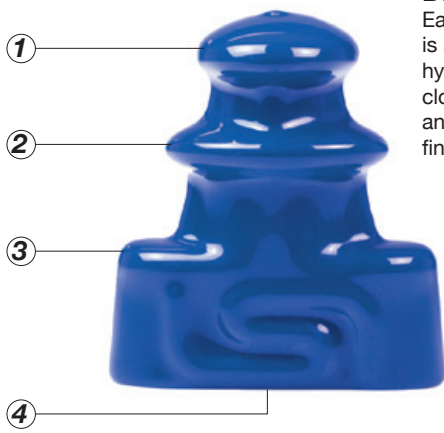


PNEUMOSTOP® DEVICE TECHNOLOGY GUIDE

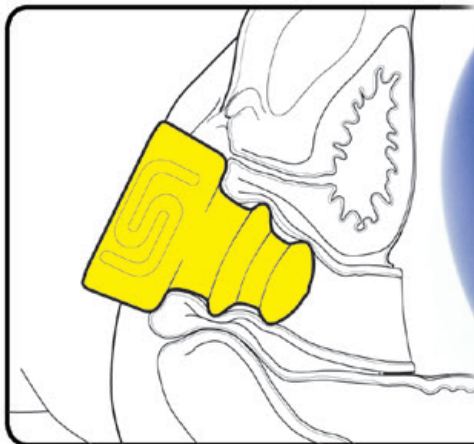
READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1 PNEUMOSTOP® DEVICE



DESCRIPTION

Each sterile pouch contains one single patient use *PNEUMOSTOP® DEVICE*. The *PNEUMOSTOP® DEVICE* is a soft disposable vaginal canal occluder designed to maintain pneumoperitoneum during laparoscopic hysterectomy after removal of the uterine specimen. The external features of this device, starting at its closed end, include a smaller horizontal elliptical occluder ①, then a larger vertical elliptical occluder ② and an insertion stop ridge ③. The *PNEUMOSTOP® DEVICE* is hollow to enable placement of the operator's fingers within the device's internal cavity ④ to assist in its installation within a patient's vaginal canal.



INDICATIONS



The LSI SOLUTIONS® *PNEUMOSTOP® DEVICE* is intended to reduce the risk of pneumoperitoneum loss during laparoscopic hysterectomy procedures.

LSI SOLUTIONS®

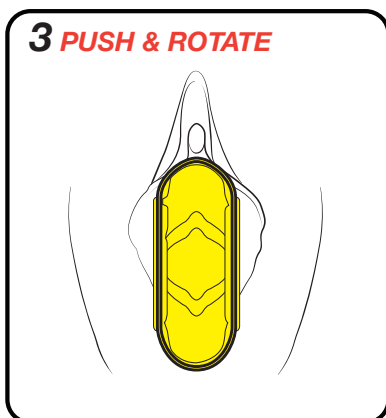
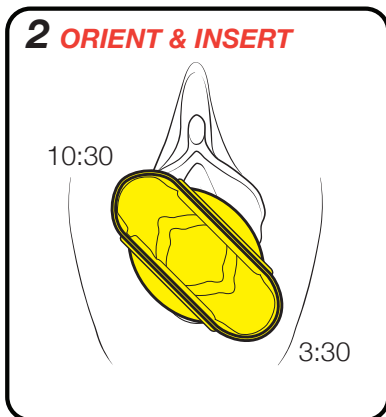
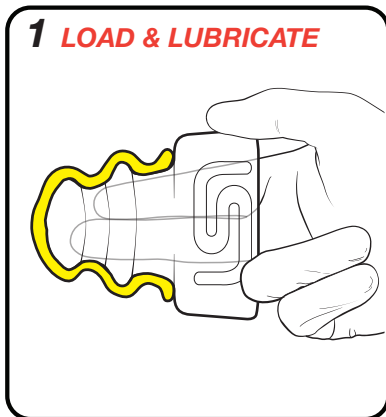
FIG. 2

PNEUMOSTOP® DEVICE ORDERING

SUPPLIED: STERILE

	REORDER	PRODUCT	DESCRIPTION
 x 6	REF 110200	<i>PNEUMOSTOP® DEVICE</i>	6 Shelf Boxes (3 Devices per Shelf Box)
 x 6	REF 110230	<i>PNEUMOSTOP® PLUS DEVICE</i>	6 Shelf Boxes (3 Devices per Shelf Box)

PREPARATION & PLACEMENT



USAGE: DEVICE PLACEMENT

- LOAD** the device onto the operator's hand by placing the middle and index fingers into device cavity. Always **LUBRICATE** device exterior.
- ORIENT** *PNEUMOSTOP*® *DEVICE* at a 45° angle (insertion stop ridge at 10:30 position), then **INSERT** gently by advancing device through the introitus until reaching the insertion stop ridge. (Hand not shown)
- PUSH & ROTATE** the device until it is oriented vertically (upper insertion stop ridge at 12:00) to engage the internal anatomical features of the patient's vaginal canal opening. Remove fingers from device cavity.

USAGE: DEVICE REMOVAL

- Disengage device by rotating device back 45° and gently pull to remove it from patient.

CONTRAINDICATIONS

- Minimally invasive surgical procedures should only be performed by physicians having adequate training and familiarity with endoscopic techniques. In addition, medical literature should be consulted relative to techniques, complications and hazards prior to the performance of minimally invasive procedures.
- PNEUMOSTOP*® *DEVICE* should only be used by appropriately trained health care professionals trained in handling sterile devices in the operating room.
- PNEUMOSTOP*® *DEVICE* should only be used in surgical patients under general anesthesia and when indicated during an operative procedure.
- Do not use device in excessively large vaginal canals in which adequate occlusion may be compromised.

WARNINGS

- Federal (U.S.A.) law restricts this device to sale, distribution and use by, or on, the order of a physician.
- Read and become familiar with all instructions, warnings, and cautions before using this product.
- Do not contact the *PNEUMOSTOP*® *DEVICE* with any type of energized tools.
- Do not resterilize the *PNEUMOSTOP*® *DEVICE*. The performance of the *PNEUMOSTOP*® *DEVICE* after cleaning or other reprocessing has not been validated and is not supported by LSI SOLUTIONS®.
- PNEUMOSTOP*® *DEVICE* must be removed from each patient while the patient is still under general anesthesia.
- Do not use this technology under conditions in which excessive tissue compression or tension can lead to tissue damage. For example, do not use the *PNEUMOSTOP*® *DEVICE* through an excessively narrow, restrictive or deformed vaginal canal or pelvic floor, which could significantly impair smooth passage and safe use of these devices.
- Inspect packaging prior to use. Discard opened, unused, expired or damaged devices or devices in damaged primary packaging.

PRECAUTIONS

- Care must be taken when inserting this or any vaginal occlusion device to avoid advancing the device incorrectly (e.g., too far or too quickly). Device insertion should be easy, smooth and controlled to minimize the risks of trauma to the patient or damage to the device.
- Care must be taken to avoid unintended removal of other devices, such as urinary catheters, during *PNEUMOSTOP*® *DEVICE* placement and removal.
- Any foreign body inadvertently left in a patient, including a *PNEUMOSTOP*® *DEVICE*, may be associated with serious complications, such as infection, bleeding, discomfort, wound complications, etc.
- Use of this technology requires appropriate laparoscopic surgical techniques for minimally invasive gynecologic surgery based on the surgical circumstances and the experience of the surgeon.

ADVERSE REACTIONS

Adverse effects associated with the use of such products can include, but are not limited to: infected wounds, acute inflammatory tissue reaction and transitory local irritation.

DISPOSAL

After device removal, dispose of the *PNEUMOSTOP*® *DEVICE* according to local biological hazardous material requirements. **DO NOT ATTEMPT TO REUSE THE *PNEUMOSTOP*® *DEVICE*.**



Patents: www.lsisolutions.com/patents

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Symbol Glossary: www.lsisolutions.com/symbols



LSI SOLUTIONS®
 7796 Victor-Mendon Road
 Victor, New York 14564 U.S.A.
 Phone: 585.869.6600
 Customer Service: 866.575.3493
 Technical Support: 866.428.9092
 Fax: 585.742.8086
www.lsisolutions.com

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