SECONDSIGHT

Argus® 2s
Retinal Prosthesis System

User Manual

REF 095004-001 A

Rx Only: Federal law restricts this device to sale by or on the order of a physician.

HUMANITARIAN DEVICE: Authorized by Federal (U.S.) law to provide electrical stimulation of the retina to induce visual perception in blind patients with severe to profound retinitis pigmentosa and bare light or no light perception in both eyes. The effectiveness of this device for this use has not been demonstrated

Argus® 2s
Retinal Prosthesis System

User Manual

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Chapter 1: Glossary

Term	Definition
Choroid	A thin layer of cells between the retina and the sclera that contains pigments and blood vessels. The blood vessels bring oxygen and nutrients to the retina.(See Figure 1)
Conjunctiva	A thin layer of tissue that covers the white part of the eye and the inner surface of the eyelids. (See Figure 1)
Cornea	The clear layer of tissue, shaped like a dome, which lies on top of the iris and the pupil. The cornea is the eye's outer lens. It gives the eye its major focusing ability. (See Figure 1)

Term	Definition
Cyst	A closed sack of abnormal tissue that may contain air, fluids, or semi-solid material.
Diagnosis	The identification of disease by its symptoms.
Electrode Array	A grid of electrodes used to stimulate the retina.
Electrical Stimulation	A technique that uses electrical currents to activate nerve fibers.
Electromagnetic Interference (EMI)	A field of energy (electrical, magnetic, or both) created by electronic equipment. This field of energy may be strong enough to disrupt the normal operation of your Argus 2s System.
Electrostatic Discharge (ESD)	A brief unwanted flow of electrical current that can cause damage to electronic equipment.

Term	Definition
Incision	The surgical cut created in your eye so that the Argus II Implant can be placed in your eye.
Iris	The iris is the round structure in the eye that gives the eye color. For example, blue-eyed people have a blue iris while brown-eyed people have a brown iris. The center of the iris is an opening called the pupil. The iris controls the size of the pupil when it reacts to the amount of light that is present. (See Figure 1)
Radio Frequency (RF)	Any electromagnetic frequency within the range used for wireless communication.

Term	Definition
Retina	A thin layer of nerve cells at the back of the eye that changes light into nerve impulses that travel to the brain. (See Figure 1)
Sclera	The white outer part of the eye made of tough tissue that allows the eye to keep its shape and helps to protect the delicate inner parts of the eye. (See Figure 1)
Therapy	Treatment of disease or disorders.
VPU (Video Processing Unit)	The part of the Argus 2s System that you carry. It processes the information that is sent to and from the implant inside your eye. You can choose different settings on the VPU.

Figure 1: Parts of the Human Eye

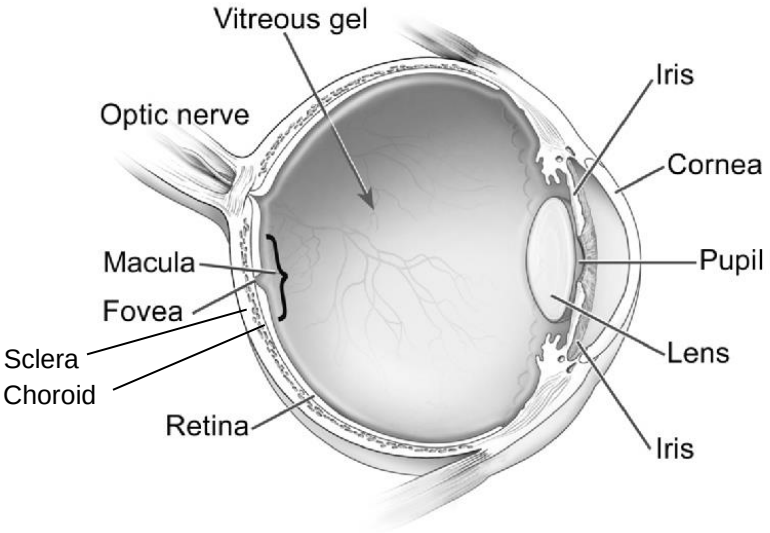


Image courtesy of the National Eye Institute, National Institutes of Health

Chapter 2: Descriptive Information

Indications for Use

The Argus 2s Retinal Prosthesis System is intended to provide electrical stimulation of the retina to induce visual perception in blind patients. You are eligible for the Argus 2s system if you have severe to profound retinitis pigmentosa and you meet the following criteria:

- You must be an adult, age 25 years or older.
- You must have bare light or no light perception in both eyes. If you do not have any remaining light perception, your doctor will test your eye to make sure it will respond to electrical stimulation.
- You need to have been able to see objects, shapes and lines in the past.
- In the eye that will be implanted, you either need to have an artificial lens or no lens at all. (If the eye that will be implanted still has a natural lens, your doctor will remove this lens during the implant surgery.)
- You must be willing and able to follow the recommended schedule of clinical follow-up, device programming and visual rehabilitation after you are implanted.

Your doctor will implant the Argus II Implant in only one of your eyes, most likely the eye that has the worse vision.

Your doctor will discuss with you which eye is best for the implant before your implant surgery.

Device Description

The Argus 2s Retinal Prosthesis System consists of the following main parts and accessories:

- Argus II Retinal Prosthesis (Implant)
- Argus 2s Video Processing Unit (VPU)
- Argus 2s Glasses
- Accessories:
    - Lenses, Clear or Dark
    - Glasses Cable
    - Rechargeable Battery (for use in VPU)
    - Battery Charger
    - Belt Holster
    - VPU Straps
    - Travel Case

WARNING  **Do not use any equipment with your Argus 2s System other than that supplied by Second Sight.**

If you use cables or batteries not supplied by Second Sight, your Argus 2s system may be more likely to experience interference from other electronic devices. The use of non-approved cables or batteries may also cause the Argus 2s system to interfere with other electronic equipment.

Refer to the Appendices A for more information about interference with other electronic equipment.

How Does the Argus 2s System Work?

You will have the Argus II Retinal Prosthesis implanted in and around your eye. You must wear the glasses and turn on the VPU to use the system.

When you are using the system, a small video camera on the glasses captures images in real time. The glasses send these images to the VPU. The VPU changes these video images into electrical signals and sends them back to the glasses. The antenna on the glasses sends the signals wirelessly to the implant. The implant then sends out small pulses of electricity to your retina. These pulses stimulate your retina. Your retina sends the nerve signals along the optic nerve to your brain. You perceive these pulses as patterns of light. Over time, you may learn how to interpret these visual patterns as objects and shapes.

Note: The implant is “on” only when you are wearing the glasses and have the VPU turned on. Otherwise, the implant is “off”.

The sections below describe each of the parts of the Argus 2s system.

Argus II Retinal Prosthesis (Implant)

The implant consists of four parts: (1) the electronics case (2) the implant antenna, (3) the electrode array, and (4) the scleral band.

Figure 2 shows how the implant looks after it has been implanted. Part of the implant sits on the outside of your eye and part goes inside your eye. The implant is not visible to other people.

The electronics case, implant antenna and scleral band sit on the outside of the eye. The scleral band wraps around your eye and holds the implant in place. A thin layer of tissue that covers the white part of the eye also covers the parts of the implant that sit on the outside of the eye.

A cable connects the electronics package to the electrode array. This cable enters your eye through an incision made during surgery. At the end of cable is the electrode array. The electrode array is attached to the surface of your retina with a retinal tack. The implant is not visible to other people.

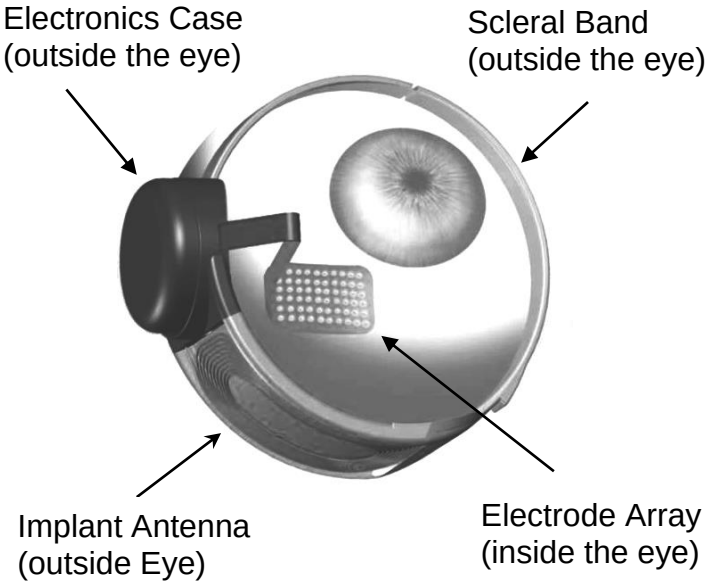
The electrode array provides electrical stimulation to your retina. It has 60 electrodes arranged in a rectangular grid. Fifty-five of these electrodes are turned on at the time of implant. Up to five of the remaining electrodes may be functional. These could be turned ON only to replace an electrode that is not working.

Patient Contacting Materials of the Implant and Tack

The implant and retinal tack are made of following materials:

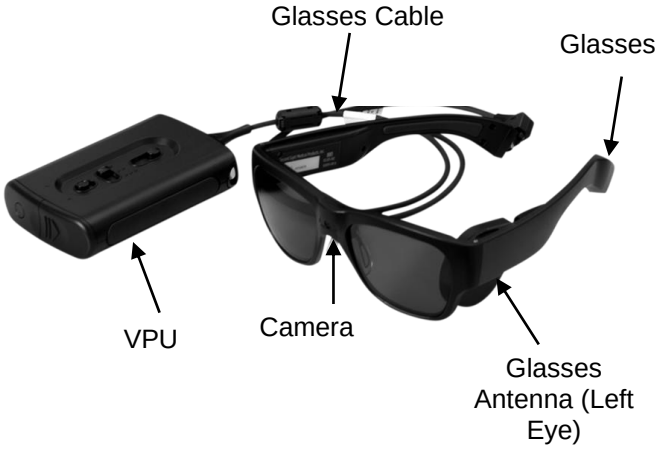
- Niobium
- Platinum
- Polyimide (plastic)
- Silicone Rubber
- Titanium

Figure 2: Implant on a Right Eye
(looking at your eyeball)



External Equipment – VPU and Glasses

Figure 3: External Equipment



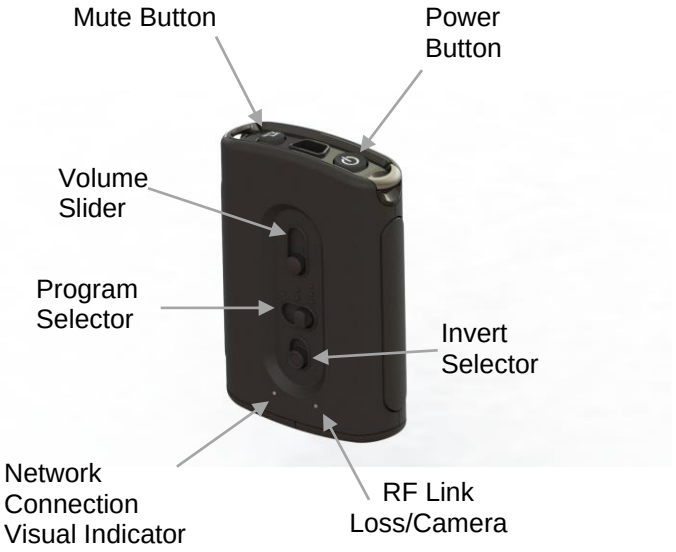
The VPU and glasses must be used together for the system to work. The VPU and glasses connect with a cable. One end of the cable plugs into the end of the arm of the glasses, the other end plugs into a port on the top of the VPU. Each end of the cable has a different shape so that you can easily tell which end goes into each device.

Video Processing Unit (VPU)

The VPU allows you to turn the system on and off, choose different programs, and control the volume of audible tones. Using the buttons on the VPU, you can choose different stimulation programs to suit your surroundings.

The VPU keeps track of when you turn it on and off. It also keeps a record of how well your implant and VPU are working. The VPU also records when there is break in the wireless link between the implant and glasses. Your clinician can check all of this information when you visit the clinic.

Figure 4: VPU


Mute Button
Power Button
Volume Slider
Program Selector
Invert Selector
Network Connection Visual Indicator
RF Link Loss/Camera


Loops for securing VPU Strap to VPU
Second Sight
Argus® 2s
Video Processing Unit
REF 913200
Micro USB Port

Table 1 describes the parts of the VPU. Table 2 describes the accessories that you use with the VPU.

Table 1: VPU Controls

Control	Description
Power Button	The power button is round and indented. With the front of the VPU facing you, the Power Button is located on the top right side of the VPU. To turn on the VPU, hold the button down for 2-3 seconds until you hear a beep. The light on the button is green when the VPU is on. Push the button again to turn off the VPU.
Mute Button	The mute button is round and raised up. It is on the top left side of the VPU. The VPU has audible alerts as well as vibratory alerts.

Control	Description
Mute Button (con't)	The VPU can be set to have both audible and vibratory alerts, only vibratory alerts or no alerts. Note that if the VPU is set to vibration alerts and no alerts, the audible alerts for low battery and VPU Error will still sound. To set the VPU to vibration alerts, push the mute button once. To set the VPU to no alerts, push and hold the mute button.
Volume Slider	The slider is located on front side of the VPU towards the top. Slide it up and down to control the volume of all audible tones made by the VPU.
Program Selector	The Program Selector is on front of the VPU in the middle. It is below the Volume Slider. You can move it into three different positions. This allows you to choose from one of three programs on the VPU.
Invert Selector	The invert selector is below the Program Selector. Move this switch up and down to invert the image from black-to-white and white-to-black.

Control	Description
Network Connection Button	The Network Connection button is on the bottom left hand side of the VPU. Your clinician uses it during programming to start the connection between your VPU to the programming computer.
Battery Door	The battery door is on the bottom right hand side of the VPU. Slide this door open to remove and replace the battery.
Indicators Lights	There are two LED lights on the front of the VPU. The amber light on the right indicates there is an issue with the VPU or system. The blue light on the left is only used in the clinic during programming.
Glasses cable port	The glasses cable port is on the top of the VPU between the Power button and the mute button. This is where the Glasses Cable plugs into the VPU.
VPU Strap Loops	The VPU Strap can be attached to the loops so that the VPU can be worn on a variety of ways.

Control	Description
USB Port	This port is located on the back of the VPU. It is used by the clinician during Programming. Do not remove the cover over this port.

Table 2: VPU Accessories

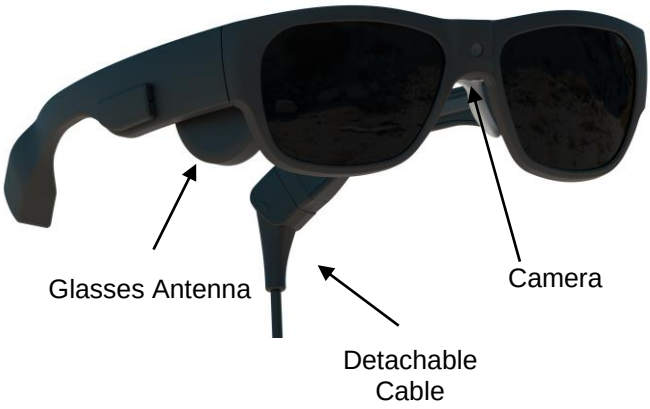
Accessory	Description
Rechargeable Battery	The VPU is powered with a rechargeable battery. Only use the rechargeable batteries provided to you by Second Sight.
Battery Charger	The battery charger is used to recharge the batteries provided with the Argus 2s system.
Belt Holster	The belt holster attaches to a belt so that the VPU can be worn at the waist.
VPU Strap	The VPU strap is a cloth strap that clips to the loops at top of the VPU. The VPU can be worn either over the shoulder or around your neck using the strap. The VPU strap comes in two

Accessory	Description
	lengths.

Glasses

The glasses have a small video camera in the bridge above the nose. There is also a round antenna on one of the arms. The antenna will be either on the left or right arm depending on which eye is implanted. The antenna sends power to the implant and links wirelessly with it. Figure 5 shows the glasses. Table 3 provides a description of the parts of the glasses.

Figure 5: Glasses for the Right Eye

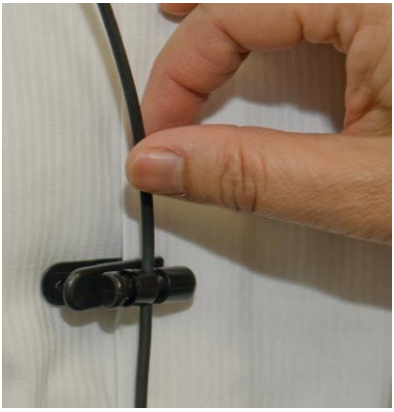


The glasses cable comes with a clip attached. This clip can be used to secure the cable to your clothing to help prevent it from being tangled as seen in Figure 6.

Figure 6: How to Use the Cable Clip

a) Press to open the cable holder

b) Push the cable into place and release



c) Clip on clothes

Patient-Contacting Materials of the Glasses

The glasses are mostly made of plastic and include the following materials:

- Nylon
- Silicone
- PVC - Polyvinyl Chloride
- PET - Polyethylene Terephthalate
- Stainless Steel

Table 3: Glasses Components and Accessories

Component	Description
Camera	A small video camera is located in the center of the glasses frame above the nose bridge. The camera sends video images to the VPU.
Glasses Antenna	The glasses antenna contains the receiver and transmitter to link wirelessly with the implant. The antenna is located on the same side of the glasses as the eye with the implant.

Component	Description
Glasses Cable	The glasses cable is used to connect the glasses to the VPU. It comes in two lengths so that the VPU can be worn in different ways. Each end of the cable has a uniquely shaped connector so that it can only be attached in the correct way.
Cable Clip	The cable clip can be used to attach the glasses cable to your clothes. It comes attached to the cable. The clip can be moved along the length of the cable. To attach or remove the clip from the cable, press both ends of the cable holder on the clip and slide the cable in or out, as shown in Figure 6.

Component	Description
Replaceable Lenses	The glasses come with two sets of lenses, clear and dark. You will receive the glasses with the dark lenses installed, but they can easily be replaced with the clear lenses. You can tell the lenses apart as the dark lenses have a notch on the lower outside corner of the lens. The clear lenses do not have a notch.
Travel Case	The travel case is used to safely store and transport the VPU, glasses and batteries.

Argus 2s System Wireless Information

The Argus 2s Glasses use wireless technology to power the implant and to send and receive information from the implant. Table 4 below describes information about the wireless technology used in the Argus 2s system.

Table 4: Wireless Technology Specifications

Frequency (to the implant)	3.156 Megahertz (MHz)
Frequency (from the implant)	473 – 490 Kilohertz (KHz)

Bandwidth (to the implant)	13 Kilohertz (KHz)
Bandwidth (from the implant)	20 Kilohertz (KHz)
Power (to the implant)	Amplitude modulation (AM) Less than 1.2 watts
Power (from the implant)	Frequency shift keying (FSK) Less than 10 microwatts
Wireless Link Performance	The system maintains wireless link more than 90% of the time when the antenna is approximately 1 inch (2.5 cm) or closer to the implant.

Wireless Security

The Argus II implant only operates if it is within a very short distance from the antenna on the glasses. The Argus 2s system uses coded signals to make it harder for outside sources to accidentally, or intentionally, control the system. The Argus 2s system does not store or send any information, such as your name, that would allow you to be identified.

Wireless Link

In order for your Argus 2s system to work, the glasses must maintain the wireless link with the implant. For the wireless

link to work, the glasses antenna must be close to the implant. To make sure the system works properly, wear your glasses in the same position as they were during the programing session in the clinic. When the wireless link between the glasses and implant is lost, a tone will sound, and will continue to sound, until the wireless link is restored. You may lose the link in the presence of strong magnetic or radio fields. Refer to the section entitled “Possible Interference with Other Electronic Devices” on page 36 and Appendix A, page 113 for more information on interference related to the wireless system.

For Troubleshooting regarding link loss, see the Troubleshooting section on page 80.

Argus 2s Patient Devices

The following items are included in your Argus 2s Retinal Prosthesis system:

Table 5: Patient Devices

Description	Catalog / Product Number
Argus 2s Video Processing Unit	013300-001
Argus 2s Glasses (only one):	
Glasses, Right Eye, Medium	012200-001
Glasses, Right Eye, Large	012202-001
Glasses, Left Eye, Medium	012201-001
Glasses, Left Eye, Large	012203-001
Glasses Accessories: Replacement lenses, cleaning cloth.*Contains wide nosepiece.	
Clear Lenses, Medium*	012603-001
Clear Lenses, Large*	012600-001
Dark Lenses, Medium	012601-001

Description	Catalog / Product Number
Dark Lenses, Large	012602-001
VPU Battery Charger (XTAR VC2 Plus Master)	300300-209
VPU Battery Charger Power Supply	300300-210
Rechargeable VPU Batteries (4)	013400-001
Glasses Cables, 1 16 inch, 1 30 inch.	014402-001
VPU Accessories: 1 Long VPU Strap, 1 Short VPU Strap, 1 Belt Holster	013500-001

When the Device Should Not be Used (Contraindications)

You should not have the Argus II Retinal Prosthesis implanted if you:

- Have an eye disease or condition that could prevent the Argus 2s system from working properly.
- Have an eye structure or condition that could make it difficult to successfully implant the Argus II Implant or recover following surgery. For example, if you have a very long or very short eye, you may not be eligible for the Argus II Implant.
- Have eye diseases or conditions that make it difficult for your doctor to see inside your eye. For example, if you have a cloudy cornea, you may not be eligible for the Argus II Implant.
- Are unable to undergo general anesthesia
- Are unable to take the recommended antibiotic and steroid medications that you need to take before and after implant surgery.
- Have a metallic or active implantable device in your head. For example, if you have a cochlear implant, you are not eligible for an Argus II Implant.
- Have any disease or condition that prevents you from understanding or giving your informed consent. For example, if you have difficulty remembering things, you may not be eligible for an Argus II Implant. Your doctor

may ask you to have a psychological evaluation to make sure you are qualified for this device.

- Have any disease or condition that prevents you from having medical follow-up or having the VPU programmed.
- Tend to rub your eye a lot.

General Warnings and Precautions

Warnings

Once you have an Argus II Implant:

- **Do not** undergo **short wave or microwave diathermy**. These procedures could cause high electrical current in the implant electrodes that could cause tissue damage or serious injury. Diathermy may also cause permanent damage to the implant.
- **Do not** undergo **electroconvulsive therapy (ECT)**. ECT may damage your eye or your Argus II Implant.
- **Avoid lithotripsy or high output ultrasound**. These procedures may harm you or damage the implant. If you need one of these procedures**,** inform your doctor that you have this implant. Your doctor should contact Second Sight Medical Products for instructions on how to perform these procedures in someone who has an Argus II Implant.
- **Do not enter a room housing a magnetic resonance imaging (MRI) System that has a rating other than 1.5 or 3.0 Tesla**, even if you are not using Argus 2s

system.

Only the Argus II implant has been tested for use with MRI. The **Argus II Implant is classified as an MR Conditional** device.

If you have an Argus II Implant, you may undergo an MRI procedure ONLY if it is performed using a 1.5 or 3.0 Tesla MRI System and ONLY following special instructions. Before having an MRI procedure, tell your doctor that you have the Argus II Implant. Your doctor should contact Second Sight Medical Products for these instructions on how to perform an MRI in someone who has an Argus II Implant.

If you feel any pain during the MRI procedure, tell the technician immediately.

Do not take the VPU or glasses into the MR system room. The VPU and glasses are MR Unsafe. Severe harm to people in the MR system room or damage to this equipment may result.

- **Do not** use the Argus 2s system within 3 feet (0.9 meters) of **medical monitoring, diagnostic or life support equipment.** Using the Argus 2s system near this equipment may cause the equipment to function improperly. If someone notices that interference is occurring, turn off the Argus 2s VPU or extend the distance between yourself and the equipment.
- **Do not** receive treatment with **monopolar electrosurgical equipment**. Monopolar electrosurgical

equipment may damage the implant or the tissue around the implant.

General Precautions

- **Stop** using the Argus 2s system if you experience any uncomfortable feeling such as pain. Should this occur, immediately take off the Argus 2s Glasses or turn off the Argus 2s VPU. Then contact your doctor or programming clinician to report the problem.
- Contact your doctor promptly if you feel any pain or watering in your implanted eye or if you have the feeling that something is in your implanted eye. This may be a sign that you have a complication on the outside or inside of your eye. If your doctor does not examine your eye when you have these symptoms, you may develop an infection in your eye or have other serious complications.
- The long-term effects of electrical stimulation are unknown. It may cause damage to the retina or optic nerve. This sort of damage could lead to a decline in your normal remaining vision and/or how well you see with the Argus 2s system. It could also prevent you from getting a replacement Argus II Implant or another type of retinal implant or treatment in the future.
- **Do not** use anyone else's VPU. Only use the VPU that your clinician programmed for you. Using someone else's VPU may limit how well you see with the Argus 2s system. It could also cause you pain if it provides stimulation that is too strong.

- **Avoid** physical impact or extreme direct pressure to the eye. This could cause injury to your eye, movement of the implant in your eye, or damage to the implant. If this occurs, contact your physician.
- **Avoid** rubbing your implanted eye. This may dislodge the implant or cause eye irritation.
- **Do not** rely on the Argus 2s system as your only aid when walking. The Argus 2s system will not provide you with enough vision to walk safely without any other aids. Even though you have the Argus II Implant, continue to use your other mobility aids (for example, canes, dogs) at all times.
- **Do not** use the Argus 2s system during pregnancy or when nursing a baby. Second Sight has not evaluated the use of the Argus 2s system by women who are pregnant or who are nursing a child.
- **Keep the device away** from children, pets or pests.

Electromagnetic Interference (EMI)

Electromagnetic interference is a field of energy (electrical, magnetic, or both) created by equipment found in public environments that may be strong enough to interfere with the normal operation of your Argus 2s system.

The Argus 2s system meets international standards for electromagnetic compatibility (See Chapter 8, page 107, for more information). The Argus 2s system continues to operate in a “safe mode” in the presence of any electromagnetic interference that you would come across during your normal everyday activity.

It is important to note, however, that in certain circumstances, electromagnetic interference could cause:

- Serious injury. Exposure of your implant to EMI may result in your implant heating and damaging nearby retinal tissue. See “Warnings” on page 28.

- Damage to your Argus II Implant. Damage to the implant may require replacement; or result in loss of, or permanent change in the performance of the Argus 2s system. See “Warnings” on page 28.

- Unexpected shutdown of the Argus 2s VPU. EMI may cause your VPU to turn off suddenly.

- Interruption of Stimulation. EMI may cause a momentary interruption of stimulation.

If you suspect that electronic equipment is causing interference with your Argus 2s system, you should do the following:

1. Move away from the equipment or object thought to be causing the interference.
2. If possible, turn off the equipment or object causing the interference.
3. Tell the equipment operator or your doctor what happened.

If you continue to experience interference, or if you think that your Argus 2s system is not working as well as it did before you encountered the interference, please contact your doctor.

The following sections provide additional information regarding potential sources of electromagnetic interference:

- *Precautions Regarding Other Medical Procedures, page 34*
- *Possible Interference from Other Electronic Devices, page 36*
- *Air Travel, General Travel and International Use, page 39*

The potential effects of EMI from devices or procedures are summarized in Appendix A, page 113. Additional information about electromagnetic compatibility can be found in the Product Insert.

Precautions Regarding Other Medical Procedures

General Information (applicable to all procedures)

- If you need to undergo any of the procedures listed below, please inform your doctor that you have a retinal prosthesis in your eye. Your doctor should contact Second Sight at 1-818-833-5060 for more information.
- **Do not wear or use your Argus 2s Glasses or VPU when undergoing a medical test or procedure, unless you are having a vision test.** Using or wearing the Argus 2s Glasses or VPU during these procedures could cause you harm. It might also make it difficult for your doctor to understand the results of the test. It could also damage the Argus 2s equipment.
- Once the procedure is complete, you should have your clinician test your Argus II Implant as soon as possible to make sure it is still working properly. Damage to the implant may not be immediately detectable.

Information about Specific Procedures

- **Magnetic Resonance Imaging (MRI)** – Refer to section “Warnings” on page 28 for information about MRI.
- **Avoid** the use of **laser, fragmatome or phacoemulsification** in your implanted eye. These procedures may damage the Argus II Implant.

- **Avoid** the use of **bipolar electrosurgical equipment** in your implanted eye. This equipment may damage the Argus II Implant.
- You may undergo computed tomography scan (**CT Scans) or Diagnostic Ultrasound**. However, if you need a scan or ultrasound in the area where the Argus II Implant is located, the implant may block or blur the image making the scan unreadable in this area.
- Use of **defibrillators or radiation therapy** to the head may permanently damage the Argus II Implant. However, this should not stop you from receiving these treatments if necessary.
- The effects of **cobalt treatment or linear acceleration techniques** on the implant are unknown.

Possible Interference from Other Electronic Devices

- **Avoid Theft or metal detectors** (such as those located in entrances to public buildings and department stores) and **airport or security screening devices**. If you must pass through one of these devices, turn off your VPU, walk through the scanner, and quickly move away from the area. **Do not** lean on these scanners or linger in their path. These devices may temporarily interrupt Argus 2s stimulation if you are using the Argus 2s system within 1 yard (0.9 meters) of them. Your Argus 2s system will start operating normally when you move away from these devices. You should show your patient identification card to any attendant in the area who may be able to assist you in bypassing these devices.
- **Avoid Electronic Article Surveillance (EAS) systems, EAS Tag Deactivators, and Radiofrequency identification (RFID)** systems. These systems may temporarily interrupt Argus 2s stimulation if you are using your Argus 2s system within 3.5 yards (3.2 meters) of them. Your Argus 2s system will start operating normally when you move away from these devices. RFID systems, EAS systems and tag deactivators send out energy fields that wirelessly communicate with tags attached to objects such as merchandise, materials and people. Businesses use these systems for security, theft prevention, tracking and inventory control. Retail stores, libraries, government buildings, warehouses and offices often use these systems. For example, security tags attached to clothing contain RFID tags.

- **Avoid** handling the VPU and glasses if you suspect there may be **static electricity** present. Static electricity may interfere with normal operation or cause damage to the Argus 2s system. For example, walking across carpet in a low humidity environment can cause you to build up static electricity.
- The Argus 2s system may interfere with the normal operation of some models of **hearing aids**. If you wear a hearing aid, you should have it tested with the Argus 2s system before implant surgery to make sure both the hearing aid and Argus 2s system will function properly.
- **Avoid home appliances,** such as microwaves, and some **devices with antennae,** such as cell phones, when using the Argus 2s system. Home appliances and devices with antennae may temporarily interrupt Argus 2s stimulation. The table below lists the distance at which interruption of stimulation may occur with these systems.

Table 6: Separation Distances

Type of device	Distance from the Argus 2s system
Another Argus 2s system	12 inches (30.5 cm)
Cell phone	12 inches (30.5 cm)
Cordless phone	12 inches (30.5 cm)
Bluetooth device	12 inches (30.5 cm)
Microwave oven	12 inches (30.5 cm)
WiFi Access Point	12 inches (30.5 cm)

Wireless Router	12 inches

Devices with antennae may be marked with the following symbol: 

Normal operation will resume when you move away from these items.

- **Do not** turn on the Argus 2s system on an **airplane**. The Argus 2s system operates using wireless technology that could interfere with the safe operation of an airplane.
- **Avoid** commercial electrical equipment, communication equipment, high voltage lines, power lines or generators, electric steel furnaces, or large magnetized speakers. These types of equipment may temporarily interrupt Argus 2s system function. Normal operation should resume when you move away from these objects.

  Examples of commercial electrical equipment include arc welders, induction furnaces and resistance welders. Examples of communication equipment include microwave transmitters, linear power amplifiers and high-power amateur transmitters.

Air Travel, General Travel and International Use

CAUTION: Do not turn on the VPU or use the Argus 2s system on an airplane. The Argus 2s system operates using wireless technologies that could interfere with the safe operation of an airplane.

You may want to travel with your Argus 2s system. When travelling and not using the Argus 2s system, store the Glasses and VPU in the travel case.

If you will be traveling outside the United States, you may need an adapter to plug the VPU battery charger into the electrical outlet.

Bring your patient identification card with you to assist in going through security systems. The section below describes the patient identification card. Turn off the VPU when you go through security.

If your eye is experiencing any medical complications before your trip, speak with your doctor to determine if it is safe for you to travel, especially on a plane. You may also wish to speak with your doctor in advance of your trip to obtain the name of a local ophthalmologist in the event of any complications during your trip.

For more information about travel, contact the Transportation Security Administration (TSA):

Website:	www.tsa.gov
Email:	TSA-ContactCenter@dhs.gov
TSA General Phone Number:	866-289-9673
TSA Cares Phone Number:	855-787-2227

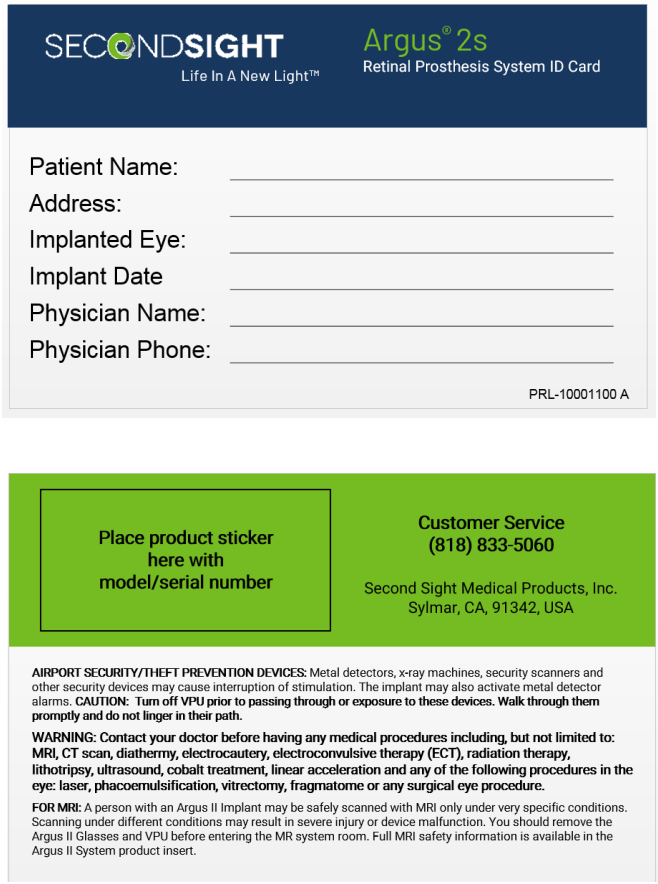
TSA Cares is a toll-free helpline designed to assist travelers with disabilities and medical conditions, prior to getting to the airport. You should call TSA Cares 72 hours ahead of traveling so that the TSA has the opportunity to coordinate checkpoint support with a TSA Customer Service Manager located at the airport when necessary.

Your Patient Identification Card

You will receive a patient identification (ID) card after your implant surgery. This card provides basic information about

your implant and lists your doctor’s name and telephone number. The information is important for others to know in case you need to bypass a security system or in the event of a medical emergency. Keep this card with you at all times. To assist you in locating the card in your wallet, the plastic covering for the card has two clipped corners on one side that you will be able to feel. Refer to Figure 7 below for an example of a patient ID card. This figure does not show the plastic covering with the clipped edges.

Figure 7: Patient ID Card



If you change your address or doctor's information, contact Second Sight to obtain a new card. Include the current information and indicate the changes. You may either call 1-818-833-5060 with the information or send it to the following address:

Second Sight Medical Products, Inc.
Device Registration
13170 Telfair Ave
Sylmar, CA 91342, USA

In addition to your Patient Identification Card, you may want to wear a Medical Alert Bracelet. If you choose to purchase one of these bracelets, you should include the following information on it:

Active Implantable Device on (right or left) Eye
See Patient ID Card in my wallet
Doctor's Phone is (XXX) XXX-XXXX

Risks and Probable Benefits

Risks

There are risks to having surgery and risks of having the Argus Implant. Listed below are many of the problems you might come across having and using the Argus 2s system. Some of the risks listed happened to implanted patients, some did not. Some patients experienced more than one event. Some events are minor, some more severe. Certain events are more likely to occur than others are. For information about the risks experienced by patients, please refer to Chapter 5.

Surgical Risks

To receive the Argus 2s system, you will need to have surgery. During this surgery, your doctor will implant the Argus II Implant in and around the eye. You will need to have general anesthesia. Any surgery where you are under general anesthesia carries some risk.

The following are rare but possible general risks of surgery:

- Blood clots in the legs or lungs (pulmonary embolism or deep vein thrombosis)
- Blood loss requiring transfusion
- Difficulty to urinate
- Chest pain, heart attack, or respiratory failure
- Allergic reaction to the anesthetic

After the surgery, your eye will need to heal. You may have side effects from the medicine you need to take after the surgery.

Risks of the Argus System

Once you have the implant, there are risks associated with having an implant in your eye. There are also the risks of having electricity stimulate the nerve cells in your eye.

The following are risks specific to the Argus II Implant:

- The implant or the sutures holding the implant in place on your eye could wear through the layer of tissue that covers the eye. If the implant or the sutures wear through this tissue, you may feel pain or discomfort. This type of event can also lead to an infection in your eye. Sometimes surgery is required to re-cover the exposed parts to protect the other tissues of your eye and prevent more pain or infection. If surgery cannot resolve the problem, your doctor may need to remove the implant from your eye.
- One or more of the wounds from the surgery could open. This can cause discomfort and can lead to an infection in the eye. If surgery cannot repair the opening in the tissue, your doctor may need to remove the implant from your eye.
- Infection in the eye is serious and needs to be treated quickly. Normally, your doctor would inject medicine into your eye to treat the infection. If this does not work, your doctor may need to remove the implant from your

eye. In rare cases, if you have an infection that cannot be resolved you may need to have your eye removed.

- Your eye pressure may get too high or too low. Normally, your doctor would give you medication to treat this. Your doctor may also need to inject air or oil into your eye. In more severe cases, you may need surgery to return your eye pressure to normal. In rare cases, if the eye pressure gets extremely low, you may need to have your eye removed.
- Separation of the layers of the eye, or a tear in the retina (the innermost layer) may need surgery or treatment with a laser to fix. In some cases, these events may affect how well the Argus 2s system works.
- Large-scale growth of cells in the eye that pull on the retina or growth of strands of tissue that pull on the inner lining of the eye may lead to separation of the layers of the eye. If this happens to you, you may need surgery to repair this problem.
- The implant could move or the retinal tack holding the implant could become loose. You may need surgery to adjust the position of the implant in your eye or to re-tack it to your retina.
- The implant could stop working due to mechanical or electrical problems. Surgery, physical impact to the eye, or exposure to harmful levels of energy could also damage the implant. If the implant stops working, you may need surgery to remove the device.

- You may need to have surgery to move the implant to a new position to improve how well it functions.
- The implant could cause electric shock. A skin burn could also occur due to too much heating of the glasses or VPU. Contact your doctor or programming clinician right away if you experience these events. There may be a malfunction in your Argus 2s system.
- Some pain in or around the eye may occur right after surgery. This pain usually goes away in a few days or weeks. If you have any pain in the eye or headaches after you have recovered from the eye surgery, report it to your doctor. Note that this pain may occur while you are using the Argus 2s system or when the system is off. Usually, your clinician can adjust the program on your VPU to eliminate any discomfort that occurs when the system is on.
- After implantation surgery, you may notice some decrease in how much light you can see. If this happens, you should tell your doctor. While this problem may go away on its own, it is possible that this change could be permanent.
- An eyelash caught under the conjunctiva can cause discomfort. Your doctor will use a pair of tweezers to remove the eyelash if this occurs.
- Damage to or interference with the eye muscles or eyelids, including drooping of the eyelid may occur. Often, this does not require any treatment. In severe cases, you may need surgery to repair the damage.

- Implantation of this device may prevent you from receiving future treatments for retinitis pigmentosa in the implanted eye. Your other eye, however, will be available for alternative treatments.
- There is a possibility of damage to your retina due to injury, too much stimulation, or heating of the implant.
- The implant could affect how the nerves in your face work. This could cause twitching in your face or could affect how the muscles in your face work. This could affect how you do things such as smile or frown.
- The implant could wear through the layers of tissue beneath it. If part of the implant moves into the eye, you might need surgery to either repair the tissue or remove the implant.
- Your body may have an allergic reaction to the materials in the implant or glasses. The following materials in the implant contact the tissues and fluids in your eye: niobium, titanium, polyimide, silicone rubber, and platinum. The materials in the glasses contact your skin. These materials include the following: carbon fiber, polycarbonate, plastic elastomeric, acrylonitrile butadiene styrene (ABS), thermoplastic elastomeric, aluminum, polyvinyl chloride (PVC) and nylon. If the reaction is severe, you may need to have the implant removed or stop using the Argus 2s system.
- The Argus 2s system could distract you from noticing cues from your other aides. You could fall or bump into something even while using the system. **Do not** rely on the Argus 2s system as your only aid when walking.

The following events may occur occasionally and typically resolve on their own or with medication:

- Infection outside the eye
- Redness and irritation in or around the eye
- Irritation caused by the sutures
- Separation of the choroid from the sclera
- Bleeding in the eye
- Clouding, thinning, scraping, or folding of the cornea
- Blood vessels, deposits, rough spots, “threads” or mucus on the cornea
- Dryness of the cornea
- Dry eye or watering eye
- Cysts on the eye
- Nausea or dizziness

The following events may occur occasionally and typically do not require any treatment:

- Swelling of the retina or choroid
- Splitting of the layers of the retina
- Fold(s) in the retina
- Growth of blood vessels on the iris
- Formation of scar tissue in the eye
- Fluid building up in the choroid
- Feeling that something is in the eye

- Movement of the tissue patch used to cover the implant
- Increase in eye movements that you cannot control

Possible "Cascade" of Adverse Events

There is the risk that one event could lead to another. One event could cause other events to get worse. If this happens, it may take several visits to your doctor, several treatments, and/or surgery to treat. If the events do not resolve, you may need to have the implant removed. In the extreme case, your doctor may have to remove your eye.

Limitations of the Argus 2s system

The Argus 2s system provides a form of vision that differs from the vision you used to have. It does not restore normal vision. It does not slow or reverse the progression of your disease. In addition, it will not replace your normal visual aids. You will have to learn how to use the Argus 2s system with your other aides (such as a dog or a cane) and techniques. When you are not using the Argus 2s system, your vision will return to its original impaired state.

When first using the system, you may not be able to tell exactly what you are looking at. Learning to understand the signals from the device and use it in your everyday life may be a challenging process. You will need training to learn how to interpret the vision provided by the Argus 2s system.

How Much Field of View Can the Argus 2s system Give Me?

The Argus 2s system delivers electrical signals to your retina that will allow you to see spots of light. The implant is designed to give you a visual field of about 3.5 inches by 6.5 inches (9 by 16.5 centimeters) at arm's length, or slightly larger than a standard 3 x 5-inch index card. However, the actual size of light you see when the system turns on all the electrodes together may be larger or smaller.

Each implant has 60 electrodes. Not every electrode in the array will be able to allow you to see a spot of light on its own. For most subjects in the clinical trial (28 out of 30) the number of electrodes that could do this was less than 60. If fewer than 20 of the 60 electrodes produce spots of light on their own, your clinician may change the program on the VPU to turn on groups of electrodes at the same time. A “quad” is a group of four electrodes next to each other on the array that stimulate at the same time.

It is possible that not all of your electrodes will be used and, as a result, your visual field may be reduced. In addition, the total number of electrodes that provide spots of light can decrease over time. A single electrode could stop working or parts of your retina could stop responding to the signal sent by that electrode.

What will the spots of light look like to me?

Electrodes in the Argus 2s system do not always create circular spots of light. Sometimes the light looks like a line or a wedge. During the clinical trial, three subjects were asked

to draw what they saw when a single electrode was activated. In these three subjects, the spots of light ranged in length from 0.75 inches (1.9 cm) (if they were being viewed from an arm's length away) to 18 inches (45.7 cm).

The first subject reported a non-circular shape in 20 of the 29 electrodes tested. The second subject reported a non-circular shape in 24 of the 24 electrodes tested. The final subject reported a non-circular shape in 16 of the 29 electrodes tested.

In these three subjects, the size of the individual light spots ranged from less than 1 square inch (6.5 square centimeters) in size (if they were being viewed from an arm's length away) to 46 square inches (297 square centimeters). Most of the electrodes created spots of light that were less than five square inches (32.3 square centimeters) in size.

What Are the Probable Benefits of the Argus 2s system?

The Argus 2s system may help you do tasks visually, rather than by touch. During the clinical trial, some subjects were able to locate lights and windows, follow lines in a crosswalk, or avoid running into things as they walked. Some subjects could sort laundry or determine where other people were located in a room. About half of the subjects were able to read very large letters (about 9 inches high viewed from 1 foot away or about 23 centimeters high viewed from 0.3 meters away). A few subjects were able to read smaller letters (about 1-2 inches high viewed from 1 foot away or about 2.5-5 centimeters high viewed from 0.3 meters away) and short words. In addition, many subjects reported

enjoying seeing light and motion after being blind for many years and having a greater feeling of connection to their environment and to other people.

Results varied among clinical trial subjects. While the majority of subjects received a benefit from the Argus II System on multiple tests and exams, some subjects reported receiving no benefit.

Chapter 3: What to Expect Before, During and After Surgery

Before Surgery

Two days before surgery, you will start taking antibiotics.

The Day of Surgery

Below is general information about how the Argus II System is implanted.

1. On the day of surgery, you will come to the hospital. The surgical procedure will generally last four hours, but it may be shorter or longer. During the implant procedure, you will undergo general anesthesia.
2. If you have a natural lens in your eye, your doctor will remove it before inserting the implant. If you have an intraocular lens in your eye, your doctor will likely leave it in place.
3. Your doctor will pull back the conjunctiva (the thin tissue that covers the white part of your eye and the inside of your eyelid). If your eye orbit is small, your doctor may need to make a small cut at the outer corner of the eyelids to make it easier to place the device.
4. Your doctor will then place the implant around your eye. Your doctor will adjust the implant so that it fits snugly against your eye. Your doctor will secure the band on the implant around your eye using a small silicone sleeve.

Your doctor will stich the implant to your eye to hold it in place.

5. Your doctor will then make small hole in the wall of your eye and will remove all of the gel-like fluid inside your eye. Your doctor will replace the fluid with a saline solution.
6. If you have a thin layer of tissue over your retina, your doctor may remove this by gently peeling it off the retina.
7. Your doctor will then attach the electrode array of the implant to your retina with a small retinal tack. Your doctor will test the implant to make sure it is functioning properly.
8. If the device is functioning properly, your doctor will close all of the cuts in your eye. Your doctor will then place a thin layer of tissue (from a human donor) over a small portion of the implant on the outside of your eye.
9. Your doctor will close the conjunctiva with stitches that will dissolve over time.
10. Your doctor will patch your eye and you will be escorted to the recovery room.
11. After you recover from surgery, you will leave the hospital with instructions to take oral medication and use eye drops to control swelling, infection, and pain.
12. Your doctor may elect to admit you overnight to the hospital for observation, or could discharge you the same day as the surgery.

After Surgery

After you have the Argus II Implant, you will need to return several times to the clinic for clinical follow-up, device programming, and visual rehabilitation. You should consider living close enough to the clinic or temporarily relocate closer to the clinic to allow you to fully participate in the recommended follow-up.

Recovering from Surgery

After your surgery and discharge from the hospital, your doctor or nurse will provide you with instructions on how to recover. These instructions will include information about what medications you will need to take and when you will need to return for follow-up visits. Always follow these instructions.

If you experience any medical complications with your implant, it is important to follow the instructions provided by your doctor for how to treat these complications.

It may take several weeks for you to recover from surgery. During this time, you may feel discomfort around your eye. If you notice unusual symptoms, contact your doctor.

Clinical Follow-Up

The day after surgery, your doctor will examine your eye. You will return to the hospital one week later to have your eye checked again. At this time, if the doctor feels that you have recovered well enough from your surgery, you will

begin to have your Argus II System custom programmed for you (See Device Programming section below).

You will need to continue to return to the hospital periodically so that your doctor can check the health of your eye. These periodic visits will continue as long as the Argus II Implant remains in your eye. A typical follow up schedule might include visits at 2 weeks, 1 month, 3 months, 6 months, and 12 months followed by annual or semi-annual visits.

Device Programming

In order for you to see anything from the Argus II System, it will need to be custom programmed, or “fitted” for you. Someone other than your doctor will likely perform this programming. This person, a “programming clinician” could be another doctor, nurse or technician.

Initial Programming Sessions

The purpose of the initial programming sessions is simple: to find suitable stimulation levels so that the first visual program can be set on your VPU. To do this, you will need to come to the clinic where your clinician will connect the VPU to a special computer. The programming clinician will provide electrical stimulation to one electrode at a time. Your clinician will record your response to the stimulation. Your clinician will use these responses to create custom programs. Your clinician will download these programs to your VPU so you can use your Argus II System.

In case stimulating one electrode at a time is determined to be insufficient, the clinician may choose to stimulate groups of four electrodes next to each other (called a “quad”) at the same time. If the clinician chooses to use quad stimulation, the clinical will divide the entire array into 15 quads arranged in 3 rows of 5 columns. For people who need quad stimulation, quad electrode stimulation usually results in brighter perception than single electrode stimulation. Also, a larger region of your array may become usable with quad stimulation, resulting in a larger field of view. These features may allow you to make better use of the device even if single electrode stimulation gives you little vision.

CAUTION: Please note that the effect of using quad stimulation compared to single electrode stimulation was not specifically studied during the clinical trial.

Depending on your results, this initial programming may take one visit lasting one to two hours, or it may take a few such visits.

Preparing for Using the Argus II System at Home

Once your clinician downloads the programs to your VPU, your clinician will turn on the VPU. You will then start to see spots of light. Your clinician will then adjust the camera position to line it up with how the implant is located inside your eye.

You clinician will show you how to connect the glasses to the VPU, how to operate the controls and switches on the VPU, and how to understand the alarms and indicator lights. Your

clinician will train you how to perform simple troubleshooting and how to care and maintain your Argus II System.

You will need to come to the clinician many times in the 4-6 weeks after surgery to have your system programmed and to receive training. Once you complete these two activities, you will be able to start using your Argus II System at home. Typically, patients in the clinical trial started home use of the System one to three months after their implant surgery.

Follow-up Programming

After the initial programming sessions, you may need to visit your programming clinician on a regular basis for a tune up. The brightness of perception and the number of electrodes that can give you perception may decrease over time. If your perceptual experience with the device changes, you should contact your programming clinician for a follow-up programming session.

Visual Rehabilitation

It is important to learn how to use the device to fit your specific needs. Second Sight has a recommended visual rehabilitation program. This rehabilitation program will allow you to improve your use of the system. It should increase your ability to perform daily activities and help reach your goals for using the Argus II System. A typical rehabilitation program may include five to ten one hour sessions. These might take place at the hospital, at another institution, in your home, at your work, or some combination of these settings.

Your doctor can provide more details about your rehabilitation program.

As part of this rehabilitation program, you may receive some items to take home with you to help you practice and learn more about the system. It is important to spend time practicing in order to maximize the benefit that you get from the system.

The Importance of Following a Care Regimen

The following guidelines about your Argus II System will help to ensure that you receive the safest and most beneficial treatment.

Always tell any medical personnel that you have an implant in your eye and tell them where it is located. If they have any questions, they should contact your doctor or Second Sight at 1-818-833-5060.

If you experience any unusual symptoms that you think are related to your Argus II Implant, contact your doctor.

If you have a family member or caregiver, ask them to read this manual along with you. There may be situations where you will need their assistance.

Go to all follow-up appointments. This will ensure that you get the best care.

When to Call Your Doctor

Call your doctor if any of the following situations occur:

- You are experiencing any pain or discomfort in your implanted eye.
- You feel any discomfort during stimulation. First, turn off your Argus II System (by shutting off the VPU or taking off your glasses), then call your doctor.
- You are having any difficulty operating your Argus II System or any of the components break.
- You feel like the information/stimulation you receive from your Argus II System is getting worse.
- You experience any unusual symptoms that you think electromagnetic interference is causing.

Chapter 4:Using Your Device

Setup Instructions

To set up the equipment for use you will need to:

1. Charge the battery
2. Insert the battery into the VPU
3. Connect the glasses to the VPU
4. Put on the VPU
5. Put on the glasses

Charge the battery. Before using the battery for the first time, charge it fully. To insert the battery into the charger, push the round end of the battery against the spring in the middle of the battery slot. Pushing the spring away from the charger's power cable, push down until the battery is in the charging slot. When inserting the battery, ensure that the battery is fully seated in the charger before letting go of the battery. This will prevent the battery from popping out of the charger. A digital display on the charger indicates when the battery is charged. It takes 3-4 hours to fully charge a discharged battery. A sighted individual can check if the battery is fully charged.

Insert the battery into the VPU. Open the battery door by pushing down while sliding it to the outside of the VPU. One end of the battery is completely round, the other has a flat side. Hold the end of the battery with the flat side. With the flat side facing the open battery door, insert the battery, round end first, into the battery slot. The battery is shaped so that it can only be inserted into the compartment in the correct direction, so you may have to rotate the battery until it slides into the slot. **Do not force the battery into the slot**. When the battery is in the correct position, it will easily slide into the compartment. Close the door and slide it back into position.

Figure 8: Slide the battery door to open

Figure 9: Open Battery Door on VPU

Figure 10: Insert the Battery

CAUTION: Do not use any batteries with the VPU other than those given to you by Second Sight. Use of other batteries may damage the VPU or cause it to function improperly and void the manufacturer's warranty.

Do not use the battery if the shrink-wrap

covering on the battery is damaged or torn.

Connect the glasses and the VPU. The glasses and VPU need to be connected by the glasses cable in order for the system to work. Your Argus 2s system comes with two Argus 2s Glasses Cables of different lengths. You can change the cable depending upon how you would like to wear the VPU.

a Make sure the VPU is turned off before connecting the cable.

b Select the cable length that is appropriate for where you are wearing the VPU.

c Locate the end of the cable with the rectangle shaped connector. This connector plugs into the end of the arm of the glasses that does not have the antenna on it.

d Hold the connector so that it angles down and the cable hangs from the connector. Plug the connector into the end of the arm of the glasses.

Figure 11: Connect the Glasses Cable

e The other end of the cable has a trapezoid shape. This plugs into the top of the VPU. There is a raised horizontal line on the front of this connector. That line should face the front of the VPU when inserting the connector into the VPU.

CAUTION: Do not pull the glasses cable out of the VPU at an angle as this may damage the receptacle or the VPU.

Put on the VPU. The VPU can be worn many ways. It can be worn on your waist using the belt holster, around your neck or shoulder using the VPU Strap, or you can carry it in a pocket.

Put on the Glasses. Using both hands, gently put on the glasses as you would a typical pair of glasses. Adjust the cable so that it is comfortable.

CAUTION: Do not change the position of the glasses antenna. The antenna position is set by your clinician to optimize performance of the device. Changing the antenna position may cause loss and/or interruption of stimulation. Contact your clinician if your VPU issues alerts frequently.

CAUTION: Use care when putting on the glasses. Do not over-extend the glasses arms as this could break them. Do not try to fold the arms of the glasses, as this will break them.

Operating Instructions

CAUTION: Do not exchange your VPU with another patient's VPU. If you use another patient's VPU, you could have uncomfortable stimulation.

CAUTION: If you experience any discomfort during the use of the device, please contact your clinician or Second Sight promptly.

CAUTION: If the glasses become uncomfortably warm discontinue use until the they cool down to their usual operating temperature. Use extra caution if you have

sensitive skin or are taking medication that causes skin sensitivity. If the problem continues, contact Second Sight.

Since the camera on the glasses may not work well in dimly lit environments, make sure that you have enough light when you are using the system. If you are inside, you should always make sure the lights are on in the room.

To turn on the VPU. Make sure you are wearing the glasses before turning on the VPU. To turn on the VPU, press the power button for two to three seconds, then release. You will hear a single tone indicating the VPU is on.

VPU Start-up tests. After booting up, which takes approximately 20 seconds, you will hear a musical tone. The VPU then performs a series of tests. These tests last 20-50 seconds. You may or may not see something during these tests.

To change programs. The Program Selector has three positions. Each position has a different program that your clinician has created for different lighting and contrast conditions. To choose a different program, slide the switch to the desired position. It will click into position.

To invert the image. To invert the image from black-to-white and white-to-black, slide the invert button on the front of the VPU up and down. The up position activates invert mode.

To mute audible tones and vibrations. To mute the audible tones, press the mute button on the top left of the VPU, vibrations will still occur in this mode. To disable both tones and vibration, press and hold the mute button. The Low Battery and VPU Error tones will still play even when the VPU tones have been muted.

To turn off the VPU. To turn off the VPU press the power button and hold it down for one second. As the VPU is turning off you will hear a tone, all indicator lights on the VPU will turn off.

To replace the lenses

To remove the lenses:

1. Hold the glasses with the front of the glasses facing away from you.

2. Be careful not to touch the front of the camera. Place your thumbs on the inside of one of the lenses near the upper corner closest to the camera.

3. Firmly push the lens away from you with your thumbs. It may help to pull slightly on the frame with your other fingers as you are pushing. The lens will pop out.

To install a new pair of lenses:

Note: The dark lenses have a notch on the lower outside corner of the lens. The clear lenses do not have a notch.

1. Hold the glasses with the front of the glasses facing towards you.

2. Locate the groove inside the glasses frame into which the lenses fit.

3. Hold the lens so that the curved side faces up towards you.

4. Locate the corner of the lens that has a sharper corner than the others do.

5. Place the sharper corner of the lens in the corner of inside groove nearest the camera.

6. Using your thumbs push down on the lens to seat it in the groove of the lens opening. It may help to pull the frame slightly with your other fingers.

When you are finished using the system:

1. Turn off the VPU

2. Disconnect the glasses from the VPU.

If storing the system, remove the battery.LED's and Audible Tones

The VPU uses tones to provide you with information about the status of the VPU and glasses and to tell you about problems with the Argus 2s system. Table 7 summarizes the meaning of these indicators.

Table 7: Audible Tones and LED's

Sound	Lights	Meaning
Single tone	The Power button will	The VPU is starting up.

Sound	Lights	Meaning
followed approximately 20-seconds later by a musical tone	be solid before the musical tone, after the tone it will blink quickly during start-up. It will blink slowly during system use.	
Musical tone	The Power button is not illuminated when VPU is off.	The VPU is turning off.
Quick Musical Tone	The amber LED on the front right of the VPU is blinking.	The battery level is low.
Four rapid tones.	The amber LED on the front right of the VPU is on. The light will blink if the link is intermittent.	There is a loss of link between the implant antenna and glasses antenna.
Single gong sound	The amber LED on the VPU is on.	VPU Error, Glasses cable not connected to VPU.
Quick beeping tone	The amber LED on the VPU is on.	Glasses Cable not connected. Camera read error.

Battery Life

The battery will last approximately 2 hours. Actual battery life may vary. Once the battery runs out of charge you will need to recharge it.

VPU settings as well as when and where you use your device will all affect how long the battery charge lasts. Battery capacity will drop gradually over time with use of the VPU. If the battery charge is not lasting very long after you charge it, the battery has probably reached the end of its life. Contact your clinician or Second Sight for a new battery.

Recharging the Batteries

Four rechargeable batteries, and one battery charger, are provided with the Argus 2s system.

The battery must be removed from the VPU for charging.

> **To remove the battery.** Hold the VPU with the battery door facing up. Open the battery door by pushing down on the door while sliding it towards the outside of the VPU. While holding your hand over the battery door opening, turn the VPU so that the opening is facing down. The battery will slide out of the VPU.

Follow the instructions supplied with the charger to recharge the battery. Additional batteries may be purchased from Second Sight.

Checking the Function of the Device

It is important that you periodically check the Argus 2s system for normal wear and tear. If you notice any exposed wires on the glasses or loose or broken parts on the glasses or VPU, contact your clinician. In addition, if you notice a decline in the link between the implant and glasses (for

example, if the RF link alert is beeping more frequently than normal), contact your clinician.

Cleaning

To clean your VPU, glasses or cables, follow the instructions below:

1. Use a can of compressed air to remove dust and debris from the equipment. Use the compressed air as directed by the manufacturer.
2. Use a clean, slightly damp cloth to clean the equipment. Gently rub the areas that require cleaning.
3. Use a clean, dry cloth to dry the equipment after cleaning it.
4. Use a soft cloth to remove smudges and fingerprints from the glasses and camera lens on the glasses.

> **CAUTION: Do not use any cleaning solutions or solvents to clean the equipment. This may damage the equipment or its labels.**

Maintenance

The Argus 2s system does not contain any user serviceable parts.

> **CAUTION: If your VPU or glasses are not working properly, contact either your clinician or Second Sight for assistance. Do not try to fix the equipment yourself**

as you may experience an injury, violate the product warranty, or damage the equipment.

Handling and Storage

Be careful when storing and handling the VPU and glasses. Improper care or storage can damage the equipment. Follow the guidelines below to help improve the lifetime of the equipment.

Magnetically-sensitive storage devices. Do not place magnetically-sensitive storage devices near the Argus 2s system while it is operating. Examples of these storage devices include credit cards, computer floppy disks and hard disks. The electromagnetic field generated by the Argus 2s system may damage or erase the information that is stored on magnetically-sensitive storage devices.

Metal objects. Do not allow any metal objects within 6 inches (15.2 cm) of the glasses antenna while the VPU is in use. If metal objects get too close to the antenna, the antenna could overheat, which would cause the VPU to turn off. The VPU will not work until reset by trained personnel.

Unapproved components. Use only components and accessories supplied by Second Sight with the Argus 2s system. If you use unapproved components, you may damage the equipment, resulting in loss of stimulation and/or injury. If you use unapproved components, you will also void the manufacturer's warranty.

Exposure to liquid. Do not expose the VPU and glasses to water (for example, rain, shower, swimming pool, or ocean) or other liquids. Liquids may damage the VPU or glasses. The glasses may be exposed to light rain, but the VPU may not.

> **CAUTION: If the VPU becomes wet, turn off the VPU, remove the battery and allow the VPU to dry completely before using the system again.**

Transport and Storage of the Argus 2s VPU and Glasses. Transport and store the packaged Argus 2s VPU and glasses at temperatures between 32°F (0°C) and 113°F (45°C).

Usage temperature range. The temperature range for normal use should be between 32°F (0°C) and 125°F (52°C). The glasses can be expected to be 7°F (4°C) warmer than the environment in which it is used; up to 133°F (56°C) at the maximum specified use temperature.

Handling the glasses. The glasses are fragile. Handle them with care, especially when putting them on or taking them off. Though the arms of the glasses move slightly, do not over-extend the arms of the glasses when putting them on or taking them off as this may break them. The arms of the glasses do not fold. Trying to fold them will break them. Use care when attaching or removing any cables or plugs as rough handling can damage the cables or equipment. Do not wrap the cable around the VPU or glasses, over time this may damage the cable.

Traveling with the external devices. Store the VPU, glasses, and batteries in the travel case provided by Second Sight. The travel case is designed to protect the equipment. Do not place anything on top of the glasses or VPU.

Expected Failure Time and Its Effect on You

The Argus II Implant is designed to operate for at least five years. Laboratory testing has demonstrated that the implant should last that long. Insufficient time has elapsed in actual clinical use to provide proof that the device will function properly for more than five years, but performance to date and laboratory testing suggest that it will.

One way the implant could fail is that it could stop responding to signals from the glasses and stop stimulating. If it fails in this manner, you should not experience any harmful effects. In such a rare case, the implant may be removed and replaced if possible and desired.

The VPU and glasses are much more susceptible to handling and breakage than the implant. This equipment may be replaced if necessary.

Rechargeable battery life is described in “Battery Life”, page 71 of this chapter.

How to Safely Dispose of the Device

Follow the safety precautions below when you are transporting, storing or disposing of any components of the

Argus 2s system. During transport, storage and handling for disposal, the following safety precautions should be considered:

WARNING

During transport, storage and handling for disposal, the following safety precautions should be considered:

Do not dispose of the VPU batteries or battery charger in a fire as this may cause an explosion and/or the release of toxic fumes.

Do not dismantle the battery, as some ingredients can be flammable or harmful.

Store used batteries for disposal in a clean dry environment out of direct sunlight and away from extreme heat.

WARNING

Dirt and wetness may cause short-circuits and heat. Heat may cause leakage of flammable gas, which may result in fire, rupture or explosion.
Store used batteries in a well-ventilated area. If used batteries are short-circuited, abnormally

charged or force-discharged, leakage of flammable gas may be caused. This could possibly result in fire, rupture or explosion.

Do not mix used batteries with other materials. If the batteries are short-circuited, abnormally charged or force-discharged the heat generated may ignite flammable wastes and cause a fire.

VPU and Glasses

Follow local and state regulations regarding the proper disposal of electronics to dispose of the VPU or glasses. If you are exchanging or replacing your equipment through your clinician, your clinician will be responsible for following these regulations.

Rechargeable Batteries and Battery Charger

The VPU uses rechargeable batteries. If you detect any leakage of fluid from the battery, stop using it and replace it with a new one. Dispose of a battery or battery charger when it reaches the end of life. Follow procedures that comply with your local regulations and the package insert of the battery charger for proper disposal methods.

Explant

If you have the Argus II Implant explanted for any reason, contact Second Sight immediately except in the event of medical emergency. Your doctor must return the explanted device to Second Sight for evaluation, warranty purposes and final disposition. Your doctor should request a biohazard (explant) kit from the Second Sight office (see contact information in Chapter 7, page 105.)

Disposal of Packaging Material

Dispose of the shipping carton and packaging materials for the Argus 2s system components according to local regulations.

Chapter 5: Troubleshooting

If you have a problem with any part of your Argus 2s system, look for the problem in Tables 8 and 9 below. Instructions for how to fix the problem are provided in the table.

If you cannot find the problem in the tables below, or if the recommendations do not fix the problem, contact your doctor or programming clinician. You can also use the information provided in Chapter 7, page 105 of this manual to contact Second Sight.

CAUTION: If you encounter a clinical or physical problem (such as eye pain or discomfort) related to the Argus 2s system, please contact your doctor or programming clinician immediately.

Table 8: Troubleshooting

Symptom	Corrective Action
The VPU does not start	1. Install a fully charged battery. Refer to instructions provided in Chapter 4, “Remove the Battery” and “Insert the battery” 2. Check that you are

Symptom	Corrective Action
The VPU does not start (continued)	pressing the correct button. The power button is the indented circular-shaped button on the top of the VPU (see Figure 4). 3. Check that you are pressing the power button for at least two seconds. If the button is pressed for less than two seconds, the VPU will not turn on.

Symptom	Corrective Action
The VPU shuts off suddenly without an audible warning	1. Install a fully charged battery. Refer to instructions “Insert the battery” provided in Chapter 4. 2. Turn on the VPU to see if this occurs again. 3. If the problem persists or occurs again randomly when the battery is charged, contact either your clinician or your Second Sight representative for advanced troubleshooting.
The VPU is on, but I don’t see anything	1. Check that the VPU is on by pressing the mute button. If a tone is heard or a vibration occurs, then the VPU is on. If no sound is heard, wait 1-2 minutes and press the mute button again. If

Symptom	Corrective Action
The VPU is on, but I don't see anything (continued)	no sound is heard, the VPU is off. Press the power button to turn the VPU on. 2. Check that the VPU is not making any audible tones. Check to see if the alarms are muted. 3. Check that the glasses cable is securely plugged into the VPU and glasses. 4. If the RF link tone is sounding, (four quick tones in a row) gently press the antenna mounted on the glasses closer to your eye. If the audible tone stops and resumes when you stop pressing the antenna, this indicates that your external antenna needs to be adjusted. Contact your clinician to adjust the antenna. 5. Check that nothing is blocking the camera

Symptom	Corrective Action
	on the glasses. 6. Check that the lens on the camera is clean. Refer to “Cleaning” in Chapter 3. 7. Check that there is enough lighting. 8. Try inverting the image (from black-to-white or white-to-black) using the invert button on the top of the VPU. 9. Try changing the program setting. 10. Check the blue LED on the front of the VPU is **not** on. If the blue light is on, this indicates that the Network button has been accidentally pushed. Stimulation should begin again in ~15 seconds.

Symptom	Corrective Action
The VPU is on, but the image seems distorted	1. Check that nothing is blocking the camera on the glasses. 2. Check that the lens on the camera is clean. Refer to Chapter 3, “Cleaning.” 3. Try using one of the other program settings to see if there is an improvement.
The VPU is on, but my perception is dimmer than usual	1. Check that nothing is blocking the camera on the glasses. 2. Check that the lens on the camera is clean. Refer Chapter 3, “Cleaning.” 3. Check that there is enough lighting. 4. Try inverting the image (from black-to-white or white-to-black). 5. Try using one of the other program settings to see if there is an improvement. 6. Contact your clinician if

Symptom	Corrective Action
	problem persists.
The antenna on the glasses seems warmer than usual	1. Re-adjust the glasses to see if the antenna cools down to its usual operating temperature. If the problem continues or the antenna is getting unusually warm, contact Second Sight using the contact information provided in Chapter 7, page105.
Mute button not responding as expected.	The mute button may have been pressed more than once. Re-press the mute button until desired mode is achieved.

If the problem continues, contact your clinician or use the information in Chapter 7, page 105, to contact Second Sight.

Table 9: Indicator Lights and Tones

Symptom	Corrective Action
The amber light is on and I hear four quick tones (loss of RF link)	1. Re-adjust the glasses to see if the light turns off. 2. You may need to restrict your eye movement to maintain the link between the implant antenna and the glasses antenna.
Amber light is blinking and I heard a musical tone	Low battery. Promptly replace the battery with a fully charged battery.
The VPU is not operating as intended, but I do not hear any audible tones	Press mute button to verify audible tones are “on”.

If the problem persists, contact your programming clinician or use the information in Chapter 7, page 105 to contact Second Sight.

Chapter 6: Additional information

Clinical Studies

Introduction

Argus 2s Changes and Clinical Evaluation

The Argus 2s system has overall the same functionality as the approved Argus II system with some upgrades to the glasses and VPU. However, the implant part of the system is identical to the approved Argus II implant.

The glasses were re-designed for better fit and comfort and a feature was added to improve the adjustment of the antenna to help improve the RF link between the implant antenna and the glasses antenna. A new digital camera was also added to the glasses to help improve performance in low light conditions.

The VPU was also re-designed. It is smaller and lighter weight. A new loop mechanism allows the VPU to be held in a variety of ways using the VPU Strap. There is also a new battery design that makes inserting and removing the battery easier.

The upgrades were validated during a clinical evaluation study to ensure that the Argus 2s

System meets requirements for performance and usability. A total of eight (8) patients and six (6) clinicians participated in the study.

Overall, patients reported that the Argus 2s Glasses were comfortable, easier to take on and off, and fit well. Users also found the VPU comfortable to use and wear.

Argus II Clinical Studies

Second Sight performed a clinical study to test the Argus II System. In this study, thirty subjects were implanted with the Argus II Implant. Fourteen of these subjects lived in the United States and sixteen lived in Europe.

As of March 2012, subjects had been implanted for an average of 3.5 years. The shortest length of implant was 1.2 years and the longest length of implant was 4.8 years.

One subject had the Argus II Implant removed at 1.2 years after implant due to a complication. The Argus II Implant failed in one subject at 4 years after implant. In the other 28 subjects, the Argus II Implant was still implanted and working.

Side Effects and Complications

During the study, 28 of the 30 subjects experienced at least one side effect or complication related to the Argus II System or the surgery to implant the device. Two subjects had no side effects.

Of the 28 subjects, 17 had non-serious side effects that either were treated with medication or did not require any treatment at all. Six subjects had one serious complication that was treated with medication or a simple surgery (for example, repairing a suture used to close the wound in the eye). Five subjects had multiple serious complications, some of which were treated with surgery. Of these last five subjects, four had a "cascade" of events, meaning that one complication led to another complication.

Serious Complications

Below is a list of the serious complications during the study. Of the 30 subjects:

- 4 subjects had a decrease in the pressure of the eye, making the eye soft
- 3 subjects had an opening of the surgical wound where the eye tissue covers the implant.
- 3 subjects had a portion of the implant wear through the tissue that covers it, leaving that part of the implant uncovered.
- 3 subjects had an infection in the eye

- 2 subjects had a partial separation of their retina from the eye wall

- 2 subjects had their retinal tack come out of the retina requiring a re-tack procedure
- 1 subject had a thinning and clouding of the cornea caused by an infection in the cornea
- 1 subject had an infection in the front chamber of the eye
- 1 subject experienced a tear in his retina

Serious complications were treated with surgery, unless they were a severe infection. Severe infections were treated by either giving the subject a shot of medication into the eye or by giving the subject medicated eye drops.

As mentioned above, some subjects had several serious complications. More than half of the serious complications happened within 6 months of implant surgery, although two happened as late as 2 years after implant.

Other Side Effects

Below is a list of other side effects that occurred during the study as of March 2012. Some of these side effects needed no treatment and others were treated with medication. Some subjects had several of these side effects. Of the 30 subjects:

- 11 subjects had a thin layer of tissue grow on the retina
- 10 subjects had redness of the conjunctiva
- 9 subjects had pain in or around the eye
- 9 subjects had swelling of the retina
- 7 subjects had surgery to adjust the position of the implant in the eye to improve how well it worked
- 7 subjects had a decrease in the pressure of the eye, making the eye soft
- 6 subjects had irritation caused by the sutures
- 6 subjects had fluid collected under the choroid
- 4 subjects had redness or irritation of the conjunctiva (“pink eye”)
- 9 subjects had redness or irritation inside the eye
- 4 subjects had bleeding in the back part of the eye
- 3 subjects had blood in the front of the eye
- 3 subjects had headaches
- The following side effects occurred in 2 subjects each:
    - Increase in pressure of the eye
    - Blood vessels growing on the cornea
    - Watering eye
    - “Threads” on the cornea
    - Redness and irritation due to deposits on the cornea

- The following side effects occurred in 1 subject each:
    - Large-scale growth of cells in the eye that pulled on the retina
    - Growth of strands of tissue that pulled on the inner lining of the eye
    - The feeling that something is in the eye
    - Build-up of fluid in the choroid
    - Scar tissue inside the eye
    - Scar tissue around the tack used to hold the implant to the retina
    - Cyst on the conjunctiva
    - An opening of the surgical wound where the eye tissue covers the implant
    - A portion of the implant wore through the tissue that covers it, leaving that part of the implant uncovered.
    - Scraping of the cornea
    - Dryness of the cornea
    - Rough spot on the cornea
    - Folding of the cornea
    - Torn suture
    - Decrease in how much light the subject could see
    - Increase in uncontrolled eye movements
    - Drooping of the eyelid
    - Fluid causing partial separation of the retina from the choroid

- Partial separation of the retina from the choroid due to pulling or shrinking of the retina
- Folds in the retina
- Splitting of the layers of the retina
- Growth of blood vessels in the iris
- Movement of the tissue patch used to cover the implant
- Redness and irritation of the sclera
- Eyelash below the conjunctiva
- Nausea
- Dizziness

Device Function

During the clinical trial, most subjects experienced changes in the number of electrodes that were programmed in the VPU. As of March 2012, this number ranged from as few as 8 electrodes in some subjects to as many as 60 electrodes in other subjects. The average number of electrodes programmed for stimulation in the VPU was 38.

The stimulation limit was lower for home use than for clinical testing. Because of this, some electrodes that were programmed for stimulation in the VPU were not able to independently produce light perception during home use. As of March 2012, the number of electrodes that produced light perception when they were stimulated one-at-a-time at the lower home use

level ranged from 0 electrodes in some subjects to as many as 60 electrodes in other subjects. The *average* number of electrodes that produced light perception when they were stimulated one-at-a-time at the lower home use level was 13.4.

During the clinical trial, 13 subjects had fewer than 20 electrodes that produced perception of light when stimulating one electrode at a time. 8 of these 13 subjects did not have any individual electrodes that, on their own, produced perception of light. The clinician changed the VPU programming to quad stimulation in some of these subjects in order to allow them to have perception over a larger part of the electrode array. Refer to page 57 for a description of quad stimulation. As of March 2012, 6 of these 13 subjects were using quad stimulation. In the clinical trial, no attempt was made to directly compare whether quad stimulation provided better vision than single electrode stimulation.

Probable Benefit

Tests of Vision

All 30 subjects were able to see spots of light when the Argus II System was on.

All 30 subjects did better on tests of their vision when they were using the Argus II System compared to when they were not using the

System. However, the extent that each subject's vision improved varied. Three tests were used to measure subjects' vision with the Argus II System.

In the first test, called "Square Localization," subjects had to touch a white square that appeared on a black computer screen. On average, subjects did better on this test with the Argus II System on versus when the System was off at each time point. At one year after implant, 15 of 16 subjects tested did better on this test with their Argus II System on versus with the System off.

The second test was harder than the first test. In the second test, called "Direction of Motion," subjects watched a computer screen where a white bar moved across the screen in different directions. Subjects had to draw on the screen the direction that they thought the bar was moving. On average, subjects did better on this test with the Argus II System on versus off at each time point. At one year after implant, 10 of 16 subjects did better on this test with their Argus II System on versus with the System off.

The third test was the hardest of the three tests. In the third test, called "Grating Visual Acuity," black and white stripes with decreasing width were shown on a computer screen. The stripes were drawn in one of four directions, either up and

down, left to right, diagonally to the left or diagonally to the right. Subjects had to say which direction the stripes were drawn. When using the Argus II System, 8 of the 30 subjects could correctly tell the direction of the stripes. When not using the Argus II System, none of the subjects could do this test correctly.

Line and Door Tests

The line and door tests were used to test how well subjects could follow a white line on the ground and find the door in a room. At every follow-up visit after implant, subjects were better at doing these tasks when using the Argus II System versus when they were not using the Argus II system.

Use of Argus II System in Daily Life and Quality of Life

Subjects completed two surveys to measure the effect of the Argus II System on their quality of life and their everyday life. One survey, the Massof Activity Inventory, showed that during the study, subjects reported a small improvement in how easy it was for them to do everyday tasks. The other survey showed no change in quality of life during the study.

A low-vision therapist also spoke with the subjects and visited their homes to judge what affect the Argus II System was having on subjects' lives.

These therapists found that 20 of the 26 participating subjects received benefit from the Argus II System, while the remaining 6 subjects were not getting benefit from the system.

Conclusions

The results of this clinical study showed that the probable benefits of the Argus II System are greater than its risks for patients with loss of vision due to retinitis pigmentosa.

Information about Retinitis Pigmentosa

Retinitis pigmentosa (RP) is an eye disease, which causes damage to the retina. This damage results in a loss of vision. The retina is the layer of tissue at the back of the inside of the eye. The cells in the retina convert light into signals to nerve cells, which send signals to the brain. The brain then tells us what we see. The disease is named for the dark deposits which appear in the retina.

RP can be caused by a genetic defect, which will cause it to run in families. Early symptoms of the disease often are first experienced in childhood (loss of the ability to see at night or in very low light). Later the disease may lead to blurring of vision, tunnel vision, loss of central vision or loss of the ability to see colors. In many cases, these severe vision problems do not occur until early adulthood. In advanced stages of the disease, RP

can lead to a person being able to see only very bright flashes of light. In the worst case, the person may experience total blindness.

Warranty

Argus 2s Limited Warranty on Retinal Prosthesis (Implant)

This warranty applies to a person implanted with an Implant (You). This warranty is provided by Second Sight Medical Products, Inc. (Us, We, or Our).

If an Argus II Implant stops working within 3 years from the date of implant, due to Our not making the Argus II Implant within specifications, We will replace Your Implant. This warranty is limited to Implant failures. This warranty does not apply to failures due to surgical problems. This warranty does not apply to failures due to Your medical condition. An Implant failure must be confirmed by Us before it is explanted.

WARRANTY DISCLAIMER:

WE EXPRESSLY DISCLAIM ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE. WE WILL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES CAUSED BY THE IMPLANT'S FAILURE TO FUNCTION WITHIN THE NORMAL TOLERANCES WHETHER THE CLAIM IS

BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

If we choose, we may replace the Implant even if the failure is not covered.

Argus 2s Limited Warranty on External Devices

External Devices include the video processing unit (VPU), glasses, battery, battery charger base and battery charger AC adaptor.

We warrant that the Argus 2s VPU and Glasses will be free from defects in workmanship and materials for 1 year from the date of first VPU programming (or date of purchase if bought separately).

We further warrant that the supplied battery charger and rechargeable batteries are free from defects in workmanship and materials for 3 months from the date of first VPU programming (or time of purchase if bought separately). The battery charger includes the charger base and AC adaptor.

We will repair or replace a defective External Device, or at Our option, provide full credit equal to the purchase price of the defective External Device. You may apply the credit towards the purchase of replacement components.

WE EXPRESSLY DISCLAIM ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE.

Product claims under Our Limited Warranty on External Devices are subject to the following conditions:

1. The product registration forms for the VPU and glasses must be completed and returned to Us within 30 days of first programming or receipt of the product.

2. Warranty claim items must be returned to Us within 30 days after receipt of replacement part(s).

3. We must be able to confirm the failure.

4. This warranty excludes defects caused by: fire, floods, lightning, natural disasters and other calamities defined as “Acts of God;”. This warranty excludes defects caused by accident, misuse, abuse, negligence, water damage, improper programming or failure to operate the External Device according to our instructions. This warranty excludes defects caused by wear and tear resulting in cosmetic or exterior damage. This warranty excludes defects caused by attempts to repair, maintain, or modify the equipment by You or

anyone else. This warranty excludes defects caused by attachment of an External Device to any device not supplied by Us without Our prior approval. This warranty excludes defects caused by cable breakage. Appropriate care should be taken to prevent forces from damaging cables. This warranty excludes defects caused by battery cell depletion, which may occur during the warranty period and is not considered a defect in workmanship or material—The batteries have a specified capacity, which may deplete at different rates depending on the settings used and failure to recharge as specified in the operator's manual. Note: Per operator instructions, batteries should be used promptly after receipt, should not be stored for future use, periodically recharged and must be kept within temperature range. This warranty excludes defects caused by accessories not listed with this limited warranty.

5. For a replacement component the warranty will run only to the warranty period for the original component that was purchased by You.

The terms and conditions of this warranty limitation may be different in each country depending on local laws.

For information on Our warranties or if You believe a device is not working properly, please contact us using the contact information in Chapter 7, page 105.

Chapter 7: Contact Information

Second Sight Medical Products welcomes your comments about the Argus 2s Retinal Prosthesis System or your suggestions to improve the product. Please feel free to contact us for technical assistance, replacement parts, or your suggestions.

Second Sight Medical Products, Inc.

13170 Telfair Ave
Sylmar, CA 91342 USA
Phone: +1 818 833 5060
Fax: +1 818 833 5067

E-mail: service@secondsight.com
www.secondsight.com

Write important telephone numbers here

Resource	Telephone number:
Clinic	
Physician	
Device disposal contact:	

Chapter 8: Symbols and Regulatory Classifications

Symbols

The following symbols appear on components of the Argus 2s system. The symbols and their meanings are described below.

Table 10: Symbols

Symbol	Meaning
REF	Catalog number
SN	Serial number
LOT	Lot number
	Date of manufacture
	Consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself
	Follow instructions for use
	Storage temperature range

Symbol	Meaning
	Keep Dry
	Non-ionizing radiation (Radio frequency radiation)
	Manufactured by
	Type BF Applied Part
	MR Conditional
	MR Unsafe

Regulatory Classifications

The Argus 2s system meets the requirements of several international standards and directives. The table below indicates how the Argus 2s system is classified according to each of these standards and directives. For detailed information regarding electromagnetic environments, please see Appendix A, page 113.

Table 11: Regulatory Classifications

Standards / Directives	Regulatory Classifications
IEC 60601-1	Classification: Internally Powered Type BF Applied Part IP22 – Device protected from touch by fingers and objects greater than 12 millimeters. Protected from water spray less than 15 degrees from vertical.

Standards / Directives	Regulatory Classifications
IEC 60601-1-2 Classifications (CISPR 11 Electromagnetic Emissions)	Classification: Group 1 Equipment Equipment in which there is intentionally generated and/or used conductively coupled radio frequency energy, which is necessary for the internal functioning of the equipment itself. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. Class B Equipment Equipment suitable for use in all establishments including your home.

Standards / Directives	Regulatory Classifications
IEC 60601-1-2 (Electromagnetic Immunity)	Classification: The Argus 2s system may experience interference from ESD, power frequency magnetic fields, and conducted and radiated RF.
IEC 60601-1-11	Classification: P22, Protected from touch by fingers and objects greater than 12 millimeter. Protected from water spray less than 15 degrees from vertical.

Standards / Directives	Regulatory Classifications
R&TTE Directive	Classification: Product Type 1 - Inductive loop antenna transmitter tested with an integral antenna Receiver Class 2 - Function critical Short Range Device (SRD) communication media; i.e. when a failure to operate correctly causes loss of function but does not constitute a safety hazard.

Appendix A: Potential Effects of Electromagnetic Interference (EMI)

Information for Users (FCC Rules)

FCC waiver DA 11-1951, has been granted to Second Sight Medical Product Inc. This allows the Argus II system to operate with emissions at the fundamental frequency (3.156 MHz) not to exceed 119 µV/m at 30 meters and has been used to pass the radiated emissions limits (for the fundamental frequency) for intentional radiators as called out in FCC 47 CFR Part 15, Subpart C – §15.209.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for Class B Digital Device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures.

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver

Appendix A: Potential Effects of Electromagnetic Interference

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected

- Consult the dealer or an experienced radio/TV technician for help

Any changes or modifications not expressly approved by Second Sight Medical Products, Inc. could void the user's authority to operate the equipment.

Table 12: Potential effects of EMI from devices or procedures

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus 2s System	Temporary Interruption of Stimulation	Image Artifact[a]	
Airport screening device			✓		Page 36
Bipolar electrosurgical equipment		✓			Page 35
Bluetooth device			✓		Page 37
Cell phones or cordless phones			✓		Page 37
Computed tomography (CT) Scan				✓	Page 35

Appendix A: Potential Effects of Electromagnetic Interference

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus 2s System	Temporary Interruption of Stimulation	Image Artifact[a]	
Commercial electrical equipment (for example, arc welders induction furnaces, resistance welders, etc.)			✓		Page 39
Communication equipment (such as microwave transmitters, linear power amplifiers and high-power amateur transmitters)			✓		Page 39
Defibrillator		✓			Page 35
Diagnostic Ultrasound				✓	Page 35
Diathermy	✓	✓			Page 28
Electric steel furnaces			✓		Page 39
Electroconvulsive therapy (ECT)	✓	✓			Page 28

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus 2s System	Temporary Interruption of Stimulation	Image Artifact[a]	
Electronic article surveillance (EAS) systems and EAS tag deactivators			✓		Page 36
Fragmatome		✓			Page 34
Hearing aids			✓		Page 37
High output ultrasound	✓	✓			Page 39
High voltage lines, power lines or generators			✓		Page 39
Home appliances			✓		Page 37
Large magnetized speakers			✓		Page 39
Laser		✓			Page 34
Lithotripsy	✓	✓			Page 28
Magnetic resonance imaging (MRI)	✓	✓		✓	Page 29
Metal detector			✓		Page 36
Phacoemulsification		✓			Page 34

Appendix A: Potential Effects of Electromagnetic Interference

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus 2s System	Temporary Interruption of Stimulation	Image Artifact[a]	
Radiofrequency identification (RFID) systems			✓		Page 36
Theft detector			✓		Page 36
Therapeutic ionizing radiation to the head		✓			Page 35
WiFi access point			✓		Page 37
Wireless router			✓		Page 38

[a] If the medical procedure is being performed to evaluate the area where the Argus 2s Implant is located, the implant may block or blur the image making it unreadable in this area.

Appendix A: Potential Effects of Electromagnetic Interference

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