



Mr. Michael E. Adjodha  
Center for Devices and Radiological Health (HFZ-480)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

RE: Dental Products Panel; Meeting of October 11 & 12

September 23, 2005

Dear Mr. Adjodha,

I would like to present our company's comments concerning the classification of Dental Retraction Cords that will be discussed in the above referenced meeting in Gaithersburg. I am the President of the Pascal Company, Incorporated, which is located in Bellevue, WA.

As a manufacturer of Retraction Cords, Pascal is obviously interested in any decision concerning retraction cord classification. The purpose of this letter is to present to the panel as much information concerning the issues connected with these products to assist the board in making an informed decision based on the history, usage and variations in medicament used with retraction cords.

I would like to begin by giving a short background of the product. Although I am not an actual eyewitness to the early part of this history, I have heard much of the following from Mr. Benjamin Paschall, the owner of Pascal, and for the events subsequent to 1978 I can personally attest to them.

Pascal Company, Inc. was founded in Seattle, WA in 1935. Ben's father (also named Benjamin) suffered from asthma. He had read reports from Germany about the synthetic production of epinephrine, and its potential use as an asthma treatment. He began manufacturing racemic epinephrine HCl for his own use, and then decided to begin to market it under the trade name *Breatheasy*. This was an epinephrine solution that was dispensed from hand-blown glass nebulizers. As far as we know, this was the first commercial use of epinephrine in the US.

The company had a good deal of success in marketing the product across the US

and Canada. After discussions with local dentists in the Seattle area, Pascal introduced an 8% buffered solution of racemic epinephrine HCl (called *Racemistat*) in 1947 for use in the dental profession. This solution was used by dentists to assist in gingival retraction. They would soak cotton thread (hereinafter called cord) and pellets directly in the solution themselves before application. Epinephrine is a vasoconstrictor, and is utilized for hemorrhage control during surgical procedures.

In 1956, the Bell family (a member of whom had worked at Pascal) founded a competing firm called Belpport Inc., located in Camarillo, CA (Note: the Gingi-pak [Belpport] website states that they began making retraction cord in 1954. According to Ben Paschall, the actual date is 1956). They too began manufacturing an 8% solution of epinephrine. Shortly thereafter, they began to manufacture a product called Gingi-Pak, which consisted of a length of cord soaked with epinephrine, which was then dried and placed in a bottle. Pascal had been working on the same idea before (prior to the founding of Belpport), and came out virtually simultaneously with a similar cord, called *Racord*. The various sizes of cord are made with string that consists of individual strands of cotton thread that are twisted together. *Racord* is still very popular within the US market, as is Gingi-pak.

The product was continually developed by Pascal to include various sizes of cord. Gingi-pak and Pascal used different numbering systems to denote the size of cord. Gingi-pak utilizes an arbitrary system of their own making, calling the thinnest size cord "0" and the rest "1, 2 and 3" (3 being the thickest). Pascal used the same numbering system that is used by industry for crochet thread; its numbering system is therefore #7 (thinnest), 8, 9, and 10. All other subsequent manufacturers of retraction cord have utilized the Gingi-Pak system.

Pascal subsequently introduced the products *Pascord* (in 1966) and *Retrax* (in 1974). *Pascord* uses Aluminum Sulfate instead of racemic epinephrine as an astringent agent, dried onto twisted cord. *Retrax* is twisted cord without medicament. Aluminum Sulfate does not have the systemic properties that epinephrine has, but rather operates as an astringent. In the 1970s, Pascal introduced *Racord Two*, which is a combination of a reduced amount of epinephrine combined with zinc phenolsulfanate. It is designed to achieve the best qualities of epinephrine and astringent materials, retaining much of the vasoconstriction properties of epinephrine products (but with a reduced quantity for a greater margin of safety for the patient) and the astringent qualities inherent in zinc phenolsulfanate.

In the late 1970s, Pascal introduced cords (called *Siltrax*) which are made with braided cord (which, as the name implies, has the individual strands braided rather than twisted together). These cords are otherwise identical to each other in medicament i.e. *Racord* is the same as *Siltrax EPI*; *Pascord* is the same as *Siltrax AS*; *Racord Two* is the same as *Siltrax PLUS*; *Retrax* is the same as *Siltrax Plain*. A number of other companies also began making braided cords. In 2004, Pascal introduced *KnitTrax*, which is untreated cord that (as the name implies) has the strands knitted together.

It should be understood that different companies use different astringent agents when making their cords. While Pascal uses Aluminum Sulfate for our *Pascord* and *Siltrax AS* products, and zinc phenolsulfanate on our *Racord Two* and *Siltrax PLUS* products, other companies used different agents. These include aluminum potassium sulfate, ferric sulfate and aluminum chloride; some companies advertise their cords as "non-epinephrine" without specifying what is actually on the cord.

Originally, retraction cords were treated by the FDA as drug items. It is only fairly recently that they have been classed as medical devices. In Europe, untreated cords and cords containing Aluminum Sulfate (or similar astringent agents) are regulated by the European Union Commission as medical devices. Racemic Epinephrine HCl is not in the European Pharmacopoeia and is not allowed in some countries; in others it is regulated by the individual country's drug regulatory agency which corresponds to the US FDA.

Pascal commissioned a study in 1991 at the University of Washington in Seattle to test the efficacy and safety of its *Siltrax* retraction cords. This study showed that *Siltrax AS* (with Aluminum Sulfate) had the highest retraction rate (91.7%), while *Siltrax Plain* had the lowest retraction rate (56.3%). *Siltrax PLUS* (87.5%) and *Siltrax EPI* (85.4%) had similar rates. It is worth noting that, even though the added medicaments make a major contribution to the overall effectiveness of the cords, over half of the retraction properties of these cords are due purely to the physical displacement of the tissue by the cord itself and not due to the medicaments. This fact may be of some relevance in classifying retraction cords as a device.

Pascal Retraction Cords have a 50 year history of safety and effectiveness. Total unit sales since 1998 alone exceed 2 million bottles. Beyond an occasional occurrence of elevated heartbeat due to exposure to epinephrine (perhaps a dozen or so instances over 50 years), Pascal has had no other medical complaints or issues with our cords. Our 1991 study found that there were absolutely no systemic reactions in the patients who had used either our untreated or our aluminum sulfate cords. We have never received any reports of adverse effects from these types of cords whatsoever.

There is the issue of the usage of epinephrine in these cords. Epinephrine is used due to its vasoconstriction qualities; it operates systemically rather than mechanically like the astringent cords. It is for this reason that in Germany (for example) the epinephrine cords are treated as a drug, while the plain and astringent cords are treated as medical devices. The study Pascal commissioned found that on average, the patients who had *Siltrax EPI* used in their treatment had their heartbeat go up by 10 beats per minute; the *Siltrax PLUS* patients had an increased heartbeat of 4 beats per minute. The patients who had *Siltrax AS* and *Siltrax Plain* had no increase in heartbeat. Still, the risk would appear to be minor for those patients who are not contraindicated for exposure to epinephrine. In a different study ("Hemostatic Efficacy and Cardiovascular Effects of Agents Used During Endodontic Surgery", performed by Francine J. Vickers, DDS, J. Craig Baumgartner, DDS, PhD, and Gordon Marshall, DMD, published in the Journal of Endodontics of April, 2002) which compared a Pascal epinephrine product (Racellet #3 pellets, each pellet containing 0.55mg of REH) and a Ferric Sulfate product for cardiovascular effects. The results of this study found no evidence of cardiovascular changes when either product was used. The authors surmised that the vasoconstrictive effect on the capillaries is so localized and immediate that there is no further uptake of epinephrine into the bloodstream. They also conjectured that the use of a local anesthetic may have contributed to this effect. The authors then cite other studies that both agreed and disagreed with their findings that there were no changes in blood pressure when epinephrine was used during surgical procedures.

It is important to point out that the Pascal cords are manufactured by a process that assures that there is a known, controlled amount of medicament applied to each section of cord. This offers far more assurance to the dentist of being able to control the amount of patient exposure to the medicament. Many dentists, especially in the US, prefer epinephrine to astringent agents; if these pre-medicated cords would be removed

from the marketplace, dentists would simply take plain cords and soak them with the medicament themselves. They would have no way of knowing how much medicament they were administering to each patient. It seems far safer for the patients to have a controlled amount rather than an unknown amount applied. It would not make sense to over-regulate a method of controlled application, while leaving un-regulated another method of application that is imprecise in the extreme.

It is our understanding that the FDA has previously granted a 510K to Ultradent for its epinephrine cord, which would obviously indicate that FDA now considers it a device. We had asked for guidance from FDA personnel on this issue back in the early 1990s, and were told that the FDA was unsure which way to classify this item. Up to the time we learned that the FDA had issued this 510K, we had always assumed that our treated retraction cords were drugs. We would be interested in knowing what the FDA's rationale is on this issue. I certainly can see the rationale for the untreated and astringent cords being treated as devices. I can also understand FDA's reluctance in splitting the responsibility for these products between the drug and medical device sections of FDA. The fact that over 50% of the desired retraction effect occurs mechanically does supply a rationale for treating the products as medical devices. But as a matter of logic, does that make epinephrine solutions medical devices when they are used for this same purpose?

In conclusion, the use of Pascal Retraction Cords on millions of patients over a 50 year span with virtually no side effects should preclude any decision of making these items a Class III device, and a strong argument against making them Class II devices. Using retraction cords that have been pre-treated with a known quantity of medicament is probably much safer than having the dental practitioner soak his own cords. It does not make sense to tighten regulations on a technique that is inherently safer, causing an increase in expense that would drive the end user to choose a less safe procedure.

I will be attending the Dental Products Panel meetings on October 11 and 12 in Gaithersburg. From the rather cursory agenda that has been described in the CDRH advisory of this meeting, I am unsure how much attention will be devoted to this particular topic; the panel appears to have a very large agenda of topics to cover. It is our hope that the Panel will take into consideration the long history of safe and effective use of these products when making its decision on classification.

Sincerely,

David Watton

President

Pascal Company, Inc.