ONE COMPLETE SOLUTION.

VersaOne™ Access System

The Access Trocar Portfolio Product Information Guide

Medtronic
Further, Together

A NOTE TO YOU. OUR VALUED CUSTOMER.

Medtronic's universal trocar platform is designed for standardization and performance in and out of the OR. In partnership with our customers, we conducted numerous surgeon interviews, focus groups and pre-clinical labs with one goal in mind — to design a product that meets the demanding needs of surgeons while delivering a reliable, consistent outcome. The result was a redesigned platform that delivers product performance and simplifies our overall product line without limiting choice.

The redesigned platform not only offers greater flexibility, as all obturators (blunt, bladed, bladeless, optical) fit through the same cannula, it allows us to reduce the number of SKUs by more than 20%. This simplifies the product line, increases efficiency and potentially reduces costs due to there being fewer SKUs to manage.

In addition, you will see a redesign to our trocar packaging. The majority of our trocars are packaged in a soft pouch, which is 100% recyclable, easy to open, and includes intuitive graphics to identify appropriate usage. It will allow you to not only care for your patients, but the environment as well.

The following product families have been improved to better meet your needs:

- Bluntport™ PLUS Trocar
- Versaport™ Optical Trocar
- Versaport™ V2 Bladed Trocar
- Versaport™ Bladeless Trocar

Yours in partnership,

Global Marketing, Medtronic

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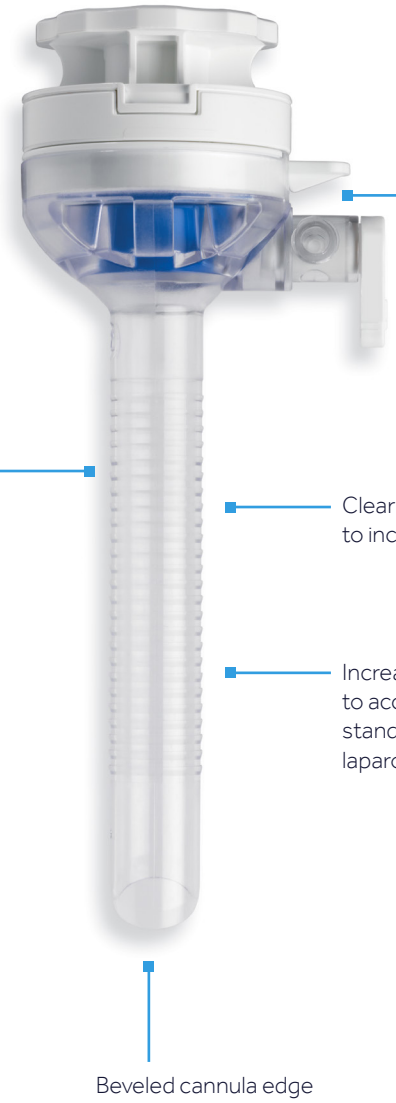
PRODUCT OVERVIEW
WHERE QUALITY AND EFFICIENCY COME TOGETHER.

Advantages of the Universal Cannula



Funneled entry, enhanced seal allows smooth instrument exchange[1]

Seal converter release button for easy specimen removal / introduce needles

Advanced fixation ribs to securely keep cannula from moving during surgical procedure

Clear cannula designed to increase visualization

Increased inner diameter to accommodate standard 12 mm laparoscopic instruments

Beveled cannula edge

Low profile seal housing for maneuverability in tight spaces

Low profile two-way stopcock for controlled insufflation and desufflation

One cannula that accommodates any 5 mm VersaOne™ access system obturator

1. Based on internal test report# 2143-123. Applies to Medtronic 12 mm trocars, when compared to the Versaport™ Bladeless 12 mm trocar. March 2013.

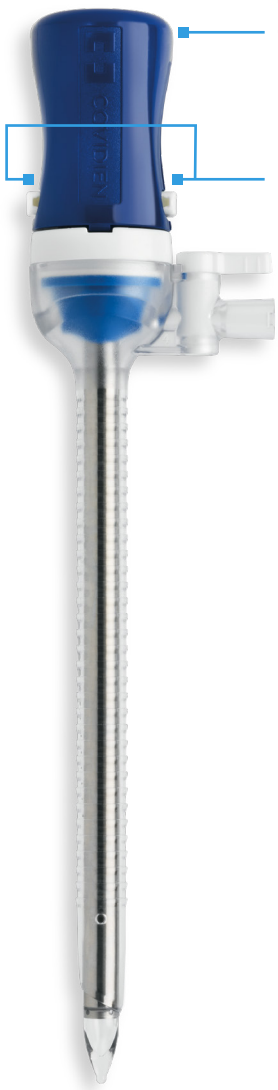
FEATURES AND BENEFITS
VERSAONE™ OPTICAL TROCAR

Advantages of the Optical Trocar

Interlocking snap feature to secure obturator during insertion

Passive scope lock designed to hold laparoscope in place while in the obturator

Unique "dolphin nose" tip facilitates controlled tissue separation enabling smooth insertion through reduced penetration force[1]



Ergonomic low profile obturator provides control and comfort during insertion

Interlocking snap feature to secure obturator during insertion

1. Based on internal test report #2143-114, Applies to Medtronic 12 mm trocars, when compared to Applied Kii™* (12 mm trocar, Z-thread cannula). March 2013.

FEATURES AND BENEFITS
VERSAONE™ BLUNT TROCAR

Advantages of the Blunt Trocar

FEATURES AND BENEFITS
VERSAONE™ BLADED TROCAR

Advantages of the Bladed Trocar

Bladed obturator has a safety lock to inform user when blade is exposed

Safety lock indicates when blade is shielded or exposed

Sharpened on both sides, the uniquely designed blade divides tissue cleanly and precisely with control upon insertion through the abdominal wall

Ergonomic low profile obturator provides control and comfort during insertion

"Dolphin nose" parabolic shield retracts over blade once through peritoneum for safety

FEATURES AND BENEFITS
VERSAONE™ BLADELESS TROCAR

Advantages of the Bladeless Trocar

1. Applies to Medtronic 12 mm trocars, when compared to Applied Kii™* (12 mm trocar, Z-thread cannula). Reference to Medtronic Engineering Report #2143-114 dated March 2013.

FEATURES AND BENEFITS
REDESIGNED PACKAGING

Sustainable for your OR and the environment

New packaging reduces packaging weight by 50%[1]

Soft pouch packaging reduces storage space

Clip to ensure stability during shipping

Clear labeling makes it easy to identify obturator tip, trocar size, and cannula length

1. Eichler Sustainability Presentation, June 27, 2014 Samanatha Smith, Sr. Packaging Engineer.

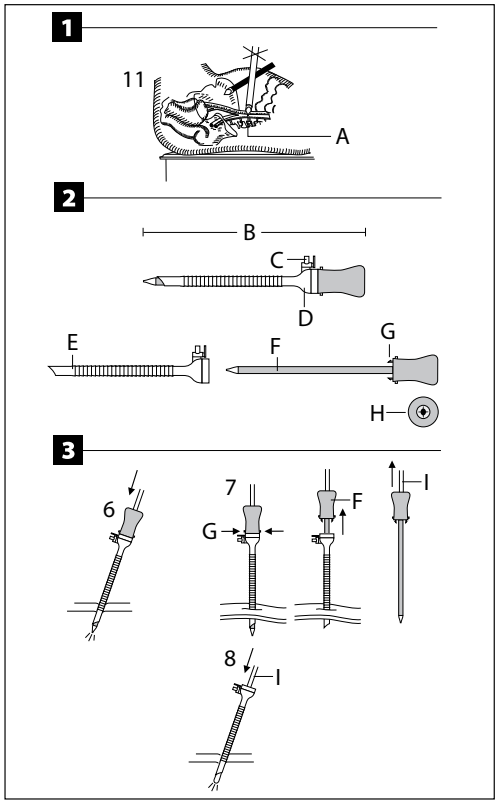
INSTRUCTIONS FOR USE
VERSAONE™ OPTICAL 5 MM TROCAR

Always refer to product instructions for use for complete indications, contraindications, warnings, precautions and operating instructions.

COVIDIEN™

VersaOne™
Optical Trocar

PT00016983



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 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™ V2 optical trocar is available in the following configurations:

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

The obturator housing contains a scope retention mechanism. 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. There is a stopcock valve for insufflation and desufflation.

INDICATIONS

The VersaOne™ 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 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. Before endoscopic instruments and accessories from different manufacturers are used, verify compatibility and ensure that electrical isolation or grounding is not compromised.

8. 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.

9. 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.

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

11. 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.

A) ABDOMINAL AORTA

12. 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) STOPCOCK

D) LOW PROFILE HOUSING WITH SEAL

E) TROCAR CANNULA

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. Cannula and obturator are packaged side by side. Prior to insertion of laparoscope, insert obturator into cannula until the interlocking snap feature is engaged.

2. Connect the appropriately sized 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 VersaOne™ 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.

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).

9. 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 VersaOne™ optical trocar from the abdominal or chest cavity, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.

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

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STERILE EO

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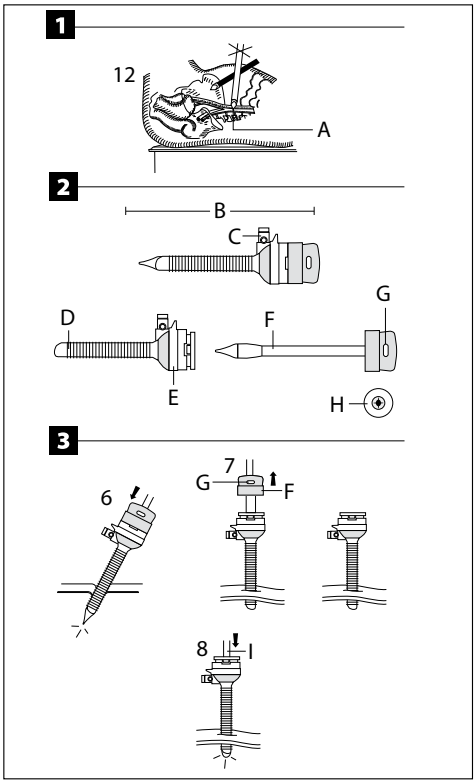
2015 / 10 - 4

INSTRUCTIONS FOR USE
VERSAONE™ OPTICAL 11 MM AND 12 MM TROCAR

COVIDIEN™

VersaOne™
Optical Trocar

PT00015248



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DESCRIPTION

The VersaOne™ V2 optical trocar is available in the following configurations:

Diameter	Length	Cannula
11 mm	100 mm Standard	Universal Fixation Cannula
11 mm	150 mm Long	Universal Fixation Cannula
12 mm	70 mm Short	Universal Fixation Cannula
12 mm	100 mm Standard	Universal Fixation Cannula
12 mm	150 mm Long	Universal Fixation Cannula
12 mm	100 mm Standard	Universal Smooth Cannula

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 having to inadvertently remove the proximal seal. There is a 3-way stopcock for insufflation and rapid desufflation.

INDICATIONS

The VersaOne™ 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 maintain appropriate pneumoperitoneum during 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 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. Before endoscopic instruments and accessories from different manufacturers are used, verify compatibility and ensure that electrical isolation or grounding is not compromised.

8. The VersaOne™ optical self-adjusting seal can accommodate instruments ranging from 5mm to the indicated diameter. Use of instruments less than 5 mm 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. 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 endoscopic instruments to minimize the potential of inadvertent damage to the seal.

12. 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.

A) ABDOMINAL AORTA

13. Insufflation of the abdomen prior to the insertion of the VersaOne™ 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.

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. Cannula and obturator are packaged side by side. 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 VersaOne™ 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

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 VersaOne™ 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.

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, and 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 VersaOne™ optical trocar from the abdominal or chest cavity, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.

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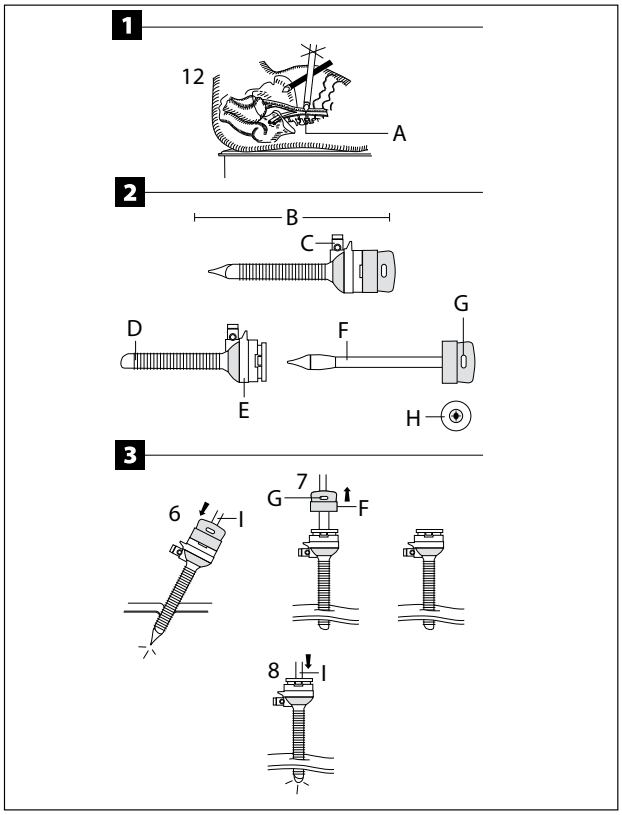
INSTRUCTIONS FOR USE
VERSAONE™ OPTICAL 15 MM TROCAR

COVIDIEN™

VersaOne™
Optical Trocar

PT00009242



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DESCRIPTION
The VersaOne™ V2 optical trocar is available in the following configuration:

Diameter	Length	Cannula
15 mm	100 mm Standard	Universal Fixation Cannula

Each size is suitable for use with instruments ranging from 5 mm up to 15mm.

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 having to inadvertently remove the proximal seal. There is a 3-way stopcock for insufflation and rapid desufflation.

INDICATIONS
The VersaOne™ 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 maintain appropriate pneumoperitoneum during 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 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. Before endoscopic instruments and accessories from different manufacturers are used, verify compatibility and ensure that electrical isolation or grounding is not compromised.
8. The VersaOne™ optical self-adjusting seal can accommodate instruments ranging from 5mm to 15mm. 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. 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 endoscopic instruments to minimize the potential of inadvertent damage to the seal.
12. 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.

A) ABDOMINAL AORTA

13. Insufflation of the abdomen prior to the insertion of the VersaOne™ 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.
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

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

1. Cannula and obturator are packaged side by side. 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 VersaOne™ 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 VersaOne™ 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.

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 VersaOne™ optical trocar from the abdominal or chest cavity, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.

STERILE EO

Rx ONLY

Do not use if package is opened or damaged

Caution, consult accompanying documents

CE 0123

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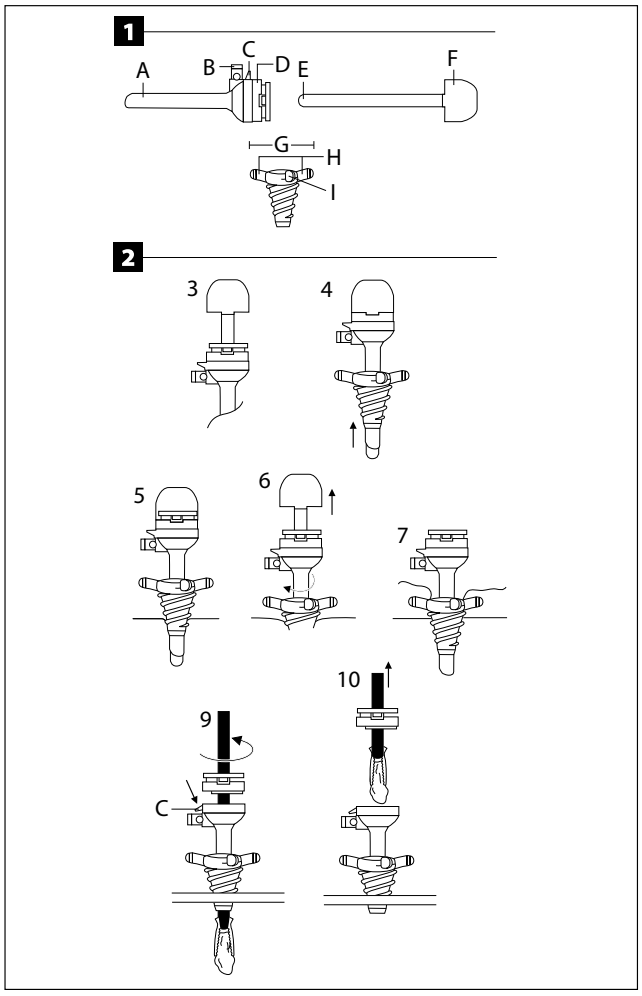
2015 / 07 - 4

INSTRUCTIONS FOR USE
VERSAONE™ BLUNT TROCAR

VersaOne™
Blunt Trocar

PT00002536



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 Covidien™ VersaOne™ blunt trocar 12mm is available with a threaded anchoring device. The VersaOne™ blunt trocar 12mm consists of a blunt-tipped obturator and an anchoring device to secure the trocar into place. Upon entry into a free space in the abdominal or chest cavity, the blunt tip aids in reducing the potential for injury to internal structures.

The self-adjusting seal, accommodating instruments ranging from 5 mm to 12 mm, is designed to effectively reduce the size of the seal's diameter without loss of pneumoperitoneum. There is a 3-way stopcock for gas insufflation and rapid desufflation.

The threaded anchoring device is designed to secure the trocar firmly into place. A spring mechanism allows the anchoring device to be placed up and down the shaft of the trocar sleeve for precise depth insertion. The threaded anchoring device includes a tie-down bar. Sutures are wrapped around the two (2) notches of the tie-down bar to secure the instrument in place during instrument manipulation and to reduce gas leakage.

INDICATIONS

The VersaOne™ blunt trocar 12 mm is intended for use in a variety of gynecologic, general, thoracic, and urologic endoscopic procedures to create and maintain a port of entry.

CONTRAINDICATIONS

This device is not intended for use except as indicated. In addition, it is not intended for use when endoscopic techniques generally are contraindicated.

WARNINGS AND PRECAUTIONS

1. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. A thorough 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 and/or patient.

2. Verify mechanical and electrical compatibility of devices from different manufacturers prior to using them together in a procedure.

3. Both before and after removal of the VersaOne™ blunt trocar 12 mm 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.

4. The self-adjusting seal can accommodate instruments ranging from 5 mm up to 12 mm. Use of instruments less than 5 mm in diameter can result in loss of pneumoperitoneum.

5. Prior to specimen removal, ensure that the self-adjusting seal is removed and pulled up onto the shaft of the instrument. Removal of the seal housing is accomplished by pressing down on the release lever above the stopcock and rotating the housing hub counterclockwise.

6. THE PRESENCE OF A BLUNT-TIPPED OBTURATOR IS NOT A SUBSTITUTE FOR ADHERENCE BY THE USER TO PROPER ENDOSCOPIC TECHNIQUES.

7. If the trocar incision is 10 mm or larger, the underlying fascia should be closed at the completion of the procedure, (e.g., by suturing, to reduce the potential for incisional hernias.)

8. 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.

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

10. This device is not intended for use except as indicated. DISCARD AFTER USE. DO NOT RESTERILIZE.

1 SCHEMATIC VIEW

A) TROCAR SLEEVE

B) 3-WAY STOPCOCK

C) RELEASE LEVER

D) SELF-ADJUSTING SEAL WITH SPECIMEN REMOVAL BUTTON

E) BLUNT TIP

F) OBTURATOR

G) Bluntgrip™ THREADED ANCHORING DEVICE

H) TIE-DOWN BAR

I) SPRING LEVER

2 INSTRUCTIONS FOR USE

NOTE: The stopcock is packaged in the CLOSED position.

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

THE PRESENCE OF A BLUNT-TIPPED OBTURATOR IS NOT A SUBSTITUTE FOR ADHERENCE BY THE USER TO PROPER ENDOSCOPIC TECHNIQUES.

1. Make an incision large enough to accommodate the size of the trocar sleeve at the site of placement. Bluntly dissect through the fascia and peritoneum in a routine approach for open laparoscopy.

2. Using two sutures of adequate tensile strength, pass one through each fascial edge, and then tag them.

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

4. Prior to insertion place either the threaded anchoring device onto the shaft of the trocar sleeve. The spring mechanism allows for adjusting the anchoring device up and down the shaft of the trocar sleeve for precise depth insertion. Squeeze both levers together and slide the grip to the desired location on the trocar sleeve.

NOTE: The self-adjusting seal must be attached to the trocar sleeve during insertion of the trocar into the body.

5. Gently insert the VersaOne™ blunt trocar 12 mm into the peritoneal cavity. (The trocar may be used with or without visualization for primary and secondary insertions).

6. Remove the obturator from the trocar sleeve. Turn the trocar sleeve clockwise until the anchoring device is firmly secured in the incision site and snug against the tissue. Tightening the threaded anchoring device against the body wall helps secure the trocar against the tissue when the trocar is manipulated at various angles.

7. Wrap fascial sutures around the two (2) notches on the tie-down bar of the anchoring device. Once the sutures are wrapped around the two (2) notches on the tie-down bar, the anchoring device remains securely positioned.

8. The trocar sleeve can accept 5 mm-12 mm sized instruments through the sleeve with its built-in self-adjusting seal without the use of a converter.

9. For specimen removal, remove the seal housing by pressing down on the release lever above the stopcock and rotating housing hub counterclockwise.

C) RELEASE LEVER

10. Proceed with the removal of the specimen through the trocar sleeve. Once the specimen is removed, replace the self-adjusting seal before reinserting instruments.

11. At the completion of the procedure, unwrap the suture from the tie-down bar on the threaded anchoring device, squeeze the spring levers together and turn the tie-down bar counter-clockwise and remove the trocar sleeve. Then proceed to tie the suture to close the trocar site.

STERILE EO

Rx ONLY

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Caution, consult accompanying documents

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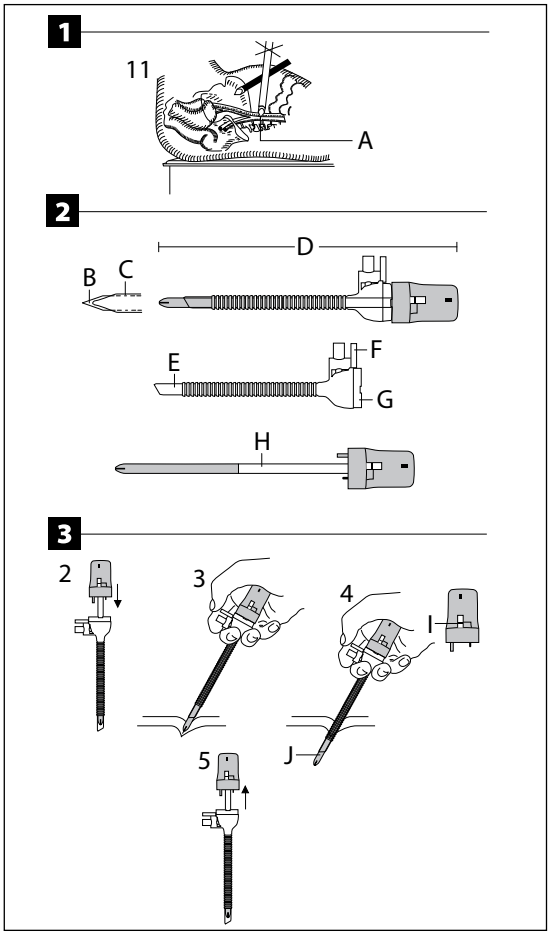
2015 / 01 - 7

INSTRUCTIONS FOR USE
VERSAONE™ BLADED 5 MM TROCAR

VersaOne™
Bladed Trocar

PT00004057



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IMPORTANT!

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DESCRIPTION

The Covidien™ VersaOne™ 5mm bladed trocar is available with smooth or ribbed fixation cannula configurations and in short and standard trocar lengths. The VersaOne™ 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 trocar sleeve 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 desufflation.

INDICATIONS

The VersaOne™ bladed 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.

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. In addition, prior to the performance of endoscopic procedures, medical literature should be consulted relative to techniques, complications and hazards.

3. The VersaOne™ 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, and exposing internal structures to injury.

5. Both before and after removal of the VersaOne™ 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.

6. 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.

7. ONCE ENTRY HAS BEEN MADE INTO FREE SPACE IN THE ABDOMINAL OR CHEST CAVITY, CARE MUST BE TAKEN NOT TO REARM THE VersaOne™ BLADED TROCAR WITH V2 PARABOLIC SHIELD. 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 VersaOne™ bladed trocar with V2 parabolic shield 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.

8. 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.

9. 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.

10. 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.

11. 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.

A) ABDOMINAL AORTA

12. 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) LINEAR BLADE

C) SHIELD

D) TROCAR ASSEMBLY

E) TROCAR CANNULA

F) STOPCOCK

G) SEAL

H) OBTURATOR

3 INSTRUCTIONS FOR USE

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

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

NOTE: The stopcock is shipped in the closed position and should remain closed before use. The stopcock is in the closed position when the lever is perpendicular to luer connection of the stopcock.

- To insufflate the abdomen, turn the stopcock parallel to the luer connection.
- To close valve, turn the stopcock perpendicular to the luer connection.
- 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. One way to ensure that an adequate incision is made is to press the trocar sleeve against the body wall, making a round impression, and then incise the diameter of the impression plus an appropriate additional amount to accommodate the sleeve, e.g., 2 mm for the 5 mm trocar. Note that a short incision may cause the skin to offer resistance to the trocar sleeve, increasing the penetration force and reducing the surgeon's control during entry. Position the VersaOne™ bladed trocar at the appropriate angle to the elevated abdomen. (See "WARNINGS AND PRECAUTIONS" #11 for abdominal procedure.)

CAUTION: The VersaOne™ bladed trocar is sharper than reusable trocars and, therefore, generally requires the application of less force for insertion.

CAUTION: 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.

NOTE: In an abdominal procedure the incorrect perpendicular trocar insertions, as depicted by the crossed-out trocar in the foreground, may result in aortic puncture. (See diagram 11.)

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

3. Squeeze down on the top of the obturator with the palm of the hand to unlock the shield. While maintaining compression of the handle, introduce the VersaOne™ bladed 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 linear blade. When insertion is performed, the shield indicator moves from the shield ON position (sharp linear blade shielded) to the shield OFF position (sharp linear blade exposed). Once the front end of the outer cannula 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 linear blade is shielded. The shield is now locked in the protected ON position. Each time 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.

CAUTION: Once entry has been made into free space in the abdominal or chest cavity, care must be taken not to rearm the VersaOne™ 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. If the red flag is in the OFF position following entry and the surgeon believes the VersaOne™ bladed trocar is in an extraperitoneal space, then the obturator should be removed and a laparoscope inserted 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 linear blade 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.

I) RED FLAG

J) SHIELD (FORWARD)

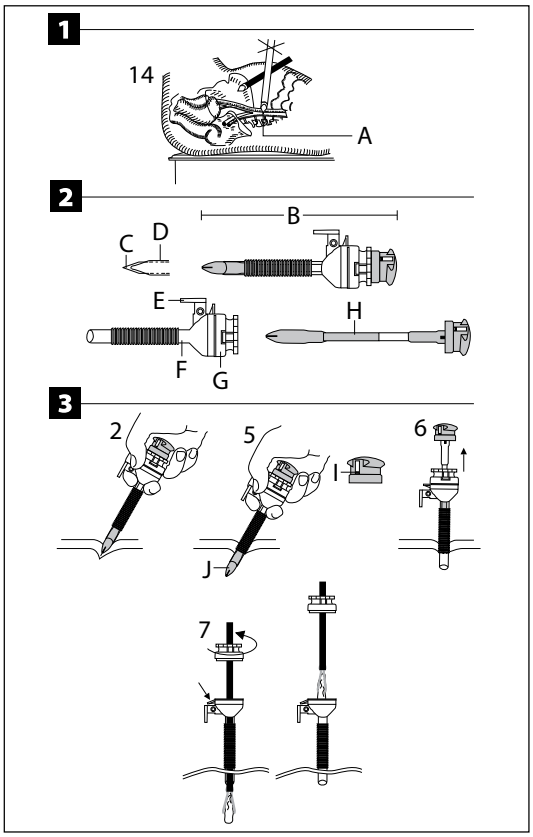
5.When the instrument is in the desired position within the abdominal or chest cavity, remove the obturator from the trocar sleeve, leaving the sleeve in place.

INSTRUCTIONS FOR USE
VERSAONE™ BLADED 11 MM AND 12 MM TROCAR

VersaOne™

Bladed Trocar

PT00004056



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DESCRIPTION

The Covidien™ VersaOne™ bladed trocar is available in 5 mm-11 mm diameter by 100 mm standard length, 5 mm-12 mm diameter by 100 mm standard length and 5 mm-12 mm diameter with 150 mm long length in both smooth or ribbed fixation cannula configurations. The VersaOne™ bladed trocar has a sharp linear blade with a spring-loaded locking shield. Upon entry into a free space the shield advances to cover the blade, reducing the potential for injury to internal structures.

The trocar sleeve contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or withdrawn. The seal system in the VersaOne™ bladed trocar is self-adjusting and accommodates instruments ranging from 5 mm to 11 mm in diameter for trocars marked as 11 mm and 5 mm to 12 mm in diameter on trocars marked as 12 mm. There is a stopcock valve for insufflation and rapid desufflation.

INDICATIONS

The VersaOne™ bladed 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.

1 WARNINGS AND PRECAUTIONS

1. Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may reduce available free space, 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 VersaOne™ bladed trocar is sharper than reusable trocars and generally requires less force for insertion. Excessive force may reduce the user's control of the angle and the depth of insertion, which may increase the risk of injury to internal structures.

4. Adhesions, anatomical anomalies or other obstructions may prevent or delay the advancement of the shield leaving the linear blade exposed, which may increase the risk of injury to internal structures.

5. The self-adjusting seal in the VersaOne™ bladed trocar can accommodate instruments ranging from 5 mm to 11 mm in diameter for trocars marked as 11 mm and 5 mm to 12 mm in diameter on trocars marked as 12 mm. Use of instruments less than 5 mm in diameter can result in loss of pneumoperitoneum.

6. Before and after removal of the VersaOne™ bladed trocar from the abdominal or chest cavity, inspect the site for hemostasis. Bleeding may 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 shield indicator does not move from the ON to the OFF position as this indicates that the trocar tip will not be exposed for penetration.

8. ONCE ENTRY HAS BEEN MADE INTO FREE SPACE IN THE ABDOMINAL OR CHEST CAVITY, CARE MUST BE TAKEN NOT TO REARM THE TROCAR. If the compression (squeezing) of the handle assembly is stopped and then restarted, the trocar would then be rearmed and the shield will be free to move. Continued advancement of the exposed blade 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 selected site is indicated prior to inserting the trocar.

10. Before endoscopic instruments and accessories from different manufacturers are used together, 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. 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 care when introducing or removing sharp-edged or sharp-angled endoscopic instruments to minimize the potential of inadvertent damage to the seal.

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.

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) TROCAR ASSEMBLY

C) LINEAR BLADE

D) SHIELD

E) STOPCOCK

F) TROCAR CANNULA

G) SELF-ADJUSTING SEAL

H) OBTURATOR

I) RED FLAG (IN "ON" POSITION)

J) SHIELD FORWARD

3 INSTRUCTIONS FOR USE

THE PRESENCE OF THE SHIELD ON THE VersaOne™ 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 open the valve, 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 VersaOne™ 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) RED FLAG (IN "ON" POSITION)

J) SHIELD FORWARD

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 using the 5 mm-11 mm, 5 mm-12 mm and 5 mm-12 mm long trocar cannulas for specimen removal, rotate the VersaOne™ self-adjusting seal counter-clockwise while depressing the specimen removal button and slide the seal onto the shaft of the instrument. Once the VersaOne™ self-adjusting seal is on the shaft of the instrument, proceed with the removal of the specimen by pulling the specimen through the trocar cannula . Once the specimen is removed, replace the VersaOne™ seal before reinserting instruments.

8. 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 trocar from the operative site. A back and forth twisting motion will facilitate removal of the trocar.

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

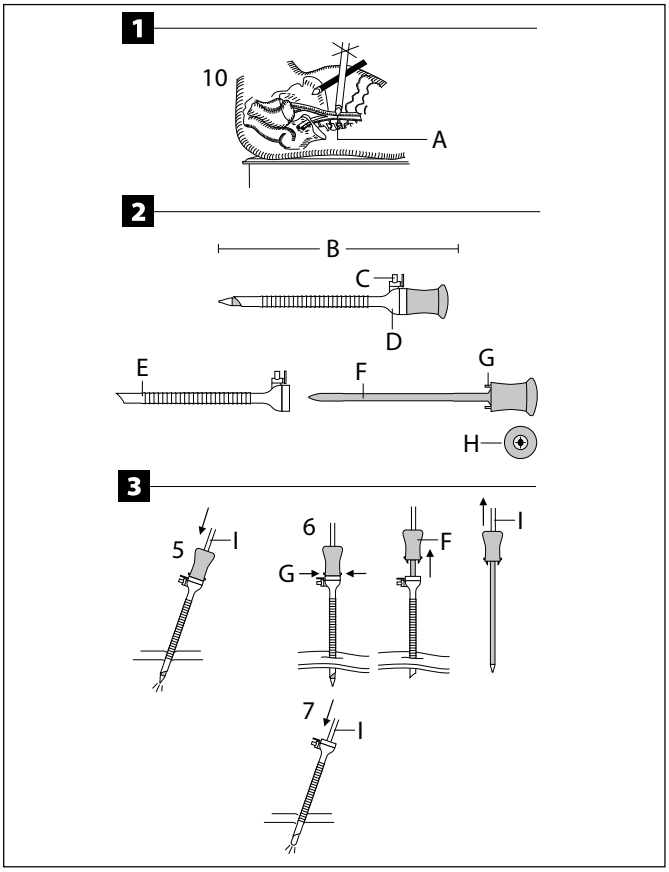
WARNING: If the trocar incision is 10 mm or larger, the underlying fascia should be closed to reduce the potential for incisional hernias.

INSTRUCTIONS FOR USE
VERSAONE™ BLADELESS 5 MM TROCAR

VersaOne™

Bladeless Trocar

PT00004632



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DESCRIPTION

The 5mm VersaOne™ V2 bladeless trocars are available in the following configurations:

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

The trocar housing contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or withdrawn. The 5 mm VersaOne™ seal system accommodates 5 mm instruments. There is a stopcock valve for insufflation and rapid desufflation.

INDICATIONS

The VersaOne™ bladeless trocars are 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.

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 are familiar 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. Before and after removal of the VersaOne™ bladeless trocar from the abdominal or chest cavity, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.

5. 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.

6. Before endoscopic instruments and accessories from different manufacturers are used, verify compatibility and ensure that electrical isolation or grounding is not compromised.

7. 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.

8. 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.

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

10. 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.

A) ABDOMINAL AORTA

11. 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) TROCAR CANNULA

D) STOPCOCK

E) LOW PROFILE HOUSING WITH SEAL

F) OBTURATOR

3 INSTRUCTIONS FOR USE

NOTE: The stopcock is shipped in the closed position and should remain closed before use. The stopcock is in the closed position when the lever is perpendicular to luer connection of the stopcock.

- To insufflate the abdomen, turn the stopcock parallel to the luer connection.
- To close valve, turn the stopcock perpendicular to the luer connection.

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 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 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. Cannula and obturator are packaged side by side. Prior to insertion of laparoscope, insert obturator into cannula.

3. Position the trocar at the appropriate angle to the abdomen while squeezing the top of the obturator completely against the seal housing. While maintaining compression on the obturator, introduce the trocar through the skin incision, applying continuous downward pressure.

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

5. To insufflate, attach gas line to the stopcock and open the lever. Stopcock lever is open for abdominal insufflation when lever is parallel to gas line.

6. When the procedure is complete, the abdomen may be desufflated by opening the stopcock. Remove the cannula from the operative site. A twisting motion will facilitate removal of the fixation cannula.

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

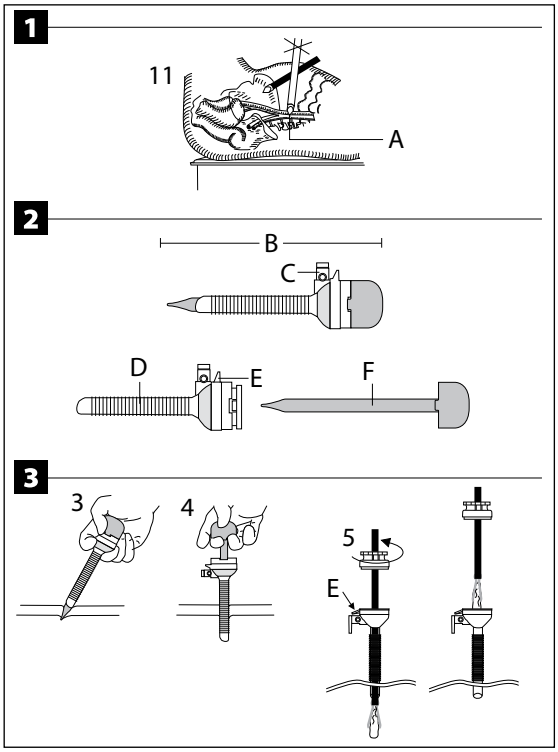
WARNING: Closure of the fascia is at the discretion of the surgeon. Underlying fascia may be closed, e.g., by suturing to reduce the potential for incisional hernias.

INSTRUCTIONS FOR USE
VERSAONE™ BLADELESS 8 MM, 11 MM, AND 12 MM TROCAR

VersaOne™

Bladeless Trocar

PT00034179



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

DESCRIPTION

The VersaOne™ V2 bladeless trocars are available in the following configurations:

Diameter	Length	Cannula
8 mm	100 mm Standard	Universal Fixation Cannula
11 mm	100 mm Standard	Universal Fixation Cannula
12 mm	70 mm Short	Universal Fixation Cannula
12 mm	100 mm Standard	Universal Fixation Cannula
12 mm	150 mm Long	Universal Fixation Cannula
12 mm	100 mm Standard	Universal Smooth Cannula

The trocar sleeve contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or withdrawn. The seal system in the VersaOne™ bladeless trocar is self-adjusting and accommodates instruments ranging from 5 mm to 8 mm in diameter for trocars marked as 8 mm, 5 mm to 11 mm in diameter for trocars marked as 11 mm and 5 mm to 12 mm in diameter on trocars marked as 12 mm. There is a stopcock valve for insufflation and rapid desufflation.

INDICATIONS

The VersaOne™ bladeless trocars are 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.

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 who are familiar 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 self-adjusting seal in the VersaOne™ bladeless trocar can accommodate instruments ranging from 5 mm to 8 mm in diameter for trocars marked as 8 mm, 5 mm to 11 mm in diameter for trocars marked as 11 mm and 5 mm to 12 mm in diameter on trocars marked as 12 mm. Use of instruments less than 5 mm in diameter can result in loss of pneumoperitoneum.
5. Before and after removal of the VersaOne™ bladeless 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. 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.
9. 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.
10. Use care when introducing or removing sharp-edged or sharp-angled endoscopic instruments to minimize the potential of inadvertent damage to the seal.
11. 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.

A) ABDOMINAL AORTA

12. 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

3 INSTRUCTIONS FOR USE

1. Insufflation of the abdomen prior to the insertion of the VersaOne™ bladeless 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.
2. 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.

3. 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.

B) TROCAR ASSEMBLY

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

D) TROCAR CANNULA

F) OBTURATOR

5. When using the VersaOne™ bladeless 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).

6. 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.

C) 3-WAY STOPCOCK

WARNING: Before and after removal of the VersaOne™ bladeless 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.

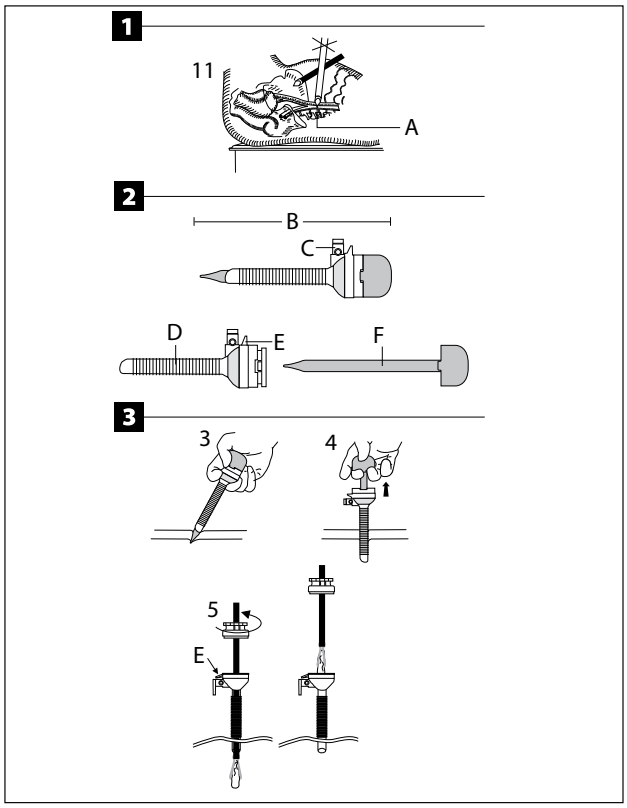
STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

INSTRUCTIONS FOR USE
VERSAONE™ BLADELESS 15 MM TROCAR

COVIDIEN™

VersaOne™
Bladeless Trocar

PT00009243



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™ V2 bladeless trocars are available in the following configurations:

Diameter	Length	Cannula
15 mm	100 mm Standard	Universal Fixation Cannula
15 mm	150 mm Long	Universal Fixation Cannula

The trocar sleeve contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or withdrawn. The seal system in the VersaOne™ bladeless trocar is self-adjusting and accommodates instruments ranging from 5 mm to 15 mm in diameter. There is a stopcock valve for insufflation and rapid desufflation.

INDICATIONS

The VersaOne™ bladeless trocars are 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.

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 who are familiar 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 self-adjusting seal in the VersaOne™ bladeless trocar can accommodate instruments ranging from 5mm to 15mm in diameter. Use of instruments less than 5mm in diameter can result in loss of pneumoperitoneum.

5. Before and after removal of the VersaOne™ bladeless 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. Before endoscopic instruments and accessories from different manufacturers are used, verify compatibility and ensure that electrical isolation or grounding is not compromised.

8. 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.

9. 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.

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

11. 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.

A) ABDOMINAL AORTA

12. 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

3 INSTRUCTIONS FOR USE

1. Insufflation of the abdomen prior to the insertion of the VersaOne™ bladeless 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.

2. 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.

3. 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.

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

5. When using the VersaOne™ bladeless 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).

6. 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 VersaOne™ bladeless trocar from the abdominal or chest cavity, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.

STERILE EO

Rx ONLY

Do not use if package is opened or damaged

Caution, consult accompanying documents

CE 0123

Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.

EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

www.covidien.com

2015 / 07 - 5

510(K) CLEARANCE
VERSAONE™ OPTICAL 5 MM TROCAR

SEP. 6. 2011 5:21PM NO. 8940 P. 1/3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Covidien
% Ms. Angela Van Arsdale
Regulatory Affairs Product Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

SEP - 1 2011

Re: K112349
Trade/Device Name: Versaport™ V2 Bladeless Optical Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 15, 2011
Received: August 16, 2011

Dear Ms. Arsdale:

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. 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 requirements, including, but not limited to: registration and listing (21

510(K) CLEARANCE
VERSAONE™ OPTICAL 5 MM TROCAR (CONT'D.)

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) CLEARANCE
VERSAONE™ OPTICAL 11 MM AND 12 MM TROCAR

MAR. 14. 2013 6:34PM NO. 3786 P. 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2013

Covidien, Formerly US Surgical a Division of Tyco Healthcare
% Ms. Sarah Rizk
Senior Product Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K130435
Trade/Device Name: Versaport™ V2 Bladeless Optical Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 21, 2013
Received: February 21, 2013

Dear Ms. Rizk:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

510(K) CLEARANCE
VERSAONE™ OPTICAL
11 MM AND 12 MM TROCAR (CONT'D.)

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR

Peter D. Bumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) CLEARANCE
VERSAONE™ OPTICAL 15 MM TROCAR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 1, 2016

Covidien
Trang Huynh
Senior Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K160230
Trade/Device Name: VersaOne ™ Optical Trocar 15mm
VersaOne ™ Bladeless Trocar 15mm
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 29, 2016
Received: February 1, 2016

Dear Trang Huynh:

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. 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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

510(K) CLEARANCE
VERSAONE™ OPTICAL 15 MM TROCAR (CONT'D.)

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) CLEARANCE
VERSAONE™ BLUNT TROCAR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 9, 2014

Covidien
% Ms. Mary Mellows
Senior Regulatory Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K142547
Trade/Device Name: Bluntport Blunt Trocar with Threaded Anchor 5mm-12mm
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 7, 2014
Received: November 10, 2014

Dear Ms. Mellows:

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. 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.

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510(K) CLEARANCE
VERSAONE™ BLUNT TROCAR (CONT'D.)

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) CLEARANCE
VERSAONE™ BLADED 5 MM TROCAR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 22, 2016

Covidien
Trang Huynh
Senior Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K152149
Trade/Device Name: VersaOne™ V2 Bladed Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 15, 2016
Received: January 20, 2016

Dear Trang Huynh:

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. 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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

510(K) CLEARANCE
VERSAONE™ BLADED 5 MM TROCAR (CONT'D.)

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) CLEARANCE
VERSAONE™ BLADED 11 MM AND 12 MM TROCAR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 2, 2015

Covidien
Ms. Trang Huynh
Senior Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K151548
Trade/Device Name: VersaOne™ Bladed Trocar and VersaOne™ Bladeless Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 2, 2015
Received: June 9, 2015

Dear Ms. Huynh:

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. 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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

510(K) CLEARANCE
VERSAONE™ BLADED 11 MM AND 12 MM TROCAR (CONT'D.)

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) CLEARANCE
VERSAONE™ BLADELESS 5 MM, 11 MM AND 12 MM TROCAR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 2, 2015

Covidien
Ms. Trang Huynh
Senior Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K151548
Trade/Device Name: VersaOne™ Bladed Trocar and VersaOne™ Bladeless Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 2, 2015
Received: June 9, 2015

Dear Ms. Huynh:

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. 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 requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

510(K) CLEARANCE
VERSAONE™ BLADELESS 5 MM, 11 MM, AND 12 MM TROCAR (CONT'D.)

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) CLEARANCE
VERSAONE™ BLADELESS 8 MM TROCAR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 18, 2016

Covidien LLC
Ms. Trang Huynh
Principal Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K162584
Trade/Device Name: VersaOne™ Bladeless Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 11, 2016
Received: October 12, 2016

Dear Ms. Huynh:

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. 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.

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510(K) CLEARANCE
VERSAONE™ BLADELESS 8 MM TROCAR (CONT'D.)

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely,

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) CLEARANCE
VERSAONE™ BLADELESS 15 MM TROCAR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 1, 2016

Covidien
Trang Huynh
Senior Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K160230
Trade/Device Name: VersaOne ™ Optical Trocar 15mm
VersaOne ™ Bladeless Trocar 15mm
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 29, 2016
Received: February 1, 2016

Dear Trang Huynh:

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. 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.

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510(K) CLEARANCE
VERSAONE™ BLADELESS 15 MM TROCAR (CONT'D.)

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ORDERING INFORMATION
EXPERIENCE ACCESS WITHOUT EXCESS.

VersaOne™ Optical Trocar	5 mm	11 mm	12 mm	15 mm
Short Length Fixation Cannula (70 mm)	**ONB5SHF**		**ONB12SHF**	
Standard Length Fixation Cannula (100 mm)	**ONB5STF**	**ONB11STF**	**ONB12STF**	**ONB15STF**
Standard Length Smooth Cannula (100 mm)			**ONB12STS**	
Standard Length Dual Pack Cannula (100 mm)	**ONB5STF2C**			
Long Length Fixation Cannula (150 mm)	**ONB5LGF**	**ONB11LGF**	**ONB12LGF**	
Sold six units per box				
VersaOne™ Blunt Trocar with Threaded Anchor	**5 mm**	**11 mm**	**12 mm**	
Standard Length Smooth Cannula (100 mm)			**BPT12STS**	
Sold three units per box				
VersaOne™ Bladed Trocar	**5 mm**	**11 mm**	**12 mm**	
Short Length Fixation Cannula (70 mm)	**B5SHF**			
Short Length Smooth Cannula (70 mm)	**B5SHS**			
Standard Length Fixation Cannula (100 mm)	**B5STF**	**B11STF**	**B12STF**	
Standard Length Smooth Cannula (100 mm)	**B5STS**	**B11STS**	**B12STS**	
Long Length Fixation Cannula (150 mm)			**B12LGF**	
Long Length Smooth Cannula (150 mm)			**B12LGS**	
Sold six units per box				

ORDERING INFORMATION
EXPERIENCE ACCESS WITHOUT EXCESS.

VersaOne™ Bladeless Trocar	5 mm	8 mm	11 mm	12 mm	15 mm
Short Length Fixation Cannula (70 mm)	**NONB5SHF**			**NONB12SHF**	
Standard Length Fixation Cannula (100 mm)	**NONB5STF**	**NONB8STF**	**NONB11STF**	**NONB12STF**	**NONB15STF**
Standard Length Smooth Cannula (100 mm)				**NONB12STS**	
Long Length Fixation Cannula (150 mm)	**NONB5LGF**			**NONB12LGF**	**NONB15LGF**
Sold six units per box					
VersaOne™ Universal Cannula					
Short Length Fixation (70 mm)	**UNVCA5SHF**				
Standard Length Fixation (100 mm)	**UNVCA5STF**		**UNVCA11STF**		
Standard Length Smooth (100 mm)				**UNVCA12STS**	
Long Length Fixation (150 mm)	**UNVCA5LGF**			**UNVCA12LGF**	
Sold six units per box					

Contact your Medtronic representative for more information at **800-722-8772** or visit our website **medtronic.com/covidien**

555 Long Wharf Drive
New Haven, CT 06511

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Medtronic