

CONSUMER ALERT ON GENERIC DENTAL WAX

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Did you know that generic dental wax is the last known product in healthcare without several quality and safety features that have been in place for over 25 years? Generic unlabeled dental wax is the most commonly dispensed product to patients in orthodontic treatment and 75% of patients are children. This paper explains the background on why these healthcare product standards have been so widely adopted and why patients should not continue to use dental wax that is in violation of these basic quality standards.

Following is a summary of the quality, safety, and compliance features addressed in this paper. OrthoDots® CLEAR is the world's first high quality alternative that meets all critical healthcare product standards and is superior to dental wax in both performance and aesthetics.



Quality, Safety, and Compliance Features	Generic Dental Wax	OrthoDots® CLEAR
Hygienic Unit-of-Use Packaging for safe patient and in-office use	NO	YES
Tamper Evident Packaging	NO	YES
Labeling with Product Traceability	NO	YES
Disclosure of Ingredients	NO	YES
Compliant with Regulations in the U.S. and EU	NO	YES

In a recent survey of orthodontic residents in the U.S., a majority of residents surveyed believe it is not acceptable to dispense a dental wax product to their patients without any of the above quality and safety features.

Product Purpose and Use

In determining the appropriate level of quality and safety requirements for dental wax relative to other healthcare products, it is important to first understand its purpose and use.

Dental wax is commonly dispensed to patients to treat irritation and abrasions caused by orthodontic appliances. Traditional dental wax requires the patient to tear off a “pea-sized piece” of material from a bulk piece contained in an unlabeled plastic container. As dental wax is commonly known to crumble and/or fall off, it is a commonly accepted fact that the material is frequently swallowed. Additionally, given the intended use for these products, they of course consistently come in contact with saliva and even blood.

Hygienic Unit-of-Use Packaging

“Since dental wax comes in contact with saliva and even blood, traditional dental wax is not appropriate for patients to repeatedly handle the same piece of material over and over. Also, it should never be shared among patients — and we know this occasionally happens, particularly with many kids in orthodontic treatment in our schools,” explains Dr. Eric Hannapel, Orthodontist and co-inventor of OrthoDots. “We have also encountered known cases where elementary schools have dispensed dental wax to different children from the same pack. And in many instances, schools are receiving these cases of generic wax from local orthodontists to promote their practice in the community.”

“Safe and convenient use for our patients is the primary reason why we found it essential to package OrthoDots in hygienic, single-use applications. We believe generic wax is the last commonly dispensed healthcare product used for a similar purpose that is not in hygienic single-use packaging. When you stop and think about it, why has it taken so long for a product used for this purpose to be packaged in hygienic applications? It’s what we’ve expected for decades from bandages and all other types of medical devices.”

According to Dr. Mike Silver, OrVance's Director of R&D and Technical Affairs, "Our research also indicates that orthodontic residents are embracing the need for more hygienic packaging. When we surveyed orthodontic residents from dental schools across the U.S., 69% said it was either 'important' or 'very important' that a product used for this purpose is hygienic and in individual-use packaging. And the majority of residents surveyed also indicated that the product must be in unit-of-use packaging in order to be used in the practice setting."

Tamper-Evident Packaging

For decades, virtually all consumable healthcare products have had packaging with a tamper-evident feature. The tamper-evident packaging feature was born out of the Tylenol® tampering incident in September of 1982 that led to seven murders.

In the year following, while Johnson & Johnson's Tylenol sales plummeted, they invested \$100 million to develop packaging that would better prevent tampering. J&J's leadership gave birth to the implementation of tamper-evident packaging that is now prevalent not just with healthcare products but with virtually all processed foods as well. J&J's proactive handling of this tragedy became a classic case study in business schools across the nation.

According to the regulations of the Food and Drug Administration, a tamper-evident package "is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred." The traditional dental wax that is still commonly dispensed to patients offers no protective barrier or indication whether tampering may have occurred.

Commodity Dental Wax



Typically in a plastic case, easily opened & closed with no evidence of entry

OrthoDots® CLEAR



OrthoDots® CLEAR offers single-use peel-back packaging that provides visible evidence of opening (single-use cannot be resealed after opening)

Proper Labeling with Product Traceability

Unlabeled dental wax also lacks proper labeling with manufacturer lot codes on the package that is given to the patient. While regulations may vary by country, other commonly dispensed products offer the end consumer traceability in case there is ever a quality or safety issue. Lacking this information essentially means that in the event of a product safety issue, it would be very difficult to conduct a proper investigation. Good Manufacturing Practices (GMP's) require manufacturers to retain information on a given manufacturing "batch", including the exact ingredients that were used, time and place of manufacturing, and other information required to complete a proper quality investigation.

The recent Romaine lettuce crisis is an example of how the lack of product traceability can make the investigation and containment of a quality issue very difficult. In June 2018, the US Center for Disease Control and Prevention announced that since the first romaine lettuce E. Coli outbreak, 197 people across 35 states had become ill, and five people had died. Although authorities had no way of knowing exactly where the outbreak came from, their investigation led them to believe that the contaminated produce came from somewhere in Arizona, yet the source of contamination was never found.

This is not to say that the manufacturers of generic dental wax have no batch control or product traceability. The unlabeled dental wax is however lacking product lot codes on the individual pack that is given to the patient. Providing traceability on the individual unit is certainly a best practice throughout healthcare in order to properly address any patient-level quality issues. Without it, any mass notification and containment of a quality issue to the end patient level would be virtually impossible. Most consumers can recall

communications from a manufacturer through the media to return or discard product from a given lot number that appears on the package. Without this information on the package itself, this of course would not be possible.



Dental wax as typically dispensed to patients by healthcare professionals: no directions for use or lot codes for traceability



OrthoDots® CLEAR includes directions for use and lot codes for traceability.

Disclosure of Ingredients

When considering the purpose and use of dental wax, we believe disclosure of ingredients is a very basic consumer expectation. Traditional dental wax is not only lacking the disclosure of ingredients for the end patient, but it is generally not even made available to the orthodontic practice. No one will argue that today's consumers expect to know what they are putting into their bodies, yet the ingredients are unknown for the vast majority of the dental wax dispensed to patients.

Regulatory Compliance

While regulations vary by country, unlabeled dental wax does in fact violate regulations that have been in place for over 25 years in many of the world's leading orthodontic markets. For example, the medical device regulations for orthodontic wax in the European Union (EU) does require labeling with traceability for each unit, yet most of the dental wax dispensed globally still lacks this information on the end unit dispensed to the patient. OrVance has confirmed this regulatory requirement with opinions from two global regulatory firms as well as confirmation with the regulatory authorities in a leading healthcare market in the EU.

Performance & Aesthetics

Traditional dental wax also is obsolete in both performance and aesthetics. OrthoDots® CLEAR is the first orthodontic wax to provide the following benefits to practices and patients:



Performance and Aesthetic Features	Generic Dental Wax	OrthoDots® CLEAR
Sticks and Stays the Best (with proprietary adhesive)	NO	YES
Clear (17X more transparent than dental wax)	NO	YES
20X more pliable than dental wax (easier to mold)	NO	YES
Best for use on all appliances including Clear Aligner Trays	NO	YES

Made in U.S.A. | Patents Pending

OrthoDots® CLEAR is now the #1 orthodontic wax in U.S. orthodontic resident programs with over 80% of the residents surveyed saying they intend to use OrthoDots® CLEAR in their practice. Ask your Orthodontist for OrthoDots® CLEAR or learn where to buy at orvance.com.

Sources:

1. OrVance Survey to Orthodontic Residents in the U.S., March 2019
2. OrthoDots® CLEAR: Raising the Bar in Quality, Safety, and Compliance, May 2018
3. Why OrthoDots® CLEAR is Poised to Replace Dental Wax, November 2017
4. Post-romaine lettuce outbreaks: Lessons in traceability, Michelle Arcand, June 2018

