

QUICK TIPS

IMPORTANT - This Quick Tips guide is an abbreviated and excerpted form of the complete Instructions For Use. Its purpose is to provide a convenient reference during the application of the aerFree™ Airway Management System.

DO NOT ATTEMPT TO USE THE aerFree AMS WITHOUT READING, AND BECOMING FAMILIAR WITH THE COMPLETE IFU.

WARNING:

Maximum duration of use:

- Use is limited to procedures less than 2 hours in duration, based on the maximal time of exposure to the aerFree AMS in clinical studies which focused on carotid blood flow.
- Use of the aerFree AMS is not a substitute for continuously monitoring the patient's respiratory status

- Just prior to inducing sedation, apply the aerFree collar as follows:

- Skin prep should be accomplished utilizing 1 or more alcohol swabs to cleanse the area of aerFree application. This should include an area from 1 inch above the mandible to 3 inches below the mandible from earlobe to earlobe
- Connect the aerFree AMS to a regulated source of vacuum, and adjust the vacuum level to a value between -40 and -48 cm H₂O (-29 to -35 mm Hg) (Figure 2).

- Place patient in supine position.

- Remove protective liner from the adhesive gel, being careful to keep it clean and free of any contaminants prior to placing it on the patient (Figure 3).

- Rest Chin Cup symmetrically on patient's chin, with reference arrow pointing up towards patient's nose (Figure 4).

- Grasp the lateral ends of collar and hold away from patient's skin, while rotating the bottom edge of the collar toward the suprasternal notch. When the bottom of the sealing flange is resting on the patient's skin, release the lateral ends, allowing the entire flange to contact the patient's skin, without overlapping the ears (Figure 4).

- Verify that the flange is flat against the patient's skin along its entire perimeter. If necessary, reposition collar so that the flange is not on top of the patient's ear(s) or hair, and no visible air gaps exist between the flange and the patient's skin. To reposition the collar, gently peel the adhesive gel away from the patient's skin; it will retain its adhesive quality.

- The positioning of the collar and effectiveness of the seal can be verified by observing that the vacuum gauge on the regulator shows a value within the operating range. If the vacuum level displayed on the regulator does not rise to the operating range it may indicate a leak along the collar flange. If necessary to resolve a leak, the collar may be peeled off patient's skin and carefully repositioned.

Figure 1

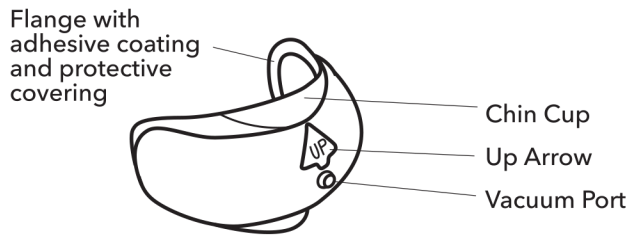


Figure 2

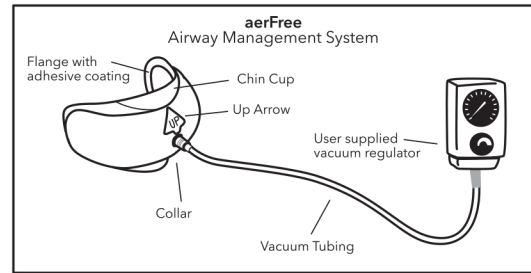


Figure 3

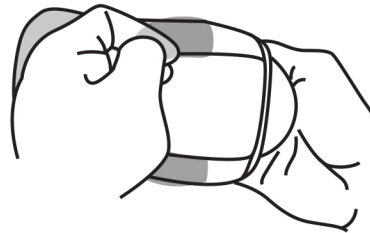


Figure 4



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