INVICTUS

MINIMALLY INVASIVE

SACRO-ILIAC FUSION SYSTEM

INVICTUS MEDICAL

ANCHORED ACCESS PORTAL
103-005
TOWARD SACRUM
ANCHORED ACCESS PORTAL 103-005 SM122403
RATCHETING PALM HANDLES
(FIXED T-HANDLES)

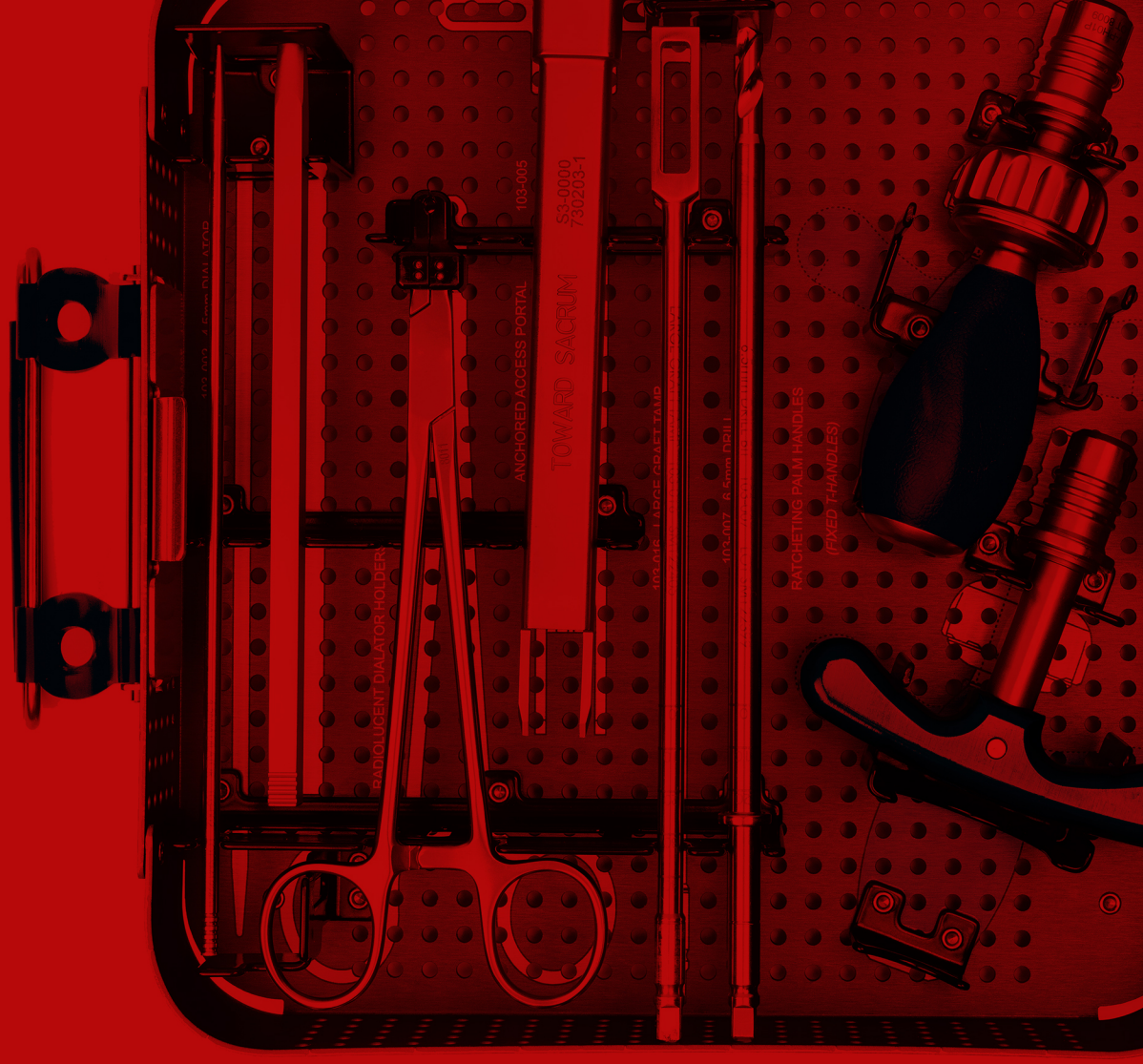

ISIRH-001


REVERSE


TOWARD SACRUM
ANCHORED ACCESS PORTAL 103-005 SM122403


RECTANGULAR DILATOR 103-004 LOT SM122402

Table of Contents


RADIOLUCENT DILATOR HOLDER
ANCHORED ACCESS PORTAL
TOWARD SACRUM
S3-0000
730203-1
103-005
RATCHETING PALM HANDLES
(FIXED T-HANDLES)

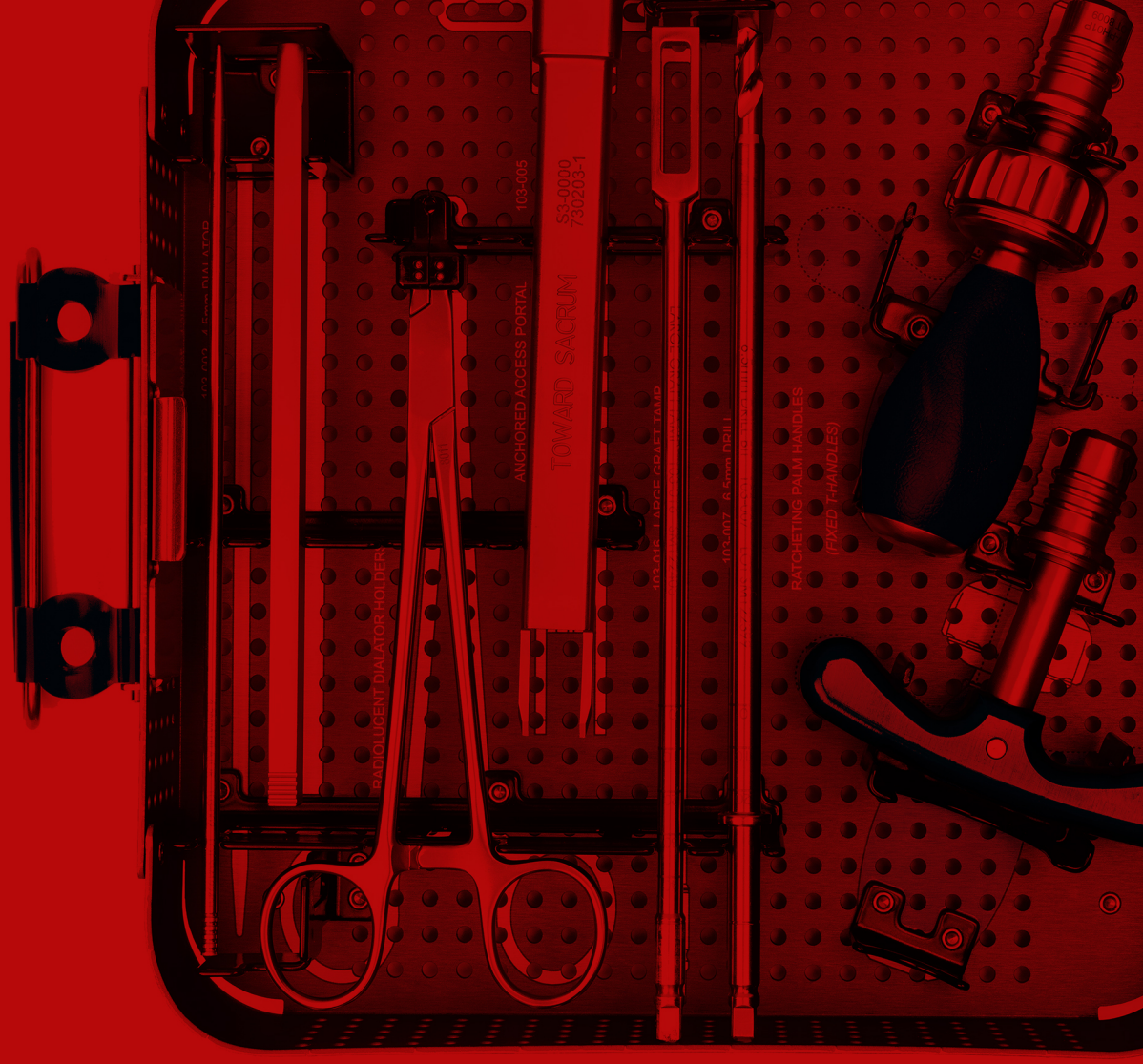
1. PURPOSE

Purpose

1

The purpose of this document is to provide users with information on the SI Fusion Allograft & Posterior Minimally Invasive (PMI) Manual Instrument Set. This document will include information on what instruments are provided in the set and the intended use of each.

The set includes manual instruments designed with a focus of giving users a comprehensive and flexible option for use in an operating environment for Sacroiliac (SI) joint preparation. In particular, the Invictus Medical, SI allograft bone dowel supplied by Bone Bank.



2. PRODUCT DESCRIPTION

Product Description

2

The instrumentation provided is focused on site approach, access, tissue preparation, and bone graft delivery. This instrumentation set is designed with a focus on the access and preparation for fusion surgery of the sacroiliac (SI) joints.

Some key highlights include:

Access:
The access instruments are comprised of sequential dilators and an anchored access portal. The purpose of these instruments is to determine surgical site approach and to provide users with the appropriate working access.

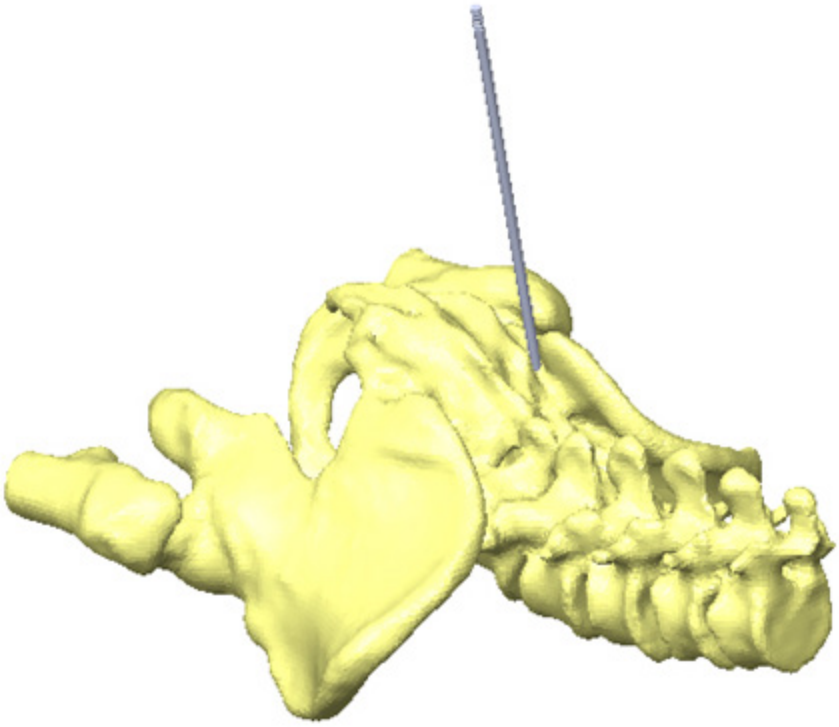
Preparation:
The bony tissue preparation instruments are comprised of a drill bit. The drill bit is a well understood manual instrument that is commonly used for bony tissue removal and preparation. The instrument connects to a standard ¼" square quick connect handle which is also provided.

Graft Delivery:
The delivery instruments are comprised of a bone graft ring, bone graft tubes and two tamps. The large graft tamp may be used for placement of the allograft, whereas the small graft tamp may be used in conjunction with the graft tubes. Each are commonly used instruments that are well understood for their respective intended use.

Dilation

Step 1

Use the **4.5mm Dilator (103-002)** in combination with fluoroscopic imaging to determine initial trajectory to the SI joint.

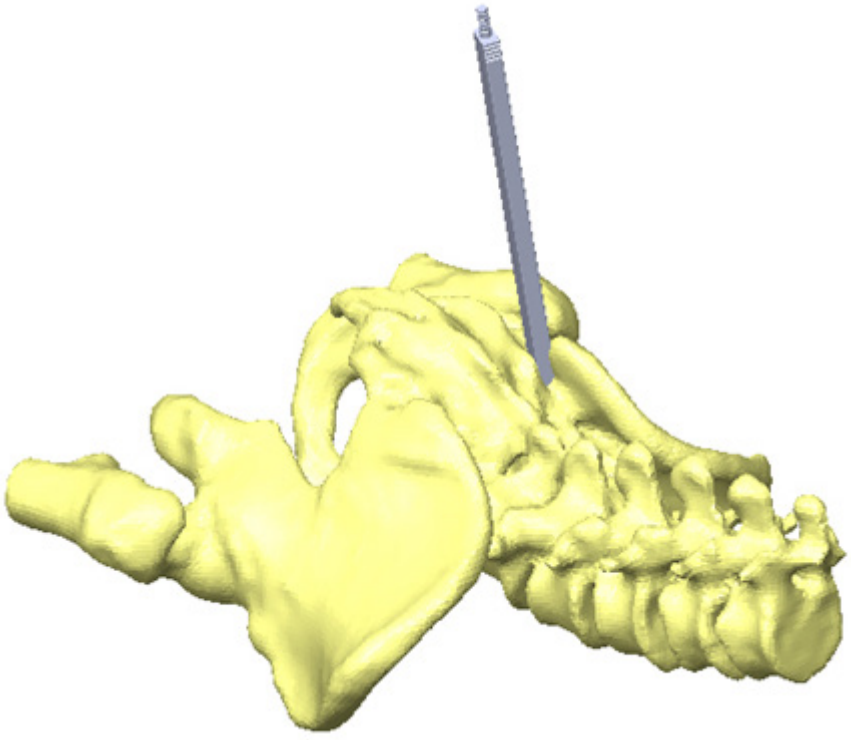


Step 2

Pass the **Rectangular Dilator (103-004)** over the 4.5mm Dilator.

Again, you may confirm trajectory using fluoroscopic imaging.

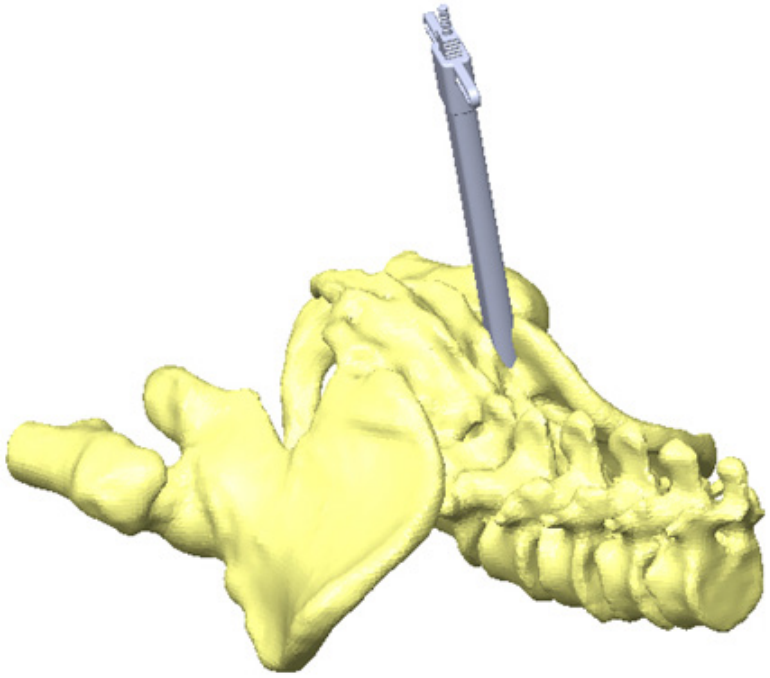
.



Step 3

Pass the Anchored **Access Portal (103-005)** over the Rectangular Dilator.

The anchored access portal has distal features to assist with docking into bony tissue to prevent unintentional movement. Attention should be paid to ensure proper alignment of the distal tangs.

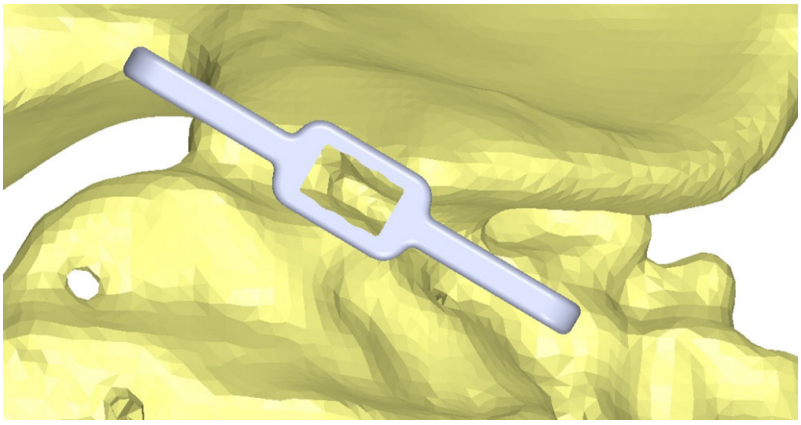


Step 4

Once the Access Portal is positioned where desired, the sequential dilators should be removed to visualize access to the site.

The position of the Access Portal may be confirmed using fluoroscopic imaging.

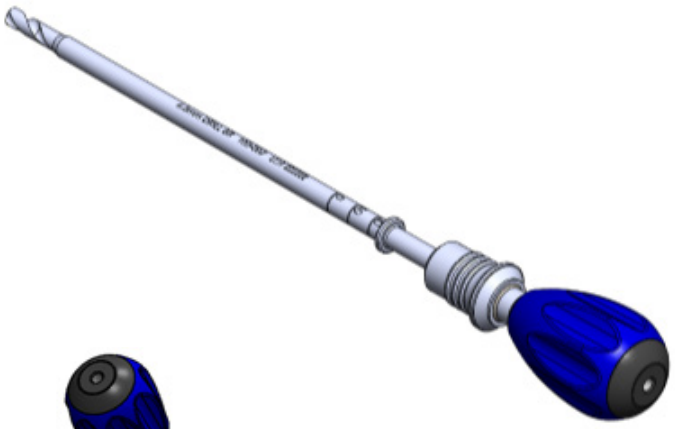
Note: Ensure Access Portal is anchored and positioned prior to removing dilators.



Site Preparation

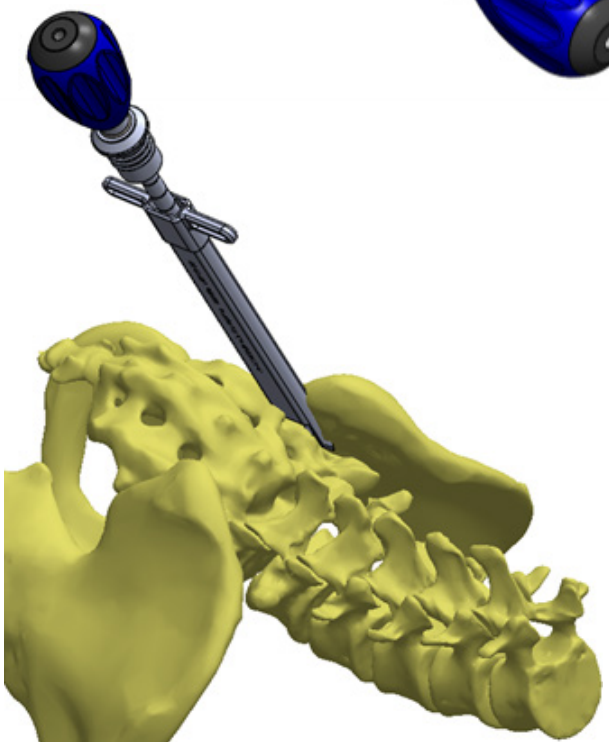
Once access has been gained the drill bit can be used at the discretion of the physician to perform any bony prep work. The preparation instrument is designed to pass through the Access Portal. The instrument has sharp features at the distal working end and care should be taken during use and when exchanging instrumentation.

All instruments are constructed from medical grade stainless steels and can be visualized on fluoroscopic imaging if needed to confirm positioning.



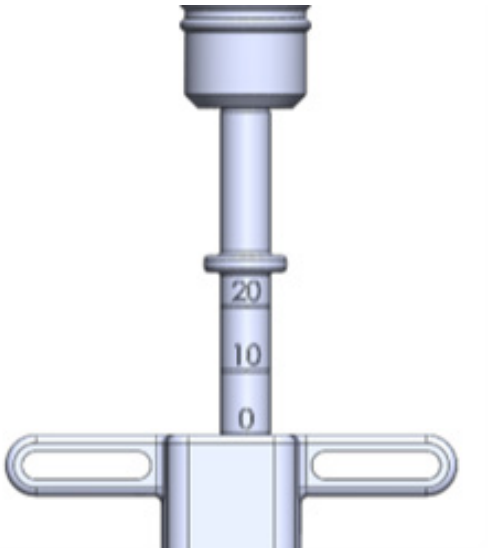
Step 5

The **6.5mm Drill (103-007)** is intended to be used with the **Quick Connect Palm handle.**



The 6.5mm Drill is designed to be used as any drill would, utilizing a rotary motion to create the intended results. A clockwise motion will advance the drill and a counterclockwise motion will back the drill out.

The laser marked indication on the proximal portion of the drill indicates depth. A positive stop is located at 25mm.

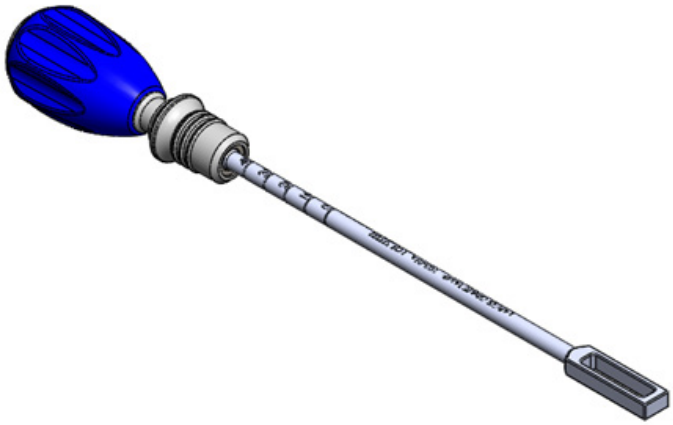


Site Delivery

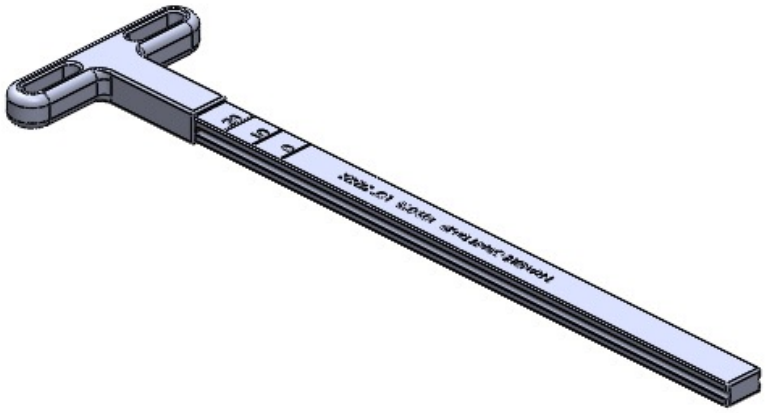
Once the site has been prepared the Bone Graft Delivery instruments can be used to deliver the physicians choice of bone graft.

Step 6

The **Large Graft Tamp (103-016)** should be assembled with **Quick Connect Palm Handle** for use.

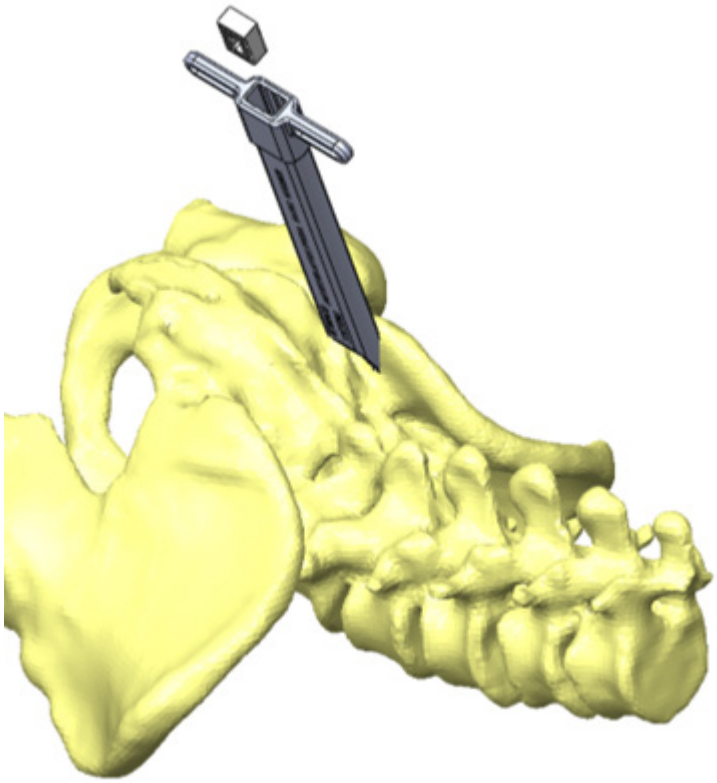


Alternatively, the **T-Handle Graft Tamp (103-033)** can also be used in lieu of the 103-016 tamp above.

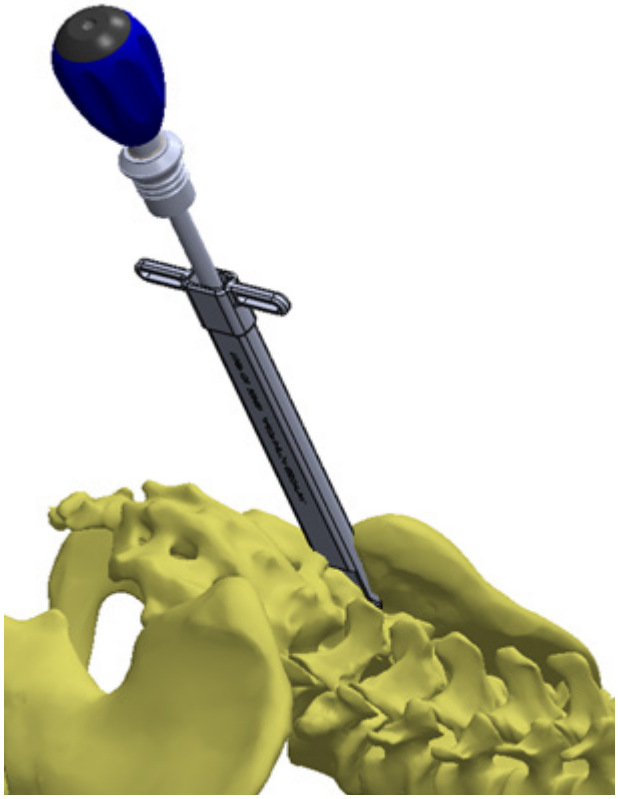


Step 7

Insert the SI Allograft implant or other bone matrix into the Anchored Access Portal.



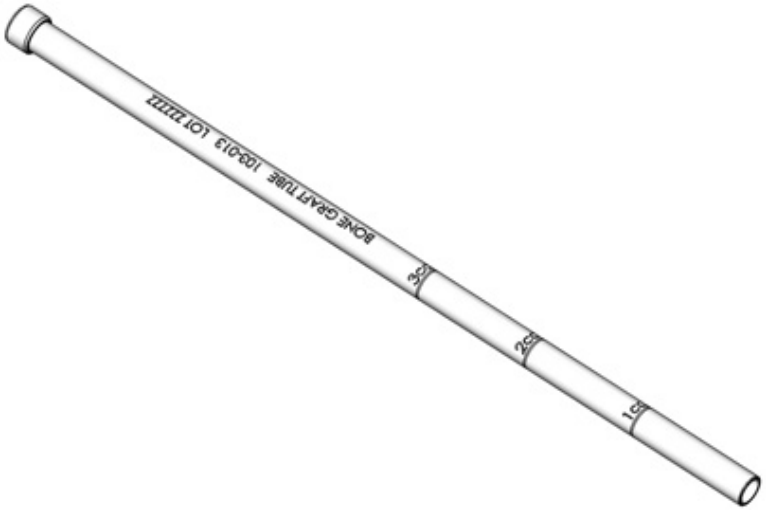
The **Large Graft Tamp** may be used to further deploy or manipulate the allograft and assist with final delivery by passing it through the **Anchored Access Portal.**



Alternatively, the **T-Handle Graft Tamp** may be used to further deploy or manipulate the allograft and assist with final delivery by passing it through the **Anchored Access Portal.**

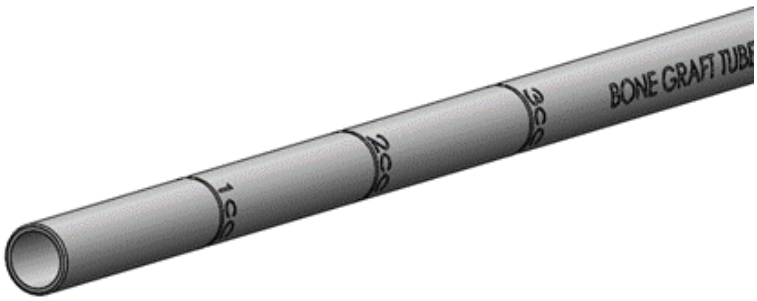
Step 8

The **Bone Graft Funnel (103-013)** must first be loaded with the bone graft, of the surgeon's choice, to the desired volume on the back table.



Graduations of 1cc, 2cc, and 3cc are indicated on the tube via laser markings, the tube **should not** be filled with more than 3cc's of bone graft. If more than 3cc's are required, there are multiple bone graft tubes included in the system that can be used.

When loading bone graft material into the **Bone Graft Tube** it should be done from the distal end of the instrument.



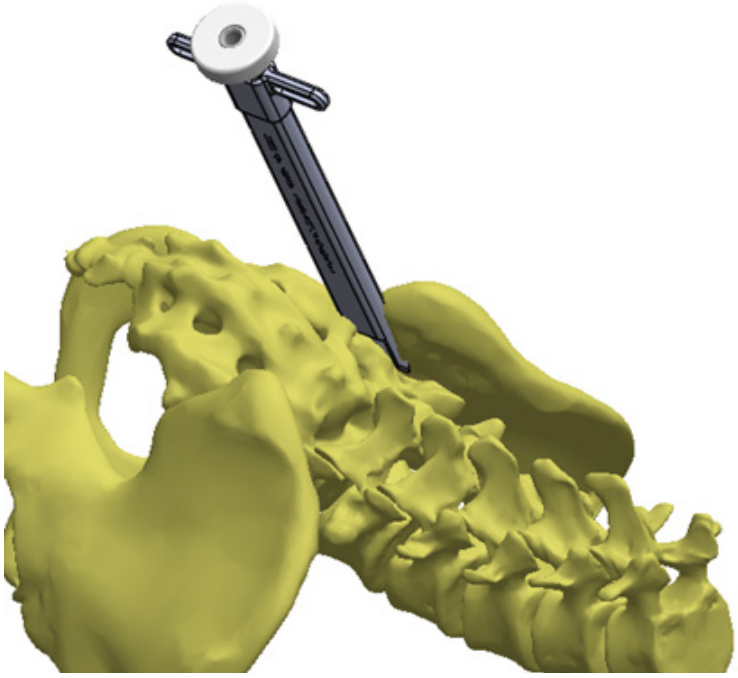
The **Bone Graft Tube** should be assembled with the **Bone Graft Ring (103-023**) prior to use.

When installing the **Bone Graft Ring (103-023),** ensure the ring is installed such that the recessed pocket accepts the shoulder portion of the **Bone Graft Tube.** When installed properly the Bone Graft Tube should fully seat in the Bone Graft Ring.

Note: This gives the user a feature to securely hold while tamping graft material out of the tube.

The **Bone Graft Tamp (103-015)** should be assembled with the **Quick Connect Palm Handle** for use.

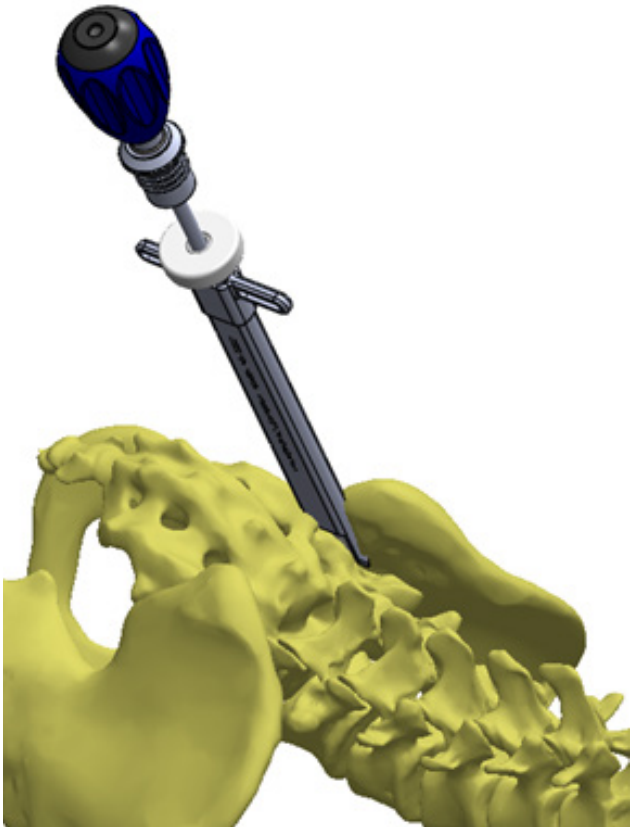
Once the **Bone Graft Tube** is ready for use with graft installed, pass it through the **Access Portal** for use.



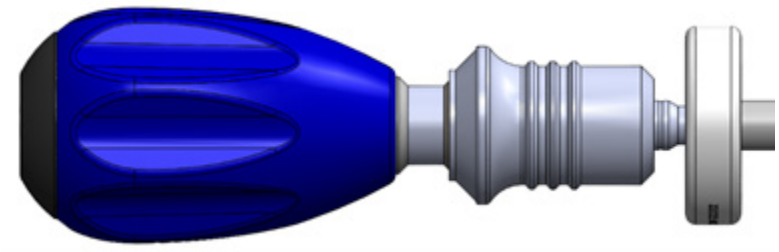
Step 9

Use the **Bone Graft Tamp (103-015)** to push the bone graft material from the **Bone Graft Tube** and into the surgical site.

Note: Repeat this process as much as needed to deliver the desired amount of bone graft.

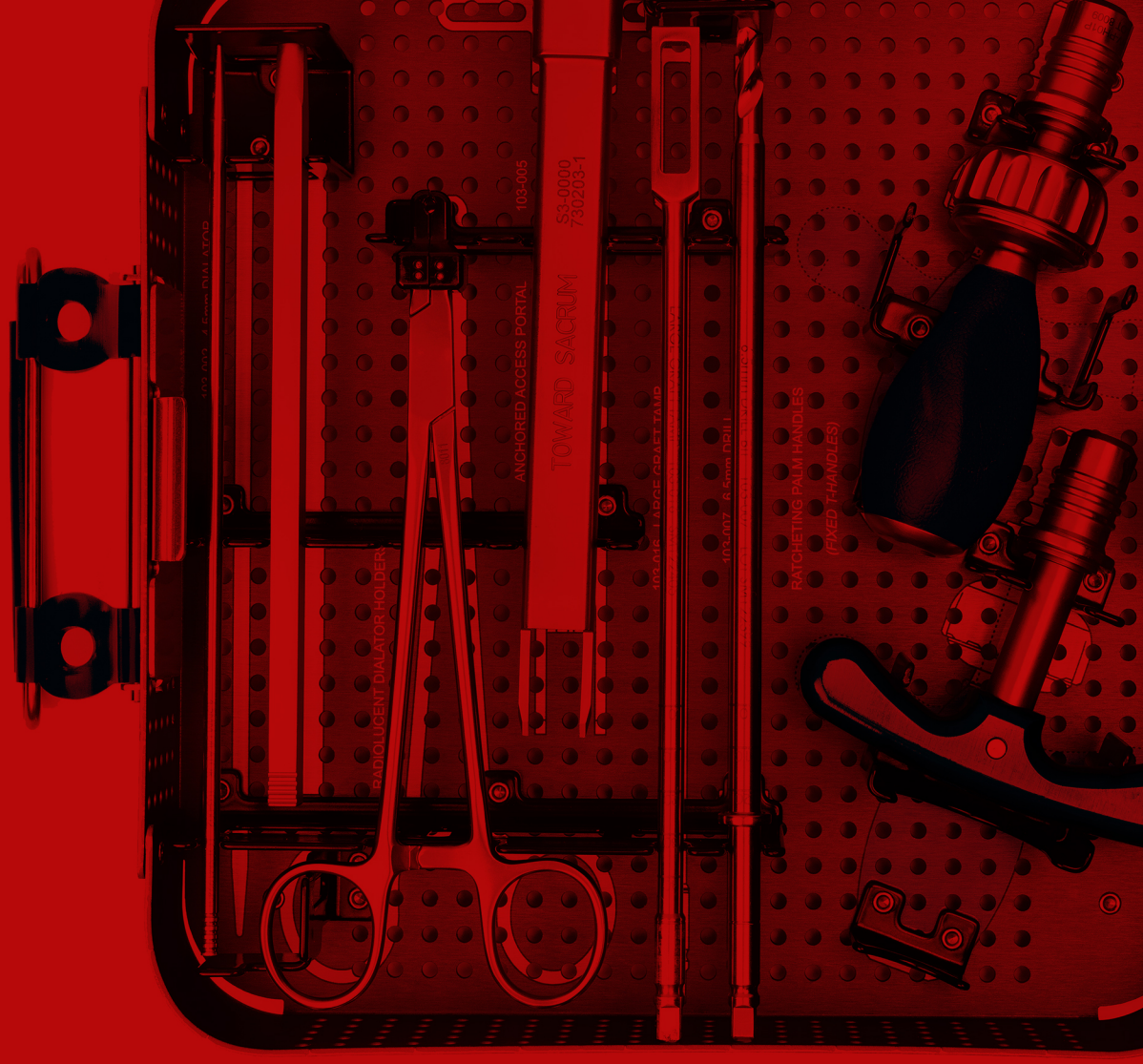


To ensure all material is pushed from the **Bone Graft Tube**, fully insert the **Bone Graft Tamp.**



Once the bone graft of choice has been delivered to the site each of the instruments should be carefully removed from the Access Portal. The Access Portal can then be carefully removed from the site, taking care to not damage the patient's soft tissue upon removal.

Once the operation has been determined to be complete, each of the instruments should be disassembled and returned to their respective locations in the instruments tray.



3. INSTRUMENT OVERVIEW

Instrument Overview

3

Below is a table of the instrumentation that is included in the system, and their respective intent for general use. In addition to the listed instruments, there are supporting off-the-shelf instruments such as ergonomic handles included in the set as well.

103-002

4.5mm Dilator

103-004

Rectangular Dilator

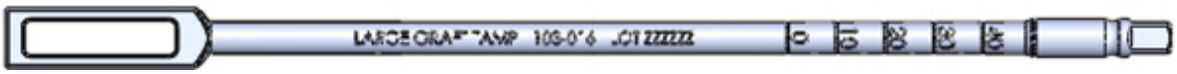
103-005 Anchored Access Portal

103-007 6.5mm Drill Bit

103-013 Bone Graft Tube

103-015 Bone Graft Tamp

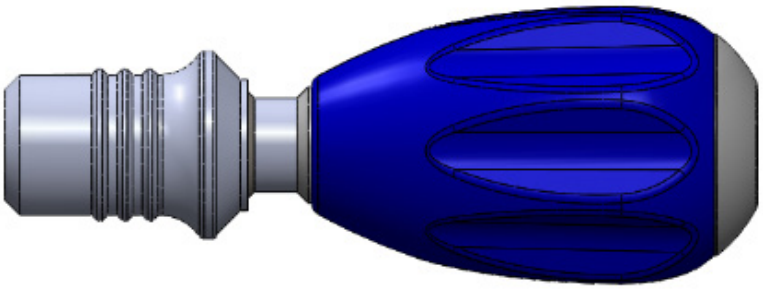
103-016 Large Graft Tamp

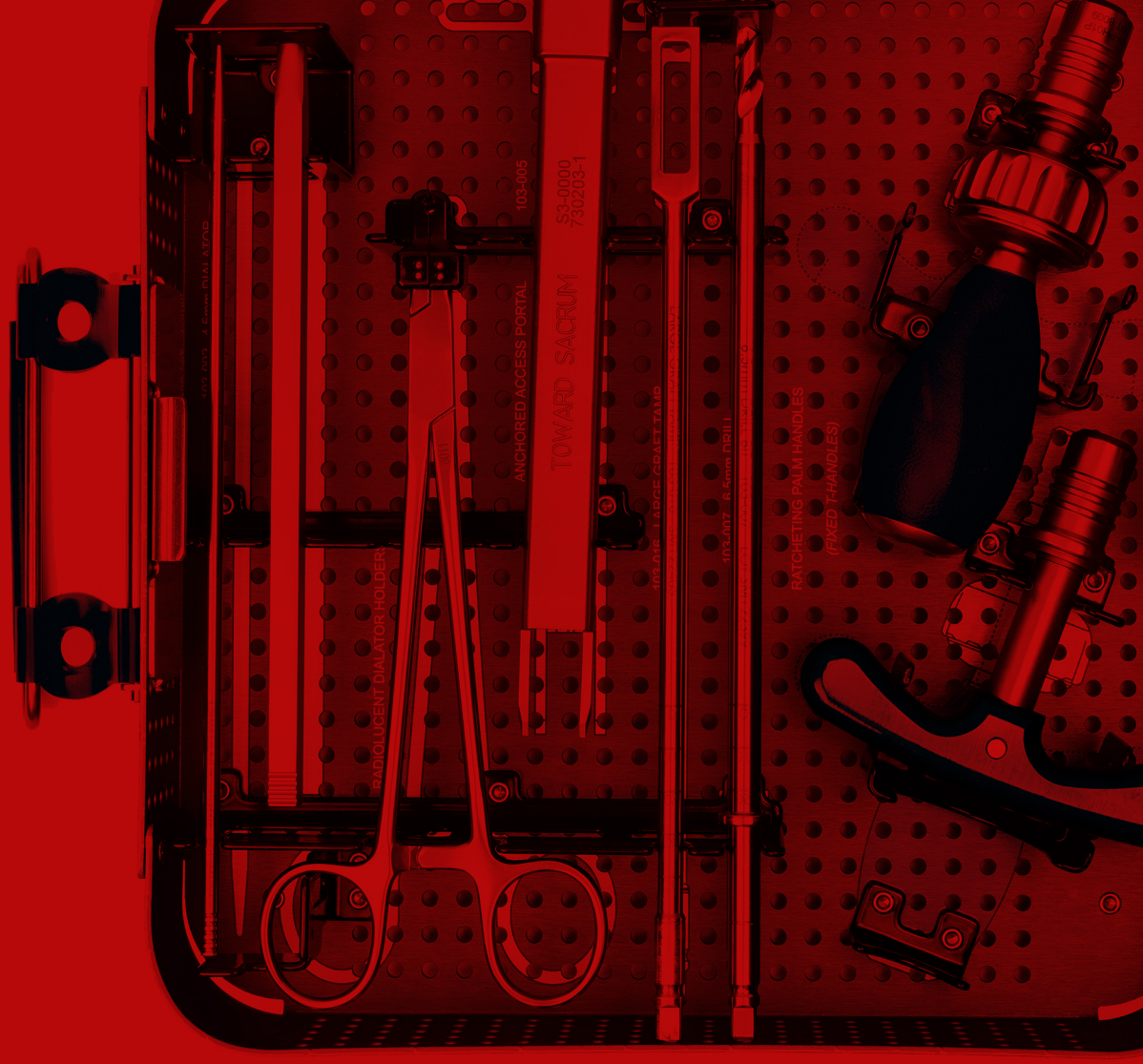


103-033 T-Handle Graft Tamp

103-023 Bone Graft Ring

9H02-121 Palm Handle





4. SAFETY PRECAUTIONS

Safety Precautions

4

The Allograft & PMI Instrument Set should only be used by trained Physicians. The instrument set should be reviewed with the provided literature prior to use until the physician is comfortable and familiar with the system. No special training, tools, software, power, or accessories are needed for the use of the system. If a user reviews the system prior to a surgery and is not familiar with use of a specific instruments or has not used one of the provided manual instruments, then extra time and care should be taken to ensure proper use. The FDA restricts the use of allograft implants to by order of physician only.

Please read all information contained in this insert. The use of an instrument for a task other than that for which it is intended, as well as improper, ineffective and insufficient maintenance can greatly reduce the life of an instrument and will invalidate the instruments warranty. Incorrect handling and care as well as misuse can lead to premature wear or can cause hazards to patients and users.

The instruments kits are supplied non-sterile and must be cleaned and sterilized prior to use according to hospital protocol and the procedures outlined in this document. Failure to follow these procedures will invalidate the instrument's warranty and can cause the instrument to fail.

Indications for Use

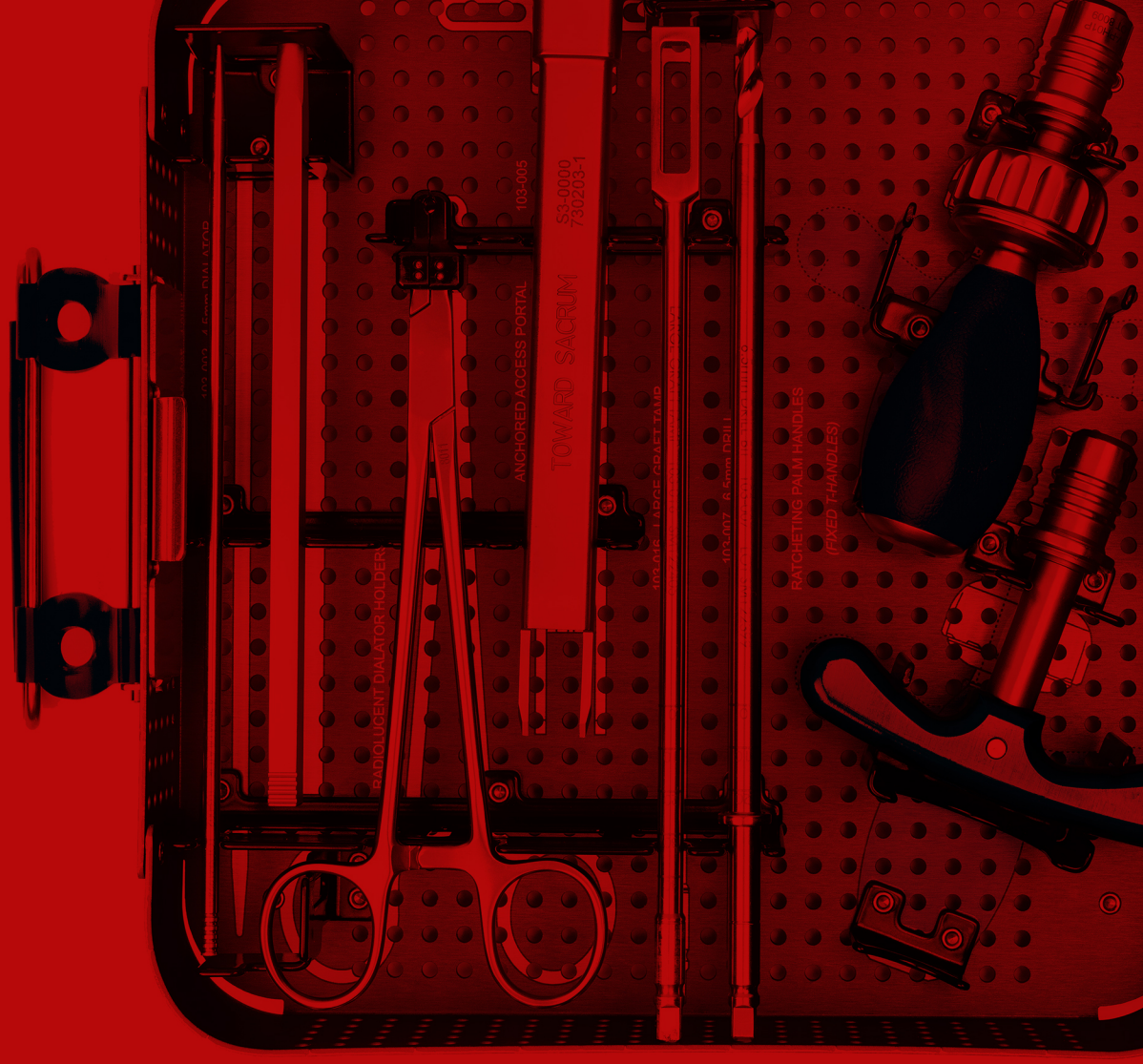
The PMI instrument sets are intended for use in conjunction with the SI allograft and/or autograft. They are designed to locate the sacroiliac joint, align the instruments, drill into the sacroiliac joint, and insert the bone graft.

Contraindications

Patients with:

- Severe degeneration of the sacroiliac joints.
- Active sepsis.
- Any known allergies or reactions to stainless steel.

Not intended for any woman that is pregnant or intends to get pregnant.



5. INSTRUCTIONS FOR USE

Instructions for Use

5

1. Localize the sacroiliac joint by fluoroscopy or directly by visualization during open procedures. Insert the 4.5mm Dilator into the plane of the sacroiliac joint. Slide the Oval Dilator over the 4.5mm Dilator. Slide the Rectangular Dilator over the Oval Dilator. Slide the Anchored Access Portal over the Rectangular Dilator. Ensure the orientation matches the laser markings on the instrument for proper positioning. i.e. “Toward Sacrum” is facing towards the patient’s sacrum. Lightly tap the Anchored Access Portal into the plane of the sacroiliac joint. (The Anchored Access Portal has a positive stop to prevent over penetration into the sacroiliac joint.)

2. Remove dilators and insert the 6.5mm drill bit into one of the two guide channels in the Anchored Access Portal. Drill to the desired depth. Remove the drill bit and repeat for the remaining guide channel.

3. Insert the 6.75mm x 15mm Box Cutter into the Anchored Access Portal. Gently use a mallet to tap the instrument to the desired depth.

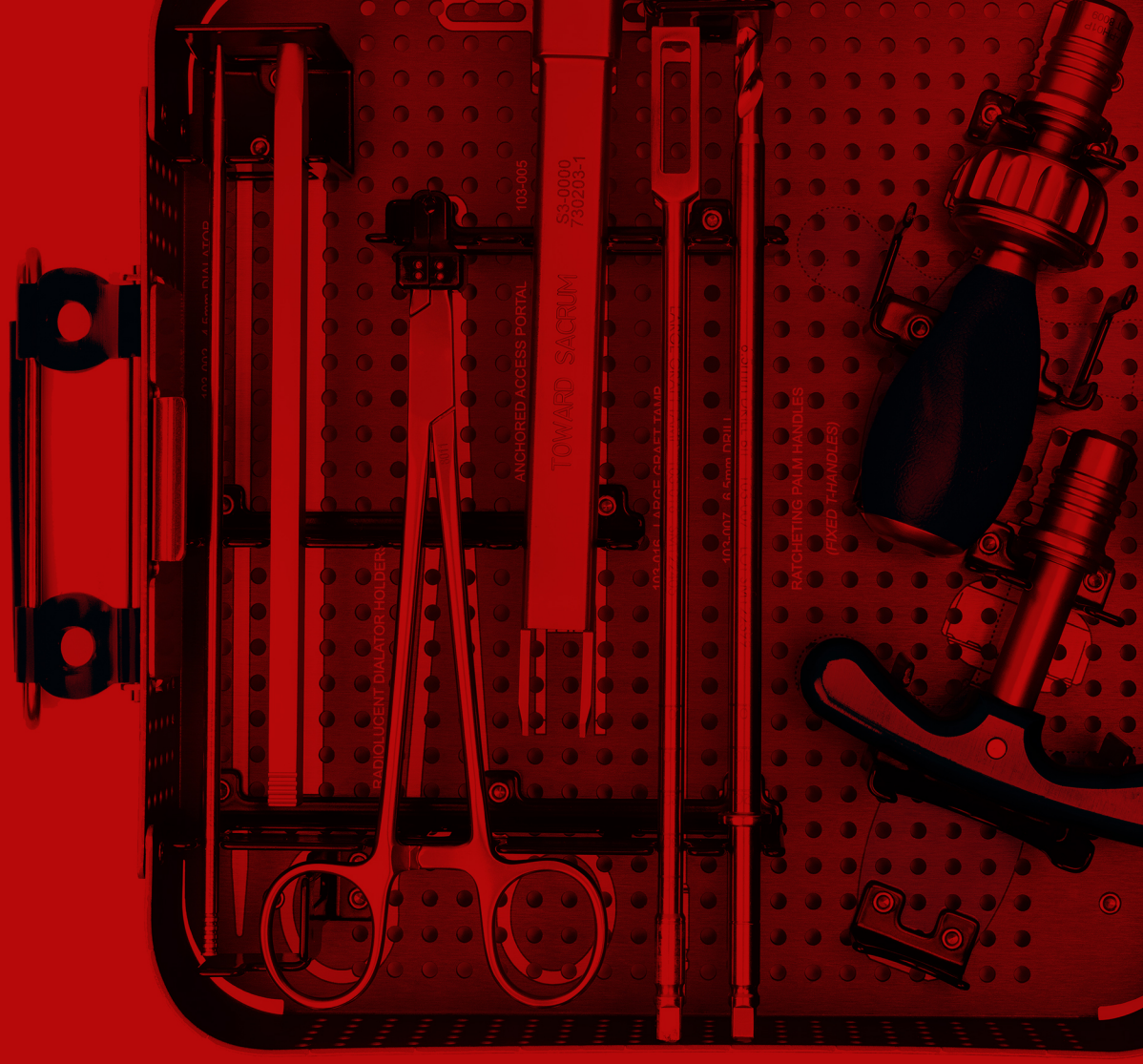
4. Deliver the allograft implant into the Anchored Access Portal. Use the Large Graft Tamp to advance the allograft to the desired depth.

5. Load the Bone Graft Tubes as desired with autograft or allograft. Place the Bone Graft Tube down one of the channels of the Anchored Access Portal until flush.

6. Deliver the autograft or allograft using the smaller Bone Graft Tamp. Repeat as necessary.

7. Repeat steps 1 through 6 for additional allograft implants on the current joint and the contralateral sacroiliac joint.

Note: The SI Fusion Allograft and PMI Instrument Set utilizes a directional access portal to assist the physician. Care should be taken to ensure proper alignment of the instrument prior to proceeding with bony tissue removal.



6. CLEANING INSTRUCTIONS

Cleaning and Maintenance

6

Test all instruments, accessories and equipment prior to each use. Written Standard Operating Procedures for the cleaning, sterilization, storage, inspection and maintenance of the instruments, accessories and equipment are recommended. Do not use in the presence of flammable liquids or anesthetics. Follow all safety precautions and instructions supplied by the manufacturer of the supplemental instruments. Failure to observe these cautions and contraindications may result in the injury, malfunction or other unanticipated occurrences or events for the operator, staff and/or the patient.

Every surgical instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Sterilize all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument. Special attention should be paid to slots, stops, ends, hollow tubes and other highly inaccessible areas. Check for cuts, voids, cracks, tears, abrasions, etc. Do not use damaged instruments. Cleaning and rinsing must take place immediately after each use for best effect. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilization. Instruments must be completely cleaned and rinsed of all foreign matter. Use warm water and a commercially available instrument pre-soak or cleaning agent. Enzymatic cleaners must be used to remove protein deposits. Follow the enzymatic cleaner's instructions, rinse thoroughly.

- Do not use corrosive cleaning agents (i.e., bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best.
- Do not use abrasive cleaners.
- Only a soft bristly brush should be used.
- Can be disinfected in the washing machine up to 203oF (95oC).
- Rinse thoroughly with distilled water.
- Prepare for storage and/or sterilization.

After cleaning and rinsing, dry instruments completely and carefully with compressed air (including inside channels and highly inaccessible areas.)

Note: After cleaning and before sterilization, treat all instruments with a water-soluble lubricant which is considered as being physiologically safe, especially their blades, ends, stops, snaps and all moveable parts.

Storage and Sterilization Instructions

Instruments must be stored in a clean, dry, moisture free area.

The instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect tips with cloth, gauze or tubing if stored in drawers. Instruments are reusable and meet AAMI standards for sterilization. Use steam autoclave sterilization. Thoroughly clean instruments of all debris, tissue and foreign matter prior to sterilization. Follow the sterilizer manufacturer's instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the instruments be sterilized including the internal surface of tubes and channels. Allow instrument to air cool to room temperature before use.

Use steam autoclave sterilization only.

Cycle Type	Temperature	Minimum Exposure Time
Pre-vacuum	270˚F - 275˚F (132˚C - 135˚C)	4 minutes

Minimum Dry Time	Minimum Cool Time
20 minutes	30 minutes

Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. *(Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.)*

Caution: Autoclave temperatures should not exceed 279˚F (135˚C); handles, insulation or other non-metallic parts may be damaged.

Do not sterilize with hot air.

Revision History

Revision	Description of Revision
01	Initial Release.
02	Revised to show paired down instrument set.

Title	Print Name	Signature	Date
Author	Chase Thornburg		
Reviewer	Blake Boesel		