
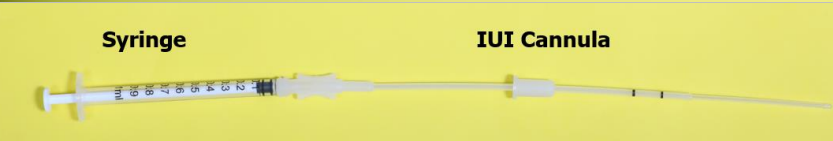


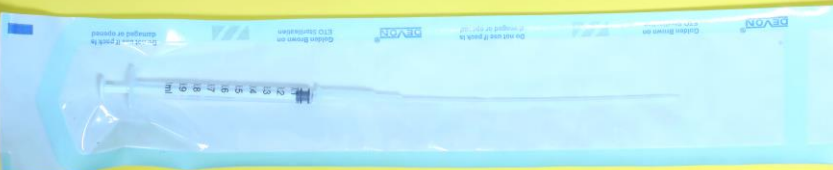





**DEVON INNOVATIONS PRIVATE LIMITED  
BANGALORE**

**Intrauterine Insemination Cannula - Without Hydrophilic coated**

Product Name	Packing	Image
Intrauterine Insemination Cannula- Without Hydrophilic coated	With Packing	
	Without Packing	 <p><b>Syringe</b> <b>IUI Cannula</b></p>

Catheter-Straight/Curved- (Open end/closed end)		
Curved	With Packing	
	Without Packing	 <p><b>IUI Cannula</b> <b>Syringe</b></p>
Straight	With Packing	
	Without Packing	 <p><b>IUI Cannula</b> <b>Syringe</b></p>

**INTENDED PURPOSE:**

Used for introduction of washed spermatozoa into a woman's uterus. IUI Catheter (Cannula) this has the IUI Catheter and a sheath.

**MEDICAL INDICATONS:**

- Unexplained infertility
- Subfertility
- Ovulatory infertility



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**TARGET PATIENT POPULATION:**

Adult Female

**INTENDED USERS:**

Gynecologist

**CLINICAL BENEFITS:**

- High Success Rate
- Easy to use
- Accurate delivery of actual number of motile sperm
- Reduces trauma
- Increased pregnancy rate
- Better performance
- Less invasive & cost Effective
- Less contamination

**SPECIFICATION:**

**a) Intrauterine Insemination Cannula-without Hydrophilic coated:**

Information Required	Details
Size(F)	6-8F
Length (cm)	11/7.5cm; 12/9 cm; 12cm /15cm ,14cm / 10.5cm; 17cm / 12cm; 17.3cm / 13cm

**b) Catheter-Straight/ Curved- (Open end/Closed End):**

Information Required	Details
Size(F)	6F
Length (cm)	11cm

**SHELF LIFE:**

The Intrauterine Insemination Cannula has a shelf life of 3 years.

**RESIDUAL RISKS:**

- Infection
- Abdominal bloating or swelling
- Toxic to environment

**CONTRAINDICATIONS:**

**a) Intrauterine Insemination Cannula-without Hydrophilic coated:**

Should not be used in the presence of chronic cervical infection, or after recent pelvic inflammatory disease, for intra-fallopian procedures and for embryo transfers.

**b) Catheter-Straight/ Curved- (Open end/Closed End):**

Uterine cramping, Pelvic infection resulting from the insemination, formation of antibodies to sperm.



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**PRECAUTIONS:**

- Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use, and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.
- All Health care professionals is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- Ensure correct placement to avoid injury or incorrect deposition of spermatozoa.
- If patient experiences excessive pain or bleeding, discontinue the procedure and assess before continuing.
- If resistance is encountered during insertion, do not force the catheter; withdraw carefully and use a new sterile catheter.
- If spermatozoa cannot be introduced due to blockage, withdraw and replace with a new device.

**CAUTIONS:**

- The sale of this device is restricted by or on the order of a Gynecologist.

**WARNING:**

- The Intrauterine Insemination Cannula is intended for single use only.
- Do not use device if there is any indication that the sterility of the device has been compromised.
- Excessive force during insertion may cause uterine or cervical trauma.
- **Duration of Use**
  - Short term only, not for Continuous use
- **Adverse effects:**
  - Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance. Follow up procedures.
- **Reuse**
  - Reuse of single-use devices creates a potential risk of patient or user infections due to contamination. This contamination may lead to injury, illness, or death of the patient.

**UNDESIRABLE SIDE EFFECTS:**

- There's a slight risk of developing an infection as a result of the procedure.
- Spotting. Sometimes the process of placing the catheter in the uterus causes a small amount of vaginal bleeding

**DIRECTIONS FOR USE:**

Open the package carefully to avoid damaging the product. Incorrect removal of the product from the package may leads to Infection.

**a) Intrauterine Insemination Cannula-without Hydrophilic coated:**

- Connect the cannula to a syringe and rinse it with the saline water.
- Load with the sperm preparation and purge to expel air.



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- Insert a speculum.
- Wipe the cervix carefully.
- If necessary, place the cervix in the uterine axis using Pozzi forceps to help the cannula introduction.
- A slight rotation of the cannula helps overcome certain cervical obstacles.
- Once the endo cervical orifice has been cleared, gently push the cannula tip up to the insemination site.
- Place the tip of the catheter under fluoroscopic visualization and slowly inject washed spermatozoa in to the uterine cavity.
- Remove the cannula

**b) Catheter-Straight/ Curved- (Open end/Closed End):**

- Affix end of catheter to syringe and load the catheter with washed Sperm.
- The patient is made to lie down and place the legs in stirrups.
- The catheter tip is threaded through the vagina and cervix and in to the uterus.
- The plunger on the syringe is pressed and this causes the sperm specimen to Flow through the catheter in to the uterus.
- The catheter is then withdrawn and the speculum removed.
- Remove and discard the syringe/catheter assembly.

**STERILITY:**

These products are supplied in a package which is sterilized by using Ethylene Oxide. Do not use the products if the package is damaged. If used it leads to Infection.

**STORAGE CONDITION:**





Keep in cool and dry place. Store the products at temperatures between 5°C to 40°C. Do not expose to direct sun light.

**DISPOSITION:**

The product shall be disposed as per medical device disposal regulation.

**NOTE:**

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	MANUFACTURER		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	DATE OF MANUFACTURE		USE-BY DATE



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SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	BATCH CODE		COUNTRY OF MANUFACTURE
	STERILIZED USING ETHYLENE OXIDE		DO NOT RESTERILIZE
	DO NOT USE IF PACKAGE IS DAMAGED		SINGLE STERILE BARRIER SYSTEM
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
	TEMPERATURE LIMIT		DO NOT RE-USE
	CONSULT INSTRUCTIONS FOR USE		CAUTION
	MEDICAL DEVICE		UNIQUE DEVICE IDENTIFIER



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**REVISION HISTORY:**

Doc. No.	Revision Number	Revision Date	Description
CRP 7.2 F (9)	00	23.08.2025	INSTRUCTIONS FOR USE(IFU)