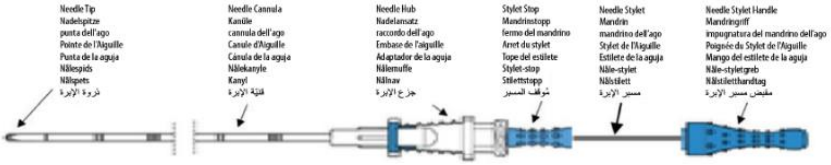
VISICOIL™MR

LINEAR FIDUCIAL MARKER



DESCRIPTION

VISICOIL MR is a multi-modality fiducial Imaging marker used to radiographically mark soft tissue for future therapeutic procedures. The coil is made of high-purity platinum wire (99.95%) and is available in a variety of diameters (0.35 mm, 0.50 mm, 0.75 mm, and 1.00 mm) and lengths (0.50 cm, 1.00 cm, and 2.00 cm). The device is pre-loaded in Stainless Steel needles, and are available in a variety of gauges (18g, 19g, 20g, 21g, 22g) and lengths (8cm, 15cm, 20cm, 30cm, and 38.5cm). Device has a paraffin wax (Beeswax/Bone wax) plug at the tip to keep the coil from coming out. The multi-modality linear fiducial marker offers high visibility in ultrasound, X-ray based imaging, and Magnetic Resonance Imaging (MRI) modalities. The dense mass of the VISICOIL MR is recommended for improved imaging in all X-ray based imaging devices and other electromagnetic properties for enhanced visibility within Magnetic Resonance Imaging (MRI). The fiducial marker is a passive device and is permanently implanted in the patient's soft tissue. The device is provided sterile for single use by Ethylene Oxide [STERILE|EO] sterilization.

INTENDED POPULATION

The target population includes patients undergoing radiation therapy or other therapeutic procedures where image-guided identification of tissue via x-ray based imaging, Magnetic Resonance Imaging (MRI), or ultrasound aides the physician in performing a procedure.

INTENDED PURPOSE

The marker is intended for use to radiographically mark soft tissue for future therapeutic procedures.

CONTRAINDICATIONS

Uncorrectable coagulopathy

POSSIBLE COMPLICATIONS

The VISICOIL MR may be placed in soft tissue. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome.

- Allergy to the VISICOIL MR (Platinum) materials or foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to implantation.
- Migration - Fiducial markers may move away from where they were originally implanted. There must be sufficient time between the implantation of markers and treatment for the markers to stabilize.

Possible complications specific to the device may include:

- Rectal Implant: Coagulopathy or Anti-coagulants that cannot be stopped.
- Trans-Rectal Implant for Prostate: Chronic Inflammatory Bowel Disease (Should go Transperineal).

Other complications associated with surgical procedure may include:

Bleeding, Fever, Foreign body reactions necessitating medical intervention, Infection, Inflammation, Pain, Pancreatitis, Perforation, Peritonitis, Pneumothorax, Tumor Seeding.

WARNINGS

VISICOIL MR [STERILE|EO] must not be re-sterilized.

- Device for single use only. Never reuse any implant.
- Re-use of single-use devices creates a potential risk to the patient and/or the user. It may lead to contamination and/or impairment of functional capability. Contamination and/or the limited functionality of the device may lead to injury of the patient.
- Do not use the device after the expiration of the sterilization date or if the sterile packaging is damaged or has already been opened. Use the properly stored product by the date stated on the packaging.
- Prior to use read all instructions, precautions, and warnings. Failure to do so may result in severe patient injury.
- Do not alter the needle or any other kit/set component during insertion, use, or removal.
- **Stainless-steel needle is not intended for use with MRI guided implants.**

CAUTIONS:

- This product may only be used by a qualified healthcare professional.
- Aseptic technique should be employed to avoid contamination of the needle portions that will be inserted through the skin and into tissue including the tips and shaft.
- Only introducer needles that have been tested to be MR Conditional or MR Safe should be used in the MR room for MR guided placement.

MR SAFETY INFORMATION

Non-clinical testing has demonstrated that the VISICOIL MR Marker (Platinum) is MR Conditional. A patient 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 the 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, VISICOIL MR is expected to produce a maximum temperature rise of 1.6° C after 15 minutes of continuous scanning.

CAUTION: The stainless-steel needle is not intended for use with MRI guided implants.

ARTIFACT TESTING

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

DIRECTIONS FOR USE

The information contained in this package insert is necessary but not sufficient for a clinical procedure. The device should be used by physicians trained on the procedure for which the device is intended. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

Presurgical Procedure

- Position the patient appropriately. Scan patient with ultrasound, X-ray based imaging, , and/or MRI for anatomical landmarks and to ascertain needle puncture site, angle and expected depth to reach the targeted site(s).

NOTE: CONSULT INSTRUCTIONS FOR USE FROM ULTRASOUND, X-RAY BASED IMAGING OR MRI IMAGING MACHINE MANUFACTURER.

- The procedure needs to be performed using aseptic technique to avoid contamination of the device. Disinfect the site thoroughly.

VISICOIL PRE-LOADED VERSIONS

Preparation

• Prior to opening pouch, ensure coil has not been displaced into the pouch.
•Carefully remove pre-loaded needles from the sterile pouch using aseptic procedures. Ensure plastic protective tube is intact.
•Carefully remove the device assembly from the pouch. The marker should slide freely.
•Inspect the implant needle and assembly for damage.
•If the plastic protective cover is dislodged, proceed with caution as the tip of the needle is sharp and delicate. Re-engage protector if necessary
•Remove protective tube when ready for use.
•The patient is usually under general or local anesthesia

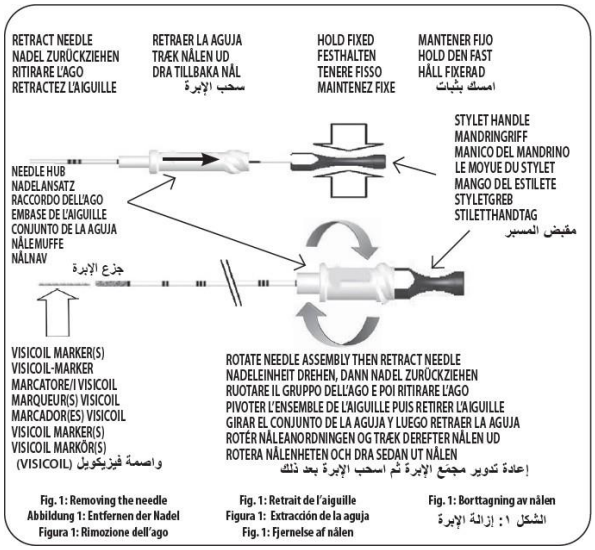


Fig. 1: Removing the needle
Abbildung 1: Entfernen der Nadel
Figura 1: Rimozione dell'ago

Fig. 1: Retrait de l'aiguille
Figura 1: Extracción de la aguja
Fig. 1: Fjernelse af nålen

الشكل ١: إزالة الإبرة

Needle and Marker 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 (Linear Deployment)

•Pull back on stylet handle exposing stylet lock and remove stylet lock.
•Carefully advance stylet into needle until there is slight resistance.
•The 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 rotate and 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 if linear deployment is desired.
•Advance the stylet if a collapsed deployment is preferred (Only with 0.35mm size)
CAUTION: Ensure hub and styler handle are completely in contact while gently rotation to ensure the marker separates from the delivery system.

Removing the Needle

•Once the VISICOIL marker is fully deployed, gently rotate needle assembly prior to removing.
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 and discard.
NOTE: Discard needle in the appropriate sharps disposal container.

PACKAGING

The VISICOIL MR Markers are sterile devices in the form of a coil. The device is shipped sterile and packaged in a Mylar/Tyvek pouch as a single package. The device is sterilized with Ethylene Oxide sterilization. Handle with care.

HANDLING AND STORAGE

Device should be stored under general office conditions. Protect device from direct exposure to light, heat, and humidity. Device should be handled with caution as they are delicate and should be opened with care. Rough handling can cause damage to the device. Additional handling of the marker may result in damage. Uncontaminated defective product should be returned to IZI Medical Products.

CUSTOMER COMPLAINTS

Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/ or performance directly to IZI Medical Products. Email: visicoil@izimed.com Tel: For North America and the European Union 410-594-9403. When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint, and patient case number. Notify IZI Medical Products immediately of an incident resulting in patient death or serious injury.

Incident Reporting

In the event of a serious incident that has occurred in relation to the device should be reported to IZI, contact information in further information section, and the competent authority of the member state in which the user and/or patient is established.

FURTHER INFORMATION

For information on the summary of clinical safety and performance, or further directions for the use of this product contact IZI Medical Products Customer Service, email: VISICOIL MR@izimed.com | Tel: +1 410-594-9403

VISICOIL MR is a registered trademark of IZI Medical Products.

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2024-03-28

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