

Type1 Catheter and Guide

Type2 Catheter, Guide with Obturator

Type3 Stylet

General Information

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

Symbols on the Label

	Do not reuse		Sterilized using Irradiation		Sterilized using Ethylene Oxide Gas
	Manufacturer		Use By		Batch Code
	Re-order Number		Consult Instructions for Use		

Indication for Use

Kitazato ET Catheters are intended for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilization.

Contraindications

This catheter should not be used in the presence of active intrauterine infection, a sexually transmitted disease or a recent uterine perforation on a patient, or for a patient who currently pregnant or carrying a intrauterine contraceptive device in their body.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Cautions

- (1) Read Instructions For Use before use.
- (2) This catheter is not designed to be re-used or re-sterilized; the device is single use only.
- (3) Bleeding may occur as a result of localized trauma due to insertion of the catheter through the cervix.
- (4) To reduce the risk of perforation, if any resistance is felt while inserting the catheter, do not force the catheter against the resistance.
- (5) Do not apply excessive force to the catheter during the shaping process as this may damage the catheter resulting in patient injury or harm.
- (6) Do not use the device in any manner except for the transfer of embryos.
- (7) Confirm the specification (length) of the catheter prior to use.
- (8) Do not use the product if past the expiration date.
- (9) Immediately use after opening the package.
- (10) Do not use the device if the package is opened or damaged.
- (11) Do not use the device if abnormalities such as breakage are detected.
- (12) Confirm adaptability with the other medical equipment to be used.
- (13) Do not wash the inside of the catheter with sterilized saline before infusing the catheter with embryo or gamete. It may cause risks for aspirating embryo or gamete.
- (14) Infection may occur due to bacterial contamination of the device during vaginal manipulation. This may result in urinary tract infection (UTI), pelvic inflammatory disease (PID), or uterine infection.
- (15) Embryo transfer procedure should only be performed by physicians trained in Assisted Reproductive Technique.

Product Design

Type1 Kitazato ET Catheter is composed of a Catheter and a Guide. The Catheter shaft is offered in lengths of 22cm and 25cm, and the guide in 17cm and 20cm. The Type2 Kitazato ET Catheter is composed of a Catheter, a Guide and an Obturator. The obturator is closed end and used to keep the guide free of cervical mucus during insertion. The Type2 catheter shaft is offered in lengths of 22cm, 25cm and 40cm, and the guide in 17cm and 20cm. The proximal part of the catheter shaft is open-end. The depth mark is printed on all catheters in a series of 1cm graduations from the distal part to 7cm, and is printed on the guide in a series of 1cm graduations from the line at 4cm to 8cm. The uterine cavity is observed under ultrasound, however, all guides and catheters have the option of with or without an echo reflective tip, to be confirmed by ultrasound image and high visibility image under ultrasound can be observed.

There are models of Type 1 and Type 2 catheters that include an echo line. The echo line does not contain gas bubbles, but it contains hollow glass microspheres.

Type3 is a Stylet to provide more rigidity to the Guide. When it is difficult to insert the guide into the uterine cavity, Type3 Stylet sheath can be utilized for assistance together with the guide.

- Type1 – Catheter and Guide

[illegible]

Outer Diameter of Guide Shaft (French size)	1.90 mm (3Fr)	1.90 mm (3Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)
Guide Length	170mm	200mm	170mm	170mm	200mm	200mm
Guide Echo Chip	Yes	Yes	No	No	No	No
Guide Tip Shape	Round	Round	Straight	Round	Straight	Round

Model Number and Description	Model Number Type1-v4 214335 4Fr 250mm Catheter and Guide	Model Number Type1-v4 214435 4Fr 250mm Catheter and Guide	Model Number Type1-v5 213342 3Fr 220mm RYDEN Catheter and Guide	Model Number Type1-v5 213352 3Fr 220mm RYDEN Catheter and Guide	Model Number Type1-v6 213365 3Fr 250mm RYDEN Catheter and Guide	Model Number Type1-v6 213375 3Fr 250mm RYDEN Catheter and Guide
Outer Diameter of Catheter Shaft (French Size)	1.35 mm (4 Fr)	1.35 mm (4 Fr)	1.00 mm (3 Fr)	1.00 mm (3 Fr)	1.00 mm (3 Fr)	1.00 mm (3 Fr)
Catheter Length	250 mm	250 mm	220 mm	220 mm	250 mm	250 mm
Echogenic Catheter	No	No	No	Yes	No	Yes
Catheter Shaft Composition	Silicone	Silicone	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Catheter Shaft Connector Composition	ABS (White)	ABS (White)	ABS (White)	ABS (White)	ABS (White)	ABS (White)
Stiffener Composition	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304
Outer Diameter of Guide Shaft (French size)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)
Guide Length	200mm	200mm	170mm	170mm	200mm	200mm
Guide Echo Chip	No	No	Yes	Yes	Yes	Yes
Guide Tip Shape	Straight	Round	Round	Round	Round	Round

• Type2 – Catheter and Guide with Obturator

Model Number and description	Model Number Type2-v1 223332 3Fr 220mm Catheter, Guide with Obturator	Model Number Type2-v1 233332 3Fr 220mm Catheter, Guide with Obturator and Stylet	Model Number Type2-v2 223335 3Fr 250mm Catheter, Guide with Obturator	Model Number Type2-v2 233335 3Fr 250mm Catheter, Guide with Obturator and Stylet	Model Number Type2-v3 224332 4Fr 220mm Catheter, Guide with Obturator	Model Number Type2-v3 224432 4Fr 220mm Catheter, Guide with Obturator
Outer Diameter of Catheter Shaft (French Size)	1.0 mm (3 Fr)	1.0 mm (3 Fr)	1.0 mm (3 Fr)	1.0 mm (3 Fr)	1.35 mm (4 Fr)	1.35 mm (4 Fr)
Catheter Length	220 mm	220 mm	250 mm	250 mm	220 mm	220 mm
Echogenic Catheter	No	No	No	No	No	No
Catheter Shaft Composition	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone
Stiffener Composition	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304
Outer Diameter of Guide Shaft (French Size)	1.90 mm (3Fr)	1.90 mm (3Fr)	1.90 mm (3Fr)	1.90 mm (3Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)
Guide Length	170 mm	170 mm	200 mm	200 mm	170 mm	170 mm
Guide Echo Chip	Yes	Yes	Yes	Yes	No	No
Guide Tip Shape	Round	Round	Round	Round	Straight	Round

Model Number and description	Model Number Type2-v3 234332 4Fr 220mm Catheter, Guide with Obturator and Stylet	Model Number Type2-v4 224335 4Fr 250mm Catheter, Guide with Obturator	Model Number Type2-v4 224435 4Fr 250mm Catheter, Guide with Obturator	Model Number Type2-v4 234335 4Fr 250mm Catheter, Guide with Obturator and Stylet	Model Number Type2-v5 223350 3Fr 400mm Catheter, Guide with Obturator	Model Number Type2-v5 233350 3Fr 400mm Catheter, Guide with Obturator and Stylet
Outer Diameter of Catheter Shaft (French Size)	1.35 mm (4 Fr)	1.35 mm (4 Fr)	1.35 mm (4 Fr)	1.35 mm (4 Fr)	1.0 mm (3 Fr)	1.0 mm (3 Fr)
Catheter Length	220 mm	250 mm	250 mm	250 mm	400 mm	400 mm

Echogenic Catheter	No	No	No	No	No	No
Catheter Shaft Composition	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone
Stiffener Composition	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Polyimide	Polyimide
Outer Diameter of Guide Shaft (French Size)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)	1.90 mm (3Fr)	1.90 mm (3Fr)
Guide Length	170 mm	200 mm	200 mm	200 mm	200 mm	200 mm
Guide Echo Chip	No	No	No	No	Yes	Yes
Guide Tip Shape	Round	Straight	Round	Round	Round	Round

Model Number and description	Model Number Type2-v6 223342 3Fr 220mm RYDEN Catheter, Guide with Obturator	Model Number Type2-v6 223352 3Fr 220mm RYDEN Catheter, Guide with Obturator	Model Number Type2-v7 223365 3Fr 250mm RYDEN Catheter, Guide with Obturator	Model Number Type2-v7 223375 3Fr 250mm RYDEN Catheter, Guide with Obturator
Outer Diameter of Catheter Shaft (French Size)	1.0 mm (3 Fr)	1.0 mm (3 Fr)	1.0 mm (3 Fr)	1.0 mm (3 Fr)
Catheter Length	220 mm	220 mm	250 mm	250 mm
Echogenic Catheter	No	Yes	No	Yes
Catheter Shaft Composition	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Stiffener Composition	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304
Outer Diameter of Guide Shaft (French Size)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)	2.20 mm (4Fr)
Guide Length	170 mm	170 mm	200 mm	200 mm
Guide Echo Chip	Yes	Yes	Yes	Yes
Guide Tip Shape	Round	Round	Round	Round

• Type3 - Stylet sheath

Model Number and Description	Model Number Type3-v1 243027 3Fr Stylet for 170mm Guide	Model Number Type3-v2 243030 3Fr Stylet for 200mm Guide	Model Number Type3-v3 244027 4Fr Stylet for 170mm Guide	Model Number Type3-v4 244030 4Fr Stylet for 200mm Guide
Outer Diameter of Stylet sheath	1.20 mm	1.20 mm	1.60 mm	1.60 mm
Length	170 mm	200 mm	170 mm	200 mm
Stainless core	Yes	Yes	Yes	Yes

Instructions for use

- (1) Check the condition of the cervix prior to the insertion of the catheter to ascertain the depth of the uterus and any uterine anteversion or retroflexion present in individual patients. (This is preferably done during a previous examination and not on the day of the embryo transfer when disturbance of the uterus should be minimized.)
- (2) Place patient in a lithotomy or knee-chest position.
- (3) Insert vaginal speculum to expose cervix.
- (4) Select the ET Catheter appropriate to the anatomical condition of the uterine cervix.
- (5) Slowly insert the Guide catheter into the uterus through the cervix together with an Obturator, if necessary.
The Guide may not be inserted smoothly if the cervix is sharply curved. In this case, Type3 Stylet sheath can be utilized for assistance together with the guide. Gently remove the guide catheter from the patient, then make the Type3 Stylet ready. Bend the tip of the stylet/guide catheter according to the curvature of the uterine cervix, and slowly insert the stylet/guide catheter into the uterine cervix. After insertion, calmly remove the stylet from the guide while holding the guide catheter.
- (6) Connect the ET Catheter to a syringe and aspirate embryos from the tip of the catheter.
Note: the syringe is not included with the catheter.
- (7) Place the catheter loaded with embryos into the uterine cavity through the guide catheter, ensuring that the ET Catheter is introduced into the uterine cavity properly under ultrasonic echo.
- (8) After insertion into the uterine cavity, slowly press the plunger of the syringe to expel the embryos into the uterine cavity.
- (9) Remove the catheter, check for retention of embryos, and discard the catheter.

After Use

- (1) Discard the syringe, catheter and any other material used as medical waste according to Universal Precautions and/or hospital protocol.
- (2) Remove the speculum and allow the patient to rest.

Storage condition

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

Specification

Sterility assurance Level (SAL) of 10^{-6}

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

Bacterial Endotoxin <20 EU/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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