

## Intended Use

The oocyte aspiration needles are used for transvaginal aspiration and flushing of oocytes from the ovarian follicles of women undergoing IVF treatment. The product is intended for single use on one patient.

*The intended users are specialized personnel (physicians, medical doctors) in fertility clinics. The product may only be used by specifically qualified personnel with appropriate expertise, experience and training.*

## Product description

- All oocyte aspiration needles are made of stainless steel and, depending on the variant, have a plastic handle or a stainless steel handle. The products are sterilized by gamma-irradiation and sterile packed individually.
- The oocyte aspiration needles are available in different sizes and designs for the respective field of application and individual user requirements. A summary of the various available specifications is described below.
  - Available sizes of needle: Gauge 16, 17, 18, 19, 20, 21, 22
  - Types of cut (tip): „Lancet bevel“ or „Back Cut Bevel“
  - Ultrasonic markings (tip): 5-ring milled, 20-ring milled, dots, micro blasted, black etched
  - Versions (only in part): single lumen system without flushing, single lumen system with flushing, single lumen medical stainless steel, double lumen medical stainless steel
  - Different lengths of tubing and connections

For detailed specifications please refer to the product brochure.

## Pre-use checks

- Check the integrity of the packaging and the product. If the sterile packaging is damaged, please discard the product.
- Check the expiration date. If the expiration date has expired, please discard the product.

## Preparation

- Open the sterile packaging by pulling the foil evenly from the paper with a wide, firm grip.
- Visually check that the follicle aspiration needle is not damaged.

## Instruction for Use

- Position the patient in a dorsal lithotomy position and expose the cervix to view using a vaginal speculum.
- Cleanse before inserting the needle following your standard protocol.
- Connect the product to the co-used products (pump, etc.).
- If necessary, attach the needle guide (not part of the kit) to the ultrasound probe.
- If necessary, the follicle aspiration needle can be locked to the holder of the ultrasound probe.
- Insert the needle according to your standard procedure and localize the follicles with the assistance of ultrasound.
- Aspirate (and flush) the oocytes from the follicles, and collect the oocytes in a tube.
- When focusing on the other ovary, remove the needle first and reposition on the ultrasound transducer.
- Remove the needle from the uterus.
- Discard of the used product as indicated under national law.
- Let your patient recover.

## Quality control

- Sterilized by gamma radiation to a sterility assurance level (SAL) of  $10^{-6}$ .
- Limulus Amoebocyte Lysate Test (LAL)
- Non-toxic to embryos - detected by mouse embryo assay (MEA).
- Batch analysis certificate available on request.

## Contraindications

- There are no known contraindications associated with the use of the product.

## Explanation of symbols

	Consult instructions of use		Do not use if the packaging is damaged
	Catalogue number		Store dry
	Lot number		Keep away from sunlight
	Sterilized by irradiation		Date of Manufacture
	Do not resterilize		Manufacturer
	Expiration date		Caution
	Do not reuse		

## Storage instructions

- We recommend a clean, dry and protected from direct sunlight storage.

## Disposal

- Dispose of the follicle aspiration needle and packaging in a suitable container, in accordance with national regulations.

## Warnings

- The product may only be used by qualified personnel with appropriate knowledge, experience and training.
- Handle products with care. The follicle aspiration needle is sharp and pointed at the tip - cut and puncture injuries.
- The handling of biological samples and accessories must be carried out observing and complying with the applicable hygiene and safety regulations.
- Do not reuse - the products are for single use only.
- Do not use if product or packaging is damaged before use.
- Keep away from direct sunlight and protect from moisture.
- Do not use after the expiration date.
- Intended for intended use only.

## Contraindications

- The product should not be used in patients with vaginal or intrauterine infection, sexually transmitted infections or current pregnancy.
- The responsibility to select the product diameter that is suitable for the respective patient situation rests solely with the doctor responsible for carrying out the egg retrieval. Gynemed declines all responsibility for damage to the patient in the event of incorrect product selection.
- Do not use in case of (chronic) cervical infection.
- Do not use in case of acute or recent inflammation of the abdomen.

## Possible known complications

- Hematuria can occur due to penetration of the urinary bladder. This complication usually resolves spontaneously after 24 hours.
- When the needle passes through the bladder, urine can extravasate into the abdominal cavity. Signs of this known complication should be monitored. In general, however, this does not involve pain or undesirable side effects.
- The puncture process can lead to infections (e.g. inflammatory pelvic diseases, urinary tract infections, cystitis and intrauterine infections). It is recommended to rinse the needles (as well as all other aids) with sterile, embryo-compatible culture media and to work strictly sterile.
- The occurrence of vaginal bleeding associated with transvaginal access through egg aspiration is known. The bleeding can generally be stopped quickly by compression.