

CHEMO

MOUTHPIECE®

INFORMATION FOR PATIENTS

Chemo Mouthpiece® 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.

FDA 510(k) Cleared

Please see important Safety Information on Page 11 and accompanying full Prescribing Information, also available at ChemoMouthpiece.com



The Chemo Mouthpiece® is Clinically Proven to Reduce the Incidence and Severity of Oral Mucositis

Your healthcare provider has prescribed the Chemo Mouthpiece® oral cryotherapy device to help reduce the incidence and severity of oral mucositis (OM) during your treatment. This brochure provides important information about oral mucositis and the Chemo Mouthpiece® device.

What is oral mucositis (OM)?

Oral mucositis is a painful and debilitating side effect of many chemotherapy drugs, characterized by inflammation and ulceration of mucous membranes in the mouth. These painful sores can occur throughout the mouth including on the hard and soft palate, tongue, gums, cheeks and lips.

Am I at risk for oral mucositis?

Oral mucositis is a common side effect of many different chemotherapy treatments.

A significant proportion of chemotherapy patients will experience some grade of oral mucositis, and many factors may affect the onset and severity of chemotherapy-induced oral mucositis.

How Might Oral Mucositis Affect Me?

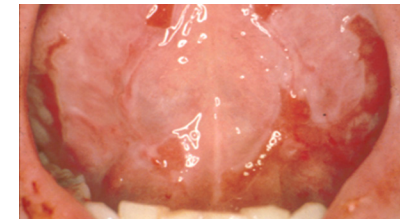
Oral mucositis is graded on a progressively worsening scale from 1 to 4 and is associated with significant complications and pain. OM can alter (dose limit), postpone, or lead to suspension of cancer treatment. OM affects quality of life by making it painful and difficult to eat, swallow, talk and sleep. Development and progression of OM may cause clinically significant problems, including:

- * Opioid and/or analgesic use for pain
- * Dose-limiting or interruption of treatment
- * Weight loss from inability to intake nutrition
- * Pathway for infection
- * Increased ER visits and admittance
- * Significantly increased healthcare costs
- * Difficulty eating, talking, sleeping

World Health Organization (WHO) Oral Mucositis Grade Scale



Example of oral mucositis.

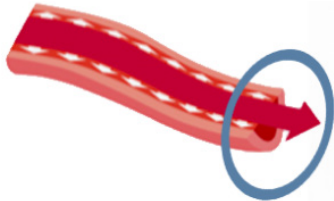


What Is The Chemo Mouthpiece® ?

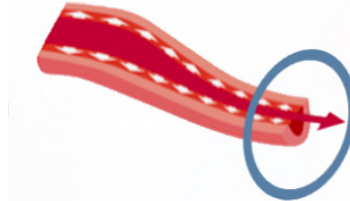
The Chemo Mouthpiece® is an oral cryotherapy (cold temperature) device invented by a cancer survivor who experienced the debilitating effects of oral mucositis during chemotherapy.

When a cold Chemo Mouthpiece® is placed in the mouth, the cooling effect of the device causes vasoconstriction of local blood vessels which physically decreases the flow of systemically circulating chemotherapy in the oral cavity. This reduces the damage chemotherapy drugs can cause to the mucous membranes in your mouth, thus reducing the occurrence and severity of oral mucositis.

without Chemo Mouthpiece®



with Chemo Mouthpiece®



The Chemo Mouthpiece® is an FDA 510(k) Cleared medical device made from components that are Generally Recognized As Safe (GRAS): medical grade silicone, filtered water, HDPE plastic and a proprietary saline solution.

Your Chemo Mouthpiece® devices are self-contained, pre-filled and reusable throughout your treatment.

The unique design delivers cold temperature throughout the inside of the mouth, with the base of the device extending outward and containing two tubes to assist in breathing.

BEFORE



AFTER



Data on file

Thermal imaging shows how the Chemo Mouthpiece® cools the entire oral cavity evenly. Darker areas represent colder temperatures.



Intended Use (without Insulated sleeve for illustration purposes).

EASY TO USE THROUGHOUT TREATMENT!

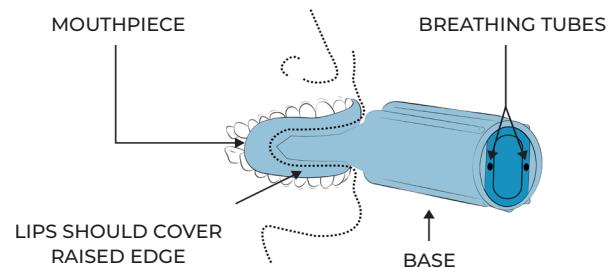
PRIOR TO USE: Place all your Chemo Mouthpiece® devices in their unopened double sealed packaging in the freezer for a minimum of 6 hours. After 6 hours, the blue center core will be frozen solid, the outer chamber will remain liquid, and the devices will be ready for use.

BEFORE INFUSION: 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 it with you to the infusion center. Save the resealable bags for future use.

AT THE INFUSION CENTER: 10-15 minutes prior to infusion remove one Chemo Mouthpiece® from the cooler and slide its base into the insulated sleeve.

FIT THE DEVICE INTO YOUR MOUTH: Place the Chemo Mouthpiece® into your mouth as shown in the diagram below with your lips over the raised edge. Once inserted into your mouth, occasionally squeeze the insulated sleeve/base to circulate cold water inside the device.

TIP: Tilt your head back while using the Chemo Mouthpiece® (see pic. on Page 5). The device has breathing tubes to facilitate normal breathing.



USE EARLY - USE OFTEN!

DURING INFUSION: Each device will stay frozen for 30 minutes. During infusion, after every 30 minutes, replace the Chemo Mouthpiece® device with a fresh, frozen device from your cooler. You may take a 5-minute break if needed from using the device at the time of substitution.

Following the conclusion of your infusion, please continue to use a Chemo Mouthpiece® for 10-15 minutes.

AT HOME: Bring your devices home after your infusion and follow the Cleaning, Care and Reuse Instructions.

The Chemo Mouthpiece® should be used at home two or more times starting the day of infusion and two or more 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.

IMPORTANT: Better results have been clinically demonstrated with more frequent use.

In the clinical trial, patients adhering to use of the Chemo Mouthpiece® experienced less pain, for less time, and used less opioids and analgesics compared to the control arm.¹

**SIGNIFICANTLY LESS PAIN
ELIMINATE THE USE OF OPIOIDS**



(1) Data on file. See Page 9

Please see full Instructions For Use / Tips For Use and Prescriber Information included with your Chemo Mouthpiece® Patient Kit



The Chemo Mouthpiece® has been studied in a randomized, prospective, multi-center clinical trial.

ClinicalTrial.gov ID: NCT04595838

Primary results of the clinical trial demonstrated a statistically significant reduction in oral pain reported by patients, and a statistically significant reduction in use of opioids and analgesic medications through two cycles of chemotherapy.¹

The Chemo Mouthpiece® was studied in a clinical trial involving patients with various types of cancer who received different chemotherapy treatments. The results demonstrated that the device is effective across a wide range of anti-cancer medications.

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(1) Data on file. See Page 9

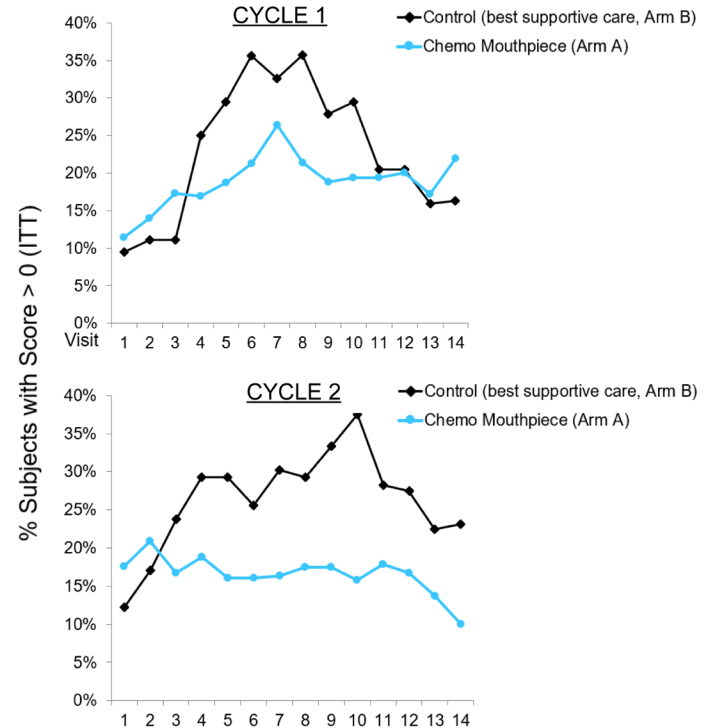
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Less Pain And Less Analgesic Use

A statistically significant outcome was noted in the reduction of pain scores reported per visit in chemotherapy cycles 1 & 2 (see graph at right). **Using the Chemo Mouthpiece® device resulted in a 46% reduction in visits where the patient reported any mucosal pain¹**, indicating there was little or no development of oral mucositis in these patients.

Additionally, a statistically significant outcome was noted in the reduction of opioid and analgesic use in chemo cycles 1 & 2. **Using the Chemo Mouthpiece® device resulted in a 68% reduction in number of patients reporting any opioid or analgesic use for mucosal pain compared to the control arm¹**. Reducing the need for opioids and/or other pain medications reduces the side effects and risks inherent with those interventions, such as constipation, nausea & vomiting, and loss of appetite.



(1) Data on file

GOOD ORAL HYGIENE IS EXTREMELY IMPORTANT DURING YOUR CANCER TREATMENT.

Tips for oral hygiene

- * Brush your teeth gently with a soft toothbrush
- * Rinse your mouth with a salt water and sodium bicarbonate (baking soda) solution
- * If you wear dentures, clean them daily

Tips for eating and drinking

- * Drink plenty of water
- * Avoid foods that are acidic, spicy, coarse, or very hot
- * Do not use tobacco products
- * Do not consume alcohol

Be sure to discuss oral care protocol with your doctor.



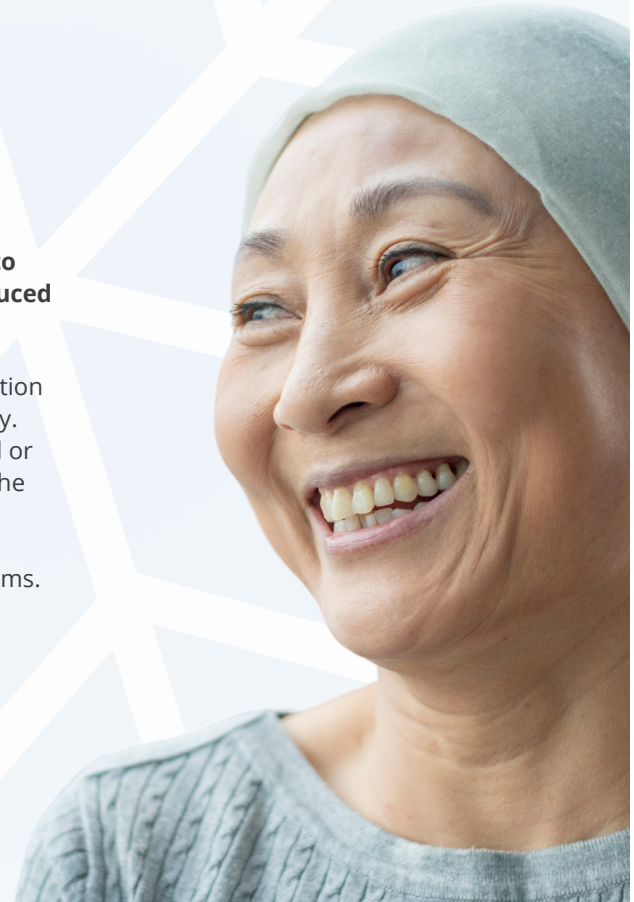
INDICATION AND IMPORTANT SAFETY INFORMATION

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.

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 (e.g. oxaliplatin).

Do not use if the packaging or the Chemo Mouthpiece® is damaged.



Report all adverse events, complaints, or incidents to InfuSystem at 1-800-315-3287 or email CMP@infusystem.com.

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