

Argus® II Retinal Prosthesis System

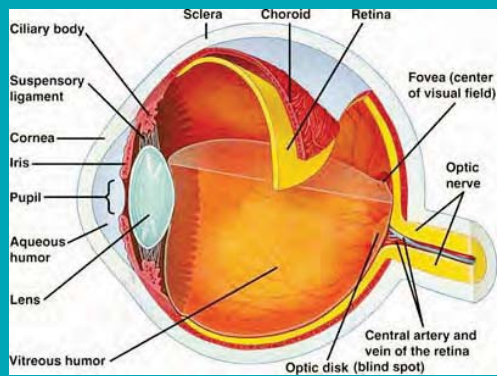
Restoring vision to the blind

Gregoire Cosendai, PhD VP Europe

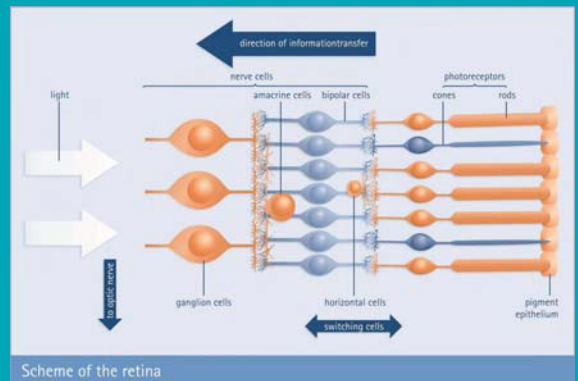
The Eye



The Eye's structures



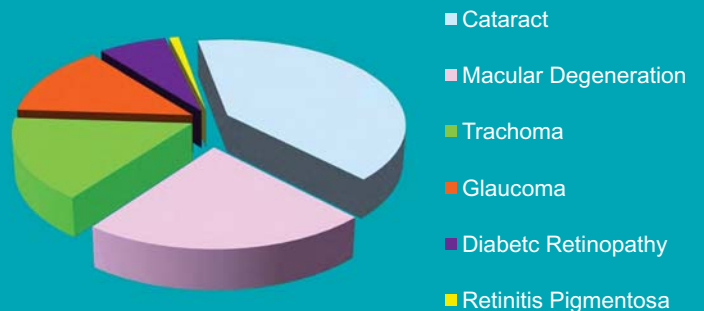
Retina: The Eye's Brain



45 Million BLIND People in The World



Causes of Blindness



What is Retinitis Pigmentosa (RP)

- A group of inherited diseases causing retinal degeneration
- Abnormalities of the photoreceptors or the retinal pigment epithelium cause loss of vision
- Incidence of RP in the US is estimated at 100,000

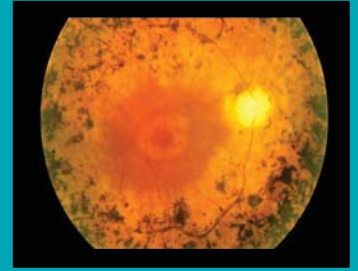
...and Macular Degeneration

- Macula suffers thinning and atrophy
- Leading cause of permanent visual impairment (ages 50+)
- Incidence in US is over 1.7 million

Retinitis Pigmentosa

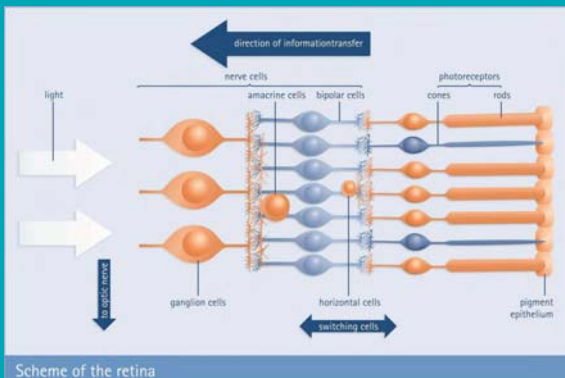


healthy retina



RP retina

Photoreceptor death



How does RP Blindness progress?

Generally:

- Night vision loss by age 20 - Stage I
- Peripheral vision loss by age 30 - Stage II
- Legal blindness by age 40 - Stage III
- Complete blindness - Stage IV

No treatment

Research Therapeutic Strategies

1. Repair the Genes (I-II)
2. Slow the disease (I-II)
3. Regenerate photo receptors (II-IV)
4. Make other cells perceive light (III-IV)
5. Bypass retina (III-IV)

A "Second Sight"

Second Sight® Medical Products Inc.

Founded: 1998

Product: Retinal Prosthesis

Target Population:

Retinitis Pigmentosa (RP)

Founders:

Al Mann

Other private investors

President: Robert Greenberg

Other Funding:

NIH DOE

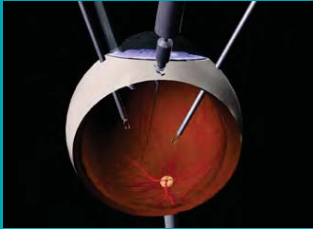


Argus® II Epiretinal Prosthesis Systems

Twenty years ago, in 1992...

Acute Human Studies

- 1-2 hours of stimulation
- 15 patients
- Local anesthesia
- Demonstrated perception of phosphenes

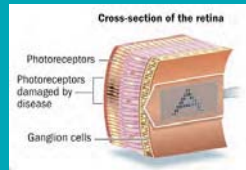


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Argus® Epiretinal Prosthesis Systems

...towards the active implantable device:

- Uses electrical stimulation to bypass defective photoreceptors and stimulate remaining viable retinal cells.
- Image data from an external camera is wirelessly transmitted to the implant which stimulates electrodes in an array on the retina to produce formed vision.
- Robust and designed to last a lifetime.



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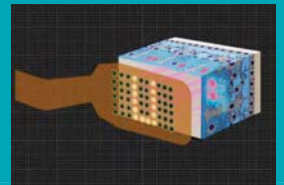
Argus® II Retinal Prosthesis System



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Argus® II Retinal Prosthesis System

- Argus II is intended to provide electrical stimulation of the retina to induce visual perception in blind individuals
- Argus II is approved for use in the European Economic Area (CE Mark)



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Argus® II Retinal Prosthesis System

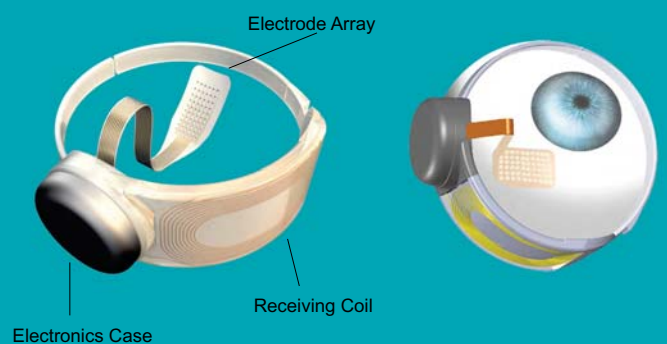
Indications for Use:

- Adults, age 25 years or older
- Severe to profound outer retinal degeneration
- Some residual light perception remains, the retina must be able to respond to electrical stimulation
- Previous history of useful form vision



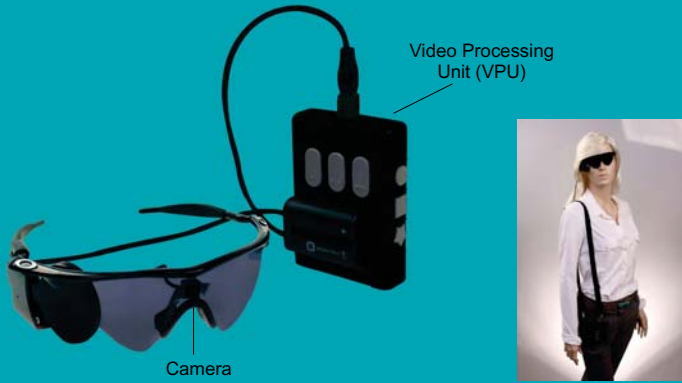
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Argus® II Retinal Prosthesis System



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Argus® II Retinal Prosthesis System



Argus® II Surgery

Argus® II Surgical Procedure



Scientific Results of Argus® II

Enrolment / Demographics

	Worldwide
Subjects (n)	30* (26 right eye, 4 left eye)
Age at Time of Implant (years)	58 \pm 10 (range 27 – 77)
Female : Males	9 : 21
# Years Implanted	2.7
Median Surgery Time (hours)	4:04 (range 1:53 – 8:32)
Diagnostic at implant	29 Retinitis Pigmentosa 1 Choroideremia
Acuity at implant	30 Bare Light Perception (worst seeing eye implanted, comparable vision in both eyes)

Performance Measurements



Performance Tests



Performance With System

Performance	% of subjects who perform better with System ON versus OFF
Visual Function Test	
Visual percepts	100%
Square localization	96% perform better ON vs. OFF
Direction of motion	57% perform better ON vs. OFF
Grating visual acuity	23% perform better ON vs. OFF (>2.9logMAR) Best acuity 1.8 logMAR (20/1260)
Orientation / Mobility	
Following a line	significantly better ON vs. OFF ($p < 0.05$)
Finding a door	significantly better ON vs. OFF ($p < 0.05$)

Ophthalmology

Reprint

Interim Results from the International Trial of Second Sight's Visual Prosthesis

Mark S. Humayun, Jessy D. Dorn, Lyndon da Cruz, Gislin Dagnelie, José-Alain Sahel, Paulo E. Stanga, Artur V. Cideciyan, Jacques L. Duncan, Dean Elliott, Eugene Fliley, Allen C. Ho, Arturo Santos, Avinoam B. Safran, Arias Arditi, Lucian V. Del Priore, Robert J. Greenberg

Benefits of Argus® II

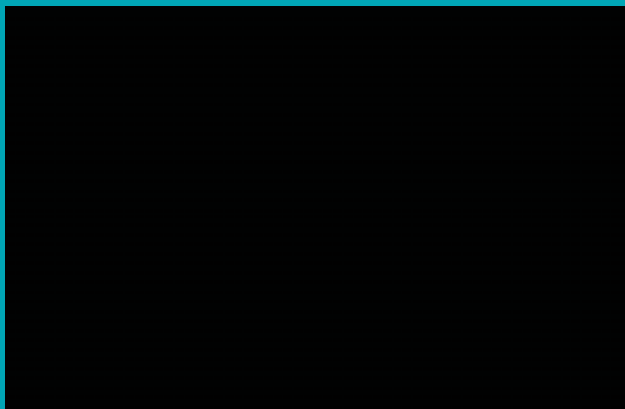
- Improvements in ability to perform visual tasks demonstrated in many patients
 - Object detection
 - Direction of motion
 - Orientation and mobility
 - Visual acuity



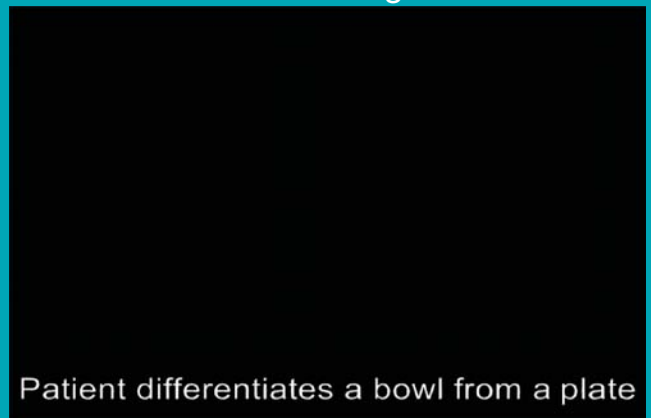
Benefits of Argus® II



Benefits of Argus® II

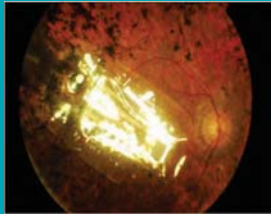


Benefits of Argus® II



Features of Argus® II

- Most clinical experience of any retinal prosthesis ever developed
- As of May 2011, 86 patient-years experience has been gathered overall



Features of Argus® II

- Conventional vitreo-retinal surgery that can be done in as little as 2 hours (mean is 4 hours)
- Minimal time from implantation to first system use and use at home



Features of Argus® II

- Upgradable hardware and software to benefit from future innovations
- Video processor with adjustable settings for individual preferences - ex.:
 - Edge enhancement
 - Contrast enhancement
- Individually programmable electrodes



Features of Argus® II

- Implant is MR conditional
- 20° maximum possible field of view
 - Can be compared to a 30 cm (12 in.) ruler held out at arm's length
- Audible signals that provide information on system functionality



THANK YOU