

# IUI #4220

## Intra uterine Insemination Catheter

Important product information  
Read carefully before use

**Disposable – discard after single use**  
**Caution: federal (USA) law restricts this device to sale by or on the order of a physician**  
**Sterile: unless pouch is damaged or opened**

### Product Description:

The IUI #4220 is a single-use, sterile, disposable, flexible, step-down catheter with two, opposing, lateral ports, each located 1.5 mm from its rounded, smooth and closed distal tip. The IUI #4220 is indicated for use in intra uterine artificial insemination. The device has an overall length of 20.6 cm including a 3.3 cm long polyethylene adapter that is permanently affixed at its proximal end. The effective (intended for insertion) portion of the device is comprised of a 17.3 cm long, clear polyethylene tube with a 1.85 mm OD (Outside Diameter) and a 1.50 ID (Inside Diameter) that is uniform throughout its length and is capable of containing 0.325 ml of fluid. The proximal 12.9 cm of this tube is tightly surrounded by an outer, clear polypropylene sheath with a 2.5 mm OD for all but its distal 16 mm of length within which it gradually steps

down (tapers) to accomplish a smooth transition with the 1.85 OD of the inner tube; thereby leaving the distal 4.4 cm of the inner tube exposed. The proximal circumference of both the inner tube and the outer sheath are molded directly into the distal end of the adapter so that only the lumen of the inner tube can provide a channel for flow. The design results in a single-channel catheter with two segments each having different degrees of flexibility: 1) a highly flexible, 1.85 mm OD, 4.4 cm long distal segment and 2) a more rigid 2.5 mm OD 12.9 cm long proximal segment. A marker on the adapter is positioned at a right angle of the plane of the catheter's two distal lateral ports to enable orientation of those ports within the uterus when they cannot be seen. A polyethylene positioner, which can be moved along the outer tube, can be used to limit the insertion following prior determination of uterine depth. The default location of the positioner is at 6.0 cm from the external distal tip of the catheter, which corresponds to the ideal position of insemination for the “average” uterine depth of 7.0 cm.

### Indications for Use:

Intra uterine Artificial Insemination

**Contraindications:**  
Do not use in the presence of cervical infection

Do not use in the presence or after recent Pelvic Inflammatory disease

### Warnings:

Always use washed spermatozoa when performing intrauterine (including intracervical) artificial insemination. The introduction of unwashed spermatozoa into the uterus with the IUI #4220 or by whatever other means can result in severe adverse reaction which may include anaphylactic shock. Please refer to published medical literature for methods of preparing spermatozoa for intrauterine artificial insemination before performing this procedure.

### Precautions:

By virtue of its flexibility and small diameter, the IUI #4220 can be introduced into the uterus with minimal danger of uterine wall perforation. However, care should be taken, prior to its insertion, to ascertain the depth of the uterus and any uterine ante flexion 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).

In no case should the device be forced against digitally felt resistance. If passage of the IUI #4220 through the cervical canal is not found to be easily

achievable, the device should not be forced and the possibility of the presence of pathologic cervical stenosis considered.

### Adverse reactions:

No adverse reactions associated with the use of the IUI #4220 have been reported. However, as with any instrument, which passes through the internal cervical os, mild cramping may be expected. In every case the direction for use should be followed; taking note of contra-indications, warnings and precautions.

Manufactured by: Gynetics Medical Products N.V., B-3930 Hamont-Achel, Belgium

How supplied: Product number: #4220

Packaged: 5 boxes of 25 individually sterile packed, disposable devices.

Distributed by:  
Conception Technologies

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### Directions for use:

1. With the patient in the dorsal lithotomy position expose the uterine cervix to view with a vaginal speculum.
2. Firmly attach a syringe (preferably 5ml or 3ml) with the plunger fully depressed, to the adaptor at the proximal end of the IUI #4220.
3. Draw 1.0 ml of air into the syringe. Then place the distal tip of the IUI #4220 into the specimen of WASHED SPERMATOZOA so that both the lateral ports are immersed in the specimen. Now aspirate the desired quantity of the specimen into the lumen of the catheter by retraction of the syringe plunger. (The clear tubular portion of the IUI #4220 has a capacity of approximately 0.364 ml of fluid).
4. Having previously determined the depth and direction of the patient's uterus, gently

introduce the distal tip of the IUI #4220 into the external cervical os and advance it through the cervical canal into the uterine cavity until resistance is felt. The distal tip of the catheter should then be at the uterine fundus. Now retract the IUI #4220 approximately 1.0 cm. (At the point that the narrower distal segment of the catheter steps up in size from 1.85 to 2.5 mm a total of 4.4 cm of the catheters length will have been inserted). The positioner may be used to limit insertion of the IUI #4220. The default location of the positioner is at 6.0 cm from the external distal tip of the catheter, which corresponds to the ideal position of insemination for the "average" uterine depth of 7.0 cm. Using appropriate aseptic techniques, the positioner should be moved along the outer tube so that the distal end of the positioner is placed

at a distance equal to uterine depth minus 1.0 cm from the distal tip of the catheter.

**Note:** The small OD of the distal segment of the IUI #4220 and the added control provided by its more rigid proximal segment usually permits its easy insertion. If any difficulty with insertion or bending of the catheter occurs, gently rotate the catheter while advancing it close to the cervix. If the uterus is significantly flexed anteriorly or posteriorly, gentle traction on the cervix with a tenaculum may be required to accomplish full insertion. In no case should force be used against resistance to achieve insertion.

5. With the distal tip of the IUI #4220 now positioned at 1.0 cm from the uterine fundus, rotate the catheter to bring the marking on the adaptor to the top. This orients the two lateral ports at the distal end of

6. Slowly inject the washed spermatozoa into the uterine cavity by depressing the syringe plunger fully. The 1.0 ml of air initially drawn into the syringe prior to loading the catheter with the specimen plus the air that was contained in the catheter will help to assure that all the specimen is expelled during the initial injection. Should there be any doubt about the complete expulsion of the specimen, remove the syringe from the adaptor; reload the syringe with air; reattach the syringe to the adaptor; then slowly inject the air to expel any remaining specimen into the uterine cavity.
7. Following the complete expulsion of the specimen, slowly withdraw the IUI #4220 from the uterus and discard it. Remove the speculum and allow the patient to rest.

