TYPENEX MEDICAL

Adult Anesthesia Breathing Circuit Kit

Instructions for Use

Adult Anesthesia Breathing Circuits

Instructions for use

Product name

Disposable Anesthetic Breathing Circuits.

Performance index

Item	Requirement
Intended delivered volume	≥ 300 ml
Flow resistance limit	< 6 Pa/l/min
Compliance limit	< 5 ml/hPa
Maximum working temperature when attached to a heated humidifier	45°C
Maximum working pressure when attached to a heated humidifier	35 kPa

Intended use

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

Indications

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

Intended patient group

Patients who can not breathe spontaneously due to being in general anesthesia, postoperative recovery or intensive care, and aged > 2 years.

Intended users

Professional medical staff who have been trained by anesthesia and first-aid knowledge.

Contraindications

1. Pneumothorax and mediastinal emphysema without drainage.
2. Bullae of lung.
3. Hypovolemic shock revamping.
4. Severe pulmonary hemorrhage.
5. Ischemic heart disease and congestive heart failure.

Directions for use

1. Ensure there is no damage in packaging and the device, including its accessories are not missing.
2. Prior to use, fully extend the tubing system and pressurize to check for leakage, occlusion and malfunction.
3. 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. Confirm all connections are securely fastened.

Warning

1. Prohibition of use if packaging or product is damaged.
2. Prohibition of use past expired date.
3. Prohibition of repeated use.
4. This product should be used under the guidance of professional medical personnel.
5. Do not soak, wash, or sterilize this product.
6. The product shall be destroyed after use.
7. If the flow resistance and compliance exceeds the limit, inhaled gasses will be possibly separate and bubble formation appears.
8. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/ or patient is established.
9. After use, the device shall be isolated and managed as waste, not stored at will. It should be destroyed and disposed of in accordance with the local laws and regulations. Do not discard at will to avoid infection or microbial hazards.

Transportation and storage

1. The device shall be stored in a room temperature, non-corrosive gas, relative humidity <80% and clean environment.
2. Avoid stress, direct sunlight, rain and snow.

Shelf life

The shelf life is 5 years.

Bacterial Virus Filter

Instructions for use

Product name

Disposable Bacterial Virus Filter.

Product structure

The single-use respiratory filter consists of a housing (including an upper and lower cover), filter material, and screw cap.

Product performance

- The exterior of the filter housing should be smooth and clean, free from burrs, stains, impurities, dents, or cracks.
- At a pressure of 0.2 MPa, the flow rate should be ≥30 L/min.
- Under a flow rate of 30 L/min, the pressure difference between the two ends of the product should not exceed 0.2 kPa.
- Under a flow rate of 60 L/min, the pressure drop between the two ends of the product should not exceed 0.5 kPa.
- The leakage rate of the filter housing should not exceed 25 mL/min.

Indications

This product is used in conjunction with anesthesia and respiratory equipment to reduce the number of inhaled or exhaled particulate matter by patients.

Instructions for use

Open the package, connect the patient end of the product to the ventilatory device, and the other end to the breathing circuit.

Precautions and warnings

1. Inspect the product for integrity before use; do not use if damaged.
2. Ensure the product's patency.
3. Do not use the product after the expiration date.
4. For single use only; dispose of the product properly after use.
5. Do not soak, wash, or sterilize this product.
6. After opening the package, check that the device inside is intact.
7. Confirm all connections are securely fastened prior to use.
8. For professional use only; follow the operating procedures strictly.
9. Dispose of the product according to relevant regulations from the hospital or local health authorities by qualified or authorized institutions.
10. Discontinue use immediately if an allergic reaction occurs.
11. The product should not be used for more than 24 hours.
12. Intended use environment: normal room temperature.

Storage and transportation conditions

1. Avoid heavy pressure during transportation; protect from direct sunlight and rain/snow exposure.
2. Store in a well-ventilated, clean indoor environment at room temperature, with humidity between 10%-95% (non-condensing), and free from corrosive gasses.

Contraindications

1. Not to be used by patients with a large amount of foamy or viscous secretions, dehydration, hemoptysis, or respiratory tract injury.
2. Not suitable for patients with severe pulmonary insufficiency who cannot tolerate increased airway resistance.
3. Not to be used by patients allergic to polypropylene.

Manufacturing date and expiration

Refer to the kit package and label for the manufacturing and expiration dates.

Shelf life

The product has a shelf life of five years when stored, transported and used under the recommended conditions.

Anesthesia Masks

Instructions for use

Product name

Disposable Anesthetic Masks (non sterile).

Parts description

As is shown in Figure 1, the Anesthetic Mask consists of a shell (1), air cushion (2), retaining ring (3), and inflation port (4).

The inflation port shall allow users to inflate and deflate the air cushion using a syringe without a needle. The retaining ring shall not detach while operating mask.

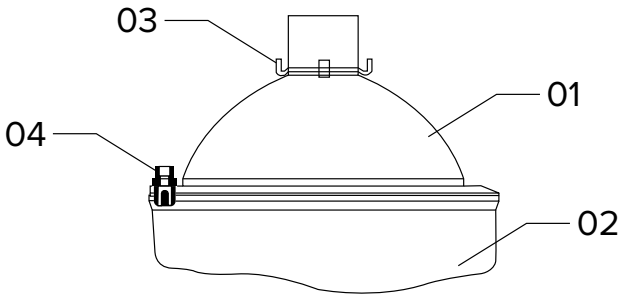

Figure 1: Anesthesia Mask Diagram

Intended use

The Disposable Anesthetic Mask is used as a passage for anesthetic gas to enter into the patient's body, which is usually used with simple respirator, ventilator or anesthetic machine in medical institutions. This kit does not come with anesthetic gas.

Contraindication

N/A.

⚠ Attention

1. Excessive pressure applied to face mask can lead to facial and/or optic nerve damage.
2. The device is designed to be used with a standard 15 mm/ 22 mm connector.
3. Disposal of Anesthetic Masks shall be in accordance with local regulations.
4. Refrain from pressing rigid parts of the mask against the face, nose or eyes.

⚠ Warnings

1. Do not use if the device or package is damaged.
2. Do not use if the device has passed its expiration date.
3. Do not use in the presence of flammable anesthetics.
4. The device is only to be used by medical professionals with the required knowledge and training.
5. The device is for single use and reuse is forbidden, or it may cause cross infection.
6. The device shall not be contacted with oil, or it may cause contamination and discomfort.
7. Do not soak, wash, or sterilize.

Operation method and placement

1. Unpack the mask and check the air cushion for proper inflation pressure.
2. Connect the mask to a breathing circuit that is connected with a respirator, ventilator or anesthetic machine.
3. Place the air cushion on the patient's chin first.
4. Roll the air cushion up the face with gentle, but firm pressure.
5. Be sure all connections are secured, then open the machine and let gas pass through the circuit and mask, to finally be absorbed.
6. If there's a concern of mask failure, please replace it immediately.

Storage conditions

1. The device should be stored in a non-corrosive gas, relative humidity < 80% and clean environment.
2. Avoid hard pressure, direct sunlight and rain-snow exposure.

Caution

1. This device contains or has presence of DEHP (see symbol glossary).

Shelf life

The shelf life is 3 years.

Breathing Bag

Instructions for use

Product name

Breathing Bag.

Main structural components of the product

This product consists of a breathing bag and breathing bag connector. The breathing bag is made from elastic rubber, and used with anesthesia circuits.

Intended use

The breathing bag is used for storing anesthetic, oxygen, or other medical gasses from an anesthesia or breathing machine during anesthesia procedures.

Instructions for use

1. Confirm that the product's packaging is intact before use. Replace bag if there is damage to packaging.
2. Connect the product to the anesthesia/breathing machine according to the operation specification of the machine.
3. Tighten all connections to prevent air leakage and loosening.
4. Use the product correctly according to the specification of the anesthesia machine.
5. After use, dispose of the product according to medical waste disposal procedures.

Precautions and warnings

1. Carefully read the instructions before use.
2. Use immediately after opening, dispose of product after single use as medical waste.
3. Do not use if package is damaged.
4. Do not soak, wash, or sterilize.

Storage conditions

Store the product in a cool, dry room, avoiding direct sunlight exposure and overheating.

Production date, expiration date

Refer to the label for production date and expiration date.

Shelf life

The shelf life is 5 years.

GSL - Gas Sampling Line

Instructions for use

Scope of application

It is used in combination with the monitor and breathing pipe to transport the patient's exhaled gas for the monitor.

Contraindication

N/A.

Installation and use methods

The sampling tube features a male luer lock connector, which securely attaches to the female luer lock connectors on both the breathing line and the monitor. This allows for the extraction of exhaled gasses into the monitor for measurement.

Sterilization method

Non-sterile.

Precautions and warnings

1. Do not use if the packaging or product is damaged.
2. Carbon dioxide sampling tubes are strictly prohibited for reuse.
3. Use this product only under the guidance of medical professionals.
4. It is strictly forbidden to reuse the sampling tube used in the anesthesia machine and ventilator.
5. Do not soak, wash, or sterilize this product.
6. After use, the products shall be disposed of in accordance with the requirements of the Regulations on Medical Waste Management.

Storage and transportation conditions

1. Do not stress during transportation; avoid direct sunlight, rain and snow;
2. It should be stored in a relative humidity of no more than 80%, no corrosive gasses, and in a well ventilated and clean room.

Shelf life

Under the conditions of complying with the rules of storage, transportation, storage and use, the use period is 5 years from the date of production.

Symbols Glossary

Symbol	Meaning	Description of Symbol	ISO 15223-1
	Consult Instructions for Use	Indicates the need for the user to consult the Instructions for Use	5.4.3
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	5.4.4
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	5.2.8
	Do not reuse	Indicates a medical device that is intended for one single use only	5.4.2
	Keep dry	Indicates a medical device that needs to be protected from moisture	5.3.4
	Manufacturer	Indicates the medical device manufacturer	5.1.1
	Date of Manufacture	Indicates the date when the medical device was manufactured	5.1.3
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	5.1.5
	Medical Device	Indicates the item is a medical device	5.7.7
	Use by Date	Indicates the date after which the medical device is not to be used	5.1.4
	Keep Away From Sunlight	Indicates a medical device that needs to be protected from light sources	5.3.2
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	5.1.6
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	5.3.7
	Contains or presence of DEHP (Anesthesia Masks Only)	Indicates the presence of di-(2-ethylhexyl) phthalate (DEHP) or DEHP as a material of construction within the medical device or the packaging of a medical device.	N/A

Manufactured for Typenex® Medical, LLC
303 East Wacker Drive, Suite 1030
Chicago, Illinois 60601 USA

P 866-897-3639
F 866-897-3630
W www.typenex.com