

Hand Fracture System

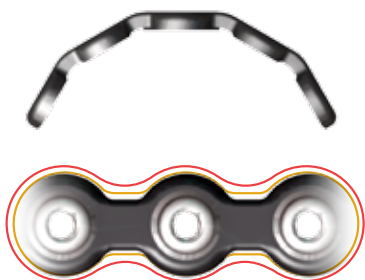
Sales Sheet

BIOMET

A.L.P.S. Hand Fracture System

Flexibility in Your Hands

The A.L.P.S. Hand Fracture System represents the next generation in anatomic plate design. Available in 1.5 mm and 2.5 mm sizes with five different shapes, the plates combine the benefits of low profile titanium plate metallurgy with the advantages of multi-planar locked screw technology. These features allow the formation of a three-dimensional matrix of fixed and variable angle screws to create a true subchondral scaffold with locking screw technology that can provide strong fixation in comminuted fractures or osteoporotic bone.



Low profile Design

Low profile, anatomically contoured Hand Fracture System plates were designed to be low profile, yet strong. The 2.5 mm plates are nearly as small as a **competitive 2.0 mm plate**, yet stronger than the **competitive 2.4 mm plate**!

Locking Plate System:

- A low profile helps minimize potential discomfort and soft tissue irritation
- Contoured plates mimic the anatomy of the fingers and hand bones
- Flexible Plating Technology delivers in-situ contourability



F.A.S.T. Guide® Technology

Fast, accurate surgeries through F.A.S.T. Guide Technology:

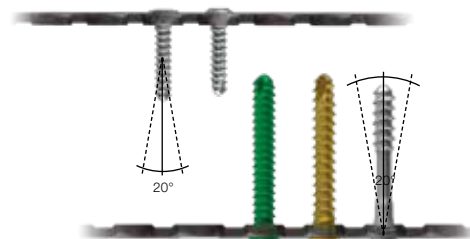
- Facilitate accurate drilling
- Pre-loaded and disposable
- Save time in the OR since no intraoperative assembly is required
- Color coded guides make plate identification easy:

Gold guide = 2.5 mm plates

Silver guide = 1.5 mm plates

Indications for Use:

For stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstructions of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis and craniomaxillofacial skeleton, particularly in osteopenic bone.



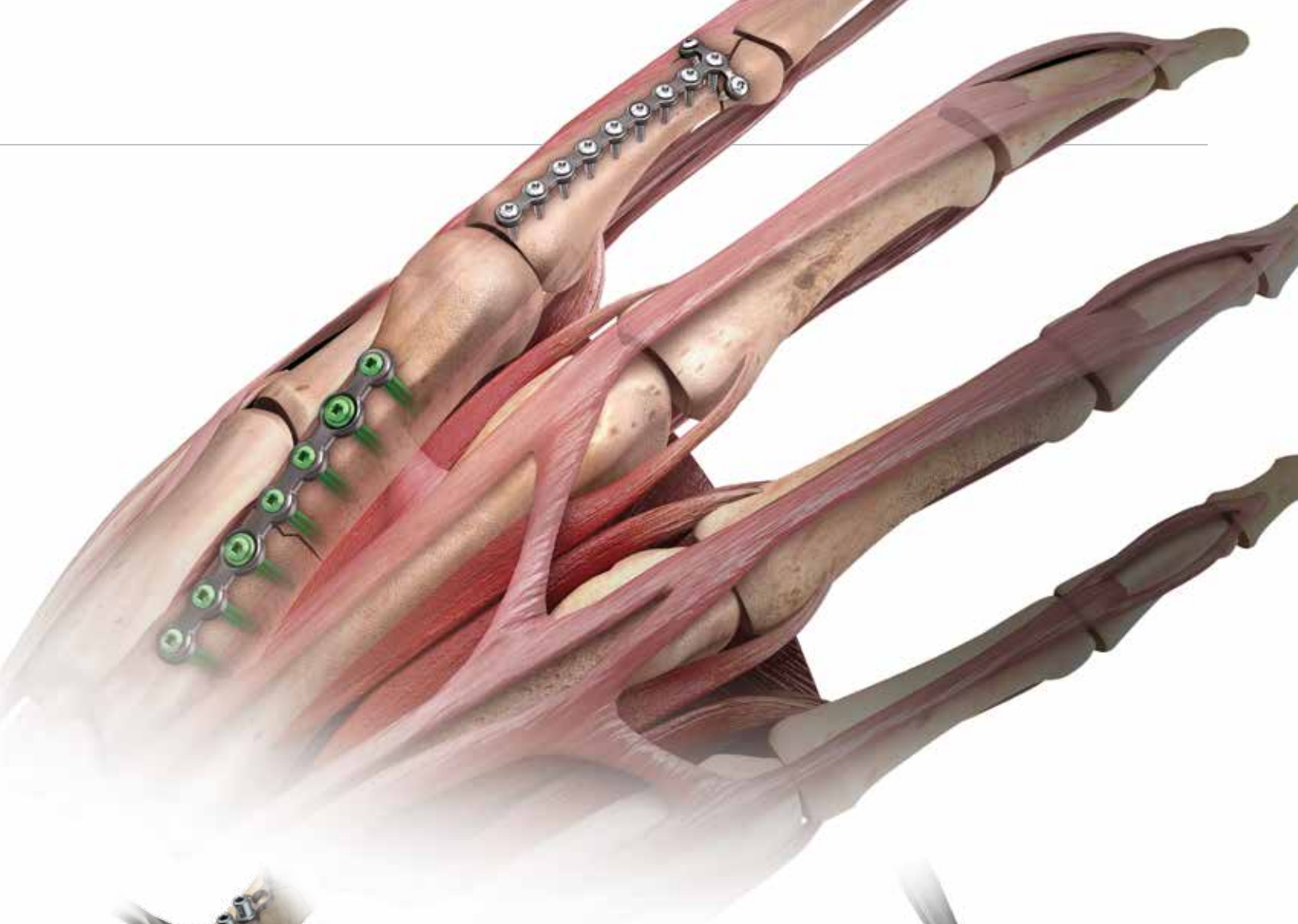
Multiple Screw Options

Locking, non-locking, and multi-directional screw options:

- Locking screws establish fixed angle construct for strong fixation, particularly in osteopenic bone
- Co-Cr multi-directional screws provide locked angular stability in a 20° cone from fixed angle axis
- Compression non-locking screws create up to 1 mm of axial compression in slotted nodes

1 Data on file at Biomet, Inc.

2 Technical Assessment of Materials for Fracture Fixation, 0173-97-005 (Rev. 2)



TiMAX™

Plate Customization

Plates were designed to be modified to meet the needs of the patient and the fracture.

The simple chart below demonstrates some of the plate shapes that can be created from the basic 5 shapes.



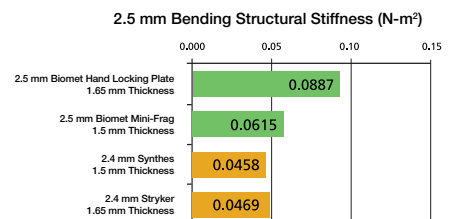
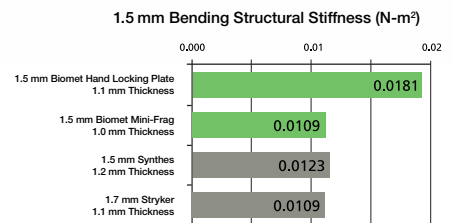
TiMAX™ Material

The Hand Fracture System takes advantage of TiMAX, an anodized Ti alloy, to provide a strong yet contoured plate.

TiMAX proprietary surface treatment increases fatigue strength over standard Ti alloys while decreasing frictional characteristics, notch sensitivity, and the likelihood of galling of titanium.

This anodization process also creates a surface on the plate that discourages bony ingrowth, which can minimize complications during removal of the implants after fracture healing.²

Flexible But Strong



1.5 / 1.3 mm Module Components

Product#	Description
1312-20-151	1.5 mm Locking plate, Straight
1312-20-152	1.5 mm Locking plate, T-Shape
1312-20-153	1.5 mm Locking plate, Y-Shape
1312-20-154	1.5 mm Locking plate, T/Y Shape
1312-20-155	1.5 mm Locking plate, Web
1312-20-157	1.5 mm Locking plate, Small T-Shape
1312-20-308 – 1312-20-324	Non Locking Screw 1.3 mm X 8 mm - 24 mm
1312-20-508 – 1312-20-524	Non Locking Screw 1.5 mm X 8 mm - 24 mm
1312-20-408 – 1312-20-424	Locking Screw 1.5 mm X 8 mm - 24 mm
2312-20-200	1.0 mm Drill Bit w/ Mini-Quick Connect
2312-20-201	1.3 mm Drill Bit w/ Mini-Quick Connect
2312-20-202	1.1 mm Drill Bit w/ Mini-Quick Connect
2312-20-203	1.5 mm Drill Bit w/ Mini-Quick Connect
2312-20-206	1.3 mm / 1.5 mm Countersink
2312-20-208	1.3 mm Driver Bit
2312-20-209	1.5 mm Driver Bit
2312-20-109	1.5 mm plate Holder
2312-20-102	1.5 mm Plate Bender
2312-20-103	1.5 mm Plate Bender End
2312-20-106	1.0 mm / 1.3 mm Soft Tissue Guide
2312-20-116	1.1 mm / 1.5 mm Soft Tissue Guide
2312-20-104	1.3 mm / 1.5 mm Bone Depth Gauge
2312-20-210	Screw pickup
2312-20-121	1.5 mm BDG Bicortical Cap (Optional)
1312-20-124	1.5 mm Bicortical Bone Depth Gauge (Optional)

Instrument Tray Components

Product#	Description
MQC	MQC Handle
2312-20-114	Cutting Pliers
9399-99-469	Periosteal Elevator 3 mm
9399-99-518	Stagbeetle Forceps
9399-99-444	Reduction Forceps w/narrow points
9399-99-277	Retractor Mini Hohmann
2312-20-115	K-Wire Towel Clamp
1642-06-028	K-Wire 6" Trocar Point .028 OD
1642-06-035	K-Wire 6" Trocar Point .035 OD
1642-06-045	K-Wire 6" Trocar Point .045 OD
1642-06-062	K-Wire 6" Trocar Point .062 OD
2312-20-117	MQC to AO Adapter

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

2.5 mm Module Components

Product#	Description
1312-20-251	2.5 mm Locking plate, Straight
1312-20-252	2.5 mm Locking plate, T-Shape
1312-20-253	2.5 mm Locking plate, Y-Shape
1312-20-254	2.5 mm Locking plate, T/Y Shape
1312-20-255	2.5 mm Locking plate, Web
SP08000 – SP28000	Screw Peg 2.5 mm X 8 mm - 28 mm
FP08 – FP28	Fully Threaded Peg 2.5 mm X 8 mm - 28 mm
1312-11-110 – 1312-11-128	Multi-Directional Threaded Peg 2.5 mm X 10 mm - 28 mm
1312-20-025	2.5 mm Threaded Washer
2312-20-204	2.0 mm Drill Bit w/ Mini-Quick Connect
2312-20-205	2.5 mm Drill Bit w/ Mini-Quick Connect
2312-20-207	2.0 mm / 2.5 mm Countersink
2312-20-211	2.0 mm / 2.5 mm Driver Bit
2312-11-002	MDTP Driver Bit
2312-07-012	2.0 mm plate Holder
2312-20-100	2.0 mm Plate Bender
2312-20-101	2.0 mm Plate Bender End
2312-20-107	2.0 mm / 2.5 mm Soft Tissue Guide
2312-20-105	2.0 mm / 2.5 mm Bone Depth Gauge
2312-20-122	2.5 mm BDG Bicortical Cap (Optional)
1312-20-125	2.5 mm Bicortical Bone Depth Gauge (Optional)

Screws, Plates, Intramedullary Nails, Compression Hip Screws, Pins and Wires

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).

NOTE: Do not remove F.A.S.T. Guide® inserts prior to sterilization.

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ORTHOPEDICS

One Surgeon. One Patient.

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