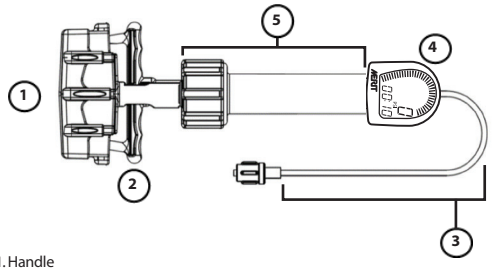
DiamondTOUCH™ Syringe

English

INSTRUCTIONS FOR USE

DESCRIPTION
The DiamondTOUCH™ Syringe is a 30mL disposable device with a threaded plunger assembly and a flexible high pressure extension tube. The DiamondTOUCH Syringe is designed to generate positive and negative pressure, and monitor positive pressures over a range of zero to 514 PSI (zero to +35ATM/BAR).



1. Handle
2. Clutch
3. Extension Tube
4. Pressure Gauge
5. Barrel (contains plunger)

℞ Only **CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE
The DiamondTOUCH Syringe is intended for percutaneous delivery of bone cement. The device can also be used for inflating and deflating interventional devices, and to measure pressure.

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. Press the blue button behind the DiamondTOUCH 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.

Notes:

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.

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.

4. Prepare the DiamondTOUCH Syringe:
   a. Squeeze the clutch 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) when used for cement delivery or liquid contrast media for inflation and deflation of interventional devices.
   c. Squeeze the clutch on the DiamondTOUCH Syringe and pull back the handle to develop a negative pressure and fill the syringe with fluid. Do so until the entire syringe is filled.
   d. While holding vertical, push handle against table or other solid surface to remove any air in syringe and extension tube.
   e. If additional fluid is needed in the DiamondTOUCH Syringe, squeeze the clutch and pull back fully to aspirate with sterile water (or saline), or liquid contrast media.
   f. 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.

PRECAUTIONS
When using for inflatable bone tamps only use liquid contrast media (a 60% solution is recommended). Follow manufacturer's instructions for contrast media indications, usage, and cautions.

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

CEMENT DELIVERY

1. Assemble cement and delivery system components per IFU.
2. After inserting needle into patient, begin delivery of bone cement by rotating the DiamondTOUCH Syringe handle in the CLOCKWISE direction. Once bone cement exits the needle tip, stop cement flow by squeezing and releasing the clutch on the syringe. Wipe needle tip clean.
3. Under image guidance, deliver bone cement by rotating the handle in the CLOCKWISE direction.
4. To stop bone cement delivery, squeeze and release the clutch on the DiamondTOUCH Syringe. To re-engage (if necessary), squeeze the clutch and push the handle forward until resistance is met, then release clutch. 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 367 PSI (25 ATM) or lower.

BALLOON INFLATION AND DEFLATION
To inflate the balloon, squeeze the clutch and advance the plunger until resistance is met. Release grip on the clutch, locking the plunger in position.

To increase pressure, while assessing balloon inflation under image guidance, rotate the handle clockwise until the desired inflation pressure or size of the balloon is reached. The lock mechanism maintains the pressure.NOTE: Loss of pressure may indicate a leak in the system.

To deflate the balloon, rotate the handle counterclockwise to release pressure to 25 ATM or lower. Squeeze the clutch and pull back to generate a negative pressure. Release grip on the clutch to lock the plunger in the negative pressure position.

CAUTION: The quick release clutch mechanism will activate (signaled by a clicking sound) if the operator exceeds the maximum pressure for the DiamondTOUCH Syringe. Once this has occurred, the clutch mechanism may disengage at lower pressures during subsequent attempts to increase pressure.

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.

U.S. and Foreign Patents Pending.

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	**150 kHz to 80 MHz** $d=[1.2]\sqrt{P}$	**80 MHz to 800 MHz** $d=[1.2]\sqrt{P}$	**800 MHz to 2.5 GHz** $d=[2.3]\sqrt{P}$
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

Users should follow local guidelines and practices regulating the disposal of infected waste products.

SYMBOL GLOSSARY

STERILE EO	Sterilized using Ethylene Oxide
	Caution: Consult accompanying documents
	Manufacturer
	Temperature limitations
	Do not use if package is damaged
	Single Use Device, DO NOT REUSE
EC REP	Authorized Representative in the European Community
℞ Only	Federal (USA) law restricts this device to sale by or on the order of a physician.
REF	Catalog Number
LOT	Lot Number
	Use By
	Interference may occur in the vicinity of equipment marked with this symbol
	Non-pyrogenic
	Contains Batteries - Do Not Remove

Medical Device
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.

MERIT MEDICAL®

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CE 2797

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