

# Fluorescence Visualization Technology

## A NEW TOOL FOR ORAL MUCOSAL EXAMINATION

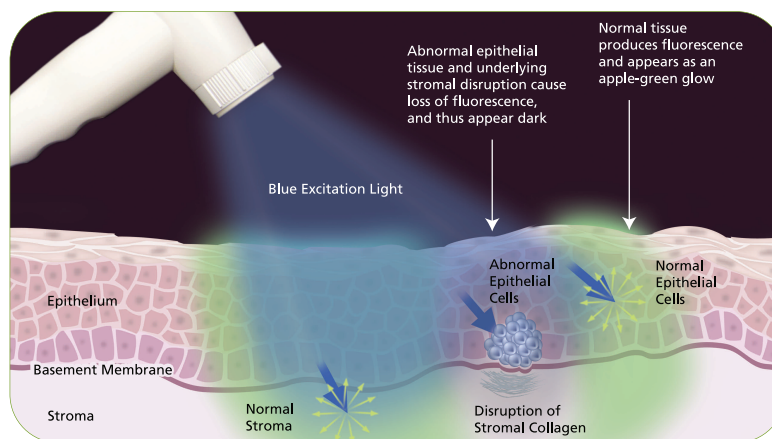
The VELscope® System is a revolutionary hand-held device that provides dentists, hygienists, and other oral health care professionals with an easy-to-use adjunctive mucosal examination system for the early detection of abnormal tissue. The VELscope® System patented technology platform was developed by the British Columbia Cancer Agency in collaboration with MD Anderson Cancer Center, with funding provided in part by the NIH. It is based on the direct visualization of tissue fluorescence and the changes in fluorescence that occur when abnormalities are present. The VELscope® System Handpiece emits a safe blue light into the oral cavity, which excites the tissue from the surface of the epithelium through to the basement membrane and into the stroma beneath, causing it to fluoresce. The clinician is then able to immediately view the different fluorescence responses to help differentiate between normal and abnormal tissue. In fact, the VELscope® System is the only adjunctive device cleared by the FDA and Health Canada to help discover oral mucosal lesions that might not be apparent or visible to the naked eye and to help surgeons determine the appropriate surgical margin for tumor excision. Under examination with the VELscope® System, abnormal tissue typically appears as an irregular, dark area that stands out against the otherwise normal, green fluorescence pattern of surrounding healthy tissue.

*"Without VELscope neither I, the oral surgeon, nor the head and neck surgeon could visualize the lesion... VELscope literally saved the patient's life."*

Dr. A Palombaro, Binghamton, NY

*"Adding VELscope to our diagnostic protocol... has resulted in detection of dangerous lesions that would have otherwise been undetected."*

Dr. E Truelove, Seattle, WA



## ORAL CANCER KILLS ONE PERSON EVERY HOUR, 24 HOURS A DAY IN NORTH AMERICA

- The incidence of oral cancer increased 11% in the United States in 2007
- Unlike several other cancers, the survival rate for oral cancer has remained unchanged for decades
- The overall 5-year survival rate for oral cancer is 52%, but when discovered early, it increases to 80% - 90%
- Unfortunately, only 35% of oral cancer cases are diagnosed in the early stages. Why? Because there have been few advances made in screening techniques and there are significant limitations inherent to white light and chemiluminescence light examination of the oral mucosa
- Pre-malignant changes actually start below the surface, at the basement membrane. These changes may not be apparent to the naked eye until the disease progresses to the surface

## NEW FDA 510(K) CLEARANCE & HEALTH CANADA APPROVAL

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.



Get it early. Get it all.™

**VELscope®**  
The Oral Cancer Screening System

# Single Out Suspicious Tissue...Early Discovery Can Save Lives

## SYSTEM FEATURES:

- Painless, non-invasive, with no rinses or stains required
- An examination with the VELscope® System takes only one or two minutes and is easy to incorporate into your workflow
- Oral lesion mapping, tracking and patient management forms available online. Optional third-party photo-documentation solutions also available
- Flexible positioning: space-saving vertical or low profile horizontal orientation... your choice
- Disposable VELsheath/Barrier ensures asepsis
- Disposable anti-fog VELcap helps maintain asepsis and protects the Handpiece special filtering optics
- Convenient disposable VELtractor assists clinicians as a "third hand" during the examination and also serves as a measuring guide

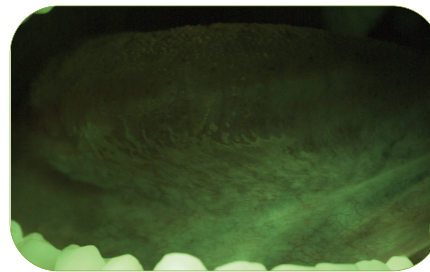
## VELSCOPE PROVIDES IMMEDIATE BENEFITS FOR THE PATIENT, CLINICIAN AND PRACTICE

The VELscope® System combines minimal per-patient costs with more effective screening. The investment for VELscope can be quickly recouped, yielding a substantial earning potential for the practice. Through the CDT code D0431\*, an increasing number of insurance companies are recognizing VELscope as an adjunctive screening device.

\* U.S. only. Code will vary for other countries.

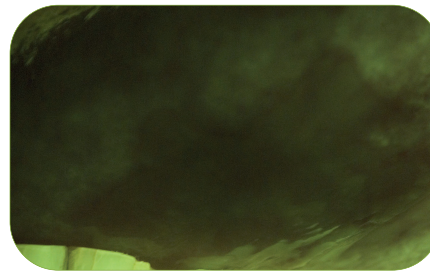
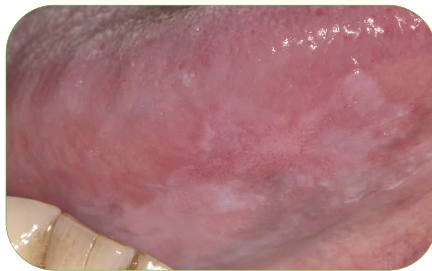
## EXAMPLES OF DIRECT VISUALIZATION UNDER BOTH WHITE LIGHT AND VELSCOPE EXAMINATION

No apparent lesion



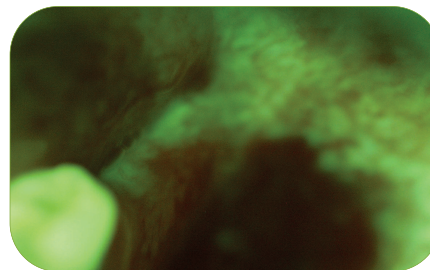
Normal fluorescence pattern

Visible leukoplakia



Irregular, dark area visible under fluorescence visualization. Biopsy-confirmed severe dysplasia

No apparent lesion



Irregular, dark area visible under fluorescence visualization. Biopsy-confirmed CIS

Images courtesy of the British Columbia Oral Cancer Prevention Program

For further information about VELscope and LED Dental Inc., please visit our website at [www.velscope.com](http://www.velscope.com).

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