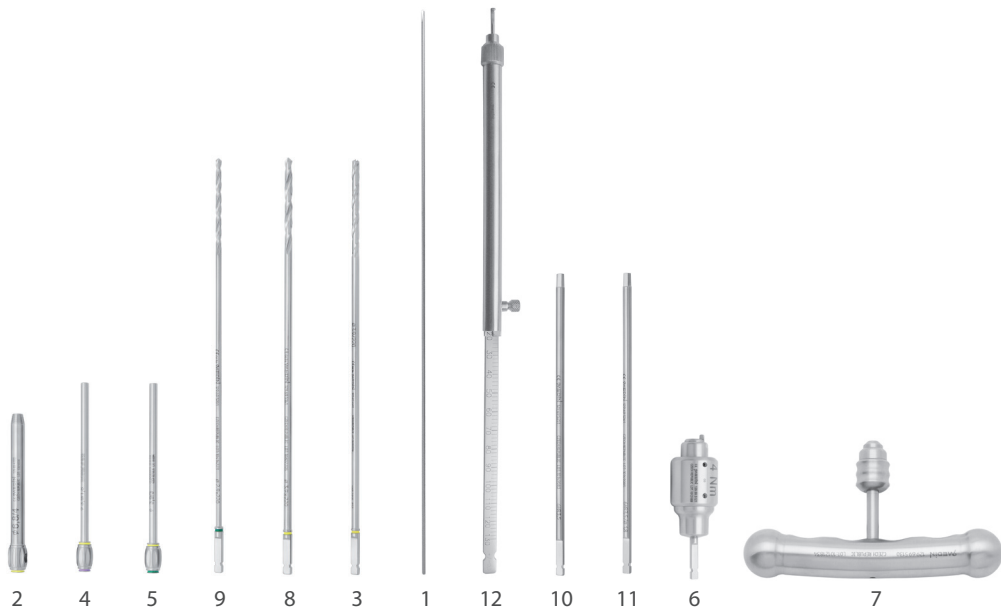
SSt	Ti	A
129 79 9421	129 79 9424	14 mm
129 79 9431	129 79 9434	16 mm
129 79 9441	129 79 9444	18 mm
129 79 9521	129 79 9524	20 mm
129 79 9451	129 79 9454	22 mm
129 79 9461	129 79 9464	24 mm
129 79 9541	129 79 9544	26 mm
129 79 9471	129 79 9474	28 mm
129 79 9551	129 79 9554	30 mm
129 79 9481	129 79 9484	32 mm
129 79 9491	129 79 9494	34 mm
129 79 9571	129 79 9574	36 mm
129 79 9501	129 79 9504	38 mm
129 79 9581	129 79 9584	40 mm
129 79 9511	129 79 9514	42 mm
129 79 9521	129 79 9524	44 mm
129 79 9531	129 79 9534	46 mm
129 79 9541	129 79 9544	48 mm
129 79 9601	129 79 9604	50 mm
129 79 9551	129 79 9554	52 mm
129 79 9561	129 79 9564	54 mm
129 79 9571	129 79 9574	56 mm
129 79 9581	129 79 9584	58 mm
129 79 9621	129 79 9624	60 mm
129 79 9631	129 79 9634	65 mm
129 79 9641	129 79 9644	70 mm
129 79 9651	129 79 9654	75 mm
129 79 9661	129 79 9664	80 mm
129 79 9671	129 79 9674	85 mm
129 79 9681	129 79 9684	90 mm
129 79 9691	129 79 9694	95 mm
129 79 9701	129 79 9704	100 mm
129 79 9711	129 79 9714	105 mm
129 79 9721	129 79 9724	110 mm

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

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

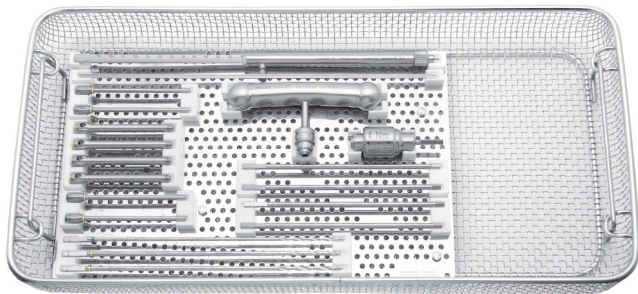
PROXIMAL TIBIAL PLATE

INSTRUMENTS FOR ANGULARLY STABLE PLATES WITH SCREWS 5 mm



139 09 0260
set

			number of pcs
1	129 09 2550	K-wire MEDIN Ø 1.5 mm; 300 mm	3
2	129 69 4300	Aiming sleeve lockable Ø 6.8/Ø 4 mm; 80 mm	4
3	129 69 4401	Cannulated drill Ø 3.9 mm; 220 mm	1
4	129 69 4410	Guide sleeve Ø 4/1.8 mm; 95 mm	2
5	129 69 4430	Guide sleeve Ø 4/3 mm; 95 mm	2
6	129 69 5121	Torque limiter 4 Nm	1
7	129 69 5130	Screwdriver handle	1
8	129 69 5141	Drill Ø 3.9 mm; 220 mm	1
9	129 69 5201	Drill Ø 2.9 mm; 220 mm	1
10	129 69 5251	Screwdriver; hexagon 3.5 mm	2
11	129 69 5261	Cannulated screwdriver; hexagon 3.5 mm	2
12	129 79 8910	Depth gauge for screws Ø 4.5–6.5 mm	1



Instruments for angularly stable plates with screws 3,5 and 5/3,5 mm
139 09 0265
540 × 240 × 90 mm
sieve with instruments



Stand for locking screws 5
129 69 5741
214 × 186 mm
height 120 mm



Stand for locking screws 5/3,5
129 69 6390
214 × 126 mm
height 120 mm



Stand for cannulated locking screws 5
129 69 6395
214 × 126 mm
height 120 mm

