

Step-By-Step Examination Guide

Note: This is an abbreviated clinical guide. Please see the Sapphire® Plus Lesion Detection Training DVD or User's Guide for more detailed information.

1. Review the patient's relevant medical and dental history.
2. Conduct a thorough extra-oral and intra-oral examination both visually and manually, palpating all the structures of the head and neck.
3. Repeat the intra-oral examination using Sapphire Plus Lesion Detection by viewing the oral cavity through the Handpiece (Figure 1). Maintain a distance of approximately 4-6 inches from the oral cavity to optimize the visualization of the natural tissue fluorescence.
4. Abnormal tissue typically appears as an irregular, dark area that stands out against the otherwise normal, green fluorescence pattern of surrounding healthy tissue.
5. If a suspicious area is discovered, reevaluate under white light and Sapphire Plus Lesion Detection trying to identify what might have caused the region to appear abnormal. Take into consideration its appearance under both Sapphire Plus Lesion Detection and white light, its response to palpation, and salient patient history information.
6. Photo-document any areas of concern both under white light and through the Sapphire Plus Lesion Detection.
7. Record all relevant findings. Documentation forms are available on your training DVD sent with your original shipment.



Figure 1 – Sapphire Plus Lesion Detection examination:
The clinician shines the blue excitation light into the patient's oral cavity and looks through the Sapphire Plus Lesion Detection Handpiece

8. Inform the patient of all relevant findings and the appropriate course of action.
9. Follow up or refer as appropriate.

Fluorescence Visualization in the “Normal” Mouth

- Understand what a normal oral cavity looks like under Sapphire Plus Lesion Detection to best appreciate what may be abnormal.
 - The attached gingiva and anterior tonsillar pillars, for example, often have a naturally darker appearance.
 - Pigmented tissue appearing dark under white light usually also looks dark under Sapphire Plus Lesion Detection.
- Inflammation typically appears darker under Sapphire Plus Lesion Detection due to the excess blood content.
- The oral cavity is naturally exposed to varying degrees of chronic irritation and mild inflammation.
 - Due to inflammation, the buccal mucosa, lateral surfaces of the tongue and hard palate may sometimes show darker areas typically characterized by poorly-defined borders.
- Hyperkeratosis may often appear bright under Sapphire Plus Lesion Detection because of strong keratin fluorescence.

Some Characteristics that Increase Suspicion of Dysplasia and/or Oral Cancer

- Highly darkened appearance—strong loss of fluorescence
- High-risk location (e.g., lateral/ventral tongue)
- Unilateral presentation
- Asymmetry and/or irregular shape
- Extension over more than one kind of oral structure

Blanching

- Observe the suspicious, typically darker, area through the Sapphire Plus Lesion Detection handpiece while applying a light amount of pressure with the back side of an explorer or similar instrument in a sweeping motion to diffuse any blood from the area.
- If the normal green fluorescence returns with this pressure, then the lesion may have an inflammatory component.
- For some important considerations when interpreting the effects of blanching, see the Sapphire Plus Lesion Detection Training DVD.

Follow-up

- If a suspicious area cannot be ruled out as benign, it is usually appropriate to perform a follow-up examination (typically in 2 weeks).
- At this time, evaluate whether the suspicious area has changed, especially if the presumed causative agent has been removed.
- If the suspicious area has not cleared up after this follow-up time, use your clinical judgment and proceed with further investigation according to the regular standard of care (e.g. referral to a specialist, etc.)

Surgical Biopsy – The Gold Standard

- Remember: the gold standard for diagnosing precancerous and cancerous lesions in the soft tissues of the oral cavity is surgical biopsy.
- A biopsy showing dysplasia is NOT a “false positive”; discovering lesions early in the disease development process allows for the highest probability of a favourable treatment outcome.



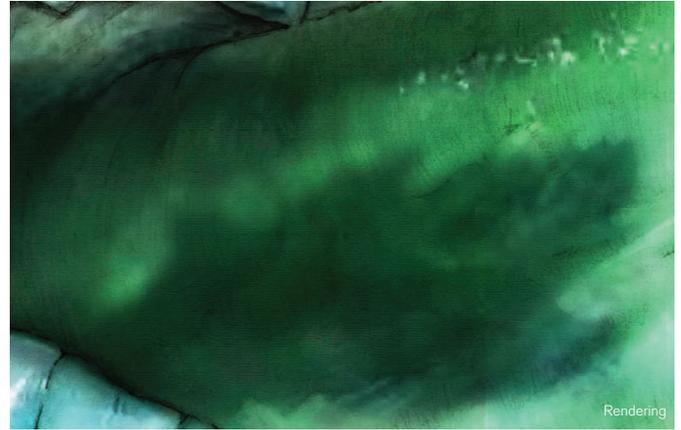
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LESION DETECTION

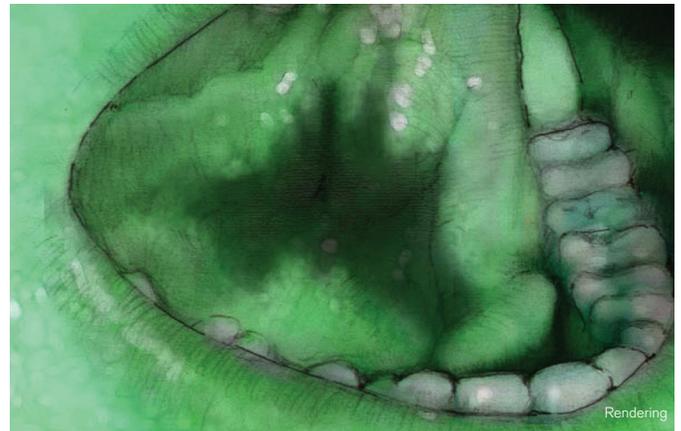
Figure 2 – A small representative example of the appearance of healthy vs. suspicious oral tissue under both incandescent light and Sapphire® Plus Lesion Detection.



No apparent lesion



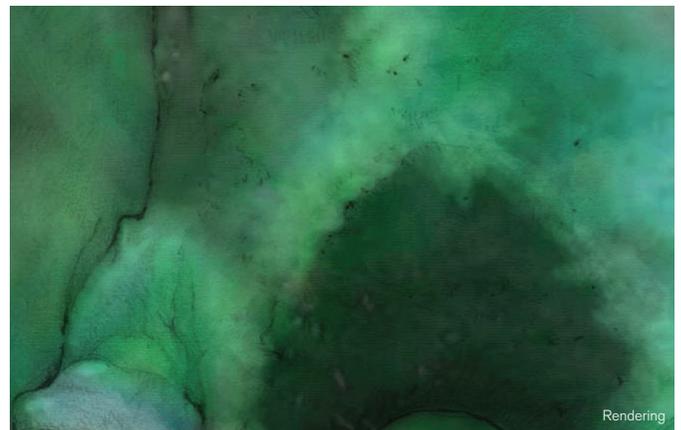
Normal, green fluorescence pattern



Lesion that didn't look suspicious that turned out to be cancer



No apparent lesion



Irregular, dark area—confirmed through biopsy to be Carcinoma In Situ (CIS)

FOR MORE INFORMATION, CONTACT YOUR DEALER OR VISIT WWW.DENMAT.COM

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