Carbon Medical Technologies, Inc.

BiomarC® *PRO* Marker

Directions for Use

DESCRIPTION

BiomarC *PRO* Marker is a sterile, pyrogen free, single patient use, pyrolytic carbon coated discrete marker that is visible on standard radiographs and Magnetic Resonance Imaging (MRI).

BiomarC *PRO* Marker is supplied in a preloaded delivery device system or in individual packages which may be used with commercially available delivery devices per the table below.

Table 1

BiomarC *PRO* Marker	Minimum Delivery Needle Internal Diameter (in inches)
040139 – 0.9 x 5mm	N/A
040138 – 1.0 x 5mm	N/A
040137 – 1.0 x 10mm	N/A

INDICATIONS

The BiomarC *PRO* Marker is indicated for use to radiographically mark soft tissue for future surgical procedures.

CONTRAINDICATIONS

None known.

WARNINGS

Do not insert BiomarC *PRO* Marker into blood vessels.

Preloaded BiomarC *PRO* Marker **Stainless Steel** 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 *PRO* 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.
- BiomarC *PRO* Marker 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 *PRO* Marker 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 device 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 *PRO* 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 Carbon Medical Technologies, Inc. at 1-888-207-0262.**

MRI INFORMATION

MR CONDITIONAL

The BiomarC *PRO* Marker is MR Conditional

Non-clinical testing demonstrated that the BiomarC *PRO* Marker is MR conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 36,000-Gauss/cm (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence)
- First Level Controlled Operating Mode of operation for the MR system

MRI-Related Heating

In non-clinical testing the BiomarC *PRO* Marker produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in a 3-Tesla MR system (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI):

MR system reported, whole body averaged SAR	2.9-W/kg
Calorimetry measured values, whole body averaged SAR	2.7-W/kg
Highest temperature change	1.5°C
Temperature scaled to whole body averaged SAR of 4-W/kg	2.1°C

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the BiomarC *PRO* Marker. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5-mm relative to the size and shape of the BiomarC *PRO* Marker.

Artifact size is dependent on the type of pulse sequence used for imaging (larger for gradient echo pulse sequences and smaller for spin echo pulse sequences), the frequency encoding direction (larger if the frequency encoding direction is parallel to the device and smaller if it is perpendicular to the device), and the size of the field of view. Positional errors and artifacts on MR images will be smaller for MR systems with lower static magnetic field strengths using the same imaging parameters as those operating at higher static magnetic field strengths.

Carbon Medical Technologies, Inc.

BiomarC® *PRO* Marker

Directions for Use

INSTRUCTIONS FOR USE

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

1. Inspect the BiomarC *PRO* Marker package to insure that the package integrity has not been compromised. The product is sterile through the expiration date unless the seal is broken.

BiomarC *PRO* Marker - Individually Packaged

2. Using standard sterile aseptic technique, remove the BiomarC *PRO* Marker from the package.
3. Take a single BiomarC *PRO* Marker and insert it into a commercially available delivery device with stylet having a minimum internal diameter per Table 1.
4. Advance stylet into hub of the device so that BiomarC *PRO* Marker is visible at the distal end of the device.
5. When placement of the BiomarC *PRO* Marker is desired, advance the delivery device to the targeted site. Locate the target area using appropriate imaging technique.
6. Completely advance the stylet forward and then rotate 180° to release the BiomarC *PRO* Marker from the delivery device.
7. With the stylet completely advanced, remove entire delivery device.
8. Dispose of the device and stylet properly.
9. Confirm final marker position with desired imaging.

BiomarC *PRO* Marker – Preloaded System

2. Using standard sterile aseptic technique, remove the BiomarC *PRO* Marker System from the package. **REMOVE THE SHEATH.** Inspect the device for signs of damage.
3. When placement of the BiomarC *PRO* Marker is desired, advance the device to the targeted site. Locate the target area using appropriate imaging technique.
4. Remove the stylet lock, if applicable.
5. Align the arrow on the device hub with the center of the aperture of the biopsy device, if applicable.
6. Completely advance the stylet forward and then rotate 180° to release the BiomarC *PRO* Marker from the device.
7. With the stylet completely advanced, remove entire delivery system.
8. Dispose of the delivery system properly.
9. Confirm final marker position with desired imaging.

HOW SUPPLIED

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

BiomarC *PRO* Marker Systems are individually packaged and supplied one (1) package to a box.

STORAGE

Product should be stored at room temperature.

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® *PRO* Marker is a Registered Trademark of Carbon Medical Technologies, Inc.

BiomarC® *PRO* Marker is manufactured by:

Carbon Medical Technologies, Inc.
1290 Hammond Rd.
Saint Paul, MN 55110 USA
Customer Service: 1-888-207-0262

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

℞ Only

©2015 Carbon Medical Technologies, Inc. All Rights Reserved.