



Small Fragment Plating System

Surgical Technique



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A.L.P.S. Small Fragment Plating System

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A.L.P.S. Small Fragment Plating System



Hybrid plating technology for compression and locked fixation

Compression screw Fixation

- The oval screw hole can accept non-locking screws to allow for up to 64 degrees of axial and 34 degrees of transverse screw angulation while offering 3 mm of axial compression.
- The screws can be positioned and used in compression, neutral and buttress modes.

Locked Screw Fixation

- The round threaded screw holes accept screws that will lock into position when tightened to establish a fixed angle construct for strong fixation in osteopenic bone or when optimal screw purchase is required.

The Small Fragment System is a titanium plate and screw system that fuses locking screw technology with conventional plating techniques. The set was designed to maximize treatment options when managing fractures requiring small fragment fixation, as well as, to serve as the core system for additional anatomic implants.

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Introduction

The Small Fragment System combines our traditional system with the enhanced benefits of locking screw technology. The compression plate features two distinct plate hole designs, each serving an intended purpose without compromising performance. The hybrid construction of this plate offers the surgeon the ability to combine standard interfragmentary compression with the added stability of fixed angle locking. This construct will protect the compression and lag screws while providing stability across extensive comminution, unstable metaphyseal fractures or in osteopenic bone.

Indications for Use:

Fixation of fractures, osteotomies, nonunions of the:

- Fibula
- Olecranon
- Humerus
- Radius
- Ulna
- Distal tibia
- Clavicle



System Contents:

- 3.5 mm locking compression plates
- One-third tubular plates, non-locking
- 16 mm, 20 mm and 25 mm spider washers
- 3.5 mm cortical screws, locking
- 3.5 mm cortical screws, non-locking
- 4.0 mm cancellous screws, locking
- 4.0 mm cancellous lag screws, non-locking
- 4.0 mm cancellous screws, full thread, non-locking
- 4.0 mm cannulated cancellous lag screws, non-locking
- Optional: 2.7 mm cortical screws, non-locking



Features:

3.5 mm Locking Compression Plate:

- Uniform hole spacing
- Compression, neutral and buttress screw positions
- Threaded holes for locking screw option
- 64 degrees of axial screw angulation
- 34 degrees of transverse screw angulation
- 3 mm of compression
- Bullet-shaped ends for submuscular plate insertion
- 5 – 14 holes

3.5 mm Locking Cortical Screw:

- Larger core diameter and shallower thread pitch for improved bending and shear strength compared to a standard 3.5 mm cortical screw
- Self-tapping tip minimizes the need for pre-tapping and eases screw insertion
- T-15 drive
- Tapered screw head helps ensure alignment of the screw head into the plate hole
- Tapered threaded head minimizes screw back-out and construct pullout
- Available in lengths of 10 – 70 mm

4.0 mm Locking Cancellous Screw:

- Self-tapping tip minimizes the need for pre-tapping and eases screw insertion
- T-15 drive
- Tapered screw head helps ensure alignment of the screw head into the plate hole
- Tapered threaded head minimizes screw back-out and construct pullout
- Available in lengths of 10 – 70 mm

A.L.P.S. Small Fragment Plating System



Figure 1



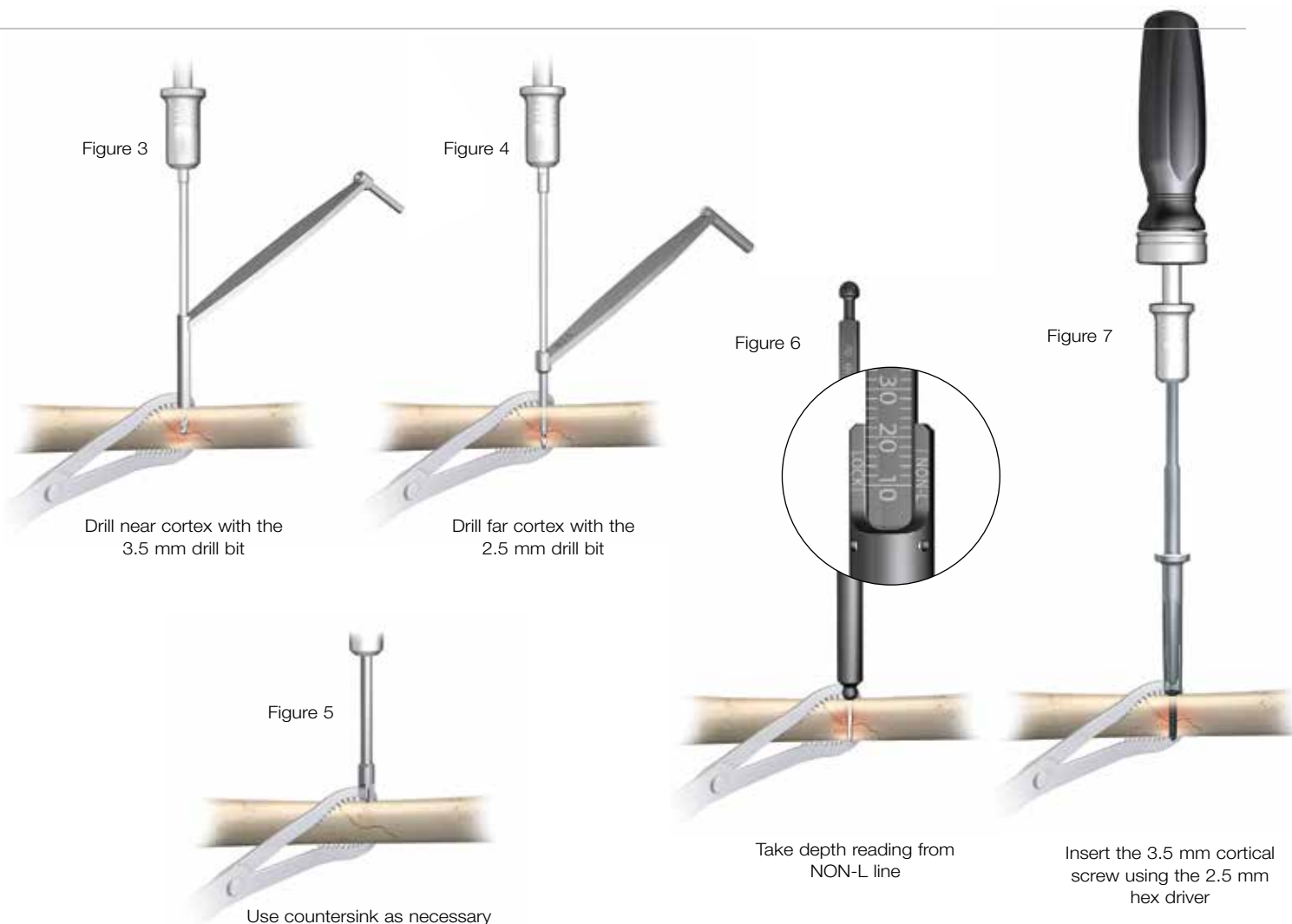
Figure 2

Interfragmentary Fixation

Interfragmentary fixation uses lag screws (Figure 1) to apply compression across the fracture surface.

Intra-articular and epiphyseal fractures are frequent indications for interfragmentary fixation.

To apply compression across the fracture site, the screw threads must engage only the far fragment. If the screw threads engage the near cortex, the fracture will be distracted, and compression will not be possible. The 3.5 mm cortical screws are generally selected for use in diaphyseal bone. The 4.0 mm cancellous bone screws are generally used in metaphyseal or osteopenic bone (Figure 2).



3.5 mm Cortical Screws (8150-37-0XX)

Reduce the fracture and maintain the reduction with bone forceps. Drill a gliding hole in the near cortex with the 3.5 mm Drill Bit (8290-32-070) using the 2.5/3.5 mm Drill Guide (8241-96-000) (Figure 3).

Note: For oblique fractures, guide the drill bit so it bisects the angle between a line perpendicular to the plane of the fracture and a line perpendicular to the axis of the bone.

Insert the 2.5 mm drill guide into the glide hole. Drill a pilot hole into the far cortex with the 2.5 mm Drill Bit (8290-29-070) (Figure 4).

Note: If necessary, prepare the near cortex with the Countersink (8241-58-100) to allow the screw head to sit flush on the cortical surface (Figure 5).

Determine the required screw length by taking a direct reading from the NON-L line on the Small Fragment Depth Gauge (2142-35-100) (Figure 6).

Note: In hard or dense bone, tap the pilot hole in the far cortex with the 3.5 mm Cortical Tap (8241-50-070) prior to attempting to insert the screw. The 2.5/3.5 mm drill guide can be used as a tissue protector.

Insert the appropriate length 3.5 mm Cortical Screw (8150-37-0XX) by hand or with power using the Screw Holder Sleeve (8241-66-000) over the 2.5 mm Hex Driver (8241-57-071) in the Ratchet Handle (8261-66-000) or drill (Figure 7). Always perform final seating of the screw by hand.

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Figure 8

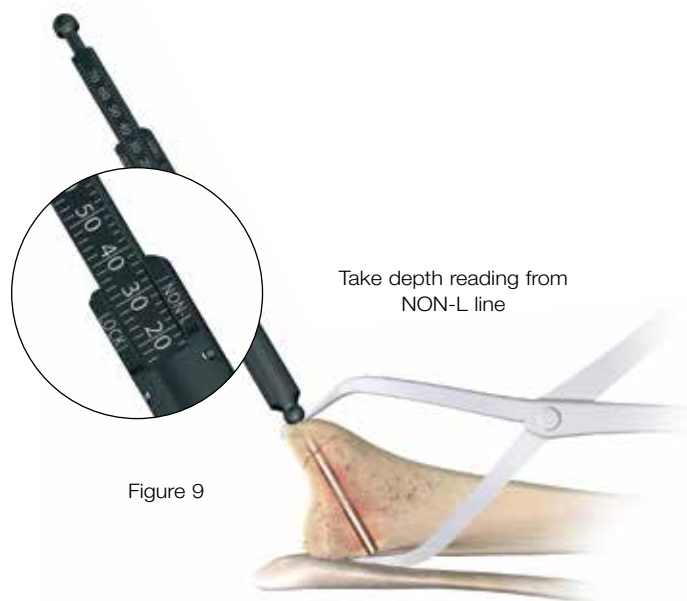


Figure 9

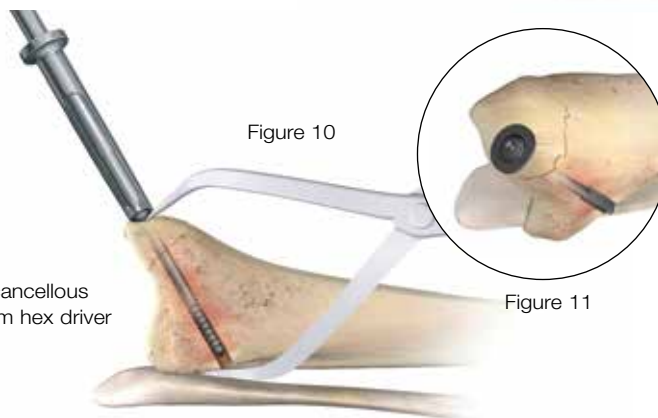


Figure 10

Figure 11

4.0 mm Cancellous Lag Screws (8155-40-0XX)

Reduce the fracture and maintain the reduction with bone forceps. Drill both cortices with the 2.9 mm Drill Bit (8290-31-070) perpendicular to the plane of the fracture using the 2.9/4.0 mm Drill Guide (2141-29-400). Advance the drill across the fracture site to the required depth, confirming the position with image intensification (Figure 8).

Determine the required screw length by taking a direct reading from the NON-L line on the Small Fragment Depth Gauge (Figure 9).

Insert the appropriate length 4.0 mm Cancellous Lag Screw (8155-40-0XX) by hand or with power using the screw holder sleeve over the 2.5 mm hex driver in the ratchet handle or drill. Always perform final seating of the screw by hand (Figure 10).

Note: In soft cancellous bone, the use of the Flat (14460) or Cupped Washer (14461), may prevent the screw head from sinking into the near cortex and allow better compression across the fracture site (Figure 11).

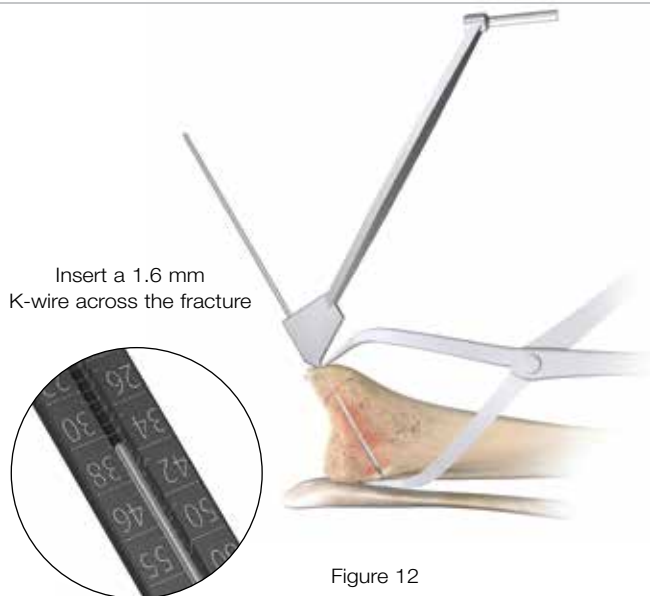


Figure 12



Figure 13

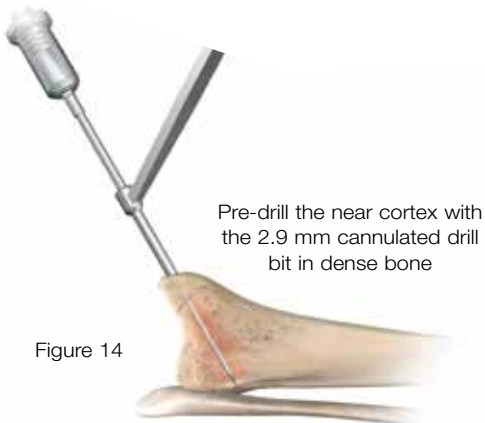


Figure 14

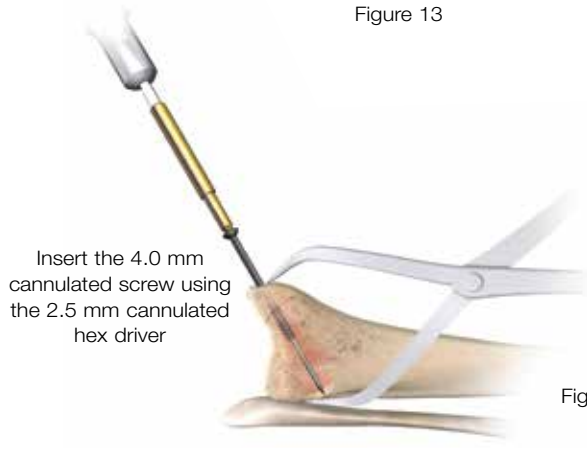


Figure 15

4.0 mm Cannulated Cancellous Screws (14376-XX)

Reduce the fracture and maintain the reduction with bone forceps. Insert a 1.6 mm x 6 in. K-wire (8290-16-006 or 14425-6) perpendicular to the plane of the fracture using the 1.6/2.9 mm Drill Guide (8241-64-070). Advance the K-wire across the fracture site to the required depth, confirming the position with image intensification (Figure 12).

Place the K-wire Depth Gauge (13545) over the K-wire and hold firmly against the bone. Read the required screw length directly off the gauge at the end of the K-wire (Figure 13).

Note: In dense bone, it may be necessary to pre-drill the near cortex and screw path with the 2.9 mm Cannulated Drill Bit (8290-30-070) using the 1.6/2.9 mm drill guide (Figure 14). Care should be taken to avoid drilling the far cortex as the K-wire will loosen.

Place the selected self-drilling, self-tapping 4.0 mm Cannulated Cancellous Screw (14376-XX) over the K-wire and insert by hand or with power using the Cannulated Hex Driver (8241-56-070) in the ratchet handle or drill. Perform final seating of the screw by hand. Remove the K-wire (Figure 15).

In soft bone, the use of the flat or cupped washer may prevent the screw head from sinking into the near cortex and allow better compression across the fracture site.

Caution: Cannulated screwdrivers should always be used over a K-wire.

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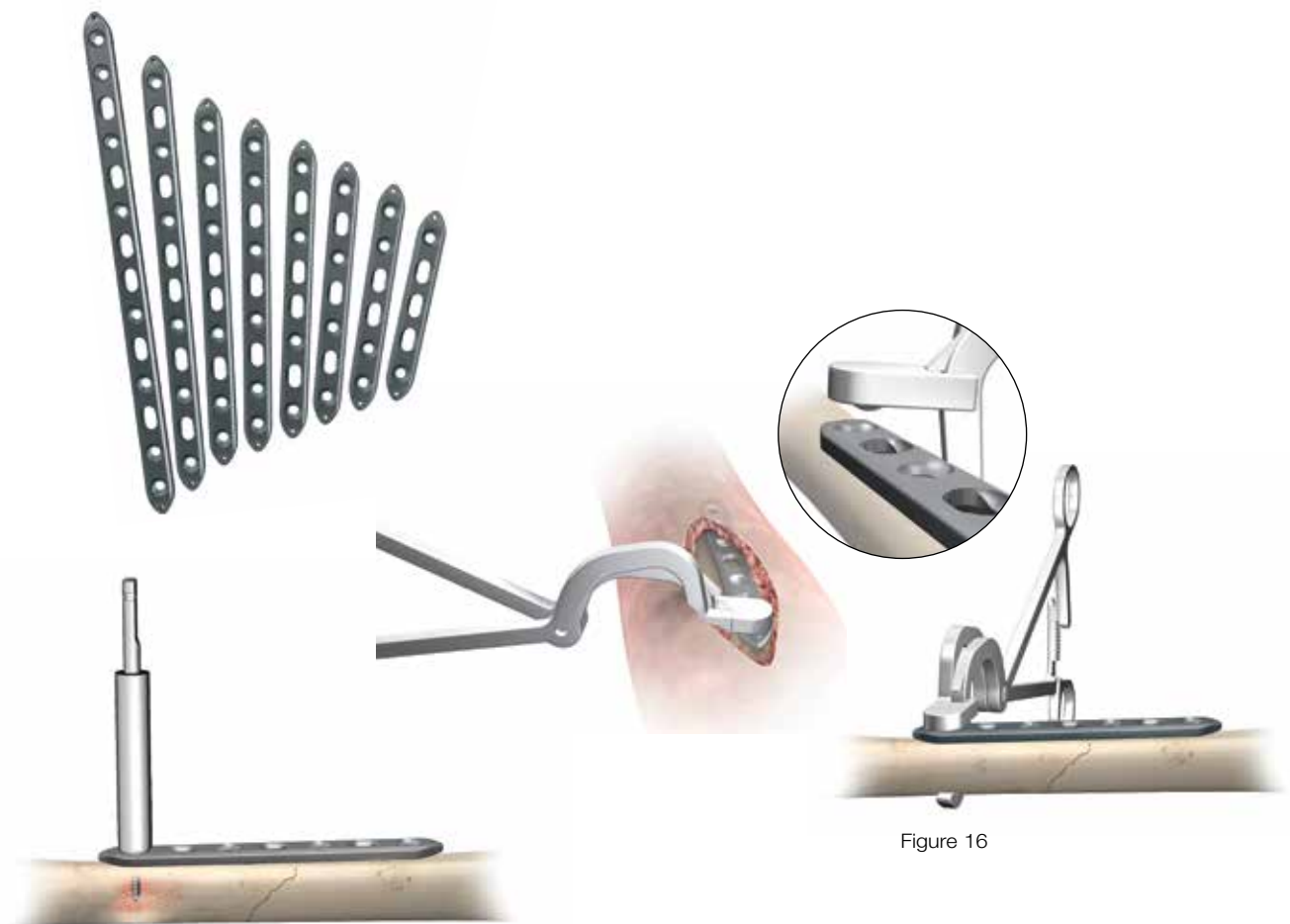


Figure 16

Plate Selection

Locking Compression Plate (8162-35-0XX)

Plate Selection: A plate should be selected that has a minimum of three screw holes in each main fracture fragment. Longer plates are generally recommended, as this will increase the working length of the plate. Screws should, however, be placed in the holes nearest the fracture and at the ends of the plate. Typically, non-locked screws are used for interfragmentary compression and to bring the plate down to the new cortex, locked screws are placed in threaded plate holes and should only be inserted after non-locked screws have pulled the plate to the bone. When straight plates are used on straight bones (e.g. ulna), the plate must be slightly pre-bent to assure compression of the far cortex and avoid fracture gapping.

Note: Bending should occur between the plate holes and not through any threaded holes.

Reduction and Temporary Placement: Position the center of the plate over the fracture site and hold in place with plate bone forceps or the provisional fixation pins.

Use of the Provisional Fixation Pin (8242-99-000/1) Avoid placing the provisional fixation pin in a screw hole that will be needed immediately for implant fixation. The self-drilling pin has quick connect for power insertion. Advance the pin slowly until the shoulder of the pin contacts the plate and pulls it down to the bone. Advancing the pin beyond that point may result in stripping of the threads.

Use of the Plate Bone Forceps (2142-76-000) Slide the serrated foot of one limb of the clamp onto the under-surface of the bone while inserting the protrusion of the other limb into a plate hole. The "c" shape of the clamp minimizes soft tissue damage (Figure 16).

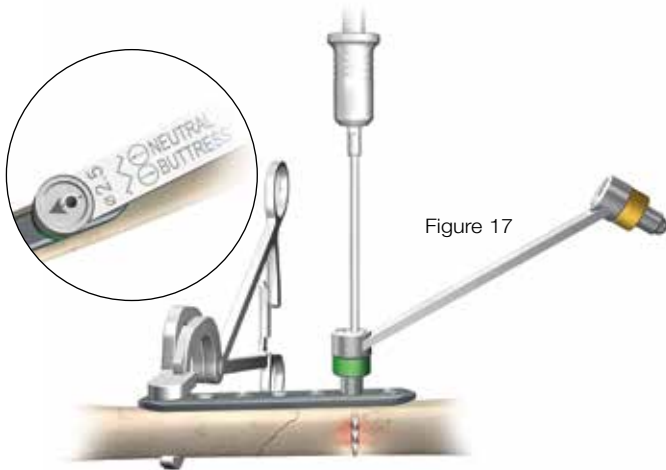


Figure 17

Drill with the 2.5 mm drill bit in the neutral position

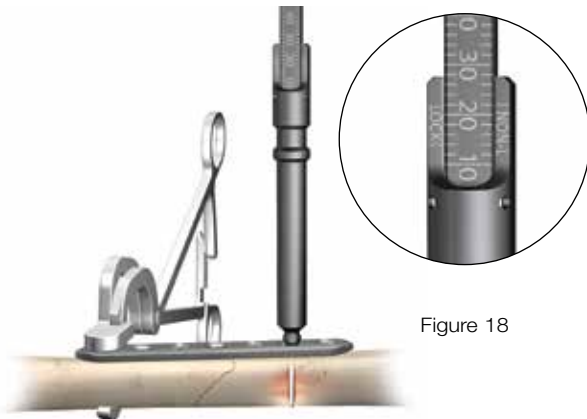


Figure 18

Take the depth reading from the NON-L line

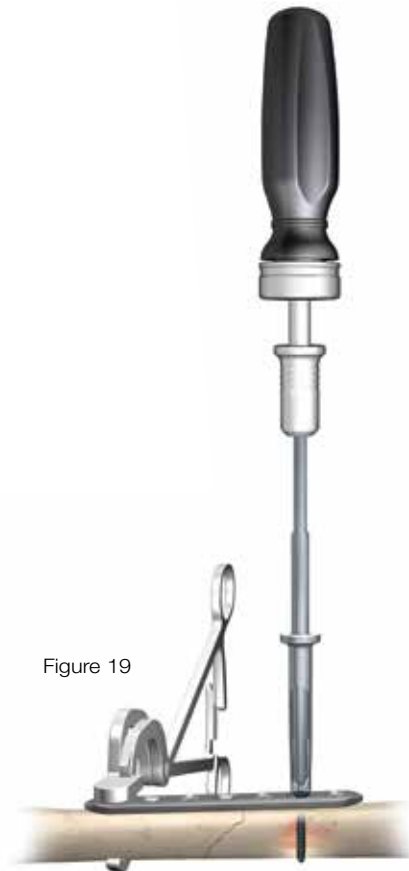


Figure 19

Insert the 3.5 mm non-locking cortical screw using the 2.5 mm hex driver

Plate Insertion

Screw Insertion

Determine the type of screw to be used: 3.5 mm locking cortical, 3.5 mm non-locking cortical, 4.0 mm locking cancellous or 4.0 mm non-locking cancellous. Any combination of screws can be used. If a combination of locking and non-locking screws is used, a non-locking screw should be inserted first to pull the plate to the bone.

Neutral Insertion of a 3.5 mm Non-Locking



3.5 mm non-locking cortical screw



4.0 mm non-locking cancellous screw



3.5 mm locking cortical screw



4.0 mm locking cancellous screw

Cortical Screw in a Compression Slot

Insert the neutral (green) end of the 2.5 mm ACP Drill Guide (8241-68-000) into the compression slot with the arrow pointed toward the fracture line (Figure 17). Drill through both cortices with the 2.5 mm drill bit.

Measure the drilled hole with the small fragment depth gauge by taking a direct reading from the NON-L line (Figure 18).

Insert the appropriate length 3.5 mm non-locking cortical screw with the screw holder sleeve over the 2.5 mm hex driver coupled to the ratchet handle (Figure 19).

CAUTION: The arrow on the neutral (green) end of the 2.5 mm ACP Drill Guide must point toward the fracture site to ensure neutral screw placement.

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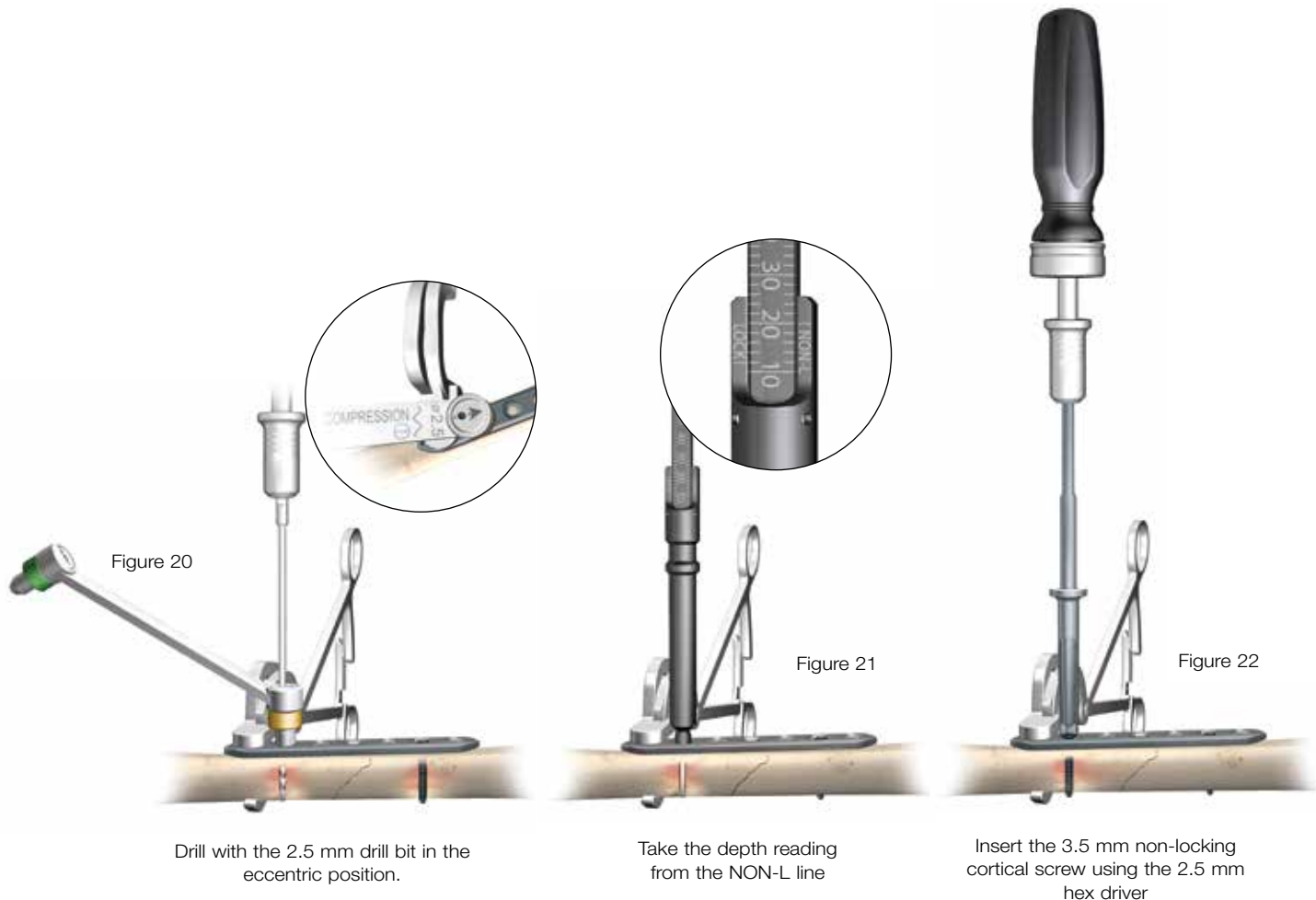


Plate Insertion

Dynamic Compression/Eccentric Insertion of a 3.5 mm Non-Locking Cortical Screw in a Compression Slot

Insert the compression (gold) end of the 2.5 mm ACP drill guide into the compression slot with the arrow pointed toward the fracture line. Drill through both cortices with the 2.5 mm drill bit (Figure 20).

Measure the drilled hole with the small fragment depth gauge by taking a direct reading from the NON-L line (Figure 21).

Insert the appropriate length 3.5 mm non-locking cortical screw with the screw holder sleeve over the 2.5 mm hex driver coupled to the ratchet handle (Figure 22).

CAUTION: The arrow on the compression end of the 2.5 mm ACP Drill Guide must point toward the fracture site to obtain compression. If the arrow is misdirected away from the fracture, distraction of the fracture will occur.

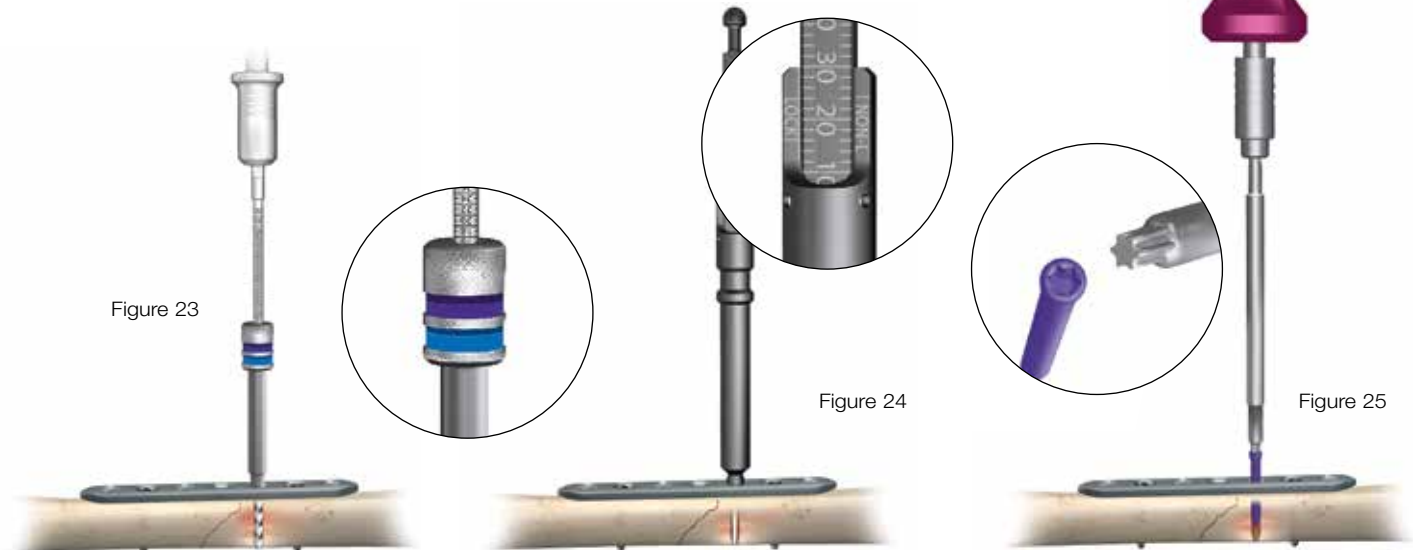


Figure 23

Figure 24

Figure 25

Drill with the 2.7 mm calibrated drill bit reading the depth from the top of the drill guide

Take the depth reading from the LOCK line

Insert the locking screw using the T-15 driver on the torque-limiting handle

Insertion of a Locking Screw (3.5 mm Cortical 8161-35-0XX or 4.0 mm Cancellous 8161-40-0XX) in a Threaded Hole

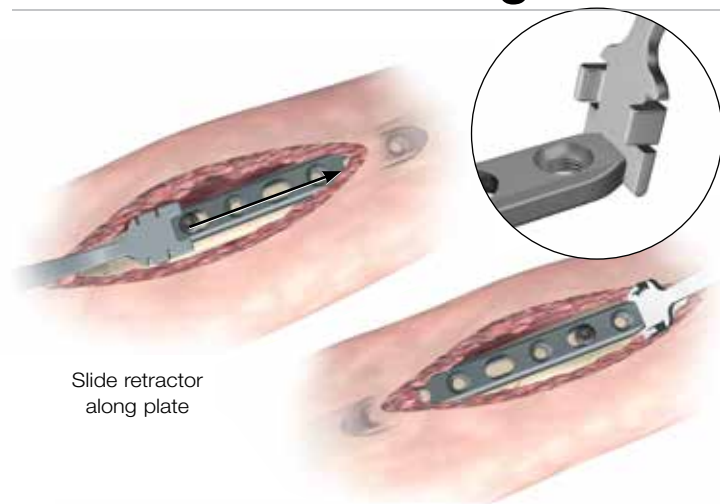
Screw the 2.7 mm Locking Drill Guide (2142-07-027) into a threaded plate hole until fully seated. Drill with the 2.7 mm Calibrated Drill Bit (2142-27-070) to the desired depth and read the depth measurement from the calibrated drill bit at the top of the drill guide (Figure 23). Remove the 2.7 mm locking drill guide.

Note: If a second method of measurement is desired, measure the drilled hole by taking a direct reading from the Lock line on the small fragment depth gauge (Figure 24).

Insert the selected locking screw with the T-15 Driver (2142-15-070) coupled to the 2.0 Nm Torque-Limiting Screwdriver Handle (2141-18-001) (Figure 25).

Tip: Using a power screwdriver is not recommended for insertion of any locking screws. Perform all final screw tightening by hand with the torque-limiting screwdriver handle.

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Slide retractor along plate

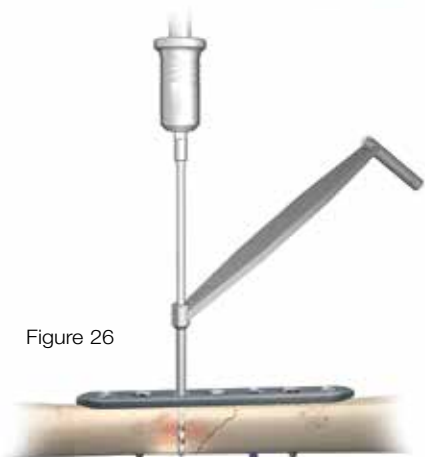


Figure 26

Drill with the 2.5 mm drill bit through the 2.5/3.5 mm drill guide

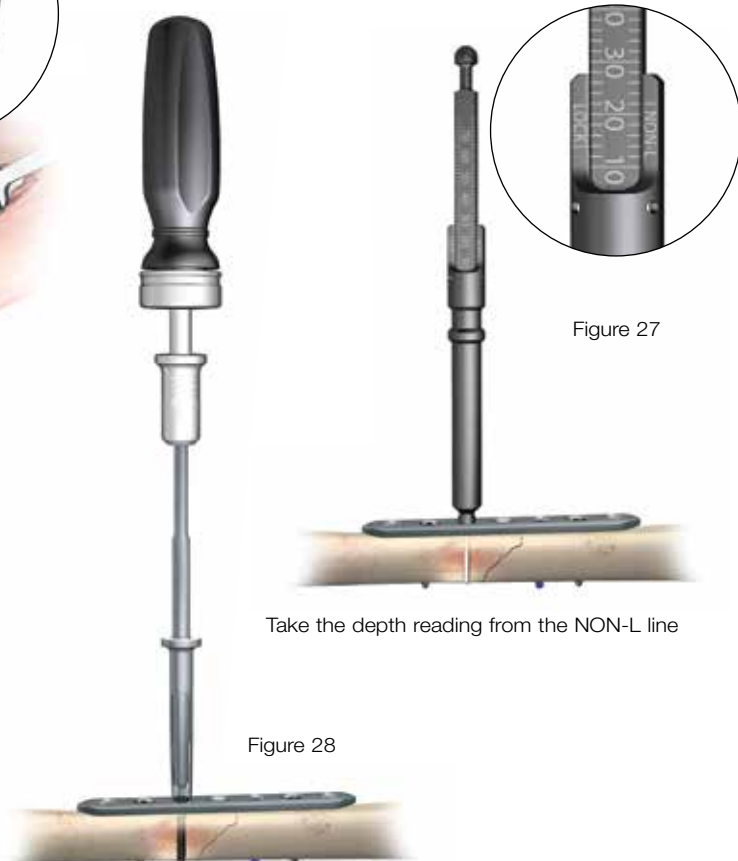


Figure 27

Take the depth reading from the NON-L line

Figure 28

Insert the 3.5 mm non-locking cortical screw using the 2.5 mm hex driver

Plate End Retractor

The retractor is designed to retract soft tissue when accessing the terminal screw holes of the plate. Slide the rails of the retractor along the plate edges and then raise the handle toward the end of the incision, allowing the cutout to fit over the contoured end of the plate.

Insertion of a 3.5 mm Non-locking Cortical Screw in a Threaded Hole

Insert the 2.5 mm end of the 2.5/3.5 mm drill guide into the threaded hole and drill through both cortices with the 2.5 mm drill bit (Figure 26). Measure the drilled hole by taking a direct reading from the NON-L line on the small fragment depth gauge (Figure 27).

Insert the appropriate length 3.5 mm non-locking cortical screw with the screw holder sleeve over the 2.5 mm hex driver coupled to the ratchet handle (Figure 28).

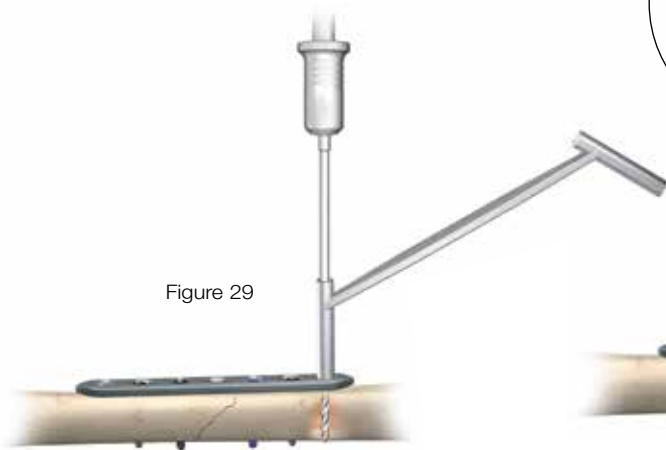


Figure 29

Drill with the 2.9 mm drill bit through the 2.9/4.0 mm drill guide



Figure 30

Take the depth reading from the NON-L line

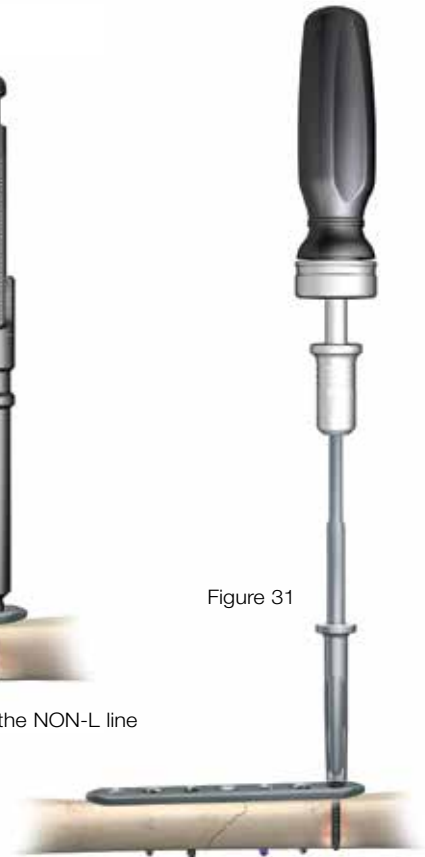


Figure 31

Insert the 4.0 mm cancellous screw using the 2.5 mm hex driver

Insertion of a 4.0 mm Non-locking Cancellous Screw into any Plate Hole

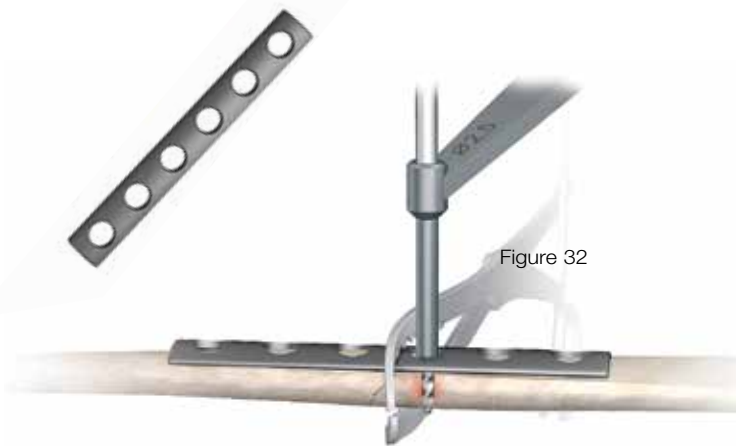
Insert the 2.9 mm end of the 2.9/4.0 mm drill guide into the plate hole and drill through both cortices with the 2.9 mm drill bit (Figure 29).

Measure the drilled hole by taking a direct reading from the NON-L line on the small fragment depth gauge (Figure 30).

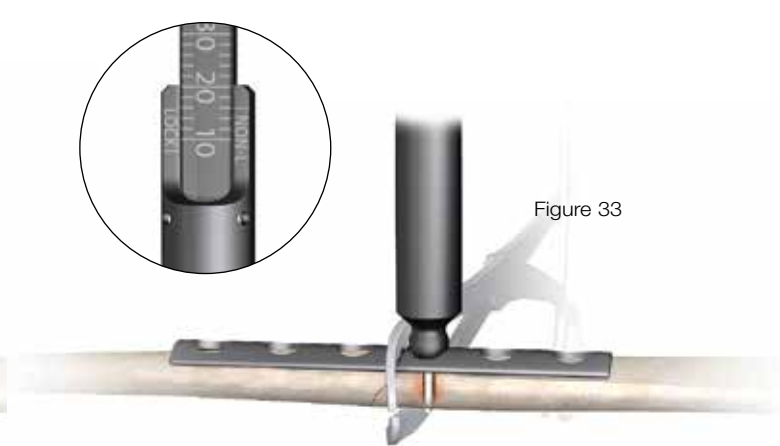
Insert the appropriate length 4.0 mm cancellous screw with the screw holder sleeve over the 2.5 mm hex driver coupled to the ratchet handle (Figure 31).

Tip: A tap (for each screw type) is available for use in dense bone.

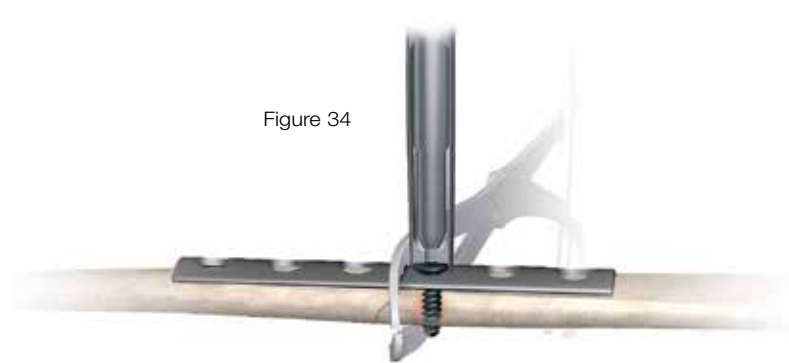
A.L.P.S. Small Fragment Plating System



Drill with the 2.5 mm drill bit through the 2.5/3.5 mm drill guide



Take a direct reading from the NON-L line on the depth gauge



Insert the 3.5 mm non-locking cortical screw using the 2.5 mm hex driver

One-Third Tubular Plate (14355-XX)

The one-third tubular plate is 1.3 mm thick and may be useful in areas with minimal soft tissue coverage, such as the olecranon and distal end of the ulna.

Note: It is recommended that the plate be long enough to allow screws to be placed through at least five or six cortices on either side of the fracture. If a longer plate is used, it is not necessary to fill every hole.

The oval holes allow eccentric positioning of the screws, which can be used for axial compression of a fracture when the plate is applied as a tension band plate. The plate is contoured to the shape of the bone utilizing a bending template as a model.

The fracture is reduced and the plate is applied to the bone and held in place with reduction forceps. Using a screw hole near the fracture, drill a hole through both cortices with the 2.5 mm drill bit and the 2.5/3.5 mm drill guide (Figure 32). Measure the drilled hole by taking a direct reading from the NON-L line on the small fragment depth gauge (Figure 33).

Select the appropriate length 3.5 mm cortical screw and insert with the screw holder sleeve over the 2.5 mm hex driver, but do not fully tighten (Figure 34).

Figure 35



Eccentrically place a screw on the opposite side of the fracture



Figure 36

In the screw hole near the fracture in the opposite fragment, place the 2.5 mm tip of the 2.5/3.5 mm drill guide in the eccentric position away from the fracture and drill through both cortices with the 2.5 mm drill bit (Figure 35). Measure the drilled hole by taking a direct reading from the NON-L line on the small fragment depth gauge and insert the selected 3.5 mm cortical screw. Tighten the first screw.

Add the remaining screws as determined by the fracture pattern. Perform final tightening of all screws (Figure 36).

Note: A 4.0 mm cancellous screw can be used if the screw is used in cancellous bone. The 4.0 mm cancellous screws utilize a 2.9 mm drill bit, a 4.0 mm tap and corresponding drill guides and tissue protectors.

The plate can also be applied as a neutralization plate in fractures with butterfly fragments or spiral components. After fracture reduction interfragmentary fixation with independent lag screws is performed to stabilize the fracture. The plate is then applied in neutral mode (no compression) using 3.5 mm cortical screws or 4.0 mm cancellous screws according to the bone type.

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Figure 37

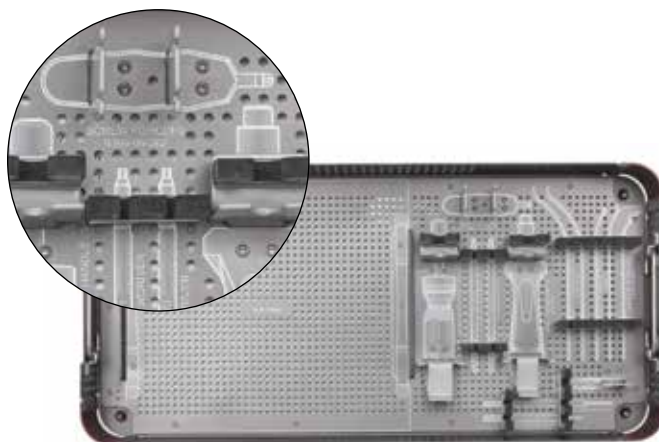


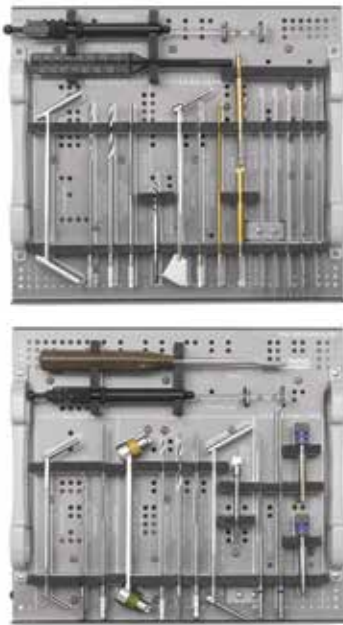
Figure 38

Instrument Trays

The small fragment case was designed to reflect the varied functional requirements of our customers. The system consists of two screw modules, one plate module and two instrument trays (Figure 37).

The entire system can be housed in one large base or it can be split into a separate instrument and implant base.

The trays contain three-dimensional graphics for rapid implant and instrument identification enhancing both surgical and processing efficiencies (Figure 38).



The screw instruments
double sided flip tray

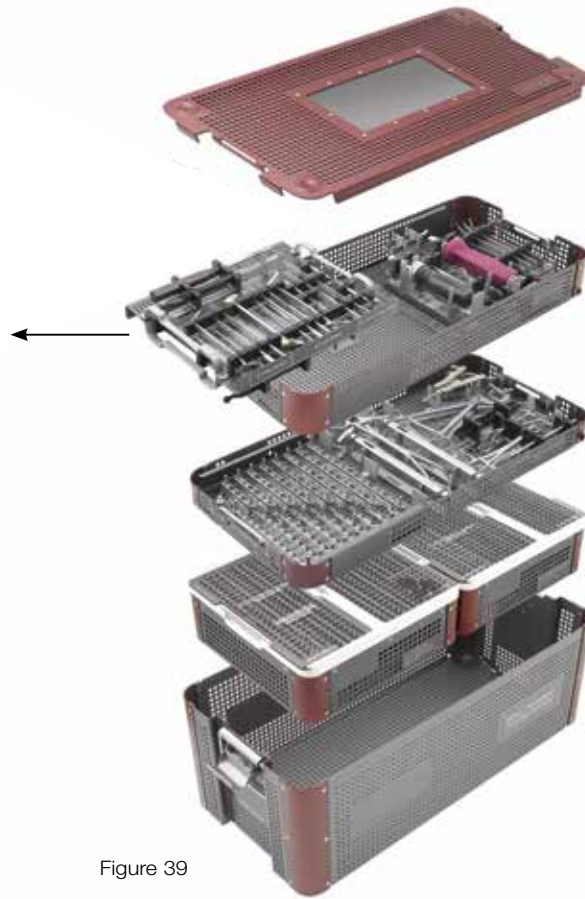
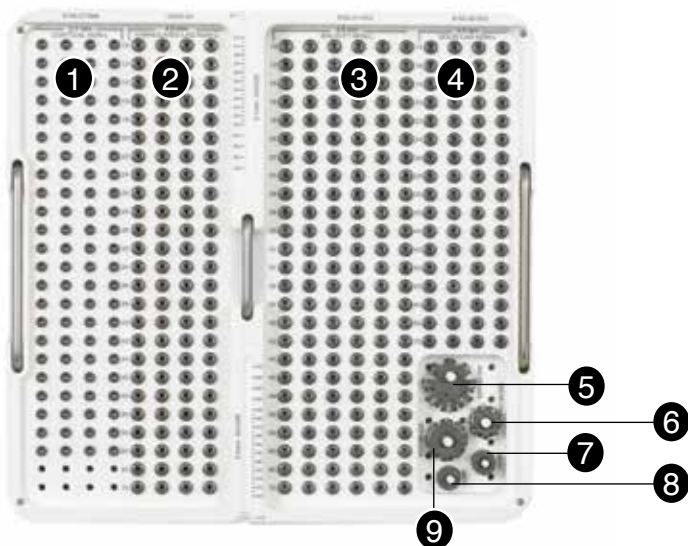


Figure 39

The screw instruments are contained on an innovative “flip” tray that can be placed on the Mayo stand permitting rapid transition between the various screw types. Everything needed for implant insertion is at your fingertips (Figure 39).

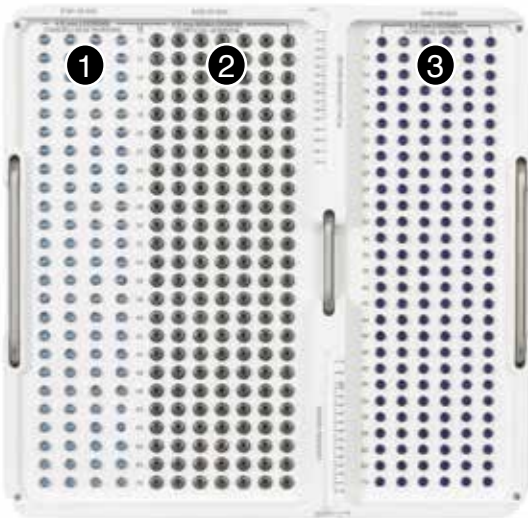
A.L.P.S. Small Fragment Plating System

Instrument Trays



Small Fragment Screw Modules

- | | |
|----------------|--|
| 1. 8140-27-0XX | 2.7 mm Cortical Screws, Non-locking (Optional)
10 – 50 mm in 2 mm increments
50 – 70 mm in 5 mm increments |
| 2. 14376-XX | 4.0 mm Cannulated Cancellous Screws Partial Thread, Non-locking
10 – 50 mm in 2 mm increments
50 – 70 mm in 5 mm increments |
| 3. 8153-41-0XX | 4.0 mm Cancellous Screws Full Thread, Non-locking
10 – 50 mm in 2 mm increments
50 – 70 mm in 5 mm increments |
| 4. 8155-40-0XX | 4.0 mm Cancellous Screws Partial Thread, Non-locking
14 – 30 mm in 2 mm increments
30 – 70 mm in 5 mm increments |
| 5. 8141-00-004 | 25 mm Spider Plate, Offset* |
| 6. 8141-00-002 | 16 mm Spider Plate |
| 7. 14460 | Flat Washer |
| 8. 14461 | Cup Washer |
| 9. 8141-00-003 | 20 mm Spider Plate
The Spider Plates are indicated for fixation of metaphyseal fractures of the distal tibia, proximal metaphyseal tibia fractures and proximal humeral head/shaft fractures. |



Small Fragment Screw Modules

- | | |
|----------------|--|
| 1. 8161-40-0XX | 4.0 mm Cancellous Screws, Full Thread, Locking
10 – 50 mm in 2 mm increments
50 – 70 mm in 5 mm increments |
| 2. 8150-37-0XX | 3.5 mm Cortical Screws, Non-Locking
10 – 50 mm in 2 mm increments
50 – 70 mm in 5 mm increments |
| 3. 8161-35-0XX | 3.5 mm Cortical Screws, Locking
10 – 60 mm in 2 mm increments
60 – 70 mm in 5 mm increments |

A.L.P.S. Small Fragment Plating System

Instrument Trays

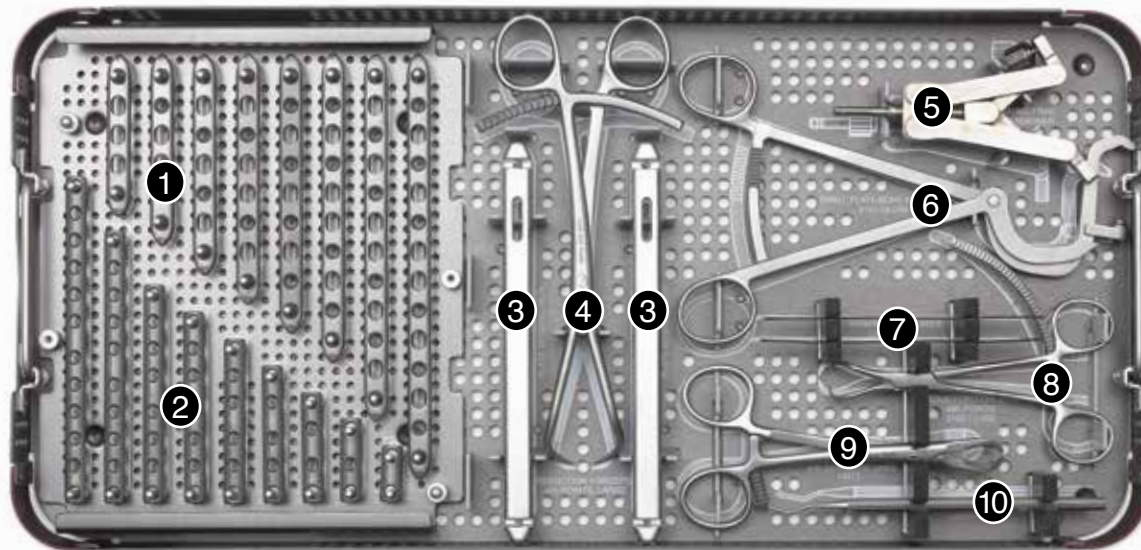


Plate Module/Reduction Instrument Tray

1. 3.5 mm Locking Compression Plates

8162-35-005	5 Hole	72.6 mm
8162-35-006	6 Hole	85.6 mm
8162-35-007	7 Hole	98.6 mm
8162-35-008	8 Hole	111.6 mm
8162-35-009	9 Hole	124.6 mm
8162-35-010	10 Hole	137.6 mm
8162-35-012	12 Hole	163.6 mm
8162-35-014	14 Hole	189.6 mm

Profile:

Width: 10.3 mm

Thickness: 3.7 mm

Distance between center of holes: 13 mm

2. 3.5 mm 100 Degree Tubular Plates

14355-2	2 Hole	25 mm
14355-3	3 Hole	37 mm
14355-4	4 Hole	49 mm
14355-5	5 Hole	61 mm
14355-6	6 Hole	73 mm
14355-7	7 Hole	85 mm
14355-8	8 Hole	97 mm
14355-10	10 Hole	109 mm
14355-12	12 Hole	121 mm

Profile:

Width: 9.2 mm

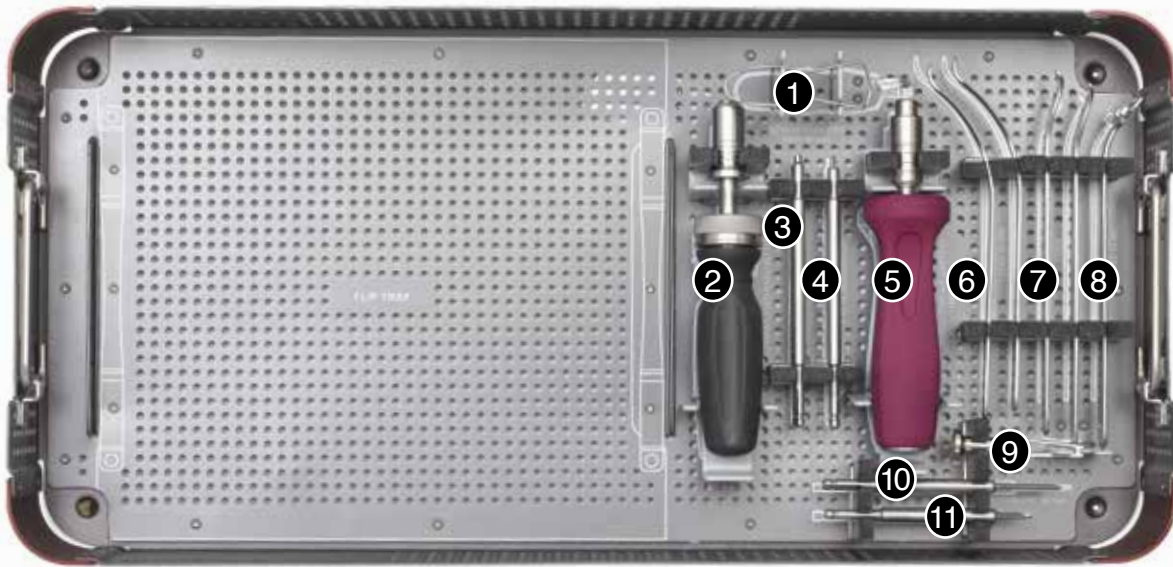
Thickness: 1.3 mm

Distance between center of holes: 11.4 mm

Distance between central holes: 16 mm

- | | | |
|-----|-------------|--|
| 3. | 8241-29-000 | Plate Bending Irons, 2 each |
| 4. | 13577 | Reduction Forceps with Points, Large |
| 5. | 2142-76-001 | Small Frag Tensioner |
| 6. | 2142-76-000 | Small Plate/Bone Forceps |
| 7. | 2142-74-000 | Bending Templates, 2 each |
| 8. | 2142-13-568 | Reduction Forceps with Points, 2 each |
| 9. | 13573 | Reduction Forceps with Serrated Jaws, 2 each |
| 10. | 13572 | Sharp Hook |

The tubular plates are indicated for fracture fixation of the fibula, lateral malleolus, metatarsals, metacarpals, olecranon, distal humerus, humeral head, radius, ulna and intra-articular distal tibia.

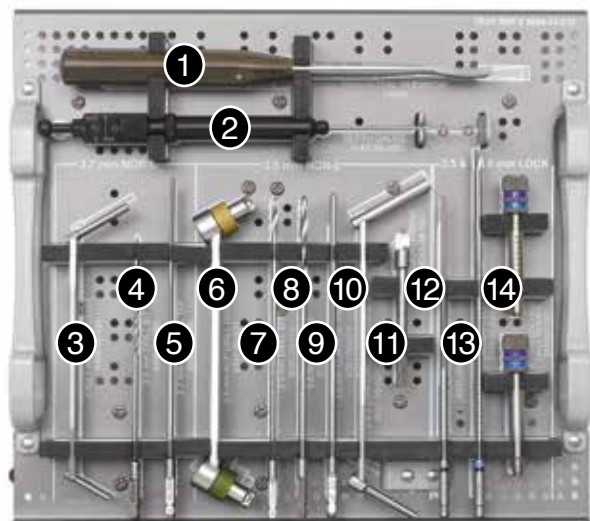


Screw Instrument Tray

- | | |
|-----------------|----------------------------------|
| 1. 9399-99-262 | Screw Forceps |
| 2. 8261-66-000 | Cannulated Ratchet Handle |
| 3. 8241-57-071 | 2.5 mm Hex Screwdriver, 2 each |
| 4. 2142-15-070 | T-15 Screwdriver, 2 each |
| 5. 2141-18-001 | 2.0 Nm Torque-Limiting Handle |
| 6. 2142-75-000 | Bent Hohmann Retractors, 2 each |
| 7. 13569 | Cobra Hohmann Retractors, 2 each |
| 8. 2142-13-567 | Plate End Retractor |
| 9. 8241-66-000 | Screw Holder Sleeve |
| 10. 8242-99-001 | Fixation Pin, 26 mm, 2 each |
| 11. 8242-99-000 | Fixation Pin, 12 mm, 2 each |

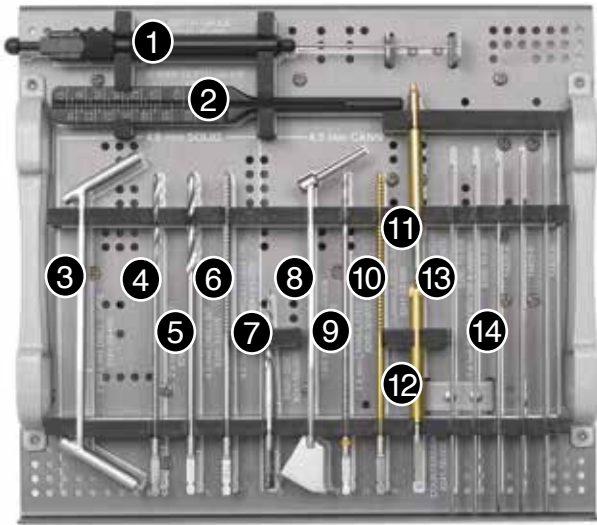
A.L.P.S. Small Fragment Plating System

Instrument Trays



Flip Tray - Side 1

- | | |
|-----------------|-------------------------------------|
| 1. 13566 | Periosteal Elevator |
| 2. 2142-35-100 | Depth Gauge |
| 3. 9399-99-435 | 2.0/2.7 mm Drill Guide |
| 4. 9399-99-382 | 2.0 mm Drill Bit, 2 each |
| 5. 9399-99-386 | 2.7 mm Cortical Tap, 2 each |
| 6. 8241-68-000 | 2.5 mm ACP Drill Guide |
| 7. 8290-29-070 | 2.5 mm Drill Bit, 2 each |
| 8. 8290-32-070 | 3.5 mm Drill Bit, 2 each |
| 9. 8241-50-070 | 3.5 mm Cortical Tap, 2 each |
| 10. 8241-96-000 | 2.5/3.5 mm Drill Guide |
| 11. 8241-58-100 | Countersink |
| 12. 8241-35-077 | 3.5 mm Locking Cortical Tap, 2 each |
| 13. 2142-27-070 | 2.7 mm Calibrated Drill Bit, 2 each |
| 14. 2142-07-027 | 2.7 mm Locking Drill Guides |



Flip Tray - Side 2

- | | | |
|-----|-------------|-------------------------------------|
| 1. | 2142-35-100 | Depth Gauge |
| 2. | 13545 | K-Wire Depth Gauge |
| 3. | 2141-29-400 | 2.9/4.0 mm Drill Guide |
| 4. | 8290-31-070 | 2.9 mm Drill Bit, 2 each |
| 5. | 8290-33-070 | 4.0 mm Drill Bit, 2 each |
| 6. | 8290-61-070 | 4.0 mm Cancellous Tap, 2 each |
| 7. | 8241-59-000 | Easy Out |
| 8. | 8241-64-070 | 1.6/2.9 mm Drill Guide |
| 9. | 8290-30-070 | 2.9 mm Cannulated Drill Bit, 2 each |
| 10. | 8241-62-000 | 4.0 mm Cannulated Tap, 2 each |
| 11. | 8241-56-070 | Cannulated Screwdriver, 2 each |
| 12. | 8241-58-000 | Cannulated Countersink |
| 13. | 8290-16-006 | 1.6 mm Threaded Tip K-Wires, 6 each |
| 14. | 14425-6 | 1.6 mm K-Wires, 12 each |

Important:

This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications:

The use of metallic surgical appliances (screws, plates, intramedullary nails, compression hip screws, pins and wires) provides the orthopaedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide to normal healing, and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subjected to repeated stress in use, which can result in metal fatigue.

Contraindications:

Screws, plates, intramedullary nails, compression hip screws, pins and wires are contraindicated in: active infection, conditions which tend to retard healing such as blood supply limitations, previous infections, insufficient quantity or quality of bone to permit stabilization of the fracture complex, conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process, foreign body sensitivity, and cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients.

Additional Contraindication for Orthopaedic Screws and Plates only:

Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.

Additional Contraindication for Retrograde Femoral Nailing:

A history of septic arthritis of the knee and knee extension contracture with inability to attain at least 45° of flexion.

Additional Contraindications for Compression Hip Screws only:

Inadequate implant support due to the lack of medial buttress.

Warnings and Precautions:

Bone screws and pins are intended for partial weight bearing and non-weight bearing applications. These components cannot be expected to withstand the unsupported stresses of full weight bearing.

Adverse Events:

The following are the most frequent adverse events after fixation with orthopaedic screws, plates, intramedullary nails, compression hip screws, pins and wires: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation; infection and allergies and adverse reactions to the device material. Surgeons should take care when targeting and drilling for the proximal screws in any tibial nail with oblique proximal screws. Care should be taken as the drill bit is advanced to penetrate the far cortex. Advancing the drill bit too far in this area may cause injury to the deep peroneal nerve. Fluoroscopy should be used to verify correct positioning of the drill bit.

Additional Adverse Events for Compression Hip Screw only:

Screw cutout of the femoral head (usually associated with osteoporotic bone).

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For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the product labeling.



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