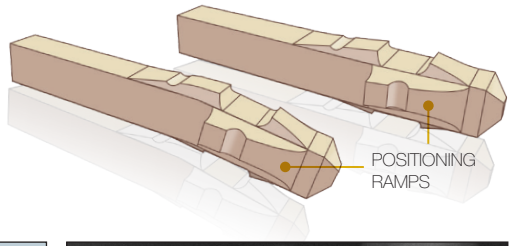
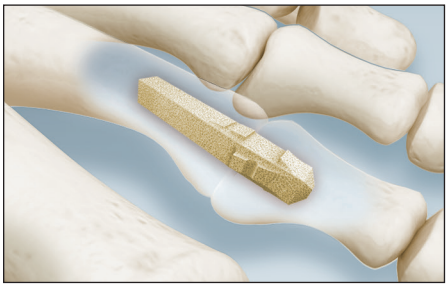
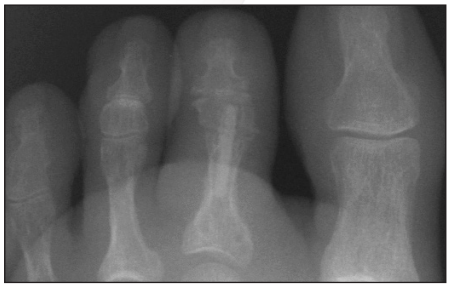
ENGINEERED STERILE ALLOGRAFT FOR ARTHRODESIS

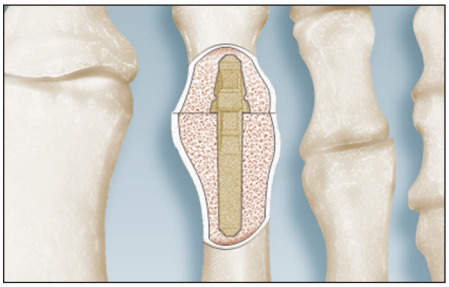
AlloAid® PIP

Sterile Cortical Bone with Osteoconductive Properties









Straight & 10° Angled in 2 Sizes Each

Press-fit Placement with Positioning Ramp

Osteoconductive Scaffolding for Bone Growth

In2Bones

A GLOBAL EXTREMITY COMPANY

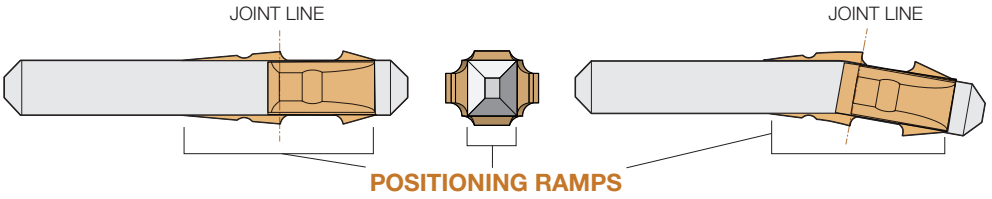
ENGINEERED STERILE ALLOGRAFT FOR ARTHRODESIS

AlloAid® PIP

Straight and 10° Angled Configurations

The AlloAid® PIP is a sterile, engineered Allograft. The Allograft is supplied in 2 sizes featuring both straight & 10° angled configurations. The AlloAid® PIP complies with all FDA, AATB and State Regulatory requirements for donor screening, recovery and testing.

Straight and 10° Angled Configurations

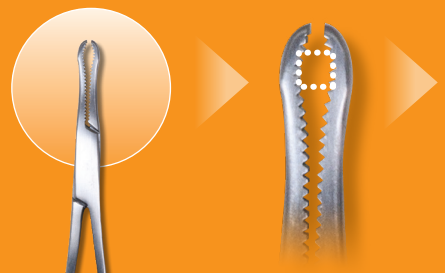


2 Overall Sizes: 2.5 x 16mm and 2.9 x 19mm

The AlloAid® PIP 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.

Simple, Supplied Instruments

Sterile Delivery



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

1:1,000,000 Sterility

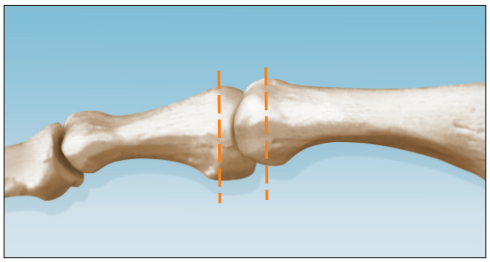
10^{-6}

10^{-3}

KNOW YOUR PRODUCT SAL. The AlloAid® PIP 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**.

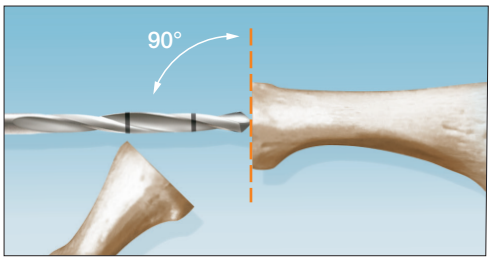
For more information on the use of AlloAid® PIP Allograft, please refer to the AlloAid PIP product insert.

Surgical Technique - Straight Configuration



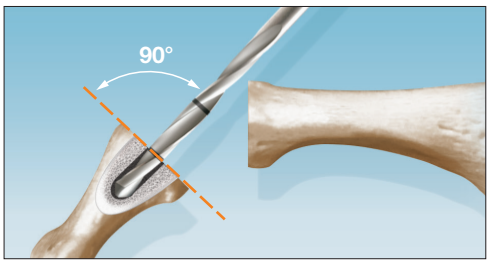
Dissection and Joint Preparation

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



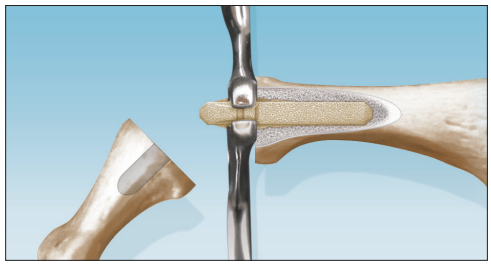
Proximal Phalanx Preparation

Select the appropriate diameter Reamer and hold the reamer at 90 degrees while keeping it central within the canal. Advance until the proximal line of the Reamer is flush with the bone surface.



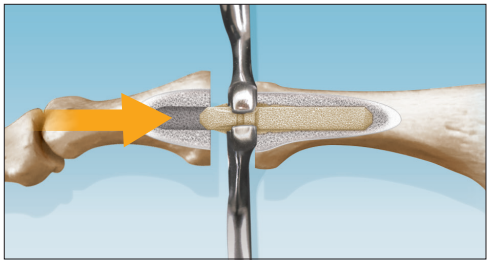
Middle Phalanx Preparation

Hold Reamer at 90 degrees to the resected surface of the bone and keep it central within the canal. Advance until the distal line of the Reamer is flush with the bone surface. Remove the AlloAid PIP Allograft from the sterile package.



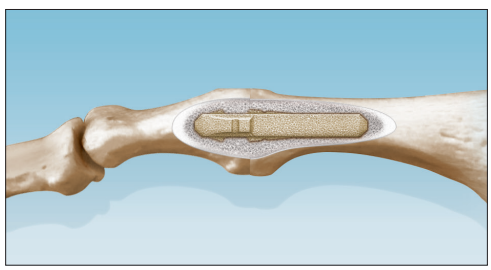
Allograft Placement

Insert proximally using provided Forceps. **FIG. A** taking care not to squeeze the Allograft. Holding the Allograft at the transition, **FIG. B**. Apply slow steady pressure until the Allograft is fully seated position and distal Positioning Ramp touches the resected proximal phalanx.



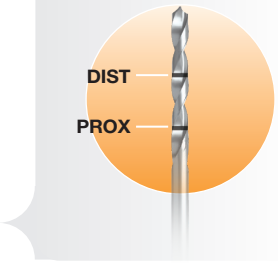
Allograft Placement

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



Closure using surgeon preference

NOTE: The AlloAid® PIP Allograft does not allow for the immediate resumption of activity by the patient and is not designed to support immediate weight bearing. 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.



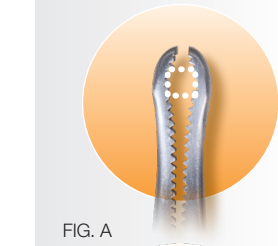
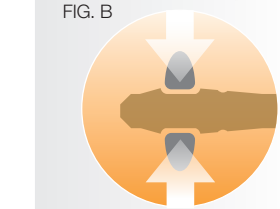
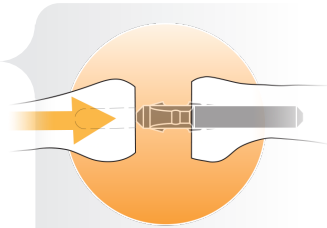


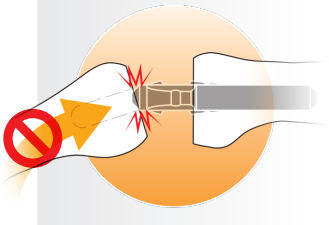
FIG. A

FIG. B



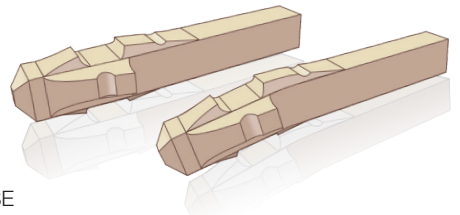
Grip with Forceps just distal of the Positioning Ramps



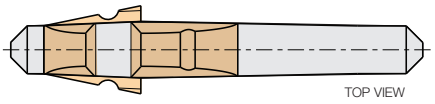


ENGINEERED STERILE ALLOGRAFT FOR ARTHRODESIS

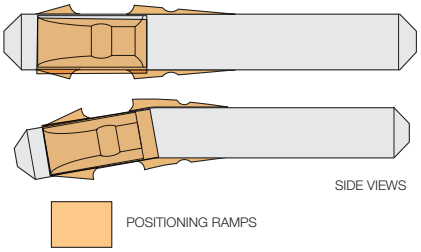
AlloAid® PIP



- 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 both straight & 10° angled configurations.
- This allograft complies with all FDA, AATB and State Regulatory requirements for donor screening, recovery and testing.



Straight and 10° Angled Configurations



ORDER INFO

CAT NO.	DESCRIPTION	SIZE	CONFIGURATION
APA 001	AlloAid PIP Allograft	2.5 x 16mm	Straight
APA 002	AlloAid PIP Allograft	2.5 x 16mm	Angled
APA 003	AlloAid PIP Allograft	2.9 x 19mm	Straight
APA 004	AlloAid PIP Allograft	2.9 x 19mm	Angled

STERILE DISPOSABLE INSTRUMENT KIT INCLUDES:

2 - Calibrated Reamers

1 - Bone Graft Forceps

INDICATION FOR USE

AlloAid® PIP allograft is a Human Cellular and Tissue Based Product (HCT/P) per 21 CFR Part 1271. AlloAid® PIP sterile machined cortical bone allografts are intended for transplant in small bone fusion procedures. Each allograft is restricted to homologous use for transplant in fusion surgical procedures on a single occasion by a licensed physician or surgeon.

WARNINGS AND PRECAUTIONS

An allograft may not elicit proper response from the recipient (e.g. fusion/union with adjacent tissue). It is possible for a host site to become infected. The allograft may not provide mechanical support and collapse, or may cause an inflammatory response. Current technologies may not preclude the transmission of infectious agents or disease, including hepatitis and HIV.

AlloAid® PIP may contain trace amounts of one or more processing agents including iodine, ethanol, hydrogen peroxide, gentamicin and/or vancomycin. It should not be used in patients with sensitivities to these processing agents.

TRANSPORTATION, STORAGE AND HANDLING

AlloAid® PIP 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® PIP 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® PIP 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.

In2Bones

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