CE

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RAPID O2 Cricothyroidotomy Insufflation Device – non-sterile, single-use

Product # = 2290-001 **GMDN Code; 45926**

Medical device class; 2A

Intended use

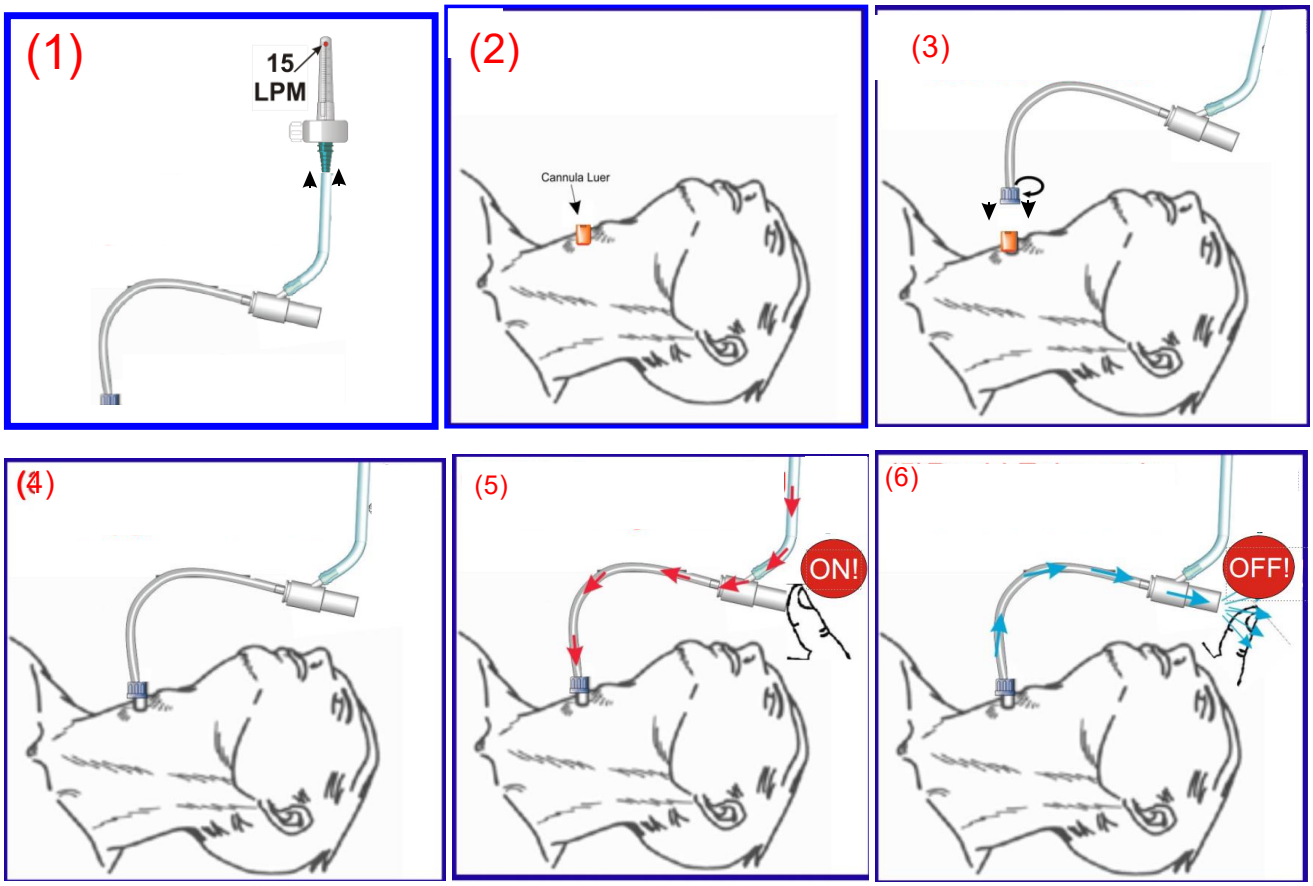
For use in emergency Can't Intubate, Can't Oxygenate (CICO) scenarios by anaesthetists when conventional airway management has failed and percutaneous jet oxygenation is required to oxygenate the patient.

Intended user

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

Instructions for use

These instructions assume the needle, syringe and IV cannula have been selected by the user for this procedure. Therefore, the performance of these items will be the responsibility of the user's own risk analysis. The Rapid O2 Insufflation 2290-001 device will deliver the appropriate oxygen delivery to the device once it is in situ according to the instructions below:



1. Connect the oxygen tube to the oxygen supply set to 15 LPM test that flow is operating through the Rapid O2 device before connection to luer on I.V. cannula.
2. Confirm position of the cricothyroid/tracheal cannula (not supplied) with a check aspiration.
3. Connect the Luer lock connector to the catheter and ensure it is secure using quick swivel option onthe 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

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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.

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

a. Store in clean and dry place.
b. Do not use if the package open or damaged
c. 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 forreprocessing 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 the cannula and reset position slightly to allow it to reset and undo the kink. Then continue procedure.
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 user as the pressure builds and the user should be aware of this indication of over pressure.
3. Disconnect of oxygen tube or cannula. If no oxygen flow is present check all connections of oxygen tube to flow meter and the 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.

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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Meditech Systems Ltd, Unit 3 Shrublands Estate, Shearstock, Shaftesbury, Dorset, SP7 9PT, England

orders@meditechsystems.co.uk Tel: +44(0)1747 821546 Fax: +44(0)1747 825038

Facebook: @meditechsystemslimited LinkedIn: meditech-systems-limited Twitter: @MeditechLtd

EU Authorised Representative
Clowrey Consultancy
Address; White House at Bridge, Holycross Village, Thurles, County Tipperary, E41 EC65, Eire.

Tel: +44(0)7888744362 E-mail: clowreyconsult@gmail.com

ADVERSE INCIDENT REPORTING

Adverse incidents may be reported to the Competent Authority in the country / region where theincident 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.

= Use by date

= Lot or batch number.

= Device catalogue number / product code / stock

= Date of manufacture.

= Caution

= Sterilised by ethylene oxide (sterile devices only)

= Details of EU Representative

= Humidity storage limitations (sterile devices only)

= Do not reprocess / re-sterilise

CE 1639 =CE mark with notified body number

= Manufacturer

= Consult instructions for use

= Keep away from sunlight

= Keep dry

= Contains latex

= Do not use of packaging is wet or damaged.

= Contains or Presence of Phthalates.

= Storage temperature limitations (sterile devices only)

= Unique device identifier

= Latex Free

Reference; BS EN ISO 15223-1