

EndoGuidance Endoscopic Access Port Instruction for Use

The following information should be read before using this device.

INTENDED USE:

The EndoGuidance Endoscopic Access Port is used for laparoscopic procedures. It provides a port for instruments to be used in the abdominal region. The product is available with sterile package, and has several lengths for different patients and procedures requested.

CONTRAINDICATIONS/SIDE EFFECTS:

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

There are no potential side effect identified so far.

PERFORMANCE CLAIM:

1. Trocar filling valve and sealing cap should be no leakage under the pressure of 4kPa
2. The Cannula will fit the obturator well, smoothly.
3. The Product is provided Sterile, Single-use.

DIRECTIONS FOR USE:

1. Remove the obturator and cannula from the package tray, and assemble them together.
2. When you use the auto-locking trocar (Press the locking button to activate the protection shield, only applicable for Key Switch System). Hold straight and insert into abdominal region, the inner shaft will engage shield and protect the inside organs from damage. When the shield retracts, an audible "click" will be heard.
3. When you use the bladeless trocar, hasson trocar, visible trocar or secondary trocar, please cut a small line with surgical knife in the marked position. Hold straight and rotate the kit clockwise together.
4. Rotate the threads clockwise to adjust the cannula depth in the peritoneal cavity.
5. When the trocar is in the desired position, remove the obturator. Leave the cannula in place. To remove threaded cannula, rotate the threaded cannula counterclockwise.
6. Connect Insufflation pump with luer lock adaptor or Trocar's gas port for gas insufflation into patient's abdominal cavity. When the insufflation pump is used, please follow instructions of Insufflation pump.

CAUTIONS/WARNINGS:

1. This device is single-use and can't be re-used or re-sterilized. Do not use if package is opened or damaged. It may cause cross-infection if reused.
2. Endoscopic procedures must be performed only by physicians with adequate training and knowledge of these procedures. In addition, medical literature should be consulted regarding techniques, hazards, contraindications and complications prior to the performance of these procedures.
3. Before using endoscopic instruments and accessories from different manufacturers in a procedure, verify compatibility and ensure that electrical isolation or grounding is not compromised.
4. A complete understanding of techniques and principles involved in electrosurgical procedures is necessary to avoid burn or shock hazard to patient and/or operator.
5. Do not attempt to use the trocar if the shield dose not move when you insert into cavity.
6. The trocar tip will be briefly exposed prior to engagement of shield, so the standard precautionary measures used in all trocar insertions must be followed.
7. Trocars should not be inadvertently rearmed for additional penetration while the cannula is still in body cavity.
8. The site needs to be inspected for homeostasis after the trocar assembly is removed from cavity.
9. Without the appropriate adapter, using endoscopic instruments with smaller diameters than that of the cannula may cause desufflation of the cavity.
10. Federal (U.S.A) law restricts this device to sale, distribution, and use by, or on the order of a

physician.




















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Symbol	Definition	Symbol	Definition
	No Latex		Expiry Date
	EO Sterilized		unique device identifier
	Do Not Reuse		Indicates the medical device manufacturer
	Do not use if package is damaged.		DEHP Free
	Do not reuse		Indicates a medical device is non-pyrogenic
	Consult Instruction for Use		Indicates the item is a medical device
	Model Number		This device is prescription only
	Lot Number		Indicates a single sterile barrier.
	Manufacture Date		Single sterile barrier system with protective packaging outside