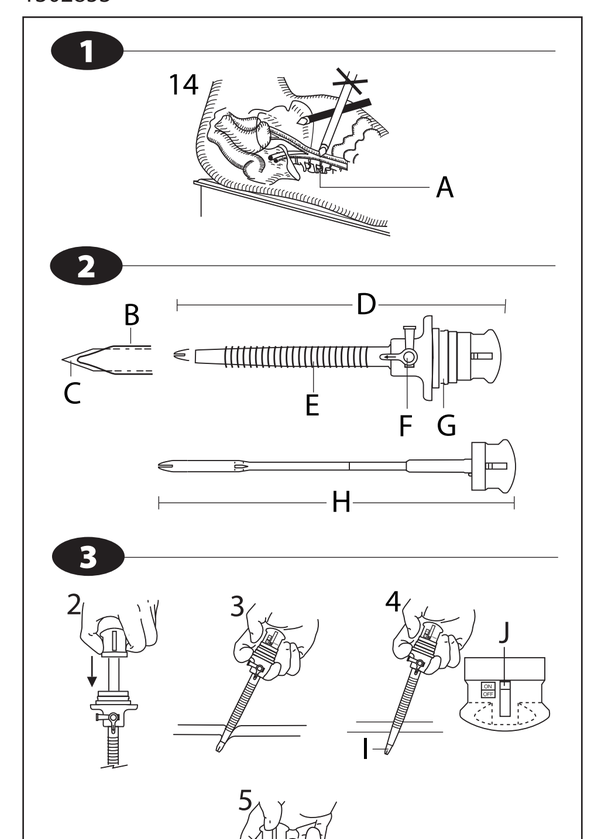
Box size: 4.19 x 9.75
Overall size: 18 x 21
Folds to: 3 x 7

COVIDIEN™

Versaport™

V2 Bladed Trocar with Fixation Cannula

1302853



EN

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 and patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The Versaport™ V2 bladed trocar with fixation cannula is available in 5 mm short and 5 mm diameter with a radiolucent fixation sleeve and shield.

The Versaport™ V2 bladed trocar has a sharp linear blade and a spring-loaded locking shield. Upon entry into a free space in the abdominal or chest cavity, the shield advances to cover the linear blade, reducing the potential for injury to internal structures. The seal housing contains an internal seal to prevent gas leakage when instruments are inserted or withdrawn, without loss of pneumoperitoneum. There is a stopcock valve for gas insufflation and rapid desufflation.

NOTE: The Versaport™ V2 fixation sleeve is not for use with the Spring Grip™ anchoring devices, or the Step™ and VersaStep™ access systems.

INDICATIONS

The Versaport™ V2 bladed trocar with fixation cannula has application in gynecologic, general, thoracic and urologic endoscopic procedures to establish a port of entry for instrumentation.

CONTRAINDICATIONS

1. This device is not intended for use when endoscopic techniques generally 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, thereby impeding the advancement of the shield and 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. The Versaport™ V2 bladed trocar is sharper than reusable trocars and, therefore, generally requires the application of less force for insertion. Exerting excessive force may reduce the user's control of the angle and the depth of insertion of the trocar tip, increasing the risk of injury to internal structures.
4. Adhesions, anatomical anomalies, or other obstructions may prevent or delay advancement of the shield, leaving the sharp linear blade uncovered, exposing internal structures to injury.
5. The seal is designed to be used with 5 mm instruments. Use of instruments less than 5 mm in diameter can result in loss of pneumoperitoneum.
6. Both before and after removal of the Versaport™ V2 bladed trocar from the abdominal or chest cavity, inspect the operative site for hemostasis. Bleeding can be controlled by electrocautery or manual sutures. At the surgeon's discretion, a laparotomy or thoracotomy may be performed.
7. Do not attempt to insert the trocar if the red flag in the safety indicator does not move from the ON to the OFF position, as the trocar tip will not be exposed for abdominal or chest penetration.
8. ONCE ENTRY HAS BEEN MADE INTO FREE SPACE IN THE ABDOMINAL OR CHEST CAVITY, CARE MUST BE TAKEN NOT TO REARM THE Versaport™ V2 BLADED TROCAR. If the compression (squeezing) of the handle assembly is stopped and then restarted, the shield will again be free to move back if sufficient force is applied against the front end of the shield. The Versaport™ V2 bladed trocar would then be rearmed in the penetration mode. Continued advancement of the exposed sharp linear blade at this point could cause injury to internal structures.
9. Thoracoscopy is not indicated unless at least a limited intrapleural space exists (air or fluid filled). For this reason, needle aspiration through the site selected is necessary before actually inserting the trocar.
10. Before endoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that electrical isolation or grounding is not compromised.
11. 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.
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. If the trocar incision is 10 mm or larger, the underlying fascia should be closed, e.g., by suturing to reduce the potential for incisional hernias.
14. In an abdominal procedure the incorrect perpendicular trocar insertions, as depicted by the crossed-out trocar in the foreground, may result in aortic puncture. Note the abdominal aorta at (A). The solid black trocar shows the correct angle of insertion. The patient is shown in the Trendelenburg position.

A) ABDOMINAL AORTA

15. 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) SHIELD
C) LINEAR BLADE
D) TROCAR ASSEMBLY
E) TROCAR SLEEVE
F) STOPCOCK
G) SEAL
H) OBTURATOR

3 INSTRUCTIONS FOR USE

THE PRESENCE OF THE SHIELD ON THE Versaport™ V2 BLADED TROCAR IS NOT A SUBSTITUTE FOR ADHERENCE BY THE PHYSICIAN TO PROPER ENDOSCOPIC TECHNIQUES.

NOTE: The stopcock is packaged in the closed position.

- To insufflate the abdomen, turn the stopcock clockwise.
- To close valve, turn the stopcock downward.
- To rapidly desufflate the abdomen, turn the stopcock counterclockwise.

1. Creation of pneumoperitoneum in the abdomen is recommended prior to insertion of the trocar. Prepare the abdominal or thoracic cavity for trocar insertion by making an incision adequate to accommodate the sleeve diameter.

An incision that is too short may cause additional resistance to penetration, increasing the force needed and reducing the surgeon's control during entry.

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

2. Position the trocar at the appropriate angle to the abdomen while squeezing down on the top of the obturator to unlock the shield. While maintaining compression on the handle, introduce the trocar through the skin incision, applying continuous downward pressure during entry.

NOTE: The red flag in the indicator window is an integral part of the shield which shows the position of the shield. During insertion, the red flag moves from the ON position (blade shielded) to the OFF position (blade exposed).

3. When the shield retracts to expose the trocar tip there will be an audible click; once the distal end of the sleeve has passed into free space the shield will spring forward and the red flag will return to the ON position. There will be a second click when the shield advances to cover the tip.

WARNING: Once entry has been made into free space, care must be taken not to rearm the Versaport™ V2 bladed trocar.

If compression (squeezing) of the handle assembly is stopped and then restarted, the shield could move back, exposing the trocar blade.

4. If the red flag remains in the off position following entry, the surgeon should remove the obturator and insert a laparoscope for visual inspection of the instrument's entry point. If entry was incomplete, repeat instruction #3.
5. Upon entering the free space, the shield will cover the linear blade and lock into place. The red flag will be in the ON position as confirmed by an audible click.

I) SHIELD FORWARD
J) RED FLAG (IN "ON" POSITION)

6. When the instrument is in the desired position within the abdominal or chest cavity, remove the obturator from the trocar sleeve, leaving the sleeve in place. Appropriately sized endoscopic instruments may now be inserted and removed through the trocar sleeve.

NOTE: Use care when introducing or removing sharp-edged or sharp-angled endoscopic instruments to minimize the potential of inadvertent damage to the seal.

7. When the procedure is complete, the abdomen may be desufflated by opening the stopcock (counterclockwise) to vent. To rapidly desufflate the abdomen, turn the stopcock fully counterclockwise. Remove the sleeve from the operative site. A twisting motion back and forth will facilitate removal of the fixation cannula.

WARNING: Before and after removal of the Versaport™ V2 bladed trocar and fixation cannula from the abdominal or chest cavity, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.

WARNING: If the trocar incision is 10 mm or larger, the underlying fascia should be closed to reduce the potential for incisional hernias.

AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

FR

Trocart à lame V2 avec canule de fixation

DE

V2-Trokar mit Klinge und Fixierkanüle

IT

Trocar V2 con lama dotato di cannula di fissaggio

ES

Trocar con bisturí V2 y cánula de fijación

PT

Trocarte com lâmina V2 com cânula de fixação

NL

V2-trocar met messen met fixatiecanule

SV

V2-bladförsedd troakar med fixationskanyl

DA

V2-trokar med kniv og fikseringskanyle

FI

V2-teräinen troakaari ja kiinnityskanyyli

EL

Τροκάρ V2 με λεπίδα και σωληνίσκο καθήλωσης

PL

Trokar z nożem V2 i kaniulą mocującą

TR

Sabitleme Kanülüne Sahip V2 Bıçaklı Trokar

RU

Троакар V2 с лезвием и с фиксирующей канюлей

CS

Trokar s ostřím V2 s fixační kanylou

Do not use if package is opened or damaged. / Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage. / Bei geöffneter oder beschädigter Verpackung nicht verwenden. / Non utilizzare se la confezione è aperta o danneggiata. / No usar el dispositivo si la envoltura está abierta o dañada. / Não utilizar se a embalagem estiver aberta ou danificada. / Niet gebruiken als de verpakking beschadigd of geopend is. / Får ej användas om förpackningen är öppnad eller skadad. / Må ikke anvendes, hvis emballagen er åbnet eller beskadiget. / Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut. / Μη χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά. / Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone. / Ambalaj açılmış ya da zarar görmüşse kullanmayın. / Не используйте изделие, если упаковка вскрыта или повреждена. / Pokud je balení otevřené nebo poškozené, produkt nepoužívejte.

STERILE EO

Rx ONLY

Caution, consult accompanying documents

130°F 54°C Upper temperature limit

86°F 30°C 59°F 15°C Store at room temperature

CE 0123

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