Instructions

Medical Purpose/Indication

 Acu-Tip is a thermocautery device used for localized soft tissue trimming and hemostasis during oral surgery.

Operating Principle

 This handheld, battery-powered device delivers thermal energy through a heating element to the patient by pressing an activation switch.

Patient Population

· No restriction.

Site of Use and Site Conditions

- · Site of Use: No restrictions.
- Site Condition: Aseptic.

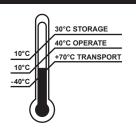
Intended User Profile

- Qualifications: Licensed medical professional.
- · Knowledge: Read and understand these supplied instructions.
- Experience: Training on soft tissue surgical techniques or training under surveillance/supervision.

CAUTERY



STORAGE 10 to 75% non-condensing OPERATE 30 to 75% non-condensing TRANSPORT 10 to 100% including condensation



NON-STERILE / SINGLE-USE TIPS



Read instructions before use



Do not use if packaging is damaged or opened



For professional use only



Do not reuse. This is a single use device.

HANDLE



For professional use only



Read instructions before use



Manufactured for

PRACTICON

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CAUTIONS

- DO NOT autoclave the Acu-Tip handle. Damage may occur.
- DO NOT use this device if the packaging is damaged or opened.
- DO NOT apply excessive force on the cautery during use. This
 may cause the tip to bend or break.
- The recommended duty cycle is 2 seconds ON and 6 seconds OFF for no longer than 15 minutes continuous time. Excessive activation may cause handle to overheat.

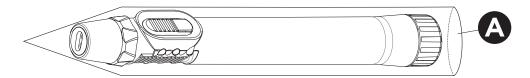
WARNINGS

- Tip (heating element) cannot be effectively cleaned or sterilized by the user and therefore cannot be reused safely. It is intended for single use only. Any attempt by the user to clean and resterilize the tip may result in device failure, bio-incompatibility, infection, or other risks to the patient.
- Always remove the tip when the device is in storage or not in use. Failure to do so could result in fire.
- DO NOT use in the presence of flammable gases/materials or oxygen rich environments. Fire could result.
- Acu-Tip produces heat in excess of 1,000°F, which can cause burns or fire from misuse.
- Prolonged tissue exposure to cautery may lead to damage of adjacent tissue.
- Cautery tip will remain hot immediately after deactivation and may cause inadvertent burns to user or patient.
- When ready for disposal, deactivate the cautery before discarding the device in a biohazard or "sharps" container. First, remove the cautery tip, then remove batteries by turning the rear cap. Failure to follow this instruction could result in unintended activation of the cautery and may cause a fire in the disposal container.

Applying Barrier Sheath

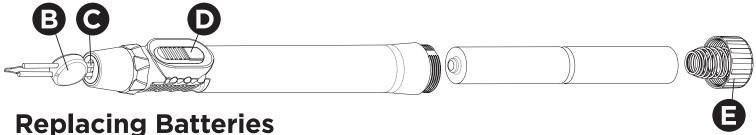
- 1. Remove cautery tip from handle before applying barrier sheath.
- 2. Holding the barrier sheath (A) with the open end up, insert the handle into the sheath.
- 3. Slide the handle forward, until the nose of the handle is at the end of the sheath.

IMPORTANT: Visually inspect barrier sheath for damage after application to the handle and prior to placing in sterile field.



Replacing Tips

- 1. Handle the tip with care, avoiding the fragile wire. Always hold the tip by the plastic grip (B) to avoid damage.
- 2. Insert the cautery tip into the handle by pushing the two electrodes posts (C) through the barrier sheath.
- 3. In order to make proper contact with the batteries, insert the tip all the way into the handle until the plastic grip is against the front of the handle. DO NOT FORCE. It should slide easily into place.
- 4. Activate the unit by depressing the power button (D).
- 5. After use, remove tip and barrier sheath and dispose of properly.



- 1. Remove cautery tip before beginning battery replacement procedure.
- 2. To remove depleted batteries, unscrew the rear cap (E) by turning counter-clockwise.
- 3. Remove the cap and tilt the handle so the batteries slide out. A gentle downward shake may be required.
- 4. Insert new AA alkaline batteries positive end first (never use carbon zinc batteries in this device).
- 5. Replace rear cap and turn clockwise until tightly closed.

Cleaning the Handle

- 1. Use only disinfectant wipes to clean the Acu-Tip handle.
- 2. DO NOT put handle in autoclave.

Replacement parts

Additional Acu-Tip Replacement Tips and QUIKsheath™ Barriers are available from Practicon:

70-51712 Acu-Tip Short Replacement Tip

70-51713 Acu-Tip Long Replacement Tip

70-51714 Acu-Tip 45° Replacement Tip

70-19721 QUIKsheath Barriers Low-Speed Straight are approximately 8" long. Non-sterile. 500 per box.

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