

VOLGA® CYSTO-GASTRO SET

Instructions for Use

Medorah Meditek Pvt. Ltd.

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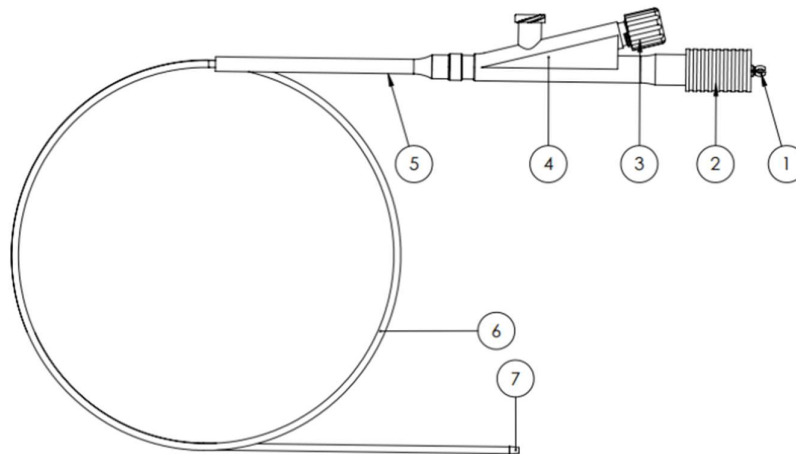
VOLGA® Cysto-Gastro Set

Intended Use

The Cysto-Gastro set is used as an electrosurgical accessory to electrosurgically puncture a hole in the transgastric or transduodenal wall and into a pancreatic pseudocyst, when it is visibly bulging into the gastrointestinal tract. It is sterile and is intended for single use.

Device Description

The **VOLGA® Cysto-Gastro set** is a sterile, single-use system for controlled endoscopic drainage of pancreatic cysts and pseudocysts. It features a stainless-steel diathermic tip on an inner wire and an outer sheath. The proximal handle includes connectors for active cords and a port for contrast fluid injection, which is equipped with a bush to prevent backflow of fluid. A high-visibility guidewire provides stable placement within the cyst, ensuring secure tract maintenance. The device is ergonomically designed and supplied pre-sterilized to allow safe and precise electrosurgical puncture under endoscopic or ultrasound guidance.



①	RF connector
②	Cautery cap
③	Handle cap
④	Heat Shrink Tube
⑤	Outer Sheath
⑥	Diathermic metal tip

Contraindications

The Cysto-Gastro set should not be used in patients for whom therapeutic endoscopic procedures, particularly pancreatic interventions, are inappropriate. Specific contraindications include:

- Portal hypertension or pseudo-aneurysms in regional vessels.
- Procedures involving the central cardiovascular system.
- Severe comorbid conditions such as heart failure, coronary artery disease, or liver cirrhosis.
- Ileus, peritonitis, or active inflammatory bowel disease.
- Bleeding disorders or other coagulopathies.
- Limited life expectancy due to malignant disease.

Precautions

- Cysto-Gastro Sets are not recommended to be used on pancreatic pseudocysts that are less than 4 cm in diameter.
- These devices are compatible with an endoscope accessory channel of 2.8 mm or larger.
- The guidewire diameter and the inner lumen of the wire-guided device must be compatible.
- Injection of contrast media during ERCP must be monitored fluoroscopically. Overfilling of the pancreatic duct may cause pancreatitis.
- The Cysto-Gastro sets are only used in conjunction with electrosurgical equipment, active cords and endoscopes.
- Do not touch other tissue areas with the tip when using electrosurgical parts (danger of perforation). During electrosurgical parts usage, no contrast fluids can be injected.

Potential Complications

Possible complications associated with ERCP, but are not limited to:

- Pain
- Hemorrhage
- Abscess
- Pancreatitis
- Gastric or duodenal perforation
- Septicemia/infection
- Abdominal pain
- Coagulation disorders
- Burns on the handle due to poor electrosurgical plug connection

Warnings

- Do not use the device if the pouch is opened or damaged, and note that it is intended for single use only.
- Reuse, reprocessing, or re-sterilization may compromise the device's structural integrity, potentially leading to device failure and resulting in patient injury,

illness, or death. These actions may also increase the risk of contamination, including patient infection or cross-infection, and the transmission of infectious diseases.

- Operators and assistants should wear protective gloves to prevent accidental burns. Universal precautions must be followed in all cases.
- Contamination of the device may result in patient injury, illness, or death. After use, dispose of the device and its packaging according to hospital, administrative, and/or local government regulations.

Procedure

- Upon removing the device from its package, carefully uncoil it.
- Inspect the device for any defects or abnormalities. Do not use it if there are unintended rough surfaces, sharp edges, or protrusions.
- Confirm the location and size of the cyst or pseudocyst under endoscopic and/or ultrasound guidance.
- Insert the endoscope until reaching the target site. Advance the cysto-gastro set through the working channel of the endoscope to the gastrointestinal wall adjacent to the cyst.
- If needed, inject contrast through the lateral Luer-Lock adapter at the proximal end of the device, then advance a guidewire through the device and into the cyst.
- With the electrosurgical unit turned off, ensure the active cord fits securely into both the device handle and the electrosurgical unit.
- Connect the electrosurgical unit to the device.
- Advance the metal diathermic tip to the puncture site and activate the electrosurgical unit using the foot switch. Carefully puncture and dilate the cyst opening.
- Once the puncture is complete, turn off the electrosurgical unit and disconnect the active cord from the device handle.
- Remove the cysto-gastro set from the endoscopic accessory channel, ensuring that any guidewire or other accessories remain in place if used.

Disposal of a used device

The used device must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of the user.

Symbols used on product label

	Manufacturing Date		Expiry Date
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	Catalogue Number		Do Not Reuse
	Consult Instructions for use		Caution
	Keep away from direct sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Keep dry		Do Not Resterilize
	Sterile by Ethylene Oxide		Temperature Limit

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by the appropriate procedures. This warranty is in lieu of and excludes all other warranties not expressly set forth herein which are beyond Medorah Meditek Pvt. Ltd. control such as warranties implied to the application of law, sales or specially purpose suitability after handling over, storage, cleaning and sterilization of this product as well as matters related to the patient, diagnosis, treatment, surgical procedures, and any other details. Medorah Meditek Pvt. Ltd. shall not be liable for any incidental, or consequential loss, damage or expense directly or indirectly arising from the use of this product other than the replacement of it. Medorah Meditek Pvt. Ltd. shall neither take any additional responsibility nor authorize such responsibility or duty to other persons related to this product.



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