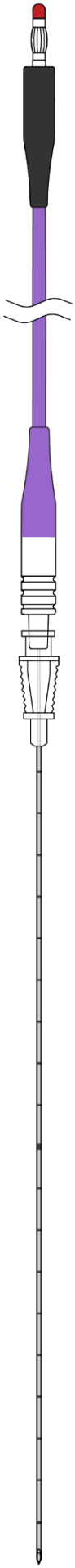


Aliya™ Ablation Device

Instructions For Use

Aliya™ 19G Needle GTI-00023

Aliya™ Electrode GTI-00024

℞ Only

GALVANIZE THERAPEUTICS

LBL-00048 Rev D 2021-08

1. Intended Use

The Aliya Ablation Device is intended for use as part of the Aliya System for surgical ablation of soft tissue.

2. Contraindications

None

3. ⚠ Warnings

DO NOT attach any products or components to the Aliya Ablation Device that are not part of the Aliya System. Attachments may damage the insulation and lead to patient injury.

DO NOT use a device with damaged insulation. Doing so may result in injury to the patient or operating room personnel.

DO NOT use the Aliya Ablation Device under MRI image guidance. The Aliya Ablation Device has not been tested for MRI compatibility. Doing so may result in patient injury.

DO NOT disengage the electrode from the needle while energy is being delivered. Doing so could result in injury to the patient or operating room personnel.

DO NOT continue the procedure if the needle or electrode is damaged at any point during preparation or use. Doing so may result in injury to the patient or operating room personnel.

DO NOT re-sterilize or reuse the device. The needle and electrode are single-use devices. Reuse may lead to patient injury, illness, or death.

4. ⚠ Cautions

READ these instructions for use and the Aliya System User Manual before use of the Aliya Ablation Device.

DO NOT use if package is received damaged or open. Doing so may result in injury to the patient or operating room personnel. Contents supplied sterile using an ethylene oxide process.

5. Potential Adverse Effects

- Arrhythmia
- Injury to anatomical structure
- Hematoma
- Hemorrhage
- Hemothorax
- Infection
- Muscle Contraction
- Pneumothorax
- Venous Thrombosis
- Burn
- Impact functionality of an implantable device
- Ablative Injury
- Procedural Complication
- Pain
- Patient does not receive benefits of therapy
- Transient injury to critical anatomical structure
- Bleeding
- Inflammation
- Fever
- Shock
- Mild-Allergic reaction (itching, redness, or rash)
- Charring

6. Product Illustration

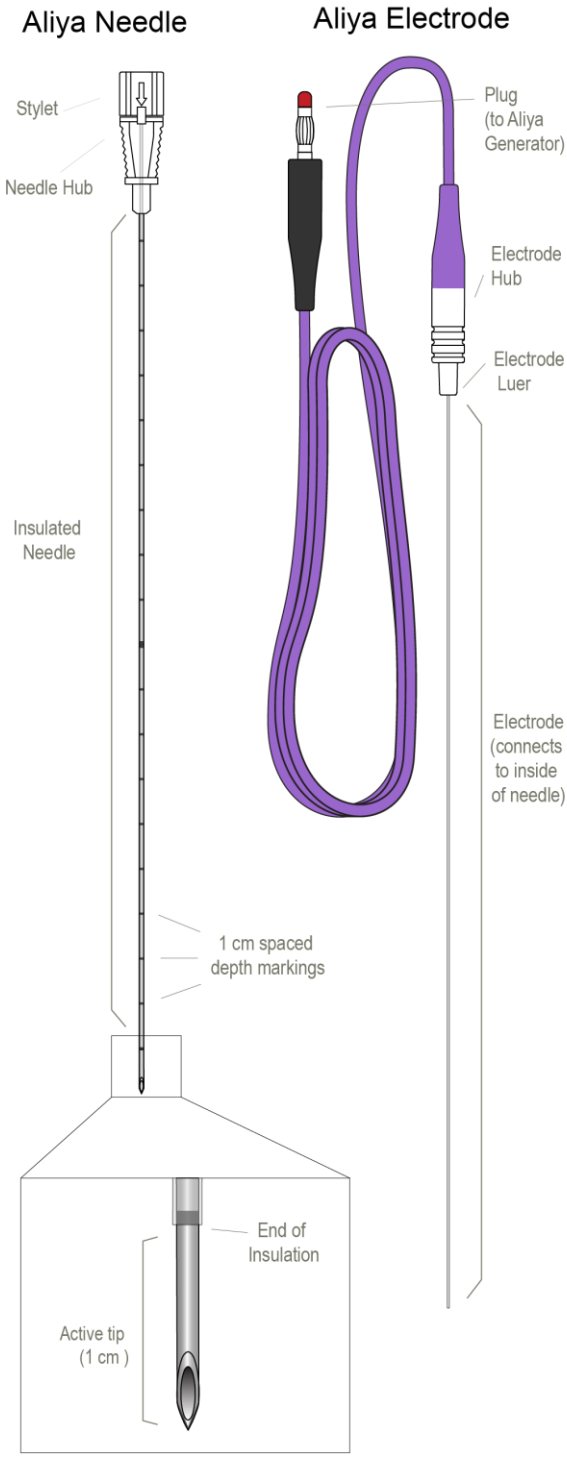
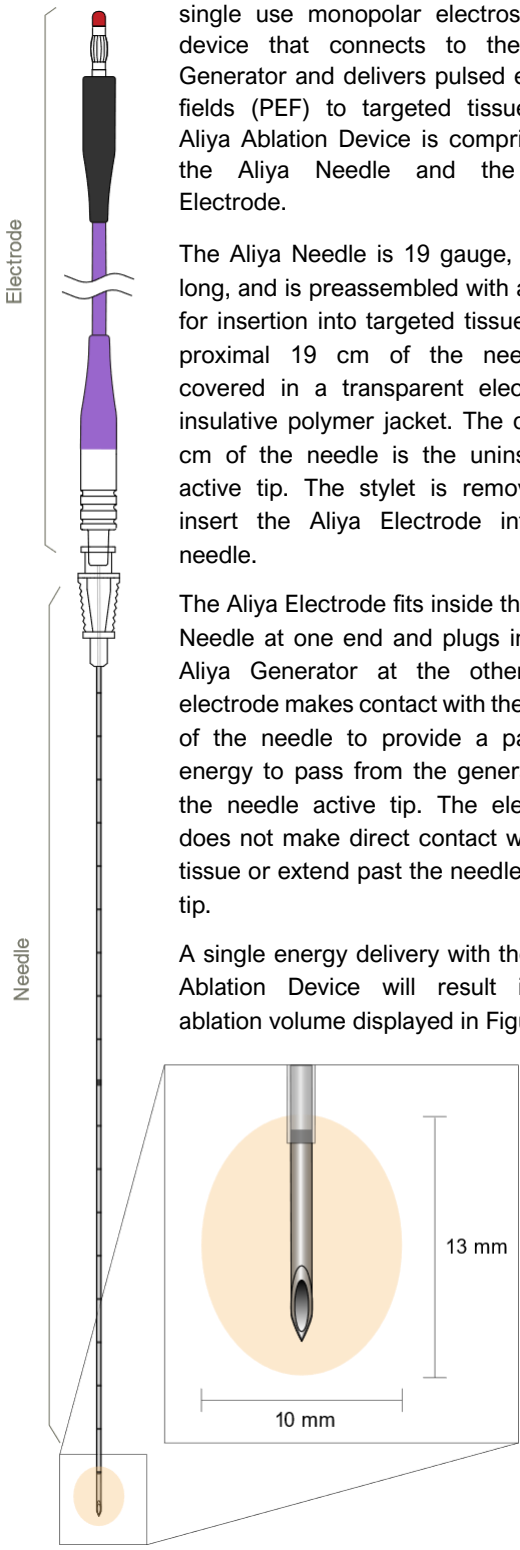


Figure 1. Aliya Ablation Device Components

7. General Description



The Aliya Ablation Device is a sterile single use monopolar electrosurgical device that connects to the Aliya Generator and delivers pulsed electric fields (PEF) to targeted tissue. The Aliya Ablation Device is comprised of the Aliya Needle and the Aliya Electrode.

The Aliya Needle is 19 gauge, 20 cm long, and is preassembled with a stylet for insertion into targeted tissue. The proximal 19 cm of the needle is covered in a transparent electrically insulative polymer jacket. The distal 1 cm of the needle is the uninsulated active tip. The stylet is removed to insert the Aliya Electrode into the needle.

The Aliya Electrode fits inside the Aliya Needle at one end and plugs into the Aliya Generator at the other. The electrode makes contact with the inside of the needle to provide a path for energy to pass from the generator to the needle active tip. The electrode does not make direct contact with the tissue or extend past the needle active tip.

A single energy delivery with the Aliya Ablation Device will result in the ablation volume displayed in Figure 2.

Figure 2. Approximate ablation volume for one energy delivery based on in vivo porcine data. Dimensions are 13 mm ± 3mm vertically and 10 mm ± 1mm horizontally. Tolerances represent one standard deviation.

8. Instructions for Use

Review the Aliya System User Manual before using the Aliya Ablation Device.

1. Remove the Aliya Electrode from the pouch using sterile technique.

2. Plug the Aliya Electrode into the Generator, keeping all surfaces distal to the hub in the sterile field.

3. Remove the Aliya Needle from the pouch using sterile technique. Handle the needle by gripping the needle hub at the proximal end.

4. Remove the protective tubes covering the needle and electrode.

5. Insert the needle and advance it through the tissue until the active tip has reached the target site. Use the depth markings on the needle and imaging (e.g., Computed Tomography, Fluoroscopy, or Ultrasound) for guidance during needle placement.

6. Remove the stylet. Be careful to hold the needle in position while removing the stylet.

7. Insert the Aliya Electrode through the needle hub. Advance the electrode into the needle until the electrode luer meets the needle hub.

8. Press the electrode luer gently into the needle hub to fix in place.

9. Confirm the active tip of the needle is in the target site using imaging.

10. Refer to the Aliya System User Manual for instructions on energy delivery.

11. If needed, hold the needle by the hub to maintain needle position until energy delivery has completed.

12. If needed, reposition the needle and repeat energy delivery to achieve the desired ablation volume. One needle can be used for up to 8 energy deliveries.

13. When the desired ablation volume has been achieved, remove the needle and electrode from the patient.

14. Unplug the electrode from the Aliya generator.

15. Dispose of the needle, electrode, and stylet in accordance with facility guidelines.

9. Handling and Storage

The Aliya Ablation Device should be stored in a cool dry place; avoid exposure to moisture, sunlight, and extreme temperatures.

10. For Further Information

Reference the Aliya System User Manual for troubleshooting steps.

If further information on this product is needed, please contact a Galvanize Therapeutics Representative.

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11. Symbol Legend

	Catalogue number		Prescription only
	Quantity		Keep dry
	Batch code		Keep away from sunlight
	Use-by date		Do not re-use
	Manufacturer		Do not resterilize
	Date of manufacture		Do not use if package is damaged
	Caution		Sterilized using ethylene oxide
	Consult instructions for use		Magnetic Resonance (MR) unsafe
	Temperature limit		Humidity limit