

# ZQuiet® S.A.

## Oral Appliance System for Treating Snoring & Obstructive Sleep Apnea

### Patient Instructions for Use and Care

#### Device Description

The ZQuiet® S.A. is a pre-fabricated, non-custom oral appliance that provides advancement of the lower jaw to treat snoring and Obstructive Sleep Apnea (OSA). The ZQuiet® S.A. comes in four sizes that provide progressive advancement of the jaw in 2mm increments. Each mouthpiece consists of an upper and lower tray that fits comfortably over the teeth and is joined by a flexible hinge to allow the mouth to open and close. The trays are designed to position the lower jaw slightly forward to open the airway in the back of the throat.

#### Prescription Device

**Caution:** The sale of this device is by prescription only.

#### Indications for Use

ZQuiet® S.A. is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in adults.

#### Instructions

1. Follow your physician's instruction for using the ZQuiet® S.A. device.
2. Prior to first use, thoroughly clean ZQuiet® S.A. according to the cleaning instructions in the following section.
3. There are 4 mouthpiece sizes (marked A, B, C & D), each providing an increasing amount of jaw advancement. Device A has the least advancement and Device D has the greatest. Each are identified with both a number and a corresponding letter (0&A, 2&B, 4&C, and 6&D) inside of a circle on the under side of the upper tray (Diagram 1). Unless otherwise instructed, select the mouthpiece with the least advancement marked with both the "0" and "A" as the initial mouthpiece to begin treatment.

#### What to expect from your new ZQuiet® S.A.

Just like anything new, for many people ZQuiet® S.A. takes a little time to get used to wearing. After all, most of us are not accustomed to sleeping with a mouthpiece. So it may take some users up to a few nights to get over any possible drooling, unusual sensations in the teeth or jaw, or even slight discomfort. ZQuiet® S.A. is designed to be sleek and low profile so it should fit comfortably in your mouth during sleep. Stick with it and you will be rewarded with quiet, restful sleep. For any jaw discomfort you may experience when you wake up, or other concerns, please review the "Tips" section.

#### Possible Side Effects

Some of the following possible side effects can be associated with use of The ZQuiet® S.A. Many of these are normal during the adjustment period with any oral appliance and should disappear with continued use:

- Slight tooth or gingival discomfort due to pressure from the appliance.
- Increased salivation initially.
- Inadvertent removal of the appliance during sleep.
- Slight jaw soreness or tightness.
- A sensation of bite change after removing the device which is normal and subsides within an hour or two.

#### Cleaning Instructions

Clean your ZQuiet® S.A. each morning to minimize harmful germs and bacteria as follows:

1. Fill a cup, bowl or basin with very warm water and a small amount of mild soap or detergent.

4. Before every use, rinse thoroughly with warm water. When inserting ZQuiet® S.A., hold the mouthpiece in the folded position with the upper tray with the "Contoured Cut-Out" facing up. Insert ZQuiet® S.A. with the hinges towards the rear of your mouth (see Diagram 2) until your teeth settle into the upper and lower trays. You should notice that your lower jaw will feel slightly more forward than normal.

5. If snoring persists, it is indicative that more jaw advancement may be necessary. Proceed to use the device that provides the next level of advancement. If snoring still persists, repeat this process again for the next level of advancement until satisfactory results are achieved. If you experience jaw discomfort with the increased advancements, return to the previous device of lesser jaw advancement. If more serious pain persists (lasting more than 2 hours), discontinue use immediately and contact your prescribing physician or dentist.

6. Upon waking, gently remove the device and follow the recommended cleaning and storage instructions.

All patients who have been diagnosed with OSA should undergo some type of objective sleep testing to evaluate the efficacy of the treatment.

#### Contraindications

ZQuiet® S.A. is contraindicated for patients with loose teeth, orthodontia, full dentures or advanced periodontal disease. This device is also contraindicated for patients that have central sleep apnea, severe respiratory disorders, or have been diagnosed with temporomandibular joint disorders (TMD). ZQuiet® S.A. is not for use by anyone under the age of 18.

2. Using a toothbrush, scrub all surfaces of the device vigorously for about 1-2 minutes.
3. Rinse thoroughly with clean warm water to remove all soap.
4. After rinsing, shake off all excess water and pat dry with a soft clean towel.
5. Store device in the supplied case at room temperature to prevent damage.

**Important:** Do not soak ZQuiet® S.A. in mouthwash, especially if the mouthwash contains alcohol.

#### Comfort Tips

- Get used to your ZQuiet® S.A. initially by wearing it for short periods of time (30 minutes while watching TV or reading).
- Upon waking in the morning, your bite may feel slightly out of alignment. This sensation should go away during the next couple of hours; gently chewing some sugarless gum can help speed up the process.
- If you experience morning jaw soreness, use a gentle fingertip massage by placing your index and middle fingers on both sides of your jaw just in front of your ears. Bite down to feel this muscle contract so you can pinpoint exactly where to massage. Now, relax the jaw muscle and use your fingers to gently massage this muscle in a circular motion.
- If your jaw muscles are particularly sore, take a night off. Give your jaw muscles a chance to rest as you slowly become accustomed to using your ZQuiet® S.A.
- Place a warm washcloth over the affected jaw muscles for up to 20 minutes, 3 or 4 times per day.
- To provide further relief from any jaw soreness, consider

Diagram 1

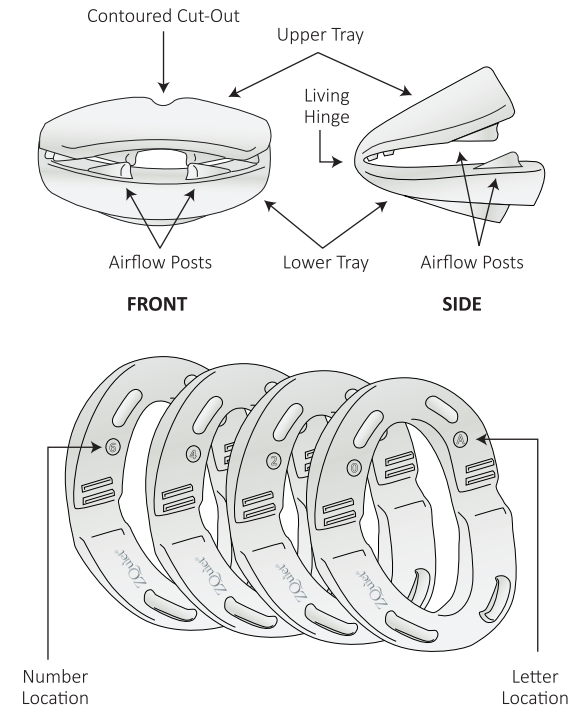
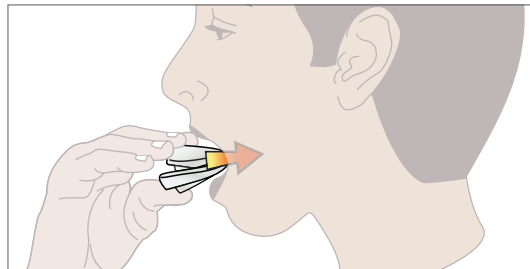


Diagram 2  
Proper Insertion



#### Precautions

Each patient's medical history including history of asthma, breathing, or respiratory disorders, or other relevant health problems should be considered before prescribing the device. Proper screening and diagnosis by a qualified medical professional should be completed before prescribing the device for obstructive sleep apnea.

#### Warning

Usage of ZQuiet® S.A. may cause:

- Tooth movement or changes in dental occlusion.
- Gingival or dental soreness.
- Pain or soreness to the temporomandibular joint.
- Obstruction of oral breathing.
- Excessive salivation.

taking an over-the counter anti-inflammatory pain medication. It is important to use over-the-counter medicines responsibly and in accordance with labeling, and speak with a doctor or pharmacist if you have any questions.

- For additional comfort, you can trim your ZQuiet® S.A. with small scissors to improve its fit. After trimming and to avoid irritation to gums, use fingernail file or emery board to smooth any rough edges.
- Discontinue use and consult your doctor or dentist for acute or persistent pain lasting more than 2 hours, clicking or popping sensation in the jaws, or sudden limited jaw mobility.

#### Distributed by:

Kinwood Healthcare Limited  
10/F, Sino Cheer Plaza, 23 Jordan Road,  
Kowloon, Hong Kong  
<https://www.sleepkinwood.com/>

Copyright ©2016 Sleeping Well, LLC. All Rights Reserved  
ZQuiet® is a Registered Trademark of Sleeping Well, LLC.  
U.S. Patent #8166976, Foreign Patents Pending  
ZQSA.d-IFU 01.16

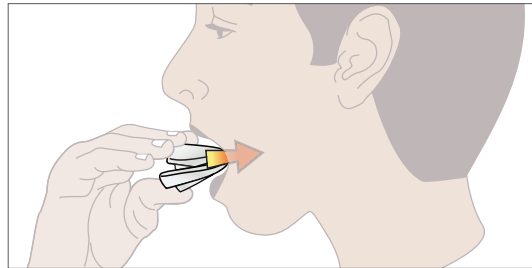
# ZQuiet® S.A.

## 止鼻鼾及睡眠窒息症牙膠

### 治療鼻鼾及阻塞性 睡眠窒息症之口腔裝置

## 使用與保養說明

圖 2  
正確的插入方式



或呼吸系統疾病、或其他相關健康問題。處方牙膠作為阻塞性睡眠窒息症的治療，需由合資格的醫療專科人士進行及完成適當的篩查及診斷。

### 警告

ZQuiet® S.A. 牙膠可能會導致：

- 牙齒移動或牙齒咬合改變。
- 齒齦或牙齒酸痛。
- 顫顎關節疼痛或酸痛。
- 口部呼吸不順。
- 唾液分泌過多。

### 使用 ZQuiet® S.A. 牙膠的新體驗

就如嘗試新的事物，許多人在開始使用牙膠時都需要經

### 產品介紹

ZQuiet® S.A. 牙膠為預製、非訂製的口腔裝置，作用是將下顎調整於一個稍為前傾的位置以治療鼻鼾及阻塞性睡眠窒息症。ZQuiet® S.A. 提供四個漸進尺寸的牙膠，每個的相應前傾增幅為兩毫米。牙膠由上下托片組成，將牙齒舒適地固定在內，連接托片的活動折葉則能讓口腔自由開合；下顎被調整向前傾後，喉嚨後部的呼吸道便得以擴闊，使空氣流通更順暢。

### 處方產品

注意：ZQuiet® S.A. 牙膠需經由註冊醫生或牙醫處方。

### 用途

ZQuiet® S.A. 牙膠用於治療成人夜間鼻鼾症狀及輕度至中度的阻塞性睡眠窒息症。

### 使用說明

1. 請依照您的醫生或牙醫的指示使用 ZQuiet® S.A. 牙膠。
2. 使用前，請依照後段的清潔說明將牙膠清洗乾淨。
3. 盒內有四個分別標示為 A、B、C 及 D 號的牙膠，提供不同程度的下顎前傾幅度。A 號牙膠的下顎前傾幅度最細，D 號最大。它們分別以數字及英文字母 (0 及 A、2 及 B、4 及 C、6 及 D) 標誌於牙膠的上托片底部 (參閱圖一)。除非得到指示，否則請先由最小 (即標誌為“0”及“A”) 的牙膠開始使用。

歷適應期。由於大部分人不習慣於在睡覺時配戴牙膠，因此有些人需要用上多晚以克服及適應流口水、牙齒或下顎異樣甚至輕微不適的感覺。ZQuiet® S.A. 牙膠的柔滑及獨特設計讓您在配戴時提供最佳的舒適度，堅持使用便能為您帶來寧靜及安睡的回報。

對於醒來後任何下顎不適或其他問題，請參考後段的“保持舒適的秘訣”。

### 可能的副作用

使用 ZQuiet® S.A. 牙膠可能會出現以下某些反應。這些都是使用牙膠於適應期出現的正常反應，持續使用應會消失：

- 牙齒或齒齦由於牙膠的壓力以致有些不適感覺。
- 初期唾液分泌會增多。
- 睡眠期間，牙膠從口中脫落。
- 下顎輕微酸痛或緊張
- 除去牙膠後，感覺咬合改變。這種感覺是正常的，應該會在一至兩小時內消除。

### 清潔說明

每天早上，請依照下列說明清潔 ZQuiet® S.A. 牙膠，減少有害病菌和細菌滋生：

1. 準備一隻杯或碗，加入溫水及少許溫和肥皂或清潔劑。
2. 以牙刷擦洗牙膠的所有表面約一至兩分鐘。

4. 每次使用前先將牙膠用溫水徹底沖洗。插入前，將牙膠對摺，有輪廓切口的上托片朝上；折葉朝口腔後方 (參閱圖2) 將牙膠插入口中，直至您的牙齒貼合在上下托片內。您應會注意到下巴比正常位置稍微往前。
5. 使用後如果鼻鼾聲持續，表示需轉用下一強度的牙膠以增加下顎前傾的幅度 (即由 A 號轉為 B 號)。如鼻鼾聲仍然持續，重複此步驟直至達到理想效果。如果在試用較大幅度牙膠過程中出現下顎不適，請回復使用前一號的牙膠。如果出現嚴重疼痛超過兩小時，請停止使用並與醫生或牙醫聯絡。

6. 醒來後，輕輕取出牙膠，然後依照建議說明進行清潔和保存。

所有被確診的阻塞性睡眠窒息症病人，應進行客觀性的睡眠測試，以評估牙膠的治療功效。

### 禁忌症

ZQuiet® S.A. 牙膠不適合正進行牙齒矯正術、使用整口假牙、牙齒或假牙即將鬆脫及患有重度牙周病的病人。亦不適用於確診罹患中樞性睡眠窒息症、嚴重呼吸疾病及顫顎關節障礙症 (TMD) 的病人使用。未滿 18 歲人士不可使用。

### 注意事項

處方牙膠前應考慮每位病人的醫療病歷包括哮喘、呼吸

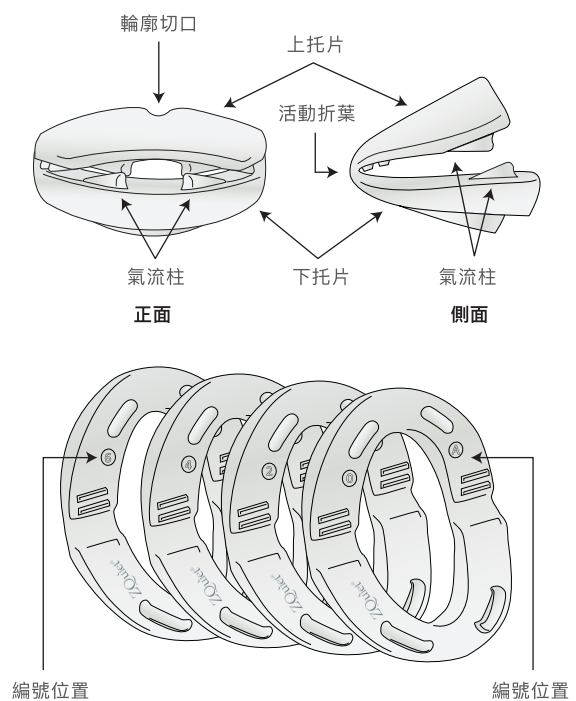
3. 以乾淨的溫水徹底洗淨所有肥皂泡沫。
4. 清洗完畢後，將多餘的水分甩乾，然後以柔軟乾淨的毛巾拍乾。
5. ZQuiet® S.A. 牙膠裝入隨附的保存盒內，保存於室溫下。

**重要事項：**請勿將 ZQuiet® S.A. 牙膠浸泡在漱口水中，尤其不可使用含酒精的漱口水。

### 保持舒適的秘訣

- 初期可短暫試戴以加快適應 (如在看書或看電視的時候戴上 ZQuiet® S.A. 牙膠約 30 分鐘。)
- 早上醒來後，你可能感覺到輕微的咬合改變，這種感覺應該會在其後的一至兩小時內消除。可以輕輕咀嚼無糖口香糖幫助加快過程。
- 如果你出現下顎酸痛情況，可加以按摩。方法是首先將食指及中指置於兩邊耳朵前方的顎骨位置，然後咬住牙齒，手指指出肌肉收緊的位置，再放鬆肌肉及用手指打圈輕緩按摩此處肌肉。
- 如果下顎肌肉異常酸痛，當天晚上可暫停使用，讓肌肉稍為休息。
- 以溫熱毛巾暖敷不適的下顎肌肉位置二十分鐘，每日三至四次。
- 如有需要，可使用消炎止痛藥。但使用時需注意依照藥物包裝指示，有疑問請向醫生或藥劑師查詢。

圖 1



- 您可以使用小剪刀裁剪 ZQuiet® S.A. 牙膠，以提高貼服度和舒適度。裁剪之後，請使用指甲剝刀或磨刀修整粗糙的邊緣。
- 如果出現急性劇痛或疼痛持續超過兩小時，下顎活動時發出聲響/不順暢或活動受阻的情況，請停止使用並諮詢醫生或牙醫。

### 總代理：

健和醫療保健有限公司  
香港九龍佐敦道 23 號新寶廣場 10 樓全層  
<https://www.sleepkinwood.com/>

Copyright ©2016 Sleeping Well, LLC. All Rights Reserved  
ZQuiet® is a Registered Trademark of Sleeping Well, LLC.  
U.S. Patent #8166976, Foreign Patents Pending  
ZQSA.d-IFU 01.16