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CE 1639

SU2290-002 RAPID O2 Cricothyroidotomy Procedure Set - sterile single-use

Medical device class; 2A **GMDN Code; 45926**

Intended use

For use in emergency Can't Intubate, Can't Oxygenate (CICO) scenarios by anaesthetists when conventional airway management has failed and percutaneous jet ventilation is required to oxygenate the patient.

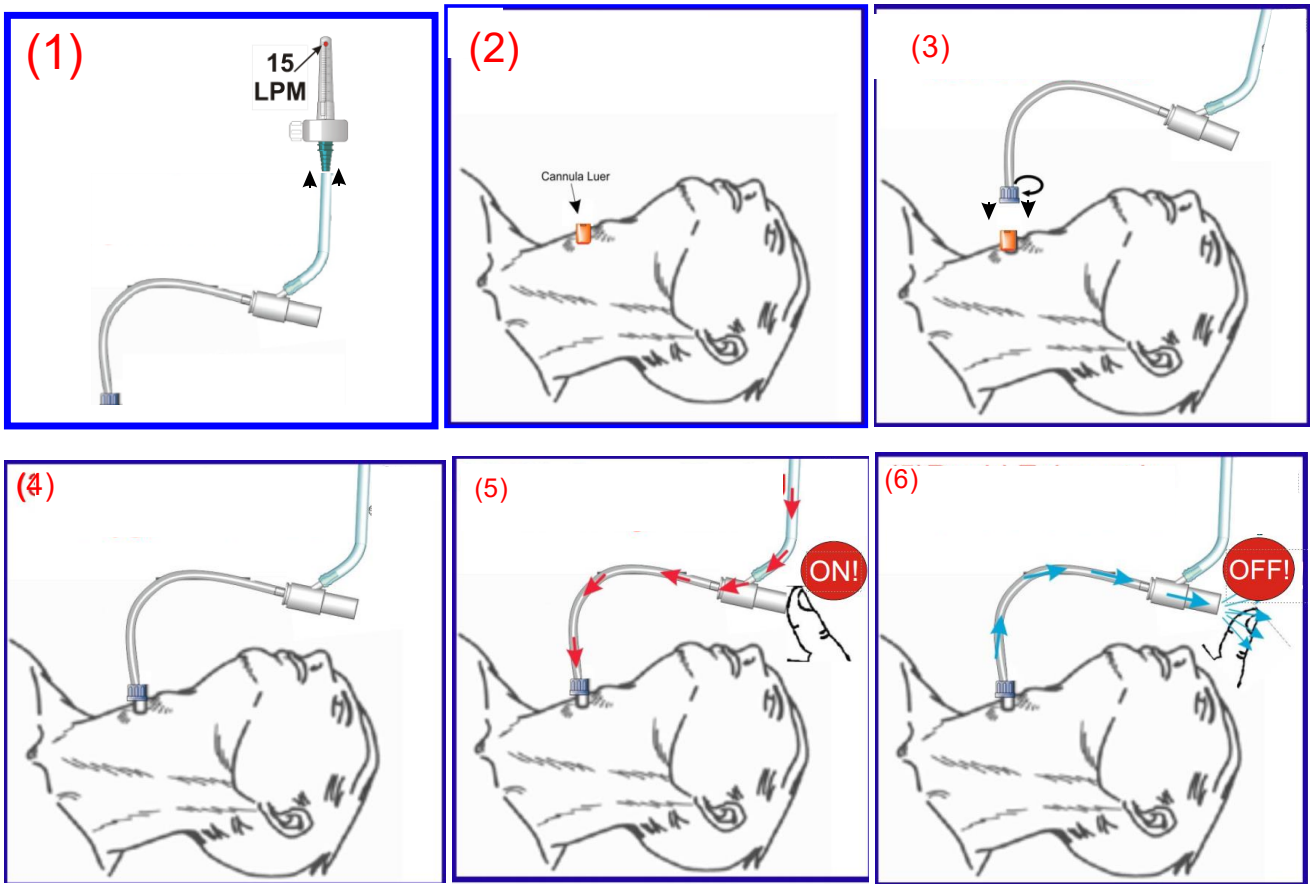
Intended user

The device intended for use by anaesthetists or or other personnel qualified for emergency front-of-neck access procedures.

Intended use environment

Emergency Cricothyroidotomy used in Operating Theatres, Emergency departments, Paramedic situations where a conventional airway cannot be placed in order to provide the patient with adequate airway for oxygen and gas delivery.

Instructions for use



1. Connect the oxygen tube to the oxygen supply set to 15 LPM. Confirm that there is gas flow through the Rapid O2 device before connection to Luer on I.V. cannula.
2. Confirm position of the cricothyroid/tracheal cannula with a check aspiration.
3. Connect the Luer lock connector to the cannula and ensure it is secure using quick swivel option on the Rapid-O2
4. RapidO2 connected to cannula and flowmeter.

5. Place thumb on onto the YELLOW outlet on the rapid O2 to direct oxygen into the patient's trachea/lungs
6. **ON** Hold for 4 seconds this will deliver 1000ml , **OFF** then remove thumb to allow exhaust.
7. Wait for oxygen saturations (SaO_2) to improve and follow up with 2 second bursts (500ml) as needed to maintain oxygenation.

Recommended Standard Adult protocol from Royal Perth Hospital Studies.

Recommended Standard Adult protocol

1. **After cannula insertion confirm that it is possible to freely aspirate air before attaching RapidO2**
2. **Connect Rapid O2 to flowmeter set at 15 $l.min^{-1}$ (10 $l.min^{-1}$ acceptable)**
3. **First jet: Occlude exhaust port with thumb for four seconds.**
4. **Wait for response.**
5. **Second and subsequent jets: Deliver jet of two seconds duration after SaO_2 have peaked then dropped by 5% or after 30 seconds if oxygenation inadequate.**
6) **Proceed to site large bore cuffed airway**

Storage

- ⇨ Do not store at temperature or humidity in excess of the limits shown on the device label.
- ⇨ Store in clean and dry place.
- ⇨ Do not use if the package open or damaged
- ⇨ Do not store in direct sunlight

Reprocessing

DISPOSABLE FOR SINGLE PATIENT USE NOT INTENDED FOR CLEANING OR REPROCESSING

There is a risk of cross contamination if these devices are reused. They have not been validated for reprocessing or reuse.

CONTRAINDICATIONS

Due to high pressure oxygenation being required for this procedure to deliver oxygen quickly into the patient's lungs there is a risk of **barotrauma.** The design of the Rapid O2 has minimised this possibility to the lowest level possible but the user must take note of the tactile feedback at their thumb which indicates high pressure build up in lungs.

Release thumb to allow exhaust and release of pressure in the lungs.

Also check patient cannula for kink as this could also be the cause.

WARNINGS AND CAUTIONS

1. High pressure at the thumb exhaust port can indicate kinked cannula if this occurs, please check cannula and reset position slightly to allow it to un kink.
2. Holding the thumb for longer than appropriate can cause high pressure in lungs which can lead to **barotrauma** in extreme instance. The thumb covering the exhaust opening will indicate this to the users the pressure builds and user should be aware of overpressure.
3. Disconnect of oxygen tube or cannula. If no oxygen flow is present check all connection of oxygen tube to flow meter and cannula connection.
4. Care must be taken to avoid needle stick injury from the trocar.
5. The Rapid O2 has not been approved for use on infants below the age of 1 year.

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Disposal information

The device must be disposed of using local procedures for the disposal of contaminated medical waste.
The materials are capable of being recycled.

Dispose of the trocar using sharps disposal procedure.

Ordering information:

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ADVERSE INCIDENT REPORTING

Adverse incidents may be reported to the Competent Authority in the country / region where the incident occurred.
This is an explanation of the symbols only, that may be found on Meditech Systems Ltd's products.

Note; these symbols may not be present on every device label

= Single Use. The definition of single use is for use on a single patient for a single procedure.	= Manufacturer
= Use by date	= Consult instructions for use
= Lot or batch number.	= Keep away from sunlight
= Device catalogue number / product code / stock	= Keep dry
= Date of manufacture.	= Contains latex
= Caution	= Do not use of packaging is wet or damaged.
= Sterilised by ethylene oxide (sterile devices only)	= Contains or Presence of Phthalates.
= Details of EU Representative	= Storage temperature limitations (sterile devices only)
= Humidity storage limitations (sterile devices only)	= Unique device identifier
= Do not reprocess / re-sterilise	= Latex Free
CE 1639 =CE mark with notified body number	

Reference; BS EN ISO 15223-1

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