Respire Info and Patient Instructions

**INSTRUCTION FOR USE**

**Indication for Use**
The Respire Blue Series is indicated for the treatment of Snoring and Obstructive Sleep Apnea (OSA).
The oral sleep appliance is intended to be worn during the night to help place the patient's jaw in an optimal position so they can inhale and exhale more air per breath, and in turn reduce a patient's snoring and sleep apnea.

**Device Description**
Respire Blue Series is a patented device which is custom-made for each patient. Each device consists of two dental plates (upper and lower), which are made of Acrylic.
The attachment on the appliance is further anterior and enables movement of the appliance, thus the patient can open and close while wearing the appliance. The appliance is open in the front to add comfort by allowing the patient to inhale and exhale more air per breath.
Respire Blue Series are offered in two options: (1) Hard/Soft which has a dual laminate layer that provides a soft layer on the tooth surface (2) Hard devices which are all acrylic and retained with ball clasps, this allows the device to be tightened if it becomes loose.

**What is sleep apnea?**
Sleep apnea is the temporary stoppage of breathing during sleep, often resulting in daytime sleepiness. There are three types of apnea: obstructive, central, and mixed; of the three, obstructive is the most common. Despite the difference in the root cause of each type, in all three, people with untreated sleep apnea stop breathing repeatedly during their sleep, sometimes hundreds of times during the night and often for a minute or longer.
Obstructive sleep apnea (OSA) is caused by a blockage of the airway, usually when the soft tissue in the rear of the throat collapses and closes during sleep. In central sleep apnea, the airway is not blocked but the brain fails to signal the muscles to breathe. Mixed apnea, as the name implies, is a combination of the two. With each apneic event, the brain briefly arouses people with sleep apnea in order for them to resume breathing, but consequently sleep is extremely fragmented and of poor quality.

**Packaging Contains**
- Respire Blue Series
- Protective Case
- Titration Screw Key

**Patient Instructions of Use**
1. Place upper component gently onto upper teeth by hand (do not bite into place, as this may cause clasping or soft-layer distortion). Press up to ensure plate is seated securely and fits comfortably.
2. Place lower component gently by hand onto lower teeth (do not bite into place, as this may cause clasping or soft-layer distortion). Press down on both sides to ensure plate is seated securely and fits comfortably.
3. Once the upper and lower components are seated firmly in mouth, make sure appliance’s flat planes are in even contact throughout the arch when jaw is closed.
4. If appliance needs any adjustments, adjust to clinician’s guidance and recommendation.
5. It may take a few nights to get used to the appliance. Some muscle tenderness may occur. If any severe pain occurs, please contact your practitioner immediately.

Ongoing Maintenance
Brush teeth thoroughly daily and floss teeth to a clean finish (failure to brush and floss teeth can lead to premature discoloration of appliance). Discoloration will not affect function or longevity of device. Clean your device daily, see instructions below. It is recommended that adjusting the screws of Respire Blue Series should only be handled only by your physician. It is recommended for the patient to have the first follow up visit after 7-10 days of using the device, and then after 30 days, and then every 6 months.

Cleaning and Storage
1. Upon removal from the mouth, appliance should be rinsed in cold water and then cleaned with toothpaste and a SOFT toothbrush.
2. The appliance should be soaked in partial denture cleaner; we recommend the use of a full tablet of Polident for five minutes, once per week.
3. Store in a glass of clean water. By storing in water, the acrylic will not dry out and will prevent cracks, corrosion and possible discoloration of the metal components.

Contraindications
The device is contraindicated for patients who:
- Have central sleep apnea
- Have severe respiratory disorders
- Have loose teeth or advanced periodontal disease
- Are under 18 years of age
- Are allergic to Acrylic (Methyl Methacrylate)

Warnings
It is recommended for the patient to have a checkup every 6 months to ensure a proper fit of the device.

If any of the items listed below occur, stop using the device and contact your doctor. Use of the device may cause:
- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Excessive salivation.

Precautions
Dentists should consider the medical history of the patients, including history of asthma, breathing or respiratory disorders, or other relevant health problems and refer the patient to the appropriate healthcare provider before prescribing the device.

Prescription Device
Caution: Federal law restricts this device to sale by or on the order of a physician / practitioner licensed by the law of the State in which he practices to use or order the use of the device.

Warranty
Respire Blue Series is a unique patented device which is made from high quality materials. If your device is broken, stop using the device and contact your physician to have it repaired immediately.
Rx only

Prescription warning "Caution: Federal law restricts this device to sale by or on the order of a physician/practitioner licensed by the law of the State in which he practices to use or order the use of the device"

Attention, See instruction for Use

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12.2011/Ver.02