CE 1023

ULTRALOCK DISTAL RADIUS PLATING SYSTEM – Surgical Technique

AO PRINCIPLES:

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation:

1. **Anatomic reduction:** Fracture Reduction and fixation to restore anatomical relationships.
2. **Stable fixation:** Fracturefixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.
3. **Preservation of blood supply:** Preservationof the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.
4. **Early, active mobilization:** Early and Safe Mobilization and rehabilitation of the injured part and the patient as a whole.

Intended Use:

The Ultra Lock Distal Radius system consisting Distal Radius Plating systemis intended for temporary fixation, correction or stabilization in the Distal Radius anatomical region.

Indications:

Displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius.

Dorsal approach

Dorsally displaced fractures

Extra-articular fractures with metaphyseal defect (AO classification 23-A3)

Open joint reconstruction (AO classification 23-C1, C2, C3)

Combination of distal radius with carpal and metacarpal fractures

Corrective osteotomies

Volar approach

Reversed Barton

Palmarly displaced extra-articular fractures (Goyrand- Smith)

Dorsally displaced extra-articular (Colles) and articular fractures

Extra-articular fractures with extension into the shaft (extra-long plates)

Contraindications:

Since external fixation devices are oftenused in emergency situations to treatpatients with acute injuries, there areno absolute contraindications for use.The surgeon's education, training andprofessional judgment must be reliedupon to choose the most appropriatedevice and treatment for eachindividual patient. Whenever possible,the device chosen should be of a typeindicated for the fracture being treatedand/or for the procedure beingutilized.

Conditions presenting an increasedrisk of failure include:

• Insufficient quantity or quality ofbone which would inhibitappropriate fixation of the device.

• Compromised vascularity that wouldinhibit adequate blood supply to thefracture or operative site.

• Previous history of infections.

• Any neuromuscular deficit whichcould interfere with the patient'sability to limit weight bearing.

• Any neuromuscular deficit whichplaces an unusually heavy load onthe device during the healing period.

• Malignancy in the fracture area.

• Mental, physical or neurologicalconditions which may impair thepatient's ability to cooperate with thepostoperative regimen.

• Patients with a compromisedimmune system.

• Pre-existing internal fixation that prohibits proper pin placement

Plates Features:

Anatomically precontoured

- Minimal irritation of ligaments andsoft tissue from a flat plate and screw profile, rounded edges and polished surfaces.
- Some plates are precontoured anddo not have to bebent.

Dorsal plates

Small plate and screw dimensions enable a two-plate technique. Both locking and Cortical screws can be inserted in the shaft.

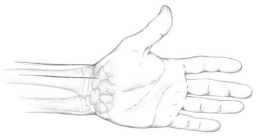
Volar plates

Depending on the indication, plates are selected with juxtaarticular or extraarticular placement. Both locking andCorticalscrews 2.5mm or 2.7mm can be inserted in theshaft.

Juxtaarticularplates

Extraarticularplates

Volar Surgical Technique



Preoperative Planning- General Technique

1. Plate selection and contouring

The plates are available in various shapes and lengths which allow the surgeon to select fragment-specific treatment of distal radius fractures. Decide on the desired volar or dorsal approach and select the plates according to the fracture pattern and anatomy of the radius.

Onlysomeplatesareanatomicallypre-contoured(allVolarplates and the straight plates for the radial column).Contour the plates to the anatomy with the Plate Benders.

Precautions:

- Theplateholeshavebeendesignedtoacceptsome-degreeofdeformation.Theundercutshelpensurethat the threaded holes will not be distorted with typical contouring.Significantdistortionofthethreadedholeswillreduce lockingeffectiveness.
- Reverse bending or use of the incorrect instrumentation for bending may weaken the plate and lead topremature plate failure (e.g. breakage). Do not bend the plate beyond what is required to match theanatomy.

2. Screw insertion

Determine whether cortical screws or locking screws will be used for Fixation in the shaft. Locking screws in the distal arm(headoftheplate)maybeanadvantageto supportthe articular surface and prevent loss of reduction.

Recommendation: Use locking head screws in the distal arm of the plates, and locking head and/or cortical screws in the shaft of the plates. If a combination of cortical screws and locking head screws is used, a cortical screw should be used first

to pull the plate to the bone.

Warning: If a locking head screw is used first, care should be taken to ensure that the plate is held securely to the bone, to avoid spinning of the plate.

Note: 2.7mm cortical screws can only be used in the combination hole of the volar plates.

Insertion of Cortical Screws:

Pre-drill screw hole

The insertion of cortical screws – 2.7mm is described using the example of a Volar plate.

According to the selected screw diameter use the appropriate Drill Sleeve 2mm to pre-drill the screw hole either neutrally (buttress) or off-center (compression).

For the Cortical screw 2.7mm, use the 2mm drill bit for the gliding hole.

Determine screw length

Use the Depth Gauge for screws 2.5/2.7mm to determine the screw length.

Pick up screw

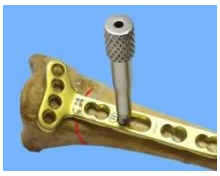
Select and pick up the appropriate cortical screw using the Hexagonal Screwdriver 2.5/2.7mm.

Insert self-tapping Cortical Screw- 2.7mm

Insert the self-tapping cortical screw with the Hexagonal Screw Driver 2.5/2.7mm.

Insertion of Locking Screws -2.5mm:

Insert Locking drill sleeve 2mm



The insertion of locking screws is described using the example of an extra articularvolarplate.

Screw the Locking Drill Sleeve for 2.5mm screwsvertically into a threaded hole until fully seated. This is very much needed to ensure central drilling of the screw hole so that the final screw head shall fit into the plate's hole flushing to the plate and locking threads of the screws shall engaged in plate firmly.

Predrill screw hole

With the Drill Sleeve for 2.5mm screws, use 2mm drill bit to drill to the desired depth.

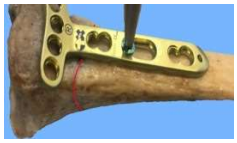
Determine screw length

Use the Depth Gauge for screws 2.5/2.7mm to determine the screw length.

Pick up screw

Select and pick up the appropriate screw using the Hexagonal Screw Driver 2.5/2.7mm

Insert Cortical Locking screw 2.5mm

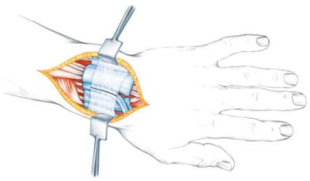


Insert the cortical locking screw manually with the Hexagonal Screwdriver. Carefully tighten the locking screw, as excessive force is not necessary to produce effective screw locking.

Alternatively, to apply the correct amount of torque use the

Torque Limit Screw Driver-2.5/2.7mm for torque up to 0.8Nm at the time of inserting final few threads of the screw.

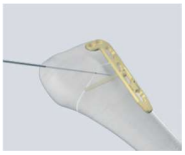
Surgical Technique – Dorsal Approach

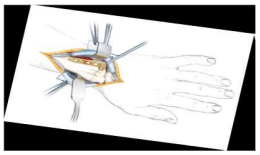


Temporary fixation of fracture with K- wire

Reduction can be preliminarily held with K-wires of 1.5mm or 1.8mm. A wire introduced across the radial styloid will fit into a small notch (horse-shoe tip) in the distal end of the straight radial plate

Apply Dorso-Ulnar plate



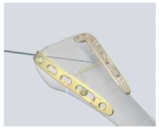


Provisionally position the plate according to anatomy and fracture pattern. Contour the plate to the bone's anatomy with the Plate benders.

Preliminarily fix the plate by inserting a cortical screw 2.7mm in the elongatedcombi-hole of the proximal shaft.

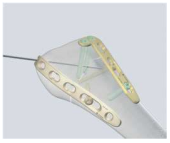
The plate supports the intermediate column and fixes thedorso-ulnar fragment.

Apply Dorso-Radial plate



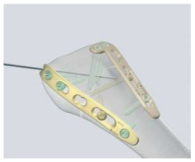
Contour radial plate to the anatomy with Plate Benders Ifnecessary. Use the horse-shoe tip to position the radial plate properly. Correct placement of the radial plate is crucial. After positioning, preliminarily fix the plate by inserting a cortical screw 2.7mm in the elongated combi-hole of the proximal shaft.
Check the reduction and position of the plates by image intensifier.
The osteosynthesis is then completed as follows:

Insert the screws in the Dorso-Ulnar plate



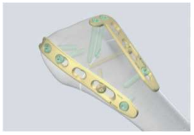
Insert a locking or a cortical screw 2.7mm in the most proximal hole in the shaft of the plate (1). Complete internal fixation by inserting locking screws of 2.5mm in the distal arm of the plate

Insert the screws in the Dorso-Radial plate



Insert a locking screw 2.5mm in the most proximal hole in the shaft of the plate. Complete internal fixation by inserting locking screws in the distal arm of the plate.

Final fixation



A final fluoroscopy is performed to confirm correct reduction of the fracture, length and position of the implants.
Correct placement of the plates is crucial to provide sufficient support to the radial styloid. In an anterior view during intra-operative fluoroscopy, the dorso-ulnar plate should be projected almost antero-posteriorly, the dorso-radial plate almost laterally, and vice versa for the lateral view. If the plates appear to be parallel, the dorso-radial plate is positioned too far on the ulnar side.

Precaution: Do not cut the plates distally. The sharp cut end may lead to lesions of the extensor tendons.

Postoperative treatment: A palmar splint is applied for the first few days to prevent the patient from holding the hand in palmar flexion. Early function is then initiated

Implant Removal:

The UltraLock Distal Radius Plates should first be removed by following screw removal technique of cortical screws. Take care while removing locking screws, first unlock all screws from the plate with Hexagonal Screw Driver 2.5/2,7mm then remove the screws completely from the bone. This prevents rotation of the plate when removing the last locking screw. Ensure that the tip of the screw driver sits fully into the head of the screws. Partial engagement may lead to wear out of screw head or screw driver tip. Don't use high torque while removing the screws.If screw head gets damaged during removal, use the screw removal instruments to remove damage head screws.

Note: The final decision of removing the implants shall be taken by the operating surgeon only. It is recommended that the implant used as an aid for healing should be removed once its service is over after proper consultation and examination by the operating surgeon in final follow up, particularly in younger and more active patients.

CAUTION:

Used Implants:

Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fail to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. Therefore reuse of implants are strictly not recommended.

Disposal of Used Implants:

Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed of properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment. Dispose of the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

PACKAGING MATERIAL DISPOSAL: The packaging material of this device is made of LDPE and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such a way that keep out of reach of children and stray animals.

SINGLE BRAND USAGE: Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices

MRI Information

IMPORTANT:

The implants contained in this surgical technique have not been evaluated for Compatibility and safety in MR environment nor tested for Heating and Migration in MR environment.

ULTRALOCK DISTAL RADIUS PLATING SYSTEM – Surgical Technique

Product Details:

CE 1023

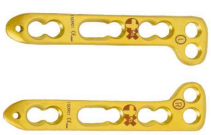
Ultra Lock® Plating System - Small Fragment

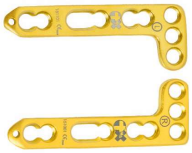
Dorsal Distal Radius Locking Plates Straight

Size	S.S.	Titanium
5 Holes	2024.S05	2024.TS05
6 Holes	2024.S06	2024.TS06

Intended Use	For Internal Fixation of Distal Radius
Profile	7.5mm x 2mm, 2.5/2.7mm Screw compatible, 0.7mm thread pitch
Material	SS 316L & Titanium

Dorsal Distal Radius Locking Plates L-90° Angled





Size	S.S.	Titanium
2+3 Holes	2024.123(L/R)	2024.T123(L/R)
2+4 Holes	2024.124(L/R)	2024.T124(L/R)
3+3 Holes	2024.133(L/R)	2024.T133(L/R)
3+4 Holes	2024.134(L/R)	2024.T134(L/R)

Intended Use	For Internal Fixation of Distal Radius
Profile	7.5mm x 2mm, 2.5/2.7mm Screw compatible, 0.7mm thread pitch
Material	SS 316L & Titanium

Dorsal Distal Radius Locking Plates L Oblique Angled

Size	S.S.	Titanium
3+3 Holes	2024.233(L/R)	2024.T233(L/R)
3+4 Holes	2024.234(L/R)	2024.T234(L/R)

Intended Use	For Internal Fixation of Distal Radius
Profile	7.5mm x 2mm, 2.5/2.7mm Screw compatible, 0.7mm thread pitch
Material	SS 316L & Titanium

Dorsal Distal Radius Locking Plates T Shape

Size	S.S.	Titanium
3+3 Holes	2024.3330	2024.T3330
3+4 Holes	2024.3340	2024.T3340

Intended Use	For Internal Fixation of Distal Radius
Profile	7.5mm x 2mm, 2.5/2.7mm Screw compatible, 0.7mm thread pitch
Material	SS 316L & Titanium

Ultra Lock® Plating System - Small Fragment

CE 1023

Volar Distal Radius Locking Plates
Extra-Articular

Size	S.S.	Titanium
4+3 Holes	2025.043 (L/R)	2025.T043 (L/R)
4+4 Holes	2025.044 (L/R)	2025.T044 (L/R)
4+5 Holes	2025.045 (L/R)	2025.T045 (L/R)
5+3 Holes	2025.053 (L/R)	2025.T053 (L/R)
5+4 Holes	2025.054 (L/R)	2025.T054 (L/R)
5+5 Holes	2025.055 (L/R)	2025.T055 (L/R)

Intended Use	For Internal Fixation of Distal Radius
Profile	7.5mm x 2mm, 2.5/2.7mm Screw compatible, 0.7mm thread pitch
Material	SS 316L & Titanium

Volar Distal Radius Locking Plates
Juxta-Articular

Size	S.S.	Titanium
5+3 Holes	2025.153 (L/R)	2025.T153 (L/R)
5+4 Holes	2025.154 (L/R)	2025.T154 (L/R)
5+5 Holes	2025.155 (L/R)	2025.T155 (L/R)

Intended Use	For Internal Fixation of Distal Radius
Profile	7.5mm x 2mm, 2.5/2.7mm Screw compatible, 0.7mm thread pitch
Material	SS 316L & Titanium

ULTRALOCK DISTAL RADIUS PLATING SYSTEM – Surgical Technique

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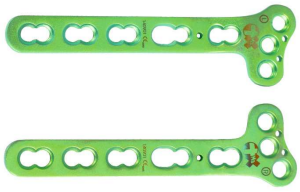
Ultra Lock® Plating System - Small Fragment

'T' Locking Plates for Distal Radius

Size	S.S.	Titanium
3 Holes	209.003	209.T003
4 Holes	209.004	209.T004
5 Holes	209.005	209.T005
6 Holes	209.006	209.T006
7 Holes	209.007	209.T007

Intended Use	For Internal Fixation of Distal Radius
Profile	10mm x 2.5mm profile, 4mm compatible, 0.8mm thread pitch
Material	SS 316L & Titanium

Oblique 'T' Locking Plates for Distal Radius



Size	S.S.	Titanium
3 Holes	201.003 (L/R)	201.T003 (L/R)
4 Holes	201.004 (L/R)	201.T004 (L/R)
5 Holes	201.005 (L/R)	201.T005 (L/R)
6 Holes	201.006 (L/R)	201.T006 (L/R)
7 Holes	201.007 (L/R)	201.T007 (L/R)

Intended Use	For Internal Fixation of Distal Radius
Profile	10mm x 2.5mm profile, 4mm compatible, 0.8mm thread pitch
Material	SS 316L & Titanium

ULTRALOCK DISTAL RADIUS PLATING SYSTEM – Surgical Technique

Ultra Lock® Plating System - Small Fragment Instruments

CE

Drill Bits - 2mm

Size	Screws Size	Reference
2mm x 5"	Cortical Screws - 2.7mm & Cortical Locking Screws - 2.5mm	552.205

Drill Sleeve - 2mm

Size	Screws Size	Reference
2.0mm x 1.5"	Cortical Locking Screws - 2.5mm	555.200

Drill Bits - 2.2mm

Size	Screws Size	Reference
2.2mm x 6"	Cortical Locking Screws - 3mm	552.226

Drill Sleeve - 2.2mm

Size	Screws Size	Reference
2.2mm x 2.5"	Cortical Locking Screws - 3mm	555.220

Drill Bits - 2.5mm

Size	Screws Size	Reference
2.5mm x 8"	Cancellous Locking Screws - 4mm	552.258

Drill Sleeve - 2.5mm

Size	Screws Size	Reference
2.5mm x 2.5"	Cancellous Locking Screws - 4mm	555.250

Drill Bits - 2.5/2.7mm

Size	Screws Size	Reference
2.5mm x 5"	Cortical Screws - 3.5mm x 14 TPI	552.255
2.7mm x 5"	Cortical Screws - 3.5mm x 20 TPI	552.275

Drill & Tap Sleeve Double Ended

Size	Screws Size	Reference
2.7mm x 3.5mm	Cortical Screws - 3.5mm x 20 TPI	558.350

Drill Bits - 3.2mm

Size	Screws Size	Reference
3.2mm x 6"	Cortical Locking Screws - 4mm	552.326
3.2mm x 8"	Cortical Locking Screws - 4mm	552.328

Drill Sleeve - 3.2mm

Size	Screws Size	Reference
3.2mm x 3"	Cortical Locking Screws - 4mm	555.320

CE

Ultra Lock® Plating System - Small Fragment Instruments

Drill Sleeve With Handle

Size	Reference
2mm	558.200

Depth Gauge

Size	Reference
2.5/2.7mm	254.250

Hexagonal Screw Driver

Size	Screws Size	Reference
2.5mm/2.7mm	Cortical Screws - 2.7mm & Cortical Locking Screws - 2.5mm	569.125

Tommy Bar

Reference
943.001

Hexagonal Screw Driver

Size	Screws Size	Reference
3.5mm	Cortical Screws - 3.5mm & Cortical Locking Screws - 3mm,4mm Cancellous Locking Screws- 4mm	569.135

Reduction Bone Holding Forceps - Pointed

Size	Reference
6"	273.006

Reduction Bone Holding Forceps with K wire Guide

Size	Reference
6"	704.106

Plate Bender In Pair

Size	Reference
Small	571.001

Torque Limit Screw driver

Size	Reference
4mm	925.001

Depth Gauge

Size	Reference
3.5mm	561.235

CE 1023

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