



510(k)
Cleared

Clinically Proven To Help Patients Reduce the Incidence and Severity of Oral Mucositis

Oral Mucositis Relief for Chemotherapy Patients



The Chemo Mouthpiece is a prescription-only, specially designed oral cryotherapy device for adult chemotherapy patients that cools the entire oral cavity and mucosa. The Chemo Mouthpiece can be used during and after chemotherapy treatments to reduce symptoms of oral discomfort and pain.

Clinical Trial Shows Chemo Mouthpiece Effectiveness

A randomized, placebo-controlled, prospective, multi-center trial to assess the efficacy of the Chemo Mouthpiece cryotherapy device versus best supportive oral care in mitigating and easing the symptoms of chemotherapy-related oral mucositis revealed:

Chemo Mouthpiece (CMP) Significantly Reduced Pain

In the per protocol population of the clinical trial, **23.9% of patients reported any mucosal pain in the control arm vs. 12.8% in the CMP arm (p value < .001)**, representing a statistically significant **46% reduction in visits where patients reported any mucosal pain.**

68%
REDUCTION

CMP Significantly Reduced Analgesic Use

The CMP arm resulted in a **68% reduction in the number of patients using opioids and/or other analgesics** in the per protocol analysis, representing a **3x decrease vs. patients using pain medications in the control arm.**

(Data on file with Chemo Mouthpiece.)

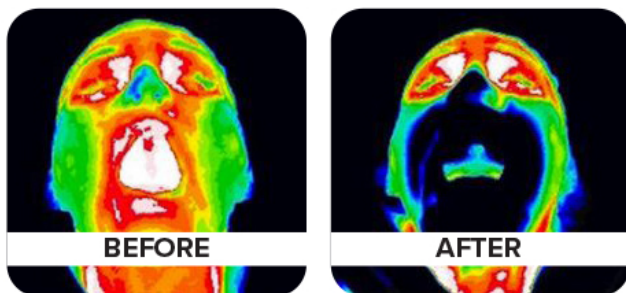


Chemo Mouthpiece is a safe and effective cold therapy method used for the reduction of pain, inflammation and swelling. The Chemo Mouthpiece is an oral cryotherapy device consisting of four components: HDPE plastic, medical-grade silicone, filtered water and proprietary saline solution.

The Science Behind the Chemo Mouthpiece

The Chemo Mouthpiece uses cryotherapy to alter the body's condition. Applying near-freezing temperatures to the mouth tissues forces the blood vessels in those tissues to shrink, reducing circulation and allowing less chemotherapy drugs to reach the mouth.

When placed in a standard freezer, the inner filtered water chamber freezes solid, while the chamber filled with the saline solution will not freeze solid. **The frozen inner chamber allows the circulating proprietary saline solution in the outer chamber to stay very cold, which cools the patient's entire oral cavity.**



The Chemo Mouthpiece reduced patients' oral temperatures by an average of 31.2 degrees F, while ice chips only reduce it by an average of 23.2 degrees F. It also cooled their oral cavities more uniformly. (Data on file with Chemo Mouthpiece.)

Reliable and Effective Oral Cryotherapy for the Reduction in Incidence and Severity of Oral Mucositis

- ✓ Cools the oral cavity uniformly
- ✓ Tolerable for those with sensitive teeth
- ✓ Soothes inflamed tissue and provides relief
- ✓ Stays frozen for up to 30+ minutes
- ✓ Single-patient, multi-use
- ✓ One size fits most adult patients
- ✓ Portable and medication-free
- ✓ Easily cleaned with warm water and soap

1-800-962-9656
chemomouthpiece.com

Chemo Mouthpiece is a trademark of ChemoMouthpiece, LLC

The Chemo Mouthpiece can be used during and after infusion, both at the infusion clinic and at home.

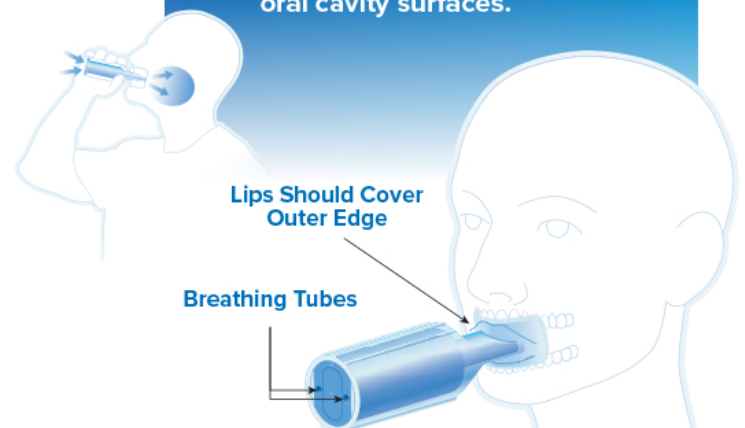


The Chemo Mouthpiece Patient Kit Contains:

- Six mouthpiece devices
- Two insulated sleeves
- Seven cold packs
- Two cleaning brushes
- One insulated cooler

PATIENT USE

Patients insert the mouthpiece into their mouths, placing their lips over the outer edge. Occasionally squeeze the insulated base to circulate cold water inside the mouthpiece. The integrated breathing tubes assist with normal breathing, and the mouthpiece will press comfortably against a patient's oral cavity surfaces.



Contact Your InfuSystem Representative at 1-800-962-9656
or email info@infusystem.com

InfuSystem[®]
SAFE. SMART. TRUSTED.™