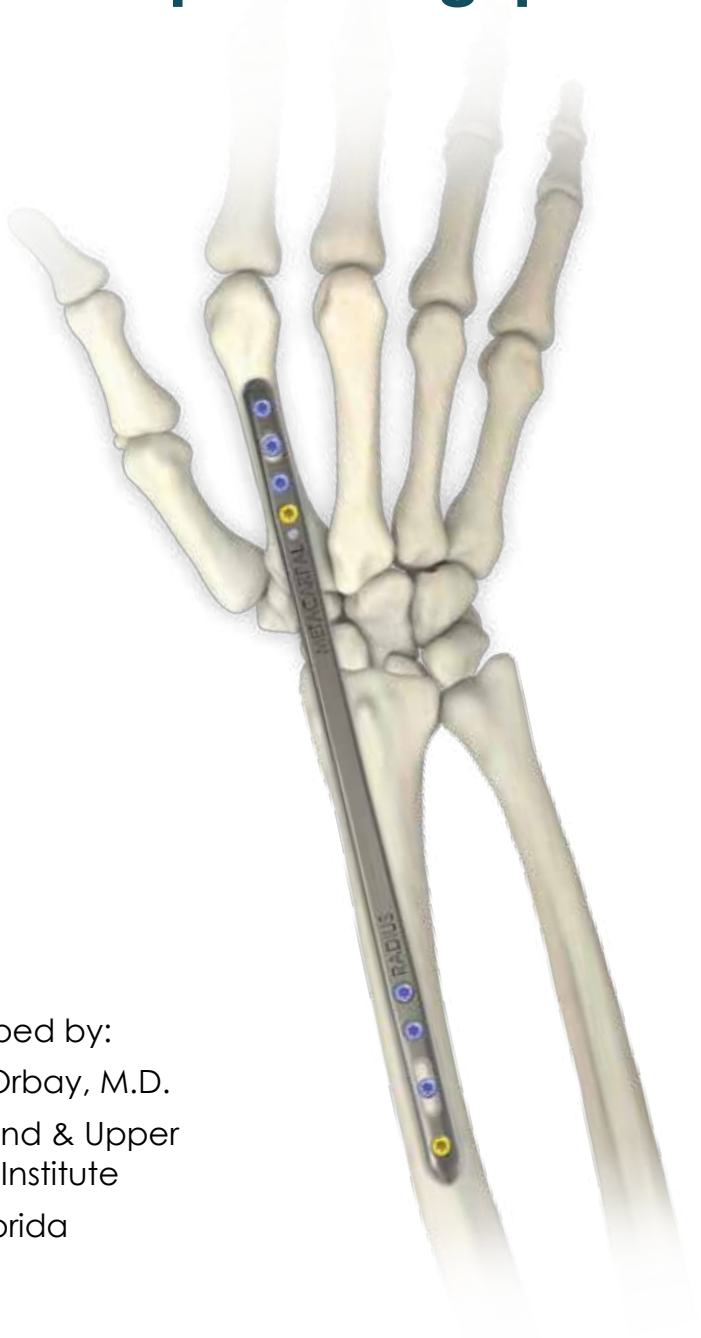
SURGICAL TECHNIQUE GUIDE

GEMINUS®

dorsal spanning plate



As described by:

Jorge L. Orbay, M.D.

Miami Hand & Upper Extremity Institute

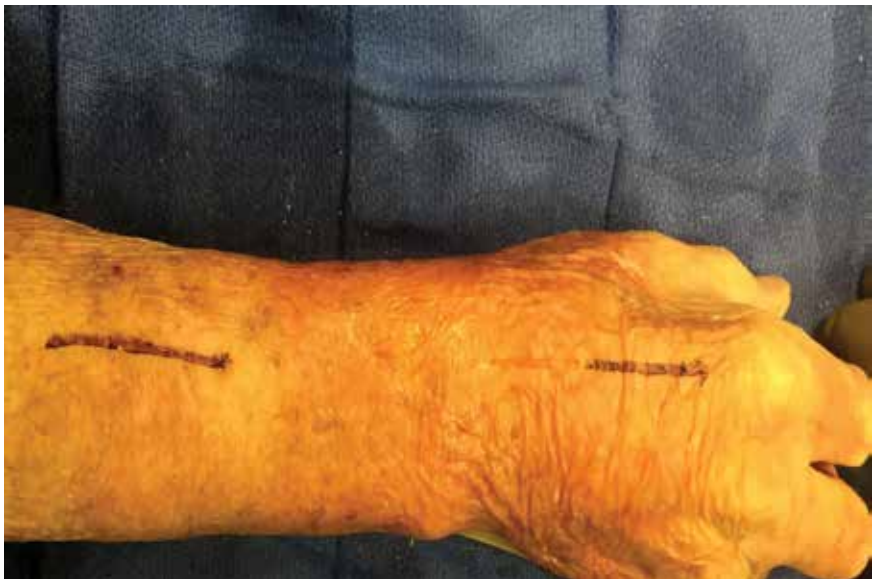
Miami, Florida

Distributed in the UK by

LEDA

1 FRACTURE REDUCTION

Apply traction and reduce the fracture.



2 CONFIRM REDUCTION

Confirm fracture reduction using fluoroscopy.

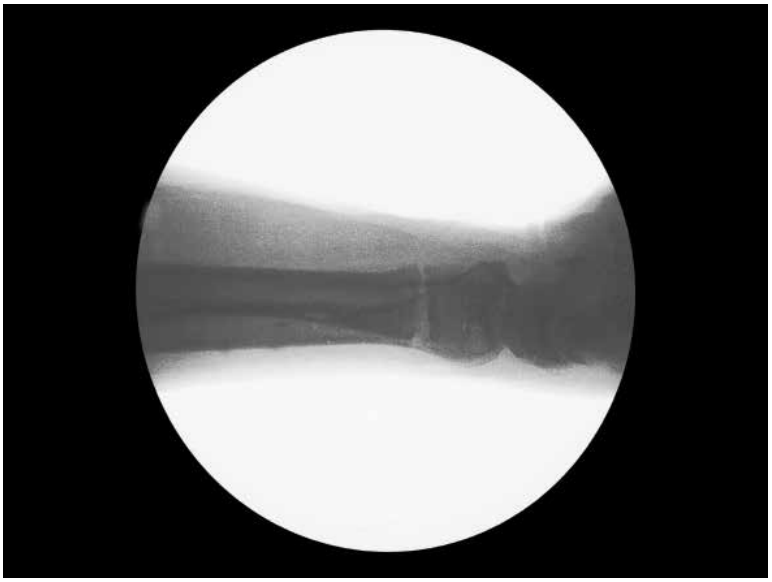
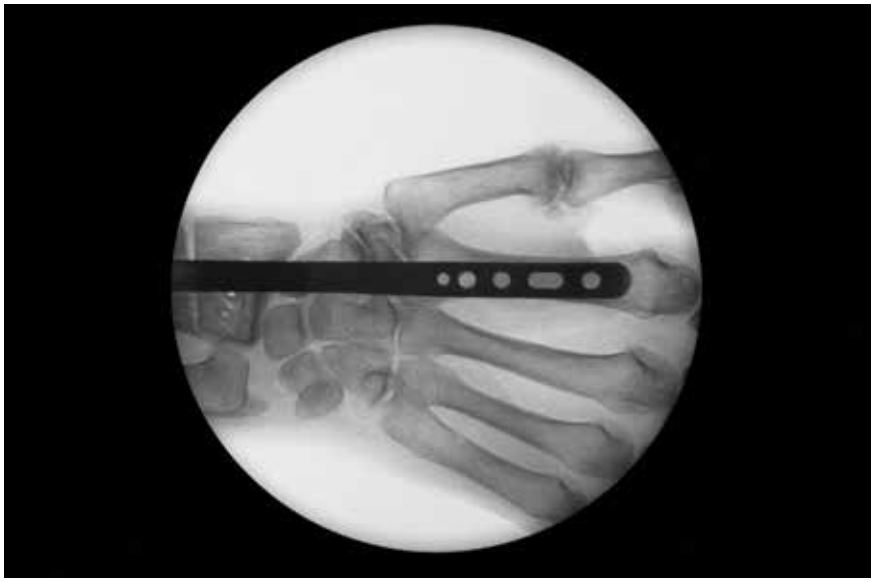


PLATE ORIENTATION 3

The Dorsal Spanning Plate is anatomically designed with a metacarpal and a radial end. Correctly orient the plate over the 2nd or 3rd metacarpal and the radius.

PLATE PLACEMENT 4



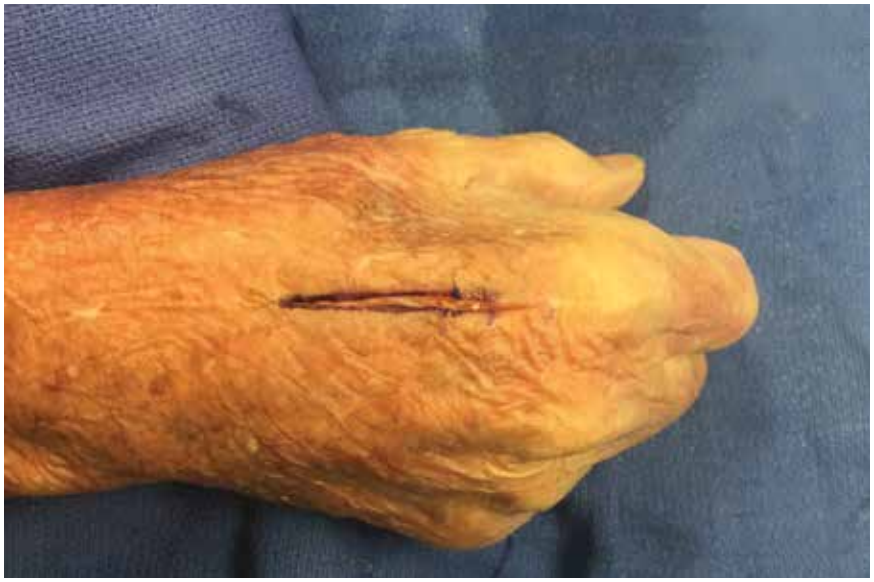
Verify plate placement using fluoroscopy. Mark the distal and proximal end points.

5 INSERTION HANDLE ASSEMBLY

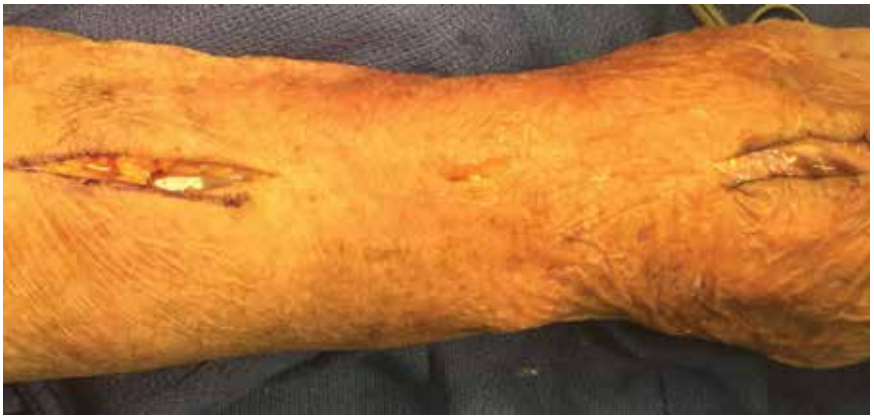
Attach the Insertion Handle to the most proximal hole at the metacarpal end of the Dorsal Spanning plate. Fully tighten with the T-10 driver.

6 FIRST EXPOSURE

Make a 3 cm distal incision centered over the metacarpal.



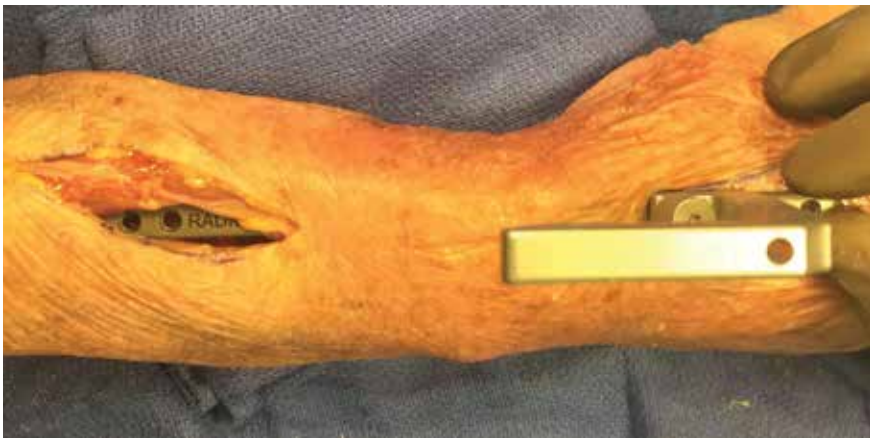
SECOND EXPOSURE 7



Make the 4 cm proximal incision at the level of the previously marked location. Expose the radial shaft and be sure to identify and protect the radial sensory nerve.

NOTE:
If placed on the 2nd metacarpal, ensure that the plate is placed under the EPL. If placed on the 3rd metacarpal, release and mobilize the third and fourth compartments to allow the plate to pass beneath the tendons.

PLATE INSERTION 8



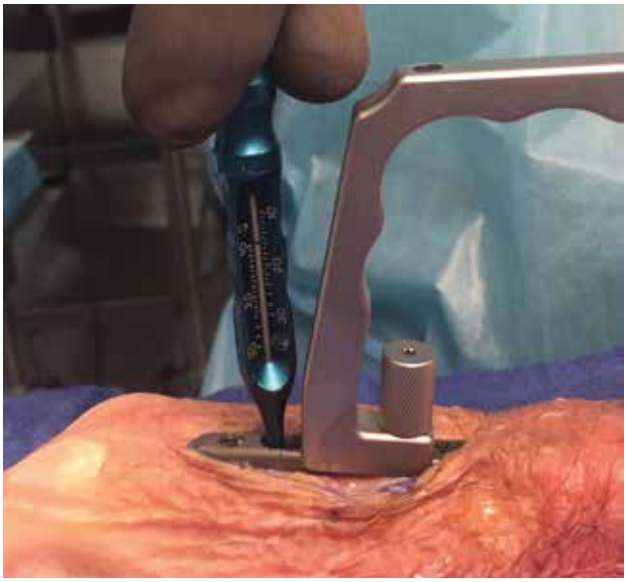
Insert the plate retrograde through the distal incision along the dorsal surface of the radius. The proximal end of the plate is designed to facilitate insertion deep to the extensor tendons. Verify that the extensor tendons remain superficial to the plate.

9 DRILL

Drill through the gliding hole of the metacarpal end of the plate using the 2.3mm bit.

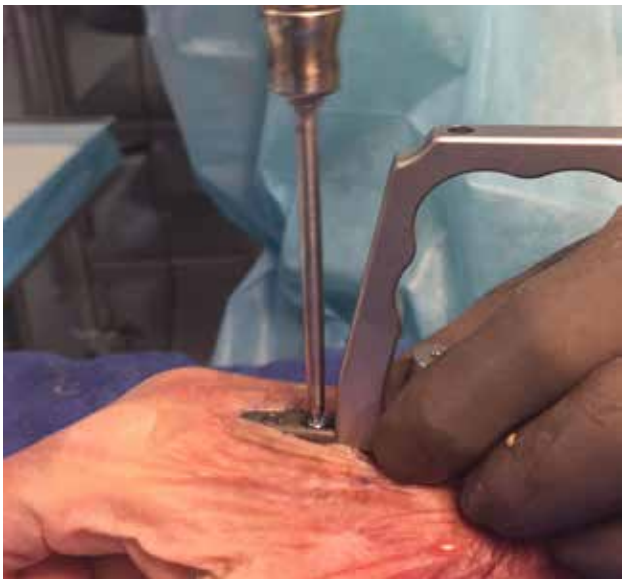
10 SCREW LENGTH MEASUREMENT

Measure the screw length using the Depth Gauge.



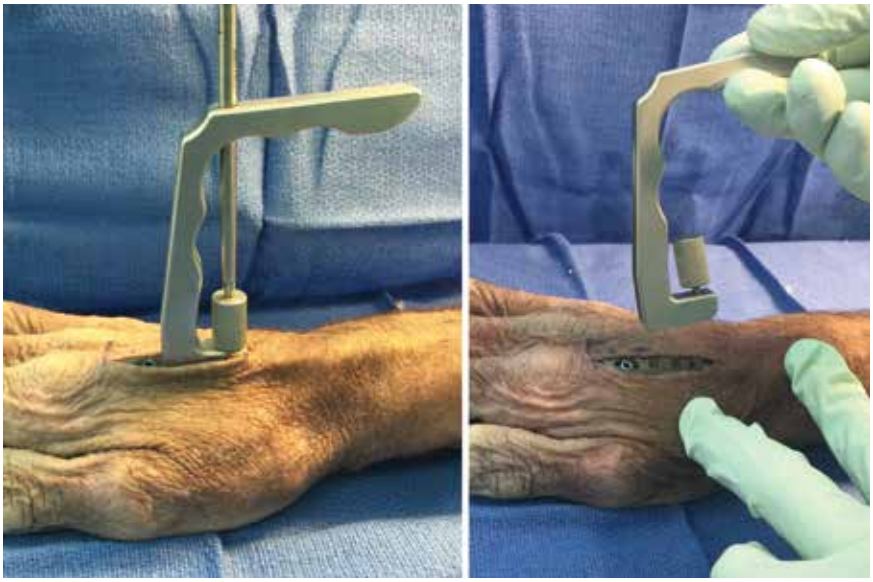
The Depth Gauge has a dual scale. The bottom scale should be used to measure directly through the plate.

COMPRESSION SCREW INSERTION 11



Insert and fully tighten a 3.0mm compression screw using the T-10 driver.

HANDLE REMOVAL 12

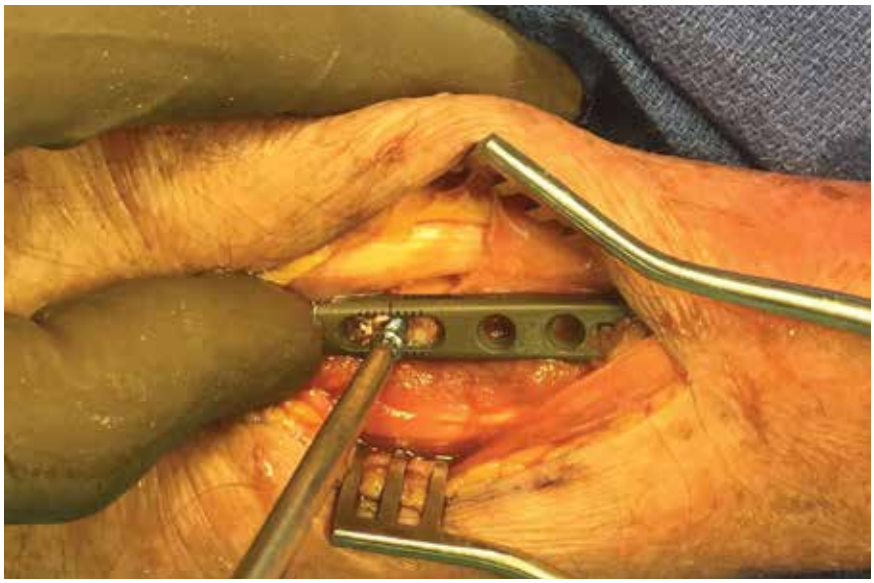


Remove the Insertion Handle. The T-10 driver may facilitate the removal of the lock screw.

13 PROXIMAL & RADIAL PLATE FIXATION

Adjust traction to achieve reduction.

NOTE:
Use of fluoroscopy may be helpful to confirm radial length and proper reduction.

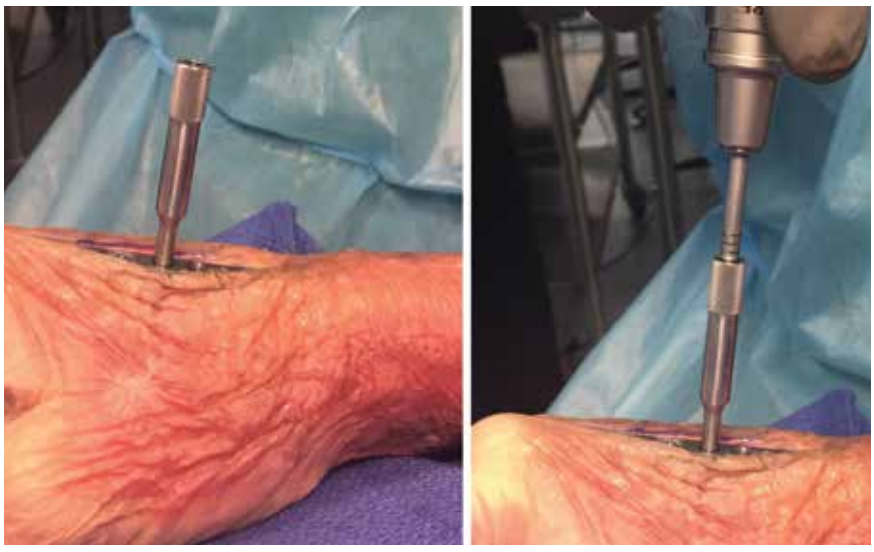


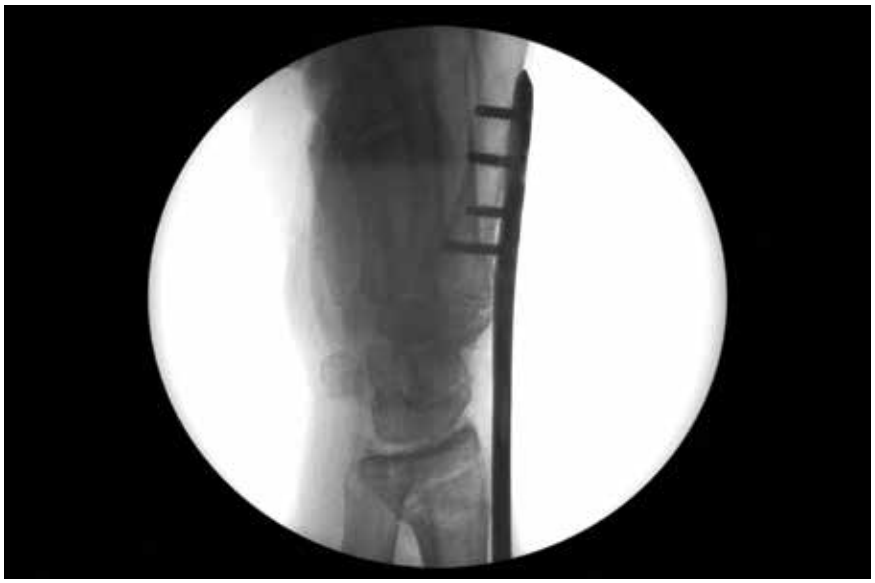
14 FINAL PLATE FIXATION

Secure the Thread-In Drill Guide into a threaded hole of the plate. Using the Thread-in Drill Guide, drill, measure and fill at least 2 of the remaining holes at both ends of the plate using the T-10 Driver.

Either 3.0mm Compression or Locking Screws may be used.The Thread-In Drill Guide in conjunction with the 2.3mm bit may be used to measure screw length.

Care should be taken to ensure that no screws are placed in the joint.





Using the T-10 Driver, insert either a 3.0mm locking or compression screws in the remaining threaded holes at both ends of the plate. Confirm that all screws have been fully tightened.

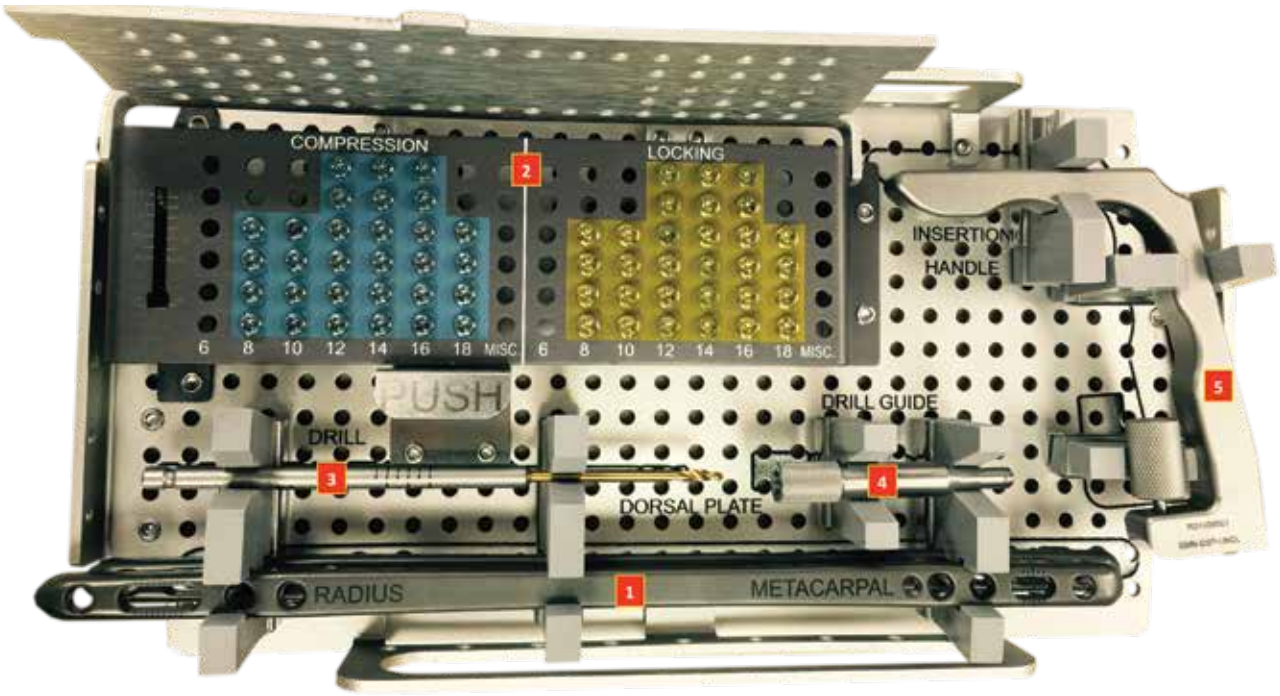
Confirm proper reduction, screw length and screw placement using fluoroscopy.

Close all incisions in normal fashion. The plate is removed after the fracture has healed.

NOTES:

GEMINUS Dorsal Spanning Plate – GMN-DSP-SYS

INSTRUMENT TRAY (Standard Configuration)



Loc #	Catalog #	Description
1	GMN-DSP-210	Dorsal Spanning Plate
	MTLS-30080-TS	Screw, Multi-Thread, Locking, 3.0mm x 8mm, Ti
	MTLS-30100-TS	Screw, Multi-Thread, Locking, 3.0mm x 10mm, Ti
	MTLS-30120-TS	Screw, Multi-Thread, Locking, 3.0mm x 12mm, Ti
	MTLS-30140-TS	Screw, Multi-Thread, Locking, 3.0mm x 14mm, Ti
2	MTLS-30160-TS	Screw, Multi-Thread, Locking, 3.0mm x 16mm, Ti
	MTLS-30180-TS	Screw, Multi-Thread, Locking, 3.0mm x 18mm, Ti
	MTNL-30080-TS	Screw, Multi-Thread, Compression, 3.0mm x 8mm, Ti
	MTNL-30100-TS	Screw, Multi-Thread, Compression, 3.0mm x 10mm, Ti
	MTNL-30120-TS	Screw, Multi-Thread, Compression, 3.0mm x 12mm, Ti
	MTNL-30140-TS	Screw, Multi-Thread, Compression, 3.0mm x 14mm, Ti
	MTNL-30160-TS	Screw, Multi-Thread, Compression, 3.0mm x 16mm, Ti
	MTNL-30180-TS	Screw, Multi-Thread, Compression, 3.0mm x 18mm, Ti

Instruments

3	DRLL-SSC-23040	Drill, 2.3mm X 40mm
4	TPDG-THD-DG23	Thread-In Drill Guide, 2.3mm
5	GMN-DSP-HNDL	Assembled, Handle, Dorsal Spanning Plate
6	GMN-DSP-TRAY	Instrument Tray, Dorsal Spanning Plate

DORSAL SPANNING PLATE QUICK REFERENCE CHART

Dorsal Spanning Plate

Screw, Multi-Thread, Locking, 3.0mm

Screw, Multi-Thread, Compression, 3.0mm

Drill, 2.3mm X 40mm

Thread-in Drill Guide, 2.3mm

Handle, Dorsal Spanning Plate

ADDITIONAL INFORMATION

Contraindications:
Prior to using the Dorsal Spanning Plate System, ensure that none of the following patient conditions are present: active or latent infection, sepsis, osteoporosis, insufficient quantity or quality of bone and/or soft tissue, material sensitivity (if sensitivity is suspected, tests are performed prior to implantation), or patients who are unwilling or incapable of following post operative care instructions.

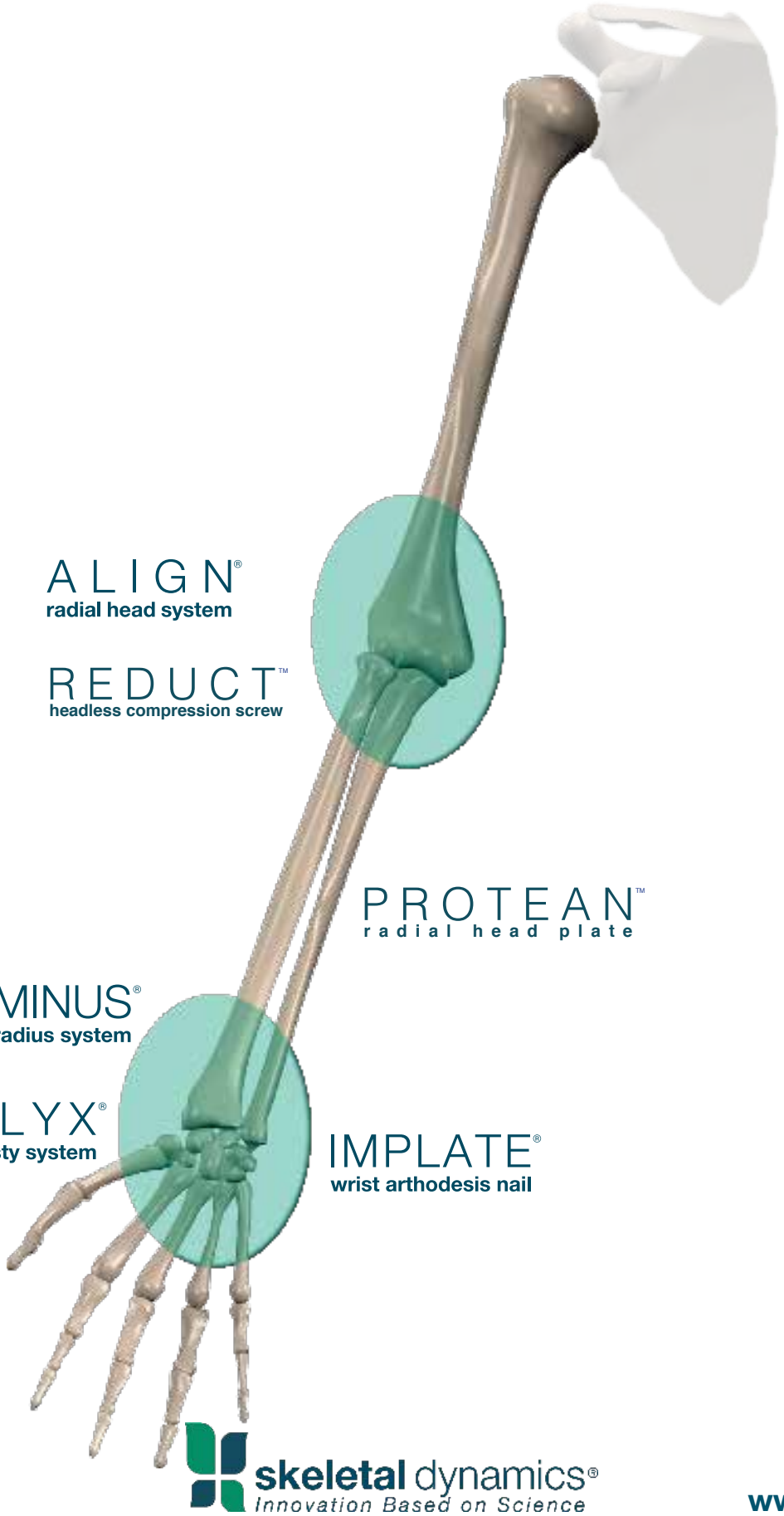
Warnings:
- All screws must be implanted and fully tightened into the plate to maintain the integrity and strength of the finished construct. If the screws are not attached and/or fully tightened, a non-union, delayed union or construct failure may occur.
- The information in this document should be shared with the patient.
- The patient must be cautioned, preferably in writing, about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, non-union, device or treatment failure as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the device.
- The patient should be informed about the importance of following the post-operative rehabilitation prescribed in order to fully understand the possible limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- Potential construct failures such as stress fractures of the bones, loosening of the construct and/or fixation, delayed fusion, non-fusion, or incomplete healing may occur as a result of non-compliance to post-operative rehabilitation, excessive wrist activities or construct overloading.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive physical activity. Device breakage may occur when the implant is subjected to excessive loading associated with delayed union or nonunion. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration.
- The components of these systems have not been evaluated for safety and compatibility in the MR environment; nor have they been tested for heating or migration in the MR environment.
- DO NOT reuse any of the implantable components. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection, which may result in patient injury.

Precautions:
- Protect the system's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the system, inspect all implants and instruments for wear, disfiguration and physical damage. If evidence of wear, disfiguration or physical damage is found, DO NOT use and contact your local Skeletal Dynamics representative or the Skeletal Dynamics Customer Care Department.
- DO NOT permanently implant the K-Wires; they are intended to be used during provisional fixation only.
- DO NOT use screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- DO NOT mix implant components from different manufacturers for metallurgical, biomechanical and functional reasons. The system is to be used only with Skeletal Dynamics instruments, implants and accessories.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Accuracy of Depth and Screw Gauges are within ± 1.0mm.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drills.
- Seek medical help immediately if implant malfunctions.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiring revision surgery to replace the implant or to carry out alternative procedures. To maintain traceability of the implantable components, you must record each of the respective components LOT numbers into the patient records post implantation.

Potential Adverse Events:
Possible adverse effects associated with wrist surgery include infection, non-union, pain, stiffness, discomfort, or abnormal sensations and nerve or soft tissue damage due to the use of an implant or due to surgical trauma. The implant may break due to excessive activity, prolonged loading, incomplete healing, or excessive force on the implant during insertion. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

NOTES:

NOTES:



ALIGN®
radial head system

REDUCT™
headless compression screw

PROTEAN™
radial head plate

GEMINUS®
distal radius system

STABLYX®
cmc arthroplasty system

IMPLATE®
wrist arthodesis nail

skeletal dynamics®
Innovation Based on Science

Distributed in the UK by

LEDA

+44 (0)203 714 2301
sales@ledaortho.com
www.ledaortho.com

MKT-00060-00RAB
August 2015

8905 SW 87th Avenue, Miami, Florida 33176 Tele: 877 753 5396

Designed and Manufactured in the USA