

INDICATION FOR USE

The Chemo Mouthpiece is intended to be used to cool the oral mucosa to reduce the incidence and severity of chemotherapy induced oral mucositis in adult patients.

Note: Unit will arrive double sealed; a vacuum sealed bag inside of a re-sealable vacuum sealed bag (save this bag).

DEVICE SPECIFICATIONS

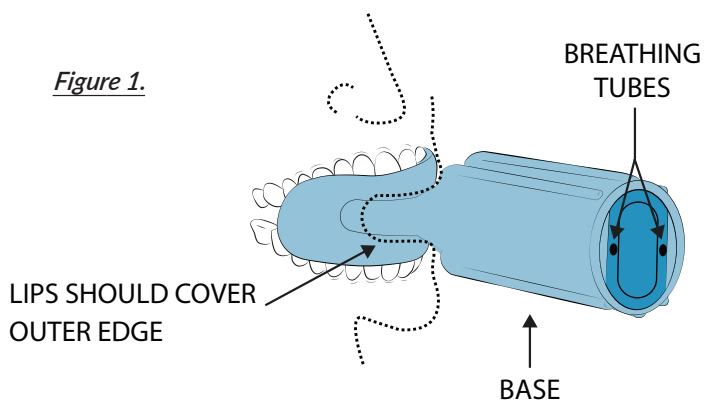
Material Specifications: The Chemo Mouthpiece device is made from medical grade silicone, filtered water and saline solution. The Chemo Mouthpiece is provided prefilled and it is not intended to be filled or refilled by the patient.

Cooling Capacity: The regular size frozen Chemo Mouthpiece allows for an average of 37.4°F of cooling after ½ hour of application, (with a range of 35.1° F to 39.6° F) while the small size Chemo Mouthpiece allows for an average of 33.6°F of cooling after ½ hour of application, (with a range of 31.8° F to 35.5° F). Please note that temperature reduction may vary depending on the ambient temperature of the oral cavity.

This is a single patient, multi-use device.

INSTRUCTIONS FOR USE

1. Prior to use, place all of your Chemo Mouthpieces in the unopened double sealed packaging in the freezer for a minimum of 6 hours. After 6 hours, the blue center core will be frozen solid, and the devices will be ready for use.
2. Immediately prior to going to your infusion, place each of your devices, the insulated sleeve, and the cold packs into the provided cooler and bring with you to the infusion center. Please save the resealable bags for future use.
3. 10-15 minutes prior to infusion remove one Chemo Mouthpiece from the cooler and slide its base into the insulated sleeve.
4. Place the Chemo Mouthpiece chamber into your mouth and place your lips over the outer edge. See Figure 1 below.
5. Once inserted into your mouth, occasionally squeeze the insulated sleeve/base to circulate cold water inside the device.
6. Tilt head back while using the Chemo Mouthpiece. The device has breathing tubes to facilitate normal breathing.
7. Each Device will stay frozen for 30 minutes. During infusion, after every 30 minutes, replace the Chemo Mouthpiece device with



fresh, frozen device from your cooler. You may take a 5-minute break if needed from using the device at the time of substitution.

8. Following the conclusion of your infusion, please continue to use a Chemo Mouthpiece for 10-15 minutes.
9. Bring your devices home after your infusion and follow the Cleaning, Care and Reuse Instructions below.
10. The Chemo Mouthpiece should be used at home once starting the day of infusion and two times per day for the next five days. Each session with the device should last 30 minutes. Rotate between units to avoid using the same device on the same day.

CLEANING, CARE AND REUSE

11. Clean your devices with soap and hot water. Use the supplied cleaning brush to clean inside the breathing tubes. If you have a sore in your mouth, you should use an antibacterial denture cleanser to clean the unit.
12. After cleaning, allow the devices to dry. Place each device back into a re-sealable bag and store in the freezer. The Chemo Mouthpiece must be refrozen within 24 hours after use and must always be stored in the freezer.
13. The Chemo Mouthpiece can be stored at room temperature in its unopened vacuum sealed packaging for up to 24 months. Once opened, the device must be stored in the freezer in the resealable bag.

PRODUCT DISPOSAL

The Chemo Mouthpiece can be disposed of in ordinary municipal waste. Please adhere to applicable local regulations for disposal.


Note: The unit may produce condensation and the insulated sleeve might become damp while in use.

Note: Any serious incident that has occurred in relation to the Chemo Mouthpiece should be reported to the manufacturer at 866-496-8858 or support@chemomouthpiece.com

Manufactured by:

 ChemoMouthpiece, LLC
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Wilmington, DE 19810, United States of America

Questions or Comments:

 +1 866-496-8858
support@chemomouthpiece.com
www.chemomouthpiece.com

Rx Only Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

CHEMO MOUTHPIECE®

TIPS FOR USING THE PATIENT KIT

1. Once the Chemo Mouthpiece is properly frozen according to the provided instructions, reference [Figure 2](#), bring it with you to the infusion in the cooler provided to you.
2. Do not forget to place the provided cold packs into the cooler along with your Chemo Mouthpieces.
3. Do not forget the insulated sleeve. Place the insulated sleeve over the Chemo Mouthpiece while it is in use. The insulated sleeve provides additional insulation keeping your mouthpiece cold for longer. See [Figure 3](#).
4. The cooler will keep the Chemo Mouthpieces frozen for up to 8 hours. This allows you to complete any necessary activities and still have a frozen unit ready when needed for treatment.
5. When using the Chemo Mouthpiece, make sure to properly position the teeth tray portion, while in use inside your mouth. See [Figures 1 and 4](#).
6. If you have any questions or concerns, please reach out to our team. Send us an email to support@chemomouthpiece.com or give us a call, +1-866-496-8858.
7. There is also a helpful, instructional video on our website that thoroughly explains how to properly use the Chemo Mouthpiece.

WARNINGS/PRECAUTIONS:

STOP USING THE DEVICE IF SKIN IRRITATION OR SENSITIVITIES DEVELOP OR IF THE DEVICE LEAKS OR DOES NOT MAINTAIN ITS MATERIAL INTEGRITY.

DO NOT USE IF YOU HAVE SENSITIVITY TO SILICONE.

DO NOT BITE; BITING MAY CAUSE THE DEVICE TO FAIL FOR ITS INTENDED USE.

DO NOT BOIL OR PUT IN THE DISHWASHER TO CLEAN THE DEVICE.

DO NOT USE THE DEVICE WITHOUT STORING IT IN THE FREEZER (BEFORE & AFTER USAGE).

THE DEVICE IS SAFE TO USE. IF YOU DON'T FIND ANY RELIEF FROM THE ORAL DISCOMFORT, THEN PLEASE CONSULT THE MEDICAL PROFESSIONALS.

DO NOT USE THE DEVICE IF YOU HAVE SEVERE RESPIRATORY DISTRESS OR CARDIAC RELATED PROBLEMS.

DO NOT USE IF PACKAGING IS DAMAGED OR IF THE CHEMO MOUTHPIECE IS DAMAGED. CONTACT CHEMOMOUTHPIECE, LLC FOR REPLACEMENT AND INSTRUCTIONS.

ANATOMY OF THE DEVICE

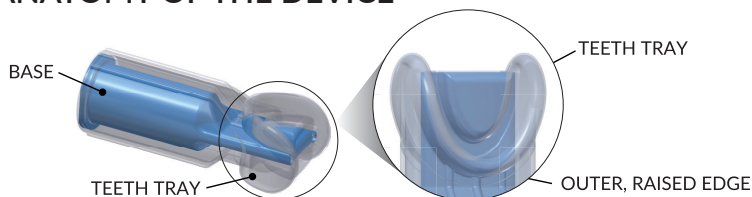


Figure 2: Freeze the device for at least SIX hours before first use.

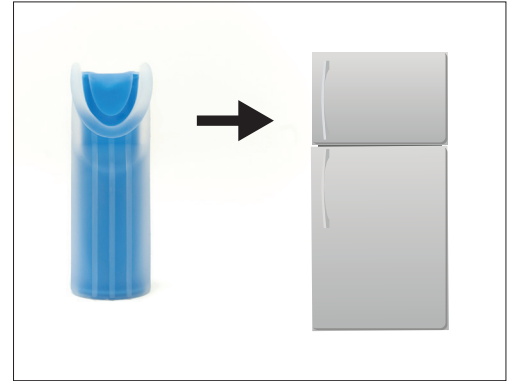


Figure 3: Place the insulated sleeve on the base of the mouthpiece while in use.



Figure 4: Below is a patient properly using the device, with his lips over the outer edge.



Note: The insulated sleeve was removed for demonstration.

The entire team at ChemoMouthpiece wishes you well on your journey.
We know this is a difficult time, but please don't lose hope!

