# INSTRUCTIONS FOR USE - EN

## DEVICE 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 / UNDESIREABLE SIDE EFFECTS

- 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, resterilization, or reuse 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.
- 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 info@carbonmed.com and the competent authority of the Member State.**

## MRI INFORMATION

## MR CONDITIONAL

**MR 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.

## SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

For additional information, the SSCP is available in the European database on medical devices (EUDAMED) and is linked to the Basic UDI-DI. Visit https://ec.europa.eu/tools/eudamed and search **Basic UDI-DI: 0858015005002UT**.

## INSTRUCTIONS FOR 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 STERILE R

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.

## 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.

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℞ Only

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|---|---|
| CE 2797 | CE Mark and Notified Body Number (EN)<br>Marchio CE e numero di identificazione dell'organismo notificato (IT)<br>Marcado CE y número de organismo notificado (ES) |
| QTY | Quantity (EN)<br>Quantità (IT)<br>Cantidad (ES) |
| LOT | Batch Code (EN)<br>Numero di lotto (IT)<br>Código del lote (ES) |
| REF | Catalog number (EN)<br>Numero di catalogo (IT)<br>Número de catálogo (ES) |
| | Use by Date (EN)<br>Scadenza (IT)<br>Fecha de caducidad (ES) |
| | Manufacturer and Date of Manufacture (YYYY-DD-MM) (EN)<br>Produttore e data di fabbricazione (AAAA-MM-GG) (IT)<br>Fabricante y fecha de fabricación (AAAA-MM-DD) (ES) |
| EC REP | Authorized Representative in the European Community (EN)<br>Rappresentante autorizzato per la Comunità Europea (IT)<br>Representante autorizado en la Comunidad Europea (ES) |
| | Consult Instructions for Use (EN)<br>Consultare le istruzioni per l'uso (IT)<br>Consultar las instrucciones de uso (ES) |
| | Do not use if package is damaged (EN)<br>Non utilizzare il prodotto se la confezione è danneggiata (IT)<br>No utilizar el paquete si está dañado (ES) |
| ℞ Only | By prescription (EN)<br>Su prescrizione (IT)<br>Por prescripción (ES) |
| | Do not re-use (EN)<br>Non riutilizzare (IT)<br>No reutilizar (ES) |
| | Single Sterile Barrier System (EN)<br>Sistema a singola barriera sterile (IT)<br>Sistema de barrera estéril único (ES) |
| STERILE R | Sterilized using irradiation (EN)<br>Sterilizzato mediante radiazioni (IT)<br>Esterilizado por radiación (ES) |
| MR | MR Conditional (EN)<br>A compatibilità RM condizionata (IT)<br>Compatible con RM (ES) |
| MD | Medical Device (EN)<br>Dispositivo medico (IT)<br>Producto sanitario (ES) |
| | Distributor (EN)<br>Distributore (IT)<br>Distribuidor (ES) |
| | Importer (EN)<br>Importatore (IT)<br>Importador (ES) |
| | Compatible With (EN)<br>Compatibile con (IT)<br>Compatible con (ES) |
| | Do not re-sterilize (EN)<br>Non risterilizzare (IT)<br>No volver a esterilizar (ES) |
| | Patient identification (EN)<br>Identificazione del paziente (IT)<br>Identificación del paciente (ES) |
| | Health care centre or Doctor (EN)<br>Medico o centro sanitario (IT)<br>Centro de atención sanitaria o médico (ES) |
| 31 | Date (EN)<br>Data (IT)<br>Fecha (ES) |

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