BiomarC® Restore Fiducial Marker
Directions for Use

DESCRIPTION

BiomarC Restore Fiducial Marker is a sterile, single patient use, pyrolytic carbon coated discrete marker embedded in a glucan aspect that is visible on kV X-ray, CT, CBCT, mammography, ultrasound, and MRI.

INDICATIONS

BiomarC Restore Fiducial Marker is intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic body radiotherapy (SBRT) and radiotherapy target localization.

CONTRAINDICATIONS

None known.

WARNINGS

The BiomarC Restore Fiducial Marker should not be placed in the presence of infection.

PRECAUTIONS

Only qualified physicians should use this device. The physician is responsible for its proper clinical use.

Though rare, hypersensitivity, immune response or foreign body reaction are possible with use of the BiomarC Restore Fiducial Marker. As with any implanted device, the implant site should be monitored for any sign of irritation or reaction following the procedure.

Infection is a possible adverse reaction as a result of any surgical procedure. Physicians should monitor the patient to ensure no sign of infection following the procedure.

The BiomarC Restore Fiducial Marker is supplied sterile in a sealed package and is intended for single use only. Reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of this device may lead to injury, illness or death of the patient. 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 and/or distort contents which may result in patient injury, illness or death.

Unless the packaging is damaged, the BiomarC Restore Fiducial Marker will remain sterile until used or expired.

POSSIBLE ADVERSE EVENTS

Possible adverse reactions (*e.g.*, infection) that may be associated with the use of the BiomarC Restore 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 651-653-8512.**

MRI INFORMATION

MR CONDITIONAL

The BiomarC Restore Fiducial Marker is MR Conditional

Non-clinical testing demonstrated that the BiomarC Restore 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 Restore 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 Restore 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 pyrolytic carbon coated discrete markers.

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.

INSTRUCTIONS FOR USE

Verify compatibility of all accessories prior to use.

1. Inspect the BiomarC Restore 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.

PREPARATION

1. Remove the BiomarC Restore Fiducial Marker from the sterile packaging.
2. Visually inspect the product for any damage.

INSERTION

1. Using sterile technique, place the BiomarC Restore Fiducial Marker in the desired tissue site.
2. Close the surgical cavity using standard surgical technique.

HOW SUPPLIED

BiomarC Restore Fiducial Marker is individually packaged and supplied one (1) device to a box.

STORAGE

The BiomarC Restore Fiducial Marker should be stored at room temperature.

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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' 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.

Manufactured by:
Carbon Medical Technologies, Inc.
1290 Hammond Rd.
Saint Paul, MN 55110 USA
651-653-8512

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

QTY	Quantity
LOT	Batch Code
REF	Catalog Number
	Use by Date
	Manufacturer and Date of Manufacture (YYYY-MM-DD)
	Consult Instructions for Use
	Do not use if package is damaged
Rx ONLY	By prescription
	Do not re-use
	Single Sterile Barrier System
STERILE R	Sterilized using Irradiation
MR	MR Conditional
MD	Medical Device

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