Dentsply Sirona and Zephyr Sleep Technologies, together, present The Simple Sleep Solution

U.S. Food and Drug Administration grants De Novo FDA Clearance for the MATRx plus™ available for sale to the dental community in the United States through Dentsply Sirona. The Simple Sleep Solution combines Dentsply Sirona 3D Imaging, MATRx plus™, SICAT Air and OPTISLEEP for the only complete 3D solution for the analysis and treatment of obstructive sleep apnea (OSA).

York/Salzburg/Calgary, September 13th, 2018. De Novo request for the MATRx plus™ - the first ever “at-home” class II medical device to identify patients suitable for oral appliance therapy. Ideally suited for a Dental office, the MATRx plus is a multi-function device capable of performing both: i) a standard home sleep test (HST); and ii) an oral appliance trial.

The MATRx plus’ unique and innovative tablet-based design is easy-to-use with instructional videos walking patients through the self-administered test in the comfort of their own home. Offering real-time, cloud connectivity, the MATRx plus simultaneously brings the patient’s study to the dentist’s office, the Sleep Physician’s office and Zephyr’s servers allowing for instant collaboration amongst health professionals and responsive customer support. The MATRx plus technology uses proprietary algorithms, AI and machine learning.

Dentsply Sirona 3D Imaging is led by the Orthophos SL 3D Ai and The Simple Sleep Solution rounds out a complete service offering from Dentsply Sirona which already includes digital solutions for Implants and Endodontics. Now every Orthophos SL 3D Ai system in the US, will be bundled with The Simple Sleep Solution.

Using an oral appliance to treat OSA is not new; however, in the past, dentists and sleep physicians have been plagued with high treatment failure rates (30-40%) and arduous titration protocols and guesswork to determine a treatment position. This is now all changed. The MATRx plus tells the medical professional IF a patient can be treated (reducing the failure rate) and HOW to treat by offering a therapeutic treatment position. The dentist uses this information to order and configure the oral appliance efficiently and effectively in a patient-friendly matter. “Never before has providing a sleep appliance been so easy” says Dr. Shouresh Charkhandeh, Zephyr’s Chief Dental Officer and renowned educator and researcher of dental sleep medicine.

Sleep-related breathing disorders, including OSA, affect as many as 25 percent of North American adults with most (over 85%) remaining undiagnosed and untreated. OSA has become arguably the most prevalent chronic non-communicable disease in industrialized society. In addition to a poor quality of life, OSA conveys an increased risk of cardiovascular disease, high blood pressure, type II diabetes and industrial and motor vehicle accidents. “Finally, we are able to confidently
prescribe an alternative therapy to CPAP and invasive surgery to treat OSA” says Dr. John Remmers, Zephyr’s Chief Medical Officer. “Using The Simple Sleep Solution with the **MATRx plus** to responsibly and confidently select patients for oral appliances is the missing link to effectively treating a broader population”.

Dentsply Sirona and SICAT brought the first 3D solution for the airway analysis and appliance-based therapy for Obstructive Sleep Apnea. “The FDA clearance for the MATRx plus is a significant achievement for Zephyr Sleep Technologies, our partner in delivering the final piece for the first and only end-to-end 3D solution for obstructive sleep apnea” says Walter Petersohn, Dentsply Sirona’s Chief Commercial Office. US Dentists will be able to learn more about integrating the Simple Sleep Solution for the very first time at Dentsply Sirona World September 13th, 2018 from clinicians who pioneered the technology and are instrumental to introducing this solution in the US.

**OPTISLEEP explained**

OPTISLEEP is a two-piece appliance, offering patient comfort due to its slim design. The durable material and connector design are stable and enable both complete sealing of the lips and normal breathing. The exchangeable connectors come in 10 sizes that allow you to flexibly adjust the grade of protrusion. OPTISLEEP covers all teeth to avoid the elongation of individual teeth, and the continuous covering of the occlusal plane allows for a relaxed jaw position.

“The great visualization options of the software clearly facilitate our communication with the patient,” says Dr. Tarun Agarwal, DDS, “the advantages of an appliance-based treatment can be easily demonstrated. Especially the slim design makes wearing OPTISLEEP very comfortable for patients and motivates them to start treatment.”

**A plethora of benefits for users**

Professionals like Dr. Tarun Agarwal benefit from this innovative product by adding new procedural options with 3D imaging to their repertoire. Dentsply Sirona 3D cone beam systems not only produce high quality images at a low dose, they also streamline workflows, resulting in shorter visits, predictable outcomes and greater patient satisfaction. These benefits result in greater certainty to when making difficult diagnoses, while providing the opportunity to offer practice-building, patient-pleasing treatment modalities including obstructive sleep apnea, implantology, endodontics, orthodontics and more. Creating an efficient clinical workflow, the MATRx plus is an easy-to-integrate solution that enables professionals to attract new patients, while providing existing patients with comprehensive consultation and treatment, thus increasing their quality of life.

The Simple Sleep Solution is exclusively available with the purchase of the Orthophos SL 3D Ai. Visit [www.thesimplesleepsolution.com](http://www.thesimplesleepsolution.com)
IMAGES are available for > Download on the website.

Image 1: Dentsply Sirona MATRx plus™ Recorder-Tablet.

Image 2: SICAT Air visualizing an obstructed upper airway within the Galileos 3D volume.

Image 3: Dentsply Sirona OPTISLEEP device.

Image 4: Dentsply Sirona Orthophos SL.