ALPS
LARGE FRAGMENT SYSTEM

Large Fragment
Plating System

Surgical Technique

BIOMET®

A.L.P.S.™ Large Fragment Plating System

Contents

A.L.P.S.™ Large Fragment Plating System

Hybrid Compression Plating Technology (HCP®) for compression and locked fixation

Compression screw fixation

The oval screw hole can accept non-locking screws to allow for up to 90 degrees of axial and 32 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 Biomet Large 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 large fragment fixation, as well as, to serve as the core system for additional anatomic implants.

Introduction

The Biomet Large 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 large fragment fixation.

Indications for Use:

Fixation of fractures of various long bones such as the:

- femur
- tibia
- humerus

The Hybrid Compression Plates are further indicated for use in fixation of osteopenic bone and fixation stabilization of nonunions, malunions, and osteotomies.

System Contents:

- 4.5 mm Hybrid Compression Plates (HCP®), Broad and Narrow
- T - Plates
- L - Plates
- 4.5 mm Cortical Screws, Locking
- 4.5 mm Cortical Screws, Non-locking
- 5.5 mm Cancellous Screws, Locking
- 6.5 mm Cancellous Lag Screws, 22 mm Thread, Non-locking
- 6.5 mm Cancellous Lag Screws, 40 mm Thread, Non-locking
- 6.5 mm Cancellous Screws, Full Thread, Non-locking
- 4.5 mm Flat Washers
- 6.5 mm Cupped Washers
- 6.5 mm Flat Washers

4.5 mm Hybrid Compression Plate (HCP®)

Features:

4.5 mm Hybrid Compression Plate (HCP®)

- Uniform hole spacing
- Compression, neutral and buttress screw positions
- Threaded holes for locking screw option
- 90 degrees of axial screw angulation
- 32 degrees of transverse screw angulation
- 3 mm of compression
- Bullet-shaped plate ends for submuscular insertion
- 4 – 14 holes, Narrow Plate
- 6 – 14 holes, Broad Plate

4.5 mm Locking Cortical Screw

- Larger core diameter and thread pitch compared to a standard 4.5 mm cortical screw
- Self tapping tip minimizes the need for pre-tapping and eases screw insertion
- Hex 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 8 – 60 mm in 2 mm increments and 65 mm

5.5 mm Locking Cancellous Screw

- Hex 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 26 – 50 mm, 55 – 100 mm in 5 mm increments

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 applications 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 4.5 mm cortical screws are generally selected for use in diaphyseal bone. The 6.5 mm cancellous bone screws are generally used in metaphyseal bone (Figure 2).

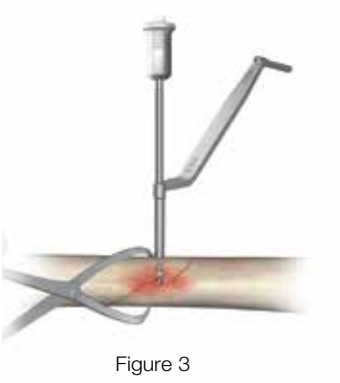


Figure 3
Drill near cortex with the
4.5 mm drill bit

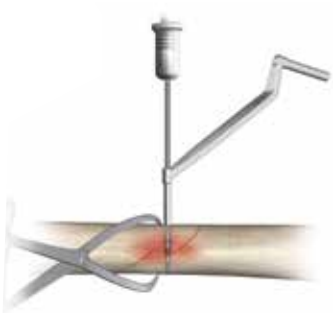


Figure 4
Drill far cortex with the
3.2 mm drill bit

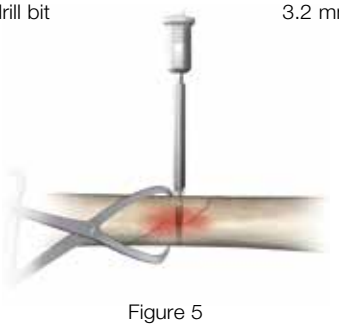


Figure 5
Use countersink as necessary

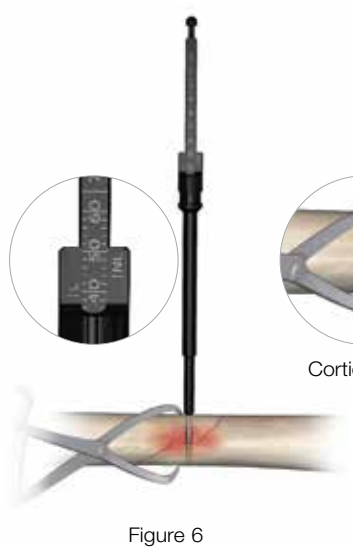


Figure 6
Take depth reading from
NL line

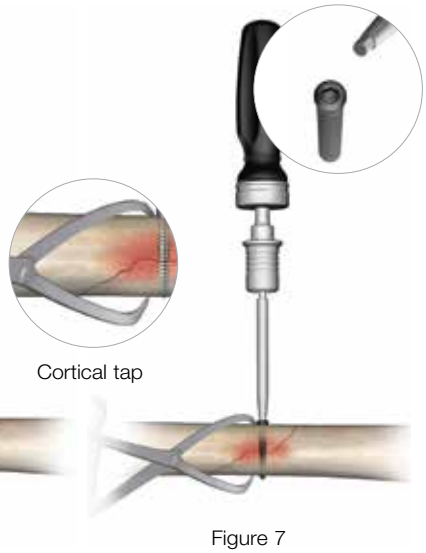


Figure 7
Insert the 4.5 mm cortical screw
using the 3.5 mm hex driver

4.5 mm Cortical Screws (Cat. No. 8157-45-0XX)

Reduce the fracture and maintain the reduction with bone forceps. Drill a gliding hole in the near cortex with the 4.5 mm Drill Bit (Cat. No. 8242-73-000) using the 3.2/4.5 Double Drill Guide (Cat. No. 8241-97-000) (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 3.2 mm drill guide into the glide hole. Drill a pilot hole into the far cortex with the 3.2 mm Drill Bit (Cat. No. 9399-99-315) (Figure 4).

Note: If necessary, prepare the near cortex with the Countersink (Cat. No. 8242-20-100) 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 NL line on the Large Fragment Depth Gauge (Cat. No. 8162-99-007) (Figure 6).

Note: In hard or dense bone, tap the pilot hole in the far cortex with the 4.5 mm Cortical Tap (Cat. No. 8242-45-070) prior to attempting to insert the screw. The 3.2/4.5 mm double drill guide can be used as a tissue protector.

Insert the appropriate length 4.5 mm Cortical Screw (Cat. No. 8157-45-0XX) screw by hand with the Ratchet Handle (Cat. No. 2141-24-000) or power drill by using the 4.5 mm Driver Shank (Cat. No. 8242-19-000) (Figure 7). Always perform final seating of the screw by hand.

Figure 8
Drill perpendicular to the fracture plane with the 3.8 mm drill bit

Figure 9
Take depth reading from NL line

Figure 10
Insert the 6.5 mm cancellousscrew using the 3.5 mm hex driver

22 mm Thread Length
(Cat. No. 8157-62-0XX)

40 mm Thread Length
(Cat. No. 8157-64-0XX)

Figure 11

6.5 mm Cancellous Lag Screws

The cancellous lag screw is available with 22 or 40 mm thread length portions. The threaded portion will reside in the far fragment only, thus determining the appropriate thread length.

Reduce the fracture and maintain the reduction with bone forceps. Drill both cortices with the 3.8 mm Drill Bit (Cat. No. 8162-99-013) perpendicular to the plane of the fracture using the 3.8/6.5 mm Drill Guide (Cat. No.8242-21-000). Advance the drill across the fracture site to the required depth, confirming the position with image intensification (Figure 8).

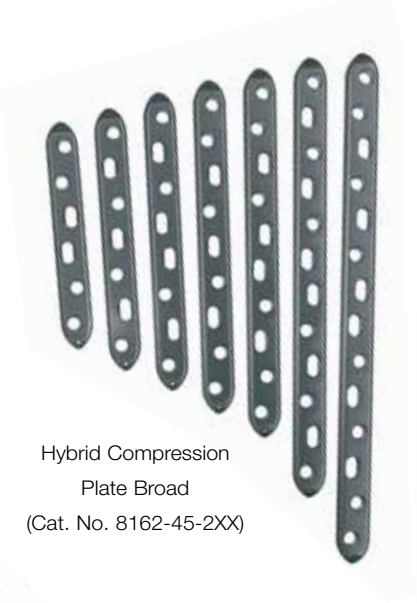
Determine the required screw length by taking a direct reading from the NL line on the Large Fragment Depth Gauge (Figure 9).

Note: In hard or dense bone, tap the near cortex with the 6.5 mm Cancellous Tap (Cat. No. 8242-75-000) prior to attempting to insert the screw. The 3.8/6.5 mm drill guide can be used as a soft tissue protector.

Insert the appropriate length 6.5 mm cancellous lag screw (Cat. No. 8157-62-0XX/8157-64-0XX) by hand or with power using the 4.5/6.5 Screwdriver Shank. Always perform final seating of the screw by hand (Figure 10).

Note: In soft cancellous 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 (Figure 11).

Hybrid Compression Plate Narrow
(Cat. No. 8162-45-0XX)



Hybrid Compression
Plate Broad
(Cat. No. 8162-45-2XX)

Figure 12

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 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 reduction forceps or the provisional fixation pins.

Use of the Provisional Fixation Pin (Cat. No. 8162-99-001/6) Avoid placing the provisional fixation pin in a screw hole that will be needed immediately for implant fixation. The self-drilling pin has a 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 (Figure 12).

Note: Advancing the pin beyond that point may result in stripping of the threads.

4.5 mm non-locking cortical screw

4.5 mm locking cortical screw

6.5 mm non-locking cancellous screw

5.5 mm locking cancellous screw

Figure 13
The Articulating Tensioning Device.

Plate Insertion

Determine the type of screw to be used: 4.5 mm locking cortical, 4.5 mm non-locking cortical, 5.5 mm locking cancellous or 6.5 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.

Articulating Tensioning Device

The Articulating Tensioning Device (Cat. No. 8162-99-005) is to be used in conjunction with the 4.5 mm Hybrid Broad or Narrow Compression plates (HCP®) in order to achieve additional compression of a fracture. This device can be used in fractures of the humerus, femur and tibia when fracture gaps exist that exceed 2 mm and when active compression plating techniques are not possible or ineffective (Figure 13).

First, the proper technique requires that one fully extends the arms of the tensioner. Next, the hybrid compression plate is fixed to the main portion of the bone. This can be accomplished with a couple non-locking compression screws. The articulating tensioner is then attached to the plate by means of the tensioner set screw. This set screw threads directly into the last locked hole of the plate.

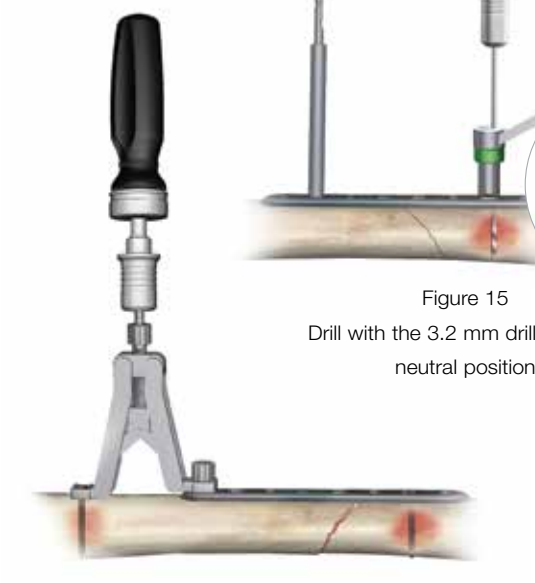


Figure 14
The Articulating Tensioning Device is to be used in conjunction with the 4.5 mm Hybrid Broad or Narrow Compression plates in order to achieve additional compression of a fracture.

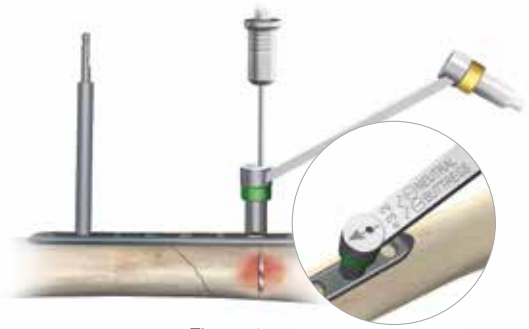


Figure 15
Drill with the 3.2 mm drill bit in the neutral position

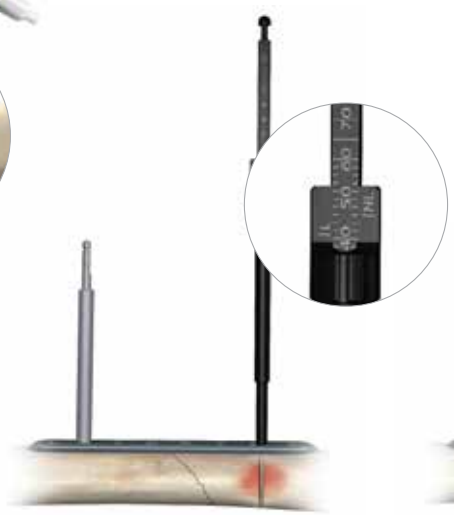


Figure 16
Take the depth reading from the NL line

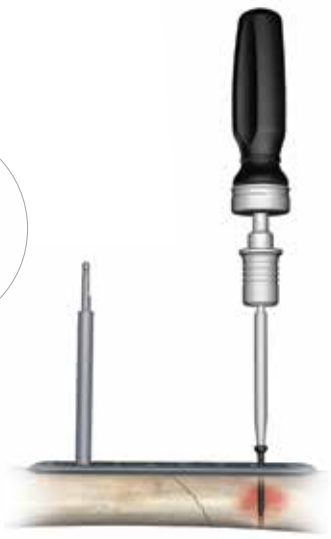


Figure 17
Insert the 4.5 mm non-locking cortical screw using the 3.5 mm hex driver

A non-locked 4.5 mm Cortical Screw (Cat. No. 8157-45-0XX) is used to connect the opposite end of the tensioner to the other main segment of bone. Next, one must connect the Ratchet Screwdriver Handle (Cat. No. 2141-24-000) to the top of the tensioner. To compress the fracture, screw the ratchet clockwise, which will draw the arms of the tensioner towards the center, thus reducing the fracture (Figure 14).

Note: Special care should be given when using the articulating tensioner in oblique fractures of the diaphysis. The tensioner should compress the fracture so that the loose fracture segment is forced into the anxilla that is formed from the main bone segment and plate.

Neutral Insertion of a 4.5 mm Non-Locking Cortical Screw in a Compression Slot

Insert the neutral (green) end of the 3.2 mm ACP Drill Guide (Cat. No. 8242-26-000) into the compression slot with the arrow pointed toward the fracture line (Figure 15). Drill through both cortices with the 3.2 mm drill bit.

CAUTION: The arrow on the neutral (green) end of the 3.2 mm ACP drill guide must point toward the fracture site to ensure neutral screw placement.

Measure the drilled hole with the large fragment depth gauge by taking a direct reading from the NL line (Figure 16).

Insert the appropriate length 4.5 mm non-locking cortical screw with the 3.5 mm hex driver coupled to the ratchet handle (Figure 17).

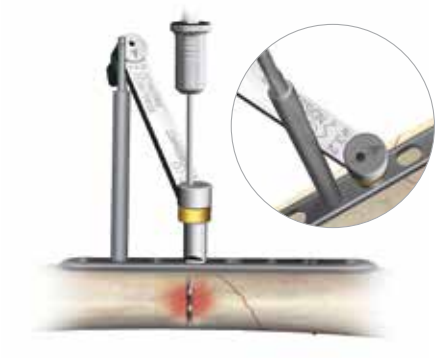


Figure 18
Drill with the 3.2 mm drill bit
in the eccentric position.

Figure 19
Take the depth reading
from the NL line

Figure 20
Insert the 4.5 mm non-locking
cortical screw using the 3.5 mm hex driver

Dynamic Compression/Eccentric Insertion of a 4.5 mm Non-Locking Cortical Screw in a Compression Slot

Insert the compression (gold) end of the 3.2 mm ACP drill guide into the compression slot with the arrow pointed toward the fracture line. Drill through both cortices with the 3.2 mm drill bit (Figure 18).

CAUTION: The arrow on the compression end of the 3.2 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. Measure the drilled hole with the large fragment depth gauge by taking a direct reading from the NL line (Figure 19).

Insert the appropriate length 4.5 mm non-locking cortical screw with the 3.5 mm hex driver coupled to the ratchet handle (Figure 20).

Figure 21
Drill with the 3.8 mm calibrated drill bit reading the depth from the top of the drill guide

Figure 22
Take the depth reading from the L line

Figure 23
Insert the locking screw using the 3.5 mm hex driver on the torque-limiting handle

Insertion of a 4.5 mm Locking Cortical Screw or 5.5 mm Locking Cancellous Screw in a Threaded Hole

(4.5 mm Cortical Cat. No. 8161-45-2XX or 5.5 mm Cancellous Cat. No. 8161-55-XXX)

Screw the 3.8 mm Locking Drill Guide (Cat. No. 8162-99-012) into a threaded plate hole until fully seated. Drill with the 3.8 mm Calibrated Drill Bit (Cat. No. 8162-99-009) to the desired depth and read the depth measurement from the calibrated drill bit at the top of the drill guide (Figure 21). Remove the 3.8 mm locking drill guide.

Note: If a second method of measurement is desired, measure the drilled hole by taking a direct reading from the L line on the large fragment depth gauge (Figure 22).

Insert the selected locking screw with the 3.5 mm Hex Driver coupled to the 4.5 Nm Torque-Limiting Screwdriver Handle (Cat. No. 8162-99-016) (Figure 23).

Tip: Using a power screwdriver is not recommended for insertion of any locking screws. If using power, it should be at a slow speed. Perform all final screw tightening by hand with the torque-limiting screwdriver.

Figure 24
Drill with the 3.2 mm drill bit through the 3.2/4.5 mm drill guide

Figure 25
Take the depth reading from the NL line

Figure 26
Insert the 4.5 mm non-locking cortical screw using the 3.5 mm hex driver

Insertion of a 4.5 mm Non-Locking Cortical Screw in a Threaded Hole

Insert the 3.2 mm end of the 3.2/4.5 mm drill guide into the threaded hole and drill through both cortices with the 3.2 mm drill bit (Figure 24).

Measure the drilled hole by taking a direct reading from the NL line on the large fragment depth gauge (Figure 25).

Insert the appropriate length 4.5 mm non-locking cortical screw with the 3.5 mm hex driver coupled to the ratchet handle (Figure 26).

Figure 27
Drill with the 3.8 mm drill bit through the 3.8/6.5 mm drill guide

Figure 28
Take the depth reading from the NL line

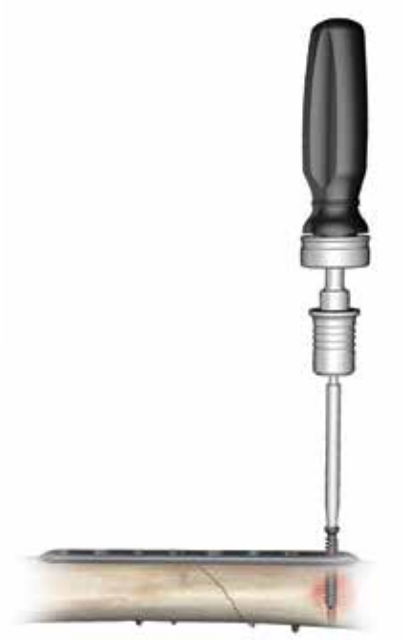


Figure 29
Insert the 6.5 mm cancellous screw using the 3.5 mm hex driver

Insertion of a 6.5 mm Non-Locking Cancellous Screw (Cat. No. 8157-61-XXX) into any Plate Hole

Insert the 3.8 mm end of the 3.8 mm/6.5 mm drill guide into the plate hole and drill through both cortices with the 3.8 mm drill bit (Figure 27).

Measure the drilled hole by taking a direct reading from the NL line on the large fragment depth gauge (Figure 28).

Insert the appropriate length 6.5 mm cancellous screw with the 3.5 mm hex driver coupled to the ratchet handle (Figure 29).

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

Figure 1

Figure 2

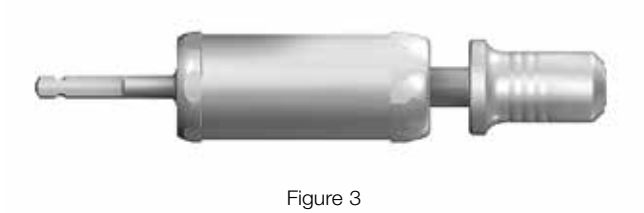


Figure 3

Optional Instruments

1. 2141-19-000 Femoral Bone Clamp
2. 8162-99-011 Large Fragment Bone Clamp
3. 2142-04-035 Torque Limiting Power Adaptor

Case Layout

The large 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 30).

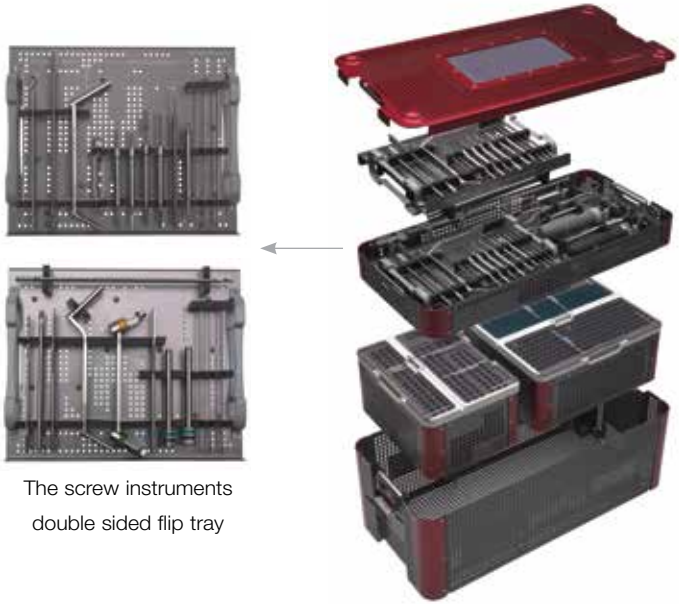
The entire system can be housed in one large base or it can be split into a separate instrument and implant base.

The trays contain three-dimensional graphics for rapid implant and instrument identification enhancing both surgical and processing efficiencies (Figure 31).

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 32).

Figure 30

Figure 31



The screw instruments double sided flip tray

Figure 32

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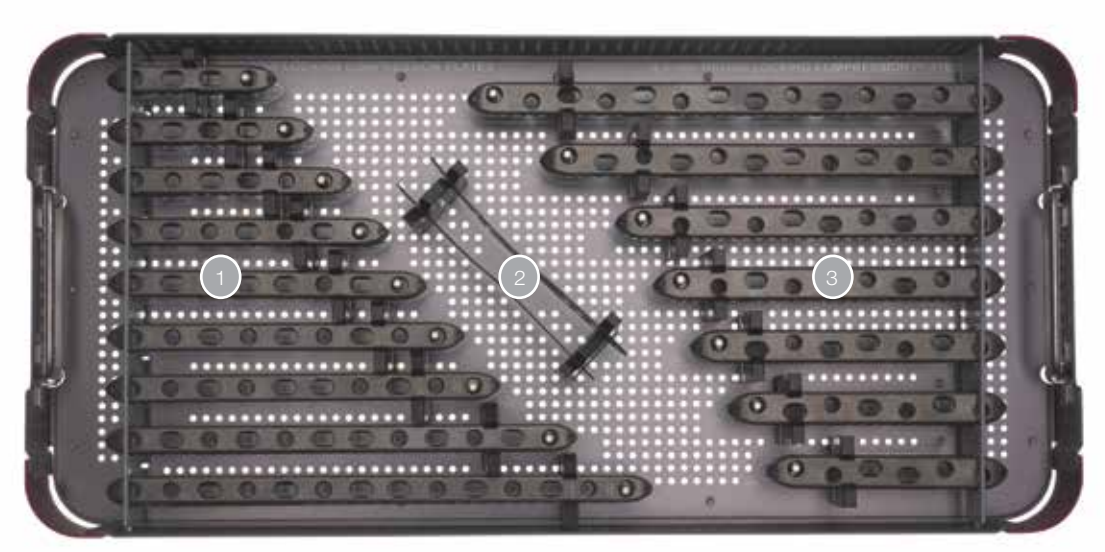
A.L.P.S.™ Large Fragment Plating System

Implant Trays

Large Fragment Screw Modules

1. 8157-61-XXX — 6.5 mm Cancellous Screws FT
   25 – 110 mm in 5 mm increments
2. 8157-62-XXX — 6.5 mm Cancellous Screws
   22 mm Thread
   40 – 110 mm in 5 mm increments
3. 14260/14261/14097 — Flat/Cupped/Spider Washers
4. 8157-64-XXX — 6.5 mm Cancellous Screws
   40 mm Thread
   60 – 110 mm in 5 mm increments
5. 8157-45-XXX — 4.5 mm Non-locking Cortical Screws
   14 – 60 mm in 2 mm increments
   65 – 70 mm
6. 8161-45-2XX — 4.5 mm Locking Cortical Screws
   8 – 60 mm in 2 mm increments
   65 mm
7. 8161-55-XXX — 5.5 mm Locking Cancellous Screws
   26 – 50 mm in 2 mm increments
   65 – 100 mm in 5 mm increments



1. 4.5 mm Narrow Hybrid Compression Plates

8162-45-004	4 Hole Plate
8162-45-005	5 Hole Plate
8162-45-006	6 Hole Plate
8162-45-007	7 Hole Plate
8162-45-008	8 Hole Plate
8162-45-009	9 Hole Plate
8162-45-010	10 Hole Plate
8162-45-012	12 Hole Plate
8162-45-014	14 Hole Plate

2. Bending Template

8162-99-002	7 Hole

3. 4.5 mm Broad Hybrid Compression Plates

8162-45-206	6 Hole Plate
8162-45-207	7 Hole Plate
8162-45-208	8 Hole Plate
8162-45-209	9 Hole Plate
8162-45-210	10 Hole Plate
8162-45-212	12 Hole Plate
8162-45-214	14 Hole Plate

A.L.P.S.™ Large Fragment Plating System

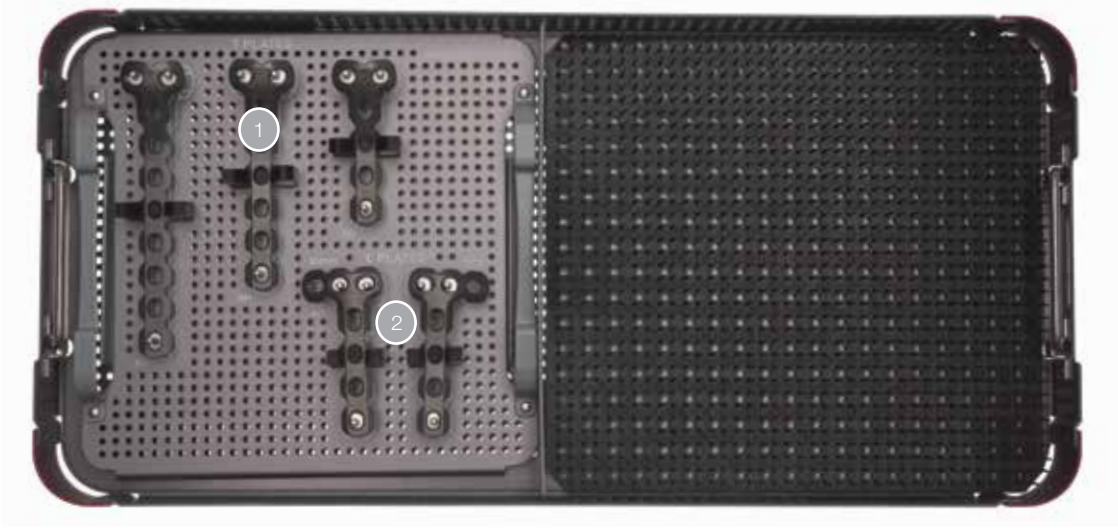


Plate Module/Reduction Instrument Tray

1. 143614 4.5 mm T Plate 4 Hole
   143616 4.5 mm T Plate 6 Hole
   143618 4.5 mm T Plate 8 Hole
2. 143454 4 Hole Recon T Plate Right
   143444 4 Hole Recon T Plate Left

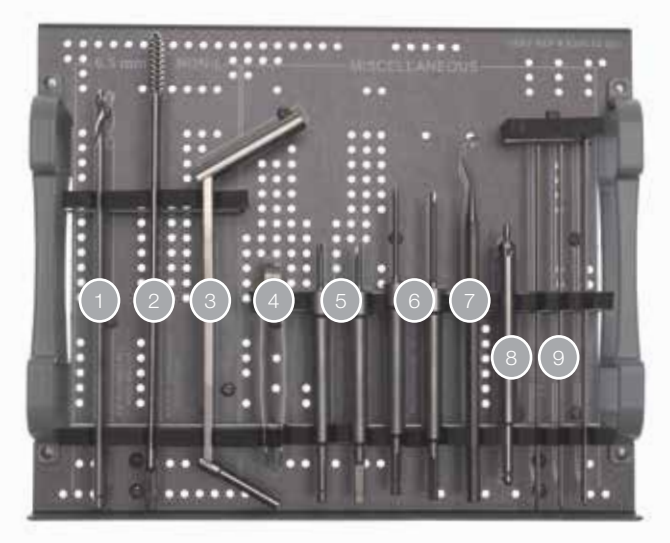
These non-locking plates are indicated for use on the tibia, femur and humerus.

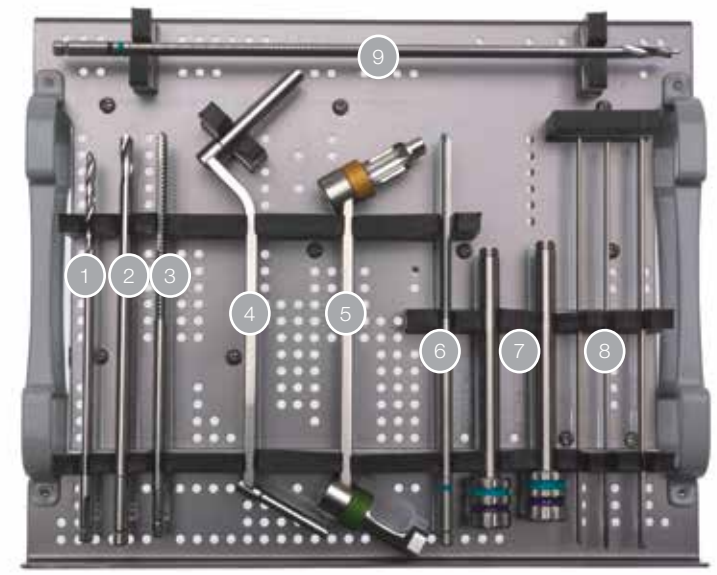
Instrument Trays

Screw Instrument Tray

1. 2142-04-035 Torque Limiting Adaptor
2. 13577 Large Forceps with Points
3. 8242-19-000 4.5/6.5 Screwdriver Shank
4. 8162-99-016 4.5 Nm Torque Limiting Handle
5. 2141-26-035 3.5 Hex Extractor
6. 2141-24-000 Ratchet Handle
7. 2810-01-004 Hudson Handle
8. 8162-99-007 Hook Depth Gauge

A.L.P.S.™ Large Fragment Plating System





Flip Tray - Side 1

1.	8162-99-013	3.8 mm Drill Bit
2.	8242-75-000	6.5 mm Cancellous Tap
3.	8242-21-000	3.8/6.5 mm Drill Guide
4.	13571	Screw Forceps
5.	8162-99-001	Provisional Fixation Pin 20 mm
6.	8162-99-006	Provisional Fixation Pin 40 mm
7.	13572	Sharp Hook
8.	8242-20-100	4.5/6.5 mm Countersink
9.	141796 &144256	K Wires

Flip Tray - Side 2

1.	9399-99-315	3.2 mm Drill Bit
2.	8242-73-000	4.5 mm Solid Drill Bit
3.	8242-45-070	4.5 mm Cortical Tap
4.	8241-97-000	3.2/4.5 mm Double Drill Guide
5.	8242-26-000	3.2 mm ACP Drill Guide
6.	8162-99-010	4.5 mm Locking Cortical Tap
7.	8162-99-012	3.8 Locking Drill Guide
8.	141796 & 144256	K Wires
9.	8162-99-009	3.8 mm Calibrated Drill Bit

Figure 40

Figure 41

The large 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.

The entire system can be housed in one large base (Figure 40) or it can be split into a separate instrument and implant base (Figure 41).

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 Large Fragment Locking Plating System is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation and stabilization of non-unions, malunions, and osteotomies.

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.

Biomet as the manufacturer of medical devices, does not practice medicine. Each surgeon is responsible for the appropriate selection of implant(s) and techniques for each individual patient.

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

BIOMET® TRAUMA

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