Gynix Hysteroscopy Sheath: SM-GVS

GYNIX™

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Device Description

The Gynix Hysteroscope Sheath is intended for use only with a compatible 1.8mm hysteroscope such as the Gynecare Versascope Hysteroscope and the Alphascope Hysteroscope (for further information on compatibility with your system please contact Schultz Medical at info@schultzmedical.co.uk) .

The Gynix Sheath is a single use, sterile device comprised of both metal and plastic components. The sheath incorporates a channel for insufflation via the attached tubing and connector and also an expandable channel for insertion of hysteroscopic instruments. The rotational collar provides convenient viewing perspective of the uterine cavity.

Usage Indications

The Gynix Sheath is used to establish and maintain distension in the uterus and provide access in the uterine cavity for the compatible hysteroscope and other hysteroscopic instruments during diagnostic and operative hysteroscopic procedures including:

Diagnostic

- · Infertility and pregnancy wastage
- · Abnormal uterine bleeding
- · Evaluation of abnormal hysterosalpingogram
- · Intrauterine foreign body
- · Amenorrhea
- · Pelvic pain

Operative

- · Removal of submucous fibroids and large polyps
- · Directed biopsy
- · Transaction of intrauterine adhesions
- · Submucous myomectomy
- · Transaction of intrauterine septa
- · Endometrial ablation

Contra Indications

The Gynix Sheath is not intended for use where hysteroscopic procedures are contraindicated such as in the presence of acute pelvic inflammatory disease.

Precautions

- · Vaginal ultrasonography before hysteroscopy may identify clinical conditions that may alter patient management. Intrauterine distension can usually be accomplished with pressures the range of 35 – 75mm Hg
- · Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75 – 80mm Hg

Warnings

· Suspicion of pregnancy should necessitate a pregnancy test prior to the performance of diagnostic hysteroscopy
· Only adequately trained personnel who are familiar with hysteroscopy should perform hysteroscopic
procedures. Refer to medical literature relative to techniques, complications and hazards prior to performance of any hysteroscopic procedure
· In the event of using hysteroscopic instruments and accessories from different manufacturers together during a procedure, verify compatibility prior to initiation of the procedure
· When using a fluid distension medium, strict fluid intake and output monitoring should be carried out. Excessive intake of distension fluid can lead to fluid overload. Potential complications of Continuous Flow Hysteroscopy are:
  I. Hypnoatremia
  II. Hypothermia
  III. Pulmonary oedema
  IV. Cerebral oedema
· Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels and ureter
· Failure to follow all applicable instructions may result in serious surgical consequences
· Refer to appropriate user manual indications to ensure that all safety precautions are taken
· A thorough understanding of the principles and techniques involved in laser, electrosurgical and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or grounding is not compromised.
  Electrosurgical instruments should not be immersed in liquid unless the instruments are specifically designed and labelled to function in liquid

Presentation

The Gynix Sheath is supplied in a sterile pouch for single use only. The device will remain sterile until the expiry date as long as the package is unopened and undamaged. This is a single use device so should not be resterilised. Reuse of this device (or any portion of this device) may create a risk of product degradation and cross
contamination which may lead to infection or transmission of blood borne pathogens to patients and users.

Instructions for use

1. Open the package and present the sheath using aseptic technique. Using sterile technique, remove the sheath from the package. To avoid damage, do not flip the instrument into the sterile field
2. Remove the protective cover from the introducer tip
3. Attach an irrigation line to the insufflation tube of the introducer and an outflow line to the outflow line
   connector
4. Place the sterile, compatible hysteroscope through the scope port of the sheath until the scope snaps into place
5. Attach the hysteroscope to the light source and camera if desired

6. With the clamp upon the insufflation tube open and outflow clamp closed, begin flow of distension media prior to introducing the sheath (and attached hysteroscope if applicable) into the cervical canal. Slow introduction into the cervical canal will allow the distension media to enhance ease of entry
7. With the clamp on the insufflation tube open and the outflow clamp closed, insufflate to the desired level of pressure and volume or until an adequate field of view is attained. If outflow is desired, open the roller clamp on the outflow tube and insert an outflow cannula. Regulate desired distension and outflow by adjusting the clamp on the outflow tube
   WARNING: Failure to open the clamp on the outflow tube and/or failure to use the outflow cannula may result in
   over-distension of the uterus or excessive intravasation of fluid
8. At the end of the procedure, ensure any instruments within the instrument port are in the closed position or have been withdrawn from the instrument port prior to withdrawing the sheath
   CAUTION: Failure to close the instruments may result in damage to the sheath and potentially pieces being left behind in the patient

Disposal

Discard after use in accordance with hospital biohazard policy. Resterilisation may compromise the integrity of the device and lead to serious surgical consequences.

Storage

Handle with care. Storage of this device should be in a cool dry place that protects it from extremes of temperature and humidity in an area with good ventilation.

Warranty Disclaimer

Schultz Medical Ltd shall not be liable for any special, incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Schultz Medical Ltd neither assumes nor authorises any other person to assume for them, any other or additional liability or responsibility in connection with this device.

For technical / clinical support call 01772 250298.

CE

CE Mark and identification number of Notified Body. Product confirms to the essential requirements of the medical Device Directive 93/42/EEC

Do not resterilise

Use by

STERILE Sterilised

LOT Batch code

Do not reuse

Caution: see instructions for use

Manufactured by:

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