



## **FDA Clears Two Expanded Indications For VELscope® Regarding Detection and Excision of Oral Cancer**

### ***LED Dental Device Intended to Help Detect Lesions That Might Not Be Visible With Conventional Exams And to Help Determine Surgical Margins***

VANCOUVER, British Columbia—April 11, 2007—LED Dental Inc. announced today that it has received clearance from the U.S. Food and Drug Administration to expand the indications for use for its VELscope Oral Cancer Screening System. The two expanded indications involve the ability to help detect lesions that may not be visible under traditional white light examinations, including precancerous and cancerous growths, and the ability to help surgeons ensure that all diseased tissue is successfully removed when excising cancerous lesions.

#### **Indications For Use**

According to the indications for use recently cleared by the FDA, "VELscope is intended to be used by a dentist or health-care provider as an adjunct to traditional oral examination by incandescent light to enhance the visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or pre-malignant dysplasia. VELscope is further intended to be used by a surgeon to help identify diseased tissue around a clinically apparent lesion and thus aid in determining the appropriate margin for surgical excision."

These expanded indications for use are based on two studies conducted by scientists at the British Columbia Cancer Agency and published in the January 2007 issue of *Head and Neck* and the November 2006 issue of *Clinical Cancer Research*. The first study reported cases in which VELscope facilitated the detection of precancerous or cancerous tissue that was *not* visible to an expert under conventional white light visualization. In the second study, in which VELscope was used to help identify surgical margins, 90 percent of the biopsy samples taken from areas that were beyond the clinically-apparent boundary but identified by VELscope as suspicious were ultimately diagnosed as either cancer or dysplasia. Moreover, 50 percent of the tumors exhibited cancer or dysplasia at or beyond the traditional 10 mm surgical margin.

#### **Oral Cancer: The Forgotten Disease**

Oral cancer is one of the few forms of cancer that have *not* experienced a significantly decreased mortality rate in the past 30 years. Deaths from oral cancer are higher than from cervical, testicular, laryngeal or thyroid cancer. It is estimated that over 34,000 Americans will develop oral cancer in 2007, and that only about half of them will be alive in five years. One American dies of this disease every hour of every day.

The traditional profile of an oral cancer victim is that of a heavy user of tobacco and alcohol who is at least 40 years old. However, the number of victims who do *not* fit this profile has been growing at an alarming rate in recent years. One reason may be the growth in the occurrence of the human papilloma virus (HPV), one strain of which is now thought to be a possible cause of oral cancer. Because of this, many health professionals are now

recommending that annual oral cancer screenings be performed not merely on the traditional at-risk group, but on all adults 18 years-old and older.

**Oral Cancer: Detectable and Treatable**

The high mortality rate of oral cancer is largely the result of the late stage at which the disease is typically detected. Fortunately, the 5-year survival rate is estimated to be 80% or higher when oral cancer is detected at early stages. Annual dental hygiene exams are generally considered to be the ideal opportunity to conduct an oral cancer screening. The VELscope exam is intended to supplement the conventional white light visual exam and can be given by a hygienist in only one or two minutes.

“VELscope is uniquely able to help facilitate the early detection of oral cancer, as it is the only adjunctive device cleared as an aid in the identification of lesions that may not be apparent under white light examination, including precancerous or cancerous lesions,” said Steven Semmelmayr, president and CEO of LED Dental Inc. and its parent, LED Medical Diagnostics Inc. “Moreover, VELscope is the only adjunctive device cleared to help surgeons minimize the risk of inadequate tissue removal.”

“We have been gratified by the response we have received from dental practices about VELscope,” said Semmelmayr. “Their staffs appreciate the fact that a VELscope exam is easy to perform and completely non-invasive, while their patients are grateful that the practice is not only demonstrating a serious concern for their health, but might even save their life.” VELscope is available for purchase throughout the United States through Becker-Parkin Dental, Benco Dental Supply, Burkhart Dental Supply, Patterson Dental and Sullivan-Schein Dental.

**About LED Dental**

LED Dental Inc. is a wholly-owned subsidiary of LED Medical Diagnostics Inc., which was founded in 2003 and is headquartered in Vancouver, British Columbia. For more information, call 1-888-541-4614, or visit [www.VELscope.com](http://www.VELscope.com).

**LED Medical Diagnostics Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995**

The Private Securities Litigation Reform Act of 1995 provides a “safe harbor” for forward-looking statements. Certain information included in this press release (as well as information included in oral statements or other written statements made or to be made by the company) contains statements that are forward-looking, such as statements relating to anticipated future revenues of the company and success of current product offerings. Such forward-looking information involves important risks and uncertainties that could significantly affect anticipated results in the future and, accordingly, such results may differ materially from those expressed in any forward-looking statements made by or on behalf of the company. For a description of additional risks and uncertainties, please refer to the company’s filings with the Securities and Exchange Commission.

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