



PRESS RELEASE

FOR IMMEDIATE RELEASE

Panthera Dental offers support to healthcare professionals to ensure no sleep apnea patient is left behind in the wake of the Philips CPAP product recall.

In response to the Philips recall, which could leave many patients in USA without treatment in the short term, Panthera Dental is offering a fast-track turnaround on the production of its appliances to get patients back on effective treatment quicker.

Panthera Dental (Quebec, Canada) is a leading North American manufacturer of custom-made oral appliances; an alternative to CPAP for the treatment of obstructive sleep apnea. The company has developed an advanced digital manufacturing process, allowing it to produce highly customized nylon CAD/CAM oral appliances quickly and at scale.

Quebec, June 23, 2021. Panthera Dental is offering its support in response to the voluntary recall notification¹ issued by Royal Philips on its Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices. The recall affects patients and providers in USA, though a field safety notice is also likely to cause disruption in the rest of the world. Philips issued the recall after becoming aware of degradation in the polyurethane foam within certain device models.

“We want to support healthcare professionals by helping to minimize the interruption in treatment for sleep apnea patients. Our CAD/CAM oral appliances are produced with an advanced digital process that we developed and refined over 10 years working with sleep dental experts in North America,” said *Beatrice Robichaud, Co-Founder and VP Marketing & Customer Experience at Panthera Dental.*

“Our Manufacturing 4.0 technology gives us the flexibility to respond to a crisis, allowing us to simultaneously increase production capacity while maintaining a fast 10-day turnaround, without compromising on quality or precision. Indeed we responded in a similar way in 2018, helping to ensure that no patient was left behind when ResMed ceased distribution of their nylon oral appliance in North America.”

The demand for Oral Appliance Therapy (OAT) has grown dramatically in recent years as a first-line treatment for mild and moderate obstructive sleep apnea (OSA) and as an alternative treatment for patients unable to tolerate CPAP. Studies have shown that CPAP is often more effective than OAT when in use, but OAT is often better tolerated and used for more hours of the night; therefore the two therapies have an equivalent effectiveness profile.²

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Panthera Dental's custom-made Digital Sleep Apnea Devices (D-SADs) are designed and manufactured using 100% medical grade type-12 polyamide nylon, a material that has proved to be a game changer in oral appliance manufacture, being at once light, smooth, strong, flexible, highly durable and safe. D-SADs are also extremely customisable and can be adapted to every possible patient morphology, from basic to the most complex.

More information about Panthera Dental is available on the Panthera Dental website:

www.pantheradental.com

www.pantherasleep.com

About Panthera Dental

Panthera Dental designs, manufactures and markets dental prosthetic, implantology and sleep breathing disorder solutions using a cutting-edge CAD/CAM process and superior quality materials. Both a pioneer and a leader in the field of custom-made dental solutions, our proprietary technology allows us to offer next-generation products to the widest range of patients possible. Panthera Dental is headquartered in Quebec City, Canada, with subsidiaries in the USA and France, and associates worldwide.

References:

1. Philips Recall Notification: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-issues-recall-notification-mitigate-potential-health-risks-related-sound-abatement-foam#recall-announcement>
2. Fernanda R. Almeida, DDS, MSc, PhD and Nick Bansback, PhD. Long-Term Effectiveness of Oral Appliance versus CPAP Therapy and the Emerging Importance of Understanding Patient Preferences. *Sleep*. 2013 Sep 1; 36(9): 1271–1272.

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