allwin® Medical Devices

TRACKABLE INTRA UTERINE INSEMINATION CATHETER

Description:

CODE	Description
T-IUI	TRACKABLE IUI Intra Uterine Insemination Catheter with Malleable Stylet
T-IUI-O	TRACKABLE IUI Intra Uterine Insemination Catheter with Malleable Stylet (Open Tip)

Configuration:
See brochure

Indications for use:
Allwin Intra Uterine Insemination Catheters are intended for the introduction of washed spermatozoa into the uterine cavity.

Contraindications:
- Cervical infection
- Recent pelvic inflammation.
- Sexually transmitted disease
- Pregnancy
- Confirmed or suspected intrauterine device
- Uterine perforation.

Complications:
- Uterine wall perforation
- Bleeding

Caution:
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- To reduce the risk of perforation, if any resistance is felt while inserting the catheter, do not force the catheter against the resistance.

Warning / Precaution:
- Do not use if package is opened or damaged.
- Not intended for IVF, GIFT or other Intra Fallopian tube procedure.
- 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.
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- For single use only.
- Do not re-sterilize.
- Only experienced surgeon should use this device.
- Storage temperature between 5ºC to 30ºC.

Instruction for Use:
1. Before to the procedure, check the condition of the cervix prior to the insertion of the catheter, to ascertain the depth of the uterus and any uterine anteflexion or retroflexion present in individual patients.
2. Place the patient in the dorsal lithotomy position with her feet in stirrups.
3. Position a vaginal speculum within the vagina so the external cervical os can be visualized during catheter insertion.
4. Cleanse the cervix with an appropriate cleansing solution.
5. If necessary, for added rigidity, pass the stylet into the catheter prior to insertion. Ensure the stylet is pressed securely into the catheter hub via the luer slip fit.
6. Guide the catheter through the cervix and into the uterine cavity. **Note**: ink marks or depth positioners can be used to facilitate placement.
7. After insertion, remove the stylet and affix the adaptor of the catheter to a syringe preloaded with washed sperm solution.
8. Slowly press the plunger of the syringe to introduce the sperm into the uterine cavity.
9. Following injection, remove the catheter, discard the catheter, syringe, and other materials used.

NOTE-1 Human Sperm Survival Assay (HSSA) > 80% of control motility at 24 hours
NOTE-2 Endotoxin Testing: ≤ 20 EU/device

Do not reuse, reprocess & resterilize:
Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:
The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

EU REP
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Single Sterile Barrier system with protective packaging inside

CE 0123

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