



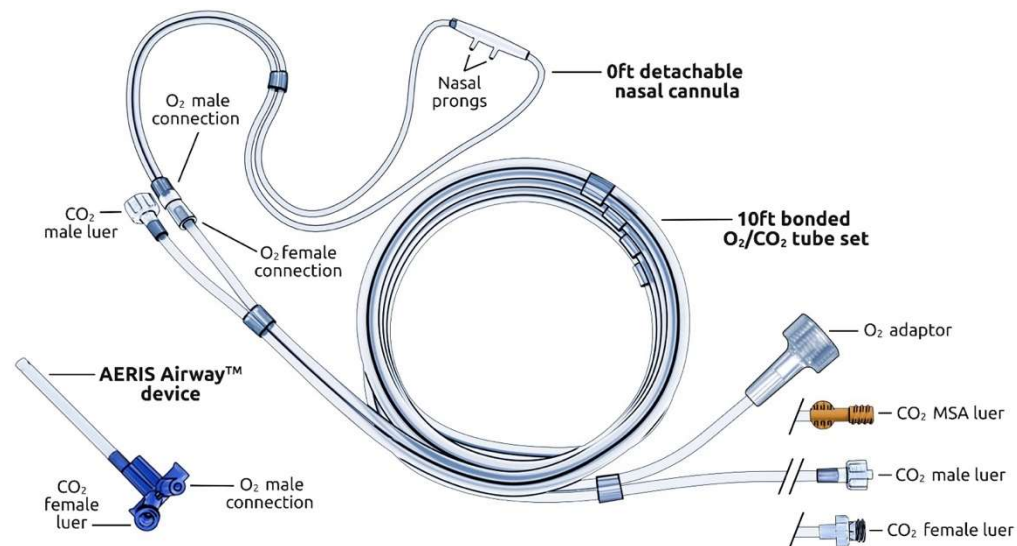
Instructions for Use (IFU)

These directions are intended for use by qualified medical personnel.

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.

Ensure the tube set used with the AERIS Airway® device and nasal cannula has the proper Luer connection for the patient monitor used to obtain capnometry readings and capnography waveforms.

INDICATIONS FOR USE:

The AERIS Airway® Kit contains a single-use, disposable nasal cannula and a single-use, disposable AERIS Airway device intended for use on adult patients to deliver supplemental oxygen and provide a means for exhaled gas monitoring through an external patient monitor.

INTENDED USE:

The AERIS Airway® Kit is intended for use in adult patients who are spontaneously breathing during monitored anesthesia care, intravenous sedation, or deep extubation. The device is intended to deliver supplemental oxygen and provide a means for monitoring exhaled carbon dioxide through a compatible external patient monitor.

COMPATIBILITY:

The AERIS Airway is designed to fit within the central lumen of adult-sized Guedel oropharyngeal airways (OPAs) sized 80–110mm and nasopharyngeal airways (NPAs) sized 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. Visually inspect the device packaging for damage prior to use. DO NOT use after the expiration date or if the package is opened or damaged.
- The AERIS Airway Kit components are disposable and packaged for single-patient use only. DO NOT reuse, reprocess, or sterilize. Reusing, reprocessing, or sterilizing 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 sterilizing the AERIS Airway Kit components may create a risk of contamination and cause patient infection or cross-infection. Contamination of the device components may result in patient injury, illness, or death.

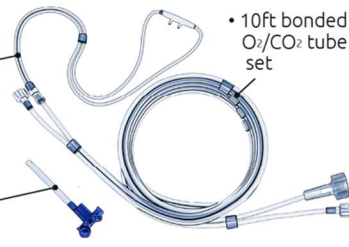
CONTRAINDICATIONS:

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; Berman OPAs; and Guedel OPAs with a nonstandard internal lumen, such as a catheter guide channel or other modified airway passage (for example, Teleflex Hudson RCI® Cath-Guide® Guedel Airway or Intersurgical® Guedel Airway).

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

1 PRE-PROCEDURE

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

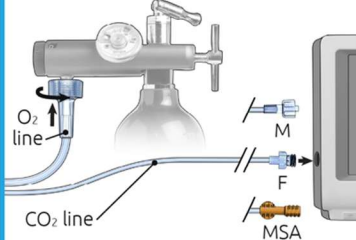
- 0ft detachable nasal cannula (preconnected)
 - 10ft bonded O₂/CO₂ tube set
 - AERIS Airway™ device
- 

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

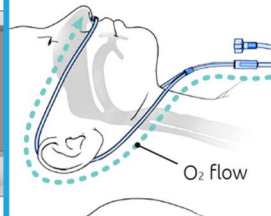


NOTE: AERIS Airway is compatible with 80-110mm Guedel OPAs

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

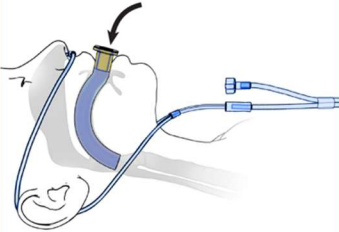


1D Place detachable nasal cannula on patient, turn on O₂ and pre-oxygenate.

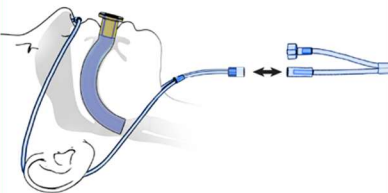


2 INTRA-PROCEDURE

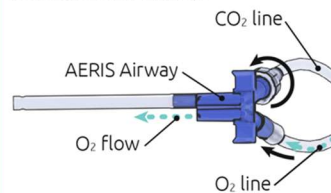
2A Induce patient and place OPA into patient's mouth.



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.



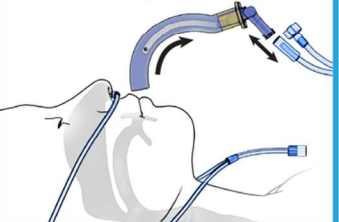
2D Maintain OPA position and insert **AERIS Airway** with connected O₂/CO₂ lines into OPA until device is snug within OPA. Begin procedure.



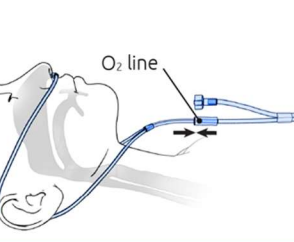
NOTE: The AERIS Airway can be oriented towards the feet or head.

3 POST-PROCEDURE

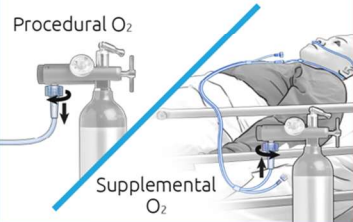
3A Remove the **AERIS Airway**/OPA. Disconnect O₂/CO₂ lines from the AERIS Airway.



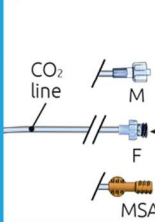
3B Reconnect O₂ line to nasal cannula (from Step 2B).



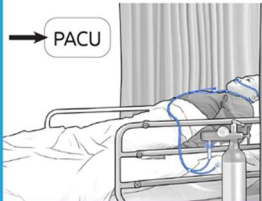
3C Disconnect O₂ line from procedural O₂ source and connect to supplemental O₂ and turn on O₂.



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)
- AERIS Airway device

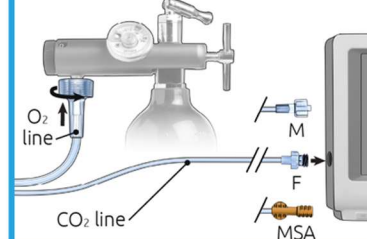


1B Clinician selects appropriate size nasopharyngeal airway (NPA).

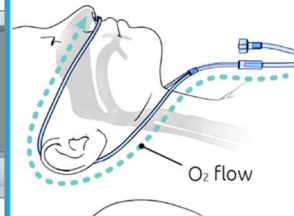


NOTE: AERIS Airway is compatible with 24-36Fr NPAs

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

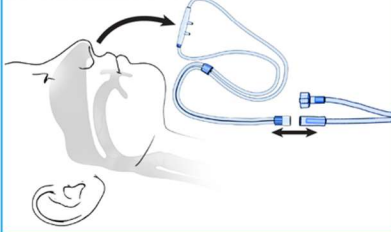


1D Place detachable nasal cannula on patient, turn on O₂ and pre-oxygenate.

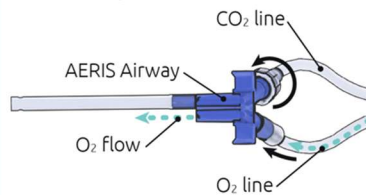


2 INTRA-PROCEDURE

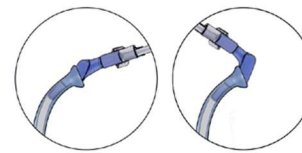
2A Detach O₂ line from nasal cannula. Do not discard nasal cannula, keep for post-procedure use.



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

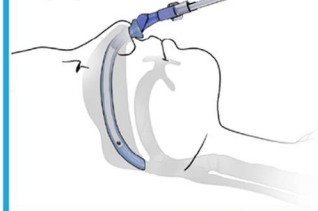


2C Insert **AERIS Airway** with connected O₂/CO₂ lines into NPA until device is snug within the NPA.



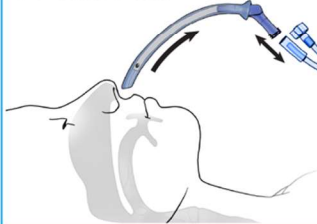
NOTE: Insert AERIS Airway in any orientation that allows full insertion of device into NPA.

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

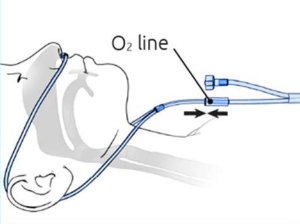


3 POST-PROCEDURE

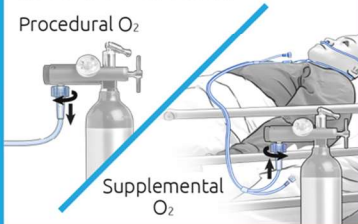
3A Remove the NPA/AERIS Airway. Disconnect O₂/CO₂ lines from the AERIS Airway.



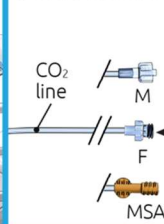
3B Reconnect O₂ line to nasal cannula (from Step 2A) and replace nasal cannula on patient.



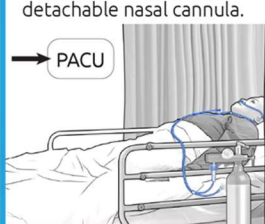
3C Disconnect O₂ line from procedural O₂ source and connect to supplemental O₂ source and turn on O₂.



3D Disconnect CO₂ line from patient monitor.



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



AERIS AIRWAY® HOW TO PLACE IN OPA AND NPA



Read Before Using AERIS Airway®

The Detachable Nasal Cannula is for pre-procedure and post-procedure oxygenation.

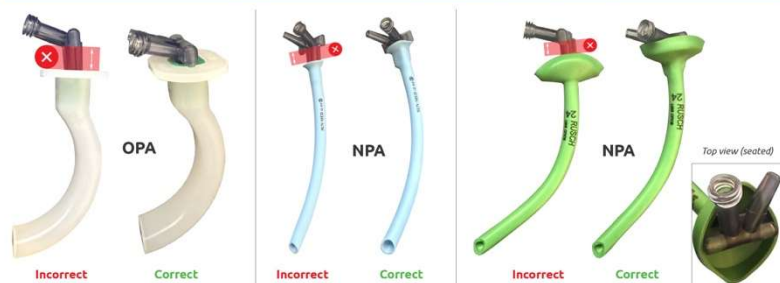
The AERIS Airway® fits adult-size Guedel OPAs (80mm-110mm).

• (AERIS® does not fit in Intersurgical® OPAs.)

The AERIS Airway® fits adult-size NPAs (24-36Fr). The following manufacturers' NPAs are recommended for the best fit:

- AirLife®'s SunMed PVC Nasopharyngeal Airway (remove the 15mm connector first)
- Teleflex®'s RUSCH Robertazzi Nasopharyngeal Airway

The AERIS AIRWAY®'s Hub Must Be Fully Seated in an OPA or NPA for Optimal O₂ Delivery and EtCO₂ Sampling



Clinical Essentials Before Using AERIS Airway®



Incorrect

OPA



Incorrect

NPA



Correct



Correct

For More
New User Info:



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AERIS AIRWAY® OXYGEN SUPPLY CONNECTION, FLOW SETTING, AND FUNCTIONAL VERIFICATION:

Connect the oxygen supply tubing to the oxygen inlet of the AERIS Airway® Kit. Set the oxygen flow rate within the validated range of 2–8 L/min, based on the patient's clinical needs and institutional protocol. Do not use oxygen flow rates below 2 L/min or above 8 L/min. Connect the CO₂ sampling line to a compatible external patient monitor using the appropriate tube-set configuration.

Before patient use, verify that oxygen is flowing through the device and that the patient monitor displays a capnography waveform and capnometry readings.

During use, continuously monitor the patient's respiratory status, oxygenation, and capnography per institutional protocol. Do not rely solely on the AERIS Airway Kit for assessment of ventilation or oxygenation. Confirm device function after placement and whenever the device, airway, tubing, oxygen flow, or patient condition changes.

HOW SUPPLIED:

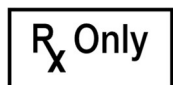
Each AERIS Airway® Kit contains: AERIS Airway device, Detachable Nasal Cannula, 10ft O₂/CO₂ Tube Set with either a Male Luer, a Female Luer, or an MSA Luer. The AERIS Airway® Kit is supplied nonsterile for single-patient use. Discard after use.

SAFE DISPOSAL:

Dispose of device in accordance with local, state, or national regulations.

STORAGE CONDITIONS:

Store product inside containers or outer boxes in a clean, dry area. Avoid exposure 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.

AERIS® and AERIS Airway® are registered trademarks, and Airway Innovations™ is a trademark of Airway Innovations, Inc.

CONTACT INFORMATION:

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Buffalo Grove, IL 60089
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airwayinnovations.com

Please report adverse events involving the AERIS Airway® Kit to Airway Innovations™ using the above information, and to the authority having jurisdiction

P/N: IFU-001 Rev4