

# CariFree<sup>®</sup>

## Caries Control Solutions Protocol

- Perform caries risk assessment using the Caries Risk Assessment Form and Caries Susceptibility Testing Meter, or radiographs, health and dental history review, visual exam, etc.

### At Risk Patients:

- Receive dietary and behavioral counseling based on their individual risk factors
- Receive an application of CariFree Fluoride Varnish
- Receive the CariFree 3-month Treatment Kit
  - ❖ This Kit will allow them to use the Treatment Rinse 2 times daily for the first month followed by the Maintenance Rinse 2 times daily for the next 2 months. They will also be using the CariFree Oral Neutralizer Gel daily throughout the 3 months, and they have been supplied with a sample of the CariFree Xylitol Gum and Boost Mouth Spray.
- At 3 months, re-assess for caries-activity
- Repeat Fluoride Varnish application
- If patients are assessed to still be at risk, they should take home another Treatment Kit
- If they now appear to be stable, they should take home a CariFree 3-month Prevention Kit

! These patients should have caries risk assessment performed every 6 months

### Low Risk Patients:

- Reinforce good dietary and oral hygiene practices
- Receive the CariFree 3-month Prevention Kit
  - ❖ This Kit will allow the patient to use the Maintenance Rinse 2 times daily for 3 months. They will also be using the CariFree Oral Neutralizer Gel daily and have been supplied with a sample of the CariFree Xylitol Gum.
  - ❖ They may opt for the CariFree Starter Kit, which includes a 1-month supply of the Maintenance Rinse and Oral Neutralizer Gel.

! These patients should have caries risk assessment performed annually

## Monitor Results

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3 months after the initiation of antimicrobial therapy with the CariFree products, patients should be re-assessed to determine the results of the antimicrobial therapy. Patients that now exhibit reduced risk and a CariScreen Meter reading in the low risk range can proceed with definitive restorative treatment and then be placed into normal re-care scheduling.

Patients that still have elevated CariScreen Meter readings will need to be re-cycled into the CariFree Treatment Rinse and CariFree Maintenance Rinse regimen. The patient should be tested again 3 months after initiation of therapy. This cycle of antimicrobial rinse therapy and subsequent testing should continue until the patient exhibits a low CariScreen Meter reading, which may take multiple courses of treatment. It is important to note that Meter readings may vary *either* up or down within a risk level while working to convert a biofilm back to healthy. These variations are normal, and treatment should proceed until a low risk reading is attained. All low and at risk patients should continue with the CariFree Maintenance Rinse, Oral Neutralizer Gel, Xylitol Gum and CariFree Boost if indicated, on an ongoing daily basis.

## Specific Directions for Use

### Caries Risk Assessment Form

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All Disease Indicators are identified. Disease Indicators are those factors that if just one exists, automatically place your patient in the “at risk” category. Other Risk Factors are then evaluated. Even in the absence of Disease Indicators, two identified Risk Factors will also place your patient “at risk.” A Caries Susceptibility Testing Meter reading is taken as another data point in the risk assessment. These factors are all weighed and clinical judgment is used to make a low risk or at risk diagnosis.

### CariScreen™ Caries Susceptibility Test

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#### Preparing the Patient:

This simple screening test requires only a couple of minutes to perform. The patient should have a mouth at rest, which in general terms means no mechanical activity, brushing, flossing, swishing, chewing, eating etc. for a period of 60 minutes prior to the test. **Always perform this test prior to any other procedure during a patient visit.** The CariScreen Caries Susceptibility Test is being used to measure bacterial ATP present on the teeth surfaces, as an indication of levels of cariogenic bacteria in the oral biofilm. Excessive mechanical activity of the mouth may produce increased levels of somatic ATP from the gingival and mucosa and can result in incorrect high numbers or false positive results.

#### Taking Swab Samples:

When collecting a sample make sure to use aseptic techniques. Do not touch the swab or the inside of the sampling device with ungloved fingers.

Holding the swab tube, twist and pull the top of the swab out of the swab tube. The swab tip comes pre-moistened for collection. Condensation may be visible on the inside of the swab tube; this is normal. Once hands are gloved, hold the swab near the tip to allow for firm pressure and accuracy when swabbing. Carefully swab the buccal surface of a maxillary molar in the gingival third **without touching the gingiva** with the swab tip. Swab the tip across the tooth surface **three times** (not two and not four) from mesial to distal. Use the maxillary right first molar (#3) if it is present; if not present select the second molar or premolar to swab instead. Using the

same swab, carefully swab a maxillary incisor in the gingival third with the same protocol: swab **three times** (not two and not four) across the surface from mesial to distal **being sure not to contact the gingiva**. Use the maxillary right central incisor (#8) if it is present; if not present, select another incisor and swab it with the same protocol.

After swabbing the desired test area, place swab back in swab tube. The sample must be read in the CariScreen Meter within 60 seconds. This test is technique sensitive, so for best results, follow the directions carefully, develop good sampling techniques, and be consistent with your sampling methodology. Consistency in your sampling technique will yield the most reliable results over time. If you are not able to swab the recommended teeth, #3 and #8, be sure to record which teeth you did swab on that patient, so you can swab the same two teeth at all subsequent appointments.

### Reading the Results

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To activate the device, hold the swab tube firmly, and using the thumb and forefinger, break the snap valve by bending the bulb forward and backward. Squeeze the bulb twice, expelling all the liquid down the swab shaft. Bathe the swab bud in liquid by shaking vigorously for 10 seconds.

Once the CariScreen Meter has undergone its 60 second self-calibration, insert the CariScreen Swab device into the CariScreen meter, close lid and read the results by pressing "OK". A 15-second sequence will then commence. Results should be read within one minute of activation of the CariScreen Swab device. Please refer to the CariScreen instrument manual for operating instructions.

At the end of this count-down, the Relative Light Unit (RLU) reading will appear on the screen in a value of 1-9999. Record this number for the patient on the Caries Risk Assessment Form and/or in the patient chart. Values established on the first clinical trial indicate the following:

| Caries Risk Level | RLU Values     |
|-------------------|----------------|
| Low Risk          | Below 1,500    |
| At Risk           | 1,501 to 9,999 |

### **Fluoride Varnish**

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Patients that demonstrate a moderate or high caries risk should undergo immediate CariFree Fluoride Varnish application as recommended by the ADA. Moderate and high risk adults should have this application at least every 6 months, and moderate and high risk children at 3 month intervals. See instructions for application included in the box.

### **Treatment Rinse**

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Patients that are at risk should undergo antimicrobial therapy in addition to behavior management of specific risk factors.

The CariFree Treatment Rinse is a two component rinse that is mixed in single use amounts at the time of each use. The antimicrobial agents used in this rinse are not stable in a single combined solution, so they must be mixed together immediately prior to each use. This results in a very effective antimicrobial rinse at a health promoting pH.

The patient should mix 5 ml of component A and 5 ml of component B into the supplied cup, for a total of 10 ml of mixed rinse. They should swish vigorously with the rinse for 1 minute, and then expectorate. **It is important not to swallow the antimicrobial rinse.**

It is best to rinse after brushing and flossing. This regimen should be followed until both boxes of the Treatment Rinse are gone, approximately 1 month, depending on compliance.

### Maintenance Rinse

Following completion of the therapeutic antimicrobial CariFree Treatment Rinse therapy, the patient should be placed on the CariFree Maintenance Rinse. This rinse is a single component rinse designed to help the patient maintain low cariogenic bacterial levels in their oral biofilm while selecting for a healthy bacterial population. It will also aid in remineralization and provides a therapeutic dose of xylitol, if used twice daily. Due to an elevated, health promoting pH and a lack of acidic preservative, this product should be used daily until it is completely gone.

The patient may elect (and it is suggested) to use the CariFree Maintenance Rinse indefinitely at least once per day to help maintain their health and prevent the caries infection from returning. Three months from the initiation of the Rinse therapy with the CariFree Treatment Rinse, and while still using the CariFree Maintenance Rinse and Oral Neutralizer Gel, they should be re-assessed to determine progress of the antimicrobial therapy. The patient should be treated based on previous recommendations as well as CariFree Decision Tree.

### Oral Neutralizer Gel

The CariFree Oral Neutralizer Gel is a completely non-abrasive, refreshing tooth gel that combines the proven benefits of xylitol with CariFree's patent pending pH+ technology. The result is a minty, foaming gel that leaves your breath fresh, and your teeth feeling clean and smooth. Use in place of toothpaste at least 2 times daily.

This same fluoride-free formula is available in a fun grape flavor that kids love.

### Oral Neutralizer SugarFree Gum Xylitol Gum

CariFree Xylitol gum combines the proven benefits of chewing a xylitol gum with the added benefit of a pH booster. CariFree Oral Neutralizer Gum is specifically designed to deliver decay-reducing xylitol and can also neutralize the oral biofilm with patent pending pH+ technology. CariFree Oral Neutralizer Gum comes in a refreshing mint flavor. Chew 3-5 pieces daily to fight tooth decay.

### BOOST Boost Mouth Spray

For patients suffering from xerostomia the Boost Mouth Spray may be recommended to relieve symptoms. The Boost may also be recommended for low and at risk patients for use after meals to elevate the oral pH and apply xylitol.

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## Caries Control Solutions Protocol



**Risk Assessment**

**At Risk**

Fluoride Varnish



3 Month Reassessment

Fluoride Varnish

**At Risk**

**Low Risk**



**Low Risk**



Reassess in 1 year