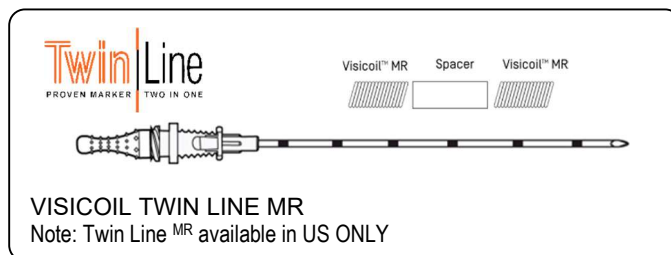


VISICOIL™ TWIN LINE MR Instructions For Use

DESCRIPTION

VISICOIL™ TWIN LINE MR Marker consist of two flexible coils of Platinum wire separated by a PGLA spacer, pre-loaded in a needle. These coils are provided in lengths of 0.5cm for the 0.50 mm and, 0.75 mm O.D. size.



Use Directions For Use below for all VISICOIL TWIN LINE MR Marker products.

ACTIONS

The clinical efficacy of the VISICOIL™ MR marker derives solely from the coil design and the density of its material, Platinum (Pt). The coil design enables the device to be viewed under ultrasound and the density of the material allows for visualization under CT, x-ray, fluoroscopy, portal imaging, and Magnetic resonance imaging (MRI)

INDICATIONS

The VISICOIL TWIN LINE MR marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

CONTRAINDICATIONS

None

WARNINGS

The VISICOIL MR Markers and spacer should slide freely within the introducer needle. Do not use excessive force to deploy the marker. This product may only be used by a qualified healthcare professional.

SHIPPING CONTAINER

Each VISICOIL TWIN LINE MR are shipped STERILE pre-loaded into an introducer needle packaged inside a sealed pouch. The 0.50 mm VISICOIL markers are supplied in 20 or 21 gauge pre-waxed introducer needles. The 0.75 mm VISICOIL markers are supplied in 18 or 19 gauge pre-waxed introducer needle.

PRODUCT HANDLING

VISICOIL MR Markers and their packaging should be handled with caution as they are delicate devices.

DEVICE DAMAGE

Rough handling can cause damage to the VISICOIL MR markers. Do not attempt to remove the VISICOIL MR markers or spacer from the preloaded needle. Additional handling of the marker may result in a damaged coil. Defective markers and needles should be returned to RadioMed Corporation.

ADVERSE REACTIONS

No adverse reactions involving the VISICOIL™ MR markers have been reported.

MR Safety Information

Non-clinical testing has demonstrated that the Visicoil MR Marker is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla, only
- Maximum spatial field gradient of 3,000 gauss/cm or less
- Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15_minutes if scanning in the normal operating mode of operation for the MR system.
- Under the scan conditions defined above, the Visicoil MR Marker is expected to produce a maximum temperature rise of less than 1.6° C after 15_minutes of continuous scanning.

Artifact testing

In non-clinical testing, the image artifact caused by the 1.00mm 2cm long Visicoil MR Marker extends approximately 8 mm from this implant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

CAUTION: The introducer needles are MR Unsafe. Do not bring the needles into the MR room.

Preparation

- Prior to opening pouch, ensure coils or spacer have not been displaced into pouch.
- Carefully remove preloaded needles from the sterile pouch using aseptic procedures. Ensure plastic protective tip is intact.
- If plastic protective cover is dislodged, proceed with caution, as tip of needle is sharp and delicate. Re-engage protector if necessary.
- Remove protector when ready for use.
- Patient is usually under general or local anesthesia.

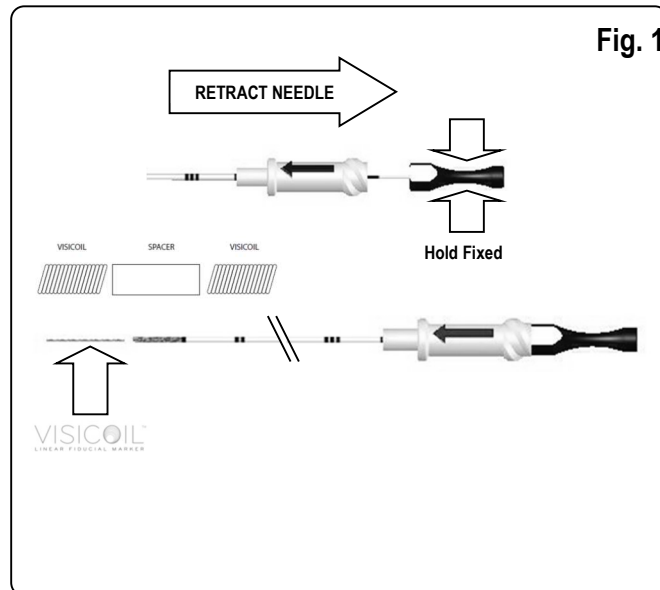
Needle Location

- **Communicate with Radiation Oncologist to identify optimal marker placement locations**
- The needles are usually guided to their intended location under ultrasound or CT guidance. Align the tip of the needle with the desired marker location. Confirm needle/marker location.

Deploying the VISICOIL™ TwinLine MR Marker

- Pull back on stylet handle exposing stylet lock and remove stylet lock
- Carefully advance stylet into needle until there is slight resistance.
- Stylet is now up against the VISICOIL inside the needle.
- Securely hold stylet handle fixed in space (DO NOT ADVANCE)
- Securely grasp implantation needle HUB, carefully retract needle cannula while NOT moving the stylet handle. This will leave the VISICOIL marker(s) linear. A moment of resistance is expected as the coil breaks through the bone wax tip.
- **CAUTION: DO NOT INJECT THE VISICOIL (The VISICOIL markers may advance to an unintended position or rotated potentially impacting center to center spacing of coils)**
- **CAUTION:** Ensure hub and stylet handle are completely in contact while gently rotating to ensure
- Prior to removal of needle, rotate needle assembly. This will ensure bone wax is completely separated from coil.

NOTE: If significant resistance is felt while the VISICOIL TwinLine MR Marker is inside of the needle, remove the entire system prior to deployment.



NOTE: Discard needle in an appropriate sharps disposal container.

HOW SUPPLIED:

CAUTION: VISICOIL markers are supplied STERILE and for single use only.

CAUTION: Federal Law (US only) restricts this device to sale by or on the order of a physician.

CAUTION: Do not use if packaging is damaged or open as sterility may have been compromised.

Manufactured by:

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VISICOIL™
LINEAR FIDUCIAL MARKER