

Euro-Med® Biopsy Punches

INSTRUCTIONS FOR USE

Product #	PUNCHES
64-689	Tischler-Morgan
64-691	Baby Tischler
64-675	Kevorkian-Pacific
64-660	Coppleson
64-679	Tischler-Kevorkian
64-690	Mini-Townsend
64-677	Burke
64-695	Baggish
64-687	Eppendorfer
64-681	Wittner, Angled
64-685	Kevorkian
64-670	Schubert

Product #	ROTATING PUNCHES
64-649	Mini-Townsend Tip

Product #	ROTATING PUNCH TIPS
64-484	Tischler-Morgan Tip
64-460	Mini-Townsend Tip
64-489	Oval Tip
64-488	Kevorkian Tip
64-756	Tischler Down Tip
64-751	Tischler Up Tip
64-656	Mini Down Tip
64-651	Mini Up Tip

R_x Only CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician

DEVICE DESCRIPTION

Cervical Biopsy Punch instruments are available from CooperSurgical's Euro-Med line and are available in a wide variety of types which should suit the needs of the most demanding practitioner. By having an assortment of punches in an office, the practitioner can choose the proper instrument for a specific need rather than attempting to use the same device in every clinical situation which may produce more painful procedures and less than adequate tissue specimens.

Current Biopsy Punches are stronger and smaller than those previously offered and maintain a sharper cutting edge with minimal maintenance. Dual spring locks in the handle and anchoring teeth at the biopsy teeth allow for excellent tactile control and prevents slippage during procedures. The exclusive Shur-Lock™ thumb tab helps to prevent loss of the tissue specimen during transfer to the fixative.

Practitioners should evaluate the various instruments to decide which are most comfortable and clinically useful in the individual situation. The configuration and size of the biopsy bit, the need for a rotating punch to allow better visualization, and angled tips for use just inside the exocervix or far laterally on the portio are useful variations that should also be considered.

INDICATIONS FOR USE

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

Some of the indications include (not a complete list):

- Abnormal Pap Smear with colposcopic or cervicographic findings of cervical cancer, CIN or HPV.
- Gross lesion of the cervix.
- Bleeding area of the cervix.
- Gross lesions of the vagina.
- Condyloma, VIN or vulvar lesions

CONTRAINDICATIONS

One should always consider the need to have a tissue diagnosis relative to the risk of other conditions such as coagulation disorder, severe heart failure, and hypovolemic shock and extreme care should be taken in the presence of active infections such as gonorrhea, herpes, or chlamydia. However, a biopsy may be helpful in making these diagnoses. The risk of pelvic inflammatory disease may be increased in these situations. Excess bleeding may occur during pregnancy and precautions should be taken in advance to control a bleeding problem if it occurs. Smaller punches and only partial filling of the punch will reduce excessive bleeding. Other causes or sources of bleeding may need to be evaluated such as post-menopausal bleeding, anovulatory bleeding, intermenstrual bleeding, or bleeding from a complication of pregnancy.

WARNINGS

The patient should avoid vaginal intercourse or extensive physical activities for 72 hours. She may have a small amount of bleeding or discharge for a few days. Heavier bleeding should be reported, evaluated and can usually be controlled locally.

INSTRUCTIONS FOR USE

For cervical or vaginal biopsies, a vaginal speculum or other instrument is necessary for visualization. The cervix should be well centered in the speculum and excess secretions wiped away with a cotton ball or swab. Colposcopy may have preceded the biopsy to identify the most potentially serious sites for biopsy. If endocervical curettage is to be done, it is usually done prior to the cervical biopsy.

The instrument is chosen and the fixed edge of the punch placed on the inner or endocervical portion of the lesion. It is helpful to set the inner tooth on the surface of the lesion prior to squeezing the handles to obtain the specimen.

The patient should be warned that she will feel a small amount of pain with the biopsy, different from the more cramping nature that accompanied the endocervical curettage if that procedure was done. No anesthesia is used for cervical biopsies. 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, Monsel's solution (AstrinGyn®) or AgNO₃. Rarely is suturing necessary.

Vaginal biopsies 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.

CLEANING AND STERILIZATION

CARE

Thorough maintenance will ensure proper function of the Euro-Med instruments. It is important to clean and sterilize each instrument immediately after each procedure. Proper maintenance will also extend the life of the instrument.

- Handle each instrument individually. Do not handle in groups or stacks.
- Inspect the instrument for integrity of movable parts (jaws, hinges, etc.), signs of damage (broken or cracked) or missing hardware (screws). Damage to movable parts can result in sub-standard performance of the instrument.
- Check insulation for cuts, voids, cracks, tears, abrasions, etc. on the instrument to be used with an ESU (electrosurgical unit).
- Rinsing and cleaning must take place immediately following the instrument's use for decontamination. Adherent particles may resist cleaning or cause staining.
- Wear protective gloves during the cleaning procedure

CLEANING

1. Prepare the neutral pH enzyme cleaning solution (Enzol®) at 75% concentration (11.7 mL/L) of that recommended by the cleaning agent manufacturer.
2. Soak the devices in the cleaning solution for 1 minute. Record the time.
3. Clean the devices by washing with a soft bristle brush in the cleaning solution until all soil has been visually removed. Record the total time spent brushing the device.
4. Remove from the cleaning solution and rinse the devices in tap water for 0.5 minute. Record the time.
5. Prepare another batch of the neutral pH enzyme cleaning solution (Enzol®) at 75% concentration (11.7 mL/L) of that recommended by the cleaning agent manufacturer.
6. Soak the devices for 1 minute. Record the time.
7. Remove the devices from the cleaning solution and rinse in tap water for 0.5 minute. Record the time.
8. Visually inspect the instruments for visible contamination or debris and then dry with a lint free wipe.

STERILIZATION

WARNING: Do not sterilize these instruments with Ethylene Oxide (EO), Liquid Chemical (Cold Soak) or Sterrad

Recommended Steam Autoclave Sterilization Parameters

- The instrument(s) should be thoroughly cleaned of all foreign matter prior to sterilization following the steps above.








STERILIZATION PROCESS	EXPOSURE TEMPERATURE	EXPOSURE TIME	DRY TIME
Gravity Displacement	250° F / 121° C	30 minutes	30 minutes
Pre-vacuum	270° F / 132° C	4 minutes	30 minutes
Pre-vacuum	273° F / 134° C	3 minutes	30 minutes

STORAGE

Instruments should be stored dry in a moisture free area.

The instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect from damage if stored in drawers.

EXPLANATION OF SYMBOLS

-  Reorder number
-  Lot number
-  Consult instructions for use
-  Caution
-  Non-sterile
Sterilize before use
-  Do not use if package is damaged
-  Manufacturer

R_x Only

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