

OrthoDots® CLEAR

Raising the Bar in Quality, Safety, and Compliance



A White Paper By:

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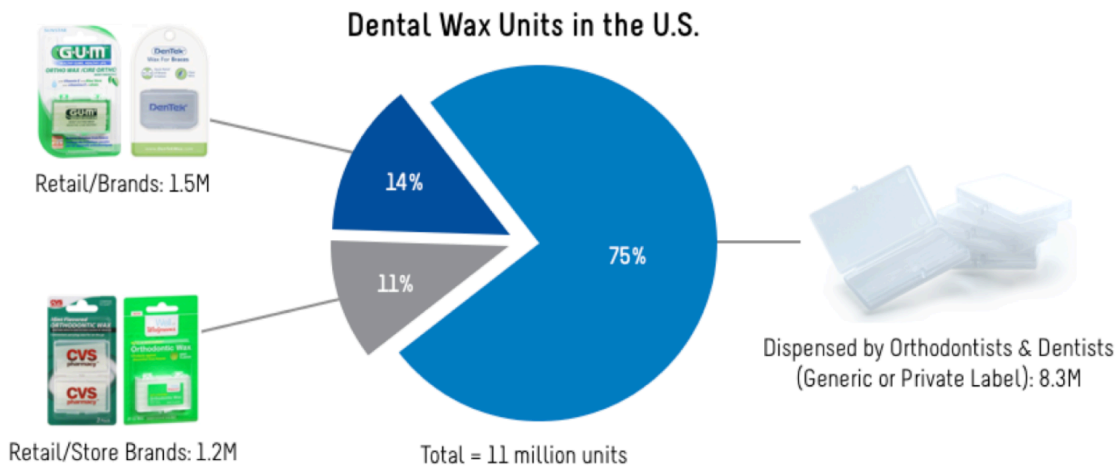
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ABSTRACT

This white paper compares OrthoDots CLEAR to commodity dental wax on the aspects of quality, safety, and regulatory compliance. Historically, commodity dental wax has been the only broadly available product on the market and the product most commonly dispensed by Orthodontists for pain and abrasions caused from orthodontic treatment.

In the U.S. alone, it is estimated that 11 million packs of dental wax are dispensed or purchased by consumers annually. Orthodontists or Dentists dispense about 75%, or 8 million packs, in generic plastic containers with no labeling (see below).



While OrthoDots CLEAR are shown to be much more effective and preferred by patients over dental wax on several key product features^{1,2}, this paper is focused on appropriate levels of quality, safety, and regulatory compliance for product use both in the practice setting and for take-home patient use.



Dental wax as typically dispensed by Orthodontists and Dentists: Five strips of “wax” in plastic containers with no labeling or lot codes.

The commodity dental wax supplied to the Orthodontic industry has been used for many decades; however, this paper concludes that it is no longer up to the quality and safety standards of other healthcare products that are sold to consumers or used in a healthcare setting.

This paper explores the following topics regarding appropriate levels of quality and safety for this class of healthcare products:

- Intended use and purpose relative to other healthcare products (i.e., likelihood of ingesting and contact with bodily fluids)
- Appropriate packaging for intended use
- Disclosure of product ingredients
- Manufacturing standards
- Labeling and product traceability in the event of a quality or safety issue
- Regulatory requirements and trends

PRODUCT PURPOSE AND USE

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

Traditional dental wax requires the patient to tear off a pea-sized piece of “wax” from a bulk piece contained in an unlabeled package. As dental wax is known to crumble and/or fall off, it is occasionally swallowed and ingested. Additionally, given the intended use for these products, they also consistently come in contact with saliva and even blood.

According to Dr. Silver, co-inventor of OrthoDots, “Knowing our product would occasionally be ingested and that it would likely come in contact with bodily fluids required us to carefully consider many quality and safety issues. These include the ingredients we use, appropriate manufacturing standards, how our product should be packaged, appropriate labeling, and product traceability.”

“When we talked to well established Orthodontists, many of them admitted to not giving this much thought as commodity dental wax has been used by their profession even before they had braces as kids. However, our research and findings in the broader healthcare arena were much more shocking: We simply could not find any similar consumer healthcare product that was not packaged in hygienic unit-of-use packaging, with no disclosure of ingredients, and without labeling or lot codes for traceability in the event of a potential quality or safety issue. Additionally, when talking with professionals in other healthcare sectors, they unanimously agreed that unlabeled dental wax in its current form is no longer appropriate for its intended use, especially considering that it’s primarily used by children.”

“This is, of course, no fault to the Orthodontic profession as no high-quality alternative to dental wax has existed up until now. With the launch of OrthoDots, we have not only made a more effective product than commodity dental wax^{1,2}, but we

have also addressed all the essential quality and safety standards professionals and patients have come to expect from today’s consumer healthcare products.”

APPROPRIATE PACKAGING FOR INTENDED USE

“Since products used for this purpose come in contact with saliva and even blood, traditional dental wax is not appropriate to share among patients — and we know this occasionally happens with traditional dental wax,” explains Dr. Eric Hannapel, Orthodontist and co-inventor of OrthoDots. “Safe and convenient use for our patients is the primary reason why we chose to package OrthoDots in single-use applications. We believe dental wax could literally be the last consumer healthcare product used for a similar purpose that is not in hygienic unit-of-use packaging. As a result, we expect practices, patients, and parents will quickly appreciate how OrthoDots are packaged to meet this important need. When you stop and think about it, why has it taken so long for a product used for this purpose to be packaged in single-hygienic applications? It’s what we expect from bandages and all other medical devices.”

According to Dr. Silver, “Our research also indicates that younger Orthodontists and residents in orthodontic schools that are being trained in current healthcare standards are embracing the need for unit-of-use 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 packaging³. Additionally, 53% of the residents surveyed have never used dental wax for in-office application. And 64% indicated that the product should be in unit-of-use packaging in order to be used in the practice setting.”



Dental wax is not convenient or appropriate for use in the practice setting. OrthoDots CLEAR is the only product in unit-of-use packaging designed for chairside application.



Unit-of-use packaging for more convenient and hygienic patient use

Furthermore, virtually all products in the U.S. that are intended to go into the mouth and potentially ingested now have packaging with a tamper-evident feature. 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."⁴ The OrthoDots unit-of-use packaging provides this feature, whereas the commodity dental wax currently dispensed to patients offers absolutely no indication whether tampering may have occurred.

MANUFACTURING STANDARDS

In the U.S., the regulatory classification of traditional dental wax and OrthoDots currently do not require compliance with Current Good Manufacturing Practices (cGMP's)^{5,6}, which is an FDA requirement for most medical devices and all pharmaceutical products. Even so, according to Dr. Silver, "Knowing how these products are used by consumers, OrVance made it a priority to voluntarily comply with these manufacturing standards."

"Furthermore, OrthoDots CLEAR are manufactured in the U.S., and we source all materials and packaging components from within the U.S., where we can best monitor and control quality. By contrast, all the leading dental wax brands sold in the U.S. are made in China⁷."

INGREDIENTS

Because orthodontic protection products are placed in the mouth and occasionally ingested, it is also important to consider the ingredients used to make them.

According to Dr. Silver, "While the regulatory requirements of these medical devices do not currently require full disclosure of ingredients, manufacturers of course need to be diligent when considering the ingredients that can safely be ingested. Additionally, we believe ingredients should be disclosed. As 'wax' is likely to be comprised of many different ingredients, it's not clear to professionals and patients what is included in these products. We believe this is especially important given there are many different manufacturers of commodity dental wax from all over the world, under minimal requirements for quality manufacturing standards."

"OrthoDots CLEAR are made from just two high quality ingredients: medical grade silicone and PVP (polyvinylpyrrolidone). PVP has a long history of use in many oral care products, nutritional supplements, and pharmaceuticals with limited risks to patient safety. Both of these ingredients are made in the U.S. under Current Good Manufacturing Practices (cGMP's) and have a strong safety profile. While we are not required to disclose ingredients, we decided to provide this transparency."

LABELING AND PRODUCT TRACEABILITY

Please see the next page for a comparison between unlabeled dental wax and OrthoDots CLEAR, both as typically dispensed to patients by Orthodontists.



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.

According to Anne Armstrong, Director of Quality and Compliance for OrVance, “Our findings indicate that most dental wax sold to Orthodontists for dispensing to patients does not have lot codes and manufacturer or distributor identification on the package that is given to the patient. While regulations may vary by country, we concluded that a product used for this purpose should offer the end consumer traceability in case there is ever a quality or safety issue.”

“What’s more, regulations in the EU do in fact require OrthoDots and dental wax to provide traceability⁸. The regulations further state that such information must appear on the packaging for each unit, or, if not practicable, on the packaging of multiple devices⁹. Given how these products are used, I think most would agree that they should offer traceability on each unit as virtually all other healthcare products provide. Leading retailers in the U.S. require labeling and traceability on each unit of dental wax sold to consumers. Likewise, we believe this same level of traceability should be provided on all products dispensed to patients. It is a regulatory requirement to do so in the EU if practicable; dental wax sold at retail stores are labeled with this information, indicating that it is practicable.”

REGULATORY COMPLIANCE

According to Andrea Cook, an orthodontic clinical consultant, “OrthoDots not only offers a better product to maximize patient satisfaction, but it also offers a better option for more convenient and hygienic use. The ProPack provides the only single-use application on the market and is fully compliant with CDC and FDA guidelines for products used on multiple patients in healthcare settings¹⁰.”

Dental wax and OrthoDots CLEAR are both regulated as a Class 1 medical device in the U.S. (Product Code EGD), Canada (Product Code 76EGD), and the EU^{4, 11-12}.

According to Ron Schutt, OrVance's President/CEO, "OrVance has invested substantially to research regulatory requirements and to ensure compliance with regulations in the United States, Canada, and the European Union. Raising the bar on quality, safety, and regulatory compliance has substantial upfront and variable costs, but it's the right thing to do. And because of the investments we've made in these areas, OrVance intends to continue to advocate for a more level playing field for the competitive products used for this purpose. This is especially critical as it relates to commodity manufacturers that are self-certifying for CE marking in the EU."

According to Dr. Silver, "We have also encountered manufacturers of unlabeled dental wax that claim their product is fully compliant in virtually all global markets. While our regulatory efforts at this time are limited to the United States, Canada, and the EU, we would caution our customers from assuming that the unlabeled dental wax they are distributing to Orthos around the world is fully compliant with local regulations in all countries. Additionally, it is also our opinion that current regulations in the EU do not indemnify distributors that are selling non-compliant medical devices — even if they are doing it unknowingly."

An important modification to the EU Medical Device Regulations (MDR) that will take effect in May 2020 is a change in the liability status of the Authorized Representative. This regulation states the following: "Where the manufacturer is not established in a Member State and has not complied with its labeling obligations, the Authorised Representative shall be legally liable for defective devices on the same basis, and jointly and severally with, the manufacturer."¹³

According to Elizabeth Rose, Senior Consultant of Medical Device Regulatory Affairs for the MAPI Group, "As a result of the new medical device regulations, the Authorized Representatives will have more of a hands-on requirement than previously, especially for self-certifying Class I devices. Due to the regulatory changes, the Authorized Representatives will be reviewing and making recommendations to ensure a product is in complete compliance with the MDR. Authorized Representatives will be highly scrutinizing technical files for CE marking because they will now be more accountable for any non-compliance issues found. We saw these new practices firsthand during the CE marking process for the OrthoDots CLEAR devices. OrVance's Authorized Representative conducted a thorough review and provided justified comments with recommendations to ensure compliance. In my professional career I have not seen an Authorized Representative provide such a comprehensive review of a Class I, non-sterile, non-measuring device to ensure the CE mark was being applied properly."

SUMMARY

The conclusion of this paper is that OrthoDots CLEAR provides many benefits over traditional dental wax when considering the important issues of quality, safety, and regulatory compliance for both in-office and take-home patient use. Please see the table below for a summary of our findings.

	OrthoDots® CLEAR	Commodity/ Unlabeled Dental Wax
Ingestible/possible to swallow?	YES, but sticks better than dental wax and does not crumble (over 30X more tear-resistant than dental wax)	YES, commonly known to crumble and/or fall off & be swallowed
Ingredients	Medical Grade Silicone, PVP	Unknown/Undisclosed
Product known to come in contact with bodily fluids (saliva & blood)?	YES, sharing prevented by unit-of-use packaging	YES, should never be shared
Hygienic, unit-of-use packaging for safe in-office and patient use?	YES	NO
Packaging offers Tamper Evident feature?	YES	NO
Manufactured under current Good Manufacturing Practices (cGMPs)?	YES (voluntarily comply)	Unknown (not required)
Place of manufacturing	U.S.A. (including all materials & components)	Various countries, most imported from China
Packaging provides labeling & lot codes for traceability in event of quality or safety issue?	YES	NO

Dr. Mart McClellan, orthodontist in Kenilworth, Illinois, former President of the Illinois Society of Orthodontists, and advisor to OrVance, added, “When I learned about the significant advancements in quality and safety OrthoDots provide over the common dental wax, my advice to OrVance has been to place more emphasis on these important features in their communications to our profession. My staff and patients love OrthoDots as a more effective solution to improve patient comfort and satisfaction with the orthodontic experience. But it is also clear that my patients and their parents are increasingly concerned about hygiene and the safety of products used over the course of their treatment. Because our profession must keep quality and the safety of our patients as the highest priority, I strongly support the findings in this white paper and believe that at a minimum, products used for orthodontic protection should be packaged in hygienic unit-of-use packaging like virtually all similar healthcare products.”

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13. Medical Device Directive 2017/745, Article 11 - Authorised Representative, paragraph 5.

AUTHOR BIOS

Michael E. Silver, PhD

Dr. Silver has a PhD in chemistry from Cornell University and is a professor emeritus at Hope College. Mike has over 30 years of experience in academia and working with industry to develop novel materials and intellectual property in the healthcare arena. Mike is also the principal inventor of OrthoDots, an inventor on numerous issued patents, and the co-author of the textbook Introductory Chemistry: Atoms First (Pearson, 5th edition). He currently leads product development, intellectual property, and technical affairs for OrVance LLC in Grand Rapids, Michigan.

Mart G. McClellan, DDS, MS

Dr. McClellan is a practicing orthodontist in Illinois, former President of the Illinois Society of Orthodontists, and on the advisory board of OrVance LLC. Mart received his dental degree from Northwestern University and did his orthodontic residency at the University of Michigan. He is also a writer and national lecturer at several top universities in the mid-west. Mart is also President of Macro Wealth Management, a Registered Investment Advisor (RIA), and is registered in multiple states in the areas of securities and insurance.

Anne Armstrong

Anne has over 25 years of experience in Quality Control/Assurance at the management level in both the manufacturing and retail sides of the business. Anne has designed several Quality Programs for GMP start-up operations and also has an extensive background conducting training & audits to ensure Quality/Compliance, and interpreting/following FDA regulations.

Ronald J. Schutt

Ron has over 25 years of experience in healthcare and previously served as vice president of consumer healthcare marketing at Perrigo Company (NYSE: PRGO), where he championed major healthcare initiatives and led several of the most successful product launches in the company's history. He is also the founder and principal of RJ Schutt & Associates and serves as the founding president/CEO for OrVance LLC in Grand Rapids, Michigan.