


## EXPLANATION OF SYMBOLS


**REF** Reorder Number


**LOT** Batch Code

 Use By

**STERILE**  Ethylene Oxide Sterilized

 Do Not Reuse

 Latex Free

 **Attention:**  
See instructions for use.

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# MX500 • 60 cc Handyvak Locking Syringe

## For use with 2 mm thru 7 mm Cannula-Curette

### Directions for Use

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#### DEVICE DESCRIPTION



- For early detection of endometrial carcinoma
- The Cannula-Curette is supplied in assorted sizes: 2 mm and 3 mm (stainless steel) and 3 mm thru 7 mm (flexible and semi-rigid). They are individually sterilized and packaged as a completely disposable device for office or clinic use.

Note: The 8 mm thru 12 mm Cannula-Curettes (rigid plastic) are to be used with suction pump and swivel handle or Tis-U-Trap only. The 8 mm thru 12 mm size Cannula-Curette should NOT be used with 60 cc Handyvak Locking Syringe.

#### WARNINGS

- Do not depress the syringe plunger while Cannula-Curette is in uterus.
- If the vacuum is lost, proceed to step 3 after resetting locking device.
- Any cervical manipulation may cause a vaso-vagal reaction. Patient should be watched for evidence of unusual pallor, nausea, vertigo or weakness. By remaining recumbent for 3 to 10 minutes these symptoms usually disappear.
- Patients experiencing continued bleeding with cramps may require reaspiration. This may be an indication of retained tissue.
- If patient remains febrile consider evaluation and treatment for pelvic infection.
- Possible perforation of the uterus must be guarded against both while sounding the uterus and using this device. No undue force should be exerted at any time.

#### CAUTION

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

#### INDICATIONS FOR USE

The primary uses for this device are for endometrial sampling especially of those patients with a higher risk of cancer. The device may also be used in the following situations: evaluation of infertility, and incomplete abortion (up to 7 weeks gestation). This self contained device affords a quiet, simple office procedure for obtaining an endometrial tissue sample for histologic evaluation.

#### CONTRAINDICATIONS

- This device is contraindicated where viable pregnancy is suspected and desired.
- Patients suffering from diseases or conditions which contraindicate outpatient surgical procedures, e.g., pelvic inflammatory disease, acute infections of the cervix, clotting mechanism deficiencies, severe anemia, heart disease or extreme anxiety.



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- In general the same criteria for regular endometrial biopsy or D & C must be followed in office curettage. Contraindications of conventional D & C are contraindications for office curettage. Instructions to patients should be generally similar for both procedures.

## DIRECTIONS FOR USE

Any endometrial biopsy should be preceded by a routine bimanual examination. If no contraindications for endometrial curettage are present (see contraindications), the cervix and vault should be swabbed with an antiseptic solution. It may be necessary to grasp the cervix with a tenaculum and apply gentle traction to straighten endocervical canal. Request for anesthesia is rare in endometrial biopsy.

In rare cases when it remains difficult to insert the desired Curette size, Millex™ Dilateria (Laminaria) should be considered for prior dilatation. (If the smallest size is placed into the cervix 1 to 6 hours preceding the vacuum curettage, the cervix will be dilated and softened, and will pass the curette with ease).

- Carefully sound uterus to determine position and depth of uterine cavity.  
NOTE: It is recommended that you transfer this measurement to patient's chart.
- Insert curette to depth determined by uterine sounding, if a flexible curette is used, be certain that stylet is removed after curette has passed the internal cervical os. There may be a minimal amount of pain when the curette is inserted. This may be reduced by placing a cotton swab soaked in a dilute solution of a suitable topical anesthetic within the internal os for approximately one minute before inserting curette.

**Note:** Before Attaching Syringe to Curette the 60 cc Handyvak Locking Syringe is shipped with first notch engaged. To start procedure turn plunger ¼ turn counter clockwise and press plunger to bottom of syringe barrel.

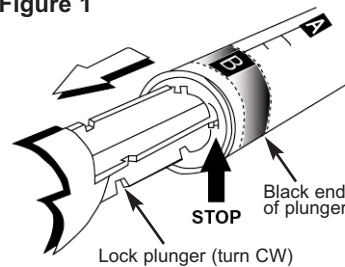
- Tightly attach the curette to the Handyvak Syringe. Twist to lock in place. The curette and syringe are ready for use.
- Hold barrel of syringe firmly. Withdraw plunger until black end of plunger is aligned with either barrel markings Block **A** or Block **B**.

- To lock plunger, twist ¼ turn to the right (clockwise) See **Figure 1**
- To unlock plunger, twist ¼ turn to left (counter clockwise). See **Figure 2**

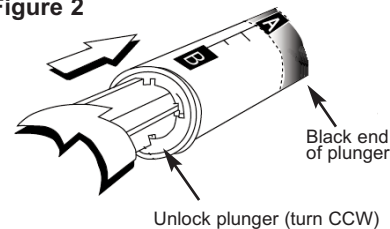
Position **A**: For more sensitive cannula-curette feel.

Position **B**: For maximum negative pressure (especially when using larger size cannula-curettes).

**Figure 1**



**Figure 2**



## CAUTION

The plunger must be in a locked position (Block **A** or Block **B**) before you begin the curettage.

- Follow usual curettage procedures and precautions. Better control is achieved if the curette itself is held and manipulated, not just the syringe. On the flexible and semi-rigid models the word Millex™ is approximately in line with the curette edge for ease of determining which quadrant the sample is coming from. On the 2 mm and 3 mm (stainless steel) curettes, the flat portion of the curette base is approximately in line with the curette edge.
- If it becomes necessary to reduce or eliminate vacuum:
  - Twist to detach curette from Handyvak Syringe.  
NOTE: If any specimen is in the syringe, it is wise to perform this step over a clean collection jar to catch the sample. Small collection jar should be half filled with fixative.
  - To disengage, turn plunger ¼ turn counter clockwise and press plunger to bottom of syringe barrel.
  - Collect any sample material as it is expressed. Handyvak Syringe is now in its original (unused) position.
  - If further curettage is required, reattach Handyvak Syringe as in step 3 and proceed.
- When procedure is completed:
  - Withdraw curette from the uterine cavity.
  - Hold curette over the clean collection jar with fixative to catch the specimen. Withdraw plunger slightly. Turn ¼ turn counter clockwise.
  - Push plunger into barrel of syringe thus expressing sample into collection jar. Many experts recommend using the syringe to draw a small amount of fixative into curette and then expressing this into collection jar. This serves to rinse both the curette and syringe.
  - Discard curette and syringe. Add additional fixative to jar containing endometrial tissue sample. Note: endometrial tissue is highly hygroscopic and requires about 10 times its volume in fixative to keep in a satisfactory condition for a reasonable period of time. Also, if endometrial tissue is not properly fixed within one hour of the biopsy, analysis by the pathologist is compromised.
  - Identify sample and tightly close the collection jar. Sample is ready for delivery to the laboratory.
- In later gestational stages, it may be necessary to dilate the cervix: Dilateria (Laminaria) should be considered in these cases. Such cases generally require larger size curettes to be used with a suction pump and swivel handle. Curettes sizes 8 mm or larger should NOT be used with a 60 cc syringe as a suction source.
- Post Operative instructions to Patient: Contact physician any time you have a question, a fever above 101.4 °F, bleeding or cramps in excess of normal menstruation or any unusual pain.
- Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous Waste practices.