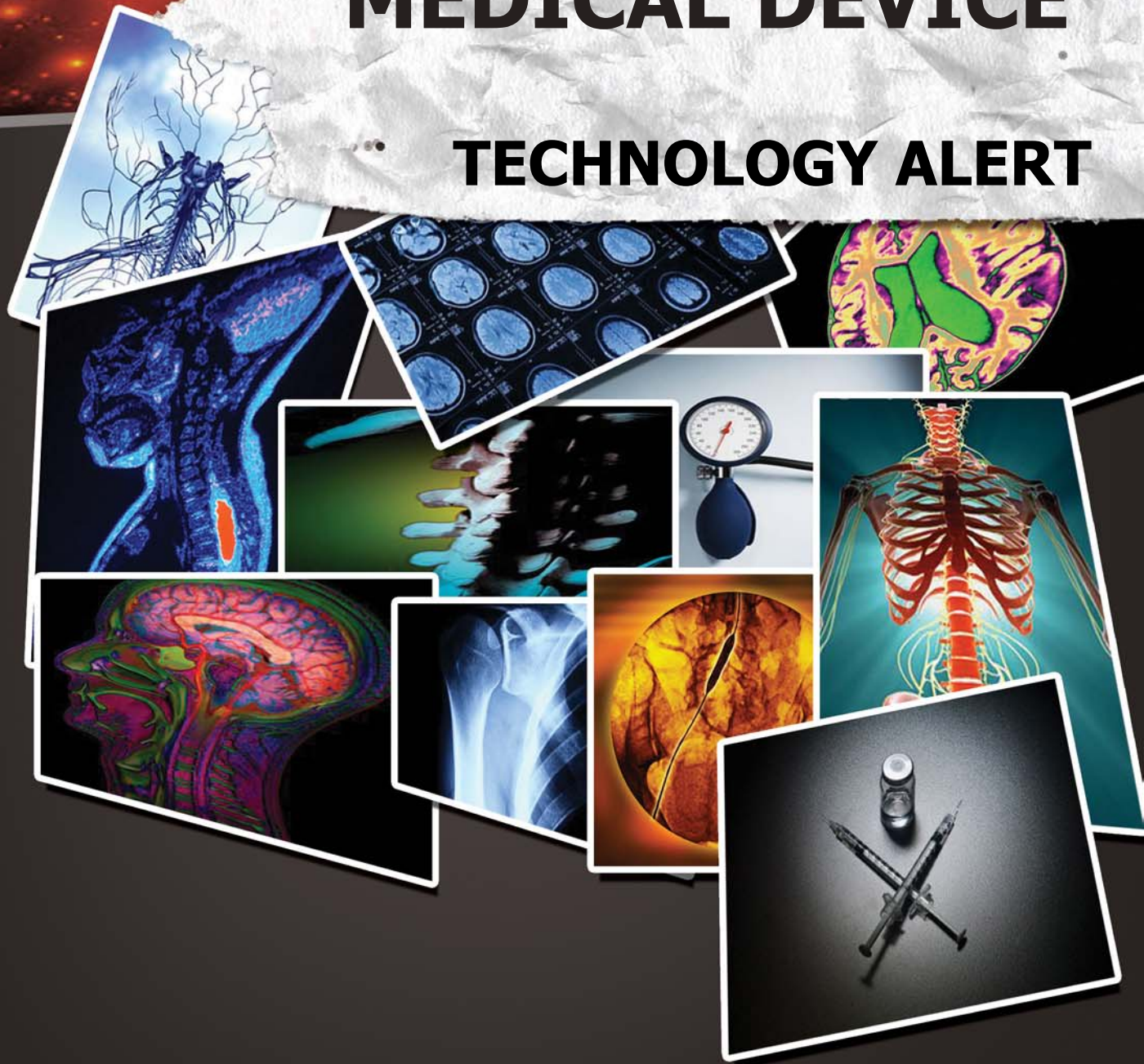


# TECHNICAL INSIGHTS

## MEDICAL DEVICE

### TECHNOLOGY ALERT



## **CLINICAL TRIALS IN COMMERCIALIZING RETINAL IMPLANTS**

The use of medical technology to treat debilitating vision disorders have been explored for more than a decade. Currently, more than 20 research groups are working in the area of designing a retinal implant. (Source: Institute of Ophthalmic Research, University of Tuebingen, Germany). Currently available devices target patients suffering from retinal disorders such as retinitis pigmentosa (RP) and other outer retinal degenerative disorders.

Retina Implant AG, Reutlingen, Germany is the developer of a retina implant, a subretinal chip that primarily targets an eye disorder affecting approximately 200,000 people worldwide, Retinitis Pigmentosa. The development was initially undertaken by a research consortium funded by German Ministry of Education and Research. The research was led by Eberhart Zrenner from the Center for Ophthalmology, Tuebingen, Germany, who has been developing the subretinal chip since 1995. He has demonstrated its biocompatibility, safety, efficacy, and biostability in animals and subsequent publications in reputed journals. The intellectual property (IP) portfolio of his development was later transferred Retina Implant AG in Reutlingen, Germany, which focuses on commercializing the retina implant.

The implant is designed in the form of a microchip with a size of 3 mm diameter, 50 micrometers in thickness and offers a resolution of 1500 pixels. Each pixel spans a size of  $70 \text{ um}^2 \times 70 \text{ um}^2$ , offering a visual field of 12 degrees, which aids high mobility and better object recognition. The microchip incorporates miniature photocells that absorbs light incident on the eye surface and converts it into electrical energy. Finally, the object perceived by the visual cortex is a result of the stimulation of the retinal nerves.

On a comparison note to other implants such as the Rizzo implant and Second Sight implants, Retina Implant differs in its approach in two key aspects. Primarily, the implant is inserted subretinal, which offers transmission of optical information along the natural vision pathway with a large visual field (8 degrees to 12 degrees). Further, it has also eliminated the need for an external camera, which is a part of other implants. On March 25<sup>th</sup>, 2010, the company announced initiation of a clinical trial, which will be lead by Robert MacLaren from the Nuffield Laboratory of Ophthalmology in Oxford University. The clinical trial is

planned for the time duration of 12 months and will be implanted in six patients suffering from RP. Speaking to *Technical Insights*, Walter Wrobel, CEO of Retina Implant AG said, "The clinical trial gave us very good knowledge on the safety and effectiveness of [the] Retina Implant. We had one patient from Finland who was able to read large letters of about 8 cm, and was also able to recognize fruits such as banana, apple."

The company expects CE approval for its Retina Implant by 2011. Wrobel said, "We have no clinical trials ongoing in the USA, and we are concentrating on the European market and the CE approval." The company currently observes the potential for its technology to penetrate the Japanese market and is planning to explore it after successful commercialization in Europe. A few aspects such as the subretinal approach and chip circuit design are patented under United States Patent and Trademark Office (USPTO) and European Patent Office (EPO). Wrobel said, "There was an agreement between the partners that, if a financial investor is ready to fund the development of this marketable device, then the IP portfolio would be sold as whole to this investor. In 2006 we found an investor who invested €15 million in the company, which helped us to hire employees and buy patents from the subretinal consortium." Wrobel also believes that their well-protected IP portfolio eliminates other competitive forces to employ a subretinal approach in their developments. The Retina Implant is planned to be commercially available at an estimated price of €40,000 primarily targeting patients suffering from RP. The company also has plans to explore the potential of its device for other central vision disorders such as age-related macular degeneration (AMD).

Details: Dr. Walter Wrobel, President & CEO, Gerhard-Kindler-Str. 8, D-72770, Reutlingen, Germany. Phone: +49-7121-39403; Ext.111. Fax: +49-7121-3640; Ext.115. E-mail: [walter.wrobel@retina-implant.de](mailto:walter.wrobel@retina-implant.de). URL: [www.retina-implant.de](http://www.retina-implant.de).