

# CSDS

## Caries Status Disclosing Solution

### INSTRUCTIONS FOR USE

#### NOTICES

ARTG No. 353791

RM Creighton Dental Pty Ltd  
Australia

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#### 1. Product Contents

The product consists of two parts packaged within a black outer card box:

##### Part A: 40% Silver Fluoride Solution

Volume: 3 ml

Contains: Silver fluoride (0.4 g per ml), water.

This compound will be packaged within a **black** card box, in a **black** dropper bottle with a **red** cap.

##### Part B: 10% Stabilised Stannous Fluoride Solution

Volume: 3 ml

Contains: Stannous fluoride (0.1 g per ml), water glycerol and sorbitol.

This compound will be packaged within a white card box, in a natural dropper bottle with a **white** cap.

#### 2. Indications

The Caries Status Disclosing Solution is used to monitor the status of active carious lesions in primary molar teeth where the lesion has reached the point of distinct cavitation.

#### 3. Contraindications

- Do not use on lesions that have reached the dental pulp.
- Do not use in situations where adequate cotton roll isolation of the treatment site cannot be achieved.
- Do not use on patients with a known allergy to tin or silver.

#### 4. Warnings and Cautions

- For use by dental professionals only.
- Keep in a safe storage area out of the reach of children.
- The solutions must only be applied topically using a microbrush.
- If silver fluoride accidentally touches the oral mucosa it may cause a temporary stain which usually disappears within 24 hours.
- Harmful if solutions from bottles accidentally swallowed. If swallowed do not induce vomiting. Give patient glass of milk or water. Then see a doctor.
- Keep away from eyes. If in eyes hold eyes open and flood with water for at least 15 minutes. Then see a doctor.
- Upon contact, the silver fluoride solution may cause staining of skin, clothes and bench tops.
- Standard protective clothing (glasses, gown, gloves) should be worn by clinic staff during treatment application and the standard procedure of protective glasses being worn by the patient should be followed.
- Patients must be warned that lesions treated with Caries Status Disclosing Solution will turn black.
- Treatment may lead to staining of old restorations that have defective margins.
- Do not use if labels are missing, packaging is damaged or bottle tamperproof cap is broken.
- Always check contents of packaging prior to use. Do not use if the products are not packaged as described under "Product Contents".
- Check expiry date before each use. Do not use if product past its expiry date.

#### 5. Procedure

The CARIES STATUS DISCLOSING SOLUTION treatment involves topical application of the Silver Fluoride solution (Part A) on the lesion followed by application of the Stannous Fluoride Solution (Part B). The Stannous Fluoride solution precipitates silver, and turns the lesion black. The presence of a surface black mat indicates the lesion is not progressing. A lighter colour indicates that caries activity may have recommenced and that treatment or restoration of the lesion may be required.

Caries Status Disclosing Solution treatment requires the following equipment:

- Junior Garmers Cotton Roll Holders (left and right)
- 2 x micro-brushes
- 2 x dappen dishes
- Cotton rolls
- Stomahesive wafer (Convatec), or Orabase Protective Paste (Convatec).

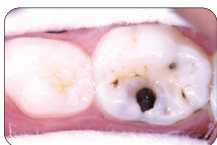
#### 6. Clinical Procedure

- Isolate tooth with lesion to be treated with cotton rolls. For teeth in the lower posterior quadrants, the use of Junior Garmers Cotton Roll Holders is mandatory.
  - For children, place one drop of Silver Fluoride Solution (Part A) into a dappen dish.
  - Dip micro-brush in solution.
  - Wet surface of lesion using the micro-brush and leave solution in place for at least one minute.
  - Dip a new microbrush into the stannous fluoride and apply to the previously treated site.
  - Wipe off excess with a pellet of cotton wool.
  - Cover the treated site with a piece of Stomahesive wafer.
  - Alternatively cover the treated site with a smear of Orabase Protective Paste.
- (Both the above products contain the food ingredients gelatin, pectin and sodium carboxymethylcellulose).

- l. Dismiss patient. The wafer and ointment will slowly dissolve in mouth fluids.
- m. Soak up unused solutions from each dappen dishe. Do not re-use.
- n. Discard micro-brush used for the procedure after use on each patient.
- o. Treatments can be repeated every 3 to 6 months if required.

**7. Interpretation of Results.**

Based on a clinical trial (Craig et al., BMC Oral Health 2013;13:73) it was found that lesions that had lost part or all of the black surface stain over time were 4.6 times more likely to have decay progression. The sensitivity of the approach in the context that an incomplete or absent black surface was a diagnostic aid for decay progression was 80%, whereas the specificity referring to situations where an uninterrupted black surface was present and decay had not progressed was 81%.



Above: Appearance of a carious lesion immediately after treatment with CSDS. The surface has a uniform black colour.

Above: Appearance of the same carious lesion 6 months after the initial treatment. The surface has lost its uniform black colour. This is an indication of lesion progression and the situation should be investigated further.

**8. Handling silver stains caused by Silver Fluoride Solution (Part A)**

**a. On skin**

Apply povidone iodine with very gentle rubbing. Stain will slowly disappear. (If nothing is done, stain will gradually disappear after a few days).

**b. On clothing**

Prolonged soaking in mild bleach like, Napisan (the mild bleach used for clothes or babies' diapers).

**c. On bench tops**

Apply household bleach (sodium hypochlorite) immediately. Some stains don't become evident until sometime later so use the technique below.

Apply household bleach to the area and cover evenly with a paper napkin and leave overnight.

**9. Storage instructions**

Do not transport or store the compounds at a temperature below 5°C or above 25°C.









**10. Disposal instruction**

Soak up any remaining solution in the dappen dish with the end of a cotton roll and dispose of it carefully.

**11. Reporting**

Customers, depending on location, should use the following address and telephone number for reporting adverse reactions or complications involving this device:

**12. Definitions**

	DO NOT USE IF PACKAGE IS DAMAGED
	READ INSTRUCTIONS BEFORE USE
LOT	LOT NUMBER
	'EXPIRY DATE'
	ATTENTION! SEE INSTRUCTIONS FOR USE
	PRODUCT SHOULD BE KEPT DRY
	STORE BETWEEN 5°C AND 25°C
	MANUFACTURER
	KEEP AWAY FROM SUNLIGHT

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