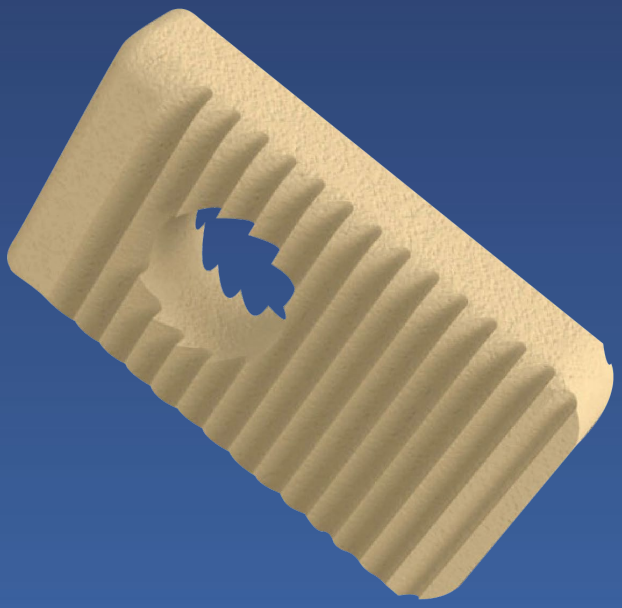
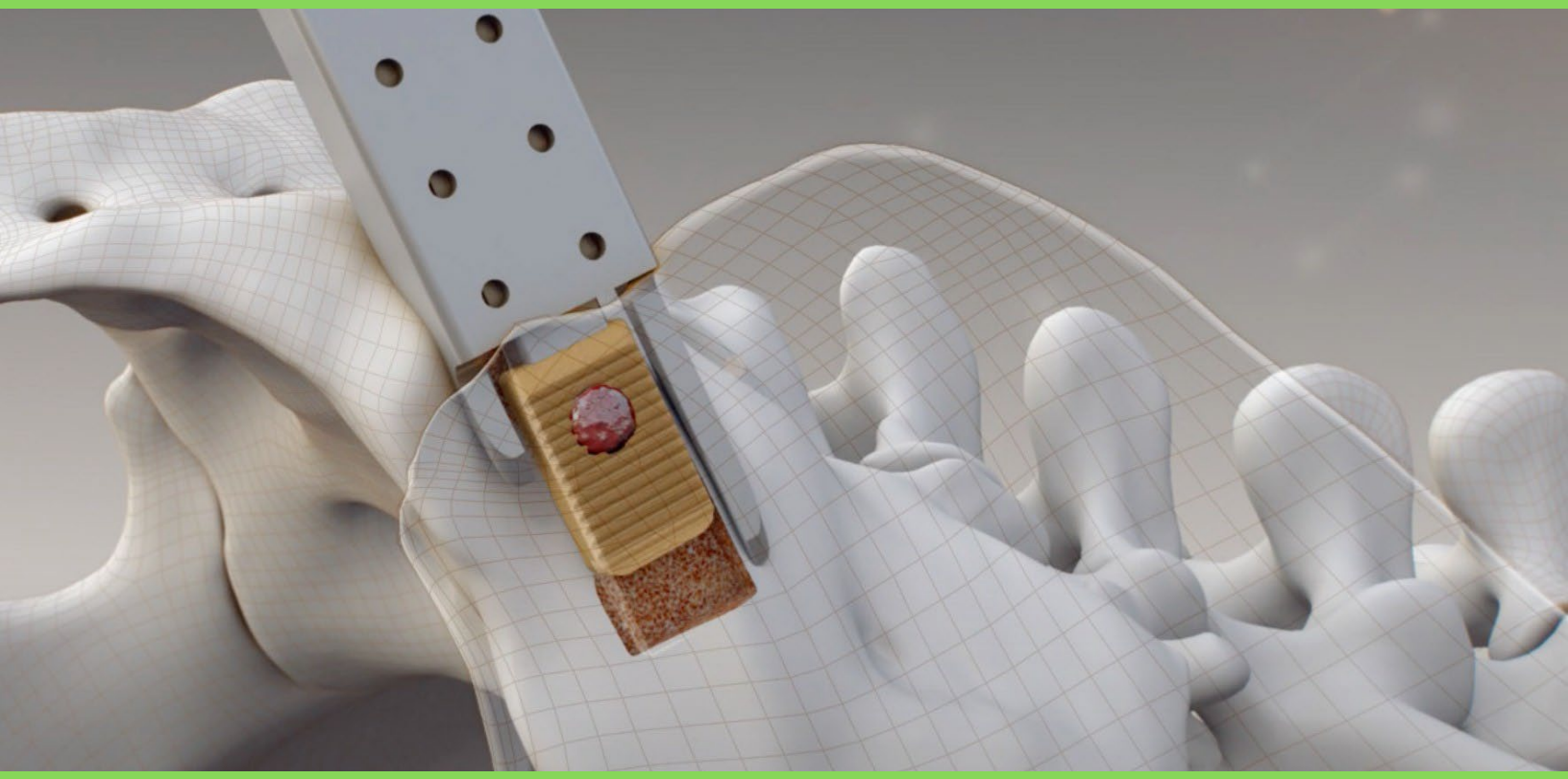
VYRSA™ pro

SI FUSION SYSTEM





SURGICAL TECHNIQUE GUIDE

VYRSA™ TECHNOLOGIES

vyrsatech.com
info@vyrsatech.com

VYPR-800-001 REV B
JUNE2024

VYRSA™ pro

VYPR-800-001 Rev B
June 2024

TABLE OF CONTENTS

IMPORTANT INFORMATION

DESCRIPTION

The VYRSA™ Pro SI Fusion System (VYRSA™ Pro) utilizes reusable instruments that are manufactured from a variety of materials commonly used in orthopedic and neurological procedures which meet applicable national and/or international standards.

INDICATIONS FOR USE

The VYRSA™ Pro orthopedic manual surgical instruments are intended for use in surgical procedures to manipulate tissue, bone, or for use with other devices in orthopedic surgery.

FOR MORE INFORMATION ON THE VYRSA™ PRO INSTRUMENTS, SEE THE GENERAL INSTRUMENTS IFU.

FOR MORE INFORMATION ON THE ALLOGRAFT TISSUE, SEE THE MTF ALLOGRAFT TISSUE IFU.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

INSTRUMENT OVERVIEW

A.
JOINT FINDER
CW-131-001

B.
RIGHT WORKING CANNULA
CW-119-001

C.
LEFT WORKING CANNULA
CW-119-002

D.
TAMP
CW-107-001

E.
DRILL GUIDE
CW-120-001

F. JOINT FINDER
EXTENDER
CW-118-001

G. BOX CHISEL
CW-111-005

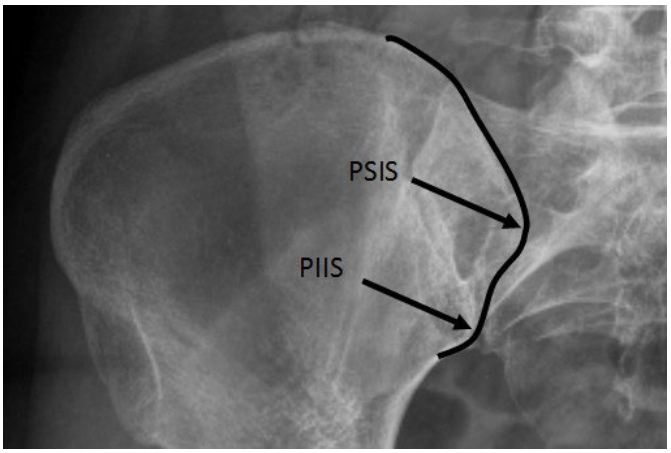
H. INSERTER ASSEMBLY
CW-103-002
CW-103-008
CW-103-009

APPROACH

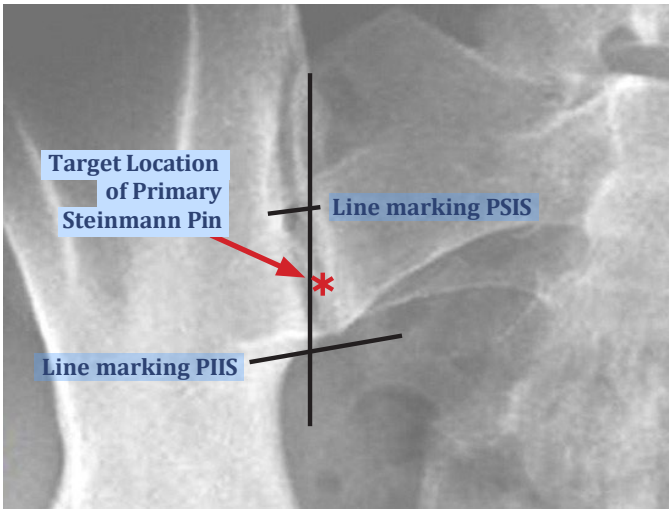
LOCATING THE SI JOINT

With the patient in the prone position, obtain AP and LATERAL views to identify the anatomy of the joint.

After the joint is identified and in the AP X-Ray frame, locate the Posterior Superior Iliac Spine (PSIS) and the Posterior Inferior Iliac Spine (PIIS).

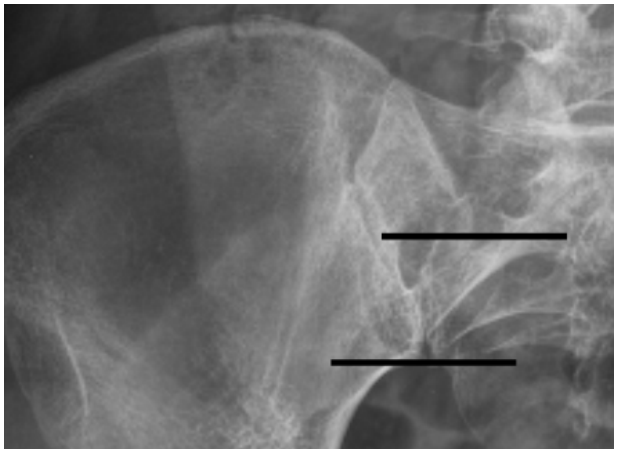


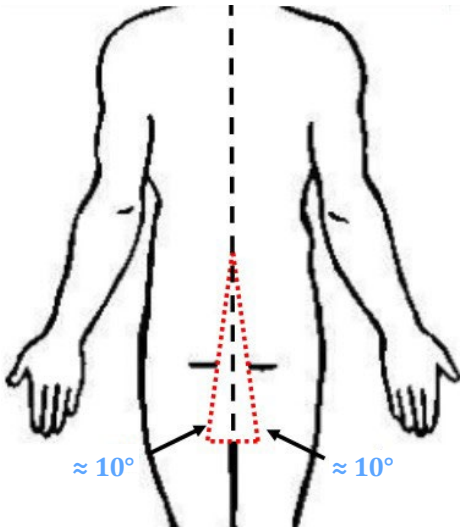
Direct AP X-ray of the SI Joint



Once the PSIS and the PIIS are located, rotate the C-Arm 20° medially while still visualizing the joint. Lay the guide wire on the skin, align the wire with the angle of the joint from the PSIS to the PIIS, and mark the oblique angle.

Place a guide wire on the skin over the PSIS and take an X-ray to properly locate it. Once located mark. Repeat the same process to mark the PIIS on the skin.





Desired skin mark angulation

The desired angle of the mark on the skin should be slightly greater than 10°, originating from the midline.

POSITIONING THE PIN

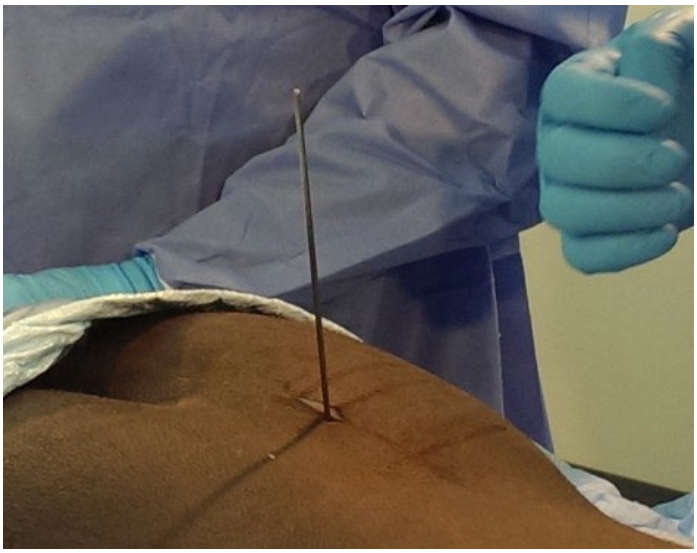
INCISION AND PIN PLACEMENT

Make a stab incision along the joint line and insert the Steinmann Pin (CW-130-005) into the SI Joint.

Tap the pin into the joint space to establish the pin firmly in the joint while maintaining angulation. The pin should enter the joint at the oblique 20° angle. Once the pin is in the desired location, extend the incision approximately 10mm superior and inferior.

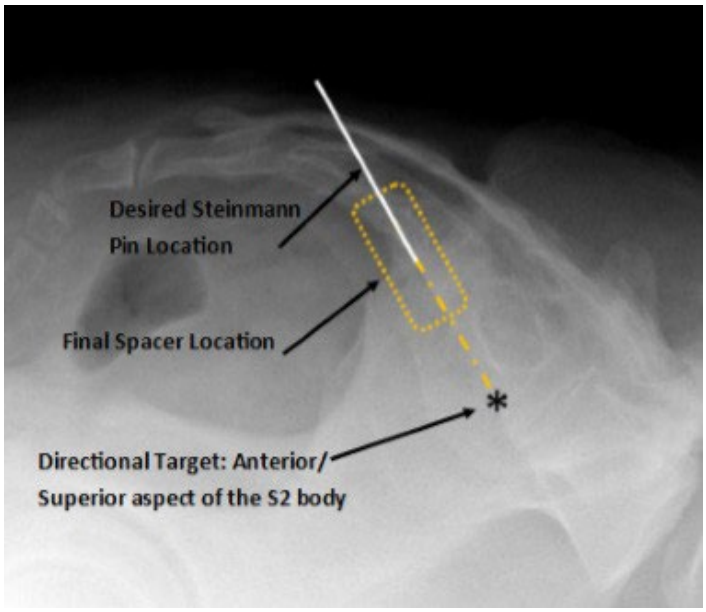
Verify the pin location with Lateral and Oblique AP fluoroscopic images. *Ultrasound imaging can also be utilized to verify this location.*

CAUTION: If the pin becomes bent during the insertion, remove immediately and replace it with a new pin.



PIN ANGULATION

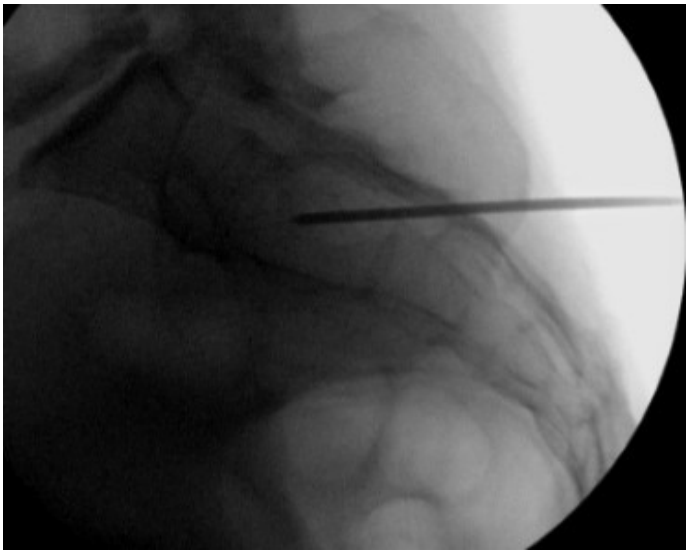
Tilt the Steinmann Pin inferiorly 20° (maintaining the oblique angle of 20°) so that the pin aims toward the anterior/ superior aspect of the S2 sacral body. The pin should be directed parallel to the anterior wall of the sacrum. Note the concave nature of the sacrum. The actual joint location in this area is 15-20mm anterior of this surface. Use a lateral view to verify the trajectory.



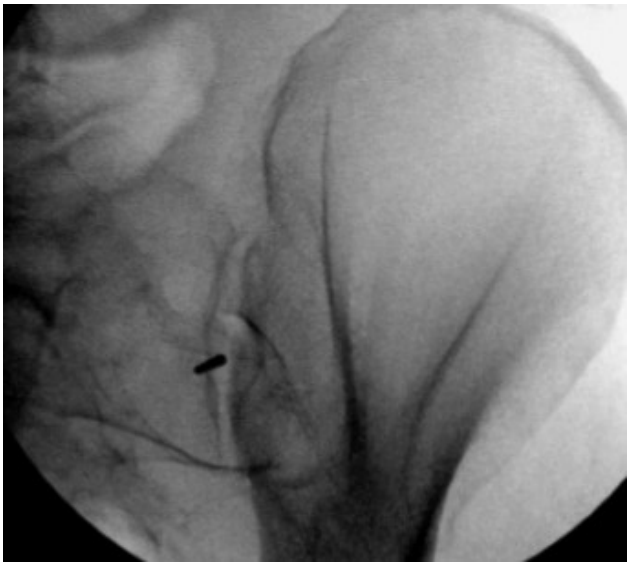
FINAL PIN POSITION

Advance the pin so that it is approximately 35-40mm into the joint space, with the trocar tip terminating at the anterior/ superior aspect of the S2 sacral body.

Verify the final location of the pin with Lateral, Direct AP and Oblique AP views.



DIRECT LATERAL

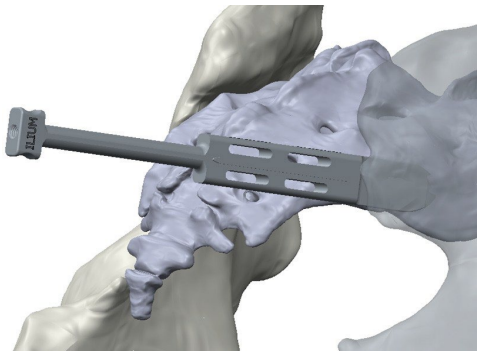


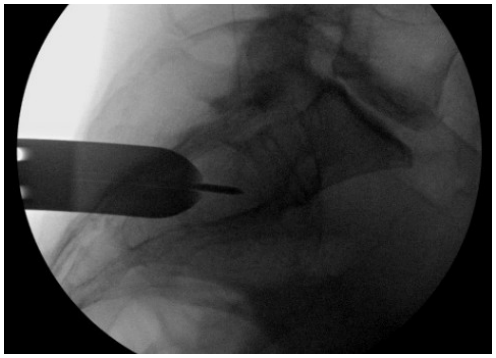
OBLIQUE

JOINT FINDER / DILATOR INSERTION

Insert the Joint Finder / Dilator (CW-131-001) over the Steinmann Pin and slide down until it contacts the joint. Rotate the Joint Finder until it aligns until it aligns with the auricular surface of the sacrum. Verify the trajectory and position with Lateral and AP radiographs.

Impact the Joint Finder over the Steinmann Pin until the Joint Finder contacts the top of the Posterior Inferior Iliac Spine. If the Steinmann Pin is exposed on the proximal end of the joint finder during impaction, thread on the Joint Finder Extender / Dilator Extender (CW-118-001). Impact on the Joint Finder Extender to prevent the Steinmann Pin from traveling deeper into the joint.



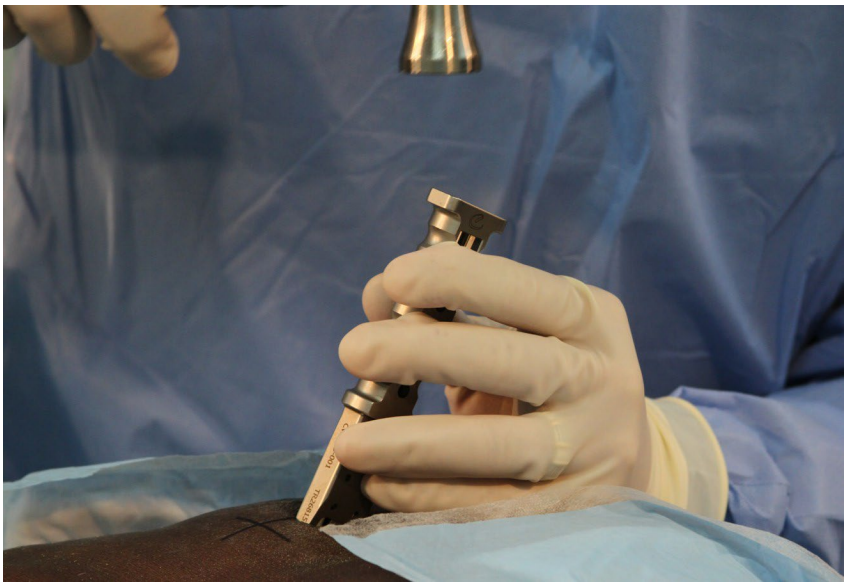


If utilized, remove Joint Finder Extender before moving on to the next step.

WORKING CANNULA INSERTION

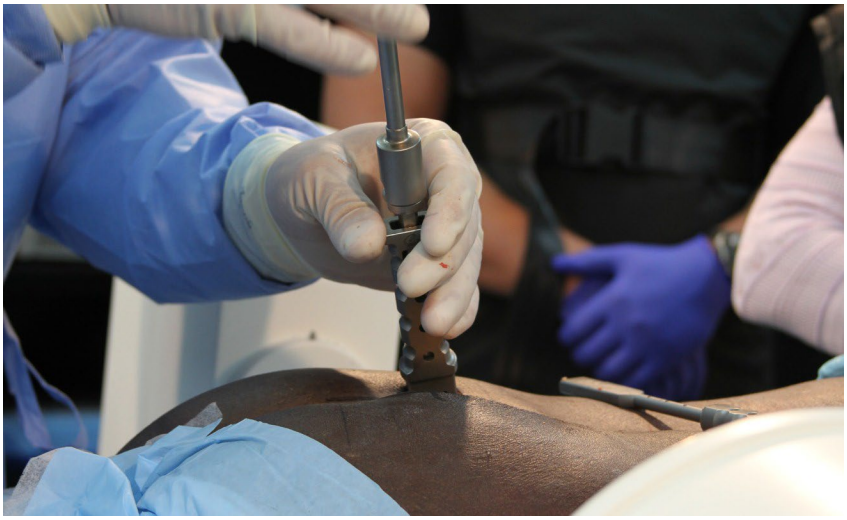
Choose the appropriate Working Cannula Left (CW-119-002) or Right (CW-119-001). Place the desired Working Cannula over the Joint Finder and slide down into the joint, making sure the side marked ilium faces the ilium. Impact the Working Cannula over the Joint Finder until rear surfaces of the two instruments are flush. Thread the Joint Finder Extender into the back surface of the Joint Finder and remove the Joint Finder.

If necessary, use the Slap Hammer connection on the Joint Finder Extender to remove from the Working Cannula. Once removed, remove the Steinmann Pin from the Joint.



Insertion of the Working Cannula

Left Working Cannula



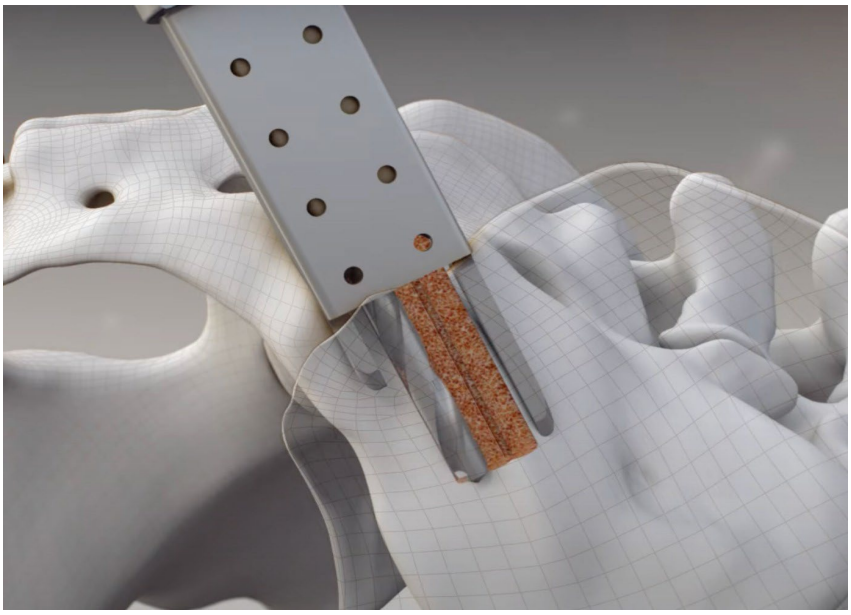
The Joint Finder being removed with the Slap-Hammer

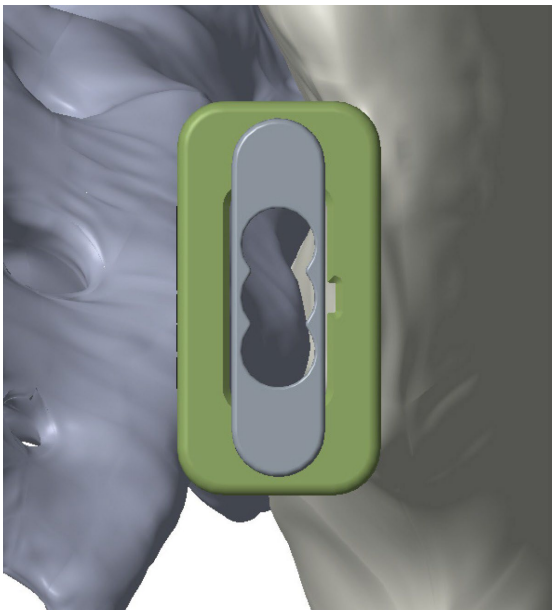
Right Working Cannula

PREPARING THE JOINT SPACE

DRILLING OUT THE JOINT SPACE

Insert the Drill Guide (CW-120-001) into the Working Cannula and drill 3 holes into the joint space.

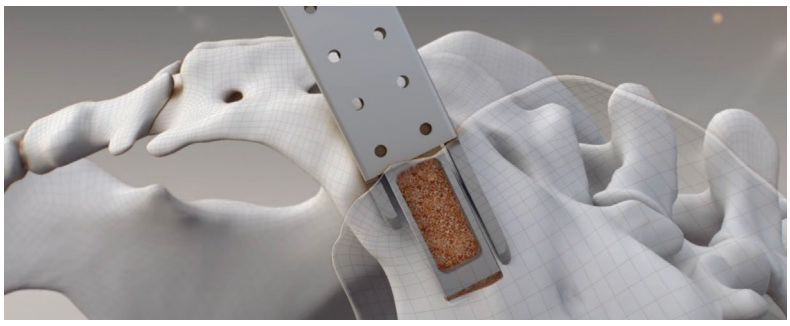




Drill through Drill Guide

CHISELING THE JOINT SPACE

Place the Box Chisel (CW-111-006) into the Working Cannula. Impact the end of the Chisel to the desired depth of the implant using the etching on the side of the Chisel. If necessary, use the Slap Hammer connection on the proximal end to remove the Chisel from the Working Cannula. Following removal, use of the Rasp (VYPR-106-001) is optional.

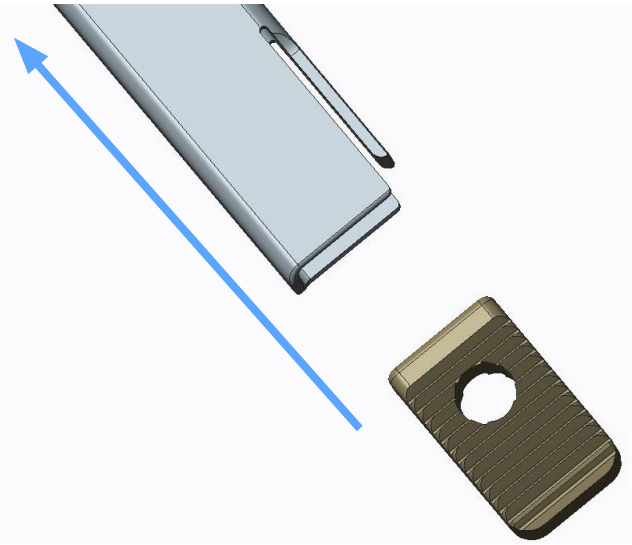


Remove excess material with Box Chisel

LOAD AND INSERT THE IMPLANT

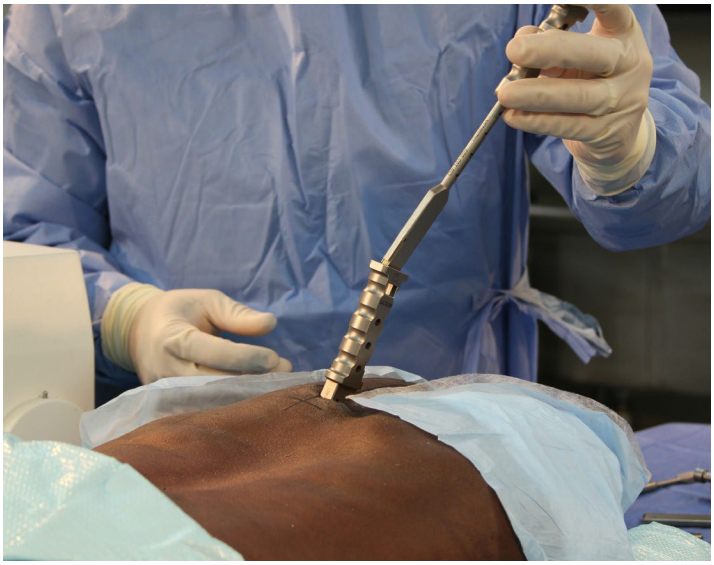
LOAD THE IMPLANT

Assemble the Implant Inserter by inserting the Inserter Rod (CW-103-008) into the distal end of the Inserter Handle (CW-103-009) and thread the Inserter Head (CW-103-002) on the proximal threads. Remove the allograft spacer (VY-001XX) from the sterile packaging and place the side of the Implant with the graft hole into the Inserter Handle first. If desired, fill the graft hole with autograft before assembly.



IMPLANT INSERTION

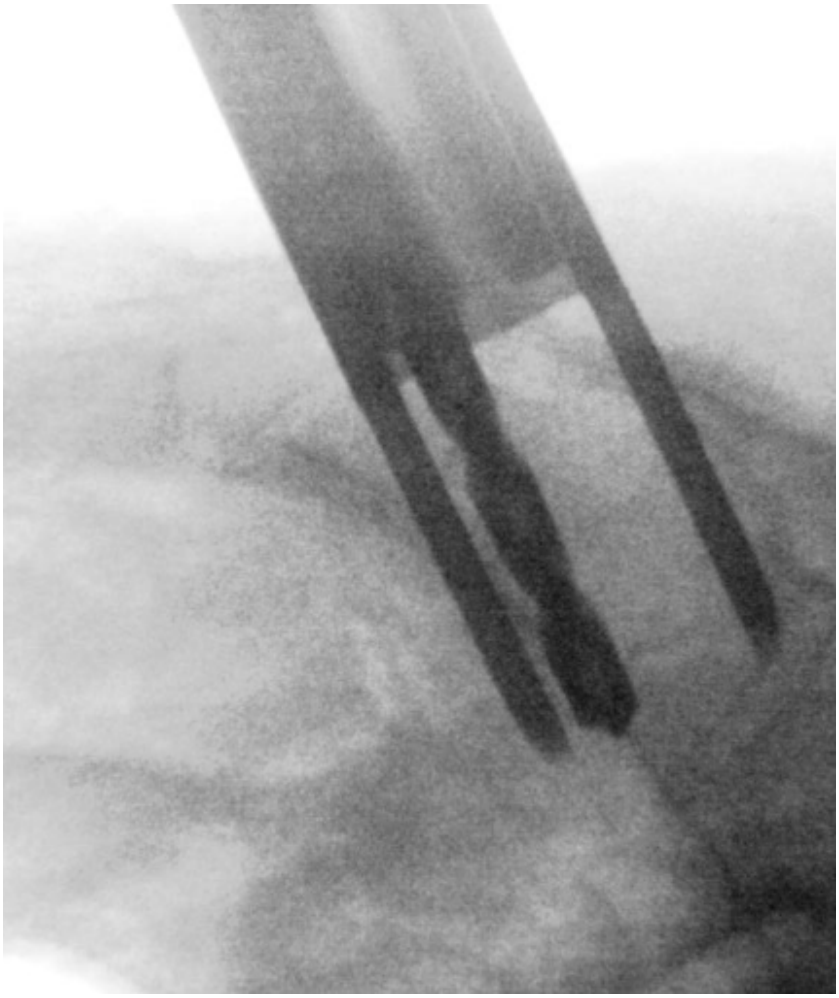
Slide the Inserter Assembly into the Working Cannula until it bottoms out on the rear surface. Impact the Inserter Head to deploy the implant into the cavity.



Once the implant is free of the Inserter Assembly, remove the assembly. If necessary, insert the Tamp (CW-107-001) into the Working Cannula and tap the Tamp to advance the implant until it bottoms out in the cavity. When the implant reaches its final depth, remove all instruments.

REMOVAL TECHNIQUE

Insert the Working Cannula into the joint space and insert the drill guide into the cannula. Drill 3 holes through the implant. Use the Box Chisel or suction to remove any remaining fragments of the spacer. If necessary, use rongeurs to remove any pieces of the implant that remain.



GENERAL INSTRUMENTS IFU

VYRSA™ General Instruments

INSTRUCTIONS FOR USE

NON-STERILE PRODUCT

BEFORE USING THE PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Reusable instruments are manufactured from a variety of materials commonly used in orthopedic and neurological procedures which meet applicable national and/or international standards.

INDICATIONS FOR USE

These orthopedic manual surgical instruments are intended for use in surgical procedures to manipulate tissue, bone, or for use with other devices in orthopedic surgery. An instrument may incorporate a measuring function which has uses as described on the label and the instrument.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

SURGICAL PROCEDURE

Please contact a customer service representative or company representative for the surgical procedure.

PATIENT SELECTION

The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome.

WARNINGS

1. Breakage, slippage, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient, or surgical or processing personnel.
2. Improper maintenance, handling, or inadequate cleaning procedures can render the instrument) unsuitable for their intended purpose or may even be dangerous to the patient or surgical or processing personnel.
3. The surgeon should use extreme caution when working in close proximity to vital organs, nerves, or vessels. Excessive force should not be used when positioning instruments, since it could cause injury to the patient.

PRECAUTIONS

1. Excessive force applied by instruments to implants can dislodge devices.
2. Exposing instruments to temperatures in excess of 275°F (135°C) may modify the physical characteristics. If instruments are exposed to temperature exceeding 275°F (135°C), perform an additional inspection to ensure they function as intended. See the EXAMINATION section for more information.
3. Extreme care should be taken to ensure instruments remain in good working order. During the procedure, the proper functioning of instruments is extremely important. Instruments should not be bent or damaged.
4. Misuse of instruments, resulting in corrosion, "freezing-up", scratching, loosening, bending, or fracture of components of an instrument may inhibit or prevent proper function.
5. Instruments should be carefully placed on trays, cleaned after each use, and stored in a dry environment.
6. Do not use instruments for any action for which they were not intended.
7. Regularly review the operational state of all instruments and, if necessary, contact VYRSA™ for replacement.
8. To avoid injury, the instrument should be carefully examined for functionality or damage prior to use. A damaged instrument should not be used. Based upon use risk, additional back-up instruments should be available in the set.
9. Preoperative and operating procedures, including knowledge of surgical techniques, are important considerations in the successful use of instruments by the surgeon. The proper selection and the compliance of the patient will greatly affect the results.
10. Proper patient selection and operative care are critical to the success of the surgery and avoidance of injury during surgery. Read and follow all other product information supplied by the manufacturer.
11. Special precautions are needed during pediatric use. Care should be taken when using instruments in pediatric patients, since these patients can be more susceptible to the stresses involved in their use.
12. Ensure instruments with a measuring function are not worn and any surface engravings are clearly visible.

Possible adverse effects include, but are not limited to the following:

- Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs, or joints.
- Infection if instruments are not properly cleaned and sterilized.
- Pain, discomfort, or abnormal sensations resulting from the use of the device.
- Nerve damage due to surgical trauma.
- Dural leak in cases of excessive load application.
- Impingement of close vessels, nerves, and organs by slippage or misplacement of the instrument.
- Bending, loosening or fracture of the implants or instruments
- Vascular damage could result in catastrophic or fatal bleeding.
- Reflex sympathetic dystrophy
- Hemorrhage of the blood vessels and/or hematomas
- Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.
- Cutting of skin or gloves of surgical or processing personnel.
- Bony fracture in cases of deformed or weak bone.
- Tissue damage to the patient, physical injury to surgical personnel, and/or increased operating time that may result from the accidental disassembly of multi-component instruments occurring during surgery.
- The methods of use of instruments are determined by the user's experience and training in surgical procedures. A successful result is not always achieved in every surgical case. This fact is especially true in surgery where other patient conditions may compromise the results.

EXAMINATION

Instruments must always be examined by the user pre/post cleaning and prior to surgery. Examination should be thorough and must include a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, deformation, or distortion, and that all components are complete.

Visual Inspection

As applicable, ensure the following:

- All laser markings and other markings are legible.
- No cracks are present in instrument handles or any part of the instrument.
- Discoloration, corrosion, stains, or rust does not exist. If present, follow the instructions in the Limitations on Processing section of this document.
- There is no handle/shaft separation, and the handle-to-shaft connection is secure.
- No cuts or gouges in the surface are present.
- There is no damage to the working ends or tips. The working end should be free of cracks, sharp edged gouges, and other damage. When applicable, the working end should be sharp.
- There is no damage to threads.
- All parts are present and free of damage and deterioration. Examples of parts that may be missing, loose, or damaged include set screws, springs, curved springs, pins, and prongs.

VY-900-002_RevA
Issue Date: March 2024

- Mating ends are free of damage (nicks, gouges, bends, etc.) that would interfere with the mating function.
- Cannulated instruments are inspected for cleanliness.

Functional Inspection

As applicable, ensure the following:
Instruments:

- Any moving parts move freely, without sticking, binding, or grinding.
- Springs return the handle of the instrument to its original position.
- Retention tabs hold appropriate mating parts and are not damaged.
- The instrument will function as intended with the appropriate mating parts.
- Ball detents will hold mating parts and are free from damage.
- Sharp edges are sharp to the touch and are not dull, have no nicks, or any other damage.
- Tips meet when appropriate.
- Ratcheting mechanisms are functional. This includes handles, latches, and other mechanisms. All teeth should be present and functional.
- Driver tips are not worn beyond functional use. If necessary, mate the instrument with the appropriate part.

CLEANING OF REUSABLE INSTRUMENTS

MANUAL CLEANING OF INSTRUMENTS AFTER USE

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instrument(s), in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instruments for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
12. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Flush device with deionized water, or equivalent, by placing the device under the water flow for a minimum of 3x.
15. Actuate parts, if applicable 3x, under running deionized water, or equivalent.
16. Rinse lumens, tubes, or cannula under running deionized water, or equivalent, 4x.
17. Use heat or lint-free cloth to dry devices following final rinse.

AUTOMATED CLEANING FOR INSTRUMENTS AFTER USE

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instruments, in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instruments for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
12. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Load the instrument(s) into the appropriate washer-disinfector.
15. Select the cycle which reflects the following parameters:

AUTOMATIC WASHER

Phase	Recirculation Time (min)	Temperature	Detergent Type & Concentration
Pre-wash 1	01:00	Cold tap water	N/A
Wash 1	05:00	43˚C tap water (Set point)	Enzymatic detergent per washer instructions
Rinse 1	01:00	Warm tap water	N/A
Pure Water Rinse	01:00	43˚C deionized water	N/A
Dry Time	10:00	90°C	N/A

STERILIZATION FOR INSTRUMENTS

Warning: VYRSA™ Technologies does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, VYRSA™ recommends the following parameters:

Method	**Steam**	**Steam**
Cycle	Gravity Displacement (Wrapped)	Pre-vacuum (Wrapped)
Preconditioning Pulses	N/A	4
Temperature	132°C (270°F)	132°C (270°F)
Exposure Time	15 minutes	4 minutes
Drying Time	45 minutes	45 minutes
Open Door Drying Time	15 minutes	15 minutes

Note: An FDA Cleared Wrap must be used.

*VYRSA™ Technologies has validations for the above sterilization cycles and has the data on file. The validated sterilization parameters are compliant with the full cycle validation approach per ANSI/AAMI/ISO 17665-1, Annex D. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

VY-900-002_RevA
Issue Date: March 2024

Limitations on Processing

- Repeated processing has minimal effect on these instruments.
- End of life is determined by excessive wear and damage from normal use.
- See the EXAMINATION section of this document including the Visual and Function inspection subsections to determine if the device is at the end of its useful life.

MRI Information

The VYRSA General Instruments have not been evaluated for safety in the MR (Magnetic Resonance) environment. The VYRSA General Instruments are not intended for implantation.

SYMBOLS

Symbol	Definition	Reference
	Catalogue Number-Indicates the manufacturer's catalogue number to that the medical device can be identified	ISO 15223-1:2021 Symbol 5.1.6
	Batch code-Indicates the manufacturer's batch code so that the batch or log can be identified	ISO 15223-1:2021 Symbol 5.1.5
	Non-sterile-Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1:2021 Symbol 5.2.7
	Prescription Only-Caution: Federal law restricts this device to sale by or on the order of a physician	FDA 801.15(c)(1)(i)(F)
	Consult Instructions for Use-Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021 Symbol 5.4.3
	Manufacturer-Indicates the medical device manufacturer	ISO 15223-1:2021 Symbol 5.1.1
	Unique Device Identifier (UDI)-Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021 Symbol 5.7.10
	Date of Manufacture-Indicates the date when the medical device was manufactured	ISO 15223-1:2021 Symbol 5.1.3

FOR FURTHER INFORMATION

If further information on this product or the Surgical Technique Guide is needed, please contact VYRSA™ Technologies at the number listed below:

MANUFACTURED BY:
VYRSA™ Technologies
501 Allendale Rd, Suite 101B
King of Prussia, PA 19406
Phone: (484) 427-7060

VY-900-002_RevA
Issue Date: March 2024

MTF ALLOGRAFT TISSUE IFU

PI -3, Rev 23, 08/2021
RM -156

MTF BIOLOGICS ALLOGRAFT TISSUE INSTRUCTIONS FOR USE

READ BEFORE USING
DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP <71> Sterility Tests.
Not Terminally Sterilized. Do Not Sterilize.

THIS TISSUE WAS RECOVERED FROM A DECEASED DONOR FROM WHOM LEGAL AUTHORIZATION OR CONSENT HAS BEEN OBTAINED. THIS RECOVERY WAS PERFORMED USING ASEPTIC TECHNIQUES. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS.

Description and Indication for Use
MUSCULOSKELETAL TRANSPLANT FOUNDATION (MTF) tissues are supplied in a variety of standard sized units designed for surgical use by qualified health care professionals (e.g., physicians, dentists, and/or podiatrists). Processed human bone and soft tissue have been used in a variety of surgical applications and in combination with prosthetic devices. The amount and size of allograft necessary for a surgical procedure is based upon an individual surgeon's preference and the size and type of defect. The description of the tissue, serial number, expiration date, product code, size and/or amount, and additional information are printed on the allograft container label.

Cautions and Warnings
ALL ALLOGRAFTS ARE FOR SINGLE PATIENT USE ONLY. Do not use portions of an allograft from one container on multiple patients. Do not sterilize. Trace amounts of Gentamicin, Primaxin, Amphotericin B antibiotics, Penicillin G, Streptomycin Sulfate, Dexamethasone Sodium Phosphate, vitamins, and Dulbecco's Modified Eagle Medium (DMEM) may be present. Tissue is exposed to processing solutions that may contain detergents and alcohol. Trace amounts of processing solutions may remain. Caution should be exercised if the patient is allergic to any of these substances.

Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials.

This allograft must not be used under any of the following conditions:
- If the container seal is damaged, or not intact.
- If the container has any physical damage.
- If the container label or identifying bar code is severely damaged, not readable or is missing.
- If the freeze-dried allograft container has been allowed to freeze or has otherwise been damaged.
- If the freeze-dried allograft has been rehydrated for more than 24 hours.
- If the frozen allograft has not been used within 24 hours of thawing or has been stored at temperatures that exceed recommended storage temperatures. (See "Frozen Bone and Soft Tissue")
- If the expiration date shown on the container label has passed.

Use caution in the following circumstances:
- Fever
- Uncontrolled diabetes
- Low vascularity of the surround tissue
- Local or systemic infection
- Dehiscence and or necrosis due to poor revascularization
- Inability to cooperate with and/or comprehend post-operative instructions

Precautions
Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and Testing). Transmission of infectious diseases may occur despite careful donor selection and laboratory testing, including serology and nucleic acid testing (NAT). Bacterial infection at the site of grafting may occur. ***Within the United States*: Adverse outcomes attributable to the tissue must be promptly reported to MTF.** ***Outside of the United States*: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.**

Adverse Effects
Possible adverse effects of using human tissues include but are not limited to:
- Infection of soft tissue and/or bone (osteomyelitis)
- Immune response of non-infectious cause, including fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Fracture of the newly formed bone
- Disease transmission or undesirable immune response

Allograft Information
Processing and packaging are performed under controlled aseptic conditions in an ISO Class 4 environment.
- Tissue that is aseptically processed with no exposure to gamma radiation is labeled as follows: "Tissue is recovered and processed under aseptic conditions" and "Passes USP <71> Sterility Tests".
- Tissue that is aseptically processed and treated with low-dose gamma radiation is labeled as follows: "Tissue is recovered and processed under aseptic conditions. Treated with gamma radiation" and "Passes USP <71> Sterility Tests".

Preoperative Preparation
Preparation of the host bed is important for allograft incorporation. The host bed should be free of infection prior to grafting. Whenever possible, the allograft should be securely fixed to the host bone to aid in incorporation and to prevent displacement of the graft.

FREEZE-DRIED BONE, FREEZE-DRIED DEMINERALIZED BONE AND FREEZE-DRIED SOFT TISSUE

Freeze-dried bone, freeze-dried demineralized bone and freeze-dried soft tissue have been preserved using lyophilization (freeze-drying) to lower the total water content to 6% or less.

Freeze-Dried Packaging Note: Tissues preserved by freeze-drying are packaged in nested plastic trays, screw top jars, plastic bottles, or flexible pouches. Some tissues may be wrapped in gauze prior to packaging. The gauze (if present) will be wrapped around the tissue must be removed from the tissue prior to tissue implantation.

Storage
Store containers of freeze-dried tissue at ambient temperature. In order to maintain integrity of seal, do not freeze. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant. If storage conditions or container seal have been compromised before intended use, the tissue should be discarded.

Reconstitution/Rehydration Procedure
To obtain the best clinical results and prevent graft failure the procedure and recommendations listed below should be followed.

Preparation for Use
The decision to rehydrate MTF freeze-dried tissue prior to transplantation should be based upon the surgeon's preference. For tissues that are to be cut, shaped, drilled or used for weight bearing purposes, excessive force should not be applied to the lyophilized bone during manipulation or upon implantation. For ease of handling, it is recommended that freeze-dried soft tissue (i.e. tendon and ligaments) be rehydrated prior to use.

Recommended instruction for handling freeze-dried tissue:
- Allograft tissue should be maintained in an aseptic environment at all times to prevent the possibility of contamination.
- It is common surgical practice to rehydrate freeze-dried tissue in an acceptable sterile irrigant (i.e. normal saline or Lactated Ringers Solution). Antibiotics may be used with the irrigant according to surgeon preference.
- Patient sensitivity to antibiotics used to rehydrate allograft tissues should be checked prior to use. Concentration of antibiotic solutions should be less than normally indicated for I.V. administration.
- Use new solutions for each allograft.
- Sufficient solution should be prepared to completely cover the tissue. Tissues should be implanted or discarded within 24 hours of opening the final tissue container provided the allograft tissue is maintained in an aseptic environment.

Tissue packaged in nested plastic trays:
Open tissues packaged in nested plastic trays using the following procedure. Note: The inner and outer tray components are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.
1. Peel back lid of outer tray. NOTE: Once the outer tray is opened, allograft should be used promptly. Inner tray, alone, although a sterile barrier, is not intended for storage of allograft, as it may not provide an adequate moisture barrier.
2. Grasp the pull-tab on the lid of the inner tray to remove it from the outer tray and pass it into the sterile field.
3. Peel back lid of inner tray. Transfer tissues to a sterile container for reconstitution.
4. Completely immerse the tissue in the reconstitution solution.
5. Rinse each tissue thoroughly with sterile irrigant prior to transplantation. Note: Some freeze-dried bone and soft tissue allografts are packaged with gauze. If gauze is present with the tissue, remove gauze and discard.

Tissue packaged in screw top jar in plastic tray:
Open tissues packaged in a screw top jar in a plastic tray using the following procedure:
Note: The inner jar and its outer tray are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.
1. Peel back lid of outer tray. NOTE: Once the outer tray is opened, allograft should be used promptly. Inner container, alone, is not intended for storage of allograft, as it may not provide an adequate moisture barrier.
2. Grasp the top and bottom of the container by placing fingers in the open area provided to remove it from the outer tray and pass it into the sterile field.
3. Remove the threaded cap by twisting and breaking the tamper evident tab. Transfer tissues to a sterile container for reconstitution.
4. Completely immerse the tissue in the reconstitution solution.
5. Rinse each tissue thoroughly with sterile irrigant prior to transplantation. Note: Some freeze-dried bone and soft tissue allografts are packaged with gauze. If gauze is present with the tissue, remove gauze and discard.

Tissue packaged in plastic bottle in plastic tray:
Open tissue packaged in a plastic bottle in plastic tray using the following procedure:
Note: The inner bottle and the outer tray are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.

1. Peel back lid of outer tray. NOTE: Once the outer tray is opened, allograft tissue should be used promptly. Inner container, alone, is not intended for storage of allograft, as it may not provide an adequate moisture barrier.
2. Remove the inner bottle from outer tray and pass it into the sterile field.
3. Remove the red cap and aluminum collar from the bottle. NOTE: fragments of the red cap may break off.
4. Remove the rubber stopper. Note: The container shall be held firmly on a hard surface while removing stopper to prevent spillage.
5. Deposit the contents of the bottle into a sterile container for reconstitution.
6. Completely immerse the tissue in the reconstitution solution.
7. Rinse each tissue thoroughly with sterile irrigant prior to transplantation. Note: Some freeze dried bone and soft tissue allografts are packaged with gauze. If gauze is present with tissue, remove gauze and discard.

Tissue packaged in flexible pouches
This allograft has been aseptically packaged into sterilized packaging components. Use standard aseptic/sterile techniques to open the package and make ready for use.
1. Peel open the outer pouch.
2. Pass inner pouch to sterile field.
3. Peel open inner pouch.
4. Remove tissue.
5. Implant as per surgeon's preference.

Note: The decision to rehydrate MTF freeze-dried bone prior to transplantation should be based upon the surgeon's preference.

FROZEN BONE AND FROZEN SOFT TISSUE
Bone and soft tissues preserved by freezing have been stored at -40ºC to -90ºC until time of shipping, and are shipped on dry ice.

Storage
It is recommended that the frozen bone or soft tissue be stored on dry ice or in a -40ºC to -90ºC environment until time of surgery. Storage of a package containing allograft at or below -90ºC or in liquid nitrogen (vapor or liquid phase) may compromise package integrity. Short-term storage of less than six months at the user's facility at -20ºC to -39ºC is acceptable. If the thawed tissue is not used within 24 hours of thawing it must be discarded. Packaged tissue thawed 2 hours or less may be returned to frozen storage provided the package seal has not been breached. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant.

Preparation for Use
1. Cut open outer bag with non-sterile scissors and remove sterile peel pouch.
2. Open the peelable pouch using proper sterile technique.
3. Pass off inner vacuum-sealed bag into sterile field.
4. Cut open vacuum-sealed bag with sterile scissors and remove tissue.

Thawing
1. It is recommended that frozen allograft be placed into a sterile stainless steel basin or equivalent containing a warm (39ºC+/- 2ºC) sterile irrigant (i.e. normal saline or Lactated Ringers Solution). Antibiotics may be used with the irrigant according to surgeon's preference.
2. The tissue thaw time is per surgeon's preference. Soft tissue only: remove remaining cloth layers (if present).
3. The allograft should then be rinsed 3 times in Lactated Ringers Solution or normal saline.

Donor Screening and Testing
Prior to donation, the donor's medical/social history was screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by the MTF Medical Board of Trustees. Donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and registered with the FDA. The donor blood samples were tested for:
- Hepatitis B virus (HBV) surface antigen
- Hepatitis B virus core antibody
- Hepatitis C virus (HCV) antibody
- HIV-1/2 antibody
- Syphilis
- HIV -1 NAT
- HCV NAT
- HBV NAT

Additional testing of SARS-CoV-2, HTLV I & II and/or West Nile Virus (as applicable) may also have been performed. All infectious disease test results passed acceptability for screening. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, consent, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening, including laboratory testing, meet or exceed current standards established by the American Association of Tissue Banks.

Patient Record
Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. A TissueTrace® Tracking Form and peel-off stickers have been included with each package of tissue. Please record the patient ID, name and address of the transplant facility, allograft tissue information (using the peel-off stickers), and comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively, a system for electronic submission may be used and sent to MTFTTC@Sceris.com. ***Within the United States*:** Once completed, the bottom page of the form should be returned to MTF using the self-addressed mailer. Copies of this information should be retained by the transplant facility for future reference. ***Outside of the United States*:** Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained by the hospital for future reference.

Reference: Current MTF policies and procedures are in compliance with current FDA, AATB and other regulatory requirements.

Definitions of Label Symbols


Consult instructions for use


Do Not Reuse

For Translation of Instructions for Use

www.mtfbiologics.org

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Processed and distributed by: Musculoskeletal Transplant Foundation
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Within the United States: 800.433.6576
Outside of the United States: +1.732.661.0202

All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

CAUTION: Restricted to use by a physician, dentist and/or podiatrist.

SET CONTENTS

PART NUMBER	DESCRIPTION
VY-100-34	QC Cannulated Handle - T-Handle Ratchet
VY-104-098	Mallet
VY-100-05-0180	Slap Hammer Assembly
CW-103-002	Inserter Head
CW-103-008	Inserter Rod Assembly
CW-103-009	Inserter Handle Assembly
CW-107-001	Spacer Tamp
CW-111-006	Box Chisel
CW-118-001	Dilator Extender / Joint Finder Extender
CW-119-001	Working Cannula, Right
CW-119-002	Working Cannula, Left
CW-120-001	Spacer Drill Guide
CW-125-019	Ø6mm x 190mm Drill Bit 1/4" Quick Connect
CW-125-021	Ø6mm x 210mm Drill Bit 1/4" Quick Connect
CW-130-005	Ø2mm x 190mm Steinmann Pin Round Tip (SS)
CW-131-001	Dilator / Joint Finder
VY-500-001	VYRSA - 3/4 Case Lid
VYPR-106-001	Rasp
VYPR-501-001	VYRSA Pro - Instrument Tray

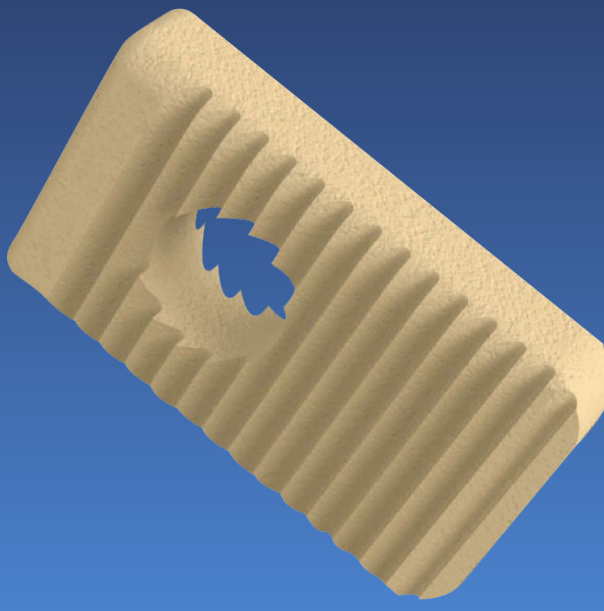
ALLOGRAFT PART NUMBER	DESCRIPTION
VY-00120	Allograft Spacer 6 W x 15 H, 20mm, MTF
VY-00125	Allograft Spacer 6 W x 15 H, 25mm, MTF
VY-00130	Allograft Spacer 6 W x 15 H, 30mm, MTF
VY-00135	Allograft Spacer 6 W x 15 H, 35mm, MTF

NOTES

VYRSA™ pro

SI FUSION SYSTEM

SURGICAL TECHNIQUE GUIDE



VYRSA™ TECHNOLOGIES

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