



EN: ENGLISH

Bongo Rx

Instructions for Use – 14012 Rev C

Description

The Bongo Rx is an intranasal device that is placed just inside the nostrils. The Bongo Rx operates as follows:

- During inhalation, small Valves open to allow you to breathe normally through the device.
- During exhalation, the Valves close (you will feel a resistance to exhalation) and exhaled air is vented out through the bottom of the device.

The Bongo Rx may be reused multiple times by a single patient.

Intended Use

Bongo Rx is indicated for use in the treatment of mild to moderate obstructive sleep apnea (OSA) in adults > 66 lbs (> 30 kg).

Contraindications

This device is contraindicated for use in patients with the following conditions:

- Severe breathing disorders including hypercapnic respiratory failure, respiratory muscle weakness, bullous lung disease (as seen in some types of emphysema), bypassed upper airway, pneumothorax, pneumomediastinum, etc.
- Severe heart disease (including heart failure)
- Pathologically low blood pressure
- An acute upper respiratory (including nasal, sinus or middle ear) inflammation or infection, or perforation of the ear drum

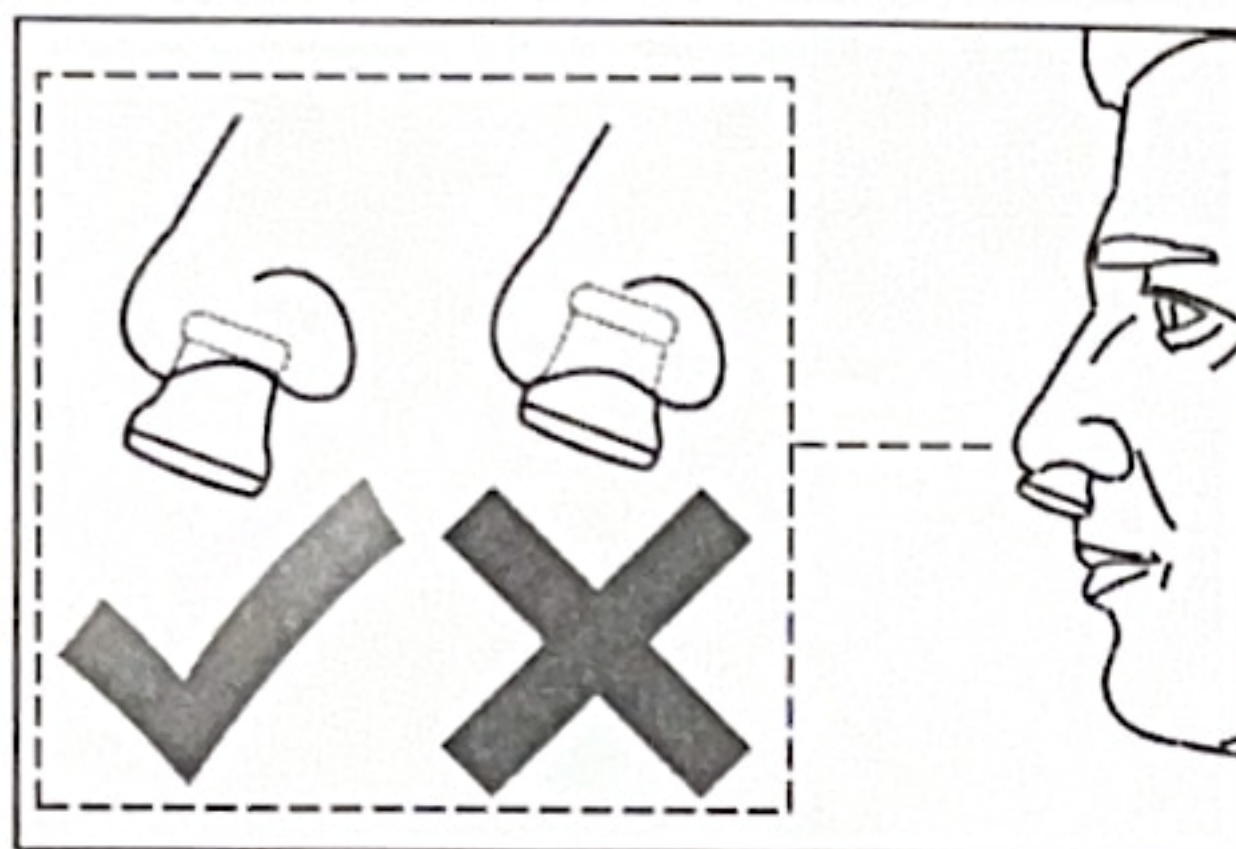
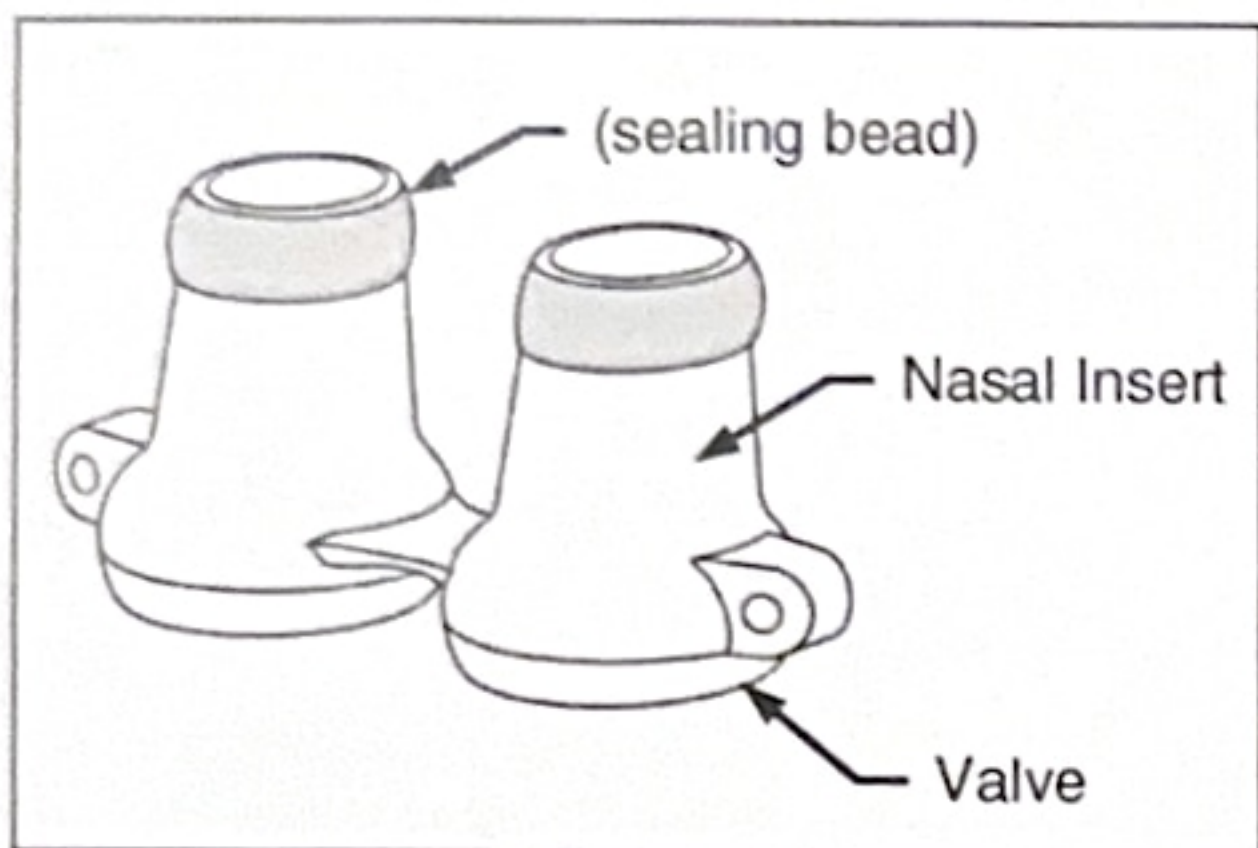
Warnings

- In the USA, federal law restricts this device to sale by, or on the order of, a physician. (Rx ONLY). The device should be used with the recommendation of your physician or licensed health care provider authorized to write the prescription.
- Patients who are unable to breathe through their mouth or experience excessive discomfort when breathing through the device should discontinue use of the device and contact a physician.
- Patients who develop nasal, sinus or ear infection or inflammation should discontinue use of the device and contact a physician.
- Patients who develop any reaction or notice any redness or irritation of the nose or skin should discontinue use of the device and contact a physician. The device consists of silicone, polycarbonate, nylon, spandex, as well as metal snaps.
- This device is intended for single-patient use only and thus use by multiple patients is to be avoided due to the risk of transmitting infection. Do not attempt to sterilize or use disinfectants on this device.
- Do not obstruct the Valves or any of the vents.
- If the patient experiences any continuation or recurrence of symptoms of OSA after using the device, the patient should consult their physician. Assessment of effectiveness and follow-up testing and evaluation should be conducted to ensure adequate treatment effect.

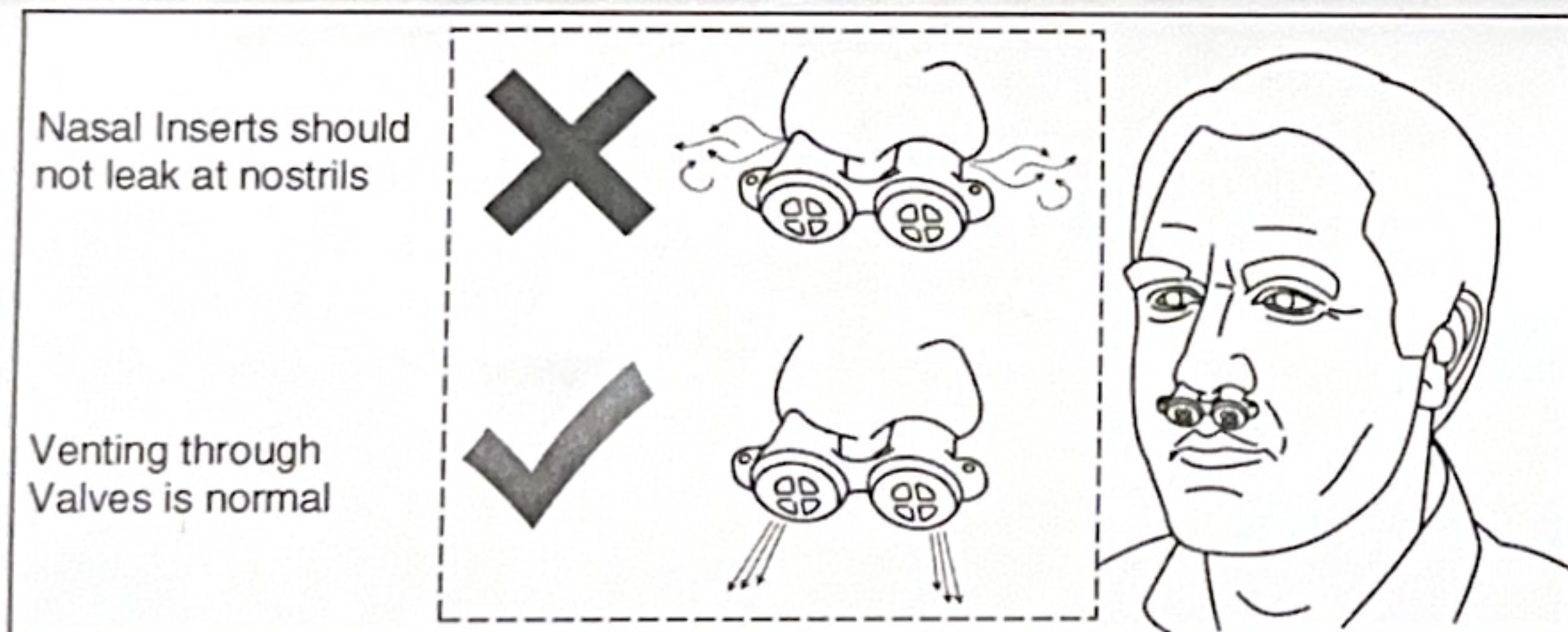
Selecting your Nasal Insert Size

There are four different sizes available for the Bongo Rx in the "All Sizes Starter Kit". NOTE: The Nasal Inserts have a size marking (either a SM, MD, LG, or XL). NOTE: It is highly recommended to try all four sizes before selecting your final size. To find the correct size:

1. Start with the smallest size (SM).
2. Gently insert the sealing beads of the Nasal Inserts until the sealing beads are just inside your nostrils. (NOTE: You should not need to insert the Nasal Inserts past the sealing beads as pushing the sealing beads too far inside your nostrils may cause leaks and/or discomfort).



3. If the fit of the Nasal Inserts is too loose and they will not stay in your nose, then try the next larger size Nasal Inserts.
4. Repeat this process until you find the size that feels snug but not too tight in the nose.
5. Test the seal to your nose by covering the bottoms of both Valves with your thumbs and then exhaling with your mouth closed. You should not detect any air leaks escaping around the sealing beads of the Nasal Inserts.



6. If you feel a leak around your nostrils, then try the next larger size Nasal Inserts and repeat step 5. (NOTE: Exhaled air venting through the bottom of the Valves is normal).

(For further fitting instructions, please reference the video located at www.AirAvant.com)

Applying the Device

1. Prior to first use and after every use, clean the device as described in the Cleaning Instructions.
2. Insert the sealing beads of the Nasal Inserts into your nostrils as described in the Sizing section.
3. To remove the device, gently pull the Nasal Inserts out of your nose.

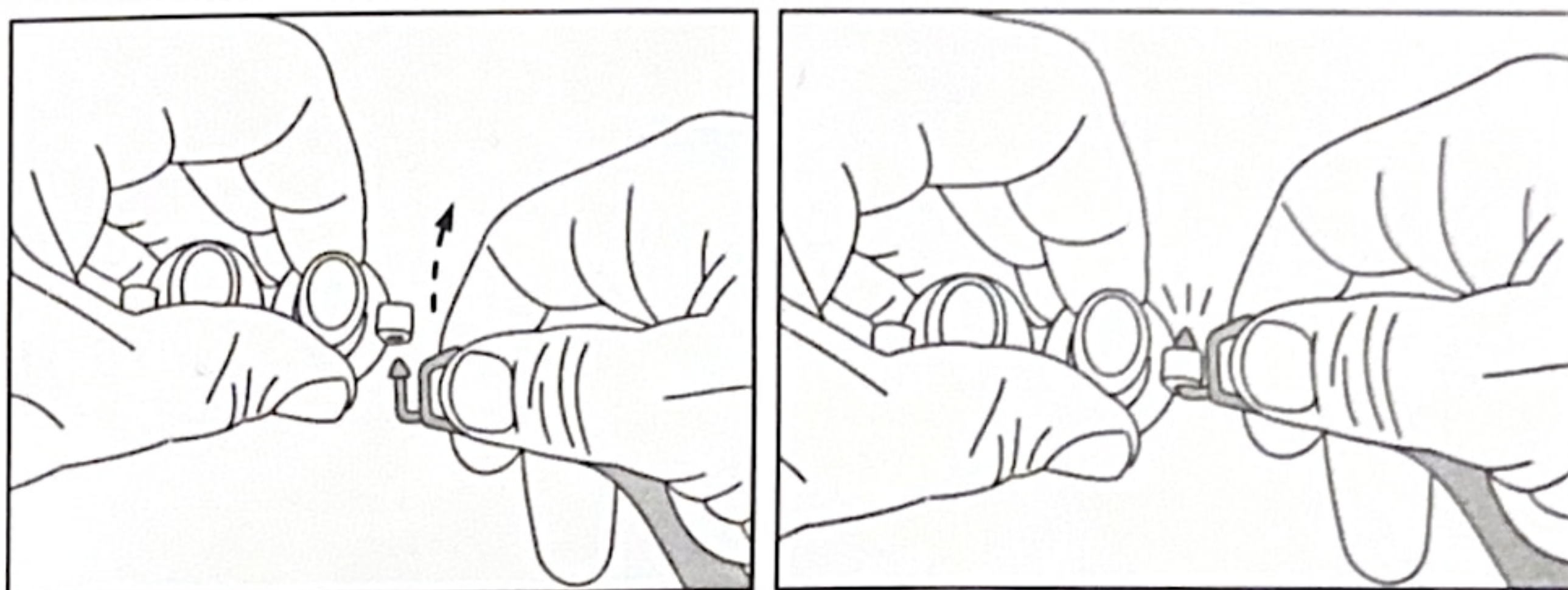
Getting Used to Bongo Rx

It may take you several days to get used to wearing the device. This is normal. You may want to first wear the device while you are reading or watching TV to get used to the feel. You can also exhale through your mouth occasionally when wearing the device until you fall asleep. Just try to relax. If you wake up feeling uncomfortable during the night, take the device off and try again tomorrow.

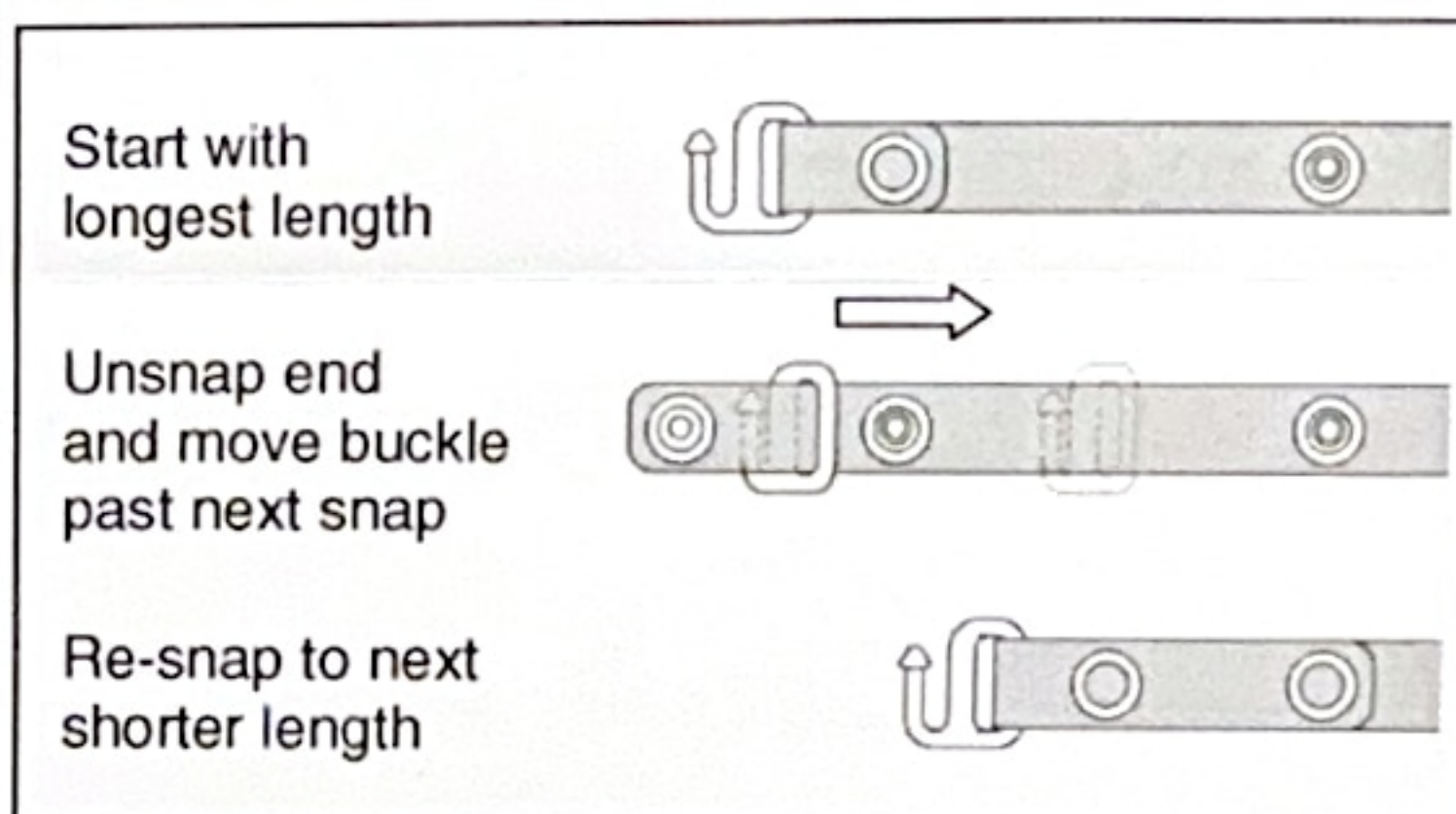
Using the Device with the Optional "Zero-Tension™" Headgear Accessory

Try using the Nasal Inserts first without the Headgear. If the Nasal Inserts tend to inadvertently dislodge during use, then you may try the Headgear accessory for further stability.

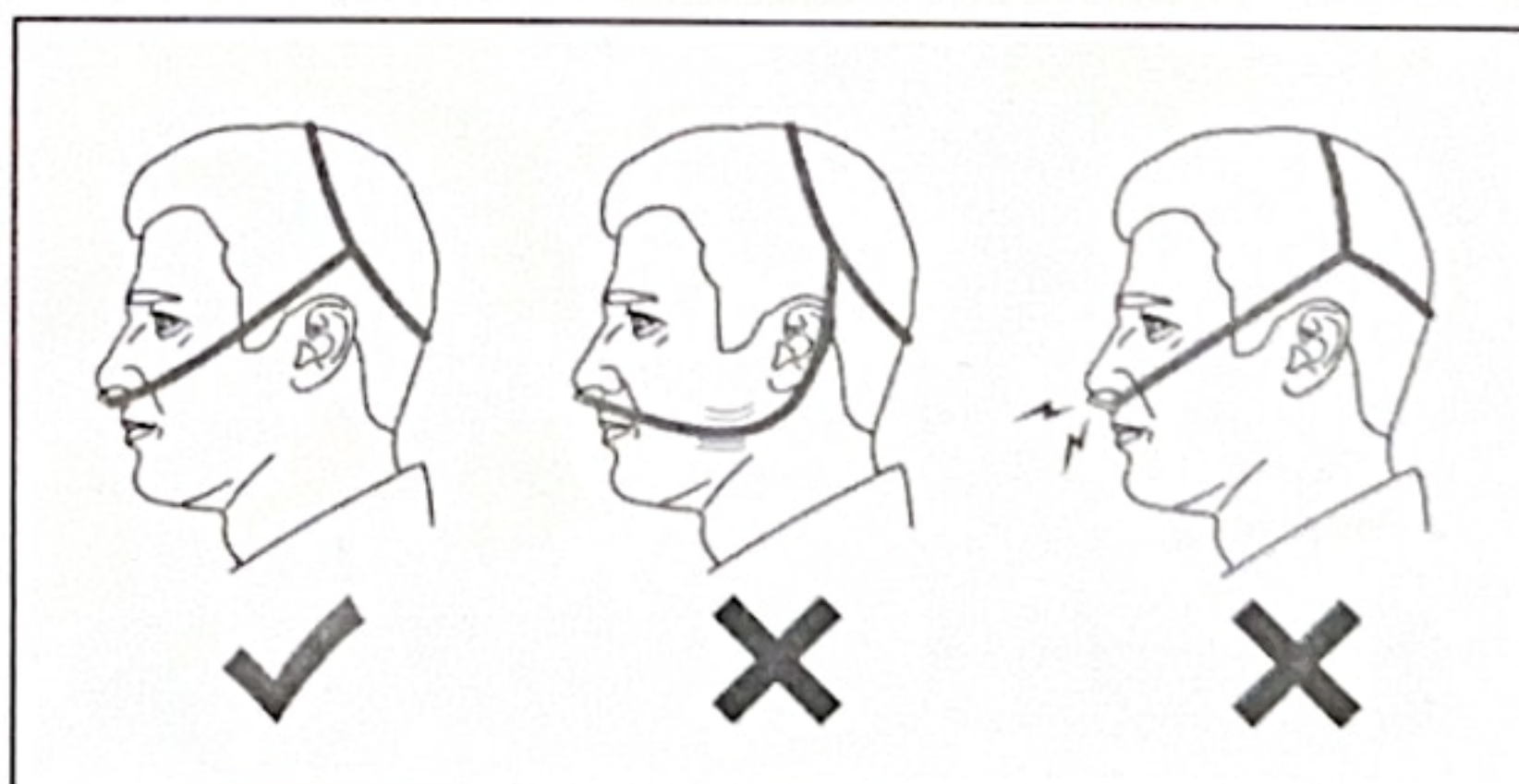
1. Attach the Headgear to the Nasal Inserts using the Quick Connect Buckles.



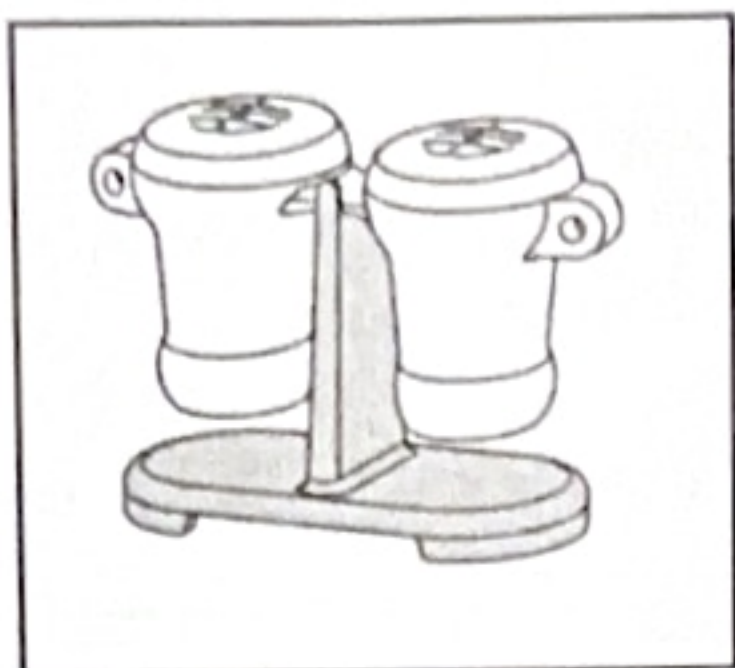
2. The length of the Headgear straps may be adjusted for your comfort, as shown below. Please begin with the longest strap configuration when selecting your size. (NOTE: Adjustments to the length of Headgear straps should be done equally on both sides).



3. Stretch the Headgear over your head and gently insert the sealing beads of the Nasal Inserts into your nostrils as described previously.
4. Adjust the Headgear position on your head, as well as the strap lengths, as needed until the device fits comfortably. (NOTE: The Headgear should be just tight enough to provide additional security of the Nasal Inserts without pushing the Nasal Inserts further into your nose. Over-tightening the headgear may cause leaks and/or discomfort.)



Using the Drying Stand and Travel Case Accessories (included in multi-unit packs only)



The Drying Stand may be used to elevate the Nasal Inserts while drying (see Cleaning Instructions).



The Travel Case may be used to hold the device during travel. Do not use the Travel Case for daily or extended storage.

Cleaning Instructions

- (NOTE: The Nasal Inserts should be washed after each use; the Headgear should be washed weekly.)
1. Remove the Headgear from the Nasal Inserts. (NOTE: Do not disassemble the Buckles from the Headgear.)
 2. Do NOT attempt to disassemble any other components as this is not needed and can damage your device.
 3. Gently hand-wash the Nasal Inserts and Headgear in warm, soapy water. (NOTE: Only use pure, unscented soap.) (NOTE: Do not use alcohol, petroleum products, or strong cleaners. Do not machine wash, scrub, or wipe any component. All of these may cause damage and reduce the life of the product.)
 4. Gently rinse all components and shake out excess water from inside the Nasal Inserts.
 5. Allow all components to completely air-dry, away from direct sunlight.
 6. Make sure that all vents are free of any obstructions and that the Valves move freely.
 7. Carefully inspect each component for any wear or damage. Discontinue use if you notice any cracks in the plastic, any tears or hardening of the flexible parts, any significant fraying or loss of elasticity of the headgear, or if the Valves do not move freely, and contact your healthcare provider for a replacement. Discoloration is normal after several washings and should not be considered sign of wear. (NOTE: The entire device should be replaced at least every 90 days.)

Storage and Disposal

Ensure the device is thoroughly clean and dry before storing it for any length of time. Store the device in a dry, ventilated place out of direct sunlight. This device does not contain any hazardous substances and may be disposed of with your normal household refuse.

Storage Temperature:
-20° to 60°C
(-4 to 140°F)



Not Made with
Natural Rubber
Latex

For patent and trademark
information, please see
www.AirAvant.com

Manufactured for:

AIRAVANT
MEDICAL

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Designed, molded, and
assembled in the USA

Reorder Information

Part Number	Description	Part Number	Description
BNG500	Bongo Rx - All Sizes Starter Kit (includes 1 of each size)	BNG530	Replacement Headgear Accessory for Bongo Rx
BNG502	Bongo Rx - Annual Replenishment Pack - SM (includes 4 of size SM)		
BNG503	Bongo Rx - Annual Replenishment Pack - MD (includes 4 of size MD)		
BNG504	Bongo Rx - Annual Replenishment Pack - LG (includes 4 of size LG)		
BNG505	Bongo Rx - Annual Replenishment Pack - XL (includes 4 of size XL)		