Augmenix, Inc.

TraceIT® Tissue Marker
Instructions for Use

DESCRIPTION

TraceIT® Tissue Marker is a sterile, single use, product consisting of a pre-filled glass syringe containing the synthetic, radiopaque cross-linked PEG hydrogel with an endcap. The pre-filled glass syringe, sterile plastic luer-luer connector, plastic receiving syringe, and a 1" needle are packaged inside a poly-Tyvek pouch within a larger poly-Tyvek pouch. As some hydrogel/carrier separation can potentially occur during storage, two syringes are provided to allow for mixing (by injecting back and forth 5 times between the syringes so the material ends up inside the plastic receiving syringe) immediately prior to use. TraceIT Tissue Marker is provided in a 1mL and 3mL configuration.

The maximum injection volume of TraceIT hydrogel, for a single location, is 1mL. TraceIT hydrogel is visible on ultrasound, computed tomography (CT), and Magnetic Resonance Imaging (MRI) for approximately three (3) months and is absorbed and cleared from the body within approximately seven (7) months of implantation. TraceIT hydrogel implant is MR Safe. The 304-stainless steel applicator needle is MR Unsafe; all other TraceIT Tissue Marker delivery components are MR Safe.

INDICATIONS

TraceIT® Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures. TraceIT hydrogel is intended to mark tissue for at least 3 months after injection.

CONTRAINDICATIONS

None known.

WARNINGS

- Do not inject TraceIT hydrogel in blood vessels. TraceIT hydrogel injection into blood vessels may cause vascular occulusion.
- Avoid using on patients with non-viable tissue, e.g., ischemic tissue

PRECAUTIONS

- Only persons having adequate training and familiarity with minimally invasive biopsy techniques should perform invasive biopsy procedures. Consult medical literature relative to techniques, complications, and hazards prior to performing any minimally invasive procedure.
- 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 TraceIT Tissue Marker in a procedure, verify compatibility prior to initiation of the procedure.
- TraceIT Tissue Marker is not recommended for use in patients with breast implants.
- Do not use in the presence of infection.
- TraceIT Tissue 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, TraceIT Tissue 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, syringes and needles may be potential biohazards. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.

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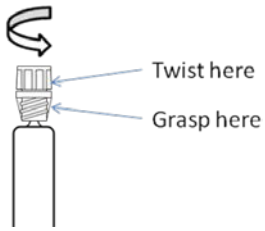
POSSIBLE ADVERSE EVENTS

- Possible adverse reactions that may be associated with the use of TraceIT Tissue Marker. The patient should be counseled to report adverse events to the treating physician. Physicians should report device related adverse events to Augmenix at (781) 895-3235.
- List of Possible Adverse Events
    - Injection site pain
    - Vascular occlusion
    - Local inflammatory response
    - Local infection
    - Embolic phenomena
    - Bleeding

INSTRUCTIONS FOR USE

Verify compatibility of all minimally invasive instruments and accessories prior to use (refer to **Precautions**).

1. Inspect the TraceIT Tissue Marker package to ensure that the package integrity has not been compromised. The product is sterile through the expiration date unless the seal is broken.
2. Using standard sterile technique, remove the TraceIT Tissue Marker components from the package and place in the sterile field.
3. Hold the bottom half of the endcap (clear section) on the pre-filled glass syringe. Twist off the top half (opaque section) of the cap.



4. Hold the pre-filled glass syringe with the tip upwards.
5. Attach plastic plastic luer-luer connector to the glass syringe. Ensure the connector is securely fastened.
6. Empty all air from the plastic 1mL or 3mL receiving syringe and attach to the other end of the luer-luer connector.
7. Inject entire TraceIT hydrogel volume into the plastic 1mL or 3mL receiving syringe via the connector.
8. Move entire volume back and forth from the glass syringe to the plastic syringe five (5) times, with the material ending up inside the plastic syringe.
9. Remove and discard the glass syringe and luer-luer connector from the plastic syringe.
10. Attach the enclosed 1” needle to the plastic syringe; inject a sufficient volume of hydrogel to remove air from the needle.
11. Locate the target site using the desired imaging modality.
12. Aspirate to assure needle is not in a vascular space.

    Warning: Do not inject TraceIT hydrogel in blood vessels. TraceIT hydrogel injection into blood vessels may cause vascular occulusion.

13. Inject up to 1mL of the TraceIT hydrogel at the target site. Confirm injection with desired imaging modality.

    Note: Wipe gel off needle hub before attaching a new syringe.

14. Dispose of the needle and syringe properly.

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HOW SUPPLIED

TraceIT Tissue Marker is provided in a 1mL and 3mL configuration as shown below:

Syringe Volume	Delivery Device	Catalog Number	Units in Box
1mL	25G x 1 inch (2.5cm) Needle	TH-1011	1
		TH-1015	5
3mL	21G x 1 inch (2.5cm) Needle	TH-1031	1
		TH-1035	5

Note: The maximum injection volume of TraceIT hydrogel, for a single location, is 1mL.

STORAGE

TraceIT Tissue Marker should be stored at room temperature, 15° C – 25° C (60° F – 77° F).

WARRANTY

Augmenix, Inc. warrants that reasonable care has been used in the design and manufacturing of this device. This warranty is in lieu of and excludes all other warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Augmenix's control directly affect the device and the results obtained from its use. Augmenix's obligation under this warranty is limited to the replacement of this device and Augmenix shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Augmenix neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

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

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