



Second Sight

# Argus<sup>®</sup> II Retinal Prosthesis System

## Patient Manual

**REF**

090000-002

**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.

900028-001 Rev C3





**Argus<sup>®</sup> II**  
**Retinal Prosthesis System**

**Patient Manual**

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# **Chapter 1: Important Information**

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## **Indications for Use**

The Argus II Retinal Prosthesis System is intended to provide electrical stimulation of the retina to induce visual perception in blind patients. It is indicated for use in patients with severe to profound retinitis pigmentosa who meet the following criteria:

- Are an adult, age 25 years or older.
- Have bare light or no light perception in both eyes. (If you do not have any remaining light perception, you will be tested to make sure that your eye will respond to electrical stimulation.)
- Were able to see objects, shapes and lines in the past.
- Have no lens or an artificial lens in the eye that will be implanted (If you have a natural lens in the eye that will be implanted, it will be removed during the implant surgery.)
- Are willing and able to receive the recommended post-implant clinical follow-up, device fitting and visual rehabilitation.

The Argus II implant will be implanted in only one eye, most likely the eye that has the worse vision.

## **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 II System from working properly (for example, optic nerve disease, central retinal artery or vein occlusion, history of retinal detachment, trauma, or severe strabismus).
- Have an eye structure or condition (for example, a very long or very short eye, as measured from the front to the back of the eye) that could make it difficult to successfully implant the Argus II Implant or recover following surgery.
- Have eye diseases or conditions (other than cataracts) which make it difficult for your doctor to see inside your eye (for example, a cloudy cornea, etc.).
- Are unable to undergo general anesthesia or take the recommended antibiotic and steroid medications you will need to take before and after surgery.
- Have a metallic or active implantable device (for example, a cochlear implant) in your head.

- Have any disease or condition (for example, significant mental decline) that prevents you from understanding or giving your informed consent, from undergoing the programming the device after it is implanted, or from having medical follow-up. Your doctor may ask you to have a psychological evaluation to make sure you are qualified for this device.
- Tend to rub your eye a lot.

## **General Warnings and Precautions**

### **Warnings**

- If 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.
- If you have an Argus II Implant, do not undergo **electroconvulsive therapy (ECT)** as ECT may damage your eye or your Argus II implant.
- If you have an Argus II Implant and need to undergo **lithotripsy or high output ultrasound**, inform your doctor that you have this implant. If you have an Argus II

Implant, these treatments may harm you or damage the implant. Your doctor should contact Second Sight Medical Products for instructions in how to perform these procedures in someone who has an Argus II Implant.

- The Argus II Implant has been classified as an **MR Conditional** device. If you have an Argus II Implant, you may undergo a magnetic resonance imaging (MRI) procedure **ONLY** if it is performed using a 1.5 or 3.0 Tesla MRI System and **ONLY** following special instruction. Before having an MRI procedure, tell your doctor that you have the Argus II Implant. Your doctor should contact Second Sight Medical Products for instructions in how to perform an MRI in someone who has an Argus II Implant.
- If you have an Argus II Implant, you should not enter a room housing an **MRI** System that is not 1.5 or 3.0 Tesla, even if the Argus II System is not being used.
- The Argus II System may cause **medical monitoring, diagnostic or life support equipment** to function improperly. Do not use the Argus II System within 3 feet of this type of equipment. If someone notices that interference is occurring, turn off the

Argus II VPU or extend the distance between yourself and the equipment.

- If you have an Argus II Implant do not receive treatment with **monopolar electrosurgical equipment**. Monopolar electrosurgical equipment may damage the implant or the tissue around the implant.

### **General Precautions**

- If you experience any **uncomfortable feeling** while using the Argus II System (for example, pain), immediately stop using the system by removing the Argus II Glasses or by turning off the Argus II VPU.
- 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 II System. It could also prevent you from getting a replacement Argus II Implant or another type of retinal implant in the future.
- Only **use a VPU that has been specifically programmed for you** by your clinician. Using someone else's VPU may limit how well you see with the Argus II System and may cause you physical discomfort from overstimulation.

- Avoid **physical impact or extreme direct pressure to the eye** as this may result in injury to the eye, movement or damage to the Argus II Implant. If either of these occurs, contact your physician.
- Avoid **rubbing the eye** that has the implant as this may dislodge the implant or cause eye irritation.
- Even though you have the Argus II Implant, **continue to use your other mobility aids** (for example, canes, dogs, etc.) at all times.
- Use of the Argus II System during **pregnancy and nursing** has not been evaluated.

### **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 II System.

The Argus II System meets international standards for electromagnetic compatibility (Refer to “Symbols and Regulatory Classifications” on page 88 for more information). The Argus II System is designed to continue to operate in a “safe mode” in the presence of any electromagnetic

interference that you would encounter during your normal every day 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 3.
- Damage to your Argus II implant. Damage to the implant may require replacement; or result in loss of, or irreversible change in the performance of the Argus II System. See “Warnings” on page 3.
- Unexpected Turning off of the Argus II VPU. EMI may cause your VPU to turn off unexpectedly.
- Interruption of Stimulation. EMI may cause a momentary interruption of stimulation.

If you enter an environment which maybe causing interference with your Argus II 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 II System is not working as well as it did before you encountered the interference, please contact your doctor.

Refer to the *Precautions Regarding Other Medical Procedures*, the *Possible Interference with Other Electronic Devices*, or the *Travel or International Use* sections of this manual for additional information regarding potential sources of electromagnetic interference and how to use your Argus II System in these environments.

### **Precautions Regarding Other Medical 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.

Remove the Argus II Glasses and VPU before having any medical or test procedure that involves the use of other medical equipment. Once the

procedure is complete, you should have your Argus II Implant tested by your clinician as soon as possible to make sure it is still functioning properly.

- The use of **laser, phacoemulsification, fragmatome** may damage the Argus II Implant.
- The use of **bipolar electrosurgical equipment** may damage the Argus II Implant.
- You may undergo **CT Scans or Diagnostic Ultrasound**. However, if a scan or ultrasound is performed 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 therapeutic ionizing radiation** to the head may permanently damage the Argus II Implant. However, this should not stop you from receiving these treatments, if necessary. The Argus II Implant should be tested as soon as possible following these procedures to determine whether the implant is still functioning properly. Damage to the implant may not be immediately detectable.

- The effects of **cobalt treatment or linear acceleration techniques** on the implant are unknown.

### **Possible Interference with Other Electronic Devices**

- **Theft or metal detectors** (such as those located in entrances to public buildings and department stores) and **airport or security screening devices** may interfere with the Argus II System causing interruption of stimulation. When possible, it is best to avoid these devices or turn the VPU off when passing through these systems. You should show your patient identification card to any attendant in the area who may be able to assist you in bypassing these devices. If unavoidable, walk through the scanner and promptly move away from the area. Do not lean on these scanners or linger in their path.
- **Static electricity** may interfere with normal operation or cause damage to the Argus II System. Common situations that create static electricity include putting on or removing clothes, or dragging feet across a carpet or rug when there is very low humidity (for example, humidity below 30%). Static electricity can be removed by touching a metal object. Avoid handling the

VPU and glasses if you think there is a lot of static electricity present.

- The Argus II 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 II System before you are implanted, to make sure both the hearing aid and Argus II System will function properly.
- Some **home appliances** (for example, microwaves and computer monitors) and some **devices with antennae** (for example, walkie-talkies, amateur radios, cell phones, and FM systems) may temporarily interrupt Argus II stimulation if the Argus II System is located within 1 – 3 yards of them. Devices with antennae may be marked with the following symbol:



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

- When the Argus II system is used in very close proximity to **marine radios**, normal operation of the system may be temporarily interrupted. Normal operation will resume when you move away from these items.
- The Argus II System operates using wireless technology which could interfere

with the safe operation of an **airplane**. Do not turn on the Argus II System on an airplane.

- **Commercial electrical equipment** (such as arc welders, induction furnaces or resistance welders), **communication equipment** (such as microwave transmitters, linear power amplifiers and high-power amateur transmitters), **high voltage lines, power lines or generators, electric steel furnaces, or large magnetized speakers** may temporarily interrupt Argus II System function. Normal operation should resume when you move away from these objects.

### Travel or International Use

You may want to travel with your Argus II System. When travelling and not using the system, it is recommended that you store the external system in the travel case.

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

Bring your patient identification card with you to assist in going through security systems (this card

is described in the section below). You should turn off the VPU when you go through security.

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

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.

## **Your Patient Identification Card**

After you are implanted with the Argus II device, you will receive a patient identification card. 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 should you need to bypass a security system or in the case of a medical emergency. Keep this card with you at all times. One of the corners of this card has been clipped to allow you to tell it apart from other cards in your wallet.

If you change your address or doctor's information, contact Second Sight. Include the

current information and indicate the changes. You may either call 1-818-833-5060 with the information or send it to:

Second Sight Medical Products, Inc.  
Device Registration  
12744 San Fernando Rd., Bldg. 3  
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, it is recommended that you include the following information on it:

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

## **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 may be 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 system is getting worse.
- You experience any unusual symptoms that you think may be caused by

electromagnetic interference (such as theft detectors).

## **Recovering From Surgery or Any Adverse Events**

After your surgery, your doctor or nurse will provide you with instructions on how to recover. These instructions often include information about the healing process, medications to take, and when 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 to recover from surgery. During this time, you may feel discomfort around your eye. If you notice unusual symptoms, contact your doctor.

## **Risks and Benefits**

### **Risks of the Argus II System**

Risks associated with the Argus II System include surgical risks, possible side effects, and potential device complications. These are described below.

#### **Risks of Surgery**

The risks of implanting the Argus II Implant are similar to the risks of other eye surgeries and general anesthesia. These risks may include:

- Chest pain or heart attack
- Allergic reaction to the anesthesia or to the implant materials
- Blood clots in the legs or lungs (pulmonary embolism or deep vein thrombosis)
- Respiratory failure
- Blood loss requiring transfusion
- Infection
- Hospitalization
- Urinary retention
- Bleeding in the eye
- A tear, hole or other damage to the retina
- Damage to the eye muscles or eye lids

### Possible Side Effects

Side effects of the surgery, the presence of the Argus II Implant in the eye, or the use of the Argus II System may include:

- Thinning of the tissue that covers the implant

- Opening of one or more of the of the surgical wounds
- A decrease or increase in the internal pressure in your eye
- Detachment or tear of the retina or the choroid (a thin layer of cells behind the retina)
- Clouding or thinning of the cornea
- Blood vessels, deposits or mucus developing on the cornea
- Formation of blood vessels on the iris
- Corneal dryness
- Redness and irritation in or around the eye (inflammation)
- Irritation caused by the sutures
- Pain in or around the eye
- Headaches
- Formation of scar tissue in the eye
- Dry eye or watering eye
- Cysts on the eye
- Swelling of the retina or choroid
- Decrease in remaining light perception
- Foreign body sensation
- Nausea or vertigo

- Increase in involuntary eye movement (nystagmus)
- Drooping of the eyelid
- Removal of the eye, if serious complications cannot be adequately treated
- Implantation of this device may prevent you from receiving alternative treatments for retinitis pigmentosa that may be developed in the future.

### Possible Device Complications

- There may be pain, lack of healing, or infection where the implant is located.
- The implant could wear through the layer of tissue covering it or could wear into the eye.
- The implant could move or the retinal tack could become loose. You may need surgery to adjust the position of the implant in your eye or re-tack it to your retina.
- The device may need to be repositioned to improve how well it functions
- The implant could stop working due to mechanical or electrical problems, damage caused by the surgical procedure, impact to the device, or exposure to harmful levels of energy. Any of these may require surgery to remove the device.

- Your body may have an allergic reaction to the materials in the implant or in the glasses, both of which come into contact with your body. (The following materials in the implant and glasses come into contact with your body: niobium, titanium, silicone, platinum and plastic. While these materials are commonly used to make medical implants and have passed testing to show that they should not cause a reaction, it is still possible that you may have a reaction to them.)
- There is a possibility of damage to your retina due to trauma, too much stimulation, or heating of the implant.
- The implant could cause facial nerve stimulation, electric shock, or skin burn due to too much heating of the external equipment.
- The system could cause you to fall or bump into something.

### Possible “Cascade” of Complications

There is the possibility that one complication could lead to other complications. In addition, a complication could lead to the worsening of other complications. Sometimes, it may take several visits to your doctor, several treatments, and/or possibly surgery to treat a “cascade” of complications. If the complication(s) cannot be

adequately treated, you may ultimately need to have the Argus II implant removed from your eye or possibly in the extreme case have your eye, itself, removed.

## **Benefits and Limitations of the Argus II System**

The Argus II System provides an artificial form of vision; it will not restore normal vision. The system will not slow or reverse the progression of your disease. In addition, the system will not replace your normal visual aids (such as a cane). When you are not using the Argus II System, your vision will return to its original impaired state.

Learning to interpret the information from the device and incorporate it into your functional life may be a challenging process. You will have to learn how to combine the information provided by the Argus II System with your existing assistive devices (such as a dog or cane) and with the techniques you already use to cope with your visual impairment.

When you use the Argus II System, it will deliver electrical stimulation to your retina that will allow you to see phosphenes (spots of light). The apparent size of the electrode array in visual space may be about 3.5 inches by 6.5 inches, or slightly larger than a standard 3 x 5 index card held at arm's length. However, the actual size of light you see when all the electrodes are turned on together may be larger or smaller than this due to individual variation. At first, you may not be able to tell exactly what you are looking at. You will need

training to learn how to interpret the vision provided by the Argus II System.

The Argus II System may help you perform tasks visually, rather than by touch. For example, during the clinical trial some subjects were able to use the Argus II System to locate lights and windows, follow lines on the ground (for example in a cross walk), avoid obstacles as they walked, sort laundry, determine where other people were located, and recognize large font letters and words. In addition, many subjects reported enjoying seeing light after being blind for many years and having a greater feeling of connection 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 2: Device Description

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The Argus II Retinal Prosthesis System consists of the following main components and accessories:

- Argus II Retinal Prosthesis (“Implant”)
- Argus II Video Processing Unit (“VPU”)
- Argus II Glasses (“Glasses”)
- Accessories:
  - VPU Rechargeable Battery
  - VPU Battery Charger
  - VPU Pouch
  - Travel Case

### **WARNING**



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

**The use of cables or batteries other than those supplied by Second Sight may result in your Argus II system being more effected by electromagnetic interference from other devices. Use of non-approved cables or batteries may also result in the Argus II System interfering with the performance of other electronic equipment.**

**Refer to the section on  
Electromagnetic Interference  
(EMI) for more information.**

The Argus II Retinal Prosthesis is implanted in and around your eyeball. To turn on and use the implant, you will need to wear the glasses and VPU (which together are referred to as the “external equipment.”)

The system works as follows. A miniature video camera on the glasses captures a scene. The video is sent to the VPU where it is processed and converted into instructions that are sent back to the glasses via a cable. These instructions are sent wirelessly to a receiver in the implant. The signals are then sent to the electrode array, which emits small pulses of electricity. These pulses stimulate your retina’s remaining cells, which send the signals along the optic nerve to your brain, resulting in the perception of light. Over time, you may learn how to interpret these visual patterns as recognizable objects.

Note: The implant is powered only when you are wearing the glasses and have the VPU turned on; otherwise, the implant is off.

Each of these individual components is described below.

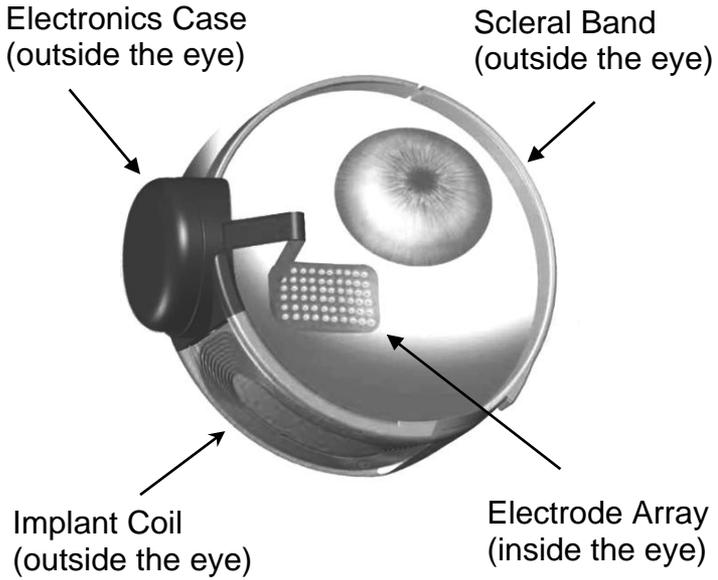
## **Argus II Retinal Prosthesis (Implant)**

The implant consists of four parts: (1) the electronics case (2) the implant coil, (3) electrode array, and (4) the scleral band. The implant is made of metal, plastic and silicone.

Figure 1 shows the implant as it looks once implanted around and inside the eye. Part of the implant sits on the outside of your eye (but underneath a thin layer of tissue that covers the white part of the eye) and is held in place with the scleral band that wraps around your eye. The electrode array, which stimulates your retina, has 60 electrodes arranged in a rectangular grid, 55 of which are turned on at the time of implant. Up to 5 of the remaining electrodes may be functional and could be turned on to replace an electrode if it fails post-implant.

The implant has a cable that is attached to the electronics case and is then fed through an incision in your eye. The portion of the array with the electrodes is attached onto your retina with a retinal tack. The implant is not visible to other people.

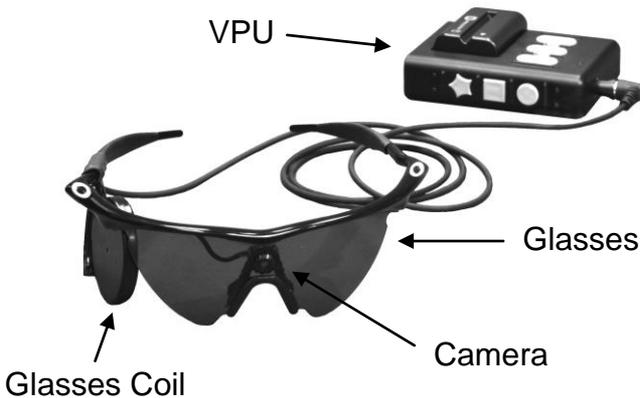
**Figure 1: Implant on a Right Eye  
(looking at your eyeball)**



## External Equipment

A photo of the VPU, glasses, and battery is provided in Figure 2. A description of each of these components follows.

**Figure 2: External Equipment**



### **Video Processing Unit (VPU)**

The VPU allows you to turn stimulation on and off and select the stimulation settings best suited to your current environment. It is made of metal and has rubber buttons. The VPU is connected to the glasses using a cable, and both must be worn in order to power the implant. When the VPU is on and you are wearing the glasses, the VPU is in constant communication with the implant. The VPU also tracks when it is switched on and off, how well your implant and VPU function, and

whether the communication between the implant and VPU is interrupted. Your clinician can monitor this information when you visit the clinic.

The VPU buttons are large and shaped so that they can be easily identified by touch. The glasses receptacle connects the VPU to the glasses. The communication adapter connector connects the VPU to a computer which is only used during testing in the clinic. When not in use, the communication adapter connector on the VPU is covered by a metal door. The VPU with the battery weighs about half a pound, see Figure 3 for a diagram of the VPU.





<b>Component</b>	<b>Description</b>
Inverse Setting Button	The square-shaped button located on the right-hand side of the VPU is used to invert the image from black-to-white and white-to-black. Each time the button is pressed, the image is inverted. It is set to the “non-invert” mode every time the VPU is switched on.
Audible RF Link Alarm Button	The star-shaped button located on the bottom of the right side of the VPU is used to enable or disable the audible alarm that indicates if the communication link with the implant has been interrupted. The default setting is “RF link alarm on”. It is set to the “RF link alarm on” mode every time the VPU is switched on.

<b>Component</b>	<b>Description</b>
Battery Receptacle	The battery receptacle, located on the bottom third of the front panel, is where the rechargeable battery is installed on the VPU. The receptacle has a keying mechanism that prevents incorrect installation of the battery.
Battery Latch	The battery latch, located on the left side of the VPU, is a two-position, sliding latch that automatically slides into the “locked” position when a battery is properly inserted into the receptacle. To remove a battery, you must first slide the latch to its “un-locked” position. Refer to Chapter 4 for details about inserting and removing the battery.
LED Indicators	Three indicator lights are located on the front of the VPU in between the oval control buttons. These give a visual indication of the operating status of the VPU.

Component	Description
Glasses Receptacle	The glasses receptacle is a round connector on the top of the VPU that accepts the glasses cable plug. Refer to Chapter 4, “Connecting the glasses to the VPU” for more information.
Communication Adapter (CA) Connector	Located on the bottom of the VPU, this rectangular-shaped connector accepts the cable coming from the communication adapter. Used only in the clinic, it is protected by a metal door when not in use.

**Table 2: VPU Accessories**

Accessory	Description
Battery	Small and medium sized rechargeable batteries are available for use with the VPU. Only use rechargeable batteries provided to you by Second Sight.

Accessory	Description
Battery Charger	Depleted batteries can be recharged by using the battery charger that is provided with the Argus II System.
VPU Pouch	The pouch allows the VPU to be worn on the body. It can be adjusted to hold the VPU in the most comfortable orientation.

## **Glasses**

The glasses, which are made of plastic, have a miniature video camera in the bridge above the nose and a coil on one of the earpieces, which is used to power and communicate with the implant. The glasses are connected to the VPU by a cable. See Figure 4.

Table 3 provides a description of the components that make up the glasses and their associated accessories.

**Figure 4: Glasses for the Right Eye**



**Table 3: Glasses Components and Accessories**

<b>Component</b>	<b>Description</b>
Glasses	The glasses provide a convenient and discreet way to house the video camera and the coil needed to power and communicate with the implant.

<b>Component</b>	<b>Description</b>
Camera	A miniature video camera is mounted in the center of the glasses frame, directly above the nose bridge. When the system is operating, the camera conveys a steady stream of video images to the VPU, via a cable.
Glasses Coil	The glasses coil contains the receiver and transmitter antennae. The coil is mounted to the temple of the glasses on the side where the implant is located. It is used to communicate wirelessly with the implant.
Cable  Cable (continued)	The cable provides a connection between the glasses and the VPU. The cable has three functions: (1) To power the camera and convey video signals from the camera to the VPU; (2) To send data and power from the VPU to the glasses coil; and (3) To convey implant status information from the glasses coil to the VPU.

Component	Description
	<p>The cable is part of the glasses assembly and cannot be removed from the glasses.</p> <p>If the cable breaks or malfunctions, the glasses should be replaced. Contact your clinician or Second Sight using the information provided in Chapter 6 for replacement parts.</p>
Travel Case	<p>A durable case is provided to safely store and transport the VPU, glasses and batteries when not in use. See Figure 5.</p>

**Figure 5: Travel Case**



## **Argus II System Wireless Information**

The Argus II Glasses use wireless technology to communicate with and power the Implant. Table 4 summarizes information about the wireless technology used in the Argus II System.

**Table 4: Wireless Technology Information**

	<b>Details</b>
How to Achieve Wireless Link with the Glasses	Wear the glasses as you would a normal pair of glasses. Your clinician will position the glasses coil to ensure that it will have good wireless link with the implant. The glasses and the implant will automatically connect and operate when the glasses are placed on your head and the VPU is turned on. Refer to “Wearing the Glasses” on page 52 for more details.
Wireless Specifications:	
Frequency (to the implant)	3.156 Megahertz (MHz.)
Frequency	473 – 490 Kilohertz (KHz.)

	<b>Details</b>
(from the implant)	
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	Wireless link active more than 90% of the time when the coil is approximately 1 inch or closer to the implant. For Troubleshooting regarding link loss, refer to page 77.

	<b>Details</b>
Wireless Security	The wireless system is designed so the implant will only operate if it is within a very short distance of the glasses. The Argus II System uses a proprietary communication protocol to reduce the likelihood of inadvertent control or malicious “hacking” of the System. No identifiable personal data are transmitted by the Argus II System.
Interference related to the wireless system	<b>CAUTION: Refer to the Possible Interference with Other Electronic Devices section on page 10.</b>

## **Argus II Patient Catalog**

The following items are included in your Argus II Retinal Prosthesis Patient Catalog:

**Table 5: Patient Catalog**

<b>Description</b>	<b>Catalog / Product Number</b>
Argus II Video Processing Unit including Patient Manual	013003
VPU Batteries:  Small battery Sony InfoLITHIUM M Series Model Number NP-FM500H  Medium battery Sony InfoLITHIUM M Series Model Number NP-QM71D	100200-001       100200-002
Argus II Glasses: 4 possible configurations  Glasses, Right Eye, Dark Lenses Glasses, Right Eye, Clear Lenses Glasses, Left Eye, Dark Lenses Glasses, Left Eye, Clear Lenses	    012011 012012 012013 012014
VPU Battery Charger	100200-004
Argus II Travel Case	012930
Argus II VPU Pouch	013931



# Chapter 3: Preparing for Your Device

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## Implantation Surgery

Below is general information about how the Argus II System is implanted. Your doctor will provide you with more specific information.

1. Two days before surgery, you may be instructed to start taking antibiotics.
2. On the day of surgery, you will be admitted 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.
3. If you have a natural lens in your eye, the surgeon will remove it before inserting the implant. If you have an intraocular lens in your eye, the surgeon will likely leave it in place.
4. The conjunctiva (the thin tissue that covers the white part of your eye) will be pulled back. If your eye orbit is small, the surgeon may need to make a small cut at the outer corner of the eyelids to make it easier to place the device.
5. The surgeon will then place the implant around your eye. It will be adjusted and positioned to

fit snugly against your eye. The band on the implant will be secured around your eye using a small plastic sleeve. Stitches will be placed on the implant to hold it in place on your eye.

- 6.** The surgeon will then make small hole in the wall of your eye and will remove all of the gel-like fluid inside your eye. The fluid will be replaced with a saline solution.
- 7.** If you have a thin layer of tissue over your retina, your surgeon may remove this by gently peeling it off the retina.
- 8.** Your surgeon will then attach the electrode array of the implant to your retina with a tack. The implant will then be tested to ensure that it is functioning properly.
- 9.** If the device is functioning properly, all of the cuts in your eye will be closed and a thin layer of tissue (from a human donor) will be placed over a small portion of the implant on the outside of your eye.
- 10.** The conjunctiva (the thin tissue that covers the white part of your eye) will be closed with stitches that will dissolve over time.
- 11.** Your eye will be patched and you will be escorted to the recovery room.

12. After you recover from surgery, you will be discharged from the hospital with instructions to take a prescribed oral medication and use eye drops to control swelling, infection, and pain. You will probably not need to spend the night in the hospital.
13. You will need to return to the hospital the next day so the doctor can check 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 adequately from your surgery, fitting and programming of the device may begin.

## **Post-Implant Care**

After you are implanted with the Argus II Implant, you will need to return several times to the clinic for clinical follow-up, device fitting and programming, and visual rehabilitation. Each of these is described in more detail below. You should consider living close enough to the clinic, or be willing to temporarily relocate closer to the clinic, to allow you to fully participate in the recommended follow-up.

### **Clinical Follow-Up**

You will need to return to the hospital periodically so that the doctor can check the health of your

eye. These periodic visits will continue as long as the Argus II implant remains in your eye.

## **Device Fitting and Programming**

After the implant surgery, you are about to start the exciting and long journey of living and working with your Argus II System. First, the system will need to be programmed, or “fitted”, in order for you to “see” anything from the device.

### **Initial Fitting Sessions**

The purpose of the initial fitting sessions is simple: to find suitable stimulation levels across all of the electrodes so that the first visual program can be set on your VPU. This is achieved by having you come to the clinic where your video processing unit (VPU) will be connected to a special computer. Your clinician will use the software to command the implant to provide electrical stimulation. Your response to the stimulation will be recorded and used to create custom programs that can be downloaded to your VPU for you to use in your everyday life.

### **Preparing for Using the Argus II System at Home**

Once the programs are created and downloaded to the VPU, the device can be connected to the glasses, turned on and you will start to perceive spots of light, also known as phosphenes, from the

device. The video signal is captured by the camera mounted on the glasses. The camera will be adjusted by your clinician to line up with how the implant is positioned inside your eye.

You will also be trained on how to connect the glasses to the VPU, how to operate the controls and switches on the VPU, how to understand the alarms and LED lights, simple troubleshooting, and care and maintenance of your Argus II System.

Several of these fitting and training sessions must be conducted over the course of 4-6 weeks following the surgery before you can use the 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 fitting sessions, you may need to visit your clinician on a regular basis in order to fine-tune the program. If your perceptual experience with the device changes, you should contact your clinician for a follow-up programming session.

### **Visual Rehabilitation**

Following device implantation, it is very important to participate in the recommended visual

rehabilitation program. This rehabilitation program is designed to allow you to improve your ability to perform daily activities and reach your goals with the Argus II System.

# Chapter 4: Using Your Device

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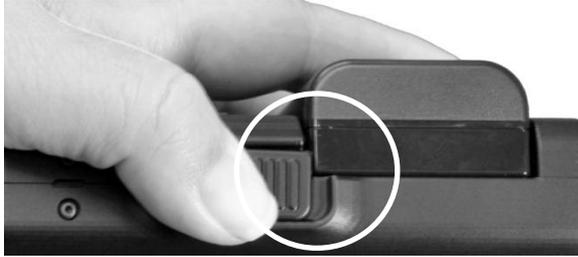
## Setup Instructions

To set up the equipment for use, follow the instructions below.

- 1. Charge the battery.** Before first use of a battery, charge it fully. To charge the battery, plug in the battery charger and place the battery in the receptacle of the charger. It takes approximately three hours to fully-charge a battery. The following can be checked by a sighted individual. When the battery is charging, the orange charge light is on. When the battery is fully charged, the light will be off.
- 2. Install the battery.** To install the rechargeable battery, slide the VPU battery latch so that it opens (as shown in Figure 6 below). While holding the latch open, slide the battery in the receptacle away from the latch until the battery latch automatically slides into its locked position.
- 3. Remove the battery.** To remove the battery, slide the VPU battery latch so that it opens (toward the top of the VPU). Holding the latch open, slide the battery as far as you can

toward the latch and lift it out of the receptacle. Release the latch.

**Figure 6: Battery Latch Being Held Open**



- 4. Confirm proper installation of the battery.** Confirm that the battery is properly installed by gently pulling it. If the battery comes loose, it was not properly installed. Perform Step 2 again to properly re-install the battery.

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

- 5. Wearing the VPU.** Place the VPU in the pouch and lock it in place using the Velcro<sup>®</sup> strap near the right side of the VPU next to the star-shaped button. Insert the battery into the receptacle and secure the VPU in place with the other Velcro strap. The VPU pouch can be worn on the body.

- 6. Connecting the glasses to the VPU.** The glasses are equipped with a cable that is inserted into the glasses receptacle located on the top of the VPU. To connect the glasses to the VPU, perform the following steps:
- (a) Always make sure the VPU is turned off before connecting the glasses.
  - (b) Grasp the cable and hold it by the rubber piece at the end. Notice that the rubber piece makes an L-shape. This L-shape aids in proper orientation of the plug.
  - (c) Locate the round-shaped glasses receptacle on the VPU.
  - (d) Insert the cable plug into the glasses receptacle. Ensure that the cable end of the plug is pointed towards the right side of the VPU where the circular power button is located. Apply pressure to insert the plug into the glasses receptacle. If the plug does not insert, gently rotate it for proper alignment while trying to insert it. Once aligned, the plug will insert into the glasses receptacle.
  - (e) Push the plug firmly into the receptacle until you hear a click. Note that the plug does not lock.

**7. Disconnecting the glasses from the VPU.**

Always turn the VPU off before disconnecting the glasses. If you need to disconnect the glasses from the VPU, hold the VPU firmly in one hand. Using the other hand, grasp the L-shaped plug at the end of the glasses cable and gently pull it straight away from 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.**

- 8. Wearing the glasses.** Using both hands, gently put on the glasses as you would a normal pair of glasses. Adjust the cable so that it is comfortable and does not catch on anything such as your arms or clothes. The cable may be threaded inside your clothing to prevent it from getting caught on objects while you move.

**CAUTION: Do not adjust the position of the glasses coil. The coil position is set by your clinician or Second Sight personnel to optimize performance of the device. Changing the coil position may cause loss and/or interruption of stimulation. Contact your clinician if your VPU audible alarm beeps frequently.**

**CAUTION: Use care when putting on the glasses. Do not over-extend the glasses arms as this could break them.**

**CAUTION: Do not attempt to adjust the camera mounted on the glasses as it may cause damage or misalignment of the camera.**

## **Operating Instructions**

**CAUTION: Do not exchange your VPU with another patient's VPU. Each VPU is programmed for one patient and can cause uncomfortable stimulation if used by another patient.**

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

To use the VPU and glasses, follow the instructions below.

- 1. Lighting Conditions.** The Argus II System uses the camera in the glasses to capture the video image that is sent to your implant. Since the camera does not work well in dimly lit environments, it is important to make sure that you have enough light in your surroundings when you are using the System. If you are inside, you should always make sure the lights

are on in the room. It is also recommended that a sighted individual confirm that your lights are working properly.

- 2. Turning on the VPU.** Put the glasses on as described above. To turn on the VPU, press the circular power button on the side of the VPU and hold it down for approximately two seconds until you hear four short beeps.
- 3. System start-up tests.** Immediately after the VPU is turned on, the system performs a series of tests. These tests last approximately 30 seconds. During this time the green indicator light will blink quickly. You may or may not see something during these tests. Once these tests are complete, stimulation will begin and the green indicator light will blink more slowly (1blink per second) to indicate that the system is operating properly.
- 4. Possible clicking noise from the glasses coil.** This is part of the normal operation of the system and does not indicate a failure of any kind.
- 5. Changing program settings.** The VPU has 3 program settings that are selectable by pressing one of the three oval-shaped buttons on the front of the VPU. The oval-shaped button with a single circle corresponds to Program Setting 1. The button with two circles

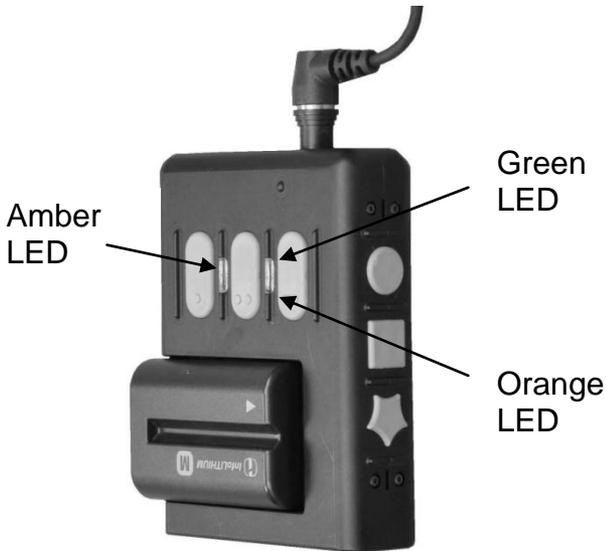
corresponds to Program Setting 2 while the oval button with a small bar corresponds to Program Setting 3. The user may change the program being used to suit different lighting or contrast conditions. When the VPU is first turned on it defaults to Program Setting 1. Each time the Program Setting is changed the VPU will produce a short beep.

- 6. Inverting the image.** To invert the image from black-to-white and white-to-black, press the square button located in the middle of the right-hand side of the VPU. Each time the button is pressed, the image will invert and the VPU will beep.
- 7. Audible RF link alarm.** The star-shaped button next to the inverse button is a toggle switch for turning on/off the VPU audible alarm that indicates when the communication link with the implant has been temporarily lost.
- 8. Turning off the VPU.** To turn off the VPU, press the power button and hold it down for approximately one second. One beep followed by a pause, followed by two short beeps will signal that the system is turning off. Once the VPU is off, all indicator lights on the VPU will be off.

## **LED Indicators and Audible Alarms**

The VPU uses both visual and audible indicators to provide information about the status of the VPU and glasses and problems that can occur with the Argus II System. Table 5 and Table 6 summarize the meaning of these indicators. Their location on the VPU is shown in Figure 7 below.

**Figure 7: VPU LED Indicator Colors**



**Table 6: LED Indicators**

<b>LED Color</b>	<b>Light flashing</b>	<b>Meaning</b>
Green	Fast periodic blinking	The VPU is going through system start-up diagnostic testing.
Green	Slow periodic blinking (1 per second)	The VPU is operating normally.
Orange	Solid	There is a problem with the video signal. (For example, the glasses cable is not connected to the VPU).
Amber	Solid	There is a loss of communication between the implant coil and glasses coil.

<b>LED Color</b>	<b>Light flashing</b>	<b>Meaning</b>
Amber	Blinking	There is intermittent communication between the implant coil and the glasses coil.

**Table 7: Audible Alarms**

<b>Sound</b>	<b>Meaning</b>
Single short beep	A button has been pressed (for example, a Program Setting or Inverse Setting Button).
One beep followed by a pause, followed by two short beeps	The VPU is turning off.
Four short beeps	The VPU is starting up.
Three short beeps	An error has occurred and the VPU is about to shut down automatically.

<b>Sound</b>	<b>Meaning</b>
Periodic beeping pattern (3 short beeps followed by 1 long beep, followed by 3 short beeps, followed by a long pause)	The battery level is low.
Slow periodic beep (1 every 2 seconds)	There is a problem with the video signal.
Fast periodic beep (2 per second)	There is a loss of communication between the implant coil and glasses coil. This alarm can be turned off by pressing the star-shaped button on the right side of the VPU (the Audible RF Link Alarm Button).

### **Battery Life**

Actual battery life may vary based on settings, usage patterns, and environmental conditions. On average, the small rechargeable battery will last 2.5 to 3.5 hours and the medium battery will last 4

to 6 hours before needing to be recharged. Battery capacity will drop gradually over time with use of the system. When the available battery time is shortened considerably, a probable cause is that the battery has reached the end of its life. Contact your clinician or Second Sight for a replacement battery.

### **Recharging the Batteries**

One small rechargeable battery, one medium rechargeable battery and one battery charger are provided with the Argus II System. 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 to periodically check the Argus II 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 doctor. In addition, if you notice a decline in the link between the implant and glasses (for example, if the RF link alarm is beeping more frequently than normal), contact your doctor.

### **Cleaning**

To clean the battery contacts, follow the instructions in the battery package.

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

1. Use a clean, slightly damp cloth to clean the equipment. Gently rub the areas that require cleaning.
2. Use a clean, dry cloth to dry the equipment after cleaning it.
3. Use a can of compressed air to remove dust and debris from the system. Use the compressed air as directed by the manufacturer.
4. Use a soft cloth to remove minor 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 as this may damage the equipment or its labels.**

## **Maintenance**

The Argus II System does not contain any user serviceable parts.

**CAUTION: Do not attempt to service, open, repair, or conduct maintenance on any of your equipment as you may experience an injury, violate the product warranty, or damage the equipment.**

**CAUTION: Contact your clinician or Second Sight using the contact information provided in Chapter 7 if your equipment requires maintenance or is not working properly.**

## **Handling and Storage**

Take care when storing and handling the VPU and glasses. Improper care or storage can result in damage to the equipment. Following the guidelines below can improve the lifetime of this equipment.

- 1. Magnetically-sensitive storage devices.** Do not place magnetically-sensitive storage devices (credit cards, computer floppy disks or hard disks) near the Argus II System while it is operating. The electromagnetic field generated by the operational system may corrupt the information stored on such devices.
- 2. Metal objects.** Do not allow any metal objects within 6 inches (15.2 cm) of the glasses coil while the VPU is in use. Should this happen, the VPU will detect the possibility of this coil overheating and turn off. The VPU will not work until reset by trained personnel.
- 3. Unapproved components.** Use only components and accessories supplied by Second Sight with the Argus II System. The

use of unapproved components may cause damage to the equipment, resulting in loss of stimulation and/or injury. It will also void the manufacturer's warranty.

- 4. Exposure to liquid.** Do not expose the VPU and glasses to water (for example, rain, shower, swimming pool, or ocean) or other liquids as they may damage the equipment. The glasses may be exposed to light rain, but the VPU may not.
- 5. Storage of the Argus II VPU and Glasses.** Store the packaged Argus II VPU and glasses at temperatures between 32°F (0°C) and 113°F (45°C). Do not expose the external equipment to temperatures below 32°F or above 113°F as this may result in damage that renders the device inoperable.
- 6. Usage temperature range.** The temperature range for normal use should be between 32°F (0°C) and 104°F (40°C).
- 7. Handling the glasses.** The glasses are fragile. Handle them with care, especially when putting them on or taking them off. Do not over-extend the arms of the glasses when putting them on or taking them off as this may break them. Do not fold the arms of the glasses to shut them. The arms are not designed to be closed and

trying to fold them may 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 since, over time, this may cause damage to the cable.

- 8. Traveling with the external devices.** It is recommended that you store the VPU, glasses, and batteries in the travel case provided by Second Sight as this is designed to protect the equipment. It is also recommended that you uninstall the battery from the VPU during transit, to avoid accidentally turning on the VPU which could drain the battery. Do not place anything on top of the glasses or VPU.
- 9. Loss of RF link.** The Argus II Implant is driven by the external coil housed on the Argus II Glasses. Shifting the Argus II Glasses outside the range of the Argus II Implant may result in a decrease or loss of stimulation. Additionally, you may need to restrict your eye movements to maintain the link between the implant coil and glasses coil.
- 10. Interference.** The Argus II System may interfere with certain radio frequencies. If interference occurs, you should extend the distance between you and the source of interference, or turn off the Argus II VPU.

## **Expected Failure Time and Mode and Its Effect on You**

The Argus II Implant was designed to operate for at least five years, and laboratory testing has demonstrated that the design is capable of that lifetime. 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 possible failure mode of the implant is that it could stop responding to signals from the glasses and thus stop stimulating. If it fails in this manner, you should not experience any harmful effects. The implant may be safely removed and replaced if desired.

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

Wearout failure of the rechargeable battery is described in the “Operating Instructions” section of this chapter.

## Instructions on How to Safely Dispose of the Device

### **WARNING**



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

**Do not dispose of the VPU batteries or the 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. Dirt and wetness may cause short-circuits and heat. Heat may cause leakage of flammable gas which may result in fire, rupture or explosion.**

**WARNING**



**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 possibly resulting 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 an exchange or replacement of equipment is occurring through your clinician, they will ensure that the equipment is properly returned.

### **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 or battery charger for proper disposal methods.

### **Argus II Implant**

If the Argus II Implant is explanted for any reason, Second Sight must be contacted first except in the event of medical emergency. The explanted unit must be returned to Second Sight for evaluation, warranty purposes and final disposition. Your clinician should request a biohazard (explant) kit from the Second Sight office (see contact information in Chapter 7).

### **Disposal of Packaging Material**

The shipping carton for the Argus II System components or accessories, and packaging materials should be disposed of according to local regulations.

## Chapter 5: Troubleshooting

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If you encounter a problem with any part of your system, look for the problem in Table 8 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, then contact your clinician or use the information provided in Chapter 7 of this manual to contact Second Sight.

**CAUTION: If you encounter a clinical or physical problem (such as chronic eye pain or discomfort) related to the Argus II System, please contact your clinician immediately.**

**Table 8: Troubleshooting**

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
The VPU does not start	1. Check that the battery is installed properly. If it is not installed properly, refer to instructions in Chapter 4, "Install the battery."

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU does not start (continued)</p>	<ol style="list-style-type: none"> <li>2. Install a fully-charged battery. Refer to instructions provided in Chapter 4, "Install the battery."</li> <li>3. Ensure that you are pressing the correct button. The power button is the circular-shaped one on the right side panel of the VPU (see Figure 3).</li> <li>4. Ensure 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.</li> </ol>
<p>The VPU produces an audible warning (three short beeps) and shuts off suddenly</p>	<p>Turn on the VPU to see if this occurs again. If the problem persists, contact either your clinician or your Second Sight representative.</p>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU shuts off suddenly without an audible warning</p>	<ol style="list-style-type: none"> <li>1. Install a fully-charged battery. Refer to instructions “Install the battery” provided in Chapter 4.</li> <li>2. Turn on the VPU to see if this occurs again.</li> <li>3. If the VPU fails to restart, remove the battery for at least 5 minutes. Then, install again.</li> <li>4. Put on glasses. Turn on the VPU again and stimulation should restart.</li> <li>5. 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.</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU is on, but I don't see anything</p>	<ol style="list-style-type: none"> <li data-bbox="497 261 884 542">1. Confirm that the VPU is on by pressing any button on the VPU other than the power button. If a beep is heard, then the VPU is on.</li> <li data-bbox="497 553 884 922">2. Ensure that the VPU is not making any audible alarms. Check if the audible RF link alarm switch is on. If it is, check that the glasses cable is properly plugged into the VPU glasses receptacle.</li> <li data-bbox="497 933 884 1425">3. Gently press the coil mounted on the glasses closer to your eye. If the audible alarm stops beeping and resumes beeping when you stop pressing the coil, this indicates that your external coil needs to be adjusted to ensure the communication</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU is on, but I don't see anything (continued)</p>	<p>between the external coil and the implant is reliable.</p> <ol style="list-style-type: none"> <li>4. Ensure that nothing is blocking the camera on the glasses. If there is something blocking the camera, try to remove the obstruction.</li> <li>5. Ensure that the lens on the camera is clean. Refer to "Cleaning" in Chapter 4.</li> <li>6. Ensure that your surroundings have adequate lighting.</li> <li>7. Try inverting the image (from black-to-white or white-to-black) by pressing the square-shaped settings button.</li> <li>8. Try changing the program setting.</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU is on, but the image seems distorted</p>	<ol style="list-style-type: none"> <li>1. Ensure that nothing is blocking the camera on the glasses.</li> <li>2. Ensure that the lens on the camera is clean. Refer to Chapter 4, "Cleaning."</li> <li>3. Try using one of the other program settings to see if there is an improvement.</li> </ol>
<p>The VPU is on, but my perception is dimmer than usual</p>	<ol style="list-style-type: none"> <li>1. Ensure that nothing is blocking the camera on the glasses. If there is something blocking the camera, try to remove the obstruction.</li> <li>2. Ensure that the lens on the camera is clean. Refer Chapter 4, "Cleaning."</li> <li>3. Ensure that your surroundings have adequate lighting.</li> <li>4. Ensure that you are using the correct stimulation setting.</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU is on, but my perception is dimmer than usual (continued)</p>	<p>Switch between the normal/invert settings by pressing the square-shaped invert button.</p> <ol style="list-style-type: none"> <li>5. Ensure that the intended Program Setting is being used to provide the optimum perception by experimenting with the different Program Setting buttons.</li> <li>6. Switch off the VPU for 10 minutes and switch it back on.</li> </ol>
<p>The coil on the glasses seems warmer than usual</p>	<p>Re-adjust the glasses to see if the coil cools down to its usual operating temperature. If the problem is persistent or the coil is getting unusually warm, contact Second Sight using the contact information provided in Chapter 7.</p>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
There is a clicking noise from the area of the coil on the glasses	This is part of the normal operation of the system and does not indicate a failure of any kind.
Nosepiece comes off the glasses	<ol style="list-style-type: none"> <li>1. Turn the glasses over and lay them on a flat surface so that the top of the frame is in contact with surface.</li> <li>2. Take the nosepiece and place it on the underside of the lens where the nosepiece should be attached.</li> <li>3. Press firmly. This should lock the nosepiece back in place.</li> </ol>

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

**Table 9: LED Indicators**

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
The green LED is not blinking	<ol style="list-style-type: none"><li>1. Change to a fully charged battery.</li><li>2. Turn off the VPU and turn it back on again to see if the problem is fixed. If it is not fixed then contact Second Sight using the contact information provided in Chapter 7.</li></ol>
The orange LED turns on (loss of video signal)	<ol style="list-style-type: none"><li>1. Ensure that the green light is still blinking.</li><li>2. Check that the glasses cable is properly connected to the glasses receptacle on the VPU. Refer to Chapter 4, "Connecting the glasses to the VPU."</li></ol>
The amber LED turns on (loss of RF link)	<ol style="list-style-type: none"><li>1. Ensure that the green light is still blinking.</li><li>2. Re-adjust the glasses to see if the light turns off.</li><li>3. If step 2 does not fix the problem, check that the glasses cable is properly</li></ol>

Symptom	Cause and/or Corrective Action
	<p>connected to the glasses receptacle. Refer to Chapter 4, “Connecting the glasses to the VPU.”</p> <p>4. You may need to restrict your eye movement to maintain the link between the implant coil and the glasses coil.</p>

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

**Table 10: Audible Alarms**

Symptom	Cause and/or Corrective Action
<p>The VPU shuts off suddenly emitting three short beeps (error-induced VPU shutdown)</p>	<p>Try powering up the VPU to see if this occurs again. If the VPU continues to shut itself off, contact Second Sight using the contact information provided in Chapter 7.</p>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU emits the following periodic beeping pattern: 3 short beeps followed by 1 long beep, followed by 3 short beeps, followed by a long pause (low battery voltage warning)</p>	<ol style="list-style-type: none"> <li>1. Turn off the VPU.</li> <li>2. Install a fully-charged battery onto the VPU. Refer to instructions provided in Chapter 4, "Install the battery."</li> <li>3. Power up the VPU; allow the VPU to finish the start-up test and ensure the same beeping pattern does not occur after the start-up test.</li> </ol>
<p>The VPU emits a slow periodic beep once every 2 seconds (loss of video signal)</p>	<ol style="list-style-type: none"> <li>1. Ensure that the green light is still blinking approximately 1 blink per second.</li> <li>2. Check that the glasses cable is properly connected to the glasses receptacle on the VPU. Refer to Chapter 4, "Connecting the glasses to the VPU."</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU emits fast periodic beeps about 2 per second (loss of RF link)</p>	<ol style="list-style-type: none"> <li>1. Allow the VPU to finish the start-up test and ensure that the green light is blinking approximately 1 blink per second.</li> <li>2. Re-adjust the glasses and gently press the external coil closer to your eye to see if the amber light turns off.</li> <li>3. Limit your eye movements and look straight ahead.</li> <li>4. If steps 2 and 3 are unsuccessful in correcting the problem, check that the glasses cable is properly connected to the glasses receptacle – if not, follow instructions in Chapter 4, “Connecting the glasses to the VPU.”</li> <li>5. This fast periodic beeping related to the temporary loss of</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU emits fast periodic beeps about 2 per second (loss of RF link, continued)</p>	<p>communication with the implant can be turned off by pressing the star-shaped switch on the right side of the VPU.</p>
<p>The VPU is not operating as intended, but I do not hear any audible alarms</p>	<p>Press the star-shaped audible RF link alarm switch to ensure the RF link alarm is “on”. If you still cannot hear any audible alarms, a sighted person should check whether the amber or the orange light is on. If not, you will not hear any audible alarms. If the amber or the orange light is on, ensure that the VPU is within your normal hearing range. To test it, you may want to put it next to your ear.</p>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU operates as intended, but I hear an unexpected audible alarm</p>	<ol style="list-style-type: none"> <li>1. Refer to Table 6 from Chapter 4 of the manual for an explanation of the audible alarms.</li> <li>2. If you still cannot recognize the audible indicator, turn off the VPU and try turning it on to see if this sound occurs again.</li> <li>3. Install a fully-charged battery. Refer to instructions provided in Chapter 4, "Install the battery."</li> </ol>

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

## **Chapter 6: Additional information**

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### **Warranty**

#### **Argus II Limited Warranty on Retinal Prosthesis (Implant)**

If an Argus II Implant fails to function within normal tolerances within 3 years from the date of implantation as a result of a failure to manufacture the Argus II Implant in accordance with Second Sight Medical Products' (Second Sight's) manufacturing specifications, Second Sight Medical Products, Inc. will provide a functionally-equivalent Second Sight replacement implant. This warranty is limited to implant failures, and does not apply to out of specification performance due to surgical complications or the patient's medical condition.

Claims under the Argus II Limited Warranty on Retinal Prosthesis (Implant) are subject to the following conditions and limitations:

1. The implant must be implanted before the end of the "Use By" date marked on the package.
2. The Implant Registration Form provided by Second Sight is completed and received by Second Sight.

3. Implant failure must be confirmed by Second Sight before explantation and replacement of the device.
4. The explanted unit must be returned to Second Sight for analysis within 15 days of explantation along with a report describing the circumstances of the removal. Explanted devices returned to Second Sight for analysis become the property of Second Sight.

**WARRANTY DISCLAIMER:**

**SECOND SIGHT EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE. SECOND SIGHT WILL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES CAUSED BY THE IMPLANT'S FAILURE TO FUNCTION WITHIN THE NORMAL TOLERANCES WITHIN 3 YEARS WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.**

Second Sight reserves the right, in its sole discretion, to provide a functionally-equivalent Second Sight replacement implant even if the failure to perform within normal tolerances during the Three-Year Limited Warranty period is for

reasons other than a failure to manufacture the implant in accordance with Second Sight's manufacturing specifications.

### **Argus II Limited Warranty on External Devices**

Second Sight warrants to the purchaser of a new Argus II Video Processing Unit (VPU) or Glasses or Operating Room Coil (OR coil) that it is free from defects in workmanship and materials for a period of two years from the date of initial VPU fitting (or time of purchase if purchased separately).

Second Sight further warrants to the purchaser of a new Argus II VPU that the supplied battery charger (including charger base and AC adaptor) and rechargeable batteries are free from defects in workmanship and materials for a period of 3 months from the date of initial VPU fitting (or time of purchase if purchased separately).

The exclusive remedy for breach of this warranty is: (a) repair or replacement of the defective VPU, glasses, OR coil or charger with a functionally equivalent Second Sight replacement product, or (b) at Second Sight's option, full credit equal to the original purchase price of the defective VPU, glasses, OR coil or charger to be applied towards the purchase of a new replacement component.

**SECOND SIGHT EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE. Any accessory items included with the VPU are warranted for a period of 3 months from initial VPU fitting (or time of purchase if purchased separately).**

Product claims under Second Sight Limited Warranty on External Devices are subject to the following conditions and limitations:

1. The product registration forms for the VPU and glasses must be completed and returned to Second Sight within 30 days of initial fitting or receipt of the product in order to receive the benefits of this warranty.
2. Items covered by this warranty that are the subject of the warranty claim must be returned to Second Sight (or its authorized agent) within 30 days after receipt of replacement part (s).
3. Second Sight must be able to confirm the component failure.
4. This warranty specifically excludes defects caused by: (a) fire, floods, lightning, natural disasters and other calamities defined as “Acts of God;” (b) accident, misuse, abuse, negligence, water immersion damage, improper fitting or connecting of components or failure to operate the VPU, glasses or charger

in accordance with the manufacturer's instructions; (c) wear and tear resulting in cosmetic or exterior damage; (d) attempts to repair, maintain, or modify the equipment by the customer or any third party not authorized by Second Sight; (e) performance problems caused by attachment of any component of an Argus II VPU or glasses or OR coil to any equipment or device not supplied by Second Sight without the prior approval of Second Sight; (f) cable breakage (appropriate care should be taken to prevent forces from damaging cables); (g) 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); or (h) 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 the purchaser.

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

For information regarding the above warranties or in the event of suspected device failure, please contact Second Sight using the contact information provided in Chapter 7.

## Symbols and Regulatory Classifications

The following symbols appear on components of the Argus II System. The symbols and their meanings are described below.

**Table 11: Symbols**

Symbol	Meaning
	Catalog number
	Serial number
	Lot number
	Date of manufacture
	Warning and/or consult accompanying documents

Symbol	Meaning
	Storage temperature range
	Keep Dry
	Non-ionizing radiation (Radio frequency radiation)
	Manufactured by
	Type B Applied Part
	MR Conditional

The Argus II System meets the requirements of several international standards and directives. The table below indicates how the Argus II System is classified according to each of these standards and directives.

**Table 12: Regulatory Classifications, including Electromagnetic Compatibility**

Standards / Directives	Regulatory Classifications
EN60601-1	<p>Classification:</p> <p>Internally Powered Type B Applied Part IPX0 Continuous Operation</p>
R&TTE Directive	<p>Classification:</p> <p><u>Product Type 1</u> - Inductive loop coil transmitter tested with an integral antenna</p> <p><u>Receiver Class 2</u> - 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.</p>

Standards / Directives	Regulatory Classifications
<p>CISPR 11 (Electromagnetic Emissions)</p>	<p>Classification:</p> <p><u>Group 1 Equipment</u> - 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</p> <p><u>Class B Equipment</u> - equipment suitable for use in all establishments including your home.</p>

**Table 13: Recommended Separation Distances  
Between Portable and Mobile RF  
Communications Equipment and the  
Argus II System**

Rated maximum output power of transmitter (Watts)	Separation distance according to frequency of transmitter (Feet)	
	150 kHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.0384	0.0764
0.1	0.384	0.764
1	3.84	7.64
10	38.4	76.4
100	384	764

## **Chapter 7: User Assistance**

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Second Sight Medical Products, Inc. is committed to providing the highest quality products and service to our customers. We welcome your comments about the Argus II Retinal Prosthesis System or your suggestions to improve the product. Please feel free to contact Second Sight or your clinicians for technical assistance, replacement parts, or your suggestions.

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[www.2-sight.com](http://www.2-sight.com)

**Write your important telephone numbers here**

<b>Resource</b>	<b>Telephone number:</b>
Clinic	
Physician	
Device disposal contact:	

## Chapter 8: Glossary

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Term	Definition
Choroid	A thin layer of cells at the back of the eyeball that sits behind the retina
Communication Adapter (CA)	A device that is connected to the VPU when the VPU is hooked up to a computer in the clinic
Conjunctiva	A thin layer of tissue that covers the white part of the eye.
Cornea	The clear layer of tissue which forms the front part of the eye
Cyst	A closed sack of tissue which may contain air, fluids, or semi-solid material
Diagnostic	Of or relating to the identification or disease by its symptoms and signs

<b>Term</b>	<b>Definition</b>
Electrode Array	A rectangular 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 equipment found in public environments that may be strong enough to interfere with the normal operation of your Argus II System
Electrostatic Discharge (ESD)	A momentary unwarranted flow of electrical current that can cause damage to electronic equipment
Incision	The cutting of or into body tissues or organs (especially by a surgeon as part of an operation)

Term	Definition
Iris	A thin, circular structure in the eye, responsible for controlling the diameter and size of the pupils
LED	Light Emitting Diode
Radio Frequency (RF)	An alternating current that gives rise to an electromagnetic wave when applied to an antenna
Retina	A thin layer of cells at the back of the eyeball which converts light into nerve impulses that travel to the brain
Sclera	The white outer coating of the eye made of tough tissue which allows the eye to keep its shape and helps to protect the delicate inner parts of the eye
Therapeutic	Of or relating to the treatment of disease or disorders

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