

Instructions For Use

TOWAKO® Method

General Information

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

Symbols on the Label

	DO NOT REUSE		DO NOT RESTERILIZE		STERILIZED USING IRRADIATION
	USE BY		BATCH CODE		MANUFACTURER
	RE-ORDER NUMBER		CONSULT INSTRUCTIONS FOR USE		DO NOT USE IF PACKAGE IS DAMAGED
	STERILIZED USING ETHYLENE OXIDE GAS		EC REPRESENTATIVE		

Intended use

The Kitazato "TOWAKO® Method" is intended for transferring embryo(s) following in vitro fertilization procedure into endometrial cavity through the myometrium using needle and catheter.

Caution

Do not press catheter strongly when it seems to be difficult pass the uterus. It may cause bleeding.

Contraindications

- No reuse. It may cause infection when reuse.
- No re-sterilization.

Instructions for use

- (1) Position the patient in the lithotomy position. Perform pelvic examination using a vaginal speculum. Check the condition of the endocervix and the endometrial membrane, and decide the length and angle of the puncture needle and the catheter before use.
- (2) Wash the vulva and the vagina with sterilized saline and dry them. Antisepticize the puncture site.
- (3) Connect a syringe to the connector of the catheter and aspirate embryo to the catheter under microscope.
- (4) Make a puncture in the puncture site using the puncture needle. Insert the catheter in the inner part of the puncture needle.
- (5) Check the catheter reached to the uterus under ultrasound. Slowly press the plunger of the syringe and expel the embryo into the uterus.
- (6) After injecting the embryo into the uterus, carefully remove the catheter and puncture needle.
- (7) Check for retention of embryos in catheter under microscope.
- (8) Remove the vaginal speculum and keep the patient at rest. After using the puncture needle, press the puncture site with gauze. If there is no bleeding, put an adhesive tape on it and observe it for 15 to 30 minutes.

Cautions for use

- (1) Check the specification (length) of the catheter before opening it.
- (2) Check the specification (length) of the puncture needle before opening it.
- (3) When using other medical equipment such as ultrasonic sound wave, check the compatibility.
- (4) Do not wash inside of the catheter with sterilized saline before aspirating embryo into the catheter. Because the sterilized saline remains in the catheter, it may cause troubles for aspirating embryo.
- (5) Pay enough attention to the needle tip and do not touch it until it is used for puncture. An efficacy of the puncture may deteriorate.
- (6) Confirm a route of the puncture enough before puncturing the needle.
- (7) Read this Instructions For Use before use by all means.
- (8) Do not use the product that it was past an expiration date.
- (9) Immediately use after opening the package.
- (10) If the product has abnormalities that its package has been broken or it has been damaged before opening it, do not use it.
- (11) Do not jack up forcedly and/or reprocess.
- (12) Use the product by operator that has seasoned knowledge about procedure for the product.
- (13) Do not use the product except for transfer of embryo.
- (14) Use the product aseptically. Carry out enough precautionary measures for bacteria.
- (15) Throw the product away promptly after having used it.
- (16) Do not refurbish.
- (17) Store away from high temperature, high humidity, the water wet.

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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