

INSTRUCTIONS FOR USE

FDA Cleared
Air ASSIST™
Effortless Distension, Exceptional Outcomes.

by **Gastro**
CONCEPTS

DEVICE DESCRIPTION

The Gastro Concepts Air Assist™ Device is a single-use device that is used to aid in maintaining air/CO₂ insufflation during a colonoscopy. The Air Assist™, a single-use device, comprises a cylindrical body with a conical-shaped tip and an open channel for endoscope insertion. Positioned against the anus (not inserted into the rectum), it forms a temporary seal, maintaining air/CO₂ insufflation leading to adequate colonic distension for enhanced visualization.

INDICATION FOR USE

Air Assist™ is intended to slide over the outer surface of an endoscope to facilitate endoscopic therapy by providing a manual, reversible method to control the insufflation (air/CO₂) so the physician can better maintain an appropriate field of view.

CAUTION

Rx only. Federal law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS

Use of the Gastro Concepts Air Assist™ is contraindicated when, in the judgment of the physician, use of this device would be contrary to the best interest of the patient.

POSSIBLE COMPLICATIONS

Potential complications associated with the use of the Air Assist™ device are the same as those associated with colonoscopy procedures. For further information, please refer to current medical literature.

INSTRUCTIONS FOR USE

- The Air Assist™ Device can only be used with endoscopes ranging from 11.5mm to 13mm in diameter.
- Remove Air Assist™ device from packaging.
- Inspect the device and check the pliability, integrity and general condition prior to use. Discard if any issues are noticed.
- Add a small amount of surgical lubricant to the interior wall of the Air Assist™ device and apply surgical lubricant to the colonoscope in the usual fashion.
- Thread the Air Assist™ device over the distal end of the endoscope with the conical tip facing away from the control section and toward the tip of the scope.
- Advance the Air Assist™ in a retrograde fashion toward the control section of the Colonoscope/Endoscope allowing ample scope for insertion.
- Begin the Colonoscopy in the usual manner.
- When experiencing colon collapse, slide the Air Assist™ device distally in contact with the anus to provide a seal to assist in maintaining insufflation.



Air Assist™ Product Configuration: 10-unit kit GC-AA-10-K 100-unit case GC-AA-100-C

LB-001
Rev.2



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INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE (CONT.)

- Firm hand-held pressure is recommended to maintain Air Assist™ contact with the anus.
- When the Air Assist™ is no longer needed, the device can be slid back up the endoscope and reapplied to the anus as needed for on demand maintenance of air insufflation.

NOTES

- Introduce instrumentation only through the endoscope.
- The Air Assist™ device should never be inserted into the anal cavity.

PRECAUTIONS

- This device was designed and tested for single patient use only. Do not reuse, reprocess or sterilize this device.
- Reuse, reprocessing or sterilization may alter the structural and/or functional integrity of this device.

WARNINGS

- Do not use if the product packaging is damaged.
- Reuse introduces a risk of residual contamination may lead to patient injury, infection, illness or death.
- To minimize any contact surface friction, add 2-5ml of sterile lubricant to the interior wall of the device and/or exterior wall of the scope.
- The Air Assist™ device should never be placed in the anal cavity. The device should sit adjacent to the anus.
- Management of intraluminal pressure is at the discretion of the physician.
- Only an endoscope should be placed through the Air Assist™.
- Compressing the Air Assist™ device can lead to compression of the endoscope.
- Failure to follow the instructions provided in this document may result in sub-optimal results

STORAGE AND HANDLING

- If the packaging is damaged or opened, the product must not be used.
- Discard any unused material after opening.
- Sterilization is not possible.
- Store at controlled room temperature 15-29°C (59-85°F).

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