

宁波新跃医疗科技股份有限公司

使用说明书

产品名称：麻醉机和呼吸机用呼吸管路

文件编号：RD/S-116-0001

文件版本：A/0

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Instruction for Use

1. Product Name: Disposable Anesthetic Breathing Circuits

2. Product Types:

Model	Description
A1	Breathing circuits
A2	Coaxial circuits
A3	Duo limb circuits
A4	Breathing circuit including sampling tubes
A5	Accessories
A6	Anesthetic circuit including sampling tubes
B	Anesthetic circuit

3. Performance index:

Item	requirement
Intended delivered volume	NLT 300 ml
Flow resistance limit	NMT 0.18kPa at flow 30 l/min
Compliance limit	NMT 50 mL/kPa at 6 kPa
Maximum working temperature when attached to a heated humidifier	45 °C
Maximum working pressure when attached to a heated humidifier	35 kPa

4. Intended use:

The breathing circuit is used in combination with anesthesia machine, respiratory machine or humidifier to establish a respiratory conduit for patients

5. Indications:

Patients who can not breathe spontaneously due to being in general anesthesia, postoperative recovery or intensive care.

6. Contraindications:

- (1) Pneumothorax and its mediastinal emphysema without drainage.
- (2) Bullae of lung.
- (3) Hypovolemic shock revamping.
- (4) Severe pulmonary hemorrhage.

(5) Ischemic heart disease and congestive heart failure

7. Directions for use:

(1) Unpack the package, take out the device.

(2) The bend joint end of the device is connected to the mask or tracheal tube, and the connector end connected to the anesthesia or breathing machine.

8. Warning:

(1) Prohibition of the use of packaging or product damage.

(2) Prohibition of the use of over expire date.

(3) Disposable absorbent condensate humidifier is prohibited for repeated use.

(4) This product should be used under the guidance of professional medical personnel.

(5) The product shall be destroyed after use.

(6) If the flow resistance and compliance exceeds the limit, inhaled gases will be possibly separate and bubble formation appears.

9. Transportation & Storage

The device should be stored in a temperature 10 °C ~40 °C , relative humidity NMT 80%, non-corrosive gas and well-ventilated clean environment.

10. Shelf life

The device is sterilized by ethylene oxide, and shelf life is 2 years after sterilization.



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
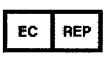








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No.	Symbol	Meaning	No.	Symbol	Meaning
1		DATE OF MANUFACTURE	9		BATCH CODE
2		DO NOT REUSE	10		STERILIZED USING ETHYLENE OXIDE
3		CAUTION	11		CONSULT INSTRUCTIONS FOR USE
4		MANUFACTURER	12		USE BY
5		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	13		DO NOT USE IF PACKAGE IS DAMAGED
6		THE PRODUCT HAS PASSED CE CERTIFICATION	14		CONTAINS OR PRESENCE OF DEHP
7		KEEP DRY	15		DO NOT RESTERILIZE
8		KEEP AWAY FROM SUNLIGHT			

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