ST/85A



INTRAMEDULLARY OSTEOSYNTHESIS OF DISTAL RADIUS FRACTURES WITH RADIAL NAIL

- IMPLANTS
- INSTRUMENT SET 15.0429.100
- SURGICAL TECHNIQUE



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SYMBOLS DESCRIPTION

Ti	Titanium or titanium alloy	\odot	Cannulated
St	Steel		Locking
	Left		Diameter
R	Right		Inner diameter
LR	Available versions: left/right	\bigcirc	Recommended length range for a particular nail
Len	Length	\bigcirc	Angle
\bigcirc	Torx drive	16 ÷ 90	Available lengths
	Torx drive cannulated	Ster Non Ster	Available in sterile/ non- sterile condition
\bigcirc	Hexagonal drive	-	
\bigcirc	Hexagonal drive cannulated	-	
	Caution - pay attention to a special procedure.		
	Perform the activity under X-Ray control.		
i	Information about the next stages of a procedure.		
	Proceed to the next stage.		
	Return to the specified stage and repeat the activity.		
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.		
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.		

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The manufacturer reserves the right to introduce design changes. Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

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1. INTRODUCTION

DRONes radial nail was designed with the help and under the supervision of Maciej Piotrowski, MD, PhD. The presented method develops the treatment philosophy promoted by Adalbert Kapandja. DRONes intramedullary implant is intended to combine both: the stable fixation of comminuted fractures and smallest possible surgical traumatization of soft tissues. Such osteosynthesis ensures early mobility, and undamaged soft tissues do not hinder rehabilitation process and quick recovery of the wrist functions. Additionally, minimal damage to the blood supply of the bone fragments does not adversely affect bone union.

Intramedullary osteosynthesis of radius with radial nail consists of:

- implants (intramedullary nail, locking screws),
- · instrument set for implants insertion and removal,
- surgical technique.

Intramedullary osteosynthesis of radius with radial nail allows for stable reduction of fracture fragments in distal radius.

The presented range of implants is made of materials in accordance with ISO 5832 standards.

Indicated use:

- distal radius fractures ('loco typico' fractures) according to the AO classification, types: A2, A3, C1, C2 and some C3 fractures Contraindicated for:
- C3 type fractures with the size of fracture fragments precluding stable anchoring of fixation screws
- fractures not extending to the radial styloid process, e.g. some Barton-type fractures, 'die punch' fractures.



AO Classification of fractures

An example: fracture of the radius; left limb; DRONes nail used.



Before surgery





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After surgery





8 weeks after surgery





Left limb mobility 8 weeks after surgery





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2. IMPLANTS

CHARFIX2 RADIAL NAIL L-68

CHARFIX2 RADIAL NAIL L-79

CHARFIX2 RADIAL NAIL L-85

IMPLANTS

CHARFIX2 Locking screw 2.4

\bigcirc	\bigcirc
12	3.5332.012
14	3.5332.014
16	3.5332.016
18	3.5332.018
20	3.5332.020
22	3.5332.022
24	3.5332.024
26	3.5332.026
28	3.5332.028
30	3.5332.030
32	3.5332.032
34	3.5332.034
36	3.5332.036
38	3.5332.038
40	3.5332.040
42	3.5332.042
44	3.5332.044
46	3.5332.046
48	3.5332.048
50	3.5332.050

(Ti)

Len

4.0ChLP screw VA 2.4

Len	Co
8	4.5235.008
10	4.5235.010
12	4.5235.012
14	4.5235.014
16	4.5235.016
18	4.5235.018
20	4.5235.020
22	4.5235.022
24	4.5235.024
26	4.5235.026
28	4.5235.028
30	4.5235.030
32	4.5235.032
34	4.5235.034
36	4.5235.036
38	4.5235.038

Stand for implants and radial nails

15.0429.600

3. INSTRUMENT SET

Instrument set for radial nails		15.042	9.100
	Name	Catalogue No.	Pcs
	Targeter arm	40.6751.000	1
E2 EL A Civil 48,6730 CE	Targeter B	40.6750.000	1
	Connecting screw M3	40.6753.000	2
	Protective guide 5.5/3.5	40.6754.000	2
	Drill guide 3.5/1.8	40.6755.000	2
> [Protective guide 6.5/4.5	40.6757.000	2
	Drill guide 4.5/1.8	40.6758.000	2
	Trocar 4.5	40.6759.000	1
	Drill 1.8/245	40.6760.000	3
	Kirschner wire 1.8/245	40.6778.000	3
	Screw length measure	40.6773.000	1
ອາມາສາມສາມສາມສາມ ການການການການການ	Screw length measure	40.6761.000	1
	Depth measure	40.4640.000	1
	Drill	40.6763.000	1
	Flexible medullary reamer 6.0	40.6770.000	1
	Flexible medullary reamer 5.0	40.6771.000	1
	Handle ratchet device	40.6654.000	1
	Screwdriver tip T8	40.6775.000	1
	Screwdriver tip T8.0	40.5682.000	1
	File	40.6776.000	1

Curved awl 5.0	40.6766.000	1
Impactor-extractor	40.6768.000	1
Mallet	40.6769.000	1
Guide VA 1.8	40.5928.018	1
Drill 1,8/110	40.2063.111	2
Bender	40.6777.000	1
Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	1
Stand	14.0429.100	1
Container with solid bottom 1/1 595x275x86mm	12.0750.100	1

4. SURGICAL TECHNIQUE

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The following description covers the most important stages of the implantation of the radial nails; however, it is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure and its application in each individual case.

4.1. INTRODUCTION

Patient positioning on the X-Ray transparent operating table is an integral part of the surgery. Intramedullary osteosynthesis presented in this method requires intraoperative radiological control.

Each surgical treatment must be planned carefully. Prior to surgery, take appropriate X-Ray images of the entire radius with adjacent joints (*in ap and lateral position*) so as not to miss any damage to its proximal and medial parts. Measure also the width of the medullary canal in the lateral projection (*depending on the nail length*), 5-6 cm proximal to the fracture gap. Should there appear any doubt, take a comparative X-Ray image of the opposite limb and/or perform computed tomography (CT).

4.1.1. PATIENT POSITIONING

Position the patient supine with their hand supported on the X-Ray transparent operating table.

The classical Henry approach (*between the radial artery and the first extensor compartment*) with the hand positioned in an intermediate position (*between pronation and supination*) is used. Perform 6 cm long skin incision along the radial bone proximally, starting 1 cm distally to the fracture gap. Retract and secure the superficial branch of the radial nerve, cut the retinaculum of the first extensor compartment and retract the tendons. If the fracture gap is located close to the brachioradialis attachment, peel off the dorsal half of the attachment to facilitate the nail insertion. The skin incision must ensure free access to the plate part of the DRONes implant and screw insertion.

CAUTION!

Before qualifying the patient for treatment with use of DRONes radial nail, verify, on the X-Ray image, the width of the medullary canal 5-6 cm proximally to the fracture gap.

• When preparing the approach, carefully retract the terminal branches of the superficial branch of the radial nerve.

• To protect the tendons against abrasion, cut,zig-zag' the sheath of the first extensor compartment to sew its ends over the plate part after nail implantation.

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4.2. OPENING THE FRACTURE GAP AND PREPARATION OF THE MEDULLARY CANAL FOR RADIAL NAIL INSERTION

1. Having located the fracture gap, use the curved awl 5.0 [40.6766] to create a hole in this gap for nail insertion (*see point 4.3*).

2. If the medullary canal diameter 5 cm proximal to the fracture gap in the frontal plane (*lateral X-Ray projection*) is 6 mm, use the file **[40.6776]** to ream and enlarge the inside of the canal.

 If the medullary canal diameter 5 cm proximal to the fracture gap in the frontal plane (*lateral X-Ray projection*) is smaller than 6 mm, use flexible medullary reamer 5.0 [40.6771] and then 6.0 [40.6770] to ream and enlarge the inside of the canal.

	40.6770.000
	40.6771.000

CAUTION! Insert the reamer as axially as possible in relation to the medullary canal. To do so, the broken epiphysis can be temporarily displaced towards the dorsal or palmar side. Ream the canal using oscillation mode or high speed, starting already in the wider part of the canal moving slowly into the narrow part. This reduces the perforation risk and/or breakage of the cortex from the elbow side.

4.3. NAIL-TO-TARGETER ASSEMBLY, NAIL IMPLANTATION

 Attach targeter arm [40.6751] to the plate part of the nail using connecting screw M3 [40.6753].

2. Attach targeter B [40.6750] to the targeter arm [40.6751] and insert the nail through the prepared fracture gap into the medullary canal. Perform axial wrist traction while nail insertion. Adjust the position of the nail to the bone, so that the plate part adheres as close as possible to the bone. Re-align bone fragments. Use fluoroscopy to control the position of bone fragments. Should, after manual fracture reduction, the palmar tilt be insufficient, correct the adjustment with Kirschner wire 2.0 as proposed by A. Kapandji. In this method a Kirschner wire is inserted into the fracture gap dorsally, and then the part protruding above the skin in moved towards the hand increasing the palmar tilt of the distal radius fragment. Lock the obtained reposition by inserting the Kirschner wire through the palm cortex. Use several Kirschner wires for comminuted fractures. After locking the nail with screws, the wires should be removed.

CAUTION! While locking the nail with screws, they can collide with implanted Kirschner wire.

Remove the targeter B [40.6750].

Kapandji's method - X-Ray images

When inserting the nail, make sure that the plate part of the nail does not exert pressure on the tendons and superficial branch of the radial nerve.

Use X-Ray control to verify the position of the nail in the medullary canal.

Should the nail be properly positioned at this stage, skip the step 3.

 Attach impactor - extractor [40.6768] to the targeter arm [40.6751]. Use mallet [40.6769] to achieve the desired position of the nail in the bone. Remove the impactor - extractor.

 For better adjustment of the implant to the curvature of the bone, the nails with elongated plate part - CHARFIX2 Radial nail L-79 [3.5322.002], CHARFIX2 Radial nail L-86 [3.5322.003], CHARFIX2 Radial nail L-96 [3.5324.002] or CHARFIX2 Radial nail L-103 [3.5324.003] - can be shaped using a bender [40.6777].

4.4. LOCKING THE NAIL IN THE PROXIMAL PART

Holes in the proximal part are located perpendicular to the shaft part of the nail. There are two holes in the radial nail [**3.5324.xxx**], and a single one in the radial nails [**3.5322.xxx**] in the proximal part, for locking screws 2.4 insertion. Use targeter B and three parallel locking holes provided therein for locking the proximal part of the nail. The hole closest to the plate part of the nail, marked ,A', shall be used for locking the nails [**3.5322.xxx**] with a single hole in the proximal part. The other two holes, marked ,B1' and ,B2' are intended for the nail [**3.5324.xxx**] with two holes in the proximal part. Remembered that when using a longer nail, the width of the medullary canal 6 cm proximal to the fracture gap should be measured on the X-Ray image.

 Attach targeter B [40.6750] to the targeter arm [40.6751]. Insert protective guide 6.5/4.5 [40.6757] with trocar 4.5 [40.6759] to the appropriate hole in the targeter B. Use the trocar to mark on the cortex an entry point for a drill and simultaneously push the protective guide as close to the bone as possible.

Remove the trocar.

2. Use protective guide 6.5/4.5 [40.6757] and drill [40.6763] mounted in a drive to initially drill a hole for the drill 1.8, to a depth of up to 2mm.

Remove the drill.

40.6763.000

CAUTION! Do not skip this stage as it ensures the correct insertion of the drill 1.8 mm, which is bending-prone. Do not touch targeter B [40.6750] while drilling.

5. Use quick coupling handle 3/16" [40.5636.100] with installed screwdriver tip T8 [40.6775] and protective guide 6.5/4.5 [40.6757] to insert the locking screw 2.4 of a suitable length.

Remove quick coupling handle, screwdriver tip and protective guide.

CAUTION! The holes in the proximal part of the nail are threaded, so locking screws 2,4 are locked in the nail and therefore they do not need to be tightened up.

4.5. LOCKING THE NAIL IN ITS PLATE PART

Five holes in the central part of the nail are located multiplanar and are intended for locking screws 2.4. Use holes marked with numbers from '1' to '5' on targeter B to implant the screws in the middle part of the implant.

The screw inserted through the hole '1' is located closest to the radial styloid process, the others move away in the ulnar direction. Introduce all the screws that stabilize the fragments (*the distal one*). If some screws do not enter the distal fracture fragment, e.g. through the hole '5', then there is no need to insert that screw, because it does not affect the stability of the fracture fixation.

1. Insert trocar 4.5 [40.6759] into the protective guide 6.5/4.5 [40.6757] and then both into the appropriate hole in the targeter B. Use trocar to mark on the cortex an entry point for the drill and simultaneously push the protective guide as close to the bone as possible.

Remove the trocar.

4 5

Remove the drill.

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Insert the drill guide 4.5/1.8 [40.6758] into the protective guide
6.5/4.5 [40.6757]. Use the drive and the drill 1.8/245 [40.6760] to drill a hole in the radius through first cortex layer and the hole in the nail.

Should point 4b be applied. remove the drill 1.8/245 and drill guides 4.5/1.8.

Drill under X-Ray control.

CAUTION! Do not penetrate the articular surface! The screws are to support the articular surface, and when drilled through, the base of the bone will migrate proximally during rehabilitation, and the screws will penetrate the joint. Stop drilling 2 mm from the subchondral layer.

Remove the screw length measure, drill 1.8/245 and drill guides 4.5/1.8.

.....

40.6761.000

5. Position adequately and press the protective guide 6.5/4.5 [40.6757] again as close to the bone as possible. Use quick coupling handle 3/16" [40.5636.100] with installed screwdriver tip T8 [40.6775] and protective guide 6.5/4.5 [40.6757] to insert the locking screw 2.4 of a suitable length.

Remove quick coupling handle, screwdriver tip and protective guide.

CAUTION! The holes in the proximal part of the nail are threaded, so locking screws 2,4 are locked in the nail and therefore they do not need to be tightened up.

When implanting the rest of screws in central part of the nail, proceed as presented in point 4.6. from stage 1 to 6.

4.6. LOCKING THE NAIL IN ITS PLATE PART

Three holes located in the bone-based plate part are provided for VA-type screws 2.4 insertion; one hole in the axis of the nail is positioned perpendicular to the outer surface of the plate part, and two angular holes are located on the sides. The holes located on the sides can be locked with targeter B using the holes marked *"Screws VA"*. All three holes can be locked using drill guide 3.5/1.8 and the *"free hand"* technique. The advantage of the *"free hand"* technique is the possibility of inserting the screw in any direction with up to 15° deviation from the hole axis.

4.6.1. LOCKING THE NAIL IN ITS PLATE PART WITH TARGETER B

1. Insert the drill guide 3.5/1.8 [40.6755] into protective guide 5.5/3.5 [40.6754] and then both into the corresponding hole in the targeter B [40.6750]. The drill guide should be screwed into the locking hole.

When implanting the next VA screw, proceed as presented in point 4.6.1. from stage 1 to 4.

4.6.2. LOCKING THE NAIL IN ITS PLATE PART WITH DRILL GUIDE 3.5/1.8

Use quick coupling handle 3/16" [40.5636.100] with installed screwdriver tip T8
 [40.6775] to insert the 4.0ChLP screw VA 2.4 of a suitable length.

Remove quick coupling handle and screwdriver tip.

Having implanted the nail, make sure that the nail does not exert pressure on the tendons and the radial nerve branch. Place the tendons on the plate part of the nail.

When implanting the rest of VA screws, proceed as presented in point 4.6.2. from stage 1 to 4.

At this stage, when locking the nail, remove the targeter arm **[40.6751]** and targeter B **[40.6750]** from the nail.

 Insert the guide VA 1.8 [40.5928.018] fully into the axis of locking hole. Position the guide as required. The guide can be positioned at 15° in each direction in relation to the axis of the locking hole.

40.5928.018

Exceeding a deviation angle of more than 15° may prevent the VA screw from being locked properly in the hole!

- Sta

2. Use the guide VA 1.8 [40.5928.018] and drill 1.8/110 [40.2063.111] to drill a hole in the radial bone passing through the nail hole and the first cortex layer.

Take advantage of a 15-degree locking range of the VA guide and insert the drill and then the VA screw parallel to the articular surface, as close as possible to the subchondral layer (*2mm from it*), up to the area of the radioulnar joint. The drill guide 3.5/1.8 **[40.6755]** installed in the plate would indicate the safe zone (*small palmar-dorsal range*), so that the VA screws will not collide with the green screws divergently locked in the nail in dorsal or palmar direction.

Remove drill and drill guide

Drill under X-Ray control to avoid the collision of the drill with already implanted screws. Do not change the drilling plane defined by the drill guide 3.5/1.8 [40.6755] in the palmar-dorsal direction!

3. Use the depth measure [40.4640] to determine the length of the screw VA 2.4.

Remove the depth measure.

 40.4640.000

Use quick coupling handle 3/16" [40.5636.100] with installed screwdriver tip T8
 [40.5682] to insert the 4.0ChLP screw VA 2.4 of a suitable length.

Remove quick coupling handle and screwdriver tip.

Having implanted the nail, make sure that the nail does not exert pressure on the tendons and the radial nerve branch. Place the tendons on the plate part of the nail.

When implanting the rest of VA screws using this method, proceed as presented in point 4.6.3. from stage 1 to 4.

4.7. FRACTURE FRAGMENTS REPOSITION

If the radial bone cannot be lengthened in relation to the ulna (*e.g. in inveterate fractures*) when compared to a healthy wrist (*consider 'ulna plus', 'ulna minus', 'neutral' variances*), then the order the screws are inserted needs to be changed. Start with screws inserted into the plate part first.

1. Introduce the nail into the medullary canal, as described in section 4.2. and 4.3.

2. Introduce the screws into the epiphysis through the plate part of the nail as presented in section 4.6.

 Use the targeter arm [40.6751], impactor-extractor [40.6768] and mallet [40.6769] to insert the nail and distal fracture attached thereto up until the radial bone is anatomically aligned with the ulna.

4. Secure the obtained reposition with a locking screw 2.4 in the proximal part as shown in point 4.4.

5. Insert the remaining locking screws in the central part as in point 4.5.

4.8. RADIAL NAIL REMOVAL

 Use quick coupling handle 3/16" [40.5636.100] with installed screwdriver tip T8 [40.5682] to remove all locking screws 2.4 and screws VA 2.4.

 Position the targater arm [40.6751] on the plate part of the nail and join them using connecting screw M3 [40.6753]. Attach the targeter B [40.6750] to the targeter arm [40.6751]. Moving in all directions, loosen and then remove the nail.

Remove the targeters.

3. Using a bone rongeur, available at the operating theater, make a hole for the nail removal.

Repeat steps 2 and 3 several times if necessary.

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 Attach the targater arm [40.6751] to the plate part of the nail again. Attach impactor-extractor [40.6768] and using the mallet [40.6769], remove the nail from the medullary cannal.

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Lewickie 3b 16-061 Juchnowiec Kościelny Polska tel. +48 85 86 86 100 fax +48 85 86 86 101 chm@chm.eu www.chm.eu

