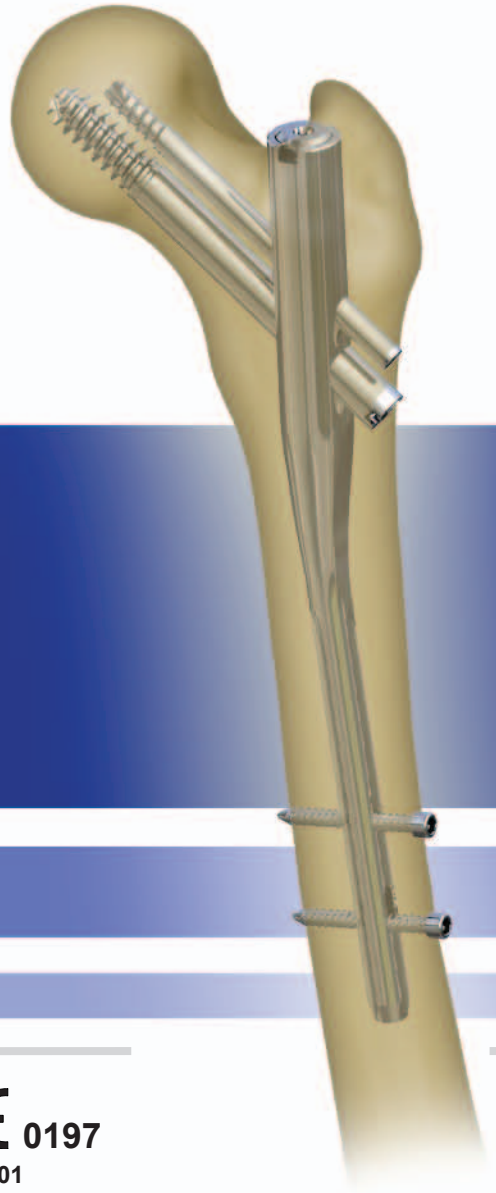
instruction

INTERMEDULLARY OSTEOSYNTHESIS OF FEMUR BY TROCHANTERIC NAILS

IMPLANTS
INSTRUMENT SET
SURGICAL TECHNIQUE



CHARFIX system

6D

CE 0197
ISO 9001
ISO 13485

ChM®

Edition 6D dated 04.05.2010, reviewed 02.08.2010

I. INTRODUCTION

CHARFIX system – INTRAMEDULLARY OSTEOSYTHESIS OF FEMUR BY TROCHANTERIC NAILS consists of:
• implants (intramedullary nail, join screws, locking screws, end cap),
• instrument set for implants insertion and removal after finished treatment,
• instruction for use.

Intramedullary osteosynthesis of femur by trochanteric nails provides stable fragments fixation of the peritrochanter part of the femur. Application of two join screws provides protection against femur neck rotation.

Indication for use:
• intertrochanteric fractures,
• transtrochanteric fractures,
• subtrochanteric fractures.

Examples of femur fractures treated with trochanter nails.

Good results are obtained in case of:
• pathological damages (one-place) as well as ipsilateral by the intertrochanter area,
• pathological damages (one-place) as well as ipsilateral of femur shaft.

Additionally good results are obtained in case of:
• multifragmental fractures of trochanter – subtrochanter area,
• basic fractures of femur neck.

II. IMPLANTS

System includes implants as follows:
• trochanteric solid nails with diameter 8÷16 (graded 1mm) and length from 200÷600mm (graded 5mm),
• locking screws 4.5,
• end cup M8,
• join screws 11,
• anti-rotary pin 6.5,
• compressive screw (locking option with one join screw).

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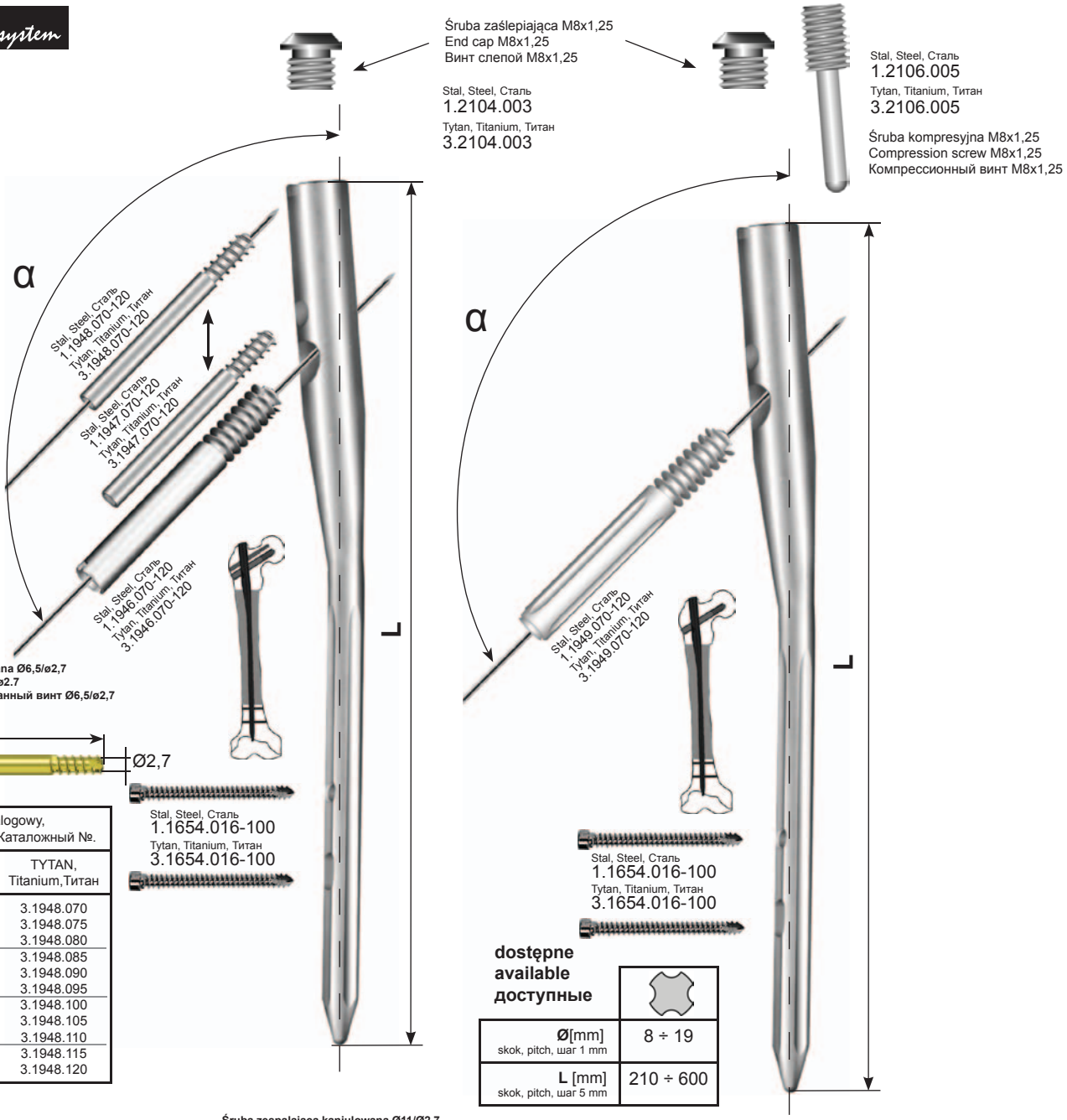
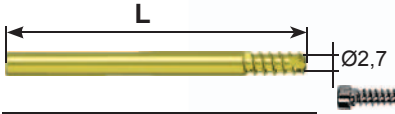
CHARFIX system



Śruba zespalająca kaniulowana Ø6,5/ø2,7
Join cannulated screw Ø6.5/ø2.7
Фиксационный канюлированный винт Ø6,5/ø2,7

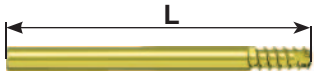


L	Nr katalogowy, Catalogue no., Каталожный №.	
	Stal, Steel, Сталь	TYTAN, Titanium,Титан
70	1.1948.070	3.1948.070
75	1.1948.075	3.1948.075
80	1.1948.080	3.1948.080
85	1.1948.085	3.1948.085
90	1.1948.090	3.1948.090
95	1.1948.095	3.1948.095
100	1.1948.100	3.1948.100
105	1.1948.105	3.1948.105
110	1.1948.110	3.1948.110
115	1.1948.115	3.1948.115
120	1.1948.120	3.1948.120

dostępne
available
доступные

Ø[mm] skok, pitch, шаг 1 mm	8 ÷ 19
L [mm] skok, pitch, шаг 5 mm	210 ÷ 600

Śruba zespalająca Ø6,5
Join screw Ø6.5
Фиксационный винт Ø6,5



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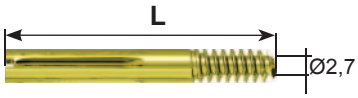
75	1.1947.075	3.1947.075
80	1.1947.080	3.1947.080
85	1.1947.085	3.1947.085
90	1.1947.090	3.1947.090
95	1.1947.095	3.1947.095
100	1.1947.100	3.1947.100
105	1.1947.105	3.1947.105
110	1.1947.110	3.1947.110
115	1.1947.115	3.1947.115
120	1.1947.120	3.1947.120

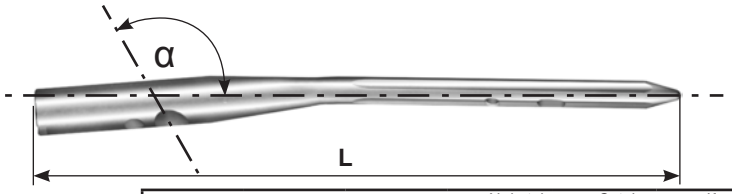
Śruba zespalająca kaniulowana Ø11/Ø2,7
Join cannulated screw Ø11/Ø2.7
Фиксационный канюлированный винт Ø11/Ø2,7

L	Nr katalogowy, Catalogue no., Каталожный №.	
	Stal, Steel, Сталь	TYTAN, Titanium,Титан
70	1.1946.070	3.1946.070
75	1.1946.075	3.1946.075
80	1.1946.080	3.1946.080
85	1.1946.085	3.1946.085
90	1.1946.090	3.1946.090
95	1.1946.095	3.1946.095
100	1.1946.100	3.1946.100
105	1.1946.105	3.1946.105
110	1.1946.110	3.1946.110
115	1.1946.115	3.1946.115
120	1.1946.120	3.1946.120

Śruba zespalająca kaniulowana Ø11/Ø2,7
Join cannulated screw Ø11/Ø2.7
Фиксационный канюлированный винт Ø11/Ø2,7



L	Nr katalogowy, Catalogue no., Каталожный №.	
	Stal, Steel, Сталь	TYTAN, Titanium, Титан
70	1.1949.070	3.1949.070
75	1.1949.075	3.1949.075
80	1.1949.080	3.1949.080
85	1.1949.085	3.1949.085
90	1.1949.090	3.1949.090
95	1.1949.095	3.1949.095
100	1.1949.100	3.1949.100
105	1.1949.105	3.1949.105
110	1.1949.110	3.1949.110
115	1.1949.115	3.1949.115
120	1.1949.120	3.1949.120



Zalecane Suggested Рекомендуемые

		Nr katalogowy, Catalogue no., Каталожный №.									
		Stal, Steel, Сталь					Tytan, Titanium, Титан				
α	L	ø10	ø11	ø12	ø13	ø14	ø10	ø11	ø12	ø13	ø14
120°	200	1.4996.200	1.4997.200	1.4998.200	1.4999.200	1.5000.200	3.4996.200	3.4997.200	3.4998.200	3.4999.200	3.5000.200
	220	1.4996.220	1.4997.220	1.4998.220	1.4999.220	1.5000.220	3.4996.220	3.4997.220	3.4998.220	3.4999.220	3.5000.220
	240	1.4996.240	1.4997.240	1.4998.240	1.4999.240	1.5000.240	3.4996.240	3.4997.240	3.4998.240	3.4999.240	3.5000.240
	260*	1.4996.260	1.4997.260	1.4998.260	1.4999.260	1.5000.260	3.4996.260	3.4997.260	3.4998.260	3.4999.260	3.5000.260
	280*	1.4996.280	1.4997.280	1.4998.280	1.4999.280	1.5000.280	3.4996.280	3.4997.280	3.4998.280	3.4999.280	3.5000.280
125°	200	1.2257.200	1.2258.200	1.2259.200	1.2284.200	1.2287.200	3.2257.200	3.2258.200	3.2259.200	3.2284.200	3.2287.200
	220	1.2257.220	1.2258.220	1.2259.220	1.2284.220	1.2287.220	3.2257.220	3.2258.220	3.2259.220	3.2284.220	3.2287.220
	240	1.2257.240	1.2258.240	1.2259.240	1.2284.240	1.2287.240	3.2257.240	3.2258.240	3.2259.240	3.2284.240	3.2287.240
	260*	1.2257.260	1.2258.260	1.2259.260	1.2284.260	1.2287.260	3.2257.260	3.2258.260	3.2259.260	3.2284.260	3.2287.260
	280*	1.2257.280	1.2258.280	1.2259.280	1.2284.280	1.2287.280	3.2257.280	3.2258.280	3.2259.280	3.2284.280	3.2287.280
130°	200	1.2260.200	1.2261.200	1.2262.200	1.2285.200	1.2288.200	3.2260.200	3.2261.200	3.2262.200	3.2285.200	3.2288.200
	220	1.2260.220	1.2261.220	1.2262.220	1.2285.220	1.2288.220	3.2260.220	3.2261.220	3.2262.220	3.2285.220	3.2288.220
	240	1.2260.240	1.2261.240	1.2262.240	1.2285.240	1.2288.240	3.2260.240	3.2261.240	3.2262.240	3.2285.240	3.2288.240
	260*	1.2260.260	1.2261.260	1.2262.260	1.2285.260	1.2288.260	3.2260.260	3.2261.260	3.2262.260	3.2285.260	3.2288.260
	280*	1.2260.280	1.2261.280	1.2262.280	1.2285.280	1.2288.280	3.2260.280	3.2261.280	3.2262.280	3.2285.280	3.2288.280
135°	200	1.2263.200	1.2264.200	1.2265.200	1.2286.200	1.2289.200	3.2263.200	3.2264.200	3.2265.200	3.2286.200	3.2289.200
	220	1.2263.220	1.2264.220	1.2265.220	1.2286.220	1.2289.220	3.2263.220	3.2264.220	3.2265.220	3.2286.220	3.2289.220
	240	1.2263.240	1.2264.240	1.2265.240	1.2286.240	1.2289.240	3.2263.240	3.2264.240	3.2265.240	3.2286.240	3.2289.240
	260*	1.2263.260	1.2264.260	1.2265.260	1.2286.260	1.2289.260	3.2263.260	3.2264.260	3.2265.260	3.2286.260	3.2289.260
	280*	1.2263.280	1.2264.280	1.2265.280	1.2286.280	1.2289.280	3.2263.280	3.2264.280	3.2265.280	3.2286.280	3.2289.280

* zamówienie specjalne · special order · специальный заказ

DŁUGI PRAWY, Right long, Длинный правый

Zalecane Suggested Рекомендуемые

		Nr katalogowy, Catalogue no., Каталожный №.									
		Stal, Steel, Сталь					Tytan, Titanium, Титан				
α	**L	ø10	ø11	ø12	ø13	ø14	ø10	ø11	ø12	ø13	ø14
120°	340	1.5010.340	1.5012.340	1.5014.340	1.5016.340	1.5018.340	3.5010.340	3.5012.340	3.5014.340	3.5016.340	3.5018.340
	360	1.5010.360	1.5012.360	1.5014.360	1.5016.360	1.5018.360	3.5010.360	3.5012.360	3.5014.360	3.5016.360	3.5018.360
	380	1.5010.380	1.5012.380	1.5014.380	1.5016.380	1.5018.380	3.5010.380	3.5012.380	3.5014.380	3.5016.380	3.5018.380
	400	1.5010.400	1.5012.400	1.5014.400	1.5016.400	1.5018.400	3.5010.400	3.5012.400	3.5014.400	3.5016.400	3.5018.400
	420	1.5010.420	1.5012.420	1.5014.420	1.5016.420	1.5018.420	3.5010.420	3.5012.420	3.5014.420	3.5016.420	3.5018.420
125°	340	1.2266.340	1.2268.340	1.2270.340	1.2290.340	1.2292.340	3.2266.340	3.2268.340	3.2270.340	3.2290.340	3.2292.340
	360	1.2266.360	1.2268.360	1.2270.360	1.2290.360	1.2292.360	3.2266.360	3.2268.360	3.2270.360	3.2290.360	3.2292.360
	380	1.2266.380	1.2268.380	1.2270.380	1.2290.380	1.2292.380	3.2266.380	3.2268.380	3.2270.380	3.2290.380	3.2292.380
	400	1.2266.400	1.2268.400	1.2270.400	1.2290.400	1.2292.400	3.2266.400	3.2268.400	3.2270.400	3.2290.400	3.2292.400
	420	1.2266.420	1.2268.420	1.2270.420	1.2290.420	1.2292.420	3.2266.280	3.2268.420	3.2270.420	3.2290.420	3.2292.420
130°	340	1.2272.340	1.2274.340	1.2276.340	1.2294.340	1.2296.340	3.2272.340	3.2274.340	3.2276.340	3.2294.340	3.2296.340
	360	1.2272.360	1.2274.360	1.2276.360	1.2294.360	1.2296.360	3.2272.360	3.2274.360	3.2276.360	3.2294.360	3.2296.360
	380	1.2272.380	1.2274.380	1.2276.380	1.2294.380	1.2296.380	3.2272.380	3.2274.380	3.2276.380	3.2294.380	3.2296.380
	400	1.2272.400	1.2274.400	1.2276.400	1.2294.400	1.2296.400	3.2272.400	3.2274.400	3.2276.400	3.2294.400	3.2296.400
	420	1.2272.420	1.2274.420	1.2276.420	1.2294.420	1.2296.420	3.2272.420	3.2274.420	3.2276.420	3.2294.420	3.2296.420
135°	340	1.2278.340	1.2280.340	1.2282.340	1.2298.340	1.2320.340	3.2278.340	3.2280.340	3.2282.340	3.2298.340	3.2320.340
	360	1.2278.360	1.2280.360	1.2282.360	1.2298.360	1.2320.360	3.2278.360	3.2280.360	3.2282.360	3.2298.360	3.2320.360
	380	1.2278.380	1.2280.380	1.2282.380	1.2298.380	1.2320.380	3.2278.380	3.2280.380	3.2282.380	3.2298.380	3.2320.380
	400	1.2278.400	1.2280.400	1.2282.400	1.2298.400	1.2320.400	3.2278.400	3.2280.400	3.2282.400	3.2298.400	3.2320.400
	420	1.2278.420	1.2280.420	1.2282.420	1.2298.420	1.2320.420	3.2278.420	3.2280.420	3.2282.420	3.2298.420	3.2320.420

DŁUGI LEWY, Left long, Длинный левый

Zalecane Suggested Рекомендуемые

		Nr katalogowy, Catalogue no., Каталожный №.									
		Stal, Steel, Сталь					Tytan, Titanium, Титан				
α	**L	ø10	ø11	ø12	ø13	ø14	ø10	ø11	ø12	ø13	ø14
120°	340	1.5011.340	1.5013.340	1.5015.340	1.5017.340	1.5019.340	3.5011.340	3.5013.340	3.5015.340	3.5017.340	3.5019.340
	360	1.5011.360	1.5013.360	1.5015.360	1.5017.360	1.5019.360	3.5011.360	3.5013.360	3.5015.360	3.5017.360	3.5019.360
	380	1.5011.380	1.5013.380	1.5015.380	1.5017.380	1.5019.380	3.5011.380	3.5013.380	3.5015.380	3.5017.380	3.5019.380
	400	1.5011.400	1.5013.400	1.5015.400	1.5017.400	1.5019.400	3.5011.400	3.5013.400	3.5015.400	3.5017.400	3.5019.400
	420	1.5011.420	1.5013.420	1.5015.420	1.5017.420	1.5019.420	3.5011.420	3.5013.420	3.5015.420	3.5017.420	3.5019.420
125°	340	1.2267.340	1.2269.340	1.2271.340	1.2291.340	1.2293.340	3.2267.340	3.2269.340	3.2271.340	3.2291.340	3.2293.340
	360	1.2267.360	1.2269.360	1.2271.360	1.2291.360	1.2293.360	3.2267.360	3.2269.360	3.2271.360	3.2291.360	3.2293.360
	380	1.2267.380	1.2269.380	1.2271.380	1.2291.380	1.2293.380	3.2267.380	3.2269.380	3.2271.380	3.2291.380	3.2293.380
	400	1.2267.400	1.2269.400	1.2271.400	1.2291.400	1.2293.400	3.2267.400	3.2269.400	3.2271.400	3.2291.400	3.2293.400
	420	1.2267.420	1.2269.420	1.2271.420	1.2291.420	1.2293.420	3.2267.280	3.2269.420	3.2271.420	3.2291.420	3.2293.420
130°	340	1.2273.340	1.2275.340	1.2277.340	1.2295.340	1.2297.340	3.2273.340	3.2275.340	3.2277.340	3.2295.340	3.2297.340
	360	1.2273.360	1.2275.360	1.2277.360	1.2295.360	1.2297.360	3.2273.360	3.2275.360	3.2277.360	3.2295.360	3.2297.360
	380	1.2273.380	1.2275.380	1.2277.380	1.2295.380	1.2297.380	3.2273.380	3.2275.380	3.2277.380	3.2295.380	3.2297.380
	400	1.2273.400	1.2275.400	1.2277.400	1.2295.400	1.2297.400	3.2273.400	3.2275.400	3.2277.400	3.2295.400	3.2297.400
	420	1.2273.420	1.2275.420	1.2277.420	1.2295.420	1.2297.420	3.2273.420	3.2275.420	3.2277.420	3.2295.420	3.2297.420
135°	340	1.2279.340	1.2281.340	1.2283.340	1.2299.340	1.2321.340	3.2279.340	3.2281.340	3.2283.340	3.2299.340	3.2321.340
	360	1.2279.360	1.2281.360	1.2283.360	1.2299.360	1.2321.360	3.2279.360	3.2281.360	3.2283.360	3.2299.360	3.2321.360
	380	1.2279.380	1.2281.380	1.2283.380	1.2299.380	1.2321.380	3.2279.380	3.2281.380	3.2283.380	3.2299.380	3.2321.380
	400	1.2279.400	1.2281.400	1.2283.400	1.2299.400	1.2321.400	3.2279.400	3.2281.400	3.2283.400	3.2299.400	3.2321.400
	420	1.2279.420	1.2281.420	1.2283.420	1.2299.420	1.2321.420	3.2279.420	3.2281.420	3.2283.420	3.2299.420	3.2321.420

**** dostępne są gwoździe o długości do 600 mm · available up to 600 mm · доступные стержени до 600 мм**

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tel. +48 85 713-13-20÷25 fax +48 85 713-13-19 e-mail: chm@chm.eu

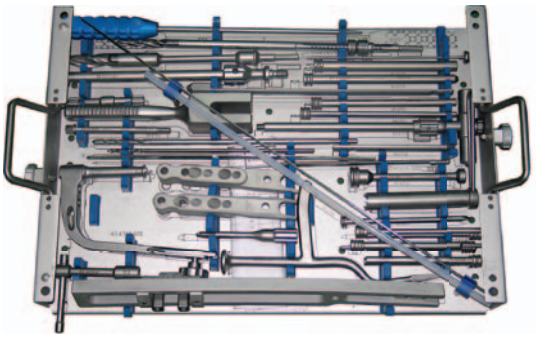
III. INSTRUMENT SET

CHARFIX system

Instrument set **[40.4700.000]** is used for peritrochanter fractures of the femur fixation and implants removal after finished treatment. All instruments are placed in a stand with a lid which enables sterilization and transport to the operating suite.

Instrument set consists of:

Lp. No. №	Nr katalogowy, Catalogue no., Каталожный №	Nazwa	Name	Название	Szt. Pcs Шт.
1	40.4701	Ramię celownika	Arm target	Плечо целенаправителя	1
2	40.4703	Śruba łącząca M8x1,25	Connecting screw M8x1.25	Винт соединительный M8x1,25	1
3	40.4707	Celownik 120°/130°	Target 120°/130°	Целенаправитель 120°/130°	1
4	40.4708	Celownik 125°/135°	Target 125°/135°	Целенаправитель 125°/135°	1
5	40.4710	Łącznik wybijaka M8/M12	Connector M8/M12	Соединитель M8/M12	1
6	40.4711	Prowadnica ochronna 20,0/17,0	Protective guide 20.0/17.0	Направитель-протектор 20,0/17,0	1
7	40.4712	Prowadnica 17,0/2,5	Guide 17.0/2.5	Направитель 17,0/2,5	1
8	40.4713	Trokar 2,5	Trocar 2.5	Троакар 2,5	1
9	40.4714	Gwóźdź prowadzący Kirschnera 2,5/350	Kirschner wire 2.5/350	Спица Киршнера 2,5/350	1
10	40.4715	Wiertło kaniulowane 17,0	Cannulated drill 17.0	Сверло с канюлированное 17,0	1
11	40.4718	Prowadnica wiertła 13,0/11,0	Drill guide 13.0/11.0	Направитель сверла 13,0/11,0	1
12	40.4719	Prowadnica 11/2,5	Guide 11/2.5	Направитель 11/2,5	1
13	40.4721	Prowadnica wiertła 9,0/6,5	Drill guide 9.0/6.5	Направитель сверла 9,0/6,5	1
14	40.4722	Prowadnica 6,5/2,5	Guide 6.5/2.5	Направитель 6,5/2,5	1
15	40.4724	Wzorzec długości śrub kaniulowanych	Cannulated screw length measure	Измеритель длины канюлированных винтов	1
16	40.4725	Wiertło kaniulowane 6,5	Cannulated drill 6.5	Сверло с канюлированное 6,5	1
17	40.4727	Śrubokręt kaniulowany S4/2,7	Cannulated screwdriver S4/2.7	Отвертка канюлированная S4/2,7	1
18	40.4728	Wiertło kaniulowane 2-stopniowe 11/6,5	Cannulated drill 2-gradual 11/6.5	Сверло канюлированное 2-град. 11/6,5	1
19	40.4729	Klucz kompresyjny	Compression wrench	Ключ компрессионный	1
20	40.3614	Prowadnica ochronna 9/6,5	Protective guide 9/6.5	Направитель-протектор 9/6,5	2
21	40.3615	Prowadnica wiertła 6,5/3,5	Drill guide 6.5/3.5	Направитель сверла 6,5/3,5	2
22	40.3616	Ustawiak 9/4,5	Set block 9/4.5	Инструмент установочный 9/4,5	2
23	40.3617	Trokar 6,5	Trocar 6.5	Троакар 6,5	1
24	40.1374	Wzorzec długości wkrętów	Screw length measure	Измеритель длины винтов	1
25	40.3604	Śrubokręt S 3,5	Screwdriver S 3.5	Отвертка S 3,5	1
26	40.5330	Wiertło ze skalą 3,5/250	Drill with scale 3.5/250	Сверло с измерительной шкалой 3,5/250	2
27	40.3322	Celownik dalszy D	Distal target D	Целенаправитель дистальный	1
28	40.3326	Szydło kaniulowane 13	Cannulated awl 13	Шило канюлированное 13	1
29	40.3648	Klucz nasadowy S11	Socket wrench S11	Ключ торцовый S11	1
30	40.5070	Wbijak - wybijak	Impactor-extractor	Импактор-экстрактор	1
31	40.3667	Pobijak	Mallet	Пробойник	1
32	40.1348	Prowadnica rurkowa	Teflon pipe guide	Трубка-направитель	1
33	40.1351	Uchwyt drutu prowadzącego	Handle guide rod	Держатель направляющей проволоки	1
34	40.3673	Drut prowadzący 2,5/600	Guide rod 2.5/600	Проволока направляющая 2,5/600	1
35	40.4798	Miarka długości gwoździa	Nail length measure	Измеритель длины стержня	1
36	40.4740	Statyw	Stand	Подставка	1



40.4700

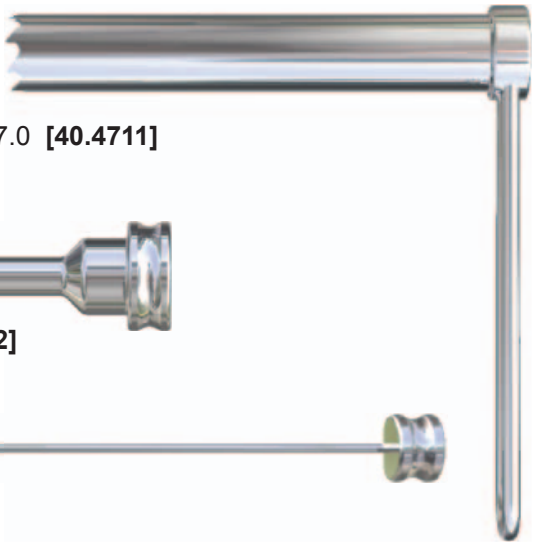
1. Arm target **[40.4701]**

2. Connecting screw M8x1. **[40.4703]**

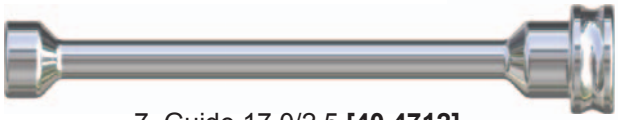
4. Target 120°/130° **[40.4707]**

3. Target 125°/ 135° **[40.4708]**

5. Connector M8/M12 **[40.4710]**



6. Protective guide 20.0/17.0 **[40.4711]**



7. Guide 17.0/2.5 **[40.4712]**

8. Trocar 2.5 **[40.4713]**

9. Kirschner wire **[40.4714]**

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10. Cannulated drill 17.0 **[40.4705]**

11. Drill guide 13.0/11.0 **[40.4718]**

12. Guide 13.0/2.5 **[40.4719]**

13. Drill guide 9/6.5 **[40.4721]**

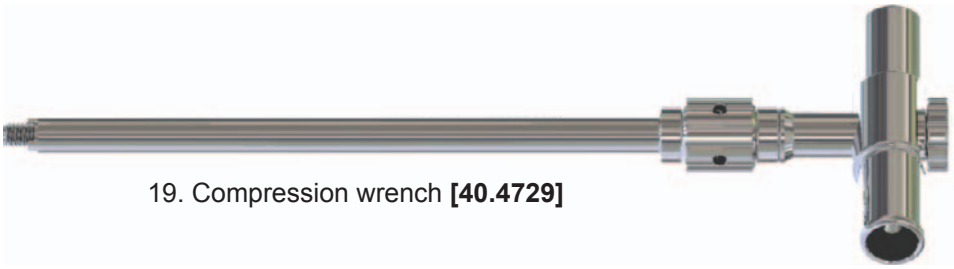
14. Guide 6.5/2.5 **[40.4722]**

15. Cannulated screw length measure **[40.4724]**

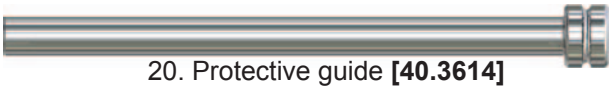
16. Canulated drill **[40.4725]**

17. Cannulated screwdriver S4/2.7 **[40.4727]**

18. Cannulated drill 2-gradual 11/6.5 **[40.4728]**



19. Compression wrench **[40.4729]**



20. Protective guide **[40.3614]**

21. Protective guide **[40.3615]**

22. Set block 9/6.5 **[40.3616]**

23. Trocar 6.5 **[40.3617]**

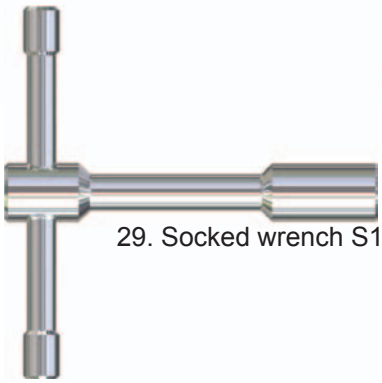
24. Screw lenght measure **[40.1374]**

25. Screwdriver S3.5 **[40.3604]**

26. Drill with scale 3.5/250 **[40.5330]**

27. Distal target D **[40.3322]**

28. Cannuled awl 13 **[40.3326]**



29. Socked wrench S11 **[40.3648]**

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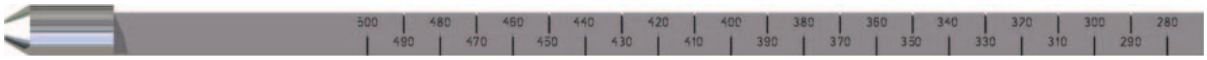
30. Impactor-extractor **[40.5070]**

31. Mallet **[40.3667]**

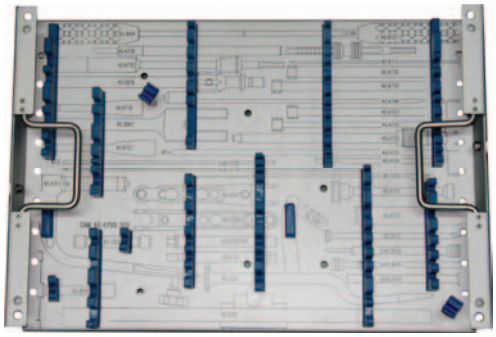
32. Teflon pipe guide **[40.1348]**

33. Handle guide rod **[40.1351]**

34. Guide rod **[40.3673]**



35. Nail lenght measure **[40.4798]**



36. Stand **[40.4740]**

IV. SURGICAL TECHNIQUE

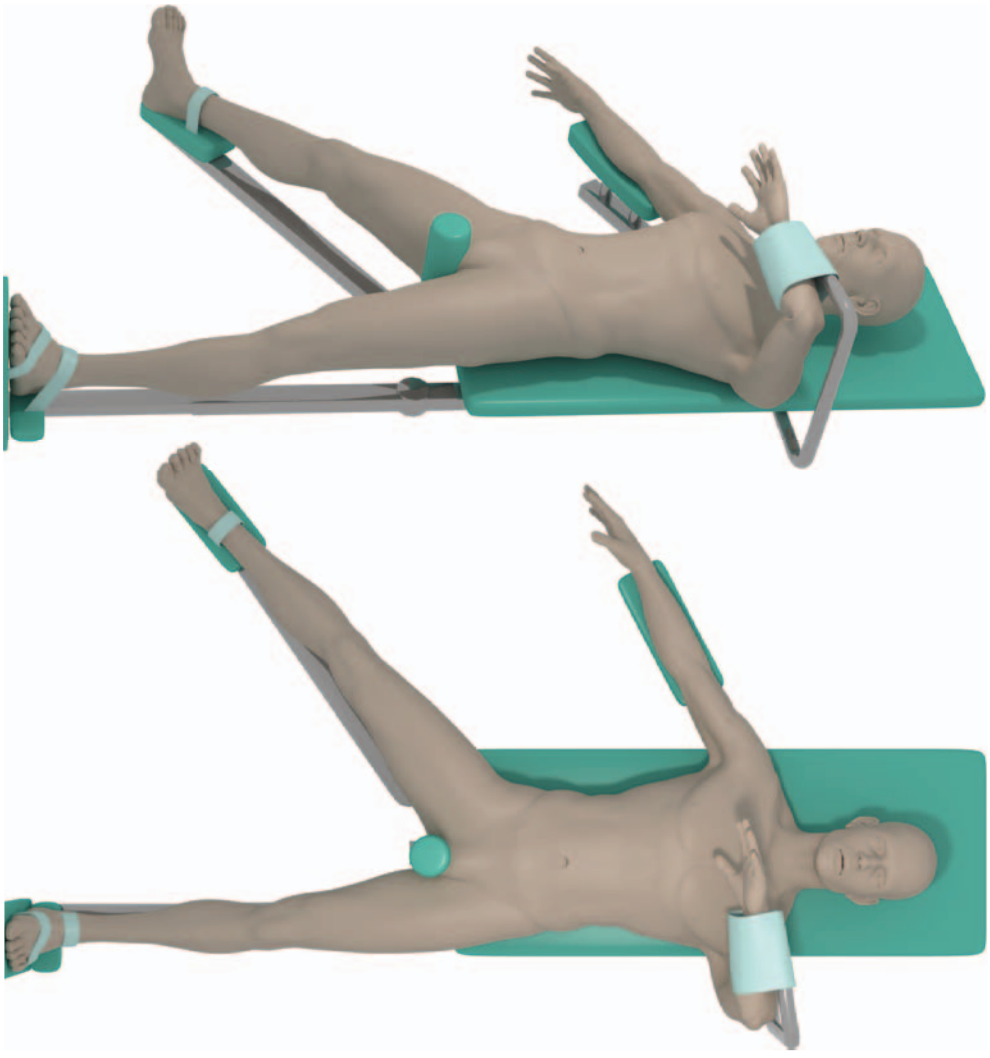
IV.1. Introduction

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 enable fracture reduction and nail insertion.
Patient positioning on the traction table is an integral part of the surgical procedure. Presented method of intramedullary osteosynthesis requires image intensifier visualization.

Each operating procedure must be carefully planned. X-Ray of the entire femur is essential in order to not overlook the injuries in proximal or distal part. It is especially important in cases of pathological subtrochanteric fractures.

Special attention should be paid on concurrent neck fractures or proximal epiphysis multi-fragment fractures, and the possibility of their occurrence during the procedure. During the operation secondary fractures of main fragments may occur. The condition of hip joint is also important. Fixation may be difficult if not impossible to perform in advanced arthrosis or contracture. In addition, it should be checked whether the alloplasty of hip or knee has been performed on the fractured limb.

The procedure has to be carried out on the table equipped with traction device. The patient shall be placed supine or on the side. Side position enables the approach to the greater trochanter, which is especially important in overweight patients. Supine position provides less favorable access to the grater trochanter, but makes all other stages considerably easier (especially rotary corrections). In the presented method supine position is recommended with traction applied on the condyles of the operated femur.



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

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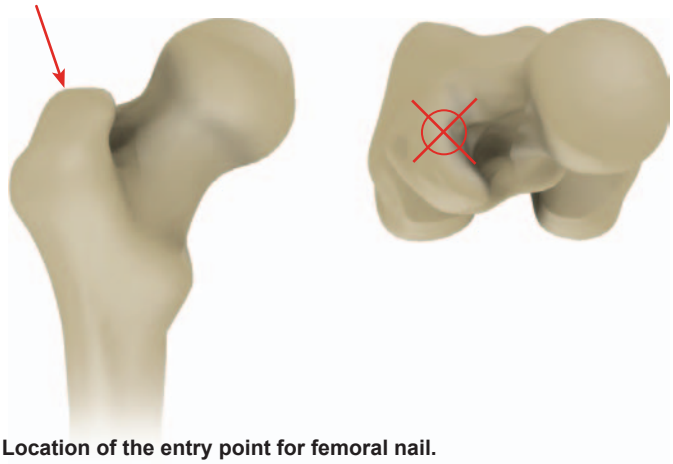
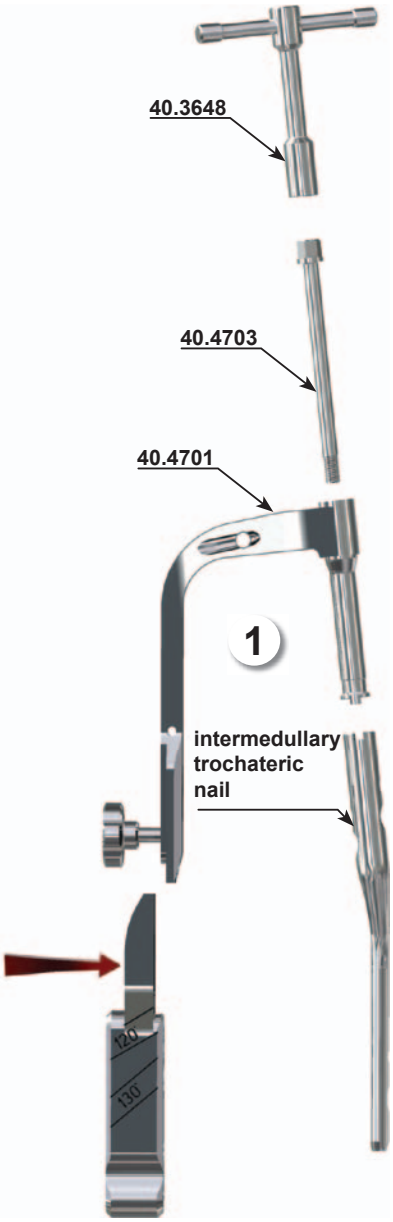
Lateral surgical approach shall be applied. The incision shall be started near the tip of greater trochanter in line with the femoral shaft axis for 8 cm in length. The longer incision is necessary in overweight patients. In the same direction a fascia incision is to be made. Fibers of greater gluteal muscle are to be then separated, thus providing approach to the tip of greater trochanter.



Location of the entry point for femoral nail.

The trochanteric nail should be introduce in such a way that its axis was proximately in the line with the medullary canal axis. This improves the distribution of forces transfering mechanical load for patient who starts walking.

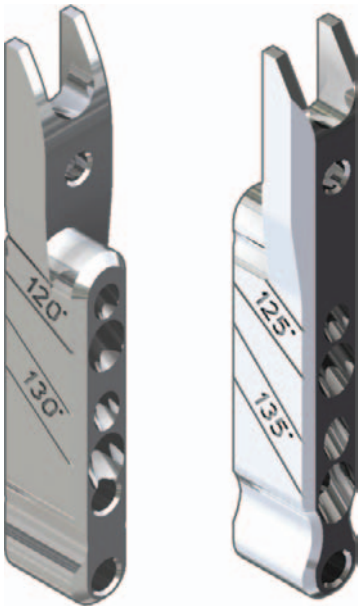


Below description describe most important steps during implantation of intramedullary interlocking trochanteric femur nails, nevertheless it is not a detailed instruction for use. A surgeon decides about choosing the surgical technique and its application in each individual case.

Basing on X-Rays of fractured and healthy femurs, a surgeon chooses the appropriate angle, length and diameter of nail.

IV.2. Preparation for implantation of short trochanteric nail 120°,125°,130° or 135°.

1 Using the Connecting Screw **[40.4703]** and the Socked Wrench S11 **[40.3648]**, mount the intramedullary nail to the Arm Target **[40.4701]**. Depending on chosen nail angle, mount the Target to the Arm Target.



120°/130°
40.4707

125°/135°
40.4708

- For 120° and 130° nails use the Target **[40.4707]**,
- For 125° and 135° nails use the Target **[40.4708]**.

After checking out the holes concentricity in the Target and in the nail; the Target should be dismounted for time of nail insertion into the medullary canal.

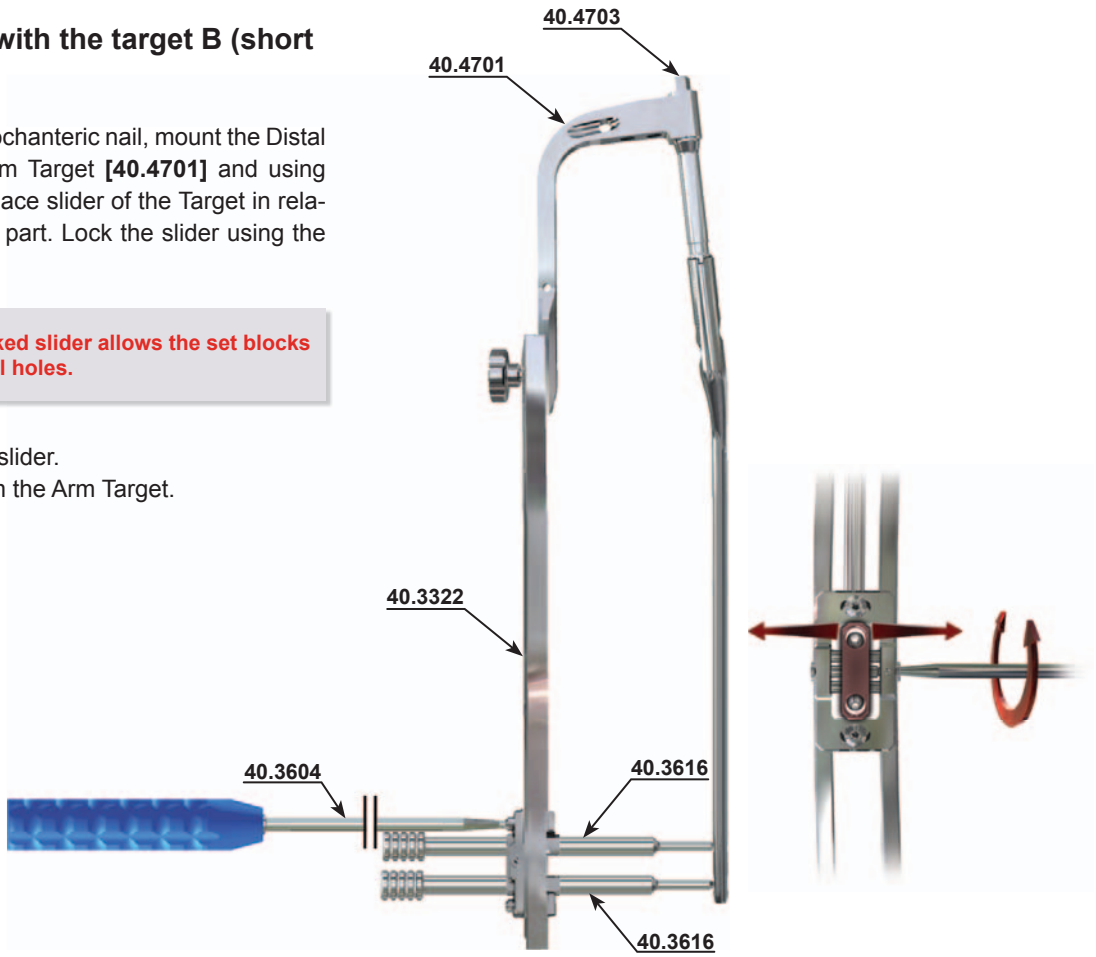
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

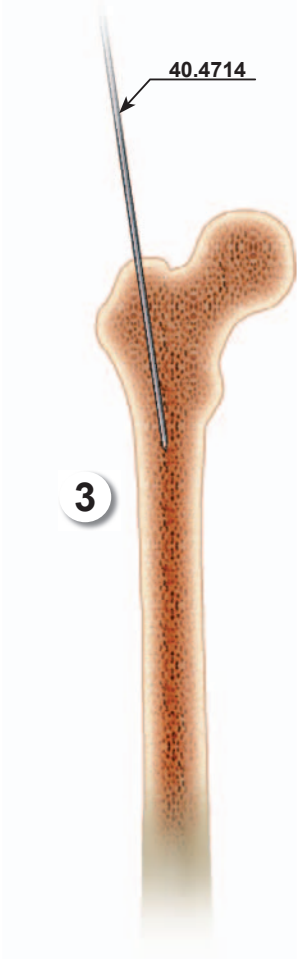
IV.3. Connecting the nail with the target B (short and long nails)

2 In case of using the long trochanteric nail, mount the Distal Target D **[40.3322]** the Arm Target **[40.4701]** and using two Set Blocks 9/4.5 **[40.3616]** place slider of the Target in relation to nail locking holes in distal part. Lock the slider using the Screwdriver S3.5 **[40.3604]**.

Properly placed and locked slider allows the set blocks smoothly hitting into nail holes.

Remove the Set Blocks from the slider.
Dismount the Distal Target D from the Arm Target.





IV.4. Opening and preparation the medullary canal for nail insertion (short and long nails)

3 Make a skin incision near the tip of a grater trochanter. After localization the entry point, using the surgical drive insert the Kirschner Wire 2.5/350 **[40.4714]** into medullary canal, at an angle coresponding to the angle of nail shaft deviation to the angle of main axis (about 6 degrees). The process shall be performed under the control of image intensifier.

Kirschner wire is a guide for Cannulated Drill 17.
Kirschner wire is a single use instrument.

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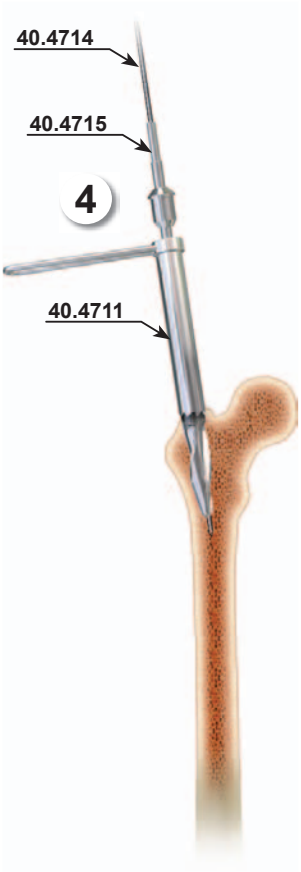
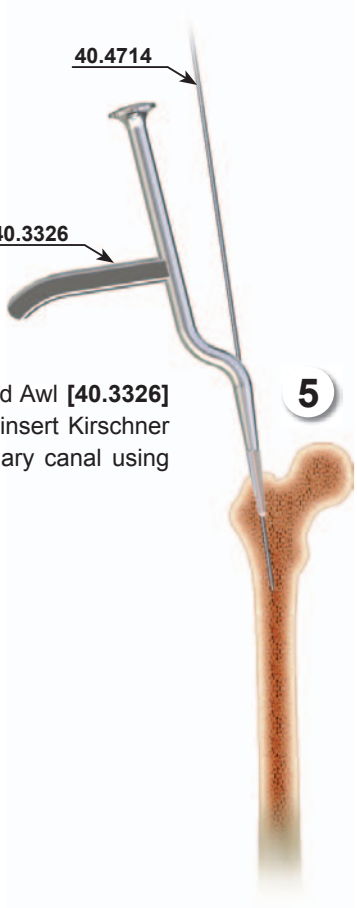


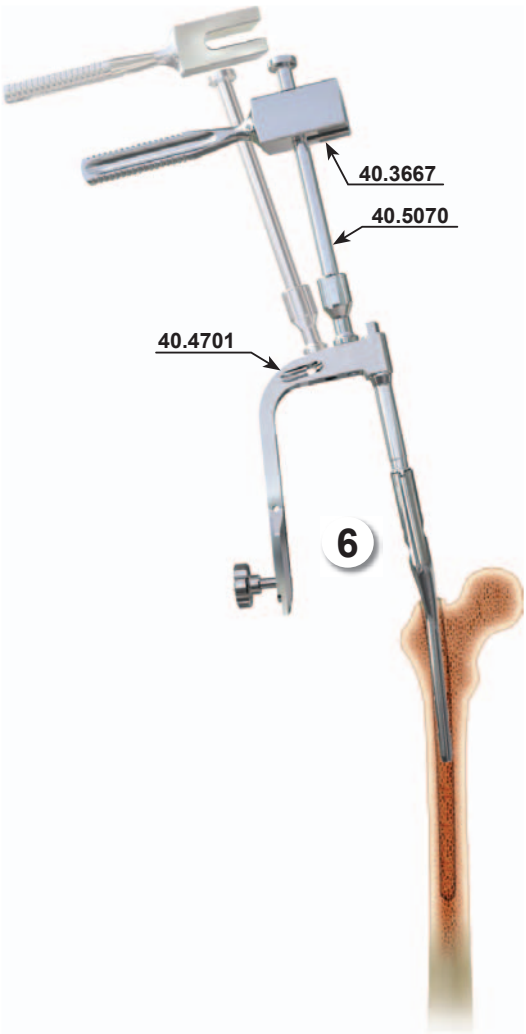
4 Open the medullary canal using the Cannulated Drill 17 **[40.4715]** leading in the Protective Guide 20.0/17.0 **[40.4711]** via Kirschner Wire **[40.4714]**. Slowly ream the medullary canal until the Cannulated Drill 17 rests on the Protective Guide.

Remove the Protective Guide, the Cannulated Drill and Kirschner Wire.



5 To open the medullary canal, the Cannulated Awl **[40.3326]** may be used as well. Using surgical drive, insert Kirschner wire **[40.4714]** into medullary canal. Open medullary canal using the Cannulated Awl, leading via Kirschner Wire.

Remove the Cannulated Awl and Kirschner Wire.



IV.5. Nail insertion (short and long nails)

6 Insert the nail into medullary canal under the image intensifier control. If necessity of intraoperative nail removal occurs, there is no need to dismount the nail from the Target

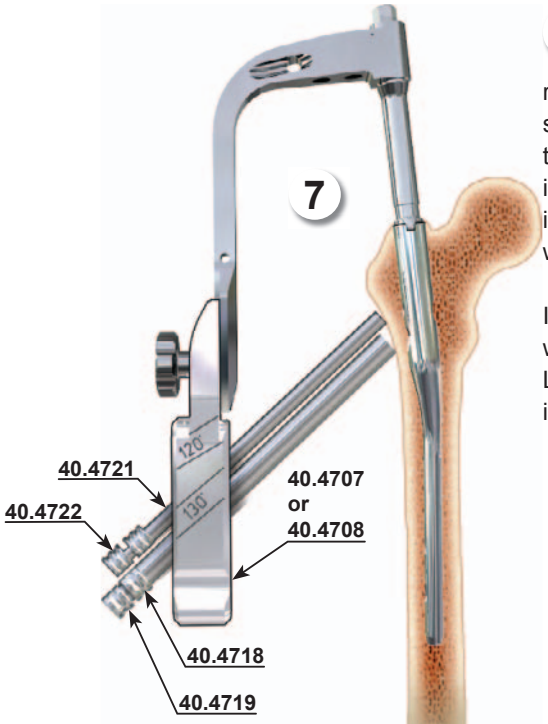
In this case connect the Arm Target **[40.4701]** with the Impactor–Extractor **[40.5070]** and using the Mallet **[40.3667]** remove the nail from the medullary canal. The Arm Target **[40.4701]** allows to mount the Impactor–Extractor **[40.5070]** in two different positions.

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

IV.6a. Nail locking by join screw and anti-rotate pin in proximal part (short and long nails) - version with cannulated join screw ([1.1946] or [3.1946])

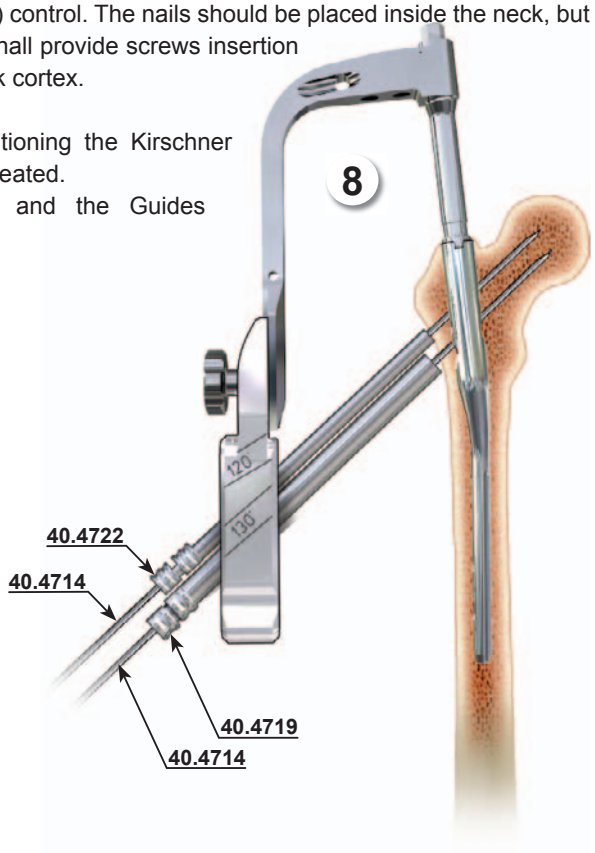
Nail should be always locked with two join screws.

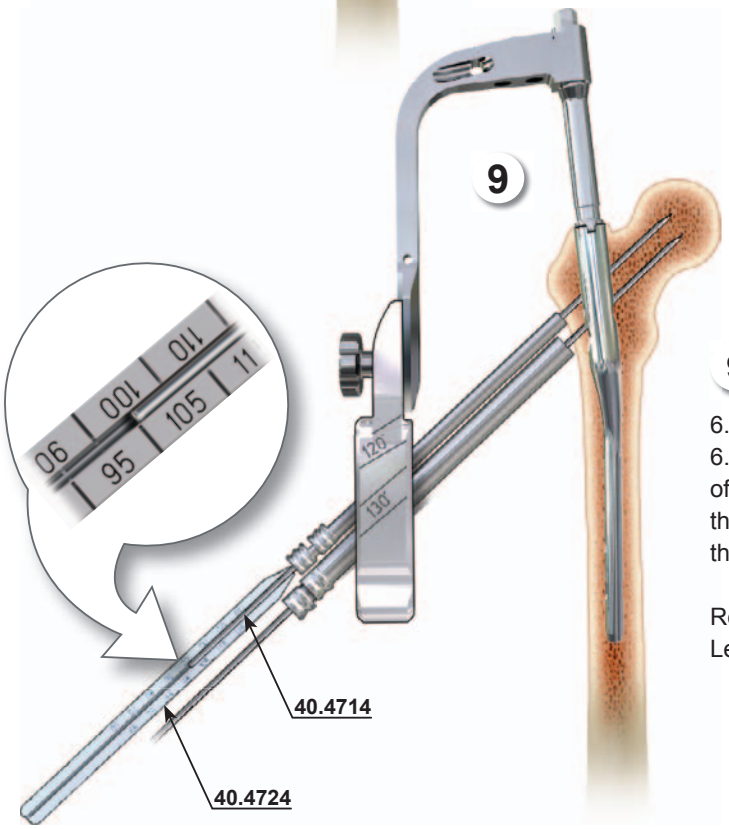
7 Mount chosen Target **[40.4707]** or **[40.4708]** to the Arm Target. Insert the Drill Guide 9.0/6.5 **[40.4721]** within the Guide 6.5/2.5 **[40.4722]** into smaller hole of the Target. Insert the Drill Guide 13.0/11.0 **[40.4718]** within Guide 11/2.5 **[40.4719]** to the bigger hole of the target.



8 Mount the Kirschner Wire **[40.4714]** onto the surgical drive and advance such system into the Guide 6.5/2.5 **[40.4722]** drill the hole in such a way to not perforate the femur head. Mount Kirschner Wire onto the surgical drive and advance such system into the Guide 11/2.5 **[40.4719]** and drill the hole in such a way to not perforate the femur head. The above mentioned process should be performed under the image intensifier (AP and lateral view) control. The nails should be placed inside the neck, but its deviation from the middle shall provide screws insertion without disturbance of the neck cortex.

In case of inappropriate positioning the Kirschner wires, the process shall be repeated.
Leave the Kirschner Wires and the Guides in the holes.





9 Insert the Cannulated Screw Length Measure **[40.4724]** onto the Kirschner wire **[40.4714]** (inserted in the Guide 6.5/2.5 **[40.4722]**), in such way that its tip rests on the Guide 6.5/2.5. Read the length of the Cannulated Join Screw on scale of the measure indicated by the end of the Kirschner wire. During the measure the tip of the length measure should rest on the Guide 6.5/2.5, and the Guide on cortex.

Remove the Screw Length Measure and the Guide 6.5/2.5.
Leave Kirschner Wire.

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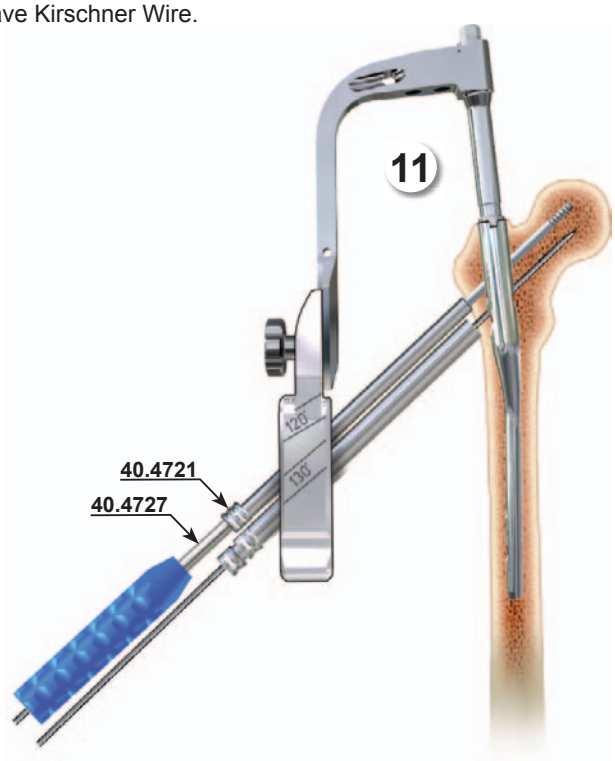
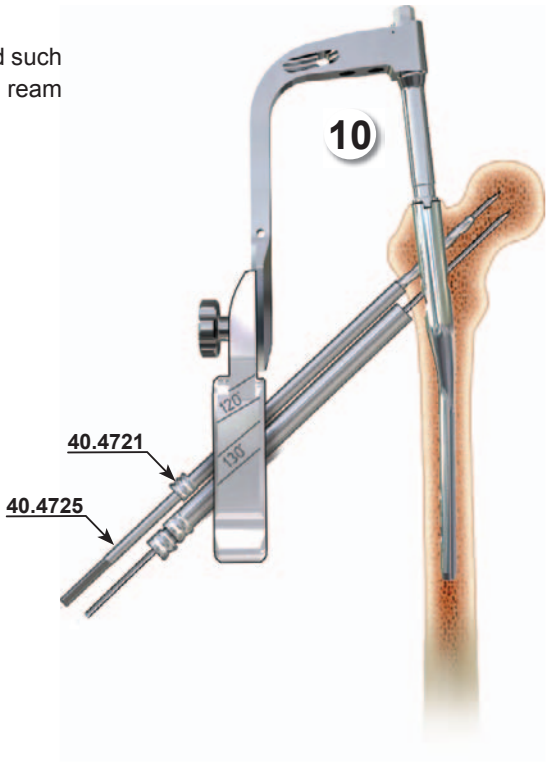
10 Mount the Cannulated Drill 6.5 **[40.4725]** on the surgical drive, then lead such system via Kirschner wire through the Drill Guide 9.0/6.5 **[40.4721]** and ream the hole in first cortical layer (to the nail placed in medullary canal).

Remove the Cannulated Drill.
Leave Kirschner Wire.





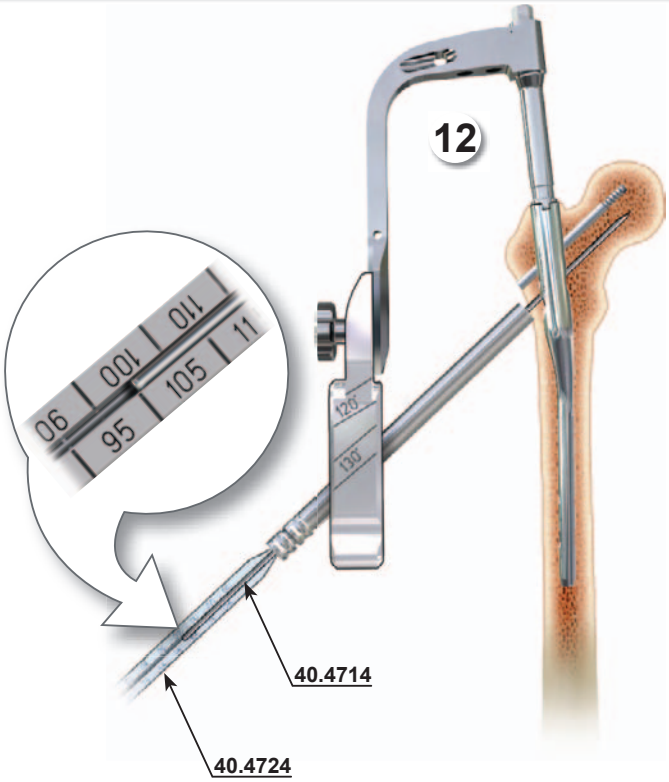
11 Mount appropriate Joint Cannulated Screw 6.5 **[40.4724]** onto Kirschner Wire **[40.4714]**. Insert Joint Cannulated Screw 6.5 into femur neck using the Cannulated Screwdriver **[40.4727]** until the tip of the Screwdriver rests on the Drill Guide 9.0/6.5 **[40.4721]**.

Remove the Screwdriver, Kirschner Wire and the Drill Guide.

The other possibility allows to lock trochanteric nail with use of solid join screw 6.5 instead of cannulated join screw 6.5. In such case, the Kirschner Wire should be removed before insertion of the join screw. And the screw should be connected with the Cannulated Screwdriver [40.4727] and inserted into femur neck throughout the Protective Guide 9.0/6.5 until it rests on the guide.

12 Insert the Cannulated Screw Length Measure **[40.4724]** onto the Kirschner wire **[40.4714]** inserted in the femoral neck (in guide 11/2.5 **[40.4719]**) in such way that its tip rests on the Guide 11/2.5. Read the length of Cannulated Join Screw on scale of the measure indicated by the end of the Kirschner wire. During measure the tip of the length measure should rest on the Guide 11/2.5.

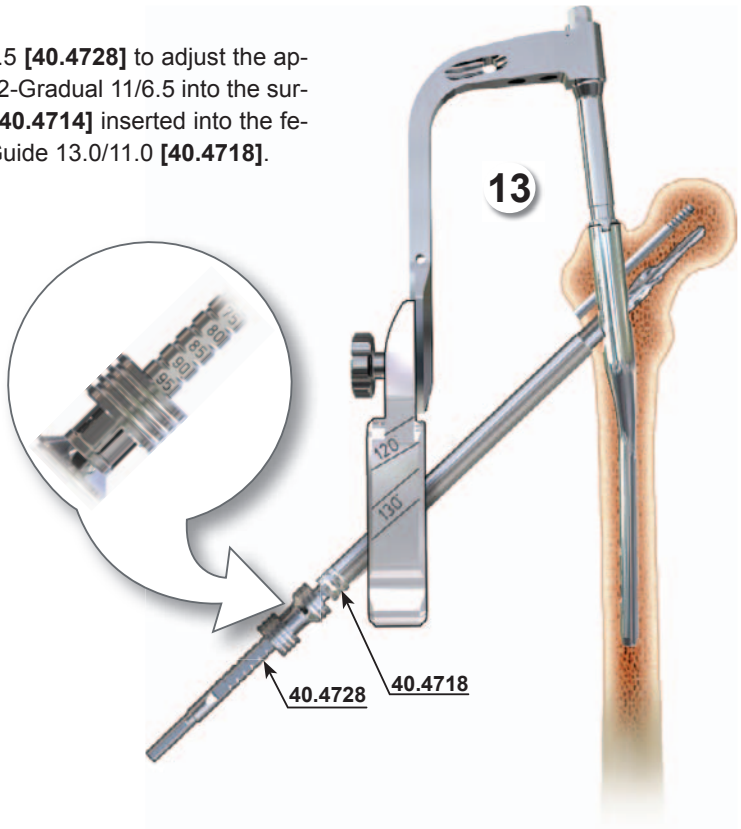
Remove the Screw Length Measure and the Guide 11.0/2.5.
Leave Kirschner Wire.

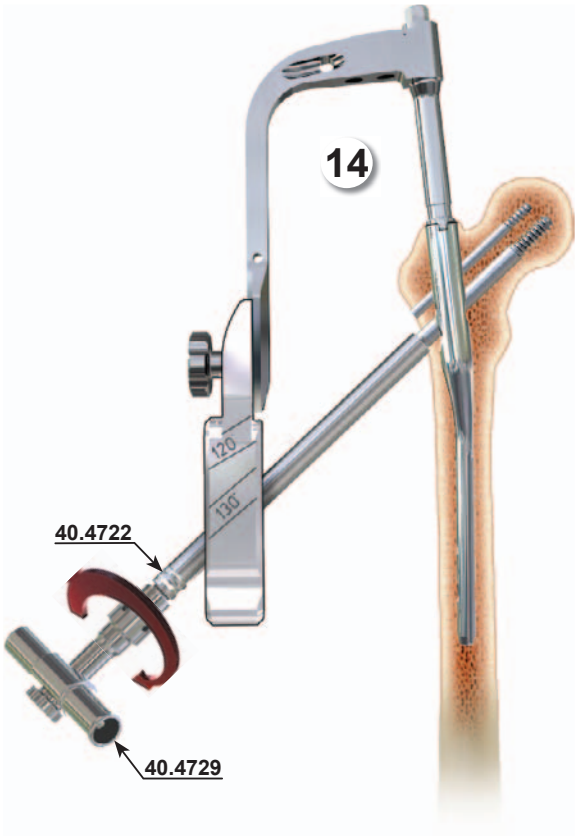


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

13 Use the slider on the Cannulated Drill 2-Gradual 11/6.5 **[40.4728]** to adjust the appropriate depth of drilling. Mount the Cannulated Drill 2-Gradual 11/6.5 into the surgical drive, and advance such system onto Kirschner Wire **[40.4714]** inserted into the femur neck and drill a hole until the slider rests onto the Drill Guide 13.0/11.0 **[40.4718]**.

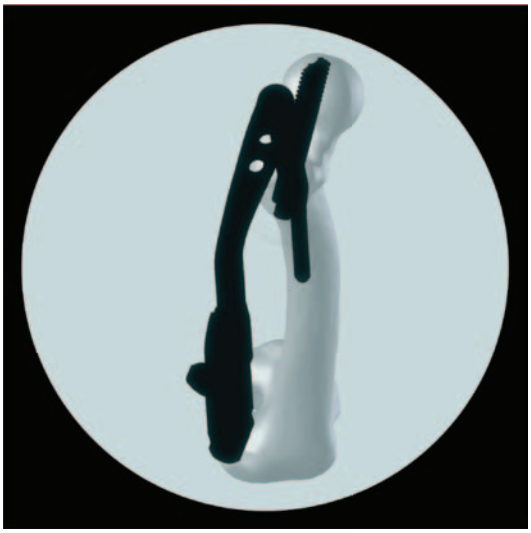
Remove the Cannulated Drill.
Leave Kirschner Wire and the Drill Guide.





14 Mount previously selected Join Screw **[1.1946]** or **[3.1946]** on the Compression Wrench **[40.4729]**.
Turn opposite the nut of the Wrench until it rests on the wrench sleeve. Insert previously determined the Cannulated Join Screw on the Kirschner Wire **[40.4714]**. Insert the join screw into femur neck, using the Compressive Wrench via Kirschner Wire, until the nut rests on the Drill Guide 13.0/11.0 **[40.4718]**. If necessary use the nut on the Compressive Wrench to make compression of the bone fragments.

Remove the Compressive Wrench, Kirschner Wire and the Drill Guide.



The correctness of fracture fixation of the femoral neck shall be verified by X-Rays in two projections. Little dimensions of the Target additionally deviated for the antetorsion angle enables the X-Ray in lateral position (the C arm is placed under the angle with respect to the target). Visible in the radiological image nail together with locking elements can be helpful to confirm the correctness of locking.

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

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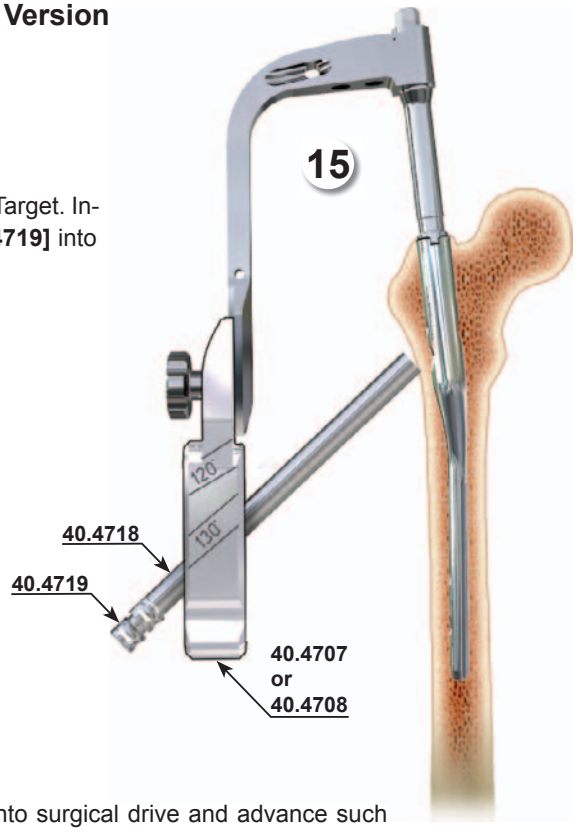
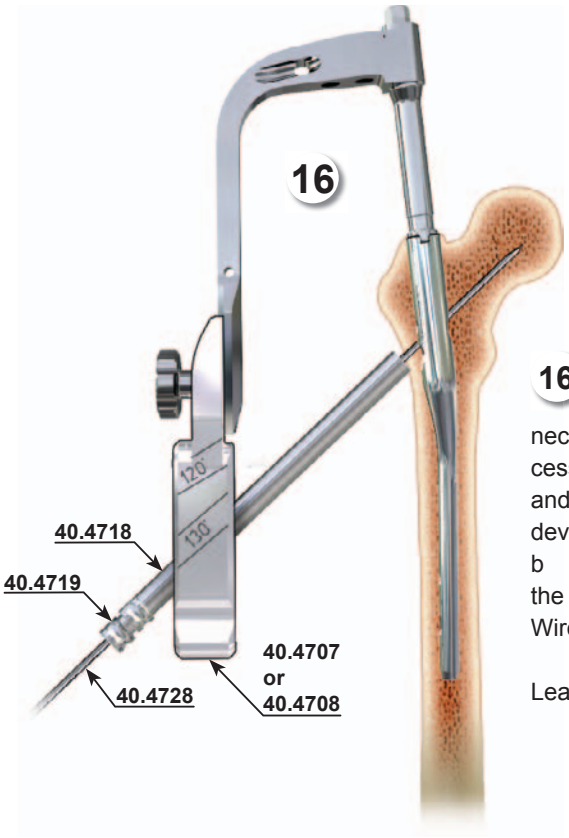
IV.6b. Locking of the trochanteric nail in proximal part by end cap with anti - rotate protection of compressive screw - Version with cannulated join screw [1.1949] or [3.1949]

15 Mount previously chosen Target **[40.4707]** or **[40.4708]** into the Arm Target. Insert the Drill Guide 13.0/11.0 **[40.4718]** within the Guide 11/2.5 **[40.4719]** into the bigger hole of the target.





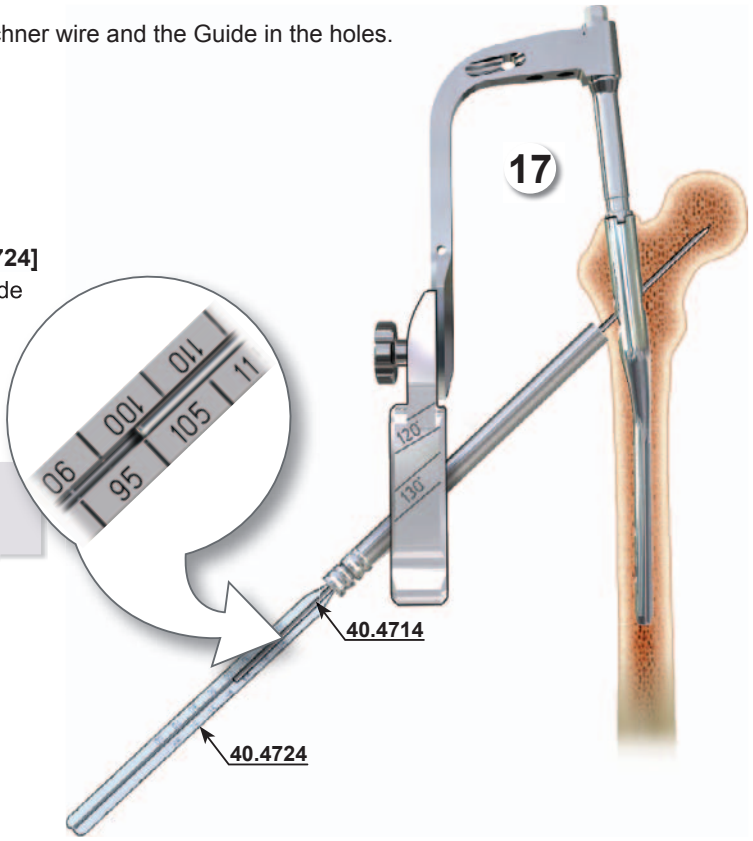
16 Mount Kirschner Wire into surgical drive and advance such system through the Guide 11/2.5 **[40.4719]** into the femoral neck (do not perforate the femur head). The above mentioned process should be performed under the control of image intensifier (AP and lateral view). The nails should be placed in the neck, but their deviation from the middle shall provide the screws insertion without breaking the neck cortex. In case of inappropriate positioning of the Kirschner Wires, the process shall be repeated.

Leave the Kirschner wire and the Guide in the holes.

17 Insert the Cannulated Screw Length Measure **[40.4724]** via Kirschner Wire **[40.4714]** (inserted in the Guide 11/2.5 **[40.4719]**) in such way that its tip rests on the Guide 11/2.5. Read the length of the Cannulated Join Screw on the scale of the measure indicated by the end of Kirschner Wire.

During the measure the tip of the length measure should be supported on the Guide 11/2.5.

Remove the Screw Length Measure and the Guide 11/2.5. Leave Kirschner Wire.



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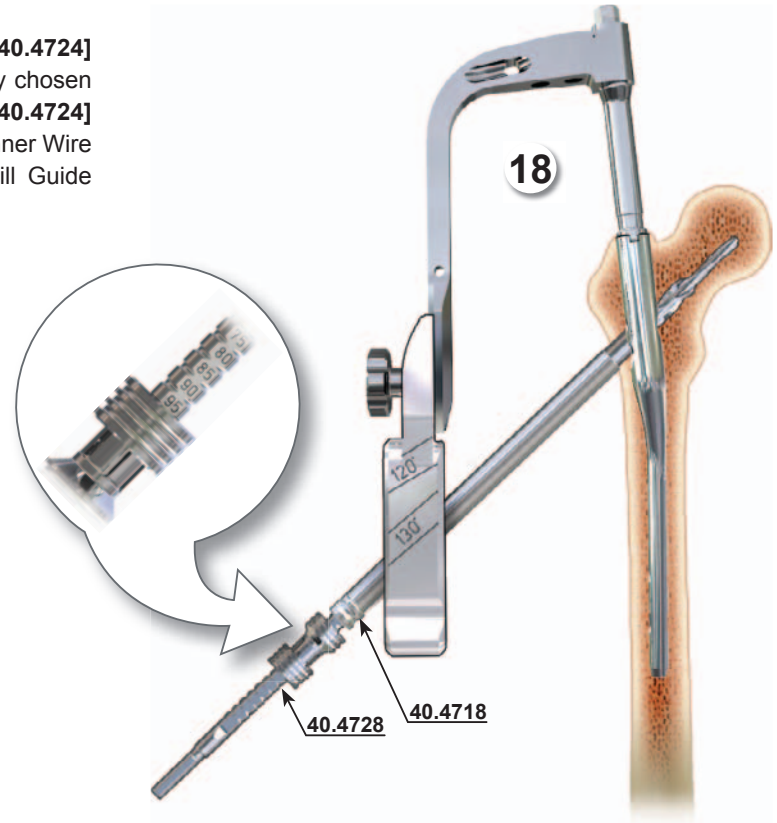
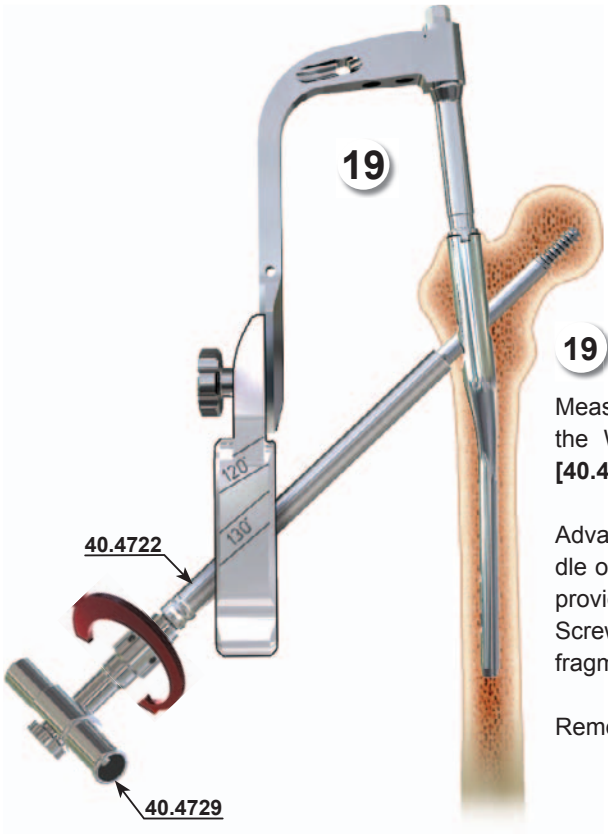
18 Using the slider on the Cannulated Drill 2-Gradual **[40.4724]** adjust the drilling depth corresponding to previously chosen join screw. Mount the Cannulated Drill 2-Gradual **[40.4724]** on the surgical drive, and insert such system on the Kirschner Wire **[40.4714]** and drill the hole until slider rests on the Drill Guide 13.0/11.0 **[40.4718]**.

Remove the Cannulated Drill.
Leave the Kirschner Wire and the Drill Guide.





19 Mount the Compression Wrench **[40.4729]** to the Join Screw **[1.1946]** or **[3.1946]** with previously determined length by the Cannulated Screw Length Measure **[40.4724]**. Tight up the nut on the Compression Wrench until it rests on the Wrench Sleeve. Insert the Cannulated Join Screw onto Kirschner Wire **[40.4714]**.

Advance the Cannulated Join Screw into femur neck using the Wrench. The Handle of the wrench should be placed in the plane with the main axis of femur. This provides correct placement of Join Screw and facilitates inserting the Compression Screw. If necessary, use the nut of the Compressive Wrench to compress the bone fragments.

Remove the Wrench, the Kirschner wire and the Drill Guide.

19a Insert the Compression Screw through proximal hole in the nail, this way to hit into 1 of 4 grooves on the Join Screw. In case of using the Screw **[1.1949]** or **[3.1949]** first insert the Compression Screw **[1.2106.005]** or **[3.2106.005]** into threaded hole, and next advance the End Cap. Use the Screwdriver S3.5 **[40.3604]**.

The screw may be placed in two positions:
- dynamic, when the compression screw is not tighten and allows sliding the screw inside the nail without possibility of turning (compression screw is maximum tighten and next is loosen of ¼ rotation),
- static, after interfragmental pressure compression screw is to be maximum tightened.

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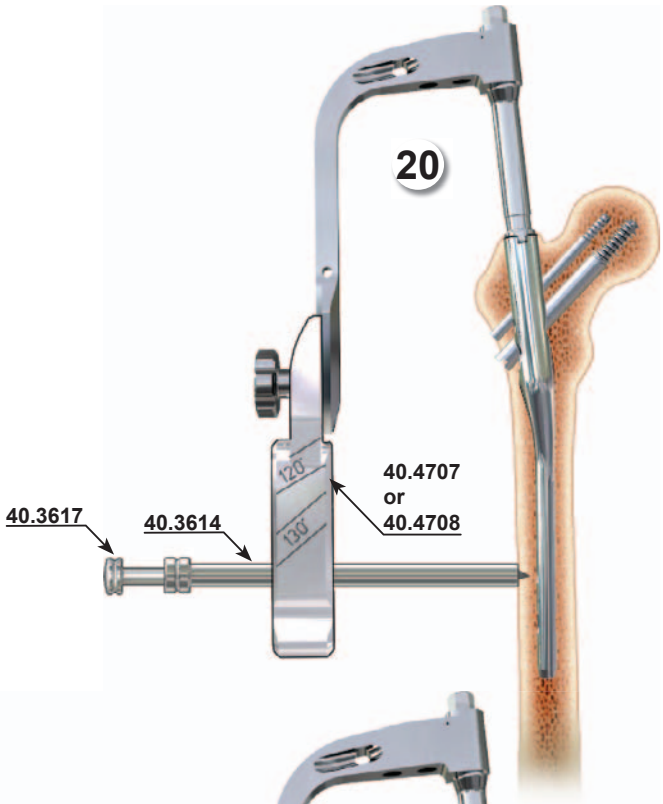
IV.7. Distal locking of the short trochanteric nail

20 Insert the Protective Guide 9/6.5 **[40.3614]** with the Trocar 6.5 **[40.4617]** into the proximal hole in the Target **[40.4707]** or **[40.4708]**. Mark the entry point for the locking screw, then make an incision of the soft tissues. Advanced the Trocar until it reaches the cortex and mark the entry point for the drill. Advance the Protective Guide together with the Trocar in such a way that it end is placed as close to the bone as possible.

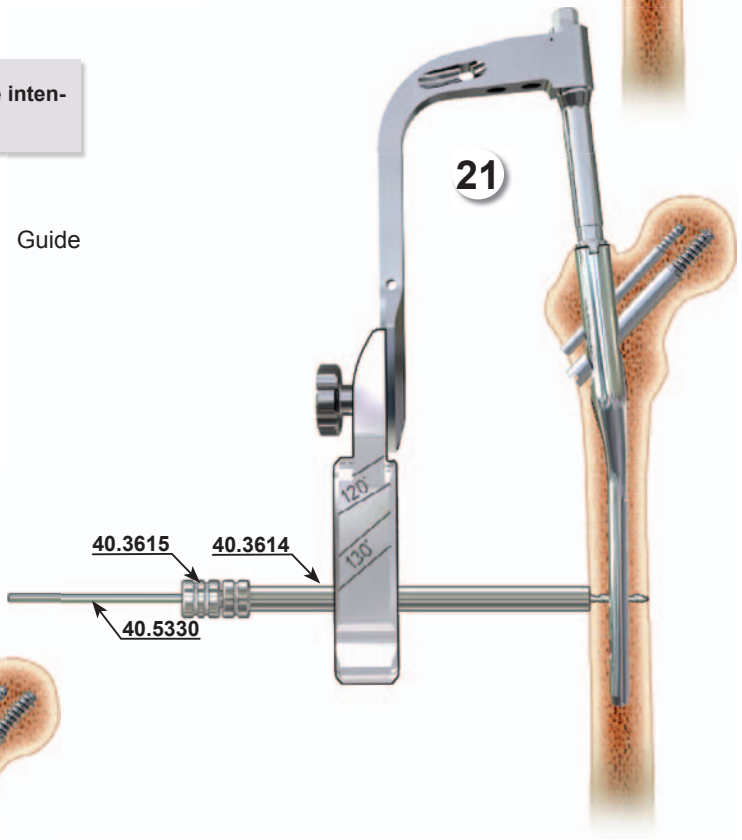
Remove the Trocar.
Leave the Protective Guide in the hole of the Target.

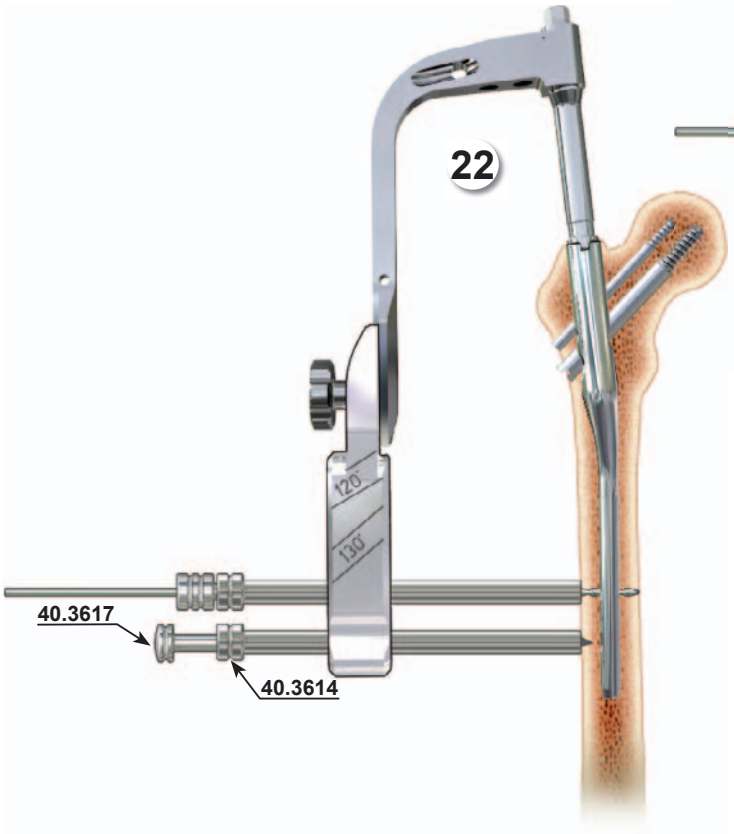


21 Insert the Drill Guide 6.5/3.5 **[40.3615]** into the Protective Guide 9/6.5 **[40.3614]**. Use the surgical drive to lead the Drill With Scale 3.5/250 **[40.5330]** into the Drill Guide, and drill a hole in the femur through both cortex layers and the hole in the nail. The scale on the Drill indicates length of locking element.

Drilling process should be controlled with image intensifier.

Dismount the surgical drive.
Leave the Drill, the Drill Guide and the Protective Guide in the hole.





22 Insert the Protective Guide 9/6.5 **[40.3614]** with the Trocar 6.5 **[40.3617]** into the second (distal) hole in the target. Advance the Trocar until it reaches the cortex and mark the entry point for the drill. Advance the Protective Guide together with the Trocar in such a way that its tip is placed as closely to the bone as possible.

Remove the Trocar.
Leave the Protective Guide in the hole of the target.

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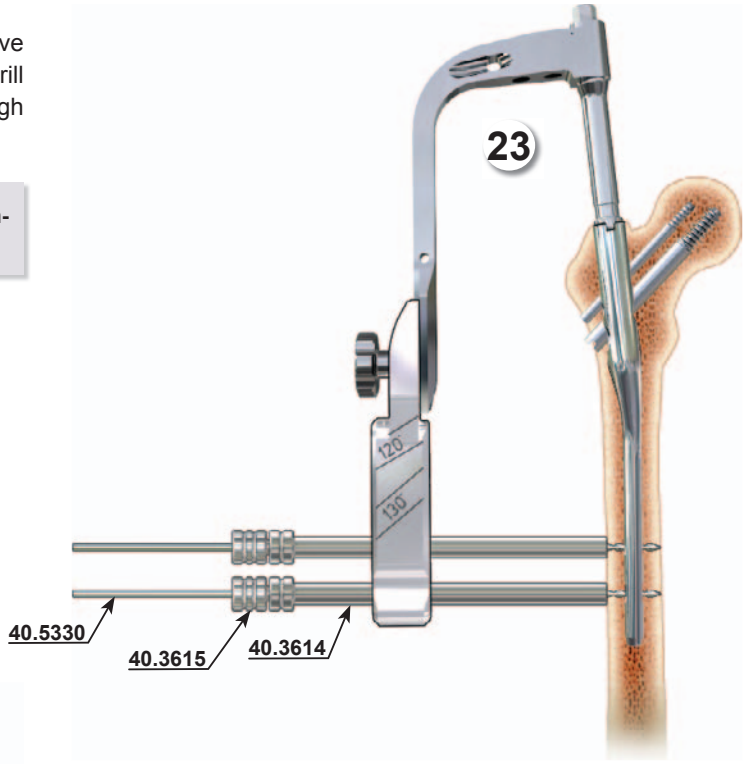
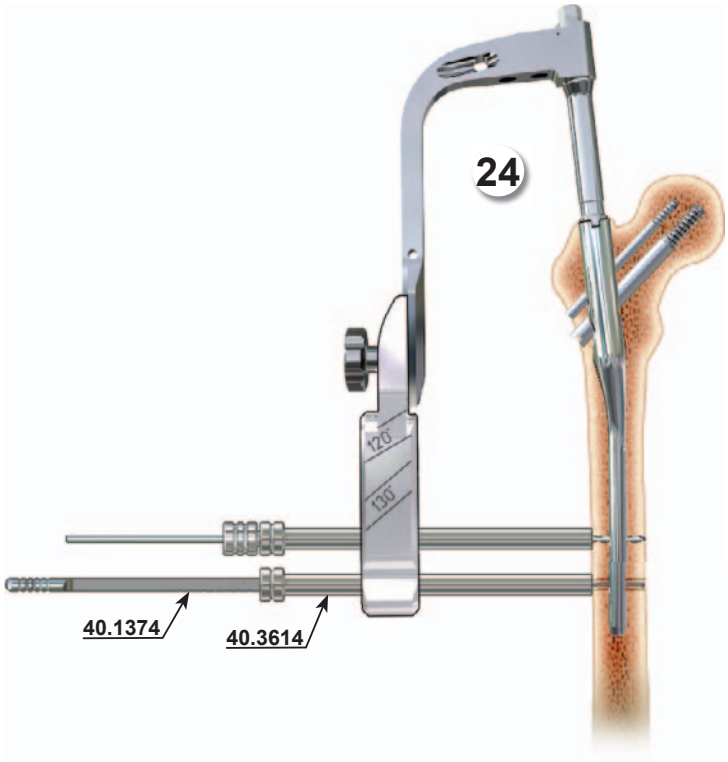
23 Insert the Drill Guide 6.5/3.5 **[40.3615]** into the Protective Guide 9/6,5 **[40.3614]**. Use the surgical drill to lead the Drill With Scale 3.5/250 **[40.5330]** and drill the hole into femur through both cortex layers and the hole in the nail.

Drilling process should be controlled with image intensifier.

The scale on the Drill indicates length of locking element.

Remove the Drill and the Drill Guide.
Leave the Protective Guide in the hole.



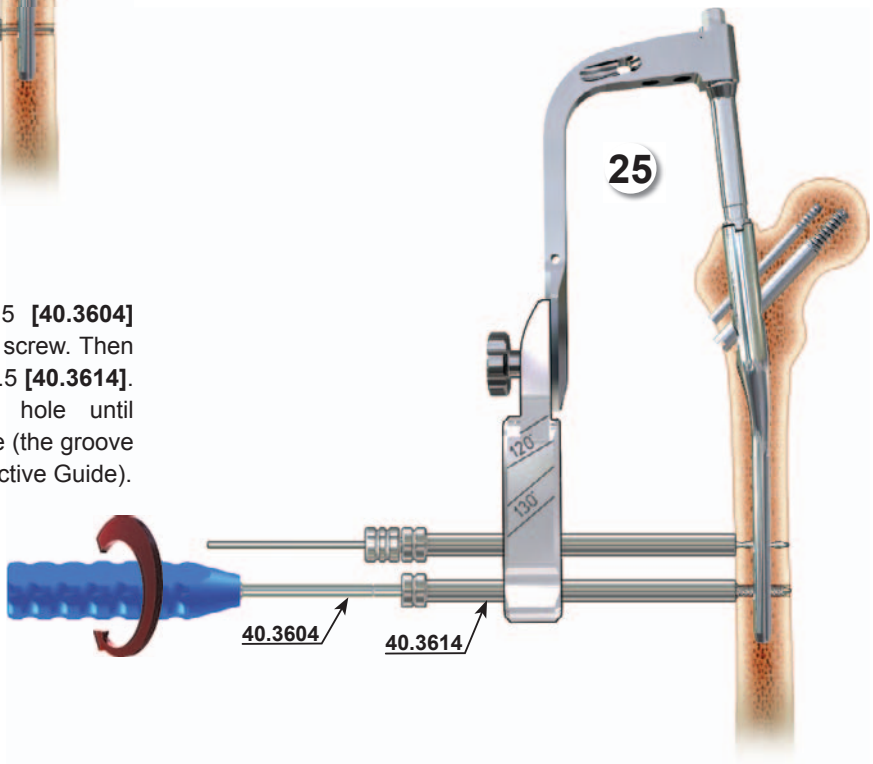


24 Insert the Screw Length Measure **[40.1374]** into drilled hole of the bone and through Protective Guide 9/6.5 **[40.3614]** until its hook reaches the ”exit” plane of the hole. Read the length of locking screw on the scale B-D. During the measurement the Protective Guide should rest on the cortex bone.

Remove the Screw Length Measure.
Leave the Protective Guide in the hole of the Target.

25 Connect the tip of the Screwdriver S 3.5 **[40.3604]** to the hexagonal socked of selected locking screw. Then advance such system into the Protective Guide 9/6.5 **[40.3614]**. Insert the locking screw into the prepared hole until the hea 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 the Protective Guide.



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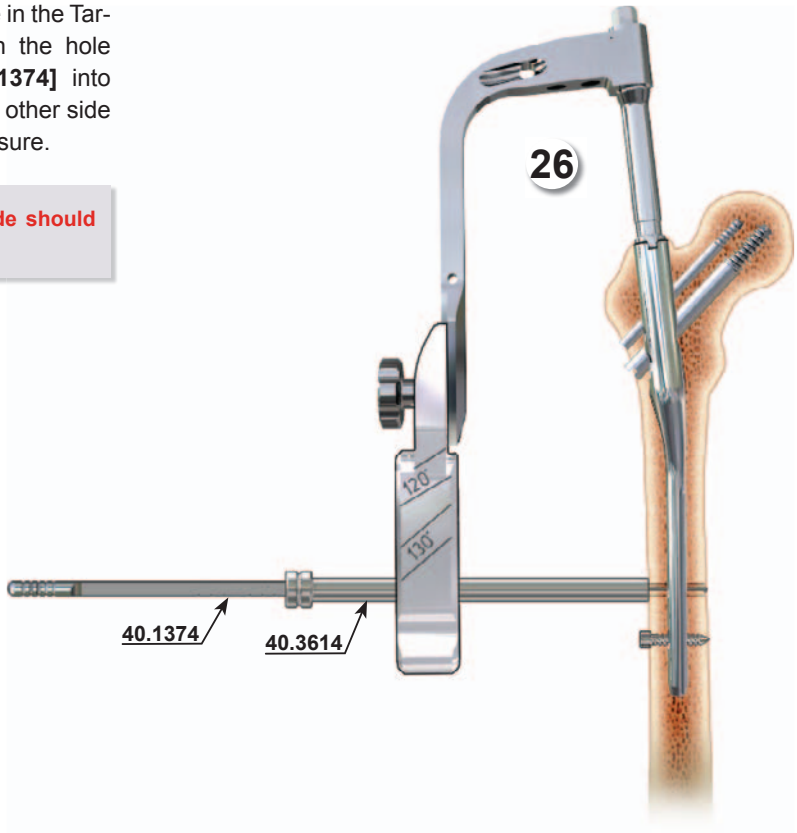
26 Remove the Drill With Scale 3.5/250 **[40.5330]** and the Drill Guide 6.5/3.5 **[40.3615]** out of the proximal hole in the Target. Leave the Protective Guide 9/6.5 **[40.3614]** in the hole of Target. Insert the Screw Length Measure **[40.1374]** into the drilled hole until its hook reaches the cortex of the other side of the bone. Read the length of the screw on the measure.

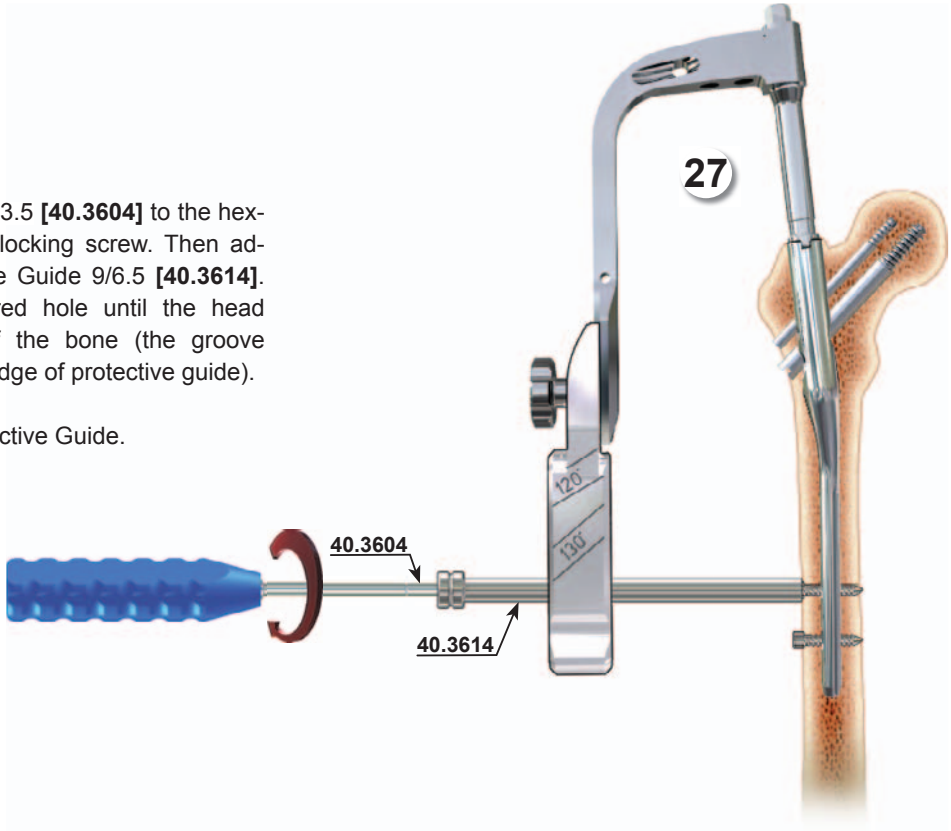
During the measurement the Protective Guide should rest on the cortex of bone.

Remove the Screw Length Measure.
Leave the Protective Guide in place.



27 Connect the tip of Screwdriver S3.5 **[40.3604]** to the hexagonal socked of the selected locking screw. Then advance such system into the Protective Guide 9/6.5 **[40.3614]**. Insert the locking screw into 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 the Protective Guide.



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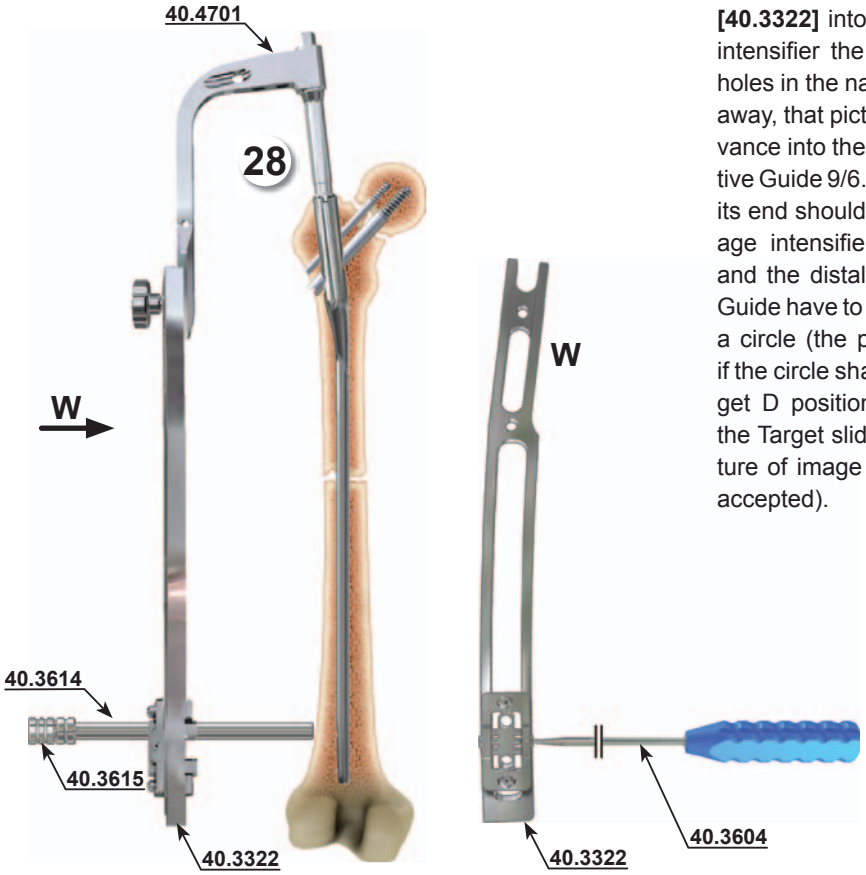
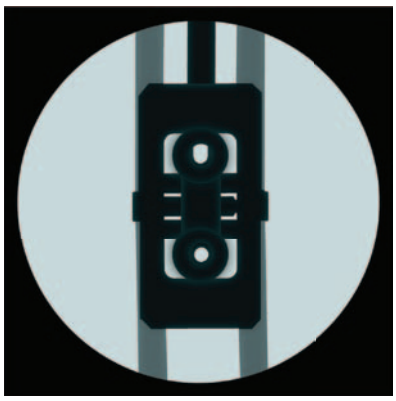
IV.8. Distal locking of the long trochanteric nail



28 After locking the long trochanteric nail in proximal part and dismounting the Target B; mount the Distal Target D **[40.3322]** into the Arm Target **[40.4701]**. Control with an image intensifier the position of the holes in Target slider and distal holes in the nail. The image intensifier should be position in such away, that picture of the nail hole (proximal or distal) is circle. Advance into the appropriate hole of the Distal Target D the Protective Guide 9/6.5 **[40.3614]** within the Drill Guide 6.5/3.5 **[40.3615]**, its end should rest on soft tissue of the limb. Control with an image intensifier the position of the holes in the Target slider and the distal holes in nail. The holes in the nail and the Drill Guide have to cover and the picture on image intensifier has to be a circle (the picture similar to circle is also accepted). In case if the circle shape does not appear on the screen, correct the Target D position. Use the Screwdriver S3.5 **[40.3604]** to move the Target slider (by the screw rotation left or right) until the picture of image intensifier is circle (the picture similar to circle is accepted).

INCORRECT POSITION



CORRECT POSITION

29 Remove the Drill Guide 6.5/3.5 **[40.3615]** out of the Protective Guide 9/6.5 **[40.3614]**.

Locking of distal screws should be proceed in accordance with stages 16 up to 23.

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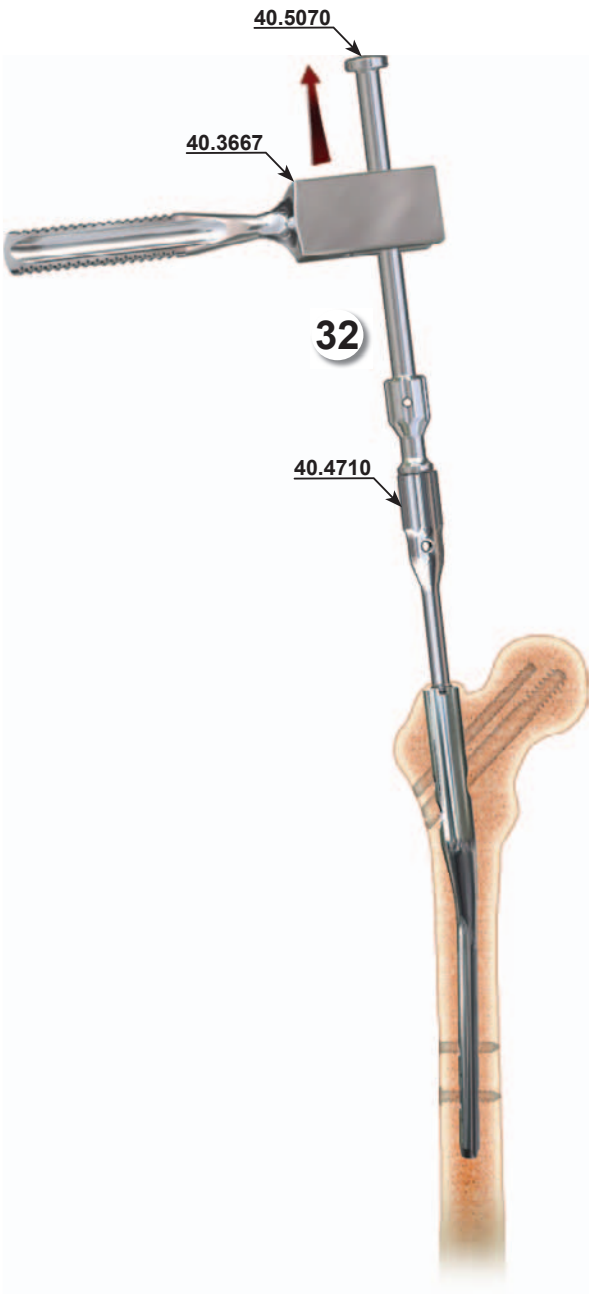
IV.9. Inserting End Cap (short and long nails)

30 Use the Socked Wrench S11 **[40.3648]** to unscrew the Connecting Screw **[40.4703]** from the shaft of the trochanteric nail. Dismount the Arm Target **[40.4701]** from the nail locked in medullary canal.

31 In order to secure the inner thread of the nail form bone ingrowth, insert the End Cap (implant) using the Screw-driver S3.5 **[40.3604]**.

IV.10. Nail extraction (short and long nails)

32 Use the Screwdriver S3.5 **[40.3604]** to unscrew the End Cap and all screws and locking screws. Insert the Connector of Extractor M8/M12 **[40.4710]** into treaded shaft of the nail. Mount the Impactor-Extractor **[40.5070]** to the Connector and use the Mallet **[40.3667]** to remove the nail from medullary canal.



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REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

Instruments manufactured by ChM Ltd. are made of stainless steel, aluminium alloys and plastics according to ISO standards. Each medical instrument is exposed to occurrence of corrosion, stains and damage, if not treated with special care and recommendations below.

1. Materials

Devices are produced of corrosion-resistant steels. The protective layer (passive layer) against corrosion is formed on the surface of the stainless steel due to high content of chromium.
Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdriver, awl or wrench, etc. The protective oxide layer, which may be dyed or stay in natural colour (silvery-grey), is formed on the aluminium as an effect of electrochemical surface treatment on its surface.
Devices made of aluminium with processed layer have a good corrosion resistance. The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts due to chemical interference on the processed aluminium surface shall be avoided.
Devices are mainly manufactured out of following plastics: POM-C (Polyoxymethylene Copolymer), PEEK (Polyetheretherketone) and teflon (PTFE). The above mentioned materials can be processed (washed, cleaned, sterilized) at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfection with pH values from 4 to 9.5.

If the material of the device cannot be specified, please contact ChM Ltd. company representative.

2. Disinfection and cleaning

Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quality of used detergent, the technique of cleaning (manual/machine), the correct rinsing and drying, the proper preparation of the instrument, the time, the temperature. Internal procedures of sterilizers, recommendations of cleaning and disinfection agents, as well as recommendations for cleaning and sterilizing automatic machines shall be observed.

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

1. Before the first use, the product has to be thoroughly washed in the warm water with washing-disinfecting detergent. It is important to follow the instructions and restrictions specified by the producer of those detergent. It is recommended to use water solutions of cleaning-disinfection agents with a neutral pH.
2. After use, for at least 10 minutes the product has to be immediately soaked in an aqueous disinfectant solution of enzyme detergent with a netural pH (with a disinfection properties) normally used for reusable medical devices (remember to prevent drying out any organic remains on the product surface). Follow all the instructions specified by the producer of those enzyme detergents.
3. Carefully scrub/clean the surfaces and crevices of the product using a soft cloth without leaving threads, or brushes made of plastic, only the nylon brushes are recommended. Do not use brushes made of metal, bristles or damaging material as they can cause physical or chemical corrosion.
4. Next, thoroughly rinse the instrument under the warm running water, paying particular attention for carefully rinsing the slots. Use nylon brushes making multiple moves back and forth on the surface of the product. It is recommended to rinse in demineralized water, in order to avoid water stains and corrosion caused by chlorides, found in the ordinary water, and to avoid forming the stains on the surface 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 are removed.

If there are any residues of human tissue or any other contamination, repeat all stages of the cleaning process.

6. Then, the instrument has to undergo a process of machine washing in the washer-disinfector (use washing-disinfecting agents recommended for reusable medical devices and instruments).

Procedure of washing with the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfection agents manufacturer.

3. Sterilization

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds as residues after disinfection and sterilization processes, without structure damages (cracks, fractures, bending, peeling). Remember that sterilization is not substitute for cleaning process!

Devices manufactured out of plastics (PEEK, PTFE, POM-C) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.

Sterilization of surgical instruments shall be carried out using equipment and under the conditions that conform to applicable standards. It is recommended to sterilize in steam sterilizers where sterilizing agent is water vapour. Recommended parameters of the sterilization method: temperature min. 134°C, pressure of 2 atm.

The above given parameters of sterilization are to be absolutely observed.

Validated sterilization methods are allowed. Durability and strength of instruments highly depend on their usage. Careful usage consistent with intended application of the product, prevents product damaging and prolongs its life.

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