

Instruction for Use

Track Finder Bulb Irrigator

Device Description

Track Finder Bulb Irrigator is the elegantly simple irrigation device that provides the physician the option of controlling the flow of irrigation. The result is greater accuracy and enhanced visualization during endoscopic procedures. Intended for single use. Delivered in sterile peel-open package. Intended duration of use is 1 day. The configurations available include:

Family	Length (Cm)	Catalogue Number
Track Finder Bulb Irrigator	15 32.5 (Connector)	AMPLGP013

Intended Purpose

Track Finder Bulb Irrigators are used during endoscopy procedure for controlled continuous or bolus irrigation.

Performance Characteristics of the device

Improved visualization. Bulb compresses in various hand-held positions, and fits easily and unobtrusively in one hand.

Continuous flow and pulsatile action with minimal tubing. Accurate delivery of bolus irrigation. Optional control by physician or assistant. Scope moves easily with bulb attached. Attaches to any scope. Less cumbersome than syringe administration.

Indications

- Used during endoscopy procedure
- Both continuous and bolus irrigation.

Contraindications

- Primary disease of the stomach.
- Local Irritation
- Hemorrhage
- Skin excoriation from leaking of gastric contents, and wound infection.

Precautions, Warnings& Complications

Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use and in accordance with these instructions.

Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions:

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgement. The doctor must be trained in the proper use of the device.
- The intended user of the device must be a Gastroenterologist/ Urologist.
- Do not use the device if there is any indication that the sterility of the device has been compromised.

Warnings:

- The device is for single use only.
- Dispose of all components as infectious waste. Users of this device have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient: Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infections.
- This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the Physician is practicing.
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Intended Patient Population

- Track Finder Bulb Irrigator is used in patients undergoing endoscopy procedures.
- The device can be used in patients of all age groups.

Shelf-life and Storage condition of the Product

The shelf life of the Track Finder Bulb Irrigator is 3 years (Indicated on product label with the following use-by symbol).

Store the Track Finder Bulb Irrigator at a temperature between 12°-35°C and a Humidity range of 30%-75%.

Store in a dry, cool place. Avoid extended exposure to sun light.

Sterility – This product is Sterile unless the package has been opened or damaged

- The Track Finder Bulb Irrigators have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage in the Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- The Track Finder Bulb Irrigators are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Open the package at the Chevron Side (‘V’ Notch) of the pouch.
- Suggested instructions for using Track Finder Bulb Irrigators:
- Standard Luer lock fittings attach to any cystoscope, hysteroscope or any other endoscope where the surgeon requires or benefits from improved results during delicate procedures. Attach the device to the scope. Attach bulb to irrigation. Squeeze bulb to flush system.
- Duration of contact with the body is 1 day.

Removal Instructions

To disassemble, remove the device from the scope.


















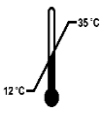



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Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		CE Mark		Do not Re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								

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Bibliography

- Single Use Medical Device
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices- Information to be supplied by the manufacturer.