

Frequently Asked Questions

What is the indication for use of aerSleep™?

The aerSleep™ system has been approved by Health Canada for use as an aid for maintaining an open, upper airway in adults diagnosed with obstructive sleep apnea. Use of the aerSleep system, including home use by patients, must be prescribed and trained by qualified health care professionals (HCPs).

What is the Health Canada classification for aerSleep™?

aerSleep is a Class II device cleared by Health Canada on June 8, 2017. The license number is 99285.

What are the benefits of aerSleep compared to other devices?

aerSleep allows sleep without limitations. aerSleep is non-invasive and no masks, headgear, hoses, or cords are required. It is very simple and easy to use.

How do aerSleep™ and aer+™ technology work?

The aerSleep system is a device that utilizes continuous negative external pressure, aer+™ technology (formerly known as cNEP), to reduce the occurrence of upper airway collapse during sleep. The aerSleep system consists of a soft, flexible, silicone collar fitted on the mandible and exterior neck area with a built-in, rechargeable battery and vacuum air pump module. The pump module uses continuous negative external pressure on the outside of the neck to gently open the airway and maintain airflow.

What clinical studies support aerSleep's effectiveness?

Health Canada approval was received on June 8, 2017 based on a Clinical Study conducted at the Toronto Sleep Institute. The study concluded, in subjects with all degrees of OSA severity, the aerSleep device offers a safe and effective option for people who find the aerSleep device easier to use, more acceptable and better tolerated than other treatment alternatives. In patients, AHI and ODI were significantly reduced compared to their baseline values.

How many sizes are there of aerSleep™?

There are two collars, Size 1 and Size 2. Your clinician will fit you during the fitting assessment with the correct size. Additional sizes are anticipated in the future.

Can children use aerSleep™?

No, aerSleep is only approved for use by adults.

Is aerSleep™ a single patient-use disposable or reusable?

aerSleep is a non-sterile, single patient-use, reusable medical device cleared as a Class II Device for sale only in Canada.

How do I wear aerSleep™?

The aerSleep system is applied by first double tapping the pump module to start the pump. Then, rest the chin cup on the patient's chin, and then rotate the collar downward until the bottom of the collar touches the patient's neck and the sides of the collar contacts and seals against the patient's neck and jaw. It's important that the upper edge of the collar is as close as possible to being parallel with your mandible. Please refer to the aerSleep Overview Video and Instructions For Use for more comprehensive instructions on how to correctly apply aerSleep.

How do I turn on aerSleep™?

Double tap the pump module to turn on aerSleep and you should hear the pump now working. A solid green light indicates that aerSleep is fully charged and ready for use. If the green light is blinking, it means the battery is not fully charged and should be charged.



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How do I turn off the aerSleep™ system?

aerSleep will automatically turn off approximately one minute after it has been removed.

How do I clean aerSleep™?

Since the pump module cannot be removed, do not use water, soaps or other cleaning products or you may damage the pump module. aerSleep should be cleaned daily as needed using a lint free wipe, such as CPAP wipes or medical-use alcohol wipes (70% isopropyl)

What therapy pressure can be used with aerSleep™?

aerSleep can be operated between -25 to -30 cm H₂O.

What is the service life of the aerSleep™ system?

The aerSleep system is designed to last for 2 years.

How long will the battery life of the pump module last per each night of use?

The estimated duration of the battery life is 10 hours of continuous operation and is dependent on how well the collar is applied.

What is the weight of the aerSleep™ system?

The weight is approximately 165 grams (5.8 ounces) for Size 1 and 155 grams (5.5 ounces) for Size 2.

What is the aerSleep™ collar made of?

aerSleep consists of a soft, flexible collar made from medical grade silicone and does not contain latex. It is also DEHP free.

Is there reimbursement for aerSleep™?

There is currently no reimbursement for the aerSleep system in Canada.

Will aerSleep™ work with facial hair?

No, aerSleep will not work on patients who have facial hair around the mandible and exterior neck area, such as a full beard. The flange or sides of aerSleep's collar must lay flat along the skin, which allows for an airtight seal to form, and the presence of hair creates opportunities for air leaks to occur. If patients have facial hair, they are recommended to shave several hours prior to use of aerSleep.

What is the purpose of the gel on the collar's sides?

The gel on the collar's sides is provided to assist patients in the initial few months with acclimation to use of the aerSleep system. The gel acts as training wheels and after a few months, the gel will wear off. Please note that the gel is not necessary for retaining the collar in place at night, and is only intended as a helpful tool.

Will the gel on the collar leave any residue on the patient's neck?

No, the gel on the collar should not leave residue on the neck.

Are there any skin issues after using the device?

In clinical trials, only mild redness under the collar's flange was observed, which self-resolved in about 20-30 minutes. Some people may have a possible allergic reaction to silicone materials, and should consult with their doctor if an allergic reaction occurs.

What if I want to discontinue use of aerSleep™?

Contact your local AvantSleep office to schedule a return of your aerSleep system and aerSleep tablet.

