

A Medical Device Manufacturer with Products for People with Profound Hearing Loss or Impairment, Sophono, Inc. Offers the Sophono Alpha 2™ System, the Only Abutment-Free, Implantable, Bone-Anchored Hearing System Available Today

**Healthcare
Medical Devices**

Sophono, Inc.
5744 Central Avenue
Boulder, CO 80301
877 604 9441
www.sophono.com



**Jim Kasic
CEO**

BIO: Jim Kasic is a serial entrepreneur with over 20 years of experience in the Class II and III medical device industry. Jim is the president and CEO of Sophono, Inc. a manufacturer and distributor of implantable hearing devices. He is also the founder of Boulder BioMed, Inc. a medical product commercialization consulting firm, and 7L, LLC, a company that is pioneering a new treatment for morbid obesity. His range of experience spans large, multi-national organizations as well as start-ups with a domestic and

international scope. These include W.L. Gore and Associates, Boston Scientific, Battelle Memorial Institute, and Otologics. Among his accomplishments are the development of several unique implantable medical devices in vascular and otolaryngology fields. Mr. Kasic has been responsible for creating and successfully executing strategies in product and market development, and has built engineering, research, and sales and marketing organizations. These activities have resulted in more than 30 U.S. and international patents, and dozens of scientific publications. Mr. Kasic holds a Bachelor of Science degree in physics, a Master of Science degree in chemical/biological engineering from the University of Colorado and a Masters of Business Administration.

About Sophono, Inc.
www.sophono.com

Sophono, Inc. is a medical device manufacturer specializing in abutment-free, implantable, bone conduction hearing systems. The company's products are designed for individuals suffering from severe to profound hearing loss or impairment. The Sophono Alpha 2™ System is the only abutment-free, implantable, bone-anchored hearing system available today. Treating those with conductive hearing loss, mixed hearing loss, and single-ear deafness, the FDA-cleared Alpha 2 eliminates the problematic abutment of devices by using magnets to affix external sound processors.

Sophono corporate headquarters and manufacturing operations are located in Boulder, Colo. The company, incorporated in 2009, maintains an office in Germany, works with more than 20

distributors, and is actively selling in more than 30 countries.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Mr. Kasic, would you tell us the concept behind Sophono?

Mr. Kasic: At Sophono, we make an implantable hearing device used to treat conductive hearing loss and single-sided hearing loss.

CEOCFO: In terms of causes of hearing loss or types, how common are the areas that you work with, and what were the solutions available prior to Sophono?

Mr. Kasic: For conductive hearing loss and for single-sided hearing loss, we see an annual incident in the space of somewhere between 300,000 and 400,000 new cases every year. Because this portion of the hearing loss market is not well penetrated, only about 20,000 of those people – who need hearing help – receive treatment each year. We forecast that the backlog of patients who have not been treated over the years now numbers several million.

CEOCFO: What have you developed that is able to correct the problems?

Mr. Kasic: The reason for conductive hearing loss is that sounds cannot get from the outside ambient atmosphere to the patient's hearing organ (the cochlea). What Sophono has developed is an implant that consists of two small magnets, which a surgeon implants behind the ear on the skull. The wound is then closed. After it heals, an audiologist attaches an electrical mechanical vibrator – which we call a

sound processor – to the side of the head; it adheres via magnetic force.

The reason why this is novel, and important to patients and caregivers, is because there is no abutment; nothing sticking out of the patient's head. The traditional way of treating this type of ailment is to put a titanium stud through the skin and screw it to the patient's skull. Part of the stud is then in the patient's skull, and the other part of the stud sticks out of the patient's skin. With that technology, an audio processor clips onto this stud and then vibrates the skull. Along with being unsightly, this stud is fraught with complications from skin overgrowth and skin reactions. As skin is not designed to have something sticking out of it, these studs often get caught during physical activity and are torn out of the skull. With Sophono's approach, the implant lies completely under the skin and has none of these problems.

CEOCFO: What were the challenges in putting together the device, and why has this not been tried before?

Mr. Kasic: In Sophono's case, it was a matter of people slapping their heads and wondering why they never thought of it. Twenty years ago, the answer was to put a stud in the side of the head; it became an accepted practice. A generation of caregivers has grown up with this technology and believe it is the appropriate technology for treating this type of patient. When we explain our technology and the advantages, the response is usually, "Wow! This is so simple! How come nobody ever did it before?" Our answer is that we were willing to think outside of the box. The challenges for Sophono have been not so much in technical development, but more in the marketplace, gaining acceptance and overcoming the entrenched technology.

CEOCFO: How have you addressed the problem that you just mentioned?

Mr. Kasic: Sophono is addressing the challenge through a great deal of education, going back to the fundamental science, and comparing its clinical results to the clinical results of the en-

trenched product. It is about educating people on the clinical outcomes, and how Sophono achieves the same or better clinical outcomes than the incumbent product.

CEOCFO: Are you able to work with organizations that work with people with hearing problems in addition to the medical community?

Mr. Kasic: Yes, to a certain extent. There are not many very large non-profit or community organizations that specifically deal with hearing loss, so we have focused on building awareness and building these types of activities ourselves.

CEOCFO: There was a recent FDA clearance; is that the first?

Mr. Kasic: No, it was a market expansion. The recent FDA clearance was for our implant patients to be able to have an MRI. We obtained our CE mark in March of 2010. We received our FDA clearance to sell the product

"Sophono has a patented, sustainable technology that offers Sophono a decisive competitive advantage over the other hearing technologies. Our area of the hearing device market is the fastest-growing part of the hearing market today."- Jim Kasic

in the United States in June of 2011. We have been on the European market for almost three years and then on the US market for not quite two. Those were both with initial product design and since then we have increased our product offering all within the same family of products for treating conductive hearing loss and single-sided deafness.

CEOCFO: Is it easier today?

Mr. Kasic: It is getting easier to sell because we are able to provide more clinical data. We have more clinical centers, physicians and audiologists offering our products to their patients, and are seeing a snowball effect. Many people want to see somebody else do it before they will accept it; they want to see good clinical data before they will start. It is the chicken-and-egg syndrome: If you do not have people using the technology, you cannot get anybody else to start. Now that we have a good base, we are able to build on that, and things are starting to move faster and faster all the time.

For example, a year ago, Sophono "opened" one new center a week. Now, it's four to five new centers every week. Activity has really accelerated over the last year.

CEOCFO: Would you tell us what opening a center means for Sophono?

Mr. Kasic: Opening a center is when a particular hospital or physician's practice has its first Sophono patient implant. It means that Sophono has moved from providing the initial education on the technology and device to that physician's practice/hospital to the point where the center is purchasing the device and has patients for the device.

CEOCFO: Is the device reimbursable?

Mr. Kasic: Yes. The Sophono device is reimbursable. In fact, that is one of the reasons this technology has appealed to me so much in the time I have been in the healthcare industry (15 years) and medical products industry (more than 25 years). We have a technology that actually has a real advantage over the current technologies – an advantage that is not marginal, but quite

profound from a cosmetics perspective, from a reliability perspective, and from a lack-of-complications perspective. AND it is in a reimbursable market. We have all the reimbursement codes that allow payment from both private insurance and Medicare and Medicaid.

CEOCFO: What kind of business growth has the company achieved?

Mr. Kasic: Sophono is growing rapidly. We are seeing sales growth of 5-10 percent each month, which does add up. To get another 5 percent in sales each month means that we had to sell much more than we did the month before.

CEOCFO: Why should the business and investment community pay attention to Sophono, and what makes Sophono an exceptional company?

Mr. Kasic: I would like to say the people make it exceptional. I have a really good group of people who are all very knowledgeable in the hearing industry

and in implantable hearing devices. On top of that, I believe Sophono has a patented, sustainable technology that offers Sophono a decisive competitive advantage over the other hearing technologies. Our area of the

hearing device market is the fastest-growing part of the hearing market today – and with society's aging population, the hearing market itself is growing fairly rapidly. From an investor or collaborator standpoint, what

Sophono offers is huge market potential and a rapidly growing company – one that could easily dovetail into a company that already has a significant footprint in the hearing industry.



Sophono, Inc.

5744 Central Avenue

Boulder, CO 80301

877 604 9441

www.sophono.com