Q&A's for Riva Star
USA Release
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Q. What is the product registered to do?
A. This device is indicated for the treatment of dentinal hypersensitivity, for use in adults over the age of 21.

Q. What are the active ingredients?
A. Reinforce that is has silver diamine fluoride (SDF) and potassium iodide (KI) which forms immediate relief.

Q. SDF in literature is well documented as causing black staining. Is this also true for Riva Star?
A. That is correct, it is well known from many literature articles that silver diamine fluoride causes black staining (I have listed these articles below). Our system is patented by the addition of another component, potassium iodide, which bonds with the silver to form silver iodide. It is the free silver that causes the black staining, thereby with the introduction of potassium iodide to form a reaction precipitate of silver iodide, there is consequently no staining.
FDA statement – The fundamental principle and mode of action of Riva Star and the predicate devices in reducing dentinal hypersensitivity is the occlusion of open dentin tubules by the formation of a precipitate.
Both Riva Star and primary predicate Advantage Arrest employ silver diamine fluoride as the main chemical to form the precipitate to occlude the open dentinal tubules. Riva Star, however, also uses a second component, potassium iodide solution, which allows for an immediate reaction precipitate of silver iodide to be formed to occlude the open dentinal tubules.

March 22, 2018 -- Potassium iodide (KI) may lessen the black staining associated with silver diamine fluoride (SDF) on restored teeth, according to research presented on March 22 at the 2018 American Association of Dental Research (AADR) meeting in Fort Lauderdale, FL.

"Silver diamine fluoride offers an alternative caries treatment paradigm that is quick and low-cost for low-income children and the elderly, such as those under nursing care," study co-author Carolyn Primus, PhD, told *DrBicuspid.com*. "Treatments of teeth with SDF with KI significantly reduced discoloration."

From FDA submission:

> Riva Star, however, is a two component device, with the two components, silver diamine fluoride and potassium iodide, reacting together to form the immediate precipitate of silver iodide to occlude the dentinal tubules. These two supplied components ensure complete reaction and that no free silver ions remain that would otherwise cause tooth staining. The concept of adding another constituent was also noted by Pashley *et al* (1981), and Isobel *at al (2009)*, that similarly, when using silver nitrate alone compared to when adding sodium chloride to silver nitrate, resulted in less of a reduction in hydraulic conductance and tooth staining.

Pashley study explaining that silver products (produced black staining): 010_Pashley DH Greenhill JD The effects of desensitizing.pdf

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The combinations of sodium sulfate and barium chloride (in either order), potassium carbonate plus calcium chloride or sodium carbonate plus calcium chloride produced white precipitates which appeared to completely wash off the discs with rinsing. The combination of silver nitrate plus formalin produced a black precipitate with a round bead of metallic silver metal in the center of the O ring. When viewing the fractured edge of discs treated with this combination, the black precipitate was seen to extend into the dentin a minimum of two-thirds of the disc thickness. Discs treated with silver nitrate followed by buffer immediately developed a white precipitate. This precipitate was rinsed off and hydraulic conductances redetermined. Upon observing the same discs 12 h later, the treated area was completely black. Observation of the edge of the disc after fracturing revealed that the black precipitate penetrated at least two-thirds of the thick-

A study on Riva Star and the known effects of silver diamine fluoride staining: Riva Star paper.PDF

It is known that diamine silver fluoride produces a black pigmentation, whether in carious or non-carious dentin. This produces an esthetic challenge for the material. This study used a formulation of diamine silver fluoride at various concentrations from 30% to 35% according to the manufacturer's specifications. After application, the use of potassium iodide is indicated to mask the staining produced by the diamine silver fluoride through the generation of a white precipitate of silver iodide. However, the effect of this treatment regarding effective stain reduction and the interaction with different restoration materials has not yet been determined. Because of this, we intend to carry out further studies to evaluate these variables.[17]

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Control of Dentinal Hypersensitivity

In 1935, Grossman (41) reported some requirements of ideal treatment for DH, which can still be applied nowadays. The treatment must act fast, be effective for long periods, be easy to apply, not irritate the pulp, not cause pain, not stain the teeth and be constantly effective.

Silver nitrate reduces DH by fast coagulation of the Tomes processes forming silver albuminate, which acquires a dark color when exposed to light, blackening the tooth surface. The subsequent use of sodium chloride reduces the pigmentation. Thus, due to tooth darkening, this technique is not well accepted among patients. Studies using dentin disks obtained from extracted teeth showed that the presence of proteins in the dentinal tubules has little to do with the reduction of dentin hydraulic conductivity caused by the silver nitrate (62).

Q. How is this system unique to other competitor products in the market?
A. Riva Star is patented by SDI as a system of SDF and KI. It was developed by three Australian leading clinicians.