

ANGIODYNAMICS®

INCORPORATED

SINGLE ELECTRODE PROBE



INSTRUCTIONS FOR USE

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IC 038 Rev. B

CAUTION

Federal (USA) law restricts this device to sale by or use under the order of a physician.

This device is sterilized by ethylene oxide. The device is sterile and intended for single patient use. Sterile unless the package is opened or damaged. Do not re-sterilize.

The probe is intended for use with an AngioDynamics irreversible electroporation generator only. The physician must read the generator's User Manual thoroughly before operating the unit.

Avoid short circuiting the electrodes when delivering pulses.

POTENTIAL ADVERSE EFFECTS

The following adverse reactions have been reported with soft tissue ablation:

Dissection
Perforation
Hemorrhage
Hematoma
Infection

WARNINGS

Do NOT use a device with damaged insulation.

Do NOT attach anything to the device unless it is supplied by AngioDynamics and indicated for use with this device. Attachments may damage the insulation and contribute to patient injury.

PRODUCT DESCRIPTION

The single electrode probe consists of a primary trocar with an adjustable electrode. The probe is 15cm in length and includes a main cable with a connector.

INDICATIONS FOR USE

The single electrode probe is intended for surgical ablation of soft tissue.

INSTRUCTIONS FOR USE

1. Review and become familiar with operation of the generator. Refer to the generator's user manual.
2. Inspect all the devices and packaging for damage prior to use. Do NOT use any devices that are damaged or if the sterile barrier is breached.
3. Using sterile technique, open the package and carefully remove the device.
4. Turn on the generator.
5. Using imaging guidance, place a pair of single electrode probes in the targeted tissue. Markings on the trocar shaft can assist in placement of the device. The markings extend up the shaft in 5mm increments.
6. Verify the position of the probes with imaging.
7. Verify the length of the exposed electrode indicated by the trigger on the handle.
8. Attach the cable connectors to the generator.

Note: If excessive force is required to connect the cable to the generator, check to see if the pin in the cable connector is bent.

9. Program the generator with the parameters required to achieve the desired ablation zone. Refer to the generator manual for specific programming instructions.

- a. Typical results (based on in vitro porcine data) for two probes spaced 1cm apart with the active electrode length set at 2 cm.

Generator Settings:

Probe +	Probe -	Voltage	Pulse Length	N. Pulses
1	2	2000	100	90

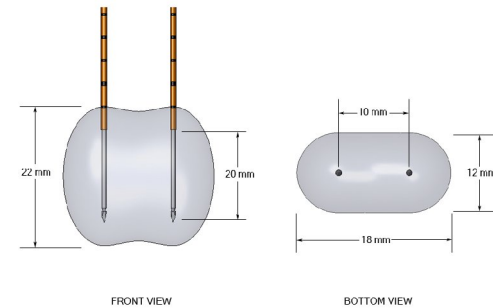


Figure 1: Typical ablation results based on in vitro porcine data.

- b. Typical results (based on in vitro porcine data) for two probes spaced 1.5cm apart with the active electrode length set at 2 cm.

Generator Settings:

Probe +	Probe -	Voltage	Pulse Length	N. Pulses
1	2	2500	100	90

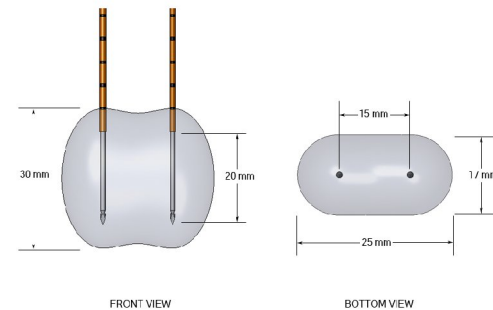


Figure 2: Typical ablation results based on in vitro porcine data.

10. Deliver the treatment.
11. After the ablation is complete, review the treatment screen to ensure that the treatment was delivered.