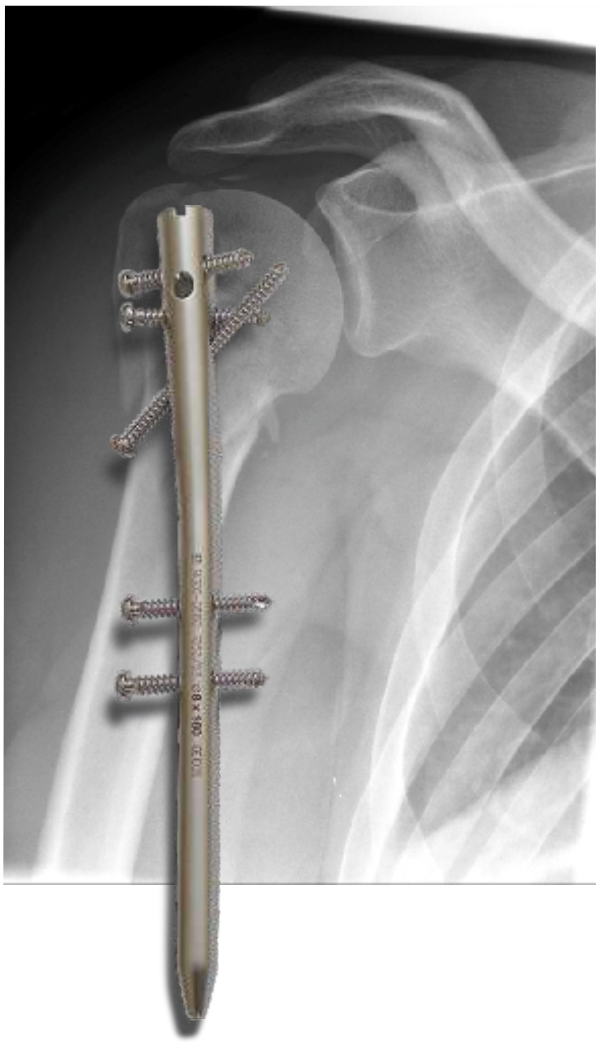
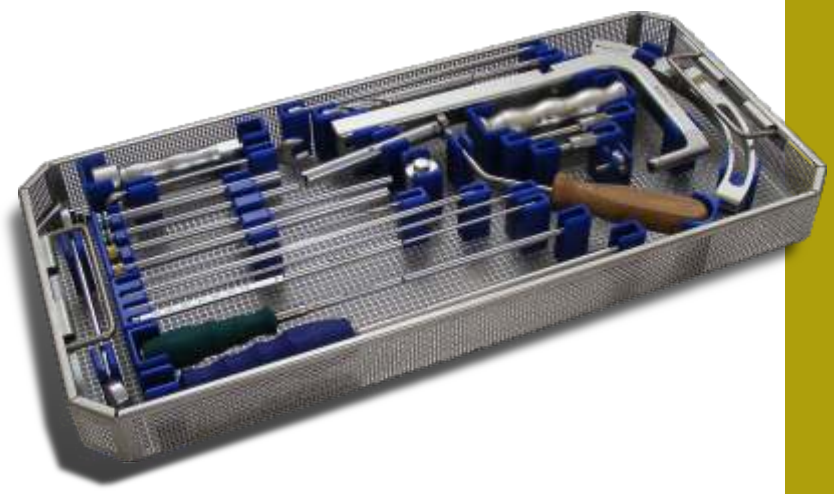
1.6

INTRAMEDULLARY NAILING • PROXIMAL HUMERUS



M P H T

MULTILOCKING PROXIMAL HUMERAL TREATMENT NAIL IMPLANTS AND OPERATING MANUAL



medimetal®
Medical Products Manufacturing and Trading Ltd.

Before starting use the product

Before each use, carefully check the operability of implants and surgical instruments, and ensure they are free of any damage. If you notice any cracks, fractures, deformations, discoloration or any damages that indicate improper storage, imperfect sterilization or prior incorrect treatment, do not use the device. Always carry out the assembly, fitting and operation test of the implants and instruments to be used for the implantation. The product may only be used if the fittings are perfect, the dimensions are accurate, the clamping components work properly and the angles are correctly set.

Requirements regarding the user

The instruments and implants may only be used by qualified surgeons who are familiar with the surgical practice, with the relevant medical literature and are sufficiently experienced in the use of implants and instruments. The operating surgeon is responsible for identifying the correct indication, selecting the implants and conducting the surgical procedure in conformity with the relevant medical practice.

Contraindications

Use of the implant is not recommended if the medical condition of the patient does not allow successful acceptance of the device, or if the recovery of the patient is hindered by causes such as reduced blood circulation, bone system of poor quality or quantity, existing infection, rehabilitation excluded due to the mental condition of the patient etc.

General warnings

Before the surgical procedure, the patient should be informed about the possible disadvantages of implant use. When selecting the implant, the type of the bone fracture as well as the weight and activity level of the patient should always be taken into consideration. Since the solidity of the implant is limited, overloading due to overweight should be avoided. The biomechanical loading of the implant should be as minimal as possible.
The process of recovery should be monitored during the use of the implant. In the event of repeated loading or prolonged bone recovery, the implants may be deformed or dislocated, which should be prevented by timely interventions. Strong and/or repeated deformation of the implant should be avoided. The implants are only for single use, re-implantation is prohibited.
The appropriate type and correct size of the implants must be identified according to the characteristics of the particular case. Before the surgical procedure, the user manuals supplied with the other required devices, e.g. implants, should be carefully studied.

Applied materials

The applied materials are high-quality and high-tensile, nonmagnetic, stainless steel and titanium alloy materials specially developed for implants. Combined use with other materials or products supplied by other manufacturers may lead to harmful processes for which Medimetal Ltd. will not accept any responsibility.

Protection, packaging and preparation for use

The implants are packaged in clean condition, free of any production-related contaminations. Before use, such storage conditions must be ensured that will preserve the integrity of the packaging. The implants should be stored in a clean, dry place, protected from exposure to extreme temperatures and chemicals.

Sterilization

Before use, unpack and sterilize the implant in accordance with the relevant instructions. Do not touch the implant with bare hands. The surgical instruments should be sterilized together with the instrument tray. The instructions provided by the manufacturer of the sterilization equipment must always be followed.

Interactions with medicinal products

It is not known whether the implants interact with medicinal products.

TÜVRheinland® CERT ISO 9001 EN ISO 13485

CE 1008

Implants for MPHT nailing

System of implants:

Material: steel or titanium alloy
MPHT (multilocking proximal humeral treatment) nail, short, solid, diameter 8 and 9 mm,
cat. nr.: 14300-08140; 14300-08160
34300-08140; 34300-08160 (titanium alloy)
14300-09140; 14300-09160
34300-09140; 34300-09160 (titanium alloy)

MPHT (multilocking proximal humeral treatment) nail, long, solid, diameter 8 and 9 mm,
cat. nr.: 14300-08180; 14300-08200
34300-08180; 34300-08200 (titanium alloy)
14300-09180; 14300-09200
34300-09180; 34300-09200 (titanium alloy)

Locking screw, diameter 3,9 mm, cat. nr.: from 12201-39020 up to 12201-39070
from 32201-39020 up to 32201-39070 (titanium alloy)

Surgical set (complete with instruments), cat. nr.: 94300-00000

Indications of the proximal humeral treatment nail (MPHT):

The proximal humeral nail (MPHT: multilocking proximal humeral treatment nail) treats mainly the fractures of the humeral head and the diahpyseal fractures directly below the humeral head. The fracture fragments can be fixed in four directions at the same time, allowing the fixation of tuberculum maius, tuberculum minus and the cartilaginous head. Solid and cannulated versions are available in the product range. A targeting arm facilitates the distal locking.

Design of the MPHT-implants:

The nail was designed according to the three-dimensional characteristics of the bone anatomy. Its proximal end is available with two diameter sizes. The shaft, which fits to the diaphyseal part, is thinning. In order to enable an easy implantation, the nails are curved, however they can be used universally for the left - and for the right hand side. Screw heads ensure a good pressure-distribution, preventing the head from further ruptures.

Proximal locking in four different planes.

The decrease of diameter of the longer nail fits to the change of the intramedullary´s anatomical size.

CE 1008

MPHT - proximal humeral nail, short, solid

L (mm)	Catalogue number			
	⌀ 8		⌀ 9	
	steel	titanium alloy	steel	titanium alloy
140	14300-08140	34300-08140	14300-09140	34300-09140
160	14300-08160	34300-08160	14300-09160	34300-09160

MPHT - proximal humeral nail, long, solid

L (mm)	Catalogue number			
	⌀ 8		⌀ 9	
	steel	titanium alloy	steel	titanium alloy
180	14300-08180	34300-08180	14300-09180	34300-09180
200	14300-08200	34300-08200	14300-09200	34300-09200

Locking screw

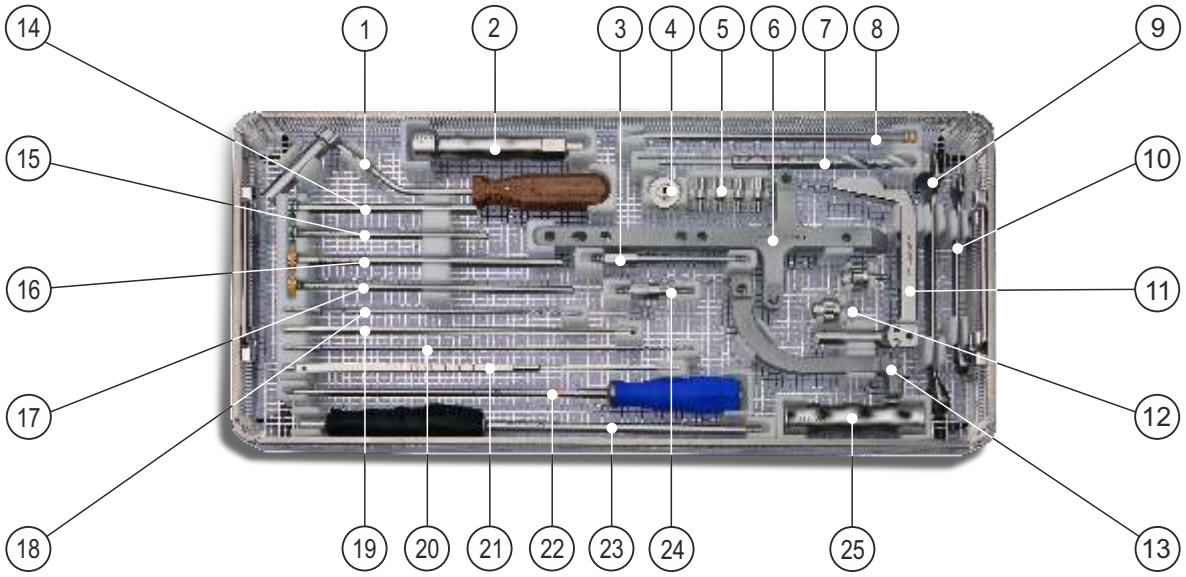
Thread diameter: 3,9 mm
Core diameter: 3,2 mm
Pitch: 1,25 mm
Hex width: 2,5 mm

L (mm)	Cat. nr.:	
	steel	titanium alloy
20	12201-39020	32201-39020
22	12201-39022	32201-39022
24	12201-39024	32201-39024
26	12201-39026	32201-39026
28	12201-39028	32201-39028
30	12201-39030	32201-39030
32	12201-39032	32201-39032
34	12201-39034	32201-39034
35	12201-39035	32201-39035
36	12201-39036	32201-39036
38	12201-39038	32201-39038
40	12201-39040	32201-39040
42	12201-39042	32201-39042

L (mm)	Cat. nr.:	
	steel	titanium alloy
44	12201-39044	32201-39044
45	12201-39045	32201-39045
46	12201-39046	32201-39046
48	12201-39048	32201-39048
50	12201-39050	32201-39050
52	12201-39052	32201-39052
54	12201-39054	32201-39054
55	12201-39055	32201-39055
56	12201-39056	32201-39056
58	12201-39058	32201-39058
60	12201-39060	32201-39060
65	12201-39065	32201-39065
70	12201-39070	32201-39070

Surgical set

Operating tray, complete with instruments:
Cat. nr.: 94300-00000 (Empty tray, with instrument holder, cat. nr.: 94300-10000)



Pos.	Cat. nr.	Description	pcs
1.	94300-01300	Soft tissue protector with handle	1
2.	94290-01600	Impactor, cannulated	1
3.	94300-00500	Threaded stem	1
4.	94290-01003	Bumper for hammer guide	1
5.	94300-02600	Fixing screw for sleeve	4
6.	94300-02200	Targeting arm, lateral	1
7.	99031-10200	Spiral drill, cannulated, 10/2,2 × 200 mm	1
8.	94300-00600	Pointer	1
9.	99000-00009	Wrench, 17 mm	1
10.	99000-00008	Wrench, 11 mm	1
11.	94300-02100	Targeting arm	1
12.	94300-02400	Fixing screw	2
13.	94300-02300	Aiming arm, anterior	1
14.	94300-00700	Soft tissue protector, short, green, 8/6-132 mm	1
15.	94300-00900	Drill sleeve, green, short, 6/3,2-140 mm	1
16.	94300-00800	Soft tissue protector, long, yellow, 8/6-192 mm	1
17.	94300-01000	Drill sleeve, long, yellow, 6/3,2-203 mm	1
18.	99020-32210	Spiral drill with quick coupling, 3,2 × 210 mm	1
19.	15000-20250	Kirschner wire, 2,0 × 250 mm	4
20.	99020-32290	Spiral drill with quick coupling, 3,2 × 290 mm	1
21.	94300-01100	Length gauge for locking screw	1
22.	94300-01200	Screwdriver	1
23.	94290-01000	Hammer guide shaft	1
24.	94290-00600	Threaded removal stem	1
25.	94290-01100	Hammer	1

Pos.	Cat. no.	Description	pcs
1.	94300-01300	Soft tissue protector wit handle	1

Pos.	Cat. nr.	Description	pcs
2.	94290-01600	Impactor, cannulated	1

Pos.	Cat. nr.	Description	pcs
3.	94300-00500	Threaded stem	1

Pos.	Cat. nr.	Description	pcs
4.	94290-01003	Bumper for hammer guide	1

Pos.	Cat. nr.	Description	pcs
5.	94300-02600	Fixing screw	4

Pos.	Cat. nr.	Description	pcs
6.	94300-02200	Aiming arm, lateral	1

Pos.	Cat. nr.	Description	pcs
7.	99031-10200	Spiral drill, cannulated 10/ 2,2 × 200 mm	1

Pos.	Cat. nr.	Description	pcs
8.	94300-00600	Pointer	1

Pos.	Cat. nr.	Description	pcs
9.	99000-00009	Wrench 17 mm	1

Pos.	Cat. nr.	Description	pcs
10.	99000-00008	Wrench, 11 mm	1

Pos.	Cat. nr.	Description	pcs
11.	94300-02100	Targeting arm	1

Pos.	Cat. nr.	Description	pcs
12.	94300-02400	Fixing screw for targeting arm	2

Pos.	Cat. nr.	Description	pcs
13.	94300-02300	Aiming arm, anterior	1

Pos.	Cat. nr.	Description	pcs
14.	94300-00700	Soft tissue protector, short, green 8/6 - 132 mm	1

Pos.	Cat. nr.	Description	pcs
15.	94300-00900	Drill sleeve, short, green 6/3 - 140 mm	1

Pos.	Cat. no.	Description	pcs
16.	94300-00800	Soft tissue protector, long, yellow 8/6 - 192 mm	1

Pos.	Cat. nr.	Description	pcs
17.	94300-01000	Drill sleeve, long, yellow 6/3,2 - 203 mm	1

Pos.	Cat. no.	Description	pcs
18.	99020-32210	Spiral drill with quick couplung 3,2 × 210 mm	1

Pos.	Cat. no.	Description	pcs
19.	15000-20250	Kirschner wire 2,0 × 250 mm	3

Pos.	Cat. no.	Description	pcs
20.	99020-32290	Spiral drill with quick coupling 3,2 × 290 mm	1

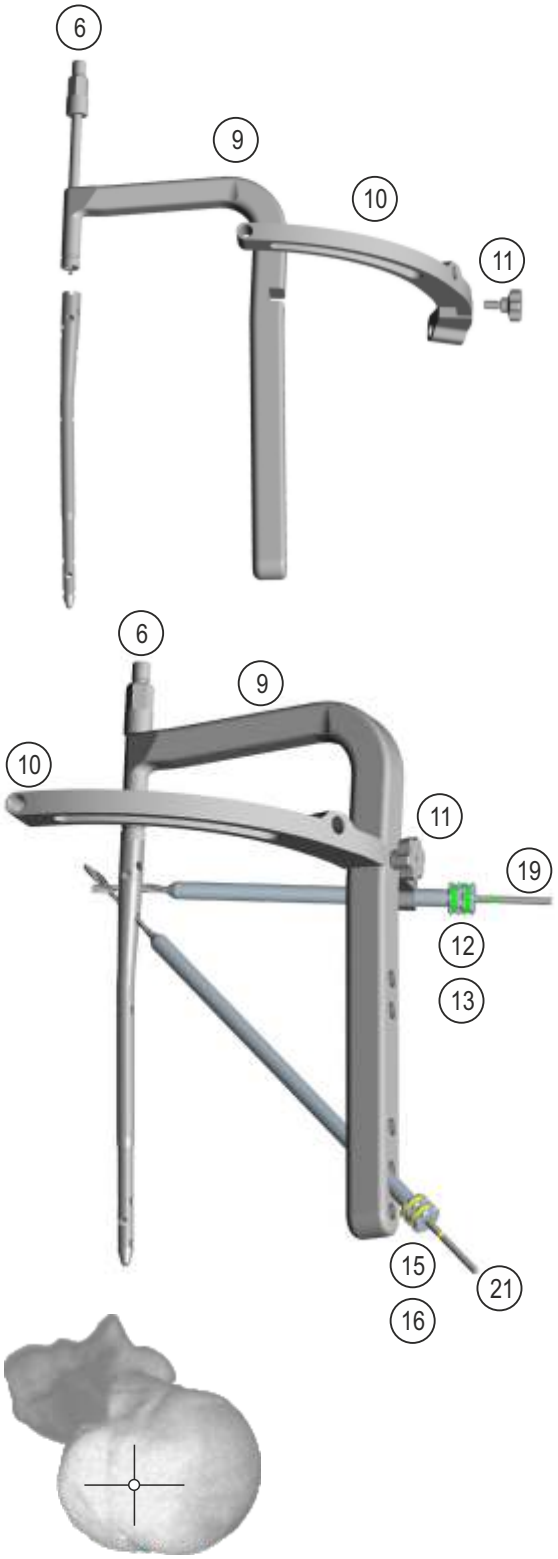
Pos.	Cat. no.	Description	pcs
21.	94300-01100	Length gauge for locking screw	1

Pos.	Cat. no.	Description	pcs
22.	94300-01200	Screw driver	1

Pos.	Cat. no.	Description	pcs
23.	94290-01000	Hammer guide shaft	1

Pos.	Cat. nr.	Description	pcs
24.	94290-00600	Threaded removal stem	1

Pos.	Cat. nr.	Description	pcs
25.	94290-01100	Hammer	1



The fracture indication of MPHT (proximal humeral) nail is given by the fracture of the head of proximal humerus.
(According to the AO classification: 11-A, 11-B, 11-C,
According to the Neer classification : III/2, IV/3, V/3, VI/3)

1 We determine the size of the implant by preoperative radiographic planning.

By laying, usually the chair position can be used which ensures the appropriate access.
We place the injured arm on the table outside for retro-version and extension.

2 Before the operation, check the avaibility of the necessary tools. To avoid any mailfunction of the elements, please perform an installation test.

Assemble the aiming arm(9) and the selected MPHT nail, then fix them with the help of threaded impactor shaft (6) and wrenches (2).

Insert the axial arm (10) according to its right-or left position properly to slot of the aiming arm (9). It can be fixed by the fixing screw (11).

For testing of the aiming holes, fix into each other the soft tissue protector marked with yellow (16) and the drill sleeve(15) and thread it. With the help of the yellow-sleeve and 290-mm spiral drill (21), the targeting of the oblique locking hole can be verified.

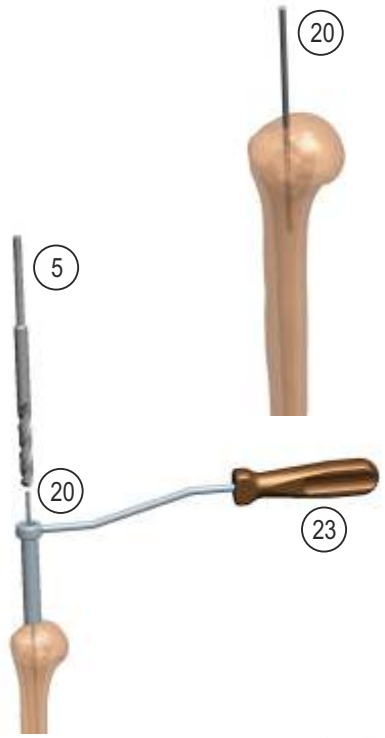
According to the previous check, all the other locking holes can be verified by the drill unit built up from the green sleeves (12) (13), and by the 210-mm spiral drill (19).

3 After the excavation we determine the correct opening point of the intramedullary.

4 Through the point of penetration to the intramedullary we drive the Kirschner wire (20) in, we determine the right direction by X-ray control.

With the help of the soft tissue protector shaft (23) we insert 10 mm cannulated spiral drill (5) on the Kirschner (20), and then we can open the intramedullary.

We can remove the Kirschner wire after the implementation of the holes have been completed.



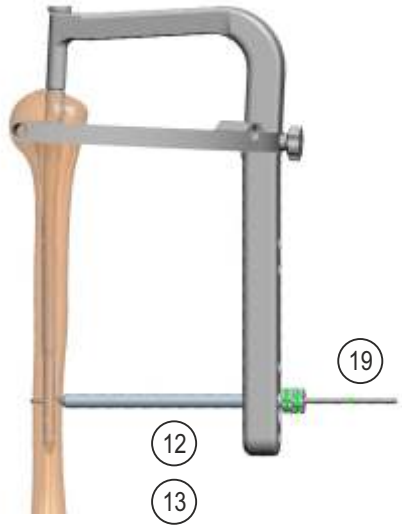
5 For leading the nail in, and the correction of the depth - only if it is necessary - drop-weight can also be used. The hammer shaft block (1) is available for this.

(Alternatively, through the aiming arm (9) the removal –impactor shaft (17) can be connected. Place the hammer (8), and close the end of the stem with the removal-impactor bumper (4).)

By removing of the aids, we need to ensure the threaded impactor shaft (6) by wrench (2) to avoid any twist out.

Attention!
Adjust the nail position until the depth and direction of the rotation angle position to set up correctly. The correct depth is indicated by a slot which is designed at the connection between the nail and the aiming arm which needs to be placed to the same height with contour of the bone.

The rotational position is adequate if the AP direction for the holes points exactly to tuberculum minus.

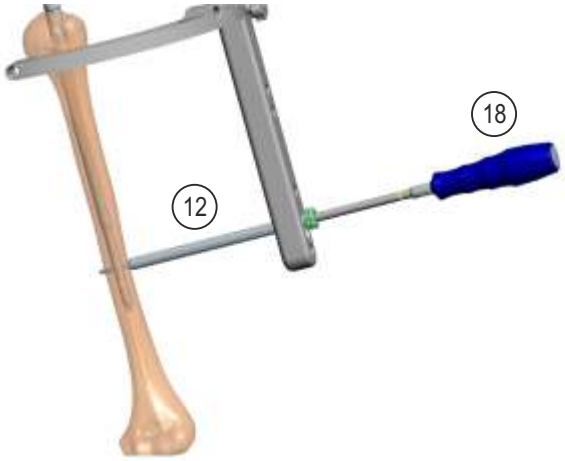


6 For distal targeting drive the green soft tissue protector (12) and the drill sleeve (13) into the required hole of the aiming device, impacting till the surface of the bone.

With the use of the green marked 3.2 × 210 mm spiral drill (19) we prepare a bi-cortical core hole.

7 We remove the drill sleeve, and we drive the length gauge (22) to the core hole while keeping the soft tissue protector. The calibration of the green marked length gauge can be read at the front surface of soft tissue protector.

We can get the required length of locking screws if we increase the reading with over- elongation on cortical, which is on the other side.



8 After the removal of the length gauge, the locking screw can drive in through the soft tissue protector (12). The shaft of the screwdriver (18) helps to controll the position of the locking screw.

If necessary, the distal locking can be replied, due to the use of the holes of the aiming device.

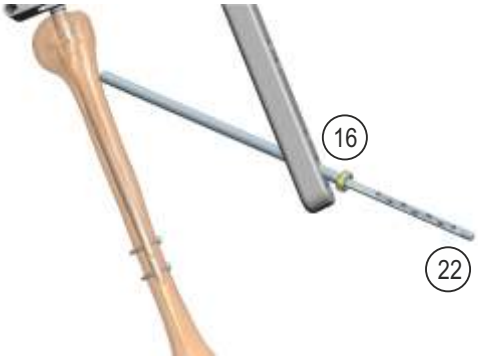
9 The locking plains for the proximal locking can be chosen according to the healing of the fracture. For selecting of the oblique locking direction the assembly of the yellow soft tissue protector (16) and drill sleeve (15) is required.

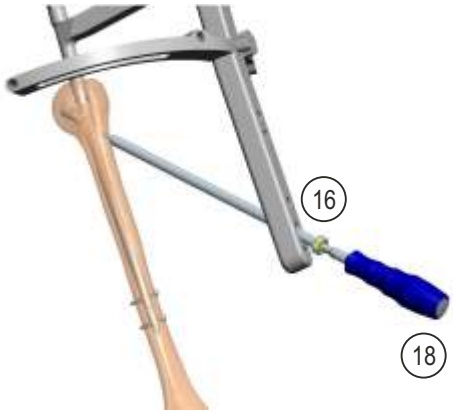
For penetration of the drill, a pionter needs to be used (3) and to prevent the drill from slipping.

The preparation of the locking screw's right place occurs with a yellow marked drill for core hole (21). Check the depth on the image intensifier.

10 We can determine directly the length of the locking screw by reading the yellow side of the length gauge (22).

We drive the locking screw with the appropiate length in; the calibration of the screwdriver (18) can give information about the position of the screw.

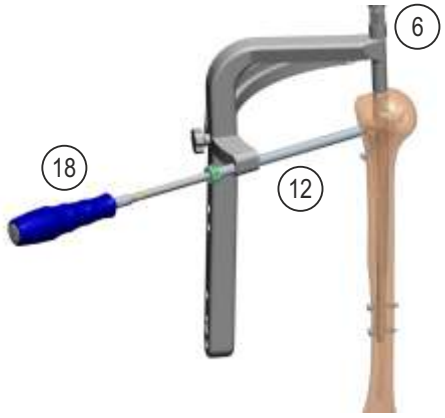




11 For inserting of the locking screws with horizontal plane, the combination of the green soft tissue protector (12) and drill sleeve (13) must be used. The drilling must be carried out only to the necessary depth. The process needs to be checked on the image intensifier.

The required length value is given by the scale marked with green on the front side of the soft tissue protector (12). The calibration of the screwdriver's stem (18) shows the current position of the locking screw.

After the total fixation of the fracture with the removal of the threaded impactor shaft (6) we disconnect the aiming arm from the nail, then we knots.



12 After surgery check the restoration of shoulder function.

Examine the regeneration process several times during the healing. Check the position of the implants 24 hours, 7 days, 4-, 8- and 12 weeks after surgery. The check needs to be done in each case by using two-way X-ray.

13 For removing of the implants we need to take free the proximal end of the nail and we fix the threaded removal shaft to the thread (7). Screw the removal –impactor shaft (17), on which we fix the hammer (8) and the end of the removal –impactor shaft (17) needs to be closed with removal-impactor bumper (4)

Next, we remove all the locking screws.

Then we can remove the free MPHT nails, with gentle beats from the intramedullary.

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