

bleep
We give a bleep about sleep.

Eclipse Halos™ Application Instructions
Visit www.bleepsleep.com/instructions for step-by-step guide
Halos are covered as a Nasal Pillow Cushion by Medicare
For more information contact us at: 919-619-7170
REF 100589 Requires Eclipse Connector Kit for Use. Visit www.bleepsleep.com/instructions for step-by-step video guide.



Patient Instruction Manual and Guide for Use
Rev-1, Item-100626

USE OF MAGNETS in the Eclipse Mask

Magnets are used in the Eclipse mask. The magnetic field strength is 65 mT. Ensure the mask is kept at least 0.8 inches (2 cm) away from any active medical implant or medical device that can be impacted by the magnetic field (e.g., pacemaker, defibrillators, neurostimulators, cochlear implants, hearing aids) to avoid possible effects from localized magnetic fields.

WELCOME TO ECLIPSE

As a new user of Eclipse™ we want to say thank you for choosing our innovatively designed treatment for sleep apnea that introduces a new industry first called MagSeal™. What you will find in this guide are the instructions and intended use for Eclipse MagSeal technology and Halos, how system should be applied for best outcomes, details on properly cleaning and maintaining, as well as best practices for a successful night of using the Eclipse headgear-free CPAP interface system.

INTENDED USE

The Bleep Eclipse interface is intended for use by individuals who have been diagnosed by a Physician as requiring CPAP or Bilevel treatment and should not be used outside the guidance of a trained medical provider or respiratory therapist. The Bleep Eclipse interface is intended for single patient adult (>66 lb/30 kg) use in the home, hospital or other clinical setting. The interface is only intended for use as directed within the instruction manual provided with the Bleep Eclipse. Please read the entire patient instruction manual and guide prior to use. Best outcomes, details on properly cleaning and maintaining, as well as best practices for a successful night of using the Eclipse headgear-free CPAP interface system.

OPERATING INSTRUCTIONS

The operating pressure range of the mask is recommended for 4 to 20 cm H2O. The transport and storage temperature range of the mask is -20 to 60°C (-4 to 140°F). The operating temperature range of the mask is 10 to 40°C (50 to 104°F).

BEFORE EACH USE OBSERVE THESE WARNINGS

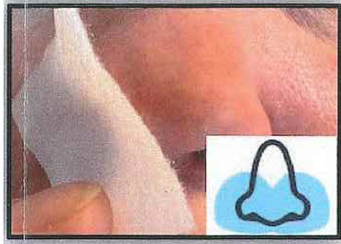
- US Federal Law restricts this device to sale by or on order of a physician.
- Make sure that the patient has cleaned and dried the skin contact surface under and around the sides of the nose and cheek areas using a mild astringent such as witch hazel or isopropyl alcohol. Skin types will vary and some end users will need to use alcohol. This is imperative to a successful application and long-term effective nightly use. Not cleaning the skin properly will result in faulty use and CPAP leaks around the application site. Soap or makeup removers are not suitable to prep the skin.
- If you have a known allergy to adhesive, we recommended you sample the 3M surgical foam called Halos™ before long term use. Halos™ are located on paper sleeves inside the boxes. Cut off one of the tails of the Halo™ tapes, clean the application site along the inside of the bicep and apply for 7-8 hours. If you have an allergic reaction after application, discontinue using immediately and seek the advice of a medical professional or your treating physician.
- Adjust the temperature of your room such that you will not perspire and sweat.
- Be sure to clean your Eclipse frame prior to use and that it is clear of obstructive material.
- Always be sure to observe the mask for damage. Do not use if there are any noticeable defects, cracks, tears or improperly sealed areas on the frame. Contact your local dealer and request replacement part(s), and loop strap and white filter (This item is called the Vent Diffuser and it is used to dampen the sound from the CO2 exhaust), are free of obstruction. Do not use if the vents are blocked or restriction is apparent. The vent holes must be clear at all times. Do not seal off the vent holes.
- The medical reason for this is that rebreathing exhaled air in any CPAP
- Take time to confirm the vent holes along the bottom of the interface, covered by a black hook mask for extended periods of time, beyond a few minutes, can cause suffocation and inadequate air by which to breathe properly and can be dangerous or life threatening. The vent diffuser (black strap/white filter) does not impede airflow, but acts to quiet the sound of exhalation.
- The interface should only be worn when CPAP or BILEVEL therapy is turned on. Once the interface is connected to the adhesive Eclipse™, be sure that the CPAP or BILEVEL device the patient is using has been turned on and is blowing air.
- Discontinue using Eclipse and Halos in their entirety if discomfort, allergic reaction or irritation occur, and contact your healthcare provider and sleep therapist.
- Do not use the interface if you are feeling sick with symptoms of nausea or have vomiting.
- Discontinue all use of product if any symptoms occur with: tooth, gum or jaw soreness, severe headache, chest discomfort, shortness of breath or eye pain. Be careful to follow all precautions when using supplemental oxygen in conjunction with the interface. Consult with your healthcare provider, respiratory therapist and interface dealer for additional service questions when using supplemental oxygen with this device.

- At low CPAP or BILEVEL pressures, some rebreathing may occur, which is fairly normal with most CPAP masks.
- Use with humidification if experiencing nasal congestion or dry air.
- Important Note: Failure to follow the operating instructions may compromise the performance and safety of the mask. Bleep Eclipse™ Halos are for single use. Dispose of them after use. The stainless steel rings can be recycled. The Eclipse™ frame has a recommended service life of 90 days and should be replaced after being used for 90 days or as needed.

APPLYING THE ECLIPSE™ CORRECTLY EVERY TIME

The first step to applying your Eclipse Halos is to thoroughly clean the nose area (sides and base of your nose, and the entire nostril area), with an astringent like witch hazel or isopropyl alcohol to remove all oils, makeup and dirt. It is the most important part of applying your Halos, and once done correctly will enable you to easily fit the Eclipse consistently. Once your face has properly been cleaned you should dry your face and skin around your nose and cheeks. Then you can begin the process of the Halos application.

PLEASE READ THESE INSTRUCTIONS IN FULL BEFORE APPLYING HALOS AND USING ECLIPSE



STEP 1

Clean areas around the nose and nostrils of makeup, oil or dirt using a mild astringent like witch hazel (for oilier, skin you may need to use isopropyl alcohol, as skin types can vary and stronger astringents may be needed. If Halos do not hold for 7-8 hours, you most likely need a stronger astringent). Pat your nose dry with a towel. Do NOT use soaps or makeup removing wipes; they contain oils and ingredients that will cause the Halos to not adhere consistently. Do not apply lotion to the nasal area.

PRO TIP

- A. Trimming Halos** - The interior edge of the second Halo should overlap the interior adhesive edge of the first Halo without covering any portion of the Halo metal ring itself. When adhesive overlaps the ring, it will cause a leak.
- B. Mustache Hair** - You MUST trim mustache hair by 1/8" inch below nostrils to present smooth skin. Halos will not seal over hair.
- C. Personalizing Halos** - The tails of the Halo tapes can be trimmed to customize the footprint you Halos will not seal over hair.



INCORRECT OVERLAP - TAPE CANNOT OVERLAP THE METAL RINGS THIS WILL CAUSE LEAKS.



MUSTACHE HAIR - TRIM SMOOTH 1/8"
TRIM AS NEEDED TO FIT YOUR NOSE

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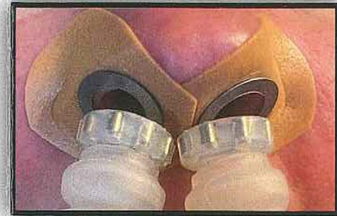
SEAL AROUND NOSTRIL, CAREFUL TO AVOID CREASES OR PUCKERS.



BE SURE TAPE DOES NOT COVER THE METAL HALO RING.

STEP 2

Apply the first Halo adhesive (2a) by lining up the Halos ring and centering over the first nostril. Apply pressure around the septum and lip area first, then around the nostril to the outside of the nose. The second Halo may need to have the interior edge of adhesive trimmed so that it does NOT overlap the first Halo ring (2b). Overlapping the adhesive onto the metal ring itself can cause a leak. Ensure you have a good seal by firmly pressing onto the skin (the adhesive is pressure sensitive). You may find that you can trim the ends of the Halos™ tape a 1/8" each evening until you are satisfied with coverage and adherence (See Pro Tips under Step1), depending on size of nose and needs. Leftover trimmed tape can be reapplied in areas you feel need extra support.



CENTER ECLIPSE™ FRAME OVER HALOS WITH MAGSEAL™ OPENINGS TO OBTAIN CORRECT SEAL.

STEP 3

Attach the Eclipse™ magnetic frame to the Halos™ and be sure the magnetic ports are centered over the Halos™. This can be accomplished by sliding the magnetic ports across the Halos, if needed. Attach to your CPAP unit. Once you are comfortable with this step applying the Eclipse™ frame can be done at bedside.

STEP 4

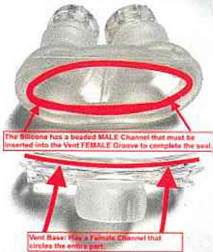


Settle in for the best night's sleep you've ever had! Connect your Eclipse™ frame to your CPAP machine using the connector swivel at the end of the interface tubing to your existing CPAP tube, turn the CPAP or BILEVEL device on and test for leaks. If you need to get up to use the restroom or take off Eclipse™ frame, slip your thumbs up behind the Eclipse silicone (Photo 5 to right), next to your lips and slide the magnetic ports toward the tip of your nose. Avoid pulling or yanking the Magnet-Ports off the Halos as this could dislodge the adhesive and cause a leak.

PRO TIP

Removal of the Eclipse from the Halos - Make sure to hold at top, do not pull from base or pull from hose. Hold at top of frame around the magnetic ports and gently push off toward the end of your nose. Removal of the Eclipse from the Halos - Make sure to hold at top, do not pull from base or pull from hose. Hold at top of frame around the magnetic ports and gently push off toward the end of your nose.

REMOVING THE NIGHTLY ECLIPSE HALOS AFTER SLEEP



The Bottom has a beaded MALE Channel that must be inserted into the Vent FEMALE Channel to complete the seal.
Vent Base Film a Female Channel that locks the entire piece.

First, remove the the Eclipse frame by sliding the magnetic ports toward the tip of your nose and off the Halo rings. Once the Eclipse frame has been removed, gently peel back the edge of one of the Bleep Halo patches at the outside of the nose. After detaching one edge from your skin, grip the adhesive and gradually peel down, using your fingers of your other hand to hold the skin beside your nose in place. Gradually remove the tape from the sides of your nose in a downward motion, being careful not to yank or rip the adhesive patches away from your skin. Always pull down so that the final process of removing the adhesive ends below the underside of the nose. Never pull upward to remove Halos. This will optimally protect the skin. The Halos are for one time use. Discard Halos after removal. The stainless steel rings may be peeled off the adhesive and recycled.

LEAKING

If your Halos leak air against your face, press down firmly around the tape to properly seal against the skin. If you still experience leaks, you may need to clean your face again with a stronger astringent, dry your skin and reapply new Halos, making sure your skin is clear of all oils and lotions, and is adequately dry enough for the adhesive to secure properly against. Remember, soaps contain oils and moisturizers and their residue can get left behind on the skin and impact the ability of the tape to stay on correctly.

CHIN STRAP or MOUTH TAPE

If a substantial amount of air is leaking out of your mouth during use, or you get a dry mouth, you may find it beneficial to use a chin strap to assist with this. As with any health related question or concern, consult with your healthcare provider, respiratory therapist or local dealer for guidance on options that exist for you, as there are many types of chin straps and mouth taping solutions to choose from.

CONDENSATION or WHISTLING

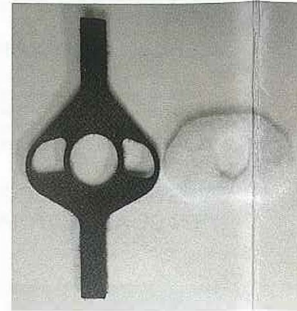
If you experience whistling sounds or excessive condensation in your mask, you may need to turn down your humidifier. Do this gradually, over a few nights, to avoid reducing the humidity too much. Please consult with your healthcare professional before doing so.

CPAP TUBE MANAGEMENT

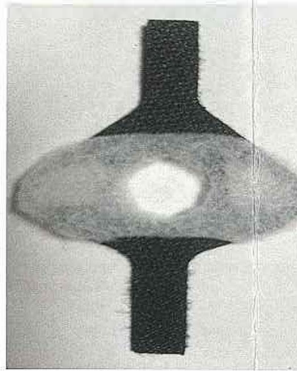
Bleep recommends using a CPAP Tube Management or Hanger System to manage the primary CPAP tube over the top of your head.

Replacing the Eclipse Vent Diffuser should take place once a month or as needed. The task is simple:

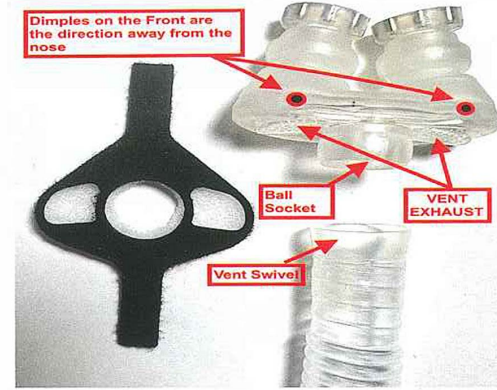
1. Visit BleepSleep.com for a list of vendors and purchase the needed replacement.



2. Overlap the White Filter Material onto the black hook and loop strap with the correct orientation as shown above.



3. Disconnect the ball socket on the vent from the tube swivel as shown below.



4. Disconnect the ball socket on the vent from the tube swivel as shown below.

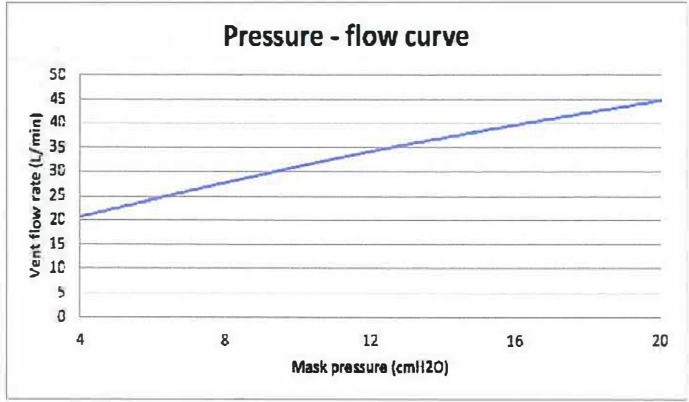


5. Disconnect the ball socket on the vent from the tube swivel as shown below.



CLEANING YOUR BLEEP ECLIPSE MASK:

1. Place the Eclipse frame into lukewarm water that contains a mild soap. Agitate back and forth for 20-30 seconds to immerse fully in the soapy solution. Let soak for 10 minutes.
2. Following the 10-minute soak, rinse thoroughly in fresh water, ensuring that all soap residue is removed and allow to air dry.
3. Leave all parts to dry out of direct sunlight. Make sure the White Filter in the Vent Diffuser is dry before use.



MASK DEAD SPACE 10.0 ml (the physical dead space is the empty volume of the mask to the end of the swivel below the exhaust)

SOUND:

The Sound Power Level of the mask is 21.2 DBA with uncertainty 5 DBA.
The Sound Pressure Level of the mask is 18.58 DBA with uncertainty 5 DBA.

Warning:

- Do not wash the Eclipse frame in the dishwasher.
- Do not clean the mask with products that contain chlorine, bleach, moisturizer, antiseptic, anti bacterial agents or alcohol.
- Do not wash your mask in boiling hot water as this may affect the shape of the interface and its proper ability to create functioning seals. Note: Failure to follow the cleaning instructions may compromise the performance and safety of the mask. Frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified, or exceeding the number of processing cycles can have an effect.
- DISPOSAL - Your mask may be dis:

TECHNICAL SPECIFICATIONS

Mask Pressure (cm H2O)	Mask Pressure (cm H2O)			
	4	6	8	10
Vent Flow Rate (L/min)	21	24	28	31
	24	28	31	34

RESISTANCE TO FLOW DATA
Drop in pressure (through mask at given flow rate)
• At 50 L/min 1.7 cm H2O
• At 100 L/min 7.5 cm H2O

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For a list of patents related to this



