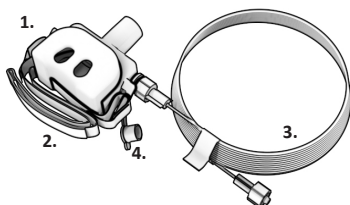


Reference #	Description
PX-A-1005	XChange™ Device

XChange™ Device

1. XChange Device
2. Strap
3. Gas sampling tube
4. Sampling port cap



Device Description

The XChange Device is a multi-port nasal positive airway pressure apparatus consisting of a conforming nasal seal and an air chamber, which includes a standard 15mm male fresh gas supply port and an exhaled gas sampling port. The fresh gas supply port can be used to connect a respiratory circuit or anesthesia circuit. The gas sampling port can be used for sampling exhaled gases for monitoring, such as end-tidal CO₂, via the gas sampling tube provided.

Indications for Use

The XChange Device is a nasal mask that creates a seal when positioned over a patient's nasal base to direct anesthesia gas, air, and / or oxygen to the upper airway during the continuum of anesthesia care.

The XChange Device has a means for sampling expired gases from the patient's exhaled breath from the nasal areas.

The XChange Device is a single use device, intended for short-term (<24 hours) use on adult patients (>30 kg.).

The XChange Device is to be used under clinical supervision with adequate alarms and safety systems for monitoring and treatment of ventilatory failure.

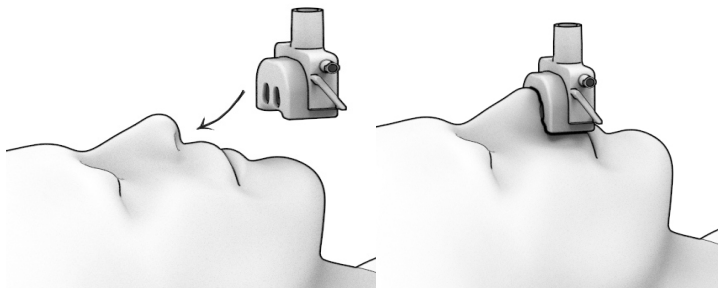
Contraindications for Use

The XChange Device is contraindicated for use in long-term ventilation conditions and treatment of sleep apnea.

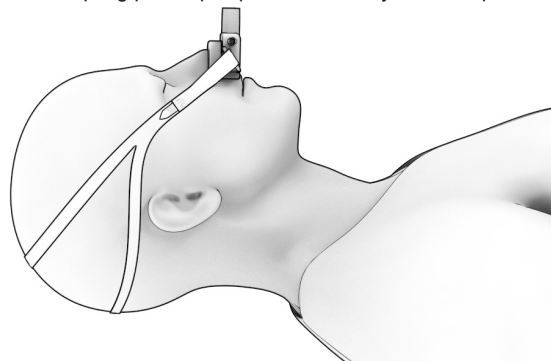
The XChange Device is not intended as an interface for high-flow nasal oxygen (HFNO) or any gases at flow rates greater than 15 LPM.

Directions for Use

1. Remove contents from packaging and inspect for damage before use.
2. The gas sampling tube is pre-attached to the gas sampling port. To sample exhaled gas for monitoring, connect the tube to the gas monitoring equipment and refer to the IFU. If not sampling expired gases, detach the gas sampling tubing from the XChange Device and close the sampling port cap over the sampling port.
3. With the patient in the supine position, place the XChange Device over the nasal base with the openings in the conforming nasal seal aligned with the nares.



4. Place the head strap over the patient's crown and adjust position for comfort. If required, adjust the hook and loop tabs on the head strap to achieve placement between the conforming nasal seal and the nasal base. Verify that the sampling port cap is positioned away from the patient's eye.



5. When interfacing the XChange Device with a respiratory circuit or anesthesia circuit, connect the circuit to the 15mm gas supply port and refer to the circuit IFU.
6. Make sure all connections are secure. To use the XChange Device for nasal positive airway pressure, only connect with a circuit or device that has an exhalation port.
7. For any gas, air, or oxygen leak that are identified in the circuit, adjust the XChange Device straps and/or position against the nasal base to achieve the required seal with the desired circuit configuration.
8. To remove the XChange Device, simply detach the head strap from its connection and lift off the patient.

Cautions

Federal (USA) law restricts these devices to sale by or on the order of a physician.

1. This device must only be used by medical personnel well trained in manual ventilation and airway maintenance techniques.
2. Do not autoclave, gas, or chemically sterilize the device.
3. Reuse of this device may pose a risk of cross-contamination and it may not perform as intended.
4. When using this device, it is recommended that clinicians continually monitor oxygenation and ventilation. Flow rates and pressure levels shall be based on clinical experience and judgement.
5. Facial hair and unusual mandibular anatomy may potentially lead to poor device performance.

Disposal Specifications

Dispose this device in accordance with local, state, and federal regulations. Decontaminate and dispose of all potentially biohazardous material.

Technical Specifications

Deadspace volume: 12ml

Storage Conditions:

Temperature [-4° to 140° F (-20° to +60° C)]

Relative Humidity [0% to 95%, non-condensing]

All materials in contact with the patient have proven biocompatible profiles.

Warnings

1. The health care provider should confirm proper fit prior to use. If a seal cannot be achieved, an alternate device should be used.
2. This device should only be used on patients >66lbs/30kg.
3. When using the head strap, do not use excessive pressure at any time; such action could lead to injury. Continually monitor the head strap to avoid patient skin injury.
4. This device may not be suitable for those predisposed to aspiration.
5. This device is only for use by a trained health care provider. Read all instructions prior to first use.
6. This device shall be used in accordance with this IFU. Read all sections of this IFU prior to use. Improper use of this device may cause serious injury.
7. Do not allow smoking or use this device near spark, open flame, or in toxic or hazardous atmospheres.
8. This device is a single use device and is not to be used by more than one patient. Do not clean or sterilize. Sterilization or use of cleaning solutions may result in retention of harmful residues or leave the device non-functional.
9. Do not use this device with an oral or nasopharyngeal airway device; such action may lead to oxygen desaturation.
10. Clinician should monitor and control inspiratory pressures during use of this device, as maintaining a proper seal of the nasal airway may be difficult and the use of high peak airway pressures may increase the risk for gastric insufflation.
11. Do not use on patients with nasal obstruction, nosebleed, nose fracture, or after nasal surgery.
12. During use of this device, a continuous gas flow must be maintained, not to exceed 15 LPM.
13. Flow rates can generate excessive airway pressure.
14. Excessive nasal interface pressure against the nasal base can lead to facial/or nasal nerve damage.
15. When used with anesthetic gases, ensure there is a proper connection to waste gas scavenging.
16. Discontinue use of the device if there is an allergic reaction to any part of the device.
17. Monitor periodically the patient's oxygen levels while device is in use.
18. Monitor periodically peak airway pressures to avoid over-pressurization. Over-pressurization could cause lung injury (barotrauma).
19. The effect of device dead space on patient ventilation should be evaluated on an individual basis.
20. For nasal positive airway pressure, only connect with a respiratory or anesthesia circuit that has its own exhalation limb or valve.
21. Monitor nasal airway periodically during use of the device for indications of dryness/ or soreness.



Do not re-use



Catalogue number



Lot Number



Quantity



Use By



Consult Instructions for Use



Not made with DEHP



Not made with natural rubber latex



Country of origin



Unique Device Identifier



U.S. Federal law restricts this device to sales by or on the order of a physician



Manufacturer



Date of Manufacture



Non-Sterile



Caution



Temperature Limitation



Humidity Limitation

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Patent: US 12,453,833 B2; US 12,558,508 B2;
Other patents pending.