

instruction

OSTEOSYNTHESIS OF FEMUR REVERSED METHOD (CONDYLAR APPROACH).

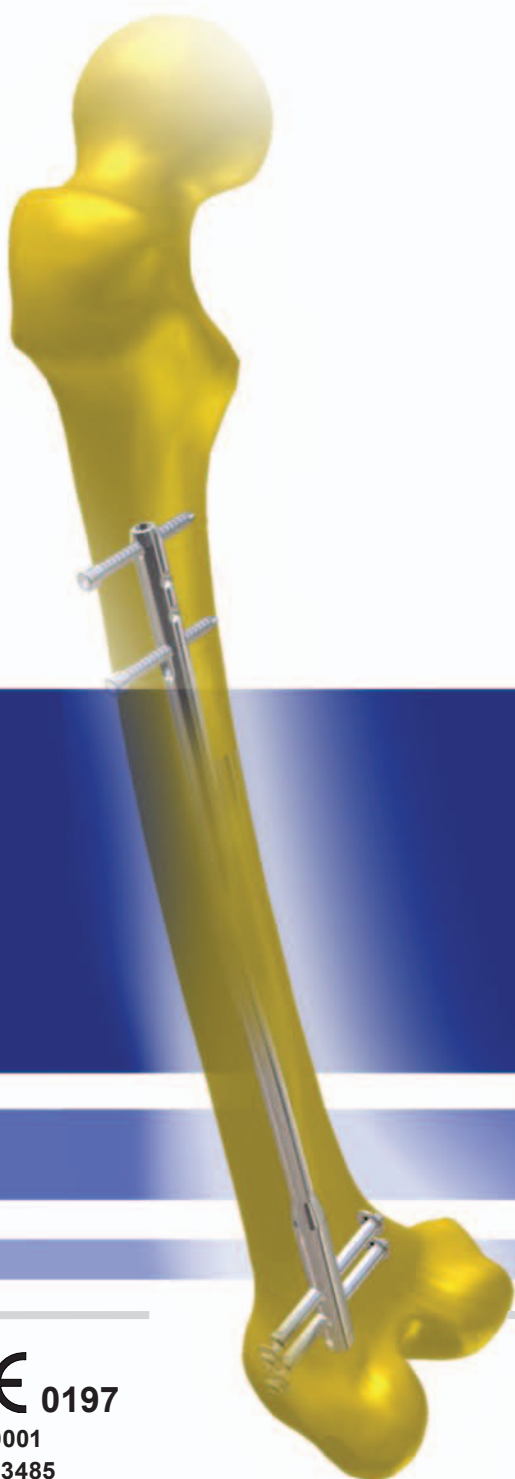
IMPLANTS ◦
INSTRUMENT SET ◦
SURGICAL TECHNIQUE ◦

CHARFIX *system*

23C

CE 0197
ISO 9001
ISO 13485

ChM®



I. IMPLANTS FOR REVERSED METHOD	4
II. INSTRUMENT SET FOR REVERSED METHOD [40.3660].....	5
III. SURGICAL TECHNIQUE REVERSED METHOD (CONDYLAR APPROACH).....	9
III.1. GENERAL ISSUES	9
III.2. PREPARATION OF THE MEDULLARY CANAL FOR NAIL INSERTION	10
III.3. PREPARATION OF THE TARGETING DEVICE, NAIL INSERTION	12
III.4. DISTAL LOCKING OF THE NAIL.....	13
<i>III.4.1. OPTION I: Locking with screws</i>	<i>13</i>
<i>III.4.2. OPTION II: Locking with locking set</i>	<i>14</i>
III.5. PROXIMAL LOCKING OF THE NAIL	15
III.6. REMOVAL OF TARGETING DEVICE, PLACING BLIND SCREW	17
III.7. NAIL EXTRACTION	17

I. IMPLANTS FOR REVERSED METHOD

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

Ø8÷19

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

Stal, Steel, Сталь
1.2104.002
Tytan, Titanium, Титан
3.2104.002

Śruba zaślepiająca M10x1
End cap M10x1
Винт слепой M10x1

ZESTAW BLOKUJĄCY BLOCKING SET БЛОКИРУЮЩИЙ НАБОР

Komplet - Set - Комплект

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

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

Ø8÷19

L	Nr katalogowy, Catalogue no., Каталогный №.									
	STAL, Steel, Сталь					TYTAN, Titanium, Титан				
	Ø9	Ø10	Ø11	Ø12	Ø13	Ø9	Ø10	Ø11	Ø12	Ø13
160	1.2369.160	1.2123.160	1.2124.160	1.2126.160	1.2127.160	3.2369.160	3.2119.160	3.2120.160	3.2121.160	3.2122.160
170	1.2369.170	1.2123.170	1.2124.170	1.2126.170	1.2127.170	3.2369.170	3.2119.170	3.2120.170	3.2121.170	3.2122.170
180	1.2369.180	1.2123.180	1.2124.180	1.2126.180	1.2127.180	3.2369.180	3.2119.180	3.2120.180	3.2121.180	3.2122.180
190	1.2369.190	1.2123.190	1.2124.190	1.2126.190	1.2127.190	3.2369.190	3.2119.190	3.2120.190	3.2121.190	3.2122.190
200	1.2369.200	1.2123.200	1.2124.200	1.2126.200	1.2127.200	3.2369.200	3.2119.200	3.2120.200	3.2121.200	3.2122.200
210	1.2369.210	1.2123.210	1.2124.210	1.2126.210	1.2127.210	3.2369.210	3.2119.210	3.2120.210	3.2121.210	3.2122.210
220	1.2369.220	1.2119.220	1.2120.220	1.2126.220	1.2127.220	3.2369.220	3.2119.220	3.2120.220	3.2121.220	3.2122.220
230	1.2369.230	1.2119.230	1.2120.230	1.2126.230	1.2127.230	3.2369.230	3.2119.230	3.2120.230	3.2121.230	3.2122.230
240	1.2369.240	1.2119.240	1.2120.240	1.2126.240	1.2127.240	3.2369.240	3.2119.240	3.2120.240	3.2121.240	3.2122.240
250	1.2369.250	1.2119.250	1.2120.250	1.2126.250	1.2127.250	3.2369.250	3.2119.250	3.2120.250	3.2121.250	3.2122.250
260	1.2369.260	1.2119.260	1.2120.260	1.2126.260	1.2127.260	3.2369.260	3.2119.260	3.2120.260	3.2121.260	3.2122.260
270	1.2369.270	1.2119.270	1.2120.270	1.2126.270	1.2127.270	3.2369.270	3.2119.270	3.2120.270	3.2121.270	3.2122.270
280	1.2369.280	1.2119.280	1.2120.280	1.2126.280	1.2127.280	3.2369.280	3.2119.280	3.2120.280	3.2121.280	3.2122.280
290	1.2369.290	1.2119.290	1.2120.290	1.2126.290	1.2127.290	3.2369.290	3.2119.290	3.2120.290	3.2121.290	3.2122.290
300	1.2369.300	1.2119.300	1.2120.300	1.2126.300	1.2127.300	3.2369.300	3.2119.300	3.2120.300	3.2121.300	3.2122.300
310	1.2369.310	1.2119.310	1.2120.310	1.2126.310	1.2127.310	3.2369.310	3.2119.310	3.2120.310	3.2121.310	3.2122.310
320	1.2369.320	1.2119.320	1.2120.320	1.2126.320	1.2127.320	3.2369.320	3.2119.320	3.2120.320	3.2121.320	3.2122.320
330	1.2369.330	1.2119.330	1.2120.330	1.2126.330	1.2127.330	3.2369.330	3.2119.330	3.2120.330	3.2121.330	3.2122.330
340	1.2369.340	1.2119.340	1.2120.340	1.2126.340	1.2127.340	3.2369.340	3.2119.340	3.2120.340	3.2121.340	3.2122.340
350	1.2369.350	1.2119.350	1.2120.350	1.2126.350	1.2127.350	3.2369.350	3.2119.350	3.2120.350	3.2121.350	3.2122.350
360	1.2369.360	1.2119.360	1.2120.360	1.2126.360	1.2127.360	3.2369.360	3.2119.360	3.2120.360	3.2121.360	3.2122.360
370	1.2369.370	1.2119.370	1.2120.370	1.2126.370	1.2127.370	3.2369.370	3.2119.370	3.2120.370	3.2121.370	3.2122.370
380	1.2369.380	1.2119.380	1.2120.380	1.2126.380	1.2127.380	3.2369.380	3.2119.380	3.2120.380	3.2121.380	3.2122.380
390	1.2369.390	1.2119.390	1.2120.390	1.2126.390	1.2127.390	3.2369.390	3.2119.390	3.2120.390	3.2121.390	3.2122.390
400	1.2369.400	1.2119.400	1.2120.400	1.2126.400	1.2127.400	3.2369.400	3.2119.400	3.2120.400	3.2121.400	3.2122.400
410	1.2369.410	1.2119.410	1.2120.410	1.2126.410	1.2127.410	3.2369.410	3.2119.410	3.2120.410	3.2121.410	3.2122.410
420	1.2369.420	1.2119.420	1.2120.420	1.2126.420	1.2127.420	3.2369.420	3.2119.420	3.2120.420	3.2121.420	3.2122.420
430	1.2369.430	1.2119.430	1.2120.430	1.2126.430	1.2127.430	3.2369.430	3.2119.430	3.2120.430	3.2121.430	3.2122.430
440	1.2369.440	1.2119.440	1.2120.440	1.2126.440	1.2127.440	3.2369.440	3.2119.440	3.2120.440	3.2121.440	3.2122.440

Stal, Steel, Сталь
1.1654.030 -110
Tytan, Titanium, Титан
3.1654.030 -110

Stal, Steel, Сталь
1.2104.002
Tytan, Titanium, Титан
3.2104.002

Śruba zaślepiająca M10x1
End cap M10x1
Винт слепой M10x1

dostępne
available
доступные

Ø[mm]	8 ÷ 19	8 ÷ 19
skok, pitch, шаг 1 mm		
L [mm]	140 ÷ 600	140 ÷ 600
skok, pitch, шаг 5 mm		

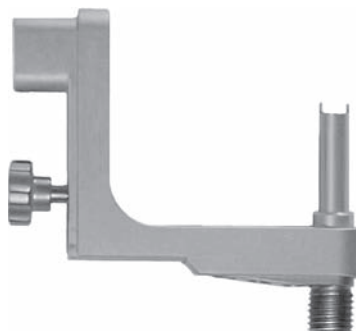
II. INSTRUMENT SET FOR REVERSED METHOD [40.3660]

CHARFIX^{system}

Lp.	Nr katalogowy No catalogue Каталожный №	Nazwa	Name	Название	Szt.
1.	40.3656	Celownik dalszy D	Distal target D	Целенаправитель дистальный Д	1
2.	40.3657	Celownik bliższy	Proximal target	Целенаправитель проксимальный	1
3.	40.3668	Gwóźdź Kirschnera Ø2/310	Kirschner wire Ø2/310	Спица Киршнера Ø2/310	4
4.	40.3658	Śruba łącząca M10x1	Connecting screw M10x1	Винт соединительный M10x1	1
5.	40.3662	Prowadnica ochronna 11/9	Protective guide 11/9	Направитель-протектор 11/9	2
6.	40.3614	Prowadnica ochronna 9/6,5	Protective guide 9/6,5	Направитель-протектор 9/6,5	2
7.	40.3615	Prowadnica wiertła 6,5/3,5	Drill guide 6.5/3.5	Проводник сверла 6,5/3,5	2
8.	40.3617	Trokar 6,5	Trocar 6.5	Троакар 6,5	1
9.	40.3616	Ustawiak 9/4,5	Set block 9/4.5	Инструмент установочный 9/4,5	2
10.	40.3696	Prowadnica wiertła 6,5/4,5	Drill guide 6.5/4.5	Проводник сверла 6,5/4,5	1
11.	40.3663	Miarka głębokości	Depth measure	Измеритель глубины	1
12.	40.3664	Prowadnik sworznia	Bolt guide	Направитель шпильки	1
13.	40.3665	Wbijak-wybijak	Impactor-extractor	Импактор-экстрактор	1
14.	40.3666	Łącznik M10x1/ M16	Connector M10x1/ M16	Соединитель M10x1/ M16	1
15.	40.3667	Pobijak	Mallet	Пробойник	1
16.	40.3619	Śrubokręt S3,5	Screwdriver S3.5	Отвертка S3,5	2
17.	40.3326	Szydło kaniulowane "13"	Cannulated awl "13"	Шило каниюлированное "13"	1
18.	40.1374	Miarka długości wkrętów	Screw length measure	Измеритель длины винтов	1
19.	40.1344	Celownik D	Target D	Целенаправитель дистальный Д	1
20.	40.1354	Trokar krótki 7	Trocar short 7	Троакар короткий 7	1
21.	40.1358	Prowadnica wiertła krótka 7/3,5	Short drill guide 7/3.5	Направитель сверла короткий 7/3,5	1
22.	40.1361	Klucz nasadowy S11	Socket wrench S11	Ключ торцовый S11	1
23.	40.1351	Uchwyt drutu prowadzącego	Handle guide rod	Держатель направляющей проволоки	1
24.	40.1389	Drut prowadzący 3,5/600	Guide rod 3.5/600	Проволока направляющая 3,5/600	1
25.	40.1348	Prowadnica rurkowa	Teflon pipe guide	Трубка-направитель	1
26.	40.5330	Wiertło ze skalą Ø3,5/250	Drill with scale Ø3.5/250	Сверло с измерительной шкалой Ø3,5/250	2
27.	40.5334	Wiertło ze skalą Ø4,5/300	Drill with scale Ø4.5/300	Сверло с измерительной шкалой Ø4,5/300	1
28.	40.5335	Wiertło ze skalą Ø6,5/300	Drill with scale Ø6.5/300	Сверло с измерительной шкалой Ø6,5/300	1
29.	40.3659	Statyw	Stand	Подставка	1

40.3660





1. Distal target [40.3656]



2. Proximal Target [40.3657]



3. Kirschner wire Ø2/310 mm [40.3668]



4. Connecting screw M10x1 [40.3658]



5. Protective guide Ø11/Ø9/123 mm [40.3662]



6. Protective guide Ø9/Ø6,5 [40.3614]



7. Drilling guide Ø6,5/Ø3,5 [40.3615]



8. Trocar Ø6,5 [40.3617]



9. Setting pin Ø9/ Ø4,5 [40.3616]



10. Drilling guide Ø6,5/Ø4,5 [40.3696]



11. Depth gauge [40.3663]



12. Bolt driver [40.3664]



13. Impactor-extractor [40.3665]



14. Connecto M10x1/ M16 [40.3666]



15. Mallet [40.3667]



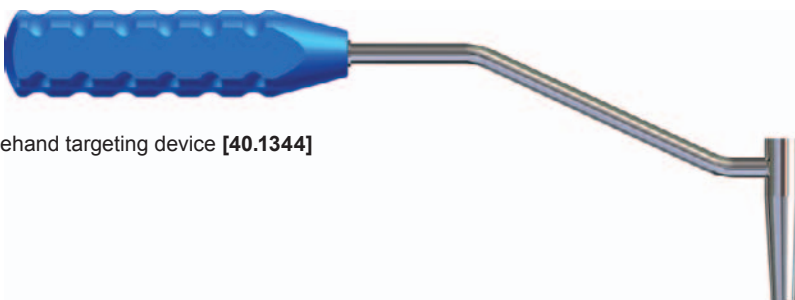
16. Hexagonal screwdriver S3,5 [40.3619]



17. Cannulated awl [40.3326]



18. Screw length measuring gauge [40.1374]



19. Freehand targeting device [40.1344]



20. Short trocar Ø7 **[40.1354]**



21. Short drill guide Ø7/ Ø3,5 **[40.1358]**



22. Socket wrench S11 **[40.1361]**



23. the Handle Guide Rod **[40.1351]**



24. Guide rod Ø3.5x600 mm **[40.1389]**



25. Teflon Pipe Guide **[40.1348]**



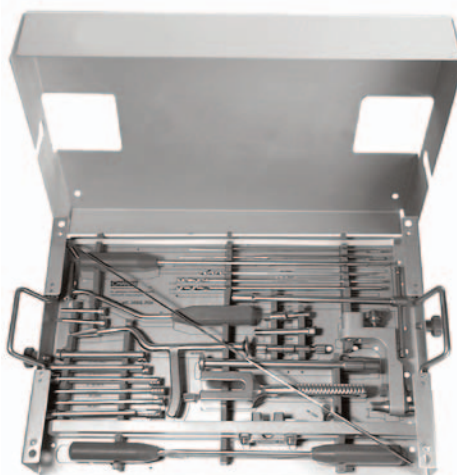
26. Drill with scale Ø3,5/250 mm **[40.5330]**



27. Drill with scale Ø4,5/300 mm **[40.5334]**



28. Drill with scale Ø6,5/300 mm **[40.5335]**



29. Case [Cat. no. **40.3659**]

III. SURGICAL TECHNIQUE REVERSED METHOD (*CONDYLAR APPROACH*)

III.1. GENERAL ISSUES

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

CHARFIX system provides reversed nails with diameters:

- 10, 11 or 12 mm and length between 160 and 440 mm.

To lock the nail distally (*by the knee joint*) depending on the type of fracture one may use:

- two locking screws A 6,5 mm, or
- two locking sets.

There are five sizes of locking sets:

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

Locking set consists of a bolt, two washers and a securing screw.

Locking screws are used to lock the nail proximally.

The nail features anatomical shape-its distal end is bent 5°.

Each surgical procedure has to be precisely planned.

Before the operation adequate X-Rays have to be made in order to examine the type of fracture and assess the dimensions of needed implant (*diameter and length*).

The operation should be performed on the patient in supine position, with tourniquet on and the knee joint bent 90°.

Nailing may be performed with or without reaming of medullary canal.

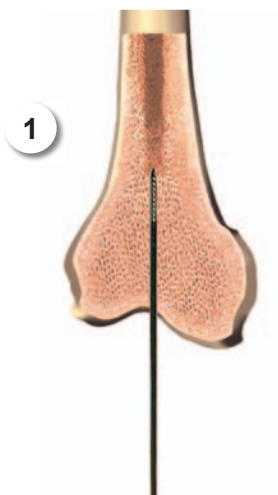
In both cases the diameter of medullary canal ought to be bigger than the diameter of used nail; if canal is reamed its final diameter should be 1.5 to 2 mm wider than the diameter of the nail. In both cases the canal has to be additionally reamed in distal part (*entry point*) with a Ø13.0 reamer at the distance of first 6 cm (*diameter of the nail in distal end is 12 mm*).



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

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

III.2. PREPARATION OF THE MEDULLARY CANAL FOR NAIL INSERTION



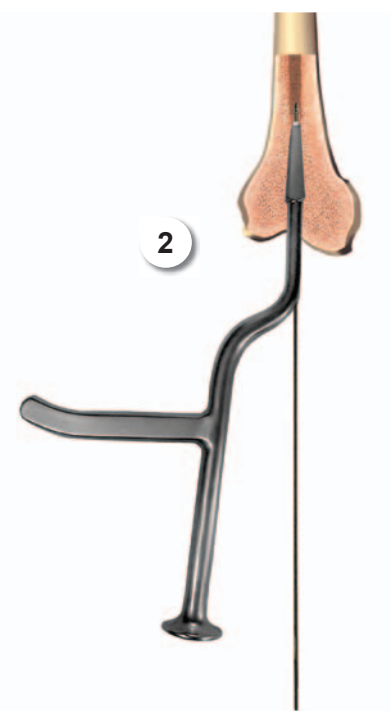
- 1 Make incision over the middle of patellar ligament or more paracentrally. Expose intercondylar region (*split the fibers of ligament or move it laterally*). Mark on the bone the entry point for Kirschner wire. Advance Kirschner Wire 2/310 mm [40.3668] through the cortex into the medullary canal.

Properly installed Kirschner wire is in line with canal axis.

Control this step with image intensifier.

Kirschner wire act as guide for the Cannulated Awl.

Kirschner wire is single use only.



- 2 Open the medullary canal with the Cannulated Awl [40.3326] at the depth of approx 6 cm.

Remove the Awl and Kirschner Wire.



- 3 Introduce the guide wire of flexible reamers into the medullary canal until its tip reaches proximal epiphysis of femur.

If medullary canal is reamed, gradually increase the diameter of canal with steps of 0.5 mm, until the diameter 1.5 to 2.0 mm wider than the diameter of the femoral nail, for the depth at least equal to the nail length is reached.

In both cases, ie. when the medullary canal was reamed or not, the canal should be reamed using Ø13 reamer to the depth of approx. 6 cm.

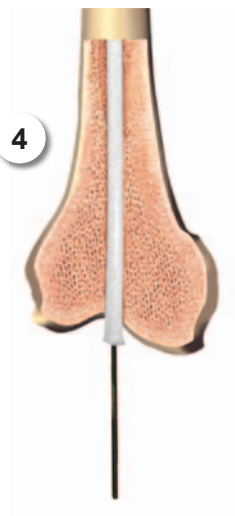
Remove the flexible reamer.

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



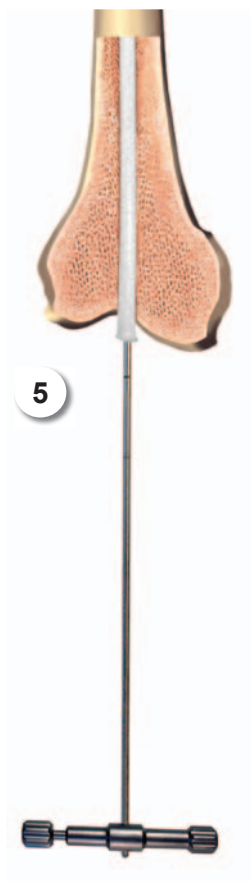
NOTE!

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



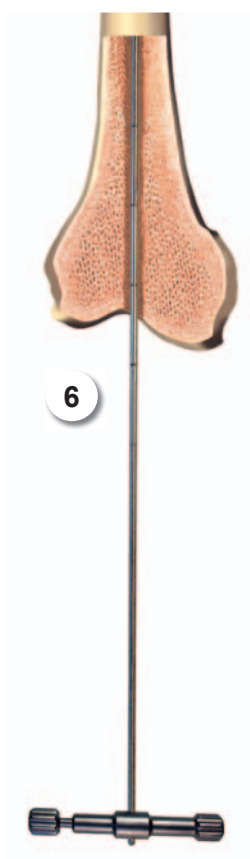
- 4** Introduce the Teflon Pipe Guide [40.1348] onto the flexible reamer guide left in the medullary canal.

Remove the flexible reamer guide.



- 5** Mount the Handle Guide Rod [40.1351] on the Guide Rod [40.1389] and advance the rod into the Teflon Pipe Tube until its tip reaches the proximal epiphysis.

Remove the Handle Guide Rod [40.1351] off the Guide Rod.
Remove the Teflon Pipe Guide [40.1348].



- 6** Remove the flexible reamer guide.
Mount the Handle Guide Rod [40.1351] on the Guide Rod [40.1389] and advance the rod into the Teflon Pipe Guide until its tip reaches the proximal epiphysis.

Remove the the Handle Guide Rod [40.1351] from the Guide Rod.

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

III.3. PREPARATION OF THE TARGETING DEVICE, NAIL INSERTION

- 7** Mount the Proximal Target **[40.3657]** on the arm of the Distal Target D **[40.3656]** and secure it with a lock-nut (*included in distal targeting device*).



IMPORTANT!

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

Using the Socket Wrench S11 **[40.1361]** fix the intramedullary nail to the Distal Target D **[40.3656]** with the Connecting Screw **[40.3658]**.

With a pair of the Set Blocks **[40.3616]** place the slider of Proximal Target in line with proximal locking holes of intramedullary nail.

Secure the slider of the Proximal Target with the Hexagonal Screwdriver **[40.3619]**.

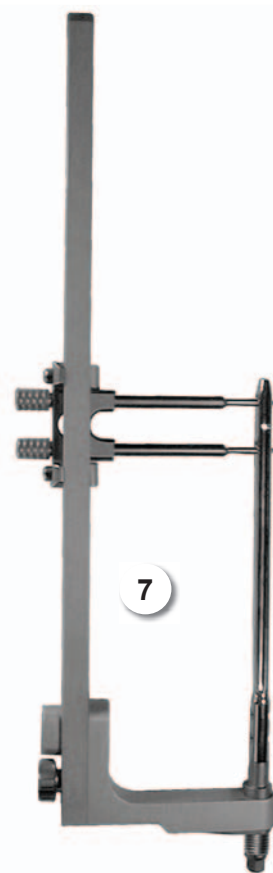


CHECK!

Properly set and secured slider allows smoothly setting the Set Block into the nail holes.

Remove the Set Blocks from the Target.

Dismount the Proximal Target off the arm of the Distal Target D.

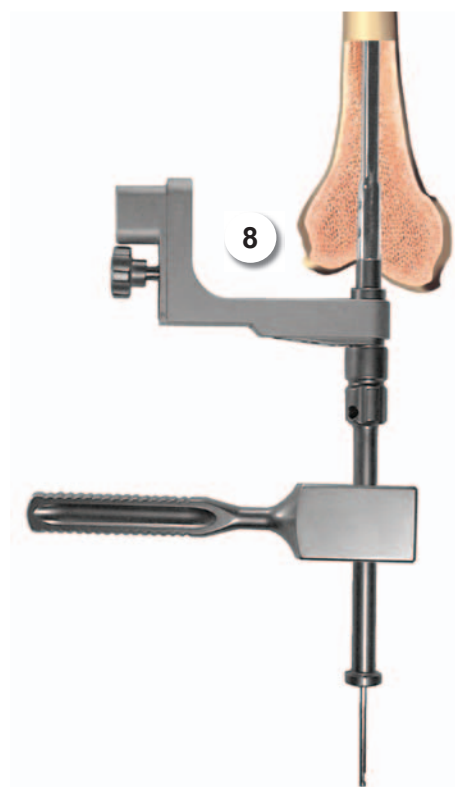


- 8** Connect the Impactor-Extractor **[40.3665]** to the Distal Target D with the nail (*screw the impactor onto the sleeve of the targeting device*).

Introduce the intramedullary nail into the medullary canal via the Guide Rod **[40.1389]**.

Advance the nail (*reducing the fracture*) into the medullary canal using the Mallet **[40.3667]** until the adequate depth is reached.

Remove the Impactor-Extractor off the Target, remove the Guide Rod.

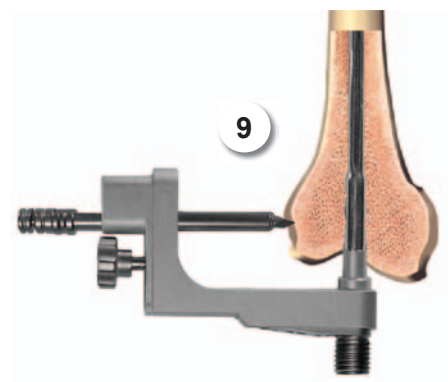


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

III.4. DISTAL LOCKING OF THE NAIL

9 Insert the Protective Guides [40.3662] and [40.3614] and the Trocar [40.3617] into the proximal hole of the Target. Mark the entry point and make adequate incision of the soft tissues. Advance the Trocar with the Protective Guides until they reach the cortex bone. Mark with the Trocar the entry point for the drill.

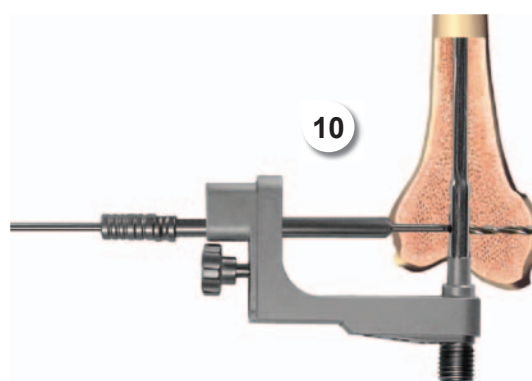
Remove the Trocar.
Leave the Protective Guides [40.3662] and [40.3614] in the hole of the Target Device.



III.4.1. OPTION I: Locking with screws

10 Insert the Drill Guide Ø4.5 mm [40.3696] into the Protective Guides.

Mount the Drill With Scale [40.5330] on the surgical drive and advance it through the Drill Guide. Drill the hole for locking screw. The scale on the drill indicates the length of the locking element.



Control drilling process with image intensifier.

Remove the Drill, Drill Guide [40.3696] and Protective Guide [40.3614].

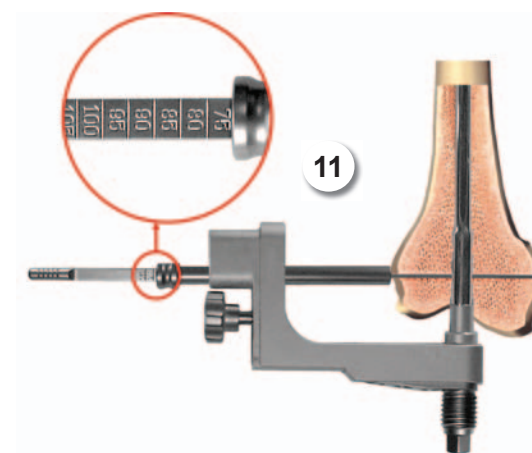
Leave the Protective Guide [40.3662] in the hole of the Target.

11 Insert the Screw Length Measure [40.3663] through the Protective Guide into the drilled hole until its hook reaches the cortex on the other side of the bone.

The scale on the drill indicates length of the locking screw. 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.

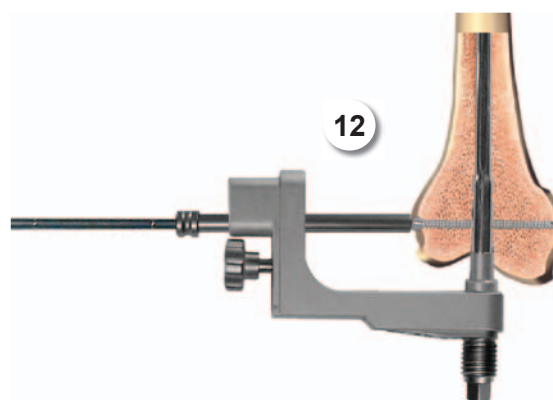


12 Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of the selected locking screw.

Then advance both into the Protective Guide. Insert the locking screw into 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 the Protective Guide.

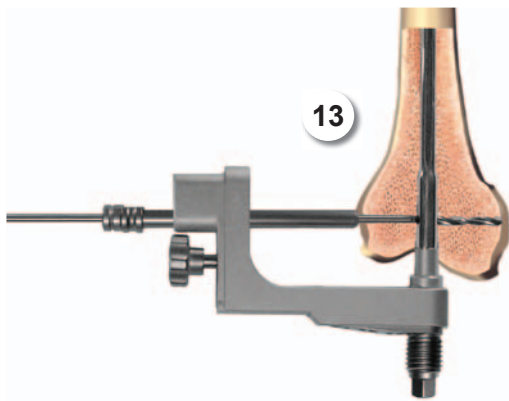
For distal locking of the nail use locking screws with diameter 6.5 mm.



To insert the second screw repeat steps [9] to [12] for the second distal hole.

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

III.4.2. OPTION II: Locking with locking set

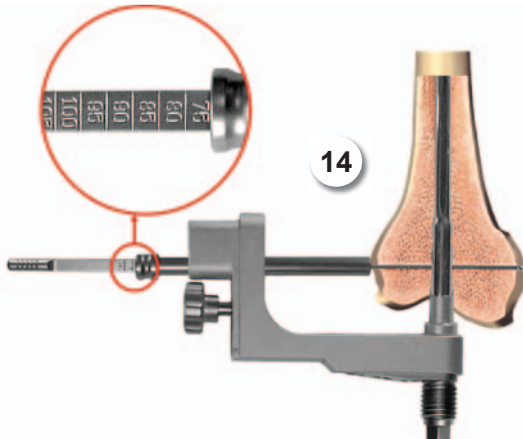


- 13** The Drill Guide [40.3514] and the Protective Guide [40.3662] shall be placed in same the hole of the Target.
Mount the Drill With Scale Ø6.5/300 mm [40.5335] on the surgical drive and advance it through the Drill Guide. Drill the hole through the bone. The scale on the Drill indicates the length of the locking element.

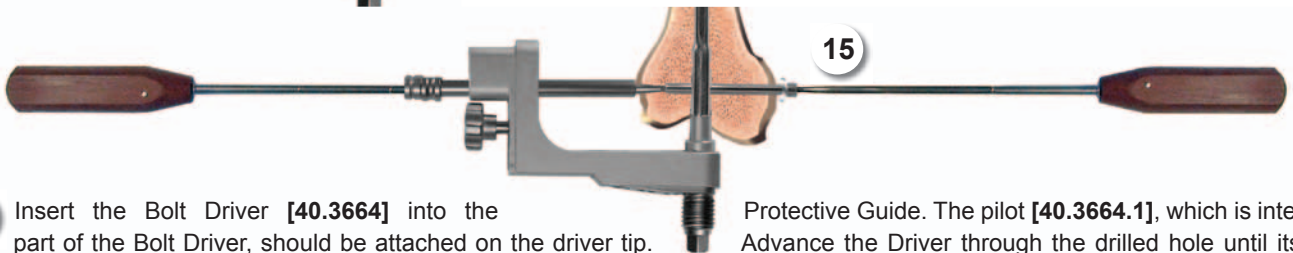


Control drilling process with image intensifier.
With help of image intensifier make incision of the soft tissues over the exit point of the drill.

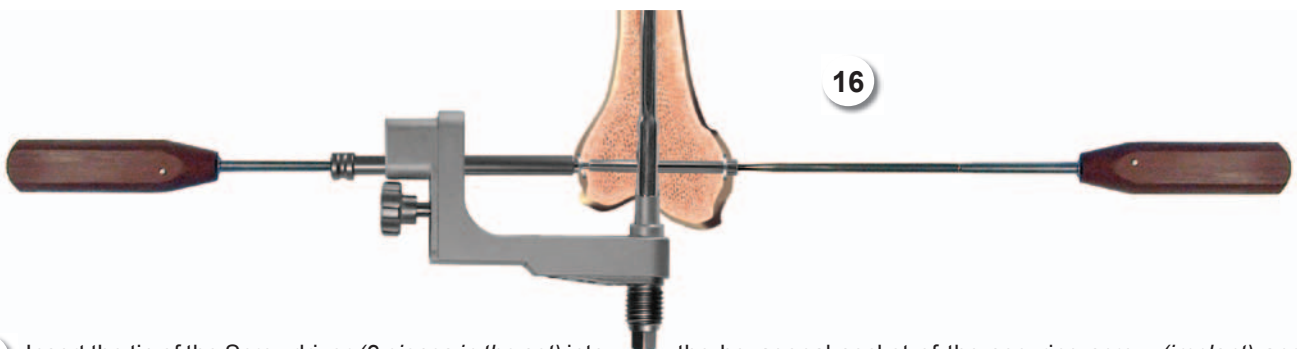
Remove the Drill and the Drill Guide [40.3614].



- 14** Introduce the Screw Length Measure [40.3663] through the Protective Guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Deduct 10 mm from the measure to get a characteristics of the needed locking set.
Select locking set with adequate range, e.g. with reading "75" the characteristics amounts to "65", therefore locking set 60 with range between 60 and 75 mm is adequate. During measurement the Protective Guide should rest on the cortex bone. Remove the screw length Measure. Leave the Protective Guide in the hole of the Target.



- 15** Insert the Bolt Driver [40.3664] into the part of the Bolt Driver, should be attached on the driver tip. Advance the Driver through the drilled hole until its tipers tip. Put the Bolt (*implant*) through the washer (*implant*) and insert it onto the bolt driver using the screwdriver [40.3619]. Advance the bolt into the hole in the bone (*head of the bolt should rest on the cortex with washer between*).
Unscrew the Bolt Driver from the bolt and remove it from Protective Guide. Leave the Protective Guide [40.3662] in the hole of the Target.



- 16** Insert the tip of the Screwdriver (*2 pieces in the set*) into the hexagonal socket of the securing screw (*implant*) and advance both into the Protective Guide. Put the second washer (*implant*) over the securing screw when it leaves the hole in the bone.
Screw the securing screw in the threaded hole in the bolt (*hold the bolt with the screwdriver*). Two screwdrivers are used to secure the locking set (*securing screw two washers bolt*). Remove the Screwdrivers and the Protective Guide.



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

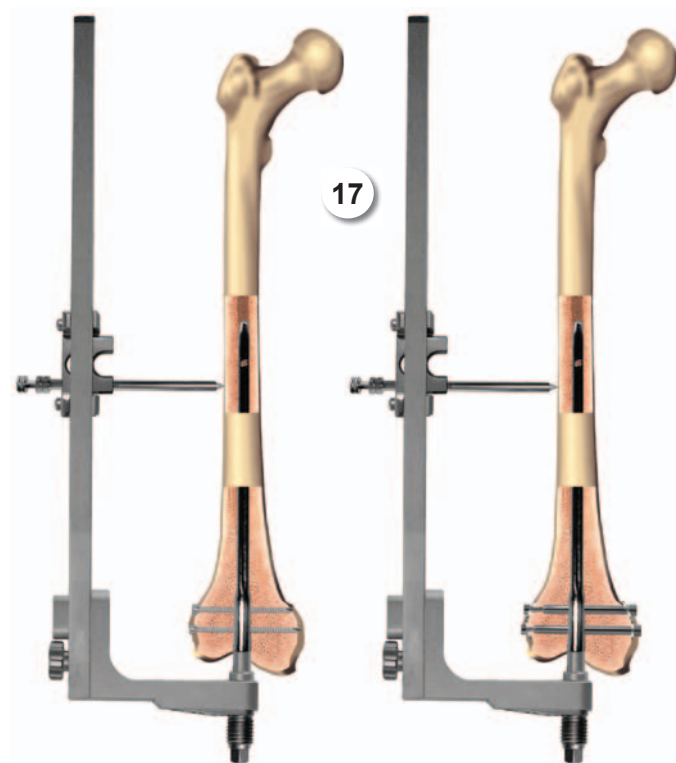
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

III.5. PROXIMAL LOCKING OF THE NAIL

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

1. Mount the Proximal Target [40.3657] again on the arm of the Distal Target D [40.3656] and secure it with a lock-nut (*included in distal targeting device*). If properly installed, the signs >RIGHT< or >LEFT< on both targets should comply.
2. Verify with the image intensifier the position of holes in the nail and in Target slider.

The centers of the holes have to be in line.



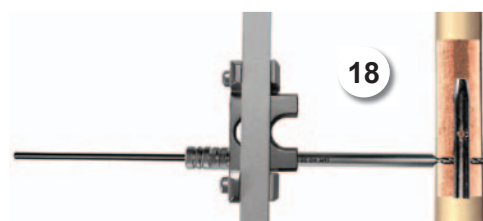
- 17** Insert the Protective Guide [40.3614] with the Trocar [40.3617] into the distal hole in the slider of Proximal Target.

Mark the entry point of the Trocar, make the adequate incision of the soft tissues.

Advance the Trocar together with the Protective Guide until it reaches the cortex bone. Using the Trocar mark the entry point for the Drill.

Remove the Trocar.

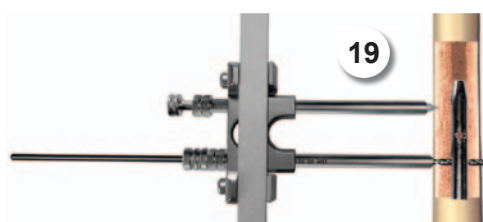
Leave the Protective Guide in the hole of the Target.



- 18** Insert the Drill Guide Ø3.5 mm [40.3615] (*with two grooves*) into the Protective Guide left in the hole of the slider.

Mount the Drill With Scale [40.5330] on the surgical drive and advance it through the Drill Guide. The scale on the Drill indicates the length of the locking element. Drill the hole in the femoral shaft through both cortex layers and the hole in the nail.

Disconnect the drive and the Drill and leave in place Drill together with Drill Guide and Protective Guide.



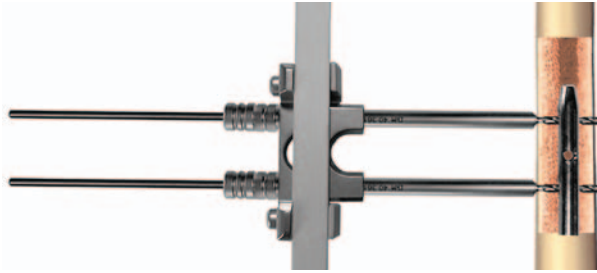
- 19** Insert the Protective Guide [40.3614] (*with one groove on the handle*) with the Trocar [40.3617] into the second hole in the slider of the Proximal Target.

Advance the Trocar until it reaches the cortex bone and mark the entry point for the Drill. Advance the Protective Guide together with the Trocar until it touches the bone.

Remove the Trocar.

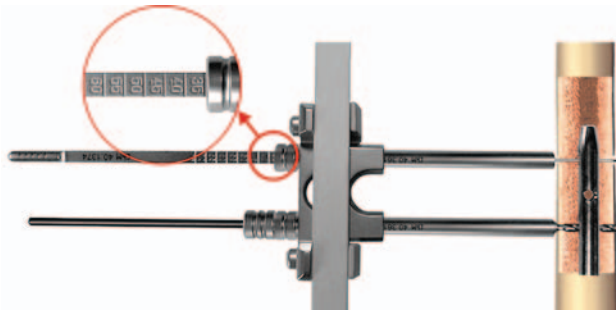
Leave the Protective Guide in the hole of the slider.

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



- 20** Insert the Drill Guide Ø3.5 mm [40.3615] (with two grooves) into the Protective Guide.

Mount the Drill With Scale 3.5/250 [40.5330] on the surgical drive and advance it through the Drill Guide. The scale on the drill indicates the length of the locking element. Drill the hole in the femoral shaft through both cortex layers and the hole in the nail. Remove the Drill and the Drill Guide. Leave the Protective Guide into the hole of the slider.

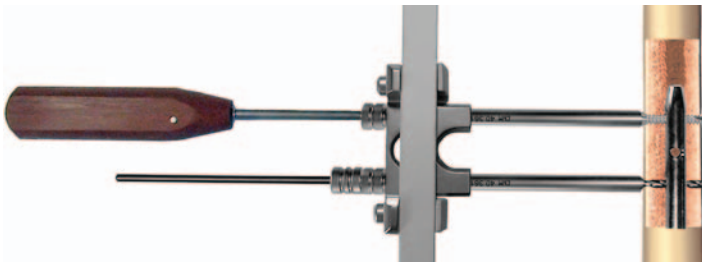


- 21** Insert the Screw Length Measure [40.1374] through the Protective Guide into the drilled hole until its hook reaches the cortex on the other side of the bone.

Read the length of the locking screw on the B-D scale. During the measurement the Protective Guide should rest on the cortex bone.

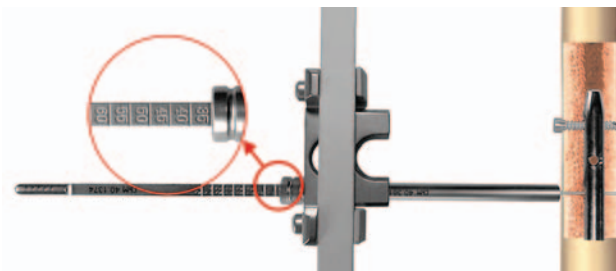
Remove the Screw Length Measure.

Leave the Protective Guide in the hole of the slider.



- 22** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw into the prepared hole until the head of the screw reaches the cortex of the bone (the groove on the screwdriver shaft matches the edge of protective guide).

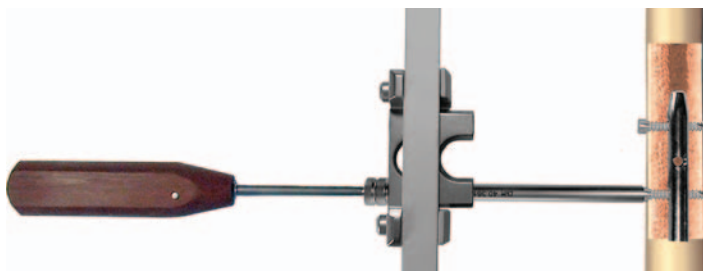
Remove the Screwdriver and the Protective Guide.



- 23** Remove the Drill from the distal hole in the slider of the Target. Leave the Protective Guide in the hole of the slider. Introduce the Screw Length Measure [40.1374] through the Protective Guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the B-D scale.

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

Remove the Screw Length Measure.



- 24** Insert the tip of the Screwdriver [40.3619] into the hexagonal socket of the selected locking screw. Then advance both into the protective guide. Insert the locking screw into 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 the Protective Guide.

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

III.6. REMOVAL OF TARGETING DEVICE, PLACING BLIND SCREW



25 Use the Socket Wrench S11 [40.1361] to remove the Connecting Screw [40.3658] of the nail shaft and dismount the Target from the nail locked in the medullary canal. Disassemble the Target.



26 In order to secure the inner thread of the nail from bone ingrowth, insert the End Cup (implant) using the Screwdriver [40.3619].

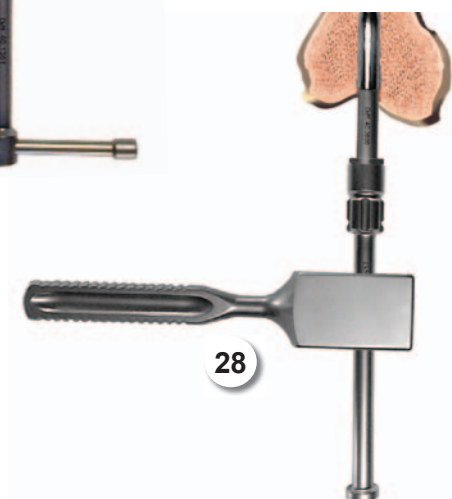


III.7. NAIL EXTRACTION

27 Use the Screwdriver [40.3619] to remove the End Cup or from the nail shaft.

Use the Screwdriver to remove all locking screws. Use two Screwdrivers to remove locking set.

Use the Socked Wrench [40.1361] to insert the Connector [40.3666] into the threaded hole in the nail.



28 Attach the Extractor [40.3665] to the connector and using the Mallet [40.3667] remove the nail from the medullary canal.

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



REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS



Instruments manufactured by ChM Ltd. are made of stainless steel, aluminium alloys and plastics 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 neutral 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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- 4 Intramedullary osteosynthesis of humerus**
- 7 Intramedullary osteosynthesis of fibula and forearm**
- 6 Intermedullary osteosynthesis of femur by trochanteric nails**
- 8 Dynamic Hip (DSB)/ Condylar (DSK) stabilizer**
- 9 Spine stabilization CHARSPINE**
- 15 Tibial and femoral angular set block**
- 20 Radial Head Prosthesis KPS**
- 22 Locking plates**
- 23 Intramedullary osteosynthesis of femur (reversed method) 40.3660**
- 24 Intramedullary osteosynthesis of femur 40.5060.000**
- 25 Intramedullary osteosynthesis of tibia 40.5370.500**
- 28 Intramedullary osteosynthesis of femur by trochanteric nail - ChFN**
- 29 Cervical locking plate system**
- 30 Proximal humeral plate**
- 31 Femoral plates**
- 32 4.0 ChLP plates for distal part of radial bone**
- 35 Spine stabilization [6mm]**
- 36 ChLP screws removing**
- 37 Stabilization of the pubic symphysis**
- 38 Intramedullary tibia osteosynthesis with CHARFIX2 nails**
- 40 Intervertebral cages BS PEEK CAGE**

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