WECK VISTA BLADELESS LAPAROSCOPIC ACCESS PORTS

IMPORTANT: The instructions provided are intended to facilitate the use of the Weck Vista Bladeless 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 Bladeless Access Port is indicated for use in thoracic, abdominal, gynecological 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 Bladeless Access Ports, confirm the compatibility of all instruments and accessories. Prepare the patient in accordance with the proper surgical techniques before insertion of the Weck Vista Bladeless 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, align the arrows, and lock both components securely together. Confirm that the tip is properly aligned.
3. Perform initial insufflation using standard surgical techniques.
4. Make an adequate incision at the puncture site to ease insertion. Introduce the obturator and cannula through the incision and apply continuous but controlled pressure with a deliberate rotating motion of approximately 180°. Once the primary port is in place, insert all secondary ports under direct visualization.
5. Once proper placement of the device has been established in the abdominal or thoracic cavity, press the locking tabs to remove the obturator, maintaining the position of the cannula. When obturator is removed, the internal valve automatically closes.
6. Insufflation may be maintained by attaching insufflation tubing to the stopcock on the cannula. When an instrument is inserted in the cannula, an outer seal maintains insufflation. The seal mechanism also maintains insufflation in the absence of an instrument in the cannula.
7. If additional stabilization of the cannula is required, the physician may suture the cannula in place by threading standard suture material through suture opening located at the base of the cannula head.
8. For rapid desufflation or removal of a tissue sample during the procedure, use your index finger to compress the locking lever located on the head of the cannula. While maintaining locking lever compression, turn the blue end of the cannula head counter-compression, turn the blue end of the cannula head counter-clockwise, until it returns to its original locked position.

WARNINGS AND PRECAUTIONS:

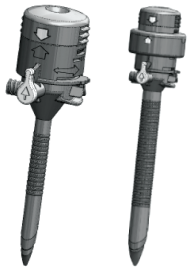
- The complications and risks of minimally invasive procedures should be reviewed prior to their performance through consultation of medical literature. Only persons having adequate training and familiarity should perform minimally invasive procedures.
- Although precautionary measures involved in obturator 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 procedures.
- Desufflation of the abdominal thoracic cavity may result from introducing instruments with a smaller diameter than the Weck Vista Bladeless Access Ports.
- 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 Bladeless Access Ports 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 a loss of functionality. Re-use of single use only products may result in degraded performance or a loss of functionality. Re-use of single use only products may result in exposure to viral, bacteria, 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 re-sterilized.

WECK® VISTA™

Bladeless Laparoscopic Access Ports

REF 43507R, 40507R, 40513R, 40811R, 41213R, 41510R, 40591213R, 40511RC, 405910RC, 405912RC

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