

SILENTNITE™

Snore Prevention Device

Specialist Information

Before a Silent Nite™ is made for your patient, we wish to provide you with background information relating to the device, snoring, obstructive sleep apnea and other issues.

SNORING

Studies have shown that in industrialised countries approximately 40% of the population snore. The percentile increases to 60% with men above the age of 60.

Snoring occurs when soft tissue vibrates. During sleep, muscle tone in the neck and pharynx decreases, so does tissue tension, resulting in partial or even complete obstruction of the airway. This is particularly noticeable when subjects are lying on their backs.

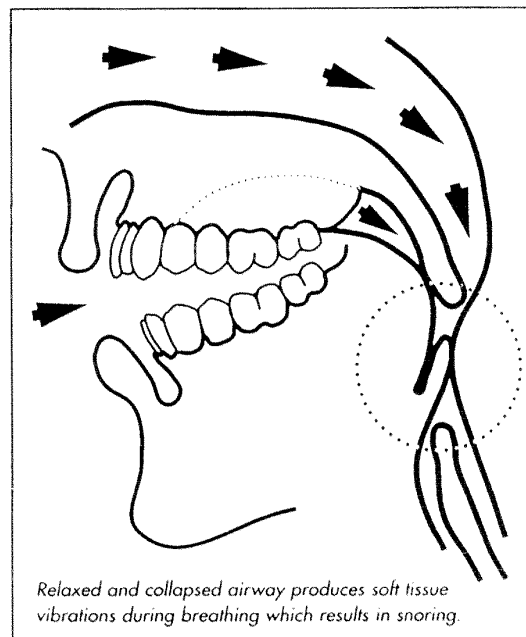
When the pharyngeal space narrows and the body's reflexes attempt to maintain air volume, air intake velocity increases. This stimulates the vibration of soft tissues, such as the soft palate and the uvulum.

Snoring is aggravated by corpulence, alcohol and other sedatives. The removal or reduction of these may be sufficient to remedy the condition.

OBSTRUCTIVE SLEEP APNEA AND HYPOPNEA

Obstructive sleep apnea is defined as a respiratory arrest of more than 10 seconds.

Hypopnea is a decrease in blood oxygen concentration resulting from a reduction in respiratory volumes during sleep.



At a certain level of severity, obstructive sleep apnea and hypopnea, either individually or combined, are diseases that result in narcolepsy (uncontrolled sleep attacks). There can be other serious secondary effects.

The severity of the disease is assessed using the apnea/hypopnea index. This is calculated by adding the number of apnea (longer than 10 sec) and hypopnea episodes and dividing the result by the number of hours sleep. An index up to 5 is considered normal, 6 - 10 is considered light sleep apnea, 11 - 20 is mid range and 20 - 40 is severe sleep apnea. The number of apnea and hypopnea episodes can only be determined in a sleep laboratory.

As a consequence, the retention of residual teeth should be assessed.

In all cases of sleep apnea, the effectiveness of the **Silent Nite™**, when fitted, should be tested in a sleep laboratory.

Silent Nite™ is contraindicated in cases of myofacial dysfunction, arthropathy of the temporomandibular joint and advanced periodontal problems.

Silent Nite™ is based on sound principles. A large number of successful applications make it the most effective and acceptable intraoral anti-snoring and sleep apnea control device that is available. However, the effectiveness, durability and acceptance of **Silent Nite™** can vary, therefore cannot be guaranteed.

CALIBRATION OF SILENT NITE™

A **Silent Nite™** questionnaire must be completed. The questionnaire provides evidence of how a patient's snoring occurs and whether or not the presence of sleep apnea should be suspected. It is helpful if the patient completes the form with his or her partner.

If the patient snores only when lying on his or her back, the **Silent Nite™** will be set to the patient's normal bite, which is the most comfortable position. Connectors of different lengths are used to obtain optimum performance.

Silent Nite™ will continue to function successfully when the patient's jaw falls open. A patient's comfort will be increased by grinding contact points into the device.

WEARING SILENT NITE™

Before the **Silent Nite™** is worn, the connectors should always be checked to ensure that they are firmly attached.

Initially, discomfort may be experienced and the mandible may feel slightly out of alignment when lymphatic liquid flows into the TMJ. On awakening, the liquid will be quickly resorbed and any feelings of discomfort will rapidly dissipate.

The function, acceptance and effectiveness of the **Silent Nite™** should be checked from time to time.

UNCONDITIONAL GUARANTEE

To ensure patient satisfaction, **Silent Nite™** is supplied with an unconditional 30 day money back guarantee.

RECOMMENDED FEES

The suggested patient fee is \$395.00. The laboratory fee including free pick up, delivery and adjustment is \$230.00.

PROCEDURE FOR PRESCRIBING A SILENT NITE™

1. Ask the patient to complete a **Silent Nite™** questionnaire.
2. Take upper and lower impressions of all tooth structure including gingival margins.
3. Pour models in a HARD stone. (These are destroyed in production).
4. Complete a **Silent Nite™** Order Form including the payment details. With the exception of Government and institutional

METHODS OF TREATMENT

CPAP Machines

CPAP Machines use positive pressure to keep the airway open. The systems are effective even in severe apnea cases. However, they are inconvenient, expensive and bulky. The machines must be adjusted in sleep laboratories.

Surgery

Surgery is usually performed to remove respiratory impairing structures, such as enlarged tonsils, adenoids etc.. Surgery has had little success in the cure of apnea with the exception of the correction of mandibular retrognathias. Widely differing rates of success in curing snoring (20 - 40 %) have been reported.

Intraoral Devices

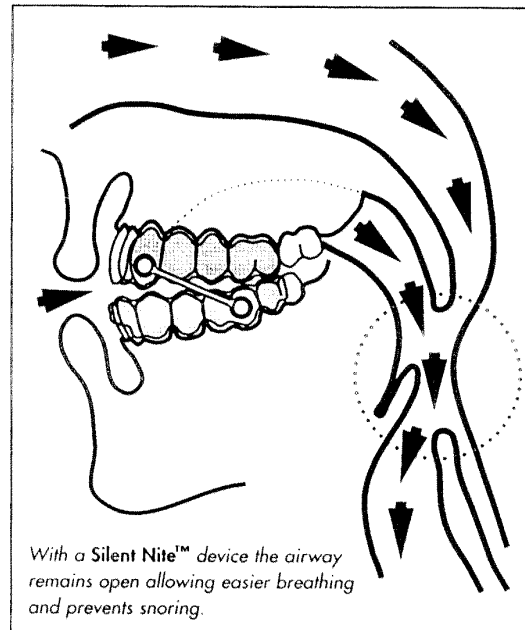
These devices usually operate by placing the mandible in an anterior position to open the pharynx. Acceptance rates can be as low as 2% but as long as the patient tolerates their use, they can be successful in curing mid range obstructive sleep apnea as well as snoring.

SILENT NITE™

Silent Nite™ is an intraoral device which is highly acceptable to patients because it is small and comfortable

Like other oral devices, the **Silent Nite™** opens the pharyngeal space when the mandible is placed in an anterior position.

The **Silent Nite™** consists of two transparent splints, one each for the upper and lower jaws. The mandible is held in a predetermined position by 2 connectors that are fixed to the splints.



The **Silent Nite™** is designed so that any further opening of the mouth increases the anterior position of the lower jaw. As a consequence air intake velocity and therefore snoring, decreases.

Jaw movement is possible with the **Silent Nite™** which makes it a comfortable and effective anti-snoring aid. Lateral and downward movements of the lower jaw are limited.

THE EFFECTIVENESS OF SILENT NITE™

As snoring is caused in almost all cases by constriction of the airways, **Silent Nite™** will be successful even when a patient's nose is blocked.

Because of its compact design, the device does not inhibit breathing through the mouth.

Corpulence, alcohol or other sedatives may affect the performance of the device.

Silent Nite™ cannot be used with edentulous patients and should only be fixed to a partial denture which has adequate retention.

bodies, payment is by credit card, cheque, or money order.

5. Pack carefully together with the Questionnaire and Order Form.
6. Complete a SILENT NITE/TNT Express Couriers consignment note and despatch bag. **Do not use any other consignment notes.**
7. Phone 131150 for Australia wide pick up.

DELIVERY OF SILENT NITE™

The **Silent Nite™** device will be delivered by express courier within 7 days with the exception of some outlying areas, which may take a few days longer.

FITTING AND REMOVAL

Fitting

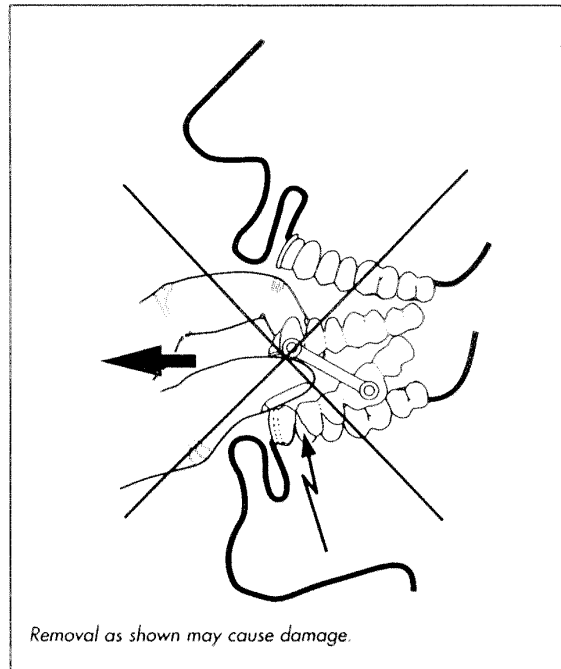
1. With two fingers push the **lower** splint into place.
2. Fit the **upper** splint by applying pressure at the connector hinges.

Removal

1. With two fingers ease the **upper** splint by applying pressure at the connector hinges.
2. Ease the **lower** splint by applying pressure at the connector hinges.

PATIENT INSTRUCTIONS

Silent Nite™ is supplied in a strong ventilated container. It is important that the patient understands the instructions to fit, remove and care for the **Silent Nite™**.



Removal as shown may cause damage.

FREE ADJUSTMENT

1. **Silent Nite™** will be adjusted free of charge.
2. Different lengths connectors are used to change the position of the mandible. Obviously the more protrusively the device is set, the greater the possibility that a patient may experience discomfort.
3. Carefully pack the **Silent Nite™** and use the SILENT NITE/TNT Express Courier consignment note and despatch bag to return the **Silent Nite™**.
4. Phone 131150 for Australia wide pick up.

TECHNICAL SUPPORT

Sydney

Telephone 02 9979 8200 or 1800 242 634

Facsimile 02 9979 8022

SILENTNITE™

Snore Prevention Device

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Snore Prevention Device

Questionnaire

Patients are to complete this questionnaire with their partner at home and then return it to this office

Name: Date:

- | | YES | SOMETIMES | NO |
|--|--------------------------|--------------------------|--------------------------|
| 1. Do you snore only when lying on your back?
<i>(please ask your partner, if possible)</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Do you only snore when your mouth is open?
<i>(please ask your partner, if possible)</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

No anteriorization of the lower jaw with **Silent Nite**

No anteriorization of the lower jaw with **Silent Nite**, eventually a shorter connector may be substituted after a 10-day testing period.

Anteriorization of the lower jaw with **Silent Nite** necessary. See below.

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| 3. Do you snore noisily?
<i>(please ask your partner, if possible)</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Do you feel tired in the morning? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Do you awake with a headache? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Do you have problems concentrating for a long time? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Does sleep suddenly overcome you or do you doze off unintentionally during the day? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Did breathing stop at any time during sleep and did you gasp for breath afterwards?
<i>(please ask your partner, if possible)</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Indication of obstructive sleep apnea, examination by sleep disorder specialist recommended. If prescribed, anteriorization of the lower jaw with **Silent Nite** is necessary.

Obstructive sleep apnea cannot be excluded. Examination by sleep disorder specialist recommended. If prescribed, anteriorization of the lower jaw with **Silent Nite** is necessary.

Obstructive sleep apnea is probably not present.
Anteriorization of the lower jaw with **Silent Nite** is necessary.

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| 9. Do you feel stiffness in the area of the mandibular (jaw) joints? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Do your jaw muscles feel strained or tense in the morning? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Do you grind or grit your teeth?
<i>(please ask your partner, if possible)</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Treatment with **Silent Nite** is contraindicated because it could cause further damage to the mandibular joint.

Before prescribing **Silent Nite**, it is necessary to find if mandibular joint disease is present.

Mandibular joint disease probably does not exist. Treatment with **Silent Nite** is indicated.

This questionnaire does not claim to be complete nor does it release the treating doctor from recommending alternative treatment. Patients where an obstructive sleep apnea is suspected should be referred to a sleep laboratory. In this case the efficacy of the **Silent Nite** should be examined there as well.

This questionnaire was developed by Dr. Hans-Peter Kopp after many years of snore research and treatment in Pfalzgrafenweiler, Germany.

