GOCCLES®

Glasses for Oral Cancer - Curing Light Exposed - Screening

Instruction For Use

This medical device is designed to simplify and facilitate the early detection of oral cancer through auto-fluorescence examination.
Goccles is a new innovative device that permits an easy, non invasive and non-painful examination of the oral cavity, able to reveal cancerous and pre-cancerous lesions.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a qualified health care professional.

Intended
G.O.C.C.L.E.S. is intended to be used by qualified health-care providers to enhance the identification and visualization of the oral mucosal abnormalites that may not be apparent or visible.

Mechanism of action
This device allows the examination of auto-fluorescence of the oral cavity in order to enhance the identification and visualization of the oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer and premalignant dysplasia. The G.o.c.c.l.e.s.-based examination is thus recommended as complementary methodology to be used together with the standard naked eye-based examination.
While the visualization of the oral cavity with the naked eye can make out only a small fraction of the spectral characteristics that differentiate healthy tissue from the diseased one, the optical methods based on tissue auto-fluorescence improve the ability to detect cancerous lesions in the oral cavity. The fluorophore of interest is the flavin adenine dinucleotide (FAD), which in its oxidized form responds to a light of 450nm (blue-violet) emitting a fluorescence wavelength around 515nm. In cancer cell tissue fluorescence of the oxidized FAD irradiated with light blue-violet decreases due to alterations in the metabolism of the affected cells .
Accordingly the G.o.c.c.l.e.s. has to be used with its compatible light source "G.o.c.c.l.e.s. light" that is characterized by an emission range of 440-490 nm including the excitation peak of FAD.

Warning and Contraindication
No limitation or contraindication of use is known.
It is important that before conducting the examination it must be ensured that the patient has not ingested substances that can alter the effect of fluorescence (eg: licorice , coffee, other pigments).

Non-conforming use
The device must not be modified in its structure. This may lead to erroneous results, safety risk and the damage of the device.
The device may only be used according to the described conditions.

Warranty
The warranty is void when:
- The instructions for use are not followed as shown.
- There is alteration to or demounting of the unit.
- There is damage of a mechanical origin, damage from the environment, or natural wear and tear.
- Placement or structure is not appropriate.

Storage
Store in a cool and dry place, not to exceed the following range of temperature: -10°C - +50°C.

Shelf life
The shelf life of the device has been determined by Pierrel Pharma to be within 2 years from its first usage given that the full functioning of the filters can not be guaranteed after 2 years of frequent use.

Staff training
For the use and maintenance of the product, the specialized medical staff must observe and apply the instructions for use.

Checking at delivery
Check the packaging immediately upon delivery and the device during unpacking for any visible damage.

Cleaning
The device can be cleaned using running water and dried with a soft non-abrasive cloth; lenses with anti- fog coating should only be cleaned using a soft cloth.
For disinfection with specific products, contact Pierrel Pharma.

Disposal
Follow the national regulations for the disposal of municipal waste.
The product does not contain hazardous substances.

Specifications
- Bandwidth optic transmittance range: 470- 610 nm
- Weight: 110g

Manufactured for:
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GOCCLES® EYES ON PREVENTION

GOCCLES®

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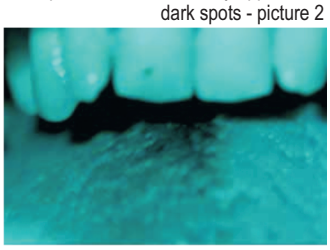
GUIDE TO EXAMINATION WITH GOCCLES®

Abnormal tissue typically should appear as an irregular, dark area - picture 1

The presence of dark pigments such as liquorice or coffee usually appears as dark spots - picture 2



PRELIMINARY NOTES

- Read all instructions before using the product.
- Understand how a healthy oral cavity looks like through Goccles in order to appreciate what may be abnormal.
- Collect the patient's relevant medical and dental history before proceeding with the screening.

EXAMINATION

1. Conduct an extra-oral and intra-oral examination with the naked eye, also palpating all the structures of the head and neck.
2. Repeat the intra-oral examination using Goccles eyewear in combination with a dental curing light.

- Reduce the room light for better contrast.
- The device has to be worn in adherence to the face, avoiding external light to reach the operator's eyes. Use the provided neck cord to optimize the fitting.
- Characteristics of the curing light: emission spectrum between 380 and 500 nm, emission peak between 440 and 480 nm. **IMPORTANT:** Provide the patient a proper device for eye protection: orange filters with UV525 protection are the best solution.
- While performing the examination, maintain the curing light at a distance of approximately 20-50 cm from the oral cavity to optimize the visualization of the natural tissue fluorescence.

3. Abnormal tissue typically should appear as an irregular, dark area that stands out against the green fluorescence pattern of surrounding healthy tissues (picture 1).
4. If a suspicious area is discovered, re-evaluate it trying to identify any causes for the region to appear abnormal. Take into consideration its consistence, its appearance both with naked eye and through Goccles and any relevant patient history the information.
5. Record all significant findings and inform the patient about the appropriate course of action.

FOLLOW UP

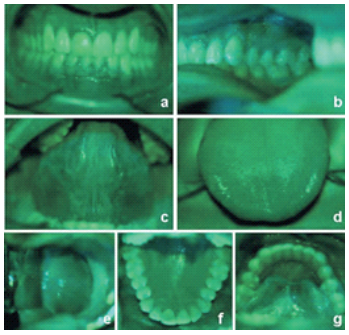
- If lesions or alterations of the oral mucosa are found, it's crucial that the clinician examines the patient after a couple of weeks.
- Proceed with a new investigation of the oral cavity with Goccles to assess the presence of the abnormal area. After that, evaluate any change in the area, also checking if the presumed causative agent has been removed.
- If the abnormal area has not disappeared, continue the examination recommending the patient to see a specialist for further investigations.

Characteristics of suspicious lesions and oral cancer

- Leukoplakia: a white patch that cannot be wiped off with gauze and with no obvious explanation.
- Erythroplakia: a fiery red patch that cannot be characterized either clinically or pathologically.
- Erythroleukoplakia: an abnormal patch of red and white tissue on mucous membranes in the mouth
- Evident loss of fluorescence
- The lateral tongue and floor of mouth are the regions at greatest risk for cancer development
- Asymmetry and/or irregular shape
- The lesion doesn't spontaneously resolve and generally increases in size over time

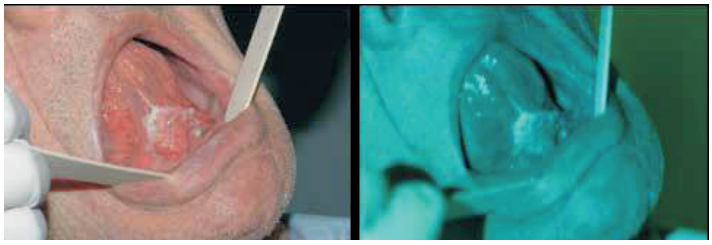
Other phenomenon evident through fluorescence visualization

- The presence of dark pigments (such as liquorice or coffee) usually appears as dark spots both with naked eye inspection and autofluorescence examination with Goccles (picture 2)
- Inflammation typically appears as darker areas characterized by poorly-defined borders due to the excess of blood content. If the normal flourescence returns after a light pressure on the region, then the lesion may have an inflammatory origin
- Hyperkeratosis may often appear bright through Goccles because of strong keratin fluorescence. Goccles is not suitable for the study of hyperkeratotic lesions, however it can help to identify their margins which appear as a dark halo surrounding the main lesion



Mucosa of a healthy individual aooears as the examination of auto-fluorescence; a,b: vestibular gingival; c: lingual belly; d: dorsum of the tongue; e: buccal mucosa; f: hard palate; g: floor of the mouth.

Loss of fluorescence in patients with mild dysplasia; a: patient with lichen oral planus; b: tha same patient with loss of fluorescence of buccal mucosa (arrows); patient who has already undergone previous biopsies for leukoplakia, left buccal mucosa; d: halo intralesional loss of fluorescence within the apparently normal mucosa (arrows)



Hyper-fluorescence in a patient with hyperkeratotic lesion (base of tongue and floor of the mouth)

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