

Instruction for Use



CAUTERY TIP CLEANER

Variant : NA
Product Class as REGULATION (EU) 2017/745 : Is
Product Class as per Medical Device Rule 2017 : A
Duration of use : Transient



DESCRIPTION

Device Description Cautery Tip Cleaners assist in the cleaning and removing of material from cautery tips during surgical procedures. Our tip cleaner consists of a 1.8 X 1.8" foam pad with abrasive material on one side and strong adhesive on the other for attachment to both disposable and non-disposable drapes.

Device Consists:

Foam- Polyester/Polyurethane, Radiopaque Thread- Barium

The device does not contain;

- DEHP
- medicinal substance, including a human blood or plasma derivative,
- tissues or cells, or their derivatives, of human origin
- tissues or cells of animal origin, or their derivatives.

Patient Target Group: All Age groups.

Product Packaging

- The product is available in non-toxic, medical-grade, sterile packing, that allows for maintaining product sterility to the point of use and to maintaining aseptic presentation.
- The product is a single-use device.

INTENDED USE

Cautery tip Cleaner, intended use is as an electrosurgical accessory to clean uncoated cautery blades that are part of an electrosurgical pencil. The product is usually placed somewhere on the sterile field, typically on the mayo stand.

MODE OF ACTION

Cautery tip cleaner designed to be used to periodically wipe clean the tip used in an electrically-mediated surgical technique for cutting, coagulating, or cauterizing tissue. This device is typically abrasive on one side to facilitate cleaning

INDICATION FOR USE

Pre-application

- Remove backing and apply to the appropriate surface.

Application

- Wipe cautery tip on pad to remove debris.

INTENDED USERS:

- Product is recommended to use by qualified medical/paramedic staff.

CONTRAINDICATION

- There are no known contraindications for this product.

CLINICAL BENEFITS

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

CAUTION /WARNING

- Do not use the product if the package is damaged or open.
- The product is designed for single use only.
- Do not re-sterilize.
- If reused it may lead to cross-contamination
- Troubleshooting: User Paramedic staff should be aware & able to troubleshoot the certain complications may occur during the application.

RISKS OF RE-USE

- A device designated, as 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.
- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has legal implications:
 - anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness;
 - Anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
- Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and, therefore, the performance may be compromised.
- If re-used it may lead, but not limited to cross-infection.

STORAGE

Based on the stability study report as per ICH guidelines the recommended storage condition in between Temp 15°C to 40°C and maintaining the relative humidity condition 50 to 75%. In case of any tempering in the packaging, the product condition may be affected even incase store at above defined condition. Product Sterility is valid for three years, from the manufacturing of the product.

DISCLAIMER

The condition of the device must be verified prior to use. BL is not responsible for any damage to person, property, etc. from any inappropriate or recommended use of the device, including reuse. Reuse could cause infection or serious health issues.

DISPOSITION

Dispose off/Discard the used Device, in accordance with your country's health care and safety regulations.








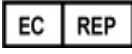






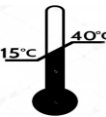





GOODS RETURN POLICY

Refer to the company's return goods policy.

Please contact the branch office or customer service at bls@bllifesciences.com or call +91 11 45100100

Company Website Link to product IFU: <https://www.bllifesciences.com>

SYMBOLS USED ON PRODUCT LABEL

Symbol			
Meaning	Caution	2460 Conformity of European Norm with Notified Body Number	Manufacturer
Symbol			
Meaning	Do not re-use	Use-by date	Date of Manufacture
Symbol			
Meaning	Batch/Lot Number	Authorized representative in the European Community	Sterilized using ethylene oxide Single sterile barrier system
Symbol			
Meaning	Do not resterilize	Consult Instruction for use	Non-pyrogenic
Symbol			
Meaning	Do not use if package is damaged	Catalogue number	Temperature Limit
Symbol			
Meaning	Fragile, handle with care	Keep dry	This way up
Symbol			
Meaning	Keep away from sunlight	Stacking limit by number	

Symbol



Meaning

Medical device



Unique Device Identifier



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