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## An alternative to CPAP



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"The mission of BRYGGS Medical is to increase awareness to patients and sleep professionals that there is a viable alternative to CPAP for the treatment of Obstructive Sleep Apnea in the form of an affordable, reusable EPAP device, which we call the ULTepap™" Geoff Sleeper

**CEOCFO:** *Mr. Sleeper, would you tell us the idea behind Bryggs Medical?*

**Mr. Sleeper:** Having had previously owned and operated a sleep lab, we found that a fair amount of people that had obstructive sleep apnea really did not want to go on CPAP. A lot of the problem with CPAP is the six-foot tethering to a bedside table, the blower, and all the commotion that goes with humidification and filters, etc. There is an alternative out there called EPAP which is Expiratory Positive Airway Pressure.

There was only one cleared device on the market when I had my lab. However, the problem and limitation with that device was that it was a disposable; people had to replace it every month and they got tired of paying on a monthly basis for the rest of their lives, as there usually is not much treatment for OSA outside of being continuously treated. The patients all asked if we could come up with a reusable device and that was the concept at Bryggs. We are now in production with an FDA cleared EPAP device which we have named ULTepap™.

**CEOCFO:** *How does the device work?*

**Mr. Sleeper:** I will start with CPAP because a lot of people are much more familiar with that. CPAP stands for Continuous Positive Airway Pressure. It works as the name implies, providing constant or continuous pressure in the upper airway to keep the airway open to prevent obstructions. EPAP stands for Expiratory Positive Airway Pressure and there are three devices on the market now and it works on some sort of valving system that when you inhale you do not sense any resistance but when you exhale there is resistance causing back pressure that keeps the upper airway open. It has been shown in articles dating back to 1983 to be pretty much as efficacious as CPAP but it has gone relatively unknown.

**CEOCFO: *Why has EPAP been overlooked?***

**Mr. Sleeper:** For starters, there was about a 25-year gap between the first article published showing the efficacy of EPAP which was in 1983, and the first commercially available device was not until 2008 which means 25 years where nobody pursued EPAP, and why they did not, I am not sure. These articles just got lost in the shuffle because the first EPAP publication was about two years after the first CPAP publication. I do not have good answers as to why it was ignored all those years.

**CEOCFO: *How does your device differ from what is on the market; the EPAP products that are available today?***

**Mr. Sleeper:** There are two others currently available; one is the aforementioned device that is a disposable, a one-night use only. It keeps the valves in place by a Band-Aid type adhesive. It works very well and has been proven over and over to work well. The problem is that a box of these goes anywhere from \$60 to \$70 dollars a month and that is usually a lifetime expense. People do not want to spend forever.

There is another device and it is reusable, but the problem is the back pressure that it creates is very low and some sleep labs reported to me that it does not work for their patients. It is more of an anti-snoring device, although they do have one study that indicates that it does work for obstructive sleep apnea.

**CEOCFO: *How did you develop, design and test your reusable EPAP solution, ULTeap™?***

**Mr. Sleeper:** It was a great deal of work. It took us the better part of two years to make sure that our patent was allowed before we started spending the money out of our own pockets to bring it to market. That is another three-and-a-half-year process. We were gratified that we got the patent.

Three-and-a-half years sounds like a long time but in the patent world it is instantaneous. The amount of prior art they were able to scrape up to compare it was practically nothing so we knew that we had a unique design. That was the first stage. The second stage was that we then had to come up with the proper valving back pressures and we had to create a series of testing devices so that took another couple of years to come up with the final design on that.

**CEOCFO: *What type of cleaning is involved?***

**Mr. Sleeper:** You are probably familiar with the washing instructions for your CPAP mask which is warm soapy water, rinse gently and then air dry. That is exactly the same with us. Our device is almost essentially a nasal pillow CPAP Mask with a couple valves inserted.

**CEOCFO: *Now that you have the FDA clearance, where do you go from here?***

**Mr. Sleeper:** We just got up into production so now have a local rep that we are using here just to introduce the device locally at first.

**CEOCFO: *It seems hard to resist. Where do you see the challenges? Is it that the old model is so entrenched?***

**Mr. Sleeper:** The old model is so entrenched. The problem is that the manufacture of the disposable device had a very unfortunate start. They were cleared by the FDA in 2008 or 2010. The problem was they got off to a bad start and ended up going bankrupt, not because the device did not work but there were business issues.

I had a sleep center and we were a preferred provider for them and after they went bankrupt, they came back as a new company and they were on back-order for a year. The first commercial foray into EPAP ended flat on its face and when you say EPAP, nobody is rushing to do it. CPAP business internationally is a multibillion-dollar business so it is pretty entrenched.

**CEOFCO:** *Are you concerned that companies involved now will try to thwart your efforts?*

**Mr. Sleeper:** We start with the fact that there is a fairly high non-adherence rate to CPAP and we say for your patients that cannot tolerate CPAP, use EPAP. Most of the literature over the years has shown better adherence to EPAP over CPAP for all the obvious reasons. We start working our way in by positioning ourselves not as a competitor but as an adjunct for non-adherence patients. It is also indicated only for mild to moderate sleep apnea so the severe obstructive sleep apnea patients absolutely need CPAP or bi-level, so it does not compete in that arena. The compliance rate for CPAP increases as the severity goes up because the effect to the patient is more dramatic. For mild obstructive sleep apnea patients, EPAP may be indicated I think over CPAP just because it is easier to use.

The second thing is I know the major players out there and I have been involved with them for years. I have noticed a trend, that besides being manufacturers of CPAP they also are starting to acquire companies that manufacture alternatives to CPAP because when they cannot sell a CPAP device, their revenue stops right at the end of that patient, whereas I have noticed that one major manufacturer of CPAP has gotten into the oral appliance business and I think you will see other manufacturers following suit when they get into the alternatives as well. If you look at it from a clinical standpoint it is a huge market and there is plenty of room for everybody. I think what is best for the patient is what they should be selling.

**CEOFCO:** *Is the idea to reach out to doctors? Is it always the specialist or would primary care physicians prescribe this as well?*

**Mr. Sleeper:** Yes, to both. We have a three-point strategy. First, is to reach out to the physicians, both the board-certified sleep doctors as well as the family practitioners. Frankly the first line of defense is your family practitioner or internal medicine or primary care physician. This device requires a physician prescription so it gives us the opportunity when a patient hears about it to go back to the prescribing physician and get in front of them and talk about it. This can be difficult in a pandemic but we do it by phone at the moment.

**CEOFCO:** *How are you reaching out to patients?*

**Mr. Sleeper:** Having about zero budget for advertising, I am not sure, but we are doing a lot of word-of-mouth right now. When people find out that there is an alternative to CPAP, we get a lot of attention. We do not directly distribute; we go through distributors and the distributors typically are called the DME/HME dealer. The Medicare official terminology is Durable Medical Equipment, but the industry likes to call themselves Home Medical Equipment. These people are the ones we sell to, as well as the sleep labs. They in turn sell retail to the patient

**CEOCFO: *Are you looking for funding or partnerships?***

**Mr. Sleeper:** We are self-funded and I think we are ok in that. If you take on an investor then you dilute your portion and I do not think any of the partners want to dilute it any further. If it flounders after a while, we might do that but right now we are self-funded and we have had enough interest that we think we can slowly build this up and be successful.

**CEOCFO: *What gives you confidence going forward?***

**Mr. Sleeper:** I have been in sleep related businesses almost my entire life and my real last name is Sleeper. They have all worked so I do not see why this will not.

**CEOCFO: *What might people miss when they look at Bryggs Medical and ULTepap that they should understand?***

**Mr. Sleeper:** On our website, which is in its infancy, I did make a point in including references on there because I do not want to convey the impression that EPAP is just some gimmick that somebody just thought up overnight. Not that I expect a patient to sit there and read a thousand articles, but I want them to see the wealth and breadth of the literature that supports this thing.

The other thing that we do emphasis and probably not enough is that if you look at these articles in aggregates since 1983, there is roughly seven to ten days process to acclimate to this device. If somebody were to put this device on in one night and say they hate it, they are missing out on effective therapy. Others put it on and say they had the best sleep of their life and wish they had done it thirty years ago, but the take away here is it often takes time to acclimate.

**CEOCFO: *Is it reimbursable?***

**Mr. Sleeper:** Not at this point. It does not have a billing code but the device retails for \$149, which is probably a typical deductible for a CPAP device.

**CEOCFO: *Are there replacement parts or disposables involved?***

**Mr. Sleeper:** There is a standard CPAP headgear so that is a disposable. I could guess it could be billed every six months which is the allowable for CPAP. I do not know if they would make a distinction but it is off-the-shelf CPAP headgear. Other than that, the warrantee for the device, which is highly regulated by the FDA, is 90 days, similar to CPAP masks. Other than the headgear, there are no separate parts at the present.

At some point down the line we will probably have the cartridges which are the valving system, we might have that separately and available

from the body which provides the nasal pillows. Right now, the assembly is a little tricky and I do not want people doing it out there, I want to simplify the design before I make that available.

**CEOCFO: *Why pay attention to Bryggs Medical and ULTepap?***

**Mr. Sleeper:** People are very interested in an alternative to CPAP. Right now, the most popular alternative is oral appliances or mandibular repositioning, and there are pros and cons to that as there is to everything. With some people it really affects their bite or the joints in the mandible. Therefore, having a viable alternative to CPAP is extremely valuable.

