Important Information – Please Read Before Use

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

INDICATIONS
The StabiliT® MX Vertebral Augmentation 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 MX Vertebral Augmentation System is a system for the controlled delivery of StabiliT Bone Cement in the treatment of vertebral compression fractures. The StabiliT MX Vertebral Augmentation System consists of different combinations of the components below (Figure 1).

INSTRUCTIONS FOR USE

StabiliT® MX Vertebral Augmentation System with PowerCURVE® Navigating Osteotome
(For use with StabiliT® Bone Cement)

Figure 1: StabiliT MX Vertebral Augmentation System
The Saturate Mixing System is intended for mixing of StabiliT Bone Cement.

The Deployment Handle (A) is the rotating portion that articulates the distal tip of the device. The Tip Indicator (B) indicates the direction in which the tip will articulate (C). The Tip Articulated Osteotome (#8): The PowerCURVE Navigating Osteotome is intended for scraping or coring of bone in the spine. It is to be used with the StabiliT Introducer. The Shaft is 3.0 mm in outer diameter. Table 1: Timing of Various Activities at Different Ambient Temperatures

Figure 2: Power/CURVE Navigating Osteotome

How supplied

All components are provided sterile. These devices are intended for single use only. DO NOT re-sterilize and/or reuse. If package is open or damaged DO NOT use 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 a compromise in the posterior column of the vertebral body or the walls of the pedicles.
- 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.

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 MX Vertebral Augmentation System.
- 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, experience, and thorough familiarity with the use and application of this product.
- Always use image guidance with radiographic equipment that provides high quality imaging to avoid patient injury. Use appropriate imaging techniques to confirm correct Working Cannula placement (before and during advancement and after removal); absence of damage to surrounding structures, and appropriate location of the delivered bone cement. Imaging, such as venography, can be used to assess the ability of the vertebra to contain the delivered bone cement.
- It is essential to maintain strict sterile technique during the procedure and during all phases of handling this product.
- Precise Working Cannula placement is required for this procedure. 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 LDC to deliver bone cement to the vertebral body.
- The introducer stylet must be in place inside the Working Cannula during use of the Introducer (e.g., insertion, removal, manipulation).
- Removal of the introducer must be performed by rotation and axial motion. DO NOT bend the tip sideways (e.g., lateral motion).
- Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.

Table 1: Timing of Various Activities at Different Ambient Temperatures
• Dispose of used product per local, state and federal blood borne pathogen controls including biohazard sharps container and disposal procedures.

• DO NOT use if package is opened or damaged. All devices are provided sterile. All devices are sterilized using gamma radiation. 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.

• 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 or removal. DO NOT use the StraightLine Osteotome or Power/ Curve Navigating Osteotome in fractures due to pararcal or prostatic cancer metastasis of the spine. DO NOT use the Power/ Curve Navigating Osteotome to scrape or core bone in more than one vertebra.

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 device 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 securely tightened. Improperly secured connections could result in disconnection during injection.

• DO NOT insert the StraightLine Osteotome into the Working Cannula if the Stylet is still attached to the StraightLine Osteotome, as it may result in inadequate coring of the bone.

• 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.

CAUTION: Inspect the DiamondTOUCH Syringe tubing to ensure that there is no air in the system prior to cement delivery.

CAUTION: The volume change of fluid dispensed may not be accurate due to compliance of the plastic components as pressure changes.

CAUTION: If applied pressure does not indicate on gauge/digital display, discontinue use immediately and replace it with a new unit.

REUSE PRECAUTION STATEMENT

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or re sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re sterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

ADVERSE EVENTS

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements for vertebroplasty or kyphoplasty include myocordial 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
- Bunions
- Short-term cardiac irregularities
- Heterotopic bone formation

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

- Leaks 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 kyphoplasty or vertebroplasty include:

- Pneumonia
- Interosseous neuralgia
- Collapse of a vertebral segment to the adjacent 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 during Working Cannula insertion
- Compression of the spinal cord with paralytic or loss of feeling

Adverse events potentially associated with use of the StabiliB Introducer, Power/Curve Navigating Osteotome or StraightLine Osteotomes include:

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

PREPARATION AND USE

Check packaging for damage prior to placing contents in sterile field. Remove product from package using standard sterile technique. Check all components for damage. Mix bone cement per the StabiliB Bone Cement and Saturate Mixing System IFU. Prepare the DiamondTOUCH Syringe.
NOTE:  

a. The syringe will default to PSI mode when initially turned on. To change the pressure display to read ATM/Bar, press and hold the blue button until “ATM/Bar” flashes four times. The display is now in “ATM/Bar” mode. To change back to PSI, press and hold the blue button once again.

b. When in PSI mode, the tick marks on the left of the display that represent pressure will be limited to 350 PSI (2.8 ATM). If the DiamondTOUCH is pressurized past 350 PSI, the grouping of tick marks on the left will flash.

The numerical digits in the center of the display will continue to show actual pressure throughout the device’s pressure range (-6 to 514 PSI). After pressure reading has been taken, a graph bar or tick mark will remain to mark the highest point of pressure. Pressing the blue button once quickly will display last pressure reading information and a indicator on the display. After the next pressure reading has started, the last tick mark will disappear.

c. To conserve power the backlight will automatically turn off after ten minutes of inactivity. However, the microprocessor will continue to monitor the pressure. Pressing the blue button will reactivate the backlight.

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

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

f. Squeeze the clutch on the DiamondTOUCH Syringe and pull back the handle to fill the syringe with fluid. Do so until the entire syringe is filled.

g. While holding vertical, push handle against table or other solid surface to remove any air in syringe and extension tube.

h. If additional fluid is needed in the DiamondTOUCH Syringe, squeeze the clutch and pull back fully to aspirate with sterile water (or saline).

i. Optional device stickers are included to be attached to the DiamondTOUCH Syringe to identify the fluid being used in the syringe. The white sticker may be used to identify sterile water, the blue sticker for saline, and the yellow sticker for contrast (contrast not associated with the StabiliT MX Vertebral Augmentation System).

j. Mix bone cement per the StabiliT Cement and Saturation Mixing System IFU.

CAUTION: If the DiamondTOUCH Syringe LCD displays anything besides the pressure and time windows as shown above, the syringe is defective. Please return the syringe to Merit Medical for credit.

Access the vertebral body using the StabiliT Introducer.

b. Once the StabiliT Introducer is positioned in the vertebral body, remove the Stylet with a counterclockwise rotation, leaving the Working Cannula in place.

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 onto 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 injury or device malfunction.

d. Confirm the Hydraulic Coupler is securely attached to the Master Syringe.

e. Securely connect the Master Syringe with Coupler to the end of the DiamondTOUCH Syringe extension tube.

f. As the Articulating Tip exits the Working Cannula turn the Deployment Handle to bend the Articulating Tip toward the intended location.

3. The Articulating Tip is the distal portion of the PowerCURVE, the Tip Indicator points in the direction of the articulating tip bending.

4. The Deployment Handle is the rotating portion of the PowerCURVE Handle.  

   a. The Articulating Tip is the distal portion of the PowerCURVE, the Tip Indicator points in the direction of the articulating tip bending.

   b. The Deployment Handle is the rotating portion of the PowerCURVE Handle.  

   1. Turning the Deployment Handle one (1) full 360° turn clockwise will cause the Articulating Tip to fully bend.

   2. Turning the Deployment Handle counter-clockwise will cause the Articulating Tip to straighten.

   3. Do not turn the Deployment Handle greater than one (1) full 360° turn clockwise.

   4. Ensure the Articulating Tip is fully extended in the straight position prior to insertion into the Working Cannula.

   5. Remove the stylet from the Working Cannula.

   6. Insert the PowerCURVE into the Working Cannula until the first laser mark on the shaft is even with the proximal end of the luer on the Working Cannula. Confirm by image guidance that the distal end of the PowerCURVE is at the distal end of the Working Cannula before proceeding. When fully inserted into Working Cannula, the shaft extends approximately 31 mm beyond the distal end of the Working Cannula.

   7. As the Articulating Tip exits the Working Cannula turn the Deployment Handle to bend the Articulating Tip in the direction of the Tip Indicator on the PowerCURVE shaft.

   8. The PowerCURVE can be advanced to the desired position using image guidance.

   9. Care should be taken at all times to NEVER strike the arms of the Deployment Handle, especially when rotated from its starting position.
Cement delivery

a. Confirm that the DiamondTOUCH Syringe trigger is released to ensure that the plunger is locked in position.
b. Prime the LDC with bone cement by rotating the DiamondTOUCH Syringe handle in the CLOCKWISE direction. Once bone cement exits the LDC tip, stop cement flow by squeezing the trigger on the DiamondTOUCH Syringe. Release trigger to lock the plunger in the withdrawn position. Wipe LDC tip clean.
c. Under image guidance, stabilize the Working Cannula and insert the LDC until the rotating wheel contacts the Working Cannula luer. Rotate the LDC wheel to lock the LDC to the Working Cannula.
d. When prepared to deliver bone cement, squeeze the DiamondTOUCH 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.
e. To stop bone cement delivery, squeeze the trigger on the DiamondTOUCH Syringe. Release trigger to lock the plunger in the withdrawn position. 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 quick release mechanism should be used to stop flow and relieve pressure when the gauge indicates 25 ATM or lower.

Table 1: Timing of Various Activities at Different Ambient Temperatures

<table>
<thead>
<tr>
<th>Activity</th>
<th>Approximate Cumulative Time From Initiation of Saturation (minutes)</th>
<th>Minimum Setting Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Cement Saturation</td>
<td>0-10 minutes</td>
<td>0-5 minutes</td>
</tr>
<tr>
<td>and Preparation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(See Bone Cement (FU))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone Cement Delivery</td>
<td>10-45 minutes (35 minutes working time)</td>
<td>5-60 minutes (35 minutes working time)</td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
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Table 2: Effect of Ambient Temperature on Cement

<table>
<thead>
<tr>
<th>Temperature ºF (ºC)</th>
<th>Minimum Setting Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>81 (27)</td>
<td>35</td>
</tr>
<tr>
<td>73 (23)</td>
<td>51</td>
</tr>
<tr>
<td>66 (19)</td>
<td>82</td>
</tr>
</tbody>
</table>

Table 2: Separation Distances Between Portable and Mobile Radio Frequency (RF) Communications Equipment and the DiamondTOUCH™ Syringe

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power (in watts) W.

Caution: Following completion of bone cement delivery, remove the LDC from the Working Cannula within 1 minute and immediately insert and lock the Sytylet in the Working Cannula. If no additional bone cement delivery is required, remove Introducer (Cannula with Stylet). Warning: Removal of the Working Cannula should only be performed after insertion of the Sytylet by rotation and axial motion. DO NOT bend Working Cannula sideways, patient injury may occur.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure that it is used in such an environment.

Immunity Test |
---|
IEC 60601 test level |
Compliance level |
Electromagnetic environment guidance |
Electrostatic discharge (ESD) IEC 61000-4-2: ESD ±6 kV contact ±8 kV air |
Increasing relative humidity will reduce the potential for ESD related difficulties
### 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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Caution: Consult accompanying documents</td>
</tr>
<tr>
<td>📀</td>
<td>Authorized Representative in the European Community</td>
</tr>
<tr>
<td>🌞</td>
<td>Sterilized using Irradiation</td>
</tr>
<tr>
<td>🌞</td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td>🌞</td>
<td>Sterilized using Ethylene Oxide</td>
</tr>
<tr>
<td>🌞</td>
<td>Keep away from moisture</td>
</tr>
<tr>
<td>🌞</td>
<td>Sterilized using Aseptic Processing Techniques</td>
</tr>
<tr>
<td>🌞</td>
<td>Flammable</td>
</tr>
<tr>
<td>🟢</td>
<td>Lot Number</td>
</tr>
<tr>
<td>🟢</td>
<td>Single Use Device, DO NOT REUSE</td>
</tr>
<tr>
<td>🟢</td>
<td>Catalog Number</td>
</tr>
<tr>
<td>🟢</td>
<td>Store below 25°C</td>
</tr>
<tr>
<td>🟢</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🟢</td>
<td>Do not use if package is opened or damaged</td>
</tr>
<tr>
<td>🟢</td>
<td>Diamond tip</td>
</tr>
<tr>
<td>🟢</td>
<td>Short</td>
</tr>
<tr>
<td>🟢</td>
<td>Bevel Tip</td>
</tr>
<tr>
<td>🟢</td>
<td>Long</td>
</tr>
<tr>
<td>🟢</td>
<td>Cannula Gauge</td>
</tr>
<tr>
<td>🟢</td>
<td>Introducer Gauge/Locking Delivery Cannula Gauge</td>
</tr>
<tr>
<td>🟢</td>
<td>Do not Resterilize</td>
</tr>
<tr>
<td>🟢</td>
<td>Quantity</td>
</tr>
<tr>
<td>🟢</td>
<td>Interference may occur in the vicinity of equipment marked with this symbol</td>
</tr>
<tr>
<td>🟢</td>
<td>Contains Batteries—Do Not Remove</td>
</tr>
<tr>
<td>🟢</td>
<td>RxOnly: Federal (USA) law restricts this device to sale by or on the order of a physician</td>
</tr>
<tr>
<td>🟢</td>
<td>Medical Device</td>
</tr>
<tr>
<td>🟢</td>
<td>Sterile Package</td>
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</table>

For the State of California, U.S.A. only
Perchlorate Material: special handling may apply.
See www.dtsc.ca.gov/hazardouswaste/perchlorate
Perchlorate Material: Lithium battery contains perchlorate.

Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748

Authorized Representative:
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Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22

www.merit.com