Labeling for Carisolv™

CAUTION – Federal law (USA) restricts this device to sale by or on the order of a physician or dentist.

DESCRIPTION
The Carisolv™ Non-invasive Dental Caries Removal System is comprised of a 0.5 ml solution containing 0.5% sodium hypochlorite, which is mixed with 0.5 ml solution, with pH 11, containing amino acids, CMC, sodium chloride, Erythrosine (E127B), purified water and sodium hydroxide. The two solutions are supplied in two separate syringes which are mixed together just before use. The two syringes have male and female connecting parts. These are attached and the solutions are mixed without air contact. After mixing the solutions form a gel substance that remains fully active for approximately 30 minutes. The mixed gel solution is then placed in a dappen dish and the gel is applied to the dental caries with the aid of a hand instrument or small forceps.

The Carisolv™ system also includes a set of hand instruments, which aid in applying the caries removal gel solution and in the excavating of the carious material. The instrument set contains four different handles with eight different removable tips. The tips range in diameter from 0.3 – 2.0 mm and differ slightly in shape. The shape is designed to improve the capability of accessing the carious material once the gel solution is applied.

INDICATIONS
Carisolv™ is indicated for the chemo-mechanical softening and removal of dentin caries when used in conjunction with a dental handpiece.

CONTRAINDICATIONS
None known.

WARNINGS
None known.

PRECAUTIONS
1. Do not use if not stored correctly. Store in refrigerator at 39-50°F.
2. Do not use left-over mixed gel. Once the gel has been mixed, its effect will begin to decline after about 30 minutes.
3. In case of:
   Eye contact: Flush promptly with flowing water. If irritation develops, consult a physician.
   Skin contact: Wash area with mild soap and water. If rash results, contact a physician.
   Inhalation: Fresh air.
   Ingestion: Consult a physician.

ADVERSE REACTIONS
In clinical studies #1, #2, #4, #5 no adverse reactions were observed when using Carisolv™. In study #3, an experimental evaluation of Carisolv™ on soft tissue (mucosa), three patients (one with a dry mouth symptom) out of 34 patients showed temporary (within 72 hours) mild symptoms of irritation of the mucosa.

CLINICAL STUDY RESULTS

Multi-center Study #1

Primary safety and effectiveness data was based on a prospective randomized study conducted at four centers, involving 137 subjects. Caries were removed with traditional drilling or gel. Gel was applied onto the carious dentin, and the caries was removed with hand instruments. New gel was applied and the procedure was repeated until no more carious material could be removed. One hundred thirteeen patients received gel treatment, and 24 received the dental handpiece alone. Total caries removal was achieved in 108/113 cases with the dental handpiece and gel, and in 19/24 cases with the handpiece (four patients selected for handpiece alone did complete treatment). No adverse effects were reported. It was concluded that dentin caries was effectively removed using Carisolv without any adverse reactions.

Clinical Study #2

The objective of this study was to evaluate the safety and efficacy of the Carisolv™ method for removal of root caries, comparing it to the conventional method for removal of caries by drilling. Thirty-eight patients with 60 cavities have been included in the study. Of the cavities 34 were randomized for treatment with Carisolv™ and 26 for drilling. Twenty-two of the patients were treated on two cavities, one with Carisolv™ and one with drilling.

All of the cavities treated with Carisolv™ became caries free and all but one of those in the drilling group. Only 4 patients asked for anesthesia in the Carisolv™ group compared to 6 patients in the control group. In the Carisolv™ group patients without anesthesia experienced no pain, while 12 out of those without anesthesia in the drilling group experienced a little pain.

This study supports the safety and efficacy for the use of Carisolv™ on root surface caries. The benefits with Carisolv™ are comparable to drilling or better. No adverse events were observed.

Clinical (experimental) Study #3

A clinical study to evaluate the effect of Carisolv™ on healthy oral mucosa was conducted. Pledgets of blotting paper were soaked in either one drop of Carisolv™ or one drop of sodium hypochlorite. One of each was put either side of the frenula of the lower lip and was left on the oral mucosa for three minutes. The study included 34 subjects.

After three minutes none of the trial persons showed any kind of change of the oral mucosa. One person showed after one hour a slightly etched structure, as well as a slight blush on the test side. All other (33) persons were clinically symptom free. After 24 hours three persons showed symptoms: one person was somewhat swollen – this was the "dry mouth" person, two persons showed a blush. All symptoms were found on the test side. After 72 hours none of the trial persons showed any symptoms.

The results show that Carisolv™ has no adverse effect on the mucosa.

DIRECTION FOR USE

Preparation

When necessary, the cavity is opened with a rotating instrument or a hand instrument and any remaining filling that is not to be saved is removed. Apply a rubber dam if necessary.

Use

1. Hold the syringes (one with red gel and one with sodium hypochlorite) with their openings upwards. Remove the corks, keep the syringes upright and screw them together.
2. Mix the liquids by pressing alternately on the ends of the syringes until the color of the liquids is homogeneous. Press all the liquid into one of the syringes.
3. Pour the mixed liquid into a suitable container or keep it in the transparent syringe and apply it to the cavity using a cannula with a Luerlock.
4. A drop of the gel is removed from the container with a Carisolv™ hand instrument and applied to the carious dentine. *Make sure that the carious lesion is thoroughly soaked by the gel!*
5. Allow the chemistry to work for at least 30 seconds.
6. Select a Carisolv™ instrument to match the size, position and accessibility of the cavity. Scrape off the superficial softened carious dentine. Then continue to work carefully using scraping or rotating movements.
7. Remove the softened carious dentine with the instrument. Avoid flushing or drying the cavity.
8. Gradually add new gel and continue scraping. Repeat this procedure until the gel is no longer cloudy and the surface feels hard using the instrument. Check extra carefully for caries at the dentino enamel junction.
9. If the cavity feels free from caries, remove the gel and wipe the cavity with a moistened cotton pellet or rinse it, inspect and check it with a sharp probe.
10. If the cavity is not free from caries, apply new gel and continue scraping. *Note- If the cavity has been dried with air, the treated surface looks frosted, not shiny as it is after excavation using a drill.*
11. Adjust the periphery of the cavity with a hand instrument or a drill. Restore the tooth with a suitable filling material according to the manufacturer's instructions.

Note- Once the gel has been mixed, its effect will begin to decline after about 30 minutes.
Any gel that is left over should be destroyed in accordance with local regulations.

Storage Conditions and Shelf Life

Shelf life for this device has been established at 12 months when refrigerated, or one month when stored at room temperature.