BiomarC®

Tissue Marker

Directions for Use

DESCRIPTION

BiomarC Tissue Markers are sterile, single patient use, pyrolytic carbon coated zirconium oxide discrete markers that are visible on standard radiographs (x-ray, mammography, fluoroscopy, kV, and CT) as well as ultrasound, and Magnetic Resonance Imaging (MRI). BiomarC Tissue Markers are placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location.

The implanted BiomarC Tissue Marker has been tested for Magnetic Resonance Imaging (MRI) safety at 3.0 Tesla field strength or less.

BiomarC Tissue Markers are supplied pre-loaded in a sterile, pyrogen free, single patient use deployment device.

INDICATIONS

BiomarC Tissue Markers are indicated for use to radiographically mark soft tissue at the surgical site during a surgical procedure or for future procedures.

CONTRAINDICATIONS

None known.

WARNINGS

Do not insert BiomarC into blood vessels.

BiomarC rigid delivery systems are not compatible with MRI delivery.

PRECAUTIONS

Only physicians qualified in the appropriate surgical techniques and procedures should use this device.

Minimally invasive instruments may vary in size from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together and in conjunction with the BiomarC Tissue Marker in a procedure, **verify compatibility prior to initiation of the procedure**.

The BiomarC needle delivery devices are not recommended for patients with breast implants due to the risk of puncturing the implant capsule with the sharp device.

Do not use in the presence of infection.

Do not re-use. BiomarC Tissue Markers are intended for single use only.

Do not re-sterilize. This may damage or distort contents. Unless the packaging is damaged, BiomarC Tissue Markers will remain sterile until used or expired.

Prior to use, do not expose package to organic solvents, ionizing radiation or ultraviolet light.

After use, the delivery system may be a potential biohazard. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.

POSSIBLE ADVERSE EVENTS

Possible adverse reactions (e.g. infection) that may be associated with the use of the BiomarC Tissue Marker are similar to those associated with the use of other marking devices. The patient should be counseled to report adverse events to the treating physician. **Physicians should report device-related adverse events to Devicor Medical Products at 1-877-9-A-MAMMO.**

HOW SUPPLIED

BiomarC Tissue Markers are individually packaged and supplied ten (10) packages to a box.

STORAGE

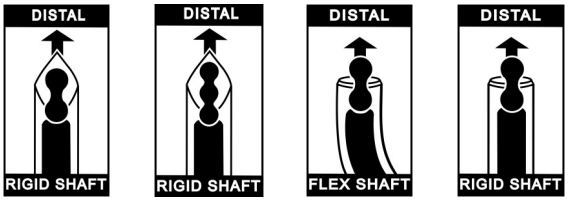
Product should be at room temperature.

DIRECTIONS FOR USE

Verify compatibility of all minimally invasive instruments and accessories prior to use (refer to **Precautions**).

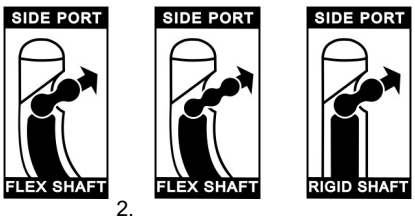
1. Inspect the BiomarC Tissue Marker package to ensure that neither the package integrity nor the contents have been compromised or damaged. **DO NOT USE** if compromised or damaged.

BiomarC Tissue Marker - Distal Delivery



2. Using standard sterile aseptic technique, remove the BiomarC Tissue Marker system from the package. **REMOVE THE TIP COVER.** Inspect the delivery system for signs of damage.
3. When placement of the BiomarC Tissue Marker is desired, advance the device to the targeted site. Locate the target area using appropriate imaging technique.
4. Completely advance the stylet forward to release the BiomarC Tissue Marker from the delivery system.
5. With the stylet completely advanced, rotate 180° and slowly remove the entire delivery system.
6. Dispose of the delivery system properly.
7. Confirm final marker position with desired imaging.

BiomarC Tissue Marker - Side Port Delivery



2. Using standard sterile aseptic technique, remove the BiomarC Tissue Marker system from the package. **REMOVE THE TIP COVER.** Inspect the delivery system for signs of damage.
3. When placement of the BiomarC Tissue Marker is desired, advance the delivery system to the targeted site. NOTE: Depth indicating devices (Catalog 040236) are marked on the shaft for use with a 9cm, 12cm or 14cm ATEC® Biopsy device. Advance the device until the appropriate mark aligns with the hub of the biopsy device. Locate the target area using appropriate imaging technique. Ensure the BiomarC device is fully inserted until it contacts the end of the biopsy device aperture.
4. The BiomarC device is marked with an arrow on the hub to indicate the side port position. Align the arrow on the hub with the center of the aperture of the biopsy device and completely advance the stylet forward to release the BiomarC Tissue Marker from the delivery system. **Always deploy the marker towards the biopsy cavity**.
5. Rotate the outer cannula of the biopsy device 180 degrees.
6. Verify the deployment and proper position of the marker prior to removal of the delivery system with the appropriate imaging modality.
7. Slowly remove the biopsy device and the BiomarC device as one unit.
8. Dispose of the delivery system properly.
9. Confirm final marker position with desired imaging.

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WARRANTY

The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling and storage of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond the manufacturer's control directly affect the device and the results obtained from its use. The manufacturer's obligation under this warranty is limited to the replacement of this device and the manufacturer shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Prices and specifications are subject to change without notice.

BiomarC® is a registered trademark of Carbon Medical Technologies, Inc.

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Devicor Medical Products, Inc.
Email: us.customerservice@leicabiosystems.com
Customer Service: 1-877-9-A-MAMMO
Mammotome.com

Manufactured by:

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

℞ Only

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