IFU for AccuCuff™ Cuff Pressure Indicator

Cuff Pressure Indicator, with Luer Lock Red, Laryngeal

DESCRIPTION

Product Code: ACC0100R
Product Colour: Red

1. AccuCuff is used for indicating the cuff pressure of all versions of Laryngeal Masks that require an inflation pressure of between 40-60cmH₂O.

2. A is the inflation gate which connects with a syringe or other inflation devices. B is the luer locking connector which connects to the Laryngeal Mask via the inflation pilot balloon on the inflation line.

- During inflation of the cuff, the piston within the AccuCuff will start moving towards the green zone, the base of the piston is black in colour allowing the position to be seen.

- The green zone indicates the safe inflation pressures. When the black line of the piston is within the green zone the correct safe sealing pressure can be achieved.

- If the pressure increases, the black line will move beyond the green zone towards the red line indicating that the cuff is over inflated.

- When the device is fully deflated, the black line will be below the white line indicating negative pressure and that the cuff is fully deflated. The Laryngeal Mask can be safely

FIG 1: Correct Pressure
FIG 2: Negative Pressure

FIG 3: Over Inflated

WARNING/PRECAUTIONS

1. Sterile product. Sterilised by Ethylene Oxide
2. Single Use Only. Do not use it if package is damaged, opened or is not within shelf life date.
3. Safely dispose of product after use

DIRECTION FOR USE

1. Only to be used by qualified clinical staff
2. Only to be used for connection to Laryngeal Masks
3. Do not use with any Endotracheal or Tracheostomy Devices
4. Do not use if the packaging has been opened or damaged
5. Ensure that all connections are connected to the syringe or Airway Device by a push and twist action to ensure a secure leak tight seal
6. Inflate the cuff of the airway device until a seal has been achieved and the black piston line is within the green zone
7. Do not over inflate to achieve the Laryngeal cuff seal
8. Ensure the cuff is fully deflated before attempting to remove the airway device
9. Single Use device - do not reuse or reprocess
STORAGE CONDITIONS

stored in the relative humidity of not more than 80%, no corrosive gas and in a clean and ventilated environment
MEANING OF SYMBOLS ON PACKAGE

- Do not re-use
- Manufacturer
- Use-by date
- Date of manufacture
- Batch code
- Authorised representative in the European Community
- Sterilized by ethylene oxide
- Keep away from sunlight
- Do not use if package is damaged
- Keep dry
- Consult instructions for use

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