OPENING THE DOOR TO EASY PORT-SITE CLOSURES.¹

VersaOne™ Fascial Closure System

Product information guide
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We’re excited to introduce the latest advancement in our VersaOne™ trocar platform family: the VersaOne™ fascial closure system.

Like all of our VersaOne™ trocars, it provides access to standard laparoscopic instruments. But it also delivers consistent closure of the port site.

This unique device is part of our commitment to helping you improve procedural efficiency — from the initial moments of surgery to the final suture.†

†Compared to the competitive closure device, suture passer, and suture only.
The VersaOne™ fascial closure system is a multifunctional tool that serves as a trocar and a fascial closure device. It delivers:

- Consistent port-site closure¹
- Added procedural efficiency¹,†
- Ease of use¹

Addressing a Procedural Need

We developed the VersaOne™ fascial closure system because there’s a need for a consistent solution for closures at the port site.¹

Traditional fascial closure techniques:

**TRADITIONAL SUTURING**

Difficult and imprecise, especially in obese patients and in all laterally placed trocar site²

**SUTURE PASSER**

Inexact suture placement³

**CLOSURE DEVICE**

Reinsertion after trocar removal

†Compared to the competitive closure device, suture passer, and suture only.
Consistent Closure
The VersaOne™ fascial closure system is designed to facilitate closure of the fascia at 5 mm on either side of the wound.4–7

Efficient Access and Closure
The all-in-one system can help save time because it:
• Eliminates the need to remove trocar before closure
• Makes reinsufflation unnecessary — pneumoperitoneum can be maintained throughout the procedure
• May help to reduce the number of SKUs required
ALL-IN-ONE ACCESS AND CLOSURE

How to use the VersaOne™ fascial closure system

System Components
1. Guide
2. Distal black band
3. Distal cannula window
4. Proximal black band
5. Arrow
6. Obturor

Reusable Suture Passer
1. Needle tip
2. Flush port
3. Cleaning spacer
**STEP 1**
Remove the seal housing on the cannula by rotating the self-adjusting seal counter-clockwise while depressing the specimen removal button.

Important: Do not insert the guide into the seal housing.

**STEP 2**
Fully insert the disposable guide into the cannula until a click is heard and the guide is locked in place.

**STEP 3**
Ensure the distal black band on the cannula is aligned with the peritoneum and the proximal black band is below the skin.
STEP 4
Grasp a short tail of suture with the suture passer.†

STEP 5
A. Insert the suture passer down either one of the two guide channels. Advance the suture passer and suture through the tissue and into the abdominal cavity.
B. Use the secondary grasper from the alternate port to grasp the suture. Release the suture from the suture passer jaw.

STEP 6
A. Insert the empty suture passer down the opposite guide channel into the abdominal cavity to grab the suture.
B. Pick up the suture and remove it through the guide.
C. Remove the cannula and guide assembly from defect and tie off.

† The trocar and guide will accommodate Karl Storz™ BERC closure instrument.8,9
March 8, 2017

Corium LLC
Mr. Gary LaBree
Sr. Regulatory Affairs Specialist
46 Middlebrook Avenue
North Haven, Connecticut 06473

Res. K105634
Title/Device Name: VersaOne Facial Closure System Blended Tissue, VersaOne Facial Closure System Endoscopic Tissue, VersaOne Facial Closure System Optical Tissue
Registration Number: 21 CFR 888.1500
Registration Name: Endoplasics and accessories
Regulatory Class: Class II
Product Code: GCJ
Device: March 1, 2017
Received: March 3, 2017

Dear Mr. Labree:

We have reviewed your submission for your device and we have determined that the device is substantially equivalent (as indicated by the submission) to legally marketed predicate devices marketed in accordance with the existing device labeling. For additional information regarding your device, please contact the Division of Industry and Consumer Education at 1-800-638-2041 or 888-796-7700 to request additional information.

Sincerely,

Jennifer R. Stevenson, M.D.
Regional Director
Office of Device Evaluation
Center for Devices and Radiological Health
# ORDERING INFORMATION

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<tr>
<td>ONB12STFCS</td>
<td>VersaOne™ Fascial Closure System Optical Trocar</td>
<td>6 units per box</td>
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<tr>
<td>B12STFCS</td>
<td>VersaOne™ Fascial Closure System Bladed Trocar</td>
<td>6 units per box</td>
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<tr>
<td>FCSPASS</td>
<td>VersaOne™ Fascial Closure System Reusable Suture Passer</td>
<td>1 unit per box</td>
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For more information or to order the VersaOne™ fascial closure device, call 800-772-8772
Visit us at medtronic.com/versaone-closure

Important: Always refer to the instructions for use (IFU) supplied with the product for complete instructions, indications, contraindications, warnings, and precautions.

4. Based on internal report #RE00003570, VOC summary detailing customer requirements for project DoubleTime, as compiled from surveys at SAGES 2013: 16 out of 16 surgeons agreed, Nov. 5, 2014.
5. Based on internal report #RE00079705, Fascial closure system bite size verification, Nov. 5, 2014.