

INSTRUCTIONS FOR USE:

1. Position the patient in the lithotomy position on operating table. Local or general anesthetic may be administered as necessary.
2. Carefully remove the needle from the packaging maintaining the sterility of the product.
3. The sterile needle should be inspected for tip sharpness and kinking of any supplied tubing.
4. Connect the needle's vacuum tubing to a vacuum pump. The vacuum used with a specific gauge and/or type of ovum pick-up needle is at the discretion of the clinician performing the procedure.
5. For needle sets, fit the silicone stopper onto the collection tube (designed to fit 15 mL Falcon tubes).
6. The aspiration system should be tested for patency by placing the tip in a spare test tube containing approximately 5 mL of culture medium and applying vacuum. Before proceeding, change the collection test tube.
7. Introduce an ultrasound transducer into the vaginal fornix to visualize the ovary and follicles. Identify the follicles to be aspirated. Check for the presence of blood vessels in and around the ovary and determine a direct path into the ovarian follicles to be aspirated.
8. Insert the aspiration needle or guide needle into the transducer needle guide. Ensure the tubing does not become kinked during use. Puncture vaginal wall with needle or guide needle. If guide needle used, advance aspiration needle in preparation for follicle puncture.
9. Following visualization of the follicle to be aspirated, line up the follicle using the needle guide on the ultrasound monitor and advance the needle tip into the center of an ovarian follicle via a rapid, stabbing motion. The combination of the needle bevel and curved tip enhances visualization of the position of the needle tip. The handle indent indicates bevel orientation as well as facilitating grip.
10. Apply vacuum to aspirate the follicular contents into the test tube. As the follicle collapses, rotate the needle tip within the follicle to curette the follicular walls. If required the follicle can be flushed, as described below. Repeat steps 9 and 10 on the remaining follicles.
11. Withdraw the needle from the patient and reposition the transducer to visualize the remaining ovary. Repeat steps 8 to 10.
12. At the completion of the aspiration procedure, remove the needle from the ultrasound guide, rinse with flushing buffer and then discard in an appropriate sharps container.

SEE PRODUCT LABEL FOR:



Follicle Aspiration Needle- English
FOLLASNE-IF1

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FOLLICLE ASPIRATION NEEDLE

DEVICE DESCRIPTION:

The Follicle Aspiration Needle is used to harvest ovarian tissue, as well as flush oocytes from the follicles.

INDICATIONS FOR USE:

Oocyte Pick-Up Needle is used in infertility treatment for the transvaginal retrieval of oocytes from follicles for IVF and ICSI procedures.

CONTRAINDICATIONS:

This device should not be used in the presence of:

- Active pelvic infection
- Sexually transmitted disease
- Pregnancy
- Confirmed or suspected intrauterine device
- Uterine perforation

WARNINGS:

Intended for one time use only. This is a sterile device and should be stored at room temperature away from direct sunlight. If the product package is open or damaged when received, do not use the device.

CAUTION:

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

PRECAUTIONS:

Where possible, the needle tip should be kept within the stroma or follicles to prevent the aspiration of air into the needle. This minimizes the potential for oocyte damage and 'frothing' in the test tube. Hematuria may occur due to the aspiration needle penetrating a filled bladder during transvaginal ultrasound aspiration. This complication typically resolves spontaneously within a day. Extravasation of urine may occur within the abdominal cavity if a needle puncture traverses the bladder. Patients should be monitored for evidence of this known complication; however, there is typically no associated discomfort or adverse sequelae. Infection may be introduced via needle puncture and result in urinary tract infection (UTI), pelvic inflammatory disease (PID), uterine infection or cystitis. Vaginal bleeding has been reported to be associated with the transvaginal route for oocyte retrieval via needle aspiration. Bleeding is typically easily controlled with direct pressure.

ADVERSE REACTIONS:

There have not been any reports of any adverse reactions to the Follicle Aspiration Needle.