

OrthoDots® CLEAR

FREE Resident Product Program

Lunch & Learn Presentation

January, 2020

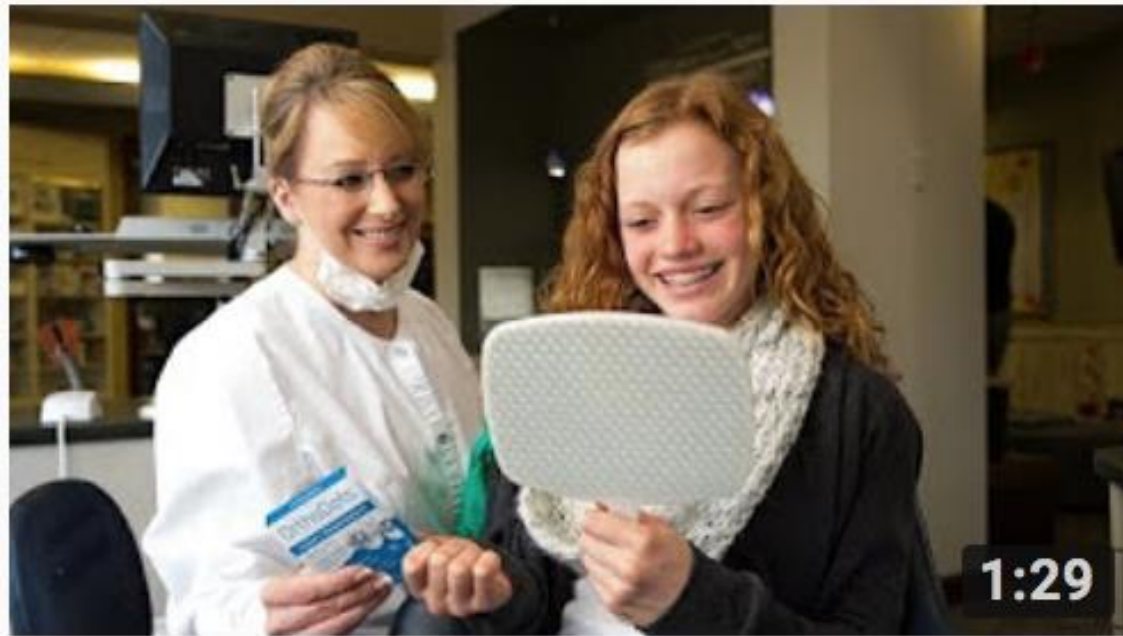


Resident Program Lunch & Learn

Key Topics

- 1) Performance & Aesthetic Benefits of OrthoDots® CLEAR vs. Conventional Dental Wax
- 2) The unmet need to address Pain & Abrasions for Patients in Clear Aligner Treatment
- 3) Minimal Quality, Safety, and Compliance requirements for products dispensed to your patients

OrthoDots® CLEAR Product Video



<https://www.youtube.com/watch?v=JK1ap4H82wg&feature=youtu.be>

Who is OrVance?

- Michigan-based Company Exclusively Focused on development of Proprietary Oral Care Products.
- Over 90% Owned by Orthodontists, Dentists, and it's Managing Partners.
- All Product Development and Manufacturing within U.S.
- Over 100 Years of Collective Experience in Developing, Branding, and Commercializing high-quality Consumer Healthcare Products.
- Partnerships in Place with growing list of Key Suppliers and Retailers.
- Recognized as “2019 Top 10 Dental Solutions Provider” by Med Tech Outlook.
- Bios of Leadership Team in Appendix.

OrVance® Named Top 10 Dental Solutions Provider

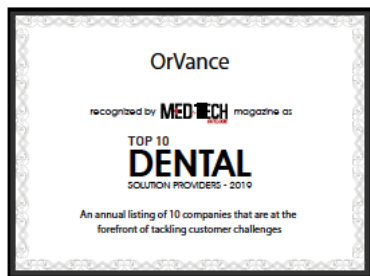
DENTAL SPECIAL

MEDICALTECHOUTLOOK.COM

MED TECH OUTLOOK

APRIL - 2019

TOP 10 DENTAL SOLUTION PROVIDERS - 2019



COMPANY:

OrVance

WEBSITE:

orvance.com

KEY PERSON:

Ron Schutt
CEO & Business Development

DESCRIPTION:

Delivers innovative oral care solutions and technology, offering better protection against abrasions caused by orthodontic treatment

Like any other vertical of the medical world, the field of Dentistry has slowly begun to reap the benefits of adopting digital technologies in an attempt to make dental procedures effective, non-invasive, and desirable. While "smart" bluetooth-enabled toothbrushes have already revolutionized the oral-hygiene market with its capabilities to track patients' brushing habits and keep their doctors informed in real-time through a mobile application, many other technical innovations are surfacing—poised to redefine the world of dentistry and how oral health is perceived.

For instance, dentists have been successful in replacing the good-old manually-made dentures with precision-fitted digital dentures made using advanced software in a fraction of the time and without any of the hassle. Intra-Oral cameras are being implemented by doctors to address one of the biggest pain-points that patients face during a surgery—having to sit in the dentist's chair for hours with their mouths open wide. With this technology, doctors can look inside the patients' mouth using a dental mirror with a camera embedded in it and observe the images through a laptop or a PC. Furthermore on making procedures hassle-free, the concept of teledentistry addresses yet another hurdle patients face—making it to their appointments. This technology also enables doctors to capture images, take notes, diagnose, and share the data with other dentists if need be. Consultation also becomes easier as it can be conducted through messaging or even video calling.

Today, oral care specialists and technicians believe that digitalization will not only help treat patients better but will also play a huge role in education and research. Dental institutes have adopted augmented reality to demonstrate techniques on dental models and allow the students to practice without harming an actual patient.

To give dental care leaders a glimpse of the latest-and-great technologies and solution providers in the market, our distinguished selection panel, comprising CEOs, CIOs, VCs, industry analysts and the editorial board of Healthcare Tech Outlook have narrowed down the top ten dental solution providers that exhibit competence in delivering dental care solutions.

We present to you Healthcare Tech Outlook's "Top 10 Dental Solution Providers - 2019."

OrVance

OrthoDots® CLEAR: Innovative and Compliant Alternative to Dental Wax

A source of wider smiles among patients and oral care practices is OrVance LLC, a developer of proprietary orthodontic products committed to delivering world-class innovation in orthodontics and dentistry. The company's flagship product focuses on providing a radical alternative to generic dental wax. Being the only broadly available product in the market dispensed by orthodontists for abrasions caused from orthodontic treatment, generic dental wax has stayed in the market without innovation for more than five decades. "Moreover, aside from being obsolete in performance and aesthetics, we believe generic dental wax has become more of a liability to the orthodontic profession since it lacks universally accepted quality and safety features that have been in place for more than 25 years," says Ron Schutt, the CEO of OrVance LLC. The common unlabeled dental wax is also noncompliant with current and upcoming regulations in the EU. On the other hand, OrVance's flagship product, OrthoDots CLEAR delivers on all the essential quality and regulatory requirements that generic dental wax does not—hygienic unit-of-use packaging, tamper-evident packaging, proper labeling for product traceability, and disclosure of ingredients. In terms of regulatory compliance, OrthoDots is the world's first globally compliant orthodontic wax that is fully compliant for sales in the U.S., the European Union, and 26 other countries.

Traditional dental wax requires the patient to tear off a pea-sized piece of "wax" from a bulk piece, which is not hygienic or appropriate for in-office application. The wax being opaque appears unattractive. Without adhesive, traditional wax typically crumbles and is occasionally swallowed and ingested. This necessitates quality and safety controls in terms of the ingredients used along with appropriate manufacturing, packaging, and labeling. In contrast, patients and orthodontists can safely and conveniently use OrthoDots with their hygienic single-use packaging. The product's package insert conveys universally comprehensible instructions for use, and their website displays product information in 33 different languages including all languages across the EU. OrthoDots are manufactured in the U.S. sourcing all materials from within the country to best control quality. The product's two ingredients—medical grade silicone and polyvinylpyrrolidone (PVP) are made in the U.S. following Current Good Manufacturing Practices (CGMPs) ensuring a strong safety profile. However, generic dental wax is made by many different manufacturers and most of the U.S. retail brands are made in China. Furthermore, with its moisture-activated adhesive, OrthoDots sticks to orthodontic

MED TECH
TOP 10
DENTAL
SOLUTION PROVIDERS - 2019



Ron Schutt

appliances including clear aligner trays for a prolonged duration and is non-toxic and latex-free. OrthoDots exhibits superior performance being 30x more tear-resistant, 17x more transparent and 20x more pliable than dental wax.

According to the preliminary results of OrVance's recent survey of U.S. orthodontic residents regarding products used for the treatment of pain and irritation caused by orthodontic appliances, 100 percent residents agree that "mitigation of pain from irritation is an important part of orthodontic treatment." Majority of the residents are against using generic dental wax without the required safety and quality features. Illustrating OrVance's noteworthy impact on orthodontics, over 80 percent of the residents express appreciation for the features of OrthoDots and intend to incorporate it into their practice.

In terms of competition, "OrVance is working with and not against leading suppliers and stakeholders in the orthodontic industry," states Schutt. The company is partnering with leading suppliers globally to immediately bring them into compliance with current healthcare standards and regulations. OrVance is simultaneously encouraging practices to promptly stop dispensing commodity dental wax to their patients and return it to their suppliers. "With our partners, our goal is to replace all noncompliant wax in the orthodontic industry by early 2020 before the new MDR goes into effect."

OrVance is also turning their attention towards the U.S. brick and mortar retail channel for growth. "We also want to leverage OrthoDots and following products to enhance the orthodontic profession in the eyes of the consumer," concludes Schutt. ■

Why should Orthodontists care about solutions for Pain & Abrasions?

- Pain, Abrasions, and Bleeding affect virtually ALL patients in treatment (including patients in the growing clear aligner segment)
- Pain from Orthodontic treatment indexes high relative to other sources of pain
- In the Orthodontic Profession, Pain is known to be a leading cause for:
 - Resistance to treatment
 - Patient complaints
 - Emergency/unscheduled Visits
- 100% of Ortho Residents agree that “mitigation of pain from irritation is an important part of orthodontic treatment”*

* Source: *OrVance Survey to Orthodontic Residents in the U.S., March 2019*

The Only Broadly Available Solution has been Conventional Dental Wax

- Highly Commoditized – All Leading Retail Brands are imported from China.
- Dental Wax is Not Effective - Biggest Complaints: Doesn't stick or stay in place, crumbles, opaque, doesn't work with Aligner Trays, not hygienic...
- Conventional Dental Wax in the Pro Channel is NOT compliant with current Healthcare Product Quality/Safety Standards.
- Commonly Dispensed/Unlabeled Dental Wax now proven to be in violation of medical device regulations in both the U.S. and EU*.



As sold at retail in the U.S. (all above Made in China)



As typically dispensed to patients globally (violates quality/safety standards and medical device regulations in both the U.S. & EU)

OrthoDots® CLEAR Outperforms Conventional Wax on ALL Consumer Attributes



| Performance and Aesthetic Features | OrthoDots® CLEAR | Conventional Dental Wax |
|--|------------------|-------------------------|
| Sticks and stays the best (with proprietary adhesive) | ✓ | ✗ |
| Clear (17X more transparent than dental wax) | ✓ | ✗ |
| 20X more pliable than dental wax (easier to mold) | ✓ | ✗ |
| Best for use on all appliances including clear aligner trays | ✓ | ✗ |

Patients LOVE OrthoDots® CLEAR ...

- ★★★★★ **Thank God!** 41 Yrs old with braces for less than a week. I was going to have them removed... Then while doing research I found these OrthoDots. Crisis diverted
- ★★★★★ This stuff is **amazing** and does exactly what it says... **I'm telling my dentist, ortho, and dental surgeon about this product.**
- ★★★★★ **These are life changing!** The water activated adhesion make these easy to use and effective. They last all day and easier to apply than those long strings of wax
- ★★★★★ **OrthoDots saved me from giving up my Invisalign treatments!** If your Invisalign trays are cutting into the soft tissue of your mouth you need these!!!

Key Metrics used by OrVance in Developing OrthoDots® CLEAR

OrthoDots® CLEAR vs. Leading Dental Wax Products (X = times more)

| | GUM® Ortho Wax | Dentek® Wax for Braces | Leading Generic Wax (Ortho Channel) |
|--|----------------|------------------------|-------------------------------------|
| Pliability: Softer and more moldable(1) | 20.9X | n/a | 18.8X |
| Tear Resistance: Stays intact and likelihood of removing in one piece(2) | 82.7X | n/a | 33.1X |
| Light Transmittance: Transparency(3) | 30.1X | 16.8X | 18.9X |

And Coming Soon: New & Improved Adhesive (will stick and stay even better)!

(1,2) The Test Method employed was ASTM D412C

(3) Testing performed using a dual-beam Hitachi U-2910 UV-Vis spectrometer

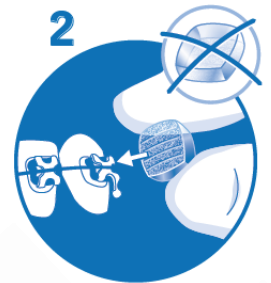
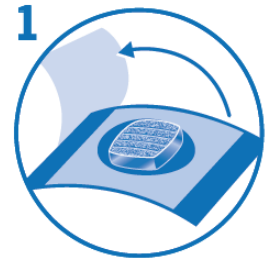
Instructions for Use

(provided in illustration and in 33 languages)

1. Open the individual application.
2. Only the coated side that is visible through the package has adhesive.
3. Press and pinch the adhesive side to the appliance that is causing pain for 3-5 seconds.

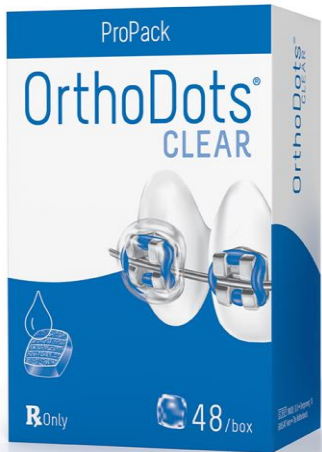
Common Questions:

- Can you eat/drink with OrthoDots? YES
- How long do they last? OrthoDots can stay on for up to 48 hours; however, we recommend removal before brushing.

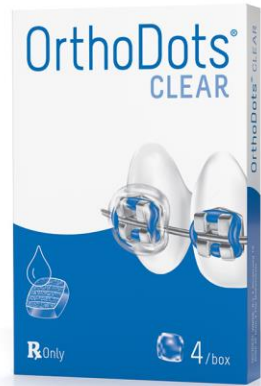


OrthoDots® CLEAR Offering by Channel

Professional Channel (Rx Only)



ProPack (48's) –
for in-office use



Sample Patient
Packs (4's)

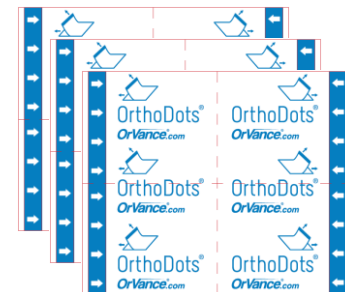
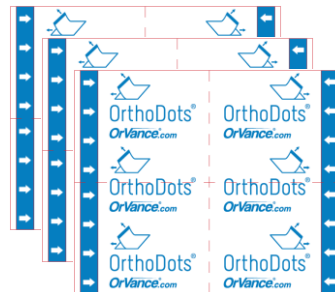
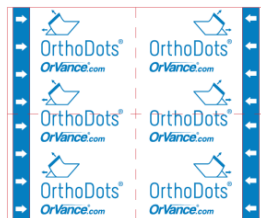
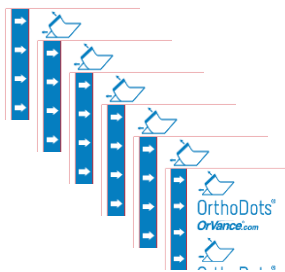


Patient Packs
(12's)

Retail Channel



Consumer/Retail
(12's)



- Rx packaging globally compliant with pictorial instructions

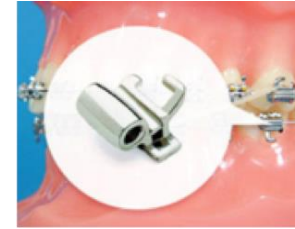
***OrthoDots® CLEAR is designed to work best on
ALL Appliances including Clear Aligner Trays
(not just for “Braces” like Conventional Dental Wax)***



Lingual (hidden) Braces



Expanders



Buccal Tubes



TAD (Temporary Anchorage Device)



Herbst Appliance

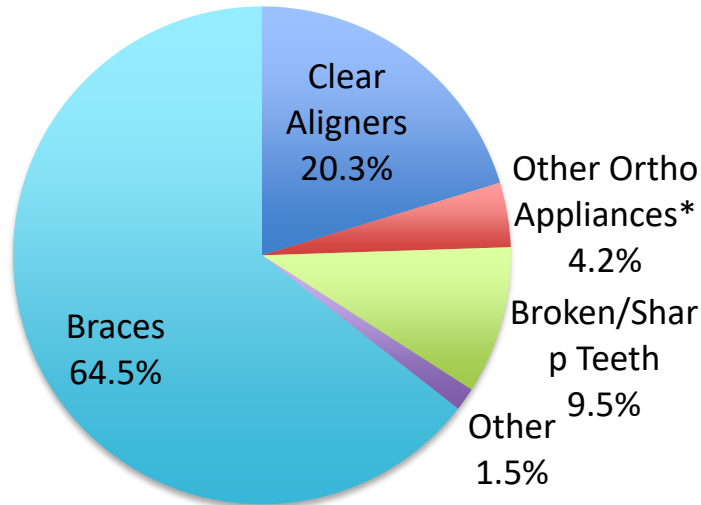


Clear Aligner Trays

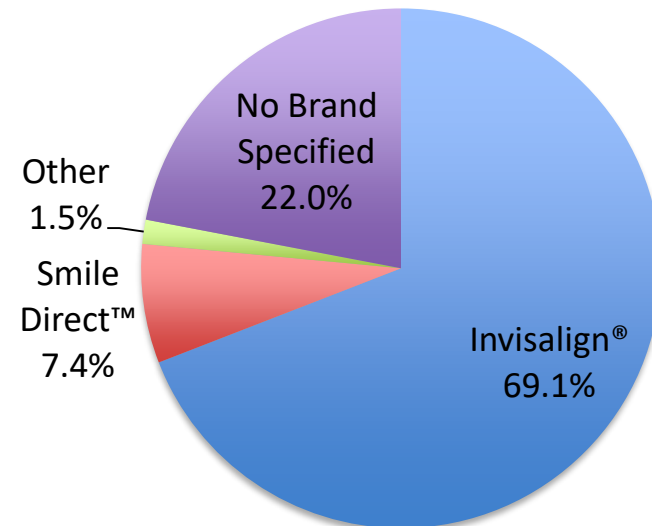
***“Great product. Useful not just on brackets but also on irritating TAD heads!”
Dr. Sabastian Baumgaertel, National KOL/Speaker, Clinical Associate Professor at Case Western University***

NEW Patient Research on the Use of Conventional Dental Wax

Reason for Dental Wax Usage



Clear Aligner Brands Named



- Over 20% usage is for Clear Aligners even though conventional wax:
 - Is not effective and not intended or marketed for use with Aligner Trays
 - Is not commonly dispensed to patients in clear aligner treatment
- Consumer data shows that a solution for Clear Aligners has been an unmet need AND essential to maximize patient compliance and satisfaction

*What are Patients Saying About Pain and Abrasions from Clear Aligner Trays?**

- “...every week I replace my old tray and put a new one in and every week there's a sharp edge somewhere that cuts my mouth or tongue.”
- “I just got aligners from Smile Direct Club and after three days, my mouth was in so much pain. I tried filing the aligners and it didn't not work...”
- “I don't know if this is true for braces, but wax is horrible for invisalign...”
- “I discovered the hard way that my tongue was getting cut up from the edge of the trays along the inside of my front teeth. Googling the problem led me to dental wax...”
- “Day 1 of Invisalign and my mouth was KILLING ME.. I bought some wax from a pharmacy...”
- “OrthoDots saved me from giving up my Invisalign treatments!”

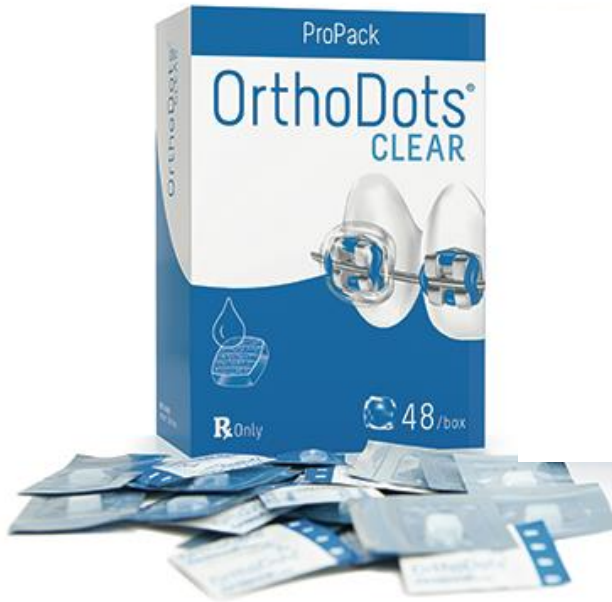
OrthoDots[®] CLEAR is the FIRST/ONLY Solution for Clear Aligner Trays!

- The ONLY solution that will stick to wet aligner tray edges AND gum tissue.
- Will accelerate the obsolescence of Conventional Dental Wax: Is not effective for patients with Clear Aligners AND is not aesthetically acceptable.



- Protection from Irritating Edges
- FIRST/ONLY product that adheres to wet Aligner edges and gum tissue
- Transparency (a MUST for clear aligner treatment)

OrthoDots® CLEAR ProPack



- ✓ Unmet Need - the ONLY product designed for fast/hygienic in-office application.
- ✓ Application time of only 10 seconds!



*81% of U.S. Ortho Residents surveyed say that Unit-of-Use packaging is important for chairside application**

OrthoDots® CLEAR for your Patients at Retail and Online

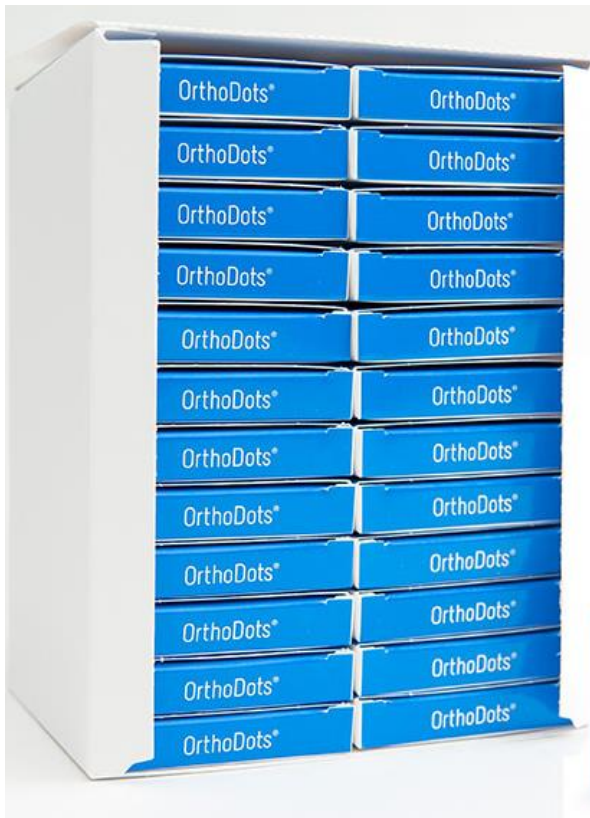
- The most widely available dental wax alternative for your patients.
- First Ortho Wax with claim/benefit ***“Relieves Pain”*** from orthodontic appliances.
- New high impact graphics.



For Your Patients:



Patient Packs come with CVS Coupons for ongoing patient needs...



\$1.00 OFF ORTHODOTS® CLEAR

At your participating
CVS pharmacy®

OrthoDots®
BRAND ORTHODONTIC PROTECTION
CLEAR
Believes Pain and Irritation from orthodontic appliances
MOISTURE-ACTIVATED ADHESIVE
Stays on longer than dental wax
12 hygiene applications

The New Standard for Orthodontic Wax
The newest technology for patient comfort and satisfaction

- ✓ Moisture-activated adhesive
- ✓ Sticks better and stays longer
- ✓ Works on all appliances
- ✓ Transparent medical-grade silicone
- ✓ Hygienic single-use packaging

MANUFACTURER'S COUPON
EXPIRES 12/31/2020

Also available for purchase at **CVS.com** and **amazon**

CONSUMER AND RETAILER: OrVance will redeem one coupon per purchase in accordance with our coupon redemption policy. Copies available upon request. Coupon may not be reproduced or transferred. MAIL COUPONS TO: ORVA-UNIVERSAL, P.O. Box 222510 Hollywood, FL 33022-2510 Cash Value .001e. Void where taxed or restricted. Void if transferred or copied.

0040232-021801

CPN021801

- *Tear-pad of 25 in every case of patient packs*
- *To pass along value to patients for ongoing needs*
- *Eliminates emergency patient visits and minimizes product costs to the practice*

OrthoDots® CLEAR now the #1 Brand in U.S. Orthodontic Resident Programs

- Since Launching Free Product Program in June of 2018, already Converted 65% of the 69 Resident Programs in the U.S.*
- Survey of Residents indicates that OrthoDots® CLEAR is poised to totally displace Conventional Dental Wax**:
 - The majority of residents surveyed said it is no longer appropriate to dispense dental wax to patients with none of the following quality and safety features: unit-of-use hygienic packaging, tamper-evident packaging, compliant labeling/product traceability, and disclosure of ingredients.
 - None of the residents surveyed could name another healthcare product, other than dental wax, that is lacking all of the aforementioned features.
 - 88% of residents say they intend to use OrthoDots® CLEAR as the replacement for commodity dental wax in their practice.

* OrVance Launches Free Product Program to all Orthodontic Resident Programs in North America, 6/19/18

** Survey Confirms Traditional Dental Wax is Obsolete and will be Discontinued by the Orthodontic Profession, 3/25/2019



The NEW Global Standard...

(product information in 33 Languages!)

orthodots.com



- English
- العربية (Arabic)
- Български (Bulgarian)
- 简体中文 (Chinese (Simplified))
- Hrvatski (Croatian)
- Čeština (Czech)
- Dansk (Danish)
- Nederlands (Dutch)
- Eesti (Estonian)
- Suomi (Finnish)
- Français (French)
- Deutsch (German)
- Ελληνικά (Greek)
- עברית (Hebrew)
- हिन्दी (Hindi)
- Magyar (Hungarian)
- bahasa Indonesia (Indonesian)
- Italiano (Italian)
- 日本語 (Japanese)
- 한국어 (Korean)
- Latviešu (Latvian)
- Lietuvos (Lithuanian)
- Lëtzebuergesch (Luxembourgish)
- polski (Polish)
- Português (Portuguese (Portugal))
- Português (Portuguese (Brazil))
- Română (Romanian)
- Русский (Russian)
- Slovenčina (Slovak)
- Español (Spanish)
- Svenska (Swedish)
- ไทย (Thai)
- Tiếng Việt (Vietnamese)



Globally compliant labeling with Insert in 33 languages (included in all Rx packaging)



Industry Education & Promotion by OrVance

Online Video Placements

orthotown
e-newsletter

January 26, 2018

Introducing OrthoDots® CLEAR
OrVance has launched OrthoDots Clear, a transparent version of the company's flagship product, OrthoDots. OrthoDots was launched in 2015 and designed to be a more effective solution than traditional dental wax. The product combines a proprietary moisture-activated adhesive with a medical grade silicone for a longer lasting and more comfortable solution. [Learn More...](#)

Connect with Orthotown

Connect with Howard

<https://www.youtube.com/watch?v=EnjNL-tgEDY>

Full Page Ads

The **NEW** Global Standard for Ortho Wax Is Here!

NEW packaging offers the world's first ortho wax compliant for global sales (including product insert in 33 languages)

Already adopted by **over 50% of ortho resident programs** in North America

| Features & Benefits | OrthoDots® CLEAR | Traditional Dental Wax |
|---|------------------|------------------------|
| Formulated by both orthodontists and patients | ✓ | ✗ |
| Structure of ingredients | ✓ | ✗ |
| Hygienic single use packaging for safe in-office and patient use | ✓ | ✗ |
| Temper-resistant packaging | ✓ | ✗ |
| Labeling with product translucency | ✓ | ✗ |
| Compliant with regulatory requirements in both America and the EU | ✓ | ✗ |

Now available at leading suppliers & retailers. Learn where to buy at orvance.com

Contact us at service@orvance.com for your FREE ProPack.

White Papers

OrthoDots® CLEAR
Raising the Bar in Quality, Safety, and Compliance

A White Paper By:
Dr. Michael Silver (PhD Chemistry) | Dr. Mark McCollan (DDS, MS) | Anne Armstrong | Ron Schutt

CONFIDENTIAL - Pre-Release Copy
May 2018

November 2017

Ortho Sales Sheets

Introducing **OrthoDots® CLEAR**, the newest technology for patient comfort and satisfaction.

OrthoDots® CLEAR are made from a medical-grade silicone that is preferred over dental wax because it performs better, is transparent, and provides hygienic packaging for safe patient and in-office use.

ProPack (48's) **Patient Packs (12's)**

Medical-grade silicone - Safe to use while eating and drinking - Non-toxic if swallowed and latex-free

| Features & Benefits | OrthoDots® CLEAR | Traditional Dental Wax |
|--|------------------|------------------------|
| Safe to use while eating and drinking | ✓ | ✗ |
| Non-toxic if swallowed and latex-free | ✓ | ✗ |
| Hygienic single use packaging for safe in-office and patient use | ✓ | ✗ |
| Temper-resistant packaging | ✓ | ✗ |
| Labeling with product translucency | ✓ | ✗ |
| Compliant for global sales | ✓ | ✗ |

- Open the individual application
- Use the control side that is visible through the packaging film
- Press and push any free side into the application to locking position.

Now available from major suppliers and retailers — learn where to buy at orvance.com.

Press Releases

ORTHODONTIC NEWS

OrVance White Paper Looks at OrthoDots CLEAR Dental Wax Quality, Safety, and Compliance

The new white paper, which looks at OrVance's OrthoDots CLEAR dental wax product, concludes that traditional dental wax is no longer up to the standards of other consumer healthcare products.

FREE Resident Program

OrVance
A HENRY SCHEIN COMPANY

GORP Exclusive

We are pleased to announce a **FREE** product program with the launch of our new and improved OrthoDots. The next generation of OrthoDots provide all the same benefits PLUS it works even better and provides a new easy open packaging feature.

OrthoDots combine a medical grade silicone with a proprietary Moisture Activated Technology to produce an easier and more effective application that stays on much longer than competitive products. The silicone material used in OrthoDots is over 30 times more pliable than the leading brand of dental wax, preventing the crumbling associated with traditional wax products.

OrthoDots also offer unsurpassed hygienic benefits, providing two packaging options specifically designed to comply with FDA guidelines for medical devices that are likely to be used across multiple patients. The ProPack offers 48 individually packaged applications to enable fast and hygienic use on multiple patients. The Patient Pack option provides 4 individually packaged applications for more hygienic and convenient patient use.

Contact Us

To take advantage of this FREE Product Program, simply contact us at service@orvance.com and inform us of the number of residents in your program, the primary contact information, and shipping address.

Available for your practice Available for your patients

HENRY SCHEIN PATTERSON DENTAL **CVSHealth**
OrVance.com **amazon.com**

Email & Social Media

Ron Schutt commented on this

Ron Schutt
President/CEO at OrVance
7mo

Checkout this video on our newest product for Orthodontic treatment - invented and made right here in West Michigan!

Safe to use while eating and drinking

OrthoDots® CLEAR
youtube.com

16 Likes · 4 Comments

Like Comment Share

Tradeshows/Conferences

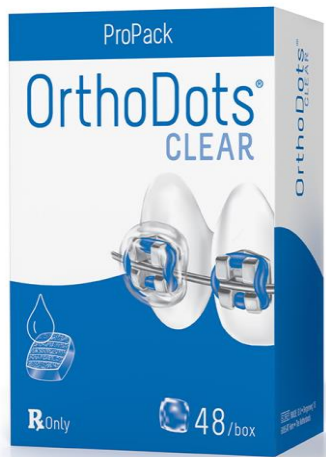
AAO American Association of Orthodontists®
My Life. My Smile. My Orthodontist.®

30th ANNIVERSARY
2018
GORP
ANN ARBOR, MI

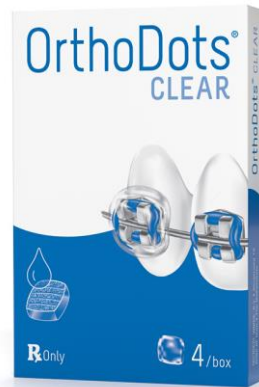
IDS
2019

Pricing (Ortho & Retail Channels)

Professional Channel*



ProPack (48's)
MSRP = \$9.99



Patient Packs (4's)
Case of 24 = \$23.76
(\$0.99 each)



Patient Packs (12's)
Case of 24 = \$59.76
(\$2.49 each)

Retail Channel**



Consumer/Retail (12's)
MSRP/CVS = \$5.99

* FREE to Resident Programs in North America

**Pricing on Amazon is currently \$13.99 for 2 Patient Packs (12's)

Growing Distribution Through Leading U.S. and Global Supply Sources

For Your Practice:



For Your Patients:



FREE to Orthodontic Resident Programs

OrVance®

OrVance®

Conventional Wax is the Last Commonly Dispensed Product WITHOUT any of the Following Quality, Safety, and Compliance Features¹⁻³



| Quality, Safety, and Compliance Features | OrthoDots® CLEAR | Conventional Dental Wax |
|---|------------------|-------------------------|
| Hygienic unit-of-use packaging for safe patient and in-office use | ✓ | ✗ |
| Tamper-evident packaging | ✓ | ✗ |
| Labeling with product traceability | ✓ | ✗ |
| Disclosure of ingredients | ✓ | ✗ |
| Compliant with FDA medical device regulations ¹⁻² | ✓ | ✗ |

Made in U.S.A. | Patents Pending

1. OrthoDots® CLEAR: Raising the Bar in Quality, Safety, and Compliance, May 2018
2. Research Concludes Dental Wax Dispensed to Patients Violates Regulatory Requirements in the U.S. and European Union”, December 2019
3. OrVance Survey to Orthodontic Residents in the U.S., March 2019

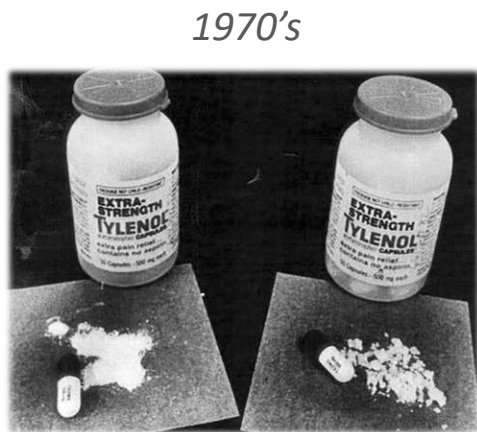
What is Tamper-Evident Packaging and why is it important?

Background:

- In September of 1982, there were 7 murders from the Tylenol® tampering incident (with cyanide) - the first death was a 12 year old girl from a Chicago suburb.
- In the following year, while Johnson & Johnson's Tylenol sales plummeted, they invested \$100 million (over \$250 million in today's dollars) to develop packaging that would better prevent tampering.
- J&J's leadership gave birth to the implementation of tamper-evident packaging for all foods and healthcare products.
- Their proactive handling of this tragedy became a classic case study in business schools across the nation.

What is Tamper-Evident Packaging and why is it important? (Cont.)

- FDA defines a tamper-evident package as “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.”
- Today ALL Consumer Products have a Tamper-Evident Feature:



OrthoDots® CLEAR finally Provides Patients an Ortho Wax with a Tamper-Evident Feature!

Being the most commonly dispensed product by orthodontists with 75% of patients being children, who can argue that dental wax does not need a tamper-evident feature?

Commodity Dental Wax



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)

Product Traceability: a Universally Accepted Quality & Safety Standard for Decades

(Why is it important?)



SPONSORED

Post-romaine lettuce outbreaks: Lessons in traceability

- Romaine lettuce crisis teaches the risks to consumers and industry without traceability*
- 197 across 35 States became ill, 5 people died
- Contamination was thought to be from AZ but source of contamination was never identified
- Damaged consumer confidence and farmers globally - sales fell by 45% and prices were down by 60%*



Most commonly dispensed dental wax with no labeling



OrthoDots® CLEAR provides required labeling for product traceability

Dental Wax may be the very last product of its type in healthcare that offers no product traceability.

*Dental Wax without Traceability Violates Medical Device Regulations in both the U.S. and European Union**



- FDA Regulations requires Name and Place of Business of the Manufacturer, Packer or Distributor.
- EU Regulations requires Name & Address of Manufacturer, Name & Location of Authorized Representative (if imported) and lot number.

Dental Wax without traceability blatantly violates universally accepted regulations that have been in place for over 25 years!

Risk Factors related to Patient Safety & FDA Compliance:

- Dental Wax is a High Volume Product (dispensed to virtually ALL patients in orthodontic treatment)
- 75% of Patients are Children
- Many different manufactures, most in China, and ingredients are undisclosed in most cases
- Absence of traceability compromises FDA Adverse Event Reporting Requirements

Editorial from Leading Orthodontic Trade Publication



PRODUCTS

Should a Modern Orthodontic Practice Still Dispense Dental Wax?

Published on May 30, 2019

By Alison Werner

What product do patients most connect to when they are in braces?

What product do you most commonly dispense to your patients?

More than likely both you and your patients will answer: dental wax.

So how is it that this one product that is a key component of orthodontic treatment often falls short when it comes to quality and safety standards?

The dental wax dispensed by orthodontic practices is the last commonly dispensed healthcare product that does not feature hygienic unit-of-use packaging, tamper evident packaging, labeling with product traceability, or ingredient disclosure. The product and its packaging have remained largely unchanged for decades. But now, a new product has entered the orthodontic space to challenge dental wax's prominence as the go to product for patients seeking relief from pain and...

Full article can be read at:

<http://www.orthodonticproductsonline.com/2019/05/orthodontic-practice-dispense-dental-wax-orthodots/>

New Evidence on the Noncompliance of Conventional Dental Wax

RESEARCH CONCLUDES DENTAL WAX DISPENSED TO PATIENTS VIOLATES REGULATORY REQUIREMENTS IN THE U.S. AND EUROPEAN UNION



A Whitepaper By:

Michael Silver, PhD | H. Carl Jenkins, JD | Mart McClellan DDS, MS | Anne Armstrong | Ron Schutt

December 2019

- NEW Whitepaper with evidence of noncompliance in BOTH the U.S. and European Union (EU).
- Noncompliance with the FD&C Act confirmed directly with the FDA's Division of Dental Devices.
- Addresses implications to patient safety and Adverse Event Reporting.
- Co-authored by regulatory law firm and 3rd Party experts.
- Included review and input from U.S. Orthodontic Resident Programs and Key Opinion Leaders.

Full Whitepaper @:

<https://orvance.com/orthodontic-product-white-papers/>

The Overall Challenge AND Opportunity...

Summed up in a quote from one Orthodontist (over 50):

“...sounds interesting but the dental wax that we have dispensed for decades is available at basically every drugstore and apparently no regulatory body cares.”

The Opportunity:

- We’ve NEVER heard such a comment from Orthodontic Residents, Faculty, or Orthodontists under 40 years old.
- Industry Suppliers agree that unlabeled dental wax is noncompliant: only indifference, need for education, and enforcement remains...
- OrthoDots® CLEAR is the ONLY wax alternative with a strong retail presence for easy patient access (critical for acceptance by orthodontists)

Next Steps & Recommendations for your Resident Program

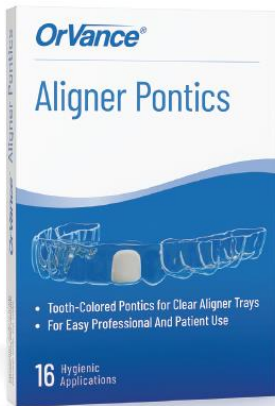
- Adopt OrthoDots® CLEAR as the new standard of care for your Resident Program.
- Immediately Ban noncompliant dental wax from your program (*IF any conventional dental wax is still dispensed, ensure that it meets the minimal quality, safety, and regulatory requirements covered in this whitepaper**).
- OrVance will provide your program Free OrthoDots® CLEAR (For each Resident OrVance will provide: one ProPack/48's & one Case of 24 Patient Packs with CVS Coupons).
- Contact us at service@orvance.com for replenishment needs.
- We will follow up with a survey to learn how we can further improve OrthoDots® and to ensure we best support the clinical and patient needs of your Resident Program.



Newest Product from OrVance:

Introducing OrVance® Aligner Pontics

OrVance® Aligner Pontics are specifically designed to fill the space of missing (or partially missing) teeth in clear aligner trays and retainers during orthodontic treatment and dental procedures.



Sold to Practices in packs of six

Maximizes patient satisfaction and convenience:

- Tooth-colored (most common A2 shade).
- Easy for patient to mold, wear, and remove.
- Application tool included in each pack.
- Individual hygienic packaging for safe in-office and patient use.
- Made from medical-grade silicone and food-safe colorants.

Ideal for the Practice:

- Designed for patient use vs. in-office application.
- Eliminates the time and cost required to customize trays with fabricated pontics.
- Also designed for use with clear retainers during implant procedures.



Also works with chipped/broken teeth

- Designed for easy patient use – eliminates time & costs to customize trays with fabricated pontics.
- Same hygienic unit-of-use packaging configuration as OrthoDots® CLEAR.
- Will accelerate OrthoDots® CLEAR acceptance as the ONLY solution for Clear Aligner Trays.

Made in U.S.A. | Patent Pending

Thank You!

Questions or Feedback?

OrVance Leadership Team Bios

Ron Schutt, President/CEO

Ron has over 25 years of experience in consumer healthcare and previously served as vice president of consumer healthcare marketing at Perrigo Company (NYSE: PRGO), where he led product development, marketing, and major healthcare initiatives that resulted in several of the most successful product launches in the company's history. He is also the founder and principal of RJ Schutt & Associates.

Mike Silver PhD, Director of R&D and Technical Affairs

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® and author of numerous issued patents.

Paul Terranova, VP of Sales & Marketing

Paul has 30 years of experience in the consumer packaged goods industry and spent the last 22 years in various sales and marketing positions at Perrigo, a leading consumer healthcare company. Paul's experience in collaborating with customers to achieve mutual success is his passion.

Mike Smurr, Director of Professional Channel Sales & Marketing

Mike has spent over 35 years in the dental market with time on both the manufacturing and distribution sides of the business. He recently retired from Patterson Dental (NASDAQ: PDCO) where he was the Director of Marketing, Merchandise, responsible for manufacturer relations and the sales & marketing of all merchandise. Mike is also the Founder and Principal of MTS Partners, LLC.

Mark Metzler, Director of Operations and Customer Service

Mark has over 30 years experience working with leading Global Consumer Health Care Companies. Previously served over 20 years at Perrigo Company (NYSE: PRGO) responsible for directing Export Business Development, Sales, and Marketing for the International Consumer Healthcare Division.

Eric D. Hannapel, DDS, MS, PC, Co-Founder & Innovation Advisor

Dr. Hannapel has been a practicing orthodontist since 1996 and received his dental degree and orthodontic residency from the University of Michigan. Eric also donates his time on the Cleft Palate Board of Specialists at Helen DeVos Children's Hospital in Grand Rapids, Michigan and provides treatment. He also teaches at the University of Michigan in the Orthodontics & Pediatric Dentistry department as an adjunct clinical assistant professor.

Endorsements

“We are pleased to award OrVance the Michigan State Trade Expansion Program (MI-STEP) grant to support their efforts in expanding their international sales for their innovative OrthoDots® CLEAR product. The MEDC grant for OrVance is specifically designed to help fund their efforts in expanding sales throughout the European Union. We are proud to have OrVance as an emerging company in the healthcare sector here in Michigan and we are committed to support their growth globally.”

Jeff Mason, CEO Michigan Economic Development Corporation (MEDC)

“The innovation OrthoDots® CLEAR brings to the global orthodontic industry is another example of how West Michigan serves as a such a great platform for innovation and manufacturing within the healthcare sector. We will continue to support OrVance in their efforts to improve the quality, safety, and performance of products for patients in orthodontic treatment.”

Birgit Klohs, President & CEO, The Right Place

“OrVance is a great example of an emerging specialty medical device company right here in Michigan that is bringing real innovation in patient care. Their flagship OrthoDots® CLEAR product delivers much needed advancements in the quality, safety, and efficacy to patients in orthodontic treatment.”

**Norman Beauchamp MD MHS, Dean College of Human Medicine
Michigan State University**

“Scrutiny of our profession is certain to increase if we continue to ignore the noncompliance and poor performance of the most commonly dispensed product in our profession. We need more urgency within our profession to address this patient need.

**Dr. Mart McClellan, Orthodontist, Author, Advisor to OrVance
Former President, Illinois Society of Orthodontists**

“OrthoDots® CLEAR not only performs and looks much better than generic wax, but it is the only ortho wax that meets current healthcare product quality standards. Now that we finally have a better solution that complies with today’s healthcare standards, we need all dental wax suppliers to our profession to address the inadequate quality of what they’re offering or get out of the ortho wax business.”

Scott Tyler DDS MS, Orthodontist and Advisor to OrVance, TDR Orthodontics

“OrthoDots not only offers a better product to maximize patient satisfaction, but it also offers a better option for more hygienic use. The OrthoDots® 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 settings.”

Andrea Cook, Orthodontic Clinical Consultant

“I have appreciated learning about OrthoDots® CLEAR and the noncompliance of generic wax as a case study in my MBA program. As someone that works in the medical device industry, OrthoDots® clearly addresses long overdue quality and safety needs for patients in orthodontic treatment.”

Yujing Xue, MBA Candidate, University of Chicago Booth School of Business

“We’re proud to have OrVance as one of our newest members. The needed innovation they bring to the orthodontic profession shows how the Grand Rapids area is such a vibrant place to develop and commercialize real solutions within healthcare.”

Rick Baker, President & CEO, Grand Rapids Chamber of Commerce