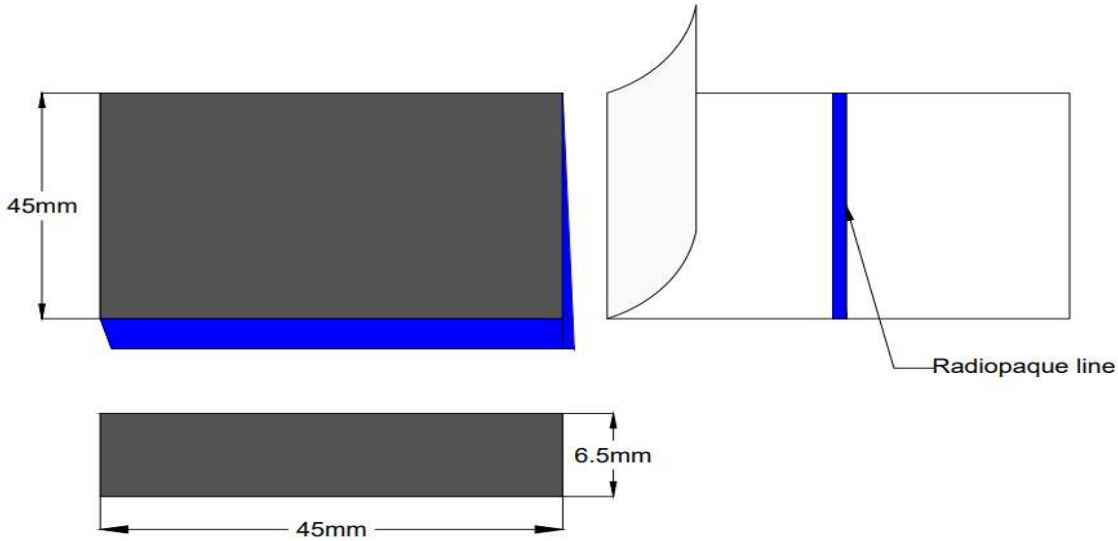
Prymax Surg
Cautery Tip Cleaner

DEVICE DESCRIPTION:

Device contains Abrasive pad designed for the removal of material from electrode tips during an electrosurgical procedure when using blades, pencil tips, or monopolar or bipolar cautery probes. Features an adhesive backing for universal placement in the sterile field. Single-use, sterile product with radiopaque material.

Drawing of product:



MATERIAL USED:
Foam pad, Ethyl-2-Cyano Acrylate, Polymethyl methacrylate

INTENDED PURPOSE:
INTENDED USE: The Cautery Tip Cleaner is intended to keep electrosurgical blades, pencil tips and mono-polar or bi-polar cautery probes free of debris during surgery.

INTENDED USER: The device is intended to be used only by a qualified medical professional.

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender.

INDICATIONS:

Prepared by:	Approved By:

Surface-level skin lesions like skin tags, angiomas, cherry angiomas, sebaceous hyperplasia, actinic keratosis and even malignant lesions like basal cell carcinoma

CONTRAINDICATIONS:
There are no absolute contraindications to electrocautery.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

CLINICAL BENEFITS:

Cautery Tip cleaners ensure safety and hygiene, reducing the risk of infection by removing potentially harmful debris from surgical equipment.

PERFORMANCE CHARACTERISTICS:

- Removal of debris

INSTRUCTIONS FOR USE:

- Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- Open the product in sterile environment.
- Remove the set from the package using a sterile technique.
- Remove backing and apply to the appropriate surface.
- Wipe cautery tip on pad to remove debris.

WARNING & PRECAUTIONS:

- Strictly for use in sterile processing area. Not for use in the operating room.
- Do not use if the sterile pack is opened or damaged.
- Ensure all additional warnings and/or cautions contained in this IFU.
- The use of this product is restricted to a qualified medical professional.
- Sterile, Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.

ADVERSE EFFECTS:
Nil

RE-USE HAZARDS:

- Transmission of infection from one patient to another.

PACKAGING:

- The device is packed in paper Pouch, which is further packed in inner carton & master carton.

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STERILIZATION:

- Device is EO sterilized, and sterilization is done in-house.

STORAGE CONDITION:

- Temperature Limit: 15^{o}C to 40^{o}C.

DEVICE SHELF LIFE: 3 Year

COUNTRY CODE: 356

DISPOSAL

- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:

- In case of any serious adverse event please report the same to info@prymaxhealthcare.com & gloizou@compliancems.com.au.
- Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

GOODS RETURN POLICY

Refer to the company's return good policy.
Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818.

SYMBOLS USED ON PRODUCT LABEL

Lot number

Do not re-use

Sterilized by Ethylene Oxide

Manufacturing date

Use-by date

Caution

Prepared by:	Approved By:

Non-pyrogenic

Do not resterilize

Catalogue number

Manufacturer

Storage Temperature Range

Conformité Européenne

Do not use if package is damaged

Consult instructions for use

Single Sterile Barrier System

UDI Carrier

Medical Device

Country of Manufacturer

Manufactured By:

Prymax Healthcare LLP.,

53/17,Industrial Area NIT, Faridabad,
Haryana, INDIA -121001
www.Prymaxhealthcare.com

EC REP:

Compliance Management Solutions
Europe LTD
2 Bulgaria Str. ,2850 Petrich, Bulgaria
E-mail: gloizou@compliancems.com.au
Contact No.: +61 4 33 124266

Prepared by:	Approved By: