StabiliT® VP Vertebroplasty System & StabiliT® VP Fracture Kits

English

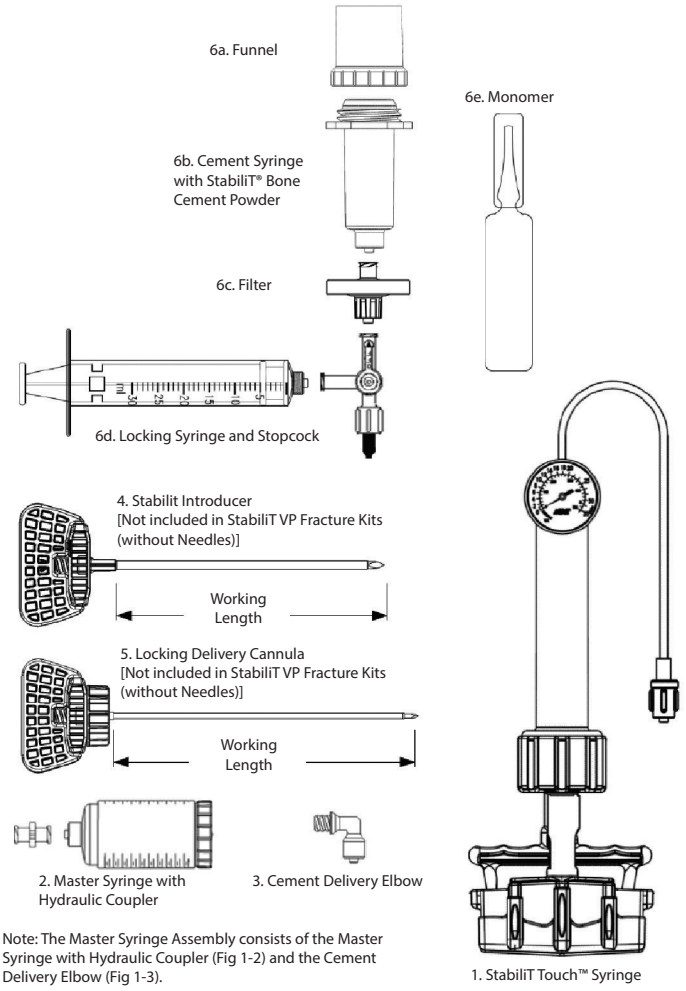
INSTRUCTIONS FOR USE

Important Information – Please Read Before Use

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.

INDICATIONS
The StabiliT® VP Vertebroplasty System is intended for percutaneous delivery of StabiliT® Bone Cement. The StabiliT® Bone Cement is indicated for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

DESCRIPTION
The StabiliT® VP Vertebroplasty System provides controlled delivery of StabiliT Bone Cement High Viscosity Spinal Cement in the treatment of vertebral compression fractures. The StabiliT VP Vertebroplasty System is offered in different configurations of components (i.e., StabiliT VP Fracture Kits); refer to the product labeling for a detailed list of individual kit contents.



Note: The Master Syringe Assembly consists of the Master Syringe with Hydraulic Coupler (Fig 1-2) and the Cement Delivery Elbow (Fig 1-3).

Figure 1 : StabiliT VP Vertebroplasty System

CONTENTS
- StabiliT Touch Syringe (Fig 1-1): Used for delivering bone cement into the vertebral body.
- Master Syringe with Hydraulic Coupler (Fig 1-2): The Master Syringe and Hydraulic Coupler are intended for the delivery of StabiliT Bone Cement.
- Cement Delivery Elbow (Fig 1-3): Used to connect the Cement Syringe to the Locking Delivery Cannula for bone cement delivery.
- Locking Delivery Cannula (LDC) with diamond tip (Fig 1-5), if supplied: The LDC is intended for percutaneous access to bone in the spine and bone cement delivery.

Device	Cannula Gauge	Tip Style	Locking Thumb Wheel	Working Length (with stylet)
Locking Delivery Cannula (Short)	11G	Diamond	Yes	12.8 cm
Locking Delivery Cannula (Long)	11G	Diamond	Yes	14.9 cm

- StabiliT Introducer with diamond tip (Fig 1-4): The StabiliT Introducer is used for percutaneous access to bone in the spine. The device is packaged with a diamond tip Stylet and Cannula. See the chart below for the device information.

Device	Cannula Gauge	Tip Style	Working Length (with stylet)
StabiliT Introducer (Short)	10G	Diamond	10 cm
StabiliT Introducer (Long)	10G	Diamond	12 cm

- StabiliT Bone Cement and Saturate Mixing System (Fig 1-6):
  - » The StabiliT Bone Cement is indicated for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).
  - » The Saturate Mixing System is intended for mixing of StabiliT Bone Cement.
    - Funnel (Fig 1-6a)
    - Cement Syringe with StabiliT Bone Cement Powder (Fig 1-6b)
    - Filter (Fig 1-6c)
    - Locking Syringe and Stopcock (Fig 1-6d)
    - Monomer (Fig 1-6e)

HOW SUPPLIED
The StabiliT Touch Syringe, StabiliT Introducer, Locking Delivery Cannula, Master Syringe with Hydraulic Coupler, Cement Delivery Elbow, and StabiliT Bone Cement and Saturate Mixing System are provided sterile. These devices are intended for single use only. DO NOT re-sterilize and/or reuse. DO NOT use if package is open or damaged and notify the manufacturer.

CONTRAINDICATIONS
- The use of this product is contraindicated in patients with coagulation disorders, or with severe pulmonary insufficiency.
- The use of this product is contraindicated in patients with extended vertebral collapse superior to 2/3 of the standard thickness, and destruction of the posterior wall with epidural extension of the pathologic tissue and clinical signs of medullar compression.
- The use of PMMA bone cement is contraindicated in the presence of active or incompletely treated infection at the site where the bone cement is to be applied.
- This product should not be used in patients with sensitivity to any of the components of the PMMA bone cement.
- Evidence of safety for use of this bone cement material in children or during pregnancy or lactation has not been established.

WARNINGS
- Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.
- Thoroughly read the IFUs for each device, including the StabiliT Bone Cement and Saturate Mixing System, (if packaged separately or along with this IFU) before use. The IFU must be followed to perform a procedure using the StabiliT VP products.
- For safe and effective use, this device should only be used by qualified physicians with training in the clinical procedure in which it is being used. The physician should have specific training and experience, and thorough familiarity with the use and application of this product. Physicians using the device should be familiar with the physiology and pathology of the selected anatomy, and be trained in the performance of the chosen surgical technique.
- Always use image guidance with radiographic equipment that provides high quality imaging to avoid patient injury. Use imaging techniques to confirm placement of instrumentation (before and during advancement and after removal) including Working Cannula placement; absence of damage to surrounding structures, and appropriate location of delivered bone cement. Imaging, such as venography, can be used to assess the ability of the vertebra to contain the delivered bone cement.
- All devices are provided sterile. Do not re-sterilize. It is essential to maintain strict sterile technique during all phases of handling and use of this product.

- These devices are intended for single-use only. Do not re-sterilize or re-use. Reconditioning, refurbishing, repair, modification, or re-sterilization of the device(s) to enable further use is expressly prohibited, as it may result in patient injury including loss of function and/or infection.
- Do not use if package is opened or damaged.
- Percutaneous vertebroplasty or kyphoplasty procedures should only be performed in medical settings in which emergency decompressive surgery is available.
- Precise Working Cannula placement is required for this procedure. Cannula insertion within the vertebra should be performed under fluoroscopic or CT image guidance. Incorrect device placement could result in patient injury.
- The Working Cannula (part of the StabiliT Introducer) is not intended for delivering bone cement. Always use the Locking Delivery Cannula to deliver bone cement to the vertebral body.
- The Introducer Stylet must be in place inside the Working Cannula during use (e.g. insertion, removal, manipulation).
- Do NOT bend Cannula; patient injury may occur. Removal of the Working Cannula must be performed with a rotation and axial motion with the Stylet in place.
- Do NOT use excessive force when manipulating the device; breakage of the device may require intervention or retrieval.
- Dispose of used product per local, state and federal blood borne pathogen controls including biohazard sharps container and disposal procedures.
- For devices penetrating bone, DO NOT use if dense bone, including traumatic fractures, is encountered. Device damage resulting in patient injury may occur. Breakage of the device may require intervention for retrieval.
- Following completion of cement delivery, the pressure in the system should be relieved and the Locking Delivery Cannula removed within one minute of completing cement delivery, or prior to cement hardening.
- The Introducer Stylet or the Locking Delivery Cannula should be inserted and engaged with the Working Cannula during Introducer removal or manipulation.

PRECAUTIONS

- Examine all packaging prior to opening. DO NOT use device if damaged or the sterile packaging is breached. Contact the manufacturer if package is opened or damaged.
- Use the devices in this kit prior to the Use By Date noted on the device packaging.
- Wear safety glasses or a face shield when delivering the bone cement.
- Ensure that all luer lock connectors are tightened securely. Improperly secured connections could result in disconnection during injection.
- Exercise caution in cases involving extensive vertebral destruction and significant vertebral collapse (i.e., the vertebral body is less than 1/3 of its original height). Such cases may lead to a technically difficult procedure.

ADVERSE EVENTS

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements for vertebroplasty or kyphoplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early within the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.

The most frequent adverse reactions reported with acrylic bone cement intended for vertebroplasty or kyphoplasty are:

- Transitory fall in blood pressure
- Thrombophlebitis
- Hemorrhage and hematoma
- Superficial or deep wound infection
- Bursitis
- Short-term cardiac irregularities
- Heterotopic bone formation

Other reported adverse events for acrylic bone cements intended for vertebroplasty or kyphoplasty include

- Leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae.
- Pyrexia
- Hematuria
- Dysuria
- Bladder fistula
- Anaphylaxis
- Transitory worsening of pain due to heat released during polymerization
- Nerve entrapment and dysphasia due to extrusion of the bone cement beyond its intended application
- Adhesions and stricture of the ileum due to heat released during polymerization

Potential adverse events associated with vertebroplasty or kyphoplasty include:

- Pneumonia
- Intercostal neuralgia
- Collapse of a vertebra adjacent to the one injected, due to an osteoporotic disease
- Pneumothorax
- Extravasation of bone cement into soft tissue
- Fracture of a pedicle
- Rib fracture in patients with diffuse osteopenia, especially during thoracic vertebroplasty or kyphoplasty procedures, due to the significant downward force exerted during Working Cannula insertion
- Compression of the spinal cord with paralysis or loss of feeling

Adverse events potentially associated with use of the StabiliT Introducer include:

- Nerve injury including puncture of the cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Pulmonary embolism
- Hemothorax or pneumothorax
- Infection, including deep or superficial wound infection
- Unintended puncture wounds including vascular puncture and dural tear
- Hemorrhage
- Hematoma
- Pain

PREPARATION AND USE

1. Check packaging for damage prior to placing contents in sterile field.

2. Remove product from package using standard sterile technique.

3. Check all components for damage. If the pressure gauge needle on the StabiliT Touch Syringe is resting outside the "0" box, do not use.

4. Mix bone cement per the StabiliT Bone Cement and Saturate Mixing System IFU.

5. Prepare the StabiliT Touch Syringe

a. Squeeze the trigger and advance the plunger with enough force to completely remove any air present in the syringe.

b. Submerge the end of the extension tube in sterile water (or saline).

c. Squeeze the trigger on the StabiliT Touch Syringe and pull back the handle to fill the Syringe with fluid. Do so until the entire Syringe is filled.

d. Invert the StabiliT Touch Syringe, squeeze the trigger, and advance the plunger to remove any remaining air in the syringe and extension tube.

e. Squeeze the trigger on the StabiliT Touch Syringe and pull back fully to aspirate with sterile water (or saline). **Caution:** Inspect the StabiliT Touch Syringe tubing to ensure that there is no air in the system.

6. Access to the vertebral body

a. When using the Locking Delivery Cannula in conjunction with the StabiliT Introducer:
- Direct the StabiliT Introducer into the vertebral body utilizing image guidance checking AP/Lateral images to confirm proper placement.
- Once the StabiliT Introducer is positioned in the vertebral body, remove the Stylet with a counterclockwise turn leaving the Working Cannula in place.

b. When using the Locking Delivery Cannula for direct access to the vertebral body:
- Direct the Locking Delivery Cannula into the vertebral body utilizing image guidance checking AP/Lateral images to confirm proper placement.
- Once the Locking Delivery Cannula is positioned in the vertebral body, remove the Stylet with a counterclockwise rotation, leaving the Working Cannula in place.

7. Assemble system components

a. Prior to bone cement delivery (see Table 1) remove the Filter and Funnel Assembly. Clean the Cement Syringe of excess bone cement

b. Completely thread the Cement Syringe into the Cement Delivery Elbow.

c. Thread the Master Syringe onto the Cement Syringe. **Caution:** Ensure Master Syringe is FULLY threaded onto Cement Syringe before proceeding. Not doing so can cause user injury or device malfunction.

d. Confirm that the Hydraulic Coupler is securely connected to the Master Syringe.

e. When using the Locking Delivery Cannula in conjunction with the StabiliT Introducer:
- Remove the LDC Stylet from the Cannula
- Securely attach the Locking Delivery Cannula to the Cement Delivery Elbow.
- Securely connect the StabiliT Touch Syringe extension tube luer to the Hydraulic Coupler attached to the Master Syringe. **Caution:** Do not begin bone cement delivery until saturation and preparation time are complete (see Table 1).

f. When using the Locking Delivery Cannula for direct access to the vertebral body:
- Securely attach the Cement Delivery Elbow to the Locking Delivery Cannula.
- Securely connect the StabiliT Touch Syringe extension tube luer to the Hydraulic Coupler attached to the Master Syringe. **Caution:** Do not begin bone cement delivery until saturation and preparation time are complete (see Table 1).

8. Cement delivery

a. Confirm that the StabiliT Touch Syringe trigger is released to ensure that the plunger is locked in position.

b. When using the Locking Delivery Cannula in conjunction with the StabiliT Introducer:

- Prime the LDC with bone cement by rotating the StabiliT Touch Syringe handle in the CLOCKWISE direction. Once bone cement exits LDC tip, stop cement flow by squeezing the trigger on the StabiliT Touch Syringe. Release the trigger to lock the plunger in the withdrawn position. Wipe the LDC tip clean.
- Under image guidance, stabilize the Working Cannula and insert the LDC into the Working Cannula until the locking thumb wheel contacts the Working Cannula luer. Rotate the LDC locking thumb wheel to firmly connect LDC and the Working Cannula. Properly position the LDC in the vertebral body.

c. When prepared to deliver bone cement squeeze the StabiliT Touch Syringe trigger and push the handle forward until resistance is met and release the trigger. Under image guidance, deliver bone cement by rotating the handle in the CLOCKWISE direction. **Warning:** Use image guidance to confirm location of cement delivery.

d. To stop bone cement delivery, squeeze the trigger on the StabiliT Touch Syringe. Release trigger to lock the plunger in the withdrawn position. To re-engage, squeeze the trigger and push the handle forward until resistance is met, then release trigger. Continue delivering bone cement by rotating the handle in the CLOCKWISE direction. **Caution:** To protect the threads of the lock release handle, the gauge must indicate 25 ATM or lower before the quick release mechanism is used. **Caution:** The quick release mechanism will activate (signaled by a clicking sound) if the operator exceeds the maximum pressure for the StabiliT Touch Syringe. Once this has occurred, the quick release mechanism may disengage at lower pressures during subsequent attempts to deliver cement. **Caution:** At the completion of the procedure remove the Locking Delivery Cannula from the vertebral body, under image guidance. When using the LDC in conjunction with the StabiliT Introducer, remove the LDC from the Working Cannula, reinsert and lock the Stylet in the Working Cannula. If no additional bone cement delivery is required, remove Introducer (Cannula with Stylet) under image guidance. **Warning:** Do not remove the Working Cannula without the Stylet in place. DO NOT bend Working Cannula, patient injury may occur.

Table 1: Timing of Various Activities at Different Ambient Temperatures

Activity	Approximate Cumulative Time From Initiation of Saturation (minutes)	
	@ 18-19 °C (65-67 °F)	@ 20-23 °C (68-74 °F)
Bone Cement Saturation and Preparation (See Bone Cement IFU)	0-10 minutes	0-5 minutes
Bone Cement Delivery	10-45 minutes (35 minutes working time)	5-40 minutes (35 minutes working time)

Table 2: Effect of Ambient Temperature on Cement

Temperature °F (°C)	Minimum Setting Time (minutes)
81 (27)	35
73 (23)	51
66 (19)	82

STORAGE & HANDLING

Handle with care. Store in original packaging in a clean, cool, and dry location. Avoid exposure to temperature and humidity extremes.

SYMBOL GLOSSARY

⚠	Caution		Use By
	Consult Instructions For Use	EC REP	Authorized Representative in the European Community
STERILE R	Sterilized using irradiation (Introducer, Master Syringe Assembly)		Keep away from sunlight
STERILE EO	Sterilized using Ethylene Oxide (Bone Cement Powder, Delivery Syringe and Bone Cement & Saturate Mixing System)		Keep away from moisture
STERILE A	Sterilized using aseptic processing techniques (Bone Cement Liquid)		Flammable
LOT	Lot Number		Single Use Device, DO NOT REUSE
REF	Catalog Number	25°C	Upper Limit of Temperature 25°C
LATEX	No Latex		Manufacturer
	Do not use if package is opened or damaged	QTY:	Quantity
S	Shorter length instrument	10/11G	10 and 11 gauge cannulas, outer diameter
L	Longer length instrument		Do not Resterilize
MD	Medical Device	Sterile Package	Sterile Package

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