

**Chemo Mouthpiece® Oral Cryotherapy Device**  
**FDA 510(k) Cleared**

**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.**



**WARNINGS/PRECAUTIONS:**

**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 the packaging or the Chemo Mouthpiece® is damaged. Report all Adverse events, complaints or incidents to ChemoMouthpiece, LLC at 866-496-8858 or email [support@chemomouthpiece.com](mailto:support@chemomouthpiece.com).**

**Please see full Instructions For Use and Prescriber Information, available at [ChemoMouthpiece.com](http://ChemoMouthpiece.com).**



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Rev. ISI-ENG-072026