

Q&A with Stuart Heatherington, Founder and CEO of Bleep, LLC. bringing to market the First one-size-fits-all Mask-less CPAP Device for the Treatment of Sleep Apnea



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CEOCFO: *Mr. Heatherington, I see on your website "Finally a Sleep Apnea Solution that Doesn't Suck." Would you tell us about DreamPort?*

Mr. Heatherington: Bleep DreamPort is essentially the first mask-less solution for treatment of sleep apnea that actually answers all the problems patients have complained about with regard to the CPAP interface for a mask. We have removed all the headgear and made it one-size-fits-all and have precluded it from being able to leak when you sleep with it at home which is important for getting a better night of sleep and more sleep consolidation for the end-user.

CEOCFO: *How have you been able to come up with a design that works and does not annoy?*

Mr. Heatherington: It was a 3:30 in the morning back of the napkin kind of epiphany that just kind of hit me. I was doing a CE event for credits at the beach and woke up and had the idea and jotted it down on the back of a napkin and I talked to my wife for about an hour and a half about it. Later that weekend I went to Lowes and cobbled together some parts that I needed to create a proof of concept. I slept with it that night and said hey this thing has some real opportunity here to be a game-changing CPAP interface. From that point forward we hired an engineer, hired an attorney and got the ball moving.

CEOCFO: *What is the standard CPAP mechanism and what is DreamPort?*

Mr. Heatherington: There are two different CPAP mask interfaces that are on the market. One of them is a nasal mask which covers the nose with a silicone shell and the other is a nasal pillow mask. That is two silicone prongs which protrude up into the nostrils about a quarter of an inch. Both of them have a delivery system where air is piped up through the mask, through a tube, from a CPAP unit that sits on your bedside table. Varying degrees of pressure are needed in order to stabilize a patient's airway in order to keep them from having sleep apnea. In situations where they have been diagnosed, they are going to be adding one of those two interfaces unless they get to the full-faced mask which we are not a full-face mask. We are not competing in that part of the market, yet. The nasal mask is regarded as a more popular CPAP interface and the nasal pillow mask is less popular. But both of them have their upsides and both of them all have headgear that holds it on with a blend of Velcro and straps across the top and back of your head. It can cause a lot of pain on your face and it can hold the mask or silicone cushion onto your nose or inside your nostrils much tighter than you would like, in order to keep the seal engaged with your skin. They can be big and clunky, and they can leak because if you do not have the headgear on properly or snug enough, then the mask can wake you up and fragment your sleep. What is different about the DreamPort is we removed every bit of the headgear and we have two little adhesive strips that have two ports that are adhered to the outside of the nostrils. There is a hole there and you line up that hole with your

nostril and then you just take this adhesive patch and cover up your nostril and now you have this little port that hangs down and the two of them become essentially extensions of your nostrils. We have a small silicone connector that grabs those two ports and engages them. We have removed all the headgear that causes pain or marks on your face and the adhesive attaches to your nose creating a perfect seal every time. It is a one-size-fits-all option. It provides a better night of sleep and more comfort. It would be the smallest and lightest thing on the market and it is a revolutionary game-changer for sleep apnea interfaces.

CEOCFO: *How does the adhesive stay in place if you are tossing and turning or perspiring?*

Mr. Heatherington: The tossing and turning is not a problem. We have a video on the website that we call the 1lb. weight challenge. It's basically me hanging a 1lb. weight from a nasal pillow mask first and then a 1lb. weight from a nasal mask. What you will see is the 1lb. weight significantly dislodges the nasal mask and the nasal pillow mask from proper engagement against my skin. Whereas with us when the DreamPort is applied, it seals off against your skin. It is a hypo-allergenic surgical tape and it is very strong and durable. But it's also very user-friendly to your skin. It has just the right amount of grip in order to stay on your face adequately and provide a perfect seal but at the same time not tear your skin or cause allergic reactions or irritation around your face from repetitive wear. 3M makes the product and it is a medical grade surgical foam tape. You do have to clean the skin and remove the oils prior to application and that is very critical to the success of using the product.

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CEOCFO: *Why has this been missed as a potential solution over the years?*

Mr. Heatherington: I think a lot of engineering solutions are predicated on looking at one idea and saying we can make it lighter...regarding nasal pillow masks or traditional nasal CPAP masks. They change the headgear and tweak the general concept, but beyond that there has been a failure to think out of the box. Compounding that problem is the fact that insurance provides specific reimbursement codes for the mask cushion, which is the silicone part that goes on the mask. There are two different reimbursement codes, one for the nasal cushion and one for the nasal pillow cushion. Insurance coding follows the guideline that if you have something that engages and covers your nose, that is a nasal cushion. If you have something in your nostrils, well that is a nasal pillow. We know also that you get a reimbursement code for headgear. So the middle-man makes money from having a headgear. Well the middle-man does not want to lose the ability to bill for headgear in most cases and neither does the manufacturer. As an engineer, you are kind of pigeonholed into having to think of ways to create something that still retains all of the elements that allow for the middle-man to actually bill insurance or products so that they can get reimbursed on because the vast majority of all CPAPS are run through insurance. But I wanted to be different. So I decided to step out of the other guys' comfort zone in all design aspects. We removed the headgear completely. It was time for it go. But we still had to create a component that would fit within the structure and the confines of what Medicare gives as a reimbursement code. When you look at the language for a nasal cushion, we fit the language of a nasal cushion in three different places, whereas with the nasal pillow we meet the language of a nasal pillow in only one instance. We fall out of the box but without putting ourselves so far out of the box that we couldn't still look at retaining reimbursement for a nasal cushion. That was paramount to be able to get to market because if you cannot get a reimbursement code, a lot of companies are not going to want to carry your product. They will not be reimbursed for it. It was stepping out of the box and, at the same time, knowing we have an opportunity to still achieve insurance reimbursement. We are 99% sure we are going to get all our insurance reimbursement coding. So that was a big gut check, going places the other guys haven't been willing to go before.

CEOCFO: *What has been the reaction from the medical community?*

Mr. Heatherington: The reaction has been incredibly exciting. We just attended MedTrade this past year in Atlanta and we had a suite in a hotel across the street. We were routinely bringing individuals in from companies to see a demo of the device or try the device on themselves. You would have thought we had a baby with the amount of the congratulations we were getting in the room when they would see it. People began to grasp what it means and how it could be a game-changing medical device in an industry that has a 50% to 60% fail rate for people getting on compliance. A lot of that fail rate is in part due to the actual interface because they will hurt your face and sting, they're cumbersome, they leak and wake you up. Even though it is fixing your sleep apnea, it leaks so much that your sleep is still as fragmented as it was when you had the sleep apnea. The problem is if you don't see a benefit in therapy you stop using it. People were looking at it and they were like, "Oh wow, this is really amazing. We want to carry this product and how long is it going to be

before you clear FDA, and what are the hurdles?" They are asking all the right questions and are intrigued. A lot of companies have already given us orders and letters of intent in order to hold product for them.

CEOCFO: *What is the prevalence of sleep apnea in the US?*

Mr. Heatherington: Statistics would tell you there is probably 40 million potential CPAP users or patients that are probably or could be diagnosed with sleep apnea. Depending on what information you see out there, somewhere between seven to ten million current CPAP users are in the United States alone right now. If you take into consideration 50% of patients fail out on CPAP therapy, then that means there were 14 to 20 some odd million patients that have been introduced to CPAP and half of them have fallen out. It is tied to obesity, and that certainly exacerbates it. But there is a physiological driven complexity that lurks underneath, which most people are not aware of. By that I mean hereditary factors. It's the size of your tongue or tonsils. Are they too large? Is your airway too narrow? Do you have an under-bite where your jaw is slightly protruding back further into the throat? In a lot of cases people can have some mild snoring and what not because of those things and as they get older and put on weight it gets worse. Over a period of ten years they go from borderline apnea to adding thirty or forty lbs. and having full blown sleep apnea. It's a culmination of all these things in certain situations that influence the outcome. Then when you add weight to it, it is like throwing gasoline on a fire.

CEOCFO: *Where are you today with the product?*

Mr. Heatherington: We have filed for FDA. We expect FDA clearance in April this year and then within 90 days after getting FDA clearance, we will get our insurance reimbursement codes and our goal is to bring product to market at the beginning of Q4 this year.

CEOCFO: *What can you share about your strategy?*

Mr. Heatherington: Our go-to-market strategy is reaching out to the durable medical equipment people which are essentially the middle-men. We'll go in and demo product, because seeing is believing. Also, we hope to influence the D2C market where they do not have to have insurance in order to bill it. Even more than that, we want to penetrate the sleep lab market. We know that we have a great pricing structure for sleep labs and we are going to go into sleep labs with a one-night, one-time disposable that has never been used before. Whereas traditionally with the sleep lab, when you come in and have been diagnosed with sleep apnea on your first night in, they bring you in for a second night for a CPAP titration. The second night you spend the whole night on CPAP. Generally, the sleep lab buys what is called a lab mask and that mask can have a significant impact on your bottom line as a sleep lab and generally you are fitting a patient with three to four of them. Many of the governing bodies that oversee the sleep labs have rules and procedures for how you need to clean your equipment. A lot of the new procedures really enforce that the lab mask get thrown away at the end of the evening. Sleep labs are spending \$10 to \$15 on a mask and throwing three to four of those away in a night, and in some cases, if it's a crazy night and you cannot quite get the right fit, you might put five or six masks on a patient and toss them all out in the morning. That's a lot of waste. Whereas we can come in and give you a true one night disposable. It's one-size-fits-all and you do not have to carry thirty masks and four different cushions for every one of those masks in the fitting stage of treating a patient. So at the end of the night you are only throwing away one mask. Generally, in the sleep lab setting as you put a patient on therapy, as the night progresses, the CPAP pressures go up and as the pressures go up, the mask has a tendency to leak. The technician that has overseen the patient study will be going in and out of the room multiple times during the night depending upon how difficult it is to get a proper seal. The more you go in and out of the room, the more you are basically disturbing the patient. But the goal is for them to have a good night's sleep so they are more inclined to want to stick to therapy. With us, we eliminate that, once the device is on, it does not matter how low or high the CPAP unit goes. This thing holds a great seal and you do not have to go in and adjust it, it increases profitability for the lab, it increases compliance and it increases labor productivity in the lab setting as well. From a clinical perspective, we answer a lot of needs and we feel like if patients are introduced to it in the sleep lab, then they are going to demand the product when they come out of the sleep lab.

CEOCFO: *Why is Bleep, LLC a much-needed game-changer?*

Mr. Heatherington: The big reason you want to pay attention to us is we are going to improve compliance in the sleep apnea world. That's going to mean better outcomes for all end users, new or old, healthier patients and more people sticking with CPAP therapy. When we say better outcomes, we mean things like reduce high blood pressure, unnecessary medicine intake for treating the side effects of untreated sleep apnea and daytime sleepiness. We are going to make patients less tired who are operating heavy equipment such as driving trucks or trains. In addition, you're going to get better productivity in your work day compared to being on another CPAP mask where your sleep is more fragmented. And we're going to do all of this without the lines on your face and in your hair that other masks leave behind. Across the board, we answer a lot of problems and we have seen huge benefits that we can bring to the sleep apnea community.