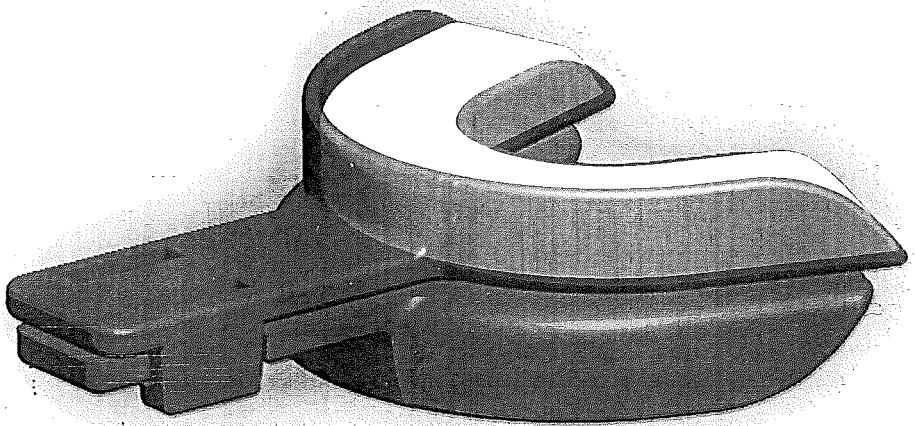


SLEEPSAVER[®]

INSTRUCTIONS FOR USE

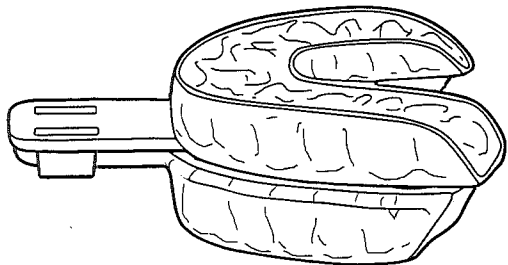


Presented With Compliments From
www.DirectHomeMedical.com

End The Nightly Torture
Of Chinstraps & Full Face CPAP Masks

DCC# 14-237

INSTRUCTIONS FOR USE



The SLEEPSAVER® is an accessory to the utilization of CPAP or Bi-level ventilator therapy. It will minimize open-mouth breathing.

SLEEPSAVER® is a single patient use for adults weighing more than 66 lb (30 Kg) used at home, hospital or other clinical settings per order of a physician.

It is suggested that you become comfortable with this device by wearing the mouthpiece for several hours prior to actual initial use.

Contraindications:

The SLEEPSAVER® is exclusively an accessory to the utilization of CPAP or Bi-level ventilator therapy. It should not be used separately for the treatment of any respiratory or other physical conditions.

- Do not use if teeth or fillings are loose and seek advice from a dentist if unsure before using the device.
- Refit the appliance if too tight and discontinue use if discomfort persists.
- Discontinue use if a reaction is caused by any part of the device and consult a physician.
- Discontinue use if experiencing discomfort and consult physician.
- Discontinue use if device is damaged or cracked and seek replacement.

- Do not use device if vomiting or feeling nauseous.
- Do not use if patient is unable to remove device independently.
- Device is for single patient use.
- Use on adults only (>66lb/30kg)
- Shake hot water off both mouthpieces before placing in mouth.
- In the event of muscle or jaw pain, discontinue use and consult physician.
- Do not block or modify airway relationship of upper and lower mouthpieces.

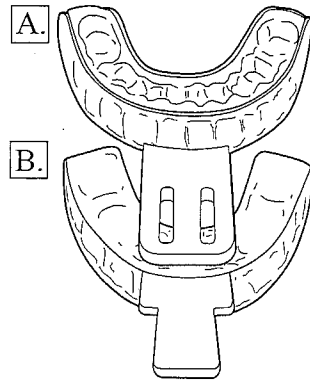
The preparation of this device requires forming of the dental impression through the use of hot water in the range of hot soup or hot beverages. The softened material will be applied with sufficient pressure against your upper and lower teeth to make an accurate dental impression.

⚠ Caution: If you have any serious problems whatsoever concerning the condition of your teeth, gums or mouth such as, but not limited to loose fillings, removable bridges, dentures, sore gum problems or any other physiological problems such as TMJ or sensitivity to hot liquids or foods you should not utilize this device without consulting with your physician or dentist to determine if this device can safely be used by you.

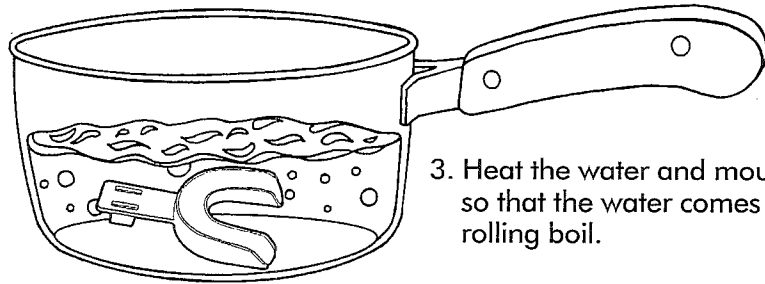
All information provided to you through any means of communication is for informational purposes only and is not a substitute for professional medical advice. Only your healthcare provider should diagnose your healthcare problems and prescribe treatment. All information should be read thoroughly prior to purchase and use. If you have or suspect that you have a medical problem, consult with your healthcare provider.

CUSTOM FORMING THE SLEEPSAVER®

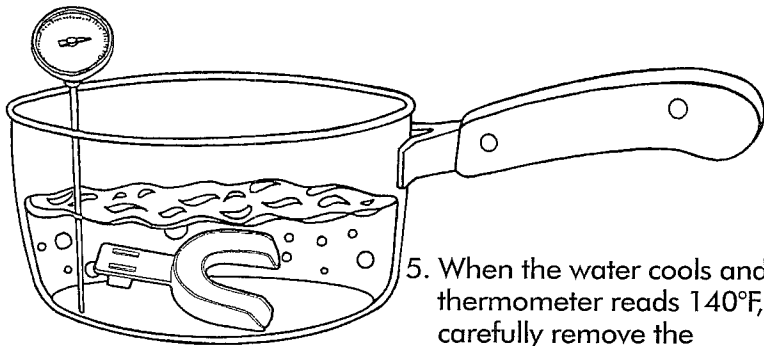
- Note that there are two components:
A. Slotted Upper Teeth Component
B. Lower Teeth Component



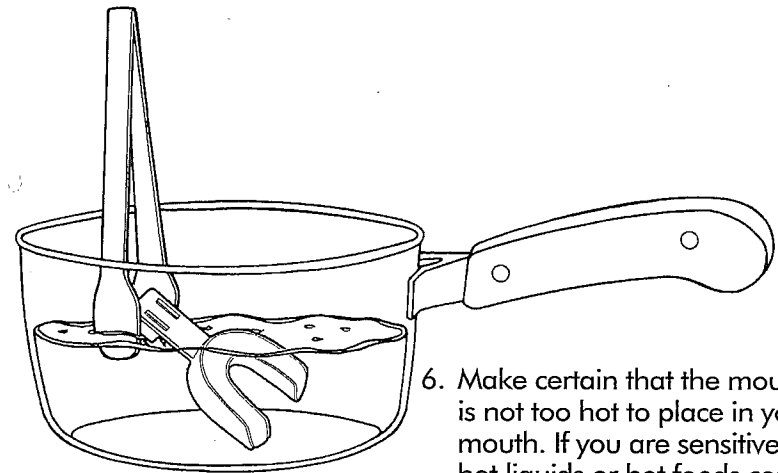
- Disassemble device and place **ONLY** the slotted component in a small pot and add enough water to cover mouthpiece by at least two inches of water.



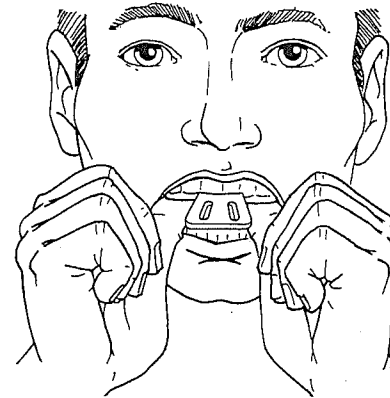
- Heat the water and mouthpiece so that the water comes to a rolling boil.
- Remove the pot from water and place thermometer into water to determine water temperature.



- When the water cools and the thermometer reads 140°F, carefully remove the mouthpiece with tongs and shake off excess water.



- Make certain that the mouthpiece is not too hot to place in your mouth. If you are sensitive to hot liquids or hot foods consult with your physician prior to proceeding. Using a mirror, quickly center the mouthpiece directly under your nose and place the heated mouthpiece up against your upper teeth, with front teeth as far forward as possible in mouthpiece.

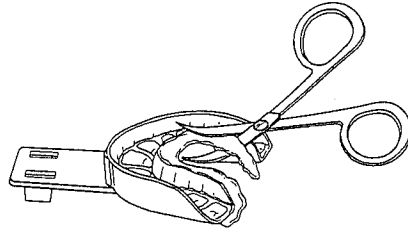


- With fingers and thumbs press mouthpiece upwards to insert your teeth firmly into the impression material.

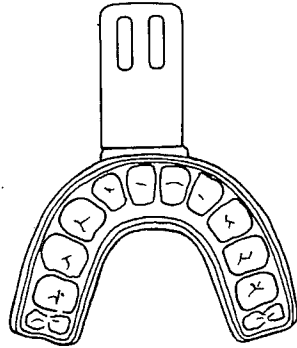
VERY IMPORTANT - Do not remove the mouthpiece for approximately 5 minutes so that the filler material can cool down and solidify. If you remove too soon, you will not have a good impression of your upper teeth and the mouthpiece will not stay affixed to your upper teeth.

- Gently press downward on the mouthpiece to remove it from your upper teeth.

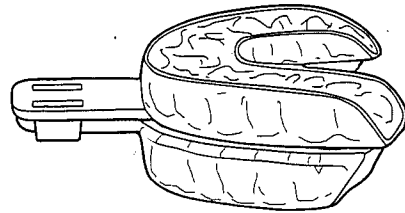
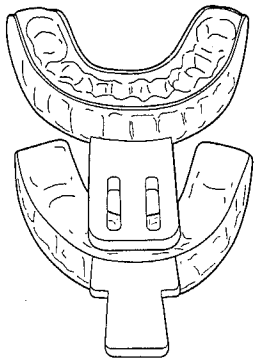
9. While the mouthpiece is still warm use small or rounded scissors to trim the excess filler material.



10. Patients: Check the fit of your mouthpiece. It should press comfortably onto your upper teeth and stay in place. If the mouthpiece is too loose, it is possible to redo the impression only one additional time by reheating the mouthpiece, flattening the filler material and redoing the entire process.



11. Follow the same procedure for custom fitting the Lower Teeth Component.



12. Reconnect the upper and lower SLEEPSAVER® components.

For sanitary reasons the SLEEPSAVER® should be replaced every 90 days.

CLEANING INSTRUCTIONS

DAILY: Wash the SLEEPSAVER® components with ACTIPRO® Cool Water Mouthpiece Cleanser or with warm, soapy water. Do not use soaps with added scent or excessively hot water. Rinse well and allow to air dry out of direct sunlight.

Caution: Do not use alcohol on any components. Do not use solutions containing vinegar, bleach, chlorine, aromatics, moisturizers, antibacterial agents, or scented oils to clean any part of the system. These solutions may damage and reduce the life of the product. Do not expose any part of the device to direct sunlight as it may deteriorate the product.

If any visible deterioration of a component is apparent (cracking, tears, etc.), the component should be discarded and/or replaced.

Daily inspection of device is recommended to replace and discontinue if signs of wear or damage is observed.

Upon receipt and /or before use, carefully inspect all parts for any sign of defect.

SIZING INFORMATION

The SLEEPSAVER® is available in one size suited for Adults 18+ years with medium jaw configuration. There is a finite range of jaw sizes that will fit comfortably within the arch form of the device. Outside of this range (either larger or smaller), the plastic flanges of the device will prevent the device from fitting over and being retained on the teeth. These larger and smaller jaw size ranges can be given empirical numbers based on the exact size of the SLEEPSAVER®. The range is from 27 to 35 mm measured from canine cusp tip to cusp tip. That means that if the intercanine cusp tip measurement is less than 27 mm or greater than 35 mm, the SLEEPSAVER® is not suitable.

