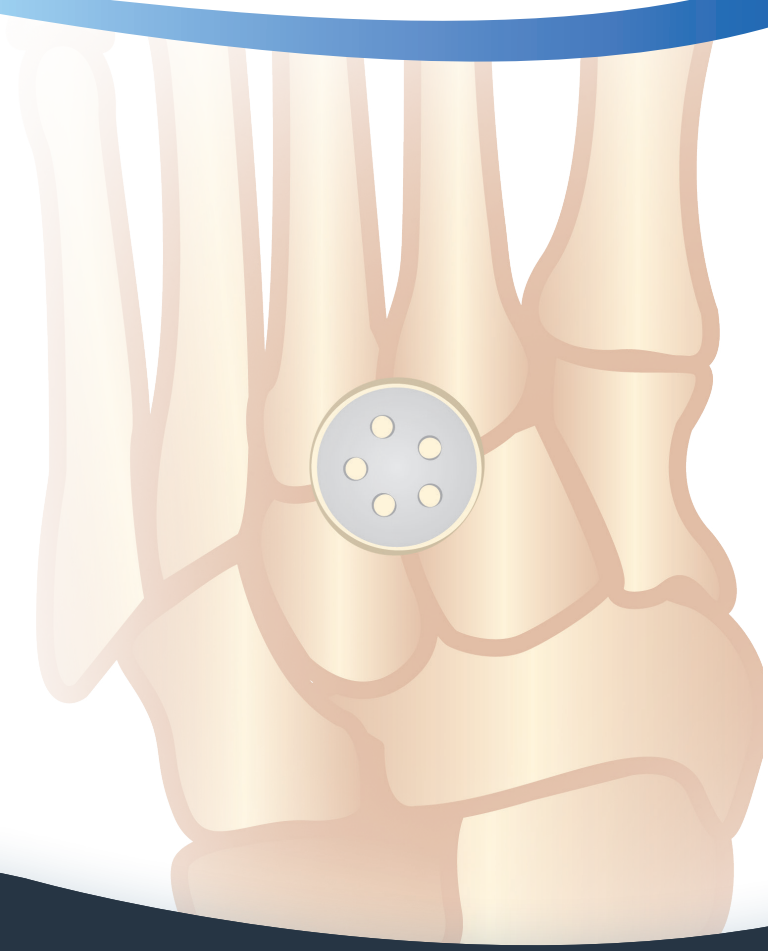
arthrosurface®

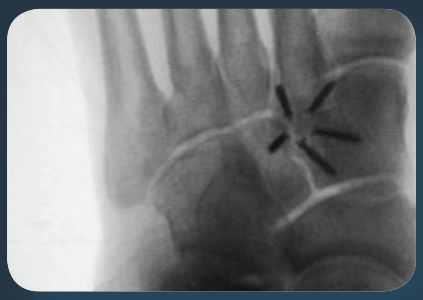
Technique Guide

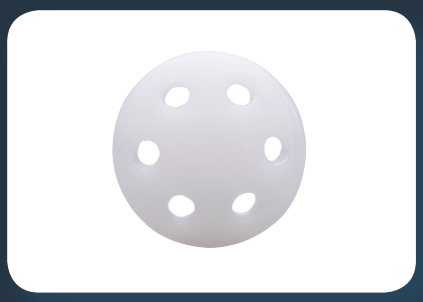
Allograft Fusion System

OsteoMATE®

The OsteoMATE® Allograft Fusion System is fashioned from dense cortical bone harvested from human femur or tibia and is designed to provide circumferential bone contact for integration into the patients' host bone.







- ☑ Bone removed during site preparation is replaced with bone allograft *(not metal or PEEK implants)*
- ☑ Divergent angled screw holes provide rigid graft fixation
- ☑ Screw guide serves as the allograft trial, allowing you to precisely orient all fixation screw locations prior to placing any screws
- ☑ Allograft is provided Sterile, ready to use and shelf stable for 5 years

Description

The OsteoMATE® Allograft Fusion System consists of a shaped human tissue cortical bone allograft, bone screws and a single-use, packaged, sterile and disposable instrument kit used to facilitate surgical site preparation and placement of the allograft.

Materials

Allograft:	Shaped Human Tissue Cortical Bone Allograft
Bone Screws:	Implant Grade Ti-6AL-4V
Surgical Instruments:	Medical Grade Stainless Steel and High Temperature Plastics

Indications For Use

The OsteoMATE® Allograft Fusion System is intended to be used for the treatment of fracture fixation, osteotomies, reconstruction revision surgery and arthrodesis of small bones in upper and lower extremities.

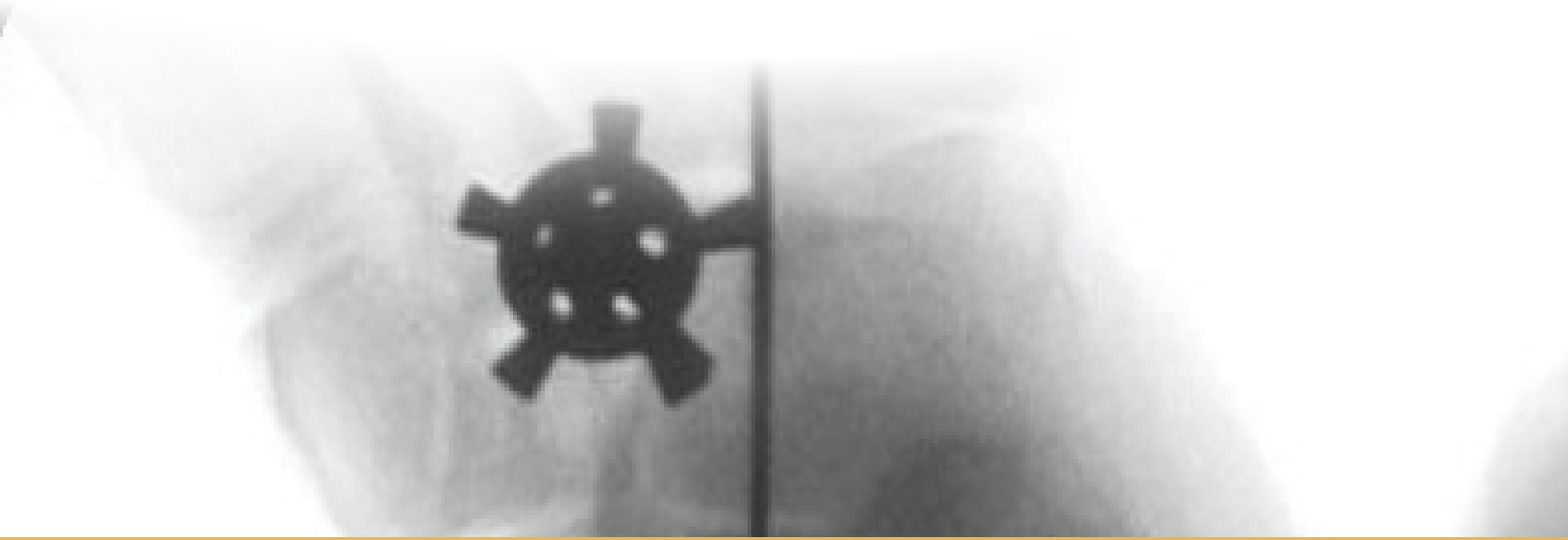
Contraindications

Absolute contraindications include:

- Previous or current infection at or near the surgical 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 allograft support or screw fixation.
- Patients with known allergies or hypersensitivity to implant grade stainless steel or titanium alloys typically used in prosthetic devices.

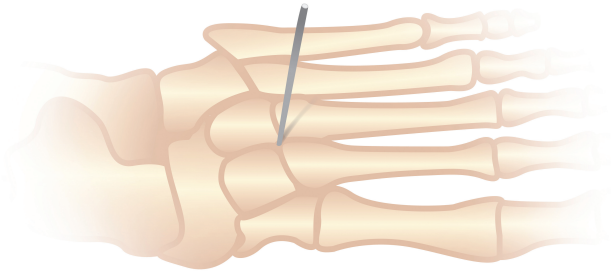
Relative contraidications include:

- Uncooperative patient or patient incapable of following preoperative and postoperative instructions.
- 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 surgical site.
- Rapid joint destruction or bone resorption visible on roentgenogram

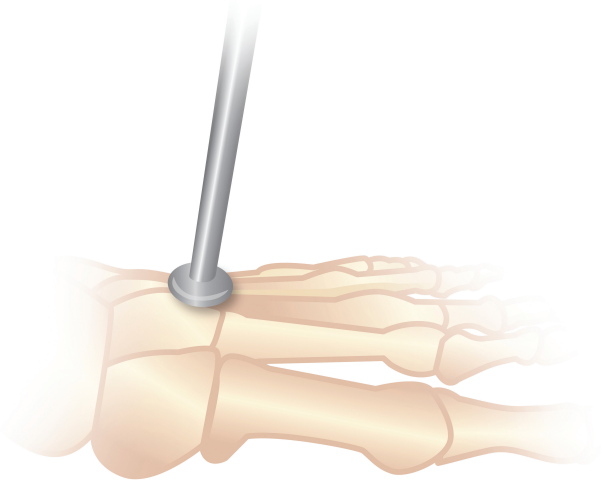


Surgical Technique

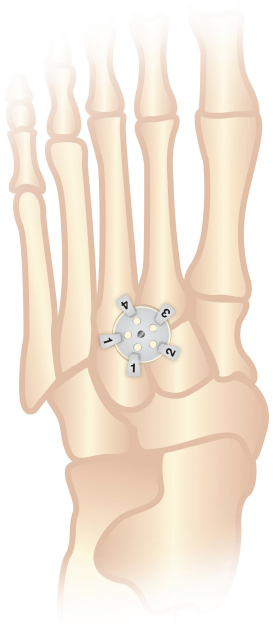
1. Insert **Guide Pin** using a pin/wire driver central to the desired location of the fracture fixation or fusion site.



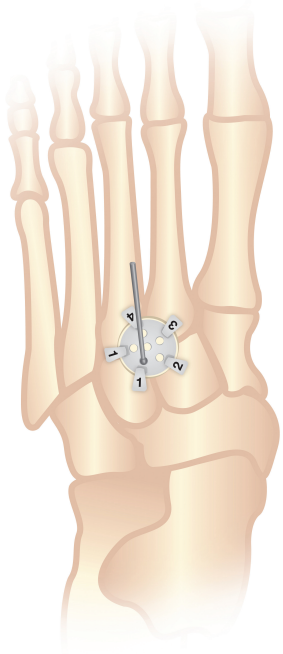
2. Introduce **Reamer** over the **Guide Pin** and advance under power until the proximal surface of the **Reamer** is flush with the surrounding bone surface.



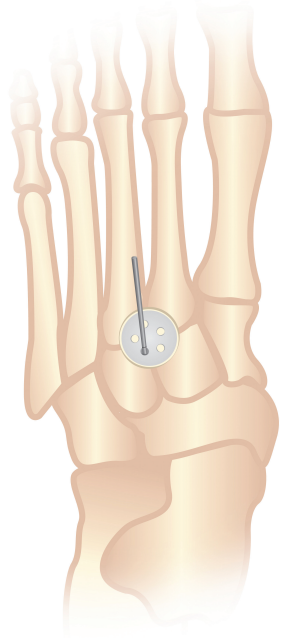
3. Remove the **Reamer** and introduce the **Screw Guide** over the **Guide Pin**. Align the **Screw Guide** in the desired orientation of final **Bone Screw** placement. Radiographic imaging can be used to confirm the desired orientation of **Bone Screw** placement.



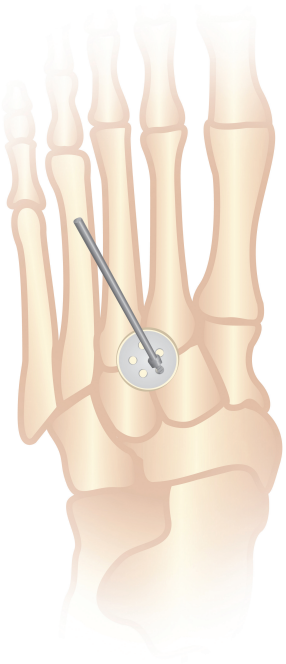
4. Remove the **Guide Pin** from the central hole and insert it into one of the **Bone Screw** holes in the **Screw Guide**. Required **Bone Screw** length can now be determined using the laser markings on the **Guide Pin**.



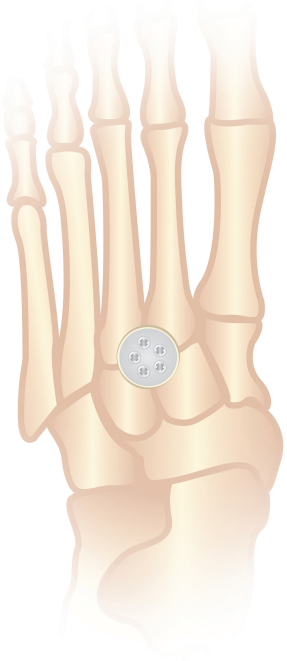
5. Remove the **Screw Guide** and introduce the **OsteoMATE® Allograft** over the **Guide Pin** and into the reamed socket. Ensure that the proximal surface of the **OsteoMATE® Allograft** is flush with the surrounding bone.



6. Load the pin/wire driver with appropriate length 2.7 mm diameter snap-off **Bone Screw** and insert through one of the **OsteoMATE® Allograft** holes. Bend or tilt pin/wire driver away from center axis to snap-off shaft from **Bone Screw** once its head is in contact with **OsteoMATE® Allograft**. The **Screw Driver** may be used to adjust final placement of **Bone Screw.**



7. Remove the **Guide Pin** and repeat step 6 for remaining **OsteoMATE® Allograft** holes. Confirm final placement and position radiographically.



Warnings & Precautions

Proper surgical techniques are the responsibility of the medical professional. To achieve desired outcomes with the OsteoMATE® Allograft Fusion 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. As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes individuals with bleeding disorders of any etiology, long-term steroidal therapy, or immunosuppressive therapy or high dosage radiation therapy. Every patient is different and patient results may vary.The OsteoMATE® instruments are furnished as tools to facilitate surgical site preparation and positioning the OsteoMATE® Allograft. Each surgeon must evaluate the appropriateness of the instruments and techniques for each patient based on his or her own medical training and expertise.

It is very important to maintain the surgical 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 the allograft, which can lead to bending or breaking. The presence of motion or forces across the surgical site in cases of delayed union or nonunion may lead to allograft bending or breakage due to fatigue. The use of the allograft should be avoided if excessive loading cannot be prevented at or near the surgical site. Post-operative care is extremely important. The surgeon must warn the patient against noncompliance with post-operative instructions, which could lead to allograft bending or breakage requiring a revision surgery. Unless otherwise noted, the patient should employ adequate external support and restrict physical activities that may lead to stresses being placed on the allograft 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. The OsteoMATE® Allograft Fusion System is designed for single patient use only and is not intended to undergo or withstand any form of alterations, such as disassembly, cleaning or re-sterilization, after single patient use. Reuse can eventually compromise patient safety. Examples of hazards related to the reuse of these components include, but are not limited to: significant degradation in device performance, cross- infection, and contamination. Inspect components prior to use for damage during shipment or storage. Verify that components are within expiry date on package label. Expired product should be properly discarded.

Possible Adverse Effects

General risks and complications may include, but are not limited to: infection, allergic reaction, loosening or loss of fixation of the graft, poor integration of the graft bleeding, injury to nerves, etc. Tissue reactions such as macrophage and foreign body reaction at or near the surgical site. Intraoperative or postoperative bone fracture. Post-operative pain or incomplete resolution of pre-operative symptoms. Complications may occur with tissue transplantation and surgeons should discuss these possible adverse events with their patients:

- Transmission of disease of unknown etiology
- Transmission of unknown infectious agents including, but not limited to, HIV, Hepatitis, syphilis and bacteria
- Immune rejection of HCT/P

Any adverse outcomes potentially related to this system must be promptly reported to Arthrosurface, Inc.

Sterility

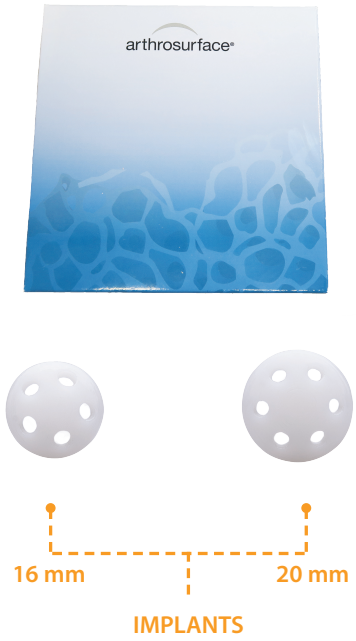
The OsteoMATE® Allograft Fusion System components are sterilized by exposure to gamma radiation. Do not resterilize any components. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only. Refer to the OsteoMATE® Donated Human Allograft Tissue package insert for sterility information related to the shaped human tissue cortical bone allograft. Refer to the OsteoMATE® Bone Screws package insert for sterility information related to the bone screws.

Caution

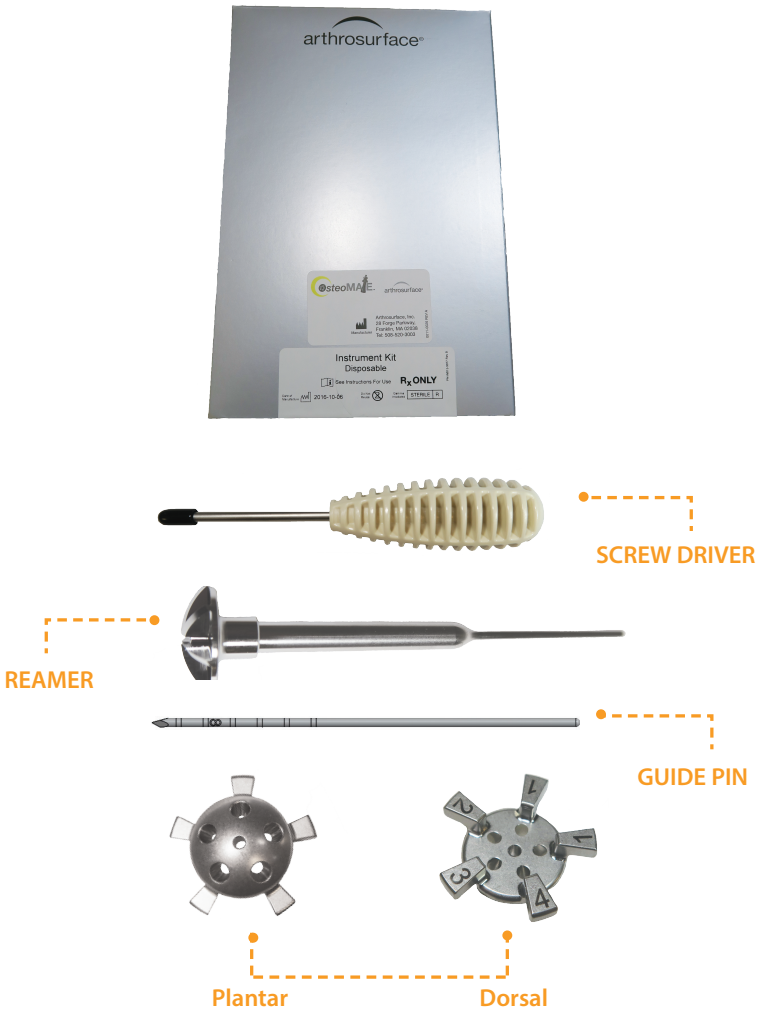
Federal Law (USA) restricts this device to sale by or on the order of a physician.

Instrumentation

OsteoMATE® Allograft, Sterile



OsteoMATE® Instruments, Disposable



Bone Screw (5-Pack)

System Catalog

Instruments

9K00-0100	Instrument Kit, Disposable
9K00-0500	Sizers & Pin Kit, Disposable

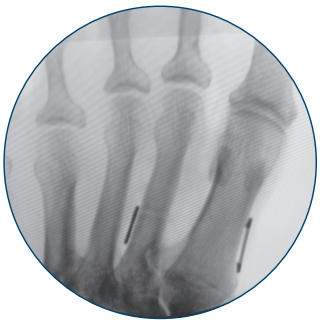
Allograft

9K00-0160	Allograft, Ø 16mm
9K00-0200	Allograft, Ø 20mm

Bone Screws

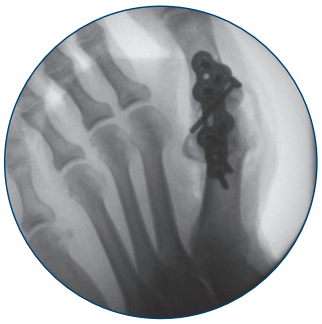
9A2D-B008	Snap-off Bone Screw, Ø 2.7 mm x 8 mm
9A2D-B010	Snap-off Bone Screw, Ø 2.7 mm x 10 mm
9A2D-B012	Snap-off Bone Screw, Ø 2.7 mm x 12 mm
9A2D-B014	Snap-off Bone Screw, Ø 2.7 mm x 14 mm
9A2D-B016	Snap-off Bone Screw, Ø 2.7 mm x 16 mm
9A2D-B018	Snap-off Bone Screw, Ø 2.7 mm x 18 mm
9A2D-B020	Snap-off Bone Screw, Ø 2.7 mm x 20 mm
9A2D-B022	Snap-off Bone Screw, Ø 2.7 mm x 22 mm
9A2D-B024	Snap-off Bone Screw, Ø 2.7 mm x 24 mm

Arthrosurface® currently provides the following trauma & osteotomy products:



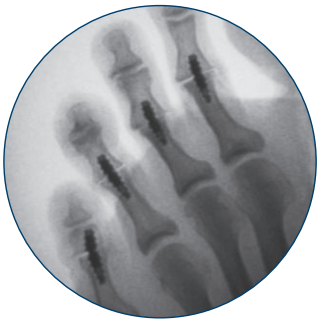
KiSSLOC®

Suture System



CheckMATE

Fusion Plate



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Hammertoe Correction

arthrosurface®

For more information, visit our website:
www.arthrosurface.com

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This pamphlet and information is intended for markets where regulatory approval has been granted.

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