Carbon Medical Technologies, Inc.

BiomarC® Preloaded Tissue Marker Device

Directions for Use

CE 2797

DESCRIPTION

BiomarC Tissue Marker is a sterile, single patient use, pyrolytic carbon coated zirconium oxide discrete marker that is visible on standard radiographs (x-ray, mammography, fluoroscopy, kV, and CT) as well as ultrasound, and Magnetic Resonance Imaging (MRI) at up to 4.0 Tesla field strength. BiomarC Tissue Marker is 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.

INDICATIONS

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

BiomarC Tissue Marker is supplied pre-loaded in the delivery device.

CONTRAINDICATIONS

None known.

WARNINGS

Do not insert BiomarC into blood vessels.

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 Preloaded Tissue Marker Device in a procedure, **verify compatibility prior to initiation of the procedure**.
- BiomarC Preloaded Tissue Marker Device is not recommended for patients with breast implants due to the risks of puncturing the implant capsule with the sharp device.
- Do not use in the presence of infection.
- BiomarC Preloaded Tissue Marker Device is supplied sterile in a sealed package and is intended for single use only. Carefully examine each unit to verify that neither the contents nor the sterile package has been damaged in shipment. **DO NOT USE** if damaged.
- **Do not re-sterilize**. This may damage or distort contents. Unless the packaging is damaged, BiomarC Preloaded Tissue Marker Device will remain sterile until used or expired.
- Prior to use, do not expose package to organic solvents, ionizing radiation or ultraviolet light.
- After use, device may be 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 Preloaded Tissue Marker Device 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 events to Carbon Medical Technologies, Inc. at 651-653-8512.**

INSTRUCTIONS FOR USE

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

1. Inspect the BiomarC Preloaded Tissue Marker Device package to insure that the package integrity has not been compromised. The product is sterile through the expiration date unless the seal is broken.
2. Using standard sterile aseptic technique, remove the BiomarC Preloaded Tissue Marker Device from the package. **REMOVE THE TIP COVER**. Inspect the device for signs of damage.
3. Locate the target area using the appropriate imaging technique (Catalog 040113, 040117, 040135, 040228, 040239, 040300, 040306, 040307, 040308, 040310, 040317, 040318 and 040320 are not compatible with MRI).
4. When placement of the BiomarC Tissue Marker is desired, advance the device to the targeted site. **NOTE:** Depth indicating Devices (Catalog 040228) are marked on the shaft for use with a 9 cm, 12 cm or 14 cm ATEC® Biopsy Probe. Advance the device until the appropriate mark aligns with the hub of the biopsy probe **(See Figure 1). NOTE:** Sideport Devices (Catalog 040203, 040220, 040222, 040226, 040228 and 040239) are marked near the handle to indicate the sideport position to allow BiomarC Tissue Marker deployment. This also designates deployment location when used in conjunction with a probe from another manufacturer.
   - *If resistance is felt, excessive force should not be applied to overcome the resistance.*
   - *The cutter on the biopsy probe should never be activated while the BiomarC device is loaded in the biopsy probe.*
5. If product contains a stylet lock, remove before use.
6. Completely advance the stylet forward to release the BiomarC Tissue Marker from the device.
7. With the stylet completely advanced, remove entire delivery system. If using in conjunction with a biopsy probe, remove the BiomarC Delivery Device and the probe together as a single unit from the site.
8. Dispose of the delivery system properly.
9. Confirm final marker position with desired imaging.

HOW SUPPLIED

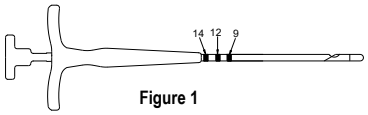

Figure 1

BiomarC Preloaded Tissue Marker Device is individually packaged and supplied one (1), three (3) or ten (10) packages to a box.

STORAGE

There are no special storage instructions for BiomarC Preloaded Tissue Marker Device. Prior to use, the product should be at room temperature, 15 °C - 32 °C (60 °F - 90 °F).

WARRANTY

Carbon Medical Technologies, Inc. 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, storage, cleaning and sterilization of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Carbon Medical Technologies' control directly affect the device and the results obtained from its use. Carbon Medical Technologies' obligation under this warranty is limited to the replacement of this device and Carbon Medical Technologies shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Carbon Medical Technologies 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® Preloaded Tissue Marker Device is a registered trademark of Carbon Medical Technologies, Inc.

ATEC® is a registered trademark of Hologic, Inc.

BiomarC® Preloaded Tissue Marker is manufactured by:

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Saint Paul, Minnesota 55110 USA

EC REP
Authorized Representative:
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