Laparoscopic Port-Site Fascial Closure Device Review and Catalog

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Review of evidence for port site fascial closure

A number of factors have been identified which are significantly correlated with hernia development and reoccurrence. These include non-modifiable factors such as age and male gender, and modifiable ones such as obesity, diabetes, immunosuppression, smoking and COPD[1,2]. It is important patients and providers still address these underlying risk factors even though just the use of a laparoscopic port site is not traditionally considered a hernia.

Laparoscopic surgery has evolved significantly since its introduction nearly forty years ago. Understanding nuances which contribute to port site hernia occurrence can therefore be challenging as technique and technology have considerably changed. Factors, however which have been consistently associated with port-site hernia development include trochar size, abdominal location and port-site enlargement.

Port size

Perhaps one of the most studied factors in port site hernias is trochar size. A 1997 prospective study identified 5mm trochars to be associated with only one of 16 hernias (6.3%) in 870 patients[3]. Similarly, a 2010 systematic review identified only 2 cases (2.0%) from 5mm ports of 99 hernias[4], and this trend continues through more recently published work as well; 2.7% in a 2011 systematic review[5], and 3% in a 2017 retrospective review[6]. All other hernias in these studies occurred with ports 10mm or greater. A 2020 systematic review by Gutierrez compared port-site closure vs. none for both 5mm and 10mm trochars and identified a herniation rate of 0% and 0.08% for 5mm ports and 0.14% and 0.2% for 10mm ports[7].

Unequivocally single port systems have been associated with significantly greater rates of port-site hernias with a 2021 single center trial reporting an 8% incidence at 2 years[8], and a 2018 review of 13 studies reporting a 5.2% incidence at a median follow-up of 4 months[9].

Abdominal location

Several factors regarding trochar location on the abdominal wall have been associated with increased incidence of port-site hernia. Overall hernias occur most commonly at the umbilical port site but have been observed in all port-site locations.

A 2010 review by Bunting et.al. identified 89% of 99 hernias to be at the umbilicus with the remaining 11% upper abdominal[4]. A 2017 review by Lambertz et. al. identified a more even distribution with 44% of 54 hernias umbilical or peri-umbilical, 35% epigastric and 20% lateral abdominal wall[6]. A 2020 review by Gutierrez calculated incidence by site with the highest of 1.2% at the umbilicus, extraumbilical at 0.33% and subxiphoid 0.60%[7].

One repeatedly identified factor associated with port-site hernia is midline location. In a 2011 systematic review Owens et. al. observed that 57% of port-site hernias occurred in the midline[5]

while Gutierrez et. al. determined an overall midline port-site hernia incidence of 0.71% as compared to off-midline at 0.28%, a 2.5 fold difference[7].

Port-site extension

Port-site extension or enlargement for specimen extraction was one of the earlier identified factors associated with hernia development. Nassar in 1997 found extension to have been involved in 12 of 16 (75%) port-site hernias[3]. Ki et. al in 2019 identified extension to have occurred in 10 of 18 (56%) hernias[10], and Bunting et. al in 2010 identified extension to have been a significant risk factor in a majority of included studies[4].

Other factors

In their 1997 prospective study, Nassar et. al. identified pre-existing umbilical hernia as a significant risk factor for post-operative port-site hernia[3]. Of 870 laparoscopic cholecystectomies, 12% presented with an incidental finding of umbilical hernia which was subsequently used as a port-site and closed primarily with suture. However, of sixteen port-site hernias identified in their study, four (25%) had hernias pre-operatively. Bunting et. al similarly identified pre-existing umbilical hernia as a significant risk factor for port-site hernia development in their 2010 systematic review[4].

Other risk factors suggested for port-site hernia include: Older age[4,10], higher BMI[10], sarcopenia[10], length of surgery[10], presence of a rectus diastasis[10], port-site infection[3–5] and male gender[3,4].

Devices

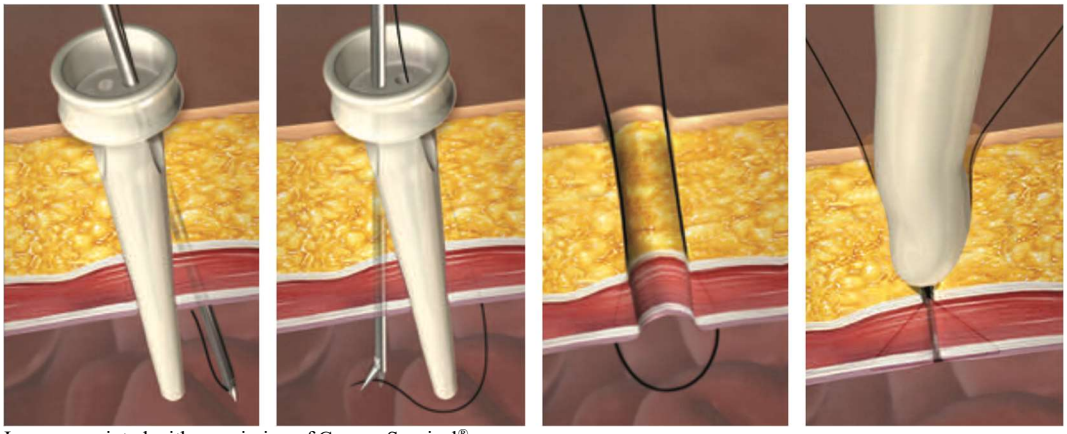
Product	Entry	Disposable	Unprotected sharp	Requires a trochar	Fits through a trochar	Functional length	Width
Carter-Thomason CloseSure®	1998	Yes	Yes	No	No	6 – 10 cm	**
Carter-Thomason II™	2012	Yes	Yes	No	Yes	11 – 15 cm	**
Efx Classic™	2010	Yes	Yes	No	No	5.7 - 10.1 cm	1.3 – 1.7cm
Efx Shield®	2015	Yes	No	No	No	6.1 cm	1.3 cm
CrossBow™ and Longbow™	2015	Yes	Yes	No	No	7cm 9cm	1.4cm
EZ Stitch™	2020	Yes	No	No	No	17cm	1.4cm
Lapro-Shark™	2016	Yes	No	No	No	7.6 cm	1.2 - 2.9 cm
SutureClose™	2016	Yes	Yes	No	No	6 cm	1.4 cm
VersaOne™	2017	Partially	Yes	Yes	Yes (Limited)	5.1cm	1.2cm
NeoClose®	2018	Yes	Yes	No	No	**	**

M-close™	2019	Yes	No	No	Yes	10.2 cm	1 cm

**Manufacturer prefers not to disclose/Proprietary

Carter-Thomason CloseSure System®

Manufacturer: Cooper Surgical®
Entry Date: 1998



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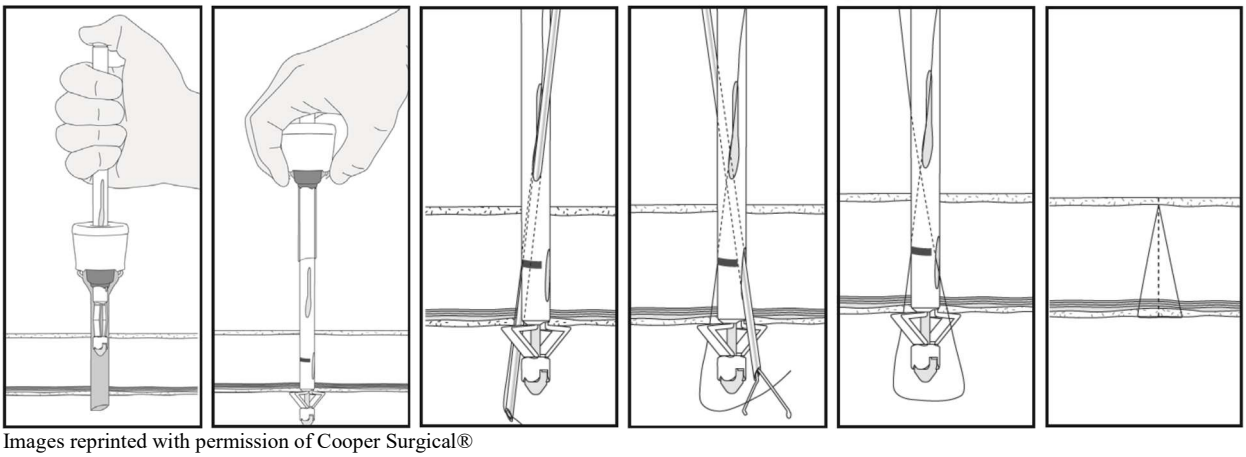
Mechanism: Suture passer needle paired with cone tip guide
Components:

1. Needle guide
2. Suture retriever needle

Disposability: Disposable
Unprotected Sharp: Yes
Requires a trochar: No
Fits through a trochar: No
Fascial bite: Variable based on depth
Functional dimensions:
Length (Bottom of the flange to the needle exit sites)
5mm Guide:
10/12 Guide: 6 cm
15mm Guide: 7 cm
XL 10/12 Guide: 10 cm
XL 15mm Guide: 10 cm
Width (Maximal cone diameter): Manufacturer prefers not to disclose
Cooper Surgical CloseSure System (Documentation Link)
Cooper Surgical Product Comparison (Documentation Link)

Carter-Thomason® II Port Closure System

Manufacturer: Cooper Surgical®
Entry Date: 2012



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Mechanism: Suture passer needle paired with stick guide with distal collapsable non-needle-obstructing wings
Components:
1. Needle guide
2. Suture retriever needle

Disposability: Disposable
Unprotected Sharp: Yes
Requires a trochar: No
Fits through a trochar: Yes
Fascial bite: Variable based on depth
Functional dimensions:
Length (Top of the anchoring wings to needle entry point)
10/12 System: 11 cm
15mm System: 11 cm
XL 10/12 System: 15 cm
XL 15mm System: 14 cm
Width (Maximal width of the shaft): Manufacturer prefers not to disclose
Cooper Surgical Carter Thomason II (Documentation Link)
Cooper Surgical Product Comparison (Documentation Link)

EFx Classic™ Fascial Closure System

Manufacturer: Teleflex™ Weck®
Entry Date: 2010

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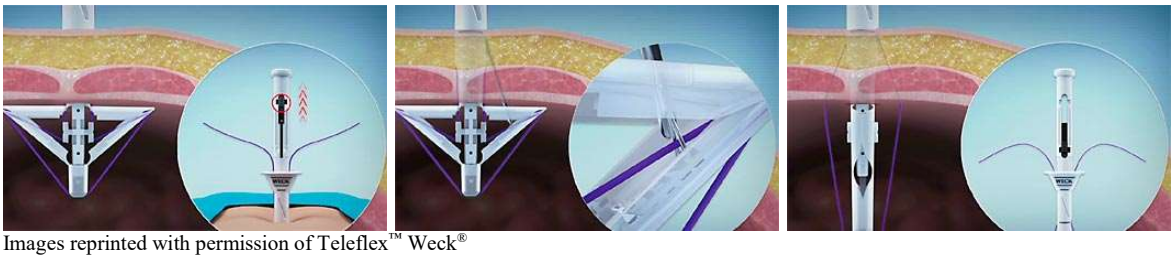
Mechanism: Suture passer needle paired with cone tip guide
Components:
1. Needle guide
2. Suture retriever needle

Disposability: Disposable with optional reusable Berci needle passer
Unprotected Sharp: Yes

Requires a trochar: No
Fits through a trochar: No
Fascial bite: Variable based on depth
Functional dimensions:
Length (Bottom of the flange to the needle exit sites):
10/12 Guide: 5.7 cm
15mm Guide: 10.1 cm
Width (Maximal cone diameter):
10/12 Guide: 1.3 cm
15mm Guide: 1.7 cm
Teleflex Weck EFx Shield and EFx Classic (Documentation Link)

EFx Shield® Fascial Closure System

Manufacturer: Teleflex™ Weck®
Entry Date: 2015



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Mechanism: Suture passer needle paired with stick guide with distal collapsable needle-obstructing wings

Components:

1. Needle guide
2. Suture retriever needle

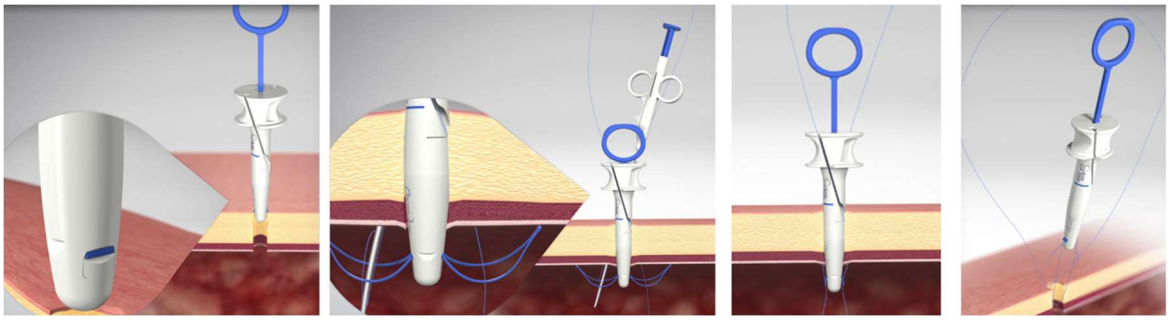
Disposability: Disposable
Unprotected Sharp: No
Requires a trochar: No
Fits through a trochar: No
Fascial bite: 1cm (Guide shaft to needle entry site on wing)
Functional dimensions:

Length: 6.1 cm (Top of wings to tapered neck below suture entry)
Width: 1.3 cm (Shaft diameter)

Teleflex Weck EFx Shield and EFx Classic (Documentation Link)

CrossBow™ and LongBow™ Closure Device

Manufacturer: Suture Ease
Entry Date: 2015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Mechanism: Suture passer needle paired with cone tip guide with retractable snare loops
Components:
1. Needle guide
2. Suture retriever needle

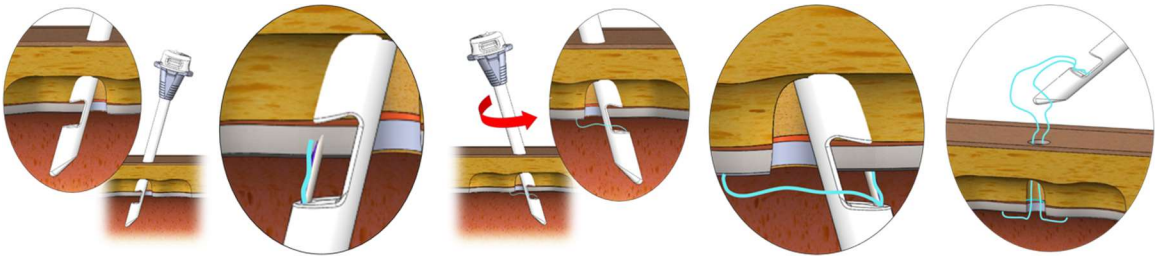
Disposability: Disposable
Unprotected Sharp: Yes
Requires a trochar: No
Fits through a trochar: No
Fascial bite: Variable based on depth (Indicated with marks along shaft)
Functional dimensions:

Crossbow
Length: 7cm (Bottom of the flange to the snares)
Width: 1.4cm (Maximal width of the cone)
Longbow
Length: 9cm (Bottom of the flange to the snares)
Width: 1.4cm (Maximal width of the cone)

Suture Ease CrossBow (Documentation Link)
Suture Ease CrossBow Bariatric (Documentation Link)

EZ Stitch™ Port Site Closure System

Manufacturer: Suture Ease
Entry Date: 2020



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Mechanism: Stick-style needle guide with "C"-shaped guide slot and suture passer
Components:

1. Needle guide
2. Suture retriever needle

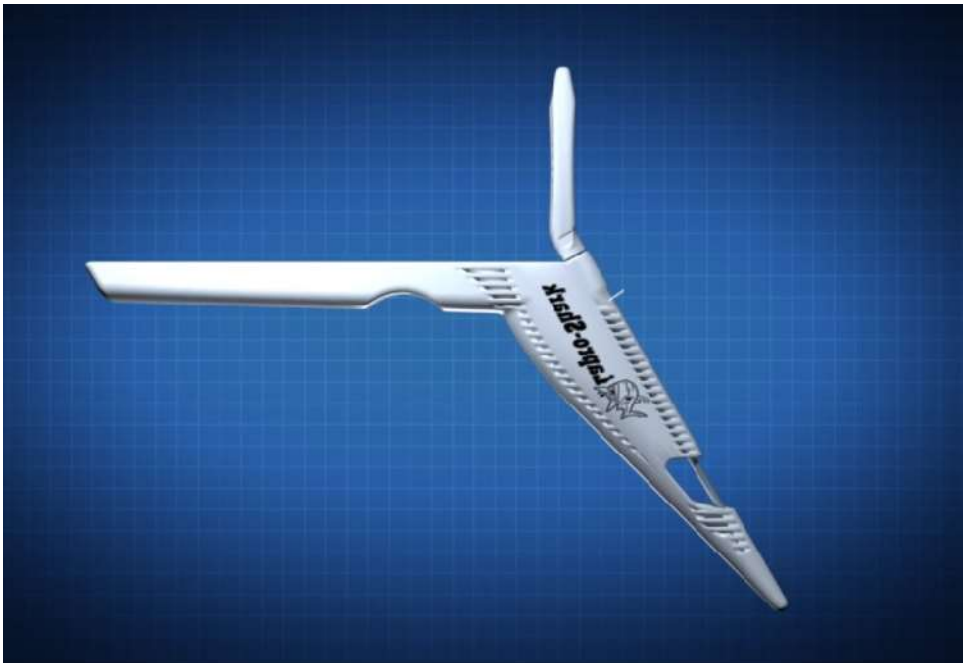
Disposability: Disposable
Unprotected Sharp: No
Requires a trochar: No
Fits through a trochar: No
Fascial bite: 7.5mm (Needle to back of “C” slot)
Functional dimensions:

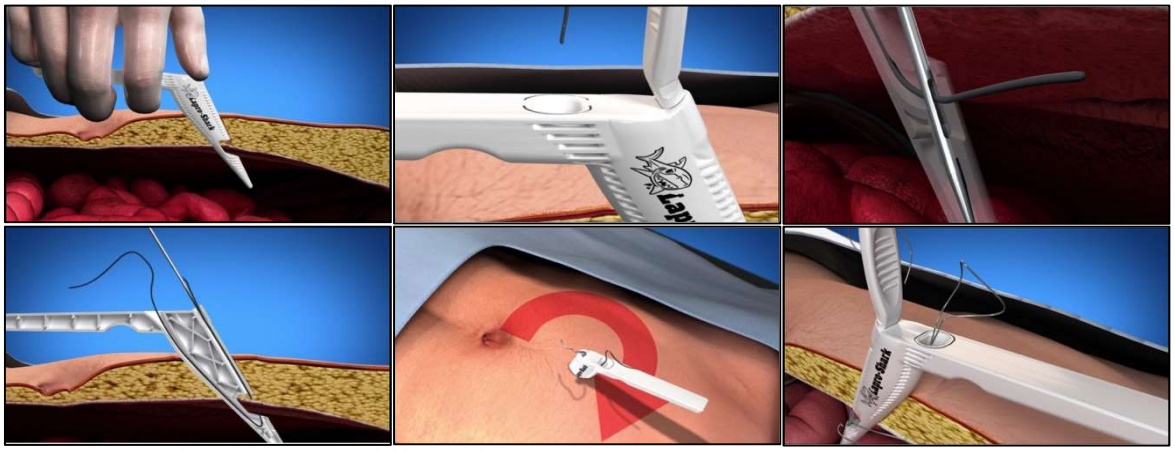
Length: 17cm (skin-contacting flange to the bottom of the “C”-shaped fascial catch)
Width: 1.4cm diameter

Suture Ease EZ Stitch (Documentation Link)

Lapro-Shark™ Laparoscopic Port Closure Device

Manufacturer: Brainchild Surgical Devices
Entry Date: 2016





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Mechanism: "C"-shaped guide slot with needle guide
Components:

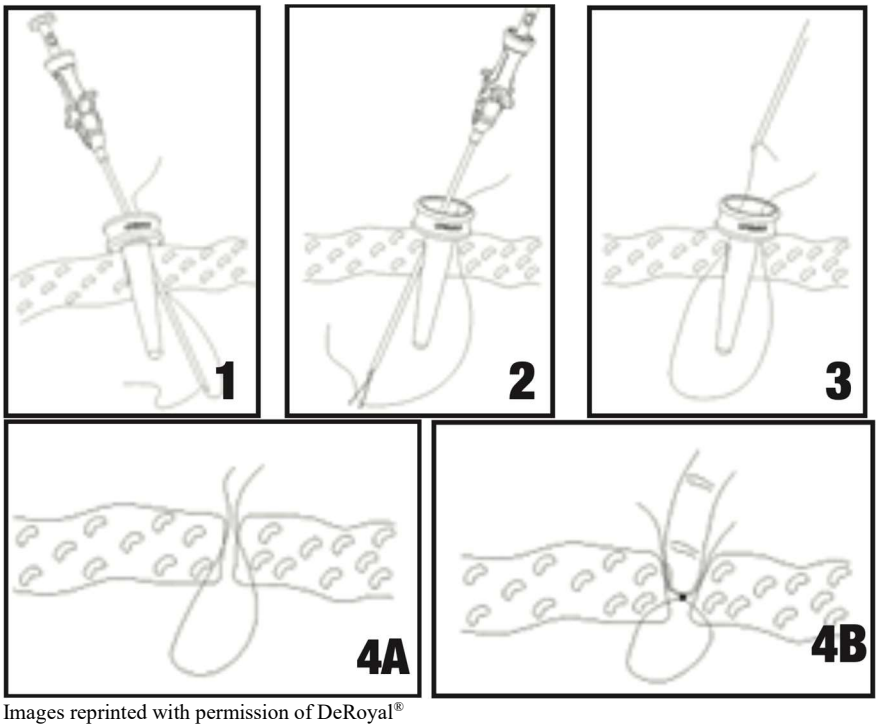
1. Needle guide
2. Suture retriever needle

Disposability: Disposable
Unprotected Sharp: No
Requires a trochar: No
Fits through a trochar: No

Fascial bite: 1cm (Needle to back of “C” slot)
Functional dimensions:
Length: 7.6cm (Bottom of the "C" to the entry point of the needle)
Width: 1.2 - 2.9cm (Tapered)
Brainchild Surgical LaproShark (Documentation Link)

SutureClose™ Laparoscopic Port Closure System

Manufacturer: DeRoyal®
Entry Date: 2016



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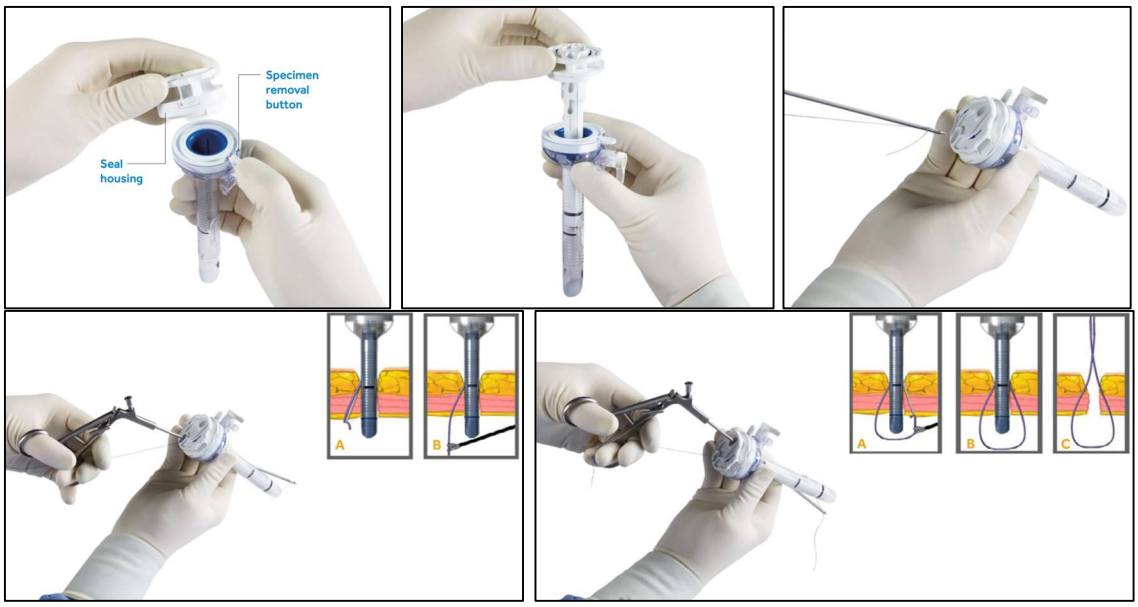
Mechanism: Suture passer needle paired with cone tip guide
Components:

1. Needle guide
2. Suture retriever needle

Disposability: Disposable
Unprotected Sharp: Yes
Requires a trochar: No
Fits through a trochar: No
Fascial bite: Variable based on depth
Functional dimensions:
Length: 6 cm (Bottom of the flange to the needle exit sites)
Width: 1.4 cm (Maximal cone diameter)
DeRoyal SutureClose (Documentation Link)

VersaOne™ Fascial Closure System

Manufacturer: Medtronic Covidien
Entry Date: 2017



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Mechanism: Suture passer needle guide obturator placed through existing trochar
Components:

1. Trochar
2. Obturator (Bladed or Optical)
3. Guide
4. Suture passer (sold separately)

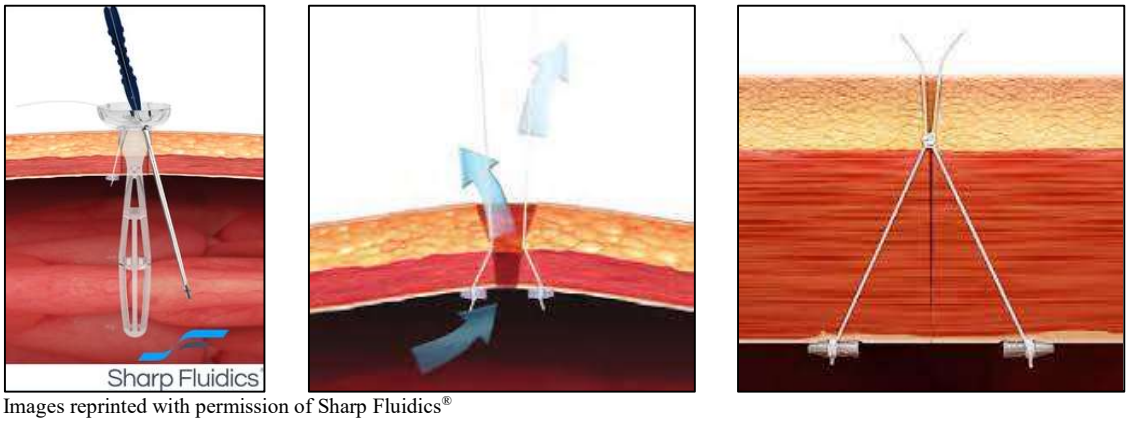
Disposability: Disposable, however requires the reusable suture passer
Unprotected Sharp: Yes
Requires a trochar: Yes (Can be used as a needle guide without the trochar)
Fits through a trochar: Yes (Only designated VersaOne trochar)
Fascial bite: Variable based on depth
Functional dimensions:

Length: 5.1 cm (Bottom of the flange to the needle exit sites)
Width: 1.2 cm (Trochar diameter)

VersaOne Fascial Closure System (Documentation Link)

NeoClose® AnchorGuard

Manufacturer: Sharp Fluidics®
Entry Date: 2018



Images reprinted with permission of Sharp Fluidics®

Mechanism: Suture passer needle with pre-loaded anchors and suture paired with cone tip guide
Components:

1. Needle guide
2. Suture passers with pre-loaded PDS anchors and sutures

Disposability: Disposable
Unprotected Sharp: Yes
Requires a trochar: No
Fits through a trochar: No
Fascial bite: Variable based on depth
Functional dimensions:

Length: 9.9 cm (Total length)

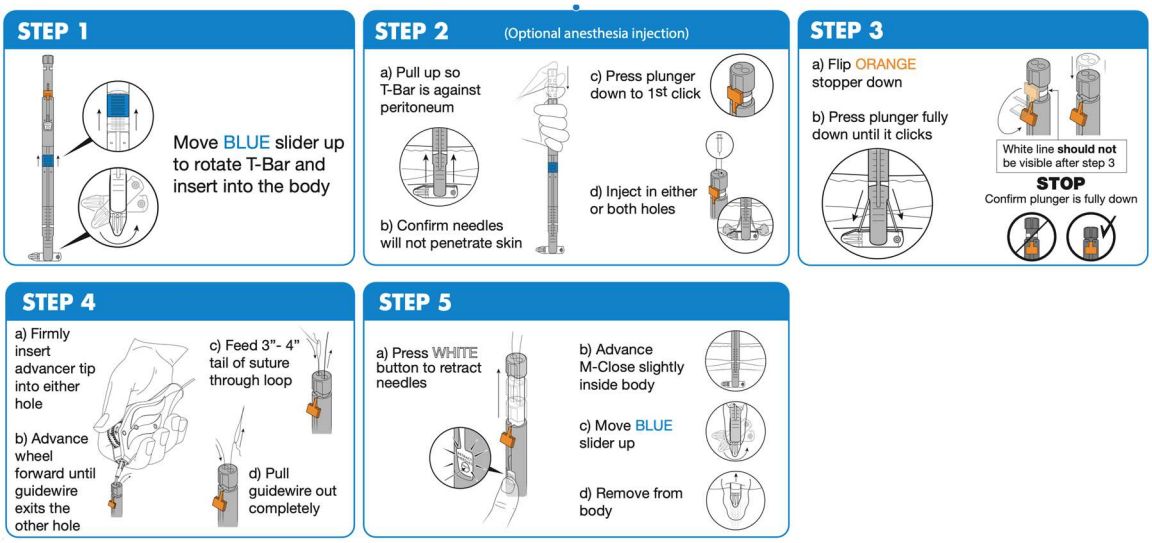
Width (Maximal cone diameter): Manufacturer prefers not to disclose – Recommended ranges: Small guide (5-12mm), Large guide (8-15mm)

Sharp Fluidics NeoClose (Documentation Link)

M-Close™ Kit

Manufacturer: New Wave Endo-Surgery™

Entry Date: 2019



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Mechanism: Stick device with deployable anvil and needles that a wire and suture are passed through. Local anesthetic can also be used through the needles

Components:

1. Stick with anvil and needles
2. Wire
3. Wire passer
4. Kit also includes separate nerve block needle

Disposability: Disposable

Unprotected Sharp: No

Requires a trochar: No

Fits through a trochar: Yes

For ports <12mm, the trochar is removed and the M-close is inserted through the skin

Will fit through bariatric trochars up to 150mm in length

Fascial bite: 1cm (Shaft to needle entry site on T-bar)
Functional dimensions: 1cm
Length: 4 inches (10.2cm) (Top of the T-bar to the slider button)
Width: 1.2 cm
New Wave Endo M-close (Documentation Link)

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