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Obstructive sleep apnea treatment will change. But who will lead the way?

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[1]Three medical device companies are poised to drastically change obstructive sleep apnea treatment forever.

But is sleep apnea big enough for all of them?

The three have developed an implantable neurostimulation therapy to treat patients who suffer moderate to severe obstructive sleep apnea (OSA). They have raised a fair amount of money from investors. And all three need to prove to physicians that this novel therapy will be an alternative to what is considered the gold standard in treating OSA.

Inspire Medical Systems [2] and Apnex Medical [3], both from Minnesota, are technically similar in that both companies are developing technologies that sense respiration and deliver mild stimulation to treat obstructive sleep apnea. A third company based in San Diego – ImThera – is also developing an implantable solution, but unlike Inspire and Apnex, the product doesn't have a mechanism to sense respiration.

Here are the differences:

The technology

Apnex Medical senses respiration using two leads. The wires are placed just under the skin along the rib cage to measure bio-impedance around the lungs to track respiration, which tells the Apnex system when to deliver the stimulation to the largest muscle in the tongue. Bio-impedance tracks how living organisms respond to electrical current. CEO Chas McKhann

believes this method of sensing respiration is better than using pressure sensors.

Inspire, on the other hand, uses a pulmonary pressure sensor to sense respiration, but an executive drew attention to the fact that the device has only one sensing lead as opposed to Apnex's two.

"A surgeon is going to use fewer implanted components and fewer surgical incisions with our system in comparison," said Randy Ban, senior vice president of external operations. "We think that's going to be good for the patient."

But ImThera's chief executive believes the company's device will more easily win over physicians compared with either of its Midwestern competitors precisely because the technology doesn't sense respiration. ImThera's device stimulates multiple muscles of the tongue compared with Apnex's and Inspire's device, which only stimulates the largest muscle.

"The real reason they are sensing respiration is because they are worried about fatigue that comes from stimulating the same muscle," said Marcelo Lima, ImThera's CEO. "We target multiple muscles through six contacts affecting three or four muscle groups and we rotate them on an off."

He noted unlike Apnex and Inspire – whose therapy is aimed at forcing the tongue toward the front of the mouth, thereby preventing it from falling backward and blocking the patient's airway — ImThera's device flattens the back of the tongue, stiffens the side and protrudes the front of the tongue to prevent airway blockage that causes sleep apnea.

The investors

Inspire has raised $24 million from the likes of Kleiner Perkins Caufield Byers, Synergy Life Sciences Partners, GDN Holdings and U.S. Venture Partners. Medtronic, from which Inspire was created, has a big ownership stake in the company and also helps to manufacture certain parts, Ban said.

Apnex Medical has raised more — $30 million to date. Its investors are New Enterprise Associates, Domain Associates, Polaris Ventures and Michael Berman, a Minnesota-based medical device industry investor and entrepreneur.

ImThera has raised $10.6 million from wealthy individuals with expertise in medical device and biotech, as well as from physicians. The company is currently in another funding round with a strategic investor and an institutional investor, Lima said.

The path to regulatory approval

For the time being at least, it looks like Inspire is ahead in that the company has already received European clearance and a nod from the U.S. Food and Drug Administration regarding the study design for a full-scale clinical trial.

Inspire is currently recruiting patients at several among the 20 medical centers where the so-called STAR (Stimulation Therapy for Apnea Reduction) trial is being conducted. Most of the centers are in the U.S., but some are in Germany, France and the Netherlands. The estimated number of patients who will be enrolled is 480 and the expected completion date, including a one-year follow-up, is April 2013, according to Clinicaltrials.gov.

Inspire's Ban believes the company will enjoy significant first-mover advantage in the obstructive sleep apnea market. That confidence stems from the fact that Inspire has already conducted three feasibility studies and also because time and money have been spent in developing a market-ready product.

"We are currently in a commercially grade system and should be able to move right into a

commercialization with the system we use in our clinical trials," Ban said in a recent interview.

He expects a PMA approval in late 2013.

Strategy

Although Inspire won CE Mark clearance late last year, Inspire has yet to launch in Europe. Ban said the strategy has been slow and deliberate to allow Inspire officials to get more clinical experience with their product and choose patients carefully.

On the other hand, Apnex Medical is taking a different approach to Europe. Apnex, which hopes to get European clearance soon, plans to have what could be a limited commercial launch in Europe either late 2011 or early 2012, McKhann said.

ImThera expects to get CE Mark approval shortly as well and expects to launch there in second quarter.

In the U.S., both Apnex and ImThera are awaiting FDA clearance to begin enrolling patients in clinical trials.

ImThera's Lima said that because its device does not have the sensing mechanism which requires leads, more complex surgery and is more expensive, the market will adopt it more readily.

For his part, McKhann dismissed the notion that Inspire would have significant advantage if they came out with a product first.

"This is a market that's going to take a fair amount of market development to build experience and understanding about the therapy," McKhann said. "It's entirely possible that the first company out there has to do a fair amount of heavy lifting and one right behind it can come on board very quickly."

He added that there is opportunity for both companies to be successful given the large patient population. About 18 million people have obstructive sleep apnea in the U.S. and only 3 million are prescribed with continuous positive airway pressure masks, said Dr. Joseph Kaplan, director of Mayo Clinic's new sleep center in Jacksonville, Florida and a sleep apnea expert.

Can they persuade physicians?

CPAP masks are widely considered to be the gold standard for treating OSA. Ban and McKhann said the goal is to provide an alternative to patients who cannot stand to use those masks. That's because while CPAP works, the masks and the tubes make it cumbersome to use. Some people who are claustrophobic or who have skin rashes cannot tolerate it. Others simply don't want to use it.

"Studies have shown that 30 to 60 percent of people are not able to use that compliantly and routinely, and therefore there is a very large group of patients that are looking for something different," Ban of Inspire said.

While Kaplan agreed that patient compliance is an issue, his compliance percentage was higher and he wasn't sure that an implanted surgical solution would be the best treatment.

"Seventy percent of patients with sleep apnea are obese and if you can get them to lose weight, then the sleep apnea goes away or at least dramatically improves," he said, noting that there has been no published data about implanted neurostimulation therapy. "If you treat the sleep apnea but don't treat the obesity, they are still at risk for diabetes, vascular

disease stroke, heart attack. I kind of like the approach that gets the weight off — like bariatric surgery. It solves several problems."

URLs in this post:

[1] Image: **http://www.medcitynews.com/wordpress/wp-content/uploads/sleep_flickr.jpg**
[2] Inspire Medical Systems: **http://www.medcitynews.com../../2010/11/inspire-medical-gets-regulator-oks-for-sleep-apnea-therapy/**
[3] Apnex Medical: **http://www.medcitynews.com../../2010/06/apnex-medical-names-former-bsx-and-jj-executive-as-its-new-ceo/**