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**CSA Medical Announces Expansion of truFreeze® Label to Include Barrett's Esophagus with Low Grade Dysplasia**

**From Barrett's Esophagus to Malignancy – Only truFreeze®**

**Boston, MA – August 30, 2017:** CSA Medical announced on Thursday, the expansion of its truFreeze® label with the addition of Barrett's Esophagus with low grade dysplasia. This expansion comes after 510(k) submission of clinical data supporting the use of truFreeze Spray Cryotherapy in patients with BE and low grade dysplasia. With this clearance, FDA has now recognized the safety and effectiveness of the truFreeze system to ablate BE with LGD as well as HGD and malignancies, thus providing physicians the ability to treat a variety of benign and malignant lesions in the esophagus with just one device.

Barrett's Esophagus is a complication of Gastro Esophageal Reflux Disease (GERD) in which the tissue lining the esophagus changes form due to the presence of stomach acid on the tissue over time. In low grade dysplasia, this change in tissue is progressing to the formation of pre-cancerous cells, and intervention is recommended. It is estimated that 0.5 – 2.0% of adults have Barrett's Esophagus<sup>1</sup>.

"Over the past few years, studies have underscored the potential risk for Barrett's esophagus with low grade dysplasia to progress to esophageal adenocarcinoma" said Michael S. Smith, MD, MBA, incoming Chief of Gastroenterology and Hepatology at Mount Sinai West and Mount Sinai St. Luke's Hospitals and Associate Professor of Medicine at the Icahn School of Medicine at Mount Sinai in New York. "Intervening at this level of dysplasia has become common practice and is recognized in our society guidelines. My colleagues and I have used liquid nitrogen spray cryotherapy for over a decade to treat Barrett's esophagus with high levels of efficacy and patient tolerability. With approval of this expanded label, the FDA has recognized spray cryotherapy's ability to positively impact the lives of our Barrett's patients."

"We are pleased to have obtained FDA clearance to expand our indications for use to include Barrett's Esophagus with low grade dysplasia as an example of benign disease ablation as well as our present indication for Barrett's Esophagus with high grade dysplasia and malignant disease ablation. The data set that formed the basis of this claim came from our prospective post market registry that delineated ablation using truFreeze spray cryotherapy as specified in our instructions for use. Achieving a CE-D rate of 95.5% in this patient cohort is in keeping with numerous previously published truFreeze reports," says Ellen Sheets MD, CEO and President of CSA Medical.

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<sup>1</sup> Runge, T, et al, Epidemiology of Barrett's Esophagus and Esophageal Adenocarcinoma, [Gastroenterol Clin North Am.](#) 2015 Jun; 44(2): 203-31.

This label expansion solidifies truFreeze as a treatment option for Barrett's Esophagus, and supports coverage decisions for truFreeze patient treatments.

**About CSA Medical**

CSA Medical, Inc. develops and manufactures a proprietary interventional spray cryotherapy technology platform utilizing unique properties of liquid nitrogen spray delivered by a software driven device with specialty catheters that enable delivery of spray cryogen inside the body to flash freeze and destroy unwanted tissue allowing for a rejuvenative pattern of healing. CSA manufactures and distributes this technology in the USA as the truFreeze<sup>®</sup> system which is currently used to ablate benign (e.g. Barrett's Esophagus with high grade dysplasia) and malignant lesions.

To learn more about our technology, please visit <http://csamedical.com/>.

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