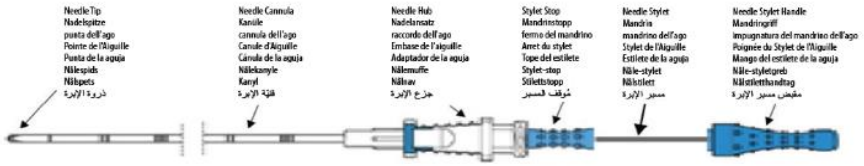
IZI Medical



GOLD FIDUCIAL MARKER INSTRUCTIONS FOR USE

DESCRIPTION
Gold Fiducial Markers are designed for use in conjunction with conventional radiation therapy methods. The Pre-Loaded marker(s) is cut from high-purity gold wire (99.99%) and is available in two diameters (1mm and 1.2mm) and two lengths (3mm and 5mm). The device is pre-loaded in Stainless Steel needles, and are available in two gauges (17g and 18g) and two lengths (20cm and 30cm). Device has a paraffin wax (Beeswax/Bone wax) plug at the tip to keep the fiducial marker from coming out. The fiducial marker offers visibility in ultrasound, X-ray based imaging, and Magnetic Resonance Imaging (MRI) modalities. The device is a passive device and is permanently implanted in the patient via percutaneous, endoscopic ultrasound (EUS), endobronchial ultrasound (EBUS), or bronchoscope. 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.

INTENDED USER
The intended users for fiducial markers are trained medical professionals involved in the planning and execution of various medical procedures, particularly those related to medical imaging and radiation therapy.

CONTRAINDICATIONS
Uncorrectable coagulopathy

POSSIBLE COMPLICATIONS
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 Fiducial 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
Gold Fiducial Markers [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.
• Use only if the package is intact
• 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.

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 Gold Fiducial Markers are 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, the marker is expected to produce a maximum temperature rise of 2.4° C after 15 minutes of continuous scanning.

DIRECTIONS FOR USE
The information contained in this package insert is necessary but not sufficient for the use of this device. 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, CT, X-ray, fluoroscopy, 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, CT, X-RAY, FLUOROSCOPY, FLUOROSCOPY, OR MRI IMAGING MACHINE MANUFACTURER.
• The procedure needs to be performed using aseptic technique to avoid contamination of the device. Disinfect the site thoroughly.

PRE-LOADED GOLD FIDUCIAL MARKER

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

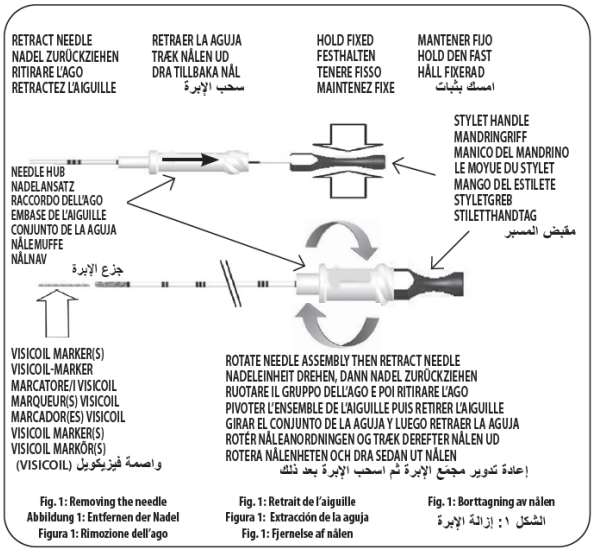


Fig. 1: Removing the needle
Abbildung 1: Entfernen der Nadel
Figura 1: Rimozione dell'ago

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

Fig. 1: Borttagning av 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 marker

•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 marker 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.
•A moment of resistance is expected as the marker breaks through the bone wax tip.
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 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 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

Gold Fiducial Markers are sterile devices in the form of a cylinder. 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, +1 (901) 432-7202. 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@izimed.com | Tel: +1 410-594-9403

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www.izimed.com/products/gold-fiducial-markers
2024-03-28

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