

EZ Glide™ Manipulator

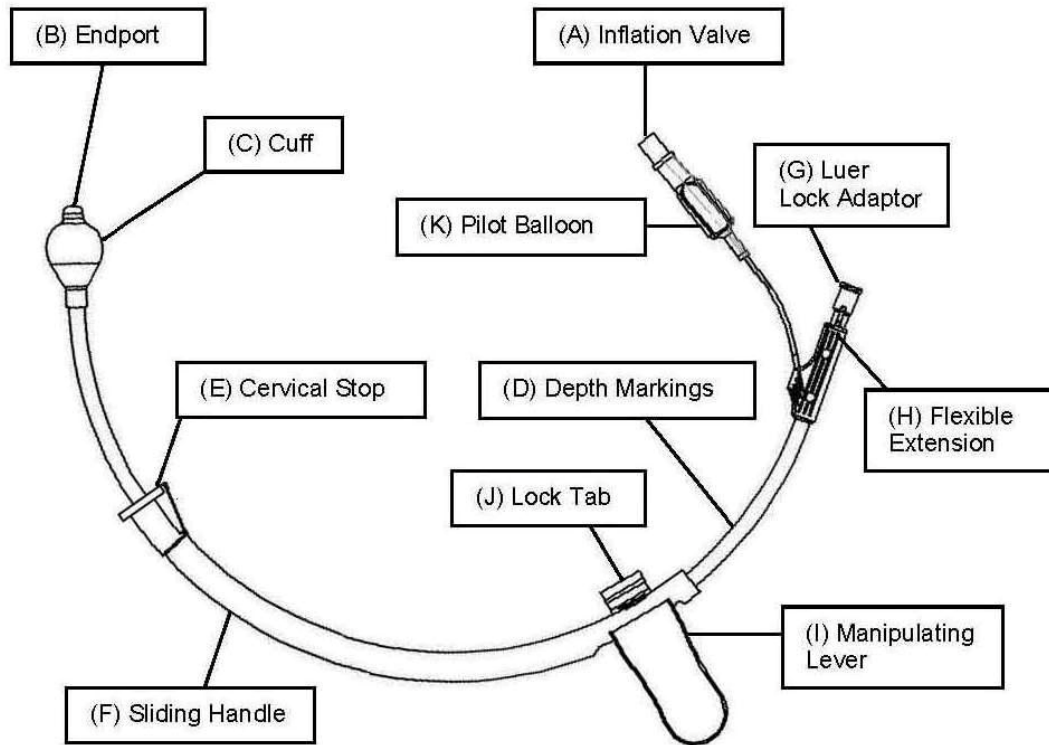


Figure 1

EZ Glide Manipulator Features:

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|--------------------|-----------------------|-----------------------|
| A. Inflation Valve | E. Cervical Stop | I. Manipulating Lever |
| B. Endport | F. Sliding Handle | J. Lock Tab |
| C. Cuff | G. Luer Lock Adaptor | K. Pilot Balloon |
| D. Depth Markings | H. Flexible Extension | |

DESCRIPTION:

The EZ Glide Manipulator is both a uterine manipulator and a uterine injector. This is a sterile (ethylene oxide) disposable, single use, product that does not contain latex. The shaft has two lumens, one for inflation of a 10cc intrauterine cuff and the other for injection of fluid through the product and out the distal endport. The product is curved to accommodate the female anatomy.

The EZ Glide Manipulator features a sliding handle that can be locked to the catheter shaft. This allows positioning the cervical stop at the desired measured depth. The cuff is inflated in the uterus and retracted against the internal os. The cervical stop is pressed firmly against the cervix by advancing the handle while holding the catheter shaft. When the handle is locked, the EZ Glide maintains a secure, trauma-free hold on the uterus. The instrument has a length of 14.5 inches (37cm) and an outside diameter of 5mm (15 Fr).

INDICATIONS:

- Manipulation of the uterus during Laparoscopy, Minilaparotomy, Fertility Examination, and Salpingoplasty.
- Sealing of the cervical os to inject fluid into the uterus.

CONTRAINDICATIONS:

- Pregnancy
- Uterine or tubal infection

WARNINGS:

- Excessive force in manipulation may result in uterine perforation or may cause the product to bend or break, resulting in uterine or vaginal trauma.
- Neglecting to lock the handle or neglecting to lock the handle at the correct sounded depth may result in uterine trauma during manipulation.
- Inflate the cuff before manipulation to avoid uterine trauma.
- Insert the Uterine Manipulator along the proper axis to avoid uterine trauma.

PRECAUTIONS:

- Test inflatable cuff for possible damage prior to product use.
- Lubricate catheter tip before insertion.
- Check for necessity to dilate cervix to ease product insertion and to avoid tearing cuff.
- When injecting any liquid media adhere to appropriate manufacturer’s advice.

ADVERSE REACTIONS:

- Cramping
- Infection
- Uterine trauma or perforation
- Uterine spasm

DIRECTIONS FOR USE (See Figure 1):

1. Assure that the package containing the product has not been punctured or damaged.
2. Be sure the Sliding Handle (F) is not locked and glides smoothly.
3. Using a standard syringe, test the inflatable Cuff (C) by injecting 6cc of air into Inflation Valve (A). Deflate cuff after test.
4. Sound the uterus for depth and direction.
5. Dilate cervix to #14 Hank size, if necessary.
6. Lubricate the Endport (B) and Cuff (C) for ease of insertion. Carefully guide the EZ Glide Manipulator along the natural axis of the cervix to avoid injury.
7. Position proximal end of the Sliding Handle (F) on catheter shaft at the same cm Depth Markings (D) as sounded depth. If the fundus is sounded at 6 cm, set the handle at the 6 cm Depth Marking (D).
8. While maintaining the sounded depth handle position, advance the instrument into the uterus until the Cervical Stop (E) presses on the cervix. Slowly inflate the cuff with a syringe by injecting 3 to 10cc of air through the Inflation Valve (A). Hold thumb on plunger as you remove syringe from Inflation Valve (A) to prevent reflux of air back into syringe.
9. Slowly advance the Sliding Handle (F) while holding the catheter shaft to snug the Cervical Stop (E) against the cervix. Note the change in Depth Markings (D). Lock the Sliding Handle (F) to the shaft by snapping the Lock Tab (J) onto its mating part. The EZ Glide Manipulator is now locked and firmly grasping the uterus.
10. NOTE: A Depth Marking (D) of 6 cm, for example, is equivalent to a distance of 5 cm from Endport (B) to the Cervical Stop (E). This 1 cm difference provides a margin of safety in depth of insertion.
11. To insure that the Cuff (C) has not ruptured during procedure, check the tautness of the Pilot Balloon (K). A soft balloon indicates a ruptured or leaking cuff.
12. Apply gentle traction on the instrument to be sure it is properly placed.
13. Before manipulating or injecting, check that the Cuff (C) is inflated by observing Pilot Balloon (K) inflation. The cervical seal will be lost should cuff break. A deflated cuff increases the danger of uterine trauma.
14. Grasp the Manipulating Lever (I) to manipulate with a mechanical advantage.
15. Inject through the Luer Lock Adaptor (G) by attaching a syringe. The Flexible Extension (H) provides strain relief for syringe movement.
16. To remove the EZ Glide Manipulator, insert syringe deeply in the Inflation Valve (A) and deflate Cuff (C). Unlock Sliding Handle (F) by lifting Lock Tab (J). Carefully withdraw the instrument. Check before discarding instrument to be sure it is intact and no parts remain in the patient.

PRODUCT INFORMATION:

Product Number: TMI1171
 OD Size 5mm
 Length: 37cm
 Packaging: 12 sterile units per box

MANUFACTURED BY:

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