

*instruction*

# INTRAMEDULLARY OSTEOSYNTHESIS OF HUMERUS

IMPLANTS ◦  
INSTRUMENT SET ◦  
SURGICAL TECHNIQUE ◦



**CHARFIX** *system*

**4F**

**CE** 0197

ISO 9001  
ISO 13485

**ChM**®



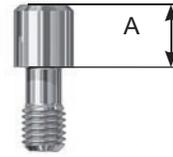
<b>I. IMPLANTS .....</b>	<b>5</b>
<i>I.1. Reconstruction nail.....</i>	<i>5</i>
<b>II. INTRODUCTION.....</b>	<b>9</b>
<b>III. INSTRUMENT SET .....</b>	<b>13</b>
<b>IV. SURGICAL TECHNIQUE .....</b>	<b>17</b>
<i>IV.1. Introduction .....</i>	<i>17</i>
<i>IV.2. Opening of the medullary canal (proximal insertion of the humeral nail).....</i>	<i>17</i>
<i>IV.3. Preparation of the medullary canal.....</i>	<i>18</i>
<i>IV.4. Assembling of a compression humeral nail. Target B positioning. Nail insertion into medullary canal. ....</i>	<i>19</i>
<i>IV.5. Distal locking of the nail .....</i>	<i>20</i>
<i>IV.6. Proximal locking of the nail.....</i>	<i>23</i>
<i>IV.6.A. Dynamic and dynamic with compression method (compressive).....</i>	<i>23</i>
<i>IV.7. Static method.....</i>	<i>25</i>
<i>IV.8. Oblique locking of the nail.....</i>	<i>27</i>
<i>IV.9. Humeral nail removal from the Target. Placing Compression screw or end cap.....</i>	<i>29</i>
<i>IV.10. Proximal locking of a short reconstruction humeral nail.....</i>	<i>30</i>
<i>IV.11. Distal locking of a short reconstruction humeral nail.....</i>	<i>34</i>
<i>IV.12. Distal locking of a long reconstruction humeral nail.....</i>	<i>37</i>
<i>IV.13. Proximal locking of a long reconstruction humeral nail.....</i>	<i>41</i>
<i>IV.14. Distal locking of the nail by “freehand” technique .....</i>	<i>45</i>
<i>IV.15. Nail extraction .....</i>	<i>46</i>
<i>IV.16. Distal nail insertion into the medullary canal.....</i>	<i>47</i>

Śruba kompresyjna M7x1  
Compression screw M7x1  
Компрессионный винт M7x1

Śruba zaslepiająca M7x1  
End cap M7x1  
Винт слепой M7x1

dostępne available доступные			
	Ø [mm] skok, pitch, шаг 1 mm	6 ÷ 13	6 ÷ 13
	L [mm] skok, pitch, шаг 5 mm	180 ÷ 400	180 ÷ 400

Stal, Steel, Сталь  
1.2106.004  
Tytan, Titanium, Титан  
3.2106.004

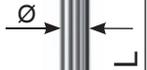
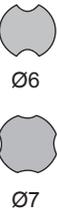


A	Nr katalogowy, Catalogue no., № по кат..	
	Stal, Steel, Стал	TYTAN, Titanium, Титан
0	1.2104.500	3.2104.500
+5	1.2104.505	3.2104.505
+10	1.2104.510	3.2104.510
+15	1.2104.515	3.2104.515
+20	1.2104.520	3.2104.520
+25	1.2104.525	3.2104.525
+30	1.2104.530	3.2104.530

Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075



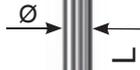
Stal, Steel, Сталь  
1.1655.016 -060  
Tytan, Titanium, Титан  
3.1655.016 -060



Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075



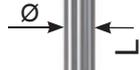
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Tytan, Titanium, Титан  
3.1654.016 -060



Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075



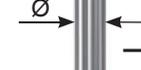
Stal, Steel, Сталь  
1.1655.016 -060  
Tytan, Titanium, Титан  
3.1655.016 -060



Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075



Stal, Steel, Сталь  
1.1654.016 -060  
Tytan, Titanium, Титан  
3.1654.016 -060



Stal, Steel, Сталь  
1.1655.016 -100  
Tytan, Titanium, Титан  
3.1655.016 -100



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



Stal, Steel, Сталь  
1.1655.016 -100  
Tytan, Titanium, Титан  
3.1655.016 -100



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



L [mm]	Ø	STAL	TYTAN
		Steel, Сталь	Titanium, Титан
180	6	1.2099.180	3.2099.180
200		1.2099.200	3.2099.200
220		1.2099.220	3.2099.220
240	7	1.2099.240	3.2099.240
260		1.2099.260	3.2099.260
280		1.2099.280	3.2099.280
300		1.2099.300	3.2099.300
320		1.2099.320	3.2099.320
180	7	1.2100.180	3.2100.180
200		1.2100.200	3.2100.200
220		1.2100.220	3.2100.220
240	9	1.2100.240	3.2100.240
260		1.2100.260	3.2100.260
280		1.2100.280	3.2100.280
300		1.2100.300	3.2100.300
320		1.2100.320	3.2100.320

L [mm]	Ø	STAL	TYTAN
		Steel, Сталь	Titanium, Титан
180	8	1.2097.180	3.2097.180
200		1.2097.200	3.2097.200
220		1.2097.220	3.2097.220
240	9	1.2097.240	3.2097.240
260		1.2097.260	3.2097.260
280		1.2097.280	3.2097.280
300		1.2097.300	3.2097.300
320		1.2097.320	3.2097.320
180	9	1.2098.180	3.2098.180
200		1.2098.200	3.2098.200
220		1.2098.220	3.2098.220
240	7	1.2098.240	3.2098.240
260		1.2098.260	3.2098.260
280		1.2098.280	3.2098.280
300		1.2098.300	3.2098.300
320		1.2098.320	3.2098.320

L [mm]	Ø	STAL	TYTAN
		Steel, Сталь	Titanium, Титан
180	6	1.2383.180	3.2383.180
200		1.2383.200	3.2383.200
220		1.2383.220	3.2383.220
240	7	1.2383.240	3.2383.240
260		1.2383.260	3.2383.260
280		1.2383.280	3.2383.280
300		1.2383.300	3.2383.300
320		1.2383.320	3.2383.320
180	7	1.2384.180	3.2384.180
200		1.2384.200	3.2384.200
220		1.2384.220	3.2384.220
240	9	1.2384.240	3.2384.240
260		1.2384.260	3.2384.260
280		1.2384.280	3.2384.280
300		1.2384.300	3.2384.300
320		1.2384.320	3.2384.320

L [mm]	Ø	STAL	TYTAN
		Steel, Сталь	Titanium, Титан
180	8	1.2095.180	3.2095.180
200		1.2095.200	3.2095.200
220		1.2095.220	3.2095.220
240	9	1.2095.240	3.2095.240
260		1.2095.260	3.2095.260
280		1.2095.280	3.2095.280
300		1.2095.300	3.2095.300
320		1.2095.320	3.2095.320
180	9	1.2096.180	3.2096.180
200		1.2096.200	3.2096.200
220		1.2096.220	3.2096.220
240	7	1.2096.240	3.2096.240
260		1.2096.260	3.2096.260
280		1.2096.280	3.2096.280
300		1.2096.300	3.2096.300
320		1.2096.320	3.2096.320

I. IMPLANTS

I.1. Reconstruction nail

A	Nr katalogowy, Catalogue no., № по кат..	
	Stal, Steel, Стал	TYTAN, Titanium, Титан
0	1.2104.200	3.2104.200
+5	1.2104.205	3.2104.205
+10	1.2104.210	3.2104.210
+15	1.2104.215	3.2104.215
+20	1.2104.220	3.2104.220
+25	1.2104.225	3.2104.225
+30	1.2104.230	3.2104.230

Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075

Ø4,5  
Lub, Or, Либо  
Ø5,0

Stal, Steel, Сталь  
1.1657.026 -100  
Tytan, Titanium, Титан  
3.1657.026 -100

Gwintowane otwory rekonstrukcyjne  
Threaded reconstruction holes  
Винтовые отверстия во всяком стержнях

Śruba zaślepiająca M7x1  
End cap M7x1  
Винт слепой M7x1



Stal, Steel, Сталь  
1.1655.016 - 060  
Tytan, Titanium, Титан  
3.1655.016 - 060

Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075

Ø4,5  
Lub, Or, Либо  
Ø5,0

Stal, Steel, Сталь  
1.1657.026 -100  
Tytan, Titanium, Титан  
3.1657.026 -100

Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075

Ø4,5  
Lub, Or, Либо  
Ø5,0

Stal, Steel, Сталь  
1.1657.026 -100  
Tytan, Titanium, Титан  
3.1657.026 -100

Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075

Ø4,5  
Lub, Or, Либо  
Ø5,0

Stal, Steel, Сталь  
1.1657.026 -100  
Tytan, Titanium, Титан  
3.1657.026 -100

Nr katalogowy, Catalogue no., № по кат..			
Ø	L [mm]	Stal, Steel, Стал	TYTAN, Titanium, Титан
6	150	1.2450.150	3.2450.150
7	150	1.2452.150	3.2452.150

Stal, Steel, Сталь  
1.1654.016 - 060  
Tytan, Titanium, Титан  
3.1654.016 - 060

Stal, Steel, Сталь  
1.1655.016 - 060  
Tytan, Titanium, Титан  
3.1655.016 - 060

Stal, Steel, Сталь  
1.1654.016 - 060  
Tytan, Titanium, Титан  
3.1654.016 - 060

Nr katalogowy, Catalogue no., № по кат..			
Ø	L [mm]	Stal, Steel, Стал	TYTAN, Titanium, Титан
8	150	1.2454.150	3.2454.150
9	150	1.2456.150	3.2456.150

Nr katalogowy, Catalogue no., № по кат..			
Ø	L [mm]	Stal, Steel, Стал	TYTAN, Titanium, Титан
6	150	1.2430.150	3.2430.150
7	150	1.2432.150	3.2432.150

Nr katalogowy, Catalogue no., № по кат..			
Ø	L [mm]	Stal, Steel, Стал	TYTAN, Titanium, Титан
8	150	1.2434.150	3.2434.150
9	150	1.2436.150	3.2436.150

dostępne available доступные			
Ø [mm]	skok, pitch, шаг 1 mm	6 ÷ 14	6 ÷ 14
L [mm]	skok, pitch, шаг 5 mm	150 ÷ 200	150 ÷ 200

A	Nr katalogowy, Catalogue no., № по кат..	
	Stal, Steel, Стал	TYTAN, Titanium, Титан
0	1.2104.200	3.2104.200
+5	1.2104.205	3.2104.205
+10	1.2104.210	3.2104.210
+15	1.2104.215	3.2104.215
+20	1.2104.220	3.2104.220
+25	1.2104.225	3.2104.225
+30	1.2104.230	3.2104.230

Gwintowane otwory rekonstrukcyjne  
Threaded reconstruction holes  
Винтовые отверстия во всяком стержнях

Śruba zaślepiająca M7x1  
End cap M7x1  
Винт слепой M7x1

Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075

Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075

Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075

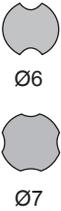
Stal, Steel, Сталь  
1.1653.025 -075  
Tytan, Titanium, Титан  
3.1653.025 -075

Stal, Steel, Сталь  
1.1657.016 -060  
Tytan, Titanium, Титан  
3.1657.016 -060

Stal, Steel, Сталь  
1.1657.016 -060  
Tytan, Titanium, Титан  
3.1657.016 -060

Stal, Steel, Сталь  
1.1657.016 -060  
Tytan, Titanium, Титан  
3.1657.016 -060

Stal, Steel, Сталь  
1.1657.016 -060  
Tytan, Titanium, Титан  
3.1657.016 -060



dostępne available доступные		Ø [mm]	
skok, pitch, шаг 1 mm		6 ÷ 14	8 ÷ 14
L [mm]		150 ÷ 200	
skok, pitch, шаг 5 mm		150 ÷ 200	150 ÷ 200

Stal, Steel, Сталь  
1.1655.016 -100  
Tytan, Titanium, Титан  
3.1655.016 -100

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

Stal, Steel, Сталь  
1.1655.016 -100  
Tytan, Titanium, Титан  
3.1655.016 -100

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

L [mm]	Ø	STAL Steel, Сталь	TYTAN Titanium, Титан
220	6	1.2451.220	3.2451.220
240		1.2451.240	3.2451.240
260		1.2451.260	3.2451.260
280		1.2451.280	3.2451.280
300		1.2451.300	3.2451.300
320	1.2451.320	3.2451.320	
220	7	1.2453.220	3.2453.220
240		1.2453.240	3.2453.240
260		1.2453.260	3.2453.260
280		1.2453.280	3.2453.280
300		1.2453.300	3.2453.300
320	1.2453.320	3.2453.320	

L [mm]	Ø	STAL Steel, Сталь	TYTAN Titanium, Титан
220	8	1.2455.220	3.2455.220
240		1.2455.240	3.2455.240
260		1.2455.260	3.2455.260
280		1.2455.280	3.2455.280
300		1.2455.300	3.2455.300
320	1.2455.320	3.2455.320	
220	9	1.2457.220	3.2457.220
240		1.2457.240	3.2457.240
260		1.2457.260	3.2457.260
280		1.2457.280	3.2457.280
300		1.2457.300	3.2457.300
320	1.2457.320	3.2457.320	

L [mm]	Ø	STAL Steel, Сталь	TYTAN Titanium, Титан
220	6	1.2431.220	3.2431.220
240		1.2431.240	3.2431.240
260		1.2431.260	3.2431.260
280		1.2431.280	3.2431.280
300		1.2431.300	3.2431.300
320	1.2431.320	3.2431.320	
220	7	1.2433.220	3.2433.220
240		1.2433.240	3.2433.240
260		1.2433.260	3.2433.260
280		1.2433.280	3.2433.280
300		1.2433.300	3.2433.300
320	1.2433.320	3.2433.320	

L [mm]	Ø	STAL Steel, Сталь	TYTAN Titanium, Титан
220	8	1.2435.220	3.2435.220
240		1.2435.240	3.2435.240
260		1.2435.260	3.2435.260
280		1.2435.280	3.2435.280
300		1.2435.300	3.2435.300
320	1.2435.320	3.2435.320	
220	9	1.2437.220	3.2437.220
240		1.2437.240	3.2437.240
260		1.2437.260	3.2437.260
280		1.2437.280	3.2437.280
300		1.2437.300	3.2437.300
320	1.2437.320	3.2437.320	

**Wkręt blokujący Ø5,0**  
**Distal screw Ø5.0**  
**Блокирующий винт Ø5,0**

L [mm]	Nr katalogowy, Catalogue no., № по кат.	
	STAL, Steel, Сталь	TYTAN, Titanium, Титан
16	1.1657.016	3.1657.016
18	1.1657.018	3.1657.018
20	1.1657.020	3.1657.020
22	1.1657.022	3.1657.022
24	1.1657.024	3.1657.024
25	1.1657.025	3.1657.025
26	1.1657.026	3.1657.026
28	1.1657.028	3.1657.028
30	1.1657.030	3.1657.030
35	1.1657.035	3.1657.035
40	1.1657.040	3.1657.040
45	1.1657.045	3.1657.045
50	1.1657.050	3.1657.050
55	1.1657.055	3.1657.055
60	1.1657.060	3.1657.060
65	1.1657.065	3.1657.065
70	1.1657.070	3.1657.070
75	1.1657.075	3.1657.075
80	1.1657.080	3.1657.080
85	1.1657.085	3.1657.085
90	1.1657.090	3.1657.090
95	1.1657.095	3.1657.095
100	1.1657.100	3.1657.100

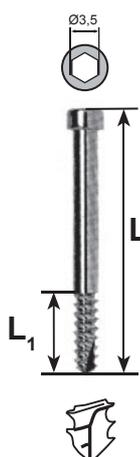


**Wkręt blokujący Ø4,5**  
**Distal screw Ø4.5**  
**Блокирующий винт Ø4,5**

L [mm]	Nr katalogowy, Catalogue no., № по кат.	
	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 Ø3,5**  
**Distal screw Ø3.5**  
**Блокирующий винт Ø3,5**

L [mm]	Nr katalogowy, Catalogue no., № по кат.	
	STAL, Steel, Сталь	TYTAN, Titanium, Титан
16	1.1655.016	3.1655.016
18	1.1655.018	3.1655.018
20	1.1655.020	3.1655.020
22	1.1655.022	3.1655.022
24	1.1655.024	3.1655.024
26	1.1655.026	3.1655.026
28	1.1655.028	3.1655.028
30	1.1655.030	3.1655.030
32	1.1655.032	3.1655.032
34	1.1655.034	3.1655.034
36	1.1655.036	3.1655.036
38	1.1655.038	3.1655.038
40	1.1655.040	3.1655.040
45	1.1655.045	3.1655.045
50	1.1655.050	3.1655.050
55	1.1655.055	3.1655.055
60	1.1655.060	3.1655.060



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

L [mm]	L <sub>1</sub> [mm]	Nr katalogowy, Catalogue no., № по кат.	
		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



## II. INTRODUCTION

**CHARFIX** *system*

- INTRAMEDULLARY OSTEOSYNTHESIS OF HUMERUS, consist of:

- Implants (intramedullary nail, locking screws, end cap or compression screw),
- Instrument set for implantation and extraction after finished treatment,
- Instruction on how to manage instrument set (surgical technique).

Intramedullary osteosynthesis provides stable fixation of fractured shaft of the bone, it is recommended to use in following cases:

- Pathological comminuted fractures,
- Difficult fractures with closed and opened (I grade) damages,
- Malunion of fractures of humeral shaft after treatment with other methods.

**CHARFIX** *system*

provides the following methods of intramedullary fixation depending on the type of humeral fracture:

### Static Method

Static fixation is used in multi-fragment fractures when the fragments of fractured bone don't cling in the axial line. In this fixation, to lock the nail with screws are used all holes in distal part, and in proximal part of the nail - one round hole or two holes (round and oblong).



## Dynamic Method

Dynamic fixation may be used in case of good cortex contact of fragments of fractured bone in transverse and oblique fractures, also in false joints. All distal holes and one proximal hole of the intramedullary humeral nail are used in that fixation.

Dynamic fixation enables axial displacement of bone fragments while loading the limb, in this way physiological stimulus is forming to create bone scar and its reconstruction into the lamellar bone.

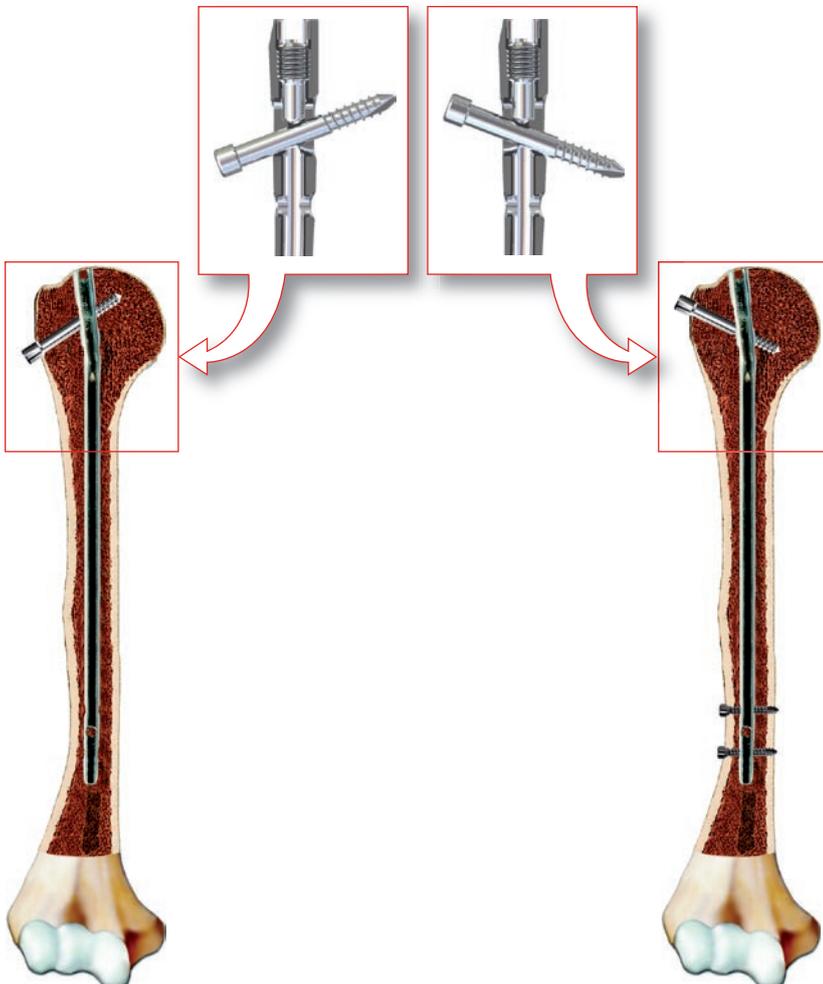


## Dynamic with compression method

In dynamic with compression method (compressive fixation) the compressive screw is axial screwed into internal threaded hole of the nail shaft in order to put pressure on locking screw which locked the nail. The compressive fixation eliminates all micro-movements in the initial stage of fracture treatment.



## Oblique locking of the nail



**Distal inserting of the nail**

Humeral bone fractures located in area of shaft, metaphysis and epiphysis of humeral bone may be also connect using intramedullary CHM nail inserted from distal epiphysis area.

**Exemplary versions of locking of reconstructive humeral nail:**

## INTRODUCTION

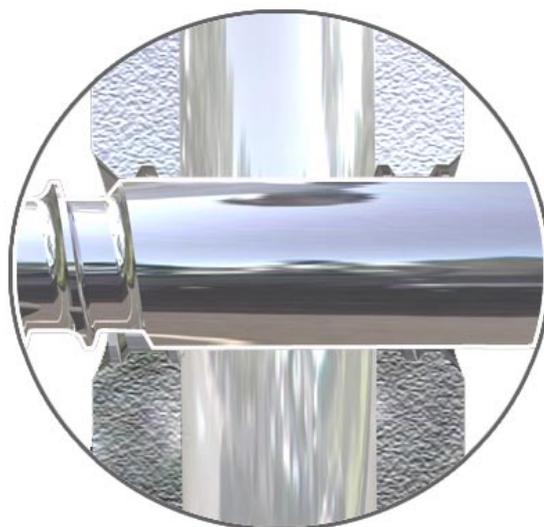
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Reconstructive intramedullary humeral nail is offered in:

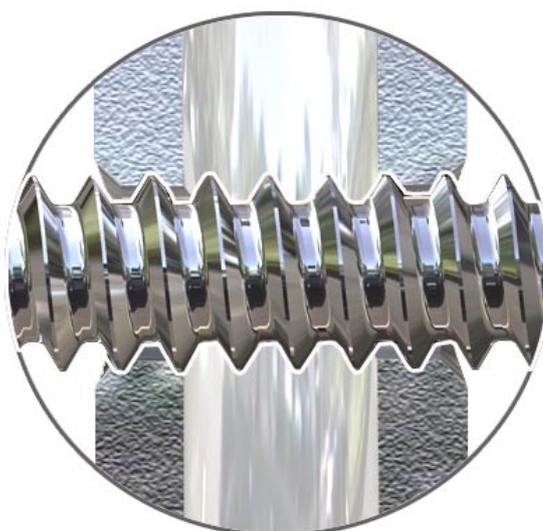
- diameter range from 6 to 14mm (with pitch 1mm);
- in solid and cannula version;
- length range from 150 to 215mm in short version and from 220 to 400mm in long version;
- made of stainless steel and titan alloy.

Nail design make implantation possible to right and left limb. To the nails in short and long version is used the same target. Locking nail in short version in distal part is performed using holes marked on the target as "RECONSTRUCTION", whereas nails in long version are locked using slider located on target slider (before implantation it is necessary to place slider this way that set blocks led onto holes of the slider freely hit on holes on the nail), or using "free hand" technique. In the proximal part the nail has 4 holes letting for uniting damaged fragments of the head of the humerus. Thanks to applying in the proximal part threaded locking holes, reconstruction humeral nail allows for optional locking at using:

- proximal screw  $\varnothing 4,5$



- locking screw  $\varnothing 5,0$ , which by anchoring in the nail prevents angle displacement and moving of fractured bone fragments (using threaded hole in the nail)



## III. INSTRUMENT SET

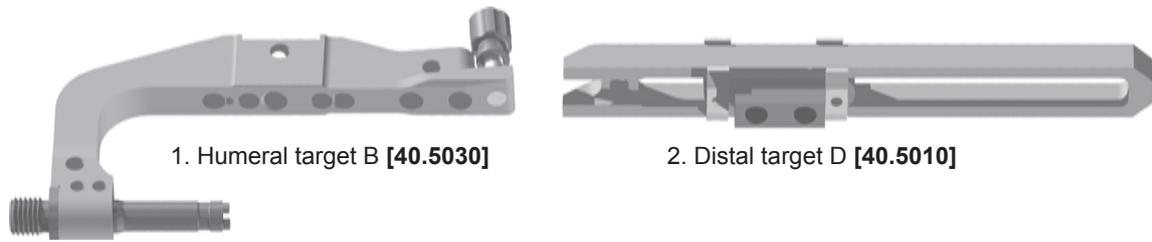
The fixation of the humeral shaft fracture and removal of the implants after finished treatment is carried out with instrument set [40.5020.000]. All instruments are placed in the stand with a lid which facilitates storage and transport to the operating suite. The instrument set consists of the following instruments:

Lp.	Nr katalogowy Catalogue no. № по кат.	Nazwa	Name	Название	Szt.
1	40.5030.000	Celownik ramienny B	Humeral target B	Целенаправитель проксимальный	1
2	40.5010.000	Celownik D	Distal target D	Целенаправитель дистальный	1
3	40.5024.000	Celownik kątowy	Angular reconstruction target	Целенаправитель угловой	1
4	40.5023.000	Śruba łącząca M7x1spec. L=101	Connecting screw M7x1spec. L=101	Винт соединительный M7x1 специальный L=101	1
5	40.5023.100	Śruba łącząca M7x1spec. L=95	Connecting screw M7x1spec. L=95	Винт соединительный M7x1 специальный L=95	1
6	40.3644.000	Ustawiak	Set block	Инструмент установочный	2
7	40.3645.100	Prowadnica ochronna 9/6,5	Protective guide 6.5/9	Направитель-протектор 9,0/6,5	2
8	40.3646.100	Prowadnica wiertła 6,5/3,5	Drill guide 6.5/3.5	Направитель сверла 6,5/3,5	2
9	40.3661.100	Prowadnica wiertła 6,5/2,8	Drill guide 6.5/2.8	Направитель сверла 6,5/2,8	2
10	40.3697.100	Prowadnica wiertła 6,5/4,5	Drill guide 6.5/4.5	Направитель сверла 6,5/4,5	1
11	40.3647.000	Trokar 6,5	Trocar 6.5	Троакар 6,5	1
12	40.1344.000	Celownik D	Target D	Целенаправитель дистальный	1
13	40.1354.000	Trokar krótki 7	Trocar short 7	Троакар короткий 7,0	1
14	40.1358.000	Prowadnica wiertła krótka 7/3,5	Drill guide short 7/3.5	Направитель сверла короткий 7/3,5	1
15	40.3670.000	Prowadnica wiertła 7/2,8	Drill guide 7/2.8	Направитель сверла 7/2,8	1
16	40.3665.000	Wbijak - wybijak	Impactor-extractor	Импактор-экстрактор	1
17	40.3667.000	Pobijak	Mallet	Пробойник	1
18	40.4751.000	Łącznik M7/M16	Connector M7/M16	Соединитель M7/M16	1
19	40.3619.000	Śrubokręt sześciokątny S 3,5	Hexagonal screwdriver 3.5	Отвертка S 3,5	1
20	40.3648.000	Klucz nasadowy S11	Socket wrench S11	Ключ торцовый S11	1
21	40.3698.100	Wzorzec długości wkrętów	Screw length measuring gauge	Измеритель длины винтов	1
22	40.5025.000	Drut prowadzący 1,8/500mm	Guide rod 1.8/500	Проволока направляющая 1,8/500	1
23	40.1351.000	Uchwyt drutu prowadzącego	Handle guide rod	Держатель направляющей проволоки	1
24	40.3699.000	Prowadnica rurkowa 7/290	Teflon pipe guide 7/290	Трубка-направитель 7/290	1
25	40.5332.000	Wiertło ze skalą 2,8/220mm	Drill with scale 2.8/220	Сверло с измерительной шкалой 2,8/220	2
26	40.5331.000	Wiertło ze skalą 3,5/220mm	Drill with scale 3.5/220	Сверло с измерительной шкалой 3,5/220	2
27	40.5336.000	Wiertło ze skalą 4,5/220mm	Drill with scale 4.5/220	Сверло с измерительной шкалой 4,5/220	1
29	40.4799.000	Wzorzec długości gwoździ	Nail length measuring gauge	Измеритель длины стержня	1
30	40.5065.009	Wkładka celująca 9,0	Insertion target 9.0	Целенаправительный вкладыш 9,0	4
28	40.4492.000	Statyw	Stand	Подставка	1

40.5020.000

The performance of the operation requires some necessary devices which are basic equipment of the operating theatre:

- electric drive,
- set of flexible intramedullary reamers in diameters between 6,0 and 11,0 mm, with guide and handle,
- set of awls (standard and cannulated),
- set of surgical drills,
- Kirchner wires,
- hammers,
- and others.



1. Humeral target B [40.5030]

2. Distal target D [40.5010]



3. Angular reconstruction target [40.5024]



4. Connecting screw M7x1spec. L=101 [40.5023]



5. Connecting screw M7x1spec. L=95 [40.5023.100]



6. Set block Ø3,5/Ø4,5 [40.3644]



7. Protective guide 6.5/9 [40.3645.100]



8. Drill guide 6.5/3.5 [40.3646.100]



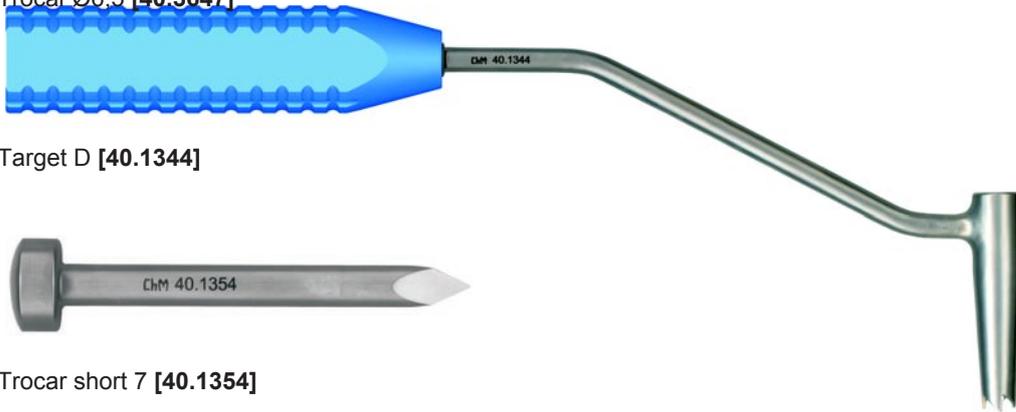
9. Drill guide Ø6,5/Ø2,8 [40.3661.100]



10. Drill guide Ø6,5/Ø4,5 [40.3697.100]



11. Trocar Ø6.5 [40.3647]



12. Target D [40.1344]



13. Trocar short 7 [40.1354]



14. Drill guide short 7/3.5 [40.1358]



15. Drill guide 7/2.8 [40.3670]



16. Impactor-extractor [40.3665]



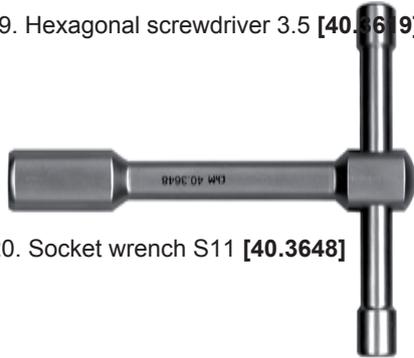
17. Mallet [40.3667]



18. Connector M7/M16 [40.4751]



19. Hexagonal screwdriver 3.5 [40.3619]



20. Socket wrench S11 [40.3648]



21. Screw length measure [40.3698.100]



22. Guide rod Ø1,8/500 [40.5025]



23. Handle guide rod [40.1351]



24. Teflon pipe guide 7/290 [40.3699]



25. Drill with scale Ø2,8/220 [40.5332]



26. Drill with scale Ø3,5/220 [40.5331]



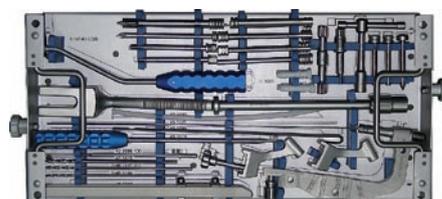
27. Drill with scale Ø4,5/220 [40.5336]



28. Nail length measure [40.4799]



29. Insertion target 9.0 [40.5065.009]



30. Stand [40.4492]

## IV. SURGICAL TECHNIQUE

### IV.1. Introduction

X-ray of the humeral fracture in AP and lateral position shall be performed before starting the operation in order to define the fracture type and make a choice of intramedullary nail size (length, diameter). Sometimes x-ray of opposite healthy humerus shall be also performed. The operation shall be performed on operating table equipped with traction and image intensifier (C-arm device) with patient placed supine or on the healthy side (depends on surgeon), on the edge of the table with radioluced base under the arm. The intramedullary nail can be inserted into medullary canal as follows:

- proximally (from humeral joint side),
- distally (from distal part of bone shaft).

The surgical approach of proximal intramedullary nail shall be prepared by:

- skin incision for 2-3cm, starting from clavicle-shoulder joint in anterior-lateral direction, in parallel with fibers of deltoid muscle,
- splitting fibers of deltoid muscle,
- exposing of supraspinous muscle attachment and his slight splitting.

### IV.2. Opening of the medullary canal (proximal insertion of the humeral nail)

**1** After preparing the surgical approach (description: Chapter IV.1. Surgical technique / Introduction p.19) in order to open the medullary canal using electric drive insert Kirschner wire (Kirschner wire Ø2/310mm recommended) a little bit medial, to the greater tuberculum, in the axis of medullary canal.

**This step should be performed under the control of fluoroscopy.**

The Kirchner wire acts as a guide for cannulated awl.

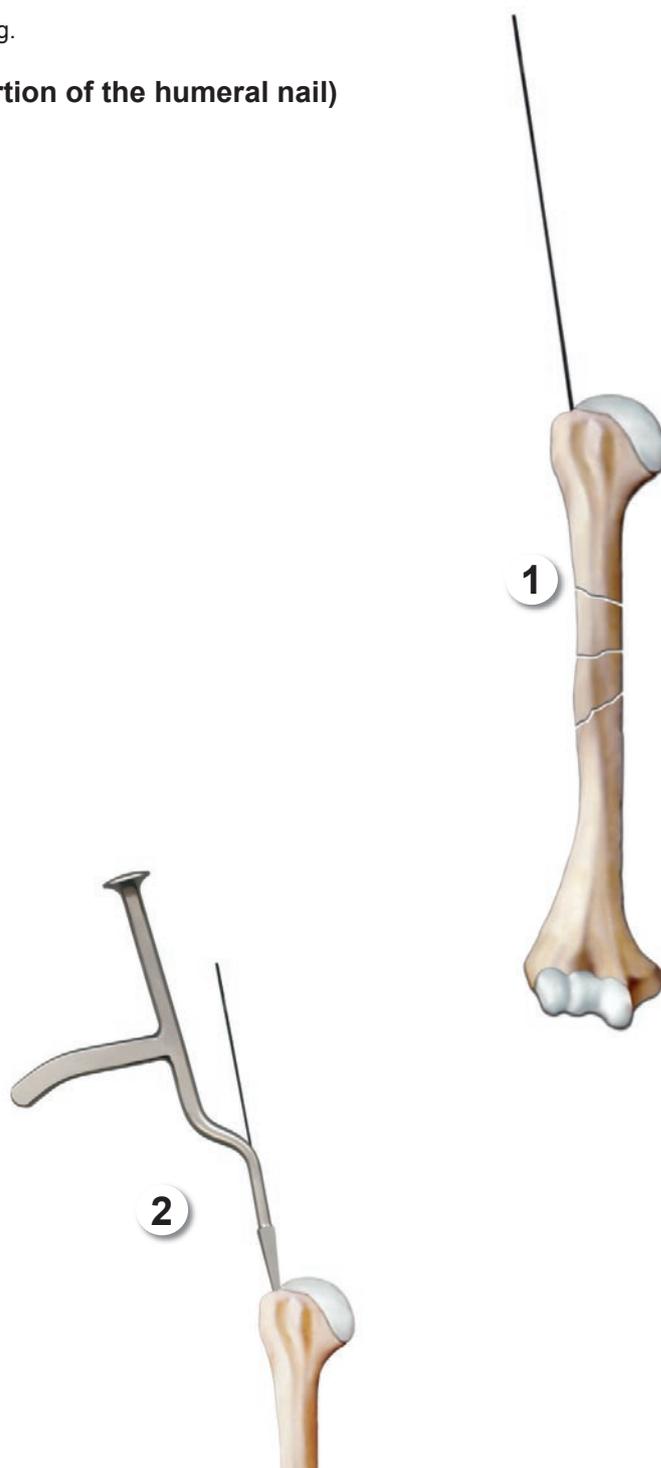
*The Kirchner wire is a single use instrument.*

**2** Using cannulated awl (not included in ChM Humeral Instrument Set) leading via the Kirschner wire, open the medullary canal in depth for approx. 7 cm.

Remove the awl and Kirchner wire.



**It is recommended to open medullary canal with technique describe in steps 1 and 2. The surgeon can use other opening medullary canal technique depending on equipment of the operation suite.**



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

## IV.3. Preparation of the medullary canal

### Reamed canal

**3** Insert the Guide Rod [40.5025] into the medullary canal on required depth, doing reduction of fracture at the same time. Gradually widen the medullary canal with flexible reamers every 0,5mm, until reach the diameter  $\varnothing 0,5\text{mm}$  wider than the diameter of the humeral nail, for the depth not lesser than the nail length.

The proximal part of the medullary canal should be reamed to the diameter  $\varnothing 11\text{mm}$  to the depth of approx. 7cm. (proximal part of a nail is wider than its distal part).

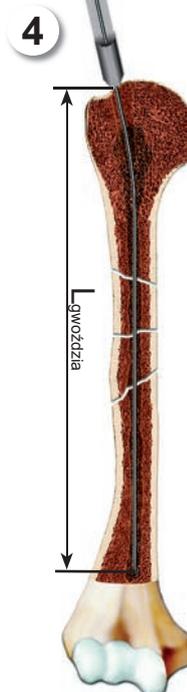
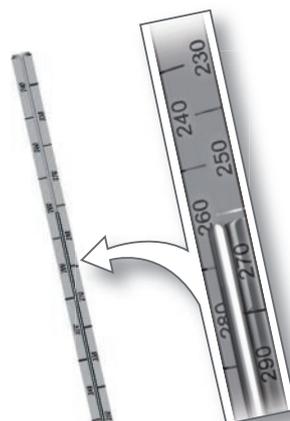
Remove the Flexible Reamer.

Leave the Guide Rod [40.5025] in the medullary canal.

**4** Put the Nail Length Measure [40.4799] onto the Guide Rod [40.5025] until it reaches the bone. The end of the Guide Rod indicate the length of the implant.

**5** In case of a solid nail, using the Handle Guide Rod [40.1351] remove the Guide Rod [40.5025] from the medullary canal.

The medullary canal is prepared for the humeral nail insertion.



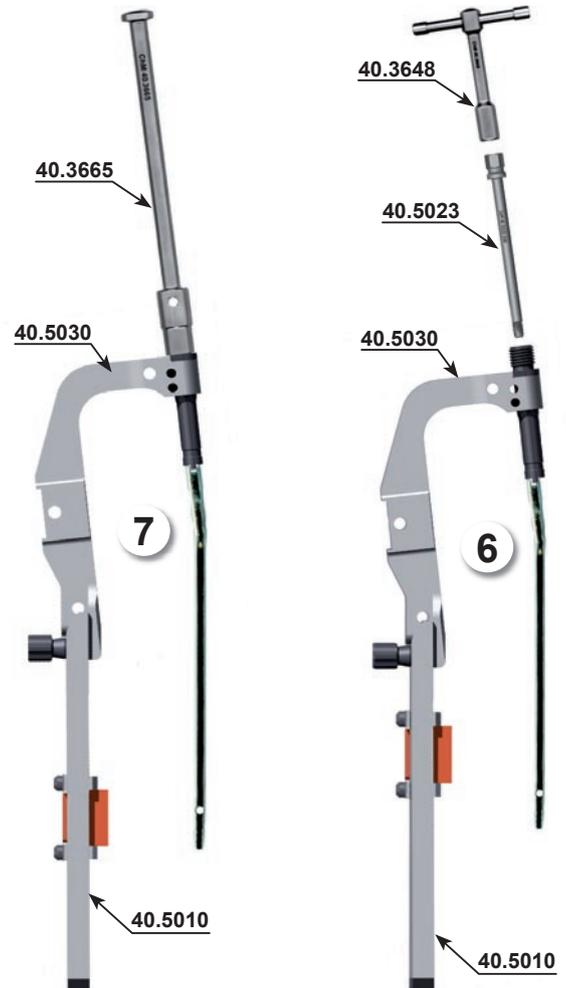
**IV.4. Assembling of a compression humeral nail.  
Target B positioning. Nail insertion into me-  
dullary canal.**

**6** Using the Socket Wrench [40.3648] and the Connecting Screw [40.5023.000] fix the intramedullary nail to the Target B [40.5030]. Target B [40.5030] and Target D [40.5010] are a universal instruments used with compression and reconstruction humeral nails. There are several holes in its proximal part enable locking the nails. The holes on target are described as follows:

- **STAT** – enable insertion of a locking screw in the round hole in a compression nail,
- **COMPRESSION** – enable insertion of a locking screw in the oval hole in compression nail,
- **ANGULAR** – enable oblique insertion of a locking screw in the oval hole in compression nail,
- **RECONSTRUCTION** – enable locking a short reconstruction nail in its distal part.

In order to eliminate failure insertion of a locking screw, it is recommended using Setting Pins [40.3644] inserted in the holes in the Target B to make control of the overlapping of the holes in the Target and the holes in the nail. It is also recommended to close the remaining holes with Insertion Targets [40.5065.009].

 **Properly installed nail shall be positioned parallel to the arm of Target B.**

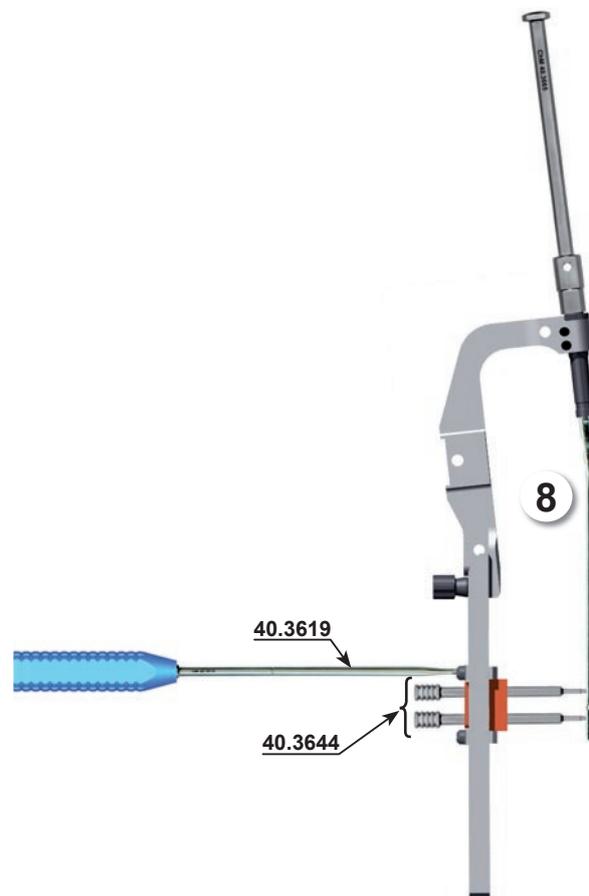


**7** Connect Impactor – Extractor [40.3665] to the assembled system (attach on the threaded tip of the Target B sleeve [40.5030]).

**8** Using two Setting Pins [40.3644] place the slider of Target B in line with distal locking holes of intramedullary nail. Lock the slider of the target using hexagonal Screwdriver [40.3619].

 **CHECK: Properly set and secured slider means that setting pins advance the holes in the nail smoothly.**

Remove the Setting Pins from the Target B.



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

- 9 Using Mallet [40.3667] insert the humeral nail into the medullary canal at the correct depth



The cannulated nail is being inserted into the humeral medullary canal on the Guide Rod [40.5025]. The solid nail is inserted directly into the humeral medullary canal (without using the Guide Rod).

Dismount the Impactor-Extractor off the Guide.  
Remove the Guide Rod (only when cannulated nail is used for the implantation).

## IV.5. Distal locking of the nail

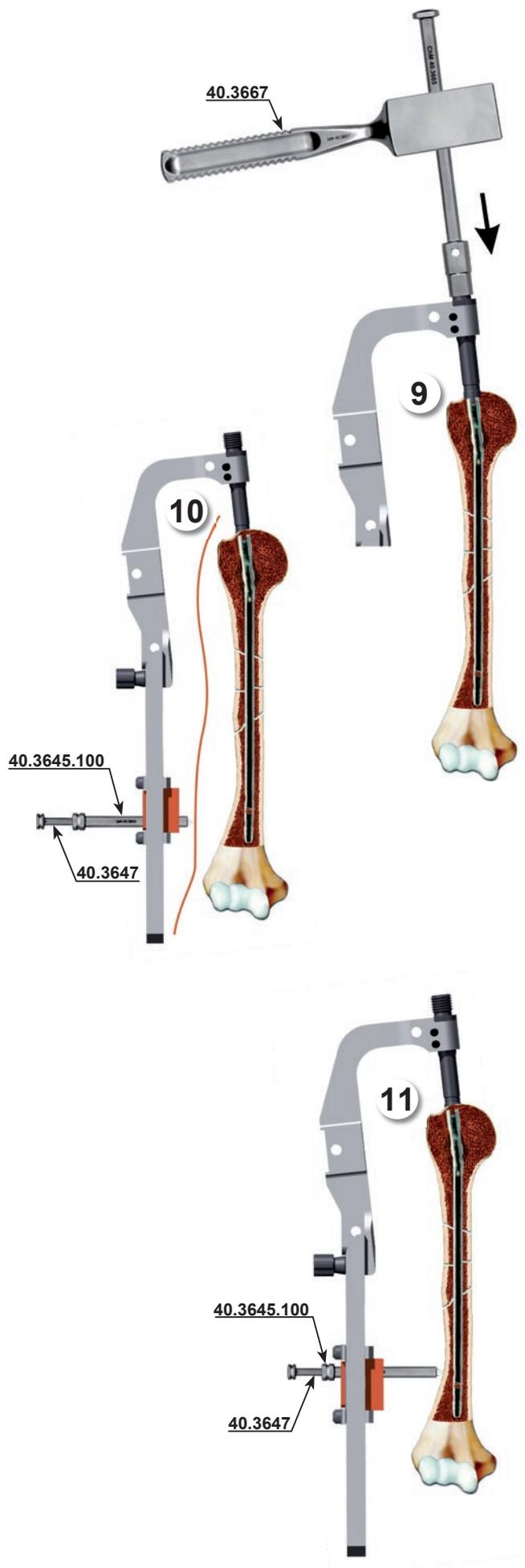
- 10 Before starting distal locking of the nail, do the following:  
Verify with the x-ray image intensifier and Insertion Targets [40.5065.009] the mutual position of holes in the slider of Target B and distal holes of the intramedullary nail.

The holes in the nail and the slider have to be in line.

Insert Protective Guide [40.3645.100] with Trocar [40.3647] successively into the proximal and distal holes in the slider of Target B and mark the points on the skin for inserting a locking screws. Next make incision through the soft tissues, approx. 1,5cm in length.

- 11 Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into the hole in the slider of Target B. Advance the Protective guide with Trocar into prepared incision this way to put its ending close as possible of cortex. Using the Trocar mark the point for a canal for a locking screw.

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.

**12** Drill the hole in the humeral bone for locking screw insertion.

**OPTION I:**

Concerning implantation using Ø8 or Ø9mm nails (for locking use Ø4.5 screws). Insert the Drill Guide Ø3.5 [40.3646.100] into the Protective Guide [40.3645.100]. Mount the Ø3.5/220 Drill Bit [40.5331] on the surgical drive and advance it through the Drill Guide Ø3.5mm [40.3646.100]. Drill the hole in the humerus through the two cortex layers under the control of fluoroscopy. The scale on Drill Bit indicate length of locking element.

**OPCJA II:**

Concerning implantation using Ø6 or Ø7mm nails (for locking use Ø3.5 screws). Insert the Drill Guide Ø2.8mm [40.3661.100] into the Protective Guide [40.3645.100]. Mount the Ø2.8/220 Drill Bit [40.5332] on the surgical drive and advance it through the Drill Guide [40.3661.100]. Drill the hole in the humerus through the two cortex layers under the control of fluoroscopy. The scale on Drill Bit indicate length of locking element.

Disconnect the surgical drive and the Drill Bit.  
Leave in place the Drill Bit together with Drill Guide and Protective Guide.

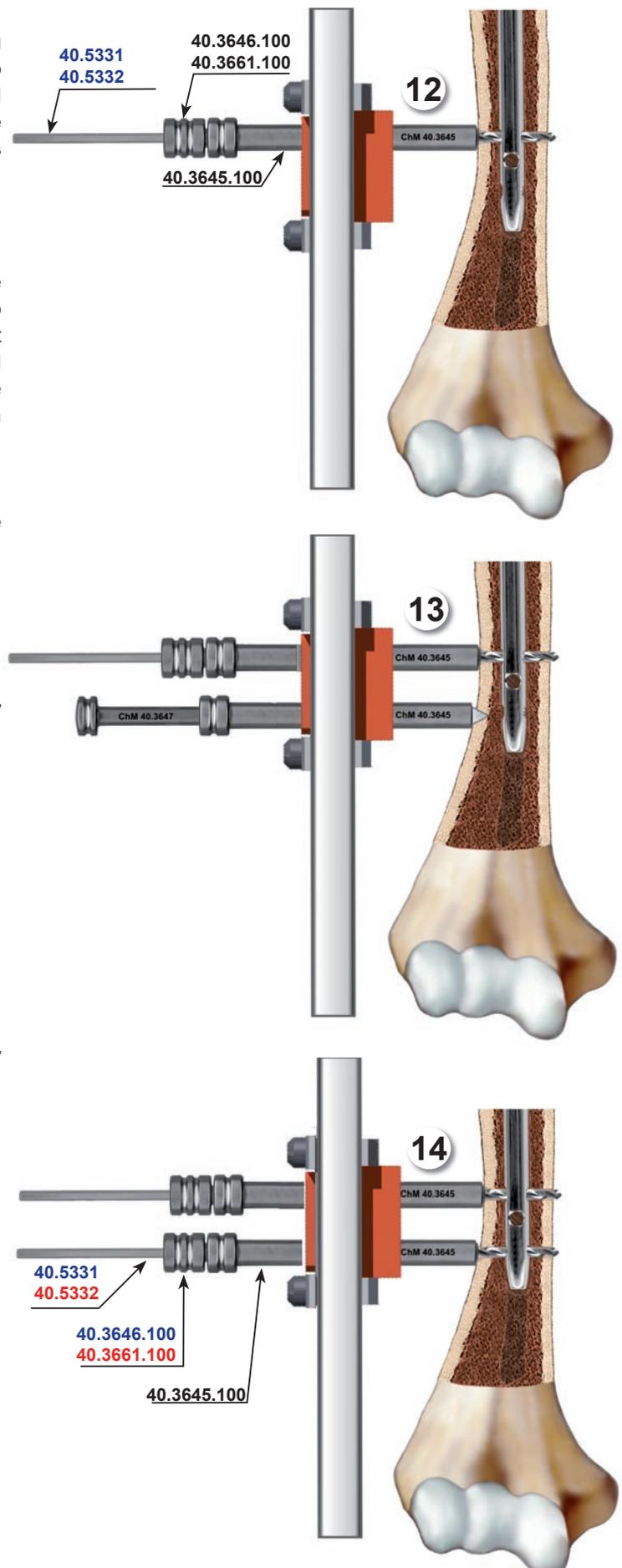
**OPTION I ([40.3645.100] - [40.3646.100] - [40.5331])**

**OPTION II ([40.3645.100] - [40.3661.100] - [40.5332])**

**13** Mark the point for canal making for second locking screw insertion. Repeat 11 step.

**14** Make the canal in the bone for the second locking screw insertion. Repeat 12 step. Remove the Drill Bit [40.5331] or [40.5332] and the Drill Guide [40.3646.100] or [40.3661.100] just after reaming of the canal.

Leave the Protective Guide in the hole of the slider of Target B.

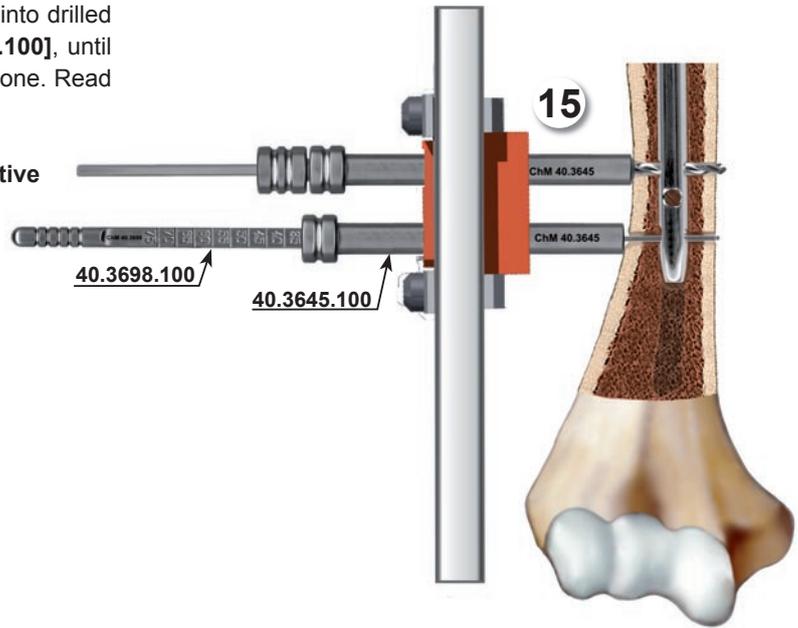


*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

- 15** Through protective guide [40.3645.100] insert into drilled hole in bone Screw Length Measure [40.3698.100], until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the B-D scale.

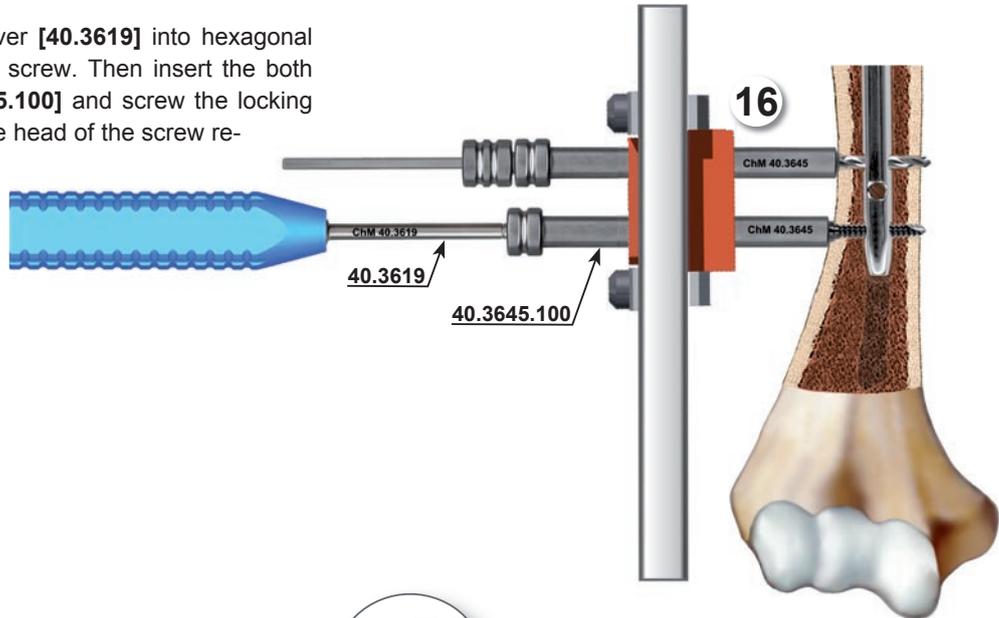
**During the measurement the end of the Protective Guide should rest on the cortex of the bone.**

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



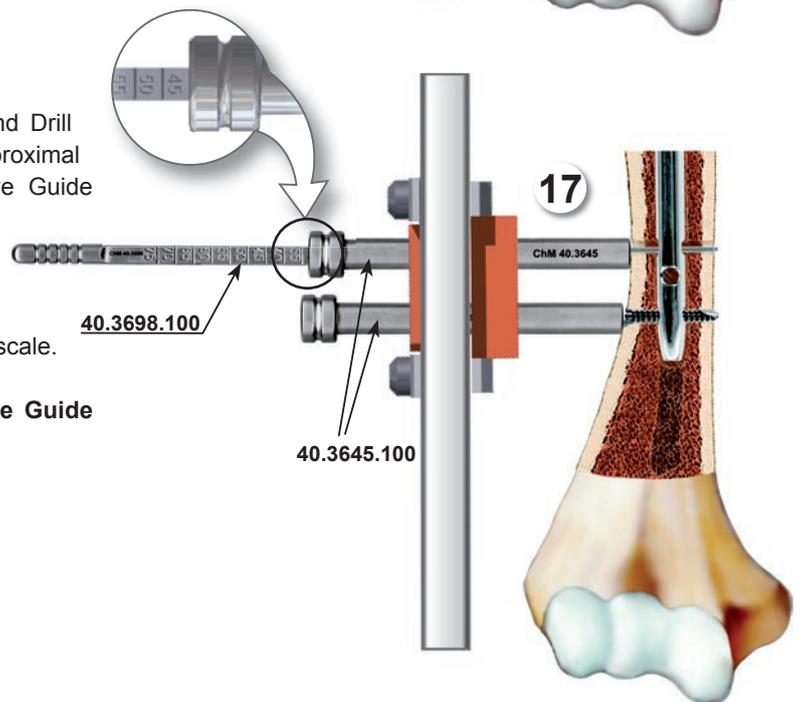
- 16** Put the tip of the Screwdriver [40.3619] into hexagonal head of the definite locking screw. Then insert the both into the Protective Guide [40.3645.100] and screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the Screwdriver shaft matches the edge of the Protective Guide).

Remove the Screwdriver.



- 17** Remove the Drill Bit [40.5331] or [40.5332] and Drill Guide [40.3646.100] or [40.3661.100] from the proximal hole of the slider of Target B. Leave the Protective Guide [40.3645.100] in the hole of the slider. Through Protective Guide [40.3645.100] insert into drilled hole in bone Screw Length Measure [40.3698.100], until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the B-D scale.

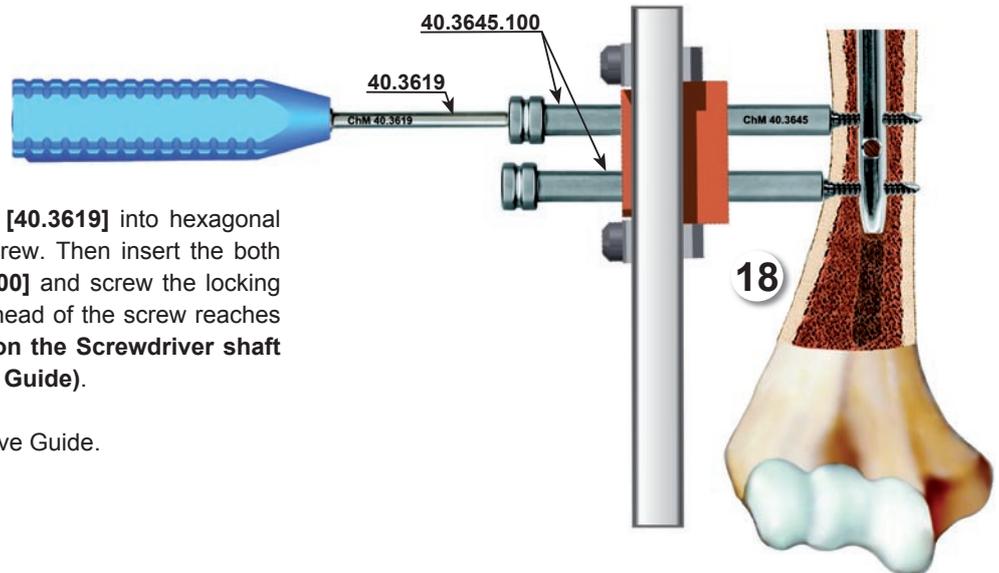
**During the measurement the end of the Protective Guide should rest on the cortex of the bone.**



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

- 18** Put the tip of the Screwdriver [40.3619] into hexagonal head of the definite locking screw. Then insert the both into the Protective Guide [40.3645.100] and 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 the Protective Guide).

Remove the Screwdriver and Protective Guide.



## IV.6. Proximal locking of the nail

### IV.6.A. Dynamic and dynamic with compression method (compressive)



The hole marked as **COMPRESSION** on the proximal part of the Target B should be used in dynamic or compressive intramedullary fixation.

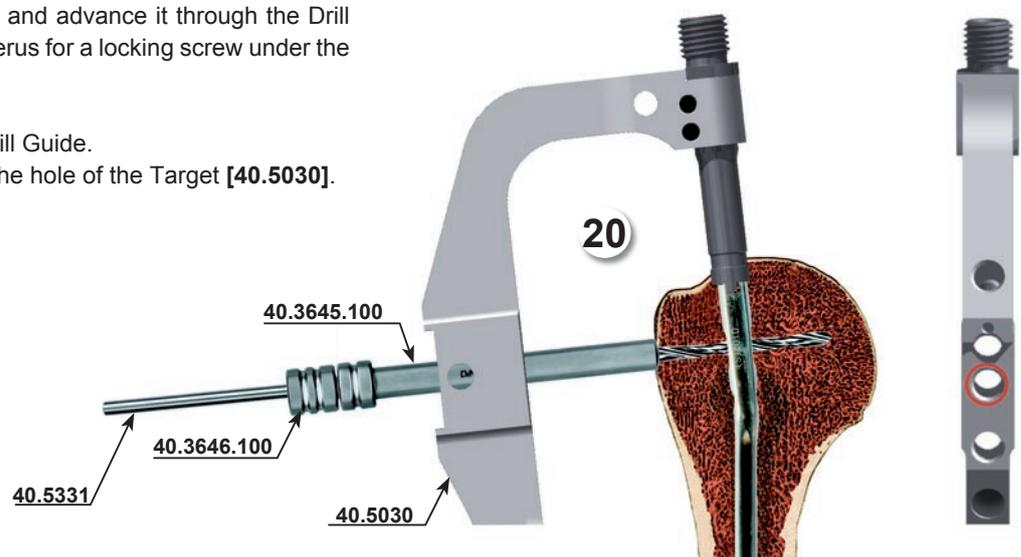
- 19** Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into the hole marked as **COMPRESSION** in the Target B. After marking the entry point of the locking screw on the skin by the Trocar, make an adequate incision though soft tissues approx. 1,5cm in length. Immerse the Protective guide with Trocar into prepared incision this way to put its end as close as possible of cortex. Mark the point of entry for the Drill Bit.

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



- 20** Insert Drill Guide Ø3.5 [40.3646.100] into the Protective Guide [40.3645.100]. Mount the Ø3.5/220 Drill Bit [40.5331] on the surgical drive and advance it through the Drill Guide. Drill the hole in the humerus for a locking screw under the control of fluoroscopy.

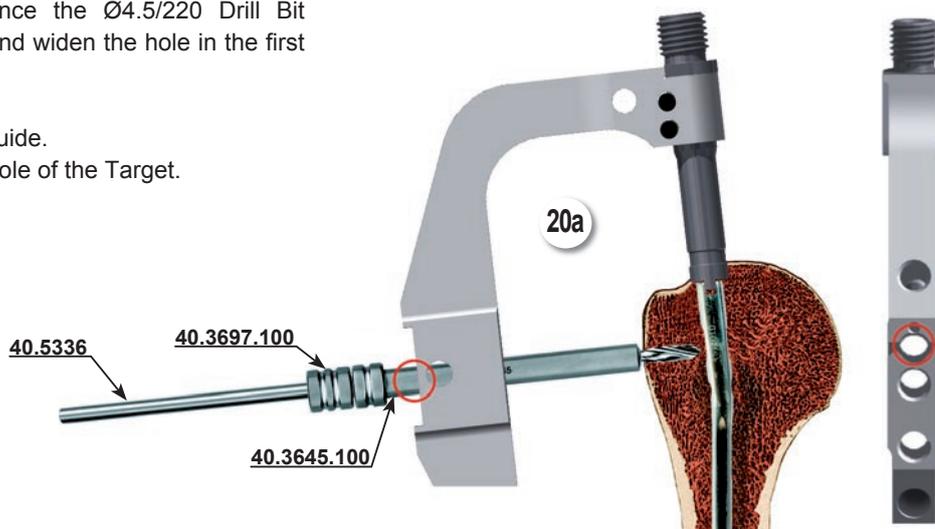
Remove the Drill Bit and the Drill Guide.  
Leave the Protective Guide in the hole of the Target [40.5030].



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

**20a** Insert the Drill Guide Ø4.5 [40.3697.100] into the Protective Guide [40.3645.100]. Advance the Ø4.5/220 Drill Bit [40.5336] through the Drill Guide and widen the hole in the first bone cortex.

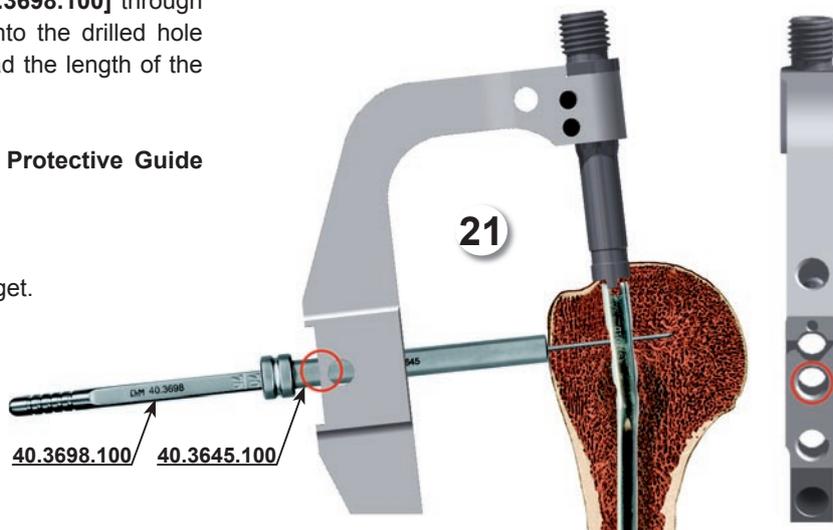
Remove the Drill Bit and the Drill Guide.  
Leave the Protective Guide in the hole of the Target.



**21** Insert the Screw Length Measure [40.3698.100] through the Protective Guide [40.3645.100] into the drilled hole until its tip reaches the end of the hole. Read the length of the locking screw on the D-B scale of measure.

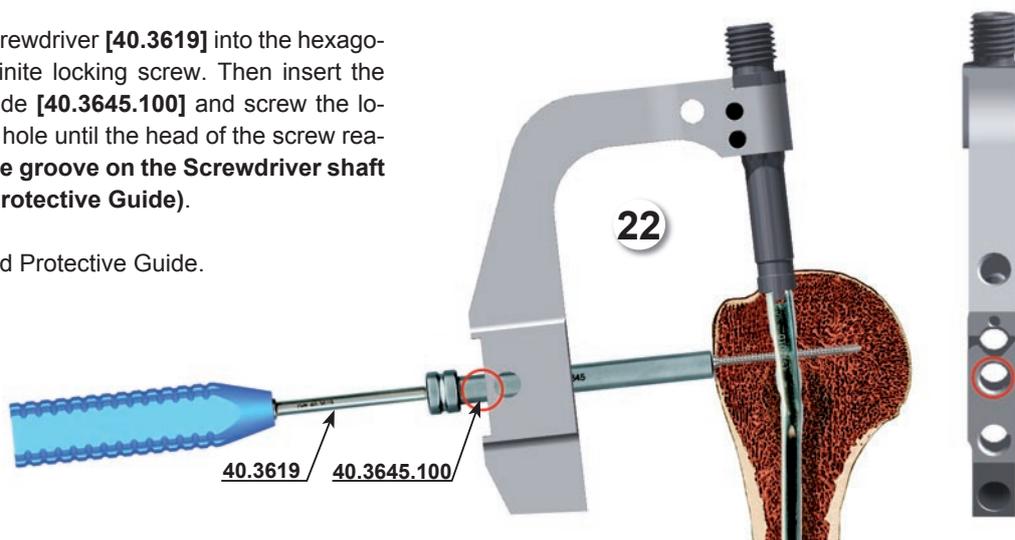
**During the measurement the end of the Protective Guide should rest on the cortex bone.**

Remove the Screw length measure.  
Leave the Protective guide in hole of the Target.



**22** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of the definite locking screw. Then insert the both into the Protective Guide [40.3645.100] and screw the locking screw in the prepared hole until the head of the screw reaches the cortex the bone (**the groove on the Screwdriver shaft matches the edge of the Protective Guide**).

Remove the Screwdriver and Protective Guide.



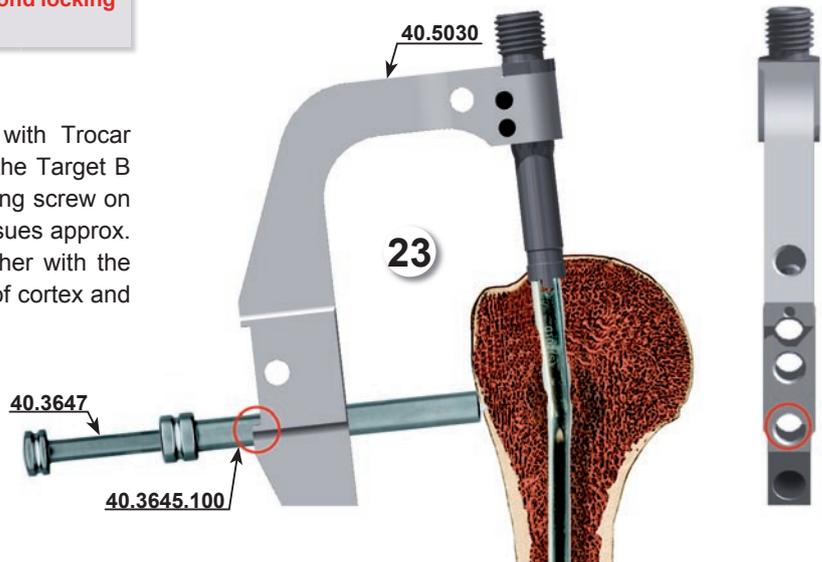
*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

**IV.7. Static method**



The hole marked as **STAT** on the proximal part of the Target should be used in static fixation. The second hole may be used for nail locking by the second locking screw (by proximal screw).

**23** Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into the hole marked as STAT in the Target B [40.5030]. After marking the entry point of the locking screw on the skin, make an adequate incision through soft tissues approx. 1.5cm in length. Insert the Protective Guide together with the Trocar this way to put its ending close as possible of cortex and mark the point of entry for the Drill Bit. Remove the Trocar. Leave the Protective Guide in the hole of the Target.



**24** Drill the hole in the humeral bone for locking screw insertion.

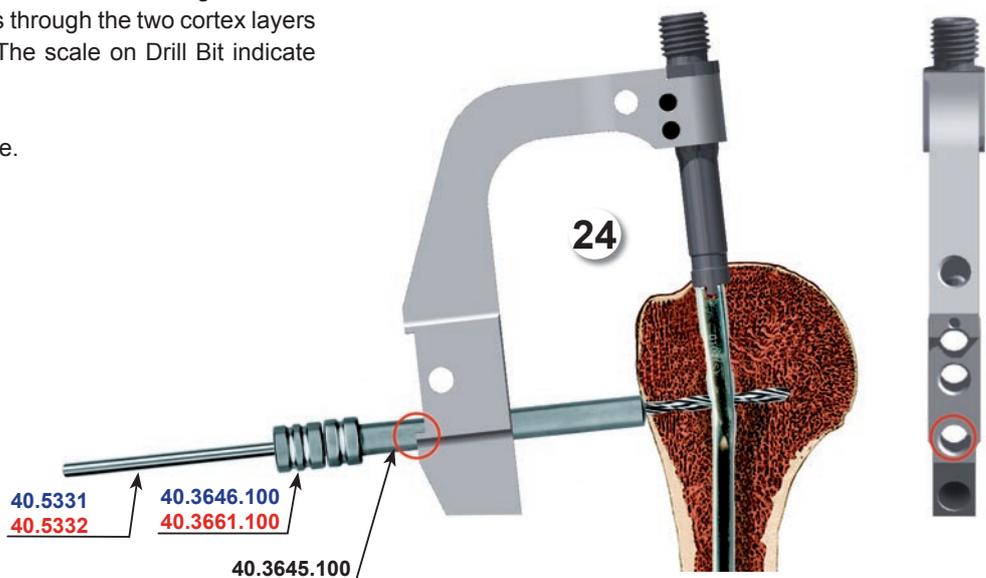
**OPTION I:**

Concerning implantation using Ø8 or Ø9mm nails (for locking use Ø4.5 screws). Insert the Drill Guide Ø3.5mm [40.3646.100] into the Protective Guide [40.3645.100]. Mount the Ø3.5/220 Drill Bit [40.5331] on the surgical drive and advance it through the Drill Guide. Drill the hole in the humerus through the two cortex layers under the control of fluoroscopy. The scale on Drill Bit indicate length of locking element.

**OPTION II:**

Concerning implantation using Ø6 or Ø7mm nails (for locking use Ø3.5 screws). Insert the Drill Guide Ø2.8mm [40.3661.100] into the Protective Guide [40.3645.100]. Mount the Ø2.8/220 Drill Bit [40.5332] on the surgical drive and advance it through the Drill Guide. Drill the hole in the humerus through the two cortex layers under the control of fluoroscopy. The scale on Drill Bit indicate length of locking element.

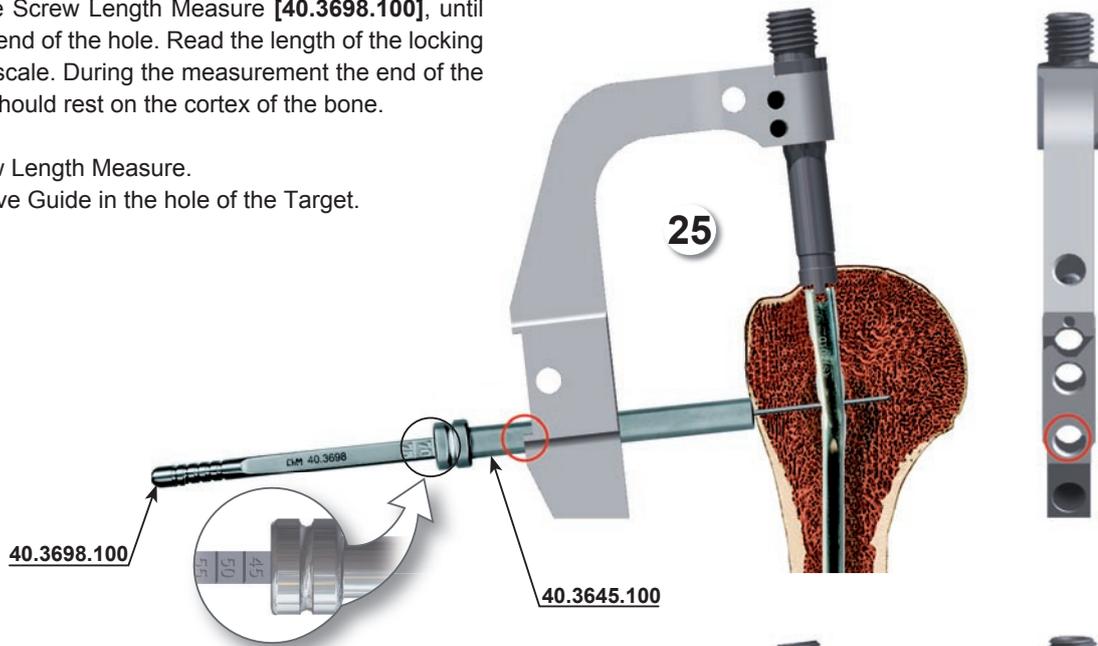
Remove the Drill Bit and Drill Guide.  
Leave in place Protective Guide.



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

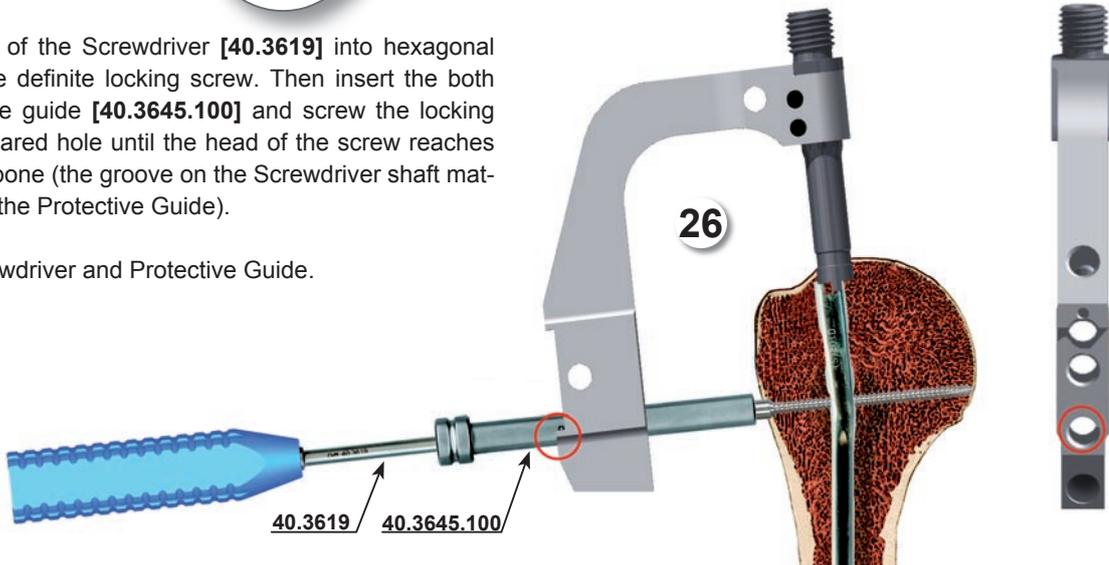
- 25** Through Protective Guide [40.3645.100] insert into drilled hole in bone Screw Length Measure [40.3698.100], until its tip reaches the end of the hole. Read the length of the locking screw on the B-D scale. During the measurement the end of the Protective Guide should rest on the cortex of the bone.

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



- 26** Put the tip of the Screwdriver [40.3619] into hexagonal head of the definite locking screw. Then insert the both into the Protective guide [40.3645.100] and 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 the Protective Guide).

Remove the Screwdriver and Protective Guide.

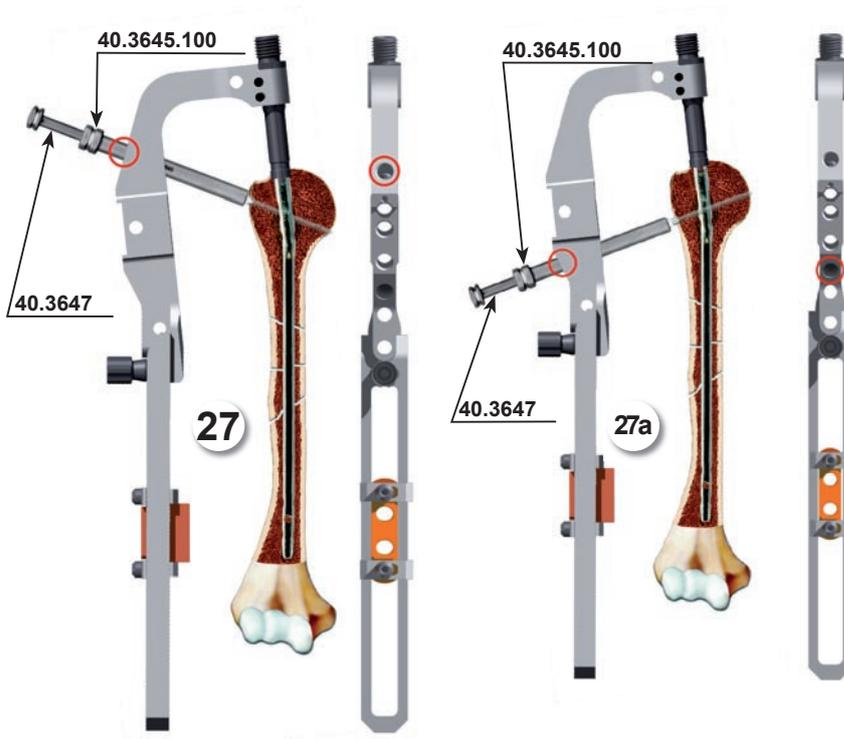


**!** If the surgeon decides to lock the nail in the proximal part with two locking screws, insertion of second screw should be performed as shown in steps from [20] to [22] (chapter IV.6.A from page 23 to 24).

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

### IV.8. Oblique locking of the nail

Design of the Target [40.5030] enables oblique insertion of locking screw in proximal part of the nail through the holes marked **ANGULAR** in the Target and compression using compression screw. Before starting steps connected with oblique locking of the nail, do the following: Verify with the x-ray image intensifier the mutual position of the holes in the slider of Target B and the holes in proximal part of the intramedullary nail.



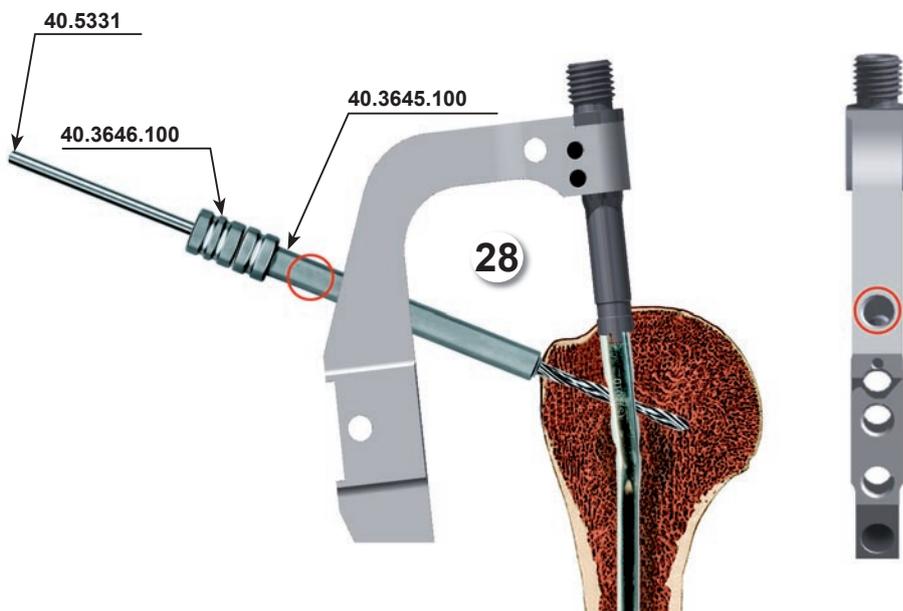
**The holes in the nail and the slider have to be in line.**

**27** Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into the hole marked as **ANGULAR** in the Target B [40.5030]. After marking the entry point of the locking screw on the skin, make an adequate incision though soft tissues 1.5cm in length. Insert the Protective Guide together with the Trocar this way to put its end as close as possible of cortex mark the point of entry for the Drill Bit.

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

**28** Insert the Drill Guide Ø3.5 [40.3646.100] into the Protective Guide [40.3645.100]. Mount the Ø3.5/220 Drill Bit [40.5331] on the surgical drive and advance it through the Drill Guide. Drill the hole for locking screw in the humerus under the control of fluoroscopy.

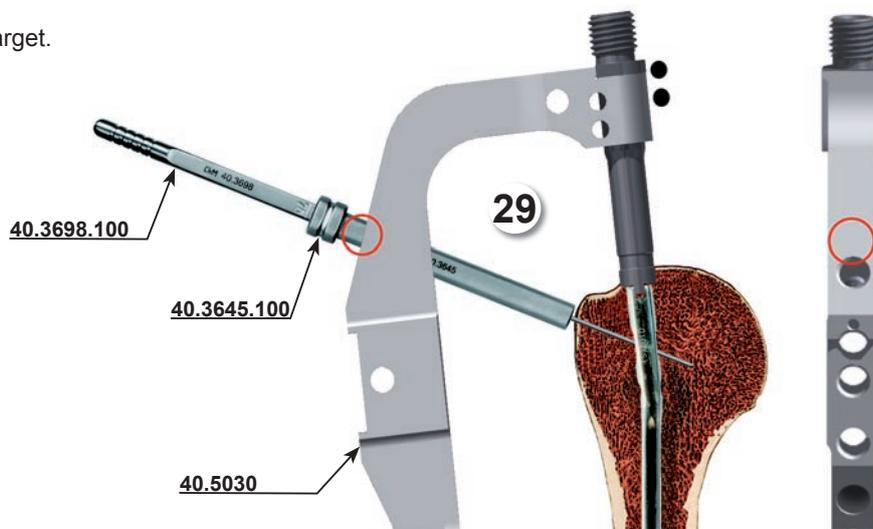
Remove the Drill Bit and the Drill Guide.  
Leave the Protective Guide in the hole of Target [40.5030].



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

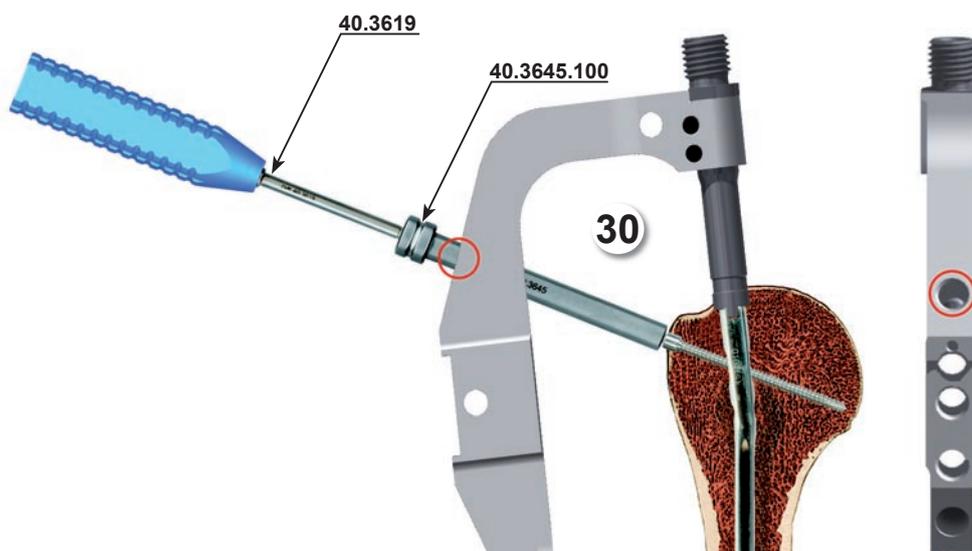
- 29** Insert the Screw Length Measure [40.3698.100] through the Protective Guide [40.3645.100] into the drilled hole until its tip reaches the end of the hole. Read the length of the locking screw on B-D scale of measure.

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



- 30** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of the definite locking screw [1.1654]. Then insert the both into the Protective Guide [40.3645.100] and screw the locking screw in the prepared hole (the groove on the Screwdriver shaft matches the edge of the Protective Guide).

Remove the Screwdriver and Protective Guide

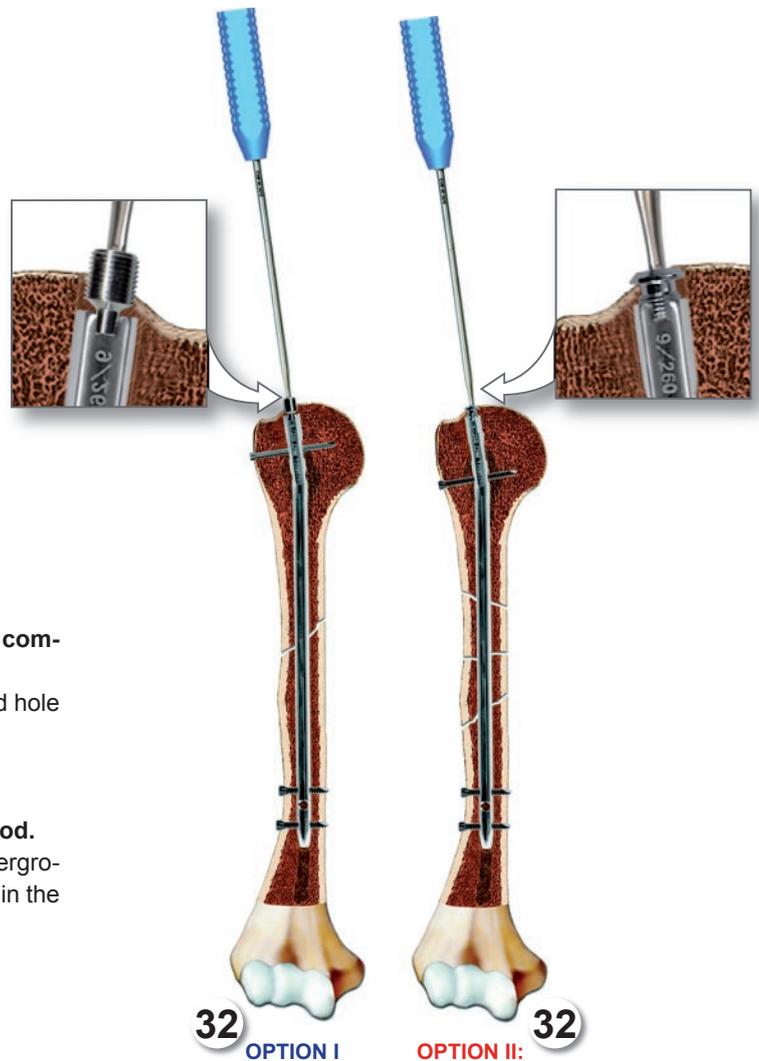


*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

**IV.9. Humeral nail removal from the Target. Placing Compression screw or end cap.**



**31** Dismount the Target B [40.5030] from the nail: using Socket Wrench [40.3648] unscrew the Connecting Screw [40.5023] out of the nail locked in the medullary canal.



**32** Screw Compression screw in or end cap.

**OPTION I:**

**Screwing compression screw in concern dynamic with compression method (compressive).**

Screw the compression screw in (implant) into the threaded hole in the nail shaft using the Screwdriver [40.3619].

**OPTION II:**

**Screwing end cap in concern dynamic and static method.**

In order to secure the inner thread of the nail from bone overgrowth, screw the end cap (implant) in into the threaded hole in the nail shaft using the Screwdriver [40.3619].

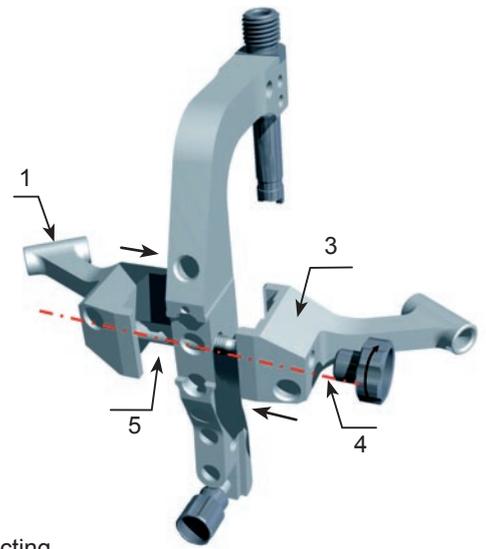
**32** OPTION I

**32** OPTION II:

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

**IV.10. Proximal locking of a short reconstruction humeral nail**

In order to lock reconstruction humeral nail it is necessary to mount the Angular Target [40.5024] to the Target B [40.5030] as showed on the picture on the side. Put screwed shaft (5) of the Angular Target I (1) into lateral hole of the Target B [40.5030] then into the connective hole (3) of Angular Target II. Connect parts by screwing the nut (4).



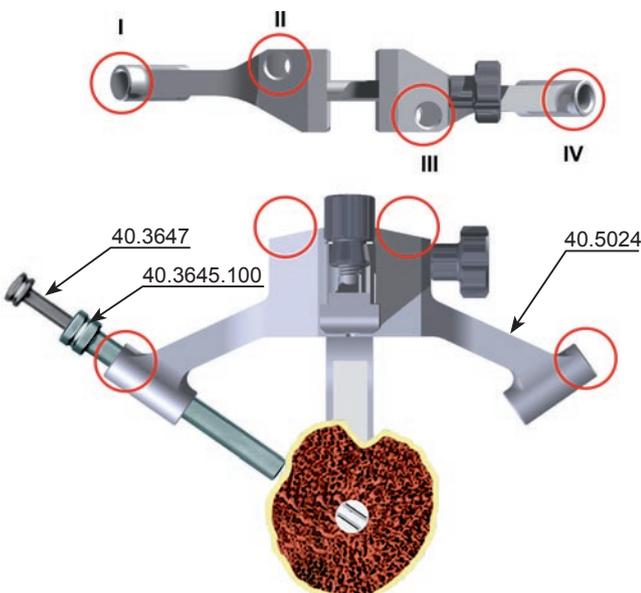
- 33** Using the Socket Wrench [40.3648] and the Connecting Screw [40.5023.100] connect the intramedullary nail to the leading sleeve of the Target B [40.5030].

 **Properly installed nail shall be positioned parallel to the arm of Target B.**

- 34** Connect the Impactor-Extractor [40.3665] to the installed system (screw in on the threaded tip of the Target B leading sleeve [40.5030]).

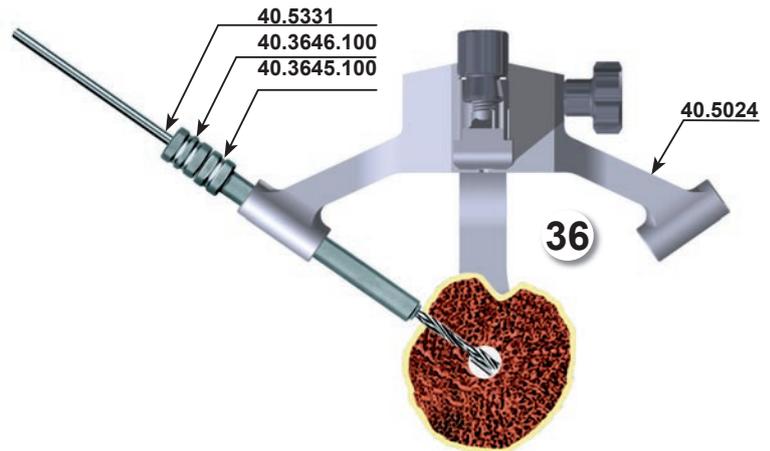
- 35** Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into one of the holes I, II, III or IV in the Angular Target [40.5024]. After marking the entry point of the locking screw on the skin, make an adequate incision though the soft tissues approx. 1.5cm in length. Insert the Protective Guide together with the Trocar this way to put its end as close as possible of cortex and mark the point of entry for the Drill Bit.

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

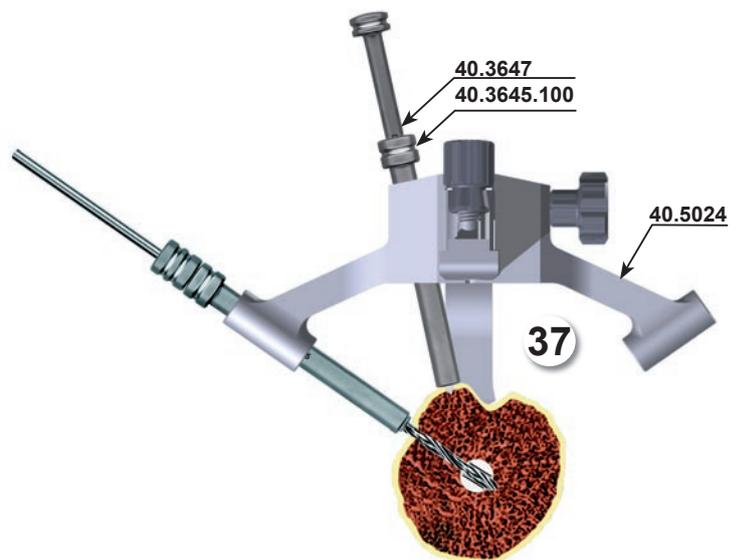


*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

**36** Insert the Drill Guide Ø3.5 [40.3646.100] into the Protective Guide [40.3645.100]. Mount the Ø3.5/220 Drill Bit [40.5331] on the surgical drive and advance it through the Drill Guide. Drill the hole for locking screw in the humerus under the control of fluoroscopy. Leave the Protective Guide with the Drill Bit and the Drill Guide in the hole of the Target [40.5030].

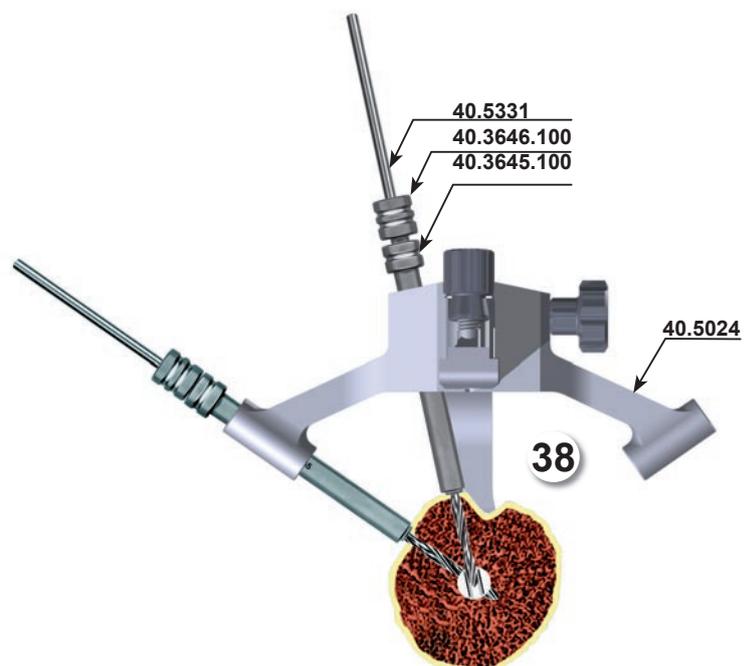


**37** Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into the next hole of the Angular Target [40.5024]. After marking the entry point of the locking screw on the skin, make an adequate incision through the soft tissues approx. 1.5cm in length. Insert the Protective Guide together with the Trocar this way to put its end as close as possible of cortex and mark the point of entry for the Drill Bit.



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

**38** Insert the Drill Guide Ø3.5 [40.3646.100] into the Protective Guide [40.3645.100]. Mount the Ø3.5/220 Drill Bit [40.5331] on the surgical drive and advance it through the Drill Guide. Drill the hole for locking screw in the humerus under the control of fluoroscopy.

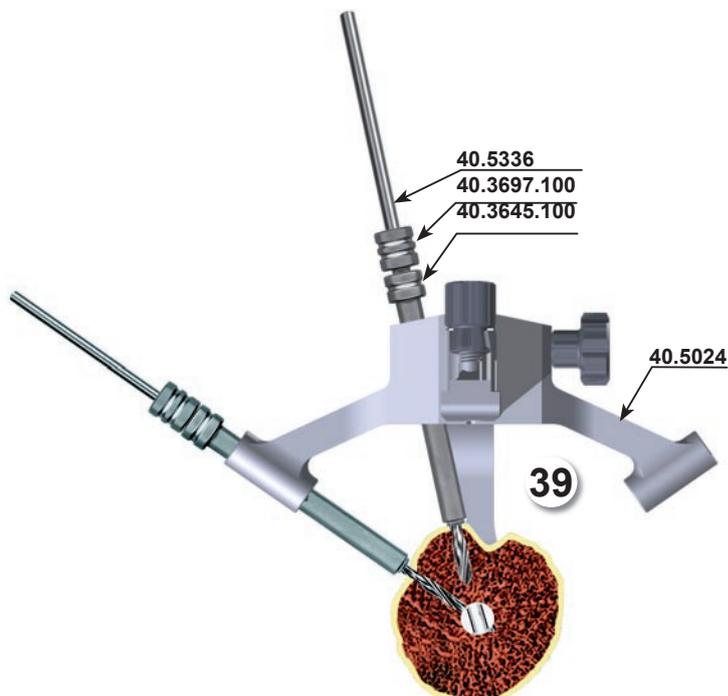


Remove the Drill Guide.  
Leave the Protective Guide in the hole of the Target [40.5030].

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

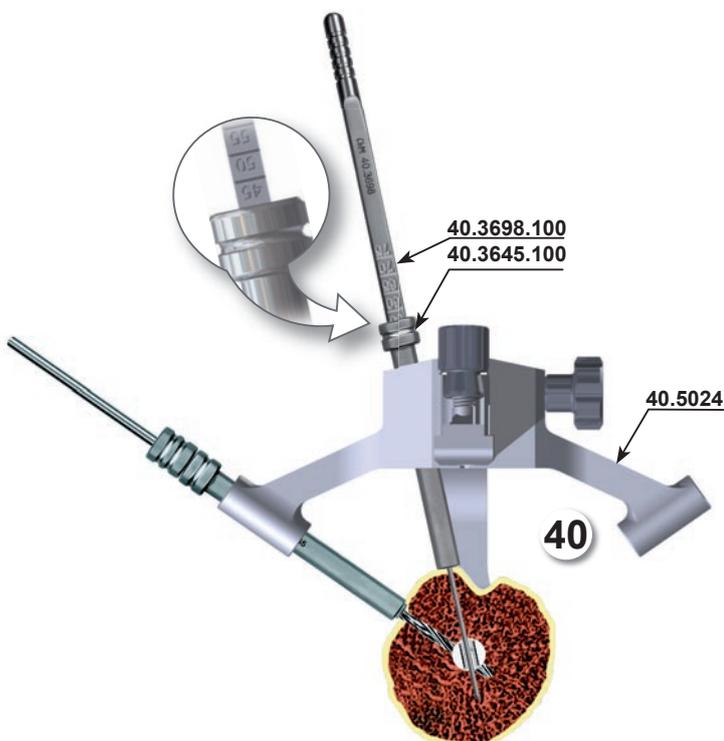
- 39** In case of nail locking by locking screws  $\varnothing 4,5$  [1.1653] one should using Drill Bit  $\varnothing 4,5/220$  [40.5336] ream the hole in the first bone cortex (first: insert Drill Guide  $\varnothing 4,5$  [40.3697.100] into Protective Guide [40.3645.100]).

Remove the Drill Bit and the Drill Guide.  
Leave the Protective Guide in the hole of the Target.



- 40** Insert the Screw Length Measure [40.3698.100] through the Protective Guide [40.3645.100] into the drilled hole until its tip reaches the end of the hole. Read the length of the locking screw on B-D scale of measure.

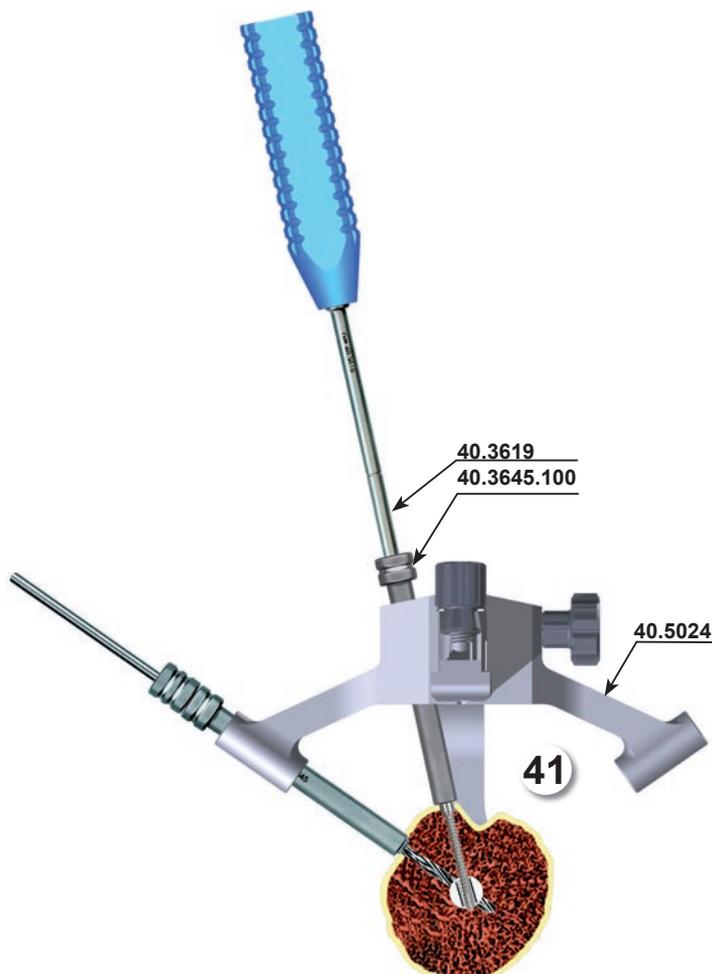
Remove the Screw Length Measure.  
Leave the Protective Guide in hole of the Target.



- 41** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of locking screw:

-  $\varnothing 4,5$  [1.1653] in case of standard locking; or  
-  $\varnothing 5,0$  [1.1657] in case of locking in threaded hole of the nail.  
Then insert the both into the Protective Guide [40.3645.100] and carefully screw the locking screw in the prepared hole (until the groove on the Screwdriver shaft matches the edge of the Protective Guide).

Remove the Screwdriver.  
Leave Protective Guide.

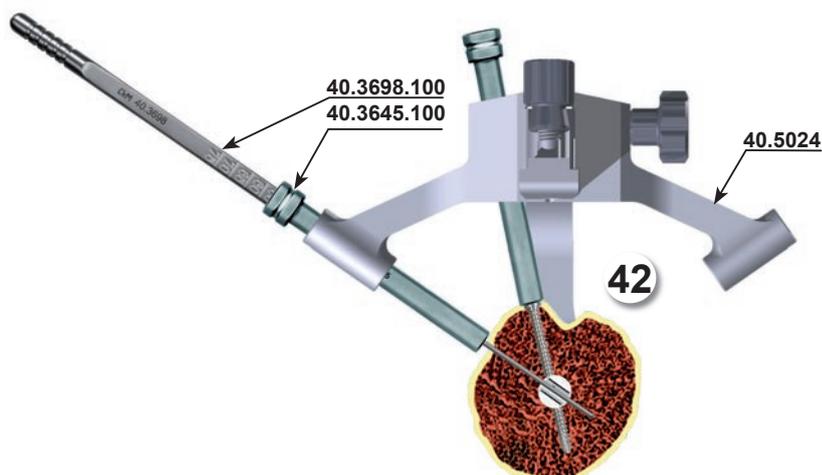


*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

**42** Remove the Drill Bit [40.5331] and the Drill Guide [40.3646.100] from the proximal hole of the target. Leave in hole Protective Guide [40.3645.100]. Insert the Screw Length Measure [40.3698.100] through the Protective Guide [40.3645.100] into the drilled hole until its tip reaches the end of the hole. Read the length of the locking screw on B-D scale of measuring gauge.

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

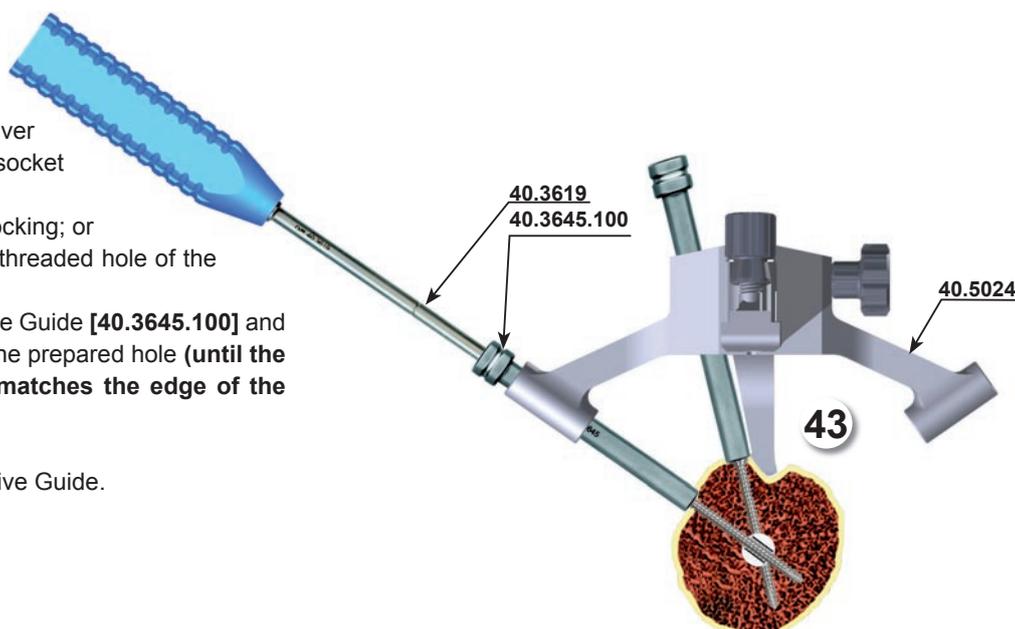
Remove the Screw Length Measure.  
Leave the Protective Guide in hole of the Target.



**43** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of locking screw:  
- Ø4,5 [1.1653] in case of standard locking; or  
- Ø5,0 [1.1657] in case of locking in threaded hole of the nail.

Then insert the both into the Protective Guide [40.3645.100] and carefully screw the locking screw in the prepared hole (until the groove on the Screwdriver shaft matches the edge of the Protective Guide).

Remove the Screwdriver and Protective Guide.



**44** In order to facilitate of nail locking in proximal part in another holes it is recommend (after making the first hole and check on RADIOGRAPH correctness of its effect) to left the Drill in the hole and start to lock the rest of holes or make nail interlocking and left Protective Guide on the head of locking screw in order to improve the system: nail – Target.

Repeat steps 37-41 in order to lock the nail using other holes in the Target.

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

**IV.11. Distal locking of a short reconstruction humeral nail**

**45** Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into the hole of the Target B marked as **RECONSTRUCTION** [40.5030]. After marking the entry point of the locking screw on the skin, make an adequate incision through soft tissues 1.5cm in length. Advance the Protective Guide together with the Trocar this way to put its end as close as possible of cortex and mark the point of entry for the Drill Bit.

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

**46** Drill the hole in bone for locking screw insertion.

**OPTION I:**

**Concerning implantation using Ø8 or Ø9mm nails** (for locking use Ø4.5 screws). Insert the Drill Guide Ø3.5mm [40.3646.100] into the Protective Guide [40.3645.100]. Mount the Ø3.5/220 Drill Bit [40.5331] on the surgical drive and advance it through the Drill Guide [40.3646] and drill the hole in the humerus through the two cortex layers under the control of fluoroscopy. The scale on the Drill Bit indicate length of locking element.

**OPTION II:**

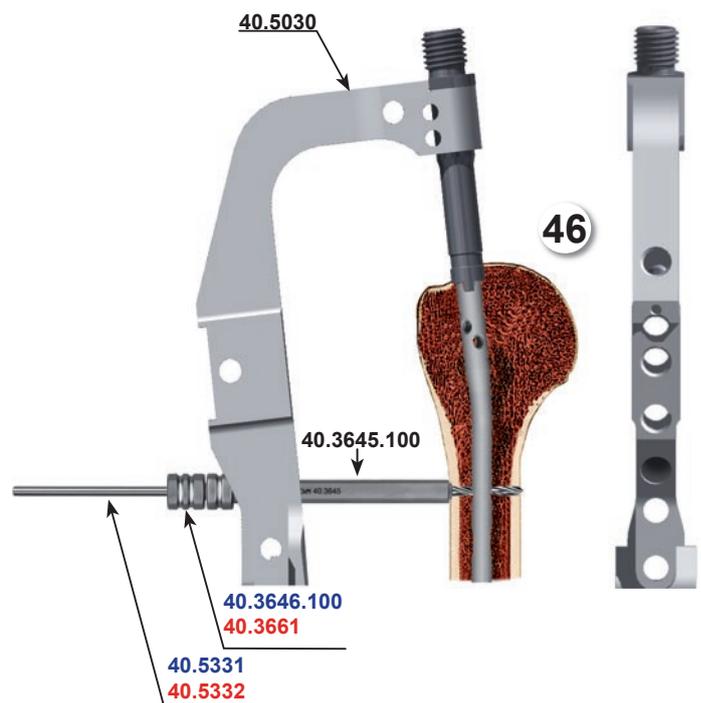
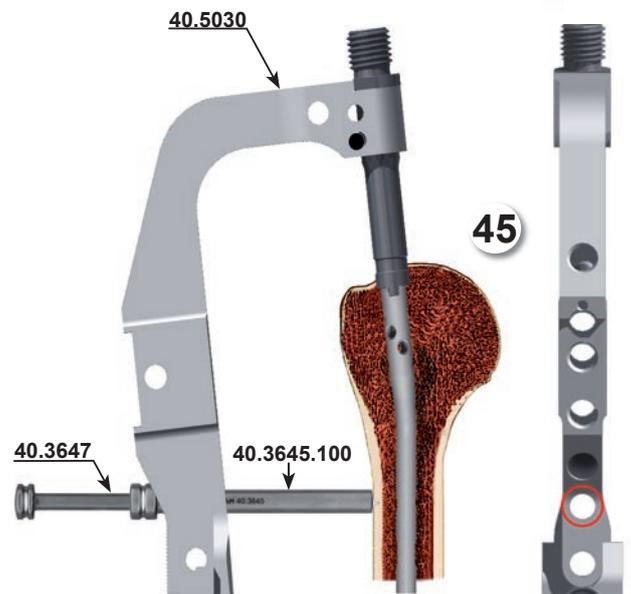
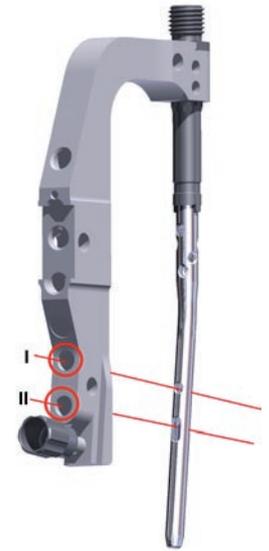
**Concerning implantation using Ø6 or Ø7mm nails** (for locking use Ø3.5 screws). Insert the Drill Guide Ø2.8mm [40.3661] into the Protective Guide [40.3645.100]. Mount the Ø2.8/220 Drill Bit [40.5332] on the surgical drive and advance it through the Drill Guide. Drill the hole in the humerus through the two cortex layers under the control of fluoroscopy. The scale on the Drill Bit indicate length of locking element.

After disconnect the surgical drive and Drill, leave in place system:

Protective Guide – Drill Guide – Drill.

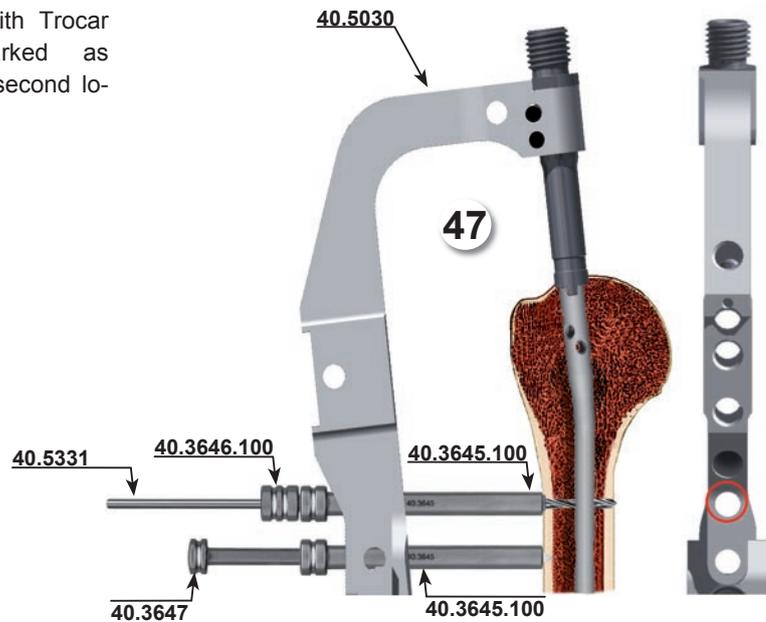
**OPTION I** ([40.3645] - [40.3646.100] - [40.5331])

**OPTION II** ([40.3645] - [40.3661] - [40.5332])



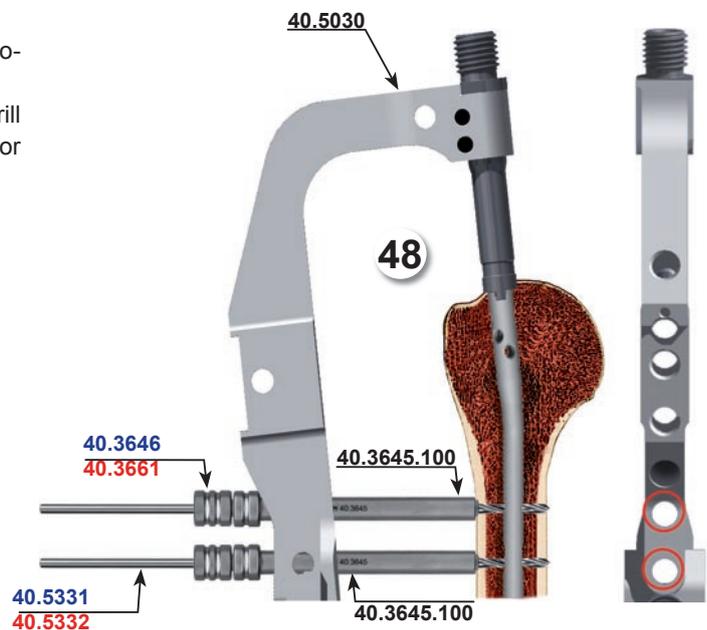
*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

**47** Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into the second hole marked as **RECONSTRUCTION**. Mark the entry point for the second locking screw. In this order one should repeat step 45.



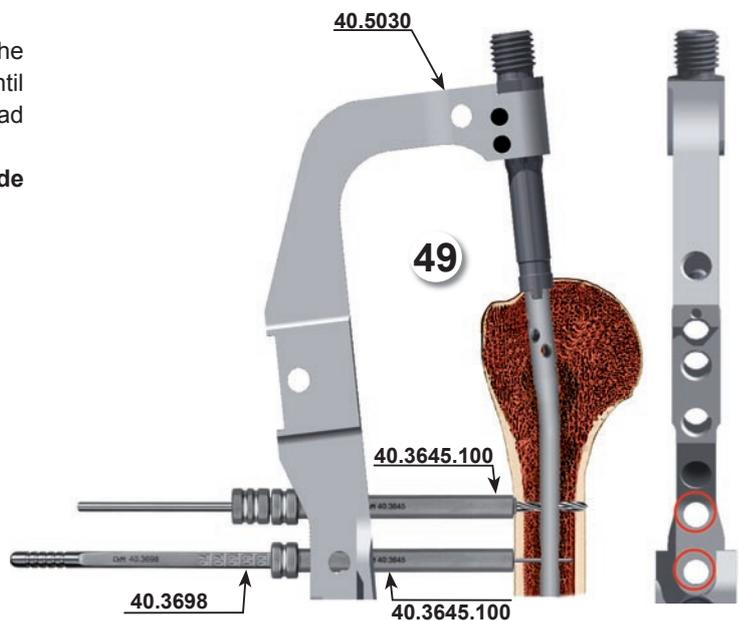
**48** Drill the hole in the humerus for inserting the second locking screw. In this order one should repeat step 46. Directly after making the hole one should remove the Drill [40.5331] or [40.5332] and Drill Guide [40.3646.100] or [40.3661].

Leave the Protective Guide in the hole of the Target slider.



**49** Insert the Screw Length Measure [40.3698] through the Protective Guide [40.3645.100] 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 B-D scale of measure. **During the measurement the end of the Protective Guide should rest on the cortex bone.**

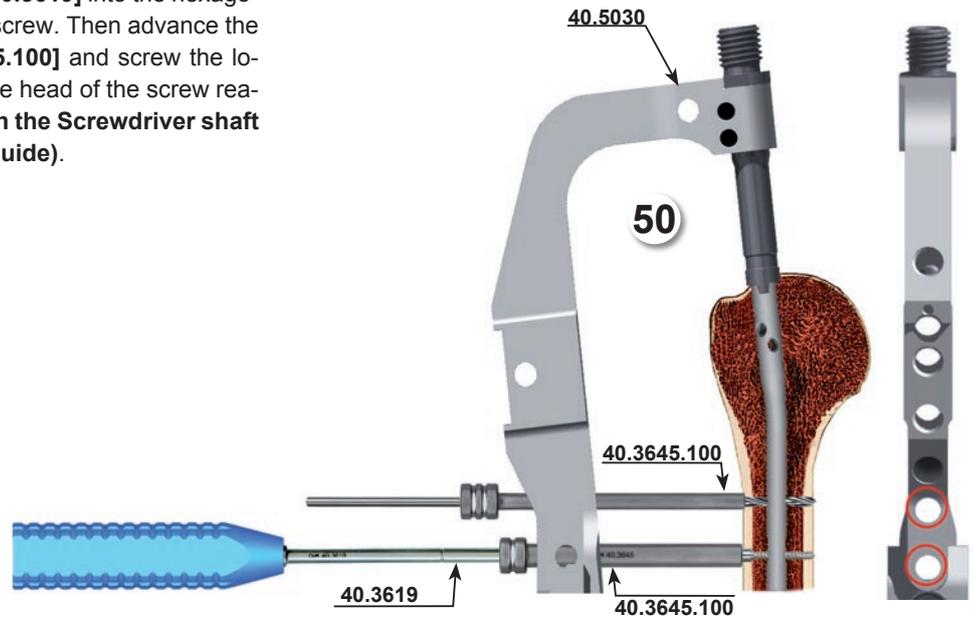
Remove the Screw Length Measure.  
Leave the Protective Guide in hole of Target.



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

- 50** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of the definite locking screw. Then advance the both into the Protective Guide [40.3645.100] and screw the locking screw in the prepared hole until the head of the screw reaches the cortex the bone (the groove on the Screwdriver shaft matches the edge of the Protective Guide).

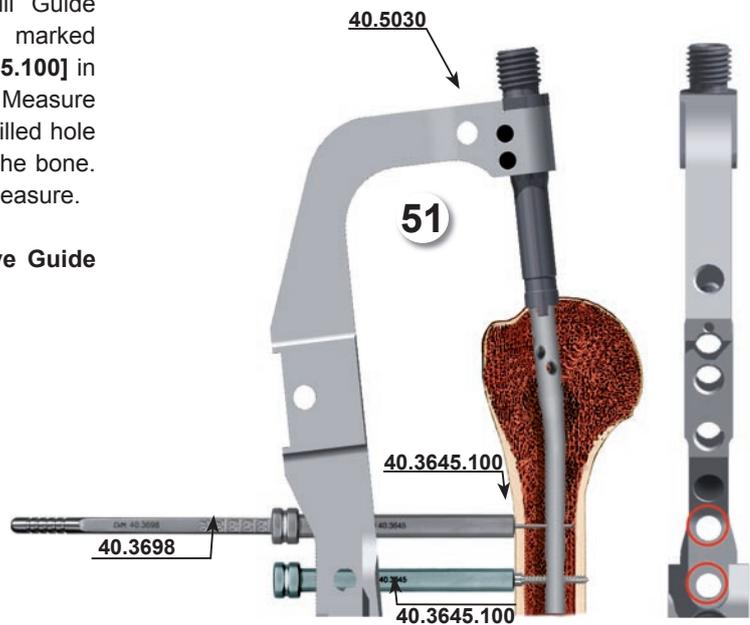
Remove the Screwdriver.



- 51** Remove the Drill Bit [40.5331] and the Drill Guide [40.3646.100] from the first hole marked **RECONSTRUCTION**. Leave Protective Guide [40.3645.100] in the hole of the slider. Introduce the Screw Length Measure [40.3698.100] 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 B-D scale of measure.

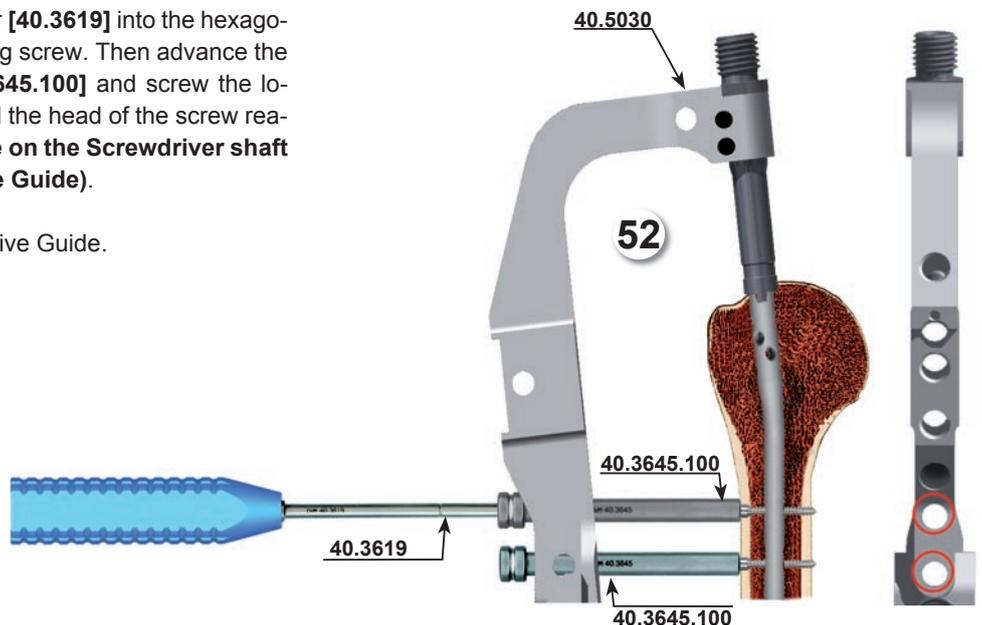
During the measurement the end of the Protective Guide should rest on the cortex bone.

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



- 52** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of the definite locking screw. Then advance the both into the Protective guide [40.3645.100] and screw the locking screw in the prepared hole until the head of the screw reaches the cortex the bone (the groove on the Screwdriver shaft matches the edge of the 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.12. Distal locking of a long reconstruction humeral nail**

Before starting distal locking of the nail, do the following: Verify using x-ray image intensifier and Insertion Targets [40.5065.009] the mutual holes position in the slider of the Target and holes in distal part of the nail.

**Holes in the nail and the slider have to be in line.**



**53** Insert Protective Guide [40.3645.100] with Trocar [40.3647] into the proximal hole in the slider of the Target. After marking the points on the skin for inserting a locking screws make incision through the soft tissues, approx. 1,5cm in length. Advance the protective guide with Trocar into prepared incision this way to put its end as close as possible of cortex. Using the Trocar mark the point for a canal for a locking screw.

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

**54** Drill the hole in bone for locking screw insertion.

**OPTION I:**

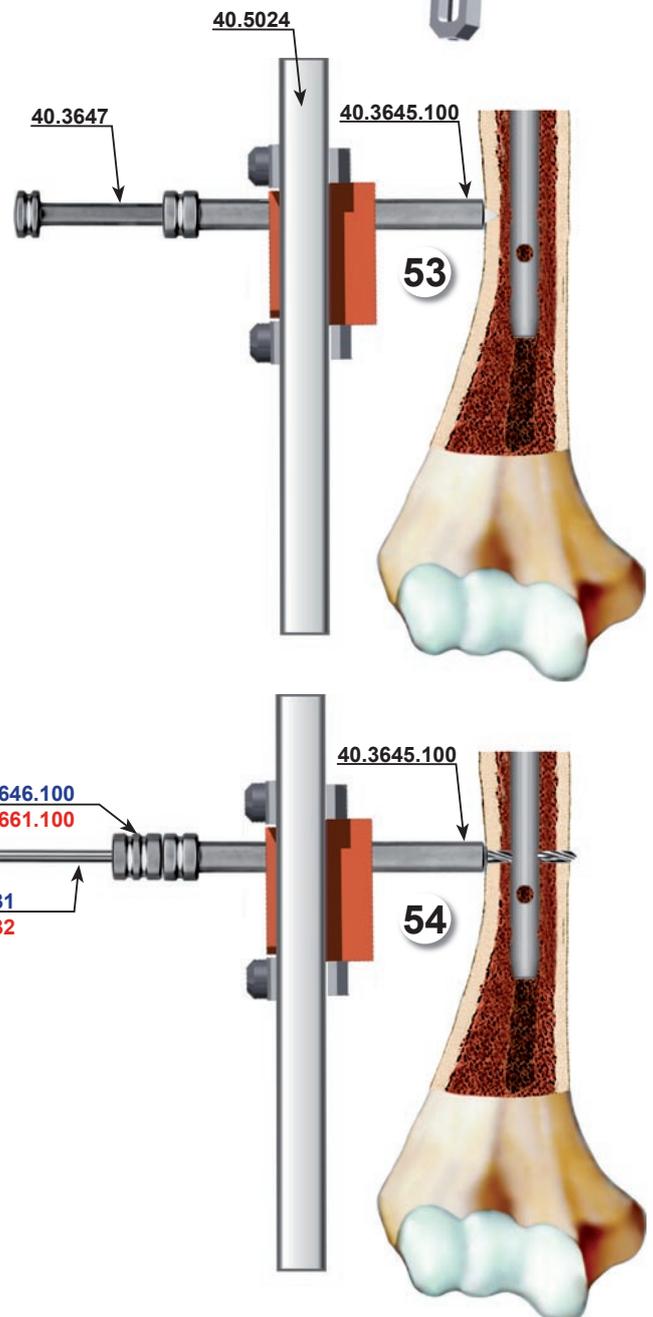
**Concerning implantation using Ø8 or Ø9 mm nails** (for locking use Ø4.5 screws). Insert the Drill Guide Ø3.5mm [40.3646.100] into the Protective Guide [40.3645.100]. Mount the Ø3.5/220 Drill Bit [40.5331] on the surgical drive and advance it through the Drill Guide [40.3646.100] and drill the hole in the humerus through the two cortex layers under the control of fluoroscopy. The scale on the Drill Bit indicate length of locking element.

**OPTION II:**

**Concerning implantation using Ø6 or Ø7 mm nails** (for locking use Ø3.5 screws). Insert the Drill Guide Ø2.8mm [40.3661.100] into the Protective Guide [40.3645.100]. Mount the Ø2.8/220 Drill Bit [40.5332] on the surgical drive and advance it through the Drill Guide. Drill the hole in the humerus through the two cortex layers under the control of fluoroscopy. The scale on the Drill Bit indicate length of locking element. After disconnect the surgical drive and Drill, leave in place system: Protective Guide – Drill Guide – Drill.

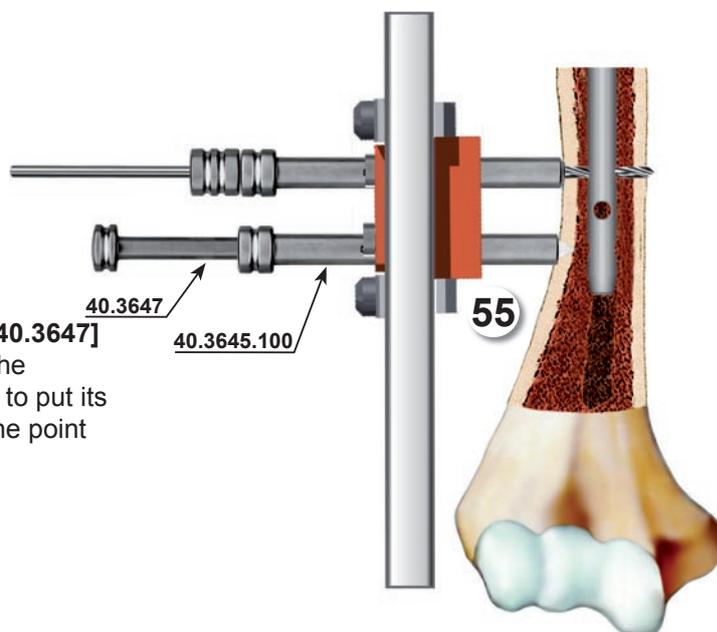
**OPTION I** ([40.3645.100] - [40.3646.100] - [40.2137.200]);

**OPTION II** ([40.3645.100] - [40.3661.100] - [40.2044]).



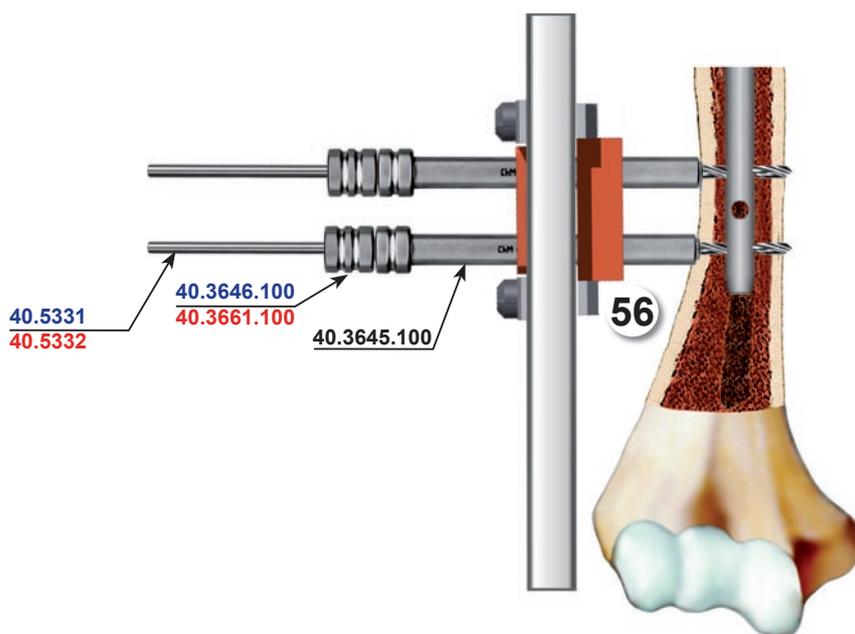
*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

- 55** Insert Protective Guide [40.3645.100] with Trocar [40.3647] into the distal hole in the slider of Target B. Advance the Protective Guide with Trocar into prepared incision this way to put its end as close as possible of cortex. Using the Trocar mark the point for a canal for a locking screw. Remove the Trocar. Leave the Protective Guide in the hole of the slider.



- 56** Make the canal in the bone for the second locking screw insertion. Repeat 12 step. Remove the Drill Bit [40.5331] or [40.5332] and the Drill Guide [40.3646.100] or [40.3661.100] just after reaming of the canal.

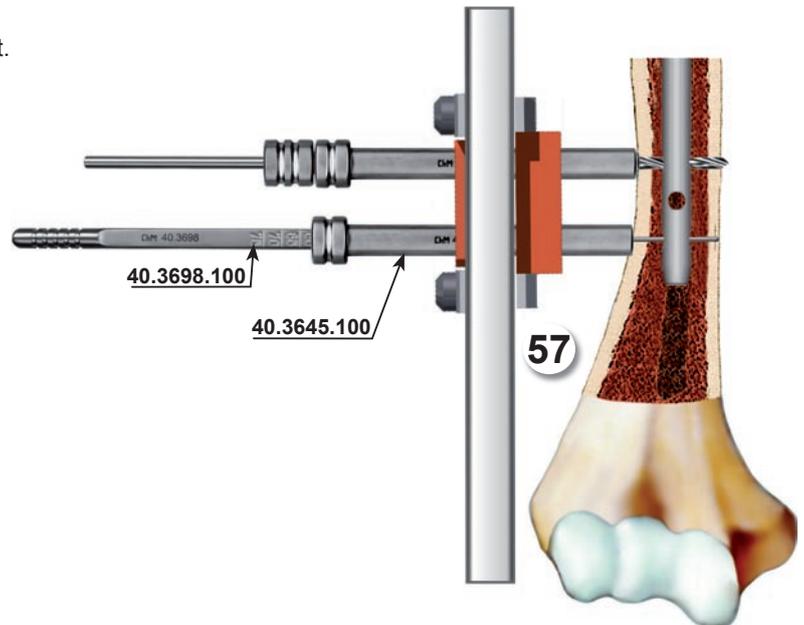
Leave the Protective Guide in the hole of the slider of Target B.



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

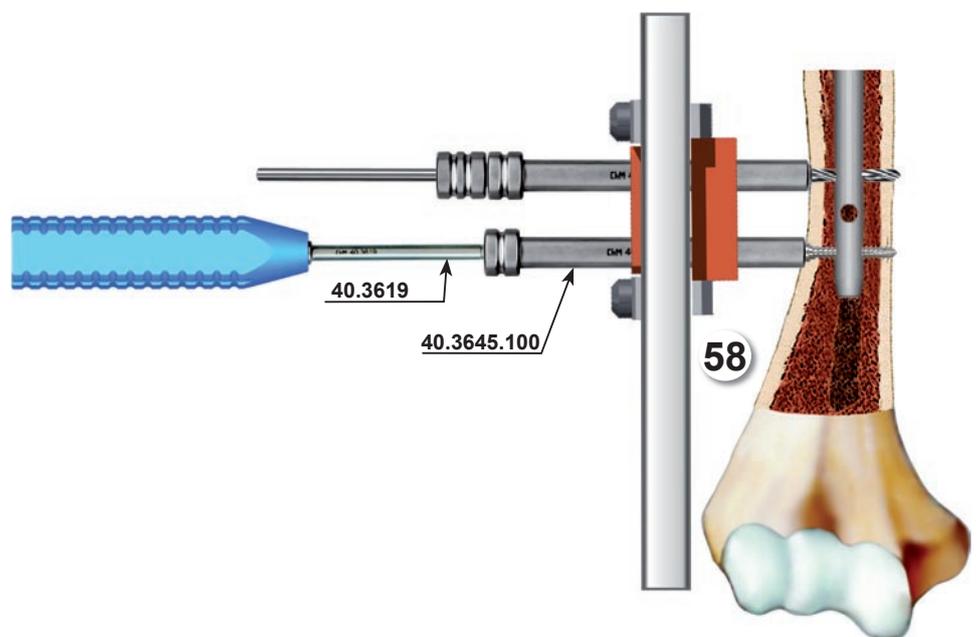
- 57** Through Protective Guide [40.3645.100] insert into drilled hole in bone Screw Length Measure [40.3698.100], until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the B-D scale. **During the measurement the end of the Protective Guide should rest on the cortex of the bone.**

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



- 58** Put the tip of the Screwdriver [40.3619] into hexagonal head of the definite locking screw. Then insert the both into the Protective Guide [40.3645.100] and 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 the Protective Guide**).

Remove the Screwdriver.



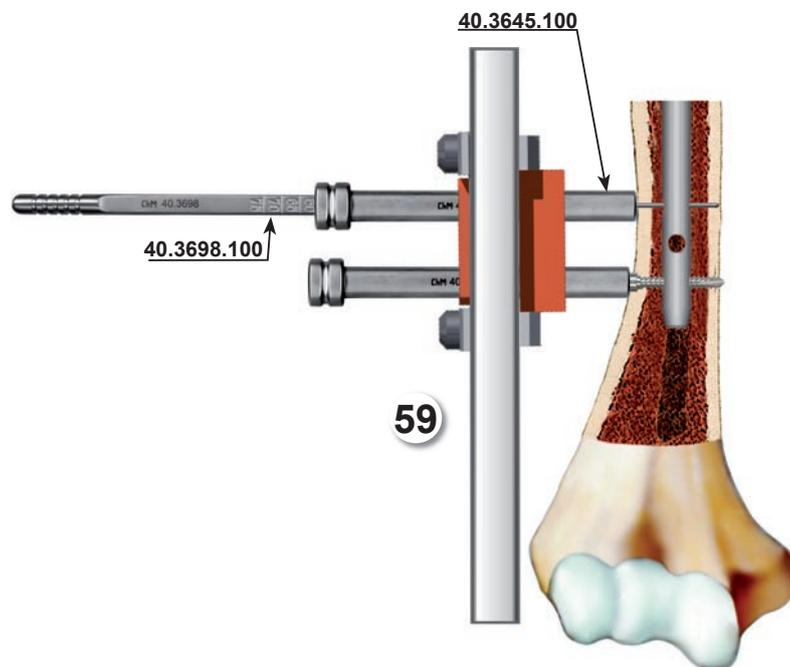
*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

- 59** Through Protective Guide insert into drilled hole in bone screw Length Measure [40.3698.100], until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the B-D scale.

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

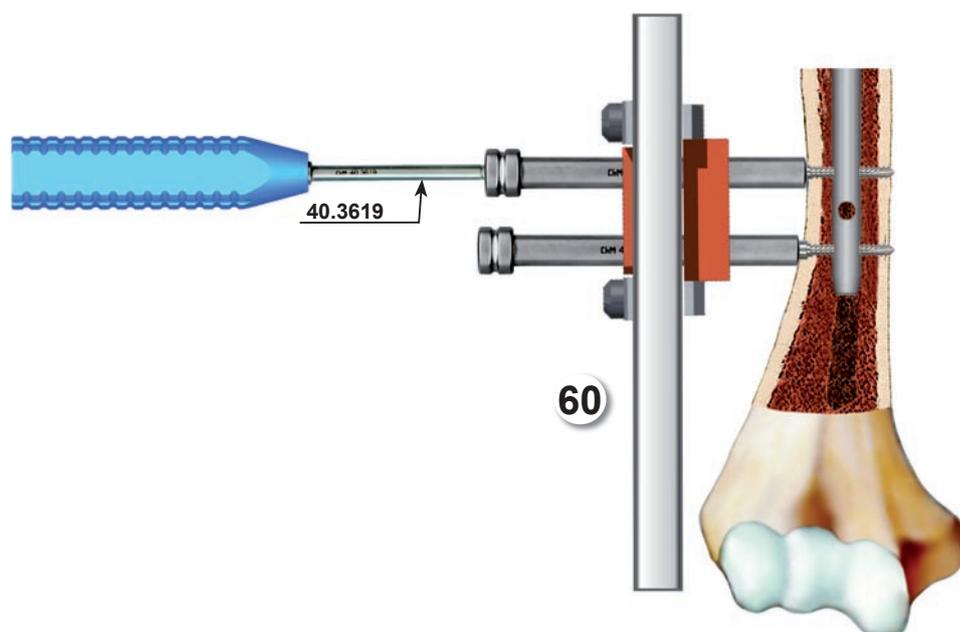
Remove Screw Length Measure.

Leave Protective Guide in the hole of the Target's slider.



- 60** Put the tip of the Screwdriver [40.3619] into hexagonal head of the definite locking screw. Then insert the both into the Protective Guide [40.3645.100] and 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 the Protective Guide**).

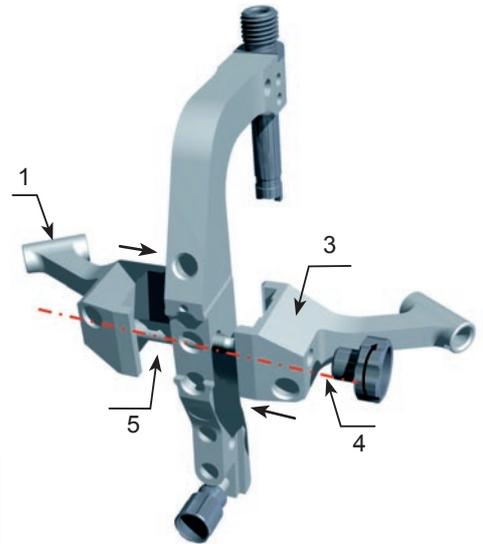
Remove the Screwdriver and Protective Guide.



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

**IV.13. Proximal locking of a long reconstruction humeral nail**

In order to lock reconstruction humeral nail it is necessary to assemble the Angular Target [40.5024] to the Target B [40.5030] as showed on the picture on the side. Put threaded shaft (5) of the Angular Target I (1) into lateral hole of the Target B [40.5030] then into the joint hole (3) of Angular Target II. Combine parts by screwing the nut (4).



- 61** Using the Socket Wrench [40.3648] and the Connecting Screw [40.5023.100] fix the intramedullary nail to the leading sleeve of the Target B [40.5030].

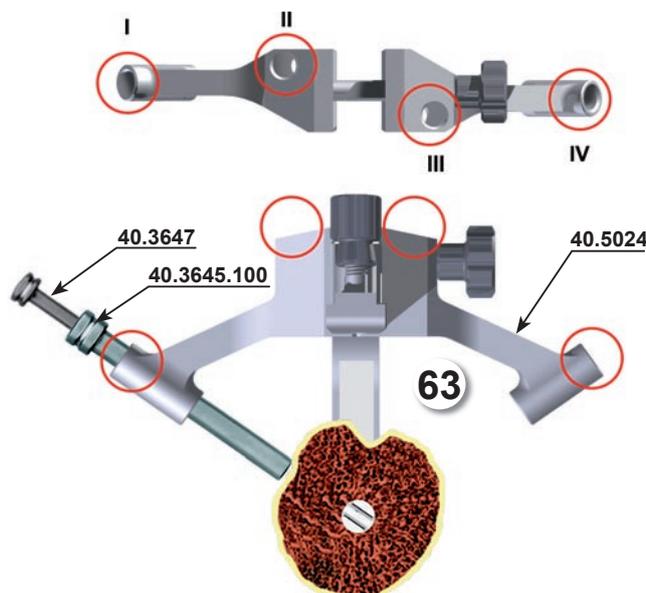
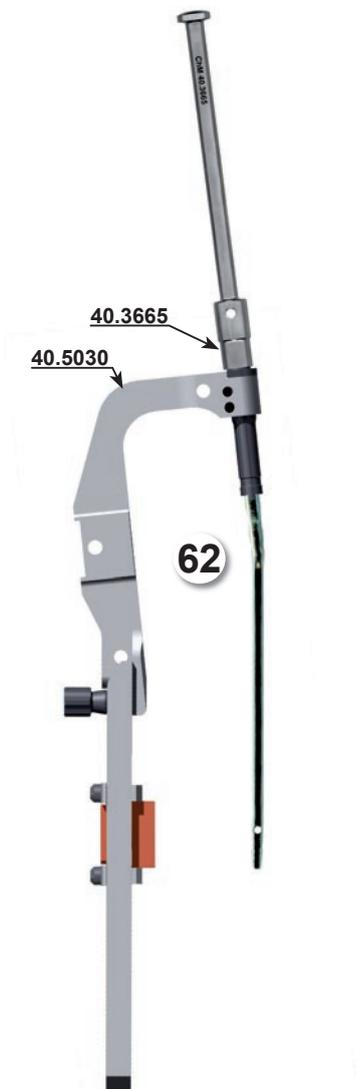


**Properly installed nail shall be positioned parallel to the arm of Target B.**

- 62** Connect the Impactor-Extractor [40.3665] to the installed system (attach on the threaded tip of the Target B leading sleeve [40.5030]).

- 63** Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into one of the holes I, II, III or IV in the Angular Target [40.5024]. After marking the entry point of the locking screw on the skin, make an adequate incision though soft tissues approx. 1.5cm in length. Advance the Protective Guide together with the Trocar this way to put its end as close as possible of cortex and mark the point of entry for the Drill Bit.

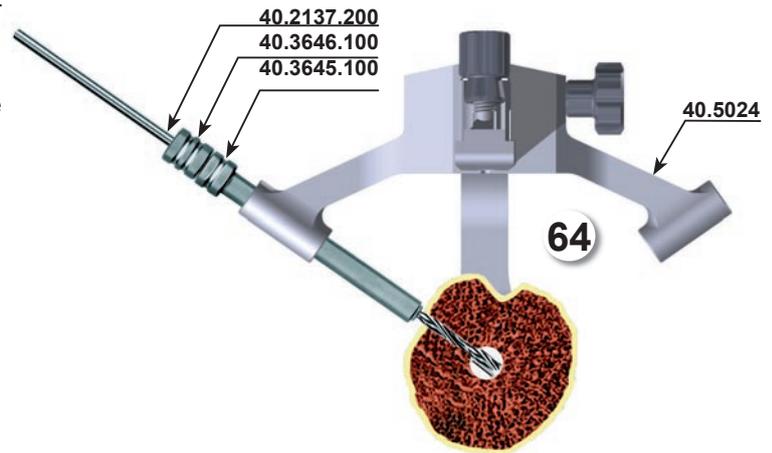
Remove the Trocar.  
Leave the Protective Guide in the hole of Angular Target.



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

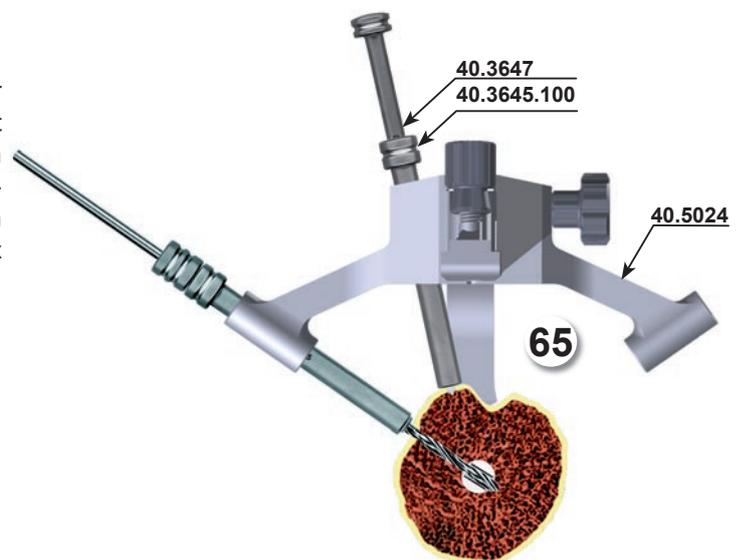
- 64** Insert the Drill Guide Ø3.5 [40.3646] into the Protective Guide [40.3645.100]. Mount the Ø3.5/200 Drill Bit [40.2137.100] on the surgical drive and advance it through the Drill Guide. Drill the hole for locking screw in the humerus under the control of fluoroscopy.

Leave the Protective Guide with the Drill Bit and the Drill Guide in the hole of the target [40.5030].



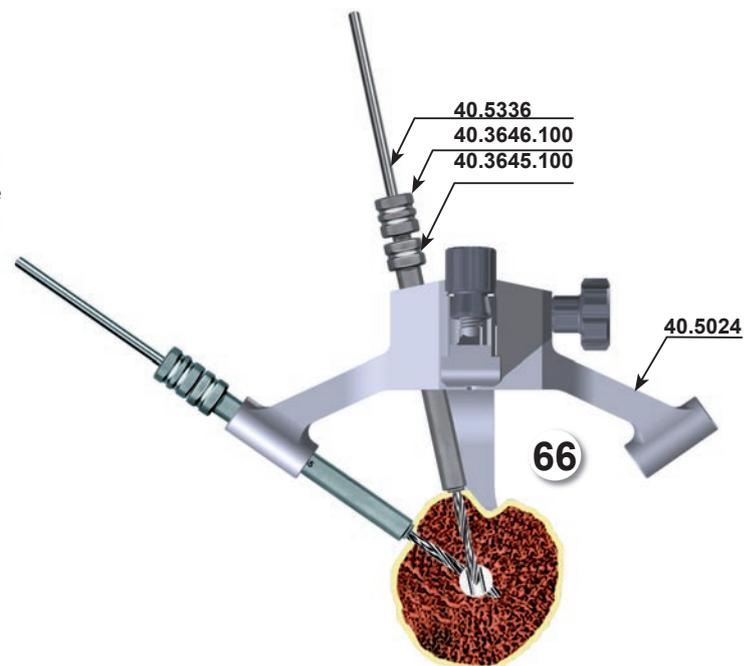
- 65** Insert the Protective Guide [40.3645.100] with Trocar [40.3647] into the next hole of the Angular Target [40.5024]. After marking the entry point of the locking screw on the skin, make an adequate incision through the soft tissues approx. 1.5cm in length. Insert the Protective Guide together with the Trocar this way to put its end as close as possible of cortex and mark the point of entry for the Drill Bit.

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



- 66** In case of nail locking by locking screws Ø4,5 [1.1653.xxx] one should using Drill Bit Ø4,5/220 [40.5336] ream the hole in the first bone cortex (first: insert Drill Guide Ø4,5 [40.3697.100] into Protective Guide [40.3645.100]).

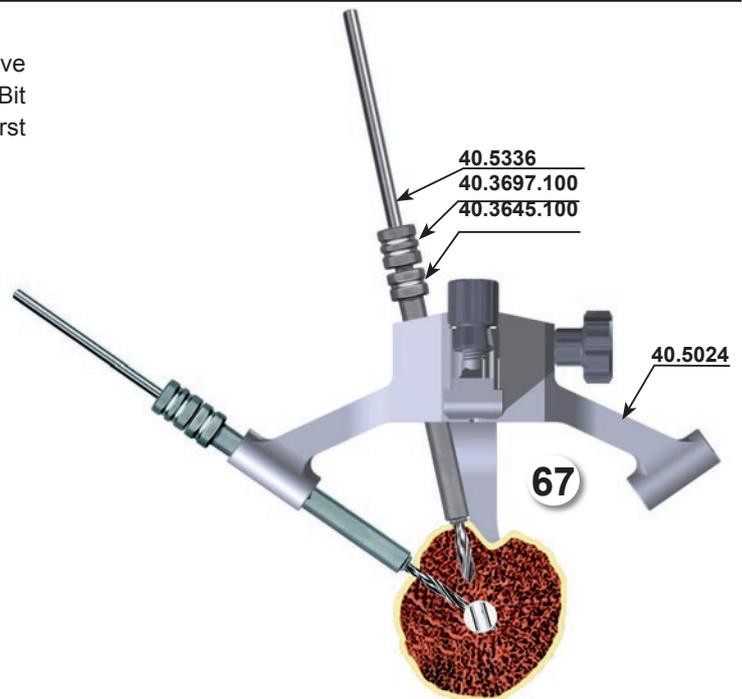
Remove the Drill bit and the Drill guide.  
Leave the Protective Guide in the hole of the Target.



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

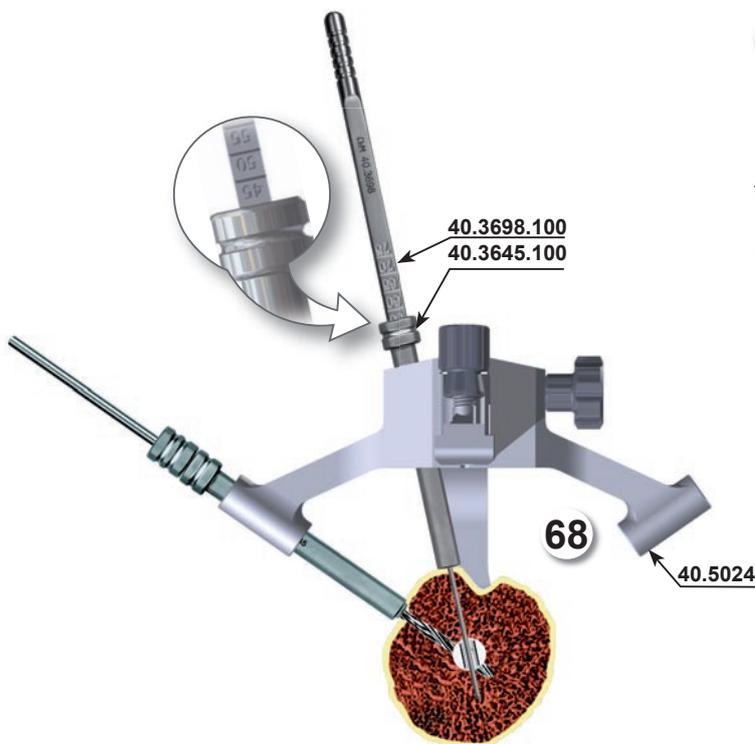
- 67** Insert the Drill Guide Ø4.5 [40.3697.100] into the Protective Guide [40.3645.100]. Advance the Ø4.5/220 Drill Bit [40.5336] through the Drill Guide and widen the hole in the first bone cortex.

Remove the Drill Bit and the Drill Guide.  
Leave the Protective Guide in the hole of the Target.



- 68** Remove the Drill Bit [40.5331] and the Drill Guide [40.3646.100] from the proximal hole of the Target. Leave in hole Protective Guide [40.3645.100]. Insert the Screw Length Measure [40.3698.100] through the Protective Guide [40.3645.100] into the drilled hole until its tip reaches the end of the hole. Read the length of the locking screw on B-D scale of measure. During the measurement the end of the Protective Guide should rest on the cortex bone.

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

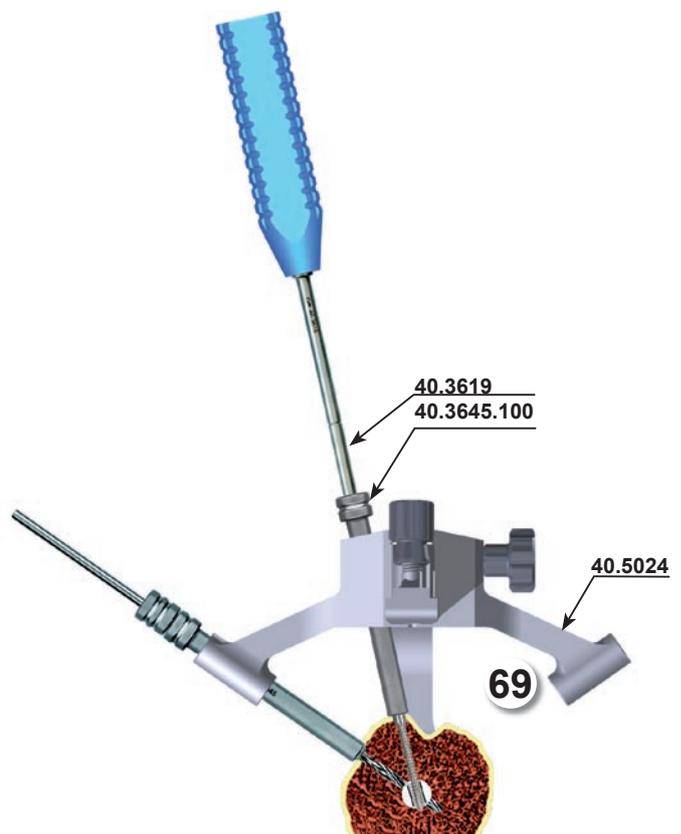


- 69** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of locking screw:

- Ø4,5 [1.1653] in case of standard locking; or
- Ø5,0 [1.1657] in case of locking in threaded hole of the nail.

Then insert the both into the Protective Guide [40.3645.100] and carefully screw the locking screw in the prepared hole (until the groove on the Screwdriver shaft matches the edge of the Protective Guide).

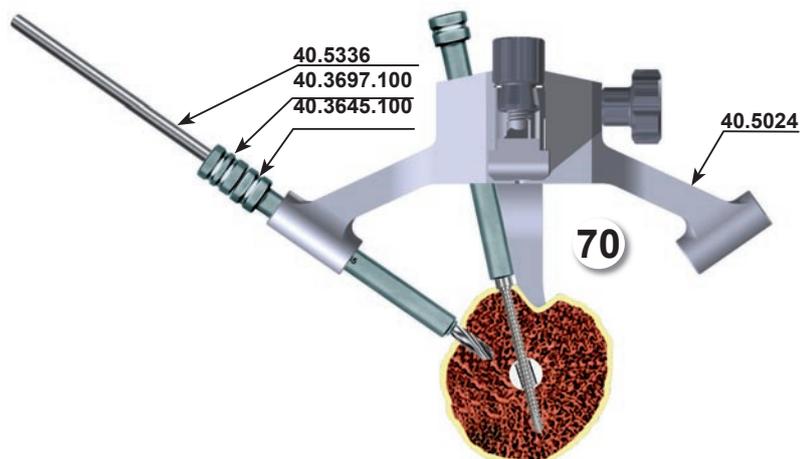
Remove the Screwdriver.  
Leave Protective Guide.



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

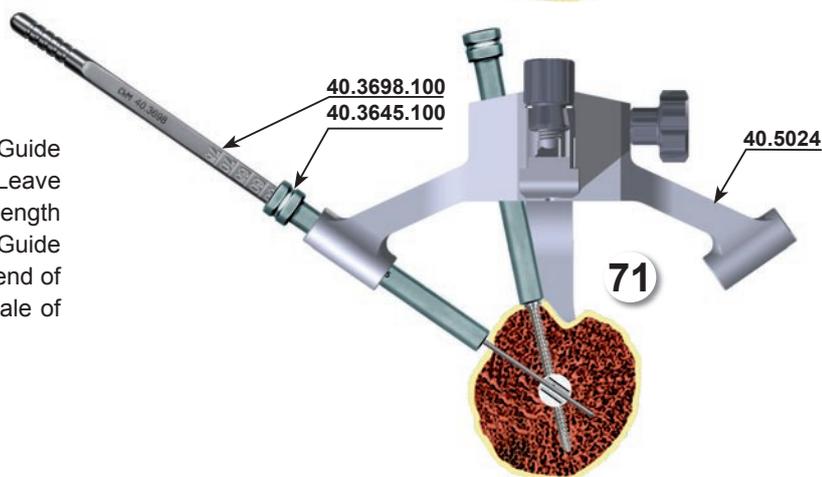
- 70** Remove Drill Guide Ø3,5 [40.3646.100] and Drill Bit Ø3,5/220 [40.5331] from first hole. Leave Protective Guide. Insert Drill Guide Ø4,5 [40.3697.100] into Protective Guide. Leading Drill Bit Ø4,5/220mm [40.5336] in Protective Guide, widen hole in the first cortex layer.

Remove Drill Bit and Drill Guide.  
Leave Protective Guide in the hole of Target.



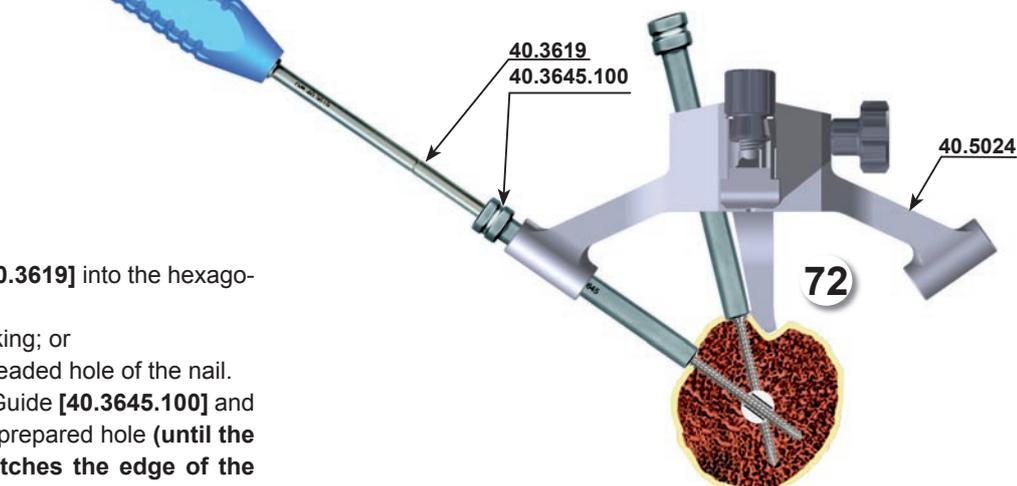
- 71** Remove the Drill Bit [40.5331] and the Drill Guide [40.3646.100] from the proximal hole of the Target. Leave in hole Protective Guide [40.3645.100]. Insert the Screw Length Measure [40.3698.100] through the Protective Guide [40.3645.100] into the drilled hole until its tip reaches the end of the hole. Read the length of the locking screw on B-D scale of measuring gauge.

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



- 72** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of locking screw:  
- Ø4,5 [1.1653] in case of standard locking; or  
- Ø5,0 [1.1657] in case of locking in threaded hole of the nail.  
Then insert the both into the Protective Guide [40.3645.100] and carefully screw the locking screw in the prepared hole (until the groove on the Screwdriver shaft matches the edge of the Protective Guide).

Remove the Screwdriver and Protective Guide.



In order to facilitate of nail locking in proximal part in another holes it is recommend (after making the first hole and check on RTG photograph correctness of its effect) to left the Drill in the hole and start to lock the rest of holes or make nail interlocking and left Protective Guide on the head of locking screw in order to improve the rigid of system: nail – Target. Repeat steps 55-64 in order to lock the nail using other holes in the Target.

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

**IV.14. Distal locking of the nail by “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 through the soft tissues, each about 1.5cm in length.



**73** Using fluoroscopy place the freehand Target D [40.1344] in line to 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 sink into the cortex.** Insert the Short Trocar [40.1354] into the hole in the Target D, advance it until it reaches cortex and mark the entry point for the Drill.

Remove the Trocar.  
Leave the Target D in place.

**74** Drill the hole in the humeral bone for locking screw insertion.

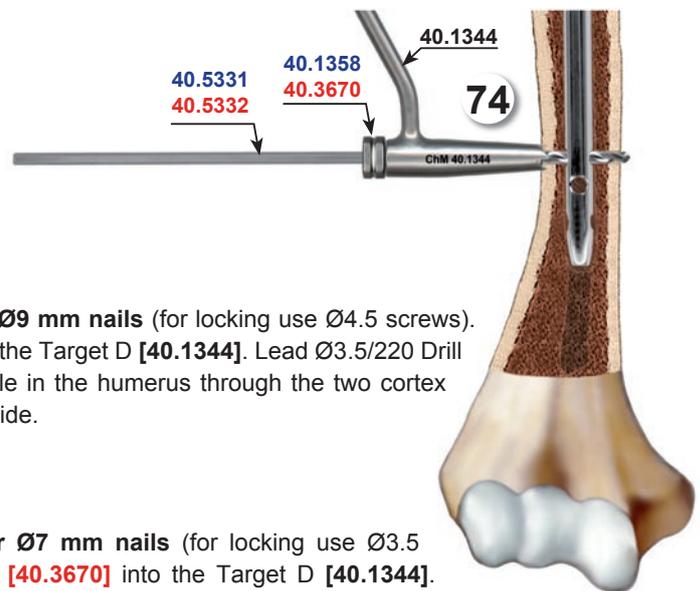
**OPTION I:**

**Concerning implantation using Ø8 or Ø9 mm nails** (for locking use Ø4.5 screws). Insert the Drill Guide Ø3.5 [40.1358] into the Target D [40.1344]. Lead Ø3.5/220 Drill Bit [40.5331] in Drill Guide, drill the hole in the humerus through the two cortex layers. Remove the Drill Bit and Drill Guide. Leave in place Target D.

**OPTION II:**

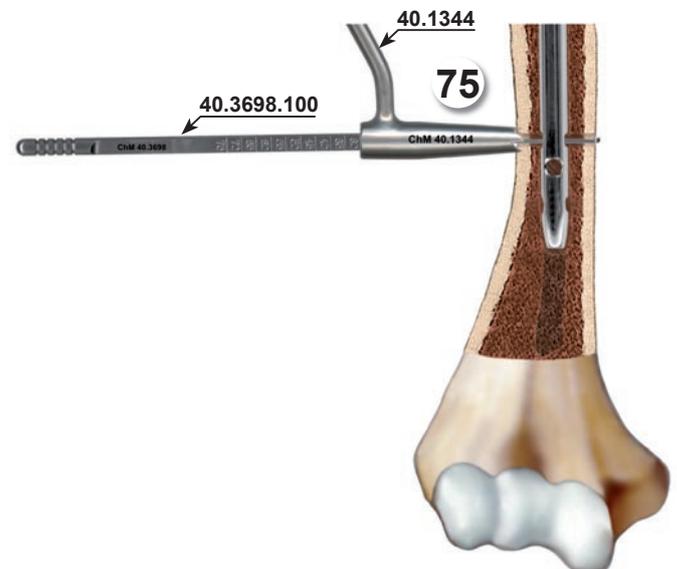
**Concerning implantation using Ø6 or Ø7 mm nails** (for locking use Ø3.5 screws). Insert the Drill Guide Ø2.8mm [40.3670] into the Target D [40.1344]. Lead Ø2.8/220 Drill Bit [40.5332] in Drill Guide, drill the hole in the humerus through the two cortex layers.

Remove the Drill Bit and Drill Guide.

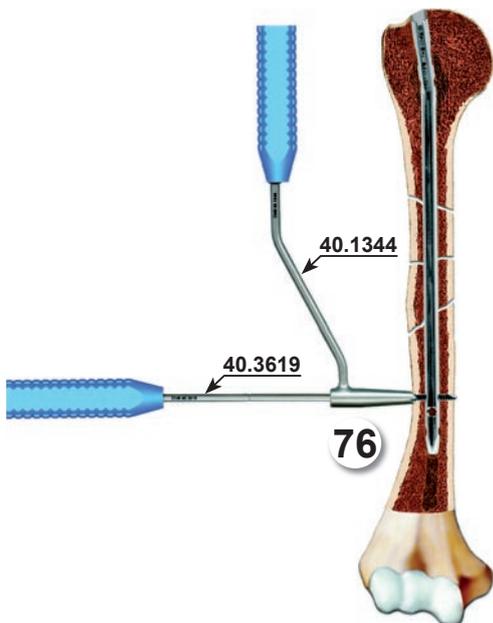


**75** Insert the Screw Length Measure [40.3698.100] through the hole of Target D [40.1344] into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the scale D of the measure.

Remove the Screw Length Measure.  
Leave the Target D in place.



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



**76** Put the tip of the Screwdriver [40.3619] into the hexagonal socket of the defined locking screw. Then advance the both into the hole in Target D [40.1344] and screw the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone.

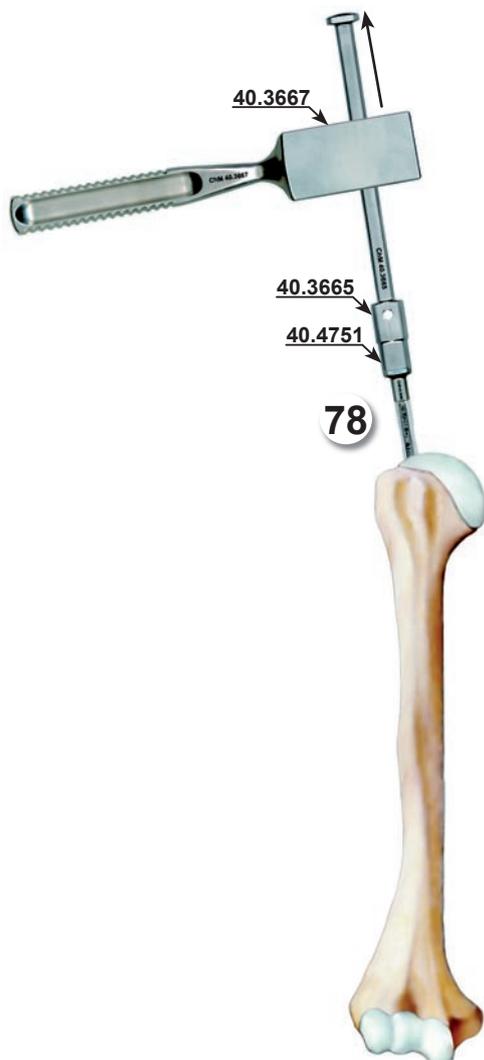
Remove the Screwdriver and Target D.



**In order to lock the nail in the second distal hole repeat the steps /30/ to /33/.**

**IV.15. Nail extraction**

**77** Use the Screwdriver [40.3619] to remove the end cap or Compression Screw from the nail shaft. Using the Socket Wrench [40.3648] screw in the Connector [40.4751] into the threaded hole in the nail.



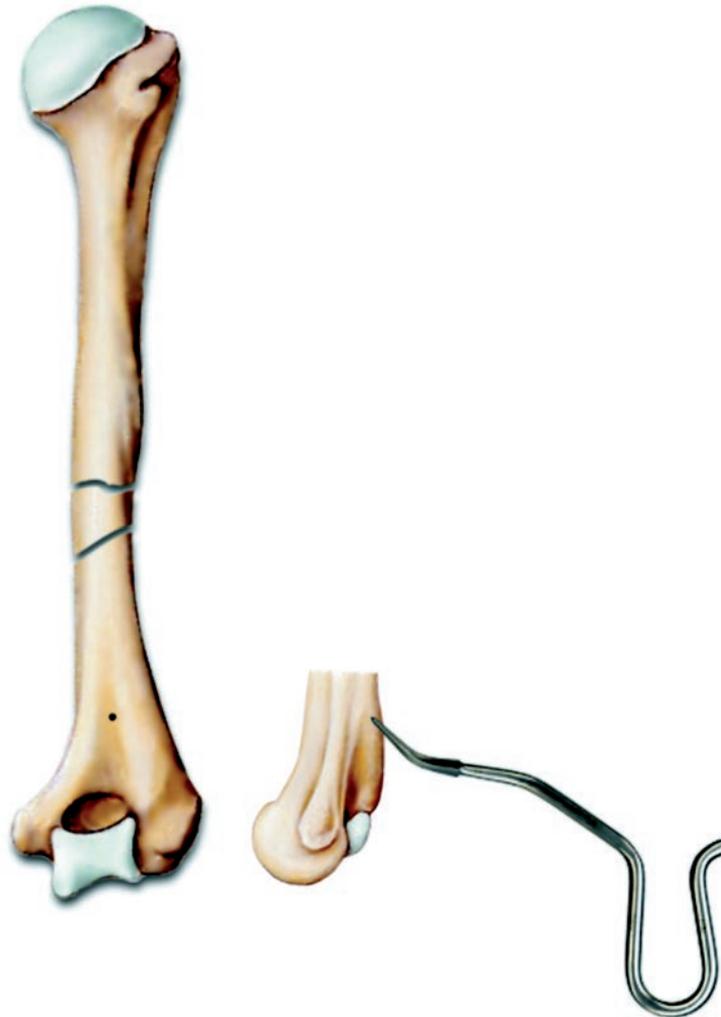
**78** Using the Screwdriver unscrew all the locking screws. Attach the Extractor-Impactor [40.3665] to the Connector and with help of the Mallet [40.3667] extract the nail from the medullary canal.

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

**IV.16. Distal nail insertion into the medullary canal**

**Medullary canal open for nail insertion.**

After defining the point of entry for nail implantation, make the skin incision through the soft tissues. Using cannulated awl (not included in ChM Instrument set) pierce the cortex of bone, open the medullary canal. Depending on the equipment in the operating theatre, the surgeon may use a different way of opening the medullary canal.



**In order to prepare the medullary canal for nail implantation from the distal part and further activities concerning osteosynthesis of humerus, the technique of implantation from proximal part should be applied, as described in steps 10-26 (p. 20-26).**

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





# REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

ChM®

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 than 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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