

Prescriber Information for the CHEMO MOUTHPIECE® Device

An Intra-Oral Cryotherapy Device

Indication for Use: (Rx Only)

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.

Device Description:

The Chemo Mouthpiece® is an intra-oral cryotherapy device that when used in its frozen state in the oral cavity, will vasoconstrict the blood vessels in the mouth thereby decreasing the flow of chemotherapy in the oral cavity. The Chemo Mouthpiece® Device is a prescription only product for use during chemotherapy infusions and at home after infusions are completed. The Chemo Mouthpiece® is a single patient, multi-use device. 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.

Device Specification (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.

Chemo Mouthpiece Patient Kit Directions:

The Chemo Mouthpiece® Device is a prescription only product for use during chemotherapy infusions and at home after infusions are completed. Once the device is prescribed, patients receive a Patient Kit at home. It contains six Chemo Mouthpiece® devices. Patients should place the Chemo Mouthpiece® device units in their unopened double sealed packaging in the freezer for a minimum of 6 hours. This will ensure that the center blue core is frozen solid and the device is ready for use. The patients should bring the frozen devices to their infusion appointments. Just prior to transportation to the infusion clinic, the patient should remove the frozen device units from the packaging and place them into the provided cooler along with the provided freezer cooling pads for transportation to the clinical infusion center.

Directions for Use and Administration at the infusion Clinic:

Patient will use a fresh frozen device beginning 10-15 minutes before the start of the chemotherapy infusion to precondition the oral cavity and begin vasoconstriction. Patient will slide a frozen device into the insulated sleeve. The patient will fit the Chemo Mouthpiece® chamber into their mouth and place their lips over the outer edge. Once inserted, the patient will occasionally squeeze the insulated sleeve/base to circulate the cold fluid inside the Chemo Mouthpiece®. The Chemo Mouthpiece® has breathing tubes to facilitate normal breathing. (See Diagram 1.) The patient should tilt his/her head back for comfort while the device is used. (See Diagram 2.)

The patient will continue using a frozen Chemo Mouthpiece® device throughout the duration of their infusion. A new fresh frozen device should be substituted every 30 minutes to ensure proper oral cavity cooling. Depending on patient tolerance of the device, patients may take an optional 5 minute break at that time of substitution. Following the conclusion of the chemotherapy infusion, the patient will continue to use a device for an additional 10-15 minutes.

Quantity of Device Units Needed:

The number of devices a patient will need at the infusion center is based on their individual chemotherapy infusion length, (one unit for each ½ hour of infusion time).

An Example of Device Quantity Usage is as Follows:

If the chemotherapy regimen is 1 hour in length and the pre and post infusion periods add a total of an additional ½ hour, the patient will use three frozen units during the entire 1.5 hour period.

Post Clinical Infusion Site Use at Home by Patient:

Patient will bring the used devices home and clean them according to the instructions for use. Patients should refreeze the units in the resealable bags after cleaning. Patients are instructed to use a fresh frozen device after returning home starting on the day of infusion and for the next five days. Patients will use the device at home two times per day for at least 30 minutes each time. In cases where the patient cannot tolerate the device in their mouth for the entire 30 minutes, they may take a 5-minute break.



WARNINGS AND SPECIAL PRECAUTIONS FOR USE:

DO NOT USE IF THE PATIENT HAS A SENSITIVITY TO SILICONE.

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

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

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).

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

CAUTION SHOULD BE TAKEN WHEN USED WITH DRUGS THAT HAVE AN ADVERSE EVENT OF COLD AVERSION (ie. OXALIPLATIN).

DO NOT USE IF PACKAGING OR THE CHEMO MOUTHPIECE IS DAMAGED.

Contact ChemoMouthpiece, LLC. for replacement and instructions.

NOTICE: Report all Adverse events, complaints or incidents to ChemoMouthpiece, LLC at 866-496-8858 or email support@chemomouthpiece.com

Pediatric Use:

The use of the Chemo Mouthpiece® device has not been studied in the pediatric population.

Interactions with Other Medicinal Products:

There are no known adverse interactions of this product with other medicinal products.

How Supplied:

The Chemo Mouthpiece® is provided in a six pack configuration as well as a two pack supplemental configuration when a patient needs additional units based on their chemotherapy infusion duration at the clinic. The six pack contains; six devices, six freezer gel pads, an insulated cooler, an insulated sleeve as well as wire brushes to clean the breathing tubes.

Storage:

The Chemo Mouthpiece® has an expiry of two years and must be stored in its vacuum sealed unopened bag. Once the vacuum sealed bag is opened, the Chemo Mouthpiece® must be stored in the freezer.

Caution:

Federal law restricts this device to sale by or on the order of a physician or properly licensed medical practitioner. RX Only.

Disposal:

Mouthpiece can be disposed of in ordinary municipal waste.

DIAGRAM 1 - Mouthpiece Design

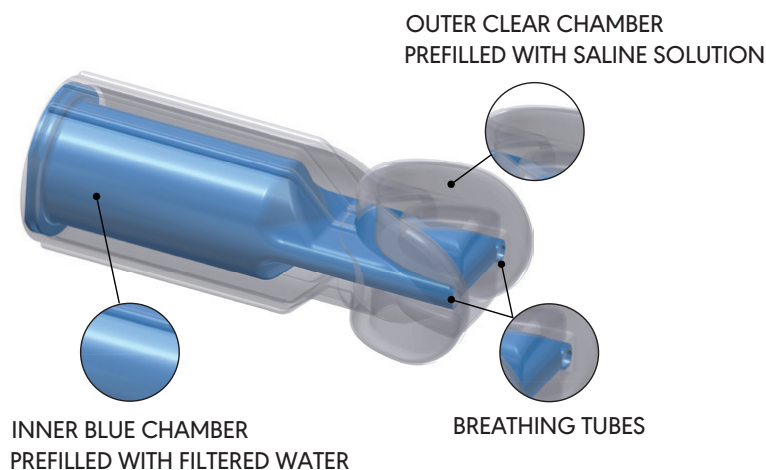


DIAGRAM 2 - Intended Use (without Insulated sleeve for illustration purposes)



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

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For further information visit: www.chemomouthpiece.com

VERSION 10/14/2024