

Brighton™

Bipolar Coagulation Probe

INSTRUCTIONS FOR USE

INTENDED USE:

The Bipolar Coagulation Probe is intended to be passed through an endoscope's working channel to provide hemostasis throughout the gastrointestinal tract.

WARNING:

- DO NOT ATTEMPT TO REPAIR.
- For single use only. Do not reuse, reprocess or resterilize.
- The complications associated with the use of this device on patients with implanted electronic devices have not been evaluated. Prior to use, confirm with the implanted electronic device manufacturer that the use of this device in conjunction with the implanted electronic device is appropriate and safe.
- The use of the Bipolar Coagulation Probe should only be performed under direct endoscopic visualization.
- The Bipolar Coagulation Probe should never be used in a monopolar mode of operation.
- Maximum recurring peak voltage is 1400Vp-p. Do not use at higher recurring peak voltages.
- The device should not be passed through an endoscope whose distal end is deflected at an angle more than approximately 15 degrees.
- Possible explosion hazard if used in the presence of flammable anesthetics or naturally produced methane gas.

PRECAUTIONS:

- Inspect the Bipolar Coagulation Probe and packaging for damage prior to use. Do not use product if opened or damaged. Confirm that the device is consistent with the package label. Contact MERIT ENDOTEK™ Customer Service to report and replace damaged product.
- Refer to the product packaging for product working length and maximum catheter outer diameter.
- A thorough understanding of the technical principles, clinical applications, and risks associated with the use of bipolar coagulation probe is necessary before using this product. Use of this device should be restricted to use by or under the supervision of physicians trained in endoscopic procedures.

INSTRUCTIONS FOR USE:

- 1) Inspect probe for tubing kinks and any other defects.
- 2) Connect the flushing port luer connector to a syringe or pump filled with saline. The saline will aid in irrigation of the site prior to bipolar coagulation.
- 3) Connect the plug to the appropriate bipolar electrosurgical generator.
- 4) Test the probe to ensure proper working condition.
 - Immerse the tip of the catheter into a saline solution.
 - Remove the catheter tip from the solution.
 - Immediately after removing the catheter tip from the saline, activate the generator.

Note: The saline should bubble on the probe tip if the device is functional.

- Turn generator off.
- 5) Immediately prior to insertion into the endoscope, the probe tip must be immersed in saline for at least 5 seconds to activate the hydrophilic coating.

- 6) Advance probe into the working channel of the endoscope and into the desired location.

- 7) Proceed with bipolar coagulation.

- 8) Dispose of used probe consistent with standard protocols for biohazard waste disposal.

STORAGE:

Store in a cool, dry place.

REUSE PRECAUTION STATEMENT

Contents supplied **STERILE** using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your MERIT ENDOTEK™ representative.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

WARRANTY

The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is exclusive and manufacturer makes no other representations or warranties of any kind to customers, its end users, or to any third parties with respect to the device and hereby expressly disclaims any and all other warranties, express or implied, statutory or otherwise, including, but not limited to, infringement and the implied warranties of merchantability and fitness for a particular purpose, even if manufacturer is aware of such purpose. Handling and storage of this device, as well as other factors relating to the patient, diagnosis, treatment, implant procedures, and other matters beyond the control of the manufacturer, directly affect the device and the results obtained from its use. The manufacturer's obligation under this warranty is limited to the replacement of the device. Under no circumstances shall manufacturer be liable to customer or any other person or entity for any punitive, special, incidental or consequential damages directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty shall not apply, and manufacturer assumes no liability with respect to, devices that have been (i) modified, changed, altered, misused, mishandled, repaired, reused, reprocessed, refurbished or resterilized; (ii) subjected to improper maintenance, testing or storage, accident, tampering, or inadequate protection against shock, vibration, excessively high or low temperatures, overpressure, or physical, environmental or electrical stress; (iii) been used outside the approved "Indications for Use" as cleared by the relevant competent authority, used contrary to the use outlined in the device specifications, or in an application or environment for which such device was not designed or contemplated; or (iv) distributed or used contrary to applicable federal, state, local or regulatory standards.

RX only: CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.



Single Use



Caution: Consult accompanying document

STERILE EO

Sterile if package is unopened or undamaged

MERITMEDICAL
ENDOTEK™

CE 0086



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EC REP

Authorized Representative:

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