

**Table 3: Analysis of Apnea Index by OSA Severity**

|  | N  | Mean  | Median | Min to Max | STD   | LSMean | 95% CI         |
|--|----|-------|--------|------------|-------|--------|----------------|
| <b>Mild OSA (control night 5&lt;AHI≤15)</b>      |    |       |        |            |       |        |                |
| Control  | 23 | 3.7   | 2.5    | 0 to 11    | 3.09  |        |                |
| Treatment  | 23 | 2.1   | 0.9    | 0 to 8     | 2.36  |        |                |
| Treatment - Control                              | 23 | -1.6  | -1.3   | -11 to 5   | 3.46  | -12.6  | (-30.8, 5.6)   |
| <b>Moderate OSA (control night 15&lt;AHI≤30)</b> |    |       |        |            |       |        |                |
| Control  | 20 | 10.1  | 10.0   | 0 to 19    | 4.88  |        |                |
| Treatment  | 20 | 3.0   | 1.6    | 0 to 20    | 4.46  |        |                |
| Treatment - Control                              | 20 | -7.1  | -7.9   | -18 to 8   | 6.61  | -13.9  | (-21.5, -6.3)  |
| <b>Severe OSA (control night AHI&gt;30)</b>      |    |       |        |            |       |        |                |
| Control  | 15 | 46.1  | 41.7   | 16 to 90   | 24.78 |        |                |
| Treatment  | 15 | 22.8  | 7.4    | 0 to 91    | 30.95 |        |                |
| Treatment - Control                              | 15 | -23.3 | -25.0  | -62 to 7   | 17.82 | -23.9  | (-31.9, -16.0) |

Note: One-way ANOVA with factors of severity and severity \* control night interaction. 95% confidence intervals are for LSMMeans.

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

|  | N  | Mean  | Median | Min to Max | STD   | LSMean | 95% CI        |
|--|----|-------|--------|------------|-------|--------|---------------|
| <b>Mild OSA (control night 5&lt;AHI≤15)</b>      |    |       |        |            |       |        |               |
| Control  | 23 | 3.1   | 3.0    | 0 to 9     | 2.28  |        |               |
| Treatment  | 23 | 3.2   | 2.3    | 0 to 14    | 3.38  |        |               |
| Treatment - Control                              | 23 | 0.1   | -0.6   | -6 to 13   | 3.92  | -8.7   | (-22.9, 5.5)  |
| <b>Moderate OSA (control night 15&lt;AHI≤30)</b> |    |       |        |            |       |        |               |
| Control  | 20 | 8.4   | 8.1    | 0 to 20    | 4.88  |        |               |
| Treatment  | 20 | 5.3   | 3.3    | 0 to 20    | 5.14  |        |               |
| Treatment - Control                              | 20 | -3.1  | -3.3   | -17 to 11  | 6.27  | -6.7   | (-11.4, -2.1) |
| <b>Severe OSA (control night AHI&gt;30)</b>      |    |       |        |            |       |        |               |
| Control  | 15 | 34.6  | 35.2   | 4 to 80    | 22.24 |        |               |
| Treatment  | 15 | 23.7  | 14.9   | 0 to 78    | 22.67 |        |               |
| Treatment - Control                              | 15 | -11.0 | -7.7   | -48 to 0   | 12.73 | -7.9   | (-13.3, -2.4) |

Note: One-way ANOVA with factors of severity and severity\*control night interaction. 95% confidence intervals are for LSMMeans.

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

<sup>1</sup>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

**Manufacturer Information:**

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

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Patents pending.

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**Provent™ Professional 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 prescribing this device.

**Description**

Provent™ Professional Sleep Apnea Therapy is a disposable nasal device.

The Provent nasal device is placed just inside the nostrils and is held in place by adhesive tape. 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. The expiratory resistance created by the Provent nasal device helps maintain an open airway during sleep.

**Indication**

Provent Professional 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, 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

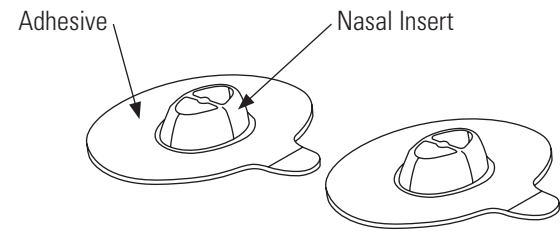
- The safety and effectiveness of Provent Professional Sleep Apnea Therapy in pregnant women, children under the age of 18, and patients with central sleep apnea has not been established.

- 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.

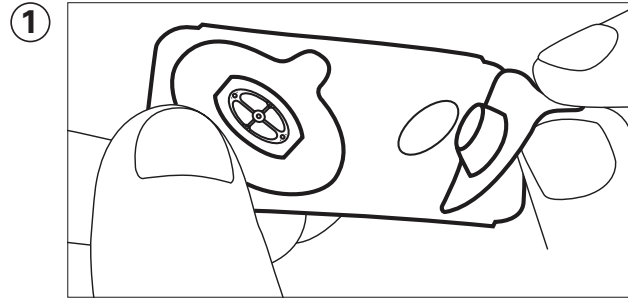
- Patients should not use the Provent nasal device if they have any sores, abrasions, or skin or mucosal irritation on or around the entrance to the nose.

**Adverse Reactions**

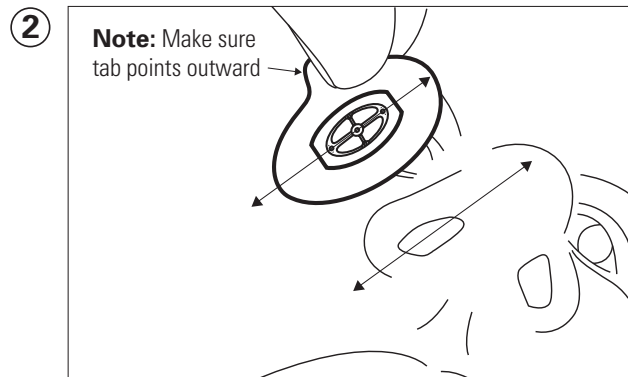
Potential adverse reactions include mouth breathing which may worsen snoring or OSA; nasal, sinus or middle ear discomfort; nose bleed; dry mouth; nostril pain or dilation; and headache.



**Directions For Use**



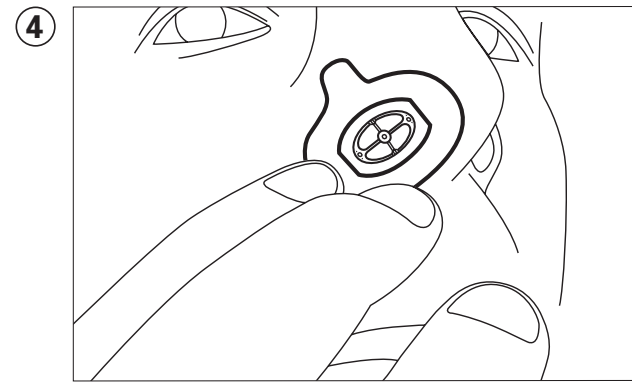
Peel off the paper backing from the adhesive.



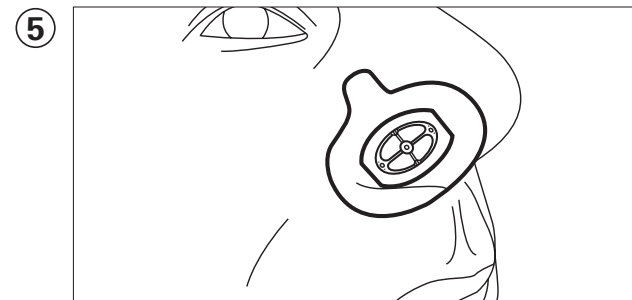
Align the nasal insert with the angle of one of the nostrils to ensure a good seal. Make sure the side tab points outward.



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



Press down all around the nasal device to help you get a good seal. Check to make sure there are no folds creases which would let out air.



Once in place, the side adhesive tab should wrap up and around the outside of the nostril. Repeat steps 1-4 for the other nostril.

Once both nasal inserts are in place, use a mirror to check that both 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 nasal inserts.

If you find that one of the nasal inserts is not positioned correctly as described here, remove the insert and dispose of it before trying again with a new device.

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

Patients should be instructed to breathe through their mouth while falling asleep if mouth breathing is more comfortable than nasal breathing through the device.

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 Professional Sleep Apnea Therapy, the patient should consult with his or her physician.

**Clinical Data**

Below is a summary of the clinical trials of Provent Professional Sleep Apnea Therapy.

**Objective of the studies:**

The objective of the studies was to evaluate the effectiveness of Provent Professional 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<sup>1</sup> 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  $\geq 5$ )

|  | N  | Mean  | Median | Min to Max | STD   | p-value* |
|--|----|-------|--------|------------|-------|----------|
| <b>Apnea-Hypopnea Index (apneas and hypopneas per hour of TST)</b> |    |       |        |            |       |          |
| Control Night  | 58 | 26.6  | 16.7   | 5 to 105   | 24.85 |          |
| Treatment Night  | 58 | 13.7  | 7.5    | 0 to 101   | 20.13 |          |
| Treatment - Control  | 58 | -12.9 | -9.6   | -71 to 16  | 15.64 | <.001    |
| <b>Apnea Index (apneas per hour of TST)</b>                        |    |       |        |            |       |          |
| Control Night  | 58 | 16.9  | 9.0    | 0 to 90    | 21.77 |          |
| Treatment Night  | 58 | 7.8   | 2.0    | 0 to 91    | 18.03 |          |
| Treatment - Control  | 58 | -9.1  | -5.6   | -62 to 8   | 13.19 | <.001    |
| <b>Oxygen Desaturation Index (3% desaturations per hour)</b>       |    |       |        |            |       |          |
| Control Night  | 58 | 13.1  | 7.0    | 0 to 80    | 17.37 |          |
| Treatment Night  | 58 | 9.2   | 3.8    | 0 to 78    | 14.65 |          |
| Treatment - Control  | 58 | -3.9  | -2.4   | -48 to 13  | 8.86  | 0.001    |

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         |
|--|----|-------|--------|------------|-------|--------|----------------|
| <b>Mild OSA (control night 5&lt;AHI≤15)</b>      |    |       |        |            |       |        |                |
| Control  | 23 | 9.4   | 9.0    | 5 to 15    | 3.79  |        |                |
| Treatment  | 23 | 5.8   | 4.2    | 0 to 22    | 5.18  |        |                |
| Treatment - Control                              | 23 | -3.6  | -4.1   | -12 to 16  | 6.41  | -20.7  | (-44.4, 2.9)   |
| <b>Moderate OSA (control night 15&lt;AHI≤30)</b> |    |       |        |            |       |        |                |
| Control  | 20 | 19.6  | 17.7   | 15 to 30   | 4.12  |        |                |
| Treatment  | 20 | 7.7   | 6.3    | 2 to 24    | 5.63  |        |                |
| Treatment - Control                              | 20 | -11.9 | -13.5  | -27 to 7   | 7.72  | -21.2  | (-32.0, -10.4) |
| <b>Severe OSA (control night AHI&gt;30)</b>      |    |       |        |            |       |        |                |
| Control  | 15 | 62.4  | 56.6   | 31 to 105  | 23.28 |        |                |
| Treatment  | 15 | 33.8  | 20.9   | 2 to 101   | 31.22 |        |                |
| Treatment - Control                              | 15 | -28.5 | -26.2  | -71 to 6   | 21.11 | -28.1  | (-39.7, -16.5) |

Note: One-way ANOVA with factors of severity and severity \* control night interaction. 95% confidence intervals are for LSMMeans.