A.L.P.S. Minimally-Invasive and Mesh Calcaneus Plating System

Design Rationale and Surgical Technique
Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it’s meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally-invasive surgical technique, advanced biomaterials, or a custom, patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.
# A.L.P.S. Minimally-Invasive and Mesh Calcaneus Plating System

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A.L.P.S. Minimally-Invasive and Mesh Calcaneus Plating System

The A.L.P.S. Minimally-Invasive and Mesh Calcaneus Plating System features two unique and anatomically contoured plate designs that address a variety of calcaneus fractures, while meeting the stress requirements present in the trabecular anatomy of the calcaneus. These titanium plates offer TiMAX surface treatment benefits of increased fatigue strength compared to 316L Electropolished Stainless Steel, Type I Anodized titanium, and machined titanium. Anatomic screw trajectories are designed to maximize screw position and limit intra-articular and neurovascular compromise.

The MIS (minimally-invasive) plates are designed for a sinus tarsi, minimal incision approach that offers less soft tissue interruption than a significantly longer extensile lateral incision. Unique and easy to use carbon fiber Targeting Guides are designed to maximize screw purchase and trajectory to limit injury to tendinous and neurovascular structures, while limiting intra-articular screw placement.

The Mesh plates provide an enlarged surface over the MIS plates to accommodate lateral wall comminution. The Mesh plate is a hybrid of the MIS plate and the A.L.P.S. Locking Calcaneus Plate design with additional F.A.S.T. Tabs superiorly placed and anterior F.A.S.T. Tabs that span the calcaneocuboid joint for fractures with anterior process comminution.

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These two new plate designs expand upon Biomet’s existing non-locking perimeter plate and the A.L.P.S. locking calcaneus plate portfolio therefore providing comprehensive plating options for calcaneus fracture management.
Minimally-Invasive Plates (MIS)

MIS plates are designed to meet the needs of a variety of calcaneus fractures. Small and large standard plates are designed for intra-articular fractures of the calcaneus, whereas the small extended 2-Hole, large extended 2-Hole, and large extended 3-Hole plates are designed for more comminuted fractures that require posterior fixation. These anatomically contoured plates are not designed to be bent or altered by the surgeon. Adequate reduction of the calcaneus will allow good plate/bone apposition. Modification of the plate will alter targeting guide alignment. When using the MIS extended plates, it is recommended that at least two screws are inserted in the anterior, central and posterior regions of the plate.
Large Standard

Small Standard

Small Extended 2-Hole

Large Extended 2-Hole

Large Extended 3-Hole

Superior

Central

Inferior

Posterior
Mesh Plates

The Mesh plates are a hybrid of the MIS and A.L.P.S. Locking Calcaneus plates, and are designed to address comminuted fractures where additional screw options may be required. The Mesh plates provide both strength to the inner area of the plate, and flexibility with perimeter F.A.S.T. Tabs that can be contoured to the calcaneus anatomy as needed. In addition, the anterior F.A.S.T. Tabs allow the surgeon to place screws into the cuboid, thus spanning the comminuted anterior process of the calcaneus. These screws may be removed percutaneously after the fracture has healed. The two anterior extensions on the Mesh plate are designed to insert screws into the cuboid so a comminuted anterior process can be spanned, holding it out to length during bone healing. The screws in these two holes can be removed percutaneously, or left in place for calcaneocuboid joint arthrodesis if necessary.
Carbon Fiber Targeting Guides

The unique and easy to use carbon fiber targeting guides (small and large) are designed to maximize screw purchase and trajectory to limit injury to tendinous and neurovascular structures, while limiting intra-articular screw placement. The targeting guides are rigid for accurate screw insertion, radiolucent for enhanced x-ray visualization, and allow for percutaneous screw placement.
Plate position is determined by the angle of Gissane using the horizontal slots designed in the targeting guide. These slots are 10 mm in length and are 5 mm apart vertically. By sliding a k-wire through one of these slots and completely across the floor of the sinus tarsi, the guide is designed to ensure that the screw inserted just inferior to these slots (through the “C” hole) will be placed within the sustentaculum tali and not violate the subtalar joint.
The anatomic shape of the plate allows screw trajectories to correspond to the complicated anatomy of the calcaneus. The subtalar joint line helps to direct the trajectory of the initial screw into the substantial bone of the sustentaculum tali. Screw trajectories could be slightly varied (outside of the targeting guide) with either 3.5 mm Multi-Directional Locking Screws or 3.5 mm Low Profile Non-Locking Screws. Anatomic screw trajectories are designed to maximize screw position and limit intra-articular and neurovascular compromise as can be seen in the below views.
Screw Options

The A.L.P.S. portfolio offers multiple screw options including 2.7 mm, 3.5 mm and 4.0 mm locking screws that can be inserted into any locking hole, giving the surgeon intraoperative flexibility. In addition to these locking screw designs, a cobalt chrome 3.5 mm Multi-Directional Locking Screw is available when the fixed trajectory of the screw hole may not be ideal. This allows the surgeon to direct the screw up to 15 degrees (30 degree cone of angulation) off center. A 3.5 mm Low Profile Non-Locking Cortical Screw is also available to compress the plate to the bone. The design of this screw allows the head to sit level with the plate hole as shown in the illustration below.
Instrumentation & Delivery System

Use with A.L.P.S. Total Foot System

- Instrumentation
- Screws
  - 2.7 mm Locking Cortical
  - 3.5 mm Locking Cortical
  - 3.5 mm Low Profile Non-Locking Cortical
  - 3.5 Multi-Directional Locking Cancellous

*A.L.P.S. Small Fragment System
3.5/4.0 mm screw caddy required if 4.0 mm Locking Screws needed
A.L.P.S. Minimally-Invasive Calcaneus Plate

Surgical Technique
A.L.P.S. Minimally-Invasive Calcaneus Plate

Surgical Technique

Patient Positioning
Place the patient in the lateral position with the lateral aspect of the calcaneus facing up and prepare the patient using standard operating protocols (Figure 1).

Exposure and Approach
For a sinus tarsi (minimally-invasive) approach, locate the subtalar joint and begin the incision posterior and distal to the fibular head, across the anterior process of the calcaneus, superior to the peroneal tendons, to the calcaneocuboid joint (Figure 2). Ensure that the sural nerve and peroneal tendon sheath are not disturbed. The incision should be approximately 5–8 cm in length.
Exposure and Approach (cont.)

A Cobb Elevator (110008333) can be used to lift the flap and elevate the soft tissue (Figure 3) from the calcaneus to ease insertion of the plate posteriorly. The markings on the Cobb Elevator can be used to estimate the depth of the sub-periosteal dissection needed to place the posterior arm on the MIS plate. It’s imperative to reflect the sheath attachment on the peroneal tubercle.

Fragment Reduction

Provisional fixation is achieved with k-wires. Take care to ensure that k-wire positioning does not interfere with plate positioning. Drill a 5 mm Schanz Pin (110008327) into the posterior tuberosity depending on fracture pattern (Figure 4). Perform standard reduction technique to restore anatomic alignment prior to plate placement.
Templating
Using plate templates, determine the plate design and size (appropriate for the calcaneus and fracture pattern) by placing the template on top of the skin over the fracture and obtain a fluoroscopic image (Figure 5). The template can also be inserted through the incision and into position prior to fluoroscopic imaging and then the template must be removed.

Plate and Targeting Guide Assembly
Once the appropriate implant has been selected, attach the Targeting Guide Locking Sleeve (110008308) to the most anterior/superior hole on the plate (Hole B) using a T-15 Star Screwdriver (2142-15-070) and gently tighten to the plate (Figure 6).
Plate and Targeting Guide Assembly (cont.)

The Targeting Guide must match the plate size chosen. (i.e. small guide with small plate, large guide with large plate.) There are right-specific and left-specific Targeting Guides. For illustrative purposes, a small left 2-Hole extended MIS calcaneus plate (110008269) and small left Targeting Guide (110008301) are shown above.

Slide the Targeting Guide over the Locking Sleeve through hole “B” in the guide (Figure 7), and rotate the guide slightly until the notches of the tip are captured by the indents in the plate (Figure 7 inset).

Secure the Targeting Guide to the Targeting Guide Locking Sleeve with the Locking Nut (110008311) by screwing it down firmly against the guide (Figure 8).

Plate Insertion and Positioning

Holding the Targeting Guide/plate assembly, insert the posterior end of the plate through the small incision, directing it posteriorly until the plate is in the desired position over the calcaneus (Figure 9). Obtain a fluoroscopic image to determine initial positioning of the plate.
A.L.P.S. Minimally-Invasive Calcaneus Plate

Surgical Technique

The Targeting Guide is designed with two slots marked S1 and S2 (Figure 10). To determine the appropriate placement of the plate relative to the posterior facet, gently push a 1.6 mm k-wire (Figure 11) through one of the slots and across the sinus tarsi. While the Targeting Guide is uniquely designed to accurately determine the trajectory, the surgeon should verify that the k-wire is directed correctly through the floor of the sinus tarsi (axial) by visualizing the position with lateral (Figure 12) and Harris (axial fluoroscopic) views (Figure 13). Medially, the k-wire should be located superior to the sustentaculum tali.

This technique should allow the screw to be inserted in hole “C” without violating the subtalar joint. By placing the k-wire in the slot marked “S1,” the screw in hole “C” is 5 mm closer to the subtalar joint than if the k-wire was placed in slot “S2.” When the k-wire is placed in “S2,” the screw is located 10 mm further from the subtalar joint. Either hole should ensure that the tip of the screw should be contained with the sustentaculum tali.
Plate Insertion and Positioning (cont.)

Once the appropriate placement of the plate has been determined relative to the sinus tarsi, a final adjustment can be made by sliding the plate anterior (Figure 14) or posterior (Figure 15) over the sinus tarsi k-wire so that the anterior aspect of the plate avoids the calcaneocuboid joint.

After the final position of the plate has been determined, provisional fixation is provided by inserting 1.6 mm k-wires through the k-wire holes marked Z1 and Z3 that are aligned with the k-wire holes in the plate (Figure 16). A third point of fixation can be achieved using hole Z2 if so desired. Finally, remove the k-wire from the slot, as provisional fixation has been accomplished.
Surgical Technique

Screw Insertion

It is important to insert the first screw into hole “C” (Figure 17) to confirm that the tip of the screw will be contained in the sustentaculum tali before inserting additional screws. Use a 3.5 mm Low Profile Non-Locking Cortical Screw to compress the plate to the bone.

Insert the Trocar (110008315) (Figure 18) through the Soft Tissue Guide (110008313) (Figure 19) and insert this assembly into hole “C” on the Targeting Guide.

IMPORTANT: You should finger tighten this assembly only. Do not tighten with the T-15 screwdriver as this may make it difficult to remove the Trocar from the Soft Tissue Guide.

Note that while the tip of the Trocar is contacting the bone, the Soft Tissue Guide is not attached to the plate, but only the Targeting Guide.
Screw Insertion (cont.)

Next, unthread and remove the Trocar and insert the Locking Drill Guide (110008317) into the Soft Tissue Guide (Figure 20). The threaded end of the drill guide will attach directly to the plate.

Drill through the Locking Drill Guide using a 2.7 mm Calibrated Drill Bit (2142-27-070), stopping just at the medial cortex in the sustentaculum tali and reference the screw length on the calibrated drill bit off of the top of the Locking Drill Guide (Figure 21).

Optional: A lag technique can be performed to compress the articular fragments by first drilling the 2.7 mm drill through the Locking Drill Guide. Then remove the drill guide and perforate the near cortex with a 3.5 mm drill.
Screw Insertion (cont.)

As an alternative technique, a Depth Gauge (110018220) can be used to measure screw length. Remove the Locking Drill Guide from the Soft Tissue Guide and insert the Depth Gauge through the Soft Tissue Guide and reference the screw length on the Depth Gauge off of the top of the Soft Tissue Guide (Figure 22). For the 3.5 mm Low Profile Non-Locking Cortical Screw, utilize the Non-Locking side of the Depth Gauge marked clearly on the handle.

Insert the 3.5 mm Low Profile Non-Locking Cortical Screw through the Soft Tissue Guide (Figure 23) until the head is completely seated, compressing the plate to the bone. Remove the Soft Tissue Guide.
Screw Insertion (cont.)

Place the second screw in the most posterior hole of the plate through the Targeting Guide using either a 3.5 mm Cortical Locking Screw or non-locking screw (Figure 24).

Utilize the prior drilling technique to determine the length of screw required for hole “H.” If using the Depth Gauge to determine the length of a locking screw, utilize the “locking” side of the Depth Gauge clearly marked on the handle.

All locking screws should utilize the magenta-colored Torque Limiting Screw Driver Handle (2141-18-001) and T15 Star Driver (2142-15-070).

Note: Continue advancing the screw until an audible click is heard, and then advance again until a second click is heard. This will ensure that the screw has been appropriately locked to the plate (Figure 25).

With two points of fixation achieved, the most posterior k-wires in the “Z” holes can now be removed.

Note: For the small extended plates, the most posterior hole on the Small Targeting Guide is the “H” hole. For the large extended plates, the most posterior hole on the Large Targeting Guide is the “J” hole. If using the targeting guide for small and large plates (non-extended) the most superior hole is the “E” hole.
Surgical Technique

Central Grouping  Optional Holes  Posterior Grouping

Large 3-Hole Extended Plate

Central Grouping  Optional Hole  Posterior Grouping

Small/Large 2-Hole Extended Plate

Anterior Grouping

Small/Large Plate

Screw Insertion (cont.)

It is not necessary to fill all of the holes on the larger plates. However, at least two screws should be inserted in each of the three hole groupings of the 3-Hole extended plate.

The remaining holes can be filled with any of the following screw options and in any sequence desired:

- **2.7 mm Locking Cortical Screw**
- **3.5 mm Low Profile Non-Locking Cortical Screw**
- **3.5 mm Locking Cortical Screw**
- **3.5 mm Multi-Directional Locking Cancellous Screw**
- **4.0 mm Locking Cancellous Screw**

(*Only available in A.L.P.S. Small Fragment System*)
Screw Insertion (cont.)

Before the final screw can be inserted, the Targeting Guide must be detached from the plate. Remove the Locking Nut (Figure 26) and slide the Targeting Guide off of the Locking Sleeve (Figure 27).

Remove the Locking Sleeve from the plate with the T-15 driver (Figure 28).
Screw Insertion (cont.)

Insert the Locking Drill Guide into hole “B.” Secure it by finger tightening then drill through the Locking Drill Guide using a 2.7 mm Calibrated Drill Bit (Figure 29), stopping just at the medial cortex of the anterior process.

Reference the screw depth on the calibrated drill bit from the top of the Locking Drill Guide (Figure 30). Then remove the drill bit and Locking Drill Guide.
Screw Insertion (cont.)

The Small Fragment Depth Gauge (2142-35-100) from the A.L.P.S. Total Foot System may be used as an alternative screw measuring method by removing the Threaded Drill Guide and inserting the Depth Gauge through the drilled hole down to the plate (Figure 31). Reference the measurement and remove the Depth Gauge.

**Note:** Take care to measure with the appropriate side of the depth gauge for either a locking or non-locking screw.

Insert the final screw into hole “B” per the screw insertion technique described previously (Figure 32).
Wound Closure and Postoperative Protocol

Once the final screw has been inserted (Figure 33), and prior to wound closure, verify plate and screw placement via lateral, A/P, Harris axial and Broden’s views.

Standard layered wound closure and appropriate postoperative protocol follows per surgeon preference.
A.L.P.S. Mesh
Calcaneus Plate

Surgical Technique
A.L.P.S. Mesh Calcaneus Plate

Surgical Technique

Patient Positioning
Place the patient in the lateral position with the lateral aspect of the calcaneus facing up and prepare the patient using standard operating protocols (Figure 1).

Exposure and Approach
The calcaneus is approached through an extensile lateral incision (Figure 2) by reflecting the tendons and sural nerve in the full thickness flap. The flap can be retracted with blunt retractors or k-wires using the “no touch” technique (Figure 3), depending on surgeon preference.
Fragment Reduction

After adequate exposure and irrigation of hematoma, the fracture should be reduced and provisionally stabilized with k-wires (Figure 4). A Schanz pin is inserted into the calcaneus at the posterior/inferior corner of the incision to be used as a handle for subsequent reduction. The reduction is verified with fluoroscopic views including: A/P, lateral, Harris axial and Broden’s views of the foot.

Templating

Once reduction is verified, Mesh Calcaneal Templates can be useful in determining plate to bone contouring and size prior to inserting the plate onto the bone (Figure 5). Remove the template after determining the appropriate size implant to use.
Plate Insertion and Positioning

Position the plate implant on the lateral surface of the calcaneus and verify final size and placement (Figure 6).

The two most anterior F.A.S.T. Tabs on the Mesh plate are useful as a plate extension to span the calcaneocuboid joint when the anterior process is comminuted, maintaining lateral column length.

Ensure that the two F.A.S.T. Tabs are aligned over the cuboid, and not in the joint space. If initial spanning or arthrodesis of the calcaneocuboid joint is not desired, remove the two anterior F.A.S.T. Tabs prior to plate insertion by either using plate cutters, or bending the F.A.S.T. Tabs off using the Foot Multi-Planar Benders (2142-88-004) (Figure 7).

Note: Once the bone has healed following surgery, the two screws in the F.A.S.T. Tabs can be removed percutaneously leaving the tabs in place. If arthrodesis of the calcaneocuboid joint is desired, the screws can be left in place or may be broken off and removed after healing has occurred.
Plate Insertion and Positioning (cont.)

Adjust the plate such that the angle of Gissane hole is 5 mm inferior to the floor of the sinus tarsi, and provisionally fixate by placing 1.6 mm k-wires in each of the three k-wire holes on the Mesh plate (Figure 8).

Provisional fixation has the added advantage of allowing the surgeon to predict the trajectory of a plate/screw construct relative to important articular structures with fluoroscopy. If a trajectory is deemed inadequate, the surgeon has several options; bend the plate intraoperatively, employ a 3.5 mm Multi-Directional Screw, or use a 3.5 mm Low-Profile Non-Locking Screw to establish a new trajectory.

Screw Insertion

While Targeting Guides can be attached to the Mesh plates and utilized for initial plate placement (by following the previous technique for the MIS plates), the Mesh plates are primarily used with an open, extensile lateral approach, and it is not necessary to use the Targeting Guides.

As a technique option, with the plate provisionally fixed at three points, insert a 1.6 mm k-wire through the hole at the angle of Gissane (Figure 9). The wire should be directed medially into the sustentaculum tali with position verified via fluoroscopy.
Screw Insertion (cont.)

The first screw inserted should be a non-locking screw to compress the plate to the bone. Insert a 2.7 mm drill through the 2.7/2.0 mm Double Drill Guide (9399-99-435) from the A.L.P.S. Total Foot System and advance through the cortex of the sustentaculum tali.

Determine screw length by using the Small Fragment Depth Gauge from the A.L.P.S. Total Foot System (2142-35-100) and insert a 3.5 mm Low Profile Cortical Non-Locking Screw until the screw is fully seated and the plate is reduced to the bone (Figure 11).

Remove the k-wire next to the inserted screw, then follow the same screw insertion technique to exchange the remaining provisional k-wires with 3.5 mm Low Profile Cortical Non-Locking Screws.
Screw Insertion (cont.)

With the plate reduced to the bone with Non-Locking Screws, the anatomical shape of the plate can be further refined in situ with plate benders.

The two F.A.S.T. Tabs on the superior aspect of the plate are designed to capture both the anterior process, or floor of the sinus tarsi, and the superior margin of the posterior calcaneus. This can be achieved by utilizing Foot Multi-Planar Benders (2142-88-004) and bending the F.A.S.T. Tabs down onto the bone superiorly (Figure 12). If this additional fixation is not required, simply bend the F.A.S.T. Tabs up approximately 45 degrees, and then back down towards the bone until the tabs break off.

In addition, if anterior plate extension across the calcaneocuboid joint is desired, bend the two most anterior F.A.S.T. Tabs down onto the cuboid for precise anatomic fit using the Foot Multi-Planar Benders (Figure 13).

**Note:** The Mesh Calcaneal Plate is designed to be contoured along a single axis. Therefore, only the end of the bender without tabs can be used when contouring or adjusting the plate and screw trajectories. In addition, only one bridge section should be contoured at a time.

**Caution:** Unless the F.A.S.T. Tabs are intentionally being removed, each bend should be in one direction only; reverse or over bending may weaken or cause the plate to break.
A.L.P.S. Mesh Calcaneus Plate

Surgical Technique

Screw Insertion (cont.)

Additional locking or non-locking screws can then be placed as needed in the remaining screw holes to secure the fracture.

When filling a hole around the perimeter of the plate that has an attached F.A.S.T. Guide, first drill through the F.A.S.T. Guide using a 2.7 mm Drill Bit (Figure 14). Measure the screw length off of the gold measuring sleeve of the drill bit. Then remove the F.A.S.T. Guide with the T-15 Star Driver (Figure 15).

As an option to alter screw trajectory, the F.A.S.T. Guide can be removed and the 2.7 mm drill bit may be utilized with the 2.7/2.0 mm Double Drill Guide from the A.L.P.S. Total Foot System.
Screw Insertion (cont.)

Note: The Small Fragment Depth Gauge may also be used to verify screw length by removing the F.A.S.T. Guide and inserting the depth gauge (Figure 16).

Insert the selected locking or non-locking screw accordingly (Figure 17).

All screw holes can be made variable angle by removing the F.A.S.T. Guide prior to drilling utilizing the 3.5 mm Multi-Directional or 3.5 mm Low Profile Non-Locking Screws.
Screw Insertion (cont.)

If additional screws are required to be inserted into the “core” or inner area of the plate where screw holes do not have F.A.S.T. Guides, insert the Locking Drill Guide into a hole (Figure 18) and drill through the guide using a 2.7 mm Calibrated Drill Bit. Reference the screw depth on the calibrated drill bit off of the top of the Threaded Drill Guide (Figure 19). Remove the drill bit and drill guide and insert the selected screw.
Screw Insertion (cont.)

It is not necessary to fill each hole on the plate. The number of screws required is determined by the surgeon.

Wound Closure and Postoperative Protocol

Once the final screw has been inserted (Figure 20), and prior to wound closure, verify plate and screw placement via lateral, A/P, Harris axial and Broden's view.

Standard layered wound closure and appropriate postoperative protocol follows per surgeon preference.
A.L.P.S. Minimally-Invasive Calcaneus Plate

MIS Plates

MIS Lock Calc
Plate Small
(Left & Right)

MIS Lock Calc
Plate Large
(Left & Right)

MIS Lock Calc
Plate Small
Extended 2-Hole
(Left & Right)

MIS Lock Calc
Plate Large
Extended 2-Hole
(Left & Right)

MIS Lock Calc
Plate Large
Extended 3-Hole
(Left & Right)
Mesh Plates

Mesh Small
(Left & Right)
- 2 mm thickness
- 75 mm
- 45 mm

Mesh Large
(Left & Right)
- 2 mm thickness
- 82 mm
- 48 mm

Mesh X-Large
(Left & Right)
- 2 mm thickness
- 89 mm
- 53 mm
## A.L.P.S. Minimally-Invasive and Mesh Calcaneus Plating System

### Ordering Information

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*Sterile part codes are only to be ordered by EMEA and International markets.
## Ordering Information

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<th>NON-STERILE</th>
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INDICATIONS
The Biomet A.L.P.S. Calcaneal Plating System is intended for fixation of fractures, fusions, and osteotomies of the calcaneus.

The use of metallic surgical appliances 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
(orthopaedic screws, intramedullary nails, plates, compression hip screws, pins and wires):

- Cases where there is an active infection.
- Conditions which tend to retard healing such as, blood supply limitations, previous infections, etc.
- Insufficient quantity or quality of bone to permit stabilization of the fracture.
- Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process.
- Foreign body sensitivity – where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantations.
- Cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients.

Additional Contraindications – 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.

1. Data on File at Biomet. Mechanical testing #DVA-107504-DVER.
   Mechanical testing is not necessarily indicative of clinical performance.

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