

## DESCRIPTION

BiomarC Fiducial 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 Fiducial Markers are supplied preloaded in a sterile, pyrogen free, single patient use deployment device or individually packaged.

Table 1

BiomarC Fiducial Marker	Minimum Delivery Needle Internal Diameter (in inches)
040101	0.0315"

## INDICATIONS

BiomarC Fiducial Markers are intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization.

## CONTRAINDICATIONS

None known.

## WARNINGS

Do not insert BiomarC Fiducial Marker into blood vessels.

Do not insert a suture needle through the hole of the BiomarC *Secure* Fiducial Marker. Only the suture material is to be in contact with the marker.

Do not use metallic sutures with BiomarC *Secure* Fiducial Marker.

Preloaded BiomarC Fiducial Marker Systems are not compatible with MRI delivery.

## PRECAUTIONS

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

When sutures are used together with BiomarC *Secure* Fiducial Marker, verify compatibility prior to initiation of the procedure.

Do not use in the presence of infection.

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

**Do not re-sterilize.** This may damage or distort contents. Unless the packaging is damaged, BiomarC Fiducial 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 Fiducial 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 Fiducial Marker is MR Conditional

Non-clinical testing demonstrated that the BiomarC Fiducial 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 Fiducial 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 Fiducial 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 2-mm relative to the size and shape of the BiomarC Fiducial 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.



# BiomarC® Fiducial Marker

## Directions for Use

### INSTRUCTIONS FOR USE

Verify compatibility of all accessories prior to use.

1. Inspect the BiomarC Fiducial 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 Fiducial Marker – Preloaded System**

2. Using standard aseptic technique, remove the BiomarC Fiducial Marker System from the package. **REMOVE THE TIP COVER.** Inspect the delivery system for signs of damage.
3. When placement of the BiomarC Fiducial Marker is desired, advance the delivery system to the targeted site. Locate the target area using appropriate imaging technique.
4. If applicable, remove the stylet lock.
5. Completely advance the stylet forward to release the BiomarC Fiducial Marker from the delivery system.
6. With the stylet completely advanced, remove entire delivery system.
7. Dispose of the delivery system properly.
8. Confirm final marker position with desired imaging.
9. Repeat above steps with additional BiomarC Fiducial Marker Systems to completely constitute the desired reference frame.

#### **BiomarC Fiducial Marker - Individually Packaged**

2. Using standard aseptic technique, remove the BiomarC Fiducial Marker from the package.
3. Take a single BiomarC Fiducial Marker and insert it into a commercially available delivery needle with stylet having a minimum internal diameter per Table 1.
4. Advance stylet into hub of needle so that BiomarC Fiducial Marker is visible at the distal end of the needle.
5. When placement of the BiomarC Fiducial Marker is desired, advance the needle to the targeted site. Locate the target area using appropriate imaging technique.
6. Completely advance the stylet forward to release BiomarC Fiducial Marker from the needle.
7. With the stylet completely advanced, remove entire needle system.
8. Dispose of the needle system properly.
9. Confirm final marker position with desired imaging.
10. Repeat above steps with additional BiomarC Fiducial Markers to completely constitute the desired reference frame.

#### **BiomarC Secure Fiducial Marker - Individually Packaged**

2. Using standard aseptic technique, remove the BiomarC Secure Fiducial Marker from the package.
3. Locate the target area.
4. Secure marker to targeted site using suture of choice. **Do not insert a suture needle through the suture hole of the BiomarC Secure Fiducial Marker.**
5. Repeat above steps with additional BiomarC Secure Fiducial Markers to completely constitute the desired reference frame.

### HOW SUPPLIED

Preloaded BiomarC Fiducial Markers are individually packaged and supplied one (1) or three (3) packages to a box.

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

BiomarC Secure Fiducial Markers are individually packaged and supplied ten (10) packages 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® Fiducial Marker is a Registered Trademark of Carbon Medical Technologies, Inc.

BiomarC® Fiducial 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.**

