WECK VISTA™ BALLOON OPEN LAPAROSCOPIC ACCESS PORT

WECK® VISTA™

REF 410944S
Size: 10mm x 53mm
REF 410944
Size: 10mm x 70mm
REF 410944L
Size: 10mm x 100mm
REF 412944
Size: 12mm x 70mm
REF 412944L
Size: 12mm x 100mm

Figure 1



Figure 2

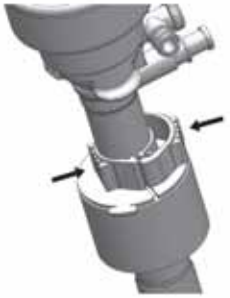
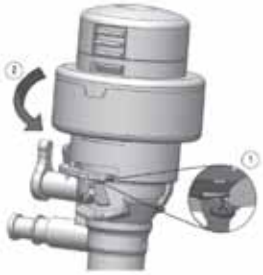
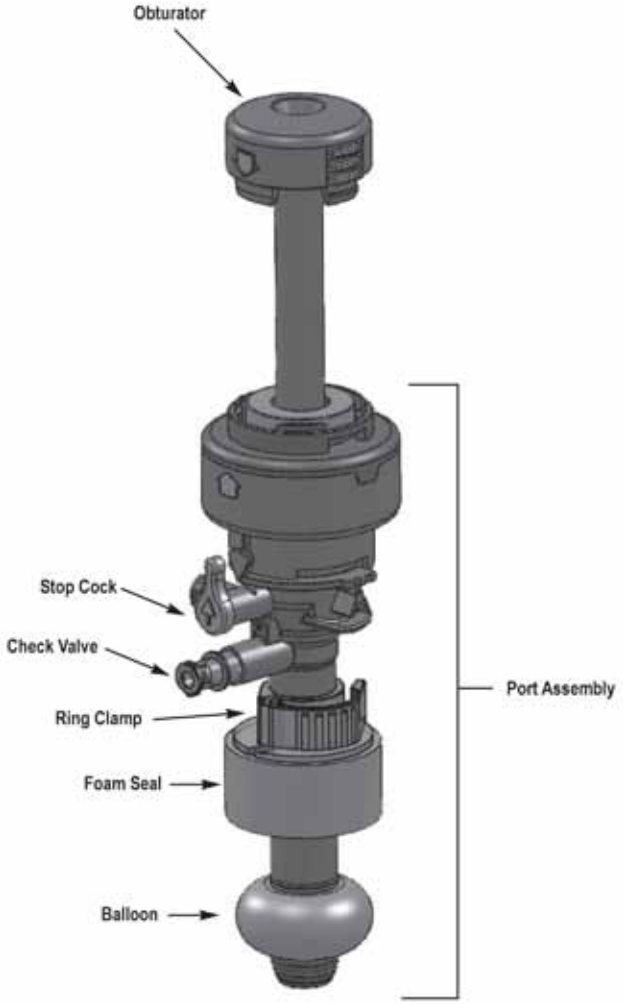


Figure 3



Figure 4





Do not use if package has been opened or damaged. Ne pas utiliser si l'emballage est ouvert ou endommagé. Nicht verwenden, wenn die Verpackung offen oder beschädigt ist. Non utilizzare se la confezione è stata aperta o danneggiata. No utilizar si el envase está abierto o dañado. Não utilize se a embalagem estiver aberta ou danificada. Må ikke anvendes, hvis pakningen er åbnet eller beskadiget. Niet gebruiken indien de verpakking geopend of beschadigd is. Får inte användas om förpackningen har öppnats eller skadats. Nie używać, jeśli opakowanie zostało wcześniej otwarte lub uszkodzone. Ambalaj daha önce açılmış veya hasarlıysa kullanmayın. Ne uporabite, če je bila ovojnina predhodno odprta ali poškodovana. Не используйте, если упаковка была ранее вскрыта или повреждена.

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WECK VISTA™ BALLOON OPEN LAPAROSCOPIC ACCESS PORT

Please review the following information thoroughly before use.

Important: The instructions provided are intended to facilitate the use of the Weck Vista Balloon Open Laparoscopic Access Port. They are not intended to be an implication of trocar introduction methods. Properly following the instructions is essential to the safe and effective use of the product. Failure to do so may result in adverse surgical results.

Product Indications: The Weck Vista Balloon Open Laparoscopic Access Port is indicated for use in thoracic, abdominal, and gynecologic minimally invasive surgical procedures to provide a pathway for the introduction of endoscopic surgical devices.

Contraindications: Where minimally invasive techniques are contraindicated, other methods and instrumentation should be employed.

Instructions for Use: Before using the Weck Vista Balloon Open Laparoscopic Access Port, confirm the compatibility of all instruments and accessories. Prepare the patient in accordance with proper surgical techniques before insertion of the Weck Vista Balloon Open Laparoscopic Access Port.

1. Remove the device from the package using standard sterile technique. To prevent damage, care should be taken not to allow the device to fall into the sterile field.
2. Insert the obturator into the cannula, aligning arrows between components until both lock securely together (See Figure 1).
3. Make an adequate incision at the desired site. Carefully dissect the tissue down to, and through, the desired tissue plane.
4. Unlock the Foam Seal by unsnapping the lock ring tab on the Ring Clamp, and slide the Foam Seal to the top of the cannula. Insert the Weck Vista Balloon Open Laparoscopic Access Port into the incision until the balloon portion at the distal tip is placed within the desired space.
5. Fill the provided syringe with 10CC OF STERILE LIQUID OR 15CC OF AIR. Attach the syringe to the Check Valve and inflate slowly. CAUTION: OVER-INFLATION OF THE BALLOON MAY CAUSE IT TO RUPTURE. NOTE THAT 10CC OF FLUID OR 15CC OF AIR WILL COMPLETELY INFLATE THE BALLOON AND FURTHER INFLATION IS UNNECESSARY AND WILL INCREASE THE RISK OF BALLOON RUPTURE.
6. Pull up on the port while firmly pushing down the Foam Seal to the skin, compressing the Foam Seal. Lock the Foam Seal into place by placing the thumb and forefinger on the ribbed portions of the Ring Clamp and depressing until the Ring Clamp locks (See Figure 2). To unlock or reposition the Foam Seal, simply unlock the tab on the Ring Clamp and move the Foam Seal to the new position.
7. Once proper placement of the device has been established, press the locking tabs on the obturator to remove it (See Figure 3). When obturator is removed, the internal valve automatically closes.
8. To insufflate, attach insufflation tubing to the stopcock on the cannula and open the stopcock. When an instrument is inserted into the cannula, an outer seal maintains insufflation. The seal mechanism also maintains insufflation in the absence of an instrument in the cannula.
9. To remove the Weck Vista Balloon Open Laparoscopic Access Port, reattach the syringe to the Check Valve. Draw back on the plunger until all fluid or air has been removed and the balloon is fully deflated. Remove the Open Access Port only after the balloon has been fully deflated.
10. For rapid desufflation or removal of a tissue sample during the procedure, use your index finger to compress the locking lever located on the blue end of cannula head. While maintaining locking lever compression, turn the blue end of the cannula head counter-clockwise 90° (See Figure 4). This will completely open the internal valve assembly. Once tissue sampling or desufflation is complete, rotate the blue end of cannula head clockwise, until it returns to its original locked position.

Warnings and Precautions:

- The complications and risks of minimally invasive procedures should be reviewed prior to their performance through consultation of medical literature. Only persons having adequate training and familiarity should perform minimally invasive procedures.
- Although precautionary measures involved in obturator insertions must be observed, the uniquely designed obturator tip is intended to reduce the possibility of injury to surrounding anatomic structures.
- Due to the variance in diameter of minimally invasive instruments, compatibility should be confirmed before initiating any minimally invasive procedure.
- Desufflation of the abdominal or thoracic cavity may result from introducing instruments with a smaller diameter than the Weck Vista Balloon Open Laparoscopic Access Port.
- Discontinue advancement of the obturator device once complete entry has been established into the abdominal or thoracic cavity in order to avoid injury to surrounding structures.
- Insertion and removal of instruments through the cannula should be done carefully to prevent unintentional damage to the internal seals, which may compromise insufflation. To ensure smooth insertion, avoid inserting instruments at an angle. Always attempt to insert instrumentation straight down the cannula.
- After removing the Weck Vista Balloon Open Laparoscopic Access Port from the cavity, always inspect the insertion site for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Properly discard using accepted disposal practices.
- Re-processing of products intended for single use only may result in degraded performance or loss of functionality. Re-use of single use only products may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilization methods and instructions for reprocessing to original specifications are not available for these products. This product is not designed to be cleaned, disinfected, or sterilized.

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