

## **Proposed Labeling**

### **The Apinator™ - Clinician Information**

**Caution:** Federal (U.S.) law restricts this device to sale by or on the written order of a licensed physician or dentist

### **Indications and Important Safeguards**

SAVE THESE INSTRUCTIONS

*The following words in the Clinician Information have special significance:*

**Warning:** means there is a possibility of injury to your self

**Note:** indicates points of particular interest for more efficient and convenient operation

**Indication For Use:** The Apinator™ is intended for use on adult patients 18 years of age and older as an aid for the reduction and/or alleviation of snoring and mild to moderate obstructive sleep apnea. The Apinator™ can be used as a temporary or trial device to determine efficacy and patient tolerance to oral appliance therapy. When result is determined to be successful, permanent vacuum formed retainers are fabricated by a dentist and Apinator™ is refitted in simmering water and becomes a permanent device.

**Contraindications:** This device is contraindicated for patients with loose teeth, loose dental work, numerous missing teeth, dentures or other oral conditions that would be adversely affected by wearing an intraoral dental device which maintains the jaws in a protrusive jaw position. The Apinator™ is also contraindicated for patients who have central apnea, severe respiratory disorders, or are under eighteen years of age.

### **Device Description**

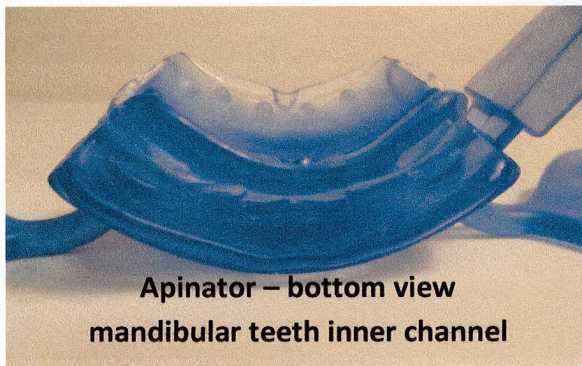
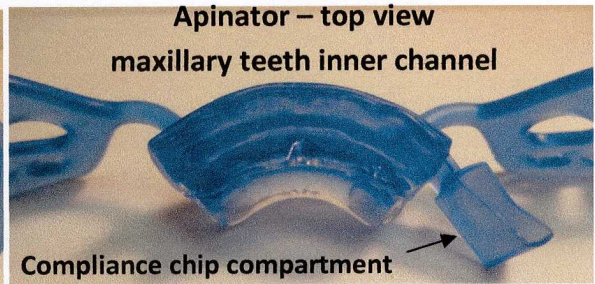
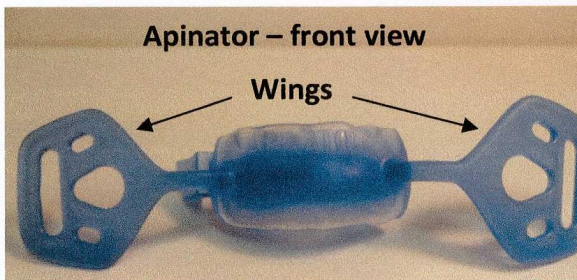
The Apinator™ is an innovative, dual-layer oral mouthpiece. The inner layer softens in hot water, between 170 – 180° Fahrenheit and takes the shape of the front teeth for a snug comfortable fit. The outer layer remains stable in the simmering water and maintains the Apinator's shape.

### **Features of the Apinator™:**

- Easy to fit
- Effective for treatment of snoring and mild to moderate sleep apnea
- Oral airway dilator
- Takes up very little space in the mouth

- Creates more room in the palate for the tongue
- Supports the lower jaw in a position to maximize oral airway size
- Reasonable cost
- Durable
- Can be used as a trial device, temporary device or permanent oral appliance
- Easily and inexpensively accommodates a compliance chip

**Pictures of The Apinator™**



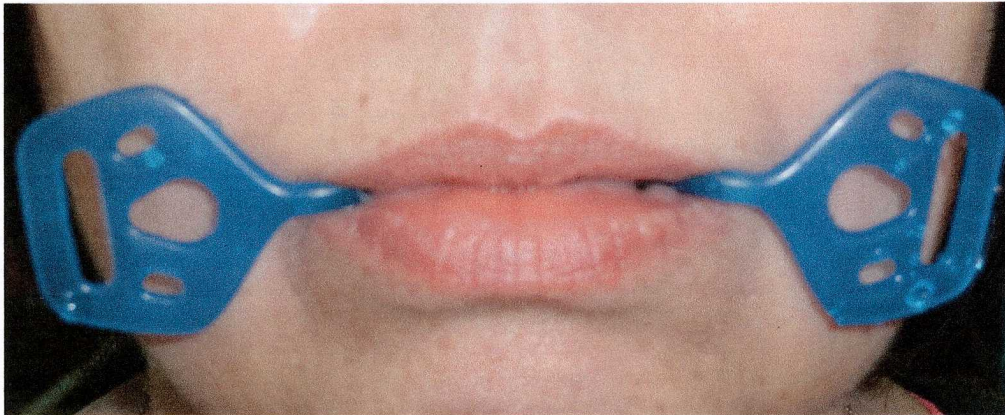
Permanent Apinator including vacuum formed retainers in place on articulator and models showing tongue space in posterior region. Apinator is attached to Elastic/Velcro neck band.



Hold Apinator by right wing and dip in 170-180°F water for 30 seconds



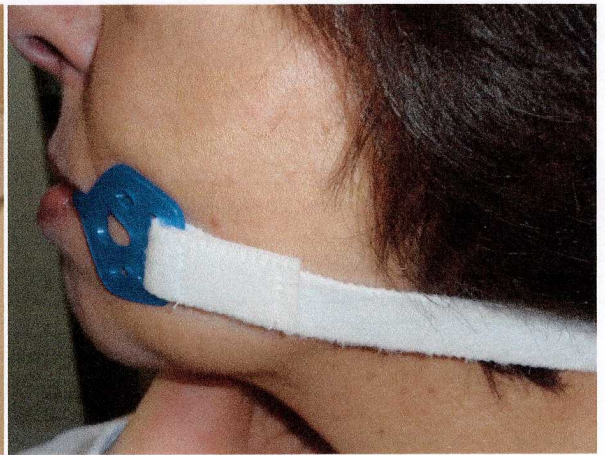
Clinician inserts Apinator in patient's mouth



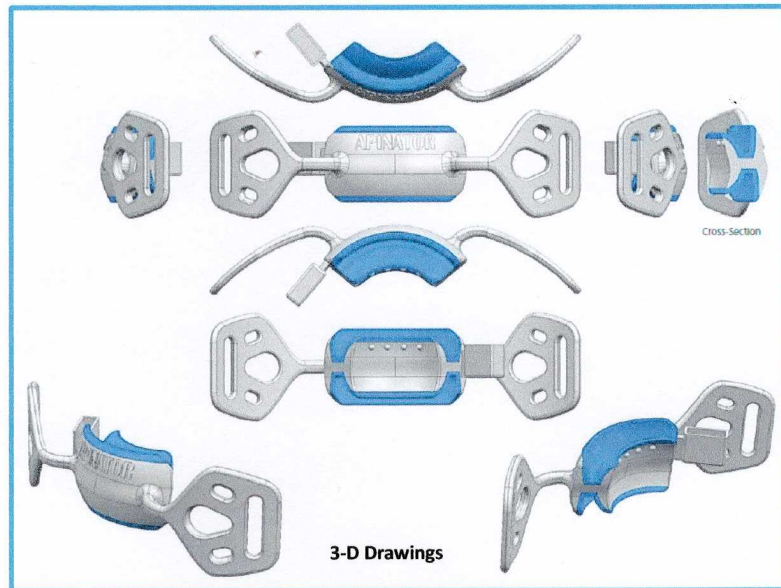
**Apinator in patient's mouth. Lips are closed, tongue is positioned in the roof of the mouth and the patient can breathe through her nose.**



**Elastic/Velcro neck strap is attached to wing of the Apinator.**



**Apinator in mouth with elastic/Velcro neck strap**



**3-D Drawings**

## **Scientific Concepts/Device Design**

The more room created for the tongue in the mouth, the less likely the tongue is to collapse on the airway during sleep. Tongue space in the mouth can be increased in two ways: 1) advance the mandible forward and 2) increase the interarch vertical dimension. The Apinator™ further maximizes the gain by being the smallest possible size thereby taking up the least intraoral space. The Apinator™ by virtue of its innovative extraoral rings, reduces appliance bulk in the mouth and creates more intraoral tongue space than other appliances.

The Apinator™, as a permanent device, has three component parts; an upper vacuum-formed retainer, a lower vacuum-formed retainer and a soft, flexible anterior repositioning jig with external retention rings. The Apinator™ will support the mandible during sleep in a position in which the dental arches are more vertically open and more protrusive than they would normally be. This is the basic formula of most sleep appliances. The unique premise on which the Apinator™ is based is that adequate space for the tongue in the mouth supercedes specific determination of vertical and protrusive measurements in other devices that take up tongue space in the palate or interarch area with material or adjustment mechanisms. The vacuum formed retainers are a second stage procedure to prevent movement of teeth in a treatment altered position of muscle and tongue activity.

The Apinator™ has a unique extraoral elastic/Velcro strap to assist retention, prevent accidental dislodging, swallowing, and allow reduction of the intraoral size of the device. During sleep the intraoral component can be held in place by biting into it and keeping the lips together, frictional fit of the moldable material of the inner channel or by an elastic/Velcro band attached to the extraoral wings and wrapped around the back of the head.

The Apinator™ can accommodate a compliance chip for patients whose job requires proof of adherence. If the compliance chip compartment is not needed, it can be cut off with a scissors.

### **Materials:**

1. Inner channel: Composite Thermal Elastomeric (TPE) – DIOSHY TPE GP-0210M, FDA 177.1640
  2. Outer material: Composite Thermal Elastomeric (TPE) – DIOSHY TPE HP-980E-NC, FDA 177.1640
  3. Elastic/Velcro strap: Velcro is made of 100% nylon; Elastic band is made of 100% nylon
- All materials are FDA approved as safe and biocompatible.

**Note:** Read all instruction before using The Apinator™.

### **Warnings**

- The Apinator™ is intended for use on adult patients 18 years of age and older as an aid for the reduction and/or alleviation of snoring and mild to moderate obstructive sleep apnea. The Apinator™ can be used as a temporary or trial device to determine efficacy and patient tolerance to oral appliance therapy. When result is determined to be successful, permanent vacuum formed retainers are fabricated by a dentist and the Apinator™ is refitted in simmering water and becomes a permanent device.
- If symptoms of breathing difficulty or other respiratory disorders exist or persist with or without use of the Apinator™ the patient should contact their doctor immediately.
- The patient may experience soreness or discomfort in their jaw or teeth. If the discomfort persists, the patient should contact you, their dentist or healthcare provider.
- In the morning the patient may sense a change in their bite. This sensation should disappear within one hour. If it continues for more than two hours, instruct the patient to chew a piece of sugarless gum for 15-30 minutes or until their back teeth are meeting. If they cannot get back to their old bite and experience pain or discomfort trying, they should contact you.
- Under normal circumstances the patient should **not** experience obstruction of oral breathing with the Apinator™ appliance in their mouth. If they do experience breathing difficulty with the Apinator™ appliance in place, the patient should consult their sleep physician.
- The patient should return to you, the dentist or doctor who fit the Apinator™ every six months for a re-evaluation. If the appliance becomes loose, damaged or does not fit properly at any time, the patient should contact you.

### **Possible Side Effects**

There are possible side effects associated with use of the Apinator™ appliance. These side effects are not common. If the patient experiences any of the following side effects they should contact you, the dentist or doctor who prescribed the Apinator™.

- Slight tooth or gingival discomfort, due to pressure from the appliance
- Excessive salivation initially. This will improve as the patient becomes accustomed to wearing the Apinator™.
- Slight jaw soreness or tightness initially that will ease with wearing the appliance
- Morning sensation of bite change. This will subside between 30 minutes and 2 hours after the Apinator™ is removed. If this perceived bite change

persists longer, chewing a piece of sugarless gum will usually correct this problem. If it does not, the patient should contact you, the dentist or doctor who prescribed and fitted the Apinator™.

- Apinator™ comes out while the patient is asleep. This usually stops after an adjustment period. The elastic/Velcro band will help prevent this from happening.
- Movement of teeth should not occur with vacuum formed retainers being worn. When used as a permanent device, upper and lower retainers will prevent tooth movement. Movement of teeth, should the patient feel that it may be occurring, the patient should contact the prescribing dentist or doctor. When used as a temporary or trial device without retainers, the patient must be instructed that the temporary or trial period should not exceed 8-12 weeks.
- Permanent bite change. This should not occur, but with a timely call to the prescribing dentist or doctor when the patient first notices this symptom, exercises can be prescribed.
- Allergic or toxic reaction to the materials in the appliance. If this occurs, the patient should discontinue use and call the prescribing dentist or doctor immediately.

### **Patient's Directions For Daily Use**

Please instruct your patient to inspect the Apinator™ and retainers (if applicable) each day prior to use. If the patient notices any cracks or tears, they should contact you, the prescribing dentist or doctor.

### **Instructions to the Patient:**

#### **Phase I – Temporary or Trial Device**

1. Insert the Apinator™ over your lower front teeth into the custom grooves. Gently slide your lower jaw forward and close your upper front teeth into the upper custom grooves and both arches are engaged in the Apinator™. Attach the elastic/Velcro strap from one extraoral wing around the back of your neck and into the extraoral wing on the opposite side. The strap should be snug without pulling the extraoral wings.

2. Remove the Apinator™ in the morning.

#### **Phase II – Permanent appliance**

1. You have upper and lower retainers. Your Apinator™ is a permanent device. Position the retainer over one arch and use your thumbs to firmly snap it on to your teeth. Repeat this process for the opposing arch.

2. Insert the Apinator™ over your lower front teeth into the custom grooves. Gently slide your lower jaw forward and close your upper front teeth into the upper custom grooves and both arches are engaged in the Apinator™. Attach the elastic/Velcro strap from one extraoral wing around the back of your neck and into the extraoral wing on the opposite side. The strap should be snug without pulling the extraoral wings.

3. When you remove the Apinator™ in the morning, remove front blue component and then remove the upper and lower retainers.

**Warning:** When the appliance is not in your mouth it should be stored dry in its container and kept in a drawer or medicine cabinet. If you have pets (dogs or cats) it is a near certainty that they will chew up the Apinator™ appliance if it is not stored properly.

### **Homecare Instructions for Your Patient:**

Each morning after use, clean your Apinator™ appliance with a toothbrush and toothpaste. Rinse well and store dry in your container away from children and pets.

When you visit your prescribing dentist or doctor for your six month appliance check, it is recommended that you bring the appliance with you so the dentist or doctor can check your Apinator™ appliance.

**Warning:** Eating or drinking high sugar foods before inserting the Apinator™ could cause tooth decay and damage your teeth. Should you do this, always brush, floss and rinse before inserting your appliance for the night.

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**Prior to Prescribing the Apinator™ to a Patient,** the dentist or doctor should consider the medical history of the patient including history of asthma, breathing or respiratory disorders or other relevant health problems. If a concern exists, the patient should be referred to the appropriate healthcare provider before prescribing the device.

### **Oral Appliance Protocol**

#### **(I) Medical Assessment**

A) Dentist/doctor/other, on the basis of a screening refers patient to sleep specialist

B) Consultation, objective testing and diagnosis by a sleep specialist

C) CPAP is usually tried and the patient has experienced CPAP failure or is CPAP intolerant

D) Patient has mild to moderate obstructive sleep apnea and an oral appliance is indicated in the expert opinion of the sleep expert

E) Referral for oral appliance to dentist, doctor or prescribed by sleep specialists. Written referral letter to dentist or doctor should include diagnosis expressed as part of a treatment plan, plus interpretation and summary printout of sleep study.

F) Apinator™ can be used as a temporary or trial device to determine efficacy and patient tolerance to oral appliance therapy.

- Option 1 - When result is determined to be successful, permanent vacuum formed retainers are fabricated by a dentist and the Apinator™ is refitted in simmering water and becomes a permanent device.
- Option 2 - When result is determined to be successful, a custom device is prescribed.

## (II) Dental Assessment

A) History – medical and dental

B) Examination by dentist

C) Consultation and treatment plan

D) Possible referral to original referrer or other medical specialist

E) Written report

## (III) Clinical Standards

The American Academy of Sleep Medicine has established as criteria for oral appliances to define successful treatment of obstructive sleep apnea syndrome:

A) post-treatment Apnea-Hypopnea Index (AHI) 10 or below

B) post-treatment AHI reduced by at least 50% from baseline AHI

C) both criteria are met

## (IV) Clinical procedure

A) Baseline objective testing - polysomnogram



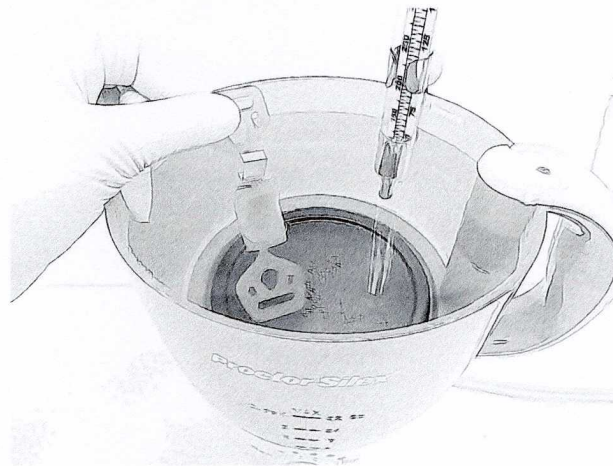
- B) Appliance is customized for patient and delivered the same day
- C) Patient signs informed consent, given appliance instructions
- D) Efficacy of appliance is tested using PSG
- E) When result is determined to be successful:
  - Option 1 - permanent vacuum formed retainers are fabricated by a dentist and the Apinator™ is refitted in simmering water and becomes a permanent device.
  - Option 2 - When result is determined to be successful, a custom device is prescribed.
- F) Completion of treatment, written letter to sleep specialist explaining results, and recommendation for follow-up

(V) Periodic Evaluation

- A) Six month recalls for two years following appliance fabrication to check effectiveness, fit, TMJ status and check for possible tooth shifting or bite change
- B) Annual recall after two year period
- C) A caries screening is recommended at all recalls

If neither clinical standard for success as described in (III) above is met, use of the Apinator™ should be discontinued and the patient should return to the sleep specialist for a referral to a dentist for treatment with a custom appliance or treatment with CPAP.

**Instructions For Fitting An Apinator™**



Supplies necessary:

- Pot for heating water, at least six inches in diameter and preferably six inches deep.
  - An electric simmer pot or hot pot with rheostatic control knob is preferred
  - A thermometer that clips to pot and measures at least to 212° Fahrenheit
  - Timer, watch or a clock with a second hand
1. Heat water in pot to simmer. (*Use enough water in pot to immerse the Apinator™ to the height of the compliance chip pouch.*)
  2. Maintain water temperature between 170° - 180° Fahrenheit by using a thermometer (and a rheostat control on the pot if available)
  3. At the recommended range for water temperature, the Apinator™ may be comfortably held by the right wing while immersed in the water.
  4. Immerse the Apinator™ into hot water for 30 seconds
  5. Remove Apinator™ from hot water after 30 second immersion and insert it centered in the mouth over the front teeth. The word, APINATOR must be positioned right side up in the mouth.
  6. Instruct the patient to bite into the upper and lower blue grooves in the Apinator™ until they feel firm resistance and then hold that position. *Caution the patient that biting too hard into the heat-softened Apinator™ will cause over-closure and decrease effectiveness of their device.*
  7. Instruct them to close their lips, push out with their tongue and push in with their lips and suck in to get a firm seal of the Apinator™ to the front teeth.
  8. Finger pressure on the lips may help get a firmer seal.
  9. Sucking and swallowing during the setting time draws out air and water and also assists getting a firm seal.
  10. After 60 seconds remove the Apinator™ from the mouth and run it under cold water for 10-15 seconds
  11. Retry the Apinator™ in the mouth to confirm the snug fit.
  12. If the fit is not firm and snug, repeat steps 1 - 11.

**Phase II** instructions for refitting the Apinator™ over retainers: Repeat steps 1-12.

## **Patient Information for Use with the Apinator™**

Prescription Use Only  
Part 21 CFR 801 Subpart D

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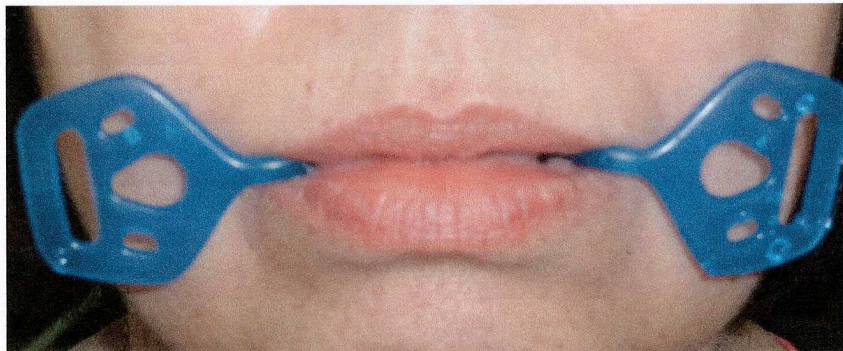
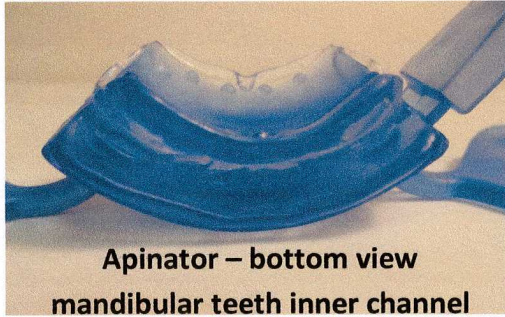
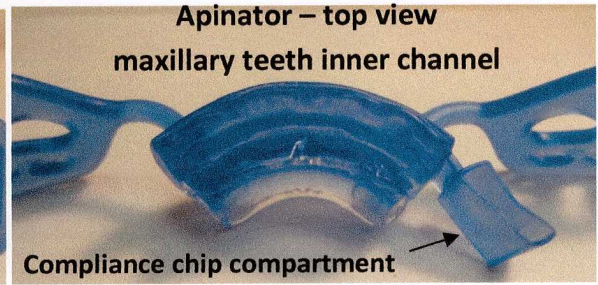
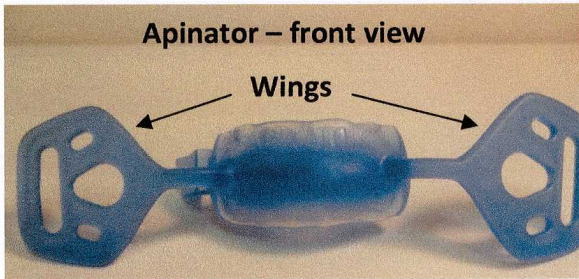
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- Durable
- Can be used as a trial device, temporary device or permanent oral appliance
- Easily and inexpensively accommodates a compliance chip

**Pictures of The Apinator™**



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**Warning:** Eating or drinking high sugar foods before inserting the Apinator™ could cause tooth decay and damage your teeth. Should you do this, always brush, floss and rinse before inserting your appliance for the night.

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- You should return to your prescribing dentist or doctor who fit the Apinator™ every six months for a re-evaluation. If the appliance becomes loose, damaged or does not fit properly at any time, contact your prescribing dentist or doctor.

### **Possible Side Effects**

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- Slight jaw soreness or tightness initially that will ease with wearing the appliance
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- Apinator™ comes out while asleep. This usually stops after an adjustment period. The elastic/Velcro band will help prevent this from happening.
- Movement of teeth. When used as a permanent device, upper and lower retainers will prevent tooth movement. Movement of teeth should not occur with vacuum formed retainers being worn. Should you feel that it may be occurring, please contact the prescribing dentist or doctor. When used as a

temporary or trial device without retainers, the trial period should not exceed 8-12 weeks.

- Permanent bite change. This should not occur, if all of the above directions are followed.
- Allergic or toxic reaction to the materials in the appliance. If this occurs, you should discontinue use and call the prescribing dentist or doctor immediately.

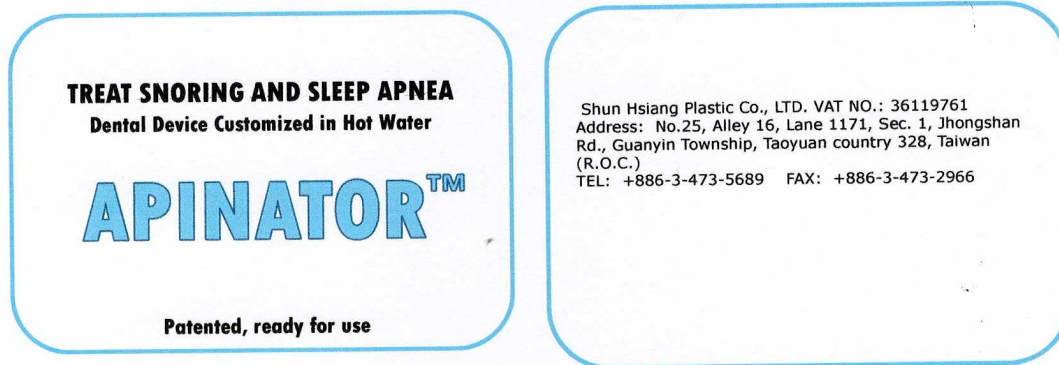
### **Packaging of the Apinator™**

The Apinator™ is attainable by prescription only (Rx ONLY). The Apinator™ will be shipped to the prescribing dentist or doctor who will deliver the appliance to the patient.

The Apinator™ will be manufactured by:

Shun Hsiang Plastic Co., LTD. VAT NO.: 36119761  
Address: No.25, Alley 16, Lane 1171, Sec. 1, Jhongshan Rd., Guanyin Township,  
Taoyuan country 328, Taiwan (R.O.C.)  
TEL: +886-3-473-5689 FAX: +886-3-473-2966

The Apinator™ will be sent to prescribing dentists and doctors in a labeled container. (labels below) Clinician instructions, patient instructions and elastic/Velcro neck strap will be in a separate plastic zipper bag.



Copy of Shun Hsiang Plastic Co. Certificate of Registration ISO 9001:2008 is included in this section.

Copy of labeling for predicate devices is included in this section.



# Certificate of Registration

This certificate has been awarded to

**Shun Hsiang Plastic Co., Ltd.**

No. 25, Alley 16, Lane 1171, Sec. 1, Jhongsan Rd., Guanyin Town,  
Taoyuan County, Taiwan (R.O.C.)

in recognition of the organization's Quality Management System which complies with

**ISO 9001:2008**

The scope of activities covered by this certificate is defined below

**Manufacture and Sales of Plastic Molding Injection Products and Parts**

**Certificate Number:**

13321/A/0001/UK/En

**Date of Issue: (Original)**

17 February 2005

**Date of Issue:**

17 February 2014

**Issue No:**

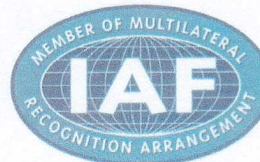
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**Expiry Date:**

16 February 2017

Issued by:

On behalf of the Schemes Manager



N16



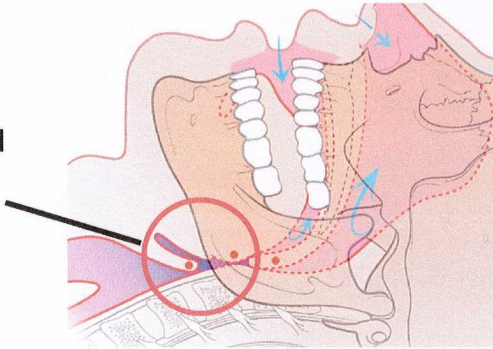


EMA works by opening the bite and gently advancing the mandible (or jaw) with elastic straps to increase airway space.

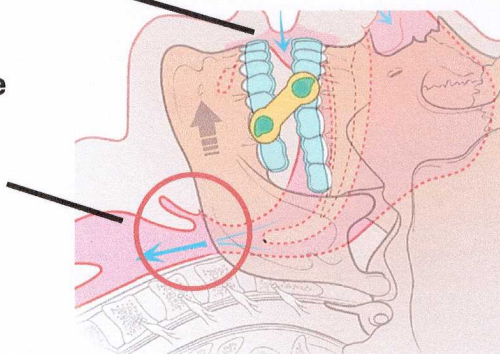
This custom made oral appliance is only available through dental professionals.

**Ask your dentist if EMA is right for you.**

**Closed airway obstructed by soft tissues**



**Open, free flowing airway**



Patients should consult their medical doctor and dentist to evaluate their condition to determine if a dental device is suitable for them. The patient's medical history, including a history of asthma, breathing or respiratory disorders, or other relevant health problems, should be considered in determining whether this device is appropriate. An oral appliance may be contraindicated if any of the following apply to the patient: central sleep apnea, severe respiratory disorders, a history of TMJ problems, loose teeth or advanced periodontal disease, or if the patient is under the age of 18. Patients should be aware that use of the oral appliance may cause tooth movement or changes in dental occlusion, gingival or dental soreness, pain or soreness to the temporomandibular joint, obstruction of oral breathing and excessive salivation. The information provided herein is general and does not constitute advice in any specific patient case.

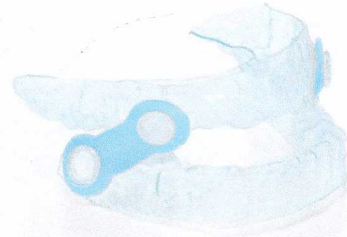


**1-800-407-3326**  
**glidewell dental.com**



11G 10M

**Does snoring keep you awake?**



**For a better night's sleep.**



**Snoring and Obstructive Sleep Apnea**

**can be treated safely and effectively with the EMA oral appliance**





For a better night's sleep.

## Obstructive Sleep Apnea & Snoring

Obstructive sleep apnea is a debilitating sleep-related breathing disorder defined as the cessation of breathing for 10 seconds or more (apnea is a Greek word meaning "without air"). During sleep, the body's muscles relax causing the soft tissue of the airway to collapse, obstructing the airway. The body reacts to the closure of the airway by disrupting deep sleep enough to start breathing again, but deprives the sufferer of getting a "good night's sleep".

Obstructive sleep apnea (OSA) afflicts over 40 million Americans. Untreated, OSA can lead to heart disease, strokes and excessive daytime sleepiness. Did you know that over 100,000\* people are killed or injured each year in crashes attributed to a driver who has fallen asleep at the wheel?

At least 80 million Americans snore (snoring is a sign of restricted airflow and impeded breathing during sleep), which can result in excessive day-time sleepiness, adversely affect the sleep quality of the snorer's bed partner, and diminish the overall quality of life.



NHTSA estimate

## Treatment of OSA & Snoring

The American Academy of Sleep Medicine now recommends oral appliances such as EMA as a front line of treatment for snoring and sleep apnea, and in cases where CPAP (Continuous Positive Airway Pressure) has not been tolerated. What people like about oral appliances is that they fit entirely inside the mouth, they are portable, they do not use electricity or make noise that would bother a sleeping partner, and they allow the wearer to change sleep positions. EMA is FDA approved for the treatment of both obstructive sleep apnea and snoring.

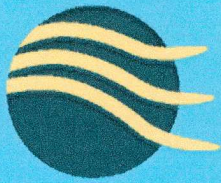


*"For years I had accepted chronic fatigue as a natural progression of aging, not realizing that the lack of restful sleep was the real problem. I still remember vividly the first morning after I wore my EMA. It was the best night's sleep I'd had in years!"*

Bryan R, USA

Dr. Donald E. Frantz invented the EMA appliance (pictured above) in 1993 to treat his own sleep apnea. EMA offers advantages not found in other oral appliances:

- you can talk and even drink water while wearing it
- it is completely free of metal and the EMA elastic straps are latex free
- you can easily change the EMA elastic straps yourself; no additional trips to the dentist needed



# NBM<sup>®</sup>

homepage

mouthpiece

hmb heavy mouth  
breather

tongue positioner/  
pacifier/trainer

mouth breathing

nose breathe<sup>®</sup>  
technology

traditional  
chinese medicine

editorial

research

benefits

order

orthodontics

about us

comments

links

## The Nose Breathe for Heavy Mouth Breather

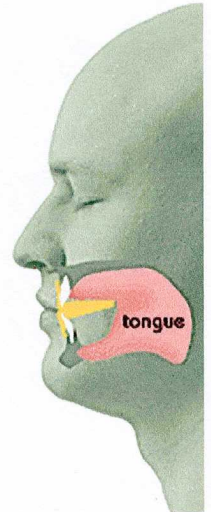
### Are you a heavy mouth breather?

Seeking a simple and effective solution to heavy mouth breathing [especially during sleep] has been a major concern for a large number in our society. Snoring has become an everyday occurrence. It is much more common than many care to admit. With the extension of the original Nose Breathe to the lower jaw, the lip seal pressure increases sufficiently to reduce or completely eliminate heavy mouth breathing during sleep in even the most stubborn cases.

There are two special versions of Nose Breathe: Nose Breathe with Oral Shield (NB/OS) and Nose Breathe for Heavy Mouth Breather (NB/HMB). If you breathe through your mouth, you could be intimidated. You could feel like not enough air is coming through your nose. I recommend training yourself to breathe through your nose, and you can do so with the original Nose Breathe. If you already breathe through your nose, you are ready for the Nose Breathe with Oral Shield and Nose Breathe for Heavy Mouth Breather. Surprisingly, many of our clients have adapted well to using the NB/OS and NB/HMB as initial appliances.

The research study, "Snoring Control Using a New Tongue-Retaining Oral Appliance" by R. Cartwright, S. Sue\*, J. Cygan, M. Smith, F. Diaz, R. Wenzel conducted at Rush University Medical Center, Chicago and \* Private Practice in Hawaii concluded that, nasal breathing can effectively reduce snoring and mild sleep apnea. The study was presented at the Associated Professional Sleep Societies (APSS) 18th Annual Convention at Philadelphia, June, 2004. The abstract was published in the Journal of Sleep, Vol. 27, 2004, 412.

A small percentage (less than 15%) of heavy snorers is nose breathing. Often, the tongue is in the neutral position: forward, directly back of the two upper front teeth, and pressed against the roof of the mouth. This is excellent! Nose breathing snorers are less likely to suffer from sleep apnea. The average, loud, noisy snorers are the mouth breathing type (greater than 85%). This is the group that is more likely to suffer from sleep apnea. Controlling snoring at the early stage of sleep apnea is significant because recent studies are showing that snoring is progressive and within six years: heavy snorers will develop high blood pressure, likely to suffer from a stroke, and/or their snoring has



**Mouthpiece** -  
Patent No.  
#6,295,988  
**Oral Shield** -  
Patent No.  
#6,295,988  
**Nose Breathe  
for Heavy  
Mouth Breather** -  
Patent No.  
#6,053,168  
**Tongue  
Positioner/  
Pacifier/Trainer**

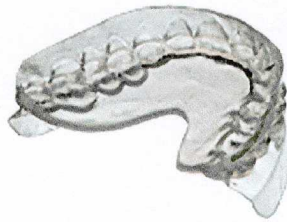
Patent No.  
#6,412,489

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progressed to moderate and severe sleep apnea. Whatever path one chooses [CPAP, surgical technique, oral appliance, drugs, herbal remedies, dieting, weight loss, exercise,]; to be successful, one has to start with nasal breathing. Achieving proper breathing is foundational!



Nose Breathe for Heavy Mouth Breather (NB/HMB)



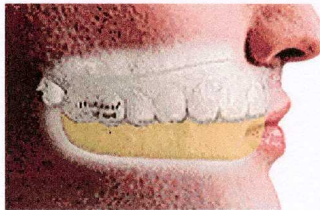
Nose Breathe with Oral Shield (NB/OS)

The Nose Breathe with Oral Shield and Nose Breathe for Heavy Mouth Breather function similarly to the original Nose Breathe. The difference is a stronger lip seal. Understanding the idea of lip seal is key to understanding the uniqueness of the Nose Breathe mouthpieces. The lip seal is fundamental, almost invisible, and occurs naturally. It is found only in nose breathing! Zen masters since ancient times have known the secret. When the tongue is placed at the roof of the mouth, it prevents the tongue from falling into the back of the throat. The tongue is held forward and away from the back of the throat by the naturally occurring lip seal and a forward "tongue suction".

Deepak Chopra, M.D., author, makes a simple and profound statement, "Breathing is the link between the biological and spiritual elements of our nature." When one is in a meditative state, one is nose breathing.



Through correct breathing and a more focused and centered-living, one may recognize the opportunity of beginning a journey of self discovery to ones true inner nature.



### See what others are saying:

Dr. Sue's [INTERVIEW](#): as published in Dentaltown, a professional magazine that goes to all the dentists and dental hygienists in the US.

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