

Mona Lisa[®] Aspiration Needle

Instructions for use

Intended use

For ultrasound-guided transvaginal collection and transport of oocytes from ovarian follicles.

Product description

The Mona Lisa Aspiration Needle is a sterile, latex-free, single use device. The device consists of a single-lumen stainless steel needle, attached to tubing in a single unit. The needle with 3 bevel lancet shape point is available in different gauge sizes and lengths. Each needle having echo marking at the distal tip for ultrasound reflection and guidance, and a plastic hub with orientation nipple at the proximal end to aid guidance. Tubing is attached to the proximal end of the needle and protrudes until it terminates in a silicone bung.

Contraindications

The presence of chronic cervical infection or in the presence of or after recent Pelvic Inflammatory Disease (PID) contraindicate the use of this product.

Not intended for intrafallopian tube procedures.

Precautions and warnings

- Oocyte recovery should be performed under either general anaesthetic or analgesia.
- Apply pressure suprapubically and enter the follicles with a stabbing movement if the ovaries are mobile.
- To minimize trauma and the possibility of bleeding, keep the needle tip within the ovary between aspirations.
- When fitting the syringe, care should be taken to avoid damage to any extracted oocytes that may be located in the Luer taper.
- Do not re-sterilize.
- Do not use if packaging is damaged.
- Failure to use ultrasound to locate the follicles may result in failure to obtain the required sample and/or tissue damage.
- If a vacuum pump is used, ensure that the recovery portion of the tubing extends to the lower section of the test tube to prevent damage to the zona pellucida of aspirated follicles.
- If vaginal bleeding is experienced post-collection, steady pressure with a sponge and forceps should be applied or an absorbable suture placed.

Technical support



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Distributor:













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Directions for use

Below are suggested directions for use. The final decision on the technique used is the responsibility of the physician in charge.

1. Place the patient in the lithotomy position, prepare the vulva and vagina for full aseptic technique and cover the area in sterile drapes.
2. Cover the ultrasound transducer with a sterile polyethylene sleeve with a small amount of coupling gel covering the end of the probe within the sleeve. Introduce into the vagina and scan the pelvis to establish the position of the uterus, the development of the endometrium and the number and position of follicles to be aspirated. Remove the transducer.
3. Remove the Mona Lisa Aspiration Needle from its packaging and insert the needle into the needle guide of the ultrasound transducer, ensuring that there is smooth movement along its length.
4. Attach a sterile plastic test tube to the silicone bung, ensuring that the recovery portion of tubing reaches lower in the tube. Attach a syringe or vacuum pump to the Luer lock of the tubing.
5. Insert the ultrasound transducer and needle into the vagina and direct the probe towards the posterolateral aspect of the vaginal fornix. Manipulate the probe until the follicles appear in close proximity to the needle.
6. Advance the needle into the nearest follicle. The tip of the needle can be seen in the follicle, the contents of which are then aspirated until empty by means of the attached syringe or vacuum pump. Gentle manipulation of the follicle may assist separation of oocytes from the follicle wall.
7. Remove the plastic test tube from the silicone bung when full. A second tube can be used if a large volume of follicular fluid is obtained.
8. Withdraw the needle from the follicle and with the needle tip within the ovary, attach another sterile plastic test tube and repeat with the next follicle.
9. When all follicles in one ovary have been aspirated, repeat the procedure with the other ovary. When all accessible follicles have been emptied, aspirate any blood or fluid that is present within the pouch of Douglas.
10. Withdraw the transducer and needle. Check the vagina for any signs of bleeding and allow the patient to rest.
11. Dispose of the Mona Lisa Aspiration Needle in accordance with local medical hazardous waste practices.

Used symbols

SYMBOL	MEANING
RUN	Run number
	Catalogue number
	Batch code / Lot
	Use by (expiry date) (YYYY-MM-DD)
	Manufacturer
	CE mark
	Mouse Embryo Assay
	Limulus Amoebocyte Lysate
	Do not reuse
	Temperature limitations (store at 0° - 35°C)
	Irradiation sterilized
	Do not use if package is damaged
	Consult instructions for use