



Phoneris® Inner Cannulae and Phoneris® AeroFlex® Ventilator Circuit Connector

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

INDICATIONS FOR USE:

The Phoneris Inner Cannulae and AeroFlex Ventilator Circuit Connector are indicated for maintenance of patients with tracheostomies. Both the Phoneris Inner Cannulae and AeroFlex Ventilator Circuit Connector are single use, disposable devices which are an accessory to a tracheostomy tube, serving as an interlocking, detachable, coupling between the ventilator circuit and tracheostomy tube.

DESCRIPTION:

The Phoneris Inner Cannulae is a sterile replacement inner cannula intended to be utilized in the tracheostomy tube as indicated on the package label. The Phoneris Inner Cannulae is designed to specifically mate with the appropriate Phoneris AeroFlex Ventilator Circuit Connector of the same style to decrease the risk of disconnection. The Phoneris AeroFlex Ventilator Circuit Connector is intended to connect to the ventilator circuit of a ventilator utilized to enable mechanical ventilation for the patient.

CONTRAINDICATIONS:

There are no known contraindications associated with the utilization of this product.

WARNING:

- Read the complete Instructions for Use prior to product utilization.
- All procedures must comply with your institution's written protocols and procedures.
- Determine the brand and size of the patient's tracheostomy tube. Be certain that the Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector are the correct style and size for the tracheostomy tube.
- The Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector should only be used by trained personnel.
- It is recommended that the Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector be replaced a minimum of every 24-hours or sooner if required by your institution's written policies and procedures for airway maintenance.
- The Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector are for single patient use only. Do not reuse!
- The Phoneris Inner Cannulae is supplied sterile. Do not use if the package has been opened, damaged or broken. Do not resterilize!
- The Phoneris AeroFlex Ventilator Circuit Connector is supplied non-sterile. Do not use if the package has been opened, damaged or broken.
- Do not use the Phoneris Inner Cannulae and/or the Phoneris AeroFlex Ventilator Circuit Connector if the use date is beyond the expiration date printed on packaging.
- Prior to utilizing the Phoneris Inner Cannula and Phoneris AeroFlex ensure that the tracheostomy tube is properly secured to the patient through appropriate means so as to prevent accidental decannulation.

CAUTION

- The Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector are manufactured from medical grade plastics and do not contain latex material.
- Care should be taken when disposing of either the Phoneris Inner Cannulae or the Phoneris AeroFlex Ventilator Circuit Connector to ensure compliance with applicable regulations for the disposal of biologically hazardous waste.

STORAGE

- Store the Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector in their original packaging under controlled environmental conditions.
- Do not expose the Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector to temperatures above 120°F (40°C).

Manufactured for



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INSTRUCTIONS FOR USE

1. Utilizing your institution's protocol for Airway maintenance, prepare the patient for the replacement of the Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector by collecting all required supplies including the Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector. Be certain that the Phoneris Inner Cannulae is the correct size and style for the tracheostomy tube of the patient. .
2. Use universal protection when changing the Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector.
3. Prepare a clean working area.
4. Open all packages.
5. Turn the ventilator to stand-by mode. Disconnect the ventilator circuit from the Phoneris AeroFlex Ventilator Circuit Connector.
6. Disconnect the Phoneris AeroFlex Ventilator Circuit Connector by rotating the AeroFlex Ventilator Circuit Connector clockwise or counterclockwise until the AeroFlex arms are disengaged from the Phoneris Inner Cannulae.
7. Remove the Phoneris Inner Cannulae from the tracheostomy tube by squeezing the tabs on the 15mm connector until both snap-locks clear the ridged lock on the outer cannula. Withdraw slowly.
8. Dispose of the removed Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit Connector.
9. Clean the tracheostomy tube if necessary.
10. The Phoneris Inner Cannulae may be moistened with sterile saline or a water soluble lubricant to facilitate insertion
Note:
 - a. If using a water soluble lubricant verify that the lubricant does not enter and occlude the tracheostomy tube lumen which may restrict ventilation.
 - b. To avoid applying pressure against the patient, the tabs on the connector should be held open, while the neck plate is stabilized with your free hand during the locking procedure.
11. Insert the Phoneris Inner Cannulae with 15 mm snap-lock connector and lock into position. To lock the Phoneris Inner Cannulae in place, push connector until both snap-locks clear the ridged lock on the outer cannula.
Note:
 - a. It may be easier to lock one side of the Inner Cannulae first and then lock the second side of the Inner Cannulae.
 - b. Check to ensure that both locks are appropriately engaged on the outer cannula.
12. Attach the Phoneris AeroFlex Ventilator Circuit Connector to the Phoneris Inner Cannulae by aligning the arrows and engaging the fingers on the AeroFlex Ventilator Circuit Connector to lock on the ridge of the Phoneris Inner Cannulae. Insure both fingers on the AeroFlex are in the locked position to the Phoneris Inner Cannulae.
13. Attach the Phoneris AeroFlex Ventilator Circuit Connector to the ventilator circuit.
Note:
 - a. Check to ensure maintenance of a constant seal to the ventilator circuit.
14. Turn the ventilator from stand-by mode to on and resume the previous ventilator settings or if ordered by the physician, change the ventilator settings to the new settings. The patient's respirations and vital signs should be routinely evaluated after replacing the Phoneris Inner Cannulae and the Phoneris AeroFlex Ventilator Circuit per your institution's protocol.
Note:
 - a. If there are problems then the attending physician should be immediately contacted.