



ECE 370
Introduction to Biomedical Engineering

Implantable Devices

Did you know that ...



- **Hearing loss is the 4th most prevalent disability after mobility, pain and agility.**
- **40% of persons over the age of 65 report a significant hearing loss**
- **Today's youth are also at risk of significant hearing loss**
 - At 85 dB, you can listen to music for 8 hours with no damage. But for every 3 dB increase, cut that time in half.
 - 4 hours for 88 dB
 - 2 hours for 91 dB (subway, lawnmower)
 - ½ hour for 97 dB (motorcycle)
 - 15 minutes at 100 dB (school dance)
 - for a concert which can be 110 dB and above... less than a minute!



Hearing Loss



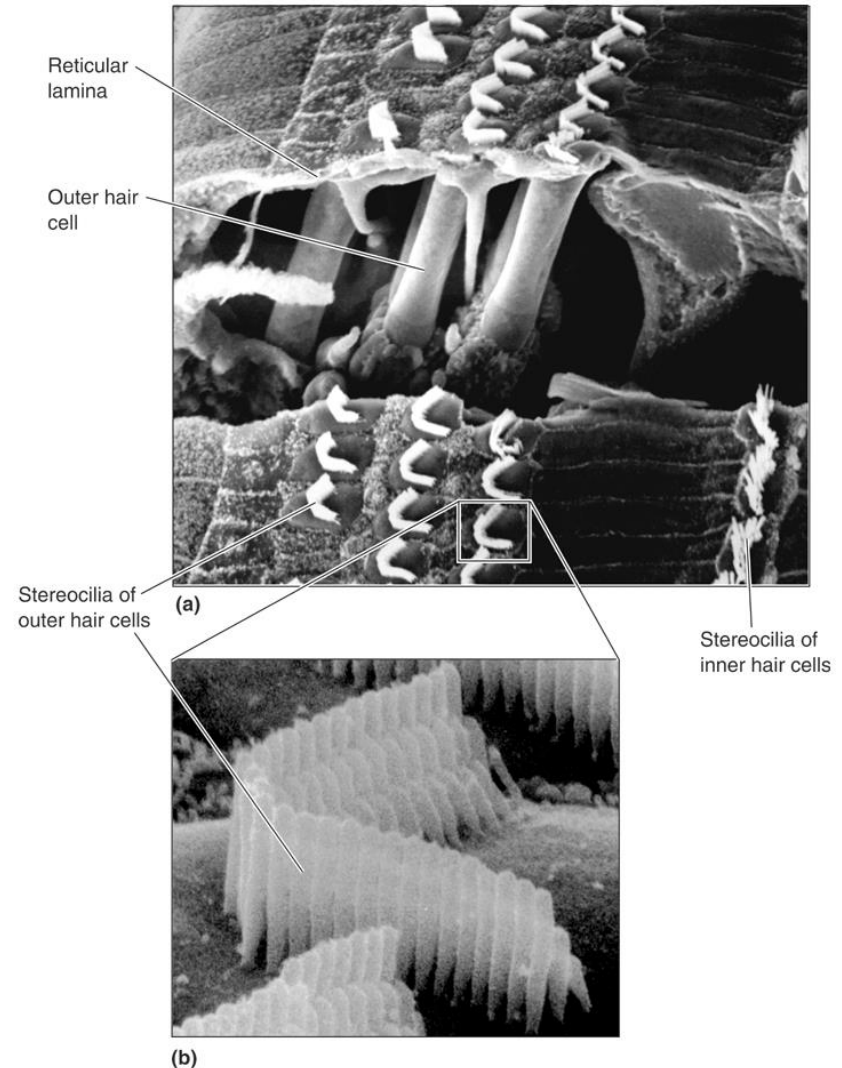
- **Deafness**

- **Conductive**

- Sound waves not adequately conducted through external and middle portions of ear
 - Blockage, rupture of ear drum, middle ear infection, middle ear adhesions
 - Hearing aids might help

- **Sensorineural**

- Sound waves conducted but not translated into electrical signals
 - Neural presbycusis, certain antibiotics, poisoning
 - Cochlear implants might help
 - Electrical devices stimulating the auditory nerve directly

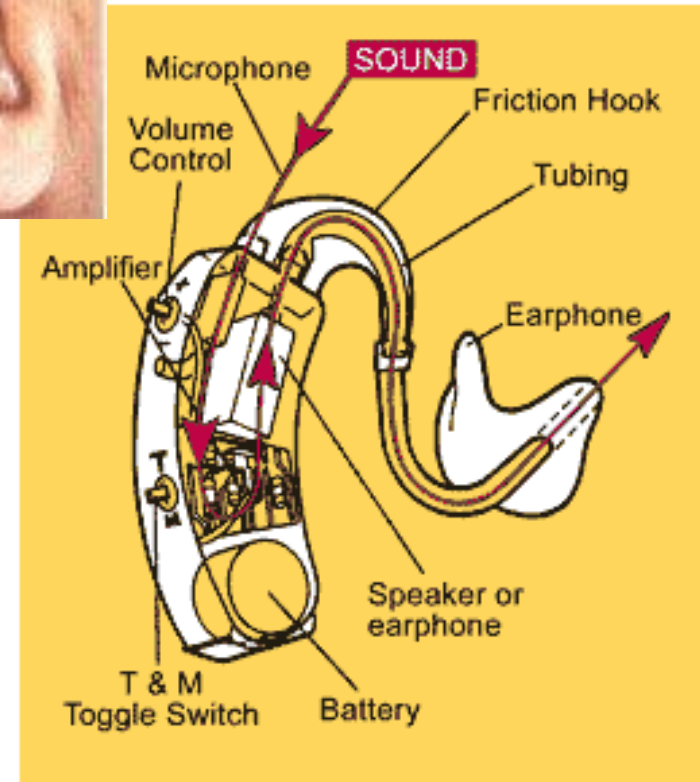


Neuroscience: Exploring the Brain, 3rd Ed, Bear, Connors, and Paradiso Copyright © 2007 Lippincott Williams & Wilkins

Hearing Aids



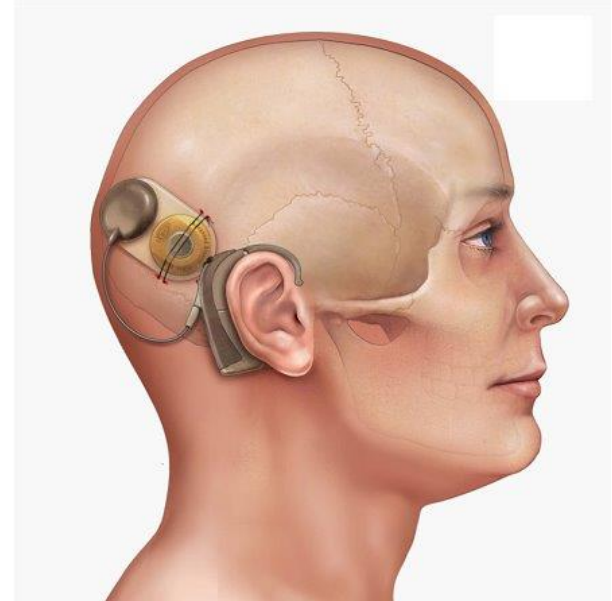
- **Conductive hearing loss → hearing aids**
- **Common parts of hearing aids**
 - A battery
 - A microphone
 - An amplifier
 - Loudspeaker
- **Hearing aids amplify all sounds**
 - Including noise
- **Hearing aids will help hearing in many situations**
 - Benefits of hearing aids depend on several factors
- **Hearing aids do not completely correct a hearing loss 100%**
- **Adjusting to hearing aid(s) is a long process**



Cochlear Implants



- **Sensorineural hearing loss → cochlear implants**
- **How is a Cochlear Implant Different from a Hearing Aid?**
 - Hearing Aids:
 - Acoustically amplify sound
 - rely on the responsiveness of surviving hair cells
 - Cochlear Implants:
 - Bypass damaged hair cells
 - Convert the acoustic input signal into electrical impulses to stimulate the auditory nerve fibers in the cochlea.

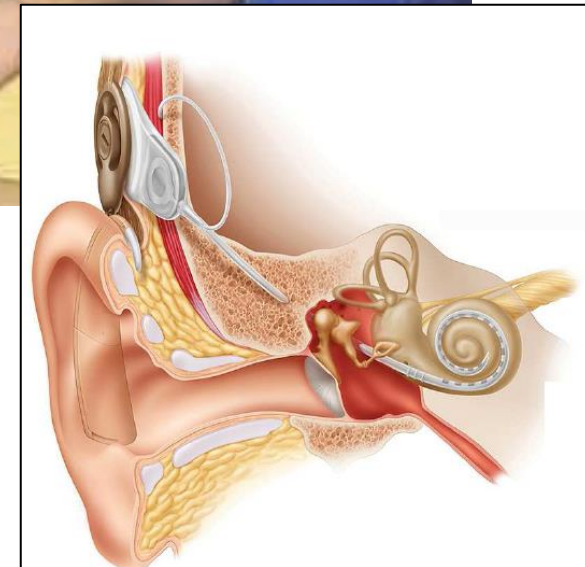


Cochlear Implants



- **What is a Cochlear Implants?**

- A small, electronic device that helps provide sound to a person who is severely hard-of-hearing or who is severely deaf.
- Gives deaf users a sense of sound and helps in understanding speech.
- Cochlear implants do not produce normal hearing or make sounds louder like hearing aids do.

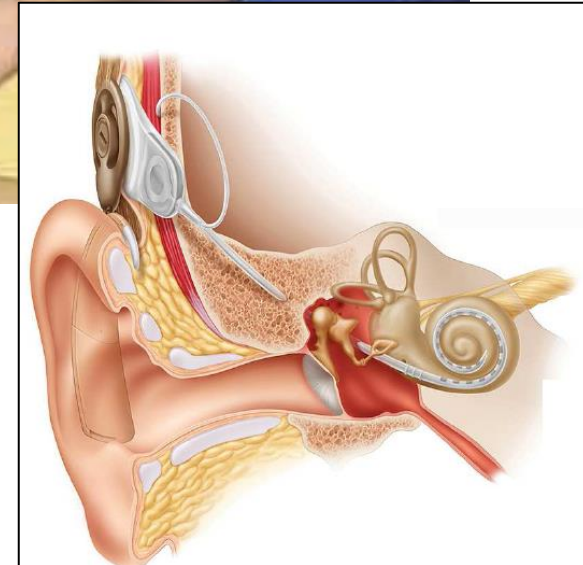


Cochlear Implants



- **What is a Cochlear Implants?**

- The cochlear implant bypasses damaged parts of the inner ear and electronically stimulates the nerve of hearing. Part of the device is surgically implanted in the skull behind the ear and tiny wires are inserted into the cochlea.



Cochlear Implants



History

- **Pre-1960's**
 - beginning studies of electrical stimulation on humans
- **1960's**
 - active research of electrical stimulation in human ears
- **1970's**
 - first wearable implants designed for long-term stimulation
- **1980's**
 - commercial development of the cochlear implant device began
- **1985**
 - United States Food & Drug Administration (FDA) granted the first approval for implantation in adults
- **1990**
 - FDA granted approval for cochlear implants in children
- **Today**
 - cochlear implantation is a safe and effective medical procedure for individuals who are severely to profoundly deaf with minimal benefits from conventional hearing aids



Cochlear Implants



- **Parts of a cochlear implant**

- **External**

- Microphone: allows sound from the environment to be picked up.
 - Speech Processor: arranges sounds picked up by a microphone.
 - Remote control

- **Implantable**

- Receiver/Stimulator & Transmitter: receives signals from the speech processor and converts them into electric impulses
 - Electrode Array: a group of electrodes that collects the impulses from the stimulator and sends them to different regions of the auditory nerve

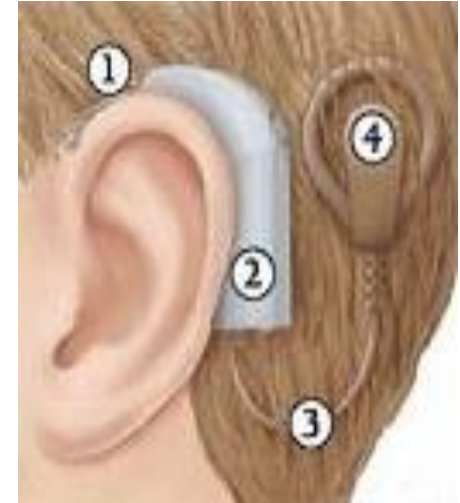


Cochlear Implants



- **How cochlear implants work**

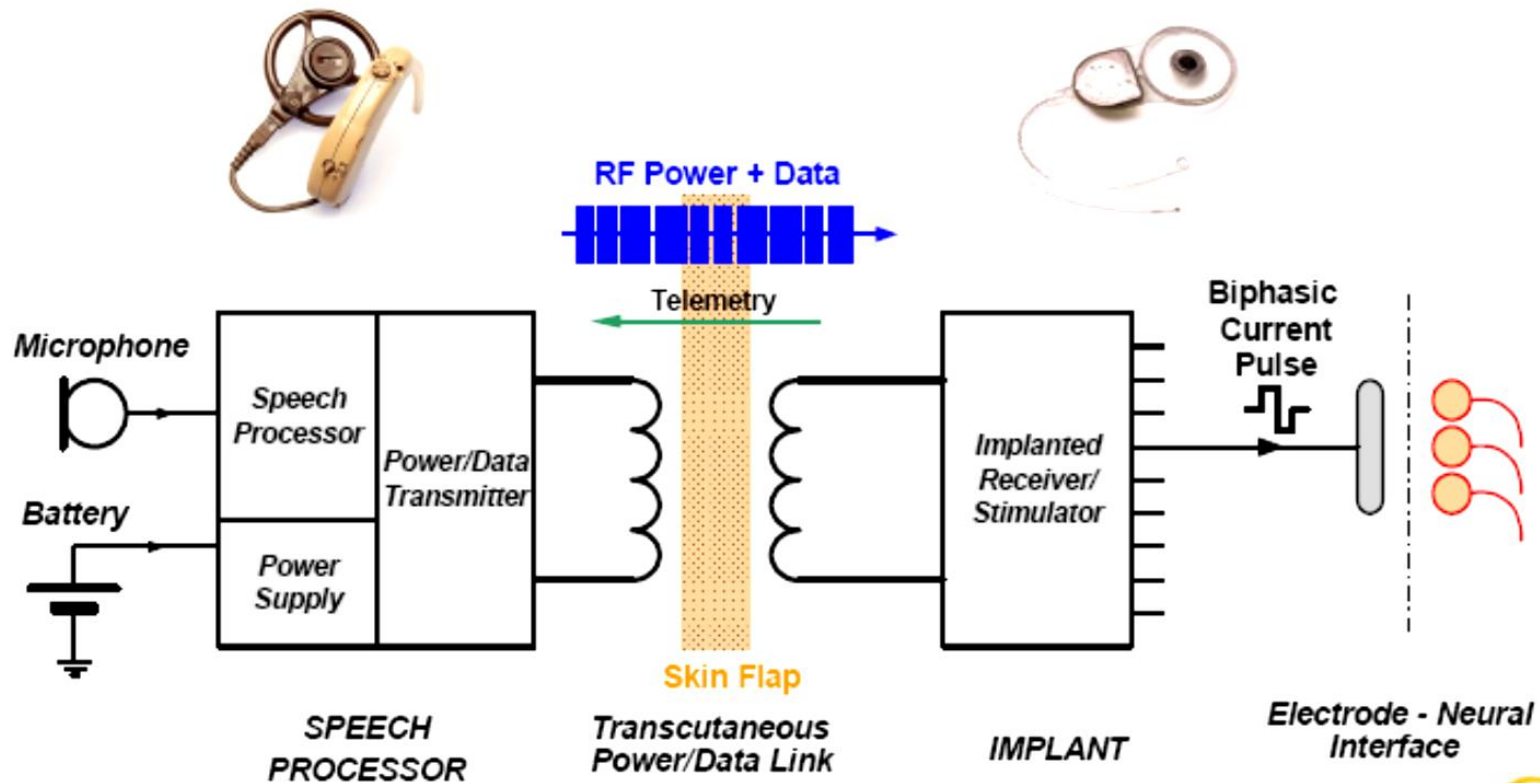
1. Sounds are picked up by the small, directional microphone located in the ear level processor.
2. The speech processor filters, analyzes and digitizes the sound into coded signals.
3. The coded signals are sent from the speech processor to the transmitting coil.
4. The transmitting coil sends the coded signals as FM radio signals to the cochlear implant under the skin.
5. The cochlear implant delivers the appropriate electrical energy to the array of electrodes which has been inserted into the cochlea.
6. The electrodes along the array stimulate the remaining auditory nerve fibers in the cochlea.
7. The resulting electrical sound information is sent through the auditory system to the brain for interpretation.



Cochlear Implants



- **Block Diagram for Typical Cochlear Implant System**

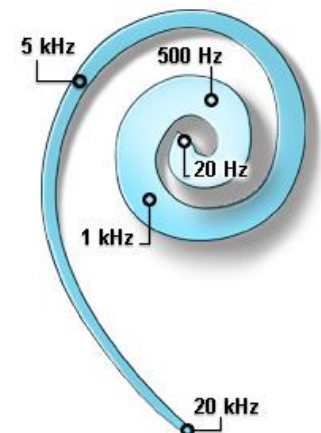


Cochlear Implants



Cochlear Implant Characteristics

- **Electrode design (e.g., number of electrodes, electrode configuration)**
 - Electrode placement
 - Near the round window of the cochlea (extracochlear), or
 - In the scala tympani (intracochlear) (most common), or
 - On the surface of the cochlear nucleus.
 - Orientation of electrodes with respect to the excitable tissue is also important
- Number of electrodes and spacing of contacts
 - Affects the resolution for coding frequencies.
 - Larger number of electrodes, the finer the resolution.
 - Single-channel implant:
 - Only transmits temporal information, loudness cues and rate information.
 - Multiple-channel implant:
 - Electrodes that stimulate different regions of the cochlea.
 - Transmits pitch information as well as temporal information.



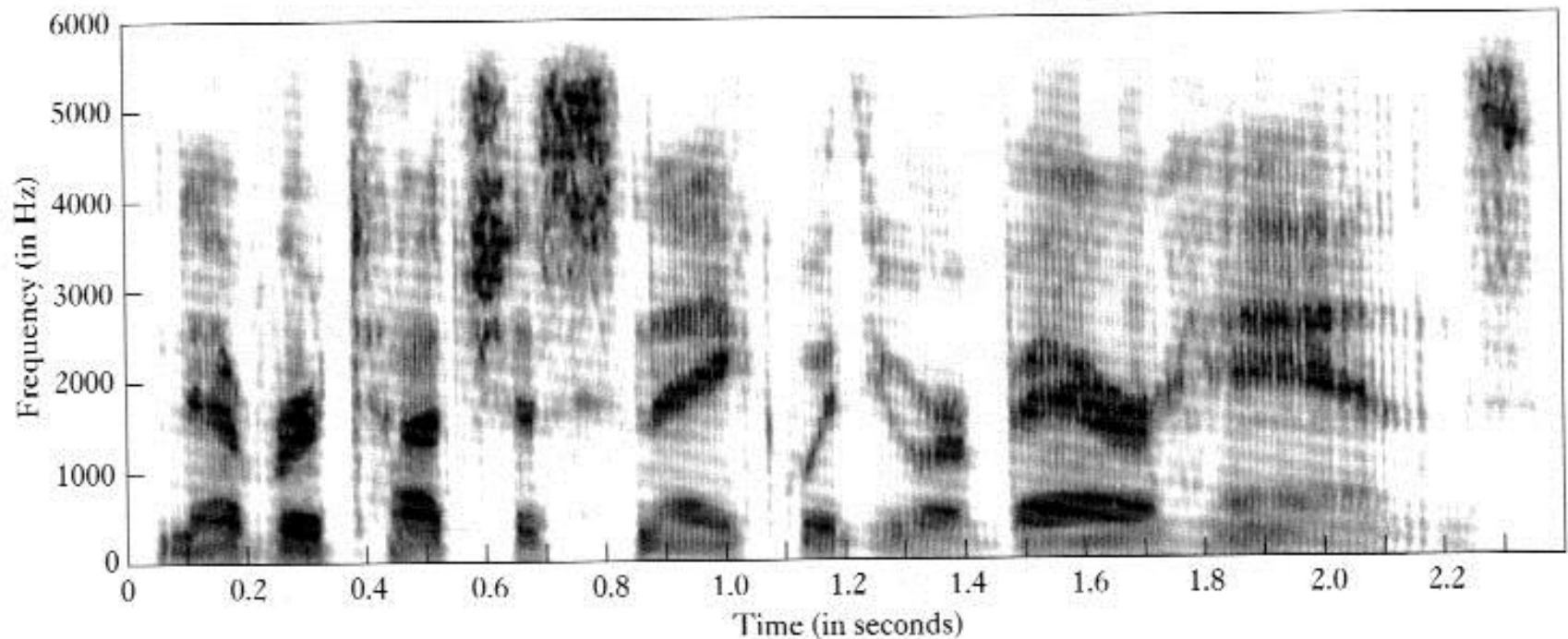
Cochlear Implants



Cochlear Implant Characteristics

- So How Many Channels do you need?

“Never touch a snake with your bare hands.”



Cochlear Implants



Cochlear Implant Characteristics

- **So How Many Channels do you need?**
 - 4 is enough for simple speech in quiet
 - More channels needed for more difficult materials or in noise or with less experience
 - Even more channels needed for even simple familiar melody recognition
 - Are lots of channels even enough for complex musical pitch and sound quality?

Cochlear implant simulations:

- Single channel



- 2 channels



- 3 channels



- 4 channels



- 6 channels



- 8 channels



Cochlear Implants



Cochlear Implant Characteristics

• Type of stimulation - analog or pulsatile

- Analog stimulation
 - The acoustic waveform is bandpass filtered, and the filtered waveforms are presented to all electrodes simultaneously in analog form.
 - Nervous system will sort out and/or make use of all the information contained in the raw acoustic waveforms.
 - Disadvantage
 - Simultaneous stimulation may cause channel interactions.
- Pulsatile stimulation
 - The information is delivered to the electrodes using a set of narrow pulses.
 - Advantage
 - Delivered in a non-overlapping (i.e., non-simultaneous) fashion, thereby minimizing channel interactions.

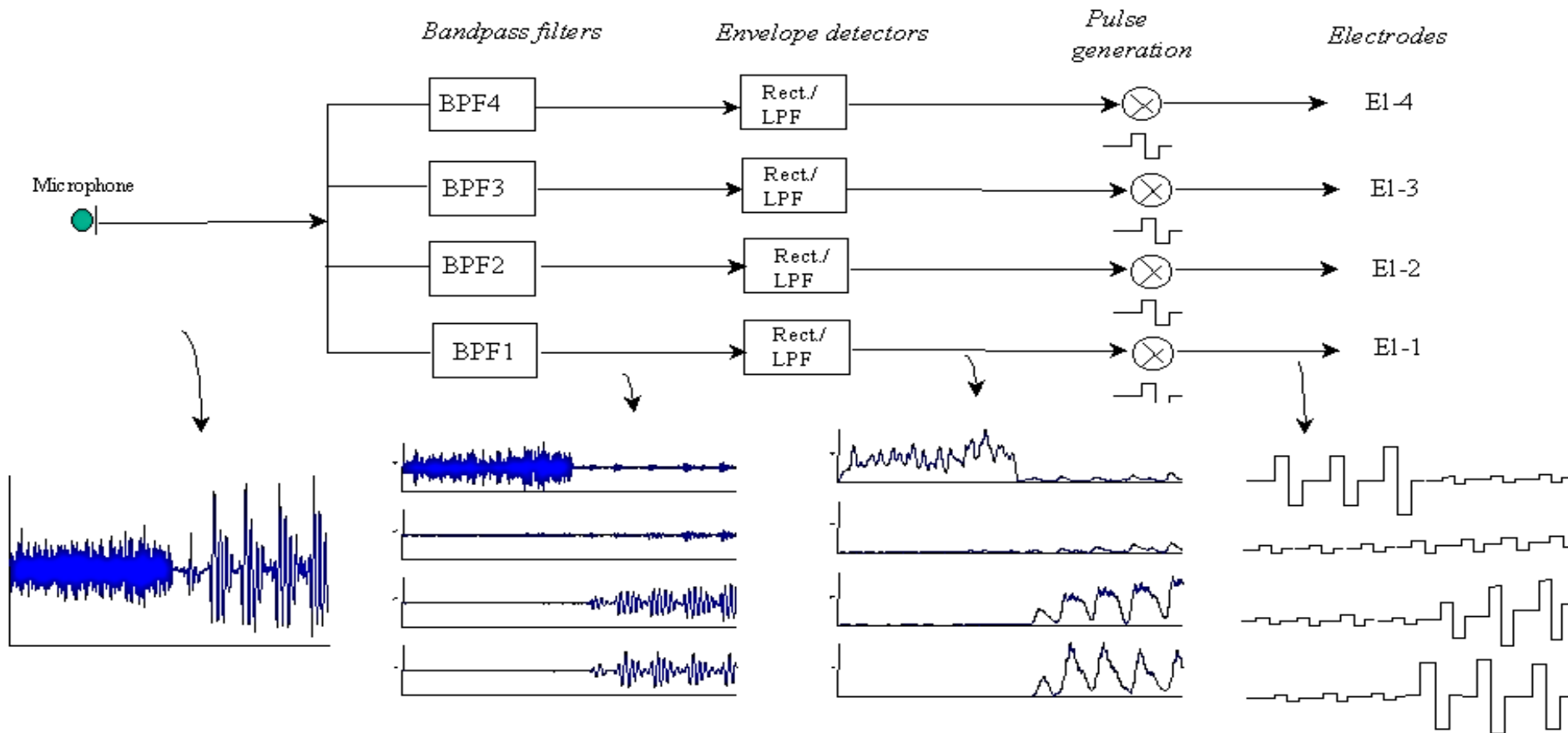
• Modes of stimulation

- Bipolar:
 - All electrodes inside the cochlea
 - Stimulation takes place between two electrodes.
- Common-ground:
 - All electrodes inside the cochlea
 - Stimulation takes place between one electrode and all other electrodes.
- Monopolar:
 - One extra-cochlear electrode
 - Stimulation between an intracochlear and the extra-cochlear electrodes.

Cochlear Implants



- Four Channel example



Cochlear Implants



- **Cochlear Implant Characteristics**
- **Transmission link - transcutaneous or percutaneous**
 - Transcutaneous system transmits the stimuli through a radio frequency link.
 - External transmitter encode the stimulus information for radio-frequency transmission from an external coil to an implanted coil.
 - Transmitter and the implanted receiver are held in place on the scalp by a magnet.
 - Disadvantage:
 - Implanted electronics may fail, and require a surgery replacement.
 - Transcutaneous connector contains magnetic materials which are incompatible with MRI scanners.
 - Percutaneous system transmits the stimuli to the electrodes directly through plug connections.
 - No implanted electronics except the electrodes.
 - Advantages of percutaneous are flexibility and signal transparency.
- **Signal processing - waveform representation or feature extraction.**
 - Spectral peak (Nucleus)
 - Continuous interleaved sampling (Med-El, Nucleus, Clarion)
 - Advanced combined encoder (Nucleus)
 - Simultaneous analog strategy (Clarion)

Cochlear Implants



Safety Considerations

- **Biomaterials:**

- with the proper choice of materials there is no infection, just a minor fibrous sheath around the implant.

- **Electrode Insertion trauma:**

- factors: surgical technique, dimensions, array's mechanical properties
- If damage occurs to basilar membrane and dendrites, could lead to retrograde deterioration. However, are few and far between in most sensorineural hearing loss cases.
- For most part damage is minimal.

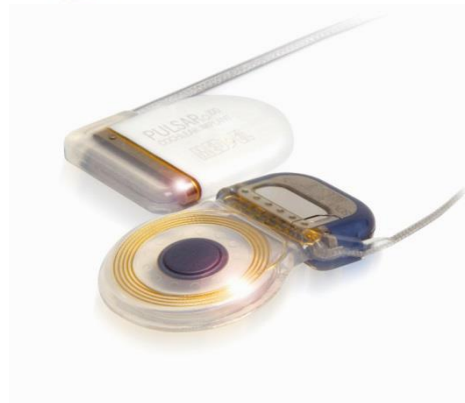
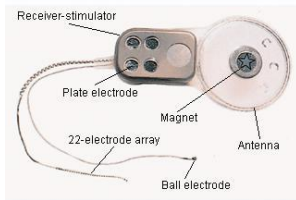
- **Chronic Electrical Stimulation**

- Platinum electrodes: virtually no corrosion or depletion
- Doesn't destroy AN, in fact can help keep auditory nerve and cells in cochlear nucleus healthy (Leake et al 1992)
- impedances and thresholds stabilize several days post implant

Cochlear Implants



• Manufacturers



Cochlear Corporation

- First FDA approved multichannel devices
- 22 channels available for stimulation

Advanced Bionics

- 16 channels with 16 individual current drivers
- Titanium casing

Med-El Corporation

- less signal loss and less power consumption
- 12 channels of stimulation

Cochlear Implants



- **Who is a Candidate?**
- **Candidates for implants are adults or children (12 months or older) with all of the following:**
 - Profound or severe hearing loss in both ears (nerve deafness).
 - Have tried hearing aids but receive little or no benefit from them in understanding speech by listening alone.
 - No medical reason to avoid surgery.
 - A commitment to auditory/oral communication and its intensive therapy.
 - Realistic expectations about results.
- **~70,000 recipients worldwide (~21,000 in the U.S.)**
 - *
 - 50% children (12 mo-17 years); 50% adults *



Cochlear Implants



- **Who benefits from cochlear implants?**

- Adults
 - Cochlear implants can benefit adults.
 - Adults can learn how to recognize the signal provided by the implant with sounds that they memorize.
- Children
 - Most children receive implants between the ages of two and six years old.
 - Neural plasticity
 - For speech articulation: 2-3 years
 - For Listening: 6-8 years
 - Children who have cochlear implants can benefit from them by allowing them to help build upon their language, speech, and social skills.
 - Helps children get back their sense of hearing.



Cochlear Implants



- **What are some potential benefits?**

- Better speech understanding compared to a hearing aid
- Awareness and responsiveness to environmental sounds
- Less dependence on family members for day to day living
- Reconnection with the world of sound
- Facilitation of communication with family and loved ones
- Ability to talk on the phone
- Better appreciation of music



Cochlear Implants



- **How much does it cost?**

- Costs connected to cochlear implants starts at the pre-operation, surgery, post-operation, and therapy/rehabilitation.
- The average cost for the entire procedure including the post-operation and therapy/rehabilitation exceeds \$40,000.

- **How does someone receive cochlear implants?**

- Cochlear implants are surgically implanted behind the person's ear.
- A person with cochlear implants also receives a certain type of therapy to learn how to get a sense of hearing.

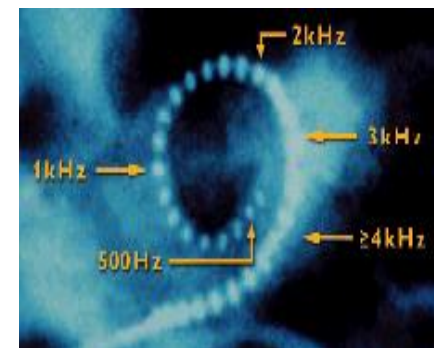
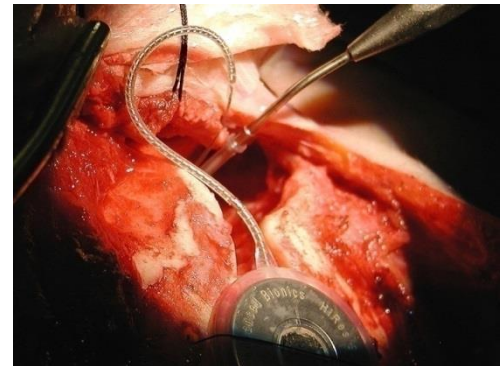
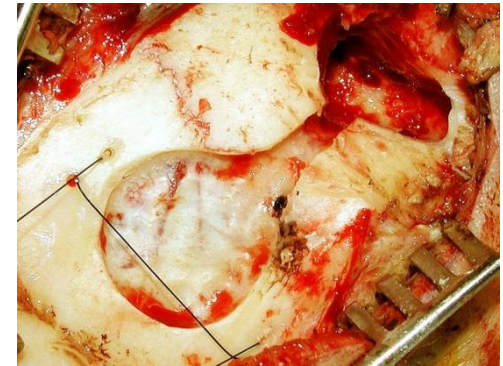


Cochlear Implants



• Procedure

- Evaluation
 - Audiological
 - Medical
- Surgery
 - Inpatient procedure
 - Requires general anesthesia
 - Duration ~ 3-4 hours
- Impedance check on all electrodes
- Neural response testing to help estimate required levels
- X-Ray to confirm position of internal device



Cochlear Implants



- **After the surgery**

- Initial stimulation: 4-6 weeks post surgery
- Adjustments made regularly based on feedback from patients, parents, therapists and educators
- Rehabilitation to meet specific patient needs
- Regular follow-up appointments



Cochlear Implants



- **Factors Effecting Cochlear Implant Performance**

- Duration of deafness
- Age of onset of deafness
- Age at implantation
- Duration of cochlear implant use
- Other:
 - Number of remaining auditory nerve fibers
 - Electrode placement and insertion depth
 - Dynamic range



Cochlear Implants



- **Positive psychological & social benefits**

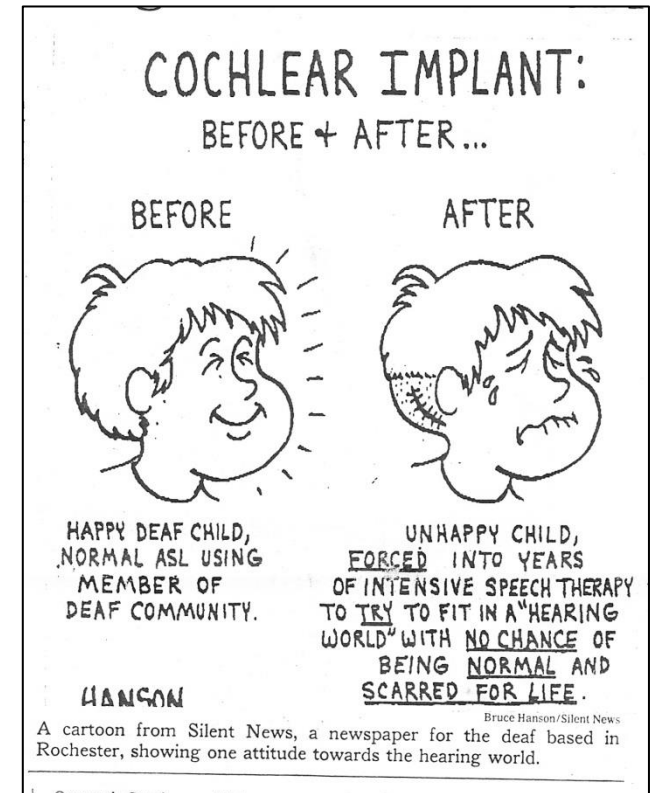
- Decline in:
 - Loneliness
 - Depression
 - Social isolation
- Increase in:
 - Self-esteem
 - Independence
 - Social integration
 - Vocational prospect

- **Negative psychological & social impacts**

- Concerns about the maintenance and/or malfunctioning of the Cochlear Implant
- Difficulty in background noise
- Unreasonable expectations on the part of the implant user or their family and friends

- **Views of people in the Deaf Community**

- Cochlear implants threaten sign language and Deaf culture



Cochlear Implants



• Future Research Directions

- Better understanding of fundamental mechanisms
- Better speech processing algorithms
- Electrode design improvements
- Objective fitting for young children
- Aesthetics (smaller, totally implantable)

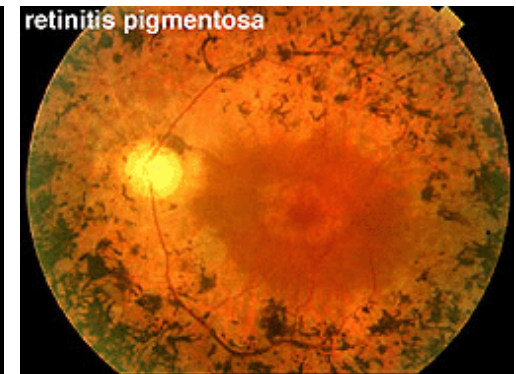


Retinal diseases



- **Retinitis pigmentosa**

- Loss of photoreceptors in periphery, working inward
- Genetic, strikes at age 15-60
- Typically a decade or less to go blind
- 100,000 cases in US, 1.7M worldwide
- Affects 1 in 3500 births



Retinal diseases



- **Age-related macular degeneration**

- Loss of photoreceptors in macula (center), working outward
- Strikes at age 60-80 with increasing incidence
- May take decades to go blind
- Presently afflicts 1.7 million in the U.S., tens of millions worldwide
- 700,000 new cases annually in the U.S. alone



Visual Prosthesis



- **Visual Prosthesis**

- An electronic implantable device to restore functional vision to patients with certain forms of blindness, primarily retinal degenerative diseases.
- The device works by stimulating nerves in the visual system based on an image from an external camera.

- **Goals**

- provide visual perception to blind patients
- high resolution
- long-lasting
- adjustable
- Convenient to use
- comfortable to wear

- **Prostheses are categorized into two major types:**

- Extraocular
 - The device is placed outside the eye
- Intraocular
 - The device is placed inside the eye



Visual Prosthesis



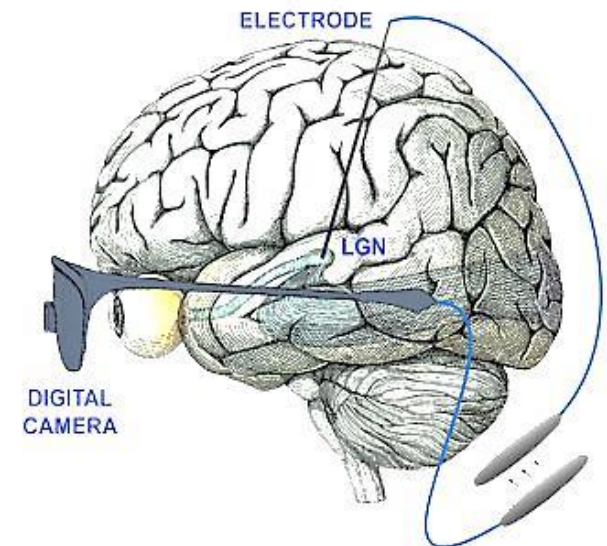
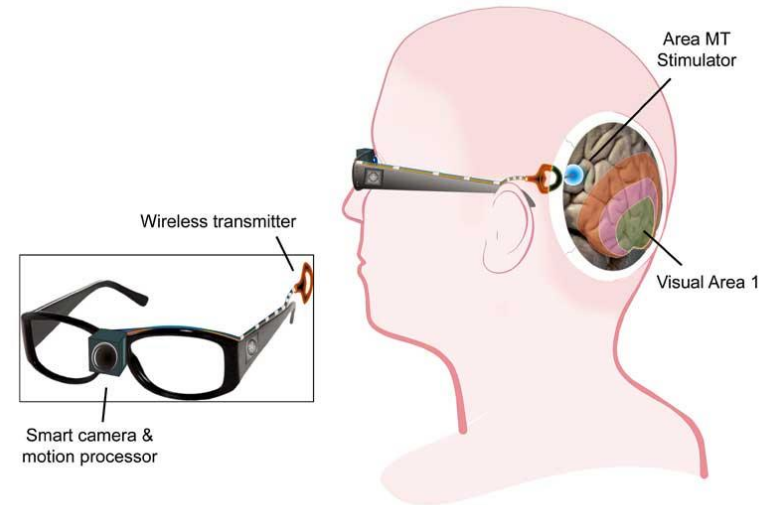
- **Extraocular Prosthesis**

- Intracortical

- Electrodes implanted in the visual cortex
 - 100-152 intracortical microelectrodes
 - recognize any letter or number
 - Navigate around
 - a risk of infection which requires removal of the implant
 - it difficult for electrode arrays to completely the entire area

- Optic nerve prostheses

- uses spiral cuff electrodes to stimulate the optic nerve and create visual sensations
 - blind volunteer was able to interact with the environment by demonstrating basic pattern recognition skills such as recognition of different shapes, line orientations and even letters in some cases
 - requires a large number of contacts which can increase the risk of damage to the optic nerve

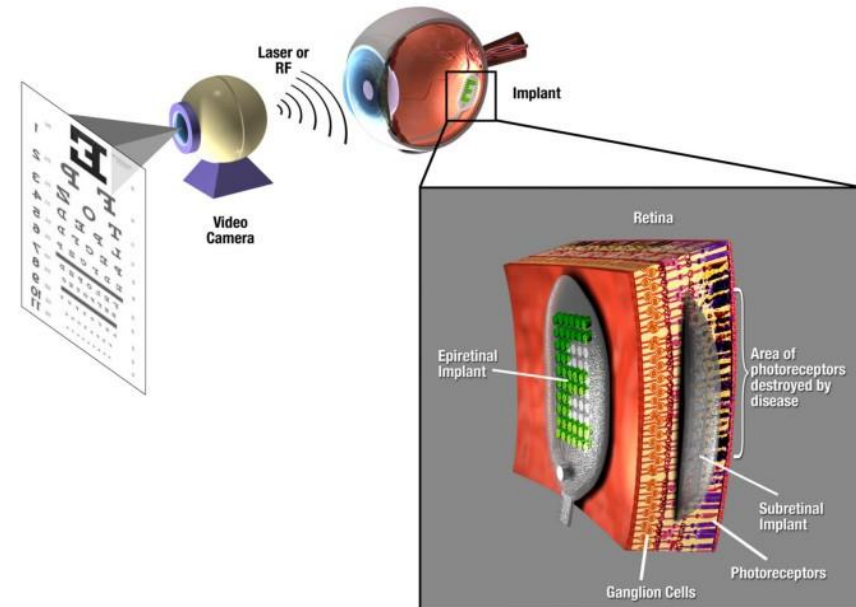


Retinal Prosthesis



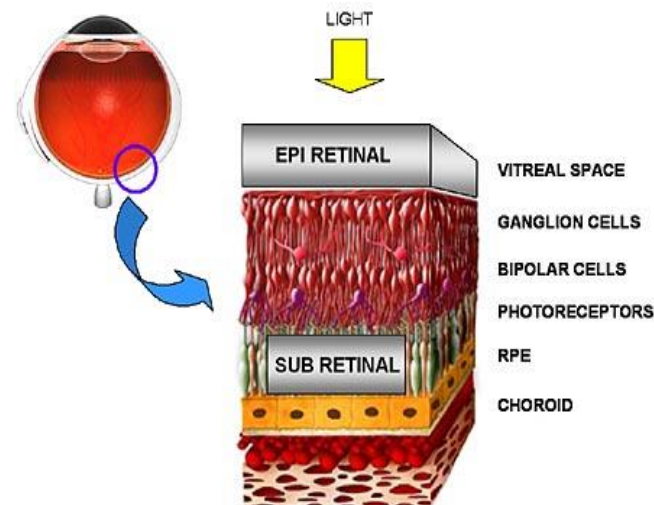
- **The Concept of a Retinal Prosthesis**

- Acquire an image
- Process to determine how the image maps onto an electrical stimulation pattern on the retina
- Telemeter the commands
- Transmit commands to an electrode array to stimulate retina



- **Intraocular prostheses belong to two major categories:**

- Epiretinal
- Subretinal.



Retinal Prosthesis

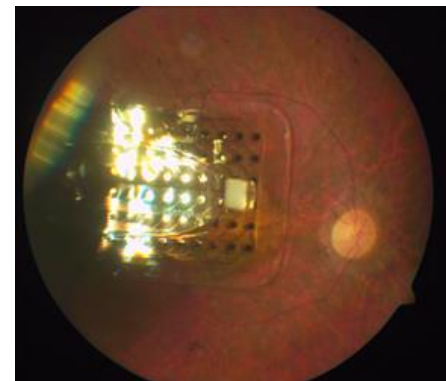
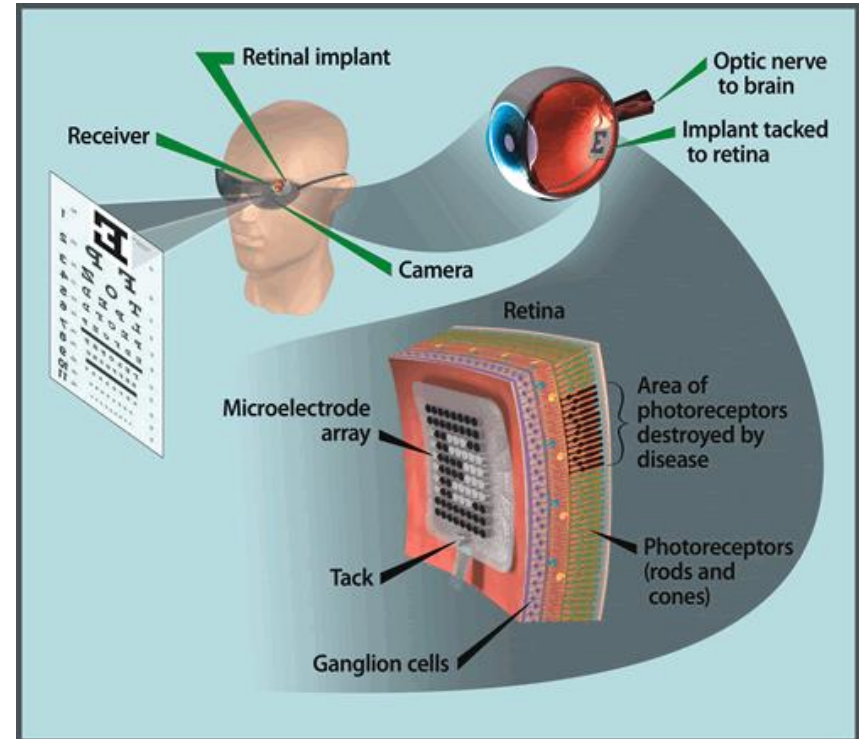


- **Epiretinal prosthesis**

- Implanted on the inner part of the retina
- Requires power and data telemetry from a camera
- Patients capable of differentiating basic forms of motion, perceiving light and dark and even shooting baskets

- **Example: Argus II**

- 60 electrodes
- Wireless data transfer,
- MEMS components for better fixing of the device in the eye ball.
- This implant is approved in EU and the USA (\$100,000).
- Patient need some training to interpret what their brains show them.
- Researchers are already working on a third version with 240 electrodes.



Retinal Prosthesis



- Components (The Argus®II)



Internal Parts

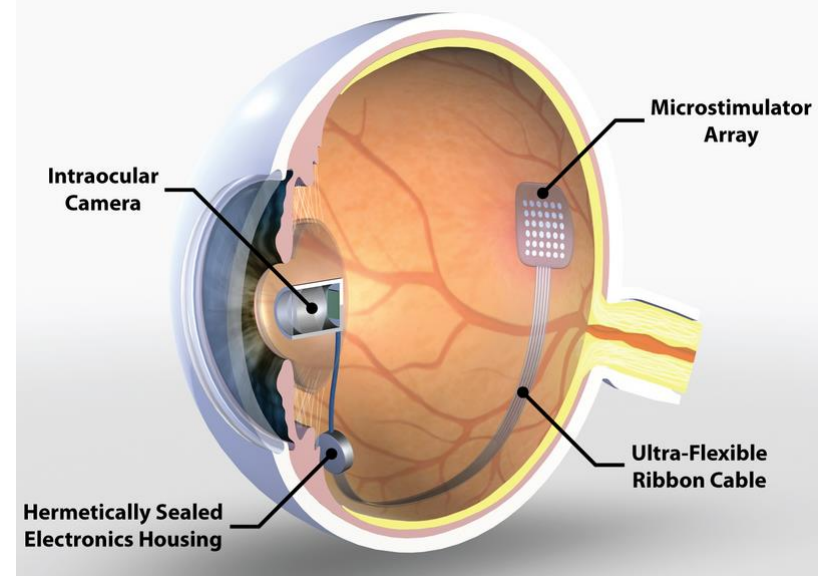
External Parts

Retinal Prosthesis



- **Advantages of epiretinal prosthesis**

- The electrical device is mostly kept outside the retinal surface
 - The heat at the retinal surface is at low levels → the prosthesis is virtually harmless to the eye
- The surgery process is easier.
- The device can be placed on the entire vitreous cavity in order to minimize disruption to the retina.
 - Future: intraocular camera
- Epiretinal prostheses can be larger than subretinal prostheses.
- The approach does not require the remaining retinal cells (e.g. bipolar and amacrine cells) for information processing.

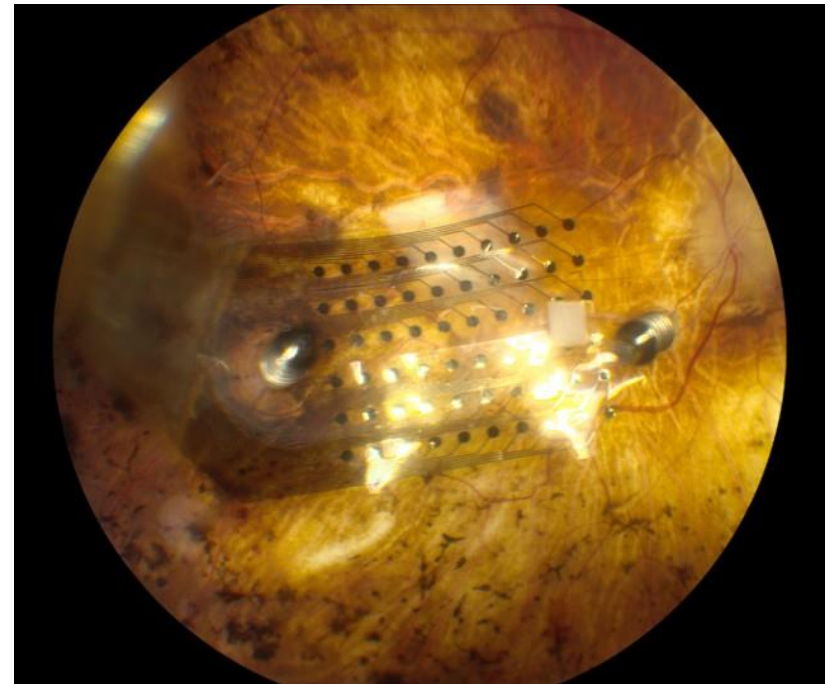


Retinal Prosthesis



- **Disadvantages of epiretinal prosthesis**

- The remaining retinal neural cells are not used to process the information
 - An external camera is required in order to allow for some degree of pre-processing
 - Information does not pass through inter-neurons
- The shape and material of the electrode array substrate poses several challenges.
 - Electrode array carefully fixed to the curved retinal surface for consistent stimulation and to avoid retinal tearing
- The image processing performed by the retina must be replicated in order for the neurons to be stimulated with meaningful signals

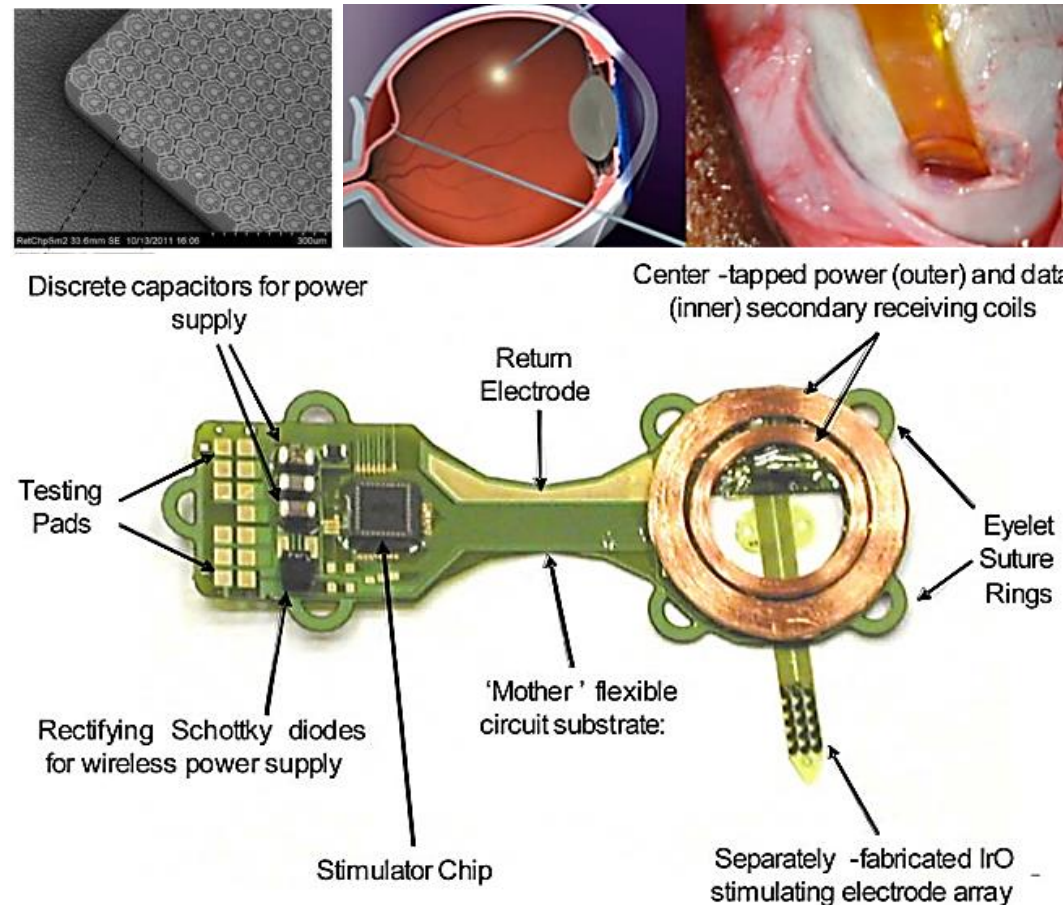


Retinal Prosthesis



- **Subretinal prostheses**

- Placed between the bipolar cells and photoreceptor cells
- Consists of thin electrode plates
- Assembled by several thousand subunits
 - Each subunit is a combination of a micro-photodiode and a stimulating electrode
 - Converts light originating from the outside scene into electrical signals that can stimulate the remaining functional retinal cells
- The photodiodes also provide the energy for the subunits by converting the light to electrical current

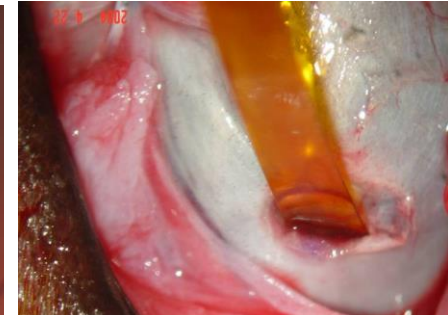
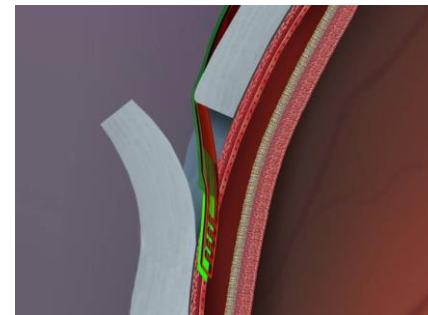
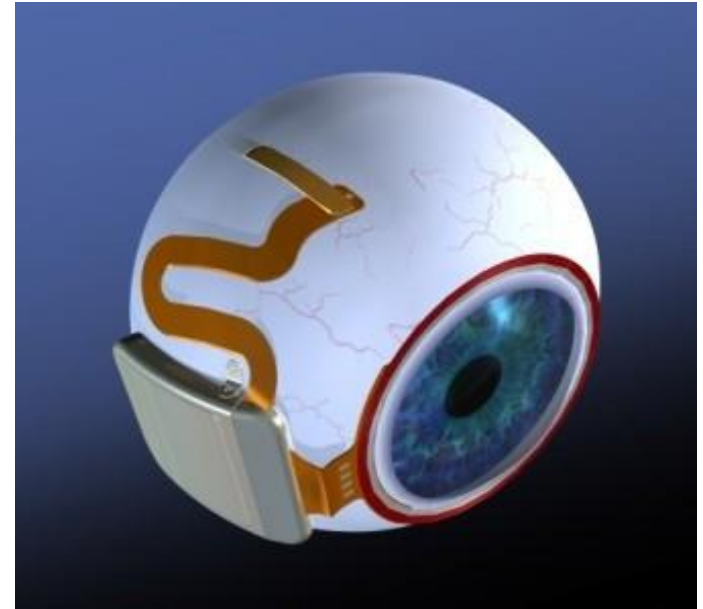


Retinal Prosthesis



- **Advantages**

- No need for a camera or power supply
 - Completely implantable
- The remaining retinal tissues can be used for information processing
 - Information compatibility with the rest of the visual system
 - Helps lessen the need for external processing and hence decreases the amount of power needed
- It is easier to remain in place without leading to retinal detachment
- Easier placement
 - Electrode array enters the space under the retina through the scleral wall of the eye.

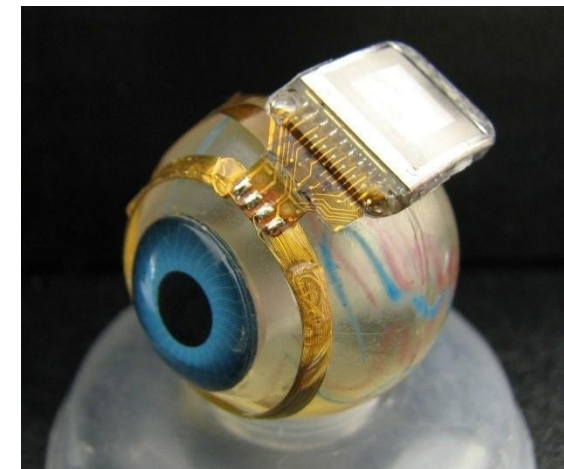


Retinal Prosthesis



- **Disadvantages**

- Power stability is an issue
 - Light absorption in the solar cells is not sufficient nor consistent
 - External power source to ensure the prosthesis functions reliably
- The inter-neurons on which the prosthesis is relying (i.e. bipolar and amacrine cells) might be heavily re-organized as a consequence of retinal damage
 - The information conveyed to ganglion cells might be uninterpretable.
- The distribution of the nutritional supply between the choroid and the retina maybe disrupted → further damage to the retina

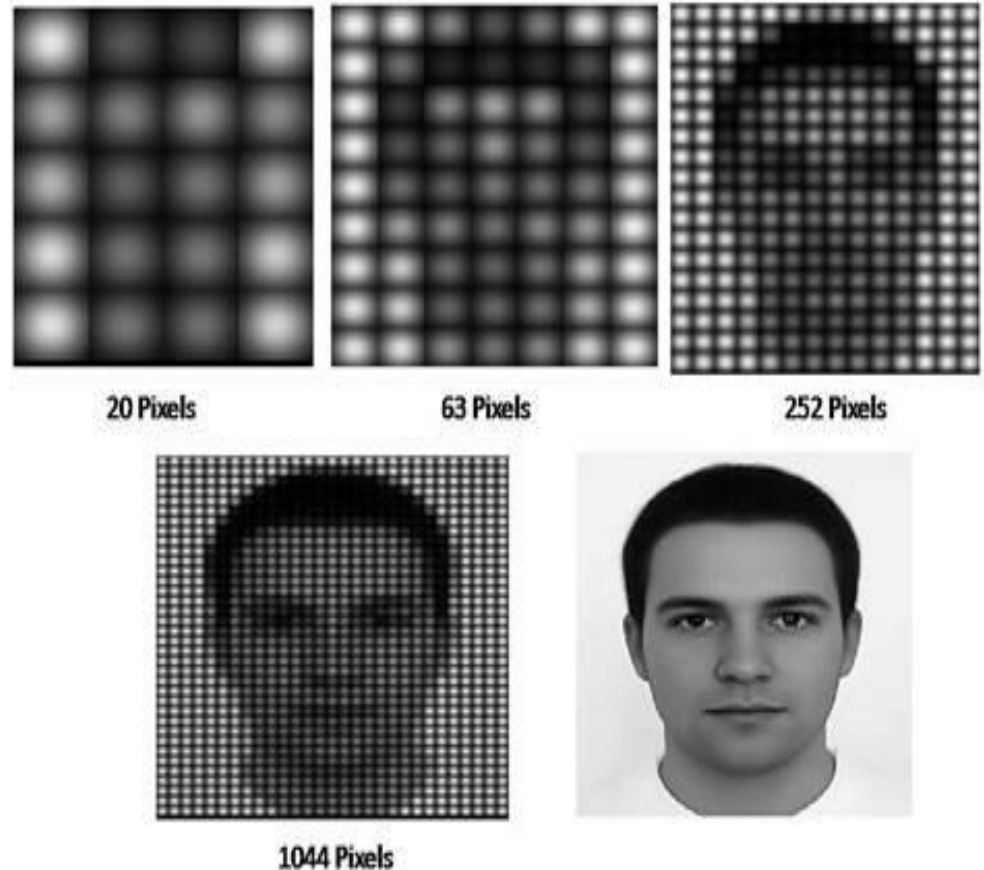


Retinal Prosthesis



- **Image processing Issues**

- Number of electrodes result in poor images → pixelation
- More intelligent approaches needed to pass most salient information
- Simulation software attempt to convert images to spikes to better approximate neuronal behavior



Βηματοδότης



- **Μεταβάλλει τον καρδιακό ρυθμό**

- ανταποκρίνεται στις ανάγκες βηματοδοτικά σήματα μοιάζουν πολύ με τα φυσιολογικά
- αντικαθιστά τα σήματα του φλεβόκομβου που καθυστερούν ή χάνονται
- βοηθά στο χρονικό συντονισμό μεταξύ κόλπων-κοιλιών
- εξασφαλίζει τη σύσπαση των κοιλιών σε επαρκή συχνότητα

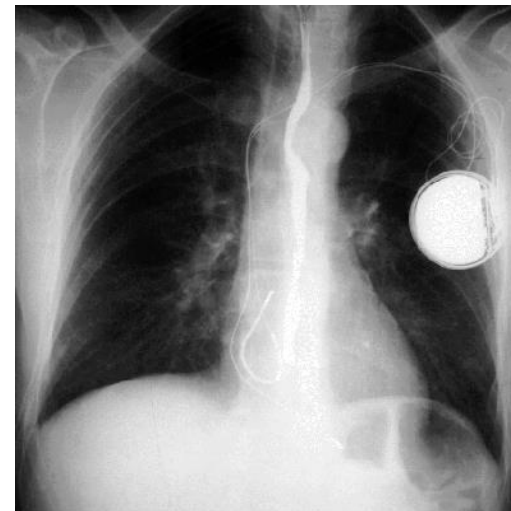
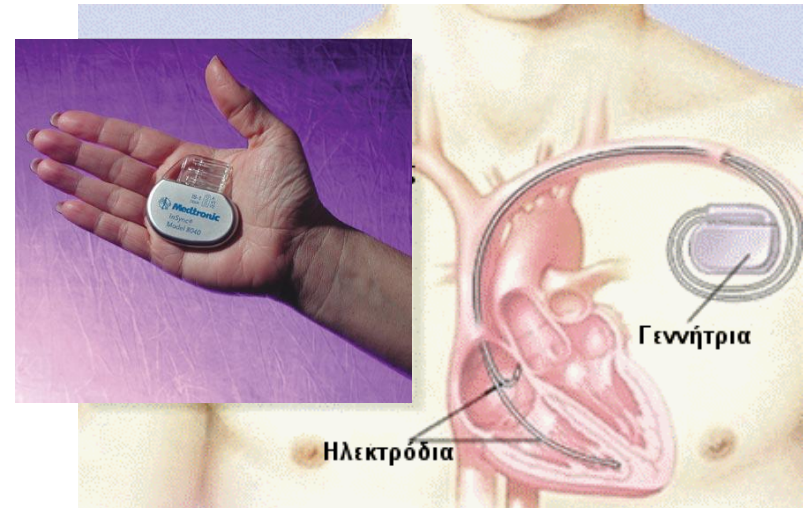
- **Χαρακτηριστικά**

- αίσθησης (αναγνώριση των φυσικών παλμών της καρδιάς)
- βηματοδότηση (αποστολή ερεθίσματος ικανού να διεγείρει την καρδιά όταν χρειάζεται)
- βηματοδοτική συχνότητα (συχνότητα των ερεθισμάτων που εκπέμπει ο βηματοδότης)
- οι λειτουργίες μπορούν να ρυθμιστούν από τον γιατρό εξωτερικά μέσω ειδικών συσκευών
 - ανταποκρίνεται πλήρως στις ανάγκες του ασθενούς

- **Η γεννήτρια τοποθετείται κάτω από το δέρμα**

- **Ένα ή δύο καλώδια**

- ξεκινούν από τον βηματοδότη
- μέσω της κεφαλικής φλέβας
- ένα στον δεξιό κόλπο
- ένα στην δεξιά κοιλία





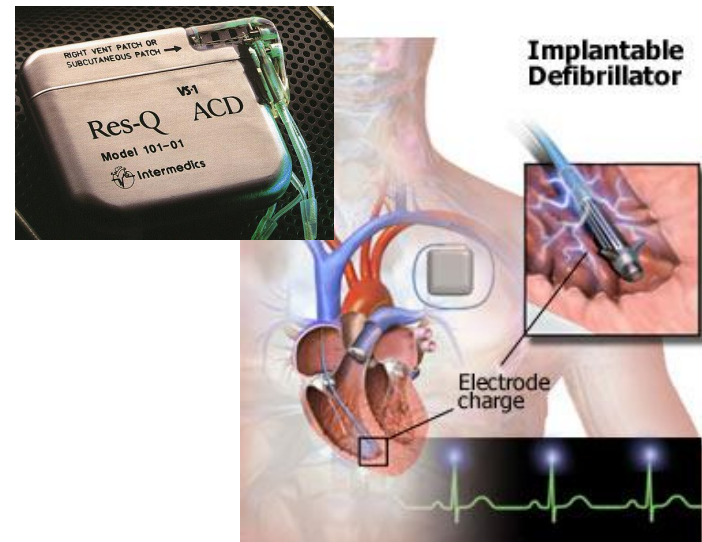
- **Εμφυτεύσιμος απινιδωτής**

- λίγο μεγαλύτερος από βηματοδότη
- η γεννήτρια τοποθετείται στο θωρακικό τοίχωμα
- διαφλέβια εμφύτευση
- ένα ή και δύο ηλεκτρόδια
- αυτόματη ανάταξη τη κοιλιακής ταχυκαρδίας ή μαρμαρυγής
 - επεισόδια κοιλιακής μαρμαρυγής, τα οποία ανατάσσονται με ηλεκτρικό σοκ και δεν προλαμβάνονται με φαρμακευτική θεραπεία

- **Η αρρυθμική θνητότητα εξαλείφεται σχεδόν απόλυτα**

- **Παρέχουν την δυνατότητα βηματοδότησης καθώς και καταγραφής των αρρυθμιών**

- αργότερα αναλύονται και λαμβάνονται σωστότερες αποφάσεις



Brain Pacemakers



- Small battery powered pacemaker that emits electronic impulses
- Inserted in affected area of brain
- Commonly used in Parkinson's Disease patients, epileptics, and people who have tremors
- Also known as a method of deep brain stimulation
- Have over 60,000 customizable options

