

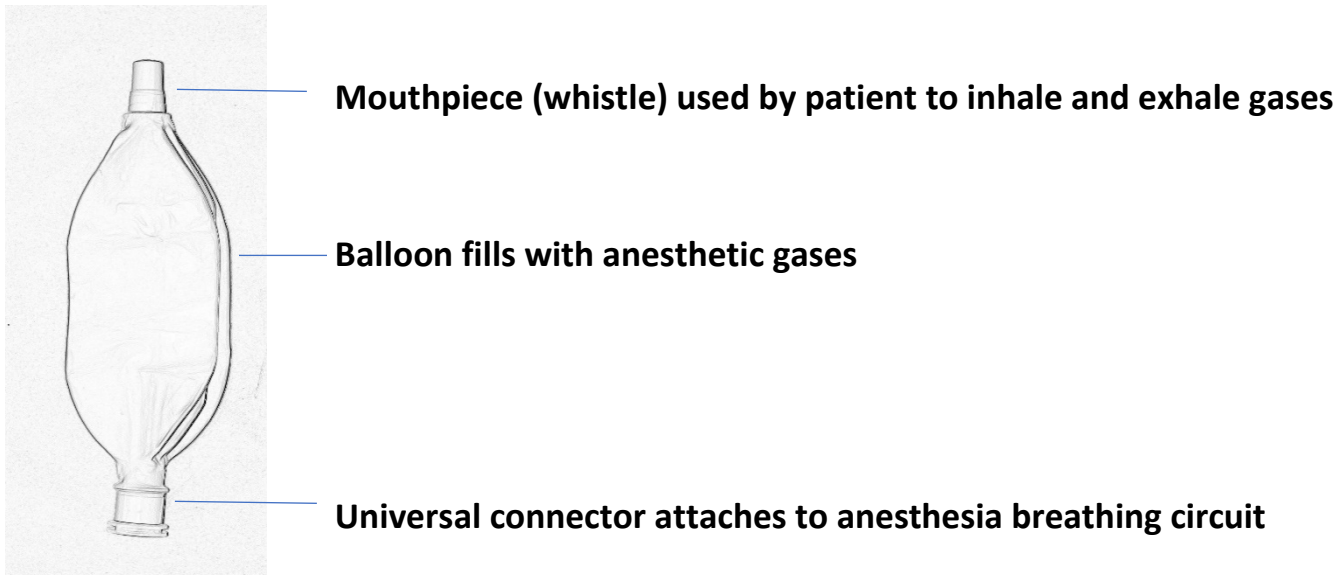
Pediatric Device for Induction of Anesthesia (PeDIA)

Instructions For Use:

Please read all instructions before operating device.

The Pediatric Device for Induction of Anesthesia (PeDIA) is a single-use, disposable, mask-free anesthetic delivery system and method used for children 3 years and older.

PeDIA Balloons come individually packed and are not meant to be sold separately. Simply tear the individual plastic wrap and the PeDIA Balloon is ready to use.















Indications:

The pediatric device for induction of anesthesia (PeDIA) is an alternative to a face mask for the inhalation induction of anesthesia, and is intended for the delivery of nitrous and/or anesthetic

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gases to children age three years and older. It is intended to be used prior to IV insertion, LMA/endotracheal intubation, and/or conversion to a standard mask induction

Symbols:









	Consult instructions for use
	Single use; disposable
	Keep dry
	Caution
	No components of the PeDIA are made of latex
	Disposables delivered are non-sterile
	Federal law restricts this device to sale by or on the order of a physician
	Manufacturer of Record
	Date of manufactured unit
	Catalog Number
	Lot Number
	Do not use if packaging is open or damaged

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Do:

	Do perform an anesthesia machine check per ASA guidelines to include the scavenger system
	Do instruct the child on the proper use of the device
	Do inspect the device for signs of damage
	Do set and maintain the Adjustable Pressure Limiting Valve (APL or <i>pop-off</i>) to minimum

Do Not:

	DO NOT separate the body of the device from the mouthpiece
	DO NOT send any portion of the device home with the child
	DO NOT use if the device is damaged
	DO NOT use if the packaging is damaged
	DO NOT use with combustible volatile anesthetics
	DO NOT sterilize the device
	DO NOT reuse the device or share between patients
	DO NOT use with children who cannot or will not follow directions



Discontinue use with signs of increased pressure within the PeDIA such as:

- A taut balloon or increase peak inspiratory pressures (PIP).
- Any signs of patient distress
- The patient cannot or will not follow directions

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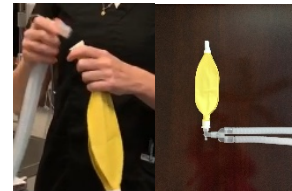
Instructions to give the child:

1. Seal lips around whistle/mouthpiece
2. Inhale and exhale through the mouthpiece
 - a. Balloon will slightly inflate and deflate with respirations
 - b. Whistle will make siren sound

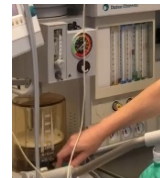


Instructions for the medical professional:

1. Attach the universal connector of the PeDIA to the anesthesia breathing circuit using a gentle push (the motion/force similar to attaching an anesthesia mask)



2. Turn the APL valve (*pop-off*) to minimum.



3. Obstruct the whistle/mouthpiece using your thumb/finger to trap gases inside balloon.



4. Turn up flows of oxygen and nitrous oxide sufficient to inflate the 2-liter PeDIA.



5. Hand the child the inflated PeDIA Balloon.
 - a. Be sure the child seals their lips around the mouthpiece.

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6. As the child exhales and inhales, observe the system is working properly.
 - a. PIPs remain low
 - b. Balloon slightly inflates and deflates

7. After 2-3 breaths, dial-in the volatile anesthetic of choice.*



8. When the child falls asleep or is too sleepy to hold a properly seal lips around whistle, take the PeDIA from the child and lay the child supine.
9. Detach PeDIA from the anesthesia circuit using a gentle pull (the motion/force similar to detaching an anesthesia mask).
10. Attach the anesthesia mask to the breathing circuit.**
11. Support patient respiration with mask-ventilation and continue induction/intubation.
12. Discard the PeDIA per facility protocol.

*Noncombustible anesthetic agents should be used with gas flows and anesthetic concentrations determined by the anesthesia provider.

**Before switching to a mask, the practitioner may elect vent the gasses into the circuit.