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).

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. Setup the power source per instructions.
2. Dispense the DiamondTOUCH Syringe and cement delivery system components per IFU.
3. Assemble cement delivery system components per instructions.
4. Place the DiamondTOUCH Syringe in the sterile field.

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 releasing and re-engaging the clutches 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.

Balloons 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 counter-clockwise until the desired inflation pressure or size of the balloon is reached. The lock mechanism maintains the pressure. Release grip on the clutch to lock the plunger in the negative pressure position.

Guidance and Manufacturer’s Declaration – Electromagnetic Immunity
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.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>KC-6000I tested to</th>
<th>Compliance level</th>
<th>Electromagnetic environment guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±8 kV contact</td>
<td>±6 kV contact</td>
<td>Increasing relative humidity will reduce the potential for ESD- related difficulties</td>
</tr>
<tr>
<td>Latch</td>
<td>±8 kV air</td>
<td>±6 kV air</td>
<td></td>
</tr>
</tbody>
</table>

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

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

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 counter-clockwise until the desired inflation pressure or size of the balloon is reached. The lock mechanism maintains the 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 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 cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contact 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.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (in watts)</th>
<th>Separation distance according to frequency of transmitter (in meters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>0.01</td>
</tr>
<tr>
<td>80 MHz to 800 MHz</td>
<td>0.1</td>
</tr>
<tr>
<td>800 MHz to 2.5 GHz</td>
<td>1.0</td>
</tr>
</tbody>
</table>

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.

DIAMANTOUCHE SYRINGE