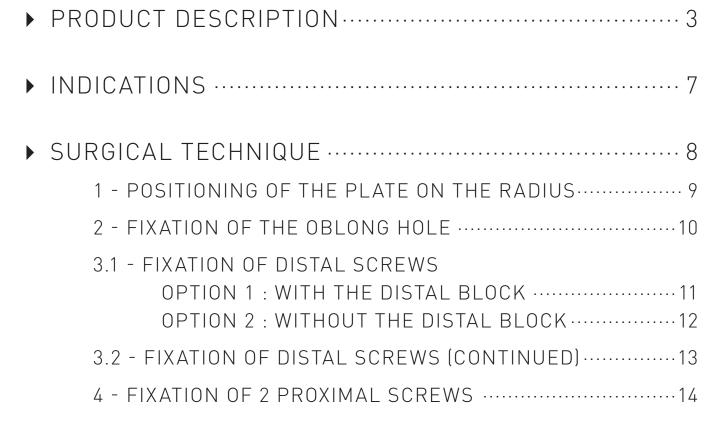


NeoView®

PLATE FOR DISTAL FRACTURES OF THE RADIUS







► REFERENCES15



NEOVIEW® PLATE FOR DISTAL FRACTURES OF THE RADIUS

- The plate present a distal low profile to prevent any irritation of soft tissues or lesion of the flexor tendons.
- The plate is preformed to the anatomy of the radius and therefore respects its alignment on the watershed line.
- The plate is fixed with single diameter screw.
- The plate is available in 2 sizes: 'Narrow' and 'Large' (left and right-hand side).
- The oblong hole helps to correctly position the plate in relation to the fracture site.





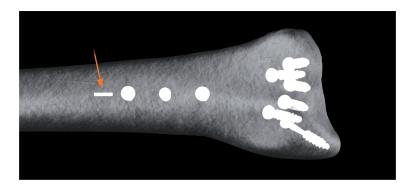
DISTAL BLOCK

- This instrument is delivered sterile and ready to use on the plate.
- The pre-oriented holes in the plate show where the screws should go.
- It is equipped with a metal radio-opaque end, which also reproduces the watershed line, thus enabling control of the positioning of the plate intraoperatively.



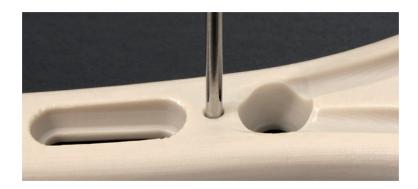
PEEK-OPTIMA®

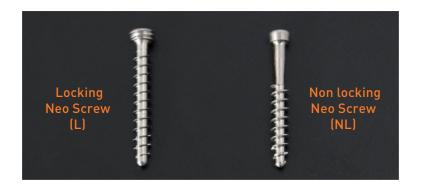
- The Neoview[®] plate is made from Peek-Optima[®].
- A material which is recognized for its mechanical properties and its radio-transparent qualities.



X-RAY MARKERS

• The plate has a X-Ray marker in its proximal part enabling control of its alignment on the radius.



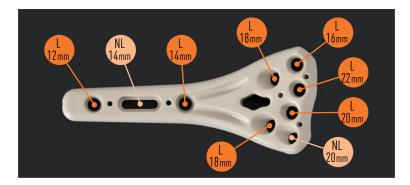


HOLES FOR WIRES

• Holes for K-wire for temporary stabilization of the plate.

NEO SCREWS

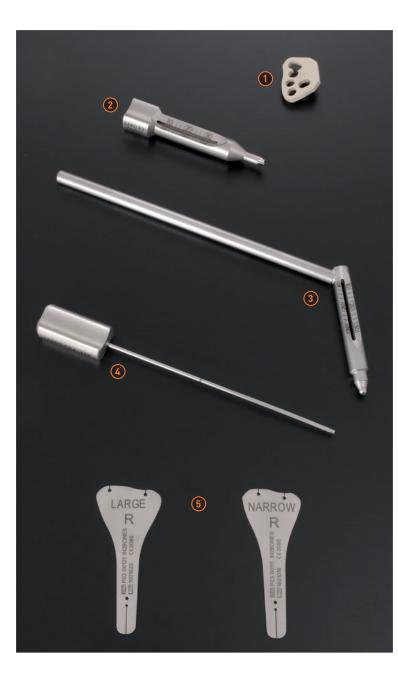
- Screws with the same diameter (diam. 2.7 mm).
- 'Locking' screws (L) enable stabilization of bone fragments.
- 'Non locking' screws (NL) enable the recoil and reduction of the bone on the plate.
- ▶ Angular freedom of screws (+/- 10°).



NEO SCREW'S POSITIONING (RECOMMENDATIONS)

- The screw lengths must suit the patient's anatomy.
- The Neoview[®] screw kit includes these recommended screws.

Note: Using a maximum of 2 non locking screws on the fitting assembly is recommended (including one in the oblo<u>ng hole</u>).



INSTRUMENTATION

► DISTAL BLOCK ①

It guides the positioning of the plate in relation to the watershed line due to its radio-opaque strip, as well as the pre-orientation of the distal screws.

The block is delivered sterile with the plate.

The surgeon can choose whether to use the distal block for fixing the screws or not.

Fixation of distal screws with block (Option 1), without block (Option 2).

▶ LOCKING DRILL GUIDE ②

This guide must be used with the distal block.

The guide must be positioned and locked in the plate (maximum 1/4 turn rotation).

▶ ANGULARY DRILL GUIDE ③

This guide is directly positioned on the plate without the distal block. It enables the positioning of the screws with an angulation of $+/-10^{\circ}$ in relation to the orientation of the holes of the plate.

> Note: The angulation must not be greater than 10° in order to prevent the screw head from going beyond the plate.

This guide <u>must</u> be used for the oblong hole.

► DEPTH GAUGE ④

Fitted with a marker, it can be used with the graduated drill guides to determine the necessary screw depth.

► TRIAL PLATES 5



INDICATIONS

 The NEOVIEW[®] Plate is intended for fixation of intraarticular and extra-articular fractures of the distal radius and reconstruction of the distal radius.

CONTRAINDICATIONS

- The implant should not be used in a patient who currently has, or who has history of:
 - acute or chronic inflammations, whether local or systemic,
 - > active infections,
 - > sensitivity/allergies to the implant materials.

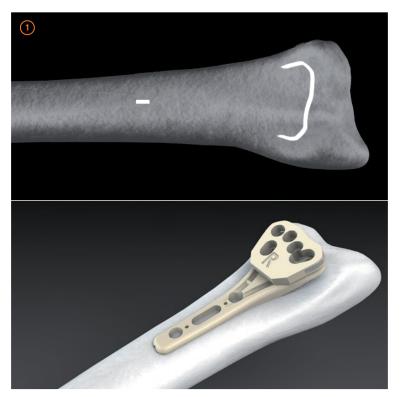


NEOVIEW® SURGICAL TECHNIQUE



In2Bones® as the manufacturer of this device, does not practice medicine. The surgeon who performs any implant procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient. This Surgical Technique Manual is furnished for information purposes, as an aid to use properly the device and its dedicated instruments.

1 - POSITIONING OF THE PLATE ON THE RADIUS



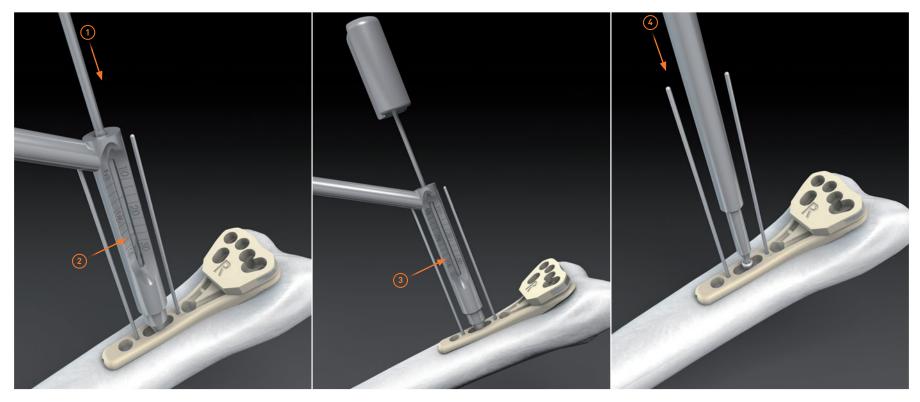
- The choice of the implant (narrow or large) can be made using the trial plates.
- Due to the radio-transparent quality of the plate and its block, two radio-opaque markers have been inserted in the proximal and the distal parts of the assembly.
- ► The radio-opaque edge of the distal block exactly reproduces that of the implant and emphasizes the watershed line. It therefore lets you guide the anatomical positioning of the implant by intraoperative fluoroscopy. 1



 Once the plate is positioned correctly, temporarily fixing it with K-wires (2) and/or with a non locking screw in the oblong hole is strongly recommended (see placement technique next page)

In order to prevent tendon rupture, the Neoview[®] plate should be positioned proximal to the watershed line.

2 - FIXATION OF THE OBLONG HOLE

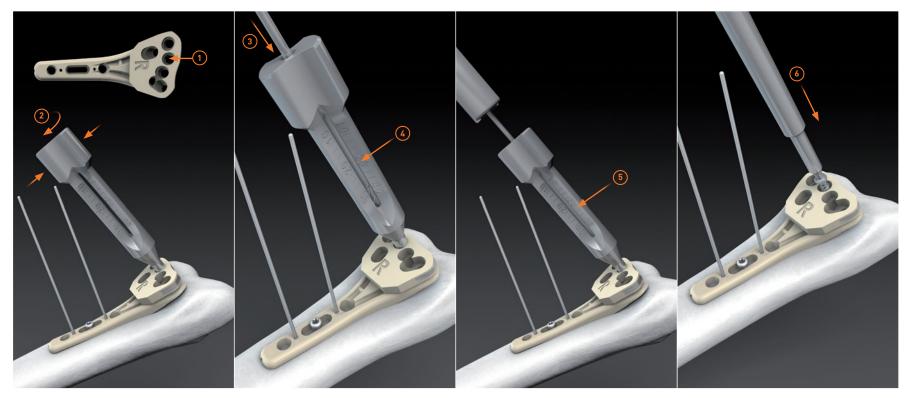


- Position the angular guide in the oblong hole perpendicular to the plate.
- Drill the hole with the drill bit using the guide. 1

It is imperative to always use a drill guide to prevent any damage the plate during drilling.

- Determining the correct screw length is performed directly with the drill bit, via laser marking ⁽²⁾, or by using the depth gauge. ⁽³⁾
- Insert a non locking screw without tightening it (the final tightening will be done at the end of the surgical operation).

3.1 - OPTION 1: FIXATION OF DISTAL SCREWS WITH THE DISTAL BLOCK



- ▶ For this option, use the locking drill guide.
- ► The distal part of the Neoview[®] plate is fixed starting with the most distal screw. ¹
- ► Insert the locking drill guide through the distal block hole and lock in the plate. ②

The guide must be screwed in a maximum 1/4 turn in the plate respecting the direction pre-determined by the block.

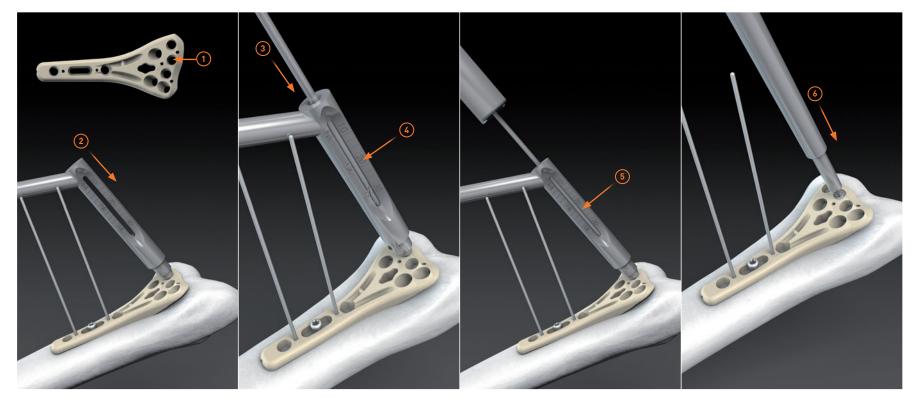
- Ensure the stability of the assembly before drilling.
- Drill the hole with the drill bit through the guide. ③

- Measure the screw length on the drill guide:
 - ightarrow either direct reading with the drill bit m 4
 - \rightarrow or with the depth gage (5)
- Remove the locking guide and insert the screw (non locking if needed) through the distal block with the screwdriver T7 6

The screw head must be flush with the plate

Do not apply excessive torque during screw tightening as this may damage the bone or implant

3.1 - OPTION 2: FIXATION OF DISTAL SCREWS WITHOUT THE DISTAL BLOCK



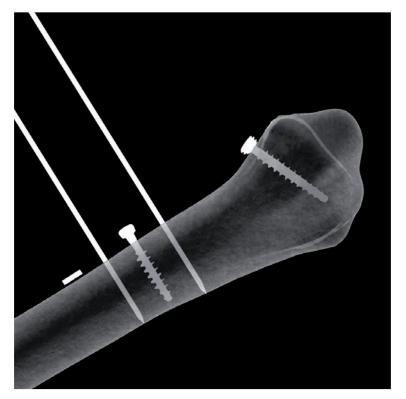
- ▶ For this option, use the angulary drill guide.
- ▶ Remove the distal block.
- ► The distal part of the Neoview[®] plate is fixed starting with the most distal screw. 1
- Place the angulary guide directly on the plate 2.
 An angulation freedom of +/- 10° in relation to the orientation of the hole is possible.
- ▶ Drill using the angulary guide. ③

- Measure the screw length on the drill guide:
 - ightarrow either direct reading on the drill bit m (4)
 - \rightarrow or with the depth gage \bigcirc
- ▶ Remove the angulary guide and insert the screw with the screwdriver T7 ⁶

The screw head must be flush with the plate

Do not apply excessive torque during screw tightening as this may damage the bone or implant

3.2 - FIXATION OF DISTAL SCREWS (CONTINUED)



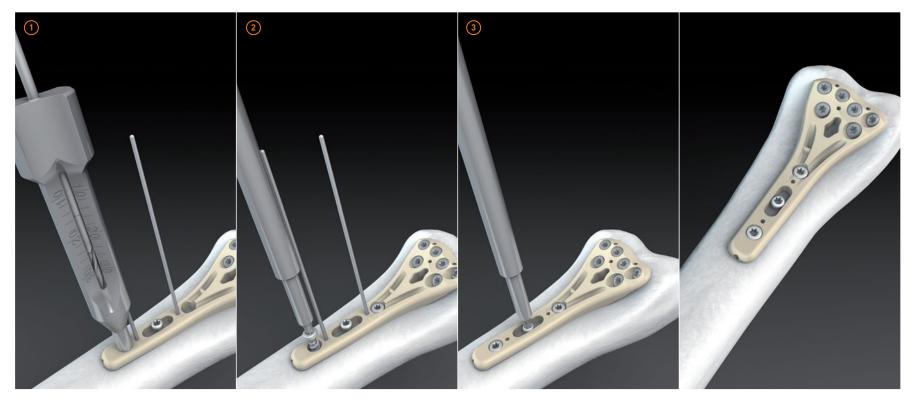
 After inserting the most distal screw, a control using lateral fluoroscopy is recommended to verify that the screw has not entered the joint space.



 The other distal screws are then inserted repeating the same surgical procedure as before (option 1 or 2 as selected by the user).

It is imperative to always use a drill guide to prevent any damage the plate during drilling.

4 - FIXATION OF 2 PROXIMAL SCREWS



- Always use a drill guide so as not to damage the plate: The choice of the guide (locking or angulary) is up to the surgeon. (1)
- ► The two proximal screws are to be inserted using the same technique as described above. ②
- Final step: tighten the screw in the oblong hole. ③

The screw head must be flush with the plate

Do not apply excessive torque during screw tightening as this may damage the bone or implant

POST-OPERATIVE RECOMMENDATIONS

- The post-operative recommendations depend on many factors and should be adapted to each situation depending on the assessment and according to the surgeon's recommendations.
- Any concomitant diaphyseal or metaphyseal fracture of the ulna requires a complementary immobilization or an associated osteosynthesis to permit early mobilization.



15

P30 SP110	NEOVIEW [®] Plate kit	Narrow	Right
P30 SP210	NEOVIEW [®] Plate kit	Narrow	Left
P30 SP120	NEOVIEW [®] Plate kit	Large	Right
P30 SP220	NEOVIEW [®] Plate kit	Large	Left

INSTRUMENTS

G01 00231	Non Cannulated Screwdriver T7
P03 00011	Locking drill guide
P03 00061	Angulary drill guide
P03 00021	Depth gauge
P03 00111	Trial Plate - Narrow
P03 00121	Trial Plate - Large
P03 00051	Drill diam 2.0 A0 Lg 125 mm
K10 NS071	K-wire diam 1 mm Lg 70 mm
K10 NS100	K-wire diam 1 mm Lg 100mm
P03 10011	Neoview® Container (232 x 232 x 45)

NEO* SCREWS (per unit in sterile tube)

Length	Non locking - NL
12 mm	W27 ST012
14 mm	W27 ST014
16 mm	W27 ST016
18 mm	W27 ST018
20 mm	W27 ST020
22 mm	W27 ST022
24 mm	W27 ST024
	12 mm 14 mm 16 mm 18 mm 20 mm 22 mm

NEOVIEW[®] SCREWS SET

W27 ST900	Set of Neoview [®] screws containing:		
	NE0 screw	Quantity	
	Locking - Lg 12 mm	1	
	Locking - Lg 14 mm	1	
	Locking - Lg 16 mm	1	
	Locking - Lg 18 mm	2	
	Locking - Lg 20 mm	2	
	Locking - Lg 22 mm	1	
	Non Locking - Lg 14 mm	1	
	Non Locking - Lg 20 mm	1	



RECOMMENDATION

• It is recommended to carefully read the instructions for use in the package insert.

DEVICES

- ▶ Implants: CE Class IIb CE0086
- ▶ Trial implants: CE Class IIa CE0086
- ▶ Instruments:
 - > Instruments connected to a power driver: Class IIa CE0086
 - → Instruments with measuring function: Class lm CE0086
 - > Other instruments: Class I CE

REIMBURSEMENT

Reimbursement may vary from countries to countries.
 Check with local authorities.

MANUFACTURER

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DOCUMENT

- ▶ Reference: ST-NEOVIEW-EN-052016
- ▶ Date of revision: 05/2016
- ▶ Version 01

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

Always refer to the appropriate instructions for use for complete clinical instructions.

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