



TroClose1200™

Novel Integrated
Port Closure System
Simple, Secure & Safe

Exclusively Distributed by:



Simple

Secure

Safe

Cannula

Obturator

Ribbed cannula

Suture

Absorbable anchor

Bladeless
Obturator tip

The TroClose 1200™ Advantage

Gordon Surgical has developed a **novel integrated port closure system*** that offers surgeons a simple, secure and safe solution to open and suture closed the abdominal wall during laparoscopic procedures.

Instead of inserting fascia closure sutures at the end of a procedure,

Gordian's **uniquely designed "2-in-1" trocar*** efficiently inserts sutures into the tissue surrounding the trocar at the beginning of the procedure. When the trocar is removed; the surgeon closes the fascia by simply tying the TroClose 1200™ sutures together.

*First & only integrated port closure system available worldwide



Quick Guide on using TroClose 1200™

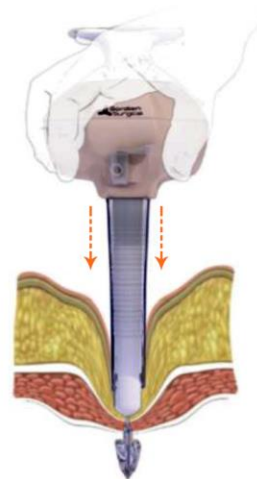
Introduction



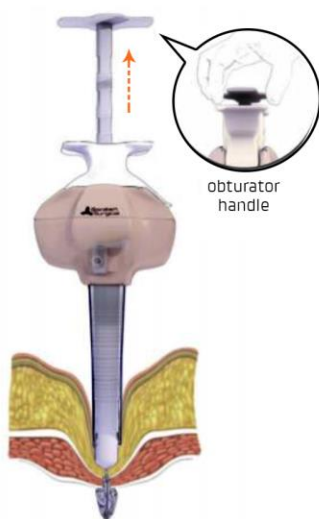
1 | Insert the obturator into the cannula until there is an audible "click".



2 | using a twisting motion, **penetrate** both fascia and the peritoneum until the tip of the trocar assembly has passed the peritoneum.



3 | Pull the obturator handle up until it "clicks", so as to activate the anchor deployment system.

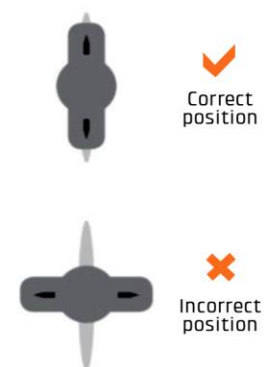


4 | Pull up the trocar assembly so that the tip is firmly against the peritoneum.



Note

In thin patients when the anchors appear to be above the skin, verify that the anchors are **aligned** with the skin incision as in the diagram below. If the alignment is not correct, the anchors could penetrate into the skin.

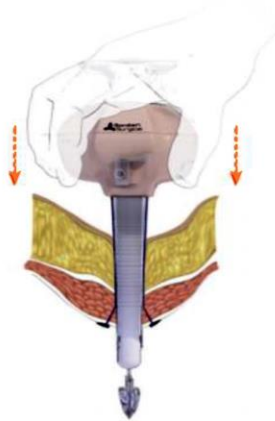


Quick Guide on using TroClose 1200™

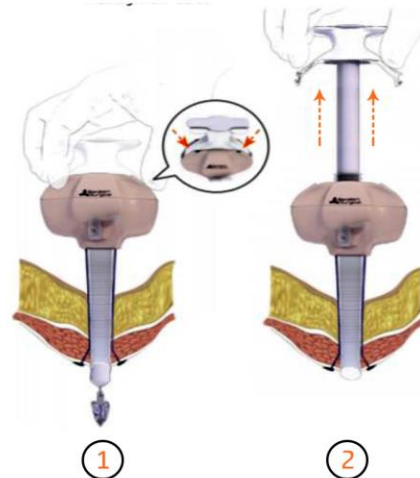
- 5** | While keeping the upward pressure on the trocar assembly (keep the tip against the peritoneum), press the obturator handle fully until there is an audible "click". This will release the anchors attached to the sutures.



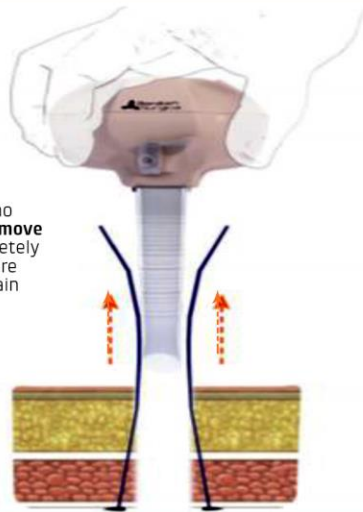
- 6** | Push the trocar assembly into the abdomen before removing the obturator.



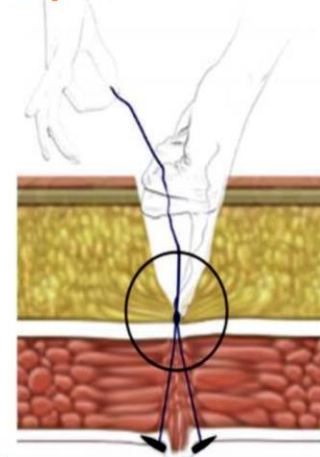
- 7** | Press both sides of the obturator to release it from the cannula, and pull the obturator out. The port is ready for use.



- 8** | When the port is no longer required, remove the cannula completely until the sutures are released (and remain outside the skin)



- 9** | Tie the sutures to close the port.



Natan Zundel, MD Jackson North Medical Center
Miami Beach, FL, USA

We have used TroClose1200™ and found it to be very friendly to use, safe and an excellent port closure device. To date, we have not noted any hernias or other clinically significant issues. TroClose1200™ provides quick full-fascial closure in the obese patient population."

Use of a Novel Integrated Port Closure System - A Multi-Center Study

David Hazzan, et al. "Use of a Novel Integrated Port Closure System - A Multi-Center Study". EC Endocrinology and Metabolic Research 5.5 (2020): 31-38.

Background: The incidence of port site hernia (PSH) after laparoscopic surgery can reach up to 4%. The fascial closure at the port site can be challenging in some cases.

A prospective, single-arm, multi-center, international, open-label, non-randomized clinical study to evaluate a new integrated port closure system (Gordian TroClose™ 1200 by Gordian Surgical™), is presented.

The study was conducted with the approval of four ethics committees according to the regulations at each site (Helsinki Committee of the Baruch Padeh Medical Center, Poriya, Israel; Helsinki Committee of the Lady Davis Carmel Medical Center, Haifa, Israel; The Israeli Ministry of Health; and the Institutional Ethics Committee of the Kirloskar Hospital, Hyderabad, India). Patients (n=50) aged 18 - 65 years who were scheduled for laparoscopic surgery with at least one 12 mm trocar and were willing to attend the follow up meetings were enrolled. **Patients were followed for two and six weeks and for one year.**

The **primary efficacy endpoint** was defined as the ability of the TroClose1200 to serve as a working channel as well as the capability to close the abdominal fascia at the end of the procedure. **Surgeons were asked to evaluate the use of the trocar with a 1 to 5 score questionnaire (Table 1).**

Table 1: Surgeon's assessment of ease of use of TroClose 1200

Ease of Use Question (Score 1 - 5)	No.	Mean	SD*	Median	Range	Percentage of 5/5 score [CI**]
Penetrating the abdominal wall	50	4.88	0.44	5.00	3.00 - 5.00	92.0% [80.8% - 97.8%]
Deployment of the anchors and sutures	50	4.96	0.20	5.00	4.00 - 5.00	96.0% [86.3% - 99.5%]
Instrument use and replacement	50	4.82	0.39	5.00	4.00 - 5.00	82.0% [68.6% - 91.4%]
Closure of the fascia	50	4.92	0.34	5.00	3.00 - 5.00	94.0% [83.5% - 98.7%]

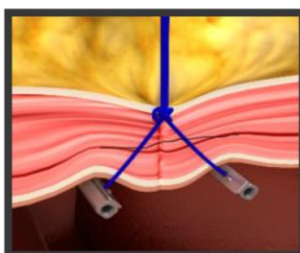
Conclusion

- ✓ The surgeons were very satisfied with the new device's performance, with an average range of 4.8 - 5.0 out of 5.0 in the usability question.
- ✓ No port PSH related to TroClose 1200 device was diagnosed at one year of follow-up.

TroClose 1200™ Application



A. TroClose 1200 cannula & anchors in-situ in the abdominal wall, after deployment and removal of the obturator



B. TroClose 1200 anchors in place just before port site closure, after cannula has been removed



C. Illustration of port site closure with anchors and tied sutures

What the surgeons are saying:



Michal Vix, MD

University Hospital of Strasbourg
- IRCAD
Strasbourg, France

"Gordian's TroClose 1200 is a very effective system, easy to use and especially useful for younger surgeons, as the learning curve is very short. TroClose 1200 has significant advantage over other standard closure devices on the market. Indeed, there is definitely a place for the Gordian's surgical product in the worldwide market."



Barry Salky, MD

Mount Sinai Hospital
New York, New York

"TroClose is a simple and effective device. Besides saving time in the OR, it will reduce inadvertent injury."



Philip Schauer, MD

Cleveland Clinic
Cleveland, OH, USA

"I found the TroClose 1200 to be an easy-to-use device. It functioned very well and the closure was satisfactory."

TroClose 1200™ specifications

- ❖ 12 mm bladeless
- ❖ 115 mm ribbed cannula
- ❖ Single-use only
- ❖ EtO Sterilized
- ❖ Fully absorbable PLGA anchors
- ❖ Braided PLGA absorbable sutures (similar to USP 0)

CE 2409



- ✓ TroClose1200™ – the World's first and only "2-in-1" port and fascial closure system
- ✓ Patented, and clinically validated
- ✓ FDA-cleared, CE-marked, and ISO 13485 Certified

Available as

Description	Cat#
TroClose™1200 - Obturator & cannula	GSTC1200
TroClose™1200 - Cannula Only	GSTC1200C



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