TenFUSE PIP Allograft

SURGICAL TECHNIQUE
1. 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.

2. Proximal Phalanx Preparation
Select the appropriate diameter (2.0mm or 2.7mm) Depth Reamer and hold the reamer at 90 degrees while keeping it central within the canal. Advance until the proximal line of the Depth Reamer is flush with the bone surface.

NOTE: If a free-hand reamer start is questionable, use a k-wire for starting alignment before drilling. This can used for both steps 2 & 3.

3. Middle Phalanx Preparation
Hold Depth 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 Depth Reamer is flush with the bone surface.

4. Allograft Placement
Remove the corresponding TenFUSE PIP Allograft from the sterile package and insert proximally using retaining forceps or hemostat taking care not to squeeze the Allograft. Holding the Allograft at the transition, just distal to the "collar" FIG. B, apply slow steady pressure until the Allograft "clicks" down to a fully seated position and forceps touch the resected proximal phalanx.

NOTE:
1. Do not torque or apply excessive force to the TenFUSE PIP Allograft during insertion.
2. If the allograft does not advance with slow and steady pressure, remove the portion that is inside the bone and re-drill the canal. Do not use excessive force to seat the allograft.

5. Allograft Placement
Manually reduce middle phalanx over the distal end of the TenFUSE PIP Allograft with the Forceps remaining in-place until the middle phalanx is partially reduced. Apply slow steady pressure until the middle phalanx is flush with the Forceps.

NOTE:
1. Full clearance of the middle phalanx is required prior to reduction over the Allograft.
2. Do not apply any bending/torque force to the TenFUSE PIP Allograft while implanting, FIG. C.

6. Close using standard method

NOTE: The TenFUSE 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.

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**Sterile Allograft**

The TenFUSE™ PIP is a sterile allograft that is partially demineralized to maintain inductive and conductive properties.

**Sterility**
The TenFUSE PIP Allograft is sterilized to an SAL of 10^6. This Sterility Assurance Level designates the odds of finding an unsterile product to be 1 in a million. An SAL of 10^6 is the orthopedic industry sterility standard for implants.

The TenFUSE PIP Allograft is designed with a DEPTH STOP to help accurately position the implant. The Octagonal shape and ridges resist rotation. It is tapered on the proximal end to promote ease of insertion.

The TenFUSE PIP Allograft is available in both straight & 10° angled configurations. This allograft complies with all FDA, AATB and State Regulatory requirements for donor screening, recovery and testing.
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TenFUSE PIP Allograft Implant

**DIMENSIONS**

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*10⁻⁶ Safety...*

**KNOW YOUR PRODUCT SAL.** The TenFUSE 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 odds 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.

The enclosed surgical procedure is furnished for informational purposes only. Each surgeon must evaluate the appropriateness of the allograft/device and techniques based on his or her own medical training, clinical judgement and surgical experience. Proper surgical techniques and procedures are the responsibility of the medical professional. Solana Surgical cannot recommend a device or procedure that is suitable for all patients. Indications, contraindications, warnings, and precautions are listed in the implant package insert and should be reviewed by the physician and operating room personnel.

Solana Surgical, LLC
6363 Poplar Ave
Memphis, TN 38119
TF: 855-214-1860
V: 901-818-1860
F: 855-540-1861

www.SolanaSurgical.com

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