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:

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<th>PART NUMBER</th>
<th>CURETTE TYPE &amp; SIZE</th>
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<td>MX403, MX404</td>
<td>Flexible: 3, 4 mm, 5, 6, 7 mm</td>
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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
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 facing upward, detach the curette from the Tis-U-Trap and place funnel into opening.

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

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.

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.

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

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 hysterectomy
- Extraction prior to endometrial ablation in patients with dysfunctional uterine bleeding
- Investigation of dysfunctional uterine bleeding

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.
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.

B. HOLD TIS-U-TRAP WITH CURETTE FACING UPWARD TO DRAIN BLOOD AND FIXATIVE FROM THE TIS-U-TRAP. TURN OFF SUCTION PUMP.

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.

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.

C. 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.

CLEANSE CERVIX FOR INTRAUTERINE PROCEDURE. AFTER SOUNING UTERINE CAVITY, INSERT THE CURETTE TO THE FUNDSUS. IF FLEXIBLE CURETTE IS USED WITH STYLET, REMOVE AND DISCARD THE STYLET ONCE THE CURETTE IS PAST THE INTERNAL OS.

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.

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 FUNDSUS. 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 FUNDSUS 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.

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.
TIS-U-TRAP™
UTERINE SUCTION CURETTE SET
INSTRUCTIONS FOR USE

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