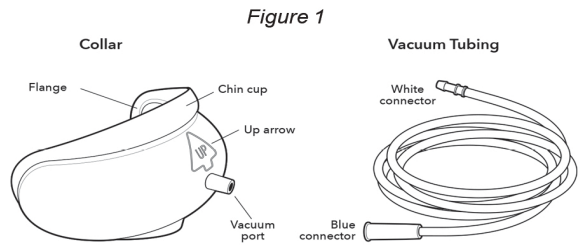


aerFree® Airway Management System Non-Invasive External Airway

Introduction

Upper airway collapse is a common occurrence during sleep, sedation, and anesthesia. The aerFree Airway Management System (AMS) utilizes patented aer+ technology (application of negative pressure to a patient's neck over the upper airway to comfortably and non-invasively hold the airway open) to simply and safely support the patency of the upper airway during medical and surgical procedures requiring mild to moderate levels of sedation.

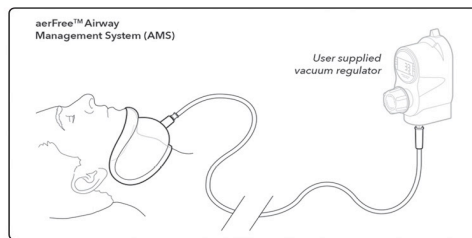
Please review and become familiar with the components of the aerFree AMS (Figure 1). The System consists of a single-patient use, soft, flexible collar, placed on the front portion of the neck and connected via vacuum tubing to a regulated external vacuum source in the operating range of -40 to -48 cm H₂O (-29 to -35 mm Hg). This vacuum range has been found to increase upper airway patency in patients undergoing mild to moderate sedation.



System Description

The aerFree AMS consists of a soft, flexible collar and vacuum tubing. The collar is fitted on the front of the patient's neck. During use, the aerFree AMS is attached by means of tubing to a vacuum source (Figure2).

Figure 2



When the collar is properly applied to the patient, and connected to a vacuum source, it creates an airtight chamber that reduces the pressure in front of the upper airway. The reduced pressure within the collar allows the underlying tissue to move anteriorly, helping to maintain an open upper airway. The nominal operating vacuum for the aerFree AMS is -33 mm Hg (-45 cm H₂O), which is set by the clinician.

Once the operating vacuum is established, the airtight seal will maintain the vacuum. If an air leak should occur, the vacuum level within the collar will drop. This decrease in vacuum will be indicated on the regulator gauge. If this occurs, the collar fit and position should be re-evaluated.

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Indications for Use

The aerFree AMS is to be used as an aid for maintaining the patency of the upper airway in spontaneously breathing adults undergoing medical procedures less than 2 hours in duration, where the patient is intended to have mild to moderate sedation with non-propofol containing medications.

The aerFree AMS should only be used by individuals who have reviewed the Instructions for Use.

The aerFree AMS is non-sterile, for single-patient use, and disposable. Visit www.aerFree.com for training videos and resources for using the System.

Maximum Duration of Use

aerFree AMS use is limited to 2 hours' duration based on the maximal time of exposure to the aerFree AMS in clinical studies focused on carotid blood flow.

Patient Setup and Monitoring

1. Prep the skin using alcohol wipes on the area where the collar will be applied. Skin prep should be accomplished utilizing 1 or more alcohol wipes to cleanse an area from 1 inch above the mandible to 3 inches below the mandible, and from earlobe to earlobe.
2. Remove the aerFree AMS from its packaging and inspect for damage.
3. Connect the blue end of the tubing to the vacuum source and adjust the vacuum level to a nominal value of -33 mm Hg (-45 cm H₂O) (Figure 3).
NOTE: Occlude the end of the tubing with a finger over the opening while adjusting the vacuum level. When the tubing is not occluded, the vacuum level on the gauge will be low.
4. Patient should be in supine position.
5. Hold the System by the outer surface with both hands, being careful not to deform the collar (Figure 4).
 - a) Position the collar so that the UP arrow is aligned with the center of the patient's chin, and pointing toward the patient's nose (Figure 4).
 - b) Without deforming the collar, rotate it inward until the lower flange contacts the neck (Figure 4).
 - c) Allow the ends of the Collar to contact the patient just below the ear.
 - d) The Collar should cover the anterior surface of the neck without overlapping the earlobes (Figure 5).
6. Verify that the flange is flat against the patient's skin along its entire perimeter, and that the flange forms an airtight seal with the patient's neck.
7. When the collar is properly sealed to the patient's neck, the displayed vacuum will increase to the pre-set value. If the vacuum does not return to the pre-set value, reposition the collar on the neck, and check for leaks at the tubing connection points (See System Troubleshooting).

Figure 3

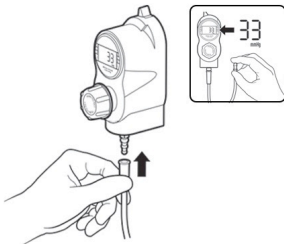


Figure 4

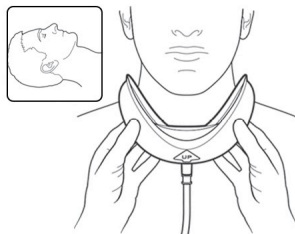


Figure 5



Wall Vacuum Source Specifications

The aerFree AMS is intended to be used in conjunction with a regulated external vacuum source, in the operating range of -20 to -35 mm Hg (-40 to -48 cm H₂O). Use of a vacuum regulator connected to a central or portable vacuum system is recommended. The regulator should permit the clinician to set the vacuum to a value within the operating range.

It's recommended that the aerFree AMS be used with a vacuum regulator with a vacuum limiting feature, or other feature such as digital display to aid in preventing the vacuum from being set to a value exceeding the maximum value of -37 mm Hg (-50 cm H₂O), such as Ohio Medical Thoracic Vacuum Regulator 1275, or Ohio Medical PC28D digital regulator, or equivalent.

Safety Information

Important: Before using aerFree AMS, carefully read the entire Instructions for Use, especially ALL Warnings, Cautions and Notes, which are listed throughout.

A **WARNING** indicates if or when something can hurt the clinician or patient.

A **CAUTION** indicates if or when something can damage the System.

A **CONTRAINDICATION** indicates the patient can be harmed if the System is used.

The following **WARNINGS** apply to the use of the aerFree AMS.

- Use of aerFree AMS is not a substitute for continuously monitoring the patient's respiratory status.
- Airway obstruction and respiratory distress may still occur while aerFree AMS is in use.
- This System should not be used during medical procedures involving propofol.
- The System is intended for external use only on intact skin.
- Use is limited to 2 hours' duration
- Do not use aerFree AMS on any patient where an airtight seal cannot be obtained with the collar on the patient's neck, e.g., patients with excessive sweating, if the collar flanges extend over the ears, or patient has excessive facial hair.
- Excessive filling of collar with loose neck tissue may reduce effectiveness of the aerFree AMS in opening a patient's airway, i.e. the skin blocks the vacuum port.
- Ensure that the UP arrow on the collar is pointing up, toward the top of the patient's head.
- Only connect the System to a regulated external vacuum source that can be set to provide the treatment range of -29 to -35 mm Hg (-40 to -48 cm H₂O).
- Not indicated for patients with known carotid vascular disease.
- Not indicated for patients who are an aspiration risk.
- Not indicated for patients with anatomical abnormalities in the pharyngeal region such as enlarged tonsils or pharyngeal malignancy.
- Not indicated for patients with anatomical abnormalities of the cervical region which prevent adequate collar fit or function such as current or previous neck surgery/injury, previous radiation therapy, tracheal deviation, tracheostomy, scleroderma and CREST syndrome.
- Screen patients for unknown carotid vascular disease, which includes the following:
 - A history of CVA or TIA of uncertain etiology.
 - Carotid bruit on physical examination.
 - Diminished carotid pulse on physical examination.

The following **CAUTIONS** apply to the use of aerFree AMS.

- Avoid exposure of the aerFree AMS to extreme heat or harsh solvents to avoid damaging the product.
- Never operate the aerFree AMS if it appears damaged in any way.
- Report any defects in or malfunction to your supplier.

CONTRAINDICATION

Use of aerFree AMS is CONTRAINDICATED in patients with cutaneous hypersensitivity to silicone rubber materials.

System Troubleshooting

Issue Observed	Potential Cause	Corrective Action
DOES NOT ATTACH OR SEAL PROPERLY TO PATIENT'S NECK	Collar incorrectly positioned Vacuum regulator may be turned off, and/or vacuum source or tubing may be blocked Collar doesn't fit patient	Refer to positioning instructions – Re-position if necessary Verify the external vacuum source is turned on and is adjusted to the proper operating range. Check tubing for leaks at connection points and/or blockage Discontinue use of collar
DOES NOT MAINTAIN A PATENT AIRWAY (Airway obstruction and/or respiratory distress still occurs)	Flexible tubing may be kinked or blocked. Patient may not respond to aerFree	Ensure flexible tubing is not blocked Use alternative means of maintaining airway patency
REDNESS, IRRITATION OR SWELLING DEVELOPS UNDER COLLAR	Patient sensitivity to System materials	Discontinue use of collar

System Specifications

Product Code	30-5001
Size	Medium
Maximum Operating Period	2 hours
Operational Vacuum Range	-29 to -35 mm Hg (-40 to -48 cm H ₂ O)
Nominal Vacuum Level	-33 mm Hg (-45 cm H ₂ O)
Maximum Vacuum Level	-37 mm Hg (-50 cm H ₂ O)
Operating Temperature Range	15°C to 46°C (59° F to 115° F)
Operating Altitude	Sea level to 8,000 feet (2438 m)
Storage and Transportation Temperature Range	-20°C to 60°C (-4° F to 140° F)

About aerFree LLC

aerFree is a company focused on developing medical devices to help patients breathe better when their upper airway is at risk of collapsing. These devices are based on using aer+ Technology, applying negative pressure to a patient's neck over the upper airway to comfortably and non-invasively hold the airway open.

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Instructions for Use - Addendum

aerFree® Airway Management System *Non-Invasive External Airway*

Summary of Clinical Testing Results

Title: Continuous negative external pressure (cNEP) reduces respiratory impairment during screening colonoscopy: a pilot study.

Published: Endoscopy, 2016 Jun;48(6):584-7

Authors: Kais SS1, Klein KB2, Rose RM3, Endemann S1, Coyle WJ1.

BACKGROUND AND STUDY AIMS: Drugs administered during gastrointestinal procedures cause increased collapsibility of the upper airway, which may lead to respiratory impairment. We evaluated the ability of continuous negative external pressure (cNEP) to lessen respiratory impairment during screening colonoscopy.

PATIENTS AND METHODS: The initial 24 patients served as controls, while the next 30 received cNEP. cNEP was delivered by a soft silicone collar placed over the anterior neck. The primary endpoint was the frequency of respiratory impairment, defined as either: (i) a decline from baseline of >4% in oxygen saturation, or (ii) apnea lasting ≥ 20 seconds.

RESULTS: Mean respiratory impairment episodes were 3.50 in the no-cNEP group vs. 1.92 in the cNEP group, a reduction of 45% ($P = 0.022$). Apneas ≥ 20 seconds occurred in 74% of the no-cNEP group and 28% of the cNEP group ($P = 0.002$). While 42% of the no-cNEP group required increased supplemental oxygen, this was true for only 10% of the cNEP group ($P = 0.01$). cNEP adverse events were minimal.

ADVERSE EVENTS: Adverse events were limited to mild cutaneous erythema at the site of contact of the cNEP collar with the neck (40% of the cNEP group). In all cases, this resolved spontaneously within 20 minutes of removal of the collar.

CONCLUSIONS: During screening colonoscopy, sedation-related respiratory impairment is significantly reduced by cNEP.