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The First All-Cloth CPAP Mask

Two years after transcending the plastic paradigm, Circadiance LLC of Murrysville, Pa, has updated its original cloth nasal CPAP mask with the new SleepWeaver ADVANCE. The new unit is smaller, fits a broader range of patients, and continues 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 our conversation with **David Groll, CEO of Circadiance**, we explore the thinking that motivated the cloth concept, and learn about the new and improved benefits of the SleepWeaver ADVANCE.

Describe the design of the SleepWeaver ADVANCE nasal CPAP mask?

SleepWeaver is the first all-cloth CPAP mask. 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 from wearing it. The mask works by using the properties of a balloon. And since all points inside of a balloon are equal pressure, when patients wear the mask, they do not have any pressure points from the mask—so they get a leak-free seal with no pressure points.

What sets it apart from other masks in the field?

All other masks on the market are made of plastic, so the fact that this one is made of cloth certainly sets it apart. Other masks all have some kind of a rigid plastic frame with an elastomer cushion. And because they are all made of plastic, they all have the same limitations. They have to be put against the patient's skin—hard enough so that the air does not leak out of the mask—and that overcomes the profusion pressure in the tissue where the mask makes contact and causes soreness and pain.

The SleepWeaver is a much more natural way to interface a CPAP system to a patient. If you think about it, it does not make very much sense to wear plastic. You would not wear plastic pajamas; you would not 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 and using all cloth to interface the machine to the patient.

Why have we not gone beyond plastic until the SleepWeaver?

Plastic has quite a history. Oxygen mask technology came out of the military going all the way back to world war II, when they had to put oxygen masks on pilots for high altitude flight. They started making rubber masks, and that moved on to industrial mask technology, and ultimately medical mask technology using rubber and plastic. Because of the nature of the manufacturing process, it is a lot easier to make. You can mold plastic and rubber to a lot of different shapes, and that technology has evolved into what is today the modern CPAP mask.

Several years ago, I started to think about how to approach the problem in a completely different and novel way, and it occurred to me that we had taken the basic plastic technology about as far as it was going to go. All the masks are OK. They are pretty good, but they all have the same limitations. To get a truly better product, we had to go back to first principles and think about what we were trying to accomplish. Basically, I could not think of a better way to design a mask using plastic, so I thought about other materials that might do a better job. That is when I came up with the idea of trying to use cloth. I probably went through about a hundred design revisions to get to the point where I could find a cloth that would create a good seal, hold pressure, and adequately conform to the patient's facial anatomy.

How do improvements in your product directly affect patient care?

The fundamental issue with CPAP therapy is that it requires voluntary participation by the patient. It requires an active decision that patients have to make every night to wear their CPAP equipment. They are not going to do that if there is a lot

of discomfort. What is worse—the negative symptoms from not sleeping, or the pain from wearing the equipment?

We can improve compliance by making the mask more comfortable. Compliance is the number one issue, and the single biggest issue with compliance is the comfort of the masks. We are focused on making a more comfortable mask that will help improve patient compliance.

We get feedback all the time from our patients. The typical story is that they have tried 8, 10, 12, and even 20 different types of masks, and they come across ours and say it is the most comfortable one that they have ever worn. These are people that recognize that they need to get their sleep, they have to have the therapy, but they are so intolerant of existing masks that every chance they get; they will try a new one. They are experienced users.

What feedback have you gotten back from clinicians and patients?

We get a lot of feedback from clinicians, and they say they can see a place for this product in their practice and they see this as a great alternative. They think this mask has tremendous potential to become a leading product in the market. Some give us design ideas and say "Have you thought about doing it this way?" because they see issues in their lab, and they have suggestions for things we could incorporate into the product.

Every doctor is a little bit of an engineer, and they want to see these products improved. They are clear about what the problems are, and others are actually able to point out the problems and the solutions. We take all of those, record them, and as we go into making design changes we try to rank and rate the various features and improvements that people want to see. We ultimately incorporate as many of those into the design as we can.

What level of user input has gone into the design and development of this product?

The original SleepWeaver product was introduced 2 years ago on April 1, 2007, and we sold that product for the first 2 years. We have recently introduced the Sleepweaver ADVANCE, which is the second-generation product. We made a number of major design revisions to incorporate all of the user feedback that we received over the first 2 years of marketing. In particular, we made the product much smaller and better looking. We made it fit a broader range of patients. It is a one-size-fits-all product, but that's a pretty tall order, so we now fit a very wide range of the population. We made every effort to fit an even broader range of the population with the new product.

We have made a number of ergonomic changes to the headgear, so it is easier to put on and take off. All those factors—size, fit, and usability—are part of the new product.

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. 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.

Are there any other products in the pipeline?

We think there is broad applicability of this cloth mask technology in sleep apnea and the positive pressure ventilation space. We are looking at all those areas. There will be other products that we introduce in the future that are extensions to the SleepWeaver product line.