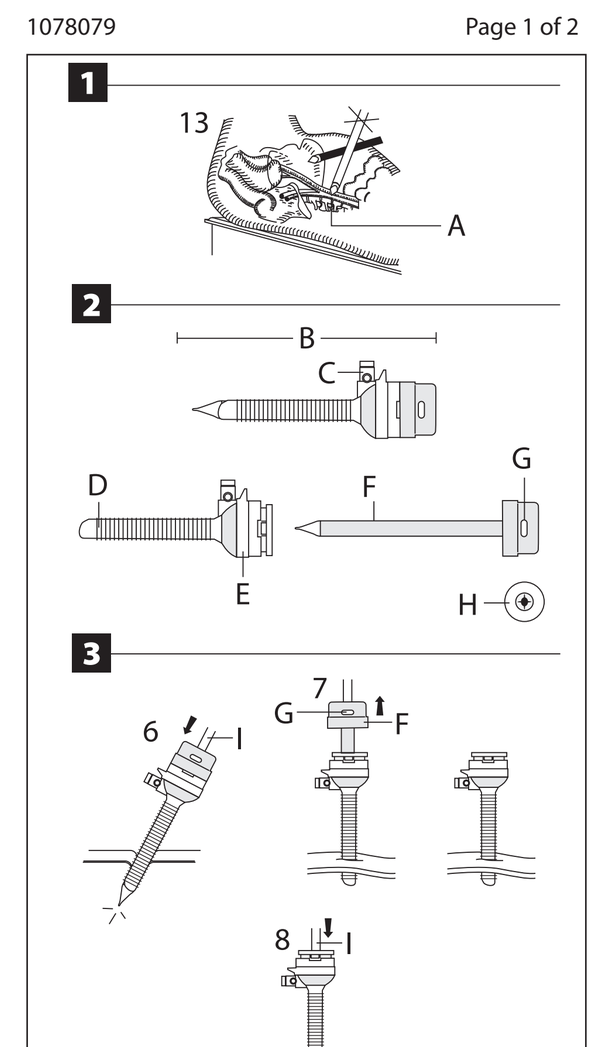
Box size: 4.19 x 9.75
Overall size: 18 x 20.5
Folds to: 3 x 6.833

COVIDIEN™

Versaport™
Bladeless Optical Trocar

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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.
IMPORTANT!
This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination, patient infection and/or device malfunction. Do not reuse, reprocess or resterilize this device.

DESCRIPTION
The Versaport™ V2 Bladeless Optical Trocars are available in various sizes: 11 mm and 12 mm with different lengths: standard (100 mm), long (150 mm), and short (70 mm). The Versaport™ V2 Bladeless Optical trocar with transparent fixation / smooth cannula, and obturator distal end allows optical entry for visualization of tissue layers during insertion. Each size is suitable for use with instruments ranging from 5 mm up to the indicated trocar size.

The obturator housing contains a scope retention mechanism. The trocar housing contains internal seals to prevent loss of pneumoperitoneum. The proximal seal can be twisted off for passing specimens or other devices; a specimen removal button prevents inadvertent removal. There is a 3-way stopcock for insufflation and rapid desufflation.

NOTE: The Versaport™ Bladeless Optical trocar transparent fixation/ smooth cannula sleeves and obturators may not be compatible with other Covidien™ trocar systems.

INDICATIONS
The Versaport™ Bladeless Optical trocars are intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry. The trocar may be used with or without visualization for primary and secondary insertions.

CONTRAINDICATIONS
1. This device is not intended for use when endoscopic techniques are contraindicated.
2. This device is not intended for use except as indicated.

1 WARNINGS AND PRECAUTIONS
1. Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may reduce available free space, increasing the risk of injury to internal structures.
2. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Medical literature relative to techniques, complications and hazards should be consulted prior to use.
3. An insufficient skin incision may cause increased penetration force which may reduce the surgeon's control during entry. An incision too large may increase the potential for port instability.
4. The optical features in the distal end of the obturator are intended to minimize the likelihood of penetrating injury to intra-abdominal and intra-thoracic structures, however, standard precautionary measures employed in all obturator insertions must be observed.
5. Before and after removal of the Versaport™ Bladeless Optical trocar from the abdominal or chest cavity, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.
6. Thoracoscopy is not indicated unless at least a limited intrapleural space exists (air or fluid filled). For this reason, needle aspiration through the selected site is indicated prior to inserting the trocar.
7. Before endoscopic instruments and accessories from different manufacturers are used, verify compatibility and ensure that electrical isolation or grounding is not compromised.
8. The Versaport™ Bladeless Optical self-adjusting seal can accommodate instruments ranging from 5mm to the indicated diameter. Use of instruments less than 5mm in diameter can result in loss of pneumoperitoneum.
9. A thorough understanding of the principles and techniques involved in laser laparoscopy and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and operator(s), and damage to the instrument.
10. The Versaport™ Bladeless Optical trocar with transparent fixation/smooth cannula sleeve is not compatible with other Covidien™ trocar systems.
11. Closure of the fascia is at the discretion of the surgeon. Underlying fascia may be closed, e.g., by suturing to reduce the potential for incisional hernias.
12. Use care when introducing or removing sharp-edged or sharp-angled endoscopic instruments to minimize the potential of inadvertent damage to the seal.
13. In abdominal procedures, the incorrect perpendicular trocar insertion (depicted by the crossed-out trocar in the illustration) could result in an aortic puncture (note the abdominal aorta (A)). The solid black trocar shows the correct angle of insertion with the patient in the Trendelenburg position.
A) ABDOMINAL AORTA
14. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

2 SCHEMATIC VIEW
B) TROCAR ASSEMBLY
C) 3-WAY STOPCOCK
D) TROCAR CANNULA
E) SELF ADJUSTING SEAL WITH SPECIMEN REMOVAL BUTTON
F) OBTURATOR
G) INTERLOCKING SNAPS
H) SCOPE RETENTION MECHANISM

3 INSTRUCTIONS FOR USE
This device may be used with or without visualization for primary and secondary insertions.
1. Prior to insertion of laparoscope, insert obturator into cannula until the interlocking snap feature is engaged.
2. Connect a 10 mm 0° laparoscope to the light supply and monitor as directed in the manufacturer's instructions. Verify proper connection of the laparoscope and ensure the clarity of the picture on the monitor. Insert laparoscope into the obturator housing until it reaches the distal end of the obturator.
3. To provide a clear image on the monitor, once the laparoscope is inserted into the obturator, touch the tip of the distal end of the obturator to a convenient soft sterile surface, and focus the camera.
4. Insufflation of the abdomen prior to the insertion of the Versaport™ Bladeless Optical trocar is at the discretion of the surgeon as determined by the conditions of each case. The potential for abdominal adhesions or anatomical anomalies should be considered before using this device without first establishing pneumoperitoneum.
5. Prepare the abdominal or thoracic cavity for trocar insertion by making an incision adequate to accommodate the cannula diameter.

An insufficient incision may cause increased penetration force which may reduce the surgeon's control during entry. An incision too large may increase the potential for port instability.

WARNING: The failure to make an adequate incision, the application of excessive force or incorrect insertion may increase the risk of injury to internal structures.

6. Position the trocar assembly at the appropriate angle to the abdomen and while maintaining compression on the obturator, introduce the trocar assembly through the skin incision utilizing a clocking motion, applying continuous downward pressure.
7. When the trocar assembly is in the desired position within the abdominal or chest cavity, remove the obturator from the trocar cannula by depressing the interlocking snaps, leaving the cannula in place, remove the laparoscope from the obturator.
G) INTERLOCKING SNAPS
F) OBTURATOR
I) LAPAROSCOPE
8. Reinsert the laparoscope through the port to facilitate visualization of secondary port entry into the abdominal cavity.
I) LAPAROSCOPE
If no laparoscope is required, appropriately sized endoscopic instruments may now be inserted and removed through the trocar cannula.
9. When using the Versaport™ Bladeless Optical trocar for specimen removal, rotate the self-adjusting seal counter-clockwise while depressing the specimen removal button and slide the seal onto the shaft of the instrument. Once the seal is on the shaft of the instrument, proceed with removing the specimen by pulling it through the cannula. Only specimens which fit comfortably within the cannula should be removed in this manner.
E) SELF ADJUSTING SEAL WITH SPECIMEN REMOVAL BUTTON

WARNING: To prevent damage to the seal system, follow manufacturer's instructions when inserting or removing instrumentation utilizing jaws or components that open and close, ensure that the instrument jaws or components are in the closed position (where applicable).

10. When the procedure is complete, the abdomen may be desufflated by opening the stopcock. Remove the cannula from the operative site. A twisting motion while pulling axially on the port will facilitate removal of the fixation cannula.

WARNING: Before and after removal of the Versaport™ Bladeless Optical trocar from the abdominal or chest cavity, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.

WARNING: Closure of the fascia is at the discretion of the surgeon. Underlying fascia may be closed, e.g., by suturing to reduce the potential for incisional hernias.

STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

FR
Trocart optique sans lame

DE
Optik-Trokar ohne Klinge

IT
Trocar ottico senza lama

ES
Trocar óptico sin bisturí

PT
Trocarte óptico sem lâmina

NL
Optische trocar zonder messen

SV
Optisk troakar utan kniv

DA
Optisk trokar uden kniv

FI
Terätön optinen troakaari

EL
Οπτικό τροκάρ χωρίς λεπίδα

PL
Optyczny trokar bez noża

TR
Bıçaksız Optik Trokar

RU
Оптический троакар без лезвия

CS
Bezčepelový optický trokar

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STERILE EO | Rx ONLY | Caution, consult accompanying documents | CE 0123

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