STANDARD TROCAR® (ST19) INSTRUCTIONS FOR USE

STANDARD BARIATRICS® STANDARD TROCAR®

ST19 – Standard Trocar®
19mm trocar with 5mm diameter adaptor and Introducer Sheath

INDICATIONS FOR USE
The Standard Trocar® is a sterile, single-use device consisting of an obturator, a cannula, a 5mm adapter and introducer sheath. This system is indicated for use in general and abdominal minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments.

INTENDED USE
The Standard Trocar® is intended to be used by a surgeon on a single patient during a single laparoscopic surgery under normal operating conditions. It is intended to create and maintain a port of entry into the body through tissue planes and/or potential spaces for endoscopic instruments.

DEVICE DESCRIPTION
The Standard Trocar® is a gamma sterilized, hand-held, disposable trocar with a rounded conical point. The device contains a 5 mm adaptor that may be used with 4.9 mm – 5.5 mm diameter instruments. The device also contains a 19mm introducer sheath that may be used with 19mm instruments (Figure 1).

Figure 1: The Standard Trocar® Assembly, Cannula, 5mm Adapter, Introducer Sheath and Obturator components

WARNINGS
1. Do not use the Standard Trocar® if damaged or if packaging is open or damaged.
2. Do not resterilize/reuse the Standard Trocar®. Reuse risks the Standard Trocar® degradation and cross-contamination, which can lead to infection or transmission of bloodborne pathogens to patients and users.
3. Use the Standard Trocar® in accordance with these instructions for use. Improper use may cause serious injury.
4. Read all sections of this insert prior to use.

WARNINGS CONTINUED
5. Introducer sheath should be used on all long 19mm instruments that pose a risk of loss of insufflation during insertion.
6. Proper insertion site closure must be performed
7. Maintain visualization of the obturator tip during insertion to avoid injuries

PRECAUTIONS
1. The Standard Trocar® is supplied sterile. Inspect packaging prior to use to ensure there is no damage.
2. Extra care should be used during insertion into and removal from the body cavity of angular and asymmetrical instruments.
3. To minimize eversion of the seal when using highly textured surfaces, coat surfaces with sterile lubricant prior to insertion.
4. Use caution when removing the Standard Trocar® obturator from cannula.
5. Staplers and clamps should be fully closed during passage to avoid potential damage to cannula.
6. To minimize the risks associated with access port placement, ensure:
   - direct laparoscopic visualization is utilized
   - appropriate patient positioning to shift organs away from access port placement site
   - an adequate level of insufflation
   - obturator tip is pointing away from major vessels, organs, and other anatomic structures
   - moderate, controlled pressure is employed when placing the access port
7. As with all trocars, instrument compatibility should be evaluated prior to use.
8. The Standard Trocar® does NOT have an insufflation port. If insufflation is desired, another trocar must be used to insufflate the abdominal cavity.

DIRECTIONS FOR USE
Prior to use, inspect the package of all sterile components to ensure that the integrity has not been compromised.

1. Using sterile technique, remove the Standard Trocar® components from packaging.

2. Visually inspect the Standard Trocar® for damage.

3. Assemble the Standard Trocar® for insertion. Insert obturator into cannula.

4. Make an incision in the skin at the desired placement site long enough to accept the tip and cannula of the system assembly.

5. Utilizing direct laparoscopic visualization, carefully insert the Standard Trocar® into the abdominal wall and apply continuous downward force while gently rotating the entire system in alternating clockwise and counterclockwise directions until the cannula is placed as desired.

6. The Standard Trocar® may be sutured to patient utilizing suture holes on the side of the cannula.

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7. Remove the obturator by depressing the locking snaps on the sides of the obturator cap and insert the 5mm reducer (adapter) if needed.

8. A 5 mm instrument may be inserted into the trocar.

9. Remove 5 mm adaptor (if used), by depressing the locking snaps on the sides of the 5mm adapter cap, leaving access to the 19 mm trocar cannula.

10. Insert 19 mm instrument such as Titan SGS® Stapler into 19mm introducer sheath. If used with Titan SGS® Stapler, pull introducer sheath back until the red band can be seen through the sheath. To prevent loss of insufflation, do not move introducer sheath forward until Titan SGS® Stapler is fully inserted.

11. Insert the 19 mm instrument through the 19mm trocar as indicated in the IFU.

12. Remove the 19mm instrument and Introducer sheath simultaneously from the Standard Trocar® to avoid loss of insufflation.

13. Remove the Standard Trocar® from the patient and close the surgical defect accordingly.

14. Dispose of the Standard Trocar® per hospital guidelines.

INSPECTION AND HANDLING

The Standard Trocar® devices are carefully inspected before shipment. The Standard Trocar® and packaging should be inspected upon receipt as packaging may become damaged in transit. All of the Standard Trocar® components must be inspected prior to use. Instruments should be handled and operated by personnel familiar with their use. Handle the Standard Trocar® with care at all times.

HOW SUPPLIED

The Standard Trocar® is provided sterile and intended for single patient use. Ensure sterile packaging is intact prior to use. Dispose of device per local ordinances. Do not resterilize, reprocess or reuse the Standard Trocar®.

PACKAGING AND STORAGE

The Standard Trocar® is provided in sterile packing and should be stored at room temperature. Avoid prolonged exposure to elevated temperatures. The Standard Trocar® should always be handled with great care in transportation and storage.

SYMBOLOGY

Symbol	Definition	Reference Standard/ Requirement
Rx ONLY	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	21 CFR 801, Reference # 109
MD	Medical Device	ISO 15223-1, Reference # 5.7.7
REF	Catalogue Number	ISO 15223-1, Reference # 5.1.6 21 CFR 820.120
LOT	Batch Code	ISO 15223-1, Reference # 5.1.5 21 CFR 820.65
	Consult Instructions for Use	ISO 15223-1, Reference # 5.4.3
	Date of Manufacture	ISO 15223-1, Reference # 5.1.3
	Manufacturer	ISO 15223-1, Reference # 5.1.1
	Distributor	ISO 15223-1, Reference # 5.1.9
	Use- by Date	ISO 15223-1, Reference # 5.1.4 21 CFR 801.18
STERILE R	Sterilized using gamma irradiation	ISO 15223-1, Reference # 5.2.4
	Single Sterile Barrier System	ISO 15223-1, Reference # 5.2.11
2 STERILIZE	Do no resterilize	ISO 15223-1, Reference # 5.2.6
2	Do not re-use	ISO 15223-1, Reference # 5.4.2
	Do not use if the package is damaged	ISO 15223-1, Reference # 5.2.8
LATEX	Not made with natural rubber latex	N/A

Standards:
Code of Federal Regulations (CFR) Title 21, Part 801 – Labeling
Code of Federal Regulations (CFR) Title 21, Part 820 – Quality System Regulation
ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied

QUESTIONS

For questions related to this product please contact Standard Bariatrics® customer service: 513-620-7751

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