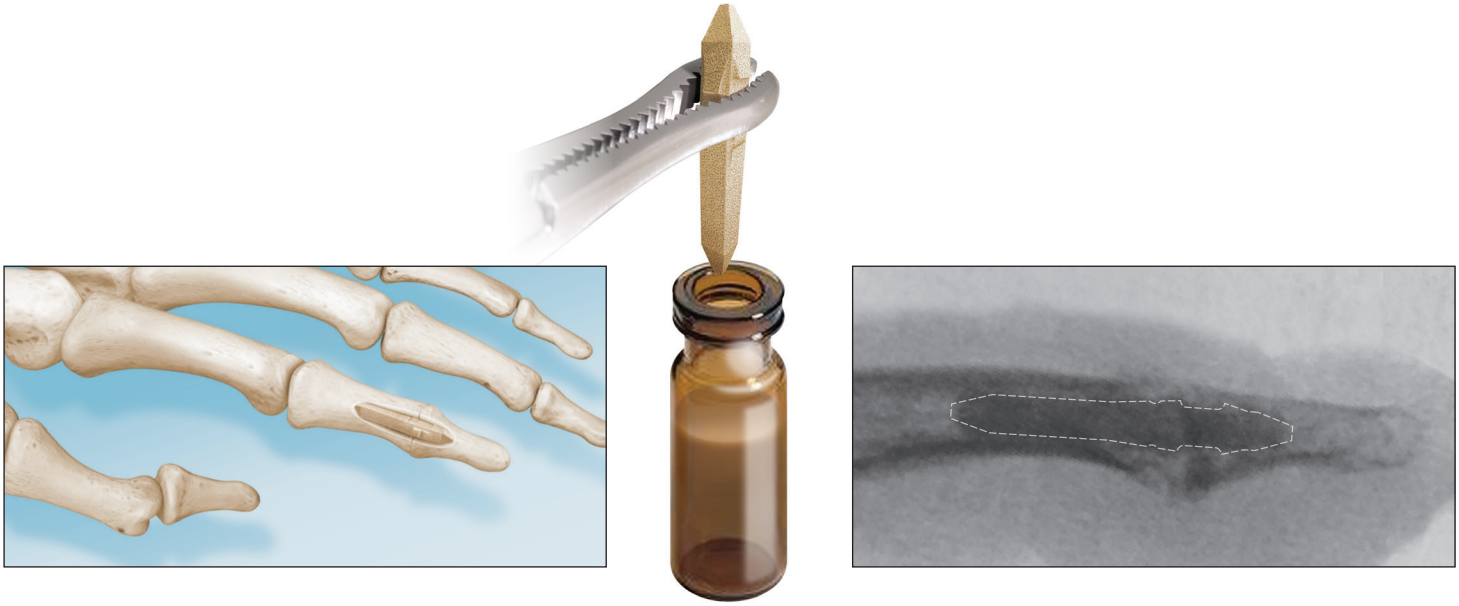
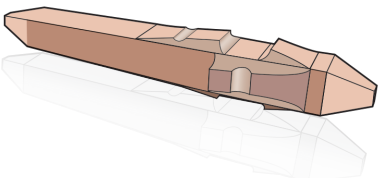
ENGINEERED STERILE ALLOGRAFT FOR ARTHRODESIS

AlloAid® DIP

Sterile Cortical Bone with Osteoconductive Properties





Press-fit Placement with Positioning Ramps

Osteoconductive Scaffolding for Bone Growth

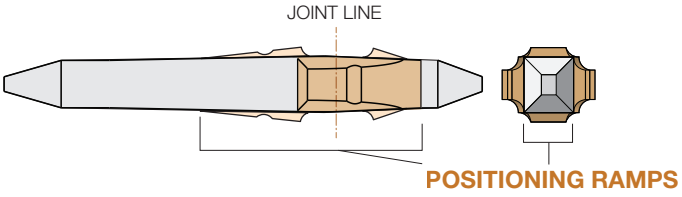
In2Bones

A GLOBAL EXTREMITY COMPANY

ENGINEERED STERILE ALLOGRAFT FOR ARTHRODESIS

AlloAid® DIP

The AlloAid® DIP is a sterile, engineered Allograft. The Allograft is supplied in 2 sizes. The AlloAid® DIP complies with all FDA, AATB and State Regulatory requirements for donor screening, recovery and testing.



2 Sizes: 2.3 x 17mm and 2.7 x 19mm

The AlloAid® DIP Allograft is designed with Positioning Ramps at the joint line to help accurately position the Implant and assure a press fit, and reduce the chance of subsidence. The cross-sectional shape and tapered design resists rotation. Tapered ends help with the ease of insertion.

Sterile Instrument Kit

The AlloAid® DIP Allograft is accompanied by a simple and convenient instrument set that includes laser-marked Reamers, K-Wire and bowed-nose Forceps.

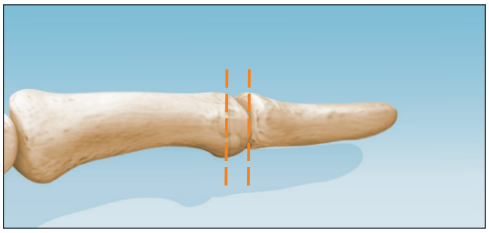
1:1,000,000 Sterility

10^{-6}

KNOW YOUR PRODUCT SAL. The AlloAid® DIP Allograft is terminally sterilized using a validated gamma irradiation process at an SAL (Sterility Assurance Level) of 10^{-6}. This representation of SAL illustrates the occurrence of a living microorganism surviving the sterilization process. SAL 10^{-6} designates the probability of finding an unsterile product to be **1 in 1 million**. Competitive tissue products may be sterilized to an SAL of 10^{-3}. This increases the odds of finding an unsterile product to **1 in 1 thousand**.

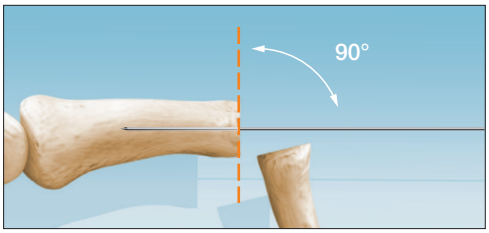
For more information on the use of AlloAid® DIP Allograft, please refer to the AlloAid DIP product insert.

Surgical Technique



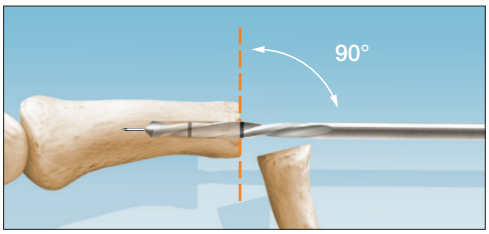
Dissection and Joint Preparation

A standard dorsolinear incision over the DIP joint. Dissect soft tissue until the DIP joint is exposed. Resect the middle phalanx and remove distal cartilage.

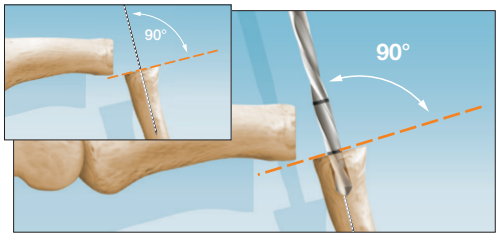


Middle Phalanx Preparation

Drill the provided K-Wire into the central part of the canal in the middle phalanx. Use of fluoroscopy is recommended to confirm the K-Wire position is in the center of the bone on AP and lateral views.

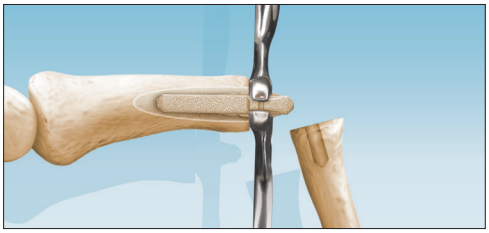


Select the appropriate diameter Reamer and drill over the K-Wire advancing until the proximal line of the Reamer is flush with the bone surface **FIG. A**.



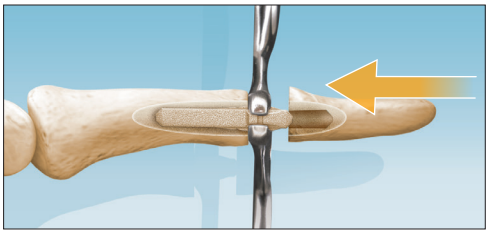
Distal Phalanx Preparation

Drill the provided K-Wire into the central part of the canal in the distal phalanx. Use of fluoroscopy is recommended to confirm the K-Wire position is in the center of the bone on AP and lateral views. Advance the Reamer over K-wire until the distal line of the Reamer is flush with the bone surface.



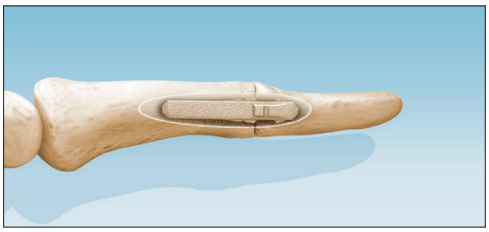
Allograft Placement

Remove the AlloAid® DIP Allograft from the sterile package. Insert proximally using provided Forceps. **FIG. B** taking care not to squeeze the Allograft. Holding the Allograft at the transition, **FIG. C**. Apply slow steady pressure until the Allograft is fully seated.



Allograft Placement

Manually reduce distal phalanx over the distal end of the AlloAid® DIP Allograft until the distal phalanx is fully reduced. Reduce directly over the Implant, do not twist on.



Closure using surgeon preference

NOTE: The AlloAid® DIP Allograft does not allow for the immediate resumption of activity by the patient. The surgeon must determine the length of time (approximately 6 weeks) required to accomplish a fusion and inform the patient regarding activity levels during the healing period. Patient compliance during the healing period is critical for a successful outcome.

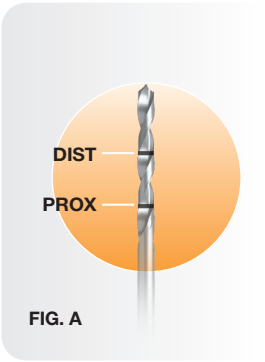
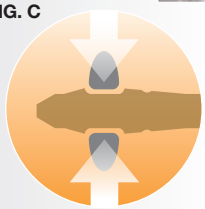


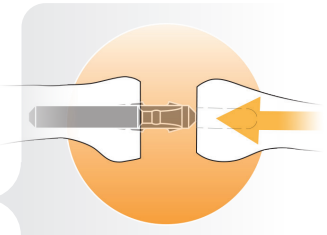
FIG. A

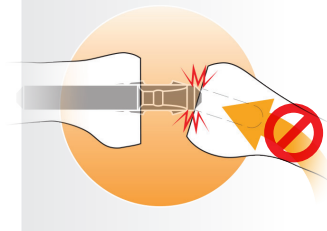
FIG. B

FIG. C



Grip with Forceps just distal of the Positioning Ramps





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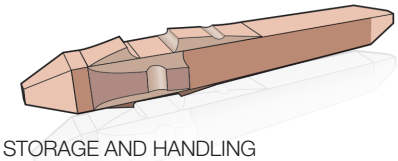
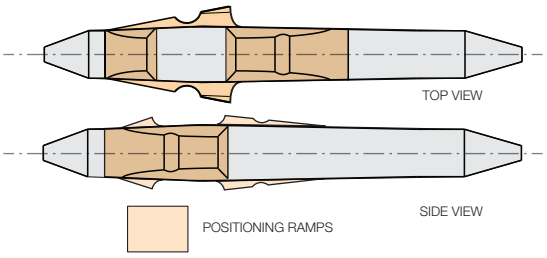
AlloAid® DIP



- Designed with Positioning Ramps to help accurately position the implant and assure a press-fit.
- Sterile allograft has conductive properties.
- No post-op hardware removal needed
- Available in 2 sizes.
- This allograft complies with all FDA, AATB and State Regulatory requirements for donor screening, recovery and testing.



ORDER INFO - Sterile Implants and Single Use Instrument Set

CAT NO.	DESCRIPTION	SIZE
ADA 001	AlloAid® DIP Allograft	2.3 x 17mm
ADA 002	AlloAid® DIP Allograft	2.7 x 19mm
C01 S0003	AlloAid® DIP Allograft Instrument Kit	

TRANSPORTATION, STORAGE AND HANDLING

AlloAid® DIP is supplied ready to use and must be stored between 2°C and 40°C (36°F and 104°F) until prepared for use. It is the responsibility of the transplant facility or clinician to maintain the allograft intended for transplantation in the appropriate recommended storage conditions prior to transplant.

STERILITY

AlloAid® DIP is provided sterile following an internationally recognized validation method and a proprietary irradiation system using gamma radiation to a Sterility Assurance Level of 10^{-6}.

INSTRUCTIONS FOR USE

AlloAid® DIP should not be used if:

- the expiration date shown on the labeling has passed,
- the packaging is damaged or compromised, or
- the recommended storage conditions have not been maintained.

Do not re-sterilize or reuse once opened.

The inner bottle and allograft are sterile. The outer peel pouch is not sterile.

1. Examine outer peel pouch. Do not use if there is evidence that the integrity of the outer pouch has been compromised.
2. Aseptically present the inner bottle onto a sterile field.
3. Remove the safety seal band / cap.
4. Remove the stopper of the bottle and pour the contents into a sterile preparation basin on the sterile field. The allograft is ready for use.
5. The allograft must be used during the surgical procedure once opened. If opened and not implanted, the graft must not be re-sterilized and must be discarded.

TRACEABILITY

The FDA requires traceability from the donor to the recipient. The physician is responsible for completing the recipient records to ensure traceability. As a convenience, pre-printed peel-off labels are included with each allograft. Using the labels, record the allograft tissue identification information in the patient medical record.

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