

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 InfuSystem Inc., at 1-800-315-3287 or email CMP@infusystem.com.

Please see full Instructions For Use and Prescriber Information, available at ChemoMouthpiece.com.



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