

Kitazato ET Catheter

Type1 EC-PRO

Type2 EC-PRO Supported

Type3 EC-PRO Master

Type4 EC-PRO Master Supported

Type5 EC-PRO Stylet Sheath

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 ET catheters are intended for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilisation.

Kitazato ET Catheter is provided in various configurations (Type 1 through Type 5), which consist of the following components:

- Transfer Catheter, in 18 and 23 cm lengths, for delivery of embryos into the uterine cavity;
- Guide Catheter, in 14 and 19 cm lengths, to guide the insertion of the transfer catheter and reinforce it during use;
- Trial Catheter, in 18 and 23 cm lengths, used to confirm the curvature of the cervix and if the cervix is passable prior to the transfer procedure;
- Stylet Sheath, in 13.5 and 18.5 cm, used to increase the strength of the Guide Catheter during insertion.

Contraindications

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

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

Precautions

- (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 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.

Product Design

Kitazato ET Catheter is composed of a Transfer Catheter with Trial, and a Guide Catheter. The transfer and trial catheters have a shaft offered in 18cm and 23cm lengths, while the guide is 14cm and 19cm in length. The proximal part of the transfer catheter shaft is open-end, and the corresponding trial catheters are closed end (no hole). The Type2 and Type4 Catheters have a stainless steel outer stiffener to maintain firmness while manipulating them through the guide catheter into the uterine cavity, Type5 Stylet sheath can be utilized with the guide catheter for assistance in inserting the catheter when the cervix is greatly curved. The depth mark is printed on all transfer catheters and guides in a series of 1cm graduations from the distal part to 4cm. The depth mark is printed on the guide catheter in a series of 1cm graduations from the proximal tip to 5cm.

The uterine cavity is observed under ultrasound, however, all guides and catheters can be confirmed by ultrasound image and the Type3 and Type4 Catheters have an Echo Line to provide high visibility under ultrasound.

The echo line does not contain gas bubbles, but it contains hollow glass microspheres.

- Type1 - Kitazato ET Catheter EC-PRO

Model Number and Description	Model Number Type 1 - v1 215028 4.7Fr 180mm EC-PRO Inner Catheter and Outer Guide	Model Number Type 1 - v1 225428 4.7Fr 180mm EC-PRO Inner Catheter and Outer Guide	Model Number Type 1 - v2 215033 4.7Fr 230mm EC-PRO Inner Catheter and Outer Guide	Model Number Type 1 - v2 225433 4.7Fr 230mm EC-PRO Inner Catheter and Outer Guide
Outer Diameter of Shaft of Catheter (French Size)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)
Length	180mm	180mm	230mm	230mm
Depth Marking	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm
Echo Line	No	No	No	No
Tip and Opening Configuration	Open end hole	Open end hole	Open end hole	Open end hole
Catheter Composition	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Catheter Connector Composition	ABS (White)	ABS (White)	ABS (White)	ABS (White)
Outer Stiffener Composition	No	No	No	No
Outer Diameter of Shaft of Guide Catheter (French Size)	2.2 mm	2.2 mm	2.2 mm	2.2 mm
Length	140mm	140mm	190mm	190mm
Laser Marking	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm
Guide Catheter Composition	Fluoric resin	Fluoric resin	Fluoric resin	Fluoric resin
Catheter Connector Composition	ABS (Red)	ABS (Red)	ABS (Green)	ABS (Green)
Obturator	No	Yes	No	Yes

Model Number and Description	Model Number Type 1 - v3 275028 4.7Fr 180mm EC-PRO Inner Catheter and	Model Number Type 1 - v4 275033 4.7Fr 230mm EC-PRO Inner Catheter and	Model Number Type 1 - v5 205028 4.7Fr 180mm EC-PRO Inner Catheter	Model Number Type 1 - v6 205033 4.7Fr 230mm EC-PRO Inner Catheter
Outer Diameter of Shaft of Catheter (French Size)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)
Length	180mm	230mm	180mm	230mm
Depth Marking	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm
Echo Line	No	No	No	No
Tip and Opening Configuration	Closed end	Closed end	Open end hole	Open end hole
Catheter Composition	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Catheter Connector Composition	ABS (Light Gray)	ABS (Light Gray)	ABS (White)	ABS (White)
Outer Stiffener Composition	No	No	No	No
Outer Diameter of Shaft of Guide Catheter (French Size)	2.2 mm	2.2 mm	2.2 mm	2.2 mm
Length	140mm	190mm	140mm	190mm
Laser Marking	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm
Guide Catheter Composition	Fluoric resin	Fluoric resin	Fluoric resin	Fluoric resin
Catheter Connector Composition	ABS (Red)	ABS (Green)	ABS (Red)	ABS (Green)
Obturator	No	No	No	No

- Type2 - Kitazato ET Catheter EC-PRO Supported

Model Number and Description	Model Number Type2-v1 215128 4.7Fr 180mm EC-PRO Supported Inner Catheter and Outer Guide	Model Number Type2-v1 225528 4.7Fr 180mm EC-PRO Supported Inner Catheter and Outer Guide	Model Number Type2-v2 215133 4.7Fr 230mm EC-PRO Supported Inner Catheter and Outer Guide	Model Number Type2-v2 225533 4.7Fr 230mm EC-PRO Supported Inner Catheter and Outer Guide
Outer Diameter of Shaft of Catheter (French Size)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)
Length	180mm	180mm	230mm	230mm
Depth Marking	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm
Echo Line	No	No	No	No
Tip and Opening Configuration	Open end hole	Open end hole	Open end hole	Open end hole
Catheter Composition	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Catheter Connector Composition	ABS (White)	ABS (White)	ABS (White)	ABS (White)
Outer Stiffener Composition	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304
Outer Diameter of Shaft of Guide Catheter (French Size)	2.2 mm	2.2 mm	2.2 mm	2.2 mm
Length	140mm	140mm	190mm	190mm
Laser Marking	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm
Guide Catheter Composition	Fluoric resin	Fluoric resin	Fluoric resin	Fluoric resin
Catheter Connector Composition	ABS (Red)	ABS (Red)	ABS (Green)	ABS (Green)
Obturator	No	Yes	No	Yes

Model Number and Description	Model Number Type2-v3 275128 4.7Fr 180mm EC-PRO Supported Inner Catheter and Outer Guide	Model Number Type2-v4 275133 4.7Fr 230mm EC-PRO Supported Inner Catheter and Outer Guide	Model Number Type2-v5 205128 4.7Fr 180mm EC-PRO Inner Catheter	Model Number Type2-v6 205133 4.7Fr 230mm EC-PRO Inner Catheter
Outer Diameter of Shaft of Catheter (French Size)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)
Length	180mm	230mm	180mm	230mm
Depth Marking	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm
Echo Line	No	No	No	No
Tip and Opening Configuration	Closed end	Closed end	Open end hole	Open end hole
Catheter Composition	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Catheter Connector Composition	ABS (Light Gray)	ABS (Light Gray)	ABS (White)	ABS (White)
Outer Stiffener Composition	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304
Outer Diameter of Shaft of Guide Catheter (French Size)	2.2 mm	2.2 mm	No	No
Length	140mm	190mm	No	No
Laser Marking	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	No	No
Guide Catheter Composition	Fluoric resin	Fluoric resin	No	No
Catheter Connector Composition	ABS (Red)	ABS (Green)	No	No
Obturator	No	No	No	No

- Type3 - Kitazato ET Catheter EC-PRO Master

Model Number and Description	Model Number Type 3-v1 215228 4.7Fr 180mm EC-PRO Master Inner Catheter and Outer Guide	Model Number Type 3-v1 225628 4.7Fr 180mm EC-PRO Master Inner Catheter and Outer Guide	Model Number Type 3-v2 215233 4.7Fr 230mm EC-PRO Master Inner Catheter and Outer Guide	Model Number Type 3-v2 225633 4.7Fr 230mm EC-PRO Master Inner Catheter and Outer Guide
Outer Diameter of Shaft of Catheter (French Size)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)
Length	180mm	180mm	230mm	230mm
Depth Marking	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm
Echo Line	Yes	Yes	Yes	Yes
Tip and Opening Configuration	Open end hole	Open end hole	Open end hole	Open end hole
Catheter Composition	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Catheter Connector Composition	ABS (Yellow)	ABS (Yellow)	ABS (Yellow)	ABS (Yellow)
Outer Stiffener Composition	No	No	No	No
Outer Diameter of Shaft of Guide Catheter (French Size)	2.2 mm	2.2 mm	2.2 mm	2.2 mm
Length	140mm	140mm	190mm	190mm
Laser Marking	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm
Guide Catheter Composition	Fluoric resin	Fluoric resin	Fluoric resin	Fluoric resin
Catheter Connector Composition	ABS (Red)	ABS (Red)	ABS (Green)	ABS (Green)
Obturator	No	Yes	No	Yes

Model Number and Description	Model Number Type 3-v3 275228 4.7Fr 180mm EC-PRO Master Inner Catheter and Outer Guide	Model Number Type 3-v4 275233 4.7Fr 230mm EC-PRO Master Inner Catheter and Outer Guide	Model Number Type 3-v5 205228 4.7Fr 180mm EC-PRO Master Inner Catheter	Model Number Type 3-v6 205233 4.7Fr 230mm EC-PRO Master Inner Catheter
Outer Diameter of Shaft of Catheter (French Size)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)
Length	180mm	230mm	180mm	230mm
Depth Marking	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm	A series of 1cm graduations from the distal part to 4cm
Echo Line	Yes	Yes	Yes	Yes
Tip and Opening Configuration	Closed end	Closed end	Open end hole	Open end hole
Catheter Composition	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Catheter Connector Composition	ABS (Dark Gray)	ABS (Dark Gray)	ABS (Yellow)	ABS (Yellow)
Outer Stiffener Composition	No	No	No	No
Outer Diameter of Shaft of Guide Catheter (French Size)	2.2 mm	2.2 mm	No	No
Length	140mm	190mm	No	No
Laser Marking	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	No	No
Guide Catheter Composition	Fluoric resin	Fluoric resin	No	No
Catheter Connector Composition	ABS (Red)	ABS (Green)	No	No
Obturator	No	No	No	No

- Type4 - Kitazato ET Catheter EC-PRO Master Supported

Model Number and Description	Model Number Type4-v1 215328 4.7Fr 180mm EC-PRO Master Supported Inner Catheter and Outer Guide	Model Number Type4-v1 225728 4.7Fr 180mm EC-PRO Master Supported Inner Catheter and Outer Guide	Model Number Type4-v2 215333 4.7Fr 230mm EC-PRO Master Supported Inner Catheter and Outer Guide	Model Number Type4-v2 225733 4.7Fr 230mm EC-PRO Master Supported Inner Catheter and Outer Guide
Outer Diameter of Shaft of Catheter (French Size)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)
Length	180mm	180mm	230mm	230mm
Depth Marking	A series of 1cm graduations from the distal part to	A series of 1cm graduations from the distal part to	A series of 1cm graduations from the distal part to	A series of 1cm graduations from the distal part to
Echo Line	Yes	Yes	Yes	Yes
Tip and Opening Configuration	Open end hole	Open end hole	Open end hole	Open end hole
Catheter Composition	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Catheter Connector Composition	ABS (Yellow)	ABS (Yellow)	ABS (Yellow)	ABS (Yellow)
Outer Stiffener Composition	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Outer Diameter of Shaft of Guide Catheter (French Size)	2.2 mm	2.2 mm	2.2 mm	2.2 mm
Length	140mm	140mm	190mm	190mm
Laser Marking	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm
Guide Catheter Composition	Fluoric resin	Fluoric resin	Fluoric resin	Fluoric resin
Catheter Connector Composition	ABS (Red)	ABS (Red)	ABS (Green)	ABS (Green)
Obturator	No	Yes	No	Yes

Model Number and Description	Model Number Type4-v3 275328 4.7Fr 180mm EC-PRO Master Supported Inner Catheter and Outer Guide	Model Number Type4-v4 275333 4.7Fr 230mm EC-PRO Master Supported Inner Catheter and Outer Guide	Model Number Type4-v5 205328 4.7Fr 180mm EC-PRO Master Supported Inner Catheter	Model Number Type4-v6 205333 4.7Fr 230mm EC-PRO Master Supported Inner Catheter
Outer Diameter of Shaft of Catheter (French Size)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)	1.55 mm (4.7 Fr)
Length	180mm	230mm	180mm	230mm
Depth Marking	A series of 1cm graduations from the distal part to	A series of 1cm graduations from the distal part to	A series of 1cm graduations from the distal part to	A series of 1cm graduations from the distal part to
Echo Line	Yes	Yes	Yes	Yes
Tip and Opening Configuration	Closed end	Closed end	Open end hole	Open end hole
Catheter Composition	Polyurethane	Polyurethane	Polyurethane	Polyurethane
Catheter Connector Composition	ABS (Dark Gray)	ABS (Dark Gray)	ABS (Yellow)	ABS (Yellow)
Outer Stiffener Composition	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Outer Diameter of Shaft of Guide Catheter (French Size)	2.2 mm	2.2 mm	No	No
Length	140mm	190mm	No	No
Laser Marking	A series of 1cm graduations from the tip to 5cm	A series of 1cm graduations from the tip to 5cm	No	No
Guide Catheter Composition	Fluoric resin	Fluoric resin	No	No
Catheter Connector Composition	ABS (Red)	ABS (Green)	No	No
Obturator	No	No	No	No

- Type5 - Kitazato ET Catheter EC-PRO Stylet sheath

Model Number and Description	Model Number Type5-v1 294025 4.7Fr EC-PRO Soft Stylet sheath for 140mm Outer Guide	Model Number Type5-v1 294125 4.7Fr EC-PRO Hard Stylet sheath for 140mm Outer Guide	Model Number Type5-v2 294030 4.7Fr EC-PRO Soft Stylet sheath for 190mm Outer Guide	Model Number Type5-v2 294130 4.7Fr EC-PRO Hard Stylet sheath for 190mm Outer Guide
Outer Diameter of Stylet sheath	1.60 mm	1.60 mm	1.60 mm	1.60 mm
Length	140mm	140mm	190mm	190mm
Sheath Composition	12Nylon	12Nylon	12Nylon	12Nylon
Connector Composition	ABS (Red)	ABS (Red)	ABS (Green)	ABS (Green)
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 retroversion 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 catheter into the uterus through the cervix together with a trial catheter/guide catheter, if necessary.
 - (a) Where the trial catheter can be inserted smoothly:
Check if the trial catheter inserted into the uterine cavity properly under ultrasound. Then, remove the trial catheter while holding the guide catheter.
 - (b) Where the trial catheter cannot be inserted smoothly:
The trial catheter may not be inserted smoothly if the cervix is sharply curved. In this case, gently remove the trial catheter/ guide catheter, then prepare the stylet/ guide catheter. Bend the tip of the stylet/ guide catheter according to the curvature of the uterine cervix. Slowly insert the stylet/ guide catheter into the uterine cervix. After insertion, gently remove the stylet while holding the guide catheter in place.
- (6) Connect the ET Catheter to a syringe and aspirate embryos to the tip of the catheter. Note: the syringe is not included with the catheter.
- (7) Place the catheter containing embryos into the uterine cavity through the guide catheter, ensuring that the ET Catheter is introduced into the uterine cavity properly under ultrasonic echo. The Supported ET Catheter aids in manipulation through the guide catheter.
- (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.

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.