Auto Suture™

VERSAPORT™ PLUS RPF

SINGLE USE TROCAR AND SLEEVE WITH SHIELD AND FLIP TOP SEAL

1302942

ENGLISH

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 Auto Suture™ VERSAPORT™ PLUS RPF trocar is available in a 15 mm size with a radiolucent sleeve and shield. The VERSAPORT™ PLUS RPF trocar has a sharp pyramidal tip and a spring-loaded shield. Upon entry into a free space in the abdominal or chest cavity, the shield advances to cover the pyramidal trocar tip, reducing the potential for injury to internal structures.

A VERSAPORT™ PLUS seal, accommodating instruments ranging from 10 mm - 15 mm or 5 mm - 12 mm as appropriate, is designed to adjust the size of the trocar seal diameter to allow insertion of smaller sized instruments without loss of pneumoperitoneum. There is a stopcock valve for gas insufflation and rapid desufflation.

When using a 5 mm instrument through the fixed VERSAPORT™ PLUS 10 mm - 15 mm seal, the flip top 5 mm reducer seal must be used to avoid loss of pneumoperitoneum during the procedure. Remove the flip top 5 mm reducer seal from the sterile package and fit it onto the top of the VERSASEAL™ PLUS seal 10 - 15 mm hub. The reducer seal may be removed and replaced as needed.

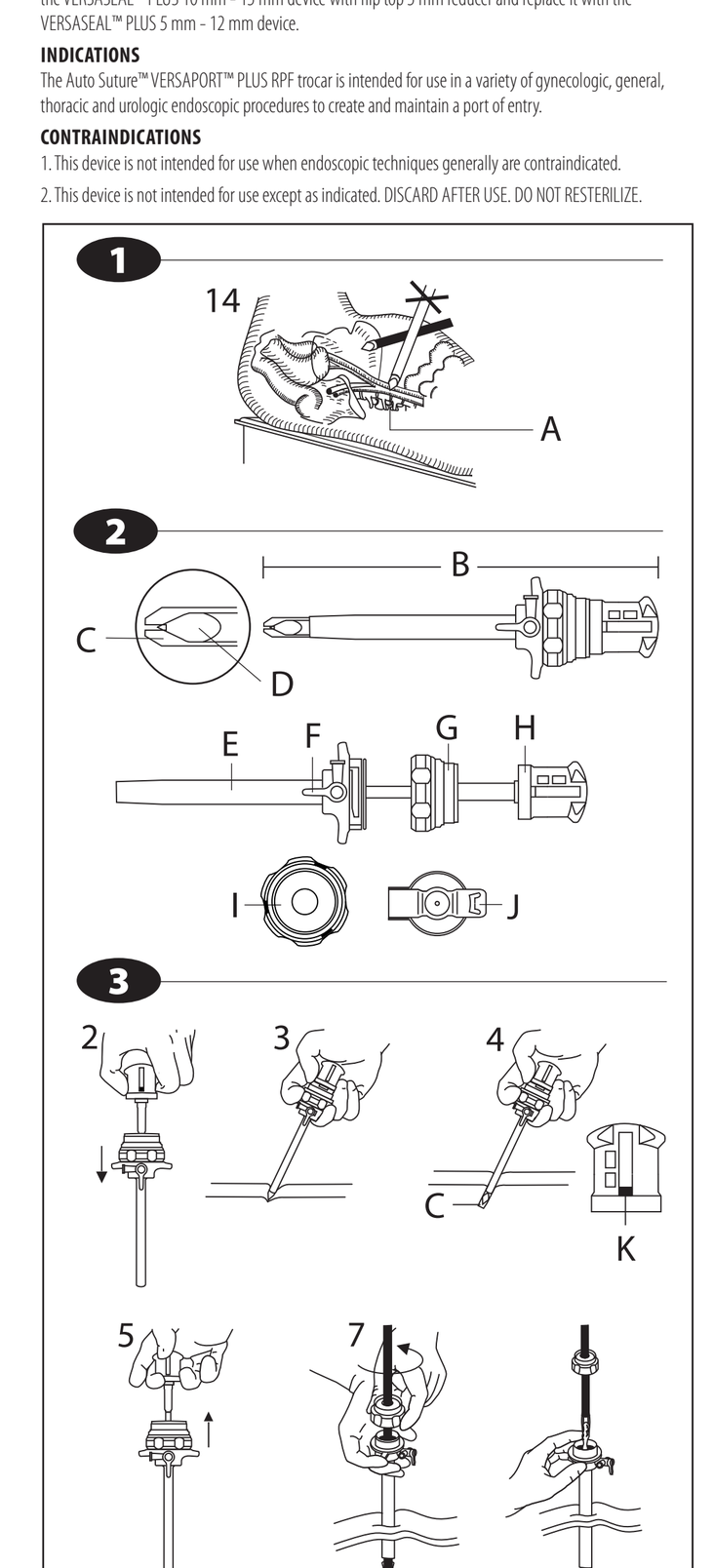
When using 5 mm - 12 mm instruments, an additional VERSASEAL™ PLUS 5 mm - 12 mm device may be substituted for the fixed 10 mm - 15 mm seal and flip top 5 mm reducer. In that case remove the VERSASEAL™ PLUS 10 mm - 15 mm device with flip top 5 mm reducer and replace it with the VERSASEAL™ PLUS 5 mm - 12 mm device.

INDICATIONS

The Auto Suture™ VERSAPORT™ PLUS RPF trocar is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.

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. DISCARD AFTER USE. DO NOT RESTERILIZE.



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. A through understanding of the operating principles, risks versus benefits, and the hazards involved in utilizing an endoscopic approach is necessary to avoid possible injury to the user/or patient.
3. Verify mechanical and electrical compatibility of devices from different manufacturers prior to using them together in a procedure.
4. The VERSAPORT™ PLUS RPF 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.
5. Adhesions, anatomical anomalies, or other obstructions may prevent or delay advancement of the shield, leaving the sharp pyramidal tip uncovered, exposing internal structures to injury.
6. The VERSAPORT™ PLUS seal can accommodate instruments ranging from 10 mm - 15 mm in diameter (as appropriate). Use of instruments less than 10 mm in diameter can result in loss of pneumoperitoneum without the use of the flip top 5 mm reducer seal or the VERSASEAL™ PLUS 5mm - 12mm device.
7. Both before and after removal of the VERSAPORT™ PLUS RPF 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.
8. 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.
9. ONCE ENTRY HAS BEEN MADE INTO FREE SPACE IN THE ABDOMINAL OR CHEST CAVITY, CARE MUST BE TAKEN NOT TO REARM THE VERSAPORT™ PLUS RPF 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™ PLUS RPF trocar would then be rearmed in the penetration mode. Continued advancement of the exposed sharp pyramidal tip at this point could cause injury to internal structures.
10. Prior to specimen removal, ensure that the VERSAPORT™ PLUS seal is pulled up onto the shaft of the instrument.
11. 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.
12. 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.
13. Use special care when introducing or removing sharp-edged or sharp-angled endoscopic instruments to minimize the potential of inadvertent damage to the seal.
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 in the Trendelenburg position.

A) ABDOMINAL AORTA

2 SCHEMATIC VIEW

B) TROCAR ASSEMBLY
C) SHIELD (FORWARD)
D) PYRAMIDAL TIP
E) TROCAR SLEEVE
F) STOPCOCK
G) 10 -15 mm SEAL
H) OBTURATOR
I) TOP VIEW 5 -12 mm VERSASEAL™ PLUS SEAL
J) FLIP TOP 5 mm REDUCER SEAL

3 INSTRUCTIONS FOR USE

THE PRESENCE OF THE SHIELD ON THE VERSAPORT™ PLUS RPF 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 desufflate the abdomen, turn the stopcock counterclockwise.

1. Creation of pneumoperitoneum in the abdomen is recommended prior to insertion of the trocar. Thereafter, prepare the abdominal or thoracic cavity for trocar insertion by making an adequate incision to accommodate the sleeve circumference. Note that a short incision may cause the skin to offer resistance to the trocar sleeve, increasing the penetration force and reducing control during entry. Position the VERSAPORT™ PLUS RPF trocar at the appropriate angle to the elevated abdomen. (See WARNINGS AND PRECAUTIONS No. 14 for abdominal procedure.) The VERSAPORT™ PLUS RPF trocar is sharper than reusable trocars and, therefore, generally requires the application of less force for insertion.

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

2. Prior to introducing the trocar through the skin incision, insert the obturator into the trocar sleeve.

NOTE: When using the 15 mm trocar, the removable upper seal must be attached to the lower seal and cannula assembly during the insertion of the trocar into the body.

3. Squeeze down on the top of the obturator to unlock the shield. While maintaining compression of the handle, introduce the VERSAPORT™ PLUS RPF trocar through the skin incision. Apply continuous downward pressure during entry of the trocar.

NOTE: The red flag in the indicator window is an integral part of the shield. Its purpose is to show the position of the shield relative to the pyramidal tip. When insertion is performed, the shield indicator moves from the shield ON position (sharp pyramidal tip shielded) to the shield OFF position (sharp pyramidal tip exposed). Once the front end of the outer sleeve has passed through the abdominal or chest wall into free space, the shield will spring forward. The red flag will return to the ON position showing that the sharp pyramidal tip is shielded. The shield is now locked in the protected ON position. When the shield retracts, exposing the trocar tip, there is an audible click. When the shield advances to cover the trocar tip, there is a second audible click. ONCE ENTRY HAS BEEN MADE INTO FREE SPACE IN THE ABDOMINAL OR CHEST CAVITY, CARE MUST BE TAKEN NOT TO REARM THE VERSAPORT™ PLUS RPF 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.

If following entry, the red flag remains in the off position 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.

4. Upon entering the free space in the abdominal or thoracic cavity, the shield covers the pyramidal piercing tip and locks into place, reducing the potential for injury to internal structures. The red flag in the shield indicator appears in the ON position and is confirmed by an audible click.

C) SHIELD (FORWARD)
K) RED FLAG (IN "ON" POSITION)

5. 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.
6. The trocar sleeve is now positioned in the body cavity.

NOTE: 15 mm instruments will not fit through the VERSASEAL™ PLUS 5 mm-12 mm device.

7. When using the 15 mm trocar sleeve for specimen removal, unscrew the VERSAPORT™ PLUS seal and pull it up onto the shaft of the instrument. Once the VERSAPORT™ PLUS seal is on the shaft of the instrument, proceed with the removal of the specimen by pulling the specimen through the sleeve. Once the specimen is removed, replace the VERSAPORT™ PLUS seal before reinserting instruments.
8. If the trocar incision is 10 mm or larger, the underlying fascia should be closed to reduce the potential for incisional hernias.

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

< 54° C / 130° F **DO NOT EXPOSE TO TEMPERATURES ABOVE 130° F (54° C).**

FRANÇAIS

TROCART ET MANCHON A USAGE UNIQUE AVEC ECRAN ET JOINT RABATTABLE

CONSERVER A TEMPERATURE AMBIANTE.
EVITER L'EXPOSITION PROLONGEE A DES TEMPERATURES ELEVEES.

< 54° C / 130° F **NE PAS EXPOSER A DES TEMPERATURES SUPERIEURES A 54° C.**

DEUTSCH

EINMAL-TROKAR UND -HÜLSE MIT ABSCHIRMUNG UND SCHNAPP-DICHTUNG

BEI ZIMMERTEMPERATUR LAGERN.
NICHT ÜBER LÄNGERE ZEIT HINWEG ERHÖHTEN TEMPERATUREN AUSSETZEN.

< 54° C / 130° F **NICHT TEMPERATUREN ÜBER 54 °C AUSSETZEN.**

ITALIANO

TREQUARTI MONOUSO E MANICOTTO CON PROTEZIONE E GUARNIZIONE REGOLABILE

CONSERVARE A TEMPERATURA AMBIENTE.
EVITARE ESPOSIZIONI PROLUNGATE A TEMPERATURE ELEVATE.

< 54° C / 130° F **NON ESPORRE A TEMPERATURE SUPERIORI A 54 °C (130 °F).**

ESPAÑOL

TROCAR DE UN SOLO USO Y MANGUITO CON PANTALLA Y SELLO ABATIBLE

ALMACENAR A TEMPERATURA AMBIENTE.
EVITAR LA EXPOSICIÓN PROLONGADA A TEMPERATURAS ELEVADAS.

< 54° C / 130° F **NO EXPONER A TEMPERATURAS SUPERIORES A 54 °C.**

PORTUGUÊS

TROCARTE DE USO ÚNICO E BAINHA COM PROTEÇÃO DE SEGURANÇA E VEDAÇÃO FLIP TOP

MANTENHA EM TEMPERATURA AMBIENTE.
EVITE A EXPOSIÇÃO PROLONGADA A TEMPERATURAS ELEVADAS.

< 54° C / 130° F **NÃO EXPONHA A TEMPERATURAS ACIMA DE 54°C.**

NEDERLANDS

TROCAR EN HULS MET SCHILD EN FLIPTOP AFSLUITER VOOR EENMALIG GEBRUIK

BEWAREN OP KAMERTEMPERATUUR.
VERMIJD LANGDURIGE BLOOTSTELLING AAN HOGE TEMPERATUREN.

< 54° C / 130° F **NIET BLOOTSTELLEN AAN TEMPERATUREN BOVEN 54°C (130°F).**

SVENSKA

ENGÅNGSTROAKAR OCH HYLSA MED SKYDD OCH TÄTNING MED LOCK

FÖRVARAS VID RUMSTEMPERATUR.
FÅR EJ UTSÄTTAS FÖR HÖGA TEMPERATURER UNDER LÄNGRE TID.

< 54° C / 130° F **FÅR EJ UTSÄTTAS FÖR TEMPERATURER ÖVER 54 °C.**

DANSK

ENGANGSTROKAR OG HYLSTER MED SKÆRM OG VIPPEFORSEGLING

OPBEVARES VED STUETEMPERATUR.
MÅ IKKE UDSÆTTES FOR HØJ TEMPERATUR I LÆNGERE TID.

< 54° C / 130° F **MÅ IKKE UDSÆTTES FOR TEMPERATUR OVER 54 °C.**

SUOMI

SUOJUKSELLA JA FLIP-TOP-TIIVISTEELLÄ VARUSTETTU KERTAKÄYTTÖINEN TROAKAARI JA SUOJAHYLSY

SÄILYTETTÄVÄ HUONEENLÄMMÖSSÄ.
VÄLTETTÄVÄ PITKÄAIKAISTA ALTISTUSTA KORKEILLE LÄMPÖTILOILLE.

< 54° C / 130° F **EI SAA ALTISTAA YLI 54 °C:N LÄMPÖTILALLE.**

ΕΛΛΗΝΙΚΑ

ΤΡΟΚΑΡ ΚΑΙ ΠΕΡΙΒΛΗΜΑ ΜΙΑΣ ΧΡΗΣΗΣ ΜΕ ΠΡΟΣΤΑΤΕΥΤΙΚΟ ΚΑΙ ΣΦΡΑΓΙΣΜΑ ΑΝΑΣΤΡΕΦΟΜΕΝΗΣ ΚΟΡΥΦΗΣ

ΦΥΛΑΣΣΕΤΑΙ ΣΕ ΘΕΡΜΟΚΡΑΣΙΑ ΔΩΜΑΤΙΟΥ.
ΑΠΟΦΥΓΕΤΕ ΤΗΝ ΠΑΡΑΤΕΤΑΜΕΝΗ ΕΚΘΕΣΗ ΣΕ ΥΨΗΛΕΣ ΘΕΡΜΟΚΡΑΣΙΕΣ.

< 54° C / 130° F **ΜΗΝ ΑΦΗΝΕΤΕ ΤΟ ΠΡΟΪΟΝ ΕΚΤΕΘΕΙΜΕΝΟ ΣΕ ΘΕΡΜΟΚΡΑΣΙΕΣ ΑΝΩ ΤΩΝ 54° C (130° F).**

POLSKI

JEDNORAZOWY TROKAR I TULEJA Z EKRANEM ORAZ PRZERZUTNĄ SZCZYTOWĄ USZCZELKĄ

PRZECHOWYWAĆ W TEMPERATURZE POKOJOWEJ.
UNIKAĆ PRZEDŁUŻONEJ EKSPOZYCJI NA PODWYŻSZONE TEMPERATURY.

< 54° C / 130° F **NIE WOLNO WYSTAWIAĆ NA DZIAŁANIE TEMPERATUR WYŻSZYCH NIŻ 54° C.**

TÜRKIYE

KORUMALI VE ÜSTTEN DÖNER KAPAKLI CONTALI TEK KULLANIMLIK TROKAR VE KILIF

ODA SICAKLIĞINDA SAKLAYIN.
UZUN SÜRE YÜKSEK SICAKLIKLARDA KALMASINA İZİN VERMEYİN.

< 54° C / 130° F **130°F'DAN (54° C'DAN) YÜKSEK SICAKLIKLARA MARUZ BIRAKMAYIN.**

РУССКИЙ ЯЗЫК

ОДНОРАЗОВЫЙ ТРОАКАР И ГИЛЬЗА С ЗАСЛОНКОЙ И УПЛОТНЕНИЕМ С ОТКИДНЫМ ВЕРХОМ

ХРАНИТЬ ПРИ КОМНАТНОЙ ТЕМПЕРАТУРЕ.
НЕ ПОДВЕРГАТЬ ДЛИТЕЛЬНОМУ ВОЗДЕЙСТВИЮ ПОВЫШЕННОЙ ТЕМПЕРАТУРЫ.

< 54° C / 130° F **НЕ ПОДВЕРГАТЬ ВОЗДЕЙСТВИЮ ТЕМПЕРАТУРЫ ВЫШЕ 54° C.**

ČESKÁ REPUBLIKA

JEDNORÁZOVÝ TROKAR A OBJÍMKA S KRYTEM A REDUKČNÍM TĚSNĚNÍM

SKLADUJTE PŘI POKOJOVÉ TEPLOTĚ.
NEVYSTAVUJTE PO DELŠÍ DOBU ZVÝŠENÝM TEPLOTÁM.

< 54° C / 130° F **NEVYSTAVUJTE TEPLOTÁM NAD 54°C.**

MAGYARORSZÁG

EGYSZER HASZNÁLATOS TROKÁR VÉDŐELEMZELL ÉS LEHAJTHATÓ TÖMÍTÉSSEL

SZOBAHŐMÉRSÉKLETEN TÁROLANDÓ.
KERÜLJE A MAGAS HŐMÉRSÉKLETEN TÖRTÉNŐ HUZAMOSABB IDEJŰ TÁROLÁST.

< 54° C / 130° F **NE TEGYE KI 54 °C-NÁL MAGASABB HŐMÉRSÉKLETNEK.**

CE 0123 ℞only

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Box size: 4.19 x 9.75
Overall size: 18 x 23.5
Folds to: 3 x 7.833