ONE COMPLETE SOLUTION.

VersaOne™ Access System

The Access Trocar Portfolio
Product Information Guide

Medtronic
Further, Together
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
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT OVERVIEW</td>
<td>4</td>
</tr>
<tr>
<td>FEATURES AND BENEFITS</td>
<td>5</td>
</tr>
<tr>
<td>IFU</td>
<td>10</td>
</tr>
<tr>
<td>510(k) CLEARANCE</td>
<td>17</td>
</tr>
<tr>
<td>ORDERING INFORMATION</td>
<td>29</td>
</tr>
</tbody>
</table>
Advantages of the Universal Cannula

- Funneled entry, enhanced seal allows smooth instrument exchange\(^1\)
- 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
- Seal converter release button for easy specimen removal / introduce needles
- 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

- Ergonomic low profile obturator provides control and comfort during insertion.
- Passive scope lock designed to hold laparoscope in place while in the obturator.
- Interlocking snap feature to secure obturator during insertion.
- Unique "dolphin nose" tip facilitates controlled tissue separation enabling smooth insertion through reduced penetration force.

1. Based on internal test report #2143-114, Applies to Medtronic 12 mm trocars, when compared to Applied Ki™ (12 mm trocar, Z-thread cannula). March 2013.
Advantages of the Blunt Trocar

- Threaded anchor ensures trocar placement and is designed to maintain pneumoperitoneum.
- Blunt tip reduces potential of injury to internal structures upon insertion.
- Finger grip allows for easy repositioning of the threaded anchor on the shaft of the cannula.
- Two suturing wings to secure suture tie down.
- Low profile hub to accommodate a variety of users.
Advantages of the Bladed Trocar

- **Bladed obturator has a safety lock to inform user when blade is exposed**
- **Ergonomic low profile obturator provides control and comfort during insertion**
- **Safety lock indicates when blade is shielded or exposed**
- **“Dolphin nose” parabolic shield retracts over blade once through peritoneum for safety**
- **Sharpened on both sides, the uniquely designed blade divides tissue cleanly and precisely with control upon insertion through the abdominal wall**
FEATURES AND BENEFITS
VERSAONE™
BLADELESS TROCAR

Advantages of the Bladeless Trocar

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

1. Unique “dolphin nose” tip facilitates smoother insertion for easier trocar placement.

2. Ergonomic design provides control and comfort during laparoscopic procedures.

3. Facilitates controlled separation.

1. Applies to Medtronic 12 mm trocars, when compared to Applied Ki™ (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

- Clip to ensure stability during shipping
- Clear labeling makes it easy to identify obturator tip, trocar size, and cannula length
- New packaging reduces packaging weight by 50%¹
- Soft pouch packaging reduces storage space

¹ Eichler Sustainability Presentation, June 27, 2014 Samantha Smith, Sr. Packaging Engineer.
INSTRUCTIONS FOR USE
VERSANO™ OPTICAL
5 MM TROCAR

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

![VersaOne™ Optical Trocar]

**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 licensure to practice, 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 reduce the potential for perforation.

4. The optical fibers at the distal end of the trocar are intended to minimize the likelihood of penetrating injury to intra-abdominal and retro-thoracic organs; however, standard percutaneous instruments employed in all abdominal instruments must be observed.

5. Before and after removal of the VersaOne™ optical trocar from the abdominal or chest cavity, inspect the site for herniation. Blinding may be caused by electrosurgery or manual sutures.

6. Threading is obtained when a threaded trocar is used (air or fluid film). For this reason, needle aspiration through the selected trocar is indicated prior to entering 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 endoscopic procedures is essential to avoid shock and 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 accidental hernia.

10. Use care when introducing a sharpened or sharp-ended angulated instrument to minimize the potential of inadvertent damage to the skin.

11. In abdominal procedures, the inserter topless trocar inserter (projected by the closed-out trocar in the illustration) could result in an arthritic puncture (under the abdominal aorta (10)). The solid black block shows the correct angle of insertion.

**INDICATIONS**

5 mm 100 mm standard Universal fixation cannula

5 mm 150 mm long Universal fixation cannula

5 mm 150 mm, long variant Universal fixation cannula

**INSTRUCTIONS FOR USE**

This device may be used within the following information thoroughos!

**IMPORTANT!**

This device is designed to assist in using the product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Review of operating instructions of this device may lead to failure and subsequent patient injury including breaking of the product components with potential for a retained foreign body. Reviewing and/or interpretation of this device may create the risk of contamination, patient infection and/or device malfunctions. Do not re-use, reprocess or re-manufacture the device.

**DESCRIPTION**

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

- **Diameter**
  - 5 mm
- **Length**
  - Standard Universal fixation
  - Universal fixation
  - 70 mm Port Universal fixation

The trocar being used is a scope retention mechanism. The trocar being used is an internal seal to prevent passage of gases, when used, into the port of the instrument. The port of the instrument is accommodates 5 mm instruments. There is a stopcock value for insufflation and deflation.

**INDICATIONS**

The VersaOne™ optical trocar is intended for use in a variety of gynaecologic, general, thoracic and 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. The device is not intended for use where endoscopic techniques are contraindicated.

2. The device is not intended for your use except as an accessory.
INSTRUCTIONS FOR USE

**VERSAONE™ OPTICAL 11 MM AND 12 MM TROCAR**

**Covidien**

VersaOne™ Optical Trocar

PT0015248

---

1. Before and after the removal of the VersaOne™ optical trocar from the abdominal or chest cavity, inspect the site for hernias. Hernias may be controlled by electrocautery or manual sutures.

5. Remove the trocar assembly from the obturator using the obturator's spears. After removing the obturator, do not allow air to enter the pleural or peritoneal cavity.

6. Performance of the above surgical procedures requires a deep understanding of the anatomy and safe and effective use of electrocautery.

---

**BEFORE USING PRODUCT; READ THE FOLLOWING INFORMATION THROUGHOUT.**

**IMPORTANT!**

This booklet is designed to assist in using the product. It is not a reference for surgical techniques.

**DESCRIPTION**

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

- **Length**
  - 11 mm
  - 12 mm

- **Diameter**
  - 70 mm
  - 110 mm

- **Material**
  - Universal PC/Polycarbonate
  - Universal Suede/Leather

---

**INSTRUCTIONS FOR USE**

**SCHÉMA DE L'ASSEMBLAGE**

- **BAC**
- **CANULE**
- **D'ASYMÉTRIQUE**
- **TROCAR**
- **OBTURATOR**
- **DE RÉGLAGE**
- **DE LA COMMANDE**
- **DE LA COMMANDE**

---

**WARNINGS AND PRECAUTIONS**

1. This device is not intended for use with non-flouroscopic guidance.

2. This device is not intended for use by non-medical personnel.

---

**PEARLS OF WISDOM**

- **INDICATIONS**
  - The VersaOne™ optical trocar is intended for use in general and abdominal surgery.

- **CONTRAINDICATIONS**
  - The VersaOne™ optical trocar is contraindicated in cases of confirmed or suspected abdominal or chest cavity hernias.

---

**STORAGE**

- **STORAGE**
  - The VersaOne™ optical trocar must be stored in a dry environment.

---

**CUSTOMER SUPPORT**

- **CUSTOMER SUPPORT**
  - For more information, please contact Covidien.

---

**LEGAL NOTICES**

- **LEGAL NOTICES**
  - Please refer to the product's package insert for additional information.

---

**REFERENCES**

- **REFERENCES**
  - For a complete list of references, please consult the product's package insert.
**INSTRUCTIONS FOR USE**

**VERSACEONE™ OPTICAL 15 MM TROCAR**

**Covidien**

**VersaOne™ Optical Trocar**

PT0009242

---

**BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY. IMPORTANCE**

This booklet is provided to assist in using the product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Failure or representation of this device may lead to its fall in 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 increase the potential for port instability.

**DESCRIPTION**

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

<table>
<thead>
<tr>
<th>Size</th>
<th>Length</th>
<th>Cannula</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 mm Standard Cannula</td>
<td>100 mm</td>
<td></td>
</tr>
</tbody>
</table>

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

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.

**INSTRUCTIONS FOR USE**

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

1. Cannula and obturator are packaged sterilely packed. Prior to insertion of laparoscope, insert obturator into cannula until the interlocking snap 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 integrity of the seal on the obturator.
3. Insert laparoscope into the obturator housing until it reaches the distal end of the obturator.
4. To provide a clear image on the monitor, vice the laparoscope is inserted into the obturator, make sure the distal end of the obturator is at the correct site, and focus the camera.
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.

**WARNINGS AND PRECAUTIONS**

1. Failure to maintain appropriate pneumoperitoneum during abdominal procedures may reduce 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 shows that 10 mm endoscopic procedures have reduced morbidity and mortality compared to open procedures.
3. To provide a clear image on the monitor, once the laparoscope is inserted into the obturator, the surgeon should control the camera housing.
4. The VersaOne™ optical trocar is intended for use in a single procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

---

**STERILE**

Do not use if package is opened or damaged. Carbon; consult accompanying documents.

© 2015 Covidien

Covidien is a trademark of Covidien Corporation.

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

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

www.covidien.com

Covidien, Covidien with logo, and Covidien logos are trademarks of Covidien AG. Other brands are trademarks of their respective owners.

2015-07-4
**VersaOne™ Blunt Trocar**

**PT00002536**

**INDICATIONS**

This device was designed, tested and manufactured for single patient use only. Its design and engineering of this device may lead to its failure and subsequent patient injury. Repackaging and re-resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or repackage this device.

**DESCRIPTION**

The VersaOne™ Blunt trocar sleeve is available with a threaded anchoring device. The VersaOne™ Blunt trocar 12 mm consists of a blunt-tipped obturator and an anchoring device to secure the trocar sleeve in place. Open entry into a free space in the abdomen or thorax using the blunt tip is 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 sealed diameter without loss of gas pressure retention. There is a 3 to 1 size ratio for gas insufflation and rapid desufflation.

The threaded anchoring device is designed to secure the trocar firmly in place. A spring mechanism allows for adjusting the anchoring device upon and down the shaft of the trocar sleeve. The anchoring device is designed to secure the Ancora™ hernia system in the abdominal wall. The ancora™ hernia system is not a substitute for adherance by the user to proper endoscopic techniques.

**WARNING AND PRECAUTIONS**

Do not use the ancora™ hernia system unless adequate training has been provided. Do not resterilize.

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. Insert the obturator into the trocar sleeve. Turn the trocar sleeve clockwise until the anchoring device is firmly secured in the incision site and snug against the skin.

4. Prior to insertion place either the threaded anchoring device onto the shaft of the trocar sleeve. The anchoring device remains securely positioned.

5. 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.

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

7. Prior to introduction place either the threaded anchoring device onto the shaft of the trocar sleeve. The anchoring device remains securely positioned.

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

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

**VERSAONE™ BLADED**

**5 MM TROCAR**

**VersaOne™ Bladed Trocar**

**K00004057**

---

**BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.**

**IMPORTANT!**

This booklet was designed to assist in using this product. It is not a reference to surgical techniques.

The device was designed, tested, and manufactured for single patient use. Either linear or repositioning of the device may lead to its failure and subsequent patient injury. Reprocessing and/or reconditioning of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or extend the life of this device.

**DESCRIPTION**

The VersaOne™ 5mm bladed trocar has a sharp inner blade and a spring-loaded locking shield. Upon entry into a free space in the abdominal or chest cavity, the shield advances over the inner 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 inflation and deflation.

**INDICATIONS**

The VersaOne™ bladed trocar is intended for use in a variety of gynecologic, general, thoracic, and laparoscopic procedures to create and maintain a port of entry.

**CONTRAINDICATIONS**

- This device is not intended for use where endoscopic techniques generally are contraindicated.
- This device is not intended for use except as indicated.

**WARNINGS AND PRECAUTIONS**

- Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may reduce available free space, thereby hindering the advancement of the sheath and increasing the risk of injury to internal structures.
- 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 enlarge 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 sheath, leaving the sharp linear blade unseated, and exposing internal structures to injury.

5. Both before and after removal of the VersaOne™ bladed trocar from the abdominal or chest cavity, ensure the operator is free from herniation. Breathing can be controlled by electrocardiogram or manual cues. In all surgically discrete, a laparoscopy or thoracoscopy may be required.

6. Do not attempt to insert the trocar if the red flag in the safety indicator does not move from the Off position to the On position. The trocar will not be exposed for abdominal or chest pneumoperitoneum.

7. Once the entry site is made, the trocar will retract to the protected ON position. Each time the shield retracts, exposing the trocar tip, there is an audible second declick. Continued advancement of the exposed sharp linear blade at this point could cause injury to internal structures.

8. If thoracoscopy is indicated to expose the chest cavity at the operator’s discretion. (See "WARNINGS AND PRECAUTIONS" for abdominal procedures.)

9. A thorough understanding of the principles and techniques involved in laparoscopy and electrocautery procedures is essential in avoiding shock and burn hazards in both patient and operator(s), and damage to the instrument.

10. In an abdominal procedure, the instrument penetrates the abdominal wall to alternating trocar insertion, as depicted by the cross-over trocar in the foregroung, may result in aortic puncture. Note the abdominal aorta at (A). The solid black trocar shows the correct angle of insertion.

**K00004057**

**ENDICISIONS**

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

2. **NOTE:** The stopcock is shipped in the closed position and should remain closed before use.

3. **NOTE:** The trocar is in the closed position when the lever is perpendicular to the connection of the stopcock, for introduction into the body, or in a position of 90 degrees to the surface of the open chest cavity. If the lever is not perpendicular to the stopcock, the device will be returned to a closed position.

4. **NOTE:** The trocar is in the closed position when the lever is perpendicular to the connection of the stopcock, for introduction into the body, or in a position of 90 degrees to the surface of the open chest cavity. If the lever is not perpendicular to the stopcock, the device will be returned to a closed position.

**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 instrument penetrates the abdominal wall to alternating trocar insertion, as depicted by the cross-over trocar in the foregroung, may result in aortic puncture. (See diagram.)

2. **NOTE:** Before introducing the trocar through the skin incision, insert the obturator into the trocar sleeve.

3. **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 inserted, the red flag indicates the position of the blade within the sheath. When the flag is visible, the shield is either in the Off position or in the protected Off position. When the flag is not visible, the shield is in the On position. When the flag is visible, the shield is either in the Off position or in the protected Off position. When the flag is not visible, the shield is in the On position.
**INSTRUCTIONS FOR USE**

**VERSAONE™ BLADED 11 MM AND 12 MM TROCAR**

**VersaOne™ Bladed Trocar**

**PT00004056**

---

**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. Proper orientation of this device may lead to failure and subsequent patient injury. Reprocessign and/or resterilization of this device may increase the risk of contaminant and patient infection. Do not reprocess this device.

**DESCRIPTION**

The VersaOne™ Bladed trocar is available in 5 mm – 11 mm diameter by 100 mm standard length, 1 mm – 12 mm diameter by 150 mm standard length and 1 mm – 12 mm diameter with 100 mm length in 7°, 15° and 45° bladed fascial canal configurations. The VersaOne™ Bladed trocar has a sharp blade with a spring loaded distal shield. Upon entry into the fascial plane the shield advances to cover the blade, ending the potential for injury to internal structures. The trocar sleeve contains a internal stopper mechanism for circumventing where instruments are inserted or withdrawn. The solid 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 or trocars marked as 12 mm. There is a stopck valve for in-material and rapid disconnection.

**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 as a gastric stapler.

---

**WARNING AND PRECAUTIONS**

1. Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may result in inadequate tissue seal and may require additional time for peritoneal inspection.

2. Thoracic procedures should be performed only by physicians having adequate training and familiarity with thoracic procedures. Medical literature review to techniques, complications, and hazards should be consulted prior to use.

3. The VersaOne™ Bladed trocar in sharper than usual trocars and generally requires less force for insertion. Excessive force may prevent 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 trocar through the fascial opening, which may increase the risk of injury to internal structures.

5. The self-adjusting valve 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 or 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 a trocar if the red flag in the shield indicates it does not move freely to the OFF position as this indicates that the trocar tip will not be recessed for penetration.

8. Once ENT has been made into FREE SPACE IN THE ABDOMINAL OR CHEST CAVITY, CARD MUST BE TAKEN NOT TO REMOVE THE TROCAR. If the compression (squeezing) of the handle assembly is stopped and then resumed, the trocar would then be damaged and the shield will be free to move. Continued advancement of the required blade could cause injury to internal structures.

9. Thoracoscopic in induced atelectasis at least a limited intrapleural space exists (see or fluid fill). For this reason, a needle aspiration through the selected trocar 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 aseptic technique and thoracic procedures is essential to avoid shock and burns 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 visceral 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.

---

**INSTRUCTIONS FOR USE**

**THE PRESENCE OF THE SHIELD ON THE VersaOne™ TROCAR IS NOT A SUBSTITUTE FOR ADEQUACY BY THE PHYSICIAN TO PREPARE ENDOSCOPIC TECHNIQUES.**

**NOTE:** The stopcock is packaged in the closed position.

1. To open the valve, turn the trocar clockwise.
2. To close valve, turn the trocar counterclockwise.
3. 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 trocar diameter.

---

**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 maintaining a steady pressure on the trocar to avoid cutting through the fascial plane.

3. When the trocar fails to accept the trocar spigot there will be an audible click, cease the distal end of the hand has passed into the space the shield will spring forward and the red flag will return to the OFF 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 remove 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 open 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 instructions 1-3.

5. Upon entering the free space, the shield will cover the blade and lock into place. The red flag will be in the ON position as confirmed by an audible click.

6. **SHIELD FORWARD**

---

**INSTRUCTIONS FOR USE**

**THE PRESENCE OF THE SHIELD ON THE VersaOne™ TROCAR IS NOT A SUBSTITUTE FOR ADEQUACY BY THE PHYSICIAN TO PREPARE ENDOCSOPIC TECHNIQUES.**

**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).

7. When the shield reaches to expose the trocar spigot there will be an audible click, cease the distal end of the hand has passed into the space the shield will spring forward and the red flag will return to the OFF 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 remove 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.

8. If the red flag remains in the open 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 instructions 1-3.

9. Upon entering the free space, the shield will cover the blade and lock into place. The red flag will be in the ON position as confirmed by an audible click.

10. **SHIELD FORWARD**

---

**INSTRUCTIONS FOR USE**

**THE PRESENCE OF THE SHIELD ON THE VersaOne™ TROCAR IS NOT A SUBSTITUTE FOR ADEQUACY BY THE PHYSICIAN TO PREPARE ENDOCSOPIC TECHNIQUES.**

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

11. When using the 5 mm – 11 mm, 5 mm – 12 mm and 5 mm – 12 mm trocar cannulas for specimen removal, insert the VersaOne™ off adjusting shield onto trocar handle while depressing the specimen removal button and slide the rod into the shaft of the instrument. Once the VersaOne™ off adjusting shield 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™ on adjusting shield and remove the instrument.

12. If the procedure is complete, the instruments may be disinfected by opening the trocar (counterclockwise) to 90° and disinfact the shaft of the abdomen, turn the trocar fully counterclockwise. Remove the trocar from the operative site. A lock and both twisting may 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

VERSATONE™ BLADELESS 5 MM TROCAR

VersaOne™
Bladeless Trocar
PT00004632

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 pneumoperitoneum 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 suture.
5. Pneumoperitoneum is not ideal and will at least admit limited intraperitoneal space (i.e., 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 the electrical isolation 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 withdrawing sharp-edged or sharp-angled endoscopic instruments to minimize the potential of inadvertent injury, damage to the seal or loss of pneumoperitoneum.

CAUTIONS

1. The devices provided STERILE and are intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

SCHEMATIC VIEW

A) ABDOMINAL AORTA
B) TROCAR ASSEMBLY
C) STOPCOCK
D) HIGH PROFILE HOUSING WITH SEAL
E) LOW PROFILE HOUSING WITH SEAL

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 the luer connection of the stopcock.

1. To insufflate the abdomen, turn the stopcock parallel to the luer connection.

2. Insert the obturator into the cannula. Prior to inserting the 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 into the abdominal cavity.

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. Upon retractor use, reposition instruments may now be inserted and removed through the trocar sleeve.

5. To insufflate, attach a luer to the stopcock and open the lever. Insufflation is complete when a twisting motion will facilitate removal of the luer.

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

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.

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 intended for use where endoscopic techniques are contraindicated.
2. This device is intended for use except as indicated.

IMPORTANT!

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 needle aspiration 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 intended for use where endoscopic techniques are contraindicated.
2. This device is intended for use except as indicated.
INSTRUCTIONS FOR USE

VERSANO™ BLADELESS
8 MM, 11 MM, AND 12 MM TROCAR

VersaOne™
Bladeless Trocar

PT0034179

1. **WARNINGS AND PRECAUTIONS**
   1. Failure to establish and maintain appropriate pneumoperitoneum in an abdominal procedure 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 pneumoperitoneum may cause increased ventilation force which may reduce the surgeon’s control during entry.
   4. The self-adjusting seal of 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. Thoroughly inspect the trocar site for local dimpling or indentation before using the trocar for any further procedures.
   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 laparoscopic and endoscopic 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 a requisite of the surgery. Underlying fascia may be closed, e.g., by suturing to reduce the
      potential for intestinal hernias.
   10. Skin care when introducing or removing sharp-edged or sharp-pointed endoscopic instruments to minimize the
       potential of inadvertent damage to the skin.
   11. In abdominal procedures, the incorrect perpendicularly inserted trocar (percutaneously inserted trocar in the
       illustrations) could result in an aortic puncture (see the abdominal aorta [A]). The solid black trocar shows the correct
       angle of insertion.
   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**
   A) TROCAR ASSEMBLY
   B) 11 MM TROCARlock
   C) TROCAR CANNULA
   D) SELF-ADJUSTING SEAL, WITH SPECIMEN REMOVAL BUTTON
   E) OBTURATOR

3. **INSTRUCTIONS FOR USE**
   1. Insufflation of the abdomen prior to the insertion of the VersaOne™ bladeless trocar 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.
   3. An insufficient insufflation may cause increased ventilation force which may reduce the surgeon’s control during entry.
      An insufflation too large may increase the potential for paralytic ileus.
   4. **WARNING:** To make an adequate incision, the application of excessive force or incorrect incisions may increase the risk of
      injury to internal structures.
   5. Position the trocar assembly at the appropriate angle to the abdomen while maintaining compression on the
      obturator, introduce the trocar assembly through the skin incision utilizing a clockwise motion, applying continuous
      downward pressure.
   6. **WARNING:** If 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.
   7. **WARNING:** To prevent damage to the cannula, follow manufacturer’s instructions when inserting or removing instrumentation utilizing jaws or components that are open and close, ensure that the instrument jaws or components are in the closed position (where applicable).
   8. **WARNING:** Prior to reinsertion of the VersaOne™ bladeless trocar, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.

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

---

**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 reutilization of this device may create the risk of
contamination, patient infection and/or device malfunction. Do not reuse, repurpose or reutilize this device.

**DESCRIPTION**

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

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Length</th>
<th>Cannula</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 mm</td>
<td>100 mm Standard</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>11 mm</td>
<td>100 mm Standard</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>12 mm</td>
<td>70 mm Short</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>12 mm</td>
<td>100 mm Standard</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>12 mm</td>
<td>110 mm Long</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>12 mm</td>
<td>100 mm Standard</td>
<td>Universal Smooth Cannula</td>
</tr>
</tbody>
</table>

The trocar sleeve contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or
withdrawn. The self-centering 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
deflation.

**INDICATIONS**

The VersaOne™ bladeless trocars are intended for use in a variety of general, laparoscopic, 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 are generally contraindicated.
2. This device is not intended for use except as indicated.

---

**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 reutilization of this device may create the risk of
contamination, patient infection and/or device malfunction. Do not reuse, repurpose or reutilize this device.

**DESCRIPTION**

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

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Length</th>
<th>Cannula</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 mm</td>
<td>100 mm Standard</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>11 mm</td>
<td>100 mm Standard</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>12 mm</td>
<td>70 mm Short</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>12 mm</td>
<td>100 mm Standard</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>12 mm</td>
<td>110 mm Long</td>
<td>Universal Fluid Cannula</td>
</tr>
<tr>
<td>12 mm</td>
<td>100 mm Standard</td>
<td>Universal Smooth Cannula</td>
</tr>
</tbody>
</table>

The trocar sleeve contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or
withdrawn. The self-centering 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
deflation.

**INDICATIONS**

The VersaOne™ bladeless trocars are intended for use in a variety of general, laparoscopic, 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 are generally contraindicated.
2. This device is not intended for use except as indicated.
INSTRUCTIONS FOR USE
VERSANO™ BLADELESS
15 MM TROCAR

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THROUGHOUT.

IMPORTANT!

This device is not intended for use when endoscopic techniques generally are contraindicated.

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 reviewed prior to use.

3. An insufficient incision may cause increased penetration force which may reduce the surgeon's control during entry. An incision too large may increase the risk of injury to internal structures.

4. Thoroughly inspect the selected site before introducing or removing sharp-edged or sharp-angled endoscopic instruments to minimize the potential for inadvertent damage to the surrounding tissue.

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 suction.

6. Closure of the fascia at the discretion of the surgeon. Underlying fascia may be closed, e.g., by using a continuous horizontal mattress suture or a similar technique that allows for a tension-free closure.

7. Do not use when endoscopic techniques generally are contraindicated.

CONTRAINDICATIONS

1. This device is not intended for use except as indicated.

2. This device is not intended for use when endoscopic techniques generally are contraindicated.

INDICATIONS

1. This device is intended for use in a variety of general, gynecologic, urologic and thoracic endoscopic procedures to create and maintain a port of entry.

DESCRIPTION

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

- **11 mm Universal Fixation Cannula**
- **15 mm Universal Fixation Cannula**
- **15 mm 100 mm Long Universal Fixation Cannula**
- **15 mm 150 mm Long Universal Fixation Cannula**

The trocar cannulas are available in lengths of 100 mm and 150 mm. The trocar assembly 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.

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 the 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. Be sure the incision is adequate to accommodate the largest instrument that will be used through the trocar.

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. Close the fascial incision and suturing of the fascia may permit the surgeon to control bleeding. A continuous horizontal mattress suture may be used for a tension-free closure.

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 ensure proper seating of the trocar.

7. Closure of the fascia at the discretion of the surgeon is indicated prior to inserting the trocar.

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 suction.

8. Thorough knowledge of the principles and techniques involved in laser laparoscopy and endoscopic 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 at the discretion of the surgeon. Underlying fascia may be closed, e.g., by using a continuous horizontal mattress suture or a similar technique that allows for a tension-free closure.

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

11. In abdominal procedures, the incision perpendicular to the fascia (e.g., by the transverse incision in the illustration) could result in an aortic puncture. Inserting the trocar at a 90° angle to the abdominal aorta (A). The solid black line shows the correct angle of insertion.

A) ABDOMINAL AORTA

B) TROCAR ASSEMBLY

C) 3-WAY STOPCOCK

D) TROCAR CANNULA

E) USE ADJUSTING VALVE WITH SPECIMEN REMOVAL BUCKET

F) OBTURATOR

SCHEMATIC VIEW

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

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

Re: K112349
Trade/Device Name: Versaport™V2 Bladeless Optical Trocar
Regulation Number: 21 CFR 886.1500
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 890 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
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/CenterforDevicesandRadiologicalHealth/CDRH
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” (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.

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

Sincerely yours,

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

Enclosure
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 §76.1500
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 marketedpredicate 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
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 or 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" (21 CFR 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,

Peter D. Bumm, MD

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

Enclosure
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-
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](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](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](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

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
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.

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 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.

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
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
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.

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,

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
VERSARO™ BLADED
11 MM AND 12 MM TROCAR

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
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" (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.

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

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...
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
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.

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 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.

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,

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
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-
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.

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

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.

<table>
<thead>
<tr>
<th>VersaOne™ Optical Trocar</th>
<th>5 mm</th>
<th>11 mm</th>
<th>12 mm</th>
<th>15 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Length Fixation Cannula (70 mm)</td>
<td>ONB5SSHF</td>
<td></td>
<td>ONB12SSHF</td>
<td></td>
</tr>
<tr>
<td>Standard Length Fixation Cannula (100 mm)</td>
<td>ONB5STF</td>
<td>ONB11STF</td>
<td>ONB12STF</td>
<td>ONB15STF</td>
</tr>
<tr>
<td>Standard Length Smooth Cannula (100 mm)</td>
<td></td>
<td></td>
<td>ONB12STS</td>
<td></td>
</tr>
<tr>
<td>Standard Length Dual Pack Cannula (100 mm)</td>
<td>ONB5STF2C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long Length Fixation Cannula (150 mm)</td>
<td>ONB5LGF</td>
<td>ONB11LGF</td>
<td>ONB12LGF</td>
<td></td>
</tr>
<tr>
<td>Sold six units per box</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VersaOne™ Blunt Trocar with Threaded Anchor</th>
<th>5 mm</th>
<th>11 mm</th>
<th>12 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Length Smooth Cannula (100 mm)</td>
<td></td>
<td></td>
<td>BPT12STS</td>
</tr>
<tr>
<td>Sold three units per box</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VersaOne™ Bladed Trocar</th>
<th>5 mm</th>
<th>11 mm</th>
<th>12 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Length Fixation Cannula (70 mm)</td>
<td>B5SHF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short Length Smooth Cannula (70 mm)</td>
<td>B5SHS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard Length Fixation Cannula (100 mm)</td>
<td>B5STF</td>
<td>B11STF</td>
<td>B12STF</td>
</tr>
<tr>
<td>Standard Length Smooth Cannula (100 mm)</td>
<td>B5STS</td>
<td>B11STS</td>
<td>B12STS</td>
</tr>
<tr>
<td>Long Length Fixation Cannula (150 mm)</td>
<td></td>
<td></td>
<td>B12LGF</td>
</tr>
<tr>
<td>Long Length Smooth Cannula (150 mm)</td>
<td></td>
<td></td>
<td>B12LGS</td>
</tr>
<tr>
<td>Sold six units per box</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## ORDERING INFORMATION

**EXPERIENCE ACCESS WITHOUT EXCESS.**

<table>
<thead>
<tr>
<th>VersaOne™ Bladeless Trocar</th>
<th>5 mm</th>
<th>8 mm</th>
<th>11 mm</th>
<th>12 mm</th>
<th>15 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Length Fixation Cannula (70 mm)</td>
<td>NONB5SHF</td>
<td></td>
<td></td>
<td></td>
<td>NONB12SHF</td>
</tr>
<tr>
<td>Standard Length Fixation Cannula (100 mm)</td>
<td>NONB5STF</td>
<td>NONB8STF</td>
<td>NONB11STF</td>
<td>NONB12STF</td>
<td>NONB15STF</td>
</tr>
<tr>
<td>Standard Length Smooth Cannula (100 mm)</td>
<td></td>
<td></td>
<td></td>
<td>NONB12STS</td>
<td></td>
</tr>
<tr>
<td>Long Length Fixation Cannula (150 mm)</td>
<td>NONB5LGF</td>
<td></td>
<td></td>
<td></td>
<td>NONB12LGF</td>
</tr>
</tbody>
</table>

Sold six units per box

<table>
<thead>
<tr>
<th>VersaOne™ Universal Cannula</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Length Fixation (70 mm)</td>
<td>UNVCA5SHF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard Length Fixation (100 mm)</td>
<td>UNVCA5STF</td>
<td>UNVCA11STF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard Length Smooth (100 mm)</td>
<td></td>
<td></td>
<td></td>
<td>UNVCA12STS</td>
<td></td>
</tr>
<tr>
<td>Long Length Fixation (150 mm)</td>
<td>UNVCA5LGF</td>
<td></td>
<td></td>
<td>UNVCA12LGF</td>
<td></td>
</tr>
</tbody>
</table>

Sold six units per box
Contact your Medtronic representative for more information at
**800-722-8772** or visit our website
[medtronic.com/covidien](http://medtronic.com/covidien)