ST

SURGICAL
TECHNIQUE

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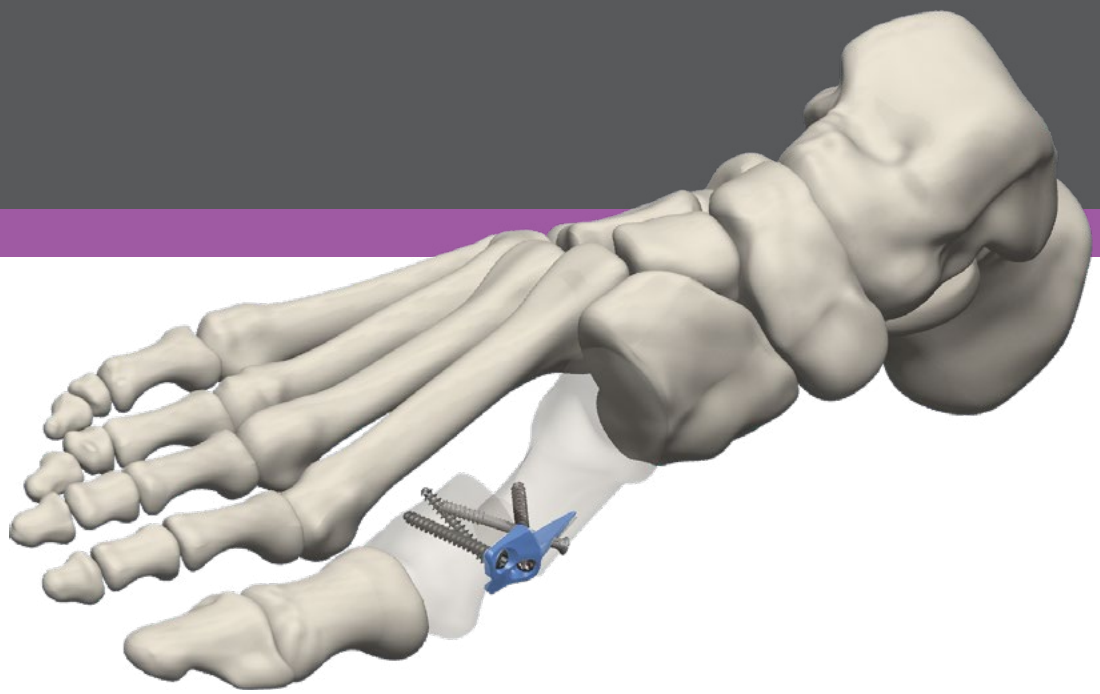
MINIMALLY INVASIVE BUNION (M.I.B.) PLATING SYSTEM

BUNION SYSTEM



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A UNIQUE APPROACH TO
TRIPLANAR HALLUX VALGUS CORRECTION

DJO® is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals, with special thanks to Nathan Graves, DPM. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient. Please refer to the MIB Instructions for Use (900-01-016) for further information.

See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions, if applicable. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient.

WHY THE MINIMALLY INVASIVE BUNION (M.I.B.) APPROACH?

There are an exhaustible number of procedures aimed at correcting hallux abducto valgus deformities. Recent literature suggests that a triplanar approach is more advantageous than other options to realign the 1st ray.[1] The importance of this approach is apparent as the leading cause of bunion reoccurrence is post-operative sesamoid position of a 4 or greater and HAV angle of greater than 8 degrees.[2]

A first metatarsal cuneiform fusion is thought to be the most common option for triplanar correction, but a large number of patients do not fit the parameters of this procedure. A greater number are resistant because of the large incision, increased healing time, and higher non-union rates.[3]

Recently, there have been advances in minimally invasive procedures to correct bunions, which allows the surgeon to easily obtain triplanar correction. Regularly, this distal procedure requires the surgeon to translate the capital fragment 40% to 90% laterally. With such large translation, is it difficult to visualize how the procedure site can be stabilized or heal. DJO has developed a plate that allows for stable fixation with a large translation and rotation of the capital fragment.

The Minimally Invasive Bunion Plating System takes a unique approach to triplanar Hallux Valgus correction. The technique allows for simultaneous correction in the frontal, transverse, and sagittal planes by utilizing a transverse cut. The smaller medial incision required for implantation decreases soft tissue disruption compared to other bunionectomy correction procedures. The plate itself masks the osteotomy for minimal medial palpability through a distal shoulder transition to a proximal intramedullary spade. Multi-directional compression and stabilization are achieved in the osteotomy by using 2.4mm distal locking screws in conjunction with two anti-rotational crossing interfragmentary screws.

1. Dayton P et al. Why Frontal Place Correction is a Vital Component of Bunion Surgery. Podiatry Today. 2017 July:30(7): 28-34.

2. Park CH, Lee W-C. Recurrence of Hallux Valgus Can Be Predicted from Immediate Postoperative Non-Weight-Bearing Radiographs. J Bone Joint Surg Am. 2017 99:1190-1197.

3. Saffo G, Desnoyers R, Wooster M, et al. First Metatarsocuneiform Joint Arthrodesis: A Five-Year Retrospective Analysis. J Foot Surgery. 1989;5:459-465.

INDICATIONS AND CONTRADICTIONS

INDICATIONS
MINIMALLY INVASIVE BUNION PLATING SYSTEM

The Minimally Invasive Bunion Plating System is indicated for:

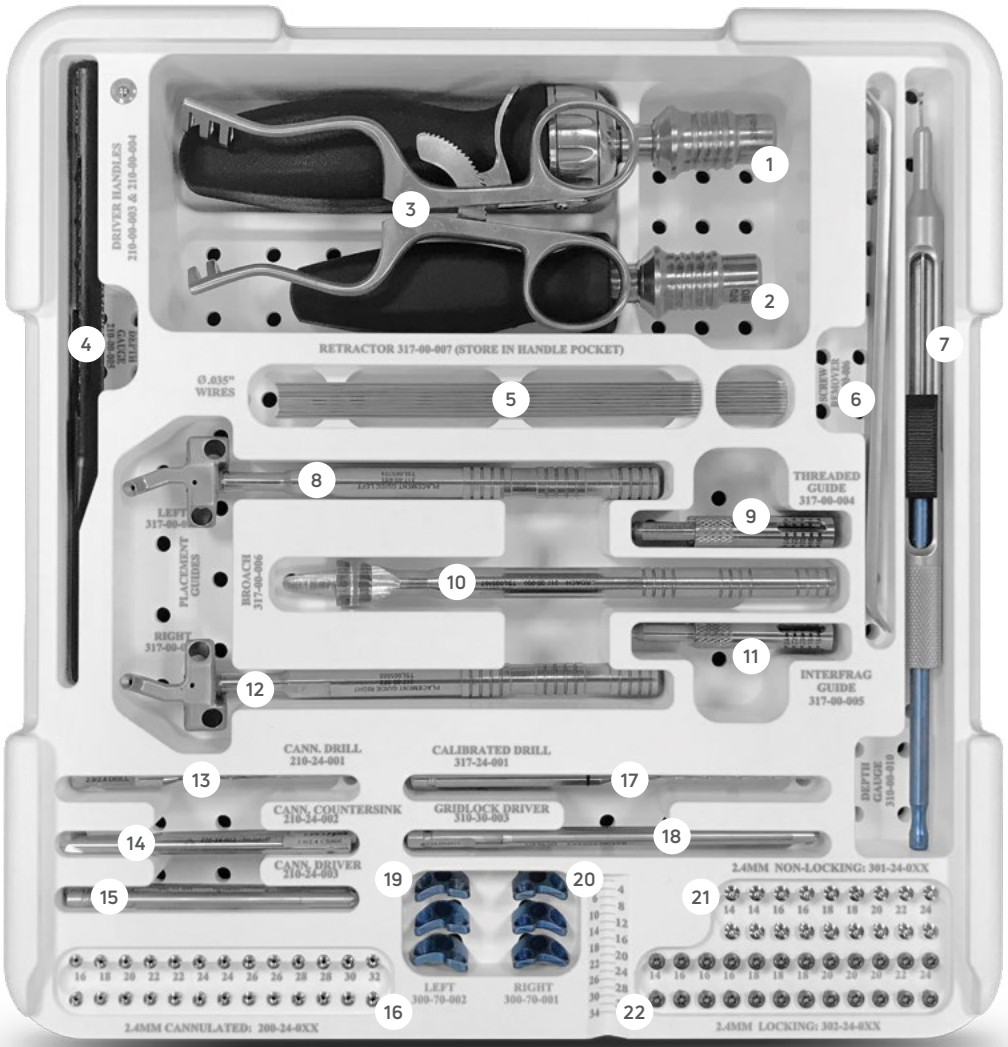
- Fixation of osteotomies
- Corrective procedures of the hallux and associated disorders such as hallux valgus

CONTRAINDICATIONS
MINIMALLY INVASIVE BUNION PLATING SYSTEM

The Minimally Invasibe Bunion Plating System is contraindicated for:

- Cases of active or suspected infection
- Patients who are immunocompromised
- Patients previously sensitized to titanium
- Patients with certain metabolic diseases
- Patients exhibiting disorders that would cause the patient to ignore the limitations of internal fixation

TRAY OVERHEAD



#	DESCRIPTION	PART #	QTY
1	RATCHETING CANNULATED DRIVER HANDLE	210-00-004	1
2	CANNULATED DRIVER HANDLE	210-00-003	1
3	TISSUE RETRACTOR	317-00-007	1
4	CANNULATED DEPTH GAUGE	210-00-005	1
5	0.035" x 5" K-WIRE STANDARD	210-24-004	10
6	SCREW REMOVER	210-00-006	1
7	GRIDLOCK DEPTH GAUGE	310-00-010	1
8	MIB PLATE PLACEMENT GUIDE, LEFT	317-00-003	1
9	MIB THREADED DRILL GUIDE	317-00-004	2
10	MIB BROACH	317-00-006	1
11	MIB INTERFRAG DRILL GUIDE	317-00-005	2
12	MIB PLATE PLACEMENT GUIDE, RIGHT	317-00-002	1
13	2.0/2.4 MM CANNULATED DRILL BIT	210-24-001	2
14	2.0/2.4 MM CANNULATED COUNTERSINK	210-24-002	2
15	2.0/2.4 MM CANNULATED SCREW DRIVER BIT	210-24-003	2
16	2.4 MM TIGER CANNULATED SCREWS	200-24-0XX	
17	MIB 2.4 SCREW CALIBRATED PILOT DRILL BIT	317-24-001	3
18	GRIDLOCK SCREW DRIVER BIT	310-30-003	2
19	MINIMALLY INVASIVE BUNION PLATE, LEFT	300-70-002	3
20	MINIMALLY INVASIVE BUNION PLATE, RIGHT	300-70-001	3
21	2.4 MM NON-LOCKING GRIDLOCK PLATING SCREWS	301-24-0XX	
22	2.4 MM GRIDLOCK PLATING LOCKING SCREWS	302-24-0XX	

PREOPERATIVE PLANNING

The Trilliant Surgical MIB Plating system is designed for 1st metatarsal bunionectomies with mild to moderate intermedullary (IM) angles. For bunions with severe IM angles, the system is not recommended (FIGURE 1).

For a minimally invasive bunion procedure with the Trilliant Surgical MIB Plating system, it is recommended that the patient is in the supine position.

Optional: a lateral release of the Adductor Hallucis Tendon may be performed to allow for increased rotational positioning. This is a clinical decision.

Make a 2 cm longitudinal, medial incision over the intended osteotomy site. **Precaution:** The incision size may vary depending on surgeon preference and patient anatomy (FIGURE 2). A 2 cm incision is recommended to provide adequate access for hardware while limiting the final incision size.

Create a transverse osteotomy through the metatarsal using a saw and angling the osteotomy towards the fifth metatarsal head (FIGURE 3). Split the difference of the perpendicular plane to the long axis of the metatarsal and perpendicular to the weight-bearing surface.

Optional: A removal of the medial eminence may be performed to avoid interference with plate placement and reduce potential for palpability. This is an intraoperative decision.

FIGURE 1

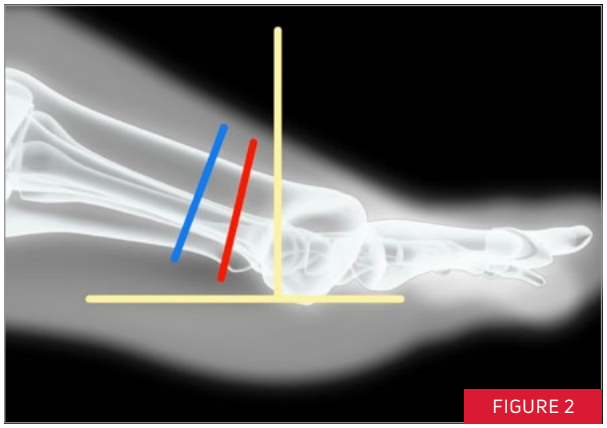


FIGURE 2

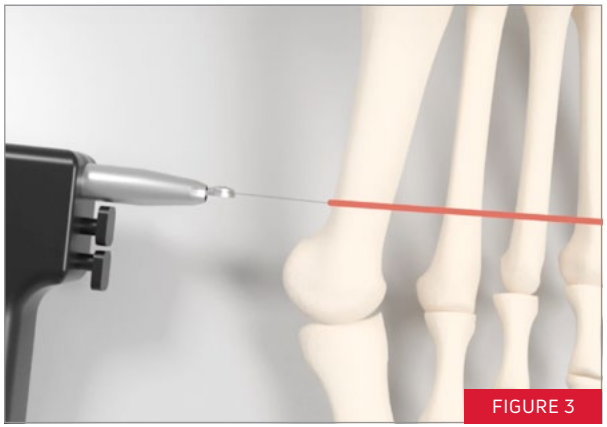


FIGURE 3

PREPARE THE DEFORMITY FOR THE PLATE PLACEMENT CONSTRUCT

Manually or with the use of a small mallet, use the MIB Broach (**317-00-006**) to broach at the apex of the deformity in the proximal medullary canal while manually translating and distracting the distal bone segment (FIGURE 4, FIGURE 5, FIGURE 6).

Precaution: The broach should not be used as a lever as it can lead to incorrect placement of the implant.

Remove the broach from the medullary canal.

FIGURE 4

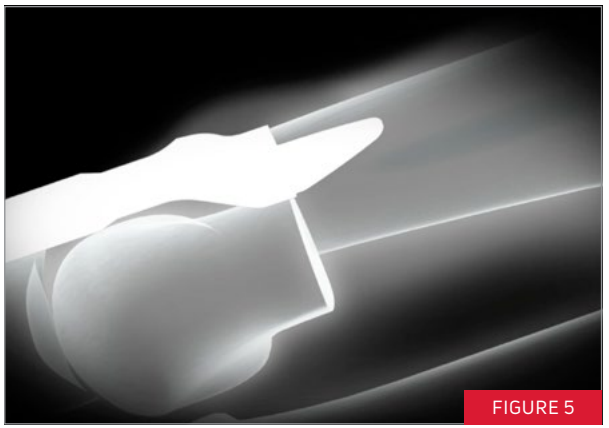


FIGURE 5

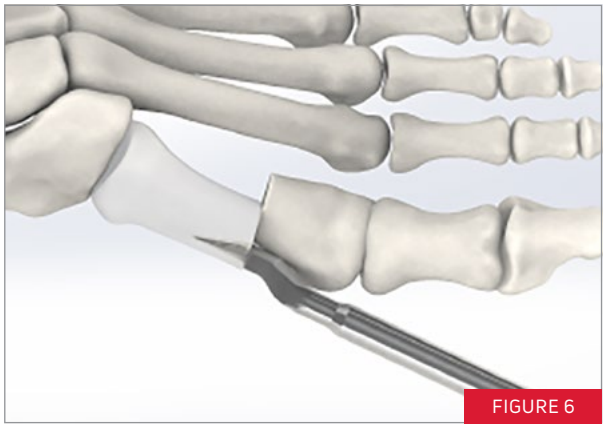


FIGURE 6

MINIMALLY INVASIVE BUNION PLATE PREPARATION

ASSEMBLE THE PLATE PLACEMENT CONSTRUCT

Select the desired Minimally Invasive Bunion Plate, Right (**300-70-001**) or Minimally Invasive Bunion Plate, Left (**300-70-002**) for the procedure (FIGURE 7, FIGURE 8).

Secure the MIB Plate Placement Guide to the Minimally Invasive Bunion Plate by threading quantity 2 of the MIB Threaded Drill Guide (**317-00-004**) through the MIB Plate Placement Guide and on the Minimally Invasive Bunion Plate.

FIGURE 7

FIGURE 8

MIB Threaded Drill Guide
(317-00-004)

MIB Plate Placement Guide
Right - (317-00-002) Left - (317-00-003)

MIB Broach
(317-00-006)

MINIMALLY INVASIVE BUNION PLATE INSERTION AND DEFORMITY CORRECTION

Insert the Minimally Invasive Bunion Plate on the Plate Placement Guide into the broached region of the proximal fragment (FIGURE 9). Prior to insertion, the distal segment should be rotated for varus correction, ensuring proper repositioning of the sesamoids below the metatarsal head (FIGURE 10).

Temporarily secure the construct by inserting (2) 0.035" x 5" K-Wire Standard (**210-24-004**) so that the K-Wires protrude through the distal/lateral cortex (FIGURE 11, FIGURE 12). One K-Wire is inserted in the distal K-Wire hole of the Minimally Invasive Bunion Plate and is used for temporary positional fixation. The other K-Wire is inserted into the proximal interfragmentary screw hole of the Minimally Invasive MIB Plate and will be used for the 2.4mm Tiger Cannulated Screw.

Confirm placement and desired correction is sufficient before proceeding to the next step.

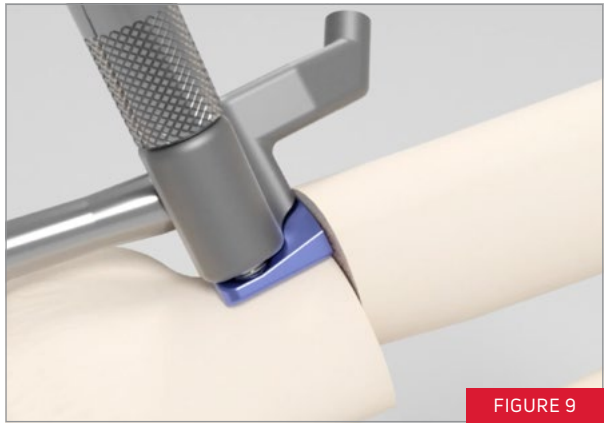


FIGURE 9

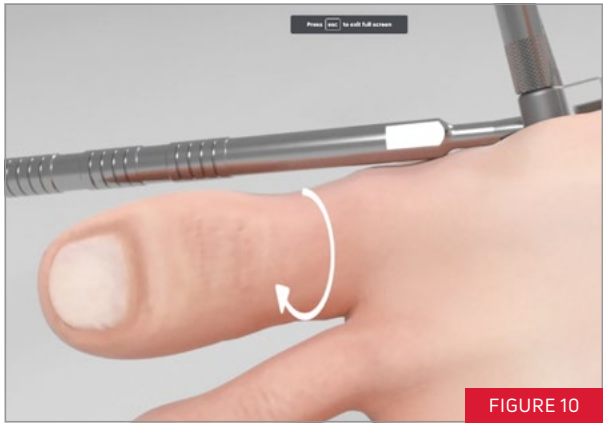


FIGURE 10

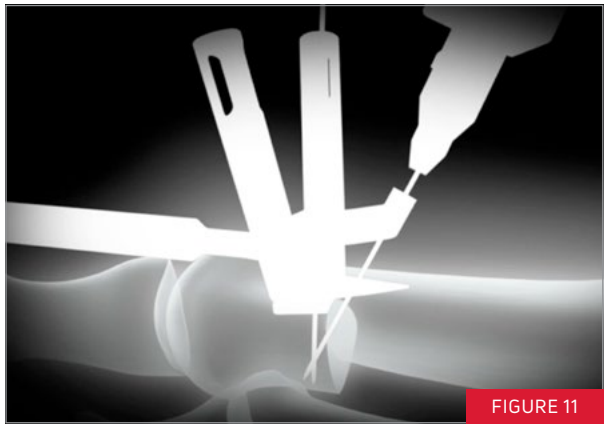


FIGURE 11

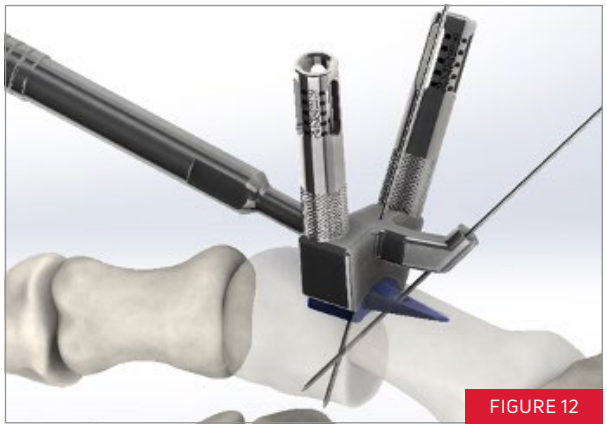


FIGURE 12

CONSTRUCT STABILIZATION

Use the MIB 2.4mm Calibrated Pilot Drill Bit (**317-24-001**) with the Threaded Drill Guide to measure for the length of the 2.4mm Gridlock Locking Screw.

Pilot drill through one of the MIB Threaded Drill Guides using the MIB 2.4mm Calibrated Pilot Drill Bit (**317-24-001**) until the drill bit engages with the distal/lateral cortex of the distal fragment (FIGURE 15).

Use the calibration on the MIB Threaded Drill Guide and the MIB 2.4mm Calibrated Pilot Drill Bit to measure for the length of the 2.4mm Gridlock Locking Screw (FIGURE 15). Once the desired length is confirmed, complete drilling of the distal/lateral cortex.

Remove the MIB Threaded Drill Guide from the assembly and insert the appropriate length 2.4mm Gridlock Locking Screw into the pilot hole through the Plate Placement Guide using the Gridlock Screw Driver Bit (**310-30-003**) (FIGURE 16).

Repeat the above steps for the second distal locking hole of the plate.

Remove distal K-Wire from the Plate Placement Guide and remove the Plate Placement Guide by sliding it over the proximal K-Wire.

FIGURE 17 shows both distal locking screws fully inserted.

Alternative Measuring Method: Use the Gridlock Depth Gauge (**310-00-010**) to measure for the length of the 2.4 mm Gridlock Locking Screw instead of the laser marked readings on the MIB threaded drill guide as depicted.

Calibrated Pilot Drill Bit (317-24-001)

MIB Threaded Drill Guide (317-00-004)

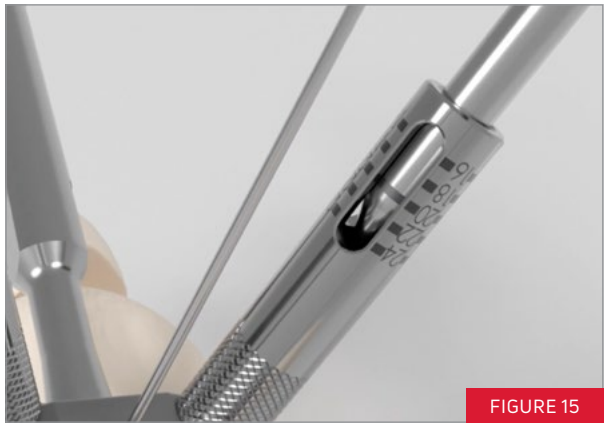


FIGURE 15

FIGURE 16

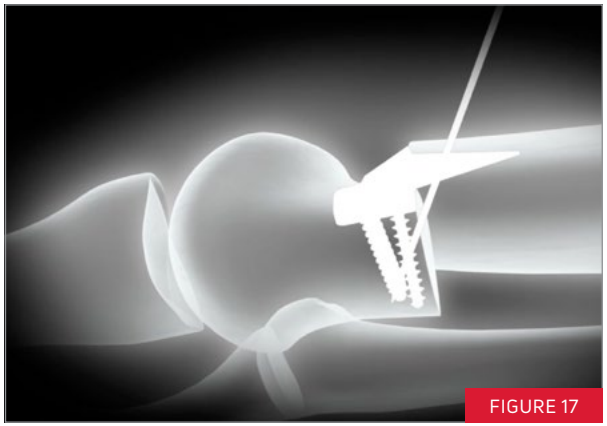


FIGURE 17

INSERT DISTAL INTERFRAGMENTARY SCREW

Use the 2.4mm Gridlock Non-Locking Screw as the Distal Interfragmentary Screw and the MIB Interfrag Drill Guide (**317-00-005**) and MIB 2.4mm Calibrated Pilot Drill Bit for Screw Length Measurement.

Insert the MIB Interfrag Drill Guide (**317-00-005**) into the distal interfragmentary screw hole in the distal portion of the Minimally Invasive Bunion plate. Use the MIB 2.4mm Calibrated Pilot Drill Bit to pilot drill until the drill bit starts to engage with the distal/lateral cortex of the proximal fragment (FIGURE 18).

Use the calibrations on the MIB Interfrag Drill Guide and MIB 2.4mm Calibrated Pilot Drill Bit to measure for the length of the 2.4mm Gridlock Non-Locking Screw (FIGURE 19).

Complete drilling until the drill protrudes through the distal/lateral cortex of the proximal fragment. Remove the Interfrag Drill Guide and insert an appropriate length 2.4mm Gridlock Non-Locking Screw into the pilot hole using the Gridlock Screw Driver Bit (**310-30-003**).

Alternative Measuring Technique: use the 2.4mm Gridlock Non-Locking Screw as the Distal Interfragmentary Screw and the Gridlock Depth Gauge for Screw Length Measurement

Alternative: use the 2.4mm Tiger Cannulated Screw as the Distal Interfragmentary Screw

Insert a K-Wire into the distal interfragmentary screw hole until it penetrates the distal/lateral cortex of the proximal fragment

Confirm length of 2.4mm Tiger Cannulated Screw using the Cannulated Depth Gauge

Use the 2.0/2.4mm Cannulated Drill Bit to pilot drill until the drill protrudes through the distal/lateral cortex of the proximal fragment

Slide the appropriate length 2.4mm Tiger Cannulated Screw over the K-Wire and drive the Screw into the bone using the either the 2.0/2.4mm Cannulated Screw Driver Bit or the 2.0/2.4mm Tiger Cannulated Slip Fit Driver (210-24-008)

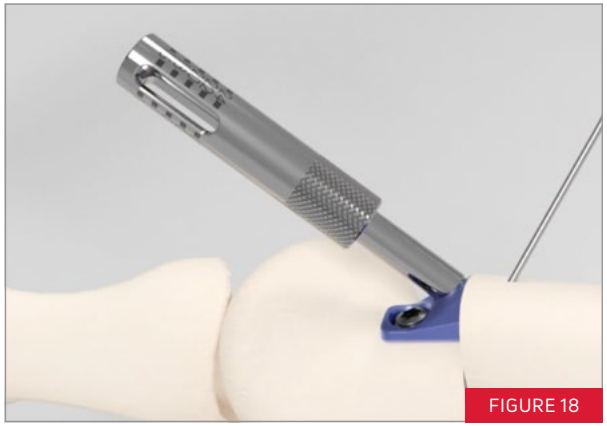


FIGURE 18

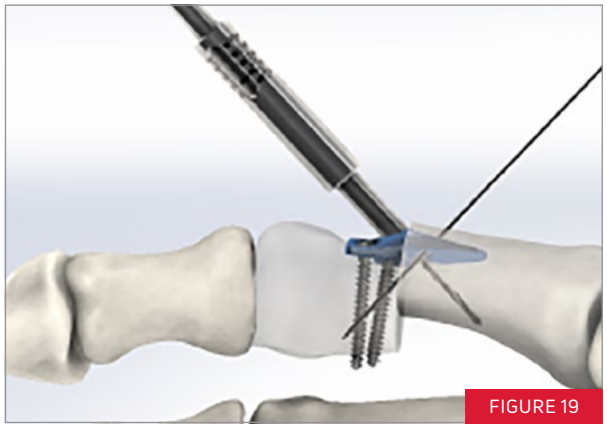


FIGURE 19

INSERT PROXIMAL INTERFRAGMENTARY SCREW

Slide the 2.0/2.4mm Cannulated Countersink (**210-24-002**) over the remaining K-Wire and countersink until the desired recess has been made in the bone for the head of the 2.4 Tiger Cannulated Screw.

Confirm the desired screw length by examining the end of the K-Wire in relation to the marks on the Cannulated Depth Gauge (**210-00-005**) (FIGURE 20).

> ⚠ **PRECAUTION:** It is imperative that the K-Wire protrude through the distal/lateral cortex for this measurement. If the K-Wire does not protrude through the distal/lateral cortex, either adjust the K-Wire or add 4 mm to the screw length measurement from the Cannulated Depth Gauge (FIGURE 21).

Slide the appropriate Tiger 2.4mm Cannulated Screw over the K-Wire and insert the screw using the 2.0/2.4mm Cannulated Screw Driver Bit (**210-24-003**) until desired compression is achieved.

Alternatively, the 2.0/2.4mm Tiger Cannulated Slip Fit Driver (**210-24-008**) can be used to allow for deeper engagement in the screw head.

Remove and discard the K-Wire.

FIGURE 20

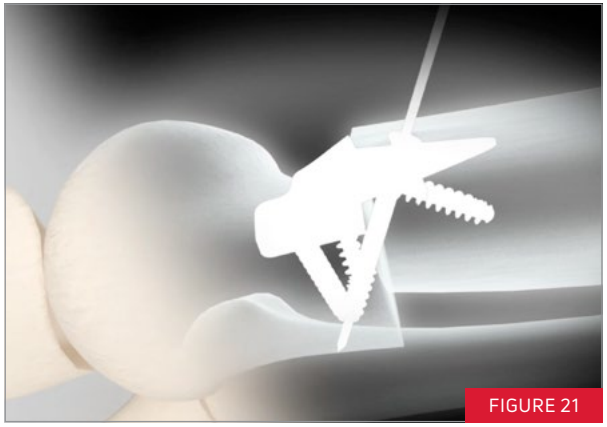


FIGURE 21

CLOSURE

Close the surgical site per standard surgical technique.

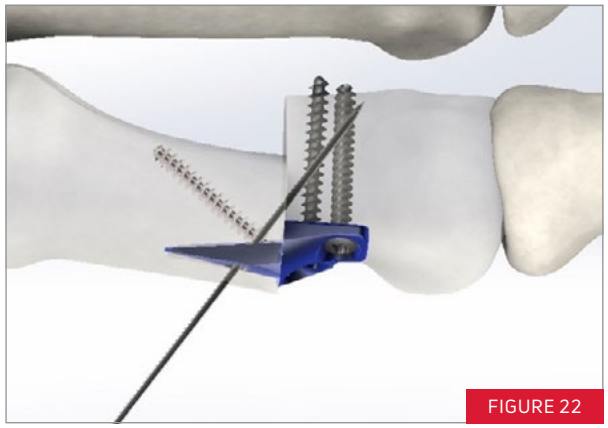


FIGURE 22

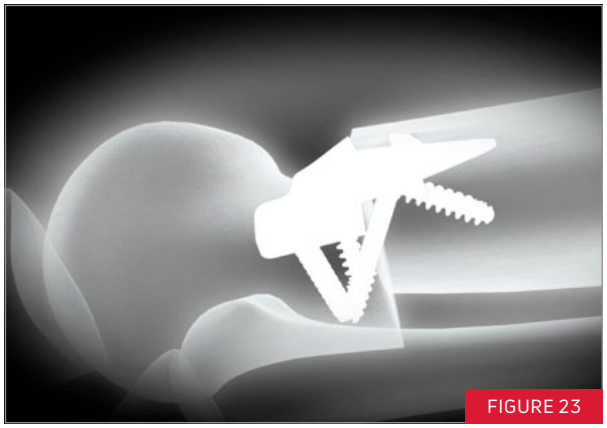


FIGURE 23

2 days P.O. *10 days P.O.* *3 weeks P.O.* *5 weeks P.O.* *3 months P.O.*

FIGURE 24

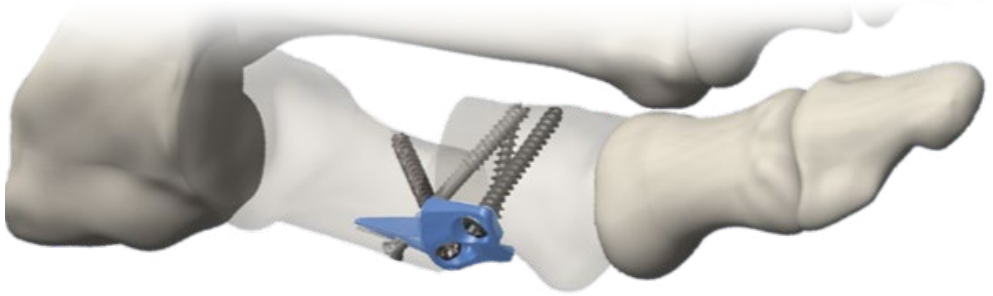
REMOVAL TECHNIQUE

Locate the plate and screws with intra-operative imaging.

Palpate the plate and remove surrounding soft tissue to gain maximum exposure.

Engage screw heads with appropriate driver and rotate counterclockwise until screws are removed. Use a forceps or pickup to remove the plate. It is recommended to use Freers or pickups in the now empty distal holes of the plate to loosen and remove the plate.

Once the plate and screws are removed, they should be treated as medical waste and disposed of accordingly.



⚠ PRECAUTION:

- Remove the plate only if lateral osseous or fibrous fusion has occurred.
- The shelf on the medial eminence can be removed if seen. It's recommended that lateral fusion should be seen if this is to be done. If the eminence is not removed, but the surgeon desires to fill the existing bone void in the medullary canal, it can be filled with cancellous bone graft.

ORDERING INFORMATION

MINIMALLY INVASIVE BUNION PLATES	
300-70-001	Minimally Invasive Bunion Plate, Right
300-70-002	Minimally Invasive Bunion Plate, Left

2.4MM TIGER CANNULATED SCREWS	
200-24-016	2.4 x 16mm Tiger Cannulated Screw
200-24-018	2.4 x 18mm Tiger Cannulated Screw
200-24-020	2.4 x 20mm Tiger Cannulated Screw
200-24-022	2.4 x 22mm Tiger Cannulated Screw
200-24-024	2.4 x 24mm Tiger Cannulated Screw
200-24-026	2.4 x 26mm Tiger Cannulated Screw
200-24-028	2.4 x 28mm Tiger Cannulated Screw
200-24-030	2.4 x 30mm Tiger Cannulated Screw
200-24-032	2.4 x 32mm Tiger Cannulated Screw

2.4MM GRIDLOCK PLATING SCREWS	
301-24-014	2.4 x 14mm Gridlock Plating Screw
301-24-016	2.4 x 16mm Gridlock Plating Screw
301-24-018	2.4 x 18mm Gridlock Plating Screw
301-24-020	2.4 x 20mm Gridlock Plating Screw
301-24-022	2.4 x 22mm Gridlock Plating Screw
301-24-024	2.4 x 24mm Gridlock Plating Screw

2.4MM GRIDLOCK PLATING LOCKING SCREWS	
302-24-014	2.4 x 14mm Gridlock Locking Screw
302-24-016	2.4 x 16mm Gridlock Locking Screw
302-24-018	2.4 x 18mm Gridlock Locking Screw
302-24-020	2.4 x 20mm Gridlock Locking Screw
302-24-022	2.4 x 22mm Gridlock Locking Screw
302-24-024	2.4 x 24mm Gridlock Locking Screw

DISPOSABLES & SEMI DISPOSABLES	
210-24-001	2.0/2.4mm Cannulated Drill Bit
210-24-002	2.0/2.4mm Cannulated Countersink
210-24-003	2.0/2.4mm Cannulated Screw Driver Bit
210-24-004	0.035" x 5" K-Wire Standard
210-24-005	0.035" x 5" K-Wire Partially Threaded
310-30-003	Gridlock Screw Driver Bit
317-24-001	MIB 2.4mm Screw Calibrated Pilot Drill Bit

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