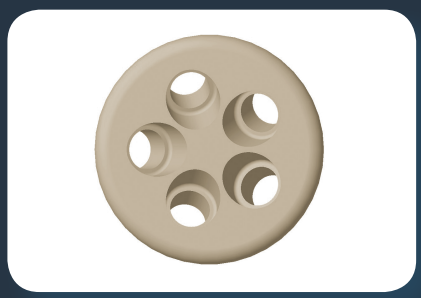
arthrosurface®

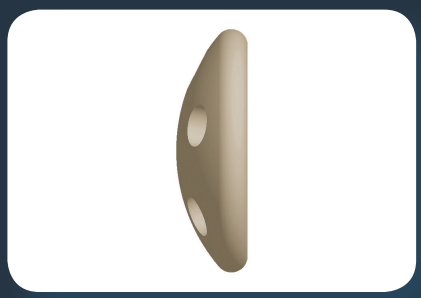
Technique Guide

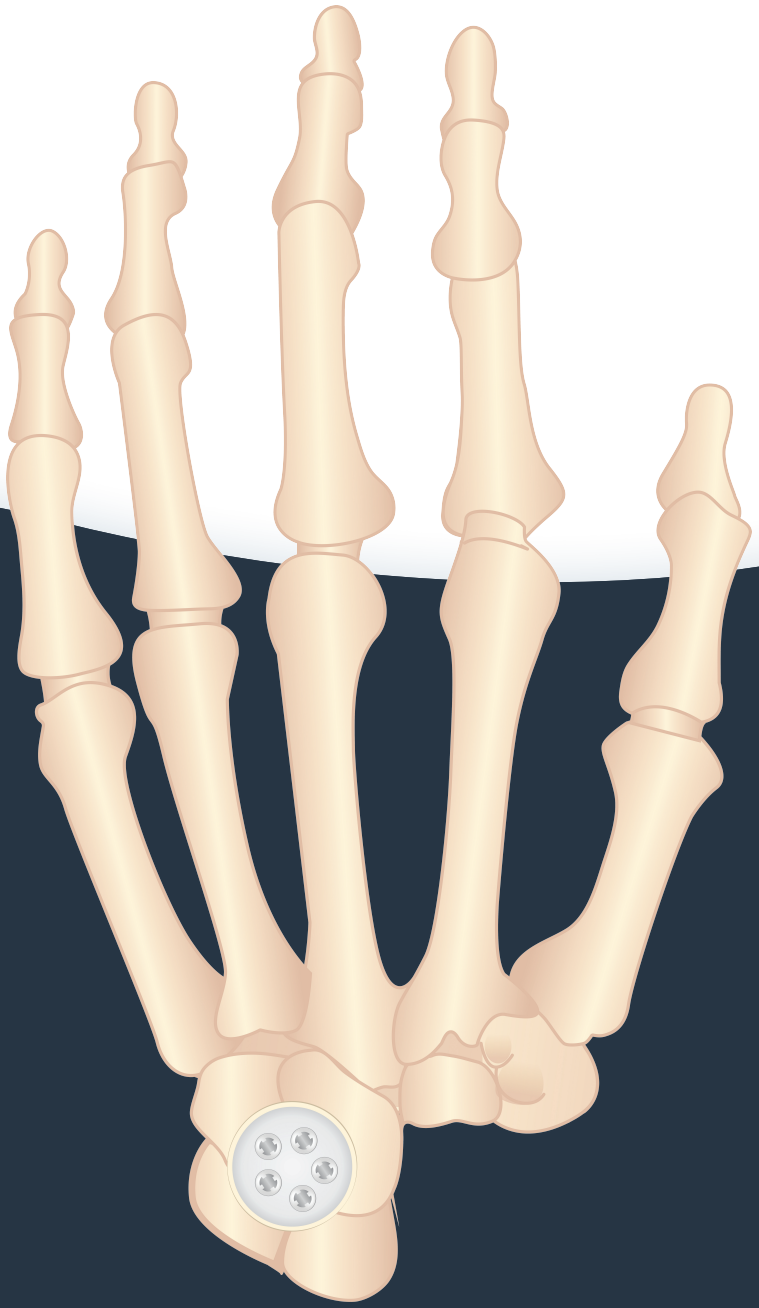
Allograft Fusion System

OsteoMAIE™

The First Four Corner Arthrodesis System Comprised of Allograft Bone







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.

Refer to the OsteoMATE™ Donated Human Allograft Tissue package insert for additional indications and instructions for use of the shaped human tissue cortical bone allograft.

Refer to the OsteoMATE™ Bone Screws package insert for additional indications and instructions for use of the bone screws.

Patient Population

Patient Selection Factors to be Considered Include:

- Failure of previous conservative treatment options in correcting deformity and achieving pain relief.
- Need to obtain pain relief and improve function.
- Adequacy of native bone stock to support allograft tissue.
- Patient's age indicative of skeletal maturity.
- Functionality and/or stability of patient's vascular and musculotendinous system.
- Patient's overall well-being, including the ability and willingness to follow pre & post-operative treatment regimen.

Contraindications

Absolute contraindications include:

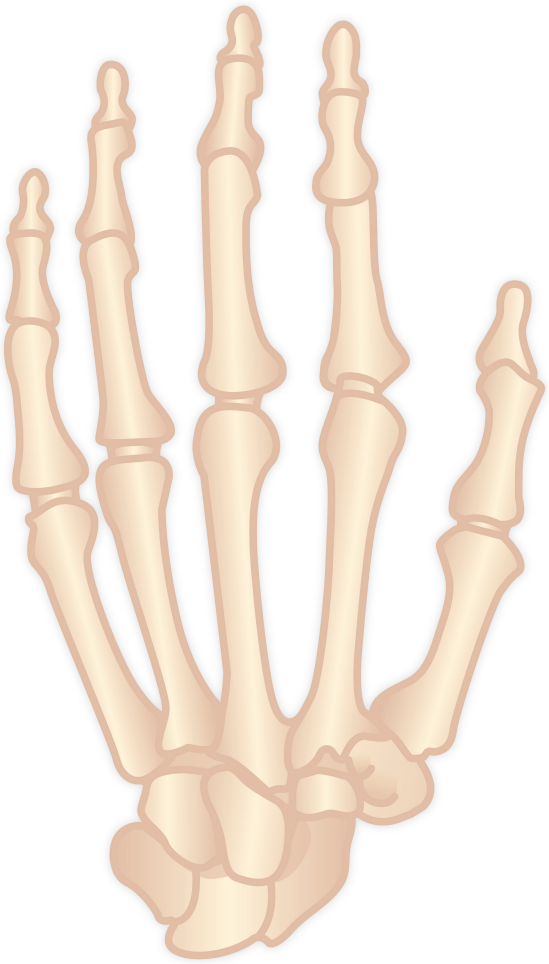
- Previous or current infection at or near the surgical site.
- Pre-existing conditions such as limited blood supply that may significantly affect the healing response.
- Patients having malignant primary or metastatic tumors that may preclude adequate allograft support or screw fixation.
- Patients 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. Enter the radiocarpal and midcarpal joints taking care to protect the extrinsic ligaments, extensor tendons, sensory nerves and other supportive soft tissue structures.



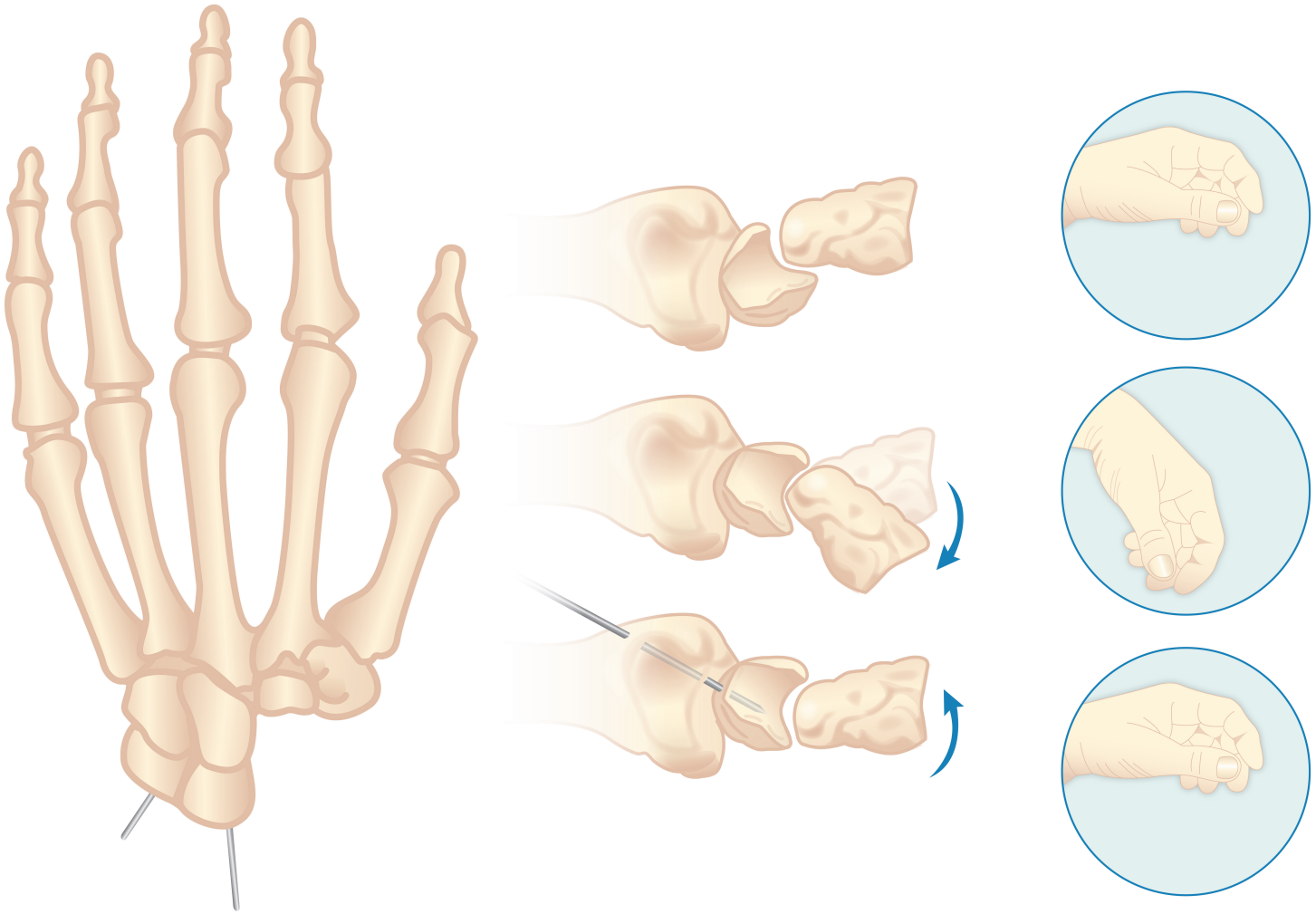
2. Based on patient requirement and surgeon preference, the scaphoid can be partially or completely excised.

3. Using an osteotome, rongeur, curette, burr or other similar tool, decorticate joint fusion articular surfaces. Cartilage from the capitolunate, triquetrohamate, capitohamate and lunotriquetral joint surfaces must be completely removed. This step is critical in achieving successful fusion.

Surgical Technique Continued

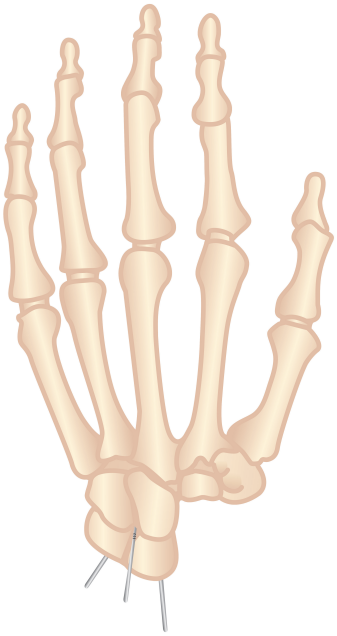
4. Reduce and temporarily affix the radiocarpal joint in a neutral alignment using K-wires.

   Tip: Place the K-wires volarly to avoid interference with the reaming step. Correct any alignment deformity of the radiolunate and/or capitolunate joint(s) at this point to prevent dorsal or volar impingement following fusion.

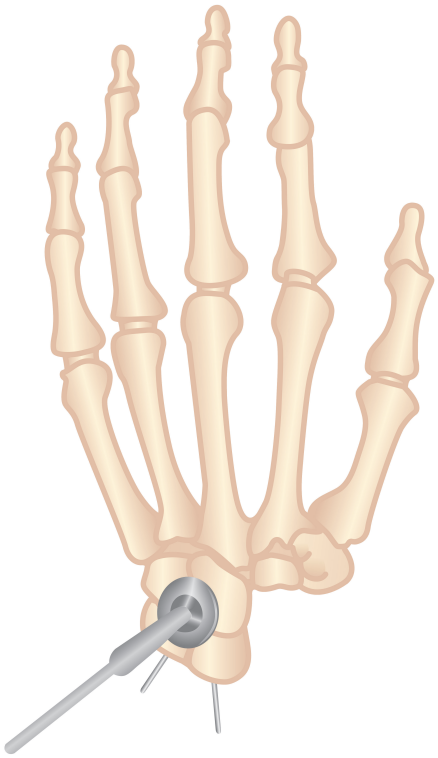


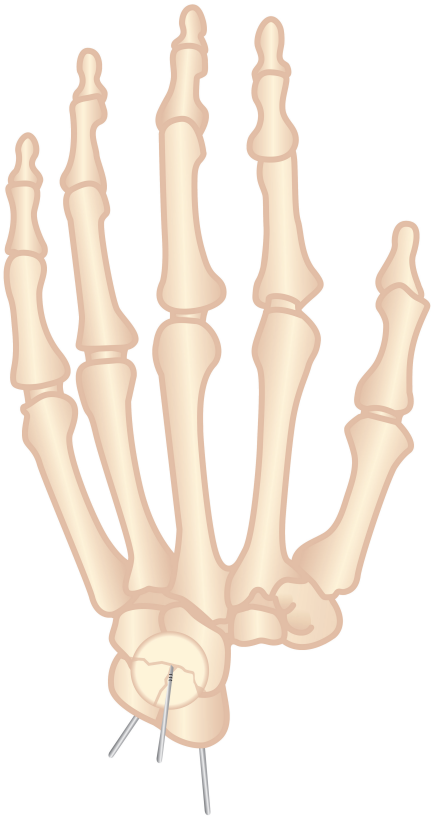
5. Insert the **Guide Pin** using a wire driver central to the desired location of the fusion site, to a depth of 20mm.

   *Tip: The **Guide Pin** may be inserted into the corner of the capitate, hamate or lunate. The **Screw Guide** may be used to confirm that all bones being fused will be reamed equally.*



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



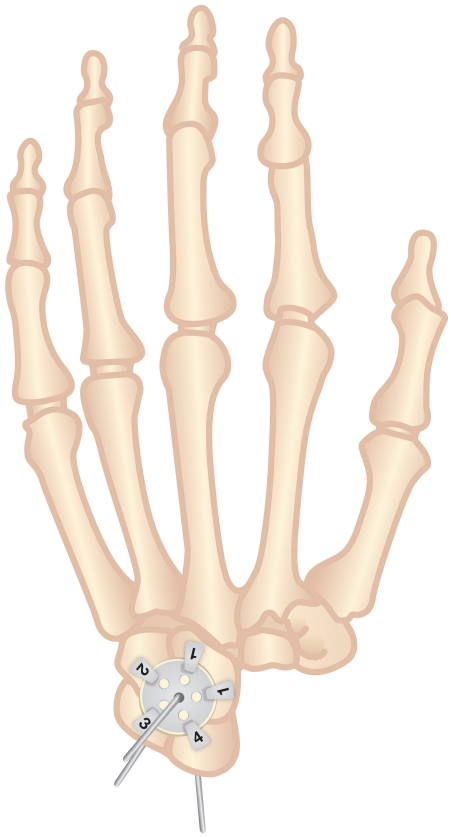


Surgical Technique Continued

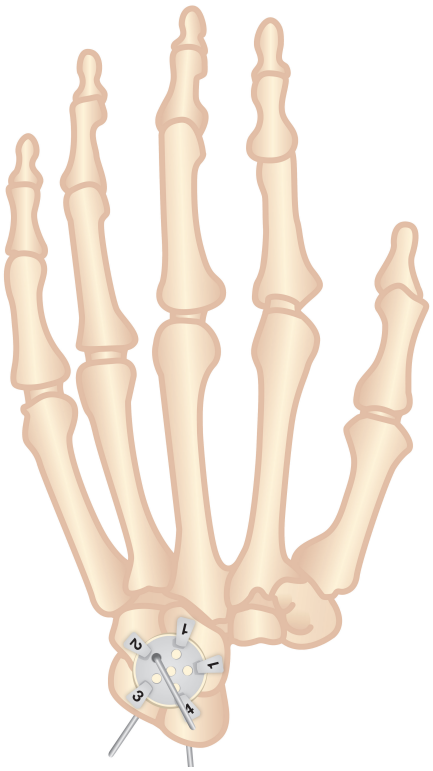
7. Remove the **Reamer** and introduce the **Screw Guide** over the **Guide Pin**. Align the **Screw Guide** such that the tabs labeled '1' align with the capitate, '2' with the hamate, '3' with the triquetrum and '4' with the lunate.

   Note: Autologous bone graft may now be packed in between the joint surfaces to be arthrodesed.

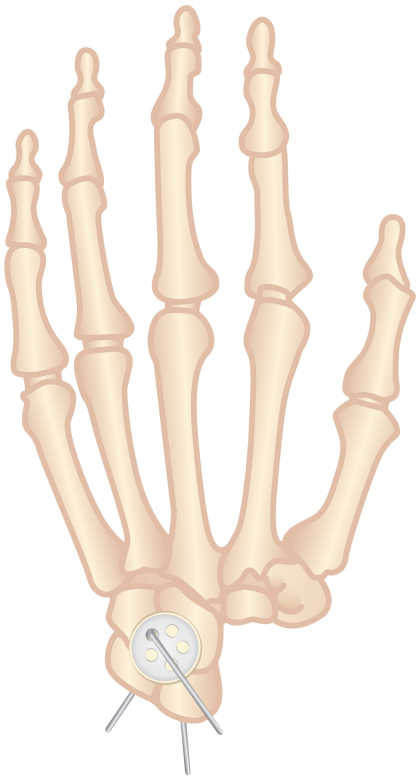
   Tip: Use fluoroscopic imaging to confirm alignment of the ***Screw Guide*** *tabs as described above*



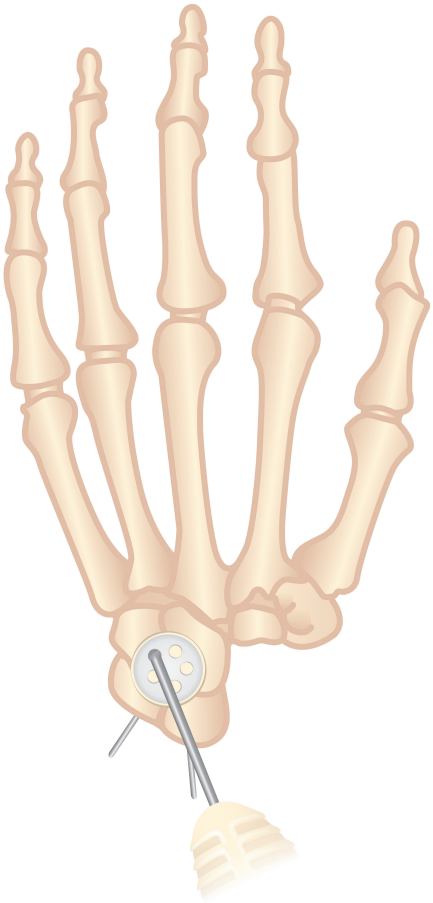
8. While securely holding the position of the **Screw Guide**, remove the **Guide Pin** from the central hole and insert it into one of the **Bone Screw** holes in the **Screw Guide**. Required **Bone Screw** length can now be determined using the laser markings on the **Guide Pin**.



9. 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. If not flush, then repeat Step 6.

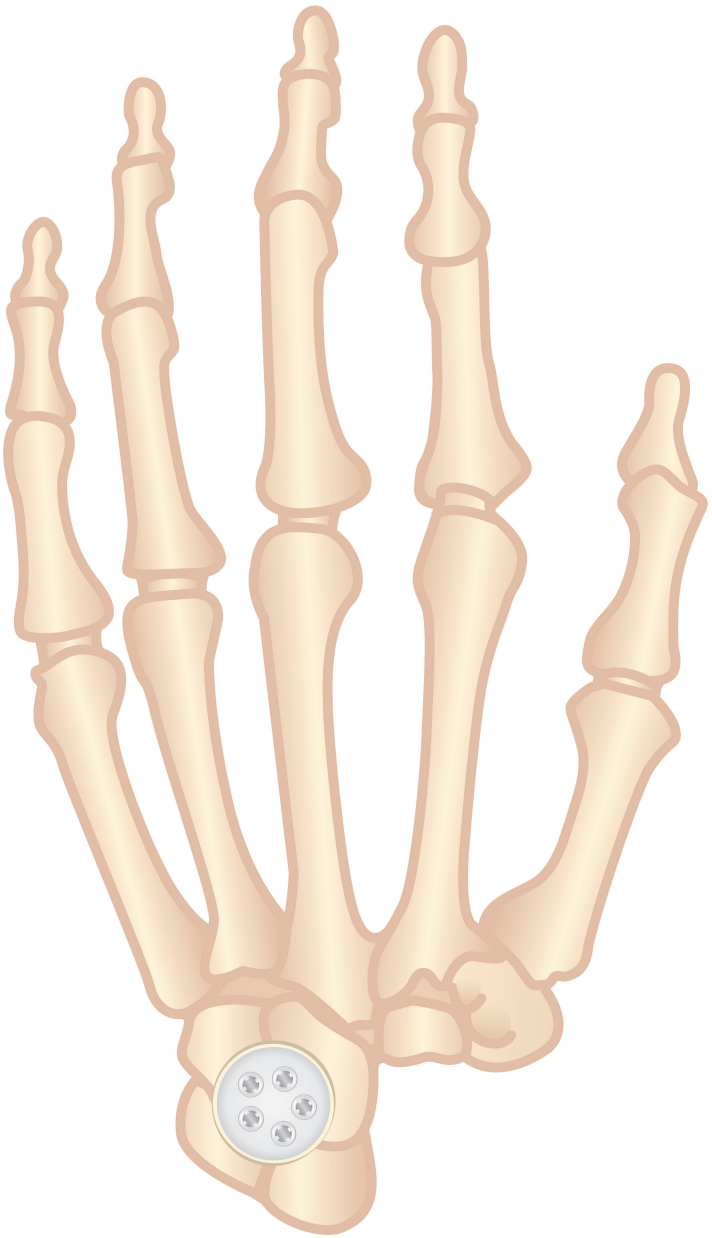


10. Load the wire driver with appropriate length 2.7mm diameter snap-off **Bone Screw**. Insert it half way through one of the **OsteoMATE™ Allograft** holes under power (at low speed). Remove the wire driver and insert the **Screw Driver** over the **Bone Screw Shaft**. Manually insert the **Bone Screw** to lock the allograft to the bone. While pressing down on the allograft, bend or tilt the **Screw Driver** to snap-off the shaft from the **Bone Screw** head.



Surgical Technique Continued

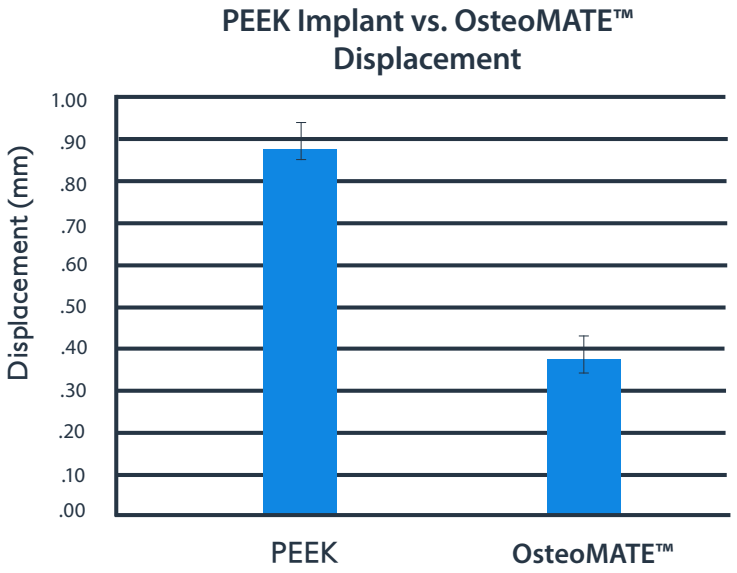
11. Remove the temporary K-wires as required and repeat step 10 for remaining **OsteoMATE™ Allograft** holes. Using radiographic or fluoroscopic imaging, ensure appropriateness of the **Bone Screw** lengths to avoid irritation of the surrounding soft tissues and joints, and to minimize radiocarpal impingement following fusion. Confirm final placement and position radiographically.



Biomechanical Testing

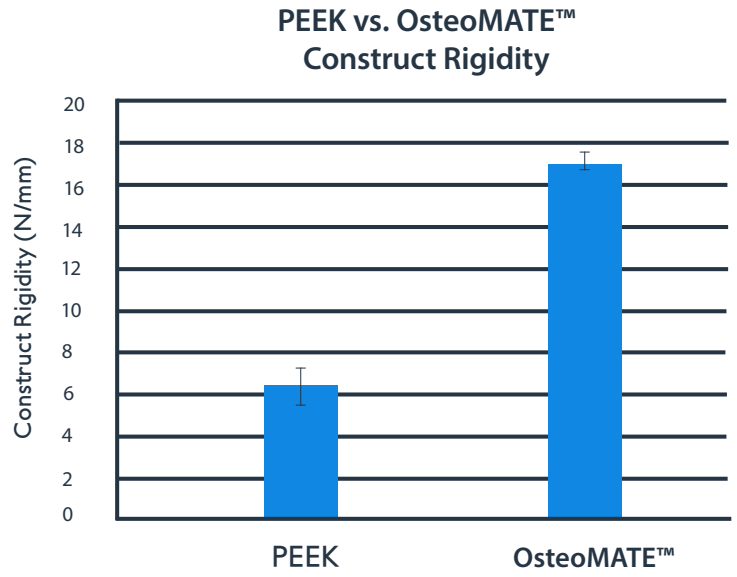
Displacement Test:

- **The displacement (or micromotion) at the joint following implantation of the OsteoMATE™ allograft was less than half (0.42 times) compared to that following placement of a PEEK implant.**
- To determine joint displacement following implantation, a bending moment or torque of 80 N-cm was applied for a total of 5000 cycles.[1, 2]
- This simulates the wrist motion experienced during normal, day to day activities prior to bony or fibrous union.



Rigidity Test:

- **The rigidity (or bending stiffness) at the joint following implantation of the OsteoMATE™ allograft was more than double (2.5 times) compared to that following placement of a PEEK implant.**
- To determine joint rigidity following implantation, a one-time bending moment or torque was applied at the joint to simulate the motion of wrist extension.



Summary

The success of any arthrodesis depends on the stability achieved at the fixation site.[1, 2] The OsteoMATE™ Allograft Fusion System has superior biomechanical properties compared to a PEEK implant, and provides for a stiff, strong and immobile fixation, which may lead to improved union rate. It offers benefits over metal and PEEK dorsal circular plates in that it is composed of human cortical tissue allograft, which has similar elastic modulus as normal human bone and provides for a natural scaffold for the native bone to integrate into and remodel as the fusion progresses. Unlike metal the OsteoMATE™ Allograft is radiolucent to allow for post-op visualization of the fusion and unlike PEEK it is capable of osseointegration.

References

1. *Kraisarin, J., et al. "Biomechanical comparison of three fixation techniques used for four-corner arthrodesis." Journal of Hand Surgery (European Volume) 36.7 (2011): 560-567.*
2. *Rudnick, Benjamin, et al. "Four-corner arthrodesis with a radiolucent locking dorsal circular plate: technique and outcomes." Hand 9.3 (2014): 315-321.*

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

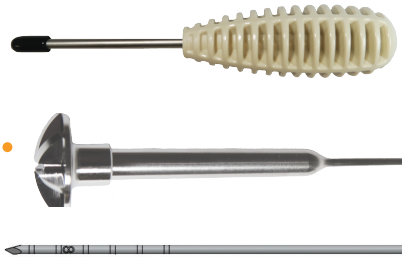
Federal Law (USA) restricts this device to sale by or on the order of a physician.

Instrumentation

OsteoMATE® Allograft, Sterile

ALLOGRAFT
IMPLANT

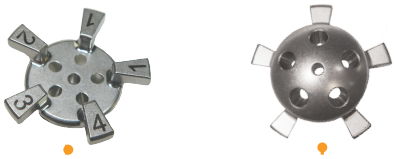
OsteoMATE® Instruments, Sterile, Disposable



SCREW DRIVER

REAMER

GUIDE PIN



Top

Bottom

SCREW GUIDE

System Catalog

Instruments

9K00-0100	Instrument Kit, Disposable

Allograft

8K00-0160	OsteoMATE™ Disk Allograft, Ø16mm

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®

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

28 Forge Parkway • Franklin, MA 02038
1 508 520 3003
fax: 1 508 528 3785

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

PN 4001-3013 Rev. A