

## INDUSTRY FOCUS

ADVANCED MEDICAL TECHNOLOGIES

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## VITAL SIGNS

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## The Price of a Good Night's Sleep: Insights into the US Oral Appliance Market

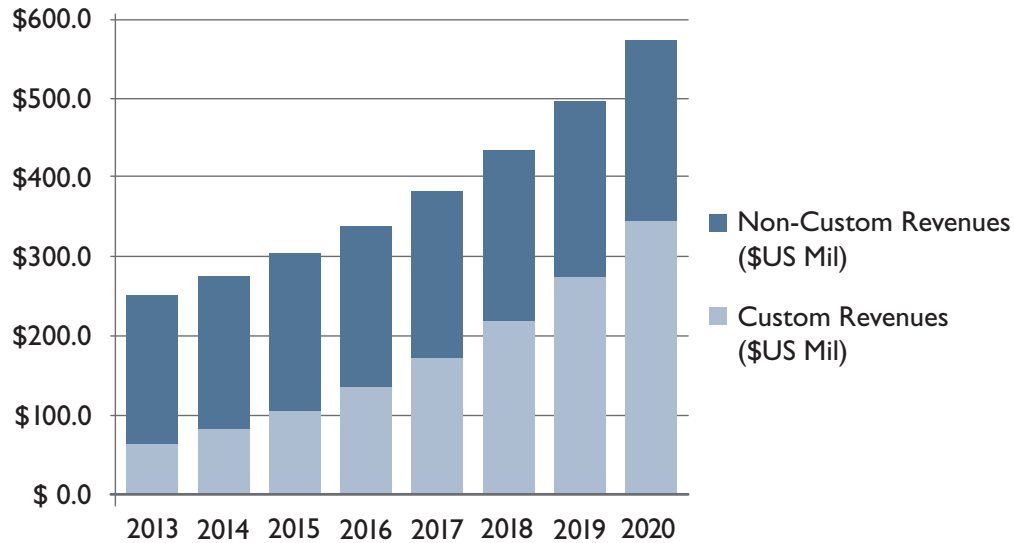
### *Treatments for Sleep Apnea*



Oral appliances (OAs) are devices that can be used in the treatment of sleep disorders, more specifically, sleep apnea. Sleep apnea is defined as the shallow or temporary interruption of breathing that can continually wake up individuals throughout the night. One of the most common symptoms individuals may experience is snoring. Due to the lack of sleep, individuals may have a constant feeling of fatigue during the day but have no memory of not sleeping well. According to the American Sleep Apnea Association,

about 22 million Americans suffer from sleep apnea, but a vast majority of individuals remain undiagnosed. Untreated sleep apnea can lead to various comorbidities such as stroke, high blood pressure and heart disease. To those who obtain a proper diagnosis, there are two main non-surgical treatment options: oral appliances or positive airway pressure (PAP). OA devices are similar to retainers or athletic mouthguards in the fact that they are all products worn within the mouth. OAs provide assistance with sleep apnea in a variety of ways, but the common objective is preventing airway obstruction. PAP, the most popular and recognizable method of treatment, is a machine and face mask ... combination most commonly worn over the nose and/or mouth. While both techniques have their benefits and drawbacks, OAs have been increasing in popularity as an alternative treatment method as they are less invasive and expensive. Frost & Sullivan anticipates that the United States (US) OA market will double by the year 2020, with custom appliances seeing five times the revenue increase during that period (Exhibit I).



**Exhibit I – US Market for Oral Appliances for Obstructive Sleep Apnea (2013-2020)**

#### ***Growing Interest in Oral Appliances***

The gold standard for sleep disorder product adoption relies heavily on the feasibility of device compliance, supporting evidence, and cost (Exhibit 2). A device is most effective in relieving sleep apnea if an individual is consistent in wearing it. Research supporting this states that mandibular advancement devices (a form of OA) had higher compliance rates than PAP because individuals reported wearing the device for longer periods of time throughout the night (A Randomized, Controlled Study of Mandibular Advancement Splint for Obstructive Sleep Apnea, American Journal of Respiratory and Critical Care Medicine, Vol. 163, May 2001, <http://www.ncbi.nlm.nih.gov/pubmed/11371418>). Compliance success could be attributed to OAs being quieter, more portable and comfortable as well as less expensive. This resonates with a significant portion of the population that refuses treatment due to the more disruptive nature of PAP on patients' lifestyles. However, due to the lack of physician and dentist training on the effectiveness of OA, they are not as well-known as PAP. The multi-billion dollar PAP industry is well-established with a commercial operation behind it, whereas OAs are still in the initial stages and considered more specialized. Due to the large difference in market size and maturity, there is also less evidence supporting OAs as a first-line treatment when compared to PAP. Only a select population will tolerate and consistently use PAP, and with increasing evidence, OAs could be positioned to consumers, clinicians and payors as a primary method of treatment for sleep apnea.

## Exhibit 2 – Drivers and Restraints in the US

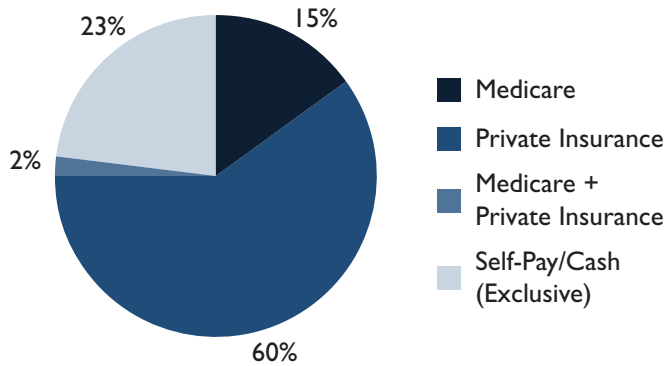
Drivers	Restraints
OAs are Already Established as Standard of Care over PAP in Parts of Europe, Demonstrating Feasibility of Transforming Care Practices in the United States	PAP Market Leaders Exert Very Strong Control Over US Sleep Market and Fight Against Greater Adoption of OAs, Which Could Threaten their Market
Growing Body of Evidence Supporting Use of OAs as Primary Treatment Alternative to PAP Thanks to Better Compliance	More Contraindications for OA Compared to PAP, Making it a More Selective Treatment
Strong Patient Preference for OA Compared to PAP	Requires Cooperation Between Sleep Physician and Dentist to be Most Effective, but Cultural, Educational and Economic Gaps Remain
OAs are More Cost-Effective than PAP, Encouraging More Payors to Reevaluate Adoption of the Therapy	Confusion Between Boil-and-Bite and Truly Custom-Fit Products Raises Physician Skepticism – 120+ Products in Market is Bewildering
New Diagnostic and Compliance Monitoring Technology for OAs Put it on an Even Playing Field with PAP for Demonstrating/Documenting Outcomes to Payors	High Price of Custom OAs, Even with Insurance, Limits Patient Population
More Multidisciplinary Sleep Clinics and Referral Networks are Developing to Encourage Doctor/Dentist Collaboration	Sleep Physicians' Distrust of Referring Patients to Dentists without Accreditation or Proven, Consistent Outcomes – History of Bad Actors in the Dental Market
Aging and Obese Population Contributing to Higher Rates of OSA, Increased Awareness and Diagnosis of the Condition	Most Dentists Not In Medical Insurance Networks and Unfamiliar/Uncomfortable with Billing Process
New Entry by Major Players (ResMed w/Narval and Henry Schein w/SleepComplete) Supporting Growth in Field	Development of Pills and Implantable Stimulators, Which Could Reduce Need for PAP and OA Treatment for OSA

**Product Cost and Coverage**

One of the biggest barriers to growth in the OA market is billing. Sleep dentists and physicians will need to work together for the referral process, and dentists will become involved in medical billing. The complexity involved in medical billing where they have traditionally stayed away from due the complexity of insurance coding and reimbursements has kept many dentists away from these products in the past. The majority of OAs are paid for by private insurance or out of pocket as Medicare has been limited in its willingness to accept them as a sleep apnea treatment (Exhibit 4). Even if a device is covered by private insurance or Medicare, consumers are still responsible for co-pays and other out-of-pocket expenses. OAs have therefore become more expensive to a patient than PAP, which is fully covered and reimbursed, and has kept many clinicians from offering this alternative treatment.



### Exhibit 3 – Payment Method for Custom Oral Appliances in the US



Private insurance is the fastest growing portion of the market, but what amount private insurers cover and under what conditions varies widely.

Medicare patients are more likely to use PAP than OA because of increased severity of symptoms and contraindication due to dental issues (e.g., dentures, etc.)

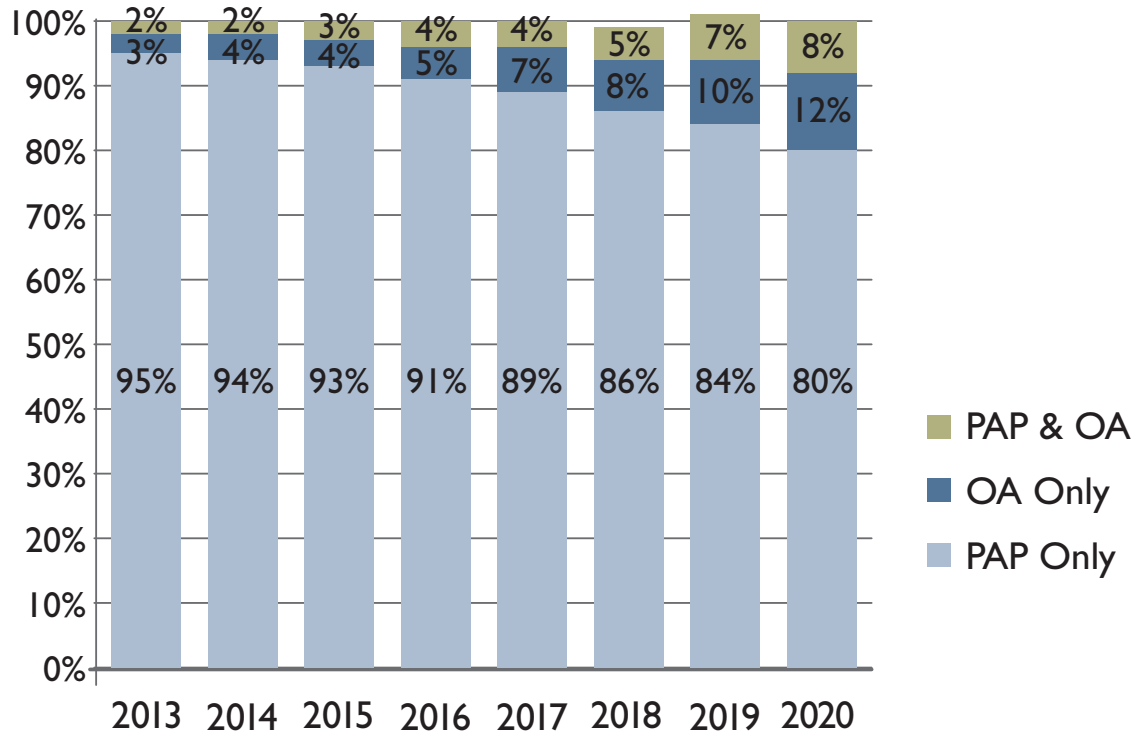
Exclusively cash pay is shrinking as more insurers cover OAs and dentists become part of networks and more comfortable billing insurance.

Medicare + Private Insurance is very small. Supplemental policies are usually targeted at drug costs as opposed to sleep dentistry.

#### The United States vs. Europe

Though growing, the OA market in the US is immature when compared to Europe. In the US, nearly 93% of the sleep apnea population uses only PAP (Exhibit 3). In contrast, parts of Europe use OAs more frequently as a primary treatment and they have become a standard of care. According to the 2014 SomnoMed annual report, its OAs in the Netherlands are used 54% of the time. Some may attribute this to Europe's socialized healthcare, which recognizes the cost benefits of OA treatments. With the ability to price cap payments to dentists, OAs are generally half the price, without out-of-pocket expenses. This makes it a less-expensive treatment for payors than traditional PAP. Others could fault insurance and PAP companies who have been slow to recognize alternative treatments to PAP. However, a few companies in the US are looking forward with mergers and acquisitions. An example of this would be ResMed acquiring Laboratories Narval, a French OA company, in 2009. Frost & Sullivan expects market consolidation among top competitors as OA presence in the US grows.



**Exhibit 4 – OSA Patients by Treatment Method in the US****Market Consolidation**

The OA market is crowded and highly fragmented as there are more than 120 different devices that have been cleared by the FDA. Clinicians can offer either custom or non-custom devices, depending on the patients' needs and their offerings. Non-custom devices can be molded and completed right at the dentist office. They are inexpensive, quickly made, and can be a successful indicator of whether or not OA treatment works for that individual. Custom refers to the product being measured, molded and sent to a specific OA lab for product manufacturing. This process is more costly, but it also has superior results as the device is specially tailored to each patient. The OA market is still in the beginning stages, but there is potential to evolve from custom dentist designs that are sold at a regional level to a more traditional medical device market where a select number of standard devices are pushed nationally or internationally. Over time, the market will further consolidate with dentists choosing fewer designs and manufacturers. Nevertheless, dentists will likely keep three to five OA designs on hand to meet the varying needs of each patient. Product consolidation will allow dentists to make decisions based off the strength of supporting evidence, price, performance, referral network and insurance coverage. The OA market should grow exponentially in the coming years as patient education on product use as well as increased clinician training on the benefits of OA when compared to PAP (Exhibit 5).

## Exhibit 5 - Technology and Market Roadmap for the US

Field	2014-2016	2017-2019	2020+
Clinical Practice	<ul style="list-style-type: none"> <li>• Growing awareness and education of value in OAs for OSA</li> <li>• Accreditation and credentialing of sleep dental specialists to strengthen credibility</li> <li>• Strengthening of doctor/dental referral relationships</li> </ul>	<ul style="list-style-type: none"> <li>• Expansion of doctor/dentist sleep practices</li> <li>• Full acceptance from clinicians on benefits of OA</li> <li>• Clear referral pathways</li> </ul>	<ul style="list-style-type: none"> <li>• Growing preference for OA as primary treatment method among payors and many physicians</li> </ul>
Technology	<ul style="list-style-type: none"> <li>• Increased use of CAD/CAM manufacturing</li> <li>• Integration of diagnostic/compliance monitoring technology in OAs</li> <li>• Evolution of non-custom OA products as bridge to custom OA therapy</li> </ul>	<ul style="list-style-type: none"> <li>• Better diagnostics and screening developed to ensure OA patients get optimal therapy the first time with limited risk for failure</li> <li>• More durable products</li> <li>• Combination OA/PAP therapy</li> </ul>	<ul style="list-style-type: none"> <li>• Advanced sensing technologies and other features integrated to monitor and treat other related conditions</li> </ul>
Patients	<ul style="list-style-type: none"> <li>• Younger, affluent and milder-symptom patients as target market</li> <li>• Increased use of AutoPAP/home sleep testing for OA adjustment/titration</li> </ul>	<ul style="list-style-type: none"> <li>• Expanded use of PAP/OA together in more severe patients</li> </ul>	<ul style="list-style-type: none"> <li>• Adoption of OA for treating other conditions – heart failure, diabetes, etc.</li> </ul>
Financial	<ul style="list-style-type: none"> <li>• Private payors begin to place price ceilings on OAs or a tiered formulary like CMS</li> <li>• Prices for OAs decline under competition</li> </ul>	<ul style="list-style-type: none"> <li>• CMS approval of new OA designs for Medicare reimbursement</li> </ul>	<ul style="list-style-type: none"> <li>• Market size and spend becomes large enough to warrant heightened regulatory attention from government</li> </ul>
Market	<ul style="list-style-type: none"> <li>• Transformation from a custom/cottage industry to more standardized medical device field Prices for OAs decline under competition</li> </ul>	<ul style="list-style-type: none"> <li>• Consolidation and vertical integration of major competitors</li> </ul>	<ul style="list-style-type: none"> <li>• Expansion of OA treatment into new fields – headaches, asthma, cardiovascular, cancer, etc.</li> </ul>

## Looking Forward

The OA marketplace is an example of how reimbursement patterns and economic incentives can have a significant impact on device utilization. As much as we like to see product innovation growing an industry, this is not the case in sleep apnea. There are plenty of inventive OA devices that can reduce airway obstructions, but the adoption rates for these products are unusually low when compared to foreign countries. We share many of the same devices, but reimbursement rates are drastically different. If the environment were to change to one that encourages alternative treatments such as OAs, a larger population of individuals could be successfully treated for sleep apnea.

## Exhibit 6 – Major US Market Competitors

Custom OA Manufacturers	Distributors	Dental Labs	Sleep Medicine Franchises	Non-custom OA Manufacturers
SomnoMed (SomnoDent)	Henry Schein	Gergen's Orthodontic Lab	eOs Sleep	GlideWell Dental Labs (Silent Nite sl)
Strong Dental (SUAD)	Patterson Dental	DynaFlex	SleepQuest	Pure Sleep Co. (PureSleep)
ResMed (Narval CC)	Benco Dental	Great Lakes Orthodontics		SleepingWell (ZQuiet)
Airway Management (TAP)	Dentsply	Glidewell		Apnea Sciences (SnoreRx)
Dream Systems Dental Labs (Oasys)				
Respire Medical (Respire)				
Myerson (EMA)				
Modern Dental Laboratory (The Moses)				

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