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

English

INSTRUCTIONS FOR USE

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 High Viscosity Spinal Cement in the treatment of vertebral compression fractures. The StabiliT MX Vertebral Augmentation System consists of different combinations of the components below (Figure 1).

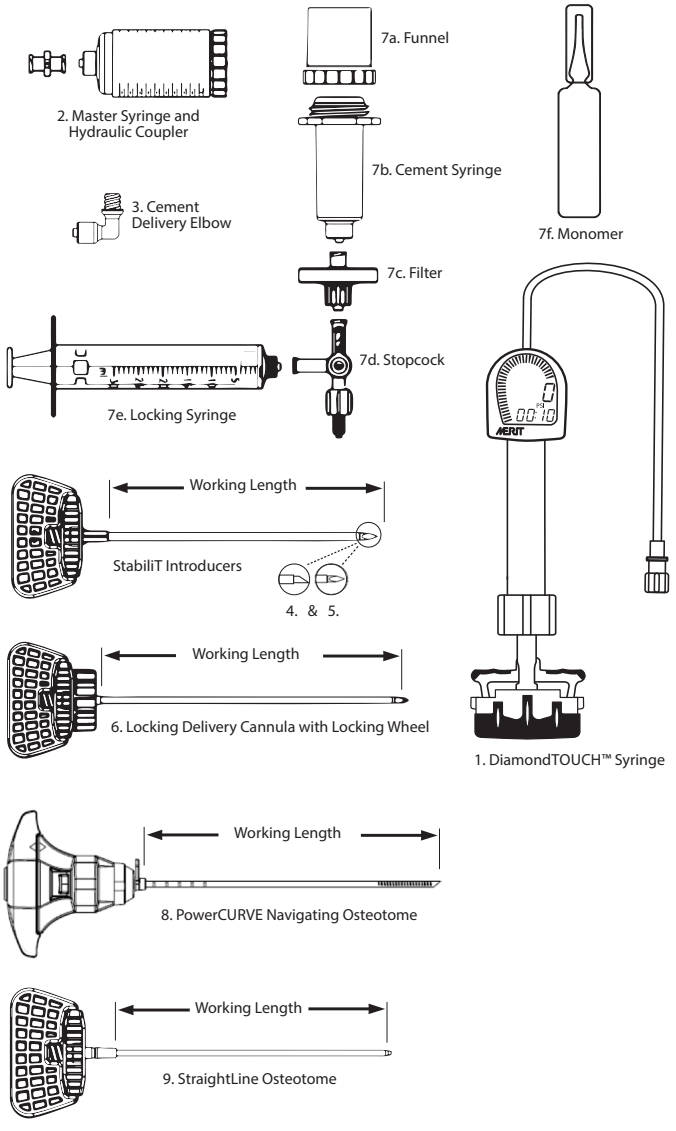


Figure 1: StabiliT MX Vertebral Augmentation System

CONTENTS

- DiamondTOUCH™ Syringe (#1): For delivering bone cement into the vertebral body.
- Master Syringe and Hydraulic Coupler (#2): Intended for the delivery of StabiliT Bone Cement.
- Cement Delivery Elbow (#3): Connects the Cement Syringe to the Locking Delivery Cannula
- StabiliT Introducer with bevel tip (#4) and diamond tip (#5): Used for percutaneous bone access.

Device	Working Length
StabiliT Introducer, Short	10 cm
StabiliT Introducer, Long	12 cm

Locking Delivery Cannula (LDC) with diamond tip (#6): For percutaneous bone access and bone cement delivery.

Device	Working Length
Locking Delivery Cannula, Short	12.8 cm
Locking Delivery Cannula, Long	14.9 cm

- StabiliT Bone Cement and Saturate Mixing System (#7):
  - » 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 (#7a)
    - Cement Syringe (#7b): Contains StabiliT Bone Cement Powder
    - Filter (#7c)
    - Stopcock (#7d)
    - Locking syringe (#7e)
    - Monomer (#7f)
- PowerCURVE Navigating 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.
  - » 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).

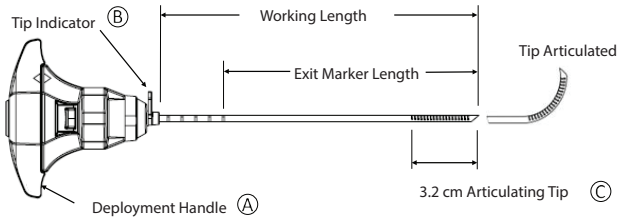


Figure 2: PowerCURVE Navigating Osteotome

Device	Exit Marker	Working Length
PowerCURVE Navigating Osteotome, Short	12.0 cm	15.1 cm
PowerCURVE Navigating Osteotome, Long	14.0 cm	17.1 cm

VertecoR™ StraightLine Cement Staging Osteotome (SLO) (#9); The VertecoR StraightLine Cement Staging Osteotome is intended for scraping or coring of bone in the spine. It is packaged with a blunt tip stylet. 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

Device	Working Length
VertecoR StraightLine Cement Staging Osteotome, Short	13.5 cm
VertecoR StraightLine Cement Staging Osteotome, Long	15.5 cm

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 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 cannula sideways; patient injury may occur.
- 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-sterilizer or re-use. Reconditioning, refurbishing, repair, modification, or resterilization 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 retrieval.
- DO NOT use the StraightLine Osteotome or PowerCURVE Navigating Osteotome in fractures due to pararenal or prostatic cancer metastasis of the spine.
- DO NOT use the PowerCURVE 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 resterilization 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 resterilization 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 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 kyphoplasty or vertebroplasty 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, PowerCURVE Navigating Osteotome or StraightLine Osteotomes include:

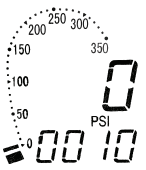
- Nerve injury including puncture of the cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Pulmonary embolism
- Hemothorax or pneumothorax
- Infection, including deep or superficial wound infection
- Unintended puncture wounds including vascular puncture and dural tear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

PREPARATION AND USE

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 StabiliT Bone Cement and Saturate Mixing System IFU.
Prepare the DiamondTOUCH Syringe.
Press the blue button behind the DiamondTOUCH Delivery Syringe LCD display near the tubing to power the device on. The LCD will display "Zero" for two seconds and then the device will be ready for use. At this point the syringe will begin its incremental time keeping.

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 (23.8 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. The device will power itself off after 90 consecutive minutes at zero pressure.

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 Saturate 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.

a. Under image guidance direct the StabiliT Introducer into the vertebral body, while checking A/P and lateral images to confirm proper device placement.

b. Once the StabiliT Introducer is positioned in the vertebral body, remove the Stylet with a counterclockwise turn, 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 user 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. Caution: Do not begin bone cement delivery until saturation and preparation time is complete (see Table 1).

Create an access channel and a cement staging cavity for bone cement delivery using the SLO and the PowerCURVE. WARNING: Use image guidance and follow the IFU to avoid patient injury.

a. Use the SLO to create an access channel and a cement staging area in the bone:

- Remove the Stylet from the SLO and set aside prior to inserting the SLO in the Working Cannula.
- Remove the Stylet from the Working Cannula.
- Using image guidance, advance the SLO through the Working Cannula. Once in contact with bone, verify placement of the tip of the SLO at the intended location. The Introducer/SLO stop limits the SLO shaft to extend 15 mm beyond the distal end of the Working Cannula. Always verify placement under image guidance.
- Using image guidance, advance the tip of the SLO to the desired location to carefully scrape or core the bone. Caution: The location of the Working Cannula in the vertebra should be monitored before and during advancement of the SLO.
- When scraping or coring is complete, stabilize the Working Cannula and remove the SLO.

b. Use the PowerCURVE to create targeted access channels and cement staging cavities in the bone:

- The Articulating Tip is the distal portion of the PowerCURVE, the Tip Indicator points in the direction of the articulating tip bending.
- 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.
- Ensure the Articulating Tip is fully extended in the straight position prior to insertion into the Working Cannula.
- Remove the stylet from the Working Cannula.
- 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.
- 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.
- The PowerCURVE can be advanced to the desired position using image guidance.
- Care should be taken at all times to NEVER strike the arms of the Deployment Handle, especially when rotated from its starting position.
- When the Articulating Tip is substantially deployed, the PowerCURVE should not be rotated.
  1. The rotation limiting mechanism will slip if the large handle is rotated while the Articulating Tip is substantially articulated in dense bone. Caution: The location of the Working Cannula in the vertebra should be monitored before, and during advancement of the PowerCURVE through the Working Cannula.
- When cavity creation is complete, use imaging guidance to straighten the Articulating Tip by returning the Deployment Handle to its starting position. Caution: Straightening the Articulating Tip should be done slowly and under imaging guidance while carefully monitoring the position of the tip of the device. Straighten the device by turning the Deployment Handle counter clockwise.
- Under imaging guidance, remove the PowerCURVE from the StabiliT Introducer's Working Cannula.
- The location of the StabiliT Introducer Working Cannula in the vertebra should be monitored and adjusted if necessary after removal of the PowerCURVE.
- Using image guidance (and stabilizing the Working Cannula), the PowerCURVE can be carefully withdrawn and advanced multiple times to scrape or core bone until the desired cavity (size and location) is created.

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. 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 quick release mechanism should be used to stop flow and relieve pressure when the gauge indicates 25 ATM or lower. **Caution:** The quick release mechanism will activate (signaled by a clicking sound) if the operator exceeds the maximum pressure for the DiamondTOUCH Syringe. Once this has occurred, the quick release mechanism may disengage at lower pressures during subsequent attempts to increase pressure. **Caution:** Following completion of bone cement delivery, remove the LDC from the Working Cannula within 1 minute and immediately insert and lock the Stylet 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 Stylet by rotation and axial motion. DO NOT bend Working Cannula sideways, 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

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RADIO FREQUENCY (RF) COMMUNICATIONS EQUIPMENT AND THE DIAMONDTOUCH™ SYRINGE

The DiamondTOUCH Syringe is intended for use in an electromagnetic environment in which RF radiated disturbances are controlled. The user of the DiamondTOUCH Syringe can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DiamondTOUCH Syringe as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (in meters) m		
Rated maximum output power of transmitter (in watts) W	150kHz to 80 MHz d=[1.2] √ P	80 MHz to 800 MHz d=[1.2] √ P	800 MHz to 2.5 GHz d=[2.3] √ P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

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 rating of the transmitter in watts (W) according to the transmitter manufacturer.

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 61000-4-20	±6 kV contact ±8 kV air	±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

⚠	Caution: Consult accompanying documents		Use By
	Consult Instructions For Use	EC REP	Authorized Representative in the European Community
STERILE R	Sterilized using Irradiation		Keep away from sunlight
STERILE EO	Sterilized using Ethylene Oxide		Keep away from moisture
STERILE A	Sterilized using Asceptic Processing Techniques		Flammable
LOT	Lot Number		Single Use Device, DO NOT REUSE
REF	Catalog Number	25°C	Store below 25°C
LATEX	No Latex		Manufacturer
	Do not use if package is opened or damaged		Diamond tip
S	Short		Bevel Tip
L	Long	# G	Cannula Gauge
LEN # cm	Device Length in Centimeters	# / # G	Introducer Gauge/Locking Delivery Cannula Gauge
2	Do not Resterilize	QTY:	Quantity
	Interference may occur in the vicinty of equipment marked with this symbol		Contains Batteries-Do Not Remove
Rx Only	RxOnly: Federal (USA) law restricts this device to sale by or on the order of a physician	MD	Medical Device
Sterile Package	Sterile Package		

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.

MERITMEDICAL®

CE 2797

www.merit.com

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

EC REP **Authorized Representative:**
Merit Medical Ireland Ltd,
Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22

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