

instruction

INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR

IMPLANTS ◦
INSTRUMENT SET 40.5090 ◦
SURGICAL TECHNIQUE ◦

CHARFIX *system*

24D

CE 0197
ISO 9001
ISO 13485

ChM®



Important Information

Charfix System Intramedullary Osteosynthesis of Femur meets international quality standards. Implants and surgical instruments are manufactured and delivered to the user in accordance with requirements of:

- ISO 9001/ISO 13485;
- Quality System;
- Council Directive 93/42/EEC

The instruments must be washed and sterilized before the every use.

After use the instruments should be washed immediately in order to remove any organic matter (blood, tissues). Washing may be carried out in warm water using polymeric brush and appropriate solutions (containing anti-corrosion agent) approved for use in medicine. Machined washing is recommended (in ultrasonic camber).

After washing and drying the instruments shall be placed in the case and closed with its lid. Instrument set should be stored in dry condition in temperature ranging from 5 to 30°C and humidity not exceeding 70%.

The instrument set shall sterilized (in moist heat or dry heat up to 200°C) in accordance with duly medical procedures. Sterilization in autoclave is recommended.

The instruments constituting the instrument set (made of stainless steel, aluminum alloys and polymers) are subjected to mechanical damages and corrosion process.

It is recommended to follow:

- rules of use presented in the manual of the instrument set,
- appropriate medical rules concerning washing, sterilization and storage of medical instruments.

NON-STERILE
STERILIZE BEFORE USE

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I. INTRODUCTION

CHARFIX system provides, depending on the type of femoral fracture, following methods of intramedullary fixation:

- reconstructive,
- compressive, dynamic, static,
- reversed (condylar approach).

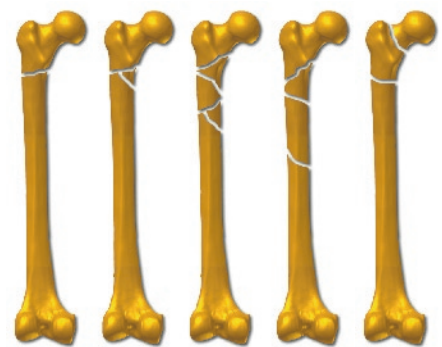
Each fixation method of **CHARFIX system** comes with:

- adequate selection of implants (intramedullary nails, screws, locking screws),
- instrument sets for implants insertion and removal,
- instructions on how to manage instrument set (surgical technique).

I.1. Reconstructive method

Reconstruction nails are used for intramedullary fixation of proximal femur in neck or trochanteric fractures. Angular position of reconstructive screws results in anatomical position of the head and trochanteric region against the femoral shaft. The nail comes in two versions: right nail for the right femur, left nail for the left femur.

Position of the implants in femur:

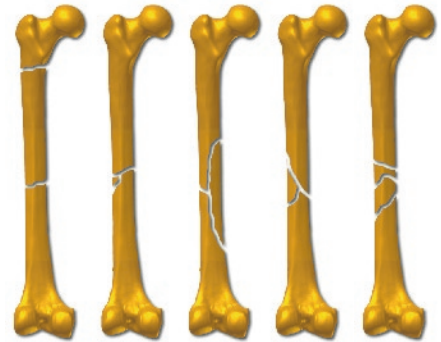
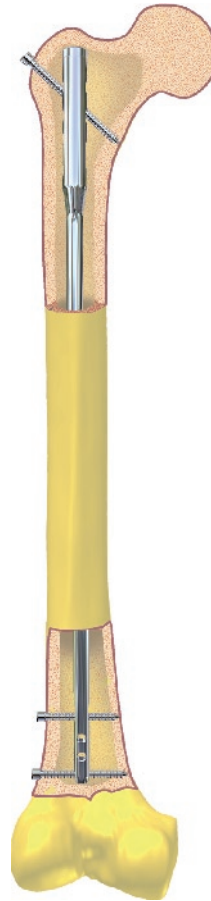


Examples of fractures that may be treated with this method:

Reconstruction nails may be used for fixation of the femoral fractures with static method. In such case:

- right nail should be used for fixation of the fractures of left femur,
- left nail should be used for fixation of the fractures of right femur,

Position of the implants in femur:

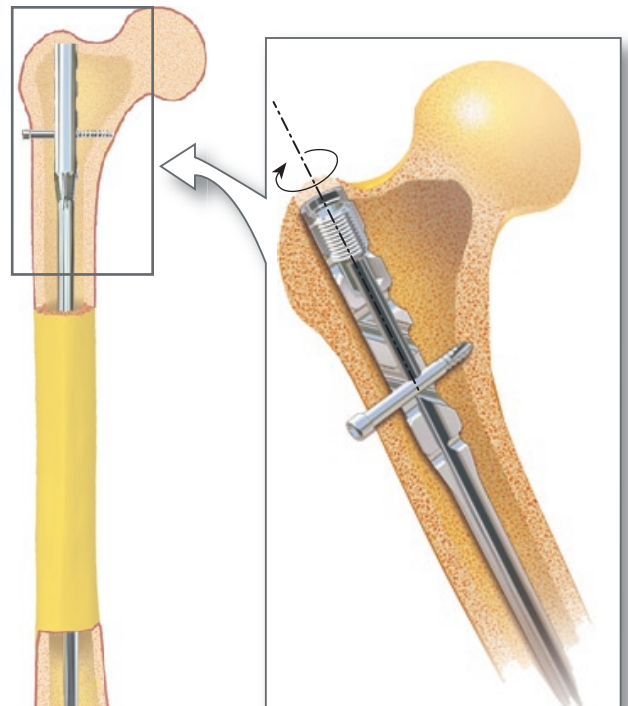


Examples of shaft fractures that may be treated with this method:

I.2. Compressive, dynamic and static method

Compression nails are used in intramedullar fixations of femoral shaft fractures, provided that fractures can't be closed than 3cm from locking screw.

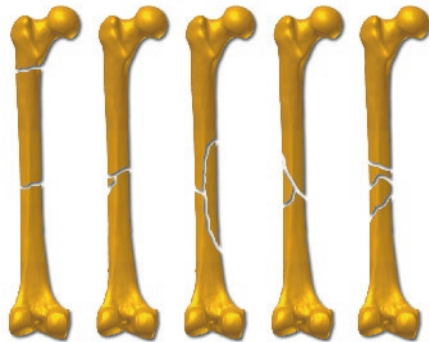
Nail design allow to treatment with compressive, dynamic and static method.



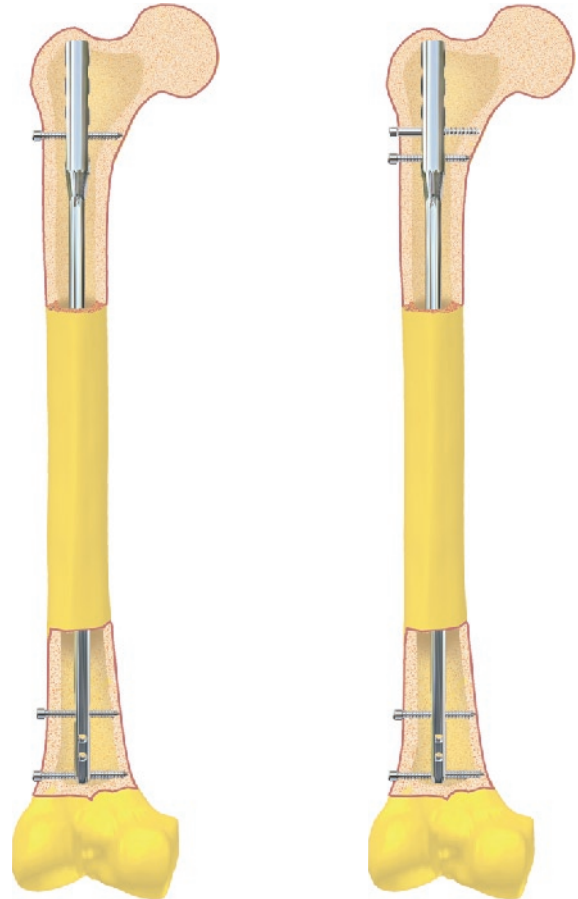
Compressive

Static method

optional interlocking screw provides additional locking of the fracture, when needed.



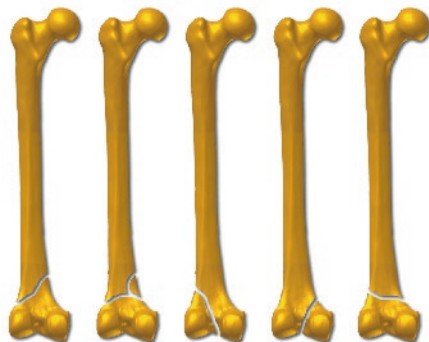
Examples of shaft fractures that may be treated with this method:



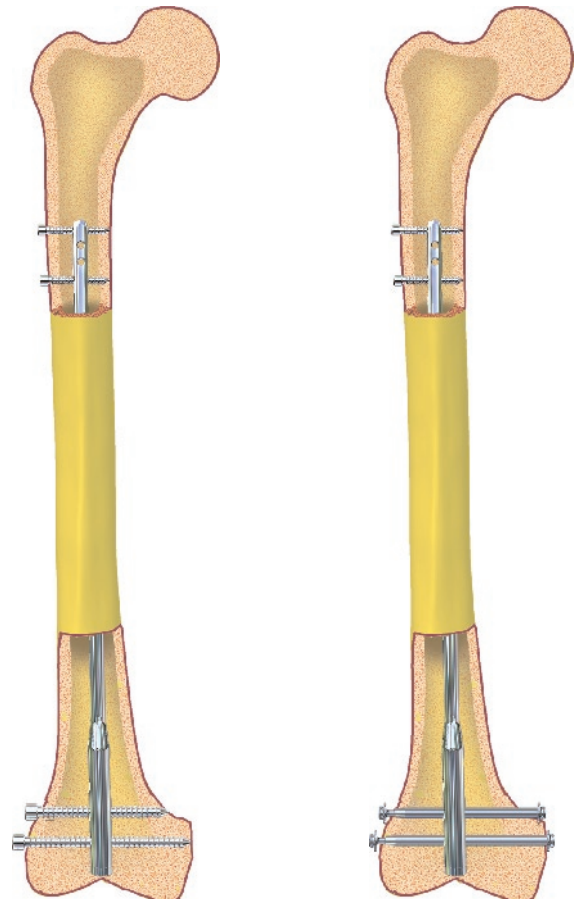
1.3. Reversed method (condylar approach)

Intramedullary nails inserted from distal end of the femur are used for fixation of femur when other methods (reconstructive, compressive, dynamic or static) cannot be utilized. Reversed method may be used when a prosthesis or other implant is already present in proximal femur, and in case of multi-fragment condylar fractures.

Position of the implant in femur:



Examples of shaft fractures that may be treated with this method:



II. IMPLANTS

II.1. Reconstructive, compressive and reversed method implants

Śruba kompresyjna

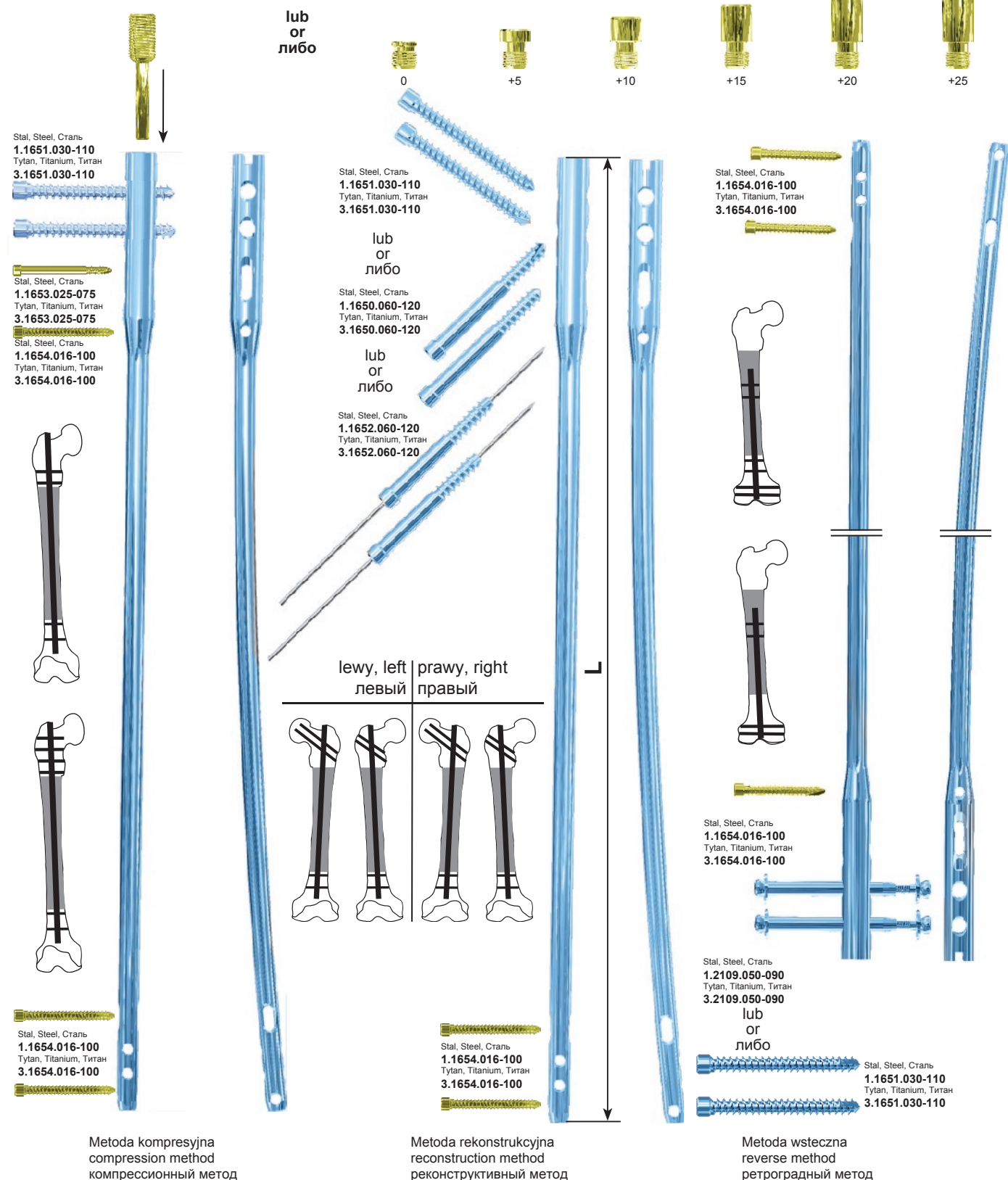
Compression screw

Винт компрессионный

Stal, Steel, Сталь	Tytan, Titanium, Титан
1.2106.007	3.2106.007

Śruba zaślepiająca M10x1 · End cap M10x1 · Винт слепой M10x1

Stal, Steel, Сталь 1.2104.300	Stal, Steel, Сталь 1.2104.305	Stal, Steel, Сталь 1.2104.310	Stal, Steel, Сталь 1.2104.315	Stal, Steel, Сталь 1.2104.320	Stal, Steel, Сталь 1.2104.325
Tytan, Titanium, Титан 3.2104.300	Tytan, Titanium, Титан 3.2104.305	Tytan, Titanium, Титан 3.2104.310	Tytan, Titanium, Титан 3.2104.315	Tytan, Titanium, Титан 3.2104.320	Tytan, Titanium, Титан 3.2104.325





Ø8÷19



Ø8÷10



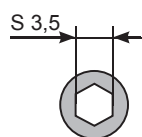
Ø11÷19

dostępne available		
dostępne		
Ø[mm]	8 ÷ 19	8 ÷ 19
skok, pitch, war 1 mm		
L [mm]	160 ÷ 600	160 ÷ 600
skok, pitch, war 5 mm		

STAL, Steel, Сталь						ТУТАН, Titanium, Титан					
L [mm]	Ø	lewý, left левый	prawy, right правый	lewý, left левый	prawy, right правый	L [mm]	Ø	lewý, left левый	prawy, right правый	lewý, left левый	prawy, right правый
200	9	1.2855.200	1.2854.200	3.2855.200	3.2854.200	200	12	1.2861.200	1.2860.200	3.2861.200	3.2860.200
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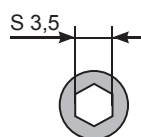
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L [mm]	Ø	lewý, left левый	prawy, right правый	lewý, left левый	prawy, right правый	L [mm]	Ø	lewý, left левый	prawy, right правый	lewý, left левый	prawy, right правый
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240		1.2881.240	1.2880.240	3.2881.240	3.2880.240	240		1.2887.240	1.2886.240	3.2887.240	3.2886.240
260		1.2881.260	1.2880.260	3.2881.260	3.2880.260	260		1.2887.260	1.2886.260	3.2887.260	3.2886.260
280		1.2881.280	1.2880.280	3.2881.280	3.2880.280	280		1.2887.280	1.2886.280	3.2887.280	3.2886.280
300		1.2881.300	1.2880.300	3.2881.300	3.2880.300	300		1.2887.300	1.2886.300	3.2887.300	3.2886.300
320		1.2881.320	1.2880.320	3.2881.320	3.2880.320	320		1.2887.320	1.2886.320	3.2887.320	3.2886.320
340		1.2881.340	1.2880.340	3.2881.340	3.2880.340	340		1.2887.340	1.2886.340	3.2887.340	3.2886.340
360	1.2881.360	1.2880.360	3.2881.360	3.2880.360	360	1.2887.360	1.2886.360	3.2887.360	3.2886.360		
380	1.2881.380	1.2880.380	3.2881.380	3.2880.380	380	1.2887.380	1.2886.380	3.2887.380	3.2886.380		
400	1.2881.400	1.2880.400	3.2881.400	3.2880.400	400	1.2887.400	1.2886.400	3.2887.400	3.2886.400		
420	1.2881.420	1.2880.420	3.2881.420	3.2880.420	420	1.2887.420	1.2886.420	3.2887.420	3.2886.420		
440	1.2881.440	1.2880.440	3.2881.440	3.2880.440	440	1.2887.440	1.2886.440	3.2887.440	3.2886.440		
460	1.2881.460	1.2880.460	3.2881.460	3.2880.460	460	1.2887.460	1.2886.460	3.2887.460	3.2886.460		
480	1.2881.480	1.2880.480	3.2881.480	3.2880.480	480	1.2887.480	1.2886.480	3.2887.480	3.2886.480		

Wkręt blokujący Ø4,5
Distal screw Ø4.5
Блокирующий винт Ø4,5



Nr katalogowy, Catalogue no., № по кат.		
L [mm]	STAL, Steel, Сталь	TYTAN, Titanium, Титан
16	1.1654.016	3.1654.016
18	1.1654.018	3.1654.018
20	1.1654.020	3.1654.020
22	1.1654.022	3.1654.022
24	1.1654.024	3.1654.024
25	1.1654.025	3.1654.025
26	1.1654.026	3.1654.026
28	1.1654.028	3.1654.028
30	1.1654.030	3.1654.030
35	1.1654.035	3.1654.035
40	1.1654.040	3.1654.040
45	1.1654.045	3.1654.045
50	1.1654.050	3.1654.050
55	1.1654.055	3.1654.055
60	1.1654.060	3.1654.060
65	1.1654.065	3.1654.065
70	1.1654.070	3.1654.070
75	1.1654.075	3.1654.075
80	1.1654.080	3.1654.080
85	1.1654.085	3.1654.085
90	1.1654.090	3.1654.090
95	1.1654.095	3.1654.095
100	1.1654.100	3.1654.100

Wkręt blokujący trzonowy Ø4,5
Proximal screw Ø4.5
Блокирующий проксимальный Ø4,5



Nr katalogowy,
Catalogue no., № по кат.

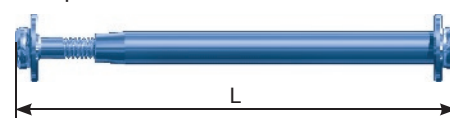
L [mm]	L1 [mm]	STAL, Steel, Сталь	TYTAN, Titanium, Титан
25	12	1.1653.025	3.1653.025
30	12	1.1653.030	3.1653.030
35	16	1.1653.035	3.1653.035
40	16	1.1653.040	3.1653.040
45	16	1.1653.045	3.1653.045
50	18	1.1653.050	3.1653.050
55	18	1.1653.055	3.1653.055
60	18	1.1653.060	3.1653.060
65	20	1.1653.065	3.1653.065
70	20	1.1653.070	3.1653.070
75	20	1.1653.075	3.1653.075
80	22	1.1653.080	3.1653.080
85	22	1.1653.085	3.1653.085
90	22	1.1653.090	3.1653.090

Technical drawing of a yellow metal screw. The drawing shows the screw from a side perspective. The total length of the screw is indicated by a vertical dimension line on the left, labeled 'L'. The length of the threaded portion of the shaft is indicated by a vertical dimension line at the bottom, labeled 'L1'. The screw has a hexagonal head and a threaded shaft.

Small icon of a yellow metal screw head, showing the hexagonal shape and the threads on the shaft.

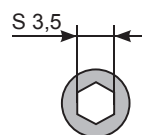
Zestaw blokujący Ø6,5
Blocking set Ø6.5
Блокирующий набор Ø6,5

Komplet / Set / Комплект



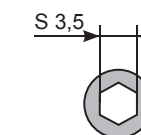
L [mm]	Zakres Range Диапазон	STAL, Steel, Сталь	TYTAN, Titanium, Титан
50	50-65 [mm]	1.2109.050	3.2109.050
60	60-75 [mm]	1.2109.060	3.2109.060
70	70-85 [mm]	1.2109.070	3.2109.070
80	80-95 [mm]	1.2109.080	3.2109.080
90	90-105 [mm]	1.2109.090	3.2109.090

Wkręt blokujący Ø6,5
Distal screw Ø6.5
Блокирующий винт Ø6,5



Nr katalogowy, Catalogue no., № по кат.		
L [mm]	STAL, Steel, Сталь	TYTAN, Titanium, Титан
30	1.1651.030	3.1651.030
35	1.1651.035	3.1651.035
40	1.1651.040	3.1651.040
45	1.1651.045	3.1651.045
50	1.1651.050	3.1651.050
55	1.1651.055	3.1651.055
60	1.1651.060	3.1651.060
65	1.1651.065	3.1651.065
70	1.1651.070	3.1651.070
75	1.1651.075	3.1651.075
80	1.1651.080	3.1651.080
85	1.1651.085	3.1651.085
90	1.1651.090	3.1651.090
95	1.1651.095	3.1651.095
100	1.1651.100	3.1651.100
105	1.1651.105	3.1651.105
110	1.1651.110	3.1651.110

Wkręt rekonstrukcyjny Ø6,5
Reconstructive screw Ø6.5
Реконструктивный винт Ø6,5



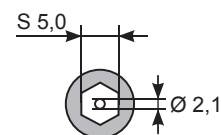
Nr katalogowy,
Catalogue no., № по кат.

L [mm]	L1 [mm]	STAL, Steel, Сталь	TYTAN, Titanium, Титан
60	25	1.1650.060	3.1650.060
65	25	1.1650.065	3.1650.065
70	25	1.1650.070	3.1650.070
75	25	1.1650.075	3.1650.075
80	25	1.1650.080	3.1650.080
85	25	1.1650.085	3.1650.085
90	25	1.1650.090	3.1650.090
95	32	1.1650.095	3.1650.095
100	32	1.1650.100	3.1650.100
105	32	1.1650.105	3.1650.105
110	32	1.1650.110	3.1650.110
115	32	1.1650.115	3.1650.115
120	32	1.1650.120	3.1650.120

Technical drawing of a screw. The drawing shows a blue-colored screw with a hexagonal head and a threaded shank. A vertical dimension line on the left indicates the total length of the screw, labeled 'L'. Another vertical dimension line, starting from the base of the head and ending at the bottom of the threaded section, is labeled 'L1'. The screw is shown in a perspective view, with the threads clearly visible on the shank.

A small, stylized icon of a screw head, showing a hexagonal shape with a central cross-shaped slot.

kaniulowany
cannulated
канюлированный



Nr katalogowy,
Catalogue no., № по кат.

		STAL, Steel, Сталь	TYTAN, Titanium, Титан
L [mm]	L1 [mm]		
60	25	1.1652.060	3.1652.060
65	25	1.1652.065	3.1652.065
70	25	1.1652.070	3.1652.070
75	25	1.1652.075	3.1652.075
80	25	1.1652.080	3.1652.080
85	25	1.1652.085	3.1652.085
90	25	1.1652.090	3.1652.090
95	32	1.1652.095	3.1652.095
100	32	1.1652.100	3.1652.100
105	32	1.1652.105	3.1652.105
110	32	1.1652.110	3.1652.110
115	32	1.1652.115	3.1652.115
120	32	1.1652.120	3.1652.120

III. INSTRUMENT SET

III.1. Introduction

Fixation of the femoral fractures in reconstructive, compressive dynamic and static method is carried out with a single instrument set. The above mentioned methods also require to have a set of flexible intramedullary reamers in following diameters:

8 [40.3854], 8,5 [40.3855], 9 [40.3856], 9,5 [40.3857], 10 [40.3858], 10,5 [40.3859], 11 [40.3860], 11,5 [40.3861], 12 [40.3862], 12,5 [40.3863], 13 [40.3864], 13,5 [40.3865], 14 [40.3866], 14,5 [40.3867], 15 [40.3868] and surgical drive or handle for manual reaming.

The operation shall be performed on operating table equipped with traction and C-arm device.

III.2. Instrument set for reconstructive, compressive and reversed method [40.5090]

The set of instruments and devices are placed on a stand with a lid which facilitates sterilization and transport to the operating room.

Lp.	Nr katalogowy Catalogue no. № no kat.	Nazwa	Name	Название	Szt.
1	40.5091.000	Ramię celownika	Arm target	Плечо целенаправителя	1
2	40.5097.000	Celownik 135	Target 135	Целенаправитель 135	1
3	40.5093.000	Celownik dalszy D	Distal target D	Целенаправитель дистальный Д	1
4	40.5094.000	Śruba łącząca M10x1 L=55	Connecting screw M10x1 L=55	Винт соединительный M10x1 L=55	1
5	40.5095.000	Śruba łącząca M10x1 L=66	Connecting screw M10x1 L=66	Винт соединительный M10x1 L=66	1
6	40.5096.000	Śruba kompresyjna	Compression screw	Компрессионный винт	1
7	40.4798.000	Miarka długości gwoździ	Nail length measure	Измеритель длины стержня	1
8	40.3327.000	Trokar 9	Trocar 9	Трокар 9	1
9	40.3328.000	Prowadnica ochronna 11/9	Protective guide 11/9	Направитель-протектор 11/9	2
10	40.3329.000	Prowadnica wiertła 9/6,5	Drill guide 9/6.5	Направитель сверла 9/6,5	1
11	40.3330.000	Prowadnica wiertła 9/4,5	Drill guide 9/4.5	Направитель сверла 9/4,5	1
12	40.3331.000	Prowadnica Kirschnera	Kirschner guide	Направитель Киршнера	1
13	40.3332.000	Miarka długości wkrętów rekonstrukcyjnych	Reconstruction screw length measure	Измеритель длины реконструктивных винтов	1
14	40.3333.000	Gwóźdź Kirschnera 2,0/380	Kirschner wire 2.0/380	Спица Киршнера 2,0/380	4
15	40.3614.000	Prowadnica ochronna 9/6,5	Protective guide 9/6.5	Направитель-протектор 9/6,5	2
16	40.3615.000	Prowadnica wiertła 6,5/3,5	Drill guide 6.5/3.5	Направитель сверла 6,5/3,5	2
17	40.3616.000	Ustawiak 9/4,5	Set block 9/4.5	Инструмент установочный 9/4,5	2
18	40.3617.000	Trokar 6,5	Trocar 6.5	Трокар 6,5	1
19	40.3696.000	Prowadnica wiertła 6,5/4,5	Drill guide 6.5/4.5	Направитель сверла 6,5/4,5	1
20	40.1374.000	Miarka długości wkrętów	Screw length measure	Измеритель длины винтов	1
21	40.5523.000	Szydło wygięte 8,0	Curved awl 8.0	Шило изогнутое 8,0	1
22	40.5507.000	Wbijak - wybijak	Impactor-extractor	Импактор-экстрактор	1
23	40.3667.000	Pobijak	Mallet	Пробойник	1
24	40.5071.000	Łącznik M10x1/M12	Connector	Соединитель	1
25	40.5526.000	Klucz S10	Wrench S10	Ключ S10	1
26	40.1348.000	Prowadnica rurkowa	Teflon pipe guide	Трубка-направитель	1
27	40.3925.000	Drut prowadzący 3,0/600	Guide rod 3.0/600	Спица-направитель 3,0/600	1
28	40.1351.000	Uchwyt drutu prowadzącego	Handle guide rod	Держатель направляющей проволоки	1
29	40.3604.000	Śrubokręt S 3,5	Screwdriver S 3.5	Отвертка S 3,5	1
30	40.5333.000	Wiertło ze skalą 4,5/350	Drill with scale 4.5/350	Сверло с измерительной шкалой 4,5/350	1
31	40.5330.000	Wiertło ze skalą 3,5/250	Drill with scale 3.5/250	Сверло с измерительной шкалой 3,5/250	2
32	40.2068.350	Wiertło 6,5/350	Drill 6.5/350	Сверло 6,5/350	1
33	40.3674.000	Wiertło kaniulowane 6,5/300	Cannulated drill 6.5/300	Сверло каниюлированное 6,5/300	1
34	40.3675.000	Wkrętak kaniulowany S 5,0/2,2	Cannulated screwdriver S 5.0/2.2	Отвертка каниюлированная S 5,0/2,2	1
35	40.3676.000	Miarka długości wkrętów kaniulowanych	Reconstruction screw length measure	Измеритель длины реконструктивных винтов	1
36	40.5065.009	Wkładka celująca 9,0	Insert target 9.0	Направительный вкладыш 9,0	2
37	40.5065.011	Wkładka celująca 11,0	Insert target 11.0	Направительный вкладыш 11,0	2
38	40.5074.000	Śrubokręt S 3,5	Screwdriver S	Отвертка S	1
39	40.5075.000	Prowadnik sworznia	Bolt guide	Направитель шпильки	1
40	40.1387.000	Wiertło 4,5/250	Drill 4.5/250	Сверло 4,5/250	1
41	40.1344.000	Celownik D	Target D	Направитель дистальный Д	1
42	40.1358.000	Prowadnica wiertła krótka 7/3,5	Drill guide short 7/3.5	Направитель сверла короткий 7/3,5	1
43	40.1354.000	Trokar krótki 7	Trocar short 7	Трокар короткий 7	1
44	40.3662.000	Prowadnica ochronna 11/9	Protective guide 11/9	Направитель-протектор 11/9	1
45	40.5099.000	Statyw	Stand	Подставка	1

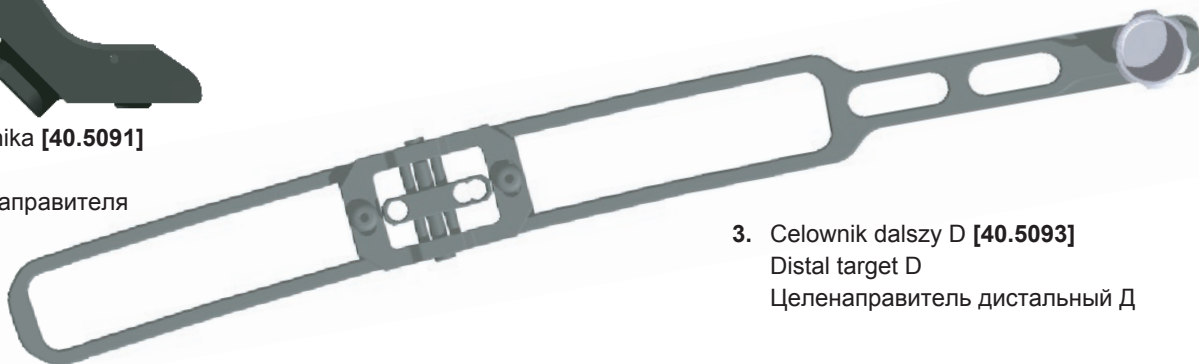
40.5090



1. Ramię celownika [40.5091]
Arm target
Плечо целенаправителя



2. Celownik 135 [40.5097]
Target 135
Целенаправитель 135



3. Celownik dalszy D [40.5093]
Distal target D
Целенаправитель дистальный Д



4. Śruba łącząca M10x1 L=55 [40.5094]
Connecting screw M10x1 L=55
Винт соединительный M10x1 L=55



6. Śruba kompresyjna [40.5096]
Compression screw
Компрессионный винт



5. Śruba łącząca M10x1 L=66 [40.5095]
Connecting screw M10x1 L=66
Винт соединительный M10x1 L=66



7. Miarka długości gwoździ [40.4798]
Nail length measure
Измеритель длины стержня



8. Trokar Ø9 [40.3327]
Trocar 9
Трокар 9



10. Prowadnica wiertła Ø9/Ø6,5 [40.3329]
Drill guide 9/6.5
Направитель сверла 9/6,5



9. Prowadnica ochronna Ø11/Ø9 [40.3328]
Protective guide 11/9
Направитель-протектор 11/9



11. Prowadnica wiertła Ø9/Ø4,5 [40.3330]
Drill guide 9/4.5
Направитель сверла 9/4,5



12. Prowadnica Kirschnera [40.3331]
Kirschner guide
Направитель Киршнера



13. Miarka długości wkrętów rekonstrukcyjnych [40.3332]
Reconstruction screw length measuring gauge
Измеритель длины реконструктивных винтов



14. Gwoździ Kirschnera Ø2/380 [40.3333]
Kirschner wire Ø2/380
Спица Киршнера Ø2/380



15. Prowadnica ochronna Ø9/Ø6,5 [40.3614]

Protective guide Ø9/ Ø6.5

Направитель-протектор Ø9/6,5



16. Prowadnica wiertła Ø6,5/ Ø3,5 [40.3615]

Drill guide 6.5/3.5

Направитель сверла 6,5/3,5



17. Ustawiak Ø9/Ø4.5 [40.3616]

Set block 9/4.5

Инструмент установочный 9/4,5



18. Trokar Ø6,5 [40.3617]

Trocar 6.5

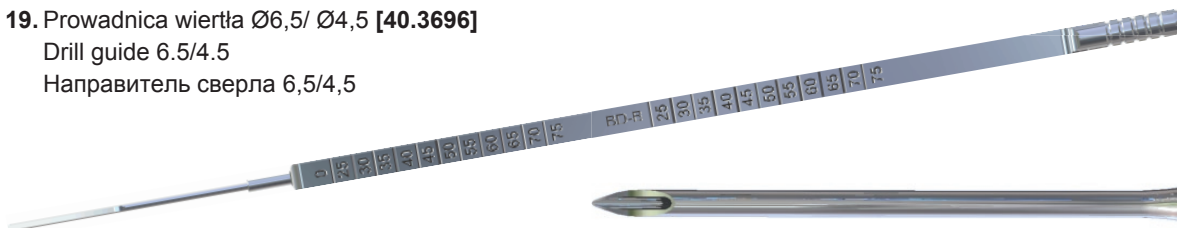
Трокар 6,5



19. Prowadnica wiertła Ø6,5/ Ø4,5 [40.3696]

Drill guide 6.5/4.5

Направитель сверла 6,5/4,5



20. Miarka długości wkrętów [40.1374]

Screw length measure

Измеритель длины винтов



21. Szydło wygięte 8,0 [40.5523]

Curved awl 8,0

Шило изогнутое 8,0



22. Wbijak - wybijak [40.5507]



23. Pobijak [40.3667]

Mallet

Пробойник



24. Łącznik M10x1/M12 [40.5071]

Connector M10x1/M12

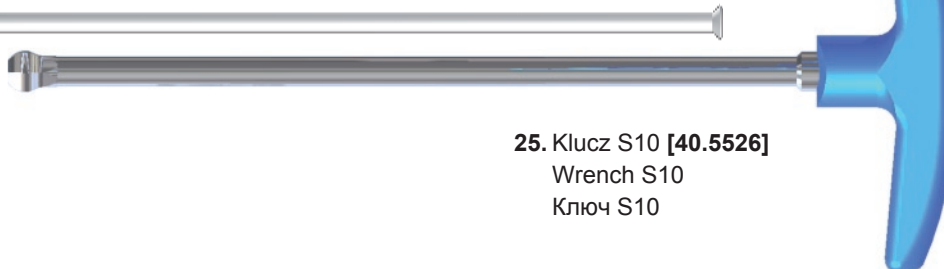
Соединитель M10x1/M12



26. Prowadnica rurkowa [40.1348]

Teflon pipe guide

Трубка-направитель



25. Klucz S10 [40.5526]

Wrench S10

Ключ S10

27. Drut prowadzący Ø3,0/600 [40.3925]

Guide rod 3.0/600

Спица-направитель 3,0/600



28. Uchwyt drutu prowadzącego [40.1351]

Handle guide rod

Держатель направляющей проволоки



29. Śrubokręt S3,5 [40.3604]

Screwdriver S 3.5

Отвертка S 3,5

30. Wiertło ze skalą Ø4,5/350 [40.5333]

Drill with scale 4.5/350

Сверло с измерительной шкалой 4,5/350

31. Wiertło ze skalą Ø3,5/250 [40.5330]

Drill with scale 3.5/250

Сверло с измерительной шкалой 3,5/250

32. Wiertło Ø6,5 / 350 [40.2068.350]

Drill 6.5/350

Сверло 6,5/350

33. Wiertło kaniulowane Ø6,5/300 [40.3674]

Cannulated drill 6.5/300

Сверло канюлированное 6,5/300

34. Wkrętak kaniulowany S5,0/2,2 [40.3675]

Cannulated screwdriver S5.0/2.2

Отвертка канюлированная S 5,0/2,2

35. Miarka długości wkrętów kaniulowanych [40.3676]

Reconstruction screw length measuring gauge

Измеритель длины реконструктивных винтов

36. Wkładka celująca 9,0. [40.5065.009]

Insertion target 9.0

Целенаправительный вкладыш 9,0

37. Wkładka celująca 11,0. [40.5065.011]

Insertion target 11.0

Целенаправительный вкладыш 11,0

38. Śrubokręt S3,5 [40.5074]

Screwdriver S 3.5

Отвертка S 3,5

39. Prowadnik sworznia [40.5075]

Bolt guide

Направитель шпильки

41. Celownik D [40.1344]

Target D

Целенаправитель дистальный D

40. Wiertło Ø4,5 / 250 [40.1387]

Drill 4.5/250

Сверло 4,5/250

42. Prowadnica wiertła krótka Ø7 / Ø3,5 [40.1358]

Drill guide short 7/3.5

Направитель сверла короткий 7/3,5

43. Trokar krótki Ø7 [40.1354]

Trocar short 7

Троакар короткий 7

44. Prowadnica ochronna Ø11/Ø9 [40.3662]

Protective guide Ø11/ Ø9

Направитель-протектор Ø11/ Ø9

45. Statyw [40.5099]

Stand

Подставка

IV. SURGICAL TECHNIQUE

IV.1. METHODS: reconstructive, compressive, dynamic, static

IV.1.1. Introduction

Locking the nail with screws means that the nail does not have to fit tight the medullary canal. When inserted without canal reaming following diameters of the nail should be used: Ø8, 9, 10, 11mm. Nails with diameter Ø12, 13, 14 are meant for the cases where reaming cannot be avoided. Please note, that the diameter of reamed canal shall be about 2mm wider than the diameter of the nail. In every case a hole shall be made in proximal part of femur, Ø13mm in diameter for the nails sizes Ø8, 9, 10, 11, 12, 13 mm or Ø14mm for the nail size 14, and 8mm in depth. It will facilitate insertion of proximal part of the nail, where it is made thicker. The surgeon decides about possible reaming after examining of the shape of canal and type of fracture.

Reaming of medullary canal is not recommended in patients with chest injuries due to the risk of fat embolus.

When the patient cannot be operated at the day of femoral fracture, it is recommended to apply strong traction for 2 to 3 days to spread the fragments. This will considerably facilitate fracture reduction and nail insertion. Applying the traction is an integral part of the operating procedure. Presented method of intramedullary osteosynthesis require image intensifier (C-arm). Each operating procedure must be carefully planned. X-ray of the entire femur is essential in order to not overlook of the injuries in its proximal or distal part. It is especially important in cases of pathological subtrochanteric fractures. Special attention should be made on concurrent neck fractures or proximal epiphysis multi-fragment fractures, and the possibility of its occurrence during the procedure. During the operation secondary fractures of main fragments may occur.

In such cases the dynamic stabilization has to be replaced by a static one. The condition of hip joint is also very important. In advanced arthrosis or contracture fixation may be difficult or even impossible to perform. In addition it should be checked whether alloplasty of hip or knee has been performed on the fractured limb.

The procedure has to be carried out on the operating table with traction with the patient placed supine or on the side. Side position facilitates the approach to the greater trochanter, which is especially important with overweight patients.

Supine position provides less favorable access to the greater trochanter, but makes all other stages of the operation considerably easier (especially rotary corrections).

In the presented method supine position is recommended with traction applied on the condyles of the operated femur.

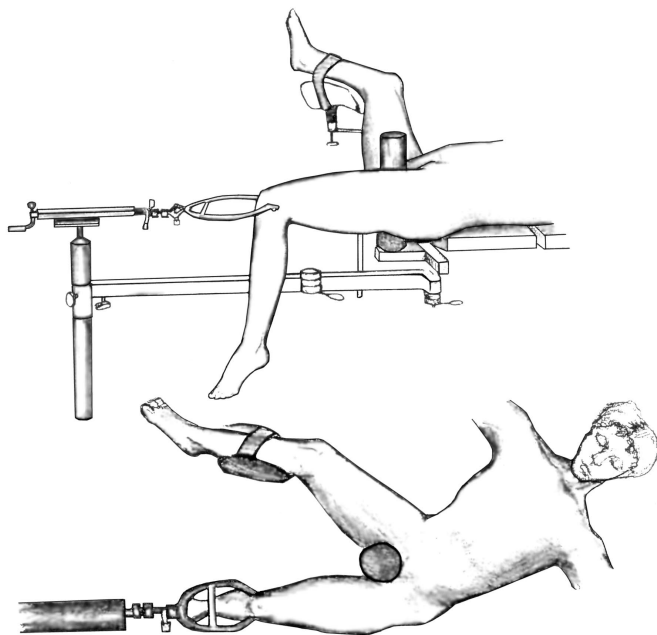
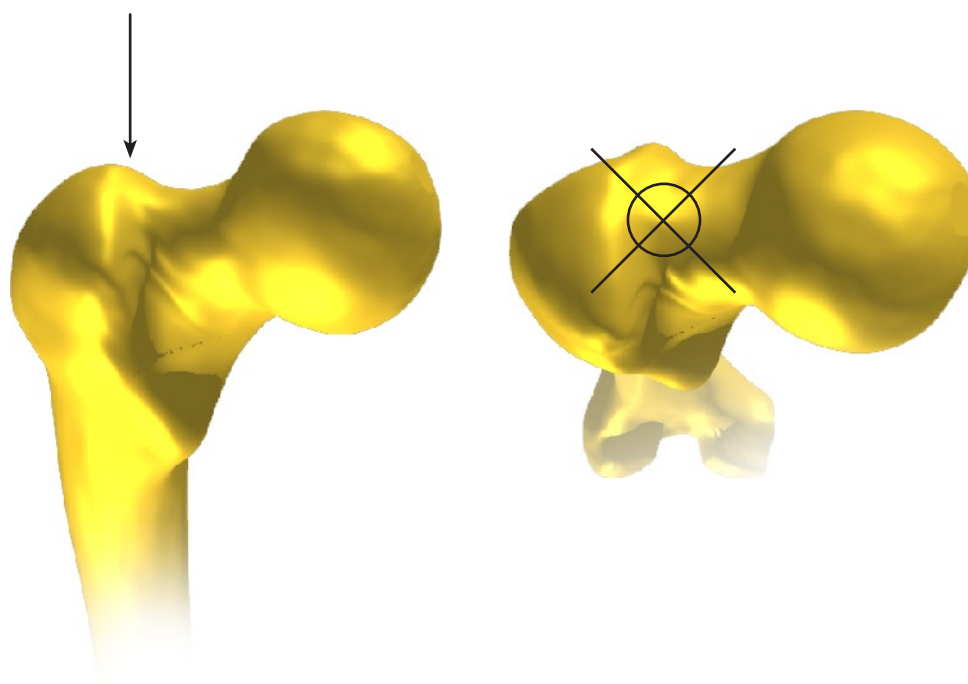


Fig. 1. Supine position of the patient for intramedullary osteosynthesis of femur.

Lateral surgical approach shall be applied starting the incision near the tip of greater trochanter in line with the femoral shaft axis for 8cm. The incision should be longer in patients with overweight. In the same direction an incision is made in fascia. Fibers of greater gluteal muscle are then split, thus providing approach to the tip of greater trochanter. The point of entry of the nail should be located in line with the axis of medullary canal. It can be found in practice in a following way. If one finds the tip of greater trochanter then the insertion point is "a little bit paracentrally" and to the front in a place where one should feel small dale (fossa piriformis) with index finger (see Fig. 2)

Fig. 2 Location of the entry point for femoral nail.

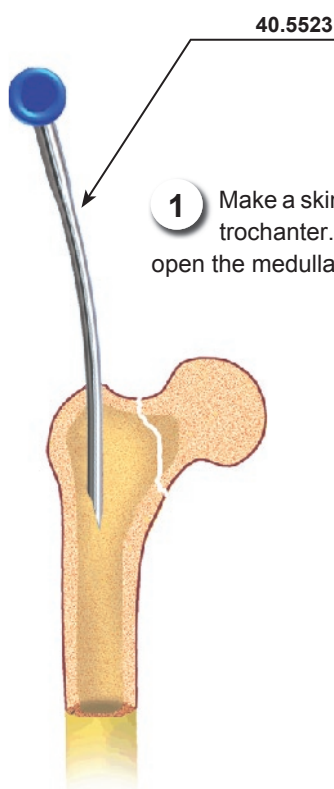


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

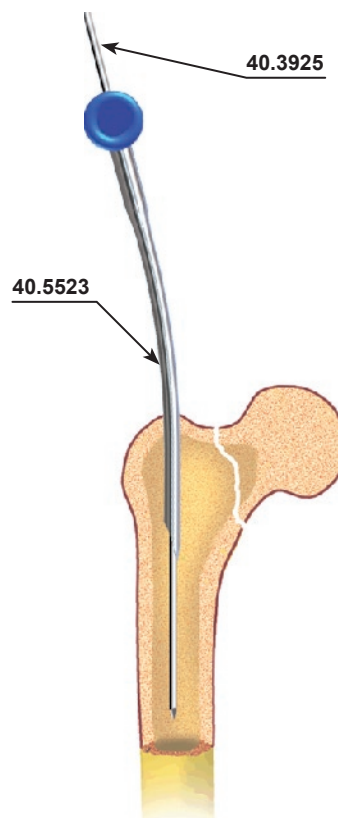
ATTENTION! The following paragraphs describe most important steps during implantation of intramedullary interlocking femur nails nevertheless it is not a detailed instruction of use. The surgeon decides about choosing the surgical technique and its application in each individual case.

On the basis of x-rays of fractured femur and of the healthy one, the surgeon decides about the type of nail, its length and diameter.

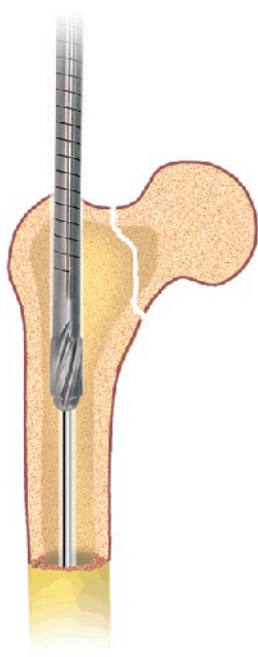
IV.1.2. Preparation of the medullary canal and nail insertion



- 1 Make a skin incision near the tip of greater trochanter. Using curved awl [40.5523] open the medullary canal to a depth approx.



- 2 Introduce Kirschner wire [40.3925] with mounted handle guide rod [40.1351]. Correctly inserted wire should be in line with axis of medullary canal. (this step should be performed under the control of image intensifier.). Remove handle guide rod [40.1351] and curved awl [40.5523].



- 3 Introduce the guide wire [40.3925] of flexible reamers into the medullary canal until its tip reaches distal epiphysis of femur. If medullary canal is reamed, gradually increase the diameter of canal with steps of 0.5 mm, until one reaches the diameter 1.5 to 2.0 mm wider than the diameter of the femoral nail, for the depth at least equal to the nail length (but not lesser). In both cases, ie. when the medullary canal was reamed or not, the canal should be reamed using Ø13 or Ø14 reamer to the depth of approx. 8 cm.

Remove the flexible reamer.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

NOTE! Steps [4] and [5] are applicable only if the medullary canal has been reamed or if has been used another reamer guide.
Otherwise please go directly to the step [6].

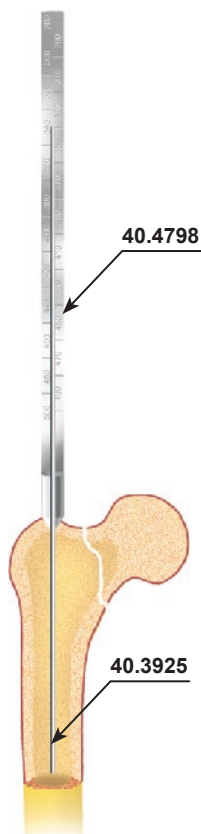
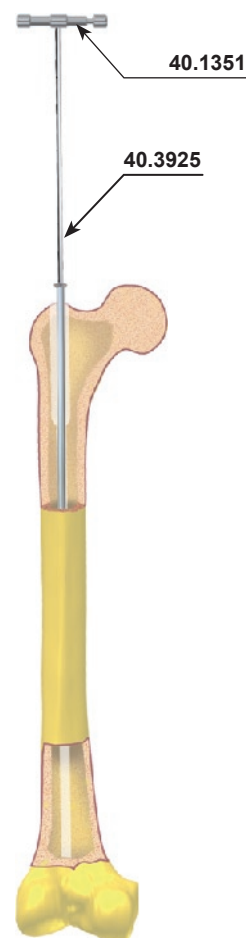


- 4 Introduce the Teflon pipe guide (Teflon tube) [40.1348] onto the flexible reamer guide until it reaches the end of medullary canal in distal femur.

Remove the flexible reamer guide.

- 5 Mount the handle guide rod (T-handle) [40.1351] on the guide rod [40.3925] in 600mm length and advance the rod into the teflon tube until its tip reaches the distal epiphysis.

Remove the T-handle [40.1351] from the guide rod.
Remove the Teflon pipe guide [40.1348].



- 6 Nail length measuring gauge [40.4798] introduce on guide rod as long as it support on the bone. Read the meter on the nail measuring gauge to asses the length of intramedullary nail.

Remove measuring gauge from the guide rod. In case of solid nail, remove guide rod from medullary canal. Medullary canal is ready for nail insertion.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

- 7** Using connecting screw:
- **[40.5095]** in case of reconstruction and compression nail usage,
 - **[40.5094]** in case of universal nail usage by use wrench S10 **[40.5526]** fix the intramedullary nail to the arm target **[40.5091]**.

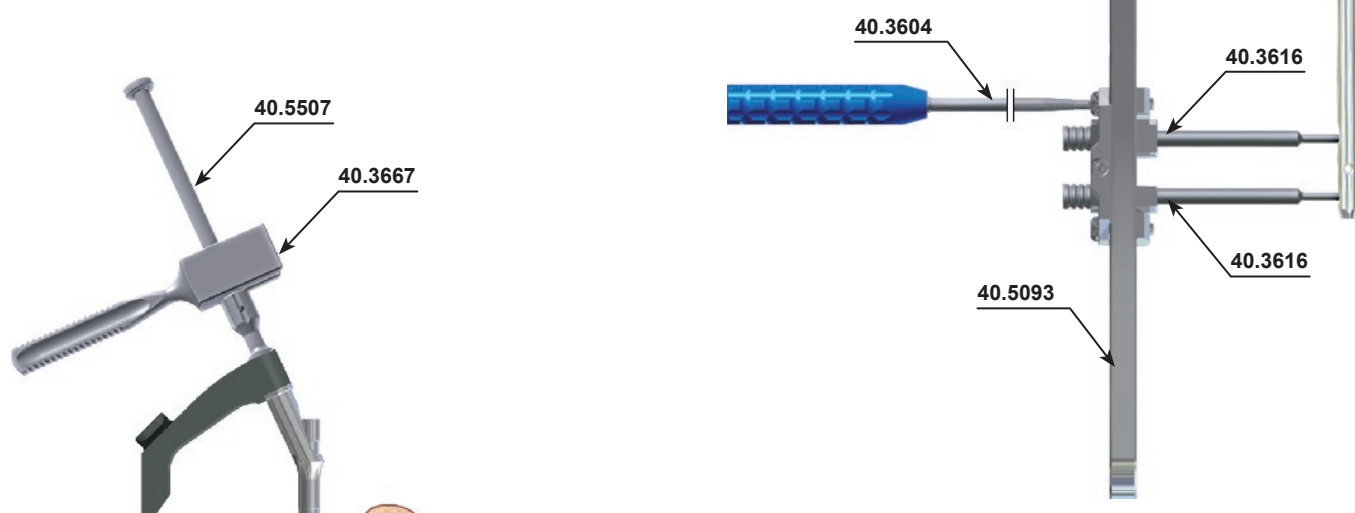
To the arm target fix distal target D **[40.5093]**. With a pair of setting pins **[40.3616]** place the slider of distal target in line with distal locking holes of intramedullary nail.

Secure the slider of the distal target with screwdriver **[40.3604]**.

CHECK: Properly set and secured slider make possible smoothly hitting in the holes in the nail.

Remove the setting pins from the target.

Dismount the distal target **[40.5093]** off the arm of proximal target **[40.5091]**.

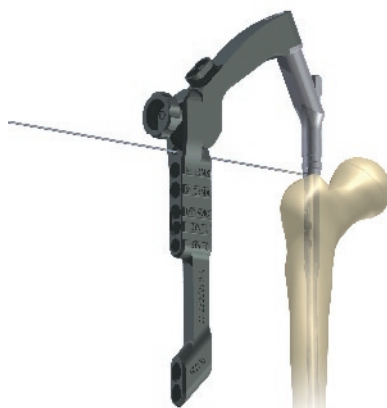


- 8** Screw down impactor-extractor **[40.5507]** on the proximal arm target **[40.5091]** with fixed intramedullary nail. Introduce the nail into the medullary canal via the remaining guide rod **[40.3925]**. Advance the nail by pushing and maneuvering until it reaches adequate depth. After introducing remove guide rod **[40.3925]**.

Dismount impactor-extractor **[40.5507]** from proximal target

- 8a** To the arm target **[40.5091]** fix distal target B **[40.5097]**.

Using Kirschner wire inserted in the hole of the target B **[40.5097]** (marked "0") it is possible to check correctly hollow nail in the femur.

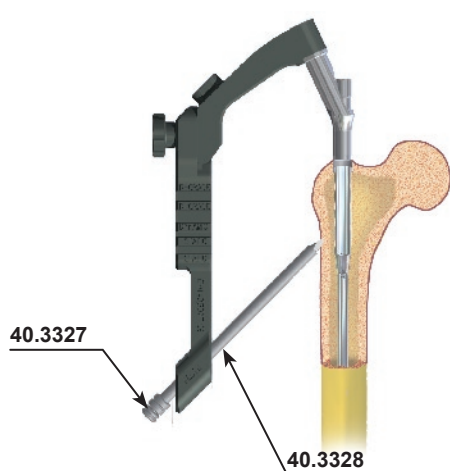


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.2. RECONSTRUCTIVE METHOD

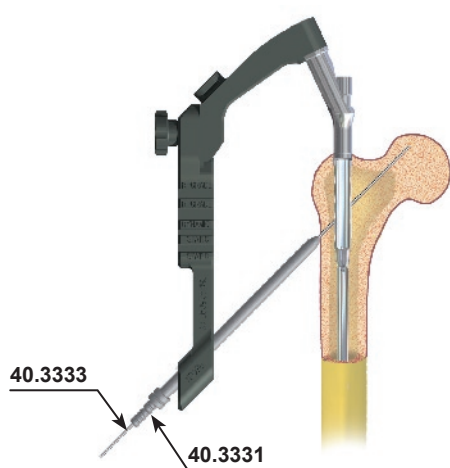
IV.2.1. Proximal locking of the nail

IV.2.1.a. **OPTION I:** Locking with reconstruction screws



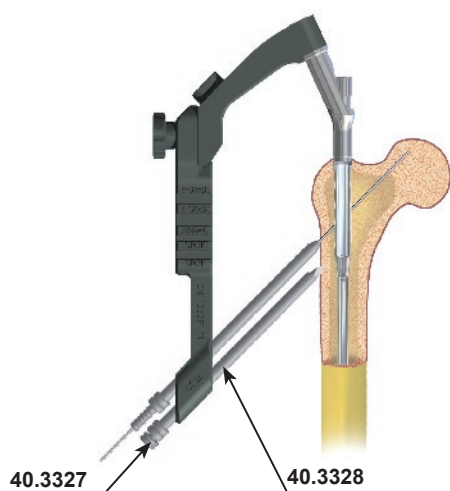
- 9** To the arm target [40.5091] fix distal target B [40.5097].
Introduce the protective guide [40.3328] with trocar [40.3327] into the first proximally placed hole in proximal target.
Mark the point of entry of the trocar, make an adequate incision of the soft tissues. Advance the trocar until it reaches the cortex bone and mark the point of entry for the drill bit. Advance the protective guide together with the trocar until it touches the bone.

Remove the trocar.
Leave the protective guide in the hole.



- 10** Introduce the Kirschner guide [40.3331] and Kirschner wire Ø2.0/380 [40.3333] into the protective guide. Mount the wire in the drill and with its help advance the wire into the femoral neck but do not to perforate the femoral head. The above step should be controlled with image intensifier (A/P view). Check also the position of the wire in the lateral view. The wire should be in the middle of the neck, deviation is acceptable if allows the screw to be introduced without damaging outer cortex of the neck. In case of mis-positioning of the wire, repeat this step.

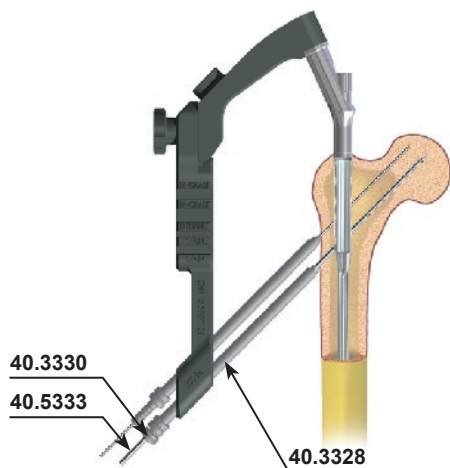
Leave the Kirschner wire.
Kirschner guide and protective guide in place.



- 11** Introduce the protective guide [40.3328] with trocar [40.3327] into the other hole in proximal target [40.5097]. Advance the trocar until it reaches the cortex bone and mark the point of entry for the drill bit. Advance the protective guide together with the trocar until it touches the bone.

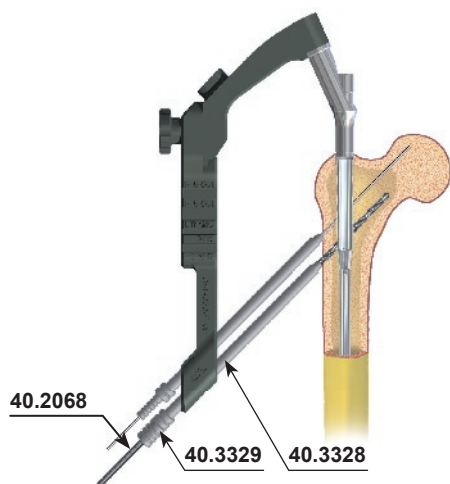
Remove the trocar.
Leave the protective guide in the hole.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



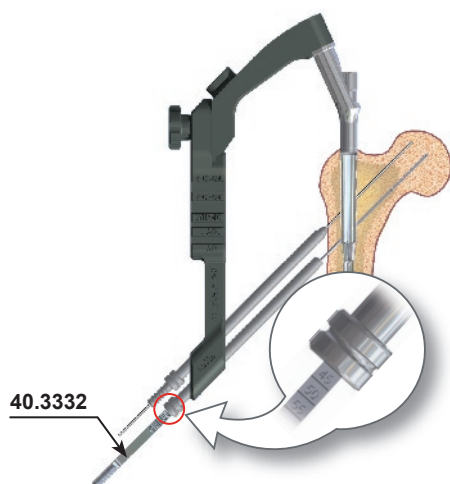
- 12** Introduce the drill guide Ø 4.5mm **[40.3330]** (with two grooves on the handle) into the protective guide **[40.3328]** in second hole of the target. Mount the long Ø 4.5/350mm drill bit **[40.5333]** on the surgical drive and advance it through the drill guide. The scale on the drill shows length of the locking element. Drill the hole in the femoral neck (through the proximal hole in the nail) until it reaches adequate depth, put prevent perforating the head. Control the drilling procedure with the image intensifier.

Remove the drill bit and the drilling guide.
Leave the protective guide in the hole of target.



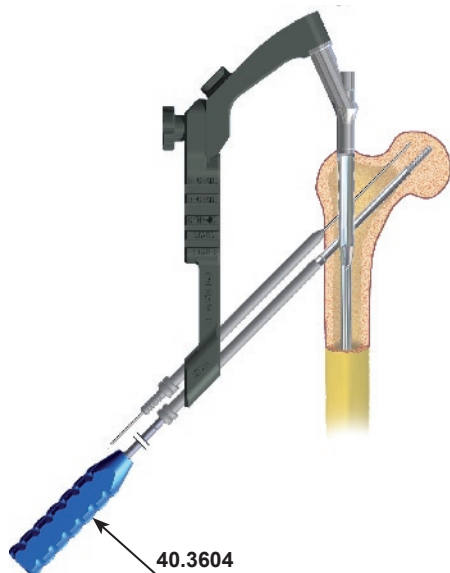
- 13** Introduce the drill guide Ø 6.5mm **[40.3329]** (with three grooves) into the protective guide **[40.3328]**. Mount the Ø 6.5/350mm drill bit **[40.2068]** on the surgical drive and advance it through the drill guide. Ream the hole in the femoral neck for the depth lesser approx 30mm than before drilled hole with Ø4.5 drill (due to the length of the thread on the reconstructive screw). Control the reaming procedure with the image intensifier.

Remove the drill bit and the drill guide.
Leave the protective guide in the hole of target.



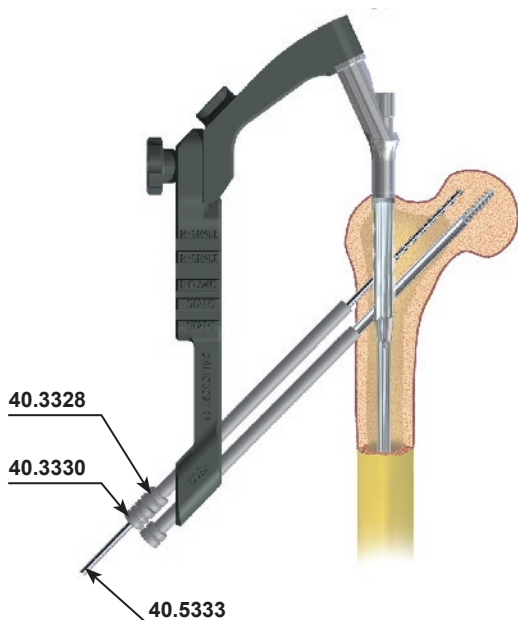
- 14** Introduce the reconstruction screw length gauge **[40.3332]** through the protective guide into the drilled hole until it reaches its end. Read the length of the reconstructive screw on the gauge. During measurement the end of the protective guide should rest on the cortex bone.

Remove the screw length gauge.
Leave the protective guide in the hole of target.



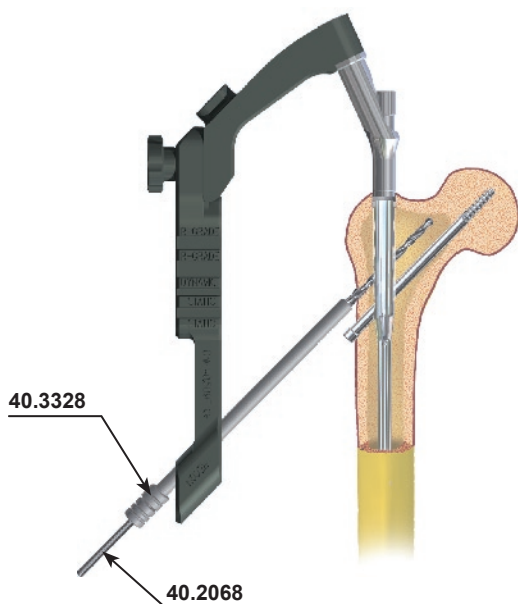
- 15** Introduce the tip of the screwdriver **[40.3604]** into the hexagonal socket of the selected reconstructive screw. Then advance the both into the protective guide. Screw in the reconstructive screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver.



- 16** Remove the Kirschner wire and Kirschner guide from protective guide **[40.3328]** from the first hole of target. Introduce the drill guide Ø4.5mm **[40.3330]** (with two grooves on the handle) into the protective guide **[40.3328]** (with one groove) left in hole of the target. Mount the long Ø4.5/350 mm drill bit **[40.5333]** on the surgical drive and advance it through the drill guide. The scale on the drill shows length of the locking element. Drill the hole in the femoral neck (through the proximal hole in the nail) until it reaches adequate depth, put prevent perforating the head. Control the drilling procedure with the image intensifier.

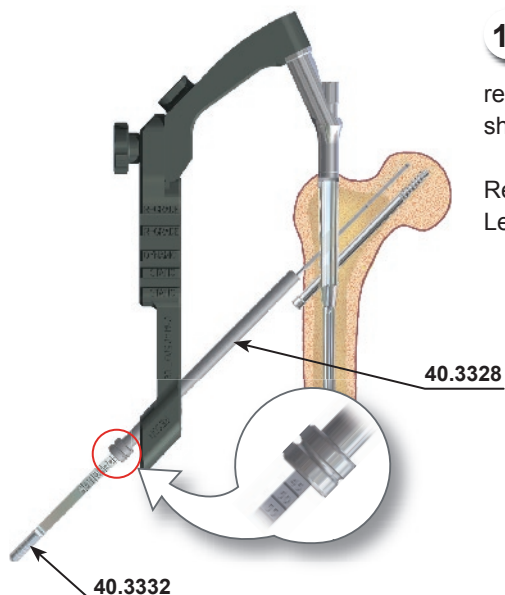
Remove the drill bit and the drill guide.
Leave the protective guide in the hole of target.



- 17** Introduce the drill guide Ø6.5 mm **[40.3329]** (with three grooves) into the protective guide. Mount the Ø6.5/350 mm drill bit **[40.2068]** on the surgical drive and advance it through the drill guide. Ream the hole in the femoral neck for the lesser depth approx 30mm than before drilled hole with Ø4.5 drill (due to the length of the thread on the reconstructive screw). Control the reaming procedure with the image intensifier.

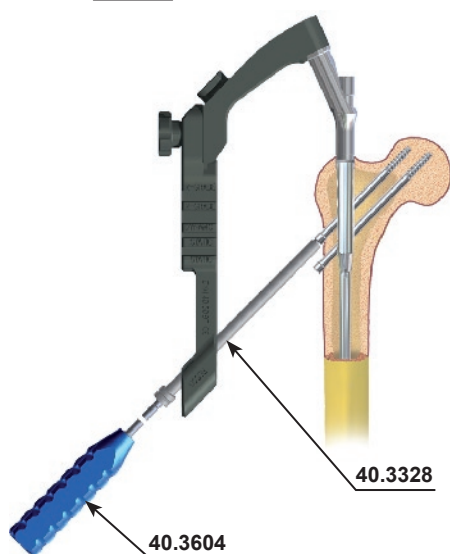
Remove the drill bit and the drill guide.
Leave the protective guide in the hole of target.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



- 18** Introduce the reconstruction screw length gauge **[40.3332]** through the protective guide into the drilled hole until it reaches its end. Read the length of the reconstructive screw on the gauge. During measurement the end of the protective guide should rest on the cortex bone.

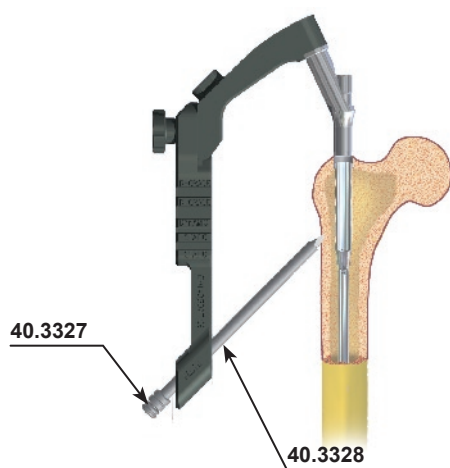
Remove the screw length gauge.
Leave the protective guide in the hole of target.



- 19** Introduce the tip of the screwdriver **[40.3604]** into the hexagonal socket of the selected reconstructive screw. Then advance the both into the protective guide. Screw the reconstructive screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

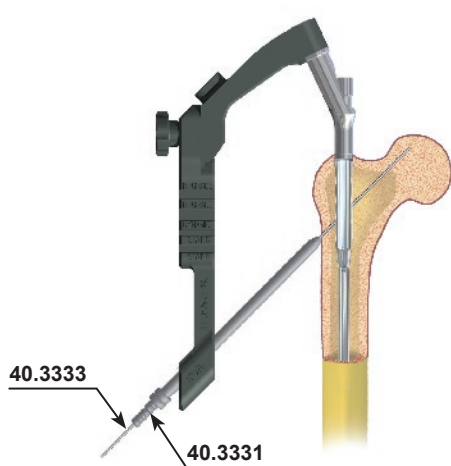
Remove the screwdriver and protective guide.

IV.2.1.b. **OPTION II:** Locking with cannulated reconstructive screws



- 20** Introduce the protective guide **[40.3328]** with trocar **[40.3327]** into the first proximally hole in proximal target B **[40.5097]**. Mark the point of entry of the trocar, make an adequate incision of the soft tissues. Advance the trocar until it reaches the cortex bone and mark the point of entry for the drill bit. Advance the protective guide together with the trocar until it touches the bone.

Remove the trocar.
Leave the protective guide in the hole.

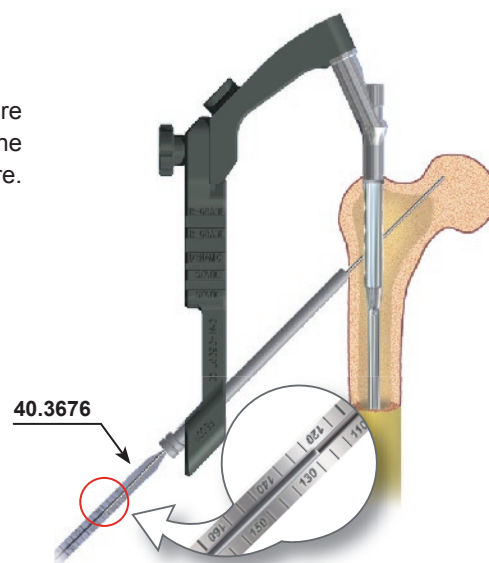


- 21** Introduce the Kirschner guide [40.3331] and Kirschner wire 2.0/380mm [40.3333] into the protective guide [40.3328]. Mount the wire in the surgical drive and with its help advance the wire into the femoral neck but do not perforate the femoral head. The above step should be controlled with image intensifier (A/P view). Check also the position of the wire in the lateral view. The wire should be in the middle of the neck, deviation is acceptable if allows the screw to be introduced without damaging outer cortex of the neck. Use only Kirschner wires 2.0/380 [40.3333] with diameter 2.0 mm and 380 mm length. In case of mis-positioning of the wire, repeat this step.

Remove the Kirschner guide.
Leave the Kirschner wire in place.

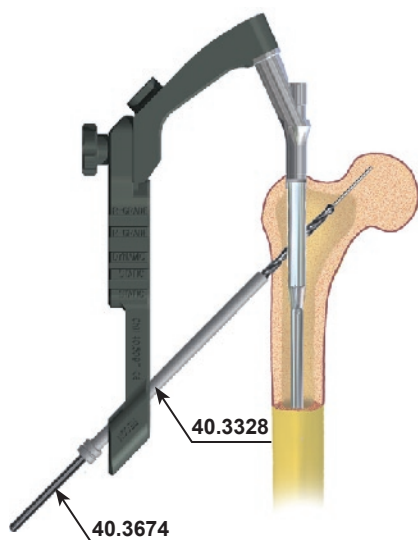
- 22** Introduce the cannulated screw length gauge [40.3676] via the Kirschner wire drilled into the femoral head until its tip touches the protective guide. Read the length of the cannulated reconstructive screw, defined by the end of the Kirschner wire. During measurement the end of the gauge should rest on the cortex bone.

Remove the screw length gauge.
Leave the Kirschner wire in place.



- 23** Mount the Ø6.5mm cannulated drill bit [40.3674] on the surgical drive and advance via Kirschner wire mounted in the femoral neck. Drill the hole through the first cortex (up to the nail placed in medullary canal).

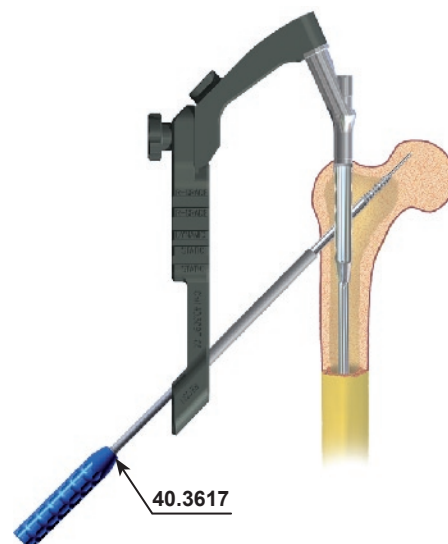
Remove the cannulated drill bit.
Leave the Kirschner wire.



- 24** Put the selected cannulated reconstructive screw via the Kirschner wire. Advance the cannulated screwdriver [40.3675] via the Kirschner wire going through a proximal hole of the nail and screw the cannulated reconstructive screw in until its head reaches cortex.

Remove the screwdriver and Kirschner wire.

NOTE! To introduce second reconstructive screw, repeat steps [21] to [24] for the second hole in target.



The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

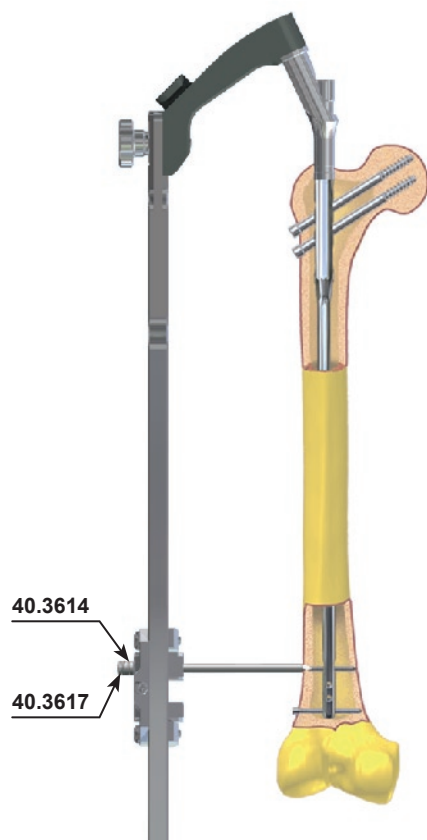
One should check correctness of femur neck fixation by taking RTG photographs in two projections. Small overall dimensions of target B which is additionally deviation at antetorsion angle allow for taking RTG photograph in lateral position (C-arm is then positioned at small angle in relation to target position). Nail at radiological image with its locking elements can be helpful at confirming the correctness of locking.



IV.2.2. Distal locking of the nail

Before continuing with steps connected with distal locking of the nail do the following:

1. Mount distal target [40.5093] again on the arm of the proximal target [40.5091] and secure it with a lock-nut (included in proximal target).
If properly installed, the signs >>RIGHT<< or >>LEFT<< on both target should comply.
2. Verify with the image intensifier the position of holes in the nail and in target slider. The centers of the holes in nail and target have to be in line.

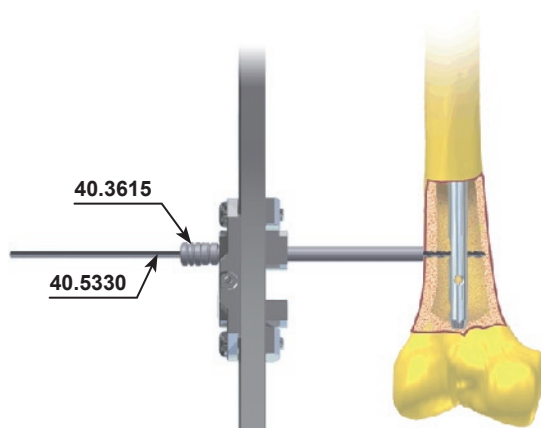


- 25** Introduce the protective guide [40.3614] (with one groove on the handle) with trocar [40.3617] into the proximal hole in the slider of distal target. Mark the point of entry of the trocar, make an adequate incision of the soft tissues. Advance the trocar until it reaches the cortex bone and mark the point of entry for the drill bit. Advance the protective guide together with the trocar until it touches the bone.

Remove the trocar.

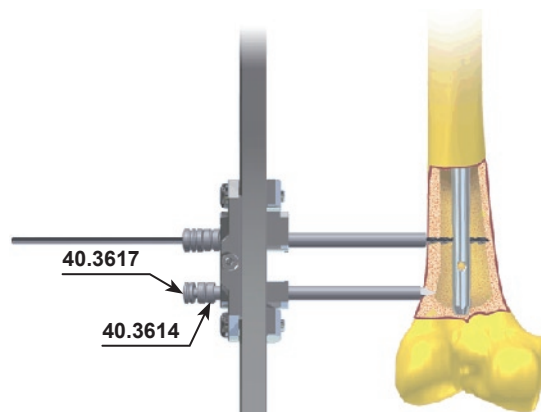
Leave the protective guide in the hole of the slider.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



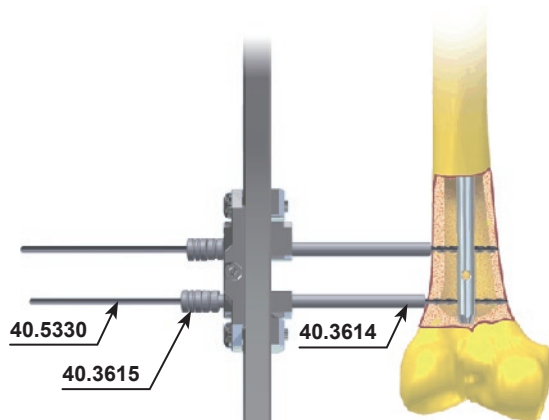
- 26** Introduce the drill guide Ø3.5mm [40.3615] (with two grooves) into the protective guide left in the hole of the slider. Mount the Ø3.5/250mm drill bit [40.5330] on the surgical drive and advance it through the drill guide. Drill the hole in the femoral shaft through both cortex layers and the hole in the nail. The scale on the drill shows length of the locking element.

Disconnect the drive and the drill bit and leave in place drill bit together with drill guide and protective guide



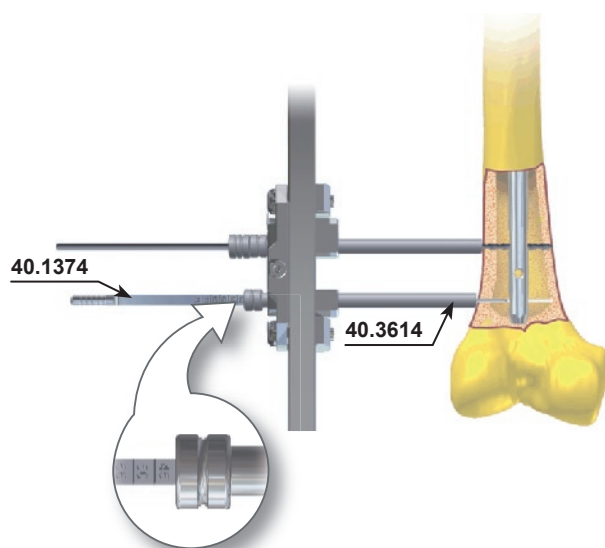
- 27** Introduce the protective guide [40.3614] (with one groove on the handle) with trocar [40.3617] into the second hole in the slider of distal target. Mark the point of entry of the trocar, make an adequate incision of the soft tissues. Advance the trocar until it reaches the cortex bone and mark the point of entry for the drill bit. Advance the protective guide together with the trocar until it touches the bone.

Remove the trocar.
Leave the protective guide in the hole.



- 28** Introduce the drill guide Ø3.5mm [40.3615] (with two grooves) into the protective guide [40.3614] left in the hole of the slider. Mount the Ø3.5/250mm drill bit [40.5330] on the surgical drive and advance it through the drill guide. Drill the hole in the femoral shaft through both cortex layers and the hole in the nail. The scale on the drill shows length of the locking element.

Remove the drill bit and drill guide.
Leave the protective guide in the hole of the slider.

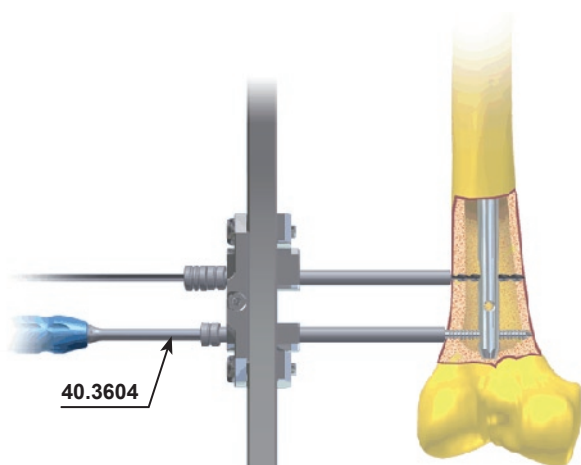


- 29** Introduce the screw length gauge [40.1374] through the protective guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the gauge.

During measurement the protective guide should rest on the cortex bone.

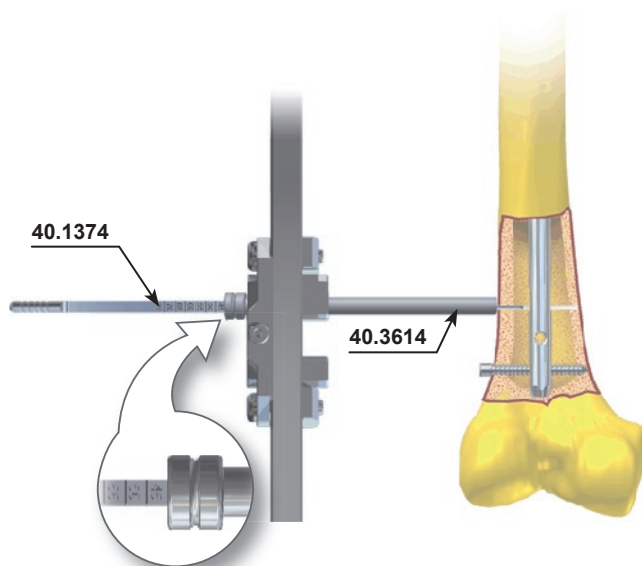
Remove the screw length gauge.
Leave the protective guide in place..

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



- 30** Introduce the tip of the screwdriver [40.3604] into the hexagonal socket of the selected locking screw. Then advance the both into the protective guide. Screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

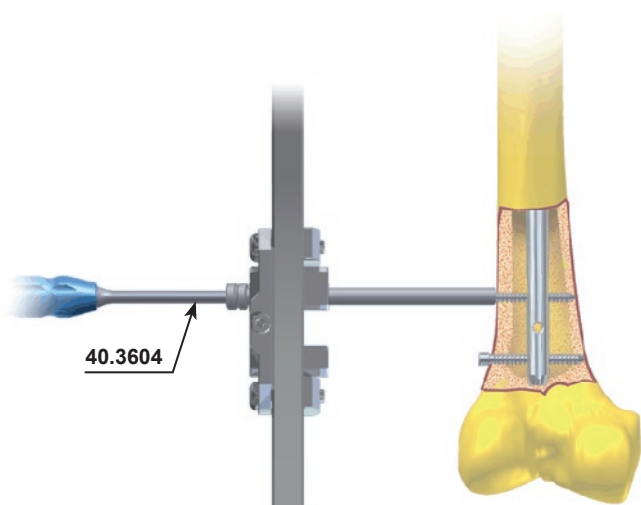
Remove the screwdriver and protective guide.



- 31** Remove the drill bit and drill guide from proximal hole in the slider of the target. Leave the protective guide in the hole of the slider. Introduce the screw length gauge [40.1374] through the protective guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the gauge.

During measurement the protective guide should rest on the cortex bone.

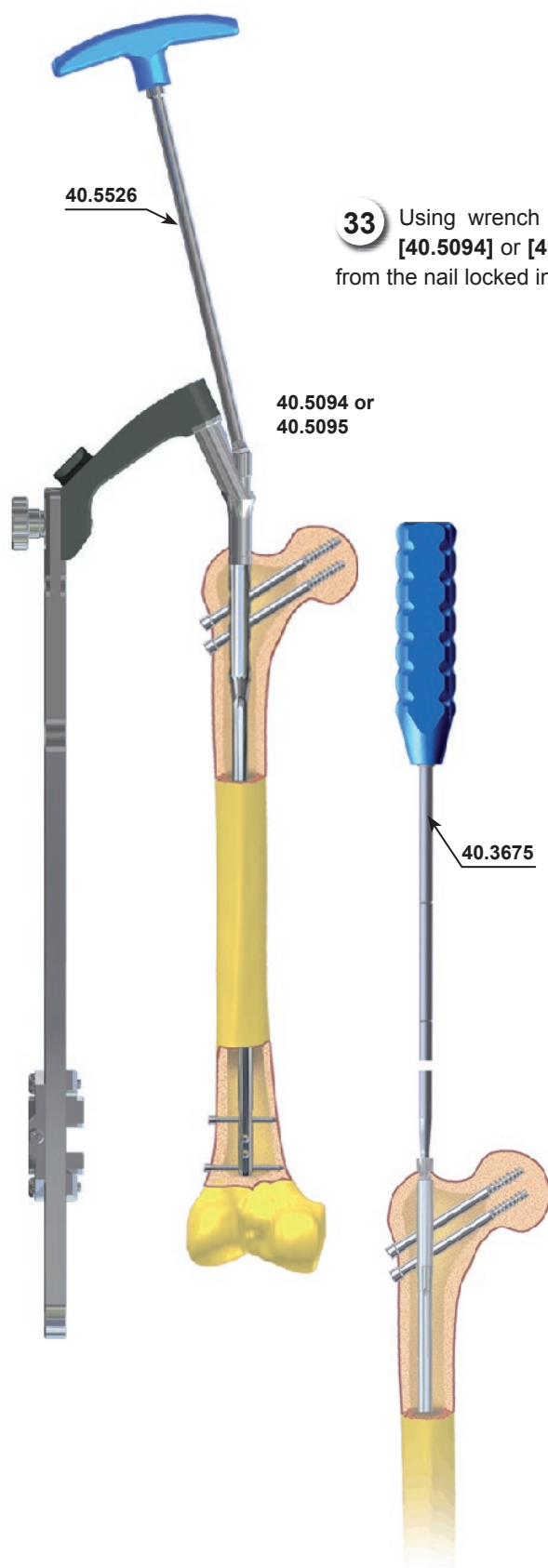
Remove the screw length gauge.
Leave the protective guide in place.



- 32** Introduce the tip of the screwdriver [40.3604] into the hexagonal socket of the selected locking screw. Then advance the both into the protective guide. Screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver and protective guide.

IV.2.3. Target removal, placing end cap



33 Using wrench S10 [40.5526] unscrew the connecting screw [40.5094] or [40.5095] of the nail shaft and dismount the target from the nail locked in the medullary canal.

1.2104.3xx
universal nail
3.2104.3xx

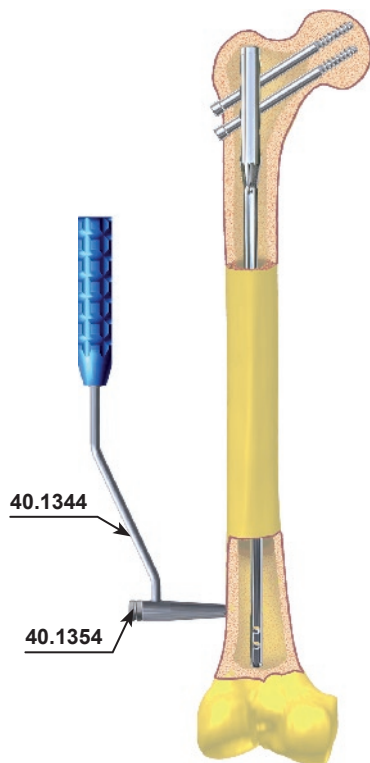
1.2104.4xx
reconstruction nail
3.2104.4xxx

34 In order to secure the inner thread of the nail from bone overgrowth, using the screwdriver [40.3675] screw in:
- the end cap [1.2104.3xx] or [3.2104.3xx] in case of universal nail use;
- the end cap [1.2104.4xx] or [3.2104.4xx] in case of reconstruction nail use.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

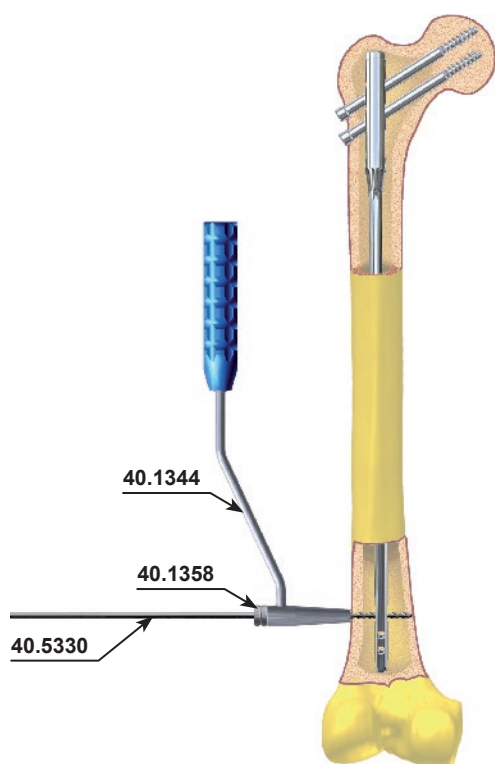
IV.2.4. Distal locking of the nail “freehand technique”

With this technique an image intensifier is used to identify the entry points for the drill bits and to control the drilling of the holes. It is recommended to use angular attachment with the surgical drive when drilling the holes, so that surgeon's hands are not directly exposed to x-rays. After marking the entry points on the skin, incisions are made in the marked places though the soft tissues, each about 1.5cm in length.



- 35** Using the image intensifier place the freehand target **[40.1344]** in line with the hole in the nail. The centers of the holes in the target and the nail have to match. The teeth of the freehand target have to be merged in the cortex. Introduce the short trocar **[40.1354]** into the hole in target, advance it until it reaches cortex and mark the entry point for the drill.

Remove the trocar.
Leave the target in place.



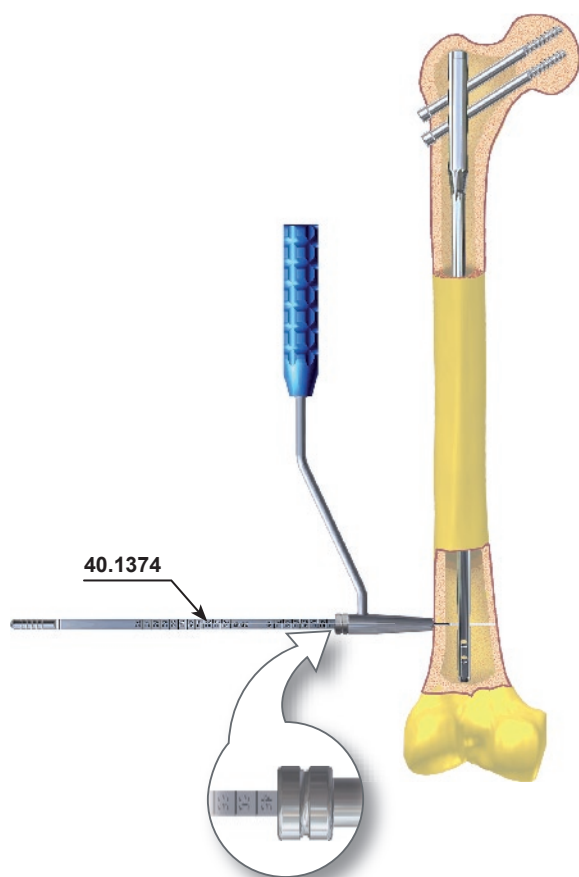
- 36** Introduce the short drill guide Ø3.5mm **[40.1358]** into the hole in target. Mount the Ø3.5/250mm drill bit **[40.5330]** on the surgical drive and advance it through the drill guide. Drill the hole in the femoral shaft through both cortex layers and the hole in the nail. The scale on the drill shows length of the locking element.

Remove the drill bit and drill guide.
Leave the target in place.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

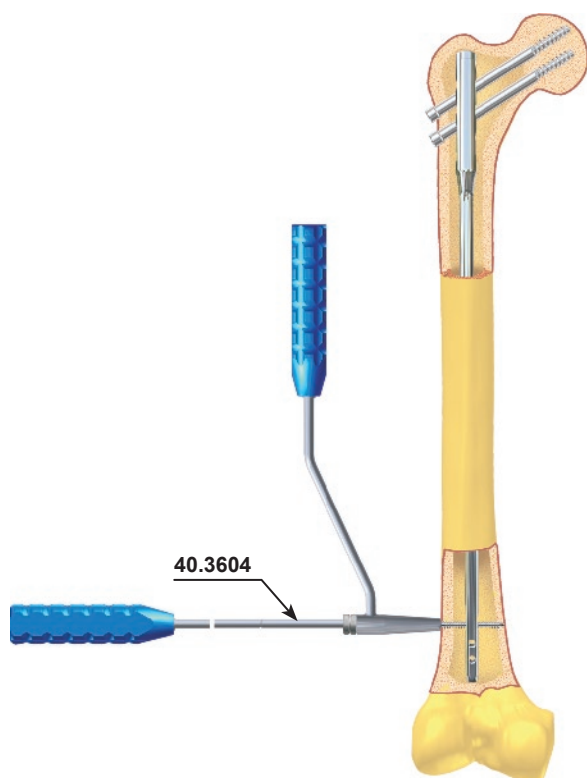
- 37** Introduce the screw length gauge **[40.1374]** through the protective guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the gauge scale D.

Remove the screw length gauge.
Leave the target in place.



- 38** Introduce the tip of the screwdriver **[40.3604]** into the hexagonal socket of the selected locking screw. Then advance the both into the hole in target. Screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone.

Remove the screwdriver and target.

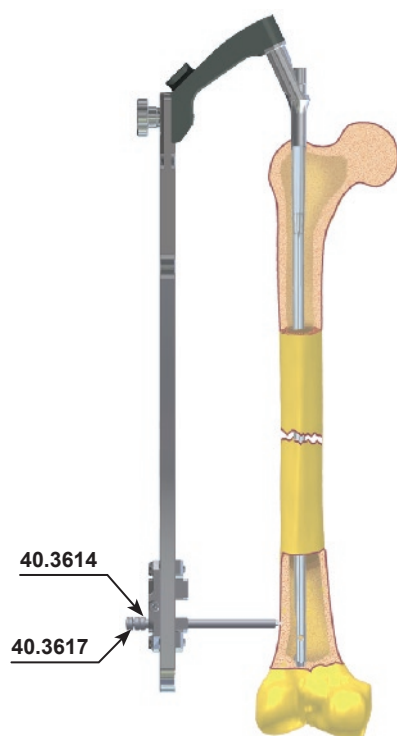


IV.3. DYNAMIC AND COMPRESSIVE METHODS

IV.3.1. Distal locking of the nail

Before continuing with steps connected with distal locking of the nail do the following:

1. Mount distal target [40.5093] again on the arm of the proximal target [40.5091] and secure it with a lock-nut (included in proximal target).
If properly installed, the signs >>RIGHT<< or >>LEFT<< on both target should comply.
2. Verify with the image intensifier the position of holes in the nail and in target slider. The centers of the holes in nail and target have to be in line.



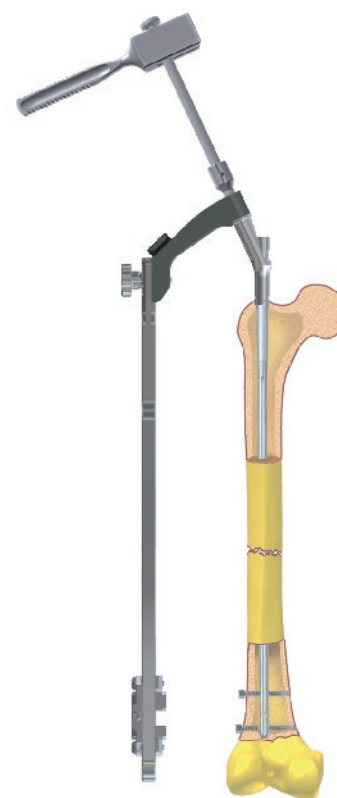
- 39** Introduce the protective guide [40.3614] (with one groove on the handle) with trocar [40.3617] into the proximal hole in the slider of distal target. Mark the point of entry if the locking screw on the skin and make adequate incision through soft tissues. Advance trocar until it reaches cortex and mark the entry point for the drill. Advance protective guide together with the trocar until it touches the cortex.

Remove trocar.

Leave the protective guide in the hole of slider.

NOTE! For the rest of the procedure follow the steps 26 to 32, from page 30 to 31.

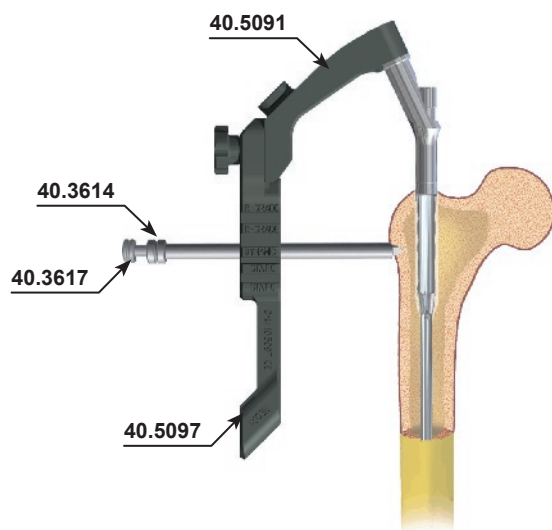
- 40** It is possible to make a reduction of fracture after locking nail in distal part by slightly knocking out nail, and next locking the nail in proximal part.



The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

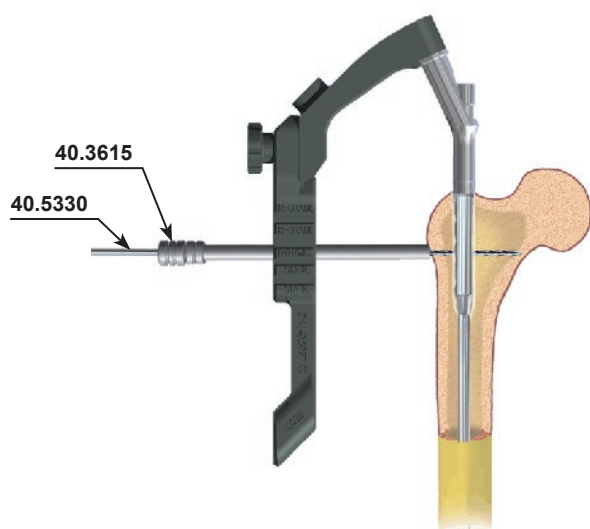
IV.3.2. Proximal locking of the nail

Important note! In compressive and dynamic methods of femoral fixation with use of intramedullary nail, from the two holes in proximal target [40.5097] marked >>COMPRESSION<< use only one, the proximal hole.



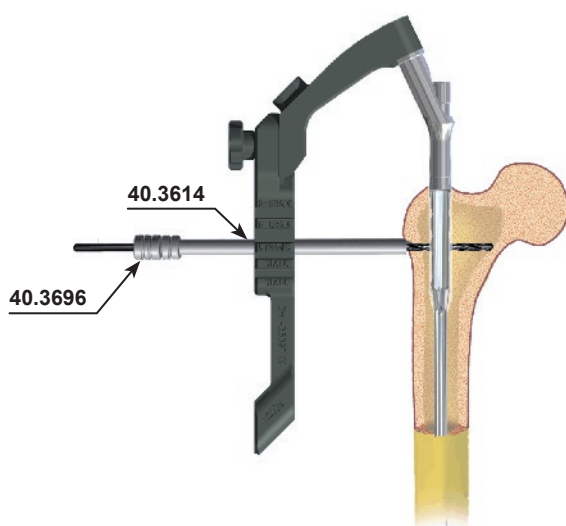
- 41** To the arm target [40.5091] fix distal target B [40.5097].
Introduce the protective guide [40.3614] (with one groove on the handle) with trocar [40.3617] into the proximal hole in proximal target [40.5097]. Mark the point of entry of the locking screw on the skin and make adequate incision through soft tissues 1.5cm in length. Advance trocar until it reaches cortex and mark the entry point for the drill. Advance protective guide together with the trocar until it touches the cortex.

Remove trocar.
Leave the protective guide in the hole of target.



- 42** Introduce the Ø3.5mm drill guide [40.3615] (with two grooves) into the protective guide. Mount the Ø3.5/250 mm drill bit [40.5330] on the surgical drive and advance it through the drill guide. The scale on the drill shows length of the locking element. Drill the hole in the femur through both cortex layers and the hole in the nail.

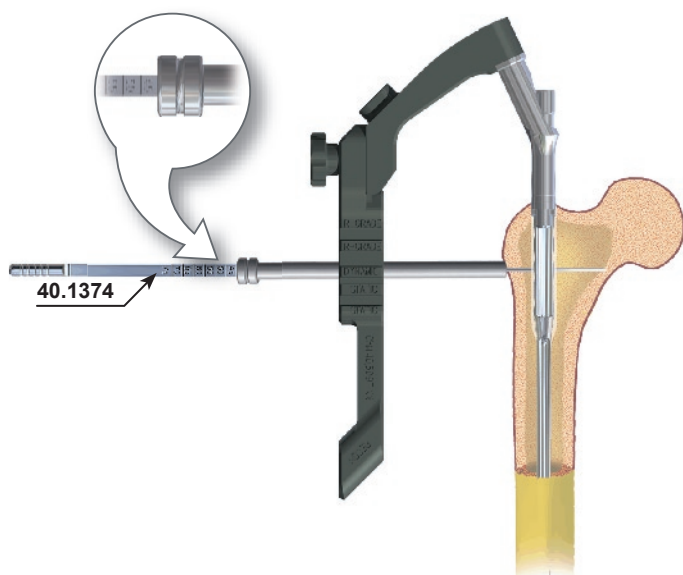
Remove the drill bit and drill guide.
Leave the protective guide in the hole of target.



- 43** Introduce the Ø4.5mm drill guide [40.3696] into the protective guide [40.3614]. Mount the Ø4.5/250mm drill bit on the surgical drive and advance it through the drill guide. Drill the hole in the femur through first cortex only up to the hole in the nail.

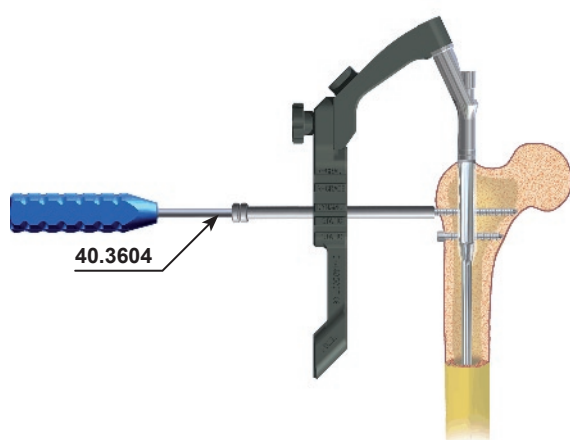
Remove the drill bit and drill guide.
Leave the protective guide in the hole of target.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



- 44** Introduce the screw length gauge **[40.1374]** through the protective guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the gauge scale B-D. During the measurement the end of the protective guide should rest on the cortex.

Remove the screw length gauge.
Leave the protective guide in the hole of target.



- 45** Introduce the tip of the screwdriver **[40.3604]** into the hexagonal socket of the selected locking screw. Then advance the both into the protective guide. Screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

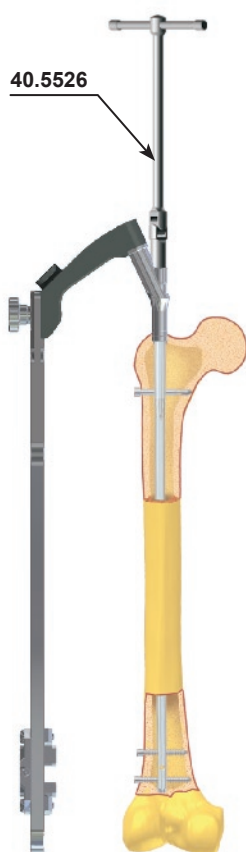
Remove the screwdriver and protective guide.



- 45a** In order to realize intraoperative compression, using screwdriver S3.5 **[40.3604]** drive the compression screw **[40.5096]** in the connecting screw M10x1, which join the intramedullary nail with arm target. While the compression screw tip meet the locking screw shank a sensible resistance occurs; from this moment further screwing in the compression screw will effect the fragments compression. The procedure should be performed under the control of X-ray image intensifier, monitoring the interfragmental fissure.

- 45b** In order to preserve fragments compression the nail can be statically fixed using the »STATIC« hole located distally to the »DYNAMIC« hole. In order to perform the above repeat the actions from steps 41-45.

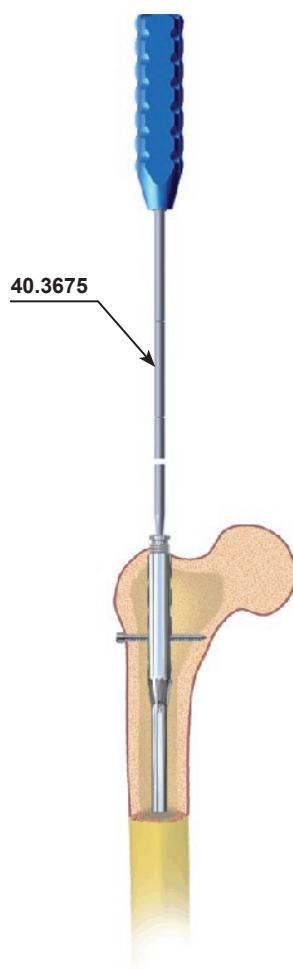
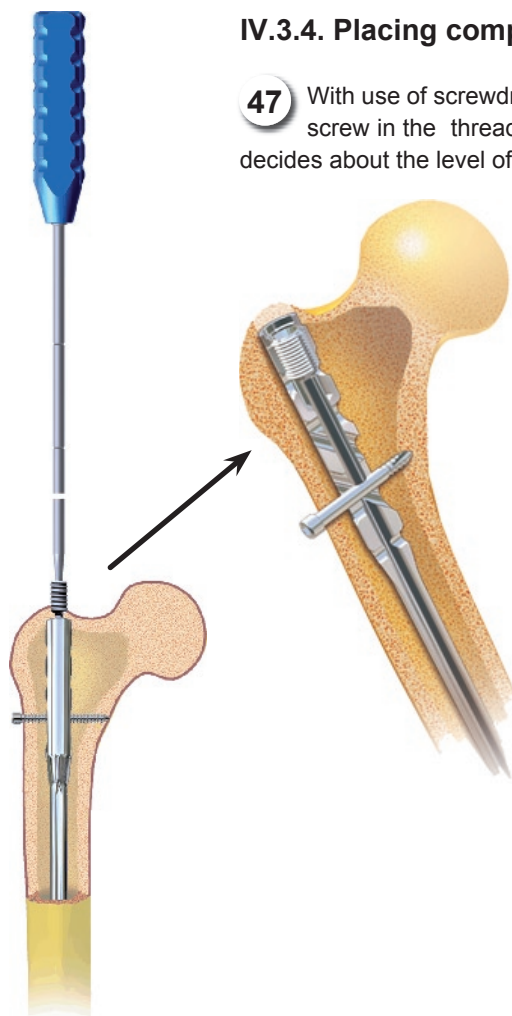
IV.3.3. Target removal



- 46** Using wrench S10 [40.5526] unscrew the connecting screw [40.5094] or [40.5095] out of the nail shaft and dismount the target from the nail locked in the medullary canal.

IV.3.4. Placing compression screw

- 47** With use of screwdriver [40.3604] screw the compression screw in the threaded hole in the nail shaft. The surgeon decides about the level of compression applied.



IV.3.5. Placing end cap (Applies to the dynamic method only)

- 48** In order to secure the inner thread of the nail from bone overgrowth, using the screwdriver [40.3675] screw in:
- the end cap [1.2104.3xx] or [3.2104.3xx] in case of universal nail usage;
 - the end cap [1.2104.4xx] or [3.2104.3xx] in case of compression nail usage.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.4. STATIC METHOD

IV.4.1. Distal locking of the nail

Before starting with steps connected with distal locking of the nail do the following:

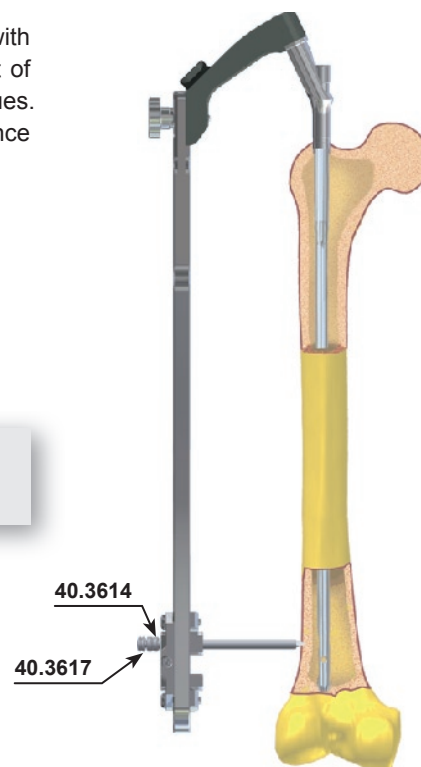
1. Mount distal target [40.5093] again on the arm of the proximal target [40.5091] and secure it with a lock-nut (included in proximal target).
If properly installed, the signs >>RIGHT<< or >>LEFT<< on both target should comply.
2. Verify with the image intensifier the position of holes in the nail and in target slider. The centers of the holes have to be in line.

- 49** Introduce the protective guide [40.3614] (with one groove on the handle) with trocar [40.3617] into the hole in the slider of distal target D. Mark the point of entry of the locking screw on the skin and make adequate incision through soft tissues. Advance trocar until it reaches cortex and mark the entry point for the drill. Advance protective guide together with the trocar until it.

Remove trocar.

Leave the protective guide in the hole of slider.

NOTE! For the rest of the procedure follow the steps 26 to 32, from page 30 to 31.



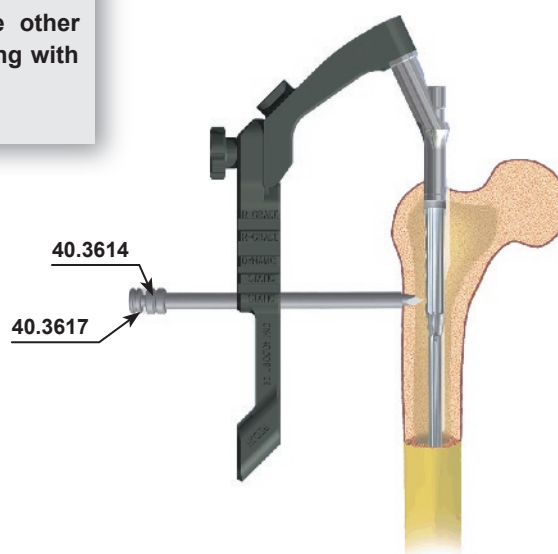
IV.4.2. Proximal locking of the nail

Important note! In static method of femoral fixation with use of intramedullary nail, from the two holes in proximal target [40.5097] marked >>COMPRESSION<< use only one, distal hole. The other hole (proximal hole) may be used for additional locking with second locking screw.

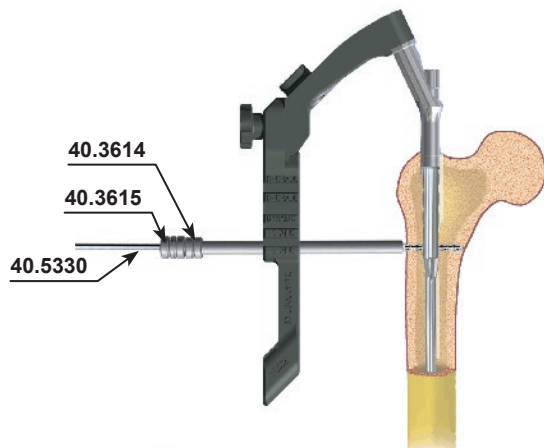
- 50** Introduce the protective guide [40.3614] (with one groove on the handle) with trocar [40.3617] into the distal hole in proximal target. Mark the point of entry of the locking screw on the skin and make adequate incision through soft tissues, 1.5cm in length. Advance trocar until it reaches cortex and mark the entry point for the drill. Advance protective guide together with the trocar until it touches the cortex.

Remove trocar.

Leave the protective guide in the hole of target.

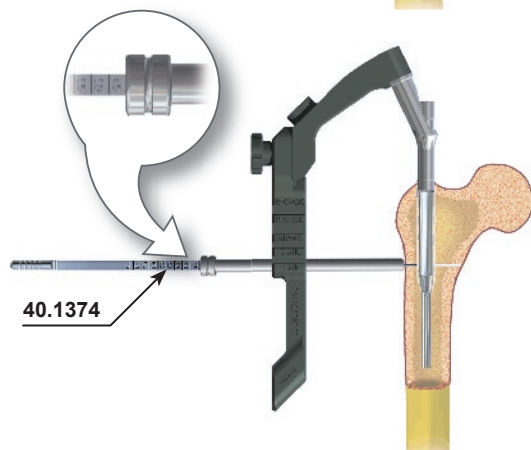


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



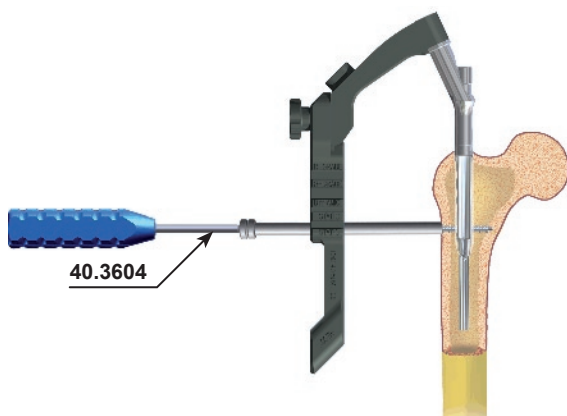
- 51** Introduce the Ø3.5mm drill guide [40.3615] (with two grooves) into the protective guide [40.3614]. Mount the Ø3.5/250mm drill bit [40.5330] on the surgical drive and advance it through the drill guide. The scale on the drill shows length of the locking element. Drill the hole in the femur through both cortex layers and the hole in the nail.

Remove the drill bit and drill guide.
Leave the protective guide in the hole of target.



- 52** Introduce the screw length gauge [40.1374] through the protective guide [40.3614] into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the gauge scale B-D. During measurement the end of the protective guide should rest on the cortex.

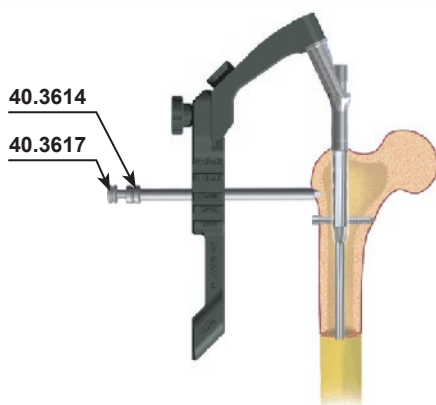
Remove the screw length gauge.



- 53** Leave the protective guide in the hole of target. Introduce the tip of the screwdriver [40.3604] into the hexagonal socket of the selected locking screw. Then advance the both into the protective guide. Screw the locking screw in the prepared hole until the head of the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver and protective guide.

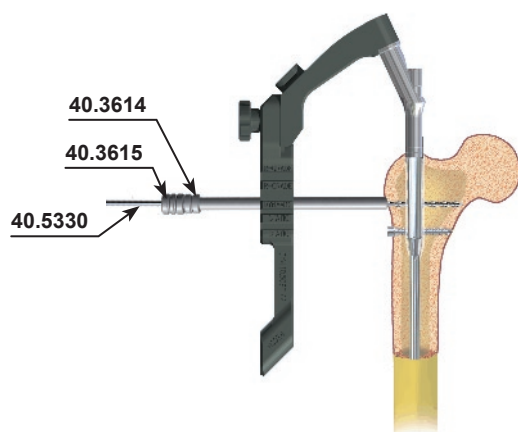
NOTE! If surgeon decides to lock the nail in the proximal part with two screws, insertion of second screw should be performed as shown in steps [50] to [53]. Otherwise omit these steps.



- 54** Introduce the protective guide [40.3614] (with one groove on the handle) with trocar [40.3617] into the proximal hole in proximal target. Mark the point of entry of the locking screw on the skin and make adequate incision through soft tissues. Advance trocar until it reaches cortex and mark the entry point for the drill. Advance protective guide together with the trocar until it touches the bone.

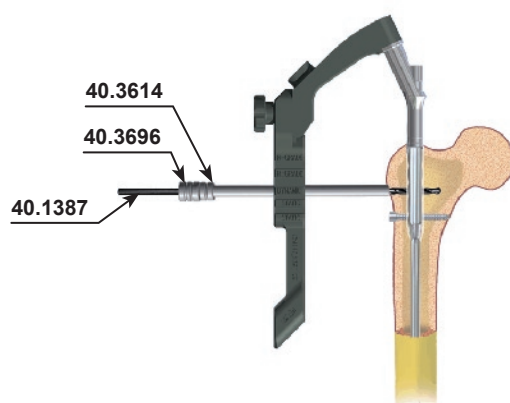
Remove trocar.
Leave the protective guide in the hole of target.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



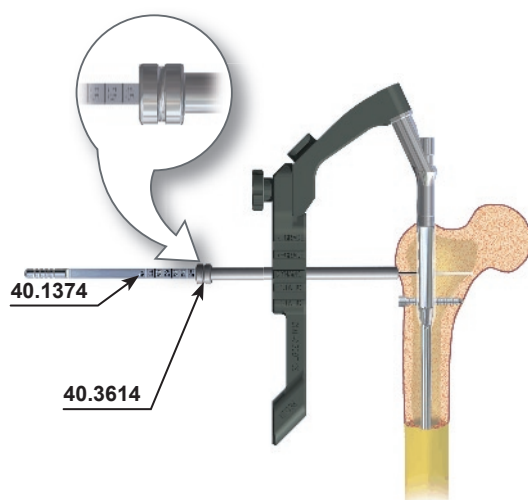
- 55** Introduce the Ø3.5mm drill guide **[40.3615]** (with two grooves) into the protective guide. Mount the Ø3.5/250 mm drill bit **[40.5330]** on the surgical drive and advance it through the drill guide. The scale on the drill shows length of the locking element. Drill the hole in the femur through both cortex layers and the hole in the nail.

Remove the drill bit and drill guide.
Leave the protective guide in the hole of target.



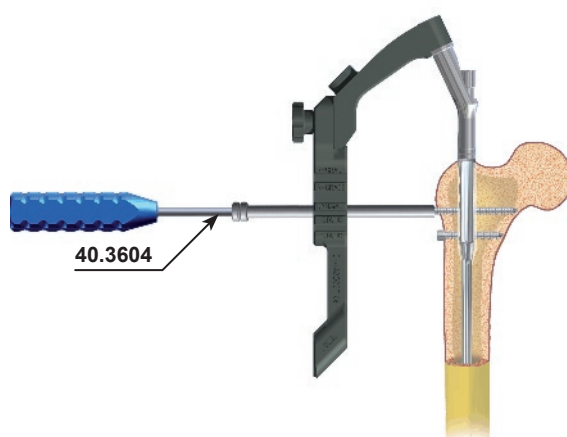
- 56** Introduce the Ø4.5mm drill guide **[40.3696]** (with three grooves) into the protective guide. Mount the Ø4.5/250mm drill bit **[40.1387]** on the surgical drive and advance it through the drilling guide. Drill the hole in the femur through first cortex only up to the hole in the nail.

Remove the drill bit and drill guide.
Leave the protective guide in the hole of target.



- 57** Introduce the screw length gauge **[40.1374]** through the protective guide **[40.3614]** into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the gauge scale B-D. During measurement the end of the protective guide should rest on the cortex.

Remove the screw length gauge.
Leave the protective guide in the hole of target.



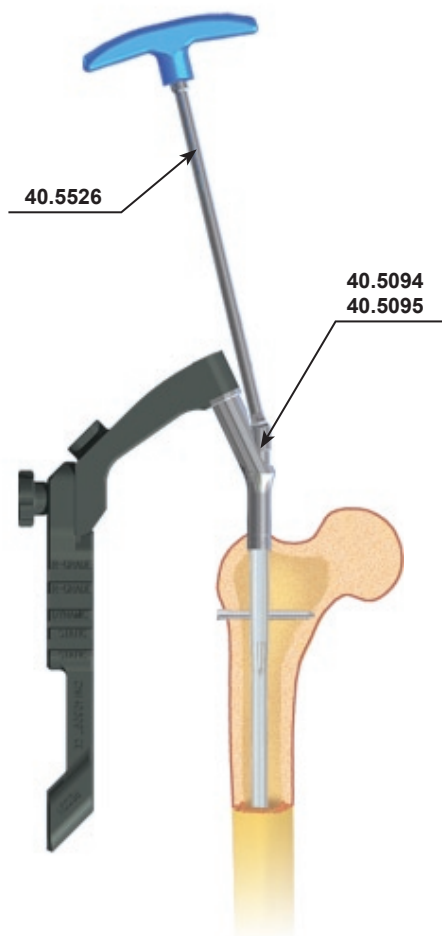
- 58** Introduce the tip of the screwdriver **[40.3604]** into the hexagonal socket of the selected locking screw. Then advance the both into the protective guide. Screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver and protective guide.

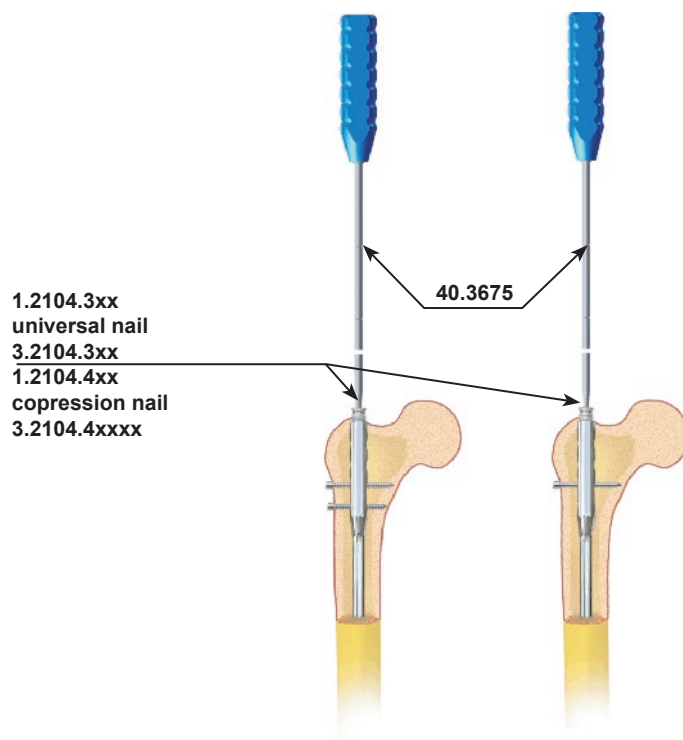
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.4.3. Target removal, placing end cap

- 59** Using wrench S10 [40.5526] unscrew the connecting screw [40.5094] or [40.5095] out of the nail shaft and dismount the target from the nail locked in the medullary canal.



- 60** In order to secure the inner thread of the nail from bone overgrowth, using the screwdriver [40.3675] screw in:
- the end cap [1.2104.3xx] or [3.2104.3xx] in case of universal nail usage;
 - the end cap [1.2104.4xx] or [3.2104.4xx] in case of compression nail usage.



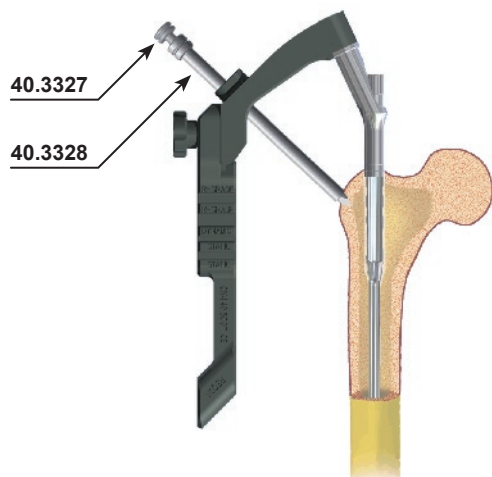
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.5. STATIC METHOD WITH USE OF RECONSTRUCTION NAIL

IV.5.1. Proximal locking of the nail

In the static method may use intramedullary reconstruction nails for fixation of femoral fragments, then:

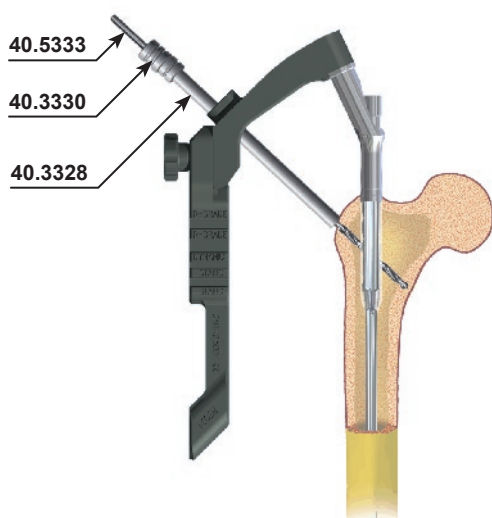
- right nail (market RIGHT) should be used for fixation of the left femur,
- left nail (market LEFT) should be used for fixation of the right femur.



- 61** Introduce the protective guide [40.3328] (with one groove on the handle) with trocar [40.3327] into the hole in proximal target [40.5091]. Mark the point of entry of the locking screw, make an adequate incision of the soft tissues. Advance the trocar until it reaches the cortex bone and mark the point of entry for the drill bit. Advance the protective guide together with the trocar until it touches the bone.

Remove the trocar.

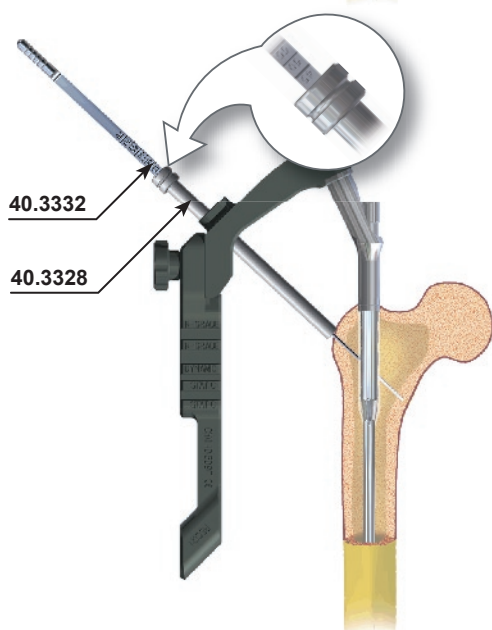
Leave the protective guide in the hole of target.



- 62** Introduce the drill guide Ø4.5mm [40.3330] (with two grooves) into the protective guide. Mount the Ø4.5/350mm drill bit [40.5333] on the surgical drive and advance it through the drill guide. Drill the hole in the femur through the both cortex layers and the hole in the nail.

Remove the drill bit and the drill guide.

Leave the protective guide in the hole of target.

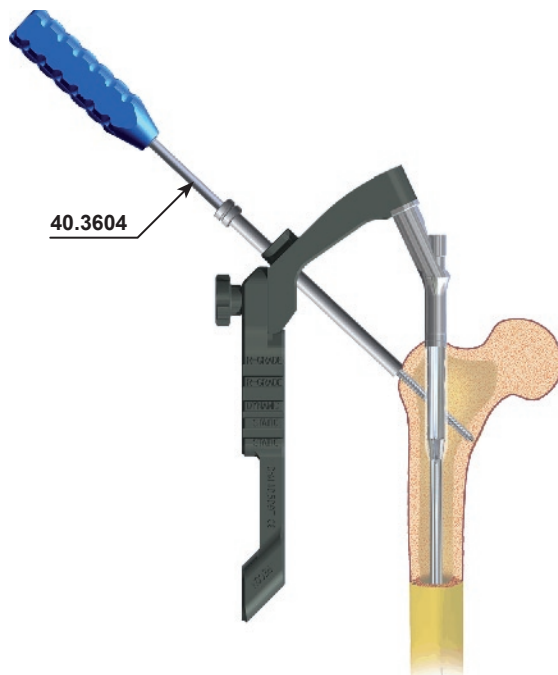


- 63** Introduce the reconstructive screw length gauge [40.3332] through the protective guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the reconstruction screw on the gauge. During measurement the end of the protective guide should rest on the cortex bone.

Remove the screw length gauge.

Leave the protective guide in the hole of target.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



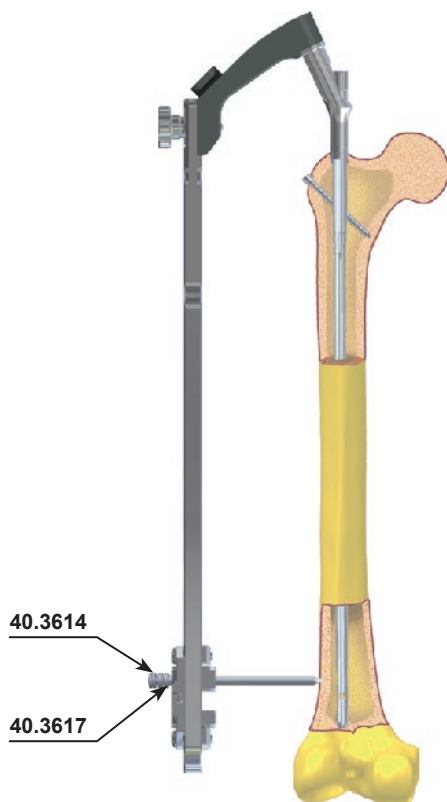
- 64** Introduce the tip of the screwdriver [40.3604] into the hexagonal socket of the selected locking screw. For locking use only a locking screw with 6,5mm diameter and length determined in previous step. Then advance the both into the protective guide. Screw the reconstructive screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver and protective guide.

IV.5.2. Distal locking of the nail

Before starting with steps connected with distal locking of the nail do the following:

1. Mount distal target [40.5093] again on the arm of the proximal target [40.5091] and secure it with a lock-nut (included in proximal target).
If properly installed, the signs >>RIGHT<< or >>LEFT<< on both target should comply.
2. Verify with the image intensifier the position of holes in the nail and in target slider. The centers of the holes have to be in line.



- 65** Introduce the protective guide [40.3614] (with one groove on the handle/ with trocar [40.3617] into the hole in the slider of distal target. Mark the point of entry of the locking screw on the skin and make adequate incision through soft tissues. Advance trocar until it reaches cortex and mark the entry point for the drill. Advance protective guide together with the trocar until it touches the cortex.

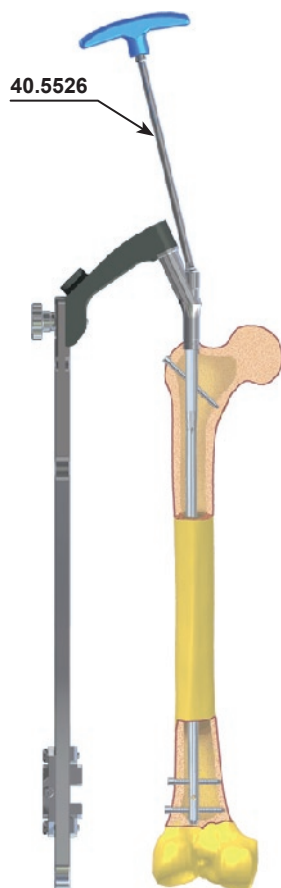
Remove trocar.

Leave the protective guide in the hole of slider of target.

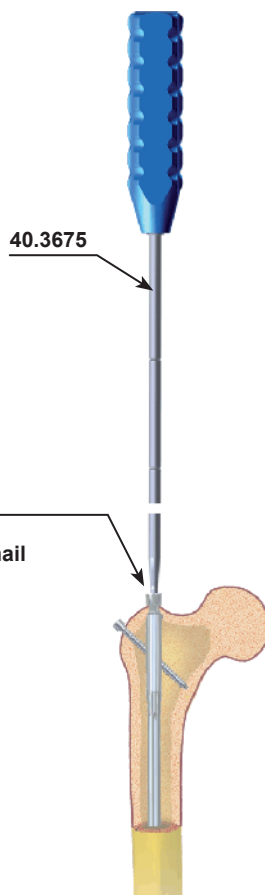
NOTE! For the rest of the procedure follow the steps [26] to [32] from page 30 to 31.

IV.5.3. Target removal, placing end cap

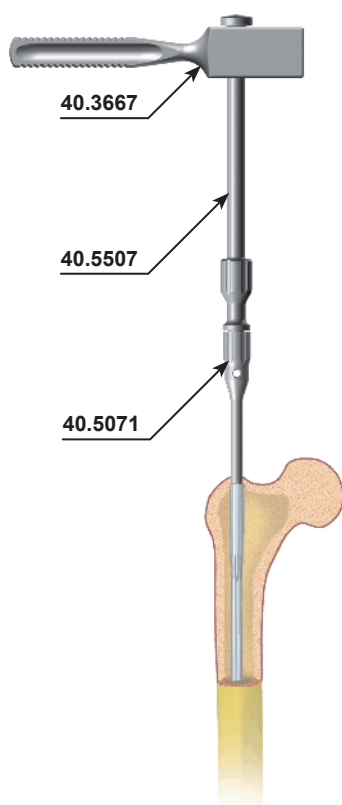
- 66** Using wrench S10 [40.5526] unscrew the connecting screw [40.5094] or [40.5095] out of the nail shaft and dismount the target from the nail locked in the medullary canal.



1.2104.3xx
universal nail
3.2104.3xx
1.2104.4xx
compression nail
3.2104.4xxxx



- 67** In order to secure the inner thread of the nail from bone overgrowth, using the screwdriver [40.3675] screw in:
- the end cap [1.2104.3xx] or [3.2104.3xx] in case of universal nail usage;
 - the end cap [1.2104.4xx] or [1.2104.3xx] in case of compression nail usage.



IV.6. NAIL EXTRACTION

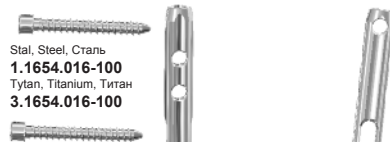
- 68** Use the screwdriver [40.3675] to remove the end cap and screwdriver [40.4604] to remove compression screw from the nail shaft. Screw the connector [40.5071] in to the threaded hole in the nail. Using the screwdriver [40.3604] unscrew all the locking screws. Attach the impactor-extractor [40.5507] to the connector and with help of mallet [40.3667] extract the nail from the medullary canal.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.7. SURGICAL TECHNIQUE - REVERSED METHOD (CONDYLAR APPROACH)

IV.7.a. Implants of reversed method

Metoda wsteczna
reverse method
ретроградный метод



Stal, Steel, Сталь
1.1654.016-100
Tytan, Titanium, Титан
3.1654.016-100

Stal, Steel, Сталь
1.2109.050-090
Tytan, Titanium, Титан
3.2109.050-090



либо





Stal
1.2104.002
Tytan
3.2104.002

Śruba zaślepiająca M10x1
End cap M10x1
Винт слепой M10x1

dostępne
available
доступные

Ø[mm]	8 + 19	8 + 19
skok, pitch, шаг 1 mm		
L [mm]	240 + 600	240 + 600
skok, pitch, шаг 5 mm		

		STAL, Steel, Сталь				TYTAN, Titanium, Титан						STAL, Steel, Сталь				TYTAN, Titanium, Титан			
L [mm]	Ø	lewý, left левый	prawy, right правый	lewý, left левый	prawy, right правый	L [mm]	Ø	lewý, left левый	prawy, right правый	lewý, left левый	prawy, right правый	L [mm]	Ø	lewý, left левый	prawy, right правый	lewý, left левый	prawy, right правый	lewý, left левый	prawy, right правый
200	9	1.2855.200	1.2854.200	3.2855.200	3.2854.200	200	12	1.2861.200	1.2860.200	3.2861.200	3.2860.200	200	13	1.2863.200	1.2862.200	3.2863.200	3.2862.200	3.2863.200	3.2862.200
220		1.2855.220	1.2854.220	3.2855.220	3.2854.220	220		1.2861.220	1.2860.220	3.2861.220	3.2860.220	220		1.2863.220	1.2862.220	3.2863.220	3.2862.220	3.2863.220	3.2862.220
240		1.2855.240	1.2854.240	3.2855.240	3.2854.240	240		1.2861.240	1.2860.240	3.2861.240	3.2860.240	240		1.2863.240	1.2862.240	3.2863.240	3.2862.240	3.2863.240	3.2862.240
260		1.2855.260	1.2854.260	3.2855.260	3.2854.260	260		1.2861.260	1.2860.260	3.2861.260	3.2860.260	260		1.2863.260	1.2862.260	3.2863.260	3.2862.260	3.2863.260	3.2862.260
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		STAL, Steel, Сталь		TYTAN, Titanium, Титан				STAL, Steel, Сталь		TYTAN, Titanium, Титан	
L [mm]	Ø	lewý, left левый	prawy, right, правый	lewý, left левый	prawy, right, правый	L [mm]	Ø	lewý, left левый	prawy, right, правый	lewý, left левый	prawy, right, правый
200	8	1.2877.200	1.2876.200	3.2877.200	3.2876.200	200	11	1.2883.200	1.2882.200	3.2883.200	3.2882.200
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340	1.2881.340		1.2880.340	3.2881.340	3.2880.340	340	1.2887.340	1.2886.340		3.2887.340	3.2886.340
360	13	1.2881.360	1.2880.360	3.2881.360	3.2880.360	360	16	1.2887.360	1.2886.360	3.2887.360	3.2886.360
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460		1.2881.460	1.2880.460	3.2881.460	3.2880.460	460		1.2887.460	1.2886.460	3.2887.460	3.2886.460
480		1.2881.480	1.2880.480	3.2881.480	3.2880.480	480		1.2887.480	1.2886.480	3.2887.480	3.2886.480

IV.7.1. Introduction

Reversed nailing of the femur provides fixation in cases with fracture above the knee joint (up to 20cm from distal end of femur) or multi-fragment fractures of condyle. The reverse nail may also be used when a hip prosthesis or other implant is already implanted in proximal femur.

CHARFIX system provides reversed nails with diameters Ø10, 11 or 12mm and length between 160 and 440 mm. To lock the nail distally (by the knee joint) depending on the type of fracture one may use:

- two locking screws Ø6,5mm or,
- two locking sets.

There are five sizes of locking sets:

- 50, with range between 50 and 65 mm,
- 60, with range between 60 and 75 mm,
- 60, with range between 70 and 85 mm,
- 70, with range between 80 and 95 mm,
- 90, with range between 90 and 105 mm.

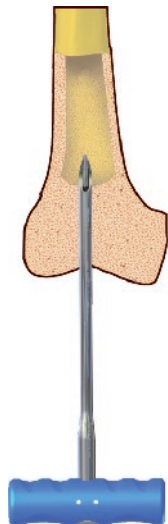
Locking set consists of a bolt, two washers and a locking screw. Locking screws are used to lock the nail proximally. The nail features anatomical shape - its distal end is 5° bent.

Each surgical procedure has to be precisely planned. Before the operation adequate x-rays have to be made in order to examine the type of fracture and assess the dimensions of implant needed (diameter and length). The operation should be performed on the patient in supine position, with tourniquet on and the knee joint bent 90°.

Nailing may be performed with or without reaming of medullary canal. In both cases the diameter of medullary canal ought to be bigger than the diameter of used nail; if canal is reamed its final diameter should be 1.5 to 2mm wider than the diameter of the nail. In both cases the canal has to be additionally reamed in distal part (entry point) with a Ø13.0 reamer at the distance of first 6cm (diameter of the nail in distal end is 12mm).

The following paragraphs describe most important steps during implantation of intramedullary interlocking femur nails nevertheless it is not a detailed instruction of use. The surgeon decides about choosing the surgical technique and its application in each individual case.

On the basis of x-rays of fractured femur and of the healthy one, the surgeon decides about the length and diameter of the nail.

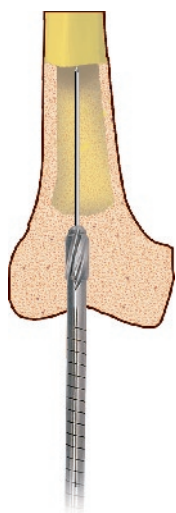
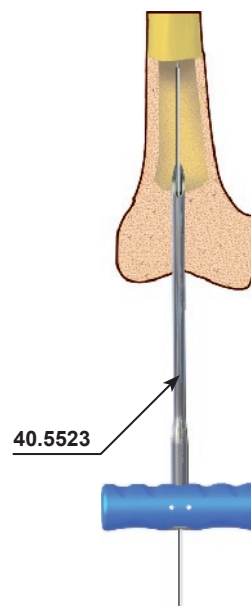


- 1 Make an incision over the middle of patellar ligament or more paracentrally. Expose intercondylar region (split the fibers of ligament or move it laterally). Open the medullary canal with curved awl [40.5523] at the depth of approx 6 cm.

Control this step with image intensifier.

- 2 Introduce the Kirschner wire [40.3925] with mounted handle guide rod [40.1351] and advance into the medullary canal.

Remove handle guide rod [40.1351].
Remove curved awl [40.5523]

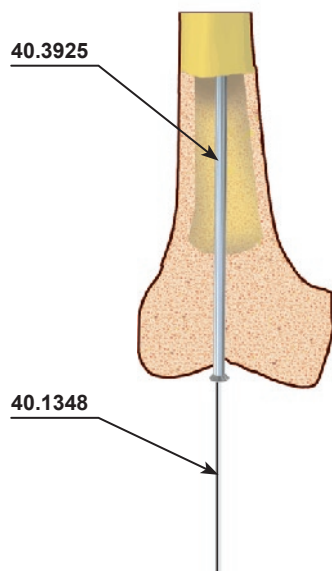


- 3 Introduce the guide wire of flexible reamers into the medullary canal until its tip reaches proximal epiphysis of femur. If medullary canal is reamed, gradually increase the diameter of canal with steps of 0.5mm, until one reaches the diameter 1.5 to 2.0mm wider than the diameter of the femoral nail, for the depth at least equal to the nail length (but not lesser). In both cases, ie. when the medullary canal was reamed or not, the canal should be reamed using Ø13 reamer to the depth of approx. 6cm.

Remove the flexible reamer.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

NOTE! Steps [4] and [5] are applicable only if the medullary canal has been reamed before nailing. If the medullary canal is not reamed, ream the distal end of canal using Ø13 reamer to the depth of approx. 6cm. (as specified in [3]) and go directly to the step [6], omitting steps [4] and [5].

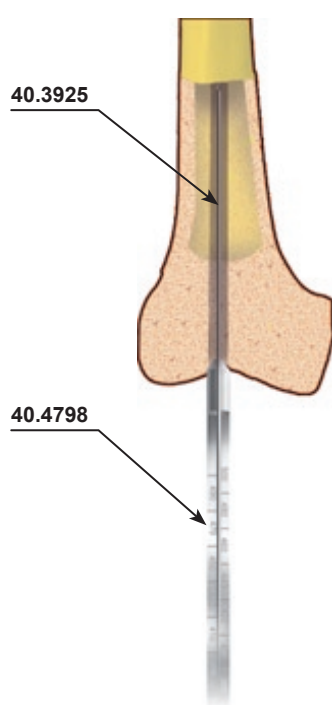
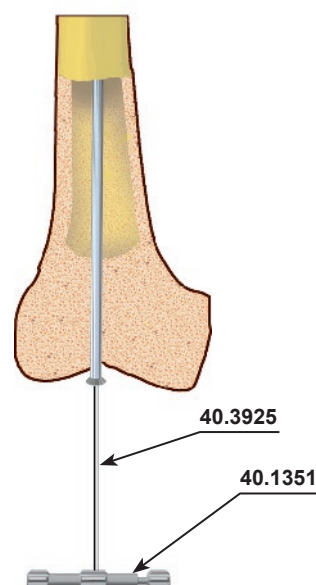


- 4 Introduce the teflon tube [40.1348] onto the flexible reamer guide left in the medullary canal.

Remove the flexible reamer guide.

- 5 Mount the handle guide rod [40.1351] on the guide rod [40.3925] and advance the rod into the teflon tube until its tip reaches the proximal epiphysis.

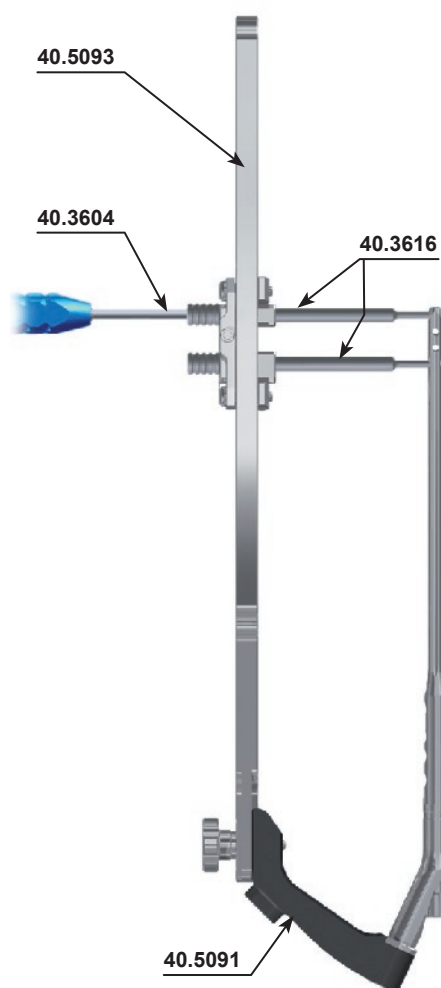
Remove the handle guide rod [40.1351] off the guide rod.
Remove the teflon tube [40.1348].



- 6 Nail length measuring gauge [40.4798] introduce on guide rod till it support on the bone. Read the meter on the nail measuring gauge to assess the length of intramedullary nail. Remove measuring gauge from the guide rod. In case of solid nail, remove guide rod from medullary canal. Medullary canal is ready for nail insertion.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.7.2. Nail assembling to the target, nail insertion into the medullary canal



- 7 Mount proximal target [40.5091] on the arm of the distal target [40.5093] and secure it with a lock-nut (included in distal target).

NOTE! When operating right limb the target should be connected so that the >>RIGHT<< signs on both are in line. In case of left limb - the >>LEFT<< signs on both are in line.

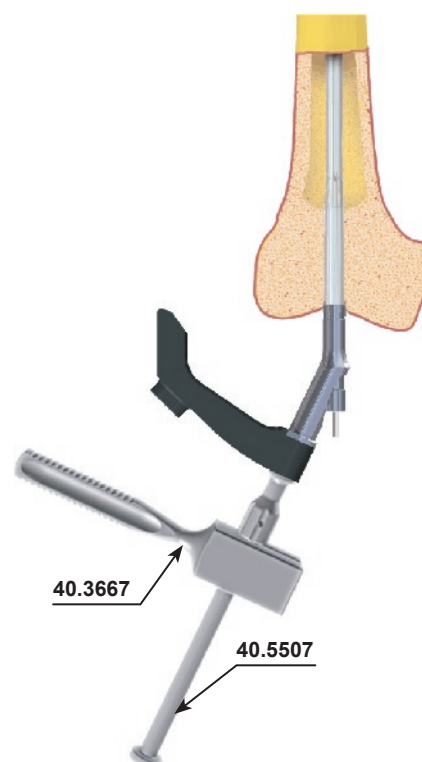
Using socket wrench [40.5526] fix the intramedullary nail to the distal target with connecting screw [40.5094]. With a pair of setting pins [40.3616] place the slider of proximal target in line with proximal locking holes of intramedullary nail. Secure the slider of the proximal target with hexagonal screwdriver [40.3604].

CHECK! Properly set and secured slider means that setting pins smoothly hitting the holes in the nail.

Remove the setting pins from the target.
Dismount the proximal target off the arm of distal target.

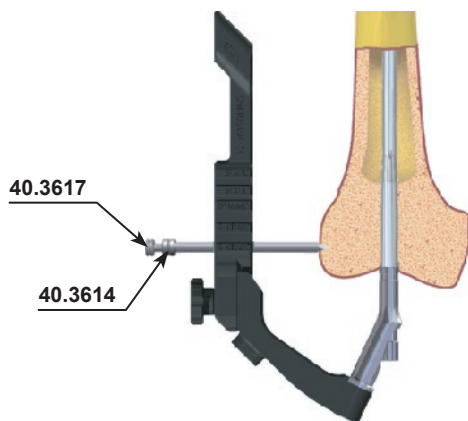
- 8 On the proximal target [40.5091] (with attached nail) screw down impactor-extractor [40.5507]. Introduce the intramedullary nail into the medullary canal via the guiding rod [40.3925]. Advance the nail (reducing the fracture) into the medullary canal until adequate depth is reached.

Remove the guide rod [40.3925].
Unscrew impactor-extractor [40.5507] off the target.



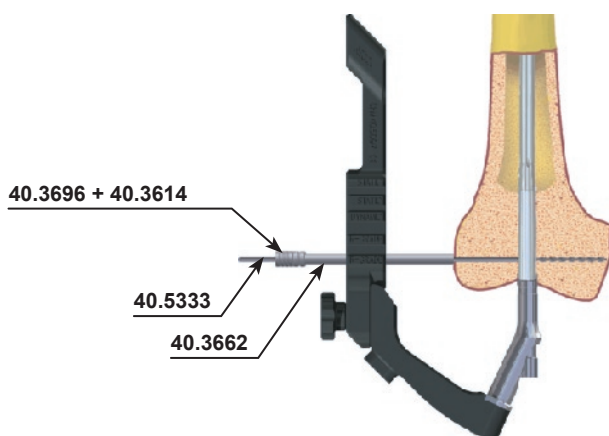
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.7.3. Distal locking of the nail



- 9** To the arm target [40.5091] fix distal target B [40.5097]. Introduce the protective guides [40.3614] and [40.3662] and trocar [40.3617] into target hole positioned in the most proximal. Mark the point of entry of the trocar, make an adequate incision of the soft tissues. Advance the trocar with protective guides until they reach the cortex bone. Mark with the trocar the point of entry for the drill bit.

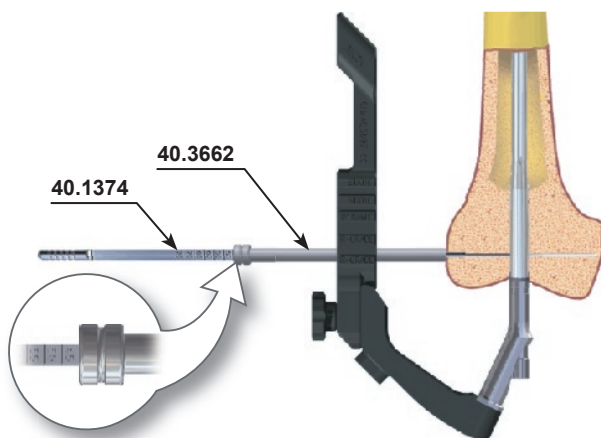
Remove the trocar.
Leave the protective guides in the hole of the target.



IV.7.3.a. **OPTION I** - Locking with screws

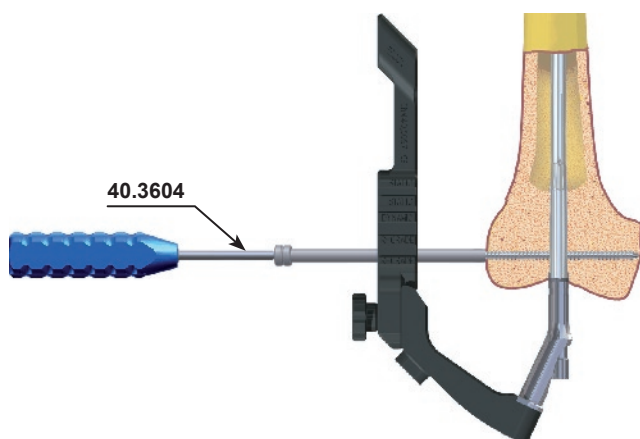
- 10** Introduce the drill guide Ø4.5mm [40.3696] into the protective guides [40.3662] + [40.3614]. Mount the Ø4.5/350mm drill bit [40.5333] on the surgical drive and advance it through the drill guide. Drill the hole for locking screw. The scale on the drill shows length of the locking element. Control drilling with image intensifier.

Remove the drill bit, drill guide [40.3696].
Leave the protective guide [40.3662] in the hole of the target.



- 11** Introduce the screw length gauge [40.1374] through the protective guide [40.3662] into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the needed locking screw on the gauge. During measurement the protective guide should rest on the cortex bone.

Remove the screw length gauge.
Leave the protective guide in the hole of the target.



- 12** Introduce the tip of the screwdriver [40.3604] into the hexagonal socket of the selected locking screw. Then advance the both into the protective guide. Screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver and protective guide.
For distal locking of the nail use locking screws with diameter 6.5mm.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.7.3.b. **OPTION II** - Locking with locking set (bolt - two washers - securing screw)

13 The drill guide [40.3614] and the protective guide [40.3662] are in the hole of target. Mount the Ø6.5/300mm drill bit [40.2068] on the surgical drive and advance it through the drill guide. Drill the hole throughout the bone. Control drilling with image intensifier. With help of image intensifier make incision of the soft tissues over the exit point of the drill.

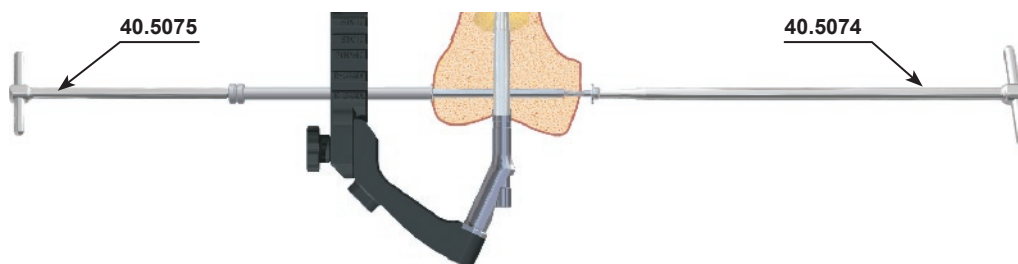
Remove the drill bit.
Leave protective guides on target.

14 Introduce the screw length gauge [40.1374] through the protective guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Deduct 10mm from the reading on the gauge, to get a characteristics of the locking set needed. Select locking set with adequate range, e.g. with reading "75" the characteristics amounts to "65", therefore locking set 60 with range between 60 and 75 mm is adequate. During measurement the protective guide should rest on the cortex bone.

Remove the screw length gauge.
Leave the protective guide in the hole of the target.

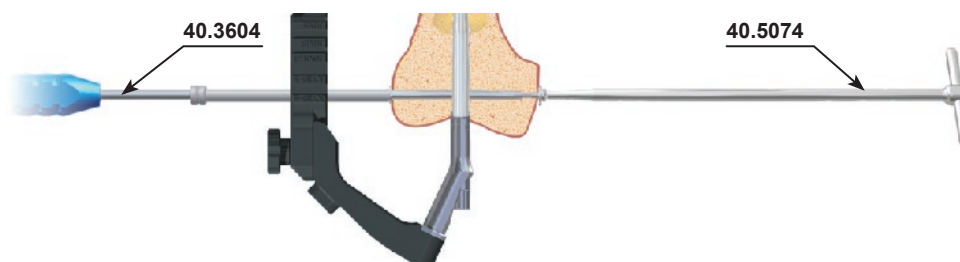
15 Introduce the bolt driver [40.5075] into the protective guide. The pilot [40.5075] which is integral part of the bolt driver, should be attached on the driver tip. Advance the driver through the drilled hole until its tip leaves the hole from the other side. Remove the pilot from the drivers tip. Put the bolt (implant) through the washer (implant) and screw it in onto the bolt driver using the screwdriver [40.5074]. Advance the bolt into the hole in the bone (head of the bolt should rest on the cortex with washer between).

Unscrew the bolt driver from the bolt and remove it from protective guide.



16 Introduce the tip of the screwdriver [40.3604] into the hexagonal socket of the securing screw (implant) and advance the both into the protective guide. Put the washer (implant) over the locking screw when it leaves the protective guide and enters the hole in the bone. Screw the locking screw in the threaded hole in the bolt (hold the bolt with the screwdriver). Two screwdrivers are used to secure the locking set (securing screw, two washers, bolt).

Remove the screwdrivers and protective guide.



NOTE! To secure second locking set for the other distal hole follow the steps [13] to [16].

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

IV.7.4. Proximal locking of the nail

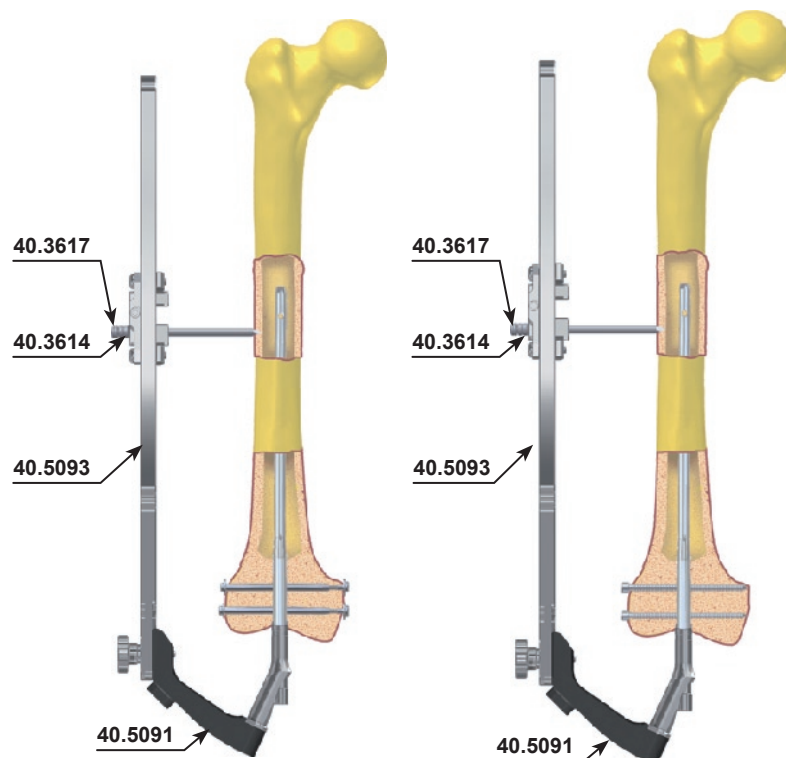
Before continuing with steps connected with proximal locking of the nail do the following:

1. Mount proximal target **[40.5091]** again on the arm of the distal target **[40.5093]** and secure it with a lock-nut (included in distal target).
If properly installed, the signs >>RIGHT<< or >>LEFT<< on both target should comply.
2. Verify with the image intensifier the position of holes in the nail and in target slider. The centers of the holes have to be in line.

- 17** Introduce the protective guide **[40.3614]** with trocar **[40.3617]** into the distal hole in the slider of proximal target. Mark the point of entry of the trocar, make an adequate incision of the soft tissues. Advance the trocar together with protective guide until it reaches the cortex bone. Using trocar mark the point of entry for the drill bit.

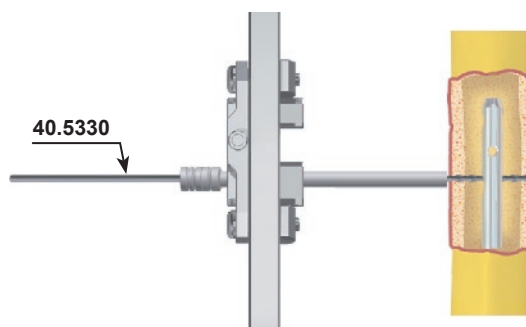
Remove the trocar.

Leave the protective guide in the hole of the target



- 18** Introduce the drill guide Ø3.5mm **[40.3615]** (with two grooves) into the protective guide **[40.3614]** left in the hole of the slider. Mount the Ø3.5/250mm drill bit **[40.5330]** on the surgical drive and advance it through the drill guide. The scale on the drill shows length of the locking element. Drill the hole in the femoral shaft through both cortex layers and the hole in the nail.

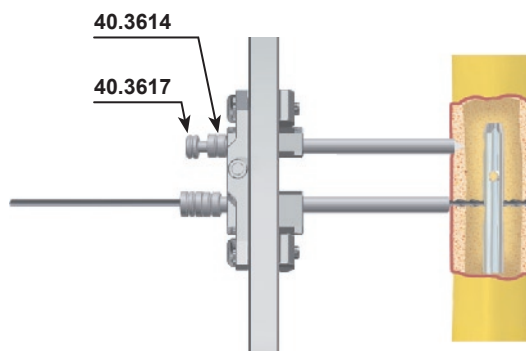
Disconnect the drive from the drill bit and leave in place system: protective guide - drill guide - drill bit.



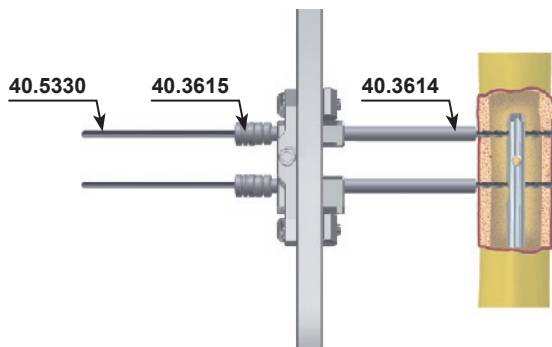
- 19** Introduce the protective guide **[40.3614]** (with one groove on the handle) with trocar **[40.3617]** into the second hole in the slider of proximal target. Advance the trocar until it reaches the cortex bone and mark the point of entry for the drill bit. Advance the protective guide together with the trocar until it touches the bone.

Remove the trocar.

Leave the protective guide in the hole of the slider.

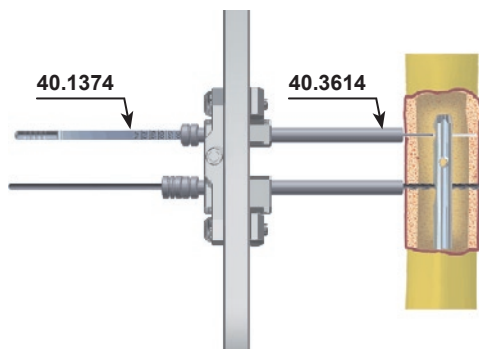


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



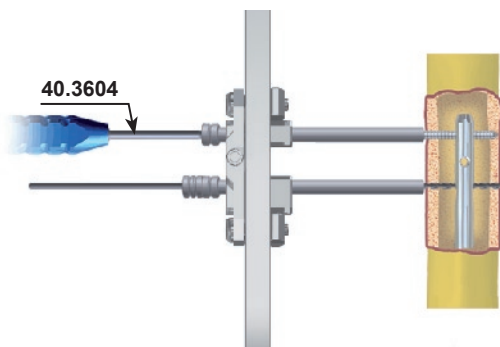
- 20** Introduce the drill guide Ø3.5mm [40.3615] (with two grooves) into the protective guide [40.3614]. Mount the Ø3.5/250mm drill bit [40.5330] on the surgical drive and advance it through the drill guide. The scale on the drill shows length of the locking element. Drill the hole in the femoral shaft through both cortex layers and the hole in the nail.

Remove the drill bit and drill guide.
Leave the protective guide in the hole of the slider.



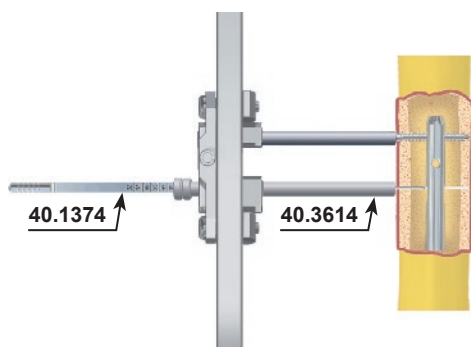
- 21** Introduce the screw length gauge [40.1374] through the protective guide [40.3614] into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the gauge B-D scale. During measurement the protective guide should rest on the cortex bone.

Remove the screw length gauge.
Leave the protective guide in the hole of the slider.



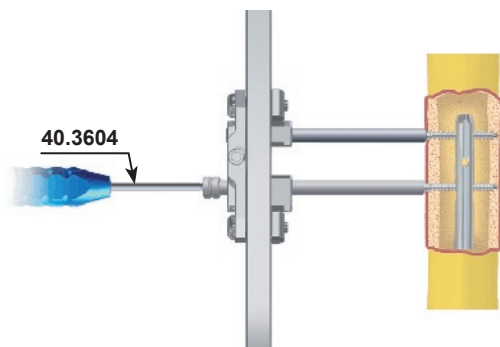
- 22** Introduce the tip of the screwdriver [40.3604] into the hexagonal socket of the selected locking screw. Then advance the both into the protective guide. Screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver and protective guide.



- 23** Remove the drill bit from distal hole in the slider of the target. Leave the protective guide in the hole of the slider. Introduce the screw length gauge [40.1374] through the protective guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the gauge B-D scale. During measurement the protective guide should rest on the cortex bone.

Remove the screw length gauge.



- 24** Introduce the tip of the screwdriver [40.3604] into the hexagonal socket of the selected locking screw. Then advance the both into the protective guide. Screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver and protective guide.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

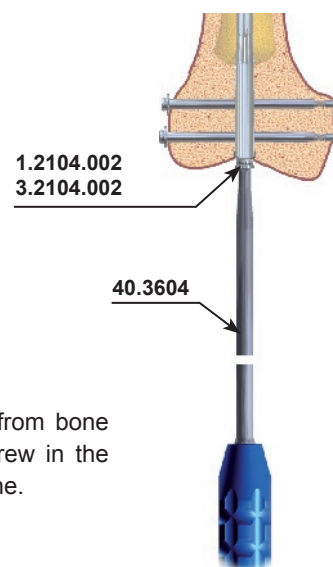
NOTE! Proximal locking of the nail may be also performed using freehand technique.
The procedure is described within reconstructive method. Refer to steps [35] to [38].

IV.7.5. Target removal and placing end cap



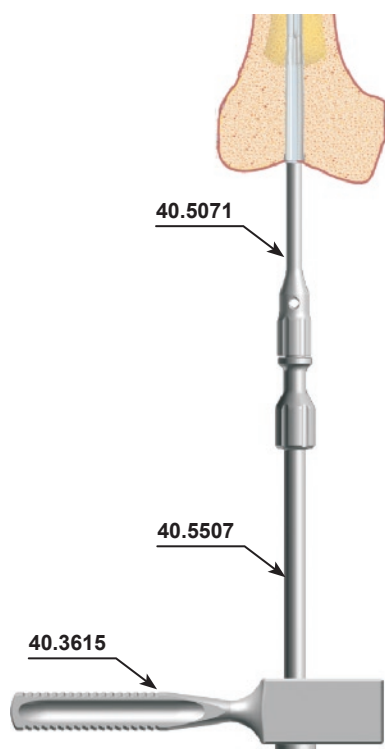
- 25** Using wrench S10 [40.5526] unscrew the connecting screw [40.5094] out of the nail shaft and dismount the target from the nail locked in the medullary canal.

Disassemble the target.



- 26** In order to secure the inner thread of the nail from bone overgrowth, using the screwdriver [40.3604] screw in the end cap [1.2104.002] or [3.2104.002] (implant) inside the.

IV.7.6. Nail extraction



- 27** Use the screwdriver [40.3604] to remove the end cap from the nail shaft. Using the screwdriver [40.3604] unscrew all the locking screws (use 2 screwdrivers to remove locking set). Using socket wrench screw the connector [40.5071] in to the threaded hole in the nail. Attach the extractor [40.5507] to the connector and using mallet [40.3667] extract the nail from the medullary canal.

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS



Instruments manufactured by ChM Ltd. are made of stainless steel, aluminium alloys and plastics for use in medicine according to obligatory procedures. Each medical instrument is exposed to the occurrence of corrosion, stains and damage, if not treated with due care and recommendations below.

1. Materials

Devices produced of corrosion-resistant steels. Thanks to high content of chromium the protective layer - passive layer is formed on the surface of the stainless steel, which layer protects the device against corrosion.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles for screwdrivers, awls, wrenches etc. By electrochemical surface treatment the protective oxide layer is formed on the aluminium surface, which may be dyed or a natural colour (silvery-grey). Devices made of aluminium with processed layer have a good corrosion resistance. Avoiding of contact with: strong alkaline cleaning and disinfecting agents, solutions containing iodine and some metal salts because of chemical interference on the processed aluminium surface.

Plastics used for devices manufacturing by ChM are mainly: POM-C (Polyoxymethylene Copolymer), PEEK (Polyetheretherketone) and teflon (PTFE). The above materials can be processed (washed, cleaned, sterilized) at temperatures no higher than 140°C, are stable in aqueous solution of washing-disinfection with pH values from 4 to 9.5.



If the material of the device can not be specified, please contact with a ChM company representative.

2. Disinfection and cleaning

Effective cleaning is a complicated procedure depending on the following factors: water quality, type and quality of detergent used, cleaning technique (manual/machine), suitable rinse and drying, the proper preparation of the instrument, time, temperature. It should also observe internal procedures of sterilizers, recommendations of cleaning and disinfection agents, recommendations for cleaning and sterilizing automatic machines.



Read and follow the instructions and restrictions specified by the manufactures of the agents used for disinfection and cleaning procedures.

1. Before first use, the product must be thoroughly washed in hot water with washing-disinfecting agents. Follow the instructions and restrictions specified by the manufactures of those products. It is recommended to use water solutions of cleaning-disinfection agents with a pH neutral.
2. After use, the product has to be immediately subjected to soaking for at least 10 minutes in an water solution of enzyme detergent with a pH neutral (with a disinfection properties) normally used for medical devices for multiple use (prevent the drying out of any organic remains on the product). Follow the instructions specified by the manufacturer of the detergent enzyme.
3. Carefully scrub/clean the surfaces and crevices of the product using a soft cloth without leaving threads or brushes made of plastic (preferred nylon brushes). It is forbidden to use metal brushes and made of hair or materials that could cause physical or chemical corrosion.
4. Next thoroughly rinse the instrument under warm running water, paying particular Uwaga to carefully rinsing of slots. During rinsing use cleaning brushes (nylon), make multiple moves back and forth on the surface of the product. In order to avoid water stains it is recommended to rinse in demineralized water. Use of the demineralized water to avoid corrosion caused by chlorides, found in ordinary water, and also to avoid forming of stains on the surface of such as anodized. During the rinsing manually remove the adherent remains.
5. Visually inspect the entire surface of the product to ensure that all contaminations were removed.



If human tissue remains, dirt or dust are still present, repeat the cleaning process.

6. Then subject the instrument to machine washing in a washer-disinfector (with washing-disinfecting agents suitable for medical tools and instruments for multiple use).



Procedure of washing with the washer-disinfector perform with an accordance to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions use for prepared by the washing-disinfection agents manufacturer.

3. Sterilization

Each time prior to sterilization procedure and usage of the device, it must be controlled: the device should be efficient, without toxic compounds as residue after disinfection and sterilization procedures, without structure damages (cracks, fractures, bending, peeling). Remember that sterilization do not substitute the cleaning process!



Devices made of plastics (PEEK, PTFE, POM-C) may be sterilized by any other available sterilization method validated in the centre, and the temperature of sterilization is not higher then 140°C.

Sterilization of surgical instruments has to be performed by usage of devices and in conditions according to current standards. The instruments should be sterilized in steam sterilizers in which the sterilizing agent is water vapour. Recommended parameters of steam sterilization: temperature min. 134°C, pressure of 2 atm.



Please strictly observe the above parameters of sterilization.

Validated sterilization methods are allowed. Durability and strength of instruments in a high degree depends on how they are used. Careful usage consistent with intended use of the product, protects against damage and prolongs its life.



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- 4F Intramedullary osteosynthesis of humerus**
- 6D Intermedullary osteosynthesis of femur trochanteric nails**
- 8D Dynamic Hip (DSB)/ Condylar (DSK) stabilizer**
- 9D Spine stabilization CHARSPINE**
- 15B Tibial and femoral angular set block**
- 20B Radial Head Prosthesis KPS**
- 22C Locking plates**
- 23C Intramedullary osteosynthesis of femur (reversed method) 40.3660**
- 24D Intramedullary osteosynthesis of femur 40.5060.000**
- 25B Intramedullary osteosynthesis of tibia 40.5000.100**
- 28C Intramedullary osteosynthesis of femur by trochanteric nail - ChFN**
- 30C Proximal humeral plate**
- 32C 4.0 ChLP plates for distal part of radial bone**
- 35B Spine stabilization (6mm)**
- 36B ChLP screws removing**

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