Carbon Medical Technologies, Inc.

Fiducial Marker

Directions for Use

DESCRIPTION

The fiducial 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).

The fiducial marker is supplied in a preloaded delivery device system or in individual packages which may be used with commercially available needles per the table below.

Table 1

Marker	Minimum Delivery Needle Internal Diameter (in inches)
040142 - 1.0 x 5 mm	0.0405
040151 - 1.0 x 5 mm	0.0405
040153 - 0.5 x 5 mm	0.0405

INDICATIONS

The 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 fiducial marker into blood vessels.

Preloaded **stainless steel** fiducial marker 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 fiducial marker in a procedure, **verify compatibility prior to initiation of the procedure**.
- Do not use in the presence of infection.
- The fiducial 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, the fiducial 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 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 fiducial marker is MR Conditional

Non-clinical testing demonstrated that the fiducial marker is MR Conditional. A patient with this device can be scanned safely under the following conditions:

- Static magnetic field of 3 T or less
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (0.4 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)

Under the scan conditions defined above, the marker is expected to produce a maximum temperature rise of 2.1 ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the marker extends approximately 5 mm from the marker when imaged with a gradient echo pulse sequence and a 3 T MRI system.

It is recommended that the implanting physician encourage patients to register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

A labeling insert with MRI information is included in the product packaging to assist in registering the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

Carbon Medical Technologies, Inc.

Fiducial 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 fiducial 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.

Fiducial Marker - Individually Packaged

2. Using standard sterile aseptic technique, remove the fiducial marker from the package.
3. Take a single 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 the fiducial marker is visible at the distal end of the needle.
5. When placement of the 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 the fiducial marker from the needle.
7. With the stylet completely advanced, remove entire needle system.
8. Dispose of the needle and stylet properly.
9. Confirm final fiducial marker position with desired imaging.

Fiducial Marker – Preloaded System

2. Using standard sterile aseptic technique, remove the fiducial marker system from the package. **REMOVE THE NEEDLE SHEATH.** Inspect the device for signs of damage.
3. When placement of the fiducial marker system is desired, advance the device to the targeted site. Locate the target area using appropriate imaging technique.
4. Remove the stylet lock.
5. Completely advance the stylet forward to release the fiducial marker from the device.
6. With the stylet completely advanced, remove entire delivery system.
7. Dispose of the delivery system properly.
8. Confirm final fiducial marker position with desired imaging.

HOW SUPPLIED

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

Fiducial marker systems are individually packaged and supplied three (3) 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' 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.

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

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