Instruction for Use

Respiratory Circuit

Variant : Adult and Peadtrics
Product Class as REGULATION (EU) 2017/745 : IIa
Product Class as per Medical Device Rule 2017 : IIa
Duration of use : Short Term

DESCRIPTION

- The Corrugated / Expendable circuit is used to deliver gas from a positive pressure ventilator to the patient. It is typically comprised of tubing that is 22 mm of inside diameter for adult circuit and 15 mm of inside diameter for pediatric circuit. A Respiratory circuit is a medical device used to deliver oxygen, remove carbon dioxide, and deliver inhalational anesthetic agents to a patient.

The device does not contain;

- DEHP
- medicinal substance, including a human blood or plasma derivative,
- tissues or cells, or their derivatives, of human origin
- tissues or cells of animal origin, or their derivatives.

Patient Target Group: All Age groups.

Product Packaging

- The product is available in non-toxic, medical-grade, non-sterile packing,
- The product is a single-use device.

INTENDED USE

- Respiratory circuit is used to deliver oxygen, remove carbon dioxide, and deliver inhalational anesthetic agents to a patient

MODE OF ACTION

- Respiratory therapists and those who work in critical care must learn and understand the principles of mechanical ventilation, including the following:
- Ventilation
- Oxygenation
- Lung compliance
- Airway resistance
- Dead space ventilation

INDICATION

- Breathing obstruction
- Anesthesia

INSTRUCTIONS FOR USE

- Check that the tubes are undamaged before installing them in the pump. During use constantly check for any signs of wear, cracks, leaks or air intake and take the appropriate action.
- Adjust tube occlusion prior to each procedure in accordance with the manufacturer's instructions for use. Improper occlusion may cause deterioration of the under- tubes, excessive wear, breathing flow reading.
- Prior to use, the user is advised to read the labelling information on the labels and IFU.
- User is advised further to examine the integrity of the pack, and opens the pack by tearing the plastic pouch from the specified area indicated on the pack.
- Connect the respiratory circuit tubing (Corrugated/adult) to the ventilator through the cuff connector side.
- Remove the Cap from the elbow so that the another end get ready to connect.
- Connect the another end of the circuit to the patient's mask through the elbow.
- If Respiratory circuit is supplied with individual HME filter, then user has to detach Respiratory Y from the Elbow manually. Then attach one end of the HME filter to the Respiratory Y and another end to the Elbow.
- Now the Respiratory circuit is ready for use.

INTENDED USERS:

Any registered medical doctor, nurse, enrolled nurse, anesthetics technician, or a student in any of those fields. Medical professionals use Respiratory circuit in the Emergency room

CONTRAINDICATION

- This device is not designed, sold, or intended for use except as indicated.
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS

- It converts continuous gas flow from the anesthesia machine to the intermittent flow of breathing, facilitates controlled or assisted respiration, and provides other functions such as gas sampling and pressure and spirometric measurements.

CAUTION/WARNING

- Do not use the product if the package is damaged or open.
- A spare device must always be available during respiration. After some time of use in particular situations which may lead the respiration to believe that the safety of the patient may be jeopardized, replace the device.

RISKS OF RE-USE

- A device designated, as 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended tobe reprocessed and used again, even on the same patient.

Prepared by:	Approved By:

- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has legal implications:
  - anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness;
  - Anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
- Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and, therefore, the performance may be compromised.
- If re-used it may lead, but not limited to cross-infection.
- Troubleshooting: User Paramedic staff should be aware & able to troubleshoot the certain complications may occur during the application of the product such as;

STORAGE

Based on the stability study report as per ICH guidelines the recommended storage condition in between Temp 15˚C to 40˚C and maintaining the relative humiditycondition 50 to 75%. In case of any tempering in the packaging, the product condition may be affected even incase store at above defined condition.

DISCLAIMER

The condition of the device must be verified prior to use. Prymax is not responsible for any damage to person, property, etc. from any inappropriate or recommended useof the device, including reuse. Reuse could cause infection or serious health issues.

DISPOSITION

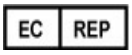
Dispose off/Discard the used Device, in accordance with your country's health care and safety regulations.

GOODS RETURN POLICY

Refer to the company's return goods policy.
Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818

Company Website Link to product IFU: https://www.prymaxhealthcare.com

SYMBOLS USED ON PRODUCT LABEL

Symbol			
Meaning	Caution	Medical Device	Manufacturer
Symbol			
Meaning	Do not re-use	Use-by date	Date of Manufacture
Symbol			
Meaning	Batch/Lot Number	Authorized representative in theEuropean Community	Conformity of European Number
Symbol			
Meaning	Unique Device Identifier	Consult Instruction for use	Stacking limit by number
Symbol			
Meaning	Do not use if package is damaged	Catalogue number	Temperature Limit

Prepared by:	Approved By:

Symbol			
Meaning	Fragile, handle with care	Keep dry	This way Up

Symbol		
Meaning	Keep away from sunlight	

PRYMAX HEALTHCARE LLP.
Address:53/17 Industrial Area NIT,
Faridabad-121001,
E-mail: info@prymaxhealthcare.com,
Website: www.prymaxhealthcare.com
Phone +91-129-4011818

EC REP

Compliance Management Solutions Europe Ltd.
2 Bulgaria Str.,2850 Petrich, Bulgaria
E-mail: gloizou@compliancems.com.au
Contact No.: +61 4 33 124266
SRN of EC Rep: BG-AR-000020809

Prepared by:	Approved By: