



BEAURAY

PRODUCT LITERATURE | GYNECOLOGICAL INSTRUMENTS

Loop Electrode - Instructions for Use

Official Manufacturer IFU | English

The following pages reproduce the manufacturer's official document without alteration. For availability, quotations and support in Canada, please contact Beauray Inc.

CANADIAN SALES & SUPPORT

Beauray Inc.

info@beauray.co

+1 437 607 5116 | Thornhill, Ontario, Canada

For Canadian product inquiries, contact Beauray Inc.

Instructions for Use

Single-Use[®]

The electrodes have insulated shafts measuring 12cm in length. Loop electrodes have a U-shaped yoke. The insulation is essential in preventing heat transfer to tissues and thermocoagulating the lesional epithelium during excision.

Loop electrodes are made of thin 0.2mm hard tungsten wire with high melting temperature and excellent conductivity of current. To prevent excessive tissue removal, loop electrodes are shallow.

The largest loop electrode measures 25mm wide x 22mm deep and is designed for loop electrosurgical excision procedures of the cervix. The smallest loop electrode measures 5mm wide x 5mm deep and is designed for electrosurgical excision procedures of the vaginal and external anogenital lesions.

In dense fibrous tissue, the loop wire tends to bend. When the wire bends, the yoke precedes the wire and the electrode has to be removed prematurely once the electrode shaft has reached the vaginal wall. This results in an incomplete excision of the lesional tissue.

The maximum depth of tissue that can be removed with a single excisional pass using a 10mm deep electrode is 9mm because the cross bar of the electrode prevents deeper penetration. With a 8mm deep electrode, the depth is 7mm, etc.

Loop shaped electrodes are used for noninvasive cervical lesions. Those with square or rectangular configurations are generally used for HPV related condylomata acuminata and intraepithelial neoplasia of the vagina, vulva, perineal area, and penis. The flat shape of the rectangular and square loop electrodes allows for better and even depth control than the curved radius style electrodes. Electrodes with 12cm long shafts are designed for the cervix and vagina.

Contraindications:

Absolute contradictions include hypovolemic shock, cardiac decompensation (Class IV) and coagulopathy/ blood dyscrasia; acute/chronic severe, active infection caused by chlamydia, gonococcus, herpes, and other aerobic and anaerobic organisms; intraepithelial disease extending to or close to lower uterine segment; severe allergic reaction to local anesthetic and iodine solutions, and/or refusal to sign informed consent form.

Relative contraindications include clinically apparent invasive cancer (punch biopsy is sufficient for histologic diagnosis); pregnancy (except in expert hands when invasion is suspected); less than 3 months postpartum and hypoplastic DES cervix.

Review of contraindications to electrosurgery use as provided by the manufacturer of the electrosurgery generator must be read prior to use.

Precautions:

Loop electrosurgical excision is a powerful surgical procedure with occasional intraoperative and postoperative complications. You **must obtain informed and signed consent** prior to the procedure.

Adequate anesthesia and complete visualization of the lesional area should be obtained before initiating electrosurgical procedures. It is recommended that voltage/power are kept as low as possible to achieve the desired effect.

For additional safety, the vaginal walls may be protected from activated electrodes and inadvertent cuts and burns by placing a latex condom over the speculum blades and cutting off the condom tip. The use of condoms or a vaginal retractor is of great help to retract relaxed vaginal side walls thus allowing for good visualization of the cervix and vaginal fornix.

Prior to any loop electrosurgical excision procedures, make a dry pass with the electrode under colposcopic guidance. This will determine that the path of the activated electrode will not be obstructed prior to excision.

These electrodes should never be used for any female sterilization procedures.

Care:

All electrodes are ready to use, sterile, sealed in their individual procedure blister trays. Do not clean or sterilize the electrodes. Dispose of each electrode after use. Do not reuse.

Sterilization

DO NOT STERILIZE!

Disposal:

As a sterile, single-use[®] instrument, an individual electrode should be disposed of immediately after use. The method used to dispose of the electrode should relate to the tissue or fluids it has contacted. Established standard practice for disposal of biohazards should be employed. This means that after use, the electrode should be placed in a properly marked biohazard container, and disposed of by a properly validated biohazard disposal firm or person.