WECK®

Weck Reusable Obturator

REF 4050788S, 405188 410988, 45188S, 412988

ENGLISH

IMPORTANT:
The instructions provided are intended to facilitate the use of the Weck® Reusable Obturator. 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 Reusable Obturator is indicated for use with appropriate disposable WECK Vista™ cannulas 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 Reusable Obturator, confirm the compatibility of all instruments and accessories. Prepare the patient in accordance with proper surgical techniques before insertion of the Weck Reusable Obturator.

REUSABLE OBTURATOR (REF)	MATCHING DISPOSABLE CANNULA (REF)
4050788S	4050722
405188	40511C, 40511RC
410988	405910C, 405910RC
45188S	451022U
412988	405912C, 405912RC

1. Sterilize device before use. Insert the reusable obturator into the cannula until both components lock securely together. Confirm that the tip is properly aligned.
2. Perform initial insufflation using standard surgical techniques.
3. Make an adequate incision at the puncture site to ease insertion. Introduce the Weck Reusable 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.
4. Once proper placement of the device has been established in the abdominal or thoracic cavity, remove the Weck Reusable Obturator, maintaining the position of the cannula. When Weck Reusable Obturator is removed, the internal valve automatically closes.

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.
- 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.

CLEANING
The instruments are approved to be cleaned according to each of the following options:

Automatic Processing Instructions For Use with Alkaline or Enzymatic Detergents	Manual Processing Instructions For Use with Enzymatic Detergents
PRE-CLEANING • Soak the instrument in tap water for a minimum time of 5 minutes and clean with a soft brush. • Disassemble the instrument (if applicable). • Brush under water with a soft brush until all visible residues are removed.	**PRE-CLEANING** • Soak the instrument in tap water for a minimum time of 5 minutes and clean with a soft brush. • Disassemble the instrument (if applicable). • Brush under water with a soft-bristled brush until all visible residues are removed.
CLEANING • Place the opened instrument in a wire basket on the slide-in tray and start the cleaning process. • Pre-rinse for 1 minute with cold water. • Empty. • Pre-rinse for 3 minutes with cold water. • Empty. • Wash for 5 minutes at 131°F (55°C) with a 0.5% alkaline detergent or at 113°F (45°C) with a 0.5% enzymatic detergent. • Empty. • Neutralize for 3 minutes with warm water (>104 °F [>40°C]). • Empty. • Rinse for 2 minutes with warm water (>104 °F [>40°C]). • Empty. **Note:** The preparation of concentration, temperature and application time of the cleaning agent must be according to the instructions for use provided by the detergent manufacturer. Detergents must be approved for use with metal reusable general surgical instruments.	**CLEANING** • Place the instrument in an ultrasound bath at 104°F (40°C) with a 0.5 % enzymatic detergent. • Sonicate for 15 minutes (minimum). • Remove the instrument and flush with de-ionized water for approximately 15 seconds while simultaneously brushing using a soft-bristled brush until all detergent residue has been removed. **Note:** The preparation of concentration, temperature and application time of the cleaning agent must be according to the instructions for use provided by the detergent manufacturer. Detergents must be approved for use with metal reusable general surgical instruments.
DRYING Dry the outside of the instruments using the drying cycle of the cleaning equipment. If necessary, instruments can be dried by hand with a sterile lint-free cloth. Compressed, filtered air can be used for instruments with lumens.	**DRYING** Dry instruments with a sterile lint-free cloth. Compressed, filtered air can be used for instruments with lumens.
DISINFECTION Teleflex® does not provide disinfection instructions due to the sterility instructions provided.	**DISINFECTION** Teleflex does not provide disinfection instructions due to the sterility instructions provided.
Visually inspect the instruments for any signs of debris. If debris is still visible, repeat the entire cleaning procedure.	Visually inspect the instruments for any signs of debris. If debris is still visible, repeat the entire cleaning procedure.

STERILIZATION
The instruments are approved to be sterilized according to the following parameters:

Sterilization Method	Instrument Configuration	Temperature (minimum)	Exposure Time (minimum)	Drying Time (minimum)
USA Parameters				
Pre-vacuum	Wrapped	270°F (132°C)	4 minutes	10 minutes
Gravity Displacement	Wrapped	250°F (121°C)	30 minutes	10 minutes
Outside USA Parameters				
Pre-vacuum	Wrapped	273°F (134°C)	3 minutes	10 minutes
Gravity Displacement	Wrapped	270°F (132°C)	10 minutes	10 minutes

LIFE EXPECTANCY
Immediately following each complete sterilization cycle the instrument should be inspected prior to use. The instruments should be inspected for signs of rust, cracking, pitting, breaking, staining and/ or discoloration, burrs, sharp edges or protrusion as well as any another signs of defect. Special attention should be paid to ensure the instrument shaft is perpendicular to the instrument cap. Instruments found with any signs of the aforementioned defects are not safe for use with patients and should be immediately discarded.

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NON STERILE **Rx ONLY**

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