

Instructions For Use

Kitazato IUI Catheter

Product Model Numbers

- Type4 - Kitazato IUI Catheter with Outer Stiffener Type
131194 Soft type, 180mm Catheter
131114 Soft type, 100mm Catheter
131192 Intermediate type, 180mm Catheter
131112 Intermediate type, 100mm Catheter
- Type5 - Kitazato IUI Catheter with Outer Stiffener with Stainless Center Core Type
131191 Hard type, 180mm Catheter
131111 Hard type, 100mm Catheter
131196 Ultimate type, 180mm Catheter
131116 Ultimate type, 100mm Catheter

General Information

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

Symbols on the Label

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

Indication for Use

Kitazato IUI Catheter consist of the following versions:

- Kitazato IUI Catheter with Outer Stiffener with or without Stylet Cannula, 18 cm, model number Type 4-v1 and Type 4-v2
 - Kitazato IUI Catheter with Outer Stiffener with or without Stylet Cannula, 10 cm, model number Type 4-v3 and Type 4-v4
 - Kitazato IUI Catheter with Outer Stiffener with Stainless Steel Core, 18 cm, model number Type 5-v1 and Type 5-v2
 - Kitazato IUI Catheter with Outer Stiffener with Stainless Steel Core, 10 cm, model number Type 5-v3 and Type 5-v4
- Kitazato IUI Catheter is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.

Quality Control Testing

Sterility: USP <71>
Endotoxin: <20 EU/device
HSSA: ≥70% motility at 24h
Sterility assurance level: SAL10⁻⁶

Contraindications

- Not intended for intrafallopian tube procedures
- Should not be used in the presence of a cervical infection
- Should not be used in the presence of or after recent pelvic inflammatory disease

Warnings

Always use washed spermatozoa when performing intrauterine artificial insemination. The introduction of unwashed spermatozoa into the uterus may result in severe adverse reactions, including anaphylactic shock. Please refer to published medical literature for methods of preparing spermatozoa for intrauterine artificial insemination before performing the procedure.

Cautions

- (1) Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
- (2) Read Instructions For Use before use.
- (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) This catheter is not designed to be re-used or re-sterilized; the device is single use only.
- (6) Confirm the length of the catheter prior to use.
- (7) Do not use the product if past the expiration date.
- (8) Immediately use after opening the package.
- (9) Do not use the device if the package is damaged.
- (10) Do not use the device if abnormalities such as breakage are detected.
- (11) Do not apply excessive force to the catheter during the shaping process as this may damage the catheter resulting in patient injury or harm.
- (12) Do not use the device in any manner except for the transfer of washed spermatozoa.
- (13) Device should be handled and used under aseptic conditions to prevent contamination.

Product Design

Type5 -Kitazato IUI Catheter contains an Outer Stiffener with Stainless Center Core Type
The model numbers Type 4 and Type 5 IUI Catheters have the depth marking to be used as a reference for the depth of the uterine cavity.

The depth marking can be used as a reference to know the depth to reach the uterine cavity by pre-measuring the depth of the patient's uterus. When the catheter is inserted into the cervix and the depth marking contacts the entrance of the uterine cervix, the operator can know that the tip of the shaft has reached the pre-determined location in the uterine cavity.

Type4 catheter is composed of the shaft containing the outer stiffener and the connector.

Type5 catheter is made up of the shaft having the outer stiffener and stainless center core. These two shafts for Type4 and Type5

have two side-holes at the distal end.

There are two options in length of the shaft, 18cm and 10cm, and the shaft has a depth marking at 5, 6, 7, and 8 cm from the tip of the catheter.

Materials of Type4 catheter are polyvinyl chloride (not made with DEHP) shaft and ABS connector.

Materials of Type5 catheter are polyvinyl chloride (not made with DEHP) shaft, ABS connector and SUS304 stainless steel.

The connector of Kitazato IUI Catheter has 6% taper that can be attached to a 6% tapered connector syringe. (Note: The syringe is not offered with catheters)

• Type4 - Kitazato IUI Catheter with Outer Stiffener Type

Model Number and Description	Model Number 131194 Soft type, 180mm Catheter	Model Number 131192 Intermediate type, 180mm Catheter	Model Number 131114 Soft type, 100mm Catheter	Model Number 131112 Intermediate type, 100mm Catheter
Outer Diameter of Main Shaft of Catheter (French Size)	1.70 mm (5 Fr)	2.0 mm (6 Fr)	1.70 mm (5 Fr)	2.0 mm (6 Fr)
Outer Diameter of Outer Stiffener of Catheter (French Size)	2.5 mm (7.5 Fr)	2.5 mm (7.5 Fr)	2.5 mm (7.5 Fr)	2.5 mm (7.5 Fr)
Length	180mm	180mm	100mm	100mm
Depth Marking	Centimeter marks are located at 5, 6, 7, and 8 cm from tip on the outer stiffener	Centimeter marks are located at 5, 6, 7, and 8 cm from tip on the outer stiffener	Centimeter marks are located at 5, 6, 7, and 8 cm from tip on the outer stiffener	Centimeter marks are located at 5, 6, 7, and 8 cm from tip on the outer stiffener
Tip and Opening Configuration	The tip is closed and smoothly rounded; two side holes end type	The tip is closed and smoothly rounded; two side holes end type	The tip is closed and smoothly rounded; two side holes end type	The tip is closed and smoothly rounded; two side holes end type
Catheter Composition	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP
Catheter Connector Composition	ABS (White)	ABS (Light Gray)	ABS (White)	ABS (Light Gray)
Outer Stiffener Composition	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP

• Type5 - Kitazato IUI Catheter with Outer Stiffener with Stainless Center Core Type

Model Number and Description	Model Number 131191 Hard type, 180mm Catheter	Model Number 131196 Ultimate type, 180mm Catheter	Model Number 131111 Hard type, 100mm Catheter	Model Number 131116 Ultimate type, 100mm Catheter
Outer Diameter of Main Shaft of Catheter (French Size)	2.0 mm (6 Fr)	2.0 mm (6 Fr)	2.0 mm (6 Fr)	2.0 mm (6 Fr)
Outer Diameter of Outer Stiffener of Catheter (French Size)	2.5 mm (7.5 Fr)	2.5 mm (7.5 Fr)	2.5 mm (7.5 Fr)	2.5 mm (7.5 Fr)
Outer Diameter of Center Core	0.65mm	0.50m	0.65mm	0.50mm
Length	180mm	180mm	100mm	100mm
Depth Marking	Depth marks are located at 5, 6, 7, and 8 cm from the tip on the outer stiffer	Depth marks are located at 5, 6, 7, and 8 cm from the tip on the outer stiffer	Depth marks are located at 5, 6, 7, and 8 cm from the tip on the outer stiffer	Depth marks are located at 5, 6, 7, and 8 cm from the tip on the outer stiffer
Tip and Opening Configuration	The tip is closed and smoothly rounded; two side holes end type	The tip is closed and smoothly rounded; two side holes end type	The tip is closed and smoothly rounded; two side holes end type	The tip is closed and smoothly rounded; two side holes end type
Catheter Composition	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP
Catheter Connector Composition	ABS (Dark Gray)	ABS (Gray)	ABS (Dark Gray)	ABS (Gray)
Outer Stiffener Composition	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP	Polyvinyl chloride not made with DEHP
Catheter Center Core Composition	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304	Stainless Steel SUS 304

Instructions for Use

Before 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 antelexion or retroflexion present in individual patients. (This is preferably done during a previous examination and not on the day of the artificial insemination when disturbance of the uterus should be minimized.)
- (2) Position the patient in the lithotomy position. Insert vaginal speculum to expose cervix. The insertion depth of the catheter has been determined by pre-measuring the depth of the patient's uterus using standard techniques, e.g. transvaginal ultrasound or a uterine sound probe with graduations.
- (3) Select the IUI Catheter appropriate to the anatomical condition of the uterine cervix.
- (4) Wash the vulva and the vagina with sterilized saline copiously and dry them.
- (5) Connect the 6% tapered syringe to the proximal connector of IUI Catheter (**note:** the syringe is not included with the catheter).
- (6) Load the catheter with washed spermatozoa solution.
 - (a) Connect the syringe to the proximal end of the catheter. The volume in the IUI catheter is approximately as follows.
(131194 and 131192: 0.08mL, 131114 and 131112: 0.04mL, 131191 0.03mL, 131196 0.09mL, 131111 0.02mL, 131116 0.05mL) Ensure that a sufficient volume of sperm solution is aspirated to account for this loss during delivery.
 - (b) Place the distal tip of the IUI Catheter so the port is immersed in the sperm solution.
 - (c) Aspirate the desired amount of washed sperm by retracting the plunger of the syringe.

During Use

- (1) Having previously determined the depth and direction of the patient's uterus, gently insert the catheter into the cervix. When using the IUI Catheter model number Type 4 and model number Type 5, the operator can determine when the tip of the shaft reaches the uterine cavity when the depth mark contacts the entrance of the uterine cervix.
- (2) To reduce the risk of perforation, if any resistance is felt while inserting the catheter, do not force the catheter against the resistance. If necessary, make sure the tip of the shaft is at a suitable angle to pass through the cervix smoothly.
- (3) If utilizing the depth marker, this can be moved along the shaft of the catheter using appropriate aseptic techniques so the distal end is in the correct position.
- (4) After insertion in the uterine cavity, slowly press the plunger of the syringe fully to inject the washed spermatozoa into the uterine cavity.
- (5) Following the complete expulsion of the specimen, carefully remove the IUI 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

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.