

Euro-Med[®] Skin Punches

INSTRUCTIONS FOR USE

STERILE DISPOSABLE PRODUCT #'s

DD-2MM • 2mm • Green
DD-3MM • 3mm • Blue
DD-4MM • 4mm • Yellow
DD-5MM • 5mm • Pink
DD-6MM • 6mm • Orange

NON-STERILE REUSABLE PRODUCT #'s

68-180 • Keyes Vulvar Punch Set

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

DEVICE DESCRIPTION

Euro-Med® Skin punches are available from CooperSurgical's Euro-Med line as disposable single-use (see front cover for product range) or as stainless steel resterilizable instruments. These punches are indicated for biopsy of skin lesions and are particularly useful for vulvar biopsies.

INDICATIONS FOR USE

- Suspicion of malignancy, initial or recurrent vulvar dystrophies
- Granulomatous lesions
- Ulcerated lesions
- Papillomatous lesions
- Recurrent or recalcitrant condylomata

CONTRAINDICATIONS

None. However, complete visualization of the tissue is required.

WARNINGS

The patient should be informed of the slight pain of the local anesthetic and pressure of the biopsy itself. Minimal bleeding may be noted after the procedure but should respond to pressure alone.

PRECAUTIONS

The patient should not be allergic to local anesthetic. Multiple biopsies may be necessary and if malignancy is suspected, additional sampling may be necessary at a later time. Although small lesions may be removed by the punch, usually additional medical or surgical treatment may be necessary.

INSTRUCTIONS FOR USE

If punch is not provided STERILE, sterilize before use. Vulvar biopsies can usually be performed with local anesthesia. Occasionally, general or regional anesthesia may be required. The size of the punch should be large enough to obtain an adequate tissue sample. Additional equipment necessary includes: antiseptic, local anesthetic, silver nitrate stick, Monsel's solution (AstrinGyn®), fine suture, needle holder, fine scissors, 4" X 4" gauze, fine tissue forceps, fixative, sterile towel or drape for instrument tray.

After prepping with an antiseptic, local anesthesia is infiltrated from the lateral margin of the lesion, underneath the lesion itself. The biopsy punch is held against the lesion, usually in the center of the lesion and pressure applied while using a twisting motion to penetrate the surface. The sample plug is lifted with tissue forceps and cut at the base. Multiple biopsies may be necessary in larger lesions or with multiple lesions. After the biopsies are placed in a fixative, on a piece of paper toweling or in a tissue cassette, homeostasis is achieved by silver nitrate, Monsel's solution (AstrinGyn®) or suture. No dressing is usually necessary. The location (s) of the biopsy (ies) should be diagrammed on the patient's chart and the pathology request form. When applicable, separate specimen jars should be used to identify each of the lesions.

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.
- 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 with cloth or gauze if stored in drawers.

EXPLANATION OF SYMBOLS

REF	Reorder number		Non-sterile Sterilize before use (Note: For Keyes stainless steel punches only)		Not made with natural rubber latex
LOT	Lot number		Do not use if package is damaged		Manufacturer
	Consult instructions for use		Do not re-use	STERILE EO	Sterilized using ethylene oxide
	Caution		Do not re-sterilize	R_x Only	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

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