

# TIS-U-TRAP™

## UTERINE SUCTION CURETTE SET

### INSTRUCTIONS FOR USE

#### DEVICE DESCRIPTION

The Tis-U-Trap™ Uterine Suction Curette Set is a sterile, single-use device used for endometrial tissue retrieval and collection. The Tis-U-Trap Set requires an external vacuum source.

Each Tis-U-Trap Set is sterile packed with a curette, collection chamber and label, double-sealing cap, funnel and zip bag. For your convenience, the Tis-U-Trap Set comes in the following types and sizes:

PART NUMBER	CURETTE TYPE & SIZE	FILTER DESIGN
MX403, MX404 MX405, MX406, MX407	<b>Flexible:</b> 3, 4 mm 5, 6, & 7 mm	Flat Cone
MX413, MX414 MX415, MX416, MX417	<b>Semi-Rigid:</b> 3, 4 mm 5, 6, & 7 mm	Flat Cone
MX448 - MX452 (respectively)	<b>Rigid:</b> 8, 9, 10, 11 & 12 mm	Cone
MX422, MX423	<b>Stainless Steel:</b> 2, 3 mm	Flat



NOTE: The Tis-U-Trap collection chambers can be purchased separately.  
Flat filter design: MX400FLAT; Cone filter design: MX400CONE

#### WARNINGS

- Use of the device without sounding of the uterus and the ensuing curettage may result in perforation of the uterine wall.

#### CAUTIONS

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

#### PRECAUTIONS

- Cervical manipulation may cause a vaso-vagal reaction.
- Patients with a stenotic cervix may require anesthesia.
- Patient may experience pelvic discomfort for the duration of suction. There may be spotting and mild cramping after the procedure has been performed. The patient should be instructed to contact her physician if bleeding persists or if low-grade fever is present.
- Inadequate tissue collection may occur in the presence of the following conditions: atrophic endometrium, enlarged uterine cavity, or existence of large polyps or fibroids.

#### INDICATIONS FOR USE

At the discretion of the physician, this device is indicated for uterine cancer screening and periodic endometrial monitoring of those patients with higher risk factors for cancer (i.e., obesity, hypertension, diabetes, nulliparity infertility and dysfunctional bleeding). Additional Indications for Use include:

- Detection of endometrial hyperplasia
- Detection of endometrial cancer
- Endometrial dating
- Initial endometrial biopsy prior to prescribing estrogen replacement therapy

## INDICATIONS FOR USE (continued)

- Periodic monitoring of endometrial tissue in women receiving estrogen replacement therapy
- Examination of glandular epithelium to determine ovulation and endometrial response to hormonal excretion and therapy
- Infertility investigation and/or detection of infertility pathology
- Bacterial culturing
- Monitoring patient receiving therapy for breast cancer
- Secondary amenorrhea
- Extraction of uterine menstrual content
- Extraction following spontaneous or incomplete abortion
- Extraction prior to hysteroscopy
- Extraction prior to endometrial ablation in patients with dysfunctional uterine bleeding
- Investigation of dysfunctional uterine bleeding

## CONTRAINDICATIONS

- Use of small size curettes for incomplete abortions of seven weeks or longer gestation (where tissue may clog the curette). The larger suction cannula-curettes are available for this usage.
- Patients in whom pregnancy is suspected, patients with, or recovering from, pelvic inflammatory disease or patients with any suspected cervical or pelvic infection
- Patients suffering from disease or conditions that would, under any circumstances, contraindicate out-patient surgical treatment

## PRIOR TO USE

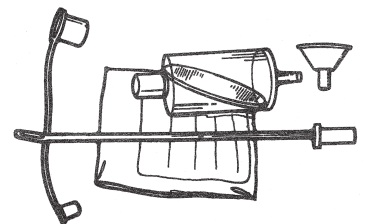
VACUUM SOURCE: For effective operation of the Tis-U-Trap™ Uterine Suction Curette Set, it is necessary to have a vacuum source capable of producing 25-28 inches of Hg (57-70 cm) of negative pressure within seconds of activation. This source must have a trap to prevent any fluid from getting into the pump mechanism. It is also desirable to have “lightweight” in-line plastic tubing allowing easier manipulation of the curette.

## INSTRUCTIONS FOR USE

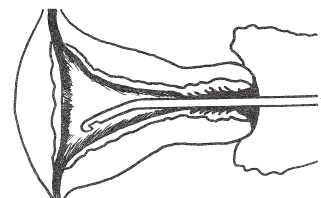
Prepare the vaginal area and cervix for an intrauterine procedure. Sound the uterus to determine its position and the proper curette size. Measure the depth of the uterine cavity. For ease of curette insertion, position the uterus using a tenaculum and perform dilation, if needed. No anesthesia or premedication is necessary to insert the curette in most cases.

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- 1** Open package. Check contents for Tis-U-Trap, curette, double sealing cap, funnel, Patient Identification label and Pathologist zip bag.

Affix Patient Identification label to the Tis-U-Trap. Attach the small port of the Tis-U-Trap to the 1/4 inch tubing on the suction pump.



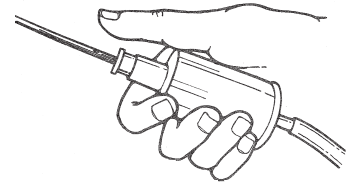
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- 2** Cleanse cervix for intrauterine procedure. After sounding uterine cavity, insert the curette to the fundus. If flexible curette is used with stilet, remove and discard the stilet once the curette is past the internal os.



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Attach the curette to the Tis-U-Trap™. Switch pump ON. The vacuum is controlled by covering the vacuum release hole located on the curette next to the Tis-U-Trap. For convenience, the vacuum release hole and curette edge are aligned. With thumb completely covering the vacuum release hole, wait three seconds before manipulating curette to allow the suction pump time to produce the required negative pressure for effective operation.



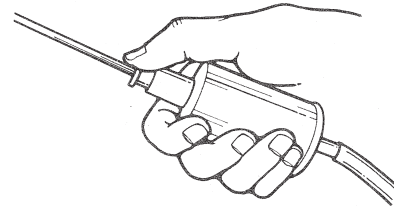
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Use long, slow strokes to obtain tissue from all four quadrants. At the **end** of each pass, **uncover** the vacuum release hole until the curette is brought back to its original position at the top of the fundus. The vacuum release hole at the proximal end of the curette is always **covered** during the downward stroke with the curette, and **uncovered** when the curette is moved back up to the top of the fundus for another pass.

In the event of an apparent clogging, withdraw the curette completely so that air is aspirated through the distal openings to suck the mucosa from the curette into the Tis-U-Trap. **Cover the vacuum release hole during withdrawal.**

**Uncover** the vacuum release hole when reintroducing the curette into the uterus. Once the curette is reinserted, cover the hole and wait three seconds before manipulating curette, to allow negative pressure to build.

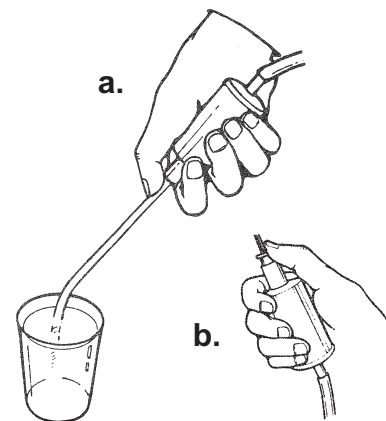


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a. Within one hour of the endometrial biopsy, aspirate a fixative (formalin or other suitable fixative) while the pump is still operating. Fixative may be aspirated directly from any clean container through the curette and Tis-U-Trap. This serves the dual purpose of cleansing the tissue of possible blood clots and ensuring that only a minimal amount of tissue remains in the curette. Cover the vacuum release hole during this operation. **DO NOT** reintroduce the curette into the uterus once it has been exposed to the fixative.

b. Hold Tis-U-Trap with curette facing upward to drain blood and fixative from the Tis-U-Trap. Turn OFF suction pump.

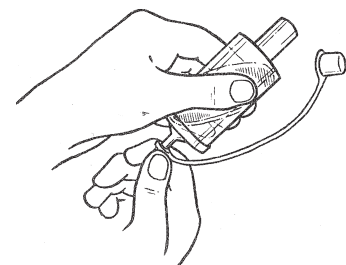


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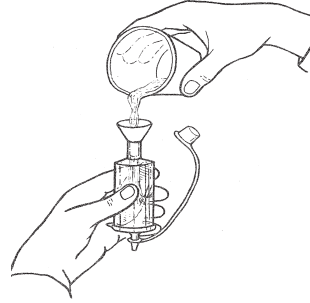
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Locate the double sealing cap. While holding the Tis-U-Trap, detach the 1/4 inch tubing. Affix the small end of the double sealing cap with a twisting motion to the small port on the Tis-U-Trap.

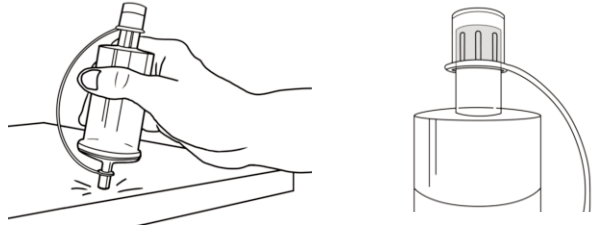
Holding the Tis-U-Trap with the curette port up, detach the curette from the Tis-U-Trap and place funnel into opening.



**7** Fill the entire Tis-U-Trap™ with fixative.

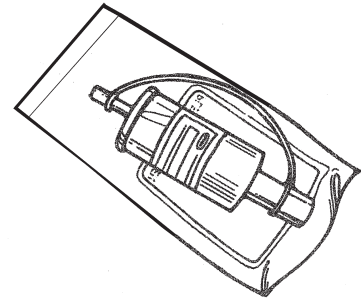


**8** Affix the large end of the double sealing cap with a twisting motion to the large port of the Tis-U-Trap. Tap **both** ends smartly on the work surface, and check that the edge of the Trap is at or beyond the top of the visual markers of the cap on **both** ends, ensuring that the Trap is securely sealed.



**9** Place the sealed Tis-U-Trap into the zip bag. Place the zip bag with contents on its side for approximately 10 minutes—allowing the caps to swell to form a perfect seal on the Tis-U-Trap ports. Zip the bag closed.

NOTE: A small amount of solution may leak out until the plastic caps swell. No tissue will be lost.



**10** Dispose of curette in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

#### EXPLANATION OF SYMBOLS

REF Reorder number

LOT Batch code

Use-by date

STERILE EO Sterilize using ethylene oxide

Do not re-use

Caution

Consult instructions for use.

Not made with natural rubber latex

Rx ONLY Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Do not use if package is damaged

BIOHAZARD Biological Risks

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**CooperSurgical**

Made in the USA

95 Corporate Drive, • Trumbull, CT 06611 USA  
Phone: (800) 243-2974 • Fax: (800) 262-0105  
www.coopersurgical.com

International  
Phone: (203) 601-9818  
Fax: (203) 601-4747

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