GUIDANCE FOR THE CONTENT OF PREMARKET NOTIFICATIONS

FOR

LOOP AND ROLLERBALL ELECTRODES FOR GYN

ELECTROSURGICAL EXCISIONS

OBSTETRICS-GYNECOLOGY DEVICES BRANCH
DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT,
AND RADIOLOGICAL DEVICES
OFFICE OF DEVICE EVALUATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

JULY 29, 1991

Loop and Rollerball Electrodes for GYN Electrosurgical Excisions:

Labeling Requirements

Labeling for loop and rollerball electrodes and the electrosurgical units (ESUs) that power these electrodes for their gynecological applications must be labeled in accordance with 21 CFR 801.109. For further guidance with respect to the general aspects of device labeling, refer to the regulatory manual entitled, "LABELING: Regulatory Requirements for Medical Devices" (HHS Publication FDA 86-4203).

FDA recommends that a professional use guide be prepared as a labeling supplement that provides the following information based on findings from studies of the device(s):

-- Indication(s)
-- Contraindication(s)
-- Warning(s)
-- Precaution(s)
-- Instructions for Use

This labeling must provide guidance with respect to the selection of electrodes and recommended ranges for important operating parameters. Labeling ~~must~~ may also contain the following statements:

1) Indication(s)

a. Cervical Conizations

b. Large Loop Excision of the Transformation Zone (LLETZ) in the Diagnosis and Treatment of Some Cervical Intraepithelial Neoplasias (CIN) and Dysplasias

c. External Anogenital Lesions

d. Large Vaginal Intraepithelial Neoplastic (VAIN) Lesions

Such indications must be supported by clinical data before they can be used as product claims.

2) Contraindications

a. Pregnancy

b. Acute or active inflammation of the cervix, endometrium, fallopian tube, ovary or peritoneum (cervicitis, endometritis, tubo-ovarian inflammatory disease or pelvic inflammatory disease)

c. Invasive cancer that is visible on examination

d. Known or suspected cervical changes secondary to DES (diethylstilbestrol) intrauterine exposure

3) No Long Term Follow-up

No long-term follow-up studies with this device have been performed as to recurrence rates, and the effects of loop electrosurgical excision procedures on pregnancy outcome are not known.

4) Electrosurgical Tissue Effect

Delivery of continuous sinusoid waveform currents through a small electrode at appropriate power levels can cause rapid heating of the intracellular fluids in the cells in close proximity to the electrode, turning these fluids to steam. The significant increase in volume (approximately 5 times) causes cellular structure to rupture, creating the clinical effect of [CUT], with little or no hemostatic effect along the margin of the divided tissue. Delivery of short duration pulses of R.F. currents through a small electrode at appropriate power levels can cause heating of intracellular fluids at a more gradual pace. This allows evaporation of these fluids without rupturing the cellular structure, creating the clinical effect of desiccation, or [COAG], without the division of tissue. By varying the pulse to an intermediate duration, it is possible to get a clinical effect to combine, or "blend", the clinical characteristics of CUT and COAG, yielding the effect referred to as [BLEND], where tissue is divided with a desirable amount of hemostasis along the margins of the divided tissue.

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

5) Technique Guidance

Labeling regarding loop excision techniques must include the following statements:

a. The endocervix is commonly not included in the loop excision, and the results of endocervical curettage (ECC) do not appear to be predictive of either residual or invasive disease after loop excision procedures. If the ECC is positive for dysplasia, a standard cone biopsy should be considered.

b. Loop excision procedures performed with small diameter wire loop electrodes produce multiple small pieces of cervical tissue and provide a less acceptable tissue specimen for histopathologic analysis. The effectiveness of the procedure and the influence of electrode design are not completely understood.

c. Larger lesions involving multiple quadrants of the cervix are more difficult to remove with either the small or large diameter loop electrodes.

6) Small Diameter Loop vs. Large Diameter Loop

The histological quality of the specimens obtained using the small diameter loop was inferior to that obtained with the large diameter loop. This is because more of the epithelium comes in direct contact with the small diameter electrode than with the large diameter electrode, and that part of the electrode is not insulated. This results in more thermal damage to the tissue. In [Insert rate(s) found in clinical studies.], the amount of thermal damage precluded histological evaluation of the excised tissue. In addition, since multiple, often irregular, strips of epithelium are excised from the cervix, it is often difficult for the pathologist to orient the specimens for optimal histopathological examination.

7) Thermal Injury and Defects of Tissue Treated with Loop Electrodes

Possible injury to cervical tissue may include: (i) thermal coagulation injury of the cervix, up to one-third the thickness of normal epithelium of the cervix, (ii) fragmentation of squamous epithelium of the cervix attributable to long exposure periods along the excision site that allows heat to dissipate laterally, and (iii) partial coagulation of the endocervical epithelium because of lateral radiation of heat.

Loop electrosurgical excision procedures may also produce thermal defects at the periphery of the excised tissue and may make histopathologic interpretation difficult or impossible and may prevent accurate diagnosis and the evaluation of the need for further treatment.

8) Professional Use Only/Proper Training

CAUTION: Federal law restricts this device to sale by or on the order of a physician. This device SHOULD NOT be used without proper training and preceptorship.