

Pro-Ception™ Fertility Cannula

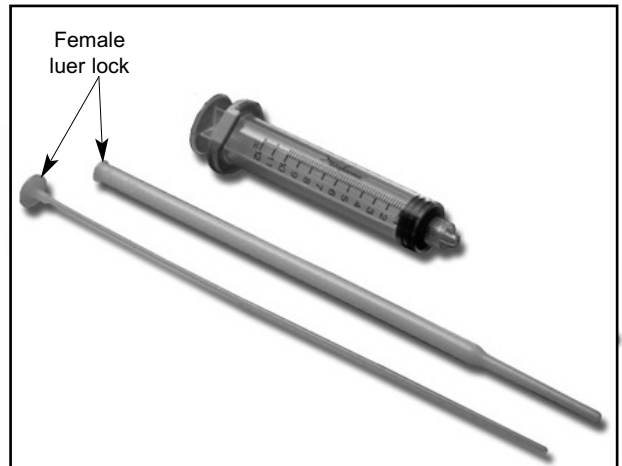
MX710 • Cannula

MX720 • Cannula with Vacu-Lok Syringe

Instructions for Use

DEVICE DESCRIPTION

This cannula with Vacu-Lok Control Syringe is designed for the following procedures: postcoital testing (Huhner), removal of mucus plug, testing interaction of sperm and cervical mucus viscosity, fractional sampling of cervical mucus, determination of ovulation, identification of antisperm antibodies, and microscopic determination of colonizing microorganisms.



INDICATIONS FOR USE

Fertility assessment such as: postcoital testing (Huhner), removal of mucus plug, testing interaction of sperm and cervical mucus viscosity, fractional sampling of cervical mucus, determination of ovulation, identification of antisperm antibodies, and microscopic determination of colonizing microorganisms.

WARNING

- Contents supplied sterile. Do not use if sterile barrier is damaged.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.
- Care should be taken prior to insertion to avoid perforation of the uterine cavity. In no case should the device be forced against resistance.

CAUTION

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

PRECAUTION

In any sampling from the cervical canal, use care in monitoring the patient for vasovagal reactions. Patient should be watched for evidence of unusual pallor, nausea, vertigo or weakness. These symptoms will generally respond to about 15 minutes of rest and/or a mild analgesic.

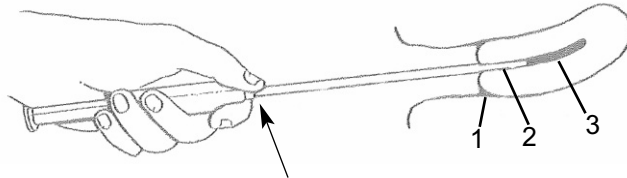
DIRECTIONS FOR USE

Postcoital examination should be scheduled one to three days **prior** to expected rise in basal body temperature (BBT) to ensure the postcoital test (PCT) is performed during the time of maximal estrogen stimulation.

The PCT should be performed within 2 to 3 hours of coitus since reports have shown the maximum number of sperm are present in the cervical canal 2 to 2-1/2 hours after coitus.

Post-Coital Test (Huhner Test)

1. To facilitate a trauma-free passage, cannula should be hand formed (not bent) into the necessary curvature before removing from sterile packet.
2. Before aspirating cervical mucus, cleanse cervix and surrounding vaginal area using a **dry** cotton swab.
3. Cervical mucus/semen specimen is procured at different levels by the use of a series of **Sterile Cannula**.



- (1) Posterior vaginal fornix*
- (2) External os.
- (3) Internal os.

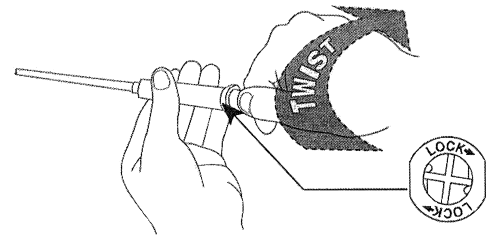
* A smear from the posterior vaginal fornix should always be obtained to ensure sperm were deposited into the vaginal vault.

4. Stylet should be left in position as cannula is inserted to positions 2 and 3 to prevent contamination with cells from a previously sampled area.
5. Once in position, the stylet is removed and a luer lock collar syringe attached. Moderate suction is applied immediately by withdrawing plunger and locking plunger in place.

To Lock Plunger:

Depress plunger to the bottom of syringe barrel. This is the starting position of the syringe when it is attached to the cannula curette. Withdraw plunger to desired level of negative pressure. One-hand control of syringe/curette assembly is obtained by twisting withdrawn plunger 1/4 turn clockwise to lock-in negative pressure. (Check to be sure plunger is secure)

- 6 cc gives you 15 inches of negative pressure (approximate)
- 9 cc give you 18 inches of negative pressure (approximate)
- 12 cc gives you 20 inches of negative pressure (approximate)



6. The CANNULA is removed and the outside of it is wiped off with sterile gauze to remove additional cells picked up during withdrawal.
7. To express material onto slide, **unlock** plunger by twisting **counter-clockwise** (to the left) 1/4 of a turn. If any mucus is left in cannula, reintroduce stylet into cannula expressing remaining mucus onto slide.

EXPLANATION OF SYMBOLS



Reorder number



Not made with natural rubber latex



Batch code



Do not re-use



Use-by date



Consult instructions for use



Sterilized using ethylene oxide



Do not re-sterilize

R_x Only

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Do not use if package is damaged



Caution



Manufacturer

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