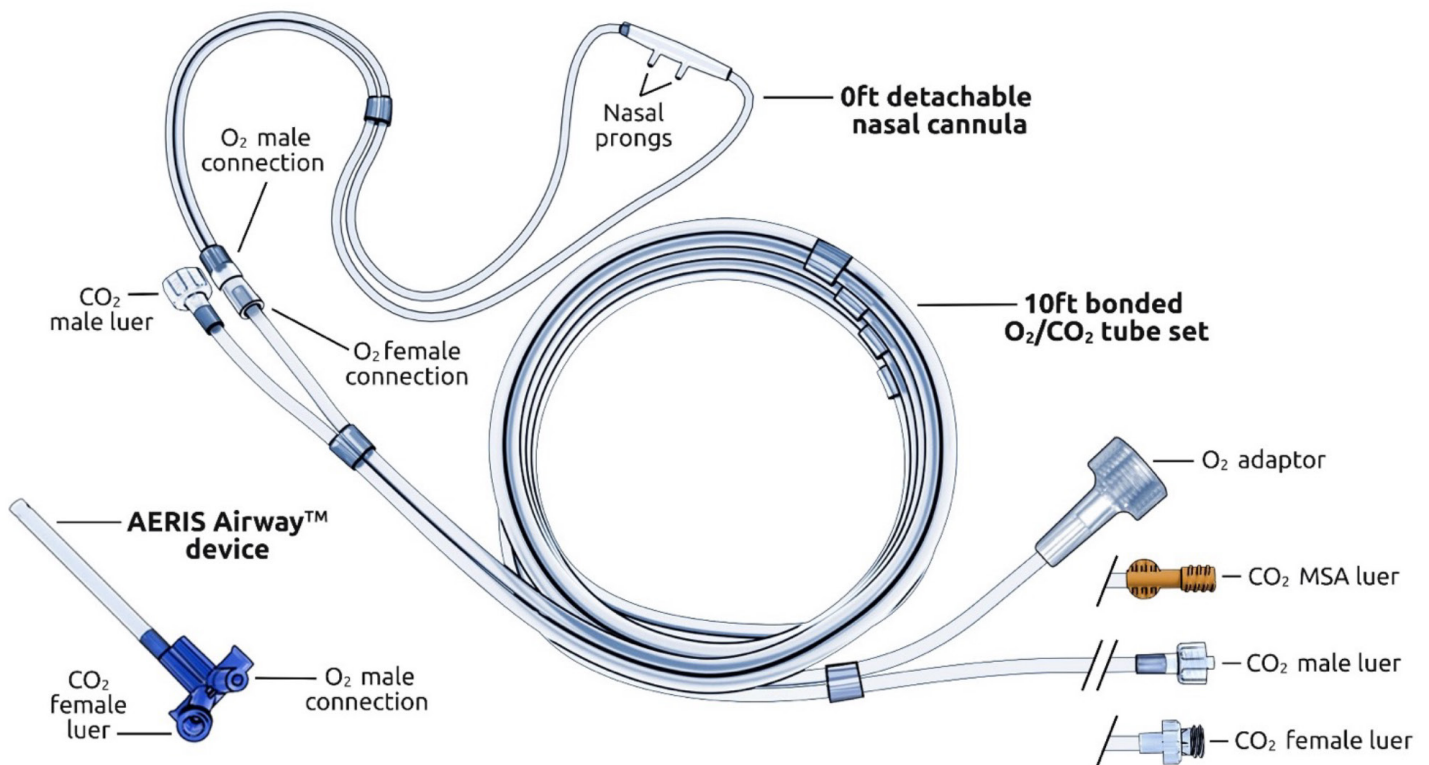


These directions are general guidelines intended for use by qualified medical personnel. The instructions, indications, and contraindications given are not exhaustive. It is the clinician's responsibility to ensure this product's safe, correct use.

AERIS Airway™ - Male Luer Kit (101MM)

AERIS Airway™ - Female Luer Kit (101MF)

AERIS Airway™ - MSA Luer Kit (101MSA)



IMPORTANT: BEFORE USING THE PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

These Instructions for Use are designed to assist in the proper use of this product. These instructions are general guidelines intended for use by qualified medical personnel.

Ensure that the AERIS Airway™ device and tube set with the proper Luer connection for the patient monitor is used to obtain capnometry readings and capnography waveforms.

INTENDED USE: The AERIS Airway™ is a single-use, disposable device that delivers supplemental oxygen and provides a means to attach to patient monitors for monitoring exhalation.

INDICATIONS FOR USE: The device is indicated for patients who are spontaneously breathing, under I.V. sedation, have an obtunded gag reflex, and are under monitored anesthesia care. The AERIS Airway™ is designed to fit in the central lumen of adult-sized Guedel Oropharyngeal Airways (OPAs) sized from 80–110mm and Nasopharyngeal Airways (NPAs) sized from 24–36Fr.

WARNINGS: Failure to follow these instructions may result in serious complications or adverse procedural outcomes.

The AERIS Airway™ Kit is intended for use only by anesthesia providers who are qualified and trained in both general and intravenous anesthetic administration.

These Instructions for Use do not provide guidance or protocols for administering anesthesia. The anesthesia provider is responsible for selecting the appropriate procedure, assessing the suitability of this product for the patient, and determining the specific techniques to be used.

The enclosed components of the AERIS Airway™ Kit are non-sterile. DO NOT use after the expiration date or if the package is opened or damaged.

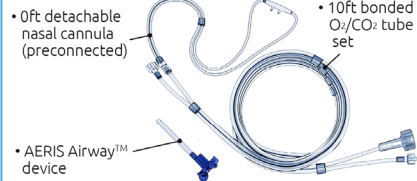
The AERIS Airway™ Kit device components are disposable and packaged for single-patient use only. Do not reuse, reprocess, or resterilize. Reusing, reprocessing, or resterilizing may compromise the structural integrity of the device components and/or lead to device components' failure, which may result in patient injury, illness, or death. Also, reprocessing or resterilizing the AERIS Airway™ Kit device components may create a risk of contamination and cause patient infection or cross-infection. Contamination of the device components may lead to the patient's injury, illness, or death.

CONTRAINDICATIONS: The AERIS Airway™ is contraindicated for use with Guedel OPAs less than 80mm or greater than 110mm, NPAs less than 24Fr or greater than 36Fr, Intersurgical Guedel OPAs, and Berman OPAs.

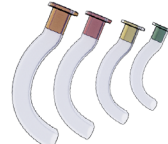
AERIS AIRWAY™ KIT FOR USE WITH OROPHARYNGEAL AIRWAY (OPA)

1 PRE-PROCEDURE

1A Open **AERIS™ Kit** which contains 3 components:

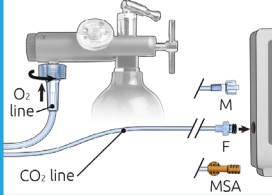
- 0ft detachable nasal cannula (preconnected)
 - 10ft bonded O₂/CO₂ tube set
 - AERIS Airway™ device
- 

1B Clinician selects appropriate size oropharyngeal airway (OPA).

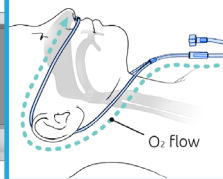


NOTE: AERIS Airway is compatible with 80-110mm Guedel OPAs

1C Connect O₂ line to oxygen source and CO₂ line to patient monitor.

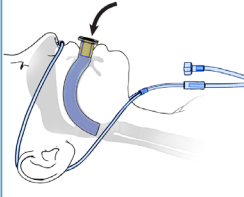


1D Place detachable nasal cannula on patient, turn on O₂ and pre-oxygenate.

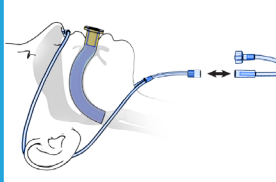


2 INTRA-PROCEDURE

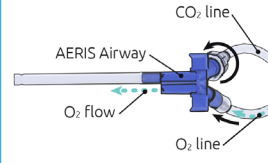
2A Induce patient and place OPA into patient's mouth.



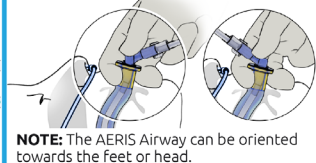
2B Detach O₂ line from nasal cannula. Leave nasal cannula in place for post-procedure use.



2C Connect patient side of O₂ & CO₂ lines to the **AERIS Airway** and confirm O₂ is freely flowing through AERIS Airway.

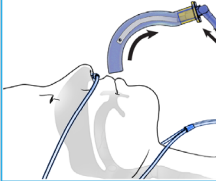


2D Maintain OPA position and insert **AERIS Airway** with connected O₂/CO₂ lines into OPA until device is snug within OPA. Begin procedure.

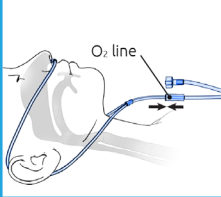


3 POST-PROCEDURE

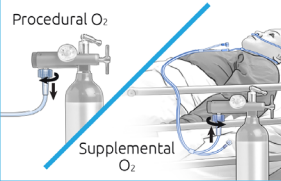
3A Remove the **AERIS Airway/OPA**. Disconnect O₂/CO₂ lines from the AERIS Airway.



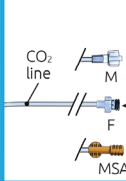
3B Reconnect O₂ line to nasal cannula (from Step 2B).



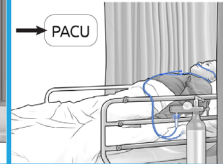
3C Disconnect O₂ line from procedural O₂ source and connect to supplemental O₂ source and turn on O₂.



3D Disconnect CO₂ line from patient monitor.



3E Transfer the patient to PACU with supplemental oxygen flowing through detachable nasal cannula.



AERIS AIRWAY™ KIT FOR USE WITH NASOPHARYNGEAL AIRWAY (NPA)

1 PRE-PROCEDURE

1A Open **AERIS™ Kit** which contains 3 components:

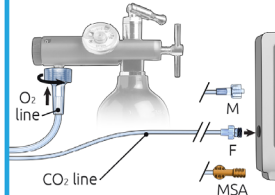
- 0ft detachable nasal cannula (preconnect)
 - 10ft bonded O₂/CO₂ tube set
 - AERIS Airway device
- 

1B Clinician selects appropriate size nasopharyngeal airway (NPA).

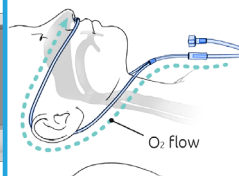


NOTE: AERIS Airway is compatible with 24-36Fr NPAs

1C Connect O₂ line to oxygen source and CO₂ line to patient monitor.

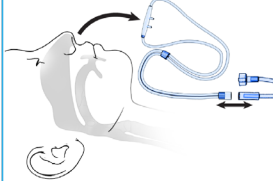


1D Place detachable nasal cannula on patient, turn on O₂ and pre-oxygenate.

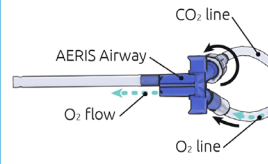


2 INTRA-PROCEDURE

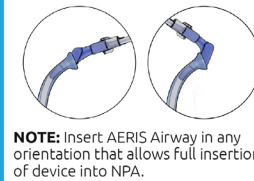
2A Detach O₂ line from nasal cannula. Do not discard nasal cannula, keep for post-procedure use.



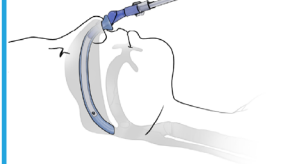
2B Connect patient side of O₂ & CO₂ lines to the **AERIS Airway** and confirm O₂ is freely flowing through AERIS Airway.



2C Insert **AERIS Airway** with connected O₂/CO₂ lines into NPA until device is snug within the NPA.

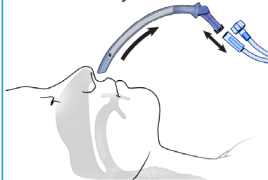


2D Induce patient and insert **NPA/AERIS Airway** with connected O₂/CO₂ lines into patient's nostril. Begin procedure.

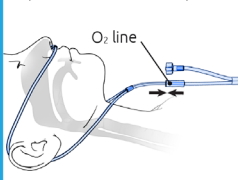


3 POST-PROCEDURE

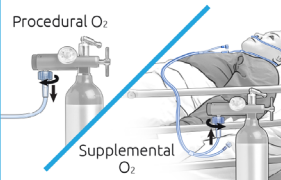
3A Remove the **NPA/AERIS Airway**. Disconnect O₂/CO₂ lines from the AERIS Airway.



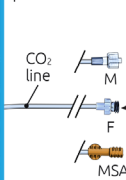
3B Reconnect O₂ line to nasal cannula (from Step 2A) and replace nasal cannula on patient.



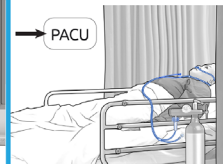
3C Disconnect O₂ line from procedural O₂ source and connect to supplemental O₂ source and turn on O₂.



3D Disconnect CO₂ line from patient monitor.



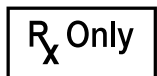
3E Transfer the patient to PACU with supplemental oxygen flowing through detachable nasal cannula.



HOW SUPPLIED: Each AERIS Airway™ Kit contains: AERIS Airway™, 0ft Nasal Cannula, 10ft O₂/CO₂ tube set with either a MSA, Male or Female Luer. The AERIS Airway™ Kit is supplied nonsterile for single-patient use. Discard after use.

STORAGE CONDITIONS: Store product inside containers or outer boxes in a clean, dry area. Do not expose to direct sunlight or UV light. Store product at normal ambient room temperature.

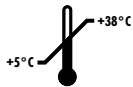
MEANINGS OF SYMBOLS ON PACKAGE:



CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.



CONSULT
INSTRUCTIONS FOR USE



STORAGE
TEMPERATURE
RANGE



PRODUCT HAS NOT
BEEN STERILIZED



NO LATEX



DEHP
DEHP
FREE



MR SAFE



DO NOT RE-USE



Airway Innovations, Inc.
1360 Busch Pkwy
Buffalo Grove, IL 60089
844-772-3747

airwayinnovations.com

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P/N: IFU-001 Rev3