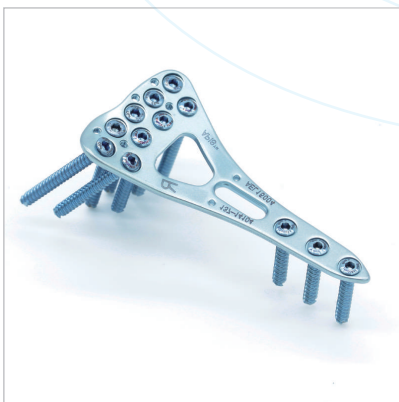
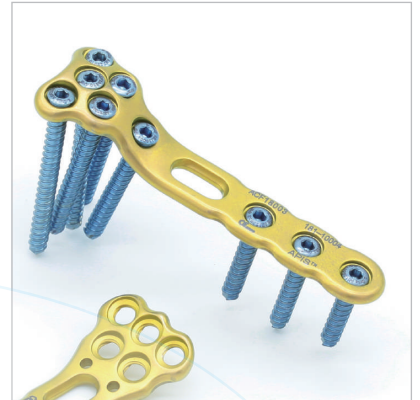
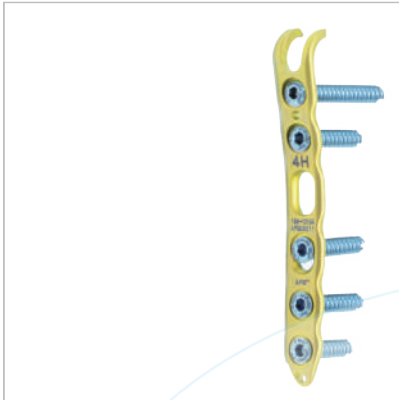


DRLP (Distal Radius Locking Plate)
DULP (Distal Ulna Locking Plate)
PRLP (Proximal Radius Locking Plate)
System - Surgical Technique Guide



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1 - 2	Introduction
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9 - 14	Ordering Information Implants & Instruments
15	Product Information

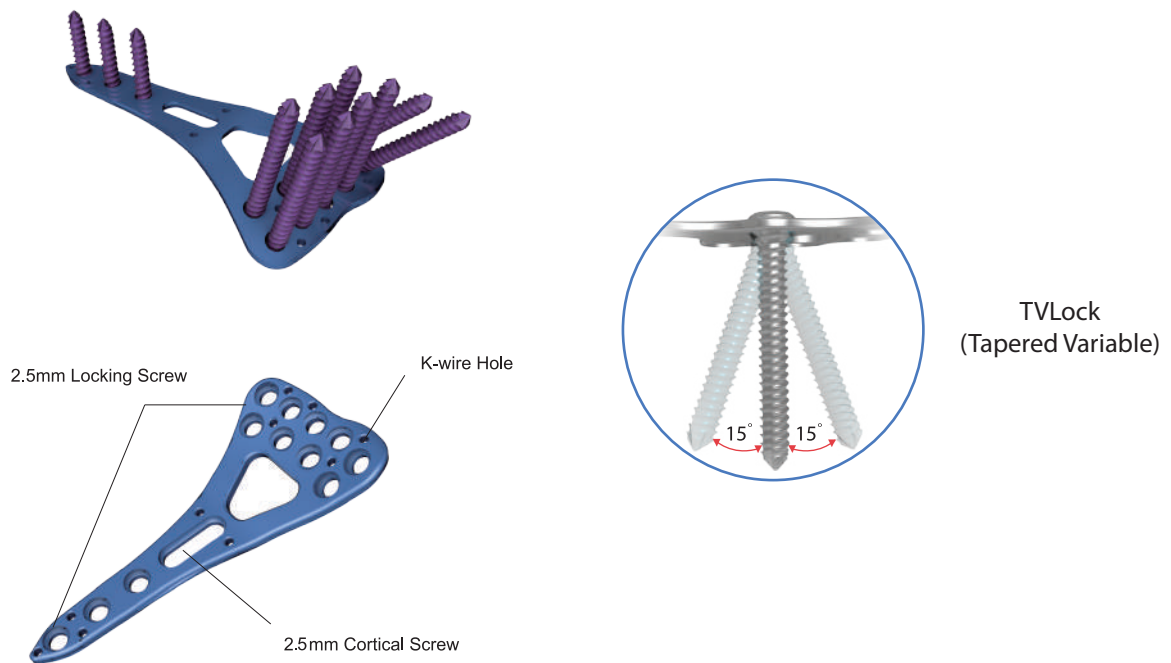
- 1) Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.
- 2) Refer to Instructions for Use for additional information.

DRLP(Distal Radius Locking Plate) System

TDM introduces the second generation Distal Radius Locking Plate(DRLP) System designed and developed with experienced surgeon consulting team. The System is the 2nd Generation Plating System at TDM. The system has two plate families for repairing intra-articular fracture nonunions and malunion of the distal radius, innovative, various optional instrumentation for effective fracture management.

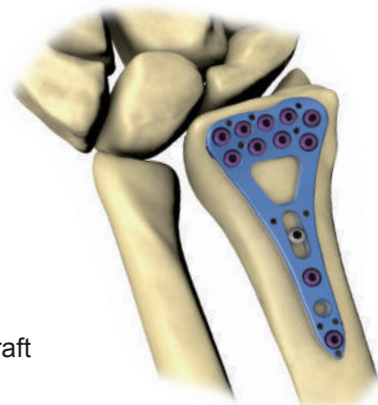
key features include :

- Low Profile Plate; Thickness 1.5mm
- Both fixed angle Locking and variable angle locking are available.
- Precise Screw Placement & Anatomic Plate Design
- Reduces Soft-tissue irritation and implant prominence



Intra-Articular Plate

- Distal fitting to offer full coverage for complex intra-articular fracture
- Targeting the styloid with two screw
- Beveled Plate edge minimize irritation
- Window for fracture visualization and articular reconstruction and bone graft



Intra-Articular Plate

Screw Type

- 2.5mm Locking Screw Self tapping
- 2.5mm Locking Screw, Blunt Tip
- 2.5mm Cortical Screw, Low Profile

* Torque limiting handle 0.6Nm for 2.5mm Locking Screw



Self tapping Tip

Blunt Tip

Cortical Screw, Low Profile

Three Drill Target Guide Option



* Option

Intra-articular Fractures Correction Osteotomies

DULP(Distal Ulna Locking Plate) System



Distal Ulna Locking Plate, Volar



Distal Ulna Locking Plate, Hook

DRLP(Distal Radius Locking Plate) System

Approach

Make an incision approximately 8 cm to 10 cm. Dissect between the FCR and the radial artery, exposing the pronator quadratus. Detach the pronator quadratus from the later border of the radius and elevate it toward the ulna.

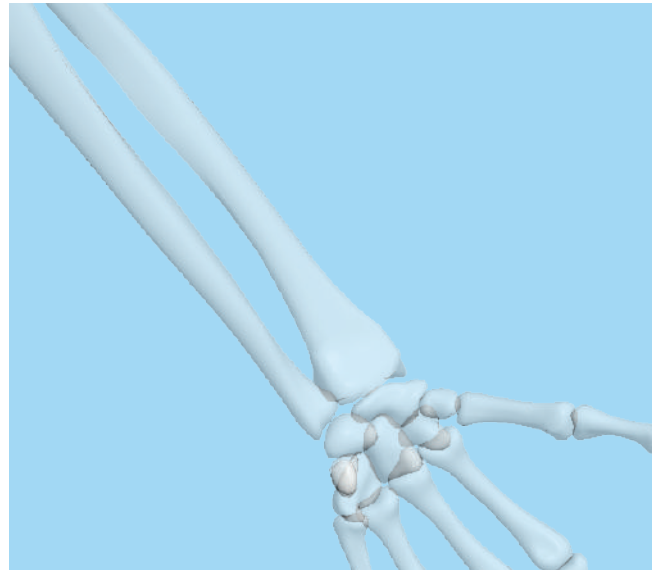
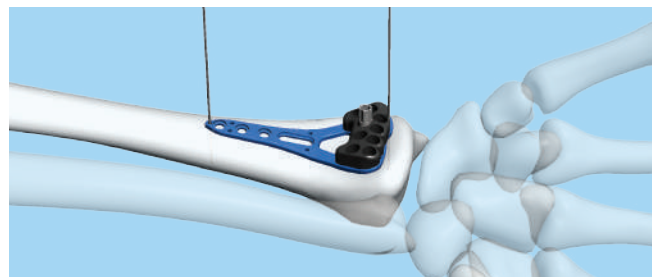
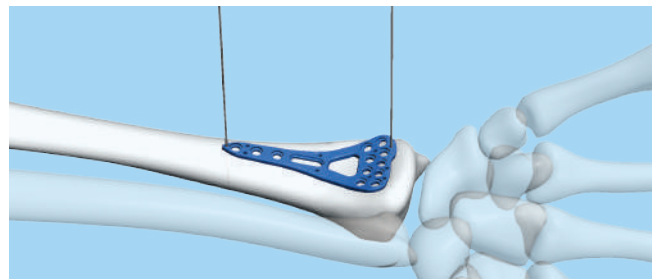


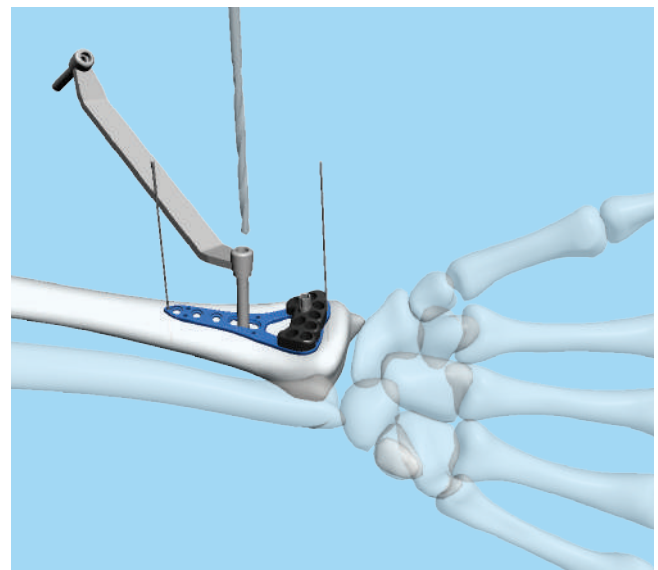
Plate Placement and Temporary Fixation

The fracture is reduced and Once the appropriate plate is selected, attach the corresponding the Drill Block. The plate's position is then fixed proximally with K-wire and distally with a K-wire.

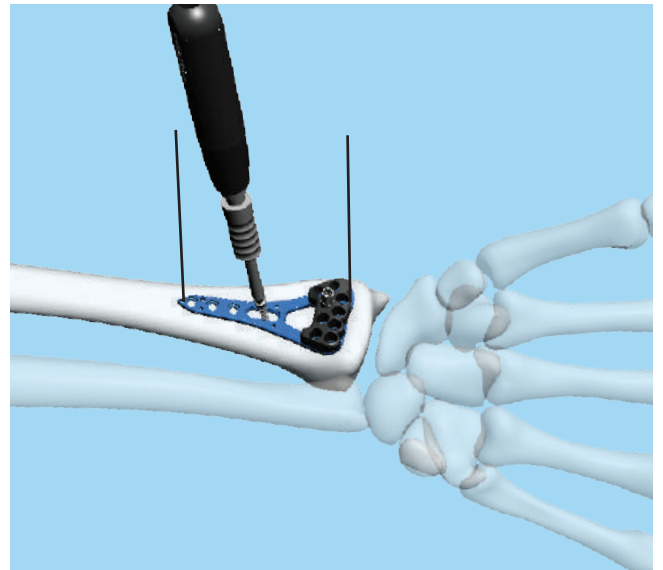
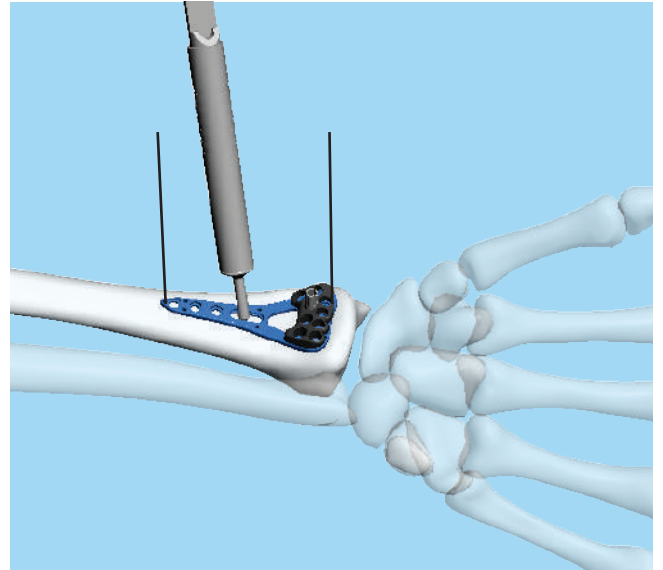


Proximal Placement

Place the first 2.5mm Cortical Screw (for Distal radius Locking Plate- Intra-Articular) screw through the slot in the plate. The position of the plate relative to the articular surface can then be adjusted by sliding the plate proximal or distal under fluroscopy. Attach the Double sleeve in the conventional hole of Plate. Using $\Phi 2.0\text{mm}$ Drill Bit, drill through the far cortex.

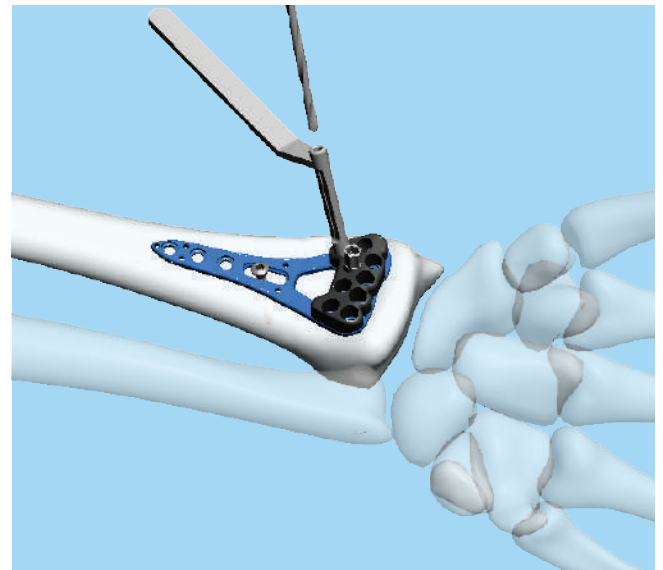


Drill depth is measured with Depth Gauge.
Select and insert the appropriate length 2.5mm cortical screw.



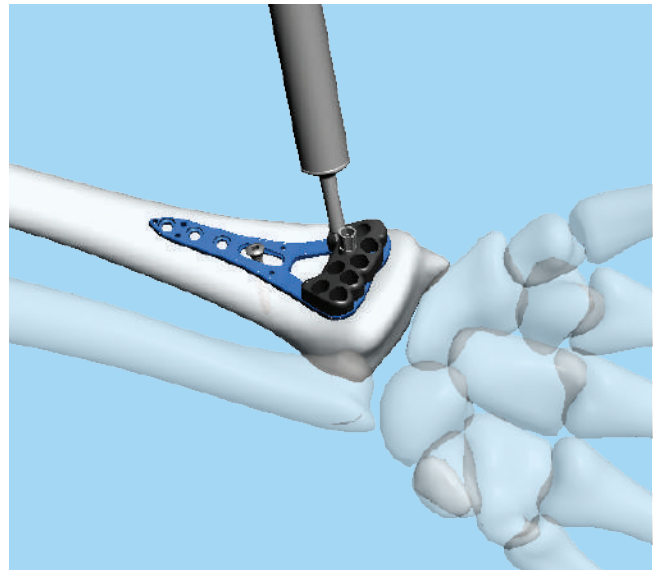
Locking Screw in distal part of Plate

A K-wire maybe placed through the distal holes on the Drill block and plate. The fracture reduction, plate position, and the location of the K-wire relative to the joint is assessed under fluoroscopy. If the distal K-wires do not penetrate the joint, the distal 2.5mm Locking screws will not either. Care should be taken not to angle the distal K-wires.



7 Surgical Technique

Target one of the distal holes first. Insert the Drill Sleeve Single Handle into one of the holes, followed by the 2.0mm drill. Screw length is measured by using the depth gauge.



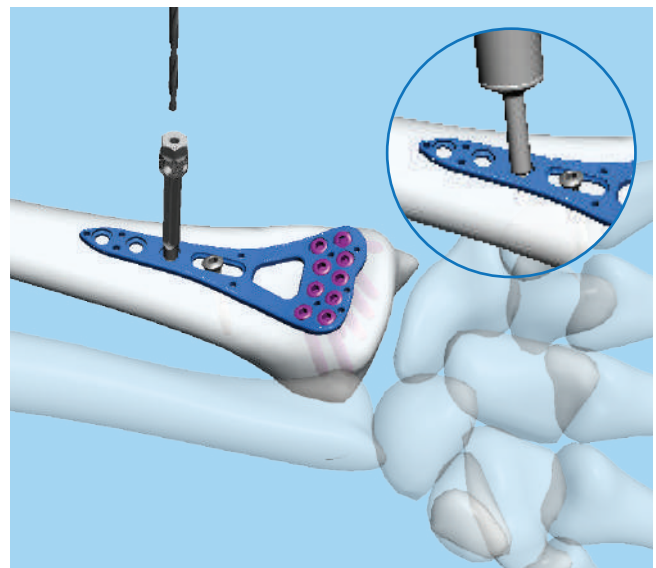
There are two type of 2.5mm Locking screw that can be in any of distal holes of the plate. 2.5mm Locking screw or 2.5mm Locking screw, blunt tip. All 2.5mm Locking screw are inserted using 1.5mm Hexagonal Driver shaft and Torque limiting Handle 0.6Nm.

* It is useful to use blunt tip screws at the distal.



Locking Screw Placement in Proximal part of the Plate

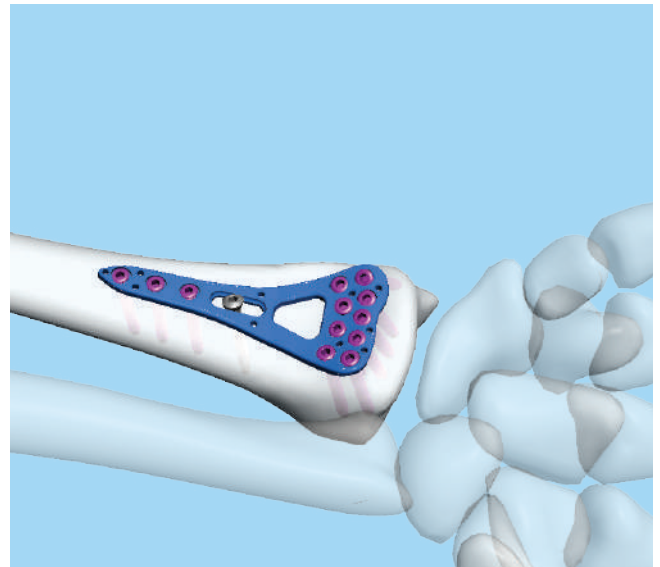
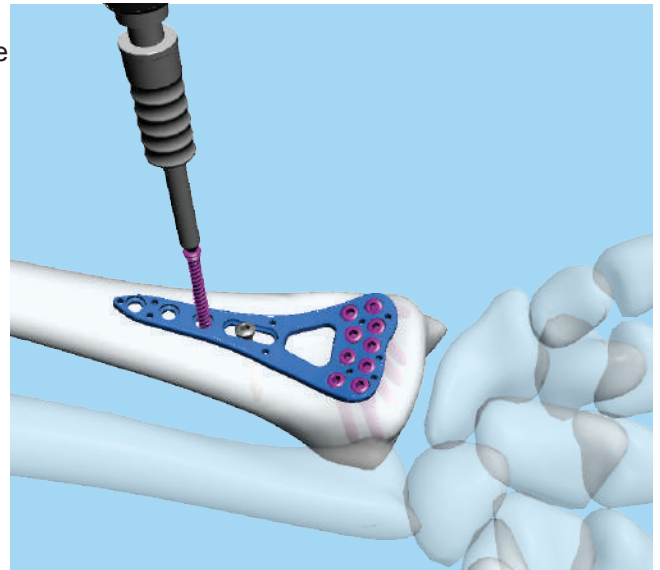
Select one of the remaining proximal holes and insert the 2.0mm Locking Drill sleeve and Drill Sleeve Single Handle. Drill with the 2.0mm drill and measure with the depth gauge.



Insert the proper length 2.5mm locking screw using the 1.5mm Hexagonal Driver shaft and Torque limiting Handle 0.6Nm, taking care that the screw does not exit the bone dorsally. Using the same process, drill and place the final locking screw.

*** caution**

Structurally, If excessive force is applied to the screw when using the 1.5mm Hexagonal Driver, damage may occur. In case of damage, remove the fragment immediately and replace it with a normal product.



Closure and Post-op Protocol

Following thorough radiographic evaluation, check alignment and rotation, then close. Start immediate finger range of motion and forearm rotation post-op. Allow early functional use of the hand for light ADLs. Support the wrist according to bone quality and stability.

DULP(Distal Ulna Locking Plate) System

Plate Placement

The proper size of plate will be selected from in the system. And if the plate positioning is selected, place the plate on the bone or in order to have stable placement of plate.

From the baseline, you can insert the Locking Screw on distal side. Use Locking Drill Sleeve and 2.0 Drill Bit when drilling.

You can use the Depth Gauge to measure for appropriate screw length.

Checking Reduction and Fixation

An intraoperative radiograph is recommended to check the position of the screws and the final reduction of the fracture.



PRLP(Proximal Radius Locking Plate) System

Plate Placement

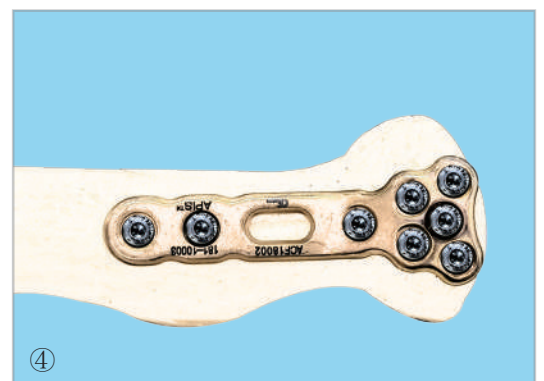
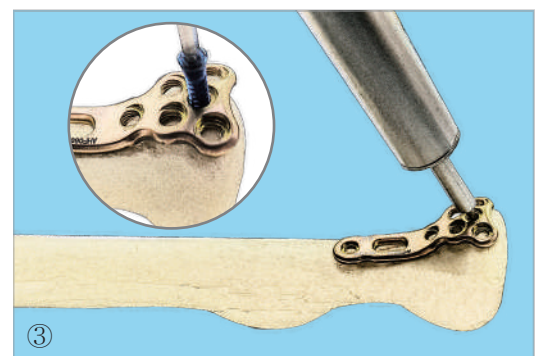
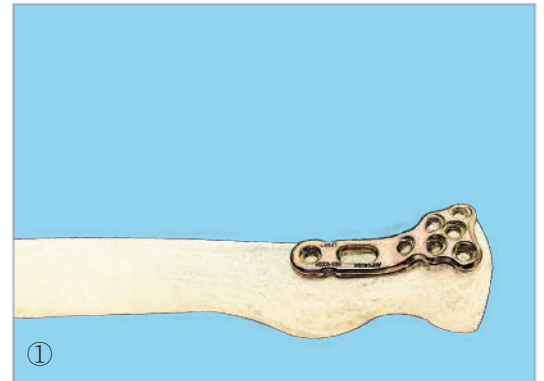
The proper size of plate will be selected from in the system. And if the plate positioning is selected, place the plate on the bone or in order to have stable placement of plate.

From the baseline, you can insert the Locking Screw on distal side. Use Locking Drill Sleeve and 2.0 Drill Bit when drilling.

You can use the Depth Gauge to measure for appropriate screw length.

Checking Reduction and Fixation

An intraoperative radiograph is recommended to check the position of the screws and the final reduction of the fracture.



11 Ordering Information

Implants (* Option)

DRLP, Intra Articular

Cat No.	Size
137-14102	Rt / 2H
137-14103	Rt / 3H
137-14104	Rt / 4H
* 137-14105	Rt / 5H
* 137-14106	Rt / 6H
* 137-14108	Rt / 8H
* 137-14110	Rt / 10H
137-14202	Lt / 2H
137-14203	Lt / 3H
137-14204	Lt / 4H
* 137-14205	Lt / 5H
* 137-14206	Lt / 6H
* 137-14208	Lt / 8H
* 137-14210	Lt / 10H



DRLP, Intra Articular, Small

Cat No.	Size
137-14302	Rt / 2H
137-14303	Rt / 3H
137-14304	Rt / 4H
* 137-14305	Rt / 5H
* 137-14306	Rt / 6H
* 137-14308	Rt / 8H
* 137-14310	Rt / 10H
137-14402	Lt / 2H
137-14403	Lt / 3H
137-14404	Lt / 4H
* 137-14405	Lt / 5H
* 137-14406	Lt / 6H
* 137-14408	Lt / 8H
* 137-14410	Lt / 10H



PRLP

Cat No.	Size
190-11002	2H
190-11003	3H
190-11004	4H
190-11005	5H



PRLP, Buttress

Cat No.	Size
190-10002	2H
190-10003	3H
190-10004	4H
190-10005	5H



DULP, Volar

Cat No.	Size
193-12003	Rt / 3H
193-12004	Rt / 4H
193-12005	Rt / 5H
193-11003	Lt / 3H
193-11004	Lt / 4H
193-11005	Lt / 5H



DULP, Hook

Cat No.	Size
193-10102	2H
193-10103	3H
193-10104	4H
193-10105	5H
193-10106	6H



2.5mm Locking Screw, Small Head

Cat No.	Size
225-24110	10mm
225-24112	12mm
225-24114	14mm
225-24116	16mm
225-24118	18mm
225-24120	20mm
225-24122	22mm
225-24124	24mm
225-24126	26mm
225-24128	28mm
225-24130	30mm



2.5mm Locking Screw, Blunt Tip

Cat No.	Size
225-25110	10mm
225-25112	12mm
225-25114	14mm
225-25116	16mm
225-25118	18mm
225-25120	20mm
225-25122	22mm
225-25124	24mm
225-25126	26mm
225-25128	28mm
225-25130	30mm



2.5mm Cortical Screw, Low Profile Head

Cat No.	Size
225-21010	10mm
225-21012	12mm
225-21014	14mm
225-21016	16mm
225-21018	18mm
225-21020	20mm
225-21022	22mm
225-21024	24mm














2.5mm Cannulated Locking Screw

Cat No.	Size
725-25010	10mm
725-25012	12mm
725-25014	14mm
725-25016	16mm
725-25018	18mm
725-25020	20mm
725-25022	22mm
725-25024	24mm
725-25026	26mm
725-25028	28mm
725-25030	30mm



13 Ordering Information

Instruments (* Option)

901-01020	Drill Bit	Φ 2.0x85 mm		
* 901-31120	Drill Bit, AO Chuck	Ø2.0x130mm		
901-12020	Locking Drill Sleeve	Φ 2.0 mm		
901-13020	Locking Drill Sleeve, Single Handle	Φ 2.0 mm		
901-04020	Depth Gauge	1.5/2.0mm		
901-05415	Screw Driver, Holding	Hex 1.5 mm		
901-15415	Screw Driver Shaft, Holding	Hex 1.5mm/Small Chuck		
901-10160L	Drilling Block, DRLP, Small		Left	
901-10160R	Drilling Block, DRLP, Small		Right	
901-10260L	Drilling Block, DRLP, Intra Articular, Small		Left	
901-10260R	Drilling Block, DRLP, Intra Articular, Small		Right	
901-13007	Torque Limit Handle	0.6 Nm/Small Chuck		
901-08001	Holding Forcep	All Size		
* 901-14020	Pre-Load Drill Guide	Φ 2.0 mm		

Container for DRLP / DULP / PRLP

■ GENERAL INFORMATION :

The TDM Plates and Screw system consists of a family of flat and contoured plates and screws that make up the Mini and Mid Locking Plate and Screw System and the Small Locking Plate and Screw System. The Plates are constructed from Titanium alloy (Ti-6AL-4V) or pure Titanium (Ti) and come in a variety of configurations. The Plates are intended to be used with solid locking and non-locking screws and non-locking low profile screws. The screws are constructed from titanium alloy (Ti-6AL-4V) and are available as threaded locking screws, cortical or cancellous from 1.5mm to 4.0mm in diameter and range from 6mm to 70mm in length. Implant material specification: Titanium alloy (Ti-6AL-4V) or Pure Titanium (Ti)

■ WARNINGS AND PRECAUTIONS :

The TDM implant is a single use device and must never be reused. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user. Only a trained physician with knowledge of orthopedic procedures should use this device. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The patient must be aware of temporary limitations of physical activity and danger of complications after procedure. In case of products that need bending during procedure, do not bend forcedly, try to keep the bending at a minimal level, and do not straighten the bent product since the product could be damaged. All metallic implant devices used for this surgical procedure should have the same metallurgical composition. Post-operatively, the patient must be warned that failure to follow doctor's instructions may cause the following: delay in bone union caused by overweight, reoperation due to bone union failure or graft damage, etc. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture is healed, particularly in young, active patients. The surgeon must make the final decision on implant removal if either of these occurs. Devices that have been implanted for a long period of time may require the use of screw removal instrumentation. Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur.

- (1) Corrosion and possible increased risk of infection
- (2) Migration of implant position resulting in injury
- (3) Risk of additional injury from postoperative trauma
- (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult
- (5) Pain, discomfort, or abnormal sensations due to the presence of the device
- (6) Bone loss due to stress shielding

The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management. It is the responsibility of the physician to rely on his professional education, training and judgment to choose the most appropriate device and treatment option.

This device is provided non-sterile and must be sterilized prior to use following the recommendations provided in the Instructions for use.

Inspect device for any noticeable physical deformations, cracks, pinholes, foreign substances, prior to use. Use the appropriately sized drill bit for the screw. Screws should be inserted by hand and not with powered equipment.

■ INDICATIONS :

Mini Mid Locking Plate and Screw System: The Mini and Mid Locking Plate and Screw System is intended to be used in the hands, wrist, and small bones in the foot.

Small Locking Plate and Screw System: The small locking plate and screw system is indicated for the clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, fibula and other small bones.

The TDM Screws (1.5mm and larger, solid) are intended to be used with the plate for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula.

■ CONTRAINDICATIONS:

Do not use for surgeries other than those indicated. In case of material sensitivity, documented or suspected, appropriate tests should be performed for material suitability prior to implantation. Severe osteoporosis, compromised bone stock, insufficient or immature bone may not be suitable for use of this device. Any active or suspected latent infection, sepsis or marked local inflammation in or around the surgical area. Physical interference with other implants during implantation or use. Compromised vascularity, inadequate skin or neurovascular status. Patients who are unwilling or incapable of following post-operative care instructions.

■ ADVERSE EFFECTS

The potential complications associated with the use of the TDM Plate and Screw system may include

Infections, both deep and superficial

Pain or discomfort

Foreign body reactions

Loosening, bending, cracking or fracture of implant components

Loss of anatomic position with nonunion or malunion may occur

Delayed correction in alignment

Bone resorption or over-production



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