



Lapidus Arthrodesis System Instructions for Use

Description

The AlignMATE™ Lapidus Arthrodesis System consists of bone plates and bone screws (locking, non-locking and interfragmentary), which are intended to be used for surgical fusion or arthrodesis between two bone segments (ex. 1st metatarsal-cuneiform fusion as in a Lapidus procedure). All implant components are manufactured from implant grade titanium alloy.

Materials

Bone Plates: Implant Grade Ti-6Al-4V Alloy
Bone Screws: Implant Grade Ti-6Al-4V Alloy
Surgical Instruments: Medical Grade Stainless Steel and High Temperature Plastics

Indications for Use

Intended for the treatment of fracture fixation, osteotomies (ex. Akin, Chevron, Scarf, Weil), reconstruction, revision surgery and arthrodesis of small bones in the upper and lower extremities.

Patient Population

Patient Selection Factors to be Considered Include:

- Failure of previous conservative treatment options in correcting deformity and achieving pain relief.
- Adequacy of bone stock to support implant components.
- Patient's age indicative of skeletal maturity.
- Functionality and/or stability of patient's musculotendinous system.

- Patient's overall well-being, including the ability and willingness to follow pre and post-operative treatment regimen.

Contraindications

Absolute Contraindications Include:

- Previous or current infection at or near the implantation site.
- Pre-existing conditions such as limited blood supply that may significantly affect the healing response.
- Patients having malignant primary or metastatic tumors that may preclude adequate bone support or screw fixation.
- Patients with known allergies or hypersensitivity to implant grade titanium alloy typically used in prosthetic devices.

Relative Contraindications Include:

- Poor bone quality or quantity that may lead to inadequate stabilization/fusion of the joint complex.
- Metabolic disorders that may impair the formation or healing of bone.
- Infections at remote sites, which may spread to the implant site.
- Rapid joint destruction or bone resorption visible on roentgenogram.

Warnings and Precautions

- Pre-operative and operative procedures, including knowledge of surgical technique, proper selection and placement of implant components are important considerations in the successful utilization of the AlignMATE™ Lapidus Arthrodesis System.
- The potential for success in joint fusion and/or fracture fixation is increased by proper implant selection. The patient's anatomy and indication will determine the size of the bone plate and screws to be used. The size and shape of human bones presents limitations on the size and strength of the implant components.

- To achieve desired outcomes with the AlignMATE™ Lapidus Arthrodesis System, pre-operative patient evaluation is extremely important. Patient's weight, occupation, activity level, mental condition, foreign body sensitivity and any degenerative diseases are important factors to consider. These conditions must be evaluated as a part of the pre-operative planning.
- The AlignMATE™ Lapidus Arthrodesis System implant components are manufactured from metal, and CANNOT be expected to withstand the range of motion, activity level and loads experienced by normal, healthy bone. These implants are intended to be used as a guide to normal healing, and not to replace normal body structure.
- It is very important to maintain the implant site in an immobilized state until bony union is confirmed via clinical or radiographic examination. Failure to do so will result in excessive and repeated stresses being placed on implant components, which can lead to bending or breaking of the implants due to normal metal fatigue.
- The presence of motion or forces across the fusion site in cases of delayed union or nonunion may lead to implant bending or breakage due to metal fatigue.
- All surgical implants are subjected to repeated stresses that can result in failure. The use of an implant should be avoided if excessive loading cannot be prevented at or near the implant site.
- Post-operative care is extremely important. The surgeon must warn the patient against noncompliance with post-operative instructions, which could lead to implant bending or breakage requiring a revision surgery and/or implant removal.
- Unless otherwise noted, the patient should employ adequate external support and restrict physical activities that may lead to stresses being placed on the implant components or allow motion at the fusion site and thus lead to delayed healing. An active, debilitated or demented patient who cannot properly utilize weight support devices may be at higher risk during post-operative rehabilitation.

- Accepted practices in post-operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post-operative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.
- Correct implant handling is extremely important for successful outcomes. Implant components should not be bent, reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and cause internal stress concentrations, which may become the focal point for eventual failure of the implant system.
- No other metallic implantable devices are to be used in conjunction with the AlignMATE™ Lapidus Arthrodesis System at the implant site. Doing so may compromise implant performance and patient safety.
- No implant component must be reused. The AlignMATE™ Lapidus Arthrodesis System implant components are Single Use devices that have not been designed to undergo or withstand any form of alterations, such as disassembly, cleaning or re-sterilization, after single patient use. Reuse can eventually compromise implant performance and patient safety.
- Implant removal is at the sole discretion of the surgeon. Whenever possible and practical for the individual patient, the AlignMATE™ Lapidus Arthrodesis System implant components should be removed once their service as an aid to the healing process is accomplished, particularly in younger and more active patients. Great care must be taken while removing the implant components.
- The AlignMATE™ Lapidus Arthrodesis System should be inspected by surgeon or surgical staff prior to use for any signs of wear or damage. Any discrepancies, damages or other issues with the packaging, labeling or implant components should be reported and brought to the notice of the manufacturer.

MR Safety Information

- The AlignMATE™ Lapidus Arthrodesis System implant components have not been evaluated for safety and compatibility in the MR environment. These have not been tested for heating, migration or image artifact in the MR environment. The safety of the AlignMATE™ Lapidus Arthrodesis System implant components in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Possible Adverse Effects and Complications

- Loosening, bending, cracking or fracture of the bone plates and bone screws attributable to malunion, nonunion or osteoporosis.
- Loss of anatomic position with malunion or nonunion with rotation or angulation.
- Infection, both deep or superficial, or allergic reaction.
- Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed from similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
- Embolism
- Tissue reactions such as macrophage and foreign body reaction at or near implant site.
- Fretting or crevice corrosion can occur at the interface of bone plates and bone screws.
- Fatigue fracture of the implants as a result of bone resorption around the implant components.
- Intraoperative or postoperative bone fracture.
- Post-operative pain or incomplete resolution of pre-operative symptoms.

Sterility

Bone Plates

The AlignMATE™ Lapidus Arthrodesis System's bone plate with pre-assembled nubbins, and IF guide, are packaged together and provided STERILE. They are sterilized by exposure to gamma irradiation. Do not resterilize any components. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only. Note: Pre-assembled nubbins and IF guide are for guidance purposes only. In accordance with the surgical technique, the nubbins and IF guide are to be disassembled from the bone plate and disposed after intended use.

IF Bone Screw

The AlignMATE™ Lapidus Arthrodesis System's Interfragmentary or IF Bone Screws are individually packaged and provided STERILE. They are sterilized by exposure to gamma irradiation. Do not resterilize any components. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only.

Pin Kit and Driver Kit

The AlignMATE™ Lapidus Arthrodesis System's guide pin, drill pin and tack pins i.e. the Pin Kit, and the cannulated drill pin and screw driver i.e. Driver Kit, are packaged and provided STERILE. These are sterilized by exposure to gamma irradiation. Do not resterilize any components. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only. Dispose after intended use.

Instrument Kit

The AlignMATE™ Lapidus Arthrodesis System is to be used with CheckMATE® instrument kit. Reference the CheckMATE® IFU for processing and sterilization information of the screw caddy with bone screws (single use) and surgical instruments (reusable).

Caution

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Surgical Procedure

It is the surgeon's responsibility to become familiar with the procedure and obtain necessary training prior to performing implantation using the AlignMATE™ Lapidus Arthrodesis System. The AlignMATE™ Lapidus Arthrodesis System's Bone Plates and Bone Screws are intended to be implanted with the aid of Arthrosurface, Inc.'s CheckMATE® MTP Arthrodesis System Reusable Instrument Set.

A basic outline of the procedure is provided herein, and is as follows:

1. Expose the 1st metatarsal-cuneiform (MC) joint and prepare the joint surfaces using standard orthopaedic techniques. Decorticate the joint surfaces using either a sagittal saw or a standard curettage technique using osteotomes or rongeurs.



2. Select the appropriate side (right or left), large or small bone plate based on the patient anatomy. Align the joint in the desired orientation of fixation and temporarily fixate the bone plate to the bones using tack pins, making sure to align the laser line on the bone plate with the 1st MC joint line.
3. Insert a tack pin in any one or both of the distal bone plate holes to fixate the bone plate to the metatarsal bone. Insert another tack pin on the proximal end of the pin slot to fixate the bone plate to the cuneiform bone.



4. Load the compression clamp on the proximal tack pin and any one of the distal nubbins. Compress the 1st MC joint.



5. Create pilot holes through the proximal bone plate hole nubbins using either a drill pin or a tack pin. Remove the proximal nubbins and discard them. Measure the proximal, superior bone screw length required using the depth gauge instrument.



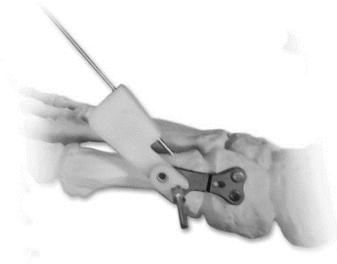
6. Insert a non-locking screw.



7. Similarly, measure and insert a locking screw in the proximal, inferior bone plate hole. Note: Based on preference, the surgeon can choose to insert either a locking or a non-locking bone screw in either of the proximal bone plate holes. Remove the compression clamp and the proximal tack pin from the pin slot.



8. Place the interfragmentary (IF) guide over the distal bone plate nubbins. Insert a guide pin through the IF guide's pin slot and across the 1st MC joint. Use fluoroscopy to confirm that the tip of the guide pin is flush with the inferior surface of the cuneiform bone.



9. Remove the IF guide and place the IF depth gauge over the guide pin to determine the IF screw length required.



10. Remove the IF depth gauge. Create a pilot hole using the cannulated drill pin over the guide pin. The countersink instrument may now be used to create a recess in the metatarsal bone for flush placement of the IF screw head.



11. If using the cannulated screw, remove the drill pin and leave the guide pin in place. Insert the cannulated screw over the guide pin and implant using the cannulated screw driver. If using the solid core screw, remove the drill pin and guide pin and implant the IF screw using the screw driver from the instrument tray. Note: Based on surgeon preference, Steps 8 through 11 can be performed prior to Step 4.



12. Complete the implantation procedure by creating pilot holes, discarding the nubbins, followed by measuring and inserting either locking or non-locking bone screws in the distal bone plate holes.



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