Medtronic

Product information guide

Trocar stability – from access to closure.[1,†,‡]

VersaOne™ optical trocar with fixation balloon cannula

Expanding the VersaOne™ access family

†Based on in vivo fixation testing four hours after penetration with an in-vivo porcine model.

‡Preclinical results may not correlate with clinical performance in humans.

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Access. Stability. Control.[1,2,†,‡,§]

Every surgery has its challenges – but a trocar that doesn't stay in place shouldn't be one of them. Combining a stabilizer balloon and antimigration collar, the VersaOne™ optical trocar with fixation balloon cannula delivers reliable stability, whether your procedure lasts 45 minutes – or four hours.[1,†,‡]

Its benefits include:

- Consistent, reliable access[1,3,†,‡,††]
- Reduced migration risk[1,‡,Ω]
- Adaptability when you want it[4,‡,††]

100%

of surgeons surveyed said the device provided excellent fixation throughout their procedure[3,‡,††]

†Based on in vivo fixation testing 4 hours after penetration with an in vivo porcine model.
‡Preclinical results may not correlate with clinical performance in humans.
§ VersaOne™ fixation balloon cannula portfolio includes 5 mm short, standard, and long devices.
Ω Compared to competitive Endopath XCEL™* ribbed, Kii™* Z thread trocars and Medtronic VersaOne™ optical trocar with fixation cannula.
††17 out of 17 surgeons surveyed after use agreed.

Features and benefits

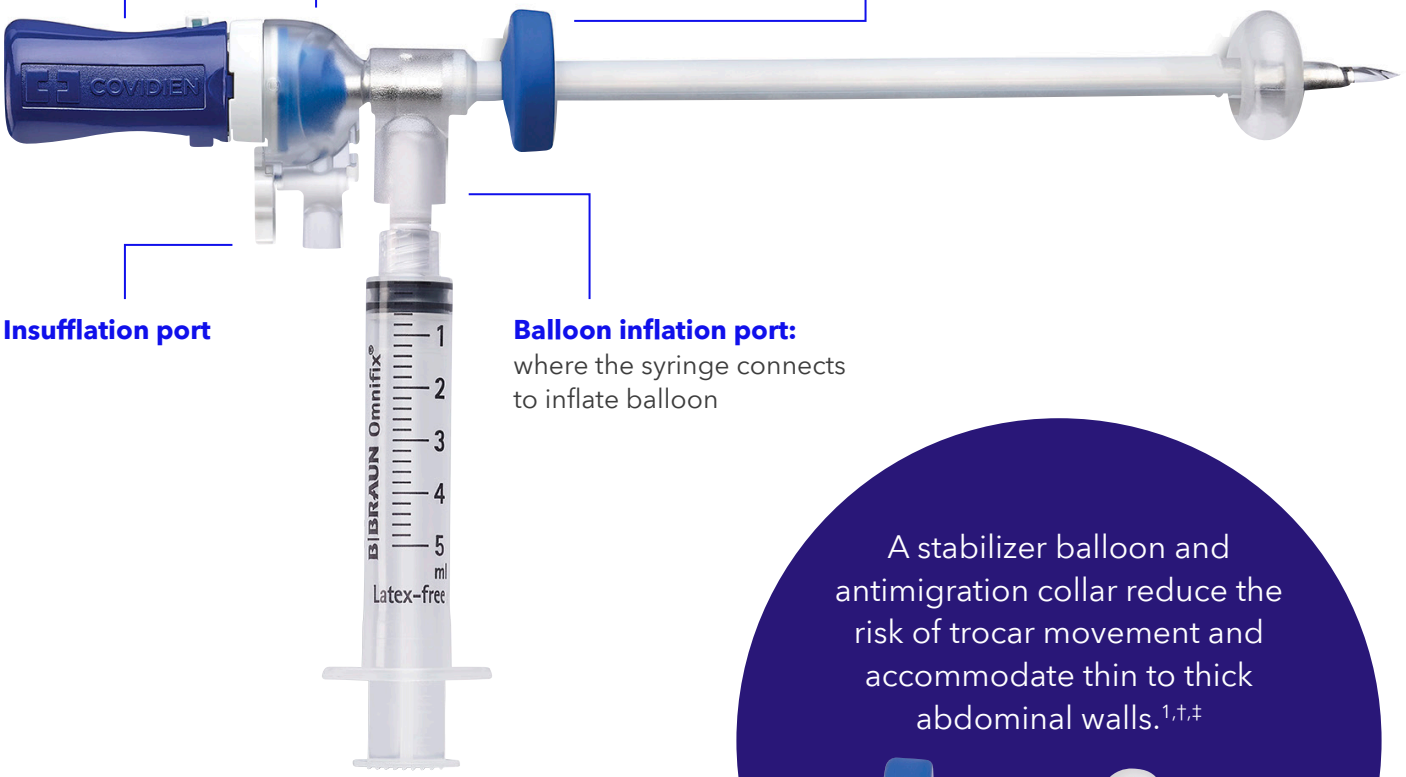
5 MM optical trocar

Compatible with 5 mm standard length VersaOne™ optical obturators: passive scope lock design to hold laparoscope in place while in the obturator

Low profile: provides greater flexibility when placing multiple ports

Antimigration collar: reduces the risk of internal trocar movement[1,†,‡]

Stabilizer balloon: provides superior abdominal fixation[1,†,‡]



Insufflation port

Balloon inflation port: where the syringe connects to inflate balloon

A stabilizer balloon and antimigration collar reduce the risk of trocar movement and accommodate thin to thick abdominal walls.[1,†,‡]

†Preclinical results may not correlate with clinical performance in humans.

‡Compared to competitive Endopath XCEL™* ribbed, Kii™* Z thread trocars and Medtronic VersaOne™ optical trocar with fixation cannula.

Supports instrument exchanges[1,3,†,‡]

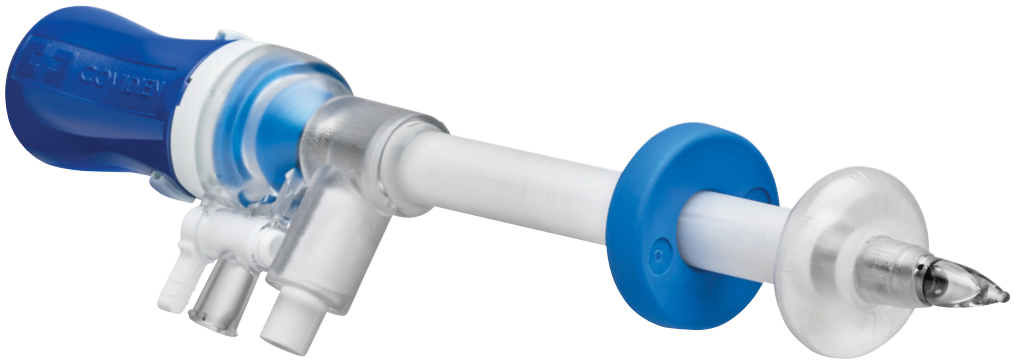
Improved fixation[1,‡,§]

Minimal depth penetration[1,3,‡,Ω]

Reliable trocar fixation during multiple instrument exchanges[1,3,†,Ω]

Prevents internal and external trocar migration[1,3,‡,§,Ω]

Balloon position allows for maximum working space[1,3,‡,Ω]



Your instruments need to move, your trocar doesn't.

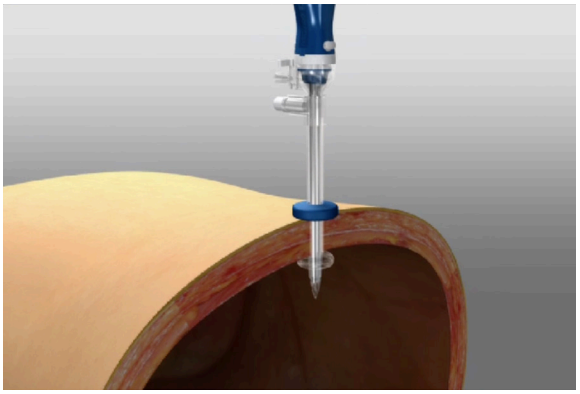
†17 out of 17 surgeons surveyed after use agreed.
‡Preclinical results may not correlate with clinical performance in humans.
§Compared to competitive Endopath XCEL™* ribbed, Kii™* Z thread trocars and Medtronic VersaOne™ optical trocar with fixation cannula.
ΩBased on simulated use with an in vivo porcine model. 16 out of 17 surgeons surveyed after use agreed.

Clinical overview

Reliable stability, so you can focus on what matters most.[3,5,‡,‡]

- Added stability for greater focus on the procedure[1,3,5,‡,‡]
- The ability to maintain desired depth into the abdominal cavity, maximizing internal working space[1,3,‡,§]
- Easy balloon inflation to give you frustration-free stability[3,†,‡]

Significantly reduced migration risk, so you and your staff can set it – and forget it.[1,‡,Ω]



- A stabilizer balloon and antimigration collar that reduce the risk of trocar movement[1,‡,Ω]
- Superior abdominal wall retention to prevent trocar migration or slippage out of the incision[1,‡,Ω]
- Confident stability from thin to thick abdominal walls[2,†,‡]

Adaptability when you want it. Security when you need it.[4,†,‡]

- Consistent, stable access – whether a procedure lasts 45 minutes or four hours[1,‡,††]
- Reliable trocar fixation during multiple instrument exchanges[1,3,†,‡]
- Excellent pnuemo sealing around the incision site[1,3,†,‡]

†Based on simulated use with an in vivo porcine model.17 out of 17 surgeons surveyed after use agreed.
‡Preclinical results may not correlate with clinical performance in humans.
§Based on simulated use with an in vivo porcine model. 16 out of 17 surgeons surveyed after use agreed.
ΩCompared to competitive Endopath XCEL™* ribbed, Kii™* Z thread trocars and Medtronic VersaOne™ optical trocar with fixation cannula.
††Based on in vivo fixation testing 4 hours after penetration with an in vivo porcine model.

Competitive comparisons

vs. VersaOne™ optical trocar with fixation cannula

	VersaOne™ optical trocar with fixation cannula	VersaOne™ optical trocar with fixation balloon cannula
Trocar code	ONB5SHF (5 x 70 mm) ONB5STF (5 x 100 mm) ONB5LGF (5 x 150 mm)	ONB5SHB (5 x 70 mm) ONB5STB (5 x 100 mm) ONB5LGB (5 x 150 mm)
Cannula only code	UNVCA5SHF (5 x 70 mm) UNVCA5STF (5 x 100 mm) UNVCA5LGF (5 x 150 mm)	UNVCA5STB (5 x 100 mm)
Inner diameter	6 mm (0.235 inches)	6 mm (0.235 inches)
Outer diameter	8.46 mm (0.304 inches)	9.2 mm (0.365 inches)

vs. competitor products

	Balloon trocar	Balloon trocar	Balloon trocar	Non-balloon trocar	Non-balloon trocar
	Medtronic VersaOne™ optical trocar with fixation balloon cannula	Applied Kii Optical Access System	Applied Kii Fios™*	Ethicon Endopath Xcel™* Optiview™*	Ethicon Endopath Xcel™*
Trocar code	ONB5SHB (5 x 70 mm) ONB5STB (5 x 100 mm) ONB5LGB (5 x 150 mm)	N/A CFR03 (5 x 100 mm) CFR01 (5 x 150 mm)	CFF05 (5 x 75 mm) CFF03 (5 x 100 mm) CFF01 (5 x 150 mm)	2B5ST (5 x 75 mm) 2B5LT (5 x 100 mm) 2B5XT (5 x 150 mm)	B5ST (5 x 75 mm) B5LT (5 x 100 mm) B5XT (5 x 150 mm)
Cannula only code	UNVCA5STB (5 x 100 mm)	CFS03 (5 x 75 mm) CFS02 (5 x 100 mm) CFS01 (5 x 150 mm)	CFS03 (5 x 75 mm) CFS02 (5 x 100 mm) CFS01 (5 x 150 mm)	2CB5ST (5 mm x 75 mm) 2CB5LT (5 mm x 100 mm) N/A	2CB5ST (5 mm x 75 mm) 2CB5LT (5 mm x 100 mm) N/A
Inner diameter	6 mm (0.235 inches)	7 mm (0.275 inches)	7 mm (0.275 inches)	6 mm (0.234 inches)	6 mm (0.234 inches)
Outer diameter	9.2 mm (0.365 inches)	9.4 mm (0.370 inches)	9.4 mm (0.370 inches)	7.7 mm (0.302 inches)	7.7 mm (0.302 inches)

FDA 510(k) clearance letter

U.S. FOOD & DRUG ADMINISTRATION

Covidien
Michael Mach
Senior Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

June 27, 2022

Re: K213818
Trade/Device Name: VersaOne Optical Trocar with Fixation Ballon Cannula, VersaOne Universal Fixation Balloon Cannula
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 29, 2022
Received: May 2, 2022

Dear Michael Mach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

The 510(k) letter only confirms the device's legal market status in the US and should not be interpreted as an FDA approval or endorsement of the product.

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Colin K. Chen -S
Digitally signed by Colin K. Chen -S
Date: 2022.06.27 14:43:38 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Instructions for use (IFU)

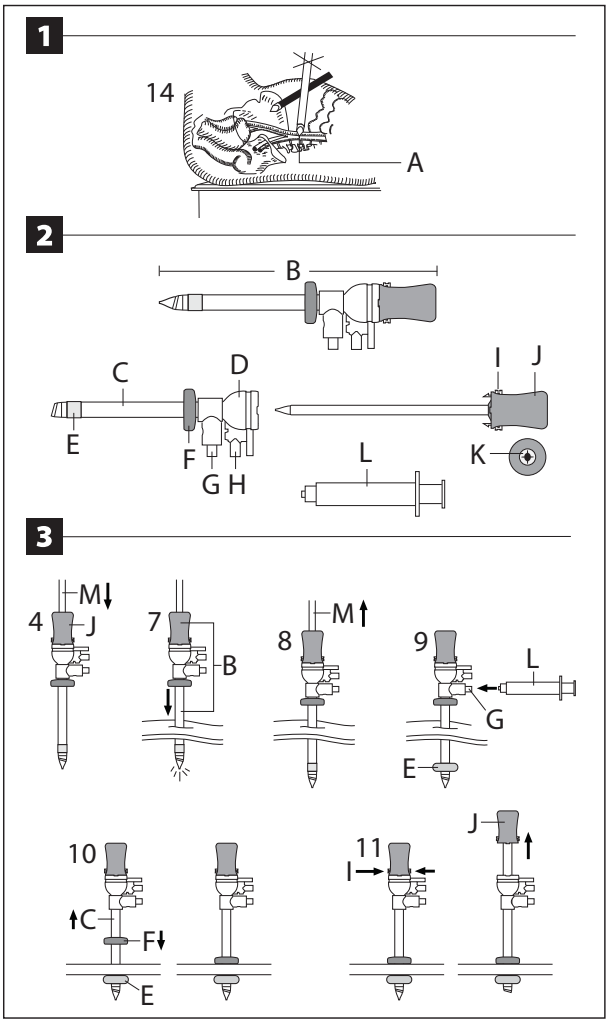
COVIDIEN™

VersaOne™

Optical Trocar with Fixation Balloon Cannula and Universal Fixation Balloon Cannula

PT00170697

(92)PT00170697



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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 including breakage of the product components with potential for a retained foreign body. 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 VersaOne™ Optical Trocar with Fixation Balloon Cannula is available in the following configurations:

Diameter	Length	Cannula
5 mm	100 mm Standard	Universal Fixation Balloon Cannula
5 mm	150 mm Long	Universal Fixation Balloon Cannula
5 mm	70 mm Short	Universal Fixation Balloon Cannula

The VersaOne™ universal fixation balloon cannula is compatible with 5 mm standard length VersaOne™ optical obturators.

The VersaOne™ universal fixation balloon cannula is compatible with the syringe provided with the VersaOne™ optical trocar with fixation balloon cannula.

The VersaOne™ universal fixation balloon cannula is available in the following configurations:

Diameter	Length	Cannula
5 mm	100 mm Standard	Universal Fixation Balloon Cannula

The VersaOne™ optical trocar with fixation balloon cannula utilizes a balloon made from a thermoplastic elastomer (not made with natural rubber latex) that when inflated with air provides cannula fixation. The fixation balloon used in combination with the anti-migration collar provides cannula stability during surgery. The trocar housing contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted into the port or withdrawn completely from the port. The seal system accommodates 5 mm instruments. The cannula has a stopcock valve for insufflation and desufflation and the obturator housing contains a scope retention mechanism.

The patient population on which the VersaOne™ optical trocar with fixation balloon cannula is indicated for use is widely varied with respect to patient age, body type, and nationality. The products can be used with patients of varying age groups, weights, races, cultures, and sexes, except where contraindicated. Surgeons should consider specific patient factors before deciding if the device is suitable for use.

Intended users are healthcare professionals who have been trained in applicable surgical procedures and approaches involving trocar devices prior to employing this device.

INDICATIONS/INTENDED PURPOSES

The VersaOne™ optical trocar with fixation balloon cannula is indicated for use in general, gynecologic, thoracic and urologic minimally invasive surgical procedures.

The intended purpose of the device is to create and maintain a port of entry. The trocar may be used with or without visualization for primary and secondary insertions.

CLINICAL BENEFIT

Trocars are used to gain access to the body cavity and maintain a surgical space within the body for the use of laparoscopic instruments and executing surgical technique during minimally invasive procedures. The clinical benefits of minimally invasive procedures with trocar utilization compared to open procedures includes fewer postoperative complications, less postoperative pain, reduced incision length, and a shorter hospital stay.

CONTRAINDICATIONS

1. This device is not intended for use when minimally invasive 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. Minimally invasive procedures should be performed only by physicians having adequate training and familiarity with laparoscopic techniques. A thorough understanding of the operating principles, risk versus benefits, and the hazards involved in utilizing a minimally invasive approach is necessary to avoid possible injury to the user and/or patient.
3. An insufficient skin incision may cause increased penetration force which may reduce the surgeon's control during entry. A skin 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 VersaOne™ 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 indicated when 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. The VersaOne™ universal fixation balloon cannula should only be used with the optical obturator from VersaOne™ optical trocars and syringe provided with the VersaOne™ optical trocar with fixation balloon cannula in a single-patient-single-episode procedure.
8. Before laparoscopic instruments and accessories from different manufacturers are used, verify compatibility and ensure that electrical isolation or grounding is not compromised.
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. 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.
11. Use care when introducing or removing sharp-edged or sharp-angled laparoscopic instruments to minimize the potential of inadvertent damage to the seal.
12. Damage to the balloon by instruments used during insertion and in the course of a procedure may cause device failure.
13. Care should be taken when introducing secondary trocars to avoid damaging the distal balloon.
14. 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.
15. This device is provided STERILE and is intended for use in a SINGLE patient procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.
16. Sterile unless packaging has been opened or damaged. Dispose of used devices and unused devices with opened or damaged packaging in accordance with the end-user's medical and biological waste disposal requirements.

IFU current as of 03/2024 when this Brochure was approved by Medtronic. For the most current IFU, please contact your Medtronic sales rep.

ADVERSE REACTIONS

While every attempt has been made to reduce patient and user risks, all surgeries using this device carry some residual risk, even when used by trained physicians. The potential adverse events associated with the use of this device are tissue damage, infection, perforation, bowel burn, thermal burn, hernia and great vessel perforation.

In the event that a serious incident has occurred related to device use, immediately report the event to Covidien, the competent authorities, and any other regulators as required.

2 SCHEMATIC VIEW

B) BALLOON TROCAR ASSEMBLY

C) CANNULA

D) LOW PROFILE HOUSING WITH SEAL

E) FIXATION BALLOON

F) ANTI-MIGRATION COLLAR

G) BALLOON INFLATION VALVE

H) STOPCOCK

I) INTERLOCKING SNAPS

J) OBTURATOR

K) SCOPE RETENTION MECHANISM

L) SYRINGE

3 INSTRUCTIONS FOR USE

The instructions listed below apply to both the VersaOne™ optical trocar with fixation balloon cannula and universal fixation balloon cannula.

This device may be used with or without visualization for primary and secondary insertions.

1. The VersaOne™ universal fixation balloon cannula requires a 5 mm standard length VersaOne™ optical obturator.
2. The VersaOne™ universal fixation balloon cannula requires the syringe provided with the 5 mm VersaOne™ optical trocar with fixation balloon cannula.
3. Remove the protective cap and insert the obturator into the cannula until the interlocking snap feature is engaged.
4. Setup an appropriately sized 0° laparoscope as directed by the manufacturer's instructions. Insert laparoscope (M) into the obturator (J) housing until it reaches the distal end of the obturator.
5. Insufflation of the abdomen prior to the insertion of the 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.
6. Prepare the abdominal cavity for trocar insertion by making a skin incision adequate to accommodate the cannula diameter. An insufficient skin incision may cause increased penetration force which may reduce the surgeon's control during entry. A skin incision too large may increase the potential for port instability.

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

7. Position the balloon trocar assembly (B) at the appropriate angle to the abdomen and introduce the trocar assembly through the skin incision utilizing a clocking motion while applying continuous downward pressure.
8. When the trocar assembly is in the desired position within the abdominal cavity, remove the laparoscope (M) from the obturator leaving the balloon trocar assembly in place.
9. Using the syringe (L) provided, inflate the fixation balloon (E) through the balloon inflation valve (G) with 5 ml of air.

WARNING: Over inflation of the balloon may cause it to rupture.

10. Pull back the cannula (C) until resistance from the inflated fixation balloon (E) is felt. Slide the anti-migration collar (F) down to the skin.
11. Depress the interlocking snaps (I) and remove the obturator (J) from the cannula.
12. If insufflation is desired, attach insufflation tubing to the stopcock. Appropriately sized laparoscopic instruments may now be inserted and removed through the cannula.

WARNING: To prevent damage to the balloon, care should be taken when placing additional trocars and when inserting or removing instrumentation.

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).

13. To remove the cannula from the operative site, first fully depress the plunger on the syringe. Firmly press the tip of the syringe into the balloon inflation valve. Draw the syringe plunger back to deflate the fixation balloon. Once the fixation balloon is deflated, remove the cannula. Using a twisting motion while pulling axially on the port may facilitate removal.

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

STORE AT ROOM TEMPERATURE.

Ordering information

For more information on the VersaOne™ optical trocar with fixation balloon cannula, call 800-772-8772 or visit us at **medtronic.com/versaone-balloon**

Order code	Diameter	Length
ONB5SHB	5 mm	70 mm short optical trocar with fixation balloon cannula
ONB5STB	5 mm	100 mm standard optical trocar with fixation balloon cannula
ONB5LGB	5 mm	150 mm long optical trocar with fixation balloon cannula
UNVCA5STB	5 mm	100 mm standard optical trocar with fixation balloon cannula only

Quantity per box: 6

1. Based on internal report #RE00453137, VersaOne™ optical trocar with fixation balloon cannula 5 mm in vivo claims evaluation lab report. June 26, 2023.
2. ONB5SHB, ONB5STB, ONB5LGB
3. Based on internal report #RE00471794, VersaOne™ optical trocar with fixation balloon cannula 5 mm surgeon use questionnaire. July 26, 2023.
4. Based on internal report #RE00322029, 5mm VersaOne™ advanced fixation trocar (Project Benri phase 1) validation/summative report. Sept. 21, 2021.
5. Based on internal report #RE00472645, VersaOne™ optical trocar with fixation balloon cannula 5 mm messaging research qualitative report. Aug. 1, 2023.

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