GUIDELINES FOR EVALUATION OF LAPAROSCOPIC BIPOLAR AND THERMAL COAGULATORS (AND ACCESSORIES)

Prepared by the Endoscopic and Electrosurgical Device Subcommittee

Subcommittee Members

Theodore H. Freilich, D.O. (Subcommittee Chairman)
Richard P. Dickey, M.D., Ph.D.

Consultants

Jordan M. Phillips, M.D.
John G. Sciarra, M.D., Ph.D.
Richard M. Soderstrom, M.D.

GUIDELINES FOR EVALUATION OF LAPAROSCOPIC BIPOLAR AND THERMAL COAGULATORS (AND ACCESSORIES)

Introduction

These general guidelines for a product development protocol for laparoscopic bipolar coagulators (and accessories) have been prepared by the Endoscopic and Electrosurgical Devices Subcommittee of the Obstetrical and Gynecological Device Classification Panel, Bureau of Medical Devices and Diagnostic Products, Food and Drug Administration. The subcommittee Members are:

Theodore H. Freilich, D.O. (Subcommittee Chairman)
Richard P. Dickey, M.D., Ph.D.
Robert Quint (Consumer Representative)

Consultants are:

Jordan M. Phillips, M.D.
John Sciarra, M.D.
Richard Soderstrom, M.D.

The guidelines are intended as overall guides to the investigation of laparoscopic bipolar coagulators (and accessories). The place for specifics is in the individual product development protocols. Specific protocols will be evaluated and approved on their own merits.

Objective

The objective of preclinical and clinical investigations is to assess the relative safety of the laparoscopic bipolar coagulators, their effectiveness in achieving permanent sterilization, the risks or undesirable effects and the relative relationship of these assessments.

I. Preclinical Guidelines (Phase I)

A. Description (design of device)

The applicant should provide detailed drawings and descriptions of the device and its accessories. The physical characteristics of the device should be indicated and the rationale for the design should be stated in the light of the relevant literature.

Design characteristics to be indicated:

1. design of forceps

2. design of generator

   The generator should conform to the standards which are being developed for unipolar coagulator.

3. information for routine maintenance and regular testing.

B. Sterilization Process

Appropriate information to carry out the sterilization process

C. Animal Study

A small study (5 animals) using suitable animal models, that is swine or cow. One hundred per cent efficacy should be demonstrated by coagulating the fallopian tube. The coagulated fallopian tube should be transected and the histological evidence of tissue destruction of the tube as the end point be determined.

II. Clinical Guidelines

Prior to clinical testing, it must be documented that appropriate animal study for the proposed clinical trial has been carried out. Animal findings relevant to the safety and effectiveness of laparoscopic bipolar coagulator to be completed prior to initiation of phase II clinical studies.

Investigations of this nature are to be conducted in such a way that the participating subjects of patients are exposed to the least possible risk consistent with the anticipated benefit.

The patients must be fully informed of:

1. the benefits and risks of other sterilization methods

2. the risks as well as benefits of laparoscopic bipolar coagulators in general and any specific risk of the bipolar coagulators being investigated

3. an experimental device is to be used in a patient for sterilization and the possibility of pregnancy as well s the potential hazards of pregnancy

4. the possibility that the patient may be necessary to subsequently need to utilize other methods to ensure permanent female sterilization

5. the patient should also be advised that she must agree to remain in communication with the investigator of the manufacturer with proper time limit in order that the long term failure may be detected.

A. Investigational Clinical Study (Phase II)

The intent of Phase II is to determine the safety, reliability of equipment, and initial efficacy of bipolar sterilization without exposing patient to the risk of pregnancy. Phase II clinical studies are to be performed using the experimental laparoscopic bipolar coagulators on the patient who is to have a hysterectomy. The principle investigator must use the prototype device in 10 patients, with two more investigators who are experienced in performing the permanent sterilization procedures. Each investigator will perform the sterilization on 10 patients. These trials should be performed to determine the histological evidence of the tissue damage of endosalpinx as compared to the histological evidence of the tissue damage of endosalpinx using unipolar coagulator.

1. Patient information and consent must follow HEW Guidelines on Protection of Human Subjects-Federal Register Vol. 40, No. 50. p. 11854-11858.

   Patients must be advised that an investigational device is being used and informed consent must be executed by the patient.

2. Criteria for selecting investigators

   The investigators must be experienced in conducting the permanent sterilization procedures using unipolar coagulators.

3. Data needed to record and analyze for evaluation of safety and effectiveness.

   a. histological evidence of tissue destruction of endosalpinx using bipolar coagulator as compared to the histological evidence of tissue destruction of endosalpinx using unipolar coagulator

   b. burns

   c. hemorrhage

d. tears

e. difficulty in removing the instrument

f. improper functioning of the instruments

g. inability to complete the procedure

h. necessity for laparotomy and additional treatments

i. The hystersalpingogram should be performed during preovulatory cycle after four months post-surgery at a pressure of 150 millimeter mercury. An alternative method of contraception should be provided to the patient until the hysterosalingogram confirms the closure of the tubes.

Phase II studies must be repeated each time when instrument is changed or a new prototype developed, unless waived by the review committee.

B. Clinical Study (Phase III)

The clinical study (Phase III) should follow the guidelines in the investigational clinical studies (Phase II) for the following:

1. patient informed consent (in addition - late failure, pregnancy)

2. patient will be women requiring tubal sterilization and who will not be requesting a hysterectomy

3. criteria for selecting investigators

4. data needed to record for evaluation of safety and effectiveness. There is no need to record histological data.

The number of patients to be institutes in order to determine the effectiveness of the device should be 100 patients with no less then five investigators.

The final prototype must be used in all cases. Phase III must be repeated each time a model is changed or a new prototype developed, unless waived by the review committee.

III. Post Marketing Surveillance (Phase IV)

A. Post marketing surveillance is needed for permanent sterilization with bipolar coagulators for the following reasons:

1. the possibility of pregnancy occurring due to recannulization or fistula formation. The need to determine whether late failure results in ectopic rather than intrauterine pregnancy as compared to other tubal sterilization technique.

2. the need to warn patients to take additional preventative measures in the event that a greater pregnancy rate than reported for unipolar sterilization is found as a result of extended studies.

A. The required post-marketing surveillance:

1. the patients in clinical Phase III should be followed for an extended period of time. The patients are required to remain in communication with the investigator or the manufacturer for at least two years.

2. The individual protocol should include a system to determine the long-term safety and efficacy (intrauterine and ectopic pregnancy) for at last two years post marketing. This study is to include at least 1500 patients in addition to those in Phase III.

3. The manufacturer is to keep records of regional distribution and final distribution of those devices. (that is, individual physician or clinics or hospitals). In the event of recall, the manufacturer will provide this information to the FDA.

4. The manufacturer should conduct a late failure reporting system in order to actively solicit failure of the permanent sterilization procedures from physicians and hospitals. The manufacturer should provide educational information for the use of the laparoscopic bipolar coagulators and its accessories to the physicians and the hospitals.