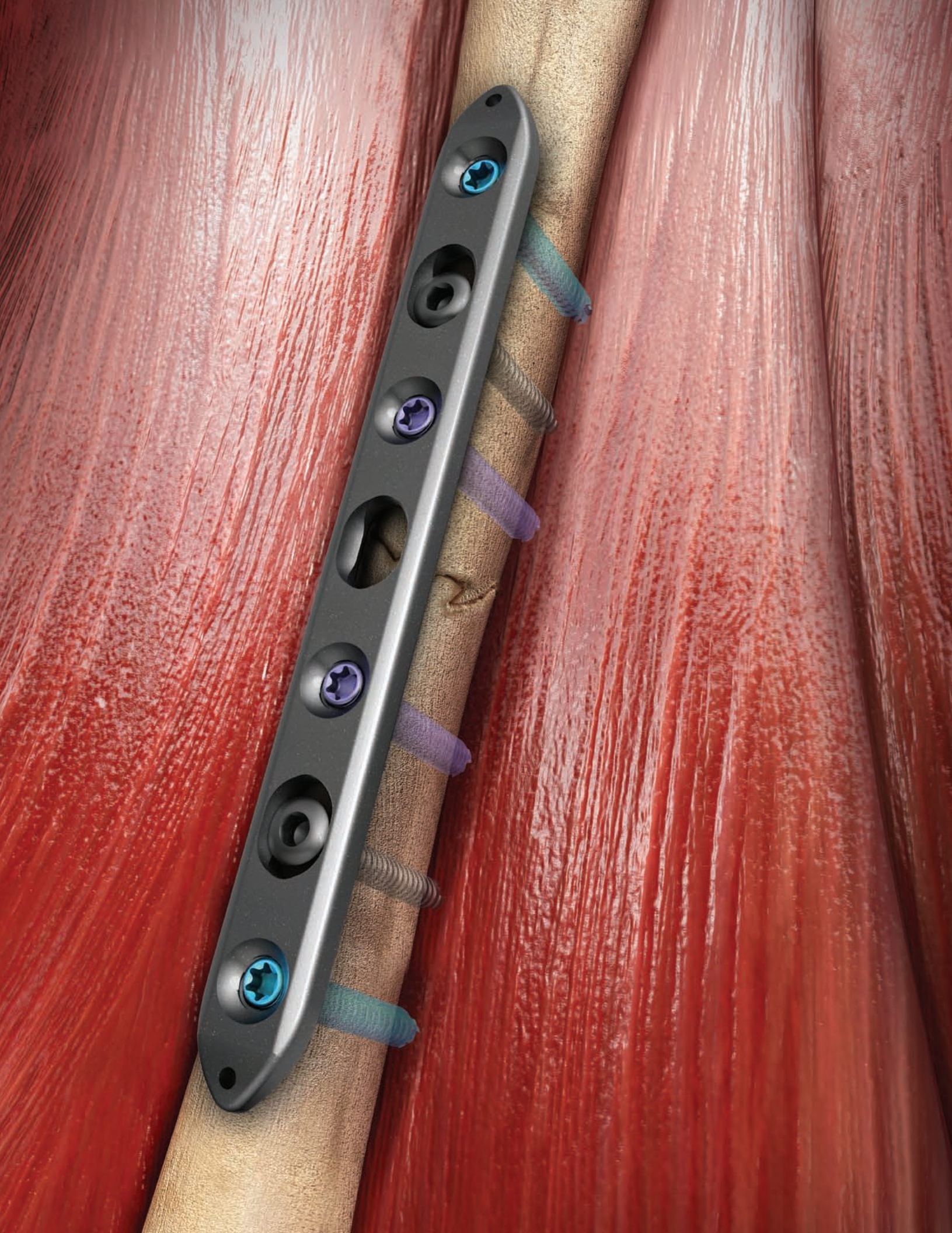




Small Fragment Plating System

Securing optimal fixation through locked
and compression plating technology



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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 improved fixation in osteopenic bone or when optimal screw purchase is required.

The DePuy 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.

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
- distal 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

Interfragmentary Fixation



Figure 1

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.



Figure 2

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 (Cat. No. 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 (Cat. No. 8290-32-070) using the 2.5/3.5 mm Drill Guide (Cat. No. 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.

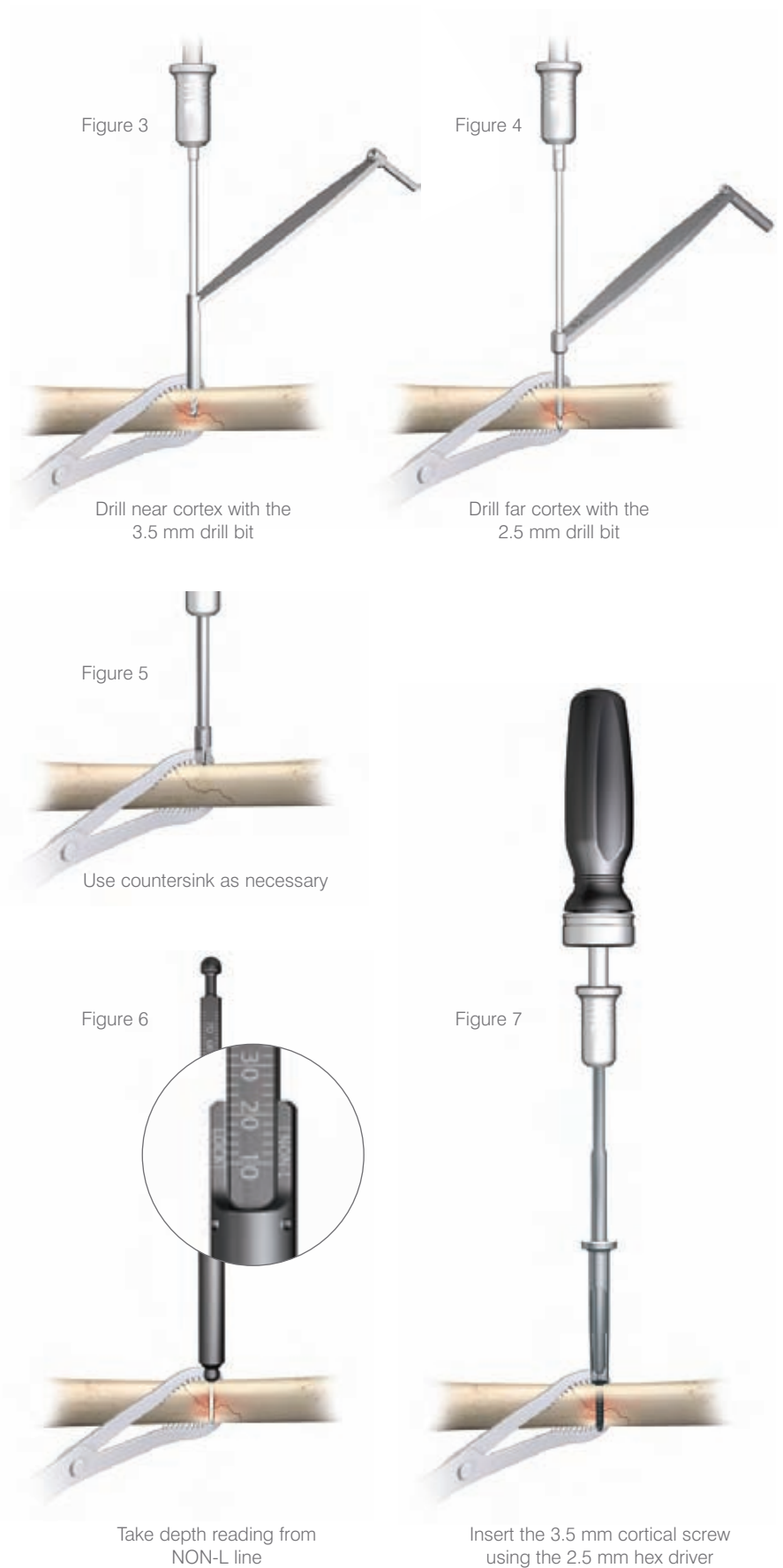
Insert the 2.5 mm drill guide into the glide hole. Drill a pilot hole into the far cortex with the 2.5 mm Drill Bit (Cat. No. 8290-29-070) (Figure 4).

Note: If necessary, prepare the near cortex with the Countersink (Cat. No. 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 (Cat. No. 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 (Cat. No. 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 (Cat. No. 8150-37-0XX) by hand or with power using the Screw Holder Sleeve (Cat. No. 8241-66-000) over the 2.5 mm Hex Driver (Cat. No. 8241-57-071) in the Ratchet Handle (Cat. No. 8261-66-000) or drill (Figure 7). Always perform final seating of the screw by hand.



Interfragmentary Fixation



Figure 8

Drill perpendicular to the fracture plane with the 2.9 mm drill bit

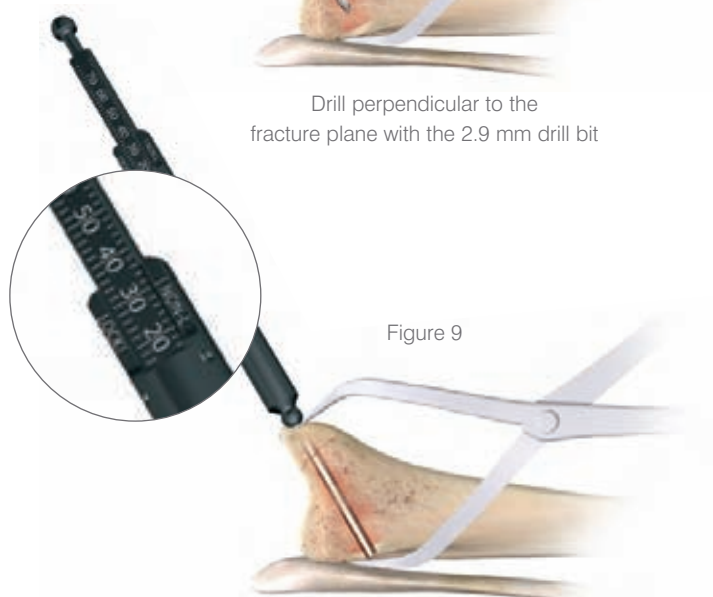


Figure 9

Take depth reading from NON-L line

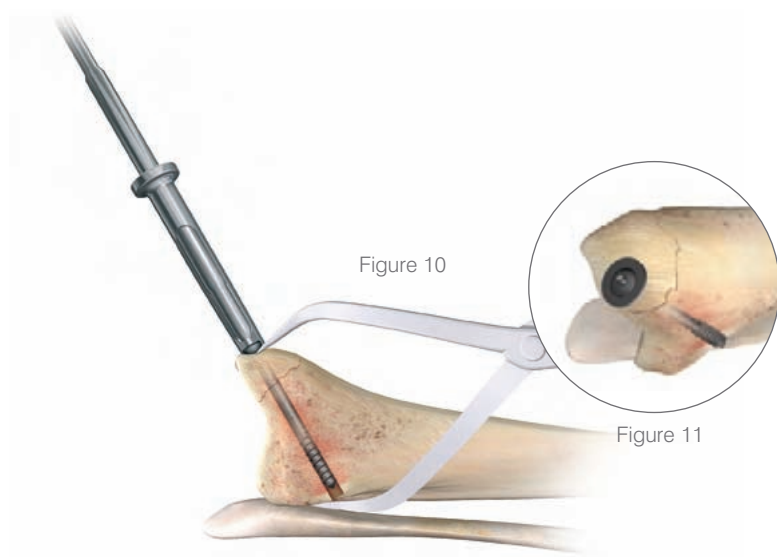


Figure 10

Figure 11

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

4.0 mm Cancellous Lag Screws

(Cat. no. 8155-40-0XX)

Reduce the fracture and maintain the reduction with bone forceps. Drill both cortices with the 2.9 mm Drill Bit (Cat. No. 8290-31-070) perpendicular to the plane of the fracture using the 2.9/4.0 mm Drill Guide (Cat. No. 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 (Cat. No. 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 (Cat. No. 14460) or Cupped Washer (Cat. No. 14461), may prevent the screw head from sinking into the near cortex and allow better compression across the fracture site (Figure 11).

4.0 mm Cannulated Cancellous Screws (Cat. No. 14376-XX)

Reduce the fracture and maintain the reduction with bone forceps. Insert a 1.6 mm x 6 in. K-wire (Cat. No. 8290-16-006 or 14425-6) perpendicular to the plane of the fracture using the 1.6/2.9 mm Drill Guide (Cat. No. 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 (Cat. No. 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 (Cat. No. 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 (Cat. No. 14376-XX) over the K-wire and insert by hand or with power using the Cannulated Hex Driver (Cat. No. 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.

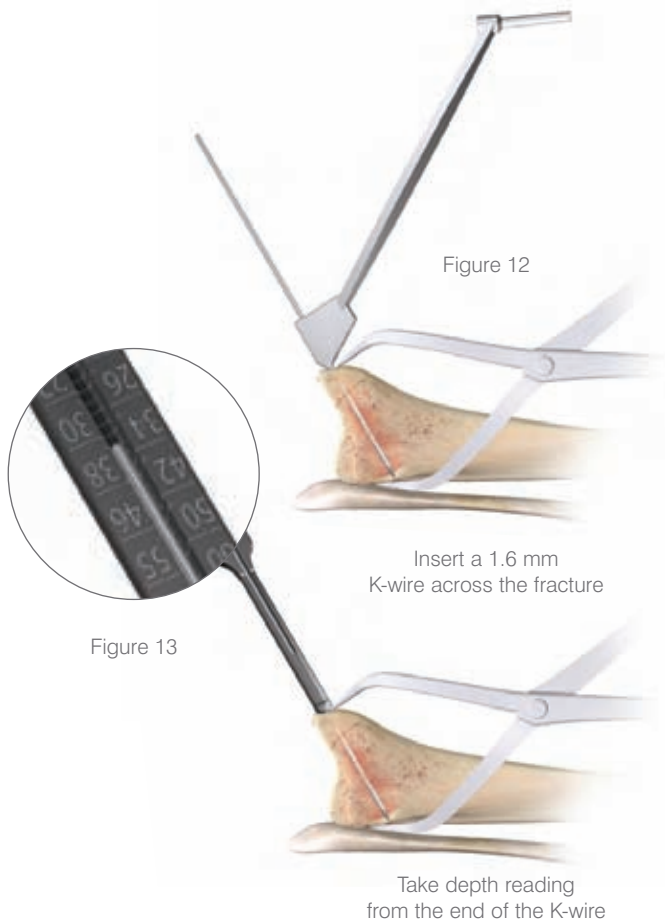


Plate Selection



Locking Compression Plate (Cat. No. 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. Screw holes are an option for screw placement, not a requirement. 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 near cortex, with locked screws placed in selected, as well as terminal screw holes. 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

(Cat. No. 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

(Cat. No. 2142-76-000) Slide the serrated foot of one limb of the clamp onto the undersurface 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).



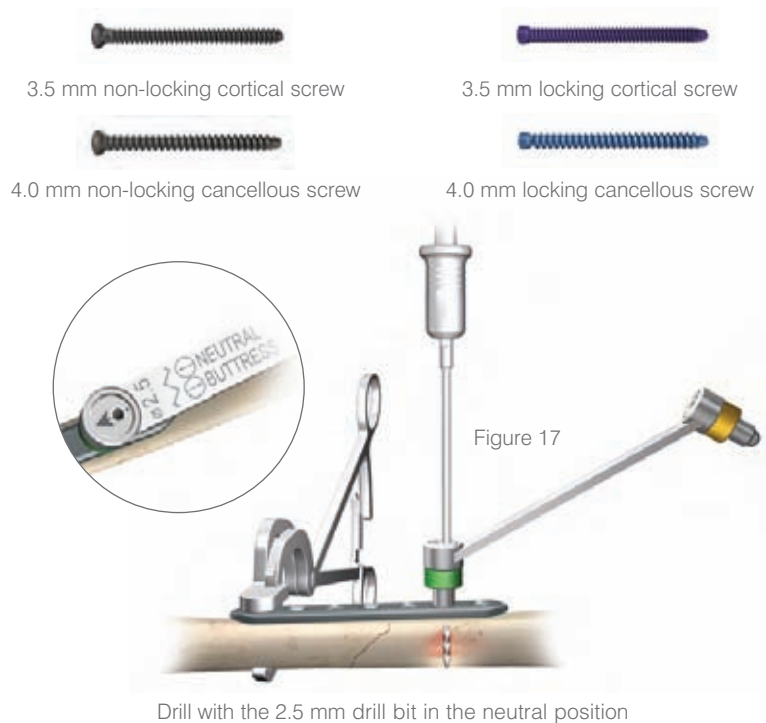
Figure 16

Plate Insertion

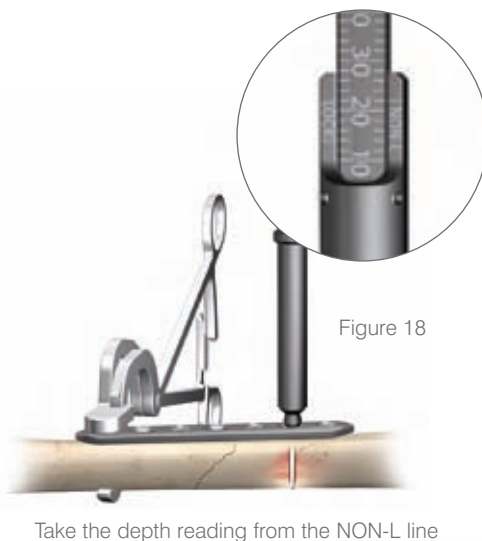
Screw Insertion: Determine the type of screw to be used: 3.5 mm locking cortical, 3.5 mm non-locking cortical, 4.0 mm locking cancellous or 4.0 mm non-locking cancellous. Any combination of screws can be used. If a combination of locking and non-locking screws is used, a non-locking screw should be inserted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

Neutral Insertion of a 3.5 mm Non-Locking Cortical Screw in a Compression Slot

Insert the neutral (green) end of the 2.5 mm ACP Drill Guide (Cat. No. 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.



Plate Insertion

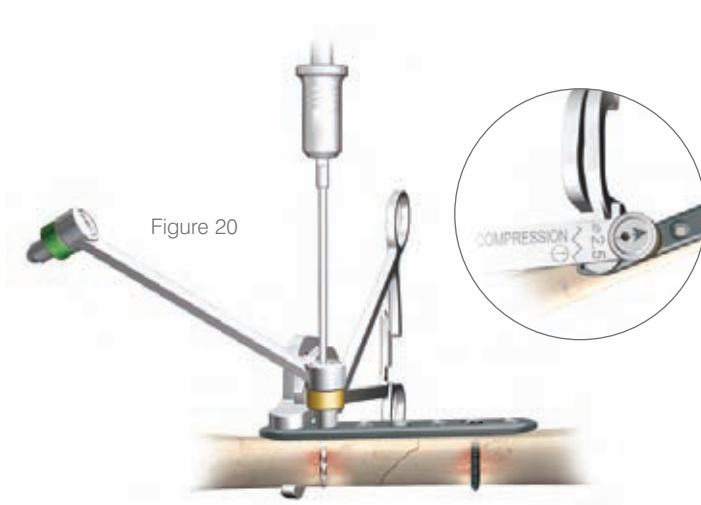


Figure 20

Drill with the 2.5 mm drill bit in the eccentric position.

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).



Figure 21

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



Figure 22

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

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.

Insertion of a Locking Screw (3.5 mm Cortical Cat. No. 8161-35-0XX or 4.0 mm Cancellous Cat. No. 8161-40-0XX) in a Threaded Hole

Screw the 2.7 mm Locking Drill Guide (Cat. No. 2142-07-027) into a threaded plate hole until fully seated. Drill with the 2.7 mm Calibrated Drill Bit (Cat. No. 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.

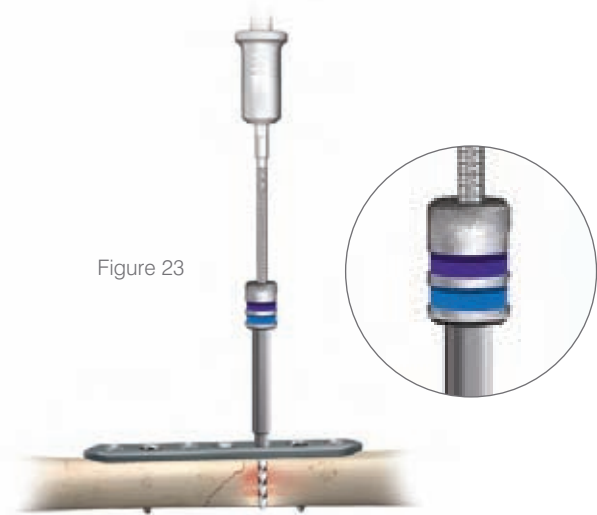


Figure 23

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



Figure 24

Take the depth reading from the LOCK line

Insert the selected locking screw with the T-15 Driver (Cat. No. 2142-15-070) coupled to the 2.0 Nm Torque-Limiting Screwdriver Handle (Cat. No. 2141-18-001) (Figure 25).

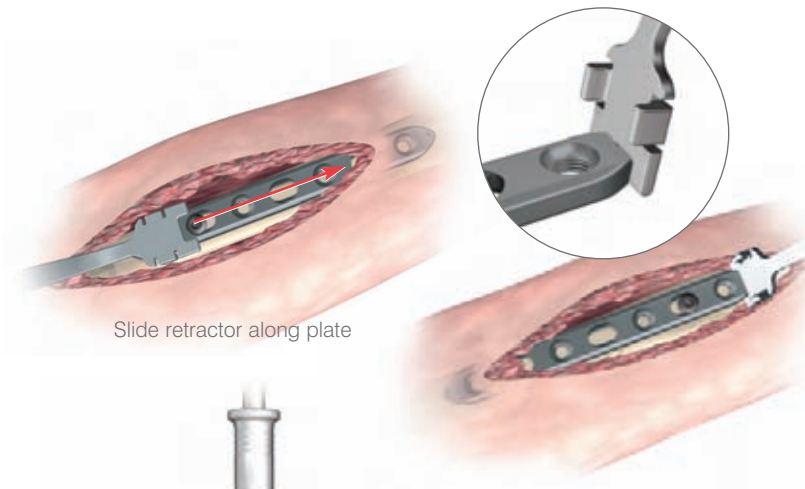
Tip: Using a power screwdriver is not recommended for insertion of any locking screws. Perform all final screw tightening by hand with the torque-limiting screwdriver handle.



Figure 25

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

Plate Insertion



Slide retractor along plate

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.

Figure 26



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

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).

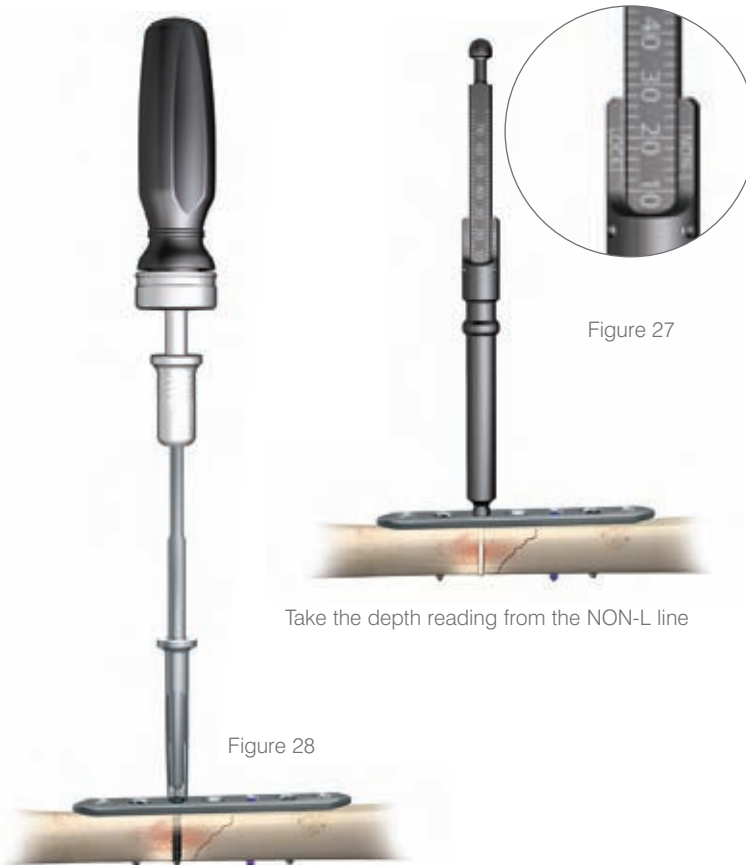


Figure 27

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

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).

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).



Figure 29

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

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

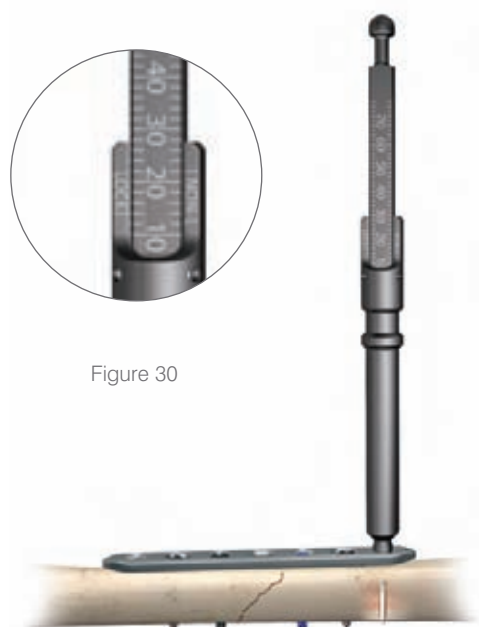


Figure 30

Take the depth reading from the NON-L line

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.

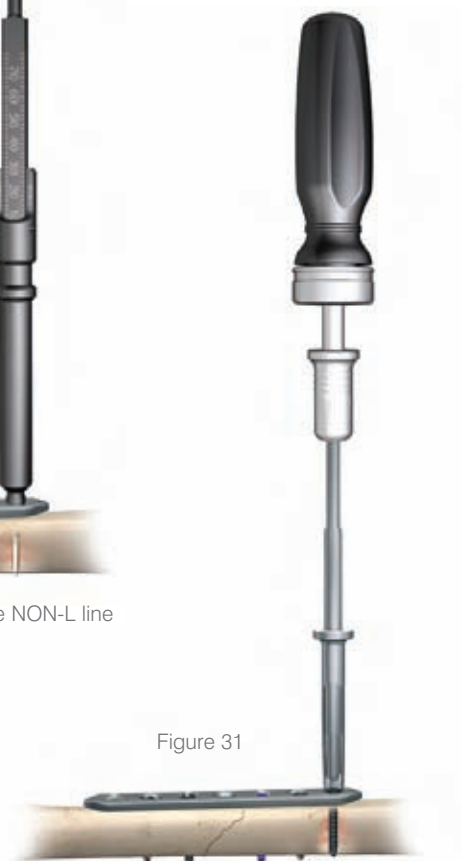


Figure 31

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

Plate Insertion

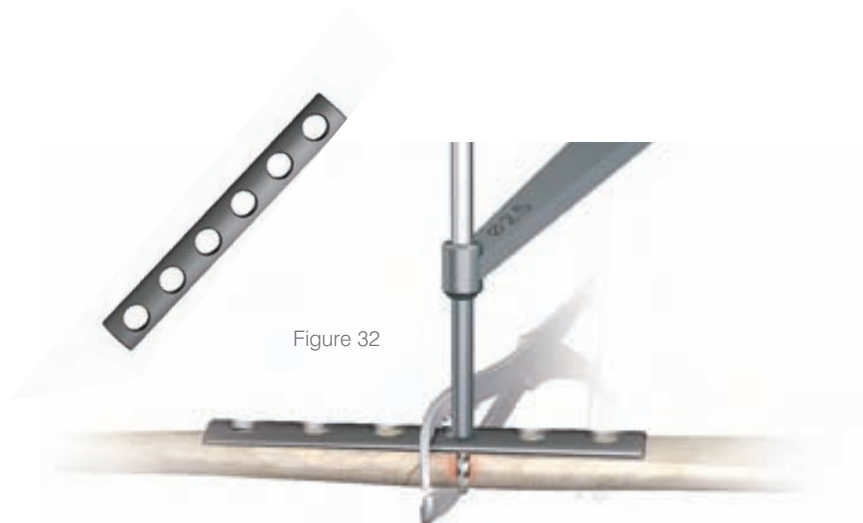


Figure 32

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

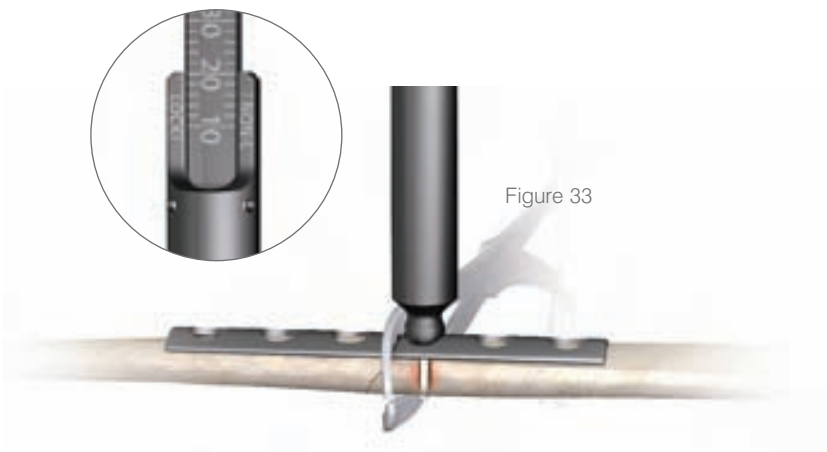


Figure 33

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



Figure 34

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

One-Third Tubular Plate (Cat. No. 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 lateral malleolus, 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).

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.



Figure 35

Eccentrically place a screw
on the opposite side of the fracture

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



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.

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.



Figure 37

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

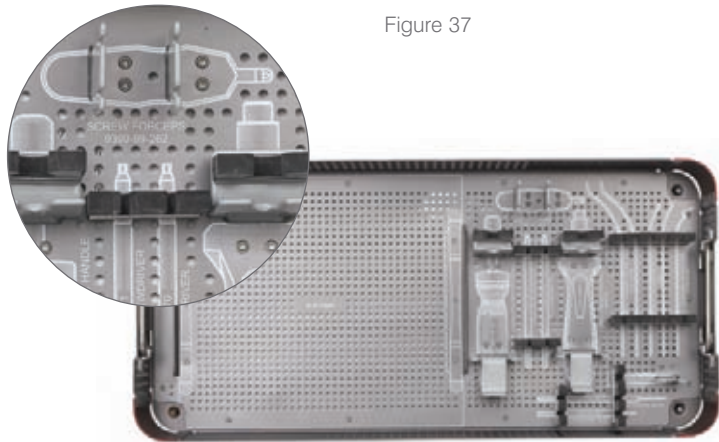


Figure 38

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 (Figures 39).

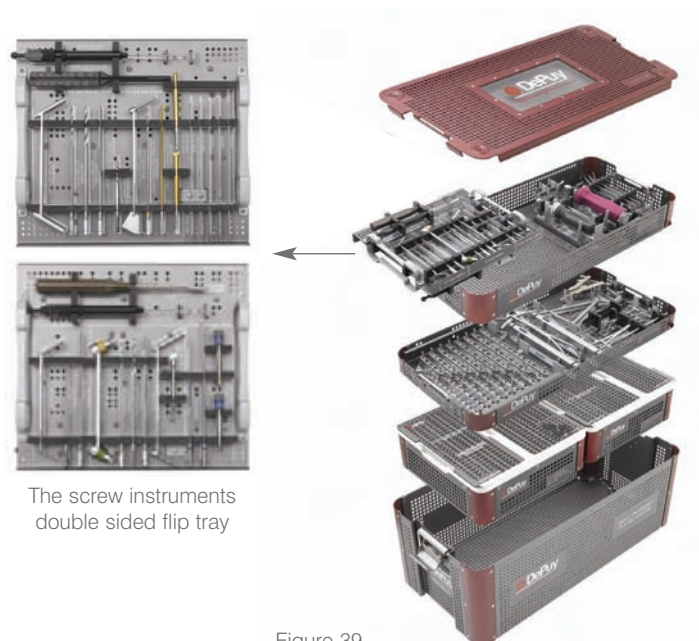


Figure 39

Surgeon Design Team

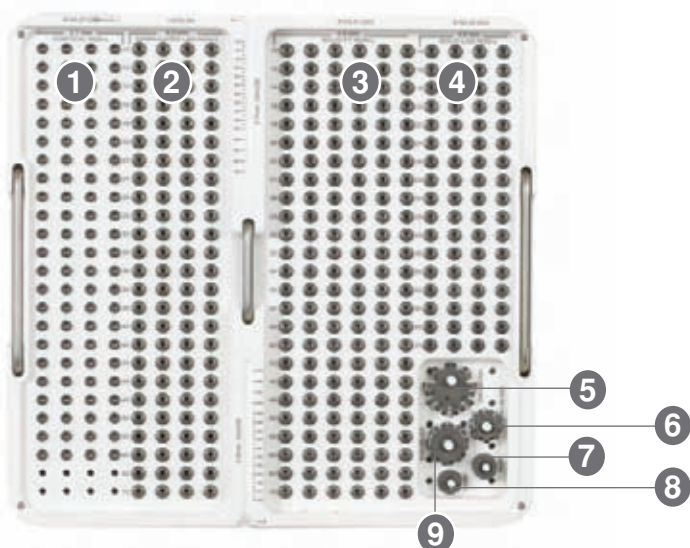
Roy Sanders, M.D.
Chief, Department of Orthopaedics,
Tampa General Hospital
Director, Orthopaedic Trauma Services,
Florida Orthopaedic Institute,
Tampa, Florida

George Haidukewych, M.D.
Orthopaedic Trauma Service,
Florida Orthopaedic Institute,
Tampa General Hospital,
Tampa, Florida

David M. Huebner, M.D.
Director of Orthopaedic Trauma,
Good Samaritan Hospital,
Kearney, Nebraska

Michael Wich, M.D.
Deputy Head,
Department of Trauma and Orthopaedic Surgery,
Unfallkrankenhaus Berlin,
Berlin, Germany

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 |



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 |

Instrument Trays

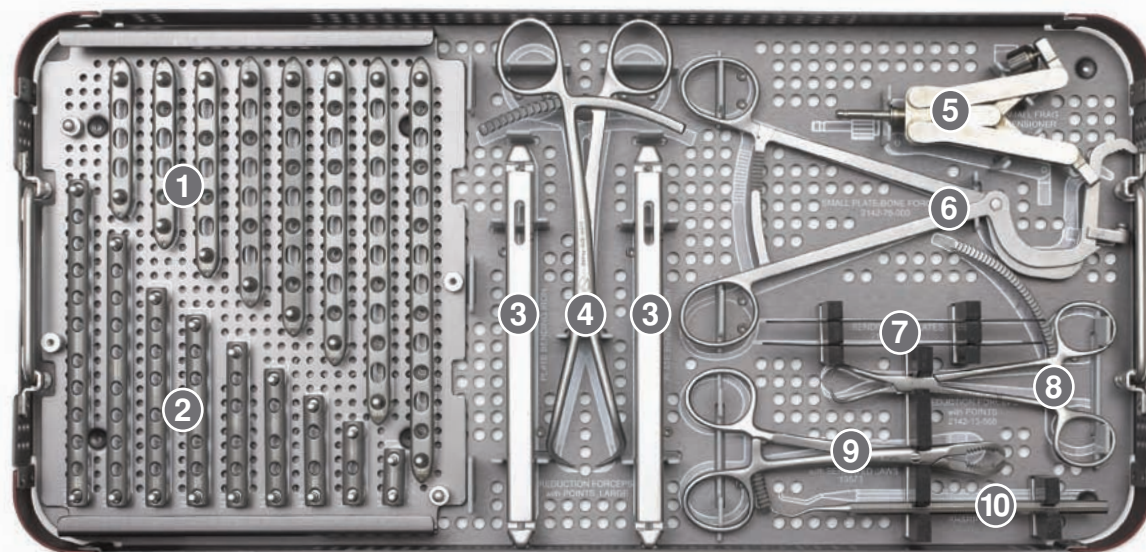


Plate Module/Reduction Instrument Tray

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

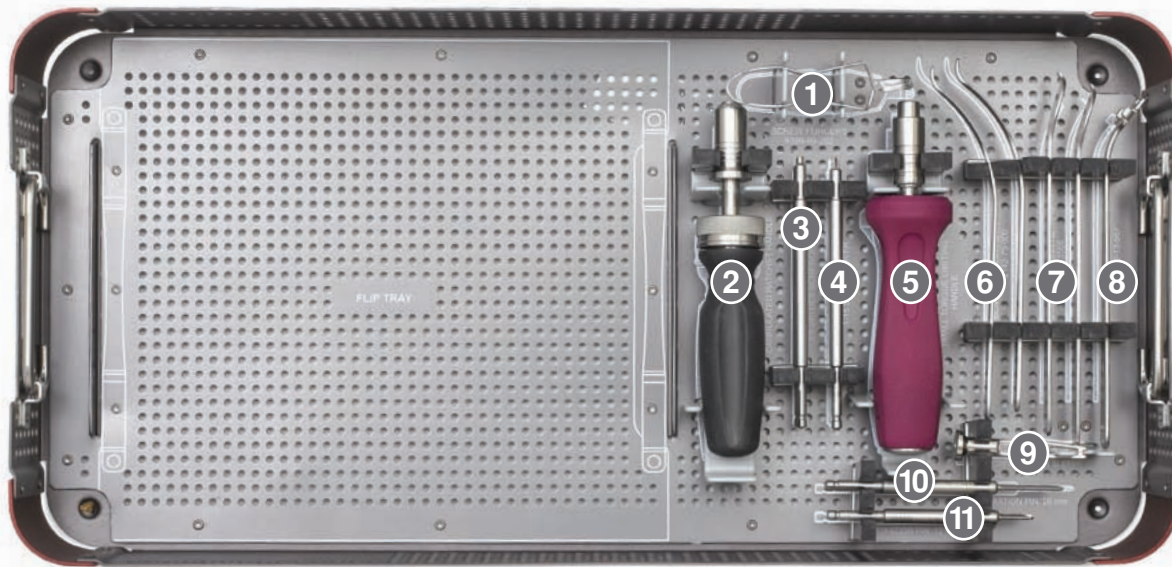
Thickness: 1.3 mm

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 |

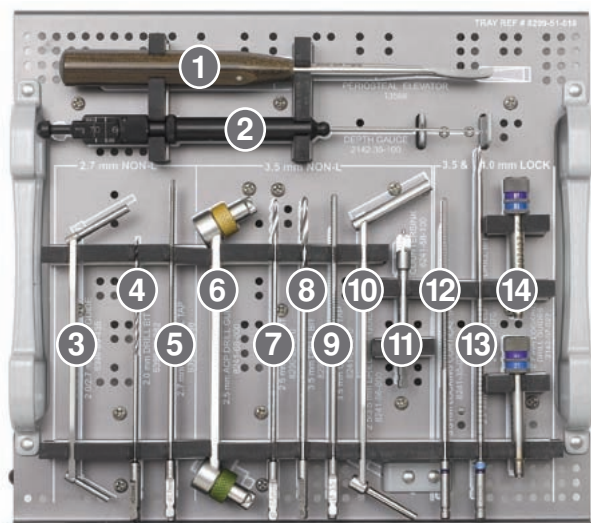
Instrument Trays



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 |

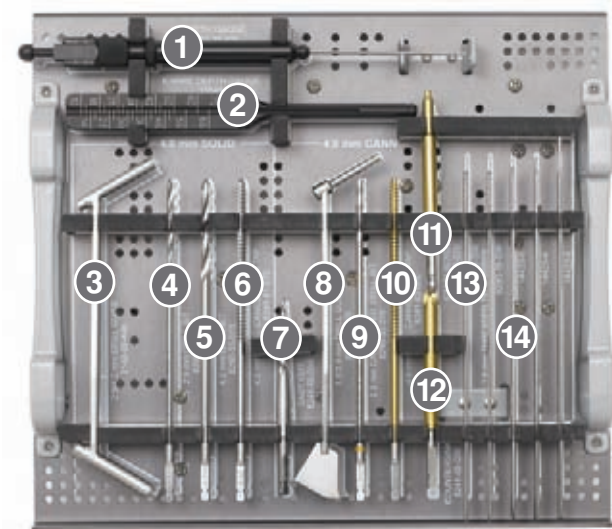
Instrument Trays



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 |

Instrument Trays



Flip Tray - Side 2

- | | |
|-----------------|-------------------------------------|
| 1. 2142-35-100 | Depth Gauge |
| 2. 13545 | K-Wire Depth Gauge |
| 3. 2142-29-400 | 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 bone plates and screws 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:

- 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
- Cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients
- 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:

Bone screws and plates 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 plates and screws: 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.



DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46580-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 371 4865

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (0)113 387 7800
Fax: +44 (0)113 387 7890

