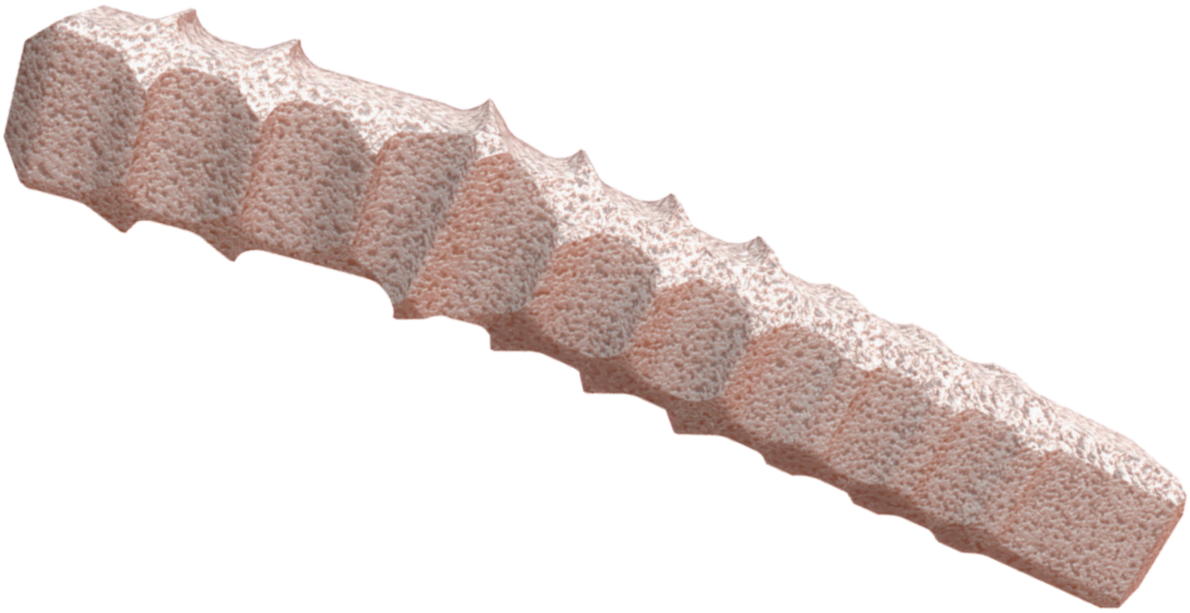
stryker

Tenfuse® PIP

Sterile Allograft

Operative technique



Tenfuse® PIP
Sterile Allograft

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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this operative technique and the package insert is available on the website listed.

Introduction

The Tenfuse PIP is a sterile allograft designed for digital arthrodesis with no postoperative hardware removal necessary. The Tenfuse PIP Allograft is available in both straight and 10° angled configurations.

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.

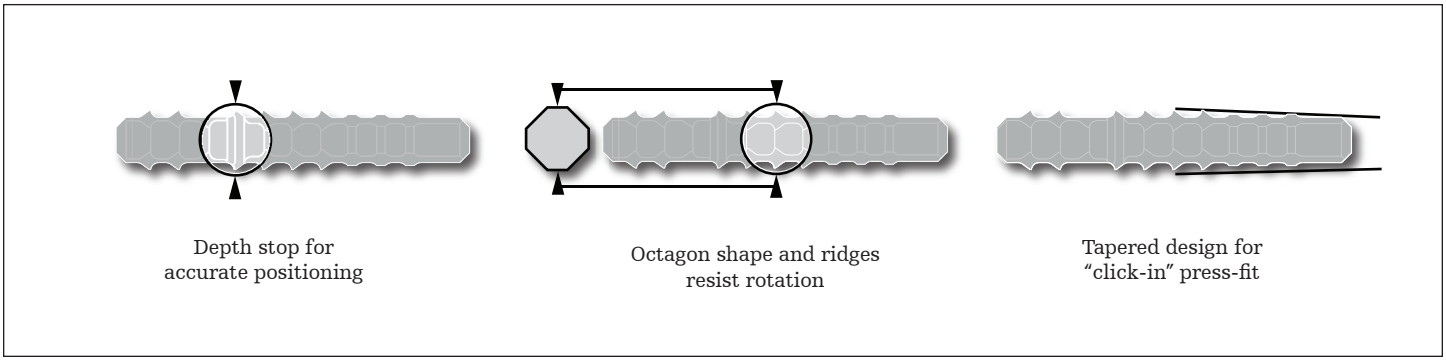


Figure 1

Indications and contraindications

Indications

The Tenfuse machined, sterile bone matrix allografts are intended for transplant in small bone with fusion procedures. Each allograft package is intended for use in one patient, on a single occasion by a licensed physician or surgeon.

Contraindications

Use of this allograft in patients exhibiting metabolic bone disorder/disease or evidence of necrosis is not recommended. Conditions that could inhibit the intended response include, but are not limited to, the following:

- Risk for pseudoarthrosis or failure to fuse
- Osteopenia that may lead to unacceptable allograft subsidence
- Active metastatic process
- Uncontrolled diabetes
- Compromised vascularity of surrounding tissue
- Local, latent or systemic infection
- Poor nutrition or general medical condition
- Inability to adhere to and/or comprehend postoperative instructions

The enclosed allograft may contain trace amounts of processing agents listed in the warnings section of the insert. The allograft should not be used in patients sensitive or allergic to these specific agents.

Warnings

Potential adverse effects that may result from placement of the Tenfuse machined, sterile bone matrix allograft include, but are not limited to the following: surgical site or systemic infection; hypersensitive; allergic or other immune response; failure to provide the desired mechanical support and/or breakage; failure to elicit the intended response (fusion/union with adjacent tissue) and disease transmission.

- Avoid usage of Tenfuse machined, sterile bone matrix allograft in patients who are allergic to or have exhibited sensitivity to gentamycin and vancomycin.
- Trace amount of processing agents may include iodine, ethanol, hydrogen peroxide, gentamycin or vancomycin.
- Tenfuse machined, sterile bone matrix allograft is for single patient use only. Unused allograft, whole or partial, may not be repackaged.
- Do not re-sterilize.
- Stryker makes no claims regarding to the biologic or biomechanical properties.

Prior to use of the system, the surgeon should refer to the product instructions for use package insert for warnings, precautions, indications, contraindications and adverse effects. Instructions for use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this operative technique and the instructions for use package inserts are available on stryker.com under the link for prescribing information.

Operative technique

Step 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.

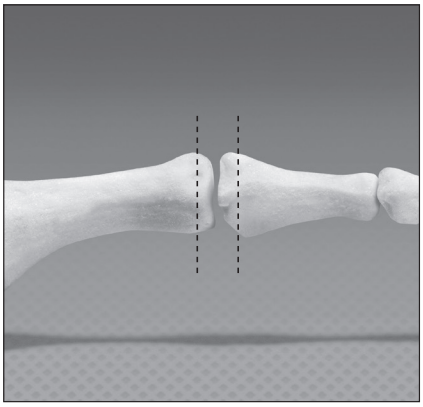


Figure 2

Step 2: Proximal phalanx preparation

Select the appropriate diameter (2.0mm or 2.7mm) depth reamer and hold the reamer at 90° while keeping it central within the canal. Under power, advance until the proximal line of the depth reamer is flush with the bone surface.

NOTICE

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

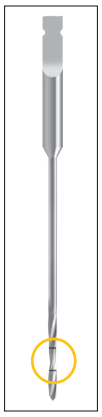


Figure 3

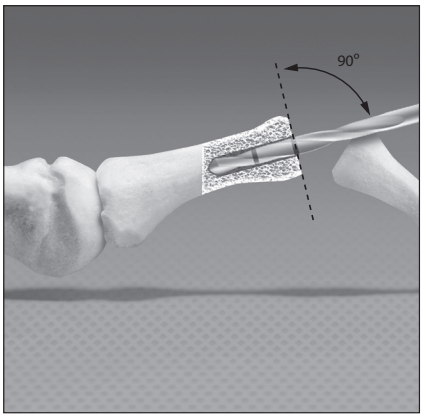


Figure 4

Step 3: Middle phalanx preparation

Hold depth reamer at 90° to the resected surface of the bone and keep it central within the canal. Under power, advance until the distal line of the depth reamer is flush with the bone surface. Remove the Tenfuse PIP Allograft from the sterile package.

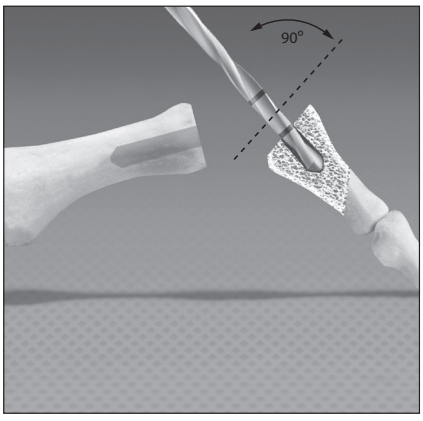
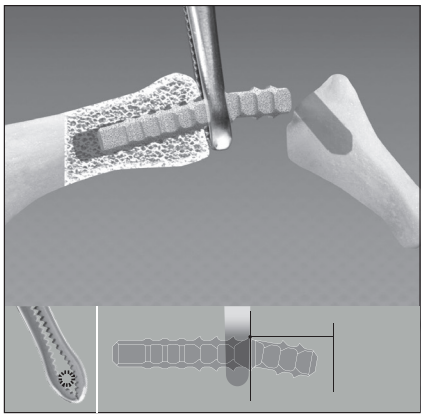


Figure 5

Step 4: Allograft placement

Insert proximally, using provided forceps and taking care not to squeeze the allograft. Holding the allograft at the transition, apply slow steady pressure until the allograft "clicks" down to a fully seated position and forceps touch the resected proximal phalanx.



Grip allograft using forceps just distal of depth stop collar

Figure 6

Step 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.

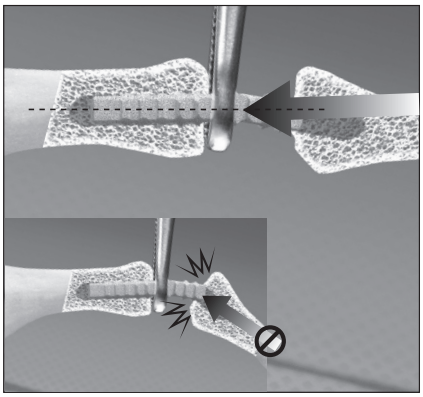


Figure 7

Step 6: Closure

Close using standard method.

Figure 8

NOTICE

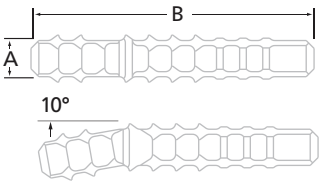
The Tenfuse PIP Allograft does not allow for the immediate resumption of activity by the patient and is not designed to support immediate weight bearing. The surgeon must determine the length of time (approximately six weeks) required to accomplish a fusion and inform the patient regarding activity levels during the healing period. Patient compliance during the healing period is critical for a successful outcome.

Ordering information

Part number	Alt. part number*	Description	Width A	Length B
	TFF-2015	PIP allograft, sterile	2.0mm	15mm, 0°
	TFF-2015A	PIP allograft, sterile	2.0mm	15mm, 10°
	TFF-2718	PIP allograft, sterile	2.7mm	18mm, 0°
	TFF-2718A	PIP allograft, sterile	2.7mm	18mm, 10°
7810S0020	XDR20S	Depth reamer, sterile	2.0mm diameter	
7810S0027	XDR27S	Depth reamer, sterile	2.7mm diameter	
78100000	TFF-KIT	Instrument kit, sterile**		

* Alt. part number is the Solana part number.

** The single-use kit contains 2.0mm reamer, 2.7mm reamer, and bone forceps.



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Foot & Ankle

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