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DRPx

OIC Locking Distal Radius and Dorsal Spanning Surgical Technique Guide

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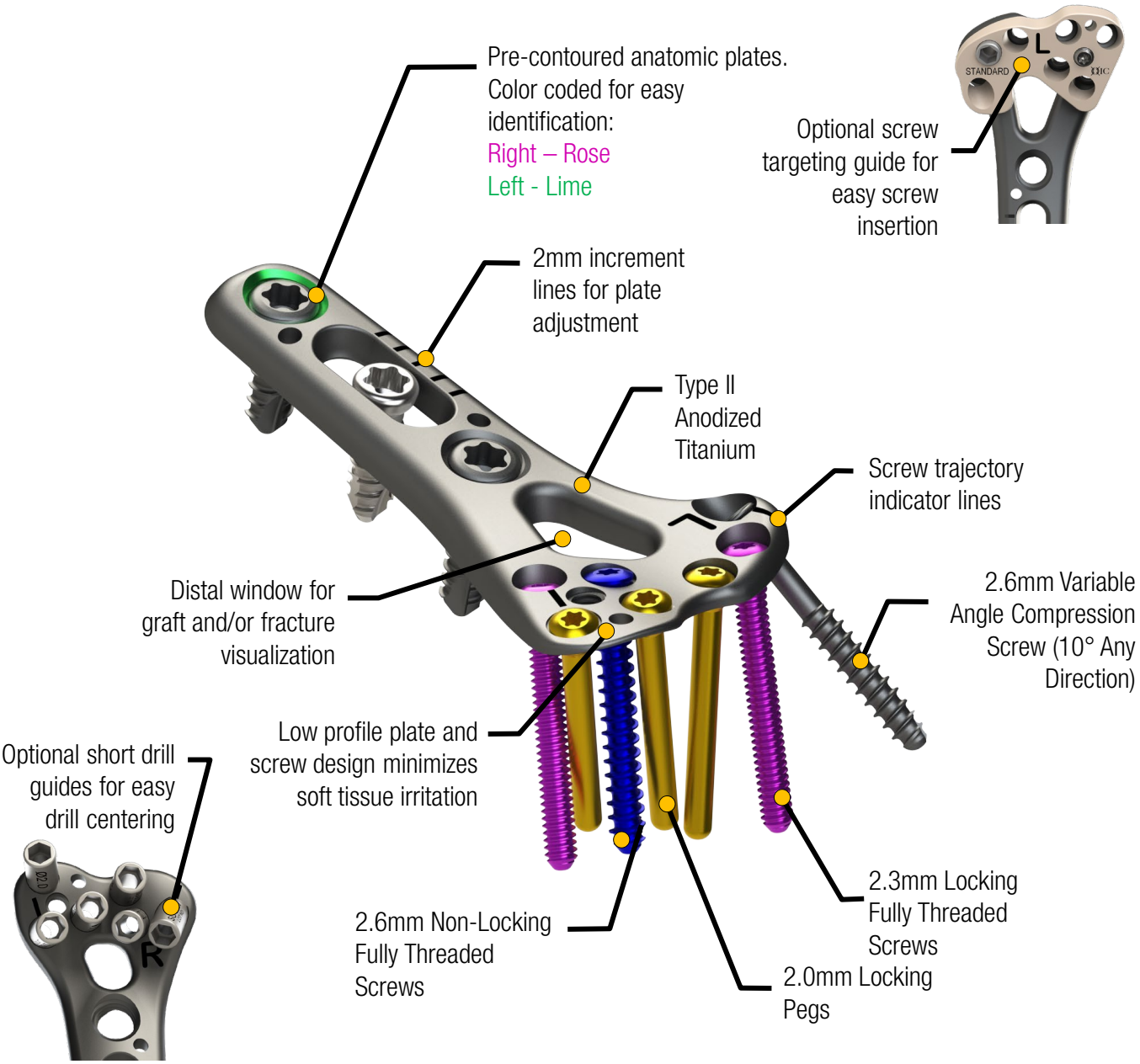
The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the specific needs of the patient.

System Features

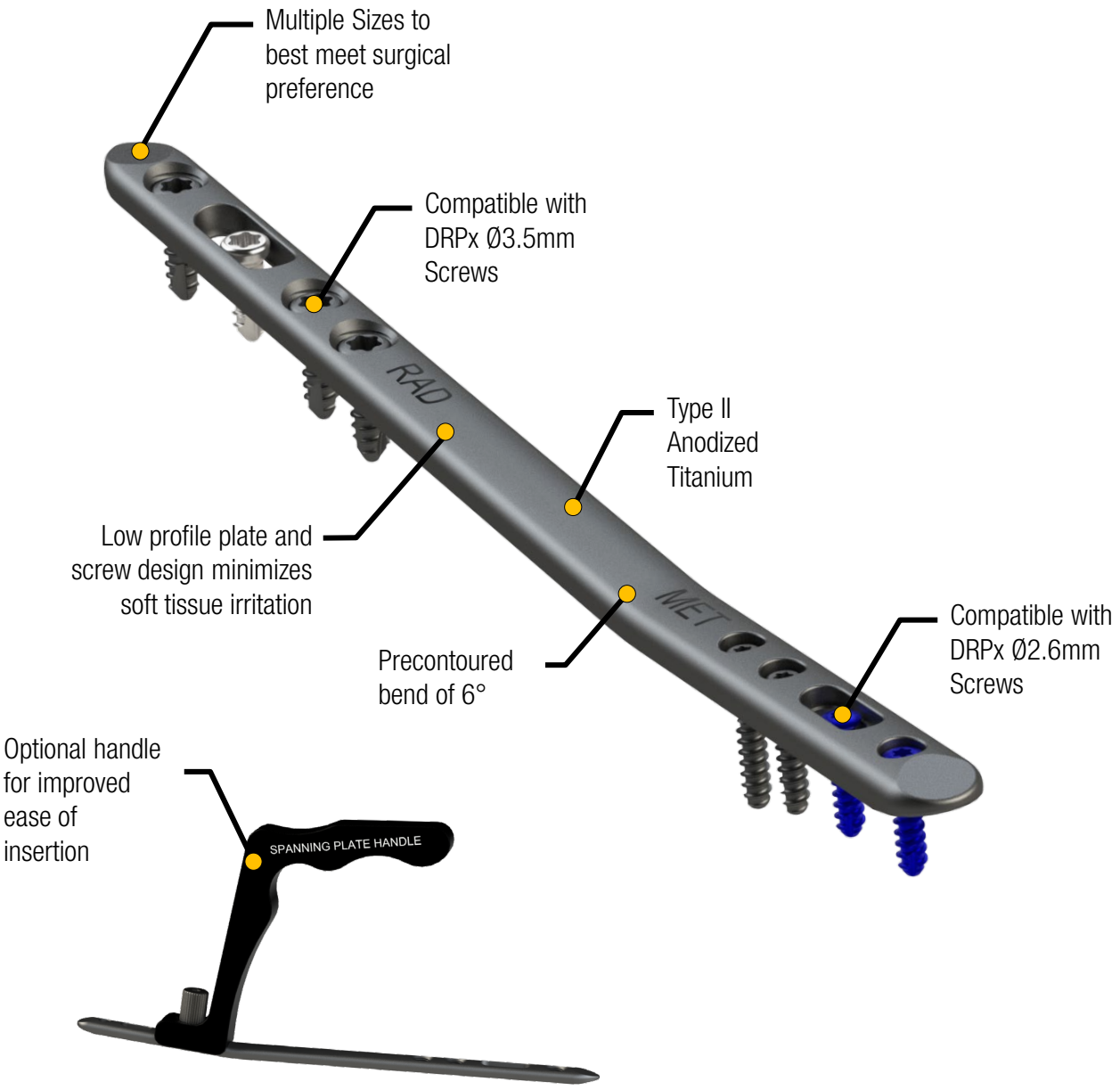
DISTAL RADIUS DRPx

The OIC DRPx Distal Radius Plating System has been developed to incorporate current state-of-art distal radius plating concepts with traditional bone plating concepts to address all distal radius fracture patterns. The DRPx system provides fixation for all fracture types and patterns. Screw options include locking peg fixation, non-locking screw fixation, and locking fixed and variable angle, compression screw fixation.



DORSAL SPANNING PLATE

The OIC Dorsal Spanning Plate completes OIC's distal radius plating system, DRPx, providing surgeons with an internal temporary spanning solution for highly comminuted fractures. Ø3.5mm Screws and Ø2.6mm Screws are compatible with the Dorsal Planning Plate and shorter screw sizes are offered.



Indications and Warnings

INDICATIONS FOR USE

The DRPx Locking Distal Radius Plate System is indicated for the fixation of intra- and extra-articular fractures and osteotomies of the distal radius.

CONTRAINDICATIONS

- Sensitivity to implant material
- Active or latent infection
- Osteoporosis
- Insufficient quantity or quality of bone/soft tissue
- Conditions which tend to retard healing such as blood supply limitations, previous infections, etc.
- Insufficient quantity or quality of bone to permit stabilization of the fracture complex and/or fusion of the joints
- Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process
- Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized

WARNINGS AND PRECAUTIONS

For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the method of application, instruments, and the recommended surgical technique for this device. The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening and migration. The patient must be cautioned, preferably in writing, about the use, limitation, and possible adverse effects of this implant including the possibility of the device failing as a result of loose fixation, stress, excessive activity, or weight bearing or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing.

The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail. Osteoporotic patients are also at risk for loss of fixation and construct failure due to the poor quality of their bone.

Once applied, the implant should never be reused. Although it may appear undamaged, previous stresses may have created imperfections that could reduce its service life.

Indications and Warnings

Even with anatomic reduction, lack of fracture gap and appropriate construct creation, initial weight bearing restrictions are indicated. In order to prevent loss of correction and premature plate failure, it is recommended that partial weight bearing be instituted for 6-12 weeks followed by advancement to full weight bearing only when radiographs confirm significant callus and bony healing.

Instruments shall be inspected for wear or damage prior to usage.

Protect implant appliances against scratching and nicking, which may cause stress concentrations leading to failure. In no case should an implant be sharply or reverse bent, notched, gouged, reamed, scratched or cut.

All implant materials for the DRPx Locking Distal Radius Plate System are implant grade Ti6Al4V. This material is not ferromagnetic, susceptible to aging, nor will steam sterilization have an effect on the materials properties. The instruments are made from stainless steel, aluminum, PEEK and phenolic plastic. The system is to be used only in skeletally mature adult patients.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The OIC DRPx Locking Distal Radius Plate has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of OIC DRPx Locking Distal Radius Plate in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

ADVERSE EFFECTS

Fracture of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material. Pain, discomfort, or abnormal sensations due to the presence of an implant. Nerve damage resulting from surgical trauma. Necrosis of bone or bone resorption. Necrosis of tissue or inadequate healing.

SURGICAL TECHNIQUE

Distal Radius DRPx

1 Exposure

A longitudinal incision is made just radial to the flexor carpi radialis (FCR) tendon. Retract tendon ulnarly and incise fascia in the floor to expose pronator while protecting radial neurovascular bundle. Detach pronator quadratus in L-shaped fashion and retract towards ulna. Leave the volar wrist capsule intact. Detach brachioradialis if needed for additional exposure.

2 Fracture Reduction

Fractures should be reduced utilizing standard reduction techniques. Care should be taken to avoid additional stripping of the periosteum. K-wires can be utilized for temporary fixation of comminuted fragments. In some cases, K-wires can also be placed through holes provided in the plate for provisional plate fixation **FIG 1**.

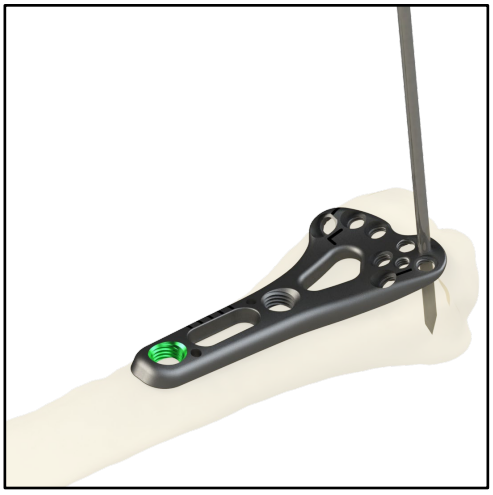


Figure 1

3 Plate Insertion

The plate is made to sit along the distal aspect of the radius to support articular fracture fragments. Select appropriate plate dependent on fracture pattern and patient anatomy. Right plates are marked with a “R” and have the most proximal shaft hole Rose colored while the Left plates are marked with a “L” and have the most proximal shaft hole Lime Green colored. Plate length should be determined based on fracture pattern. Many anatomic variants exist so plate contour may need to be adjusted. This can be accomplished utilizing bending irons, a plate bending press, or pliers, according to standard techniques. The plate should be inserted on reduced bone when able. In some cases, the plate will need to be utilized as a reduction tool if fracture instability or comminution does not allow for prior reduction. Hold plate in position with reduction forceps or K-wires as needed. Ensure proper contour prior to screw insertion. Variable angle screws allow for very distal plate position.

4 Initial Proximal Screw Placement

Typically, the first screw to be placed is a 3.5mm non-locking cortical screw (ST-35##) through the slot in the plate. Using the Ø2.8mm Drill Bit (DR28-095C) and the Ø2.8mm Hand-Held Drill Guide (DG-2828), drill to the far cortex **FIG 2.**

Drill depth and screw size can be measured by either reading the calibration marks on the drill bit off the top of the drill guide or by using the DRPx depth gauge (01-SF25) after the drill guide has been removed **FIG 3.**

Insert the appropriate length 3.5mm non-locking screw using the T15 driver (01-T15110). The screw may need to be downsized after the plate has been reduced **FIG 4.**

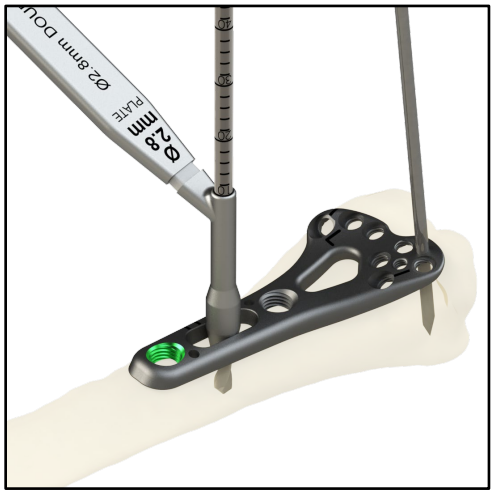


Figure 2

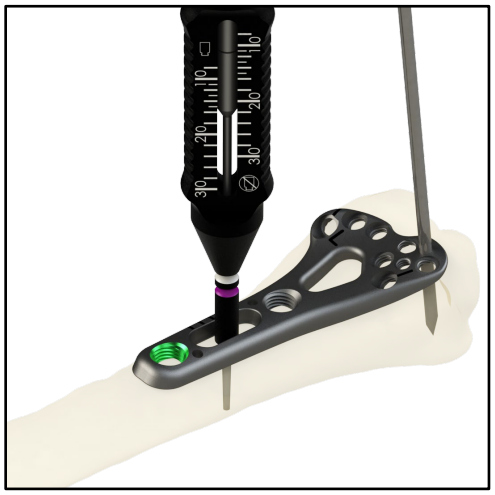


Figure 3

Figure 4

5 Distal Screw Placement

There are multiple methods to place the distal screws/pegs. The first three methods described below will place the screws at a trajectory that is determined by the direction of the respective plate hole, we call this *"fixed"* placement. The last method will provide for variable angle screw placement. This choice is left to the operating surgeon and is dependent on fracture pattern, patient anatomy, plate contour and surgeon preference.

A- *"Fixed" Screw Placement w/ Distal Targeting Guide*: Any distal end screw/peg can be placed through the corresponding targeting guide (left/right and narrow/standard). Attach the correct guide to the plate with the T6 driver (01-T06090) **FIG 5**.

Figure 5

Before final tightening of built-in targeting guide screw, thread a preferred drill guide (01-SF24, LG-0020, SG-0020) through any targeting hole, then tighten the targeting guide screw **FIG 6**. Note: K-wire guide and short drill guide may be inserted using the 2.5mm hex on the T6 driver (01-T06090).

Figure 6(a):
Ø1.6mm K-Wire Guide (01-SF24)

Figure 6(b):
Ø2.0mm Thread-In Drill Guide (LG-0020)

Figure 6(c):
Ø2.0mm Short Drill Guide (SG-0020)

A - *"Fixed" Screw Placement w/ Distal Targeting Guide*: The preferred drill guide (LG-0020, SG-0020, DG-2020) and corresponding Ø2.0mm drill bit (DR20-095C) can then be utilized to prepare the bone for the subsequent screw or peg **FIG 7**. The preferred drill guide must be removed prior to screw/peg fixation through that hole.

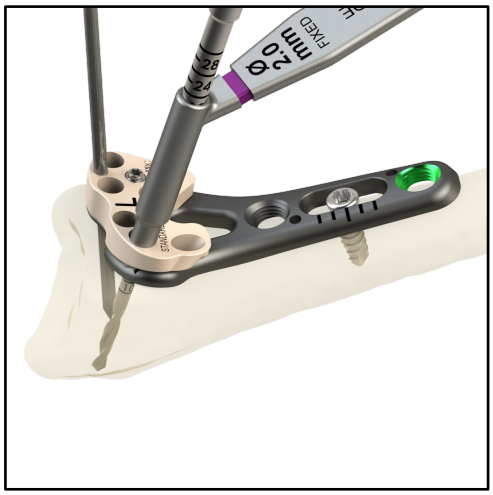


Figure 7

Drill depth and corresponding screw size are then measured by either reading the calibration marks on the drill bit or by using the DRPx depth gauge (01-SF25) through the targeting guide after the preferred drill guide has been removed **FIG 8**.

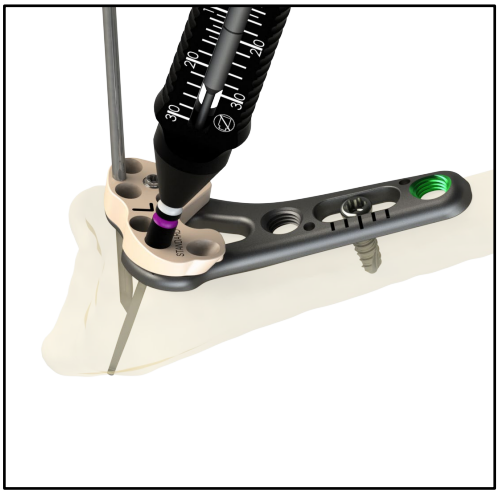


Figure 8

Once screw length is determined, insert the appropriate distal end screw/peg through the targeting guide using the T6 driver (01-T06090) **FIG 9** Repeat this step for each plate hole receiving a screw/peg. Remove the targeting guide once all screws have been inserted.

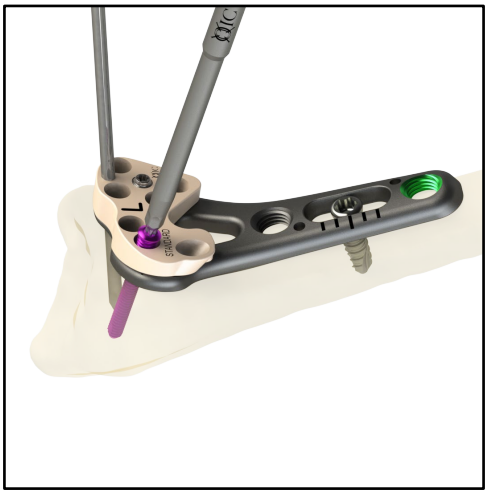
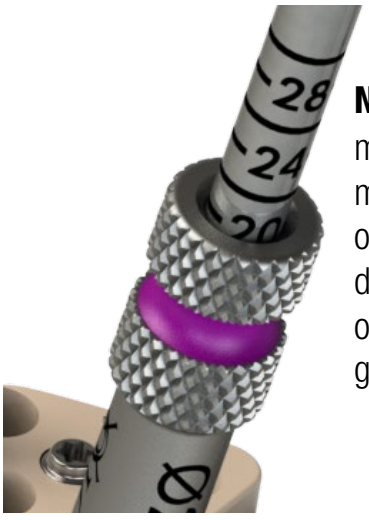


Figure 9



Note: Calibration marks may be measured off the tops of both the hand-held drill guide (DG-2020) or the thread-in drill guide (LG-0020).

B - *"Fixed" Screw Placement w/ Short Drill Guides*: On the back-table, thread short drill guides (SG-0020) in all the distal end plate holes with the use of the T6 driver (01-T06090) and the small quick connect handle (01-4006).

The Ø2.0mm drill bit (DR20-095C) can then be utilized through the short guides to prepare the bone for the subsequent screw/peg **FIG 10**. The drill depth and corresponding screw size can be measured by using the DRPx depth gauge (01-SF25) and the appropriate scale **FIG 11**. Either measure off the short guide or off the top of the plate with the short guide removed and use appropriate scale.

The short drill guides will need to be removed with the T6 driver (01-T06090) prior to screw/peg fixation. Insert the appropriate length distal end screw/peg using the T6 driver **FIG 12**.

Note: Calibration marks may be measured off the top of short drill guides (SG-0020).

Figure 10

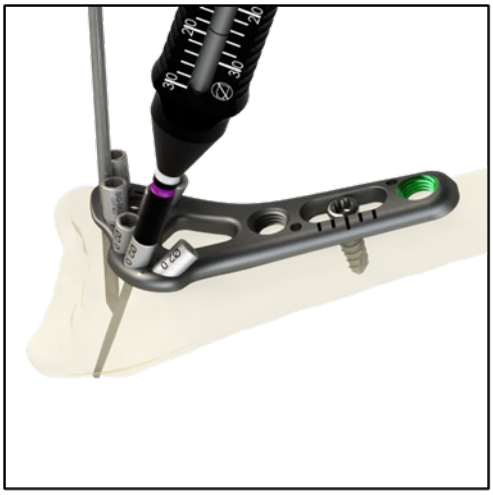


Figure 11

Figure 12

C - *"Fixed" Screw Placement w/ Thread-in Locking Guide*: Thread the Ø2.0mm thread-in drill guide (LG-0020) in by hand. The Ø2.0mm drill bit (DR20-095C) can then be utilized to prepare the bone for the subsequent screw/peg **FIG 13**.

Drill depth and corresponding screw size can be measured by either reading the calibration marks on the drill bit off the top of the thread-in drill guide or with the DRPx depth gauge (01-SF25) after the Locking Guide has been removed **FIG 14**.

With the thread-in drill guide removed, insert the appropriate length distal end screw/peg using the T6 driver (01-T06090). Repeat this step for each plate hole receiving a screw/peg **FIG 15**.

Note: The DRPx depth gauge (01-SF25) has two scales. The top measures off short guides (SG-0020), the bottom measures off the plate.

Figure 13

Figure 14

Figure 15

D – *Variable Angle Placement w/ Variable Angle Hand-Held Drill Guide*: The "VA" marked end of the Ø2.0mm hand-held drill guide (DG-2020) and corresponding Ø2.0mm drill bit (DR20-095C) are utilized to prepare the bone for the subsequent screw/peg **FIG 16**. The "VA" end of the hand-held drill guide will allow for up to 10° of angulation in any direction relative to the central axis of respective plate hole.

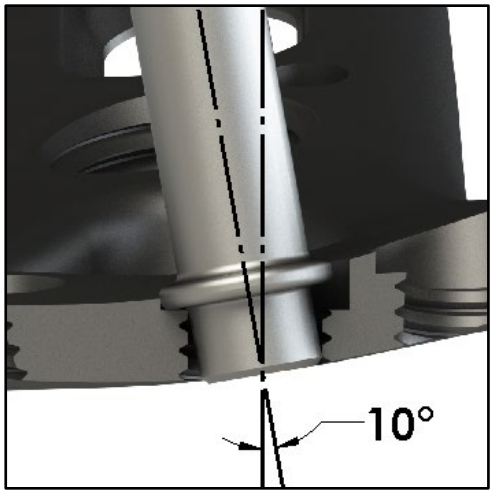


Figure 16

Drill depth and corresponding screw size can be measured by either reading the calibration marks on the drill bit off the top of the drill guide or with the DRPx depth gauge (01-SF25) after the drill guide has been removed **FIG 17**.

Figure 17

Insert, the appropriate length variable angle compression screw (VLX-26##) using the T6 driver (01-T06090) until the screw has locked with the plate **FIG 18**. Repeat this step for each plate hole receiving a variable angle compression screw. Utilize any of the previous methods to fill the remaining distal end holes with "fixed" or "VA" screws/pegs.

Caution: Due to the thin plate profile, avoid using the VLX variable angle screw in the most distal ulnar holes.

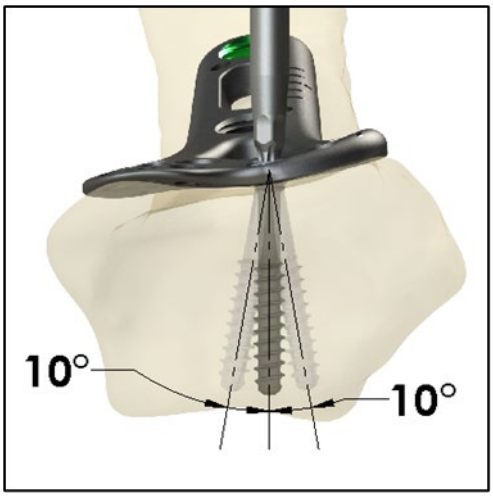


Figure 18

6 Final Proximal Screw(s) Placement

3.5 mm locking or 3.5mm non-locking screws can be used in the shaft holes. To place screws at a *fixed angle (identical trajectory to plate hole)*, attach the Ø2.8mm thread-in drill guide (LG-0028) to the T15 driver (01-T15110) and thread into the plate **FIG 19**. Alternatively, the "*fixed*" side of the hand-held drill guide (DG-2828) can be used. Drill using the Ø2.8mm drill bit (DR28-095C).

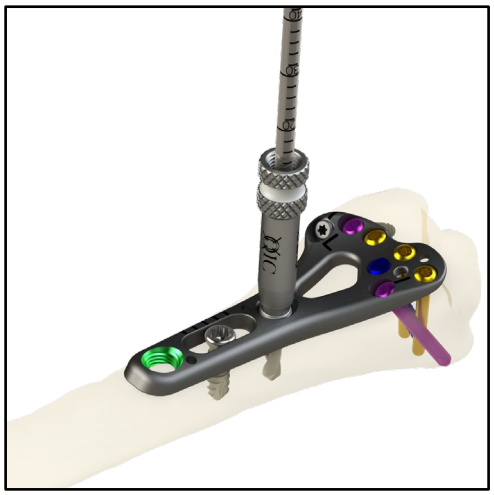


Figure 19

Drill depth and screw size can be measured by reading the calibration marks on the drill bit off the top of the drill guide or with the DRPx depth gauge (01-SF25) after the drill guide has been removed. Insert the appropriate length 3.5mm locking or non-locking screw using the T15 driver **FIG 20**.

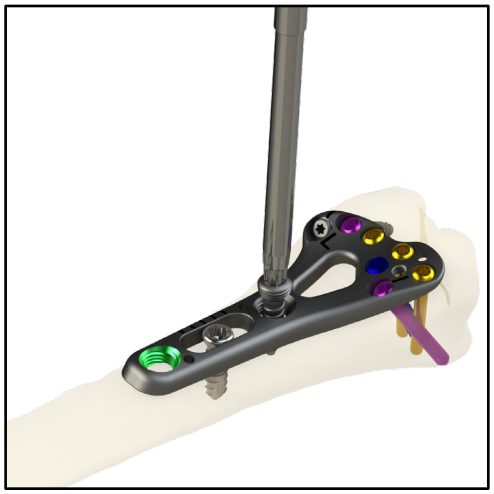


Figure 20

To place non-locking screws at a *variable angle*, place the variable angle side of the hand-held drill guide (DG-2828) at the desired angle. Drill using the Ø2.8mm drill bit (DR28-095C). Drill depth and screw size can be measured by reading the calibration marks on the drill bit off the top of the drill guide or with the depth gauge after the drill guide has been removed. Insert the appropriate length 3.5mm non-locking screw using the T15 driver.

Note: The DRPx depth gauge measures accurately for both proximal shaft screws (from bottom of plate) and distal pegs/screws (from top of plate). Use the bottom scale for both instances.

7 Wound Closure and Post-Op Protocol

Confirm reduction and hardware position prior to closure with fluoroscopic imaging and direct visualization. AP, 20 degree lateral and carpal tunnel views should be utilized to confirm reduction and absence of intra-articular or prominent dorsal hardware. Layered wound closure is recommended. Provide patients with a sling for comfort and initiate immediate range of motion. Weight-bearing is left to surgeon discretion.

8 Optional: Plate Removal

If the plate requires removal, use the appropriate included drivers to remove all non-locking screws from the plate. Locking screws should be the last screws removed to prevent rotation of plate during removal. Remove all distal volar screws before finally removing remaining proximal shaft locking screws. The plate may be freely removed after all screws have been removed.

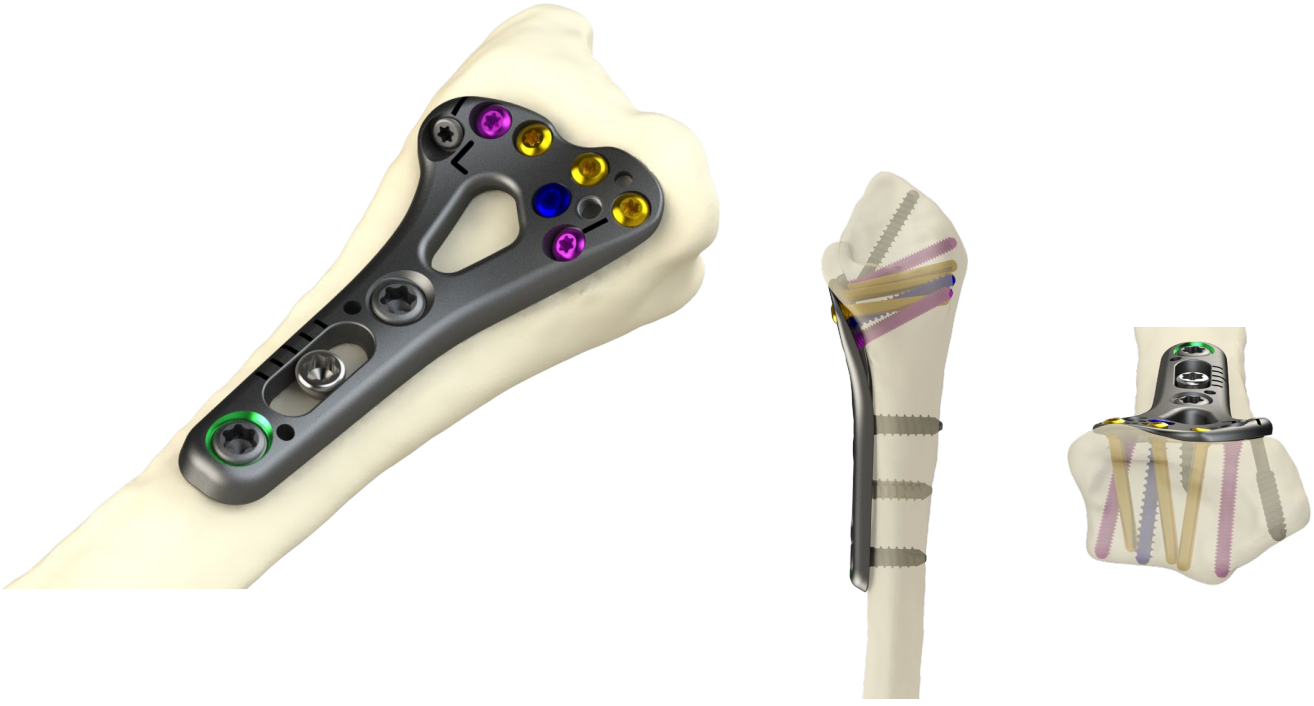
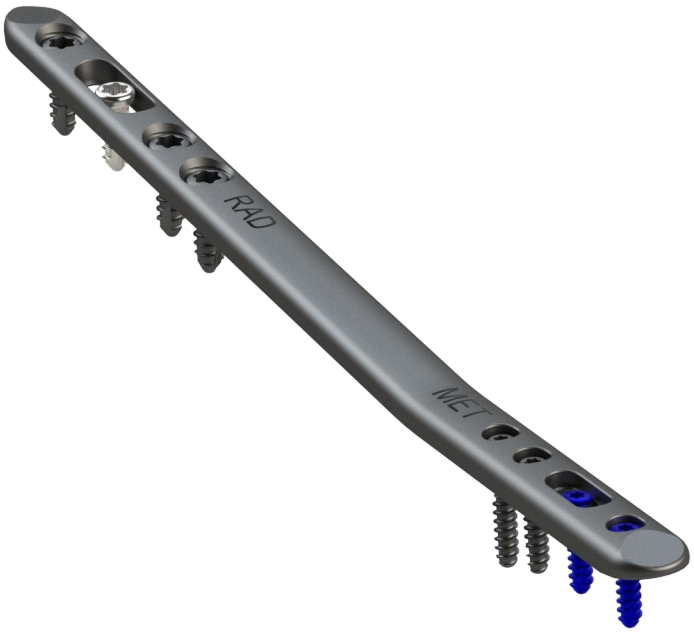


Figure 21: Distal screw trajectories upon completed insertion.

SURGICAL TECHNIQUE

Dorsal Spanning Plate



1 Fracture Reduction

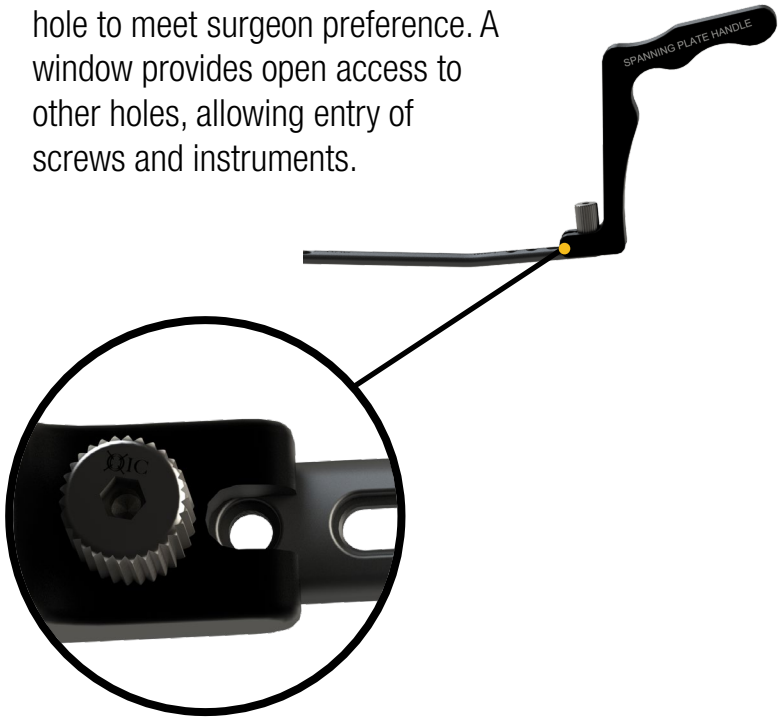
Longitudinal traction is used to assess the benefits of ligamentotaxis for restoration of the articular surface. Finger traps are applied to the index and middle fingers with 10 lbs. of traction off the end of the table. Under fluoroscopy the Agee closed reduction maneuver is performed; a combination of longitudinal traction and palmar translation to restore radial length, inclination and sagittal tilt. This maneuver will reveal the integrity of the volar ulnar corner of the radius. Finally, pronate the hand to correct the supination deformity.

2 Plate Preparation

Once the appropriately sized plate is determined , secure the spanning plate handle (01-SF26) to any threaded hole found on the distal end of the plate. The hex end of the T-6 driver (01-T06090) may be used to securely tighten the handle to plate **FIG 22**.

Figure 22

Note: The Spanning Plate handle may be secured to any distal screw hole to meet surgeon preference. A window provides open access to other holes, allowing entry of screws and instruments.



Caution: When choosing a spanning plate in conjunction with DRPx Plate, *use the longer 210mm plate* to avoid screw collision.

3 Plate Insertion

A 5-7 cm incision is made at the base of the 2nd or 3rd metacarpal and continued along the shaft. The insertions of the extensor carpi radialis longus (ECRL) and the extensor carpi radialis brevis (ECRB) are identified as they pass beneath the distal edge of the second dorsal wrist compartment to insert on the 2nd and 3rd metacarpal bases, respectively.

A second incision is made just proximal to the outcropper muscle bellies of the abductor pollicis longus (APL) and the extensor pollicis brevis (EPB), in line with the ECRL and ECRB tendons. The interval between the ECRL and ECRB is developed, and the diaphysis of the radius is exposed. A third, or periarticular, incision may also be used to assess, reduce and stabilize the articular surface.

Typically, the plate is passed proximally through the metacarpal compartment. Alternatively, the plate can be inserted proximally beneath the muscle bellies of the outcroppers extraperiosteally and advanced distally between the ECRL and ECRB tendons. Note that some resistance will be encountered due to dorsal bend of spanning plate.

The plate is superimposed over the radial diaphysis to the metadiaphysis of the metacarpal, and verified with a C-arm. Mark the skin at the level of the proximal and distal screw holes. The subcutaneous tissues are infiltrated with 0.25% bupivacaine with epinephrine to promote hemostasis. A tourniquet is not routinely used.

4 Initial Screw Placement

After passing the plate, it is then secured to the metacarpal by placing a non-locking 2.6mm cortical screw (STX-26XX) through the most distal hole **FIG 23.** The proximal end of the plate is then identified in the forearm. If the radial length has not been restored, the plate is pushed distally until the length is reestablished.

Figure 23

5 Plate Alignment

With a wrist in neutral rotation, and the plate aligned on the metacarpal and radial shafts, a non-locking 3.5mm screw (ST-35XX) is placed into the distal end of the slotted hole to allow for additional distraction **FIG 24**. Intra-articular reduction may be further adjusted by using limited periarticular incisions to allow: direct manipulation of articular fragments; placement of subchondral bone graft; repair of intercarpal ligament injuries; and augmentation of fractures with K-wires, Buttress Pins, Hook Plates or Pin Plates. Displaced volar ulnar corner fragments that are not reduced with the Bridge Plate alone require buttress support.

Figure 24

Note: All instruments and screws in the DRPx system are used for both the Spanning Plate and the Distal Radius Plate. Purple bands correspond to metacarpal (distal) instrumentation while white bands correspond to radius (proximal) instrumentation.

6 Final Screw Placement

The remaining holes are secured with locking or non-locking screws inserted with bicortical purchase. NOTE: Only Ø2.6mm screws (VLX & STX) should be used in the distal, metacarpal side of the spanning plate.

7 Wound Closure and Post-Op Protocol

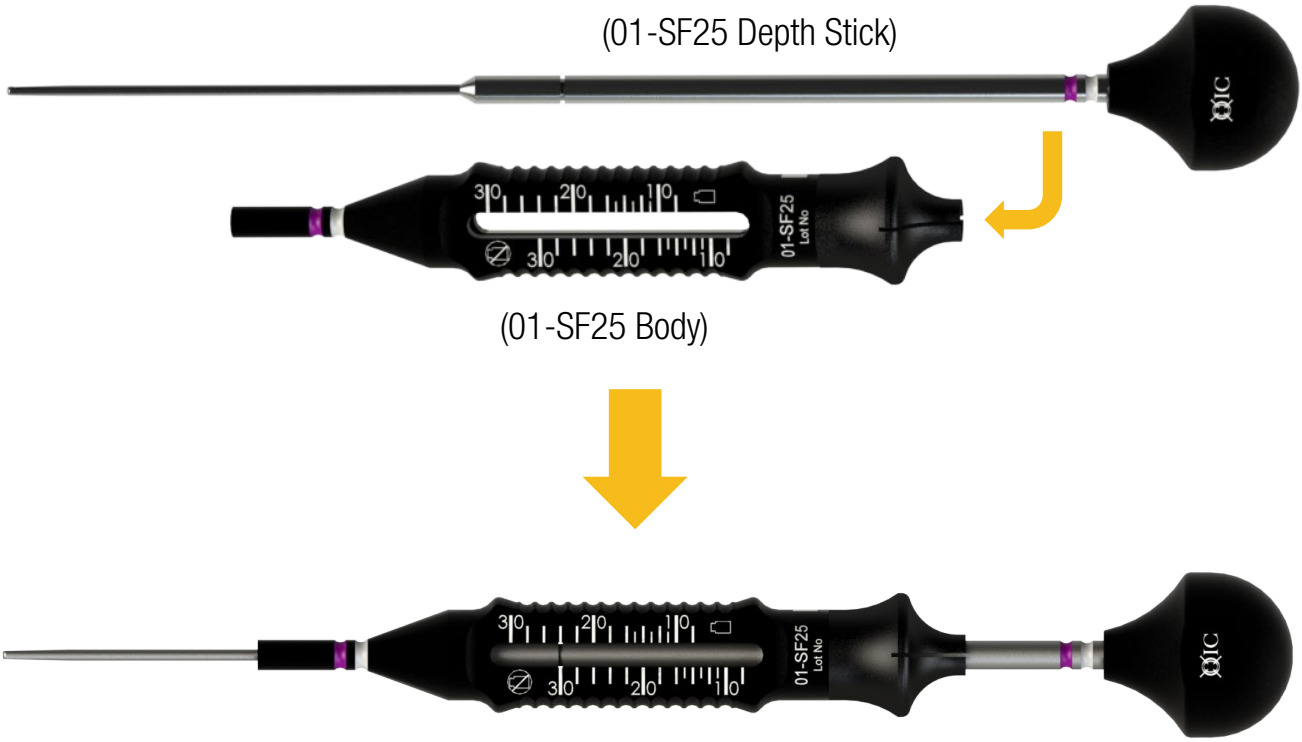
Confirm reduction and hardware position prior to closure with fluoroscopic imaging and direct visualization. Layered wound closure is recommended. The DRUJ is assessed and if stable, then the limb is immobilized in a long arm splint with the forearm in 60° of supination for the first 10-14 days. If unstable, then repair or reconstruction of the DRUJ and triangular fibrocartilage complex is undertaken. In rare instances where the patient's condition does not allow prolonging the operation, manually reduce the ulnar head into the sigmoid notch and pass at least two 1.6mm K-wires through the ulna into the radius proximal to the DRUJ.

Digit range of motion exercises start within 24 hours. Load bearing through the forearm and elbow is allowed immediately, as well as the use of a platform crutch when the patient is physiologically stable. At 1 month postoperatively the platform is removed and weight bearing is allowed through the hand grip of regular crutches. Lifting and carrying is restricted to approximately 10 lbs. until the fracture has healed.

DRUJ stability and forearm motion are assessed at 2 weeks. If the patient can supinate the forearm with little effort and the DRUJ is stable, then splinting is discontinued. Axial loading through the extremity is allowed for transfers and all weight-bearing needs. If supination is difficult or if the DRUJ was reconstructed acutely, then a removable long arm splint is fabricated. If the DRUJ was transfixed with K-wires, then the wires are removed on the third postoperative week and DRUJ stability is reassessed. Supplemental K-wires for articular fixation are removed 6 weeks postoperatively. The plate and screws are removed usually no earlier than 12 weeks after injury.

DRPx Depth Gauge

CAUTION: When inserting and removing the depth stick into the depth gauge body, exercise caution as tip of depth stick is prone to bending.



Implants - Plates

Catalog Information

Narrow DRPx Plates	
Part No.	Description
DRPX-N0345L	Left Narrow 3 Hole
DRPX-N0345R	Right Narrow 3 Hole
DRPX-N0453L	Left Narrow 4 Hole
DRPX-N0453R	Right Narrow 4 Hole

Standard DRPx Plates	
Part No.	Description
DRPX-S0351L	Left Standard 3 Hole
DRPX-S0351R	Right Standard 3 Hole
DRPX-S0459L	Left Standard 4 Hole
DRPX-S0459R	Right Standard 4 Hole

Dorsal Spanning Plates	
Part No.	Description
DSP-08160	160mm Spanning Plate
DSP-08210	210mm Spanning Plate

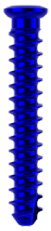
Implants - Screws

Ø2.3mm Locking Screws

Part No.	Description
LSX-2314	2.3mm x 14mm
LSX-2316	2.3mm x 16mm
LSX-2318	2.3mm x 18mm
LSX-2320	2.3mm x 20mm
LSX-2322	2.3mm x 22mm
LSX-2324	2.3mm x 24mm
LSX-2326	2.3mm x 26mm
LSX-2328	2.3mm x 28mm

Ø2.0mm Locking Pegs

Part No.	Description
LPX-2014	2.0mm x 14mm
LPX-2016	2.0mm x 16mm
LPX-2018	2.0mm x 18mm
LPX-2020	2.0mm x 20mm
LPX-2022	2.0mm x 22mm
LPX-2024	2.0mm x 24mm
LPX-2026	2.0mm x 26mm
LPX-2028	2.0mm x 28mm



Ø2.6mm Non-Locking Cortex Screws

Part No.	Description
STX-2608	2.6mm x 08mm*
STX-2610	2.6mm x 10mm*
STX-2612	2.6mm x 12mm*
STX-2614	2.6mm x 14mm
STX-2616	2.6mm x 16mm
STX-2618	2.6mm x 18mm
STX-2620	2.6mm x 20mm
STX-2622	2.6mm x 22mm
STX-2624	2.6mm x 24mm
STX-2626	2.6mm x 26mm
STX-2628	2.6mm x 28mm

Ø2.6mm Variable Angle Locking Screws

Part No.	Description
VLX-2608	2.6mm x 08mm*
VLX-2610	2.6mm x 10mm*
VLX-2612	2.6mm x 12mm*
VLX-2614	2.6mm x 14mm
VLX-2616	2.6mm x 16mm
VLX-2618	2.6mm x 18mm
VLX-2620	2.6mm x 20mm
VLX-2622	2.6mm x 22mm
VLX-2624	2.6mm x 24mm
VLX-2626	2.6mm x 26mm
VLX-2628	2.6mm x 28mm

* Screws are located in the auxiliary Dorsal Spanning Plate caddy

Implants – Screws (Cont.)

Ø3.5mm Locking Screws	
Part No.	Description
LS-3510	3.5mm x 10mm
LS-3512	3.5mm x 12mm
LS-3514	3.5mm x 14mm
LS-3516	3.5mm x 16mm
LS-3518	3.5mm x 18mm

Ø3.5mm Non-Locking Cortex Screws	
Part No.	Description
ST-3510	3.5mm x 10mm
ST-3511	3.5mm x 11mm
ST-3512	3.5mm x 12mm
ST-3513	3.5mm x 13mm
ST-3514	3.5mm x 14mm
ST-3515	3.5mm x 15mm
ST-3516	3.5mm x 16mm
ST-3518	3.5mm x 18mm

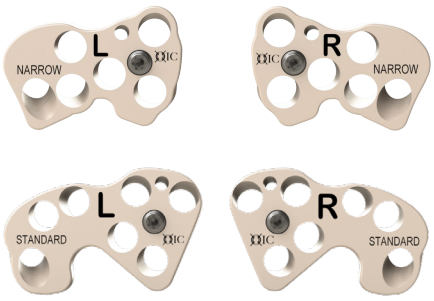
Disposable Instruments

KW160-150 Ø1.6mm K-Wire

DR20-095C Drill Bit, Ø2.0mm x 95mm Calibrated

DR28-095C Drill Bit, Ø2.8mm x 95mm Calibrated

Reusable Instruments



RADIOLUCENT GUIDES	
Part No.	Description
01-DRPX01L	Left Narrow Guide
01-DRPX01R	Right Narrow Guide
01-DRPX02L	Left Standard Guide
01-DRPX02R	Right Standard Guide

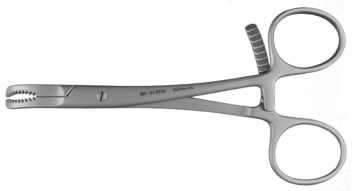
Reusable Instruments (Cont.)

Catalog Information

SG-0020	Ø2.0mm Short Drill Guide	
LG-0020	Ø2.0mm Thread-in Locking Drill Guide	
01-SF24	Ø1.6mm K-wire Thread-in Guide	
LG-0028	Ø2.8mm Thread-in Locking Drill Guide	
01-T06090	T6 Driver, QC T6 x 90mm	
01-T15110	T15 Driver, QC T15 x 110mm	
DG-2020	Ø2.0/Ø2.0mm Hand-Held Drill Guide	
DG-2828	Ø2.8/Ø2.8mm Hand-Held Drill Guide	

Reusable Instruments (Cont.)

Catalog Information

01-SF25	DRPx Depth Gauge	
01-SF03	Lobster Claw Reduction Forceps	
01-SF04	Pointed Reduction Forceps	
01-4006	Small QC Handle	
01-SF26	Dorsal Spanning Plate Handle	

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

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