Synopsis of Oral Cancer Screening Aids and Oral CDx Brush Biopsy Test (Project 11-022)

This synopsis provides information obtained from manufacturers on several oral cancer screening aids and one brush biopsy test. Four screening products and one brush biopsy test have been included in the synopsis. The Oroscoptic DK oral cancer screening device was discontinued in 2011.

Oral cancer is the sixth most common malignancy in the world, with over 400,000 cases being reported worldwide.[1,2] In 2010 over 36,000 new cases of oral cancer were diagnosed in the United States with the malignancy occurring twice as often in men than women. Approximately 7,800 people die of oral cancer each year, and based on rates from 2007, about one in every 100 men and women born today will be diagnosed with oral cancer in their lifetime.[3] Despite numerous advances in treatment, the 5-year survival rate has remained approximately 50% for the past 50 years.[4] This poor prognosis is likely due to several factors. Frequently, oral cancer is associated with the development of multiple primary tumors, and the rate of second primary tumors (3-7% per year) is higher than for any other malignancy.[5] The most common cause of treatment failure and death in oral cancer patients is their second primary tumor. Furthermore, poor survival rates can also be attributed to the advanced extent of disease at the time of diagnosis, with over 60% of patients presenting in stages III and IV.[6] This seems particularly disturbing since the disease arises in the oral epithelium which is easily accessible to direct visual and tactile examination.

Risk factors for oral cancer include tobacco and alcohol use, smokeless tobacco, and an ethnic predilection in African American males which is double the death rate of Caucasian populations. High-risk sites are the tongue and the floor of the mouth. The average age at diagnosis is 62 years, but a rapidly growing number of younger patients without traditional risk factors are being diagnosed with HPV-related oropharyngeal tumors on the tonsils and base of the tongue. [7] Symptoms of oral cancer can present in many forms, but the typical presentation is a non-healing ulcer, either painful or non-painful. Other suspicious characteristics are white or red spots, bleeding sores, increased mouth pain, loose teeth, ill-fitting dentures, non-healing extraction sockets, mouth numbness, difficulty swallowing, change in speech or a lump in the neck. Any white/red lesion in the mouth that has not healed within three weeks should be evaluated by a dentist or oral surgeon.

Pre-cancerous lesions have been categorized by color and include leukoplakia (white), erythroplakia (red), and erythroleukoplakia (red and white mixed). Leukoplakia has been associated with a malignant change in 1% to 3% of cases. Erythroleukoplakia is associated with a 25% malignant change.[7] Many precancerous lesions will never develop into cancer but their recognition is important so the lesions can be biopsied and monitored.

The gold standard for detecting oral lesions is the conventional oral examination. This routine examination should be performed with good lighting, a dental mirror and adequate retraction to allow for direct inspection, both visually and tactile, of all mucosal surfaces and particularly the high-risk sites: the lateral border of the tongue, ventral surface of the tongue, and the floor of the mouth. Next, an examination of the neck is important with particular emphasis placed on the lymph nodes.

The visual detection of oral premalignant lesions has been problematic. In contrast, skin lesions such as melanoma have sensitivity and specificity rates of 93 and 98%.[2] Oral cancer and precancer lesions are often subtle and rarely demonstrate the clinical characteristics observed in advanced cases: ulceration, induration, pain and cervical lymphadenopathy. Besides their clinical subtlety, premalignant lesions are highly heterogenous in presentation and can mimic a variety of common benign or reactive conditions. Many premalignant and early cancerous lesions are not readily detectable to the naked eye; therefore, additional screening aids for oral cancer are desperately needed. Unfortunately, no technology to date has provided definitive evidence to suggest that it improves the sensitivity or specificity of oral cancer screening beyond the clinical oral examination alone.

When reviewing the tables, please remember that the information has been provided by the manufacturers, and not necessarily confirmed by DECS evaluation.

Click here to view the oral cancer screening aids and one brush biopsy test.

References:

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2. American Cancer Society: Cancer Facts and Figures; 2005. <http://www.cancer.org/docroot/STT/stt_0.asp>.
3. Howlander N, Noone AM, Krapcho M, Ney-man et al (eds.). SEER Cancer Statistics Review, 1975-2008, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2008/, based on November 2010 SEER data submission, posted to the SEER Web site, 2011.
4. SEER Cancer Statistics Review; 1973-1998. <http://seer.cancer.gov/csr/1973_1998/index.html>.
5. Day GL, Blot WJ. Second Primary Tumors in Patients with Oral Cancer. *Cancer* 1992;70(1):14-9.
6. Lingen MW, Kalmar JR, Karrison T, Speight PM. Critical Evaluation of Diagnostic Aids for the Detection of Oral Cancer. Oral Oncology 2007;
7. American Association of Oral and Maxillofacial Surgeons. Oral Cancer: Approaches to Screening, Diagnosis, and Treatment. American Association of Oral and Maxillofacial Surgeons Surgical Update.

SYNOPSIS OF ORAL CANCER ADJUNCTIVE SCREENING AIDS*

Product/Model	ViziLite® Plus	VELscope Vx
Manufacturer or Distributor	Zila Pharmaceuticals (A Division of Tolmar) 701 Centre Avenue Fort Collins, CO 80526 www.zila.com	LED Dental Inc. 5589 Byrne Rd, Suite 235 Burnaby, BC, Canada V5J 3J1 www.velscope.com
Phone/FAX Numbers	Comm: (970) 212-4500 Toll Free: (800) 228-5595	Comm: 604-434-4614 Toll Free: (888) 541-4614 FAX: 604-434-4612
ISO Certification	Yes	Yes
Detection Method	Tissue Reflectance	Autofluorescence
Procedure or Protocol	Oral rinse with 1% acetic acid then visualization with blue-white light source at 440 nanometers. Abnormal tissue is reported to appear distinctly white when illuminated by this wavelength.	Direct visualization
Power Source	No power source is required for this product. The product is a single use, disposable screening kit.	Lithium-ion rechargeable battery; optional corded operation
Dimensions	Height: 6 inches Width: 0.5 inches Depth: 0.5 inches Weight: 0.4 ounces	Height: 8.6 inches Width: 2.2 inches Depth: 3.4 inches Weight: 14.6 oz.
Accessories included	40 Pack Kit includes a stadium packaging design that allows to storage within the operatory, individually packaged refractor and light stick, and container of 1% acetic acid for dispersing to each client.	Charging Cradle (also functions as a stand for the handpiece when not in use); Patient Safety Glasses; 16-pack VELcap disposables; 16-pack VELsheath disposables; 50 Oral Cancer Foundation Brochures; 50 VELscope Vx Patient Brochures; Support and Training Disk (includes extensive training videos and electronic documentation); printed and laminated Quick Reference and clinical Step-by-Step Guides.
Suggested Retail Cost	40 Pack ($780.00), Supplement T-Blue® Pack ($186.96), Eyewear ($49.95)	$2749.99 USD – VELscope Vx System $230.40 USD – VELcap Vx (disposable) – box of 128 $39.95 USD – VELsheath Vx (disposable) – box of 250 $499 USD – VELscope Vx Camera System
Suggested Govt Cost	40 Pack ($540.00), Supplement T-Blue® Pack ($175.77), Eyewear ($39.60)	$2418.90 USD – VELscope Vx System $176.01 USD – VELcap Vx (disposable) – box of 128 $30.52 USD – VELsheath Vx (disposable) – box of 250 $439.86 USD – VELscope Vx Camera System
Warranty	Vizilite Plus ® Oral Screening Products are warranted to be free of defects through the labeled expiration date of the product. To return Vizilite Plus ® products that not expired, please you're your	Full 1-year warranty

	Customer Service Specialist at 800-752-2564 to obtain a RMA number. No returns will be processed without a RMA number	
How is a preliminary positive test made?	Initially, the lesion in the mouth will be illuminated with the chemoluminescent light and will appear to be a white area. Following this assessment, the use of T-Blue® stained in the area of the white lesion will signify diseased cells that should be biopsied for further assessment to determine if the lesion is benign or cancerous.	The VELscope Vx does NOT perform a diagnostic test but rather is an adjunctive (and therefore complementary) visualization tool that has comparable objective to the head and neck exam: the detection and location of tissue abnormalities that warrant further follow-up and/or referral as appropriate. Its major value in the hands of the primary care practitioner is to help discover abnormalities that might otherwise have been overlooked. As such, it helps in the discovery of all oral disease and is not restricted only to oral cancer or potentially malignant dysplasia, although its high sensitivity to these types of lesions is certainly one of its main advantages. A properly trained user becomes alerted to problematic soft tissue areas in the oral cavity by observing abnormal fluorescence patterns consisting typically of irregular areas of loss of fluorescence which stand out against the normal fluorescence pattern of healthy tissue. Just like under conventional lighting, abnormal areas detected via fluorescence should always be considered within the full clinical context, and next steps rely on appropriate use of clinical judgment. The VELscope Vx can also be used by the specialist to: better appreciate the full scope of mucosal involvement of a particular lesion under consideration; help in biopsy site selection; assist in the determination of surgical margins during lesion excision.
Additional Notes/Features	A clinical study has shown that the use of ViziLite® Plus with TBlue® after a conventional visual examination resulted in no false negative outcomes, meaning in this clinical study ViziLite® Plus with TBlue® identified *every* lesion that had precancerous cells or cancer, significantly reducing the number of false positive lesions identified during standard visual examinations – limiting the number of biopsies that may have normally been performed. Quick and easy-to-use system that incorporates seamlessly into an existing oral cancer screening examination. Small device makes it easy to see all areas of the oral cavity. Disposable technology eliminates cross-contamination. TBlue® is manufactured in a GMP facility, providing consistency in product quality. ViziLite® Plus with TBlue® "No Regrets" Promise: No	The 16 high-power blue/violet LEDs generate significantly more excitation power density than any of its competitors enabling the straightforward visualization of the autofluorescence tissue response in a wide range of ambient light conditions. The bright fluorescence response and the viewing handpiece design combine to allow the straightforward acquisition of bright, high-quality tissue autofluorescence photographs in essentially a 'point and shoot' modality. LED Dental has developed a camera system for the VELscope Vx that is delivered to the customer, pre-configured and ready-to-shoot (with the exception of needing to charge the camera battery first). The user just attaches the camera system to the clinician side of the handpiece and takes pictures through the filters as if they were taking normal photographs. This allows easy photo documentation of tissue areas (the camera can be used to acquire conventional, white light pictures as well); considering the growing importance of photo-documentation of oral soft-tissue as a standard part of the patient work-up, LED Dental recommends its new camera system as an integral component of adjunctive state-of-the-art autofluorescence examinations.

	costly capital investment, no technology obsolescence and support limitations as next generation products are introduced. No claims without supporting clinical studies. No limitations when viewing oral cavity due to size of device.	

* The manufacturers provided data in this table. The listing or omission of a product in this table does not imply endorsement, approval, or disapproval by DECS.

SYNOPSIS OF ORAL CANCER ADJUNCTIVE SCREENING AIDS*

Product/Model	StarDental Identafi®	Microlux™ AdDent Inc.
Manufacturer or Distributor	StarDental, Division of DentalEZ 1816 Colonial Village Lane Lancaster, PA 17601 www.dentalez.com www.identafi.com	AdDent Inc 43 Miry Brook Rd. Danbury, Ct. 06810 www.addent.com
Phone/FAX Numbers	Comm: 610-725-8004 FAX: 610-725-9894	Comm: 203-778-0020 Toll Free: 855-211-3413 FAX: 203-792-2275
ISO Certification	Yes	Pending
Detection Method	auto fluorescence and tissue reflectance	Tissue Reflectance
Procedure or Protocol	No special procedure required prior to visualization. Device does require use of special filter glasses during part of the procedure. Glasses are included with kit. Disposable plastic sheath with angled mouth mirror also used with device for aid in visualization. Twenty-five (25) disposable mirrored sheaths provided with initial purchase.	1% acetic acid rinse
Power Source	2 disposable AA batteries. Can use rechargeable batteries.	3 N Style batteries and LED
Dimensions	Wand: 10 inches long, 5/8th inches in diameter at base. Height: 10.5 cm Width: 27 cm Depth: 40 cm Weight: 5 lbs	Height: 6 7/8 inches Width: 5/8 inches Depth: 5/8 inches Weight: 0.15 lb
Accessories included	Special filtered clinician glasses. 4 AA batteries, 25 disposable mirrored sheaths (75 additional included in price. Shipped upon device registration	PN 110035 includes Microlux™ DL with 6 bottles of Rinse.
Suggested Retail Cost	$3795.00.	$279.00
Suggested Govt Cost	$2087.25	$167.40
Warranty	Full 1-year warranty	Full 1-year warranty
How is a preliminary positive test made?	A suspect lesion will appear dark under the devices patented violet autofluorescence setting. The green amber wavelength feature enables clinicians to observe differences between normal and abnormal tissue vasculature.	Patient rinses with ½ bottle of 1% acetic acid for 30 seconds. Doctor dims the lights and examines the interior of the mouth. If there are any abnormal lesions are present, it will show as a white raised area.
Additional Notes/Features	Device uses both autofluorescence and reflectance technology. The three different light wavelengths aid in the early detection of oral tissue changes that may not be visible by normal examination techniques. The Identafi takes advantage of the mucosal tissue's normal fluorescence properties. Normal tissue will fluoresce when exposed to the units patented 405nm wavelength while	The Price is lower than competitors and is cordless, The tip is autoclaveable, and a sleeve is available to cover it. One bottle of rinse is sufficient for 2 patients. After initital purchase, the cost per patient is $5.00 Other attachments are available for this base unit which make it a multi-purpose unit. These are: Transillulminator light guide, Lighted mirror, Endo lite attachment to detect root fractures and

	abnormal tissue appears dark. The green amber wavelength feature, unique to the StarDental Identafi® enables clinicians to observe differences between normal and abnormal tissue vasculature. The white light function is used for the conventional tissue exam	interproximal Caries – and illuminated perio probe.

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SYNOPSIS OF ORAL CDx BRUSH BIOPSY ANALYSIS*

Product/Model	The OralCDx Brush Biopsy
Manufacturer or Distributor	CDx Diagnostics 2 Executive Blvd, Suite 102 Suffern, NY 10901
Phone/FAX Numbers	Comm: 845-369-7096 Toll Free: 877-712-7874 FAX: 845-368-7461
ISO Certification	Yes
Detection Method	Transepithelial Brush Biopsy for Computer-Assisted Analysis
Procedure or Protocol	The OralCDx Brush Biopsy is non-invasive test used to rule out pre-cancer and cancer from small oral lesions. The kit consists of an easy-to-use, patented tissue sampling brush that obtains a complete epithelial sample. Specimens are analyzed by a revolutionary computer system which highlights potentially abnormal cells for pathologist review. The brush biopsy enables the pathologists to find the earliest cellular evidence of disease and issue a definitive lab report.
Power Source	N/A
Dimensions	N/A
Accessories included	Brush biopsy kit includes all materials needed to perform one brush biopsy. Kit Parts: Brush Biopsy kit includes: brush, slide in slide holder, 2 fixative pouches, vial with solution in resealable bag with padding, test form, and instructions
Suggested Retail Cost	Call for rate
Suggested Govt Cost	Call for Government rate for laboratory analysis
Warranty	N/A
How is a preliminary positive test made?	Pathologists using advanced computer technology analyze each case and issue a result. If evidence of per-cancerous cells and/or cell clusters are seen on the samples a positive result will be rendered.
Additional Notes/Features	

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