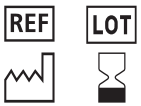
INSTRUCTIONS FOR USE:

Use a vaginal speculum in kit to get a line-of-sight on the cervix. Examine the cervix with a colposcope. (MedGyn has several types of colposcopes available for purchase if needed). The cervix should be well centered in the speculum and excess secretions wiped away with a cotton ball or swab in kit. If endocervical curettage is to be done, it is usually done prior to the cervical biopsy. Endocervical curette not included in Colposcopy Set.

1. Place the fixed edge of the biopsy punch on the inner or endocervical portion of the lesion.
2. It is helpful to set the bottom tooth on the surface of the lesion prior to squeezing the handles to obtain the specimen.
3. The patient should be warned that she will feel a small amount of paint with the biopsy, different from the cramping nature that accompanied the endocervical curettage if that procedure was done.
4. Additional biopsies are taken as needed and placed in a fixative of the pathologist's choice. Placing the small specimen on a piece of rough paper towel may help orient the tissue for fixation.The bleeding sites are controlled with pressure or Monsel's solution provided.
5. Vaginal bossies may be more easily obtained with the additional use of a small skin hook to hold the tissue. Local anesthesia will be necessary for lesions in the lower one-third of the vagina or on the vulva. The sites of vulvar biopsies are usually near the center of the lesion, in a non-necrotic area.

SEE PRODUCT LABEL FOR:



Colposcopy Kit IFU - English
DISPOCST-IF1

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MedGyn

COLPOSCOPY KIT

Instructions for use

DEVICE DESCRIPTION:

The MedGyn Disposable Colposcopy Set comes with common items used during a colposcopy procedure in an all-in-one, single-use, pre-sterilized kit. A list of the items in the kits are listed in Figure1-1. There is a choice of single-use biopsy punch or no biopsy punch.

INDICATIONS FOR USE:

Cervical Biopsy Punches are indicated whenever obtaining a tissue specimen is necessary. Although of particular importance in obtaining cervical biopsies, all of these instruments are also ideal for vaginal bossies or even vulvar skin biopsies or to excise all lesions.

SOME OF THE INDICATIONS INCLUDE
(Not a complete list):

- Abnormal pap smear with colposcopies or cervicographic findings of cervical cancer, CIN or HPV
- Gross lesion of the cervix
- Bleeding lesion of the cervix
- Condyloma, VIN or vulvar lesion

CONTRAINDICATIONS:

You should always consider the need to have a tissue diagnosis relative to the risk or other conditions such as coagulation disorder, severe heart failure, or hypovolemic shock. Other causes or sources of bleeding may need to be evaluated such as post-menopause bleeding, anovulatory bleeding, intermenstrual bleeding from a complication of pregnancy.

WARNINGS:

The patient should avoid vaginal intercourse or extensive physical activities for 48 hours as patient may have a small amount of bleeding or discharge for a few days. Heavier bleeding should be reported.

ADVERSE REACTIONS:

- Any cervical manipulation may cause a reaction. Patient should be watched for unusual weakness or nausea.
- In rare cases there may be mild cramp or spotting. If bleeding persists, patient should be instructed to contact her physician

PRODUCTS INCLUDED IN SET:

Large plastic tray, 10.5”x12.3”x1”	1
Small plastic tray, 5.3”x4.8”x 2”	1
Disposable LED Speculum	1
Cervical dilator/Os Finder	1
Tenaculum, Pozzy	1
Cherron Forceps	1
Monsel’s Solution, 8mL	1
Cotten swab, 8”	2
Sanitary Napkin	1
Sterile Gauze	2
Over wrap, 30”x30”	1
Povidone-iodine solution, 0.75 Fl. oz	3
Sponge Swab	2