

Changing the Paradigm: Soft Cloth Technology and CPAP Nasal Masks

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New **SleepWeaver ADVANCE All Cloth CPAP Nasal Mask** debuts at SLEEP 2009 23rd Annual Meeting of the Associated Professional Sleep Societies, (APSS) June 6–11, at the Washington State Convention and Trade Center in Seattle, Washington.

The product attracted a lot of attention in the exhibition hall. Circadiance LLC, makers of the soft cloth CPAP mask hope to capitalize on the momentum with a new and improved version of their groundbreaking fabric design.

Ask the CEO of Circadiance LLC if his showcase product is flimsy, and he will likely agree with you. With the undeniably flexible nature of Circadiance's SleepWeaver, the company's soft cloth nasal CPAP mask has managed to build a solid reputation.

THE NEW MASK

At the recent Sleep 2009 show in Seattle, Murrysville, Pa-based Circadiance sought to expand and update that image with its new SleepWeaver ADVANCE, a smaller unit that CEO David Groll says fits a broader range of patients. The new mask continues the soft cloth design formula that still stands in stark contrast to its hard plastic competitors.

SleepWeaver was the first (and still the only) all-cloth CPAP mask since Circadiance has filed multiple patents around the technology. All contact points are made of soft cloth, and there are no buckles, clips, or rigid features that can mark a patient's face. Groll compares the properties of the mask to a balloon, with all points applying equal pressure for a leak-free seal.

A year ago, the company launched the original SleepWeaver product at Sleep 2008 in Baltimore, a move that led to heavy traffic at the company's booth. Buoyed by the product's strong reception, Circadiance hopes the new ADVANCE will convince even more sleep doctors to sing the praises of soft cloth technology. "We offer a distinct alternative, when we ask doctors, 'How many of your patients like to have a hard plastic mask on their face?' the answer is always, 'None.'"

Since 2008, the company has achieved sustained growth in line with the massive OSA awareness push in the media and the clinical world. While the CPAP mask market is undeniably crowded, and deep-pocketed competitors abound, the Circadiance team are confident that innovation will keep their foot in the door. "The response has been overwhelming," says Groll. "We have had tremendous interest

here in Seattle, both from our customers who previously used the original SleepWeaver, and from those who have only recently learned of the soft cloth mask approach. We are placing a lot of these products into sleep labs, and we are expecting continued growth in sleep lab referrals for the SleepWeaver ADVANCE."

AWAKE AT THE SWITCH

With enhanced aesthetics and more efficient headgear, the ADVANCE features a number of improvements taken directly from user input. Collecting the thoughts of actual patients is a nod toward the essential compliance qualifications inherent in today's CPAP reimbursement climate.

For the convenience of sleep labs and HME providers alike, Groll says the ADVANCE, much like its predecessor, can be serviced in just 15 minutes. Likewise, he believes patients will respond to the product's intuitive fitting setup with minimal help. "It is easy to use and many patients try it on and immediately understand how to fit it". "We use sales reps to educate sleep professionals, we have information available on our Web site, and we have a customer support line to answer any questions live."

Groll acknowledges that users and professionals have gotten used to the idea of using hard plastic on the face, but he hopes to highlight the comfort issues and fundamentally change the paradigm—no small chore to be sure. As a manufacturer, the difficulty in working with soft cloth starts at the beginning. Without the ability to mold plastic in virtually limitless ways, Circadiance had to look for a new way to reach its dream. After more than a hundred design revisions, Groll finally found a cloth that would create a good seal, hold pressure, and adequately conform to the patient's facial anatomy. "I could not think of a better way to design a mask using plastic. So we reached that goal by switching to a completely different material.

With additional innovations such as ambulatory sleep monitoring on the rise, Groll says the demand for truly different products will fuel a willingness among patients to try new things. If home-based testing can continue to provide the same reliable results seen in lab-based tests, the market will only expand and smaller innovative companies will make an impact.

THE FUTURE

How far can you stretch cloth? With the philosophy that time yields wisdom, Groll believes the soft cloth paradigm shift will only continue, with additional refinements inevitable. "It is our intention to continue to introduce new and different versions of soft cloth masks for obstructive sleep apnea," says Groll. "And different versions of the SleepWeaver mask are in the pipeline. Before Sleep 2010 [San Antonio], we will have other new products to offer."

Sleep lab directors looking to get in on the textile-driven innovation can call Circadiance for samples. As part of the company's sleep lab program, lab directors can explore marketing, education, and a variety of purchase agreements.

“We provide demonstration displays for our products, so they can include that in their fitting rooms,” says Groll. “We also have our customer care line to walk them through the process and get them set up—and to service the units afterwards.”

On the patient side, Groll points out that any medical treatment that requires compliance from apnea sufferers must put comfort first. Discomfort leads to negative symptoms, which leads to patients giving up the mask and choosing to live with the effects of sleep apnea.

Feedback collected by Circadiance indicates that most patients have tried eight, 10, 12, and even 20 different types of masks. “These are people that recognize that they need to get their sleep and they have to have the therapy,” says Groll. “They are experienced users, but they are so intolerant of existing masks that every chance they get, they will try a new one. They come across ours and say it is the most comfortable one that they have ever worn.”

GOOD LISTENER

In addition to patients, Groll incorporated feedback from clinicians when designing the new SleepWeaver ADVANCE. Calling every doctor “a little bit of an engineer,” Circadiance’s

CEO relishes the input he gets from professionals and takes the time to record suggestions for future consideration.

After introducing the original SleepWeaver product more than 2 years ago, the second SleepWeaver ADVANCE is evidence of this commitment to user input. With major design revisions to make those suggestions a reality, Groll is quick to point out that not every mask is right for every person. With this in mind, Groll says the ADVANCE fits a wide range of face shapes with its ergonomic headgear.

With an eye toward continued refinement, the Circadiance team are also looking to apply soft cloth technology to the positive pressure ventilation market, a move that will expand the company’s reach to include respiratory departments and home care companies. Groll hopes the application of soft cloth technology will ultimately transcend the sleep world and cause people to view fabric in a new light. “If you think about it, it doesn’t make very much sense to wear hard plastic,” says Groll. “You wouldn’t wear plastic pajamas, and you wouldn’t have plastic bed sheets. Everybody in the CPAP business has gotten used to the idea of using hard plastic on the face, but there are a lot of problems, and it causes a lot of discomfort. We have overcome all of this by changing the paradigm.”

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