


# Clinical Instructions for Using Silver Diamine Fluoride (SDF) in Dental Caries Management

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Compendium

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Douglas A. Young, DDS, EdD, MBA, MS; Ryan L. Quock, DDS; Jeremy Horst, DDS, PhD; Roopwant Kaur, BDS, MS; Jeanette K. MacLean, DDS; John C. Frachella, DMD; Steve Duffin, DDS; Adriana Semprum-Clavier, DDS, MS; and Andrea G. Ferreira Zandona, DDS, MSD, PhD

## Abstract

*Background:* Manufacturer instructions for 38% silver diamine fluoride (SDF) are limited to current FDA clearance for tooth desensitization. There is a need for instructions to provide best-practice recommendations for off-label use of SDF for caries prevention and arrest. *Methods:* The authors considered existing clinical approaches to the use of 38% SDF at pH 10 for the prevention and arrest of active dental caries, in light of the best current evidence. Application of SDF, with or without subsequent direct restoration, is included. The content was reviewed by stakeholders including but not limited to those listed on the consensus statement (Appendix A, below). *Results:* 38% SDF for the prevention and arrest of active caries lesions, as well as compatibility with common direct restorative materials, such as glass-ionomer cement and resin composite, has a foundation in the scientific literature. A practical decision-flow diagram and accompanying best practices for treatment of caries lesions, based on clinical access and intention to restore, were developed based on available evidence and expert clinical observation when no evidence was available. *Conclusions:* Based on the best available evidence, a logical approach can be adopted regarding the practical use of 38% SDF for caries prevention and arrest. *Practical implications:* SDF used as per these instructions for prevention on high-risk tooth surfaces and arrest of active caries lesions has a place in the practitioner's dental caries management armamentarium. When SDF is applied to active lesions, it can be used with or without subsequent restoration, depending on clinical context, expert judgment, and patient input.

*Authors' note:* Appendix A Consensus Statement, which appears at the end of this article, sets the stage for this review of silver diamine fluoride, and readers may benefit from reading it first. Additionally, the practical decision flow diagram ([Figure 1](#)) will be useful

*to readers, both in helping to organize consumption of this article's content as well as applying its content to clinical scenarios.*

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In the "Evidence-based Clinical Practice Guideline on Nonrestorative Treatments for Carious Lesions" from the American Dental Association (2018), silver diamine fluoride (SDF) is recommended to arrest cavitated coronal carious lesions on primary or permanent teeth.<sup>1,2</sup> Once arrested, demineralization and lesion progression is halted. Systematic reviews and meta-analyses of controlled clinical trials conclude that SDF should be used as a preventive agent on high-risk surfaces.<sup>3-7</sup> Mechanistic studies suggest that SDF should be applied under restorative materials as a liner to harden infected or affected decayed dentin<sup>8-13</sup> and provide long-term antibacterial effects.<sup>14-16</sup>

Because current US Food and Drug Administration (FDA) clearance for SDF is for treatment of tooth sensitivity (and not dental caries prevention or lesion arrest), there are no manufacturers' instructions for use of SDF to prevent or arrest dental caries lesions. Similar to fluoride varnish, this off-label use is permissible and appropriate under US law. This instructional article provides recommendations for the arrest and prevention of dental caries lesions using 38% SDF solution at pH 10 (Appendix B, SDF at a Glance) based on current available evidence. It should be noted that these instructions and protocols are not applicable nor intended for other products that contain a higher ammonia component and higher pH, which require a gingival barrier or dental dam to prevent soft-tissue burns,<sup>17</sup> or the addition of potassium iodide. For reader convenience, a flow diagram of the clinical use of SDF on an active lesion has been developed and is provided ([Figure 1](#)). Subsequent sections of these instructions are section-titled to sync with the diagram. The flow diagram is reflective of the international consensus statements on carious tissue removal and when to intervene in the caries process,<sup>18,19</sup> and is in accord with the original meanings of the terms "cavity" and "cariou" as indicating that a full enamel cavitation is necessary for bacteria to infect the dentin and therefore possibly indicate invasive treatment.

## **Instructions for Application of SDF**

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Always obtain informed consent and discuss how the use of SDF and subsequent applications must be used in conjunction with existing caries management and prevention strategies. The following step-by-step protocol is based on both published research and clinical experience. When combined with other minimally invasive caries management techniques as presented in this article it is expected that incorporation of SDF into restorative procedures will yield significant advantages for long-term disease management. Presently, there is no strong scientific evidence supporting the effectiveness of any one protocol over another. Commonly used alternatives are noted. Particularly, drying with cotton gauze instead of compressed air avoids production of microbial aerosols during SDF application.

1. *Use of personal protective equipment (PPE)* for patient (safety glasses, plastic lined bib, other skin and clothes protection as indicated) and operator (safety glasses, mask, gloves, gown, etc) is strongly recommended. Protective coverings to protect clinical environmental surfaces are also advised.

2. *Dispense SDF* into a plastic dappen dish for immediate use; recap bottle immediately. One drop treats up to five surfaces, depending on the size of the lesion or surface.

Note: When using unit-dose capsules (~0.13 ml ≈ four drops) the following instructions apply: (A) Place a unit dose upright on a plastic-lined tray or countertop. (B) Tap the unit on the counter/tray to ensure the liquid is at the bottom of the container. (C) Hold a 2x2 gauze over the ampoule and carefully snap off the cap while holding the base. (D) Dispose of the gauze and cap inside of your gloves in a proper receptacle. (E) Re-glove and apply as described in the subsequent sections.

3. *Utilize optional extraoral protection* for the lips and surrounding area using petroleum jelly or lip balm. Scented lip balm or a dab of toothpaste on the tongue may be used to mask any smell or taste perceived by some patients. Protecting the intraoral soft tissues is not needed, and the material could inadvertently get on the lesion or surface and inhibit SDF uptake.

4. *Isolate tooth surfaces to be treated and protect other areas at risk for unwanted staining* by using gauze, cotton rolls, absorbent triangles, a saliva ejector, and/or suction bite-block device. A clinical dental assistant may be helpful, especially when applying SDF in young patients or difficult situations.

5. *No caries removal* is necessary prior to applying SDF.

6. *Dry the area* to be treated as well as the surrounding high-risk surfaces with compressed air to control excess moisture. Dry with high-speed vacuum and/or cotton/gauze if compressed air is not available or if drying is not well tolerated by the patient, or if aerosol is a concern. Use of gauze avoids microbial aerosol production from the flow compressed air on saliva, but may decrease absorption.

7. *Saturate the lesion or high-risk surface with SDF using a microbrush and allow absorption of SDF by capillary action for at least 1 minute.* Do not rinse, light-cure, or blow compressed air while the SDF is being absorbed. Some clinicians prefer to lightly scrub the SDF into the lesion or surface while applying, to release the liquid's surface tension. Avoid contact of SDF with unintended structures. After waiting at least 1 minute for the SDF to absorb, lightly blot any excess SDF with cotton.

8. *Apply a varnish such as fluoride varnish on top of the SDF (optional)* to keep the SDF in contact with the caries lesion or high-risk surface for as long as possible, prevent saliva from diluting the SDF, reduce risk of unwanted stain on other tooth surfaces, and to mask the

taste from the SDF.<sup>20,21</sup> NOTE: *If a restoration is going to be placed on the same day as SDF application, do NOT complete this step.*

9. *Cleanup* by carefully bringing all materials to a waste receptacle while avoiding contact or dripping, for example, by inverting into a glove.

## **Approximal Techniques**

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SDF can be applied to an approximal caries lesion and other difficult-to-access high-risk surfaces by two methods. Both rely on capillary action:

*Method 1:* Simply desiccate/dry the contact point with compressed air or cotton and then saturate the contact area with SDF using a microbrush on the occlusal, facial, and lingual embrasures.

*Method 2:* Use woven unwaxed floss ([Figure 2](#) and [Figure 3](#)).<sup>22</sup> Place the dry "fuzzy" part of the floss into the dry, isolated contact and apply SDF to the floss with a microbrush on the lingual, buccal, and over the occlusal aspect. Do not move the floss. Remove the floss after at least 1 minute. It is important to protect the soft tissues (e.g., with a gloved finger) from any SDF migrating along the floss.

## **SDF Recall and Re-application Recommendations (When No Restoration is Placed)**

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If no restoration is planned, repeated applications of SDF are recommended, at least annually.<sup>6,23-26</sup> Greater effectiveness is achieved with biannual than annual application<sup>25,26</sup> and increased frequency of applications early in treatment.<sup>27</sup>

## **Restoring SDF-Treated Lesions**

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The rationale for restoring SDF-treated lesions may include but is not limited to eliminating food traps and improving cleansability, restoring form and function, and enhancing esthetics. Restorative options are guided by evidence, clinical judgment, and patient decisions. A recent large trial in young children that compared SDF to a placebo placed at a separate visit prior to restoration showed the combination of SDF and restoration with selective caries removal using atraumatic restorative treatment (ART) to be clinically compatible.<sup>28</sup> A successful restoration has a sealed margin that prevents nutrients from reaching bacteria in deeper areas, halting the demineralization process. Indeed, if clean margins can be achieved and a sealed restoration placed, SDF may not always be needed.

Conservative cavity preparation with selective caries removal<sup>29,30</sup> focuses on clean healthy external cavity preparation walls (from enamel margins through the dentino-enamel junction [DEJ]).<sup>18,29-31</sup> Light-curing in the presence of free silver can darken the restoration and/or margins. If clean margins can be achieved *after* SDF placement it will limit SDF to

the internal portion of the preparation and minimize staining at the junction of the tooth and restoration. When bonding SDF-treated dentin with resin adhesives, rinse at least 1 minute after SDF application to optimize bond strength.<sup>32</sup> The concluding sections offer some additional best practice treatment suggestions and examples.

## **Glass-Ionomer/Resin-Modified Glass-Ionomer Cement Best Practices**

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Silver-modified atraumatic restorative treatment (SMART) is defined here as a modified application of the atraumatic restorative treatment (ART) philosophy, that allows the flexibility to use SDF with or without cleaning the margins-using rotary or other minimally invasive methods-before placing a restoration. SMART is often indicated for its combination of characteristics, including selective caries removal sealing off nutrient sources from remaining bacteria,<sup>29,30</sup> antimicrobial activity,<sup>14-16</sup> desensitization,<sup>33</sup> remineralization,<sup>10</sup> and restoration of active cavitated carious lesions.<sup>34</sup>

Glass-ionomer cement (GIC) is the preferred material for SMART restorations because it is the only restorative material that is water-based and has a significant anticaries effect,<sup>35-37</sup> with less recurrent decay at the margins<sup>38,39</sup> and adjacent surfaces.<sup>40-42</sup> The long-term release of fluoride ions supports remineralization,<sup>43,44</sup> and as these ions are released from the GIC they are also able to be "recharged" by ions from other sources such as fluoride toothpaste.<sup>45</sup> GIC restorations have been shown to be antibacterial and to decrease acidogenicity of the biofilm, most likely from the fluoride release.<sup>46</sup>

### ***Option A. Multiple-Appointment SMART: Arrest First With SDF, Then Restore Later***

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Apply SDF once or more depending on the activity and size of the lesion(s), wait 2 to 4 weeks, then restore or seal with material of choice. During the intervening period, the lesion will harden, creating a foundation twice as hard as healthy dentin.<sup>13</sup> Also, the free silver will dissipate, avoiding stain to the restoration or sealant material. Dramatically less or even no caries removal is necessary depending on the hardening or arrest of the lesion.<sup>47</sup> Stain in areas that would show through can be selectively excavated (external walls) or blocked with opaquer (internal walls) prior to restoration.

### ***Option B. Same-Day SMART: SDF During a Restorative or Sealant Procedure Using GIC or Resin-Modified Glass Ionomer***

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Same-day SMART restorations and sealants may turn gray when placed at the same appointment (as noted for light-cured materials) ([Figure 4](#) and [Figure 5](#)). This can be minimized or eliminated by first placing SDF, then completely cleaning the perimeter of the preparation as in selective caries removal<sup>18,29-31</sup> and rinsing, followed by restoration with conventional GIC, or resin-modified glass ionomer (RMGI) as described in the 11-step

procedure below. Note that CDT code D1354 contains no language that precludes delivery of a restorative (or any other) procedure on the same date of service, but does preclude mechanical removal of sound tooth structure.

The suggested instructions for same-day SMART restorations/sealants are as follows:

1. *Remove biofilm and pellicle* with pumice or defocused air abrasion, or with cotton products if using microbial aerosol precautions, in the surrounding area of the lesion to be treated (GIC has no chemical bond to biofilm or pellicle).<sup>35,48-50</sup>
2. *Apply SDF* as per the step-by-step instructions detailed previously. (Note: Some clinicians prefer to wait and apply the SDF after dentin conditioning at step 7.)
3. *Clean the perimeter of the lesion*<sup>30</sup> using your preferred technique (rotary handpiece, air abrasion, or hand instruments such as hand drills or spoon excavators).
4. *Condition the lesion and surrounding areas with 20% polyacrylic acid* for 10 seconds (removing the smear layer and activating the surface for ionic exchange). It is important to condition not just the lesion but the surrounding areas as well.
5. *Rinse with water for 10 seconds and blot dry* (leaving a moist "glossy" surface).
6. *Place a matrix and wedge, if needed.*
7. If any contamination occurs, rinse briefly again with water and blot dry with cotton (*leave a moist "glossy" surface*). (Note: Some clinicians prefer to apply the SDF at this step after dentin conditioning rather than in step 2.)
8. *Mix the GIC or RMGI* for 10 seconds and apply immediately to the cavitation to prevent voids.
9. *Work quickly to place, shape, and remove excess* because any increase in temperature will greatly decrease manufacturer's stated working time. *Avoid over-manipulating the GIC* once initial gel crosslinking has begun (when the setting GIC begins to lose its gloss).<sup>48</sup>
10. *Protect from water loss or water gain.* Do not allow the GIC to dry out or become diluted with water/saliva.<sup>48,51,52</sup> Methods for preventing excess water loss or water gain from or to the GIC include turning suction isolation systems down or off during set, and/or coating the surface of the GIC with a microbrush dipped in unfilled resin, using a damp (not drenched) cotton-tip applicator, or gloved finger remoisten with water/saliva.<sup>48,51,52</sup>
11. *Do not disturb the restorative material while it is setting* (approximately 2.5 to 3.5 minutes for GIC or until RMGI is light-cured).<sup>48</sup> Once set, if placing anatomy, or finishing and polishing, use water to prevent desiccation.<sup>48</sup>

Instruct the patient not to chew on SMART restorations for at least 1 to 2 hours (for large restorations, 48 hours is even safer), or recommend a soft diet for 2 days.

## **Resin Composite Best Practices**

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Dentin caries arrested by SDF can be treated similarly to caries arrested by other processes. Principles of cavity preparation, based on material selection, should be followed. As such, because a primary aim of a successful restoration is a well-sealed margin, conservative cavity preparation should focus on external walls (emphasis on enamel margins and the DEJ); infected, demineralized, or SDF-stained tooth structure should be removed from these areas. Stained but arrested axial and pulpal walls can be left free of mechanical preparation. It should be noted that SDF-treated dentin is compatible with resin-bonding adhesives ([Figure 6](#) and [Figure 7](#)).<sup>32,53-55</sup>

### ***Option A. Multiple-Appointment SDF-Resin: Arrest First With SDF, Then Restore Later***

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Wait 2 to 4 weeks after the last SDF application prior to restoring with a resin composite. To avoid "show through" of dark axial/pulpal dentin on the primary area of esthetic concern, use an opaque restorative material, like traditional GIC for the entire definitive restoration or as a base for a sandwich technique. Alternatively, an opaque RMGI liner can be placed over the dark axial/pulpal area prior to customary restoration with a more translucent material, like resin composite.

### ***Option B. Same-Day SDF-Resin: SDF During a Restorative Procedure Using Resin Composite***

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Restore with resin composite at the same appointment as SDF application. In this case, SDF should be rinsed prior to bonding.<sup>56</sup> From an esthetic perspective, same-day resin composite restoration is at risk for silver staining near the margins. To avoid this, a short ~1 second "tac"-style curing light burst after SDF application and rinsing will photo-reveal residual silver with the subset of curing units that cover the silver absorption spectrum. Many focused operating lights will precipitate the silver in 1 or 2 minutes. Once visible, selectively and minimally prepare dark silver-stained areas at the enamel margins and DEJ, leaving silver-stained dentin internally on the axial/pulpal walls. Repeat until there is no more residual silver at enamel margins and DEJ. Then, opaque and restore as above.

If a resin composite is chosen for the restorative material, the strongly preferred approach is to arrest with SDF first and then restore at a later appointment. GIC is preferable for same-day application of SDF and restoration for reasons mentioned in the previous "Glass-Ionomer/Resin-Modified Glass-Ionomer Cement Best Practices" section.

## **Conclusion**

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Using these instructions, SDF can be incorporated into all caries management protocols by utilizing a logical flow diagram. Active caries lesions can be managed with or without subsequent restoration, depending on clinical context. GIC is a preferred restorative material, especially for same-day restorations, due to its fluoride release and recharge potential. Resin composite is a restorative option and is most appropriate after prior arrest with SDF and general caries control.

## **About the Authors**

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### **Douglas A. Young, DDS, EdD, MBA, MS**

Professor Emeritus, Department of Diagnostic Sciences, University of the Pacific, Arthur A. Dugoni School of Dentistry, San Francisco, California

### **Ryan L. Quock, DDS**

Distinguished Teaching Professor, Department of Restorative Dentistry and Prosthodontics; University of Texas School of Dentistry at Houston, Houston, Texas

### **Jeremy Horst, DDS, PhD**

Director of Clinical Innovation, CareQuest Innovation Partners, Boston, Massachusetts

### **Roopwanti Kaur, BDS, MS**

Clinical Assistant Professor, Division of Operative Dentistry, Department of General Dentistry, East Carolina University School of Dental Medicine, Greenville, North Carolina

### **Jeanette K. MacLean, DDS**

Private Practice, Glendale, Arizona; Diplomate, American Board of Pediatric Dentistry; Fellow, American Academy of Pediatric Dentistry

### **John C. Frachella, DMD**

Pediatric Dental Consultant, Bend, Oregon

### **Steve Duffin, DDS**

Dental Director, NODK, LLC and Oral Health Outreach, LLC, Wilsonville, Oregon; Private Practice, Keizer, Oregon

### **Adriana Semprum-Clavier, DDS, MS**

Clinical Associate Professor, Department of Restorative Dentistry, University of Illinois at Chicago College of Dentistry, Chicago, Illinois

### **Andrea G. Ferreira Zandona, DDS, MSD, PhD**

Professor and Chair, Department of Comprehensive Care, Tufts University School of Dental Medicine, Boston, Massachusetts

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## APPENDIX A. CONSENSUS STATEMENT

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### Clinical Instructions for the Use of Silver Diamine Fluoride (SDF) for Dental Caries Management

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Silver diamine fluoride (SDF) has US Food and Drug Administration (FDA) clearance for tooth desensitization. Although leading organizations have recommended the use of SDF "off-label" for dental caries prevention and arrest, and its use in these situations is legally permitted, manufacturers are not permitted to issue instructions for these off-label uses. To address the need of clinicians and administrators for a standard protocol, a working group has compiled practical instructions for the use of SDF for caries arrest and prevention. This guidance is intended to apply to all patients, including children, adults, older adults, and patients with special healthcare needs.

Further it is recognized that:

SDF has a prominent role in the 2018 American Dental Association Evidence-based Clinical Practice Guideline on Nonrestorative Treatments for Carious Lesions.<sup>1,2</sup> SDF has been cleared by the FDA to use for tooth desensitization since 2014. In 2016, SDF was granted Breakthrough Therapy designation for caries arrest in young children by the FDA. The FDA phase III pivotal trial, which could establish SDF as the first drug to treat caries, is underway. As of 2020, reimbursement for the caries-arresting medicament application, reported with Code on Dental Procedures and Nomenclature (CDT) code D1354, was provided by most US state Medicaid programs, as well as a number of commercial dental benefit plans. CDT code D1355, which documents delivery of a caries preventive medicament, became effective as of January 1, 2021. SDF is a medicament that could be used when delivering either of these "per-tooth" procedures.

SDF is supported by the American Academy of Pediatric Dentistry (AAPD) in the 2018 "Policy on the Use of Silver Diamine Fluoride for Pediatric Dental Patients" and by the World Health Organization (WHO) in the 2017 "WHO Global Consultation on Public Health Intervention Against Early Childhood Caries."<sup>57</sup> In 2019, the FDI World Dental Federation (FDI) revised the 2002 Policy Statement on "Minimal Intervention in the Management of Dental Caries" to clarify that "an operative ("surgical") approach should only be used when specifically indicated, eg, when cavitation is such that the lesion cannot be arrested, or when there are esthetic or functional requirements."<sup>58</sup> The FDI Policy Statement includes the following principles: modification of the oral flora to favor health; patient education and informed participation; remineralization of noncavitated and cavitated lesions of enamel and dentin/cementum; minimal operative intervention of cavitated lesions; repair of defective restorations as a possible alternative to replacement.

The SDF clinical instructions presented in this article represent a foundation using the best available scientific evidence, combined with expert clinical experience and observation. These initial clinical instructions have been reviewed and their value affirmed by the following organizations, understanding that they will need updating as the body of knowledge continues to expand.

The organizations are:

Academy of General Dentistry

American Academy of Developmental Medicine and Dentistry

American Dental Hygienists' Association

Association of State and Dental Territorial Dental Directors

California Dental Association Foundation

Caries Management by Risk Assessment (CAMBRA) Coalition

Consortium of Operative Dentistry Educators

Maine Academy of General Dentistry

Northern California Academy of General Dentistry

Project Accessible Oral Health

San Francisco Dental Society

Southern Alameda County Dental Society

Special Care Dentistry Association

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## APPENDIX B. SDF AT A GLANCE

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**Material:** 38% SDF (in purified water, pH 10)

**Storage:** Avoid freezing or extreme heat

**Maximum Dose:** 260 µL (eight drops) per treatment visit<sup>59</sup> (see #7 in the Safety section of Appendix C)

### Indications:

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- Tooth hypersensitivity
- High or extreme caries risk (xerostomia or severe early childhood caries)
- Patients undergoing radiation therapy for head and neck cancers
- Active caries lesions
- Treatment challenged by behavioral or medical factors
- Difficult-to-treat dental carious lesions
- Patients without access to regular dental care
- When a less invasive treatment option is preferred
- In combination with selective caries removal<sup>29,30</sup> as a liner to harden infected or affected dentin<sup>8-13</sup> and provide antimicrobial effects<sup>8,14-16</sup>
- Preventive agent at high-risk surfaces<sup>4-6</sup>

## **SDF Actions:**

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- Desensitization<sup>33</sup>
- Prevention of new caries lesions<sup>3-5,7</sup>
- Caries indicator<sup>23</sup>
- Caries arrest<sup>1,2,60</sup>
- Hardening carious dentin<sup>8-13</sup>
  - Forms silver-protein conjugates in carious surfaces<sup>11</sup>
  - Inhibits the proteins that break down the exposed dentin organic matrix: matrix metalloproteinases,<sup>11</sup> cathepsins,<sup>9</sup> and bacterial collagenases<sup>10</sup>
  - Promotes remineralization<sup>10</sup> and decreases lesion thickness<sup>10</sup>
  - Fluoroapatite increases resistance to acid dissolution and enzymatic digestion<sup>11</sup>
- Silver ions have antimicrobial action by breaking membranes, denaturing proteins, and inhibiting DNA replication<sup>8,14-16</sup>
- Silver and fluoride ions penetrate ~25 microns into enamel<sup>14</sup> and up to 2.1 mm into dentin<sup>61</sup>
- Silver microstructures fill exposed dentinal tubules and microcavitations produced by the caries process<sup>61</sup>

## **SDF Contraindications<sup>6</sup>:**

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- Pulp exposure
  - Irreversible pulpitis
  - Allergy or intolerance to silver, fluoride, or ammonia
  - Direct exposure to open mucogingival lesions
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## **APPENDIX C: OTHER SDF CONSIDERATIONS**

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### **Advantages**

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- A quick, simple, painless, and affordable means of managing many caries lesions at one appointment
  - Procedure may not produce aerosol
  - Procedure can be completed in virtually any setting without the need for expensive dental equipment, local anesthetic, sedation or even electricity
  - Can be combined with other prevention, therapeutic, and restoration options to deliver risk-based, patient-centered comprehensive care
  - Approximately 81% of caries lesions are arrested with semi-annual application<sup>60</sup>
  - Will not stain healthy tooth structure

## **Disadvantages**

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- Does not restore form, function, or esthetics
- Some caries lesions fail to arrest with SDF treatment alone
- Permanently stains active caries lesions black
- Stains demineralized and hypomineralized, non-cavitated surfaces
- Stains clinic surfaces, clothing, and skin if not handled properly

## **Precautions Related to Unintended Staining**

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- Inform patients and use caution as early demineralization (white spots) may be subclinical
- Protect patient and clinic surfaces (see instructions for application)
- Apply to site-specific lesions versus full-mouth application (such as with fluoride varnish)
- Do not use the same brush that has come in contact with SDF to apply varnish to other teeth
- Avoid exposing SDF to strong light (curing, headlight, operatory) that has just been applied to avoid the silver ions from precipitating out of solution

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## **Stain Removal**

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Difficult with varying degrees of success. The following suggestions are made:

Lips and skin:

- Stain will go away on its own within a few days or up to a few weeks.<sup>62</sup>
- Hydrogen peroxide, makeup remover, or exfoliation with a slurry of salt may help remove or lessen the stain.

Surfaces

- Sodium hypochlorite
- Some household cleaning products

Fabrics

- Potassium iodide
- Sodium percarbonate

## **Restorations**

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- Same-day silver-modified atraumatic restorative treatment (SMART) restoratives with resin will immediately turn dark.
- Same-day SMART restoratives with no resin may turn gray over time.
- Consider conventional atraumatic restorative treatment (ART) without SDF in the esthetic zone if staining is a concern.
- Delay placement of a restoration for 2 weeks after SDF application and the restorative materials will not turn gray. Stained tooth structures may show through depending on opacity and material thickness.
- Clean/sound cavosurface margins using selective caries removal and/or opaquers can help mask SDF stain.

## **Documentation**

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- Obtain informed consent from the patient or legal guardian, reviewing the risks, benefits, and alternatives to SDF.
- CDT Code "D1354 interim caries arresting medicament application - per tooth"
- CDT Code "D1208 topical application of fluoride - excluding varnish"
- CDT Code "D1355 caries preventive medicament application - per tooth," effective January 1, 2021

## **Safety**

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- 38% SDF consists of 25% silver, 8% ammonia, and 5% fluoride, with a pH of 10 (Advantage Arrest, Elevate Oral Care).
- 0.05 ml drop of a 38% SDF contains 19 mg SDF, 4.74 mg silver, 2.24 mg fluoride.
- 0.1 ml unit dose ampule of a 38% SDF contains 38 mg SDF, 9.48 mg silver, 4.48 mg fluoride.
- In a short-term serum pharmacokinetic study, fluoride exposure was below the US Environmental Protection Agency (EPA) oral reference dose. Silver exposure exceeded the EPA oral reference dose for cumulative daily exposure over a lifetime, but for occasional use (typically biannual application) was well below the concentrations associated with toxicity.<sup>63</sup>
- In another serum pharmacokinetic study,<sup>64</sup> SDF was well tolerated and no adverse events were reported.
- No studies have yet evaluated the safety of SDF during pregnancy in women or animals, thus the authors cannot make a recommendation on use of SDF in pregnant women and suggest consideration of silver nitrate and fluoride varnish instead. There are long histories of safely using silver nitrate to cauterize HPV warts on the cervix of pregnant women<sup>24</sup> and fluoride varnish to prevent caries lesions in pregnant women.<sup>25</sup> The combination of 25% silver nitrate and fluoride varnish<sup>26</sup> has been shown to have equivalent effectiveness to SDF.<sup>27</sup>
- The SDF dose of 260 µL (eight drops) per treatment visit listed in this document is a significant change to the previous recommendation of one drop per 10 kg of body weight. The dose limit of 260 µL SDF per patient was developed to assure safety based on the weight of a small 12-month old child by the FDA drug panel for the phase III, multicenter, randomized, placebo-controlled superiority trial run by University of Michigan, New York University, and University of Iowa.<sup>59</sup>
- When covering SDF with fluoride varnish there is an additive fluoride dose. The maximum dose of 260 µL SDF (eight drops) contains 11.6 mg fluoride, essentially the same as the 11.3 mg dose in a standard 0.5 mL packet of fluoride varnish. For adults or children over 20 kg (44 lbs.), combining the full doses is safe. The individual product dose limits are based on safety for a 10 kg (15-month old) child. The authors have not encountered a situation that would require even half the dose of either SDF or fluoride varnish at this young age. Nonetheless, combined dose limits can be adjusted according to weight using a total dose of 1.13 mg/kg fluoride when a child is less than 20 kg (44 lbs.), eg, four drops of SDF and the smallest (0.25 mL) packets for fluoride varnish.

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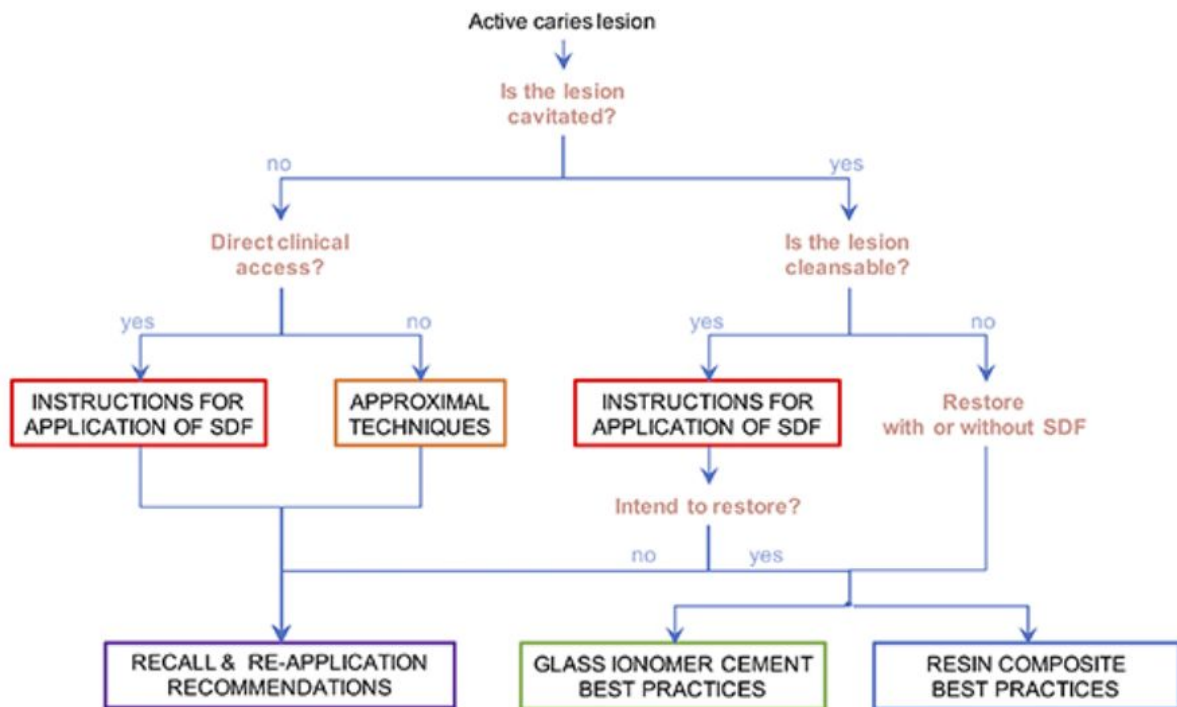
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**Image 1 of 7** Fig 1. Flow diagram of clinical use of SDF with an active lesion. Decisions for selection of interventions are guided by: presence of cavitation (an actual hole in the tooth); access (the ability to directly apply material to a lesion); and cleansability (the ability of a toothbrush to clean the entire lesion, saliva to flow through the lesion, and lack of a plaque trap). Titles of clinical best practice instructions as presented in the article are denoted here in boxes.



**Image 2 of 7** Fig 2 and Fig 3. Placement of SDF on an approximal caries lesion using woven floss. Floss is placed between the teeth (Fig 2), then SDF is applied to the floss, and allowed to soak in for at least 1 minute (Fig 3). Note the corner of the mouth is well-protected from the blue SDF on the floss with a gloved finger. (Photographs courtesy of Jeanette MacLean, DDS)



**Image 3 of 7** Fig 2 and Fig 3. Placement of SDF on an approximal caries lesion using woven floss. Floss is placed between the teeth (Fig 2), then SDF is applied to the floss, and allowed to soak in for at least 1 minute (Fig 3). Note the corner of the mouth is well-protected from the blue SDF on the floss with a gloved finger. (Photographs courtesy of Jeanette MacLean, DDS)



**Image 4 of 7** Fig 4 and Fig 5. SDF application 1 minute and conventional GIC restoration on the same day. Fig 4: Before restoration, after SDF placement. Fig 5: Immediate postoperative. There is some dark show-through around the marginal areas because of inadequate caries removal around the perimeter of the lesion. For a more esthetic result, clean 2 mm from the cavosurface margins when enamel is present and 1 mm if there is no enamel in the deeper root areas. (Photographs courtesy of Kenneth Han, DDS)



**Image 5 of 7** Fig 4 and Fig 5. SDF application 1 minute and conventional GIC restoration on the same day. Fig 4: Before restoration, after SDF placement. Fig 5: Immediate postoperative. There is some dark show-through around the marginal areas because of inadequate caries removal around the perimeter of the lesion. For a more esthetic result, clean 2 mm from the cavosurface margins when enamel is present and 1 mm if there is no enamel in the deeper





**Image 6 of 7** Fig 6 and Fig 7. Restoration of SDF-treated dentin with resin composite. Fig 6: Arrest achieved on teeth Nos. 4 and 5 buccal via two prior applications of SDF. Fig 7: Conservative preparation on Nos. 4 and 5 focused on external walls only, ie, enamel margins and DEJ. A RMGI liner was placed on SDF-stained axial wall dentin as an opaquer, followed by typical etch/primer/adhesive technique for resin composite restoration. Also, note glass-ionomer restoration on mesial No. 30; arrest with SDF and conservative preparation similar to Nos. 4 and 5. (Photographs courtesy of Dan Bentley, DDS)



**Image 7 of 7** Fig 6 and Fig 7. Restoration of SDF-treated dentin with resin composite. Fig 6: Arrest achieved on teeth Nos. 4 and 5 buccal via two prior applications of SDF. Fig 7: Conservative preparation on Nos. 4 and 5 focused on external walls only, ie, enamel margins and DEJ. A RMGI liner was placed on SDF-stained axial wall dentin as an opaquer, followed by typical etch/primer/adhesive technique for resin composite restoration. Also, note glass-ionomer restoration on mesial No. 30; arrest with SDF and conservative preparation similar to Nos. 4 and 5. (Photographs courtesy of Dan Bentley, DDS)