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STERILE DISPOSABLE LEEP/LLETZ ELECTRODES ② STERILE EO ℞ ONLY CE 0086

INSTRUCTIONS FOR USE -
This electrode is supplied sterile. To remove from its package, use aseptic technique.

Applies to all part numbers:
LE-##-###

Thomas Medical electrodes are designed to fit most electrode/pencil connections and have a standard 3/32" (2.4mm) diameter shaft.

WARNING/CAUTION -
Electrodes may be used with Electrosurgical Generators with a maximum HF Voltage rating of 5000 Volts peak to peak.

A highly visible, clean, dry, non-conductive space should be provided for accessories and electrodes when not in use. Active accessories should be kept away from patients when not in use.

Arcing at the electrode/pencil connection may result with improper electrode installation and may cause injury to the patient or operating room personnel.

DO NOT activate the generator in Coag while using a Loop Electrode. Loop Electrodes are not designed for use in the coagulation mode, loop breakage may result. If the loop of the electrode breaks, stop surgery and replace the electrode. Loop breakage may result with contact or arc of the activated electrode to metal surfaces such as an uninsulated metal speculum.

Instructions for Electrode Set-Up -
Be sure the active accessory is not connected to an electrosurgical generator and the generator is in the **OFF/STANDBY** position before inserting or changing an electrode.

DO NOT use this electrode/accessory combination if the shank and/or insulating sleeve does not fit or the insulation will not insert 1/8" (3.2mm). The shank and insulating sleeve should fit securely into the active accessory. Grasping the electrode by the insulating sleeve, insert the round shank into the electrosurgical accessory until resistance prevents progress, a minimum of 1/8" (3.2mm).

DO NOT USE in case of damage of the sterile barrier

DO NOT resterilize and reuse the electrodes due to potential risk of infection and electrical hazards.

Single Use Only - After use, discard per local hazardous waste procedures.
These Sterile Disposable Electrodes are not designed to withstand resterilization. Discard. The maximum power setting for Ball Electrodes is 30 watts in the Coag mode. Exceeding these power settings may result in product damage. Thomas Medical recommends a maximum generator power setting of 55 watts in a Cut mode or Blend (Blend 1) for Loop Electrodes.

Introduction -
Over the past twenty years in the United States and Western Europe there has been a dramatic increase in the incidence of cervical intraepithelial neoplasia (CIN).

This user's guide describes the treatment modality of loop excision of the transformation zone using electrosurgical loop electrodes. Current management of CIN includes excision and ablative modalities, each of which has specific advantages and disadvantages. Loop excision may also have value as a diagnostic procedure.

Thomas Medical loops range in width from 1.0cm to 2.0cm. As a general definition, Prendiville's term "Large Loop Excision" referred to cervical loops larger than the earlier loops used by Dr. Rene Cartier which were .05cm wide. The term LLETZ (Large Loop Excision of the Transformation Zone) was coined by Dr. Walter Prendiville in his published research (1989), describing a technique for management of CIN by excising the transformation zone using an electrosurgical loop electrode. Dr. Prendiville's research, which involved 111 patients who were treated with LLETZ, demonstrated that LLETZ has a high rate of success, resulting in a low complication rate, and provided useful and complete biopsy material for detection of microinvasive diseases.

Indications for the LLETZ procedure include -
- A cytological and colposcopic suspicion of CIN.
- A transformation zone which is fully visible and fully confined to the cervix.
- A suspicion supported by evidence (cytological or colposcopic) of microinvasive disease.

Indications for Loop Treatment of CIN -
LLETZ is indicated for those patients who have had an abnormal pap smear report with cytologic evidence of CIN, colposcopic examination of the cervix unsatisfactory finding and who, in the physician's opinion are suitable candidates for the procedures.

Relative Contraindications -
- A recurrent, persistent and troublesome cervical infection.

Contraindications -
LLETZ is contraindicated for the following:
- Patient with frank invasive cervical disease.
- Pregnancy

Informing the Patient -
Provide the patient with the following information:
- Possible treatment alternatives
- A brief description of the procedure, including sounds and sensations, and the time required to perform the entire procedure
- A description of the position which the patient will be required to maintain throughout the procedure
- A description of the patient return electrode, its purpose and where it will be applied
- An explanation of the importance of remaining still during the procedure

Supplies, Preparation and Equipment Set-Up -
The following is a suggested list of supplies:
- Acetic Acid
- Lugols Iodine Solution
- Saline Solution
- Vaginal Speculum with Smoke Evacuation Port (Non-Conductive Speculum Preferred)
- Large and Small Cotton Tipped Applicators
- Thomas Medical Electrodes
- Specimen Container/Preservation Solution
- Electrosurgical Generator
- Smoke Evacuation Unit

- Electrosurgical Pencil and Patient Return Electrode
- Local Anaesthetic, Needles for Injection

Supplies, Preparation and Equipment Set-Up (continued) -

The following is a suggested list of supplies (continued):

- Vasoconstrictor of Choice

(Additional or alternative supplies may be needed depending on physician preference or institutional policy).

1) Select the appropriate size loop and ball electrodes for the procedure
2) Verify that the electrosurgical generator is OFF (standby)
3) Insert the loop electrode into the pencil. Connect the pencil to the electrosurgical generator
4) Select the appropriate power settings on the electrosurgical generator

Thomas Medical recommends a maximum generator power setting of 55 watts in a Cut or Blend (Blend 1) mode for the loop electrodes. The Cut mode produces little or no hemostatic effect along the margin of the divided tissue.
Caution: Loop electrodes are not designed for use in the Coagulation mode. **DO NOT** activate generator in Coag while using a loop electrode. Loop breakage may result. If the loop of the electrode breaks, stop surgery and replace the electrode.

The size of the loop and ball electrodes and the type of electrosurgical generator being used determine the power requirements. The power requirement for fulguration with ball electrodes also depends on the size of the electrode being used. The maximum power setting for ball electrodes is 30 watts in the Coag mode.

Some generators have output load characteristics that cause the electrosurgical effects to vary considerably as tissue impedance increases. When such generators are used, it may be necessary to readjust the relative power during the procedure.

Patient Preparation -

Prepare the patient for the procedure:

- Apply the patient return electrode to the patient *(refer to the manufacturer's instruction for proper placement and application)*
- The upper anterior thigh is the preferred location, because it is close to the surgical site and avoids skin fold and bony prominence
- Connect the patient return electrode to the electrosurgical generator
- Drape the lesion and place the patient in the lithomy position

Instructions to Perform LLETZ –

1) Colposcopically examine the cervix in the usual manner. To enhance visualization of the lesion and the margins of the transformation zone, stain the cervix with acetic acid and/or iodine solution
2) Anesthetize the cervix using a local anesthetic agent with preferred vasoconstrictor, if it is determined the loop procedure will be performed
3) Excise the lesion, using the appropriate size loop. The results of the endocervical curettage (ECC) do not appear to be predictive of either residual or invasive disease after the loop excision. A cone biopsy or biopsy using an alternative technique should be considered, if the ECC is positive for dysplasia

The effectiveness of the procedure and the influence of electrode design are not completely understood. Loop excision procedures performed with small diameter loop electrodes produce multiple small pieces of cervical tissue and provide less acceptable tissue specimen for histopathologic analysis.
It is more difficult to remove larger lesions involving multiple quadrants of the cervix with either the small or large diameter loop electrodes.

4) Fulgurate the bed of the cervix using the appropriate ball electrode following the excision of the lesion
5) Inspect the cervix after fulgurating to make certain that any bleeding has ceased and to insure the "os" is patent
6) For histological examination prepare and preserve the tissue specimen(s) in the usual manner
7) Post procedure instructions

Patient's Post Procedure Instructions –

Provide the patient with the following information:

- Contact the physician if vaginal bleeding exceeds that experienced during a normal menstrual period, or if there is any question regarding the amount of bleeding experienced following the procedure.
- Avoid sexual intercourse and the use of vaginal tampons for two (2) to four (4) weeks.

General –

- **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician, who has been trained in electrosurgical procedures of the cervix used in management of CIN.
- **Caution: DO NOT** contact or arc the activated electrode to metal surfaces such as an uninsulated metal speculum. Loop breakage may occur..
- **DO NOT** reuse single use active electrodes.
- No long term follow-up studies to determine recurrence rates have been performed after using this device for the LLETZ procedure. Effects of LLETZ procedures on pregnancy outcome are not known.
- Conization of the cervix may increase risk of cervical incompetence and pre-term delivery.

Fire Hazard –

- **Warning: DO NOT** place accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical accessories which are activated or hot from use can cause fire.

Patient Return Electrodes –

- When applying the patient return electrode, ensure that the entire pad adheres to the patient. **DO NOT** reuse single use patient return electrodes. **DO NOT** use the return electrode if the packaging is damaged or if the gel/adhesive material is dried.
- If the patient moves or is repositioned after the patient return electrode is applied, ensure that the return electrode firmly contacts the skin and that all connections are intact.
- Avoid spilling any solutions on the return electrode. If this occurs, remove the return electrode, dry the skin and apply a new return electrode. A moist environment may cause the return electrode to peel off.

Procedures Where Visualization May Be Impaired –

Warning: For procedures where visualization may be impaired during the LLETZ procedure, be alert to these potential hazards:

- The electrode loop or ball may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation movement of the activated electrode outside the field of vision may result to injury to the patient.
- Localized burns to the patient or physician may result from electrical currents carried through conductive objects by direct contact with the active electrode.

Thermal Damage –

During loop excision, **DO NOT** stop when beginning the loop insertion into the tissue, or at any time during the procedure because the loop may adhere to the tissue and cause excessive thermal damage or make it difficult to continue the procedure.

- The histological quality of the specimens obtained using smaller loops may be inferior to that obtained with larger diameter loops because more of the epithelium comes in direct contact with the smaller loop than the larger loops and that part of the electrode is not insulated. This may result in more thermal damage to the tissue.

- Possible injury to cervical tissue may include:
  1) Thermal coagulation injuries of the cervix, up to one third (1/3) the thickness of normal epithelium of the cervix.
  2) Fragmentation of aquamous epithelium of the cervix attributable to long exposure periods along the excision site that allows heat to dissipate laterally.
  3) Partial coagulation of the endocervix epithelium because of lateral radiation of heat.
  4) Deep thermal damage to the cervix by contact desiccation rather than fulguration.