Subretinal Implant

The RETINA IMPLANT Alpha AMS

Information for Physicians
„Retinitis pigmentosa is like a room whose windows slowly close - forever."

People affected by retinitis pigmentosa (RP) will experience a slow progressive loss of visual field, in most cases eventually resulting in blindness. Our dedicated team of scientists and engineers carry out research and development with the aim of opening a window for RP patients – a window of hope.

Our implant, the RETINA IMPLANT Alpha AMS, can help restore a certain degree of useful vision.

A typical view of the fundus of the eye in retinitis pigmentosa. The arteries and veins emerging from the optic disk are clearly too narrow. Cellular refuse has collected around the retinal periphery in the form of dark pigment. Only in the center is there still an intact, red area of pigment epithelium with functional rods and cones, permitting - but only under bright illumination - a tunnel of vision. Whitish, thick, degenerated choroidal vessels still shimmer through around this remaining functional „island“. The macula, which is the area of sharpest vision in the center, is surrounded by an irregular small ring of diseased cells; this explains the reduced visual acuity.
Already in 2005, the first clinical study showed that 5 of 11 patients equipped with the first generation of our implant were able to recognise and identify the location of light sources, bright objects and, in one case, even recognise large letters of the alphabet (1/11).¹

In the following years, further clinical studies showed that our technology can provide implant carriers with useful information in the areas of both near and far vision.²

The best visual acuity measured to-date with the predecessor of the current model, the RETINA IMPLANT Alpha IMS, in one of the study participants was 20/546 (Landolt-C).² Despite a lack of colour, the limited visual field (up to 13°)³, and restricted visual acuity, some of the study participants exhibited a significant improvement in:

- light perception and localisation of objects (86%)²;
- activities of daily living (72%)²;
- experiences of daily life (45%), for example the recognition of outlines of people, faces, their own hand, buildings, headlights of cars in motion at night, etc.²

The RETINA IMPLANT Alpha AMS is the first and still the world’s only ocular implant which both has CE-approval and operates without an external camera. The eye’s own physiological signal processing capabilities remain intact and are being utilised.

Because the implant is positioned below the retina, the patient’s own eye movements and directions of gaze can be used for the localisation of objects.⁴

Experiential reports have shown that our implant can be a valuable source of support in the everyday life of patients.²
How does the RETINA IMPLANT Alpha AMS work?

The subretinal implant can partly replace the function of degenerated photoreceptors by electrically stimulating the retina to produce visual perceptions. A microchip converts incident light into electrical signals which are then passed on via electrodes to the still functional layers of the retina. These signals are then transmitted via the optic nerve to the brain, resulting in visual impressions.

The chip, 3.2 x 4 mm in size and 70 µm thick, contains 1,600 photodiodes which convert incident light into electric signals.

A receiver coil is implanted behind the ear. The transponder is magnetically connected whenever the user would like to activate the chip.

The hand-held device is used to adjust the RETINA IMPLANT Alpha AMS for optimum use.
For whom is the RETINA IMPLANT Alpha AMS best suited?

The subretinal implant was developed for patients with hereditary forms of retinal dystrophy, first and foremost retinitis pigmentosa. For the implant to do its work, the optics of the eye, along with the patient's inner retinal structures and optic nerve, must still be functional. In addition, an adequate ability to see must have developed during the patient's early years of life. At most, the patients should have only light perception in order to profit sufficiently from the implantation. Moreover, a good general state of health is a prerequisite for the surgery.

For patients with residual functional vision we offer the Transcorneal Electrostimulation (TES), a clinically tested therapy which can slow down the progression of the disease. ⁵, ⁶

For more information about the RI OkuStim system, please visit our homepage under www.retina-implant.de/en/therapy/ri-okustimr-product-magazine/

How does my patient get the RETINA IMPLANT Alpha AMS?

Treatment with our subretinal implant takes place only at certified RI Implantation Centres (www.retina-implant.de/en/services/find-a-specialist/). These clinics first determine the patient's suitability for a RETINA IMPLANT Alpha AMS. If the patient qualifies, the best individual implant size is then determined. This is followed by the implantation, which is carried out by a specially trained and qualified retinal surgeon. Experienced ophthalmologists then take over the medical aftercare of your patient.
What type of surgical intervention awaits my patient?

The implantation of the RETINA IMPLANT Alpha AMS is one of the most sophisticated operations in ophthalmology and is carried out over a period of several hours under general anesthesia. It consists of two parts: an extraocular part for retro-auricular placement of the receiver coil and an intra-ocular part in which the light-sensitive chip is positioned under the fovea centralis.

What is the course of rehabilitation?

In order to give your patient the best support to maximise the benefit from the RETINA IMPLANT Alpha AMS, an individually designed rehabilitation concept is worked out for each patient. The ophthalmologists at the RI Implantation Centre conduct regular aftercare appointments aimed at determining the state of health of the patient’s eyes. Moreover, our RI Implant Trainer arranges a series of visits at which the patient learns to adjust his or her implant to different light-conditions and to make best use of the new visual impressions in his or her personal surroundings. Specific tests are also conducted to measure visual performance and personal success. During the rehabilitation period we remain in constant contact with the physician in charge of the implantation centre in order to coordinate examination appointments in accordance with the patient's individual needs.
Will a health insurance cover the costs for the implant?

Reimbursement of the RETINA IMPLANT Alpha AMS in Germany is currently decided through the New Examination and Treatment Methods Procedure (NUB) of the statutory health insurance companies. For information on how to submit an application or reimbursement of costs in other countries than Germany, please contact us directly.

How can I inform my patient?

Please order the patient brochure - by telephone or by email. It contains further information about the RETINA IMPLANT Alpha AMS. We will gladly be available for any other questions. Also, please visit our section for professionals at www.retina-implant.de/en/login where you will find more information about the implant, the surgery, and the results of studies to-date.

Sources