

Instructions For Use

Kitazato OPU Needle with Connection Tube (model number Type2)

General Information

Refer to the label on the product or package before use.

Symbols on the Label

	DO NOT REUSE		ETHYLENE OXIDE GAS		MANUFACTURER
	USE BY		BATCH CODE		RE-ORDER NUMBER

Indication for Use

The Kitazato OPU Needles are intended to obtain oocytes from ovarian follicles.

Contraindications

- Not intended for intrafallopian tube procedures
- Should not be used in the presence of active vaginal infection, active intrauterine infection, a sexually transmitted disease, a recent uterine perforation, a recent caesarean section, current pregnancy, or after recent pelvic inflammatory disease.

Precautions

- (1) Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
- (2) Read this Instructions For Use prior to using the device.
- (3) 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.
- (4) 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, infection may be introduced via needle puncture and result in urinary tract infection (UTI), pelvic inflammatory disease (PID), uterine infection or cystitis.
- (5) 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.
- (6) The product may only be used by, or under the guidance of, a person qualified in gynaecological and follicle aspiration procedures.
- (7) Confirm the specification (gauge and length) of the needle before opening the package.
- (8) Ensure to use an appropriate transvaginal ultrasound probe guide with an inner diameter larger than the outer diameter of the needle.
- (9) Pay attention to the needle tip and do not expose the tip until it is used for puncture.
- (10) Do not use the product that is past the expiration date.
- (11) If the product has damage, the packaging has been compromised, or the package has been damaged, discard the product.
- (12) Before use, please flow a solution such as physiological saline through the needle to check for leakage. If any leakage is observed, a small air bubble might form inside the sampling tube. Do not use the product if leakage is observed.
- (13) If it is necessary to remove a clog, the procedure must be performed with the needle tip outside the body to reduce potential injury to the patient.
- (14) Throw the product away promptly after use by standard clinic protocol.
- (15) Do not re-sterilize or re-use the product; the device is single-use only.
- (16) Immediately use after opening the package.

Product Design

The needle of the Kitazato OPU Needle is passed through the probe guide of the transvaginal ultrasound and used to puncture the vaginal wall and obtain oocytes from the ovary. Details of each device type are as follows:

This Type 2 model is comprised of the OPU Needle with Connection Tube.

Model	Reference	Color of Hub	Needle O.D. (mm)	Needle Gauge	Needle Length (mm)	Needle ID (mm)	Wall Thickness (mm)	Needle Bevel Angle	Connection Tube Length (mm)	Connection Tube O.D. (mm)	Connection Tube ID (mm)	Stopper Size	Tube size Compatible with Stopper
Type2 v1/v10	326000 326355*	White	1.65	16	350	1.19	0.23	14°	800 1000	2.0	1.4	2.5	1.4 (2.5)
Type2 v2/v11	327000 357364	Light brown	1.49	17	350	1.06	0.22	14°	800 1000	2.0	1.4	2.5	1.4 (2.5)
Type2 v3/v12	328000 358359	Pink	1.25	18	350	0.86	0.20	14°	800 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 v4/v13	329000 359364	Ivory	1.06	19	350	0.74	0.16	14°	800 1000	2.0	1.0	2.5	1.0 (2.5)
Type2 v5/v14	320041 320043*	Yellow	0.90	20	350	0.64	0.13	14°	800 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 v6/v15	320042 320044*	Yellow	0.90	20	300	0.64	0.13	14°	800 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 v7/v16	321000 321040*	Green	0.80	21	300	0.54	0.13	14°	800 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 v8/v17	322000 322040*	Black	0.70	22	300	0.43	0.13	14°	800 1000	2.0	1.2	2.5	1.2 (2.5)
Type2 v9/v18	323030* 323031*	Light blue	0.63	23	300	0.39	0.12	14°	800 1000	2.0	1.0	2.5	1.0 (2.5)

*Models currently not available in US or Canadian market.

Instructions for use

- (1) Check that the Kitazato OPU Needle is intact and that the "use by" date has not expired.
- (2) Please ascertain suitability for the gauge of Kitazato OPU Needle to be used and transvaginal ultrasound probe guide. Please note that various size of transvaginal ultrasound probe guide suitable for each needle gauge are offered.
- (3) Open the Kitazato OPU Needle and check that the needle fits in with the transvaginal ultrasound probe guide.
- (4) Give local or general anaesthesia or analgesia to be used for the procedure as necessary.
- (5) Carefully remove the needle from the packaging maintaining the sterility of the product.
- (6) Attach a sterile sampling tube to the silicone stopper. Outer diameter of $15\pm 1\text{mm}$ for sterile sampling tube is recommended. Then connect the female connector for aspiration to a suction pump and turn on the pump for aspiration. The operator shall adjust to appropriate pressure, as recommended below:

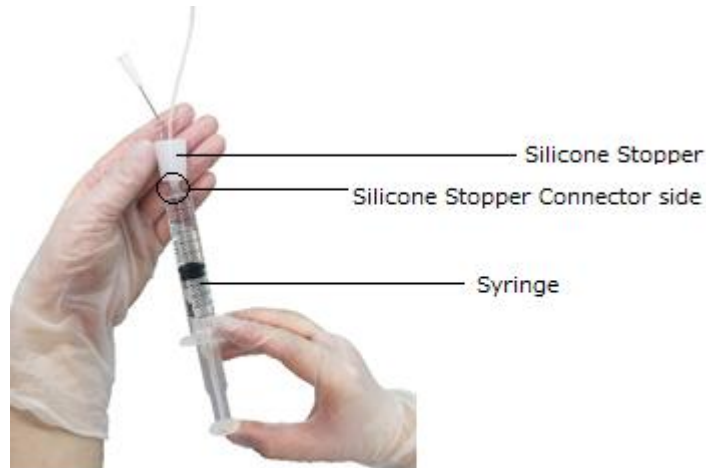
Needle Gauge	16	17	18	19	20	21	22	23
Suction pressure (mmHg)	100 $\pm$ 25	125 $\pm$ 25	150 $\pm$ 25	175 $\pm$ 25	200 $\pm$ 50	225 $\pm$ 50	250 $\pm$ 50	250 $\pm$ 50

- (7) Please check the follicle by applying the ultrasonic probe to the vaginal wall. Then insert the needle into the transvaginal ultrasound probe guide and puncture into the follicle from the vaginal wall. After the puncture, please gently aspirate follicle cell.

- (8) If the needle or the connection tube clogs upon aspiration of tissues, remove the clog using a Syringe, as shown in the adjacent image. Carefully insert the syringe to the connector side of the silicone stopper. After insertion, gently push down the syringe plunger to apply positive pressure to remove the clog. If the needle is damaged during the procedure, replace the needle with a new one.

Note: The Syringe is not provided with the OPU Needle. Please use commercially available 10cc Syringes.

Caution: This procedure must be performed with the needle tip outside the body to reduce potential injury to the patient.



- (9) Remove the needle after aspirating the oocytes.
- (10) Discard the aspiration needle according to standard clinical practice for medical hazardous waste when the procedure is finished.
- (11) Lightly press the puncture region with gauze. Apply a wound closure to the puncture region if further bleeding is not observed. Check the condition of the patient for 15 to 30 minutes or hospital protocol.
- (12) Immediately transfer the collected follicular fluid in the sterile sampling tube to a sterile dish and check condition of collected oocytes using a microscope. Oocytes are then placed in a new sterile dish and stored in a CO₂ incubator until a physician instructs further processing (e.g., cryopreservation or fertilization).

Storage condition

Store out of direct sunlight. Store product between 4°C to 30°C / 5% RH to 85% RH.

Specification

Ethylene oxide sterilized

Sterility (USP<71>) - No microbial growth

1-cell MEA $\geq 80\%$ expanded to blastocyst at 96 hours.

Bacterial Endotoxin <20EU/device.

Warranty

The manufacturer is not liable for any damage resulting from misuse or incorrect operation or failure to follow the cautions or instructions contained in this Instructions For Use or the instruction manual for any compatible medical equipment.



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