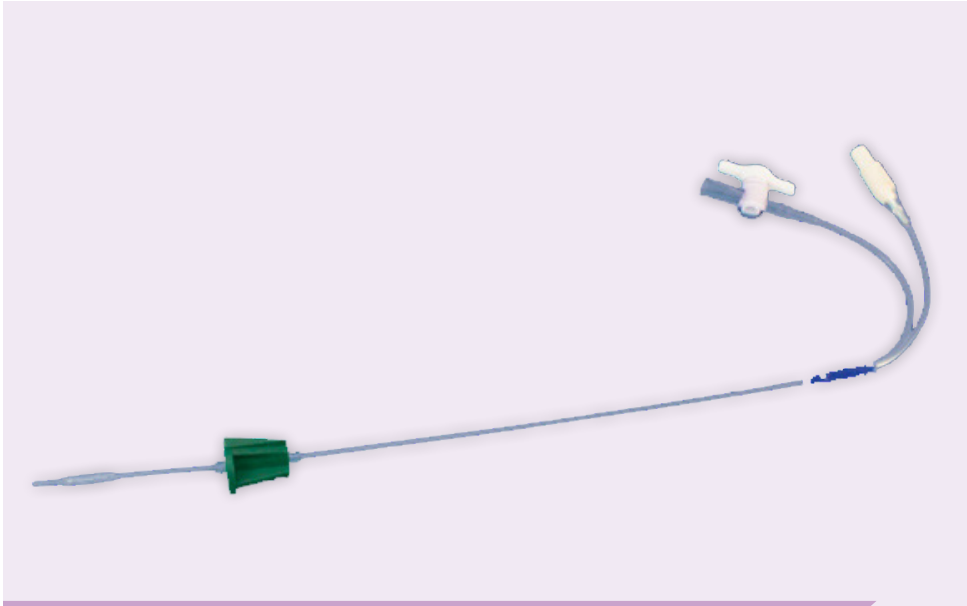
HNM MEDICAL

UTERINE INJECTOR

BOX OF 12

7272027 Rev. 0



HNM Uterine Injectors are double lumen, slightly curved and designed for single use. It was developed to facilitate diagnostic procedures such as Laparoscopy, Minilaps, Salpingoplasties and Fertility Examinations. It is a sterile disposable product consisting of plastic tube, connector and other plastic components which meets the USP recommendation for class VI testing.

PRODUCT NUMBER

HNM-36-151530 2mm

HNM-36-151531 4mm

INDICATIONS

HNM Uterine Injector is intended to be used during hysterosonography, hydrotubation, hysterosalpingogram, and salpingoplastic.

WARNINGS

- The safety and effectiveness of HNM Uterine injectors have not been demonstrated in the setting of uterine bleeding.
- DO NOT use this device when the sterile pouch has been punctured or damaged.
- Test inflatable cuff before insertion for possible leakage. DO NOT use the device while the Cuff is malfunction.
- Inject 5cc of air(UMI-4.0)/3cc of air(UMI-2.0) via Pilot Balloon with syringe to Intrauterine Cuff (A). Also, DO NOT attempt to infuse additional air into cuff. Doing so may cause harm to the patient.
- NEVER introduce fluid such as contrast media or water to inflate the Intrauterine Cuff (A). Such act will impair Intrauterine Cuff.

PRECAUTIONS

- Sound the depth and direction of uterus prior to using the Injector-4.0 or the Injector-2.0. Insert it along the proper axis to avoid uterine trauma.
- Snap firmly in place for cervical stop (E) to the tubing (F) before use. The default setting is that the cervical stop is locked on the tubing at the 6 Centimeter Marking but not firmly. Snap it back on at the appropriate sounding depth marking before use.
- Lubricate catheter tip before use.
- Check for necessity to dilate cervix before insertion to avoid tearing inflatable cuff.
- When using any liquid media, precisely follow manufacturer instruction.
- After insertion and inflation insure the cuff is properly inflated. (Squeeze pilot balloon and check its tautness.)
- A deflated cuff may cause injury and trauma to the uterus.
- Exactly follow a procedure to remove this device; INSPECT the device for intactness.

ADVERSE REACTIONS

- Perforation of the uterine wall
- Cramping
- Infection

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