

6. Direct the patient to rinse and gargle with water and expectorate. This step may be repeated.
7. Lightly dry the area swabbed with the 1% Acetic acid solution with a gauze sponge or a gentle stream of air to minimize the risk of swallowing excess ORABLU™ dye.
8. Continuing to use oral exam light in a dimly lit room (if necessary), apply 7 drops of the ORABLU™ dye to moisten one end of a new applicator swab. Apply the moistened swab to the suspicious lesion(s) that have had the pre acetic acid solution applied. Press firmly in a painting motion. Cover an area extending 2 cm in diameter around the visible lesion. Swab for 20 seconds. The ORABLU™ dye solution should be expectorated.
9. Room lights may now be turned on, the balance of the staining/decolorization procedure and exam is to be done using conventional dental illumination.
10. Apply 5 drops of the 1% Acetic acid solution to moisten one end of a new applicator swab. Apply the moistened swab to the stained lesion. Again, press firmly in a painting motion to apply the solution using a reasonable mechanical effort to remove the blue stain. Completely cover the area where any blue stain appears. Swab for 20 seconds. This step may be repeated to remove any excess dye.
11. Direct the patient to rinse and gargle with water and expectorate. This step may be repeated.
12. Measure the stained lesion and document the staining pattern. To evaluate a stained area during the exam, a swab saturated with pre- or post solution (1% Acetic Acid) is used to attempt to remove excess dye.
13. If stain remains on the swabbed area, take appropriate clinical management action by either counseling the patient that lesion(s) should be followed and schedule a future appointment; performing a biopsy of identified mucosal lesion(s); referring the patient to an appropriate specialist for further evaluation; etc.

MANUFACTURER

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ORABLU

ORAL LESION MARKING SYSTEM

INSTRUCTIONS FOR USE



DEVICE DESCRIPTION

ORABLU™ Oral Lesion Marking System consists of one bottle containing 3.0 ml 0.5% Tolonium Chloride solution, one bottle containing 6.0 ml 1% acetic acid solution, and 30 individually packaged applicator swabs. The OraBlu kit contains enough materials for approximately 10 applications.

INDICATIONS FOR USE

The ORABLU Oral Lesion Marking System is a three component swab system intended to be used by a dentist as an adjunct to traditional oral examination by incandescent light with further examination with an oral examination light manufactured by AdDent, Inc. The ORABLU Oral Lesion Marking System is used as an aid to enhance the visualization of oral mucosal irregularities by physically marking areas of oral mucosa that may warrant further investigation.

ORABLU™ ORAL LESION MARKING SYSTEM COMPONENTS

Each box contains the following components:

- One bottle of ORABLU dye (0.5% Tolonium Chloride)
- One bottle of Pre & Post Solution (1.0% Acetic Acid)
- 30 individually packaged applicator swabs
- Instructions for use
- MSDS available at: www.addent.com

CONTRAINDICATIONS

- The ORABLU™ Oral Lesion Marking System should never be used without prior conventional oral examination with incandescent light.
- The ORABLU™ Oral Lesion Marking System is contraindicated in patients with a known history of hypersensitivity to any of the ingredients or their analogs.
- The ORABLU™ Oral Lesion Marking System is contraindicated in patients who are pregnant or lactating.
- Due to the lack of safety data, the ORABLU™ Oral Lesion Marking System should not be used in children, patients with liver or renal insufficiency, or patients with difficulty swallowing.
- The ORABLU™ Oral Lesion Marking System should be used with caution in patients who may have difficulty following directions during the lesion staining procedure (e.g. patients with severe physical or mental disabilities).


WARNINGS/PRECAUTIONS

- Caution: Federal law restricts this device to sale by or on the order of a dentist or physician. .
- Removable oral prostheses should be removed and any associated trauma or inflammation given time to heal prior to use of this product.
- Care should be taken to protect clothing, as well as equipment and environmental surfaces from being stained.
- Should any of the material be accidentally swallowed, the urine and/or stools may be colored temporarily blue-green or blue, respectively. The patient should be advised of the possibility of this and assured that the color change is temporary.
- Patients should be informed prior to the ORABLU procedure that there may be a residual bluish discoloration on the vermilion border, dorsum of the tongue, and dental plaque, which usually wears off in 2-6 hours.
- Common restorative materials including porcelain, composites, and acrylics and margins of dental restorations may stain transiently; dental materials are not known to stain permanently.
- For oral use only. Keep out of reach of children.

INTERACTIONS

Interactions of the ORABLU™ Oral Lesion Marking System components with other medications have not been studied, but are unlikely.


ADVERSE EVENTS

 Patients may experience a slight burning sensation of the oral mucosa due to the acetic acid in the ORABLU™ Oral Lesion Marking System.

No severe adverse reactions are expected when the ORABLU™ Oral Lesion Marking System is used according to package instructions. Some patients may find the taste of the product unappealing and may gag.

For Chemical Emergency (Spill, Leak, Exposure or Incident) CALL INFOTRAC 24-Hour Number: 1-800-535-5053 or +1-352-323-3500 (outside USA).

OVERDOSAGE

 No adverse events have been reported in the published literature concerning the use of Tolonium Chloride in the mouth for staining oral lesions. Safety data regarding Tolonium Chloride toxicity can be found on AdDent's website. <http://www.addent.com/docs/MSDS-ORABLU.pdf>

GENERAL PROCEDURE FOR ORABLU™ ORAL LESION MARKING SYSTEM

The ORABLU™ Oral Lesion Marking System is designed to be used following conventional manual and visual oral examination with incandescent light followed by oral examination using an oral examination light from AdDent, Inc.

Any lesion identified with the oral examination light may be further evaluated using the ORABLU™ Oral Lesion Marking System (pre- and post-dye 1% Acetic Acid solution and ORABLU 0.5% Tolonium chloride dye). The ORABLU™ Oral Lesion Marking System should only be used in conjunction with a complete oral screening exam using an oral examination light. This includes:

1. Conventional manual and visual oral examination with overhead exam light
2. Examination with an oral examination light in a dimly lit exam room
3. Application of the pre-dye 1% acetic acid solution
4. Application of the ORABLU dye to any clinically suspicious mucosal abnormalities differentially identified with the oral examination light.
5. Application of the post-1% Acetic acid solution

All lesions seen using an oral examination light are potentially important. The absence of marking by the ORABLU dye of a lesion seen with an oral examination light should not preclude further analysis of the lesion, including biopsy. Any lesion seen by conventional examination or using an oral examination light may harbor pathology, and clinical judgment should always prevail when deciding the further analysis and management of these lesions.

Before using the ORABLU™ Oral Lesion Marking System, the patient should be draped with a bib to protect clothing. As expectoration is required, the patient should be positioned near a sink. During administration of the staining solutions, the patient should expectorate into a large (8-10 oz) cup that can be discarded as waste. Alternatively, the contents of the cup may be poured down the center of the drain while water is running rapidly to avoid staining the sink. If the sink or any other surface becomes discolored, the stain may be removed using a soft cloth and standard hard surface cleaner, concentrated bleach, or vinegar. Environmental surfaces or objects that cannot easily be cleaned should be removed from the area or covered.

PROCEDURE FOR STAINING OF LESIONS WITH THE ORABLU™ ORAL LESION MARKING SYSTEM

1. After performing the conventional visual examination of the oral cavity under incandescent illumination and performing the oral examination using Microlux/DL, mucosal abnormalities differentially identified by the oral examination light and deemed clinically suspicious may be stained with the ORABLU™ Oral Lesion Marking System.
2. Data regarding the location, appearance, and measured size of any oral lesion(s) should be documented in the patient's medical record.
3. Only if a mucosal abnormality is identified during the exam using an oral examination light from AdDent, Inc., may the ORABLU™ Oral Lesion Marking System be used to demarcate the identified lesion(s) for further study, referral to a specialist or biopsy.
4. Dim the room lights and using the oral exam light (if necessary), to visualize the lesion(s).
5. Apply 5 drops of the 1% Acetic acid solution to moisten one end of a new applicator swab. Apply the moistened swab to the entire area of the previously identified lesion(s). To apply, press firmly in a painting motion. Cover an area extending 2 cm in diameter around the visible lesion(s). Apply swab for 20 seconds. Direct the patient to expectorate the 1% Acetic acid solution.