

Sweet dreams device

By **THOMAS LEE**, Star Tribune (Excerpts taken from print story on July 26, 2009)



Dr. Scott Augustine, left, CEO Augustine Biomedical+Design and Josh Waldman, right, CEO PureZone Technologies, are launching PureZone, a pillowcase that delivers ultra pure air.

High-tech, anti-allergy pillow is the latest idea to spring from the mind of veteran inventor Scott Augustine.

Dr. Scott Augustine wants to breathe a little fresh air into allergy treatment. Or more specifically, a bubble of fresh air. Augustine, a successful medical device inventor, is raising \$3 million to back PureZone Technologies LLC. The Eden Prairie start-up is developing a pillow-based air filtration system that creates a bubble of fresh air around allergy patients while they sleep.

Backed by a well-received clinical study, PureZone hopes to win over skeptical allergy doctors already wary of the glut of gee-whiz air cleaning devices on the market today that promise relief to allergy sufferers.

While such devices have become staples on television infomercials, they lack scientific credibility, experts say. Although PureZone's pillow system doesn't require approval from the Food and Drug Administration, the company sponsored a small clinical study last year that yielded promising results.

"We wanted to construct a study that met all of that skepticism in the most difficult environment -- allergists themselves," said CEO Josh Waldman, a veteran medical device entrepreneur recruited by Augustine to run PureZone. "If we can convince them that this is a valid product, we felt with all of the array of air purifiers, we would be different."

Augustine Biomedical's business model-- invent products, spin off start-ups, attract investors, then sell off companies -- is a more efficient way to commercialize technology, Augustine said. Plus, it allows Augustine to retain his core R&D team. "Our objective is to create products and to create value but not to get big," Augustine said. "I think this is a huge opportunity. The big companies in the medical device industry are doing very little R&D. They just buy other companies. We can be the supplier of those companies."

High hopes

Augustine has high hopes for PureZone because he says allergy patients have such a tough time sleeping at night. To relieve symptoms, doctors recommend patients remove the sources of allergens from the house, such as rugs or pets. But patients rarely do, Waldman said. "People won't get rid of their cats and dogs," he said. "They'd just as soon get rid of their spouse."

Air purifiers are only effective within six inches of the device before mixing with dirty air, Waldman said. The PureZone system aims to create a constant bubble of clean air around a patient's head by attaching a unique charged- fiber HEPA filter to a specially designed dual-chamber pillowcase made of pure organic cotton and a hypo-allergenic barrier fabric.

According to a 2008 clinical study of 35 patients conducted by the Minneapolis-based Clinical Research Institute, patients suffering from chronic allergies on average reported sleeping better and felt a meaningful reduction in allergy symptoms like itchy eyes and runny noses. "It impressed me," said Dr. Allan Stillerman, a board certified allergist with Allergy & Asthma Specialists PA in Minneapolis, who conducted the study. "The device affects the personal air space of patients using it during the night in a fixed location, a significant period of time when they are exposed to allergens like dust mites and cat and dog hair. Other devices may remove particles, but with PureZone the patient is sleeping with his face on an air purifier." Stillerman presented his findings to the annual conference of the American Academy of Asthma Allergy and Immunology in Washington, D.C.

Dr. James Sublett, a clinical professor and section chief of pediatric allergy at the University of Louisville School of Medicine, praised the study.

"Overall, it seems like a good, well controlled study," Sublett said. "It showed statistically significant improvement in symptom scores. I think the [PureZone] concept will be very helpful to allergy patients."

Waldman says PureZone will be ready for sale in late October via its website. In the meantime, the company is preparing to initiate a second clinical trial with children and teenagers who suffer from allergy-triggered asthma with enrollment sites in Rochester, Minneapolis, Louisville, and Atlanta. PureZone has already developed a chair-based system and hopes to make portable devices for air travelers.

"That's the magic of what we are doing," Waldman said. "The bubble doesn't disappear."