PROVENT®

SLEEP APNEA THERAPY

Caution: Federal law restricts this device to sale by or on the order of a physician.

Carefully read all labeling information prior to using this device.

Description

PROVENT Sleep Apnea Therapy is a disposable nightly-use nasal device.

The PROVENT Nasal Device is placed just inside the nostrils and is held in place by adhesive. The device directs expiratory flow through small holes, which increases airway pressure during the expiratory phase of the respiratory cycle in similar fashion to the expiratory phase of CPAP therapy. This airway pressure is maintained until the start of the next inspiration. The expiratory resistance created by the PROVENT Nasal Device helps maintain an open airway during sleep. PROVENT Therapy is offered in two expiratory resistances to accommodate varying patient preferences. The PROVENT Nasal Device is a prescription-only device and should be used only after consultation with a licensed healthcare professional.

Indication

PROVENT Sleep Apnea Therapy is indicated for the treatment of obstructive sleep apnea (OSA).

Contraindications

Based on clinical studies involving similar therapies, the PROVENT Nasal Device is contraindicated for use in patients with the following conditions:

- Severe respiratory disorders (including respiratory muscle weakness, bullous lung disease such as 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 tympanic membrane.

Warnings

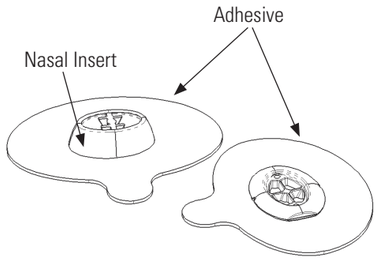
- Assessment of effectiveness and follow-up testing and evaluation should be conducted to ensure adequate treatment effect.
- Patients who experience an allergic reaction to any part of the device should discontinue use of the PROVENT Nasal Device and consult a physician.
- Patients who are unable to breathe through their mouth, experience excessive discomfort when breathing through the device, or experience any abnormal breathing patterns should discontinue use of the PROVENT Nasal Device and consult a physician.
- Patients who develop nasal, sinus or middle ear infection or inflammation should discontinue use of the PROVENT Nasal Device and consult a physician.
- Patients who experience severe epistaxis (nose bleed) should discontinue use of the PROVENT Nasal Device and consult a physician.
- Patients who develop skin or mucosal irritation, rash, sores, or other discomfort in or around the nose should discontinue use of the PROVENT Nasal Device and consult a physician.
- Keep out of reach of children.

Precautions

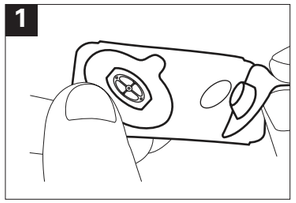
- Patients should be instructed to breathe through their mouth while falling asleep if mouth breathing is more comfortable than nasal breathing through the device.
- The safety and effectiveness of PROVENT Therapy in pregnant women, children under the age of 18, and patients with central sleep apnea have not been established.
- Patients should not use any single PROVENT Nasal Device for longer than one sleep cycle (e.g., overnight). The PROVENT Nasal Device is intended for single use only and should be disposed of after use.
- Patients should not use the PROVENT Nasal Device if they have any sores, abrasions, or skin or mucosal irritation on or around the entrance to the nose.

Adverse Reactions

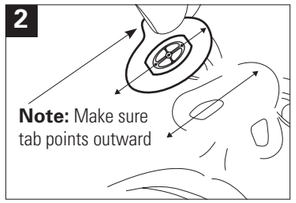
Potential adverse reactions include mouth breathing which may worsen snoring or OSA; nasal, sinus or middle ear discomfort; nose bleed; dry mouth; nostril pain or dilation; and headache.



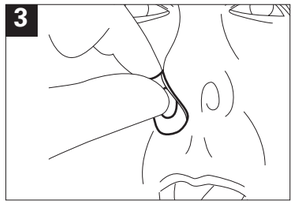
Directions For Use



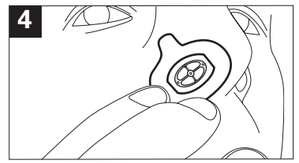
Peel off the adhesive from the paper backing.



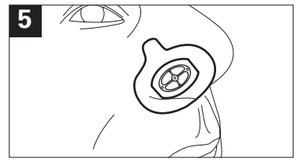
Align the long axis of nasal insert with the long axis of one of the nostrils to ensure a good seal. Make sure the side tab points outward.



Once aligned, place the nasal insert into the nostril. Stretch the lower nostril area as if shaving the area above the upper lip. This will help ensure a good seal.



Gently press down around the adhesive to ensure a good seal. Check to make sure there are no folds or creases which may compromise the seal.



Once in place, the adhesive should be adhered as shown. Repeat steps 1-4 for the other nostril.

Use a mirror to check that both devices are properly fitted. Some overlap of the adhesive portions of the two devices is common, but make sure the adhesive does not cover either of the plastic nasal inserts.

If you find that one of the devices is not positioned correctly, remove the device and try repositioning it.

Repeated repositioning of the device will weaken the adhesive and reduce the effectiveness of the device. If the adhesive no longer feels sticky, dispose of the device and apply a new one.

Patients should be instructed to breathe through the mouth while falling asleep or in through the nose and out through the mouth - whichever is more comfortable.

Remove the PROVENT Nasal Device by gently peeling the adhesive away from the nostril.

How Supplied

The PROVENT Nasal Device is supplied non-sterile and is intended for single use only. It should be stored in a cool, dry place.

Importance of Treatment Continuity

OSA is a chronic disease that should be treated every night during sleep. If the patient experiences any continuation or recurrence of symptoms of OSA after using PROVENT Sleep Apnea Therapy, the patient should consult with his or her physician.

Directions for Wearing PROVENT Therapy:

PROVENT Therapy may take some "getting used to." The device works by making it harder to breathe out through your nose, which helps create the pressure needed to treat your obstructive sleep apnea. It may require several nights of use to feel comfortable breathing with the device. These steps and tips will help you get used to wearing the PROVENT Device before and during sleep.

1. INHALE

- Inhale through your mouth or through the device - whichever is more comfortable for you to fall asleep.

2. EXHALE

- Notice the resistance when you exhale through your nose. When applied correctly, you will feel this resistance and know the device is working. This is normal.
- You can breathe out through your mouth if that feels more comfortable than breathing out through your nose.
- Generally, people switch to nasal breathing once asleep, effectively "turning on" the device.
- Do not try to force air out through the device when exhaling; relax and allow air to exit at its natural rate.

3. RELAX

- Do not engage in any activity while wearing the device—just try to fall asleep.
- Simply apply the device and go to bed.
- Keep a glass of water near your bedside, in case you wake up with a dry mouth.

4. REPEAT

- Take time to get used to wearing PROVENT Therapy.

5. COMMIT

- Use all devices provided in the pack.

Clinical Data

Below is a summary of the clinical trial data of PROVENT Sleep Apnea Therapy including pooled data of different expiratory resistances. The devices have been determined to have equivalent clinical effects.

Objective of the Studies:

The objective of the studies was to evaluate the effectiveness of PROVENT Sleep Apnea Therapy in treating obstructive sleep apnea (OSA).

Test Methods, Procedures and Conditions:

In multicenter, prospective, randomized cross-over trials, subjects underwent polysomnographic (PSG) evaluations, some with the device in place (treatment) and some without (control). To address the "first night effect," the treatment/control night order was randomized. PSG data were scored by an independent certified sleep technologist who was blinded to subject and device/control status.

Study Measures:

The Apnea-Hypopnea Index (AHI), Apnea Index (AI), duration of the apneas, Oxygen Desaturation Index (ODI), total sleep time, and sleep efficiency were compared and contrasted between control and treatment nights. The Chicago Criteria[1] were used to score sleep parameters.

Study Results:

The AHI, AI and ODI were significantly improved ($p \leq 0.001$) in the treatment nights as compared to control nights (see Table 1). Total sleep time, sleep efficiency and duration of the apneas were not significantly different, indicating that the PROVENT Nasal Device did not worsen sleep parameters and did not extend apnea duration. Further results of the first two effectiveness studies are stratified by control night OSA severity and presented below in Tables 2, 3 and 4.

Table 1: Analysis of Apnea-Hypopnea Index, Apnea Index and Oxygen Desaturation Index
(Subjects with Control Night AHI ≥ 5)

	N	Mean	Median	Min to Max	STD	p-value*
Apnea-Hypopnea Index (apneas and hypopneas per hour of TST)						
Control Night	58	26.6	16.7	5 to 105	24.85	
Treatment Night	58	14.0	7.6	0 to 97	20.05	
Treatment - Control	58	-12.6	-9.7	-62 to 8	14.10	<.001
Apnea Index (apneas per hour of TST)						
Control Night	58	16.9	9.0	0 to 90	21.77	
Treatment Night	58	7.6	2.0	0 to 84	17.16	
Treatment - Control	58	-9.2	-4.9	-62 to 8	13.03	<.001
Oxygen Desaturation Index (3% desaturations per hour)						
Control Night	58	13.1	7.0	0 to 80	17.37	
Treatment Night	58	9.5	4.6	0 to 73	14.62	
Treatment - Control	58	-3.6	-1.5	-31 to 11	7.55	<.001

Note: *p-value from a paired t-test.

Table 2: Analysis of Apnea-Hypopnea Index by OSA Severity

	N	Mean	Median	Min to Max	STD	LSMean	95% CI
Mild OSA (control night 5<AHI≤15)							
Control Night	23	9.4	9.0	5 to 15	3.79		
Treatment Night	23	5.7	4.6	0 to 14	4.16		
Treatment - Control	23	-3.8	-4.1	-12 to 8	5.12	-17.7	(-38.4, 3.1)
Moderate OSA (control night 15<AHI≤30)							
Control Night	20	19.6	17.7	15 to 30	4.12		
Treatment Night	20	7.5	6.1	2 to 24	5.18		
Treatment - Control	20	-12.0	-13.4	-24 to 7	7.26	-20.9	(-30.4, -11.4)
Severe OSA (control night AHI>30)							
Control Night	15	62.4	56.6	31 to 105	23.28		
Treatment Night	15	35.4	24.9	7 to 97	30.16		
Treatment - Control	15	-27.0	-26.2	-62 to 6	18.59	-27.8	(-37.9, -17.6)

Table 3: Analysis of Apnea Index by OSA Severity

	N	Mean	Median	Min to Max	STD	LSMean	95% CI
Mild OSA (control night 5<AHI≤15)							
Control Night	23	3.7	2.5	0 to 11	3.09		
Treatment Night	23	2.1	1.5	0 to 8	2.23		
Treatment - Control	23	-1.7	-1.2	-11 to 3	3.14	-11.6	(-28.8, 5.6)
Moderate OSA (control night 15<AHI≤30)							
Control Night	20	10.1	10.0	0 to 19	4.88		
Treatment Night	20	3.1	1.7	0 to 20	4.48		
Treatment - Control	20	-7.0	-7.6	-18 to 8	6.72	-14.0	(-21.2, -6.7)
Severe OSA (control night AHI>30)							
Control Night	15	46.1	41.7	16 to 90	24.78		
Treatment Night	15	22.2	6.2	0 to 84	29.27		
Treatment - Control	15	-23.9	-25.0	-62 to 7	16.76	-23	(-30.6, -15.5)

Table 4: Analysis of Desaturation Index (3% Desats/Hour) by OSA Severity

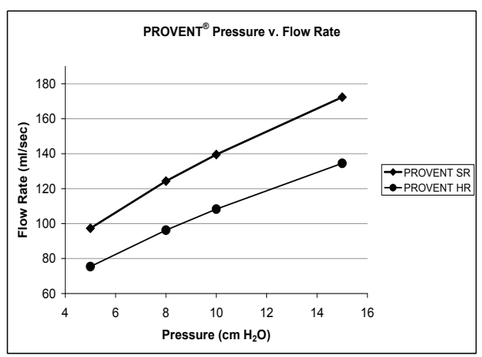
	N	Mean	Median	Min to Max	STD	LSMean	95% CI
Mild OSA (control night 5<AHI≤15)							
Control Night	23	3.1	3.0	0 to 9	2.28		
Treatment Night	23	3.1	2.5	0 to 9	2.68		
Treatment - Control	23	0.0	-0.5	-6 to 8	3.12	-7.5	(-18.8, 3.8)
Moderate OSA (control night 15<AHI≤30)							
Control Night	20	8.4	8.1	0 to 20	4.88		
Treatment Night	20	5.5	4.6	0 to 20	4.86		
Treatment - Control	20	-2.9	-2.8	-17 to 11	6.63	-7.3	(-11.0, -3.6)
Severe OSA (control night AHI>30)							
Control Night	15	34.6	35.2	4 to 80	22.24		
Treatment Night	15	24.7	13.6	1 to 73	22.15		
Treatment - Control	15	-10.0	-8.3	-31 to 1	9.55	-7.9	(-12.2, -3.6)

Note: Tables 2-4 – One-way ANOVA with factors of severity and severity * control night interaction. 95% confidence intervals are for LSMeans.

No serious adverse events were reported during the studies. The only adverse event that was possibly related to the device was a single headache.

Note: Tables 1-4 include pooled data from a clinical trial (n=26) using devices with an 80 cm H_2O·sec/liter expiratory resistance and a clinical trial (n=32) using devices of 50 and 80 cm H_2O·sec/liter expiratory resistance.

[1]American Academy of Sleep Medicine Task Force, "Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research," SLEEP, Vol. 22, No. 5, 1999: 667-689.



User Assistance Information:

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For customer service inquiries or to report an adverse event, please call: 1-888-SLP-WELL (1-888-757-9355).

Product Identifiers:

PROVENT® Sleep Apnea Therapy, High Resistance Device
08592-0001-01, 08592-0001-05
08592-0001-30, 08592-0001-10

PROVENT® Sleep Apnea Therapy, Standard Resistance Device
08592-0002-01, 08592-0002-05
08592-0002-30, 08592-0002-10

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