C Sterilization with an Approved Liquid Chemical Sterilant
Instruments must be cleaned thoroughly following steps A and B prior to cold sterilization. Cold soak solutions with 2% glutaraldehyde solution can be used for sterilizing the instruments. Instruments are to be fully immersed. Follow the manufacturer's instructions for sterilization times. Soak and rinse thoroughly in two separate sterile, deionized water baths. Dry instruments.

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.

STERILIZATION • Steam Autoclave Sterilization

- The instrument should be thoroughly cleaned of all foreign matter prior to sterilization.
- Follow the manufacturer's instructions for operation and loading of steam autoclave.
- There must be direct steam exposure to all surfaces of the instrument being sterilized.
- Autoclave temperatures should not exceed 280°F (137°C); pressure should not exceed 32 psi (2.2 atmospheres).
- Standard cycle of 270°F (132°C) for 10 minutes will vary depending on autoclave model, autoclave size, load size, and load configuration.

Allow longer times for lower temperatures. Allow instruments to cool down from autoclave to room temperature. Do not immerse in any fluid until the instrument has been allowed to cool.

Gravity Displacement Cycles	**Prevacuum Cycles**
270°—275°F / 10-15 minutes or 250°F / 15-30 minutes	270°—275°F / 3-4 minutes

ETHYLENE OXIDE

- Items should be thoroughly cleaned of all foreign matter prior to sterilization, following steps A and B.
- Follow the manufacturer's instructions for operation and loading of sterilizer. There must be direct exposure to all surfaces of the instruments being sterilized.
- Instruments should be sterilized in their "open" position.
- Contact of plastic to bare metal should be avoided.

STERILIZATION *(continued)*

RECOMMENDED HOSPITAL EHTYLENE OXIDE CYCLE

Temperature	125-130°F
50% RH (pre-humidity)	60 minutes
	-0/+10 minutes
Pre Vacuum	24" Hg ± 2" Hg
Gas Pressure	6-8 psig (550-660 mg/L EO)
Exposure Time	4 hours minimum
Post Vacuum	24" Hg 2X ± 2" Hg
Aeration	12-0/+1 hours at 120°F

NOTE The particular EO cycle should be validated per the equipment manufacturers requirements. It is recommended that each institution employ procedures which include the use of biological indicators in order to determine the effectiveness of the ethylene oxide process.

Part #34159 • Rev. 5/02

CooperSurgical
95 Corporate Drive
Trumbull, CT 06611
Phone: (203) 601-5200
Toll Free: (800) 243-2974
Fax: (800) 262-0105

Euro-Med® Biopsy Punches

DIRECTIONS 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
64-485	Oval 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

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

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DESCRIPTION

Cervical Bioipsy 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 cervicagraphic 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.

DIRECTION 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 $AgNO_3$. 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.

CARE

These instruments are made of high grade quality stainless steel and are long-lasting. They should be immediately cleaned of blood, secretions and debris after use and be sterilized. A sign of lack of sharpness is increased pain in performing a biopsy or inability to obtain a clean specimen. Sharpening service is available from CooperSurgical.

- Handle each instrument individually. Do not handle in groups or stacks.
- Replacement instruments should be kept on hand. Damage to movable parts can result in substandard performance of the instrument.
- Inspect instruments for integrity of movable parts (jaws, hinges, etc.), signs of damage (broken or cracked) or missing hardware (screws).

CLEANING

Rinsing and cleaning must take place immediately following the instruments use for decontamination. Adherent particles may resist cleaning and may cause improper sterilization.

Instruments are to be completely cleaned of all foreign matter with special attention focused on channels and movable parts in contact with body tissue and fluid. Thorough cleaning is essential prior to sterilization.

- Follow the instructions under "**CARE**" for proper handling of the instruments.
- Wear protective gloves during the cleaning procedure.
- Never use a corrosive cleaning agent (i.e. bleach).
- Fully immerse instruments in cleaning agent.

A Cleaning Agents and Equipment

- Cleaning agents and rinses at or near a neutral pH (7.0) is recommended.
- Use warm water and a mild soap.
- Do not use an abrasive cleaning solution.
- A soft bristle brush (toothbrush type) should be used.
- Round bristle brushes should be used to clean inside channels near the tips.
- An enzymatic cleaner is recommended to remove protein deposits on the instrument. Follow manufacturer's instructions and rinse thoroughly.

NOTE Soak and thoroughly rinse the instruments in warm tap water to remove cleaning agents. A final rinse in distilled water is recommended.

B Cleaning Method (after each use)

1. Rinse and/or pre-soak.
2. Manually clean with brushes using a mild soap and warm water.
3. Using a round bristle brush, clean inside the tip channel as follows:
    - warm water
    - . cleaning agent
    - warm water
4. Rinse.
5. Enzymatic cleaner.
6. Rinse.
7. Dry with cloth or gauze and filtered compressed air.
8. Inspection.
9. Prepare for storage and/or sterilization.

NOTE Dry instruments completely with compressed air (including inside channels) and/or a dry oven (maximum temperature 280°F).