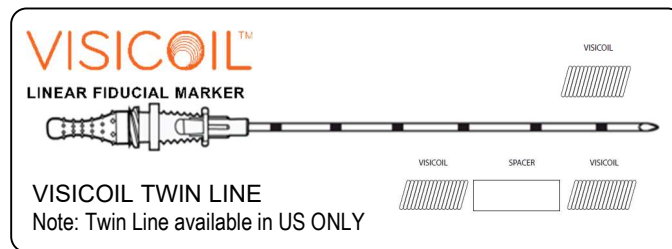


## DESCRIPTION

VISICOIL™ markers consist of a gold wire in the form of a flexible coil. These coils are offered in various diameters ranging from 0.28mm through 1.1mm and in various lengths ranging from 0.5cm through 3cm.



Instructions for Use apply to all pre-loaded VISICOIL and VISICOIL TWIN LINE Marker products.

## ACTIONS

The clinical efficacy of the VISICOIL™ marker derives solely from the coil design and the density of its material, gold (Au). 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 and portal imaging.

## INDICATIONS

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

## CONTRAINDICATIONS

None

## WARNINGS

The VISICOIL markers (And spacer for VISICOIL TWIN LINE) should slide freely within the introducer needle. Do not use excessive force to deploy. This product may only be used by a qualified healthcare professional.

## SHIPPING CONTAINER

Each VISICOIL and VISICOIL TWIN LINE is shipped STERILE pre-loaded into an appropriately sized pre-waxed introducer needle which is packaged inside a sealed pouch.

## PRODUCT HANDLING

VISICOIL markers and their packaging should be handled with caution as they are delicate devices and should be opened with care.

## DEVICE DAMAGE

Rough handling can cause damage to the VISICOIL markers. Do not attempt to remove the VISICOIL 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™ markers have been reported.

## DIRECTIONS FOR USE

### Preparation

- Prior to opening pouch, ensure coil has not been displaced into pouch.
- Carefully remove preloaded needles from the sterile pouch using aseptic procedures. Ensure plastic protective tube 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 protective tube when ready for use.
- Patient is usually under general or local anesthesia.

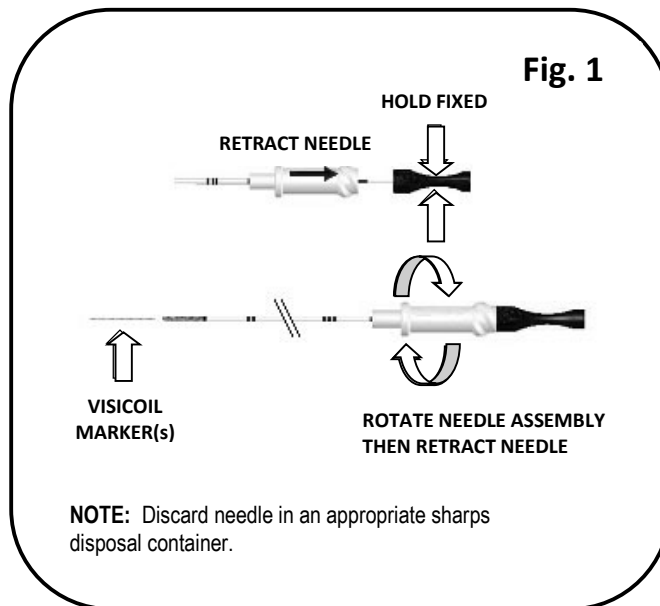
#### Needle Location

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

#### Deploying the VISICOIL™

- Pull back on stylet handle exposing stylet lock and remove stylet lock
- Carefully advance style 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! Advancing the stylet may bend the coil(s), advance the coil(s) to unintended position or rotate the coil(s) impacting targeting performance (Particularly with VISICOIL TWIN LINE).**
- Retract the needle until needle hub contacts stylet handle as shown in **Figure 1**.
- Prior to removal of needle, rotate needle assembly.
- **CAUTION: Rotating the needle assembly ensures the residual bone wax disengages from the needle tip. Not rotating needle may result in undesired marker placement.**

**NOTE:** If significant resistance is felt while the VISICOIL marker is inside of the needle, remove the entire system prior to deployment



#### **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.**

**CAUTION: The use of 1.10 mm VISICOIL is recommended when using mega voltage portal imaging systems as the visibility of the smaller coils may not be optimal in this modality.**

Manufactured by:

RadioMed Corporation  
3150 Stage Post Drive  
Ste. 106, Bartlett, TN 38133 USA  
(901) 432 7202  
[www.visicoil.com](http://www.visicoil.com)