

Cloth, Color, and Circadiance

Innovation at Circadiance continued this year with the addition of the multi-colored Zzzephyr Seal to the Pa-based company's line of cloth CPAP masks.

Almost 3 years after transcending the plastic paradigm, Circadiance LLC of Murrysville, Pa, has updated its original cloth nasal CPAP mask yet again with the new Zzzephyr Seal for use with the SleepWeaver ADVANCE Mask. Introduced at the October 2009 Medtrade Show in Atlanta, the Zzzephyr joins the ADVANCE All Cloth CPAP Nasal Mask, which also debuted this June at SLEEP 2009 in Seattle, Washington.

The SleepWeaver ADVANCE with Zzzephyr Seal inflates like a balloon, conforming to the patient's face to create a seal. Since the elastic cloth is flexible and follows the shape of each patient's face, company officials say comfort goes up while skin irritation goes down. "We're continually improving the experience for CPAP mask users," says David Groll, CEO of Circadiance. "Innovation requires thinking about the product from the user's perspective. The new Zzzephyr Seal allows us to provide patients with an even better fit, while giving them color choices that helps make their mask more attractive and personal."

Earlier this year, Groll and his engineers improved on the old SleepWeaver with the SleepWeaver ADVANCE, a smaller unit that fit a broader range of patients, while continuing the cloth design that set the first device apart from its competitors. The new ADVANCE model continues to use fabric, and benefits from the feedback of countless clinicians and patients. "In addition to the feedback that we've gotten about the design of the product, we've gotten a lot of feedback about how to work with the various players in the field, including the home care companies, sleep labs, and CPAP users," says Groll. "We have positioned our product, and our whole selling process, so that we can serve the needs of those various groups as effectively as possible. For sleep labs, we supply demo display units. We also have special pricing for sleep labs to make the product competitively priced."

Despite the product descriptions, those who receive demo units are usually surprised that the entire body of the mask is made of cloth, and all parts of the mask that contact the patient are made of cloth. It has no buckles, clips, or rigid features that can make a mark on the patient's face. Since the mask works by using the properties of a balloon, Groll explains that all points inside are of equal pressure. "If you think about it, it doesn't make very much sense to wear plastic," says Groll with a chuckle. "You wouldn't wear plastic pajamas, you wouldn't have plastic bed sheets. Everybody in the CPAP business has gotten used to the idea of using 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."

Flexible By Design

Ask Groll if his showcase products are flimsy and colorful, 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 ADVANCE mask and Zzzephyr Seal continue the soft cloth design formula that still stands in stark contrast to hard plastic competitors.

SleepWeaver was the first (and still the only) all-cloth CPAP mask, and Circadiance has filed multiple patents around the technology. 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," said Groll. "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."

Bright colors for the Zzzephyr, and more efficient headgear on the ADVANCE, are features that take their cue 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,” enthuses Groll. “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 as 2009 winds to a close he hopes to continue highlighting 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.

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 provide an instructional video on our web site and on diskette. 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.”